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Detention, Nepotism and Truancy as Predictors of Workplace Deviance in Service Organizations: India's Experience

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ABSTRACT

Objective: This study reconnoiters influence of Detention, Nepotism, and Truancy on workplace deviance of Service Organization employees with aim of ascertaining their relative and combined contributions.

Analysis: A descriptive survey analysis design was adopted for study. Using Proportionate sampling technique, a cluster of 600 respondents was selected for study. Four standardized instruments were used for information assortment. Using Pearson Product Moment Correlation Statistics and regression analysis, hypotheses generated for study were tested at 0.05 alpha (α) levels.

Findings: From this study, highlights are as follows:

1. Detention, Nepotism, and Truancy were found to ownconjointly contributed to employees' deviance conduct in service based organizations of India.
2. Also, nepotism was found to be foremost potent predictor of employees' deviance conduct.

Novelty: Its entreated that managers should not favor any employee, however, acknowledge and reward diligence supported job performance.

Keywords: *Detention, Nepotism, Truancy, Workplace Deviance, Service Organization Employees.*

INTRODUCTION

Employees are devices through which organizations will accomplish their objectives. Therefore, employees' association with their organization is significant since it will decide advancement of workplace deviance[1]. Conduct is called Deviant when "an individual or gathering of individuals damages organization's traditions, methods or inner controls, imperiling prosperity of organization or its natives"[2]. Deviant conduct speaks to acts bestowed by hierarchical people that have or are expected to own impact of harming associates, directors or organization itself[3].

Recent researches created enthusiasm for investigation of workplace deviance since its regular among employees and what is more poses very troublesome problems for organizations[4,5]. It was accounted for that 33% to 78% of all employees have occupied with one form of deviance conduct or other[6]. Therefore this study expects to seek out impact of Detention, Nepotism, and Truancy on deviance conduct of service organization employees in India.

DETENTION

Detention has been portrayed as "arriving late to work or leaving early"[7]. Coming late to work can be frightful to organization. When people don't show up on time, they are at risk of Detention. Detention is connected with exchanged off definitive efficiency which oppositely impacts creation. Diverse pros may endeavor to mimic late employees by coming to work late themselves if not particularly controlled by organization.

Nepotism

Nepotism in workplace can be dangerous and counterproductive. It is portrayed that Nepotism as exhibition of showing preference toward an exceptional individual or group[8]. It moreover views Nepotism as happening when pioneer demonstrates unique treatment towards employees their character socially connected with to damage of various employees and general performance of organization[9]. Nepotism can be intentional or surprising. Nevertheless, paying little mind to whether Ponder or surprising, it is unlawful, de-pushing, cuts down trust, isolating and can provoke employee deviant practices, for instance, employees despising work, withholding of information, uncertainty, abhor, sharpness, bits of chatter, longing and conflicts, scheming and undue progressions to favored employees[10]. It can similarly impact prosperity, nature of work and employees general proficiency[11].

Truancy

Distinctive makers have portrayed Truancy in different ways[12].Non- participation implies Truancy of an employee from work with no elucidation, without endorsement and intentionally. A maker bear witness to that unexcused unfortunate insufficiencies cut down productivity, results to low confirmation and is an extra stress for various employees which impacts both employees and organization. The testimony regarding that non-appearance is unfavorably related to job satisfaction and obligation especially satisfaction with work itself and could be an indication of regulatory issues like negative deviance which is indication of poor performance. It was in like manner announced that nonappearance at work is a break of understanding among supervisor and employees. It is moreover a creation variation from norm and an indication of issues at work.

It was seen that employees are truant due to remedial reasons while others don't appear in light of way that they are not content with their work. In like way, Personal Fund Report shows that illness, tormenting and goading, burnout, stress and low resolve, tyke care and senior care, wretchedness, partition, wounds, work pursuing and inadequate developments could be a segment of purposes behind employees being truant from their commitments while Chartered Institute of Personnel and Development absence report viewed stress as most basic explanation behind whole deal truancy.

Research Hypothesis

i. There is no significant joint contribution of Detention, Nepotism, and Truancy on service organizations employee deviance conduct.

ii. Gender will not significantly moderate combined contribution of Detention, Nepotism, and Truancy on service organizations employee deviance conduct.

iii. There is no significant relative contribution of Detention, Nepotism, and Truancy on service organizations employee deviance conduct.

iv. There is no significant direct relationship between Detention, Nepotism and Truancy and deviance conduct among employees of service organizations.

METHODOLOGY

Review Design: This review embraced clear plan of ***ex-post facto*** sort. This is on account of researchers did not control any of factors, but instead, analyst watched and portrayed impact of effectively existing free factors (Detention, Nepotism, and Truancy) on reliant variable (workplace deviance).

Sample Size: Populace for review contained all employees (including administration association employees) working in Bangalore, India. A multi-stage inspecting system was utilized to choose six organizations (3 IT and 3 BPO/KPO) that partake in review. Multi-stage examining procedure was picked on grounds that it is a phase-by-stage arrangement of testing strategy. In particular, sample for this review comprised of 600 employees (498 direct individuals and 102 managers).

Inspection:600 questionnaires were offered to all participating organizations. Out of 600 surveys conveyed, 12 were not appropriately rounded or passed up a major opportunity over span of recovery, which refute them with end goal of review. It can, in any case, be said that there was (572) 95.3% accomplishment of survey organization.

Instruments

Detention Scale: This scale involves three items including thing like "came to work late without assent" and respondents were made a demand to stick their responses on five demonstrates going from never common on how routinely they have done each on their present jobs. A Cronbach á of .71 was obtained

showing it is suitable for this study.

Nepotism Scale: This scale included thirteen items. It was used to gauge how much employees see nearness of nepotism by an organization. Individuals were made a demand to demonstrate how much some of their partners get more noteworthy flexibility, get ready, affirmation and higher boosts in salary than is typical on their specialized topics, for instance, "some of my sidekicks get more versatility than is standard in my strength in work arranges". Declarations are evaluated on a size of five-point Likert scale stretching out from unequivocally agrees to determinedly disagree. In this survey, nepotism scale has a coefficient á of .84.

Truancy Scale: This scale contains six items which were self-made including items like "delighted in a more drawn out relief than you were allowed to take" and respondents were made a demand to stick their responses on five points reaching out from never to normal on how much of time they have done each on their present businesses. A Cronbach á of .80 was gotten and that shows that scale is proper for survey.

Abnormality Scale[13]: Deviance Scale was used to measure work deviation among employees. This scale contained twenty-eight items. Individuals were made a demand to exhibit how much they have possessed with such activities like "tackled an individual matter rather than working for your supervisor". Declarations are assessed on a size of five going from never to every day. It was represented that this scale has internal steadfast nature of 0.81, and in this audit, it has inside trustworthiness of .79.

Procedure: Biographical data scale was used to assess demographic details of participants while nepotism, truancy, deviance and detention scales were administered on sample.

Data analysis: data obtained were analyzed using simple descriptive statistics analysis, Pearson product Moment Correlation Coefficient and Multiple Regression statistical tools.

RESULTS

Table-1 demonstrates unwavering quality of considerable number of factors in review. Cronbach' s alpha for deviance scale is .788, Truancy record is .801, nepotism is .840 and for detainment, scale is .707, which meets base satisfactory suggested level. For Correlation, Pearson Correlation grid was utilized. It appears from Table 1 that an opposite relationship exists amongst deviance and Truancy (- .312) at a noteworthy level (p = .01).deviance and nepotism demonstrated a concurrent relationship of .631 at critical level of .01, while a huge negative relation- ship was found amongst deviance and detainment (- .264). Outcomes likewise showed noteworthy positive connections amongst Truancy and nepotism (.471), Truancy and detention (.339), and in addition detainment and nepotism (.298).

Table 1: Mean, Standard Deviation, Cronbach's α and Correlations of Employee's deviance conduct, Truancy, Nepotism and Detention

Variable	Mean	SD	Cronbach's α	No. of items	1	2	3	4
Deviant Behaviour	76.114	9.071	0.788	28	1.00			
Truancy	15.003	6.109	0.801	6	-.312**	1.00		
Nepotism	33.207	11.273	0.84	13	.631**	.471**	1.00	
Detention	9.465	4.64	0.707	3	-.264**	.339**	.298*	1.00

Table 1: Mean, Standard Deviation, Cronbach's α and Correlations of Employee's deviance conduct, Truancy, Nepotism and Detention N=150; ** Significant at the 0.01 level (2-tailed); * Significant at the 0.05 level (2-tailed);

Results in Table 2 showed that with all marker elements (Detention, Nepotism and Truancy) in backslide indicate together expected deviance conduct (R = .441; R2 = .194; Adj. R2 = .194; F (3, 574) = 33.478; p<.05). This showed that all predictor variables accounted for 19.4% of variance in employees' deviant conduct. Null hypothesis which stated that there is no significant joint contribution of detention, nepotism and truancy on employees' deviant conduct was rejected by this finding. This implies that there is a significant joint contribution of detention, nepotism and truancy on employees' deviant conduct.

Table 2. Model summary of the regression analysis for the combined influence of Truancy, Nepotism and Detention to the prediction of employees' deviance conduct

Model	R	R^2	Adj.R^2	SE	Change Statistics	F change	df1	df2	Sig.F change
Predictor variables					R^2 change				
	0.441	0.194	0.194	13.061	0.194	33.478	3	574	0.021

a) Predictors: (constant), Truancy, Nepotism and Detention;

b) Dependent variable: Employee's Deviant conduct

Results in Table 3 revealed nature of causation of marker variable on world view variable. Most serious pointer of employees' deviance direct among marker variables of audit is nepotism (β =.472; t = 9.115; p<.05). Truancy is accompanying intense variable (β=.298; t = 4.307; p<.05), and lastly by detention (β=-.231; t = 3.001; p <.05) in prediction of employees' deviant conduct. hypothesis of no relative contribution of detention, nepotism and truancy on employees' deviant conduct was rejected by this finding. This implies that there is a significant relative contribution of detention, nepotism and truancy on employees' deviant conduct, while nepotism was found to be most potent predictor among three.

Table 3. Beta coefficients and t ratio for relative contributions of Truancy, Nepotism and Detention to the prediction of employees' deviance conduct

	Unstandardized Coefficients		Standardized Coefficients	t-ratio	Sig
	B	Std. Error	Beta (β)		
Constant	3.409	0.615		8.86	0.00
Truancy	0.226	0.135	0.298	4.31	0.01
Nepotism	0.418	0.038	0.472	9.11	0.00
Detention	-0.167	0.027	-0.231	-3.00	0.00

* Significant at the 0.05 level (2-tailed);

a) Dependent variable: Employee's Deviant conduct

Results in Table 4 exhibited that with all pointer components (Detention, Nepotism, and Truancy) entered into backsliding show promptly; there was an enormous conjecture of decline lead among male and female employees in organization. For male employees (R = .307; R2 =.094; Adj R2 = .088; F (4,248) = 19.907; p <.05), while for female employees, values are (R = .511; R2 = .261; Adj R2 = .247; F (4,322) = 8.543; p <.05). This implies that there was combined contribution of detention, nepotism and truancy to prediction of deviant conduct among both male and female employees.

Table 4. Model Summary of the multiple regression analysis of the moderating effect of gender on the influence of Trucacy, Nepotism and Detention to the prediction of employees' deviance conduct

Model	R	R^2	Adj.R^2	SE	Change Statistics	F change	df1	df2	Sig.F change
Predictor variables					R^2 change				
Male	0.307	0.094	0.088	10.771	0.388	19.907	4	248	0.013
Female	0.511	0.261	0.247	18.002	0.247	8.543	4	322	0.00

a) Predictors: (constant), Truancy, Nepotism and Detention;

b) Dependent variable: Employee's Deviant conduct

DISCUSSION

Hypothesis-1 anticipated no huge joint commitment of Truancy, nepotism, and detention on representatives' deviance conduct. Results demonstrated that all indicator factors represented 19.4% of difference in employees deviance conduct. This result certifies past discoveries[14,15] that employees take part in Deviant practices while other[16] affirmed that it is more apparent in lower class representatives since they confer greater part of their free circumstances at getting back at whoever that irritates them. Likewise, a review[17] present that hierarchical trouble making happens among employees of service organizations.

Hypothesis-2 uncovered a noteworthy expectation of Deviant conduct among male and female employees in world. This infers there was consolidated commitment of Truancy, nepotism, and detention to expectation of deviance conduct among both male and female employees in community. Finding of a review[18] makes an announcement that between 35% and 78% of all employees have occupied with one type of deviant conduct or other. In two distinct reviews[19,20], it was watched that all people in working environments have inclination of taking part in dangerous practices.

Hypothesis-3 anticipated that there is no noteworthy relative commitment of Truancy, nepotism, and detention on employees Deviant conduct. Finding uncovers noteworthy relative commitment of Truancy, nepotism, and detainment on employee's deviance conduct, while nepotism was observed to be strongest indicator among three. In light of this view, it is apparent that an employee who is disappointed may take part in some deviance conduct like not appearing for work with a specific end goal to turn tables on association. Likewise, it[21] was considered nonappearance to be a sign of lethal workplace while it[22] presents that nonappearance is a gently workplace deviance and a potential wellspring of work environment strife.

Hypothesis-4 expressed that there is no critical direct connection between Truancy, nepotism and detention and deviance conduct among representatives. Result of this finding uncovered a noteworthy direct relationship among factors either emphatically or contrarily. A back- wards relationship exist between deviance conduct, Truancy (- .312), and detention (- .264). outcomes on immediate connection between Truancy, detainment and Deviant conduct is par with past discoveries that emotions and demonstration of Truancy and detainment prompt counterproductive work practices it could be said that they cause inactivity[23], low levels of duty[24], and an absence of exertion. Likewise, another researcher[25] has demonstrated that detention adversely influences achievement of each association.

Deviant conduct and nepotism demonstrated a united relationship. Additionally, a noteworthy positive relationship was found amongst Truancy and nepotism, Truancy and detention. This outcome is in accordance[26] with that presumed that avoidance makes people feel awful about them, and rejected people revealed sentiments of uselessness and ineptitude.

CONCLUSIONS

Disclosures from this study have basic implications for employee's organization and appraisal. This is in light of fact that, an inclination is counterproductive and could incite bring down employees resolve and could be de-pushing too hard working employees especially when they feel their tireless work is not adjusted. Manager should not reinforce any illustrative in any case, and compensate persevering work in perspective of job performance. There should be awesome and target gadgets and criteria for evaluation and appraisal that is direct and fathomed by all. This will go far in diminishing employee's anomaly. Truancy which is seen as "tenderly monstrosity" work lead should be checked and controlled since it can incite more certifiable conflicts. To fulfill this, truancy technique should be set up by relationship to check and control employee willful nonappearances.

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A Comparative Study of Satisfaction of Midwives and Mothers of Adherence to Patient Rights

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ABSTRACT

Objective: This study was conducted with the aim of assessing a comparative study of satisfaction of midwives and mothers of Adherence to Patient Rights in Hospitals affiliated to in Kermanshah University of Medical Sciences.

Method: This study was a descriptive comparative study and in this study, 200 pregnant women and 100 midwives in hospitals in Kermanshah University of Medical Sciences were selected by convenience sampling. Data gathering tool was two types of researcher made questionnaire to midwives and mothers.

Results: The results of research of exploratory factor analysis showed that 4 main factors identified in this study include: the first factor: received a favorable obstetric services, the second factor: respect the privacy of the mother, the third factor: Respect for the right to choose and decide freely mother, the fourth factor: access to health information is appropriately.

Conclusion: Regarding importance of patient rights during pregnancy and the difference between the views of mothers and midwives on access to health information in this study, improve the present situation and classes for justification of nurses and midwives to better the situation should be considered as important.

Keywords: *Satisfaction, Maternity Care, Patient Rights,Midwives*

INTRODUCTION

Try to give primary rights of healthcare receivers in patients' rights framework is from first steps of healthcare system to quality improvement[1,2] As in health systems of most countries of world it's identified rights for patients that healthcare providers must respected to them. Thus, respect to patient's rights don't be dependent to personal willing of clinical staff lonely and detector and accreditation systems always monitored and evaluated respect to these rights.[3,4]

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World health organization, identified health as basic right of humans and defined that right, access to highest accessible health standards which every person must receive this services notwithstanding to race, religious, economic status and political trends.[5,6]

Today by communications, patients are more aware than last to healthcare services. Attention of mass communications to healthcare literacy, make people aware of choice right about new technologies of health.[7] Patients who are more aware from health services than others had more satisfaction.[8] Respect to patient rights, protected patients against miss use and racism and resulted in ethic improvement.[9-11] Making aware patients, sharing decision to them and respect to their rights will help to their recovery.[12,13]

Respect to mother's right and developing safe pregnancy plans are the most essential section to delivering obstetric care. Respect to reproductive health rights and individual health must supposed as axial

strategies for development. In this regard, empowerment of women considered as one of most important component to respect to reproductive rights.[14]

Mother's satisfaction is one of important efficiency, efficacy, and productivity and quality indicators in healthcare services.[15] Safe pregnancy and birth of a healthy baby without threaten mother's life is from mothers and their infant's rights. Although mortality factors between mothers and infants and ways to manage them are known, but still those kill mothers and infants unfortunately. In many countries especially poor countries due to financial limitations management of these issues are impossible. Thus health system efficacy and provide standard and optimum services, need to interaction, respect and active participation of healthcare providers and receivers.[16,17] In regarded to necessity of providing standard care for pregnant women and high importance of health for them and finding evidence based results to respect to mother's rights and also to increase pregnancy rates this research was carried out aimed to survey comparatively satisfaction of midwives and mothers of adherence to patient rights in Kermanshah University of Medical Sciences hospitals.

METHOD

This study was a descriptive comparative study and in this study, 200 pregnant women and 100 midwives in hospitals in Kermanshah University of Medical Sciences (confidence rate 95%, sampling error 0.02 and Z=1.96) were selected by convenience sampling. Inclusion criteria for midwives and mothers were: interest to participate in research, midwives who worked in maternity ward, pregnant women who had gestational age of 37 week or more, patients who are capable response to questions physically and psychologically, patients that hospitalized in maternity ward at least 24 hours, patients who hadn't elective candidate for caesarean. After selection eligible research units. Researcher introduce himself to samples and explained aim of study. Then after make inform consent and gave assurance to them about privacy issues, we disseminated questionnaire between them.

The research data gathered through two self-made questionnaires. These questionnaires included two sections. First section was containing general questions for mothers: age, education, job, number of parturition, number of child and general questions for midwives such as, age and education. Second section contains, questions related to research goals that was 20 questions for midwives and 23 questions for mothers. Questionnaires developed by use of related literatures and bylaws of ministry of health legal office for mother's rights. Question of questionnaires was related to survey four topics included, receiving optimize health services and choice rights of mothers, freedom decisions in receiving health services, respect to patient privacy and adequate and efficient access to information. These questionnaires disseminated between midwives and mothers in studied two hospitals during two months. Questions designed based on Likert scale. The tool's validity measured by content accreditation methodology. So tool disseminated between faculties of nursing and Midwifery College to accreditation.

After this phase tool was given to adviser and consular of research. The reliability of questionnaire was measured by Cronbach Alpha methodology. So questionnaires disseminated between 30 mothers and midwives in hospitals of Kermanshah University of Medical Sciences. Based on findings of research identified that questionnaire's elements between mothers was suitable (receiving optimize midwifery services: 0.83, respect to mother's privacy: 0.74, respect to choice rights of mothers and free decision making: 0.85, adequate and efficient access to information: 0.77) and also total questionnaires have suitable reliability (0.79). Also Cronbach's Alpha results between midwives was, receiving optimize midwifery services: 0.84, respect to mother's privacy: 0.73, respect to choice rights of mothers and free decision making: 0.71, adequate and efficient access to information: 0.83 and total questionnaire was 0.82. Data analysis was carried out by SPSS software version 19 and descriptive and deductive tests.

RESULTS

The average age of studied mothers was 26.4±7.6 and for midwives was 28.7±20.2 years. Maximum of parturitions that occurred in these hospitals was normal childbirth (74%) and only 26% was cesarean childbirth. Majority of mothers have diploma and under diploma degree (70%) and dominant majority of midwives had diploma or associate degree (87%). Individual features of samples in two groups was brought in table 1.

Table 1. Absolute and relative frequency of studied units

Variables		Frequency in mothers N %	Frequency in midwives N %
Age	Under 20 years	48(24)	0
	20-30	84(42)	34(34)
	30-40	52(26)	40(40)
	40	16(8)	26(26)
Education	Diploma and under diploma	140(70)	0
	Associated degree	38(19)	87(87)
	Bachelor	15(7.5)	
	Master and higher	7(3.5)	13(13)
Parturition type	Normal	148(74)	—
	Cesarean	52(26)	
Number of births	1	86(43)	—
	2	56(28)	
	3	37(18.5)	
	4	15(7.5)	
	5	6(3)	

Statistical indicators related to mother's rights questionnaire in Kermanshah University of Medical Sciences hospitals showed that in receiving optimize midwifery services factor, average and standard deviation for this element between mothers was respectively 3.67 and 0.67. Average and standard deviation between midwives was 4.24 and 0.51 respectively.

This explain that effective services have better scores from perspective of midwives than perspective of mothers.in regarded to use of 5 choices Likert scale in this research and allocated 3 score for moderate level we would explain that scores of both mothers and midwife's groups was higher than moderate level. In receiving optimize midwifery services element midwives acquired higher scores than mothers. In respect to mother's privacy element, results showed that this element between mothers have average 4.1 with standard deviation 0.74. While between midwives and from point of them this element has average 4.35 with standard deviation 0.78 which showed both groups have approximately same point.

Sub-scores of acquired average in both midwives and mother's groups were higher than moderate scores and haven't significant differences. In third element means respect to choice right and mother's freedom decision making, results showed that this element have average 3.97 with standard deviation 0.62 between mothers and have average 4.24 with standard deviation 0.49 between midwives. It could say that two groups don't have significant differences in this element's scores but both groups have evaluated this element higher than moderate. Access to suitable information as fourth element, results showed that this element have average scores 3.62 with 0.53 standard deviation between mothers and average scores 4.08 with 0.66 standard deviation between midwives which showed midwives acquired higher scores than mothers in this element table 2.

Table 2. Statistical indicators related mother's rights framework questionnaire

Variables	Mothers					Midwives				
	Frequency	Mean	SD	Min	Max	Frequency	Mean	SD	Min	Max
First factor	200	3.67	0.67	1.23	4.78	100	4.24	0.51	1.64	5
Second factor	200	4.1	0.74	1	5	100	4.35	0.78	1.21	4.84
Third factor	200	3.97	0.62	1.14	4.95	100	4.24	0.49	1.10	4.95
Fourth factor	200	3.62	0.53	1.34	4.65	100	4.18	1.66	1.11	4.87

Comparison amount of satisfaction in studied units showed that average satisfaction scores in receiving optimize midwifery services between mothers was 3.67 with 0.67 standard deviation and between midwives was 4.24 with 0.51 standard deviation. In regarded to data analysis differences between mothers and

midwives in receiving optimize midwifery services from t-test was significant (P<0.05). Comparison amount of satisfaction in studied units showed that average satisfaction scores in respect to mother's privacy between mothers was 4.1±0.74 and between midwives was 4.35±0.78. In regarded to data analysis differences between mothers and midwives in respect to mother's privacy from t-test wasn't significant (P<0.05).

DISCUSSION

Mother's rights framework mentioned that access to deferential and effective care is mother's right. Also mothers could want exact information about diagnosis, treatment type and diseases prognosis from physicians and other clinical staffs and give decisions about continuance or decline treatment procedures and maintain confidence in his care plans.[18] Finding of this section mentioned that mothers are satisfied from services relatively but averages of mothers and midwives in this element have difference. This section conclusions confirmed by Kagoya et al. and Gharibi et al.[9,19] While Masomi et al. and Khodakarami and jannesari concluded adverse results.[20,21] Similar to present study, Bayrami et al. in their research showed that 25 persent of control samples mentioned that midwives don't respect to privacy which in case group only 1% of women have same idea.[22] Results of this section confirmed by Milliez's research findings that mentioned majurity of samples satisfied from privacy measures.[23] Also Baba Mahmoodi et al. in their research founded that in respect to patient and his privacy, average scores between women patients were 18.31 and between men were 14.84. Don't existence of differences in this element showed that in this hospital both mothers and midwives and executive personnels respect to women's privacy.

Also in this research it was concluded that differences between views of mothers and midwives related to mother's choice right and free decision making wasn't significant. These conclusions showed midwives know mother's rights framework and respect to that.[24] Until recently healthcare providers supposed that without considering patient's rights they can make best decision about patient. But today situation changed and patients have various expectations from hospitals. To inform the patients and shared decisions to them and respect to their rights improve patient's recovery.[25] Baba Mahmudi et al. concluded similar findings in their research.[24] Despite of present findings, Ahmadi et al. founded that, choice right and free decision making acquired minimum scores.[26] This research finds that difference between mothers and midwives perspective in access to suitable information element was significant. Make inform the patient is a moral and ettical duty and despite current believes patient awareness don't resulted in emotional and uncontrol demands but modified expectations of providers and patients.[27] Studies proved that today patients awareness about health and hygiene increased as they knows heath and receiving healthcare is basic right of every human.[28] Of coarse new healthcare procedures are effective only with physician and patient interactions that affected outcomes positively.[29]

CONCLUSION

In regard to importance of respect to receive services rights during pregnancy course and significant differences between mothers and midwives perspectives related to access to clinical information in present research special attention is important in order to respect patient rights in hospital. Thus, improving current state and carring out educational courses for nurses and midwives must considered to improving treatment procedures.

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Ethical Clearance: The informed consent was obtained from the subjects and they were assured that their information will remain confidential.

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Indian Diabetes Risk Score for Screening of Undiagnosed Diabetes Individuals of Eluru City, Andhra Pradesh, India

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ABSTRACT

Background: Diabetes is undoubtedly one of the most challenging health problems of the 21st century. Globally as of 2013, an estimated 382 million people or 8.3% of adults, are estimated to have diabetes, out of which about 46% were undiagnosed. Diabetes is leading cause of death, disability and economic loss throughout the world.

Objectives: To assess the risk of diabetes mellitus in adults above 30 years of age in urban area of Eluru using the Indian Diabetes Risk Score (IDRS) and to determine the socio-demographic variables in relation to Diabetes risk.

Methodology: This was a community based cross sectional study carried out in the urban field practice area of Alluri Sitarama Raju Academy of Medical sciences (ASRAM), Eluru for a period of one year from May 2013 to April 2014 among 380 adults of 30 years and above age group.The data was collected using IDRS - Indian Diabetes Risk Score questionnaire which is added with demographic details of the study participants. Data was entered and analyzed using Microsoft Excel 2007 and necessary statistical tests like simple proportions and chi square test were applied.

Results: Out of 380, 136 (35.8%) had an IDRS of more than 60, 219 (57.6%) had an IDRS 30 to 50 and the remaining 25 (6.6%) had an IDRS less than 30. Approximately 14% of the study population had high abdominal obesity by waist circumference, 71% were having sedentary habits and 14.7% had family history of diabetes in either or both parents and their associations with diabetes risk score was significant (P<0.0001).

Conclusion: Indian Diabetic Risk Score is simple, user-friendly can be reliably applied as an effective screening tool for individuals with IDRS >60 high risk for diabetes in the community. The score helps to detect the undiagnosed high risk diabetic population in the community and also reduces the cost by at least 50% comparatively to other methods.

Keywords: *Age, Diabetes Mellitus, IDRS, screening tool, urban, Eluru.*

INTRODUCTION

The prevalence of type 2 diabetes is rapidly rising all over the world. Diabetes is undoubtedly one of the most challenging health problems of the 21st century. Globally as of 2013, an estimated 382 million people or 8.3% of adults, are estimated to have diabetes, out of which about 46% were undiagnosed.[1] About 80% live in low and middle income countries. This will raise the global burden of diabetes mellitus to above 592 million by 2035. This equates to approximately three new cases every10 seconds or almost 10 million per year. Diabetes is leading cause of death, disability and economic loss throughout the world and it is predicted

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to become the seventh leading cause of death in the world by the year 2030. Diabetes and its complications are major causes of early death in most countries.[1-3] The prevalence of diabetes is rising all over the world due to population growth, ageing, urbanization, industrialization, mechanization, dietary habits, increase of obesity, physical inactivity and sedentary lifestyles. This could have long-lasting adverse effects on a nation's health and economy, especially for developing countries.[1]

In 2011, 63% of the adult (aged 18–79 years) incident cases of diabetes (i.e., cases diagnosed within the past year) were diagnosed between the ages of 40 and 64 years. About 16% were diagnosed at age 18–39 years, and about 21% were diagnosed at age 65–79 years.[4-6] Community screening increases the public awareness and highlights the seriousness of the disease and could help in identifying asymptomatic individuals, who can ultimately be brought into management and can modify the course and complication of diabetes.[7] Asian Indian Type 2 Diabetes Mellitus (T2DM) subjects may be at greater lifetime risk for these complications due to the earlier onset of their disease.[8-10]

Indian Diabetes Risk Score (IRDS) developed by Madras Diabetes Research Foundation (MDRF, Chennai) and Dr. Mohan and his colleagues is a simple tool to help detect the risk of undiagnosed Type 2 Diabetes Mellitus in the community.[11] It was a simplified risk score for identifying undiagnosed diabetic subjects using four simple parameters namely age, waist circumference, physical activity and family history of diabetes. Here the minimum score is 0 and maximum is 100. A score of 60 and above is indicative of diabetes high risk. IDRS is more cost effective, involves simple non biochemical measurements and is easily applicable in a non-hospital setting. It can therefore be used as a simple first step in identifying the individuals with increased risk.

OBJECTIVES

1. To assess the risk of diabetes mellitus in adults above 30 years of age in urban area of Eluru using the Indian Diabetes Risk Score (IDRS).
2. To determine the socio-demographic variables in relation to Diabetes risk.

MATERIALS AND METHOD

This was a community based cross sectional study carried out in the urban field practice area of Alluri Sitarama Raju Academy of Medical sciences (ASRAM), Eluru for a period of one year from May 2013 to April 2014 among adults of 30 years and above age group.

Systematic random sampling method was used for the collection of sample in this study. Sample size calculated was 380 individuals 30 years and above age group in the urban health centre area which is calculated using Amrita Diabetes and Endocrine Population Survey (ADEPS) [12] a community based cross sectional survey done in urban areas of Ernakulam district in Kerala in 2005 by Menon VU, Kumar KV et al which has revealed a prevalence of Diabetes Mellitus as 19.5 per cent. This prevalence was considered to find out the sample size using $N = 4PQ / L^2$ with 95% confidence limits. Out of 412 calculated sample size, 32 study participants did not met the inclusion criteria and were excluded from the study.

The data was collected using IDRS - Indian Diabetes Risk Score questionnaire which is added with demographic details of the study participants. IDRS - Indian Diabetes Risk Score - A simplified form of score for screening undiagnosed Diabetics was a validated questionnaire [13-15] includes four variables like age, family history of diabetes, Physical activity and waist circumference measurement. An IDRS value ≥ 60 had the optimum sensitivity (72.5 %) and specificity (60.1%) and accuracy of 61.3%. IDRS has excellent predictive value for detecting undiagnosed diabetes in the community.

Four simple questions and one anthropometric measurement for waist circumference helped in deriving the information for Indian Diabetes Risk Score.

The variables were coded as follows

1. Age: <35 yr coded 0, 35- 49 yr 20 and ≥ 50 yr 30.
2. Abdominal obesity: males: waist circumference <90= 0, ≥ 90-99 cm 10, ≥100 cm= 20. females: <80= 0, ≥ 80-89 cm= 10, ≥ 90 cm=20.
3. Family history of diabetes: two non diabetic parents 0, one diabetic parent 10 and two diabetic parents 20.

4. Physical activity used three domains and was graded as vigorous 0, moderate 20 and sedentary 30.

The minimum score is 0 and the maximum score is 100. If the score is ≥60: Very HIGH RISK of having diabetes; 30 - 50: The risk of having diabetes is MEDIUM; <30: Risk of having diabetes is probably LOW.

A pilot study was conducted and tested for appropriateness of study questionnaire and the actual study was started after making necessary corrections and advises in it. Importance of the study was explained and an informed consent was taken from all the study participants before data collection and the study was approved by institutional ethical committee. The data was collected by house to house survey using interview method. A total of 380 study subjects were screened for diabetes mellitus using IDRS score and preventive measures were suggested to them.

Statistical analysis: All data collected was entered and analyzed using Microsoft Office Excel 2007 and the outcomes were expressed in percentages based on low, medium and high risk of developing diabetes using the IDRS risk score. Necessary statistical tests like proportions and chi-square test were applied.

RESULTS

A total of 380 individuals participated in the study, out of which 186 (48.9%) were males and 194 (51.1%) were females. The mean age of the study population was 44.5 years with a standard deviation of 11.5 years. About 32.6 % (124) of the study participants belong to more than 50 years age group, 97 (25%) were graduates in the study group with majority from class IV socio economic status. Table 2 shows the socio-demographic variables used in the study in relation to risk of development of diabetes risk using IDRS score.

Out of 380, 136 (35.8%) had an IDRS of more than or equal to 60; 219 (57.6%) had an IDRS 30 to 50 and the remaining 25 (6.6%) had an IDRS less than 30, which are shown in Table 1. Approximately 14% of the study population had high abdominal obesity by waist circumference, 71 % were having sedentary habits and 14.7 % had family history of diabetes in either or both parents, which are shown in Table 3.

Table 1: IDRS score classification of study population.

IDRS score category	Number	Percentage
≥ 60 (High risk)	136	35.8%
30 – 50 (Medium risk)	219	57.6%
<30 (Low risk)	25	6.6%
Total	380	100%

Table 2: Socio-demographic variables in relation to risk of development of diabetes.

Variables	Category	Frequency n (%)	p-value
Gender	Male	186 (48.9)	0.377 ns
	Female	194 (51.1)	
Literacy status	Illiterate	86 (22.6)	< 0.0001 s
	Middle school	60 (15.8)	
	High school	86 (22.6)	
	Intermediate	51 (13.4)	
	Graduation and above	97 (25.6)	
Socio economic status	Class I	18 (4.7)	< 0.0001 s
	Class II	42 (11.1)	
	Class III	130 (34.2)	
	Class IV	154 (40.5)	
	Class V	36 (9.5)	

*figures in parenthesis indicate percentage, s-significant, ns-non significant

Table 3: IDRS variables among study participants

IDRS variable	IDRS score	Frequencyn (%)	p-value
Age	0	124 (32.6)	< 0.0001 s
	20	132 (34.8)	
	30	124 (32.6)	
Abdominal obesity (waist circumference)	0	261 (68.7)	< 0.0001 s
	10	66 (17.4)	
	20	53 (13.9)	
Physical activity	0	11 (2.9)	< 0.0001 s
	20	97 (25.5)	
	30	272 (71.6)	
Family history	0	324 (85.3)	< 0.0001 s
	10	35 (9.2)	
	20	21 (5.5)	

*figures in parenthesis indicate percentage, s-significant

DISCUSSION

Among study population, 35.8% (136/380) were at high risk of developing diabetes and 57.6% (219/380) of the study population were at medium risk of developing diabetes. Only about 6.6% (25/380) were at low risk. There was no gender difference in our study in relation to diabetes risk. IDRS has excellent predictive value for detecting undiagnosed diabetes in the community with a sensitivity of 72.5% and specificity of 60.1%. There was a significant association found between diabetes risk and increasing age, waist circumference. There was a significant association found between diabetes risk and low physical activity, literacy status, socio economic status among study subjects.

Majority of the study population (71.6%) were having sedentary activity, where as in a similar study conducted by Gupta SK et.al.[15] in urban Pondicherry showed 90.5% of them belonged to mild to moderate physical activity. There was 14.7% positive family history in the study subjects which showed an significant association with diabetic risk score (< 0.0001), whereas it was 32.5% family history reported by Gupta SK et.al. [15] Majority of the study population belong to medium to high risk diabetic scores. The distribution of the population in high risk category in our study was higher than that reported by Gupta SK et.al.[15] (31.2%) and Chowdhury et.al.[16] (31.5%). In a similar undiagnosed population but lower than that reported by Nandeshwar et.al.[17] (68.8%); Geetha Mani et.al.[18] (59%) and Mohan et.al.[11] (43%). This risk difference may be due to incongruity in life styles of population. Further confirmation with oral glucose tolerance test (OGTT) is required among population with high IDRS score (≥60) to detect early occurrence of diabetes.

IDRS developed by Mohan et.al.[11] (2005), where only single waist measurement and three simple questions is one of the best diabetic risk score with very high sensitivity and specificity. It is the most useful tool to predict and screen undiagnosed diabetes in the given population.It does not require any medical or paramedical staffs to collect the data. It can be done even by a layman since it involves data like age, family history, physical activity and measurement of waist circumference. This IDRS tool is very useful in preventing the raise of prevalence of diabetes mellitus and its associated complications. Screening and early identification of the high risk individuals would help to take appropriate intervention like life style modification. It would help to prevent or to delay the onset of diabetes mellitus. Awareness was created among high risk individuals regarding risk factors and complications of Diabetes mellitus, Life style and dietary modifications have to be initiated to reverse the effects of risk factors among groups.

CONCLUSIONS

Our study demonstrates that the Indian Diabetic Risk Score is user-friendly, simple, fast, economical and effective. It can be reliably applied as an effective screening tool for individuals with IDRS ≥60 for diabetes in the community. The score helps to detect the undiagnosed high risk diabetic population in the

community. Modifications in the life style, dietary habits, health education to be incorporated to community to prevent the onset of type 2 diabetes mellitus in the future.

Ethical Clearance: taken from Institutional Ethical Committee

Source of Funding: None

Conflict of Interest: None

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Awareness and Predictors of PCOD among Undergraduate Students

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ABSTRACT

Polycystic ovarian Disease(PCOD) is one of the most common endocrine diseases in women of reproductive ages .It is a syndrome classically characterized by features of anovulation combined with signs of androgen excess.The purpose of this study was to assess the awareness of PCOD and predictors of PCOD present in undergraduate students.Present study was based on the Health Belief Model.A quantitative research approach with descriptive research design was used .The settings of the study were St.Xavier's College for women,Aluva and St.Theresa's College ,Ernakulam.By using cluster sampling method ,150 undergraduate students were selected from each college with a total of 300 students.A self administered questionnaire was used to assess the knowledge of PCOD and a checklist to assess the predictors of PCOD .Data analysis was done by using descriptive and inferential statistics. The study results showed that 48% of students had poor level of awareness regarding PCOD. The major risk factors identified were Waist- Hip ratio > 0.80 (97%). Among the subjects 22% reported manifestations suggestive of PCOD. There was a statistically significant association found between branch of education and awareness of PCOD ($P<0.05$). From the study result ,it is evident that awareness regarding PCOD is inadequate and high prevalence of risk factors and manifestations are seen among this age group.

Keywords: *Awareness, Predictors, PCOD, Under Graduate Students*

INTRODUCTION

Polycystic ovarian disease (PCOD) is one of the most common problems that may affect a woman's fertility. PCOD is a chronic hyper androgenic state which has many significant short-term and long-term implications for patients such as oligomenorrhea, amenorrhea, infertility, diabetes mellitus, cardiovascular disease, increased risk of endometrial cancer and excessive body hair[1].

The worldwide prevalence of PCOD range from 2.2% to 26% [2].The incidence of PCOD in adolescence in the year 2011 reports showed that in India 2.4% are having PCOD[3]. The reports of a study done by Nair MK et.al[4] (2011) regarding menstrual irregularity and PCOD among adolescent girls showed that of the 136 cases reported, 36 % cases were found to have PCOD.

A cohort study done by Raman N et.al (2011)[5] to find out prevalence of Poly Cystic Ovarian Syndrome in 460 Indian adolescent girls aged between 15 to 18 years from a residential college in Andhra Pradesh showed a prevalence of 9.13%.This draws attention to the issue of early diagnosis in adolescent girls among Indian adolescence. Early diagnosis can be done whenever a symptom arises.

PCOD is a condition that affects women of reproductive age group. PCOD usually starts during adolescence, but maynot be detected until women are in their late 20s or 30s as it takes a long time for symptoms to develop, and those symptoms vary widely from one women to the next[6]. PCOD is also associated with diabetic, hypertensive,cardiovascular complications also. Women with PCOD have a risk of myocardial infraction seven times than the normal. PCOD is the cause of more than 75% anovulatory infertility[7]. It affects more than 90% of obese women[8].

Early public awareness regarding PCOD can prevent the occurrence of the disease and further complications.Thus a study on PCOD has a great concern in the present scenario.

PROBLEM STATEMENT

A study to assess the awareness and predictors of PCOD among undergraduate students in selected colleges in Kochi.

OBJECTIVES OF THE STUDY

1. Identify the awareness of PCOD among undergraduate students.
2. Identify the predictors of PCOD among undergraduate students
3. Associate the awareness of PCOD among undergraduate students with selected demographic variables

METHODS AND MATERIALS

A Quantitative research approach with descriptive survey design is used for assessing the awareness and predictors of PCOD among undergraduate students.

Research settings of the present study were St.Xavier's college for women, Alua and St.Theresa's College, Ernakulam. Using cluster sampling 300 undergraduate students were selected .There were 12 undergraduate divisions in each college. From these 12 divisions, five divisions were selected randomly as a cluster using lottery method. All students in selected divisions who met inclusion criteria that are those who have attained menarche and who were available during data collection were selected for the study. Thus, 150 students were selected from each college with a total of 300 students.

Two tools developed by the investigator were used. Tool 1: It consists of Socio-demographic data and a structured questionnaire to assess the awareness of PCOD. Tool 2: A self administered checklist to assess the predictors of PCOD among undergraduate students. A Performa for assessing physical parameters was also present along with it. The content validity of the tool was checked by seven experts in the field of Obstetrics and Gynecological Nursing and got an index of 0.85.The Reliability co-efficient were 0.88 for the questionnaire and 0.7 for the checklist.

The research proposal was presented before the research committee and then ethical clearance was obtained from Thesis review committee of Amrita Institute of Medical Sciences and Research centre. Permission was obtained from the Principles of both Colleges where the study was conducted .A written informed consent was taken from the subjects of the study, before conducting the same. After selecting the Subjects using cluster sampling method, they were explained about the purpose of the study. The questionnaire and checklist were administered to the subjects .It took 20 minutes for each student to complete both tools. On the other hand height,weight, BMI, waist-hip ratio were assessed and documented in the performa by the investigator on the same day.

FINDINGS

The findings of the study were presented as follows

Socio-demographic data

The background data of undergraduate students described in Table.1

Table 1: Distribution of the undergraduate students based on demographic characteristics

n=300

Sl. No.	Demographic variables	Frequency (f)	Percentage (%)
1.	**Year of study**		
	a. First Year	88	29.33
	b. Second Year	75	25
	c. Third Year	137	45.67
2.	**Branch of study**		
	a. Arts	44	14.67
	b. Science	206	68.67
	c. Mathematics	50	16.67

Table 1: Distribution of the undergraduate students based on demographic characteristics (Contd.)

n=300

Sl. No.	Demographic variables	Frequency (f)	Percentage (%)
3.	**Religion**		
	a. Hindu	121	40.33
	b. Muslim	43	14.33
	c. Christian	133	44.33
	d. Others (Sikh)	2	0.67
	e. No religion	1	0.33
4.	**Socio-economic class**		
	a. High Class	1	0.33
	b. Middle class	299	99.67

Awareness of PCOD

n=300

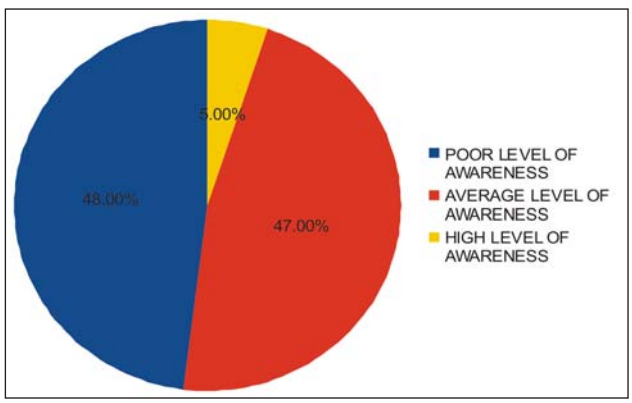


Fig.1. Pie diagram showing level of awareness of PCOD among subjects.

The awareness of PCOD is poor among 48% of students and average among 47% of students. Only five percentage of students having a good level of awareness.

Table .2: Mean scores of knowledge in different areas of PCOD

n=300

Areas of Knowledge level	Maximum score	Mean score	Mean score percentage (%)	SD
Basics of PCOD	2	0.76	38	0.69
Risk factors	4	1.99	49	1.02
Manifestations	4	1.37	34	0.88
Prevention	2	1.06	53	0.74
Management	4	1.54	38	1.17
Complications	4	1.21	30	0.82

Distribution of subjects based on Mean scores of knowledge in different areas of PCOD is given in Table 2.

Predictors of PCOD among subjects

Risk Factors of PCOD

Distribution of subjects based on the risk of PCOD is presented in figure 2.

n=300

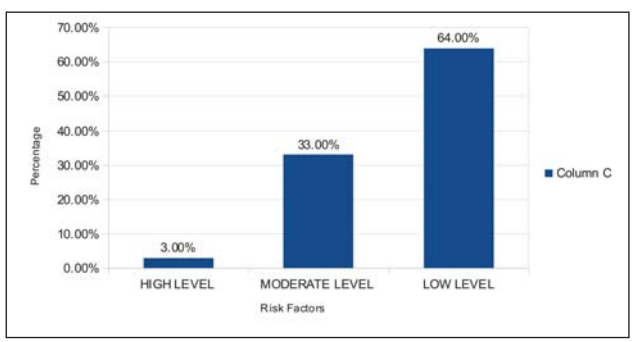


Fig. 2. Bar diagram showing distribution of participants based on the presence of risk factors

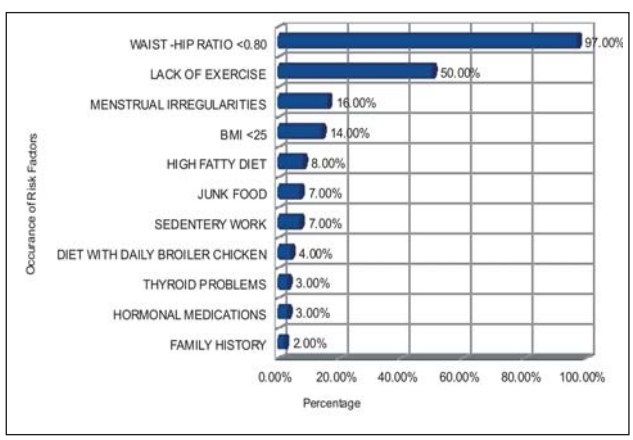


Fig. 3. Bar diagram showing frequency of occurrence of risk factors among subjects.

Increase in Waist - Hip ratio increases the risk for PCOD. Waist -Hip ratio is classified as low risk for PCOD (< 0.80) , average risk for PCOD (0.80 -0.85%) , high risk for PCOD (0.85 - 0.90) and extreme risk for PCOD (>0.90).And it is understood that 82% of subjects in high risk and 8% of subjects in extreme risk to have PCOD.

Manifestations suggestive of PCOD

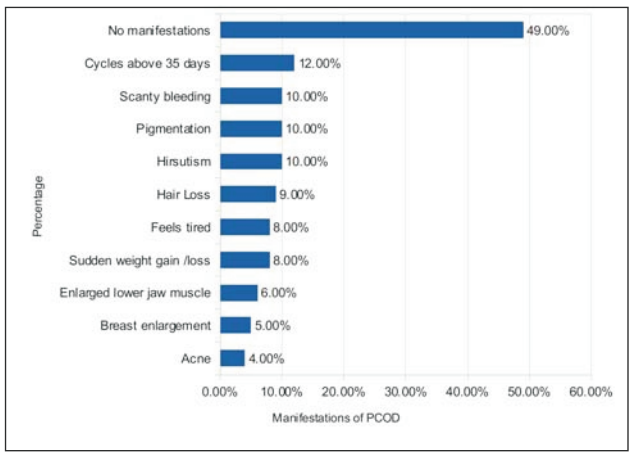


Fig. 4. Bar diagram showing occurance of manifestations of PCOD among subjects

All of the subjects were classified into having less than two manifestations and more than or equal to two manifestations(those who need further investigations to confirm PCOD and treatment.It's understood that 78% of subjects should need further investigations to confirm PCOD and treatment.

Association between awareness level of PCOD and selected demographic variables

Table 3 : Association between level of awareness on PCOD and selected demographic variables

n=300

Sl. No	Variables	p-value	Df value	Table value
1	Year of study	8.312ns	4	9.49
2	Branch of education	11.201*	4	9.49
3	Religion	6.010ns	8	15.51
4	Socio-economic status	1.087ns	2	5.99

*Significant at p<0.05, ns= not significant

DISSCUSSION

The findings of present study shows undergraduate students have inadequate knowledge regarding PCOD. 48% of students have poor level of awareness, 47 % of students have average level of awareness and 5% of students have good level of awareness.Among different areas of awareness the students scored better of students in the area of prevention of PCOD (53%). They scored least in the areas of prevention of PCOD (30%). A study conducted by colwell K lujan ME, lawson KL et.all[9] (2009) on women's perceptions of polycystic ovary syndrome following participation in a clinical research study in Sixty -eight women found that before attending the class 65% of the subjects had a poor knowledge level which was significantly increased following the intervention. While comparing the the result with that of literature ,the findings are more or less consistent in nature.

In this study predictors refers to the presence of risk factors and manifestations suggestive of PCOD as reported by the subjects in response to the checklist.

Risk factors of PCOD

The study results shows that three percentage of subjects had a high risk for getting PCOD.Also the result shows that Waist-Hip raitio more than 0.80 (72%) was the most common risk factor exhibited by the subjects. A cross-sectional analysis of 474 healthy adolescents aged 17 years was done by Neovius M,linney Y, Rossner S[10]. Meassurements of height, weight, Waist-circumference, hip - circumference and body fat percentage were obtained.BMI and WC showed strong positive correlation with body fat percentage in both sexes.(r=0.68 -0.73 :p<0.0001).The present study showed that 97% of students had a risk factor of Waist -Hip ratio more than 0.80 and 14% of students had a risk factor of BMI more than 25.

Manifestations suggestive of PCOD

Among the manifestations suggestive of PCOD, 12% of students exhibited irregular menstruation. 10% of students have scanty bleeding, pigmentation and hirsutism each. The least exhibited manifestation suggestive of PCOS was acne (4%). A study was done by Prakash PJ[11], to identify menstrual problems and related practices among 350 adolescent girls from Kerala.The study results showed that 24% of adolescent girls had irregular menstruation and 6.3% of adolescent girls had scanty menstruation.While comparing the result with that of related literature,the findings are more consistent in nature.

Year of study ,branch of education ,religion and socio-economic status were the selected demographic variables of the present study.The finding of the study showed that branch of study has significant association

with the awareness regarding PCOD among undergraduates.

The study is limitted to the subjects from two colleges of Ernakulam district so generalisation is possible within the district onlyound a deficiency in knowledge in the present study. Nurse can start an adolescent clinic for making them aware of the life style changes that affect health and the healthy lifestyle practices which they have to follow to prevent the occurrence of PCOS. She can implement college based screening programs for early identification of menstrual irregularities and the risk factors of PCOS .The study findings show the importance of including the topic menstrual irregularities, PCOS and health promoting behaviors in the syllabus of Nursing for both Undergraduate and Postgraduate Course.A nurse administrator can organize hospital based screening program for different age groups who visit OPDs. A nurse administrator can organize hospital based screening program for different age groups who visit OPDs.

CONCLUSION

The findings of the present study show that majority of undergraduate students have inadequate level of awareness regarding PCOD. The risk factors of PCOD identified were Waist-Hip ratio more than 0.80, lack of exercise and menstrual irregularity. Among the manifestations suggestive of PCOD, irregular menstruation was found to be common, followed by pigmentation and hirsutism. It concludes that Prevalence of predictors of PCOD is high among Undergraduate students. So college wise health education programmes should be conducted on the topic of PCOD and medical camps should be conducted in colleges to screen every girl who manifests any of the symptom of PCOD in order to confirm PCOD during its earlier period. This helps to prevent much co-morbidity that may occur in their future life.

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The Effectiveness of Mindfulness on the Reduction of Anxiety and Depression of Divorced Women

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ABSTRACT

This aim of this study is to evaluate the effect of mindfulness on the reduction of anxiety and depression in the divorced women of Ahvaz city. The study sample has included 30 divorced women that have been randomly selected. The subjects have been randomly divided into the control and study groups. The measurement tools in this study were: Beck Depression Inventory (BDI-II), and Beck Anxiety Inventory (BAI). This study is experimental with pretest, posttest and control group. The study group has been exposed to 8 sessions of mindfulness training that every session has lasted for 2 hours, after that the posttest has been conducted on both the control and study groups. The analysis of data by the using multivariate analysis of variance (MANOVA) with (?=0.05) level of significance has showed that mindfulness can reduce anxiety and depression in divorced women.

Keywords: *Mindfulness, anxiety, Depression, Divorced Women.*

INTRODUCTION

Mindfulness is a form of meditation that originates from the eastern teachings and religious rituals particularly Buddha; it means: paying special and purposeful attention to the current time without prejudice and judgment[1]. In mindfulness, the person in every moment is aware of his/her mind status, and after learning of the styles of mind that include doing and being, the person learns to move his/her mind from one status to another one. This process requires special training of cognitive and meta-cognitive behavioral strategies to centralize the attention process.

The mindfulness-based interventions have shown their effectiveness on the treatment of various psychological problems[2]. Beer (2003) has defined "mindfulness" as the observation of the developmental progress of internal and external motives and their emergence without any judgment[2].

Depression in the clinical meaning is the pathological and diagnosable depression with the DSM-5 official criteria. Clinical depression makes the person not to be able to do his/her regular daily life activities well (DSM-5). Depression weakens the power of judging and cause unusual behaviors; in any of these cases the patients cannot have a normal daily life[3]. We can consider depression as an emotional response to the privative and stressful situation that is associated with negative thoughts and feelings such as fear, anxiety, incompetence and sexual disorders. Anxiety is a reaction to a threat that does not exist. Morbid anxiety is a painful feeling that is associated with physical protests.

Anxiety is an abnormal personal state that is associated with fear and physical symptoms that indicates the overactive autonomic nervous system[4]. Kennerley (1995) defines anxiety as a normal phenomenon and natural response to danger or stress which turns to a problem when (its quality and

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quantity) does not fit the situation or takes too long. Anxiety is a response to stress which when it comes to danger prepares the person for action and reaction. In many cases, such an answer is logical and even vital; but, its abnormal state can affect a wide range of human activities[5]. Anxiety is a process of interacting sub-systems including cognitive, physical, emotional and behavioral; changes in one subsystem leads to changes in the other sub-system[6-7].

Due to the effect of mental disorders on individuals, families and society, the aim of this research is to investigate the effectiveness of mindfulness on the reduction of anxiety and depression in divorced women of Ahvaz city.

This study is consisted of two hypotheses

First hypothesis: Mindfulness is effective on the reduction of depression in divorced women.

Second hypothesis: Mindfulness is effective on the reduction of anxiety in divorced women.

METHOD

In this study, the experimental field research with pre-test and post-test control group has been used. The study and control groups have been selected randomly, and before applying the experimental interventions on the study and control groups, a pre-test has been conducted on them, and also a posttest has been conducted on both of the groups at the end of the intervention. The difference between the pre-test and post-test of each group has been evaluated in terms of statistical significance. Therefore, the effectiveness of mindfulness has been applied as the independent variables so its effect on depression and anxiety among the divorced women would be identified as the dependent variable.

The statistical population and sample

The statistical population of this research has been consisted of all the divorced women of Ahvaz City that have been studied in 2015. The study sample is consisted of 30 women from this statistical population that has been selected with simple random sampling method.

Research Tools

Beck Depression Inventory: This questionnaire has been developed by Beck in 1963 to assess the severity of depression and it has been revised in 1994. This scale consists of 21 articles, and every article takes the score of zero to 3. The highest score in this questionnaire is 63. Each item of this questionnaire measures one of the depression symptoms. The retest reliability of this questionnaire has been reported 0.48 to 0.86 with the mean of 0.86. Ghasemzadeh et al have reported the following coefficients for this questionnaire: 0.778 for alpha coefficient, 0.74 for test-retest coefficient, and 0.93 for its correlation with the first edition of the Beck Depression Inventory. In Iran, Dobson and Mohammadkhani have obtained 0.92 for the alpha coefficient of outpatients and 0.93 for the students, and 0.93 for the test-retest coefficient within a week. In the present study, the Cronbach's alpha has been used in order to determine the reliability of the Depression Scale that has been obtained 0.95 for the whole questionnaire which indicates the desirability of the reliability coefficient.

Beck Anxiety Inventory: It is a self-report scale with 21 questions that measures anxiety. This questionnaire has been set based on the 21 signs of anxiety; according to the Likert scale (scores of 0, 2, 1 and 3 for each question) the higher score shows more anxiety. This questionnaire mostly focuses on the physiological anxiety aspects. Three items of this scale are related to the anxious moods and its other three items are related to the certain fears, and its other questions measure the auto sings of hyperactivity and physical tension of anxiety. Beck and Clark (1988) have reported 0.93 for the internal consistency and 0.75 for the test-retest reliability of this scale. The conducted studies have shown that this test has a high validity and reliability, and its internal consistency (0.92; 0.30 to 0.76 for data correlation) is high. In a study that has been conducted on 1513 men and women from different age and gender groups in Tehran city to evaluate the reliability and validity of the Beck Anxiety Inventory on Iranian population, the test results have shown 0.72 of validity, 0.83 of reliability, and 0.92 of internal consistency. In the present study, the reliability coefficients of Anxiety Inventory have been calculated by Cronbach's alpha that has been obtained 0.92 for the whole scale which indicates the desirability of the coefficients of the questionnaire.

RESULTS

Table 1: Mean and standard deviation of the score of anxiety and depression

The study and control groups in the pretest and posttest stages

Variable	Stage	Statistical indicator	Mean	Standard deviation	Number
Anxiety	Pretest	Study	72.80	10.17	15
		Control	73.93	3.12	15
	Posttest	Study	33.20	11.75	15
		Control	76.60	1.84	15
Depression	Pretest	Study	46.40	11.74	15
		Control	43.07	4.87	15
	Posttest	Study	9.60	9.02	15
		Control	40.07	4.11	15

Table 2: According to the above table, the descriptive results of variables are shown.

The normal distribution of the scores of anxiety and depression

The normality of the distribution of the scores	Groups	Kolmogorov-Smirnov			Groups	Kolmogorov-Smirnov		
		Statistic	df	Sig		Statistic	df	Sig
Anxiety	Study	0.214	15	0.064	Control	0.167	15	0.200
Depression	Study	0.113	15	0.200	Control 0.131		15	0.200

As presented in Table 2, the null hypothesis for the normal distribution of the scores of the groups in the variables of anxiety and depression is confirmed. It means that the assumption of the normal distribution of the scores of pretest in both of the study and control groups is confirmed.

Table 3: the results of the multivariate analysis of covariance (MANCOVA) on the mean scores of the posttest of the anxiety and depression in divorced women of the study and control groups with pretest control

Name of the test	Value	DF of hypothesis	DF of error	F	Level of significance P	Eta squared	power statistical
Piliai trace test	0.796	3	23	29.95	0.0001	0.79	1.00
Wilks Lambda test	0.204	3	23	29.95	0.0001	0.79	1.00
Hotelling's trace test	3.90	3	23	29.95	0.0001	0.79	1.00
Roy's largest root test	3.90	3	23	29.95	0.0001	0.79	1.00

As it can been seen in table 3, by controlling the pretest of the significance level of all the tests, it has been shown that there is a significant difference between divorced women in the study and control groups at least in terms of one of the dependent variables (anxiety and depression) ($P<0.0001$, $F=29.95$).

Table 4: the analysis results of the covariance one-way MANCOVA on the mean scores of the posttest of the anxiety and depression of divorced women of the study and control groups with pretest control

Variable	Source of changes	Sum of squares	Degree of freedom	Mean of squares	F	Level of significance P	Eta square	Statistical power
Anxiety	Pretest	14.70	1	14.70	0.195	0.662	0.01	0.071
	Group	7076.36	1	7076.36	93.91	0.0001	0.79	1.00
	Error	1883.68	25	75.34				
Depression	Pretest	29.62	1	29.62	0.593	0.448	0.02	0.115
	Group	327.39	1	327.39	65.56	0.0001	0.72	1.00
	Error	1248.48	25	49.93				

By controlling the pretest, there is a significant difference between divorced women of study and control groups in terms of anxiety (P<0.0001, F=93.91); therefore, the first hypothesis is conformed.

Also, by controlling the pretest, there is a significant difference between divorced women of the study and control groups in terms of depression (P<0.0001, F=65.56); therefore, the second hypothesis is conformed.

DISCUSSION AND CONCLUSION

First hypothesis: Mindfulness is effective on the reduction of depression in divorced women.

The results of MANCOVA analysis in table 4 have shown that there is a significant difference between divorced women of study and control groups in terms of anxiety (P<0.0001, F=93.91). The mean comparisons have shown that mindfulness has reduced anxiety in the women of the study group compared to the control group. Thus the first hypothesis of this study is confirmed. The findings of this hypothesis are consistent with the findings of the previous researches including Beirami et al., (2013)[8], Arch et al (2013)[9], Garland and Howard (2013)[10]. These Researches have shown that mindfulness reduces anxiety in different groups, and mindfulness is always used as an effective treatment method to reduce every kind of anxiety including trait and state anxiety, social anxiety and anxiety disorders. The effectiveness of mindfulness on anxiety can be explained based on the constituent components of anxiety. The two important components of anxiety are cognitive elements and emotional elements. In other words, the effect of mindfulness can be explained based on the quality of its effects on the cognitive components of anxiety. Cognitive elements are the expected imminent damages especially and usually in the near future. It should be noted that the mental representations call the physical reactions[11]. The patients with anxiety disorders have cognitive disorders that cause the loss of their abilities to communicate effectively with the symptoms that are associated with anxiety disorder and other aspects of the environment. For example, in these patients, having concerns will hinder the normal processing of information at the time of using attention, memory or problem-solving skills. As a result, the patients with generalized anxiety disorder are likely to incorrectly describe the external motives as a threat or threatening thing [12]. On the other hand, the main basis of mindfulness-based cognitive therapy is cognitive therapy. In relation with the emotional components of anxiety, we can say that emotions play an important role in various aspects of life such as being adapted to changes and stressful events.

Emotional elements associated with feelings such as fear, horror and thrills are familiar to us; because when we want to describe the feeling of fear, we will talk about them. We are more aware of the emotional elements; while, we do not pause to reflect on our cognitive elements, we are not aware of the inner activities that are triggered by fear. In fact, emotions have an undeniable and effective role in the incidence or exacerbation of anxiety. On the other hand, one of the most important changes that may be created in the treatment of mindfulness in person is changing the emotional patterns especially emotional regulation. In general it can be said that, mindfulness reduces the anxiety in people through changing the cognitive and emotional patterns that have an important role in the incidence of anxiety.

Second hypothesis: Mindfulness is effective on the reduction of anxiety in divorced women.

The results of MANCOVA analysis in table 2 have shown that there is a significant difference between divorced women of the study and control groups in terms of depression (P<0.0001, F=65.56). The mean comparisons have shown that mindfulness reduces depression in the women of study group compared to the control group. Thus the second hypothesis of this study is confirmed. The findings of this hypothesis are consistent with the findings of the previous researchers including Rezaei, Alavi and Eftekhari (2013)[13], Garland and Howard (2013)[14], Arch et al (2013)[9]. These results have shown that this treatment reduces depression and prevents the recurrence of depression through the reduction of depressive symptoms, modification of cognitive beliefs, prevention of the symptoms of depression, mental rumination, dysfunctional thoughts and stress, reduction of negative emotional reactions, and amygdala emotion regulation, and increase of the activities of brain areas. One of the foundations of mindfulness is cognitive therapy. Beck's cognitive therapy focuses on the cognitive changes that are supposed to exist in major depressive disorder. These changes include the selective attention to the negative aspects of pathological situations and unrealistic perceptions about outcomes. These programs include the elements of cognitive therapy that separate the one's view from his/her thoughts and lead to the lack of focus. In explaining the effect of mindfulness-based cognitive therapy on depression, it can be said that one of the

most important goals of the design of this treatment is to reduce the symptoms of depression. In fact, mindfulness is expletory of the early cognitive therapies. One of the features of this treatment is mindfulness that refers to individual's awareness of the processing of information, especially about the events that may be interpreted negatively. In addition to the mentioned cases, the effect of mindfulness-based cognitive therapy can be explained by the interventions that involve the mindfulness training. It is one of the cognitive therapy or cognitive change methods. Observing the thoughts and feelings and applying the descriptive tags to them create this conception that they cannot always accurately represent the reality. For example, the feeling of fear does not mean that there is an eminent danger, and the thought of "this is my fault" is not necessarily true[15]. The practical advantage of mindfulness skills in encouraging cognitive changes is that its exercises can be performed even during the recovery, and they can prevent the depression relapse.

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A Study on Clinical Profile and Trend in Suicide Attempters in Psychiatry Consultation

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ABSTRACT

Background: There is a high risk of suicidal attempt in patients with psychiatric problems. This risk varies according to the sociodemographic status and clinical presentation. Periodic systematic profiling of suicidal risk factors in developing countries is an established need.

Objectives: The objective was to study the sociodemographic data, psychiatric disorder, precipitating events, mode of attempt and intent of attempt in suicide attempted patients.

Materials and Method: During the 2 years period all referrals were screened for the presence of suicide attempters in consultation liaison services. Those who fulfilled the criteria for suicide attempters were evaluated by using semistructured pro forma containing sociodemographic data, precipitating events, mode of attempt, psychiatric diagnosis by using ICD-10 and intent of the attempt.

Results: Adult age, rural background, house wives and students, unemployed, below matriculation educated were more represented in this study. Gender wise more females represented. More than 80% of all attempters had psychiatric disorder. Majority had a precipitating event prior to suicide attempt. The most common method of attempt was by use of insecticide poison. Many of have moderate intent in the attempt.

Conclusions: Majority of suicide attempter patients had mental illness. Early identification and treatment of these disorders would have prevented morbidity and mortality associated with this.

Keywords: *Consultation Liaison Services, Suicide Attempt, Intent*

INTRODUCTION

Suicidal attempts, are a challenging public health issue. A high suicide rate in any society is an index of social disorganization. Suicide is a complex, multidimensional phenomenon that has been studied from philosophical, sociological, and clinical perspective. Suicidal behavior and suicidality can be conceptualized as a continuum ranging from suicidal ideation to suicide attempts and completed suicide. Attempted suicide is defined as a potentially self-injurious action with a nonfatal outcome for which there is evidence, either explicit or implicit that the individual intended to kill himself or herself. The action may or may not result in injuries. The majority of suicides (85%) in the world occur in low- and middle-income countries. Over 100,000 people die by suicide in India every year. The National Crime Records Bureau's report on the number of suicides in the country is to be believed, during the decade (2004–2014), it has recorded an increase of 15.8% (1,31,666 in 2014 from 1,13,697 in 2004). The highest incidents of 16,307 suicides were reported in Maharashtra followed by 16,122 suicides in Tamil Nadu and 14,310 suicides in West Bengal accounting for 12.4%, 12.2% and 10.9% respectively of total suicides[1-4].

Suicide attempts ranging from 10 to 40 times more frequent than completed suicide. In a large WHO multicenter study on incidences of attempted suicide in Europe it was found that highest frequencies were

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among young adults between 24 and 34 years. In India, suicide attempts are more common in females, majority were Hindus, married, and the suicide rate is three times higher in rural areas than the overall national rate. Majority were staying in a nuclear family and they were unemployed[5-10] .

Poisoning (36.6%), hanging (32.1%), and self-immolation (7.9%) were the common methods used to commit suicide and poisoning is the commonest mode of attempt by the Indian population[10].

In India and elsewhere, acts of suicide are heterogeneous with respect to the level of suicide intent. Signs and symptoms that indicate suicide risk may be displayed for weeks before high-intent acts are committed,6 and strategies that seek to identify individuals at risk (e.g., depression screening)[7,8] may be required. Low-intent acts of suicide may happen quickly, which leaves little time for risk recognition.6 One strategy for reducing suicidal behavior is to reduce access to methods of suicides [9]

Suicide intent is a complicated construct that comprises 2 major elements: (1) the level of planning and forethought preceding an act of suicide (objective planning), and (2) the intended outcome and perceived lethality of the act (perceived intent)[10-12]. Although objective planning and perceived intent are related variables, they are not redundant. For example, less-planned acts of suicide may be accompanied by high perceived intent, as documented in a case series of individuals in London who attempted suicide by jumping in front of a railway train. Interviews with survivors of the attempts determined that the acts were preceded by little planning yet there was high perceived intent to die. It has been argued that the study of planning in particular can inform suicide prevention policy. Supporting this viewpoint, an investigation of suicide in India showed less-planned suicides were especially likely to be carried out by individuals who ingested pesticides stored in the home, which suggests that measures to restrict home storage of pesticides in India may have the largest effect on suicides carried out impulsively. The primary purpose of our study was to identify correlates of level of intent of suicide attempts among individuals who lived in rural areas of India and attempted suicide. We also sought to examine correlates of planning and perceived intent among individuals who lived in rural India and attempted suicide.

MATERIALS AND METHOD

This study was a prospective study and carried out over the period of 2 years from January 2012 to January 2014. It was carried out in a medical college setup and outpatient based clinic in rural area of Andhra Pradesh,south India. All the referred cases are initially evaluated by a senior resident subsequently reviewed by consultant psychiatrist. The cases are evaluated for psychiatric illness and diagnoses are made as per the ICD-10 and an appropriate treatment plans are formulated and carried out (WHO 1992)[13]. The semi-structured pro forma was made to document the information regarding sociodemographic data, source of referral, diagnosis of the physical condition, assessment of intent of the attempt,reason for psychiatry referrals, psychiatric diagnosis, and management done.

The pro forma specialized semistructured pro forma was made for patients who were admitted with deliberate self-harm. This pro forma contained besides the documentation of a sociodemographic profile, a detailed psychiatric evaluation for psychiatric illness, immediate precipitating event prior to self-harm (within a week period), method used, family history of psychiatric disorders including suicide or deliberate self-harm, current mental status examination, etc. Daily all the referrals were screened for the presence of any case with suicide attempters and this specialized semistructured pro forma was applied to gain more information related to suicide attempters.

After the initial evaluation, these patients were subsequently followed up in the in-patient setting till they are physically stable. After this, depending on the mental status examination and risk of future attempt, these patients are either transferred to psychiatry ward or are followed up in psychiatry OPD. The psychiatry management usually involves treatment of axis I and axis II diagnosis either by pharmacotherapy or psychotherapy or both.Degree of suicide intent was assessed using total scores on the Beck Suicide Intent Scale (SIS).27Terciles were used on total scores to divide case patients into subgroups according to low intent (SIS < 10, n = 85, 31%), intermediate intent (SIS 10–15, n = 98, 35%), and high intent (SIS > 15, n = 94, 34%). Terciles were also used to divide case patients into 3 levels of objective planning (< 3, 3–6, > 6) and into 3 levels of perceived intent (< 7, 7–10, > 10).

RESULTS

During the study period (2012-14) of 2 years duration we totally received referral of 100 cases from various departments for evaluation of attempted suicide and self or brought by relatives. Majority of study sample not referred by various professionals (40 patients).

Sociodemographic details are displayed in table 1 .The mean age at suicide attempt was 28.5 years (SD 11.62), with a range of 10-60 years.

Table 1. Sociodemographic data

Variables	
Age	
10-20	24
20-30	26
30-40	38
40-50	12
Gender	
Male	38
Female	62
Education	
Below 10th class	38
10th class and above	62
Marital status	
Married	56
Unmarried	40
Divorced	4
Family Status	
Nuclear	10
Joint	48
Extended	42
Occupation	
Student	25
House wife	32
Labourer	24
Teacher	4
Professional	5
Farmer	10
Religion	
Hindu	91
Muslim	5
Christian	4
Residence	
Rural	76
Urban	24
Past history of suicide attempt	34

When the subjects were assessed for psychiatric illness, nearly four-fifth (82%) of them were diagnosed to have some psychiatric disorder, with emotionally unstable/impulsive personality traits/disorder (34%) being the most common and next that was depression related disordersand others psychotic related disorders [Table 2].

Table 2 Clinical features

Provisional/Current Psychiatric Dignosis	**N%**
Impulsive/ emotionally unstable personality traits or disorder	34
Depression (unipolar/bipolar disorder)	24
Schizophrenia and other psychotic disorder	12
Adjustment disorder	12
Intentional self injury	8
Other psychiatric disorder	10

Majority of the subjects had a precipitating event prior to the suicide attempt, most common of which was interpersonal problems with family members other than spouse (22%), followed by interpersonal problems with spouse (19%)

The most common method of self-harm was consumption of pesticide poisoning (31%) followed by use of sleeping pills consumption(26%), and hanging method (14%) [Table 3]. Use of poisoning was more in female gender (62% for females and 38% for males).

Table 3: Mode of attempt

1. Poision consumption	31
2. Sleeping pills	26
3. Hanging	14
4. Fall from height	8
5. Cut throat	5
6. Drowning	5
7. Self immolation	4
8. Facing opposite to moving vehicle	4
9. Forced starvation	3

Majority of having intent to commit suicide is moderate only . Nearly one- fourth(24%) having high intent . one-fifth (21%) having low intent to commit suicide of which casual parasuicidal attempt.

DISCUSSION

The study obtained data on the sociodemographic and clinical profile of subjects with suicide attempters presenting to a tertiary care hospital referred to psychiatry consultation-liaison services for psychiatric evaluation. The sociodemographic profile of our sample was similar to that in other studies from India[14,15] .Majority of our sample comprised adults (mean age 28.5 years) suggesting that they constitute a vulnerable group. This observation is identical with previous

literature from India and the West [17] . There are reports of both male and female predominance in suicide attempters in hospital-based studies.[35] The gap between male and female suicide rates in India is relatively small and our study also shows similar finding[18] . However, this is at variance with Western literature wherein majority of attempters were females[19] . However, in Indian studies, it is common to find a higher proportion of attempters being married, as observed in this study. A considerable proportion of attempters had Life Events related to relationships and marriage. Similar results are shared by the multinational study by Fleischmann et al. in which subjects from Indian center who attempted suicide/ indulged in self-harm were more frequently married than single[20]. In India the joint family concept still exists and people are living in joint rather than in the nuclear family setups. The fact that predominance cases were from rural backgrounds also perhaps reflects the enmeshment living relations with relatives and neighbor's which makes them early presentation to our department. Though another pragmatic reason for predominance of rural subjects could be accessibility to the hospital leading to greater treatment seeking behavior.

The common method employed to execute self-harm was insecticide poisoning. Similar findings have been reported from elsewhere in India and other low- and middle-income countries[18-20].Unrestricted availability of the organophospherous poisions in Indian household for agriculture purpose is the probable cause. Easy availability of sleeping pills from pharmacies with out prescription of doctors. Restriction of access to the methods of suicide has received some attention as a possible way of prevention of suicidal death. However, it has been observed in an Indian study that when the use of pesticide was restricted, the mode of suicide changed while the total number of suicides remained static. Nevertheless, as poisoning was the most common method of suicide attempt, and pesticides were used most frequently, restricting the availability of organophosphorus compounds, banning the more toxic ones, as well as efforts to decrease the period between the ingestion and initiation of treatment by having poisoning treatment facilities in primary healthcare centers, may be helpful in preventing or lowering the rate of suicidal attempts[21-23] .

Siwach and Gupta (1995) reported marital disharmony, economic hardships, and scolding/ disagreement with other family members as the major precipitating factors[24]. Interpersonal problems and academic-related problems found in our study are in line with the same.

A variation in the type and frequency of the psychiatric disorders is noted in suicide attempters in India, although depressive disorders are common[18-24]. In this study, diagnosis of emotionally unstable/ impulsive personality traits/disorder being commonest constituting 34% subjects nearly matches the existing literature in world. Patients with mood disorder were more vulnerable than others considering planned attempts of high potential, even though most of them used chemical methods. It is to be noted that 82% of our subjects had diagnosable psychiatric illness, but most of them had not sought treatment for the same (70%). This implies that there is an urgent need to promote education regarding the nature of psychiatric disorders and their treatability across the community to allow their early detection and timely treatment thereby minimizing suicide attempt. Stigma reduction programs, effective skills on the part of primary care and family physicians for identification and management of potential suicidal persons, coverage of unreached areas in terms of better accessibility of mental healthcare should be promoted. Suicide prevention must form an integral part of community-based mental healthcare activities. The commonest site for treatment being sought was medicine and surgery where they land up with various complication related to suicide attempters. So consultation liaison services are very important in these departments and timely referral will prevent them from subsequent suicide attempt, its related morbidity and mortality.

CONCLUSION

The young age group represents the most vulnerable group nearly more than three fourth in need. Four-fifth of the patients was diagnosed with psychiatric illness at presentation, which clearly argues for need of early, prompt diagnosis and treatment of such cases so as to prevent such attempts.. Public education for early identification and help seeking for mental disorders, awareness regarding this in the healthcare staff, and facilities for management of common mental disorders in rural and urban areas would probably help.

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A Study of Organo-phosphorous Compound Poisoning with Reference to Blood Sugar and Pseudocholinesterase Levels

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ABSTRACT

Introduction: Intentional self-poisoning is one of the most common methods of suicide worldwide. Acute poisoning is an important clinical emergency and contributor to morbidity and mortality.

Aims and objectives:

1) To study the level of blood sugar in correlation with plasma pseudo cholinesterase.

2) To predict the prognosis and mortality based on pseudo cholinesterase activity. Result: 100 cases of OP poisoning were studied. 59% had random blood sugar level between 60-200mg% and 41% had sugar level more than 200mg%. Plasma pseudocholinesterase levels normal value was taken as >2900IU/L. 39% of the cases had normal value,12% were less than <1000IU/L. 39% of the patients with RBS between60-200mg% had pseudocholinesterase level >2900IU/L and none with RBS 200mg%, Pseudocholinesterase level was co-related with various type of poison consumed. 23 patients with history of consumption of monocrotophos had values below 2900IU/L, 15 patients with endosulphan consumption followed by 5 withekalux.

Conclusion: The random blood sugar level doesn't alter the mortality of OP poisoning cases and pseudocholinesterase level estimation may be measured at the level of admission to classify OP poisoning cases.

Keywords: *Organo-Phosphorous Compound; Poison; Random Blood Sugar; Pseudo Cholinesterase Level.*

INTRODUCTION

Poison is a substance, solid,liquid or gas which when introduced into the living body or brought into contact with any part produces ill-health or death. All cases of poisoning caused byeither accidental use of drugs and chemical substancesor the use of drugs by children due to curiosity are known as accidental or unintentional poisoning. Poisoning is a qualitative term used to define the potential of a chemical substance in actingadversely or deleteriously on the body. [1] Poisoning cases are increasing day-by-day due to changes in lifestyle and social behaviour[2].

It is estimated by World Health Organization (WHO) that around 0.3 million people die every year due to various poisonings.[3] OP poisoning is one of the most common poisoning seen in India. India has been predominantly an agricultural country since ancient times and pesticides/insecticides are used abundantly for cultivation and these substances are easily accessible to the people. In organo-phosphorous poisoning, common route is ingestion for suicidal

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purpose but infrequently accidental cases are also encountered where OP compounds have been ingested or inhaled by mistake. OP compounds are anti-acetyl cholinesterase which exert their toxicity by allowing acetylcholine (ACh) to overact at its receptors in the central and peripheral nervous system. The anticholinesterase effects can be evidenced biochemically by suppressed levels of serum pseudocholinesterase (PCE) and red cell cholinesterases.[4,5]

The objective of the study are to study the level of blood sugar in correlation with plasma pseudocholinesterase and to predict the prognosis and mortality based on pseudo cholinesterase activity.

MATERIALS AND METHOD

The present study was conducted at the medical emergency department, in a tertiary teaching hospital located in north Karnataka. The patients of suspected organo-phosphorous compound poison were included. A total of 100 cases of organo-phosphorous with history of OP poison consumption and eye witness were included in the study. The study was carried out for the period of 1 year. Patients who had a history of Diabetes mellitus, history of consumption of alcohol, drugs or other poisons were excluded from the study. A detailed history was taken in every case. Chief complaints of the patients were noted in each of the cases as given by patient. If the patient is in altered sensorium, the history is taken through reliable informant. A detailed general physical and systemic examination was done, with particular attention to state of consciousness, alertness, drowsiness, stupor and coma, size of the pupil and reaction to light, pulse rate and blood pressure.

Patients were given first aid measures, clear airways if necessary and to support the ventilation if necessary. Stomach wash was given, if the patient was unconscious Ryle's tube aspiration followed by cuffed ET tube with stomach wash was given. Decontamination of skin was done by changing contaminated clothes and washing the skin with soap and water, then immediately before starting specific treatment with antidote atropine, oximes and IV fluids, blood was drawn for random blood sugar levels and for plasma pseudocholinesterase as IV fluids containing dextrose and atropine alters the blood sugar levels. Random blood sugar level was calculated by Glucose-oxidaseGOD-POD end point caloric metric method.

RESULTS

The following observations were made after studying 100 cases of suspected OP poisoning cases admitted in medical emergency department, in a tertiary teaching hospital.

Table 1: Distribution of study subjects according to random blood sugar levels

Random blood sugar level	No. of cases	Percentage
<60mg%	00	00%
60-200mg%	59	59%
>200mg%	41	41%
Total	100	100%

The above table infer that, 59% had random blood sugar level between 60-200mg% and 41% had sugar level more than 200mg%

Table 2: Distribution of study subjects according to pseudocholinesterase level measured

Range	Number	Percentage
>2900 IU/L	39	39%
2000-2900 IU/L	26	26%
1000-2000IU/L	24	24%
<1000IU/L	12	12%
Total	100	100%

The above table shows Plasma pseudocholinesterase levels measured in study subjects who have consumed poison, normal value was taken as >2900IU/L. 39% of the cases had normal value, 26% of them were between 2000-2900IU/L and 12% were less than <1000IU/L.

Table 3: Comparison of pseudocholinesterase level with random blood sugar levels

Pseudocholinesterase level	RBS 60-200 mg%	RBS >200mg%
>2900 IU/L	39	00
2000-2900 IU/L	14	12
1000-2000IU/L	6	18
<1000IU/L	1	10

The above table depict, 39% of the patients with RBS between60-200mg% had pseudocholinesterase level >2900IU/L and none with RBS 200mg%, where as 21 patients with RBS between 60-200mg% were below 2900IU/L and 40 patients with RBS greater than 200mg% were below 2900IU/L.

Table 4: Pseudocholinesterase levels in various organophosphorous compound poisonings

Pseudocholinesterase level	Monocrotophos	Endosulphan	Ekalux	Trimet	Rogar	Ratnabor	Unknown	Others
>2900 IU/L	2	2	8	12	4	4	3	6
2000-2900 IU/L	5	6	4	1	1	2	3	3
1000-2000IU/L	12	8	1	0	0	0	2	1
<1000IU/L	6	1	0	0	1	0	1	1

Pseudocholinesterase level was co-related with various type of poison consumed. 23 patients with history of consumption of monocrotophos had values below 2900IU/L, 15 patients with endosulphan consumption followed by 5 in ekalux.

DISCUSSION

A study of 100 cases of suspected OP poisoning cases admitted to medical emergency department, in a tertiary teaching hospitalwere studied to know the various types of poison consumed and also to know the association of random blood sugar in co-relation with pseudocholinesterase level. Maximum number of study groups was seen in the age group 21-30 years (36%). NimalSenanayake and LaksmanKaralliedde also reported largest number of patients in the same age group[6,7]. Male predominance was seen in our study (54%), NimalSenanayake and LaksmanKaralliedde also had male predominance in their study.[7]

Studies conducted in other parts have shown that the majority of poisoned patients were young adults less than the age of 25 and the female-to-male ratio was between 1.7 and 3.[8,9] Contrast to our study's findings, some studies have shown mean age group was above 30 years and also female-to-male ratio was 1:1.[10,11]In our study 25% of the cases were due to Monocrotophos,17% due to Endosulphan. Karalliedde et al have shown that the common agents were Dimethioate, Methamidophos, Malathion, Monocrotophos and Fentthion[6].Our study subjects have shown that, 59% had random blood sugar level between 60-200mg% and 41% had sugar level more than 200mg%. Shobha et al reported transient glycosuria in 69% of patients after organophosphate poisoning. However, none of the patients had new-onset diabetes mellitus[12]. Zadik Zand Akyildiz BNet al studies have reported organophosphate intoxication presenting as diabetic ketoacidosis has been repeatedly in the pediatric population[13,14].Plasma pseudocholinesterase levels measured in study subjects who have consumed poison, normal value was taken as >2900IU/L. 39% of the cases had normal value, 26% of them were between 2000-2900IU/L and 12% were less than <1000IU/L. Low levels of Pseudocholiesterase were observed in all OP poisoning cases[15,16],where asGoswamy et al study have concluded thatlow pseudocholinesterase levels were of greatest predictive value for ventilation in op poisoning cases[17]

CONCLUSION

The significance of estimation of serum random blood sugar and pseudocholinesterasein assessment of the severity as well as prognosis in patients of OP poisoning has been elusive. Half of our study subjects were having high RBS levels and 26% were with high pseudocholinesterase levels.

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Prevalence of Intestinal Parasitic Infections in School Going Children in Rural Areas of Hapur District, UP, India

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ABSTRACT

Aim: The aim of this study was to determine the prevalence of intestinal parasitic infections in school going children in rural area.

Materialand Method: The early morning stool samples were collected from 351 apparently healthy school going children aged 3-12 years from adjacent rural area. All the stool samples were also processed by Formol-Ether (Modified Ritchef's method) concentration method to enhance the recovery of parasites and the smears were examined by wet mounts and iodine mounts.

Result: A total of 106 (30.2%) samples were found to be positive for parasites by concentration method while only 90 (25.64%) samples were positive by direct microscopy.Giardia intestinalis was the most common parasite observed.

Conclusion: Our study shows a moderately high prevalence (30.2%) of intestinal parasitic infection in school going children in rural area. Proper drinking water, waste disposal, hand washing and promotion of personal hygiene through education are important for prevention of intestinal parasitic infections in school going children.

Keywords: *Giardia Intestinalis, Stool, Concentration Method, Hand Washing*

INTRODUCTION

Parasitic diseases have been with mankind since time immemorial. Even today these diseases remain among the major cause of human misery and death in the world and an important obstacle to the development of economically less favoured countries[1]. School age children are one of the groups at high risk for intestinal parasitic infections and these infections have detrimental effects on the survival, appetite, growth, physical fitness and cognitive performance of school age children[2]. It is estimated that some 3.5 billion people are affected, and that 450 million are ill as a result of these infections, the majority being children[3]. School children aged

5-15 years suffer the highest infection rate and worm burden that attributes to poor sanitation and hygiene[4]. About 400 million school age children are infected with soil-transmitted helminths (STHs) i.e. round worm, whip worm and hook worm world-wide, a large proportion of whom are found in East Asia region[5]. School children harbour some of the most intense helminthic infections, which produce adverse effects on health, growth and scholastic performance[6]. Gastro-intestinal protozoa and helminths flourish in settings characterized by warm temperature, humidity, poor sanitation, dirty water and crowded housing. Infection rates are highest in children living in sub-Saharan Africa, followed by Asia, Latin America and the Caribbeans[7]. The problem is more in rural areas than urban areas and poly-parasitism is also seen in some areas[8].

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MATERIAL& METHOD

The study was conducted for a period of 6 months from April-September, 2016 in the Department of Microbiology at Saraswathi Institute of Medical Sciences, Hapur, UP. The stool samples were collected from 351 apparently healthy school going children aged 3-12 years from adjacent rural areas. The early morning stool samples were collected in dry, clean, wide mouthed leak-proof containers under standard technique[9] and transported to the laboratory of the institute within 4 hours of collection. Samples were examined for presence of parasites by direct wet mounts and iodine mounts. All the stool samples were also processed by Formol-Ether (Modified Ritchef's method) concentration method to enhance the recovery of parasites and the smears were examined by wet mounts and iodine mounts[10]. A standardized questionnaire was provided to the parents of participating children regarding age, gender, residence, occupation of parents, number of family members, housing conditions, domestic animals reared, regularity of deworming, water supply, type of toilets, hand washing habits and complaints like abdominal pain, teeth grinding, irritability in sleeping and peri-anal itching[2,11]. Informed consent was taken from parents, teachers and participating students.

The following formula was used to calculate the prevalence of infection[2]:

$$\text{Prevalence} = \frac{\text{Number of subjects testing positive}}{\text{Number of subjects investigated}} \times 100$$

RESULTS

Stool samples were collected from 351 students (male=198, female=153) aged 3-12 years, of which 106(30.2%) samples were found to be positive for parasites by concentration method while only 90(25.64%) samples were positive by direct microscopy (table1).

Table 1: Comparison of methods

		Direct microscopy wet mount	Direct microscopy iodine mount	Concentration methodwet mount	Concentration methodiodine mount
Total cases	351	90	90	106	106
Percentage	100	25.64%	25.64%	30.2%	30.2%

A total of 52 out of 153 female students (33.98%) and 54 out of 198 male students (27.27%) were positive for parasites in their stool samples by concentration method. Atotal of 130 parasites were observed in 106 positive samples.Out of total 130 parasites, Giardia intestinalis was observed most number of times (n=51) (39.23%) followed by Entamoeba histolytica (n=25)(19.23%), Hymenolepis nana (n=25)(19.23%), Ascaris lumbricoides (n=20)(15.38%), Hookworm (n=04)(3.07%), Trichuris trichiura (n=03)(2.30%) and Enterobius vermicularis (n=02)(1.53%)(table 2).

Table 2: Distribution of total number of parasites (n=130) in positive cases by concentration method:

Parasite	Total number (n=130)
Giardia intestinalis	51 (39.23%)
Entamoeba histolytica	25 (19.23%)
Hymenolepis nana	25 (19.23%)
Ascaris lumbricoides	20 (15.38)
Hook worm	04 (3.07%)
Trichuris trichiura	03 (2.30%)
Enterobius vermicularis	02 (1.53%)

Out of total 106 positive cases, single parasite infection was observed in 84 (79.2%) samples and mixed parasite infection in 22 (20.8%) samples. In single parasite infection cases (n=84),

the most common parasite was Giardia intestinalis (n=37)(44.04%) followed by Entamoeba histolytica (n=16)(19.04%), Hymenolepis nana (n=16)(19.04%), Ascaris lumbricoides (n=11)(13.09%), Hookworm (n=02)(2.38%), Trichuris trichiura (n=01)(1.19%) and Enterobius vermicularis (n=01)(1.19%). In mixed parasite infection cases, where 46 parasites were observed in 22 cases, the most common parasite was Giardia intestinalis (n=14) (30.43%) followed by Entamoeba histolytica (n=09)(19.56%), Hymenolepis nana (n=09)(19.56%), Ascaris lumbricoides (n=09)(19.56%), Hookworm (n=02)(4.34%), Trichuris trichiura (n=02)(4.34%) and Enterobius vermicularis (n=01)(2.17%) (table 3).

Table 3: Distribution of parasites in positive cases by concentration method:

Parasites	Single parasite infection (n=84)	Mixed parasite infection (n=46)
Giardia intestinalis	37 (44.04%)	14 (30.43%)
Entamoeba histolytica	16 (19.04%)	09 (19.56%)
Hymenolepis nana	16 (19.04%)	09 (19.56%)
Ascaris lumbricoides	11(13.09)	09 (19.56%)
Hook worm	02 (2.38%)	02 (4.34%)
Trichuris trichiura	01 (1.19%)	02 (4.34%)
Enterobius vermicularis	01 (1.19%)	01 (1.19%)

Giardia intestinalis was the most common protozoan and Hymenolepis nana was the most common helminth observed in both single and mixed parasite infection cases.

DISCUSSION

In our study, stool samples were found positive for parasites in106 (30.2%) out of 351 students. Studies from different parts of India and outside India have reported a parasitic prevalence rate of 15-64%. Our study shows a moderate rate of prevalence (30.2%) which is comparable to other studies[15,16,17,] while there are other studies that show a lower prevalence[12,13,14] and higher prevalence[1,18,19,20,21] of parasitic infection as compared to our study. Giardia intestinalis to be the predominant protozoan parasite while Hymenolepis nana was the predominant helminth in our study. Our study shows a high prevalence of intestinal protozoal infection in rural areathat can be transmitted orally by drinking contaminated water. Our study also shows a higher recovery of parasites by concentration method (30.2%) as compared to direct microscopy (25.64%). The water supply is an important risk factor for protozoal infections and several large outbreaks of giardiasis have resulted from the contamination of municipal water supplies with human waste. The ingestion of contaminated water is a common problem countrywide due to lower quality of water and faulty sewage lines and the problem is greater in rural areas that do not have proper water network or sewage system[1]. Increased access to proper water and sanitation in primary schools through hand pumps & construction of latrines, promotion of hygiene practices like proper hand washingand strengthening the capacity of education department by improving in-service teacher training are required for prevention of intestinal parasitic infections in school going children. Additional support is targeted at elementary schools to promote personal hygiene awareness and environmental sanitation among school children.

CONCLUSION

Our study shows a moderately high prevalence (30.2%) of intestinal parasitic infection in school going children in rural areas. Stool concentration methods should be used routinely to enhance recovery of intestinal parasites. Giardia intestinalis was the predominant parasite in the stool samples of participating students. Contaminated drinking water, poor sanitation and poor hygiene are important factors for intestinal parasitic infections. Proper drinking water, waste disposal, hand washing and promotion of personal hygiene through education are important for prevention of intestinal parasitic infections in school going children.

Conflict of Interest: None.

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Ethical Clearance: Taken.

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Study of Osteoporosis in Women of Malwa Region of Punjab

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ABSTRACT

98 osteoporotic women were selected for study.Out of 98 13.2% were due to advanced age(post - menopausal), 8.16%were due to pre mature menopause,6.12%were due to oligomenorrhea, 9.18% were due to hyperthyroidism, 12.2% were due to Rheumatoid Arthritis,13.2% were due to diabetes, 9.18%were due to malabsorption syndrome, 7.14 % were due to anti-convulsant Drugs, 11.2%were due to chemotherapy treatment, 10.2% were due to administration of glucocorticoids The fragile fractures of Hip were 14.2%, vertebral compression were 11.2%, wrist fractures were 7%.

This study of different cause's osteoporosisin women will be certainly helpful for the physician to differentiate the various causes .Orthopedician, radiologistto differentiate traumatic fractures from fragile fractures .moreover to dietician, medico-social workers to create awareness regarding balanced diet,risk factors and preventive measures .As bone is a most plastic tissue hence hides the most of the fatal and silent diseases like Osteoporosis.

Keywords: *Fragile. Osteopenia,prevention, risk factors.*

INTRODUCTION

Osteoporosis is a skeletal disorder of low bone density and disrupted bone architecture. fractures is a common and costly condition among the women of osteoporosis especially post menopausal .As osteoporosis is a silent disease before fracture, osteoporosis goes often un detected until a sentinel fracture event. Most common fractures are vertebral, (spines),hip (proximal femur), and wrist .often cause pain, deformity, and decreased mobility.

In Indians the common reason for osteoporosis in the people who are staying out of sun, use of clothing like Burqha, covering the head with Pallu, both which limit the exposure to the sun .moreover vegetarian diet, poverty, illiteracy and lack of balanced diet causing dietary deficiencies of protein, vitamins, calcium, and phosphates, all of which are important for bone health[1].

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In osteoporosis one has to decide if medication is necessary to help to maintain bone mass, to prevent further bone loss and reduce the risk of fractures in the constituents of bone is below normal peak density a mere cough or sneeze can cause fragile fracture of the bone[2]. Hence attempt was made to study the osteoporotic women with different causes.

MATERIAL AND METHOD

98 women of osteoporosis who were regularly visiting Adesh institute of medical sciences and research Hospital Bhatinda -151001 Punjab were selected for study Among them 13 were due to advanced age (post menopausal),8 were due to pre mature menopause, 6 were due to oligomenorrhea. 9 were due to Hyperthyroidism, 12 were due to Rheumatoid arthritis, 13 were due to diabetes (type-1 or, type-2) 9 were due to malabsorption syndrome, 7 were due to anti convulsant drugs, 11 were due to chemotherapy, 10 were due to administration of Glucocorticoids. Their BMD was below normal .Measuring bone mineral density (BMD) is the most important tool in the diagnosis of osteoporosis. The gold standard for measuring BMD is the dual-energy X-ray absorptiometry (DEXA) densitometer, a specialized X-ray device that precisely

quantifies BMD at the spine, femur, and other skeletal sites. DEXA scans are noninvasive and comfortable for the patient, with very low radiation.

Among these 98 women 14 had hip fractures, 11had vertebral compression, 7 had wrist fractures .Osteoporosis was confirmed by CT Scan or MRI studies .All the patients had blood examinations like Complete Blood Count, (CBC), Serum calcium, serum creatinine, TSH, T3,T4, LFT. Serum 25- OH .Vitamin D to rule out the cause of Osteoporosis.

OBSERVATION AND RESULTS

Table-1 Study of different causes of Osteoporosis – 13(13.2%), were due to advanced age, 8(8.16%) were due to premature menopause, 6(6.12%) were due to oligomenorrhea, 9(9.18%) were due to Hyperthyroidism .12 (12.2%) were due to Rheumatoid arthritis, 13(13.2%) were due to Diabetes, 9 (9.18%) were due to malabsorption syndrome 7 (7.14%)were due to administration of anti convulsant drugs, 11(11.2%) were due to chemotherapy Drugs, 10(10.2%) due to administration of Glucocorticoids

Table 1: Types of different causes of Osteoporosis in women of Punjab population.

Sl No	Particulars	Number of patients	Percentage (%)
1	Advanced age (post menopausal)	13	13.2
2	Premature menopause	08	8.16
3	Oligomenorrhea	O6	6.12
4	Hyperthyroidism	09	9.18
5	Rheumatoid arthritis	12	12.2
6	Diabetes (Type 1 & Type 2)	13	13.2
7	Malabsorbtion syndrome	09	9.18
8	Anticonvulsion drugs	07	7.14
9	Chemotherapy drugs	11	11.2
10	Glucocorticoids	10	10.2

Table 2: Types of Fragile fractures in Osteoporotic women of Punjab population.

Sl No.	Particulars	Number	Percentage (%)
1	Hip fracture	14	14.2
2	Vertebral compression	11	11.2
3	Wrist fracture	7	7.1

Table-2 –Types of fragile fracture in osteoporotic women –14(14.2%) had hip fractures,11(11.2%) had vertebral compression, 7 (7.1%) had wrist fractures.

DISCUSSION

In the present study 13(13.2%) of the osteoporosis were due to advanced age (post menopausal), 8 (8.16%) were due to premature menopause, 6(6.12%) were due to oligomenorrhea, 9(9.18%), were due to Hyperthyroidism, 12 (12.2%), due to rheumatoid arthritis, 13(13.2%) were due to diabetes, 9(9.18%),were due to malabsorption syndrome, 7(7.14%) due to administration of Anti convulsant drugs, 11(11.2%) were to chemotherapy drugs for treatment of malignancy .10(10.2%) were due to administration of Glucocorticoids (Table-1) These present findings are more or less in agreement with previous studies[3][4][5][6].

The fragile fractures occurring in the major trauma such as a fall from standing height, coughing or sneezing usually involves spine, ribs,hip, wrist, or humerus .In present study 14(14.2%) were Hip fractures 11 (11.2%) had vertebral compression, 7(7.1%) had wrist fractures .these are also more or less in agreement with previous studies. But many previous studies suggest that, as majority of fragile fractures occur in females don't seek the medical attention and no attempt was made to differentiate the fragile from traumatic fractures due to illiteracy and poverty[7][8].It is also reported that, osteoporosis is also due to genetic factors , bone mass may be linked to polymorphism in gene for vitamin D receptor .Hence osteoporosis varies in different racer of mankind [9].Estrogen receptor Alpha (ERAlpha) gene polymorphism may be influenced with bone metabolism resulting in accelerated age, certain diseases, drugs related to bone loss[10].

It is also established fact that, Osteoporosis in India is due to low dietary intake hence ICMR (Indian Council of Medical Research) has recommended calcium and vitamin D for various populations of India as Regular Dietary Intake (RDI) but these programmers are limited to papers and files only. Prevention of osteoporosis include proper diet during childhood, exercise, avoidance of smoking and alcohol .Optimally diet must have 1 gm of calcium daily .Regular checking of BMD level is also recommended.[11].Even osteopenia should also be taken seriously to prevent the risk factors of osteoporosis .

SUMMARY AND CONCLUSION

The present study of causes of osteoporosis, fractures of different bones will certainly help the Physician, Gynecologist, Orthopedician, Dietician and Radiologist

also. It is required to create awareness about balanced diet, regular exercise, exposure to sun, regular check up of BMD.

This study demands further genetic, nutritional and Histo-pathological study because bone is a most plastic tissue which is next to blood. As osteoblast turn into osteocyte and some are into osteoclast which reabsorb the bone for proper formation of size and shape. The exact mechanism of these bone cells,oppositional growth and interstitial growth of the bones is still unclear.

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The Effectiveness of Mindfulness-Based Group Therapy on Reducing Internet Addiction and Increasing the General Health of Adolescent Girls

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ABSTRACT

Purpose: Internet access is a growing phenomenon, and more people are among the users of the Internet every day.Therefore, the present study was conducted with the aim of investigating the effectiveness of mindfulness -based group therapy on reducing internet addiction and increasing the general health of adolescent girls.

Method: The research design was semi-experimental and the sample consisted of 24 adolescent girls selected by screening using Yang's internet addiction (score above 80) and lower general health (score higher than 23) using targeted sampling from girls' high schools in district 3 of Tabriz and were divided into control and experiment groups. The tools used in the research included Yang's internet addiction and public health. Therapeutic mindfulness package was implemented on the experiment group. Data analysis was performed using multivariate and covariance analysis.

Results: The results of the covariance analysis indicated a decrease in internet addiction and general health increase in the experiment group at the post-test stage(P<0/001).

Conclusion: Based on the findings, it can be stated that the training of mindfulness skills was effective in decreasing the rate of internet addiction and increasing the health of adolescent girls.

Keywords: *Mindfulness-based cognitive therapy, Internet addiction, General health.*

INTRODUCTION

The increasing use of internet has led to the emergence of the phenomenon of internet addiction. Today, we are witnessing the dramatic developments of technology and the cultural and social effects of internet.Electronic revolution, explosion of information and computer revolution have brought many qualitative and quantitative differences in the world over the past two decades. Internet is an harmless tool; however, the excessive and incorrect use of it has the risk of addiction[1]. On the one hand, the problem of overuse and pathological use of this technology and the problem of internet addiction has attracted the attention of psychologists,with the generalization of internet[2].Also, most users of internet in our country are youth, according to the latest research, with an average of 35% of the time spent on the use of internet in chat rooms, 28% of internet games, 30% use of electronic mail and 25% search on global networks, and the average time spent on internet is 52 minutes a week; In fact, internet addiction is an impulse control disorder and a maladaptive use of internet that results in significant clinical disorder and creates psychological, educational, and occupational problems in a person's life that it's prevalence is more and several times more than other age groups.

The health and mental health of a community is one of the health assessment pillars of various communities.Mental health plays a significant role in ensuring the dynamism and efficiency of each community[3].Previous research findings have suggested that people's psychological health is one of the factors influencing the excessive use of the Internet.Internet addiction is conceptually associated with a higher level of psychological inefficiencies such as depressed mood; obsession and suicidal ideation and phobic anxiety[4].

The effectiveness of mindfulness-based therapy has been shown to increase the pleasure of life, reduce stress and physical activity, improve psychological well-being, improve mood and reduce pain, reduce symptoms of anxiety and stress and increase mental health[5]. In other words, mindfulness is a technique that confirms thoughts and feelings by minimizing conflict about them, in combination with meditation and specific mental orientations to an experience, awareness of the present, in an irresponsible way. This concept has progressed so well in third-wave psychology that now is one of the approaches to mental interventions, the use of mindfulness in preventing types of addiction.

RESEARCH METHOD

This study was a semi-experimental research with pre-test-post-test design and control group.The sample consists of 24 adolesce girls among high school girls in district 3 of Tabriz educational system and they were selected using purposeful sampling and were screened through Young's Internet addiction questionnaire (score above 80) and lower general health (score> 23) and were randomly divided into two groups of experiment (n = 12) and control (12).The experiment group received mindfulness-based cognitive therapy interventions in 8 sessions of 90 minutes, after obtaining consent to participate in researchand the control group did not receive any interventions. The criteria for entering the research were: the lack of use of psychiatric drugs and the lack of psychological services simultaneously with the implementation of intervention.Also, the exclusion from the research was the absence of more than three sessions in the intervention process. Both groups completed the Yang Internet addiction and public health questionnaires before and after the psychological interventions.The data obtainedfrom research were analyzed using univariate and multivariate covariance analysis.

Measuring tools

Yang Internet Addiction Test (IAT): The standardized Internet addiction questionnaire, created by Kimberly Yang in 1998, is one of the most authoritative questionnaires on online addiction. The questionnaire is designed in 20 items and is executed in a 5-point Likert method from the score of one (rarely) to the score of four(always). The propositions of this test are based on the criteria of DSM-IV-TR for the diagnosis of ill-posed gambling.The obtained scores for each person categorizes him into three groups: 1. An ordinary user of the Internet; 2. A user who has been troubled by excessive use; and 3. An addict user whose excessive use of the internet affiliated him and he needs treatment. The questionnaire assesses the various aspects of Internet addiction and determines whether the excessive use of the Internet affects different aspects of a person's life or not[6].In Man study (2006), the internal validity of the questionnaire is higher than 0.92, and the validity of the review method has also been reported to be significant. Widyanto & Murranhave given the face validity of this questionnaire very high in his study entitled Psychometric properties of the Yang Internet addiction questionnaire. The six factors of prominence, excessive use, neglect of job tasks, lack of control, social problems, and impact on performance, all of which show its internal stability and validity, through factor analysis. Three factors of withdrawal symptoms, social problems, and functional impairment were obtained in another study by factor analysis that these aspects of online addiction have a direct and positive relationship with a large number of variables such as academic performance, age, gender, and Internet usage[7].

The General Health Questionnaire (GHQ28): Goldberg (1972) set the General Health Questionnaire. The main questionnaire has 60 articles. The 28-article questionnaire form was designed by implementing factor analysis method on its long form[8]. The 28-article questionnaire form was used in this study, which has four subscales of physical symptoms (articles 1 to 7), anxiety and insomnia (8 to 14), social function disorders (articles 15-21) and depression (articles 22 to 28).The scoring method in this questionnaire is from 1 to 4 for options A and D, respectively. The subject's grades in each subscale can be at least 4 and at most 28. The cutting score for the whole test is 23.Taghavi (2001) reported the reliability of this questionnaire through the method of re-examination, dualization and Cronbach's alpha by 0.70, 0.93, 0.90, respectively. Also, the correlation coefficient of 0.55 was obtained inassessing the validity of this questionnaire Middlesex Hospital Questionnaire (MHQ) using simultaneous validity method and the correlation coefficients were variable between the subtest of this questionnaire with the total score at a satisfactory level and between 0.72 and 0.87[9].

Method of implementation: Mindfulness-based cognitive therapy was provided to the experiment group participants, after selecting the sample, and control group participants did not receive any training and continued their routine. The summary of the training sessions is presented below:

Summaries of Sessions: First Session: Communicating, Defining and Conceptualizing, and the Need of Using Mindfulness Training.Second session: Familiarity with relaxation, relaxation training for 14 groups of muscles including forearm, arm, muscles behind the shin, thighs, abdomen, chest, shoulders, neck, lips, eyes, jaws and forehead. Third session: Relaxation training for 6 groups of muscles including hands and arms, legs and thighs, abdomen and chest, neck and shoulders, jaws, forehead and lips, and relaxation homemade homework. The fourth session: Mindfulness of Breathing Training: A brief overview of the session before, familiarity with the mindfulness of breathing training, teaching the technique of inhaling and exhaling with peace of mind and without thinking about anything else and teaching breathing watching technique and mindfulness of breathing homemade homework before bed for 20 minutes. Fifth Session: Teaching the technique of scanning the body: teaching techniques to pay attention to the movement of the body while breathing, focusing on the organs and movement of them, and searching for physical senses (hearing, taste and ...), mindfulness of eating homemade homework(eating with calm and paying attention to the taste and view of food). Sixth session: teaching mindfulness of thoughts: teaching attention to mind, negative and positive thoughts,thoughts being pleasant and unpleasant,allowing the entrance of negative and positive thoughts to the mind and easily removing them from the mind without judgment and deep attention to them and the home assignment of writing negative and positive experiences of the day without judging them. Seventh session: Complete Mindfulness: Repeat training sessions 4, 5 and 6 each for 20-30 minutes. Eighth session: Review and summarize previous sessions and post-test implementation.

FINDINGS

The descriptive findings of the present study indicated that the average age of participants was 18 years with a standard deviation of 4.11; all participants were female. Also, the two groups were studying in high school.

The first hypothesis of the research suggests that mindfulness-based cognitive therapy has an impact on reducing the Internet addiction of adolescent girls. Univariate covariance analysis method was used to analyze this hypothesis. Examining the equality of variance of the two groups of test and control in the post-test stage is one of the assumptions of the covariance analysis test which Levene's test for Equality of variances was used for this purpose. The Levene's test calculated for the variable was not statistically significant [post test; Internet addiction, P=0.874>0.05, F(1 and 22)=1.47]. Therefore, the assumption of the equality of variances was confirmed.

Table 1. Comparison of mean and standard deviation of internet addiction scores in experiment and control groups

Effect size	P	Control group		Experiment group		Test stage	Variable
		Standard deviation	mean	Standard deviation	mean		
0.796	0.001	8.338 9.866	81.33 80.24	6.506 4.845	84.83 34.25	Pre-test Post-test	General Health

There is a significant difference between the two experiment and control groups after controlling the scores of Internet addiction in the pre-test, in terms of the mean score of Internet addiction according to the information in Table 1. Examining the mean scores show that the mean of Internet addiction scores in the experiment group was lower than the control group.Also, the study of the splitting eta square(size of effect) indicates that mindfulness-based cognitive interventionexplains 79.6% of the variance of dependent variablewhich suggests an acceptable impact of the intervention program on the reduction of internet addiction among adolescent girls.

The second hypothesis of the research suggests thatmindfulness-based cognitive therapy is effective in increasing the general health of adolescent girls. Univariate and multivariatecovariance analysis method were used to analyze this hypothesis. The Levene's testcalculated for the variable was not statistically significant [post test; public health, P=0.943>0.05 and F(1 and 22)=1.88]. Therefore, the assumption of the equality of variances was confirmed.

Table 2. Comparison of mean and standard deviation of the overall score of general health in the experimental and control groups

Effect size	P	Control group		Experiment group		Test stage	Variable
		Standard deviation	mean	Standard deviation	mean		
0.893	0.001	8.339 5.143	51.92 56.5	6.387 4.023	65.67 20	Pre-test Post-test	General health

There is a significant difference between the two experiment and control groups after controlling the general health scores in the pre-test, in terms of the total mean score of general health according to the results in Table 2. Examining the mean scores show that the overall score of general health in the experiment group was lower than that of the control group (score below 23 in this questionnaire means high public health). Also, the study of the splitting eta square(size of effect) indicates that mindfulness-based cognitive intervention explains 89.3% of the variance of dependent variable which suggests an acceptable impact of the intervention program on increasing the public health of adolescent girls.

It should be noted that the equality test of regression coefficients was evaluated in the post-test stage through pre-test interaction of the subscales of general health and independent variable (treatment method). The interaction of these pre-tests with the in)dependent variable is not meaningful and suggests the equality of regression coefficients.This assumption was true in relation to the post-test and by observance presuppositions [post test (P=0.846>0.01 and F=38.028 and Wilk's Lambda =0.090)]. The multivariate statistics for Wilk's Lambda are not significant at 95% confidence level(a=0.05), as you can see. Therefore, the equality assumption of regression coefficients is also established. We are permitted to use this statistical test,given the assumption of multivariate covariance analysis.

There is a significant difference between the two groups in terms of the mean of all aspects of general health according to Table 3. Examining the mean scores show that the mean of all general health aspects in the experiment group was lower than the control group (The reduction in mean scores means higher general health). Also, the study of the splitting eta square(size of effect) indicates that mindfulness-based cognitive has the most effect on depression (74%) and had the least effect on anxiety and insomnia (33%).

Table 3: Comparison of mean and standard deviation of the scores of general health aspects in the experiment and control groups

Effect size	P	Control group		Experiment group		Test stage	Variable
		Standard deviation	mean	Standard deviation	mean		
40.9	0.002	4.999 4.78	12.58 12.92	3.454 2.425	15.75 4.33	Pre-test Post-test	Physical symptoms
33.8	0.007	4.078 4.461	13.92 13.58	2.021 2.065	17.08 5.08	Pre-test Post-test	Anxiety and Insomnia
39.9	0.003	5.283 4.166	12.5 13.92	2.725 2.193	15.17 4.42	Pre-test Post-test	Disruption in Social function
74.6	0.001	4.502 2.968	12.92 16.08	2.146 1.801	17.67 6.17	Pre-test Post-test	Depression

DISCUSSION AND CONCLUSION

The results showed that there is a significant difference between the two groups of experiment and control after controlling internet addiction scores in the pre-test, in terms of the mean score of Internet addiction. This finding is inconsistent with the research by Agha Yusufi et al. (2013), in which they had achieved a positive impact of mindfulness on addiction, rather than Internet addiction.No relevant research has been found on the impact of mindfulness specifically on Internet addiction. Therefore, it seems that mindfulness-based cognitive therapy that emphasizes being present at the moment and acceptance without judgment and without defensive or generally prohibiting him from his favorite behavior, helps the person to control and manage their behavior and feelings. But for the overall result, the effect of mindfulness on reducing Internet addiction, although the exact same research was not found, however, the

results are relatively similar to studies that have implicated mindfulness in reducing addictive behaviors.For example, the inclusion of this intervention in Internet addiction treatment programs could be advisable because of the positive effect of mindfulness on reducing anxiety, depression and stress of drug addicts.

Another finding of the present study showed that mindfulness-based cognitive therapy is effective in increasing general health and its components in adolescent girls.This finding is in line with the results of some studies, including Pourmohseni-Kalouri and Eslami (2016), Potek (2012) & Rosenzweig & et al. (2010).

One of the important aspects of mind-based therapy is that people learn to deal with emotions and negative thoughts. Therefore, teaching mindfulnes scan play an important role in reducing the anxiety, depression and physical symptoms of addicted adolescents to the Internet and moderate their disruptive social behaviors, with such positive techniques. It can also be noted that in the above justification, increasing awareness and attention to thoughts, excitements and practical desires is a positive aspect of mindfulness and leads to the coordination of adaptive behaviors and positive psychological states in any given field, including the proper use of the Internet, andit even enhances individual abilities in solitary and social activities and interest in these activities.

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Role of Social Support and Coping Styles in Mental Health of Women Who Apply for Divorce

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ABSTRACT

This study aimed to survey the role of social support and coping styles in mental health of women who apply for Divorce. The research method is correlation. The number of 110 women applying for divorce of Rasht city in 2013, were selected through Available sampling method and responded to social support, mental health and coping styles questionnaires. The gathered data were analyzed by Pearson correlation coefficient and stepwise regression analysis. The results showed that there exist a positive and significant relation between social support and mental health (P>0/01). Also the results indicated that the relation between problem focused coping style with mental health is positive and significant (P>0/01). The relation between emotion focused coping style and mental health is negative and significant (P>0/01). The stepwise regression analysis showed that the predictive variables could significantly predict 29 percent of variance of mental health. The results of current research in consistent with other studies indicate that social support and coping styles have an important role in mental health of women who apply for divorce.

Keywords: *Mental Health, Women, Divorce, Social Support, Coping Style*

INTRODUCTION

Quality of married life in a family is very important. While there may be various reasons in a family that the marital relationships does not have the liveliness and former Quality And couples decide to be separated. Divorce leads to the disintegration of the family and intimacy, closeness and connectedness between husband and wife disappears[1]. The mental health of couple who apply for divorce is very low. Mental health is a state of well-being and is defined to be able to overcome the stress of everyday life and freedom from anxiety. In addition, mental health, leading to increased quality of social relations and the person will have the ability to communicate constructively with others and also are consistent with themselves and their environment[2]. Sometimes marital conflicts and disputes between couples is so high and out of control And seriously have negative impact on the mental health of couples especially on the wife's mental health. If there's a decline in mental health, the power of coping correctly and efficiently with problems loses[3]. Also situation may become worse day by day And the person fails to resolve marital problems using problem-solving strategies, in conclusion likelihood of tendency to divorce would be increased[4]. In fact, we can say that there is a significant relationship between coping style and mental health.

Thus coping styles is one of the psychological variables in different aspects of life especially in the Married life. So that efficient and inefficient coping styles are associated with Married life status. For example Effective coping styles, such as problem-solving can positively and significantly predict marital satisfaction and ineffective coping styles can predict marital conflicts[5-6]. Coping strategies are defined to the cognitive and behavioral efforts for managing and reducing the tension among individuals. A conscious effort is required to deal with stress. People may choose different type of coping strategies in different situations[6]. Various factors led to a decrease in life quality of married life and bring dissatisfaction for couples. In these

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circumstances it is possible that couples experience disturbing conditions and also suffer from psychological distress. While there exist a direct relationship between efficient coping styles such as problem-solving and finally the mental health will be increased. In fact, when people can manage their unfavorable conditions and also be able to reduce their psychological distress, if they apply the efficient coping styles. Actually in can be said that efficient coping styles such as problem solving focused coping styles are associated with improving conditions and increasing the mental health of individuals[7-8.]

In addition to coping, social support is another very influential factor on mental health. In recent years Social support as a concept that refers to the importance of the social dimension of human, has gained increasing attention[9]. Social support reduces the stress caused by the traumatic event and also minimize the effects of an unpleasant experience. In addition, social Support also increase a person's well-being. Family and friends are the most influential people in the life of every one and Make the person feel loved and Valuable. As a result, people feel less loneliness and will have higher psychological adjustment and also mental health[10]. The results also indicate that there exist a significant relationship between social support and psychological and emotional well-being and social support is a significant predictor of mental health[11-12]. In fact, participating in various social networks makes that person feel heard and can communicate constructively with others. He or she can also listen to others and feel the sense of confidence[13].

Many factors will influence the tendency to divorce that should be paid attention in the studies. By identifying these factors the steps can be taken to improve marital relationships and the mental health should be increased. As a result, the divorce rate is reduced, and the quality of life and public health also will be improved. According to what was said and the important role of psychological skills such as coping and social factors such as social support on increasing of mental health, the main aim of current research is the surveying the role of coping styles and social support in mental health of women who apply for divorce.

RESEARCH METHODOLOGY

The research method is correlation. The study population included all women of Rasht city referring to the courts in order to apply for divorce in 2013. The number of 110 women were selected through Available sampling method. The researcher attended in courts and explained the aims of the study to the women, and urged them to feel free to participate in this study and stressed that their information will remain strictly confidential.

TOOLS

Social support test: This questionnaire is made by Fleming and colleagues that has 25 item and Participants must give a yes or no answer. This questionnaire measures the subscales of general perceived social support, Perceived support from family, Perceived support from friends and opinion about the importance of social support. By summing these subscales, the overall score is obtained, and with increase the score, the perceived social support is higher. During a survey of Iranian society, the reliability of the questionnaire was reported acceptable[14].

Billings & Moos coping styles questionnaire: The questionnaire is designed to measure coping strategies and has 19 items. This questionnaire measures two coping styles namely problem solving and emotion focused coping styles. Respondents are asked to rate each item on a four-point Likert-type rating scale ranging. The reported internal consistency by Cronbach's alpha of this questionnaire is 0.87 for problem solving focused coping and 0.50 for emotion focused coping[15].

General Health Questionnaire: The questionnaire is designed by Goldberg to measure four subscales of Depression, Anxiety, Social impairment and Hypochondriasis. This questionnaire has 28 items. The Respondents are asked to rate each item on a four-point Likert-type rating scale ranging. By summing these subscale, the overall score is obtained. During a study, the validity and reliability of this questionnaire was reported acceptable[16].

The gathered data were analyzed by Spss-18 using Pearson correlation coefficient and stepwise regression analysis.

FINDINGS

In in current research 110 women participated with the mean age of 30.41 and standard deviation of 6.37. Most women (55 percent) had a diploma degree. Table 1 shows the descriptive statistics (mean and standard deviation) data of the variables and also the results of Pearson correlation coefficient.

Table 1: The correlation matrix between the variables

Variables	M (SD)	1	2	3
1. Mental health	50.46 (18.40)	1		
2. Social support	7.27 (4.85)	0.23**	1	
3. problem solving focused	20.06 (5.73)	0.42**	0.27**	1
4. Emotional focused	10.80 (3.08)	-0.19**	0.02	. 140

**p> 0.01

As it is evident in Table 1, the correlation between social support and mental health is found positive and significant. Problem solving focused coping also had a significant and positive relationship with mental health. Also there exist a negative and significant relationship between emotion focused coping style and mental health. It is worth noting that all of these coefficients were significant at p<0.01 level. Table 2, shows the results of regression analysis.

Table 2: predicting mental health based on social support and coping styles

Variable entered	R	R^2	F	B	beta	T	Sig
Problem solving focused	0.42	0.17	42.77	1.28	0.39	6.18	0.00
Emotional focused	0.49	0.24	31.58	-1.48	-0.27	-4.43	0.00
Social support	0.54	0.29	26.97	0.74	0.23	3.70	0.00

Stepwise regression results in Table 2 show that the predictive variables could significantly predict mental health. Problem solving focused coping style has the most closely connection with mental health. Secondly, emotion focused coping style is a significant predictor of mental health. Finally social support is entered to the model as a significant predictive variable. Accordingly, we can say that predicted variables in the three steps of regression, explain 29 percent of the variance of mental health.

DISCUSSION AND CONCLUSION

The aim of current research is the surveying the role of coping styles and social support in prediction of mental health of women who apply for divorce. Results showed that the correlation between Problem solving focused coping style and mental health is positive and significant. Also there exist a negative and significant relationship between emotion focused coping styles and mental health which are in line with the findings of Yancura & Aldwin (2008)[7], Graven & Grant (2013)[8], Pormohamareza et al (2015)[17], Wang & Yeh (2005)[18] and Ghazanfari & Khadampoor (2008)[19].

In defining it could be argued the person with the use of problem-focused coping styles, apply the cognitive skills to solve the problem. On this basis the ways of dealing with the problems are directly checked. Usually finding appropriate solutions to the problem should bring Psychological satisfaction. On the other hand it makes order and coherence of thought and Reduce emotional and psychological distress. With the obtained Thought coherence and emotional comfort, the source of stress is better identified and May be evaluated under control. Identifying the source of stress and the power of control beyond it, would increase mental health. Moreover, identifying a source of stress by increasing confidence, Reduces distress and anxiety and improves mental health. On the contrary, the use of emotion focused coping strategies, Prevents direct and effective involvement with the problems. It impairs the intellectual coherence and emotional distress and mental health will decrease. Thought and emotional distress undermines the possibility of understanding the sources of stress and negatively affect the rate of mental health[17,19].

Also the results showed that there exist a positive and significant relationship between social support and mental health which are in line with the findings of Kim et al (2010)[20], Tak et al (2002)[21], Lee et al (2012)[22], Holtzman et al (2004)[23]. It can be said that social support from close friends or family members can help the individual to choose better and more suitable ways of dealing with the challenges of life. In fact, the person can make use of experiences and information of the friends and family and apply it in the life, especially in Married life. As a result, Married life problems, conflict, and disputes are reduced and the tendency to divorce will become low. In conclusion the social support by decreasing the marital conflicts, the rate of mental health would be increased and improved especially in women who apply for divorce[24].

Finally the results of Stepwise regression analysis showed that the predictive variables (Problem solving focused coping style, emotion focused coping style, social support) could significantly predict 29 percent of the variance of mental health. The results of current research indicate the important role of psychological skills such as coping styles and social factors such as social support on increasing of mental health of women who apply for divorce. The limits of the research include uncontrolled intermediary factors such as the socio-economic status, age, locus of control, etc. It is suggested to consider these factors in future studies. This research is done among women who apply for divorce of Rasht city on the ground of coping styles, social support and mental health, because we should be careful in generalization to the other populations. According to the important role of social support and coping styles in mental health of women who apply for divorce, it is recommended that courses based on coping skills trainings be held. Also these women be taught how to get social support and apply it appropriately in order in improve their mental health.

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Conflict of Interest: The authors declare that they have no competing interests.

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Fine Needle Aspiration Cytology as a Diagnostic Procedure in Head and Neck Swellings in Rural Population of Hapur Region (U.P.), India

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ABSTRACT

Background: Fine Needle Aspiration Cytology (FNAC) is simple, quick, inexpensive and minimally invasive technique used to diagnose different types of swellings located in the head and neck.

Aim: To assess the incidence of different sites, age, sex and distribution of inflammation.

Material & Method: May 2015 to October 2016 was carried out in the Department of Pathology, Saraswathi Institute of Medical Sciences and associated Hospital, Hapur, Uttar Pradesh, India, Which included 292 patients with head and neck swellings presenting to Outpatient clinics. Fine Needle Aspiration Diagnosis was correlated with detail of relevant clinical findings and investigation.

Results: Female most common victims with female to male ratio of 1.61: 1.Head and Neck swelling is common finding now a days and Fine Needle Aspiration Cytology is most common diagnostic procedure for such type of cases and most common method to differentiating between benign and malignant lesion. As diagnostic procedure we came to know regarding the most common lesion involved in head and neck region.

Conclusion: Fine Needle Aspiration Cytology is easy, simple, safe and non invasive procedure for diagnosis of head and neck swelling and easy way for surgeon whether to decide surgery or not.

Keywords: *Head and Neck Swellings, Fine Needle Aspiration Cytology.*

INTRODUCTION

A number of masses may develop in the head and neck region and these can also be called swellings, growths, tumors or lumps. Various diseases may affect head and neck region, which present clinically as swellings. Commonly presenting head and neck masses occur within the thyroid, salivary glands and lymph nodes. Most of these swellings, although superficially located, are related closely to the important anatomical structures of this region Less common pathologies presenting as neck swellings are from thyroglossal cysts, branchial cleft cysts, carotid body tumours, cystic hygromas, pharyngeal pouch abnormalities and lumps of skin appendages.[1,2] The most common entities occur repeatedly within the various age groups and can be differentiated with a clear understanding of embryology and anatomy of the region, and an understanding of the natural history of a specific lesion.[3] FNAC leaves no scar and seeding of the needle tract has proved to be no more than theoretical possibility. Head and Neck sites account for approximately one half of all body sites aspirated. The evaluation of head and neck mass

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is a common clinical dilemma and a condition which clinicians routinely encounter. It is evident that their early diagnoses provide the best chance of successful treatment.[4] The simultaneously occurring phenomenon of spiralling costs of medical care and hospitalization set the stage for the worldwide acceptance of fine needle aspiration cytology as a safe, simple, rapid and effective technique of obtaining an accurate tissue diagnosis.[5]

The large number of Head and Neck aspirates reflects the high incidence of head and Neck cancer in this country. The largest numbers of aspirates are from cervical lymph node enlargements, metastatic squamous carcinoma being the most common lesion encountered. However inflammatory disease of the lymph nodes is all represented.[5] FNAC is fairly accurate, a relevant clinical history and a help from radiology regarding the nature and location of swelling can further improve the likelihood of correct diagnosis.[6,7] It has contributed a great deal to transform cytology from a primarily screening tool to powerful diagnostic technique.[8]

The prime objective of study was to assess the diagnostic accuracy of FNAC in the Head and Neck tumors, to assist the surgeon in selection of the patient for surgery and palliative therapy and to help the surgeon in detecting the metastasis and staging of the certain tumors.

METHODS AND MATERIALS

The present Retro prospective study (Prospective for one year from November 2015 to October 2016 was carried out in the Department of Pathology, Saraswathi Institute of Medical Sciences and associated Hospital, Hapur, Uttar Pradesh, India. Cases for prospective study were selected from patients presented with head and neck masses attending the ENT OPD and indoor patients. Ethical considerations were met through institutional ethical committee. A written consent was taken from every patient. The background information of the subject was elucidated as per Performa with special reference to the following:-Presenting complaints with their duration noted in chronological order. Local examination of the swelling was done under the following heads - number,size, site, consistency, tenderness, fixity and over lying skin. Routine laboratory investigations along with the radiological investigations were noted.

The basic equipment needed to perform FNA was simple and relatively inexpensive. Disposable 10ml plastic syringes, 22 to 25 gauge needles, gauze pads, glass slides, alcohol, gloves, Coplin jar for immediate wet fixation of smears, container for collection of fluid from cystic lesion.

RESULT

The study included 292 cases of the age ranged from 1 to 80 years out of which 61.64% were females and 38.36% were males. Among the diagnostic outcome, higher incidences of lesion are in the neck region than in the head region. Lymph node involvement (73.29%) was common than any other lesion. Among 214 cases of lymph node lesions, 146 cases (68.22 %) were having tuberculous inflammation, 58 (27.10%) were having non - tuberculous inflammatory lesions and 10 (4.67 %) were having malignant lesions. Out of 50 cases of thyroid lesion, 46 cases (92%) were females and 4 cases (8 %) were males. 18 cases (36%) were of colloid goitre with cystic changes. 10 cases (20%) were of Hashimoto's thyroiditis. Others were Adenomatous nodule, nodular goitre, Primary hyperplasia etc. Out of the 12 salivary gland lesions, 8 cases (66.67%) were of Pleomorphic Adenoma, 2 cases were Warthin's tumor and 2 cases were of chronic sialadenitis.

Table 1: Distribution of cases as per tissue involved and gender

Tissue	Male	Female	Total
Lymph nodes	94	120	214(73.29%)
Thyroid gland	04	46	50(17.12%)
Soft tissues	10	06	16(5.48%)
Salivary glands	04	08	12(4.11%)
Total	**112**	**180**	**292(100%)**

Out of total 292 cases, 214 were of lymph nodes and 50 were of thyroid gland accounting to 73.29% and 17.12% respectively. It is clearly seen that female affection is much more as compared to males due to more thyroid pathology seen in females. (Table 1)

Table 2: Distribution of cases as per types of lesions and gender

Type of lesion	Male	Female	Total	
	No.	**No.**	**No.**	**%**
Inflammatory	92	126	218	74.66
Benign	10	50	60	20.55
Malignant	10	04	14	04.79
Total	112	180	292	100.00

Table 2 shows clearly that the incidence of malignancy is higher in males, may be due to more tobacco chewing and smoking habits.

Table 3: Distribution of cases as per different types of lesions in lymph nodes.

Variable	**Type of finding**	**Males**		**Females**		**Total**	
		No.	%	No.	%	No.	%
Inflammation	Reactive/ Nonspecific	28	29.78	30	25.00	58	27.10
	Tuberculous	60	63.83	86	71.67	146	68.22
Metastasis		06	06.38	02	1.67	08	3.74
Hodgkin's lymphoma		-	-	02	1.67	02	0.94
Total		**94**	**100**	**120**	**100**	**214**	**100**

Table 3 shows that Tuberculosis is the most common pathology in our study followed by non tuberculous inflammation

Table 4: Different malignant lesions affecting different tissues.

Tissue	**Type of lesion**	**No.**
Lymph node	Metastatic carcinoma	8
	Hodgkin's lymphoma	2
Thyroid gland	Papillary carcinoma	2
Soft tissue	Rhabdomyosarcoma	2
Total	-----	**14**

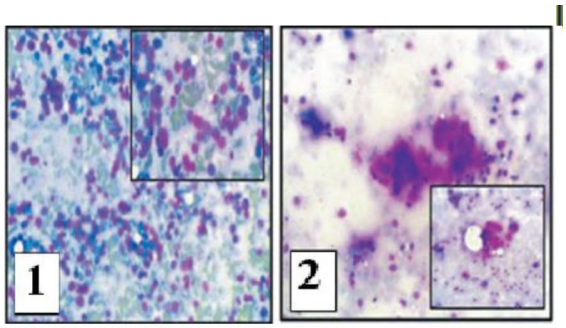


Fig. 1 & 2 NHL: Monotonous population of small lymphocytes with small inconspicuous nucleolus (Giemsa x400, x1000)

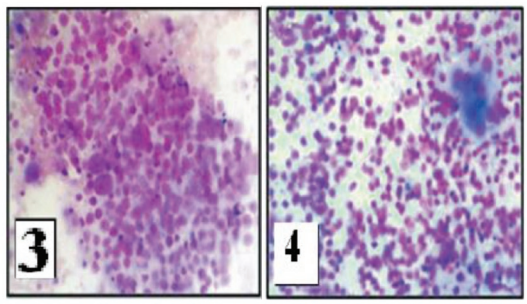


Fig. 3 Metastatic adenocarcinoma. The glandular arrangement of the malignant epithelial cells. (x400), **4**. Nasopharyngeal carcinoma: Neoplastic cells are round to cuboidal admixed with small lymphocytes. (Giemsa x400)

DISCUSSION

In the present study of 292 cases of various head and neck swellings, the results achieved were compared with different studies. Tuberculous lymphadenitis was found to be the most common pathology in our study accounting for 50% of cases followed by non - tuberculous lymphadenitis constituting 29% of cases.

El-Hag et al[9,10] carried out a similar study in Saudi Arabia over a period of five years which included 225 patients. This study was published in 2003 and it showed reactive/nonspecific Lymphadenitis to be the commonest cause of neck masses accounting for 33% of cases. Tuberculous lymphadenitis was found to be the next most common pathology constituting 21% of cases followed by malignant swellings found in 13% of cases. Out of 292 fine needle aspiration procedures, 73.29% were of lymph node tissue in present study. Also commonest site of malignancy in head and neck region are lymph nodes. Squamous cell carcinoma is one of the commonest tumours in the head and neck region. It usually presents late and with nodal metastasis.

Metastatic squamous cell carcinoma is the earliest diagnosis on FNAC.[11,12]

Prased et al study shows incidence of lymphadenopathy was slightly higher in female in William study. Same result was seen in our present study. Non-neoplastic conditions of the salivary gland that simulate tumour are cystic, sialadenitis, granulomatous disease and benign lympho-epithelial lesions. Most of disorders require medical management or minimal surgical intervention, such as cyst aspiration. Diagnosis by FNAC would clearly reduce the amount of surgery. This study also shows the maximum incidences of thyroid swellings was found during age 20-40 years while in study of Prasad et al, maximum incidence between 30 and 50 years. In study by Prasad et al female: male ratio was 5:1 and in present study female: male ratio was 11:1. Female preponderance in various thyroid lesions is comparatively well observed in present study. [10]

Pleomorphic adenoma is the commonest tumour of salivary gland. In present study out of 12 cases of salivary gland lesions, 8 cases are of Pleomorphic adenoma.

CONCLUSION

FNAC is ideal procedure for diagnosing the multiple swellings e.g. to detect metastasis with accuracy more than that of True cut biopsy. FNAC is safe, simple, sensitive, specific, and suitable for almost all sites, skills required are learnt with some practice, saves time, money, hospital theatre time and bed space. FNAC is very useful for pre-operative diagnosis of lymph node, thyroid gland, salivary gland, orbit and other swellings in head and neck region, and thus helps surgeon in selecting the patient for palliative or surgical management. In case of follicular neoplasm, exact diagnosis of follicular carcinoma or follicular adenoma cannot be decided on FNAC alone.

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Conflict of Interest- None

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Effect of Aggression Management and Violence Prevention Training Program among Nurses Working in Psychiatric and Emergency Setting-A Mixed Method Protocol

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ABSTRACT

Aim: The aim of the study is to develop, implement and evaluate the effect of an aggression management and violence prevention training program for nurses working in psychiatric and emergency setting.

Background: Aggression is a professional hazard for those who are working in the mental health care setting.

It is the duty of the nurse to provide a safe environment for the patient, caregivers and health care providers working in psychiatric setting. The concept of aggression management and violence prevention training program for nurses working in psychiatric setting is not well implemented in Indian setting.

Design: Mixed method; (Sequential exploratory design)

Method: The study comprises four phases: (i) exploration: assess the violence towards nurses (ii) Focus group discussion: collect the opinion of positive deviant nurses- What are their strength? What is needed for them? How to implement?(iii) Training: Develop an aggression management and violence prevention training program and implement the training to positive deviant nurses and trainee nurses. (iv)Discover: Identify the overall effectiveness of the program by collecting opinion from positive deviant nurses.

Discussion: This study will helps to provide new information about methods to deliver safe and secure care in psychiatric and emergency settings for both patients and health care providers. The study also facilitate to develop staff development program on aggression management and violence prevention in psychiatric and emergency setting.

Why this study is needed?

- There are no much evidence in India observing how aggression management training can be effectively applied in clinical practice of psychiatric setting
- Helps to develop a safe and secure nursing care eco system to the clients, care givers and hospital health care providers in the psychiatric setting
- Helps to utilize few positive deviant nurses and thereby build the capacity of other nurses working in psychiatric setting to manage aggression and violence

Keywords: *Aggression Management, Violence Prevention, Training Program, Psychiatric Setting.*

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INTRODUCTION

Patient aggression is a long lasting problem in psychiatric setting. It is a multifaceted problem with serious concerns. Violence can be expressed verbally or physically. [1] Most of the time it is originated from patients. Patient related violence in psychiatric setting

range from 0.07-0.25 violent cases per bed per year. It has been reported that the prevalence of violence experienced by the mental health workers due to aggressive patient behavior is between 14% and 61%. There is considerable evidence to show that training the nurses in psychiatric setting leads to minimize aggressive behavior from the patients. [2]Violence prevention training for nurses is a significant part of a wide spread approach to diminish patient aggression in psychiatric-mental health care setting.

Patient directed aggressive and violent behavior towards nurses working in psychiatric setting is a worldwide issue. Nurses spend most of the time with patients, which make them more vulnerable to any form of injuries during the process of managing aggressive patients without having knowledge and skill. Hence aggression management and violence prevention remains a challenging task to the nurses. Thousands of patients whose aggression is due to serious mental illness are secluded or restrained every day. Aggressive and violent behavior is very common among psychiatric inpatients and need to be identified early and managed efficiently. Otherwise it can promptly worsen to potentially dangerous behaviors like attacking himself or others.[3]

Livingston JD et al conducted a narrative review of literature published between 1990 and 2007 to evaluate the usefulness of staff training programs on preventing and managing violent and aggressive behaviors in psychiatric hospitals. They have found that training the staffs working in psychiatric ward on aggression management and violence prevention was very effective for some areas like minimizing the use of restraints and other forced control strategies. The investigators recommended that more methodologically strong research is needed to decisivelyconclude whether aggression management training program is effective in dropping violent behavior and damages to the staffs.[4]

A study was conducted by Arguvanli etal in Turkey to evaluate the impact of aggression management training program, especially on knowledge and attitudes of nurses working at psychiatric setting. Sample size was 27 and one group pre-test post-test design was used. The three tools used for the study were; personal information form, perception of aggression scale, and assessment form of knowledge levels of nurses regarding aggression management. The study concludes that aggression management training was very effective in increasing the knowledge level of nurses as well as for developing positive attitude towards their perception on aggression.[5]

Muthuvenkatachalam et al conducted a study in UP, India to find out whether an aggression management training program for mental health care providers would be effective in improving their knowledge and practice regarding aggression management of patients with psychiatric disorders. A convenient sample of 30 mental health care providers including 12 staff nurses and 18 ward attendants involved in direct patient care were included in the study. One group pre-test posttest design was used for the study and they have found that there was significant improvement in the knowledge score regarding aggression management from before and after the training program. The result suggests the need for aggression management training program[6].

An evaluative study was conducted by Stephane Guay et al in Canada to find out the impact of a training program on preventing and managing patients' violence in a psychiatric setting. Eighty nine participants completed a questionnaire survey before and after the training. The follow up also was done after a few months. Results showed that there is statistically significant improvement in level of exposure to violence, psychological distress and confidence in coping. The study identified that there is participants' resistance to change and also recommends further research to find out how to improve the effectiveness of the violence prevention program[1].

Violence in mental health care setting has been extensively reported, and health care workers, particularly nurses working in psychiatric-mental health care setting are not having the necessary skill to manage patient directed violence. Aggressive patients can harm self, staffs, other patients or any other caregivers if not effectively managed.[7] So all care givers are need to be trained to manage aggressive behavior of mentally ill patients. It is important for the caregivers to notice early signs of aggression to manage aggressive behavior without harming patient, self as well as others. Hence the present study is planned to assess the effect of a training program on aggression management and violence prevention among nurses working in psychiatric setting.

Aim of the study

The aim of the study is to develop, implement and evaluate the effect of an aggression management and violence prevention training program for nurses working in psychiatric and emergency setting.

The Objectives of the study are to

- Determine the occurrence of violence towards nurses working in psychiatric and emergency settings
- Assess the opinion of positive deviant nurses regarding aggression management and violence prevention
- Develop an aggression management and violence prevention training program for nurses working in psychiatric and emergency setting
- Determine the effectiveness of aggression management and violence prevention training program

The Following Hypothesis was used:

- **H1:** There will be a significant difference between the mean pre-test and post-test 1 & 2 competency scores of positive deviant nurses regarding aggression management and violence prevention
- **H2:** There will be a significant difference between the mean pre-test and post-test competency scores of trainee nurses regarding aggression management and violence prevention
- **H3:** There will be a significant association between pre-test competency scores of positive deviant nurses and trainee nurses and the selected demographic variables

Conceptual framework used for the study

Conceptual framework used for this study is based on Appreciative Inquiry Model developed by Srivastava S, Fry R and Cooper Rider D, 1990[8]. According to Cooper Rider, Appreciative Inquiry is an approach to organizational change which focuses on strengths rather than on weaknesses, fairly different to many methods to appraisal which emphasis on shortages and difficulties. The Appreciative Inquiry Model has four stages in which organizational change occurs; Discover, Dream, Design and Deliver. Discover indicates identification of organizational processes that works well and a survey is planned to assess the occurrence of violence towards nurses and also to find out the strength and weakness of the nurses. Dream represents imagining of procedures that will be working sound in the future and a focus group discussion is planned to collect the opinion of the positive deviant nurses regarding aggression management and violence prevention. Designing is planning and prioritizing processes that would work well. The researcher designed the training program based on the input given by the positive deviant nurses. The last phase is deliver which focus on implementing and evaluating the effectiveness of the training program.[9]

MATERIAL AND METHOD

The focus of this study will be on developing and implementing an evidence-based intervention on aggression management and violence prevention in psychiatric setting and observing the effect of the intervention on clients and nurses. A mixed method (Sequential exploratory design) is used in the present study. A focus group discussion was conducted among the positive deviant nurses to collect their opinion regarding aggression management and violence prevention training program and to understand the strengths and weakness of the nurses working in psychiatric setting including emergency clinic. This was the basis for the quantitative study of one group pre and posttest method. Results of the focus group discussion was used to develop the training methodology and a quasi-experimental study design was used to find the effectiveness of the training program. A participatory training program approach is used throughout the study to introduce the change and to evaluate its impact.

The study comprises of four phases. Phase I will be a survey to assess the violence towards nurses. A questionnaire called as 'facets of aggression management' was developed, validated and reliability was tested to conduct the survey. The planned sample size is 90. Phase II will be a focus group discussion to collect the opinion of positive deviant nurses; this is to find out the strength and weakness of the nurses and to identify what is working well in aggression management. A focus group lead question was formulated and validated and the estimated sample size was 30. The phase III will be a quasi-experimental design to train the nurses. The estimated sample size was 30 trainer group nurses (positive deviant nurses) and 100 trainee group nurses. The trainer group nurses will be trained by the researcher and the post test will be planned at 1 week and 3 months interval. The trainer group nurses will be training the trainee group nurses and the researcher will be an observer during their training. The trainee group nurses will be receiving one posttest after 1 week of the training. An interpretive

exercise was developed, validated and reliability was tested to assess the competency of the nurses before and after the training program. The phase IV will be the last phase of finding out the impact of the training program. An opinionnaire was developed and validated to collect the opinion of the nurse supervisors regarding the effectiveness of the training program. The opinion will be collected from 30 nurse supervisors. The estimated sample size for the entire program including attrition rate was 320.

The study will be conducted in selected hospitals of Dakshina Kannada and Udupi districts of Karnataka and the researcher got approval from 11 hospitals. The outcome variable of the study is nurses' competency on aggression management. The population of the study is registered nurses who are working in selected hospitals of Dakshina Kannada& Udupi Districts of Karnataka. The study sample comprise of nurses who are taking care of psychiatric clients / emergency clients in selected hospitals of Dakshina Kannada& Udupi Districts in Karnataka state. Purposive sampling technique was used for selecting the samples. The inclusion criteria includes nurses working in psychiatric, emergency and intensive care settings, nurses having minimum of 6 months experience in psychiatric, emergency or intensive care unit and the nurses' willingness to engage in participatory training program. The exclusion criteria includes nurses who already received the training and the nurses those who are not involved in direct patient care. In this study positive deviant nurses (trainer group nurses) are those nurses whose special, or uncommon practices and behaviors enable them to find better ways to prevent aggression and violence behavior than their co-workers who share the same resources and face the same risk. Positive deviant nurses will be selected based on the observation and evaluation done by the Nursing Superintendent.

Data collection procedure

The duration of the study is 48 months. Data collection began on November 2015. Phase I was a survey and was conducted in 7 hospitals and the approximate duration was 6 months. Phase II was a focus group discussion among positive deviant nurses and the approximate duration was 6 months. Phase III comprised of developing and implementing the training program. An aggression management and violence prevention training program was developed and validated prior to the training. The training materials consists of a module for self-preparation, a video on aggression management techniques, a set of four soft limb restrainer, and simulative methods to practice. The average duration of training program is 3 hours. Competency of the nurses were assessed before and after the training program. In phase IV, opinion of the nurse supervisors will be collected from each hospital to evaluate the overall effect of the training program. This will be done at the end of the participatory training program.

Data analysis

SPSS-16 software will be used to analyze the quantitative data. Descriptive statistics will be used to assess the violence and suitable inferential statistical tests will be used to analyze the differences in outcome measures collected during different intervals. Qualitative data will be recorded with participants' permission and selectively transcribed. NVIVO-11 software will be used to assist in the analysis. The overall impact of the training program will be decided based on the feedback given by the nurse supervisors. Outcomes of the study will be shared with the nurses those who are part of the study which will helps them to understand their strength and weakness.

DISCUSSION ABOUT FINDINGS

The study findings will supplement to knowledge formed from former research in aggression management and violence prevention that has proved benefits arising from training the nurses to ensure the safety of patients and health care providers. A study conducted by Anadolu et al 2015 revealed that aggression management training program increased the knowledge level of nurses working at psychiatric setting and brought positive changes about their perception on aggression. The author suggested to undergo aggression management and violence prevention training at regular intervals.[5]The present study also looking at similar kind of conclusion.

The study will focus to develop, implement and evaluate the effectiveness of an aggression management and violence prevention training program, which can be implemented throughout Indian setting as we don't have an accepted guideline to train the nurses. A study conducted in India (Muthuvenkatachalam et al, 2014) suggested the need for aggression management training programme for mental health care providers which may result in effective management of aggression in psychiatric hospitals.[6] The findings of the present study may contribute more to the field of violence prevention.

The study also contribute in developing a policy regarding aggression management and violence prevention.

CONCLUSION

The present study will be contributing a new area of knowledge about how the nursing team can contribute together with other members of the multi-disciplinary team to prevent and manage violence incidents directed by psychiatric patients. Also enhances safety of the nurse, patients and other health care providers. The study also facilitate to develop staff development program on aggression management and violence prevention in psychiatric and emergency setting

Conflict of Interest: There is no conflict of interest for my study

Source of Funding: Nil

Ethical Clearance:

- Institutional ethical committee approval was obtained from Kasturba Medical College, Mangaluru prior to the study
- Administrative permission was obtained from the administrative officers of the study settings
- Informed consent will be obtained from each participant prior to their participation

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The Relationship Between Marital Intimacy and Quality of Life

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ABSTRACT

Objectives: Definition of quality of life is affected by a number of factors. This study aimed to investigate the relationship between marital intimacy and quality of life of the staff in Khuzestan Water and Electricity Organization.

Method: This study was conducted by the correlation design on the married staff of the Khuzestan Water and Electricity Organization in 2016, of whom, 265 staff were selected using the multi-stage randomized sampling method. Bagarozi Marital Intimacy Questionnaire and The World Health Organization Quality of Life Questionnaire were used for data collection. Data were analyzed using SPSS software and Pearson correlation and multivariate linear regression tests.

Findings: There is a significant positive relationship between dimensions of intimacy and quality of life of the staff ($F=9.75$, $p< 0.0001$). Stepwise regression analysis also showed that only intellectual intimacy can predict the quality of life of the staff ($r=0.43$).

Conclusion: Marital intimacy increases quality of life of the staff and as physical, spiritual, aesthetical, social, emotional, psychological, intellectual and sexual intimacy of the staff increases, their quality of life increases, too.

Keywords: *Marital Intimacy, Quality of Life, Married Staff.*

INTRODUCTION

Many psychiatrists and psychologists believe that human beings from childhood to aging undergo different psychological, emotional and intellectual stages that are necessary for the next stages of life. If people cannot correctly pass through these stages, they are confused and feel inadequate. Intimacy is one of these stages. When people healthy undergo stages of childhood and adolescence, in their adulthood they should be able to experience intimacy and empathy with others notably with the opposite sex.

People who have undergone the previous stage, encounter with some problems, and have no ability to create intimacy; consequently, they experience loneliness and rejection[1]. Intimacy is a kind of feeling that causes closeness, attachment and contact. Main phenomena that play role in literature regarding the definition of intimacy include similarity, acceptance, self-closure, sexual relationships, and independence, and consistency, emotional, physical and intellectual closeness[2].

The intimacy is the ability to enter the world of other people including your spouse, so that you feel you can understand him or her. Undoubtedly, intimacy is the most important marital quality. The ability for establishing relationships is one of the most important skills of the people. Marital intimacy is to speak about the deep feelings, dreams, desires, concerns and joys. Importantly, intimacy requires the self-knowledge and considering the latent inner feelings. Without it, intimacy does not occur[3]. A happy person is one who enjoys living with love and intimacy and different problems cannot affect him or her. Mutual respect gives people comfort, safety and ability to man so that he can freely and with not coercion strive for his or other growth and development[4].

Marital intimacy is valuable because couples' commitment improves the stable relationship and is positively related to marital satisfaction compatibility. Intimacy is defined as dynamic process. Hatfield (1988) defines intimacy as a process in which people try to approach each other and discover similarities,

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differences in feelings, thoughts and behaviors. According to Sternberg (1987), intimacy is a kind of feeling that causes attachment and contacts. Schnarch (1991) defines as a process of contact, self-understanding, and self-disclosure at the presence of the spouse[5].

Marital intimacy is related to the quality of life. There are two kinds of quality of life: objective and subjective. Objective quality of life is related to social progress and cultural demands for wealth, social status and physical well-being. Objective variables are quantifiable are and related to the environment and living conditions in both individual and social dimensions. The most important variables are: A) individual dimension including variables that define the individual relationships with the certain life conditions such as necessary facilities for a healthy and comfortable life. The most important of these conditions include material well-being, housing and health; B) Social dimension: human beings are social creatures by nature and his life is defined in relation to others (within family or organizations in he works) and the community (in relation to the state and the government). The most important of these variables are: healthy and comfortable family life, healthy and productive organizational life, friends and relatives, political security and social and economic security. Zolig et al (2005) argue that the objective viewpoint considers the external conditions like income, housing, friendship networks and access to health services. On the contrary, subjective viewpoint emphasizes on subjective judgment on life satisfaction with regard to the whole life or certain areas including the satisfaction with friends or family. However, it should be noted that the human being has a mental image of reality and this kind of perception does not necessarily conform to reality. In addition, the mental image and perception of the people on reality is different from person to person. Therefore, it can be said that firstly, our perception on objective conditions and realities of life forms our feelings on life and quality of life; therefore, people themselves should feel that their quality of life is good or not; secondly, people's perception is not the same on this subject. Therefore, it may be concluded that there is a difference between youth's evaluation of life realities and goodness of quality of life and criteria that they have for evaluating their lives and parents, governors and other officials have for evaluation of life realities and this gap is extending and deepening [6].

Quality of life with awareness, consciousness or individual analysis is determined. Happiness and joy are the components that determine the good quality of life. Pain and discomfort are the sign and determinant of low quality of life. Considering the individual differences is effective in measuring the quality of life because different factors make people happy and this causes different kinds of evaluation[7].

INSTRUMENT AND METHOD

The statistical population of this study consisted of all married staff of the Khuzestan Water and Electricity Organization in 2016, of whom, 265 staff were selected using the multi-stage randomized sampling method and according to Morgan and Krejcy Table.

Statistical operation was conducted on 265 referred questionnaires. A correlational research method was used and the following instruments were used to measure the variables.

Bagarozzi intimacy questionnaire

This questionnaire was developed by Bagarozzi (2001). It consisted of 41 questions and evaluates intimacy needs in eight dimensions: emotional intimacy, psychological intimacy, intellectual intimacy, sexual intimacy, physical intimacy, spiritual intimacy, aesthetic intimacy, social-recreational intimacy. Subjects ranked from 1 *there is such a need at all* to 10 *there is high need* responds to such a need. The highest score in each dimension is 50 and in spiritual intimacy is 60. In Iran, Etemad (2005), obtained the general reliability of this questionnaire as 0.94 and its concurrent validity as 0.58[8]. In the present study, reliability of this questionnaire was determined using the Cronbach's alpha as 0.92 that shows satisfactory reliability coefficient of the questionnaire.

Table 1: Reliability coefficients of intimacy questionnaire in this study

Statistical Indicators	Reliability coefficients
Scale	**Cronbach's alpha**
Total Quality of intimacy Questionnaire	0.92
Physical intimacy	0.68
Spiritual intimacy	0.67
Aesthetic intimacy	0.79
Social intimacy	0.68
Warmth	0.78
Psychological intimacy	0.81
Intellectual intimacy	0.82
Sexual intimacy	0.86

As shown in Table 1, reliability coefficients of the intimacy questionnaire fluctuates between 0.67 and 0.92.

The World Health Organization Quality of Life Questionnaire

Short form of the World Health Organization Quality of Life Evaluation Scale (1998) has 26 items. It analyzes two questions concerning the general feelings of the people on their quality of life and individual behavior in two recent weeks in terms of the physical health (physical activities, drug and medication addiction, mobility, pain and discomfort, sleep and ability to do things) and psychological health (feelings toward body appearance, positive and negative emotions, learning, thinking, memory and concentration, self-confidence, mood and personality behaviors), social relationships and social environment[9].

Each item is scored from 1 (very low, never, too unsatisfied) to 5 (very much, always, very satisfied). It should be noted that items 3, 4 and 25 are reversely scored. Obtaining a higher score on this scale indicates a higher quality of life.

Reliability of the quality of life questionnaire shows the Cronbach's alpha between 0.66-0.84 by the developers of the World Health Organization Quality of Life Scale (1998), indicating good internal consistency. In Iran, Nasiri (2006) used three split-half or Cronbach's alpha retest methods (with three weeks interval) for reliability of the scale that were 67%, 87%, 84%, respectively. In the present study, Cronbach's alpha was 0.091. The World Health Organization (1998) uses World Health Organization quality of life questionnaire - long form to determine the validity of this form that the results of all correlation coefficients are statistically significant at 0.001. Nejat et al. (2006) showed a satisfactory correlation between all questions between 0.18 and 0.62[10].

In the present study, Cronbach's alpha was used to determine the reliability of the quality of life questionnaire that was 0.91 for the whole questionnaire, and indicated good reliability coefficients of this questionnaire.

Table 2: Reliability coefficients of quality of life questionnaire in this study

Statistical Indicators	Reliability coefficients
Scale	**Cronbach's alpha**
Total Quality of Life Questionnaire	0.91
Quality of Physical health	0.73
Quality of Psychological health	0.75
Quality of Social relationships	0.74
Quality of environmental health	0.84

As shown in Table 2, reliability coefficients of the quality of life questionnaire fluctuates between 0.73 and 0.91.

RESULTS

totally, 265 staff completed questionnaires. There was a significant relationship between different kinds of physical, spiritual, aesthetic, social, emotional, psychological, intellectual and sexual intimacy and quality of life of the staff.

In other words, as the physical, intellectual, aesthetic, social, emotional, psychological, intellectual and sexual intimacy of the staff increases, their quality of life increases, too.

Table 3: Correlation simple coefficients between eight kinds of intimacy and quality of life of the staff

Criterion variable	Statistical Indicators predictor variable	Correlation Coefficient	Sig.	Number of samples
Quality of Life	Physical intimacy	0.16	0.006	265
	Spiritual intimacy	0.23	0.0001	
	Aesthetic intimacy	0.13	0.036	
	Social intimacy	0.23	0.0001	
	Warmth	0.3	0.0001	
	Psychological intimacy	0.38	0.0001	
	Intellectual intimacy	0.43	0.0001	
	Sexual intimacy	0.2	0.001	

It was found that predictor variables of the physical intimacy ($r= 0.16$, $p<0.06$), spiritual intimacy ($r= 0.23$, $p<0.0001$), aesthetic intimacy ($r= 0.13$, $p<0.036$), social intimacy ($r= 0.23$, $p<0.0001$), emotional intimacy ($r= 0.30$, $p<0.0001$), psychological intimacy ($r= 0.38$, $p<0.0001$), intellectual intimacy ($r= 0.43$, $p<0.0001$) and sexual intimacy ($r= 0.20$, $p<0.0001$) played a main role in quality of life.

DISCUSSION AND CONCLUSION

This study aimed to investigate the relationship between marital intimacy and quality of life of the

married staff of Khuzestan Water and Electricity Organization. Results showed that there is a significant positive correlation between marital intimacy in all its dimensions and quality of life. In other words, high levels of marital intimacy is associated with high level of quality of life and low levels is related to low levels of quality of life. In the previous studies, the relationship between marital intimacy and quality of life was investigated and the results confirmed this relationship. The research results are consistent with the research results of Carr et al (2014)[11], Robles et al (2014)[12], Harper et al (2000)[13] and McCabe (1997)[14]. Finally, investigating the intimacy showed that quality of life of the married staff increases significantly as intimacy increases. In explaining this finding, it can be said that intimacy leads to strong marital relationships and martial satisfaction. People who have intimate and efficient relations benefit from certain skills. Couples with deep and stable relationships are familiar with interpersonal skills, such as listening, clear relationships, negotiation, proper management, anger and so on and use these skills in their relationships. The intimacy is the ability to enter the world of other people including your spouse, so that you feel you can understand him or her. Undoubtedly, intimacy is the most important marital quality. The ability for establishing relationships is one of the most important skills of the people.

Marital intimacy is to speak about the deep feelings, dreams, desires, concerns and joys. Importantly, intimacy requires the self-knowledge and considering the latent inner feelings. Without it, intimacy does not occur. A happy person is one who enjoys living with love and intimacy and different problems cannot affect him or her. Mutual respect, peace, reliability, and peaceful co-existence are of the main factors that are manifested through love. Only love can overcome despair. Love gives a feeling of safety and ability to the people that strive for their perfection and others with no coercion. Increasing intimacy is one of the ways to increase quality of life of the couples. As quality of life of life increases, a positive attitude is created and this increases awareness on the present time and encourage them not to judge others. Quality of life is a kind of perception that people have concerning their cultural values, goals, expectations, standards and interests. Quality of life is one of the most important dynamic and subjective phenomenon of life. It is subjective because it should be determined by the personal ideas not others and it is dynamic because it changes by passing the time and it should be measured in a certain period. Marital intimacy and quality of life are related. As the marital intimacy increases, quality of life increases, too.

Ethical Approval: Related departments should be assured about the confidentiality of the results of questionnaires.

Conflict of Interest: The authors report no conflict of interest.

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Fine Needle Aspiration of Follicular Lesions of the Thyroid: Cytohistologic Correlation and Accuracy at Hapur Region

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ABSTRACT

Background: Fine needle aspiration (FNA) is a reliable method in the initial assessment of thyroid nodules. This study evaluated the accuracy of fine needle aspiration cytology (FNAC) in cases of follicular neoplasm (FN) on the basis of histologic diagnosis, and reviewed the cytologic findings of FN according to the FNAC.

Method: Among the 50 cases diagnosed with thyroid Follicular Neoplasm by FNAC during the 3 year period from October 2013 to September 2016, 27 cases that had undergone thyroid surgery were available for review. Cytologic diagnosis was compared with the histologic diagnosis of each case.

Results: Among the 27 cases with a cytologic diagnosis of thyroid FN, histologic diagnosiswas as follows: 16 follicular adenomas (59.3%), 2 Hurthle cell adenomas (7.4%), 1 follicularcarcinomas (3.7%), 5 nodular goitres (18.5%), 1 papillary carcinomas (3.7%), and 1 Hashimoto'sthyroiditis (3.7%), resulting in a diagnostic accuracy of FNAC for thyroid FN of 70.4%.

Conclusion: This study shows that FNAC for thyroid FN is a useful primary screening method because when FN is diagnosed by FNAC, the rate of FN histological diagnosis is relatively high and however, adequate sampling and experience is a prerequisite for this procedure.

Keywords: *Thyroid Gland; Follicular Neoplasm; Fine needle Sspiration Cytology.*

INTRODUCTION

Fine needle aspiration (FNA) has been widely accepted as an initial step in the management of thyroid nodules. Recently, as the use of ultrasonographic examination has increased, the possibility of incidental findings of thyroid nodules has also increased. The fine needle aspiration cytology (FNAC) of the thyroid gland is an important and definitive method for the diagnosis of thyroid nodules.[1,2] Follicular neoplasm (FN) and Hurthle cell neoplasm(HCN) are relatively rare diseases and their cytologic diagnosisis difficult when compared with papillary carcinoma (PC) whichshows a cytologic accuracy of more than 90%. In addition, cytologic differentiation between benign and malignant tumors is not possible in FN and HCN cases. It is relied upon to distinguish benign from neoplastic/malignant thyroid nodules, thus, influencing therapeutic decisions.[3,4] However, the diagnostic efficacy of FNA declines sharply in the diagnosis of follicular patterned lesions of thyroid, i.e. separating hyperplastic/ adenomatoid nodule, follicular adenoma (FA), follicular carcinoma (FCA) and follicular variant of papillary carcinoma (FVPTC).[5,6] Most of these cases are diagnosed as follicular lesion/neoplasm and surgical excision is recommended for definite diagnosis on histopathologic examination. [7,8] According to the guidelines for the treatment of thyroid nodules, surgery is recommended for patients when FN or HCN is diagnosed byFNAC because the possibility of malignancy in this case is not known until the histologic

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diagnosis is made from the lobectomyor total thyroidectomy specimen.[1] In contrast, guidelines for the treatment of PCs are relatively well established accordingto the categories of cytologic diagnosis. FN and HCN are still rare FNAC findings. Follicular carcinoma (FC) comprises approximately 5% of thyroid cancers,[9] and because the number of FN cases is limited and FC cannot be distinguished from benign follicular adenoma (FA) on the basis of cytologic findings, describing FN cytologically in an ambiguous manner may beinevitable. Therefore, more cytologic information regarding FN and HCN are required not only for the cytologic diagnosis but also for the development of appropriate treatment guidelines.

In this study we evaluated the FNAC accuracy in FN casesbased on the histologic diagnosis and investigated the cytologicfindings to increase the probability of a correct cytologic FN diagnosis.

MATERIALS AND METHOD

At Saraswathi Institute of Medical Sciences (SIMS), Hapur,50 cases that had been diagnosed with thyroid FN by FNAC during the 3 year period from October 2013 to September 2016,27 cases that underwent thyroid surgery were available for review. FNAC was performed under ultrasonographic guidance in all cases. The FNA was performed using a 25gauge needle attached to a 10ml syringe. On average, 2 passes were made in each nodule, resulting in two airdried and two alchoholfixed smears. We reviewed the cytology slides on the basis of representative cytologic FN findings such as abundance of follicular epithelial cells, presence of micro-follicular structures, abundant cell crowding, abundant dispersed isolated cells, homogenous nuclear morphology, lack of nuclear grooves, lack of colloid material and lack of macrophages with reference to previous reports and the Bethesda system for reporting thyroid cytology. [1,2,10] Regarding HCN, we looked only for the characteristicfindings of Hurthle cells such as abundant finely granular cytoplasmsenlarged, central or eccentrically located, round nucleus, prominent nucleolus, small cells with high nuclear/ cytoplasmicratio (small cell dysplasia), and large cells with at least 2× variabilityin nuclear size (large-cell dysplasia). However, for thecytologic review we applied the same cytologic standards as in FN. After slide review, cytologic diagnosis was compared with the histologic diagnosis of each case. We selected the cases which satisfied the standard adequacy criteria for interpreting thyroidcytology. The standard adequacy criteria is the presence of atleast 6 groups of follicular cells in total on stained smears, with a minimum of 10 cells in each group.[11]

RESULTS

The patients ranged in age from 16-85 yr. A majority of the cases were female and only 2 cases were male. Ultrasonographic findings showed that 4 cases were benign, 3 cases were suspicious for malignancy, and 20 cases were indeterminate. Among the 27 cases in which surgery was performed, 24 (88.9%) were diagnosed as FN and 3 (11.1%) were diagnosed as HCN in the preoperative FNAC. Of the 27cases, 16 (59.3%) were diagnosed as FA, 2 (7.4%) were Hurthlecell adenoma (HCA), 1 (3.7%) were FC. A total of 19 cases (70.4%) were consistent with FN and the other cases included5 (18.5%) nodular goitres,1(3.7%) PCs, and 1(3.7%) Hashimoto'sthyroiditis. All 3 cases which were cytologically diagnosed as HCN were proven histologically to be non-FN. Thus, the FNAC diagnostic accuracy for FN was 70.4% (Table 1). Regarding the clinic-pathologic characteristics of the 19 cases which were diagnosed as FN. The age varied from 17 to 62 years and the average age was 38.4 years. The tumor sizes evaluated from the lobectomy or total thyroidectomy specimens ranged from 0.4 cm to 4.5 cm with an average size of 2.29 cm. The lesion sites included the right lobe, left lobe, and isthmus. Histologic subtypes were as follows: microfollicular, normofollicular, oncocytic, microfollicular with trabecular, and micro-follicular with papillary hyperplasia. These cases had generally sufficient cellularity for a properdiagnosis, and the majority showed the characteristic cytologicfindings including abundance of follicular epithelial cells, presence of microfollicular structures, abundant cell crowding, abundantdispersed isolated cells, homogenous nuclear morphology, lack of nuclear grooves, lack of colloid material and lack of macrophages. Among these cytologic features, high cellularity, abundant microfollicles, abundant cell crowding, and homogenousnuclear morphology were especially important features for the FN cytologic diagnosis (Table 2).

Table 1:Cytohistological correlation of follicular neoplasm of thyroid

Cytol-ogicaldiagn-osis	No. of cases (%)	HD Corresponds to FN (%)				HD Corresponds to NFN (%)			
		FA	HA	FC	Total	NH	PC	HT	Total
FN	24(88.9)	16(59.3)	2(7.4)	1(3.7)	19(70.4)	4(14.8)	1(3.7)	-	5(18.5)
HCN	3(11.1)	-	-	-	-	1(3.7)	1(3.7)	1(3.7)	3(11.1)
Total	27(100)	16(59.3)	2(7.4)	1(3.7)	19(70.4)	5(18.5)	2(7.4)	1(3.7)	8(29.6)

HD, histologic diagnosis; **FN**, follicular neoplasm; **HCN**, Hurthle cell neoplasm; **NFN**, non-follicular neoplasm; **FA**, follicular adenoma; **HA**, Hurthle cell adenoma

FA, oncocytic variant; **FC**, follicular carcinoma; **NH**, nodular hyperplasia; **PC**, papillary carcinoma; **HT**, Hashimoto's thyroiditis

Table 2: Cytologic features of thyroid follicular adenoma in FNAC

Cytologic features	HD Corresponds to FN (%)				HD Corresponds to NFN (%)			
	FA (n=16)	HA (n=2)	FC (n=1)	Total (n=19)	NH (n=4)	PC (n=1)	HT (n=0)	Total (n=5)
High cellularity	16(100)	2(100)	1(100)	19(100)	4(100)	1(100)	0	5(100)
Abundant microfollicles	16(100)	2(100)	1(100)	19(100)	4(100)	1(100)	0	5(100)
Abundant cell crowding	16(100)	2(100)	1(100)	19(100)	4(100)	1(100)	0	5(100)
Abundant dispersed isolated cells	15(93.8)	1(50)	1(100)	17(89.5)	3(75)	0	0	3(60)
Homogenous nuclear morphology	16(100)	2(100)	1(100)	19(100)	3(75)	0	0	3(60)
Lack of nuclear grooves	16(100)	2(100)	1(100)	19(100)	4(100)	1(100)	0	5(100)
Lack of colloid material	15(93.8)	1(50)	1(100)	17(89.5)	4(100)	1(100)	0	5(100)
Lack of macrophages	15(93.8)	1(50)	1(100)	17(89.5)	4(100)	1(100)	0	5(100)

FNAC, fine needle aspiration cytology; **HD**, histologic diagnosis; **FN**, follicular neoplasm; **NFN**, non-follicular neoplasm; **FA**, follicular adenoma; **HA**, Hurthle cell adenoma

FA, oncocytic variant; **FC**, follicular carcinoma; **NH**, nodular hyperplasia; **PC**, papillary carcinoma; **HT**, Hashimoto's thyroiditis.

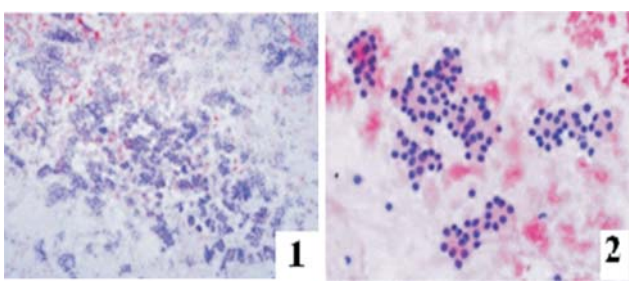


Fig. (1) Follicular adenoma (FA) shows low power view of fine needle aspiration cytology (FNAC) shows high cellularity composed of abundant microfollicles. Fig (2) The crowded follicular cells have homogenous nuclear morphology composed of round nuclei, evenly dispersed, granular chromatin and faint nucleoli.

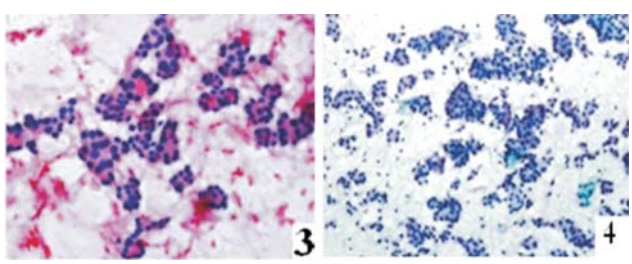


Fig. (3)Microfollicles contain small amounts of colloid. Fig.(4)Hurthle cell type. The aspirate is very cellular and consists almost exclusively of Hurthle cells in small crowded arrangements.

DISCUSSION

The purpose of cytological or pathological examination reports is to provide clinicians appropriate guidelines for the treatment of patients, including surgery to the clinicians.[12]In the field of cytology, several report formats have been developed for this purpose, and presently, most reports are provided using categorical terms. Several forms of categorical diagnosis have been introduced. Generally, they include categories of unsatisfactory, benign, suspicious for malignancy, malignancy, and some forms have additional categories such as indeterminate, atypical, or follicular neoplasia.[13] FA is defined as solitary encapsulated nodules arising in an otherwise normal thyroid that lack evidence of capsular or vascular invasion.[9] HCN is considered a biologically different disease entity from FN, but is reported in the same category as FN with the additional mention of the possibility of HCN.Traditionally, FN and HCN were ambiguously classified in cytology because of the limitations of their cytologic diagnosis. Recently, the Bethesda system for reporting thyroid cytopathology was introduced which classified FN/HCN in the

independent category. The traditional category of atypia includes the cytologic findings of suspicious FN/HCN in the terminology of follicular lesion of undetermined significance.[10] However, the cytologic diagnosis of FN/HCN remains clinically controversial when compared to PC, which provides effective guidelines for the clinician.[14,15] Using FNAC, the diagnostic accuracy of PC is more than 90%, but the distinction between malignancy and benign in FN or HCN is impossible because surgery is mandatory for the definitive diagnosis of FC or Hurthle cell carcinoma.[16] In this guideline, FNAC is recommended for nodules of more the 1.0 cm in size, nodules less than 1.0 cm in size but associated with risk factors, cystic nodules more than 2.0 cm in size, or patients with Hashimoto's thyroiditis because it is more commonly associated with PC.[17] The revised edition also used the Bethesda system for the provision of treatment guidelines.

For unsatisfactory cases, a repeat examination with follow-up or consideration of surgery is recommended. For benign cases, additional examination or treatments are not necessary. In the atypiacategory, because the malignancy rate is approximately 5-15%, a repeat FNAC with consideration of surgery is necessary. The category of suspicious malignancy or malignancy is indication for lobectomy or total thyroidectomy. For the FN, when the autonomicnodules are not found in the thyroid scan, lobectomyor total thyroidectomy is recommended. For the HCN, lobectomyor total thyroidectomy is recommended without a thyroidscan.1 In the FN or HCN cases, although a few cytologic findingscan be helpful for the suspicion of FN/HCN, the predictionvalue of malignancy is relatively low.[18] FNAC cannot providedefinitive criteria for the distinction between benign andmalignancy when FN/HCN is suspected.

In these studies, the cytologic diagnosis rate of FN was approximately 10% and a majority of FA or FC cases confirmed by histologic diagnosis showed a previous cytological diagnosis as benign, nodular hyperplasia, and even as PC.[19,20] Most pathologists do not have sufficient experience with FN/HCN. In FNAC, the most important causes of diagnostic misinterpretation were overlapping cytological features among follicular-derived lesions and inadequate/suboptimal specimens. Especially, the follicular variants of PC, FN, and adenomatous hyperplasia show overlapping cytological features making the diagnosis of FN/HCN more difficult.[19,22]

Although difficult, the ultimate purpose of FNAC in FN/HCN cases is to isolate FC. The present study showed the diagnosticspecificity of FA including HCA was 64%, with a malignancyrate of 11% when a histologic correlation was conducted. Among the malignancies, 1 FC and 2 PCs were identified. Themalignancy rate in the present study did not reach the samelevel as with the Bethesda system, but PCs were not exclusivelyincluded. Therefore, PC was successfully screened by FNACwith the relevant cytological diagnosis, and the diagnostic specificityof FN by FNAC was relatively high when compared withthe histologic diagnosis. Specifically, among the FNs, 1 FCwas successfully identified even though the number of cases was small. These results are well correlated with the clinical experience that lobectomy or total thyroidectomy is recommendedfor the cytologically suspected FN. Because thiscategory predicts the existence of FC to some extent and leadsto surgical treatment, this category has sufficient value in FNAC.

The present study started with the selection of cytologically diagnosed FN, and cases were chosen where correlation with histologic diagnosis was available. Therefore, this was a slightly different approach when compared with pre-existing methods which started with the histologically confirmed FA or FC cases and followed by analysis of their previous cytological diagnoses. However, this approach generally results in a low diagnostic FNAC rate in the case of FNs.

CONCLUSION

This study shows that FNAC for thyroid FN is a useful primary screening method because when FN is diagnosed by FNAC, the rate of FN histological diagnosis is relatively high, and however, adequate sampling and experience is a prerequisite for this procedure.

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Factors Associated with Malnutrition among Under-Five Children in Migrant Population of Udupi District

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ABSTRACT

Background: Nutritional status of the child describes not only the entire health profile of an individual but also of the entire community. Certain determinants like, the type of family, caste, and standard of living index, mother's education, housing and environmental conditions plays a significant role in protein energy malnutrition.

Objective: To determine the factors associated with prevalence of malnutrition among under five children.

Method and Material: The study used a cross-sectional design comprising of 260 under-five children and their mothers (dyad). The migrant population areas of Udupi taluk were selected through simple random sampling and the samples were selected using cluster sampling. Data were collected using demographic proforma, a semi-structured questionnaire on factors associated with malnutrition and knowledge questionnaire on malnutrition.

Results: Malnutrition was prevalent among 58.07% migrant children.There is significant association between malnutrition and gender ($\chi^2(1) = 6.985$, p value= 0.006), number of siblings ($\chi^2(2) = 7.292$, p value= 0.026),socioeconomic status ($\chi^2(2) = 10.488$, p value= 0.033), source of water supply ($\chi^2(2) = 7.073$, p value= 0.029), mothers age at the time of delivery ($\chi^2(1) = 6.478$, p value= 0.039), spacing between two children ((2) =6.886, p value= 0.043) and mid arm circumference of the child ($\chi^2(1) = 11.075$, p value= 0.011).

Conclusions: Malnutrition is highly prevalent among under-five children of migrant population. Many factors associated with malnutrion are identified in the study and apt measures should be taken to prevent the modifiable factors. Empowering caregivers helps to reduce the prevalence of malnutrition.

Keywords: *Factors, Malnutrition, Under-five, Migrant, Children, Udupi.*

INTRODUCTION

The World Health Organization (WHO) defines protein energy malnutrition (PEM) as the range of pathological conditions arising from coincidental lack in varying proportions of proteins and calories, occurring most frequently in infants and young children, commonly associated with infection [1].

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Migration and health shares an intricate relations. The ever increasing urbanization and the migration of people from rural areas to urban areas have contributed to analyze the health and nutrition status of migrants[2].

United Nations Children's Fund (UNICEF) reported in 2015 that, 90% of the world's chronically malnourished children lived in Asia and Africa. In India, 20% of the under-five children were suffer from wasting. Around 43% children were under weight and 48% are stunted. Under nutrition was very prevalent in rural areas with factors like short birth interval, illiterate mothers, malnourished mothers, and children from schedule tribes[3].

Nutritional status of the child describes not only the entire health profile of an individual but also of the

entire community. Nutritional status is associated with certain determinants like, the type of family, caste, and standard of living index, mother's education, housing and environmental conditions played a significant role in PEM. Malnutrition is more prevalent in low socio-economic groups and illiterate mother's[4].

The proportion of malnourished children in India is considerably very high when compared to other small countries. The occurrence of malnutrition among the four southern states in India was lower compared to the rest of the states in India and found that nutritional status of children was poor in Andhra Pradesh and Karnataka compared to Kerala and Tamil Nadu. The nutritional status of children depended on many factors like employment income, wealth, per capita consumption, mothers' education, sanitation and hygiene, feeding habits and health status[5].

The population moving to a new home within a state, country, or continent is the migrant population. Thirty percentage of the Indian population are the migrants.[6]Two–third of them have migrated for employment related reasons. They are vulnerableto health problems, decreased awareness to local health facility, poor living conditions and hence health of the children are widely affected. Under-nutrition is a major problem among the migrant children which contributes to the child mortality among the group.[7]

Many factors contribute to the prevalence of malnutrition. The need of integrating multiple strategies for reducing anthropometric failures among under-five children should be adopted. Health care system should concentrate on these vulnerable population and take efforts to provide health interventions accessible and available without compromising their daily efforts to earn their livelihood. Hence, the present study aims to describe the factors associated with malnutrition of childrenaged six months to five years inthe migrant population and its association with the prevalence of malnutrition.

MATERIALS AND METHOD

A quantitative study using cross sectional design was adopted to investigate the factors associated with malnutrition among 260 migrant children between the age of six months to five years of Udupi district, Karnataka.Parents of the under-five children and their child (dyad), who were willing to participate in the study were included. The migrant areas were selected randomly from the list of migrant areas of Udupi taluk and a cluster sampling technique was used to select the participants from the migrant areas from the Udupi taluk. The migrants were located in both urban and rural areas of Udupi taluk. Most of them have migrated for employment related reasons.

The data collection tools were used to collect the data which was validated, pretested and reliable. The demographic proforma to collect the background information. A semi-structured questionnaire on factors associated with malnutrition (r=0.97) was used to assess the factors associated with malnutrition. The tool consisted of various factors such as, environmental factors, maternal factors, child factors, dietary/feeding practices, health factors, and hygiene factors. A knowledge questionnaire on malnutrition were usedto assess the knowledge level of the mother regarding malnutrition. The tool consisted of 22 multiple choice questions. Each correct answer was scored as one and an incorrect answer was scored as zero. The knowledge score was further arbitrarily classified as poor knowledge (<8), average knowledge (8-14) and good knowledge (15-22). The reliability co-efficient of the tool wasestablished by Split half method using the Spearman Brown Prophesy formula.(r=0.90), which indicated that the tool was reliable.Malnutrition was assessed by measuring the weight of the child using Indian Academy of Paediatrics (IAP) classification.

Ethical approval from the Institutional Ethics Committee of Kasturba hospital Manipal, administrative permission from Tehsildar of Udupi taluk, the data was collected from the under-five children and their parents after explaining the purpose of the study and getting the informed consent. A house to house survey using the interview method was used to rule out the prevalence of malnutrition and its associated factors.

Data was analysed using SPSS package version 20.0 using descriptive and inferential statistics.

RESULTS

The results of the study showed that among 260 under-five children of the migrant population, 40 (15.4%) were between six months to one year, 106

(40.8%) were between one to three years and 114 (43.8%) children were between 3 to 5 years. Majority 250 (96.2%) belonged to Karnataka state.

The prevalence of malnutrition includes all cases of malnutrition existing at the time of data collection and was assessed by measuring the weight for age using IAP classification. Hence, the prevalence of malnutrition in the migrant population was 151 (58.07%.)

The factors associated with malnutrition was analysed and its association with malnutrition was determined and is depicted in table 1, 2 and 3 respectively. There was significant association between prevalence of malnutrition and gender ($\chi^2_{(1)}$=6.985, p value= 0.006), number of siblings $\chi^2_{(2)}$=7.292, p value= 0.026), socioeconomic status $\chi^2_{(2)}$=10.488, p value= 0.033), source of water supply $\chi^2_{(2)}$=7.073, p value= 0.029), mothers age at the time of delivery $\chi^2_{(1)}$=6.478, p value= 0.039), spacing between two children $\chi^2_{(2)}$=6.886, p value= 0.043) and mid arm circumference of the child $\chi^2_{(1)}$=11.075, p value= 0.011). Hence, gender, number of siblings, socioeconomic status, mothers age at the time of delivery, spacing between two children, and mid arm circumference, were the factors dependent on prevalence of malnutrition.

Mean knowledge score of mothers was 14.97±2.516. Majority 148 (56.9%) mothers had good knowledge and 112 (43.1 %) mothers had average knowledge about malnutrition.

Table 1: Association between prevalence of malnutrition and selected demographic factors

N=**260**

Variables	Normal	Malnutrition	χ^2	df	p value
Age group					
Infancy	16	24			0.854
Toddler	43	63	0.317	2	
Pre-schooler	50	64			
Gender					
Male	70	72			0.006*
Female	39	79	6.985	1	
Number of siblings					
Single child	52	79			0.026*
1 to 2	44	67	7.292	2	
3 to 4	13	5			
Socioeconomic status					
Lower class	90	137			0.033*
Middle class	17	14	10.488	2	
Upper class	2	0			
Father's education					
Illiterate	14	13			0.052
School certificate	92	123	10.959	2	
Graduation and honors	10	8			
Environmental factors					
Type of house					
Kutcha	77	121			0. 294
Pucca	21	17			
Mixed	2	2	3.711	3	
Tent	10	10			

*significant at $p < 0.05$ level of significance

Table 2: Association between prevalence of malnutrition and maternal factors

N=260

Variables	Normal	Malnutrition	χ^2	df	p value
Source of water supply					
Well water	23	23	7.073	2	0.029*
Tap water	69	117			
Municipality	17	11			
Mother's body mass index					
Underweight	19	37	3.166	3	0.367
Normal weight	68	93			
Overweight	19	19			
Obese	3	2			
Mother's age at the time of delivery in years					
16-20	33	67	6.478	2	0.039*
21-25	70	73			
>25	6	11			
Initiation of breastfeeding within two hours of delivery					
Yes	92	118	1.596	1	0.206
No	17	33			
Use of soap for handwashing					
Yes	64	88	0.933	1	0.334
No	52	56			
Knowledge level					
Average knowledge	41	71	2.284	1	0.083
Good knowledge	68	80			

*significant at $p < 0.05$ level of significance

Table 3: Association between prevalence of malnutrition and selected child factors

N=260

Variables	Normal	Malnutrition	χ^2	df	p value
Child factors					
Birth order					
1	69	105	5.258	2	0.262
2	25	36			
3 and above	15	10			
Child's caregiver					
Mother and grandparents	70	79	1.532	2	0.465
Neighbors and aunty	14	15			
Anganwadi	32	50			
Birth weight (kg)					
1.5 to 1.9	0	1	1.802	2	0.772
2.0 to 2.9	62	93			
3 and above	47	57			
Spacing					
<12 months	4	12	6.866	2	0.043*
2 to 4 years	46	44			
Single child	59	95			
Mid arm circumference					
Acute malnutrition	11	40	11.075	1	0.011*
Well nourished	98	111			

Table 3: Association between prevalence of malnutrition and selected child factors (Contd.)

N=260

Variables	Normal	Malnutrition	χ^2	df	p value
Dietary factors					
Use of colostrum					
Yes	91	128	0.078	1	0.780
No	18	23			

*significant at p < 0.05 level of significance

DISCUSSION

The present study showed that malnutrition of underfive children is dependent on certain factors like gender, number of siblings, socioeconomic status, spacing between two children, and mid arm circumference. Following studies supported the present study findings. A cross sectional study conducted among 157 children concluded that socio-economic status, birth weight, housing, mid- arm circumference and deficient protein intake were the factors associated with malnutrition (p<0.05)[8.]The factors that supported the present study were the mid arm circumference and socioeconomic status.

A cross sectional study on the nutritional status of under-fives in rural area of South India reported that father's education status was significantly associated with underweight, the prevalence of stunting was associated with age and socio-economic status. The prevalence rate of wasting was significantly associated with age and socio-economic status. Hence, socioeconomic status was the only factor associated with malnutrition which supported the present study. Whereas, the other factors contradicted the present study findings[9].

According to Samya and Stanley[10] low birth weight children, children who were not exclusively breast fed, birth spacing, children living in overcrowded houses and children who had more than 3 episode of acute respiratory infection in the past one year were at significantly higher risk in succumbing to malnutrition. Birth spacing was the only factor that supported the present study findings, while the other factors contradicted the study.

A study on the prevalence and determinants of malnutrition was conducted in the Kwara state, Nigeria among 127 under-five children. The study showed that gender, age of the child, education of the mother, body mass index of the mother, calorie intake, access to clean water and toileting facilities were the factors associated with malnutrition. All the factors except gender contradicted the present study[11].

The findings of the present study showed that there is significant association between prevalence of malnutrition and father's education (=7.083, p value=0.034) and spacing between two children (=5.746, p value=0.024) in infants. There is a significant association between the prevalence of malnutrition and number of siblings (=6.691, p value=0.03) in toddlers. There is a significant association between the prevalence of malnutrition and gender (=6.432, p value=0.011) and initiation of breast feeding within two hours of delivery (=5.362, p value= 0.021) in preschoolers.

A case control study was conducted on the risk factors for severe acute malnutrition (SAM) in children below five years of age in India on 191 samples. Mother's education (p=<0.001), average daily income (p=0.003), number of siblings (p=0.001), immunization profile (p=<0.001), lack of exclusive breastfeeding in the first six months (p=0.003), lack of intake of colostrum (p=0.001), practice of giving prelacteals (p=0.004) and bottle feeding (p=0.025) were found to be highly significant among children with SAM. Number of siblings was the factor that supported the present study, while the other factors contradicted the study[12.]

A study by Najunda[13]conducted on the prevalence of under-nutrition and anemia among under-five rural children in the villages of Hassan and Kodagu district of South Karnataka, India stated that factors like poverty, bad habits, changing health seeking behaviors, practices regarding delivery according to the culture, child rearing and breast feeding played an important role in child mortality. The breastfeeding factor supported the present study, while the other factors contradicted the study.

The concerns of child malnutrition for child morbidity and mortality are colossal. India is one among many countries where child malnutrition is a major underlying cause for child mortality in India.

Therefore, ruling out the nutritional status of high risk group and preventing the factors associated with it would help the health care delivery system to prevent morbidity related to under nutrition and would help the policy makers to identify the root cause for malnutrition and provide intervention for the suppression of malnutrition.

CONCLUSION

Protein energy malnutrition (PEM) is the most widespread health and nutritional concern in all the developing countries. Under-nutrition is fatal and disables millions of children. The survivors are often left with various diseases and stops them from reaching their highest intellectual potential. Proper nutrition is required for the all-round development of the child. It does not only contribute for good health but also for the growth and in turn the growth of the nation. Malnutrition in initial childhood can lead to grave, long-term concerns which in turn can impede motor, sensory, cognitive, social and emotional development. Hence, ruling out the causes contributing and taking appropriate steps in preventing it will aid in reducing the prevalence of malnutrition. Community awareness should be created and the parental knowledge should be empowered by conducting interventions programs to eliminate the root cause and thereby to lead a healthy wealthy life.

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Predicting Marital Disaffection based on Marital Conflict and Attachment Styles

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ABSTRACT

This study aimed to predict marital disaffection (boredom) based on marital conflict and attachment (secure, avoidant and anxious) styles. This study was a descriptive research of correlational type. The study population included all married students studying in Islamic Azad University of Ahvaz in 2016. By multistage sampling method, 200 students were selected and included in the study with informed consent. For data collection, the participants answered the inventories of Kayser Marital Disaffection Scale, Collins and Reid Adult Attachment Styles and Sanaee Revised Marital Conflict Scale. The data were analyzed using hierarchical regression analysis approach. The findings of this study showed that marital conflict positively and significantly predicts marital disaffection. Among the styles of attachment, avoidant and anxious attachment styles positively and significantly can predict marital disaffection, while secure attachment style is a negative and significant predictor of marital disaffection.

Keywords: *Marital Conflict, Marital Disaffection, Attachment Styles.*

INTRODUCTION

Family is the most important unit of the society. Due to providing the original structure to create a family relationship and nurture the next generation, marriage has been described as the most important and most fundamental human relationship. Evidence shows that more than 90% of the world population will be married at least once. While marriage seems to be a very good relationship, statistics indicate that marital satisfaction is not something that can be easily achieved. Therefore, marital satisfaction is an important factor that in general affects the family [1]. Marital conflicts are also considered as an index at odds with marital adjustment. With increasing conflicts between the couples' relationships, the marital discord increases, resulting in more dissatisfaction. Marital conflicts have deleterious effects on physical and psychological health of the family. Marital conflicts are positively correlated with low psychological well-being, insecure attachment styles, psychiatric disorders, depression, anxiety disorders, sexual dysfunctions and physical health problems, such as hypertension, chronic pain and ischemic heart diseases[2].

Previous studies have identified two factors for distress and confusion in marital relationships: Apparent marital conflicts or disharmony and disappointment and apathy, i.e. boredom or disaffection. Kaiser defined marital disaffection as gradual loss of emotional attachment, which involves reduced attention to the spouse, emotional estrangement and increased sense of despair and indifference the wife that consists of three steps:

Disillusion and disappointment: The clear characteristic of this stage is disillusion of marital relations. At this stage, the disillusioned persons ruminate the frustration to their spouse in complete silence[3]. Anger and hatred: The clearest feeling at this point is the feeling of hatred that seems to be due to the recurrence of negative and harmful behaviors of the couple. Since, condoning the spouse mistakes, which was easy at the first stage, is hardly possible at this stage[4].

Frustration and apathy: Emotional and physical distancing is the characteristic of the last phase of the process of disaffection. Unlike the previous stage, anger

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and hatred somewhat reduce, and the emotional coldness significantly increases. In addition, restorative behaviors of previous stages do not occur at this point due to blaming the spouse of creating the problems. Frequent marital conflicts facilitate the occurrence of marital disaffection[4]. Marital disaffection is a complex phenomenon that meanwhile involving a lot of couples is influenced by many factors such as marital conflict as well[4].

The findings indicate that attachment styles of each couple affect the individuals and relationships and cause marital conflicts[5]. Initial experiences of an individual with his/her parents or the type of emotional relationship of an individual with his/her parents in the childhood are among the important factors considered in recent years with a great impact on marital life of the couples. Collins and Read distinguished between adult attachment relationships by identifying specific aspects that were the context of discrete attachment styles[6]. These dimensions included the convenience and comfort in close relationships, the ability to rely on others and the anxiety of abandonment and the feeling of being unloved. Adults with secure attachment style in close relationships are comfortable and at ease, and feel that they can rely on others in times of need. They feel merit in the relationships and have no anxiety of being abandoned and the feeling of being unloved. The adults with insecure-anxious attachment style have a strong tendency to have close relationships and generally believe that they can rely on others. However, they are deeply concerned also about abandonment or rejection[7]. Finally, the adults with insecure avoidant attachment style are uncomfortable in intimate relationships and reliance on others. They do not worry about abandonment or rejection and tend to minimize the importance of intimate relationships[8]. The research findings indicated a significant relationship between attachment styles, marital conflict and forgiveness. Also, the rate of marital conflicts in couples who both have secure attachment style is lower, and their forgiveness is higher than the couples whose attachment styles are both insecure or the couples that the attachment style of one of them is secure and the another one's is insecure.

Due to the great influence of attachment styles of each couple's on marital relationship, and subsequently the marital conflicts, and, given their relationship with marital conflicts, one may say that each of the attachment styles is a predictor of marital disaffection as well. Then, the purpose of this study was to answer to the question that are attachment styles and marital conflicts the predictors of marital disaffection?

METHODOLOGY

The study population included all married students studying in Islamic Azad University of Ahvaz in 2016. By multistage sampling method, 200 students were selected. Thus, of 12 faculties of the University, four schools were selected in the first stage. In the second stage, 4 fields of study were chosen; in the third stage, the university entry year was individually selected for each field. All the selections were done randomly.

Kayser Marital Disaffection Scale (1996)

It is a self-reporting instrument to assess the rate of disaffection toward the spouse, and contains 21 questions that is scored in a 4-point Likert scale from "It does not apply to me at all = 1" to It completely applies to me = 4. Kayser reported the Cronbach's alpha coefficient for this tool as 0.97. In this study, Kayser reported a negative correlation between the score of disaffection and perceived marital happiness scale (r = -0.56) and the marital intimacy scale (r = -0.86) as divergent indicators of this tool[4].

Collins and Read Adult Attachment Styles Inventory

It includes 18 questions that is measured by signing on a 5-point Likert-type scale from "I does not match with my qualities at all = 1" to "It completely consistent with my qualities = 5". The scores of 0 to 4 are considered for options 1 to 5, respectively. The following variables are evaluated with the relevant questions: Secure attachment (C): Questions 1, 6, 8, 12, 13, 17, Avoidant attachment (D): Question 2, 5, 7, 14, 16, 18, Ambivalent / anxiety attachment (A): Question 3, 4, 9, 10, 11, 15. In cases where the questions should be scored reversely, the scores of 4, 3, 2, 1 and zero should be considered on options 1 to 5, respectively (Questions 1, 5, 8, 16, 17, and 18 are scored reversely)[6]. The scores of six items of each scale are summed together to and obtain the subscales scores. Collins and Read reported the Cronbach's alpha for each of its subscale in two 173-subject and 100-subject samples of students as an indicator of the validity of the test as follows: Subscale C: 0.81 and 0.82, Subscale D: 0.78 and 0.80, Subscale A: 0.85 and 0.83.

Pakdaman determined the test reliability rate by using test-retest as correlation between the two runs. The results from implementing of this questionnaire

twice with an interval of one month from each other indicated that the test is valid at confidence level of 0.95. Pakdaman has evaluated the validity of this questionnaire. The construct validity was measured by using the divergent (diagnostic) validity. The results showed that the correlation coefficient between the subscales of A & C and A & D at significance level of 0.01 are as -0.313 and -0.336, while the correlation coefficient between the subscales of C and D at a significance level of 0.014 was obtained as 0.246[9].

Sanaee Revised Marital Conflict Scale (2000)[10]

It includes 54 questions that is made to measure conflicts of couples based on clinical experiences. Each questions is set based on the 5-option Likert scale that proportionate to the responses, score of 1 to 5 will be allocated to them. In this tool, a higher score means more conflict, and lower scores mean better relationship. The questionnaire measures eight dimensions of conflicts as follows: Reduced cooperation, reduced sex, increased emotional reactions, increased gain of children's support, increased personal relationship with relatives, reduced family relationship with the partner's relatives and friends, separating financial issues from each other and reduced effective communication. The Cronbach's alpha for the total scale was calculated on a group of 270 people as 0.96. The Cronbach's alpha for the eight subtests of the test is also as follows: Reduced cooperation: 0.81, Reduced sex: 0.61, Increased emotional reaction: 0.70, Increased gain of children's support: 0.33, Increased personal relationship with relatives: 0.86, Reduced family relationship with the partner's relatives and friends: 0.89, Separating financial issues from each other: 0.51, Reduced effective communication: 0.60. This scale has a good content validity. In addition, the correlation of each question with the total score of the test had a high significance.

After familiarity of the subjects with the research objectives and ensuring them regarding the confidentiality of personal information, the research questionnaires were given to those students who have announced their readiness to response to the statements of questionnaires. The students of each class completed the questionnaires as a group. Given the number of items, the mean time to complete the questionnaire was estimated as 10 minutes. The researcher was present at place when the subjects were answering the items to answer the questions in case. In the present study, the Pearson correlation coefficient was used for data analysis and the multivariate regression analysis was employed to determine the contribution of predictor variables in anticipation of the criterion variable. The assumptions of multivariate regression analysis approach included normality and linearity of the relationships between variables[10].

RESULTS

The participants consisted of 156 women and 44 men. The average age of women and its standard deviation were as 33.17 years and 8.03, respectively, while the average age of men and its standard deviation were as 34.27 years and 7.97, respectively.

Table 1. Mean, standard deviation, kurtosis and skewness of the research variables

	Mean	Standard deviation	Kurtosis	Skewness
Marital disaffection	6.98	2.57	0.557	-0.652
Marital conflict	6.98	2.57	0.557	-0.652
Secure style	42.89	9.83	-0.207	-0.501
Avoidant style	27.79	7.30	-0.121	0.152
Ambivalent / anxious style	25.50	6.56	0.108	-.0195

Table 1 shows the kurtosis and skewness values for each of the study variables. As can be seen, the skewness and kurtosis values of none of the variables are more than ± 1. This means that the distribution of data for each of the research variables has probably been normal. This suggests that one of the basic assumptions of regression analysis is established.

The use scatterplot matrices (one of the most common methods to evaluate the assumption of linearity of relationships between variables) showed that the variables of this study have created scatterplot two by two, which is oval-shaped. Accordingly, none of the relationships between markers show clear deviation from linearity. This implies the establishment of linearity assumption of relationships between the variables.

Table 2. Hierarchical multivariate regression to predict marital disaffection

Research variables	b	SE	β	R^2	$R^2\Delta$
Stage 1					
Marital Conflict	-0.221	0.027	0.331**		
				0.082*	-
Attachment Styles					
Secure style	-0.293	0.123	-0.175*		
Avoidant style	-0.242	0.152	0.128*		
Ambivalent / anxious style	-0.009	0.086	0.017*		
					0.037*

*P < 0.05; ** p < 0.01

Table 2 shows that in total, the variables of marital conflict and attachment styles explain 11.9% of marital disaffection variance.

DISCUSSION & CONCLUSION

The results of this study demonstrated that marital conflict and avoidant / anxious attachment style positively predict marital disaffection, while secure attachment style negatively predicts marital disaffection. Consistent with the results of this study, Besharat[11] concluded that couples with secure attachment style experience greater interdependence, trust, commitment and satisfaction in their relationships, while the couples with insecure attachment styles experience more problems in their relations. Shaker, Fathi Ashtiani and Mahdavian[12] showed that in worried and denier people with secure attachment styles, there is a significant positive relationship between mental health and marital adjustment. However, in people with anxious attachment style, there is a significant negative correlation between mental health and marital adjustment. People with secure attachment styles always trust their partners. People with secure attachment style are more responsible, and rarely consider an inauspicious future for their relationships. They do not see separating as a stressful process, and this makes them not to fear from their future relations. This mind security leads them to more focus on the present and enjoy the relationships. These people express their love and interest reliably and fully, and less use ambiguous communication models. The people with secure attachment styles are comfortable in establishing intimate relationships; they are willing to get support from others; they have a positive image of themselves, and have positive expectations from others. People with secure attachment style are more responsible, and rarely consider an inauspicious future for their relationships. They do not see separating as a stressful process, and this makes them not to fear from their future relations. This mind security leads them to more focus on the present and enjoy the relationships. Insecure attachment styles, including anxious style, are a product of the experiences of loss or fluctuations in access to the attachment issue[13]. The anxious insecure attachment style is the experience of inconsistent access to attachment. This instability and volatility may reveal itself in mood irregularities and fluctuations. People with insecure attachment show different patterns in their very close and intimate relationships. The anxious people tend to find an obsession with their sex or love partner. They are alert, ready, vigilant and suspicious of their partners and experience a very low communicative satisfaction and a lot of failures and distresses. Avoidant people, compared with secure and anxious ones, have less interest in romantic relationships, especially in relationships requiring long-term commitment. Like anxious people, their very close and intimate relationships are associated with little satisfaction, and in many cases, they break up their relationships. In addition, their relations are distinguished with less intimacy and closeness[14].

Hence, people with avoidant and anxious attachment styles suffer from crisis in their close relations like marital relations, and consequently, experience conflicts in such relationships. Conflicts in the marital relationships, if not addressed and resolved correctly, would lead to discouragement of couples from each other, their distancing and make them to somehow occupy themselves with their own hobbies. Any research has its own limitations. In this study, the cross-sectional design of the study and non-evaluation of other effective factors were among the study limitations. Therefore, it is suggested to repeat this research in the form of longitudinal projects on variables such as socioeconomic status, duration of marriage, number of children, etc.

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Decompression Illness among Fishermen Divers in Tanjung Papuma Beach, Jember Regency, Indonesia

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ABSTRACT

Decompression illness is one of illness experienced by divers describes a condition characterized by a variety of symptoms resulting from exposure to high barometric pressure that cause nitrogen dissolved in body fluids and tissues, to come out of physical solution and form bubbles. The most frequently targeted anatomic locations are the shoulders, elbows, knees, and ankles. Based on bibliography, the determinant factor is multifactor, such as the characteristic of fishermen divers and factors of diving.

This study aims to assess the prevalence of decompression illness among fishermen divers and to investigate the correlation between decompression illness with individual characteristic factors and dive factors. A cross-sectional study was conducted and the respondents were recruited by using a simple random sampling method. Population of this study is 70 people and sample taken is 42 respondents. Technique of collecting data through interview based on questionnaire and examination of the symptoms. To know the level of influence of each risk factor to occurrence of Decompression illness at fishermen diver is conducted with the frequency distribution and crosstab, then analyzewith the test of logistic regression.

Sixteen divers (38,1%) had decompression illness. The result of logistic regression analysis shows that there is significant relation of diving frequency per day (p=0,005), and way to ascent (p=0,010) with the act of decompression illness. The odds of which is 7 times higher in divers who dive more than 3 times per day and 6 times higher in divers who ascent directly to surface. This data could be a foundation for implementing prevention and control measures to reduce decompression illness in the workplace.

Keywords: *Indonesia, Fishermen Divers, Decompression Illness, Individual Characteristics of Divers, Factor of Diving.*

INTRODUCTION

Tanjung Papuma, located in Indian Ocean, is the entrance of fisherman divers who want to dive in Nusa Barung Island, Bandialit Island and some of islands located at those areas with 20 meters depth. Fisherman divers in that location used compressor machine to supply air above the ship and used modified tire compressor that actually not standard equipment to diving.

Compressor divers do not adhere standard procedure, can cause potential risk of harm with the act of accident and diver related disease such as decompression illness, characterized by various symptoms and complaint[1]. Symptoms appear range from minor joint or muscular pain to various neurological disturbances, paralysis, and death[2].

It occurs as a result of the emergence of nitrogen bubbles which is actually dissolved in body fluids and tissues, but trapped in diver body especially in shoulders, elbows, knees and ankles resulting from exposure to differences barometric pressure on land and at sea[3, 4].

Decompression illness incidence at fishermen divers can be known from various symptoms that most occurred within 24 hours after surfacing and a history of diving is necessary to know that[5]. The determinant factors are individual characteristic of divers which are age and working period and dive factors which are dive frequency per week, dive frequency per day and way to ascent to surface[3].

Therefore, success of the program to maintenance of health and safety for fishermen divers cannot reach without consider of those factors[6].

A group of men between the ages of 20 and 60 earn their living by diving using compressor to gather lobster and other marine products on Tanjung Papuma Island. The fishermen divers live in Sumberrejo village, the small village in Jember Regency. They normally start diving when they finish compulsory education and continue to dive until the age of 60 unless they are unable to do so.

Observation held in Sumberrejo village reveal a number of working age men with various symptoms of decompression illness. These various symptoms are consistent with the known effects of decompression illness, suggestion that occupation related morbidity may be frequent among this population and possible common cause of mortality and morbidity.

However, there are no registries of divers, injuries, diseases, or deaths for this minority population. Therefore the purpose of this study is to assess the prevalence of decompression illness among fishermen divers and to investigate the correlation between decompression illness with individual characteristic and dive factors.

MATERIAL AND METHOD

Sampling

Population of this study is 70 people who active dive in latest 6 months and sample taken is 42 respondents. Respondents were recruited by using a simple random sampling method. This was done during repeated visits to each community with the assistance of the village heads and diving boat owners or leaders.

Technical Information

Based on field observations, a series of questionnaire was designed, translated and piloted following a Health and Safety Executive methodology[7]. In this questionnaire, most of the questions were closed and few open.The questionnaire addressed some individual identity information, history of diving, diving practices, and the 25 symptoms of decompression illness[8].

From each diver, a detailed diving history was obtained, including total number of dives per week, total number of dive per day, and how to ascent to surface.

The questionnaire included 25 items that described, using ordinary words, the consequences of neurological dysfunction. For each item, three levels of impairment were proposed: none, mild (without consequences for professional and daily living activities), severe (with consequences for activities). Each item was rated from 0 to 2 according to increasing levels of impairment[7,8].

A decompression illness event was classified as a minor or major DCI event. Minor DCI events were scored (6-25) and major DCI events were scored (26-50) according to addition of each items of 25 signs and symptoms in this questionnaire.

Divers were asked several questions about selected signs and symptoms relative to diving related illness in 24 hours after surfacing.

Statistical Analysis

Independent variables of this study is individual characteristic factors (age and working period) and dive factors (dive frequency per week, dive frequency per day, and how to ascent to surface). The dependent variable of this study is the occurrence of decompression illness.

To know the level of influence of each risk factor to occurrence of decompression illness at fishermen diver it is conducted to univariate analyze with the frequency distribution and crosstab, and analyze the bivariate with the test of logistic regression.

The level of significance considered was 0.05. All analyses were conducted using the Portable SPSS PASW Statistics 18.0.

FINDINGS

Variable	DCI event		P value	Odds ratio
	No DCI(n=26)	Minor DCI(n=16)		
Age (years old)				
⩽29	10 (38,5%)	6 (37,5%)	0,236	
30-39	10 (38,5%)	3 (18,8%)	0,407	0,500
40-49	3 (11,5%)	6 (37,5%)	0,169	3,333
⩾50	3 (11,5%)	1 (6,3%)	0,642	0,556
Working period (years)				
⩽5	8(30,8%)	7 (43,8%)		0,571
>5	18 (69,2%)	9 (56,3%)	0,396	
Dive Frequency per week (times)				
⩽3	16 (61,5%)	7 (43,8%)		2,057
>3	10 (38,5%)	9 (56,3%)	0,264	
Dive Frequency per day (times)				
⩽3	20 (76,9%)	5 (31,3%)		7,333
>3	6 (23,1%)	11 (68,8%)	0,005	
Ascent to surface				
Directly	7 (26,9%)	11 (68,8%)	0,010	5,971
Slowly	19 (73,1%)	5 (31,3%)		

Decompression Illness Event

Of all 42 study individuals, 26 (61,9%) had no DCI and 16 (38,1%) had minor DCI generally understood by the divers refer to clumsiness of arms, leg stiffness, bizarre feelings (paraesthesiae or constrictive feeling) in any part of the body, pain or burning sensation in any part of the body (accompanied by other neurological symptoms or signs), loss of balance and other signs and symptoms.

Using univariate and bivariate analysis, study individuals as well as age, working period of divers, diving frequency per week, diving frequency per day, and way to ascent were associated with decompression illness event.

Age of Divers

Basically there is no strict age limits in terms of health dives. Ideal ages to start or learn dive are 16-35 years old. Whereas, professional divers or workers have an age limit in accordance with the laws or regulations of labor, that is 16-64 years[9].

The number of minor DCI event is higher in diver d"29 years old and 40-49 years old. The number of fishermen divers aged less than 29 years and have decompression, is possible because there are many young divers who ambition to find more hunting results regardless of the depth of the dive.

The number of young divers who have not even been diving for five years are also not equipped with the right knowledge associated with the procedure dives. The young divers who dive only know how to dive from family, friends or former diver.

The diver who suffered decompression is also common in divers aged 40-49 years. This is possible because in that age, physiological ability of a person to do the job also reduced.

But the results of the simple logistic regression analysis showed that the risk factors of age is not significantly affect the incidence of decompression illness with p value> 0.05.

Occupational epidemiology said that in order to know whether the disease suffered by a worker, can develop or transmitted because of individual characteristics. These individual characteristics will affect the frequency of occurrence of disease due to the influence of sensitivity (sensitivity) or resistance to exposure (exposure) such as age, gender, and heredity[10].

Thus, age can affect the immune system of a worker on the incidence of decompression. Increasing a person's age will be correspondingly reduced his endurance, but the research that has been done, ages do not directly affect the incidence of decompression in divers fishermen. There are other risk factors that can directly affect the incidence of decompression.

Working Period of Divers

The diving experience in years was similar in individuals both with and without DCI. There are no differences between the working periods of divers with the occurrence of decompression illness (p value= 0,396).

Working period may determine a person's length of exposure to risk factors, the longer the exposure based on the life of a person will be more likely to get these risk factors.

Longer working period also provide the experience more than a little more, this is because the longer the work is getting a lot of experience and knowledge. So someone with a longer working period will also be more careful in the dive.

Thus the characteristic of the working period in this study has no direct influence on the incidence of decompression illness among fisherman divers.

Diving Frequency per Week

Frequency limits of dives per week can be done by divers in 3 times a week with the details of one day to dive and the next day to rest. It is to give a break to the body of a diver after the dive, and give the body a chance to remove the nitrogen completely.

Besides this, a lot of decompression illness appears within 24 hours after the dive, if dives are carried out the following day, it is feared the decompression symptoms will appear and will aggravate the condition of the body because of not get treatment at all[5].

The number of divers who dive more than 3 times per week due divers want to get lobster as many as they are strong in doing dives. But there are obstacles which also resulted divers do not dive more than 3 times per week that is the magnitude of the waves on that day which resulted in the fishermen divers did not dare to go to sea.

The number of divers experiencing decompression illness due to dives over 3 times in the past week in accordance with the theory that the body needs more rest so that nitrogen can be left out entirely, and the symptoms of decompression may be emerging when they do the dives on the next day. This is certainly aggravates the condition of their body.

But the results of the simple logistic regression analysis, p value > 0,05 which means the frequency of dives per week in this study did not significantly affect the incidence of decompression illness. It is possible that although dives performed more than three times a week, longer rest periods actually performed by the divers, so the nitrogen can be removed entirety and divers can dive the following day without nitrogen remaining.

Symptoms of decompression that mostly appear within 24 hours are also possible tasted a few moments after the dive so the diver rest back and be able to dive the following day without experiencing decompression. Another thing that might happen is not feeling the symptoms of decompression divers as something that it interferes with work, so dive in the next day without rest the body remains to be done within a day.

Diving Frequency per Day

Repeated dives that can be done by divers at a depth of at least 20 meters is three times according to the dive tables. This is to minimize the amount of nitrogen that is trapped in the body in the continuous dives[11].

Minimum dive frequency per day by the fishermen divers in Tanjung Papuma is two times per dives and the maximum is six times per dives. Fishermen divers who dive more than three times because of little lobster in previous location, so that they ascent to surface again and move to another location.

The number of minor DCI event is higher in divers who dive more than three times per day than divers who dive less than three times per day. The results of the simple logistic regression analysis, p value <0,05 which means the frequency of dives per day in this study significantly affect the incidence of decompression illness.

Probability of having DCI also increased 7,333 times in divers who dive more than 3 times per day.

This is consistent with the theory that the more often a person dives again, the more the nitrogen trapped in the body. When divers descend to the seabed and ascent back to the surface and then down again to the bottom of the sea, the nitrogen in the body also did not get a chance to get out entirely.

Way to ascent

There are two ways how to ascent to the surface performed by divers, directly up to the surface and paused at a certain depth. Straight up to the surface is performed by divers directly drawn by the officer on the

boat by pulling the hose divers. The second way is by stopping at a certain depth or a depth of 5 meters each with a long stop about 3 minutes. This way can also be done with a slowly ascent no faster than the smallest air bubbles released by the mouth or nose[9].

The number of minor DCI event is higher in divers who ascent to surface directly than divers who ascent slowly to the surface. There are significant relationship with p value= 0,010. Probability of having DCI also increased 5,971 times in divers who ascent to surface directly.

The number of divers experiencing decompression, due to direct ascent to the surface without giving nitrogen to come out slowly. If a diver ascent to the surface, the pressure in the body is increases and the pressure outside the body is lower than the pressure in the body. This means that the nitrogen bubbles trapped in the body will increase in volume and take a long time to be able to come out slowly. If the diver ascent quickly, the nitrogen bubbles also getting bigger and can hit some parts of the joints and nerves of the body.

CONCLUSION

Repetitive dive is an important parameter in the dives. More often dive, the greater the chance of experiencing decompression illness because more nitrogen trapped in the body. Divers should plan dives include a dive, dive, dive depth, dive time, the frequency of dives per day and rest periods in order to adjust the dive plan appropriately without reducing income as a fisherman divers.

How the diver ascent to the surface affects how quickly the nitrogen may be released outside the body. The faster ascend to the surface, so the body does not get a chance to remove nitrogen overall. Therefore, it is necessary to improve the ability, skills and understanding of the diving procedures in accordance with the operational standards dives.

Conflict of Interest: None

Source of Funding: Self

Ethical Clearance: The study was approved by the institutional Ethical Board of the Public Health, Airlangga University.

All subjects were fully informed about the procedures and objectives of this study and each subject prior to the study signed an informed consent form.

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Usage of Teaching Aids in A Medical College- Students Perceptions

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ABSTRACT

Background: Teaching and learning are active and continuous process 1. Use of teaching aids in medical education technology is swiftly changing from blackboard to virtual simulations and teaching methods range from lectures to integrated teaching. 2 The former encompasses blackboard and chalk with oral demonstrations and verbal dictations, while the latter consists of more modern teaching aids, like overhead projectors (OHPs), PowerPoint (PP) slides, Medical videos and animation clips. The current study was planned to fill the gap and to convey the opinion of students to their teachers.

Method: The present study is a cross sectional study carried out by the Department of Community Medicine, from April 2016 to June 2016 comprising of all the undergraduate students .The study was done by using pre-tested and pre-designed semi structured questionnaire. It contained questions, pertaining to the comparison, benefits and drawbacks of blackboard, PowerPoint, overhead projectors and video animation.

Results: There were 685 undergraduate students studying during the study period. 55 incomplete forms were rejected. Most of the students preferred a combination method over any single teaching aid. It was black board and powerpoint (57%) and black board and animation videos (43%).

Surprisingly in our study the preference of blackboard over other methods was not significantly higher. (53% of the students preferred blackboard and 47% preferred powerpoint.Majority of students preferred bed -side teaching (71%) over video and animation lectures.($p<0.005$).

Conclusion: Due to the changes in the medical curriculum and advancement in technology and the new generation learners, students perception regarding teaching forms an essential part for the teachers to mould their teaching to suit the present. Ideally combination teaching aid will be the most satisfied teaching aid because the inherent deficiency of one aid will be compensated by the other.

Keywords: *Black Board, Power Point, Teaching Aids.*

INTRODUCTION

Teaching and learning are active and continuous process.[1]Teaching is an art of facilitating and supporting learning character in students [3] John Dewey stated once that if we teach today as we taught yesterday, we rob our children of the tomorrow. Technological advancements of this era have revolutionised every field of life. Teaching is no exception.[4,5] Use of teaching aids in medical education technology is swiftly changing from blackboard to virtual simulations and teaching methods range from lectures to integrated teaching.[2]

Different professional institutes differ in their gross structure, teaching aids utilized and their study design.In a complex setting of a medical school it becomes essential to utilize an approach to teaching and learning that is best suited to the needs of the students.

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In India medical colleges and universities are experiencing a significant growth in student enrolment. There are 229 recognized medical colleges in India, with an approximate number of 33,528 medical students graduating annually[5, 6]In our college faculty make the use of both conventional and non-conventional methods. The former encompasses blackboard and chalk with oral demonstrations and verbal dictations, while the latter consists of more modern teaching aids, like overhead projectors (OHPs), PowerPoint (PP) slides, Medical videos and animation clips.The traditional chalk-board methodology provides strong student-teacher interaction, but its effectiveness declines as the number of students in the class increases. Furthermore, maintenance of discipline and pupil attention may get hampered by it.[2]

Microsoft powerpoint is now used and almost replacing chalk board. Text colour,font and size may be modified with ease and the visibility made catchy with contrasting slide backgrounds. Making a good powerpoint slides solely depends upon the faculty.

A mixture of results and conclusions has been drawn from the various studies conducted previously. In most of the studies black board is more acceptable method for learning than the use of powerpoint. A study of this nature was not carried out in our college.

The current study was planned to fill the gap and to convey the opinion of students to their teachers. The feedback was expected to act as a guide to educationalists in developing better, more efficient teaching designs. The study's impacts were foreseen in terms of future decision-making for academic performances by the medical academia.[8]

OBJECTIVES OF STUDY

- To understand the perceptions of medical students about the current methods of teaching aids
- To identify barriers of learning as perceived by the students.

MATERIALS AND METHOD

The present study is a cross sectional study carried out by the Department of Community Medicine, M V J Medical College and Research Hospital. The study was carried out from April 2016 to June 2016. The study population comprised of all the undergraduate students from I year MBBS to III MBBs part II. The study was done by using pre-tested and pre-designed semi structured questionnaire. It contained questions, pertaining to the comparison, benefits and drawbacks of four teaching modalities: blackboard, PowerPoint, overhead projectors and video animation. Irrespective of the teacher and topic, the students were asked to grade teaching aids that were used for teaching.

Data was collected on the various teaching methods used by our college faculty. The consent of the students was taken beforehand. The questionnaire also contained a feedback and suggestions, enquiring the reasons for liking or disliking each modality and suggestions for improvement. The data was collected, compiled and analysed using statistical packages.

Institutional ethical clearance was obtained before the start of the study.

RESULTS

There were 685 undergraduate students studying during the study period. 55 incomplete forms were rejected. Out of the 630 undergraduate students,150 were from first year and, 238 from second year and 242 from third year. There were 421 female students and 264 male students.Forms were distributed to all the undergraduate students. The most commonly encountered teaching modality for students was PP slides, followed by OHPs, blackboard teaching, animation-based lectures and the rest.

Table No 1: Preferences of teaching aids with the various determinants

		Black board(%)	Powerpoint (%)	OHP (%)	Animation/ multimedia (%)
1	Facilitated interaction between students and teacher	54	21	23	2
2	Copy diagrams easily	76	3	21	0
3	Helps in understanding the subjects better	47	43	2	8
4	Stimulates thinking	39	47	12	2

Table No 1: Preferences of teaching aids with the various determinants (Contd.)

	Black board(%)	Powerpoint (%)	OHP (%)	Animation/ multimedia (%)
5 Provides a good learning experience	27	23	21	29
6 Helps cover the entire topic properly	31	57	12	0
7 Keeps the learning session interesting	41	21	25	13
8 Able to cope up with the teaching speed of the teacher	73	11	16	0
9 Helps to grasp the context better	52	45	3	0
10 Stresses on the relevant & imp topic	47	41	3	9
11 Allows revision at the end of the session	28	45	27	0
12 Better visual quality of text and diagrams	21	61	13	5
13 More useful for small groups	87	8	5	0
14 More useful for large groups	17	48	21	14
15 Complex topics can be understood better	18	26	25	31

Table no 1 shows the preference of students for the four commonly used teaching aid used in the college with respect to the various determinants used for theory teaching sessions.

In our study most of the students preferred a combination method over any single teaching aid.It was black board and powerpoint (57%) and black board and animation videos(43%).

Surprisingly in our study the preference of blackboard over other methods was not significantly higher. (53% of the students preferred blackboard and 47% preferred powerpoint)

Peceptions regarding clinical teaching methods.

Majority of students preferred bed –side teaching (71%) over video and animation lectures.($p<0.005$).

Students thought that the use of mannequins was better to learn any practical skill and almost 92% said they would first prefer to practice such skills on a mannequin than on a live patient. The reason cited that practice on a mannequin will instil confidence in them. Videos and animation if shown will help them to retain in their memory for a longer time.

In our study there was no significant difference in the preferences of the teaching aids in theory and clinical teaching among different gender. ($p=0.05$)

The difference was found significantly when compared the first years and the rest among the teaching aids in theory ($p< 0.005$).Majority of the first years preferred blackboard (82%) and the second and final years preferred powerpoint(64%)

For clinical teaching the second years found animation and videos along with bedside teaching as better and the final year preferred bed side teaching over any other teaching aids. The difference was statistically significant ($p<0.005$)

In our study some of the students (15%) suggested that teachers should stimulate and self directed learning should be encouraged by giving some assessments. They felt the present teaching methods is more like teaching in schools. The students and the teachers relation should be like a mentor than like a teacher which is at present. Self directed learning will help them to learn more and develop lateral thinking.

The students felt long monotonous lectures with inappropriate teaching methods and large class room size as the main barriers in learning theory sessions. Whereas in clinical postings lack of space ,less clinical material ,not much practice to develop clinical skills were identified as barriers in learning clinical skills.

DISCUSSION

Our study had a slightly higher representation of females (61.4%) as compared to males which was similar to the study conducted by Papanna et al [7]with 56.6% and in another study conducted by Carpenter JM et al[8] female representation was 82%.The reason for this difference in our study was because the proportion

of female students gaining admission at our institution is higher when compared to males.

It was surprising to find that black board and powerpoint in combination was the most preferred teaching aid in our study, these findings were different from the findings of the study conducted by K Papanna et al[6,7] where black board was most preferred. It was similar to the study conducted by Lalit Mohan et al[9] and Priyadarshini et al[10]which found that both the methods were almost equally preferred thought mix of aids were the most preferred. Whereas, the Pakistan study conducted by Atif Mahmood et al [11]found that PPT was the most preferred aid .The preference for black board in our study was higher in first years than the final years. And there was no gender difference in preference of teaching aids unlike some studies did show the a difference in the preferences between boys and girls.

Majority of students preferred Bed Side teaching, for the reasons that it was the most efficient way for them to develop clinical and communication skills, learn bedside procedure and correlate better with the knowledge acquired during classrooms. They also voiced their preference for mannequins during clinics as it increases their confidence; helps gain more practical experience and practicing those skills. They also wanted to practice on mannequins before handling live patients. The students also suggested video lectures as another method which could be included as part of teaching methods The second year students specially preferred video lectures first as they were comfortable learning and seeing it. However, the cost, infrastructure required for a video lectures and development a full fledged skill lab for such a huge number of students and teaching the skill to each students, individually could be some of the constrains for the institutes.

Some reports have shown that students' inactivity in traditional teacher-centered classes would make them bored and exhausted that consequently would decrease their concentration and learning and finally would result in their absence from the classroom[11] Students also mentioned that many teachers just mention what is there in the standard textbooks which they felt can be learned by reading the textbook on their own.So the reason from staying away from classrooms.

CONCLUSIONS

Due to the changes in the medical curriculum and advancement in technology and the new generation learners, students perception regarding teaching forms an essential part for the teachers to mould their teaching to suit the present. Ideally combination teaching aid will be the most satisfied teaching aid because the inherent deficiency of one aid will be compensated by the other.

The classes could be made more interesting and interactive by giving Multiple Choice Questions related to the topic at the beginning or giving clinical scenarios. Teachers should be encouraged to use more than one teaching aid during teaching sessions. The teaching methods such as PBL, video lectures and Mannequins should be used in combination for effective teaching. Complex concepts can be best explained with videos and animation .It also helps to retain the facts better.Orientation classes to students fresh to clinics could help the students in understanding the bedside clinics better and the other barriers identified by the students needs to be addressed.

Teachers should make use of the teaching aid as a aid and use it judiciously to increase the understanding of the subject and thus improving their academic performance as whole.

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Orthopedic Treatment Results of Fully Edentulous Patients by Overdenture Supported by Endoosseous Implants and Complete Dentures (Comparative Study)

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ABSTRACT

When it comes to fully edentulous, the disadvantages of complete dentures are well known, especially in the lower jaw: poor fixation and rapid damage. In recent years, there are endoosseous implants used as reinforcing supports for complete dentures. Therefore, clinical status indicators of 106 complete dentures and 42 ones with improved fixation on endoosseous implants for a period of 7 years were compared to determine their quality and impact on stoma.

It is shown that overdenture with implants under fully edentulous superior to traditional complete dentures for durability and quality indicators. Dentures functional efficiency decline depends on denture base atrophy, false teeth abrasion, denture breakage. Mucositis and periimplantitis development leads to the removal of no more than 10.0% of implants at the end of seven years of observation.

Keywords: *Dental Implant,Denture Treatment, Implant Quality,Overdenture.*

INTRODUCTION

Fully edentulous has a negative impact not only on physical health[10,11], but also on social life by creating conditions of isolation and uncertainty[12,13]. Modern implants are expensive; therefore, the choice of the highest quality for the patient is the original objective[14].

The untimely treatment of fully edentulous can cause atrophy of the jaw[15,16] that leads to dental arch disappearance[17,18], partial atrophy of the basal areas of jaws[19] that, in turn, causes significant anatomical changes in stoma and maxillofacial area.

At the same time with the active use of dental implantation, comparative studies of clinical efficacy of traditional tooth supported or mucosa supported dentures and dentures with dental implants that replace identical arch defects remain relevant[1,2,3]. This fully applies to such dental prosthesesas complete dentures and overdenture with bar fixation to endoosseous implants[4,5,6], because the fully edentulous has being found more often in orthopaedist practice[7,8].

Thus, the purpose of the study is to compare clinical effectiveness of overdenture supported by endoosseous implants complete dentures in dynamics over 7 years.

MATERIALS AND METHOD

During 7 years, we conducted an annual survey of dental indicators and dental protheses quality in 83 patients with complete dentures (106) and in 42 patients with overdentures with bar fixation on 4 implants (42). Among the patients with complete dentures – 42.2% men and 57.8% women (among patients with dentures supported by implants – 61.9% and 38.1%).In 10.8% of patients with complete dentures, the age was 40-49, 50-59 years – 33.7%, 60 years and older – 55.4% (among patients with dentures supported by implants: 30-39 years – 4.9%, 40-49 years – 19.0%, 50-59 years – 57.1%, 60 years and older – 19.0%). Complete denture localization in the superior jaw was in 38.6% of patients, inthe lower jaw – 33.7%, in both jaws – 27.7% (among patients with dentures supported by implants – 33.3%,

66.7 % and 0.0% respectively). Denture base atrophy occurs in 39.8% and 60.2% of patients with complete dentures in medium and significant degree respectively (66.7% and 33.3% in patients with dentures supported by implants) (Figures 1, 2).

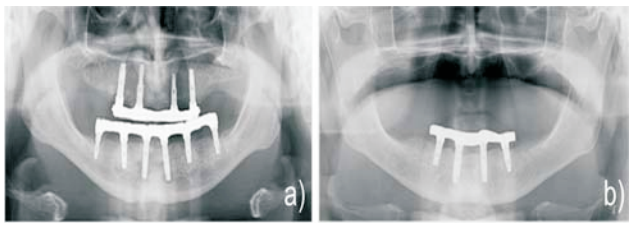


Fig. 1. Dental X-ray of patients with overdentures supported by implants: a - superior jaw, b - lower jaw.



Fig. 2. Overdentures with bar fixation to endoosseous implants

During the observation, patients took a professional oral hygiene 1-2 times a year, as well as occlusal denture correction and fixation.

The criteria for denture treatment efficiency were 38 indicators in assessing the state of dentures and subjacent tissues, in particular, the frequency of use (permanent, sometimes for aesthetic look, sometimes for chewing), poor fixation, inequality to denture base, breaking dentures, inflammation in peri-implant gingival tissue, the need in denture to be remade or replaced.

RESULTS

The average term for adaptation to complete dentures was 26,3 ± 1,8 days. The poor fixation begins to manifest itself in 1 year (6 dentures; 5.7%); after 7 years it reached of 100.0% of the remaining dentures (Figure 3). In the same way, as the service life increased the degree of denture base atrophy grew: 1 year – 2 dentures found (1.9%), after 7 years – 5 dentures (100.0%). Mucosa injury was detected after 1 year of use (5 dentures; 4.7%), it increased to 20.0% after 7 years (1 denture). Dry mouth mucosal burns were observed under a year of denture loading (4 and 2 dentures respectively, 3.8% and 1.8%), within 7 years, these phenomena were observed in one denture (20.0%). Hypaeremia of denture base was 4.7% (5 dentures) after a year of observation and reached 40.0% (2 dentures) in 7 years. Hypertrophy of denture base was detected after 3 years of use (1 denture, 1.0%) and increased to 20.0% in 7 years (1 denture). There were quite often encountered breakages of dentures in the form of cracks, fractures and splits of denture bases and false teeth fractures (often in combination). In a year, one denture was broken (0.9%), in 7 – 2 dentures (40.0%). Relocation of complete dentures due to atrophy of denture base began from the first year (3 dentures, 2.8%); after 6 years it was 14.3% (2 dentures). After a year of use, only onedenture was mended (0.9%), 20.0% – after 7 years (1 denture). False teeth abrasion grow rapidly from 2.8% (3 dentures) after 2 years of observation up to 100.0% (5 dentures) – in seven. The recession of the lower third of the face and TMJ disease manifestations were detected after two years in one denture (0.9%), respectively, after 7 years – in 80.0% and 40.0% (4 and 2 dentures). We often recorded poor hygiene of complete dentures – 24.5% of dentures in a year (26 dentures), 60.0% in 7 years (3 dentures). In this regard, and in connection with GI tract disorders, the bad breath was in 11.3% of patients (12 dentures) in a year of observation, in 40.0% (2 dentures) – in 7 years. Constant use of complete dentures is common to 69.1% of dentures (Teeth fightings present a normal state for any self-respecting sabretooth homo sapiens, particularly while staving off hunger...strong and lasting hunger) on average in a year of observation (from 91.5% under control in a year, to 20.0% - in 7 years). The rest 9.7% of complete dentures on average in a year (1.9%, 2 dentures after the first year, 1 denture in 7 years). The remaining 12.8% of dentures on average in a year we used more to create aesthetic look, and 12.6% - for chewing. Hence, in 7 years of using complete dentures, 95.3% of them had to be replaced due to some or other disadvantages. Sufficient functional quality remained only in 4.7% of dentures. This need raised at the 3 year.

In comparison with complete dentures, the term for adaptation to ones supported by implants is significantly shorter (average adaptation period 18,8 ± 1,2 days). Poor fixation was determined in 2 dentures after 2 years of use (4.8%), it reached 83.3% after 7 years (10 dentures), which is also less in comparison with complete dentures. In this case, denture base atrophy is less compared to complete dentures: 2 years – 9.6% (4 dentures), after 7 years – 91.7% (11 dentures). Mucosa injury was found in three times less than that of complete dentures. The similar situation with dry mouth: 2 years – 4.8% (2 dentures), after 7 years – 16.7% (2 dentures). There were no mucosal burns found. Hypaeremia and hypertrophy of denture base were rare. Overdentures supported by implants had damages rarely: from 2,4% in 3 years, up to 8.3% in 7 years. Relocation of overdentures supported by implants due to the atrophy of denture base began from the second 2 year (1 denture, 2.4%), it covered 6.3% (1 denture) after 7 years of use (less than in case of complete dentures). Denture mending started after 4 years of use – 1 denture (2.4%), after 7 years – 1 denture (8.3%) (much less than in case of complete dentures). False teeth abrasion rate is high, but still less in comparison with complete dentures: 9.6% (4 dentures) after 2 years observation up to 100.0% (12 dentures) – in 7 years. The recession of the lower third of the face after 2 years was found in 1 denture (2.4%) and increased to 33.3% (4 dentures) over 7 years, which is almost one and a half times less in comparison with complete dentures. TMJ manifestations are rare. Periimplantitis aggravation was only once detected at the last year of observation (8.3%), inveterate periimplantitis in the form of peri-implant recess began to appear at the 3 year of use (1 denture, 2.4%) and increased to 16.7% (2 dentures) in 7 years. In the end of observation, implant mobility occurred under 2 dentures (8.3%). Gum retractions have emerged in one denture after 3 years of use (2.4%) and in 2 dentures (12.6%) after 7 years. Chronic gum inflammation (mucositis) increased from 2.4% (1 denture) to 16.7% (2 dentures) in terms from 2 to 7 years. Seven dentures had a lack of hygiene (16.9%) over a year, 7 denturesmore (58.3%) in 7 years (these indicators are close to the case of complete dentures). Bad breath was observed in 9.5% of patients (4 dentures) after a year of observation, in 33.3% (4 dentures) – in 7 years. There were no implant fractures. The supported implant removal occurred after 6 years of use (5.0%, 1 denture); 2 dentures (16.7%) after 7 years. There were 12 implants removed (8.1% of the set). Constant use dentures supported by implants is characteristic for 97.5% of denture cases on average in a year of observation (from 100.0% in a year to 87.5% up to 7 years), which is much better in comparison with the case of complete dentures. Only 2 dentures were used in the last 2 years mostly to create aesthetic look. As a result of 7 years of dentures use supported by implants, 64.3% of them had to be replaced because of certain disadvantages (27 dentures) and 7.2% (3 dentures) required design change because of the implant was removed. The 28.5% of dentures had sufficient functional quality.

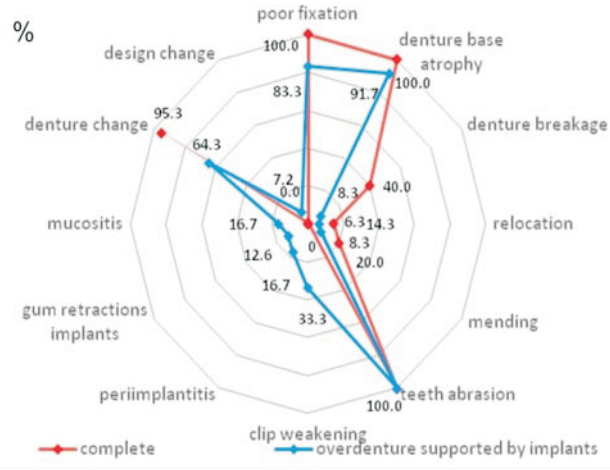


Fig. 3. Main disadvantages causing changing and removal of complete dentures and overdentures supported by implants after 7 years.

DISCUSSION

Tooth loss causes significant problems instoma and can also cause depression and feelings of inadequacy.

In choosing the implant, the patient drew his of her attention to implant durability, which is due to its high cost[20].

In addition to overdentures, there are also used fixed dentures "bridges" for fully edentulous treatment. However, they have a big disadvantage – forced remote ejection (The translator suggests it is "removal", however, she has no right to have a finger in author's pie dedicated to fantastic life of dentures as human beings in their design, fights and death. Therefore, the forced remote ejection remains for you not to miss the point) of retainer teeth in 70% of cases.

However, the contraindications for dental implantation should also be noted[9]:

- Osteoporosis and osteodystrophy;
- Insulin dependent DM;
- Hematopoietic system disease;
- Poor oral hygiene;
- Pathological dental occlusion;
- Inflammatory processes in the area of planned implantation.

Therefore, it is necessary to undergo assessment before implantation, in particular of stoma and TMJ.

CONCLUSION

Implant cleaning and regular check-ups at the dentist play major role in maintaining the implant quality. Poor cleaning leads not only to denture damage, but also can provide physical damage of stoma.

This study allows us to conclude overdentures supported by dental implants superior complete dentures in terms of allindicators. The main reasons for denture functional efficiency decline are denture base atrophy, false teeth abrasion, denture breakage. Mucositis and periimplantitis development leads to the removal of no more than 10.0% of implants at the end of seven years of observation.

Conflict of Interest: There is no conflict of interest between authors.

Source of Funding: There is no source of funding.

Ethical Clearanc: All procedures were made in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5).

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The Effect of Gymnastic Exercises on Motor Skills in Autistic Children

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ABSTRACT

The aim of the present study was to evaluate the effect of 16 week of gymnastic exercises on motor and skills of children with autism. The statistical population consisted of autistic children in a charity centre in Karaj. Thirty autistic children 8-12 years of age, who were eligible to be included in the study, were randomly selected and assigned to two test and control groups. To evaluate motor development the short form of Bruininks-Oseretski test. The test group carried out gymnastic exercises for 16 weeks (3 sessions a week, with each session lasting for 45 minutes); the control group subjects were engaged in their daily activities during the period. One-way ANOVA was used to compare the two groups. There was a significant difference in the total motor skill scores between the two groups ($P<0.05$); however, there were no significant differences between the two groups in subscales such as the speed of running and agility, strength and the speed of reaction/response between the two groups ($P>0.05$). It can be concluded from the results of the present study that gymnastic exercises might have an effective role in improving motor skills of children with autism.

Keywords: *Autism, Gymnastic, Motor Skills.*

INTRODUCTION

Autism as a general term comprises as spectrum of developmental disorder, affecting different aspects of psychological, neurological, gross and fine motor skills, communication skills and attention. Asperger syndrome or autism disorder with high function is at the extreme end of the spectrum[1-2].

The prevalence of autism spectrum disorders has increased all over the world. Studies in 1960 reported a prevalence rate of 4 in 10,000 for the autismspectrum disorders; however, the American National Institute of Mental Health estimated a prevalence rate of 1:88 in 2012 [3].

Several studies have reported problems with attention, executive functions and learning in autistic children [4].

Izawaet al. (2012) found in their study that autistic individuals were motivated by impairment of motor skills, and concluded that their mimic defects caused learning disabilities to be impaired [5].

Studies have reported at least 3 anomalies as basic defects in motor disorders of autistic subjects: a defect in gross motor skills, a defect in fine motor skills and, a defect inbalance functions[6-8].

In a study by Pitetti et al, 50 70% of autistic children exhibited a clear delay in basic motor skills[9]. In a study by Green et al (200), a prevalence rate of 79% was reported for motor disturbances in these children[10]. In addition, Ozonoff et al (2009) evaluated gross motor skills in children with autism and reported a delay in the maturation of such skills in these children [10]. In addition, Reid and Staples(2010) evaluated autistic children with TGMD-2 test and reported defects and delays in motor skills in autistic children compared to healthy subjects [11]. Coordination defects in autistic children consisted of disturbances in programming of movement, executive of two-step skills and control of

moment [12]. Lang et al (2010) evaluated autistic children with high function and reported low motor skills in these children [13].

Since sports activities have been useful in paving the way for the development of motor and cognitive skills in healthy children, hope in and attention to the useful role of sports activities and bodily activities have increased in order to decrease behavioral and motor disturbances in recent years.

A defect in motor control and behavior inhibition might be attributed to a high level of excitation and abnormal responses of these children to sensory stimuli that decrease the executive levels and the ability for executive functions[13].

Several studies have shown the effect of sports activities on improving autism spectrum disorders, especially motor disturbances[14], behavioral problems [15], and improvements in communication skills [16]. However, some studies, have shown that bodily activities and exercises have had no effects on improving motor skills in children [17].

Considering discrepancies in the results of previous studies and an increase in the number of patients with autism in the community, the present study was undertaken to evaluate the effect of gymnastic exercise for 16 weeks on motor skill development in children with autism.

MATERIALS AND METHOD

In the present descriptive/analytical study, 30 children with autism spectrum disorders, who were eligible based on inclusion criteria, were randomly selected from autistic children in a charity organization in Karaj, Iran.

Inclusion criteria

Inclusion criteria consisted of autism with high function, an age range of 8 12 years,parental consent from, IQe"70, and absence of any motor and physical inabilities.

In order to determine the severity and the level of function of autistic children, High-function Autism Spectrum Screening Questionnaire (ASSQ) was used. The validity and reliability of the Persian version of this questionnaire were confirmed in 2011 by Kasechi et al.,[18]. Cronbach's á-coefficient of this questionnaire was estimated at (r=0.64(, indicating its reliability at an acceptable level. In this study, children who gained scores >22 were considered high-function autistic children.

Determination of motor skill development

Development of children's motor skills was determined with the use of the short form of BOTMP-2 scale, which measures the development of motor skills in children 4 14 years of age and consists of 8 subtests with 14 items. Four subtests determine gross motor skills (the speed of running and agility, balance, bilateral coordination and strength), 3 subtests determine fine motor skills (the speed of reaction/response, visual-motor control and the speed and agility of the upper limb) and one subtest determines both motor skills and coordination of the upper limb [19]. The reliability coefficient of the retest of the short form of this questionnaire has been estimated at 86% [20].

PROCEDURE

After explaining the aim of the study and gaining informed consent forms, 30 children who were eligible based on inclusion criteria were included in the pre-test. The demographic data of the subjects and their consent forms were carefully examined before being included in the pre-test. The parents were reassured about the confidential nature of the demographic data and they were informed that they were able to leave the study at any stage they wanted to.The Bruininks-Oseretski pre-test was carried out and the results were recorded. After 16 weeks in the post-test, the children were re-evaluated with the same test.

Exercises

After the pre-test, the subjects in the experimental group carried out preliminary and basic gymnastic exercises in 48 sessions (3 sessions each week) for 16 weeks. Each session consisted of 10 minutes of warm-up exercises, 25 minutes of basic gymnastic exercises, and 10 minutes of cooling down. During this period, the control group subjects were engaged in their routine daily activities.

Statistical analysis

SPSS 18 was used in the present study to analyze descriptive data with descriptive statistical parameters, consisting of means and percentages. After evaluation of normality of data, one-way ANOVA was used for the analysis of hypotheses at a significance level of ($P<0.05$).

RESULTS

Table 1 presents the demographic data based on the personal data recorded in the test and control groups. Comparison of data showed no significant differences in demographic variables between the two groups (P>0.05).

Table 1. Demographic data in the two study groups

Group	Gender	Age (year)	Weight (kg)	Height (cm)
Test	8 boys/7 girls	8/40	29/51	130/97
Control	9 boys/6 girls	8/12	31/22	131/41

Since the pre-test did not reveal any significant differences between the two groups (P>0.05), only the results of post-test in the two groups were analysed statistically. Based on the results presented in Table 2, although the differences between the two groups in the total Bruininks-Oseretski scores were significant statistically, there were no significant differences in the subscales of the speed of running and agility, strength and speed of reaction/response between the two groups. Based on the data presented in Table 2, the subjects in the test group achieved significantly higher scores in the subscales of balance, bilateral cooperation, visual control of movement and speed, the agility and coordination of the upper extremity, compared to the control group.

Table 2. The results of statistical analyses of subscales of motor development

Variable	Test group mean score (SD)	Control group mean score (SD)	P	F
Bilateral coordination	6.40(4.2)	2.19(2.1)	0.001m	1.951
Balance	8.11(2.3)	5.02(1.5)	0.002m	2.342
Speed of running and agility	3.53(2.2)	3.10(0.6)	0.076	3.924
Strength	4.70 4(0.7)	4.63(2.0)	0. 121	1.082
Speed of reaction/response	21.0(5.3)	20.80(3.9)	0.016	8.560
Speed and agility of the upper limb	6.58(1.4)	4.11(0.2)	0.008m	11.019

DISCUSSION

Children with extensive developmental disturbances of autism have many problems in psychological characteristics and motor skills. The main aim of the present study was to evaluate neuropsychological and motor characteristics of children with autism after 16 weeks of gymnastic exercises.

The results of Bruininks-Oseretski test showed that the total scores of motor skills of autistic children were much lower than the standard norms. Since autistic children have cerebral deficiencies, these deficiencies exert negative effects on their motor functions, resulting in motor deficiencies. Reid and Staples (2010) [11], and Green et al (2009) [10], reported that motor skills in children with autism are much lower than those in their healthy and normal peers.

Based on the results of Bruininks-Oseretski in the present study, the total scores of motor skills of the experimental group were significantly higher than those of the control group, consistent with the results of studies by Fergusson et al (2010) [15], Pitetti et al (2007) [9],Fragla Pinkham et al (2008) [21], and Rafie et al (2016) [14]. Based on the reports of the researchers above and the results of the present study, it might be concluded that exercises and bodily activities result in the development and promotion of motor functions of these children. In other words, gymnastic exercises resulted in proper development of movement, control and coordination skills of children with autism, improving them.

However, subtests for the speed of running and agility and the speed of reaction/response did not reveal any significant differences between the two groups, and the bodily exercises used in the present study were

unable to affect these skills in the subjects in the experimental group. The results of the present study were consistent with those of studies by Rafie et al (2016) [14], Hameury (2010) [22], and Lochbaum (2003) [23], and contrary to the results of a study by Yilmaz et al (2004) [24]. To explain these results it might be pointed out that autistic children require longer times for execution of speedy tasks due to defects in motor processing, and due to defects in active memory they cannot retain data in their memory for designing and predicting exercises. Therefore, they face difficulties in time-dependent behaviors and execution of two-step and simultaneous tasks that require a rapid reaction and motor programming.

In addition, the results showed no significant differences in the mean scores of strength between the test and control groups. Since autistic children have poor muscular tonicity and muscular contraction [24], gymnastic exercises were unable to increase their muscular strength and tonicity, consistent with the results of a study by Fraglapinkham (2008) [21], who showed that exercise was unable to change strength and flexibility; however, these results are different from those reported by Yilmaz et al (2004) [24], and Rafie et al (2016) [14]. Such a discrepancy might be attributed to the age of the subjects, the number of exercise sessions and the nature and type of the exercises used.

Gymnastic exercises resulted in an increase in balance, flexibility and body control through various movements such as running, jumping and balance movements.

CONCLUSION

The results of this study showed that gymnastics exercises can engage various organs of the body and different aspects of motor activities, resulting in the necessary coordination between neurons and muscles, with a subsequent increase in fine motor, gross motor skills and balance functions in autistic children.

Conflict of Interests: The authors declare no conflict of interests.

Ethical Clearance: The consent forms were included before being in the pre-test by parents. The parents were reassured about the confidential nature of the demographic data and they were informed that they were able to leave the study at any stage they wanted to.

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A Study of Psycho-social Factors Associated with Nocturnal Enuresis in Children Between 6-10 Years of Age & Factors Affecting the Outcome of Behaviour Therapy

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ABSTRACT

Objective: To study the psycho-social factors associated with nocturnal enuresis in 6-10 years old children & factors affecting the outcome of behaviour therapy.

Method: Prospective interventional study. Fifty cases (6-10 years old) of either primary or secondary nocturnal enuresis were enrolled between April 2014 to March 2014 from OPD of Santosh Medical College and Hospital, Ghaziabad, U.P. A detailed history was elicited Urine examination and USG abdomen were done. Behaviour therapy was given as per the protocol. Primary and secondary nocturnal enuresis patients were compared with reference to psychosocial characteristics. Effect of various characteristics on treatment outcome was analysed.

Result: Male: female ratio was 1.27:1. Common associated symptoms were daytime enuresis (64%), infrequent voiding (54%) and urgency (48%). 12(24%) out of 50 children had a positive family history in either parent. Bruxism and nail biting were most commonly (13.15% each). associated with primary NE, while nail biting was most commonly associated with secondary NE (33.33%). 30% of children were having poor scholastic performance. 14(28%) out of 50 children had history of marital discord in their parents. USG abnormalities in urinary bladder were significantly higher in secondary NE (66.7%) as compared to Primary NE (15.7%). USG abnormalities of bladder were also associated with significantly lower response rate (50% with USG abnormalities vs 77.76% with normal USG).

Conclusion: Various psychological factors affect outcome of behavior therapy in PNE and SNE

Keywords: *PrimaryNocturnal Enuresis, Secondary Nocturnal Enuresis Psychosocial Factors, Behaviour Therapy.*

INTRODUCTION

Nocturnal enuresis is an important developmental problem for school age children and it can cause emotional and social problems for the child as well as family[1].In a questionnaire it was ranked 3rd amongst causes of psychological distress in children. [2]

According to American Psychiatry Association and in a review on "Current Concept on Nocturnal Enuresis", nocturnal enuresis is the involuntary loss of urine at night in absence of physical disease at an age when a child could reasonably be expected to be dry (by consensus at a developmental age of 5 years).[3, 4]It has also been defined as repeated voiding of urine into clothes on bed at least twice a week for at least 3 consecutive months in a child who is at least 5 years of age [5] Children who has never achieved consistent night time dryness are labelled to be suffering from Primary nocturnal enuresis (PNE).Secondary nocturnal enuresis (SNE) refers to passage of urine during sleep by a child who has previously been dry for at least 6 months. Prevalence of enuresis at 5 years of age is 20%. It decrease to 5% by age of 10 years. Over 15 years, prevalence is 1-2%. Boys account for 60% of cases of nocturnal enuresis. However beyond 11 years the occurrence is higher in girls than boys.[6]

The etiology of Nocturnal Enuresis is diverse. Age of 2to 5 years is a sensitive time for development of nocturnal bladder control and anxiety producing episodes during this period can affect the bladder control. Most bedwetting children are simply delayed in developing the ability to stay dry and have no other developmental issues.The body normally increases ADH levels at night, signaling the kidneys to produce less urine. This diurnal change may not be seen until about age 10.[7] A recent study, however, showed that enuretic children were harder to wake up.[8]Psychosocial issues (e.g., moving to a new town, parent conflict or divorce, arrival of a new baby, or loss of a loved one or pet, death in the family, sexual abuse, extreme bullying, hospitalization) are established as a cause of *secondary* nocturnal enuresis.[9]Urinary tract infection, attention deficit hyperactivity disorder (ADHD), constipation, caffeine, food allergies and improper toilet training, etc. are the various other factors associated with nocturnal enuresis[10].

Behavioral Therapyis a reasonable first-line approach. Guilt is initially allayed and positive reinforcement is initiated by setting up a diary or chart to monitor progress and establishing a system to reward the child for each night that he or she is dry.[5]Conditioning therapy includes using an enuresis alarm system and having the child practice imagery of awakening to urinate in the toilet or staying dry all night.The cure rate with alarm system may be as high as 70% long-term. Pharmacotherapy with imipramine and DDAVP have been evaluated in the treatment of MNE; oxybutynin is used primarily in polysymptomatic enuresis. [5]

This study was planned to assess the psychological factors associated with primary and secondary nocturnal enuresis in 6-10 years of age group, effectiveness of behavior therapy and factors affecting the response to behavior therapy

MATERIAL AND METHOD

ThisProspective interventional study was done in urban Children of age group of 6-10 years of both sex presenting at the pediatric Out Patient Department (OPD) of Santosh Medical College and Hospital, Ghaziabad, U.P between April 2014 to March 2014(12 months).*Total* 50 cases of either primary or secondary nocturnal enuresis during study period were enrolled. DSM IV criteria are used to define children with NE. children with history of Previous treatment for more than 4 week, Degenerative progressive neurological disease, Mentalretardation, Slow learners and learning disability, Any structural or functional urinary abnormalities, Diabetes Mellitus or Diabetes Insipidus, Patients exhibiting incontinence during the day were excluded.

This study was approved by the institutional review board. Consent was taken from the parents before recruitment. A detailed history was elicited covering the onset of complaints, other urinary complaints, family history, toilet training, psychological history in them with reference to scholastic performance, any parental conflicts, marital discord, arrival of new baby and any adjustment problems at home.

Mid stream morning sample was collected and examinedwithin 30 minutes for proteinuria, glucosuria and infection. If the child was found to have evidence of UTI appropriate management was administered, and then the child was recruited for the study.Ultrasoundabdomen for Bladder Volume and Bladder Capacity was done. (normal capacity would be given by the formula- [Age x year + 2] x 30).

Behavior therapy was given as per the following protocol:[11]

1) Fluid restriction: It was advised to withhold fluids intake (water, milk, cold drink etc) of child for atleast 2 hours before going to bed.

2) Star charting: - The dry nights of the child were noted and rewarded. The rewards ranged from stars on the charts in the child's room or in a family room, to pocket money or time earned for a preferred activity such as gaming depending on the parents.

3) Lifting and waking: - Involves taking the child to bathroom at night for passing urine. Waking was described as waking the child from their sleep. Lifting was described as lifting the child from their bed, without necessarily waking the child.

4) Bladder retention exercises: -The child was asked to hold his urine whenever he has desire to micturate. Initially the bladder holding was for 5 min which was gradually increased to 45 min.

5) Counseling:- If any associated psychosocial factors were found to be present, the child and family were counselled.

Patients were followed up monthly till a period of 6 months or till cured, whichever earlier.The child having achieved 14 continuous dry nights during a month was considered as cured. Appropriate statistical analysis was done using SPSS 22 Trial Version. P value less than 0.o5 was considered to be statistically significant.

OBSERVATION AND RESULTS

Table 1: Factors associated with Primary and Secondary Nocturnal Enuresis in the study group.

CharactersticsTotal(n=50)	Primary NE (n=38)(76%)	Secondary NE (n=12)(24%)	Significance
1. Sex Characteristics			
Male (28)	17(44.74%)	11 (91.67%)	<0.05
Female (22)	21 (55.26%)	1 (8.33%)	
Male : Female	0.80:1	11:1	
2. Associated Symptoms			
Day time symptoms (32)	26 (68.4%)	6 (50%)	> 0.05
Infrequent voiding (27)	19 (50%)	8 (66.67%)	> 0.05
Burning micturition (0)	0	0	NA
Urgency (24)	21 (55.26%)	3 (25%)	<0.05
Pain abdomen (6)	4 (10.52%)	2 (16.67%)	> 0.05
Vomiting (0)	0	0	NA
Encopresis (7)	6 (15.79%)	1 (8.33%)	<0.05
3. Behavioural Symptoms			
Bruxism (6)	5 (13.15%)	1 (8.33%)	<0.05
Nail biting (9)	5 (13.15%)	4 (33.33%)	< 0.05
Thumb Sucking (0)	0	0	NA
Speech Defects (6)	4 (10.52%)	2 (16.67%)	> 0.05
Total (21)	14 (36.85%)	7 (58.33%)	> 0.05
4. Psychosocial Factors			
Marital Discord (14)(28%)	14 (36.84%)	0	<0.05
Arrival of Baby (15)	5 (13.15%)	10 (83.33%)	<0.05
School Performance			
Excellent (4)	3 (7.89%)	1 (8.33%)	> 0.05
Good (25)	18 (47.36%)	7 (58.33%)	> 0.05
Average (6)	4 (10.52%)	2 (16.67%)	> 0.05
Poor (15)	13 (34.21%)	2 (16.67%)	<0.05
5. History of Enuresis in Parents			
Mother (5)	4 (10.52%)	1 (8.33%)	> 0.05
Father (3)	3 (7.89%)	0	<0.05
Both (4)	4 (10.52%)	0	<0.05
Total (12) (24%)	11 (28.94%)	1(8.33%)	<0.05
6. USG Anamolies			
Bladder Capacity Low (1)	1 (2.63%)	0	> 0.05
Bladder Volume Low (2)	0	2 (16.67%)	>0.05
Bladder Retention Capacity Low (8)	4 (10.52%)	4 (33.33%)	<0.05
Bladder Retention Volume Low (3)	1 (2.63%)	2 (16.67%)	<0.05
Total (14)(28%)	6 (15.79%)	8 (66.67%)	<0.05

Table 2: Factors affecting outcomes of behaviour therapy.

	Months Taken To Recover						Recovery (35)(70%)	Mean (months)
	2 Mo (5)	3 Mo (13)	4 Mo (12)	5 Mo (3)	6 Mo (2)	No Recovery (15)		
1. Age Group (years)								
6 – 8 (n=21)	4	5	4	1	1	6	15 (71.43%)	3.3 (±1.76)
8 – 10 (n=29)	1	8	8	2	1	9	20 (68.97%)	3.7 (±0.92)
2. Sex								
Male (n=28)	2	9	7	2	0	8	20 (71.43%)	3.53 (±0.77)
Female (n=22)	3	4	5	1	2	7	15 (68.18%)	3.79 (±1.25)
3. Type of Enuresis								
Primary (n=38)	3	11	10	1	2	11	27 (71.05%)	3.56 (±1.01)
Secondary (n=12)	2	2	2	2	0	4	8 (66.67%)	3.5 (±1.12)
4. Parents' attitude of Anger/Punishment/Rejection								
Yes (n=20)	2	5	5	1	1	6	14 (70.00%)	3.57 (±1.09)
No (n=30)	3	8	7	2	1	9	21 (70.00%)	3.52 (±1.03)
5. USG Findings								
AbnormalFindings(14)	2	3	2	0	0	7	7 (50.00%)	3.0 (±.82)
Normal Findings(36)	3	10	10	3	2	8	28(77.76%)	3.74 (±1.02)

DISCUSSION

The present was the study of psychosocial factors in nocturnal enuresis in children between 6-10 years of age group,response to behavior therapy & factors affecting treatment outcomes.

In the study group the male: female ratio was 1.27:1. These findings are in accordance with other studies, e.g., in Turkey[12] and Iran[13], but opposite to the findings from a study conducted in Aden (Yemen).[14] However, no clear explanation is available for this trend in our population.

Common associated symptoms were daytime enuresis (64%), infrequent voiding (54%) and urgency (48%). Significant difference was seen between PNE and SNE groups was found for encopresis and urgency ($p<0.05$).In a Spanish study in 1996 the authors tried to compare the characteristics between primary and secondary NE and found no significant differences in associated symptomatology. [15]

24% had a positive family history of NE in either parent. The difference ina positive family history between PNE and SNE was clinically significant ($p<0.05\%$). Studies by von Gontrad et al[16] and Akis N et al[17] also found similar result . Family history was positive in 50% of cases of nocturnal enuresis. Compared with a 15% incidence of enuresis in children from nonenuretic families, a child has 44% risk of enuresis if one parent is enuretic, and if both parents have a positive history then the chances are around 77%. [2]

Bruxism and nail biting were most common associated behavioural symptoms in PNE(13.15% each). Nail biting was most common associated symptom in SNE (33.33%).

History of marital discord in their parents was present in PNE and arrival of another sibling was, however, significantly associated with SNE. However, in literature review, psychosocial factors are more common in SNE whereas in our study we have got opposite results.30% of children having nocturnal enuresis were having poor scholastic performance. It was found more in children with PNE (34.21%) than with SNE (16.67%) ($p<0.05$).

Joinson et al[18] found that school children with NE were three-times more likely at risk of facing difficulties in their school performance.NE is around two time more prevalent if the child was facing some psychological or social disturbances.[14]

Among the cases of PNE, 15.7% demonstrated the USG abnormalities while 66.7% of SNE had their abnormalities in USG. ($p<0.05$)The Kovacevic L1 et al studyrevealed that 12.5% of enuretic children had ultrasoundabnormalaties of urinary bladder while only 5.38% controls demonstrated it[19].

Table N.2, show 35 (70%) Patients recovered from the problem by behaviour therapy.The cured children were not actively followed up for relapse (by post or telephonic inquiry). However none of the cured subjects presented to OPD again with relapse.There was no statistical difference in two age groups in response rate and mean duration. Hence it may be concluded that ageat presentation has no relationship with recovery.Similar results were found in another study from Spain [67].

The parent's attitudeof anger, punishment or rejection was found in 40% of children with nocturnal enuresis. Though it appears that the parent's attitude has an impact, the difference between two groups was not significant. Children with USG abnormalities are less likely to respond to behaviour therapy. Similar conclusions were drawn in another study by Kovacevic et al on Mono Symptomatic Nocturnal Enuresis [19].

One of the limitations of our study is its cross-sectional design that cannot study the temporal trends in NE with child's increasing age. Other limitations is recall bias of the parents and lack of confirmation of children's school performance directly from the school authorities. These factors can result in variations in the estimation of the prevalence and the role of various factors.Lack of compliance could have been a possible factor in the subjects who did not respond to the treatment.

Our findings provide new information on the psychosocial correlates of PNE and SNE and factors associated with response to beahviour therapy.

CONCLUSION

1. Urinary urgency, bruxism, marital discord, poor school performance and history of enuresis in parent(s) were more commonly associated with PNE, whereas nail biting, arrival of another sibling were more commonly associated with SNE

2. In our study, age at presentation, sex, parental attitude, type of enuresis had no impact on either response rate or mean duration to respond. USG abnormalities of bladder, however, were associated with decreased response rate. Mean duration to respond was not significantly different.

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Maternal Preconception Body Mass Index and Gestational Weight Gain: A Prospective Cohort Study Potentially to Prevent Low Birth Weight

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ABSTRACT

Pregnancy is the most critical period of growth and development change. Low and high birth weight infant would be having in the future the risk of many health problems. Adequate gestational weight gain (GWG) based on preconception body mass index (BMI) is important for optimal birth weight infants.This study aimed to 1) assess the relationship between preconception BMI and totalGWG; 2) calculate proportion of mother who does not meet weight gain recommendation. The longitudinal prospective study conducted from February 2013 to June 2014. The total 37 preconception women enrolled as samples and only 18 samples can be measured for GWG in 3rd trimester. Exclusion criteria were: 1) no data weighing for more than 3 months, 2) no records of first day of last menstrual period (LMP), and 3) miscarriage. Data of GWG compared to weight gain recommendations based on preconception BMI issued by Institute of Medicine. Collected data were analyzed by using STATA v.11. T-test was used to analyze the mean differences of BMI among groups then regression analysis was operated to assess the RR of GWG and nutritional status. We found no significant associations between preconception BMI and GWG ($p>0.05$). Based on maternal nutritional status at preconception, the highest risk not reaching GWG recommendation were in underweight women in 3rd trimester (RR=1,43 [95%CI: 1,00-2,06]) ($p<0.05$).The lower nutritional status the higher total GWG even most of maternal did not meet IOM recommendation. Therefore, underweight maternal be required to be treated properly to avoid adverse pregnant outcomes.

Keywords: *Weight Gain, Preconception, Gestational, BMI, Trimester*

INTRODUCTION

Nutrition factor of maternal plays important role for health status and quality of life both mothers and their foetus. It also influences the quality of life of their children in the future[1]. Underweight in adolescent girl increase the risk of many health problems such lack of foetal nutritent intake, low birth weight (LBW), intrauterine growth retardation, and the risk of neonatal mortality[2]. Nutrition problems of maternal and child which has short term impact such as mortality, morbidity and defect, also has long term impact which influence in the later life, intellectual, productivity and repoductive cycle as well as the cardiovascular and other metabolic diseases[3].

Birth weight is used as an indicator to predict the growth and survival of infants in addition to the nutritional status and health of the infant. In Indonesia, the latest data showed the prevalence of LBW in 2013 about 10.2%. In addition, the proportion of large birth weight (>4000 g) in Indonesia as much as 4.8% are also at risk[4], since it might be associated with increased cesarean childbirth, bleeding, and other complications in the mother[5].The weight gain is the major causes of low and high birth weight[6].

Other studies also show that low gestational weight gain increases the risk of pregnancy outcome such as LBW, premature birth and cesarean delivery as well as other pregnancy complications that can lead to

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maternal and infant mortality, especially in underweight women during preconception[7,8].A study in Albania stated that women who do not meetweight gain recommendation are more likely to deliver prematurely than those who reached the healthy gestational weight gain[9].

Excess pregnancy weight gain in those with higher BMI was associated with increased the risk of macrosomia birth, high risk of fetal death in line with increasing gestational age, and risk of placental dysfunction[10]. Many evidence confirmed clearly that the body mass index (BMI) before pregnancy is an independent predictor of many adverse pregnancy outcomes through its effect on gestational weight gain[9].

AIMS AND OBJECTIVES

The study aims to

1) Assess the relationship between preconception BMI and weight gain during pregnancy.

2) Calculate proportion of mother who does not meet weight gain recommendation

MATERIALS AND METHOD

This study was *part* of a *larger* research "The Effect of Periconceptional Multi Micronutrient Supplementation in Preventing Maternal DNA Damage in Makassar".Current research was longitudinal prospective study which was conducted in four subdistricts (Ujung Tanah, Biringkanaya, Bontoala and Tallo) from February 2013 to June 2014. From total 207 of population, 37 samples met inclusion criteria (recorded as samples enrolled previously in larger study). Exclusion criteria were no data weighing for more than 3 months, no records of first day of last menstrual period (LMP), and miscarriage. Drop out criteria was settle in a new place during the study. At the end of the study, only 18 samples can be measured for for GWG in 3rd trimester.

Data characteristics of respondents consisting of level of education, employment status, and the number of family members. Weight, height, and MUAC before pregnancy was measured to determine the preconception body mass index (BMI). Data on menstrual history and LMP of respondent were also observed. Weight measurement is performed each month at the health center (Puskesmas) during pregnancy. The data then is used to calculate the rate of increase of gestational weight and to predict the total gestational weight gain. Furthermore, these GWG data compared to the weight gain recommendations based on preconceptional BMI issued by Institute of Medicine.

Collected data was processed and analyzed by using STATA v.11 (StataCorp). T-test was used to analyze the mean differences of BMI among groups then linear regression analysis was operated to assess the rate and total of gestaional weight gain.

FINDINGS

Table 1 shows the characteristic of respondent. Most of the respondent aged 20 to 30 years old (78.4%), high education (37.8%), from middle income level (43.2%), and underweight before pregnancy (16.2%). Table 2 indicates the association between preconception BMI and gestational weight gain based on the trimester period. In the 1st trimester, for underweight BMI, weight gain was equal for all level of gestational weight gain. No significant difference between weight gain status and nutritional status in 1st trimester among groups (p=0.31). Begitu pula untuk 2nd trimester and 3rd trimester (p=0.53, p=0.49, respectively).

Table 1. Characteristic of respondent

Characteristic	n=37	%
Age		
<20 yo	4	10,8
20-30 yo	29	78,4
>30 yo	4	10,8
Education		
Elementary School	6	16,2
Junior High School	7	18,9
Senior High School	14	37,8
Diploma	5	13,5
University	5	13,5
Employment		
Unemployment	1	2,7
Enterpreneur	4	10,8
Civil servant	4	10,8
Private employer	3	8,1
Housewife	23	62,2
Others	2	5,4
Income		
Low	9	24,3
Middle	16	43,2
High	12	32,4
Nutritional Status		
Underweight	6	16,2
Normal	27	73,0
Overweight	4	10,8
Chronic energi deficiency status		
No	27	73,0
Yes	10	27,0

Table 2. Association of nutritional status before pregnancy and gestational weight gain

Nutritional Status	Gestational weight gain			n (%)	p
	Lown (%)	Middlen (%)	Highn (%)		
1st trimester (n=37)					
Underweight	2 (33,3)	2 (33,3)	2 (33,3)	6 (16,2)	0,311
Normal	17 (63,0)	8 (29,6)	2 (7,4)	27 (73,0)	
Overweight	2 (50,0)	2 (50,0)	0 (0)	4 (10,8)	
Total (n)	21 (56,8)	12 (32,4)	4 (10,8)	37 (100)	
mean±SD (kg)	1,18±1,54	1,33±1,58	2,39±2,28	1,18±1,51	
2nd trimester (n=25)					
Underweight	3 (75,0)	0 (0)	1 (25,0)	4 (16,0)	0,537
Normal	8 (40,0)	5 (25,0)	7 (35,0)	20 (80,0)	
Overweight	1 (100)	0 (0)	0 (0)	1 (4,0)	
Total (n)	12 (48,0)	5 (20,0)	8 (32,0)	25(100)	
mean±SD (Kg)	2,93±2,13	3,36±2,08	3,68±2,13	3,44±2,20	
3rd Trimester (n=18)					
Underweight	1 (50,0)	1 (50,0)	0 (0)	2 (11,1)	0,490
Normal	3 (20,0)	3 (20,0)	9 (60,0)	15 (83,3)	
Overweight	0 (0)	0 (0)	1 (100,0)	1 (5,6)	
Total (n)	4 (22,2)	4 (22,2)	10 (55,6)	18 (100)	
mean±SD (kg)	4,69±2,60	5,02±2,27	5,58±2,56	5,57±2,41	

Total weight gain during pregnancy based on preconception BMI is shown in Table 3 (n=18). In underweight status, the gestational weight gain was equal to less and sufficiency compare to recommendation (50%). In line result with the normal status in which 46.7% meet recommendation whereas 13.3% respondent were in excessive gestational weight gain status. The mean of total weight gain during pregnancy in underweight status was higher than normal and overweight status (12,65±3,32, 10,81±3,82, 7,9±0, respectively). There was no difference significantly among groups for the total of gestational weight gain based on preconception pregnancy. Only 1 respondent has overweight status before pregnancy.

Table 3. Total gestational weight gain based on preconception BMI

BMI	Total of gestational weight gain(n=18)						mean±SD (kg)	p
	Low		Middle		High			
	n	%	n	%	N	%		
Underweight1	1	14,3	1	11,1	0	0	12,65±3,32	0,846
Normal2	6	85,71	7	77,8	2	100,0	10,81±3,82	
Overweight3	0	0	1	11,1	0	0	7,9±0	
Total	7	38,9	9	50,0	2	11,1	10,81±3,82	18 (100)

[1]= recommendation GWG for underweight; low (<12,7 kg), middle (12,7-18,1 kg), high (>18,1 kg)

[2]= recommendation GWG for normal; low (<11,3 kg), middle (11,3-15,8 kg), high (>15,8 kg)

[3]= recommendation GWG for overweight; low (<6,8 kg), middle (6,8-11,3 kg), high (>11,3 kg)

Table 4. Regression analysis of nutritional status before pregnancy and GWG

BMI	1st trimester RR (95% CI)	2nd trimester II RR (95% CI)	3rd trimester RR (95% CI)	Total RR (95% CI)
Underweight	1,02 (0,58-1,76)	1,20 (0,99-1,47)	1,43 (1,00-2,06)*	1,83 (0,33-9,92)
Normal	1 (ref.)	1 (ref.)	1 (ref.)	1 (ref.)
Overweight	0,47 (0,093-2,41)	-	-	-

* p= 0.049

Table 4 demonstrated the women those underweight before pregnancy were not reaching weight gain recommendation in 1st, 2nd, and 3rd trimester (RR= 1.02; 95% CI: 0.58-1.76, RR=1.20; 95% CI: 0.99-1.47, RR=1,43; 95% CI: 1.01-2.06, respectively), while RR=1.83 (95% CI: 0.33-9.92) for total gestational weight gain recommendation. Only in 3rd trimester showed result significantly the regression analysis result conducted between preconception nutritional status and GWG recommendation (p=0.049).

DISCUSSION

Current study shows that the association of nutritional status of women before pregnancy and gestational weight gain was not significant. The lower nutritional status in preconception period the more weight gain during pregnancy although not to fulfill the weight gain as recommended. In line with the previous results of other studies that also observed changes in weight gain during pregnancy according to preconception BMI. Weight gain in underweight subject was significantly higher than in normal and overweight (P <0.001)[11].

Actually, weight gain during pregnancy is strongly influenced by various environmental and individual factors of the mothers. A longitudinal cohort of pregnant women (N = 1100) that completed research questions about weight gain during pregnancy also shows significant result about relationship between pre-pregnancy factor and gestational weight gain[12]. Other studies, A retrospective cohort study, in Peruvian pregnant women found that premature birth independently relates to the gestational weight gain and the relationship varies by pre-pregnancy BMI. Pre-pregnancy BMI and gestational weight gain were correlated inversely and also related to many factors such as parity, miscarriages, and maternal age[13].

Furthermore, adequate maternal nutrition plays pivotal role during pregnancy especially in 1st trimester. Excessive nutrition may affect the fetal growth like shown in a study that found the obese women tended to have pre-term birth[14]. Similarly, in lack of nutrition, women who suffering from insufficient nutrition cannot support healthy weight gain[15]. Based on the theory of fetal programming, nutrition is the main factor to contribute expression of the fetal genome. In addition to, retardation of placenta and fetal growth are influenced by maternal undernutrition. These condition absolutely increase the risk of low gestational weight gain[16]. Limitations of the study were no food intake control so that it could be a confounding factors. In addition to, the number of subject is small possibly affect the result.

This study conclude that the nutritional status before pregnancy, even it was not significant, affected gestational weight gain. Maternal undernutrition before pregnancy increase the risk mother have low gestational weight gain in 3rd trimester, while for maternal overweight in 1st trimester.

CONCLUSION

Although the study did not show an association between preconception BMI and gestational weight gain, but based on the results of other studies, nutritional status in preconception is need to be concerned because it affects weight gain. In current study, eventhough appeared that higher weight gain occured in the lower the nutritional status, but still did not reach the IOM recommendations. Therefore, underweight maternal be required to be treated properly to avoid adverse pregnant outcomes.

Conflict of Interest: There was no conflict of interest within this study.

Source of Funding: This research also was self funding study.

Ethical Clearance: The ethical clearance taken from ethical committee of Medical Faculty Hasanuddin Universitas.

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Microwave Breast Cancer Screening for Women Welfare

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ABSTRACT

In the battle of female cancers, breast cancer is one of the most common invasive cancers among the women worldwide. In India, Breast cancer incidence is growing at higher rate. Breast cancer has become major health problem and emerging as major cause for suffering of women across the country. According to Cancer Society, 230,000 female breast cancers and 2,300 male breast cancers are reported every year and also about 40,440 deaths are occurred. There are around 3.1 million breast cancer survivors in India. Though there is increase in breast cancer year by year, there is no concrete reason to develop breast cancers but there are risk factors which stimuli cancerous in women. Some of the risk factors include such as heredity, increase life expectancy, life style, food habits, Hormone therapy, alcohol / tobacco consumption and so on. Risk factors can be reduced by raising health awareness through media campaigns, self help groups. However, if breast cancer does occur, effective early detection of breast cancer is required to save life. There exist many screening techniques for breast cancer detection. However, they have negative and side effects and especially it is not preferred for young women because of ionized radiation. An attractive alternative of using Microwaves to detect breast tumours is a non-ionizing and indeed potentially low-cost. Flexible Microstrip antenna along with signal processing and classification can be used for cancer diagnosis. This paper analyzes the machine learning classifier algorithms for seer breast cancer dataset using WEKA software.

Keywords: *Classification, J48, Accuracy, RMSE, Confusion Matrix.*

INTRODUCTION

The breasts are made up of fat, connective and glandular tissues. Breast cancer is the common cancer among the women that starts from the breast cells. Cancer cells are abnormal in shape and multiply as many times as it can and it is out of control. Breast cancers start from inner lining of either ducts or lobules that supply milk to nipple and it is shown in Figure 1. Cancer cells that begin at inner lining of milk duct are called ductal carcinoma and it is most common type of breast cancer. There is another type of breast cancer that starts from the lobules or milk secreting glands called lobular carcinoma. There are various symptoms for breast cancer that can be experienced by patients.

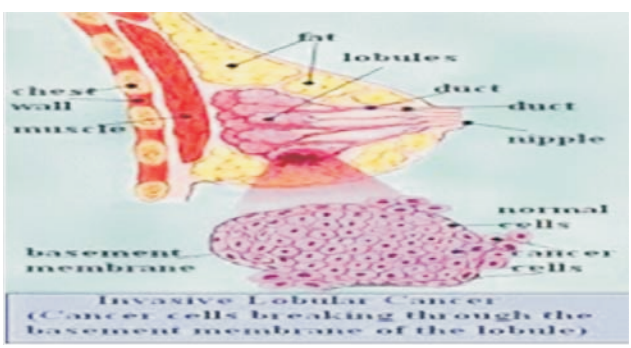


Fig. 1. Breast Cancer[10]

The symptoms includes such as lumps, change in shape, change in colour of skin, liquid oozing out from nipple. Breast cancers can be either Benign or Malignant. Benign breast tumours develop lumps in the breast, but it does not spread outside the breast. Malignant tumours are at high risk, it invades the surrounding tissues and spread to other breast or distant organs through lymphatic system.

From our analysis and understanding, it is observed that there exist different risk factors for occurrence of breast cancer in urban and rural areas. In urban areas, changes in reproductive profile change of women, Nulliparity and first birth at late age are risk factors for breast cancer. Either early menstruation or late menopause also induces cancers.

The extensive breast feeding suppresses the ovulatory cycles and reduces the risk of breast cancer. Unfortunately,urban women working in private sectors has only 3 months period of maternity leave has great impact on breast feeding, that influence the high risk factor for breast cancer.

In rural areas, health awareness programme has to be conducted through media campaigns and women self-help groups. Though there is no way to prevent the breast cancer, early detection of breast cancer is required to provide effective treatment to save the life of women.

Research Objective

The primary objective of this research is to undergo a breast cancer detection and classification using microstrip antennas.

Research Scope

The scope of the research is specific to apply various machine learning classifier algorithms on SEER Breast cancer dataset for breast cancer classification. The performance analysis of these classifiers are performed on various parameters like classification accuracy, True Positive rate, True Negative, False Positive Rate, False Negative, ROC, Precision, Recall, Sensitivity, Specificity, and RMSE.

This paper is classified as follows. Section 2 gives a brief description on existing breast cancer technologies and section 3 provides the detailed description on classifier algorithms and section 4 describes about dataset and simulation results that are obtained for various algorithms.

EXISTING METHODOLOGIES

Currently, there are different techniques used for breast cancer screening. However, these methods invasive and have undesired side effects.

X-ray Mammogram: Mammograms are used as gold standard early breast cancer detection [12]. Though Mammograms are easy to compute, it has serious limitations like invasive, high ionization, not advisable for frequent screening, high false positive / false negative rates in younger women with dense breast.It is more suitable for the women above the age of 50 - 60 years. It lacks specificity and cannot distinguish benign and malignant tumours.

Ultrasound: Utilizes sound waves to detect the breast variations and differentiates fluid-filled cysts and solid masses but fails to detect the minor tumours, whose size is less mm. Diagnosis mainly depends on the skill of the doctor.

Magnetic resonance imaging (MRI): As human tissues are absorbing nature, Radio Frequencies are absorbed and released which produce various patterns by different types of body tissues.MRI has very high operational cost. It is invasive, time consuming and cause discomfort to the patients.

Biopsy: An invasive technique to remove and examine tissue for the presence of cancer. Biopsy procedure has few limitations such as

- Risk of bleeding and infection at biopsy site
- Discomfort and painful to patients where it requires pain medication.

These serious limitations pave the way for the development of a new tool for early detection of Breast cancer.

MICROWAVE TECHNOLOGY

With drawbacks of the current diagnostic tools, development of screening methods that complement X-ray mammography is required Emerging microwave technology provides better result with the advantages of non-ionizing, comfortable, suitable for younger women, sensitive to tumours and specific to malignancies. Microwaves for breast cancer detection will improve the survival rate and decreases the breast cancer mortality.

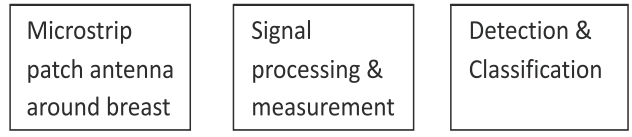


Fig. 2. Block diagram of microwave screening [13]

The microwaves utilize the principle of tissue-dependent microwave scattering and absorption is based on the dielectric properties of breast tissues[13]. The amount of signal scattered by a breast tumour cells are higher than that of normal breast tissues. The received signal from antenna can be combined using beamforming system and analyzed to detect the presence of breast tumour. The signals from various antennas are processed and classified.

Though, we have different techniques, diagnosis is made by the experienced physicians. When compared to physician, machine learning classifier algorithms are more correct and it is approximated with accuracy of 91.1% in diagnosis.

Classification

Classification plays a major role in the breast cancer

detection and classification[3]. In most of the cases classification comes out with degree of certainty. It may or may not be the probability of the instance belongs to the target class. The primary objectiveis to accurately predict the target class for each instance in the data.

All classifiers are framed with two phases, one is training phase and other is testing phase. In training phase, classifier algorithm completes its learning by generating the rules for classification by generalizing the relation among the feature attributes with the target class. In testing phase, when test data is fed to the classifier, accuracy of the classifier is determined. The classification accuracy determines the quality of the classifier.The detailed steps involved in classification are represented in below Figure 2.

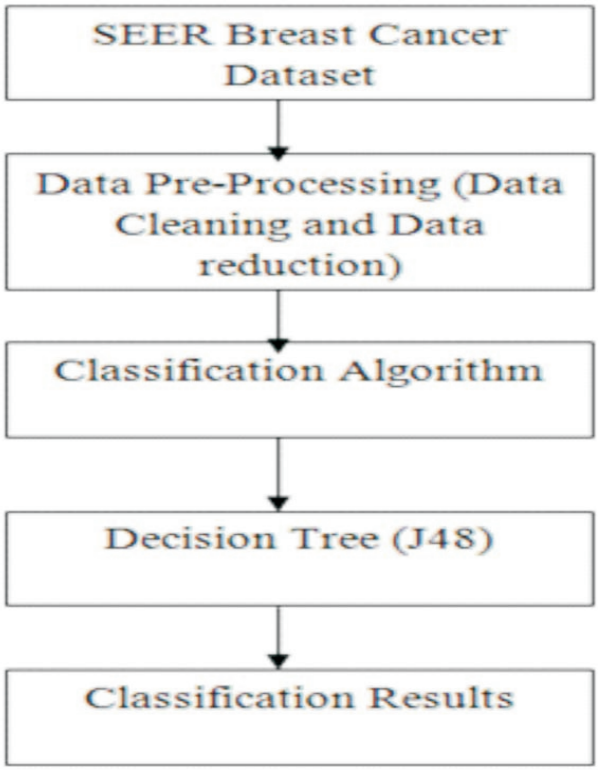


Fig. 3. Methodology for data classification[1]

Classification requires Data pre-processing to improve the quality of the data. There are various steps involved in Data pre-processing. In our analysis, data cleaning and data reduction techniques are imposed on SEER breast cancer dataset.

Data cleaning: This method pre-processes the data to handle missing values of attributes. Missing values are replaced by the mean value for that attribute.

Data reduction: Irrelevant and redundant data are removed and thus reduces the dimensionality of dataset using Feature selection techniques.

Feature selection excludes less significance attributes for the classification. There are 762691 instances with 134 attributes in Breast cancer dataset. Feature selection, choose only 12 attributes are considered for analysis.

Table 1. Dataset Attributes for Classification[6]

Attribute	Length	Description
Age at diagnosis	3	Age of the patient at diagnosis
Grade	1	Specify T-cell, B-Cell involvement in lymphoma and leukemia
EOD-Tumor Size	3	Records dimensionality of the tumour in millimetres. This field is only coded for cases diagnosed 1988-2003.
EOD-Extension	2	Extension of the tumour from primary site. This field is only coded for cases diagnosed 1988-2003.
EOD-LymphNode involve	1	Highest specific lymph node chain involved. This field is only coded for cases diagnosed 1988-2003.
Regional nodes positive	2	Exact number of regional lymph nodes that contain metastases. This field is only coded for cases diagnosed 1988-2003.
Regional nodes examined	2	Exact number of regional lymph nodes that are examined by pathologist. This field is only coded for cases diagnosed 1988-2003.
CS Tumor Size	3	Information on Tumour Size
CS Extension	3	Information on extension of Tumour
CS Lymph nodes	3	Information on involvement of lymph nodes.
CS Mets at DX	2	Information on distant metastasis.
Behavior code ICD-O-3	1	Describes on the nature of tumour as begin, in situ or malignant

Classification Algorithms

There have been various algorithms used for classification of Breast cancer.This paper provides the

detailed description on J48 decision tree algorithms and evaluates based on the performance measures like accuracy, sensitivity, specificity, entropy, ROC, PRC area and so on.

J48 Algorithm

Decision tree is supervised technique builds the classification in tree like structure with root node, branch node and leaf node[4]. The decision tree algorithms is predictive tree based algorithm where the branch node represents the choice of alternatives and leaf node represent the decision of the data with respect to the target class.Decision tree breaks down the entire dataset in to multiple subsets and builds the decision tree recursively.J48 employs top-down and greedy search.As J48 decision tree is extension of ID3, accounts information gain of the attribute for selection of the node.While constructing decision tree, J48 ignores the missing values or the values can be predicted as the mean value of the attribute.

The Algorithm

Training dataset are at root

Calculates Entropy and Information gain.Attribute with highest information gain is selected as decision node

Leaf node has zero entropy

Branch that has non-zero entropy undergo further partitioning

Algorithm executed recursively on non-leaf nodes until target class is achieved

Condition for stopping

All the samples at the particular node belongs to the same target class

Either no attributes or samples left for further split up

Simulation Results and Discussion

For this research work, J48 decision tree classifier algorithmis applied to the breast cancer dataset from Surveillance, Epidemiology, and End Results (SEER) repository.The breast cancer dataset has 769261 numbers of instances and each instance consists of 134 attributes including the class attribute. The class attribute has four values like Benign (0), uncertain benign or malignant (1), Carcinoma in situ (2) and Malignant (3). All the attributes of the data set along with their range of values are available in seer data dictionary[6].The classification algorithm is applied to the input parameters mentioned in the Table.1.

In WEKA, Data pre processing has been carried out as first step for all the 12 attributes. J48 algorithm is simulated and below shown decision tree is constructed for SEER Breast Cancer dataset.

J48 decision tree

Regional_nodes_positive <= 97
CS_Extension <= 70
Regional_nodes_examined <= 0: Malignant
Regional_nodes_examined > 0
CS_Extension <= 0
EOD_Extension <= 0: Carcinoma in situ
EOD_Extension > 0: Malignant
CS_Extension > 0
CS_Extension <= 50
Age_at_Diagnosis <= 55: Carcinoma in situ
Age_at_Diagnosis > 55
CS_Tumor_Size <= 13: Carcinoma in situ
CS_Tumor_Size >13: Malignant
CS_Extension > 50: Malignant
CS_Extension > 70: Malignant
Regional_nodes_positive > 97
CS_Extension <= 0
EOD_Extension <= 0: Carcinoma in situ
EOD_Extension > 0: Malignant
CS_Extension > 0
CS_Extension <= 70
Grade <= 4
CS_Extension <= 50
Age_at_Diagnosis <= 58: Carcinoma in situ
Age_at_Diagnosis > 58
CS_Tumor_Size <= 990: Carcinoma in situ
CS_Tumor_Size > 990: Malignant
CS_Extension > 50: Malignant
Grade > 4: Malignant
CS_Extension > 70: Malignant

The performance of the J48 classifier in detecting the breast cancer can be evaluated from the analysis of confusion matrix and below parameters are calculated.

Accuracy is the closeness of measured value to the actual or true value. The percentage of correctly classified instances from total instances can be calculated from

$$Accuracy = \frac{TP+TN}{TP+TN+FP+FN} \quad (1)$$

Precision is the measure of closeness of repeated measurements to correctly classify instances for those instances that are classified as positive.

$$Precision = \frac{TP}{TP+FP} \quad (2)$$

Recall is the measure of the positive instance that are correctly classified and it can be calculated with below equation

$$Recall = \frac{TP}{TP+FN} \quad (3)$$

F-Measure is the harmonic mean of precision and recall.F-measure use below equation for calculation

$$F\text{-}Measure = \frac{2*Recall*Precision}{Precision+Recall} \quad (4)$$

Sensitivity is the measure of correctly classified positive instances to total number of positive instances.

$$Sensitivity = \frac{TP}{TP+FN} \quad (5)$$

Specificity is the ability to classify correctly negative instances from total number of negative instances.

$$Specificity = \frac{TN}{TN+FP} \quad (6)$$

Receiver operating curve (ROC) is graphical representation of specificityagainst sensitivity. Sensitivity and specificity are inversely proportional to each other.

Kappa Statisticevaluates the prediction performance of the classifiers and it measures the inter-rate agreement of the instances.

Entropy: It is measure of amount of information a discrete variable can produce. The entropy H(X) for a discrete random variable X can be expressed as below

$$Entropy\ H(X) = \sum_{x=1}^{n} p_i \log_b p_i \quad (7)$$

RMSE is the measure of difference between the predicted and actual value.

The J48 classifier algorithms are imposed on the pre-processed data.

The simulation results of decision tree classifiers are plotted here. Confusion matrix helps us to evaluate total number of True Positive (TP), True Negative (TN), False Positive (FP) and False Negative (FN) instance. With the help of TP, TN, FP and FN value, it is possible us to validate the various performance measures such as accuracy, precision , recall, F-measure, ROC, PRC, etc.

The simulation results of the J48 decision treeclassifier for all possible values of class attribute is summarized in the Table.2.

Results of J48

Table 2. Performance parameters of J48

Parameters	Class (0)	Class(1)	Class(2)	Class(3)
TP Rate	0	0	0.68	0.983
FP Rate	0	0	0.017	0.32
Precision	0	0	0.881	0.944
Recall	0	0	0.68	0.983
F-Measure	0	0	0.767	0.963
ROC	0	0	0.891	0.891
PRC	0	0	0.782	0.972

From our analysis, J48 classifier classifies the data with 93.62% accuracy and minimum RMSE of 0.1653.It consumes less time of 42.23 seconds to build the model and size of the decision tree constructed is 31 and number of leaves are 16.

Error Results

Table 3.Error statistics of J48

Error	J48
Kappa statistic	0.7311
Mean absolute error	0.0546
Root mean squared error	0.1653
Relative absolute error	41.73%
Root relative squared error	64.62%

J48 Classifier classifies the data with minimized Mean Squared Error value of 0.1653and various error statistics are captured in Table 3.

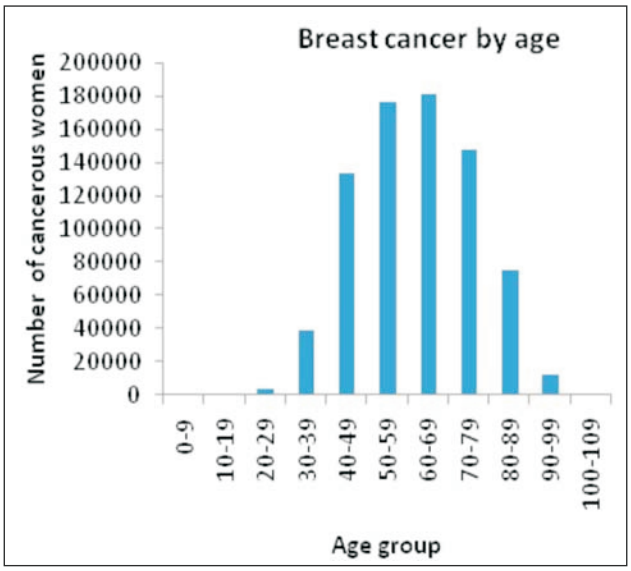


Fig. 4. Total number of Breast Cancer by Age

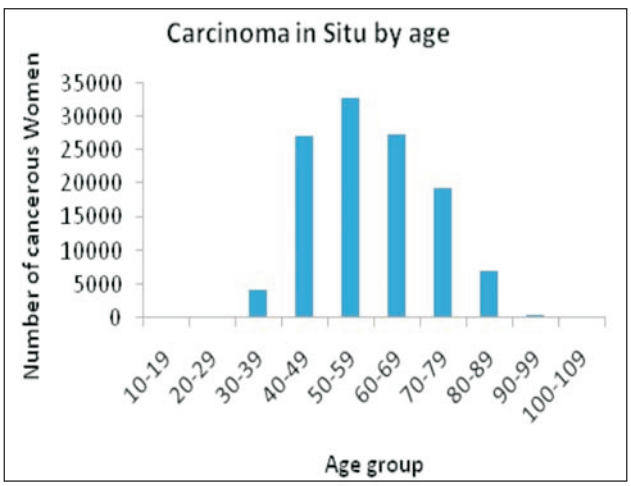


Fig. 5. Total number of Carcinoma in Situ by Age

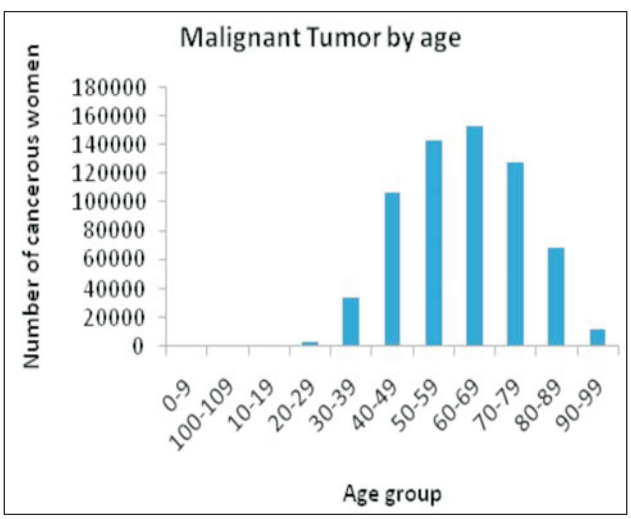


Fig. 6. Total number of Malignant tumour by Age

Breast cancer incidence at various age groups and stages are captured in Figure 4, 5 and 6.

CONCLUSION

From our analysis and observation, women between the age group of 40 -70 are most affected with breast cancer. Thus, effective and efficient early breast cancer detection and classification tools are required to reduce the mortality of women in the society. In this research work, J48 decision tree algorithm for Breast cancer classification is implemented for SEER Breast cancer dataset. The simulation results shows J48 classifier classifies the data with 93.62% accuracy and minimum RMSE of 0.1653.The future scope of the microwave screening includes the design of microstrip antenna and its signal processing.There is also scope to modify classifier algorithm based on real time data received from antenna.

Conflict of Interest- Nil
Source of Funding- Nil

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Stress among Clinical Resident Doctors of Odisha: A Multi-Centric Mixed Methodology Study

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ABSTRACT

Background: Clinical resident doctors often work long hours and in conditions that predispose to stress. The study was carried out to estimate the level of stress among clinical resident (PG) doctors of Odisha.

Methodology: This mixed methodology, cross sectional survey was conducted in the three government medical colleges of Odisha in October, 2016. The study participants were 250 resident post graduate students working in clinical departments. Study Instrument was an online semi-structured survey tool. The questionnaire for stress assessment was developed by adapting with permission the "Workplace Stress Scale" developed and trademarked by the Marlin Company, and the American Institute of Stress. © Snowball sampling method was employed for data collection. The data was analysed using GNU-PSPP ver.0.9.0 & CAQDAS-Dedoose ver.7.1.3

Results: A total of 80 females (32%) and 170 males (68%) participated in the study. The age of the participants ranged from 25 to 50 years (μ=29.16 ± 3.46 years). According to the workplace stress scale, 53 (21.2%) had low/no stress, 101 (40.4%) had moderate stress and 96 (38.4%) had severe stress. The distribution of stress was not significantly different between males and females. There was no statistically significant difference in the stress levels of 1st year, 2nd year and 3rd year residents.There was significant difference between the mean stress scores of the three institutions. (ANOVA test; F=5.5; p= 0.004). A higher proportion of residents of the Paediatrics, Medicine and Obstetrics & Gynaecology departments had moderate and severe stress. Three themes emerged from analysis of the qualitative data. Finite work hours to reduce stress; Improved guidance to build confidence; Security at workplace needs to be ensured.

Conclusion: The prevalence of stress among clinical residents of Odisha was high and measures to address the same should be undertaken.

Keywords: *Stress, PG Students, Residents, AIS Workplace Stress Scale.*

INTRODUCTION

Stress is a normal phenomenon of response to physical or psychological pressure on a person. Extended periods of stress can cause destructive changes in the body such as depression, heart disease, cancer, stroke, ulcers, back pain, headaches, raised blood pressure, indigestion, and a variety of other problems.[1]

Out of many groups who are affected by such emotional states and disorders, doctors especially the resident doctors comprise an important group because of the unique environment in which they work. [2,3]The fact that the residency period is a stressful and overwhelming time has been well documented in the literature.[4]Factors like excessive working hours, sleep deprivation, and repeated exposure to emotionally charged situations play an important role in causing stress in this group. In addition lack of job security, family and personal problems aggravate the stress.[5]These residents have a very little experience, but they are expected to be proficient clinicians,

educationists, researchers, and administrators.Due to the nature of their professions, the mental health of doctors is not only of concern to them, but also is of concern to the greater society served by them.[6]

In India, very few multi-centric studies have been done to assess the workplace stress in resident doctors. No such study has been conducted in Odisha. Hence, this study was planned to find the prevalence and distribution of stress among clinical resident doctors of Odisha and perceptions about its causes.

METHODOLOGY

This mixed methodology, cross sectional survey was conducted in the three government medical colleges of Odisha in October, 2016. The study participants were the resident post graduate students working in clinical departments of SCB Medical College-Cuttack, MKCG Medical College-Berhampur, VIMSAR- Burla and SCB Dental College- Cuttack.

Sample Size- there were 741 PG students in various departments of the three medical colleges and one dental college at the time of conducting the study. A previous study among residents of New Delhi had shown that the expected prevalence of stress among residents was 32.8%. Using this, the required minimum sample size was calculated for confidence levels of 95%, a beta error of 20% and an alpha error of 5% by EpiInfoStatcalc software. This yielded a minimum sample size of 232. Assuming a non-response rate of 10%, the sample size was rounded off to 250. As the work environment of the three government colleges was similar, it was assumed that there would be no design effect.

Study Instrument- An online semi-structured survey tool was developed using the platform of Zoho corporation for the study purpose. The tool had parts for socio-demographic characteristics, stress evaluation questionnaire and open ended qualitative questions. It had a checkbox for informed consent and was compatible with PC, mobile and tablet platforms. The questionnaire for stress assessment was developed by adapting the pre validated "Workplace Stress Scale" developed and trademarked by the Marlin Company, and the American Institute of Stress (AIS). © This had a set of 8 questions with graded answers in a Likert scale and is given in annexure-1. The tool was pretested in a pilot study with a sample of 20 residents.

Annexure-1: The Workplace Stress Scale™

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Directions: Thinking about your current job, how often does each of the following

Sl. No.	Question	Never	Rarely	Sometimes	Often	Very Often
A	Conditions at work are unpleasant or sometimes even unsafe.	1	2	3	4	5
B	I feel that my job is negatively affecting my physical or emotional well being.	1	2	3	4	5
C	I have too much work to do and/or too many unreasonable deadlines.	1	2	3	4	5
D	I find it difficult to express my opinions or feelings about my job conditions to my superiors.	1	2	3	4	5
E	I feel that job pressures interfere with my family or personal life.	1	2	3	4	5
F	I have adequate control or input over my work duties.	5	4	3	2	1
G	I receive appropriate recognition or rewards for good performance.	5	4	3	2	1
H	I am able to utilize my skills and talents to the fullest extent at work.	5	4	3	2	1

Adapted with permission from The Marlin Company, North Haven, CT

Sampling- Snowball sampling method was employed where the Principal investigator shared the study tool link with three institutional investigators, who in turn shared the link with one person each from all the departments of their institution, who were asked to share the same with all the residents of their department. Social media was used for this propagation of the study tool. This ensured that all the residents had a chance to use the study tool, if they chose to. IP address was recorded and used to prevent duplicate responses.

Data collection and analysis- The survey platform was pre-programmed to take the tool offline once the sample size of 250 was reached. Data collection and propagation of the tool was started simultaneously. The target sample size was reached within 72 hours of the start of the propagation chain. Data was provided by the survey platform in the form of an un-coded excel sheet. A Stress score was arrived at by adding the scores of the 8 questions of the Workplace stress questionnaire. Using this score, the respondents were categorised into Low/No stress (Score <20); Moderate stress (Score:21-25) and Severe Stress (Score >25).The data was coded and an open source software, GNU-PSPP ver.0.9.0 was used for quantitative analysis using appropriate statistical tests. A web based data analysis software, CAQDAS-Dedoose ver.7.1.3 was used for qualitative content analysis using deductive approach to delineate emerging themes.

Ethical considerations- Institutional Ethical Committee clearance was obtained. Informed consent was obtained from the study participants. Permission was obtained from the Deans and the Junior Doctor's Associations of the three institutions. Written permission was obtained from the copyright holders, The Marlin Company, North Haven, CT, and the American Institute of Stress, Yonkers, NY for adapting and developing the study tool.

RESULTS

A total of 80 females (32%) and 170 males (68%) participated in the study. Out of them, 120 (48%) were from SCB Medical College, 89 (35.6%) were from MKCG MC and 41 (16.4%) from VIMSAR. Among them, 75 (30%) were in their first year, 68 (27.2%) were in their second year and 107 (42.8%) were in their third year of residency. A majority of residents were from the departments of Medicine (n=43, 17.2%) followed by Obstetrics & Gynaecology (n=35, 14%), Surgery (n=34, 13.6%) and Paediatrics (n=32, 12.8%). The age of the participants ranged from 25 to 50 years (μ=29.16 ± 3.46 years). According to the workplace stress scale, 53 (21.2%) had low/no stress, 101 (40.4%) had moderate stress and 96 (38.4%) had severe stress. The distribution of stress was not significantly different between males and females and is shown in table-01.

Table 01: Prevalence and distribution of stress according to gender.

Stress levels	Gender		Total
	Female	Male	
Low / No Stress	14 (17.5%)	39 (22.9%)	53 (21.2%)
Moderate Stress	36 (45.0%)	65 (38.3%)	101(40.4%)
Severe Stress	30 (37.5%)	66 (38.8%)	96(38.4%)
Total	80 (100.0%)	170 (100.0%)	250(100.0%)

Pearson's S«²=1.40, df=2, p=0.49

Similarly, as shown in table-02, there was no statistically significant difference in the stress levels of 1st year, 2nd year and 3rd year residents.

Table 02: Distribution of stress according to year of residency

Stress Levels	Year of Residency			Total
	1st	2nd	3rd	
Low or No Stress	20 (26.7%)	12 (17.6%)	21 (19.6%)	53 (21.2%)
Moderate Stress	27 (36.0%)	32 (47.1%)	42 (39.3%)	101 (40.4%)
Severe Stress	28 (37.3%)	24 (35.3%)	44 (41.1%)	96 (38.4%)
Total	75 (100%)	68 (100%)	107 (100%)	250 (100%)

Pearson's S«²=3.12, df=4, p=0.53

There was significant difference between the mean stress scores of the three institutions(ANOVA test; F=5.5; p= 0.004) and a significantly greater proportion of residents from SCB Medical College were found to have severe stress (Table-03). The means plot is represented in Figure-01.

Table 03: Distribution of Stress according to institution

Stress	Institution			Total
	MKCG Medical College, Berhampur	SCB Medical College, Cuttack	VIMSAR, Burla	
Low or No Stress	3236.0%	1613.3%	512.2%	5321.2%
Moderate Stress	2932.6%	4840.0%	2458.5%	10140.4%
Severe Stress	2831.5%	5646.7%	1229.3%	9638.4%
Total	89100.0%	120100.0%	41100.0%	250100.0%

A higher proportion of residents of the Paediatrics, Medicine and Obstetrics & Gynaecology departments had moderate and severe stress. The department wise distribution of stress is shown in figure-02.

Three themes regarding the causes of workplace stress emerged from analysis of the qualitative data.

1. Finite work hours to reduce stress- Unlimited work hours with no fixed timings was the most common cause of stress according to most (72%) respondents.

   "Guidelines on 48 hours duty per week is necessary".

   "Why are only PGs supposed to work for unlimited time when no other faculty members do?"

   "I feel most stressed during and after a long emergency duty shift. Long duties are the cause of stress."

2. Security at workplace needs to be ensured- Poor security and fear of assault was a common cause of stress in 64% residents.

   "Lack of security is a major cause of stress in hospital"

   "Being a girl, I feel insecure working night shifts. Adequate security is needed"

3. Improved guidance to build confidence- Lack of peer support and teaching was a cause of stress in 36% residents.

   "Better classes and hands on teaching by unit heads will contribute to stress reduction".

   "Lack of skills and expertise leads to tension regarding my future. PGs should be allowed more surgeries".

DISCUSSION

The number of study participants from the three colleges and from the various clinical departments of each college was proportional to the strength of PG students in the respective institutions and departments.

According to the AIS workplace stress scale, about 21% had low/no stress, 41% had moderate stress and 38% had severe stress. In a study by Saini et al in Delhi using a different scale for stress assessment, the overall prevalence of stress was found to be 32.8% in resident doctors from all colleges. [5]Pinto et al. in their study among residentsand consultants in Goa Medical College reported 80% prevalence of stress. [7] Similarly, in a study by Sahasrabuddhe et al in Mumbai, 37.3% residents were qualified as experiencing stress. [8]

One of the reasons for such varying results might be the difference in the tools used to assess the stress. Self perception and questionnaire based tools like the Perceived Stress Scale (PSS) or the Depression anxiety stress (DAS) scale which were used in these studies might have led to a more subjective assessment of stress levels. On the other hand, the AIS Workplace Stress Survey used in the present study was developed as a simple screening measure focused on specific workplace criteria to assess stress. Another advantage of the present study was the use of a qualitative component to assess the perceived reasons for stress by the residents themselves.

In other studies worldwide, Cohen et al. reported a stress prevalence of 34% among resident doctors in Canada. [4] Sargent et al. in their study in USA also reported 33% stress among resident doctors. [9]However, the geographical settings as well as the working atmosphere of the resident doctors were totally different in thesestudies.

In this study, the hospital and departments with a greater work load and patient flow have a significantly greater proportion of their residents suffering from stress. Similar justification has been given by Saini et al

and Sahasrabuddhe et al for the difference between clinical and non-clinical departments. [5, 8]

In our study, there was no statistically significant difference in the stress levels of 1st year, 2nd year and 3rd year residents. However, in other multicentric studies from metropolitan cities of Mumbai and Delhi, the first year residents had greater stress levels. [5, 8] This may be due to different work culture in those centres as compared to Odisha.

A qualitative approach was chosen to analyse the self perceived causes of workplace stress by the residents and their suggestions to address the same. Overload of work and lack of limited work hours was the most common stressor. A report by the British Medical Association on the work related stress among junior doctors emphasizes the need to control excess workload particularly in the junior doctor cadre. [10]

CONCLUSION

The prevalence of stress is high among the resident doctors of Odisha. Measures like finite and well distributed work hours, improved peer to peer and teacher-student contact and better security for doctors at the hospitals may be implemented to address this problem. Further studies using multivariate techniquesare needed for finding the risk factors for stress in residents.

Conflict of Interest-None

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An Assessment of The Stress Levels of Students Entering Medical School in Indonesia

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ABSTRACT

Introduction: Many studies have reported that distress and related psychological health problems are higher among medical students compare to the general population. There have been no studies in Indonesia that have assess the stress level of medical students entering medical schools and longitudinally. This study assesses baseline stress levels of students entering medical schools.

Method: A cross sectional survey was conducted on 2013 intake of new medical students.We recruited 263 participants between September and October 2013 during the first two months of their university life. Level of distress was measured using an Indonesian version of the WHO General Health Questionnaire-12 (GHQ-12).

Result: Of 263 students, 52.2% were classified as being at risk of stress and 14.8% were classified as "stressed". There were no significant difference in level of stress between male and female students and those students with different socioeconomic status and geographic category($p>0.05$). However, students from lower socioeconomic background and those from rural regions reported slightly higher levels of stress, though this difference was not significant ($p>0.05$).Students who obtained specific government scholarship due to low socioeconomic status were significantly higher of stress level ($p<0.05$).

Conclusion: The study shows that new medical students had high levels of stress compare to the general public as measured by GHQ-12. Follow up study is planned to assess the effect of stress longitudinally in relation to academic performance.

Keywords: *New Medical Student, GHQ-12, Stress, Indonesia*

INTRODUCTION

The objective of the study is to examine the level of stress of new medical students as a baseline for future follow up longitudinally. The study was done in a medical school in Indonesia because newly implemented admission system entering university in the country since 2013. The new admission system is through school matching program with the admission criteria based on high school performance as an addition to the existing admission examination test. The government imposes that universities have to allocate at least 50% proportion of new students from the school matching program. In supporting the program, the government also give scholarship to all students form low socioeconomic status. The programs affect on demographic characteristic of new students with substantial proportion of students from rural and low socioeconomic status. The students from rural and low socioeconomic status may feel isolated and lead to stress.As many studies reported that students the prevalence of psychological disorders is relatively higher in medical students, which includes distress, anxiety and depression.[5,7-12] Some of the causes include feeling isolated, lack social support and financial problem.[11,23,24,26]

Stress is automatic and unspecific body response to stressor or threat as mechanism of adaptation. The response has been known as 'fight or flight responses, which means struggle or run to avoid the threats.[1] The responses of stress initially begin with alarm stage, when someone starts to aware the psychological burden or threat. If the stress or threat occurs persistently, the

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response will continue to resistance stage. The resistance toward stressor involves psychological defence and adaptation. When someone cannot adapt to the stressor, he/ she will fall into exhaustion or decompensation stage that adaptation disorderppearswhich is also knowna distress condition.[2,3]Adaptation disorders or distress appears with many psychological and physical symptoms, such as sleep and eating disorders, cognitive and emotional imbalance.[1,2,4]Someone in distress condition cannot do their daily activities normally. If the condition happens on students, there is possibilityeffect on their academic performances. On the other hand, learning in university level especially in a medical school also becomes stressor.[5-7]

METHOD

Cross sectional study has been conducted in FMAU on new medical student intake 2013. Participants were selected randomly, which 263 out of 360 students participate in the study. The data was collected between September and October 2013 in the first two months of their university life and before taking any summative exam.

Level of distress was measured by using Indonesian version of General Health Questionnaire-12 (GHQ-12). The GHQ-12 is a valid and reliable tool to assess general psychological and adaptation disorders, which has been used widely in various population. [12-17]The instrument that has been used for this study was Indonesian version of GHQ-12,[18] however the scoring system refer to the original version.[19] The Likert scale scoring system 0-3 used in this study, with possibility of the score between 0 and 36. Cut of point of general population is 11/12, and someone is identified in distress condition with the score more than 15.[15,20]The data was analysed descriptively, and later statistical analysis was employed to see relationship between demographic factors and level of stress.

RESULT

A total of 263 participants were included in the analysis of the study, which most of them were female (76%) and from middle and rich socioeconomic family background (86.3%). Majority of them are also coming from West Sumatera Province (66.9%) and high school location in town or big city (91.6%) (Table 1). The admission pathway was comparable between high school matching programs or based on high school mark and national university entry written examination. The study also found 52.2% students had GHQ-12 scores above cut off point (CoP) of general public GHQ-12.and 14.8% were distress (table-1).

Table 1. Characteristic of participant's and GHQ-12 Score

Characteristics		f (%) n=263
Sex	Male	63 (24.0)
	Female	200 (76.0)
Socioeconomic status	Poor Family	36 (13.7)
	Middle class and rich family	227 (86.3)
High school location	District region	22 (8.4)
	Town and big city	241 (91.6)
Province of origin	West Sumatera Province	176 (66.9)
	Outside of the province	87 (33.1)
Admission Pathway	High school Matching Program	159 (59.3)
	National Entry Written exam	107 (40.7)
Government Scholarship	Supported	34 (12.9)
	Not supported	229 (87.1)
GHQ-12 Score	Below CoP	125 (47.5)
	Above CoP	138 (52.5)
Level of stress	Normal	224 (85.2)
	Distress	39 (14.8)

By comparing level of distress, there were no differences among participants in the different sex, province of origin and admission pathway($p>0.05$). Participants from lower socioeconomic status were slightly more in distress level (25.0%) than participants from middle class and rich family (13.2%). The participants who schooled previously in district region were also slightly more in distress level (27.3%) than

the participants from town or big city (13.7%). However, these are not significant (P>0.05). The participants who obtained specific government scholarship for the student from low socioeconomic status were significantly more in distress level (p<0.05) (table-2).

Table 2. Relationship between demographic factors and level of stress

	Factors	Level of Stress		*p*Value#
		Normal	Distress	
Sex	Male	53 (84.1%)	10 (15.9%)	0.789
	Female	171 (85.5%)	29 (14.5%)	
Socioeconomic status	Poor family	27 (75.0%)	9 (25.0%)	0.065
	Middle class and rich family	197 (86.8%)	30 (13.2%)	
High school location	District region	16 (72.7%)	6 (27.3%)	0.086
	Town and big city	208 (86.3%)	33 (13.7%)	
Province of origin	West Sumatera province	150 (85.2%)	26 (14.8%)	0.971
	Outside of the province	74 (85.1%)	13 (14.9%)	
Admission pathway	Matching program	132 (84.6%)	24 (15.4%)	0.759
	National entry written exam	92 (86.0%)	15 (14.0%)	
Government scholarship	Supported	24 (70.6%)	10 (29.4%)	0.010
	Not supported	200 (87.3%)	29 (12.7%)	

#calculated by chi-square

DISCUSSION

Based on the GHQ-12 level of stress indicator, the study found 14.8% participants were distress. Moreover, the study revealed that 52.2% participants had GHQ-12 scores above cut off point (CoP) of general public GHQ-12. This study in Indonesian context confirms various previous study about high prevalence of distress in medical students.[5,8,10,11] The study also confirm that learning in medical school become a big stressor for the students.

Various literatures mentioned that the level of stress in medical students is relatively higher because many factors, such as academic burden[8,21,22] or dislike to study of medicine.[23] Other non-academic factors may also have significant impact, such as feeling minority,[24] lack of social support,[11] facing bad social experience[25] and financial problem.[26]All these factors may also contributed to distress condition of new medical students in FMAU. In this study we did not explore deeper the cause but we only analysed few demographic factors that possibly related to level of stress.

By comparing level of distress, there were no differences among participants in the different sex, province of origin and admission pathway(p>0.05). Participants from lower socioeconomic status were slightly more in distress level (25.0%) than participants from middle class and rich family (13.2%). The participants who scholed previously in district region were also slightly more in distress level (27.3%) than the participants from town or big city (13.7%). The participants who obtained specific government scholarship for the student from low socioeconomic status were significantly more in distress level (p<0.05).Despite we did not explore deeply, this result confirm briefly that feeling isolated, socioeconomic and financial factors also affect on level of stress.[11,24,26]

CONCLUSION

This study showed that new medical students had higher average GHQ012 score or stress level than general public and few students tend to fall into distress level. Academic and non-academic factors may contribute to the condition. Furthermore, psychological test in admission and preparation for medical students need to be considered. Further study need to be conducted to explore specific factors that cause distress in medical student in Indonesian context, and to oversee the relation to academic performance.

Ethical Clearance: A formal permission taken from dean office of Faculty of Medicine of Andalas University.

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Conflict of Interest: Nil

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Can Hypocalcaemia Predict Adverse Outcome in Malaria?- Preliminary Data From Tertiary Care Centre in Western India

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ABSTRACT

Background: In India total economic burden from malaria could be around US$ 1940 million. This study aims to find with the prevalence of hypocalcaemia in the different types of malaria, whether it has any relevance to the clinical presentation of the disease.

Method: It was a prospective observational study done in tertiary care centre over a period of 3 months. Patients more than 12 years of age and confirmed cases of malaria on thick and thin smear examination were included in the study. Treatment was given as per standard protocol and as per discretion of treating physician. Serum calcium levels and ECG were done with all other baseline biochemistry of patient.

Results: Severity of presentation, QTc prolongation, hypotension and complicated malaria were compared with presence and absences of hypocalcaemia all were(using chi square test X2)statistically significant. Abnormal Renal function, liver function and coagulation profile were found to have no correlation with hypocalcaemia.

Conclusions: This study is showing that patients who have hypocalcaemia tend to present in critical condition, have hypotension, prolonged QTc and tend to complicate.

Keywords: *Malaria,Hypocalcaemia, Prognosis, QTc*

INTRODUCTION

Malaria is a major public health issue in India. Efforts are being done to control the disease in the country.In India total economic burden from malaria could be around US$ 1940 million. Death rates are not a significant factor because 75% of the burden comes from lost earnings and 24% from treatment costs.[1]

In 2015, 1.13 million cases were reported although the reported number of deaths were declined. Overall, in the last 10 years, total malaria cases declined by 42%, from 1.92 million in 2004 to 1.1 million in 2014, combined with a 40.8% decline in malaria related deaths from 949 to 562. India contributes 70% of malaria cases and 69% of malaria deaths in the South-East Asia Region. Presently, 80% of malaria occurs among 20% of people classified as "high risk", although approximately 82% of the country's population lives in malaria transmission risk areas. [2] As we are struggling to reduce the mortality in patients with malaria,it isnecessary to find factors which will help in predicting adverse outcome in these patients. Renal failure is common complication of severe malaria occurring in up to 50% of cases in the form of ischaemic nephropathy or acute tubular necrosis.[3]Alterations in the calcium and phosphate metabolism are frequently seen in patients with acute kidney injury. The hypocalcaemia that occurs in the oliguric phase being attributed to both skeletal resistance to the action of parathyroid and deposition of calcium in the tissues.[4] Ionized hypocalcaemia, inappropriately low serum PTH concentration and hypophosphatemia have also been documented in patients with acute malaria and normal renal function. There has been mention of

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hypocalcaemia but not much data available on its prevalence or its clinical correlation with severity of illness. This study deals with the prevalence of hypocalcaemia in the different types of malaria. , whether it has any relevance to the clinical presentation of the disease,measurement of the QTc interval in ECG of patients with malaria for possible correlation with hypocalcaemia. Also to study correlation of serum calcium levels as prognosticating factor in complicated malaria. Publishing this preliminary data.

MATERIAL AND METHOD

It was a prospective observational study done in tertiary care centre over a period of 3 months Ethical approval was obtained from Institutional Ethics Committee. Subjects were recruited in the study after obtaining written informed consent.Patients more than 12 years of age and confirmed cases of malaria on thick and thin smear examination were included in the study. Pregnant and postmenopausal women were excluded from the study. Patients on calcium supplements were also excluded from the study. All patients' detailed history was taken and clinical examination was done and recorded. All baseline investigations were recorded i.e. complete haemogram, Liver function tests, renal function tests and serum calcium levels. The serum calcium levels were corrected for hypoalbuminemia [Calcium = Serum calcium + 0.02 (Normal albumin – Patient albumin)]. Treatment was given as per standard protocol and as per discretion of treating physician. A 12 lead ECG was done in all patients and the corrected QT interval (QTc) was calculated (QTc= QT/"RR). The reference range of Serum Calcium for our laboratory was 8.5-11 mg/dl. For this study hypocalcaemia was defined as any Calcium value below 8.5 mg/dl after correcting for hypoalbuminemia. Artemisinin Combination Therapy (ACT) was given to all the confirmed P. falciparum cases found positive by microscopy. Mixed infections with P. falciparum were treated as falciparum malaria. Severe malaria was defined as one or more of the following features: Impaired consciousness/coma, repeated generalized convulsions, renal failure (Serum Creatinine >3 mg/dl), jaundice (Serum Bilirubin >3 mg/dl), Severe anaemia (Hb <5 g/dl), Pulmonary oedema/acute respiratory distress syndrome, Hypoglycaemia (Plasma Glucose <40 mg/dl), Metabolic acidosis, Circulatory collapse/shock (Systolic BP <80 mm Hg), Abnormal bleeding and Disseminated intravascular coagulation (DIC).[5]

Statistical Analysis

All comparative data was analysed using chi square test($X^{2)}$ and the co-relative data was compared using the Yule's coefficient of association (Q test).

RESULTS

Total 40 patients were enrolled for the study. Demographic parameters as described in Table 1.

Table 1: Demographic parameters in patients with Malaria

Parameter	Subgroups	Number (%)
Age (years)	15-24	12 (30)
	25-34	17(43)
	35-44	8(20)
	>45	3(8)
Sex	Male	34(85)
	Female	6(15)
Malaria	Uncomplicated	29 (72.5)
	Complicated	11 (27.5)
Type of parasite	Plasmodium Vivax	2 (5)
	Plasmodium Falciparum	28 (70)
	Mixed	10 (25)
Parasitic index	< 5	27 (67.5)
	>5	13 (32.5)

8(20%) patients were found to have acute kidney injury. Liver function tests were abnormal in 11(27.5%) of patients. Cerebral malaria was seen in 8(20%) of patients. All patients withsevere malaria were investigated for disseminated intravascular coagulation (DIC). 5 patients were having altered coagulation profiles. Table 2 is showing the correlation between different investigations and hypocalcaemia.

Table 2: Correlation between Different Investigations and Hypocalcaemia.

Parameter		Normal S Calcium N=18 (%)	Hypocalcaemia N=22 (%)	P Value	Significance
Severity of presentation	Uncomplicated	16 (88.8)	7(31.8)	<0.01	Significant
	Complicated	2(11)	15(68.2)		
Renal Function	Normal	16(88.8)	16(72.7)	> 0.05	Not Significant
	AKI	2 (11)	6(27.7)		
Liver Function test	Normal	6 (33.3)	5((22.7)	> 0.05	Not Significant
	Abnormal	12(66.6)	17(77.3)		
QT interval Corrected	Normal	16(88.8)	9 (40.9)	<0.05	Significant
	Prolonged	2(11)	13(59.1)		
Blood pressure	Normal	14 (77.7)	9 (40.9)	<0.01	Significant
	Hypotension	4 (22.2)	13(59.1)		
Parasitic index	< 5	14(77.7)	11(50)	<0.001	Significant
	>5	4 (22.2)	11 (50)		
Coagulation Profile	Normal	18(100)	17(77.3)	> 0.05	Not Significant
	DIC	0	5 (22.7)		

DISCUSSION

This study was conducted with 40 patients enrolled.Young adults were the highest affected ones , with male predominance(85%) in the study group .This is due to the access to health care system is more for the male sex in male dominant society of India. Also pregnant and postpartum patients were excluded as, they are usually on calcium supplements. Females tend to ignore symptoms and carry on with the chores.

Uncomplicated malaria was 72.5% as compared to complicated malaria. 70 % were Falciparum Malaria. O.5% of patients had P Vivax and 25% with mixed infections. However there was selection bias as only indoor patients were included in the study. In our study 8(20%) of patients were found to have acute renal failure. Liver function were abnormal in11 (27.5%) of patients. Cerebral malaria was seen in 8(20%) of patients. High parasitemia was seen in 15 (37%) of patients. In patients with severe malaria patients 5 had DIC and 2 of them died. Both the patients had hypocalcaemia with hypotension and QTc prolongation on ECG.

Our study showed hypocalcaemia in 22 (55%) patients .QTc interval was prolonged in 13 out of 22 patients with hypocalcaemia.Soni, C. L. at al[6] found, hypocalcaemia in 26 cases in which QTc was prolonged. Ten patients who had convulsions, all of them were having QTc prolongation and eight had hypocalcaemia. Our study showed 2 out of 18 patients' normal Serum Calcium levels had prolonged QTc (pvalue < 0.05). There was strong association between hypocalcaemia and QTC prolongation.

This study also found a significant association between hypocalcaemia and hypotension. Out of 22 patients with hypocalcaemia 13 patients had hypotension. Patients with normal S. Calcium levels only 4 had hypotension (p value <0.01). All the 13 patients of hypotension had prolonged QTc interval on ECG. High prevalence of hypocalcaemia is also known to occur in bacteraemia patients and patients who are in critical care.[7] Hypotension, cardiac insufficiency, arrhythmia like bradycardia, ventricular fibrillation and prolonged QTc are the reported manifestations of hypocalcaemia in critically ill. Hypocalcaemia should be considered in patients with hypotension responding poorly to fluids and vaso-pressor agents.

Complicated malaria was found in 15 out of 22 patients with hypocalcaemia and 2 patients with normal Serum Calcium levels (p value < 0.01). QTc interval was prolonged in 40.9 % of patients of hypocalcaemia. Soni at al found QTc interval and serum calcium were 0.468±0.055 sec and 8.16±0.86 mg/dl respectively in complicated falciparum malaria.They found that difference in QTc and calcium levels was significant between complicated falciparum and mixed infection when compared to uncomplicated falciparum and vivax malaria (P<0.05).

In the patients presented in critical condition 68.2% had hypocalcaemia which was statistically significant (<0.01) as compared to patients who had mild presentation. The coagulation profile was abnormal in 5 patients, all had hypocalcaemia. However whether there is any correlation between the two cannot be ascertained by the current study.

8 out of the forty patients developed acute renal failure with decreased urine output. There was definite positive correlation between the presence of acute kidney injury and hypocalcaemia. By the Yule's coefficient of association, the quotient of association was 0.5, although there was no significance found after applying the chi square test. Using the odds ratio, acute kidney injury was found to be 3 times more commonly associated with hypocalcaemia than with patients having normal serum calcium levels. Therefore the renal function did not show any co-relation to hypocalcaemia. However AKI may directly or indirectly produce an acute cardiac event and it can be associated to volume overload, metabolic acidosis and electrolytes disorders such as hyperkalaemia and hypocalcaemia; coronary artery disease, left ventricular dysfunction and fibrosis have been also described in patients with AKI with consequent direct negative effects on cardiac performance[8].

CONCLUSION

This study is showing that patients who have hypocalcaemia tend to present in critical condition, have hypotension, prolonged QTc and tend to complicate. Further study needs to be done with large sample size for better understanding of outcome prediction of hypocalcaemia in Malaria.

Conflict of Interest: Nil

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Ethical Clearance: Permission was obtained from Institutional ethics committee

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Amniotic Fluid Index - A Valuable Screening Test for Predicting Fetal Distress and Perinatal Outcome

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ABSTRACT

Objective: To evaluate the predictive value of amniotic fluid index (AFI) ≤ 5 for adverse perinatal outcome in terms of cesarean section for fatal distress, birth weight, meconium staining and Apgar score.

Method: This was a prospective study of 100 antenatal women at Guru Gobind Singh Medical College and Hospital, Faridkot (Punjab) during 2013 to 2015 with gestational age between 34 and 41 weeks. The women's history clinical examination was recorded and AFI was measured and perinatal outcome was compared between two groups i.e. AFI ≤ 5 and> 5.

Results: The rate of cesarean section for fetal distress and low birth weight babies i.e. <2.5 kg was higher in patients with oligohydramnios. There was no significant difference in meconium staining and Apgar score at 5 min.

Conclusion: Oligohydramnios has a significant correlation with cesareansection for fetal distress and low birth weight babies.

Keywords: *Meconium Staining, Cesarean Section, Apgar Score, Birth Weight, Oligohydramnios, Amniotic Fluid Index.*

INTRODUCTION

Obstetrics is concerned with health and well being of both the mother and unborn child. Recognition of a fetus at risk for death or damage in utero, quantifying the risk, balancing the fetal risk against the risk of neonatal complications from immaturity and determining the optimal time and mode of intervention are the cornerstones of modern perinatal medicine. Clinical estimation of amniotic fluid volume is an important part of fetal assessment as variation in its amount has been related to a variety of pregnancy complications.

Quantification of amniotic fluid is an important component of the biophysical profile in ultrasound evaluation of fetal well being especially in third trimester. Ultrasound being a non-invasive test is ideal for application on a large scale and can be used frequently for repeated amniotic fluid volume determination in case of suspected abnormalities. Oligohydramnios has been found to be linked with still births, fetal anomalies, abnormal fetal heart rate tracings in labour, increase in cesarean section for fetal distress. Phelan defined oligohydramnios as AFI ≤ 5 cm and borderline oligohydramnios as AFI between 5 and 8 - between 36-42 weeks of gestation1. Oligohydramnios occur in about 1-5% of pregnancies at term.2 Women with oligohydramnios are more likely to have abnormal or non-reactive fetal heart rate tracings. Oligohydramnios is also the leading indication for labour induction. Oligohydramnios is associated with a high rate of pregnancy complications and increased perinatal morbidity and mortality.3 AFI must be closely monitored and measurements obtained at least once per week. An increased incidence of cord compression is associated with oligohydramnios which can lead to variable

decelerations with cord occlusion as the proximate cause of fetal distress.[3] Thus, AFI assessed ante-partum or intra-partum would help to identify women who need increased antepartum surveillance for pregnancy complications.[4]

Pregnancies with decreased AFI between 24 and 34 weeks including borderline AFI as well as oligohydramnios, were significantly more likely to be associated with major fetal malformations and in the absence of malformations they are complicated by fetal growth restriction and preterm birth.[5]

In uncomplicated pregnancies at 40 to 41.6 weeks oligohydramnios is independently associated with a higher risk of low birth weight centile.[6]

Oligohydramnios is a frequent occurrence and demands intensive fetal surveillance and proper ante partum and intra partum care. Due to intra partum complications and high rate of perinatal morbidity and mortality, rates of cesarean section are rising, but decisions between vaginal delivery and cesarean section should be well balanced so that unnecessary maternal morbidity is prevented and on the other side timely intervention can reduce perinatal morbidity and mortality.[7]

MATERIALS AND METHOD

This was a prospective study of 100 antenatal women at Guru Gobind Singh Medical College and Hospital, Faridkot during 2013 to 2015 with gestational age between 34 and 41 weeks with no known obstetric or medical complications. The exclusion criteria were the presence of obstetric on medical complications and an unwillingness to participate. The women were divided into control and study group based on AFI. AFI was measured with four quadrant technique and those women with AFI<5thpercentile i.e. AFI ≤5cm were included in the study group and women with AFI > 5cm were included in control group.

Follow up of the patients was done till they presented in labour room or were admitted to labour room.

On admission Non stress (NST) was done for both control and study groups. Those with non-reactive NST and not in active labour also had Biophysical profile done.

Documentation of obstetric interventions in the form of induction or augmentation of labour and mode of delivery was done. Documentation of neonatal outcomes in terms of birth weight, Apgar score was also done.

Admission to the NICU for perinatal morbidities like Apgar≤7, seizures, hypoglycaemia, meconium aspiration, respiratory depression and perinatal mortality was documented.

The results were recorded and tabulated.

RESULTS

Out of 100 women included in the study, 61.5% in the study group and 58.6% in the control group were primiparous which was comparable and the maternal age was also comparable in both the group as shown in table I.

The non-stress test was non-reactive in 30.7% of pregnant women in study group and only in 10.34% of control group as shown in Table III.

Table 1: Maternal demographic and obstetric characteristics

		Study Group AFI ≤5 n = 13	Control Group AFI >5 n = 87
1	Maternal age (years) (mean)	27.04 years	27.95 years
2	Nulliparty	8 (61.5%)	51 (58.6%)
3	Gestational age <37 weeks at delivery	7 (53.8%)	30 (34.4%)
4	Weight gain ≤10kg	4 (30.7%)	8 (9.19%)
5	Induction of labour	9 (69.23%)	45 (51.72%)

Table II: Obstetric and Perinatal Outcome

		Study Group AFI ≤5 n = 13	Control Group AFI >5 n = 87
1	Meconium stained liquor	2 (15.3%)	13 (14.9%)
2	Total cesarean section	9 (69.23%)	29 (33.33%)
3	Cesarean for non-reassuring fetal statue	4 (57.1%)	12 (38.7%)
4	Birth weight <2.5kg	7 (53.8%)	19 (21.8%)
5	Apgar score at 1 min <1	4 (30.7%)	10 (11.5%)
	at 5min <1	1 (7.7%)	3 (3.4%)

Table III: Distribution of NST pattern

		Study Group AFI ≤5 n = 13	Control Group AFI >5 n = 87
1	Non reaction NST	4 (30.7%)	9 (10.34%)

Table IV: Mode of Delivery

	Type of Delivery	Study Group AFI ≤5 n = 13	Control Group AFI >5 n = 87
1	Vaginal Delivery	4 (30.76%)	58 (66.66%)
2	Cesarean Section	9 (69.23%)	29 (33.33%)
3	Forceps	-	-

Table V: Neonatal Complications

Number of Deliveries = 100

	Neonatal Complications	Study Group AFI ≤5 n = 13	Control Group AFI >5 n = 87
1	Shifted with mother	8 (61.5%)	77 (66.99%)
2	Low birth weight	2 (15.38%)	-
3	Respiratory distress	2 (15.38%)	5 (5.74%)
4	Meconium aspiration	2 (15.38%)	1 (1.14%)
5	NICU admissions	5 (38.46%)	9 (10.3%)
6	Still births	1 (7.69%)	-
7	Neonatal deaths	1 (7.69%)	-

Only 33.33% delivered by cesarean section in control group while about 69.23% of the patients delivered by cesarean in study group, while 57.1% underwent cesarean section for non reassuring fetal heart rate pattern in the study group (AFI ≤5) only 35.5% underwent cesarean for the same indication in control group as shown in Tables II and Table IV.

53.8% of mothers had babies with birth weight <2.5kg in study group and only 21.8% had birth weight <2.5kg in control groups as shown in Table II.

The Apgar score of <1 at 1 min was present in 30.7% of study group and in 11.5% of the control group. The Apgar score of <7 at 5 min was present in 7.7% of study group and 3.4% of the control group as shown in Table II.

There were 38.46% of the neonatal admissions in study group and 10.3% of neonatal admissions in control group as shown in Table V.

Respiratory distress was present in 15.38% of babies of study group as compared to 5.74% of the babies of control group as shown in Table V.

Meconium stained liquor was present in 15.3% of cases in study group and in 14.9% of cases in control group which was not significant. Meconium aspiration was present in 15.38% of babies of study group and 1.14% of babies of control group as shown in Tables V.

There was no stillbirth and no neonatal death in control groups as compared to one still birth and one neonatal death in study group.

The above results show that maximum perinatal morbidity in the form of fetal distress and low Apgar scores was seen in study group with AFI ≤5 as shown in Table V.

DISCUSSION

In the present study about 13% of the patients who presented with oligohydramnios were admitted 30.7% of those patients had non-reactive NST as compared to only 10.34% in the control group with AFI >5cm.

The cesarean section rate was higher in study group where AFI ≤5 i.e. 69.23% as compared to the control group where the cesarean section rate was only 33.33% which is quite significant and is similar to the study of Chauhan et al,[8] Soumya et al[9] and Guin Gita et al.[10]

There was no differences in the meconium staining of liquor in both the groups which was similar to the study conducted by Voxman et al.[11]

The NST was non reactive in 30.7% of the cases in study group and in only 10.34% of cases in control group which is significant.

The birth weight was <2.5kg in 53.8% of babies in study group (AFI ≤5) and in 21.8% of babies in control group (AFI >5)

Locatelli et al reported that oligohydramnios independently increased the risk for small for gestation age infants.[6]

Morris et al found that 60% of babies with low birth weight had oligohydramnios indicating that oligohydramnios was associated with growth restriction.[12]

The apgar score of <7 at 1 min was present in only 4 babies (30.7%) in study group and in 10 babies (11.5%) in control group which is quite significant. A study by Grubb et al had similar results.[13]The same result was reported in study conducted by Golan et al.[14] The study by Vidyasagar et al showed similar results.[15]

CONCLUSION

Oligohydramnios is a frequent occurrence in obstetrics and is often associated with other maternal and fetal complications. Oligohydramnios is being detected more often these days due to routinely performed obstetrical ultrasound.

In the present study oligohydramnios was associated with increased cesarean delivery. A significant correlation was found between oligohydramnios and low birth weight babies. However, there was no difference in perinatal outcome in terms of meconium staining and apgar score at 5 min. When secondary outcome was measured, significant correlation was found in terms of non-reactive NST and admission to the NICU. Determination of AFI can be used as a tool to other fetal surveillance methods. It helps to identify high risk pregnancies with guarded perinatal outcome so that timely termination of pregnancy is done to improve perinatal outcome.

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Store Ambiance Influence on Consumer Impulsive Buying Behavior towards Apparel: S-O-R Model

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ABSTRACT

Guided by the S-O-R (Stimulus-Organism-Response) model. The purpose of this research is to study was to find the relationship between store ambience factors towards impulsive buying behavior of apparel among the consumers in Chennai city. Theare four important store ambience factors are being recognized like (color, odors, temperature, Participant factors)which is also endogenous variables in the study and the consumer impulsive buying behavior as a exogenous variable. Each of the store ambience factors was tested using SPSS software .The test comprises of cronbach alpha, regression test were used in order to understand the consumers reply towards the ambiance factors.Questionnaires were distributed to the respondents which were filled by the customers who already buy the apparel products. Quantitative research, Purposive sampling comprising of sample size was 250 were return out of 250 samples usable data for study were 215 samples . The respondents rates was 84%.

Keywords: *Color, Odors, Temperature, Participant factors, Apparel, Store Ambience.*

INTRODUCTION

Retail business is a type of industry with high level of struggle. The achievement of retail business is prejudiced by its quick response and its capability in accepting customers behaviors. Retail industry necessity focus to its consumer preferences and factors influence a customer's purchase decision. Store ambience factors (including Color, Odors, Temperature, Participant factors so on) outline the overall circumstance within which purchaser make choice of store range. Past study on retail atmosphere recommended that such factors affect the picture of the store. Retailers understand the significance of these factors like Color, Odors, Temperature, Participant factors and analytically attempt to benefit of an atmosphere, including fitting colors, and so on that will draw their goal of the consumers.

Consumers visiting the mall to purchase apparels were also considered for the study. Impulse buying is a persistent feature of customer behavior . It is one of the key reflection for marketing actions suitable to the difficult and wide-spread occurrence of desire buying diagonally for a mixture of products[1].Causes for impulse buying might include environmental factors such as motivation in the retail store ambience (e.g. useful implication by welcoming sales people) and individual factors[2] (e.g. shopping enjoyment)

The role of store ambiance in the achievement of retail showroom can not be ignored[3]. Retail outlets are slowlyreplace small conventional retailers. The victory of the retail industry in evaluation to habitual retailers is accredited to expediency, enormous space , low prices, option of goods.

For manufacturer and store retailers, shopping is the fine art of influence(persuasion). While there are many store ambience that can manipulate how and what the customers will buy. Though, diagram cues such as Color, Odors, Temperature, Participant factors physically powerful and most influential factors compare to the other factors [4].

OBJECTIVE OF THE STUDY

- To examine the perceptional level among consumers towards store ambience on Impulsive buying behavior on apparels among consumers in Chennai.

To analyze the association among cleanliness, Odor, Color and Participant factors

To analyze the association between store ambience and Impulsive buying behavior for apparel among consumers in Chennai .

Review of Literature

Cleanliness

Cleanliness concentrate on the look of the retail store which develops the ambiance. It influences the consumer semotion towards the store. Consumers create optimistic or pessimistic word of mouth about retail store by look at the hygiene (Banat & Wandebori, 2012). Cleanliness can develop store ambiance.[5]

Odor

Presence or absence of scent/odor in the retail chain store has perceptible influence on the customer buying behavior. Odor is a amusing fragrance that persuade consumer emotion and mood which create the consumers continue additional time and feel energized[6] .Accurate use of odorhelps to assessment of products that are unknown or not well resembled[7]. Purchasers use additional money at the store with particular odorevaluate to those customers who are uncovered to several fragrances [8].

Color

Color make emotion and influence customer performance and attitude[9]. It could arouse reminiscences, opinion and familiarity.

Participant Factors

Based on the examination of Fournier the association among customers and salespersons is incomprehensible. Consumers will form dissimilar opportunity towards salespersons support on the store ambiance. In diverse types of store, salesperson service will provides special target and errands towards their goal consumers [9]. Look, thoughts and actions of the staff, sales person would influence consumers hope towards the store ambiance[10]. Consumers feel fulfilled when the sales person are able to give surprising services practices to them e -buying behavior[11]

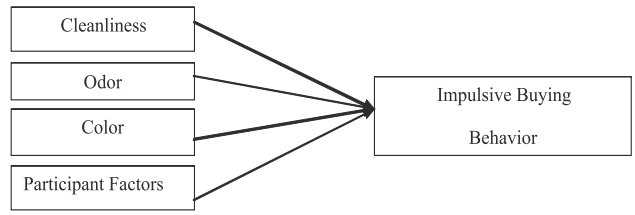
Present review of literature recommends store ecological characteristics or store ambiance influence customers recent store performance, and outlook for store purchase assessment[12].The outcome of ecological characteristics or store ambiance have been additionally examined to recognize customer impulse towards buying behavior. Several research[13].

Theoretical framework

The hypothetical framework developed for this research is foundation on the Stimulus-Organism-Response (S-O-R) Model (Mehrabian and Russell, 1974) and the impulse buying behavior literature. For example, Hulton (2013) perform a field research in a home delivering store, which was supported on the stimulus-organism-response (S-O-R) model and the retail ambiences literature; image sensory cues had a optimistic collision on customers leaning to touch products, purchase target, and entire amount of money tired also.

This research focus on the association of store ambiance towards customer emotion and impulsive buying behavior (Pan et al., 2009). There are four independent variables in store ambiance (color, odor, cleanliness ,participant factors),

Store Ambiance Factors



Source : Pan, F. C., Su, S. J., & Chiang, C. C. (2008). Dual attractiveness of winery: atmospheric cues on purchasing. International Journal of Wine Business Research, 20(2), 95-110.

Research Gaps

Research Gap 1: Though there have been research studies on store ambience, limited publication are found on the important dimensions like odor, color content among consumers India. This article helps to create the awareness towards the retailers , how to retain the consumers.

Research Gap 2 : There is very few international Context relating to store ambiance .

Research Methodology

Research design for the article is descriptive research design . The samplesize for the research was (N=215). Purposive Sampling was selected for the study

.Questionnaire was circulated among consumers in Chennai. Statistical Package for Social Science version 16.1 were use for evaluating the data.

Reliability statistic

Table 1: Reliability statistics

Variables	No. of items	Cronbach's Alpha
Cleanliness	5	.823
Color	5	.798
Odor	5	.711
Participant Factors	5	.801
Impulsive Buying Behavior	5	.761
Overall Reliability	25	.793

Reliability Statisticsindicates the uniformity of applicant's answer to the statement of questionnaire which supports the normal association between those variable. Table 1 presents A reliability test using all five constructs had Cronbach alpha ranging from 0.711 to 0.823, which were above 0.70 or standard value set by Nunnally (1978) and, therefore, considered good reliability. The items were measured using a five-point scale ranging from (1) "Strongly disagree" to (5) "Strongly agree."

The reliability analysis of the 25items , produced an overall Cronbach alpha coefficient of0.798, which proves to be significant. A study with a coefficient of 0.7 or good is considered reliable (Girden,2001).

Data Analysis and Interpretation

The structural equation model was used to test the hypothesis and find the relationship between the exogenous variables and endogenous variables. Structural equation model moves on to present the measurements and give a clear explanation on the analysis of testing the hypothesis. The SEM model clearly indicates the relationship between the Store ambiance influence impulsive buying behavior

In SEM there are actually two models, one is the Measurement model and the other is the structural model. The structural equation model was used to the extent to which a hypothesized data fits or adequately illustrates or describes the sample of data.

The model fitting steps were done to determine the goodness of fit between the hypothesized model and sample data. Goodness of fit indicates the extent to which the specified model reproduces the observed co-variance matrix among the indicator items.

For all goodness of fit measures, statistics are given in a continuum, with the independence model as the most restricted model and the saturated model as the least restricted one. Once the model is estimated, model fit ensures to compare the theory. If the theory is perfect, the observed and estimated covariance matrices will be the same.

Chi square goodness of fit metric test is done to find the relationship between theoretical specification and empirical data.

The null hypothesis of SEM is that the observed sample and the structural equation model estimated covariance matrices are equal, meaning perfect fit. The chi-square value will increase as the residuals are found. The goodness of fit was first formulated by Joreskog & Sorbom in 1982.

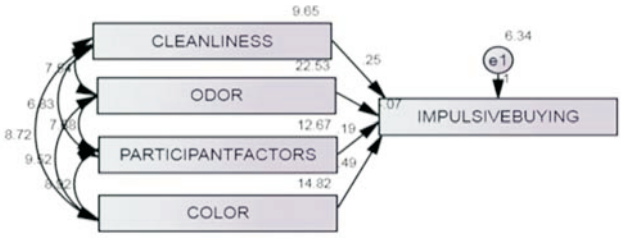


Fig. 1. Hypothesized model for the effects of exogenous variables on the endogenous variables.

Table 2: Amos output showing model fit

Model	NPAR	CMIN (x sq)	Df	P	x sq/df
Default Model	20	2.117	1	0.137	2.037
Saturated Model	21	.000	0		
Independence Model	5	710.251	15	.000	38.027

Table 3: Model fit statistics on the measurement model

Fit Statistic	Recommended	Obtained
Chi square	-	2.037
Df	-	1
x sq Significance	P<=0.05	0.001
x sq/df	<5.0	2.037
GFI	>0.90	0.98
AGFI	>0.90	0.93
NFI	>0.90	0.98
RFI	>0.90	0.94
CFI	>0.90	0.98
TLI	>0.90	0.97
RMSEA	<0.08	0.07
RMR	<0.10	0.10

FINDINGS

The results shown Table 2 provides an overview of the model fit, which includes the Number of parameters, CMIN and Degrees of freedom values.

In SEM a small chi-square value supports the model that is being tested. In this model the Chi square value is 2.037 and small compared to the Independence model which is 720.252. This shows that the Chi square value is good. It is also needed to check the value of Chi square divided by the degrees of freedom. It is said that this metric should not exceed 5 for models with good fit. Here, in the above mentioned table, the Chi square /df is 2.037 which is an acceptable model fit

The other different model fit measures used to check if the goodness of fit is acceptable is mentioned below.

From the Table 3 statistics we should understand x sq for a just –identified model generally equals zero and has no degrees of freedom. It is also noted that if Chisquare=0, the model perfectly fits the data. The Chi square here is 2.037 which is a good model fit. GFI=.98indicates that the model is perfectly fit; the GFI which is greater than 0.98 indicates good fit. In the above mentioned table the Goodness fit index obtained is >0.90 indicating that this model is a good fit model. The AGFI here is 0.93 which is also greater than the recommended value of 0.90 showing a good fit. The Normed fit index (NFI), Relative fit index (RFI), Comparative fit index (CFI) and the Tucker Lewis Index (TLI) are 0.98, 0.94, 0.98 and 0.97 respectively which is greater than 0.90 indicating the model is a good fit.

The RMSEA is 0.07 which is within the recommended level of 0.08 and RMR also is well equal to the limit showing an overall acceptable fit.

CONCLUSION

This article examine the determinants of Store ambiance and Consumer impulsive buying behavior towards apparel structural equation models (SEM) with experiential and hidden variables. Model indicates the store ambiance towards the customer also influence the impulsive buying behavior. Color, Odor, participant factors increases the buying behavior about the products based on store environment and it increases the purchase level also. Based on the Partial S-O-R model environmental stimuli influence the buyer behavior in the store . When the consumer are stay extra time to purchase because of store ambiance. Retailers are concentrate on external factors like store ambiance factors They are ready to purchase more products.

DISCUSSION AND IMPLICATION

Based on the SEM recommended store ambience has strongly influenced to buy more apparel products Finally impulsive buying behavior was calculated to see respondents to buying apparel based on store ambiance .

In nutshell, this research concluded that store ambiance is an important factor on shaping consumer impulsive buying behavior. Hence, it is essential to continuously conduct future research with in-depth knowledge on this topic because store ambiance is foreseen as vital for today s business world.

Retailer and Manufacturer also increase the awareness towards store ambiance towards apparel to the consumer. Model also proved goodness of fit based on S-O-R model. The study was limited to consumers in Chennai districts only , it can be improve to other districts also .

Ethical Clearance: NA

Source of Funding: Self

Conflict of Interest: Nil

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The Relationship Between Benzene Vapor's Exposure and Immunoglobulin among Shoes Worker in the Village of Tambak OSO Wilangun Surabaya

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ABSTRACT

Glue is one of the most important ingredient in the making of shoes, that it contains an organic solvent which is benzene. Benzene solvent in glues known by 1-2%. Benzene is known as a carcinogen category A1,confirmed human carcinogen, meaning that benzene has been ascertained and proven carcinogen in humans. Chronic exposure to benzene affects on cellular and humoral immunity. Benzene evaporates into the air very quickly allowing to be inhaled by workers. The purpose of this study are(1) to measure the levels of benzene vapor in the work environment, (2) to determine the concentration of A Immunoglobulin among workers and (3) to determine the relationship between benzene vapor exposure and workers' IgA concentration. The method used to measure the levels of benzene vapor in the workplace was gas chromatography method using GC / FID (Flame Ionization Detector) and to determine the concentration of A Immunoglobulin, venous blood sampling was done and then analyzed by Immunoturbidimetric Assay.

Benzene vapor's levels of shoes workers in workplacewas varied, from 0.0129 ppm to 2.3330 ppm which was 0.5116 ppm in average and IgA concentration experienced a value of 0.86 mg/ml to 3.80 mg/ml. Pearson product moment test was conducted on worker characteristics (age, year of service), Spearman's rank test on nutritional status and contingency coefficient C test for gender and smoking habits with IgA concentration of workers obtained all the variables had a value of p> 0.05.

The result showed that the IgA concentrations among workers which were 8 workers noted as under normal (<2 mg/ml) and 8 workers experienced a normal IgA concentration (2-3 mg/ml) while 4 others were above normal (> 3 mg/ml) with ppm benzene levels 0.0129 - 2.3330 ppm and average levels of benzene in the air amounted to 0.5116 ppm>TVL (0.5 ppm). In conclusion, twelve workers witnessed an abnormal IgA concentration (decrease / increase of the normal value).

Keywords: *Shoes Worker, Benzene, Glue, Iga Concentration.*

INTRODUCTION

Three main toxin in the shoe industry are benzene, toluene and xylene (BTX). Among those three toxin, benzene has a higher health risk than two other toxins. Benzene is a carcinogen category A1 (confirmed human carcinogen), while toluene and xylene are noted as the category A4 (not classifiable as a human carcinogen). This means that benzene has been ascertained and proven human carcinogen [(1,15).] In the shoe industry, benzene is used as a solvent glue latex. The glue used to glue the parts of the shoe, especially shoe soles. The organic solvent toluene solvent in glues containing more than 70% and solvent benzene is about 1-2%.

Indonesia sets a Threshold Limit Value (TVL) for benzene of 0.5 ppm which is according to the regulation of the Minister of Manpower and Transmigration No. PER.13 / MEN / X / 2011 in 2011 on Threshold Limit Values Physics and Chemistry Factors at Work [(13).]

Research among 79 workers in 5 shoes workshops in PIK Region Pulogadung obtained RQ> 1 (RQ realtime RQ lifetime 66% and 46%) and ECR> 10^{-4} (ECR realtime and a lifetime 100%). This means that workers in the shoe's repair shop have a risk to get the effect of non-cancer and cancer due to exposure to benzene at work even though the concentration of benzene under the

TVL that the Indonesian authorities. In average, the concentration of benzene in five shoe's repair shops is 0.2 mg/m3 (0.06 ppm) of three shops while others are 0.0194 mg/m3 (0.0293 ppm) and 0.1298 mg/m3 (0.04 ppm) [14].

In a study conducted byKurniawidjaja L Meily et al, (2012)[8]concerning respiratory complaints and health risk analysis BTX exposure to workers in the informal footwear workshops in Ciomas, Bogor regency obtained a mean grade of 1.40 ppm benzene vapor among 21 workers (63.03 %) complained of respiratory problems.

Research of Maywati Sri (2012)[11]showed that 57 workers in gluing in sandals industry Tasikmalaya obtained benzene vapor levels ranging from 0.138 ppm - 6.271 ppm. Most workers (35 or 61.4%) let alone the affected body part glue or delay cleaning up until it was completed.

Interviewed research conducted by Maryiantari (2016)[10] at RW 2 in the village of TambakOsoWilangun Surabaya showed most of workers complaints was about respiratory distress, coughing and shortness of breath which was 16 people (31.4%) and colds that noted 15 people (29.4%). While complaint about central nervous system (CNS) disorder widely perceived by the workers was headache 35 people (68.6%), fatigue 33 persons (64.7%) and drowsiness 30 people (58.8%). In addition, most workers feel headaches 2-3 times a week.

The clinical effects of benzene systemically causes disturbances in the cardiovascular, respiratory, neurological, gastrointestinal, liver, kidney, endocrine and reproductive system, dermatology, local effects, hematological, immunological, metabolic and allergic reactions. In chronic exposure of benzene showed effects on cellular and humoral immunity [2,5,12,4].

To learn and anticipate the continued effects resulting from exposure to benzene and refers to various cases in the world in respect of the use of benzene, it is deemed important to see if the same thing applies to the middle of the shoe craftsmen in the village of Tambak OsoWilangun Surabaya. To see it, there should be a study to analyze the relationship between exposures to benzene vapor in particular concentration of A Immunoglobulin (IgA) at the shoes workers in the village of TambakOsoWilangun Surabaya.

MATERIAL AND METHOD

Research design

This study used cross sectional design to measure the levels of benzene in the air with a concentration of A Immunoglobulin among shoes workers.

The place and time of the study

This research was conducted in the home shoe industry in TambakOsoWilangunSurabaya and implemented in November 2016.

Research subject

Subjects of this study was 20 workers who were healthy, not pregnant and not an alcoholic.

Questionnaires

Questionnaires were distributed to the shoes workers to obtain biographical data and other information.

Measurement of levels of benzene in the air (work environment).

Benzene concentration in the workplace was measured in eight points in seven locations of shoes workers ofTambakOsoWilangun Surabaya. All the measurements performed during the day at 12.00-14.00 PM considering that this time is the peak time of using glue, the temperature is quite high and causing benzene in glue evaporates quickly, so it easily captured the vacuum of air (vacuum pump)[9]. The chosen location was the work site where normallygluing conducted. Measurement of thebenzene concentration in the workplace carried out using the measurement method NIOSH 1501 with pipe material activated carbon absorber (charcoal) using Cromatography Gas Flame Ionisation Detector (GC-FID) techniques.

Measurement of concentrations of IgA

Venous blood was drawn as many as 3 cc and collected in EDTA tubes. Samples were then centrifuged

and the resulting blood serum samples. Examination of serum IgA were calculated using Immunoturbidimetric Assay.

FINDINGS

This study used shoes workers who were stay in site of shoes manufacturing as respondents. Shoes workers in TambakOsoWilangun usually glued by using their fingers, without any personal protective equipment or gloves, so that the solvent benzene in glue can enter through the skin. The air temperature of the workplace was high and the smell of glue fumes are so terrible, the workers also did not use a mask so that the glue vapor can be inhaled and enter through inhalation (respiratory). In fact, most workers were shirtless while smoking or even eat in that place. While the resting time, they took a rest and slept in there. Worker characteristics obtained from the questionnaire can be seen in Table 1 below:

Tabel 1. Worker characteristics

No	Variable	characteristics	Result	
			n	%
1	Age	min (23 years)	-	-
		max (63 years)	-	-
		Mean (46,6 years)	-	-
2	Gender	Male	10	50
		Female	10	50
3	Year of service	min (2,5 years)	-	-
		max (43 years)	-	-
		Mean (25,57 years)	-	-
4	Nutritional status (BMI)	thin (<18.5)	1	5
		normal (18.5 - 25)	9	45
		obese (> 25)	10	50
5	Smoking habit	Smoker	8	40
		Not smoker	12	60

Information :*BMI (Body Mass Index) is the ratio of weight (kg) by the square of height (meters).

Analysis of the relationship between benzene vapor concentration in the air and IgA concentrations in the blood of workers can be seen in Table 2.

Table 2. Levels of benzene vapor in the air with the concentration of immunoglobulin A (IgA) in the blood of workers

Workplace	Level of benzene vapor	IgAconcentration		
		< 2 mg/ml	2-3 mg/ml	> 3 mg/ml
1	0.3975	2	2	0
2	0.0129	2	1	0
3	0.3503	1	1	1
4	0.0193	0	2	0
5	0.9129*	0	0	1
6	2.3330*	2	0	0
7	0.0182	1	1	1
8	0.0485	0	1	1
Total	4.0926	8	8	4
Mean	0.5116	0.4	0.4	0.2

* Exceeding TVL levels of benzene according to Permenakertrans 13 / MEN / X / 2011 of 0.5 ppm.

Table 2 showed the IgA concentrations among workers which were 8workers noted as under normal (< 2mg/ml) and 8 workers experienced a normal IgA concentration (2-3 mg/ml) while 4 others wereabove normal (>3 mg/ml) with ppm benzene levels 0.0129 - 2.3330 ppm and average levels of benzene in the air

amounted to 0.5116 ppm>TVL (0.5 ppm). In conclusion, 12workers witnessed an abnormal IgA concentration (decrease / increase of the normal value).

To determine the relationship between the dependent variable (the concentration of IgA) and independent variables (levels of benzene in the air), a qualitative analysis was conducted by frequency distribution table while to know the relationship between the dependent variable (the concentration of IgA) and independent variables (the characteristics of workers), some analysis were used which were Pearson product moment (age, year), spearman's rank test (nutrition) and test contingency coefficient C (gender, smoking habits). All variables have a value of p>0.05, as shown in Table 3. This shows that there is no significant relationship between all the variables with a concentration of IgA.

Tabel 3. The results of worker's characteristics test by a concentration of ImmunoglobulinA (IgA) of worker's blood (α = 0,05).

No	Variabel	P value	Information
1	Age	0,489	Unsignificant
2	Gender	0,395	Unsignificant
3	length of employment	0,821	Unsignificant
4	Nutritional status (BMI)	0,056	Unsignificant
5	Smoking habit	0,395	Unsignificant

Table 3.shoesworker characteristics (age, sex, length of employment, nutritional status and smoking habits) did not have a significant relationship with the concentration of IgA in the blood of workers due to the value of p> α = 0.05.

The result of the calculation of non-carcinogenic risk characteristics (RQ) and carcinogenic risk characteristics (ECR) on all 20 workers are as shown in Table 4.

Table 4. Distribution of RQ and ECR in the shoes workers in the village of Tambak Oso Wilangun in November, 2016.

		Amount		Total
		person	%	
RQ	RQ ≤ 1	7	35	20
	RQ > 1	13	65	
ECR	ECR ≤ 1	5	25	20
	ECR > 1	15	75	

Based on the calculation of RQ and ECR in all 20 workers was obtained RQ > 1 at 65% and ECR > 1 by 75%, meaning that 65% of workers have exposure non-cancer effects due to benzene exposure and 75% of workers at risk of cancer due to benzene exposure.

This study showed that age, gender, length of employment, nutritional status and smoking habits of workers is not related to the concentration of IgA. By the analysis of the relationship benzene vapor concentration in the air with IgA concentrations in the worker's blood obtained average levels of benzene in the air amounted to 0.5116 ppm>TVL (0.5 ppm) and there were 12workers who have an abnormal IgA concentration. 8 of those experienced a decreased IgA concentration while others were increased.

In line with the research of BogadiSare et al (2000)[3]among women workers in the shoe industry concluded that there was a decrease in the concentration of IgA in workers exposed to benzene (below 15 ppm) compared to the control group, although not showed a significant correlation and confounding factors (age, duration of exposure and the smoking habits) does not affect the value of immunoglobulin. Studyof Kirkeleit J et al (2006)[7] also concluded the same thing on the oil tank working with benzene concentrations between 0.01 to 0.62 ppm which the concentration of IgA oil tank workers has decreased compared to the control group and the absence of a relationship between smoking and duration index exposure to benzene at a concentration of IgA. Similarly, Khadiga Ibrahim S. et al (2014)[6]concluded that workers who were exposed to benzene painting showed a decrease in IgA concentrations than the control group that was not exposed to benzene.

Despite the age, sex, length of employment, nutritional status and smoking habits of workers do not have a significant relationship with the concentration of IgA in the blood of workers, but shoes workers in the village of Tambak Oso Wilangun Surabaya has the effect of exposure to non cancer by 65% (13 of 20 workers have the effect of exposure to non-cancerous) and 75% (15 of 20 workers) at risk of cancer due to benzene exposure.

This study using environmental monitoring to measure exposure to benzene in the workplace, where the environmental monitoring cannot measure the amount of benzene exposure on each worker. Further research may be able to use monitoring personal such as the measurement of benzene by breathing zone or biological monitoring benzene exposure to test S-phenylmercapturic (S-PMA).

CONCLUSION

1. The average air levels of benzene in the workplace ofhome shoe industry ofTambakOsoWilangun Surabaya witnesses 0.5116 ppm, exceeding the levels of benzene according Permenakertrans NAB 13 / MEN / X / 2011 of 0.5 ppm.
2. Characteristics of workers (age, sex, length of employment, nutritional status and smoking habits) did not have a significant relationship with the concentration of Immunoglobulin A (IgA) in the blood serum of workers.
3. Of the 20 research subjects were exposed to benzene obtained 8 of them decreased concentrations of IgA and 4 increased serum concentrations of IgA.
4. RQ and ECR in all 20 workers was obtained RQ > 1 at 65% and ECR > 1 by 75%, meaning that 65% of workers have exposure non-cancer effects due to benzene exposure and 75% of workers at risk of cancer due to benzene exposure.

Conflict of Interest: None

Source of Funding: Department of Occupational Health and Safety, Airlangga University, Surabaya Indonesia

Ethical Clearance: The study was approved by the institutional Ethical Board of the Public Health, Airlangga University.

All subjects were fully informed about the procedures and objectives of this study and each subject prior to the study signed an informed consent form.

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Perceived Emotional Stress and Pre-Eclampsia: A Case-control Study

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ABSTRACT

Introduction: There is lack of consistency in association of psychosocial stress with pre-eclampsia. Women with pre-eclampsia have increased levels of corticotrophin releasing hormone and sympathetic activity. Psychological stress can be reduced by interventions.

Objectives: To find if perceived emotional stress is associated with pre-eclampsia.

Methodology: This case-control study recruited 100 pregnant women diagnosed with pre-eclampsia and 200 gestational age-matched controls. Perceived emotional stress was assessed using Cohen's PSS-10 instrument. Odds ratio was calculated and Mann Whitney U test was used to compare median PSS scores.

Results: The median PSS score among cases was found to be 14, while the median PSS score among controls was found to be 13. Statistically significant difference was observed between the scores of cases and controls.

Implications: Interventions to manage emotional stress during pregnancy may be helpful in preventing the development of pre-eclampsia.

Keywords: *Antenatal Care, Cohen's Perceived Stress Scale, Eclampsia, Hypertensive Disorders Of Pregnancy, Maternal Health, Pre-Eclampsia, Psychological Stress*

INTRODUCTION

Hypertensive disorders of pregnancy are an important cause of maternal and foetal morbidity and mortality and are known to complicate 8% of all pregnancies worldwide. [(1)]Pre-eclampsia is the commonest hypertensive state occurring in 4-7% of all pregnant women in developing and developed countries.[(2)] Hypertension accounts for 5% of maternal deaths in India.[(3)] This is a significant figure in the light of the fact that developing countries like India contribute more than half of the global burden of maternal mortality.

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The aetiology of pre-eclampsia is not precisely known, though it is understood to be occurring as a result of an interplay of immunologic, genetic and environmental factors.[(1)] Mothers aged above 30 years and primigravid, having a personal and family history of hypertensive disorders during pregnancy and having concurrent diabetes, chronic hypertension and renal diseases are at increased risk of pre-eclampsia.[(4-9)]All the above factors have shown consistent association in studies from various parts of India and other countries.[(7, 10-12)]

However, there is a lack of consistency in findings from studies that explored the association of psychological stress and pre-eclampsia. Findings from individual studies from different parts of the world have been found insignificant in some systematic reviews.[(13-19)] Women with pre-eclampsia and gestational hypertension were found to have increased levels of corticotrophin-releasing hormone and sympathetic activity, which are correlates of psychological stress.[(20)]

Psychological stress is directly amenable to interventions and can be attempted to reduce in order to improve maternal and foetal outcomes.

Present study investigated the association of perceived emotional stress with pre-eclampsia by comparing the levels of perceived emotional stress among mothers with and without pre-eclampsia.

METHODOLOGY

Mc Gann Teaching Hospital is a tertiary care hospital attached to Shivamogga Institute of Medical Sciences. We undertook this case-control study in the antenatal ward of Mc Gann Hospital. The diagnosis of pre-eclampsia was made by the consulting obstetrician based on findings of hypertension and proteinuria after 20th week of gestation. Pregnant women diagnosed with pre-eclampsia were recruited as cases, and controls were pregnant women matched for gestational age.For a minimum odds ratio of 3 to be detected, at power of 80% and 95% confidence level, a total of 100 cases and 200 controls were selected for the study. Cases were selected by simple random sampling from the antenatal OPD, from February to June 2015. Pregnant women matched by gestational age from the same day's OPD were enrolled as controls through random sampling. The controls to cases ratio was 2:1. Information on social and demographic factors such as age, religion, education and occupation was collected from the cases and controls using a pretested and semi-structured questionnaire. In order to measure perceived emotional stress, Cohen's Perceived Stress Scale (PSS-10) instrument.

PSS-10 is a widely used scale that measures perceived emotional stress. Perceived emotional stress is defined as the extent to which people perceive that their demands exceed their ability to cope. The instrument was administered to both cases and controls after testing with items translated to Kannada, the local language in the study area. Interviewers were trained and validated prior to undertaking the study. The scale has ten items, each with a 5-point Likert-based scoring. Scores above 20 are considered as high stress.

To compare proportions, χ^2 test was done and p-value less than 0.05 was considered to be statistically significant. Odds ratios with 95% confidence intervals were calculated. Statistical analysis was done on SPSS software version 20 (IBM Corporation, USA).

RESULTS

Data from total of 300 subjects were available for analysis, which comprised of 100 cases of pre-eclampsia and 200 gestational age-matched controls. Majority of pregnant women were in the age group of 21 to 25 years. Cases and controls were comparable as regards their age, residence, religion and occupation. Sociodemographic characteristics of the subjects are displayed in Table 1.

Table 1: Socio-demographic characteristics and parity of cases and controls

Sl. No.	Characteristics	Cases (Total = 100)	Controls (Total = 200)	p-value*
1	**Age (years)**			
	≤20	20 (20%)	19 (9.5%)	0.09
	21-25	43 (43%)	144 (72%)	
	26-29	22 (22%)	01 (0.5%)	
	≥30	15 (15%)	36 (18%)	
	Median age	23	24	
2	**Residence**			
	Rural	57 (57%)	124 (72%)	0.45
	Urban	43 (43%)	76 (28%)	
3	**Religion**			
	Hindu	79 (79%)	158 (94%)	1
	Muslim	21 (21%)	42 (6%)	
4	**Occupation**			
	Homemaker	86 (86%)	161 (66%)	0.26
	Working	14 (14%)	39 (34%)	
5	**Parity**			
	Primigravid	60 (60%)	69 (35%)	<0.001
	Multigravid	40 (40%)	131 (65%)	

*p-value less than 0.05 was considered to be statistically significant.

Perceived Stress Scale (PSS) scores: The median PSS score among cases was found to be 14, while the median PSS score among controls was found to be 13. Statistically significant difference was observed between the scores of cases and controls when the medians were compared by Mann-Whitney U Test. Details are tabulated in Table 2.

Table 2: Comparison of Perceived Stress Scale (PSS) scores of cases and controls

Parameters	Cases (100)	Controls (200)	p-value*	OR (95% CI)
Median	14	13		
IQR	7	5	0.045	
Scores 20	85	176		1.294 (0.646-2.593)
Scores ≥ 20	15	24		

DISCUSSION

This study found that higher levels of perceived emotional stress was associated with the cases of pre-eclampsia compared to controls. A prospective cohort study conducted in Finland by Kurki et al had demonstrated that conditions like depression and anxiety were associated with development of pre-eclampsia later in life.[21]Their findings are comparable with our results as interventions to reduce emotional stress and manage day-to-day stress have been found to have direct effects against depression symptomatology.[22]

The sociodemographic characteristics were not different among the cases and controls. This reduces chances of any confounding relationship to have falsified our findings. With majority of study subjects scoring low on the PSS instrument, we found a skewed distribution of scores. Comparison of median scores becomes more reliable in such a situation. We found that cases of pre-eclampsia had significantly high scores of stress compared to the controls. We suspected parity for its role as a confounder in the association between stress and pre-eclampsia. But, the subgroup analysis showed that stress levels were equal across all degrees of parity among our study subjects.

ViannaP *et al* had postulated that conditions of distress during pregnancy may adversely impact upon pregnancy by increasing *in vivo* cortisol levels, which, in turn can lead to endothelial dysfunction.[23] Rossi et al had undertook a study with similar design as ours, but, they found that greater pressor reactivity in women with pre-eclampsia did not specifically support that it was related to psychological or emotional stress.[24]

Pre-eclampsia is an important risk factor during pregnancy. From a public health perspective, community health workers can be an essential resource to tap for effective management of hypertensive disorders of pregnancy.[25]

CONCLUSION

This study has not identified all the risk factors of pre-eclampsia. It explored the association of emotional stress with pre-eclampsia using the Cohen's Perceived Stress Scale which measures perceived emotional stress. The finding that cases of pre-eclampsia have significantly high levels of perceived emotional stress can pave way for future research with prospective studies on a larger sample to further strengthen the evidence. Evidence of biological mechanisms of emotional stress as an agent of pre-eclampsia are substantial. Interventions to manage emotional stress during pregnancy may be helpful in preventing the development of pre-eclampsia.

Ethical Clearance: Ethical clearance for this study was taken from the Institutional Ethics Committee of Shivamogga Institute of Medical Sciences, Shivamogga.

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Effectiveness of Reiki Therapy on Dysmenorrhoea among Adolescent Girls

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ABSTRACT

Dysmenorrhoea is the most prevalent gynaecological discomfort among adolescent and women during reproductive age and it is also the main reason for sick leave or short-term absenteeism among adolescent girls.

Objectives: of the study was to determine the effectiveness of reiki therapy on dysmenorrhea during menstruation.

Method: A survey approach was used to determine the proportion of adolescent girls suffering from dysmenorrhea from different.A total of 746 adolescent girls were screened for dysmenorrhea and found positive for dysmanorhoea is 546, out of which 60 subjects were taken for second phase of the study to find out the effect of reiki therapy. The intervention carried out for 3 weeks and follow-up assessment was done during next menstrual cycle.

Results: The study results showed a 580(77.8%)dysmenorrhea among 746 adolescent girls. The reiki therapy was found to be effective Z=4.833 ($p<0.001$) and expressed the positive effect of the therapy to get relief from dysmenorrhoea.

Conclusion: The findings of the present study illustrated that dysmenorrhea is common in adolescent girls and majority of them have mild to moderate level of dysmenorrhea. Reiki therapy was found effective in reducing dysmenorrhoea.

Keywords: *Adolescent Girls, Dysmenorrhoea, Reiki Therapy.*

INTRODUCTION

Dysmenorrhea is the most prevalent gynaecological discomfort among women during reproductive age and it is also the main reason for sick leave or short-term absenteeism among adolescent girls. A systematic review of the world literature on chronic pelvic pain reports prevalence of dysmenorrhea ranging between 17% and 80%.[1] Prevalence studies also have shown several other factors that are associated with dysmenorrhea like body mass index (BMI), smoking, early menarche, prolonged menstrual flow and psychological disturbances.[2] Reiki is a Japanese technique for stress reduction and relaxation that promotes healing. It is administered by "laying on hands"and is based on idea that an unseen "life force energy" flows through us is what causes us to be alive.

Agarwal and Agarwal (2010) reported the prevalence of dysmenorrhea among 970 adolescent girls aged between 15-20 years, was 698 (79.67%). Most 237 (33.95%) of them were suffering from dysmenorrhea at every month.Shah et al., (2013) reported prevalence of primary dysmenorrhoea among 116 students aged between 18- 21 years was 52(45%) had primary dysmenorrhoea and majority (46) of them, had regular

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menstrual cycles. Mean age of menarche was 13 and 13.5 years. The study had showed that 21 (18%) of them had mild level of dysmenorrhoea, 46.4 (40%) of them had moderate level of dysmenorrhoea and 49 (42%) of students severe level of dysmenorrhoea. Prevalence of nausea & vomiting, headache, giddiness, diarrhoea was 5 (9%), 3 (5%), 7 (12.5%) and 2 (3.5%) respectively. Out of 100 students with regular menstrual cycle, 48(48%) had reported with dysmenorrhoea and 52(52%) had reported with no dysmenorrhoea.[3]

Chen, H, M, & Chen, H, C (2014) conducted a study on effect of acupressure at the Sanyinjiao point on primary dysmenorrhoea among 69 adolescent girls aged less than 21 years in Taiwan. The researcher had selected 34 students in control group and 35 students in experimental group. The participants had received acupressure in Sanyinjiao point of each leg for twenty minutes. To test the effectiveness the repeated measures of two-way ANOVA was used to analyse the scores on the Visual Analogue Score of Pain & Visual Analogue Scale for Anxiety. Among thirty-five girls from experimental group, thirty-one (87%) of girls reported that acupressure was helpful. The result of the study showed that there was a significant difference of Visual Analogue Scale of Pain ($p = 0.04$) and Visual Analogue Scale for Anxiety ($p = 0.003$) after the intervention.[4]

MATERIAL AND METHOD

A quantitative study research approach was used. A non equivalent pretest posttest control group design was used to provide reiki therapy to reduce dysmenorrhoea.

Survey was carried out to find the proportion of dysmenorrohoea among adolescent girls studying at Nursing Institutions. Data collection tools used for this survey were age, age at menarche, frequency of menstrual cycle & menstrual flow in days, family history of dysmenorrhoea, college absenteeism, exercises, medications & complementary therapies to get relief from dysmenorrhoea, warm compress and taking ginger tablets. A total of 746 adolescent girls were surveyed from the period of 6th December 2015 to 7th December 2015.

In the second phase of the study, evaluative research design was used to determine the effectiveness of reiki therapy, Sixty adolescent girls who had mild to moderate level of dysmenorrhoea were selected by using the simple random technique (chit method without replacement)30 in experimental and 30 in control group. Inclusion criteria were within the age group of 18-30 years and having mild to moderate level of dysmenorrhoea.

Informed consent was obtained from the adolescent girls after information regarding the study was explained. There was no scoring for the demographic items. To assess the level of dysmenorrhoea, standardized Wong-Baker Facial Grimace scale with six items was used. This includes intensity and duration of pain in hours on 1st, 2nd and 3rd day of menstruation. The score range was 0-10. Zero score means no pain 1-2 score means mild pain, 3-6 moderate pain and 7-10 severe pain. Content validity was done by experts from the OBG, community medicine and OBG nursing department.There was 100% agreement from all the experts.Reliability of dysmenorrhoea assessment scale was done by using test-retest method by administering the tool to 20 adolescent girls and score was 0.76. Pre-testing of the tool was done and found to be feasible. Researcher had a Master's degree in reiki therapy to provide the intervention.After assessing the pain, an intervention of reiki therapy was introduced for a period of 3 weeks- each day 30 minutes, supervised by the researcher. After three weeks of reiki therapy, level of dysmenorrhoea was assessed during their next menstrual cycle.

RESULTS

Data obtained from the study was compiled and analyzed using frequency and percentage for determining the proportion of dysmenorrhoea among adolescent girls. In survey, it was found that the proportion rate of dysmenorrhoea was 580(77.8%) out of 746 adolescent girls experienced since last six months (Table1).Table 2 depictsFrequency and percentage distribution of the level of dysmenorrhoea. Among the 580, 372(64%) had mild to moderate level of dysmenorrhoea. Among them, 296 from the college proposed for the conduct of study were identified. From these 60 were selected by simple random sampling and allotted to control and experimental group equallywho had mild to moderate level of dysmenorrhoea.

Table 3 depicts, the sample characteristics of 60 adolescent girls, 30 each in experimental and control group. Most of the students 25(83.3%) from experimental and 29(96.7%) from control group belonged to the age group of 18-22years. Majority of the students 17(56.7%) from both experimental and control group attained menarche at the age of 10-13 years. Majority of the adolescent girls 23(76.7%) from experimental group and 29(96.7%) from the control group had 20-30 days of frequency of menstrual cycle. Most of the adolescent girls 22(73.3%) from experimental group and 27(90%) from the control group had 4-6 days of menstrual flow. Majority of the adolescent girls 22(73.3%) from experimental group and 22(73.3%) from the control group were not absent to the college. Most of the adolescent girls from both the groups 29(96.7%) were not taking ginger tablets during menstruation. Majority of the adolescent girls 17(56.7%) from experimental group were not using warm water compression whereas 21(70%) from the control group were using warm water compression to get relief from pain. Table 4 depicts the symptoms experienced during menstruation before intervention of reiki therapy. Most of the adolescent girls 18(60%) from experimental group and 17(56.7%) from the control group had leg cramps. Majority of the adolescent girls 26(86.3%) from experimental group and 23(76.7%) from the control group had lower back pain. Most of the adolescent girls 20(66.7%) from both experimental and control group experienced mood swings. Table 5 depicts pre-test post-test scores of dysmenorrhoea level in experimental group, since the data was not following normality, we have used Wilcoxon signed rank test. Dysmenorrhoea score of pre-test median value was 6 and post-test was 2.5, Z=4.833 ($p<0.001$). Table 6 depicts, comparison of post-test dysmenorrhoea level scores among experimental and control group found that reiki therapy was effective in reducing dysmenorrhoea ($p<0.001$).Table 7 depicts Frequency and percentage distribution of symptoms experienced during menstruation cycle in experimental group before and after intervention. Most of the adolescent girls before the intervention18(60%), after the reiki therapy8(26.7%) had leg cramps. Majority of the adolescent girls before reiki therapy 26(86.3%) after the reiki therapy14(86.7%) after the reiki therapyhad lower back pain. Most of the adolescent girls before the reiki therapy20(66.7%) and after the reiki therapy10(33.3%) after the reiki therapy experienced mood swings.

Table 1: Proportion of nursing students suffering from dysmenorrhoea for last six months

(n=746)

Sample characteristic	(f)	(%)
Painful cramps during menstruation (during last six months)		
Yes	580	77.8
No	166	22.2

Table 2: Frequency and percentage distribution of the level of dysmenorrhoea

(n= 580)

Sample characteristic	(f)	(%)
Mild Pain	126	21.68
Moderate Pain	246	42.35
Severe Pain	208	35.97

Table 3: Frequency and percentage distribution of the sample characteristics

Sl No.	Sample Characteristics	Control group n=30		Experimental group n=30	
		(f)	(%)	(f)	(%)
1	Age (in years)				
	18-22	29	96.7	25	83.3
	23-27	1	3.3	5	16.7
2	Age at Menarche (in year)				
	13-Oct	17	56.7	17	56.7
	14-17	13	43.3	13	43.3

Table 3: Frequency and percentage distribution of the sample characteristics (Contd.)

Sl No.	Sample Characteristics	Control group n=30		Experimental group n=30	
		(f)	(%)	(f)	(%)
3	**Frequency of Menstrual Cycle (in days)**				
	20-30	29	96.7	23	76.7
	31-40	1	3.3	7	23.3
	41-50	0	0	0	0
	51-60	0	0	0	0
4	**Menstrual Flows (in days)**				
	≤3	3	10	3	10
	6-Apr	27	90	22	73.3
	9-Jul	0	0	5	16.7
5	**College absenteeism (in days)**				
	0	22	73.3	22	73.3
	1	8	26.7	6	20
	2	0	0	1	3.3
	5	0	0	1	3.4
6	**Ginger Tablets during Menstruation**				
	Yes-	1	3.3	1	3.3
	No	29	96.7	29	96.7
7	**Warm water compression**				
	Yes	21	70	13	43.3
	No	9	30	17	56.7

Table 4: Frequency and percentage distribution of symptoms experienced during menstruation cycle in experimental group and control group before intervention

n = (30+30=60)

Sl No	Sample Characteristics	Control group		Experimental group	
		(f)	(%)	(f)	(%)
1	Leg cramps				
	Yes	17	56.7	18	60
	No	13	43.3	12	40
2	Lower back pain				
	Yes	23	76.7	26	86.3
	No	7	23.3	4	13.7
3	Mood swings				
	Yes	20	66.7	20	66.7
	No	10	33.3	10	33.3

Table 5: Median, Interquartile range, Wilcoxon signed rank test value and 'p' value of pre-test and post-test score of dysmenorrhoea level in experimental group

Selected variable	Dysmenorrhoea score	Median	IQR	Z value	p value
Dysmenorrhoea	Pre-test	6	6-4	4.833	0.001*
	Post-test	2.5	2-0		

Key: *significant at <0.05 level significance

Table 6: Comparison of post-test dysmenorrhoea level of experimental and control group

(n = 60)

Selected variable	Group	Dysmenorrhoea scores				χ^2	df	P value
		No pain	Mild pain	Moderate pain	Severe pain			
Dysmenorrhoea	Control	0	5	22	3	44.735	3	0.001*
	Experimental	16	12	2	0			

Key *significant at <0.05 level significance

Table 7: Frequency and percentage distribution of symptoms experienced during menstruation cycle in experimental group before and after intervention

(n = 30)

Sl No	Sample Characteristics	Experimental group Pre test		Experimental group Post test	
		(f)	(%)	(f)	(%)
1	Leg cramps				
	Yes	18	60	8	26.7
	No	12	40	22	73.3
2	Lower back pain				
	Yes	26	86.3	14	46.7
	No	4	13.7	16	53.3
3	Mood swings				
	Yes	20	66.7	10	33.3
	No	10	33.3	20	66.7

DISCUSSION

The findings of the study showed proportion of dysmenorrhoea level was 580(77.8%) among 746 adolescent girls studying at nursing Institutions since six month. Similar findings were reported by a study conducted inGwalior to assess the prevalence of dysmenorrhea among 970 adolescent girls aged between 15-20 years, studying in the higher secondary schools. The study showed that 698 (79.67%) of adolescent girls were suffering from dysmenorrhoea. Most 237 (33.95%) of them were suffering from dysmenorrhea every month.

Latthe, et al., (2006) conducted a WHO systematic review of prevalence of chronic pelvic pain: a neglected reproductive health morbidity showed that the prevalence of dysmenorrhoea was 16.8% to 81%.The occurrence of recurring pelvic pain in the UK stated and it was between 45%- 97% in community based studies, among of them 12% reported severe dysmenorrhoea. The lowest occurrence was stated in Bulgaria (8.8%) in women hospitalized with adnexitis between the ages of 19–41 years and the highest rate of dysmenorrhea was found in Finland among (94%) of girls aged between 10–20 years.[1]

Nivashini (2015) conducted a study on prevalence of primary dysmenorrhoea along with irregular periods to determine the prevalence of primary dysmenorrhoea and irregular menstruation among 150 participants aged between 13- 23 years, studied at Saveetha Dental College, Chennai. Participants were asked to answer the questions for data collection. The study revealed that the mean age was 18.97 years and the mean age at attaining menarche was 12.83 years. Among of them 108 (72%) students get dysmenorrhoea for all the menstrual cycle. Dysmenorrhoea was experienced by 84 (56%) girls during the first and second day of menstruation. The symptoms experienced during menstruation were fainting among 50 (33.3%) students, nausea among 8 (5.3%), vomiting among 22 (14.7%), tiredness among 65 (43.3%) students.[5]

The findings of the present study showed reduction in dysmenorrhoea level afterreiki therapy Z=4.833, (P<0.001). Comparison of post-test dysmenorrhoea level among experimental and control group was computed, reiki therapy was found to be more effective in reducing dysmenorrhoea (**x2**= 44.735, df=3, p<0.001). The present study was supported by a randomized control trial on effect of knee chest position for dysmenorrhoea among 30 females aged between 18-35 years in

Karnataka. Visual analogue scale (VAS) was used to collect the data. The participants from experimental group received hot moist pack for 10 minute which was placed on their lower abdomen and were made to perform alternate knee chest position with 10 repetitions and holed for 20 seconds. The intervention was carried out for 2 days beginning from the first day of menstruation. Mann-Whitney Test was used to compare between pre and post intervention among experimental group. The study showed that the knee chest position with hot moist pack had a statistically significant effect on reduction of dysmenorrhoea in the experimental group ($p = 0.037$) on 1st day and ($p = 0.015$) on 2nd day of menstruation.[6] Another supported study was a quasi-experimental study on the effect of reiki therapy on pain and anxiety in women with abdominal hysterectomies. The 22 women aged between 40 to 73 years with abdominal hysterectomy were included in the study to evaluate the pain and levels of anxiety after hysterectomy in US. Twelve participants included in control group who had received only nursing care and ten samples included in experimental group who had received reiki session for thirty minutes with nursing care. The result of the study showed that mean pain at twenty four hours after surgery was found 5.4 for the control group and 3.8 for the experimental ($p = 0.04$). The study also revealed that there was a significant variation in anxiety level ($t = 3.17$; $p = 0.005$). So the result of the study had concluded that the reiki therapy was effective in reducing pain level and anxiety after the abdominal hysterectomy among women.[7]

CONCLUSION

Dysmenorrhoea is very common among adolescent girls. The findings of the study illustrated that dysmenorrhea is common in adolescent girls and majority of them have mild to moderate level of dysmenorrhea. Most of the adolescent girls suffering from dysmenorrhea are not consulting the doctors and take self medication. Thus, health awareness programs are needed to increase the knowledge regarding dysmenorrhea and its management among adolescent girls. All teachers from the schools should be trained to identify the students those who are suffering from dysmenorrhoea and advise them to take appropriate intervention.

Ethical Clearance: Taken from Institutional Research Committee of Manipal College of nursing Manipal, Manipal University. And Institutional Ethics Committee (IEC 671/2015) from Kasturba Hospital, Manipal.

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Visual Acuity of Dentists Under Simulated Clinical Conditions - A Cross-sectional Study

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ABSTRACT

Introduction: The quality of work carried out by the dentists depends upon a variety of factors out of which knowledge, experience, training, visual acuity and manual dexterity play a distinctive role. Good eyesight for dental professionals is essential to improve their learning, clinical performance and also to provide the best dental care for patients.

Aim & Objectives: The present study was carried out with an aim to test the visual acuity and its influence on age in dental professionals in a simulated clinical condition.

Materials & Method: Study involved a total no. of 105 dental students and teachers between the age group of 20-40years. The visual acuity was tested using a Snellen chart mounted in a class II proximal cavity in a molar tooth and was recorded at a fixed and variable distance, comparing the visual acuity with age in subjects with and without refractive errors.

Conclusion: Visual acuity evaluation of dentists using the Snellen chart showed that there was definitely a poor acuity of vision in all the experimental age groups above 20years of age with no statistical significant association between various age groups for the fixed as well as variable distance. Additionally, there was no association between visual acuity of various age groups and refractory errors

Keywords: *Visual acuity, Dentists, Age*

INTRODUCTION

The quality of work done by dentists is dependent on knowledge, skill, experience, training and manual dexterity. Most of the time, we ignore our visual deficiencies which may lead to wrong interpretation that could make our acquisition of skills and interpretation of instructions difficult.[1] Visual acuity has a staunch influence on the precision of manual work which is well-known and many professions suffer because of that. Dentistry, with its small operating field and requires manual skills and precision, demands high visual acuity to do high quality of work.[2]

At around age 40, almost all human beings develop a condition called "Presbyopia" in which the crystalline lens of human eyes loose its flexibility , which makes them difficult to focus close objects. It may seem to occur suddenly but it becomes more noticeable in individuals nearing 40 years of age. It is however the natural part of the aging process of the eye. It is not a disease but a condition and cannot be prevented.[3,4]This condition definitely influence on the diagnostic and working skill ,precision of manual work done as well as ergonomics of dentist.

Miller B. J.*et.al*. have done electronic search in the PubMed and Embase databases using the keywords "loupes," "magnification," or "visual acuity," and their

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combinations yielded no more than 70 original articles, when endodontic publications were excluded and the search was limited to dental journals.[5,6] There are very few studies conducted in dentistry regarding the co-relation between the advantages of magnification and quality of dental work with scientific evidence. Forgie A.H. *et.al* .from their study found that majority of the clinicians had attended for an eye examination within two years, the large range of time since last attendance is of concern and they suggested to encourage regular eye examinations for the dentists.[7] Several other studies investigated the influence of age and showed a loss of accommodation (presbyopia) and low contrast sensitivity under testing conditions with low illumination with increasing age.[3,6,8] Surprisingly, very little scientific research about the visual acuity of dentists, the relationship between visual acuity and precision in dental work among dental students has been published so far.

Hence the present study is carried out with an aim to test the visual acuity and the influence of age on the visual acuity in dental personnel in a simulated clinical condition to evaluate the need of magnification devices.

OBJECTIVES ARE

1. Evaluate the visual acuity of dentists using Snellen Chart
2. Comparing visual acuity with standard distance and variable distance
3. Comparing visual acuity with age
4. Evaluate and compare the visual acuity of dentists with and without refractive errors

MATERIALS AND METHOD

The study was carried out in the preclinical Phantom head laboratory of Department of Conservative dentistry &Endodontics.Ethical Committee was obtained from institutional ethical committee prior to starting of the study.The study was conducted on a total of 105 dental personnel , over a range of age groups between 20-40 and 35 subjects (dental personnel) in each age group were evaluated.

Age groups

1. Group I: 20-24 years
2. Group II: 25-29 years
3. Group III: $\geq$ 30 years

The subjects were further divided into two subgroups

1. Sub Group A: With eyeglasses (With refractive errors)
2. Sub Group B: Without eyeglasses (Without refractive errors)

Study Design

The study was conducted as a Cross-sectional survey.

Data Collection

Miniaturized Snellen charts using E-optotypes were adapted in a class II proximal cavity in the first molar tooth of the fourth quadrant. The test was performed in a dental phantom head with an operating light and using a dental mouth mirror. The visual acuity of 105 subjects was measured under the following conditions: (1) natural visual acuity with standard distance of 300 mm; (2) natural visual acuity with free choice of distance

TEST

During the visual tests the respective dental personnel were free to wear their eye glasses by choice. The position of the teeth on the phantom head unit, the phantom head unit , the eye object distance, the reading of the Snellen chart are controlled by the same expert. The smallest line (Line No.3)of the visual test that could be read without mistakes will be registered.(large letter line:No.1, Medium letter line :No.2,Small letter line:No.3)

Data management and statistical analysis

Data was analyzed using Statistical Package for Social Sciences (SPSS), version 17.0 (SPSS Inc, Chicago IL). Chi square, ANOVA and Fisher's exact tests were used for comparison of data.

RESULTS

The visual acuity was low in all the three experimental groups compared to normal standards, with Group I, II, &III showing frequencies 34%, 32.1% and 34% respectively (Table 1.)

Table 1: Showing age wise distribution of study subjects

Age group	Frequency
20-24 years	36(34%)
25-30 ears	34(32.1%)
>30 years	36(34%)

Even though Group III individuals showed lower visual acuity than individuals of Group I &II there was no statistically significant difference. Further sub Group A.-with eyeglasses (With refractive errors) showed no statistical significant with Sub Group B- without eye glasses (Without refractive errors) given in (Table 2.).

Table 2. Showing visual acuity of study subjects to variables like usage of glasses, and to distance

	20-24 years	25-30	years	>30 years	P value	
Glasses	Yes	23(41.8%)	16(29.1%)	16(29.1%)	p=0.207	Pearson Chi-Square 3.146, df 2
	No	13(25.5%)	19(37.3%)	19(37.3%)		
If,Yes	Glasses	20(43.5%)	12(26.1%)	14(40%)	p=0.359	Pearson Chi-Square =6.609, df 6
	Lens	2(25%)	4(50%)	2(5.7%)		
	Both	1(100%)	0	0		
Fixed distance	1	0	1(25%)	3(75%)	p=0.363	Pearson Chi-Square =6.566, df 6
	1,2	32(34.8%)	32(34.8%)	28(30.4%)		
	1,2,3	4(50%)	1(12.5%)	3(37.5%)		
	9	0	1(50%)	1(50%)		
Variable distance		274.75±36.51	264.17±26.59	264.54±67.22	P=0.556	F value - 0.59
	1	0	0	0	p=0.191	Pearson Chi-Square =6.109, df 4
	1,2	18(28.8%)	21(32.8%)	25(39.1%)		
	1,2,3	18(43.9%)	14(34.1%)	9(22%)		
	9	0	0	1(2.9%)		

In spite of free choice of distance being slightly better than standard distance of 300mm for the visual acuity there was no statistically significant difference between visual acuity, with distance of 300 mm; and visual acuity with free choice of distance

DISCUSSION

Consultants of medical, surgical and dental specialties need to have good visual acuity which influences the precision of manual work that they do.[9] Dentistry, with its small operating field , visual acuity of the dentist has a great role in quality of work. Martina Eichenberger*et al* concluded in one of their studies that near visual acuity varies highly between individuals and decreases during the lifetime. Independent of age or natural vision, visual acuity can be significantly improved by using magnification devices.[10] Hence the present study was conducted to test the visual acuity and the influence of age on the visual acuity in dental personnel in a simulated clinical condition to evaluate the need of magnification devices. Moreover, in dentistry, the sustained and intense visual work that they do from a close distance may put every dental professional at risk for occupational musculoskeletal problems. This injury is because of poor posture secondary to eyestrain, if visual acuity of the dentist is poor. Subconscious attempts to alter posture to improve near vision can result in musculo-skeletal complaints, as well as eyestrain.[11]If eye strain is resolved by means of loupes or operating microscopes, the operator's Posture will improve consequently.

As we grow older, there will be an increase in discrepancy between the visual demands and visual abilities, especially when we do the fine visual dental work from a close distance. Presbyopia is a reduction in the ability to attain sharp focus for near vision because of reduced elasticity of the lens found commonly among people above 40 years of age, which results in blurred near vision.[12] Professor Laurence J. Walsh has enumerated various contributing factors to eyestrain in dentistry and dental staff who suffer eyestrain or visual fatigue may experience various bodily signs and

symptoms .[11]In the present study various age groups above 20 years of age up to 40 were evaluated to find out whether dental students of younger age group are affected by visual acuity during their clinical work which demands precision. Moreover, if they take care of their vision, they can prevent postural musculoskeletal problems in future.

To simulate the realistic clinical conditions,miniaturized visual tests using E-optotypes were performed in posterior teeth of a dental phantom head with operating lamp using dental mirror, with similar test conditions suggested by Martina E. *et.al*.were proven to have adequate discriminatory properties. [10]

In New Zealand, Burton and Bridgman examined the visual acuity of a group of dentists and dental students and showed a huge individual variability and also an influence of age on visual performance. The results of the present study is in accordance with the study done by them.[13] The visual acuity was low in all the three experimental groups compared to normal standards. Group III individuals with higher age group >30, showed lower visual acuity than individuals of Group I &II but statistically not significant. Subjects with refractive errors have similar visual acuity as that of without refractive errors. This could be due to their short sightedness. But, there was no difference in their near vision.There was no statistically significant difference between individuals of all the groups with natural visual acuity, distance of 300 mm; and free natural visual acuity with free choice of distance, which is contrary to the study done by Martina E. *et.al*.groups.[10] Free choice of distance was better than standard distance of 300mm for the visual acuity. This shows all the subjects of all the age groups had problem in their visual accommodation for close distance work. This condition also warns clinical importance of ergonomics during clinical work and need of magnification device even for younger age groups during dental close distance work.

The present study recommends a free accessible visual test at a working distance to measure the visual performance of dentists including dental students to provide personalized recommendation of optical aids and magnifying devices which is suggested by Rawlinson A *et.al* as well as to reduce the future musculoskeletal problems.[14]

CONCLUSIONS

1. Visual acuity evaluation of dentists using Snellen Chart showed that there is definitely poor acuity of vision in all the experimental age groups above 20years of age .
2. Study showed there is no statistical significant association between various age groups for the fixed as well as variable distance.
3. In present experimental scenario, there is no statistical significant association between visual acuity of various age groups and refractory errors.

Referring the results of the present study it can be recommended that

Magnification tools like loupes and surgical microscopes are necessary for the proper visualization of tooth during operative procedures for the precision of work in all the age groups above 20years of age, with or without refractive errors. Therefore, routine visual acuity testing of all undergraduate dental students for perceptual and visual difficulties is recommended to improve their quality of work.

Conflict of Interest: Nil

Source of Funding: Self

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The Social and Health Problems of People Living with HIV/AIDS in Lucknow Uttar Pradesh

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ABSTRACT

HIV-related stigma and discrimination refers to prejudice, negative attitudes and abuse directed at people living with HIV and AIDS. In 35% of countries with available data, over 50% of men and women report having discriminatory attitudes towards people living with HIV. The consequences of stigma and discrimination are wide-ranging. Some people are shunned by family, peers and the wider community, while others face poor treatment in healthcare and educational settings, erosion of their an rights, and psychological damage. These all limit access to HIV testing, treatment and other HIV services. The People Living with HIV Stigma Index indicates that roughly one in every eight people living with HIV is being denied health services because of stigma and discrimination.[1]

Keywords: *HIV, health, policies, infection, NGO, interview.*

INTRODUCTION

Although stigma is considered a major barrier to effective responses to the. Research in India has shown that stigma and discrimination against HIV-positive people and those perceived to be infected are common in hospitals and act as barriers to seeking and receiving critical treatment and care services (UNAIDS 2001). The objectives of the project were to identify the strengths and limitations of existing services for HIV-infected individuals in hospitals, and to use this information to design tools and approaches for motivating hospitals to become more "PLHA-friendly" through improved policies, staff training, and services. (Excerpt).[4]

Studies carried out in different countries and in different cultures and religions have reported that patients and their families face the same problems as those in India . The first step in solving these problems is to educate the patients and their families. The best method to prevent the hopelessness experienced by the patient and their family is education and effective treatment

The aim of this study was to determine the problems that HIV/AIDS patients experience, to measure the patients' knowledge regarding HIV/AIDS and to determine their opinion regarding health and social problems and stigma

MATERIAL AND METHOD

Study design and study setting

This descriptive study was performed between January and June 2013. Because Lucknow has a high number of reported HIV cases. The infectious diseases department at the community medicine and Naaz foundation contributed to this study.

Study group

HIV-infected people and their family members were the target population for this study. As seen in the literature, a significant issue in AIDS research revolves around ensuring confidentiality; thus, it is not possible to obtain a 'representative sample'. Therefore, a purposive sampling technique was used The authors took help from the NGO people of naaz foundation who invited patients that they were already following and that fit the criteria to join the study. The inclusion criteria for participation in the study were that participants were diagnosed as HIV positive, were aware of their HIV status, were mentally capable of providing voluntary informed consent, and were willing to answer the question a counseling session prior to the interview. They were informed that this study is only for academic purposes only and the patient identity would not be disclosed.

DATA COLLECTION

The study used methods to collect data regarding the experiences, perceptions and knowledge about HIV from the participants. A pilot study was conducted to test the questionnaire and key points in the interviews with medical college students as per telling them to do the role play thinking them as having HIV/AIDS. These data were not included in the study. t the end of the sessions, the participants completed a questionnaire on demographic characteristics, HIV/AIDS and stigma. The key points of the focus groups were as follows:

- Experiences/issues with the HIV diagnosis, treatment and medication;
- Challenges of living with HIV, e.g., health services and community life;
- Stigma and segregation of people living with HIV.

The study received ethical approval and permission from the ethical committee of eras lucknow medical college.

DATA ANALYSIS

The qualitative data were analyzed manually using thematic content analysis. Then, the data were organized into meaningful segments. A code list was developed for the data and was used to rate each of the focus groups thus coded all of the transcripts, and all of the authors independently read this material and then discussed the final contents.

The quantitative data were analyzed using the software package SPSS, and general descriptive statistics were calculated. The mean knowledge and stigma scores prior to the seminar and independent variation comparisons were made using ANOVA and the two-sample *t*-test. The questionnaire consisted of 41 items (26 knowledge and 15 stigma related items) that were scored on a 3-point scale; higher scores indicated greater knowledge and a more negative feeling toward stigma. The internal consistency reliability for the Likert questionnaire was acceptable at 0.75 (Cronbach's alpha).[6]

Participant characteristics

The sociodemographic characteristics of the participants are shown in While most of the participants were men, the majority of the kin were women. Approximately 25% of the patients had a primary school education level or below. Four patients were gay and one was bisexual.

Focus group interviews related to HIV and how the infection affected their lives

In the focus group interviews, the patients and their kin mostly complained about health services. We found that discrimination by health personnel had led to problems in treatment and health problems for all of the participants. Additionally, they agreed that dental health was also an important problem. However, they explained that having more information about their illness would help them to overcome health problems more easily.

The patients stated that HIV had a negative effect on their lives. They also stated that when they first found out they were HIV positive most of them experienced psychological trauma. The period of shock, while temporary, lasted a very long time for some. During this time, they stated that they did not have psychological support and that health services were inadequate in this area or that they had not been referred to the proper resources.

They explained that living in smaller communities was problematic and that it was easier to access health services and to live anonymously in big cities. Family support was very important to the HIV-infected patients, and they emphasized that it was easier for people with family support than for those without. One participant discussed the benefits of being a member of a non-governmental organization (NGO). This patient was able to learn more about HIV at an earlier stage, and their problems were addressed earlier. Furthermore, the NGO provided an important social support system outside of the family.

The patients discussed stigma and expressed that they thought people did not have enough education about HIV. Furthermore, they felt that people were afraid of the disease, and that the media was careless and uninformed about HIV. One female patient felt that women were in a worse situation than men in India.[6]

Patients also expressed that they had financial problems and that financial problems were preventing them from accessing health services and getting

medication.

In the survey, we found that only 50% of the patients had shared their status with their spouse. Three people had hidden their status from everyone. The others had told relatives, friends or their spouse. Eight of the patients stated that they had not heard of "safe sex". Four others thought that "safe sex" meant monogamy, and the other 21 thought it was condom use. Apart from 6 of the patients, all stated that they used condoms. Of those who do not use condoms, 3 said it was unnecessary, and three said that they were not sexually active and did not use condoms.[7]

QUANTITATIVE DATA RESULTS

The answers given by the patients and their next of kin regarding HIV and its transmission are listed in table1

Table 1: Participants' knowledge level about HIV/AIDS and transmission routes

		Boys (n=110)		**Girls (n=64)**		**Total (n=174)**	
		No.	**%**	**No.**	**%**	**No.**	**%**
Correct knowledge	Blood transfusion	110	100	64	100	174	100
	Mother to child	110	100	64	100	174	100
	Intravenous drug users	110	100	64	100	174	100
	Needle stick injury	110	100	64	100	174	100
	Sexual intercourse	110	100	64	100	174	100
	Saliva	31	28.2	28	43.8	59	33.9
Misconception	Razors	97	88.2	50	78.2	147	84.6
	Hugging	3	2.7	3	3.1	6	2.80
	Toilet seat	13	11.8	7	10.9	20	11.4
Individuals known to have risk of developing HIV/AIDS							
Female CSW		39	35.5	23	35.9	62	35.6
Homosexuals		11	10.0	2	3.1	13	7.5
Multiple sex partners		39	35.5	22	34.4	61	35.1
Intravenous drug users		7	6.4	2	3.1	9	5.2
Commercial blood donors		2	1.8	3	4.7	5	2.9
Male sex workers		1	0.9	0	0.0	1	0.6
Don't know		3	2.7	6	9.4	9	5.2
X^2, p-value		1.70, 0.19					
Sexual behaviour and risk of HIV transmission							
Anal sex		22	20.0	2	3.1	24	13.8
Vaginal sex		80	72.7	43	67.2	123	70.7
Oral		4	3.6	1	1.6	5	2.9
Don't know		4	3.6	18	28.1	22	12.6
X^2, p-value		25.11, <0.0001*					
If HIV &AIDS are the same thing							
Yes		2	1.8	16	25.0	18	10.3
No		108	98.8	44	75.0	152	89.7
X^2, p-value		25.32, <0.0001*					

Table 2:The responses regarding prevention of stigma.

	Boys (n=110)		Girls (n=64)		Total (n=174)	
	No.	**%**	**No.**	**%**	**No.**	**%**
Will be friends with HIV infected people						
Yes	73	66.4	24	37.5	97	55.7
No	37	33.6	40	62.5	77	44.3
X^2, p-value	13.66, 0.0002*					
Will care for people infected with HIV						
Yes	95	86.4	58	90.6	153	87.9
No	15	13.6	6	9.4	21	12.4
X^2, p-value	0.69, 0.41					
Abstinence message for HIV transmission						
Yes	64	58.2	52	81.3	116	66.7
No	46	41.8	12	18.7	58	33.3
X^2, p-value	9.59, 0.002*					
Is HIV/AIDS curable?						
Yes	5	4.5	2	3.1	7	4.0
No	105	95.5	62	96.9	167	96.0
X^2, p-value	0.21, 0.65					
Awareness regarding condoms						
Yes	106	96.4	56	87.5	162	93.1
No	4	3.6	8	12.5	12	6.9
X^2, p-value	4.95, 0.03*					
Concept of safe sex						
Condom only	26	23.6	49	76.6	75	43.1
Monogamy	44	40.0	1	1.6	45	25.9
Both	40	36.4	14	21.8	54	31.0
X^2, p-value	25.15, <0.0001*					

Opinions of the participants related to stigma

Thirty-one percent of the patients indicated that they were ashamed of being HIV positive; 16.7% indicated that they were not invited to social events; 56.8% indicated that they had been discriminated against; and 39.3% indicated that they had been excluded. Nearly half of the patients felt guilty for being HIV positive. Approximately two-thirds of both the patients and their next of kin believed that people close to the HIV-positive person needed to be informed of the HIV positive person's status.

DISSCUSSION

In this study, we first determined the aspects of HIV education that the participants were misinformed about or did not know at all. After this, education was given emphasizing the areas that the participants were not fully informed about. Valuable data, especially in the qualitative section, were obtained in this study. Beusterien et al. reported that focus groups were a valuable qualitative method for studying issues in socially marginalized groups.

The results from the focus groups indicate that HIV-infected patients have several problems. The six focus groups had a limited number of patients with accompanying kin, despite receiving personal invitations from the authors. As the participants stated, all of the patients were very concerned about confidentiality, and we concluded that the patients who did not attend or were afraid that their confidentiality would be jeopardized. The fundamental problem for patients and next of kin was stigma.[9] They stated that knowing their HIV status has created barriers in many areas, such as in their social lives and at work, and that they

were excluded. The participants thought that the female patients felt more pressure in some social situations and were more excluded. In previous studies, it was also reported that women were more at risk for developing HIV infection during unprotected sex.[11] It has also been reported that HIV-positive women have less access to social and health services. As stressed in other studies, HIV and its related problems, which include stigma, disclosure, the future and family, were some of the patients' common problems.. Another one of the most important problems was access to health establishments and services. The participants also stated that in addition to specific treatment for HIV, other health problems had emerged such as health personnel who were not willing to treat them or who made unkind comments. This situation results in problems with treatment. The patients also stated that they were pleased with their infectious diseases doctors' approach and that they trusted them. A study by Hogan et al. found that patients preferred to learn about the disease from doctors they trusted. In the interviews, it was expressed that those infected through tainted blood or unsafe medical practices were seen as more innocent and that this influenced society's behavior towards them.[10] Additionally, in other cultures, people infected through sexual transmission experienced more negative treatment than those infected through tainted blood .

We found that only half of the patients had shared their HIV status with their spouse. However, the survey found that one-third of the respondents believed that this information should be shared with those close to the patient. The most important reason for hiding their status is stigma In total, 25% of the patients expressed that they were unaware of "safe sex", which indicates that they are not being careful about transmission. However, only 3 patients were aware of the need for condom use. It has been reported that minimizing risk-taking behavior by HIV positive patients is an important protection method .

In the focus groups discussions, the patients and their kin emphasized the need for more HIV/AIDS education. According to quantitative results, most of the patients and their kin had insufficient knowledge about HIV/AIDS. Hicks et al. determined that HIV positive patients with a low education level believed that anti-HIV treatments prevent the transmission of the disease and that this was their reason they preferred unsafe sex.Correcting misinformation regarding HIV/AIDS will lead to a decrease in risk-taking behavior

In this study, we found that participants were misinformed about infection routes. The level of knowledge that a patient has about transmission is important in regards to secondary risk and transmission to other individuals. Other studies have found that HIV positive patients have a low level of knowledge about HIV transmission routes.[12]

There were some limitations to the study. The results from the study participants are not representative of other HIV-positive individuals, and no *video* or *audio was* recorded. However, these six focus group interviews provide perspective on how much the disease has affected the lives of patients and their next of kin. Moreover, our study found that education was important for both patients and their next of kin. Patient education is important to encourage the patients to use self-help strategies.. Study reported that stigma related to HIV/AIDS needs to be explored further from a cultural standpoint to foster the development of educational programs and interventions that are culturally appropriate .

CONCLUSIONS

In conclusion, the findings from the focus groups and questionnaire indicated that there were important misconceptions about HIV/AIDS, especially regarding modes of transmission. Additionally, both patients and their families fear discrimination and stigma. This study has provided important information about the education, counseling and support needs of HIV patients and their families. The data were obtained using qualitative methods that were supported by quantitative data. Moreover, the physicians following these patients are responsible for their care.

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Comparative Post Irrigation Evaluation of Calcium Loss and its Effect on Microhardness of Radicular Dentin

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ABSTRACT

This study was conducted to compare calcium loss and microhardness reduction of radicular dentin following treatment with 17% EDTA, 10% citric acid, 5% maleic acid, and MTAD, by estimating calcium loss, and radicular dentin microhardness by using Atomic absorption spectrophotometry and by Vicker's hardness tester. The results were statistically evaluated using one way ANOVA test and performed at 95% level of confidence and Spearman's correlation test was applied to determine correlation between calcium liberation and radicular dentin microhardness. All the experimental chelating agents bring about calcium loss and reduction in microhardness from radicular dentin.Study concluded that at 5 minutes, 5% maleic acid as a chelating agent causes the maximum calcium loss and microhardness reduction from radicular dentin, followed by 10% citric acid, MTAD, and 17% EDTA. Thus 5% maleic acid was the most effective chelating agent out of those used in the study and there is a positive and significant correlation exists between calcium loss from radicular dentin and microhardness reduction.

Keywords: *Calcium loss , Microhardness , Maleic acid, MTAD, Citric acid , EDTA*

INTRODUCTION

An amorphous layer known as smear layer is formed during canal instrumentation, which is 1-40 ìmin thickness into dentinal tubules and composed of inorganic particles of calcified tissue, and organic elements like pulp debris, odontoblastic processes, microorganisms, & blood cells.[1]

It is shown that smear layer contains bacteria, and protect those within dentinal tubules, hinders penetration of intracanal disinfectants & sealers into dentinal tubules and compromise seal of the root canal filling.[2]A recent meta-analysis of leakage studies concluded that smear layer removal improves the fluid tight seal of the root canal system.[3]Hence it is important to eliminate the smear layer. Alternative use of EDTA and NaOCl has gained wide acceptance to remove the organic & inorganic remnants.[4]SEM study conducted by Niu*et al* concludedEDTA in combination with NaOCl irrigation removed more debris than EDTA alone.[5] However, 10 minute application of EDTA caused excessive peritubular&intertubular dentinal erosion and reduced dentin microhardness.[6]It causes enlargement of dentinal tubules, softening of the dentin, denaturation of the collagen fibres.Hence seach of alternative solution continues.

Various acids have been tried to remove the smear layer effectively. Maleic acid ,an acid conditioner in some adhesive systems has been reported to remove the smear layer in adhesive dentistry. Ballal*et al* found that maleic acid was similar to EDTA in endodontic smear layer removal in coronal and middle third of root canal, but a better ability at the apical third.[7]Wayman *et al* said that alternate use of 10% citric acid and 2.5% NaOCl was better than polyacrylic acid, lactic acid and phosphoric acid for smear layer removal.[8,9] MTAD, a mixture of tetracycline isomer (doxycycline hyclate), an

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acid (4.25% citric acid) and a detergent (0.5% polysorbate,Tween 80), is a new generation combination product for root canal irrigation. Torabinejad*et al* investigated the ability of MTAD to remove the smear layer and disinfect contaminated root canals.[10]Their study showed that a 5 minute application of MTAD is effective as a final rinse in removing the smear layer and bacteria from infected canal.

Calcium and phosphorous present in hydroxyapatite crystals are the main inorganic elements of dentin. Chelating agents react with Calcium ions in hydroxyapatite crystals and cause alterations in dentin chemical structure. Calcium/Phosphorus ratio of the dentin surface is changed, which alters the original proportion of organic & inorganic components. This inturn changes the permeability, microhardness, solubility characteristics of dentin, and adhesion of sealers to dentin.[11,12,13]Microhardness determination can provide indirect evidence of mineral loss or gain in dental hard tissues.Significant alteration in dentin hardness after irrigation with different chemicals indicates the direct effect of these chemical solutions on the components of dentin structure.[14]Chelating agents like EDTA, citric acid, maleic acid and MTAD have been shown to cause erosion of dentin.[15.16,17]

Hence, this study was to compare calcium loss and microhardness reduction of radicular dentin following treatment with 17% EDTA, 10% citric acid, 5% maleic acid, and MTAD, by estimating calcium loss, and radicular dentin microhardness.

MATERIALS AND METHOD

Ethical clearance for the study was obtained from Institutional ethical committee. After that 72 human mandibular premolars with type 1 canal anatomy extracted for orthodontic treatment were included. Crowns were removed at CEJ using high speed diamond bur under water cooling. A size 10 K file (DentsplyMaillefer, Baillaigues, Switzerland) was placed in the canal until visible at the apical foramen. Working length was established 1 mm short of this length. Root canals were enlarged by using hand Protaper files (DentsplyMaillefer, Baillaigues, Switzerland), upto file size F3. Irrigation during cleaning and shaping was accomplished by 2ml of 3% NaOCl solution after every file. Each root was sectioned longitudinally by starting from cervical with a low speed diamond disc and separated buccolingually to expose entire extent of root canal, one half for calcium loss estimation, and the other for microhardness estimation Each half was weighed on a precision balance and standardized to 0.22g before use.

For calcium loss estimation, cemental surface of specimens were coated with nail polish to prevent entry of irrigating solutions. Specimens were immersed in containers for 5 minutes each containing 5ml of irrigating solutions as follows:

Group IA- 17% EDTA,

Group IIA-10% citric acid,

Group IIIA- Biopure MTAD,

Group IVA- 5% maleic acid, Group

VA- Saline (control).

Solutions were maintained under constant agitation using magnetic multistirrer to homogenize extracted calcium in solution. The level of calcium in the solutions was determined using Atomic absorption spectrophotometry (GBC 932 Plus) using air-acetylene flame at a wavelength of 422.7nm. The instrument was calibrated with known standards of 0.5, 1 and 1.5 ìg/ml.

Specimens for microhardness testing were horizontally embedded in autopolymerizing acrylic resin exposing the dentin surfaces, then ground polished with carborundum paper (300, 600, 1200, 2500 grade) and polished using aluminium oxide paste. To determine baseline surface hardness of root dentin, indentations were made with Vicker's diamond indentor a minimum of 3 widely similarly positioned locations (0.5mm level to root canal wall in apical, middle, and cervical root region) using 300g load and a dwell time of 20 seconds. The values were averaged to produce one hardness value for each specimen, and converted to Vicker's numbers.

Acrylic blocks with embedded teeth (Group I to V – B) similar to A group were kept in containers containing 3% NaOCl for 5 minutes followed by 20ml of various irrigating solutions for 5 minutes.

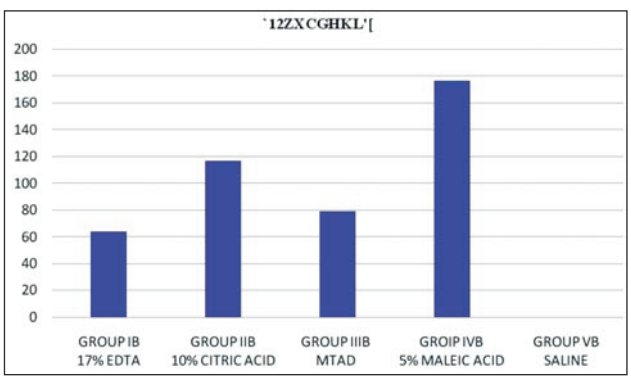
Dentin sample microhardness was measured in same manner after immersion and reduction in microhardness calculated. The results were statistically evaluated using one way ANOVA test and performed at 95% level of confidence. Spearman's correlation test was applied to determine correlation between calcium liberation and radicular dentin microhardness.

RESULTS

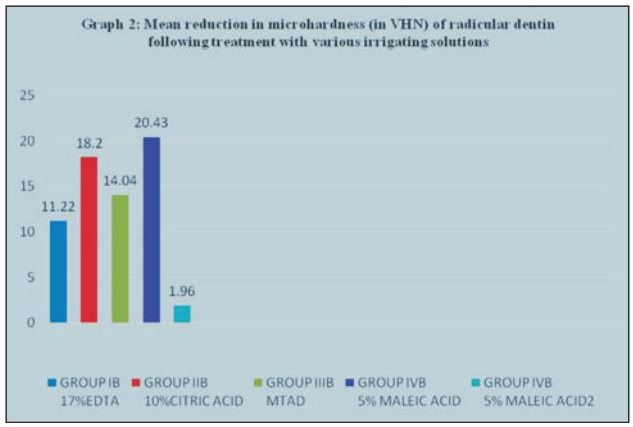
Graph 1&2 depicts Group IVA& Group IV B (5% maleic acid) showing the highest mean calcium loss and reduction in microhardness of radicular dentin followed by group IIA&II B (10% citric acid), group IIIA&IIIB (MTAD), group IA &IB (17% EDTA) and group VA&VB (saline). Intergroup comparison was done using one way Analysis of variance (ANOVA). There was a statistically significant difference among all the A groups ($p<0.05$).

Intergroup comparison using one way Analysis of variance (ANOVA) revealed Group IVB (5% maleic acid) showing a significantly higher reduction in microhardness as compared to group IB ,Group IIIB and Group VB. However, there was no significant difference in microhardness reduction between group IVB and Group IIB ($p=0.371$). Group IB showed a significantly lower reduction in microhardness as compared to group IIB (10% citric acid) and group IVB. However, there was no significant difference between group IB and group IIIB ($p=0.141$). All the experimental groups showed a significantly greater reduction in microhardness as compared to the control saline (Group VB).

A positive and significant correlation was observed withSpearman's correlation test between calcium loss from radicular dentin and microhardness reduction.. ($r=0.794$; $p<0.05$) (Diagram-1)



Graph: 1



Graph: 2

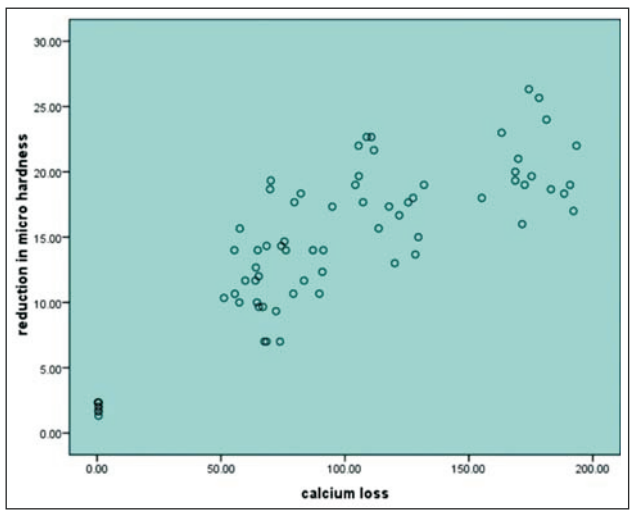


Diagram 1: Scattered diagram depicting spearman's correlation test to assess correlation between calcium loss and microhardness reduction

DISCUSSION

The erosion promoted by the irrigant can reach external resorption areas. Moreover, the erosion can reduce the dentin microhardness, consequently causing root fragility .EDTA is believed to erode dentin if the exposure time exceeds one minute.[18] Contrary to this, Scelza*et al* found that the action of EDTA was not time dependant, although a small nonsignificant increase in decalcifying activity was reported with time [19]Time periods of less than 5 minutes are not recommended for EDTA , although chelating activity is observed at between 1 and 4 minutes.[20]

It has been shown that the main effect of chelator substances occurred after 5 minutes of application. which is more realistic in terms of clinical practice.[20,21] Also, The solutions were not renewed during the 5

minute immersion as that would increase its effectiveness compared with a single continuous application over the same time because it maintains the pH at neutral levels, thereby increasing its moisturizing and decalcifying capacity.[22]

EDTA is used to enlarge root canals, remove the smear layer and prepare the dentinal walls for better adhesion of filling materials. Under neutral pH, the sodium salt of EDTA is supposed to exchange hydrogen ion by calcium during chelation with subsequent decrease in pH. Therefore not all the EDTA reacts after few hours. The autolimitation might be due to this acidification of the EDTA solution.[23]

Maleic acid is highly acidic, with a very low pH (1.47) and a higher etching potential (pKa-1.8) as compared to citric acid (pka-3.1), which may be responsible for its better demineralizing effect within a short periods of time.[24]Ballal*et al* in a similar study found that maleic acid reduced the calcium level significantly more than EDTA upto 5 minutes. However, EDTA caused significantly greater calcium loss at 10 and 15 minutes,.[16]Similar to other studies 10% citric acid showed significantly more calcium loss than 17% EDTA (Graph1).[25,26] They found that the demineralizing action of 10% citric acid significantly increased from 3 to 10 minutes, but was no longer time dependent at 15minutes .[26]

MTAD is acidic with a pH of 2.15 , capable of removing inorganic substances, hence , recommended to be used as a final irrigant before obturation, But if any remaining traces of MTAD are present in the dentinal tubules even after drying, they can continue to cause aggressive erosion of dentin, exposing collagen matrices that were 1.5 to 2 times as thick as those produced with 17% EDTA.[17, 27] In the present study, MTAD showed a significantly higher calcium loss as compared to EDTA (Graph.1)..Soumithran N*et al* found that MTAD is a better demineralizing agent than 17% EDTA and recommended that both solutions be flushed out after ten minutes, especially MTAD, which causes severe erosion of dentin after ten minutes .[27]

The higher demineralizing effect of MTAD is due to presence of both doxycycline and citric acid which act as chelating agents.[28] The pH of citric acid is 2.5 and that of 17% EDTA is 8.5,slightly alkaline. Tween 80 (detergent) enhances the contact of MTAD to the dentinal walls by lowering the surface tension.

In order to obtain a more reliable reading of dentin microhardness, 3 indentations(VH test) were taken and the mean calculated. As the microhardness of dentin may vary considerably within the same tooth,comparisons of dentin hardness values before and after treatment with irrigating solutions was made within the same root dentin sample to minimize the effect of structural variations of different teeth which is suggested by Saleh & Ettman.[18](Graph 2)

The microhardness found to be higher next to the lumen in which the tubuli are denser than periphery wheretubuli are less crowded. [29]Thus, readings were recorded at a fixed distance of 500ìm from the root canal lumen. The chelating actions of these solutions induce an adverse softening potential on the calcified components of dentin, which may have an influence on the physical and chemical properties of this heterogenous structure. and a reduction in microhardness is expected. It permits rapid preparation and facilitates the negotiation of tight small root canals.

In the present study, a positive correlation was found between microhardness loss and calcium loss from radicular dentin.(Diagram 1) Similar to study by Panighi and G'Sell said that microhardness determination can provide an indirect evidence of mineral loss or gain in the dental hard tissues .[12]

Variations in microhardness can be attributed to the concentrations of the solutions used, pH of solutions, and application time .[30] Further studies such as SEM analysis, *in vivo* studies, over an extended period of time are required to confirm the results of the present study. Further, the effect of 5% maleic acid should be done to evaluate its effect on radicular dentin.

CONCLUSION

- At 5 minutes, 5% maleic acid as a chelating agent causes the maximum calcium loss and microhardness reduction from radicular dentin, followed by 10% citric acid, MTAD, and 17% EDTA.
- There is a positive correlation exists between calcium loss from radicular dentin and microhardness reduction.

Ethical Clearance: from Institutional ethical committee, Manipal College Of Dental Sciences, , Mangalore

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Vision Related Quality of Life in Patients After Corneal Transplantation

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ABSTRACT

Aims: The aim of this study was to assess the vision-related quality of life and satisfaction of patients who underwent corneal transplantation and to evaluate the effects of corneal transplantation on the health related quality of life of patient's.

Method: A descriptive study conducted to determine the vision-related quality of life among corneal transplanted patients. The information collected by telephonic interview and direct interview method with patients (n = 30) undergoing routine follow-up examinations at least 6 month after corneal transplantation. NEI VFQ 25 instrument was completed for each participant. Association between clinical and questionnaire outcomes were evaluated using analysis of frequency percentage and chi square test.

Results: Corneal transplant recipients had an increased vision-related quality of life as demonstrated by the NEI VFQ-25 and there was an association existed between employment and vision related quality of life. Also an association with various sub scales of the questionnaire which demonstrated the positive vision related quality of life.

Keywords: *Vision Related Quality of Life, Corneal transplantation, NEI VFQ-2*

INTRODUCTION

"The face is a picture of the mind with the eyes are its interpreter"

It is well known that eyes are the important organs of vision and is the most precious sense of our body. Loss of vision is a serious complaint that requires immediate attention and if it is untreated, permanently it changes the patient's life significantly.

Cornea is as smooth and clear as glass but is strong and durable; it helps the eye in two ways: It helps to shield the rest of the eye from germs, dust, and other harmful matter. The cornea shares this protective task with the eyelids, the eye socket, tears, and the sclera, or white part of the eye. The cornea acts as the eye's outermost lens. It functions like a window that controls and focuses the entry of light into the eye. The cornea contributes between 65-75 percent of the eye's total focusing power. The cornea is one of a few relatively immunologically privileged sites within the human body. In terms of solid tissue allograft in humans, the cornea appears to be very successful with an overall first year survival rate as high as 90%. Unfortunately, the long term reality is that the overall success rate diminishes to 74% at 5 years and 62% at 10 years. In those eyes considered to be "high risk", especially those with corneal neovascularisation or ongoing ocular inflammation, the long term 10 year survival rate is less than 35%. Of greater concern is that these survival rates have not improved over the past 10 years.[35]

Success rates are also affected by the problem that needed to be fixed with the transplant. For example, research has found that the new cornea lasts for at least 10 years in 89% of people with keratoconus, 73% of people with Fuchs' dystrophy 60% to 70% of people with corneal scarring. The eye donation scene in India is very grim. If statistics are to be believed, of the 45 million blind people across the world, 15 million live in India .The sad fact is that 75% of these cases are of preventable blindness, but thanks to the nation's acute shortage of donors, most of the cases either go untreated or inadequately treated. A meager 25000 corneas are collected for transplants against the annual demand of 2, 50,000.

Earlier studies provide evidence that when the best corrected visual acuity of the both eye was evaluated there was a positive association of visual acuity with VF14 score. The findings demonstrate a high degree of criterion validity in using the VF-14 instrument to assess the outcome of corneal transplantation. This is important as rates of corneal donation are much lower than those for solid organs, suggesting there is something different about corneal donation. Although willingness, attitudes and beliefs surrounding solid-organ donation have been extensively investigated, much less is known about corneal donation success rates of cornea transplants.Experts know more about the long-term success rates of penetrating cornea transplants, which use all the layers of the cornea.

To understand the patients' situation and need, it was also important to evaluate their vision-related quality of life in addition to standard clinical variables. A number of self-reported questionnaires had been designed to address this issue, one of which is the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25). The NEI VFQ-25 is a questionnaire that was developed to evaluate the vision-related quality of life of patients with ocular diseases, and to test the psychometric properties of diseases that cause vision loss. It has been widely used to study the quality of life in patients with various ocular diseases, including cataract, glaucoma, age-related macular degeneration, and diabetic retinopathy, central or branch retinal vein occlusion retinal detachment, and Graves' ophthalmopathy.

This study aimed to assess the vision-related quality of life in corneal transplant recipients using the NEI VFQ-25. It also aimed to identify the socio-demographic factors that associate with the patients' self-assessment of perceived visual function.[40]

MATERIALS AND METHOD

The main purpose of the study was to assess the vision related quality of life in patient after corneal transplantation. Hence quantitative non experimental descriptive approach is used for the the study. The setting was Ophthalmology OPD in Amrita Institute of Medical Science , Kochi. Non probability purposive sampling technique was used based on inclusion criteria. 1. All patients underwent corneal transplantation 2. Patients who are able to understand Malayalam or English.

The original English version of the NEI VFQ-25 consists of 1 general health rating question and 11 vision-related domains, namely general vision, ocular pain, near vision, distance vision, social functioning, mental health, role difficulties, dependency, driving difficulties, colour vision, and peripheral vision. Patients who have completed the NEI VFQ 25 were considered for evaluation. The analysis of the NEIFQ25 was done in SPSS software. Result of descriptive analysis are expressed as frequency, percentage, chi square test was used to compare demographic variables in eligible interviewed patients. Thirty subjects were considered to eligible among 98 patients who underwent corneal transplantation during study period. Among the remaining eligible 68 patients, 45 did not attended the phone call, two were expired others patients did not answer for other personal reasons.

The 25-item NEI-VFQ, is a non–disease-specific (i.e, generic) instrument designed to measure the impact of Corneal transplantation on vision related quality of life. A 14-item appendix was also administered to all subjects to enhance the reliability of various sub scales of the 25 item NEI-VFQ. Thus, the NEI-VFQ used in the study contained 39 items and 12 domains, or sub scales. The 12 domains were as follows: (1) general health, (2) general vision, (3) ocular pain, (4) difficulty with short distance vision activities, (5) difficulty with long distance vision activities, (6) vision related limitations in social functioning, (7) mental health symptoms related to vision, (8) vision related role difficulties,(9) vision related dependency, (10) vision related driving difficulties,11) limitations with color vision, and (12) with peripheral vision.

RESULTS

The study showed that graft improved patient vision related quality of life. Out of 30 patients 23 patient's vision was good and remaining seven with poor vision. In our 30 sample 11 females and 19 males present. In their 8 female patients with good vision and 3 females has poor vision. In male 15 people have good vision and 4 people with poor vision. Year of the surgery have no any significant role in this study. Employment and unemployment is one of the important variable which shows an association with overall vision.

Subjects were divided into two groups according to their systemic health status. The scores of patients with vs. without systemic diseases were compared. In this study around 17 (56.7%) people with no any systemic illness and about 13(43.3%) having systemic illness. The difference in the scores for employment status was also determined .The data were entered onto a Microsoft Excel spread sheet , Socio-demographic data, including age, sex, systemic health status, and employment status before and after corneal transplant operation were

collected. rating question, and addresses a number of vision related sub scales, including general vision, difficulty with near and distance activities, limitations with peripheral and colour vision, ocular pain, social functioning, role limitations, dependency, and mental health. Subjects were asked to rate the level of severity of their difficulties in daily activities. Table (1)

Table 1: Distribution of Samples Based on Demographic Data

Sl	Demographic	Category Data	Frequency	Percentage
1	Age	Below 50 Years	5	16.5
		Above 50years	25	83.5
2	Sex	Male	19	63.3
		Female	11	36.7
3	Year of Surgery	2012	8	26.7
		2013	8	26.7
		2014	12	40
		2015	2	6.7
4	Job Status	Employed	23	76.7
		Un Employed	7	23.3
5	Systemic Illness	Present	17	56.7
		Absent	13	43.3

Table 1 shows that among 30 samples, 83.5% were above 50 years and 63.3 % were males. Regarding current job status, majority (76.7%) were working and 56.7 % had systemic illness. 40% of them undergone surgery in the year 2014.

Table 2: Association Of Eye Sight Withsubscale

Items	Classification	Vision- Eyesight				Chi Square Value	P Value
		Good		Bad			
		F	%	F	%		
Small Print Reading	No Difficulty	17	56.6	0	0		
	Difficulty	6	20	7	23.3	11.94	0.01
Figure Out Billing	No Difficulty	21	70	0	0		
	Difficulty	2	6.6	7	23.3	21.3	0
Shaving Styling	No Difficulty	20	66.6	2	6.6		
	Difficulty	3	10	5	16.6	9.35	0.007
Recognizig	No Difficulty	21	70	2	6.6		
People	Difficulty	2	6.6	5	16.6	11.8	0.03
Taking Parts In Sports	No Difficulty	20	66.6	1	3.3		
	Difficulty	3	10	6	20	13.49	0.01
Seeing Tv	No Difficulty	21	70	1	3.3		
	Difficulty	2	6.6	6	20	16.27	0
Entertaining Friends	No Difficulty	21	70	1	3.3		
	Difficulty	2	6.6	6	20	11.8	0.003
Do You Have More Help	Yes	2	6.6	5	16.6		
	No	21	70	2	6.6	11.8	0.003
Are You Limited	Yes	0	0	6	20	24.64	0
	No	23	76.6	1	3.3		
Currently Driving	Yes	8	26.6	0	0	3.32	0.143
	No	15	50	7	23.3		

Table 2 shows that the association between each sub scales of t he questionnaire with good and bad eyesight groups as computed Chi square value of variable at level of significance P= 0.05 are more than table value. So there was an association identified between these subscalesand sample groups.

Table 3: Association of pain and discomfort with demographic variable

Variables		Pain or Discomfort				Chi Square Value	P Value
		Yes		No			
		F	%	F	%		
Year Of Surgery	2012	0	0	8	26.6	6.989	.72
	2013	2	6.6	6	20		
	2014	6	20	6	2		
	2015	0	0	2	6.6		
Job Status	Unemployed	3	10	5	16.6	1.224	0.345
	Employed	5	16.6	18	60		
Systemc Illness	Disease	2	6.6	6	20	4.45	0.49
	No Disease	15	50	7	23.3		

P < 0.05 Statistically significant

There is no significant association between pain and discomfort with demographic variables. The study showed that graft improved patient's vision related quality of life. Majority of the patients (76.7%) vision was good and the remaining patients (23.3%) reported that they have poor vision. Among the samples, (36.7%) females and 63.3% males were involved. Among females, 78.95 had good vision and rest of them had (27.3%) of them found that they had poor vision. Year of surgery have no significant association with variables.

Table 4: Chi-square association of eye sight with demographic variable

Variables	Category	Total	Eye Sight				Chi Square Value	P Value
			Good		Poor			
			F	%	F	%		
Sex	Male	11	72.2	8	27.3	3	0.151	1
	Female	19	78.9	15	21.1	4		
Year of Surgery	2012	8	87.5	7	12.5	1	3.913	0.27
	2013	8	87.5	7	12.5	1		
	2014	12	58.3	7	41.5	5		
	2015	2	100	2	0	0		
Systemic Illness	No Disease	17	88.2	15	11.2	2	2.935	0.19
	Diseased	13	61.5	8	38.5	5		
Job Status	Unemployed	7	42.9	3	57.1	4	5.83	0.33
	Employed	23	87	20	13	3		

.P < 0.05 Statistically significant

The study showed that in the year 2014 have most of the transplantation occur compare to other years such as, 40% in 2012, 26.7% in 2013.

In addition, employment status also had a significant association with the eye sight. For both visual functioning, socioeconomical status, patients whose employment status remained unchanged after corneal transplantation were significantly more able when compared with those who were unemployed or retired after their operation.

Patients were divided into two groups according to their systemic health status. The scores of patients with vs. without systemic diseases were compared. In this study, 56.7% subjects with no any systemic illness and 43.3% had systemic illness. The difference in the scores for employment status was also determined. The data were entered onto a Microsoft Excel spread sheet , Socio-demographic data, including age, sex, systemic health status, and employment status before and after corneal transplant operation were collected. rating question, and addresses a number of vision related sub scales,

including general vision, difficulty with near and distance activities, limitations with peripheral and color vision, ocular pain, social functioning, role limitations, dependency, and mental health. Subjects were asked to rate the level of severity of their difficulties in daily activities.

DISCUSSION

The study was designed with following objectives; Identify the vision related quality of life corneal transplantation by using National Eye Institute Visual Functioning Questionnaire, Associate the vision related quality of life with selected variable and Identify the post transplant complication in corneal transplantation patients.

In this study, it is found that cornea transplanted recipients had good quality of life whereas another study conducted in 2012 reported that quality of life decreased. This may be due to the influence of confounding variables such as co-morbidities, other illness etc. Demographic variables like age, sex, systemic illness have no significance but there was an association found between employment status (0.033) and eyesight of the patients in both studies and the relationship is directional. Hence the results are more or less consistent in nature.

Unlike other studies, the investigator selected two subgroup people, first with good eye sight, who put rate above seven and second with poor eye sight who put rate below six. These division supported the analysis, that cornea recipients had an increased vision related quality of life and associated each group with sub scale of the Questionnaire, so the P value shows the positive significant association, with systemic diseases on the NEIVFQ-25 scores might be one of the reasons in the variations in the results of both studies.

Overall,Corneal transplant recipients had a increased vision-related quality of life as demonstrated by the NEI VFQ-25. Studies had shown that depression was common among adults with visual impairment. This is of particular relevance to corneal graft recipients. Although most patients with cataract or age-related macular degeneration are the elderly, many corneal graft recipients are young, fit adults who require corneal transplantation for indications, such as trauma, keratinize, or keratoconus. However, in this study also, more than half (56.7%) of the subjects had systemic illness. Hence the findings are more consistent with the previous study findings.

CONCLUSION

The restoration of sight is the most important purpose of corneal grafting. However, successful Corneal transplantation improves both health and lifestyle of the patients. The current study revealed that, those who had undergone corneal transplantation had a better quality of life and less incidence of post transplant complications.

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Construct Validity and Reliability of Jefferson Scale of Empathy-health Care Provider (Student version) among Final Year, Interns and Post-graduate Students of a Dental College in India

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ABSTRACT

Background: Empathy is a much talked about but ignored characteristic in India. Doctor-patients relationship goes a long way and invariably has a profound effect on the treatment outcomes. This study makes an attempt to determine the level of empathy among clinical students in the specialty of dentistry in Indian scenario.

Aim: To determine the construct validity and reliability of the Jefferson Scale of Empathy-Health Care Provider Student version (JSE-HPS) with the secondary aim of assessing empathy levels with respect to age, gender and year of study.

Settings and design: A cross-sectional observational study was conducted among clinical students of a dental institute in South India.

Method and material: The JSE-HPS was administered to 150 students from final year, interns and post-graduate students. Descriptive and inferential statistics with Principal Component Analysis was performed to determine the construct validity. The reliability measured using Cronbach's Alpha. Differences of empathy scores with respect to age and gender assessed using independent t test. One way ANOVA with Tukey's post hoc test was used for empathy scores across year of study, with level of significance at $p<0.05$.

Results: The JSE-HPS demonstrated good internal consistency (Cronbachs Alpha - 0.7). A four factor solution was found taking into consideration "understanding patients' feelings" as the principal component, followed by a relatively new "sense of confusion" and factor three and four corresponding to "ignoring the emotional component", each corresponding to 20.5 percent, 15.6 percent, 14 percent and 8.7 percent of the item variance respectively. The total mean empathy scores were found to be 93.2±15.6. Overall females were more empathic (90.03 ± 13.186) than males (86.98 ± 9.946) ($p>0.05$). Age had no significant effect on empathy scores. Within group comparison using one way ANOVA revealed significant differences for scores among interns and postgraduates ($p<0.05$).

Conclusion: This study confirms the construct validity and internal consistency of JSE-HPS for measuring the empathy in an Indian study setting. Post-graduates scored higher than the Compulsory Rotatory Resident Internship [CRRI] and final year students. Age and gender had no effect on empathy scores when compared to year of study.

Keywords: *Empathy, Dentist-Patient Relation, Social Skills, Empathy Scales*

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INTRODUCTION

Empathy was derived from two Greek terms, "em" and "pathos", meaning 'feeling into' and has its origin from the German word "Einfulung"[1]. In terms of patient care, empathy is defined as a cognitive attribute that

involves an ability to understand the patient's experiences, pain, suffering, and perspective, combined with a capability to communicate this understanding and an intention to help[2]. Both empathy and sympathy involve sharing[3] but the concept of empathy lies in cognitive understanding[4] whereas sympathy involves sharing emotions with the patients[5,6].The role of communication and understanding between health care practitioner and patient is receiving increasing attention in general dentistry[7] and in dental specialties[8, 9]. A key component to effective communication and understanding is the ability to demonstrate clinical empathy.

The role of empathy and interpersonal skills in the medical and dental setting has led to curriculum changes in medical and dental training. For instance, the American Dental Education Association (ADEA) lists providing empathic care for all patients as its second clinical competency for dental training[10]Several instruments are available to examine empathy level such as Interpersonal Reactivity Index[11], The Empathy Scale[12], The Emotional Empathy Scale[13] and Jefferson Scale of Physician Empathy (JSPE). The Jefferson Scale of Physician Empathy – Health Profession Student version (JSPE-HPS) has been validated in a variety of dental settings[14, 15].Previous studies have reported a decline in empathy among undergraduate dental students[15, 16]as they progress through their professional education. Babar et al reported the highest empathy scores among final year students than other undergraduate students[14]. A longitudinal study by Sherman and Cramer found that empathy levels drop sometime during the second year of dental training and remained low throughout dental school[17].

The Dental Council of India has mandated a total of 670 hours and 1400 hours in clinical departments (excluding general medicine and general surgery) during III BDS and IV BDS respectively[18]. To reach the above stated objective, students are generally posted in clinical departments from III BDS onwards with responsibilities increasing when they become interns and join their post-graduation in clinical departments.

The response to these responsibilities changes as students move towards higher academic years, where the empathy levels are bound to vary. We know from previous studies that students enter with high empathy scores, we also know of the decline in empathy among third year medical students and dentists but no study has emphasized what happens to empathy levels after they become interns and subsequently take up post-graduation[14, 19]. The present study was conducted with our primary objective to examine the construct validity and reliability of JSE-HPS among clinical students (final year, CRRI's and Postgraduate students) of a dental college in India. A secondary objective was to measure the empathy levels and assess the same with respect to age, gender and year of study in the present study setting.

MATERIAL AND METHOD

Study Design and Setting

A cross sectional study was conducted among the final year, CRRI's and Postgraduate students of Indira Gandhi Institute of Dental Sciences (IGIDS), Pondicherry. The assessment of empathy levels was determined using a validated self-administered Jefferson Scale of Empathy, Health Care Provider Student questionnaire. (JSE – HPS). This scale was developed by researchers at the Center for Research in Medical Education and Health Care at Jefferson Medical College to measure empathy in physicians and health care providers. The version applied (S-version) was previously adapted for use by medical and other health profession students, to take into account their attitude to the patient – doctor relationship. This instrument was found to be reliable with good internal consistency among dental students[14]. The instrument consists of 20 items answered on 7-point Likert scale which are scored from 1 (strongly disagree) to 7 (strongly agree). Among the 20 questions, 10 negatively worded items in the scale were reverse scored[2]. The total score ranges from 20-140; a higher score indicates a behavioral tendency favoring empathic engagement in patient care.

Participants

The study was conducted in the month of March 2015. Prior to the study, ethical approval was obtained from concerned authorities of IGIDS. The nature of the study was explained to the study subjects present on the day of the study and were assured that their responses will be kept confidential. Only those students who gave informed consent were included in the study. A total of 150 study subjects of the total final year,

CRRI's and Post-graduate students of Indira Gandhi Institute of Dental Sciences gave the informed consent and were included in the present study. The main reason to include only the above mentioned years (except III year's students) was to determine the empathy levels once students advance towards senior years and post-graduation.

The questionnaire was given to the students who were requested to fill in the presence of the investigator.The time given to each study subject was 15 minutes. The questionnaires had clear written instruction in English and the participants were requested to read the statements carefully and tick the appropriate response in the 7 point Likert scale of their choice. Incomplete questionnaires were rejected. The responses were not revealed to the study participants till all the questionnaires were collected on the day of study.

Statistical Analysis

The data obtained from collected forms filled with responses were entered in Microsoft Excel sheet – 2010 and subjected to statistical analysis using SPSS (SPSS Inc., IL, Chicago, USA, version 16). For statistical analysis the age was dichotomized as those < 25 years and 26 years and above. We felt that older students are more able to identify patients' perspectives with slightly more life experiences and generally students who take up post-graduation after BDS program are either 25 years or above 25 years.Empathy mean scores, standard deviations were obtained for the study subjects based on age, year of study and gender. Independent-samples t-test was used to explore whether significant differences existed between groups because of age and gender. To compare the impact of 'year of study' on empathy scores, one way analysis of variance (ANOVA)with post hoc comparison using Tukey's test was performed. The significance (p-value) was set at 0.05.

To our knowledge the JSE – HPS has been used only in a few studies[20] in India without determining the psychometric properties in an Indian scenario. We conducted a Principal Component Analysis (PCA) to examine the underlying components of JSE-HPS among dental students in Indian scenario. Data were subjected to factor analysis using a principal component factoring method and an orthogonal varimax rotation with Kaiser Normalization[21]. The Kaiser-Meyer-Olkin test (KMO) was performed to measure sampling adequacy of >0.7[14]. An Eigenvalue of >1 was used for retaining factors in PCA [21]. However, potential bias can be introduced by the use of >1 cut-off value [22] and therefore we also inspected the "Scree plot" as a superior factor selection method to determine the appropriate number of factors to retain for rotation [23]. Bartlett's test of Sphericity was used to measure significant correlations between variables [24]. The corrected item-total score correlations were also examined. Internal consistency was analyzed using Cronbach's alpha.

FINDINGS

Principal Component Analysis

The Cronbach's Alpha (internal consistency) was found to be 0.7. The 20 items of JSE-HPS were entered into iterated PCA with Kaiser Normalization. The KMO test of sampling adequacy was applied prior to factor extraction, which resulted in overall index of 0.84, suggesting that the sample was adequate for factor analysis. The Bartlett's test for sphericity showed that the inter-correlation matrix was factorable (Chi-Square (190) = 997.74, $p<0.001$). Inspection of the corresponding Scree plot and identification of an 'elbow' point after which the inclusion of additional factors does not result in substantial gains in 'variance explained' yielded the existence of at least four factors, with eigenvalues more than one. Based on the plot of the eigenvalues that leveled off after the fourth factor, a 4-factor solution was selected explaining a total of 59 percent of the item variance. The magnitude of the Eigenvalue was 6.4, 2.5, 1.6 and 1.1. These factors explained 20.5 percent, 15.6 percent, 14 percent and 8.7 percent of the item variance respectively. Factor loadings >.40 were applied as the criterion for including an item in a particular factor; the rotated factor matrix is shown in Table 1. This strategy has been used in prior validation research on this measure [15]. The principal factor corresponds to a belief that "understanding patients' experiencing and feelings" will result in better therapeutic care and health outcomes. Factor 2 indicates a "sense of confusion" within themselves regarding being professional and having no emotions for patients or trying to understand their feelings. Factor 3 and 4 corresponds to "ignoring the emotional component" for patients based on their own personal choice of lifestyle.

Table 1. Summary of Factor analysis of JSE – HPS for clinical dental students

Items	[JSE – HPS]	Factor 1	Factor 2	Factor 3	Factor 4
1.	My patients value my understanding of their feelings, which is therapeutic in its own right. [Q3]	**.819**	.179	.137	-.037
2.	I believe that empathy is an important therapeutic Factor in medical or surgical treatment. [Q5]	**.803**	.100	.078	-.102
3.	Empathy is a therapeutic skill without which success in treatment is limited. [Q4]	**.751**	.187	.240	.061
4.	I consider understanding my patients' body language as important as verbal communication in caregiver patient relationships. [Q12]	**.649**	-.318	-.181	-.047
5.	I try to think like my patients in order to render better care. [Q11]	**.642**	.145	.139	.105
6.	I try to understand what is going on in my patients' minds by paying attention to their non-verbal cues and body language. [Q13]	**.540**	.027	**.411**	-.153
7.	I try not to pay attention to my patients' emotions in [Q15] history taking or in asking about their physical health.	.062	**.767**	.068	-.093
8.	Because people are different, it is difficult for me to See things from my patients' perspective. [Q18]	-.350	-.749	.019	-.105
9.	It is difficult for me to view things from my patients' Perspectives. [Q16]	.237	**.607**	.334	.041
10.	Asking patients about what is happening in their personal lives is not helpful in understanding their physical complaints. [Q19]	.210	**.595**	.146	.209
11.	I do not allow myself to be influenced by strong personal bonds between my patients and their family members. [Q9]	.323	**.542**	-.087	.349
12.	I do not enjoy reading nonmedical literature and the arts. [Q20]	-.209	**.502**	.186	**.499**
13.	My patients feel better when I understand their feelings. [Q6]	.390	-.037	**.742**	.053
14.	Patients' illnesses can be cured only by medical or surgical treatment; therefore, emotional ties to my patients do not have a significant influence on medical or surgical outcomes. [Q7]	.150	.395	**.705**	.212
15.	An important component of the relationship with my patients is my understanding of their emotional status, as well as that of their families. [Q8]	.378	-.028	**.632**	.022
16.	Attentiveness to my patients' personal experiences does not influence treatment outcome. [Q10]	-.034	**.479**	**.572**	-.058
17.	I believe that emotion has no place in the treatment of medical illness. [Q2]	-.047	.269	**.531**	**.443**
18.	I try to imagine myself in my patients' shoes when providing care to them. [Q14]	**.487**	.029	**.518**	-.042
19.	I have a good sense of humor, which I think contributes to a better clinical outcome. [Q17]	.188	.055	-.054	-.795
20.	My understanding of how my patients and their families feel do not influence medical or surgical treatment. [Q1]	.379	.197	-.010	**.624**

*Items are listed by the order of magnitude of the factor structure coefficients within each factor. Values greater than .4 are in bold. The sequences of items have been put in the form of numbers in parenthesis.

Comparison of Empathy levels

The response rate in the present study was 80 percent (120). About 85 percent of the study subjects were below 25 years and CRRI's accounted for about 49 percent of the total number (Table 2a). Females were more in number across all the years of study (Table 2b). Overall the mean empathy scores in the present study were found to be 93.2 with a standard deviation of 15.6.

Table 2a. Distribution according to age, gender and year of study

	Variable	Percentage	(Number)
Age	≤ 25 years	85.8	(103
	≥ 26 years	14.2	(17)
Gender	Females	65.8	(79)
	Male	34.2	(41)
Year of Study	Final Year	36.7	(44)
	CRRI	49.1	(59)
	postgraduates	14.1	(17)
Total (N)			120

Table 2b. Distribution of study subjects according to Year of study and gender (percentages)

Year of study	Males	Females	Total
Final Year	31.8 (14)	68.1 (30)	41
CRRI's	32.2 (19)	67.8 (40)	59
Postgraduates	47 (8)	52.9 (9)	17
Total	41	79	120

Participants above 25 years of age scored higher than those below 25 years; but the difference was not found to be statistically significant (Table 3). Comparison of overall mean empathy scores by gender revealed that females (95.3 ± 13.186) had higher mean scores than males (89.12 ± 9.946) and the difference was not statistically significant (t=1.306, p>0.05,). Independent sample t-test revealed no statistically significant differences for the empathy scores between the two age groups (Table 3). Though not significant, females had higher score compared to males among CRRI's and post-graduates except the final year students. Males had a higher score than females among the final years which was statistically significant(t=2.11, p<0.05) (Table 4).

Table 3: Comparison of mean scores of empathy according to age and gender

Age	N	Mean Std. Deviation	Std. Error Mean	t	df	sig
< 25	103	92.5 ± 15.676	1.545	1.553	118	0.123 [NS]
>25	17	97 ± 14.97	3.63			
Gender						
Females	79	95.3 ± 13.186	2.34	1.306	118	0.194 [NS]
Males	41	89.12 ± 9.946	1.67			

P value significant at p=0.05; NS - not significant

Table 4: Comparison of Mean empathy scores across year of study across Gender

	Mean ± SD		t	df	P-Value
	Females	Males			
Final Year	88.33 ±15.2	98.71 ± 15.0	2.110	42	0.041*
CRRI's	92.73 ± 15.1	91.84 ± 18.6	.194	57	0.847†
Postgraduates	102.6 ± 12.7	96.88 ± 11.4	0.96	15	0.344†

*P value Significant at p<0.05, †NS - Not Significant

The one way between-groups ANOVA and post hoc comparison using Tukeys test was conducted to compare differences in empathy scores between study subjects according to year of study. The analysis revealed significant differences in empathy scores between the groups [(F=5.543, P=0.005), (Table 5a)]. Post hoc multiple comparison using the Tukey's test revealed that differences in the mean empathy scores for CRRI's (92.44 ± 16.1) was significantly different from mean scores of Postgraduates (99.94 ± 12.1) and final years (91.64 ± 15.7) at p<0.05 level (Table5b).

Table 5a: Comparison of mean empathy scores across year of study

Year of Study	Mean ± SD	F value	df	P-Value
Final Year	91.64 ± 15.7	5.543	238	0.005*
CRRI's	92.44 ± 16.1			
Postgraduates	99.94 ± 12.1			

One way ANOVA (*P value significant at 0.05 Level)

Table 5b: Post hoc analyses (Tukey's test) of empathy scores according to year of study

(I) YOS	(J) YOS	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
final year	CRRI	7.765*	3.010	.030	.62	14.91
	PGS	-3.876	4.315	.642	-14.12	6.37
CRRI	final year	-7.765*	3.010	.030	-14.91	-.62
	PGS	-11.641*	4.159	.016	-21.51	-1.77
PGS	final year	3.876	4.315	.642	-6.37	14.12
	CRRI	11.641*	4.159	.016	1.77	21.51

The mean difference is significant at 0.05 level

CONCLUSION

Empathy is a much talked about characteristic when it comes to doctor-patient relationship. A dental student in India manages his/her first patient in third year. Henceforth, the rapport a student develops with the patient goes a long way in terms of proper delivery of treatment and the subsequent referrals that student might get from the patients friend or relatives. This characteristic has been reported to be at greater levels initially; however there is a decline in the empathy levels after a certain time.

The findings from this study demonstrated that empathy in dental students can be reliably and validly measured using a self-reporting instrument originally developed for the measurement of empathy in medical students. The four-factor solution of the measure was similar to that found in a study conducted by Hojat et al [5] and Sherman and Cramer [15]. However, Babar et al [14] found a three-factor solution with the principal factor corresponding to understanding patient's concerns and being compassionate. The four factor solution yielded a total of 59 percent of the variable which is similar to 57.8 percent and higher than 47.8 percent as reported in literature [14, 15]. In our study we also found the students to be in a transformation stage where they feel confused whether to be compassionate or try not to mix their emotions during the treatment they provide. This could be attributed partly due to their academic requirements of completing their work as per scheduled and partly their self-conscious refusing to be professional. The above mentioned second factor was relatively a new concept, since in previous studies a second component of "compassionate care" was replaced by items which directs towards a more or less, "phase or sense of confusion". Future research is recommended before the JSPE-HPS is used in an Indian scenario given that one of the factor is slightly deviating from the ones reported in literature.

The mean empathy scores in our study setting were comparatively higher when compared to scores obtained by Babar et aland Prabhu et alamong dental students of Malaysia and India respectively[14, 20]. Our focus was more on the clinical years whereas the study done by the previous author had non-clinical students as study subjects also. Our scores were lower when compared to scores obtained by Sherman and Cramer in 2005 among dental students in Washington [15]. This disparity in scores can be attributed to the practice of evaluating a dental students' empathy as one of the clinical competency during dental training which is not mandatory in the Indian and Malaysian Scenario.

The total mean empathy scores were found to be higher for females than males. Most studies reported that women are more empathic than men and also have argued that empathy is a feminine trait and females are more receptive to emotional signals [19, 25]. Similar results were reported by studies conducted by various authors in Latin American countries as well [26-28]. Our findings are contrary to the results reported by various authors [14, 20, 29].Females outnumbered males in the present study population which parallels the trend that dentistry is commonly chosen by female students. This is also evident in the present study as only 34.2 percent of the study subjects were males.

Concerning age in the present study, we found that age had no impact on empathy scores. Even though older participants had higher scores, the difference was not significant, partly due to less participants. We also suggest that additional life experiences to deal with patients by older students may be the reason for scores at a slightly higher end, as viewed by Nunes et al in 2011[30].

Empathy levels appear to drop during the third-year of dental training when patient interaction increases. This decline in student empathy appears to be a common phenomenon emerging in the literature [9, 11-13]. Sherman and Cramer found a slight increase in empathy scores in the last year of dental school among their study subjects[15]. In our study we found constant increase in empathy scores from final year, CRRI and highest scores observed among post-graduates. This can be attributed to training in ethics, practice management and management of un-cooperative patients which begins from clinical years onwards. Yaravistsch et al [30]found that despite the fall in empathy on patient exposure, dental students seem to eventually recover. It looks like our present study has proved the above statement and year of study seems to have a significant effect.

Comparison of empathy scores across years of study showed significant differences in empathy levels between postgraduates and CRRI's and less but, significant differences between post-graduates and final years. A stepwise increase in empathy scores from final year to CRRI's and then to post-graduates was observed. This could possibly be explained by the fact that these students over a period of time were actively seeing patients and had also learned to engage with patients in clinical rotation.

Our study has several limitations. First, the nature of the study is cross-sectional; a longitudinal study tracking changes in a single cohort through dental school and potentially beyond might offer considerably more insight into the stability of characteristics such as empathy in practice. Second, our findings are limited to one dental institution only. The results may not be generalized to other dental students of different institutions. A multi-centric research with same academic curriculum and larger sample size should be on the agenda. Third, only self-reported empathy is recorded form students. This may not necessarily coincide with their behavior. Hence, behavior observation of activities and patient interaction should be monitored. Other aspects of a student's life like stress and burnout were also not considered as variables in the present study. Another aspect not taken into consideration was the specialty of the post-graduates. The above points were framed under limitations since, stability of empathy on a long run or behavioural changes across clinical years requires a separate domain among clinical competencies where 'empathy' as a specific entity isevaluated as a core competency. Empathy is rarely integrated into clinical teaching and learning, and the concept of empathy needs to be implemented and examined in more detail to improve the dentist-patient relationship.

It can be concluded that the JSE – HPS scale is a reliable indicator of empathy with good internal consistency and construct validity for clinical dental students in the present study setting. The overall empathy scores for dental students was higher than the studies conducted in India, Malaysia and lower than another study conducted in United Kingdom. Females were found to have higher empathy scores than males except in final year where the results are reversed with year of study having a significant role to play in empathy than age.

Now there is a need for further research to establish the importance of other variables for the increase in empathy scores after initial drop as mentioned in the literature. Also the need to establish convergent validity of JSPE – HPS should be among the few things first on the list.

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Comparison of Diet Quality of Low and Middle Income Adolescents in Delhi, India

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ABSTRACT

Nutritional requirements increase tremendously during adolescence. Therefore, the present study wanted to assess the nutritional quality of the diet to low and middle-income adolescents of Delhi, the capital city of India. Dietary intake was assessed for 1030, 12-16 year old children studying in private (n=4) and government schools (n=4)using a three day food record. It was found that in private school children,for all food groups the percent adequacy of consumption was significantly higher ($p<0.05$) as compared to the percent adequacy in government school children.It was found that for all nutrients except folic acid, zinc and dietary fibre, private school children had a significantly higher percent adequacy of consumption ($p<0.05$) as compared to government school children. Boys belonging to both private and government schools had percent adequacy of consumption for nutrients like calcium and vitamin B12 significantly. Higher ($p<0.05$) than girls.Girls belonging to both private and government schools had percent adequacy of consumption for energy significantly higher ($p<0.05$) than boys. Diets of government school children who came from an economically disadvantaged background, were nutritionally inadequate as compared to private school children with respect to most foods and nutrients. Private school children on the other hand, were consuming nutrients like energy, and total fat above the recommended amounts. Therefore, children and parents need to be sensitized to ensure that children in this critical growing age consume nutritionally balanced meals avoiding excess consumption of energy, especially from fat and sugar.

Keywords: *Recommended Dietary Allowance, Nutritional Adequacy, Adolescents, Malnutrition.*

INTRODUCTION

*A*dolescence is a period of peakgrowth for boys and girls. Nutritional requirements in relation to body size are more during adolescence. In a country like India there exists a triple burden of malnutrition i.e. over-nutrition, under-nutrition and micronutrient deficiencies amongst adolescents. Studies on diet surveys have shown that the diets of low income group population are inadequate when compared to recommended allowances. The common causes of undernutrition among adolescents in the poor community are less access to food and inadequate knowledge about dietary requirements[(1)]. Whereas diet surveys on the affluent groups has shown excessive intake of energy leading to obesity [(2)].The present study wanted to compare the intake of food and nutrients in two diverse socio-economic groups of adolescents residing in urban Delhi and hence comment on the quality of their diets.

MATERIALS AND METHOD

The study was conducted in private (n=4) and government/government-aided schools (n=4) of four zones of urban Delhi.A total of 1030 children (12-16 years old) studying in classes 7-11, were selected from these schools.

The diet survey was carried out by using a pre-tested 3-day food record method.The respondents were asked to record their actual consumption of foods and beverages at the time of consumption for three days i.e. two working days and one holiday. The amounts of food products consumed were assessed by using three and two-dimensional food models of standardized plates, glasses, spoons, ladles and bowls. Ethical clearance was taken from the Lady Irwin College

Institutional Ethics Committee. Written consent was sought from parents and assent from the school children.

Nutrient intake was calculated by using dietary assessment software called "DietCal Version 5 by Profound Tech Solutions Pvt. Ltd which compiles nutritive values for foods based on nutrient composition data by National Institute of Nutrition (NIN) [3]. The software was validated prior to use which showed complete agreement between the software and the nutritive values data. The mean intakes obtained were assessed for adequacy by comparing with respective Recommended Dietary Allowances(RDA) for nutrients [4] and recommended amounts of food groups [5]. Independent t-test or Mann-Whitney U-test was used for comparison of percent adequacy of nutrients and food groups across gender and school type.Chi-Square test was used for comparison across school types for adequacy of food group and nutrient intake. Those children consuming below 50% were classified as those consuming nutritionally inadequate amounts and hence at risk for deficiency.

RESULTS AND DISCUSSION

A total of 1200 children were recruited for the study, of which 1030 (86%) children completed the study.

Food Group Intake

The intake for food groups and percent adequacy has been presented in Table 1.Ultra-processed foods included foods like preserves, confectioneries, bakery products, miscellaneous snack items etc. Meat, chicken, fish and egg were consumed only by a small proportion of the respondents probably because of vegetarianism or because of high cost of these foods which may decrease the frequency of intake in the population.Individuals not consuming flesh foods need to incorporate more milk products or pulses in their diet to obtain good quality protein.

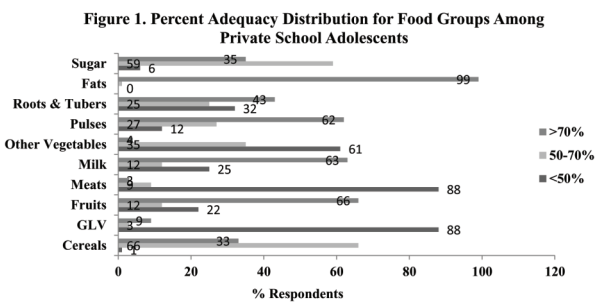
Among both private and government schools, males had percent adequacy of cereals, fats (visible), fruits and milk and milk products significantly higher than females.Among private and government schools, females had a significantly higher percent adequacy of intake of roots and tubers as compared to males.

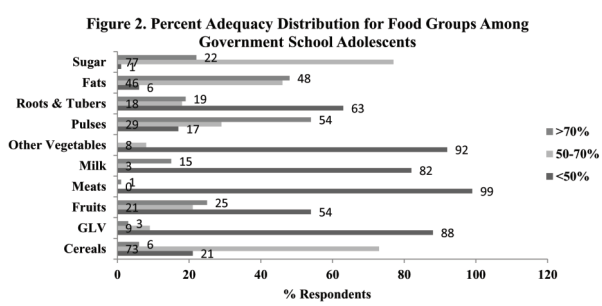
Table 1. Adequacy of Intake of Food Groups among Respondents 12-16 year olds (N=1030)

Food Group	Recommended amount for Boys (g or ml/day)	Private School Boys (n=225)		Government School Boys (n=271)		Recommended amount for Girls (g or ml/day)	Private School Girls (n=250)		Government School Girls (n=284)	
		Mean±SD (g or ml)	% Adequacy	Mean±SD (g or ml)	% Adequacy		Mean±SD (g or ml)	% Adequacy	Mean±SD (g or ml)	% Adequacy
Cereals	420	305.3±36.6	72.7[a]	236.5± 35.8	56.3[b]	300	5±23.97.	65.7[a]	149.9± 10.1	50.3[b]
Fat (Visible)	25	23.9±3.8	95.6[a]	19.6±2.5	78.4[b]	25	14.9±2.0	83[a]	13.7±9.4	59.9[b]
Pulses	60	52.5±14.5	82.0	49.8±16.3	81.7	60	49.7±18.1	80.5	47.2±17.1	78.8
Fruit	100	128.1±65.1	106.4[a]	103.9±45.8	70.2[b]	100	1±21.67.	97.9[a]	69.6±26.7	40.7[b]
Milk	500	407.3±173.2	81.1[a]	277.9±176.9	51.1[b]	500	387.3±169.4	74.7[a]	151.3±50.1	25.3[b]
Green Leafy Vegetables	100	75.9±23.7	76	70.7±18.3	70.7	100	80±18.9	80	63.2±18.1	63.2
Roots and Tubers	200	94.3±40.6	47.2[a]	72.7±21.1	36.4[b]	100	95.9±40.6	95.9[a]	55.8±15.6	55.8[b]
Other Vegetables	100	64.5±28.7	64.5	46.4±16.9	46.4[b]	100	58.7±17.2	58.7	32.4±9.2	32.4[b]
Sugar	35	23.6±4.5	67.4	24.6±2.2	70.3[b]	30	19.9±3.3	66.4	18.8±1.6	62.8[b]

[a]*Significant difference (p<0.05) in % adequacy of private school boys and girls.*

[b]*Significant difference (p<0.05) in % adequacy of government school boys and girls.*





Looking at the percent adequacy distribution for intake of food groups (Figures 1 and 2), it is clearly evident from the present study that the diets of the low-income government school children were of a poorer quality than the private school children. Fewer respondents from government schools were consuming adequate amounts (>70% of recommended quantities) of protective, body-building foods like fruits and milk. A large proportion of both middle and low-income group children were consuming less than 50% of the recommended amounts of green leafy and other vegetables. Almost all the private school children were consuming more than 70% of the recommended fat, probably as their diet had more ultra-processed foods like chips, bakery products like bread, cakes, confectioneries like chocolates and miscellaneous snack items like ice creams etc. Sugar was however being consumed by majority at a level below 70% of suggested amounts, which is desirable. In fact, some individuals reportedly did not consume sugar at all in their daily diet.

Nutrient Intake

The intake for nutrients like are presented in Table 2. Males were consuming significantly higher amount of protein, total fat, carbohydrate and calcium as compared to females ($p<0.05$). 12-14 year old children were consuming significantly higher amount of carbohydrates as compared to 15-16 year old children ($p<0.05$) which might be due to their significantly higher consumption of sugar. Private school children were consuming significantly higher amount of energy, total fat, carbohydrate, calcium, vitamin A, vitamin C and vitamin B_{12} ($p<0.05$) as compared to government school children.

In a study by Malhotra and Passi [2], among adolescent girls belonging to six districts of North India, the average percent adequacy for energy and protein was found to be 68.8% and 68.3% respectively. The present study had percent adequacy for both these nutrients slightly higher than that reported in the above study.

Table 2. Mean Nutrient Intake Among Participants (n=1030)

Nutrients	Gender			Age			Type of School		
	Male (n=496)	Female (n=534)	p-value	12-14 years (n=617)	15-16 years (n=413)	p-value	Private (n=475)	Government (n=555)	p-value
Energy(kcal)	2250± 1063.6	2099± 302.3	0.0677	2118± 965.9	2249±292.6	0.3024	2243±1083.3	2110±313.5	0.0323
Protein(g)	46.6± 8.2	42.9± 9.3	<0.001	44.7± 8.9	44.6±9.0	0.9096	45.2± 9.6	41.2± 8.4	0.0849
Total fat(g)	52.3±16.2	47.3±15.9	<0.001	50.4± 16.7	48.9± 16.6	0.9106	47.6± 15.6	39.9± 15.6	<0.001
Carbohydrate(g)	432.2±43.0	425.2±49.8	0.0163	432.0±43.3	423.4±51.0	0.0035	431.8±43.8	401.8± 48.9	0.0414
Calcium(mg)	361.3 (76.8-1333.5)	350 (76.9-1099.5)	0.0249	447.2±240.7	423.7± 215.5	0.1105	573.7±250.9	321.4± 126.1	<0.001
Iron(mg)	13.36± 4.35	13.31±4.32	0.8496	13.23± 4.43	13.48±4.18	0.3719	13.32± 4.35	13.34± 4.32	0.9479
Vitamin A(ug)	250.3±154.5	243.8±160.9	0.5140	241.7±161.7	255.3±151.0	0.1742	315.6±168.2	188.5± 120.3	<0.001
Folic acid(ug)	104.7±38.3	101.2± 42.3	0.1731	102.5±42.8	103.7±36.4	0.6361	103.5±44.1	102.5±36.8	0.6906
Vitamin C(mg)	35.6± 26.7	34.8± 24.1	0.6184	35.6±26.9	34.5± 22.8	0.5278	43.3± 29.9	28.2± 18.0	<0.001
Zinc(mg)	12.85±0.94	12.85±0.91	0.9629	12.84±0.92	12.86±0.93	0.6887	12.85±0.92	12.85±0.93	0.9917
VitaminB_{12}(ug)	0.43(0.09-2.81)	0.35(0.09-2.81)	0.8932	0.34(0.09-2.81)	0.56(0.09-2.81)	0.3951	0.71±0.55	0.52±0.39	<0.001
Dietary fibre(g)	38.6±5.6	38.4± 5.4	0.715	38.4± 5.5	38.5± 5.5	0.8985	38.5± 5.5	38.5±5.5	0.9501

Most values are Mean±SD. Values in parentheses indicate range and have been given where median values have been reported.

According to the National Nutrition Monitoring Bureau (NNMB)[6], boys in India, had 85% adequacy for proteins, 54% for fat, 40.6% adequacy for vitamin A, 90% for vitamin C, 80.5% for folic acid, 42.8% adequacy for calcium, 49.6% for iron and 60.3% for energy. Girls had 82% adequacy for proteins, 40.6% adequacy for vitamin A, 95% for vitamin C, 74% for folic acid, 40% adequacy for calcium, 40.6% for iron and 69.9% for energy. In the present study on an average, both boys and girls had higher percent adequacy for vitamin A, energy, calcium and iron as compared to NNMB data, but had lower adequacy for vitamin C and folic acid as shown in Table 3.

According to a survey by Maliye et al. [7] in Wardha, Gujarat, rural adolescent girls had percent adequacy for energy and protein as 53.4% and 76.7% respectively. Looking at Table 2, it was found that the percent adequacy reported in the present study for energy was higher but for protein was found to be lower.

In the study by Bansal et al. [8] conducted among adolescent girls residing in urban slums of Delhi, the

mean calorie consumption per day was 1392±238 Kcal,1654±254 Kcal and 1649±288 Kcal for Group I (11-12 year olds), II (13-15 year olds) and III (16-17 year olds) respectively with an approximately 70% adequacy w.r.t. RDA.The mean protein intake per day in Groups I, II and IIIwas 37.9±6.6 g, 45.2±7.0 g and 45.5±7.9 g respectively, with percent adequacy in the range of 82% to 93.8%. In the present study, the government school girls had the % nutrient adequacy for energy greater than the Bansal et al. [8] study, whereas for protein, it was less.

According to Sharma, Shukla and Kannan et al. [9] adolescent girls in Delhi, had an average daily energy intake of 1491 kcal and 827 kcal among private and government schools respectively. The protein intake for private and school girls was 57.4 g and 29.9 grams daily respectively. Looking at Table 2, it is clearly evident that in the present study the intake for energy was higher and for protein was lower in case of private school girls.

A study by Venkaiah et al. [10] among rural adolescents in North India showed that boys had 61.2% percent adequacy for calcium, 88.1% adequacy for iron, 40.5% for vitamin A and 83.8% for vitamin C. The girls had 56.3% percent adequacy for calcium, 70% adequacy for iron, 45.9% for vitamin A and 94.2% for vitamin C. The present study had percent adequacy for calcium and vitamin A for both girls and boys higher than the study done by Venkaiah et al. (2002). But the percent adequacy of iron and vitamin C for both boys and girls reported by Venkaiah et al. (2002) was higher than that reported in the present study.

Table 3. Comparison of Percent Adequacy of Nutrient Intake of Respondents (n=1030)

Nutrient	Private School Children (n=475)% Adequacy	Government School Children (n=555)% Adequacy	p-value	Private School Children (n %)		Government School Children (n%)		Chi-square statistic (p-value)
				<50% Adequacy	<50% Adequacy	<50% Adequacy	<50% Adequacy	
Energy(kcal)	88.5(70-105.5)	85.1(65.5-95.6)	0.0323	0	100	0	100	-
Protein(g)	95.8(80.6-110)	75.2(58.1-91.2)	0.0449	0	100	0	100	-
Calcium(mg)	82(58-97.5)	69.8(42.5-89.1)	<0.001	0	100	10	90	-
Iron(mg)	65.9(34.3-82.1)	54.6(28-77.7)	0.0079	18	82	33	77	29.32(p<0.001)
Vitamin A(ug)	68.5(46-89)	55.7(33-71.2)	0.0034	12	88	37	63	83.92(p<0.001)
Vitamin C (mg)	92.5(77-150.1)	68.5(48-95)	<0.001	0	100	8	92	-
Vitamin B_{12}(ug)	189(100-270)	129(70-205)	<0.001	0	100	0	100	-
Folic Acid(ug)	70.9(45-98.5)	65.4(33-81.7)	0.0516	17	83	29	71	20.35(p=0.0006)
Zinc(mg)	80.9(52-101)	73.8(48-96)	0.0901	0	100	6	94	-
Dietary Fibre(g)	83.8(68-100)	80.4(60.2-92)	0.0982	0	100	0	100	-

Values given are mean percent adequacy of the group. Values in parenthesis are the range values.

Overall as shown in Table 3, private school children had mean percent adequacy for energy, protein, calcium, iron, vitamin C, vitamin A and vitamin B_{12} significantly higher than government school children.For nutrients like, vitamin B_{12}, all private school children had adequacy higher than 100% and for vitamin C all had adequacyhigher than 70%. Besides these two nutrients, some respondents had percent adequacy greater than 100% for other nutrients also like dietary fibre, protein and energy. For vitamin $B_{12,}$ all government school children had adequacy higher than 70% and a few had adequacy higher than 100%. For other nutrients like folic acid, vitamin C, vitamin A, zinc, iron and calcium some individuals had percent adequacy < 50% and were at risk of deficiency for that nutrient.

The diet of the adolescents in the present study was clearly lacking in calcium, vitamin A and hematopoietic nutrients like iron and folic acid and enhancer of iron absorption i.e. vitamin C in the diet. This could be primarily due to lower consumption of green leafy vegetables, meat products, milk products, whole grain cereals and other colourful vegetables and roots and

tubers in diet as discussed earlier in the section on food group intake. This type of diet pattern could lead to development of micronutrient deficiencies with serious nutritional consequences in later life. School health programs need to advocate intake of well-balanced meals among school children. Some adolescents had higher energy and visible fat in their diet than the RDA, which could increase the risk of obesity and associated problems. The high intakes were probably due to higher consumption of visible fats like butter, fried foods, cheese, refined cereals and ultra-processed foods like chips, breads, cakes, pizza, noodles, ice creams, snacks etc. Therefore, these children also need to be guided about making healthy food choices in order to sustain an optimal nutritional status for their age.

CONCLUSION

Nutritional requirements increase tremendously during adolescence as it is the most critical period of development. It was found that for all food groups in private school children (middle income group) the percent adequacy of consumption was significantly higher ($p<0.05$) as compared to government school children (low income group). Boys belonging to both private and government schools had percent adequacy of consumption for food groups like visible fat, cereals, milk and fruits significantly higher than girls. Girls belonging to both private and government schools had percent adequacy of consumption for roots and tubers significantly higher than boys It was found that for all nutrients except folic acid, zinc and dietary fibre, in private school children the percent adequacy of consumption was significantly higher ($p<0.05$) as compared to government school children. Boys belonging to both private and government schools had percent adequacy of consumption for nutrients like calcium and vitamin B_{12}significantly higher ($p<0.05$) than girls. Girls belonging to both private and government schools had percent adequacy of consumption for energy significantly higher ($p<0.05$) than boys. It was clearly evident that diets of government school children were nutritionally inadequate with a higher percent of children consuming foods and nutrients <50% of recommended amounts as compared to private school children. For food/nutrient like cereals, fats, pulses, meat products, milk, fruits, green leafy vegetables, roots and tubers, other vegetables/ energy, protein, vitamin C, vitamin B_{12}, zinc and dietary fiber, some individuals had percent adequacy>100%.But what is more disturbing is that some individuals did not consume vegetables, pulses and fruits at all during the three-day survey period. Avoiding fruits, pulses or vegetables in one's diet decreases protein quality, fibre intake and the intake of protective phytochemicals, besides vitamins and minerals. Children and parents needs to be sensitized so that in this critical growing age nutritionally adequate diets are consumed keeping in mind avoidance of excess consumption of fat and sugar.

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Prevalence of Depression among Elderly People in the Place of their Residency, in the Urban Field Practice Area of Navodaya Medical College, Raichur

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ABSTRACT

Introduction: Depression is the most common psychiatric disorder among the elderly. It is not yet perceived as an important health problem in India, where few community based studies are available.

Objectives: To estimate the prevalence of depression and socio-demographic factors influencing depression in the elderly people.

Materials and Method: WHO -30 cluster gold standard sampling method was used to select the samples.7 elderly persons, sixty years and above were selected from each cluster till a sample size of 210 was achieved. The study was done in the urban field practice area of Navodaya Medical College. After obtaining informed consent from the elderly people (≥60years) a pre-tested, pre-designed, pro-forma was used to collect the data. Geriatric depression scale-Short form (GDS-SF) questionnaire was administered to 210 selected elderly population. Elderly with psychiatric morbidity and not willing to participate were excluded from study. A score of ≥5 were considered to be under depression. Data collected was analyzed using Epi inf 6 version.

Results: Out of 210 respondents interviewed 126(60%) were found to be depressed.125 were women and 85 were men out of which 77(36.7%) and 49(23.3%) were depressed respectively. Female sex, illiteracy, widowhood, low socio-economic status and other co-morbid conditions was influencing depression.

Conclusion: A high level of depression was found among elderly people using GDS-SF. Quality health care of the elderly reduces the future burden of diseases and disabilities.

Keywords: *Depression, Geriatric depression Scale (GDS-SF), Elderly people*

INTRODUCTION

Ageing is a natural process. Old age should be regarded as a normal, inevitable biological phenomenon. By 2025 the elderly population is expected to rise more than 1.2 billion with about 840 million of these in low-income countries. For the year 2010 the estimate of India's total population above 60years of age was 8% and is likely to rise to 19% by 2050[1]. A high prevalence of mental disorders is seen in old age, predominantly 'depression'-which is an affective illness characterized by depression in mood, cognition and behaviour[2]. Elderly depression is a common clinical condition in anyone over the age of 60years.

Global burden of disease(GBD) - study projection shows that depression will be the single leading cause of Disability Adjusted Life Years(DALY) by 2020 in the developing world[3]. In a meta- analysis of various study reports of community- based mental health surveys on geriatric depression disorders in those aged 60years and above conducted between 1995 and 2005 the median prevalence rate of depressive disorders in the world for elderly population was determined to be

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10.3%, while among the elderly Indian population it was determined to be 21.9% (Interquartile range 11.6% -31.1%)[4].

Depression being difficult to diagnose will lead to an increase in morbidity and mortality and health care cost along with reduction in quality of life[5].This may lead to silent epidemic[6]. Elderly people with depression are less likely to adhere to their diet, exercise and medication as compared to those without depression[7]. In spite of quantum of this problem there are very few studies from India on depression and factors influencing it.Hence the study was conducted.

OBJECTIVES

1. To estimate the prevalence of depression among elderly population.
2. To study the socio-demographic factors influencing it.

MATERIALS AND METHOD

Study design

WHO-30 cluster goldstandard sampling method was used to collect samples. The study was carried out from July 2016 to September 2016 in urban slum, field practice area of Navodaya Medical College, Raichur.

The total population of field practice area of the tertiary centre is 24,640[8].It hasthree wards.Each ward has a population of 8,213; 10,576;5,851 respectively. Cumulative population was calculated. Total cumulative population was divided by 30 to get serial interval. A number was randomly selected which was less than serial interval. That was taken as first cluster. Subsequent clusters were identified by adding serial interval to the previous one. Thus 30 clusters were identified.Each cluster was visited.Standing in a place wherefour roads meet, a bottle with a cap rotated and the direction in which the bottle cap was showing, in that direction we moved to collect the samples. 7 elderly people 60 years and above were taken as a sample from each cluster. Totally 210 people were selected from 30 clusters to study the prevalence of depression.Each sample selected was interviewed at their residence.

A pre-designed, pre-tested, pro-forma questionnaire was used to collect data. It had two parts- general information like socio-demographic profile and Geriatric Depression Scale- short form (GDS-SF). It was used to estimate depression prevalence.GDS-SF-15 item self-report assessment scale was first developed by Yesavageet al[9]. It is used as a basic screening measure of depression in the elderly. Accuracy of GDS-15 is not influenced by the severity of medical burden, age or other socio-demographic characteristics and even in the 'very old' and ill can be screened appropriately[10].

Institutional Ethical Committee clearance was obtained prior to the commencement of study. The respondents were explained the purpose of study and their signed consent was obtained. Information was obtained from consenting respondents using pre-tested questionnaire containing various parameters. The interview was conducted in the language with which the subject was familiar and the same were translated back .To ensure validity of translation independent language expert help was taken.

Exclusion criteria

Individuals above 60 years with psychiatric morbidity and those who were not willing to participate were excluded from the study.

Statistical analysis

Data collected was analyzed using Epi info 6 version.Percentages were used to calculate the number of persons depressed. Depression score≥5 was considered to be under depression.

RESULTS

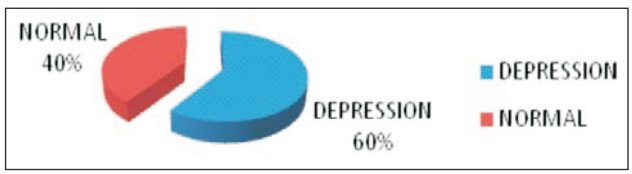
When the demographic characteristics were analyzed in the study population, out of 210 study subjects who participated in the study,59.5%(n=125) were females and40.5%(n= 85) were males. The widows were 40.0 %(n=84) in number compared to those with having spouse 41.3%(n=93). Majority of study subjects were illiterates 49.5%(n=104). Many of the elders were living with their children in a three generation family 53.3% (n=107). Majority of them were not working 64.3% (n=135) and in class IV socio-economic class 50.0%(n=105). Those with ≥ 2 co-morbid condition 60% (n=126) were depressed. The socio-demographic characteristics of the elderly are given in table-1.

Table 1: Socio-demographic characteristics with percentage of depression

Variables	Depression present(%)	Depression absent(%)
Age		
60-64yrs(n=83)	40 (19)	43(20.5)
65-69yrs(n=50)	27(12.9)	23(11.1)
70-74yrs(n=22)	12(5.7)	10(4.8)
75-79yrs(n=16)	11(5.2)	5(2.4)
80-84yrs(n=12)	10(4.8)	2(1.0)
85-89yrs(n=22)	21(10)	1(0.5)
≥90yrs (n=5)	5 (2.4)	0(0)
Sex		
Male(n=85)	49(23.3)	36(17.1)
Female(n=125)	77(36.7)	48(22.9)
Marital status		
Spousepresent(n=93)	44(21.0)	49(23.3)
Spouse absent(n=33)	25(11.9)	8(3.8)
Widow(n=84)	57(27.1)	27(12.9)
Education		
Illiterate(n=104)	71(34.2)	33(15.7)
Primary (n=47)	23(11.0)	24(11.4)
Secondary (n=38)	22(10.5)	16(7.6)
Pre-university(n=21)	**10(4.3)**	**11(5.3)**
Type of family		
Nuclear family(n=71)	45(21.4)	26(12.4)
Joint family(n=27)	14(6.7)	13(7.1)
Three generation family(n=112)	67(31.9)	45(20.5)
Occupation		
Working(n=75)	35(16.7)	40(19.0)
Not working(n=135)	91(43.3)	44(21.0)
Socio-economic status*		
Class I (n=3)	3(1.4)	0(0)
Class II (n=8)	4(1.9)	4(1.9)
Class III (n=41)	30(14.3)	11(5.2)
Class IV (n=105)	52(24.8)	53(25.2)
Class V (n=53)	37(17.6)	16(7.6)
Chronic co-morbidities		
<=2 diseases(n=126)	57(27.1)	69(32.9)
>2 diseases(n=84)	69(32.9)	15(7.1)

*Modified B.G Prasad classification; percentage in parenthesis

FIG-I Percentage of normal and depressed



When the depression rate was analyzed only 40% were normal and 60% were depression. Majority of them were mildly depressed(35.7%) and 6.2% were severely depressed.

Table 2: Shows the grades of depression.

Depression	No. of Cases
Normal(0-4)	84(40)
Mild (5-8)	75(35.7)
Moderate(9-11)	38(18.1)
Severe(12-15)	13(6.2)

*percentage in parenthesis

DISCUSSION

Studies have revealed that the prevalence rate of depression in community samples of elderly in India varies from 6% to 58%[11]. A meta- analysis study reveals the median prevalence rate of depression among Indian elderly as 21.9% (IQR 11.6-31.3%).It may be explained by the fact that meta-analysis consisted of 6 relevant studies from India, covering only 2499(0.5%) of elderly participants[4]. Our study reported a higher prevalence of depression as 60% similar to study done in rural areas which reports 61%[12].

In the present study, out of 210 study samples, high rate of depression (19%) was found in the age group of 60-64 years, may be due to smaller sample size.

The current study showed, females had a higher level of depression (36.7%) compared tomales (23.3%). This is because women, throughout their lifetime face more stressful events and have a greater sensitivity towards them. Hence they tend to get depressed. Similar results were also found in the studies done by Jain RK et al[13] and Rajkumar AP et al [14] and Poongothai S et al[15]. On the contrary, a study done in rural community in South Kerala by Sandhya G[16], a low level of depression prevalence was found in females compared to males.

Our study shows widows had a higher rate of depression(27.1%) similar to results of study conducted by Kamble SV[17]. This is because those who were having spouse feel a sense of companionship in sharing the experiences and feel less lonely.

The present study shows, those who were in three generation family found to be in more depression (31.9%) compared to other type. It is in contrast to the study conducted by Sengupta P et al[18]in Ludhiana

where elders in nuclear family found to be more depressed. This may be due to the fact that study was being done in urban slum, where most of the other family members will be outside for earning and other purposes, making elders to feel bore and no one to share their feelings and hence depressed.

High rate of depression was found in illiterate (33.8%) compared to literates. This may be due to higher financial dependency of the illiterate elderly.

This study showed those who were working are less depressed than those who were not working (43.3%).The study conducted by Pracheth R et al[19] in Dharwad of Karnataka also showed more prevalence of depression among illiterates and those who were not working.

The findings of our study indicates that depression was higher among elderly subjects belonged to low socio-economic class (class-IV) as 24.8 %. It is analogous with other studies done by Jain RK et al[12], Rajkumar AP et al[13] and Pracheth R et al[19]. This could be ascribed to the fact that, people of low socio-economic classes have poor access to quality health care due to poverty. Hence they are prone for depression.

Present study showed, those who were having ≥2 physical co-morbid illness had higher rate of depression(32.9%). When a person is having chronic diseases, negative emotional effects can also develop.Poor physical health may affect a person's independence, change the way he lives, perceives himself and relates to others.It may lead to depression.This is analogue to other studies done by Seby K et al[20] and Rajkumar AP et al[13]. Thus poor physical health is a major cause of depression in later life.

CONCLUSION

A high prevalence was found among elderly using the GDS. Geriatric depression may emerge as a public health problem, which needs for development of effective preventive strategies to halt this silent epidemic. The study concludes that GDS is an easy to administer and culturally acceptable tool to assess depression in community.There is need fora greater attention towards the physical and psychiatric problems faced by this age group. Geriatric clinics should be introduced in the health care services. Since geriatric population is increasing, public awareness and support through counseling is essential. An awareness regarding Old age pension scheme, and financial assistance for widows should be made available. Recreation facilities for elders should be available. Quality health care of the elderly reduces the future burden of diseases and disabilities.

Limitation

This study may have over-estimated the prevalence of depression since no formal method of diagnosis was employed. The tool used for assessment of depression – GDS-SF is merely a screening tool and cannot be used to replace clinical diagnosis.

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To Study the Reasons Given by Mothers of Under 5 for not Attending the Pulse Polio Immunisation at Sultanpalya UHTC of Dr. B R Ambedkar Medical College, Bangalore

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ABSTRACT

Background: Mothers are the backbone of our country as they are the ones who take the responsibility of the children's health. Hence their literacy status and their knowledge regarding the PPI is very important.

Aims and Objectives:

1) To assess the number of children <5years of age who had not gone to the booth for IPPI.

2) To find out the reasons that the mothers gave for not taking their children to the booth.

Materials and method: It was a community based cross sectional study, undertaken at Sultanpalya area of Urban Health Training Centre of Dr B.R Ambedkar Medical College

Results: Children who were not taken to booth during 1st round of PPI were 616 (36.7%) and those who were not taken to the booth for the 2nd round of PPI were 1554 (92.8%).Of the1554 children who did not attend the 2nd round of PPI, 1273(81.9%) were completely immunized, of whom maximum number of 375 (24.1%) belonged to 3-4 years of age group. Of these 1554, 260 (16.7%) were partially immunized and only 21 (1.3%) were unimmunized. The literacy status of the mothers was significantly associated with the number of children who did not attend the pulse polio. The mothers of 52.3% of the children who did not attend the pulse polio booth, were illiterateand is statistically significant (95% CI 49-54).

Conclusion: The study shows that the mothers who were educated up to primary or high school knew that the PPI had door to door visit by the health worker on the second and third day; hence they were not bringing the children to the booth on the first day of PPI. We need to educate the community on taking the responsibility of availing the health services being provided by the Government. In spite of these drawbacks we have been able to achieve the elimination of Polio Virus from India and are on the verge of eradication.

Keywords: *Pulse Polio Immunization, Children Less than 5years, Literacy Status*

INTRODUCTION

National Immunization Day (NID) commonly known as Pulse Polio Immunization with the global initiative of eradication of polio in 1998 following World Health Assembly program was launched in India in 1995, and is conducted twice in early part of each year. Additionally multiple rounds (at least two) of sub national immunization day (SNID) have been conducted over the years in high risk states/areas. In these campaigns, children in the age group of 0-5 years are administered polio drops. Over 170 million children are immunized during each NID and 77 million in SNID. Surveillance for detection of polio virus transmission is being done through acute flaccid

paralysis (AFP Surveillance) with laboratory network since 1997. Oral polio drops being provided to all children less than five years of age in routine immunization programme.[1]

The last reported cases of poliomyelitis were in West Bengal and Gujarat on 13th January 2011. On 27th March 2014, WHO declared India a polio free country.[2] Type 2 wild polio virus eradication was certified in September 2015. Type 3 has not been detected since November 2012. No wild polio virus (WPV) has been detected outside Afghanistan and Pakistan since August 2014. Hence it is of utmost importance for India to be cautious as there is a chance of the WPV to be imported into India from the neighbour borders.

Inspite of GOI making all efforts to reach out to population in the most inaccessible areas, the 'fully immunized' child still persists to be a far cry. Though every parent wants the safety of their child and protects their child from any untoward incident, we find parents who fail to immunize their children completely. It is important for the policy makers to know and understand the reasons for this failure and to further make efforts in improving the immunization status of every child in the country.

Justification

Measles Rubella vaccination campaign is being scheduled from February 7th to February 28th 2017, in view of elimination of measles and rubella. Hence parents have to be educated regarding the importance of these campaigns.

METHOD AND MATERIALS

Study Design: It was a community based cross sectional study, undertaken at Sultanpalya area of Urban Health Training Centre of Dr B.R Ambedkar Medical College.

Study Period: The study was conducted fromDecember 2011- February 2012

Sample Size: 817 Mothers of 1674 children below 5 years were interviewed.

Methodology: All the mothers of 1674 children were interviewed after taking an informed consent. A semi open ended questionnaire was self designed and pretested prior to use. Data was collected using this questionnaire and mothers were asked the reasons for not attending Pulse Polio Program. The data also contained the demographic details of the mothers being interviewed.

Data Analysis: Data entry and analysis was done using statistical software EPI Info .Percentages and 95% CI was calculated wherever applicable.

RESULTS

Of the 1674 children whose mothers were interviewed, 718 (42.9%) were male and 956 (57.1%) were female children, the ratio being 1:1.33.

Children who were not taken to booth during 1st round of PPI were 616 (36.7%) and those who were not taken to the booth for the 2nd round of PPI were 1554 (92.8%). Of these 1554, 638 (41%) were male children and 916 (58.9%) were female children.

Of the Children who were not brought to the booth, maximum number of children 251 (40.7%) were belonging to the age group of 3-4 years and least were 33 (5.3%) belonging to the age group of 1-2 years.

Of the1554 children who did not attend the 2nd round of PPI, 1273(81.9%) were completely immunized, of whom maximum number of 375 (24.1%) belonged to 3-4 years of age group. Of these 1554 260 (16.7%) were partially immunized and only 21 (1.3%h) were unimmunized.

The age of the mothers who were interviewed, was ranging between 18-44 years. Of the 817 mothers who failed to bring their children to the 2nd round of PPI, maximum number 532 (65.1%) were between the age of 20-30 years and 214 (26.2%) were less than 20 years of age.

The literacy status of the mothers interviewed is as shown in Table no 1.

The literacy status of the mothers was significantly associated with the number of children who did not attend the pulse polio. The mothers of 52.3% of the children who did not attend the pulse polio booth, were illiterate and is statistically significant (95% CI 49-54), as shown in Table 2.

The reasons given by the mothers for not bringing their children to the booth are as shown in Table no 3.

DISCUSSION

It was a small observational study conducted at one PHC but, it brought out the reasons for the children not being taken to the PPI booth.

The literacy status of the mothers was significantly associated with the number of children who did not attend the pulse polio. The mothers of 52.3% of the children who did not attend the pulse polio booth were illiterates and is statistically significant (95% CI 49-54) as shown in Table -2. In a study by N.Joseph etal the educational status was significantly associated with their awareness to bring the children to the booth[3]. A study by Chincholikar shows that knowledge about pulse polio had a direct relationship with literacy[4].

The illiterate mothers were lacking the motivation to take their children to the booth of PPI on first day , which was 58.4%. In a similar study undertaken by Asif Raza Khowaya and Sher Ali Khan[5] at Nigeria showed that 24% of the mothers gave the reason as lack of time or motivation to take their children for PPI. In another study done at Ghana, India and Pakistan , the mothers said that they were busy and hence they did not take their children to the booth[6].

Another reason observed was lack of knowledge among the mothers (3.5%) for not attending the PPI on first day. The same study by Asif Raza Khowaya[5]at Pakistan, showed 74% of the mothers had lack of knowledge about attending PPI. The study at Ghana, India and Pakistan also show that unawareness of the campaign was the reason why the mothers did not take their children to the booth[6]. A similar study by Muhammed Umar Khan[7] showed that 33.7% of mothers were lacking the knowledge about PPI.

Table no 1. Literacy status of Mothers interviewed

Literacy Status	No of Mothers	Percentage
Illiterates	354	43.3
Primary School	303	37.1
High School	160	19.6
Total	817	100

Table no 2. Association of literacy status of mothers with number of children not taken for PPI

Literacy status of mothers	Children not taken to booth	Percentage	95% CI
Illiterate	812	52.3	49-54
Primary School	515	33.1	30-35
High School	227	14.6	12-16
Total	1554	100	

Table no 3. Reasons given by mothers for not taking the child for PPI

Reasons	Number of Mothers	Percentage	95% CI
Know about door to door visit of Health worker	466	30	53-60
Lack of knowledge/ child was sick	55	3.5	5-8
Lack of motivation	296	19	32-39

Table no 4. Association of educational status with reasons for not attending PPI

Reasons	Illiterate	Percentage	Primary School	Percentage	High School	Percentage	Total
Know door to door visit of HW	113	32	239	78.9	114	71.3	466
Lack of knowledge/ Child is sick	34	9.6	17	5.6	4	2.5	55
Lack of motivation	207	58.4	47	15.5	42	26.2	296
Total	354	100	303	100	160	100	817

X^2= 0.000, $p < 0.005$, statistically significant

Conflict of Interest: Nil

Source of Support: Authors themselves

Ethical Clearance: Ethical clearance was taken from the IEC.

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An Explorative study of Operationalizing Mission Indradhanush: Experiences from Rural Health Training Centre - Sampaje

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ABSTRACT

Introduction: RHTC of KVG Medical College has achieved ≥95% FIC and booster dose coverage through Immunogram by March 2013 and sustaining till date. We operationalized MI, launched by the Government as a special drive with following 4 research questions:

1) What new lessons can be learnt?

2) What proportion of due children could be mobilized?

3) What proportion of data would qualify for reporting through Health Management Information

System (HMIS) and impact on strengthening "MCTiSation"?

4) What proportions of children would receive vaccination from private sector?

Methodology: We developed and prepared MI specific micro-plan and duelist using MCTS compatible Extended Immunogram (E-IgM) tool; provided vaccination services in 'all time mission mode' in the regular sessions itself.

Results: 7 new lessons were learnt; ~85% due children were mobilized, 40% of vaccination data qualified for reporting through HMIS, ~85% data could be MCTiSed and ~12% beneficiaries availed services from private sector. No additional impact on coverage as the baseline coverage was very high.

Conclusion and Recommendation: Critical Indicators of MI can be achieved in a very short time through the tool E-IgM and proper approach incurring no additional fatigue and expenditure.~28,000 planning units of India can potentially replicate this.

Keywords: *Immunization, Extended Immunogram, Mission mode.*

INTRODUCTION

Immunization is widely recognized as one of the worlds' most successful and cost-effective health interventions. Since the inception of Expanded Programme of Immunization in 1978, India is consistently trying to improve the coverage.1 Universal Immunization Programme, Child Survival and Safe Motherhood Programme, Reproductive and Child Health 1&2, National Rural Health Mission: all strengthened Routine Immunization (RI).2 As per District Level Household facility Survey (DLHS3:2007- 08), 14 states with 200 districts were below the National average of 71% of DPT3 coverage; 84.8% in Karnataka.3,4 For rapidly achieving >90% Fully Immunized Children (FIC), GOI declared 2012-13 as year of Intensification of Routine Immunization (IRI)through 4 intensified Immunization Weeks (IWs) as the key strategy. 5 Coverage Evaluation Survey (CES)2009 revealed FIC of

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61% and 78% for India and Karnataka respectively which rose to 65.3% and 79.4% respectively as per Rapid Survey of Children (RSOC) in 2013-14.[6,7,8] For achieving Measles elimination by 2020 as per the Vision, Mission, Objectives, Strategies and Action plan (VMOSA) of Global Vaccination Action Plan (GVAP), e" 95% coverage of Measles 2 doses has to be attained and sustained.[9] World Immunization Week 2016 aims to close the immunization gap[10]. India being signatory to the above, launched MI as a special drive in 201 districts of which 6 districts were from Karnataka. Strategy of operating 4 IWs in 4 successive months is common to IRI and MI.[11]

Why this Study and what were the Research Questions:

IRI simulation study of Jharkhand and Immunogram study of RHTC Sampaje revealed an unprecedented dramatic increase in vaccination coverage in a short period through intensification of regular sessions through use of proper tool and approach.[12,13]Though Kodagu district operating Immunogram is not in the MI list, these two studies inspired us to operationalize MI for which we raised the following 4 Research Questions (RQ) for graduating further in this field:

1) What new lessons can be learnt?

2) What would be the optimum proportion of due children who could be mobilized?

3) What proportion of data would qualify for reporting through Health Management Information System (HMIS) and would be impact on strengthening "MCTiSation" (uploading data to online Mother and Child Tracking System [MCTS] which is online)?

4) What proportions of children would receive vaccination from private sector?

METHOD

PHC Sampaje is the RHTC of KVG Medical College, using MCTS compatible E-IgM for RI services since Apr 2013. From this, MI specific micro-plan and MI specific duelist were prepared at the level of operational unit i.e. session site - the 2 key elements of MI.

Study period: April to July 2015- during the first phase of MI. The intervention upgraded the regular sessions to all time mission-mode.We obtained real-time denominators unique for MI to derive 4 critical indicators at the end of every session which provided numerators:

1) Total beneficiaries vaccinated antigen wise.

2) Total beneficiaries immunized.

3) Total children fully immunized:

a) below 1 year

b) above 1 year

4) Total children completely immunized.

MI related PHC profile

RI micro-plan depicted –17,553 Population, 236 Pregnant Women, 216 infants, 14 outreach vaccination sites, 3 fixed sessions at PHC, 8 ANMs, 38 AWWs and 15 ASHAs.

RESULTS AND DISCUSSION

In this study, results and discussions were narrated together for comprehension and to avoid repetitions.

RQ 1: What new lessons were learnt?

In spite of working for routine immunization for more than 3 decades, we learnt the following new lessons:

i. **Calculating Expected Due Children**: Annual target of infants was 216; i.e. 432 <2 year children for MI ignoring Infant Mortality Rate. Every child requires 5 visits to complete primary and booster series before 2nd birthday (1st/2nd/3rd/Measles1/ Booster+Measles2), yielding minimum 1080 children visits per year, i.e. 90 children visits per month. As births did not occur uniformly in all the 4 months it was more by 10 to15% of minimum. (Table1)

45 to 55% of annual target children have to visit in any given month in a high coverage area. It will be >55% in planning units with backlog.

Table 1: Distribution of SC wise, month wise live births

Sub-Centre (SC)	April2015	May2015	June2015	July2015	Total
Kadamakallu	0	0	1	0	01
Kannadperaje	2	0	7	2	11
Kumbalcheri	7	3	1	2	13
Kudrepaya	1	1	1	0	03
Balembi	3	2	1	1	07
Sampaje A	1	1	1	2	05
Sampaje B	0	1	2	2	05
Madenadu A	2	3	2	1	08
Madenadu B	4	2	0	1	07
Bettathuru	0	1	0	0	01
RHTC Total	20	14	16	11	61

Total 61 children were born between 01stApril and 31stJuly 2015: ranging from 0 to 7 in Kannadperaje SC & 11 to 20 in the RHTC.

Projection

Annual target of Karnataka was 1.123 million<1 year children yielding 5.62 million annual due children visits; 4.68 lakhs per monthexcluding BCG in the outreach.

India with 27 million infants yielded 135 million annual due children visits; 11.25 million per month excluding BCG in the outreach if the coverage is high.

This capacitates any programme manager to assess the adequacy of duelist.

ii. **Up-to date data maintenance shortens the due list:** Provisional duelist had 120 children in April, on data updating shortened to 99 (reduction by 17.5%). In May it was 3% and reduced to zero in June and July which is statistically significant $p<0.05$ (Table2).

This depicts adoption of mission mode for long term sustenance.

Table 2: Impact of timely data updating

Month	April 15	May 15	June 15	July 15
Provisional due list	120	102	101	104
Final due list	99	99	101	104
Shortened by %	17.5%	03%	0%	0%

In mission mode, ANMs concurrently updated vaccination data and obtained MI specific duelist.

iii. **Operating open vial policysaved ~Rs 21,400/-** by preventing avoidable vaccine wastage in4 months i.e. 200 doses of Pentavalent, 560 doses of OPV & 840 doses of DPT.

Vaccine stalk book was suitably revised for tracking temperature excursions of vaccine vials and financial loss prevention was calculated.

iv. Self-monitoring and evaluation. The tool helped in self-supervision and monitoring as it has denominator, records numerators and provides indicators. Absentees were followed up, redirected for completing the due dose for rapid clearance and vaccinating close to the schedule.

ANMs monitored and supervised themselves, sparing external monitors, setting an example of sustenance through local innovation – 5th and 6th principles of GVAP.[8]

v. Reasons for absence were listed: The reasons included more than those which were studied and listed in the CES/NFHS/DLHS. viz: staff nurses of referral centers advocated booster dose later than 18 months; waiting for additional caretaker for bringing the due twin children, election etc.

vi. Graduation of 'form' to 'tool': In July 2015, Government extended MI to other districts and provided House to House& headcount survey forms with directions to use cross sectional survey data for projecting to make annual micro-plan[14]. Survey forms were upgraded to 'tools' with help of ANMs. Survey yielded 17,598 total populations, 4107 houses, 103 'on hand' ANCs, amounting to 206 for the whole year and the target was 236, less by 30(12.71%). Similarly survey yielded 393 < 2 year

children against annual target of 432; less by 39(9%)as births did not occur uniformly in all the months and expired infants / nonresidents who received one or more doses of vaccines were not available during the survey. Hence, ANMs wisely retained RI annual target for projecting adequate logistic requirement as it was higher than MI survey data.

A pre piloted tool does required functions, simplifies and sustains the achievement than multiple fatiguing forms.

vii. Head count using survey forms of GOI missed at leastS! of due children as it is not MCTS theme based whereas E-IgM yielded 100% MI specific due list which is MCTS theme based.

Operating MCTS is for progressbut not recording the date of birth regresses and hampers updating ofMCTS, causing double loss as expressed by the ANMs – the 'Mother India'.

RQ 2: Addressing and deriving 4 critical indicators- Antigen-wise cumulative due children listed to be mobilized in 4months were 74/82/78/88 & 82 for the 1st/2nd/ 3rd/ Measles1 and Booster doses+Measles2 respectively. Of this 68(92%)/78(95%)/72(92%)/ 75(85%)/51(61%) were mobilized and vaccinated respectively. Total due children for all doses were 99/ 99/101 and 104in April/May/June and July respectively. Grand total was 403 children in 4 months of study period of which 344(85%)were mobilized and vaccinated; addressed the 1st and 2ndindicators.

FIC below one year was 85.23%, remainingwould complete Measles before 1st birthday in the subsequent sessions. RHTC has no >1 year child due for FIC. Completely immunized below 2 year was 60.71%, remaining would complete the due doses before 2nd birthday; addressed the 3rd and 4th indicators. (Table3).

Table 3: Denominators, Numerators and 4 critical Indicators of MI: all in one table

Vaccine	1st Dose	2nd Dose	3rd Dose	Measles1*	OPV / DPT Booster	Measles 2	Total
n	74	82	78	88	84	84	406
VaccinatedNo (%)	68(91.89%)	78(95.12%)	72(92.31%)	75(85.23%)	51(60.71%)	51(60.71%)	344(84.73%)

"n" is MI specific cumulative denominator of 4 rounds of 1st phase.

*FIC below one year is equal to the due children vaccinated for Measles1. This planning unit has no due children for any of the vaccines for primary dose above one year.

All the 4 critical indicators of MI - India's flagship programme can simply be derived from the denominators & numerators tabulated in a single table.
This can be a template for the planning units/block/district/state/country.

RQ 3: Qualifying data for reporting through HMIS and MCTiSation:

38%/41%/38% and 43% in Apr/May/June & July respectively - average of **40%** qualified for reporting through HMIS.

Therefore HMIS based RI indicators are not suitable for performance review at the SC and planning unit level.

Reasons for delaying/avoiding MCTiSation were explored: Reasons were many but summarized as MCTS isdependent on ANM hence 'smart-less' but ANM is not dependent on MCTS. Optimum "MCTiSation"was ~85%.

Therefore, MCTS based SMS alerts are often virtual as the output depends on the quality/quantity and the timeliness of input and hence RI indicators are not suitable for performance review at the SC and planning unit level.

RQ 4: Quantification of private participation: 13%/ 14%/16% and 5% were vaccinated by private doctors in April/May/June & July respectively and the average was 12%.

Quality compromised.

Global concern – Despite improving DPT3 coverage globally from 74% in 2000 to 86% in 2014, averting 2 to 3 million deaths due to VPDs, an estimated 18.7 million

infants were still not being reached by routine immunization services.[15] Of this 8.9 million(47.59%) were in India: "highest in the world"- a dubious distinction.[11]In Karnataka, in spite of promotive efforts, NFHS4 – 2015-16 revealed a drastic decline in FIC to 62.6% from 78% of CES 2009& 79.4% of RSOC 2013-14. DPT3 coverage also showed significant decline to 72.7% from 88.2% of CES 2009& 89.2% of RSOC 2013-14.[16]

Yearly 270 lakhs infants have to graduate FIC in the country. India buoyed when 387 lakhs children (0 to 2year)attained FIC on completion of 2 phases of MI which should be expressed against MI specific denominators.[17]

On the other hand, RHTC Sampaje which is operating E-IgM since April 2013 blended with unique approach, reached saturation hence there is no significant impact on coverage during the study period. (Table4). Denominator for booster dose and Measles2 includes all children between 480 and 730 days, hence the coverage is 85 to 87%; but all received before 24 months and no child is due beyond 24 months.

Table 4: Comparison of coverage's: as of 31 st March 2015 and 31st July 2015

	1st dose		2nd dose		3rd dose		M1		Booster		M2	
Month	March15	July15	March15	July15	March15	July15	March15	July15	March15	July15	March15	July15
n	402	475	376	457	364	433	251	315	134	188	134	188
v	402	470	375	453	357	430	238	312	114	164	114	164
%	100%	99	100	99	98	99	95	99	85	87	85	87%

The baseline coverage was already high, MI operation sustained the same.

MI denominators for FIC below and above one year are entirely different from FIC of various surveys. 3'A'ces (ANMs/AWWs/ASHAs) in triangulation, through E-IgMgenerate MI specific duelist, cumulative of which becomes the national target: a bottom-up approach. Therefore "targets" are not for dictating from "top". With E-IgM, any planning unit can prepare MI specific micro-plan and generate MI specific duelist. At the end of four successive months one can reach saturation and sustain for the rest of the year, irrespective of the baseline coverage as proved by Jharkhand and Karnataka studies.[12,13]Spending about half a billion $ for increasing the coverage @5% per year to achieve >90% by 2020 may be in vain without a locally innovated simpler MI specific tool and approach for sustenance - principles 6&5 of GVAP.[9]

CONCLUSION

RHTC Sampaje graduated further in RI. Proper tool and supportive supervision approach incorporating learning by doing and working together intensified regular sessions to all time mission mode; achieved and sustained beyond expected coverage in a short duration without additional fatigue and budget. ~28,000 planning units of India can easily replicate this.

Bottom line is that all the Medical Colleges can do this in their 1 to 3 attached planning units.Establish dedicated vaccination clinic, operating as per WHO / GOI guidelines, rolling-outDoctors and Specialists with right RI operational knowledge for vaccinating to immunize,undertake research activity, strengthen the Government, duly respect child's right to health.

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Evaluation of Vaginal pH as a Screening Tool for Bacterial Vaginosis and Impact of Screening and Treating for Bacterial Vaginosis on Preterm Births

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ABSTRACT

Introduction: Bacterial vaginosis (BV) is an avoidable cause of prematurity; therefore treatment of BV can reduce its incidence to some extent. Since half the women with BV may be asymptomatic, the adverse outcomes associated with its presence in pregnancy can only be prevented if screening for BV is done.

Objective: To evaluate effectiveness of vaginal pH as a tool to screen for Bacterial Vaginosis in early second trimester and study the impact of treatment in reducing preterm delivery

Method: A total of 440 pregnant women between 16-18 weeks of gestation who did not have complaint of vaginal discharge were randomly assigned to a study group and control group. The study group was screened for BV by vaginal pH and diagnosis was confirmed by gram staining using Nugents criteria. BV positive women were treated with metronidazole. The control group was not screened. Both groups were managed as per hospital protocol and were followed till delivery. The maternal and fetal outcomes of pregnancy, delivery and postpartum were recorded.

Results: Vaginal pH > 4.5 had a sensitivity of 100% and a specificity of 76.5%, PPV was 22.8% while NPV was 100% in diagnosing bacterial vaginosis. The prevalence of BV was found to be 6.4%. There was absolute risk reduction of 6.2% in preterm deliveries and 5.6% in PPROM. There was not much difference in birth weight between the two groups. The absolute risk reduction in neonatal respiratory complications was 4.4%.

Conclusions: Vaginal pH was found to be an effective tool for screening for BV. Treating asymptomatic BV decreases preterm births, PPROM and neonatal respiratory complications.

Keywords: *Bacterial Vaginosis, Preterm Birth, Preterm Premature Rupture of Membranes, Nugent Criteria, Vaginal pH.*

INTRODUCTION

Bacterial vaginosis (BV) is the most common lower genital tract disorder amongst women of reproductive age group [1]. The condition is not a classical infection caused by a single pathogen, but rather a complex alteration of vaginal ecosystem, where physiological lactobacilli-dominant flora is replaced by an overgrowth of mixed flora, with a high concentration of anaerobic bacteria, normally present in the vagina in substantially few numbers. It is not possible to identify a single species as a cause of bacterial vaginosis, although Gardenella Vaginalis, bacteroides species, Mobiluncus

species and Mycoplasma species are most commonly found [2,3].

The prevalence of BV in pregnancy varies from 9-23% [4]. In pregnancy, ascending infection can result in preterm labour and delivery besides various other complications such as preterm pre labour rupture of membranes (PPROM), chorioamnionitis, postpartum endometritis, postsurgical infections and abortions [5]. Prematurity is the most common cause of neonatal morbidity and mortality with a multifactorial aetiology of avoidable and unavoidable factors. BV is an avoidable cause of prematurity; therefore treatment of BV can reduce its incidence to some extent. Since half the women with BV may be asymptomatic, the adverse outcomes associated with its presence in pregnancy can only be prevented if screening for BV is done.

Diagnosis of BV is made either by Amsel's clinical criteria [6] or by gram staining based Nugent[2] / Speigels criteria[7]. The Amsel's criteria encompasses fulfilling of three of the following four criterias: presence of homogenous vaginal discharge, vaginal pH > 4.5, positive amine odour test of vaginal discharge and presence of clue cells on wet vaginal smear. All the Amsel's criteria have been evaluated, singly or in combination for the purpose of screening. Of these, vaginal pH has been found to be most sensitive, simple and inexpensive criteria and value of pH > 4.5 indicate the presence of either BV or trichomoniasis. The sensitivity for detecting BV with pH testing ranges from 84% to 100%, yet pH alone as criteria for screening has not been evaluated much in pregnancy [4].

Evidence regarding screening and treatment of asymptomatic bacterial vaginosis in pregnancy is conflicting and currently there is no consensus as to, whether to screen for or treat bacterial vaginosis in general pregnant population in order to prevent adverse outcomes, such as preterm labour, preterm birth, PROM, PPROM and various neonatal complications. However all the reviews suggest that further well designed trials are needed [8-11].

The present study was planned to determine the prevalence of Bacterial Vaginosis in asymptomatic pregnant women, evaluate effectiveness of vaginal pH as a tool to screen for BV in early second trimester and study the impact of treatment in reducing preterm delivery and other associated complication.

METHODOLOGY

This was an interventional study which was carried out in the department of Obstetrics and Gynaecology along with the Regional STD Teaching and Research Centre at a Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi. A sample size of 400 women was calculated taking prevalence of preterm birth as 20% and keeping the power of study to be 80%. Considering loss to follow up of 10%, a total of 440 subjects were enrolled in the study. All the pregnant women with gestational age between 14 to 20 weeks attending the antenatal clinic, who were willing to participate in the study, were included till the required sample size of 440 was obtained. Women with multiple gestation, olyhydroamnios, medical disorders (cardiac, respiratory, renal, liver, and endocrine), asymptomatic bacteriuria, and bleeding per vaginum were excluded from study.

After obtaining a written and informed consent, women were divided into two groups using computer generated tables. Control Group comprised of unscreened population that received the routine antenatal care. Study Group comprised of screened population which was screened by Nugent criteria and treated if found positive for Bacterial Vaginosis.

A thorough history was taken and detailed general physical examination and obstetric examination was done for both the study and control groups. In addition the women in study group had per speculum examination for amount, nature, and odour of discharge. After explaining the procedure and assuring the patient, an unlubricated Sim's speculum was introduced in the vagina and the condition of vaginal wall, cervix and nature of discharge was noted. Two swabs were then taken from the upper third of the vaginal side walls. The first swab was brought in contact with the pH paper and change in colour noted, with the second swab stick, a smear was prepared and air dried before transporting to microbiology laboratory for Nugent scoring. Care was taken to avoid mixing with cervical discharge.

Vaginal pH was measured by a phenolphthalein paper, after approximately 1 min the colour of the strip was observed and compared with the colour scale with discrimination of 0.5 to evaluate women with higher pH(>4.5).A pH of < 4.5 was classified as no bacterial

vaginosis whereas a pH of >4.5 was classified as presence of bacterial vaginosis.

The women who had a smear report consistent with BV were treated with Tablet Metronidazole 400 mg twice a day for 7 days. Both the groups were followed 4 weekly till 28 weeks, 2 weekly till 36 weeks and weekly thereafter till delivery and the data was recorded in the preset forms.

Statistical Analysis

The unpaired t- test and non parametric Mann Whitney test was used for quantitative analysis and the chi square and Fisher exact test was used for qualitative variables. A p value of <0.05 (two sided) indicated statistical significance for primary and secondary outcome. Absolute risk reduction (ARR) and number needed to treat (NNT) were used to report the effect of intervention on each outcome. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and Accuracy of vaginal pH was calculated taking Nugent score as gold standard.

RESULTS & OBSERVATIONS

The maternal and neonatal data was available for 202 women in study group and 196 women in control group (In study group 4 women developed preeclampsia and 14 women were lost to follow up. In the control group 7 women developed preeclampsia and 17 were lost to follow up. The women with preeclampsia were excluded from the study. Analysis was performed for 398 women. The results are displayed in Tables 1, 2, 3 and 4.

DISCUSSION

The prevalence of bacterial vaginosis (BV) ranges from 4 to 50% [1], depending on the racial, geographic and clinical characteristics of the study population. In asymptomatic women, the prevalence varies from 12 to 25%, and similar percentages are observed in pregnant women[1]. The reported prevalence in India varies from 8.6-32.8% [4, 12, 13]. The prevalence of BV was found to be 6.4% in this study. BV positivity was significantly higher in lower socioeconomic group, lower educational status and lower BMI group (Table-1).

Vaginal pH has been found to be a subjective, easy and reliable test. In the present study, vaginal pH > 4.5 had a sensitivity of 100% and a specificity of 76.5%, PPV was 22.8% while NPV was 100% in diagnosing bacterial vaginosis, which was similar to other studies[4]. Screening for BV by vaginal pH, a test with such high sensitivity and high negative predictive value, would help in excluding a large proportion of pregnant women from definitive testing of BV without missing any cases. In our study, out of 202 women who were screened for BV 145 had a pH <4.5 and were also tested negative by Nugent score. Only 57 (28.2%) had pH >4.5, therefore, if pH alone was used as a screening method only 28.2% women would require further evaluation. Thus, doing a simple test like pH, would not only reduce the load of work in the laboratory but also prevent the unnecessary empirical use of antibiotics.

The issue of treating asymptomatic pregnant women with BV is still unresolved. Most studies are from the west and recommendations by international obstetric societies are against treatment for asymptomatic BV +ve pregnant women [10, 11]. However, reports of benefits although few, have also been published. In a Cochrane data base of fifteen trials of good quality, involving 5888 women, the author concluded that antibiotic treatment can eradicate bacterial vaginosis in pregnancy. This review provides little evidence that screening and treating all pregnant women with asymptomatic bacterial vaginosis will prevent preterm birth (PTB) and its consequences. However, there was some suggestion that treatment before 20 weeks' gestation may reduce the risk of PTB[8].

Various meta-analyses of trials involving the screening and treating of BV in pregnancy have been published in the past and all have shown no reduction in preterm birth with treatment for BV [8, 14]. Since meta analysis are liable to numerous biases despite good quality control measures, Varma and Gupta undertook a repeat meta-analysis of screening and treating BV in pregnancy, in which they included recently published trials and applied strict criteria on data extraction [15]. The results of this analysis suggested a reduction in the incidence of preterm birth following screening and treatment for BV in low-risk women but not in high-risk women.

In the present study there was a significant decrease in the incidence of preterm delivery (<37 weeks), premature rupture of membranes, preterm premature

rupture of membranes, low birth weight and neonatal complications, between the screened and treated and unscreened population (Table 2 & 3). Both the groups were matched in socio-demographic profile, clinical profile and antenatal care, hence the difference in the adverse pregnancy outcome between the two groups were presumed to be due to screening and treating one group for BV.

CONCLUSION

Screening and treating for BV in pregnancy can result in reduction in preterm delivery, PROM, PPROM and also decrease in LBW and neonatal respiratory complications. It is a simple intervention which is safe and cost effective. Since LBW is one of the important health problems in India and neonatal mortality and morbidity rates are among indices used for comparing health care systems, BV is one of the avoidable causative factors of preterm birth and thus LBW, it would be prudent to screen and treat BV to avoid maternal and neonatal complications of the disease

The limitation of our study was the small sample of BV + women and also that repeat testing was not done at time of delivery to find infection at that time in both BV+ and BV- group.

Table 1: Sociodemographic Characters of BV +Ve and BV-ve Women

Sociodemographic character	BV +ve (N=13)		BV-ve (N=187)	
	N	%	N	%
Age (years)				
18-25(N=142)	7	4.9	135	71. %
26-35(N=57)	6	10.2	51	89.5%
>35 (N=1)	-	-	1	100%
p value- 0.339				
Socio-economic Status				
Low	10	19.2	4	80.8%
Upper Low	3	2.1	143	97.9%
Low Middle	-	-	4	100%
p value<0.001				
Education				
Uneducated	2	50	3	60%
<8th	10	5.9	163	95%
>8th	1	3.2	21	87.5%
p value-0.003				
BMI				
<18.5	2	40	2	50%
18.5-22.9	8	4.6	157	94%
>22.9	3	1.25	30	96.7%

p value-0.001

Table 2: Maternal Outcome in Study and Control Group

Gestational Age At Delivery	Screened Treated N= 202		Unscreened N= 196	
	N	%	N	%
<37 WKS	9	4.5%	21	10.7%
>37 WKS	193	95.5%	175	89.3%
p=0 .023 *ARR 0.062 **NNT-15				
Premature Rupture of Membranes				
Present	30	14.8%	42	21.4%
Absent	172	85.2%	154	78.6%
p = 0.092, *ARR 0.066 **NNT-15				

Table 2: Maternal Outcome in Study and Control Group (Contd.)

Gestational Age At Delivery	Screened Treated N= 202		Unscreened N= 196	
	N	%	N	%
Preterm Premature Rupture of Membranes				
Present	2	1%	13	6.6%
Absent	200	99%	183	93.4%
p = 0.004, *ARR 0.056 **NNT-17				
P Sepsis				
Present	0	0%	1	.5%
Absent	202	100%	195	99.5%

***ARR-0.005**

*ARR-Absolute Risk Reduction, **number needed to treat

Table 3: Neonatal Outcome in Study and Control Group

Neonatal Outcome	Screened Treated		Unscreened Untreated	
	N	%	N	%
Birth Weight				
<2.5 Kg	17	8.4%	26	13.3%
>2.5 Kg	185	91.6%	170	86.7%
P= 0.110, *ARR 0.048				
NICU admissions				
Yes	4	1.9%	63	3.1%
No	198	98.1%	190	96.9%
P=0.527, *ARR 0.010				
Neonatal Sepsis				
Present	0	0%	1	0.5%
Absent	202	100%	195	99.5%
P=0.317, *ARR 0.005				
Neonatal Respiratory Complications				
Yes	0	0%	5	2.5%
No	202	100%	191	97.5%

P= 0.044, *ARR .025

Table 4: Vaginal pH and Nugent Score

Vaginal pH (N=202)	Nugent Score (N=202)	
	Positive (>7) N=13	Negative (<7) N=189
Positive (>4.5) N=57	22.8%	77.2%
Negative (<4.5) N=145	0%	100%

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Impact of Brief Educational Intervention among Medical Students on Knowledge Regarding Tobacco and Alcohol use Disorders

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ABSTRACT

Background: Substance abuse is a major public health challenge across the globe. Medical professionals of all branches of medicine are very likely to encounter individuals with substance related health issues.Tobacco and alcohol use are among the leading causes of morbidity and mortality world-wide. Both these habits can be reduced by brief clinical interventions that are highly cost-effective.

Objective: To assess the impact of brief educational intervention on knowledge about management of tobacco and alcohol use disorders among medical students.

Methodology: This educational interventional study was conducted among third year medical students during Community Medicine postings. The session was of three hours duration carried out by faculty from Department of Community Medicine and Psychiatry as part of integrated teaching. The session had two components, initially presentation by the faculty followed by role plays by the medical students on specific scenarios. The effectiveness was assessed using a pre-tested, structured, self-administered questionnaire to assess the knowledge regarding tobacco and alcohol use disorders at baseline and after the educational intervention.

Results: There was a statistically significant increase in mean scores in both knowledge ($p<.001$) and perception regarding management of substance use ($p<.001$) after the educational intervention as compared to baseline scores. Also, 88% of students agreed that this integrated methodology helped them to improve their skills needed to counsel patients with substance use disorders

Conclusion: Educational intervention with role play by students is an effective tool to influence the knowledge regarding tobacco and alcohol use disorders. Also, integrated teaching is well appreciated by the students as effective method for teaching on substance use disorders.

Keywords: *Tobacco and Alcohol use Disorders, Educational Intervention, Role Play, Medical Students.*

INTRODUCTION

Substance abuse is a major public health challenge. All medical professionals, irrespective of their area of specialization are likely to encounter people with substance abuse disorders.[1] Tobacco and alcohol abuse are among the leading causes of morbidity and mortality across the globe.[2] Brief clinical interventions can be used to successfully reduce the intake of these substances. These interventions are highly cost-effective, and can be effectively used by family physicians with relatively little training.[3-4]

Intervention by specialists' will be essential for severe alcohol dependence.[5] However, brief interventions for problem drinkers can be used in general practice. [4] Hence Alcohol and tobacco use disorders and its management should be included in

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both undergraduate and postgraduate medical education curriculato deal with this issue which has got lot of public health implications. Recognizing this issue, the World Health Organisation and the United Nations have recommended to governments that identification and management of substance abuse should be included in medical curricula.[1]

Though the burden of tobacco and alcohol use is very high, the medical curricula of medical schools in low and middle income countries have not given much importance to train students about its cessation techniques.[6] A worldwide medical school survey regarding this has reported that these issues are usually taught non-systematically as and when the topic arose. It was found that only a tenth of surveyed medical schools had a specific module on substance use.[7] In another study conducted among medical students in three medical schools in Saudi Arabia, majority of the students (91.4%) lacked adequate knowledge about the epidemiology of smoking. Students also demonstrated a low knowledge of the health risks associated with tobacco use (average score 53%; SD=11.6), a fair (76.3%) understanding of the benefits of smoking cessation, and insufficient information about treatment of nicotine addiction. Only 20.9% of the students were confident that they were adequately prepared to counsel their patients to quit smoking.[8] It has been pointed out that at present, minimal and unstructured teaching is carried out for undergraduate medical students on the problem of substance abuse which is prevalent in more than 30% of the population.[9] Therefore, the authors planned to introduce a curriculum in the community medicine postings to address the tobacco and alcohol use disorders, keeping in mind the current needs of competency based medical education. The objective was to study the impact of module-based education on knowledge regarding the tobacco and alcohol use disorders and its management in the community.

MATERIALS AND METHOD

An interventional study was conducted among third year medical students of a Medical College for a period of six months. Third year students were selected for the study because this is a phase where they would have already been exposed to the various aspects of basic and clinical subjects with reference to the topic under study. Thus exploring their current knowledge on tobacco and alcohol use disorders and giving them adequate training on the same would help them in better interaction with patients with these disorders once they enter into their full time clinical postings and subsequently in the Internship.

A pre-tested structured self-administered questionnaire was developed to assess the knowledge regarding burden of tobacco and alcohol use, hazards of their use and basics of management of persons with these disorders. The next part of the questionnaire included self-assessment of the student's skills on counselling on a five point Likert scale. The last part of the questionnaire included the respondent's age and their residential status.After obtaining an informed consent, questionnaire was administered to assess the knowledge, attitude and practice regarding tobacco and alcohol use disorders. Students present on the day of the study were included into the study after obtaining their consent.

Intervention: Baseline evaluation was followed by an intervention i.e., educational session which included power point presentations and lectures on burden of tobacco and alcohol use disorders; health consequences of substance use, principles of cessation counselling and medical management of persons with tobacco and alcohol use by the faculties of Department of Community Medicine and Psychiatry. The educational sessions were carried out for the duration of 60 minutes followed by role play on specific case vignettes by a group of 4-5 students. Thus in a given session with 20-25 students in a batch, 4-5 role-plays were enacted and discussed in the presence of faculty and suggestions given for further improvement. This was followed by an end line survey using the same questionnaire. Post-test questionnaire included medical Student's opinion regarding teaching learning methodology of the newly introduced session on a five point Likert scale.

Variables and questionnaire: The assessment of knowledge of respondents regarding tobacco and alcohol use disorders included 17 questions related to the topic and for 16 questions each correct response in the questionnaire was assigned one mark while one question was given 4 marks. The maximum score obtained was 20 and minimum was zero. Student's own counselling skills, assessed based on a five point Likert scale, for which maximum score obtained, was 20 and

minimum was zero.

The data entry and analysis was done using SPSS version 16.0. Statistical methods employed included paired t test. *P* value of less than 0.05 was considered as significant.

RESULTS

A total of 162 students participated in the study and complete data was available for 152(93.8%) students and were analysed. It was observed that, the mean age of the students was 21.7 (SD 0.8) years and 54.9% of them were females.

Table 1 shows comparison between student's knowledge, perceptions regarding skills of management of substance use disorders. There was a statistically significant increase in mean scores in both knowledge (p<.001) and perception regarding management of substance use (p<.001) after the educational intervention as compared to baseline scores.

Table 1: Baseline and endline survey scores on knowledge and perceptions regarding management of substance use disorders (n=152)

	Base line survey	End-line survey	p-value
Knowledge	13.04±1.80	15.96±1.92	<.001*
Perception regarding management of substance use disorders	9.92±3.94	12.78±3.28	<.001*

*Statistically significant at 5% level using paired t-test. All values are mean±SD.

In the end line survey, questionnaire consisted of the student's opinion regarding teaching learning methodology of the newly introduced session. Majority of the students agreed and very few of them disagreed on the statements as mentioned in table 2.

Table 2: Medical Student's opinion regarding the different aspects of the newly introduced session on tobacco and alcohol use disorders.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree agree	Strongly
Faculty used appropriate teaching methodology (n=152)	0	2(1.3)	11(7.2)	54(35.8)	89(58.6)
The content of the session was well designed and covered all aspects required (n=151)	0	1(0.7)	15(9.9)	54(35.7)	81(53.6)
The sessions helped you to improve your skills needed to counsel patients with SUD (n=151)	2(1.3)	2(1.3)	14(9.3)	48(31.8)	85(56.3)

It was observed in the present study that, majority (88.2%) showed positive impact, very few (5.3%) had negative impact and 10(6.6%) students remained neutral following educational intervention on knowledge regarding tobacco and alcohol use disorders.

DISCUSSION

This study investigated the impact of educational intervention among medical students on knowledge regarding tobacco and alcohol use disorders and its management by using integrated teaching methods followed by enacting role plays by students.

Integrated teaching is an important strategy to promote meaningful learning and make it retain for a longer time.[10] It also helps to improve the competence of the students and enables them to make effective diagnosis. Therefore, for better treatment of the patients, integrated teaching is the need of the hour. Students learn better when they are engaged using different ways of learning, which follows the principles of adult learning. The integration of role-playing into training results in significantly better communication and strengthens patient-physician interaction during the sessions. It has further advantages as it comprises of three phases: preparation, interaction and discussion, thus promoting deeper learning.[11]

In this study, there was a significant increase in knowledge scores of students after educational intervention. In a similar study on assessing the

feedback of integrated teaching by the same authors among medical students, there was a positive response and students appreciated the introduction of the topic on tobacco and alcohol use disorders using role plays.[12] The present study also showed significant change in the perceptions of student's regarding their skills in management of substance use disorders post intervention and strengthens the evidence of previous studies.

In a study done at New York City among fourth year medical students to assess the knowledge about tobacco cessation and treatment for nicotine addiction, students had good knowledge of the epidemiology of smoking, including its prevalence and health effects, the benefits of cessation and treatment of nicotine addiction. Among them, 64% students rated their own preparation to assist patients to quit as less than adequate.[13] Review of evidence has shown a wide range in tobacco-related knowledge and training among medical students. Only 5% to 33% of third-year medical students in six countries, who responded to a global health survey about tobacco use and cessation counselling, reported receiving training about tobacco cessation.[14]

In this study we also assessed the student's perception about teaching learning methodology of the newly introduced session. It was observed that 88% of students agreed that this methodology helped them to improve their skills needed to counsel patients with substance use disorders. Integrated teaching was perceived to be useful by a majority of the students, which is similar to the results from studies carried out at Gujarat[15] and Bangalore.[16] Overall, 88.2% of students had positive impact and 6.6% had negative impact following intervention. Similar results are found in study conducted by Uma et al where 34.4% students had negative perceptions on integrated teaching.[17] They felt that it is time consuming, cuts down the time of self-study and lengthy and hence these concerns need to be addressed for better acceptance of the integrated teaching by the medical students.

In a brief educational intervention conducted to improve Medical Student Competence in managing patients exposed to Secondhand Smoke using standardized patients it was observed that the intervention were useful in enhancing the knowledge regarding Second Hand Smoke exposure and increases medical students' intent to screen.[18]

Limitations and recommendations

The overall response rate was moderate (162 students, 64.8%). In our study assessment was done immediately after intervention, so it evaluated the effects of integrated teaching on short-term knowledge acquisition rather than knowledge retention. So it is recommended to repeat the study to assess student's knowledge at the end of the course to know the effectiveness of intervention.

CONCLUSION

Educational intervention is an effective tool to improve the knowledge regarding tobacco and alcohol use disorders. Topics on this session should be held in medical colleges for medical students to create awareness on the ever increasing burden of tobacco and alcohol use disorders in the community. Innovative teaching methods like role-plays could help in understanding these topics better and also to create interest among students.

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Ethical Clearance: Students were informed their consent were taken before the session.

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Perception of Health-care Personnel Regarding Noise and Attitudes Regarding Implementation of Music in the Neonatal Intensive Care Unit

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ABSTRACT

Objective: The aim of this study was to determine the perceptions of health care personnel regarding noise present in the ambience of the Neonatal Intensive Care Unit (NICU) as well as the attitudes of health care personnel regarding implementation of music in the NICU.

Materials and Method: A cross-sectional descriptive survey using interview technique was conducted among health care personnel working in the NICU of a tertiary referral hospital in South India.

Results: Most of the health care personnel 48 (88.89%) perceived that it is difficult to control noise during emergencies in the NICU and 46 (85.19%) felt that conversation among staff may cause noise in the NICU. Health care personnel 38 (70.37%) also expressed favourable attitude towards implementation of music in the NICU to minimize the effects of noise.

Conclusions: It was found that health care personnel working in the NICU had a favorable attitude towards implementation of music in the NICU to combat the effect of noise.

Keywords: *Perceptions, Health Care Personnel, NICU, Noise, Music, Attitude*

INTRODUCTION

Measurements of background noise in the Neonatal Intensive Care Units (NICU) in India demonstrate that the equipment and machines used in the NICU generate maximum noise levels exceeding the recommendations.[1,2]It is a known fact that though the NICU enables infants to survive, noise in the environment of the NICU affects the growth and development of infants.Noise causes cognitive disabilities as well as affects the cognitive, academic, sensorimotor, social-emotional and behavioural development of infants. [3]

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To counter the effects of noise, positive effects of playing live or recorded music in the environment of the NICU for improving developmental outcomes in infants is the need of the hour. Music contributes to many positive effects for infants hospitalized to the NICU like improved oxygen saturation levels in infants[4], stabilized heart rate [4, 5], stabilized respiratory rate and reduced incidence of apneic and bradycardic episodes.[6]Music also had effects on increasing quiet sleep [5, 7, 8], decreasing responses to pain [9,10], and improving daily weight gain.[11,12,13]

Despite many studies showing significant benefits of music, implementation of music as a complementary therapy in the NICU is still a matter of debate. Even though music is non-invasive it is still not considered to be a universal standard of care. In addition, not much research has explored the perceptions of health care personnel regarding noise in the NICU, their attitudes and their preferences for implementation of music as

part of routine care in the NICU. The aim of this survey was to sensitize the health care personnel regarding the noise constantly present in the NICU and to understand their attitudes as well as their preferences regarding implementation of music in the NICU.

MATERIALS AND METHOD

The study was approved by the Ethics Review Committee of Kasturba Hospital,Manipal (ECR/146/ Inst /KA/2015). Data for the cross-sectional survey were extracted from face-to-face interviews lasting for about 25-30 minutes after obtaining informed written consent with a total of 54 health care personnel working in the NICU of a tertiary referral hospitalof South India.

Respondents were eligible if they were physicians, residents, post-graduates, interns, staff nurses, respiratory therapists, physiotherapists and other clinical staff working in the NICU. Other supporting staff like clerks, secretaries and other ancillary staff who were not involved directly in caring for infants hospitalized to the NICU were excluded. The tools included a range of questions relating to general demographics and Likert scales. Data were entered, coded and descriptive analysis was done using the Statistical Package i.e., IBM SPSS Statistics 20.

RESULTS

General Demographics

Majority of the health care personnel were females 43 (79.63%) and were aged 30±5 years. All the respondents had worked in the NICU, for the past one year however most of respondents 21 (38%) had only 5-6 years of experience working in the NICU. None of the respondents had previously undergone any musical training. Majority of the health care personnel were staff nurses 40 (74.07%) by profession.

Perception regarding noise in the NICU

Data for perception of health care personnel regarding noise in the NICU were obtained using a Likert scale andis presented in Table 1. Though 49 (90.7%) of the health care personnel perceived that too much noise in the NICU causes stress in preterm infants, 13 (24.07%) perceived that the noise level in NICU is more than the recommended levels, 17 (31.5%) perceived that preterm infants are not bothered about noise, because they can hardly hear.

Table 1: Perception of health care personnel regarding noise in the NICU

(N=54)

Item No	Perception of health care personnel regarding noise in the NICU	Agree	Disagree	Uncertain
1	The noise level in the NICU is more than the recommended levels	13 (24.07%)	25 (46.30%)	16 (29.63%)
2	Too much noise in the NICU causes stress in preterm infants	49 (90.7%)	_	5 (9.26%)
3	Noise is unavoidable in the NICU	36 (66.7%)	18 (33.33%)	_
4	It is difficult to control noise during emergency situations in the NICU	48 (88.89%)	_	6 (11.11%)
5	Noise could cause hearing impairment in infants.	25 (46.30%)	16 (29.63%)	13 (24.07%)
6.	Sudden noise causes agitation and excessive crying in infants	45 (83.33%)	9 (16.67%)	_
7.	Telephones in the NICU may contribute to noise in NICU	48 (88.9%)	_	6 (11.11%)
8.	Conversation among staff may cause noise in the NICU	46 (85.19%)	8 (14.81%)	_
9.	Loud noise will cause increase in the number of awakening and associated crying in preterm infants	20 (37.04%)	4 (7.41%)	30 (55.56%)
10.	Without sound of the alarms it is very difficult to monitor and care for infants	40 (74.07%)	9 (16.67%)	5 (9.26%)
11.	The effects of noise in NICU may have deleterious effect on physiological system of preterm infants and may be source of neonatal morbidity	42 (77.8%)	10 (18.52%)	2 (3.70%)
12.	Noise has consequences on the emotional and behavioural development of preterm infants	48 (88.9%)	6(11.11%)	_
13.	Environmental noises in the NICU are due to multiple sources (Alarms, wash basins etc)	54 (100 %)	_	_

Table 1: Perception of health care personnel regarding noise in the NICU (Contd.)

(N=54)

Item No	Perception of health care personnel regarding noise in the NICU	Agree	Disagree	Uncertain
14.	Preterm infants are not bothered about noise, because they can hardly hear	17 (31.5%)	7 (12.96%)	30 (55.56%)
15.	Noise in the NICU has deleterious effect on the health of the personnel working in the NICU	29 (53.70%)	-	25 (46.30%)

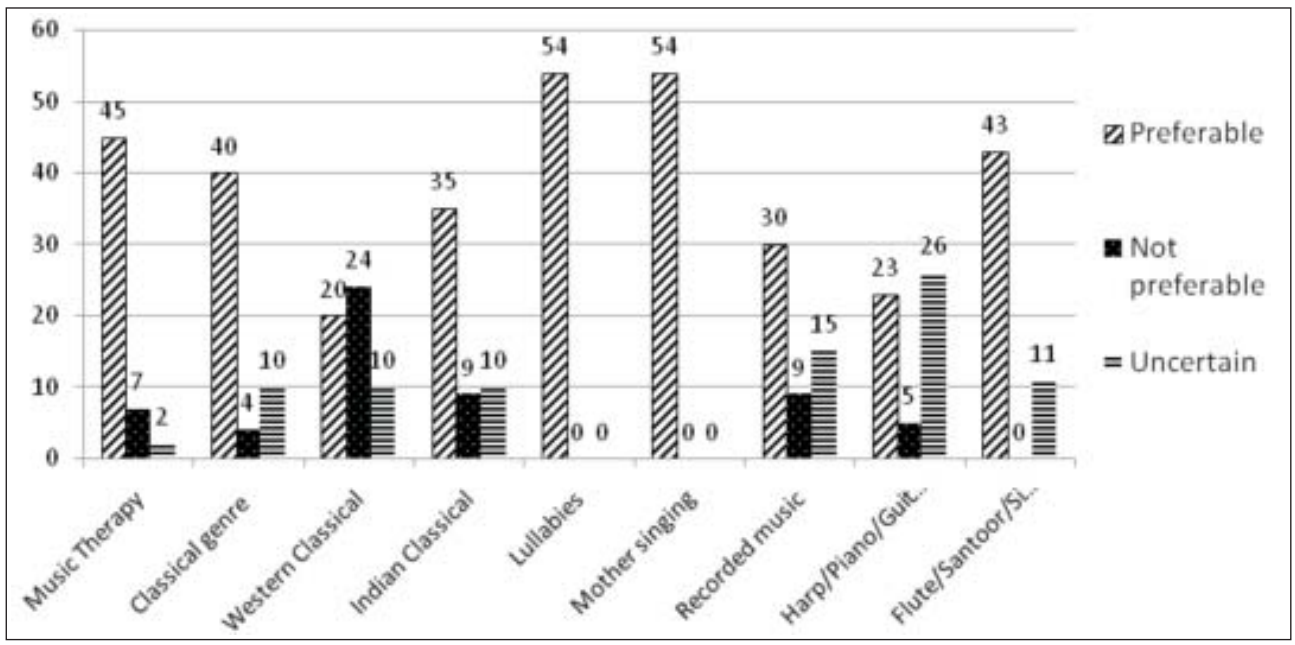


Fig. 1. General attitude of health care personnel regarding preferences of music

Table 2: Attitude of health care personnel regarding implementation of music in the NICU

(N=54)

Item No.	Likert questions on attitude of health care personnel regarding implementation of music in the NICU	Agree	Not sure	Disagree
1	Music minimizes the effects of noise in the ambience of the NICU	38(70.37%)	12 (22.22%)	4 (7.40%)
2	Music reduces crying episodes in preterm infants	44 (81.48%)	10 (18.51%)	-
3	Music may increase sleep in preterm infants	37 (68.52%)	17(31.48%)	-
4	Music may disturb the health team members during their work	4(7.40%)	16(29.62%)	34(62.96%)
5	Music enhances physical growth and development of preterm infants	31(57.41%)	10(18.51%)	5(9.26%)
6	Music stabilizes physiological parameters in preterm infants	42(77.78%)	12(22.22%)	-
7	Music helps in early recovery from illness in preterm infants	20(37.04%)	18(33.33%)	16(29.62%)
8	NICU is a very busy unit so music is not suited for this type of unit	2(3.70%)	10(18.51%)	42(77.78%)
9	Music makes babies more fussy and irritable	4(7.40%)	22(40.74%)	28(51.85%)
10	Music could interfere with infants' sleep	-	20(37.04%)	34(62.96%)
11	Music could improve appetite of preterm infants	5(9.26%)	40(74.07%)	9(16.6%)
12	Infants and staff listening to music regularly, may get addicted to it	-	12(22.22%)	42(77.78%)
13	If staff listen to music then their quality of work may be better	41(75.93%)	13(24.07%)	-
14	If proper care is provided for infants, music is not essential	14(25.93%)	5(9.26%)	35(64.81%)
15	Music will disturb the normal routine activities of the NICU	-	10 (18.51%)	44(81.48%)
16	Music could cause deafness in infants	-	22(40.74%)	32(59.26%)

Table 2: Attitude of health care personnel regarding implementation of music in the NICU (Contd.)

(N=54)

Item No.	Likert questions on attitude of health care personnel regarding implementation of music in the NICU	Agree	Not sure	Disagree
17	Music acts as complementary therapy in the NICU	54(100%)	-	-
18	Music helps to focus and perform required tasks better	47(87.03%)	7(12.96%)	-
19	Having music played in the NICU will make me proud of my workplace	54(100%)	-	-
20	Music may reduce stress in preterm infants	38(70.37%)	16(29.62%)	-
21	Health care personnel can commit mistakes if they listen to music	-	12(22.22%)	42(77.78%)
22	Music may interfere in the completion of essential tasks of health care personnel	-	9(16.6%)	45(83.33%)
23	Playing music could decrease the stress experienced by parents of preterm infants	50(92.59%)	4(7.40%)	-
24	Playing music could increase parental satisfaction of care	36(66.67%)	15(27.78%)	3(5.55%)
25	Parents can ask more doubts regarding care if music is played	2(3.70%)	10(18.51%)	42(77.78%)
26	Playing music in the NICU might make parents feel capable of caring for their infant	28(51.85%)	22(40.74%)	4(7.40%)
27	Parents' visit to NICU may be frequent, if music is played which may cause disruption of care for these infants	-	6(11.11%)	48(88.89%)
28	Music may help relieve pain during painful procedures in infants	49(90.74%)	5(9.26%)	-
29	Music may increase conversations among health care personnel	14(25.9%)	15(27.78%)	25(46.30%)
30	Parents may fear hearing loss in their infants if music is played	6(11.11%)	10(18.51%)	38(70.37%)
31	Parents may attribute any complications occurring in their infants to playing music	-	15(27.78%)	39(72.22%)
32	Playing music may help parents to be at ease when in a sophisticated environment like that of NICU	50(92.59%)	4(7.40%)	-
33	Parents may continue playing music to their infants after discharge from the NICU	44(81.48%)	10 (18.51%)	-
34	Like other noise, music may also contribute to stress in preterm infants	-	20 (37.03%)	34(62.96%)

Majority 48 (88.89%)of the health care personnel perceived that it is difficult to control noise during emergencies, 45 (83.33%) perceived sudden noise causes agitation/excessive crying in infants, 48 (88.9%) perceived telephones and 46 (85.19%) perceived conversation among staff contributes to noise. When asked whether the health care personnel perceived that noise in NICU will have deleterious effect on their health, most 25 (46.30%) were uncertain, however a great majority 29 (53.70%) agreed.

General attitude and preferences regarding music

It was essential to know the general attitude of health care personnel regarding their preferences of music. The data depicted in figure 1 show that all the respondents preferred lullabies and mothers singing to their infants. A great majority 45(83.33%) of the health care personnel preferred classical genre of music 40 (74.07%). A good number of respondents 35(64.81%) preferred Indian Classical music. Majority 43 (79.63%) of the health care personnel preferred music using instruments used in Indian classical genre of music like Flute, Santoor or Sitar.

Attitude regarding implementation of music in the NICU

Data regarding attitudes on implementation of music in the NICU is presented in Table 2, show that all the health care personnel agreed that music acts as complementary therapy and will make them proud of their workplace. Health care personnel expressed favourable attitude towards implementation of music in the NICU, since majority 38 (70.37%)agreed that music minimizes the effects of noise, reduces crying 44 (81.48%), reduces stress 38 (70.37%), increases sleep 37 (68.52%), stabilizes physiological parameters 42 (77.78%) and helps relieve pain during painful procedures 49(90.74%). A great majority 50 (92.59%)

expressed that music could decrease the stress experienced by parents and help them to be at ease when in a sophisticated NICU.

DISCUSSION

Noise is an undesirable sound, which is constantly present in the environment of an NICU that may not have control.Majority of the health care personnel perceived that sudden noise causes agitation and excessive crying in infants. These findings are in line with another study[14] that found 89% of the NICU staff considered noise as a source of stress and 80% responded that music could reduce stress in preterm infants.

A significant finding was that respondents preferred music in the NICU. A study [15]conducted among staff of the emergency department also found that 96% of the 49 staff favored background music. Background music in patient care areas was preferred to ordinary sound by caregivers and health care providers also. [16]

Another interesting finding was that the health care personnel preferred classical genre of music with a good number preferring instrumental classical music. The findings of another similar study are in support of this finding that classical music was the most preferred choice of music. Respondents in the present study preferred Flute, Santoor or Sitar, which are musical instruments used in Indian classical music compared to Harp or Acoustic guitar in a similar study. [14]The finding that music may improve sleep is also supported by similar studies. [14, 17]

Health care personnel expressed that music may decrease stress that is experienced by parents. Similar findings are reported [14, 18] that respondents had positive attitude, beliefs and intentions related to use of music as therapy in the NICU.

CONCLUSION

Findings of this study show that health care personnel have positive attitude and prefer implementation of music in the NICU. However, these findings are representative of only health care personnel working in one NICU. Despite the limitation, the study yielded evidence regarding health care personnels' attitudes. Health care personnel also preferred music to combat noise present in the environment of the NICU/.

The strength of the study was also the diverse sample that included physicians, residents, post-graduates, interns, staff nurses, respiratory therapists, physiotherapists and other clinical staff working in the NICU. In addition, the results are strengthened by high response rate from the respondents who participated in the study.

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Conflict of Interest: Nil

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Ecological Balance and Air Pollution on Environment: A Threat to Humanity

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ABSTRACT

Air, water, soil, light etc are the principal source of environment. The protection and improvement of each ingredientdependsupon the good conduct of human activities. Today the title of clever creature by the man has lost due to his own act or omission. Playing with the balanced environment and disturbing the function of the nature costs high for the humanity. There are various scientific reasons in which man itself degrading the condition of the environment. No doubt the legislators have made several bona fide legislations for the protection of the environment but the question lies in its execution of the laws. This study deals with various scientific reasons for air pollution and its effects on ecosystem. Different case laws decided by the courts have been discussed and legal remedy for the said problem has been analysed.

Keywords: *Air Pollution, Ecology, Environment, Atmosphere, Pollutants, Particulate, Protection.*

INTRODUCTION

The word "environment" relates to atmosphere or surrounding that we live in. According to the Webster Dictionary, it is defined as the "Aggregate of all the external condition and influences affecting the life and development of an organism." The legislatures has defined the environment under Section 2(a) of the Environment Protection Act, 1986, which envisages that it,"includes water, air and land and the inter-relationship which exists among and between water, air and land, and human beings, other living creatures, plants, micro-organism and property." Etymologically the fundamental notion that can be said that, the nature or the surroundings we live and is essential for our life which includes air, soil, water etc. The air we breathe becomes polluted in various ways. Sand, dust storms and volcanic eruptions introduce dust particles and other various materials. Forest fire generates smoke and gases. The decomposition of plants and animals after their death and decay generates foul smelling gases. So, air is polluted by these natural processes and these pollutants are removed by natural agencies such as rain, trees etc. Man by his own action has contributed considerably to the pollution in the atmosphere. When he first started to learn the art of cooking, he took the help of fire. There by soot and smoke generated and were mixed up with the air. As the civilisation grew, new types of pollutants were generated. The use of automobiles created numerous gas pollutants. Through the long chimneys of factories soot, particulate matters, smoke and other various ill gases are freely led into the atmosphere. For production of pesticides, drugs and other organic chemicals heavy factories were set up. The spent gases and the gaseous effluents from the factories were led into the air. In order to assess the magnitude of the problem arising out of the chemical factories, it is desirable to recapitulate the tragedy that occurred at Bhopal by the release of poisonous gases. The types of pollutants are so numerous and the quantities are so huge that natural processes can no longer be any helpful to remove these pollutants from

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the air. Man for his own living cleared forests and constructed concrete jungle. As a result of deforestation, the fall has decreased and the proportion of carbon dioxide has increased in the air. Rain and trees are the natural agencies through which the pollutants are removed from the atmosphere. But alas the man has dug his grave by his own action.

Ecological Balance

Conservation of all living species plants, animals and micro organisms and non living organisms on which they depend is vital for the development. The plants, the animals and micro organisms living in an environment constitute the ecosystem. Organisms whether belonging to plants or animals interact with each other. The study of organisms and environment comes under the science of ecology. The word 'eco' means house. Each ecosystem is then made up living things, plants, animals and micro organisms and non living organisms or abiotic substances. It can be divided into four classes: (1) Non-living substances (2) Producers (3) Consumers (4) Decomposers. In the nature, a balance exists between the various species. This has become possible because the species connected with the food chain maintained and fixed population. If at any stage by change of the environment one species is not able to multiply its population, then the balance is disturbed leading to extinction of one or more species. Animals inhale oxygen and exhale carbon dioxide. Plant inhale carbon dioxide and exhale oxygen. Hence balance between the two is established. As the population grow more and more carbon dioxide was produced. The increase in the quantity of the carbon dioxide in the air resulted in the warming of the earth and less rainfall perishes. All these are going to happen because man is playing with the natural process and disturbing the settled balance of the nature. In order to feed the increasing population, the man has started repeated cultivation of a single crop. His careless methods of cultivation have exposed the soil to erosion by wind and water. By the use of many pesticides many useful species have died, and imbalance in the nature takes place. On account of all these, man for his own survival should make attempt to remain in peace without disturbing plants and animals that make up the environment. According to Richard L Means, Sociology Professor observed that "Justification of a technological arrogance towards nature is basically an immoral act". Man in the views of many is simple an integrated part of the nature. The wisest course is to live in harmony with it and accommodate to it.

Review of Literature

According to Odum[1] in his book entitled "Ecology and Our Endangered Life Support Systems" (1953) observed that in the event that one wishes to see the cooperation of man's natural and social ascribed, human ecology must go past the standards of general ecology since man's adaptability in conduct his capacity to control quick environment and his propensity to create culture freely at condition is greater than those at different living beings. He characterized culture as "The way of individual's lives in distinguished ranges, times and settings." He called attention to the essential segment or society culture that is moderately changed quickly in time. He additionally contributed the idea of regionalism as a way to deal with the investigation of society in light of particular contrasts in both social and regular properties of various regions.

Ekins[2] in his thesis entitled "The Relationship between Economic Growth, Human Welfare and Environmental Sustainability" (1996) stated that on the planet's urban communities, the issue is rampant with the nature of the air, and the water. Today, right around more than one billion individuals live in urban communities with air quality underneath least standards set up by the World Health Organization (WHO), delivering respiratory and different afflictions from which a large portion of a million people dies every year.

The World Commission on Environment and Development (WCED) stated that "the future is to face ever increasing environmental decay, poverty, hardship and an even more polluted world".

According to World Health Organisation, (1990) report, "Pollutants of major public health concern include particulate matter, carbon monoxide, ozone, nitrogen dioxide and sulphur dioxide. Outdoor and indoor air pollution cause respiratory and other

diseases, which can be fatal."

According to a report published by The Central Pollution Control Board (CPCB) of India (2010), that gives result of the Air Quality Monitoring, Emission Inventory and Source Apportionment Study completed in the urban areas of Bangalore, Chennai, Delhi, Kanpur, Mumbai and Pune. The essential concentrate of the review was on respirable particulate matter (PM10), despite the fact that it additionally manages different toxins like NOx, SO2, Ozone (O3), PM2.5, and so forth. The report is proposed to give logical premise to the arrangement creators and different partners, for definition of methodologies and organizing activities for enhancing air quality in urban ranges. It draws and coordinates the data, information, discoveries and conclusions.

Cropper (2012)[3] observed that, the health impacts due to air pollution from coal fired plants in India.

McCubbin (1999)[4] observed that motor vehicles have altogether bigger health costs. Particulates are the most harming toxin, while ozone and different contaminations have littler impacts. Diesel vehicles cause more damages per mile than do gas vehicles, due to more noteworthy particulate emanations. Fine particles seem more hazardous than bigger particles, and ignition particles seem more risky than street tidy. The outcomes recommend that accentuation ought to be put on control of particulates.

Major Pollutants

The WHO defines air pollution as a "situation in which the outdoor atmosphere contains materials in concentration which are harmful to people or their environment". It has been estimated that the most important means by which environmental pollutants enter our body is through the respiratory system. So air pollutants are extremely harmful. The followings are the sources that generate major pollutants.

(1) Burning of non-commercial fuels: The non commercial fuels are wood, cowdung, agricultural wastes etc. These substances on burning contribute a lot of smoke and particulate matters to the air. This mostly happens in rural areas.

(2) Burning of fossil fuels: The main pollutants coming out of the burning of fossil fuels are carbon dioxide, carbon monoxide, and sulphur dioxide, oxide of nitrogen, hydrocarbons and metallic traces.

(3) Pollutants arising from factories: Different factories produce different pollutants depending upon raw materials they use for industrial purpose.

Judicial Approach on Air Pollution and Ecology

The Supreme Court of India has made several commitments to ecological law of our nation. It has engaged a considerable amount of bona fide Public Interest Litigation cases under Article 32 of the Constitution of India and the High Court are under Article 226 of the Constitution. These Courts have decided various issues concerning ecology and have built up different guidelines on environmental laws. They have utilized Art. 21 of theConstitution of India and extended the importance of the word life in that Article as including a privilege to a sound and healthy environment.

In Union Carbide Corporation v. Union of India[5], the court held that, "where an enterprise is occupied with an inherently dangerous or a hazardous activity and harm results to anybody by virtue of a mishap in the operation of such dangerous or naturally unsafe movement coming about, for instance, in getaway of poisonous gas, the enterprise is strictly and completely obligated to repay every one of the individuals who are influenced by the accident and such risk is not subject to any exemptions." Accordingly, Supreme Court created another trend of Absolute Liability without any exemption.

According Plato "If anyone intentionally spoils the water of another … let him not only pay damages, but purify the stream or cistern which contains the water…" In Vellore Citizen's Welfare Forum v. Union of India[6], the Supreme Court declared that, "the polluter pays principle is an essential feature of the sustainable development.If you make a mess, it's your duty to clean it up. It should be mentioned that in environment law, the 'polluter pays principle' does not allude to fault. Instead, it supports a remedial methodology which is

concerned with repairing natural harm. It's a rule in international environmental law where the polluting party pays for the harm or damage done to the natural environment."

In an another case M.C.Mehta v. Kamal Nath and Others[7], the Supreme Court observed that, "the Public Trust Doctrine primarily rests on the principle that certain resources like air, water, sea and the forests have such a great importance to people as a whole that it would be wholly unjustified to make them a subject of private ownership."

Scientific Remedial Measures

(1) People may be educated and encouraged to use smokeless cooking chulas in their domestic use.

(2) The factories using coal as fuel should be asked to construct long chimneys, so that smoke and gases mix with air stream carried away to far of places as a result the surrounding areas remain free from air pollutants.

(3) Electrostatic precipitators have to be used by the industries to remove particulate matters such as dust particles etc. contained in the smoke.

(4) Certain harmful gases can be removed from the smoke by passing them through water spray in a device called scrubber.

(5) The exhaust pipes of automobiles have to be fitted with anti-air pollution devices, in order to eliminate air pollution.

(6) The people should be educated about the role and importance of trees to remove air pollutants. In a massive scale trees plantation programme has to be taken up. In cities and towns open parks and recreation centres have to be construed. By the side of the roads trees have to be planted. People have to be told to plant ten trees before cutting one. Large scale a forestation will minimize air pollution, thereby helping mankind.

Legislative Measures

The Indian Constitution under Article 21 of it mandated right to life. The word life denotes the surrounding, nature or the environment we live in. This becomes the fundamental right of the citizen which is to be protected and guaranteed by the constitution of India.the state also posses immense duty to protect the environment and the nature so as to make it conducive ti live. Under the Directive Principles of State Policies the state is directed to make every endeavour to improve and safeguard the forest and wild life of the nation. It was for the first time in the year 1976 under the 42nd amendment of the Indian Constitution the responsibility of protection of the environment is imposed. Article 48-A of the Constitution of India envisages that: "The State shall endeavor to protect and improve the environment and to safeguard the forest and wildlife of the country." The amendment has been extended to the fundamental duties of the citizen to protect and improve the environment and Article 51-A (g) of the Constitution of India states that "It shall be duty of every citizen of India to protect and improve the natural environment including forests, lakes,, and wildlife and to have compassion for living creature." Hence any violation of these mandated rights, duties and obligations shall be remedied under Article 32 and Article 226 of the Indian Constitution before the Supreme Court and High Courts respectively through the public interest litigations.

CONCLUSION

Paul Bigelow Sears have rightly said, "How far must suffering and misery go before we see that even in the day of vast cities and powerful machines, the good earth is our mother and that if we destroy her, we destroy ourselves."The environmental issues in India witnessed due to rapid growth of population, industrialisation, globalisation, urbanization and making of concrete jungle at the cost of destruction of forest. Resources of our earth are god gifted. Utilization of those resources should not be done at the cost of human lives. We must join our hands to make every effort for the protection and safeguard of our earth because she is our mother and we should respect the modesty of our mother. The state in its other hand should monitor the environmental issues so as to check further loss. In the words of Sir Winston Churchill, "It is better to prepare and prevent than to repair and repent". Hence we should work for today so as to see better future for our children.

Ethical Clearance: Not required, as the research article is based on ecological balance and air pollution. The research is doctrinally undertaken.

Source of Funding : Self

Conflict of Interest : Nil

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Effect of Proper Irrigation and Sterilization of used Equipment in Endoscopic Operations on Awareness and Performance of Operation Room

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ABSTRACT

Objective: This study aimed to investigate the influence of training for proper irrigation and sterilization of used equipment in endoscopic operations, on knowledge and performance of operating room (OR) personnel.

Method: This interventional study was conducted on 61 OR personnel, in 2016. Before the intervention, all the participants completed a researcher-made questionnaire regarding their awareness of proper irrigation and sterilization of endoscopy equipment. In addition, their performance was assessed through a researcher-made checklist, before the intervention. Proper irrigation and sterilization of endoscopy equipment was instructed to the participants through three lectures (45 minutes each)in one week. The participants were asked to complete the questionnaire again, and then the observer evaluated their performance for the second time. Descriptive statistics was used for analyzing data along with Interferential statistics (paired t-test, and McNemar's non-parametric test) for determining significance. SPSS software (version 20.0) was used for data analysis.

Results: Mean±SD scores of knowledge of personnel were 11.03±3.14 before the intervention and 16.88±1.65 two weeks after intervention. Mean±SD scores of performance were 8.40±1.38 and 12.16±0.91 before and two weeks after intervention, respectively. Paired t-test showed statistically significant difference for both mean scores of knowledge and performance before and after interventions (P<0.001).

Conclusion: Training improves knowledge and performance of operating room staff regarding proper irrigation and sterilization of used endoscopic equipment. Based on the findings of this study, holding regular instructional courses for operating room personnel is crucial to keep their information up-to-date.

Keywords: *Knowledge; Performance; Sterilization; Operating Room*

INTRODUCTION

The importance of proper sterilization and irrigation of medical equipment has been noted in literature, since it can lead to nosocomial infections and occupational hazards for healthcare personnel.[1, 2] Based on the statistics, 25% of nosocomial infections are due to surgical site infections. Annually, 325000 surgical infections are reported in 106 hospital in U.S. Thus, Operating rooms can be a substantial source of nosocomial infections that are caused by a variety of microorganisms. In Iran, nosocomial infections comprise 20-25% of the infections.[3, 4]Consistent monitoring and complying with aseptic techniques can lower the risk of contamination and infection. All the personnel involved in operating room are responsible for establishing and maintaining a safe environment. Following aseptic techniques is part of this

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responsibility. All the equipment that are in contact with surgical incision and surgical site must be sterile.[5-7] In fact, medical equipment can be both beneficial and harmful for the patients, considering their role in causing nosocomial infections. By increasing the delicacy of operational equipment, their irrigation and sterilization has become more challenging. On the other hand, inappropriate use of the equipment by ignoring their functional goal along with improper irrigation and sterilization can lead to wearing out of the equipment that may be accompanied with financial losses and causalities.[8, 9] Surgical site infection can prolong hospitalization, antibiotic use, and wound care. It may also necessitate reconstructive surgery, in some cases. Managing the infection at the OR is the most effective approach to prevent nosocomial infection.[10, 11] OR is one of the most sensitive sectors of the hospital, since due to the critical nature of the operations and equipment, a smallest negligence can lead to casualty.[12, 13]In the past, open surgery was the only option for the physicians to see internal body parts, recover an organ, or remove it if necessary. However, nowadays, surgical methods with least harm have become possible in most operational procedures. Surgeons can have better access and sight of the surgical site through making very small holes on the patient's body and using advanced equipment. As a result, not only the wounds heal more rapidly, but big scars and their consequences decrease significantly.[14] Nurses play a crucial role in control and prevention of infection. Training of the nurses may reduce infection and its adverse effects, since nurses have a momentous impact in enhancing awareness and promoting healthy lifestyle due to their profession.[15] Training is an interactive process that leads to learning[16] and as a primary prevention, has a significant role in healthcare system.[17, 18] A Comprehensive training program based on the educational needs ofpersonnel can decrease healthcare costs.[19] Growing dominance of human over nature and knowledge of the unknowns, along with research for the new methods and tools to solve the problems of the society, especially in developing countries, have highlighted the importance of manpower training.Employees who use theoretical and empirical proficiencies simultaneously, are able to identify scientific and practical principles in nursing skills. Therefore, in-service training is of fundamental importance that can increase morale and efficiency of employees.[14] The present study was conducted to investigate the impact of training for proper irrigation and sterilization of used equipment of endoscopic operation on knowledge and performance of OR personnel.

METHOD

This semi-experimental interventional study was performed in 2016, in hospitals associated with Islamic Azad University, Tehran medical branch (Javaheri hospital, Bu-Ali hospital, and Amir-Al-Momenin Hospital). The study population included all OR personnel (n=61) that were selected by census method [due to limited personnel). Participants who had associate or bachelor degree of OR nursing and provided informed consent form were included in this study. Initially, researcher completed the performance assessment form regarding the method for irrigation and sterilization of endoscopy equipment by attending OR in hospitals. The knowledge of participants was evaluated using pre-test. Then, training courses for all OR personnel were held through three lectures (45 minutes each). An instructional booklet was also handed in sessions. Two weeks later, the questionnaire was filled again by the participants. The observer evaluated and recorded the personnel's performance through a checklist. Knowledge questionnaire included 20 multiple-choice questions with 1 point for each correct answer and 0 point for each false answer. Cumulative points of correct answers were counted as knowledge score. Scores were categorized in three levels of good (more than 15 points), moderate (10 to 15 points), and poor (less than 10 points). A checklist containing 13 questions with "yes" or "no" answers, was used to evaluate the performance of personnel. In this checklist, 1 point and 0 point were allocated for "Yes" and "no" answers, respectively. Scores of more than 10, 7-10, and less than 7 were considered good, moderate, and poor, respectively. The reliability of the questionnaire was assessed by pilot study on 10 participants and was confirmed with Pearson's correlation coefficient of 0.840 for knowledge and 0.733 for performance. These participants were excluded from the subsequent samplings. A total of 10 scientific committee staff of nursing department evaluated and verified content validity of the tool. Demographic information included age, sex, marital status, job,

education, work experience, employment status, and occupational position. Data was analyzed using SPSS software (version 20.0). Descriptive statistics [frequency, frequency percentage, mean, and standard deviation] was used for data analysis, while interferential statistics [paired t-test, and McNemar's non-parametric test] was utilized for determining significance.

RESULTS

The mean±SD age of the participants was 34.27±10.4 years. About 55.7% of the participants were female and 53.3% were married. In this study, 65.6% of participants had bachelor degree and 76.3% were in their project period. Average working experience of the participants was 11.55 years. The findings indicated that of total of 61 participants, 22 (36.1%) persons scored less than 10 points (weak), 35 (57.4%) participants had 10 to 15 points (moderate), and 4 (6.7%) participants scored more than 15 points (good0 in pre-test questionnaire. Besides, their performance before the intervention was as follows: 5 (8.2%) personnel scored less than 7 points (weak), 53 (86.9%) participants had 7 to 10 points (moderate0, and 3 (4.9%) had more than 10 points (good).

Then, integrative training was carried out using theoretical (lecture, question and answer, and handing booklets) and practical (demonstrating proper method for irrigation and sterilization of equipment) methods during three sessions (45 minutes each) over one week. After two weeks, participants filled the questionnaires again and the results were as follows:

In the knowledge questionnaire, none of the participants scored less than 10 (weak) points, 12 (19.7%) persons had 10 to 15 points (moderate) and 49 (80.3%) personnel had more than 15 points (good). Following the evaluation of the performance of participants after the training, using the researcher-made checklist, none of the participants had less than 7 points (weak), 4 (6.6%) had 7 to 10 points (moderate), and 57(93.4%) had more than 10 points (good).

Paired t-test indicated a statistically significant difference between knowledge scores before and after training (P<0.001, t=458.14). Mean±SD of knowledge score before (11.03±3.41) and after training (16.68±1.65) suggested that personnel's knowledge increased after training.

Similarly, a statistically significant difference was noted between mean score of performance before and after training (P<0.001, t=16.026). Mean±SD of performance increased from 8.40±1.33 before intervention to 12.16±0.91 after intervention.

Table 1. Demographic characteristics of the participants

Variable		Frequency N %	Variable		FrequencyN %
Sex	Female	34(55.7)	Marital status	Married	32(53.3)
	Male	27(44.3)		Single	28(46.7)
Education level	Diploma	7(11.5)	Employment status	Contract	12(20.3)
	Associate	10(16.4)		Promissory	1(1.7)
	Bachelor	40(65.6)		On duty	45(76.3)
	Master	4(6.6)		Official	1(1.7)
Working experience(Years)	5 >	23(38.3)	Age(Years)	30 >	30(51.7)
	5-9	10(16.7)		30-40	12(20.7)
	10-14	7(11.7)			
	15 <	20(33.3)		40 <	16(27.6)

Table 2.Knowledge on irrigation and sterilization of endoscopic equipment before and after training

Awareness(Point)	Before		After	
	N	%	N	%
10 >	22	36.1	0	0
10-15	35	57.4	12	19.7
15 <	4	6.5	49	80.3
Total	61	100	61	100
SD ± Mean	11.03±3.14		16.88±1.65	

t-test t=14.458 df=60 P<0.001

Table 3.Performance in irrigation and sterilization of endoscopic equipment before and after training

Awareness(Point)	Before		After	
	N	%	N	%
7 >	5	8.2	0	0
7-10	53	86.9	4	6.6
10 <	3	4.9	57	93.4
Total	61	100	61	100
SD ± Mean	8.4±1.38		12.16±0.91	

t-test t=16.026 df=60 P<0.001

DISCUSSION

The results of the present study indicated that training for proper irrigation and sterilization of used equipment in endoscopic operations can significantly improve knowledge and performance of OR personnel. Our findings are in line with Habibi et al. study to compare the impact of direct or distant education on knowledge, attitude and performance of OR personnel regarding irrigation and sterilization of surgical equipment.[4] Their study was indicative of the poor knowledge of study population and highlighted the importance of direct education (face to face) on increasing knowledge and improving attitude and performance of OR personnel towards irrigation and sterilization of surgical equipment. In terms of attitude after the intervention, a significant statistical difference was observed between both distant education and control groups, and direct education and control groups. Attitude was also improved significantly in both direct and distant groups. However, those who participated in direct education had better performance compared to distant education and control groups. In terms of knowledge two months after the intervention, a statistically significant difference was noted regarding performance after intervention between direct and distant education, direct education and control groups, and distant education and control groups. The findings are also consistent with Yinnon et al.study.[20] They believed that education of personnel improved their performance and decreased nosocomial infections and improved the quality of care. Similarly, Wick et al.maintained that conducting a comprehensive safe surgery program decreases infection and improves the performance of personnel, therefore, reduces mortality the costs of long-term hospitalization.[21] Leodoro et al. also reported a significant correlation between knowledge and complying with aseptic techniques by OR personnel (P<0.05). Their findings indicated that the more up-to-date the nurses be, the more they will follow sterilization principles. They emphasized on the importance of holding retraining programs during the year in order to improve knowledge of the OR personnel.[22] Based on the findings of the present study, training has a significant impact on improving knowledge and performance of OR personnel.

CONCLUSIONS

Several studies have been conducted to determine the problems of society and offer appropriate solutions, to facilitate and increase efficiency of efforts. It seems necessary for nursing and medical managers to be equipped with cutting-edge knowledge and hold regular training and retraining programs for OR personnel regarding prevention of the infection along with proper maintenance, irrigation, and sterilization of used equipment in endoscopic operations.

Conflict of Interest: There are no conûicts of interest.

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Ethical Clearance: After selecting the eligible participant, the researcher was introduced to them and the objectives of the study were elaborated for the participants. The informed consent was obtained from the subjects and they were assured that their information will remain confidential.

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Analysis of Factors Related to the Occurrence of Near Miss Accident

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ABSTRACT

Fabrication and construction services work need a serious attention since there are probabilities of a near miss accidentonits activities. According to the worker accident data in PT. Lintech Duta Pratama in 2014, there is 22 cases of minor accident and none of the major accident or the one which causes death in workers. The annual occurrence of those accidents is caused by a number of the near miss accident and potentially can cause losses for both the company and the workers.

This research analyzes the correlation between individual characteristic {age, working period, gender, education background, and the Occupational Health and Safety (OHS) training}, working fatigue, OHS motivation, and the supervisor's monitoring with the near miss accident in PT. Lintech Duta Pratama Surabaya. This research is quantitative, using cross-sectional analysis from December 2016 to January 2017.

The observation result of 15 workers of fabrication production unit shows that there is 50% who fall into the category of near miss accident. The amount of respondent used as a sample in this research is 88 workers. From the bivariate analysis, this research determines the correlation between individual characteristic (age, working period, gender, education background, and OHS training), working fatigue, OHS motivation, and the supervisor's monitoring with the near miss accident.

The result of binary logistic regression analysis with stepwise backward method indicates that there is a correlation between "age" with the occurrence of near miss accident, but it is insignificant (P - value 0.942); there is a correlation between work term with the near miss accident, but it is insignificant (P - value 0.799); there is a correlation between education background with near miss accident, but insignificant (P-value 0,644); there is a correlation between OHS training with the occurrence of near miss accident, but it is insignificant(P -value 0,890); there is a correlation between, K3 training with the occurrence of near miss accident, but it is insignificant(P -value 0,890);there is a correlation between working fatigue with the occurrence of near miss accident, but it is insignificant(P -value 0,890);there is a correlation between supervisor's monitoring with the occurrence of near miss accident, but it is insignificant(P -value 0,035).

Keywords: *Near Miss Accident, Individual Characteristic, Working Fatigue, OHS Motivation, Supervisor's Monitoring.*

INTRODUCTION

Worker accident data in PT. Lintech Duta Pratama in 2014 which fall into aminor category is 22 cases, and there is none in the major category or the one which causes death in the worker.

In 2015, worker accident data in the minor category is 7, while there is none in the major category or even the ones which cause death in the worker. The occurrence of an accident in every year is caused by the number of *near miss accident* and potentially resulting in losses for both the company and its workers. This data can't be taken lightly. Based on the initial problem findings in the field, it is possiblethat accidents can happen in PT. Lintech Duta Pratama and a specific research on the production area is needed. *Near miss accident* often happen in the production area which consists of human labor and machines because of the incompatibility of the human and the machine's work.

PT. Lintech Duta Pratama Surabaya is a company in *engineering, fabrication & construction* services. PT.

Lintech Duta Pratamahas operated the material production factory in JalanMastripNomor 70 Surabaya since the early year of 2000. PT. Lintech Duta Pratamaemploys 114 employees. The number of labor in production unit is 114 workers. The process of katy marking, lathe, roll, berding, drill, fabrication, sanblosting, andpaintinghavea high risk of the near miss accident, workplace accident, disease caused by work, and fire. These things are caused by the numbers of management factors, supervisor's role in the monitoring activities, and unsafe action performed by the worker.

MATERIAL AND METHOD

Sampling

Population in this research is the workers in the production unit in PT. Lintech Duta Pratama Surabaya which is 114 people.

The sample in this research uses Taro Yaname and Slovin's formula, the sample in used is 88 people.

Technical Information

In this research, we use *stratified random sampling*, a sampling method that considers the stratification in the population. This technique is chosen because the population in this research varies in term of the education background and the economic level.

Statistical Analysis

The independent variables in this research consist of individual characteristic (age, working period, gender, education background, and OHS training), working fatigue, OHS motivation, and the supervisor's monitoring. The dependent variable in this research is the near miss accident.

To determine the relation of several independent variables with the near miss accident, this research uses univariate analysis which uses the frequency, distribution, crosstab, and bivariate analysis to determine the logistic regression correlation

The level of significance in used is 0,05. All analysis uses statistic of SPSS 18.0.

FINDINGS

No.	Independent Variables		P-value	Near Miss Accident(%)	Normality	Min	Max
1	Respondent's characteristic	a. Age> 30 years old b. Age 18-30 years old	0,942	56,143,9	0,006	21	54
		Gender	-	-	-	1	1
		a. Working period ≥ 6 years	0,799	30,731,8	0,000	1	16
		b. Working period < 6 tahun					
		a. Recent education	0,644	51,5	0,000	1	2
		OHS training	0,890	53,57	0,000	1	2
2	Working fatigue		0,890	51,1	0,000	39	100
3	OHS Motivation		0,012	51,1	0,000	63,46	92,31
4	Supervisor's monitoring		0,035	45,5	-	-	-

The correlation between individual characteristic (age, gender, working period,education background, and OHS training) with the occurrence of Near Miss Accident.

Base on the data above, it is known that the workers above 30 years old are related to near miss accident as big as 56.1%. While the workers with 18-30 years of working period are related to the near miss accident as big as 43,9%. After the age was correlated withthe near miss accident, the result is insignificant because p-value 0.942 is more than 0,05.

It is because of the experienced workers,mature age tends to take a shortcut because they feel safe so far and it is difficult to left the habit. Aksron (2007) also reported that there is a relation between the worker's characteristics (age, working experience) with the near miss accident[4].

The analysis result of binary logistic regression shows there is no correlation between the age factor with the near miss accident. Workers within productive age perceivethenear miss accident, which they often did, as a normal thing because it never caused accident

yet for themselves so it is not considered as unsafe action. On the other side, young workers perceive their job as something new that need to be studied more so that their mistakes often happen. There is a possibility of another influencing factor that is the maturity of thought on individuals at certain ages. This hypothesis is supported by a theory which states that individuals considered as mature if they are able to conduct and thought maturely. Adulthood and maturity of people are not merely influenced by ages, the maturity itself is divided into two kinds (B. Hasan (2006: 127):

a. Instinctive maturity, a maturity inherited from the parent (heredity).

b. Intelligence maturity, a maturity obtained from the observation process on their environment so that shapes person's mindset and behavior[6,8].

Base on the research data, the workers which has aworking period as much as or more than 6 years is related to the high level of near miss accident, 30,7%. On the other side, the workers with the working period under 6 years are related to the medium level of near miss accident as big as 31,8%. After the working period was correlated between with the near miss accident, the result is insignificant because of p-value 0,799 more than 0,05.

Suma'mur (2011) states that the experience to stay alerted toward the workplace accident is getting better in accordance with the growing number of working period and the working duration in that workplace. The inexperienced worker is one of the factors which has the possibility to influence the occurrence of workplace accident as compared to workers that have already work for more than 3 years. Since the working period is unrelated to near miss accident, there is another possible factor, that is the attitude factor and the worker competency on doing the activities[10].

Base on the data above, the workers which have vocational school (SMK) as recent education is correlated with high level of near miss accident as big as 45,5%. The workers with vocational school education also correlate to medium near miss accident, as big as 51,5%. After the recent education factor was correlated with the near miss accident, the result is insignificant because p-value 0,644 is more than 0,05. A theory states that the education level of workers influence their logic when facing their task, including the prevention of an accident and avoiding accidents when they perform their task (Health Department of Indonesia, 1990) [8,11].

The research result shows that there is no correlation between recent education and near miss accident, so there is a possibility of another influencing factor, that is a Luzzo theory (Levinson, 1998:475) which states that career maturity is an important element for individuals on fulfilling their need of knowledge and skill to make a smart and realistic career decision. Career maturity is closely related to someone's skill on making adecision at work. The amount of skill possessed by individual enables them to avoid dangerous behavior that can lead to an accident[2,3].

The data above shows that workers who never participate in OHS training are related to high level of near miss accident as big as 46,42%. On the other side, they are also related to the medium level of near miss accident as big as 53,57%. The correlation between OHS with near miss accident is insignificant because p-value 0,890 is more than 0,05.

OHS training is one of the attempts to improve human resources quality in the workplace. The employee, whether they are the new one or the experience one need to take the training because of the dynamic features of the working environment, strategy, etc. The research shows that there is no correlation between OHS training with near miss accident, then there is a possibility of another influencing factor, that is working interest. It is possible for a worker who has taken a OHS training to forget the lesson if they do not actively practice it, and also there is a factor of unreadiness on receiving the OHS training material. Those two, in the end, can cause the worker to experience near miss accident at the workplace[3,7,9].

Correlation between Working Fatigue with The Occurrence of Near Miss Accident

According to the research data above, the workers who fall into "tired" category of the working fatigue level is related to the high level of near miss accident as big as 44,3%. This category also related to the medium level of near miss accident as big as 51,1%. The result of the correlation between working fatigue and near miss accident is insignificant because p-value 0,890 is more than 0,05.

Factors that influence fatigue are an internal factor and external factor. Internal factor such as a somatic factor or physical factor, nutrition, sexuality, age, knowledge, and lifestyle. External factor consists of the physical condition of working environments such as noise, temperature, lighting, chemical factor, biological factor, ergonomy factor, job category, the nature of the

job, discipline or company regulation, wage, social relation and job position (Suma'mur P.K., 1996:359)[10].

A fatigue caused by static work is different than the one caused by dynamic work. On static muscular work, by exercising 50% of muscle's maximum power, the muscle only can endure 1 minutes physical task at max, while by exercising less than 20% the physical task can be maintained fairly long. But exercising static muscle's energy at 15 % - 20% can cause a fatigue and sore if it is performed all day long(Tarwaka, et al., 2004:109). Meanwhile, Suma'mur P. K. (2009:358) said that there are five groups of fatigue causal factors, those are:

1. Monotone condition
2. The burden and the duration of work, physically and mentally.
3. The condition of working experiment, such as the weather, lighting, and noise at the workplace[10].

This research proves that there is no correlation between a working fatigue with near miss accident, then there is a possibility of another factor such as the working nutrition. This assumption is backed by a theory by Irianto (2007) that a nutrition is defined as an organism's process of using the consumed food normally through the digestion process, absorption, transportation, conserving, metabolism, and the secretion of nutrient to maintain the life, the growth, and the normal function of body's organ, and to produce energies. A good nutrition intake for the workers determine the obtained energy, if the consumed foods don't meet the human nutrition standard, it will cause the worker unable to focus at work, lack of energy, and bothering the activities that potentially causing near miss accident at work[9].

Correlation between OHS Motivation with the Occurrence of Near Miss Accident

A good OHS motivation related to the high level of near miss accident is 32 (36,4%). Meanwhile, when it is related to the medium level of near miss accident is 45 (51,1%). And the test result of its correlation is significant because p-value 0,012 is less than 0,05.

The majority of the OHS based behavior is focused on motivating the workers through contingency (such as money, reward, or position) while nurturing OHS culture focuses on motivating the workers to internalize the safety value (Dejoy, 2005)[8].

In this research, OHS motivation falls into a good category where the motivation is able to stimulate the establishment of OHS culture because of the self-awareness. This good category can be achieved because of the worker compliance with the company regulations[7].

Maslow said that we will act to fulfill the biological needs first, such as live survival and safety. Then, we will act to fulfill our emotional need such as love and pride. In the end, after all of the previous need is fulfilled, we will pursue our life goals such as a satisfaction and self-actualization. A motivation then will manifest into an attention, an effort, and a perseverance. After the satisfaction of need is fulfilled then the safety act is performed[10].

Daniel E. Mode also said that several factors which can improve the motivation for safety measure comprise of a safe working environment, a full involvement of the workers on decision making, a sincere appreciation, trust, sense of belonging, cooperations among the department, and training[9,10].

Correlation between TheSupervisor'sMonitoring with The Occurrence of Near Miss Accident

The research data above shows that supervisor's supervision within a good category is related to the high level of near miss accident as big as 30,7%. The supervisor's supervision in good category Similarly, the supervisor's monitoring with the good category associated with the medium level of near miss accident as big as 45,5%. The result of correlation test between supervisor's monitoring with near miss accident is significant because p-value 0,035 is less than 0,05.

This finding is in accordance with a theory which said that supervisors are capable of monitoring and also assess all activities that have been planned together and prevent the near miss accident and monitoring the workers to be able to carry out tasks they are responsible for the best performance (Arwani, 2005)[5,8].

The supervisor is not only carried out their task with the best, in accordance with the instructions or the requirement laid out by the company but also how to improve the process of the work in progress to prevent an accident,thenot conducive environment, andnear miss accident[10].

So in the supervisor's activities, everyone involved isnot as a passive executor, but together as partners

who have ideas, opinions, and experiences that need to be heard, appreciated, and included in the improvement effort ofthe process of production activities (Suyanto, 2008)[4,5].

CONCLUSION

There is no correlation between the worker's characteristic factor (age, working period, and personality type) with the occurrence of near miss accident, there is no correlation between working fatigue with the occurrence of near miss accident, there is a correlation between K3 motivation with near miss accident, and there is a correlation between supervisor's monitoring with near miss accident[1,5].

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All subjects were fully informed about the procedures and objectives of this study and each subject prior to the study signed an informed consent form.

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Spectrum of Rheumatological Disorders in Children from a Tertiary Care Hospital in Bhubaneswar, Odisha

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ABSTRACT

Introduction: Epidemiological data from India is lacking about prevalence of childhood rheumatological diseases, but India with 1.15 billion people(2010 Census data), "we could estimate approximatel ˜ 1.3 million children withJuvenile Idiopathic Arthritis(JIA) and 2,00,000 with Systemic Lupus Erythematosus (SLE) alone, basing on world prevalence data.But due to many factors these cases are not diagnosed and treated early; children with JIA can be misdiagnosed as Tuberculosis or Acute Rheumatic Fever (ARF), because of the lack of awareness about rheumatic diseases. On many occasions parents move here and there without proper approach, guidance and management leading to increased morbidity and mortality.

Objectives: To assess the prevalence and distribution of pediatric rheumatic diseases in a tertiary level hospital in Bhubaneswar, Odisha.

Materials and method: This retrospective study was carried out during Sep 2015 to Aug 2016. Diagnosis was reached by using classification criteria supplemented by necessary investigations.

Results: Total number of cases was 115 with female predominance (F:M ratio of 1.4:1) and mean age 8.7 yrs (range 7 months to 18 yrs). JIA (34.8%) was most common followed by Vasculitis Syndrome (15.6%), Benign Hypermobility Joint Sndrome(13%), Pain Amplification Syndrome/Fibromyalgia(13%). Juvenile Dermatomyositis (JDM),ARF, SLE, Juvenile Scleroderma, restless leg syndrome(RLS), Juvenile SjÖgren syndrome,Inflammatory Bowel Disease(IBD) and Mixed connective tissue disease (MCTD)were found in 5.2%, 4.35%, 4.35%, 2.6%, 2.6%,1.7%, 1.7% and 0.87%cases respectively. Common medications were nonsteroidal anti-inflammatory drugs(NSAIDs),prednisolone/deflazacort, disease modifying anti-rheumatic drugs(DMARD) and biologic agents; methotrexate being the anchor drug in many disorders. Physiotherapy was necessitated in 21% cases and intra-articular injections(steroids) in 26% cases. In 77% cases various combinations of treatment were required. Supplementation with folic acid, calcium, vitamin-D, proton-pump inhibitors(PPI)/H2-Blocker was done in 94% cases.

Conclusion: Rheumatological disorders in children are not uncommon in our country; prevalence of diseases varies from place to place across the world. Better awareness of parents and improved clinical acumen of pediatric practitioners will definitely allay the sufferings of affected children avoiding increased morbidity and mortality. Further, large available pool of patients in our country is an untapped clinical source that could provide the platform for further research studies.

Keywords: *Spectrum, Pediatric, Rheumatological disorders, Prevalence.*

INTRODUCTION

The prevalence of various pediatric rheumatic diseases varies across different regions of the world, with the prevalence of Juvenile Idiopathic Arthritis (JIA) ranging from 0.07 to 10/1000 children and that of SLE from 0.4 to 0.6/100000 children.[1,2] Epidemiological data from India is lacking about childhood rheumatological diseases, but India with 1.15 billion people(2010 Census data), "we could estimate approximately 1.3 million children" with JIA and 2,00,000 with SLE alone.[3] But due to many factors, these cases are not diagnosed and treated early; children with JIA can be misdiagnosed as Tuberculosis

or Acute Rheumatic Fever (ARF), because of the lack of awareness about rheumatic diseases. On many occasions parents move here and there without proper approach, guidance and management leading to increased morbidity and mortality. Although chronic arthritis has always been the core of Pediatric Rheumatology, the broader scope of the discipline gradually emerged with the recognition in children of SLE, dermatomyositis, vasculitis, scleroderma, SjÖgren syndrome and most recently, the autoinflammatory disorders.[4]Of all the specialities, rheumatology deals with broadest spectrum of the disease, both organ specific and systemic; and is sometimes considered a 'gray area' of medicine, as there are few useful diagnostic tests, sparse pathognomonic clinical signs, and therapy that lacks specificity.[4]Though defined diagnostic criteria exist for most rheumatic diseases, children sometimes present with partial criteria that evolve with time or with features of more than one rheumatic disease (overlap syndrome). Low specificity of the existing diagnostic tests and many mimicking disorders viz infection, malignancy, metabolic and orthopedic conditions pose additional challenges in reaching at the diagnosis. But early diagnosis and early institution of proper treatment are essential in rheumatological diseases of children in order to avoid not only body deformity but also involvement of vital organs like heart (ARF), eyes (JIA), kidney (SLE), lungs (Scleroderma) etc. The aim of this study is to sensitise the pediatricians about pediatric rheumatological diseases through analysis of their prevalence, pattern of presentation, hematological parameters, biomarkers and the risk factors for the development of the complications; so that early diagnosis will be achieved and prompt definitive management will be instituted.

MATERIALS AND METHOD

Study Design-A retrospective analysis of pediatric patients with rheumatological diseases diagnosed and treated as OPD or admitted cases in a tertiary care hospital of Odisha was carried out. The study period was from Sep2015 to Aug 2016. Children from age 6 months to 18 years were included in this study. Diagnosis of patients was based primarily on clinical features with established classification criteria and supported by specific laboratory / radiological tests. The mode of presentation, clinical course, treatment history, laboratory/radiological investigation reports, drugs administered, response to therapy and the complications were recorded.

Inclusion Criteria- Pediatric cases of 6 months to 18 yrs of age diagnosed and treated as OPD or indoor patients with any of the rheumatological diseases were included in the study.

Exclusion Criteria- (1) Age more than 18 yrs, (2) Trauma or mechanical causes (3) Non- rheumatological diseases with features of arthritis/vasculitis viz- Hepatitis-B, Sickle Cell disease, Infective Endocarditis etc. However, arthropathy of IBD has been included in the study as it has been included in both the European League Against Rheumatism(EULAR) and International League of Associations for Rheumatology (ILAR) criteria.

Investigations

Complete blood count (CBC), ESR, CRP, Urine-routine and microscopy were done on each case and other investigations like ASO, ECG, ANA, dS DNA, C3/ C4, RA Factor, Citrulinated Cyclic Peptide Antibody (CCPA), HLA B27, Tropoisomerase-1 (Scl-70), Anti-Uridine-1-Ribonucleoprotein (anti-U1RNP), Antinutrophil cytoplasmic antibodies (ANCA), joint aspiration and cytology and ophthalmological examination were carried out whenever necessary. Patients for biologic therapy were investigated to rule out any latent infections like tuberculosis, hepatitis-B and C.

Monitoring

All children on disease modifying antirheumatic drugs (DMARD) and biologic agents were monitored every 3-6 months with CBC, ALT and serum creatinine for detection of early toxicity and with ESR, CRP and other markers depending on the disease, for its remission or aggravation.

RESULTS

In this study, out of total 115 pediatric rheumatological cases(Table-1, Figure-1), only 34cases were admitted for initial aggressive management and physiotherapy and others were treated as OPD cases. JIA(40 cases) constituted the major portion i.e. 34.8% out of which, systemic onset JIA (SoJIA) was 8 (20% of JIA cases), oligoarthritis 4(10%), polyarthritis 6(15%), enthesitis related arthritis 19 (ERA-47.5%), psoriatic

arthritis 2(PsA-5%) and undifferentiated arthritis1 (UA-2.5%). Out of 7 reactive arthritis (ReA) cases one was post streptococcal reactive arthritis (PSRA) who initially suffered from post streptococcal glomerulonephritis, recovered from it and subsequently developed PSRA; 5 cases had history of diarrhoea/dysentery in recent past.

Table 1: Prevalence of Various Rheumatological Disorders in Children.

Disease	Sub-Type	Admitted Cases	OPD Cases	Total Cases	Age Distribution	F, M Nos
JIA	SoJIA	1	7	8	≤ 6yrs-7, >6yrs- 1	5, 3
	Oligoarticular	-	4	4	≤ 6yrs-3, >6yrs- 1	3, 1
	Polyarticular- RF -ve	-	4	4	< 10yrs-4	2, 2
	Polyarticular- RF +ve	-	2	2	≤ 10yrs- 2	2, 0
	ERA	8	11	19	≤ 10 yrs-2, >10yrs-17	5, 14
	Psoriatic Arthritis	-	2	2	< 10yrs-1, ≥ 10yrs- 1	1, 1
	UA	-	1	1	≥ 10yrs- 1	1, 0
Vasculitis Syndrome	HSP	6	0	6	< 10yrs-6	2, 4
	Kawasaki Disease(KD)	5	0	5	<1yr-1, 1-5yr-4	3, 2
	Takayasu Disease	2	O	2	≥ 10yrs- 2	2, 0
	Polyarteritis Nodosa	1	1	2	< 10yrs-1, ≥ 10yrs- 1	1, 1
	GPA	1	1	2	≥ 10yrs- 2	2, 0
	CSS	1	-	1	< 10yrs- 1	0, 1
BJHS		-	15	15	< 10yrs-5, ≥ 10yr-10	10, 5
PAS		-	15	15	< 10yrs-4, ≥ 10yr-11	11, 4
JDM		4	2	6	≥ 10yrs- 6	4, 2
Rheumatic Fever		5	-	5	≤ 10 yrs-3, ≥10yrs-2	3, 2
Juvenile SLE		-	5	5	≤ 10 yrs-4, >10yrs-1	3, 2
Juvenile Scleroderma		-	3	3	≤ 10 yrs-2, >10yrs-1	2, 1
Restless Leg Syndrome		-	3	3	≤ 10 yrs-2, >10yrs-1	3, 0
SjÖgren Syndrome		-	2	2	≥ 10yrs- 2	1, 1
IBD		-	2	2	≥ 10yrs- 2	1, 1
MCTD		-	1	1	≥ 10yrs- 1	1, 0
Total		34	81	N=115		68,47 1.4:1

Abbreviations: SoJIA-Systemic onset JIA, RF-Rhematoid Factor, ERA-Enthesitis Related Arthritis, UA-Undifferentiated Arthritis, HSP-Henoch SchÖnlein Purpura, GPA-Granulomatosis with Polyangitis, CSS-Churg Strauss Syndrome, BJHS-Benign Joint Hypermobility Syndrome, PAS-Pain Amplification Syndrome, JDM-Juvenile Dermatomyositis, MCTD-Mixed Connective Tissue Disease, IBD-Inflammatory Bowel Diseases.

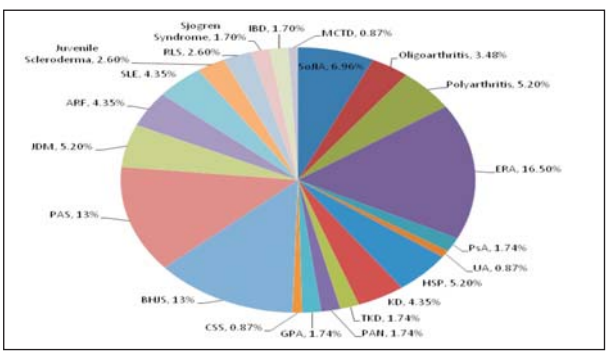


Fig. 1. Observed Distribution of Rheumatological Disorders in Children.

ReA patients responded better to Indomethacin (than other NSAIDs) and Sulphasalazine(SSZ) which was introduced with low dose in first two days to detect any adverse reaction with Sulpha; one case developed drug reaction in whom it was discontinued and treated with methotrexate. Biologic agent mainly Anti-Tumour Necrosis Factor-α (Anti-TNF-α, Etanercept)was required in 5 cases, who had aggressive course with continued fever and multiple joints involvement particularly knee and ankle. All of them were HLA-B27 positive. All ReA cases were given a course of

Azithromycin for 3 days for possible Chlamydia infection. Intra-articular steroid was given in 4 cases. Among 8 SoJIA cases 6 were polyarticular and 2 oligoarticular. They responded well to Methotrexate but 3 required biologic agent and responded well to Tocilizumab. They are being monitored at periodic interval for development of Macrophage Activation Syndrome(MAS) or Amyloidosis.

There were only 4 cases of oligoarthritis out of which 3 remained persistent oligoarthritis and one changed to extended oligoarthritis with involvement of > 4 joints, 6 months after the onset of the disease. Of total 6 polyarthritis cases 4 were RF –ve and 2 RF +ve. 3 cases of oligoarthritis and one case of RF –ve polyarthritis were ANA +ve who were subjected to ophthalmologic screening periodically for development of posterior uveitis. Out of 2 RF +ve cases one was CCPA +ve and had very aggressive course. There were 2 cases of psoriatic arthritis(PsA); one presented initially with polyarthitis, was being managed with presumptive diagnosis of undifferentiated arthritis, but after 3 months developed scaly psoriatic rashes; the other presented with polyarthritis and asymmetric dactylitis and was ANA +ve. He was subjected to ophthalmological examination to detect development of posterior uveitis. The lone case of undifferentiated arthritis (UA) was not fitting to any category and was being observed for 5 months. All these cases were managed with the anchor drug methotrxate(10mg/m BSA/wk) by oral route, 4 cases required additional leflunomide; intra-articular steroid was required in 6 cases.

After JIA, Vasculitis Syndromes(VS) was next common rheumatological disease with 18 cases(15.65%) which comprised HSP 6 cases(33.3% of VS), Kawasaki Disease 5(KD-27.8 %), Takayasu Disease2(TKD-11.1%), Polyarteritis Nodosa2 (PAN-11.1%), Granulomatosis with Polyangitis2 (GPA-11.1 %) and Churg-Strauss Syndrome1(CSS- 5.5%). One KD patient was 7 mo old baby. TKD presented in one with absent dorsalis pedis pulse and secondary hypertension because of renal artery stenosis; and in other one with Raynaud phenomenon in one hand. PAN presented in one with abdominal pain, weight loss and constitutional symptoms and in other one with purpura and skin ulceration. GPA case presented with nephritis, recurrent sinusitis in one and epitaxis and respiratory complaints in other. The lone case of CSS presented with eosinophillia and chronic asthma poorly responding to anti-asthma treatmemt. We did not find any case of microscopic polyangitis(MPA) case.ANCA test was positive in GPA and CSS. Besides HSP and KD which are common vasculitis in children and not so difficult to diagnose because of specific diagnostic criteria, it was a great challenge to diagnose other VSs mentioned above. KD patients were treated with aspirin and IVIG and were monitored for coronary artery pathology, that was detected in 2 cases. HSP cases were treated conservatively with proper hydration and analgesics; 2 cases with pain abdomen were detected in USG to have bowel edema and evolving intussusception and were treated with dexamethasone 0.2mg/Kg/day single dose IV for 5 days with good result; no case developed renal problem during follow up. Other vasculitis cases were treated with steroids, methotrexate and mycophenolate moefitil (900 mg/m^2 BSA/day).

Benign Joint Hypermobility Syndrome(BJHS)was found to be 3rd common condition presenting to our hospital with musculoskeletal pain with 15 cases(13%) comprising 9 boys and 6 girls. The diagnosis was made employing Beighton criteria. More ankle sprain was observed in these cases; complaints relating to other joints were wrist, elbow, shoulder and knee. Pes planus was detected in 5 children who were obese and above 10 yrs of age; arch was normal in lying or toe-standing and disappeared on weight bearing(standing). No one had any bladder/bowel problem due to non-neurogenic sphincter dysfunction. Reassurance about benign course of the condition,non-weight bearing exercises(cycling, swimming), supportive foot wear were helpful for many; in some children additional NSAIDs were required. Pain amplification syndrome(PAS) was detected in 15 children(13%), F:M ratio being 3:1, mean age of onset being 12-13 yrs. Diagnostic criteria employed was presenting symptom of diffuse musculoskeletal pain in atleast 3 areas of the body that persisted for atleast 3 mo in the absence of any underlying disease condition. Physical examination revealed at least 5 well defined tender points and laboratory tests were normal. Associated symptoms in these children were fatigue , nonrestorative sleep, chronic anxiety or tension, chronic headache and subjective soft tissue swelling. They were managed with graduated aerobic exercise, pain coping skill, stress management skill and sleep hygiene. Drug therapy included serotonin reuptake inhibitors(Sertaline), pregabalin and pothiaden.

Juvenile Dermatomyositis(JDM) was detected in 6 cases(5.2%), who presented with fever rash (heliotrope rash) involving nasolabial fold, proximal muscle weakness, Gottron's papules over Proximal Interphalangeal Joints(PIJs) and Distal Interphalangeal Joints (DIJs). Esophageal muscles were affected in one

child requiring tube feeding; no patient developed respiratory failure. All had nail fold capillary abnormality (thickened, wide, tortuous and absence of loops), which was easily visualized under capillaroscope. ANA was positive in 4 cases and in 3 cases ALT and CPK(total) were raised. Patients were managed with corticosteroids, methotrexate, Hydroxychloroquine(HCQ), physiotherapy and photoprotection with sun protection factor (SPF)-70 lotion even in winter and cloudy days. Bed rest was discouraged as weight bearing improves bone density and prevents contracture.

Rheumatic Fever(RF) was detected in 5 cases (4.35 %) strictly following modified Jone's criteria. Except one who had features of carditis including cardiomegaly and required both salicylates and corticosteroids, others without involvement of the heart, were treated only with salicylates and responded well. All had migratory polyarthritis mainly involving knees and ankles. Secondary prophylaxis with benzathene penicillin every 3 weeks was advised to all, for the period as per existing guidelines.

Juvenile SLE was detected in 5 children (4.35%) comprising 3 girls and 2 boys. Clinical presentation was fever, weakness, arthritis/arthalgia, oral ulcer particularly on hard palate, hematological abnormalities and renal disease. All had ANA profile abnormality, hypocomlementenemia; one had antiphospholipid antibody, 3 were dsDNA +ve. They were managed with NSAIDs, corticosteroids, mycophenolate moefetil, HCQ, and azathioprine, in different combinations. Cyclophosphamide was used in one severe case. The case with antiphospholipid antibody developed deep vein thrombosis and is on long term anticoagulation. Immunization with Pneumococcal vaccine (PCV-13 followed by PPSV-23) and annual influenza vaccine were ensured for all because of increased susceptibility to these organisms in a state of deranged immunity in SLE.

Juvenile scleroderma was detected in 3 cases(2.6%) comprising one localized scleroderma (morphea) and 2 systemic scleroderma(SSc). SSc cases presented with sclerodactyly, salt and pepper appearance on skin particularly over ear pina (representing hyperpigmented post-inflammatory changes surrounded by atrophic depigmentation), Raynaud phenomenon, gastroesophageal reflux, hypertension due to renal disease, pulmonary arterial hypertension and nail fold capillary abnormality. Muscle enzymes CPK and particularly aldolase were raised. ANA was positive, particularly anti-Scl-70(anti-topoisomerase-I). They were managed with cortiocosteroids, mycopnolate moefetil, methotrexate and vasodilators(tadalafil, nifedipine).

Restless leg syndrome was detected in 3 cases(2.6%). They presented with unpleasant feelings in the legs including crawling sensation, aching, tickling, prickling sensations and an urge to move the legs when sitting down or lying on bed. Two of them had sleep disturbance and low quality of life. All had iron deficiency anemia. They recovered with hematinics and proper sleep hygiene.

SjÖgren Syndrome(Primary) was detected in 2 (1.7%) cases, one boy(11 yrs) and a girl(14yrs). Both presented with recurrent parotitis and lymphadenopathy; the boy additionally had multiple dental carries and the girl had polyarthritis. Both had raised ESR, leucopenia; the girl was ANA +ve. They were treated with NSAID, corticosteroid and HCQ. The girl with polyarthritis, additionally required methotrexate.

Two cases (M-13yrs, F-14yrs) were detected to have arthropathies of IBD. Both of them were suffering from Crohn's disease and presented initially with arthralgia and subsequently one developed peripheral arthritis involving knees and ankles and the other patient(boy) developed sacroiliac(SI) joint arthritis. He was found to have HLA B-27 positive. Episodes of arthritis were brief lasting for 1-2 weeks and often recurred. The severity of IBD reflected in the severity of peripheral arthritis in the girl but in the patient with SI joint involvement, the arthritis persisted independent of the activity of GI disease. Both responded well to Sulphasalazine, corticosteroids and azathioprine.

One child(F-13yrs) was diagnosed to have Mixed Connective Tissue Disease, who presented with scleroedematous hands, arthralgia, Raynaud's phenomenon, esophageal dysmotility, acid reflux, dysphagia and proximal lower limb muscle weakness. ANA and anti-U1RNP were positive; nail fold capillaries were normal. She responded well to corticosteroid, HCQ and methotrexate and is being monitored for any development of ILD/pulmonary hypertension.

DISCUSSION

A wide spectrum of rheumatologic diseases was seen in our study. JIA was most frequent diagnosis

comprising 34.8% cases. This is in accordance with other reports and studies.[3] Enthesitis Related Arthritis (ERA) is more common form of JIA in our study in conformity with the study by Seth*et al*[5], in contrast to the western data where oligoarticular JIA is more common[3]. Further Polyarticluar JIA was more common than oligoarticular JIA in our study, in contrast to western studies and in conformity with other Indian reports.[6] The frequency of SoJIA in our study (20% of JIA) almost matches with the frequency from South India (13%), North India (24%) in other studies . [7,8,9] Methotrexate worked well in many cases of SoJIA in our study in contrast to findingsin western countries,[10]where it is not that effective. Only few cases required additional Cyclosporine or Tocilizumab; Anakinra has not been tried because of non availability in India. The lone case of post streptococcal reactive arthritis (PSRA)initially suffered from post streptococcal glomerulonephritis, recovered from it and subsequently developed PSRA. Though susceptible cases of JIA(SoJIA, Oligoarthritis, Seronegative Polyarthritis and PsA) were being screened regularly by ophthalmologist for uveitis, no case developed this in our study which is in accordance to its rare finding in the study by*JHT Tan et al*[11].

Vasculitis syndrome was also common in our study (15.6% of rheumatological cases) in conformity with a study from Singapore.[11]Besides two most common vasculitides HSP & KD , we detected few cases of TKD, GPA & CSS. We found many cases of non inflammatory conditions like PAS, BHJS who were much relieved after the disclosure of the diagnosis and benign nature of the disease as they have been frightened by other peripheral doctors about ongoing rheumatic diseases. One should look for these conditions in cases with musculoskeletal pain. PAS in children, also synonymous with Juvenile primary fibromyalgia syndrome(JPFS) is a common pediatric muculoskeletal pain syndrome. JPFS is an abnormality of pain processing, characterized by disordered sleep physiology, enhanced pain perception and abnormal levels of substance-P in CSF, disordered mood and dysregulation of hypothalamic-pituitary-adrenal and other neuroendocrine axes resulting in lower tender point pain threshold and increased pain sensitivity.[12]The word amplified pain refers to the idea that the body amplifies the pain in much the same way as the microphone and the speaker. It does not imply that the child is willfully hyperebolizing.[13]4.35% of our study population had SLE which is comparable to other reports from India (7%), Singapore (6.2%), USA (9.1%), Austria(6.5%).[11] SLE is reported to be more severe in Asians including Indians.Renal and CNS involvements are more common than those reported from the west and associated with higher morbidity and mortality.[13] Though SjÖgren syndrome is rare in children we diagnosed it in two children (M-11yrs & F-14yrs);it typically manifests at 35-45 yrs of age, symptoms often starts in childhood but it is under recognized. Anti-â fodrin autoantibodies directed against an apoptotic cleavage product of á-fodrin are useful diagnostic marker for juvenile SjÖgren Syndrome.

Though localised scleroderma is more common than systemic scleroderma(SSc),we came across with two SSc cases and one morphea case only. Unfortunately we could not find a single case of auto inflammatory disease in our study. All patients improved and their disease process were arrested and parents were convinced about regular medication and follow up. The anchor drug has been methotrexate in conformity with other reports.[14]

CONCLUSION

Rheumatological disorders in children are not uncommon in our country; prevalence of diseases varies from place to place across the world. Better awareness of parents and improved clinical acumen of pediatric practitioners will definitely allay the sufferings of affected children avoiding increased morbidity and mortality. Early diagnosis, timely intervention, aggressive treatment and rehabilitation are key factors. The anchor drug has been methotrexate and the dose that is used for rheumatological conditions is quite optimal and fear of its toxicity should be addressed through regular check up of CBC, ALT and Creatinine, regular folic acid supplementation except the day on which methotrexate is taken. In patients with musculoskeletal pain, non-inflammatory diseases should be looked for when CRP and ESR are within normal limits, as in our study 26% of the cases fell into these groups.This study has offered information about the spectrum and the prevalence of rheumatological disorders in children which has been underestimated by health practitioners and government agencies. Further, the large available pool of patients in our country is an untapped clinical source that could provide the platform for further research studies.

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Ethical Clearance: Since it was a retrospective observational study without any intervention and without disclosure of any personal information about the patients, ethical clearance was not considered essential.

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Fetal outcome in Gestational Diabetes Mellitus

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ABSTRACT

Background: Gestational diabetes mellitus is defined as glucose intolerance diagnosed for the first time during pregnancy and usually disappears during puerperium[6].

Objective:

1. The aim of the study is to assess maternal& fetal outcome in gestational diabetic women.
2. To assess the maternal & fetal complication of pregnant women with gestational diabetes mellitus compared with non diabetic patients who delivered in hospital during study period.

Material and Method: The present study was carried out in the department of Obstetrics and Gynecology SIMS, Hapur. The cases of normal uncomplicated pregnancy were selected from the antenatal clinic &general outpatient department.

Method: Screening for GDM was performed B/w 24-28 wks of gestational age by 50 gm glucose challenge test given orally to the patient at any time of the day, with serum glucose measured at 1 hrlater.if glucose level of one hour was > 140 mg/dl; the patient underwent a 3hr 100gm oral glucose tolerance test[2,3,4].

Conclusion: In our study there was significantly increased incidence of caesarean section, pre-eclampsia, preterm vaginal delivery, induction of labour and rate of NICU admission 16.12%(p value .00082062) were also high and statically significantly associated in GDM patients. Among our diabetic patients there was no perinatal mortality, no congenital malformation in the fetus. This could be achieved with universal screening of all pregnant patients leading to early diagnosis, strict monitoring and management of these patients.

There was no incidence of post partum bleeding and infection in our study.We recommend universal screening procedure for all pregnant patients at 24-28 wks of pregnancy[18].

Keywords: *Gestational Diabetes Mellitus, Oral Glucosetolerance Test,Universal Screening, P-Value.*

INTRODUCTION

Gestational diabetes mellitus is defined as glucose intolerance diagnosed for the first time during pregnancy (Setji, Brown &Fringlos)[15]and usually disappears during Puerperium pregnancy is a state of natural insulin resistance, which is due to placental production of human placental lactogen, estrogen, progesterone and cortisol (Hollingsworth, 1983) an insulin antagonizing hormones,loading to a remarkable increase of insulin requirement in pregnant diabetes in mind second and third trimester."According to WHO the gestational diabetes is define as carbohydrate intolerance resulting in hyperglycemia of variable severity with its onset of first recognisation during the pregnancy".The prevalence of gestational diabetes mellitus in some ethnic groups ranges from 1 to 14% depending on different screening methods, diagnostic criteria and the population screened.

The prevalence of gestational DM in India varies from 3.8% to 21% in different parts of country, depending on the geographical locations and diagnostic methods used.gestational diabetes mellitus has been found to be more prevalent in urban areas

than rural areas.(Malik WaseemRoja et al)[12]the prevalence of diabetes is increasing globally and india is no exception .In 1997 WHO estimatesthe prevalence of diabetes in adults showed an expected total rise of >120% from 135 million in 1995 to 300 million in 2025.

In study done by European journal of obs and gynaecology for screening for gestational diabetes[17].Variations in guidelines by S.Vogel, Burnand in july 2000 proposed that screening for diabetes could be :

1) Universal screening

2) Selective screening

3) Screening when clinical indicated

Though study done by various journal ,finally come to conclusion that screening for diabetes should be universal as if only higher risk patient are screened 35% of gestational diabetes will not be discovered .

The management of gestational diabetes mellitus[3] has altered markedly in recent years.It is based on universal screening of blood sugar and to establish a tight control of serum glucose levels round the clock in the patients through serial management of blood glucose by home monitoring and glycosylated hemoglobin ,adequate control of serum sugar has been associated with improved perinatal outcome more than three quarters of patients with gestational diabetes mellitus respond to diet therapy alone and the remaining patients require the addition of insulin with diet.

Table I: Carpenter and Coustan criteria for diagnosis of Gestational diabetes[7]

One-Hundred-Gram, 3-Hour Glucose Tolerance Test Values for the Diagnosis of Gestational Diabetes Mellitus[3].

Condition	Carpenter and Coustan	National Diabetes Data Group
Fasting	95	105
1-h	180	190
2-h	155	165
3-h	140	145

Data are in milligrams per deciliter.* Gestational diabetes mellitus diagnosis achieved if two or more glucose values exceed the threshold value.

Gestational diabetes mellitus achieved if one or more values exceed threshold value.

OBJECTIVE

1. The aim of the study is to assess maternal& fetal outcome in gestational diabetic women.

2. To assess the maternal & fetal complication of pregnant women with gestational diabetic mellitus compared with non diabetic patients who delivered in hospital duringthe study period.

MATERIAL AND METHOD

The present study was carried in the department of Obstetrics and Gynecology SIMS, Hapur. The cases of normal uncomplicated pregnancy were selected from the antenatal clinic &general outpatient department.

METHOD

Screening for GDM was performed B/w 24-28 wks of gestational by 50 gm glucose challenge test given orally to the patient at any time of the day, with serum glucose measured at 1 hr later and if serum glucose level of one hour was > 140 mg/dl; the patient underwent a 3hr 100gm oral glucose tolerance test.American College of Obstetricians & Gynecologist 1994 criteria for diagnosis of gestational diabetes using 100gm glucose orally.

Gestational diabetes is diagnosed[7] when any two values are met or exceeded. GDM was diagnosed e" 2 values met or exceeded the following cut-off-point. Fasting blood sugar 95mg/dl 1 hour – 180mg/dl- 2hr- 155 mg/dl; 3 hr- 140mg/dl; also an OGTT performed 6 wks post delivery was within the cut-off point. Patients diagnosed to have GDM were referred to physician and according to physician advice they were put on diabetic diet, metformin or insulin. Patients diagnosed to have GDM were put on diabetic diet for 5 days followed by a blood sugar profile to measure thefasting blood sugar and 2 hrs postprandial breakfast, lunch and dinner serum glucose levels. If the fasting blood sugar was d"100mg/dl and post prandial blood sugar levels d"125mg/dl; the patients with higher value treated with metformin or insulin. Metformin is given in dose of 500mg once or twice a day depending on the sugar status of the patients. Patients with injections of regular and NPH insulin. Twice daily (half an hour before breakfast and dinner). Control of blood sugar levels were monitored by bi- weekly BSP.

The patients were seen every two weeks and USG examination were performed every 4 weeks from the time of diagnosis.labour was induced at 40 wks in GDM patients controlled on diet alone without any pregnancy complications, if spontaneous onset had not occurred. Few patients required earlier induction of labour due to pre-eclampsic toxemia and poor biophysical profile.blood sugar was measured in the newborns of diabetic mothers 30 minutes after delivery, in case of hypoglycemia, measurements were repeated every two hours until stable values of equal to or more than 2.5mmol/l ewere obtained.

Statistical Analysis

To assess the maternal & fetal outcomes in different group of patients chi square test was used& P value less than 0.05 were considered statistically significant.

DISCUSSION

The present study is prospective study for gestational diabetes mellitus was carried out in 800 women registering in our antenatal clinic from 24-28 wk gestation using 50 gm glucose Challenge test.

In this study 800 cases of non diabetes pregnancy belonging to 24-28 wks of gestation with & without risk factors were taken.Screening for GDM was performed between 24-28 wks of gestation by 50gm glucose.Challenge test given orally to the patients at any time of the day. All patients withpositive GCT were subjected to 3hr 75 m oral glucose tolerance test.

To assess the maternal & fetal outcome in different group of patient chi squarestatically significant.In present study, most of the patients with positive screening value & abnormal OGTTduring screening belong to the age group of >25 yrs[9].similar results have been reported by TurkiGasim et al.OSullivan et al (1964) RuhinaTasmin Biswas et al (2004). OGTT was normal under age of 40 & was abnormal in 26% of these aged 40-44 & 60% of those over fifty.

Fitz Gerald et al[8],reported increasing glucose intolerance with increasing age.

Regarding BMI 35.48% women falls between the range of 185—249 & 483.38% women had BMI >25 (P Value)=0). Statistically significanceassociated.similar results have been reported by Mr. Binny M. Thomas et al (2010). Increased incidence ofglucose intolerance with increasing parity is also followed in our study.Sikender et al (1980) Mestman et al (1979) Mr. Binny M. Thomas et al (2010) reported high ceasarian rate in diabetic pregnancy.In present study the incidence of LSCS was 74.19% (P Value 0) for patient who were confirmed to be diabetic by oral glucose tolerance test rate of LSCS was high because of other complications like eclampsia&macrosomia, is our study it is significantly associated[1]. Akhtar J et al (1996) also reported pre-eclampsia of 19% in GDM patients. In our study spontaneous vaginal delivery rate was 22.58% (p value 0) in diabetic patient and it is significantly associated, assisted vaginal delivery rate was 3.22% (p value =O.82) in diabetic patient & assisted vaginal delivery rate is not significantly associated.

In present study preeclampsia was in 16.12% (P value =0.0101) of diabetic patients & it was significantly associated, in present study polyhydramnios was in 3.22% (P value=0.589) patients not significantly associated(graph-2). In our study in 19.35% (P Value=0.000606) gestational diabetic patients delivered before 36 wks & its significantly associated and rate of induction of labour was 25.80% which was less than rate of other studies.

According to our study Hypoglycemia was 9.67% (P value 0.000085) babies of gestational diabetic mother& it is significant associated[1]..similar results were also reported by Akhtar et al (1996).rate of NICU admission was 16.12% babies of gestational diabetic mothers in compression to 5.42% (P value 0.00082062) in normal mother babies(graph-1). In present study rate of NICU admission is significantly associated. In our studyHypoglycemia (P value-0.000085), macrosomia (p Value=0.03322) & rate of NICU admission (p value 0.00082062) were significantly associated[9].Turki Gasim et al (2012) also reported high rate of NICU admission (16.4%) of gestational diabetes mother babies (Table: II).

Table II: Distribution of cases according to Neonatal complications in GDM and non GDM Patients

Neonatal Complications	GDM Patients		Non GDM Patients		Chi Square	P value
	No.	%	No.	%		
Hypoglycemia	6	9.67	8	1.08	24.565	0.0000085
Macrosomia	8	12.9	44	5.96	4.534	0.03322
Hyperbilirubinemia	4	6.45	38	5.14	0.195	0.65
NICU admission	10	16.12	40	5.42	11.194	0.00082062

Rate of NICU admission, hypoglycemia, and macrosomia are high in GDM patient's baby.and this is ststistically significant.

The most common risk factors as reported in our study was history of unexplained still birth present in 30% cases in our study 48.38% women were managed by diet alone,

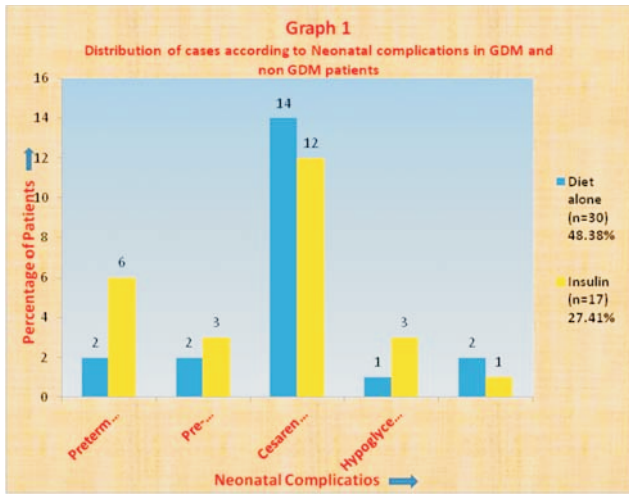
27.41% were managed by insulin St 24.19% women were managed by metformin. Rate of preterm delivery & Hypoglycemia in babies were high in women who were onmetformin & rate of cesarean section and preeclampsia were high in women who were on insulin.

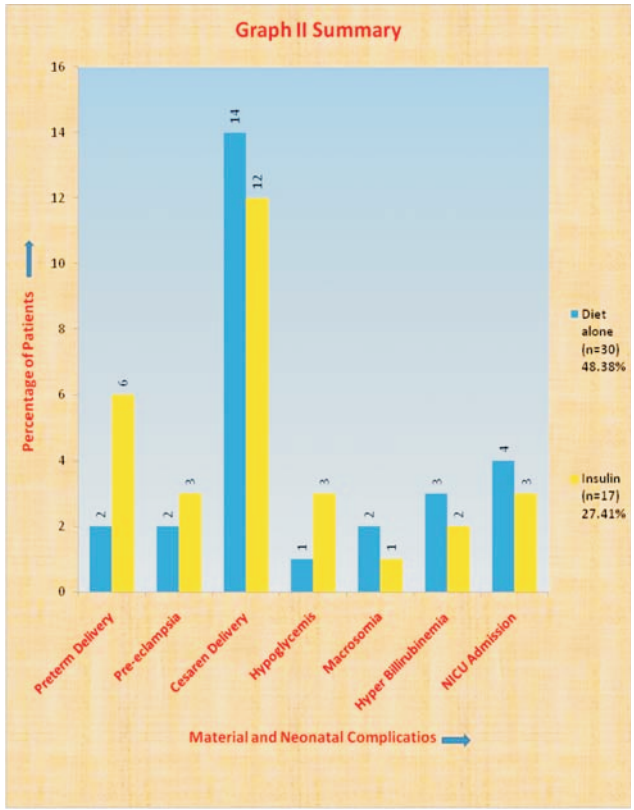
By our study we finally conclude that maternal & fetal complications were high in poorly controlled groups but complications were effectively controlled with treatment. There was no incidence of postpartum infection & bleeding.

Miller et al (1994) reported a PNMR of 5.4% in general population and 22.9% in diabetic mothers. In present study PNMR was nil in diabetic mother as patients were kept in regular follow up, thus showing effectiveness of regular follow up examination.In our study preeclampsia 16.12% (P value=0.0101) was significantly associated in GDM patients.

Premature rupture of membrane 12.90% (P value 0.02) & preterm vaginal delivery 19.32% (p value=0.00000606) were also significantly associated in GDM patients. Macrosomia 12.90% (P value=0.033) and Induction ofLabour 25.80% (P value=0) were also significantly associated in GDM Patients.in our study hypoglycemia, macrosomia ,and rate of NICU admission are significantly associated in GDM patients.andhyperbilirubinemia is not significantly associated.

Most common risk factors as reported in our study was history of unexplained still birth in 30% cases.by our study we finally concluded that overall maternal and fetal complications were high in poorly controlled groups but complications were effectively controlled with treatment.





SUMMARY & CONCLUSION

By our study we finally concluded that overall maternal and fetal complications were high in poorly glycemic controlled groups but complications were effectively controlled with treatment.Universal screening for glucose intolerance during pregnancy is essential as Indian women have high prevalence of diabetes and poor glycemic control gestational diabetes mellitus is recognized to beassociated with increased rate of adverse maternaland neonatal outcomes which are supported by the findings of this study.

In our study pre-eclampsia 16.12% (p value=0.0101)was significantly associated in GDM patients.Premature rupture of membranes 12.90% (p value=0.00000606) were also significantly associated in GDM patients.

Macrosomia 12.90% (P value 0.033) and induction

of labour 25.80% (p value is 0) were also significantly associated in GDM patients.In our study rate of NICU admission 16.12% (p value0.00082062) were also high and statistically significantly associated in GDM patients.

In our study there was significantly increased incidence of caesarean section, pre-eclampsia, preterm vaginal delivery, induction of labour and rate of NICU admission is compared with the non diabetic mother. Among our diabetic patients there was no perinatal mortality, no congenital malformation in thefoetus. This could be achieved with universal screening of all pregnant patients leading to early diagnosis, strict monitoring and management of these patients.

There was no incidence of post partum bleeding and infection in ourstudy.we recommended universal screening procedure for all pregnant patients at 24-28wks of pregnancy.

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Maternal Factors Affecting the Birth Weight of a New Born a Case Control Study

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ABSTRACT

Introduction: Low birth weight is a major public health problem in developing countries ,especially so in India. The epidemiological observations depicted that infants weighing lesser than 2500 grams are approximately 20 times more likely to die than heavier babies, closely associated with the fetal and neonatal mortality and morbidity.

Objective: To know the maternal factors affecting the birth weight of newborn.

Method: A retrospective study has been carried out from August to September 2013. A total of 100 low birth weight babies of <2.5kg's were taken as cases and 100 normal weight babies of >2.5kg's were taken as controls and their maternal age was matched. Association was assessed for the maternal factors such as gestational age, parity, Hb %, HIV status, HbsAg status, medical morbidities and obstetric morbidities.

Results: There was association between parity and low birth weight with odds ratio (2.01), gestational age and low birth weight with odds ratio (40.2). Odds ratio for medical morbidity was 1.69 and obstetric morbidity was 1.27 but they were not statistically significant. CONCLUSION:Most of the pregnant women were registered. The complications were managed well. Severe anaemia was less than 2%; except for prematurity, parity all other risk factors could be managed well in reducing the low birth weight.

Keywords: *Maternal Factors, Low Birth Weight.*

INTRODUCTION

Low birth weight (LBW) has been defined by the World Health Organization (WHO) as birth weight of less than 2,500 grams. More common in developing than developed countries. Each year about 15 -30 million infants (20 percent of all infants) are born with low birth weight.[1] In India, 30-35% babies are LBW and more than half of these infants are full term.[2] The weight of the infant at birth is a powerful predictor of infant growth and survival; it is dependent on maternal health and nutrition during pregnancy.[3] A baby's low weight at birth is either the result of preterm birth (before 37 weeks of gestation) or due to restricted fetal (intrauterine) growth.[4]A case control study would help us to findthe factors associated with low birth weight,hence the present study.

MATERIAL ANDMETHOD

The present study was a case control study which was carried out in a tertiary hospital in Belgaum. The study population were mothers who delivered in the months of August to Sept 2013. A case is defined as a mother who delivered a baby with birth weight of less than 2.5 kg and a control is defined as a mother whose baby weighed 2.5 kg. or more. These cases and controls were matched for maternal age (±2 years), and we studied the effects of parity, period of gestation, medical morbidities, obstetric morbidities and anemia on low birth weight. Inclusion criteria: mothers who delivered single babies. Exclusion criteria**:** babies born with congenital anomalies.

Sample

A total of 100 cases and 100 controls were included in the study. After identifying the baby with low birth weight using labour room record, the next born baby with normal birth weight was taken as control after matching maternal age. With the help of the maternal records, details regarding parity, period of gestation, obstetric morbidity, medical morbidity and anaemia were collected. As it was a record based study, consent was not taken. Participant's identity was not revealed hence ethical clearance was not sought for as it was not mandatory for such studies when the study was conducted.

RESULTS

A total of 100 cases and 100 controls were included in the study.

Table 1: Distribution of cases and controls according to maternal age.

Variable	Cases		Control		P Value
Age of the Mother	**No**	**%**	**No**	**%**	**0.260**
15-19	4	30	4	50	
20-24	65	52.4	59	47.6	
25-29	23	42.6	31	57.4	
≥30	7	50	7	50	

Cases and controls were matched formaternal age. Maximumi.e. 62% of mothers were in the age group of 20-24 years.There was no difference as far as maternal age is concerned between cases and controls, p value being 0.260.

Table 2: Association between maternal risk factors and low birth weight

Variables	Cases		Controls		Odds ratio	P Value
Primi	**NO.**	**%**	**NO**	**%**		
	50	51.5	34	40.5	2.01	0.016
Multipara	49	42.2	67	57.8		
Period of Gestation						
Term	82	44.8	101	52.2	40.2	<0.001
Pre-term	17	100	0	17		

Table 3: Maternal risk factors which were not associated with low birth weight.

Variable	Present/Absent	Cases		Controls		Odds Ratio	'P' Value
		NO.	**%**	**NO**	**%**		
		45	52.9	40	47.1	1.27	0.402
	Absent	54	47	61	53		
Medical Morbidity	Present	8	61.5	5	38.5	1.69	0.369
	Absent	91	48.7	96	51.3		
AnaemiA	<7 gm%	2		1		X^2 = 0.418p= 0.937	
	7-9.9 gm%	23	47.9	25	52.1		
	10-10.9 gm%	23	48.9	24	51.1		
	>11 gm%	51	50	51	50		

Parity and period of gestation were significantly associated with the low birth weight where p value was 0.016, O.R.(2.01) and <0.001,O.R.(40.02) respectively. As far as obstetric and Medical morbidity were concerned, the odds ratio being 1.27 and 1.69respectively, but this was not statistically significant with p value 0.402 and 0.369.

There was no association between maternal anaemia and low birth weight, with chi square value of 0.418 and p value 0.937.

DISCUSSION

In a study conducted atGovt.Medical college,

hospital Miraj found association between parity and LBW with adjusted odds ratio 1.70 (95% CI = 1.02-2.84).[7]Similarly in our study parity was associated with LBW, which was more among primis with odds ratio of 2.01 and p=0.016 in contrast to a study conducted in urban slum of Bhopal showed no significant association between parity and LBW with÷^{2}0.101 and p value >0.05[5]

In a study conducted at Govt. medical college,hospital Miraj found that preterm deliveries were associated with LBW with adjusted odds ratio 32.47 (95% CI=17.06-61.81).[7] Similarly our study also showed association between pre-termdelivery and low birth weight with odds ratio 40.2 and p value 0.001.In a study conducted at a hospital in Lahore found that the gestational age among cases was 34.33 ±3.16 and among controls was 38.55 ± 1.30.but they did not find the association.[8]

In a study conducted at Indira Gandhi Govt college and hospital, Nagpur found that bad obstetric history was associated with LBW with adjusted odds ratio 1.96 (95% C.I=1.41-2.72).[9]In another study conducted atGovt. medical college hospital,Miraj also found significant association between obstetric morbidity and LBW with adjusted odds ratio 8.5(95% CI= 4.92-14.66).[7] In contrast, in our study bad obstetric history was not statisticallysignificant as there was no much difference between cases and control wherein the odds ratio being 1.27 and p= 0.402. This could be because of timely interventions.

In a study conducted in two university hospitals in Tehran found that odds of giving birth to low birth weight babies was 2.69 and 4.09 for hypertension and urinary tract infection respectively, this difference was found to be statistically significant.[6] In another study conducted in Lahore, hypertension was found to be significantly associated with LBW with p value <0.001.[8] In our study the medical morbidities such as hypertension, RHD, hypothyroidism, epilepsy, congenital heart diseases, urinary tract infections was not found statistically significantwith odds ratio1.69 and p value0.369, the reason could be because of less number of participants in both the groups.

In a study conducted in SRN Hospital, MLN medical college Allahabad found that Hb level <7 gm% was significantly associated with LBW with ÷^{2} = 39.68 and p value <0.001.[10]In another study conducted in Govt medical college hospital, Mirajfound that Hb levels <11 gm% was associated with LBW with adjusted odds ratio of 9.43(95% C.I=5.45-15.86).[7]In contrast, our study showed no significant association,(÷^{2} = 0.418 and p= 0.937) as there were only 1.5 % cases with severe anaemia. In another study conducted in urban slum of Bhopal found that Hb levels <11 gm% showed no significant association with LBW with ÷^{2}0.070 and p value >0.05.[5]

Limitations

It is a hospital based study results cannot be generalized to the whole community. As we included women who delivered in the months of August-September 2013, hence it was not a representative sample.

CONCLUSION

Our study concludes that gestational age and parity (primi) were found to be significantly associated with LBW, other maternal risk factors like, medical and obstetric morbidities could be managed well to prevent LBW.

Conflict of Interest: Nil.

Source of Funding: Self.

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Premarital Sex among Rural Adolescents in North India: A School Based Study

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ABSTRACT

Background: The adolescence is a transitional stage of physical, mental and social development generally starts by puberty and ends by adulthood. Adolescents are energetic, inquisitive and have an urge to do new things but at the same time they have lack guidance and may indulge in unsafe sexual activity and also they are prone to alcohol addiction, drug abuse and other social problems.

Aim and objectives: To study prevalence of premarital sexual activity and to study various factors associated with premarital sexual activity among study subjects.

Methodology: The study was undertaken in block Beri, which serves as the field practice area of Department of Community Medicine Pt. BD Sharma PGIMS, Rohtak, Haryana, India. The study was conducted among male students of senior secondary schools of block Beri in the year 2011. The study universe comprised of 1000 malestudents in middle and late adolescence (aged 14-18 years) studying in 9th to 12th classes of the senior secondary schools in the area.

Observations: Out of 1000 study subjects, 33.7% had indulged in premarital sexual activity. The mean age of initiating sexual activity was 14.95 years. Adolescents of 14-16 yrs of age were most active involved in sexual activities as compared to other age groups of adolescent age.

Conclusions: The study concludes that a handful of adolescent are involved in premarital sexual activity and knowledge of adolescents regarding use of condom during sexual intercourse is meager. As usage of condom during sexual intercourse is also very low, hence they are at increased risk of contracting sexually transmitted infections.

Keywords: *Premarital, Sex, Adolescents, Sexual, School, Rural, Male*

INTRODUCTION

The adolescence is a transitional stage of physical, mental and social development generally starts by puberty and ends by adulthood. Adolescents are energetic, inquisitive and have an urge to do new things but at the same time they have lack guidance and may indulge in unsafe sexual activity and also they are prone to alcohol addiction, drug abuse and other social problems. WHO reported that much of the sexual activity that begins in adolescence phase is high-risk, unsafe and many a times is non-consensual[1]. WHO also reported that the adolescents, being in school and having high educational aspirations, living with both parents and having high self-efficacy to refuse unsafe or unwanted sex are protective against risky premarital sexual relations.[2] The National Family Health Survey-3 (2005-06) reported that 4% and 15% of young women and men respectively had ever experienced sex before marriage and only 14.1% of unmarried sexually active adolescent females used a contraceptive [3]. Evidence suggests that despite a conservative environment that disapproves of interactions among adolescent males and females, there are opportunities for social mixing, and young people have devised ways of developing romantic partnerships with the opposite sex [4-9]. In India, especially in Haryana, there is a great paucity of

data regarding pre marital sexual activity in rural adolescents that is why this study was planned with an objective to find out the prevalence and various factors associated with premarital sexin school going rural adolescents.

MATERIAL AND METHOD

The study was a cross-sectional, descriptive type and school based, conducted among rural male adolescentsaged 14-18 years (studying in 9th to 12th classes of the senior secondary schools) of blockB eri District Jhajjar which is field practice area of Department of Community Medicine Pt. B D Sharma PGIMS, Rohtak (Haryana) India and duration of the study was one yearsi.e year 2011. The study enrolled students having 14-18 age groups because sexual changes are more evident in this age group which leads to change in their behaviour. The Beri block has 15 governments and 4 private senior secondary schools and study included all these schools. The study recruited 1000 subjects out of 2998 total students, assuming the prevalence of premarital sexual practices as 32% at 95% level of significance and an allowable error of 10% in the study[10]. The subjects were selected by systematic random sampling from the selected schools proportionate to the strength of students in the schools. The study subjects were selected from each class by systematic random sampling.

The investigator himself approached principal of selected schools to seek cooperation and took permission to conduct the study. A semi-structured and pre-tested interview schedule in local vernacular language was used for interviewing the study subjects. Each subject was interviewed separately and a separate room was made available by the principal of the school. The confidentiality of each student was maintained. Approval was obtained from Institutional Ethical Board of Pt. B D Sharma PGIMS, Rohtak. Data was analyzed and Chi square test was applied.

OBSERVATIONS

Table I: Age at initiation of premarital sexual activity

(n=337)

Age at initiation	Subjects	Percentage
14 Years	80	23.74
15 Years	174	51.63
≥16 Years	83	24.63
Total	337	100.00

Mean age = 14.95 years.

In the study, the prevalence of premarital sexual activity in adolescents was found to be 33.7% (337/1000) i.e. nearly one third of subjects indulged in premarital sexual activity. Surprisingly, adolescents of age group 14-15 years were maximally (75.37%) involved in sexual activity and 24.63% subjects were started sexual activity in the age group 16 years and above and mean age of initiating sexual activity was 14.95 years (Table-I).

Table II: Usage of condom at the time of initiation of sexual activity

(n=337)

Age	Used condom	%age	Not used condom	%age
14 Years*	0	0.00	80	23.74
15 Years*	24	7.12	150	44.51
≥16 Years	54	16.02	29	8.61
Total	78	23.15	259	76.85

*Row 1 and 2 were combined for calculating chi square test, P value= 0.001

Table II shows that three fourth (75.37%) of subjects age group 14-15 years were maximally involved in sexual activity and only 7.12% had used condom during sexual activity. None of adolescent of age14 years used condom at the time of initiation of sexual activity. Only 16.02% of adolescents 16 years or more used condom and the difference between age wise and usage of condom at the time of initiation of sexual activity was statistically highly significant (p value =0.001).

Table III: Indulgence in sexual activity as per adolescents partner's status

n=337)

Sr. No.		Partner's status	Numbers Percentages
1	Single	248	73.59
2	Multiple non professional*	85	25.22
3	Multiple professional*	9	2.67
*subjects had multiple responses			
Indulgence in sexual activity as per their relationship with the partner (n=337)			
Sr. No.	**Relationship with partner***	**Numbers**	**Percentages**
2	Friend	165	48.96
3	Neighbour	148	43.92
4	Relative	27	8.01
5	Others	16	4.75
Places where sexual activity is performed by adolescents (n=337)			
Sr. No.	**Place of sexual activity***	**Number**	**Percentage**
1	Home	201	59.64
2	Fields	95	28.19
3	Others	42	12.46

*subjects had multiple responses,

The study enquired from subjects about indulgence in sexual activity as their partner's status and found out that majority (73.59%) adolescents had single partner and one fourth adolescents indulged in sexual activity with multiple but non professional partners Whereas, 2.67% adolescents had sex with multiple professional partners. The study also tried to found out sexual activity as per their relationship with the partner and reported that nearly half of adolescents (48.9%) who indulged in sexual activity, the partners were their friend and 43.92% subject's partners were neighbours. Surprisingly, 8% of subjects had sex with their relatives. The study also noticed that majority (59.64%) of adolescents had performed sexual activity at home while 28% subjects used fields for sexual activity while 12 % adolescents performed sex at places other than home and fieldsi.e hotel, lake, *jangal*(forest), *kothri, rajbaha*(dry canal) etc. (Table-III)

DISCUSSION

Adolescents have insufficient information and knowledge about reproductive issues which mainly come from friends/peer groups or print/electronic media. Factors like age, family environment and peer groups of adolescents are important in shaping their sexual attitude and practices. Influence either positive or negative from peer groups plays a significant role in sexual attitude and practices in this vulnerable age. The study found that 33.7%adolescents had indulged in premarital sexual activity. Even the younger adolescents 14 years(23.74%) had indulged in sexual activity followed by adolescents of 15 yrs of age (51.63%) than adolescents of more than 16 years of age (24.63%). The mean age of initiating sexual activity was 14.95 years. This shows that more adolescents are indulging in sexually activity and often take the advantage of no direct supervision and guidance by parents especially in rural areas. ICMR, New Delhi[11]reported similar findings that the range of sexual intercourse varied from 2.9% among urban girls to 28.8% among rural boys in Rajasthan, and 1.6% among urban girls to 14.4% among urban boys in Delhi. There is wide variation in adolescents regarding premarital sexual intercourse. Many international studies revealed the percentage of premarital sex among adolescent males: 24 to 75% in Asia, 44 to 66% in Latin America, 45 to 73% in sub-Saharan Africa, and 80% in some developed countries[12, 13]. In developed countries, there is higher prevalence of adolescent males who indulge in premarital sex as sex is accepted in their culture but in Indian setup sex is a taboo.

The National Behavioural Surveillance Survey[14] reported in Andhra Pradesh that more than 35% respondents aged less than 19 years have indulged in casual sex. A study conducted by Pachauri S et al.[15]in South and South East Asian countries, namely, Bangladesh, India, Nepal, Pakistan, Sri Lanka, Indonesia, Thailand, Philippines and Vietnam revealed that in India, 20-30% adolescent males and 10% adolescent females were sexually active before marriage, and 38% unmarried males and 6% unmarried females were sexually active by age 18. About 15% young men and 2% young women reported sexual experience in Vietnam, and 20% young men and 6% young women reported experience in Indonesia. Most of the studies conducted in urban areas depicted lower prevalence of premarital sexual activity whereas studies conducted in rural areas had similar findings as of the present study. Higher prevalence of premarital sexual activity in rural area can be because of the fact that there are more availability of place and opportunity. As fields are freely available and when elders are working in fields, subject's home is available for such activity.

None of adolescent aged (14years) had used condom age who indulged in sexual activity. Only 7% adolescents (15 years) and 16% adolescents (e" 16 years) had used condom. The usage of condom is very low as depicted from the above figures. The National Behavioural Surveillance Survey [14]conducted in the age group of 15-24 years reported that around 52% respondents used condoms in the last casual sex, while only 34% used condoms with all casual partners in last one year. This is not comparable to the present study as the age group is different (14 to 18 years in the present study). As most of the students are not informed about the contraception so the usage is very low. Moreover contraception is a social stigma and in rural areas still people have not accepted it. In this age group people don't want them to know such things. In the present study investigator faced resistance from school teachers to not to conduct such a study in their school but after counseling them he could manage to interview the students. The present study reported that 73% subjects had sex with one regular partner whereas 25% adolescents had sex with multiple non professional

partners. Another astonishing finding was that 2.67% adolescents had sex with multiple professional partners.

Our study shows that these adolescents are most vulnerable group for acquiring STDs and RTIs. Also the low usage of condom during sexual activity, these adolescent are at great risk of contracting sexually transmitted diseases and STI. Gupta N et al.[16] reported that only 12.9% rural adolescents knew that AIDS spread through relations with multiple sex partners and 30.4% respondents opined that one should limit oneself to one partner and it can be concluded that knowledge regarding spread of infection through multiple sex partners was very low. In the present study, nearly (49%) adolescents partner was their friend, 43% and 8% adolescents had neighbour & relatives respectively. However, 5% adolescents who had sex, the partner was either commercial sex workers or someone known to their friends. This is fact that the friends or neighbours are equally at risk of contracting infections through unprotected sex. Sathe and Sathe[17] concluded that 13.9% adolescents indulging in sex with CSWs.A study on sexuality of adolescent girls and boys in underprivileged groups in Bombay by Bhende AA[18] reported that boys generally went far away to have sex with prostitutes.

In this study 59% of adolescents had performed sexual activity at home, 28% used fields for sexual activity while 12 % performed sex at places other than home and fields. Others places include hotel, lake, *jangal*(forest), *kothri, rajbaha* (canal),*batora*(place to keep cow dung cakes). In villages when elders are at work in fields, home is the place which is freely available to them. So, home is most common and safe place used by the adolescents. Use of such varied places for sexual activity indicates that adolescents could manage to indulge in sexual activity despite presence of cultural restriction imposed by the elders in the family. The study shows the fact that sex is happening in their families and they are needed to teach about safe sex before they get infected with sexually transmitted diseases. The study also suggests that parent connections and supervision on their children may be an important factor protecting from unsafe sexual relations. With the rising trends of STDs, sex education has become the necessity at the school level and home.

Strengths and limitations: The present study not only revealed prevalence of premarital sex in rural adolescence but also tried to find out the indulgence in sexual activity as adolescents partner's status and place of sex. One of the limitations was that the study cannot rule out the underreporting of pre-marital sex in adolescents and the study focused only on the male adolescents so there is need to explore the same in adolescent girls also.

Conclusion and Recommendations

The study concludes that a handful of adolescent are involved in premarital sexual activity and knowledge of adolescents regarding use of condom during sexual intercourse is meager. As usage of condom during sexual intercourse is also very low, hence they are at increased risk of contracting sexually transmitted infections. Early onset of sexual activity in adolescents increases the risk of having RTIs/STIs especially the HIV. Hence, there is need to communicate or educate rural adolescents through their parents or health functionaries about sexual and reproductive health issues.

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Epidemiological Characteristics of Dengue Cases Reported in District Amritsar in Year 2015

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ABSTRACT

Introduction: Dengue virus is transmitted by female mosquitoes mainly, Aedes aegypti and Ae. Albopictus. It has rapidly spread in all regions of WHO in recent years.

Material and Method: Epidemiological data of confirmed cases of dengue treated in district Amritsar in year 2015 were collected; analyzed and valid conclusions were drawn.

Findings: There were 885 confirmed cases of dengue found in the year 2015. The mean time gap between date of admission and testing of cases was 5.97 ± 3.8 S. D. days. Maximum cases, 157 (73.4%) were found positive by NS-1 Ag.Maximum number of cases, 438 (49.5%) were adults of age 21 to 40 years (49.5%), there was no case below 2 years and minimum 4 (0.5%) have been found in age 2 to 5 years. Higher number of males, 591 (66.8%) and urban cases, 808 (91.3%) was found. The cases were reported from the months of August to December with peak in October.

Conclusion: The number of dengue cases, 885 reported in year 2015 was higher than 49 reported in year 2014. Higher percentage of male cases found might be due to the reason that the less number of the females come to the hospitals for seeking the treatment.Reporting of cases in months of August to December, with its peak in October resembles previous studies. Keeping the dengue spread in view, all prevention and control measures should be taken well before the onset of dengue season; and use of NICD Coolers should be promoted.

Keywords: *Dengue/DHF/DSS/NVBDCP/Aedes Aegypti/Aedes Albopictus/ Suspected Case/Confirmed Case.*

INTRODUCTION

Dengue virus belongs to family *Flaviviridae*, having four serotypes that spread by the bite of infected *Aedes* mosquitoes. It causes a wide spectrum of illness from mild asymptomatic illness to severe fatal dengue haemorrhagic fever/dengue shock syndrome (DHF/DSS).[1]It has rapidly spread in all regions of WHO in recent years. Dengue virus is transmitted by female mosquitoes mainly of the species *Aedes aegypti* and, to a lesser extent, *Ae. albopictus*. This mosquito also transmits chikungunya, yellow fever and Zika infection. Today, severe dengue affects most Asian and Latin American countries.

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Global burden of dengue

The actual numbers of dengue cases are underreported and many cases are misclassified. One recent estimate indicates 390 million dengue infections per year (95% credible interval 284–528 million), of which 96 million (67–136 million) manifest clinically (with any severity of disease).Another study, of the prevalence of dengue, estimates that 3.9 billion people, in 128 countries, are at risk of infection with dengue viruses.[2, 3]

Dengue cases and deaths in the India since 2010 have shown a cyclic (falling-rising) trends.Total number

of cases and deaths in India, in the years 2010 to 2016 is as follows: 2010 (28292 cases and 110 deaths), 2011 (18860 cases and 169 deaths), 2012 (50222 cases and 242 deaths), 2013 (75808 cases and 193 deaths), 2014 (40571 cases and 137 deaths),2015 (99913 cases and 220 deaths), 2016 (111880 and 227 deaths).In the state of Punjab the number of cases and deaths in the years 2010 to 2016 had also shown the cyclic trends. These are as follows: 2010 (4012 cases and 15 deaths), 2011(3921cases and 33 deaths), 2012 (770 cases and 9 deaths), 2013 (4117 cases and 25 deaths), 2014(472cases and 8 deaths), 2015 (14128 cases and 18 deaths),2016 (10475 cases and 11 deaths).[4]District Amritsar in year 2010 showed the reporting of 196 suspected cases and 1 death. All the cases reported were residing in the urban area only. Maximum number of cases was reported in the age group of 16 to 50 years and there was no case among infants. Higher number of cases in males was reported. Majority of cases 149 (76.02%) were reported in the months of October and November.[5] Study on trends of dengue cases in district Amritsar from the year 2009 to 2013 showed that confirmed cases of dengue found positive by Ig M Mac Elisa and NS-1 Ag Elisa Kits had been reported from the year 2009 to 2013. A rising trend of dengue was observed in these years except for the year 2012. No dengue case has been reported in infants. Maximum number of cases 161 (28.9%) have been reported in the age group 21-31 years. There were 215 (38.6%) female cases and 342 (61.4%) male cases. The difference of sex wise distribution was insignificant statistically. Out of the 557 cases 291(52.2%) were reported in October and 200 (35.9%) in November with the month wise difference highly significant statistically.[6]

The present study has been designed to studythe epidemiological characteristics of dengue cases reported in district Amritsar in year 2015

MATERIAL AND METHOD

Establishment of dengue wards: Separate dengue wards having beds covered with bed nets are established in health care institutions in districtto prevent the spread of dengue infection from the dengue patients to others.

II. Data Collection and analysis: The epidemiological data of the confirmed cases and deaths due to dengue were collected. The study population included patients having their serum samples found confirmed for dengue by IgM Mac Elisa or NS-1 Ag test done in Government Medical College, Amritsar during this period. Data collected were analyzed and the valid conclusions were drawn.[7]

FINDINGS

During the year 2015 there was the reporting of 885 confirmed cases of dengue in the district. Mean age of cases was 37.8 years ± 15.9. S.D. Mean time gap in the date of admission and testing of dengue blood samples was 6.0 days± 3.8 days S. D.

Results of test, age, sex, area, block and month wise distribution; time gap between admission and testing of dengue blood samples; and trends of dengue confirmed cases and the significance of these are shown in the following tables from No. 1 to 8.

Table 1. Test wise distribution

Test	No.	%
NS-1 Ag	578	65.3
IgM Mac ELISA	270	30.5
NS1Ag+IgM Mac ELISA'	37	4.2
Total	885	100.0

X^2 = 499.1 d. f. = 2 $p < 0.01$

Table 1 shows that maximum 578 (65.3%) confirmed cases of dengue were found positive by NS-1 Ag test. Only 37 (4.2%) were found positive by both NS1Ag+IgM Mac ELISA.Test wise difference found was highly significant statistically.

Table 2. Age wise distribution

Age in years	No.	%
2-5 yr	4	0.5
6-10 yr	31	3.5
11-20 yr	131	14.8
21-30 yr	253	28.6
31-40 yr	185	20.9
41-50 yr	129	14.6
> 50 yr	152	17.2
Total	885	100.0

X^2 = 349.5 d. f. = 6 $P < 0.01$

Table 2 shows the agewise distributionof confirmed cases of dengue. There was no confirmed case of dengue below the age of 2 years and 4(0.5%) cases in 2 to 5 years of age. Maximum number of cases 253 (28.6%) had been found in 21 to 30 years age group.Age wise difference found was highly significant statistically.

Table 3. Sex wise distribution

Sex	No.	%
Male	591	66.8
Female	294	33.2
Total	885	100.0

X^2 = 99.7 d. f. = 1 $p < 0.01$

Table 3 shows the sexwise distribution of confirmed cases of dengue. Higher number of cases 591(66.8%) of males had been found and the sexwise difference found was highly significant statistically.

Table 4. Area wise distribution

Area	No.	%
Urban	808	91.3
Rural	77	8.7
Total	885	100.0

X^2 = 603.8 d. f. = 1 $p < 0.01$

Table 4 shows the areawise distributionof confirmed cases of dengue. Most of the confirmed cases of dengue808(91.3%) were reported from the urban urea that had shown that dengue is predominantly an urban disease and the areawise difference found was highly significant statistically.

Table 5. Rural block wise distribution

Rural block	No.	%
Baba Bakala	14	18.2
Lopoke	13	16.9
Manawala	8	10.4
Ramdas	13	16.9
Tarsika	2	2.6
Threawal	5	6.5
Verka	22	28.6
Total	77	100.0

X^2 = 24.0 d. f. = 6 $p < 0.01$

Table 5 shows the rural block wise distribution of confirmed cases of dengue.There are 7 rural blocks in district Amritsar. Highest number 22 (28.6%) of cases were reported from the Verka block. This was followed by 14 (18.2%) from block Baba Bakala and 13 (16.9%) from each block Lopoke and Ramdas. The minimum 2 (2.6%) cases were reported from block Tarsika.Rural areawise difference found was highly significant statistically.

Table 6. Month wise distribution

Month	No.	%
August	26	2.9
September	180	20.3
October	458	51.8
November	210	23.7
December	11	1.2
Total	885	100.0

X^2 = 736.8 d. f. = 4 $p < 0.01$

Table 6 shows the monthwise distribution of confirmed cases of dengue.It shows that all the cases were reported in the months from August to December. The peak of the cases had been observed in the month of October followed by November and September. The monthwise difference found was highly significant statistically.

Table 7. Time gap between admission and testing of dengue blood samples

No.	885
Mean time gap	5.97
Std. Deviation	3.84

Table 7 shows the Time gap between admission and testing of dengue blood samples. The mean time gap observed was 5.97 days and S. D. 3.84 days.

Table 8. Year wise trends of dengue cases

Year	2009	2010	2011	2012	2013	2014	2015	Total
No.	53	58	176	26	244	49	885	1491
%	3.5	3.9	11.8	1.7	16.4	3.3	59.7	100.0

X^2 = 2659.8 d. f. = 6 $p < 0.01$

Table 8 is showing the trends of dengue cases in district Amritsar from 2009 to 2015. From the year 2009 to 2011 a rising trend had been observed with the decline in the year 2012 followed by a rise in year in 2013, fall in 2014 and again a sharp rise in 2015.The yearwise difference of trends found was highly significant statistically.

CONCLUSION

Age wise distribution in district Amritsar resembles the previous study conducted there in years 2009 to 2013 which showed the highest No. of cases in 21 to 30 years age & most of the cases in adult age.[6]Sex wise distribution resembles previous studies i. e. higher % of male cases than the female cases.[5, 6]Area wise distribution has shown the trend of spread of dengue from the urban to rural areas, as 84 (9.5%) cases have been reported in year 2015, while in year 2008 district Amritsar reported all the 196 suspected cases of dengue from the urban areas. This study shows to lay emphasis on prevention and control of dengue in rural areas also.[5]Month wise distribution of dengue cases resembles previous studies showing spread of the disease in months of August to December, with its peak in October.[5,6]Cyclic trends of dengue cases have been observed from year 2009 to 2015 with highest No. in 2015.

Keeping in view the epidemiological features of dengue in year 2015 discussed above the following measures are recommended:Conduct campaigns for behavior change communication before onset of dengue season like personal protective measures, environmental sanitation, no water collections in the surroundings and vector control.Control measures like establishment and maintenance of separate dengue wards in hospitals, availability of equipments, materials and drugs etc. for early diagnosis and management of dengue cases should be taken well before the onset of dengue season.Vector control measures andpromotion of the use of NICD Desert Coolers should be taken.

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Antepartum Breathing Exercises and Predictors for Spontaneous Vaginal Delivery among Primigravid and Multigravid Women: A Randomized Controlled Trial

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ABSTRACT

Introduction: Childbirth is a life-transforming experience for a woman and her family. Women should be safe during labor and birth. Childbirth preparation is generally believed as an optimistic approach to train and prepare the antenatal women to be familiar of the childbirth process. An extensive variety of non-pharmacological techniques are readily available to women in labor[1]. **Objective:** To examine the predictive factors for spontaneous onset of labor among women who have practiced antepartum breathing exercises. **Materials and methods:** A Randomized Controlled Trial was carried out to determine the effectiveness of antepartum breathing exercises on 540 women (primigravid and multigravida women). **Results:** The study findings reveals that women who had spontaneous onset of labor had 1.93 odds [95% CI (1.302-2.862), p =.001] and full term gestation (39-40 weeks) at the time of delivery had 1.368 odds [95% CI(1.905-2.069), p = 0.013] of delivering through spontaneous vaginal delivery . **Conclusion:** Deep breathing and relaxation techniques were practised during labor and bearing down at the right time aids in the progress of labor.

Keywords: *Relaxation, Breathing, Antenatal women, outcome of labor, spontaneous vaginal delivery.*

INTRODUCTION

Childbirth preparation is generally believed as an optimistic approach to train and prepare the antenatal women to be familiar of the childbirth process. The traditional nature of antepartum education that focused on transferring information about childbirth is recently reformed in equipping women to recognize and reinforce their coping capacities and building self-confidence for childbirth[2]. Time immemorial, educators have engrossed on pain reduction and relaxation techniques that mitigate stress during the childbirth. An extensive variety of non-pharmacological techniques are readily available to women in labor[2].

The Lamaze method was developed by French obstetrician Ferdinand Lamaze in the early 1950s and is one of the most common child birth preparation programs (Lamaze International, 2009). Lamaze introduced the psycho-prophylactic method in 1956, which was grounded on relaxation, as a conditioned response to labor pain and comprised of several breathing techniques that ensure adequate oxygen supply and obstruct the transmission of pain indicators from the uterus to the brain[3]. The Philosophy of Lamaze Birth is sustained by an ever-expanding body of enquiry, and delivers direction for current preparation for birth[4]. It promotes, protects, and supports every mother's right to give birth, confidence in her ability, explores variety of ways to find comfort, supported by her family and other members of the health care team.

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The aim of Lamaze organization is to escalate women's confidence in their ability to give birth and endows to make skillful decisions to take up accountability for their wellbeing, and to trust their intrinsic ability to give birth. Lamaze facilitators simplifies the process by instructing women about their body physiology, ways to accomplish greater relaxation and control, and means to preserve this process as safe and healthy[6]. Lamaze focuses on the influence of conscious, controlled breathing and relaxation. Using conscious breathing helps to get rid of stress and increase body awareness and mindfulness, and is an excellent practice for labor [7].

Breathing is one of such non-pharmacological relaxation techniques readily available and can be extensively utilized during childbirth. Breathing patterns are a learned skill which aid in adjusting the intensity and duration of breathing so as to match the uterine contraction. Conscious breathing exercises can ease birthing mother's confidence and facilitate her to handle discomfort [8]. Breathing covers all dimensions of wellbeing and is a free tool that advances life at all stages, from birth till death [9]. Breathing exercise aims at better labor outcome by avoiding unnecessary intervention and preserving mother's autonomy and ultimately enabling women to attain self-control.

A study on effects of relaxation on emotional wellbeing during pregnancy exhibited beneficial effects on physical and psychological dimensions [10]. Studies on the impact of relaxation during pregnancy reveal various beneficial effects like reduction in preterm deliveries, longer gestational age, increase in birth weight, reduction in the rate of caserean deliveries and assisted vaginal deliveries [11].

Bastani & Hidarnia, 2006 also found a reduction in women's stress and anxiety experienced after adopting realxation techniques [11]. Relaxation in another study also helped in lowering cortisol levels, production of endorphins by activation of Parasympathietic Nervous System[12], enhances psychological wellbeing results in fewer obstetrical and postnatal complications [13].

Thus breathing exercises do not require sophisticated gadgets and machinery. It only requires timely information and education and also willingness to practice on the part of expectant mothers. Hence the present study aimed at determining the effectiveness of antepartum breathing exercises and factors responsible for spontaneous vaginal delivery among primigravid and multigravid women.

METHOD

A parallel group randomized controlled trial consisting of 280 primigravid women (140 each in experimental and control group) and 260 multigravid women (130 each in experimental and control group) was conducted at the outpatient department of obstetrics and gynecology unit of a secondary health care institution of Udupi District. The present study included antenatal primigravid and multigravid women who were above 36 weeks of gestation, singleton pregnancy, without any major pregnancy complications and willing to practice breathing exercises twice daily for minimum seven days. As the women met the inclusion criteria they were randomly allocated to the experimental and control group. Women in the experimental group received antepartum breathing exercise, and the women in control group received health talk on antepartum care. Both the groups were assessed at 36 weeks of gestation and then followed up concurrently at the time of delivery (during the active phase of the first stage of labor).

After seeking administrative permission and obtaining Institutional ethical committee clearance, the subject information sheet and the informed consent was taken by the women who were randomly selected. At the first appointment (36 weeks of gestation), baseline data was collected. Women who were enrolled in the experimental group were showed a video on antenatal breathing exercises for about 6 minutes and taught on one to one basis and were asked to practice these exercises daily twice a day and also continue during active phase of first stage of labor. Compliance was monitored by asking the mother to maintain a daily log along with daily fetal movement count (Sadovsky method as advised by obstetrician) and followed up during weekly visits. All the women were followed up in the labor room during the active stage of first stage of labor. The outcome of labor was recorded by using structured observational record on outcome of labor. The data was collected and analysed using SPSS (Statistical Package for Social Sciences) version 17.

RESULTS

The data was collected from 280 primigravid women (140 from experimental and 140 were from control

group) and 260 multigravid women (130 from experimental and 130 multigravid women from control group)

Table 1: Mean and standard deviation comparison of biological characteristics of primigravid and multigravid women at baseline in experiemtal and control group N= 540

Variables	Primigravid women		Multigravid women	
	Experiemtal (n=140)	Control (n=140)	Experiemtal (n=130)	Control (n=130)
	Mean SD	Mean SD	Mean SD	Mean SD
Mean Age (in years)	26.51 ± 2.883	26.75± 3.595	29.62±3.316	29.9 ± 3.562
Period of gestation at enrolment.	36.76± 0.830	36.83± 0.873	36.46±1.289	36.61±979
Mean Hb (mg/dl)	12.07± 1.080	13.00± 0.094	11.68±1.024	11.62±1.081
Mean weight gain (in kg)	10.85± 3.776	11.28± 3.683	9.31±3.350	8.86±3.142
Mean weight gain after 36 weeks (in kg)	1.3(1.1)	1.4(1.04)	1.4(0.95)	1.2(0.72)

The table 1 reports that the mean age of women in the experimental group was 26.51 (SD ±2.883) years, and that of control group was 26.75 (SD±3.595) years. The mean period of gestation at which primigravid women were recruited/ enroled for the study in the experimental group was 36.76 (SD±0.830) weeks, and that of control group was 36.83 (SD±0.873) weeks. The mean weight gain was 10.85 (SD±3.776) kg and 11.28 (SD±3.683) kg in experimental and control group respectively.

The mean age of multigravid women in the experimental group was (M= 29.62, SD±3.316) years and that of control group was (M=29.9, SD ± 3.562) years. The mean period of gestation in weeks at which multigravid women were recruited/ enroled for the study in the experimental group was 36.46±1.289, and that of control group was 36.61±0.979 weeks. The mean hemoglobin of women in experimental and control group was 11.68 (SD±1.024) and 11.62 (SD±1.081) mg/dl. The mean weight gain throughout pregnancy in both the groups was normally distributed 9.31 (SD±3.350) kg and 8.86 (SD±3.142) kg in experimental and control group respectively.

Table 2: Adjusted odds ratio and 95% confidence interval of reporting predictive factors of spontaneous vaginal delivery in the experimental and control group after adjusting for parity. N=515

Variable	Experimental Group (*n*=267)		Control group (*n*=248)		OR (95% CI)	df	p value
	f	%	f	%			
Onset of labor							
Spontaneous	205	77	160	65	1.93	1	.001
Non spontaneous	61	23	88	35	(1.302-2.862)		
Birth weight							
≥2500 grams	256	95	229	92	1.389	1	.365
<2500 grams	11	05	92	08	(0.682-2.833)		
Period of Gestation							
39^{+1}-40^{+6} weeks	219	82	204	82	1.368	1	.013
37^{+1}-38^{+6} weeks	48	18	44	18	(1.905-2.069)		
Weight gain during pregnancy							
≥ 12 kg	81	30	85	34	0.933	1	.716
< 12 kg	186	70	163	66	(0.640-1.360)		

The data in table 2 found few factors predictive for spontaneous vaginal delivery. Women in the experimental group who had spontaneous onset of labor had 1.93 odds [95% CI (1.302-2.862), p =.001] of having spontaneous vaginal delivery than the control group, also women whose period of gestation was 39-40 weeks at the time of delivery had 1.368 odds [95% CI(1.905-2.069), p = 0.013] of delivering through spontaneous vaginal delivery than the control group.

DISCUSSION

The mean period of gestation at which primigravid women were recruited/ enrolled for the study in the experimental group was 36.76 (SD±0.830) weeks, and that of control group was 36.83 (SD±0.873) weeks and was 36.76 (SD±0.830) weeks, and 36.83 (SD±0.873) weeks.in the control group of multigraid women. This finding was similar to mean period of gestation of 37.8±1.2 weeks in the experimental group and 37.5±1.2 weeks in the control group[15]. The mean gestational age in a trial conducted by Hjelmstedt et al., (2010) was 38.65±0.91 in the massage group as compared to 39.07±0.83 weeks in control group[16].

The present study reports the mean weight gain of primigravid women throughout pregnancy was 10.85 (SD±3.776) kg and 11.28 (SD±3.683) kg in experimental and standard care group respectively. This result is consistent with the findings of the study conducted by Narendran et al., 2005 who also reports that weight gain in the intervention group who practised an integrated approach to yoga therapy was 12.35 kg calculated from the first trimester to last trimester and in the standard care group was 12.03 kg [17]. Another supporting study revealed that total weight gain during pregnancy (p <.001), discomfort during childbirth (p <.001), postnatal distress (p <.001) and birth weight (p <.001) was significantly different in the experimental group who practiced Qi breathing during pregnancy[18]. A supervised exercise of light to moderate intensity can be used to prevent excessive gestational weight gain, especially in healthy weight women[19].The prospective study conducted in India (Narendran et al., 2005) reported that interventional group (IAYT) had a statistically significant increase in mean gestational age at delivery, ie., exercise group 38 weeks and control group 37 weeks p =.10[17]. Also the period of gestation at delivery of women who underwent perineal massage was 39.3±1.3 weeks and 38.9±1.5weeks in the control group [20]. This supports the present study findings, where the mean gestational age of primigravid and multigravid women in the intervention group was 39 weeks.

The findings of the present study revealed that women in the experimental group who spontaneous onset of labor had 1.93 odds 95% CI (1.302-2.862) of having spontaneous vaginal delivery. The study by Voldner et al., 2009 supports the present findings that parity [OR 3.5, 95%CI (1.7-7.2), p <.01], mothers age [OR:2.6, 95% CI (1.3-5.3), p < .01], newborns weight ≥ 4,200 g [OR 3.7, 95% CI (1.7-8.1), p <.01], and labor augmentation [OR 4.8, 95% CI (2.6-9.1), p <.01] were predictive factors for caesarean deliveries[21]. A systematic review also supports the fidings and reports that relaxation therapies reports in increased birth weight [MD 285.00 g; 95% CI (76.94 to 493.06)] with fewer caesarean deliveries [RR 1.52; 95% CI (1.13 to 2.04)], [RR 0.38; 95% CI (0.19 to 0.78)] where more number of women have spontaneous vaginal delivery[22].

CONCLUSION

The study provides sufficient evidence that practice of breathing exercise taught during the antenatal period and performed during labor aids in the progress of labor. The combination of the evidence-based practice framework with an active-learning approach supports the development of an educational intervention that is intended to trigger the change of practice and meet the learning needs of labor and delivery.

Conflict of Interest: Nil

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Ethical Clearence: Ethical clearance for the study was taken from the Institutional Ethics Committee. (IEC 212/ 2012)

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An Increasing Health Concern in Women- A Cross Sectional Study

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ABSTRACT

Introduction: Anxiety is the leading cause of disability and a concern to all. Factors triggering anxiety disorders, are stress, physical conditions, genetic background and hormonal imbalances. Women are affected twice than men. The present study aims to determine the prevalence and correlates of Anxiety among women of reproductive age group.

Aim and Objective: To determine the prevalence and correlates of Anxiety, among women of reproductive age group in central India

Method: The present study is a Cross sectional study , conducted in field practice area of Urban Health Training Centre,(UHTC), of Department of Community Medicine, MGIMS, Sewagram.Systematic Random Sampling was done and Becks Anxiety Inventory and self prepared questionnaire was used to collect information from 370 reproductive age group women.

Results: The present research shows, the prevalence of anxiety in reproductive age group women is 31.4% and Anxiety is significantly associated, with occupation, marital status, not getting kind of family support in illness, and presence of vaginal discharge.

Discussion: There are wide study differences in the prevalence and correlates of anxiety, which may be due to different methodologies used in the studies and socio demographic and cultural variations.

Conclusion: This research revealed ,that the prevalence of Anxiety in reproductive age group is considerably high, which necessitates, highly women focused, preventive, initiatives, along withearly diagnosis and management. Most of the correlates found in the study are modifiable which can help to decrease women's anxiety.

Keywords: *Anxiety, Reproductive age Group Women, Prevalence*

INTRODUCTION

Health is a "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".[1] The ability to respond to diverse experiences of life with flexibility and a sense of purpose and a state of balance between a person and his surrounding world, and harmony between oneself and others, is achieved only with a good mental health [2]. Mental disorders are universal and no group is immune to them.[3] Out of all the mental disorders, Anxiety and depression, are more commonly found in the community and primary care settings and they have a significant impact on the well-being of a person, leading to severe disability, further contributing as a major burden on health care delivery systems.[4] One out of every four persons, will suffer with an anxiety disorder during their life. Women are at increased risk for anxiety disorders, and developmental, societal, and reproductive factors are believed to contribute to the preponderance of this vulnerability. As woman's reproductive life is characterized by marked fluctuations in levels of oestrogen and progesterone, which have the potential to modulate anxiety. Inspite of the huge morbidity caused by anxiety, research in this area is very poor and so, very little data is available, regarding the prevalence of anxiety, sex difference variation, its

determinants. This has further lead to weak health policies, programmes regarding prevention of anxiety in women.[5] This present study was planned in this direction, with the aim to determine the prevalence and correlates of Anxiety, among women of reproductive age group.

METHODOLOGY

Study Settings - The present study has been conducted in field practice area of Urban Health Training Centre,(UHTC), which is one of the Community Health Centre, of Department of Community Medicine, MGIMS, Sewagram which is situated 10 km away from the mother institute. This area covered five zones, with a total population of 5100. The main language spoken in this area was Marathi. The study was carried out after obtaining permission from Institutional Ethical Committee.

Study Design : The present study is a Cross sectional Study, carried out, over a period of 1 year (January 2015 – December 2015.) among women in reproductive age group,residing in the UHTC field area. Women who did not give consent for participation in study, diagnosed cases of severe mental illnesses, pregnant women, and women in Post partumperiod were excluded from the study.

Sampling : Considering prevalence of Anxiety to be 6.6 % [6] and by using Open EPI software, sample size was calculated to be 370 women of reproductive age group. (at confidence interval of 95 %, permissible error 2.5%, power 80%). Systematic Random Sampling was done to select the study sample in the households.

Data collection: All the women who consented to participate, were interviewed face-to-face and two tools were used to collect data . A self prepared and pre tested, brief socio-demographic questionnaire was prepared to collect data regarding women's socio demographic ,gynaecological, gender disadvantage factors. Beck Anxiety Inventory (BAI)[7,8] was used to screen anxiety in women. Psychometric Properties - The BAI is psychometrically sound. Internal consistency (Cronbach's alpha) ranges from 0.92 to 0.94 for adults and test-retest (one week interval) reliability is 0.75. Data collected through questionnaires, was entered in MS Excel spread sheet and after cleaning, it was transferred to Epi-Info version7 for further analysis.

FINDINGS

Table.1. Distribution of Sociodemographic variables

Sociodemographic variables	Frequencyn=370 (%)
Age (yrs)	
<20	32 (8.6)
20-29	111(30.0)
30-39	123(33.2)
40-49	104(28.2)
Education	
Illiterate	8 (2.2)
Primary	30(8.1)
Secondary	256(69.0)
Graduate	66(18.0)
Post Graduate	10(2.7)
Occupation	
Housewife	163 (44.0)
Student	54(14.6)
Service	40(11.0)
Labourer	45(12.0)
Business	68(18.4)
Marital status	
Unmarried	55(15.0)
Married	291(79.0)
Widowed	17(5.0)
Separated	7(1.0)
Family Type	
Nuclear	248(67.0)
Joint	122(33.0)
Socio economic status	
APL	137 (37.1)
BPL	220(59.4)
No Cards	13(3.5)

Table 1 shows that, out of the total 370 study participants, 123(33.2%) participants belonged to 30-39 yrs. age group. 256 (69.0%) participants were educated upto secondary school. 8 (2.2 %) were illiterate . 291 (79.0%) were married, 55(15.0%) were unmarried, 17(5.0 %) were widowed, and 7(1.0 %) were separated. Out of the total 370 women, 248 (67.0 %) were living in nuclear families and 220 (59.4%) were living under Below poverty line (BPL). The present research shows, that the prevalence of Anxiety in reproductive age group women is 31.4 %.The present study has also revealed that, there is 100% Counselling and Treatment gap in women having Anxiety.

Determinants

Table 2. Association of variables with Anxiety in reproductive age group women

Variable		Frequency		Unadjusted OR (95% CI)	P value
		Anxiety Present	Anxiety Absent		
1. Sociodemographic variables					
Age(N=370)	<=29 yrs	41	102	0.815(0.516 - 1.285)	0.378
	>29 yrs	75	152	1#	
Education(N=370)	< = Secondary school	93	201	1.066(0.617 - 1.844)	0.819
	> Secondary school	23	53	1#	
Occupation(N=370)	Non Working (housewives,)	67	114	1.679 (1.078- 2.617)	0.022
	Working	49	140	1#	
Marital Status(N=370)	Married	108	207	3.065 (1.398 - 6.720)	0.005
	Unmarried	8	47	1#	
2. Gender disadvantage variables					
Age at marriage(N=315)	<=23 yrs	88	170	0.765(0.424 - 1.378)	0.372
	>23yrs	23	34	1#	
Type of Abuse(N=315)	Abuse(verbal, physical,sexual)	106	202	0.210(0.040 -1.100)	0.064
	No abuse	5	2	1#	
Women's getting Support in Illness(N=370)	Absent	55	79	1.997(1.272 - 3.135)	0.003
	Present	61	175	1#	
3. Gynaecological variables					
Abortion(N=370)	Present	26	37	1.694(0.969 -2.962)	0.064
	Absent	90	217	1#	
Infertility(N=315)	Present	3	4	1.389(0.305 - 6.319)	0.671
	Absent	108	200	1#	
Menopause(N=370)	Present	17	30	1.282(0.679 -2.433)	0.446
	Absent	99	224	1#	
Vaginal discharge(N=370)	Present	28	34	2.058(1.178 – 3.599	0.011
	Absent	88	220	1#	

The above table No . 2 shows that the odds of having anxiety, in non-working women is 1.679 times higher than those who are working, suggesting association of anxiety with non working women. The odds of having anxiety, in married women is 3.065times higher than those who are unmarried, suggesting association of anxiety with married women. The odds of having anxiety, in women who are not getting family support in illness is 1.997 times higher than those who are getting family support in illness, suggesting anxiety is associated with womenwho are not getting family support in illness. The odds of having anxiety, in women who complained of vaginal discharge is 2.058times higher than those who did not complaint of vaginal discharge, suggesting anxiety is associated with women with vaginal discharge.

Thus the above Table No . 2 depicts that a significant relationship exists between Anxiety in reproductive age group women and Occupation, Marital status, not getting support in illness, Complaint of vaginal discharge, on performing univariate analysis.

CONCLUSIONS

The study has shown that the prevalence of anxiety in women is very high. This magnitude can be reduced by effective women focused preventive strategies,along with early diagnosis and management of Anxiety, at primary settings by developing universal, simple standard diagnostic tools (scales) and uniform treatment guidelines, for all health staff at primary care level. This will help, to improve, women's mental

health, and will reduce their sufferings, ultimately having a positive effect on the families, society, and the Nation.

Conflict of Interest: There is no conflict of interest

Source of Funding: Self

Ethical Clearance: Ethical clearance was obtained from the Institutional Ethical Committee of MGIMS .Sevagram

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Knowledge and Awareness about Tuberculosis in a Tertiary Care Hospital of North India

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ABSTRACT

Background: Tuberculosis (TB)is the major public health problem and important cause of death in developing countries like India. Awareness about the disease in general population is less, leading to increased morbidity. Focus of tuberculosis control program in India has now shifted to improve the knowledge, understanding symptoms, misconceptions, transmission and also to influence healthcare seeking behaviour among both TB patients and the general public. The present study focuses on the awareness about TB in general population and its correlation with literacy.

Material and method: The present study was a questionnaire based study conducted in the pulmonary medicine department of a tertiary care hospital. The questionnaire focussed on the awareness about the disease as well as its preventive and curative aspects.

Results: It was seen in the present study that awareness regarding the disease and treatment was there in the population however preventive aspect was lacking. Literate persons were more aware about the disease as compared to illiterate population.

Keywords: *Tuberculosis, Awareness, Literacy*

INTRODUCTION

Tuberculosis is a major public health problem, and is second leading cause of death due to a single infectious agent in the world after human immunodeficiency virus (HIV) [1] and is one of the leading cause of loss of healthy life years in the productive age group.[2,3] TB stands third among the leading cause of adult mortality after HIV and ischemic heart disease in low and middleincome countries.[4]

India is the country with the highest burden of TB. The World Health Organisation (WHO) statistics for 2014 give an estimated figure of 2.2 million cases of TB for India out of a global incidence of 9 million.

The estimated TB prevalence for 2014 is 2.5 million. It is estimated that about 40% of the Indian population is infected with TB bacteria, the vast majority of whom have latent rather than active TB.[5]

The greatest burden of tuberculosis incidence and mortality in India is in adults aged 15-16 years however higher prevalence is seen in persons aged 60 years and above, while lowest in childhood. Thus TB stands as a barrier to socioeconomic development.[6]

Revised National Tuberculosis Control Program (RNTCP) based on Directly Observed Therapy Short-course (DOTS) strategy was started as pilot in Oct 1993, launched in 1997, and full nationwide coverage was achieved on 24th March 2006. The misconceptions and stigma related to disease has lead to delayed detection

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and improper treatment of the same. The WHO has recommended an Advocacy, Communication and Social Mobilization (ACSM) framework for national TB Programs. [3] ACSM activities are seen as an important and necessary step to elicit greater awareness and engagement in TB control in order to achieve global TB targets.[7,8]

TB control program in India has recognized the importance of providing information, education and communication (IEC) to improve the knowledge about TB, understanding about symptoms, misconceptions about TB transmission and also to influence change in healthcare seeking behaviour among both TB patients and the general public.Since 2001, a sustained intensified IEC campaign is being done as an integral component of RNTCP and a STOP-TB initiative has adopted the strategy of ACSM to support country TB control programs.[8]

Knowledge about the common symptoms of TB and availability of free diagnosis and treatment facility for TB will help in improving the treatment seeking behaviour. This study was carried out to assess awareness regarding symptoms, causes, spread, and treatment of TB in a tertiary care centre of western Uttar Pradesh.

MATERIAL AND METHOD

The present study was an observational, descriptive, cross-sectional study conducted in the out-patient department (OPD) of Pulmonary Medicine of a tertiary care centre of north India. The study population consisted of the patient as well as attendants of the patients attending the OPD. A pre-designed questionnaire was given to all the participants after an informed consent. Study variables included in the questionnaire were age, sex, religion, residence, education, type of family, different aspects of TB knowledge i.e. heard of TB, cause and mode of transmission, symptoms, prevention, curability, and place of treatment. A total of 143 patients and attendants were interviewed over a period of 3 months. The data collected from participants was tabulated, analyzed, and interpreted by Chi square test.

RESULTS

A total of 143 participants were interviewed during the period of three months of which 59.4% were males. Maximum participants were in the age group of 25-60 years, followed by 18-25 years.Majority of the participants were Hindus, comprising 91.6%, 37.8% were educated till higher secondary, and 63.6% were from urban background. The demographic characteristics are shown in table 1. The knowledge regarding tuberculosis, in the form of its symptoms, mode of spread, cause and source of knowledge is described in table 2. Awareness regarding prevention and treatment aspects including duration of treatment and free treatment, along with its hereditary nature, mother to child transmission is described in table 3. Table 4 describes about the difference of awareness between the literate and illiterate group. It was seen that awareness about the symptoms and treatment via DOTS was similar in both the groups however there was a statistically significant difference in other aspects of tuberculosis awareness as availability of free treatment, prevention, mode of transmission, effect of HIV and mother to child transmission.

DISCUSSION

Highest burden of tuberculosis in the world is seen in India.[9] Knowledge and awareness regarding various aspects of tuberculosis is the only tool to address this problem. Government of India has initiated an ACSM program on TB to empower patients and to make people understand when and where they should seek health care through improved knowledge, changed attitudes, and participation. The study conducted at our centre also reflects the impact of the government initiative as 93% of the study population has heard about tuberculosis, similar results has been shown by some other studies also.[5-8]In a study in China by Wang et al.[10] 99.20% of general population had heard about TB. The corresponding figures were 86.80% in Ethiopia by Mesfin et al. [11] 99.10% in Delhi by Sharma et al.,[12] and 93.20% in Bihar by Devey.[13] However, in few studies the percentage was quite low as in Tamil Nadu by Kar et al., only 56% of respondents had heard about TB[14] and in Punjab by Singh et al. this rate was 75.5%.[15] In our study, and in some other studies[15-17] also, there

was some wrong beliefs about cause of TB e.g. poor diet, malnutrition, smoking, alcohol, heredity, curse, pollution etc., which may affect the timely response of potential TB patients in the health facility. There were some wrong perceptions about modes of transmission e.g. eating together, sharing food and utensils, talking face-to-face etc. in our study and in some previous other studies,[16,17] and this indicates that there was a wide knowledge gap regarding TB among the public after 14 years of DOTS implementation. Most common symptom of tuberculosis in present study was cough (86%) followed by haemoptysis (83.2%) and fever (79%).The participants had multiple responses for the symptoms. Many studies from northern India and Nepal reported almost similar type of responses with major symptom being cough, haemoptysis and fever were the subsequent responses.Studies by Khalil et al. from Aligarh [17] reported 75.0, 47.8, and 31.85%, Matta et al. from Safdarjang hospital[18] reported 59.3, 50.6, and 11.3%, Yadav et al. [19]reported 45.20, 28.90, and 44%, Subramanian et al. from south India reported 66, 13, and 15% [20], and Singh et al. from Punjab reported 40, 65, and 42% respectively.[15]

Ninety one percent of the study population knew that TB was curable like studies done in other parts of India. In Rajasthan it was shown to be 90%, while Malhotra et al. [21]from Delhi showed percentage of 94.4% and Sharma et al. as 97%. Studies done outside India showed that probably awareness about curability was quite high in India as compared to other countries. In Serbia,[22] it was reported to be 86.60%, in Ethiopia,[11] 69.40%, and in China,[10] 73.00%. However, in Split, Croatia,[16] it was 94.80% similar to studies done in India.

Knowledge of tuberculosis can be assessed if the subject knows the cause, mode of spread and prevention. In the present study most of the participants told it to be an infection caused by an agent, however a majority of subjects told bad air and smoking as the cause of tuberculosis which itself demonstrates the ignorance about the disease. Coughing was considered to be main mode of transmission of the disease and covering of mouth being the most important measure for prevention of transmission. We did not considered treatment as a part of questionnaire as in other studies. However touch contact with the patient and living with patient were also considered to be the mode of transmission and age old practice of isolation of the patients for prevention of transmission was also considered reflecting the fear, apprehension, and stigma towards the disease.Regarding treatment most of the respondents considered DOTS as the effective mode of treatment however only few preferred local doctor for treatment. This signifies that the role of government in communicating the message of treatment though DOTS via. various media is successful. Malhotra,[21]Kar,[14] reported that major population was in favour of government facility for treatment of TB, however Sharma[12] reported that major participants preferred DOTS centre and hospitals. Study from Orrisashowed that demand for DOTS is increased as a result of improved mobilization of health workers[23].

A study by Sharma et al.[12] showed that 95.50% respondents told about treatment and 30.00% about cough hygiene. Another study by Malhotra [21]reported that treatment, covering mouth while coughing, and proper disposal of sputum were known to 73.70, 46.60, and 38.90% individuals, respectively.

Most of our respondents got the knowledge about tuberculosis through some medical personnel, however other sources such as mass media, friends relatives and other patients was quite less. It shows that knowledge dissemination is more through medical personnel i.e. hospitals and probably they are playing more active part in awareness about the disease, while mass media is not very effective. Other studies have demonstrated that interpersonal contact was the most important source of knowledge [13,19] few studies demonstrated the influence of mass media to be very less similar to our study but study by Malhotra [21] revealed a opposite picture.

It is assumed that literates are better informed about tuberculosis and were more aware about various aspects of TB as compared to illiterates, which was revealed clearly from our study. Different other studies also showed similar results.[12-14,19,16,17] This difference was clearly demonstrated and significant when they were asked about, curability, transmission, effect of HIV and free treatment. However both literates and illiterates were aware about symptoms of tuberculosis, DOTS and non-hereditary nature of the disease.The government agencies appear to be successful in making all the persons aware about the symptoms of tuberculosis and

DOTS which is evident from the present study. Awareness among illiterates is required to remove myths and misconceptions and to allay the social stigma attached with it to decrease transmission of tuberculosis.

Table 1: Demographic profile of the participants

Variables		Number	Percentage
Age	<18	10	7.0
	18-25	56	39.2
	25-60	72	50.4
	>60	5	3.4
Sex	Male	85	59.4
	Female	58	40.6
Location	Urban	91	63.6
	Rural	52	36.4
Education	Illiterate	54	37.8
	Literate	89	62.2

Table 2: Distribution of study population according to knowledge of tuberculosis

Variables		Number	Percentage
Heard of TB	Yes	133	93
	No	10	7
Cause	Bad air	70	49
	Polluted water	28	19.6
	Polluted food	18	12.6
	Smoking	65	45.5
Mode of spread	Contact with TB patient	60	42
	Coughing	94	65.7
	Living with TB patient	63	44.1
	Others	8	5.6
Source	Medical personnel	88	61.5
	Media	36	25.2
	Friend	21	14.7
	Other patient	23	16.1
Symptoms	Fever	113	79
	Cough	123	86
	Haemoptysis	119	83.2
	Weight loss	5	3.4
	Others	105	73.4

Table 3: Awareness regarding prevention and treatment

Variables		Number	Percentage
Prevention	Not sharing food	10	7
	Covering patient's mouth	133	93
	Use separate toilets	30	20.9
Curability	Yes	136	95.1
	No	7	4.9
Duration	Till the symptoms	22	15.4
	2 months	9	6.3
	4 months	1	0.7
	6 months	91	63.6
	As per doctor	40	28

Table 3: Awareness regarding prevention and treatment (Contd.)

Variables		Number	Percentage
Source of treatment	DOTS	132	92.3
	Local doctor	11	7.6
Mother to child transmission	Yes	7	4.9
	No	136	95.1
Free treatment	Yes	137	95.8
	No	6	4.2
Hereditary	Yes	78	54.5
	No	65	45.5
Effect of HIV	Yes	103	72
	No	40	28

Table 4:- Difference between the literate and illiterate groups

Awareness	Illiterate n= 54	Literate n=89	Total	Chi square test and p value
Symptoms				
Fever	42	71	113	0.94
Cough	42	76	118	0.34
Haemoptysis	41	74	115	0.4
Weight loss	41	69	110	0.98
Curable	47	89	136	0.002
Treatment				
DOTS	49	84	133	0.62
Local doctor	5	5	10	0.62
Mother to child transmission	7	0	7	0.002
Effect of HIV	37	23	60	0.0001
Transmission by coughing	23	71	94	0.0001
Prevention by covering patient's mouth	46	87	133	0.01
Free treatment	48	89	137	0.005
Hereditary	28	50	78	0.74

Conflict of Interest: Nil

Source of Funding: Self

Ethical Clearance: Yes

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Prevalence of Rotavirus Diarrhea in Children of Perak, Malaysia

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ABSTRACT

Acute diarrheal diseases are an important cause of morbidity and mortality in children, especially in developing countries. Among the viral etiological agents, Rotavirus is the leading cause of diarrhea in infants and young children. Globally, every year, rotavirus infection accounts for estimated 500,000 deaths. Rotavirus infection usually results in vomiting, diarrhea and fever. Dehydration and electrolyte imbalance are the common complications. A study was undertaken to determine the prevalence of rotavirus in children with diarrhea and without diarrhea in a rural area of Perak, Malaysia.

Rotavirus rapid test rota strip (BioConcept, Belgium) kit was used to detect rotavirus in stool specimens of children of less than five years old. A total of 158 single stool specimen from each case was tested for rotavirus. Of the 60 diarrheal cases, 19 (32%) stool specimens tested positive for rotavirus. In 60 rotavirus positive cases, 17 % had diarrhea with vomiting. Over all, of the 158 tested, 24 had taken vaccine to protect against rotavirus infection. The available two rotavirus vaccines proved to be safe and effective. Mortality and morbidity due to rotavirus infection could be reduced by vaccination. Rotavirus is an important cause of diarrhea in children of below 5 years, particularly in infants. The present study recorded the detection rate of 31.7% in children with diarrhea and 17.3% without diarrhea. A simple, rapid test is useful tool to detect Rotavirus from stool specimens of children especially in a rural area.

Keywords: *Rota Virus, Prevalence, Diarrhea, Gastroenteritis, Vaccination, Rapid Test, Stool Specimen*

INTRODUCTION

Acute diarrheal diseases are an important cause of morbidity and mortality in children, especially in developing countries. As acute diarrhea can be caused by different etiological agents that include bacteria like *Escherichia coli, Salmonella* sp, viruses like rotavirus, norovirus,adenovirus parasites like *Giardia intestinalis* as a single or by mixed pathogens[1]. In developed countries,*Campylobacter jejuni* is the most common organism that cause acute diarrhea in young children[2]. Viral gastroenteritis is the most frequent cause of acute gastroenteritis (AGE) of childhood. Studies conducted in different parts of globe clearly indicate role of rotavirus as a causative agent of acute gastroenteritis especially in children.Globally, estimated 500000 children die each year from vaccine-preventable rotavirus infections[3]. The symptoms include watery diarrhea, often with vomiting and fever. Rotavirus infection can lead to mild to severe diarrhea, dehydration, metabolic acidosis and electrolyte imbalance[4].Rotavirus is known to be the common causative agent of diarrhea in young children especially in infants[5,6]. Rotavirus infection poses a significant disease burden. Preventive measures such as proper hygiene should be emphasized. Introduction of vaccination against rotavirus into the national immunization program should be examined, as it would likely be a cost-effective investment [7].A community based cross-sectional, observational study was undertaken to determine the rotavirus prevalence in children with diarrhea and without diarrhea in a rural area of Perak, Malaysia.

MATERIAL AND METHOD

This was an observational cross section community based study in a rural area of Perak, Malaysia.In rural area villages chosen were Gerik, Lenggong, Kuala Kangsar, Larut, Parit Buntar, Bagan Serai, Bukit

Gantang, Padang Rengas, Sungai Siput, Tambun, Batu Gajah, Beruas, Parit, Pasir Salak, Langkap, Taiping, Kampung Manjoi..

A total of 158 children under the age of five years were screened for rotavirus. A single fresh stool specimen was collected from each case. The rapid test kit Rota-Strip (Coris Bioconcept,Belgium) was used. This test principle is based on membrane technology with colloidal gold particles and monoclonal antibodies directed against human rota virus. About 14 drops of buffer solution is taken into a tube and a loop containing the stool specimen was mixed. The entire mixture was homogenized to smooth suspension. The Rota-strip was inserted into tube. After 10 minutes strip was taken out. The appearance of red line at test and control site indicates positive result and red line only at control site indicates negative result. The quality control of test was done by using control solution. The children younger than five years were included in this study.The sampling method that was chosen is convenient sampling.

FINDINGS

A total of 158 children were screened for rotavirus of which 60 were with acute diarrhea. Of these 60 cases of diarrhea, 19 (31.7%) were positive for rotavirus test. Out of 34 male cases, 8 were positive for rotavirus. In 26 female cases screened 11 were positive. Age wise and gender wise distribution of cases are shown in table 1. Less than one year age infants constituted 40 cases with 40% positive for rotavirus and 15 cases in less than 5 months age.There was significant association between the children age group and rotavirus infection (p-value of 0.021). The prevalence of diarrhea and rotavirus as a single causative agent was related to each other, with the p-value of 0.037. Rotavirus vaccination was found to affect the children's chances of rotavirus infection, with a significant p-value of 0.044. Of the 98 non-diarrheal children, 17 were positive for rotavirus with a detection rate of 17%. None of the children with diarrhea had rotavirus vaccination. Of the 19 cases of rotavirus positive diarrhea 6 cases (32%) had fever, vomiting and 10 (53%) had vomiting.

Table 1. Prevalence of Rotavirus in Diarrheal cases

Age Group	Female		Male		Total Diarrheal Cases	Total Rotavirus +ve
	No. Diarrheal Cases	Rotavirus +ve	No. Diarrheal Cases	Rotavirus +ve		
0-12 Months	16	9	24	7	40 (66.7%)	16 (84.2%)
13-24 Months	2	0	8	1	10 (16.7%)	1 (5.3%)
25-60 Months	8	2	2	0	10 (16.7%)	2 (10.5%)
Total	26	11	34	8	60 (100%)	19 (100%)

DISCUSSION

Table 2. Rotavirus prevalence in different places of world8-30

Number Tested	% Detection	Country	Reference
9678	20.3	Bangladesh	Afrad, et.al.,2013
201	18.9	Bolivia	McAtee et.al., 2015
149	8.7	Brazil	Luchs et.al., 2015
115	56.7	Bulgaria	Mladenova,et.al.,2015
767	34.3	China	Sai, et.al., 2014
197	39.1	Egypt	Shoeib, et.al., 2015
314	30%	Ethiopia	Ramos,et.al., 2015
1827	35.9	India	Mathew,et.al., 2014
100	30	Iran	Khoshdel,et.al.,2014
80	48.8	Iran	Shokrollahi, et.al., 2015
2381	20.1	Japan	Thongprachum, et.el., 2015
260	23	Kenya	Raini,et.al., 2015
545	57	Libya	Alkoshi, et.al., 2014
658	38	Malaysia	Loganathan, et.al., 2015

Table 2. Rotavirus prevalence in different places of world8-30 (Contd.)

Number Tested	% Detection	Country	Reference
167	16	Malaysia	Goh, et.al., 2010
393	22	Malaysia	Izzuddin, et.al., 2007
1362	24	Malaysia	Lee,et.al., 2003
1265	38.1	Malaysia	Hung,et.al., 2006
787	41.6	Mauritius	Pursem,et.al.,2014
223	28.3	Nigeria	Imade, et.al, 2015
1306	49.4	Pakistan	Alam, et.al., 2013
251	1.6	Poland	Wolak.,et.al., 2015
970	40.7	Saudi Arabia	Khalil, et.al., 2015
788	36.6	South Korea	Kin, et.al., 2014
688	30	Thailand	Chieochansin , et.al., 2015
279	23.3	Tunisia	Soltani,et.al., 2015
240	33.6	Turkey	Bozkurt et.al., 2015
5627	32.8	Uganda	Odiit, et.al., 2014

The prevalence rate of rotavirus varies from place to place and from time to time. A number of studies conducted in different parts of the world including both developed and developing countries clearly indicate rotavirus presence in diarrheal cases in infants and young children (table 2)[8-30].A study with overall enteropathogens detection rate of 45% showed that, rotavirus (30%) was the most common pathogen, followed by norovirus (12%) and adenovirus (5%)[31].

The first infection tends to be more severe with acute manifestation of diarrhea, vomiting and fever. Severe dehydration is one of the complications and necessitates hospitalization[32,33]. There was no hospitalization of any of the diarrheal cases for dehydration in the present study. No unusual symptoms were noticed in any of the rotavirus associated diarrhea. Other studies, portrayed similar results with symptoms of vomiting, and fever [34-37].

In the present study, 16 (40%) of the 40 diarrheal cases in less than 12 months age group was positive for rotavirus. Similar observation of higher detection rate was detected in infants of less than 24 months age[22,24,38]. In some studies age specific prevalence rate among children was not observed[23]. This age group infants are still dependent on their parents for their feeding and toilet needs. As there could be possible association between the hand washing practices and outcome of diarrhea, parents need to ensure that they wash their hands after each toilet usage, before eating and before preparing food for their children. Therefore, good hand hygiene plays an important role in reducing the number of diarrheal cases.

Our results revealed that rotavirus vaccine is effective as rotavirus was not detected in any of the diarrheal cases in children vaccinated with rotavirus vaccine. At present two effective vaccines RotaTeq (Merck) andRotarix (GSK Bio)against rotavirus infection are in use. There is a clear indication of reduced infant mortality rate in countries with Rotavirus vaccine in immunization schedule. Several studies reported that available both rota virus vaccines are safe, effective in reducing morbidity and mortality[39-41]andthere is no increased risk of intussusceptions[12,13].Unsafe drinking water, improper drainage system, low economic status, poor personal and public hygiene play important role in the spread of enteropathogens in community[42]. Children with malnutrition are more vulnerable because of lowered immunity.

CONCLUSION

Rotavirus is an important cause of diarrhea in children of below 5 years, particularly in infants. The present study recorded the detection rate of 31.7% in children with diarrhea and 17.3% without diarrhea. A simple, rapid test is useful tool to detect Rotavirus from stool specimens of children. There is a need to include available safe and effective vaccine in immunization schedule to control rotavirus gastroenteritis in children.

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Source of Funding: Self

Ethical Clearance: This study was given ethical clearance by University ethics committee

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Prevelance on the Occurance of Computer Vision Syndrome to VDT Operator in Bank Surabaya, Indonesia

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ABSTRACT

VDT operator is an operator who works using computer to increase their work performance. VDT operator in this case are Accountants, Bankers, Administrators, Engineers, and Secretaries. Several studies have shown an association between computer use and visual health symptoms in VDT users. The symptoms are such as eye fatigue, headache, dizzines, dry eye, blurred vision, double vision, neck pain, shoulder pain, and back pain, collectively referred to as computer vision syndrome.

This study aims to assess the prevalence of computer vision syndrome among VDT operators and to investigate the correlation between computer vision syndrome with work capacity and task demand. A cross- sectional study was conducted and the respondents were recruited by using a simple random sampling method. Population of this study were 78 people and sample taken were 40 respodents. Technique of data collection was based on questionnaire and eyes health examination of symptoms. To know the level of influence of each risk factor on the occurence of Computer Vision Syndrome at VDT operator then conducted with frequency distribution, and crosstab, then analyzed with the test of logistic regression.

Among the 40 VDT operators, 24 (60%) suffered CVS after working on computer. The results of logistic regression analysis showed that there is significant relation of work posture (p=0,030), break time among VDT users (p=0,007), and viewing distance (p=0,005). The odds of which is 5 times higher who work without ergonomics posture, 7 times higher on the operators break time among VDT use less than 4 minutes and 8 times higher among operators who look at the VDT less than 50 cm. The results of this study can be useful in preventing and reduce risk factor of computer vision syndrome in a workplace.

Keywords: *Indonesia, Visual Display Terminal Operator, Computer Vision Syndrome, Work Capacity of Operators, Factor of Task Demand*

INTRODUCTION

VDT operator is an operator who works using computer to increase their work performance. VDT operators in this case are Accountants, Bankers, Administrator, Engineers, Secretaries. Recent studies have shown that technology is associated with several health-related challenges. The health-related complaints range from visual, musculoskeletal and neural ailments which helth care providers of today have to deal with. A survey conducted by an optometrist showed that more than 10 million eye examinations performed annually in the United States for vision problems by the use of computers[1].

Physiologically, the human eye is not appropriate to stare at a computer screen. Eye works fine when used to view printed materials because of the characteristics of the characters are black with sharp angles give rise to a good contrast against the bright background. While characters on computer screens do not have the contrast or sharp corners as above, but lighter in the middle and decreases the angle . The characters are thus leading the eye to not be able to focus that keep eyes to look for a focus on one point referred to as resting point of the accomodation (RPA) and then trying to re-establish the focus on the computer screen[2].

In 200 professional workers who use computers report that 76.5% of respondents complained about the extra ocular disorders and 76% of respondents complained of ocular disorders. Most ocular complaint is a red eye by 40.7% whereas most complaints of extra ocular in a pain in the neck by 48,6 %[3].

Many individuals who work at computer experience eye-related discomfort and/ or visual problems. However based on current evidence it is unlikely that the use of computers causes permanent changes or damages the eyes or visual system.[4] Hence this study aimed to assess the prevalence of computer vision syndrome among VDT operators and to investigate the factors relating computer vision syndrome amd provide recommendations for preventing and reducing their development.

MATERIAL AND METHOD

The present study was a cross-sectional analysis done among VDT operator in Bank Surabaya. 40 VDT operator working in different section were selected by using a simple random sampling method. Inclussion criteria were as follows: the subject should be working in the current job for at least six months. Permission from the respective organization for doing the study was taken.

The following tools were used during the study: questionaire, measuring tape, and observation sheet. All VDT operator were invited to participate, and informed consent was obtained from each study subject prior to the fill questionaire and eyes health examination.

Structured questionnaires were administered to obtain information from frequent VDT users. It consist of three sections of questions. The first section requested for individual capacity like age, job section, and breaktime among VDT use. The second section requested for task demand like duration of computer use. The third section was designed to assess some of the computer vision syndrome like headache, dizzines, dry eye, double vision, neck pain, back pain, shoulder pain. The study subjects were examined for their visual acuity by using a Automatic Snellen Chart Proyektor for distant vision. Examination of eye fatigue by using a Reaction timer L77 lakassidaya were also done.

A occurance of computer vision syndrome was classified as a CVS or No CVS. Occurance of CVS were scored (>2 symptoms) and occurance of Non CVS were scored (0-2) according to addition of each items of 9 signs and symptoms in this questionnaire.

To know the level of influence of each risk factor to occurrence of computer vision syndrome at VDT operator it is conducted to univariate analyze with the frequency distribution and crosstab, and analyze the bivariate with the test of logistic regression. The level of significance considered was 0.05. All analyses were conducted using the Portable SPSS PASW Statistics 18.0.

FINDINGS

Variable	Occurance of CVS		P value	Odds ratio
	CVS(n=24)	No CVS(n=16)		
Age (years old)				
17 – 25	6 (25 %)	8 (50 %)	0,157	0,375
26 – 35	16 (66,7 %)	8 (50 %)	0,999	0,000
36 – 45	2 (8,3 %)	0 (0 %)	0,366	
Work Posture				
Ergonomy	4 (16,7 %)	8 (50 %)		
Not Ergonomy	20 (83,3 %)	8 (50 %)	0,030	5,000
Break time among VDT use (minutes)				
≥ 4	7 (29,2 %)	12 (75 %)		
< 4	17 (70,8 %)	4 (25 %)	0,007	7,286

FINDINGS (Contd.)

Variable	Occurance of CVS		P value	Odds ratio
	CVS(n=24)	No CVS(n=16)		
Duration of computer use (hours)				
> 8	13 (54,2 %)	10 (62,5 %)		
≤ 8	11 (45,8 %)	6 (37,5 %)	0,602	1,410
Viewing Distance (cm)				
≥ 50	4 (16,7 %)	10 (62,5 %)		
< 50	20 (83,3 %)	6 (37,5 %)	0,005	8,333

Occurance of Computer Vision Syndrome

The numbers of VDT operators in Bank Surabaya experiencing CVS were 24 respondents (60%), while those not experiencing CVS were 16 respondents (40%).

Complaints and symptoms most commonly experienced by an administrative officer sequentially include blurred vision, neck pain, eye fatigue, shoulder pain, back pain, dizziness, dry eyes, double vision, and headaches.

Age

This study showed that most respondents were in early adulthood, namely 26-35 years (66.7%) and the incidence of CVS was higher in the age group of respondents, this is likely due to the number of VDT operators on all three parts of this study were mostly aged 26-35 years (young adult), which can be made possible because the company is doing recruitment of employees who have at least 2 years of work experience as well as the regeneration of employees. Senior employee who has been working with computers for years were replaced by younger employees, thus the work at the computer will be charged more to younger employees.

Based on simple logistic regression test results obtained p value> 0.05, in order to take a decision that the age variable does not have a significant influence on the incidence of CVS on VDT operators. Occupational epidemiology said that in order to know whether the disease suffered by a worker can develop, transmitted, or on other workers must pay attention to the individual characteristics. These individual characteristics will affect the frequency of occurrence of disease due to the influence of sensitivity (sensitivity) or resistance to exposure (exposure) the entry of germs which can be roughly determined from conception in the womb, such as age, gender, heredity.[6]

Thus age can affect the immune system of a worker on the incidence of CVS. The increase of a person's age will be correspondingly reduced his endurance, but the research that has been done age does not directly affect the incidence of CVS on VDT operators. There are other risk factors that can directly affect the incidence of CVS.

Work Posture

Eye fatigue is one of the symptoms of CVS derived from a combination of poor ergonomics, inappropriate working posture, and visual conditions not detected[7,8].

The analysis of this study showed that the work posture significantly related to the incidence of CVS. The results of this study are similar to previous studiesstates that computer users should be at an ergonomics position to avoid neck pain, back pain, and pain head[9,10,11].

Based on observations, some of the work posture that seems unnatural done by the respondent is working on positionthe neck extension $0^0 – 20^0$when working at the computer that influences the viewing angle and position of your head held thereby affecting the skeletal neck. Unnatural working posture in general because of the characteristics of the task demands, work tools and work stations are not in accordance with the capabilities and limitations of workers[12,13,14,15].

Duration of Break During VDT Use

Working in front of a computer continuously without a break would be at risk of ocular disorder, one study reported that working more than 4 hours in front of VDT has significant relationship with astenopia[16].

The results of this study indicate that the risk of developing CVS is 7 times higher among VDT operators who took a break just under four minutes per hour after computer use . This is because many job demands and deadlines that must be resolved, and also because the number of respondents who do not realize the consequences of computer use continuously without a break, and do not yet know how to prevent the risk of eyestrain and musculoskeletal complaints. Frequency of break is recommended to recover and relax the eye accommodation system, this is to prevent eyestrain. In addition looking at objects as far as 20 ft at least twice an hour for computer use is effective to prevent visual fatigue.

Duration of Computer Use

A recent research stated that the presence of relationship between eyestrain and dry eye syndrome with working at a computer for more

than 8 hours a day[17]. But the results of this study did not show that the duration of computer use it would affect the incidence of symptoms of CVS, this is because for 8 hours the respondents did not look at the monitor continuously and respodent took a break too. Unlike the case with respondents who work for 3 hours straight without a break, it would indeed affect the occurrence of CVS. There were several respondents who took a break during the use of computers for 2-4 minutes by relaxation such as walking and provide documents to the unit / other sections or just make a coffee in the pantry. It is intended to cut the chains of fatigue that will add convenience for longer for computer users.

Viewing Distance

The distance and angle of view is not adequate when working with VDT will cause unergonomics posture, so it will affect the accommodation of the eye (visual disturbances) as well as skeletal disorders in the neck, shoulders, and back.

The results of the analysis of the relationship between the distance of the VDT with CVS events showed that working with the distance to the VDT less than 50 cm has 8 times higher risk for experiencing CVS. This research is consistent with the theory of OSHA which states that the distance of the monitor screen when working with computers should be at least 50-100 cm[18].

This is in accordance with reason or the main cause of eyestrain that is the distance of the eye too close to the monitor, thus eyes are forced to work to look at the VDT from a short distance in a considerable period of time, while the functions of the eye itself is actually not specific to look at the VDT at a close range, There are several factors in this study that may affect the results significantly. Based on the observation of the type of work performed by a worker dealing with IT is a complicated job and that requires precision. Types of IT jobs using specific software in which there are many numbers form of coding with font size of <12. This proves that the reasons for distance of the respondents to VDT that is too close (<50cm). The results of this study is in accordance with a research conducted by Chiemeke who said that complaints on the vision found in respondents who viewed a computer at a distance of 10-20 inch or less than 50 cm. So respondents are advised to look at a distance 50-100 cm to reduce the risk of CVS[19].

CONCLUSION

The risk factors that most influence occurance of CVS in this study were respondents who work with the distance to the VDT <50 cm and this is likely to 9 times higher. This is because the kind of work that the respondents had to carry out demanded them to be meticulous in entering data into the computer. It is also likely influencing the lack of blinking reflex when focusing the vision on the computer screen, thus making dry eyes and cause strain on the eye muscles. therefore VDT operators are encouraged to view the monitor at a distance of 50 -100 cm.

The results of this study indicate that the risk of developing CVS is 7 times higher among VDT operators who took a break just under four minutes per hour after computer use . Therefore it is recommended to follow the rules of the break with 20-20 - 20 of each work 20 minutes rest for 20 seconds to look at a distance of 20 ft (6 m).

The risk of CVS 7 times higher on respondents who work with unergonomics posture. This is because some of the work posture that seems unnatural done by the respondent is working position on the neck extension

0^0 – 20^0 when working at the computer that affect the magnitude of the angle of vision. Therefore VDT operators should pay attention to ergonomic working posture.

The company also should give education such as preventive measure to reduce the risk of CVS in the workplace. In addition the company must pay attention to the ergonomic design of work stations eg standard office lighting intensity of 300 lux, using an anti-glare screen, the position where the monitor is parallel or in the middle, ergonomic seat design that has a seat height, backrest and armrest.

Conflict of Interest: None

Source of Funding: Self

Ethical Clearance: The study was approved by the institutional Ethical Board of the Public Health, Airlangga University.

All subjects were fully informed about the procedures and objectives of this study and each subject prior to the study signed an informed consent form.

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Symptom Analysis of Patients with Impaired Renal Function in the Critical Care Units of Selected Tertiary Care Hospital of Udupi District, Karnataka State

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ABSTRACT

Chronic renal failure is a major worldwide health problem. An explorative survey was conducted to identify the renal impairment and symptoms experienced by the patients in critical care units of selected tertiary care hospital of Udupi District, Karnataka State with aim to identify the symptoms experienced by the patient, rank the symptoms experienced by the patient and also to classify the patients with impaired renal function according to Cockcroft and Gault method. Research instruments used were Renal Assessment Tool and also the laboratory investigations. Study finding revealed that most of the subjects belongs to the group age group 61 - 70 (46%) and majority of the subjects had primary education (53.33%). About 43% of the patient with impaired renal function had diabetes mellitus and 23% of patient were hypertensive. Sixty six point seven of the patients had oliguria, only 6.67% of patient was presented with anuria. Among them 53.33% of patients had exertional dyspnea and most of the patients 86.66% experienced fatigue, majority of the patients, 33.37% had anemia. Also 23.33% of them had muscle pain, 66.67% were ambulatory, and 33.33% of patients had nausea, vomiting and anorexia. All of the patients were conscious, 80 % of them were lethargic, and 50% of them had decreased attention span. Based on GFR and status of renal impairment according to Cockcraft and Gault method, 10% of the patient belong to Stage I, Stage II (26.67) , stage III (36.63), Stage IV (16.67%), and Stage V (10%) of impaired renal function.

Keywords: *Symptom Analysis Impaired Renal Function, Critical Care Units, Tertiary Care Hospital.*

INTRODUCTION

Renal impairment encompasses a wide spectrum of clinical problems. The diverse cause of these disorders may leads to chronic renal failure if unchecked. Compared to diseases like cancer, and Ischemic heart disease renal failure is also a major public health disease but the expense of dialysis and transplantation causes a substantial burden for individual family and to the health services.[1] The exact prevalence of chronic kidney disease in India is not clear in the absence of regular national registry data and the data provided are only by small observational series or rely on reports from personal experience, but the quality of data is quiet uneven. In India nearly 90,000 patients develop chronic renal failure every year. [2]

Renal impairment is a condition in which the kidney fails to remove the metabolic products from the blood and regulate the fluid, electrolyte balance. It is a gradual reduction in renal function. [7] Glomerular filtration rate (GFR) is the best quantification of kidney function. But because it cannot be measured directly, it is estimated from serum concentration or urinary clearance of a filtration marker. Currently serum creatinine is the most widely used method of assessing renal function in clinical practice Renal failure has different clinical presentations and sometimes patients do remain asymptomatic. [6] It is important to assess kidney function as accurately as possible, especially in older adults, since there is a progressive decline in renal function with age.[4]

The currently existing resources and skill for taking care of this large case load, both in terms of personal and health care infrastructure are not sufficient enough

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and would need to be expanded. To tackle the problem of limited access to renal replacement therapy, an important method would be to try and reduce the incidence of end stage renal disease and the need of renal replacement therapy by preventive measures. It is clear that treatment of chronic kidney disease and its advanced stage end stage renal disease is expensive and beyond the reach of average Indian. Thus it is crucial that prevention of chronic kidney disease has to be the goal of medical fraternity, government of India and the general public.[3]

Keeping this in mind an explorative survey was conducted to identify the renal impairment and symptoms experienced by the patients in critical care units of selected tertiary care hospital of Udupi District, Karnataka State conducted with the purpose of to detect the impairment in renal function and symptoms experienced at early stage, thus to prevent the progression to the end stage renal disease. The specific objectives of the study were to identify the symptoms experienced by the patient, rank the symptoms experienced by the patient, and also to classify the patients with impaired renal function according to Cockcraft and Gault method.

MATERIALS AND METHOD

Research approach was survey and an explorative design was adopted. The study was conducted in tertiary hospital of Udupi district. The population comprised of patients admitted in the Critical Care area and nephrology units of the tertiary care hospital, samples were selected using an enumerative method with the sample size of 30. Study instruments used were, Renal Assessment Tool. The assessment tool consisted of five parts. Part I – Section A: Demographic Performa, Section B: Clinical Performa, Part II – Physical examination, Part III –Laboratory Investigations and classification.

FINDINGS

Data in table 1 reveals that most of the subjects belongs to the group age group 61 – 70 (46%) and majority of the subjects had primary education (53.33%). Majority of the subjects have a monthly income in between 1001-3000/- month (53.33%) most of the patient (80%) are not having an organized ob. Most of the patients were Hindus and Muslims (33.32%) and belongs to nuclear family. And most of the patients are males (66.67%).Most of the patients (46.67) belongs to the age group of 61 to 70 and minimum number of patients belongs to 71 and above age group and less than 20 age group.

Table 1: Distribution of patients with renal impairment according to the demographic proforma

(n=30)

Characteristics	N	Percentage
Age (years)		
<20	1	3.3
21-30	2	6.67
31-40	2	6.67
41-50	2	6.67
51-60	8	26.67
61-70	14	46.67
71 and above	1	3.3
Gender		
Male	20	66.67
Female	10	33.37
Marital Status		
Single	3	10
Married	25	83.33
Divorced	-	-
Widowed	2	6.67
Educational Status		
Illiterate	-	-
Primary education	16	53.33
High School	6	20
Higher Secondary	2	6.67
Degree	2	6.67
Professional	4	13.33
Occupation		
Skilled	6	20
Unskilled	24	80
Religion		
Hindu	18	60
Muslim	10	33.33
Christian	2	6.67
Family income		
<3000	3	10
3001-5000	16	53.33
5001-7000	7	23.33
7001-9000	4	13.33
>9001	0	0

Table 2: Distribution of patients with impaired renal function based on the duration of

Present illness history	N	Percentage
On set and duration		
<3 months	3	10
3-6 months	3	10
6-9 months	2	6.67
Above one year	22	73.33

Table 2: Distribution of patients with impaired renal function based on the duration of (Contd.)

Present illness history	N	Percentage
Based on Comorbidity		
Hypertension	7	23
Diabetes mellitus	13	43
Cardiac disease	3	10
Urinary tract infection	1	3.33
Renal disease	2	6.67
System of treatment		
Allopathy	30	100

Table No 2 reveals that majority of the patient (95.06%) had the duration of the illness more than one year and all the patients resort to allopathic treatment now. And 20% of patients are treated with dialysis and drugs. Based on comorbidity about 43% of patient with impaired renal function had diabetes mellitus and 23% of patient were hypertensive and 13.33% of the patient had cardiac disease(CAD). 3.3% had nephrotic syndrome, 3.3% had IgA nephropathy.

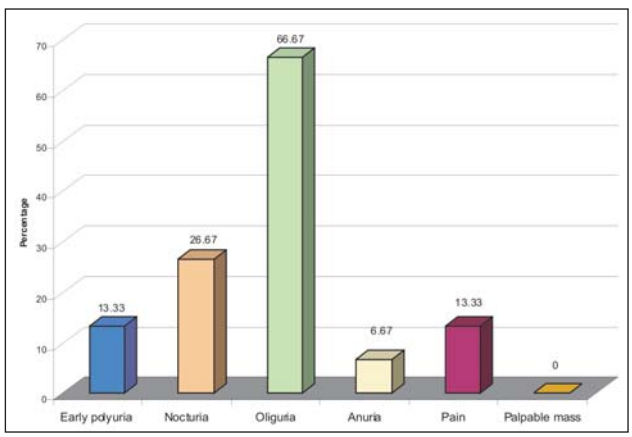


Fig. 1. Distribution of patients based on urinary system manifestations.

Fig no.1 Reveals the urinary manifestations; Sixty six point seven of the patient had oliguria, only 6.67% of patient was presented with anuria. 26.67% had nocturia and 13.33% presented with lower back pain.

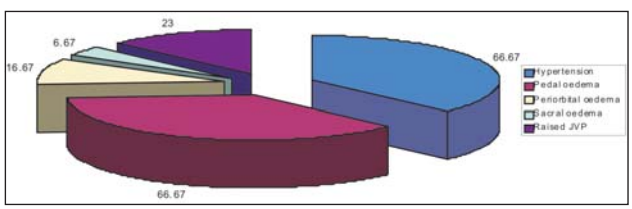


Fig. 2. Distribution of patients based on cardiovascular system manifestations

Fig. 2. reveals the cardiovascular system manifestations; 66.67% of patients had pedal edema and hypertension.

Table 3 : Distribution of patients based on the clinical manifestations (Haematologic System

(n=30)

Clinical manifestations	N	Percentage
Fatigue	26	86.66
Clubbing	3	10
Cyanosis	2	6.67
Anemia	10	33.33
Mucosal bleeding	-	-
Excessive Vaginal bleeding	1	3.33

Table 3 : Reveals the distribution of patients based on the Haematologic system clinical manifestations; most of the patients, 86.66% experienced fatigue, majority of the patients, 33.37% had anemia. Only 6.67 patients had cyanosis only 10% had clubbing of fingers.

Table 4 : Distribution of patients clinical manifestations on Respiratory and Musculoskeletal system

(n=30)

Respiratory system Clinical manifestations	N	Percentage
Dyspnoea with exertion	17	56.66
Dyspnoea without exertion	5	16.67
Cough with expectoration	3	10
Abnormal breath sounds	5	16.67
Musculoskeletal system clinical manifestations		
Fatigue	26	86.66
Joint pain	4	13.33
Muscle pain	7	23.33
Muscle cramps	15	50
Ambulatory	20	66.67
Bed ridden	3	10

Table 4. Shows that 56.66% of patients had exertional dyspnoea. Manifestations musculoskeletal system were, about86.66% of patients had fatigue, 23.33% of them had muscle pain and 66.67% were ambulatory.

Table 5 : Distribution of patients based on the clinical manifestations in Gastro Intestinal System and central nervous system clinical manifestations

(n=30)

Gastro Intestinal System Clinical manifestations	N	Percentage
Oral ulcers	4	13.33
Change in taste of food	7	23.33
Nausea	10	33.33
Vomiting	10	33.33
Anorexia	10	33.33
Hiccough	6	20
Constipation	1	3.3

Table 6 : Distribution of patients based on the clinical manifestations in Gastro Intestinal System and central nervous system clinical manifestations (Contd.)

(n=30)

Gastro Intestinal System Clinical manifestations	N	Percentage
Ascites	4	13.33
Central nervous system clinical manifestations		
Conscious	30	100
Lethargic	24	80
Decreased attention span	15	50
Slurred speech	5	16.67
Tremors	6	20
Ataxia	5	16.67

Table 5 shows that majority of the patient 33.33% of patients had nausea, vomiting and anorexia. Where as the manifestations in central nervous system included were; that all of patients were conscious, 80 % of them were lethargic, 50% of them had decreased attention span.

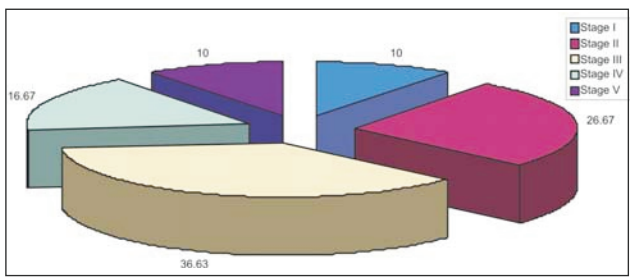


Fig. 3. Distribution of patients based on GFR and status of renal impairment according to Cockcraft and Gault method

Figure No 3 reveals that 10% of the patient belong to Stage I, Stage II (26.67) , stage III (36.63), Stage IV (16.67%), and Stage V (10%) of impaired renal function. This was calculated based on the laboratory parameters of serum creatinine and estimated GFR calculations. Laboratory investigations revealed that 68% of patients had protenuria,56.67% of patients had hyperkalemia, 65% of the patients had creatinine above 6mg/dl and 100% of patients had albuminuria.

CONCLUSION

Study finding revealed that most of the subjects belongs to the group age group 61 – 70 (46%) and majority of the subjects had primary education (53.33%). About 43% of the patient with impaired renal function had diabetes mellitus and 23% of patient were hypertensive. Sixty six point seven of the patients had oliguria, only 6.67% of patient was presented with anuria. Based on the clinical manifestations of respiratory system, 53.33% of patients had exertional dyspnoea. In musculoskeletal system most of them, 80% of patients with CRF experienced fatigue ,23.33% of patients had muscle pain, cramps and 66.67% were ambulatory. In Reproductive system, 33.33 of patients had decreased libido. Gastro Intestinal System, majority of the patient, 33.33% of patients had nausea, vomiting and anorexia. In central nervous system, majority 50% experienced reduced attention span, 20% of patients experienced tremors. Manifestations of Integumentary systems accounted about 66.67% patients, had pedal edema also experienced dry scaly skin. Laboratory investigation revealed that 68% of patients had protenuria, 56.67% of patients had hyperkalemia, 65% of the patients had creatinine above 6mg/dl and 100% of patients had albuminuria.

Distribution of patients based on GFR and stages of renal impairment according to Cockcraft and Gault method revealed 10% of the patient belong to Stage I, Stage II (26.67%) , stage III (36.63 %), Stage IV (16.67%), and Stage V (10%) of impaired renal function respectively.

DISCUSSION

There are multiple reasons why it is imperative to accurately identify persons with CKD. Persons with early-stage CKD have been shown to have high morbidity of hypertension, diabetes mellitus and its complications, anemia, malnutrition, bone disease, calcium and phosphorus metabolism disorders, impairment of functioning and well-being. validated assessments that can detect earlier stages of CKD and therapeutic interventions effective in slowing or preventing the progression toward kidney failure and its complications. under-recognition of risk factors for CKD and early stages of CKD have been postulated as one of the explanations for the increased incidence and prevalence of kidney failure. [8]

Conflict of Interest: Nil

Sources of Funding: Self funded

Ethical Clearance: Permission obtained from the head of the institution, Respective hospital administrators.

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Bacteriological Profile and Antimicrobial Susceptibility Pattern Among Critically Ill Patients; A Cross Sectional Study

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ABSTRACT

Introduction: Emergence of new organisms and changing antibiotic susceptibility pattern are challenges faced by all Intensive Care Units (ICUs). We have designed a study to identify the bacteriological profile and antimicrobial susceptibility pattern of infections among the patients admitted to the Intensive Care Unit of a tertiary care hospital.

Materials and method: This study was a cross sectional study where all patients admitted to the Intensive Care unit of a tertiary care hospital during a one year period were evaluated and clinical specimens collected from cases with suspected infections were processed as per standard microbiological tests as approved by CLSI.Cases were subsequently classified based on the CDC case definitions.

Results: A total of 107 samples were analysed in this study. Gram-negative bacteria were the predominant organisms identified, accounting for 73 % of the isolates.There was high incidence of MDR organisms in our study ranging from 17% in Pseudomonas to 57% among Acinetobacter isolates.The net rate of ESBL producers in the study was 83%.Meropenem resistance (41%-44%) was seen among isolates of Pseudomonas and Acinetobacter. 71 % of the staphylococcus isolates were methicillin resistant.

Conclusion: The important resistant patterns identified in our study were ESBL producing Gram negative bacilli(GNB) and MRSA. Most of the GNB were multi drug resistant(MDR) with maximum MDR seen with Acinetobacter.Emerging meropenem resistance and high sensitivity only to beta lactum/ betalactamase inhibitors and imipenem indicates urgent need for antibiotic stewardship in this ICU.

Keywords: *IMicrobial Drug Resistance, Antibiogram , Bacterial Sensitivity Tests.*

INTRODUCTION

Emergence of new organisms and changing antibiotic susceptibility pattern are challenges faced by all Intensive Care Units (ICUs). Gram-negative organisms predominate the microbiological scene in ICUs with increased rate of multi drug resistance emerging as a common problem. Appropriate therapy of ICU infections directed by local resistance data can have significant consequences for both patient and the healthcare system[1] The spectrum of microbial isolates do vary in different settings as do their susceptibility patterns and one needs to be aware of one's 'own bugs' for better management of infections on empirical grounds[2]. A large majority of the Hospital Acquired infections occur in ICUs although ICUs account for only a small percentage of hospital beds. Infection rates in ICUs are several times higher than in general ward. Factors such as increased cross transmission, reduced host defences , rampant antibiotic use increases infection rates and also the incidence of multi drug resistant strains of bacteria in the ICU [3] We have designed a study to identify the bacteriological profile and antimicrobial susceptibility pattern of infections among the patients admitted to the Intensive Care Unit of a tertiary care hospital.

MATERIALS AND METHOD

All patients admitted to the intensive Care Unit of atertiary care hospital duringa period of one year were included in the study. After a detailed clinical evaluation, microbiological samples from clinically suspected sites of infection were collected and processed as per standard Microbiological tests as approved by the Clinical and Laboratory Standards Institute(CLSI). Samples for culture were tested by Kirby Bauer's Disc diffusion technique. Methicillin resistant Staphylococcus aureus (MRSA) samples were tested by oxacillin agar screening methods; Penicillin resistant streptococci were to be tested by agar dilution method using oxacillin; Vancomycin resistant Enterococci(VRE)were to be tested using agar dilution method using teicoplanin. ESBLs were tested by phenotypic confirmatory test with combination test.Cases were subsequently classified based on the CDCcase definitions[4, 5].

Results/ Findings

The study was conducted for a period of one year,during which all patients admitted to the ICU were observed for signs and symptoms of infection.Table 1 shows the basic details of the study population.

Table 1. Basic details of the study population.

	Males	Females	Total
Number of patients	60 (71%)	25 (29%)	85
	Death	Discharged	Total
Number of patients	33 (39%)	52 (61%)	85
	Present on Admission	Health Care Associated	
Number of Infections	40 (49%)	41 (51%)	81
	Culture positive	Sterile on Culture	
Number of Samples	62 (57.94%)	45 (42%)	107

A total of 107 samples were analysed, out of which sputum samples were 36 (34%), Blood -24(22%), CSF-14(13%) , Pus- 10 (9%) , wound swab 7(7%) , urine -6 (6%), pleural fluid – 3 (3%) , and others 7 (7%). Gram negative organisms were the most common of the bacteria isolated in the study at 62(73%); Gram positive bacteria isolated were 18 (21%) and 5 (6%) samples grew Candida albicans. The most common Gram positive organism isolated was Staphylococcusaureus -7(9%).

The distribution of the organisms is as follows

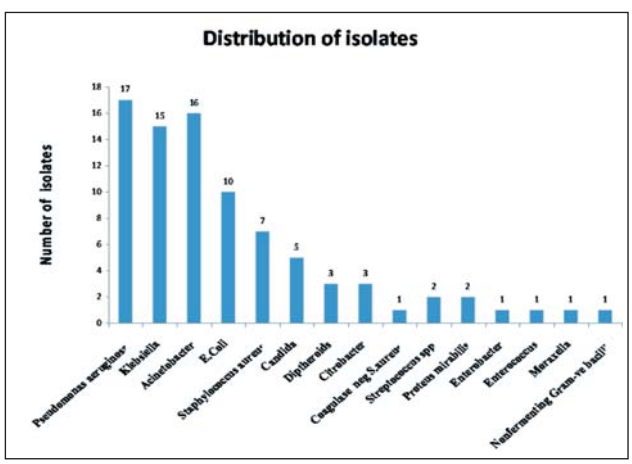


Fig. 1. Distribution of Isolates

Sensitivity Profiles

Presented below are the sensitivity profiles of the most common organisms isolated in the study,namely Pseudomonas,Acinetobacter,Klebsiella,E.coli and Staphylococcus aureus.

Out of a total of 17 isolates of Pseudomonas, 100%showed sensitivity to Imipenem,Piperacillin-tazobactum-88%,Cefoperazone-Sulbactum-88%, Ciprofloxacin 65%,Netilmycin-65%,Gentamicin-65%,Tobramycin-65%,Meropenem-59%, Aztreonam 59%,Ceftazidime-47%,Ceftriaxone-29% and Ampicillin-Sulbactum-29% sensitivity.

Percentage sensitivity of Acinetobacter to the various antibiotics tested was as follows:

Imipenem-100%,Cefoperazone-Sulbactum-100%,Piperacillin-tazobactum-81%,Ampicillin-Sulbactum-75%,Amikacin-31%,Tobramicin-31%,Gentamicin-25%,Aztreonam-25%, Chloramphenicol-18%,Ceftriaxone-18% and Ciprofloxacin-13%.

Sensitivity profile of Klebsiella was as follows:Meropenem-100%,Cefoperazone-Sulbactum-100%,Imipenem-93%,Piperacillin-Tazobactum-86%,Cefoxitin-80%, Chloramphenicol-79%, Amikacin-50%, Ciprofloxacin-40%, Aztreonam-36%, Ceftriaxone-33%, Gentamicin-21%, Cefipime-14%, Cotrimoxazole-14% and Tobramycin-7%.

The E.coli that were isolated showed 100% sensitivity to Imipenem,Meropenem,Cefoperazone-Sulbactum and Piperacillin-Tazobactum,while there was 78% sensitivity to netilmycin and Chloramphenicol; 67% were sensitive to Amikacin and Cefoxitin; 22% were sensitive to Gentamicin, Cotrimoxazole, Tobramycin, & Aztreonam and Ceftriaxone Ciprofloxacin, Cefipime, Ceftazidime and Cefuroxime showed only 11% sensitivity.

A total of 7 isolates of S.aureus were obtained, which showed the following sensitivity profile: Vancomycin-100%,Linezolid-100%,Rifampicin-100%,Teicoplanin-86%, Netilmycin-71%, Erythromycin-29%, Gentamicin-29%, Cloxacillin-29%, Methicillin-29%, Amoxacillin-29%. All the isolates were resistant to Cotrimoxazole and Penicillin.

Table 2. The prevalence of Multi Drug Resistance among the common isolates

No	Organism	Total no	No of MDR	% of MDR
1	E.Coli	10	3	33.33%
2.	Klebsiella spp	15	7	46.6%
3.	Pseudomonas	17	3	17.6%4
4.	Acinetobacter	14	8	57.14%

Patterns of resistance

There was a high incidence of Extended Spectrum Beta Lactamases(ESBLs) and Methicillin Resistant S.aureus(MRSA) among the population under study.

MRSA:S.aureus was the most common gram positive organism identified in the study.it was found that 71 %(5) of the total 9 isolates of S.aureus were MRSA.

ESBL profile:A total of 14 isolates of Klebsiella and 10 isolates of E.coli were identified during the study period. It was found that 79 %(11) of the Klebsiella and 90% (9) of the E.coli were ESBL producers. The net rate of ESBL producers in the study was 83%.

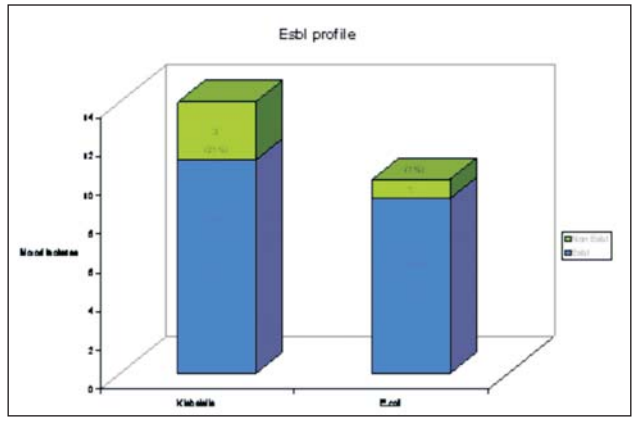


Fig. 2. Distribution of ESBLs in the study:

DISCUSSION

It is necessary to have an awareness of the prevailing infections in the ICU,the antibiotics which are likely to work against these infections , and an awareness of any newly emerging pathogens to enable early detection of outbreaks of infection.

In order to achieve this we need to create databases of infection profiles and antibiotic resistance patterns. Unfortunately the microorganisms that cause infections in one part of the world may not be the culprits in other parts. Thus data which is specific to a country or region is required in order to help formulate antibiotic policies, to test the effectiveness of antibiotic stewardship programmes and to detect and control outbreaks before it causes serious implications to health[6].

In ourstudy that was conducted over a one-year period, 85 patients were observed for clinical evidence of infection. Endotracheal aspirate/Sputum was the most common sample analysed at33% followed by blood culture accounting for 22% of the samples. The infection profile in the study showed an almost equal distribution with Healthcare Associated Infections(HAIs)forming 51% of the infections and community acquired infections having an incidence of 49%.In a study evaluating the prevalence of Nosocomial Infection in Intensive Care Units in Europe a total of 4501 patients (44.8%) were infected, and 2064(20.6%) had ICU-acquired infection [7].Due to the increased risk of antimicrobial resistance in this group,antibiotics with broader spectrum of coverage may need to be used. This underscores the need to identify the presence of HAI,so that lifesaving and

accurate empirical antibiotic coverage may be provided at an early stage.

Gram-negative bacteria were the predominant organisms identified in this study, accounting for 73 % of the isolates. Gram negative bacteria are the most common isolates in most hospitals and ICUs across the world. The Enterobacteriaceae family, is often the most common organism identified. Multi drug resistance among the Gram negative isolates is defined as resistance to e" '>/= 3 classes of drugs' first line antibiotics (namely Beta lactams, aminoglycosides and fluoroquinolones). Multidrug-resistant strains of *Pseudomonas aeruginosa, Acinetobacter baumannii*, and extended-spectrum â- Beta lactamase (ESBL)–producing or carbapenemase-producing Enterobacteriaceae, are commonlyreported across the world [8].In our study, the most common Gram negative organisms isolated were Pseudomonas-17(21%),Acinetobacter-16(20%), Klebsiella-15(19%),E.coli-10(12.5%). There was high incidence of MDR organisms in our study ranging from 17% to 57% among the above common organisms(Table 9).In the Durban ICU study [9] , the incidence of MDR Acinetobacter was 50-71%, and MDR Pseudomonas was 0 -25% across various ICUs in the hospital. These results were comparable to our study. In a study in Ethiopia [10] on isolates from wound infections, there was 97% incidence of MDR among the Gram negative isolates. In a study conducted in North India [11], the incidence of MDR was 27%, and the incidence of extensive drug resistance(those resistance to all but one/two classes of antibiotics) and pan drug resistance(resistance to all antibiotics) was 45% and 5.6% respectively.

The most common Gram positive organism identified was S.aureus.In our study Pseudomonas showed a 100% sensitivity to imipenem,and 88% sensitivity to piperacillin –tazobactum and cefoperazone-sulbactum.However sensitivity to fluoroquinolones and aminoglycosides was lower, with Ciprofloxacin having 65 % sensitivity and Amikacin showing a sensitivity of 76%.Other aminoglycosides also showed a low sensitivity rate of 65% making this antibiotic class ineffective against the Pseudomonas isolates in our study.Also, to be noted is the very high resistance rate of Pseudomonas to Meropenem,with 41 % resistance, despite the 100% sensitivity to imipenem.Third generation cephalosporins show a very poor sensitivity profile, with 57 to 70% of the isolates of Pseudomonas being resistant.

Acinetobacter was the second most common bacteria isolated in the study accounting for 20% of the isolates. Acinetobacter showed 100% sensitivity to Imipenem and to cefoperazone-sulbactum and 88% sensitivity to piperacillin –tazobactum making these antibiotics the drugs of choice for Acinetobacter infections in our ICU. However, Meropenem shows a good deal of resistance with only 56% of the Acinetobacter being sensitive to it. Aminoglycosides, monobactams and fluoroquinolones remain highly ineffective with more than 70% of the isolates of Acinetobacter being resistant.

Klebsiella and E.coli were the other most common isolates in this study. Both these organisms remain highly susceptible to carbapenems with sensitivity rates of nearly 100% and beta lactam/beta lactamase combinations of Pipercillin-tazobactum and Cefoperazone-Sulbactum showing 80% to 100% susceptibility.The ratesof ESBLs in this study was very high with 83% of the isolates being ESBL producers,thus making third generation cephalosporins ,the most ineffective drug class in this ICU.Also noted is the 50% to 93% resistance to aminoglycosides.Klebsiella retains 80% sensitivity to the Cephamycin, cefoxitin,whereas only 67% of the E.coli are sensitive to Cefoxitin.Resistance to Cefoxitin among the E.coli may indicate the emergence of AmpC Beta Lactamases among them.Specific testing for the presence of AmpC beta Lactamases was not done in this study.Despite worldwide use of *b*-lactam antibiotics, thedistribution of the enzymes responsible for resistance to oxyimino-cephalosporins and carbapenems is far from uniform. Some hospitals in the United States seem to have no ESBLs, whereas in other hospitals as many as 40 percent of *K. pneumoniae*isolates have been reported to be ceftazidime-resistant as a result of ESBL production.In a sample of more than 4700 *K. pneumoniae* isolates obtained during the period from 1997 through1999, the percentage expressing an ESBL phenotype was highest in isolates from Latin America (45.4 percent), the Western Pacific (24.6 percent), and Europe (22.6 percent) and lowest in strains from the United States (7.6 percent) and Canada (4.9 percent). In more than 13,000 isolates of *E. coli*, the percentages expressing the ESBL phenotypewere as follows: in Latin

America, 8.5 percent; in the Western Pacific, 7.9 percent; in Europe, 5.3 percent; in the United States, 3.3 percent; and in Canada, 4.2 percent.[12]

In another large data set from the United States collected from 1998 through 2001, ceftazidime resistance was present in 9.6 percent of *K. pneumoniae* isolates from intensive care units and 6.6 percent of isolates from other hospital locations[12].

As antimicrobial resistance has always been a reflection of antibiotic use, in our study as well, the very high degree of resistance to third generation cephalosporins aminoglycosides and the alarmingly high rates of ESBL producing Gram negative bacilli are an indication of the indiscriminate use of these groups of antibiotics among the population under study. In the table below we have compared resistance profiles of common microorganisms in recent similar studies conducted worldwide.

Table 3: Resistance profile of worldwide studies in comparison to our study.

Year, Study site	No of isolates	ESBL rate(%)	MRSA rate (%)	Resistance Rate of gram negative organisms /S.aureus (%)					
				Fluoroquinolones	3rd Generation Cephalosporins	Beta Lactam/ Beta Lactamase Inhibitor Combinations	Aminoglycosides	Carbapenems	Vancomycin
2014, Ethiopia[10]	150			24.7%	64.9%		41.6%		0%
2013, India[11]	2796	78%							
2013, India[13]	312			20	73%	50%	50%	72%	100%
2011, Indonesia[14]	249			56	64%		15%	24%	
2010, Durban[9]		83%	48%						
2007, India[15]	489						48.5%		
Our Study	107	83%	71%	68%	73%	11%	44%	23%	0%

As our study was conducted in a resource limited setting, most of the population in our study were naïve to the use of higher antibiotics such as carbapenems and beta lactam /beta-lactamase inhibitor combinations. Hence these drugs have retained a very high degree of sensitivity and can be considered the drugs of choice for suspected gram-negative infections in this ICU.

Staphylococcus aureus was the most common Gram positive organism isolated in this study.It was noted that 71% of the isolates were MRSA.However there was a 100% sensitivity to Vancomycin,Linezolid and Rifampicin. Teicoplanin also showed a good sensitivity rate of 86%.There was no resistance to Vancomycin in this study. There was a single isolate of enterococcus identified in this study,which was sensitive to Vancomycin,hence giving a zero incidence of Vancomycin Resistant Enterococci(VRE) in our study population.

CONCLUSION

Gram negative organisms were the most common organisms isolated in the study.The important resistant patterns identified in our study were ESBL producing Gram negative bacilli and MRSA.There was a near 100% sensitivity of all the gram negative bacilli to carbapenems, and a very good resistance profile against beta lactam/betalactamase inhibitor combinations. Most of the GNB were multi drug resistant with maximum MDR seen with Acinetobacter. Meropenem resistance(41%-44%) was seen among isolates of Pseudomonas and Acinetobacter.We need to introduce an antibiotic policy in our hospital to prevent injudicious use of antimicrobials and to preserve the sensitivity of higher antibiotics.

Conflict of Interest: None

Source of Funding: None

Ethical Clearance: Obtained from Institutional Ethics Committee.

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Root Resorption in Orthodontics: A Recent Update

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ABSTRACT

Recently due to medico-legal factors, once again a lot of interest has been generated about the root resorption which is followed by orthodontic treatment. Newer information's are being continuously added and therefore process of root resorption have been better identified and understood.

Keywords: *Root resorption, EARR, Orthodontic Treatment, Orthodontic Forces, Prevention of Root Resorption*

INTRODUCTION

Root resorption in permanent teeth was regarded as a result of trauma[1]. Ottolengui[2] was able to relate root resorption specifically to orthodontic treatment with radiographic evidence. Brezniak and Wasserstein[3]suggested the term Orthodontically induced inflammatory root resorption (OIIRR) to distinguish this type of resorption from others such as those caused by trauma, periapical lesions of periodontal disease.

Risk factors

A. General factors

1. **Gene:** Interleukin IL-1 (IL-1B)allele 1 has 5.6 fold increased risk of external apical root resorption (EARR).Interleukin 1ß (IL-1ß) (13954) gene suggest a role for this cytokine in the pathogenesis of EARR and for the protective mechanism of the cementum against root resorption.[4]Estimates from the qualitative and quantitative measurement external root resorption were 44.9% and 42 9% for monozygotic twins and 24.7% and 28.3% respectively for dizygotic twins. An overall heritability estimate of 0.34 was obtained.
2. **Ethnic groups:** Asian patients experience significantly less root resorption than white or Hispanic patients.Smale[5]recruited patients from 3 different centres in 3 countries and found no differences in resorption among the subsamples.
3. **Systemic diseases:** The number of alveolar bone osteoclasts increased in the compressed PDL areas over control which suggested that cell populations involved in resorption were influenced by inflammatory mediators produced by asthma.Nishioka[6]determined association between excessive root resorption and immune system factors and found root resorption to be 10.3% higher.
4. **Age:** When a patient is older than 11 years, risk for root resorption increases. Child patient's periodontal membrane becomes narrower and less vascularized, aplastic, alveolar bone becomes denser, and cementum becomes wider with age. Immature teeth with incomplete root formation will have the benefit of the remaining growth potential, and the post treatment elongation of the root even with EARR.

5. **Root:** The average root-shortening due to orthodontic tooth movement is approximately 10% and it ranges from 1.2 -1.5 mm. Oyama in his FEM study concluded that there was an enhanced risk for root resorption in short roots and significant higher degree of EARR in blunt roots.Apically bent and angulated roots had the highest prevalence of EARR, and the percentage was 92.11%. [7]

6. **Endodontically treated tooth:** Post orthodontic endodontically treated teeth and contralateral vital tooth was compared and found that there is no difference between the two teeth.Ioannidou-Marathiotou concluded in a meta anlysis that available literature is scarce and that root filled teeth do not increase the risk of ARR. [8]

7. **Malocclusion:** A mean of approximately 1mm of apical root shortening in class I patients while the class II division 1 patients showed a mean root shortening of more than 2 mm.Root resorption depends on the extent of displacement of incisor roots and the amount of movement required.

8. **Type of tooth:** Maxillary incisors are most commonly used to determine the apical root resorption as EARR occurs most commonly on these teeth and they are easily visualized on a lateral cephalogram.Maxillary incisors undergo more displacement than other teeth during extraction treatment. The maxillary laterals are the most often resorbed teeth followed by the centrals, mandibular centrals and then the maxillary canines mandibular first molars, and especially the distal root often is affected.

9. **Ectopic tooth:** Maxillary lateral incisor root is the area most commonly affected by ectopic eruption of the canine since the root is conical, apex is deep in the palate. All of these factors make possible the loss of an entire root within 2 months.

10. **Successor tooth:** The prognosis of retained primary mandibular molars lacking successors showed clinically significant infraocclusion ratios of more than 0.2 in 43.6 per cent of patients. Infraocclusion was estimated to be a more critical factor for the prognosis of retained primary molars than root resorption.

Mechanical factors

1. **Continuous vs Intermittent force:** The intermittent force application was obtained with a 3-day resting period followed by a 4-day force application period and found significantly less total root resorption. In a buccally tipped premolar, the greatest amount of root resorption was in the buccal-cervical area of the root.

2. **Light vs Heavy force:** The mean volume of the resorption crater in the light-force group was 3.49 fold greater and heavy group force group was 11.59 fold greater than the control group. The result showed that the severity of root resorption increased particularly with heavy forces and intrusive movements. Thus the use of light orthodontic forces, especially with incisor intrusion.

3. **Removable vs Fixed:** Heavy force (225 g) produced significantly more root resorption (9 times greater than the control) than light force (25 g) (5 times greater than the control).The teeth experiencing orthodontic movement had significantly more root resorption than did the control teeth.

4. Type of tooth movement

- **Tipping vs bodily:** The amount of tooth movement in the bodily tooth movement group was less than half that in the tipping tooth movement group. The greatest amount of tooth movement occurred in the 10gm tipping and 50gm bodily tooth movement subgroups.

- **Extrusion vs intrusion:** Root resorption from extrusive forces was limited and not significantly different from the control group. Intrusive force significantly increased the percentage of resorbed root area by 4 fold.

- **Rotation:** Examination by scanning electron microscopy revealed many concavities resorption lacunaeon the root surfaces of all rotated teeth. The resorption areas were located mainly at the medial root third, in regions that corresponded to the prominent zones of the roots.

5. **Correction of curve of spee:** Patients with severe deep bite, treated with intrusion mechanics of

accentuating and reversing the curve of spee statistically showed greater root resorption than patients with normal overbite who did not receive these mechanics.

6. **Torque:** Increased hydrostatic pressure correlated well with the locations of root resorption for each tooth undergoing torque movement and if hydrostatic pressure exceeds typical human capillary blood pressure in the PDL, the risk of root resorption increases.

7. **One phase vs two phase:** The children treated in 2 phases with a bionator followed by fixed appliances had the fewest incisors with moderate to severe OIIRR, whereas children treated in 1 phase with fixed appliances had the most resorption.

8. **Brackets:** Patients treated with Damon3 and conventionally ligated brackets with identical archwires and sequencing in all patients. The results showed that mandibular incisor root resorption was not statistically different.

9. **Duration:** One month of extra treatment time causes 0.1 and 0.2 mm of additional root resorption of the most severely resorbed central and lateral incisor, respectively.Average treatment length for patients without root resorption was 1.5 years and for the patients with severe root resorption 2.3 years

10. **Wires used:** Incisor root resorption after levelling did not differ significantly between patients treated with super-elastic and conventional stainless steel arch wires, except for a mandibular incisor.

11. **Expansion:** Root resorption after rapid maxillary expansion (RME) via cone-beam computed tomography showed statistically significant volume loss.Expansion with passive self-ligating brackets showed clinically significant amounts of expansion (approximately 3.5 mm in 8 weeks) with no apical root resorption.[9]

12. **Restorative buildups:** Restorative buildups, used to increase the vertical dimension by 2 mm for 4 weeks, caused root resorption along the sides of the teeth during the active bite-increase period.

13. **Use of implants for retraction:** The time needed for the greater amount of maxillary en-masse anterior retraction with miniscrew anchorage is longer and might dispose the patient to more apical root resorption. [10] The incidence of root resorption increased when the distance between the mini-implant and the root was less than 0.6 mm.In case of root perforation, root resorption and ankylosis occurred on the side opposite the insertion.

14. **Archwire sequence:** The studies showed that there was no statistically significant difference between archwire sequences on the maxillary left central incisor root resorption.

15. **Sliding one phase vs two phase:** The average root shortening of maxillary central and lateral incisors was 0.43 and 0.58 mm, respectively, and that of mandibular central and lateral incisors was 0.23 and 0.22 mm, respectively. No difference was found in the amount of root shortening between space closure procedures.[11]

Diagnosis

1. **OPG:** Normal anatomical structures can appear as radiolucent or radiopaque shadows superimposed over the teeth as either real or actual shadows or as a ghost or artifacts which can degrade the quality of the final image. Also roots may get magnified or foreshortened in markedly class II or class III patients.

2. **Periapical radiography:** OPG overestimated the amount of root loss by 20% or more when compared with periapical radiographs. In cases where the apices are obscured or other factors are present that might suggest higher risk for root resorption periapical films should be taken.

3. **Cone beam computed tomography:** An average of 55-91% of teeth showed some degree of root shortening in class I malocclusion. 7% of patients had one tooth or more with root shortening exceeding 4 mm, Slanted root resorption was found in up to 15% of palatal root surfaces and could be evaluated only on tomographic images. [12]

4. **Dentine phosphoproteins:** Dentine phosphoproteins (DPP) is measured in the GCF using an enzyme-linked immunosorbent assay and there is a difference in the level of DPP between a group of

patients with mild root resorption and a control group.[13]

5. **Elisa combined with electrochemistry:** The electrochemical results extended the lower end of detection from 5 pg per milliliter (by spectrophotometry) to 0.5 pgper millilitre thus it is a reliable and sensitive method to detect dentine sialophosphoprotein in gingival crevicular fluid.[14]

6. **Mass spectroscopy analysis:** The main goal was to identify novel biomarkers associated with root resorption and the protocol was able to identify 2789 and 2421 proteins in the control and resorption pooled samples, respectively [15]

MANAGEMENT

Drugs

1. **Echistatin:** Echistatin is a viper venom disintegrin (cystein rich proteins) Arginine-glycine-aspartic acid (RGD) containing peptide. It inhibits the resorptive activity of isolated clast cells. It blocks the attachment of clast cells to the substrate via interaction with theávâ3 integrin structure. Echistatin significantly decreased root resorption surface areas and reduced the number of root resorption lacunae. [16]

2. **Bisphosphonates:** Local clodronate inhibits root resorption incident to tooth movement. The topical administration of risedronate caused a significant and dose-dependent inhibition of root resorption after the orthodontic force was applied.[17]

3. **Prostaglandin:** A significant difference in root resorption was observed between the PGE2 and control. The findings show the importance of calcium ions working in association with PGE2 in stabilizing root resorption while significantly increasing OTM.

4. **Lithium:** Lithium chloride can attenuate orthodontically induce root resorption during orthodontic tooth movement and its effect on tooth movement is insignificant

5. **Nambumetone:** Nabumetone was found to be useful in reducing pulpitis, external root resorption, and pain caused by intrusive orthodontic movement, without altering tooth movement in response to the application of orthodontic force. [18]

6. **NSAID:** Prednisolone and celecoxib suppress orthodontically induced tooth movement and root resorption. High dosage (16 mg/kg) of celecoxib suppresses root resorption significantly more than low dosage(3.2 mg/kg). The mechanisms between tooth movement and root resorption are suggested to be different, which may lead to different dose thresholds of celecoxib affecting tooth movement and root resorption.

7. **Tetracycline:** Anti-inflammatory properties of tetracyclines (and their chemically modified analogues) unrelated to their antimicrobial effect has shown a significant reduction in the number of mononucleated cells on the root surface. Such cells have been related to root resorption

8. **Strontium ranelate:** The animals treated with strontium ranelate showed up to 40% less tooth movement after four weeks of orthodontic treatment and may be a viable agent for inducing tooth anchorage and reducing undesired root resorption in orthodontic treatment.

9. **Lithothamnium supplement:** Lithothamnium supplement, a calcium-rich widely used for mineral reposition, on strain-induced orthodontic tooth movement [OTM]).Studies suggests that the CaCO3 from LTT decreases the number of osteoclasts and inflammatory mediators and, consequently, reduces alveolar bone resoption. This is a demonstration that dietary intake might play a role in OTM and resorption.[19]

10. **Growth harmone:** The inhibitory effect of GH on root resorption by heavy force might be mediated by RANKL/OPG and IGF-I. Short-term GH administration may be a method with which to reduce root resorption and shorten treatment time, especially in patients who are susceptible to root resorption

Pause during the treatment

Effect of a pause in active treatment on teeth that had experienced apical RR during the initial 6-month period with fixed appliances. The results showed that

the amount of RR was significantly less in patients treated with a pause (0.4 - 0.7 mm) than in those treated with continuous forces without a pause (1.5 - 0.8 mm).

LIPUS (low-intensity pulsed ultrasound)

LIPUS at 100 or 150 MW/cm2 groups displayed decreased RR, decreased osteoclast numbers and activity levels, increased OPG/RANKL expression ratios. High-power SEM revealed reparative cementum in the LIPUS treated samples. LIPUS regulates osteoclast differentiation via the OPG/RANKL ratio, evoking a reparative effect on orthodontically induced root resorption in rats. [20]

Other

Alternative options might include prosthetic solutions to closespaces, releasing teeth from active archwires if possible, stripping instead of extracting, and early fixation of resorbed teeth

CONCLUSION

The finding of EARR is a common sequalae to orthodontic treatment. As such it needs to be part of the informed consent process which is to be taken before orthodontic treatment. Mechanical forces and other environmental factors do not adequately explain the variation seen among individual expressions of root resorption.The question if there is any ideal (optimal) force to move teeth without root resorption and whether root resorption is predictable remains unanswered. In the future, before orthodontic treatment, patients might be analyzed according to the genes IL-1 (and others) by DNA analysis from buccal swab cells. Likewise, the presence of high-risk alleles could also be verified.

Conflict of Interest: Nil

Source of Funding: Self

Ethical Clearance: Ethical clearance not required as it is a review article

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Explorating Employee Creativity as a Driver to Empower Employees in Hospitality Industry

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ABSTRACT

Objectives: To study the impact of intrinsic motivation and psychological empowerment on the employee creativity. To analyze the correlation between intrinsic motivation and psychological empowerment and its impact that relates to employee creativity.

Method/Statistical Analysis: A total of 232 questionnaires used for analysis. This study was carried out by visiting the employees in their hotels. The SPSS 20 version and AMOS were used for data analysis.

Findings: SEM was used to test the hypotheses framed and was examined with respect applicable theory.The most reported fit indices were the CF1, GF1 and AGF1.CFA was used to test each construct's convergent validity and CFA was completed with all latent variables with the entire sample in the study. All items were significant as required for convergent validity (more than 0.7).

Applications/ Improvements: This study, the data is used to infer the factors have effect on the employee creativity. The Management has to orient and train the new recruit in developing employee creativity and inculcate the creative process engagement to the employees.

Keywords: *Intrinsic Motivation, Psychological Empowerment, Employee Creativity, Chennai Hotels.*

INTRODUCTION

Empowerment is about achieving management goals, it means getting the whole team involved in attaining success in the business. According to the researches, empowered employee in the organizations will be more competitive and gain commercial advantages. Additionally it suggest that traditional command and controlled environment disempowers the organisation employees. Empowered organizations will become the norm in the modern era and the traditional disempowered organisation will be driven from business under the weight of competitive pressure, inflexibility and atrophy.The organization's success always depends on the employee performance. So success of the hotels business always depends on employee'smotivation on job. Intrinsic motivation remains an important construct, reûecting the natural human propensity to learn and assimilate[1].

Among the various factors in this study the two main factors were included such as intrinsic motivation and psychological empowerment which had relationship on employee creativity. Creative motivational orientation, enhanced by rewards, strongly affects innovative performance[2].

These reasons have risen to the development of this research in the hospitality industry. The organizations have faced challenges in the retention of employees and the competitive service quality so these were the main focal point. Consequently to investigate and understand these factors affecting the employee creativity in hospitality industry was the core intention to conduct this study.

Review of Literature

Intrinsic Motivation: It is defined as performing an action or behavior because you enjoy the activity itself, the inspiration for acting on intrinsic motivation can

be found in the action itself.Regarding to these definitions it could be inferred that intrinsic motivation creates a felt obligation by the employee even when the support from the organization is minimal.

In addition, support for the buffering role of intrinsic motivation was found, as mastery-approach goals were unrelated to turnover intention when intrinsic motivation was high.[3] The out come of a motivated employee brings about an expanding organization. . Also there exists a positive relationship between employee motivation and organizational effectiveness.[4]

Psychological Empowerment

Empowerment heightens employees' sense of personal control and motivates them to engage in work, which in turn results in positive managerial and organizational outcomes[5]Psychological empowerment is defined as "intrinsic task motivation reflecting a sense of self-control in relation to one's work and an active involvement with one's work role"[6]

Our theory is grounded in the notion that, when used jointly, these organizational resources maximize each of the three underlying psychological conditions necessary for full engagement; namely, psychological meaningfulness, safety, and availability. [7]

In the result of the employee are empowered and was strongly associated with overall performance.Thus it is understood that the well being of the employees and the growth of the organizations are a two sided coin.[8]

Employee Creativity

Employees are always the actual asset for the hospitality industry, in the competitive market an effective employee source always considered a key element for the successfulness of the business organization. The intellectual capacity of the employees helps the concern in reducing the cost of expenditures, new product developments, generating new ideas into the concern practice and procedures[9].

The job complexity and a good relationship among the supervisor and the employees enhance the creativity among the employees which in turn have a positive impact on the concerns new ideas and improve their performances.[10]. The modern use of the technology could not affect the workforce of the industry it must be considered as an added value into the industry in the improvement of the skills and creativity development of the employees as these modern equipment could not compensate a human skill, knowledge and the creativity of the employees.[11]

The Research Model

The variables and their relationship are presented in the Figure 1. In this model, Intrinsic motivation and psychological empowerment are the independent variables and the employee creativity is the dependent variable. The model also proposes that the employee creativity increases the effects of intrinsic motivation and psychological empowerment.

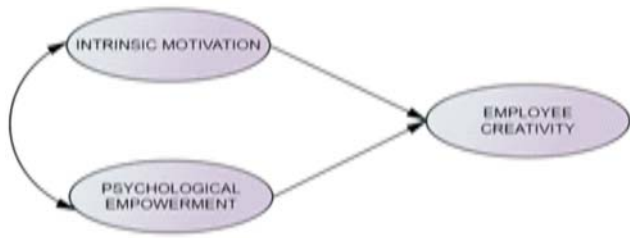


Fig. 1. The Model

HYPOTHESES

To highlight the discussion these hypotheses were proposed

H1: Intrinsic motivation has a positive and direct association with Psychological empowerment

H2: Psychological empowerment has a positive influence on employee creativity

H3: Intrinsic motivation will be positively associated with Employee creativity

OBJECTIVES OF THE STUDY

(1) To study the employee's point of intrinsic motivation and psychological empowerment

(2) To assess the correlation between Intrinsic motivation and psychological empowerment and its impact on employee creativity.

RESEARCH METHODOLOGY

Method of Data Collection and Sample.

This study targeted the employees in these hotels as their work pattern was continuous during the weekends. Data were collected from February 2017 to April 2017.In the six hotels 250 employees were

randomly selected among them male respondents were 73.3% and the female respondents were 26.7%.

MEASUREMENTS

In the questionnaire the scale was taken from Eisenberger study. [12] Intrinsic motivation has items such as take pleasure in performing new tasks and the creative work is very stimulating these items were all reworded and used in this study. All the questions in questionnaire were measured with a five point Likert scale.

DATA ANALYSIS & RESULTS

Test of the Scales

To analyze the data SPSS 20 and AMOS 20 was used. To distinguish the respondents demographic information Descriptive statistics were also used, the male respondents were 73.3% and the female respondents were 26.7%. In the statistical findings, for the scale reliability Cronbach's alpha value was tested with 56 items which was 0.920.So the calculation was further developed as the internal consistency was above the acceptable threshold. To strengthen and validate each item in the variable CFA was tested. A structural model (Figure 1) is also examined with respect applicable theory.Based on Leda Vassalou, it's found that the most reported fit indices are the CF1, GF1 and AGF1[13].Stated that the model chi-square is important, and that this statistics, with its degree of freedom and associated ρ – value, should at all times be reported.[14]

The data analysis was conducted through Structural Equation Modeling (SEM).Hypothetical model was analysed through AMOS20 and model produced fit according to the statistical fit indices (Figure 2). Confirmatory factory analysis (CFA) was engaged to test the convergent strength of each construct. CFA was completed (Figure 3) with all the latent variables with the complete sample in the study. The results from the AMOS estimates were used to test the Convergent and Discriminant validity. Standardized regression weights are the factors loadings, and these were to verify the convergent validity. All loadings in Table 1 are important as necessary for convergent strength (more than 0.7) According to Osman the average variance that is extracted among the various items should be more than 0.5 and if the factor loadings are higher than 0.5,then it is significant. [15]

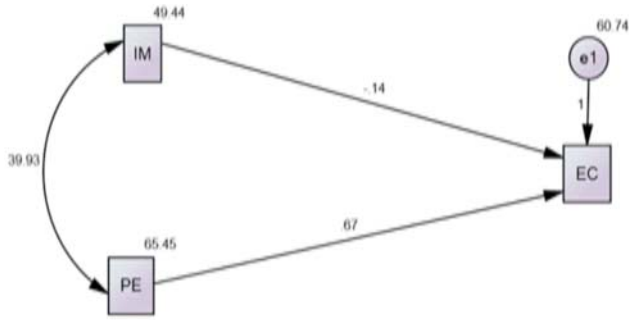


Fig. 2. SEM Model with Paths

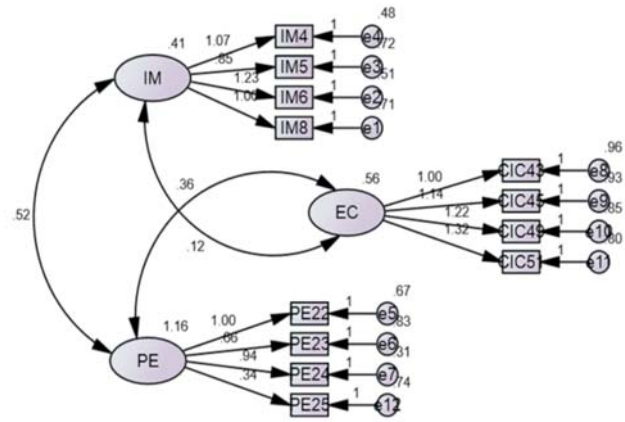


Fig. 3. CFA Model

Table 1: Standardized Regression Weights:

Paths	Estimates
STIMULATING<—Intrinsic Motivation	.703
INTERESTED<—Intrinsic Motivation	.539
INSPIRED<—Intrinsic Motivation	.740
FACECHALLENGES<—Intrinsic Motivation	.606
KEEN_PERFORMING<—Psychological Empowerment	.795
PASSIONATE_CREATIVE<—Psychological Empowerment	.619
INFLUENCES_DECISION<—Psychological Empowerment	.876
NEW IDEAS<—Employee Creativity	.606
INCREASE QUALITY<—Employee Creativity	.662
BETTER OPPORTUNITIES <—Employee Creativity	.702
PROMOTES INDIVIDUALITY <—Employee Creativity	.740

. The value of more than 0.7 suggests that the construct validity is high-quality. High construct consistency indicates that internal reliability exists. The results of this construct reliability are tabulated in the table 1. It is understood that the measures are constantly representing some factor.

Table 2: Covariances:

Path	Estimates	SE	CR	P value
PE<—> EC	.357	.079	4.521	0.000**
IM<—> EC	.122	.045	2.733	0.006**
IM<—>PE	.518	.085	6.079	0.000**

The covariances between the three variables are estimated and tabulated in the Table 2. The correlation between the variables are also estimated. These estimates are called standardized covariances. These measures are used for calculating the discriminant validity. Hence, the HBAT construct CFA model expresses discriminant validity.

Table 3. Correlations:

Path	Estimates
PE<—>EC	0.443
IM<—>EC	0.255
IM<—>PE	0.752

The Table 3, exhibits that the employees demonstrate significant positive correlations between employee creativity and intrinsic motivation. This outcome goes parallel with the end result [16]. Hence, H1 and H2 are customary in the path between intrinsic motivation and psychological empowerment, as the key value is less than <0.05, there exists a strong correlation between intrinsic motivation and psychological empowerment there fore H3 is accepted in the path of relationship between intrinsic motivation and psychological empowerment as the ρ-value is greater than 0.05 there exist a slight correlation between the variables. The present study's obtained results are similar to the previous study found that perceived organizational support has an effect on the employees in the chain hotel.[17]

Author Deci finding is consistent with this study who said that the employees experiencing high determination or more satisfied with their jobs.[19]The present data indicates that intrinsic motivation is related to the employees are stimulating, inspired, interesting and overcome challenges in creativity. The study conducted by George & Brief stated that the opportunity to carry out job activity is once own way to encourage the exploration of the skills and talents. [20] The data specifies a favorable robust for this study's hypothesized model. The direct model of this study exhibits a comparative fit index (CFI) values. The outcome of the model indicates a constructive fit of the model. Results are presented Table 4

Table 4. SEM Model Fit Summary

Fit Index	Acceptable Threshold Levels	Goodness of fit
Chi-squareχ^2	if Chi-square is 0 perfect model(UlkerColakoglu 2010))	0
GFI	Values greater than0.95	1
Incremental Fit Indices		
CFI	Values greater than 0.95(Manimalar&Sudha 2016)	1
AGFI	Values greater than 0.95	1

The Table 4 illustrates the results of the SEM model. The model fit summary is tabulated that illustrates that the chi square is significant (Relative $\chi 2(\chi 2/df)$.369, p-value>0.05), all the comparative fit indexes –, CFI, GFI, AGFI, that are greater than the threshold levels of 0.90, prove that the model is fit. Hence, the model shows an overall acceptable fit. The fit model shows that the alternative hypothesis is not accepted which proves that there is a very low positive association between intrinsic motivation and employee creativity among hospitality employees and prevails strong correlation between intrinsic motivation and psychological empowerment..

DISCUSSION

This study's data specify that the analysis exhibits the fine degree of validity. The reliability in this study show the sign of high value. Therefore, these results can be used to infer the reason for employee creativity the employee have to be intrinsically motivated and psychologically empowered. In this study the psychological empowerment has a significant effort on employee creativity. Similar study by West, M. A., & Farr, J. L. (1990)[23] stated that creativity is a valuable necessity for the economic and the organisation growth. Additionally author Roger L. Firestien(1990)[24] expressed tha tan employer's core values such as the efficiency, his creative ideas in promoting the business, effective competition in business act as main inducing powers in the enhancing of the employees work culture.This study made significant aid to the development of the employee's creativity. This study provides an insight to the employer about the employees motivation and psychological empowerment. For maintaining a competitive advantage the top level management in the hotel industry must pay more attention to this study's results to improve and develop the employee's creativity.

Implications

The results have strong implications for supervisor and managers as it would allow them to develop ideal human resources policies based on their employee's expectation in regard to their promotion and salary. The employees should develop their competence and self determination to perform creatively in their daily operation in their respective areas. This study provides an apprehending about the tactical benefits by relating practices into the circumstance for developing countries. Thus, if the hospitality employees are aware of the organizations procedure, they will make more favorable behavior towards creativity. The hotel management employees should pay more attention to develop a supporting situations to the lower level employee to increase the overall motivation and empower their employees psychologically.

Therefore it is recommended that the hospitality human resources team should amend and modify the human resources practices to suit the different level employees. Subsequently the hotel guest can enjoy the positive oriented services from the respective hoteliers.

Limitations and Scope

In this study there are some limitations, the data may enable conclusion about generalized relationship among variables. On the contrary, others factors like creative process engagement, life satisfaction, work life balance may be incorporated in the model as a moderator. In future studies, the scholars can choose from various industries.

Conflict of Interest: Nil

Source of Funding: Self

Ethical Clearance: NA

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A Study of Supine Vs. Prone Positioning on Responses of Preterm Infants on Ventilator Support- A Randomized Controlled Trial Protocol

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ABSTRACT

Background: Preterm infants spend a considerable amount of time in the Neonatal Intensive Care Unit (NICU)braving the overwhelming stimuli. The sick preterm infants are usually put on ventilator support for their respiratory problems. Ventilation is usually invasive and extremely stressful for these infants. Preterm infants, on ventilation especially on mechanical ventilation may manifest physiological instability. Disorganized sleep states, disruption of the behavioral states/organization and stress may also result in response to the external stimuli exerted due to use of ventilation. Proper positioning may help in providing the necessary supportive care required for these infants.

Methodology: A randomized trial using crossover design will be conducted. A sample size of 30 preterm infants who are admitted to the NICU and who are placed on mechanical ventilation will be assessed for eligibility to be included in the study. The parent(s) of the preterm infants will be approached for informed proxy consent. To achieve an equal distribution of prone-then-supine (P-S) and the supine-then-prone (S-P) position sequence, permuted block randomization will be performed. After the preterm infants are recruited to the study, a study assistant, not involved in the outcome assessment will allocate the preterm infant(s) to either the supine or prone positions after the opening a sealed opaque envelope having the allocation sequence.

Outcome measures (behavioral states/organization and stress responses) will be assessed at the baseline i.e., before providing a particular position, during the entire period of supine positioning and during the entire period of prone positioning.

Keywords: *Preterm Infants, Mechanical Ventilation, Supine Positioning, Prone Positioning, Behavioral States, Stress Responses*

INTRODUCTION

Preterm infants spend more time in the Neonatal Intensive Care Unit (NICU) for their continued growth and existence. Certain stimuli like light, noise and procedures done primarily for survival on preterm infants may be overwhelming. However, infants are known to regulate their responses elicited by external stimuli, like light, noise and other intrusive procedures. [1]Even though infants are able to regulate their responses to external stimuli, it is not so in the sick preterm infants, who are even more vulnerable to the these effects. To add to this, these sick preterm infants are usually put on ventilator support for their respiratory maintenance. Ventilation is usually invasive and extremely stressful for these infants. Preterm infants, on ventilation especially on mechanical ventilation may manifest physiological instability. Disorganized sleep states, disruption of the behavioral states/organization and stress may also result in response to the external stimuli exerted due to use of ventilation.

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The preterm infants' physiological parameters like heart rate (HR), respiratory rate (RR) and oxygen consumption are higher in the awake state than in the sleep state. Physiological parameters greatly influence the preterm infants' behavioral states. Studies have documented that HR as well as oxygen consumption increased when preterm infants switched from quiet sleep to awake state. [2, 3,4]Increased motor activity may in fact change respiratory patterns in these fragile infants resulting in crying, wakefulness and active sleep. [5] Awake states like crying and continued wakefulness as well sleep state like active sleep may cause increased energy expenditure.[6] Crying preterm infants could also exhibit blood pressure changes. [7]

Preterm infants who are on mechanical ventilation are usually placed in a supine position. However, it is proven that prone position improves quiet sleep in neonates. [8] Prone position has may benefits to its credit, such as it is beneficial in decreasing awake time in stable preterm infants[9] and ithelps increase the overall sleeping time in ventilated infants.[10] Prone positioning has also been suggested for preterm infants to promote better sleep and avoid crying. [11.12]Studies conducted using cross-over designs found that preterm infants, who were positioned prone had decreased awake time[9] and also prone placement increased sleep time when compared to supine placement of preterm infants.[10] In addition to sleep states, the behavioral organization cues of stress like startle, tremor and twitches are signs of autonomic instability. [13]

Support and care is an integral part of nursing care. Positioning is part of neonatal nursing integral to the supportive care the nurses provide for the vulnerable preterm infants. Positioning, per say tends to be disregarded as an important aspect of care in neonatal nursing, especially when it comes to preterm infants. There are very few studies conducted to determine the effect of positioning on behavioral states/organization and stress responses in stable preterm infants. However, there are virtually no studies attempted on ventilated preterm infants. To provide a better supportive environment for ventilated preterm infants, further evaluation of supine vs. prone positioning is essential. Therefore, the aim of the present study is to compare the effect of supine and prone positioning on behavioral states and stress responses in preterm infants on ventilator support.

OBJECTIVES OF THE STUDY

The main objectives are to

1. Compare the effects of supine and prone positioning on behavioral states of ventilated preterm infants
2. Compare the effects of supine and prone positioning on stress responses of ventilated preterm infants

HYPOTHESES

H1: There will be significant difference in the behavioral states between the supine and prone positioning in ventilated preterm infants.

H2: There will be significant difference in the stress responses between the supine and prone positioning in ventilated preterm infants.

BRIEF METHODOLOGY

Research Approach: Quantitative Approach

Research Design: Randomized Controlled Trial using crossover design

Research Setting: NICU of a tertiary referral hospital

Population: Preterm infants on ventilator support admitted to NICU of a tertiary referral hospital

Sample: Preterm infants who are $25^{0/7}$ - $34^{6/7}$ weeks Post Menstrual Age (PMA) and are admitted to the tertiary level NICU for ventilator support.

Sample size: A difference of 5% of total quiet sleep, which is a behavioral state between the supine and prone positions, will be considered clinically significant. With a standard deviation of 10% for a small group of sample, a total sample of 30 preterm infants on mechanical ventilation will be required to reach 80% power with an alpha level of <0.05.

Inclusion criteria

Preterm infants,

- who are $25^{0/7}$ - $34^{6/7}$ weeks PMA
- on ventilator support
- postnatal age d" 7 days

Exclusion criteria

Preterm infants,

having frequent changes in ventilator settings

seriously ill

with congenital malformations or dysmorphic features

Randomization and allocation

Once the preterm infants are admitted to the NICU and are placed on mechanical ventilation, they will be assessed for eligibility to be included in the study. Once the preterm infants are found eligible to be included in the study, the parent(s) of the preterm infants will be approached for informed proxy consent and participant information sheet will be provided. To achieve an equal distribution of prone-then-supine (P-S) and the supine-then- prone (S-P) position sequence, permuted block randomization will be performed. After the preterm infants are recruited to the study, a study assistant, not involved in the outcome assessment will allocate the preterm infant(s) to either the supine or prone positions after the opening a sealed opaque envelope having the allocation sequence.

Study Protocol in brief

Each infant will be assigned randomly to a position sequence, (P-S) or (S-P). Each infant will be placed in the initially allocated position (either P-S or S-P) for a period of four hours, followed by the other position for four more hours in a consecutive period. For each position, observation will be done after an initial period of stabilization that will last for 10 minutes. Following the initial period of stabilization, the behavioral states and the stress responses of the preterm infants will be recorded by outcome assessors.

Adjustments of ventilator settings will be avoided during the entire study period except for the minimal care procedures and if the infant turns out to be very sick and needs adjustments.When in supine, the preterm infant's head will be placed in the midline or slightly turned to one side to adapt to the ventilator tubing. When in prone, the infant's head will be turned to one side. In both positions, flexion of extremities will be maintained by bringing the lower extremities close to the body and the hands close to the head. The extremities will also be contained by surrounding the infant's body with a soft roll of cloth. Outcome measures (behavioral state and stress responses) will be assessed at the baseline i.e., before providing a particular position, during the entire period of supine positioning and during the entire period of prone positioning.

DATA COLLECTION INSTRUMENTS

1. Baseline proforma: To assess the baseline characteristics of the preterm infants

2. Behavioral Organization of Preterm infants' tool

   Include behavioral states/organization pertaining to three subsystems in the mechanically ventilated preterm infants namely the autonomic/visceral system, the motor system and state and attention-interaction system. The behavioral states in preterm infants on ventilator support will be measured using a valid and reliable 'Behavioral Organization of Preterm infants' tool. The tool was validated by a panel of multidisciplinary national and international experts who had assessed, reviewed, and had suggested modifications for the tool.The content experts who validated the tool were Neonatologists/Pediatricians, Clinical Psychologists and Perinatal/Neonatal nurses who had an average of above 10 years of experience in their respective disciplines. [14]

   The tool was constructed as a categorical scale with rubrics for scoring each domain clustered under the three systems. The tool has a point system scoring, with scores ranging from zero to three for the four domains in the autonomic system, scores from zero to two for the motor system having two domains and the state system and attention/ interaction system had three domains with progression of scores ranging from zero to four. The total scores obtained for each system will be further classified as scores suggesting normal, suspicious and abnormal behavioral states/organization of the preterm infants. The tool was pretested on preterm infants who were admitted to the NICU. The inter-observer and test-retest reliability of the tool was done. The tool was found to be reliable to use since the correlation magnitude of accuracy (r=0.85) calculated for all the subsystems of the instrument were slightly higher than the stability coefficient (r = 0.83) calculated for the subsystems of the instrument.

3. Stress responses proforma:Will include observation of the autonomic instability-related motor responses in preterm infants like startle, tremor, and

twitch that are recognized as infant stress signs. The startle response is defined as "sudden large amplitude jumping movement of arms or trunk or legs or whole body"; the twitch response is defined as "small amplitude, brief contractile response of extremities"; and the tremor response is defined as "trembling or quivering of extremities."[13]

These stress responses will be observed in the ventilated preterm infants during the entire period of the protocol i.e., four hours each in (P-S) or (S-P)positions. The frequencies of these responses will be recorded continuously whenever the responses would occur during the entire period of the protocol.

If any infant is not able to complete the study period, data standardization will be done. The frequency of occurrence of behavioral state and stress responses will be characterized by frequency of occurrence and will be converted into percentage of total possible time.

Ethical considerations

The study protocol is approved by the Institutional review committee (IRC), Manipal College of Nursing, Manipal University, Manipal. Ethical committee clearance for the study will be obtained from the Institutional Ethics Committee of Kasturba Hospital, Manipal. The trial will be registered in the Clinical Trials Registry of India (www.ctri.nic.in).Informed written proxy consent will be obtained from the parent(s) of the preterm infants.

Importance of the proposed study

Research

The proposed study may provide evidence for positioning as a supportive care for ventilated preterm infants. The data obtained may help in planning further studies to address shortcomings pertaining to use of a proper positioning for ventilated preterm infants.

Education

The findings of the study may equip the health care professionals working in the NICU to have an evidence base to utilize proper positioning for ventilated preterm infants.

Quality and effectiveness

Positioning is integral to the neonatal nursing. This study may help in improving the supportive environment for ventilated preterm infants to improve their behavioral states as well as minimize their stress responses.

CONCLUSION

This randomized controlled trial using a crossover design aims to establish the effectiveness of supine vs. prone positioning on behavioral state and stress responses of ventilated preterm infants. The findings gained from the study may help in providing a better supportive environment to the ventilated preterm infants by the primary care providers in the NICU i.e., the neonatal nurses.

Source of Funding: Self

Conflict of Interest: Nil

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Quantification of Weight and Duration of Schoolbag Carriage Based on Socioeconomic Status and its Correlation with Magnitude of Pain among Urban Children of West Bengal, India

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ABSTRACT

Background: Regardless of the Socio Economic Status (SES), children are exposed to musculoskeletal symptoms in different parts of the body due to heavy school bag carriage. This study aimed to quantify weight of schoolbag, duration of carriage among urban male and female children based on SES and hence nutritional status and to correlate SES with magnitude of pain.

Method: This study was conducted among urban school children from different SES of West Bengal, India (n=200). Anthropometric parameters were measured to assess the nutritional status of the children. Subjective quantification of pain was obtained from standardized questionnaire. Student's t test and product moment correlation were done between different parameters.

Results: Results revealed that all the nutritional anthropometric parameters were significantly lower in case of children from low SES. Significant difference was observed for weight of school bag between children of different SES ($p<0.05$) but no significant difference was observed for load carriage as % of Body Weight (BW) ($p>0.05$). Urban male and female children of different SES carried school bag load greater than10% of BW. Bag weight and load as % BW were significantly different between male and female of similar SES ($p<0.05$).

Majority of children suffered from pain in neck, shoulder and back. Perception of pain was higher among children of low SES. Duration of load carriagewas negatively correlated with socioeconomic score. However, it correlated positively with the pain perception.

Conclusion: Ergonomic and nutritional interventions are essential to reduce occurrences of musculoskeletal symptoms due to heavy school bag carriage.

Keywords: *School Bag Carriage, Socioeconomic Status, Nutritional Status, Perception of Pain, Load Limit Optimization.*

INTRODUCTION

School going children, be it from any socioeconomic background, rural or urban, suffer from postural and physiological stress due to mandatory load carriage in the form of their school bags. Heavy school bag carriage imposes physical loading which may lead to back pain, fatigue among children[1].

Approximately 19% (190 million) of the emerging Indian population comprise school age children among whom 30% (48 million) are currently from urban population[2]. While nutrition is the core pillar of human growth and development[3], Socio Economic Status (SES) is an important determinant of nutritional health status of an individual [4]. The pattern of growth also varies with difference in gender[5]. A comparative evaluation

of nutritional status of children belonging to different socio economic condition is necessary for assessment of musculoskeletal symptoms in order to reduce school bag carriage related stress of the children. Therefore, for optimization of the load limit, assessment of nutritional and socio-economic status is important.

Recommended load limit for school bag carriage is 10% of the Body Weight (BW)[6,7]. It is hypothesized that SES and nutritional status may be major determinants of development of musculoskeletal symptoms among children. There is scarcity of study regarding SES and nutritional status specific subjective quantification of perceived pain among children in India. This study aimed to generate the baseline data about weight of school bag, duration of carriage among urban male and female children of different SES. Attempt was made to find out the correlation between SES and magnitude of perceived pain in different body parts of urban children.

MATERIALS AND METHOD

i. Selection of subjects: School children from West Bengal, India of the age group 8-15years were randomly taken for the study and 200 (n) subjects were considered for the study. Consent letters were filled up by the parents and participants before the collection of data. Children was categorized into four different groups- urban males of high socioeconomic background (n=50), urban males of low socioeconomic group (n=50), urban females of high socioeconomic background (n=50) and urban females of low socioeconomic background (n=50). All data collection was done following guidelines of Institutional Ethical Committee (Human) and Declaration of Helsinki. Children with any sort of congenital defects or pathological conditions were not considered for the study.

ii. Evaluation of socioeconomic condition: Socioeconomic status of a family was assessed from standardized questionnaire .[4]

iii. Nutritional Anthropometry:

Height and weight of the children were measured from standardized technique. Body Mass Index (BMI) of the children was calculated[8]. Mid Upper Arm Circumference (MUAC)[9] and calf circumference [10] were the other anthropometric parameters measured to assess the nutritional status of children.

iv. Pain Mapping: The subjective quantification of body part discomfort or pain of the children exposed to daily load carriage was made with 10 point subjective scale for different body parts[11].

v. Statistical analysis: Two tailed (unpaired) Student's t test was performed to find out the significant difference between the parameters of different groups. This was followed by one tailed t test to assess which one was significantly higher or lower. Product moment correlation was done to find out the association, if any, between the different parameters. Standard statistical procedures were employed by using Minitab 17 software.

FINDINGS

Table 1: Characteristics of different physical parameters (Mean and SD upto weight carriage as % of body weight) of different groups (n=200)

Parameters	Urban male children of high SES	Urban male children of low SES	Urban female children of high SES	Urban female children of low SES
Age (years)	11.3 (2.02)	10.7(1.86)	11.4(2.11)	11.7(1.66)
Height (cm)	147.5(12.51)	135.3(12.82)	144.8(11.25)	143.3(8.41)
Weight (kg)	43.8(12.89)	28.9(8.47)	43.8(10.79)	37.2(9.67)
BMI (kg/m ^{2})	19.7(3.41)	15.5(2.27)	20.7(3.57)	18.0(3.62)
MUAC (cm)	23.6(3.61)	18.1(3.07)	24.2(3.57)	21.6(3.38)
Calf circumference (cm)	30.7(3.89)	24.7(3.28)	30.8(3.52)	27.9(3.92)
Weight of schoolbag (kg)	5.8(1.24)	3.8(1.20)	5.0(1.50)	4.2(1.46)
Weight carriage as % of BW	14.0(3.78)	14.1(6.03)	12.2(4.82)	11.7(3.96)
Percentage of children carried weight ≤ 10% of BW (%)	16	26	36	30
Percentage of children carried weight >10-15% of BW (%)	42	26	48	50
Percentage of children carried weight >15% of BW (%)	42	48	16	20

Table 2: Significant difference between parameters of different groups

Parameters of different group showing significant difference between them	pValue
Height, weight, BMI, MUAC and calf circumference of the male children between high and low SES **	$p < 0.05$
Weight, BMI, MUAC and calf circumference of the female children between high and low SES **	$p < 0.05$
Absolute weight of schoolbag of male children between high and low SES **	$p < 0.05$
Absolute weight of schoolbag of female children between high and low SES **	$p < 0.05$
Schoolbag carriage as % of BW between male and female children of similar SES **	$p < 0.05$

**= significantly higher (first group)

Table 1: Shows characteristics of different physical parameters of different groups and Table 2 shows significant difference between parameters of different groups

Table 3: Percentages of children suffering from pain in different parts of the body (n=200)

Group	Neck	Shoulder	Upper arm	Lower arm	Back	Buttock	Thigh	Legs
Urban male children of high SES	36%	56%	6%	4%	24%	6%	8%	20%
Urban female children of high SES	40%	68%	12%	8%	44%	—	12%	30%
Urban male children of low SES	44%	62%	28%	12%	64%	—	42%	56%
Urban female children of low SES	64%	66%	30%	—	62%	—	22%	56%

Table 3 shows percentage of children suffering from pain in different segments of the body. Percentage of children exposed to pain was higher in case of low SES group for both male and female.

Table 4: Correlation between mean socioeconomic score and mean magnitude of perceived pain (n=163)

Group	Segments of the body							Mean Socioeconomic score
	neck	shoulders	upper arms	lower arms	back	thighs	legs	
Urban male children of high SES	1.2	2.3	0.04	0.1	0.5	0.04	0.8	62.4
Urban female children of high SES	1.6	2.6	0.3	0.2	1.3	0.1	1.1	62.5
Urban male children of low SES	1.9	2.8	1.2	0.4	1.6	2.2	2.9	33.7
Urban female children of low SES	3.4	3.1	1.2	0.3	1.5	1.2	2.8	37.7
r value	-0.68	-0.81	-0.98	-0.92	-0.75	-0.95	-0.99	

Table 4 shows correlation between socioeconomic score and magnitude of pain. With increase in Socio Economic (SE) score, the magnitude of pain in different segments of the body was decreased.

Table 5: Correlation between mean duration of load carriage and mean socioeconomic score (n=200)

Group	Duration (min)	SE Score
Urban male children of high SES	8.9	63.0
Urban female children of high SES	9.9	62.3
Urban male children of low SES	27.6	35.3
Urban female children of low SES	26.1	37.7
r value	-0.99	

Table 5 shows the correlation between duration of load carriage and socioeconomic score. With the increase in SE score, the duration of load carriage decreased.

Table 6: Correlation between mean duration of load carriage and mean magnitude of pain perception (n=163)

Group	Segments of the body							Mean duration (min)
	neck	shoulders	upper arms	lower arms	back	thighs	legs	
Urban male children of high SES	1.2	2.3	0.04	0.1	0.5	0.04	0.8	9.1
Urban female children of high SES	1.6	2.6	0.3	0.2	1.3	0.1	1.1	10.5
Urban male children of low SES	1.9	2.8	1.2	0.4	1.6	2.2	2.9	28.4
Urban female children of low SES	3.4	3.1	1.2	0.3	1.5	1.2	2.8	25.7
r value	0.69	0.83	0.99	0.94	0.79	0.96	0.99	

Table 6 shows correlation between duration of load carriage and magnitude of pain perception. With the increase in duration of load carriage, the magnitude of pain perceived in different segments of the body increased.

Previous report revealed that under nutrition is highly prevalent in rural areas than in urban region [12]. In this study emphasis was given to school bag carriage of urban children of different SES and gender. This study showed that parameters used to assess nutritional status were significantly lower among children of low SES compared to those of high SES. All the nutritional anthropometric parameters such as height, weight, BMI, MUAC and calf circumference of the male children of high SES was significantly higher than those of children of low SES. In case of females, weight, BMI, MUAC and calf circumference of the female children of high SES was significantly higher than those of children of low SES.

This study revealed that male and female urban children of different SES were exposed to heavy school bag carriage i.e., more than 10% of their BW. Several researches revealed that the average load carried by the children varied to a great extent among studies. Studies also showed that the children carried load beyond the recommended load limit [13-15]. Irrespective of SES, it was observed that load carriage (as % of BW) was significantly higher among male children compared to that of the females, though absolute weight of schoolbag was significantly lower among male children of low SES compared to that of female children. Considering the load carriage (as % of BW), it might be stated that urban male children were more susceptible to schoolbag carriage related stress compared to female children of similar SES. Schoolbag carriage both below 10% and above 15% of BW were higher among urban male children of low SES compared to high SES. In case of female children, schoolbag carriage below 10% and above 15% load of BW were higher and lower respectively among high SES group compared to low SES group.

Previous study showed that urban children carried significantly heavier bag compared to rural children [16]. But in this study focus was given on comparative evaluation of weight of school bag and load carriage as % of BW among urban children based on SES and gender. The amount of school bag weight carried by male and female children of high SES was significantly higher compared to that of low socioeconomic status ($p<0.05$) but no significant difference was observed in weight carried as percentage of body weight. This is because the children of low SES had a low body weight thus as % the weight between the groups became insignificant.

Previous study showed the postural and perceived response of school children exposed to different load' condition. [17] Musculoskeletal symptoms among children are increasing [18]. Previous studies investigated the association between schoolbag carriage and development of musculoskeletal pain [14, 19]. Researchers showed that the association of heavy backpack use and prevalence of back pain and its lifetime prevalence was very high [13, 20]. This study also showed that children perceived pain in different segments of the body. Among the male children of high SES, pain was reported in neck, shoulder, upper arms, back and buttock region while pain was prevalent in neck, shoulder, upper arm, lower arm, back, thigh and leg in case of low SES group. Percentage of children perceiving pain was different based on their SES. Except the buttock region percentage of children belonged to low SES experiencing pain in different segments of the body were higher compared to high SES group. Female children of high SES suffered from pain in neck, shoulder, upper arms, back, leg region and along with these segment thigh region was found to be affected in case of female children of low SES. Among the females it was noted that percentage of children belonged to low SES experienced pain in different segments of the body were higher compared to high SES group.

This study revealed that lower the SES, higher was the magnitude of pain perceived although there was no significant difference in the load carriage as percentage of BW. Thus it can be stated that urban male and female children of low SES is more vulnerable to schoolbag carriage related perceived stress. Quantification of duration of school bag carriage is important because prolonged duration of load carriage may lead to repetitive stress injury among the growing children [16]. It was observed from the study, that lower the SE score, higher was the duration of load carriage and higher the duration of carriage, higher was the perception of pain.

CONCLUSION

Urban male and female children regardless of their SES are exposed to musculoskeletal symptoms such as pain and discomfort in various part of the body due to heavy school bag carriage. Modification in method of schoolbag carriage, pain management and nutritional

improvement are required to be implemented to reduce school bag carriage related stress. Thus this study revealed the necessity of SES and nutritional status specific load limit optimization among school children.

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Forming Local Support System (LSS) Model as Agent of Change Behavior of Clean and Healthy Household in Riverbanks of Banjar Regency

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ABSTRACT

PHBS is currently the theme of an important strategy in improving public health status. PHBS development program is a program that has been running since 1996. However, its success is still far from expectations. In South Kalimantan in 2015, the percentage of households with PHBS is 60.09%. The coverage of PHBS households in the work area of the District Health Office of Banjar in 2015 amounted to 52.1%.Based on the success of the previous cadre program, the alternative solution that can be done in the field is the formation of Local Support System (LSS) model as an agent of change of clean and healthy life behavior in the household order. This research uses analytic design, with Cross Sectional approach. Subjects were 90 peoples. Based on the results of the activity it was found that there was no significant correlation between knowledge, support of community leaders, and support of health officers and household PHBS strata shown with p-values of 0.337, 1,000 and 0.059, respectively.However, there is a correlation between education level and household PHBS stratum with p-value= 0,014, and there is significant difference before counseling and after counseling p-value equal to 0.0001. Suggestion from this research is LSS modeling is expected to become a model which can be one way to increase PHBS coverage of household order and to maintain positive behavior of community in applying PHBS of household order.

Keywords: *PHBS Household, Local Support System (LSS), Cadre*

INTRODUCTION

Health is a human right that must be considered for the progress of the nation and is an investment of human resources, and has a great contribution to improve the Human Development Index (HDI) [1]. According to H. L. Blum's theory, there are several factors that affect health, namely hereditary, behavior, health service, and environment[2]. Behavior is a factor that affects the degree of health is large enough (30-35% of health degree). So, it takes various efforts to change unhealthy behavior to be healthy. One of them is through the program of Clean and Healthy Behavior (PHBS) especially in the household setting[3].

PHBS in the household setting is an effort to empower household members to know, willing and able to practice clean and healthy living behaviors and play an active role in the health movement in the community. PHBS in the household is done to reach households PHBS[4]. Some household members are vulnerable to infectious and non-infectious diseases, therefore to prevent them from being empowered to implement PHBS. PHBS can prevent individuals, groups and communities from infectious and non-infectious diseases. However, if the application of PHBS is still low it will cause various diseases such as diarrhea, malnutrition, malnutrition, dengue, ISPA and others that will cause low public health status[5].

PHBS development program is a program that has been running since 1996. However, its success is still far from expectations[6]. Percentage of PHBS households in Indonesia in 2015 only reached 55.46%. As for South Kalimantan in 2015, the percentage of households with PHBS is 60.09%. The coverage of PHBS households in

the working area of Banjar Regency Health Office in 2015 was 52.1%. This figure is below the target set by the Ministry of Health in the Strategic Plan (Renstra) of the Ministry of Health 2015-2019 which set a target of 70% households PHBS by 2015. This indicates that the coverage of households who have PHBS in Kabupaten Banjar is still lacking[7,8].

Based on data known that Puskesmas Sungai Besar is a health center located in the work area of Banjarbaru City and the only health center that already has PHBS household cadres in its working area. Based on data from the Banjarbaru City Health Office on PHBS of households in 2014, the coverage of households implementing PHBS in the largest household setting is in the working area of Sungai Besar Public Health Center, which is 93.3%.So that this clinic becomes the only health center in Banjarbaru city working area that reach the target of Banjarbaru City and national target. Based on the primary data from interviews conducted, the organizer of Health Promotion Program (Promkes) at the Puskesmas Sungai Besar stated that the cadres have 80% role in the success of the PHBS program in the household order.The above-mentioned factors have an alternative solution. Based on the success of previous programs that have been done, the alternative solutions that can be implemented in the field is the formation of Local Support System (LSS) model as an agent of change clean and healthy life behavior in the domestic order.

METHOD

The design of this research is analytic, with Cross Sectional approach, which aims to find out the effectiveness of Local Support System (LSS) model as an agent of change of clean and healthy life behavior of household order in Bantaran Sungai Kabupaten Banjar. The research subjects were households located on the riverbanks of Banjar Regency with a sample of 90 peoples. Independent variable (variable independent) in this research is development of Local Support System (LSS) model, whereas dependent variable (dependent variable) is increasing PHBS coverage of household order.Data for household PHBS implementation are made in percentage form with paired T Test to see the difference after and before LSS modeling. In addition, there is also an increase in the value of each week to see the success of the LSS model.

RESULTS AND DISCUSSION

Univariate Analysis

Table 1 Distribution of Respondent Frequency Based on Household PHBS Strata, Knowledge, Education Level, Community Leader Support, and Health Officer Support.

No	Variable	Category	Frequency	Percentage(%)
1	Household PHBS Strata	Madya	36	40
		Primary	54	60
2	Knowledge	Low	11	12,2
		High	79	87,8
3	Education Level	Low	62	68,9
		High	28	31,1
4	Support of Community Leaders in Household Hygiene	Yes	77	85,6
		No	13	14,4
5	Support of Community Leaders in Mosquito larva eradication	Yes	34	37,8
		No	56	62,2
6	Support of Community Leaders for Work of Devotion	Yes	23	25,6
		No	67	74,4
7	Support Community Leaders to get involved in the Health Program	Yes	74	82,2
		No	16	17,8
8	Health Officer Support	Doesn't Support	12	13.3
		Support	78	86.7
Total			90	100

Source: Primary Data 2017

Based on table 1, results showed that respondents with the category of household PHBS strata amounted to 36 (40%) respondents. According to Auliya (2012) study, the strata PHBS of the household order, which is a level of healthy and clean living behavior in every household that has been established by the local health service that includes several strata PHBS households among others healthy pratama, healthy madya, healthy mainand healthy paripurna[9].The results also showed that respondents who have low knowledge about PHBS amounted to 11 (12.2%) of respondents. The low knowledge of respondents can be caused by a lack of information sources and the influence of the environment. According to Mubarak (2007), ease of obtaining information can help speed up a person to gain new knowledge[10]. Information is data that is processed into a form and has real value. Such information may come from electronic print media. According to research conducted by Suhaimi R (2012), another factor that affects knowledge is the environment. The environment that provides many sources of information will increase one's knowledge[11].

Based on table 1, it can be seen that the highest education level of respondents in this study are respondents with low education as many as 62 people (68.9%). Low level of education in question is not finished primary school, primary school, and junior high school / equivalent. While the meaning of high education level is SMA / equal, D3 / S1 and S2. The results of the study also showed that respondents who claimed to have no support from public figures in household hygiene of 13 (14.4%) respondents, did not get the support of community leaders in eradicating mosquito larvae of 56 (62.2%) respondents, (74.4%) of respondents, and did not get the support of community leaders in health programs for 74 (82.2%) respondents.

Community leaders are prominent and prominent people in various areas of life in society[12]. In addition, community leaders are people who have influence and respect in the community environment which is a role model for people who can instill beliefs that have a positive impact on public health. Is one of the potential in development to mobilize the community to participate in the implementation of village development in order to create national development. People have a great influence in mobilizing the wider community, because the general public is more receptive to what is described by its role models[13]. According to WiwikTapsilowati (2008) in SittiChadijah et al (2011) research, that the guidance and attention of the health sector to activities undertaken by community leaders is still lacking, so in need of active participation from health workers to be directly involved in the community[14].

Bivariate Analysis

Table 2. Statistical Test Results between Knowledge and Strata PHBS Household

No	Variable	Category	Household PHBS Strata				Total		p-value
			Madya		Primary				
			n	%	n	%	n	%	
1	Knowledge	Low	6	54,5	5	45,5	11	100	0,337
		High	30	38,0	48	62,0	78	100	
2	Education Level	Low	19	30,6	43	69,4	62	100	0,014
		High	17	60,7	11	39,3	28	100	
3	Support of Community Leaders	Doesn't Support	8	38,1	13	61,9	21	100	1,000
		Support	28	40,6	41	59,4	69	100	
4	Health Officer Support	Doesn't Support	8	66,7	4	33,3	12	100	0,059
		Support	28	35,9	50	64,1	78	100	

Source: Primary Data 2017

The result of statistical test using fisher exact test with 95% confidence level, showed no significant relationship between knowledge and household PHBS strata shown with p-value = 0,337 (> 0,05). This study is in line with the study Deksius G (2017) which states that there is no relationship between knowledge with behavior towards an event. This can be caused by respondents whose knowledge is not necessarily good

behavior clean and healthy life or take action in accordance with what is known by the respondent. The possible causes are cultural factors[15].

The result of statistical test using chi square test with 5% confidence level shows p-value = 0,014, so p-value is smaller than alpha value (<0,05) or Ho is rejected, it means there is correlation between level of education with strata PHBS in household . The results of this study are in line with the research conducted by Mursad which shows there is a significant correlation between education with the implementation of PHBS indicator on household with p-value equal to 0.0001[16]. Research by HidayatullahMursad also shows the correlation between educational level with clean and healthy life behavior with p-value 0.013[17].

The result of statistical test using chi square test with 5% confidence level shows p-value = 1,000, so p-value is bigger than alpha value (<0,05) or Ho is accepted, meaning no relation between support of public figure with strata PHBS household. Community leaders are also role models of health behavior. The result of statistical test using chi square test with 5% confidence level shows p-value = 0,059, so p-value is bigger than alpha value (<0,05) or Ho is accepted, meaning there is no relation between health officer support with strata PHBS in household.

Support from health workers will make the community have a better strata PHBS household. Although statistically there is no correlation between health care support with household PHBS strata, but descriptively shows that the higher the support of health officer, the higher the household PHBS strata owned by a community and the lower the support of the health officer, the lower the strata PHBS community households. So it can be concluded that with the support of health workers, the better indicator of household PHBS is fulfilled.

Pre Results and Post Test Community Knowledge Before and After Intervention

Table 3: Differences in Community Knowledge Before and After Intervention

No	Education Level	Before Counseling		After Counseling		P-value
		N	%	N	%	
1	Low	75	83,8	11	12,2	0,0001
2	High	15	16,7	79	87,8	
Total		90	100	90	100	

Source: Primary Data 2017

Based on table 3, it is known that prior to the extension activities, people who have high knowledge (good) to PHBS only amounted to 15 Respondents (16.7%). Whereas after doing the extension activity about PHBS in the family, there was an increase of knowledge to the society with the amount of society having high knowledge (good) to PBHS as much as 79 respondents (87,8%). Based on statistical test result using paired T test, p = value 0.0001 (<0,05). So from the test results can be concluded that there are significant differences before the extension and after the counseling. Counseling according to Ircham (2007) is a health education activity conducted by spreading the message, instilling confidence, so that people not only aware, know, and understand, but able and willing to conduct a suggestion that has to do with health[18].

The results above, in line with the research conducted by Wijayanti (2016) which shows the results that there are differences in the level of knowledge before and after the counseling with the value of p-value = 0.0001 (<0.05). The existence of a significant difference in knowledge level indicates that the influence of extension activities on knowledge. The results of this study also supported by Hermawan (2013) which states that the knowledge of students before and after given counseling increased from the category of good enough to be good[19].In some studies mentioned that extension activities always give positive effect to the increase of knowledge, so it will be better if done continuously. A person's level of knowledge is one of the most important factors for forming behavior.

CONCLUSIONS

The conclusions of this study are as follows: there is no significant relationship between knowledge, support of public figures, and support of health workers with household PHBS strata shown with p-value of 0.337, 1,000 and 0.059 respectively. There is correlation between level of education with PHBS strata in household with p-value = 0,014 and there is significant difference before doing counseling and after doing counseling p = value equal to 0.0001. The suggestion of this research is LSS modeling is expected to be a modeling that can be one way to increase the PHBS coverage of the household order and maintain the positive behavior of the community in implementing PHBS of the household order. With the cooperation of local health centers, LSS modeling is expected to be more effective in its implementation.

Ethical Clearance: This study approved and received ethical clearance from the Committee of Public Health Research Ethics of Medical Faculty, Lambung Mangkurat University, Indonesia. In this study we followed the guidelines from the Committee of Public Health Committee of Public Health Research Ethics of Medical Faculty, LambungMangkurat University, Indonesia for etchical clearance and informed consent.

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Conflict of Interest: The authors declare that they have no confict interest.

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Stakeholders' Misbehavior Conduct in HIV/AIDS Mitigations in the Era of Indonesian Decentralization and Democracy

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ABSTRACT

HIV/AIDS cases in Indonesia continues to increase in many areas leading to a disaster although various programs of prevention and control have been conducted by the government together with other stakeholders. The objective of this study is to provide information for the stakeholders on the roles of local authorities, politicians, local businessmen in the era of decentralization and democracy on mitigation and prevention of HIV-AIDS spreading. The study is descriptive qualitative research where the data was derived from performance of NGO when caring HIV-AIDS, commission of AIDS prevention as well as behavior of local authorities and politician in Kalimantan Selatan province during the period of 2010-2015. The misconduct of authorities is reflected in rent-seeking behavior hidden in the shadow of democratic system where policies issued by the local authorities is not for public needs in the prevention and mitigation of HIV-AIDS as it considered unfavorable for the benefit of the local authorities. Moving to democratic system and decentralization not automatically facilitates the policy in HIV-AIDS mitigation but ironically it gives birth to a mentally corrupted and rent seeking leaders.

Keywords: *Misbehavior, Prevention and Mitigations, HIV/AIDS*

INTRODUCTION

The growth of HIV-AIDS case in Indonesia continues exponentially in the last 10 years despite various programs of prevention, control and mitigations of HIV-AIDS have been implemented. In Kalimantan Selatan province, the last 5 years has witnessed the extremely ironical and heartbreaking increase of nearly 400%. This leads to question; what's wrong with the policy in prevention, control and mitigations of HIV-AIDS during this period ?, or whether the policy has been simply a preamble and superficial?, or perhaps HIV-AIDS patients in Indonesia are exploited simply as commercial projects by various parties?

Decentralization era in Indonesia is expected to make society more prosperous and healthier but on the contrary it makes people helpless as elected local authorities behave as kings or queens whose power is unlimited and sadly this could not be separated from governmental system reflected in the direct election of local authorities. Within Indonesian setting, this system requires the candidate to provide a huge amount of financial capital disbursed to constituents , political parties, current local authorities and other sub-system in the model to make the candidates eligible to enter the arena. Therefore, if a person is elected as local, regional authorities and also council member – due to lengthy and costly process - usually they behave arrogant like a king and adhere to rent-seeking behaviour in terms of corruption, collusion, and nepotism that permeates into various aspects of life directly felt by the public as a result of a democratic system under the name of decentralization. Rent-seeking behavior is to facilitate economic activities for one own benefit by using the resources or capital that should be the public's right.[1] Furthermore, rent-seeking behavior is quick and instant way to gain an economic advantage, without having to work hard.[2] Rent-seeking

behavior is increasing fertile because of lust and desire of businesses, bureaucracy, politicians and local authorities to immediately dredge other financial benefits. [2,3] Local authorities and member of the council elected will directly collaborate with politicians and owners of capital in determining the basis for policy and expenditure budget and absolutely control the policy that is in favour of rent-seeking and image creation. [4] The behaviour of the authorities is influenced by other actors outside government institutions including political actors and owners of capital, where this triad makes regulatory where in the end of the story it must produce financial gain quickly.[5] The purpose and benefit of this study is to provide information to the various stakeholders on theirs role in tackling and preventing the spread of HIV-AIDS, especially in Kalimantan Selatan province where within the last 5 years there have been found the increasing of nearly 400% of cases. With the result of thought and analysis of this study, it is expected to inspire the regional and local authorities, politicians, the bureaucracy and the local businessmen as well as other stakeholders create a comprehensive policy for prevention and mitigations of HIV-AIDS in respective area.

MATERIALS AND METHOD

This study is based on descriptive qualitative research derived from observation of the researchers from 2010 to 2015 in districts of Kalimantan Selatan province. Observation and data are collected from performance of NGO in caring HIV-AIDS, commission of AIDS prevention and behaviour of local authorities and politics. All the data is analysed qualitatively with literature review using as comparison related to this study. This study discusses briefly information in providing insight to various parties on how the behavior of the local authorities, bureaucracy, politicians and businessmen in the position of their role should be for the prevention and control of HIV-AIDS in the area.

RESULTS AND DISCUSSION

Government policies prefer and run the policy in economic, businesses, and infrastructure sectors for economic scale reasons which are not found in health development sectors particularly in the control and prevention of HIV-AIDS. Development this sector in terms of economic and political view is not in favor of rent-seeking officials and authorities as it is considered a waste of financial resources for inability to yield the direct economic results and most of all it can neither quickly produce financial benefits nor image creation for the local authorities and member of the board (parliamentary) elected. Therefore, the writer assesses the control and prevention of HIV-AIDS up to this point is just "lips services", even never presented during campaigns by candidates and prospective members of parliament as this issue is not favourable in positioning the image creation.

Governments democratic system aiming at electing local authorities and members of parliament directly has resulted in candidates having to pay so expensive finally to be elected that gave birth to leaders with mentality of rent-seeking behavior resulting at the increase of corruption, collusion, and nepotism. Rent-seeking behavior is a major factor of economic collapse in countries and peoples and this predatory practice that has happened in Indonesia for long time in both centre and regional level of government.[6]

The phenomenon of political corruption is not separated yet from the readiness of political system so if this to continue, the destruction will be massive in Indonesia as the political corruption has continued to target the various aspects of lives and prosperity as well as damaged the global economy. In the eyes of citizens, corruption destroys trust in the integrity of the state, institutions, and office holders. Within Indonesian setting, corruption including rent-seeking is warning us that the state and the political culture are being tested and ironically the longer not the better, instead it brings disaster.[3]

Another problem is the weakness of advocacy and access of the various stakeholders in the field of prevention, control and mitigations of HIV-AIDS in Indonesia that is obviously not enough knowledge, courage, and ability to fit into the policies of the mismanagement of authority. There are several challenges in the practice of health advocacy community, namely: the nature of politics driving

change - there is always a group that is resistant to the change - , then the second challenge is health professionals and the next challenge that last for advocacy is that public health has a linguistic gap between social approach needed for public health and individual approach typically used in health care issues.[7]

Another factor fostering misbehavior of authority or power. The predatory oligarchs are public officials who control the nation's resources for personal gain, relatives, and associates.[6] The existence of predatory mismanagement is closely related to the existence of the patrimonial bureaucracy.[8] Business relations between government actors, local political and businessmen actors are very commonplace and become a culture in the framework of a weak system of government control of the people as it is definitely a very profitable business relationships but very harmful to the people. The local businessmen as local strong men in economics are even able to dictate government policy.[9] Weakening is embedded in autonomy government to make policies for power in group pressure, especially the capital strength to play arounds in political power where the power has been able to exploit the issue of democratization and to change institutional political power to influence the policy of economic and political power itself.[10]

These figures indicate that the issue of nutritional status in society is not ideal yet as still too many people who are undernourished spreading in various parts of Indonesia Timur and Tengah while in Kalimantan Selatan province the figure reaches 24%.[11] The issue of health treatment problem in Indonesia post-reformation era indicates significant growth as Ministry of Health Republic Indonesia data released the continued increase the cases of non-communicable diseases and the more massive case of infectious diseases, such as Tuberculosis and HIV-AIDS every year. Data showed no provincial and district /city that is not infected by HIV-AIDS assumed AIDS cases are nearly one million people because it is an iceberg phenomenon, and usually transmission is over unsafe sex and having multiple partners and this becomes a question; Do Indonesians like to have unsafe sex and multiple partners?

Infants and children

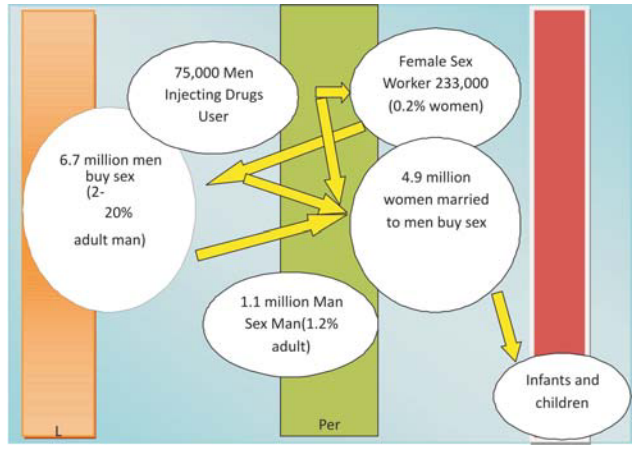


Fig. 1. Vulnerable Populations Transmission of Hiv-AIDS in the Worlds

Source: Ministry of Health Republic Indonesia, 2012

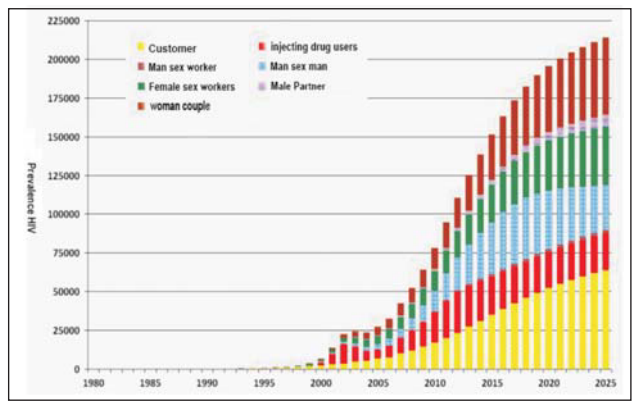


Fig. 2. Shift the Transmission Key Populations HIV-AIDS in Indoensia

Source: Commission AIDS Prevention Indonesia, 2010

In the context of prevention, control and mitigations of HIV-AIDS, in Indonesia both of central and regional governments consider the issues as unimportant and unattractive for image creation. The stakeholders in the prevention and mitigations of HIV-AIDS both at central and regional level simply make noise and struggle with their own business and never touch the implementation of regulatory observable from lack of budget allocations though it is included in the provision of resources both for human and facility operation , even in the last few years, the operation depends on the founding from abroad. In the other

hand, though activists and other stakeholders, including lecturer on universities and researchers are busy and struggling with various studies of HIV-AIDS, they are not able to use research results as bargaining power to various stakeholders in this country as lecturers on universities only meeting the obligation to serve universities three functions known as tri darma. Furthermore the condition in Indonesia is worsened with the weak stakeholders' commitments in the field of mitigations of HIV-AIDS in advocacy, and sadly, there are tendencies that they would work if there is intersection with financially feasible project.

Data show that the HIV-AIDS is still experiencing a lot of discriminated treatment and always associated with negative stigma even by health workers themselves in the health service. Discrimination occurs when negative outlooks encourage people or institutions to treat someone unfairly based on their prejudices of a person's HIV status. There are so many examples of discrimination against persons with HIV-AIDS in Indonesia.[12]

In 2015 people living with HIV-AIDS in Bogor is quarantined even deprived by his own family because it is considered a disgrace to the family.[13] Intrusion of negative perceptions to people living with HIV would cause severe psychological effect that will eventually make them become depressed and continue to the lower level of health condition of the patient.[14,15] Burdens borne by people living with HIV and their families are heavy as the patients will always take the medicine every day and yet again obstructed by the social environment then indirectly provide the double burden on them and their families. [15,16]

The lack of community's knowledge on HIV leads to discrimination against people living with HIV. Society only knows that HIV- AIDS is limited to communicable diseases and hazardous sufferers. But the majority of people still do not understand completely the expansion factor and ways to overcome them. This incomprehension cause over-protective attitude towards people living with HIV, such as discrimination by do not want to hang out with people with HIV and the stigma that people living with HIV and AIDS should be avoided.[17]

The writers observe many people living with HIV in Indonesia who are not properly cared so then how the government's responsibility towards people with HIV-Ads as health insurance known as Badan Penyelenggara Jaminan Sosial (BPJS) or Social Security Employment Agency does not cover patients with HIV-AIDS. Likewise, the mass media almost never socialize HIV-AIDS, prevention, control or mitigation and the lack of news for local officers on handling the HIV-AIDS. Leaders and state officers at the highest level are going down to the fields only for image portrayal purposes only and often is heard, read and seen in a variety of media where ministers and politicians now just love to make rowdy politics that is not favorable for development, especially in the health sector. Based on above analysis, it is already shown the mental damage of stakeholders in the field of control and mitigation of HIV-AIDS in Indonesia, and also perfect adversity and ignorance of this country to the patients and their families suffering from the HIV-AIDS.

The writers see the existence of Indonesia's Commission on HIV-AIDS Prevention both at the level of centre and regional level and find this agency is simply a symbol, or just an entertainer or a joke in discourse as it is not able to work optimally due to the capacity of human resources and limited budget. The existence of this agency is like the old saying in Malay "Hidup Segan Mati Tak Mau " roughly translated, "Too timid to live, but unwilling to die."

In conditions of such state system where the leaders of the country are only able to perform image portrayal and embrace the culture of corruption, no single policy that will be able to accelerate the handling and termination of the spread of HIV-AIDS in Indonesia unless the national system changes fundamentally that one cutting point is changing the electoral law for not directly to elect of regional and local authority.

CONCLUSION

Prevention, control and mitigations of HIV-AIDS in Indonesia are not enough just to mould commitments and regulations, but owed to the upstream of all of this that the democratic system practice in Indonesia is very expensive. Without changing in the democratic system

of the elections in parliament and president, the deployment and increasing cases of HIV-AIDS in Indonesia will continue to spread tremendously and it is flourished by the behavior of regional and local authorities, politicians, bureaucracy and the owners of capital that are corrupted, economic predatory and rent-seeker.

Ethical Clearance: This study approved and received ethical clearance from the Committee of Public Health Research Ethics of Medical Faculty, Lambung Mangkurat University, Indonesia. In this study we followed the guidelines from the Committee of Public Health Research Ethics of Medical Faculty, Lambung Mangkurat University, Indonesia for ethical clearance and informed consent. The informed consent included the research tittle, purpose, participants' right, confidentiality and signature.

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Evaluation of Waste Water Treatment Toward Physical, Chemical, and Biological Parameters in WWTP Basirih Banjarmasin, Indonesia

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ABSTRACT

Wastewater is liquid or filth containing hazardous materials that can endanger human life and other living beings, and also destructive the environment. This research aim to analyze the differences in physical parameters (Temperature and TSS), chemical (pH, BOD, NO3-N, TF-P, oil and fat), and biology (E.Coli) before and after treatment. The research design is observational analytic throught cross-sectional approach. The object used is domestic wastewater before and after treatment in WWTP Basirih Banjarmasin of year 2015. This research use paired T-test and Wilcoxon test. The results in WWTP Basirih showed that average value before and after treatment in TSS (p-value=0.079), pH (p-value=0.034), NO3-N (p-value=0.071), TF-P (p-value=0.067), oil and fat (p-value=0.028), E.Coli (p-value=0.002), temperature (p-value=0.059) and BOD (p-value=0.227). There is a difference before and after treatment in pH, oil and fat and E.Coli. Whereas there was no difference in temperature, TSS, NO3-N, TF-P,and BOD.

Keywords: *WWTP Basirih, Wastewater, Physical Parameters, Chemical Parameters, Biological Parameters.*

INTRODUCTION

Wastewater is liquid or filth from households, industry and other public places that contain hazardous materials that could endanger human life and other living beings as well as disturb the environment. According to the Minister of Environment Regulation No. 5 of 2014 on Wastewater Quality Standard mentioned that domestic waste water is waste water that comes from effort and/or settlement activities, restaurants, offices, commercial, apartments and dormitories. For that in 2005 established the feasibility study the Company Wastewater Banjarmasin city which was then on the 24th of August 2006 stood PD PAL Banjarmasin (Local Company of WTP Banjarmasin).[1, 2]

Based on data of average incoming water quality examination in PD PAL Banjarmasin 2015, Total Solid Suspense (TSS) in WWTP Basirih is 16.16 mg/l, for that TSS has suitable with the water quality criteria based on Government Regulation 82 of 2001 that is below 50 mg/l. BOD 11.96 mg/l, based on Government Regulation 82 of 2001 BOD has not suitable with water quality criteria namely 3 mg/l. While E.coli amounted to 298,000 amt/100 ml, based on Government Regulation 82 of 2001, E.coli has not suit with water quality of 1,000 amt/ml.[3]

The high level of domestic WWTP Basirih give a significant impact on the quality of health of people living along the riverbanks as diarrhea and skin diseases. Based on data from 10 diseases in the working area of the WWTP Basirih, there are 488 cases of diarrhea and gastroenteritis and 360 cases of dermatitis.[4,5]

Therefore, wastewater treatment needs to be handled properly and sustainably, so that waste water into the body of water is safe for public health and the environment. Based on this background, it is necessary to do research on the evaluation of waste water treatment

in WWTP Basirih Banjarmasin which include temperature, TSS, pH, BOD, TF-P, oils and fats, and E.coli.

MATERIALS AND METHOD

This research is an analytic observational with cross sectional study. The study was conducted at the WWTP Basirih Banjarmasin. The object used is domestic waste water before and after treatment in WWTP Basirih Banjarmasin 2016. Data processing and analyzing with the SPSS program consisted of univariate analysis to explain the distribution of each independent variable and bivariate analysis using paired T-test and Wilcoxon test. Instrument used in this research is secondary data quality checks of water in PD PAL Banjarmasin in 2016.

RESULTS AND DISCUSSION

The object of this research is domestic waste water before and after treatment in WWTP Basirih Banjarmasin in 2016. The relationship between the temperature, pH, BOD, NO3-N, TF-P, Oil and Fat, and E.Coli of the waste water treatment in WWTP Basirih can be seen in Table 1 and 2.

Table 1. Result of Paired-T Test and Wilcoxon Test of Temperature, pH, BOD, NO_3-N, TF-P, Oil and Fat, and *E.Coli* Before and After Treatment

	Temperature	TSS	pH	BOD	NO_3-N	TF-P	Oil and Fat	E.Coli
p-Value	0.059	0.079	0.034	0.227	0.071	0.067	0.028	0.002

Table 2. Difference of Temperature, pH, BOD, NO_3-N, TF-P, Oil and Fat, and *E.Coli* Before and After Treatment

Month	Temperature		TSS		pH		BOD		NO_3-N		TF-P		Oil and Fat		E.Coli	
	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A
Jan	27.1	27.2	32	24	6.9	7.37	12.6	10.4	0.347	0.325	2.5	1.79	2	0	7000	80
Feb	27.7	27.8	36	23	6.94	7.14	10.6	10.3	0.354	0.335	1.29	0.911	2.2	0	160000	170
Mar	28.5	28.5	44	30	6.97	7.1	14.8	13.9	0.296	0.287	4.15	3.25	1.8	0	160000	167
Apr	28.2	28.3	28	21	6.98	7.28	9.93	8.05	0.253	0.248	1.76	1.63	1.3	0	50000	280
May	27.7	27.9	20	17	6.96	7.3	10.6	8.45	0.361	0.318	2.93	1.72	1.3	0	460000	140
Jun	27	27	7	0.0059	6.6	7.02	10.4	8.75	0.1026	0.1372	1.9758	1.7742	1.5	1	500000	5000
Jul	27	27	4	4	6.9	7.44	13.3	13.1	0.1742	0.4063	1.9445	1.9544	1.5	1.5	1130000	3800
Aug	27	27	3	5	7.16	7.38	9.26	13.75	0.0271	0.2053	1.5641	2.367	1	1.5	89000	90
Sep	28	28	6	3	6.96	7.15	12.25	13.6	0.8229	0.9196	3.3636	3.4478	1.5	2	17000	890
Oct	28	28	14	26	6.96	6.1	15.06	4.4	0.1656	2.706	5.7022	4.5221	1.5	1.5	390000	40
Nov	28	28	61	11	6.94	7.26	7.75	11.82	0.4365	1.8459	8.257	2.0083	4	2	9000	0
Dec	27	27	20	11	7.04	7.26	17.02	4.99	0.4805	1.9211	5.0318	1.4022	0.005	0.005	13000	0
Avg	27.6	27.64	22.92	14.58	6.94	7.15	11.96	10.13	0.32	0.80	3.37	2.23	1.63	0.79	248750	888.1

Notes:
B: Value Before Treatment
A: Value After Treatment

Temperature

The result of Paired-T Test show that p-value=0.059 (p> 0.05).That mean there are no difference between average of temperature value before and after treatment in WWTP Basirih. The temperature increase are 0.14%. The level of oxidation agents is greater at higher temperatures and decay ja rang occur at low temperatures.[4,6]

The concentration of the wastewater temperature are 27 to 28.5 0 C and it has qualified with criteria of Government Regulation No.82 Year 2001, ranged from 24.64 to 30.64 0 C. The decomposition occurs due to the concentration of high temperatures. Decomposition resulting odor that bothered. If the concentration of microbes on the high water and disinfection is not done. Then it is possible for the occurrence of waterborne disease.[4,7,8]

The concentration of the waste water temperature increases. This rise in temperature caused by the performance WWTP which process waste water with a more focused treatment to reduce parameters such as BOD, TSS, and E.coli. The optimal temperature for the activity of bacteria is in the range 25-35 ° C.[6,9]

Total suspended solid (TSS)

The result of Wilcoxon Test show that p-value=0.079 (p>0.05). That mean there are no difference between average of TSS value before and after treatment in WWTP Basirih. The TSS percentage decrease before and after the treatment are 36.38%. Additionally TSS is the amount of weight in mg / l and dried mud in the waste water after a filtration with membrane measuring 0.45 micron.[7,9]

The concentration of TSS in wastewater has been qualified, ranged from 0.0059 to 30 mg/l. Where this value suitable with criteria of Government Regulation No.82 Year 2001 under 50 mg/l. The high concentration of TSS will cause turbidity so as to disturb the disinfection process for the absorption of some colloidal bacteria may protect the organism from the disinfectant. Disruption will cause the water disinfection process has become a good medium for bacteria to breed.[7, 8, 10]

The concentration of TSS in wastewater has decreased. The concentration of TSS decrease before and after cause TSS has been through the stages and the finalclarifer primnryclarifer which can decrease the concentration of TSS. [11]

pH

The result of Paired-T Test show that p-value=0.034 (p< 0.05). That mean there are a difference between average of pH value before and after treatment in WWTP Basirih. The pH percentage increase before and after the treatment are 3%. The pH value of the water is used to determine the condition of acid (hydrogen ion concentration) of waste water.[4,6,12]

The concentration of pH in wastewater has been qualified, ranged from 6.1-7.44. Where this value suitable with criteria of Government Regulation No.82 Year 2001 are 6-9. Wastewater that has make the normal pH of sterile water. While the waste water has a high pH or low pH water can kill microorganisms necessary for the purposes of certain biota. [9, 13, 14]

The concentration of pH in wastewater has increased. The increase in pH is due to the performance of the WWTP which process waste water with a more focused treatment to reduce parameters such as BOD, TSS, and E.coli. The pH value affects the BOD content of the wastewater because if the pH value is not normal it will interfere with the performance of aerobic bacteria to decompose organic matter in wastewater. Most microorganisms like pH between 7 to 8.5. [6, 9]

Biochemical oxygen demand (BOD)

The result of Paired-T Test show that p-value=0.227 (p> 0.05).That mean there are no difference between average of BOD value before and after treatment in WWTP Basirih. The BOD percentage increase before and after the treatment are 15.3%. BOD value indicates the amount of dissolved oxygen required by aerobic microorganisms to break down or oxidize bahanbahan effluent in the water. So the BOD value does not indicate the actual amount of organic material.[4, 9]

The concentration of BOD in wastewater has been not qualified, ranged from 4.4-13.9 mg/l and not suitable with criteria of Government Regulation No.82 Year 2001 are under 3 mg/l. The higher number of BOD increase difficulty for water creatures that need oxygen to survive. [8, 9, 12]

The concentration of BOD in wastewater has decreased. This is because the BOD has gone through the process of biological treatment is in the process Rotating Biological Contrctor (RBC). In the decomposition process occurs RBC pollutant compounds by microorganisms that grow on rotating discs (rotordisk).[15, 16]

The NO_3-N

The result of Paired-T Test show that p-value=0.071 (p<>0.05). That mean there are no difference between average of NO3-N value before and after treatment in WWTP Basirih. The NO3-N percentage increase before and after the treatment are 150%. NO3-N was the main form of nitrogen in natural waters and is a major nutrient for plant growth and algae.[17]

The concentration of NO3-N in wastewater has been qualified, ranged from 0.2053-2.706 mg/l. Where this value suitable with criteria of Government Regulation No.82 Year 2001 are 10 mg/l. The high nitrate concentrations can be toxic and can affect people's health such as irritation of the skin and can cause tissue damage of the skin. [8, 18]

The concentration of NO_3-N in wastewater has increased. The increase of temperature is a factor that cause an increase in the concentration of NO_3-N.While the increase in temperature due to the activity of microbes in decomposing material generates energy in the form of heat released into the environment.[6,9]

The TF-P

The result of Paired-T Test show that p-value=0.0067

(p> 0.05). That mean there are no difference between average of TF-P value before and after treatment in WWTP Basirih. The TF-P percentage decrease before and after the treatment are 51.13%. Phosphate in wastewater society is in the form of inorganic orthophosphate (PO, HPO, HrPO) increase as much as 25% of the total phosphate.[19]

The concentration of TF-P in wastewater has been not qualified, ranged from 0.911-4.5221 mg/l. Where this value not suitable with criteria of Government Regulation No.82 Year 2001 are under 0.2 mg/l. [8, 20]

The concentration of TF-P in wastewater has decreased. This is because TF-P has gone through the process of biological treatment is in the process Rotating Biological Contrctor (RBC).[15, 16]

Oil and fat

The result of Wilcoxon Test show that p-value=0.028 (p< 0.05). That mean there are difference between average of oil and fat value before and after treatment in WWTP Basirih. The oil and fat percentage decrease before and after the treatment are 51.53%. Oils and fats are organic materials are fixed and difficult to bacteria described.[9]

The concentration of oil and fat in wastewater has been qualified, ranged from 0-2 ug/l. Where this value suitable with criteria of Government Regulation No.82 Year 2001 are under 1000 ug/l. Oils and fats forming a thin layer on the surface of the water and cover the surface which resulted in limited oxygen into the water.[8,9] The concentration of oil and fat has decreased. This is because the oils and fats have been through a pretreatment for separating oil and grease from wastewater. [16]

Eschericia coli (E.Coli)

The result of Wilcoxon Test show that p-value=0.002 (p< 0.05). That mean there are difference between average of *E.Coli* value before and after treatment in WWTP Basirih. The *E.Coli* percentage decrease before and after the treatment are 99.63%. *Escherichia coli* are pathogenic, although some types of coliform are pathogens.[21]

The concentration of *E.Coli* in wastewater has been not qualified, ranged from 0-5000 amt/100 ml. Where this value not suitable with criteria of Government Regulation No.82 Year 2001 are under 1000amt/100 ml. If water containing *E.Coli* is consumed, it will possibly appear water-borne diseases. *E.Coli* can be harmful to health and it can also cause acute diarrhea. [8, 10, 21]

CONCLUSION

Based on the results of research in WWTP Basirih in Banjarmasin in 2015, there is a difference before and after treatment at TSS (p-value=0,079), pH (p-value=0,034), NO3-N (p-value=0,071), TF-P (p-value=0,067), oil and fat (p-value=0,028), and *E.coli* (p-value=0,002). Whereas there is no difference in temperature (p-value = 0.053) and BOD (p-value = 0.0162). WWTP Basirih should always maintenance and repair, still due to the excess of the standard quality parameters such as BOD, TF-P, and *E. coli*.

Ethical Clearance: This study approved and received ethical clearance from the Committee of Public Health Research Ethics of Medical Faculty, Lambung Mangkurat University, Indonesia. In this study we followed the guidelines from the Committee of Public Health Research Ethics of Medical Faculty, Lambung Mangkurat University, Indonesia for ethical clearance and informed consent. The informed consent included the research tittle, purpose, participants' right, confidentiality and signature.

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Conflict of Interest: The authors declare that they have no conflict interests.

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Bridging Healthcare with Wellness Tourism in India

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ABSTRACT

Background/Objectives: The intent of this paper is to perceive how factors such as Social Wellness, Emotional Wellness, Ayurvedha Treatment and Travel Motivation influence Customer Satisfaction of clientele in Chennai's to bridge the gap of Health and Wellness Tourism sector.

Method/Statistical Analysis: The paper uses multivariate statistical techniques to decipher the motive behind the utility of Health and Wellness Tourism.

Findings: The results of the SEM show a very strong relationship between the different variables. The independent variables are Social Wellness, Emotional Wellness, Ayurveda Tourism. The dependent variables are Customer Satisfaction and Travel Motivation.

Applications/Improvement: This paper tries to find the relationship of tourism with wellbeing. New research is emerging on the relationships between tourism and subjective well-being .With this trend in other countries we researcher studied the aspect of wellbeing in our Indian conditions.

Keywords: *Social Wellness, Emotional Wellness, Ayurveda Treatment, Travel Motivation, Customer Satisfaction.*

INTRODUCTION

Travel and tourism is quite a significant commercial industry in India. The tourism division develops at a rate of 7.8% yearly in the period of 2013-2023 which contributes to the Gross Domestic Product (GDP). India had intensified its travel facility in the past few decades which in turn increased the movement of Indian tourism. The better quality lodging facility for the tourist destinations has allowed to improve the Foreign Tourist Arrivals (FTA). This year the contribution of tourism to the country's economy is set to increase from 5.1% to 8.2% . This increase is due to expansion in the local travel, development of minimal cost airports and redesigning of air terminal base. The development of wellness tourism is being accelerated with hike of healthcare costs in advanced countries and lack of proper health care facilities in the developing countries[1].

- Health and Wellness tourism grants 6% of all domestic and international travel.
- The tourists who try to maintain wellness while voyaging (optional reason wellbeing explorers) shows 87% of wellness tourism travel and 86% of consumption.
- Health tourism provide 11.7 million direct employment opportunities, conveying $1.3 trillion of worldwide monetary benefits (1.8% of worldwide GDP in 2012).

Wellness Tourism can be defined as a state of balance-body,spirit and mind-including holistic aspects as self responsibility, care for physical condition and beauty, healthy eating, relaxation, mental activity and sensitivity to the environment, as fundamentals.

A person looking for a wellness trip is generally healthy, interested in therapies to maintain health[2].

Review of Literature

The researcher discovered likenesses in American and European understanding of wellbeing[2]. They advocated that wellness is a condition where there is concordance of body, psyche and soul. Self-duty, physical wellness, excellence care, sound nourishment, unwinding, contemplation, mental movement, training, ecological affectability, social contacts, and others are characterized as essential components which contribute towards the wellbeing and health. The wellbeing and health tourism is a subset of restorative tourism. The researcher has proposed that the

expression "Restorative Wellness" can be utilized to by one means or another coordinate the ideas of Health and Wellness – therapeutically administered program intended to rollout particular improvements to way of life which can accomplish the ideal wellbeing[3]..

This research was based on the Jan Montague (1994) on Whole Person Wellness Model.

Proposed Research Model

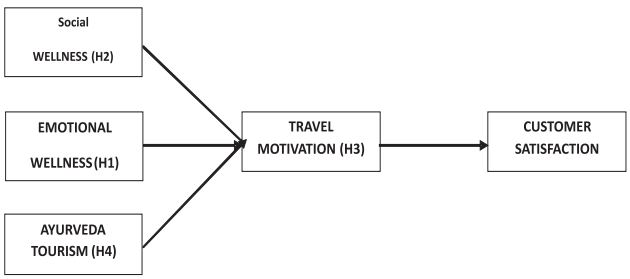


Fig. 1. Proposed model.

Emotional Wellness

The researcher has characterized emotional wellness as one's level of sorrow, nervousness, prosperity, self-control, and idealism[4]**.** From a possible future perspective, emotional wellness reflects the ability to know the optimistic approach to life. This description of the distinctive nature has been accepted by the travelers.

H1: The emotional wellness dimension positively influences the customer satisfaction

Social Wellness

Social wellness is a new dimension of looking into wellness, which revolves around oneself and the family to nurture love towards the other,group and the nature by volunteering[5]. Social wellness is all about building healthy relationship willingly fostering respectful bonding between family and the environment with original connections.

H2: The social wellness dimension positively influences the customer fulfillment

Travel Motivation

The research has expressed that destination decision has been a vital viewpoint in tourism literature[6]**.** There are different variables affecting the travel choices, a few of which are society, travel inspirations, accounts and past experiences[7]. The state tourism is liable to an accumulation of impacts and elements that decide its relative conveyance[8]. Travel motivation creates a new travel behavior and have been connected in tourism marketing strategies.

H3: The travel motivation dimension positively influences the customer satisfaction

Ayurveda Treatment

Cherishing the usage of traditional medicinal plants in healing as medicinal massages, traditional spas, for treating illness and to rehabilitate overall health and well-being. Medicinal plants will be plants containing inborn dynamic ingredients used to cure ailment or to relieve pain [9]. Ayurveda treatment is gaining popularity because of the reduced prices they are offered at compared to the medicines currently being consumed for individual well being[10].

H4: The Ayurveda Treatment dimension positively influences customer satisfaction

Customer Satisfaction

The researcher has explored the perspective of tourists about Ayurvedic wellbeing tourism prerequisite in Kerala[11]. Destination scenery, medicinal services and ayurvedic products were the reasons why travelers are inclined to India. The factors which influenced in improving satisfaction level of voyagers are reserving techniques, advancement and awareness creation, environment and of Ayurvedic Resorts.

Method-Quantitative Research

Random sampling done from the list provided by the tour operators in Chennai and also from individuals as well. To collect from individuals survey monkey a cloud application was used.

Data

The Cronbach's alpha (reliability coefficient) value for the rating scale was obtained using SPSS package (21) was 0.905 and 0.946 respectively. TheCronbach's alpha (reliability coefficient) values for Social Wellness - 0.774, Emotional Wellness - 0.748, Ayurveda Treatment - 0.798, Travel Motivation - 0.826, and Customer Satisfaction - 0.978. The value above 0.7 indicates good reliability.

Table No.1: Statistics of the variables

Demographic Variables	Mean	Standard Deviation	Skewness	Kurtosis
Social Wellness	14.0836	3.25614	-.680	1.106
Emotional Wellness	9.1855	2.53698	-.080	-.235
Ayurveda Tourism	13.0655	3.17772	-.515	-.513
Travel Motivation	27.9127	4.16446	-.284	.052
Customer Satisfaction	13.8073	3.28944	-.550	.841

The CFA is a tool which the researcher can identify the measured variable related to the observed variable. CFA is multivariate analysis in research to measure the consistency by supporting theory using AMOS 21. Individual factors are validated with the existing factors to feel the fit. In this study assumption was made that there were no cross loadings.

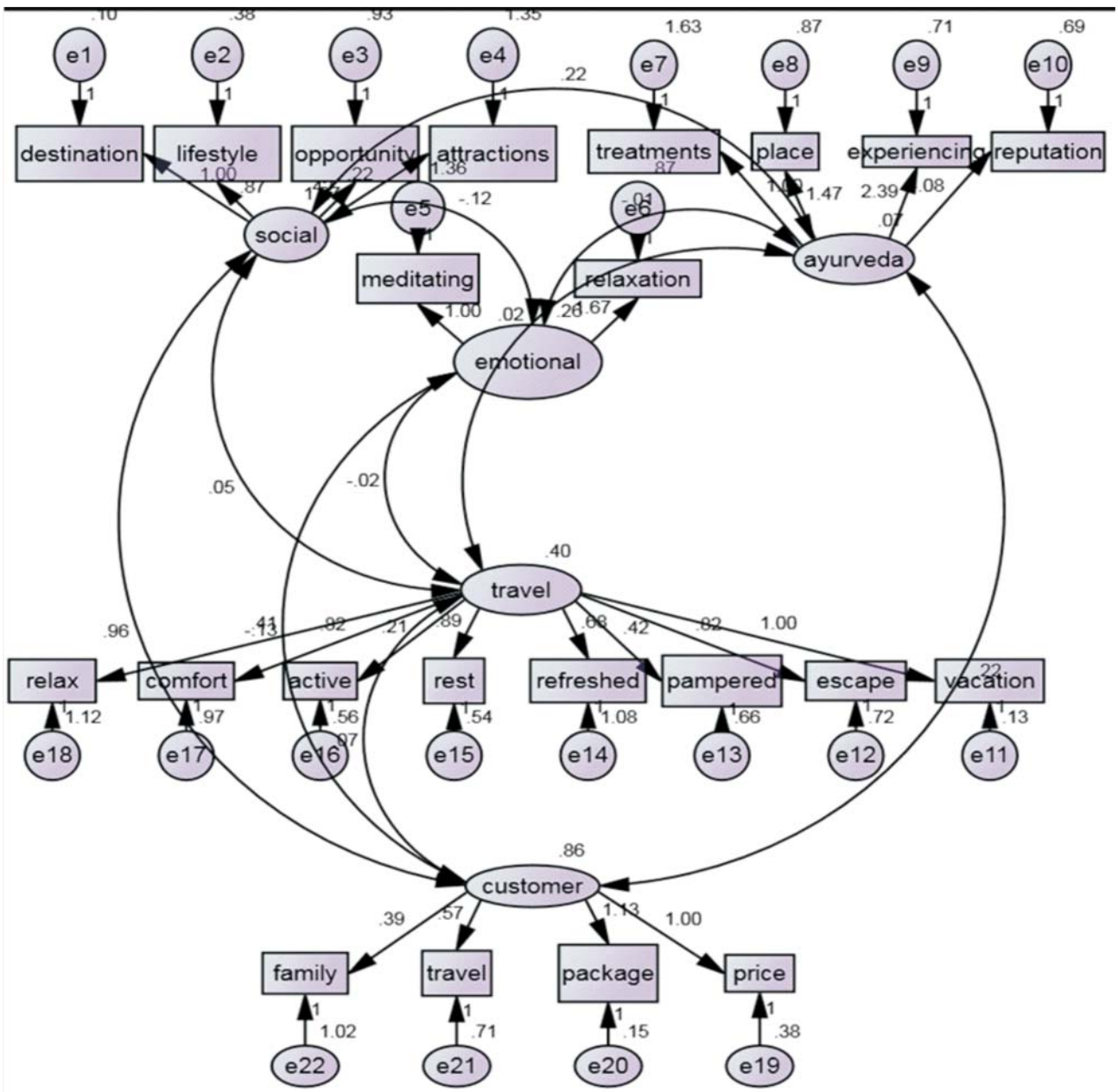


Fig. 2. Confirmatory Factor Analysis

Table 2. Showing Confirmatory Factor Analysis

	Setup		Estimate	S.E.	C.R.	P
SW 1	<—	SW	1			
SW 2	<—	SW	.852	.050	16.951	***
SW 3	<—	SW	.384	.055	7.017	***
SW 4	<—	SW	.211	.063	3.344	***
EW 1	<—	EW				
EW 2	<—	EW	1.151	.650	1.770	.077
AT 1	<—	AT				
AT2	<—	AT	1.163	.374	3.111	.002
AT 3	<—	AT	2.020	.577	3.499	***
AT 4	<—	AT	3.503	.979	3.578	***
TM 1	<—	TM				
TM 2	<—	TM	.841	.111	7.599	***
TM 3	<—	TM	.425	.093	4.582	***
TM 4	<—	TM	.690	.123	5.610	***
TM 5	<—	TM	.920	.106	8.712	***
TM 6	<—	TM	.230	.082	2.799	.005
TM 7	<—	TM	.851	.123	6.932	***
TM 8	<—	TM	.407	.118	3.437	***
CS 1	<—	CS				
CS 2	<—	CS	1.220	.097	12.618	***
CS 3	<—	CS	.588	.065	9.074	***
CS 4	<—	CS	.411	.073	5.657	***

Table 2 showing the CFA

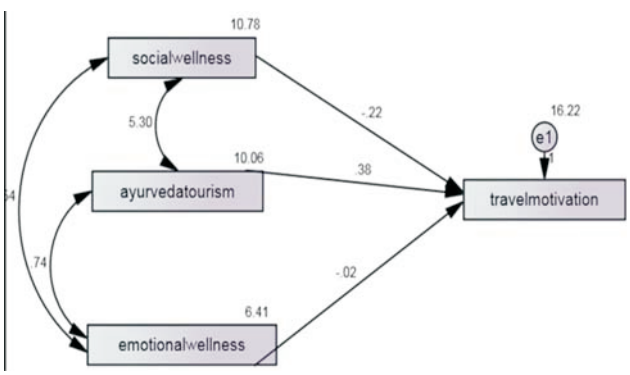


Fig. 3. Regression Model without Mediating Factor Customer Satisfaction

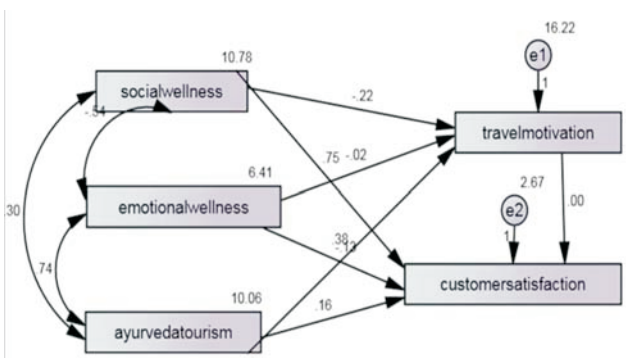


Fig. 4. Regression Model of the Structural Equation Model with Mediating Factor

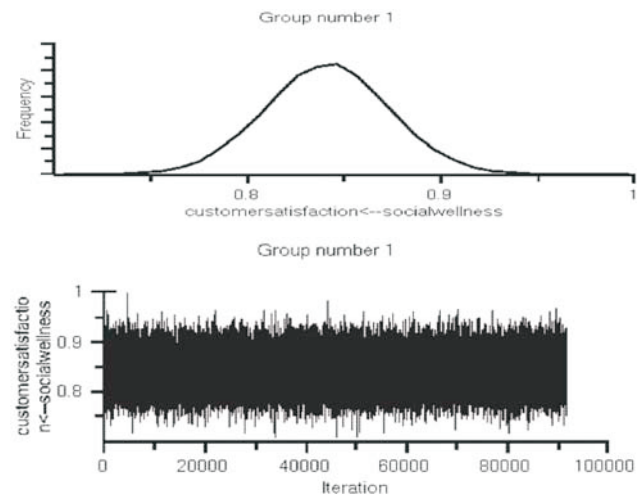


Fig.5,6, Posterior Characteristic Plots of Regression Model



Fig.7. Shows the Posterior Characteristics Plots of Regression Model

Structural Equation Model

Confirmatory factor analysis(CFA) is a comprehensive model to explain the measured factors correlate with the theory.

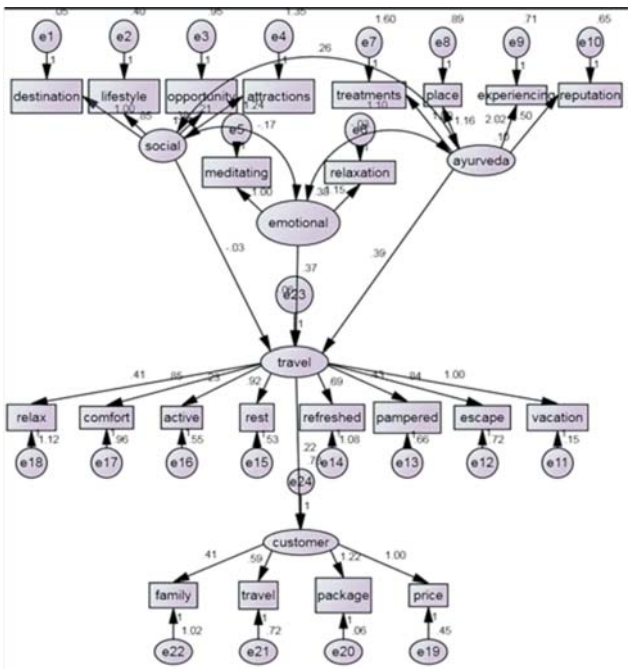


Fig. 8. Showing the SEM for model

Table 3. Showing the SEM values of significance

Path	Estimate	S.E.	C.R.	P	Result
TM <— SW	-.223	.087	2.565	.010	Significant
TM<—AT	.376	.090	4.174	***	Significant
TM<—EW	-.019	.097	.199	.002	Significant
CS<—SW	.755	.035	21.410	***	Significant
CS<—AT	.163	.037	4.465	***	Significant
CS<—EW	-.125	.040	-3.167	.002	Significant

Evaluation - Model Fitness

These were the goodness-of-fit (GOF) indices used to evaluate the model fit.

Standardized root mean square error residual - (SRMR).

Root mean square error of approximation - (RMSEA)

Tucker-Lewis Index - (TLI)

Normal fit index - (NFI)

Unadjusted goodness-of-fit indices - (GFI)

Comparative fit index - (CFI)

Chi-square $\chi 2$

In this study a combinations of Goodness-of-fit (GOF) indices were used to evaluate the model fit. Any value between 2.195 and 5 is acceptable for Chi-square.

Chi square is the statistical measure used to observe the difference between real and predicted matrix. The RMSEA value was 0.076 to consider our model to be fit.

Table No 4. Showing the Goodness of Fit Statistics for SEM Model

S. No	Measures of fit	Output of Private Label Model	Acceptable Level for good fit
1	Chi-square ($\chi 2$) at p 0.05	2169.009	Significant
2	Degree of freedom (d.f)	202	
3	Normed $\chi 2$	2.195	< 2 good: 2-5 acceptable
4	Comparative fit index (CFI)	.393	>0.90
5	Bentler – Bonett Index or Normed Fit Index (NFI)	.375	>0.90
6	Root mean squared error of approximation (RMSEA)	0.058	<0.08
7	Non Centrality Parameter (NCP)	2120.356	-
8	Non Centrality Parameter, Lower boundary (NCPLO 90)	.328	-
9	Parsimony adjusted NFI (PNFI)	.343	-
10	Parsimony adjusted CFI (PCFI)	0.795	-
11	Minimum value of Discrepancy	0.865	-
12	Lower Limit of FMIN (LO 90)	1821.056	-
13	Upper limit of FMIN (HI90)	2120.356	-
14	Browne-Cudeck Criterion (BCC)	2280.356	-
15	ECVI	8.288	-
16	LO90	7.756	-
17	HI90	8.848	-
18	MECVI	8.322	-
19	HOELTER.05	65	<= 75
20	HOELTER.01	205	At least 200

Structural Equation Model Values.

DISCUSSION

The constructs in the model (social wellness, emotional wellness, ayurveda treatment and travel motivation were significant and impact customer satisfaction. The social wellness is a critical factor (0.755) in determining the customer satisfaction. It is appreciated by the majority that for the longevity of life, general satisfaction plays a vital role which can be achieved by dedicating time for wellness, sports, and different health exercises. Financial specialists should observe this trend and venture to correlate wellness and work rate efficiency. Hence inclusion of packages that help in rejuvenation and re-energization is a necessity in treatment vacations.

India is a hub for alternative medicines such as Ayurveda, Yoga, Siddha, Homeopathy and Acupuncture. India had established treatments by herbal and other possible methods. India had proved in the integrated pharmaceutical industry.

The inclusion of packages that helps in rejuvenation and re-energizing is a necessity in treatment vacations.

CONCLUSIONS

The results indicated that Health and Wellness tourism is very suitable in India considering the climate, geography, culture and infrastructure. The current findings show that youngster less than 30 years are health conscious.

The Health and Wellness had metamorphosed among professionals who perceive it as de-stress. This study suggests that marketing strategies for Health and Wellness tourism in India should lay their hands on the individual health related needs and wants. Pampering and relaxation are key to motivational for, hence providers should locate the relaxation attributes for better experiences – the atmosphere/environment, lay out, decoration, trained staff members, and treatments.

The necessity of measuring wellness as a means to prevent illness and help target population to stay healthy and improve their level of wellness is driven by booming healthcare costs. The social wellness, travel motivationand Ayurveda treatment inventory provided cogent reliability and validity. This in depth comprehension will help in analyzing what assists people to stay healthy. The factors examined under the wellness dimensions qualify for the nuances of lifestyle, cultural differences, differing communities, levels of education and more. To provide more reliability, many existing tools are revised.

This study was necessary due to increase of health care costs and prevalence of lifestyle diseases in people. A crucial step in generating policies that helps communities to determine the factors that make up a healthy individual who is supported by society as a whole. To raise India from mediocre population health profile, public health policies should be improved.

The study also shows that emotional wellness and positive psychology is important in reducing stress and having better health. The examination of well-being dimensions from a socio cultural perspective is necessary according to the study.

Ethical Clearance: Not Applicable

Source of Funding: Self

Conflict of Interest : Nil

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Falls at Home: A Community Based Study on Awareness and Prevention among Adults

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ABSTRACT

Background: Owing to their widespread occurrence, deleterious impacts and consequences, falls continue to be a major public health challenge. As per WHO report 2016, an estimated 424, 000 fatal falls occur each year.

Objectives: To assess knowledge regarding risk factors and preventive practices for falls at home among rural households.

Material & Method: A community based cross sectional study was carried out in the field practice area of Department of Community Medicine, of a University Medical College. Total 316 households were surveyed and datarelating should be data relating to socio-demographic features, knowledge pertaining to risk factors and practice regarding measures taken for prevention of falls at home were documented.

Results: Awareness regarding predisposing factors that could lead to falls were alcohol (87%), smooth polished flooring (80.7%), poorly lit room (68.4%) and being elderly (81.3%). Majority 229 (72.5%) reported that falls on stairs could be prevented by railings for staircase while 199 (63%) reported adhering to medical advice as preventive measure. The prevalence of fall episodes in the last one year was (21) 6.6%.

Conclusions: The awareness regarding predisposing factors and prevention of falls among the rural households was good. However, the knowledge had not translated into practice.

Keywords: *Falls; Awareness; Risk Factors; Prevention; Community*

INTRODUCTION

Globally, falls are a major public health problem. According to WHO report 2016, fall occurrence is the second leading cause of unintentional injury and death, after road traffic injuries.[1] Approximately 28-35% of people aged 65 years and above fall each year increasing to 32-42% for those over 70 years of age.[2]During 2004 about one fifth of the falls related deaths (95 000 deaths) took place in India.[3] Unintentional falls accounted for 25% of all unintentional injury deaths.[4] The prevalence of falls in Indian older adults ranges from 14% to 53%.[5] The National Crime and Records Bureau, which is the only agency that collects national injury data in India, reported that in 2014, falls contributed to 3.4% of all unintentional injury deaths in the country.[6]

Falls as a cause of death are 10 times more common among the elderly.[7,8] Fall incidence as well as total cost increased with age and were higher among women.[9]A mixture of hazards at home along with a person's physical status may predispose to increased occurrence of falls.[10]Studies assessing knowledge and practice measures regarding the pre-disposing factors for falls at home among adults are sparse. This need to identify possible risk factors contributing to falls and the practice regarding preventive measures for the same in the community, were the objectives of the present study.

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MATERIALS AND METHOD

A community based cross sectional study was carried out in the field practice area of the Department of Community Medicine, of a University Medical College in 2017. Institutional ethical committee clearance (IEC 208/2017) was obtained before the initiation of the study. Written informed consent was obtained from all the study subjects. Individuals aged ≥18 years and permanent residents (defined as residing > 1 year) of the field practice area of the Department of Community Medicine, of a University Medical College were considered eligible for the study.

A pilot study was conducted to assess the awareness regarding pre-disposing factors leading to falls at home among adults. Based on the pilot study results, the sample size was estimated anticipating the proportion of households having knowledge regarding pre disposing factors for falls to be 60%, with a relative precision of 10% and a non-response rate of 10%, 316 households needed to be recruited for the study.

With the support of the Auxillary Nurse Midwives (ANMs), all the households in the locality were visited till the required sample size was reached. Any adult respondent who was available in the house during the survey was assessed for knowledge regarding pre-disposing factors for falls. Details regarding episodes of fall among any member of the household which required medical attention, in the last one year was also obtained.

A pre-designed, semi-structured and pilot tested questionnaire was used to collect relevant data. The questionnaire consisted of questions relating to socio demographic characteristics and details of fall episode in the last one year, in addition to three domains. The first domain was pertaining to knowledge regarding risk factors; second domain consisted of the risk-practices which could predispose to a fall at home and the last domain was an observation checklist for the presence of potential risk areas for falls.

Scoring: Every correct response was scored as 1 and incorrect as 0. Maximum score for knowledge was 21 and maximum score for practice was 32. Poor knowledge and practice corresponded to a score of (<Mean – 1 SD); average knowledge and practice corresponded to a score between (Mean ± 1 SD); good knowledge and practice corresponded to a score of (>Mean + 1 SD). Thus, the knowledge and practice score was divided into three categories. A score of 0-7 was poor knowledge; 8-14 average knowledge and more than 14 was considered as good knowledge. Similarly, a practice score of 0-11 corresponded to poor practice; 12-21 average practice and >21 was good practice.

The data collected was tabulated and analyzed using Statistical Package for Social Sciences (SPSS) version 15.0 and is presented as frequencies and proportions.

RESULTS

A total of 316 households were recruited into the study. Most were Hindus 263 (83.2%) followed by Christians 32 (10.1%) and Muslims 21 (6.6%). Among the recruited households 171 (54.1%) were APL card holders. Table 1 depicts the awareness regarding pre-disposing factors for fall among the rural households. According to the surveyed population smooth polished flooring (80.7%) and poorly lit room (68.4%) among the housing conditions, were the main pre-disposing factors that could lead to a fall. Among substance abuse, 87% knew that alcohol use could lead to a fall. Being older is a predisposing factor for fall and this was known to (81.3%) of people.

Falls due to side effects of antihypertensive, cold and cough medicines and anti-diabetic medications was known to 44.3%, 15.8% and 23.7% of participants respectively. Among the domestic activities, 173 (54.7%) reported wet floor while mopping the floor, reaching high objects or doing work on roof [44 (13.9%)] and bathing /washing clothes [68 (21.5%)] could predispose to falls.

Table 2 describes the knowledge regarding preventive measures for falls among the rural households. Most of the respondents 229 (72.5%) reported that railings for staircases prevents fall. With respect to health measures, adhering to medical advice for prevention of falls was reported by 199 (63%). Nearly 50% believed that improved housing conditions could prevent falls among the elderly.

Table 3 denotes the household activities and practices that could predispose to falls**.** Adequate lighting was present at entrance in 297(94%)

households, outside path 291(92.1%), hall 287(90.8%). Kitchen, bathroom and stairs had less lighting as compared to other places within the house. Slippery floor was found among 36(11.4%) households while bathroom floor was slippery among 79(25%) of the households.

Table 4 depicts socio-demographic characteristics of individuals who had experienced a fall, in the previous year, for which medical advice was sought. Out of the total households surveyed, 21 (6.6%) episodes of fall were reported. Of the 21, 14 (66.7%) episodes were among individuals aged over 60 years and 12(57.1%) were males and 9(42.9%) were females.

Table 1: Knowledge regarding Predisposing factors for falls among the rural households (n=316)

Predisposing factors for fall		**Total n(%)**
Housing conditions	Poorly lit room	216 (68.4)
	Smooth/ Polished flooring	255 (80.7)
Substance abuse	Alcohol	275 (87.0)
	Tobacco products	98 (31.0)
side effects of medication	Anti-hypertensives	140 (44.3)
	Cold and cough medicines	50 (15.8)
	Anti-diabetics	75 (23.7)
Medical conditions	Uncontrolled hypertension	225 (71.2)
	Uncontrolled diabetes	167 (52.8)
	Vertigo	146 (46.2)
	Cataract	141 (44.6)
	Severe anaemia	87 (27.5)
	Epilepsy	107 (33.9)
Age group	Under 5	205 (64.9)
	Elderly	257 (81.3)
Domestic activities leading to fall	Wet floor	173 (54.7)
	Reaching high objects/ Doing work on roof	44 (13.9)
	Bathing /Washing clothes	68 (21.5)
	Other	77 (24.3)
Risk factors for fall among children	Playing/running	211 (66.8)
	Poor housing conditions*	153 (48.4)
	Fall from bed	21 (6.6)
	Others	32 (10.1)
Risk factors for fall among elderly	Health problems	178 (56.3)
	Wet floor	89 (28.2)
	Poor housing conditions*	88 (27.8)
	Bathing	11 (3.5)
	Others	26 (8.2)

Table 2: Knowledge regarding fall prevention among the rural households. (n=316)

Preventive factors for falls		**Total n (%)**
On stairs	Railing for stair case	229 (72.5)
	Well-lit stairs	93 (29.4)
	Properly constructed stairs	105 (33.2)
Health measures	Correcting visual impairment	137 (43.4)
	Adherence to medical advice	199 (63.0)
	Exercising regularly	137 (43.4)
	Maintaining normal blood sugar & BP	124 (39.2)

Table 2: Knowledge regarding Preventive factors for falls among the rural households (n=316) (Contd.)

Preventive factors for falls		**Total n (%)**
Prevention of fall among children	Supervision	171 (54.1)
	Appropriate care / Good nutrition	18 (5.7)
	Improving housing conditions**	131 (41.5)
	Bedside railing	15 (4.7)
	Other	28 (8.9)
Prevention of fall among elderly	Walking aids	39 (12.3)
	Supervision/ Taking appropriate care	187 (59.2)
	Improvement housing	142 (44.9)
	Other	24 (7.6)

** Improving housing conditions include: Non polished flooring, clutter free floor, improved lighting and wiping the spills on the floor immediately.

Table 3: Practice Relating to Risk Factor for Falls among the Rural Households(n=316)

S No.	**Practice questions**		**n (%)**
1.	Reaching for objects placed above	Use a stable stool	203 (64.2)
		On tip toes	73 (23.1)
		Keep one furniture piece over another	05 (1.6)
		Use plastic chair	41(13.0)
2.	Cleaning the spills on the floor	Leave it to dry on its own	03(0.9)
		Wipe after few minutes	12(3.8)
		Immediately wipe off	297 (94.0)
3.	Adequate lighting	Entrance	297 (94)
		Outside path	291(92.1)
		Hall	287(90.8)
		Bedrooms	268(84.8)
		Kitchen	264(83.5)
		Corridor (n=290)	260(89.6)
		Bathroom	250 (79.1)
		Light near the bed hard to reach	103(32.6)
4.	Floor	Slippery House floor	36(11.4)
		Bathroom floor	79(25.0)
		Objects on the floor	99(31.3)
5.	Stairs (n=257)	Adequate lighting	228(88.7)
		Adequate height and breadth	212(82.5)
		With a hand rail	123(47.8)

Table 4: Socio demographic characteristics of those who had falls among interviewed rural households (n=21)

Fall episodes	**21**	**6.6%**
Age group (in years)	<18	02 (9.6)
	18-59	05 (23.8)
	≥ 60	14 (66.7)
Gender	Male	12 (57.1)
	Female	09 (42.9)
Religion	Hindu	16 (76.2)
	Muslim	03 (14.3)
	Christian	02 (9.5)
Literacy	Illiterate	05 (23.8)
	1- 10 th std	12(57.2)
	>10 th std	04 (19.1)

Table 4: Socio demographic characteristics of those who had falls among interviewed rural households (n=21) (Contd.)

Fall episodes	**21**	**6.6%**
Occupation	Working	09 (42.8)
	Not working	06 (28.5)
	Homemaker	06 (28.6)
Socio economic status	APL card holder	13 (61.9)
	BPL card holder	08 (38.1)

DISCUSSION

Falls is an important public health problem. Most falls among older adults occur inside the home.[11]Behavioral change, as well as environmental change, is essential for the success of falls-prevention programs.[12]

According to Jagnoor J et al the predominant reasons for a fall was age, uneven surfaces, physical weakness and mental health.[13] Gutta S et al reported that 45% of the elderly were found to have fallen more than once.[14] In the present study, 66.7% of the falls were seen among the age group ≥60 years.

Gutta S et al also reported that inadequate lighting and smooth flooring were responsible for 5% and 1% of the falls respectively.[14]Thus, a well-lit room and non-glary and non-smooth surface could be helpful in preventing falls. Provision of night lamps in the house to prevent falls, thus could be effective strategy for fall prevention.[15] The awareness about lighting and flooring in the present study was found to be 68.4% and 80.7% respectively.

A study by Kool B et al reported alcohol to be strongly associated with unintentional falls at home resulting in admission to hospital or death.[16] In the current study a high proportion of people 87% were aware of alcohol as a predisposing factor for falls.

Woolcott JC et al reported anti-hypertensives to have an increased risk for falls.[17]However in the present study only 44.3% were aware that anti hypertensives could result in a fall. Both older and middle-aged adults who use multiple prescription medicines are at an increased risk of falls.[18]

Visual impairment and diabetes are some of important the risk factors for falls.[19] Study done by Gutta S et al reported that poor vision and anaemia were responsible for causing 20% and 13% of the falls respectively.[14] The study subjectsin the present study were aware that cataract, old age, diabetes and anaemia could predispose to falls.

According to study done by Blake AJ et al among those with falls, ratio of female to male was 2.7: 1, this ratio approached unity with advancing age.[20] However in the present study the female to male ratio is 0.75:1. There were more males (57.1%) who had a fall as compared to females (42.9%). D'souza et al reported, slips (44.2%) and trips (25.3%) as the most prevalent causes of falls.[21] Gutta S et al reported 5% of falls due to cerebrovascular accidents which was similar to the present study where 4.7% of falls were due to cerebrovascular accident.[4]

Marshall SW reported that the use of grab bars and handrails in the bathroom was low.[22] Also a fall in the bathroom has higher chances of resulting in an injury compared to a fall in the living room.[11] In the current study, 25% had slippery bathroom floor and around 20% had inadequate bathroom lighting. 52.2% stairs did not have a hand rail and only 9.5% houses had an accessible, sturdy grab rail in the bathroom. D'souza SA et al reported that falls mostly occurred while bathing (21.1%).[21] Limited literature on awareness of risk factors and practice of preventive measures against falls is noteworthy and more research needs to be guided in this direction. The awareness pertaining to risk factors for falls and preventive measures at household level in the rural field practice area was good, but practice of preventive measures was poor. Identification of this

knowledge practice gap was a positive finding of the study, so that future corrective measures could be directed in this track.The survey was conducted during daytime, when most of the male members are out at work, so the respondents predominantly included females. Personal interviews with individuals who had experienced the fall episode would have been ideal, but was not feasible due to cross-sectional nature of the survey.Awareness campaigns to emphasize on the potential risk factors within the confines of their homes could be very beneficial, coupled with campaigns to screen homes for probable hazards.To conclude, the knowledge regarding predisposing factors and prevention of falls among the rural households was high. However, the practice did not correspond to the knowledge level. It was also noted that the prevalence of falls at home was high among older adults.

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Potential Health Risks among Oncology Staff Nurses of Selected Hospitals due to Antineoplastic Drug Exposure

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ABSTRACT

Adverse effects similar to those seen in treated cancer patients may occur in healthcare professionals who handle these drugs regularly. The main aim of the study was to explore potential health risks among staff nurses exposed to antineoplastic drugs. The study involved a purposive sample of 150 oncology staff nurses. Data were collected from 5 different hospitals with separate oncology units at Udupi district and Mangalore,Karnataka in India. The data were collected through self-administered potential health risks assessment questionnaire. The results of the study revealed that most of the participants138 (92%) had low degree of potential health risks. Major identified health problems were contact dermatitis (22.7%), nasal sores (12.7%), allergic reaction (16%), hair loss (54%), abortion (3.3%), menstrual problems (18.7%), congenital malformation, behavioral abnormality and intellectual problems in offspring's (1.3 % each).

Keywords: *Antineoplastic Drug Exposure, Potential Health Risks, Oncology Unit, Staff Nurse.*

INTRODUCTION

Antineoplastic drugs are hazardous and exposure to these drugs possesses potential health risks among healthy healthcare professionals[1]. Most antineoplastic drugs are defined as hazardous. The Occupational Safety and Health Administration had established recommendations for the safe handling of these hazardous drugs. But still there is lack of practice of standard guidelines for handling of antineoplastic drugs. Many of the studies investigating occupational exposure to chemotherapy in healthcare workers were conducted prior to the development of safe handling standards for the preparation and administration of cytotoxic drugs. Given the changes in the handling procedures for cytotoxic drugs, the risk of toxic effects in healthcare workers may have declined. Nevertheless, the potential health risks for hospital staff still exist as suggested by recent environmental contamination studies showing the presence of hazardous drug contamination on multiple surfaces in the workplace.[2]

Present study was focused to assess the potential health risks from antineoplastic drugs exposure while caring the cancer patients.There is documented evidence of abdominal pain, loss of hair, nasal sores, allergies, skin and eye injury and contact dermatitis from occupational exposure to hazardous drugs.[3]

The conceptual framework used in the present study is developed based on Rosenstock's Health Belief Model (1988). This model describes that how the perception of health and disease of and individual influences his/her health behaviour. The model explains that the individuals are more likely to take preventive actions if the perceived benefits are more than the perceived barriers. The model proposes that the staff nurses will not attempt to undertake preventive actions for antineoplastic drug exposure unless they understand that they are susceptible to health risks from these drugs exposure.[3,4]

Nurses who worked anytime in cancer center had an increased risk of breast cancer and their offspring were at risk for congenital anomalies of the eye. This study also showed that durations of exposure to antineoplastic drugs was directly associated with an

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increased risk for rectal cancer.[5] Nursing personnel have one of the highest job related injury rates of any occupation. In a study 405 participants reported infertility[6]. A study reported significantly elevated odd ratio of 1.5 for self-reported infertility due to chemotherapeutic drug handling. 3.1% birth defects in oncology staff as compared to 1.5% birth defects for non-oncology nurses and 0.3% for non-nurses.[7] Nurses who are highly exposed to antineoplastic drugs had history of taking longer time to conceive as compared to the nurses referent from antineoplastic drugs exposure. Association was reported between exposure to chemotherapy and spontaneous abortions.[7] DNA damage was significantly higher in the lymphocytes of exposed nurses than the controls. It was also found that frequency of micronuclei in peripheral blood lymphocytes was significant increase in the exposed nurses compared to control groups[8].

Purpose of the study

This study was done to explore potential health risks among staff nurses, use of personnel protective equipment and also to identify the health problems experienced by them due to the antineoplastic drugs exposure. This findings can help in preparing the quality health assessment policies and performance indicators which can safe guard the staff nurses from hazards of antineoplastic drug exposures.

MATERIALS AND METHOD

Design: Cross sectional explorative survey design was used .

Settings: The study was conducted in five different hospitals with separate oncology units at Udupi district and Mangalore, Karnataka in India.

Sampling technique: Purposive sampling technique.

Sample: Sample size consisted of 150 staff nurses who are presently working in the oncology units, transferred to another unit after working in the oncology units, and also who were willing to participate in the study.

DATA COLLECTION

Two tools were used for collecting data, Tool 1 was demographic proforma and Tool 2 was Potential health risks from antineoplastic drug exposure assessment tool. This tool had the items on risk factors, the presently experienced health problems, health problems experienced while working in the oncology unit and the duration of it. The reliability of potential health risks from antineoplastic drug exposure assessment tool was established by test –retest method and computed using correlation coefficient method. The reliability score was r = 0.89. Purpose of the study was explained and informed consent was obtained from the participants following that the questionnaire on potential health risks from antineoplastic drug exposure were distributed to all selected 150 staff nurses who is working in the oncology units. Overall response rate of 100%.

FINDINGS

Descriptive and inferential statistics were computed for all data. The Statistical Package for Social Science (SPSS version 16.0) was used to analyze the collected data.

Sample size consisted of 150 Oncology staff nurses, who were willing to participate in the study. Study result was analyzed to explore potential health risks among staff nurses exposed to antineoplastic drugs as measured by potential health risk assessment tool. The study findings showed that 119 (79.3%) participants belonged to the age group of 20-40-years, 31(20.6%) in 41-60 age group. Qualification revealed 83 (55.33%) of the participants had B.Sc. nursing degree whereas 30(20%) had GNM qualification. The participants total nursing career experience revealed 49(32.7%) had 05-10 years of experience, 30(20%) had more than 10 years of experience and 23(15.3%) had less than 5 years of experience. Years of experience in oncology unit revealed 80% (53.3%) had less than 5 years of experience in the oncology ward,52(34. 7%) had 5 to 10 years of experience 9(6%) had more than 10 years of experience in the oncology unit. None of them reported to have any specific illness prior joining to the oncology unit. Study result also focus on significant association between usage of PPE and potential health risks from antineoplastic drug exposure and significant association between usage of PPE and potential health risks from antineoplastic drugs exposure among staff nurses of oncology units.

Table 1: Association between usage of PPE and potential health risks.N=150

	Usage of PPE				
Potential health risks	**Inadequate**	**Adequate**	**$\chi 2$**	**df**	**p-value**
No risk	7	0			
Low risk	70	68	9.267	2	0.010
Medium risk	3	2			

P <0.05

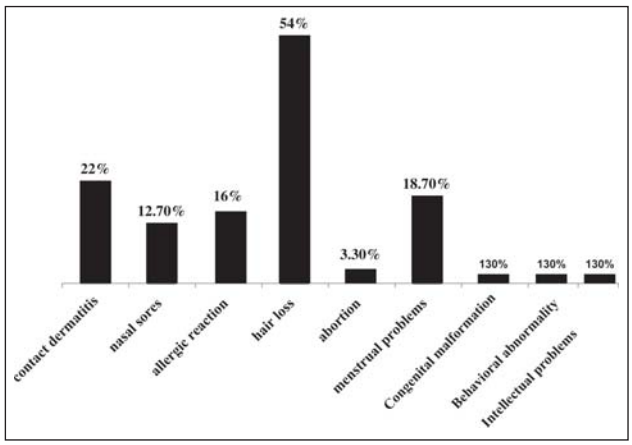


Fig. 1. Bar diagram showing common types of potential health risks from antineoplastic drug exposure in staff nurses working in oncology units.

Potential health risks from antineoplastic drug exposure

This section explains about potential health risks of oncology unit staff nurses who participated in the study and it was described in terms of risk score. The study result found that most of participants 138 (92%) had low degree of potential health risks, 7(5%) participants had medium degree of potential health risks and only 5(3%) participants were free from potential health risks.

Major identified health problems were contact dermatitis (22.7%), nasal sores (12.7%), allergic reaction (16%), hair loss (54%), abortion (3.3%), menstrual problems (18.7%), congenital malformation, behavioral abnormality and intellectual problems in offspring's (1.3 % each). The same fin dings are depicted in Fig no:1

Association between usage of PPE and potential health risks from antineoplastic drug exposure

The result of this section shows that Chi square value was 9.267 and p value at 2 degree of freedom was 0.010, which is less than 0.05. Findings of this study interpret that the usage of PPE in clinical practice by staff nurses working in oncology unit and the potential health risk s were interdependent and which decreases the degree of potential health risks from antineoplastic drug exposure.

Association between demographic variables and potential health risks

Association between duration of antineoplastic drug handling experience and potential health problems were computed using Chi square test. Chi square value for duration of antineoplastic drug handling experience was 7.829, with the p- value of 0.020 which was more than 0.05, stating that the potential health risks and duration of antineoplastic drug handling experience exposure was interdependent. But there was no significant association found between the other demographic variables.

DISCUSSION

Findings of the present study explains that most of the participants138 (92%) had low degree of potential health risks and major identified health problems were contact dermatitis (22.7%), nasal sores (12.7%), allergic reaction (16%), hair loss (54%) , abortion (3.3%) , menstrual problems (18.7%) ,congenital malformation, behavioral abnormality and intellectual problems in offspring's (1.3 % each)

The findings of present study also showed that the potential health risks and handling of antineoplastic drug was interdependent. The exposure was assessed by total work experience and duration of exposure in oncology units. The findings of the study supported the study done by R A. Pamela, S John et al on cancer incidence and adverse pregnancy outcome in registered

nurses potentially exposed to antineoplastic drugs. This study also reports that nurses who worked anytime in a cancer center had an increased risk of breast cancer, rectal cancer and their offspring were at risk for congenital anomalies of the eyes.[5]

The findings of the present study is also supported by a study done by P V Rekhadevi, et al in Hyderabad in year 2007 to assess the genotoxicity among 60 oncology nurses. Genotoxicity was detected by comet assay and micronucleus test. The test was compared with 60 people of same age and sex. The DNA damage extent was evaluated in leukocytes of all the participants by the measurement of mean comet tail length. This study found that the DNA damage was significantly higher in the lymphocytes of exposed nurses than the controls. It was also found that there was significant increase in frequency of micronuclei with peripheral blood lymphocytes in the exposed nurses compared to control groups.[8]

Ethical Clearance: Administrative permission was obtained from the respective institutional heads and also from the Institutional ethical committee of Kasturba Hospital Manipal (IEC 568/2013). Informed consent was obtained from the participants.

Conflicts of Interest: Nil

Funding: Nil

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Correlates of Quality of Life Patients with Cirrhosis of Liver Admitted in Selected Hospitals of Udupi Taluk, Karnataka

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ABSTRACT

Background: Cirrhosis of liver is a devastating and disabling chronic disease.

Aim: an explorative survey was conducted among the patients with cirrhosis of liver in Udupi taluk hospitals, with the objective to assess the Quality Of Life, emotional wellbeing, functional status, socioeconomic status, family supports of the patients with cirrhosis of liver and also to find the relationship between these variables.Data was collected using purposive sampling technique from126 patients who was conscious, alert, admitted and diagnosed with cirrhosis of liver in the selected hospitals of Udupi taluk which had more than 50 bed strength.

Results: Findings of the study revealed that majority of the samples were male 97.6% (123). Majority of them 42.1% (53) belong to the group of 51-60 years. Most of the of patients (42.1%) rated their QOL as neither poor nor good. Majority of the 52.4% (66) of the patients with cirrhosis were emotionally stable, Most of the patients 35.7% (45) were in the category of moderate dependence status. Seventeen percentages (13) of them were totally dependent.High positive correlation was shown between emotional wellbeing and quality of life. (? = 0.920 p <0.001),weak positivecorrelation was found between QOL and socio economic status (? = 0.275 (p<0.002), and also there was a weak positive correlation between QOL and family support (? = 0.44 p<0.001).

Conclusion: Samples had neither good nor poor quality of life.Emotional wellbeing and family support considerably contributed to the quality of life.

Keywords: *Quality of Life,Cirrhosis of Liver,Emotional Wellbeing, Functional Status, Family Supports.*

INTRODUCTION

Cirrhosis represents a late stage of progressive hepatic fibrosis characterized by distortion of the hepatic architecture and the formation of degenerative nodules.[1] Assessment of quality of life reflects advanced consumer centered path to health care services. Here patients own subjective feeling of their experiences are considered rather treating the patients as objects for the skillful care in the hands of health care professionals. [2]

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MATERIALS AND METHOD

A survey approach was used with an explorative design in order to achieve the objective of assessing the quality of life, emotional wellbeing, functional status, family support and socioeconomic status of patients with cirrhosis of liver also to find the relationship among quality of life, emotional wellbeing, functional status, family support and socioeconomic status of patients with cirrhosis of liver Sample comprised of 126 patients, those who were with normal sensorium, able to communicate, diagnosed with cirrhosis of liver and admitted in hospitals of Udupi taluk with 50 bed strength and above. Hence a purposive sampling technique was used for the study.Pilot study finding was used to calculate the required sample size and thefollowing formula was used to compute the sample size.

$n = (z/\ /2)^2 (\ )^2$

E^2

z/ /2 Constant at 5% level of significance (1.96)

= standard deviation of pilot study (13.96)

E = Margin of error 2.5

Calculated sample size was 120, and 126 samples were included for the study.

Objectives of the study were; to assess the QOL of the patients with cirrhosis of liver as measured by WHO QOL BREF questionnaire (r =0.83),identify the emotional wellbeing of the patients with cirrhosis of liver as measured by self-reported emotional wellbeing questionnaire (= 0.58),determine the functional status of the patient with cirrhosis of liver as measured by using Modified Barthel Index (r= 0.78),explore the socioeconomic status of the patient with cirrhosis of liver as measured by modified Kuppuswamy's modified socio-economic status scale 2012 version,identify family supports of the patients with cirrhosis of liver as measured by family supports scale (= 0.74).Regarding ethical perspective;administrative permission from the randomly selected hospitals with 100 bed strength and above in Udupi taluk, IEC permission (IEC569/ 2013),written consent was obtained from the participant and also anonymity was maintained.

FINDINGS

Majority 97.6% (123)of the samples were male. Most53 (42.1%) of them belong to the group of 51-60 years. Out of 126 samples 43 (34.1%) were having the secondary education. Majority114 (90.5%) of them were married. Most of the samples were coolie workers and98(77.8%)were belongs to Hindu religion. Majority103(81.7%)of the samples belong to nuclear family and 123 (97.6%) samples were non-vegetarian. Three patients were admitted 12 times during the course of illness. Majority 69.8% (88) of the samples knew about what they are suffering from and 114 (90.5%)sampleswerehaving habits of drinking alcohol among them 46 (40.5%) had the habit of drinking alcohol every day and 7 samples had the history of intake of 270 ml per day. The following signs and symptom were experienced by the samples with cirrhosis; tremor 89 (70.6%) anorexia 67 (53.2%) nausea 39 (31%) change in bowel habit23(18.3%) hematemesis 44 (34.9%) gastritis 2217.5% jaundice8(6.3%) palmar erythema 28 (22.2%)and peripheral edema 42 (33.3%).

Quality of life of Patients with cirrhosis of liver

The quality of life of cirrhosis of liver patients were assessed using WHOQOL BRIEF 26. It had four domainsand two items that described the overall QOL of cirrhosis of liver patient's life. The first item explained the individual's overall perception of quality of life and item number two explained the individual's over all perception of health. The four domains included were physical, psychological, social, and environmental, obtained score denoted individual's perception of quality of life in each particular domain. The mean score of each domain was used to calculate the each domain score. Obtained row score were converted to transform score as per the norm suggested by WHO.

Data presented in the table 1 denotes most (42.1%) of patients rated their QOL as neither poor nor good. Further details of satisfaction with health of cirrhosis of liver patient is described in table no: 2.

Data presented on the table 2 denotes majority of patients (54%) were neither dissatisfied nor satisfied with their own health and also none of them were very satisfied or very dissatisfied with their own health. Further details of domain wise distribution of quality of life of cirrhosis of liver patient is explained in table no:3.

Data in table 3 indicates that patients with cirrhosis of liver have higher quality of life in social domain (score 81). Low quality of life on environmental domain (score 48)

Emotional wellbeing of Patients with Cirrhosis of liver

The emotional wellbeing score were categorized in to emotionally stable (68-110) and emotionally unstable (0-67). Frequency and percentage distribution of emotional wellbeing of cirrhosis of liver patients were computed. Data presented in the table 4 denotes that 52.4% of the patients with cirrhosis were emotionally stable, remaining 47.6% were emotionally unstable.

Functional status.

Functional status of patients with cirrhosis was assessed using Modified Barthel Index. The score were

classified in to total dependence (0-20) severe dependence (21-60) moderate dependence (61-90) slight dependence (91-99) independence (100).The table 4 shows that most of the patients 45 (35.7%) were in the category of moderate dependence status and only 19.8% of patients were independent.

Socioeconomic status.

Socioeconomic statuses of the patients were assessed by Kuppuswamy's modified socioeconomic status scale. The data classified as per the tool (26-29) Upper, (16-25) Upper Middle, (11-15) Middle/Lower middle, (5-10) Lower/Upper lower, <5 Lower.The data on the table 5 shows that the majority of the patients were from middle lower classes 66 (52.4%) and least number of patients were from upper middle 22(17.5%).

Family support

Family support of the patients was assessed by family support scale. Family support was arbitrarily classified in to three categories based on attained score. Good (45 - 48) moderate (40 - 44) poor (36 - 49).Data in the table 5 shows that the majority of the patients had poor family supports 36.5% (46) and 35.7% were enjoying good family support.

Relationship between QOL and emotional wellbeing

To find the relationship between quality of life and emotional wellbeing functional status, socioeconomic status, and family supports the normality of data were tested using Shapiro-Wilk test. As the data were not normally distributed, non-parametric test Spearman's Rho was computed. The following table no 8, represents Spearman Rho computed quality of life and other variable such as emotional wellbeing, functional status, socioeconomic status, and family supports.

Relationship between QOL and emotional well being

The data in the table 8 shows that there was a highly positive correlation between emotional wellbeing and quality of life. (= 0.920 p <0.001). The findings signify that there was a significant positive relationship between quality of life and emotional wellbeing. Whereas there was no relationship found between cirrhosis and quality of life and functional status. (ñ = 0.26 1) (= 0.101). A weak positive correlation were found between quality of life and family support(ñ = 0.444) (= 0.00). Positive weak relationship were found between quality of life and socioeconomic status(ñ = 0.275) (= 0.02). Thus it can be interpreted that quality of life of patients with cirrhosis liver was interdependent of emotional wellbeing, family support and socioeconomic status, where as it was independent of functional status and also it was influenced by social domain and environmental domain.

DISCUSSION

Majority of samples with cirrhosis of liver, 42.1% (53) experienced neither poor nor good quality of life, and 54 % (68) of the people were neither dissatisfied nor satisfied with their own heath. Among the QOL domain social domain was scored highest among all the domains of quality of life with the score of 81 and environmental domain was scored least (48). Present study findings were contradicted with study findings of the Parkash et al conducted a study to assess the health related QOL and factors affecting QOL among 155 males and 118 female patients who were suffering from chronic liver disease at Karachi in 2012. Using a QOL on chronic liver disease. The study revealed that fatigue domain had incomparably decreased mean score of 4.36 when compared to other domain. Major portion of the patients had poor (<5) score suggesting that patient with chronic liver disease have poor QOL.[3]

Emotional wellbeing patients with cirrhosis of liver

Majority 52.4 % (66) of the samples with cirrhosis were emotionally stable and 47.6% (60) were emotionally unstable and there was a perfect positive relationship between QOL and emotional wellbeing found with the p value of <0.001.Qiao et al conducted a survey to evaluate the health-related quality of life among patients with hepatocellular carcinoma by TNM classification using functional assessment of cancer

therapy-hepatobiliary questionnaire in China between June 2008 and April 2009.The study was conducted among 140 samples, out of which 96.5% patients were diagnosed as cirrhosis of liver. The result shows that there was a reduction in score of QOL significantly from TNM Stage I to Stage lIlA. Physical and emotional wellbeing scores gradually decreased from Stage I (P = 0.002) to Stage lIlA (P = 0.033). Physical and emotional wellbeing were the most affected areas among patients with hepatocellular carcinoma.[4]

Functional status of patients with cirrhosis of liver

Majority (35.7%) of patients were belonging to moderate dependency status and total dependence among the samples were 13.5%.There was no relationship found between cirrhosis and quality of life (ñ = 0.261) (p = 0.101). These findings were supported by a case control study conducted by Parikh- Patel et al on activities of daily living of people having primary biliary cirrhosis at California in 2006 among 126 cases and 141 controls. The results revealed that there was significant reduction in activities of daily living of cirrhosis clients than the controls with the value of < 0.001.[5]

Socioeconomic status of patients with cirrhosis of liver

Majority (52.4%)of patients were belongs to middle lower class family income group, 30.2% of the samples were belong to upper lower class income group,and 15.7%were belong to upper middle class family income group. There was a positive weak relationship was found between quality of life and socioeconomic status. This findings were supported by the study conducted by Parkashet alto evaluate the health related QOL and factors affecting QOL in subjects with chronic liver disease at Karachi in 2012. Sample consisted of 155 males and 118 females. Results found that chronic liver disease was more in middle income patients (54%) than in high income patients (11 %).[3]

Family support of patients with cirrhosis of liver

Majority of patients (36.5%) were not enjoying the family support and there was a weak positive correlation were found between quality of life and family support. These findings were supported by the study conducted by Han et al in Korea on 2001 to identify the causes affecting the QOL among 1,748 subjects who were suffering from chronic illness using Ro's scale on QOL. The result showed that chronically ill patients were moderately satisfied with their QOL and a high mean score of 3.34 was scored in family support and least in physical activity (2.92). It concludes with the message that family support is the key area of QOL among chronically ill patients. [6]

CONCLUSION

Patients with cirrhosis of liver experienced neither good nor poor quality of life. They were neither satisfied nor dissatisfied with their health status. Emotional wellbeing and family support considerably contributed to their quality of life and also quality of life was influenced by social and environmental factors too.

Table 1: Frequency and Percentage of quality of life

n = 126

S.No	Item	Frequency %
How do you rate your quality of life?		
1.	Very poor	
2.	Poor	2318.3
3.	Neither poor nor good	5342.1
4.	Good	4334.1
5.	Very good	0705.6

Table 2: Frequency and Percentage of satisfaction with own health of patient's with cirrhosis of liver.

n= 126

S. No	Item	Frequency %
How satisfied are you with your health		
1.	Dissatisfied	2923
2 .	Neither dissatisfied nor satisfied	6854
3.	Satisfied	2923

Table 3: Domain wise Median, SD, Minimum and Maximum score of quality of life of cirrhosis of liver patient.

(n=126)

S.No	Domain	Median score	Transformed score	SD	Minimum score	Maximum score
1.	Physical					24612.361929
2.	Psychological					20571.731723
3.	Social					1318.821114
4.	Environmental					24482.252128

Table 4: Frequency and percentage distribution of emotional wellbeing and functional status of cirrhosis of liver patient

(n=126)

S. No	Emotional wellbeing	Frequency %
1.	Emotionally unstable	6047.6
2.	Emotionally stable	6652.4
Frequency and percentage distribution of functional status		
1.	Total dependence	1713.5
2.	Moderate dependence	4535.7
3.	Slight dependence	3931.0
4.	Independence	2519.8

Table 5: Frequency and percentage distribution of socioeconomic status and family support of cirrhosis of liver patient

(n=126)

S.No.	Socioeconomic status	Frequency%
1.	Upper lower	3830.2
2.	Middle lower	6652.4
3.	Upper middle	2217.5
Family support		
1.	Poor	4636.5
2.	Moderate3527.8	
3.	Good	4535.7

Table 6: Relationship between QOL and emotional wellbeing, functional status, socioeconomic status, and family supports

(n-126)

VariableEmotionalFunctionalSocioeconomicFamily
QOL0.920**0.1010.275**0.444
p- Value0.0000.2610.0020.000

(** significant at the level of 0.05)

Source of Funding: Self-funded.

Conflict of Interest: Nil

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Hair Care Product Usage Purposes and Brand Predilection of Male Consumers

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ABSTRACT

This Marketing Research was conducted to understand the male consumer behaviour in Hair Care Products (HCP) industry in Chennai city with the primary objective to explore the underlying dominant dimensions of Hair Care Product Usage Purposes (HCP-UP) and also to identify the difference between branded and unbranded consumer usage purposes of HCP for the segmentation and targeting in Indian cosmetics industry. This study was conducted among 375 male HCP consumers residing in Chennai city by using descriptive and exploratory research design by adopting convenient non-random sampling. The tools such as, percentage analysis, factor analysis and t test has been applied to explore statistical findings and empirical evidences to draw meaningful suggestions and conclusion for the implementation. The results reveal that, Enrichment and Protection are dominant dimensions of HCP-UP variables and protection don't significant difference with respect brand preference whereas, Enrichment has significant difference with respect to brand preference in hair care products industry. This study concluded that, Male consumers prefer branded products to enhance and enrich the hair rather protection and medical purposes. Further, it is suggested that to segmentation and targeting is very imperative to understand market conditions to retain customers and also to attract new consumers by fulfilling the individual needs.

Keywords: *Hair Care Product, Usage Purpose, Brand, Protection, Enrichment, Segmentation and Trageting.*

INTRODUCTION

Shampoo, conditioner, hair dye, hair growth lotions, anti-dandruff and hair colouring/styling gel are commonly known as hair care products. Globally, hair care products are available in branded as well as unbranded with variety of categories. Hair care products helps the consumers to reduce hair fall and hair loss, to relieve from dry, itchy scalp and dandruff, to make hair silky, shiny and stronger, in order to encourage hair growth and to give life to dull hair. Consumers are using hair care products to maintain personal hygiene and also to gain personal confidence with stylish appearance. Youngsters are often using hair care products to attract opposite gender by the means of improving handsomeness and also to show their social status for the acceptance among peer group and friends. In recent years, at global scenario hair care industry is witnessing a rapid growth in expansion and revenue generation. Indian Hair care products industry is also not the exception, because the market shares and sales volumes are increasing day by day.

Branding is a vital marketing tool for hair care product manufacturers in order to reach prospective consumers. Products possess high brand value will have impact among consumer loyalty as well as consumer purchase consideration aspects. The purchase consideration aspects such as, quality, contents, price, performance, advertisement, packaging, fragrance, availability, consistency, suitability, promotions, manageability, medical indications, relief, dynamism, friends and peer group influence, popularity and brand are the predominant aspects determining the hair care products usage purpose among the consumers.

Literature Review

Mamta Vyas (2014)[1] conducted an empirical study to analyse the Indian hair care products industry with

comparing myths facts versus fictions and customer satisfaction. This study also aims at finding the inducers of brand preference among consumers in hair care products usage. The result reveals that there is a significant relationship between brand preference and purchasing expectation. Khawaja Mubeenur Rahman &*et.al*(2014)[2] carried an analytical study to explore the difference market players of shampoos in India. SWOT analysis and portfolio analysis have been carried among different shampoo brands with employing Boston Consulting Group Matrix. The result reveals that hair care products industry in India is contributing the considerable portion around 9% of the FMCG sector and some top branded shampoos are placed in "stars" cell in the Bostan Consulting Group Matrix. Himani Sharma and Shallu Methta (2012)[3] said that females have higher shampoo usage and brand preference compared to males. Albert Ferror &*et.al*(2012)[4] says European market is the world largest cosmetics industry in the world. Reddy Praneeth Karnam and *et.al* (2014)[5] educated imperativeness of shampoo in FMCG category. Alexandra Madar *et.al* (2013)[6] conducted a case study to explore the animal testing issues in shampoo does not have significant impact on purchase intentions of the consumers. Anuj Thapa (2012)[7] found that price, scheme of brands and advertisements are influencing the consumer switching behaviour with regard to shampoo.

OBJECTIVES OF THE STUDY

1. To study the personal profile of the male hair care product consumers in Chennai city.
2. To identify and understand the underlying dominant dimensions of Hair care product usage purposes of male consumers.
3. To identify the differences between brand preference and Hair care product usage purposes factors of male consumers.

Research Methodology

The present study is analytical in nature and has adopted survey method for its findings. This study is based mainly on the primary data collected from the male hair care products consumers through a well-designed and well-structured questionnaire from 375 respondents residing in Chennai using convenient sampling method. The Hair care product usage purposes variable were measured using 5 point Likert scale. To check the reliability of scales, Cronbach's Alpha reliability coefficient was used. The value being 0.945 and scale are more consistent and highly reliable.

QUESTIONNAIRE DESIGN

A questionnaire was finalised with two sectionsto collect information from the male hair care product consumers.

Table 1: Questionnaire Design

Sections	No. of Variables	Scale developers
Section I(Demographic Profiles)	Eight	Baskaran. E and Balaji P. (2015)[8]
Section II(Hair Care Product Usage Purposes)	Eleven	Baskaran. E and Arulalan. M.V (2017)[9]

Statistical tools used

The data collected were subjected to percentage analysis, factor analysis, t - test using SPSS Version 17.0.

Table 2: Demographic Profiles of Respondents

Profiles	Groups With Frequency				Total
Marital Status	**Single = 198 [52.8%]**		**Married = 177 [47.2%]**		**375 [100%]**
Nature of Family	Nuclear Family = 283 [75.5%]		Joint Family = 92 [24.5]		375 [100%]
Educational Qualification	Upto School Education = 66[17.6%]	Under Graduation = 242 [64.5%]	Post Graduation = 44 [11.7%]	Professional = 23 [6.1%]	375 [100%]
Occupational Status	Private Employees= 312 [83.2%]		Others = 63 [16.8%]*		375 [100%]
Monthly Family Income	Upto Rs. 25,000= 217 [57.9%]		Above Rs. 25,000= 158 [42.1%]		375 [100%]
Brand Preference	Yes = 285 [76.0%]		No = 90 [24.0%]		375 [100%]
Regular Visit to Parlour or Spa	Yes = 147 [39.2%]		No = 228 [60.8%]		375 [100%]
Age	Upto 35 Years= 200 [53.3%]		Above 35 Years= 175 [46.7%]		375 [100%]

*Note: Others = (Students + Government Employees + Business Man's + Retired Persons)

Table 2 indicates that majority of the respondents are single (52.8%), under graduates (64.5%), private employees (83.2%), aged less than 35 years (53.3%), and earning monthly family income of upto Rs. 25,000 (57.9%). Majority of respondents are hailing from nuclear families (75.5%), preferring branded hair care products (76.0%) and not regularly visiting parlour or spa (60.8%).

Table 3: Factorisation of Hair Care Products Usage Purposes [HCP - UP] Variables

Factors &% of Variance Explained	Variables	Factor Loading	Mean	S.D	Comm-Unalities	MSA
Hair Protection Factor (HPF) 27.518%	To make hair soft, full and manageable	0.680	3.571	1.074	0.479	0.822
	To add proteins to hair	0.644	3.571	1.144	0.442	0.866
	To darken hair colour	0.635	3.437	1.135	0.425	0.882
	To give life to dull hair	0.611	3.440	1.057	0.403	0.896
	To maintain natural hair balance	0.603	3.691	1.099	0.438	0.867
	To give instant moisture to hair	0.599	3.416	1.122	0.415	0.879
	To remove pollutants and impurities from scalp	0.542	3.485	1.111	0.538	0.859
Hair Enrichment Factor (HEF) 20.638%	To relieve dry, itchy scalp and dandruff	0.824	3.701	0.945	0.689	0.791
	To reduce hair fall and hair loss	0.788	3.811	1.106	0.628	0.784
	To make hair silky, shiny and stronger	0.588	3.755	1.030	0.488	0.852
	To encourage hair growth	0.584	3.691	1.029	0.538	0.867
KMO – MSA = 0.851 and Total % of Variance Explained = 48.155						
Bartlett's Test of Sphericity Chi Square value of 1074.641 with df 55 at P Value of 0.000						

Table 3 indicates that HCP-UPVariables with their communalities and MSA values ranging from 0.403to 0.689 and 0.784 to0.896 respectively have goodness of fit for factorization. KMO-MSA value of 0.851 and chi-square value of 1074.641 with df 55 and P-value of 0.000 reveal that factor analysis can be applied for factorization of 11 HCP-UP variables. Two dominant independent HCP-UP factors have been extracted out of 11 HCP-UP variables and they together are explaining 48.155% of total variance. The most dominant factor is Hair Protection Factor (HEF) followed by Hair Enrichment Factor (HEF) in their order of dominance.

Table 4: Significance of Differences between Brand Preference and Hair Care Product Usage Purpose Factors

Factors	Groups	Mean	S.D	Mean Difference	t-value	df	P – Value	Inference
Hair Protection Factor(HPF)	Unbranded	25.000	5.201	0.512	0.845	373	0.399	Not Significant
	Branded	24.487	4.953					
Hair Enrichment Factor(HEF)	Unbranded	14.333	3.284	0.821	2.218	373	0.027	Significant
	Branded	15.154	2.988					

Table 4 shows that there is significant difference in brand preference of male consumers in hair care products usage purposes with respect to Hair Enrichment Factor (HEF) whereas, there is no significant difference in brand preference of male consumers in hair care products usage purposes with respect to Hair Protection Factor (HPF).

Major findings of the study

1. Majority of the respondents are single (52.8%), under graduates (64.5%), private employees (83.2%), aged less than 35 years (53.3%), and earning monthly family income of upto Rs. 25,000 (57.9%). Majority of respondents are hailing from nuclear

families (75.5%), preferring branded hair care products (76.0%) and not regularly visiting parlour or spa regularly (60.8%).

2. Two dominant independent HCP-UP factors have been extracted out of 11 HCP-UP variables and they together are explaining 48.155% of total variance. The most dominant factor is Hair Protection Factor (HEF) followed by Hair Enrichment Factor (HEF) in their order of dominance.

3. There is significant difference in brand preference of male consumers in hair care products usage purposes with respect to Hair Enrichment Factor (HEF) whereas, there is no significant difference in brand preference of male consumers hair care products usage purposes with respect to Hair Protection Factor (HPF).

Suggestions and conclusion

After perusal of the findings of the study, the following suggestions have been extended to benefit the various HCP stakeholders for effective product development and usage.

1. Male consumers are using hair care products for the purpose of protection and enrichment to maintain hair. The manufacturers and marketers are suggested to produce and market hair care product which makes hair, soft, dark and natural, removing pollutants, removing impurities, reducing hair fall, encouraging hair growth and also adding moisture and proteins to the hair to enhance hair care products usage and satisfaction.

2. Male consumers prefer branded products to enhance and enrich the hair rather protection and medical purposes. So, Branded manufacturers are advised to segment target male consumers using hair care products for enrichment to enhance hair care product usage purposes and usage satisfaction.

3. Male consumers are also suggested to use branded products for the purpose of hair protection along with hair enrichment.

To conclude, hair care products industry is grooming day-by-day in Indian cosmetics segment. This timely marketing research was conducted to explore dimensions of hair care products usage purposes such as, hair protection and enrichment. The manufacturers and marketers are suggested to segment and target the HCP consumers based on their usage purposes. Further results reveal that, branded products are preferred by consumers for the purpose of enrichment and there is no difference in brand preference and hair care products for protection usage.

Limitations of the study

1. This study collected data from only male respondents residing in Chennai. Hence it lacks generalisability to other cities, states and countries.

2. Owing to time and money constraints, the study restricted its sample size to only 375.

3. This study adopted Convenience Sampling Method. So, Limitations associated with Non-Random Sampling is also applicable to this study.

Scope for future studies

1. A Separate study may be conducted in future among female consumers of all age groups such as, youngsters, lower middle age group, upper middle age group and aged group respondents to explore determinants of hair care product usage purposes.

2. A Comparative study may be conducted in near future among male and female hair care product users to segment and target prospective customers to satisfy individual needs and increasing customer retention in Hair care products industry in India.

3. This study may be extended to other metropolitan cities in India.

Ethical Clearance: Yes

Conflict of Interest: Nil

Source of Funding: Self

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Effectiveness of Human Resource Practices and its Impact on Organisational Commitment among Employees in Chennai City

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ABSTRACT

Human resource management (HRM) is the strategic and coherent approach to the management of an organization's most valued assets -the people working in the organization, who individually and collectively contribute to the achievement of the objectives of the business.Organizational commitment is the individual's psychological attachment to the organization. In this study an attempt has been made to study the impact of human resource management practices on organisational commitment of the IT employees. The result reveals that Controlling Factor (CF), Procurement Factor (PF), Recruitment Factor (RF), Appreciation Factor (AF) are significantly influence the total organisational commitment of the IT employees in Chennai city. To conclude Organisation need to ensure job security, adequate pay, and better relationship with subordinates, good support and guidance to employees and effective utilization of resource through effective organizational climate and adoptable organisation culture will enrich employee commitment.

Keywords: *Human Resource Practices, Organisational Commitment, Controlling Factor (CF), Monetary Benefits Factor (MBF), Executive Development Factor (EDF), Recruitment Factor (RF), Job Enrichment Factor (JEF), Social Security Factor (SSF) and Appreciation Factor (AF).*

INTRODUCTION

Human resource management (HRM) is the strategic and coherent approach to the management of an organization's most valued assets -the people working in the organization, who in dividually and collectively contribute to the achievement of the objectives of the business. Organizational commitment is the individual's psychological attachment to the organization. The basis behind many of these studies was to find ways to improve how workers feel about their jobs so that these workers would become more committed to their organizations. Organizational commitment predicts work variables such as turnover, organizational citizenship behaviour, and job performance. Some of the factors such as role stress, empowerment, job insecurity and employability, and distribution of leadership have been shown to be connected to a worker's sense of organizational commitment.

Review of Literature

Organizational commitment can be contrasted with other work-related attitudes, such as job satisfaction, defined as an employee's feelings about their job, and organizational identification, defined as the degree to which an employee experiences a 'sense of oneness' with their organization. According to Porter *et.al* (1974)[1] noted that organizational commitment can be defined as relative strength of involvement of any individual with a particular organisation. Whereas, Kanter (1968)[2] is a view of that organizational commitment is the level to which an employee wishes to devote his energy and loyalty to a particular organisation.

Susmritisahu&*et.al* (2014)[3] conducted a study to examine the moderating role of perceived organizational support on relationship between emotional intelligence and organizational commitment. The result reveals that, emotional intelligence has

positive and significant impact on organizational commitment of employees and perceived organizational support act as significant moderator of the relationship between emotional intelligence and organizational commitment.

Mehmet METE (2014)[4] conducted a empirical study to identify the factors affecting organizational commitment and job satisfaction of financial analysts, specialists and assistant specialists working in banking sector together with service authorities. The primary data were collected with a help of structured questionnaire using convenient sampling and the data collected were subjected to analysis. The result reveals that, job satisfaction and organizational commitment of the bank personnel working in the corresponding sector affect the personnel who is in the same position and also the organizational commitment of the personnel who is no satisfied with his job is low or none. Finally they suggested revising the existing wage system.

Osman Alipour (2014)[5] investigated the relationship among the organizational justice and organisation commitment of education staff. The research is descriptive and analytical in nature. The primary data were collected through the structured questionnaire. The results showed that meaningful and positive relationship among organizational justice and organizational commitment of education staff. Also, findings of the research showed meaningful and positive relationship among distributive, procedural, and interactional justice and organizational commitment of education staff.

Mohammed MahmoudiMaymand& et.al (2014)[6] says, when individuals and teams are committed to the values and goals of the organisation, they will have a higher spirit, less job –leaving rate and more satisfactions of the work and consequently they will become more useful for the organisation. The investigation has been made to know the relationship with organizational commitment and innovation. The result reveals, there is a positive and significant association between organizational commitment and innovation. The recommended the organisation to increase the employee's affective commitment through training the required skills and in – service trainings in order to heighten their innovation.

Prabhajot KaurMahal (2012)[7] had conducted research on "Organizational Commitment and Employee Retention" and concluded that globalization has not only helped the organizations to look for proficient employees, but also to retain the expert, talented and accomplished employees. Consequently, the role of Human Resource (HR) practices in fostering employees' engagement, organizational practices in retaining employees and employees' commitment is paramount. The main objective of the study is to examine, evaluate and interpret the relation between organizational HR practices and employee commitment, and to see whether these are positively or negatively correlated, as there are not many studies which examine whether there is a positive and negative relation between HR practices and employee retention in the Indian economy.

OBJECTIVES OF THE STUDY

1. To study the personal profiles of the IT employees in Chennai City.
2. To identify the underlying dominant dimensions of Human resource practices among respondents.
3. To explore the underlying dominant dimensions of Organisational Commitment among the respondents.
4. To find out the influence of personal profiles of the respondents and Human Resource Practice factors (HRPF) on Organisational Commitment (OC).

RESEARCH METHODOLOGY

Primary data were collected with the help of a well-designed structured Questionnaire, from 300 respondents residing in Chennai using convenient sampling method. The Human Resource Practices variables and Organisational Commitment variables were measured using 5 point Likert scale. To check the reliability of scale, Cronbach's Alpha reliability coefficient was used. The value being 0.875 and 0.823, scale is more consistent and highly reliable.

Questionnaire Design

The Questionnaire has been divided into 3 sections.

Section I: Deals with personal profiles such as gender, age, educational qualification, total number of work

experience, experience in current organisation, level of employment, monthly family income.

Section II: Deals with 30 variables on Human Resource Practices among respondents.

Section III: Deals with 8 variables on Organisational Commitment variables among respondents.

Statistical Tools Used

The data collected were subjected to Percentage analysis, Factor analysis and Multiple Regression Analysis using SPSS Version 17.

Personal Profiles of the Respondents

Majority of the respondents are Male (60.3%). Sizeable portion of the respondents are Graduates (48.3%), having total experience of minimum one year to five years (38.7%) and same experience in current organisation (43.0%). Sizeable portion of the respondents working in middle level designations (44.7%) and earning Monthly Family Income between Rs.20,001 to Rs.50,000(46.7%).

Factorisation of Human Resource Management Practices (HRMP)Variables

Human Resource Management Practices (HRMP) Variables with their communality values and MSA ranging from 0.428 to 0.683 and 0.843 to 0.937 have goodness of fit for factorization. KMO-MSA value of 0.795 and chi-square value of 2765.187 with df of 465 and P-value of 0.000 reveal that factor analysis can be applied for factorization of 30 HRMP variables.Nine independent factors have been extracted out of 30 HRMP variables of which Procurement Factor (PF) is the most dominant one, followed by Controlling Factor (CF), Monetary Benefits Factor (MBF), Executive Development Factor (EDF), Recruitment Factor (RF), Job Enrichment Factor (JEF), Social Security Factor (SSF), Appreciation Factor (AF) and Counseling Factor (CF) in the order of dominance and all the factors together explaining 58.362% of variance.

Factorisation of Organisational Commitment (OC) variables

The Table 4 reveals that OC variables have communalities ranging from 0.462 to 0.738and MSA values ranging from 0.773 to 0.906. Therefore, those OC variables are fit for factorization.KMO – MSA value of 0.828 and Bartlett's Test of Sphericity Chi-Square value of 634.489 with df of 28 and P-Value of 0.000 indicate that the factor analysis can be applied to 8OC Variables. Two independent factors have been extracted out of 10OC variables of which the Recognition factor (RF) is the most dominant one, followed by Engagement factor (EF)and all the factors together explaining 57.147% of variance.

The Multiple Regression Analysis has been applied to study the significance of influence of personal profiles of the respondents and human resource management practice factors on Organisational Commitment.

OLS Model has a goodness of fit for multiple regression analysis and the linear combination of Controlling Factor (CF), Procurement Factor (PF), Recruitment Factor (RF), Appreciation Factor (AF)and Educational Qualification was significantly related to Organisational Commitment, {$F = 30.165$, $p<0.001$}. The multiple correlation coefficient is 0.582, indicating that 34% of the variance of the respondents' Organisational Commitment can be accounted for by linear combination of Controlling Factor (CF), Procurement Factor (PF), Recruitment Factor (RF), Appreciation Factor (AF)and Educational Qualification. From all these it could be said that Controlling Factor (CF), Procurement Factor (PF), Recruitment Factor (RF), Recognition Factor (RCF) are significantly and positively influence Organisational Commitment of the respondents, and Educational Qualification is also significantly influencing in the order of their influence whereas Gender, Age, Number of years of experience, Experience in Current organisation, Level of Employment, Monthly Family Income, Monetary Benefits Factor(MBF), Executive Development Factor (EDF), Job Enrichment Factor (JEF), Social Security Factor (SSF) and Counseling Factor (CF) have no significant influence Organisational Commitment of the respondents.

Major Findings of the Study

1. Majority of the respondents are Male. Sizeable portion of the respondents are Graduates, having total experience of minimum one year to five years and same experience in current organisation. Sizeable portion of the respondents working in middle level designations and earning Monthly Family Income between Rs.20,001 to Rs.50,000.

2. The underlying dominant dimensions of the human resource management practices are Procurement Factor (PF) is the most dominant one, followed by Controlling Factor (CF), Monetary Benefits Factor (MBF), Executive Development Factor (EDF), Recruitment Factor (RF), Job Enrichment Factor (JEF), Social Security Factor (SSF), Appreciation Factor (AF) and Counseling Factor (CF) in the order of dominance and the underlying latent dominant dimensions of organisational commitment is Recognition factor (RF) and Engagement factor (EF).

3. Controlling Factor (CF), Procurement Factor (PF), Recruitment Factor (RF), Recognition Factor (RCF) are significantly and positively influence Organisational Commitment of the respondents, and Educational Qualification is also significantly influencing in the order of their influence.

Suggestions and Conclusion:

1. Organisation is needed to adopt effective recruitment and procurement policies to create larger application pool with larger potential employees.

2. Management should link organisation development with individual needs for better engagement and executive development of employees.

3. Organisation should encourage the workers participation in decision-making and innovation and creativity effective organizational commitment and better job satisfaction.

This study examined the human resource practices dimensions and its impact on organisational commitment among the IT employees in Chennai City. The result reveals that procurement factors, controlling factor, monetary benefits factor, executive benefits factor, recruitment factor, job enrichment factor, social security factor, appreciation factor and counseling factor are the underlying dominant dimensions of human resource practices effectiveness among IT employees. Recognition factor (RF) and Engagement factor (EF) are dominant dimensions of organisational commitment among IT employees. To conclude Organisation need to ensure job security, adequate pay, and better relationship with subordinates, good support and guidance to employees and effective utilization of resource through effective organizational climate and adoptable organisation culture will enrich employee commitment.

Ethical Clearance: Yes

Source of Funding: Self

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Comparative Study on Effect of Misoprostol and Oxytocin in the Active Management of Third Stage of Labor in A Tertiary Hospital in Manipur, India

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ABSTRACT

Background: Hemorrhage of pregnancy is the leading cause of maternal deaths in the developing world, responsible for 25% of all global maternal deaths. Worldwide 125,000 women (out of an estimated 0.5 million maternal deaths) die due to obstetric Post-partum hemorrhage each year (WHO 1999).

Aims and Objects: The prospective randomized comparative study was carried out to compare the effectivity of oral misoprostol versus oxytocin in the active management of third stage of labor in the dept. of obstetrics and gynecology, RIMS, Imphal from September 2008 to August 2009.

Method: Sample of 200 parturient women was divided into study and control group, each group consisting of 100 women.Oral misoprostol 400 microgram and 10 IU oxytocin intramuscularly was allocated randomly among the subjects. Blood loss, any bleeding within the first 24 hours after delivery, maternal hemoglobin or hematocrit concentration pre and post-delivery, occurrence of side effects were noted. Data was entered in SPSS 16 and analyzed using mean, Chi square-test and comparison was made between groups by independent t-test. The study was conducted after the approval from the Institutional Ethical Committee.

Results: Insignificant P= 0.776 highlights that there is no variation of spontaneous vaginal delivery between the groups of women who received misoprostol and the group who received oxytocin. An interesting finding is observed in the table that those who received misoprostol has less percentage of post-partum hemorrhage in comparison with the corresponding percentage of those who received oxytocin. Only 3% of the women who received misoprostol required additional uterotonic. Regarding the side effect, the study group has more percentage i.e., 13% than that of control group (9%). This suggests that there is no significant difference in change in hemoglobin concentration between the two groups.

Conclusion: Oral misoprostol is a potent, effective and stable uterotonic with a rapid onset of action. It is as effective as standard oxytocic drugs (like oxytocin and methergin) in preventing atonic postpartum hemorrhage.

Keywords: *Post-Partum Hemorrhage, Misoprostol, Oxytocin, Active Management of Third Stage of Labor.*

INTRODUCTION

Hemorrhage of pregnancy is the leading cause of maternal deaths in the developing world, responsible for 25% of all global maternal deaths. Thus, worldwide 125,000 women (out of an estimated 0.5 million maternal deaths) die due to obstetric Post-partum hemorrhage each year (WHO 1999).

Primary post-partum hemorrhage is traditionally defined as the loss of more than 500 ml of blood from the genital tract in the first 24 hours after delivery or any loss even if less than 500ml, if associated with hemodynamic changes in the mother. Post-partum hemorrhage occurs in 2%-11% of deliveries. The main

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causes of primary PPH are uterine atony, retained placenta and lower genital tract trauma along with coagulopathy and clotting disorders. Uterine inversion and uterine rupture are less common causes[1].

About 25% maternal deaths in India are due to PPH. 10% obstetric hysterectomies are due to PPH[2].

Considering the significance of the problem, WHO and FIGO recommended active management of the third stage of labor which includes administration of uterotonics, controlled cord traction and uterine massage after delivery of placenta to control PPH[3].

Recently misoprostol, a prostaglandin E_1 analogue is used in third stage of labor is effective in the prevention of PPH[4].It has a wide range of clinical application in the induction of abortions, cervical ripening and in post-partum hemorrhage[5].

Comparison of the various uterotonic agents has pointed to misoprostol as a potential first-line agent in treating obstetric PPH[6].

Ministry of health, Government of India has approved the use of misoprostol in prevention of PPH due to uterine atony[7].

Active management of third stage of labor can decrease the occurrence of PPH. Though injectable oxytocin is still main drug used in third stage of labor, oral misoprostol can be used as an alternative. Till date there were no significant study done between misoprostol and oxytocin in the active management of third stage labor. The present study was done in order to determine if oral misoprostol is as effective as intramuscular oxytocin in the active management of the third stage of labor.

AIMS AND OBJECTS

1. To compare the effectivity of oral misoprostol versus oxytocin in the active management of third stage of labor.
2. To estimate the amount of blood loss, the percentage of women requiring manual removal of placenta in both the groups and the duration of the third stage of labor in both the groups.
3. To find out the side effects and complications and the percentage where additional oxytocic drugs and blood transfusion require in both the groups.

MATERIALS AND METHOD

The study was a prospective randomized comparative clinical study, carried out in the department of Obstetrics &Gynaecology, Regional Institute of Medical Sciences, Imphal, Manipur**,** on a sample of 200 parturient women having a singleton pregnancy, at term gestation, with vertex presentation and expecting a spontaneous vaginal delivery. High risk pregnancy was excluded from the study. They were divided in two groups- Study group and control group and each group consists of 100 women.The study was conducted for 12 months (w.e.f. September 2008 to August 2009) period. It was conducted after the approval from the Institutional Ethical Committee.

Dose schedule and mode of Administration

Misoprostol: Women of study group received 2 (two) tablets of misoprostol (400 microgram) orally after delivery of the baby and cord clamping.

Oxytocin: Women of control group received 10 IU oxytocin intramuscularly after delivery of the baby and cord clamping.

The third stage was managed by waiting for signs of placental separation.

Outcome Measures

In order to achieve the objectives of the study, the incidence of post-partum hemorrhage, estimation of average blood loss, the length of the third stage of labor, the percentage of women requiring manual removal of placenta, additional use of uterotonic agents and blood transfusion and the side effects of both the drugs were measured.After thorough checking of the data, it was processed through SPSS 16 package. For analysis, Chi square-test was applied to compare the frequency distribution of the qualitative data while for quantitative one, mean and standard deviation (SD) were calculated for each group and comparison was made between groups by independent t-test. P-values of 0.05 and 0.01 levels were considered statistical significant and highly significant respectively.

RESULTS

Table 1: Comparison of socio-demographic profile between groups

Parameters		Type of study group		Total	Test value
		Misoprostol	Oxytocin		
Parity	P0+0	47	48	95	χ^2 =.831; df =4; P =.934;
	P1+0	10	9	19	
	P2+0	19	16	35	
	P3+0	16	20	36	
	P4+0	8	7	15	
Marital status	Unmarried	2	2	4	*No test required*
	Married	98	98	196	
Educational status	Illitrate	7	16	23	χ^2 =13.130; df =4; P =.011;
	Undermatric	43	52	95	
	Matric	22	22	44	
	Intermediate	14	4	18	
	Graduate &above	14	6	20	
Occupation	House wife	90	84	174	χ^2 =4.874; df =2; P =.087;
	Student	8	16	24	
	Unemployed	2	0	2	
Religion	Hindu	74	74	148	*No test required*
	Muslim	14	14	28	
	Christian	12	12	24	
Habitat	Urban	32	36	68	χ^2 =.357; df =1; P =.550;
	Rural	68	64	132	
Economic status	Low	71	66	137	χ^2 =.579; df =1; P =.447;
	Medium	29	34	63	
Total	100	100	200		

The Table-1 deals with the comparison of socio-demographic profiles of women. Insignificant χ^2-value/ P-value for all the parameters except educational status indicates that socio-demographic factors for one group is almost the same for other group (P> 0.05).

Table 2: Comparison of different outcome in both the groups

Parameters		Type of study group		Total	Test value
		Misoprostol	Oxytocin		
Previous history of PPH	Nil	98	98	196	No test required
	Present	2	2	4	
SVD	No	55	57	112	χ^2=.081;df = 1; P=.776
	Yes	45	43	88	
Episiotomy	Nil	45	43	88	χ^2=.081;df = 1; P=.776
	Yes	55	57	112	
PPH due to uterine atonicity	Nil	97	95	192	χ^2= .521; df =1; P=.470
	Present	3	5	8	
Additional uterotonicrequired	No	97	96	193	χ^2= .148; df = 1; P=.700
	Yes	3	4	7	

Table 2: Comparison of different outcome in both the groups

Parameters		Type of study group		Total	Test value
		Misoprostol	Oxytocin		
Blood transfusion required	No	99	98	197	χ^2=.338; df =1; P=.561
	Yes	1	2	3	
MRP required	No	98	99	197	χ^2=.338; df =1; P=.561
	Yes	2	1	3	
Below 10% reduction of Hb level		63	59	122	χ^2=0.336; df =1, P= 0.562
≥10% reduction of Hb level		37	41	78	
Below 10% reduction of Hct level		44	44	88	No test required
≥10% reduction of Hct level		56	56	112	

There was 2% prevalence rate of previous history of post-partum hemorrhage in both the groups and therefore the pattern of PPH history between the groups is exactly the same. The study group has 55% episiotomy while control group has 57% episiotomy. An interesting finding is observed that those who received misoprostol had 3% of PPH in comparison of those who received oxytocin (5%). Only 3% of the women who received misoprostol required additional uterotonic such as carboprost, methergin and syntocinon which was 1% less in comparison with those who received oxytocin. Regarding the side effect, the study group had 13% than that of control group (9%).

Table 3: Comparison of mean ±SD of parameters between groups

Parameters	Type of study group		t-value	Df	P-value
	Misoprostol	Oxytocin			
	Mean ±SD	Mean ±SD			
Age(yr)	26.01±3.19	25.60±3.34	.886	198	.377
Period of gestation(wk)	38.50±1.12	38.50±1.12	No test required		
Maternal wt(kg)	61.35±3.48	61.26±3.43	.184	198	.854
Maternal ht(cm)	147.38±5.62	146.78±4.74	.816	198	.416
Pre delivery haemoglobin level(g/dl)	11.44±1.43	11.61±1.49	-.800	198	.424
Pre delivery hematocrit(%)	37.26±4.68	38.09±4.95	-1.223	198	.223
Birth wt(kg)	3.06±.34	3.16±.35	-2.074	198	.039
Post deliveryhaemoglobin level(g/dl)	10.33±1.07	10.38±1.09	-.339	198	.735
24hr post deliveryhematocrit(%)	32.56±4.20	33.14±4.26	-.958	198	.339
Drop in haematocritlevel(%)	4.67±2.96	4.85±3.05	-.423	198	.673
Drop in haemoglobin level (g/dl)	1.11±1.03	1.22±1.07	-.764	198	.446
Estimated blood loss(ml)	356.80±269.46	364.30±86.98	-.265	198	.791
Length of 3rd stage of labour(min)	6.50±1.12	7.49±1.70	-4.841	198	.000

It is observed that age in year, maternal weight in kgs and maternal height in cms are found to be little bit higher mean for the study group than that of the control group.

In contrast, all the mean values of the remaining parameters for women who received misoprostol orally are less than the corresponding values for women who received oxytocin intramuscularly. Their difference is found to be insignificant even at 5% level of significance and therefore the two drugs have the same effect on these parameters.

DISCUSSION

PPH is a major cause of maternal morbidity and mortality in both industrialized and non-industrialized countries but the absolute mortality rates are significantly higher in the developing world. This

emphasizes the role of better medical care, both preventive and therapeutic, in non- industrialized countries[8].

In our study, the demographic, socioeconomic as well as labor characteristics were comparable between both the groups. There was 2% prevalence rate of previous post-partum hemorrhage in both the groups and therefore the pattern of PPH between the misoprostol and oxytocin group is exactly the same. This is similar with the study conducted by Sultana N et al[9].

Our study shows that misoprostol group consists of 45% SVD as against 43% of oxytocin group, (P=0.776). This labor characteristic of our study is comparable to the study done by Siddiqui SM et al[10]. There was also 45% and 43% subjects delivered spontaneous vaginal delivery in misoprostol and oxytocin group respectively.

In our study, the misoprostol group has 55% episiotomy while oxytocin group has 57% episiotomy (P=0.776). The percentage of subjects required episiotomy in this study is quite higher than the percentage of the study done by Siddiqui SM et al[10]i.e. 37% in both study (misoprostol) and control (oxytocin) group delivered with episiotomy (vertex delivery with episiotomy).

The incidence of PPH in misoprostol group and oxytocin group were 3% vs 5% which is comparable to another study e.g. 7% vs 15% respectively done by Surbek DV et al[11]. A low rate of PPH (3%) was demonstrated in misoprostol wing of our study.

In our study, 3% of women of misoprostol group required additional uterotonic agents, whereas the percentage is higher for oxytocin group which is 4%. These findings are comparable to another study done by Diab KM et al[12].

In our study, 2% of women in misoprostol group required MRP, whereas in control group only 1% was required. This finding is consistent with the study done by El-Refaey H et al[13] (i.e. 2% vs 1%).

Regarding the side effects, the study group (13%) has more than the the control group (9%). Among the side effects, fever was most common i.e. 6% for misoprostol group and 7% for oxytocin group. 4% of the subjects in misoprostol group and 2% in oxytocin group complained of shivering. These findings were similar with the findings of the study conducted by Siddiqui SM et al[10]. In our study, fever and shivering was seen in 6% and 4% among misoprostol group and 7% and 2% in control group, respectively. This is also comparable to study done by Blum J et al.[14]

These undesirable side effects of misoprostol were found to be self-limiting. Lumbiganon P et al[15] have reported that although these symptoms may be of limited clinical concern, they can make the accouter suspicious of infections or malaria, leading to unnecessary investigation and treatment.

From above discussion it has been observed that in all the parameter except duration of the 3rd stage of labor, there were no significant difference between the misoprostol group and oxytocin group.

So, the study has confirmed the utility of oral misoprostol for routine management of third stage of labor.

This prospective randomized comparative clinical trial showed that orally administered misoprostol, with its rapid onset of action, is as effective as intramuscular oxytocin in minimizing blood loss in the third stage of labor.

No special training is needed to administer it and it has an acceptable safety profile. [16]

CONCLUSION

The study concludes that oral misoprostol is a potent, effective and stable uterotonic with a rapid onset of action. It has got few,transient side effects like shivering, fever, headache, abdominal pain which are subsided within 3 hour. It is as effective as standard oxytocic drugs (like oxytocin and methergin) in preventing atonic postpartum hemorrhage. Moreover, it holds promise for the obstetrician in rural areas to tide over, the "Unforgiving stage of labor", by effectively controlling PPH due to uterine atony.

Conflict of Interest: No conflict of interest.

Source of Funding: self

Ethical Clearance: The study was conducted after the approval from the Institutional Ethical Committee.

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Assessment of Pulmonary Health Status among Stone Quarry Workers At Kashipur, Silchar, Assam

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ABSTRACT

Background: Quarry workers perform tasks in unhealthy atmospheres. Quarries are scattered all over India. Morbidity is associated with this occupation.

Objective: 1) To study the socio-economic and demographic status of the region 2) To access the pulmonary health status of workers of this region

Material & Method: Present experiment is a cross sectional study on a sample size of 40 individuals. Of this, control group consisted of 20 individuals who were never exposed to quarry dust and the remaining 20 individuals are the Quarry workers. A prescribed questionnaire was given to each of the participant to obtain the basic information like age, smoking habit and addiction to alcohol etc. Pulmonary Function Test carried out by dry type computerized spirometer.

Results: Results indicate that Silica dust affects on pulmonary function parameters in quarry workers over a long time. Silica dust declines pulmonary health. Attention is to be given for suitable working atmosphere, proper ventilation, providing suitable mask and glasses to each of workers. Awareness of the individual working in quarry is essential for better health.

Keywords: *Silica Dust, Pulmonary Function Test, BMI(Body Mass Index), Demographic Parameters*

INTRODUCTION

People working in stone quarry frequently suffer from breathing problems. Silica is the main constituent of sand and rocks like stone and granite. Inhalation of these crystalline forms of silica leads to silicosis. Silicosis is not a naturally occurring disease. Many techniques are involved in stone cutting, loading and crushing. The most common form of silicosis is developed due to exposure to low concentration of silica for a long duration. There is no medical treatment of silicosis. It is the smallest particles that can deposit in the lung. Scarring of lung tissue develops stiffness which ultimately causes obstruction and shortness of breathing and can lead to permanent heart and lung disease[1] and deposits of different sizes of airborn dust in breathing zone. Increased respiratory symptoms and airway obstruction in stone quarry workers are observed among workers exposed to factory sites. Occupational health risk and mortility, reported higher among different workers of India. Developed country take more safety measures for health of workers but developing countries like India, most of the workers without safety measures[2]. There is a misconception that occupational health problem mainly related to industries. But country like India, millions of people are engaged in stone grinding, quarry workers, weaving etc[3].In India quarry workers live below the poverty line, are less educated and get poor housing facilities and medical attention. It is reported that dust of quarries contain 71% silica[4,5]. In occupational lung diseases, the deposits of dust occurs in the lung , is related with type of dusts, period of exposure, concentration and size of airborne dust in breathing zone[6]. The quarry workers

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are exposed to silica in varying concentration. The quartz is a mineral formed of rocks, composed of granite, slate and sandstones. The granite contains 30% silica, slate contains 40%where as sandstone contains pure silica[7]. Previous studies reported that stone quarry workers show pneumoconiosis in the radiological findings and obstructive symptoms of lung functions [8].It has been reported that lung function deteriotion is related to the inhalation of respirable dust by workers [9].Similar pattern of pulmonary function was observed in workers of talc dust[10],tobacco dust [11], and coal miners[12].

Stone crushing industry produces different sizes of stone, to be used as raw materials in construction of roads,highways,bridges,building and canals etc[13]. Data were collected from Zaria City in Nigeria to evaluate the socio-demographic characteristics, occupational profile, hazards, safety measures and PEFR measurement. The PEFR values(55.6%) were abnormal[13].The toxicity in the lungs caused by penetration of inhale particles and its effects depends on the amount of particle retained in the lung[14]. The pulmonary function impairment has been reported among several groups of workers [15].The construction industry are rapidly growing, in India and there arenearly 12000 stone crushing units. Due to lack of resources and awareness at crushing sites, preventive measures are generally poor. The inhaled silica is deposited in the lung and removed very slowly. So lung function deteriorates even after that retirement from work. In India 17 million non-fatal injuries and 45000 fatal injuries occur in quarries. Out of 11 million workers of occupational diseases in the world, 1.9 million workers are contributed by India and out of 0.7 million deaths in the world 0.12 million is contributed by India[16]. Occupational diseases lead to nearly1,21,000 deaths in India every year[17]. National Institute of Occupational Health observed that the chances of lung diseases are 54.5% in salate pencil,15.2% in potteres, 38% in Agate polishing, 21% in stone Quarries and 12% in stone crushing industry[17].

In the workers exposed to silica dust over a long duration of time, lung functional impairment is commonly observed[15,18,19]. Workers exposed to dusty atmosphere inhale particles of silica which cause adverse respiratory symptoms like chronic bronchitis, emphysema, acute and chronic silicosis and lung cancer[20]. Author [21]reported the major respiratory symptoms in quarry workers like cough, chest pain, catarrh and dyspnoea. Lung functional impairment was seen in among the workers[15,19]. Keeping these facts in mind, the present study was under taken to understand the gap between existing concept and pulmonary functions and respiratory health of workers.

MATERIAL & METHOD

The present experiment is a case-control cross sectional study on a sample size of 40 individuals (males) A detailed questionnaire was completed by all the subjects participated in the study. Of these, the control group consists of 20 individuals who never exposed to quarry dust. The affected group (case) also composed of 20 stone quarry workers from kashipur, about 25km away from Silchar city. Quarry workers were involved in cutting stone and doing the job of loading and unloading the stone. A detailed questionnaire was completed by all the subjects who participated in the study. The questionnaire provided detailed personal and family information, duration of exposure, smoking history, monthly income and respiratory health. Height was recorded by stadio meter without shoes and weight was recorded by standard weighing machine with light clothing. The lung function maneuvers were explained to all the subjects. All the tests were performed in standing position and the subject was asked to exhale into the mouthpiece of spirometer as forcibly as possible after maximum inspiration. Each test was repeated 3 times and the best reading was chosen for study. The lung function was carried out using Sheller's dry type digital spirometer and the parameters were recorded as FVC(Forced vital Capacity), FEV1(Forced expiratory Volume in first second), FEV1% (FEV1/FVC ratio) and PEFR(Peak Expiratory Flow Rate) measures the strength of expiratory group of muscles).

RESULTS

Table 1: Demographic parameters of Exposed andUnexposed groups

Parameters	Exposed group	Un exposed group
Age(Years)	38.76±16.50	39.50±0.92
Height(cm)	161.38±7.51	166.6±8.21
Weight(kg)	49.14±9.68	52.90±8.88
BMI(Kg/m²)	18.28±2.76	20.90±2.68
Number (N)	20	20

There is no difference between the mean age, height, weight and BMI of exposed and unexposed groups.

Table 2: Pulmonary function parameters of exposed (case) and unexposed (control) groups of stone crusher workers

Parameters	Exposed group	Un exposed group	P-value	Significance
FVC(L)	2.22±0.43	2.87±0.54	0.000073	p<.01
FEV1(L)	1.35±0.98	2.72±0.50	<0.00001	p<.01
FEV1%	72.85±22.74	92.39±5.57	0.000312	p<.01
PEFR(L/Min)	3.33±1.49	7.61±1.81	<0.00001	p<.01
Number(N)	20	20		

The Table.2 it was evident that all the parameters of pulmonary functions were significant (p<.01) between exposed and unexposed groups and the mean distribution was higher in all the parameters in control group when compared to exposed group.

DISCUSSION

This experiment was conducted to study the effects of silica dust on the lung functions in stone quarry workers exposed to silica dust for a long duration. Author[15] conducted a cross-sectional study on granite crusher workers. From this study it was observed that the workers in granite crushers had decreased FEV1. Another author[22] had conducted a cross-sectional study and showed relationship between silica dust exposure and COPD in workers in granite industries. They found respiratory problem among workers exposed to dust for 10years or more. Author[23] observed that FVC and FEV1 were significantly reduced among the workers exposed to dust. Another study author[24] stated that inhalation of silica crystal may form pneumoconiosis and silicosis among workers in long-term exposure. The author conducted a study on chest x-ray and high resolution computed tomography among the workers exposed to silica dust. In present study, all the pulmonary function parameters, FVC, FEV1, FVC%, PEFR found to be less in workers exposed to silica dust than control groups. The author[25] showed that FVCand EFV1 were lower in workers than control group. Decrease in FVC, FVC%, FEV 1& PEFR among stone quarry workers compare to control group indicate the tendency of obstructive nature of lung illness. Low FVC, FEV 1 and PEFR values indicate that probably the larger airways are affected first by silica dust. FVC is the volume of air exhaled during forced expiration. It is reduced in airway obstruction due to trapping of air.FEV1 volume of air exhale in the 1st second of FVC. It is useful to detect the generalized airway obstruction[26].

FEV1/FVC% is the volume of air expired in the 1st second expressed as percentage of FVC. It is more sensitive indicator of airway obstruction than FVC or FEV 1 alone. It is reduced in central as well as peripheral airway obstruction. PEF is maximum velocity in liters with which air is forced out of the lungs. PEF is influenced to a greater extent by narrowing of air passages. It is decreased in airway obstruction. $FEF_{25-75\%}$ is average flow rate during middle 50% of FVC. It indicates patency of the small airways [27].

Workers engaged in stone cutting are exposed to silica in varying concentration and particulate size[28].

Silicosis appears after a longterm exposure to silica dust. It depends upon several factors like dose, duration of exposure, type of silica inhale and host factors[29].

Silica particles that are 2-10um size impact at point that can change the direction surface because their inertia can change the direction rapidly. This phenomenon occurs in the areas with turbulent of flow. The areas include nasopharynx, trachea and bronchi upto 10-12 airway generations. Smaller silica particles (0.2-2um) deposit the surface by sedimentation. Silica particles less than 0.2um can contract epithelium as they diffuse in the alveolar gas in the terminal respiratory units[26]. The deposited silica dust causes irritation of mucous of respiratory passages that leads to increase mucous secretion of large airways with hypertrophy of mucous glands in tracho-bronchial tree. Proteases released from neutrophils causes hyper secretion of mucous. Increase in goblet cell of small airways leads to increasedmucous production and changes its chemical composition[26,30].Changes in viscosity and elasticity of mucous affect the clearance of mucous leading to formation of mucous plugs in the airway lumen[26].Obstructions to the air flow leads to decreased pulmonary function parameters like FVC, FEV1, FEV1/FVC% & PEFR. Silica particles between 0.5-3um sizes on reaching the alveoli are engulfed by macrophages and subsequently undergo necrosis. The new macrophages engulf the debris and the cycle is repeated[29,30]. Silica laden macrophages are carried to respiratory bronchioles; alveoli and interstitial tissue. Some of the silica dusts are transported to sub pleural and interlobar lymphatic into regional lymph nodes. Cellular aggregates containing silica are

associated with lymphocytes, plasma cells, mast cells and fibroblasts[29]. Crystalline silica, namely quartz and critobalite is much more fibrotic than amorphous silica, indicating that physical form and surface properties play some role on the pathogenesis of silicosis[31]. Silica is cytotoxic and kills macrophages which engulf it[29].The released silica dust activates macrophages, with the secretion of macrophages growth factors,IL-1, which favors fibroblast proliferation and collagen synthesis. T-helper cells activated by IL-1, release IL-2, which is a potent signal for proliferation of T cells. Macrophages migration inhibition factor, monocyte chemotactins and gamma interferon could activate macrophages and the amount of fibroblast growth factors. In this manner collagenous reaction to silicosis is mediated by immunocompetent cells[31]. In silicosis, because of fibrotic tissue, the lung cannot expand to maximum volume, even with maximum expiratory effort and maximal expiratory flow cannot rise to normal curve[32]. Results obtained in the study conducted by author [21], on symptoms and lung function parameters namely FVC,FEV1,PEFR and deteoriation are similar to our findings. The author[28] reported on FEV1/FVC%, PEFR and $FEF_{25-75\%}$ in quarry workers and their results correlate well the results of present study. In our study we observed significant reduction of FVC,FEV1,EFV1/FVC% & PEFR and positive correlation of these parameters with the duration of the work in stone quarry workers as compared to control groups.

CONCLUSION

It can be concluded that exposure to silica dust in stone quarry leads to deterioration of pulmonary function and is correlated with the duration of exposure. Protection of workers may be provided by wet working, suitable ventilation, screening of employees before hiring, providing them with suitable masks and safety glasses. Workers should be informed about health risks, suitable working conditions, personal hygiene and preventive measures. They should undergo frequent medical checkup.

Source of Funding: Self

Ethical Review and Approval: Ethical approvals wereobtained from Silchar Medical College and Assam University.

Exclusion Criteria: Smokers & persons suffering from cardio-pulmonary diseases.

Inclusion Criteria: Non-smokers quarry workers without cardio-pulmonary pathology.

Conflict of Interest: Nil

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Service Recovery- An Opportunity to Enhance Shipper's Loyalty in Ocean Freight Forwarding

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ABSTRACT

The study aims to analyse the failure of service and the service recovery solutions provided to the shippers. The dissatisfaction and the complaints raised in the freight forwarding services have not been studied to a greater extent in previous literature. The causes of failures and the actions taken for recovery from the point of shippers have been examined. The factors leading to satisfaction or dissatisfaction can be determined exactly by analysing the service failures. The relationship between the customers and the company depends on the impact of service failures and recovery strategies. The service failure would make the customersdecide to move away from the company. Providing the effective recovery solutions are highly significant for maintaining and improving the customer - company relationships.Prevention of service failure and developing the recovery strategy by dealing with it in a professional manner is very crucial for freight forwarding companies.

Keywords: *Freight Forwarder, Service Failure, Service Recovery, Loyalty*

INTRODUCTION

The freight forwarders are the third-party logistics service provider. They generally do not own any transport vehicles but provide services such as booking space from the carrier, preparing shipping documents, arranging the movement of goods from original point to destination, preparing customs clearance and advise the shippers on import/export regulations. They have a very good knowledge of shipping. They also provide some value-added services to both importers and exporters such packing and labelling, proving own transport, warehousing, distribution services. For the shipments leaving or entering our country the freight forwarders act as an interface with all the government agencies and companies involved in making the cargo available at the destination. Customers selects the forwarder if they are better service provider with better deal.Freight forwarding companies are getting diversified into fast growing logistics business and changing from traditional activities to adapt into a very new avatar.There is very limited empirical information about them. The freight forwarding industry has faced tremendous change and it is unpredictable. The viability of this industry depends on how well the forwarders meet the needs and wants of the current and future customers.

Review of Literature

Zeithmal et.al[1]states that when the perception of initial service delivery falls below the expectations of customers then it is termed as service failure. Tax et.al[2]defines that service failure is a conflict between customers and service providers in terms of the procedure fairness, behaviour, interpersonal communications and outcomes. Hue.et.al[3], identifies that the service failure encounters are more common in the process of service delivery.Dr. Dokuz[4] has identified that the most common service failure in the view of shippers is related to information, documentation, communication, operational,equipment, booking and delivery failures.

Table 1: Service failures and Service recovery

Documentation failures	Bill of lading error, invoicing error, customs declaration error
Information and communication failures	customer information errors, lack of employee knowledge, communication failures.
Operation failure	Cargo handling error, unreliability of transit time, pickup error
Equipment failure	Container was damaged and unclean, unavailability of equipment to handle cargo.
Booking and Delivery failure	Booking error, Unacceptable delay in delivery, cargo delivered without b/l.
Service recovery	Solutions
Distributive Justice	Losses and damages met, discounts, gift coupons, fair outcome, discount in freight and expenditures, paid back certain amount
Procedural Justice	Flexibility in dealing the problem, corrected invoices and b/l error, provided new containers, tried to change the carriers and other service suppliers, length of time taken to resolve problem was not longer
Interactional Justice	Apology, convincing explanations, explained the situation, swift response, employee concern, employee effort, communicated well to resolve problem

According to Adams[5] justice theory, in every service, people always weigh their inputs against the received outcomes and if there exists an equal balance then the service is considered fair, if not then it results in inequity. Distributive justice refers to the tangible resources that are rectified and compensated in the event of a service failure (Rio-Lanza[6]). Walster et.al [7]states that if the customer perceives that benefit has not been equitably allocated, the customer would experience a feeling of injustice. Studies have proven that perceived justice of tangible outcomes has a positive effect on Loyalty. Procedural justice refers to the recovery methods the firm uses to deal the service delivery problems such as speed, delay, flexibility, accessibility (Rio Lanza[6]). Sparks and Mccoll Kennedy[8] states that interaction justice is the degree of justice experienced by the customer through the service firm'semployees' interactions during recovery. Interactional justice is considered as a sub-element of procedural justice. In a recovery situation, a procedural justice would state the perceived fairness of the recovery policies adapted by the organisation.

The disconfirmation paradigm suggested by Oliver [9] Bearden and Teel[10] is the model most widely used in customer satisfaction and dissatisfaction literature. Good win and Ross [11] has evaluated recovery from a justice perspective. This article explores the Distributive justice, procedural justice and interactional justice perceived by the shipper after a service failure encounter.

This article adds to the literature in recovery by analysing and evaluating the service recovery solutions and its impact on gaining loyalty.

METHODOLOGY

Research hypothesis

H1: There exists a significant relationship between service failure in freight forwarder's service and Shipper's loyalty.

H2: There exists a significant relationship between the types of service failures in the freight forwarding industry

H3: There exists a significant positive relationship between distributive justice, procedural justice, interactive justice and Shipper's loyalty.

H4: Shippers perceived level of service recovery significantly influence Shipper's loyalty.

Samplinganddatacollection

The sampling technique applied is random sampling method. The incidents related to the service failures and the recovery strategies of the freight forwarding services are collected from the shippers. The freight forwarders have been randomly selected from the EXIM shipping times list of Freight forwarders in Chennai and the questionnaires have been distributed to their Shippers. The shippers were asked to recall the

latest service failures and solutions they have been encountered with before filling the questionnaire. Out of 200 questionnaires distributed, the valid responses were 147 only. The questionnaire has been adapted from Dr. Dokuz [4] "Typologies of freight forwarding service failures and recovery strategies" and it has been modified slightly with the help of professionals in freight forwarding companies and shippers. Moreover, the perceived recovery of the shipper after a service failure encounter is measured usingquestions related to distributive, procedural and interactional justice. Shipper's loyalty is measured by the shipper's attitude and behaviour after the service failure and service recovery encounters. A five-point Likert scale from extremely agree to extremely disagree is used. The questionnaire is divided into two sections, the first part consists of demographic information related questions such as type of business, size of company, market, years of working with the forwarding company.The next section consisted of 36 questions related to service failure, service recovery and loyalty.

Statistical analysis

Statistical package for social sciences(SPSS) is used for the analysis. Pearson correlation analysis and Regression analysis were used to prove the hypothesis. A pilot study was done prior to the actual research with 40 respondents to make sure the questionnaire was understandable by the respondents which helped to improve the questionnaire form. Internal consistency of the questionnaire is verified by Cronbach alpha reliability analysis. The questionnaire is highly reliable as the reliability of service failure is 0.739, service recovery is 0.882 and that of Shipper's loyalty is 0.943.

RESULTS AND DISCUSSIONS

Association between service failure and shipper's loyalty.

H1: There exists a significant relationship between service failure in freight forwarder's service and Shipper's loyalty.

Table2: Correlation between service failure and loyalty

		SF	LOYALTY
Service failure	Pearson Correlation	1	-.496**
	Sig. (2-tailed)		.000
	N	147	147
Loyalty	Pearson Correlation	-.496**	1
	Sig. (2-tailed)	.000	
	N	147	147

** Correlation is significant at the 0.01 level(two-tailed)

Bivariate correlation is used to measure the correlation between two variables, service failure and loyalty. It identifies the linear relationship between the variables. Since p value is less than 0.01, H0 is rejected at 1% level of significance. There exists a statistically significant linear relationship and the direction of relationship is negative. The strength of association is moderate as ($.3 < | r | < .5$). Hence it can be concluded that the service failures in the freight forwarder's service and loyalty are negatively correlated. This indicates that the increase in service failure would decrease the loyalty among the Shippers.

Association between the types of service failures in freight forwarding industry

H2: There exists a significant relationship between the types of service failures in the freight forwarding industry.

H2a: There exist a significant relationship between documentation failure,Information communication failure and booking & delivery failure.

H2b: There exists a significant relationship between Information and Communication Failure Documentation failure, operation failure, Booking and delivery failure.

H2c: Equipment failure has a significant relationship with operational failure.

Table3: Correlation between the different types of service failures

		DF	ICF	OF	EQF	BDFF
DF	Pearson Correlation	1	.371**	.087	.065	.288**
	Sig. (2-tailed)		.000	.297	.433	.000
	N	147	147	147	147	147
ICF	Pearson Correlation	.371**	1	.265**	.128	.213**
	Sig. (2-tailed)	.000		.001	.124	.009
	N	147	147	147	147	147
OF	Pearson Correlation	.087	.265**	1	.411**	.383**
	Sig. (2-tailed)	.297	.001		.000	.000
	N	147	147	147	147	147
EQF	Pearson Correlation	.065	.128	.411**	1	.095
	Sig. (2-tailed)	.433	.124	.000		.253
	N	147	147	147	147	147
BDF	Pearson Correlation	.288**	.213**	.383**	.095	1
	Sig. (2-tailed)	.000	.009	.000	.253	
	N	147	147	147	147	147

**. Correlation is significant at the 0.01 level (2-tailed).

H2a: Since p value is less than 0.01, the null hypothesis is rejected at 1% level of significance. So there exists a significant relationship between documentation failure, information communication failure, booking and delivery failure. The percentage of relationship between documentation and information failures is 13.7%, which represents moderate association, between documentation and booking and delivery failures is 8.2% which represents low association.

H2b: Since p value is less than 0.01%, the null hypothesis is rejected at 1% level of significance. This establishes that there exists a significant relationship between information and communication, documentation, operational, booking and delivery failures.

H2c: p-value less than 0.01 indicates that the null hypothesis is rejected. There exists a significant relationship between operation and equipment failures. The percentage of relationship is 17% which represents a moderate association.

Association between the service recovery and shipper's loyalty

H3: There exists a significant positive relationship between distributive justice, procedural justice, interactive justice and shipper's loyalty.

Table 4: Correlation between service recovery and Shipper's Loyalty

		SRDJ	SRPJ	SRIJ	LOYALTY
SRDJ	Pearson Correlation	1	.583**	.521**	.380**
	Sig. (2-tailed)		.000	.000	.000
	N	147	147	147	147
SRPJ	Pearson Correlation	.583**	1	.842**	.835**
	Sig. (2-tailed)	.000		.000	.000
	N	147	147	147	147
SRIJ	Pearson Correlation	.521**	.842**	1	.873**
	Sig. (2-tailed)	.000	.000		.000
	N	147	147	147	147
LOYALTY	Pearson Correlation	.380**	.835**	.873**	1
	Sig. (2-tailed)	.000	.000	.000	
	N	147	147	147	147

**. Correlation is significant at the 0.01 level (2-tailed).

The Pearson correlation test is used to determine the association between the service recovery variables such as the Distributive justice, procedural justice, interactional justice. Shipper's loyalty correlates positively and substantively with variables such as distributive justice, procedural justice, interactional justice. This makes sense as the variables indicates positive quality that's likely to contribute to better Shippers loyalty. There is a strong positive correlation between the interactional justice and loyalty, the percentage of relationship is 76.2% and is significant at 1% level. The percentage of relationship between distributive justice and procedural justice is 33%, percentage of relationship between procedural justice and interactional justice is 70%. Hence the null hypothesis is rejected.

The mediating effect of service recovery between service failure and Shipper's loyalty.

H4: Shippers perceived level of service recovery significantly influence Shipper's loyalty.

Regression analysis is done to prove the above hypothesis. Baron and Kenny[12], proposed four steps to test the mediation and the same is used to analyse the mediation effect of the service recovery variable. First, simple regression is done with Service failure taken as a predictor variable of outcome variable Shipper loyalty. In next step, linear regression done with service failure as predictor variable of outcome variable Service recovery, then Service recovery as predictor variable of outcome variable loyalty. Since, the above relationships are significant, a multiple regression analysis is done with Service failure and Service recovery predicting the Shipper's Loyalty.

Step 1: Simple regression analysis with Service failure predicting Shipper's loyalty. Regression is done to find the influence of service failure variable on Shipper's loyalty. It had been proved that service failure variable has an influence on loyalty since p value is less than 0.01.

Step 2: Simple regression analysis with Service failure predicting Service Recovery. The regression analysis is done to analyse the influence of service failure on service recovery and since p value is less than 0.01, the service failure has influence on the dependent variable service recovery.

Step 3: Simple regression analysis with Service Recovery predicting Shipper's loyalty. The regression analysis states that the independent variable service recovery has influence on the dependent variable Shipper's loyalty.

Table 5: Simple Regression-Service failure and Loyalty

Coefficients[a]					
Model	**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**Sig.**
	B	**Std. Error**	**Beta**		
1 (Constant)	38.726	3.039		12.742	.001
Service failure	-.476	.069	-.496	-6.886	.001
Dependent Variable: Loyalty					
Simple regression-Service failure and Service recovery Coefficients[a]					
Model	**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**Sig.**
	B	**Std. Error**	**Beta**		
1 (Constant)	94.591	6.696		14.125	.001
Service failure	-.875	.152	.431	-5.744	.001
a. Dependent Variable: SR					
Simple regression-Loyalty and service recovery					
Model	**Unstandardized Coefficients**		**Standardized Coefficients**	**t**	**Sig.**
	B	**Std. Error**	**Beta**		
1 (Constant)	-4.321	1.234		-3.503	.001
Service recovery	.395	.021	.837	18.408	.001
Dependent Variable: Loyalty					

Step 4: Multiple regression Analysis with Service Failure and Service Recovery predicting Shipper's Loyalty.

Table 6: Multiple Regression- service failure, service recovery and service loyalty Coefficients

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	4.585	2.850		1.609	.110
	(X1) Service failure	-.160	.047	.167	-3.439	.001
	(X2) Service recovery	.361	.023	.765	15.743	.001

a. Dependent Variable: Loyalty

Y= 4.585+(-0.160) X1+0.361X2, where 0.160 is the partial regression coefficient of X1 and 0.361 is the partial regression coefficient of X2. The above regression equation states that for each unit increase in service failure, the estimated loyalty is decreased by 0.160 and for each unit increase in the service recovery, the loyalty is increased by 0.361. Since p-value for service failure and service recovery is less than or equal to 0.01, it is proved that the service recovery variable partially mediates between service failure and shipper's loyalty. Also, the R square and the significance of F statistic explains that the model provides a good fit.

CONCLUSION

This study has highlighted the importance of service recovery in freight forwarding industry. Moreover, it provided the insights into the type of service failures prevailing in the freight forwarding and the relationship between these service failures. Service failures are more prevalent in the service sector, when these service failures are overcome by providing properservice recovery solution, it enhances the loyalty of the shipper. The service recovery plays a partial mediating effect between the service failure and Shipper's loyalty. So, the increase in the service recovery will lead to an increase in the loyalty of the shipper and thus enhances the number of loyal customers to the freight forwarder.

Conflict of Interest: Nil

Source of Funding: Self

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Risk Profile Assessment of Type 2 Diabetes in a Tertiary Care Hospital of Secunderabad

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ABSTRACT

Introduction: Cardiovascular disease is the major cause of premature mortality in patients with type 2 diabetes.

Aim: To assess the risk among type 2 diabetic patients of Secunderabad population .

Method: A cross-sectional study included 91 diabetic patients (49 males and 42 females) aged 35–75 years from the Secunderabad Area were conducted . The probable risk factors were determined by cross-tabulation of cardiometabolic parameters.

Results: Males were found to be at higher risk of developing CVD in the future as compared to females with a discernible accumulation of adverse cardiovascular risk factors among them. 38.3% patients were at high risk, 37.0% at moderate risk and 24.7% at low risk for developing CVD in the next 10 years. Systolic blood pressure, total cholesterol, triglyceride, and smoking contributed significantly to high degree of risk.

Conclusion: Presence of risk factors among diabetic patients emphasizes the need of intensive management of complications, taking into consideration of the traditional dietary pattern of the population.

Keywords: *10 years Risk assessment , type 2 Diabetes, CVD*

INTRODUCTION

Diabetic patients have a twofold to sixfold higher incidence of cardiovascular disease than nondiabetic population . Furthermore, diabetic patients with CVD sustain a worse prognosis for survival than CVD patients without diabetes and their quality of life also depreciates. Therefore, diabetes has been considered as having a risk equivalent to a nondiabetic patient with preexisting heart disease . Identification of patients at risk for CVD could felicitate the prevention or retardation of cardiovascular events [1,2].

Presence of several risk factors among diabetic patients suffering from cardiovascular disease stresses on the assessment of the individual's total burden of risk rather than on the level of any particular risk factor . Several multivariate risk prediction algorithms have been developed to predict future CVD risk but their use has lagged in primary care [3]. Sex-specific Framingham risk prediction model however has been incorporated in the report on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, Adult Treatment Panel III (NCEP ATP-III) [4].

In India, regional variation has been reported in cardiovascular disease incidence and mortality. However, there lies a significant gap in the knowledge of CVD epidemiology and associated risk factors among Indian population especially among the Secunderabad area[5]. The increasing prevalence of cardiovascular disease and diabetes emphasizes the need to bridge the gap by considering the distinct sociocultural, biological, and ethnic diversity of the Indian population. The purpose of our study was to assess the risk among type 2 diabetic patients of Secunderabad

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METHOD

This cross-sectional study included 91 diabetic patients (49 males and 42 females) aged 35–75 years who were outpatients of Gandhi Medical College and Hospital, Secunderabad during 2012-13 (2 years). The subjects were patients diagnosed as suffering from diabetes by the doctors and whose fasting glucose (FG) level was ≥126 mg/dL. Patients suffering from any cardiovascular disease were excluded from the study. The purpose of the study was explained to all the subjects prior to data collection. Informed written consent was obtained from each subject who volunteered for the study. The study protocol was approved by the Ethical Committee of our college.

The anthropometric measurements were taken using standard techniques. Standing height was measured to the nearest 0.1 centimetre with fixed stadiometer. Body weight was measured in kilograms with a weighing scale to the nearest 0.5 kilogram. Waist and hip circumferences were recorded to the nearest 0.1 cm using a flexible steel tape. Body mass index (BMI) was derived by dividing the body weight by the height squared (kg/m2). Waist hip ratio (WHR) and waist height ratio (WHtR) were calculated. The patients were classified on the basis of body mass index (BMI) using WHO classification . Central obesity was assessed by using WC (waist circumference), WHR, and WHtR standard criteria [6,7] .

Blood pressure, systolic (SBP) as well as diastolic (DBP), was recorded using an aneroid sphygmomanometer and stethoscope as recommended by the American Heart Association . Patients were stratified into hypertensive and prehypertensive based on the definition of the Seventh Report, Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure .

The patients were referred to a laboratory where intravenous blood was drawn by trained technician after a fasting period of at least 8 hours to estimate the value of fasting glucose (FG), total cholesterol (TC), triglyceride (TG), high density lipoprotein (HDL), and low density lipoprotein (LDL). After analysing the blood, biochemical profile information (report) of the patients was given to the doctor for perusal. From the measurements of TC and HDL, the TC/HDL ratio was calculated. Dyslipidemia was defined by the presence of more than one abnormal serum lipid concentration. Subjects were classified into risk categories for each lipoprotein and TC/HDL ratio based on the National Cholesterol Education Program, Adult Treatment Panel III guidelines. The uncontrolled glycemia was defined as having fasting blood glucose level >140 mg/dL [8].

The 10-year risk of cardiovascular disease (CVD) was assessed by sex-specific general risk prediction equations derived by from Framingham Heart Study.Based on the total risk score calculated, subjects were categorized to be at high (>20%), moderate (10–20%), and low (<10%) risk of cardiovascular disease

Statistical Analysis

Analysis was performed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA) software package.

RESULTS

Mean age, onset age, and duration for diabetes were 54.4 ± 9.27 years, 48.0 ± 9.41 years, and 5.5 ± 5.01 years, respectively, with no gender differences. Males were significantly higher (166.8 ± 7.60 cm) and heavier (61.7 ± 9.24 kg) than females (height—151.9 ± 8.41 cm, weight—56.8 ± 10.37 kg) but the latter had higher BMI (24.7 ± 4.78 kg/m2) as compared to males (21.1 ± 2.85 kg/m2). Mean levels for central adiposity (WC and WHtR) were also significantly higher among females than males, while the cardiometabolic risk factors, SBP (134.7 ± 16.70 mmHg), fasting glucose (190.3 ± 89.00 mg/dL), and estimated 10-year cardiovascular risk score (28.5 ± 17.22), were significantly higher among males than females (126.3 ± 13.45, 146.7 ± 84.68, and 13.9 ± 8.68 resp.).

Distribution of patients in different categories of cardiovascular risk factors has been presented in Table 1. The analysis reveals that overall 28.4% were overweight, out of which a major proportion was of females (38.1%) as compared to males (17.9%). Central obesity was also more frequent among females (WC—84.6%, WHtR—84.4%) than males (WC—15.4%, WHtR—47.2%). Considering both SBP and DBP, 61.7% of the patients were hypertensive and 33.3% were prehypertensive. Significant gender differential was observed for SBP when considered individually, with 56.4% hypertensive males in comparison to 16.7% hypertensive females and 28.2% prehypertensive males than 61.9% prehypertensive females. The most common risk factors were high triglyceride (61.7%) followed by

high HDL (35.8%). 24.7% of diabetic patients were dyslipidemic. According to the TC/HDL ratio, only 3.7% of patients were at the risk of cardiovascular diseases (table 2). However, no gender differences were found for the risk category of lipid profile. 37.0% of individuals either smoke or consume tobacco and 48.0% have a family history of diabetes. Females have better glycaemia control (55.6%) than males (24.5%). The overall estimated risk score for the present population was 21.0 (5.74 ± 15.26). High risk was found in 38.3% patients, moderate in 37.0% patients, and low in 24.7% patients . Cardiovascular risk showed significant sexual dimorphism with higher proportion of males at high risk (59.0%) than females (19.0%) while 45.2% of females were at moderate risk as compared to 28.2% of males (table 3).

DISCUSSION

Based on Framingham risk scores, approximately one-third of the subjects recruited for the study will have cardiovascular complications in the next 10 years. Males showed discernible frequency of adverse cardiovascular risk as compared to the females and had higher risk of developing CVD in the future. Similar findings have been reported by Gomes et al. [9]among Brazilian diabetic population which contradicts with the earlier studies reporting high cardiovascular mortality in women [10] .

The sex differentials in the cardiovascular risk among diabetic patients in present population could be attributed to better glycemic control among females as compared to males. Though the present study has not evaluated the direct effect of hyperglycemia on cardiovascular disease, previous literature have provided several contradicting findings concerned with detrimental effect of hyperglycemia on cardiovascular risk profile. High blood glucose level leads to oxidative stress and mitochondrial overproduction of superoxide which have been recognized in the pathogenesis of diabetic micro- and macrovascular complications[11] . Clinical trials investigating the efficacy of improving glycemic control have also reported a reduction in the risk of cardiovascular events[18]. However, some recent randomized trials have demonstrated contradicting finding with no significant improvement in cardiovascular risk as a consequence of intensive glucose lowering therapy [12].

The other probable explanation for such biological sex differences in cardiovascular morbidity risk could be the distinct biological as well as gender-related acculturation and lifestyle differences between males and females[13]. Lifestyle and cultural habits have demonstrated stronger influences on metabolic disorders than those from genetic factors[14]. In the present study, males were primarily involved in agriculture and supplement their livelihood by working in governmental and private sectors while majority of the females were homemakers.

In the present study, 38.3% of patients were at high risk, 37.0% at moderate risk, and 24.7% at low risk for developing CVD in the next 10 years according to the Framingham risk score. Systolic blood pressure, total cholesterol, triglyceride, and smoking have contributed significantly to the high risk of developing CVD in the future among these patients, which are already distinguished as risk factors for CVD. Obesity (regional and central) despite being a prominent risk marker in this population has not significantly predicted the cardiovascular risk as assessed by Framingham risk score. This is in contrast to the earlier studies which have reported regional adiposity markers to be the predictor of cardiovascular risk [15]. This finding indicates the pioneer role of metabolic risk factors in the causation of disease among otherwise normal weight or obese patients. These identified risk factors have been reported as potential predictors among both diabetic and nondiabetic individuals [16]. However, at every level of risk factor, the risk for disease increases over time with the accumulation of unfavourable metabolic factors [17].

Furthermore, a large fraction of patients (61%) had uncontrolled fasting blood glucose level which could be accredited to the rice intake, a staple diet of the population in the present study. Rice rich in carbohydrate has a high glycemic index (GI) which relates to the increased cardiovascular risk. The role of carbohydrates as a risk factor depends on their type; a high consumption of carbohydrates from high-GI foods rather than low-GI foods influences the risk of developing CVD [18]. The glycemic index value of white rice also depends on the degree of processing, cooking time, and amylose content but still is higher on average than that of whole grains[19] . These findings are in agreement with the other prospective study which has reported high dietary GI to be associated with increased CVD risk[20]. This explanation supports the current finding where total serum cholesterol and triglyceride are found to be significantly associated with the cardiovascular risk.

These findings need to be validated further through various epidemiological study designs, large sample sizes, and inclusion of various other sociodemographic and biological parameters.

Table 1 Distribution of diabetic patients in terms of BMI, WC and Blood pressure

Variables	Categories	Overall	Male	Female	Chi-square	Value
BMI	Underweight	7.4 (6)	7.7 (3)	7.1 (3)	4.109	0.128
	Overweight	28.4 (23)	17.9 (7)	38.1 (16)		
	Normal	64.2 (52)	74.4 (29)	54.8 (23)		
WC	Risk	45.7 (37)	15.4 (6)	84.6 (33)	27.819	<0.001
	Normal	54.3 (44)	84.6 (33)	26.2 (11)		
WHR	Risk	92.6 (75)	87.2 (22)	97.6 (41)	3.213	0.101
	Normal	7.4 (6)	12.8 (5)	2.4 (1)		
WHtR	Risk	64.3 (63)	47.2 (25)	84.4 (38)	14.728	<0.001
	Normal	35.7 (35)	52.8 (28)	15.6 (7)		
SBP	Hypertensive	35.8 (29)	56.4 (22)	16.7 (7)	14.348	0.001
	Prehypertensive	45.7 (37)	28.2 (11)	61.9 (26)		
	Normal	18.5 (15)	15.4 (6)	21.4 (9)		
DBP	Hypertensive	55.6 (45)	61.5 (24)	50.0 (21)	1.127	0.569

Table 2 Distribution of risk factors in terms of Lipid profile in diabetic patients

Variables	Categories	Overall	Male	Female	Chi-square	Value
Cholesterol	Risk	28.4 (23)	30.8 (12)	26.2 (11)	0.209	0.806
	Normal	71.6 (58)	69.2 (27)	73.8 (31)		
Triglyceride	Risk	61.7 (50)	59.0 (23)	64.3 (27)	0.241	0.654
	Normal	38.3 (31)	41.0 (16)	35.7 (15)		
LDL	Risk	8.6 (7)	2.1 (1)	14.3 (6)	3.519	0.110
	Normal	91.4 (74)	97.4 (38)	85.7 (36)		
HDL	Risk	35.8 (29)	41.0 (16)	31.0 (13)	0.893	0.365
	Normal	64.2 (52)	59.0 (23)	69.0 (29)		
TC/HDL ratio	Risk	3.7 (3)	5.1 (2)	2.4 (1)	0.428	0.513
	Normal	96.3 (78)	94.9 (37)	97.6 (41)		
Dyslipidemic (2 risk factors)	Yes	24.7 (20)	23.1 (9)	26.2 (11)	0.105	0.474

Table 3 Distribution of overall risk factors in diabetic patients

Variables	Categories	Overall	Male	Female	Chi-square	Value
Smoke/tobacco	Yes	37.0 (30)	43.6 (17)	31.0 (13)	1.385	0.239
	No	63.0 (51)	56.4 (22)	69.0 (29)		
Family history	Yes	48.0 (47)	49.1 (26)	46.7 (21)	0.056	0.842
	No	52.0 (52.0)	50.9 (27)	53.3 (24)		
Glycemic control	Yes	38.8 (38)	24.5 (13)	55.6 (25)	9.869	0.002
	No	61.2 (60)	75.5 (40)	44.4 (20)		
10-year cardiovascular risk	Moderate	37.0 (30)	28.2 (11)	45.2 (19)	14.300	0.001

CONCLUSION

Lifestyle interventions have been effective in the improvement of cardiovascular risk factors. Furthermore, insulin resistance preceding long before the diagnosis of diabetes enhances atherogenic risk profile and has been delineated as a potential cause for subsequent increased risk of CVD among diabetic patients .

Conflicts of Interest: NIL

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Review of Community Based Healthcare Financing in India

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ABSTRACT

Despite major improvements in recent years, life expectancy in India remains low as against countries at a similar level of development. Secluded regions of India has been confronted with multiple challenges in health care including low investment in health, lack of health financing policies, limited financial access to health services, limited health insurance coverage, lack of government aid, weak mechanism for collaborative arrangements at rural levels in the health sector. The paper is review based which discusses the framework of cross country community health care financing in reducing the social exclusion of availing health care facilities and also thrust on how the health care benefits can be reaped by the underprivileged sections of the society.

Keywords: *Financial protection, Social inclusion, Health, Social security, Community Health care*

INTRODUCTION

The constitution of World Health Organization in 1946 articulated the right to health which is outlined in the Article 12 of the International covenant on economic, social and cultural rights which has been ratified by 150 countries approximately. Countries are required to ensure availability and accessibility of quality health care facilities without any discrimination. Normand (2009) study opines access to health care facility is a prerequisite element and fundamental human right which cannot be observed in the absence of financial protection mechanism for healthcare expenditures as it aggravates poverty and leads to severe medical consequences in case of financially constrained families and most of the time they forgo the vital treatment due to unaffordability.

Community financing is effective way in reaching a large number of low-income populations who would otherwise have no financial protection against the cost of illness. Literature does not substantiate the total population covered under different healthcare schemes across countries however there are evidences which indicate the poor and socially excluded groups are not automatically reached out under these initiatives. Higher income groups are less likely to participate in community level pooling arrangements as they can afford the good healthcare services or are covered under the varied insurance schemes either at personal level or by the employer. Over the period of time expanding healthcare facilities to socially excluded segments was the agenda of the policy makers and off the time span it is evidenced that there has been an exponential growth in the studies on conceptual work, case studies and empirical papers based on the community health care financing.

The paper aims a comprehensive review of literature and the developments that has been undertaken across nations in the area of community health care financing. The paper is organized into three sections: Section I will discuss the methodology of the review. Section II will enumerate the modalities and structural determinants of community based healthcare financing in India Section III will deliberate the probable benefits of these practices on the economic growth of India

SECTION I
METHODOLOGY

Data extraction was undertaken by the authors using a predefined matrix to summarize the findings and to discuss the relevance for the current research. 50 research papers were reviewed across different countries to gauge the meaning and functioning of the community health care schemes prevailing in the varied economies. Some of the key literature is summarized in Table: 1

Table 1: Summary of the characteristics of Studies

Parameters	Authors/ Reports	Discussions	Comments
Definition of Healthcare Financing	WHO Report, 2000	To make funding available, as well as to set the right financial incentives to providers to ensure that all individuals have access to effective public health and personal health care.	The definition concludes the applicability of effective financial support across households.
	WHO Report , 2007	A good health financing system raises adequate funds for health, so that people can use needed services protected from financial catastrophe or impoverishment associated with having to pay for them. It provides incentives for providers and users to be efficient	The definition concise on the out of pocket cost incurred on healthcare at individual level of the households.
	WHO Report, 2000	Financing was a "function of a health system concerned with the mobilization, accumulation and allocation of money to cover the health needs of the people, individually and collectively"	States the formal definition of Financing healthcare which is both descriptive and comprehensive.
	Judt T. Postwar (2010).	Origin of Healthcare in 1950, post 2nd World War in Europe, governments responded to public demands for affordable health services accessible to all. US population (55.1 percent) had employment-based health insurance coverage in 2011. Of the employed population aged eighteen to sixty-four years, 68.2 percent had health insurance through their own employer or another person.	Findings suggests that origin of healthcare and the drivers that lead to the development of healthcare financing however it points out the issue related to coverage of healthcare facilities across the European economy.
	Simou E, Koutsogeorgou E. (2013)	Employer-based health insurance accounts for the majority of health care coverage in the United States.	Findings suggests that in US employer sponsored health insurance were significant however concern arises of the success of these facilities for developing economies where existence of poverty and unemployment rate are predominant.
Focus of Healthcare financing			
	Olsen (1998)	In the 21st century, average life expectancy rose above the age of 80, and health science and technology improved quality of life even at a very old age. Paper emphasized on the willingness of society for disbursement of funds for healthcare.	The study raises concern over the high cost incurred for healthcare which maybe reason for poverty, the paper recommends societal contributions as mode of healthcare financing.
Issues	NP Roos (2015)	Evidence from Canada, where health is financed mainly through taxation, study suggests that patient satisfaction, hospital performance and health outcomes were maintained despite the financial strain.	The issue raised in the paper is can taxation be sole source for financing healthcare, the paper discusses financial constraints does not significantly impact the health outcomes which may hold contradictory in Indian context.

	(Ubel, 2013).	one of the reasons it is difficult for small businesses to supply employment-based health care coverage is they do not have enough employees to reduce their actuarial risks, so smaller businesses cannot secure premiums as cheaply as large companies (Ubel, 2013).	It is revealed that employment based healthcare financing may not be effective for countries having extensive trade dependent on small and medium enterprises.
	Panos Kanavos (1999)	Although the UK does not spend more than 7 percent of its GDP on health (lower than other European countries The issue of health technology – its utilization and contribution to rising health care costs, improvement of health status and outcomes – poses additional pressures on health budgets and, increasingly, calls for an evaluation of its role.	The paper discusses the relevant attributes of accessibility, affordability and equitable distribution of healthcare facilities however it raises a concern on the overutilization on the government budgets due to rising cost of health care.

Summary statistic of the literature reviewed by publication type

	Peer reviewed journal article	Published report	Conference proceeding
Number of studies	20	14	1

Description on the Determinants of Social Inclusion and Financial Protection: In the literature, the term "community financing" has evolved into a generic expression that is used to cover a large variety of health financing arrangements. World Bank Community financing is effective in reaching a large number of low-income populations who would otherwise have no financial protection against the cost of illness. Community healthcare financing schemes (CHFS) has been one of the crucial discussion areas in varied forums and policy groups. There has been tremendous work undertaken on the conceptual aspect of community healthcare financing however there exists a gap for a systematic study in this field, widely across the nations. Papers were reviewed based on the determinants essential for implementing CHFS and the reasons that allowed these schemes to flourish where the more embedded institutions of governments and markets have been unsuccessful. Papers were also referred for identifying the challenges faced by the nations in improvising the CHFS. Commission of Macroeconomics and Health (2001) report states that most community financing schemes have evolved in the context of severe economic constraints, political instability, and lack of good governance however in economies where the government taxation system is weak, formal mechanisms of social protection for vulnerable populations are absent. The report further suggests that social and religious values have an influence on people's preferences and attitudes towards health, risks and solidarity which alters the outcome of rationale choice process between two individuals with similar cultural characteristics. Study also emphasizes that individual decisions are driven on the backing from community leaders, availability of information and family support.

One common feature of the definitions is the pre-dominant role of collective action in raising, pooling, allocating/purchasing, and/or supervising the management of health financing arrangements, even with government interventions in terms of subsidies, and access to public provider networks. Some community financing schemes cover common geographic entities, while others are based on professional affiliations and other kind of joint activity. A second common feature of community financing schemes relates to the beneficiaries of these schemes which tend to be populations that have no other financial protection or access to collective financing arrangement to cover the cost of health care. A third common feature is the voluntary nature of these schemes, and tradition of self-help and social mobilization that are embraced by the poor in many low-income countries. Encompassing micro-insurance techniques to health care presents an exceptional set of challenges under exploration. While life and crop insurance deals mainly with the financial cost of income loss, health insurance presents an additional set of issues related to financing tangible services for which the cost is neither constant nor ascertainable.

SECTION II

Modalities and structural determinants of community based healthcare financing in India

The healthcare structure in India is divided under State list and Concurrent list. The purview of State List encompasses hospitals, public health facilities while family welfare, medical education, quality of drugs are covered under the concurrent list. The Union Ministry of Health and Family Welfare is the central authority responsible for the implementation of varied health care schemes and programs in India. The health care infrastructure in rural areas has been developed as a three tier system and is based on the following population norms:

Table 2: Three Tier System

	Population Norms	
Centre	**Plain Area**	**Hilly/tribal area**
Sub Centre	5000	3000
Primary Health Centre (PHC)	30,000	20,000
Community Health Centre (CHC)	1,20,000	80,000

Source: Union Ministry of Health and Family Welfare (2011)

The Sub Centre is the most peripheral and first contact point between the primary health care system and the community. Sub Centers are assigned tasks relating to interpersonal communication in order to bring about behavioral change and provide services in relation to maternal and child health, family welfare, nutrition, immunization, diarrhea control and control of communicable diseases programmes.

PHC is the first contact point between village community and the medical officer. The PHCs were envisaged to provide an integrated curative and preventive health care to the rural population with emphasis on preventive and promotive aspects of health care. CHC is required to be manned by four medical specialists i.e. surgeon, physician, gynecologist and pediatrician supported by 21 paramedical and other staff.

Health Financing in India: A simplistic scheme to describe the current mechanism for financing healthcare in India has been tabulated [Table 3]. Although it does describe the main tenets, it does not illustrate the impact of this structure on financial protection of people, one of the important goals of the health system. Almost 80% and 40% are outpatient and inpatient care, respectively, is sourced from private sector. Although healthcare expenditure constitutes almost 5% of gross domestic product (GDP), contribution of Government is only 0.9% of GDP. Majority (71%) of healthcare expenditure is drawn from out-of-pocket (OOP) at time of service utilization which has catastrophic implications for the household. A recent report shows that percentage of persons below poverty line (BPL) at 1$ per day in India increased by 3.7% after the OOP expenditures were accounted for. Furthermore, healthcare costs for outpatient and inpatient care are inflating by 15% and 31%, respectively. Thus, the moral ground of protecting India's poor from spiralling costs of healthcare forms an imperative argument to analyse the current financing system and institute a robust risk pooling mechanism.

Table: 3 Structural Framework of Healthcare Financing in India

System Characteristics	Public Sector	Private Health Insurance	Social Health Insurance	Community based Health Insurance Schemes
Source of finance	90% from Tax	Actuarial Premium: Individual risk rated Community rated Community rated	1.75% of pay	Government
			4.75% Employer contribution	Donor subsidy
			Government subsidy	
Intermediary	Central& State Govt.	Private Companies	Employee state insurance corporation (ESIC)	Community lead
	Urban local bodies (Panchayat Raj Institutions)	GIC	CGHS	

Services	Govt. employed doctors, personnel's	Private hospitals	ESI Hospitals	Local Govt.
	District hospitals		CGHS dispensaries	Private hospitals
			Empaneled private hospitals	
Hospital payment	Paid in kind	Capitation fees	Private-Fixed Rate	Variable
			Govt.-paid in kind	

Source: Employee State Insurance Scheme and Central Govt. Health Scheme

Health expenditure as percentage of GDP in India (5%) is higher than other Asian countries–China (4.7%), Malaysia (4.2%), Sri Lanka (4.1%), Thailand (3.5%), Pakistan (2.1%), and Bangladesh (2.8%); however, public spending as percentage of total health expenditure is significantly lower in India (19%) than all these countries except Pakistan. Of the total 1201 INR per capita spent on healthcare in India, Government (both Central and State combined) spending is only 242 INR per capita. Problems of access to healthcare in India are further compounded by a lack of effective universal social security program. Figure: 1 compares the extent of social security in India and other comparable Asian economies. The figure indicates country specific distribution of deficit of social health protection in India, Bangladesh, Sri Lanka, and Thailand.

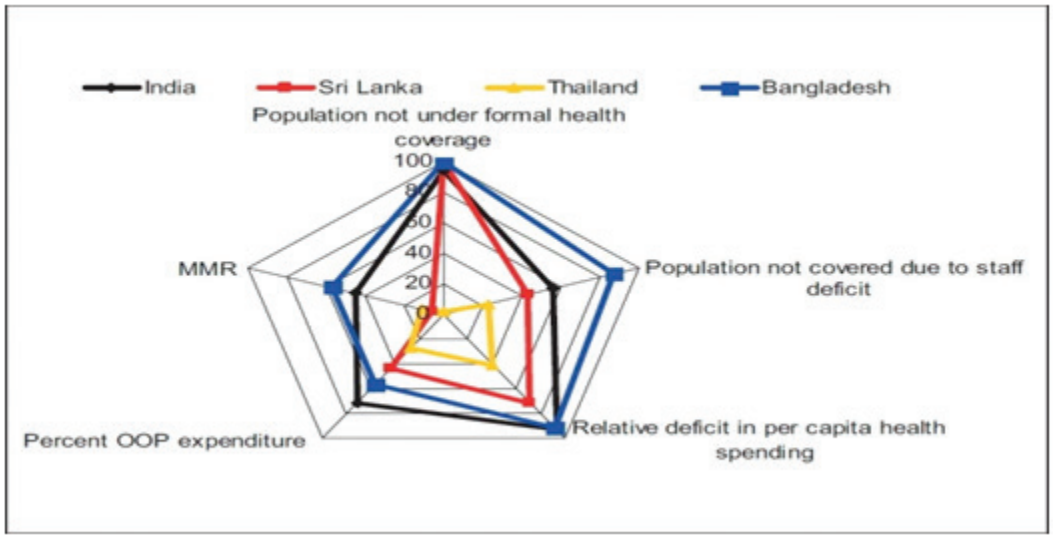


Fig. 1: Country specific distribution of deficit of social health protection

Source: Source: Based on data from ILO (2010)

Numerous community-based health insurance (CBHI) schemes hugely diverse in terms of design or implementation, coverage, and target groups exist in India. A review of these schemes highlights importance of many contextual factors (political will, social capital) for their success, with an evidence of increasing trend toward GIC-collaborated schemes. There in increasing dependence on donor funds or government subsidy for sustainability, evidence of adverse selection, and inequity with inadequate coverage of poorest among poor. Overall, there is inconclusive evidence on impact of CBHI schemes on the health system goals and further doubts over replicability and upscaling of these initiatives which may entail huge administrative costs.

Table: 4 Summary of salient micro-insurance initiatives in health in India

Name of scheme	Risk covered	Number insured	Benefit package	Scope of services	Maternity benefits	
					Type	Level
Accord – Ashwini	Health care, maternity	15,002	Rs. 2,500	Primary, secondary and tertiary	Under hospital cover	Up to Rs. 7,500
Aga Khan Health Services	Health care, maternity	15,000	No ceiling precise free OPD, no ceiling précised (hospitalization)	Primary	Discount on delivery cost	20%
Antodaya	Health care, maternity	1,138	Rs. 2,000	Primary and secondary	Under OPD/ hospital cover	Up to Rs. 2,000
Arogya Raksha Yojana Trust	Health care, maternity	150,000	Rs. 100,000	Primary, secondary and tertiary	Under hospital cover	
Arogyashree Yojana Trust	Health care	36,700,000	Rs. 150,000	Tertiary and critical illnesses		
Yeshasvini Trust	Health care, maternity	3,047,000	Rs. 100,000 (for single case) max. Rs. 1000,000 for two cases/year	Tertiary	Maternity benefits, post-natal care	Rs. 600 per delivery, Up to Rs. 2,000
Development of Humane Action (DHAN) Foundation	Health care, maternity	15,725	Rs 10,000	Primary, secondary and tertiary	Under hospital cover	75% subsidy
Karuna Trust	Health care, maternity	46,574	Rs 2500	Primary and secondary	Under hospital cover	Up to Rs. 2,500
RSBY	Health care	80,997,270	Rs 30000	Secondary and tertiary	Under hospital cover	Up to Rs. 30,000
Self-Employed Women's Association	Health care, maternity, accidental death	195,472	Rs 2000-6000	Secondary and tertiary	Cash benefit	Rs. 300 per child

Source: ILO (2010) Report

SECTION III

Community Financing – Implications in Indian Context: The reviewed literature is very rich in describing the phenomenon referred to as community financing in terms of scheme design and implementation. Although this review found several systematic patterns of performance, there continues to be a need for stronger evidence base regarding the performance of community based resource mobilization mechanisms as health care financing instruments. The review involved a range of non-randomized studies on health financing across varied countries, few of the studies were cross sectional using common parameters through different countries. The findings from the study can be categorized on the following dimensions:

(a) Community financing is an umbrella term used for many different resource mobilization instruments. The instruments vary a great extent in terms of their degree of pre-payment, risk-sharing, resource allocation mechanisms, organizational and institutional characteristics. Nevertheless, the common features they share include the predominant role of the community in mobilizing, pooling and allocating resources, solidarity mechanisms, poor beneficiary population, and voluntary participation.

(b) Performance of community based financing. (i) Community financing mechanisms have the capacity to mobilize resources for health care. However, there is a large variation in the resource mobilization capacity of various schemes. This review did not find systematic estimates about the global amount of resources mobilized through community financing schemes. (ii) Community financing is effective in reaching a large number of low-income populations who would otherwise have no financial protection against the cost of illness. There are no estimates about the total population covered through such schemes. There are indications that the poorest of the poor and socially excluded groups are not automatically reached by community financing initiatives. Higher income groups are also less likely to participate in community level pooling arrangements. (iii) Community-based health financing schemes are systematically reported to reduce the out-of-pocket spending of their members while increase their utilization of health care services.

(c) Determinants of performance: The key determinants of successful resource mobilization and effective financial protection include (i) ability to address adverse selection and rent-seeking provider behavior through revenue collection, pooling, and purchasing instruments; (ii) active

community involvement in scheme management; (iii) durable relationship between scheme and providers to achieve better value for the money for their members; and (iv) sustained donor and/ or government support.

(d) Policy Initiatives: In Indian context the healthcare system is under financed and heavily dependent on the personal cost or out of pocket spending. The draft of the National Health Policy (2015) depicts country's out of pocket health expenditure constitutes around 60% attributable to the lifestyle diseases was one of the highest in the world. Further it indicated that nearly 55 million Indian households were trapped in the net of poverty due to their healthcare spending which was financed either self by sale of assets, loans or by borrowings from friends and relatives. The government delineated the "National Health Assurance Mission" which was to provide universal accessible and affordable healthcare focus being on prolonged ailments however much could not materialized at the basic ground level.

(e) Geographical distribution: Healthcare financing in India encompasses various components varying from tax financed healthcare systems to publicly and privately managed systems catering to specific segments of the society which does not contemplate on holistic healthcare system. Insurance schemes in existent are fragmented in their distribution network thus providing cost effective affordable and accessible healthcare facilities still remains a concern area for policymakers.

(f) Financing and Investment: In India state government holds majority stake in health financing, the central government accounts for only 30% of total government health expenditure (2014-15). Over the decades there has been a considerable rise in the health spending which can be attributed to the "National Rural Health Mission" (NRHM) objective of which is to provide financial assistance at state run healthcare activities as well as provides sponsorship for new initiatives in healthcare. However there do no exists a mechanism to gauge the efficacy of these programs at an economy level.

(g) Outsourcing: In India most of the community based health programmes are dependent on third party such as trained community health workers who provide the basic preventive and curative care at the rural level. Public health care system in India is intermittent with underfunded and overcrowded hospitals and insufficient rural coverage. A weak delivery system is seen as the primary reason for poor health outcomes.

(h) Allocation of funds: The health sector has suffered the impact of under allocation and policy changes that was affected due to the implementation of Fourteenth Finance Commission recommendations. As the center's tax devolution to states was sought to be accelerated from 32% to 42%, a sharp and significant deceleration in Central government allocation to states through health schemes was also effected since 2014. Moreover, as the society route was practically not viable and dependable, the central government is currently channelizing funds through its treasury channels, this change has triggered massive amount of difficulty for health facilities to acquire adequate funds in time and to deliver services.

CONCLUSION

The future of health of individuals and populations is uncertain however all predictions for healthcare financing should be based on poverty mitigation and equitable accessibility of health care facilities. In India difference between rural and urban health status show a wide interstate disparity which are substantial and range from childhood to adulthood. The changing urban lifestyle of individuals instigates the complexities of new diseases and in rural India hygiene and addictions remain still unaddressed. Community based healthcare financing can be a tool for eradicating poverty thus there is a great scope in India. The enrollment of poor people in unorganized sector for such schemes is very challenging. The biggest challenge for such schemes is to tailor design benefit package to people's needs so that a right balance between equity and efficiency can be achieved. Success of such schemes can be achieved with collaborative efforts from both government and non-government organizations. Focus should be on studying and addressing the piecemeal approach of such schemes in providing health insurance to the poor. Establishing collaborative links with the health system and various stakeholders is the key.

SUGGESTIONS

1. Public private partnership for resource mobilization and fund management can be more effective for healthcare outreach for under privileged sections of the society.

2. Reaching out to the corporate entities for collaborative initiatives as part of their CSR activities for basic health and hygiene.
3. Collaborative arrangements with the pharmaceutical companies for provision of low cost generic medicines for poor or underprivileged sections.
4. Establishment of regulatory bodies/ committees at grass root level for measuring the reach and effective utilization of resources mobilized.
5. Providing children with basic healthcare facilities such as nutritious meals, vaccinations, generic drugs at primary school level for reducing their vulnerability to common diseases and for their overall wellbeing.

Ethical clearance: No need

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Examining Legal and Policy Provisions on Silicosis in the Context of Sandstone Mining in Karauli, Rajasthan-India

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ABSTRACT

Present study examines laws and policies on silicosis in context of sandstone mining in Karauli district of Rajasthan. Purposive sampling method was employed to select 217 respondents. FGDs and in-depth interviews were conducted to gather data. Open-ended questionnaires were developed, field tested and, used as FGDs and interviews' guide. Data were transcribed, themes identified, and interpreted. Results reveal that there is large scale of illegal mining (95%) in a vast area of the district. The Enforcement and regulatory agencies are understaffed, lacks coordination and, capacity; lease allotment process is opaque; unsuitable sites are allotted for the mining. Monitoring and reporting system is complex. Politico-bureaucratic nexus exists. Rudimentary tools used in manual mining without protective gears; rights of the unorganized miners are grossly violated. Compensation is inadequate and hardly reaches to the silicosis victims in full. There is severe shortage of the doctors, diagnostic facilities, and training opportunities. Provisions of Mines Act, 1957, Workmen Compensation Act, 1923 or Factory Act, 1948 are grossly inadequate and outdated in context of sandstone mining in the district. These findings will have far-reaching implication in terms of informed policymaking and legislation on prevention of occupational hazards and protection of the rights of the miners.

Keywords: *District Tuberculosis Officer (DTO), Director General of Mines and Safety (DGMS), Pneumoconiosis Medical Boards (PMBs), Rajasthan State Human Rights Commission (RSHRC), International Labor Organization (ILO), Rajasthan Environment & Health Administrative Board Fund (REHAB).*

INTRODUCTION

Silicosis is caused by inhalation of the hazardous silica dust. It is an occupational disease, characterized by inflammation and scaring of the lungs resulting in nodular lesions in the lungs' upper lobes[1]. It is a fatal fibrotic pulmonary disease, which is irreversible in nature[2]. The crystalline silica exposure particularly cristobalite and quartz as a human (group no-1) carcinogen[3]. This social disease originates due to interplay of multiple factors such as management choices to deploy a kind of technologies and practices in workplaces, behavior of workers, materials used, and the environment shaped by the government laws, regulation, inspection, insurance etc.[4] According to a rough estimate, there are three million working people directly exposed to silica in mines and industries like agate, slate pencil, stone cutting, silica milling, etc. Further, a large number of workers are engaged in infrastructure development activities like road building, construction of bridges, stone crushing units etc. in India[5]. According to Indian Government's own estimates, around 10 million people or more are exposed to hazardous silica dust on the jobs. India's mining industry alone provides employment to over 1.1 million people. The people engaged in unorganized mining are largely illiterate and lack understanding about the risks that come along with their occupation. Similarly, the owners are also unaware about the dangers resulting from improper workplaces[6].

In Rajasthan, there are around 3 lakhs mines worker majority of them are employed (95%) in more than 30,000 mines in Rajasthan. These mines differ in size and employ 2-10 people each[7]. However, number of people

in risk due to exposure to siliceous dust may exceed way beyond 3 lakhs since most of the sandstone mining (>95%) happens in unorganized sector. Nonetheless, this is the sector infamous for the violations of miners' rights and causing environment pollution[8]. Agriculture and mining sectors are the largest job providers in Rajasthan. Geographically, state has the largest area in India and huge mineral deposits, second after Bihar. In the state, for major minerals there are 1324 mining leases, 10851leases for minor minerals, and 19251 quarry licenses. Rajasthan has the highest numbers of small mines in India[9].

The prevalence of the silicosis ranges from 10-79% amongst high risks communities in India[10]. This variation may be due to the levels of silica dust concentration in the work environment and duration of exposure to siliceous dust. A study conducted in Karauli revealed high prevalence of (78.5%) silicosis amongst the poor miners mostly in the unorganized sector[11]. Therefore, occurrences of silicosis at epidemic level in the district requires thorough investigation. The present study examines existing laws and policies on silicosis in context of sandstone mining in Karauli district of Rajasthan.

METHODOLOGY

Followings open-ended questionnaires were developed and pilot tested to check clarity of the questions before gathering the data from the stakeholders in line with the objective of the study.

I. Questionnaires for Government and Non-Government health professionals

II. Questionnaires for Right Activists, Opinion leaders, Community leaders, and Government functionaries

III. Questionnaire for the Mines' Owners

Qualitative methods, Focus Group Discussions (FGDs) and structured interviews were employed to gather data. 217 Respondents (M 184, F 33) were drawn from the wide range of stakeholders such as mines' owners (53), Community leaders (46), Medical professionals (25), Government functionaries (30), and Human rights activists (63) having association with NGOs (25), Trade Unions of miners (2), and village level elected representatives (9) using purposive sampling method. Data were transcribed, themes identified and, interpreted.





Figure: 1 and 2: Maps of the state showing mineral deposits (Fig.1) and location of the study (Fig.2)

Source: DMG, 2016

Karauli is a backward district of Rajasthan, ranks 22nd in terms of development amongst all the 32 districts of the state of Rajasthan[12]. It ranks 22nd in terms of population, 23rd in terms of area and 13th in terms of population density in the state. The sex ratio is significantly lower (861/1000) than that of the state (928/1000). Scheduled Casts (SCs) and Scheduled Tribes (STs) population concentration is 24.3% and 22.3% respectively, the highest concentration in the state[13]. Agriculture, animal husbandry and, mining are the core occupations in the district. Sandstone occurs in layers in nature below a few feet of the mother earth. Mostly, it is mined manually using rudimentary tools like chisel and hammers. The minerals like sandstone, masonry stone, sand, silica soapstone and, white clay are found in abundance in the district.

RESULTS

Medical professionals of the district viewed Silicosis and Tuberculosis as two biggest challenges. There is acute shortage of doctors and diagnostic

facilities in the district, a single chest specialist in the entire district. No doctors have been trained or nominated for training on ILO standards of the diagnosis of silicosis. In many cases, suspect silicosis patients are treated for Tuberculosis due to similarities in symptoms of both the diseases. Silicosis cases are given symptomatic treatment. Doctors of the district were surprised to find high incidences of silicosis in the area. They wanted a study to investigate reasons for the high incidences of the disease in open cast mining. In most of the suspected cases, doctors conduct X Rays, Sputum Test, and Erythrocytes Sedimentation Rate (ESR) for Tuberculosis. However, there is no diagnosis facilities available rural areas except Diagnosis at district headquarters. No cure for silicosis is available, hence doctors prescribe bronchodilators, expectorant, and in severe cases steroids. DTO is overburdened, so far >2300 cases have been referred to the PMB Jaipur for the certification (as on Aug 2016). Moreover, there is a "bandarbaat" i.e. pilferage of their compensation money. Some individuals/entities coerce the victims for donations (5-15% of total compensation received from the Government). The PMB is a diagnosing and certifying authority; it has not been functional most of the time due to unavailability of a radiologist, a very rare commodity in Rajasthan Health Department.

Government functionaries viewed high incidences of silicosis as an outcome of poor working conditions, lack of awareness and education about health hazards, lack of preventive measures to reduce dust exposure, and exposure to dust since childhood. Further, use of the rudimentary tools and equipment such as chisels, hammers, no masks, dry drilling, etc. are other major contributors. There are innumerable small sized mines, which are remotely located and inaccessible. This makes difficult for the authorities to enforce laws in such circumstances. In addition, illegal mining a great challenge for the government.

There is extraordinary delay in payment of the compensation (at least a year from the date of application) to the victims. Ex gratia amount given from the REHAB is grossly inadequate (around 1500 $ to a living case and $3000 to the legal hire of the silicosis victim), and very difficult and cumbersome to get it. In many cases, the victims are not able to get the compensation when they are alive. Leaseholders do not keep the records of the miners as per the requirements of the laws, no registers, no identity cards, completely unorganized casual labors moving from one area to another for survival. Compensation cannot be claimed, if employer and employee relationship is not established under Workman's Compensation Act, 1923.

Community Leaders/Opinion leaders believed that high incidences of silicosis are due to drilling, blasting, chiseling, cutting, breaking, and to load and unload mined stone. Majority of them said that the patients having respiratory problem are still treated for Tuberculosis. Neither the leaseholders have mechanism to measure the dust level in their mines nor they have any facilities or health provisions for their mines' workers in the entire district. Most of the community leaders were not informed about the various legal provisions, which apply on the mines leaseholders. They exploit laborers for their poverty; hire them by giving advance money and make them work by underpaying. Leaseholders do not follow any rule of the rulebook. In addition, the Government has allotted areas that have trees for the mining and the areas that have rocks, and no trees are marked as forest areas. This is the reason leaseholders encroach on forestland. Contractors put contracted labor there; forest officials come and arrest workers. In many cases, these officials beat them up. They pay bribe to the forest officials to encroach on forestland. Due to poverty, people do not go to hospitals and delay in accessing health care services most of the workers die in young age. There are huge numbers of young widows in every village of the district. Some of the villages are known as "villages of widows". No workers get personal protective gears for mining. They are left by the contractors unattended when they become sick. In addition, sick workers become burden to their families. Mines owners report to the government that all the workers are in good health. Benefits like bonus or insurance cover are farfetched ideas. Government authorities do not do anything until paid bribes. Legislators of the area do not take up their issues at state level or any other appropriate forums. Karauli Labor Officer stationed at Bharatpur and looking after several districts; if anyone wants to complain about the labor laws violations that person has to go to Bharatpur or Jaipur.

NGO and Rights Activists said there is nothing else people can do other than mining in the district. Karauli sandstone has high concentration of silica (>80%). Wet drilling, though it is mandatory under the rules, is not

being practiced even in the licensed mines, a major cause of silicosis (maximum detections of silicosis cases in entire Rajasthan has been from Karauli district so far). Both, the DGMS and the DMG have miserably failed to enforce wet drilling. Leases are granted by the state but are monitored by the central agencies as per the law. The DGMS and Ministry of Labour & Employment, which are responsible for enforcement and welfare of mineworkers do not have adequate resources to enforce Mines Act; though have lot of inherent powers and are in a position to reign in erring mines' owners. There are lot of coordination and operational issues between DGMS, Ministry of Labor, and Ministry of Mines. Neither side is interested in talking to each other as a result shifting the responsibility game is going on. This gives a perfect opportunity for the mines' owners to violate the Mines Act blatantly. Everything is being done on paper. "*Sab hawahawai hai*".

Contractors were in view that the incidences of the silicosis in the district are being inflated. Forest areas have better quality and quantum of stone than that of actual mines' sites. This is what entice leaseholders to encroach into the forestlands. Contractors were well-versed with the provisions of various laws pertaining to the mining and disease silicosis however they said nobody in the district have any instrument to measure the threshold of hazardous silica level in the work environment. None of the contractors in the district have established any diagnostic treatment facilities for their workers. According to contractors, there is no need of measuring dust level in the mining sites since there is open cast mining in the district. They make advance payment to the contracted workers by 10-20 thousands each. Their money is adjusted according to the quantity of stone mined by the workers at the rate of 50-60 rupees per square feet. They believe that people who do mining do not get silicosis but those who do drilling get silicosis. Leaseholders use drilling once or twice in a year, which they outsource from the local people.

"*We don't have drilling machines; these machines belong to the local people. Even if we want to use our tractors or drilling machines, they do not allow us to do so. They are influential people and contractors are forced to use their services*"

They believed PMBs are being forced to diagnose Silicosis instead of Tuberculosis in patients since there is involvement of money. NGOs are behind this. There are many players in this game. They said, "*We don't employ permanent labor hence not responsible for their health conditions*". It emerged that every leaseholders has to comply with the more than a dozen government departments such as Police, Revenue, Environment Clearance, Pollution Control etc. Above all, there are Tehsildars, Collectors, dacoits and other influential people to manage. Karauli Mining Association says

"*Mining is the only industry that brings resources to the district and more than half of the district population is engaged in mining activities directly or indirectly. Unfortunately silicosis patients in the area go to the quacks and traditional healers rather approaching qualified doctors due to ignorance.*"

Contractors are questioning the applicability of the Mines Act on their acts of mining. They said, "*Any direction from the authorities for registering their mines with the DGMS is against the law; we do open cast mining and none of our mines are 6 meter deep, employ 50 people and, use explosive*" These are the conditions for applicability of the Mines Act, 1957. DGMS never investigated this and sent violation notices to the contractors.

"*We have challenged this in the High Court of Rajasthan since majority of the mining in the district happens illegally and it's useless to single out sandstone mining when there are many hazardous industries in the district like cement, stone crushers, marble etc. They have not been served violation notices.*"

Government directives to do wet mining provide toilet and drinking water facilities for the miners on sites not possible since there is water scarcity in the district. Environment Clearance Board (ECB) has directed contractors to develop water-harvesting structure in or around mining sites. This is not possible on rocky fields.

"Government asks us to put all the information online. How can we do that since our work is in jungles and these areas are hardly electrified? ECB clearance cost us around 30-40 thousand rupees; each time government imposes unnecessary taxes on us. Due to increased inspector raj, area of legal mining is decreasing and illegal mining is increasing. If they come to inspect us, we have to manage them. In addition, leaseholders also have to pay to the forest officials, police and, many others to ensure that mined stone reaches to market for sale".

DISCUSSION

High occurrences of silicosis have posed a serious challenge for the district health authorities. There is acute shortage of doctors and diagnostic facilities in Karauli district. Diagnosis facilities only available at the district headquarter but not at PHCs' levels. Doctors are not trained on international standards on silicosis diagnosis resulting in misdiagnosis and under diagnoses of large number of cases. Most of them are diagnosed and treated as TB patients. It is reported that resistance to diagnosing silicosis is due to couple of reasons. One, the law requires doctors to notify the disease to appropriate authorities and doctors do not want to take this added responsibility. There is INR 50 penalty for non-reporting. The other reason is due to lack of training to identify occupational diseases. ILO has laid down guidelines for the physicians how to read X Rays of the silicosis[14]. Rule 5 (2) (c) of Rajasthan Workmen's Compensation (Occupational Diseases) Rules, 1965 lays down that radiological interpretation shall be based on the ILO classification[15]. The DTO is overburdened with large number of cases. So far >2300 cases (as on Aug 2016) have been referred to the PMB, Jaipur for the diagnosis and certification. Since there is no cure of silicosis, doctors prescribe bronchodilators, expectorant, and in severe cases steroids. Lately, (in Dec 2014), the State Government announced the constitution of PMBs in every districts after the interventions of the RSHRC. PMB is a diagnosing and certifying authority. The PMB in Karauli, due to difficulty in getting radiologist, has not been functional, a very rare commodity in Rajasthan Health Department. There is a huge backlog of patients waiting to be examined since PMBs sits twice a month, and examine 15-20 patients per sitting[16]. In addition, only handful workers are aware about the existence of PMBs in the state[17]. It is further reported that hardly any doctors nominated to the PMBs are trained on Pneumoconiosis[15] . No contractors in the entire district have any in-house health care provisions for their mines workers; people who are into mining due to poverty die very young. There are several village in the district known as "villages of widows". It was reported by a leading national daily that in Budgar village alone there were 263 widows and Arampura village 53 widows who lost their husbands due to silicosis. No workers get personal protective equipment for mining. A similar study concluded that the majority of the mines workers (70%) do not get any safety equipment[17]. The State Government is rigid and do not accept the certification of the disease status not even by a national apex body like NIMH. Unfortunately, many people are affected with the silicosis in the area and they go to the quacks and to traditional healers rather approaching qualified doctors due to ignorance.

State Health Department is now organizing silicosis detection camps in the district. However, detection rate is dismal in the camps. MMUs deployed by the Government (10 Mobile Medical Units-MMUs for detection of silicosis in the state, every unit covers 2 districts) faces challenges related to competency of the staff and adequacy of the equipment. Initially, health authorities showed TB camps as Silicosis camps. Most of the time these MMUs are found parked in the district headquarter. The same observations were mad by the High Court of Rajasthan, which said hospitals do not have sufficient equipment for diagnosis; measures to prevent occurrences of silicosis are not initiated scientifically. The Government takes deaths due to silicosis casually[18]. In addition, it is reported that funds made available to the Health authorities from the Environment Safety Cess Fund have been used to procure equipment, which have nothing to do with the detection of silicosis[15]. Ex gratia amount to the silicosis victims is inadequate; process to claim is cumbersome and causes inordinate delay[15].

Miners in the district are working in extremely poor conditions; degree of understanding on health hazards amongst them is low, do not use personal preventive equipment, use rudimentary tools like chisel and hammers, and engage in dry drilling. A study conducted by the RSHRC in 2014 states that the workers are not using masks supplied to them. Nonetheless, these masks do not provide effective protection against silica dust. There are no alternate livelihood opportunities in the district and these unorganized workers lack bargaining power. A study concluded that the workers are not provided personal protective equipment for mining[19]. Most of the miners are poor, illiterate and come from socially disadvantaged communities. Silicosis victims cannot claim compensation since it is very difficult to prove employee and employer relationship, an essential condition of the Compensation Act, 1923. Most of the miners are working in unorganized sector since majority of mining happens illegally in the district. According to UN report 95% of mining activities in the state fall in the domain of unorganized sector[20]. Devrajan, 2016 in his

affidavit before the high court made a submission that illegal mining in forestlands is common; mafia involved are well organized and powerful[16]. A study finds that the contractors maintain no records hence workers are left with no proof to claim compensation in case of any adverse impact on their health and lives[7].

There is no political and administrative will to combat the menace of silicosis in the district; it is concerned only for revenue collection and has been insensitive towards deaths and human sufferings. Devrajan, 2016, in his report concludes that the Government is interested only in maximizing the revenues and overlooking large-scale violations of provisions of safety and security of the mines workers[16]. The Collector of the district is the Inspector of Mines. The Government has allotted areas for the mining, which have lot of trees, and the areas, which have lot of rocks and no trees are marked as forest areas, a major cause leaseholders encroach on forestlands. Government authorities do not do anything until paid bribes. Karauli Labor Officer stationed at Bharatpur and looking after several districts and remains inaccessible to the public. According to the state mineral policy, mining areas are to increase manifolds to attract investment.

Both the DGMS and DMG have miserably failed to enforce wet drilling. Leases are allotted by the state, but are monitored by the central agencies as per the law. DGMS and Ministry of Labour & Employment, which are responsible for enforcement and welfare of mineworkers, do not have adequate resources to enforce Mines Act. There are lot of coordination and operational issues between DGMS, Ministry of Labor, and Ministry of Mines. It is reported that there are multiple agencies as per the provisions of various central and state level legislations; however, a coordinated approach to address occupational health is lacking[21]. Government data is misleading. In district records, there are only 700 miners working in sandstones' mines whereas so far >2000 cases with silicosis have been confirmed. There is hardly any electricity supply at the mines' sites for wet drilling, an essential condition under Metalliferous Mines Regulations, 1986. Only insignificant numbers of mines owners in the state are doing wet drilling in the state[16].

Many of the mines contractors of the district have political affiliations. They claim PMBs are being forced to convert TB cases into Silicosis. They hold the view that in many cases, people are bringing the disease from other states since they go out in search of jobs. No leaseholders in the district have any mechanism to measure the dust level, (a legal requirement under Factories Act, 1948). They neither have their own health facilities nor appointed any doctor to examine workers periodically or treat them. Under Mines Act, 1952 and Mines Rules, 1955 initial and periodic examination is provisioned (Devrajan, 2016). Workers are contracted by paying them in advance. They are not their employees hence they cannot be blamed for workers' health conditions. It emerged that every leaseholder has to comply with the more than a dozen government departments such as Police, Revenue, Environment Clearance, Pollution Control, DGMS, and Labor etc. Above all, there are Tehsildars, Collectors, dacoits and other influential people to manage. Findings are in consonance of a study, which says that there are multiple agencies as per the provisions of various central and state level legislations[21].

Implementation of various acts on ground are grossly inadequate. Moreover, there are large number of small sized mines, which are remotely & sparsely located and are inaccessible. In addition, inadequate work force and infrastructure makes it extremely difficult for the authorities to enforce the laws even if they want to. A researcher concluded that the Government is under resourced which renders mining laws ineffective in terms of implementation[22]. The Workmen's Compensation Act. This Act has only been of theoretical interest. It is revealed that the mines owners do not maintain employment records of the workers and hence cannot file claim before the labor court[15]. Many of them sublease the mining leases to other people. A study says there are two major laws namely Mines Act, 1952 and Factories Act, 1948; which are many decades old and need amendments[22]. Contractors are not implementing provisions of the Mines Act because its provisions are not applicable on them and notices served to them are in violation of Mines Act, which they have challenged in the court of law. The Section 3 (b) of the Mines Act, 1952 says it should be an open cast mining, the depth of the mine should be more than 6 meter, more than 50 workers, and use of explosives. These provisions of the Mines Act renders majority of the mining related activities in the district beyond the purview of the law.

CONCLUSIONS

In absence of alternate livelihood opportunities in the district and rampant poverty unskilled, illiterate or semiliterate poor workers from socially disadvantaged communities are compelled to work in extremely poor and hazardous mining sector. There is involvement of powerful and well-organized mafia in carrying out large-scale illegal mining in the district. The award of mining licenses in case of minor minerals like sandstone and quartz is opaque and complex. Forested areas have been allotted for mining and rocky areas are marked as forest areas. Silicosis has posed a serious challenge to the district health authorities in terms of providing diagnosis, treatment to the patients particularly in the rural areas. Ex gratia amount to the silicosis victims is inadequate; process to claim is cumbersome and there is pilferage "bandarbaat". Enforcement and monitoring agencies have miserably failed to enforce wet drilling and other Mines Act's provisions; they have inadequate resources and competence to enforce laws; face serious coordination issues. They are doing paper work, "sab hawahawai hai". Government is interested only in maximizing the revenues and overlooking large-scale violations of provisions of safety and security of the mineworkers. Mines' owners deny the occurrences of high incidences of silicosis in the district and refuse to implement the provisions of the Mines Act, 1952, Workman's Compensation Act, 1923, and Factories Act, 1948. There is serious urgency to relook into the archaic laws and amend them according to the challenged faced by the various stakeholders in the small-scale mining sector.

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Assessment of The Knowledge, Attitude and Practice of Cervical Cancer Screening among Women Accessing Antenatal Care in Nnamdi Azikiwe University Teaching Hospital, Nnewi Southeast, Nigeria

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ABSTRACT

Background: Cervical cancer is a major public health problem worldwide. In Nigeria, it is second most common cancer. Cervical cancer, however, remains preventable. One of the methods for the prevention is cervical screening; thus, the assessment of the knowledge, attitude and practice of cervical screening among women becomes crucial.

Objective: This study sought to assess the knowledge, attitude and practice of cervical cancer screening among women accessing antenatal care in Nnamdi Azikiwe University Teaching Hospital, Nnewi, Nigeria.

Methodology: Data were collected from 150 respondents using semi-structured interviewer-administered questionnaire and analyzed using descriptive statistics.

Result: The study revealed poor knowledge of cervical cancer screening, though a significant number have positive attitude toward the screening as they indicated interest in doing the screening if provided with the opportunity. Despite this apparent positive attitude, the practice of cervical screening remained abysmally poor. This has been attributed to many factors: lack of awareness of the service, inadequate prodding to do the screening by the physicians, etc.

Research implications: This study is of benefit to gynecologists. However, as the study is based on only 150 willing respondents compared to the huge number of women who attend antenatal at NAUTH and elsewhere, the findings may not be widely generalized.

Keywords: *Attitude, Cervical Cancer, Knowledge, Practice, Screening.*

INTRODUCTION

Cervical cancer is a major public health problem worldwide[1]. Across the globe, it is the second-most common cancer in women, with 80% of cases occurring in developing countries. The World Health Organization (WHO) has estimated that the contribution of cervical cancer to adult female death is 35% with nearly 500, 000 new cases occurring each year worldwide[2]. In Nigeria, cervical cancer is second most common cancer[3]. Cervical cancer remains largely preventable. One of the methods for the prevention is cervical screening.

Screening, in medicine, is a strategy used in a population to identify an unrecognized disease in individuals without signs or symptoms[4]. Screening methods are intended for early diagnosis, and thus early intervention and management so as to decrease morbidity and mortality from a disease. Screening methods should be sensitive and specific to disease it screens for.

Cervical cancer screening is the way of identifying or diagnosing cervical cancer at an early pre-cancerous stage[4]. It belongs to secondary level of prevention of cervical cancer, thus, though a killer, cervical cancer is largely preventable[5]. It is estimated that screening at 3years intervals for women aged 35-64 years can reduce the incidence of invasive cancer by over 90%[3].

There are many methods of cervical cancer screening which include: cytology (Pap smear), visual inspection with 3 - 5% acetic acid, visual inspection with lugol's iodine, colposcopy, cervicography and human papilloma virus testing.

In America, the protocol for cervical cancer screening is that a female aged 21years or with 3 years post onset of sexual activity should be enrolled in cervical cancer screening program and should be screened every 3 to 5 years if the smear is negative, but if positive, should be screened in the next 6 months. The screening is stopped by 65 to 70 years. This protocol is what is adopted in Nigeria. However, unlike in America, Nigeria has no organized mass screening program.

It has been noted that cervical cancer is a sexually transmitted disease because of its uncommonness amongst virgins. Most is caused by a DNA virus called human papillomavirus (HPV), frequently serotypes 16 and 18[6]. It is associated with some risk factors viz: multiple sexual partners, early coitus, Immunosuppressed states, multiparity, smoking and many others.

If as been suggested that cervical screening and early detection at precancerous stage reduces the incidence of invasive cancer by 90%, it is then necessary to ask some principal questions:

(a) What is the level of knowledge about cervical screening among women predisposed to this disease?

(b) How often do these women bring themselves forth for cervical screening?

(c) What is their attitude towards cervical screening?

This paper thus, examines the knowledge, attitude and practice of cervical screening among women assessing Antenatal care in a named Hospital.

REVIEW OF LITERATURE

The review of related literature is organized under the following headings:

a. Conceptual framework

b. Theoretical framework

c. Empirical studies

Conceptual framework: The concept of cervical cancer screening is not new and dates back to the 1940s[7]. The discovery of pervasive cervical lesions is achievable through employment of different cervical cancer screening methods (e.g. Pap smear, Colposcopy and others) and allows for appropriate treatment and stops disease progression. The drawback lies in making screening and treatment available to all women at risk.

Cervical cancer screening is of great health importance especially in the developing world where organized screening programs are not readily available. It has been observed that decrease in incidence rates is more evident in countries with organized screening programmes[8]. Inadequate screening is the primary reason cervical cancer continues to claim women's lives[9].

Theoretical framework: Theories are constructs and postulations that guide or suggest a way in which individuals perceive phenomena and act or behave which in turn may influence the nature and the level of what they know or practice[10].The way persons acquire information or act is taken to depend on a person's scheme. The scheme attempts to know (knowledge), how they want to get the information (methods of learning) and how, what or which of the facts (knowledge) they want to act on (attitue)[10]. The theory is an idea or belief about something arrived through speculation or conjecture[10].

This study therefore is anchored on health belief model in assessing the knowledge, attitude and practice of cervical cancer screening in women accessing antenatal care in a named hospital in Nigeria.

The Health Belief Model (HBM), was developed to help understand why people did or did not use preventive services offered by public health departments in the 1950's and has evolved to address newer concerns in prevention and detection as well as lifestyle behaviors such as sexual risk behaviors and injury prevention[11] . It was one of the earliest behavior change models to explain human health decision making and subsequent behavior by social psychologists[12]. It came up when some people refused the offer of free chest X rays for detecting tuberculosis. HBM has core constructs: beliefs about the chances of getting a condition (Perceived susceptibility), beliefs about the seriousness of a condition and its consequences (Perceived severity), belief about the effectiveness of taking action to reduce risk or seriousness (Perceived benefits), beliefs about the material and psychological costs of taking action (Perceived barriers), factors that activate readiness to change (Cues to action), confidence in one's ability to take action (Self efficacy)[11].

EMPIRICAL STUDIES

Knowledge of cervical cancer screening: In a study done in 2011 on knowledge, attitude and practice of cervical cancer and screening among Rural and Urban women in six provinces of the democratic people's Republic of Korea; it was found that 63% of rural and 60% of urban participants had heard of cervical cancer($p>0.05$). 42% knew that it is the common cancer of female reproductive tract, 55% knew that all women are at risk, but only 36% were aware of cervical cancer preventability. Some 13% of rural and 29% of urban respondents had heard of cervical cytology testing (p 0.001)[13].

In a study in 2006 on knowledge, attitude and practice of cervical cancer screening among medical workers in Mulago, Hospital, Uganda: response rate was 92% (285). Of these, 93% considered cancer of cervix a public health problem and knowledge about Pap smear was 83% among respondents. Less than 40% knew risk factors for cervical cancer, eligibility for and screening interval. Of the female respondents, 65% didn't feel susceptible to cervical cancer[14].

Study on knowledge, attitude and practice of cervical cancer and screening among women visiting primary health centre care in Qatar which was conducted in 2008 among 500 women revealed; 85% had heard of cervical cancer and 76% had heard about the Pap smear[15].

Unang et al, (2011) study on awareness and practice of cervical smear as a procedure for cervical cancer screening among female nurses in a tertiary hospital in South-South Nigeria showed that 94.3% had heard of cervical screening and 79.5% of the respondents are aware that cervical screening is used to detect premalignant disease of the cancer[16]. This showed respondents' high knowledge of cervical cancer screening. Similar studies revealed respondents' high knowledge about cervical cancer screening too[17,18,19,8].

The knowledge of cervical cancer screening is quite impressive in these studies; however, surprisingly the knowledge did not translate to practice[20].

These studies too share an affinity in the sources of information about cervical cancer screening. Hospitals and text books ranked highest in the respondents' sources of information about cervical cancer screening.

Attitude of cervical cancer screening : Byrd et al, (2004) study on cervical cancer beliefs among young Hispanic women revealed that respondents understood the seriousness of cervical cancer, their susceptibility to cervical cancer, and benefit of pap testing; however, only 61% agreed that most young women whom they know have pap tests[21].

In a study done in Kuwait on Knowledge, Attitudes, and Practice Related to Cervical Cancer Screening showed that 30.6% had adequate attitude towards the test[8].

Arulogunet et al, (2012) study on perception and utilization of cervical cancer screening service among female nurses in University College Hospital, Ibadan, Nigeria revealed that 88% of the respondents correctly perceived cervical cancer to be preventable and 82% believed that screening should be carried out as soon as sexual intercourse starts irrespective of age[22].

A study done in 2013 at Nepal on knowledge, attitude and practice regarding cervical cancer screening amongst women visiting tertiary centre in Kathmandu, Nepal showed that more than 85% of women had positive attitude towards screening but the uptake of pap smear test in the respondents were only 10%[23].

Positive attitude towards cervical cancer screening is prime in most of the studies reviewed.

Practice of cervical cancer screening : Notwithstanding the high level of knowledge and the positive attitude towards cervical cancer screening showed by the respondents, low practice among the population used is prevalent, even among medical students, nurses and educated people. Murasa et al (2011), revealed that most nurses (84.6%) had never had a Pap smear examination. A study carried out in 2011 on knowledge, attitude and practice of cervical cancer screening among female secondary school teachers in Oshogbo, southwest, Nigeria showed 5.4% of respondent had Pap smear at the time the study was done[1].

Also, similar study done in India showed 11.6% of respondents had Pap smear[24]. Furthermore, about 18.4% of female health care providers of Chennai Corporation have ever undergone cervical cancer screening[25]. Similar studies done across the globe[26,27,28] recorded abysmal failure of the respondents to participate in cervical cancer screening, irrespective of age, education accomplishment and nature of job.

The most common reasons for non-participation in screening are lack of symptoms, lack of counseling, physician does not request and fear of vaginal examination (Murasa et al, 2011[8]. Lack of awareness of test (58.5%) and where it could be done (12.5%) were also major reasons for failure to have screening done[1]. Other reasons adduced by respondents for not being screened also included lack of awareness, non-availability of screening centres locally, cost and time[26].

METHODOLOGY

Study area: The study was carried out at Nnamdi Azikiwe University Teaching Hospital (NAUTH), Nnewi, Anambra state, Nigeria. The hospital is a tertiary institution and contains a total of 355 beds[29]. Also antenatal care services are being rendered together with other health services. The hospital trains medical student, nursing students and other paramedical students.

Situated in Nnewi a semi-urban area located on the coordinates $6^{0}1$ N.$6^{0}55$'N South East, Nigeria. NAUTH has a population of 391,227 and a population density of 7,252/sq (2,800/km) according to 2006 National Census.

As a developing city and one of the major industrial and commercial hubs in Africa, it experiences tremendous financial activities, and so it hosts banks and other financial houses[30]. It remains the centre of business trades mostly in automobile parts.

Study design: The study is designed as a triangulated study that sought to elicit both quantitative and qualitative data. Semi structured questionnaire was used to elicit a cross-sectional descriptive data on knowledge, attitude and practice of cervical cancer screening among women accessing antenatal care in Nnamdi Azikiwe University Teaching Hospital (NAUTH), Nnewi.

Study population: The study population was all the women, accessing antenatal care in Nnamdi Azikwe University Teaching Hospital who was between 15-45 years.

Sample size and sampling technique: A sample size of 150 was used. NAUTH runs antenatal clinics Mondays to Fridays where an average of 40 persons attends each day. The sample was determined by the number of persons who willingly accepted to participate in the study.

Systematic sampling technique was used. Every second person sitting on the clinic bench was given the questionnaire to fill after an informed consent. A situation where the person fails to give her consent, the questionnaire is transferred to the next person and then to the second person sitting on the clinic bench, progressively in that order.

Research instrument/ data collection: The data were collected using a semi-structured questionnaire which was interviewer administered.

The questionnaire was divided into four sections: A to D (Biodata, Knowledge, Attitude and Practice of cervical cancer respectively).

The respondents were exposed to 30 item questions. Each of the sections contains (A- 8, B- 8, C- 6, D- 8) items meant to draw out qualitative and quantitative data.

Ethical consideration: The study recognized ethical consideration and thus, verbal informed consent was obtained from all respondents after explaining the study and confidentiality guaranteed.

Data analysis: Statistical package for the social sciences (SPSS) version 20 was used for the analysis. The results were presented using tables, simple bar charts and pie charts.

Limitation: The study was based on only 150 willing respondents.

RESULTS/ FINDINGS

A total of 150 respondents were used for this study, majority (43%) of the respondents were aged 24-29years. Ninety-eight percent were married and 85.9% have conceived less than four times. Less than half of the respondents have their highest educational level as SSCE (46.3%), **See table 1.**

Only 39% of the respondents are aware of cervical cancer screening, which is surprisingly low since this is one of the topics being taught at antenatal clinic. This is possible as lateness to antenatal clinics is one of the banes of the service. **See figure 1**. Hospital and health worker (66.7%) formed the major source of information about cervical cancer screening. **See figure 2**.

Greater percentage of respondents (51.7%) knows nothing about the various methods of cervical cancer screening. However, Pap smear was the method largely known by respondents (38.3%). **See table 2.**

Table 1: Socio-demographic characteristics of respondents

Variable	Frequency	Percentage
Age		
15-23 years	12	8
24-29 years	64	42.7
30-35 years	54	36
36-40 years	6	4
41-45 years	14	9
Marital Status		
Single	4	2.7
Married	146	97.3
Number of Pregnancies ever had		
lesser than four	127	84.7
Greater than four	23	15.3
Highest level qualification		
SSCE/WACE	70	46.7
OND	8	5.3
NCE	9	6
HND	16	10.7
Bachelor's degree	30	20
Masters	1	0.7
No formal Education	16	10.7
Age of first sexual intercourse		
Less than 17	36	24
Greater than 17	114	76
Number of sexual partner		
One	130	86.7
Greater than one	20	13.3

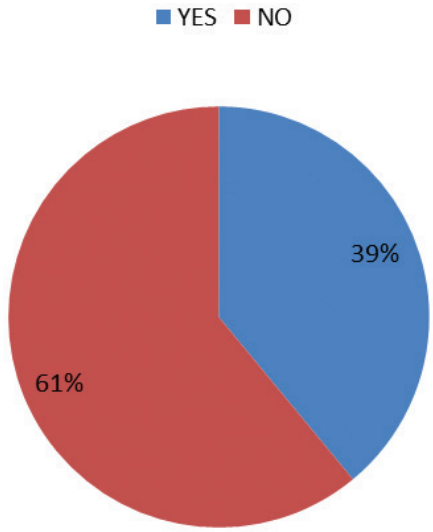


Fig. 1: Respondents that had heard of cervical cancer screening

Table 2: Respondent's Knowledge of Cervical Cancer Screening

Variable	Frequency	Percentage
Different methods respondents know		
Pap smear	23	38.3
Colposcopy	2	3.3
Visual inspection with acetic acid	4	6.7
Visual inspection with lugol iodine	3	5
Cervicography	2	3.3
Human papilloma virus testing	4	6.8
Don't know	31	51.7
Knowledge of those expected to do cervical cancer screening		
All women of child bearing age	38	64.4
Only women with symptoms of cervical cancer	5	8.5
Only women with promiscuous life style	1	1.7
Those who are sexually active	6	10.2
Don't know	10	16.9
Knowledge age the screening should be started		
<21 years	12	21.1
>21 years	25	43.9
Don't know	20	35.1
Knowledge of Interval of time the screening is done		
6 monthly	16	28.1
1 yearly	10	17.5
3 yearly	5	8.8
Don't know	25	43.9
Is not necessary	1	1.8
Knowledge on the advantages of the screening		
Early detection of cervical cancer	52	88.1
Prevents illness from the cervical cancer	7	12.1
It prevents death from the disease	3	5.2
No advantage	1	1.7
Early treatment of cervical cancer	8	13.8

Risks associated with the screening		
Fear of positive results	24	41.4%
Pain	6	10.3
Infections	4	6.9
Don't know	21	36.2
None	4	7.0

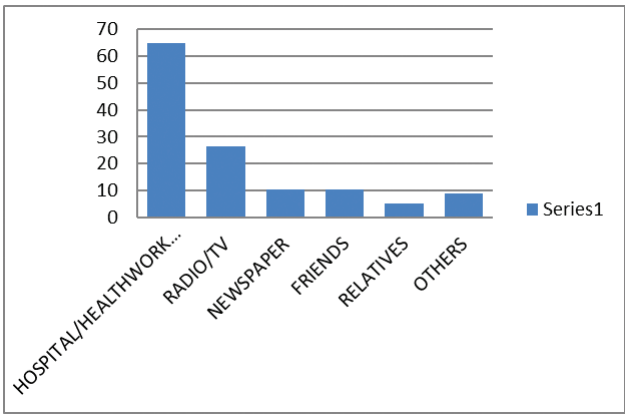


Fig. 2: Respondents' source of information

Attitude of respondents toward cervical cancer screening is very wonderful, 91% of respondents encouraged the use of cervical cancer screening as a method of prevention of cervical cancer and 94.3% agreed to do the screening if opportunity is presented to them. **See figure 3 and table 3.**

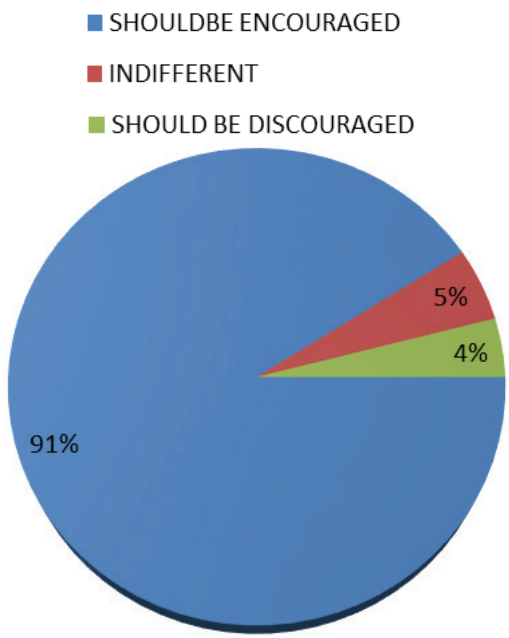


Fig. 3: respondents' opinion on practice of cervical cancer screening

Table 3: Respondent's attitude to cervical cancer screening

Variables	Frequency	Percentage
Respondents view of importance		
Yes	130	91.5
No	6	4.2
Don't know	6	4.2
Why respondent choose Yes		
Detects cervical cancer early	111	83.5
Decrease death from cervical cancer	38	28.6
Because I was told by a health worker	1	0.8
Others*	3	2.3
Why respondent choose No		
It does not prevent cervical cancer	1	16.7
It is a waste of money	1	16.7
It does more harm than good	2	33.3
Others **	2	33.3
Respondent's opinion on whether she will do the screening if an opportunity is presented		
Yes	133	94.3
No	8	5.7
Respondent's opinion on whether they will encourage their female relatives to do the test		
Yes	131	94.9
No	7	5.1

* Early treatment and cure

** Not important and not pleasing and uncomfortable as it invades privacy.

The practice of cervical cancer screening is extremely poor despite a good attitude; only 3% of the respondents have done cervical cancer screening in the past. **See figure 4**. There are many factors that discourage the respondents from doing the test, not aware of the test and physicians do not request for the test being the majority. **See table 4.**

Figure 4: Respondents that had done cervical cancer screening before

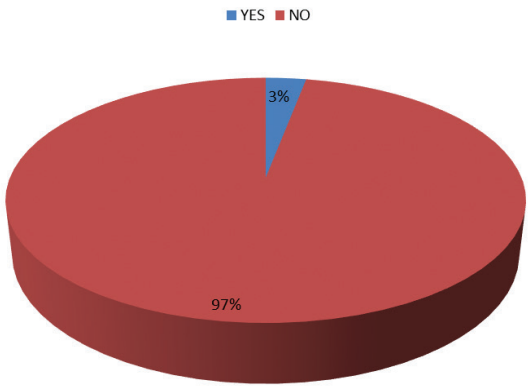


Table 4: Respondent's practice of cervical cancer screening

Variables	Frequency	Percentage
How many times respondents did the screening		
1-3 times	4	100
4-6 times	0	0
7-9 times	0	0
>9 times	0	0
Age at which respondents did the screening		
<21 years	1	33.3
21-30 years	1	33.3
>30years	1	33.3
Last time respondents did the screening		
<6 month	0	0
1 year	1	25
2 years	1	25
3 years	2	50
>3 years	0	0
Interval respondents do the screening		
Every 6 month	1	25
Every 1 year	1	25
Every 3 years	0	0
Every 6 years	0	0
Any time an opportunity comes	2	50
Where respondents did the screening		
Hospital	3	75
During an outreach	1	25
Motivation of respondents to do the test		
Just saw those doing it	1	25
I know the importance	2	50
It was free	0	0
Convinced by a friend or health worker	1	25
Was having symptoms suggestive of cervical cancer	0	0
Doctor requested it	0	0
Factors that prevent respondents from doing cervical cancer screening		
Don't know where to do it	26	17.7
Lack of symptoms	25	17.0
Fear of vaginal examination and afraid that it will pain you	2	1.4
Respondents don't have money	6	4.1
Fear of miscarriage and not becoming pregnant after doing the screening	2	1.4
Afraid of the outcome of the test	6	4.1
Does not want to be exposed to male doctors	0	0
Not aware of the test and physicians do not request	86	58.5
Other***	13	8.8

*** No reason and no time.

DISCUSSION

Cervical cancer is an avoidable disease, and one of the important ways of prevention is by the use of cervical screening health services. The women that took part in this study had poor knowledge of cervical screening as 59(39.3%) of the 150 respondents were aware of the screening. This varies with a study done in the same centre, among female nurses, which showed that 87% of respondents are aware of the service[17].Though, both groups are female; the difference was expected because the increased knowledge of the latter group will be due to the fact that they are health workers. However, this finding is similar (43.5%) to a study done among market women in Zaria[31].

Only 38.3% of respondents had heard of Pap smear as a method of screening in this study. However, in a study done among women visiting primary health care centre in Qatar using 500 respondents revealed that 76% had heard of Pap smear[15]. This arguably might be due to

the difference in sample size and perhaps the difference in the level of exposure of the respondents.

Most of the respondents got their information from the hospital/health worker (66.7%) in this study, but similar study done in Nepel asserted friends and relative to be their main source of information[23]. It might be due to the fact that the sample population of this study was antenatal women and cervical screening is usually one of the health talks given to them at each visit.

This study done showed that 90.8% of women strongly suggest that the screening be encouraged and 91.5% agreed that cervical cancer screening is important. This showed a great positive attitude towards the cervical cancer screening. This agrees with study done amongst women visiting tertiary centre in Kathmandu, which showed that more than 85% of women had positive attitude towards the screening[23]. Also, it agrees with a similar study done among market women in Zaria which revealed that 80.4% of respondent had good attitude towards cervical cancer screening.

More so, 94.3% of respondents would accept to be screened if an opportunity is given to them. This agreed with a study done in Burkina Faso among women aged 20-50 years where 96.6% of respondents would accept to be screened if an opportunity is presented to them[28].

Their cervical cancer screening uptake showed very low screening uptake (2.7%). A similar result was noticed in a study done among females attending their ante natal and gynecological clinic at Mater Misericordiae Hospital, Afikpo, where only 0.6% cervical screening uptake was noticed[26]. More so, there was a low cervical screening uptake (5.7%) in a similar study done among female nurses in the same centre (Udigwe GO, 2006).

The commonest factors that discourages the respondents from doing the screening was the fact that they are not aware of the test and physicians do not request for it (58.5%), also they don't know where it could be done (17.7%) and lack of symptoms (17.0%). These findings are similar to the study done at Oshogbo, Southwest, Nigeria where lack of awareness of test (58.5%) and where it could be done (12.5%) were the major reasons for failure to have screening done[1]. More so, a study done among nurses in a tertiary hospital in Northern-eastern India had their reasons to be due to lack of symptoms (58.4%) and physician does not request (29.9%)[24]. what perhaps cannot be overlooked in this study is the comments by some of the respondents when asked why they do not encourage cervical screening. One of them said "I find cervical screening not pleasing at all". Another said 'cervical screening makes me uncomfortable as it invades my privacy." Though the number that expressed this view is few, they may be the voices of a silent majority.

A study done in Kuwait also gave reason for not having had the screening done to be: not suggested by Doctors[8]. In this light, doctors and other care-providers should have it as a point of duty to educate all women eligible for this screening once they come in contact with them.

On analyzing the knowledge score of the respondents with the demographic profile, it was found the respondents aged 24-29 years had better knowledge of cervical cancer screening, though it was not statistically significant. However, a similar study showed women aged 50-59years to have better knowledge[23].The reason could be that those women are better exposed and they were not in my inclusion criteria.

More so, there was association between the parity of respondents on their knowledge, attitude and practice (KAP) of cervical cancer screening in this present study. Respondents that had had more than four pregnancies had more KAP, though it was not statistically significant, since the p value was >0.05. Similar result was seen in a study done in Nepel[23]. The higher KAP noticed can be explained by the fact that women with higher parity are more exposed to hospital and health workers which also concurred with their majority source of information being hospital/health workers

Respondents with bachelor's degree had better knowledge of cervical cancer screening when compared with those with SSCE. The difference was statistically significance=0.003 which was also true in a study done at Kuwait[8]. However, this contradicts a similar study done at Nepel, which revealed that respondents with primary education had better knowledge[23], though do not have explanation to that.

CONCLUSION

The study showed poor knowledge and practice of cervical cancer screening amongst women of

reproductive age accessing antenatal care in Nnamdi Azikwe University Teaching Hospital, Nnewi South East Nigeria. There was a better knowledge of the screening among respondents with bachelor's degree than those with SSCE, which was statistically significant.

However, a very impressive attitude towards cervical cancer screening was noted. The major reason that discourages respondents from doing cervical cancer screening is that they are not aware of the health service and the physicians do not request for the screening to be done. The "invasive of privacy" by cervical cancer screening, as seen by some of these respondents is remains a "voice" that cannot be overlooked.

RECOMMENDATIONS

Based on the findings of this study, the recommendations are:

a. The need for more aggressive campaigns against cervical cancer.

b. More services of mass media, hospitals, health workers and sources to create awareness and education the masses on cervical cancer screening and it's important.

c. National policy guidelines for screening of cervical cancers should be developed in Nigeria.

d. Government and non-governmental organizations (NGO) should provide more screening centers.

e. Government, NGOs, support groups and individuals should fund the screening programs and the mass media awareness about the screening.

f. Fund for further researches in cancer prevention and management should be provided.

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Systematic Literature Review of Negative Social and Psychological Factors Affecting Mobile Phone Users

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ABSTRACT

Purpose: This systematic literature review aims at; identifying social and psychological factors affecting mobile phone users. In specific reference, it studies negative social and psychological effects on mental health and behavior of mobile users.

Research Design/methodology/approach: This study is a systematic literature review of negative social and psychological effects of mobile usage on phone users. Relevant literature on the topic is classified for it's; relevance, citation counts, and chronology of publications using SCOPUS bibliographic database. 39 relevant research articles on negative social and psychological effects of mobile phone are shortlisted from initial count of 2,225. Later these articles are reorganized to thematically group into emerging factors.

Findings & Interpretation: The study classifies four negative social and psychological factors affecting mobile phone users as; social anxiety, depression & stress, addiction, object & romantic attachment. Social anxiety relates to; loneliness, psychological dependency, bulimia of contact, fear of separation, and feeling of solitude. Depression & stress is about; work-related stress, mental health, information overload, and techno-stress. Addiction to mobile phone is reported as; social extraversion, higher expenditure, and negative emotions. Lastly, literature discusses object & romantic attachment of mobile users as; sexting behavior, leisure, social engagement, media behavior, and lowering of anxiety.

Research implications: Mobile phones being pervasive in usage, understanding negative social and psychological effects on users is a relevant cause. Four identified factors could be furthered using statistical testing.

Novelty/Originality: This is an important study for its efforts in summarizing the extensive literature, and identifying social and psychological factors affecting health of mobile users.

Keywords: *mobile phone, social anxiety, depression, stress, addiction, object attachment, romantic attachment, sexting*

INTRODUCTION

In terms of personal and social challenges; modern personal communication devices like mobile phones are affecting the human being differently. There are, myriad benefits associated with use of advanced communication devices; but there are equally large personal and social challenges associated with use of such devices. Medical fraternity and research literature has reported varied psychological and social factors negatively affecting user of electronic devices, specifically related to mobile phones.

While mobile phones; connect users anytime-anywhere through audio, video, or written modes of communication; are handy for any situation may it be a general or an emergency situations; are equipped with computing capabilities & transfer of large amount data in real time; — on the other hand mobile phones are reported to; hinder human interactions, cause accidents, breach privacy & secrecy of users; —develop; mental and physical stress, social and psychological anxiety and in extreme situation develop addiction.

OBJECTIVES

This research aims to identify social and psychological factors affecting users of mobile phone devices, with specific reference to negative effects on mental health and behavior of device users.

METHODOLOGY

This study is a systematic literature review of research in area of social and psychological effects of modern communication devices like mobile phones on the users. SCOPUS bibliographic database is used to identify literature in the area of 'phone', 'anxiety', in subject subarea of 'psychology'. The scope of the research is 'articles' pertaining to social and psychological effects, and does not include medications and treatments related to the topic. Initial search resulted into 2225 research articles; the search was further refined to 39 relevant articles related to topic of concern.

Literature review is conducted in three distinct stages; at first literature is chronologically organized to study longitudinal flow of the topic; then the same literature is reorganized on citation count, to identify themes visited by the past research; and lastly the literature is again reorganized based on keywords. Once relevant themes are identified; the research articles are reorganized into logical themes and concepts. Themes are grouped- regrouped in order to arrive at a clear line of distinction with no further possible grouping. Final grouping cross-tabulated across chronology and themes is showed in Table 1.

Table 1. Literature Themes

Year	Social Anxiety	Depression & stress	Addiction	Object & romantic attachment
2007	Reid & Reid, 2007. Szilvia, Karoly, Viktor, & Peter, 2007[1].			Rees & Noyes, 2007
2008		Rubin, Cleare, & Wessely, 2008.	Ha, Chin, Park, Ryu, & Yu, 2008[2].	
2009	Ohannessian, 2009. Pierce, 2009. Harvey & Carden, 2009[3].			Ohannessian, 2009.
2010	King, Valença, & Nardi, 2010.	King et al., 2010[4].		
2011				
2012	Skierkowski & Wood, 2012[5]. Briere et al., 2012[6]. Hong et al., 2012[7].		Hong, Chiu, & Huang, 2012.	Briere et al., 2012
2013		Adams & Kisler, 20138.		
2014	S. Lee, Tam, & Chie, 2014. Cheever, Rosen, Carrier, & Chavez, 2014[9]. Andrew Lepp, Barkley, & Karpinski, 20143[8]. Chopik & Peterson, 2014[10].	Temple et al., 2014. Harwood, Dooley, Scott, & Joiner, 2014[11].		Luo, 2014. Temple et al., 2014. A. Lepp, 2014[12].
2015	Cipresso et al., 2015. Lin, Chiang, & Jiang, 2015. Y.-K. Lee et al., 2015[13].	Y.-K. Lee, Chang, Cheng, & Lin, 2015[14].		McDaniel & Drouin, 2015. Cipresso et al., 2015[15].

2016	Sapacz, Rockman, & Clark, 2016[16]. Yamazaki et al., 2016.	Elhai, Levine, Dvorak, & Hall, 2016. Panova & Lleras, 2016.	Chen et al., 2016[18]. Konok, Gigler, Bereczky, & Mikl??si,	
	Konok et al., 2016[17]. Kruger & Djerf, 2016[22]. Elhai et al., 2016. Saling & Haire, 2016[18].	J. Lee, 2016[19]. Saling & Haire, 2016[23].	2016.	Wardecker, Chopik, Boyer, & Edelstein[20], 2016[21].

DISCUSSION

Four distinct themes in relation to social and psychological effects of mobile phone, specifically in negative sense are emerged as; social anxiety, depression & stress, addiction, object & romantic attachment.

Social Anxiety: Literature discusses various perspectives of social anxiety in relation to mobile phone. Mobile phone use varies according to user personality, social anxiety, – as contrived by him, and loneliness as, – deficit in relationship. User personality can be defined through neuroticism, extraversion, agreeableness, conscientiousness, and openness-to-experience; social anxiety as prospect or presence of interpersonal evaluation of social settings – real or imaginary; and loneliness as actual or perceived deficits in maintaining interpersonal relationships in presence of distressing and unpleasant experiences; — decides mobile phone use for voice calls or text messagin[9]. The relationship is depicted in Figure 1.

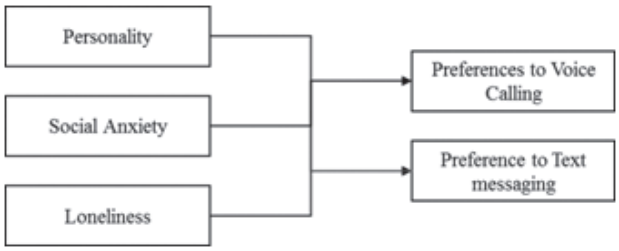


Fig. 1. Psychological factors affecting mobile phone usage behavior9.

Social anxiety and addiction-proneness of the user leads to frequent cell phone usage[16]. Experimental research in mobile usage while driving vehicle showed increased driving errors like; lane cutting, hitting stationery objects, loss of vehicle control and increased anxiety[24]. Cell phone use is considered to increase anxiety levels of phone users, the effect is evident in young students. Further, anxiety is likely to affect attitude of satisfaction with life[25]. Mobile phone users have reported experiences of listening to ringing of phones and receipt of messages even when no calls or messages are arrived; such experiences are variedly termed as 'phantom ringing', 'ringxiety', 'vibranxiety', or 'faux-cell-arm'. *Attachment anxiety* of mobile users is said to develop such phantom ringing and notification experiences; on the contrary *attachment avoidance*, could not indicate such relationship with phantom experiences.

In case mobile is 'out-of-sight', or is 'in-the-sight but not available-for-use'; user anxiety is found to increase over time,—especially for heavy and moderate users; while no significant effect found on low mobile users[26]. It is observed that teenagers are more likely to suffer from 'bulimia of contact' or 'compulsive use'. Bulimia of contact is looking for external support, which is not otherwise provided by family. Fear-of-separation and feeling-of-solitude with use of mobile phone, are another reasons of compulsive mobile use by teenagers[6]. In general text messaging is emerging as a most favored method of communication among young users[5]. Further, loneliness tends to initiate voice call making; if texting is considered to be less intimate method. On the other hand, anxiety initiates messaging behavior considering text as a superior communication medium for expressive and intimate contact[1].

Smartphone is affecting different age-groups differently; young users have higher dependency on their devices and indicate severe symptoms compared to non-smartphone users. Smartphone dependency is mainly coming through use of internet and messaging requirements. Main reason for this dependency is, the need of sociability which leads to mobile dependency and symptoms of, —anxious, lost and withdrawal/ escape tendencies[27]. Research indicate; anxiety differs over genders, age, number of close relatives & friends; number of calls & text messages to family, friends & acquaintances; as well as inclination to build new

contacts, and trust strangers. Suggested means of monitoring anxiety are; number of close relatives, friends, and using strong communication methods like mobile phones and text messaging[28]. In general, females carry higher social anxiety, as compared to male counterparts. One of the research found that females are more likely to use cell phones for text messaging and visiting online social websites compared to face-to-face talking. Social anxiety is also related to website chats and text messaging. Lack of social anxiety is directly related to making of online friends[29].

Depression & Stress: Another factor related to mobile phone usage is depression and stress. Technostress is the stress induced because of use of high tech devices. Use of technology in all areas of life is at times creating dissatisfaction30, stress and depression.

Mobile related stress and depression has two aspects; first is the stress on account of overuse of technology, and other is stress on account of non-availability of habituated technology gadgets. Research in smartphone-involvement and smartphone-use shows that; higher smartphone involvement is associated with higher depression and stress, but not anxiety; and higher smart-phone use is not significantly associated with depression, anxiety and stress. This indicate the nature of relationship the user has with smartphone which works as a predictor of depression and stress[31]. Anxiety, need-for-touch and fear-of-missing-out is found to be associated with problematic smartphone use. Depression is inversely correlated to 'frequency of use'; and frequency is directly correlated to 'need for touch'. Relationship between mobile use and depression is mediated by behavioral activism, as well as emotional suppression [18]little is known about the mechanisms that maintain this behavior. We recruited a sample of 308 participants from Amazon's Mechanical Turk labor market. Participants responded to standardized measures of problematic smartphone use, and frequency of smartphone use, depression and anxiety and possible mechanisms including behavioral activation, need for touch, fear of missing out (FoMO. Under negative experiences or feelings; strong relationship is observed between lower mental health and problem use of technology. Mobile phone offers effect of a small security blanket lowering initial negative reactions to stress. Long term use of devices as an emotional coping method may have effect on mental health[19].

Though employees positively perceive utility of smartphone for its ability to provide useful access to information; these devices also create information overload, the abundance of information; such abundance called information overload may generate negative emotions among employees[32]. At times, some people have reported electrosensitivity; the problems related to electromagnetic field. The cause of electrosensitivity is not scientifically ascertained to communication devices; but found related to psychological conditions of these people. Electrosensitivity may also be associated with technostress, the stress arising out of technology usage for increasing productivity, but are difficult to master, and are frustrating to the users[2]. Higher level of technology usage like using mobile during sleep hours is found to affect sleep quality of users; and such lower sleep quality may lead to depression. Here technology is causing sleep disruption, and is a mediating factor between device use and depression[8]. Mediating effect of sleep quality is indicated in Figure 2.



Fig. 2: Technology- Depression/Anxiety: Sleep Quality as Mediator[8]

[In comparison to traditional phones, with smartphones, the psychological factors like; locus of control, social interaction anxiety, and need for touch are strongly associated with stress among smartphone users. Materialism is found to be positively connected to stress among traditional phone users14.. The relationship is represented in Figure 3.]

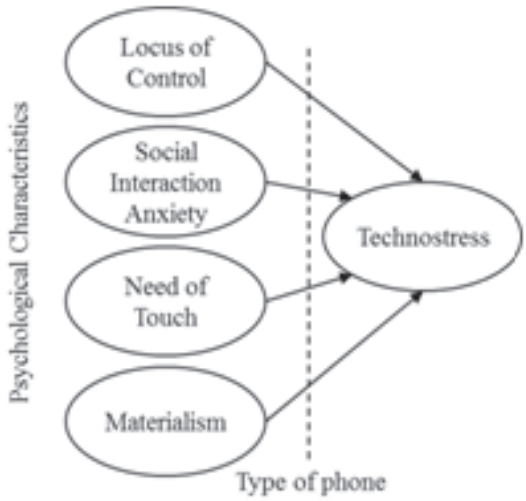


Figure 3. Effect of Psychological factors and Type of Phone used[14]

[Use of mobile phones during night hours for various reasons leads to tiredness and impaired psychological functions; further higher levels of tiredness is associated with depression, anxiety, and stress[23]. Research shows no effect of depression with sexting behavior, the behavior of using mobile devices for sending, receiving sexually explicit messages[11].]

Addiction: Addiction is the third important factor affecting mobile phones users. A positive correlation is found in psychological problems and excessive use of cell phones by adolescents. These users tends to identify themselves with their mobile phones and face difficulty in behavior control[33]. Literature discusses nomophobia, a disorder due to discomfort or anxiety developed when kept out of contact with mobile phone or computer. It is a fear of being out-of-touch. Sufferers tends to keep their mobile phones close to themselves, just to overcome need to feel safe, and being in touch[4]. As shown in Figure 4, important factors contributing to phone addiction are positive relationship of social extraversion and anxiety; and negative relationship of self-esteem with phone addiction. Addicted users are more likely to make phone calls and send messages[7].



Fig 4. Psychological Characteristics- Phone Addiction & Usage[7]

Mobile phone addicts spend more money and time on their mobile phone, and are vulnerable to negative emotions affecting them. Relationship between phone addiction and negative emotions generated is mediated by interpersonal problems[34].

Object & Romantic Attachment: Both the genders tend to use their mobile phones for different activities; gender difference also varies on internet use, internet attitude and computer anxiety; however mobile phone use and expertise level is not significantly different across both the genders[35]. Media use is also reported to differ between genders; boys tends to spend more time playing games, and girls spend more time talking on phone. In homes affected by alcoholic parents; boys used video games to reduce anxiety; and opposite pattern emerged with girls[3]. As indicated in Figure 5, cell phone usage is negatively correlated with performance and positively correlated to anxiety. Males use of mobile phone for calling, texting or daily use is not related to parent or peer attachment; however for female, calling is positively related to parental attachment and texting to peer attachment[10].

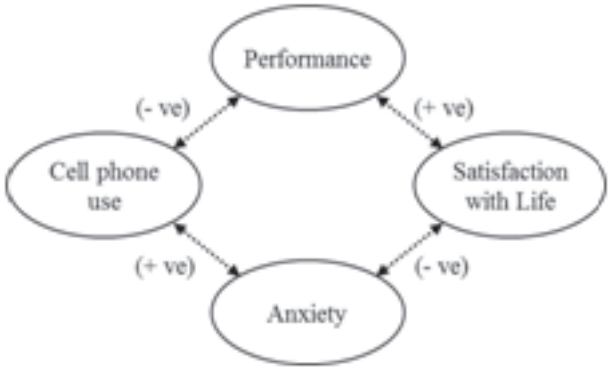


Fig. 5.Correlations between Mobile use, Performance, Anxiety, and Satisfaction with Life[10].

Teenagers view their mobile phone against feeling of solitude; if not allowed to use their phones they feel socially isolated[6]. Research suggest 11 factors of up-to-date technology and media usage as; smartphone usage, general social media usage, internet searching, e-mailing, media sharing, text messaging, video gaming, online friendships, Facebook friendships, phone calling, and television watching[36]. Use of social media is found to create significant psychophysiological pattern of arousal, valance, attention, and anxiety in user of mobile phone;— suggesting an optimal experience during pervasive use of Facebook[13].

Another interesting mobile phone usage is observed in married couple's sexting behavior; married adults prefer mobile calling feature for relationship building, and avoid sending photos or videos. This sexting behavior is mainly for relationship satisfaction, and to fend off attachment anxiety[15]. Human has biological predisposition to attachment with human, as well as non-human social partners like mobile phone. Young people tends to develop attachment with their mobile phones. They seek proximity of their mobile devices and experience distress on separation. Research in mobile phones ability to affect experience of leisure indicate; high-frequency mobile users are more dependent on

their mobile phone while experiencing leisure because of cultural co-option[21]. Avoidant attachment oriented people tend to avoid more close and immediate communication method like face-to face; they consider face-to-face interaction as less intimate, less preferred, and less likely to resolve a conflict. Instead avoidant attachment people prefer email as a form of communication[20]. Co-rumination about friendship quality of, extensively discussing, revisiting and speculating about issues mainly observed. Entry of mobile phone as a newer media of communication is affecting co-rumination effect among users[37].

CONCLUSION

Mobile phones are extensively affecting human lives; the effect of mobile phone on human beings can be summarized in four factors as; social anxiety, depression & stress, addiction, and object & romantic attachment. First factor of social anxiety, is a nervousness in social systems because of extensive use of mobile devices; second factor, depression & stress is either overdependence or non-availability of smartphone. Third factor, addiction is a state of compulsive engagement with the smartphone, the fourth factor object & romantic attachment is demographic and object oriented behavior of mobile users towards their devices. The factors identified in this research can be empirically tested and refined.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Rhetoric and Reality of Nutrition Promotion through Entertainment Education- A Review of Research from Last Six Decades

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ABSTRACT

This study examines the competency of E-E approach for nutrition education with an aim to understand its effectiveness for nutrition promotion. A systematic review was conducted by using suitable key-words and sourcing published literature from select search engines like PubMed, Google Scholar, EBSCO Host and Google. The inclusion criterion was predefined to include Indian studies that used audio-visual aids, multimedia games, internet, television and radio for education of community/health workers/stakeholders on maternal, child and adolescent nutrition.

40 studies using E-E approach for health promotion were identified (1956-2016); further 20 studies specifically incorporated E-E for nutrition promotion. The studies used E-E approach, however, the typical phases of E-E projects - formative, process and summative research were not adequately followed in some. The appealing E-E model led to nutrition knowledge acquisition in target populations however did not serve as a standalone approach to bring about behavioural change. Considering there is a dearth of literature on the use of E-E, this study attempted to examine the potential of E-E as a tool for behaviour change communication with nutritional content.

Keywords**:** *Edutainment India, Nutrition education, Multimedia, Health promotion*

INTRODUCTION

India today a developing country is facing the paradox of facing one of the fastest growing economies with the highest number of the malnourished children in the world[1]. India, while being the leader in the Information and Communication Technologies (ICT) yet is being ineffective in nutrition information dissemination to accomplish nutritional behaviour change. The gamut of under and over-nutrition disorders along with non communicable diseases has gained attention. Although extensive efforts have been made to impart nutrition education to the community to improve health and nutritional status of vulnerable population, the efforts have been scattered and varied[2]. Effective innovative and evidence-based health and nutrition promotion strategies are the need of the hour.

A characteristic distinction is often made between the terms *"nutrition education, nutrition communication, nutrition promotion* and *information, education and communication* (*IEC*)*"*[3]. However, they have universal characteristic strategies to endorse nutrition. The debate on the strategies, objectives and techniques of nutrition education continue.

Today, the conventional nutrition education approach is considered superfluous unless it is fully incorporated as colossal nutrition education stratagem with multi-component approaches[4].

"Edutainment" is a concept of an entertaining content with educational significance. Entertainment education or infotainment as advancing communication strategy has achieved prominence as a transforming agent of social and behaviour modification in many capacities including health and nutrition.[5]

Edutainment is utilising Gardner's 8.5 multiple intelligences recently which suggests that humans possess verbal/linguistic, visual/spatial, and musical/ rhythmic intelligence among other intelligences.[6]

Singhal investigated the role of mass mediated entertainment education programs in focussing on observed first order changes i.e small shifts in knowledge, attitudes and practices without any major change in primary value system. Further, the role of mass mediated entertainment education programs in generating second order changes i.e fundamental transformational shift in one's values and beliefs using entertainment education has also been investigated .[7] With the changing media scenario, education through personalised entertainment is being seen as a potential tool for improving not only nutrition knowledge but also behaviours. Although there have been some scattered research efforts to use edutainment as a means for nutrition communication, separate evaluation of edutainment as an approach for nutrition education needs to be done. Given this background, the current paper aims to critically examine research studies that used edutainment tools for nutrition education intervention in the last six decades in India.

OBJECTIVE

The present review aims to systematically provide an insight into the potential of entertainment education in nutrition research conducted in India. The review aims to analyse whether entertainment education can be used as a standalone tool for nutrition education and promotion.

METHODOLOGY

This review was designed to accumulate evidence on use of different interventions using edutainment and its outcome on target population. The studies over six decades (1956-2016) were reviewed.

Search strategy: It included studies which evaluated the use of entertainment education for the promotion of nutrition in school going children, adolescents, women and general population on communicable diseases and health and nutrition education in general. It also assessed knowledge improvement among healthcare providers recognised by government and non-government organisations. It assessed the increase in utilization of maternal, infant and child health services in India. The selected search engines were Google Scholar, EBSCO Host PubMed, Google. The keywords in combination were selected across all electronic databases as mentioned: entertainment-education in India, Nutrition education In India, Use of multimedia for kids, Health and nutrition apps , nutrition games, edutainment in India . This review included articles published from 1956 to 2016 in national and international peer reviewed journals and proceedings that are available online.

Inclusion criteria: Only Indian studies that have used multimedia and edutainment technology as a nutrition education and health promotion tool were included. The studies which focussed on the use of Audio Visual aids, digital games, multimedia, internet and other channels of communication like television and radio were selected.

Exclusion criteria: In Exclusion criteria research articles using Language other than English were excluded and studies done outside India were excluded.

Study selection process: Following the inclusion and exclusion criteria, abstracts were read ,studies were short-listed and finalised to be included .Then full articles were procured either through library search, internet search or by directly writing to the respective corresponding authors.

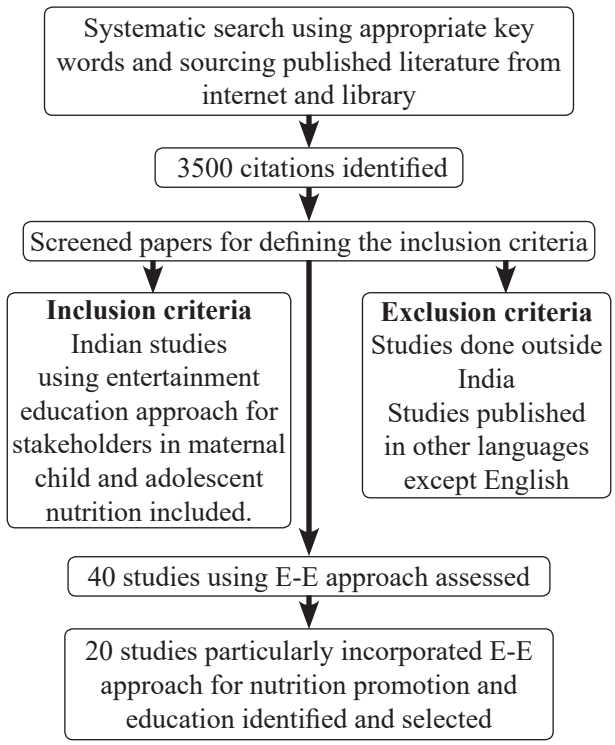


Fig. 1: Flow-chart representing the process of selection of studies for review

Data extraction: After retrieval of the full-texts of all research papers, abstracting into a predetermined format, which included the details of authors, year of publication, place of intervention, study design and study duration, the methodology the characteristics of interventions, key findings such as having multi component approach or edutainment was done.

Data analysis: Information extracted from the internet and library search were categorised in a framework that was developed by considering the target audience/ population, methods used, findings and conclusion. Table-1 presents details of the study with objectives, study settings, findings.

About the studies: The criteria for inclusion were broadly the use of E-E interventional approach for nutrition education. The total 20 studies identified and reviewed, used entertainment education approach along with conventional nutrition education.(Table-1)

Out of total studies reviewed the studies have been segregated based on interventional approach as follows:

a. Conventional nutrition education with entertainment education approach: Total 12 studies used the conventional nutrition education. The tools for conventional nutrition education used classroom lecture series, posters, personalised counselling and discussions, exhibitions, use of print media . The edutainment tools were audio visual presentations, multimedia, computer games, CD, folk dances, skits, games

b. Entertainment education approach with supplementation: Total two studies used audio visual aids for nutrition education along with supplementation of micronutrients.

c. Studies using Entertainment education approach only: Total six studies used the entertainment education tools for imparting nutrition education such as mobile games, multimedia and animation, audio visual aids etc.

The target population were pregnant and lactating women, children and adolescents. The study setting was majorly schools, rural areas and households.

The outcomes of the study analysed the role of edutainment in bringing about the change in nutrition knowledge, attitudes and practices.

Table -1 Summarising the studies using entertainment education approach

Sr. No.	Authors	Target Population and sample	Objectives	Methodology and mode of edutainment used	Findings	Conclusion
1.	Udipi et al, 19938	7-10 Years old children. N= 882	To impart nutrition education through games	The project involved pre-post test design using teaching educational games to private and municipal schools and assessment of its impact.	Learning improved with children having short attention span. and were low cost.	Games are an effective tool for health education to children.
2.	GM SubbaRao9 et al, 2006	School going children of class 8th and 9th standard Control group N= 358), the experimental group N= 312) and their teachers (5+5)	To assess the efficacy of global school-based nutrition education initiative, Feeding Minds, Fighting Hunger (FMFH), in improving nutrition-related knowledge levels of schoolchildren.	Children and teachers were grouped in control and experimental groups. .Concepts mentioned in FMFH Lesson plans were covered using skits, exhibitions, posters along with classroom education.	-Increase in knowledge of experimental schools group (17.50±0.64) from 13.00 ± 1.29 at baseline was observed. The mean scores of children did not show any significant difference post intervention. 1 and 2 (t=1.7; P=0.09).This indicated the retention of knowledge.	Experimental group showed significant improvement in the nutrition knowledge gain and retention post intervention.
3	D Raghunathrao 10 et al, 2007	Female Students 8th standard N= 164	To assess dietary habits and nutrition knowledge levels of the adolescent girls from different schools along with the efficacy of different nutrition education tools in classroom setting.	Two interventions (Intervention-1. Traditional method using print media; Intervention-2. Audio-visual CD) were carried out in a classroom setting for the experimental group.	ANOVA test indicated significant improvement (P<0.001) in the knowledge levels of the experimental group post intervention as suggested by an improvement in the mean scores from 46.7 to 58.8% , with increment of 12.27% in experimental group as against the increase from 46.8 to 49.7% in control group with increment of 2.9%, which was not significant (P>0.05).	Significant improvement after both interventions observed.

4.	TVijayapushpam 11 et al ,2008	College students, 19 years N= 207	To examine the comparative effectiveness of two different methods of communication— lectures aided by print material and a televised version of a local folk-dance form— in a South Indian state.	The knowledge levels were tested at baseline. Camp 1 received the lecture intervention and camp 2 used the televised folk-dance Intervention. Knowledge scores were measured before and after the intervention in each camp, and the two camps were compared for significant improvements in knowledge.	Comparison of the mean improvement in knowledge levels in camp 1 and camp 2 showed no significant difference in the knowledge gained . (p > o0.05) The communication methods equally effective (p>.05).	The educational intervention using the televised version of the folk art form was better in bringing about a positive improvement.
5.	AryaKiran et al12 , 2011	Number of households selected N= 105	To analyse nutrition knowledge of rural women in the study area using ICT.	Random selection of villages from Uttarakhand (2) , Communication strategy incorporating eight methods has been designed which included a wide range of media such as radio talk, posters ,charts,exhinitions ,TV film, slide show on symptoms of anaemia and importance of iron rich sources ,	The most preferred media for communication was TV (52%) followed by Radio (50%).	A communication strategy needs to be designed and implemented for disseminating nutrition Information, to rural illiterate women. .
6.	Singh and Khanna,13 2014	Males and females aged 15-25 ,(M=F) N= 80	To identify, prepare a catalogue of mobile phone games ,and assess the perception of ease and efficacy of games for playing along with content analysis of the messages in TB cricket game.	Semi structured interview schedules were used to collect data . A pre and post objective test based on game content was conducted .	73.75%Youth found the game easy to play. Hence, the average gain inscore was 1.75. The gain in average awareness score was more in female respondents (2.08) as compared to male respondents (1.80). 93.75% youth expressed willingness to acquire edutainment based mobile phone games.	New mobile phone edutainment games should be developed on issues like gender, environment, health, nutrition

7.	Hedaoo and Vali,14 2015	Students 10-12 years of age (M=F) N= 100	The objective of the study was to assess the impact of Nutrition education on nutrition knowledge and eating preferences of school going children	Three phases such as pre-test, intervention using multimedia and recipe demonstration and post test carried out To assess the improvement of nutrition knowledge	Post test suggested significant Increase from 38.7% to 75.8%. The food preference responses also changed from processed foods (60%) towards home made foods (97 %)	Introduction of supplementary curriculum in nutrition along with didactic training for the teachers should be provided.
8.	Staab, et al 15 2016	School going children 13-16 years	To assess Children's perceptions of their food and activity habits in a remote Indian city.	Photojournalist explored children's perceptions of their food and activity habits in Indian city using photo journals.	Children expressed interest in active pastimes, learning, and health, and indicated traditional, modern, local, and global influences in their lives.	Findings offer context for research and interventions.
9.	Gavaravarapu, et al4, (2016)	Adolescents (N=121)	To promote the use of food label information and informed food choices	The module was developed and implemented in intervention schools by including interactive lecture sessions ; a pictorial booklet posters an animation film for entertainment education. Mean pre- and post intervention scores of control and experimental schools were compared to assess the intervention effect and 2-sample t test was used to assess intergroup differences.	Post intervention, a significant (P<.001) improvement was observed in mean scores of the intervention group.. The composite scores significantly (P<.001) improved from before to after in the intervention group. Intra-group comparison using McNemar's test showed a significant (P < .05) improvement in all knowledge variables	Significant improvement was observed only in reading ingredients and claims on the food label and salt content of the snacks.

10..	Nalam et al16, 2017	Primary school children. (N= 305)	To develop a visual teaching aid (pictorial quiz) so as to promote activity based learning to enhance attention and retention of nutrition knowledge among	A 40 item pictorial questionnaire was finalised after content validation by experts. The questionnaire was implemented on children from government schools and corporate schools. (N= 40)Participants' knowledge was measured pre and post intervention.	The intervention led to a significant improvement in knowledge scores of participants ($p< 0.001$). The mean scores improved from 19.78 ± 3.79 to 32.16 ± 2..26 post intervention.	The findings indicated that visual aids, pictorials puzzles integrated in school curricula promote nutrition knowledge.
12.	Dachana et al 17, 2010	Schools covering midday meal program (10 urban and 10 rural areas), Karnataka	Pre and post intervention study to assess hygiene, sanitation and nutrition for school children.	Audio-visual aids covering micronutrients, hygiene and sanitation. Audio-visual aids and demonstrations for micronutrient education for 20 days for school children	Food diversity increased; sanitation, food handling practices improved. Among children, hand washing behaviors and cleanliness remarkably improved.	Small alteration in basic infrastructure is possible through proper training
13.	Pahwa et al ,18 2012	Mothers of children aged 12-71 months, Delhi slum (N=370)	To assess knowledge, attitude and practices regarding vitamin A deficiency	3phase-baseline data, intervention and follow up after 3months. Nutrition education was imparted using personal discussion,. Video, print media, focus group demonstration and peer learning process was involved	Significant improvement in knowledge and attitude towards vitamin A deficiency, diet and their role was witnessed. Importance of immunization card and preventable attitudes for vitamin A deficiency was also seen to be improved.	Nutrition education proved to be fruitful in changing knowledge and attitude among mothers from slum
14.	Vijaypushpam et al11, 2008	19-21 Y NSS volunteers, Andhra Pradesh (N=207)	To disseminate nutrition knowledge using traditional method and folk dance and assess the relative impact of these tools in improving nutrition knowledge	Both interventions were carried out after assessing their baseline knowledge regarding nutrition and obesity. First intervention developed traditional tools like using charts colour folders and lecture in local language Telugu. Intervention-2 included folk dance of 1 ½ hour on nutrition awareness.	Both the groups showed positive increase in knowledge. Classroom lectures with aids such as posters, charts, and folders were used as the method of nutrition education ($t = 0.745$, $p < .05$). Significant improvement in knowledge was also observed among the students of camp 2, where the televised version of the folk art was used ($t = 0.219$, $p < .05$).	This study indicated careful modification of folk media can be used for population awareness.

15.	Kapur et al19. 2003	9-36 month of children and their mother, Delhi slums (N=450)	To assess impact of nutrition education on mother along with supplement.	The group was divided in three intervention groups: 1 supplement group, 2nd supplement with education and one control group with placebo. Video program and calendar messages used as intervention tools.	A significant main effect of nutrition education ($p < 0.05$) and supplementation ($p < 0.05$) was observed. Overall significant positive feelings related to exclusive breast feeding for 46 months ($p < 0.001$), feeding children 45 times a day ($p < 0.001$), providing variety of foods in the child's diet ($p < 0.001$), putting the child on to the family food by one year ($p < 0.001$) and reducing the milk intake and giving more solid food ($p < 0.001$) was recorded in the nutrition education group.	Overall this research shows effectiveness of nutrition education in changing knowledge of mother on feeding practices and nutrition.
16.	Sethi et al20, 2003	Mothers of 5-19 month infants, Delhi slums (N=30)	Assess current infant feeding practice and outline need-based educational program (only 30 participants). Pre and post knowledge and behaviour study.	Communication-mix -Individual counselling -Participatory learning method -Focus group discussion -Song and street play - Posters flash card story growth chart	Grains and pulses were included by all mothers' post-intervention. Green Leafy Vegetables were incorporated in the diet by 80% at posintervention Fifty percent mothers initiated in between meal feeding two times a day post intervention.	Repeated reinforcement through communication leads to positive effect on nutrition knowledge and dietary practices.
17.	Rao et al,212008	N= 791 rural girls (16-19 years)	To determine the effectiveness of an educational intervention program on knowledge of reproductive health, among adolescent girls.	Audio visual aids such as chalk and blackboard, charts, posters and video films were used along with interactive lectures on reproductive health and diet in pregnancy.	A significant increase in overall knowledge after the intervention (from 14.4 to 68%, P < 0.01) Knowledge regarding the importance of diet during pregnancy improved from 66 to 95% following the intervention	Educational intervention program can bring about a desirable change in knowledge regarding reproductive health

18.	Saibaba et al22 ,2002	10-19 Y adolescent girls, Andhra Pradesh (N= 2500)	To assess the nutritional status and dietary intake of adolescent girls and study the impact of information, education and communication (IEC) programme on their nutritional knowledge and practices	Intensive IEC intervention was carried out for a period of 6 months through Inter Personal Communication (IPC) techniques. The IEC tools used included cooking demonstrations, posters, information booklet, innovative games and nutrition melas. Cooking demonstrations were held in all the intervention areas.	After IEC intervention significant proportion of girls could correctly identify the foods rich in various important nutrients. The average intake of greens, b-carotene rich fruits and vegetables and millets increased.The prevalence of signs and symptoms of vitamin A deficiency was reduced:	Information, education and communication along with interpersonal communication serve to be an effective tool in creating nutrition awareness.
19	Sindhu and Kumari 23 , 2014	Adolescent Girls N= 120	The objective was to plan an adolescent reproductive health communication including nutrition using edutainment	Edutainment material in print and electronic was developed on adolescent reproductive health and nutrition using a pre –post test design. ROI i.e relative profit made in investment of edutainment was calculated.	The findings revealed a significant improvement in knowledge post the ARH communication. The return on investment with regard to ARH communication was 18.9%. The present study revealed a behavior benefit operationalized through edutainment.	The study concluded that behaviour change communication through edutainment is profitable.
20.	Noronha et al,24 (2013).	Anemic pregnant women N= 225	To determine the effectiveness of a health information package using visual aids and iron supplementation for pregnant women.	Random allocation in experimental (n=75), and control group (n=75). The health seeking behaviour outcome measure included knowledge regarding anaemia, food selection ability, increase in haemoglobin level and compliance to iron supplementation.	The results showed the mean gain of knowledge scores of experimental group was comparatively higher ($p<0.01$) with significant difference in food selection between both the groups.($F(2,190)=20.92$, $p<0.01$).	The study indicated health education contributed significantly in modifying health seeking behaviour.

DISCUSSION

Entertainment media for various kinds of education fundamentally uses engaging format, an educational message and a societal transformation goal that focuses on important societal need. There is a need for more proactive programs to bring about favourable social changes.

Radio and Television have emerged as a dominant mass media In India catering to varied socioeconomic and cultural backgrounds. Television has a unique potential of bringing in best of educators, eminent personalities and specialists directly to a large number of audience and provide distance education at vocational, technical, medical and school levels.

With respect to the field of Nutrition and Dietetics, edutainment serves as a progressive step towards turning over the nutritional misconceptions and encourage healthy food habits. It was observed that often the cultural pulse of the community was neglected while delivering the nutrition messages also repetitive, ineffectual nutrition communication strategies were used.

In view of the advent of information technology from last decade and use of e-learning, contemporary methods in nutrition education have surpassed the traditional methods of nutrition promotion. A review on Nutrition communication done by SubbaRao mentions of various Studies concluding that use of computed based nutritional teaching acts as a support to conventional teaching using print media as they show a wider reach and convenience and interactivity.[25]

In light of this, innovative technologies may be used to disseminate information and bring about changes in dietary habits. Research studies have concentrated on the use of intervention and observed the knowledge gain after intervention but whether this knowledge gain has been implemented in real life situations is still a question. For an effective communication to take place it has been suggested that a multi component communication strategy using personalised multimedia, ICT and individual counselling is expedient .With the digital wall thinning among the rural and urban population, new methods of delivering nutritional information. These studies reflect multimedia and edutainment as a powerful tool for promoting healthy behaviours especially in low income and middle income countries. Although edutainment has been used in India for health promotion and for social causes, there are very limited studies done on using this technology for Nutrition education and awareness. There is an equally urgent need to look into the internal and external factors of the communicating organization, such as the organization's level of knowledge of the nutrition problem(s), the budget, the perceptions of the key human resources on community participation, their motivation levels and personal biases as these affect the communicative processes.[26] Provided these issues are being taken care of, public nutrition experts and educators, must collaborate with commercial public and private sectors involved in the commerce of information technology and persuade these technology giants to enter nutrition education communication.

The findings in this review indicate that entertainment education has been recognised as an innovative strategy for creating nutrition awareness. An example would be the personalised message delivery attributed to rise of techno savvy individuals, foreign collaborations, rise of localized entertainment and gaming industry.

However, certain ethical predicament has been brought forward in edutainment. By analysing the nutritional problem qualitatively, is important to understand the extent to which the mass media should be used as a persuasive tool for all sections of the society and classes especially in a diverse country like India .In such multi-stakeholder collaborations using researchers, educators, government and non-government organizations, corporate and academic institutes, each stakeholder should bring in their expertise and lend credibility to the nutritional messages imparted to the society.

CONCLUSION

There are no sufficient studies evidenced using edutainment as a standalone tool for nutrition education. Further studies are needed to see the impact of using only edutainment as a tool for imparting nutrition education. Also, there are inadequate studies showing dietary behaviour change after acquisition of nutritional knowledge.

There is a need for targeted behaviour change communication by utilising novel participatory methodologies such as transformative learning,

participatory learning and ethnographic edutainment along with focus group discussions and in- depth interviews to target populations regarding nutrition related messages, develop a pertinent health and nutrition content and formulate an effective interventional tool such as an "Edutainment" intervention.

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Awareness and Adaptive Practices Regarding Factors of Climate Change among Urban Residents of Pune City

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ABSTRACT

Introduction/Background: Global Warming and Climate change is expected to increase the frequency of extreme events.

Aim: A cross sectional study was conducted to assess the awareness and practices regarding factors of Climate Change among the urban residents of Pune city.

Materials and Methods: Urban area of Pune city was selected for study**.** The sample size was 116 selected by simple random methods from two different urban settings. Structured questionnaire was prepared and data was collected.

Results: The sample consists of 92 (79.3%) female and 24 (20.7%) male. 58% respondents were aware about climate change with mean 17.38 and mean adaptive practice score was 8.6 (53.89%). About 93(80%) respondents responded that climate is changing. Out of 116, 64(74%) respondents still using bio-mass as fuel. Only 60 (69%) respondents were aware of nonpolluting CNG vehicles. There is positive correlation between awareness level and adaptive practices (r= 0.678).

Research implications: It revealed that awareness level is average but adaptive practices among urban population are poor which is far below expected level. There is a need to spread mass awareness among population to reduce the impact of Climate Change.

Novelty/Originality: Paper is significant to the health educators, social activists and mass media personnel to organize mass campaign regarding global warming and climate change.

Keywords: *Adaptive practices, Awareness, Climate change, Pune, Urban residents*

INTRODUCTION

There has been an alarming effect of global warming on the climate across the world[1]. India is already a disaster prone area, with the statistics of 27 out of 35 states being disaster prone, with most disasters being water related. The process of global warming has led to an increase in the frequency and intensity of these climatic disasters. According to surveys, in the year 2012, India ranked the third highest in the world regarding the number of significant disasters, with 18 such events in one year, resulting in the death of 1103 people due to these catastrophes[2]. There is urgent need to sensitize the general population and create awareness among them to reduce the impact on their health[3].

Scientists have found out that global GHG emissions due to human activities have grown since pre-industrial times, with an increase of 70% between 1970 and 2004. Furthermore, according to the report, the continued and unabated release of greenhouse gases from human activities at or above current rates would cause further warming and induce many changes in the global climate system during the 21st century that would very likely be larger than those observed during the 20th century. Anthropogenic warming could lead to some impacts that are abrupt or irreversible, depending upon the rate and magnitude of the climate change[4]

Intergovernmental Panel on Climate Change (IPCC) assesses the climate change status worldwide[5]. Climate change is expected to increase the frequency of extreme events[6]. Major cities are main source of climate change, due to their developmental activities, migration of the peoples to the cities and industrializations[7]. Though climate change is happening, every change in the

weather should not be correlated to climate change the weather has not changed much but we, on the other hand, are changing[1]. This changing lifestyle is making us more aware about the changes in the weather[8]. This study contributes to address the issue by assessing the awareness and adaptive practices regarding factors of climate change among urban residents of Pune city.

MATERIAL AND METHODS

Cross sectional descriptive study was carried out in the urban area of Pune city, Maharashtra state of India. The aim of the study was to assess the awareness and adaptive practices regarding climate change in urban population of Pune city and to find co-relation between awareness and practices. The purpose of the study and all terms used in the questionnaire were explained to the respondents. Consent was taken and confidentiality maintained. The sample size was 116 selected by simple random methods from two different urban settings of Pune city. Structured questionnaire was prepared and data was collected. Face to face interview was taken using pre-validated questionnaire which includes open and close ended questions. In this study the researcher evaluate the awareness and adaptive practices regarding global warming and climate change according to the criteria. Data collection was done according to the objectives of the study. The data was analyzed using statistical software. The pilot study was conducted in the 1st and 2nd week of February on 16 samples from urban population in Pune city, to assess the feasibility of the study and to decide the plan for data analysis. The data was collected through structured questionnaire.

RESULTS

Total 116 respondents were interviewed using semi structured questionnaire. Maximum number of respondents were females 91 (78.4%), 39 (33.3%) samples were 25-30 years of age group, 34(30%) samples were from 31-35 years. Most of the samples were studied graduate level 46(40%). Majority of the samples were occupied in the job 50(43.3%). Majority of the samples belongs to nuclear family 70(60%). The most common source of information about climate change is television (68%) followed by radio and newspaper

Mean awareness level regarding climate change and global warming was found 17.38 (57.94%) and mean adaptive practice score was 8.6 (53.89%). About 93(80%) respondents responded that climate is changing. Out of 116, 64(74%) respondents still using bio-mass as domestic fuel. Only 60 (69%) respondents were aware of non-polluting CNG vehicles.

Majority of the respondents 75 (64.66%) opined that cities are expanding. There is large number of vehicles on roads in addition construction industry is expanding in the cities. This is big reason for climate change.

Table No. 1. Demographic description of the samples (N=116)

DEMOGRAPHIC VARIABLE	FREQUENCY (%)	DEMOGRAPHIC VARIABLE	FREQUENCY (%)
AGE		**INCOME PER MONTH**	
25-30 years	39 (33.33%)	<5000	15 (13.34%)
31-35 years	34 (30%)	6000-15000	50 (43.33%)
36-40 years	29 (25%)	16000-25000	36 (31.66%)
41-45 years	13 (11.67%)	>250000	13 (11.67%)
SEX		**TYPE OF HOUSE**	
Male	25 (21.67%)	Flat	71 (61.66%)
Female	91 (78.4%)	Chawl	10 (8.34%)
EDUCATION		Single kuccha house	35 (30%)
Secondary	25 (21.67%)	**TYPE OF FAMILY**	
Higher secondary	27 (23.33%)	Joint	25 (21.66%)
Graduate	46 (40%)	Nuclear	70 (60%)
Post graduate	17 (15%)	Separate	21 (18.34%)
OCCUPATION		**WASTE DISPOSAL**	
House wife	50 (43.33%)	burning	17 (15%)

Service	50 (43.33%)	Open air	23 (20%)
Business	15 (13.34%)	dumping	52 (45%)
Labor	0 (0%)	others	23 (20%)
NUMBER OF FAMILY MEMBERS		**WATER FACILITY**	
<2members	4 (3.33%)	Everyday	60 (51.66%)
2-4 members	75 (65%)	Alternate day	56 (48.34%)
5-7 members	33 (28.37%)	**ELECTRICITY**	
		Available	112 (96.67%)
		unavailable	4 (3.33%)

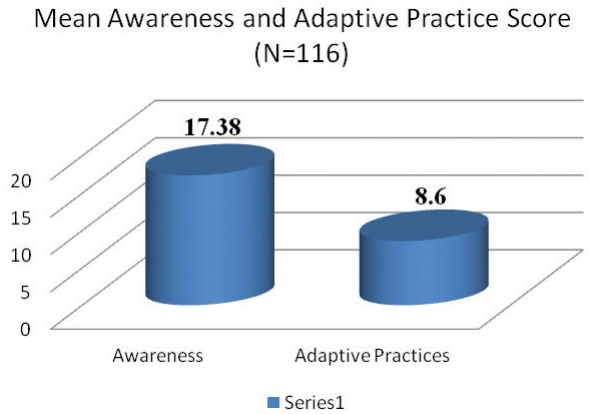


Fig. 1: Mean awareness and adaptive practices

Fig 1, shows that mean awareness score and percentage of urban population regarding global warming and climate change is 17.38 (57.94%) and the mean adaptive practice score and percentage is 8.6 (53.69%).

Table 2: Mean awareness score as per demographic variables

DEMOGRAPHIC VARIABLE	MEAN	%
25-30 years	16.95	59.47
31-35 years	18.55	61.85
36-40 years	16.40	54.66
41-45 years	17.14	44.44
Male	19	63.33
Female	15.91	51.94
Secondary	14.61	43.71
Higher secondary	13.14	48.80
Graduate	18.70	62.36
Post graduate	19.88	66.29
House wife	15	50
Service	18.65	62.17
Business	20.87	69.58
<5000	16.87	55
6000-15000	16.65	55.51
16000-25000	18.36	61.22
>250000	18	62.33

Table -3 reveals that male city residents have more knowledge i.e. 63.33% compare to female i.e. 51.94%. the post graduate people have more knowledge i.e. 66.29% followed by graduate with 62.39%, higher secondary with 43.71%, awareness level of housewife found very less i.e. 50%.

Adaptive practices of peoples regarding global warming and climate change

Variables	Yes	No
Have you contributed to tree plantation drive during last one year	61(53%)	55(47%)
I preferably utilise public transport for daily commuting	79(68%)	37(32%)
I avoid use of plastics in daily routine activities	79(68%)	37(32%)
Solar energy reduces impact of climate change	37(32%)	79(68%)
Industrial air pollution is major contributing factor for climate change	110(95%)	6(5%)
Municipal corporation is strategic organization working to reduce climatic variability	27(23%)	89(77%)
Communicable diseases rising due to climate change	89(77%)	27(23%)
I use water economically	49(42%)	67(58%)
Economical use of light, fan, AC is important to reduce Green House Gases	23(20%)	93(80%)
I believe in paperless work	112(97%)	4(3%)
Burning of garbage is dangerous to environment	73(63%)	43(37%)
Low rain fall is indication of climate change	32(28%)	84(72%)
Sea level rise and subsequent flooding are future anticipated disasters	40 (30%)	76(70%)
CNG vehicles are non polluting	60(69%)	56(31%)

The above table shows that adaptive practices of the people are very poor. Researcher asked question regarding plantation of trees only 61(53%) people gave favorable reply. Only 68% uses public transport for daily commuting 68% people not using plastics and know about harmful effect of plastics. 23% people rely on local government to tackle the issue. 97% people believe in paperless work.

DISCUSSION

This study conducted in the urban setting of the Pune city. Mean age of respondents was 31 years. Maximum respondents are female (78.4%) almost 46% of respondents are graduate, 60% people are from nuclear family, out of 116 respondents 87 (75%) of them responded that they heard about climate change and they further added that climate is changing . Majority of the respondents (61%) are unaware of green house gases, global warming, ozone depletion and consequences of climate change. Maximum respondents obtained the information regarding climate change through television (78%) followed by radio and newspapers. This result is lower than a study done on awareness of climate change in urban area of Gondar city of Ethiopia (82.25%)[9].

In table -2 graduates of Pune city have higher level of awareness than non graduates. Urban residents, better educated likely to be more aware of climate change. Only 32% respondents understood the importance of solar energy and further said use of solar energy can reduce the impact of climate change.

Mean awareness score and percentage of urban population regarding global warming and climate change is 17.38 (57.94). In the present cross sectional study 92 (80%) responded that climate is changing. Only 60 (69%) respondents are aware about use of CNG in the vehicles reduces air pollution substantially. The above findings are supported by study conducted by Pandve et al conducted study in Urban area that 92% urban population aware about climate change[3]. Although the awareness of the climate change is good but they are unaware of the future consequences. It was also observed that graduate class of people of Pune city do not have clear idea about green house gases and ozone layer depletion[3].

In the present study male have 63.33% and female have 51.94 % awareness score which indicates that male have more awareness regarding climate change than females. A study conducted by Pandey found that there was no gender difference in the knowledge level among male and female[10].

Recycling method, use of solar energy, CNG vehicles still dream for the majority of the people. IPCC also finds that green house gases are directly responsible for climate change[5]. From the 116 respondents 53% answered that they are positively contributed to plantation of the tree whereas only 32% aware about solar energy is cheapest and most energy efficient source. According to study conducted by Jain Anjali at Madhya Pradesh, 80% of urban peoples are ready to take effective action such as economical usage of automobiles, fan, air conditioners etc[11].

There is positive correlation between awareness level and adaptive practices (r= 0.678).

This study is supported by the study conducted by Moges and Daniel 2014. They found that gender, age and educational level and awareness level were not associated with adaptation practices of city of Gondar Administration Offices[9].

CONCLUSION

There was lack of awareness among urban residents of Pune city regarding global warming and climate change. Media plays very important role in dissemination information. Simple measures like avoiding bio-mass as fuel, use of public transport for travelling, plantation of tree and increase the green belt is not practiced by urban public. Simple clear messages, repeated often, by a variety of trusted public health voices within a wider policy environment that supports greenhouse gas reduction behavior and healthy lifestyles. The government of India launched the *'swacha bharat abhiyan'* is very motivating and proactive step in mitigating the issues related to climate change. The people will see the result of this very innovative campaign in forthcoming years.

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Source of funding: Self

Conflict of Interest: Nil

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A Survey of Doctors' Awareness of the Role of Communication Skills in Developing a Caring Doctor-Patient Relationship

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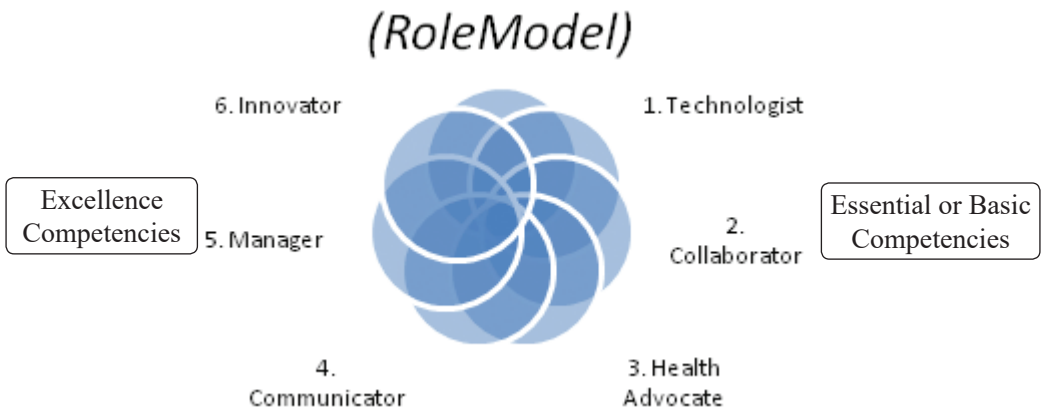
ABSTRACT

Using a questionnaire and an interview schedule, a survey about the doctors' awareness of the role of communication skills in developing a caring relationship was conducted with a sample of 75 Senior and Very Senior doctors. Questionnaires were circulated to all the 75 while additional in-depth interviews were conducted with 10 Very Senior doctors. A main question, followed by eight sub-questions, was posited and answers sought to validate the hypotheses formed. It was revealed that there existed general awareness about the positive role played by good communication in developing a caring relationship. However, there was scant understanding of the skills required to communication efficiently. Communication was largely associated with demagogy. Doctors were also not aware of the nature of communication studies as a serious discipline and its potential to provide a range of skills to communicate efficiently. Since there was little understanding of the skills involved, it was recommended that programmes of varying durations aimed both at medical students and practising doctors be developed. A list of sample topics that could form a curriculum for such programmes is suggested.

Keywords: *Communication skills, Competency modelling, Doctor-patient communication, Medical communication, Soft skills*

INTRODUCTION

The need to pay special attention to communication skills is caused by two important trends. One is the influence of quality assurance procedures with the patient as the central figure and the other one the emergence of a new medical professional. To operate successfully in the contemporary competitive environment, the new professional needs to possess not only technical competence in his or her chosen specialization but also some additional competencies. The author's own research1 proposed a new competency model of the modern-day medical professional. The model distinguished two kinds of competencies. One was called the essential or basic competencies and the other one, excellence competencies. The ideal personality, who possessed both the essential and excellence competencies, was posited as the Role Model and had six areas of competence, as shown in the following diagram:



Technologist: The technologist is a qualified professional. This is an obligatory level and indicates that the person has undergone formal education and training in the chosen field.

Collaborator: The Collaborator role requires the professional to interact cooperatively with a variety of people during the course of performing his/her professional duties.

Health Advocate: This is the social role. The practitioner is expected to reach out to the public at large to give health related educative messages.

Communicator: With this we now move into the exceptional category. An exceptional practitioner is distinguished from an average doctor through his or her ability to communicate efficiently with patients, their relatives, other professionals, members of the medical team and the society at large.

Manager: A higher level practitioner is required to manage people and resources.

Innovator: This is the highest level where a practitioner engages in the development of new research-based solutions to old problems.

Hierarchically, the six competencies are organized in a pyramidal pattern. The basic or essential competencies start at the bottom, at levels 1, 2 and 3. Those appearing at levels 4, 5 and 6 are called excellence competencies

A mature practitioner, possessing skills at all the six levels, is called the *role model.*

Since communication skills figure as one of the higher order competencies, it was felt necessary to investigate the extent to which existing medical practitioners were aware of the potential of communication skills to develop a caring relationship with patients. The necessity of good communication with patients is supported by several research studies. Important research[2,3,4,5], shows that good communication plays an important role in the healing of the patient. It has a proven therapeutic impact. Actually, this finding is of good heritage, the hallowed Hippocratic Oath emphasizes the importance of sympathetic communication between the doctor and the patient: *I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug*[6].

The importance of good communication skills on the part of doctors is recognized by the Medical Council of India.(Medical Council of India, 2011)which lists communication skills as a part of the essential competencies for qualified doctors[7].

METHODOLOGY

The study posited a main question and then broke it up into a number of sub-questions, proposing a hypothesis for each of them.

The main question: The main question was: *To what extent are medical practitioners aware of the role of communication skills in developing caring relationship with patients?*

The hypothesis was that a majority of present-day Indian doctors were not aware either of the importance of communication or about the knowledge and skills required to develop a caring relationship with patients.

The sub-questions and hypotheses: Emerging from the main question, were the following eight sub-questions:

1. What is the justification for effective medical communication between the doctor and the patient?
   - **Hypothesis:** Effective medical communication is essential for a trusting relationship between the doctor and the patient and such positive relationship can have a therapeutic effect.
2. Can a central or main feature be identified in contemporary approaches to doctor-patient relationship and communication?
   - **Hypothesis:** Although there are different approaches to doctor-patient relationship, effective medical communication has an identifiable central issue or focus.
3. Are doctors aware of the fact that there is a well=stablished discipline of communication studies?
   - **Hypothesis:** The doctors are not aware that communication studies is a well-established discipline.
4. Are doctors aware that the discipline of communication studies proposes certain models of the communication process

- **Hypothesis:** Doctors are not aware that there are well-recognized models of the communication process.

5. Are the doctors aware that knowledge of the communication models can help them to communicate effectively?
   - **Hypothesis:** Since most doctors are unlikely to be aware of the existence of communication models, they do not know that s knowledge of communication models could help them to communicate effectively.
6. What are the communication barriers a medical practitioner is likely to face while communicating with patients, their relatives and colleagues?
   - **Hypothesis:** Doctors would be aware of some of difficulties, rather than the barriers, in communicating with patients and their relatives.
7. Are the doctors overtly aware of the sensitive situations in which a medical practitioner is expected to communicate effectively?
   - **Hypothesis:** Doctors would be aware of some of the sensitive situations a doctor is likely to face during the course of performing professional duties.
8. What are the typical writing tasks a medical practitioner is required to perform during the course of his/her normal duties?
   - **Hypothesis:** Doctors would be aware of the routine and research tasks a medical professional is required to perform.

Data collection strategy: The data collection strategy consisted of both primary and secondary research techniques.

- Use of a survey questionnaire. A survey questionnaire administered to a group of 75 doctors. These included 65 Senior Doctors (i.e. those who had an experience of 10 years and above).and 10 Very Senior Doctors (Those with an experience of 25 years or more) Questionnaires were sent to these 75 doctors, of whom 49- i.e. about 66% - returned the questionnaires. All the Very Senior Doctors returned the questionnaires,
- Interview Schedule: Additionally, face-to-face interviews were conducted with 10 Very Senior Doctors who had returned the questionnaire. The aim was to encourage doctors to provide an informed feedback rather than an intuitive feedback.
- Informal interviews with students at a medical teaching institute. The author was teaching these students a course in communication skills. The aim was to find out the extent to which newcomers to the profession were aware of the importance of communication to their practice, and eventually, to their careers.
- Desk Research: Analysis of select research literature on medical communication. References include a list of the works referred to.

RESULTS AND DISCUSSION

The sub-questions and their hypotheses were tested using the methodology described above. The chief outcomes were as follows

To what extent are medical practitioners aware of the role of communication skills in developing caring relationship with patients?

The hypothesis was not supported by the findings. All the 49 respondents agreed that good communication was essential to develop a caring relationship with patients. However, only about 20% were aware that systematic research existed to support this insight. This was confirmed during the personal interviews with 10 Very Senior Doctors selected from the original 49. These doctors expressed satisfaction that their intuitive insight about the role of efficient communication had been supported by serious research and requested references to such research. However, none of the doctors was clear about the specific skills required to communicate effectively. Most considered the ability to communicate effectively to be a gift and to them good communication was synonymous with demagogy rather than a skill relevant to the medical profession.

In an educational programme about communication skills for doctors, it would be necessary to point out that several modern studies have confirmed the fact that good communication between the doctor and the patient has therapeutic effect. Research by Hall & Rand (1981) concludes that medicine is an art whose magic

and creative ability have long been recognized as residing in the interpersonal aspects of patient-physician relationship[8].Stewart (1995)asserts that Effective doctor-patient interaction and communication is central to doctor and patient satisfaction, to the clinical competence of doctors, and to the health outcomes of their patients[4]. Similar conclusions are reached at by several studies[2,3,5]. In addition, the Medical Council of India (2011) has very clearly stated the need for effective communication skills in its Vision 2015 document[7].

It is interesting to note that young medical students for whom the author was conducting a course in communication skills were not aware of the therapeutic role of communication skills. To them such a course was just an additional burden.

Can a central or main feature be identified in contemporary approaches to doctor-patient relationship and communication?

One of the questions deliberately asked the doctors if they agreed that the patient had to be treated as a client/ customer. Only 5 of the 49 responded agreed.

However, once the true implications of the term *client/customer* were explained during the personal interviews, all Very Senior Doctors agreed that the patient had to be treated as a client and was entitled to good service.

One of the major changes in the practice of medicine in the last few decades is the central role accorded to the patient. There was a time when the medical profession operated in what is sometimes called the paternalistic mode. In the paternalistic mode, the doctor was the most important entity and the patient only a secondary one. Now the universally accepted ideal mode is the patient-centred mode, in which the patient is the primary entity. The patient is the central issue or the central theme. The use of the term *ideal mode* is deliberate. A great deal of educational activity would be necessary to bring it home to both the new and experience doctors that they need to nurture and observe a service culture.

Some select major new trends in the development of a modern paradigm of patient-doctor relationship are as follows: (1) The relationship-centred approach (2) The patient-centred approach (3) The cultural competence approach (4) The person-centred approach, (5) New communication technologies and doctor-patient communication

All the above representations confirm the hypothesis that although there are different approaches to doctor-patient relationship, effective medical practice has an identifiable central issue or focus. This central issue or focus is the patient.

Are doctors aware of the fact that there is a well-established discipline of communication studies?

Out of the 49 respondents only 10 were aware of the fact that the discipline of communication studies was a well-established field of studies with a solid research base. In educational programmes, this fact should be emphasized in order to motivate doctors to master communication skills

Are doctors aware that the discipline of communication studies proposes certain models of the communication process?

As pointed out above, most doctors were not aware of the nature of communication studies as a well-established discipline and, therefore, that there were clearly identified models of the communication process. A special session had to be held with all the doctors at the request of the 10 Very Senior Doctors to explain the systematic nature of communication studies and the existence of well-defined communication models. The session included not only the original 49 doctors but an additional 21 doctors whom some of the 49 had brought with them. At these sessions, doctors were briefed about the following models of the communication process: the Linear Model, the Schramm Model, the Interactive Model, the Transactional Model, and the LEARN Model. The researcher believes that sophisticated professionals like medical practitioners tend to develop greater trust in an activity if they know of the existence of solid theory behind it.

Are the doctors aware that knowledge of the communication models will help them to communicate effectively?

The doctors were not aware of the existence of communication models, It followed that they were unable to see any role for the models in communicating effectively. In fact the general belief was that the ability to communicate was a gift, rather than something learnt.

What are the communication barriers a medical practitioner is likely to face while communicating with patients, their relatives and colleagues?

The questionnaire listed the following eight barriers in medical communication identified in a number of studies[9,10,11]:

(1) Environmental Barriers (Quality of the consulting rooms, level of comfort, lack of air conditioning etc), (2)Doctor's behaviour (brusqueness, body language, pre-occupied look etc.), (3) Inability of the doctor to provide emotional support (4) Mismatch of doctor and patient personalities and resultant styles of behaviour (an introverted doctor with an extroverted patient etc.), (5) Psychotic disorders of patients (Patients may be depressed or anxious and may behave erratically during the doctor-patient interaction),(6) Conflicted physician roles (Varying opinions given on the patient's condition by different doctors, especially when second or third opinions are sought),(7) Economic considerations (Fear of high costs may affect the patient's behaviour during the interview),(8) Stigmatizing barriers (A woman with an unwanted pregnancy, a patient with a disease like leprosy or TB. Such conditions carry a social stigma).

Questionnaire responses revealed that on an average, respondents were aware of about 3 of the barriers. The only two barriers common to all were the ones involving economic consideration and the stigmatizing barrier. The 10 Very Senior Doctors appreciated the systematic classification and felt that their clear understanding would help doctors to appreciate the difficulties of the patients and obtain more reliable information from them during medical interviews. They observed that making patients feel comfortable and putting them at ease were crucial in overcoming the barriers.

Are the doctors overtly aware of the sensitive situations in which a medical practitioner is expected to communicate effectively?

An informal initial survey was conducted, which resulted in the identification of the following 13 sensitive situations in which a typical doctor was expected to communicate:

(1) Reporting a serious diagnosis, (2) The high cost of a treatment (3) Lack of local availability of the appropriate treatment,(4)The need to perform a complicated procedure, (5) The inability of a man or a woman to have children,(6) The need to undergo an organ transplant and the likely difficulties in obtaining an organ.(7)The need to use an untried procedure and its unintended effects,(8) The failure of a procedure,(9) Reporting the permanent loss of an organ.(10) Reporting the need to terminate a pregnancy,(11) A terminal / incurable disease condition,(12) Reporting patient's death to relatives,(13) Reporting a still born infant All the 49 respondents showed their familiarity with such situations and responded positively to the question asking them whether special training was necessary to communicate in such situations. Very Senior Doctors recommended the creation of a special post in hospitals, preferably a psychiatrist, to support doctors to communicate in such situations.

What are the typical writing tasks a medical practitioner is required to perform during the course of his/her normal duties?

An article in the Singapore Medical Journal[12] identifies the following types of professional writing tasks medical practitioners perform:

Original article: Such an article provides new information based on original research.

Case report: Description of a single case, Technical note: It is also called *Technical Innovation.* It is a description of a specific technique or procedure, modification of an existing technique or new equipment applicable to a branch of medicine. Journals usually recommend a format for technical notes.

Pictorial essay: This is usually a teaching article,

Review: A review is a detailed analysis of recent developments on a specific health topic,

Commentary: This is a short article that describes the author's personal experience of a specific topic,

Editorial: Editorials take various forms.

Letters to the Editor: As pointed out earlier, these consist of short subjective responses to various issues of medical import.

All the 49 respondents to the questionnaire were aware of the tasks mentioned in the list but felt that in India most doctors would be required to perform mainly two types of tasks: routine tasks (write-up of the patient history and physical examination, progress note and discharge summary)and research tasks. Certain tasks like editorials, letters to the editors on medical

matters, pictorial essays were of marginal relevance and restricted to the inclinations of individual doctors rather than common to all. Very Senior Doctors concurred with this perception. However, they pointed out that young doctors would need training in doing precise medical writing and such training must be an obligatory part of the curriculum. With the increase in patients taking legal recourse to satisfy their grievances, such writing needed to be done with precision and great care since it could well be used as evidence.

CONCLUSIONS

The research provided a number of insights which can be of use in the development of pre-experience and lifelong training and educational activities of medical practitioners. A summary of these insights is as follows:

1. The role of the patient as a client or a customer was not understood, let alone appreciated. Unless this understanding dawns on the mass of the medical community, any effort to bring home the importance of efficient communication will largely happen in a vacuum. That a caring approach is necessary and assists in healing a condition cannot be appreciated unless the medical community understands that they are the service providers and it is their duty to provide such service in a professional manner. The first feature of a professional approach will be to ensure that the doctor actually cares for the patient. Very Senior Doctors in the sample very strongly supported this approach.
2. While all the respondents were aware of the importance of efficient communication, their opinions were based entirely on personal intuitions.
3. It is necessary, therefore, to demonstrate that the positive role good communication plays in developing a caring relationship with patients is supported by solid research.
4. In general, there was little understanding of the fact that communication studies is a well-established discipline, To most of the respondents, communication simply meant speaking and listening. The tendency was largely to associate communication skills, at best, with demagogy. That writing and reading are also acts of communication was not generally appreciated.
5. The initiative expressed by the Medical Council of India in its Vision 2015 documents needs to be supported by programmes based on a well-developed curriculum to teach communication skills. The suggested content of such a curriculum could be as follows:
   a. The importance of communicating efficiently with your patients.
   b. Communication styles and the need to develop one's own communication style.
   c. Models of the communication process and their relevance to the practice of efficient communication between doctors and patients.
   d. Importance of listening to the patient
   e. How to conduct an effective medical interview?
   f. Contemporary approaches to doctor-patient relationships and their role in efficient communication.
   g. Communication barriers and strategies for overcoming them
   h. Communicating in sensitive situations
   I. Making effective medical presentations.
   j. Medical writing
   k. Developing a complete communication personality: cognitive, affective, psych-motor and interactional aspects.

It has been proved by serious research that effective communication between the patient and the doctor is as important for patient cure as proper medical procedures. In addition there is a compelling new reason for the medical community to communicate with the patient community. Recent instances of attacks by patients and their relatives on the medical community have highlighted the importance of programmes in communication skills. It is important that such programmes are offered both to newcomers during the course of their formal education as well as to practising doctors as refresher programmes. So far as the formal programmes are concerned, consideration should be given to offering such a programme in their final years rather than during their first year. Professions usually follow the practice of starting with general purpose programmes progressing towards specialization. Communication skills should be considered a component of the specialized stage.

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Shouldn't Competence and Compassion Coexist in Medical Professionals? A Study of Psychological Androgyny in Doctors

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ABSTRACT

Medical care is based on doctor-patient relationship. Paradoxically, in medical practice, detachment is perceived as prerequisite virtue necessary for retaining objectivity for acting act competently. However, are competence and compassion essentially mutually exclusive? Socially prescribed gender behaviors, expected of men and women consider some behaviors as masculine (for e.g. competitiveness) and some as feminine (for e.g. gentleness). On the contrary, psychological androgyny suggests that both masculine and feminine behaviors reside in varying degrees in every human being to be expressed in a manner responsive to situational demands irrespective of the biological gender. This therefore can lead to blend of competence with a compassionate approach. The current study was focused on exploration of psychological androgyny in Indian doctors. Although Jung (1958), suggested that androgyny develops only in the latter half of life, the current study did not find any significant difference in psychological androgyny in scores on Bem sex- role inventory either due to age or experience when 30 young postgraduate resident doctors were compared to 30 older experienced consultants. Findings are discussed in terms of implications for training doctors for better doctor – patient interaction to help blend competence with compassion.

Keywords: *Androgyny, compassion, competence, doctors*

INTRODUCTION

Several studies have clearly shown that doctors and patients have different views on what makes good doctor-patient relationship. These differences influence the quality of interactions between doctors and patients and also impact patient compliance related health outcomes[1, 2, 3]. Medical practice constantly throws up challenges to a doctor's sense of mastery and competence. The rapid advances in knowledge regarding illnesses can be overwhelming, leading to anticipation of the possibility of humiliation and rejection if a doctor feels that he/she is failing to fulfill expectations [4]. Paradoxically, however most complaints by patients about doctors are about problems of 'communication' and not of 'clinical competence'.

Seaburn et al. used recordings and transcripts of consultation visits made by unannounced simulated patients to learn what doctors did when confronted by patients with multiple ambiguous symptoms [5]. They observed two general patterns. In the first pattern, more than half of the doctors offered a diagnosis, often very early in the visit. In addition, they did not acknowledge any sense of ambiguity to their patients since they felt that it would be an admission of incompetence. Seaburn *et al.* noted, that this first strategy appeared to be based on an expectation that physicians should always be in control [5]. In the second pattern, the other doctors in the study showed a different approach. They shared their uncertainty with their patients, presenting a range of diagnostic possibilities, late in the visit and proposed a plan for further investigations. They also acknowledged psychosocial issues and explored patients' concerns. They made frequent expressions of praise, empathy, and encouragement. These doctors were considered to be showing responses, which are congruent with theory of 'Androgyny'.

What is Androgyny?

According to Carl Jung, (1958) a Swiss psychiatrist, initially individuals focus on developing biologically congruent psychological traits. And, it is only as individuals grow older that they choose from the opposites of gender personality to establish a balanced sense of self [6]. Every person possesses a feminine

(anima) and a masculine (animus) component in their psyche. Anima contains within itself characteristics that are ascribed to the feminine, such as the ability to emotionally relate to others, creativity, intuition, receptivity, nurturing, fragility and emotionality. These characteristics are attributed more to women than men. Characteristics of the animus, on the other hand, are traditionally seen as masculine, such as logic, action orientation, decisiveness, courage, independence, competitiveness, assertiveness and leadership attributed more to men than women. Integration of the anima and animus is termed 'Androgyny'[6].

Sex roles are sets of attributes, namely attitudes, abilities, interests, and behaviors that are considered appropriate for the biological gender. However, since gender is not something that we inherently are, but something that we express in social interactions, Constantinople (1973), developed a theoretical framework which conceptualized male and female sex-roles as independent constructs rather than opposite ends of a one-dimensional continuum [7]. This led, to a new non-traditional view of gender identity where, gender identity is socially constructed rather than biologically determined. Bem (1974) built on Constantinople's conceptualization of masculinity and femininity as independent dimensions of sex role orientation by constructing an instrument known as BSRI (Bem's Sex Role Inventory), which has a masculine and feminine scale [8]. She suggested that masculinity and feminity were psychologically independent traits and people could score high on both. People scoring high on only one of the scales would actually lack the ability to show adaptive behavior while people scoring high on both scales would be psychologically androgynous. These psychologically androgynous individuals would be more adaptive to situational requirements in their responses since, they could respond both from their feminine or masculine traits irrespective of their biological gender [8].

Androgyny is not alien to Indian culture. The Aryans began to explore the relation between the male and female probably around 1500 BC in the Rigveda. The Vedas expressed a sensitive and lyrical expression between the two through the fascinating image of Lord Ardhnarishwara a manifestation of supreme divinity or the absolute. Represented in an androgynous form, it symbolizes harmony between masculine and feminine characteristics that make up a single human being. Ardhnarishwara conveys a universal reality of philosophical aspect, which can be compared to the psychological consciousness of human being[9].

Why study 'androgyny in doctors?

Doctors have to deal with diseases, disabilities, pain and death. But, there is a boundary beyond which medicine has a very small role. When doctors are forced to go beyond this boundary, they do not gain power or control. Instead they suffer [10]. However, as noted in the Seaburn *et al.* study, the expectation is usually that doctors should always be in control [5]. It's no mystery where this strategy comes from. In the course of formal medical education, the embedded message is that a good doctor should have all the answers. This creates a low tolerance for ambiguity. Not knowing is equated with incompetence [4]. In India, too students are selected for admission to various medical courses based on their scores in entrance exams, which evaluate their intellectual abilities.

However, what patients actually expect is not that doctors would always be in control. Rather, patients expect that their doctors will focus on doctor – patient interaction. This is in agreement with the core premise of relationship-centered care [11]. Psychological androgyny deconstructs an individual's behavior style into two independent domains: instrumentality ("a cognitive emphasis on task completion") and expressiveness ("an awareness and concern for the emotional needs of others"). It reminds us that we needn't choose between control and relationship. Rather, our task is to integrate them. However 'Medicine' is usually seen as a 'masculine' profession requiring rationality, authority, decisiveness, and objectivity with no place for the 'caring listening feminine' component [4]. Hence, it is important to explore if Indian doctors are capable of showing both feminine and masculine behaviour patterns required for caring and curing in the course of doctor - patient interaction. Psychological androgyny suggests the possibility that both masculine and feminine behaviours can reside in varying degrees in every human being irrespective of the biological gender. The individual then expresses these behaviours in a manner responsive to the situation irrespective of the biological gender. This can lead to blending of compassion with competence due to the greater flexibility of the androgynous individual in interpersonal interaction.

The present research: As per Jung (1958), the task of first half of life is to develop one's personality to the best of one's ability so that one can live and function in the

world [6]. However, the development inherently is one-sided because either the masculine (animus) or feminine (anima) is chosen based on biological congruence and emphasized at the expense of the other. However, in later life a call to integrate the opposite energy, the anima or the animus, arises and leads to a move towards wholeness. So, Jung (1958) had suggested that androgyny developed only in the second half of life, i.e. in the middle age[6]. The current study explored the androgyny scores of postgraduate students in medical field and compared these scores with androgyny scores of experienced specialists to observe if there were any significant differences in psychological androgyny with age and experience.

METHOD

Sample and Methodology : This study was conducted at large tertiary hospitals that have postgraduate training facilities in the city of Pune, India. The sample included 30 specialist doctors across specializations and 30 medical postgraduate students doing their residency across various specializations both medical and surgical. All specialists had at least 5 years' experience after relevant post-graduation. The postgraduates in the sample were pursuing post-graduation in the various disciplines after their basic under graduation in MBBS. Both the postgraduate and specialists sample included a variety of both medical and surgical specializations.

Specialists and postgraduate students from various specializations were approached at their place of work and provided preliminary information about the study. After obtaining their informed consent, they were asked to complete Bem's questionnaire, at their convenience and to deposit the completed questionnaires in a sealed envelope, in a collection box placed for this purpose. These sealed envelopes were opened after the collection of data across Pune was completed. This was done in order to retain anonymity and minimize social desirability bias in responding to the questionnaire.

Measures

Bem Sex Role Inventory (BSRI): The Bem Sex role inventory (BSRI) is the most widely used and validated 'Gender Role' measure in publication reporting scale reliability coefficients from 0.75 to 0.9. It consists of a list of sixty attributes and behaviors; twenty of which were verified to be more socially desirable when demonstrated by men, twenty deemed more appropriate for women and twenty of no gender-affiliation. Participants rate the characteristics on a Likert type scale ranging from 1-7 as to how applicable these characteristics are to themselves. Responses are scored using the median cut off method. Individuals scoring ≥ median on both masculine and feminine sub-scales were rated as androgynous. Individuals scoring< median on both these sub scales were rated as undifferentiated. Individuals scoring ≥median on the masculine scale but < median on the feminine scale were rated as masculine and finally individuals scoring ≥ median on the feminine scale but < median in the masculine scale were rated as feminine.

RESULTS

Participants included 30 postgraduate students, (21 males, 9 females) and 30 specialists (8 males, 22 females). The mean age of the postgraduate group sample was 26.76 years (*SD* 2.60). The mean age of the male postgraduates was 26.3 years (*SD* 2.50) and mean age of female postgraduates 27.66 years (*SD* 2.63). The mean age of specialists was 43.33 years (*SD* 5.51). The mean age of the male specialists was 43.38 years (*SD* 5.49) and mean age of female specialists 42.9 years *(SD* 4.48) .The mean number of years of experience of the specialists was 16.2 (*SD* 5.97).

Out of the 30 postgraduate participants, 40 % (n = 12; 10 males, 2 females) were androgynous while 60% (n=18; 11 males, 7 females) postgraduate participants scored in the non-androgynous range. In the experienced specialists sample, 50% doctors (n=15; 3 males, 12 females) were androgynous while rest 50% (n=15; 5 males, 10 females) scored in the non-androgynous range. Independent T test comparing means of Bem masculine *(p* = 0.26) and feminine scale scores (*p* = .35) of postgraduates and specialists did not show any significant difference between the two groups. In spite of the expectation that androgyny evolves with age[6], chi-square analysis to examine relation of androgyny in specialists and postgraduate students did not show any significant difference in the percentage of androgynous participants ($\chi 2$ (1, N = 60) =. 6060, p = .74) in the two groups.

DISCUSSION

Modernity comes with a shift from social integration through family and religion to integration through membership of interdependent occupational groups and educational meritocracy. Hence, since traditional identities are weakening, this is accompanied by changes in work and culture, especially those associated with established masculine and feminine roles [12]. Therefore, the anticipated graded progression of traditional gender specific role behavior, which is expected to evolve initially, followed by shift to androgyny in later life may not be applicable in the modern context. Moreover, pervasive influence of broad forces, such as peers, media and current popular culture, create common value systems in cohorts growing up at a particular time that distinguish them from people who grow up at different times [13]. This could explain androgyny already obvious in 40% postgraduates as compared to androgyny seen in only 50% of the specialist sample that grew up with different generational values, identities and beliefs. However, what is more worrying in the current context is that only 50% of the specialist sample was androgynous. So, are specialists more comfortable with traditional gender congruent male - masculine /female - feminine roles in spite of the changed cultural and social contexts with attendant differences in patients' expectations from their doctors?

Of the overall 15 specialists who were rated as androgynous, 12 were women. Twenge and Campbell (2008) in their study on generational differences in psychological traits found that not only are more women working, but also more recent generations of women score higher on traits like assertiveness that enhances performance at the workplace [13]. They found that by the 1990s, there was no longer a sex difference among college students on the measure of stereotypically masculine traits. Hence, it is possible that with age, the women in the specialists' sample have steadily developed their masculine traits to balance their inherent feminine traits i.e. movement towards androgyny. This is also consistent with Jung's (1958) theory of integration of the rejected animus as we grow [6]. Since increase in masculinity traits in women has greater social approval than expression of feminine traits in men [14], masculine men of previous generation will resist expressing feminine traits. In the current study only 3 of the 8 males in the experienced specialists group showed androgynous behavioral orientation in contrast to 12 men with androgynous traits out of the 21 male participants in the postgraduate group.

Since sex-role development evolves through one's lifetime [15], the traditional tightly compartmentalized masculine - feminine sex role conception, as the model of mature sex role identity is not tenable. This traditional paradigm is very limiting, as we all have to adapt to a full range of life experiences. Although there is a developmental phase of traditional masculinity-femininity development, peaking in early adolescence, its role in the life cycle is limited. Therefore, as emphasized by Pleck (1981) the great risk in sex role development is not that persons may fail to reach this traditional masculinity-femininity, but that they may never leave it [15]. Hence, various gender behavior sensitization inputs should be inculcated as a part of medical curriculum to help doctors to evolve into an androgynous sex-role orientation, if they have already not developed it.

Engel (1980), originator of bio-psychosocial approach towards medicine, believed that to understand and respond adequately to patients' suffering, and, to give them a sense of being understood, clinicians must attend simultaneously to the biological competence component and psychosocial compassion dimensions of illness [16]. Hence, androgynous behavioral approach towards patients will encourage a situation - responsive balance between socially perceived masculine component of competence and feminine component of compassion and care. This will help address the various doctor-patient interaction and communication issues facing health care sector. This therefore will also help address some aspects of violence towards doctors.

The Medical Council of India has released a vision document (2015)[17] where they aim to develop clinicians, who understand and provide preventive, curative, palliative and holistic care with compassion. The comfort level of postgraduates with androgynous behavior (40% of postgraduate sample) is very encouraging because these resident doctors are usually the first interface between Indian health care system and patients in the medical college hospital set up. This will help in training postgraduates in the 'art of caring' along with the 'science of curing'. Future research should look at reasons for preference for traditional gender roles in experienced specialists and its implication on doctor – patient interaction. This study was conducted on a limited sample of 60 doctors in one city of India, while India is

a country of various cultures across different parts of the country. Hence it is important to repeat this study across India on a bigger sample to explore variables, which influence development of androgyny.

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Systematic Review of RCT's in mHealth interventions focusing on Maternal and Child Health

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ABSTRACT

The widespread availability of mobile phones makes them a prospective tool for health related interventions. MHealth interventions have been studied in many research areas like HIV, Cancer, Smoking Cessation, Diabetic care etc. But extensive research has been limited to general areas. The aim of this review is to examine the current evidence on RCT's of mHealth interventions in the field of Maternal and Child Health.

Keywords: *Randomised Control Trial (RCT), Child health, mHealth Intervention, Maternal, Awareness*

INTRODUCTION

According to WHO, *"Mobile Health (mHealth) is an area of electronic health (eHealth) and it is the provision of health services and information via mobile technologies such as mobile phones and Personal Digital Assistants (PDAs)"*. The integration of mobile telecommunication technology into health is called as mobile health[1]

Globally, SMS is the most widely used form of communication wherein a message is sent from a sender to receiver in text form. The messages can also be sent in bulk from computer to person or vice versa. The proponents of SMS technology advocate that SMS is a simple, direct and cost effective medium of communication[2] Of late recorded voice over calls is also used to deliver health messages to vulnerable population. It has been credited as a useful public health tool, particularly in underserved settings.

Randomized Controlled Trial i.e RCT is a study in which people are allocated at random (by chance alone) to receive one of several clinical interventions. One of these interventions is the standard of comparison or control. The control may be a standard practice, a placebo ("sugar pill"), or no intervention at all. Someone who takes part in a randomized controlled trial (RCT) is called a participant or subject. RCTs seek to measure and compare the outcomes after the participants receive the interventions. Because the outcomes are measured, RCTs are quantitative studies.

In sum, RCTs are quantitative, comparative, controlled experiments in which investigators study two or more interventions in a series of individuals who receive them in random order. The RCT is one of the simplest and most powerful tools in clinical research.

Search Methods: Online databases like Pubmed, Popline, Cochrane library, peer reviewed journals, online clinical registry and gray literature were searched for relevant studies. The search included all the studies done till February 2017. The study was started in November 2016. After filtering the articles from the exclusion criteria, eleven studies were narrowed down which met the inclusion criteria. They were thoroughly read and examined to understand the scope and reach of MHealth.

Inclusion Criteria: The criteria for inclusion were that all the studies should have used mobile phone as a tool for Health Communication. It should have included Randomized Controlled Trial in its study. There were no geographical boundaries for this study. But only studies available in English were included. The subjects/ participants of the RCT should be women who were pregnant/young mothers at the time of study. One study was about women who aborted their children. So women who were pregnant but lost their child were also included in the study.

Data Collection and Analysis: The data was collected by the author since November 2016. The first stage of data collection was from online databases like Pubmed and Popline. Then the author reviewed online peer reviewed

journals to find relevant studies. Since there were very limited studies with RCT in its design including gray literature was essential. So academia and researchgate were searched for similar studies. The reference list in all the published articles were thoroughly studied by their title and when necessary with abstracts as well. In addition to all these things, the author constantly searched general Google search engine for studies which were not widely published.

The keywords used were 'mHealth, RCT, Pregnancy, Neonatal, Maternal, Child Health, mobile, text messages, and voice over calls etc'.

After collecting all the articles, articles which were repeated were removed. The author made it a point to include only completed studies. There were few studies which were still in the analysis stage, but those studies weren't included because they were yet to prove their study. Similarly, only RCT's with relevant field work were included in the study and studies explaining only the protocol for future trials were excluded.

The available data was then analyzed for a general pattern in mHealth interventions, their success failure, implications etc. The data was scrutinized to see the popular areas of research in Maternal and Child Health which uses MHealth as a Health Communication tool. The location of all the studies were also identified. Then the gaps in the research were analyzed.

Important Results

Location: Since MHealth is an amazing tool to serve the Low and Middle Income Countries, due to their lack of well developed health setup, nine out of the twelve studies were conducted in Low and Middle Income Countries with a majority in African nations.

Areas where MHealth is used as a tool for Health Communication

1. **MHealth intervention for adherence to medication:** A study in Mumbai was done by ARMMAN, a NGO in partnership with babycenter, India [3]. This project focused on adherence to medication. In their baseline survey they had found out that around 70% pregnant women fell off the iron tablets course given to them by the Government Hospital for free of cost, citing forgetfulness (54%), general dislike of pills (11%) and constipation (7%). So automated voice calls were sent to pregnant women for three days in a week, as a reminder for adherence to take iron supplements regularly along with some basic health information. RCT was conducted among 130 women for a period of three months. The difference between the treatment group and control group was 0.43grams per decilitre on average. Since, this project met with unforeseen challenges in retrieving for women with follow up visits, it lacks statistical power. But it assures that the automated voice calls can be beneficial for pregnant women.

2. **MHealth intervention to create awareness about women's health, contraceptive methods and child's health:** ARMMAN conducted a RCT in 250 villages of Rural Maharashtra. The districts covered were Osmanabad, Sholapur and Washim. The study was conducted from January 2013 to December 2015. In addition to voice calls the intervention included eight animation videos which were played by the health worker to the family members of the pregnant or new mother.

a. The result showed an increase of 36% for women who knew the importance of consuming iron and folic acid tablets.

b. There was a 46.95% increase on the women knowing at least three types of family planning methods.

In the infant scale,

i. there was an increase by 33.79% in the oral intake of ORS during a Diarrhea episode.

ii. Adherence to exclusive breast feeding increased by 43.4%.

iii. 13.5% increase in the number of infants who tripled their birth weight at the end of one year.

iv. 89.32% of the enrolled women were satisfied with the content.

Similarly, in Cambodia[4] the effect of mobile phone based intervention on post abortion contraception was studied with a RCT design. The Mobile Technology for Improved Family Planning (MOTIF) study involved women who sought safe methods to abort. 249 women were placed in a Mobile phone based intervention. There were six automated messages, interactive voice messages with counselor phone support as

and when required. 251 women were in a control group receiving standard care. It was observed that there was an effective contraceptive usage after four and twelve months of abortion – 64% vs 46% of the controlled group. Adding a mobile phone based intervention in the abortion care services had brought in significant changes in Cambodia.

In Kenya[5] family planning information was sent via text messages. Beneficiaries of m4RH, a mHealth service in Kenya were randomly selected for this trial. They were assigned with full access or limited access to the content. The content was then followed by questions sent via messages. Even though the response rate for the questions seem to be very low, the authors had concluded that the knowledge about contraception in the intervention group was 14% better than the controlled group. The authors had also observed that mHealth messages can play a vital role in increasing the knowledge but they may insufficient to cause behavior change.

In Kenya, in a RCT named as Mobile WaCH [6] SMS messages were sent to pregnant women to invite them to have their delivery in a hospital. Reminder messages were sent for their iron intake. Two way SMS was facilitated where in the patients can ask their queries. This study reported a 61% interest among the subjects.

3. **MHealth intervention to aid community workers in data collection and counseling:** In Uttar Pradesh, a project called as MSakhi was introduced to Accredited Social Health Activists (ASHA's). MSakhi is an audio/video based mobile app that provides support to ASHA's in routine activities in Maternal and Child Health Care. The content was based on National Rural Health Mission's manual and Home based New Born Care, Guidelines and formats. ASHA's used it for two purposes. First for their self education and second as a job aided counseling. registration and decision support. It has been very useful in referring and tracking high risk pregnant women, recently delivered women, newborns and infants. Auto referral was based on the ANC service delivery data. In case of death, the date, time and type of death was registered through MSakhi. While more than half of the beneficiaries (55%) surveyed in the experimental arm reported that ASHAs used mSakhi during counseling, less than a quarter (22%) of surveyed comparison arm beneficiaries reported that ASHAs used the paper-based flipbooks. Beneficiaries found mSakhi to be engaging and also reported other family members' interest in the counseling messages because of the multimedia mobile content.

4. **MHealth intervention for antenatal care, vaccination:** In Khushi project, a cluster randomized controlled trial was conducted in 96 villages of Udaipur District, Rajasthan[7] They were randomly divided into three arms. Near Field Communication sticker, Near Field Communication pendant, Near Field Communication pendant with voice call reminder in local dialect. The result showed that the pendant and pendant with voice call reminder arms did not significantly improve adherence compared to the sticker group. But the point estimates showed that there were higher odds of on time completion in the pendant with voice call group in comparison to the remaining groups.

   In a RCT to assess the Khushi Project 208 mothers and 128 children were enrolled from August to December 2015 for a study period of seven months [9] Findings suggest that the necklace worn with a Near Field Communication Pendant is the preferred form of Wearable for infants and their mothers too agreed to like it compared to a simple Near Field Communication sticker.

   In Zanzibar[10] 44% of women in the intervention group received the recommended four or more antenatal visits, compared with 31% in the control group. The odds for receiving four or more antenatal care visits were 2.39 (1.03–5.55) for women benefitting from the mobile phone intervention. 59% of intervention women stated that received text messages influenced the number of times they attended antenatal care.

   In Kenya [11], of the 397 subjects, 3.6 in the intervention group had less than four antenatal vists while 9.7% of those in the Controlled Group had less than 4 visits. Of the participants, 7.4% of those followed up had less than four antenatal visits while 18.6% of those not followed up had less than four visits.

5. **RCT to study the dose of text messages:** Text4baby is a text message service for pregnant and post partum women. Subjects for this study [11] were women soldiers from Madigan Army Medical Centre, USA. The study reported descriptive statistics including dosage of text messages delivered. The main finding was a significant effect of high exposure to text4baby on self reported alcohol consumption postpartum (OR 0.212, 95% CI 0.046 – 0.973, P=.046) as measured by the question, "Since you found out about your pregnancy, have you consumed alcoholic beverages?" The participants also reported lower quantities of alcohol consumed postpartum.
6. **MHealth intervention to promote healthy gestational weight gain for pregnant women:** In an Australian Tertiary Obstetric Hospital [13] women who were obese or overweight before their pregnancy were chosen as subjects and assigned in intervention groups or control groups. 97.6% women reported that the intervention was helpful. Secondary outcomes suggested a significantly lower GWG in the intervention group (7.8kg versus 9.7 kg) compared with the intervention group at the time of completion.

CONCLUSION

This Systematic review has helped in understanding that with regards to Maternal and Child Health, mobile phones can be used as a data collection tool, vaccine reminders, support devices for health personnel and also to communicate important messages to pregnant or new mothers and her family. This review showed a promising future for mHealth as a Health Communication tool.

Similar reviews on Maternal and Child Health took all the studies conducted in Lower and Middle Income Countries but it differed from the present study in the scope and the inclusion and exclusion criteria. Although there is some overlap, this systematic review explores the current evidence on the use of mHealth for maternal and child health intervention with RCT as a base for research therefore assuring strong data. This review agrees with previous reviews that there is a need for rigorous study on mHealth applications in Maternal and child health.

It suggests that mobile phones have the potential to bring in significant growth and developments in Maternal and Child Health both from the Provider facing technologies like a resource aid as well as User facing technology like adherence and education. User facing technology can play an important role in a resource limited country like India to avoid maternal, neonatal as well as infant deaths. The gaps in research include there are very few studies with credible clinical evidence. In most cases the sample size is too low and the change is minimal. So future research should focus more on evidence based research done with large samples.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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A Study to Assess the Parental Satisfaction about Pediatric Outpatient Department Services in a Selected Tertiary Care Hospital

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ABSTRACT

Introduction: A patient friendly atmosphere with skilled, approachable professionals spending quality time to discuss the treatment options and outcome and involvement of parents in decision making will help reducing the anxiety of the parents of sick children.

Purpose: It is very important to assess parent's satisfaction as an outcome indicator of quality of health care services. A descriptive study was carried out to find out the parental satisfaction about Pediatric OPD experiences in a selected tertiary care hospital.

Setting of the Study: The Pediatric OPDs of a tertiary care hospital at Pune.

Sample: Thirty (30) Parents of the children attending paediatric OPD.

Results: Majority i.e., 73% and 83% parents were satisfied with the services provided by the doctors and nurses respectively. 40% found OPD waiting period long, 53.3% found it difficult to find OPD and seating arrangement needs to be improved in the OPD. OPD was clean and has play & entertainment facility, reported by 63% parents. Mothers' education level and father's occupation status were found to have significant relationship with their satisfaction level.

Conclusion: The study indicates a very high level of satisfaction regarding communication and services offered by doctors, nurses, pharmacy staff. However, 33.3% parents suggested improvement in physical facilities.

Keywords: *Outpatient services, Parent, Satisfaction.*

INTRODUCTION

A child is a unique individual, not a miniature adult. Children's needs are different than those of adult. In the same way, a sick child is different from a sick adult. Illness threatens both the physical &psychological development of children. Child's sickness not only affects the child's behaviour but, also affects the parents as well as family's role position & interaction pattern[1]. Therefore, treating a sick child involves catering to the needs of family and reduction of stress of parents. Recent trends in Paediatric care include family centred, atraumatic and evidence based care. Family-centered care suggests that healthcare providers acknowledge and utilize the family's knowledge of their family member's condition and make use of the family's abilities to communicate with their family member.Family-centered care suggests that healthcare providers acknowledge and utilize the family's knowledge of their family member's condition and make use of the family's abilities to communicate with their family member.Family-centered care suggests that healthcare providers acknowledge and utilize the family's knowledge of their family member's condition and make use of the family's abilities to communicate with their family member.Family centered care suggests that health care providers acknowledge & utilize the family's knowledge of their family members' condition[1]. Parents today are comfortable with an instant exchange of knowledge through social media and online medical research. That's especially true for pediatric diseases, where family support networks not only share information and tips but also influence and sometimes

underwrite research. Parents and caregivers want information regarding the care of child, identification of complications and prognosis of the disease alongside the treatment from the health care providers. Therefore, the responsibilities of the health care givers have increased manifold. Parental satisfaction is considered as an important indicator of quality care from the perspective of the consumer and has been widely studied in many settings[2]

Parents of children with special needs have long acted as the primary care coordinators for their children, often facing stress in navigating the health care system.

Problem Statement: A study to assess the Parental satisfaction about pediatric outpatient department services in a selected tertiary care hospital.

Objectives:

1. To assess the level of parental satisfaction about paediatric outpatient department services.
2. To find out the association between the parental satisfaction with selected demographic variables.

Conceptual framework: According to Miles and Huber man (1994), conceptual framework is defined as a written or visual presentation that explains the main things to be studied in either graphically or narrative form – the key factors, concepts, or variables and the presumed relationship among them[3]

The conceptual framework for this study was developed based on King's modified goal attainment theory.

King derived the following seven hypotheses from goal attainment theory as:

1. Perceptual congruence in health care giver- patient interactions increases mutual goal setting.
2. Communication increases mutual goal setting between health care giver nurses and patients and leads to satisfactions.
3. Satisfaction in health care giver and patient increase goal attainment.
4. Goal attainment decreases stress and anxiety in vaious situations.
5. Goal attainment increases patient learning and coping ability in varioussituations.
6. Role conflict experienced by patients, care givers, or both decreases transactions in health care giver and patient interactions.
7. Congruence in role expectations and role performance increases transactions

METHODOLOGY

The research approach adopted for this study was a quantitative one.

The research design adopted for this study was exploratory, descriptive one.

Variables: In this Study, the demographic variables studied were age, sex & disease status of the child, relationship of the child with parent, education and occupation of the parents.

Sample: For the present study, thirty (30) Parents of the children attending paediatric OPD services of a tertiary care hospital were taken as sample.

Sampling Technique: Simple random sampling was practiced. Random numbers generated by the computer allotted and odd numbers of parents were selected.

Tool: The tool consisted of following parts:

Section A: Consent Form:

Section B I: Demographic Data:

1. Age of the child
2. Sex of the child
3. Disease status of the child
4. Parents' relationship with the child
5. Education of the parents
6. Father's occupation
7. Mother's occupation

Section II-IV: Satisfaction Questionnaire
Questionnaire consists of 40 two point questions regarding different aspects of satisfaction.

Section V: Suggestions/ comments for improvement of services
Validity was obtained from the experts. The tool was found reliable.

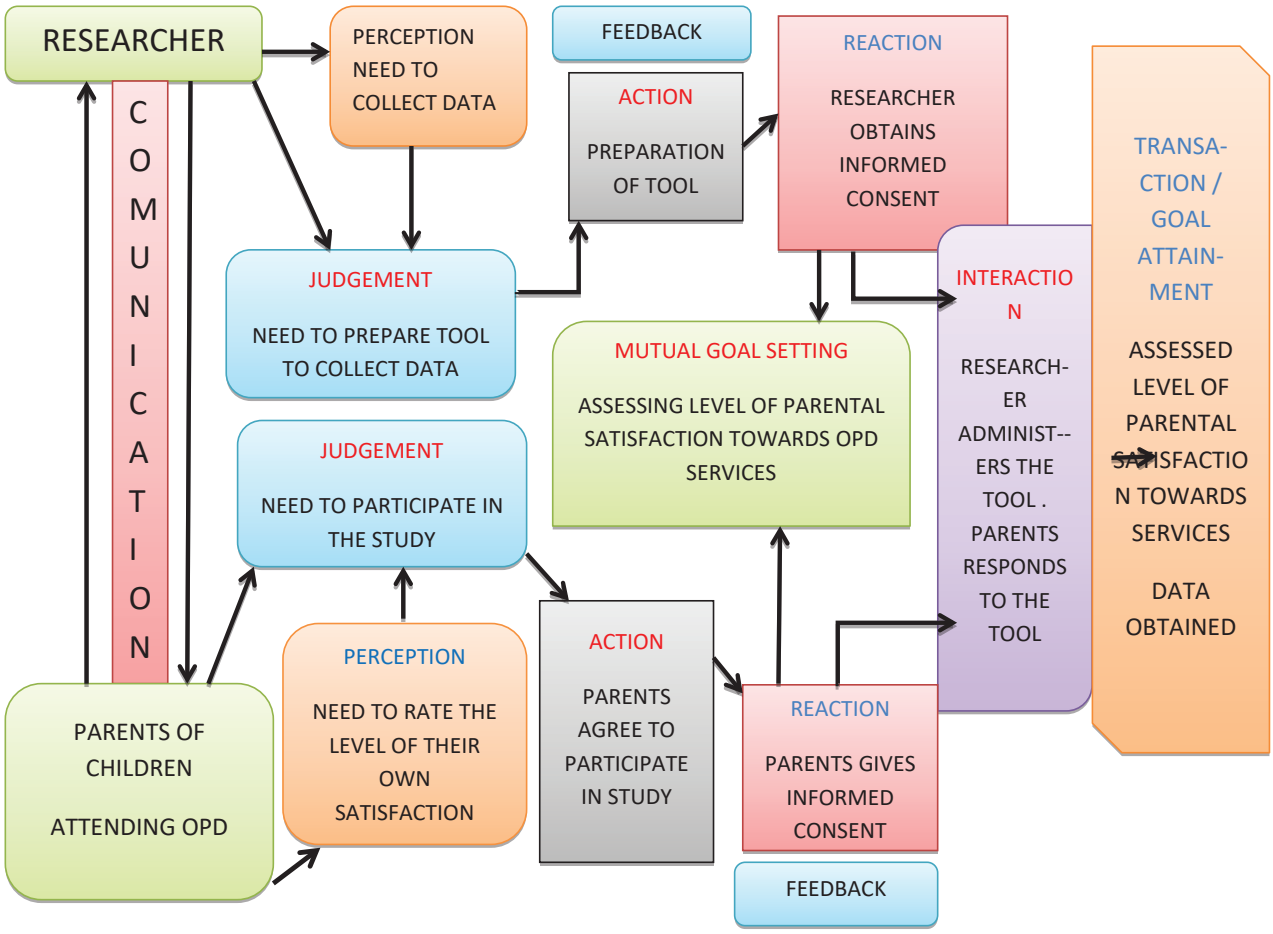


Figure 1: Conceptual framework based on King's modified goal attainment theory

RESULTS

Demographic Characteristics of Sample Population: The study conducted revealed the following demographic characteristics of the respondents that participated in the survey:

The Child's age group of most of the respondents falls below 3 years old with 56.7% while 30% of the participants have their child's age between 3 to 6 years old. More male children (53.3%) were brought to Paediatric Outpatient department by their parent while 60% of the children have acute disease condition.

The study also shows that mostly mothers (73.3%) brought their children for treatment this further confirms that child with age less than 6 years old (86.7%) is often close to their mothers who is their primary caregiver/ carer. Most of the parents (both fathers and mothers) have basic education with the fathers having Primary (30%), Graduate (43.3%) and Post graduate certificates (16.7%) while the mothers; Primary (26.7%), High school (23.3%)and Graduate (43.3%).

Table 1: Frequency Distribution and percentage of sex of the Children
N = 30

Sex of the Child	Frequency	Percentage
Male	16	53.3
Female	14	46.7

Table 2: Frequency Distribution and percentage of subjects as per relationship with the child
N= 30

Relation with the child	Frequency	Percentage
Father	08	26.7
Mother	22	73.3

Table 3: Frequency Distribution and percentage showing parent satisfaction
N= 30

S. No.	Criteria	Satisfactory		Unsatisfactory	
	CONVENIENCE	**Freq**	**%**	**Freq**	**%**
1	Registration process was easy	21	70	09	30
2	Paediatric OPD was easy to locate	18	60	12	40
3	Physical facilities were adequate(bed, chair, restroom)	20	66.7	10	33.3
4	Appropriate waiting time	17	56.7	13	43.3
5	Availability of medical supplies	22	73.3	08	26.7
6	Regular presence of clinical staff	22	73.3	08	26.7
7	Ease of coming back to visit on same day	23	76.7	07	23.3
	COURTESY				
8	Attitude & respect shown by receptionist	27	90	03	10
9	Language used by the physicians	28	93.3	02	6.7
10	Manner & attentiveness of Nurse	28	93.3	02	6.7
11	Physician's communication skill	27	90	03	10
12	Attitude & co operation of pharmacy staff	24	80	06	20
	QUALITY OF CARE				
13	Care by Nurses	26	86.7	04	13.3
14	Method of consultation & treatment	26	86.7	04	13.3

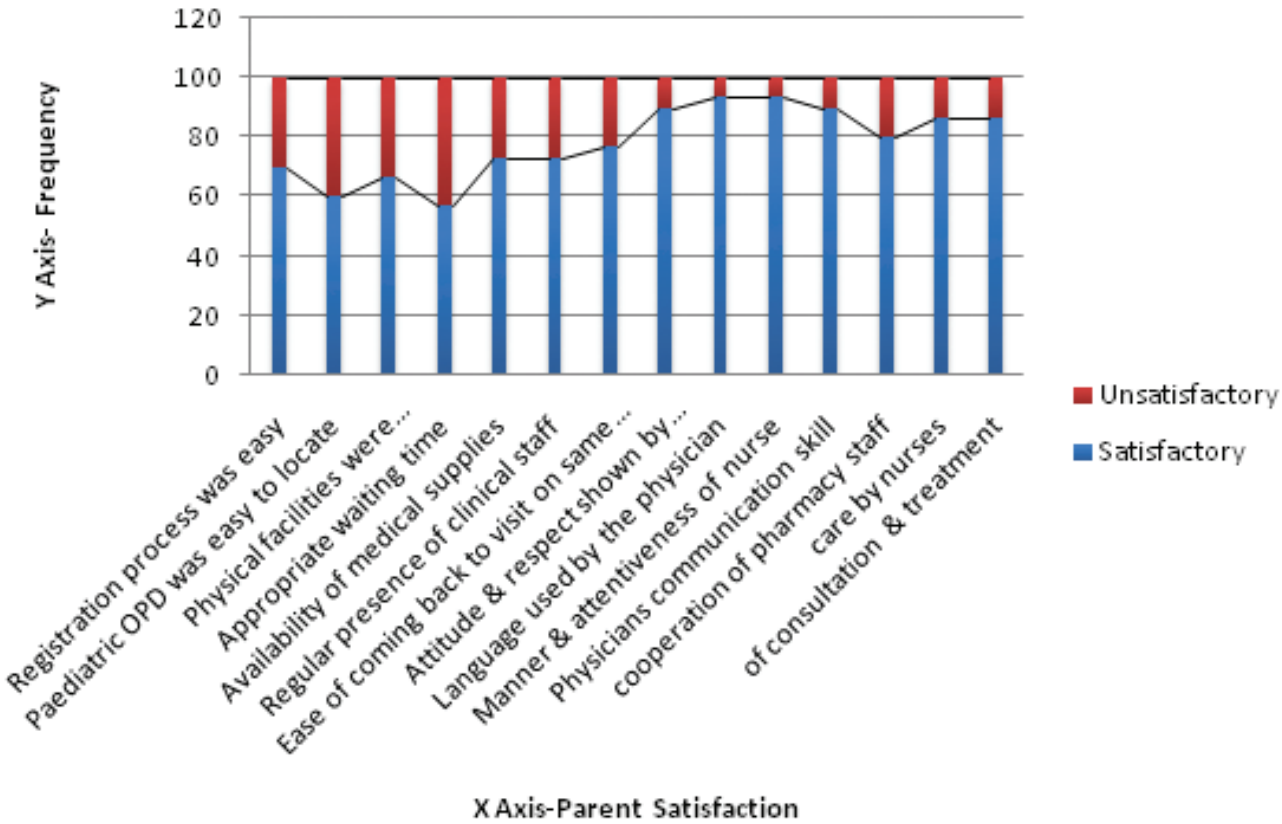


Figure 2: Parent satisfaction regarding OPD services

very high level of parent satisfaction (93.3%) regarding communication by physician and nurses, attitude and services of pharmacy staff (80%). Availability of medical supplies were satisfactory according to 73.3% parents. 66.7% were satisfied with the physical facilities, whereas 33.3% expressed that there should be more no of chairs in the OPD.

86.7%experienced that consultation and nursing care were satisfactory, whereas 13.3% rated them as unsatisfactory.

Table 4: Association between Parental Satisfaction & Demographic Variables

	MOTHER EDUCATION	N	Mean	Std. Deviation	95% Confidence Interval for Mean		Minimum	Maximum	p-value	f-value
					Lower Bound	Upper Bound				
Experience with HealthCare	Illiterate	1	19.00				19	19	0.081	2.35
	Primary	8	17.13	3.834	13.92	20.33	8	19		
	HS	7	12.71	3.039	9.90	15.53	10	19		
	Graduate	13	14.00	2.972	12.20	15.80	9	19		
	PG	1	15.00				15	15		
	Total	30	14.73	3.542	13.41	16.06	8	19		
Accessibility to services	Illiterate	1	7.00				7	7	0.009	4.25
	Primary	8	6.25	1.389	5.09	7.41	3	7		
	HS	7	4.00	2.309	1.86	6.14	2	7		
	Graduate	13	2.69	2.428	1.22	4.16	0	7		
	PG	1	7.00				7	7		
	Total	30	4.23	2.596	3.26	5.20	0	7		
Patient Satisfaction	Illiterate	1	14.00				14	14	0.016	3.77
	Primary	8	13.25	1.753	11.78	14.72	9	14		
	HS	7	10.00	3.000	7.23	12.77	6	14		
	Graduate	13	9.15	2.940	7.38	10.93	6	14		
	PG	1	14.00				14	14		
	Total	30	10.77	3.148	9.59	11.94	6	14		
Total Score	Illiterate	1	40.00				40	40	0.019	3.599
	Primary	8	36.63	6.927	30.83	42.42	20	40		
	HS	7	26.71	7.675	19.62	33.81	18	40		
	Graduate	13	25.85	7.493	21.32	30.37	19	40		
	PG	1	36.00				36	36		
	Total	30	29.73	8.606	26.52	32.95	18	40		

There is a significant association between the parental satisfaction and mother's education because more educated parents participated in the survey. It can be inferred that mother's education has a statistically significant impact on the perceived level of parental satisfaction about paediatric OPD services in the areas of Accessibility to OPD services and patient satisfaction while it has no significant impact on Experience with healthcare services. This is because experience with healthcare services cannot be easily rated. Hence, there is a significant association between the parental satisfaction and mother's education because more educated parents participated in the survey.

Table 5: Father's occupation on the perceived level of parental satisfaction

FATHER OCCUPATION		N	Mean	Std. Deviation	95% Confidence Interval for Mean		Minimum	Maximum	p-value	F-value
					Lower Bound	Upper Bound				
Experience with HealthCare	PROF	14	13.93	3.025	12.18	15.67	9	19	0.004	6.812
	SW	8	12.88	3.399	10.03	15.72	8	19		
	NS	8	18.00	2.449	15.95	20.05	12	19		
	Total	30	14.73	3.542	13.41	16.06	8	19		
Accessibility to services	Prof	14	3.14	2.538	1.68	4.61	0	7	0.028	4.07
	SW	8	4.25	2.252	2.37	6.13	2	7		
	NS	8	6.13	2.100	4.37	7.88	1	7		
	Total	30	4.23	2.596	3.26	5.20	0	7		
Patient Satisfaction	Prof	14	9.57	3.056	7.81	11.34	6	14	0.031	3.95
	SW	8	10.50	2.878	8.09	12.91	6	14		
	NS	8	13.13	2.475	11.06	15.19	7	14		
	Total	30	10.77	3.148	9.59	11.94	6	14		
Total Score	Prof	14	26.64	7.632	22.24	31.05	19	40	0.01	5.49
	SW	8	27.63	7.818	21.09	34.16	18	40		
	NS	8	37.25	6.985	31.41	43.09	20	40		
	Total	30	29.73	8.606	26.52	32.95	18	40		

Father's occupation has a statistically significant impact on the perceived level of parental satisfaction about paediatric OPD services.

Hence, there is a statistically significant association between the parental satisfaction and father's occupation because more professional and skilled workers participated in survey. Satisfaction or, dissatisfaction was least among mothers who were non skilled. Illiterate as well as highly educated mothers were more satisfied.

Fathers who were unskilled were mostly satisfied. Mothers were more satisfied than the fathers.

DISCUSSION

A large no of parents (86.7%) expressed that they were treated with respect and questions were answered gently by the nurses. Nearly all the parents (93.3%) told that they and children were prepared for the procedure and nurses took care of pain during procedure.

Satisfaction or, dissatisfaction was least among mothers who were non skilled. Illiterate as well as highly educated mothers were more satisfied[4].

Fathers who were unskilled were mostly satisfied. Mothers were more satisfied than the fathers. 86.7% experienced that consultation and nursing care were satisfactory, whereas 13.3% rated them as unsatisfactory[5].

A large no of parents (86.7%) expressed that they were treated with respect and questions were answered gently by the nurses. Nearly all the parents (93.3%) told that they and children were prepared for the procedure and nurses took care of pain during procedure.

CONCLUSION

The study indicates a very high level of satisfaction regarding communication and services offered by doctors, nurses, and pharmacy staff. However, 33.3% parents suggested improvement in physical facilities.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Evaluation of Effectiveness of the Printed Educational Material (Brochure and Pamphlets) for Cardiovascular Diseases for Use among Patients

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ABSTRACT

Online platforms and educational printed materials on health issues are creating an informed patient who actively participate in decision making, prevention and management of cardiovascular diseases. Yet the degree in which these educational printed materials create an awareness and understanding among the people is not well known. The purpose of this paper is to validate the educational materials such as brochures, pamphlets given by different hospitals like government, private, specialty, professional and charity. The objective of this paper is to understand the effectiveness of the educational materials and to evaluate if these material help the population are able to effectively make use of these materials in understanding and comprehending the content of it. The research methods adapted was mixed method using both qualitative and quantitative techniques for the qualitative method the educational materials distributed in the five kinds of hospitals 1. Government 2. Private 3. Specialty, 4. Professional and 5. Charity meeting the following criteria were sought for inclusion in the study: print format, content addressing behavioral management of cardiovascular disease (CVD) or CVD risk in individuals with diabetes, material written for an adult audience, and English language [14] and evaluated for ease of reading, understanding and comprehending using the Gunning Fog's index. Following it up with a survey questionnaire for a sample of 50 using snowball sampling method to respondents above 21 age group and those of them who have visited the hospitals for these ailments in three months. The data collected were analyzed using the Gunning Fog's Index.

Keywords: *Comprehension, Educational Materials, Gunning Fog's Index, Hospitals*

INTRODUCTION

Cardiovascular diseases (CVDS) have been escalating over the years and recently the cause of high mortality in India. Statistics shows that this is highly prevalent in India and is affecting the younger generation and catches them early as in 15 years than their counterparts in the US. Premature mortality in terms of years of life lost because of CVD in India increased by 59%, from 23.2 million (1990) to 37 million (2010). A 2015 UNESCO report said that in terms of absolute numbers, India - with 28.7 crore illiterates - was the country with the largest number of adults without basic literacy skills in 2010-11 compared to 2000-01 when it had 30.4 crore illiterates. To reach population affected by CVD and its complications, therefore, patient education materials such as printed brochures and pamphlets must meet criteria for understandability by persons with moderate to very low literacy and must be communicated in a manner that facilitates comprehension and application. The purpose of this study was to evaluate the accessibility and usability characteristics of selected print education materials and to evaluate if these material help the population are able to effectively make use of these materials in understanding and comprehending the content of it.

Educational Materials : Educational materials are additional risk minimization measures that are intended to promote the safe and effective use of the medicinal product. While the approved product information (the Summary of Product Characteristics, Package Leaflet and labelling on the medicine) provides all relevant information on the medicinal product, educational materials focus on one or more specific safety concerns related to use of the medicinal product so as to provide clear information on these specific risks and describe concisely what actions are required to prevent and minimize such risks.

Educational materials may be intended for healthcare professionals (e.g. doctors, pharmacists and nursing staff) and/or patients and caregivers. For example, educational materials may outline what a doctor needs to consider before prescribing a medicine for their patient, or what specific monitoring (e.g. regular blood tests) is required while their patient is on that medicine. They may also provide advice to patients on when to seek medical advice. Examples of educational materials for healthcare professionals include healthcare professional guides, dosing and administration guides, prescriber checklists and monitoring charts. Examples of educational materials directed at patients include patient alert cards, patient guides and patient reminder cards.

Educational materials are produced and distributed by the Marketing Authorization Holder (MAH) of the medicinal product and are specific to that medicinal product. They are not required for all medicines but rather are provided if it is considered that they will aid in optimizing the safe and effective use of the product. The materials are published with the agreement of the MAH responsible for producing them. The materials can be downloaded for use by healthcare professionals and patients. The HPRA does not provide hard copies of these materials. If hard copies are managed the relevant MAH for the medicinal product.

Apart from educational material for medicinal products, printed materials such as brochures and pamphlets also play a major role in informing the patients about a particular diseases and its treatment. These educational materials distributed in hospitals and health clinics targets a specific set of audience who are associated with a health issue. It also targets people who are likely to fall in this category either through hereditary or other lifestyle conditions. Despite of various online materials available on the internet through re-tracking and other tools to target patients, there are few limitations to this approach. They are-

1. The patients for particular diseases such as cardiovascular diseases of the aged group 40 and above are less likely to be active users of internet.
2. Web users tend to scan text than reading it closely when compared to printed materials. It was found that 79% of web users scan content.
3. Authenticity or source of the information is doubted due to massive information with various opinions is available on the internet.

Hence, it can also be said that printed educational materials use a direct method to reach out to its audience whereas online material uses an indirect method. These printed materials are targeted towards individuals suffering from cardiovascular diseases and helpful in providing information to the patients through brochures and pamphlets. The term informed patients arrives from this approach in the field on communication in the medical sector. As the targeted audience are usually in the age group of 40 years and above, the printed materials must also be designed according to the requirements of these set of audience seeking information about cardiovascular diseases. One must also understand the areas and aspects to be covered in order to communicate successfully to the audience. Sometimes these materials also be misinterpreted due to language, levels of understanding and other barriers to communication. Most of such materials are also found to be neglected often which could be due to lack of patient's interest, positioning of the brochures/pamphlets in the hospital, lack of relevance to the patients, too much of advertisements or even unattractive content in the educational material.

The study also tries to understand such patients who also seek information using different means such as television and internet. It is important to undergo a survey to understand these patients of cardiovascular diseases and implement their ideas for improving the methods of communication for the informed patients. The size of the text, style of the text, color, content and pictures also are some of the major elements of such printed materials. Apart from the effectiveness of the brochures/ pamphlets, the readability of these materials must also be tested for effective outcome. Keeping in view of other limitations to the study it is important to find ways to overcome the drawbacks for such communication methods.

Review of Literature and Theoretical Framework: Cardiovascular death is the leading cause of death in India along with diabetes. The causes are several times related to the trends in dietary and activity patterns,which has been leading to overweight and obesity, will inevitably increase in number in future. The reduction of cardiovascular disease and most other chronic diseases is possible, but will require actions by the high level of government and Indian society broadly, in addition to the healthcare system and Ministry of health and through awareness programmers.

In the recent past, in research even if the epidemic were arrested today, there would still be a huge increase in complications over the next decades. This paper tries to understand the effectiveness of educational materials and evaluate if these materials are being understood and comprehended well by the general public. Adapting the Kotter's 8 step model theory on how educational materials can be of use to the patients, the following steps were considered:

1. Create a Sense of Urgency. Most people resist change and very few are interested in bringing about a change. Probably we have to do a particular thing considering that if we don't such and such negative things will happen. Similarly, an act should be taken to make sure the positive outcomes are reflected.
2. Build a Guiding Coalition. There is no other substitute for a set of powerful, influential people from key positions on board. In this case could be the Doctors who help to disseminate that sense of urgency.
3. Form a Strategic Vision and Initiatives. A set understanding of the goal with a clear vision helps steer the entire project. There is a need to set initiatives that will help in achieving the vision.
4. Enlist a Volunteer Army. The need for a large force of people who are ready, willing and able to help make a difference play a major role. The guiding coalition is key, but so are many "boots on the ground" as possible.
5. Remove Obstacles.Identifying and removing barriers to change is absolutely essential for an expected outcome.
6. Generate Short-Term Wins. Highlighting early victories and celebrating them helps in collaborating the results. This necessarily involves robust tracking and evaluation processes. Early successes help in building momentum in a change effort.
7. Sustain Acceleration**.** As credentials build, use that as leverage to remove more obstacles, make more changes that align everything in the organization to the vision.
8. Institute Change**.** Make sure the change is embedded in the organization's culture such that it will continue whether leadership changes or not the success stories must always be told.
9. The study followed the above model to use the 8 levels of acceleration in creating awareness among the informed patients of the educational material available to them.

Educational Material requirement: The purpose of the educational material is to create an awareness and cater to the multiple information needs of cardiovascular patients. The other variables which affects the level of understanding are levels of reading, the language used and the economic and cultural background. Therefore a clear perspective of the target groups especially the patient/family/caregiver makes it easier to tailor material to the requirement of the respondents. Earlier research also shows that becoming aware of one's conditions can help in improving lifestyle and medication. Alm-Roijer et al (2004), in his study proved that there is a correlation between patients' knowledge about coronary heart disease (CHD) risk factors and maintain weight[1]. Evanoski, adds on that most often the education materials are written at higher reading level specifically for complicated cardiac problems[2].

Physician role in communication: The Medical Practitioners play a key role in explaining health related issues to their patients and also most of the pharmaceutical companies in India create educational materials for doctors rather than patients. Added to the patient's understanding of the educational materials the challenge of effectively delivering health related information to the patients is multiplied in the poor communication skills of Medical Practitioners. Most often patients are of the opinion that their medical practitioners use complicated medical jargons while the physicians are in the impression that they use common man's language [3]. Mayeaux, argues that most often Medical Practitioners use medical terms that are unknown to the common man and frequently patients are unable to comprehend and recall information given to them by their physicians [4, 5]. Another challenge to the patients, especially those with heart failure, is to undermine their physicians' treatment choices [6]. Again, another major drawback is that Medical practitioners do not know their patients' health literacy skills and assume their abilities to understand [7]. While patients in an informed society do not admit to the limitation of understanding, and therefore complicate the process of comprehending[8].

Prevention: Most of the patients are not aware that the best way to take care of themselves is by preventing the disease. Many are ignorant that CVDs is prevented. Earlier research shows that most of the heart failure patients were in the impression that the symptoms were due to ageing. Patients with a heart failure are more often ignorant of the cause for such a heart failure [6]. Fredrickson, in his study on tobacco abuse argues that there is an association between low reading ability and smoking ($p < 0.05$)[9].

General knowledge and self-care behavior: The lower the level of literacy the greater is the challenge for respondents to comprehend the causes and effects of the cardiovascular disease and to create an awareness of how to care for and prevent the disease by following a changed lifestyle. Evidences from earlier research have shown that the Patients suffering from hypertension and heart failure who have adequate general knowledge would know the need for exercises in comparison to those of them with low level of awareness. According to Williams et al, a patient's level of grasping the health literacy is a better predictor of his hypertension familiarity than his duration of diagnosed hypertension, his education level or even his age [10]. Although the individual's clinical history is invariably dependent on the patient's involvement of self-care maintaining weights, choice of food and diet, adherence to medical requirements [11]. Unfortunately, the information regarding their health and other issues are from their healthcare providers which they do not understand. In one study by Ni et al, 80 patients with heart failure were enquired about their knowledge of their condition and it was found that half (48%) said some while 38% confessed they knew little or nothing and just 14% of them confirmed they knew a lot[12].

RESEARCH METHODOLOGY

The health of individuals is intricately woven into complex of society. The rates of fatal heart attacks are 3-fold higher among persons with diabetes for less than five years but 12 fold among those with diabetes for 25 or more years [13]. India has signed the WHO Framework Convention on Tobacco control which is a main cause for Cardiovascular Diseases. Other factors which could prevent the cardiovascular disease are Promotion of Physical Activity, Promotion of Healthy Food Habits, Management of Hypertension and Tackling Alcohol Abuse. All these factors could be included in the brochures and pamphlets given by the hospitals.

Problem Statement: The purpose of this paper is to validate the educational materials such as brochures, pamphlets given by different hospitals like government, private, specialty, professional and charity and to understand the effectiveness of the educational materials and to evaluate if these material help the population are able to effectively make use of these materials in understanding and comprehending the content of it.

Research Design: The research methods adapted was mixed method using both qualitative and quantitative techniques for the qualitative method the educational materials distributed in two private hospitals meeting the following criteria were sought for inclusion in the study: print format, content addressing behavioral management of cardiovascular disease (CVD) or CVD risk in individuals with diabetes, material written for an adult audience, and English language and evaluated for ease of reading, understanding and comprehending using the Gunning Fog index[14].

Following it up with a survey using a structured questionnaire which included both close ended and open ended questions. The sample size was 50 and data was collected using a non-probability snowball technique method to respondents above 21 age group and those of them who have visited the hospitals for these ailments in three months.

Analysis of Brochure and Pamphlets

Literacy and Reading Level

To check the reading level of the brochures and pamphlets the Gunning Fog Index was used Readability tests gives a general idea of how hard the document will be to read, based only on the words it contains. The tests do not consider the respondent's perception and understanding of the printed material. The readability formula does not consider the writing style and tone and of the message. To analyze the writing style, the following checklist was used:

Language and writing style

- The educational material was checked if the following were adapted to maintain the flow and understanding of the language.
- Whether Messages were simple and kept short using words of not more than two syllable. Sentence length limited to 10 words and 3 to 5 sentences in a paragraph.

- If the written materials follow a conversational style. A conversational style has a more natural tone and is easier to read and understand.
- Present one complete idea on one page or two facing pages.
- Starting and ending the document with the most important information thus reemphasizing the message.
- Check if the brochure Uses headings and subheadings to "chunk" text. Note if heading have a complete idea and not just a word
- Leave sufficient space above headings and subheadings than below them, therefore giving a stronger visual link between the heading and the text that follows.
- Limit the number of messages. Too much of message clutter will lead to confusion.
- Clearly state the actions that readers are to take. Skip details that are nice to know but irrelevant to the reader's healthcare needs.
- Stick to one idea at a time. Skipping back and forth among topics can confuse readers.

DESIGN AND LAYOUT

Text appearance

- The font size of body copy must be 10-12 and display copy can be above 12.
- Left- justified alignment is advisable.
- Using only CAPITAL LETTERS for words or sentences. They are difficult to read.
- Use Times New Roman or Arial font. Do not use Fancy or script lettering.
- No use of Italics as it does not enhance readability.
- Use black colour on white background
- Listing out point with bullets enhance readability.

Visuals

- Graphics pictures and photographs should have caption kept near to them.
- Every visual must have only one message.
- Images and captioned should be numbered.
- Visuals need to emphasize text.
- Visuals are not used as a decorative element and needs to give a message. Simple drawing and illustrations will suffice.
- Body parts are not to be amputee, while showing internal organs external organs must also be displayed for clarity.
- The Dos need to be highlighted than the Don'ts.
- Cluttering message with graphs and info graphics to be avoided.
- Use white space optimally.
- Credit images to avoid copyright.
- Stock are repository images such as clipart, info graphics etc.

DATA ANALYSIS AND FINDINGS

The Gunning fog index is a readability test for English writing. The index estimates the years of formal education a person needs to understand the text on the first reading. A fog index of 12 requires the reading level of a U.S. high school senior (around 18 years old). The test was developed by Robert Gunning, an American businessman, in 1952. The fog index is commonly used to confirm that text can be read easily by the intended audience. Texts for a wide audience generally need a fog index less than 12. Texts requiring near-universal understanding generally need an index less than 8.

Table 1: Fox Index and reading level by grade

Fox Index	Reading level by grade
17	College graduate
16	College senior
15	College junior
14	College sophomore
13	College freshman
12	High school senior
11	High school junior
10	High school sophomore
9	High school freshman
8	Eighth grade
7	Seventh grade
6	Sixth grade

THE GUNNING FOG INDEX IS 12.47

The number of major punctuation marks, e.g. [.], was 8.

The number of words was 106.

The number of 3 + syllable words, highlighted in blue, was 19.

1. Apollo Hospital

(a) Gunning fog index-



Figure 1: Gunning Fog Index

From the above calculation it was conclude that the brochure used a language for which the Gunning Fog Index was found to be **12.47** anda fog index of 12 requires the reading level of a U.S. high school senior (around 18 years old). So this educational material is not suitable for near - universal reading which needs a score of **8.**

Language and writing style

Pros

- The brochure used appropriate number of words and paragraphs for sentences and words respectively.
- Style of writing was observed to be a natural tone whereas the layout and design elements could not complement the text.

As mentioned earlier the primary data for this research was collected through analysis of brochures from two healthcare providers based on reading level, language and writing style as well as analysis of the research questionnaire.

Brochures

- Use of repetitive text was a good attempt for recall amongst the audience.
- Flow of information with a good beginning and end was well adapted.
- Message was clearly stated.

Cons

- It was observed that topics of the brochure were too cluttered by mentioning all symptoms, risk and diagnosis of the disease in the same page.
- No subheadings were used to chunk text.
- Less spacing between the headings was also one of the drawbacks.
- More information about the diseases (some which were irrelevant for the patient) were included.

DESIGN AND LAYOUT

Text appearance

- Font sizes of the brochure is size 11 which is ideal for the audience.
- Alignment is Justified which is good.
- No use of capital letters is a plus point.
- Use of Calibri font instead of Times New Roman or Ariel.
- No use of boldface or underlining to emphasize word, phrases or *italics.*
- Good use of dark letters on a light background.
- Implementation of text with bullets adds to the effectiveness.

Visuals

- No captioning of pictures.
- Presents one message per visual.
- No numbering or sequence for images
- Visuals complement the text.
- Lack of simple visuals, depending on the audience.
- Visuals showing internal body parts does not display the outside of the body for reference.
- Expected actions or desired action from the audience was well depicted using images.
- Lack of whitespace in the brochure, too much of data was cluttered.
- No source of the image was mentioned.
- No use of stocks

Analysis of the Questionnaire: Internationally, the World Health Organization (WHO) confirms that cardiovascular diseases are the leading cause of death around the globe, accounting for 17.5 million deaths in 2012, which represents 31% of all global deaths. According to WHO 2016, in India Non-communicable diseases (NCDs), including CVDs, are estimated to account for 60% of total adult deaths in India CVDs account for over a quarter (26%) of these deaths Some of the CVD related risks factors in adults in India are outlined below: 15% of the population smoke tobacco 4.3 liters of pure alcohol consumed per person Just over a fifth (21.1%) have hypertension which can increase risk of heart attack, heart failure, kidney disease or stroke To understand the perspective of the patients on the use of the educational materials structured questionnaire was created on Google forms and using snowball techniques the data were collected. The questionnaire comprised of questions using 5 point likert scale. Data were analyzed using simples percentage methods.

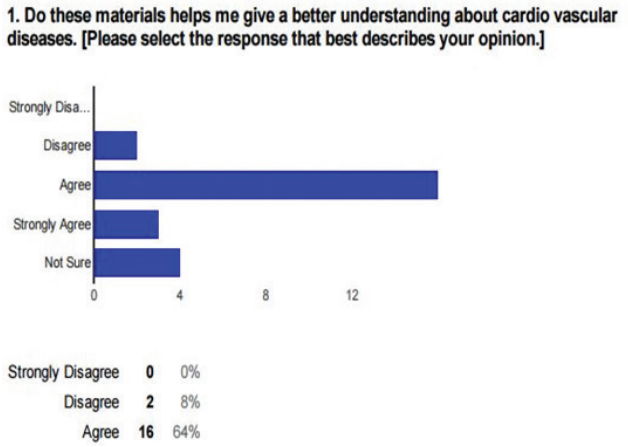


Figure 2: Question 1

Earlier studies show that the fatality rates for cardiovascular events in low-income countries, represented largely by India, was 17%; a way higher than in higher income countries, which had a case fatality rate of 6.5% and therefore the need for understanding the educational materials provided by the hospitals, a significant number (64%) of the respondents found the educational material to be simple and comprehending.

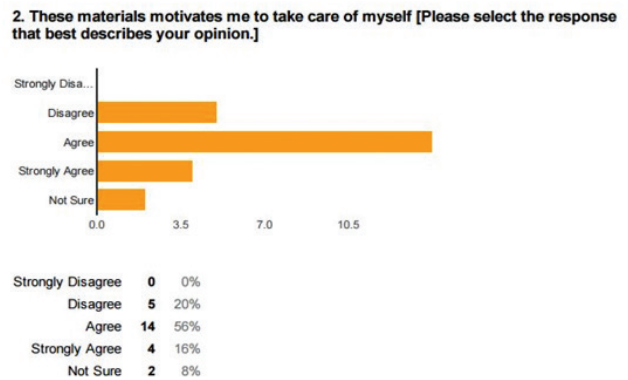


Figure 3: Question 2

It was found that the Apollo Hospital Brochure had more text than visuals. A majority of the respondents (56%) agree that the layout and placements of the materials motivate them to take care of themselves while 20% of them found the material to be incomprehensive.

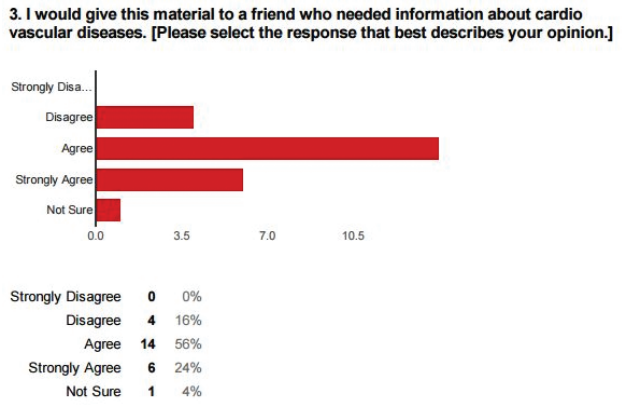


Figure 4: Question 3

Based on the results of the questionnaire it can be stated that these brochures would provide better reach to the audience as they are more likely to be passed on to others. 56% respondents agree that they would give these materials to friend who would need information on cardiovascular diseases.

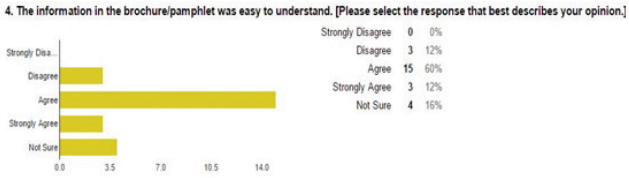


Figure 5: Question 4

The information in the brochure/pamphlet was found to be easy to understand as per the above results i.e. 60% of respondents agreed that they were able to understand the information given in the brochure easily.

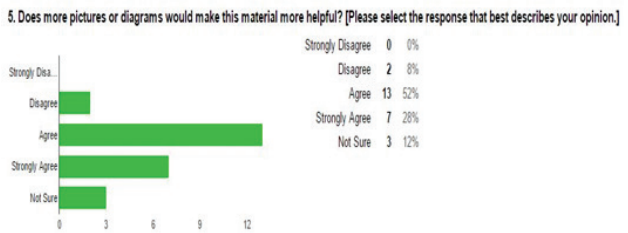


Figure 6: Question 5

Despite of agreeing that these brochures were helpful, 52% respondents agreed that use of pictures and diagrams would have made the materials more helpful and easy to interpret.

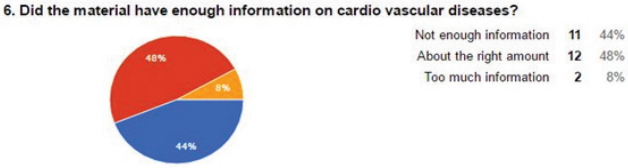


Figure 7: Question 6

48% of the sample size believed that the brochure had just the right amount of information about cardiovascular diseases and was enough as per their needs. Whereas, a close figure of 44% responded that the brochure had no enough information as per the requirement. Hence, this result demand more insight to reach to a conclusion.

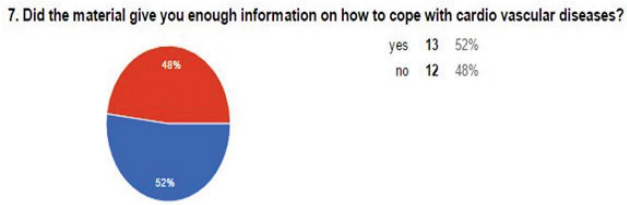


Figure 8: Question 7

Same as the previous question, the results are debatable as almost the equal amount of audience i.e. 52% and 48% believe that information was given or not given on how to cope with cardiovascular diseases as respectively.

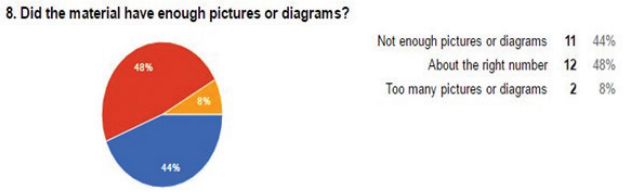


Figure 9: Question 8

48% of the respondent believed that the pictures and diagrams given in the brochure were about the right number whereas, a close percentage of 44% responded that the pictures or diagrams were not enough in these educational materials.

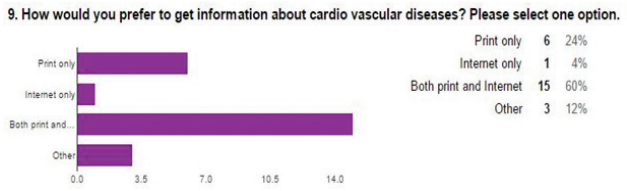


Figure 10: Question 9

Considering the present scenario 60% of the sample size preferred to get information about cardiovascular diseases from both print and the internet. A number of 6 out of 25 respondents also agreed that only print will be their preferred media for receiving information about CVD.

CONCLUSION

Based on earlier studies it was understood that the educational materials provided at healthcare centers such as, hospitals and clinics are meant for patients and not

doctors. It was also found that these materials (brochure/ pamphlets) were targeted more towards doctors and practitioners than for the general public. According to the results of analysis of these materials based on Gunning Fog Index it was found that the scale was too high and hence, was not a meant for the public that fall under average literacy rate. India having a literacy rate of 74.4% must make sure that these materials are not a barrier of communication for the remaining 26% of Indian population. Apart from literary language also plays a major role in communication, as India is a country with diverse culture it is also important to convey information in local languages for effective outcomes. The design of brochures needs to be improved to make it more user friendly and easy. Although the survey undertaken shows that the educational material was favorable and comprehendible, the potential limitation was that the survey was a pilot study and the number of respondents were few to generalize the result. As it was a snowball technique the rate of responses were slow from the age group of 25 and above who had been visiting hospitals for ailments related to cardiovascular diseases.

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Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Role of Media in Menstrual Healthcare

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ABSTRACT

Introduction/Background: Menstruation is a less talked about topic. Most girls prefer to hide it. Men, even after knowing about it feel uncomfortable to discuss it. Even for people located in urban areas and belonging to the upper-middle class of the society, menstruation is still a taboo. Females take this hard time, which occurs every month for around 5-7 days, feeling uncomfortable, lacking confidence and unhygienic. Still, they cannot share it with anyone due to the taboo that is widely spread in the society.

Purpose: This study focuses on the influence of media on the awareness of menstrual hygiene on girls of age group 17-23 and does a comparative analysis with females of age 10-14. Through the data, the analysis will be done to understand the personal experience of girls in terms of their knowledge, awareness, and level of comfort with a focus on the influence of media on these factors.

Research Design/Methodology/Approach/Materials & methods/Experimental: The research methodology used in the research was qualitative primary data collection through structured open-ended and close-ended interviews. The responses given by the interviewees were used to draw analysis from the data. The interviewee was college students (females) of age group 17-23. And to gain a better view and compare the conditions today with those prevailing with 17-23 years girls, female students of age 10-14 years were also interviewed.

Novelty/Originality: Most of the existing literature present on this issue has been centered on women residing in rural areas. Studies which have been done on urban women and their awareness of menstrual hygiene have not focused on media channels or have simply noted the lack in their awareness levels.Neither have they explained any specific measures whuch can be used to bring about a positive change in the ideology of the people.

Keywords: *Menstrual, Hygiene, Awareness, Middle class, Higher-middle class*

INTRODUCTION

Menstruation is an important aspect of every girl's life. Girls need to have proper and detailed information about it. They need to know precisely what goes on in their bodies. Whereas on the contrary, this does not happen. Dhingra, Kumar, & Kour mentioned in their research that the female respondents lacked conceptual clarity on the process of menstruation before they started menstruating due to which they faced several gynecological problems[1]. The common source of information about menstruation for the majority (83%) of girls was from mothers and friends. There were several socio-cultural taboos related to menstruation. The level of personal hygiene and management of menstruation was found to be quite unsatisfactory. 98 % of the girls believed that there should be no regular bath during the menstrual cycle. All the girls reported following these cultural practices without questioning. The results hold grave implications for professionals involved in the improvement of adolescent reproductive health, who must fight these multiple hurdles to change opinions on menstrual health.

A menarche is an important event in the life of a girl. Yet little is told to the maturing girl about it as is the case with other issues related to sexuality in most cultures. It is not an uncommon experience for girls to be unaware of menstruation until they attain menarche. Havens and Swenson, 1986; Koff & Rierdan, 1995 observed that most adolescents are either ignorant or misinformed about menses[2]. Studies have shown that girls who knew about menses had incomplete knowledge often limited to aspects of physical changes and menstrual hygiene[2]. Issues of psychological or emotional changes and the

real significance of the event were lacking, probably the result of parents' carefulness to avoid the introduction of the subject of sex[2].

Girls feel awkward in sharing their issues identified with the feminine cycle. They are mostly open about it just with their mother. In situations when mothers do not have satisfactory information through which they can fathom these issues, promote issues may emerge. It is extremely important for the girls to have appropriate natural information about such an essential procedure which goes ahead in their body[3].

In the clear majority of the Indian schools, no instruction is given about periods at the primary level. Girls are first instructed about it at the secondary level in around seventh or eighth standard. While a few girls get their menarche well before that time. This can be hazardous for them as they are not mentally prepared and all around educated about it. Generally they view it as some malady or disease and would not share it with their elders. For example, if a girl gets her menarche in class fifth or even sixth, she stays uninformed about it till she is instructed in the eighth standard. In this manner, it is essential for schools to hold sessions about feminine cycle at the primary level too.

MENSTRUATION IN INDIAN CULTURE

Menstruation is a taboo in many societies around the world including India [4,5,6,7,8,9,10,11].

Girls do not feel free to talk about this topic openly to the male members of the society. This is mainly due to inadequate primary information about the topic that is provided to the children and the customs that surround the topic. At the initial stage, girls are taught to not talk about the topic openly[12]. The message conveyed to them about menstruation being a taboo in the society further suppresses their ability to talk about it.

Girls belonging to the middle and the high class are given the knowledge about menstruation. But this knowledge is mostly given after they had attained menarche[13.] Girls describe the onset of menarche as a shocking or fearful event. In such a case, they are not well prepared for their first periods and hence they face several issues such as mentally unpreparedness, hesitation to talk about it, getting infections, premenstrual syndrome, dysmenorrhea and so on.

This issue of unawareness about menstruation is a point of concern that needs to be addressed and proper actions need to be taken for eradicating this incomplete knowledge.

Girls face an issue of inadequate knowledge about menstruation not only in rural areas but also in urban areas among the middle class and higher middle class of the society, also reported a lack of knowledge about menstruation but to a lesser degree[14,15].

MEDIA IN EVERYDAY LIFE

Media is everywhere. It has been and still is an essential part of our daily life[16,17,18]. It plays a crucial role in the learning process as well[19,20]. It has the potential to shape the personalities, change the way things are perceived and understood. Media needs to be effectively utilized to spread the knowledge and awareness about various issues.

OBJECTIVE OF RESEARCH

- To study the level of awareness and attitude towards menstruation among the girls belonging to the middle and high class of the society and the influence different media channels have on them.
- The study also tries to analyze the level of freedom they feel in discussing menstruation to the other members of the society, mainly males. It is not the primary goal of the paper. But helps in attaining the primary goal and will be listed in the suggestions.
- To identify the issues and challenges faced by adolescent girls and suggest measures solve these issues.

SAMPLE & METHODOLOGY

Structured interviews with a mix of open and close ended questions were used to capture the data. This was administered to 100 females between the ages of 17-23 years from different cities of India. All the interviewees were a part of Symbiosis International University. Additionally, 50 females of age group 10-14 years were interviewed to get a better and expanded view on the topic. It was also helpful in getting a comparison of the formal primary and secondary education that was provided to those who are now 17-23 years old and to those who are of age 10-14 years.

Verbal consent to use their information for research purpose was taken from the respondents prior to conducting interviews. They were assured of the anonymity and confidentiality of the information and they could opt out of the study at any time if they wished to. The data was then interpreted using simple descriptive statistics.

OBSERVATIONS

(Figure. 1)When asked about their reaction the first time they had their menarche, the responses ranged from being startled, frightened, perplexed, froze, and cried et cetera. 77% of the interviewees had no knowledge about their monthly cycle when they had their menarche. Out of these 53% had no clue about what to do about it and they additionally did not inform anybody about it because of dread and frenzy. 18% of them informed about it to their mother to look for guidance. Furthermore, 6% were interested in thinking about the feminine cycle and knowing more about it, rather than having dread, freezing or being alarmed. Out of the aggregate specimen, only 23% knew about it and realized what anyone can do when they get their menarche. Such a short number of respondents were educated about the feminine cycle. This is doubtlessly not decent figures, particularly when the feminine cycle is such an important part of a girl's life.

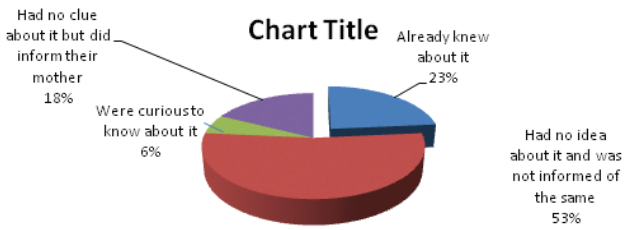


Fig. 1. Reaction on first noticing period blood/stains.

Figure 2 (2.1-2.2). Demonstrates the level of mindfulness about different aspects of the menstrual cycle. The alpha Cronbach value was 0.85, which makes the data very reliable[21]. The outcome demonstrated that on a Likert scale of 1 to 5 (5 being most educated and 1 being least educated) ; 48% respondents trusted that they completely know about onset and recurrence, 40% stated that they knew of the cramps , 37% stated that they knew the about mood swings and behaviour changes, 45% knew most about bleeding, 28% knew most about menstrual disorders, 45% knew most about disposable items and 20% knew about reusable items utilized amid periods and 37% were most mindful of customs and taboos.

Aspects	Scale				
	1	2	3	4	5
	Number of respondents				
Onset and reoccurrence	0	4	17	31	48
Cramps	4	0	31	25	40
Mood Swings and Behaviour	2	2	22	37	37
Bleeding	3	2	22	28	45
Menstrual Disorders	10	22	20	20	28
Disposable Items	2	5	28	20	45
Reusable items	6	3	10	9	7
Traditions and taboos	7	22	14	20	37

Fig. 2.1

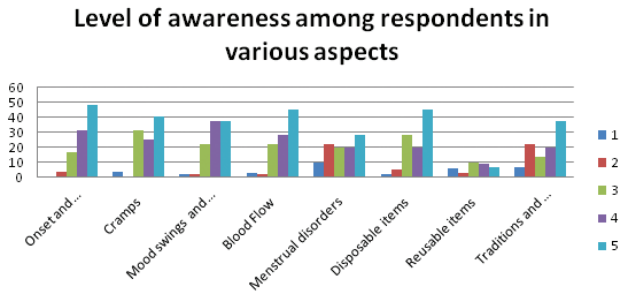


Fig. 2.2

(Figure. 3) The respondents were initially educated about monthly cycle by most their mothers (67%), companions (9%) and educators (9%). The alpha Cronbach values came to 0.78.

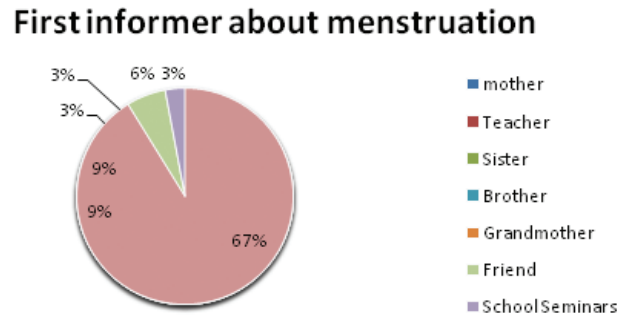


Fig. 3

(Figure 4) - When asked about the comfort level that the respondents have while talking about menstruation to the various people around them, they were mostly most comfortable with females, while this ratio being nil or very less with male members. The main reason that was told for this disproportion was the initial knowledge about menstruation being a taboo and a hormonal process not to be talked about with the male members of the society.

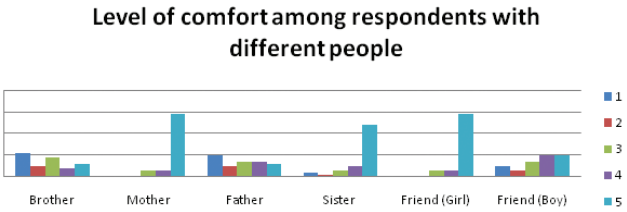


Fig. 4

(Figure 5) Respondents were also asked about the media channels they use for information regarding menstrual health. For the most part, the respondents utilized online networking to think about feminine cycle and issues identified with it (44%). Different sources of data reportedly utilized are daily paper and books (29%), the internet (15%) and television (12%).

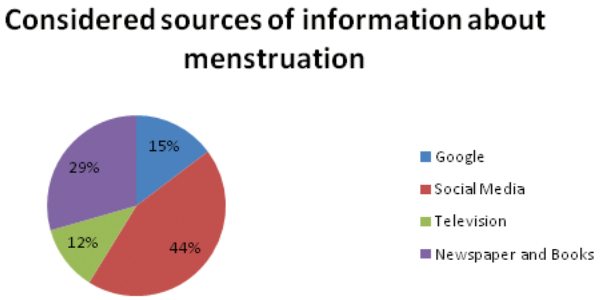


Fig. 5

(Figure 6) When asked about their attitude towards menstruation, only 25% agreed that menstruation was a normal hormonal process and that they felt free to talk about it to people. Whereas, 32% said that they did not feel very comfortable in talking about it to people. Also, that they do not have the required information on the topic. They felt a desperate need of giving more attention to the topic and a necessity of providing proper education about the topic from the primary stage. 11% felt that it cannot be talked about at all. Also when asked about it in detail they could not figure out any measures to remove this taboo. 20% felt that it is necessary for both the genders to be properly informed about it in order to remove the ongoing taboo about the topic. 8% stated the hormonal process to be dirty. When they were enquired about the reason for it, they addressed it as the belief that they have been following since they had their menarche. Only 2% felt concerned about the process and 25% felt that it is normal.

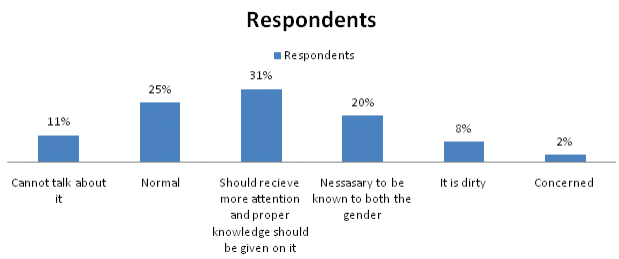


Fig. 6

To expand the understanding of the thesis, 50 females of age group 10-14 years were interviewed on the topic of menstruation. The response got was more or less the same as received by the age group of 17-23 years.

(Figure 7) The children were mostly not very comfortable in talking about this topic. 45% opted to not talk about it freely, 30% were comfortable in talking about it, 25% had their view that the topic should be more openly discussed and taught about.



Fig. 7

(Figure 8) On talking about their knowledge level 47% did not have any knowledge about the topic initially when they had their menarche. 20% knew about the topic before their menarche. 33% had a very slight knowledge only about the blood flow only through their friends.

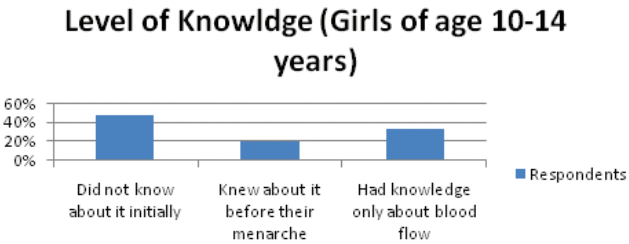


Fig. 8

(Figure 9) To gain the understanding of the source of information about periods, they were asked how they came to know about the topic. Only 30% received channelized knowledge through proper classes in school, 40% were taught about it through their mothers, 20%

came to know about it through their friends and 10% through magazines. Even though the society is opening up to the issue of menstruation, there still are a few loopholes that need to be mended.

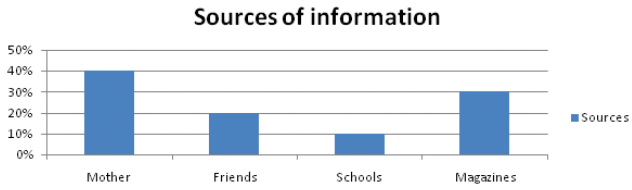


Fig. 9

CONCLUSIONS

This clearly demonstrates the level of information that the females have with respect to menstruation, is low. Menstruation being an essential part of their lives, it is critical for them to be completely mindful of it.

The respondents shared information about the comfort level that they had in talking about their menstrual cycle. A majority of respondents were most comfortable discussing it with their mothers while being least comfortable with a male member of the family. Some respondent stated that they were not comfortable talking even to their mothers about their monthly cycle.

It obviously demonstrated that the respondents, for the most part, favoured online networking which could not possibly be completely trusted to know everything about such a critical theme like a monthly cycle. The respondents additionally added that since they were not given appropriate information at their schools level about this topic they needed to utilize different mediums which, however, would not be completely reliable, still they had no other alternative.

Another practice that ought to be taken care of is gender discrimination in providing knowledge in schools. It is the act of not giving the learning about the monthly cycle to young males and females together. In schools, either the topic of menstruation is overlooked by the instructors or is instructed just to females. In co-training schools, young males and females are taken to different classes so as to teach them about adolescence. The young males are instructed about the voice getting to be distinctly more profound, developing of pubic hair, augmenting of the trunk, developing of muscles, and so on. Though females are separately instructed about the menstrual cycle and in addition alternate changes that will happen in their body. In many circumstances, educators are additionally not comfortable while clarifying the procedure of monthly cycle. Every one of these demonstrations set an ideology in respondents about monthly cycle being a subject to be not talked about. This brings down their certainty level as well as makes them take after the customary convictions and limitations encompassing period.

There are a few media which are alluded to by kids nowadays. These media can be used to advise children about the feminine cycle too. In the event that the youngsters are educated about this from a youthful age, they would not consider monthly cycle as an untalked topic in the general public. This would not just help in expanding the level of mindfulness among youngsters about the female cycle yet will likewise help respondents pick up certainty, that they have a tendency to lose amid their periods because of the conviction of monthly cycle being taken a gander at as nauseating, messy or anything negative. Media can help in making youngsters mindful that feminine cycle is only a procedure that happens in each respondents' life every month for a specific number of years. This is a wonder which demonstrates the fruitfulness of a woman.

RECOMMENDATIONS

The issue of a lesser amount of literacy about menstruation needs a solution that could give the society a better perspective about it. Most interviewees agreed with the fact that menstruation is considered as a taboo topic in the society. Most of them hesitate to talk about it openly even to the male family members. This makes their menstrual days uncomfortable. They can be provided with comfort if the male family members are aware of the hormonal process instead of being ignorant.

Effective measures can be taken to teach children of both genders that menstruation is not a taboo but a natural process that every female undergoes from the starting of her puberty.

Providing knowledge during primary education can help in forming a child's positive outlook towards menstruation. Today in most of the well-established schools, the topic of menstruation is not given much importance or is not taught seriously. In co-education institutions males and females are advised to sit in different classes to study about their hormonal changes.

This practice needs to be changed. If the same practice continues, females will continue to feel that menstruation should not be talked about to males. This will further lower their self-confidence. Therefore, instead of celebrating their puberty they consider it to be a burden. They might consider themselves to be unclean during these days. Males also will become curious. This would make them inquisitive and they might inquire about this topic to their female counterparts indirectly issue. This might increase the discomfort faced by females. Therefore, if both males and females are given proper knowledge about menstruation they would be able to understand the biology behind the process. Getting a better view about the topic will help the males support females during their periods instead of creating awkward situations making them feel bad about their periods.

Most of the females get their periods between the age of 10-12. Whereas, mostly they are given formal education about it at the age of 14-15. Since no formal education is provided at their menarche the knowledge that the females receive is either from the older female family members or internet. In this case, there are high chances that they may receive incomplete knowledge about the topic. This can lead girls to follow some myths and social beliefs. Whereas if formal education is provided at formal level itself, the females will know better about it and will know the different aspects about menstruation.

In order to provide formal education to the children at primary level itself, a small portion of menstruation can be added to their curriculum. For example, in 4th or 5th standard, they can be given a required knowledge about hygiene maintenance during periods. This information should be provided with the same importance as knowledge of first-aid.

These days children are more interested in reading comics and hence comics based on menstruation can be added as a part of their curriculum. This would add up to their learning and will also help remove the taboo about periods.

Teachers are also needed to be given training in how to teach the topic of menstruation to the children that make them feel comfortable about the topic. Even while training teachers the male and the female teachers should be made to sit together in order to give them a chance to start feeling comfortable about the topic as only when they are comfortable they can present it to the children.

For the females who have graduated from school do not have a formal source of information about menstruation. Due to this they mainly depend on Internet or Social Media (such as Facebook or Youtube) to gain information about the various aspects in menstruation. These sources cannot be fully trusted and hence the knowledge gained from these cannot be 100 cent percent safe and correct. There is no specific online portal for providing detailed and correct information about each and every aspect on menstruation. This leaves females with no other choice than to go with the information available on the internet, as stated by the respondents.

For this reason, it is necessary for an operative online portal that is operated by experienced doctors who can provide valuable and detailed information about the various aspects of menstruation. This would help in providing the females with a trustful source of information to rely on. The online portal should be having a detailed and analyzed information and contacting ways through which the people can easily approach any doctor and ask for advice about any myth or problem that people have. This portal can be kept free for information and can be kept paid at low cost for an online consultation.

The solutions to this problem regarding unawareness can be solved through, comics, providing knowledge about menstruation in primary as well as secondary level, seminars held by NGOs, television programs focusing on the issue, session for teachers to make them feel comfortable about the issue so that they may teach properly without any taboo to the students, teaching male and female students together so that boys do not feel that the topic is being hidden from them and hence they become curious. They do not have full knowledge and a part of the knowledge can be dangerous as they do not understand what all the girls are undergoing and are not able to make them comfortable and relaxed.

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Analyzing Rural Health Care Services in Select Villages and Hamlets Around Pune City with Special Reference to Government Hospitals and Schemes

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ABSTRACT

Notwithstanding seven decades of Independence, India is yet to attain the goal of 'Health for All'. Human development indices are still below acceptable marks. India has been ranked 130 out of 188 countries in the United Nations Development's 2016 Human Development Index. The country has not shown any significant results in the improvement of health care services, especially in rural areas. The aim and objectives of this paper is to study the state of rural health care services in the country with special focus on villages and hamlets around Pune and stress the need for necessary course corrections. The paper is unique as no comprehensive study has so far been undertaken to improve the rural health services around Pune City. As the Modi Government has launched the National Health Policy, the paper seeks to fill in the missing gaps in research and contribute to knowledge and development of health care in the countryside.

Keywords: *Health for All, Human Development, Special Focus, Missing Gaps*

INTRODUCTION

A Picture of Neglect: Rural health services in India are passing through a period of stress and strain. Clearly, they are in an abysmal state of affairs [1]. The vivid illustrations in the media of Dana Majhi in Odisha's Kalahandi district carrying his dead wife's body over his shoulder for over a 10-km walk for cremation on August 25, 2016 [2]; Gati Dhibar, carrying his daughter's body, for 15 km to Pechamundi village from Odisha's Angul hospital in the absence of an ambulance [3], followed by similar stories in States like Uttar Pradesh and Telangana sum up India's dismal state of health services. Maharashtra may not have faced the Dana Majhi-kind of ignominy and humiliation. However, the quality of services imparted by Government Hospitals in rural areas leaves much to be desired.

THEORETICAL FRAMEWORK

Providing rural populace access to basic health care is the main focus of this paper. According to the Institute of Medicine, health care is defined as "…the timely use of personal health services to achieve the best possible outcomes" [4]. Uplekar and George (1994) opine that access to health care would depend on four factors: "availability, awareness, affordability and accessibility to health care services" [5]. In almost every developing country, rural health is an issue of serious concern.

Lisa Bourke *et al* (2012) provide a conceptual framework for understanding rural and remote health in Australia [6]. Essentially, the framework consists of six concepts: geographic isolation, the rural locale, local health responses, broader health systems, social structures and power. Viewed through Gidden's theory of structuration, the framework provides a range of stakeholders with a guide to understanding rural and remote health. Carole Reeve *et al* (2015) give a framework for a comprehensive health service evaluation and monitoring [7]. The framework includes Donabedian's three domains of structure, process and outcomes to determine health service performances in Australia. These, in turn, depend upon sustainability, quality of patient care and the determinants of health. Alfred Coleman and Mary F. Coleman (2013) use the Activity Theory Framework to examine the e-health readiness assessment in South Africa's hospitals and other health care institutions[8].

People across the globe do face problems in getting basic health care. The poor heave a sigh of relief only when they overcome the obstacles. Penchansky and Thomas (1981) call these obstacles as "barriers" which, according to them, have five dimensions: availability, accessibility, affordability, acceptability and accommodation[9].

There are six theoretical models on health care services. These are, namely, the Health Services model (Kohn and White, 1976) [10]; the Health Behavioral model (Aday and Anderson, 1974) [11]; the Interaction model of Client Health Behavior (Mathews, S.K. *et al*, 2008) [12]; the Empowerment theory (Koroloff and Elliot, 1996) [13]; the Health Belief model (Rosenstock, 1966) [14]; and the Equity of Access Model (Adey and Anderson, 1981) [15]. Of them, the specific models which are relevant to this paper are the Empowerment theory and the Equity of Access model. The Empowerment theory stands for disadvantaged and low-income families which depend upon family associates and friends who help them reduce "barriers" such as respite care, transport, recreational opportunities, utility payments and access to health care services. Similarly, the Equity of Access model is believed to exist when services are distributed on the basis of people's need for them. The Health Belief model, defined as a Value Expectation theory, applies to factors that influence someone to take precaution. The components include "perceived susceptibility, perceived severity, perceived benefit, perceived barrier, self-efficacy and other factors such as socio-demographic variables, age, sex, income, etc" (Rosenstock, 1966)[16].

LITERATURE REVIEW

There is no dearth of literature on rural health care in India. K. Sujata Rao's volume, *Do We Care? India's Health System*, provides important insights into the working of the rural primary health care operations in the country (Rao, 2017) [17]. S.L. Goel's book, *Primary Rural Health Care System and Hospital Administration* deals with the working of primary health centres (Goel, 2008) [18]. Its focus is more on hospital administration than on rural health care – the subject for research in this paper. The volume *Jamkhed: A Comprehensive Rural Health Project* [19] by Raj Mabelle and Dr Arole Mabelle is a valuable resource on rural health infrastructure in Maharashtra's Ahmednagar District.

The researcher has also consulted scholarly journal papers. Foremost among them is the paper, "Difficulties in Accessing and Availing of Public Health Care Systems Among Rural Population in Chittoor District, Andhra Pradesh" (*International Journal of Medicine & Public Health*, 2015) [20]. He has also consulted Brijesh Purohit's paper, "Health Care System Efficiency: A Sub-State Level Analysis for Orissa" (*Urban and Regional Development Studies*, March 2016)[21]. Another good paper is, "Mapping Private- Public- Partnership in Health Organizations: India Experience" (*International Journal of Medicine and Public Health*, 2015)[22]. The researcher has also gone through Dr. K. Srinath Reddy's newspaper articles over the years.

METHODOLOGY

The methodology adopted in this research paper is primarily exploratory and descriptive. The researcher seeks to analyse the health care services in rural India with special focus on a few villages near Pune. He has conducted an Opinion Survey of 125 people through the questionnaire method to examine the current problems of rural health care in general, including the performance of programs such as the National Rural Health Mission (NRHM), the Janani Shishu Suraksha Yojana (JSSY) and the Mahatma Jyotiba Phule Jan Arogya Abhiyan (MJPJAA) in Pune's villages. The researcher visited a few villages near Symbiosis International University's Lavale campus in March, 2017 and interviewed villagers in SusGaon, Nande, Chande, Pavananagar, Pavana Dam and Pirangut.

Implications: In the light of the new National Health Policy cleared by the Narendra Modi Government on March 16, 2017, the implications of the current research work are immense: they will make a signal contribution to the nation. These are expected to influence the decision-making process and help improve the health care services. The paper is unique as no comprehensive study has so far been undertaken to improve the rural health services.

Limitations: The sample size of the questionnaire being small, the researcher has analysed only a representative of the villages; he intends to expand the scope of the study in due course.

VICTIMS OF APATHY

Shortfall of PHCs, Staff Affecting Health Services: Unfortunately, even though the number of patients visiting rural hospitals in Maharashtra has been increasing over the years, there is shortfall of staff in different categories in these hospitals. As is illustrated on Table 1

Table 1. Rural Health Infrastructure in Maharashtra

	Particulars	Required Strength	Current Position	Shortfall
1.	Sub-Centres	13410	10580	2830
2.	Primary Health Centres (PHCs)	2189	1811	378
3.	Community Health Centres	547	363	184
4.	Health Worker (Female) /ANM at Sub-Centres& PHCs	12391	22135	No shortfall
5.	Health Worker (Male) at Sub-Centres	10580	6665	3915
6.	Health Assistant (Female) at PHCs	1811	2413	No shortfall
7.	Health Assistant (Male) at PHCs	1811	2947	No shortfall
8.	Doctors at PHCs	1811	2760	No shortfall
9.	Obstetricians and Gynaecologists at CHCs	363	180	183
10.	Pediatricians at CHCs	363	181	182
11.	Total specialists at CHCs	1452	514	938
12.	Radiographers at CHCs	363	85	278
13.	Pharmacists at PHCs and CHCs	2174	2238	No shortfall
14.	Laboratory Technicians at PHCs and CHCs	2174	1285	889
15.	Nursing Staff at PHCs and CHCs	4352	8154	No shortfall

Source: Ministry of Health and Family Welfare, Government of India

The rural health infrastructure is not entirely encouraging (Sharma and Narang, 2011) [23]. According to the Government of India's Ministry of Health and Family Welfare, there is shortfall of a whopping 2830 Sub-Centres, 378 Primary Health Centres and 184 Community Health Centres in Maharashtra (Government of India, 2017) [24]. Though there should be a Primary Health Centre (PHC) for a population of 30,000, the PHCs are forced to cater large populations, imposing a huge burden on the facilities available. Most Sub-Centres and PHCs have Health Workers (Female)/ANMs, Health Assistants and Doctors, but there is a shortfall of Obstetricians and Gynaecologists, Pediatricians, Radiographers and Laboratory Technicians.

Of the 360 rural hospitals in Maharashtra covering 75 per cent of the population, Pune district has 25 hospitals under a civil surgeon with immunisation, out-patient department (OPD), pathology, gynaecology, autopsy, ambulance and other facilities. But these are inadequate and force poor patients to knock the doors of private hospitals which charge exorbitant fee.

Moreover, though the number of cardiac and cancer patients has been increasing, these hospitals have no facilities to treat them. As a result, covering long distances, the patients visit Pune's Sassoon General Hospital and Pimpri Chinchawad's Yashwantrao Chavan Hospital. The Aundh General Hospital in Pune city is a multi-speciality hospital. It has 300 beds with 14 speciality wards. However, it is not a super-speciality hospital and critical cases are referred to Sassoon General Hospital or private hospitals. The Aundh General Hospital has treated a good number of OPD patients: 2,86,228 in 2014-15, 3,22,965 in 2015-16; and 1,58,595 in 2016-17 (Bhonde and Paraste, 2016) [25]. Since the number of patients to Aundh General Hospital dropped in 2016-17, it should be upgraded to a super-speciality one.

RESULTS

Private Hospitals the Preferred Destination: What the researcher witnessed during his visit to the villages was appalling. Unlike private hospitals, Government hospitals do not have adequate infrastructure. Two kilometers away from Pirangut lies Bharati Vidyapeeth Rural Health Centre in Lavale Gram. This hospital caters to about 40,000 people in 11 villages. Here the State Government's norm of 30,000-limit for a Primary Health Centre has been violated.

Shyam (42), a construction worker, there is no political will to upgrade the facilities or open another PHC. Prakash (40), an assistant at a sugarcane juice shop, said the government is not interested to help poor people. He says, if he visits a Government hospital, he has to spend on transport and will lose his daily wage. Figure 1 shows the results of the Opinion Survey:

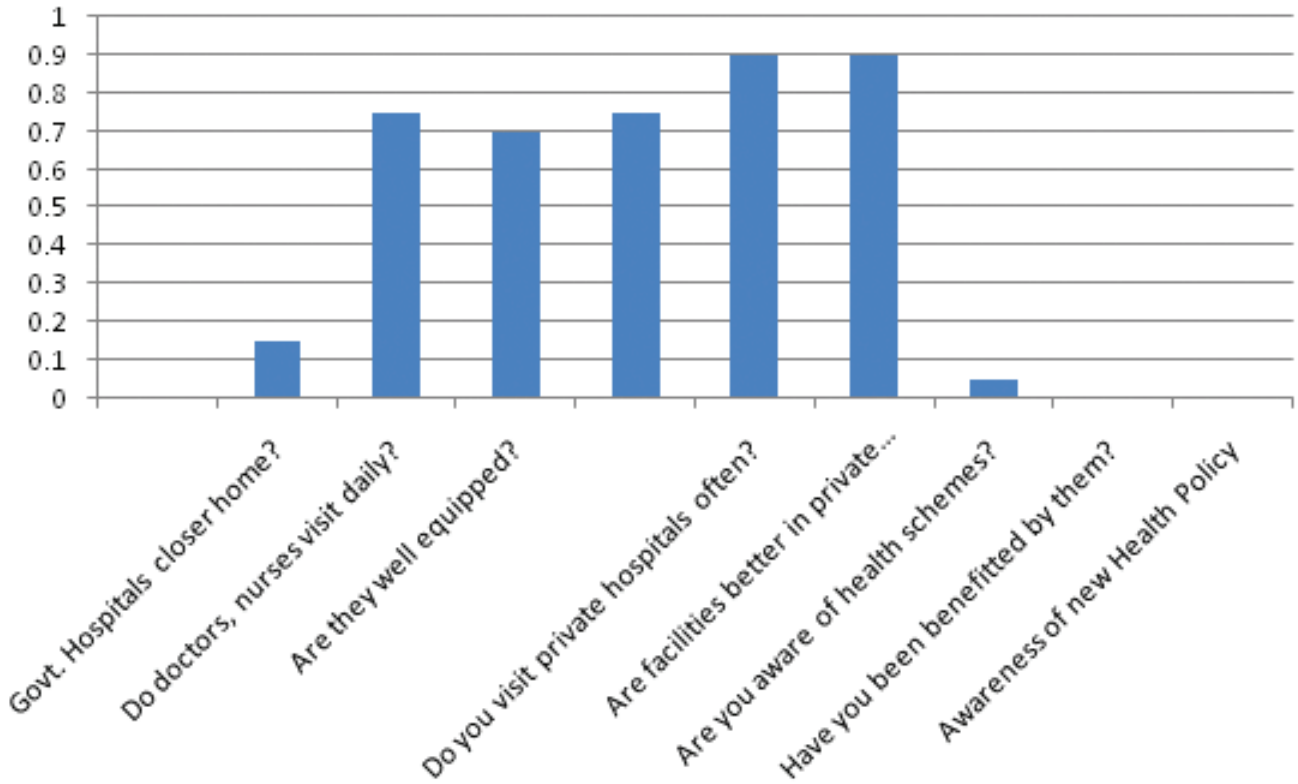


Figure 1. Opinion Survey on State of Government Hospitals in Pune's Villages

Public Hospitals Far Off Homes: The researcher interviewed 125 villagers with a questionnaire. An important finding, as illustrated on Figure 1, is that 90% of those interviewed told this researcher that they preferred private hospitals over Government or public hospitals. Their utmost concern was the near-absence of facilities in public hospitals. While 75% admitted that the doctors and staff do attend public hospitals everyday, 90% said their preference for private hospitals was because of the facilities and prompt treatment with a helpful attitude of the doctors and the staff towards them. 70 per cent said public hospitals were well equipped. Only 15% said public hospitals were not too far off their homes. Lakshman (28), a cloth shop attendant in SusGaon, said that one reason that prevents him from going to a public hospital is the long queue which, he said, is a waste of time and money. Even for checking blood pressure and sugar levels, one has to stand in the queue for hours in a Government hospital, complains Mangu Singh (38), a sugarcane juice seller. This is not the case with private hospitals, he says.

Gauri Chandare (25), a housewife, says she never visited a government hospital which is quite far off. She lauds the private hospitals for better treatment. She said medicines should be made freely available to the poor as they were expensive in the medical shops. She says, Government hospital doctors, instead of supplying medicines free of cost to patients, issue long prescriptions with an advisory to buy them in specific medical shops!

Government hospitals are also far off the village and it becomes difficult for one to visit them. 75 per cent of respondents said public hospitals do have ambulance, stretchers and wheel chairs. However, for those living in villages like SusGaon, Nande or Chande, it will take some time for the ambulance to reach these villages where as ambulances of private hospitals are promptly available, of course, for a price. One can dial 108 for a government hospital ambulance which provides free service. Dr. Niranjan Patil, Medical Officer, Family Doctor Clinic, Symbiosis Centre of Health Care, SusGaon, says while government ambulance has all

facilities, including oxygen, private ambulances are merely meant for transporting the patients to a hospital.

Lack of Awareness on Programs: A disturbing trend in the Opinion Survey is the lack of awareness on the part of most villagers on the various health programs launched by the Central Government and the Government of Maharashtra. Only five per cent of the villagers interviewed said that they knew of the National Rural Health Mission (NRHM). Yet, they are ignorant about its merits. They said they had no knowledge about the Maharashtra Government's two other programs -- the Janani Shishu Suraksha Yojana (JSSY) and the Mahatma Jyotiba Phule Jan Arogya Abhiyan (MJPJAA).

The health care facilities available in Maval Taluka, 65 kilometers from Pune, leave much to be desired. People residing near Pavana Dam hardly have any access to health care. Only two Government hospitals serve about 15,000 people in this Taluka that comprises 22 villages. Each hospital has only 30 beds to offer. The near-absence of transportation facilities has further augmented health problems in the villages that lie on either side of the Pavana Dam.

The Maharashtra Shasan Aarogya Seva Grameen Rugnalay is one of the two hospitals in Pavananagar. It is ill-equipped and inaccessible to people residing a few kilometers away. According to Dr. Vishwas Yevle, senior doctor, the hospital does not have the facility to bring patients to the hospital even in case of an emergency. "We have only one ambulance that is meant for only taking recuperating patients to their respective homes", he says.

"Absolute Neglect" of Hygiene: Pavananagar is a typical example of neglect. Dr. Sanjay Chaudhary says there is an "absolute neglect" of hygiene among villagers leading to a number of ailments. Diarrhoea, scabies, worm infections, vomiting and several such illnesses have become common in households. Dental problem is a common occurrence. While Government health programs concentrate mainly on preventive aspects by ensuring vaccination, immunization drives, vasectomy and tubectomy camps, and pulse polio programs, it is private or self-practising doctors who handle the curative measures. There are five private clinics in this village.

The Modi Government's new National Health Policy has many positive indicators aimed at providing access to all healthcare facilities across the spectrum. However, the respondents are unaware of it. They did appreciate its objectives when the researcher told them. However, they were skeptical to what extent the policy objectives will be implemented on the ground. Dr. Amul More (30), doctor of Bighnahotra Speciality Hospital, SusGaon, says, the Centre could play a crucial role on health; but Health should continue to remain in the State List only.

SYMBIOSIS CONTRIBUTION

Reaching Out To The Needy: The Symbiosis Society has been playing a redounding role in providing timely medical facilities for villagers in and around Pune. The Symbiosis Centre of Health Care (SCHC) in SusGaon, which helps zilla parishad students and anganwadis, among others, is open even on Sundays and national holidays. Every second Friday of the month, SCHC has a vaccination program, anti-natal program and an awareness campaign. According to Dr. Niranjan Patil, in-charge doctor of the clinic, a nominal fee of Rs 10 is charged from every patient. The mobile medical clinic of Symbiosis goes to interior pockets near Lavasa, Pirangut, Nande and Chande to reach out to people.

Journalism students of Pune's Symbiosis Institute of Media and Communication (SIMC) have been visiting villages in Pune District from time to time. As part of the Rural Survey Project under the R.K. Laxman Chair Professor Initiatives, Faculty of Media, Communication and Design, Symbiosis International University, spearheaded by the late Dr. Dileep Padgaonkar, the students toured these villages for socio-economic survey and reported for *Ink*, an in-house publication. The initiative is indeed laudable.

DISCUSSION

Judicious Spending, Greater Accountability: The International Code of Ethics states that a medical doctor should not be influenced by motives of profit and provide emergency care as a humanitarian duty. The Supreme Court held that Article 21 of the Indian Constitution makes it obligatory for the State to provide emergency care, a duty it cannot abdicate on grounds of financial stringency (Desai and Chand, 2007)[26]. But then, emergency care is a part of the basic health care services package. Thus, both on ethical and legal grounds, people

have a right to expect basic health care, irrespective of their economic condition and ability to pay.

Public sector expenditures on health care in India have been low (Patil *et al*, 2002)[27]. However, as experience of other countries show, the quantum of health spending is only one parameter. Of equal importance is having a strategy based on getting the real value for the money spent. For example, in China, health policy initially consisted of four main components: prevention; combining western and traditional medicine; combining healthcare with mass movements; and concentrating on rural areas. This enabled them to develop a cost-effective and need-based strategy.

China spends 3.5% of its total GDP on health; its achievements under critical indicators such as life expectancy, infant and child mortality and female literacy are more substantial than India's. The issue, thus, is not only a higher fund allocation on health but also judicious spending and optimal utilization of available resources (Rao, 1996)[28]. With increasing pressure on resources, public interventions must be defined well and administrative mechanisms formulated properly ensuring greater accountability of the health system tightened and a strategy firmly directed to the strict realization of a few but specific goals articulated (Agarwal and Sangar, 2005)[29].



Figure 2. New Health Policy Focus Areas: Accessibility, Affordability and Equity

The Narendra Modi Government's new National Health Policy to improve the health care services in the country is a good beginning. As illustrated on Figure 2, its main focus is on three areas: Accessibility, affordability and equity (Nadda, 2017)[30]. It is bound to usher in new vistas of policymaking in health governance. Prime Minister Narendra Modi has called the new policy "futuristic" (*Financial Express*, 2017)[31]. However, the Modi Government is silent on making health a right and shifting Health from the State List to the Concurrent List. Indeed, the Centre mooted the National Health Rights Act in its 2015 draft policy. Union Health Minister J.P. Nadda told Parliament that the new policy will follow an "assurance-based approach" on the implementation of the new policy (*The Hindu*, 2017)[32].

CONCLUSION

Addressing Issues of Equity and Quality: The ultimate goal of any policy or program should be to help the poor. Public policy must begin to address the issues related to equity and quality.

We need to provide a referral system that will help regulate patient flow so necessary for reducing the gross distortions in the system. Referral hospitals deserve full autonomy.

The Centre and the States should popularize their healthcare policies and programs at the grassroots level. As the study by this researcher reveals, the villagers have no idea of these programs at all, including the new National Health Policy.

No reform is possible in isolation – it needs the active participation of the providers of healthcare, people's representatives and administrators.

This researcher is convinced that if public hospitals are privatized, people will have no access to "affordable care". K. Sujata Rao aptly said that "Government intervention is an imperative, not a choice" (Rao, 2016)[33].

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Barriers to Recuperating Patient Safety and Quality Care in Health Care System in India: Need for Compliance and Comprehensive Health Care Act

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ABSTRACT

Patient safety is the fundamental principle underlying quality health care meted out by health care professionals and organizations. Considering the insufficient information on the existing challenges to patient safety and the precipitating factors of unsafe medical practices at primary healthcare levels in India, this study was conducted to redesign the multiple interventions and formulate an alternative patient-oriented healthcare model with a policy and procedural change to facilitate patient safety. In-depth interviews and focused-group discussions were conducted in primary healthcare centers in Western Maharashtra. Data were analyzed using qualitative research methods by adopting the "health system approach and thematic analysis". A comparative analysis of patient safety measures and procedures used in UK was carried out to suggest recommendations. The research findings in terms of identification of barriers to patient safety and providing an alternative healthcare framework focusing on integration of health care system and patients' rights by restructuring the health care system, using standardized procedures, regulatory framework, grievance redresses mechanisms, training as well as clinical audit are enlightening for policy makers, healthcare officials, academicians, NGOs and other civil society organizations. The recommendations, if adopted, definitely guarantee the right to health for all, especially to the disadvantaged sections of the society.

Keywords: *Barriers, Patient safety, Health care system, Health care act*

INTRODUCTION

The goal of any health care institution in a country is to provide safe, high quality health care services to the patients. Patient safety is the basic principle and cornerstone of quality health care. The low and middle-income groups in India and in other developing countries depend on public health centers for meeting their health care needs. However, in a number of cases, misdiagnosis, health care associated infections, counterfeit pharmaceuticals or unsafe injection practices and irresponsibility of the health care staff are reported vividly. Due to this scenario, policymakers, public health officials and researchers interested in improving health outcomes in low- and middle-income groups have incessantly focused on developing multiple interventions to improve patient safety. The patient safety paradigm is looking at a system of care delivery, which prevents errors and is built on a culture of safety by establishing a safeguard system involving health care professionals, organizations and patients. Patient safety practices are expected to reduce the risk of adverse effects related to exposure to medical care across a range of areas including those related to diagnosis and existing clinical and surgical practices, blood transfusion, injections, health care waste management and safe use of medicines and safe environment of care. These practices also include awareness, attitude, adaptability and ability of health care providers in mitigating the risks of unsafe care. There are multiple country specific concerns to patient safety in the public health care system due to lack of baseline data, lack of awareness, unavailability of a health care system spearheading patient safety and deficiency of dedicated financing. The medical profession is regarded as the most prestigious and pious profession in India. A doctor is seen as a God by patients and is honored a lot. In ancient India, the medical practitioners had a great responsibility on their shoulders towards their patients. They had to take an oath known as Charka's oath, which was the depiction of the highest quality of professional ethics. During the reign of King Asoka, public health was given a lot of importance and hospitals were built

by him with rules laid down for the attendants and the physicians. The oldest codified laws that were published for public at large are known to be Code of Hammurabi (2000 BC). They impose the highest duty of care on a medical practitioner; the breach of which could even result in amputation of limbs. The punishments were stringent for malpractices. In the 5th Century, 2500 years ago, a Code for Medical Ethics, called the Hippocratic Oath, was adopted that was regularizing medical profession for centuries together. The Declaration of Geneva adopted by World Health Organization is the modified version of this Oath. This is now accepted as the international code of medical ethics worldwide.

Patient safety culture can refer to "the product of individual and group values, attitudes, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety programs". While developing safety designs and reporting mechanisms for any situation or circumstance that threatens or potentially threatens the safety of patients or caregivers, the health care system should be able to view the occurrence of errors and adverse events as opportunities to make the health care system better. WHO member states agreed on world Health Assembly the resolution on patient safety, which facilitated the patient safety culture in health system. After signing the India Pledge on Patient safety, in 2006, Ministry of Health and Family welfare of Government of India undertook Hospital Patient Safety Initiative on a priority basis and appointed patient safety committees in some of the tertiary hospitals. Studies have found that patient safety climate is associated with positive outcomes such as greater error reporting by physicians, lower rates of adverse events, lower mortality rates and lower rates of readmission.

Article 47 of the Indian Constitution imposes a primary duty on State to improve public health. The State is responsible for providing public health care at the minimum possible cost to all without discrimination and is liable to take necessary steps in order to improve and regulate the health care sector to make it available to every person. The government in Maharashtra, however, seems to be insensitive towards the people as there is no law to regulate the Medical Sector, especially with reference to patient safety. There is also no provision that mandates any training for physicians for maintaining patient safety. Different corporate houses and charitable trusts have set up many private hospitals. The attitude of the government suggests that patient safety is the priority of only the private partners and not the public hospitals. In the era of medical tourism, the doctors' priorities have changed from 'patient' to 'profit', where due to the time and money required for building up a safe and secure patient safety environment, safety to the patients is still a question. In the words of wisdom of Florence Nightingale, "The very first requirement in a hospital is that it should do the sick no harm"

PATIENT SAFETY CONCEPTUAL FRAMEWORK

The conceptual outline of patient safety includes identification, detection and reduction of risk, incident recovery and system resilience; all of which occur at any point within the patient safety framework. Patient safety parameters are entrenched in structure, process and outcome of any health care delivery system. The patient safety is rooted in Incident type, detection, patient characteristics and patient outcome, organisational structure, process and outcome, the weightage of patient safety culture in medical practice as well as the legal liability[1]. There are contributing, mitigating and ameliorating factors of patient safety initiatives in a health care system. Objective of this study is to identify the potential patient safety issues or hazards in the health care settings and the research is focused on the contributing factors which are the circumstances, actions or influences that thought to have played a part in the origin or development of an incident or to increase the risk of an incident[2]. This research identified the contributing factors which act as barrier to patients' safety initiatives in India as well as the mitigating factors in public health care settings in Maharashtra. As health care staff are the key stakeholders in patient safety measures, this research is unearthing the awareness levels, availability and actions taken by the health care staff in their health care settings. Through a focussed group discussions the study is analysing the opinion of the health are staff about the available and ideal responses to unsafe care and existing and ideal responsibilities related to patient safety and their attitudes about potential areas for expansion of patient safety[3].

A quantitative analysis of providers in tertiary care hospitals in Delhi highlighted that while the participants agreed that improving safety is vital, they were unaware

of the safety intervention at their institution. An analysis of the existing legislations for health care for patient safety reflects that they are very scarce as compared to the size and problems in the health care sector. Lack of good quality data or inability to generate data related to patient safety is challenging to the safety efforts[4]. The information on the existing challenges of patient safety measures and practices and the precipitating factors of unsafe medical practice at primary health care levels in India was insufficient. Hence, this study was conducted to assess the existing legal interventions and its success level in creating a patient safety culture. It also aims to improve the understanding of the providers' perception of patient safety and challenges to enhancing care in public hospitals.

MATERIALS AND METHODS

A comparative analysis of patient safety measures, procedures and legal intervention existing in UK and India was carried out to assess the standard, gaps, interventions and concerns through a comprehensive review of published literature. In-depth interviews and focused group discussions were conducted in primary health care centers in western Maharashtra. Using convenience sampling, 12 doctors and 23 nurses participated in five focused group discussions in two primary care clinics, one secondary care center and two tertiary hospitals. Participants were informed about the purpose of the research, their responses were recorded in confidence, and every participant's informed consent to participation was taken. Focused group discussions were facilitated by using a prototype guide, which helped as a catalyst to direct discussions about their perceptions of the hurdles to patient safety in their practice milieu. During the focus group discussions held in separate rooms, only the participants and researchers were present. In the secondary and tertiary health centers, the participants were limited to doctors and nurses but in primary health centers, all members of the health care team participated. Discussions ranged from 50-90 minutes and the participation of facilitators was limited to ensuring that the discussions were active and focused[5-6]. Discussions were conducted in both Marathi and English, recorded on tape, transcribed and translated. Each discussion was initiated with the main question:"To what degree do you think patient safety is a problem in your hospital?" Follow-up questions were classified under three groups including (a) Participants' opinion of the available and ideal responses to unsafe care, (b) Participants' beliefs about existing and ideal responsibilities for patient safety, (c) Participants' attitudes about potential areas for expansion of patient safety. Facilitators did not give out the narrow definition of patient safety and motivated the participants to identify specific localized factors at the clinic-patient level that contributed to unsafe care for patients. The transcripts from the five focused group discussions were analyzed by using thematic analysis approach. This process involves generating a list of codes, applying these codes to the transcripts and obtaining a thematic framework from the codes by identifying recurring themes through tabulation.

RESULTS

An analysis of patient safety measures in the United Kingdom reflects that an independent organization, General Medical Council, is set up to look after the matters pertaining to patients, medical practitioners, including their education and up-to-date training. The Organization consists of 12 members out of which 6 are registered medical practitioners and 6 are lay persons and all of them are directly appointed by the Privy Council. The objective of the organization is to enhance the standards of medical practice by revalidation and the body is responsible for registering the medical practitioners, for setting up standards for their functioning and for addressing patient related issues. The entire quality assurance framework revolves around the patient being the central focal point of medical practice without any interventions. The council ensures the implementation of the standards prescribed through monitoring, regular visits and Regional Review Reports. The Regional Liaison Service that is offered by the council addresses issues related to both doctors and medical students through interactive sessions which help in invoking the need of maintaining standards and inculcating in them the role they can play in reporting the compromises to patient safety. All these practices help in developing a sense of responsibility and ethics towards their patients.

An integrated health policy and related legal framework to enhance the concept patient safety is absent in India. A comprehensive analysis of the existing health legislations pertaining to patient safety in India reveals that the concept of patient safety and patient

safety culture is not favored even though mention about the rights and duties of the health care staff are mentioned. For example, Indian Penal Code, Section 92 of IPC provides that when a person causes harm to another person for his benefit in good faith, though without the consent of such person or his relatives etc. he shall not be liable for any offence if the other person suffers because of such act. Section 93 saves a person from any criminal liability for any harm caused to a person due to communication made to him, if such communication was made in good faith for the benefit of such other person. To prosecute a physician under the criminal law, it must be proved that the physician did something or omitted doing something that an ordinary prudent physician acting within his senses would not have done or would have done. The Courts in India have laid down that being the noblest profession the medical practitioners are on different footing. Merely because a person has alleged a serious offence under sec 304A of the Indian Penal Code does not mean that the police must arrest the doctor. The guidelines laid down by the Court in this respect are very clear. The investigating officer and the complainant are not the experts in medicine thus making it important for the investigating officer to obtain an opinion from a third party who is an expert in that respect and who can give an unbiased opinion. The act done by the physician must be of a 'gross' or 'rash' or 'negligent' nature and must be proved by the complainant to be so. Consumer protection Act is a relief to the patients in which consumer forums are the most favored adjudicating bodies when it comes to medical negligence cases. The District, State and National forums have played a very important role in establishing the liability of the doctors for medical negligence. It is the duty of every doctor to treat a patient in case of emergency and he cannot deny it merely because the patient or his relatives have failed to pay the fees. Denying such medical aid is a deficiency in service that needs to be reprimanded. The Commission in this case reiterated that the doctors, for the sake of humanity and noble profession, should not deny services in emergency. Where a doctor fails in performing his duty of communicating the facts and alternative remedies available to a patient and where the patient suffers damage due to it, he is entitled to compensation. But the liability under the Consumer Protection Act is civil in nature.

Rules laid down by the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 clarifies duties and responsibilities of the physicians in general, towards patients and towards society. It also lays down the duties of the patient to maintain confidentiality during prognosis and ways to report unethical conduct in medical practice without fear. However, the above-mentioned rules are not sufficient to deal with the current health care situation where health care is no more regarded as social service but as an enterprise to make profits. An analysis of the Medical Council of India highlights that council is focusing more on medical education rather than enforcing the ethical standards. A Preliminary Report of the Committee on the Reform of the Indian Medical Council Act, 1956 emphasized that for effective working of the Council it must be restructured in order to have independent bodies looking into independent portfolios. The Committee has suggested that there should be different boards for dealing with registration and licensing of the doctors and clinical establishments and those for looking into the ethical standards to be adhered to by the doctors. In the absence of MCIs role in checking malpractices in the medical profession, an independent body is essential for monitoring and controlling the medical profession in totality.

Focus group discussions on Patient Safety: Contributing factors: Results

The analysis of the interactions of 12 doctors and 23 nurses reflects around 40 unique mentions of barriers to patient safety. These barriers were categorized into five major themes.

Lack of patient safety training: The doctors and especially the nurses reported inadequate training and lack of clinical experience in patient safety measures. They also reported lacunae in patient safety practices related to hand hygiene, communication system, hospital associated infections, Injection safety, transfusion safety and biomedical waste management. Other reported medical complexities causing health care errors in all the levels of health care settings included time pressures, fatigue and burnouts, complicated technology and design.

Patients' knowledge levels: Participants perceive that patients' behaviors and their attitudes were major barriers to safety. Some patterns included not following medical instructions, over use or overdose of medicines, sudden stopping of the medicines, shifting to Ayurvedic

and Homeopathic treatments without informing the Allopathic doctor and a consequent failure to follow up. Also observed were improper medicine-food interaction, fear of blame from the health care staff for non-compliance, demand for injections, antibiotics for viral infections, impatience to wait for the medicine to respond, use of over-the-counter medicines or substitutes without prescription and use of expired medicines as well as not reporting their past medical allergies and adverse reactions.

Limited resources: Participants described inadequate staffing, poor infrastructure facilities in the clinic, and insufficient supply of resources as challenges to patient safety, particularly in primary health centers. Seating arrangements, clean toilets, provision of clean drinking water, outdated medical equipment, need for a separate room for counseling and ventilated space at the centers are some of the issues that need to be addressed. Less number of hospital beds, overcrowding, lack of nurses and other staff leads to a poor quality treatment of the patients. Participants expressed that overcrowding also leads to cross infections, communication delay and absence of emergency care in clinical settings.

Fragmentation of the health care delivery system: Physicians and nurses opined about the absence of quality assurance system for equipment or drugs. Due to the shortage of stock of drugs, the patients are forced to buy drugs from outside. The medicine may come in different constitutions, resulting in the consumption of wrong drugs thereby leading to overdose. Many doctors and nurses expressed that the drug response of the medicine is the only indicator of quality to them as there is no other mechanism to ensure quality control. A holistic approach to the individuals and families is not possible because of the excessive specialization of health care providers and the thin focus on disease control program. Participants from the primary health care services agreed that the poor and the marginalized are fragmented and under resourced leading to fragmented care in the current health care delivery system along with a fragmented health care information system.

DISCUSSION

Even though the concept of patient safety is too broad, the contributing factors and mitigating factors of patient's safety in India is apparent from this study. In addition to the lack of patient safety training, professionalism, patients' knowledge levels and fragmentation of health care system, other major barriers reported were professional hierarchy, poor communication levels, lack of administrative sanctions and lack of awareness about the importance of safety among the staff and patients[7-9]. Lack of dedicated financing, lack of baseline data and checklist, absence of event reporting Performa, lack of monitoring agencies and process correction studies, systemic issues, improper protocols and best practices are also considered as barriers to patient safety in this study. Organizational structure and system inefficiency is also a relevant contributing factor. Medical Council of India needs to take proactive role and redesign its curriculum that fails to consider the new technological advancements in health care. Developing a way forward for patient safety initiatives in India requires baseline data collection and reporting systems in health care centers in addition to the development of patient safety checklists and tools. By enabling a framework for development, patient safety must be integrated into the existing training programs for the health care staff with the curriculum components informing them about the complexity of the system and system approach to errors, clinical risk management and communication and quality improvements by implementing effective reporting systems[10].

Organizational development in India demands identification of the patient safety priorities, capacity building of health care workers, adverse event reporting systems, implementing checklist and monitoring Performa for patient safety and establishment of a patient safety committee comprising representatives from the patients and community. In the current health care settings, the increasing error incidents are due to the system's failure in encouraging leadership and the absence of an integrated health care policy to ensure standard procedures, communication training and resource availability. Patient safety can be achieved only by implementing the international quality management standards and adopting accreditation practices in Indian health care settings. In India, the JCI (Joint Commission International) is an international body working to improve patient safety and is valued in global health care. NABH is another body of quality council in India that sets standards for hospitals and health care institutes. Many times, these accreditations are not a guarantee for quality assurance and patient safety but

merely a part of a marketing strategy for many private hospitals. The accreditations are not mandatory but a voluntary certification and many healthcare institutions are not working on it. As far as public health centers are concerned, the major causative factors are lack of infrastructure and health care staff, inadequate clinical procedures, multiple overlapping of legal frameworks and insufficient monitoring and evaluation of its functioning[11-13]. On the other hand, in private health care centers, absence of standardized procedures, inadequate regulatory framework, lack of accountability, profit-driven motives are the major contributing factors as barrier to patient safety.

Conclusion and recommendation: In India, we need to establish a medical culture that will not only emphasize on capacity building and curriculum development based on patient safety, but also on clinical protocols, timely reporting, regular monitoring, root cause analysis to provide preventive and corrective measures to mitigate errors. A patient faces multiple difficulties which require situational analysis to address causative factors of resource constraints, system dynamics, patient's knowledge levels and institutional policies. India needs an independent body like the one in the United Kingdom to ensure that uniform medical standards are adopted for patient safety. It is imperative to reform the structure and functioning of the Medical council of India and to revise the proposed National medical commission bill, 2016. The bill, in its present avatar, does not contain any strict regulatory and enforcement practices and is not very emphatic on the quality and skills of doctors. The NITI Aayog committee has accepted the recommendations and is positive about the formation of two bodies: one, an advisory body; the other, a policy making commission to supervise the four autonomous boards. However, there is also a need for a separate board of medical ethics to investigate and prosecute cases of unethical practices of the medical practitioners. It is true that the accreditation of clinics, pharmacies, chemists and hospitals is essential. Nevertheless, what matters in accreditations is not only the hospital infrastructure, equipment and number of doctors but also the quality of care, safety and security of the patients, which requires regular monitoring to assess the quality of care through safety precautions and clinical audit based on specific guidelines. It should be made mandatory for every clinical establishment, barring private practitioners, to have counselors appointed to guide the patients regarding their illness, treatment, benefits and side effects and to ensure proper follow-ups.

It is observed that in the absence of the grievance redressal forum within the regulatory framework, patients often resort to the consumer forum thereby creating conflict of interest between doctors and patients. Patient's grievances are not only related to medical errors, but also related to being denied emergency care services and the right to access medical records, to take a second opinion and to informed consent in the context of clinical trials. Rather than accepting the status-quo, consumer empowerment through awareness programs, through the social media is vital to educate them about right practices, patient's rights and duties as well as existing forums for grievance redressal. Today, India not only produces medical equipment, devices and vaccines but also is involved in the regulation of drugs and medical devices. Therefore, an independent scrutiny from the perspective of quality control and patient safety is desirable. It is necessary that a patient safety committee be established in every health care center that will consist of a medical superintendent, a microbiologist, a nursing superintendent, a pharmacist, a social worker, a legal expert, and a patient representative. It will ensure the accountability of the health center and monitor the clinical and safety procedures as per the standardized guidelines. The need of the hour is an independent medical forum that includes all stakeholders with a strict regulatory framework with standard treatment guidelines, reporting and monitoring, regular clinical audit with standard charter of patient's rights at national, state, district and institutional level to integrate the health care services. Health care delivery system with positive outcome to both patients and organizations in India, requires revamping of organizational structure, process and practices with a standardized and comprehensive health care policy and law with patient safety as its core principle. A strong political backing for this integrated health care policy mandate as well as professional leadership through systematic and focused approach by the implementing and monitoring agents that instills ethical and patient oriented culture in India, with strict legal mandate is indispensable for patient safety efforts in India.

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An Effort Towards Achieving Watertight Compensation System for Clinical Trial Injuries in India

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ABSTRACT

Introduction/Background: Clinical trial of any drug, device or vaccine whether new or already marketed, is associated with risks and burdens. There is need to protect participants who volunteer in trials, by way of medical treatment and compensation for trial related injuries.

Purpose: Clinical trial participants help advance medical science knowledge, but face the risk discomforts and risks for which there should be regulatory provisions by which they are reimbursed for expenses and compensated.

Research Design/Methodology: In this era of ethical medicine, India has taken an aggressive and responsible step towards clinical trial participants' protection by introducing Rule 122DAB, D and C Rule 1945 and its amendments. Schedule Y which still has some loopholes, needs to be tweaked further to make it fool proof. An attempt is made to develop more logical and rational regulations, considering all stakeholders and the negative public perception towards clinical research.

Findings & interpretation: Some of the readily modifiable factors are regulatory procedures, medical reimbursement and compensation rules. This paper analyses the rationale behind compensation guidelines for clinical research from the country's leading in clinical trials such as USA and European countries like Germany Taking into consideration the views of all stakeholders in clinical research, (i.e. sponsors, investigators, government, patients, ethics committees, lawyers and ethicists) uniform, harmonious, highly ethical yet robust compensation guidelines are proposed.

Research implications: The present study addresses the critical issue of compensation to clinical trial participants' injuries more logically and aptly by adhering to the very basic principles of ethics namely respect, beneficence and justice.

Novelty/Originality: The above study hopes to propose a watertight, ethical, uniform, harmonious yet robust compensation system for clinical research participants

Keywords: *clinical research, injuries, compensation rule, ethics.*

INTRODUCTION

It is practically impossible to expect discovery of a new safe and effective drug molecule without experimenting on human participants in any biomedical research. So also it is impracticable to perform a human research with zero adverse effects. Research related harm and injuries of varying severities are inevitable though trials often have not more than minimal risks. We have witnessed miracles in the field of biomedical science during last few decades, but we have also seen the bitter face of trials in the form of injuries and even deaths to research participants. Adverse events in clinical research range from minor headaches, pain, temporary hospitalizations to the permanent disability to sometimes death[1]. The participants compromise their wages, time and comfort by participation in the trials. During any new drug development, the investigator can usually anticipate the benefits and positive effects of the drug molecule and expect adverse effects, but often the unexpected occurs. In case of Phase-I clinical trials, the research participant does not have any direct benefit from the drug/therapy but the participant takes part into trial only for societal benefit. All the clinical trial participants

contribute largely to human progress by making themselves available for testing of new drug. All these volunteers in real sense should therefore be treated with due respect and thoroughly protected against physical, mental, social and financial harm. The ethical principle of 'Beneficence' expects for assessment of benefits of conducting a specific research in relation to the risks involved in it. According to this basic principle of ethics, these research participants should not only be protected for harm, but they should also be benefited over and above that for the benefit of mankind. On the contrary, it is observed that this aspect of clinical research is not considered by many countries' regulatory authorities and their advisory panels. The word lethargic may be used to describe the very slow and relatively unenthusiastic development of clear cut, appropriate and easy methods to grant compensation to participants.

EMERGENCE OF COMPENSATION GUIDELINES/RULES WORLDWIDE

Literature suggests that human research started early in 6th century B.C. with vegetable and meat experiments as cited in the Bible. The Hippocratic Oath, an oldest historical reference in early 5th century B.C advises physicians to treat the diseased to the best of your ability and maintain patient privacy. Unani medicine, an Indian traditional system of medicine, also has its roots in the Hippocratic beliefs. In India, the most ancient ethical codes are described in the texts of *CharakaSamhita* and *SusrutaSamhita* of Ayurveda. All these codes propagated the basic concept of non-maleficence *i.e.*, 'do no harm' which was and is the 'modus operandi' for all health care professionals in order to impart appropriate health services. All these codes of medical ethics were mainly for medical practice by physicians. Experimentation on humans was not in practice and thus the fundamental practice of medicine was relatively simple and adhering to the principles of morality. It was only during the 19th century and early 20th century that the enthusiasm for human experimentation started mounting. Western medical history refers to certain Alexandrian physicians permitted to perform vivisection on criminals and these experimenters were later referred to as medical murderers by Roman medical encyclopaedist, Celsius[2].

The worst scientific experiments in the name of medical research came to light at the Doctors' trial in Nuremberg after the World War II and shocked the entire world. The Nuremberg code was then introduced. The ten basic principles of the Nuremberg code satisfied moral, ethical and legal obligations but there was no mention of 'compensation system'. The Declaration of Helsinki (DOH), adopted by World Medical Assembly, Helsinki, Finland in 1964, and the revisions in 1975 and 1983 did not have clear guidance regarding compensation clause in case of injury during research. DOH amendment 2008, part B, No.14 mentioned that 'The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study. This document mentioned provision of compensation in the protocol. No further details about how, when and who should compensate the participant were included[3].

Tuskegee syphilis study forced the creation of the 'National Commission for the Protection of the Human Subjects of Biomedical and Behavioural Research' as well as enactment of the federal regulations governing research with humans in 1974 and release of the Belmont Report in 1979 in USA, which is the first National Guidelines for Medical Research in the US. In the Belmont Report, 1979, Part B, all the three ethical principles are explained in detail but it does not include the concept of compensation and related responsibilities[4]. Later, 25 years after the exposure of the Tuskegee study, President Bill Clinton in 1997 publically apologised and the government paid compensation in addition to setting up the Tuskegee University National Centre for Bioethics in Research and Health.

In India, the Indian Council of Medical Research (ICMR) issued a "Policy Statement on Ethical considerations for research on Human Subjects" in 1980. Many other countries and international agencies also released their respective guidelines. Thus, the necessity of adhering to the principles enunciated in the Nuremberg Code and Helsinki Declaration gained primacy in various countries during the 1970s and 80s, resulting in the formulation of numerous guidelines to protect biomedical research participants.

ICMR guideline 1980 stressed upon the factors like Ethics Committee, Informed consent, Clinical trials, Research on children and mentally disadvantaged, those with diminished autonomy, traditional medicine and publication. Further revisions took place in 2000 and

2006. ICMR Ethical Guideline for Biomedical Research 2006, Chapter III, part II states obligation of a sponsor to pay compensation (and an ancillary care) in the *a priori* agreement to provide compensation for any physical or psychological injury for which participants are entitled or agree to provide insurance coverage for an unforeseen injury whenever possible[5]. But no specific mention of compensation amount for injured participants was seen in these revisions. The draft Guideline (2016) extends the compensation clause for academic research, but this is still being debated.

The Council for International Organizations of Medical Sciences, CIOMS guideline 1993, guideline 2 states that therapy will be provided free of charge for specified types of research-related injury and whether the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury. Guideline 13 states the right of subjects to compensation. Research subjects who suffer physical injury as a result of their participation are entitled to financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death, their dependants are entitled to material compensation and the right to compensation may not be waived[6].

Thus ICMR and CIOMS guidelines definitely require the provision of compensation by the sponsor. But how, when, and the amounts are not clear. Whether there should be blanket compensation equally given to all the subjects, were some unanswered questions. CIOMS 2002 Guideline 19 states the right of injured subjects to treatment and compensation. Investigators should ensure that research subjects who suffer injury as a result of their participation are entitled to free medical treatment for such injury and to such financial or other assistance as would compensate them equitably for any resultant impairment, disability or handicap. In the case of death as a result of their participation, their dependants are entitled to compensation. Subjects must not be asked to waive the right to compensation. Commentary on Guideline 19 elaborates: Implementing a compensation system for research related injuries or death is likely to be complex; however, sponsors should seek adequate insurance against risks to cover compensation, independent of proof of fault. (CIOMS) Here, no-fault compensation system came into light but still in the form of guidelines, not legislation.

The ICH-GCP guidelines 1996, 5.8.2 and 5.8.3 states that the sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries in accordance with the applicable regulatory requirement(s). When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirement(s)[7].

All the documents mentioned above provide an ethical framework for compensation policy. Today, after having several guidelines in place, the mechanism for their interpretation, application and enforcement, still seems to be a big challenge in the area of bioethics. Most of the countries guidelines remain as guidance documents without legal status is discussed in this paper.

METHODOLOGY

Current compensation system in various countries:

- **USA:** In USA, Law of Torts is followed and the injured research participant has to go to court of law to receive compensation. Some of the bioethicists and researchers in USA have pointed out the requirement of mandatory compensation scheme for clinical trial injuries[8]. According to them, people participating in clinical trials receive riskier experimental treatments. Those people who have been harmed may have few resources to manage the research injuries associated treatment on their own. Paying bills for research related injuries on their own by the participants is a disgrace, say the experts. Further, the injured research subjects have few advocates to champion their cause. It is quite logical to understand the comfort level of a research participant who knows that he/she will be fully compensated if anything goes wrong during the new treatment trial. Critics argue about US ethics guidelines that they protect researchers more than participants[9]. They are not satisfied with US policies in case where a subject is permanently disabled and cannot work, or a subject die during a clinical trial, the sponsors have no liability of his/her lost income in first case or to the family of the subject in later case[9]. Over 40 years ago, National Commissions recommended for compensating injured subjects but to date this is not implemented.

  In 2011, the Presidential Commission for study of Bioethical issues released "Moral science:

Protecting participants in human subjects research" which again emphasized on the issue saying, human subjects should not be individually made to bear the costs of care required to treat harm resulting directly from research. In USA, some private sponsors have voluntarily agreed to ensure injured subjects' treatment cost and medical care. Some sponsors clearly state in informed-consent that in case of injury, responsibility of payment of medical expenses will lie with the subjects themselves. One Attorney who has represented many research participants in court of law opines that it is not very difficult for private sponsors to escape the liability. This is because even though the sponsors write in informed consent that compensation and medical care will be provided to injured research participant if adverse event is related to study drug, often the sponsors claim that the condition is caused by underlying disease or just by coincidence! And thus escape from liability.

Critics wonder of how these policies are being in force without agitation by affected people since long. The reasons behind it are thought as:

1. The high confidentiality of US clinical trial system does not allow the interested researchers, observers or media to access the trial related facts and findings.
2. The working of Institutional Review boards (IRBs) is not accessible from anyone outside the system.
3. Tracking of research injuries and deaths for outside agencies is not possible.
4. Approval details of research studies sponsored by private institutions cannot be easily traced. Sometimes their IRB approval and registration cannot be confirmed.
5. For the injured subjects who wish to apply for compensation legally, it is extremely difficult for them to prove in the court of law that the injury is caused by research intervention and not by worsening of underlying disease condition. Also, proving negligence by researcher and investigator becomes very difficult in court of law.
6. Some categories of subjects like international subjects or subjects in federally sponsored researches are not allowed to challenge legally in the court by tort law. Thus the tort system is said to be relatively easy to access for injured medical patients but difficult for injured research subjects.

- **Europe:** European Union (EU), clinical trials Directive 2001/20/EC provides the provision of compulsory insurance prior to commencement of clinical trials but it does not focus on the liability. The cost of insurance is one of the causes of decrease in the number of clinical trials conducted in the EU. The proposed new regulation may have taken into consideration the proper risk benefit ratio for research participants but no- fault compensation system is still not in place. For protection of research participants, 'no- fault system' spells much more than just 'mandatory insurance system'. In new regulation, the critics suggest an inclusion of mandatory insurance clause in general with liability insurance clause as per no fault compensation system. This would allow conduct of low risk or non-commercial clinical trials without insurance and needless to pay compensation if there is no causal relationship between the injury and the trial[10].

  In Germany, all the research participants are insured by an insurance policy. The insurance covers economic loss but pain or sufferings are excluded[11]. The research participant must establish a causal link of the injury to the research and liability for the injury to any other person within three years of the conclusion of the research. According to the Law all claims to damages shall be extinguished after payment by insurance.

- **Japan:** The researchers claim that currently Japan is half way to model clinical trial compensation guidelines and improvements are necessary on urgent basis[12]. In Japan there are two regulatory authorities which govern the clinical research participants' compensation. The subjects in clinical trials under the 'Pharmaceutical Affairs Act' are backed up by insurance and surely receive the compensation for injuries, whereas the subjects participating in clinical trial governed by 'Ethical guidelines on clinical research' are not much covered and not sure about the insurance facility and actual financial compensation for injury. Official statement of no-fault compensation system in consent form started since 1989 when GCP came

into effect. The sponsors remained responsible for payment of compensation. There was a clear mention of statement, 'you may not receive compensation if it is found that you did not follow your primary doctor's instructions or that the health damage was due to your own carelessness. You may receive compensation according to type and degree of health damage'. Here the paradox is seen in the concept of no-fault compensation system. Critics and researchers suggest to think and find out a good solution of compensation for elderly people or end of life stage subjects as that in cancer or other like diseases who have no possibility of being employed should be treated as an exceptional case. Critics even quote that the compensation for Phase I subjects is much more than the compensation for Phase II and Phase III trial participants which needs to be revised. But this thought seems to be illogical as there is a definite higher risk taken by a healthy volunteer in phase I study as compared to patient volunteers in phase II and III and thus it is logical to compensate phase I participants more. They further argue that it is wrong system of providing less compensation to Phase II and Phase III subjects for the drugs like anticancer drugs and other biological products which are sold into the market in large quantities with large profits. The concern is, there is no legal provision about the content and limits of compensation systems and the final regulatory authority remains mute with wait and see attitude. The people including regulatory authorities are seen to be unaware of the distinction between liability insurance and compensation insurance. In Japan, the compensation insurance in this field is undeveloped and researchers are not responding appropriately. Thus, there is an urgent need of immediate improvement including legislation.

- **Africa:** The National Health Act and South African Constitution monitor the ethical conduct of clinical trials in South Africa which is based on Belmont Report and ABPI guidelines. According to these guidelines sponsors are responsible for drawing insurance for research related injuries. The sponsors like National Institutes of Health (NIH) and Centres for Disease Control and Prevention (CDC) in its consent document assure the participants of immediate treatment for research injuries but the fact is that there is no special compensation scheme for injured participants by these sponsors as US federal regulations do not extend the facility of paying for treatment of research related harms during clinical trials. This is an issue of concern for human research ethics committees of South Africa. The vast gap between the expectations South African Human Health Research Ethics Committees and facilities provided by US sponsors persists for the compensation issues.

  The funds for treatment of injured research participants are raised from other sources like government or research participants themselves. Free treatment is provided by many principal investigators as most of the participants in developing countries do not have medical insurance. Surveys also revealed that many PIs use NIH funds for compensation purpose[13].

  The US government seems to be reluctant to the no-fault compensation system though it is a major stakeholder in biomedical research. Contrast to that, many European countries practice no-fault compensation system. Thus USA and the EU demonstrate a web of confusion as research in low and middle-income countries is considered. Many developing countries lack proper guidelines and rules for compensation for research related injuries[14].

- **Malaysia:** The no fault compensation system is found to be fairer, efficient, faster and most appropriate compensation system for clinical research related injuries. This system is said to be superior to Tort or fault based system. The society can be better served ethically by providing justice to the injured research participants or their kins by the sure and clearer compensation method. Though a few countries find it difficult to implement, the no fault compensation system is accepted positively by many countries. Some flaws in this system of compensation are difficulties of funding and accountability of system[15]. As compared to countries successfully practicing no fault compensation system, Malaysia differs in population size, political ideology, social and financial aspects of the country. Still, a tailor made model of no fault compensation system which goes well with local needs of society should be considered for Malaysia.

- **Australia:** The present compensation system in Australia is a fault based negligence scheme. This indemnity system based on negligence is slow, costly, inefficient, ill targeted and stress creating system[16].This system may lead to nonintentional errors and can lead to system failures. Researchers describe present systems antiethical from patient safety point of view. Proposed no-fault system is fairer, speedy and cost effective. Australia needs to examine the developed countries which follow no-fault compensation system and implement most comprehensive and an effective system for compensation.
- **Indian system of Compensation:** In the Drug and Cosmetics Rule 1945, Rule 122DAB states, (i) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier. (2A) In case there is no permanent injury the quantum of compensation shall be commensurate with the nature of non-p ermanent injury and loss of wages of the subject[17]. In case of decision of quantum of compensation for trial related injury/death in India, various stake holders like sponsors, investigators, ethics committees, the licensing authority and an independent expert committee constituted by the licensing authority take part at various levels. In case of an serious adverse event, the examines the case and establishes the cause of SAE and recommends to the licensing authority the quantum of compensation[18]. The licensing authority in consultation with the specially appointed Expert Committee, decides the quantum of compensation for clinical trial-related injury and passes orders within 3 months of receiving the report of serious adverse events. The sponsor shall pay the compensation for clinical trial-related death as per the order of the licensing authority, within 30 days of the receipt of the order of the licensing authority.

  The serious adverse events (SAE) are classified into: Death and SAEs other than death.

  Compensation formula is provided for the calculation of compensation with the rationale as per the Workmen Compensation Act and in general 'No Fault Compensation'.

  The formula for calculating the quantum form clinical trial related death[19].

  $$\text{Composition} = \frac{B \times F \times R}{99.37}$$

  Where,

  B = Base amount (i.e. 8 lacs)

  F = Factor depending on the age of the subject (based on Workmen Compensation Act)

  R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

  1. 0.50 terminally ill patients (expected survival not more than (NMT) 6 months)
  2. 1.0 Patient with high risk (expected survival between 6 to 24 months)
  3. 2.0 Patient with moderate risk
  4. 3.0 Patient with mild risk
  5. 4.0 Healthy Volunteers or subject of no risk

  The formula for calculating the quantum form clinical trial related injury:

  $$C^2 = A \times B\left(\frac{1-F}{100}\right) \times \left(\frac{D}{100}\right)$$

  D = Percentage disability the subject has suffered.

  C = Quantum of Compensation which would have been due for payment to the subject's nominee(s) in case of death of the subject.

  (An Annexure 1 is provided in the government document for age wise Factor-F for age 16 and above for further calculation of compensation.)

DISCUSSION

Analysis of compensation system in above countries: Though a giant player in biomedical research, US seems to be reluctant to bring into practice the law for compensation. Exactly opposite to this, many European countries have no-fault compensation system in practice. Now, when USA and EU like strong players in clinical research have such a vast difference in their compensation guidelines, the problem is faced by the

low and middle income countries where this research is exported as a part of multicentre, multicounty clinical trials. Differences in the compensation systems of these developed countries' and the developing country's own rules/guidelines for compensation may create confusion leading to under or over compensating the trial participants. Lack of uniform guidelines throughout the world for no-fault compensation system that can serve the injured participants best according to the ethical principle of beneficence is observed. Critics from not only USA, Europe and Australia, but also from Malaysia and Africa are appealing to their governments for no-fault compensation system. Every country included in this research paper has its own set of compensation policies in black and white. But each country has its own way, directives, implementing paths and execution methods for compensating the injured participants where one thing is observed that is- a solid, robust and easy procedure is totally lacking! Even India has a way long to reach an ideal model in this concern.

CONCLUSION

Need for a fool proof compensation system in India: As compared to all above countries, India seems to have elaborate procedural details for solving compensation issues by developing a unique compensation formula based on Workmen Compensation Act. Recent developments in India have led to the most stringent form of compensation, not only trial related injury but also no efficiency, making the financial risk impossible to insure20.

There are some loose ends and minute gaps to be addressed in the system. The major issue is of bridging the gap between theoretical elaborateness of procedure, specificity of compensation formula, perfectly distributed responsibilities to the stake holders etc. versus monitoring, auditing and confirming the utility and execution of current compensation system. A well designed compensation formula ensures that ethical principle of beneficence is taken care of but the system ensuring hundred percent beneficence to each and every injured participant in the country is not in place, means that the principle of justice is still fighting for its own existence. Today, there is no system in place to claim that each and every injured participant in India gets the compensation as per prescribed norms with uniform benefits. The second issue is that the Rule 122DAB for compensation was amended for betterment in 2014/15. But there is no clarity on how the injured/dead participants or their kins before the commencement of this final rule will be ensured of compensation and taken care of proper justice as the rules were different earlier and the rules have become better after that.

Confidentiality in clinical research with respect to patient identity, blinded studies, results, drug description, legal documents etc. is highly important. But there is a need for transparency and easy accessibility of compensation related documents and case studies. The information regarding how many injured clinical trial participants received compensation, how much and in what way they received the same? Did each and every injured participant get the benefit of compensation law? Is there any participant still waiting for compensation amount? Was the compensation receipt procedure really smooth for patients or their kins? Are the recipients thoroughly satisfied with the process of compensation system? All these questions still need attention by proper accountability of each stake holder of the prescribed compensation system. Thus once for all fool proof and watertight compensation system in India is needed to ensure accountability and the justice to all the stakeholders while India progresses further in clinical research.

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Post Mortem Sperm Retrieval: Legal and Ethical Concerns

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ABSTRACT

Purpose: While several countries have explicitly prohibited Post Mortem Sperm Retrieval (PMSR), there are some countries which have allowed it on a case-by-case basis. This paper attempts to raise pertinent legal and ethical concerns regarding PMSR and urges the legislature to come up with guidelines addressing the same.

Research Design/Methodology/Approach/Materials & methods/Experimental: For this paper, the Researchers have adopted a doctrinal approach. They will be undertaking a comparative study of laws, policies and landmark judgments of other countries and analyse them in Indian context. Additionally, the Researchers will also rely on opinions by medical practitioners and guidelines issued by hospitals to support their arguments on ethical concerns of PMSR.

Results & discussion/Findings &interpretation: The Researchers have identified two key legal issues concerning PMSR: consent of the deceased (Ethics Committee ASRM, 2013) and rights of the yet un-conceived child Kindregan Jr., C.P., 2015). Is the deceased's consent necessary for PMSR? In the absence of consent of the deceased, can his wife unilaterally proceed with PMSR? In a rights based legal framework, where do we place the yet unconceived child?

Research implications: The issues raised in this paper will have a far reaching impact as the concept of PMSR gains popularity. It may even prompt the legislature to address the ethical and legal concerns of PMSR by issuing a formal guideline and initiate an in-depth study of the socio-cultural implication of PMSR**.**

Novelty/Originality: PMSR is fairly novel concept in India and the legal concerns regarding it have not been yet addressed from an Indian context which this paper attempts to do.

Keywords: *Post Mortem Sperm Retrieval (PMSR), Sperm extraction, Socio-cultural implications, Legal & Ethical concerns*

INTRODUCTION

Human beings attach a lot of importance to reproduction and the upbringing of the young. Unlike most other mammals, who tend to leave their children to fend for themselves after the first few months of training and feeding, humans on the other hand strive to keep their young ones under their care and guidance as long as possible. Families form the most basic unit of society and it is often argued that degeneration of family will lead to degeneration of the social structure as a whole. Most cultures across the world provide greatest importance to procreation and upbringing of the children. The entire social structure exists to provide support towards rearing of a child into a responsible citizen of society. Parenthood is considered the greatest duty as well as the greatest joy of any human being.

Human race has devoted immense time, energy and resources over the past century towards research and development of medical science so that doctors can provide the joys of parenthood to those who have not been naturally blessed with it. Years of research have led us to a world where various methods of assisted reproduction not only exist but are extensively popular in most countries of the world. They have brought the joy of parenthood to numerous people and have given life to those who would not have been born but for them. Therefore, rightly so, medical fraternity has become God-like to those parents who could experience that joy only because of them.

However, certain assisted reproduction methods have always been shrouded with ethical, moral and legal concerns. Techniques like artificial insemination

and surrogacy have raised questions which generations prior to us never faced. None of these questions have a 'yes' or a 'no' for an answer. And as we grapple every day to find answers to these questions, new questions are posed to us. The society and the law are not able to keep up with the pace with which the medical science and technology are progressing. Soon we will be facing many more moral and legal dilemmas which may not be accommodated within our current social and legal structure.

In this paper, we are addressing the issue of Post Mortem Sperm Retrieval (PMSR). PMSR involves a "*situation where a wife or life partner requests sperm retrieval from a dead, near dead or dying husband or partner*" which can then be preserved and later used to produce his genetic offspring[1]. The idea of this paper stemmed from a recent news item where a renowned hospital in India turned down the request of wife for Post Mortem Sperm Retrieval (PMSR) of her deceased husband due to lack of adequate guidelines[2]. India is yet to form a guideline on PMSR. However, there are several other countries in the world who have already formed legal rules governing several aspects of PMSR. In this paper, we have attempted to analyze various ethical and legal concerns regarding PMSR based on current legal framework and concludes with a recommendation to the legislatures to frame guidelines addressing such concerns.

HISTORICAL BACKGROUND AND PROCESS OF SPERM EXTRACTION

Historical Background of Artificial Insemination: First known use of artificial insemination can be traced back to the fourteenth century when it was successfully performed on animals by Arabs. Most significant use has been by cattle breeders for ages to inseminate their cattle with frozen bull semen. The credit for first successful human artificial insemination can be accorded to the surgeon John Hunter who performed this miracle in England in 1770. He was followed, almost a century later, by a physician named Marion Simms, who in 1866, successfully performed artificial insemination in United States. However, Simms was not lauded for his achievement. Instead he was forced to abandon his experiment due deep-seated religious and moral scruples of the community towards unnatural impregnation of a woman. The idea of establishing frozen sperm bank was proposed by Italian scientist, Montegazza, who discovered that human sperm could survive freezing. These frozen sperms could then be used by widows whose husbands were killed at war. However, it was only in 1949 when it was discovered that sperms survive better if small amount of glycerol is added before freezing. Currently sperm is frozen and stored in a tank filled with liquid nitrogen at -328^0 Farenheit. Sperm which has been stored for over ten years has produced healthy children[3].

Process of PMSR: Dr. Cappy Rothman in 1980, for the first time, at the request of family members, performed sperm retrieval from a cadaver of a 30-year-old man who became brain dead following a motor vehicle accident[4]. There are several method of post-mortem sperm extraction and many more are evolving. These include epididymal extraction, epididymal aspiration, vas deferens irrigation and electroejaculation[5]. One of the most common ways of sperm extraction is the Needle Extraction Process which involves drawing out semen by inserting a needle into the testis. Doctors are also at a liberty to use other methods of sperm extraction as minimizing invasiveness is not a concern in case of dead persons. The doctor may extract the testis or epididymis (where the sperm matures) surgically. The doctor can then milk the epididymis or otherwise separate the sperm from the tissue. The other option involves freezing the entire epididymis or a piece of testicular tissue. Electro-ejaculation is also a popular method for extracting sperms from a cadaver. In this method, the doctor stimulates ejaculation of sperm through usual channels by administering a jolt of electricity through a conductive probe inserted into the man's anus until it is next to the prostate[6].

ETHICAL AND LEGAL CONCERNS OF PMSR: Like any other assisted reproductive process, retrieval of sperm from the deceased and use of such sperm to later bear a child poses a lot of ethical and questions. Some such questions involve critical issues involving the "rights" of the deceased. The primary issue is that of consent. Should dead men be fathering children without his explicit consent? If consent is crucial, then who can give it if the deceased has not done so? Still other questions involve the "rights" of others to both procure and control sperm and its use after death. Who has a right to a deceased man's sperm? Should there be restrictions on who can use the sperm to try to conceive

a child? Can those who would have no legal standing in a court of law ever request and utilize a cadaver's sperm, for instance long-standing heterosexual or homosexual partners? Should parents or family members be permitted to condition organ donation on post-mortem sperm retrieval? Can sperm retrieval be equated to organ donation? What if the deceased is a minor and the procurement is for lineage purposes? Finally, should retrieved sperm be made available for any purpose other than the conception of a child?[5]. It is impossible to address all ethical and moral concerns in a single research paper. In this paper, therefore, the authors will discuss the issue of whether there is ownership over sperms and whose consent is essential to gain access to a person's sperm.

Property Rights Of A Deceased On Sperm And The Issue Of Consent: In order to assess the importance of prior consent of the deceased for PMSR, we will first need to assess jurisprudentially whether deceased has any claim over the sperms. This question will lead us to the issue whether there is any property right of a human over his own organs or tissue. This is a question which has plagued the judiciary for a long time.

One of the most celebrated case concerning property rights of an individual over his own body parts was that of John Moore. The issue before the court was whether a patient has any property rights on his blood, sperm and other body substances donated during treatment. The superior court held that there can be no property interest of an individual on their own remains which can apply prospectively and therefore negated the argument of conversion. The case then went to California Court of Appeal and then finally moved to the Supreme Court of California where on the issue of conversion, the court held that there can be no interference with Moore's right of ownership or possession of his cells which he has voluntarily donated to the hospital and therefore conversion cannot be established. The court held that common law principles of property and conversion were overruled by the statutory duty of medical practitioners to use and dispose off excised body materials which had a specific object of ensuring public health and safety. The Supreme Court refusal to extend the law of conversion to Moore's cells primarily rested on two grounds. Firstly, there was no need for the extension of law of conversion to protect Mr. Moore's rights as there were other claims such as informed consent and breach of fiduciary duty which had the potential to protect his right. Secondly, they refused to extend judicial activism where specialized legislations already exist[7].

The specific issue of ownership rights over one's own sperm came up in the peculiar case of *Hecht v Superior Court*.[1] The issue before the court was whether a person can treat his own sperm as property under the probate laws and therefore dispose them off by a will.[2] The trial court relied on Moore decision to establish that Kane had no property rights over his sperms after they were ejaculated. The California Court of Appeals distinguished the facts of this case from that of Moore and analyzed the current fact situation under California probate laws. The Court held that Kane had ownership interest over his own sperms and had the authority to decide how they can be used post his death and therefore sperms were 'property' under the probate laws of California. The court further went on to hold that posthumous insemination of girlfriend was not against any public policy and refused to comment on whether a posthumously born child will be a burden to a society[5].

The specific issue of right to sperm of a deceased in the absence of any direction from the deceased himself was brought up before the French Tribunal de grande in the case of *Paraplaix c. CECOS*.[3] Alain Parpalaix was twenty-four years old when he got to know that he was suffering from testicular cancer and that the treatment will render him sterile. He made a deposit of his sperm at the Centre d'Etude et de Conservation du Sperme ("CECOS")[4] but did not give any instruction as to how it can be used in his absence. Alain condition deteriorated rapidly and two years later in a hospital ceremony he married his girlfriend Corinne and then passed away two days later. Sperm samples were released for artificial insemination only when both husband and wife consented to artificial insemination and thus both were alive to give such consent. As Alain did not provide any instruction when he made the deposit and since Corinne and Alain were not married when the deposit was made, there was lack of clarity regarding the exact intention of Alain[3]. In France, the law on assisted reproduction currently states that permission for embryo transfer or insemination can be granted with prior consent of the man and woman who are the prospective parents and who are alive at the time of the procedure. This implicitly states that PMSR is prohibited in France. This ban goes back to a 1994 law which was based on Braibant Report

of 1988 which recommended a complete prohibition on becoming a parent after the death of the spouse, even if they couple was planning parenthood prior to the death of the spouse[8].

The Court held that the French Civil Code will not apply to sperms as they are not movable, inheritable things which can be considered as "objects of deposits." The court based its decision regarding inheritance of the sperm solely on the probable intent of the Alain. As there was no written expression of his intent by Alain, the court had to rely on the circumstances surrounding the claims to decide what could have the possible intention of Alain regarding his sperms stored at CECOS. The court found Alain's wife and parents were best placed to ascertain the deep desires of his son. They could establish through their testimony that it was their child/husband's wish that Corinne became the mother of their child and it was to give effect to this wish that he got married to her in his deathbed. Moreover, CECOS had never indicated to Alain that they will not release the sperm to a third party, thereby impliedly agreed to honor his wish[3].

In United Kingdom, the question on posthumous use of sperm came up before the court in the landmark case of Diane Blood.[5] Diane Blood and her husband were planning to start a family when Mr. Blood was affected by meningitis and went into coma. Mrs. Blood persuaded the doctors to extract some of his sperm and preserve them for future. Mr. Blood soon passed away and Mrs. Blood requested Human Fertilization and Embryology Authority (HFEA) to release the sperm from the storage facility. HFEA refused to authorize the use of the sperm in British soil as there was no written consent from the deceased.(*Human Fertilization and Embryology Act* 1990 s.4(1), Schedule 3) Mrs. Blood requested that the sperm is released and delivered to a facility in Belgium which allows posthumous use of sperm without prior written consent of the deceased. However, the request was turned down by HFEA and this decision was challenged by Diane Blood in the court. She argued that the consent rule did not apply to her as per §4(1) (b) of the Human Fertilization and Embryology Act, 1990.[6] The Court of Appeal turned down this argument stating that the exception applied when the sperm is used as is and not when they are frozen. The Court of Appeal, however, upheld the argument that the denial of permission by HFEA to send the sperms abroad violated the right of Diane to undergo medical treatment in any other member country. (*Treaty of Rome* 1957 Art. 59, Art.60) While delivering the judgment, Court of Appeal clearly stated that going forward sperm of a man should not be stored without his explicit consent.[7] Mrs. Blood became mother to two healthy boys in a Brussels clinic through artificial insemination from Mr. Blood's sperms.

INTERNATIONAL SCENARIO: HOW LEGAL CONCERNS REGARDING PMSR ARE ADDRESSED IN OTHER COUNTRIES

Different countries have addressed the issue of the legality of posthumous sperm extraction in various ways. Depending upon the acceptance level prevalent generally in the society, we can categorize the legislations governing posthumous sperm extraction into three broad categories. Some countries have preferred a complete ban, while others have allowed permitted PMSR on the basis of either written consent from the donor, or implied consent obtained from the family. Typically, retrieval of sperms, like any other body organ, is regulated by laws dealing with organ donation, where as, its use is regulated by laws governing assisted reproduction. In many situation, the law is silent or there is inconsistency and lack of clarity regarding the existing legal position on PMSR.

Australia and New Zealand: Although, both Australia and New Zealand have laws dealing with assisted reproduction, they do not specifically address the issue of PMSR. On the contrary PMSR is probably governed by other laws[9].

The laws in Australia differ from state to state. In Victoria, sperm can be posthumously retrieved if the deceased had given prior consent to a "medical procedure" or with the consent of the coroner. (*Human Tissue Act 1982* (Vic) s26, s27)[8] However, in Queensland (*Transplantation and Anatomy Act 1979 (Qld)* s22 – s25) and in New South Wales (*Human Tissue Act 1983* (NSW)), courts have held that the authority of the coroner to allow extraction of tissue does not extend to removal of sperm for the purpose of artificial insemination.[9] The legal position is similar in other states of Australia such as Western Australia (*Human Tissue and Transplant Act 1982* (WA) s22, s23), Southern Australia (*Transplantation and Anatomy Act 1983* (SA) s21 – s23) and Tasmania (Human Tissue Act 1985 (Tas) s23 – s26). Law in New Zealand is silent on whether prior consent is required before posthumous

gamete retrieval. In absence of the legislative approval, the concerned authority thinks it is unethical to do so.[10]

Victoria completely prohibits use of sperm of without the written consent of the deceased. (*Assisted Reproductive Treatment Act 2008* (Vic), s.46) Similar requirement of consent exists in New South Wales. (*Assisted Reproductive Technology Act 2007* (NSW) s17, s23) However, both these state allow use of posthumously collected sperm if they were collected interstate.[11] South Australia permits posthumous use of sperm only if it was retrieved prior to the death. (*Assisted Reproductive Treatment Act 1988* (SA) s9.1) However in a recent case, Adelaide court allowed a woman to retrieve sperm posthumously because she could prove in the court that she and her husband were planning a family before her husband passed away suddenly in a motorcycle accident. The procedure had to be carried out in Canberra because of the legislative ban on posthumous sperm extraction and Australian Capital Territory is the only state that allows extraction of sperm from a deceased without prior consent[10]. In Western Australia, there is an absolute prohibition of the use of gametes retrieved following death.[12] In New Zealand as well, ECART prohibits use of sperms without prior written consent of the deceased. (NECAHR, *Guidelines for the Storage, Use, and Disposal of Sperm from a Deceased Man,* 2000)

United Kingdom: *Human Fertilization and Embryology* Act, 1990 governs artificial reproduction processes in United Kingdom. Pursuant to the ruling in Diane Blood's case, *Human Fertilisation and Embryology (Deceased Fathers) Act* was adopted in 2003. It explicitly permitted posthumous insemination as well as embryo transfer, as long as the deceased father had given his consent while alive. The mother could request that the deceased father be registered as the child's father on the birth certificate, as long as the father had signed written consent prior to his death[8].

USA: Federal laws govern tissue and organ donation (*Uniform Anatomical Gift Act and the National Organ Transplant Act*) but they are not necessarily applicable to sperm, which are classified as renewable tissue. Artificial reproduction, on the other hand is regulated by state legislation. In United States, there is lesser incentive to curb PMSR as it boosts the lucrative and highly profitable assisted reproduction market, which is primarily private owned and operated[11].

Europe: France, Germany Sweden and Canada prohibit posthumous sperm retrieval[11]. Belgium, Spain and Netherlands, on the other hand authorize post-mortem reproduction. In France

Israel: Israel can be considered as vanguard in assisted reproduction. The guidelines for posthumous sperm retrieval for the purpose of artificial insemination of the surviving female partner were issued in October 2003[12]. Israel law does not insist on a prior written consent by the deceased for allowing PMSR. It is sufficient if his widow can show that he would have consented to PMSR had he been alive. There is also provision for financial assistance to be given by the Government and State Health Insurance to cover the cost of IVF cycles required to produce two babies. A 2007 court decision established that any child conceived posthumously through IVF process using sperm collected by PMSR will be considered as a legal heir of the deceased. However, Israel's relatively permissive policies have created an unwarranted situation where there is a conflict between the widow and the parents of the deceased regarding the right to use the sperm.

Sri Lanka: Many methods for assisted reproduction are available, artificial insemination by husband, artificial insemination by donor, egg donation, embryo donation, and surrogacy. Ethical and regulatory authorities are in place for assisted reproduction technique, but there is no guideline or rule for PMSR.

Pakistan: Infertile couples in Pakistan can take help of assisted reproductive techniques like in vitro fertilization (IVF), surgical sperm retrieval, and micro assisted conception to become parents. However, any union of gametes outside a marital bond, whether by adultery or in the laboratory, is forbidden. Therefore, artificial insemination using donor sperms is strictly forbidden in all schools of Islamic law. The procedure of ovum donation and surrogacy is allowed between co-wives. However, fertilization of an ovum from cryopreserved sperm after the divorce of the couple or death of the husband strictly forbidden.

CONCLUSION: HOW CAN INDIA ADDRESS THE ISSUE OF PMSR?

Currently, there is no law in India which governs assisted reproduction. Ministry of Health and Family Welfare has introduced the Assisted Reproductive

Technology (Regulation) Bill, 2014 (ART Bill) to govern all aspects of assisted reproduction and ensure that assisted reproduction is not misused and is carried out in a safe and proper manner.(*The Assisted Reproductive Technology (Regulation) Bill* 2014, the Preamble) On September 30, 2015, India's Ministry of Health and Family Welfare, through its Department of Health Research, published draft legislation regulating Assisted Reproductive Technology (ART) for public and stakeholder comments. (*The Assisted Reproductive Technology (Regulation) Bill*, 2014) The Bill aims to establish National Board for Assisted Reproductive Technology (NBART) whose main function will be to develop new policies regarding ART.

The current social fabric of India does not warrant an extreme liberal stance on the issue such as Israel where as it will be dangerous to leave such an issue unaddressed as it may be misused for financial gain by private individuals. Considering the sensitive nature of the issue and the varied ethical questions surrounding PMSR, the authors believe that a case by case approach is most suitable. The primary power to decide on use of sperm extracted post-mortem can be given to NBART or any other statutory body established under the law. The law can mention the factors which the statutory body must take into account when deciding on a PMSR application, such as:

(a) Welfare of the unborn child and its right to a healthy childhood

(b) The social, religious and financial status of the family

(c) Consent of the parents of the deceased

(d) The relationship between the husband and the wife (if the request has been made by the wife)

(e) Whether there is any necessity of sperm preservation (especially, if the request is made by parents/other family members of an unmarried man)

(f) Whether the period of bereavement is over and the woman is in a mental state to take a rational decision

(g) Whether the child will have a satisfying childhood in presence of a father figure

As there is a brief window of 24 hours to extract viable sperm from a cadaver, guidelines can be issued to hospitals to extract the sperm whenever there is a request of PMSR from the immediate family members of the deceased and keep it in their possession and allow access only after permission of the concerned statutory authority has been obtained. If any of the parties involved is unhappy with the decision of the statutory authority they will have a right of appeal before the higher courts. The stored sperm can be released only after a final decision on this has been reached. The legal framework can also provide how a man can give prior consent for PMSR and use of the extracted sperm which will prevent any further legal hassle in this matter.

India is a country of varied culture and sentiments. Social mores dictate the acceptance of modern methods of conception through ART. Most Indian cultures are still to accept assisted reproduction as a normal way to have a family even when both husband and wife are willing. In this scenario, PMSR, which will allow a woman to conceive a child after the death of the biological father, may be more difficult to accept. Therefore if judiciary is ever faced with a question on PMSR it will have to strike a balance between right of a woman to procreate and the right of a yet-to-be conceived child to have a happy stable family with the presence of both its parents. It will also need to consider the interest of the parents of the deceased and the to-be grandparents of the child as well as the other family members of the to-be mother. All these interests need to be reconciled in the backdrop of the existing social fabric and religious sentiments of those involved which tends to heavily influence such decisions.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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1 20 Cal. Rptr. 2d 275, 276 (Cal. Ct. App. 1993).

2 Mr. William Kane committed suicide on October 30, 1991 after leaving 15 vials of sperm for his live-in girlfriend Deborah Hecht. Kane had executed a will one month before committing suicide where he mentioned his intention to father children with Deborah and also provided for them in the will. The 'Authorization to Release Specimen' form of the sperm bank was signed by Kane which allowed only Hecht or her physician to access the sperm samples. After Kane's death, his two children from previous marriage filed a suit claiming that the sperm samples need to be destroyed as the posthumously born child will disrupt the family balance and Deborah should not be conceiving Kane's child because she was not married to him.

3 Trib. gr. inst. Creteil, Aug. 1, 1984, Gazette du Palais [G.P.], Sept. 15, 1984, at 11.

4 A government backed research center and sperm bank in France

5 *R v HFEA*(1997) 2 A II ER 687

6 §4(1)(b) of Human Fertilization and Embryology Act, 1990 exempted consent requirement for those couples which had treatment together.

7 According to Lord Chief Justice Woolf, "Because this judgment makes it clear that the sperm of Mr. Blood has been preserved and stored when it should not have been, this case raises issues as to the lawfulness of the use and export of sperm which should never arise again…There should be, after this judgment has been given, no further cases where sperm is preserved without consent".

8 See also *AB v Attorney-General for the State of Victoria* (2005) VSC 180

9 *MAW versus Western Sydney Area Health Service* (2000) 49 NSWLR 231

10 Ethics Committee on Assisted Reproductive Technology (ECART) is a ministerial committee established under the Human Assisted Reproductive Technology Act 2004 that reviews, determines and monitors applications for assisted reproductive procedures and human reproductive research. http://ecart.health.govt.nz/

11 YZ v Infertility Treatment Authority (2005) VCAT 2655

12 Directions given under Human Reproductive Technology Act 1991 (WA)

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Emerging Challenges and Accountability in Surgery Mix-Up in Asia, Africa and Beyond

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ABSTRACT

The right to health is one of the basic human rights of human being. It is embodied in domestic/municipal laws as well as International instruments. In general, no one is spared in the court of law directly or indirectly who are indulged in medical negligence. First example, in 1980, when doctors operated and removed the healthy eye from a two-year-old girl, Nasreen Banu, instead of the cancerous one, blinding her for life in Sarojini Devi Eye Hospital, Hyderabad, India. Compensation may not fill the gap of organ loss. In second example the year 2007 *(in Tanzania, East Africa),* a man who was diagnosed and found to have a brain tumour was mistakenly had a knee operation instead of brain surgery. He died two weeks later due to late treatment of his brain disorder. No one was held liable. In third example/ incident in January, 2012, Bimla Nayyar *(in Oakwood, Detroit)* was wrongly had a brain surgery instead of an operation to pop up her jawbone and died two months later after the wrong operation she had undergone. Who would accountable to pay the damages? This paper is interested in investigating the magnitude of the surgery mix-up problems in Asia, Africa and beyond. The aim of the paper is to find out how does the both International Instrument plus national laws plays an important role in solving these kinds of problem. Again, the paper will investigate and find out what is the best legal practice in dealing with both the victims of the incident, doctors and their assistants, the hospital and the government as a whole in as far as the issue of professional accountability is concerned. As per the first, second and third referred incident above, the questions are who will "pay" for the organ damage/injury or death caused out of reckless health officials? The issue is whether the fiduciary compensation is equivalent to human organs or lives? The methodology followed in this paper is based on primary, secondary and tertiary source which is appropriate to accomplish International conference paper.

Keywords: *Health Problems-Accountability-Surgery Mix-Up-Legal remedies.*

INTRODUCTION

Any human endeavour is prey to human mistakes. Though there are many kinds of mistakes that can arise in these complex processes. These mistakes create so many mix ups in the medical field. Although this paper intends to dwell on surgery mix ups in different parts of the world particularly in Asia, Europe and Africa. The authors thought it is apparent at this stage to summarily explain a bit of other mix ups in the medical field. Look Alike/Sound Alike (LASA) is an area which records a lot of serious mix ups which sometimes ends in thousands of deaths. LASA is a situation where a patient is given wrong medication similar to the intended one. It is always happening where medication names are similar to each other. The medication error was given a top priority in 2007 by the Joint Commission and the World Health Organization (WHO) while the United States Pharmacopoeia (USP) Centre for the Advancement of the Patient Safety (CAPS) capitalised on the same and made it as an important agenda. Report further reveals that 16% of the medication errors between 1993 and 1998 were those of prescribing wrong drugs to patients particularly the drug name confusion. Between 2003 and 2008, more than 3,170 drugs were wrongly prescribed to patients in America and further reports reveal that many LASA confusions involved foreign drug names. Furthermore, between January 2003 and December 2006, the MEDMAX data report was published by USP where 26,000 incidents were recorded and 384 cases caused severe effects to patients who consumed wrongly prescribed medication[1].

Hampton reports that more than 7,000 deaths are recorded every year in US because of the medication error particularly wrong administration and wrong prescription of drugs[2]. In another development, Judy and others have unanimously warned about the possibility of

the continuation of the medication mix ups in Quinine and Quinidine and advice that education and alertness of personal and procedural safeguards may reduce the said problem. They further advice that all medical errors should be publicized as a means to increase awareness and avoid further medication mix ups[3].

Yildirim and others report that in all 14 cases under their study, the retained surgical sponges were successfully removed but leaving 13 patients with nonspecific abdominal pain and intestinal obstruction whereas four patients undergone an urgent surgery as the retained sponges caused intestinal obstruction and or intra-abdominal sepsis. Giving their conclusion and recommendations, Yildirim and others noted that RSS may cause very serious medical problems as well as legal problems and that strict measures should be deployed to prevent the same[4].

There is another report which discovered that among 26,462 monitored medical inpatients, 0.9 percent have died because of drugs prescribed in hospitals, pharmacy and health centres. Although these patients were seriously ill before their deaths but the excessive usage of drugs and wrong administration of the same caused their deaths. For instance, out of six deaths, five of them were due to fluid overload and one was due to excessive potassium therapy[5].

LITERATURE REVIEW

Bender has reported number of incidents including that of Suzan Buchweitz who was un intentionally implanted embryos of Robert and Denise B[6]. Another incident is that of Donna Fasani was given one Rogerses embryo whereas unethical medical conducts includes the case of fertility Doctor Cecil Jacobson who inseminated his own sperms to more than 100 women[7]. The heart touching incident is that of Dr Irvine of the University of California who sold eggs and embryos to some other people out of US without the consent of the patients[8]. As part of his conclusion Bender proposes that "*our legal systems must find appropriate and just ways to resolve the disputes that arise from these mix-ups"*[9].

It has been reported further by Professor Cynthia Mabry that the case of Julia Skolnick was the first Assistive Reproductive Technology (ART) mix-up. A brief overview of the case that a white woman who opted to be inseminated a frozen sperm of her deceased white husband she surprisingly gave birth to a black skinned baby which was later on discovered that this was due to sperm mix up during the fertility clinical procedures (The case has been narrated in length in the book written by Cynthia R. Mabry, "Who is My Real Father? A Delicate Task of Identifying a Father and Parenting Children Created From an In Vitro Mix-up, 18 NAT'L L.J. 1, 60 (2004-05) [10].

In another case which attracted most of the media houses as it was heavily reported where one white couple in Netherland gave birth to twins with different skin colours (White and Black) which was later discovered that there was a fertility clinic negligence as the sperm of a black Dutch Antilles man was mistakenly implanted to a white couple instead of his wife (Geoff Marsh & Tony Brookes, We Had Black IVF Babies Too UK Couple Not First Whites To Get Wrong Children, Express Can Reveal, (Express UK), July 9, 2002[11].

Again, there was an incident in the year 2002 which resulted in a closure of a fertility clinic known as St. George's Healthcare Trust. The incident occurred in the city of South London where "very good" embryos were implanted to another patient. Surprisingly; the embryos of the wrongly implanted patient were also mistakenly implanted to another patient in the same hospital.

Mr. Alan O-Gorman was scheduled for operation and his stomach was removed following a successful operation. The removal of his stomach was due to the danger of cancer as he was diagnosed at St. Vincent's Hospital in Dublin. It was discovered later that Alan was wrongly operated because there was a mix up of tissue samples as the hospital admitted to have committed the said mix up. Following the wrong operation Mr. Allan has undergone, he suffers severe pains everyday and about three times he overdosed the pain killers due to stress caused by the operation. The court ruled that £ 450,000 should be paid to Alan as compensation. Alan sued both the hospital and six hospital staff including three doctors[12].

Melinda Beck has revealed a medical report which suggests that the medical record mix up is a common problem in the medical field. The report found that the cardiac arrest patient was supposed to be resuscitated but the process was not taken place because clinical officers confused his record with another patient who had a do-not-resuscitate order. The report further reveals

an incident where a patient was wrongly undergone a surgery based on other patients record and the patient was found dead in the hospital room just the following day. The report covered 7,613 cases which involved 181 health care organisations from January 2013 to July 2015. 91 percent of the covered cases severely harmed the patients and two of them were absolutely fatal. These fatal incidents are elaborated hereunder:

One of the critical cases is when a patient was wrongly given a hypertension medication ten times of the usual doze. The second example is when a man was nearly to be chocked when a wrong meal tray was channelled to his hospital room while the patient was not supposed to eat after the surgery. The third incident is when a baby consumed an expressed breast milk from the wrong mother which caused him suffer severe hepatitis. The report further suggests that about 13 percent of identification problems always take place during registration when one patient might have a duplicate file or when records of two patients be mingled in one file. Citing an example on the possibility of identification errors, Mr. Marella noted that names like Marry Ellen smith, Marry E. Smith and Marry-Ellen might read as three different patients as most of the EMR systems are unable to recognize minor variations in name spellings[13].

DIFFERENT SURGERY MIX UPS IN ASIA, AFRICA AND BEYOND

Two patients were reported to have died in India because of the wrong administration of anaesthetic agent instead of Oxygen. The cause of this mix-up is said to be the fact that a pipe supplying anaesthetic agent was wrongly confused by the pipes supplying oxygen. Deaths of these two patients occurred within three days in the same hospital. Taking up this case, the Madhya Pradesh High Court noticed the government to provide detailed information on those deaths while the family requested the payment of Rs. 25 Lakh as compensation to each family of the deceased. Again, the petition prayed for the suspension of all officials involved in the saga. Either, the technical company which was taking care of the pipes was also linked in the investigation[14]. A three-member external team of ophthalmologists and healthcare specialists will be visiting the Sarojini Devi Eye Hospital on Saturday for an investigation into the contaminated saline incident. On Saturday, the investigators are set to record statements of the deputy superintendent of the hospital, Dr Rajender Gupta. Statements from other doctors, who conducted the surgeries on five patients, will be recorded and a report is expected[15].

Nasreen as a toddler was sent to the United States for treatment to prevent total blindness. “She didn’t get anything from the Government except an ex-gratia of Rs.10,000 which was inordinately delayed, and the cost for treatment in US but it was a futile exercise,” her mother recalls. Nasreen’s cancerous left eye was also removed on April 14, 1980, at a New York hospital.

The family filed a suit for damages against the State Government, Superintendent, Sarojini Devi Hospital, Dr. Dayanand Reddy, the doctor who performed the operation, and Director, Medical Services, for a Rs.10 lakh compensation way back on February 9, 1981.

The litigation spanned a lifetime, literally. Her (Nasreen Banu) father is Bahadur Khan, machine operator in the erstwhile Allwyn Metal Works, whose only dream was to bring justice to his daughter, died fighting the case in 1993. The lawyer too died. Her family members gave up the case owing to poor finances. “Khane ko mushkil hora, ab case kahan se ladhe hu.,” her sister, Yasmeen, says. Thus, the case was given a silent burial[16].

In another case, it was reported that Mr Ravi Rai was wrongly had his leg amputated at Fortis Hospital, Shalimar Bagh. The surgery was due to an accident when Ravi fell from the stairs an act which caused injuries to his right leg but unfortunately doctors/surgeon undergone surgery on his left leg. Report reveals that Ravi (Patient) informed the surgeon about the wrong leg amputation but they did not respond to him. The issue was made known to the public when Ravi informed his parents about the incident[17].

A patient by name Emmanuel Mgaya from Tanzania, who had a knee operation when he had a tumour in his brain, has died two weeks after finally having the operation[18].

It has been reported that a woman was hospitalized and undergone a heart surgery instead of respiratory infection surgery. The cause of this problem was a misunderstanding and names mix ups. In fact, a woman who had a respiratory infection and hospitalized in the Medi-clinic Kimberly, South Africa was mistakenly

taken to a theatre for the wrong heart surgery. The report reveals further that the specialist was given a wrong surname of the patient over the phone call while the two patients sharing the same surname were hospitalized in the same ward and above all they were all taken care of the same physician. Following the wrong operation taken to a patient, the hospital ended up apologizing and waved the surgery charges as they were supposed to pay for the same[19]

In November 2007, a doctor in Rhode Island Hospital drilled a hole in a wrong side of head of the patient. In this case, it was very clear to the doctor that the patient's CAT Scan showed that the patient had a brain bleeding to her scull on the left side of her head but the doctor performed the hole drilling on the right side of the head. He immediately closed the wrong hole and drills the correct one after realizing that he wrongly drilled on the left side of the head. In another incident, a Mexican girl, Jesica Santillan who was living in the United States was given a wrong blood group when she was undergoing a heart and lung transplant at the Duke University Medical Centre, Durham, North Carolina. Following the failure of the first procedure, the second procedure was performed in order to remove the wrong blood group and implant the right one. Unfortunately, the second transplant failed and Jesica into a comma and suffered brain damages which caused her death two weeks later[20].

The patient, Bimla Nayyar, died two months after the January 2012 brain surgery. Nayyar was in Oakwood's Dearborn hospital to get a procedure to "pop" her jaw bone back into place. Instead, she is dead because she received the "wrong surgery. $21M awarded for wrong operation[21].

Again, Mr. Donald Church who was successfully operated at the Washington Medical Centre and the tumour in his abdomen was successfully removed. Unfortunately, a 13 inch long metal retractor was forgotten inside the body. Report further reveals that four similar incidences happened in the same hospital between the year 1997 and 2000. Mr. Donald was paid USD 97,000 as compensation. In the similar case, Mr. Marty Makary reports that about 39 times a week doctors leave various foreign stuffs like towels and sponges. The report further reveals that for over twenty years, 6.6% of malpractice claims caused death while 32.9% permanently injured and 59.2% suffered temporary injuries. The estimated malpractice claims were 9,744 for the period of twenty years while the yearly estimation of the "never events" in the US amounts to 4,044[22].

In another incident, Mr. Willie King was hospitalized at the University Community Hospital, Tampa, Florida for the amputation of his leg. Unfortunately, the surgeon had undergone an amputation of the wrong leg. Although the surgeon realized the mix up but it was too late to rectify the mistake. The doctor was fined USD 10,000 and six month cancellation of his medical licence. Again, USD 1,150,000 was paid to Mr. King as compensation where USD 900,000 was paid by the hospital and 250,000 was paid by the surgeon himself[23].

ISSUES AND DISCUSSION

There are three issues to be noted from the review of literature which has been made above. One is on the nature of these mix ups; the second is on the results of the mix ups and; the third is on the mode on which these mix ups are being legally handled. Our discussion will be based on the raised issues available in the above part of this paper as follows:

Nature of the Surgery Mix-Ups: There are variations in the surgery mix ups as noted in the review. We have given a detailed explanation on the variations of mix ups happening in various parts of the world. There are mix ups which originate from the recklessness of the clinical officers, record officers, receptionists, ward attendants and other hospital staff who attend the patient at the very early stages of hospitalization. In the end, surgeons do the wrong operation to a wrong patient causing a huge problem to the innocent human being. Cases of these nature results in a long term traumatize situation to peoples happened to be wrongly operated.

Again, mix-ups happen when a surgeon him/her self perform a wrong procedure to a patient who have different problem. Refer to a patient who was drilled a wrong hole on the left hand of side on page 6 of this paper. Cases of this nature have nothing to do with the wrong record from the hospital attendants but rather from the negligence of the surgeon while performing the operation.

Either, a surgeon may perform an operation to a right patient, right location and successfully do the procedure but ending up leaving some medical stuff inside the patient's body. This is taking place almost every day in a number of hospitals as explained above.

Furthermore, some mix-ups are starting from the laboratory. For those who are doing fertility operations where frozen sperms are mixed with female embryos and make a baby. The mix ups happen when a wrong frozen sperm is mixed with patient's embryo and

produce unintended baby. Other mix ups also occur in prescription and administration of drugs as clearly elaborated on page 2 of this paper. This is one aspect where mix ups can happen.

The Result of Mix-Ups: The second issue is about the mix up results. This is nothing but the extent within which the wrong surgery affected the patient. As we have explained above that when a man or a woman who had his/her leg wrongly amputated, he/she will spend his/her entire life without all legs just for the negligence of some few medical practitioners. Losing an organ is a huge loss one wouldn't want to face in life. Again, if a man had a wrong brain surgery and caused a permanent brain damages would live the whole of his remaining life time suffering just because of the negligence caused by careless medical practitioners. One may also think of a man who has been given a wrong blood group and die in the process of changing the wrong blood with the correct one. This kind of loss is due to errors from the medical practitioners which is a great loss to other human beings. These are some of the results of wrong operations related to surgery mix up that are likely to happen. They are so embarrassing and above all they end up killing number of innocent human beings every day.

How Surgery Mix-Up cases are Legally Dealt: The third issue is on how these surgery mix-up cases are legally being dealt with. As it has explained above that most of these surgery mix-ups end up with payments of fiduciary compensation, closure of health care centres and hospitals and temporary cancellation of practicing licences. Again, they end up by apologies from hospital administration, from the government and from the individuals who have made mistakes in surgery rooms. To our best understanding, these compensations, apologies and temporal cancellation of practising licences are not enough at all taking into account that the loss the patient is getting is so huge and suffer for a longer period of time and sometimes a loss youth and loss of life.

CONCLUSION

Medical doctor is a noble profession and practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise reasonable degree of care in treatment or surgery. Neither the very highest nor a very low degree of care and competence, judged in the light of the particular circumstances of each case, is that the law requires.

As health care, without surgery mix and proper diagnosis plus treatment or nursing improves people survive long without illnesses ,injuries, disabilities. The consequences of living with chronic diseases are threats to the health and well-being of people living in the Asia, Africa and beyond. More attention needs to be paid to surgery mix-ups has long been neglected throughout the world but is increasingly being recognised as essential to the health of not only individuals but also societies, nations and continents.

Quality health care without surgery mix-up that is readily available, affordable, and provided by well-trained professionals equipped to identify the right problems/ diagnosis and provide the best treatments must be available to all, not just the wealthy living in towns, cities and countries or continents via., Asia, Africa and Beyond.

RECOMMENDATION

The following forms part of our recommendations regarding surgery mix ups:

Proper Procedures before and After Surgery: Authors hereby recommend that there should be proper procedures to be strictly followed before and after any surgery. This will avoid any possible mix ups in medical centres, hospitals and health centres. Since the mix up does not necessarily starts in the surgeon therefore the procedure should also involve issues related to patient's personal particulars and other records on his illness.

Involvement of Patient before Surgery: It is hereby recommended that patients who can communicate easily should be involved before surgery in order to avoid any mix up. At this moment, surgeons may ask the patient on the nature of his illness and tally with what is in the record. This will help a lot in avoiding surgery mix ups in our medical centres.

Proper Labelling: Hospitals should provide proper labels to patients identifying them and give a reasonable amount of medical information related to his/her illness and the nature of the operation he/she ought to have. This information available in the label will be compared with details available in the medical records from the file as well as oral conversation to be made by the doctor and the patient a moment before the operation. This procedure will avoid the risk of surgery mix up to a large extent.

Legal Recommendation: Every country have enacted such laws in order to keep health care costs low, in addition to helping curb medical malpractice litigation including surgical mix ups proper remedies.

Tougher Health Laws: There should be tougher health laws which will prioritise the security of the patient when attending the hospital for treatment. Either the law should put deterred punishment to those who will be found to be guilty of causing any serious health damages to any patient negligently or recklessly.

Registration of Hospitals and Health Centres: While keeping tougher health laws in place, the law should stipulate proper requirements for any hospital or health centre should meet in order to be licensed to perform surgery procedures to patients. Again, periodic survey should be made by health authorities in order to observe whether the standard of the hospital is maintained or not.

Permanent Cancellation of Practising Licences: As mentioned above, doctors have their licences temporarily been cancelled and continue practicing while the patient who has been wrongly operated or treated is continuing suffering. This is unfair at all and that authors recommend that the practicing licences should be permanently cancelled and that doctors involved in the serious surgery mix ups should not practice any longer as soon as it is established that the mix up was due to his/her medical negligence.

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Source of funding: Self

Conflict of Interest: Nil

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Biomedical Waste Management: Balancing the Equilibrium of Health and Environment

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ABSTRACT

Right to health is regarded as one of the facets of right to life. Health has close nexus with environment which is another side of the right to life. Hence, both health and environment should be always in equilibrium. Health care establishments play an important role in preserving health and wellbeing of people. The services provided and procedures conducted therein generate a lot of waste material which render these premises at a risk of infections and diseases. Biomedical Waste Management Technique is of prime importance in the process of protection of environment and ensuring healthy environment while preserving the health of people.

The Healthcare institutions do not take enough care in handling, transportation, storage and disposal of waste and thereby pose danger to in-patients, visitors and public at large. The Biomedical Waste (Management and Handling) Rules, 1998 have become ineffective as there are certain inherent shortcomings. The rules fail to protect environment in general and health of people in particular. It has led to gross violation of fundamental right to life of people. Hence the research is undertaken to critically appraise efficacy of rules governing Biomedical Waste Management in Pune City in order to find out lacunae in them and to suggest measures for achieving the balance of equilibrium in health and environment and protecting the Right to life of people.

Keywords: *Bio medical waste, Disposal of Biomedical Waste, Environmental protection, Health Care system, Right to health*

INTRODUCTION

Hospital is one of the complex institutions which is frequently visited by people from every walk of life in the society. Apart from the patients and users of health services, there are also others who provide services, maintenance of hospital, administrative staff and those who provide logistic support. All of them produce waste which is increasing in its amount and type due to advances in scientific technology and knowledge. The waste created has its impact on health as well as environment. The hospital waste, in addition to the risk for patients and personnel who handle these wastes poses a threat to public health and environment. Keeping in view inappropriate biomedical waste management, the Ministry of Environment and Forests notified the "Biomedical Waste (management and handling) Rules, 1998" in July 1998(hereinafter called as "Rules"). In accordance with these Rules (Rule 4), it is the duty of every "occupier" i.e. a person who has the control over the institution and or its premises, to take all steps to ensure that waste generated is handled without any adverse effect to human health and environment.

The hospitals, nursing homes, clinic, dispensary, animal house, pathological lab etc., are therefore required to set in place the biological waste treatment facilities. It is however not required that every institution has to have its own waste treatment facility. The rules also envisage that common facility or any other facilities can be used for waste treatment. Handling, segregation, mutilation, disinfection, storage, transportation and final disposal of biomedical waste are various steps for safe and scientific management of biomedical waste in any establishment. However, it is necessary to understand as to how far the rules are being implemented so as to protect environment and control pollution. The process of biomedical waste management is an area of research that is increasingly attracting the attention of environmental activists in general and health care professionals in particular. The present paper aims at understanding the process of evolution and the extent of environmental pollution, the

issues related to it and also their impact and influences. Hence, it attempts to elaborate the correlation between the biomedical waste disposal and environmental pollution vis-à-vis the public health.

The subject of Environmental Protection and Hospital Waste management incorporates interdisciplinary approach and involved active participation by specialists of various disciplines such as Pathology, Microbiology, Hospital Administration, Preventive & Social Medicine, Environmental Science etc. Therefore, it is an effort to display the approaches of specialists from various disciplines under one roof with a common goal of personal and environmental protection from the hazards and ill effects of biomedical wastes. The paper is founded on the understanding of socio- environmental issues, environmental policy of the State and the Central government in light of the procedure and processes involved in biomedical waste management. Also the issues arising out of biomedical waste management are giving rise to health hazards of the people involved in handling of biomedical waste management in particular and the society at large in general.

The topic of the paper involved very sensitive legal issues of environmental pollution and health but it also has been receiving a social dimension. The Hospital Waste Management Rules though have been passed in 1998, the hurdles and obstacles faced in its implementation are numerous. Providing for the law to protect the environment from getting polluted and thereby ensuring social health is not sufficient to solve the problems but some other means of making these provisions more effective have to be thought of.

CONSTITUTIONAL AND ENVIRONMENTAL PERSPECTIVE OF THE RESEARCH

Life of individual is a nature's gift to whole mankind, which is to be preserved, protected and prospered. The term 'life' signifies every aspect of the vitality which puts human beings in good shape for self-determination. Hence, life here includes bodily (including cerebral) health and freedom from the pain that betokens organic malfunctioning or injury. Sovereign Legislative Authorities have been obligated not to undo it and shall make efforts positively to secure and promote the same. This notion is reflected in all positive legal orders. Constitutions of most of the Nation States have incorporated this notion. It is also the effect of recognition of the notion in the international instruments. Right to life as a natural, fundamental and human right became an *ab-intergra* of every positive legal order in the world. Emergence of human rights fashioned it to mold in all-encompassing penumbral fusion and absorbed in its fold life, liberty, equality and justice[1].Number of International Documents pledge, guarantee and secure basic rights to individuals so that they could develop their individuality and personhood- politically, socially, morally and economically. Municipal Legal orders responded and activated themselves to this clarion call embodying in their legal structure similar provision for the said goal.

Accordingly, the Indian Constitution guarantees a bunch of fundamental rights to the individual. The Article 21 of the Indian Constitution guarantees the right to life and liberty of the individual. Though the Article 21 couched in negative language confers on every person the fundamental right to life and liberty[2]. The Right to life and liberty has been given paramount position by our Constitution[3]. The right to life, which is the most fundamental of all is also the most difficult to interpret. The Supreme Court (hereinafter referred as SC) in many cases has further expanded the Right to life in order to include Right to Clean and Pollution Free Environment, Right to Health, Right to Development etc.

The Development of Science and Technology with ever increasing world population has brought tremendous changes in the Environment[4]. Such changes upset the balance between the human life and environment and pose enormous problems affecting environment. Such problems are faced not only by the present generation but also by the future generations and hence while exploiting the natural resources, introducing advanced techniques bringing changes in the life-style as well as technology, it becomes absolutely necessary to preserve this balance. Balancing the interests of the present with those of the future has indeed become a difficult task in itself due to the selfish and unmindful tendencies of human nature. This being the problem, one witness's constant conflict of interests with matters relating to environment and development with Health as an important facet of Human existence. Health care in indeed an essential services that supports and protects the human existence. The Health care establishments are not too far from the scientific and technological advancements which in

turn create tremendous waste that needs to be managed properly to avoid again a threat to those who are associated with the establishment as well as the society. In the pursuit of preserving the health of human beings internal as well as external environment must be healthy, free from pollution and preserved. One of the techniques to preserve and protect clean and healthy environment is the science of "sanitation' which means the whole bunch of activities preventing pollution and spread of diseases and promoting health.

Biomedical Waste Management Technique is of prime importance in the process of protection of environment and ensuring healthy environment. With the emergence of too many interventions by mankind, self-cleaning capacity of the air, water and soil is lost. Such capacity is essential so as to achieve an equilibrium of nature. As a result, many countries have laid down stringent Rules and Safeguards to maintain this capacity of nature to balance in the area of waste management, particularly in the area of Bio-Medical Waste Management. An improper treatment and discharge of waste and its unhygienic disposal has created a serious problem for biotic[5] and abiotic[6] components of the environment. Handling and disposal of Waste has become a difficult task in the urban as well as rural areas.

Understanding 'Waste': Waste is generally defined as ―something which is not put into proper usage at a given time[7]. The original definition of waste 'res derilicta'[8] corresponds to the concept of 'throw away' culture. The word 'waste' refers to useless, unused, unwanted or discarded material. Waste may be classified by multitude of schemes: by physical state (solid, liquid, gaseous), and further within solid waste, by use (packaging waste, food waste, etc.), by material (glass, paper, etc.), by physical properties (combustible, compostable, recyclable) by origin (domestic, commercial, agricultural, industrial, etc.) or by safety level (hazardous, non-hazardous)[9]. In India, for regulatory purposes, waste is generally classified into municipal solid waste and hazardous waste. However, with the ever increasing health care facilities and scientific and technological advancements in health care system, another category of 'waste' is created that is 'Biomedical Waste' as distinct from the former ones. Bio-Medical Waste is defined as any waste generated during the diagnosis, testing, treatment, research or production of biological materials by either animals or mankind. It is generated at various places, such as hospitals, clinics, nursing homes, laboratories, funeral homes, dentist offices, veterinarian or physician complexes, medical transporters (e.g., ambulances), storage and treatment facilities for biological entities and it has the potential to be hazardous to human health if it is left unregulated. It contains human body parts, tissues and organs as well as animal body parts, carcasses, excreted bodily wastes, parts containing blood and wastes generated at veterinary hospitals. Besides, microbiological and biotechnological processes cultivate Bio-Medical Waste in the form of laboratory cultures, live or non-live vaccines, and human and animal cell cultures used during research. Items that come into contact with biological-waste are also considered Bio-Medical Waste originators. Needles, syringes, blades, scalpels, blood stained material or cotton balls and dirtied plasters are a few such examples. Discarded medicines, used tubing and catheters, chemicals used for disinfection purposes and any waste that is a consequence of laboratory upkeep are all instigators of Bio-Medical Waste as well[10].

Inadequate care in handling, storage and disposal of biomedical waste exposes healthcare workers, waste handlers, patients and the community in general to infections, toxic effects and serious fatal consequences as well. World Health Organization (WHO), in its classification of waste, classifies Bio-Medical Waste into the following categories: General waste, Infectious waste, Pathological waste, Radiological waste, Chemical waste, Pharmaceutical waste, Sharps and Pressurized waste. This categorization is on the basis of weight, density and constituents of the waste[11].In the context of Environmental pollution and protection of health people connected with biomedical waste, its management is very much important.

BIOMEDICAL WASTE (MANAGEMENT AND HANDLING) RULES, 2011

The Biomedical waste management Rules, 1998 were revised and the new rules were enforced in 2011. Hence, it is necessary to incorporate the new Rules as a part of research and check the efficacy of the newly drafted stringent rules in handling and disposal of biomedical waste. Accordingly, the Biomedical Waste Management Rules, 2011 are appreciated.

Ministry of Environment and Forests has revised the Bio Medical Waste (Management and Handling) Rules

promulgated under the Environment Protection Act of 1986. The Rules were called the Bio Medical Wastes (Management and Handling) Rules 2011. However, it is necessary to note that because of complexities in implementation of these rules were amended again. The 2016 Rules changes the title of earlier rules and the title is proposed to be now Biomedical Management Waste, 2016. The present rules are simpler and will prove to be more effective so as to achieve an equilibrium between health and environment.

SALIENT FEATURES OF THE 2016 RULES VIS-A-VIS 2011 RULES

Earlier rules apply to all persons who generate, collect, receive, store, transport, treat, dispose or handle biomedical waste in any form. In the 2016 Rules an exclusion clause is provided so as to exclude radio-active waste, wastes covered under Municipal Solid Waste Management Rules, 2000, lead-acid batteries, hazardous waste, e-waste, hazardous microorganisms. Such modification is introduced to bring more clarity and covers vaccination camps, blood donation camps, surgical camps or any other health care activity undertaken outside any health care establishment or facility, where biomedical waste is generated.

The new rules provide for additional duties for occupier of an institution generating biomedical waste in their premises. The rules provide that it is the duty of the occupier to make a provision within the premises for safe, ventilated and secured location for storage of segregated biomedical waste so as to avoid any secondary handling and ease out direct transportation to the common biomedical waste treatment facility. The rules provide that it is the duty of the occupier to pre-treat the laboratory waste, micro-biological waste, blood samples and blood bags through disinfection or sterilization on-site in the manner prescribed by World Health Organization or as per the guidelines of National AID's Control Organization and then send to the common biomedical waste treatment facility. Such change aims to prevent any possible microbial contamination. The occupier is required to phase out use of chlorinated plastic bags, gloves and blood bags within two years from the date of notification of the 2016 Rules so as to eliminate emission of dioxin and furans from burning of such waste. It is the duty of the occupier to provide training to all the health care workers and others who are involved in handling of biomedical waste at the time of joining and atleast once in a year thereafter. This proposition is sure to improve management of biomedical waste including collection, segregation and transport. The proposed rules also aim to protect the health of workers handling biomedical waste by imposing duty on occupier to immunize all its health care workers and others involved in handling of biomedical waste for protection against diseases including hepatitis B and tetanus. The New Rules impose duty on the occupier to implement barcode system for bags and containers containing biomedical waste so as to improve segregation, transportation and disposal systems and avoid pilferage on the way to disposal facility. In order to help, monitor and improve management the occupier is required to report all major accidents including accidents caused by fire hazards or blasts during handling and remedial action taken by State Pollution Control Board (herein after referred to as "SPCB"). The New Rules aim to improve environment in the vicinity of treatment facility by achieving standards for retention time in secondary chamber of existing incinerators and dioxin and furans within two years from the date of notification.

The new rules also take note of deficiency in the 2011 rules and prescribe changes in the process of treatment and disposal of biomedical waste. The rules provide that the occupier shall not establish on-site treatment and disposal facility if a service of common biomedical waste treatment facility is available within distance of 75 kilometers. In case where service of common biomedical waste treatment facility is not available, the occupier is required to follow the earlier rules. 2011 rules required every healthcare facility to establish biomedical waste treatment facilities like incinerator, auto clear, micro-wave system for treatment of waste generated in that facility.

In 2011 rules biomedical waste was classified into 10 categories which led to complications. In the New Rules, biomedical waste is classified into 4 categories based on treatment options. Such classification will improve segregation of waste at source so as to channelize its proper treatment and disposal. The new rules eliminated permission to store biomedical waste beyond 24 hours and provided that untreated human anatomical waste, solid waste and bio-technological waste shall not be stored beyond 48 hours and in any case if it becomes necessary to store such waste beyond such period the occupier shall take on appropriate measures so as to avoid any adverse effect on human health and environment and inform SPCB accordingly.

The New Rules provide for one-time authorization for non-bedded healthcare facilities and has linked the authorization with validity of consent orders for bedded healthcare facilities. Such change will help Central Pollution Control Board (herein after referred to as "CPCB") in making single inspection and consider both consent and authorization in one go.

The New Rules prescribe for stringent standards for emission from incinerators and reduce the permissible limit, introduce standards for dioxin and furans so as to improve the operation of incinerator and reduce the emission of pollutants in environment. The earlier rules were silent on standards for dioxin and furans. Also the earlier rules were silent on determination of site for common BIOMEDICAL WASTE treatment and disposal facility. The New Rules make the department of the State Government dealing the allocation of land responsible for providing suitable site for setting up common BIOMEDICAL WASTE treatment and disposal facility. The New Rules would eliminate the issue of getting land for waste management facility.

MONITORING THE IMPLEMENTATION

The earlier rules provided for very less importance to monitoring and implementation of the rules. The District Committee was supposed to monitor and review implementation of these rules. It hardly had any effective control on mis-function or malpractices in the process of proper handling and disposal of biomedical waste. In the New Rules the Ministry of Environment Forest and Climate change is empowered to review the implementation of rules in the country once in a year through the healthcare secretaries, CPCB and SPCBs. It further provided that the State Government shall constitute District Level monitoring committee under the chairmanship of District Collector or District Magistrate or Deputy Commissioner or Additional Magistrate to monitor the compliance of the provisions of these rules by the healthcare facilities. The District Level Monitoring Committee shall comprise of District Medical or Health Officer, representative from SPCB, Public Health Engineering Department, Municipal Corporation or local body, common biomedical waste treatment facility, registered Non-Governmental Organization in the field of biomedical waste management. It is prescribed that the District Level Monitoring Committee shall submit its report once in 6 months to State Advisory Committee and SPCB for taking further necessary action. Thus a proper mechanism is carved out for effective and proper implementation of biomedical waste management.

METHODOLOGY FOLLOWED FOR RESEARCH

For the purpose of understanding the implementation and effectiveness of Biomedical waste management Rules, empirical study was conducted. The scope the research was limited and restricted to Pune city as the Universe and the sample was taken from amongst those establishments and undertakings where bio-medical waste is generated. The sampling technique selected for the purpose of collecting data was purposive representative sampling which would reflect all kinds of such undertakings including Government Hospitals, Semi Government Hospitals, charitable hospitals, private hospitals, nursing homes, pathological laboratories, Clinics, dispensaries, animal houses, veterinary hospitals, Medical Colleges and research laboratories. It is mandatory for every establishment generating biomedical waste to register for biomedical waste management with the local authority that is Municipal Corporation, State pollution Control Board (in our case, Maharashtra State Pollution Control Board) and PASSCO Environmental Solutions Pvt. Ltd. (herein after referred to as "PASSCO"), the sole entity managing biomedical waste disposal[12]. Other parameters like, infrastructure, Capital investment for treatment of the bio-medical waste generated, cost of operation were also taken into account while selection of sample.

The data was collected by using interview method. Interviews were conducted with the help of interview schedule consisting of variety of questions included open ended questions and yes no type questions. The questions included Methods of storage and segregation at ward / department level, internal transportation, external transportation and on site final disposal / off-site disposal. Informal discussion with various hospital functionaries was carried out.

ANALYSIS OF THE DATA AND FINDINGS

It was revealed through interview that since the Biomedical Waste management Rules, 1998 have been enforced, not much had been done for its effective implementation. Not much sensitivity about impact of

Hazardous biomedical waste on public health though hazardous effects of biomedical wastewas observed thoughit is addressed at the level where it is generated. Also, it was thought as very expensive and not worth any investment to manage biomedical waste disposal. Rather, it is observed that many entities creating biomedical waste turned a blind eye when it comes to spending for waste disposal. Much of the waste generated in hospital used to go as solid waste in the usual dustbins without being treated. The waste that was highly infectious and really toxic was used to be either deeply buried, especially in the outskirts posing threat to habitat in the vicinity or it would be incinerated wherever the incineration facility was available emitting toxic fuels which would in turn proved to be dangerous to health. Installing own system of disposal of biomedical waste, especially incinerators is not affordable for small nursing homes and hospitals. Even big players providing health services do not find it affordable. Hence, the idea of common facility for disposal of biomedical waste which was floated in 2003 by the Central Pollution Control Board was then implemented in Pune City including Phursungi and Uralikanchan, the areas annexed to Pune city.

COMMON BIOMEDICAL WASTE DISPOSAL FACILITY

In Pune city PASSCO is the only one responsible for management and disposal of Biomedical Waste. It is appointed as Common Biomedical Waste Treatment Facility Operator working on behalf of Pune Municipal Corporation. It collects, transports stores treats and finally disposes of biomedical waste generated by all the registered facilities within Pune City with the help of seven vehicles to ply on dedicated routs with 480 points of collection. PASSCO is responsible for collection, transport, storage treatment and final disposal of biomedical waste. Interviews were conducted with personnel working with PASSCO who are actually handling biomedical waste for disposal.

The basic problem of disposal is posed by those entities which are functioning without any registration. They are out of the ambit of any rules and one can easily understand that these entities go scot free for their non-compliance to the rules. Also there is no monitoring as to disposal of biomedical waste and the infectious waste generated by them goes in ordinary dustbins without being treated. Also since these entities are not registered at all, it is quite evident that they are not availing services of PASSCO for use of common disposal facility. Though it cannot be authenticated, the authorities interviewed estimate that there are only 50 to 55 % entities that generate biomedical waste are registered. It means, rest of the entities are out of the surveillance by the Authorities who monitor management and disposal of biomedical waste and pose grave threat to the health as well as environment.

It is observed that since the very registration of an entity that generates the biomedical waste requires the mandatory compliance to the rules, disposal of biomedical waste is not much problematic with the involvement of PASSCO. As far as big hospitals with accreditation by Council or ISO Certification are concerned, they implement the mandate of the Rules meticulously. They conduct periodic training and spread awareness amongst the entire staff. These hospitals have proper system of monitoring the segregation, storage, treatment and handling, transportation and disposal of biomedical waste.

Private Hospitals and Nursing homes without any accreditation or ISO Certification are found a bit lethargic in implementation of Rules. Their priorities are inclined towards expansion. They are more interested in investing in advanced technology, new machinery. They are not much concerned, rather a bit ignorant as to implementation of the Rules. They do not conduct any training so as to spread awareness. They do not even wish to spend money for buying special plastic bags with color coding so as to segregate biomedical waste. Even if they make use of these special plastic bags, they tend to use it till the bag is used to its optimum utility leaving a lot of room for spreading in situ infections and disintegration of waste. Thus these hospitals become vulnerable to pollution and a hub of infectious diseases. Medical officers and staff in private clinics and dispensaries which are registered are more aware and take all the efforts to manage and dispose of biomedical waste generated by them. It is noted that the waste they generate is less hazardous and infectious as compared to hospital waste. They implement the rules efficiently and segregate waste generated properly. However, it is found that they are also reluctant in using specially designed plastic bags for storage and disposal. They also make use of the same bag for two or three days till it is full. When specifically asked about it, most of them stated that the bags are costly and hence are not affordable. Such usage poses a threat of environmental pollution as well as health hazard. It must be noted that

principle of re-use cannot be made absolutely applicable in such cases. As far as pathological laboratories and research institutes are concerned, it is observed that they are very much disciplined in management and disposal of biomedical waste generated by them.

CONCLUSIONS AND SUGGESTION

The observations and interactions revealed various aspects of biomedical waste management and disposal from point of view of the administrators, experts, authorities entrusted with the task, actual personnel who handle waste. It is consistently observation that there is tremendous ignorance and lack of public awareness about the very concept of 'biomedical waste', its management and disposal, its hazardous effects on health as well as environment.

The whole object of Biomedical Waste Management and Disposal Rules fail because of the tendency of generating waste without any registration of the entity. As stated earlier, more than 45 % health service provider generating biomedical waste are out of the purview of Rules. They are going scot free as there is no punitive action being taken against them. These unregistered entities are in fact posing threat to health and polluting environment.

The management of most of entities that generate biomedical waste look at management and disposal of biomedical waste as tick-mark exercise so that they can get all their licenses renewed. They are reluctant to keep follow up of this activity and least interested in periodical training and up-gradation in technology in the matters connected to this issue. Expenses on Biomedical waste management and disposal is always the last priority for the management.

PASSCO, the common biomedical waste treatment facility operator in Pune faces lot of difficulties. They run vehicles on a stipulated roots for collection of biomedical waste generated in the city. This scheme of collection has a well-defined schedule. However, practical difficulty experienced is that when their vehicle reaches at a particular pick-up point, the waste is not ready for pick-up. Especially when pick at big hospitals is delayed, the time scheduled down the line is collapsed. It is also experienced that in spite of periodic training imparted by the facility, waste is not properly segregated. Poor segregation adversely impacts whole purpose of disposal. Very often lack of will power, awareness and sensitivity is experienced. It is very often contended by registered entities that the entire affair of management and disposal of biomedical waste is expensive and hence there is a natural tendency to find out means and ways to shun away from responsibility. It is typical contention of small hospitals, nursing homes, clinics and dispensaries that the cost of color coded plastic bags is not affordable. Major problem that was faced by the common disposal facility is that they could not reduce the cost of color coded plastic bags. As a result, many of them try to save on it which in turn pose a threat to health and environment. Such a behavior displays lack of environment friendly attitude on the part of those who are responsible for generating biomedical waste.

The abovementioned discussions tempt for number of suggestions for effective implementation of the Rules. It is inevitable to take immediate and urgent steps to bring all the entities under purview of the Rules by way of registration with the Pune Municipal Corporation. It is expedient to take stringent punitive action on those who are generating biomedical waste but not registered with the corporation. Also, it is needed that for effective implementation of Rules, steps are taken to set proper administrative machinery in place with adequate powers. Once again proposing amendment is not advisable in the given set of circumstances. More efforts are required to spread awareness not only among the general public but also it is necessary to create sensitivity amongst those who actually generate, manage and handle biomedical waste. The present set of Rules if implemented effectively, would definitely serve the purpose.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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5. In biology, 'biotic' components are non-living chemical and physical factors in the environment. These phenomena underlie all of biology. These factors, while generally downplayed, can have enormous impact on evolution.

6. 'Abiotic' components are aspects of geo-diversity. From the viewpoint of biology, abiotic' influences may be classified as light or more generally radiation, temperature, water, the chemical surrounding composed of the terrestrial atmospheric gases, as well as soil.

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Risk Assessment of Pesticide Residues in Selected Chilli Samples by Chromatography and Mass Spectrometry

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ABSTRACT

Introduction: Vegetables and fruits being excellent source of vitamins and minerals promote good health. However, consumption of pesticides contaminated vegetables poses a major threat to public health.

Purpose: Growing population and increased pesticide usage for agricultural yield had resulted in contaminated crops. Pesticides affects environment aswell and imposes major health risk for the public. The objective of the present study is to analyze selected fresh green chilli samples in the pune region as it was used extensively in various consumer foods.

Methodology: Thirty samples of *Capsicum annum (*fresh green chillies) were procured by random sampling from various markets in Pune. Chilli plants being of small size have a greater threat from sprayed pesticides. Ethyl acetate (10 ml) and acetic acid (100 µl) were added to crush chilli samples and homogenized. The organic extract was removed after centrifugation and subjected to analysis by Gas Chromatography-Mass Spectrometry (GC-MS) and Liquid Chromatography-Mass Spectrometry (LC-MS) to determine concentration of various pesticides.

Results & discussion: Totally 229 pesticides were screened of which 77 were analysed by GC-MS and 152 were screened using LC-MS. Few of the samples exceeded the permissible limits (100ppb). Pesticide residues above the Maximum Residue Limits (MRLs) were detected in some of the samples, while most contained pesticide residues at or below MRLs. The most frequently detected pesticide residues are Ethion, Acephate, Cypermethrin, Bifenthrin, Fenithrothion, etc., in high concentrations.

Research implications: To educate farmers on the judicious use of agrochemicals thereby decreasing the burden of these chemicals in food stuffs and their impact on public health.

Novelty/originality: The present study would contribute to the existing pool of data for close scrutiny of pesticide residues in vegetables and, to protect consumer's health. This would help in providing guidelines and regulate the use of pesticides.

Keywords: *Pesticide residues, Vegetables, Risk assessment, Contamination, GC-MS, LC-MS*

INTRODUCTION

Chilli (*Capsicum annuum L.*) is considered as an important cash crop grown in India on large scale. It is tropical and sub-tropical crop from *Solanaceae* family[1]. India is largest producer of chillies with 13.53 lakh tonnes per year in 8.01 lakh tonnes[2]. Chillies are available in two varieties, the green chilli and ripe red chilli. It is used as spice in various preparations for its peculiar pungent flavour which is due to its active ingredient 'capsaicin' in the skin and septa of the fruit. There has been an increase in the cultivation of chillies due to its increasing consumption, nutritional value and cash value in developing countries like India. A survey revealed the average per capita consumption of spices (include Chillies (*Capsicum annuum)*, Black pepper *(Piper nigrum),* Coriander seeds *(Coriandrum sativum),* Cumin seeds *(Cuminum cyminum),* Garlic *(Allium sativum),* Asafoetids *(Ferula foetida),* Dry ginger *(Zingiber officinale)* and Ajowan *(Carcum copticum)* to be 9.54g [3]. Chillies have high nutritive value of vitamins A and C. Different types of microbes attack chillies at various stages from germination to harvesting. Chillies specifically are prone to qualitative and quantitative loss in growth period due to attack of insects and non-insect pests including chilli thrips, Scirtothrips dorsalis hood

and yellow mite. To compensate this loss, wide range of pesticides is used to protect these fresh produce from the damage caused by insects, mites, rodents and other pests. These pesticides help to increase shelf life and improve the quality of fresh produce. India stands 7th for use of pesticides[4]. Every year damage caused by weeds is 34% and is increasing. Government of India in association with Central Insecticide Board and Registration Committee has permitted the use pesticides like Ethion to control the damage to crop[2]. Intensive spray of this insecticide is require to protect the plant at fruity stage but has highest risk of leaving residues on the fruit[1]. The use of these pesticides has also given rise to many problems such as pollution to the environment, pesticide residues in produce, development of resistance by major insect pest and pest outbreak. Hence, it is necessary to have effective control against its toxicological limits with set standard references. Although India is a leading producer and exporter of chillies, very often these commodities are rejected due to the presence of pesticide residues. Pesticide residues has been matter of concern as they pose risk to human health such as headaches, nausea, cancer, reproductive harm and endocrine disruption, neurotoxicity, immunological effects and developmental effects. Therefore, there is a need to understand the level of pesticide residues in food. The present study aims at analysing the concentration of pesticide residue such as Ethion and Acephate (Figures 1 & 2) in chilli samples and estimates its exposure assessment to a selected population.

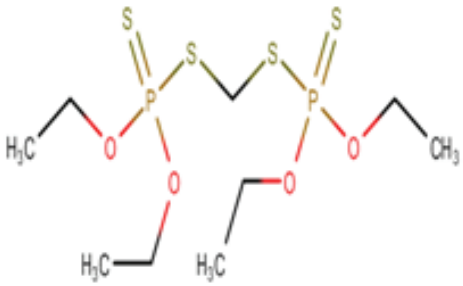


Figure 1: Structure of Ethion

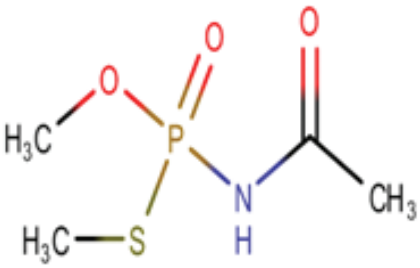


Figure 2: Structure of Acephate

MATERIALS AND METHODS

Sample collection: Thirty samples of freshly crushed chillies (without stalks) were procured from Pune markets by random sampling.

Reagents: Methanol (HPLC grade), Ethyl Acetate, Water (HPLC Grade), Anhydrous Sodium Sulphate: - pre-heated for 3 hrs. At 5000 degrees Celsius for excess water absorption from the sample, Sodium acetate (HPLC Grade) for pH maintenance, Primary Secondary Amine (PSA).

Apparatus: Centrifuge Tube (FEP) 50 ml (Tarsons test tube), Micro centrifuge tube- 2 ml, Micropipette- 1 ml, Vials -2 ml, Volumetric Pipette- 10 ml

Equipments: Blender, Homogenizer, Centrifuge, Balance 16, GCMS-MS Triple Quadra pole (Agilent Technologies 7000 C), LCMS-MS Triple Quadra pole (Agilent Technologies 6460 triple quadra pole LC/MS).

Homogenization: One kg of chilli samples was crushed, after crushing, the apparatus was rinsed with water, then with (1:1) IPA: Methanol. Again rinsed with water and used for further crushing.

Extraction: 10 grams (± 0.1g) of the homogenized sample was weighed in 50 ml centrifuge extraction tube.10 ml of HPLC grade water was added. To this homogenised sample 10ml of Ethyl Acetate was added. Then 10 g of sodium Sulphate was added to remove the excess water from the sample and 1.5 g of sodium acetate for pH maintenance was added. After this, homogenized for 5 minutes and centrifuged at 7000 rpm for 5 minutes.

Purification of samples for LCMS-MS: Three millilitre of the supernatant was taken in test tube containing 50 mg of PSA. b. Vortexed and placed aside to settle the PSA (Primary Secondary Amine). c. Two milli litre of supernatant was pipetted out in another test tube. d. 0.2 ml of 10% DEG (Di ethylene Glycol) (in Methanol) was added and evaporate to dryness under Nitrogen. e. Residue was dissolved in 0.5 ml of 0.1% Acetic Acid,1.0 ml of 0.1% Acetic acid was added and transferred in 2 ml micro centrifuge tube and vortexed for 30 seconds. f. Centrifuged at 13000 rpm for 5 minutes. g. The supernatant was taken out and filtered through 0.22µ membrane filter and 5 µl was injected into LC-MS/MS.

Purification of samples for GCMS-MS: 1 ml of supernatant was taken in 2 ml Micro centrifuge tube, which contained 50 mg of PSA (Primary Secondary

Amine). The contents were shaked it vigorously for 30 sec. Vortex and centrifuged at 13000 rpm for 5 minute followed by filtration and injection.

EXPERIMENTAL

LC Parameters: Column used was reverse phase C-18 column. Dimensions of column was 50mm X 4.6mm with particle size 1.8µ. Mobile Phase: - A. 5mM Ammonium Formate in Water. 5mM Ammonium Formate in Methanol. Flow rate: - 0.8 ml/min. Source: - ESI positive. Column Temperature was set 40°C.

Mobile phase of A consists of 5mM Ammonium Formate in water and Mobile Phase B is composed of 5mM Ammonium Formate in Methanol. Flow rate of mobile phase was set to 0.8ml/min.

Mass spectrometry (MS) Parameters: Ion source of MS was operated in ESI positive ion mode. Source temperature was set to 450 degrees. Injection volume was 5µl.

GC Parameters: Column: DB-5MS, Length-30mtr. I.D.-0.25mm, Film thickness-25µ. Oven Temperatrure: 70ºC-1.0min-50ºC/min.-150ºC-0.0min-6ºC/min-200ºC-0.0min 8ºC/min-280ºC-5.5 min.- 100ºC/min.- 300ºC-1.0 min. Injector: - PTV, Temperature Programme - 70ºC-0.08min-600ºC/min-250ºC-10min.

MS Parameters: Detector Source-EI Positive. Carrier gas Flow-He-1.2ml/min.

Household survey to assess the intake of chillies: A survey was carried out among 100 selected homemakers aged 20 years to 50 years from various societies of Kothrud, Warje and Bavdhan region, Pune. The respondents were selected by random sampling belonging to middle and high income groups. The Food frequency questionnaire (FFQ) method was used to collect the frequency of consumption of fruits and vegetables using frequency codes such as onion, tomato, radish, potato, bitter gourd, bottle gourd, brinjal, broad beans, capsicum, carrot, capsicum, green chillies, ladies finger etc among vegetables and amla, apple, banana, dates, figs, mango, pomegranate etc among fruits. However, for the present study the data on green chillies consumption was considered[5].

Food Frequency Questionnaire is a habitual method for recording dietary information of large population size usually 100 or more and usually conducted by interviewing the target group individually. The questionnaire had preliminary information about the purpose of the interview[6]. Face to face interview was conducted to clearly understand their consumption pattern[7].

The Food frequency questionnaire was designed to identify the eating pattern and frequency of green chillies consumption among the selected population.

The first part of the questionnaire included the personnel information of the respondent such as Name, Age, Education, Occupation[6].

The second part was dietary habits of the respondent and food frequency questionnaire.

Food frequency questionnaire list was divided into two parts i.e. the "vegetables above the soil" and the "vegetables below the soil."

The consumption frequency for each fruit and vegetable was measured as "Never", "once a month", "once in two weeks", "twice a week", "once a week" and "daily"[6].

RESULTS AND DISCUSSION

Farmers across the globe constantly face challenge when growing food. According to the UN Food and Agriculture organisation, an estimate of 20-40% of our global crop is lost due to plant pests and diseases. Worldwide there are about 250,000 species of plants. Three percent of these or 8000 species are weeds. Of these 8000 weeds 200-250 major problems for our food supply. Farmers spray pesticides to mitigate crop damage caused by pests, mites, infection[8].

Procured fresh chilli samples were analysed for various pesticides. 229 pesticides namely Chloropyrifos, Cypermethrin, Ethion, Acephate, Imidacloprid, Myclobutanil, Monocrotophos, Bifenthrin, Fipronil etc. were detected by LC-MS and GC-MS techniques.

From the analysed samples for pesticides Ethion and Acephate detected on LC-MS and GC-MS respectively were detected above MRL (Maximum Residue Limit). MRL for Ethion and Acephate is 0.01mg/kg.

Ethion and Acephate are compounds belonging to Organophosphorus class which are commonly used. These compounds are commonly used against various insects like thrips, jassids, aphids, ants and wasps[9]. Acephate is a sulphur containing highly reactive compound[10].

The concentration of Ethion was high in 20 samples among 30 samples i.e. in 66% of the samples. Highest

concentration to be 4598.882 ng/ml while lowest to be 11.2737 ng/ml. The permissible limit for Ethion is 10ppb (10 ng/ml). However, there were some samples which did not show any traces of Ethion.

The concentration of Aephate was high in 11 samples among 30 samples i.e. 36% of samples. Highest concentration to be 455.10 ng/ml and lowest being 15.45 ng/ml. The figures below show graphical representation of Ethion and Acephate concentration in green chilli samples.

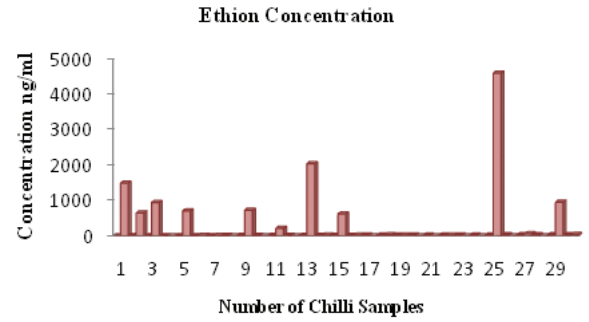


Fig. 2: concentration of Ethion in chilli samples

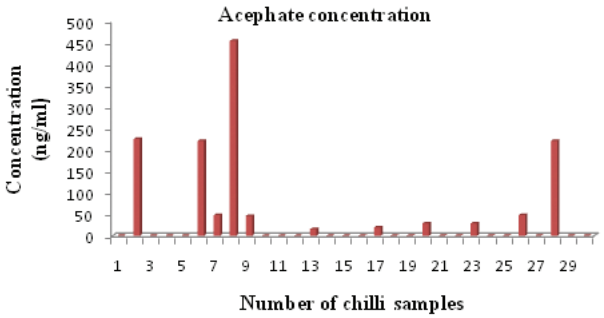


Fig. 3: Concentration of Acephate in Chilli Samples

Ethion and Acephate being members of Organophosphorus, their excess consumption is known as "Organophosphorus Poisoning". Some studies suggest that the incidence of these poisoning has been increased in past years reaching the optimum level of poisoning known as "Social Calamity". Hence, Organophosphorus poisoning is responsible for more than 50% of poisoning cases. Due to increasing number of poisoning cases, India accounts for one-third pesticide poisoning in the world[11]. Hyperglycemia is the most common disorder seen in the OP poisoning. Some studies also show that chronic exposure to small amounts of OP leads to severe error in carbohydrate metabolism. Several other organs such as pancreas, liver, muscles and brain are affected by chronic exposure to these pesticides.

The concentration of other pesticides in the samples were in the limit of MRL i.e. within the permissible limit but continuous exposure to these pesticides through green chillies with low or moderate pesticide level can accumulate in the hosts body and may prove dangerous by prolonged exposure. This is because the farmers are not aware about the good agricultural practices[12].

A diet survey was carried out among 100 selected homemakers to assess the frequency and consumption of green chillies.

The results revealed that a majority (68%) of the selected population were in the habit of consuming green chillies daily, while 15% and 14% of the population consumed chillies once in a week and twice a week.

A study revealed that the frequent use and consumption of green chillies contaminated with Ethion may lead to serious health issues such as inhibition of erythrocyte acetylcholinterase, body weight, haematological alternations lung and respiratory disorders[13]. In order to reduce the risks the farmers should be made aware regarding the safe use of the pesticides. The targeted population should also made aware of dosage of pesticides before harvesting and proper culinary processes such as washing that will reduce the residues.

CONCLUSION

In 2003, it was discussed that without the use of crop protection products, overall food production would decline, and many of the fruits and vegetables we enjoy in the store would be in short supply. Because crop protection products can help improve crop yields and supply, this keeps our food at a stable price in the grocery store.

The present study involved analysis of: Fresh chilli samples wherein 229 pesticides were identified by LC-MS and GC-MS techniques. Two pesticides namely Ethion and Acephate were predominantly detected above the permissible limit. These compounds are of concern as they are known to cause serious health issues for people chronically exposed to these compounds. Recent years there has been an increase in the production has led to the heavy use of pesticides which has further increased the concern over health effects associated with pesticide use and abuse. The household survey revealed that 68% of the respondents habitually consumed chillies in a daily basis. However, recent research showed that the concentration of Organophosphorus concentration is decreased with thorough washing[14]. It is also suggested that washing green chillies with solutions of water with salt or some chemicals like chlorine, chlorine dioxide,

hydrogen peroxide, acetic acid, hydroxyl peractic acid, iprodione have proven for reducing the pesticide levels in the green chillies[11]. Therefore, there is need for the population to use these green chillies strictly after washing and drying them by wiping them and then use in various preparations. Also, educate the pesticide sprayer (the farmer) regarding the permissible limit of pesticide.

The findings of the present study show that pesticide residues were detected in fresh chilli samples in high amounts above the permissible limits. There is a need to strictly monitor use of pesticides at the farm-level and during post-harvest periods. Such quality control mechanisms would help in diminishing the misuse of pesticides thereby ensuring that our agricultural products remain competitive in international market. There is a need to facilitate adoption and documentation of appropriate pest control procedures.

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Perceptions of EMR System by Doctors in Pune (India)

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ABSTRACT

Electronic Medical Records (EMRs) in healthcare system can reduce healthcare costs as well as improve the efficiency & effectiveness of healthcare facilities. However, only a very few physicians in small practices in India use EMR. This study focuses on examining the factors that impede or facilitate the adoption of EMR system by small physician practice. In order to execute the study, a descriptive, mixed (qualitative & quantitative) research design was used.

Survey was conducted to investigate physicians' attitudes. The responses were used to test several hypotheses. The survey included sections assessing the perceived value of using EMR, the practice demographics, and the barriers to the adoption and use of EMR. Responses were collected and analyzed using SPSS statistical tool.

The study contributes to overall understanding of the perception of physicians about EMR systems, and helps find the methods that can be used to improve the adoption of EMR systems.

Keywords: *adoption, barrier, electronic medical record, facilitator, perception.*

INTRODUCTION

Electronic Medical Records (EMRs) are a revolution in healthcare. They have a great potential to facilitate workflow and improve quality, continuity, safety and efficiency in healthcare[1,2]. By replacing many of the functions of traditional paper based medical records, EMRs promise significant advances in patient care[3]. Increased use of EMRs in practice can lead to health care savings, reduction of medical errors, and improvement in health[1,4].

Electronic Medical Record systems are the *computerized records of a patient's medical history including the details of their tests, diagnoses and treatments, in the form of text or images.* Along with the patient's medical data, they may also contain prescription and billing information. With the digitization of patient record, EMRs offer an efficient exchange of information within a facility as well as across various healthcare facilities, assisting healthcare providers in better clinical decision-making. Instant electronic access to patient records results in increased productivity. In fact, EMRs enable enhanced business process management by making available reports on all aspects of patient and administration[5].

Electronic medical record (EMR) systems offer various benefits for patients, doctors, and public health officials. They have the potential of cost savings and improving the healthcare quality[4,6,7,8]. Clinical outcomes and benefits of EMR systems include increased improvement in accuracy of records[9], reduction in medical errors[10,11] and prevention of duplicate procedures[12].

Electronic medical record systems have various advantages over paper medical records: (i) EMRs can provide easy and quick access to patient's health information. They enable secure access to information needed, unlike paper-based records which can be accessed by anyone in the facility, thus supporting high quality and efficient care. (ii) EMRs present a comprehensive patient's health information record whereas with paper-based records, hence enabling better health care decision-making, and more coordinated care. (iii) With easy, on-time access, EMRs also support better follow-up information for patients[13].

Despite broad agreement on the benefits of electronic medical records and other forms of health

information technology, health care providers have moved slowly towards adoption of these technologies[14]. The penetration of EMR in Indian market has been at a rate of 13.5 per cent[15]. Barring a few preliminary attempts to computerize basic hospital administrative and some clinical functions, there has been little appreciation or impetus given to HIT adoption[16].

This study focuses on examining the factors that impede or facilitate the adoption of EMR system by private physicians. In this paper, the results on the benefits and drawbacks that private practitioners perceive in the adoption of EMR system, are presented. Section II describes the methodology adopted to conduct the survey. Section III reports the results of the survey and section IV explains the findings of the survey. Section V concludes the paper.

METHODOLOGY

Study Design: A mixed research design (qualitative as well as quantitative), was used for the study. It aimed at exploring the views of private practitioners on the adoption of EMRs into their practices.

The study used questionnaires that sought respondent concurrence regarding barriers to and facilitation of EMR implementation. Direct observations and interviews of users were also used to collect data from study participants. The behaviour of users, including interactions between users, patients and the system, were closely noted.

Study Population: Private practitioners, from different clinical specialties - Dermatology; Ear Nose and Throat; General Practitioner; Gynaecology; Ophthalmology; Paediatric - in Pune, were approached and invited to participate in answering questionnaires.

Sample and Setting: Simple random sampling technique was used to select the sample. The final sample comprised of 250 participants from different clinical specialties. Participants included 52 Dermatologists, 35 ENT Specialists, 62 Family Physicians, 41 Ophthalmologists, 17 Gynaecologists, 32 Paediatricians and 11 physicians of Multi-Specialty.

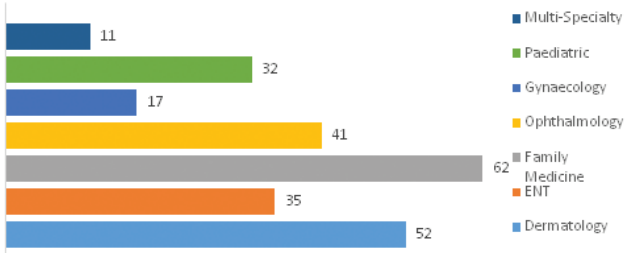


Figure 1: Respondents per Clinical Speciality Study Instrument

The survey was developed by examining and synthesizing prior hospital-based surveys of electronic records systems or related functionalities. Inputs and guidance from experts in the fields of survey research, health-information technology, and health care management helped in modification and creation of final study instrument.

The final study instrument was a 4-page structured questionnaire which was developed to obtain feedback regarding EMR adoption benefits and challenges. The questionnaire included questions about the adoption of EMR system. A series of questions assessed physicians' perceptions of the benefits of using an EMR system. The survey also asked about the factors perceived as barriers in the adoption of EMR system including financial barriers such as high implementation cost and uncertain return on investment; technical barriers such as unavailability of computers and software or hardware incompatibility; psychological barriers such as staff resistance; organizational barriers such as requirement of technical training; and privacy or security concerns such as concern about confidentiality breaches. There were also questions on use of computer in practice, internet connectivity and current use of EMR. The character of qualitative responses included personal insights, and open-ended responses that added to the richness of data. The format of the study's questions included text boxes that allowed anecdotal as well as multiple-choice responses.

The questionnaire contained twelve central questions, which included general background information. All questions, except for the general information questions and EMR utilization, captured responses using a five-point Likert scale. Responses ranged from "strongly agree" to "strongly disagree".

Survey Administration: The survey was administered between May and August 2013. Physicians from different specialities were approached and were asked to complete the written questionnaire.

Study Model: The hypothesized model was studied to determine the factors that contribute to physician perception of benefits of using an electronic medical record system.

The hypotheses were formulated as below:

H1: The facility of anywhere, anytime access to clinical data has relationship with perceived usefulness of EMR system.

H2: Enhancement in efficiency has relationship with perceived usefulness of EMR system.

H3: The ability to exchange health information has relationship with perceived usefulness of EMR system.

H4: Cost savings with the use of EMR system has relationship with perceived usefulness of EMR system.

H5: Improvement in quality of care and reduction in errors has relationship with perceived usefulness of EMR system.

H6: Improvement in productivity has relationship with perceived usefulness of EMR system.

Initial Processing of Data: Data collected from various participants was fed into the computer system and analysed for missing data and discrepancies. Two hundred and fifty (250) responses were collected by completion of the study.

The analysis was done by grouping the parameters as: innovation acceptance; perceived ease of use; perceived usefulness; economic costs and physician assurance of patient record privacy.

Statistical Analysis: SPSS software was used for storing and analysing the data. The analysis was done by determining the perceived benefits (yes or no) of using EMR from the 6 listed benefits and measuring the perception regarding the barriers using five-point Likert scale. For each of the option selected, a score of 1 was assigned, and 0 if the option remained unselected.

RESULTS

The sample population examined were physicians currently practicing medicine. The study sought to capture a diverse sample of private practitioners from across the city. Anonymity of participants was ensured as the survey instrument did not require any personal identifying information.

Survey participation was not restrictive to physicians of any specific practice type, practice size or clinical specialty. However, clinical specialties of physician participants represented a broad spectrum. Practices included independently owned and operated physician offices, and small and large physician practices. A total of 250 survey responses were analysed.

Respondent Data Analysis: The responses on all the questions were obtained from 148 respondents, while some of the respondents did not answer all the questions. The response rate for the survey was 59.2%. Respondents and non-respondents were similar with respect to specialty, practice size, experience, and practice location.

Overall, 14.1% of respondents used EMR of various forms, in their practice. Responses were received from all the areas in Pune. The greatest number of responses were recorded from the age group above 50 years (35.8%), indicating greater survey interest among a more mature care provider demographic.

The sample was chosen from a spectrum of private practitioners, including novice and experienced physicians. Table 1 shows the characteristics of respondents, comparing physicians using EMR with all the respondents. The younger physicians were amongst the highest EMR adopters.

Table 1: Characteristics of Survey Respondents

Characteristic	All (N=148)*	EMR Adopter (N=21)*	P Value ($\chi 2$ test)
Gender: Male	68.9	90.5	0.021
Age			
20-30 years	5.4	23.8	<0.001
31-40 years	24.3	47.6	
41-50 years	34.5	19.0	
> 50 years	35.8	9.5	
Experience			
1-9 years	25.7	81.0	<0.001
10-19 years	26.4	9.5	
>= 20 years	48.0	9.5	

Speciality			
Dermatology/ Cosmetology	25.0	38.1	
Ear Nose and Throat	12.8	14.3	
Family Medicine	23.6	14.3	
Gynaecology	18.2	14.3	0.614
Ophthalmology	5.4	0	
Paediatric	11.5	14.3	
Multi-Specialty	3.4	4.8	
Prior Computer Experience	16.8	100.0	<0.001

*Data is given as percentage of each group.

Perceived Usefulness of EMR: The analyses for perception of physicians regarding the benefits of using EMR was done using a hypothesized model. Both, the users as well as non-s2 of EMR, reported the same EMR features to be beneficial in their practices. The physicians perceived features of (i) anywhere, anytime access to clinical data, (ii) enhancement in efficiency, and (iii) improvement in productivity, to be the benefits of using EMR (Table 2). On the other hand, the physicians did not consider ability to exchange health information, cost savings and improvement in quality of care to be the result of using EMR system.

Apart from the varied features of EMR system, the age of respondent and current use of computer in practice also formed the factors affecting the implementation of EMR in practice.

The likelihood of implementing EMR system varied with the practice size. It was explicit from the interviews and discussions that smaller practice size was less likely to consider using an EMR.

Table 2: Perceived Usefulness of EMR

Dimension perceived to be a benefit of using EMR	All (N=148)*	P Value (χ2 test)
Anywhere, anytime access to clinical data	48.6	<0.001
Enhancement in efficiency	38.5	0.009
Ability to exchange health information	29.1	0.147
Cost savings	14.2	0.081
Improvement in quality of care	27.0	0.140
Improvement in productivity	39.2	0.002

*Data is given as percentage of each group.

Perceived Barriers in Adoption of EMR: five-point Likert scale was used to determine the perceived barriers in the adoption of EMR. Table 3 presents the median of each Likert item, along with the first quartile and third quartile. The table depicts that Financial Barrier was perceived to be the major impeding factor (87.3%, median=5.0) and the other commonly identified barriers were Organizational Barriers (58.8%, median=4.0) and Technical Barriers (50%, median=3.5).

Table 2: Perceived Barriers in Adoption of EMR

Dimension	Agree (N=148)*	Median	First Quartile	Third Quartile
Psychological Barriers	39.2	3.0	3.0	4.0
Financial Barriers	87.3	5.0	4.0	5.0
Technical Barriers	50.0	3.5	3.0	4.0
Organizational Barriers	58.8	4.0	3.0	4.0
Privacy Issues	34.5	3.0	3.0	4.0

*Data is given as percentage.

DISCUSSION

In this survey of physicians' adoption and use of EMRs, the association between physicians' demographics and their attitudes towards adoption of EMR system was determined. The results of this study showed statistically significant associations between physicians' characteristics (age and prior computer experience) and their attitudes towards adoption of the EMR system.

Of all the physicians in survey, 14.1% were using EMR in their practice. The study found that the younger generation of physicians embraced EMRs more than the older physicians. The physicians in the age group 20-40 years, especially those with the experience below 10 years, formed the majority of EMR adopters. The results were consistent with the findings of several earlier studies with respect to age[17]. These studies found age to be a predictive factor influencing EMR and other IT adoption among physicians. Other studies reported no association between age and sex, and technology adoption among physicians[18,19,20,21].

According to the study, all the physicians using EMR had a prior experience in using computers. Previous studies by Dansky et. al[22] and Van der Meijden et. al.[23] have also shown that the physicians with knowledge and prior use of computer in practice were positive towards using EMR.

In relation to key questions of the study, the relationship between perceived benefits of using EMR and willingness to adopt EMR system was also examined. Most of the survey participants considered that by implementing EMR in their practice, will provide them with anywhere, anytime access to clinical data; enhance their efficiency and improve the productivity of their practice. But not many of the survey participants regarded that the use of EMR will provide them with the benefits of exchange of health information, cost savings and the improvement in quality of care.

The results from the interviews showed that the practice size and setting had a significant impact on the possibility of implementing EMR in practice, with the likelihood of adopting EMR increasing with practice size. This is also evident from the previous studies[24,25,26,27].

On identifying the barriers to adoption of EMR system, respondents recognized financial issues i.e. high implementation cost of EMR and uncertain return on investment to be the principal barriers. The issues such as staff resistance (psychological barrier) and concern about confidentiality breaches (privacy issue) were overshadowed by the issues of requirement of technical training (organizational barrier) and unavailability of computers and software or hardware incompatibility (technical issues), along with the financial issues.

Interviews and discussions with physicians unveiled that most of the respondents believed EMR usage would disrupt the clinical encounter as it demands the attention in hunting for menus and buttons. They perceived the possibility of interaction problems with patients when using EMRs, which would possibly lead to reduced quality of care.

This study provides a detailed view of percipience of physicians towards implementation of EMR system. Despite the important information provided by this study, it had few limitations. A major limitation was that it focused on private physicians and did not assess the perspectives of other healthcare professionals who would be the potential users of EMR system. In addition, due to the low response rate and time constraints, the sample size was small. Because of the low response rate, the results of this study cannot be confidently generalized.

Another limitation was that the perception about EMR benefits and drawbacks were based on the self-reported responses of physicians. This may carry the risk of misinterpretation and raise the possibility of bias. Also, the study only reported the perceptions of physicians about technology adoption, rather than actual usage behavior. The post-implementation behavior may differ from pre-implementation self-reported perceptions or intentions to use EMR system. The study respondents had very little actual exposure to EMR system. Only a demonstration of one of the EMR systems was available to them. This might have reduced the respondents' ability to fully explore the functionality and comment on its usefulness. This lack of exposure may have increased the variability of their responses and consequently reduced the power of the study in identifying significant factors associated with attitude towards the adoption of EMR system.

Based on the results, the findings of this study have important implications for implementers, and senior managers to encourage physicians to adopt EMR system. The knowledge created through this study could potentially benefit future researchers by providing information on physicians' perceptions of technology adoption. This study also provides avenues for promoting EMR adoption among physicians and supporting the diffusion of this technology in the healthcare system.

CONCLUSION

Low adoption of the electronic medical record persists despite obvious benefits of centralized medical record management. An understanding of the problems leading to low EMR adoption was a key to finding solutions for improving the rate of EMR adoption. This study sought to identify the drivers for adoption of electronic medical record (EMR) technology. The theoretical framework of barriers towards adoption and resistance to change initially formed the basis of the study of low EMR adoption among care providers.

The survey data demonstrated that if EMR is perceived by physicians as beneficial in helping them perform clinical activities they will have a positive

attitude towards adoption of the tool. The results of this study depicted that the benefit of anywhere, anytime access to clinical data; enhancement in efficiency and improvement in productivity were the significant factors affecting physicians' attitudes towards adoption of EMR.

It was found that physicians were highly concerned about the high implementation cost of EMR and uncertain return on investment and hence were resistant to implementing EMR. Another major barrier in adoption of EMR, was the need for physician multitasking as both the entry on EMR and patient encounter, required physicians' focused attention.

The implications of these findings suggest that EMR applications, financing and user training collectively influence the adoption patterns. Assessing adoption of the EMR among private practitioners offer a considerable contribution to the existing research in the area of technology adoption among physicians.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Telemedicine-Based Community Screening of Cervical Cancer

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ABSTRACT

Introduction: Every year an estimated 122,844 women in India are newly diagnosed with cervical cancer, the 2nd most frequent cancer in India. Visual Inspection with Acetic acid (VIA) is a simple and low-cost cervical cancer screening test for a community based programme, but suffers from subjectivity as it is usually performed by minimally trained paramedics.

Purpose: To make quality assured cervical cancer screening test accessible to the community through a mobile technology intervention.

Methodology: A team of trained health personnel reaches out to women in the Pune community and imparts awareness. Consent and relevant medical information are collected from eligible women and VIA is performed by well-trained paramedics (nurses in this project) in mobile screening camps. To improve performance of VIA, digital images of cervix are captured using a portable colposcope, and are synced to a cloud system. The images and information are then accessed and evaluated by the gynecologist at the tertiary clinic. Women with abnormal screening results are requested to come to the clinic for further follow-up and investigations.

Results: Between March to November 2016, 2294 women were screened out of which 11.99% were detected with cervical abnormalities. 86.27% of them were screened for cervical cancer for the first time in their lives.

Conclusion: Telemedicine-based community cervical cancer screening approach appears feasible. In our model, the quality of VIA, usually interpreted by a paramedic, was superior as every single case was interpreted by a gynecologist, who would otherwise not be accessible in mobile camps.

Keywords: *Cervical cancer, Digital VIA, Screening, Telemedicine*

INTRODUCTION

In India, cervical cancer is the second most common cancer in women. An overall 5-

year survival of cervical cancer is determined by stage at diagnosis, and has been documented as 73.2% for early-stage localised cancer, but as low as 7.4% for advanced stage disease[1].

Table 1: Cervical cancer scenario in India[2]

Variables	India	World
Age Standardised Rate (new cases per 100,000 people)	22.0	14.0
Incidence	122,844	527,624
Mortality	67,477	25,653
Mortality rate	122.4	6.8

The major and primary risk factor for cervical cancer is persistent infection with high- risk oncogenic human papilloma virus, most oncogenic being HPV type 16 and 18[1].

Rationale: Early detection‖ remains the most important strategy all over the world to counter the burden ofcervical cancer. However, lack of awareness in women about disease symptoms, affordable screening modalities, and routine screening leads to negligence, thereby, resulting in costly delay in diagnosis and subsequent medical management [1,3]. The rationale of cervical cancer screening is based on the detection of pre-invasive lesions known as cervical intra- epithelial neoplasia (CIN). These lesions precede the development of invasive disease, usually by many years. This understanding of the natural history of cervical cancer

offers the opportunity of early detection and treatment before the development of cancer[4].

BACKGROUND

Awareness: Despite the knowledge that screening helps prevent cervical cancer by detecting the disease in early stages, organised community screening programs are absent in Indian population. In order to increase the impact of screening on early detection of disease, it is necessary to carry out specific cervical cancer education and awareness sessions for men and women to facilitate care seeking[3].

Screening programmes: The National Comprehensive Cancer Control Programme for India (NCCCPI) was started in 1975, with focus on equipping premier cancer institutions for cancer management. By 1984–1985, the focus shifted to primary prevention and early detection of cancer cases. The emphasis of the programme around 1990-1991 was on district cancer control programme. By 2008, the National programme priorities were to create and recognize new regional cancer centers (RCCs), strengthen existing RCCs, develop oncology wings in medical college hospitals, and also focus on district cancer control programme. These district cancer control programs focused on commonly prevalent cancers in India including cervical cancer which was the top killing cancer at that time. This National programme for cancer control became a part of a larger programme on non-communicable diseases called National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Disease and Stroke (NPCDCS) in 2010 [3]. Despite all these efforts and the noteworthy examples of successfully run cervical cancer screening programs in states such as Tamil Nadu, a national cervical cancer screening program for India has not yet emerged.

Screening tests: Most commonly used methods for cervical cancer screening are naked eye Visual Inspection with Acetic Acid (VIA), naked eye Visual Inspection with Lugol's Iodine (VILI), VIA with magnification (VIAM), conventional Pap smear test, liquid-based cytology (LBC) test, and HPV DNA test [1]. Colposcopy is often the reference standard test (in the absence of histology) in various studies where the screening tests are compared with each other[5].

As a result of screening by conventional Pap smear test in many developed countries, there has been a significant decline in cervical cancer incidence and associated mortality. However, screening programs do not exist in many developing countries. Also, cytology-based programmes in some low-resource settings have not been effective in reducing the burden of disease[4].

In India, due to resource constraints such as limited infrastructure, trained personnel, and implementation challenges, cytology-based screening programme have been difficult to implement on a large scale. Also, cytological interpretation is highly subjective. Hence, experienced cytologists and good quality samples are essential, but are challenging to obtain in a resource-constrained setting. Inconsistent test results leading to repeat procedures (in as many as three visits) lead to loss in follow-up of the screened subjects. LBC tests are more standardized than the conventional Pap smear, but are also expensive[1]. Unlike cytology interpretation which is subjective, HPV-DNA test is objective and is a highly reproducible test. However, at present, it is expensive and time consuming, and requires sophisticated laboratory facilities[4].

VIA: VIA is a practical and an affordable alternative to cytology based screening tests. A single VIA screening test has been calculated to reduce the lifetime risk of cervical cancer by 25%. However, VIA has its limitations: a) it requires effectively trained personnel, continuous training and supervision, b) it is often carried out by trained nurses, hence, it suffers from sub-optimal reproducibility as the interpretation can vary from personnel to personnel, c) the test has moderate sensitivity and low specificity, estimates of which vary widely – higher values achieved by doctors than by nurses[6].

The disadvantage of subjectivity and varied interpretation is associated with lack of experience and training. A strategy which can take experience and training to the field by the means of tele-interpretation by a doctor may be able to alleviate VIA's disadvantage. The potential of mobile phone based telemedicine can be tapped to assist the para-medical staff or minimally trained healthcare professionals in interpreting VIA and also in the logistics of data management. This approach will not only ensure better quality of care but will also allow for accessibility of the available resources to more women in the community.

Colposcopy: Often, VIA positive women are referred for colposcopy in order to reduce the risk of overtreatment. Colposcopy, the standard of care for patients with an abnormal screening test, may also be used for primary screening in low-resource settings[7]. Colposcopy essentially incorporates the components of VIA and VILI to visualize the cervix under magnification. In colposcopy, the transformation zone of the cervix is examined for cancer or its precursors under a good light source. After application of 3-5% acetic acid on the cervix, a cancer or its precursor may appear as well defined, dense, opaque white areas or growths. In the presence of cervical precancers or cancers, the transformation zone appears mustard yellow after the application of Lugol's iodine. The magnified view and strong illumination enables the operator to visually discriminate abnormal tissue from healthy tissues[8].

However, in many regional and national health care settings, access to colposcopy is limited to specialised clinics. The stationary colposcope in these specialised clinics have the limitations of being heavy, requiring an electrical connection and technical support. Also, it leads to additional costs to the patients and health care system because the patient needs to be brought to a stationary colposcope [8]. The limited access to doctors and the limitations of stationary colposcopes are reasons why screening colposcopy has not been employed in resource-constrained settings [7]. Hence, in low-resource settings, screening by the portable, battery-driven colposcope (i.e., Gynocular™, Gynius AB, Stockholm, Sweden) could offer an accurate, cost-effective and pragmatic approach for cervical cancer screening in the community[7].

Gynocular™ enables colposcopy in any setting and thus is made available as well as accessible to the community at large. The portable monocular colposcope has been approved as a non-invasive medical diagnostic class I tool with 5x to 12x magnification by the Swedish National Drug Authority. Other features are LED illumination, green filter, rechargeable battery, and it is also mountable on a camera tripod. The optics, resolution, and illumination of Gynocular™ are similar to that of a stationary colposcope[8].

A combination of the portable colposcope with the omnipresent internet-enabled smart phones could be a novel strategy to improve the performance and effectiveness of VIA in a community based cervical cancer screening programme. Smart phones are easy to use, and allow for immediate image capture which can be sent to an expert from a remote location in real time. This paper is aimed at evaluating the feasibility of this strategy to boost the performance and effectiveness of VIA test.

PURPOSE

1. To make women aware about cervical cancer
2. To make quality assured cervical cancer screening test accessible to the community through a mobile technology intervention

METHODOLOGY

Project population: Eligible women from area limits of Pune Municipal Corporation

Inclusion Criteria

i. Women aged between 25-65 years

ii. Women with intact uterus

Exclusion Criteria

i. Women who have had previous history of cervical cancer (documented proof of histological diagnosis)

ii. Women who have had cervical cancer screening in the past one year iii. Pregnant women

iv. Women who are menstruating on the day of examination and three days pre/post menstrual period

Project Flow: The flow of the project was modelled as follows (see Figure 1):

i. Primary Level: Education, awareness of cervical cancer

ii. Secondary Level: Screening (VIA/Colposcopy) for eligible women aged between 25-65

iii. Tertiary Level: Cervical cancer diagnosis (colposcopy, biopsy) for abnormal cases detected through screening

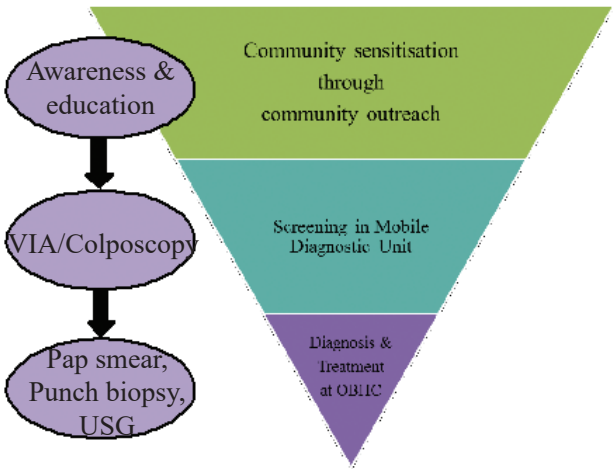


Fig 1: Operational model for community screening of cervical cancer in Pune city

Primary level: Primary healthcare workers (PHWs) organise community awareness drives, and offer information on cervical cancer and its screening techniques. This awareness drive is conducted prior to organising cancer screening camps.

Secondary level: *Interview and consent*: Printed consent forms are given or read out to the participants (in case of illiterate participants) and their signature or left thumb impression is obtained. Socio-demographic and reproductive history related information is collected during a questionnaire based interview.

Screening of subjects: The screening test is carried out after the interview and consent. A nurse examines the cervix by inserting a bivalve vaginal speculum, and captures the 1st image of the cervix on a smart phone through a portable, battery-operated colposcope (Gynocular™, Gynius AB, Stockholm, Sweden). She then performs VIA by applying 4% acetic acid to the cervix using cotton swab and captures the 2nd image of the cervix. After a minute, the women are further examined after application of Lugol's iodine and the 3rd image is captured. After this, all the data including images are synced to a cloud based system. The synced data and images obtained are then made available to the gynecologist at the central clinic - Orchid Breast Health Centre (OBHC).

Interpretation and diagnosis: The digital images are evaluated by an experienced gynecologist at OBHC.

Definition of positive results: Test is considered to be positive if definite acetowhite lesions are visualized close to the squamo-columnar junction in the transformation zone, or if the entire cervix or a growth on the cervix turns acetowhite or if there is a cervical polyp.

Tertiary level:

Follow-up visit: Depending upon test positivity detected from the digital images, the women are requested to visit OBHC for further medical follow-up and treatment at subsidised cost. In their follow-up visits, Pap smears are obtained, and colposcopies are performed by the gynaecologist. Biopsies are obtained from areas on the cervix that are assessed by colposcopy to be abnormal using Tischler-Morgan™ Biopsy Punch. All Pap smears and biopsy specimens are fixed and transported to the laboratory according to standard practice. Reports obtained from the laboratory are correlated with clinical findings and handed over to the women. Women with cervical infection are prescribed medications and advised appropriate follow-up.

*Follow up and treatment***:** Women considered positive after laboratory diagnosis are followed up and advised about treatment options. The primary healthcare workers keep in touch with these women to ensure that they seek treatment. The follow-up process is documented - method/means of follow-up, number of times the subject is followed-up, contact numbers of her and her family/ friends/neighbours, the visits to OBHC, and reason for not complying to follow-up.

Data management and statistical analysis: The data is collected and recorded using a standardised data collection format for further statistical analysis

Quality assurance: To ensure quality, thereby achieving high sensitivity, specificity, and reproducibility, and low subjectivity, all nurses and doctors involved in the project are trained and re- oriented at the beginning of the project. They also participate in periodic retraining and assessment sessions. Internal quality control measures are followed according to WHO guidelines, and wherever necessary, introduced on the field.

RESULTS

In this project, 2294 women were screened in 105 camps during a period of 9 months between March and November 2016. Table 2 summarises the socio-

demographic and reproductive characteristics of the women who participated in the cervical cancer screening programme in Pune city

Table 2: Socio-demographic characteristics and obstetric and gynaecological history of 2294 women screened in 105 camps

Parameters	Number
Mean age	37.25
Marital status - Currently married/living together	2097
Marital status - Divorced/separated	44
Marital status -Widow	142
Marital status - Never married	11
Age at menarche (average age in years)	13.89 years
Age at first sexual intercourse (average age in years)	19.77 years
Women who had multiple sexual partners	38
Number of pregnancies (average)	2.77
Number of children (average)	1.99
Age at first child birth (average age in years)	21.18
Contraception (via pill)	275
Contraception (via IUCD)	424
Number of women screened for cervical cancer for the first time ever	1979
Number of women screened positive who needed a recall visit	275
Number of women diagnosed with cervical infections	787

Awareness: Out of the 2294 women who were screened for cervical cancer in the camps, 19 79 women (86.27%) were being screened for cervical cancer for the first time in their lives (Figure 2).

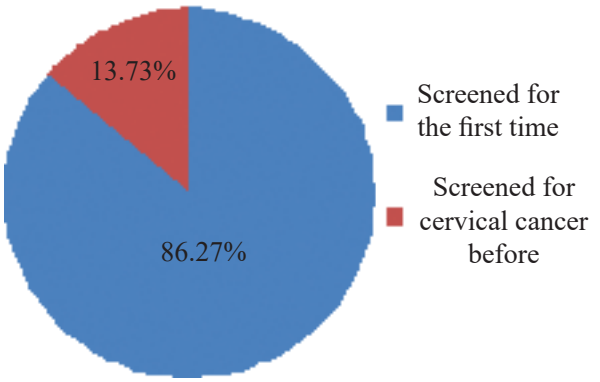


Fig. 2: Pie-chart depicting the number of women screened for cervical time for the first time ever Screening for cervical cancer

Screened-Positive: On performing the cervical cancer screening test, 275 women (11.99%) were screened positive among a total of 2294 women who participated in the screening camps (Figure 3). Apart from picking up acetowhite lesions which could be indicative of cervical pre-cancer/cancer, significant numbers of cervical infections were also picked up (34.31%).

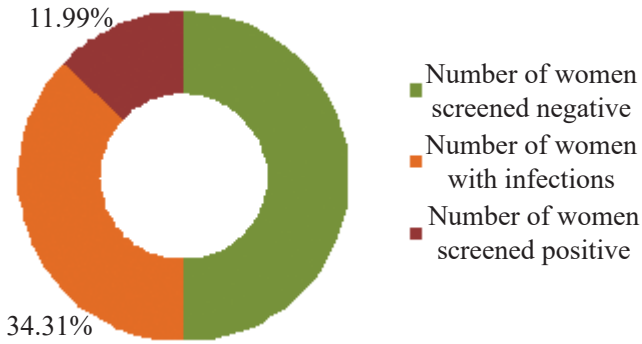


Fig. 3: Graph representing the various interpretations obtained in the screening programme including those screened positive

DISCUSSION

In India, cervical cancer is diagnosed in 122,844 women every year, and 67,477 die from the disease every year. With a population of 432.2 million women aged 15 years and older at the risk of developing the second most common cancer in women[2], there is a need to develop strategies to reach out to the community, create awareness, and detect the disease early.

Awareness: The socio-demographic profile of the women included in the current project is typical of a population which is low on healthcare service and resources. The absence of screening in majority of the participating women is a direct indication of the low awareness about cervical cancer among the participants. Knowledge and awareness of cervical cancer screening may be increased through education, which may in turn help increase screening uptake[9]. Although in our project the education and literacy status of the screened population was not captured, the screening was performed in urban Pune where female literacy rate is 81.05[10].

Screening test: The experience from western countries demonstrates that cytology based screening can prevent cervical cancer. However, the scenario in low and middle income countries (LMIC) is different. Lack of resources, both materials and human, has become a barrier for implementing large-scale screenings in LMIC. Hence,

in such settings, WHO has recommended cervical VIA as an optimal screening methodology [11].

As VIA suffers from subjectivity and lack of quality control, it is challenging to have highly skilled human resources identify true CIN2+ lesions which occur in 2–4% of patients among numerous benign changes [9,12]. A strategy to reduce the human error of the paramedic is to have an expert evaluate and interpret the test. This will also improve VIA's performance by reducing false- positive rates and increasing detection of true positive cases.

Telemedicine: Generally, VIA test is performed and interpreted by trained paramedic. In this project, the test was performed by trained health personnel but interpretation was given by a specialist, a gynaec-oncologist. For a resource constrained setting like India, where for a billion plus population, doctors are only in thousands [3], this model using Digital imaging after acetic acid application (D-VIA), provides advantages of large scale, quality assured screening [13].

These D-VIA images of the cervix can be visualised with or without magnification, and hence can aid in improving the diagnostic accuracy[9]. Conventionally, screening with D-VIA was performed using standard digital cameras and the images were archived on desktops/laptops. With the advent of the easy to use smart phones, there is an advantage of obtaining high-quality images and sharing those images and related information quickly over the internet. India is the 2nd largest user of smartphones in the world, rendering this tele-medicine approach particularly useful for the Indian population[13].

In this project, the VIA positivity rate was 11.98% which is comparable to 6.6% - 27.4% of India and other developing countries [4,14,15,16]. This implies that this model may be the way forward for routine remote cervical cancer screening programmes. It has also been observed that smart phones have the capacity to monitor subtle cervical changes. This could be used as a means of a quality assurance process in a cervical cancer screening programme[18,19].

The major limitation of this study is the significant drop-out rate of 89.09% among VIA-positive women. This loss to follow up is commonly plaguing community based screening programmes [9,20,21]. Various corrective interventions to improve the follow-up rates are being evaluated in this programme.

CONCLUSION

Remote healthcare services based on telemedicine/ smart phones hold promise of reaching out to the community to combat deadly, but curable disease like cervical cancer. Furthermore, in this project, the quality of VIA, usually interpreted by a paramedic (nurse), was improved as every single case was interpreted by a gynaecologist, who would otherwise not be accessible in mobile cancer screening camps. However, further studies are required to standardise the process of photography and to form guidelines on aspects like standardization of shot angles, the distance from the cervix etc [9]. Effective follow-up to minimise the drop-rates is critical to the success of such community based cancer detection programmes.

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Conflict of Interest: Nil

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Cloud Enabled Standard Electronic Health Record Architecture for Indian Healthcare Sector

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ABSTRACT

The current health care system in India has a three-tier structure for delivering health care services to different strata of society. Individual patient health information is scattered across many levels of the health care system in which consistent data availability at the point of care is very much essential. Currently, many healthcare sectors use hospital-centric approach to maintain and manage hospital information in which patient health information cannot be shared with another hospital at the point of care. In this work, a cloud-enabled standard Electronic Health Record (EHR) architecture is proposed, which uses the patient-centric approach in which distributed patient health records are made available in an integrated and unified manner at the point of care. Health data recording and reporting are done using standard codings such as SNOMED-CT, LOINC, DICOM and NDC. For unique identification of patient in different levels of health care system EHR system is linked with Aadhaar which enables portability of patient and gives easy access to the patient health records in local, regional and national level database. Also, Security Assertion Markup Language-Single Sign On(SAML-SSO) authentication model is adopted to access multiple services of health information after signing in once which improves the security and increase the access speed of the health information service.

Keyword: *Aadhaar, Electronic Health Records, Healthcare IT, Health Standards, SAML-SSO*

INTRODUCTION

The current scenario in Indian healthcare sector is struggling to maintain the patient health records which can be shared across three-tier structure of healthcare levels namely Primary Healthcare Centre (PHC), Secondary Care Centre (SHC), and Tertiary Care Centre (THC). Public health service sectors run by Government are overburdened with large geographical size, trend of population aging, increasing population density, inconsistent provision of care, inaccessibility of health records, illiteracy, diversity in food habit and lifestyle are various impediments[1]. Low budget for healthcare and coordination have triggered down trend in health services. Presently in most of the hospitals patient data is on paper, which is non-accessible during patient care and prevents the health care professional in providing better care to the patient. This situation demands urgent need for dissemination of knowledge by interlinking PHC, SHC, and THC by Information and Communication Technology (ICT) applications. The primary health care centers deal with patients whose medical conditions can be managed on an outpatient basis[2]. The secondary care is usually dealt in acute care hospitals whereas tertiary care requires the resources of a sophisticated medical center.

In the present scenario, Indian hospitals maintain patient information in various forms such as paper based, Electronic Medical Record (EMR) and hybrid records which use both paper and digital information. EMR is a digital repository of patient health data that contains all of a patient's medical history from one practitioner. The information stored in EMRs is not easily shared with providers outside of the hospital. A patient's record might even have to be printed out and delivered by mail to specialists and other members of the care team when required. Consider the scenario where patient has undergone series of x-rays, blood tests, and high-level test in hospital and are recorded in EMR database. If the patient visits another hospital for getting more high-tech treatment patient is not able to access the previous record and doctor will suggest repeating all the tests in higher care level.

India is the seventh largest country based on the geographical area. It has high regional variation and cultural diversity. The acceptance of a particular policy varies from one region to another region. Economic inequality in India is hindering EHR standardization process. India has different educational contours, technical knowledge and willingness to adapt to such system is a matter of concern. Hence existing international system cannot be ported to Indian scenario. Development of a system to maintain EHR considering geographical, regional, economic imbalances in India is the need of hour.

The EHR system which is present internationally has been developed using licensed platforms[3]. The hosting of licensed platforms turn out to be expensive. India is mainly focusing on cost sensitive platform for EHR system by using open source software. The development of EHR system will enforce to follow standard way of capturing the diagnosis data in all healthcare levels.

As part of the field study hospitals at different healthcare levels namely primary, secondary and tertiary healthcare center in Udupi district, Karnataka were visited. Field study was conducted to understand the process, various records formats used for recording patient information and also patient flow in all levels of healthcare settings. During this study it was observed that, sub center, primary health center and community healthcare center are maintaining yearly paper-based records such as registration book, examination book and treatment book. In the record room only current five years of patient data is maintained and later it is discarded. Because of this the continuous health data about the patient is lost. Hence present requirement for Indian healthcare scenario is to capture lifelong summary of the patient from pre-birth to post-death[5]. To solve all these issues standardization of health records and consistent data availability are essential for better functioning of health care system. The proposed standard Electronic Health Record (EHR) makes use of architectural requirements and functional specifications specified by Ministry of Health & Family Welfare (MoH&FW).

Healthcare ecosystem[5] consists of doctors, physicians, nurse, pharmacist, radiologist, lab technician, and patient. Cloud computing helps in organizing the medical record at different levels of healthcare setting. Cloud can provide several benefits to all the users of the healthcare ecosystem by connecting many health information management systems together with laboratory information system, pharmacy information system, radiology information system etc. With cloud-based EHR model, hospitals need not spend core portion of their budgets on IT infrastructure[6]. Cloud users of the hospital get the following benefit to maintain a patient record in a meaningful way. On-demand provisioning of hardware resources, tremendous flexibility in the usage level, significant cost reductions due to low infrastructure investments and the 'pay-per-use' pricing model.

The rest of the paper is organized as follows. The related work is described in Section 2, medical terminology and coding standards are described in Section 3, details of EHR generation process and proposed architecture are described in Section 4, the benefits of proposed cloud-enabled architecture is described in section 5 and Chapter 6 gives the Conclusion.

RELATED WORKS

The veterans health information systems and technology architecture (VistA) is the traditional EHR system7 used in the United States. It is a largest single medical system in United States which covers quarter of the nation's populations. VistA is a collection of 168 application packages/modules. It is not a single application.

(Bahga & Vijay K, 2013) discussed about the limitations of (VistA) with respect to the Design methodology, data interoperability, scalability and performance. Traditional EHR systems use the different unstructured way of recording patient data, and each clinical concept is maintained as a separate table which leads to a large number of tables in the database[8]. Also, a wide variety of data stored in generic data structure method leads to the problem of interoperability when sharing with the other hospitals. They also discussed that the usage of different and often conflicting technical and semantic standards in traditional EHR leads to the problem of data integration and interoperability. Different EHR standards, different technology, and different languages also lead to the problem of exchange of data between two healthcare systems. They have proposed two cloud-based models for the United States hospital to integrate different health services together namely Open Vista and cloud health information systems technology architecture (CHISTAR).

(Wang & PengWei, 2013) discussed about how information technology can be adopted in the healthcare to automate the process flow from paper-based to electronic health record[9]. They also discussed about the use of service-oriented architecture (SOA) during implementation of web-based healthcare platform techniques, and also considers some of the implementation factor which requires active recommendation and customization in healthcare services.

(Rybynok, 2011) designed a My care Web especially for emergency situations in health. i.e. availability of patient health information during emergency situations[10]. Doctor can access the patient data which is stored in the patient medical record. They also discussed cross-platform GUI issue during the access of emergency data.

(Hayrinen, Saranto, & Nykanen, 2008) presented research literatures on EHR generation flow. The objective of the work is to handle the issues such as the way EHR is defined, construction of EHR records and in what context EHRs are used[11]. The data collections processes is also reviewed.

All the above papers are not pertaining to Indian scenario. The way of capturing patient data and the patient flow in Indian hospital scenario is different. As a result, there is a need to develop EHR for Indian Hospitals.

The government of India has recommended healthcare IT standards with respect to Indian health care condition to develop standard EHR[12]. The recommendation outline mainly discussed about interoperability issue, development life cycle and key points to improve the adopting standards. Also medical, legal issues that have to be considered during the creation of EHR are discussed. There are many other issues related to medico-legal perspectives are addressed. The key issues fall within four principal categories: (i) Data ownership (ii) Data privacy and security (iii) Access control (iv) Secondary use of patient data

MEDICAL TERMINOLOGY AND CODING STANDARDS

The primary aim of the healthcare information system is to deliver lifelong clinical care at all times and to meet this requirement, syntactic and semantic interoperability of data should be maintained at all time. To meet consistent representation of the interoperability requirements, standardizing vocabularies, or mapping between different vocabularies are necessary. It is also important to have these terminologies and codes in computer processable format to aid automation and ensure that data is in an analyzable state at all times12. Therefore, a health record system must conform to the following standards:

International Classification of Disease (ICD 10)

The International Classification of Disease (ICD 10) is a widely recognized international system for recording diagnoses. By using ICD 10 codes, the patient data will be consistent when describing diseases, morbidity, and mortality.

ICD-10 code set having three, four, five, six or seven characters depending on the nature of the disease. First three characters are used for categories of disease13. Further expansion gives the details of diagnosis. Figure 1 shows an example of ICD codes.

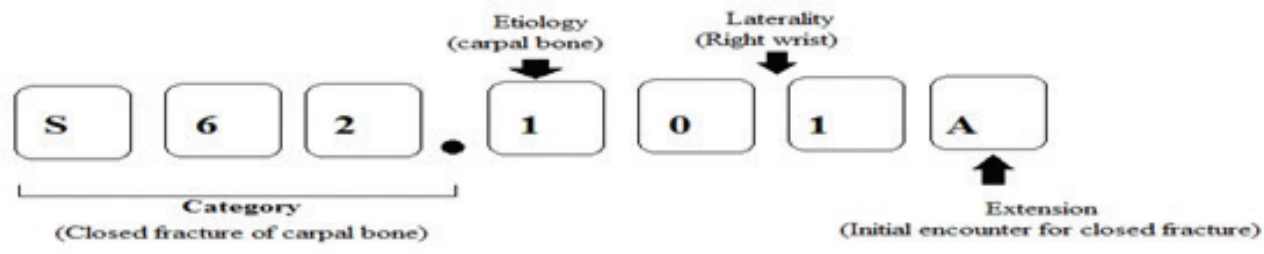


Figure 1: ICD 10 example

The main drawback of ICD 10 is running out of codes since the code numbers are the backbone of classification and the number of diseases is very large in number compared to the available codes in the ICD 10. In ICD 10, multiple disorders are grouped under one code, and some contents have little clinical relevance[14].

Systemized Nomenclature of Medicine Clinical Terms (SNOMED-CT)

SNOMED CT has no limits on the codes that can be used compared to ICD-10. SNOMED CT is the

most comprehensive, multilingual clinical healthcare terminology in the world. SNOMED CT15 stands for Systemized Nomenclature of Medicine Clinical Terms. It is having the comprehensive clinical scope and covers the procedure, diseases, and clinical data. Using this coding standard, patient health status data such as problem list, allergies and diagnosis, and rules are stored in a consistent way across the site of care. By standardizing, the terminology allows clinically relevant meaning based retrieval and allows more accurate reporting of data. SNOMED CT is a clinically validated, semantically rich, controlled vocabulary that facilitates evolutionary growth in expressivity to meet emerging requirements.

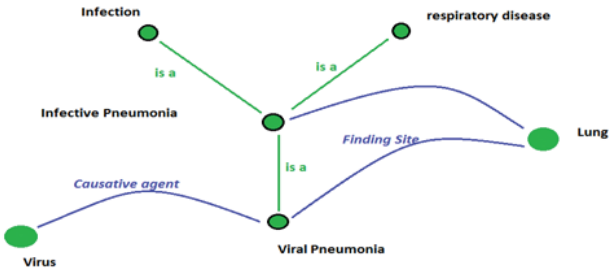


Figure 2: An example for viral pneumonia using SNOMED-CT

The SNOMED CT can easily be integrated with an EHR system for better user interface and simple capture of clinical ideas and sharing of information taking advantage of global terminology. SNOMED CT has been divided into 19 hierarchy. Every code concept is linked to related concepts (attribute relationships). An example for viral pneumonia using SNOMED-CT is shown in Figure 2.

Logical Observation Identifiers Names and Codes (LOINC)

LOINC provides a set of universal names and ID codes for identifying laboratory and clinical test results in hospitals[16]. Different hospital uses different standards to capture the laboratory data. When the patient moves from one hospital to another hospital, there are some chance that hospital might ask the patient to repeat the test. During this time, the patient has to repeat the laboratory procedure. In order to avoid the repetition all hospitals' medical procedure should record using LOINC codes.

Digital Imaging and Communications in Medicine (DICOM)

Digital Imaging and Communications in Medicine (DICOM) is a standard for handling biomedical and therapeutic information in all the discipline of the healthcare sector. The main goal of DICOM Standards is to improve workflow efficiency between the imaging system and another information system[17]. DICOM helps in connecting different health center together to share information in a standard way by using digital image information. Currently, DICOM works as an upper layer protocol that is used in TCP/IP protocol suite. Application layer protocol is independent of the physical network, and with its unique properties enables to communicate any two compatible set of services and information object.

METHODOLOGY

The methodology adopted for developing the cloud-enabled standards Electronic Health Records is described in this section.

Electronic health record generation process

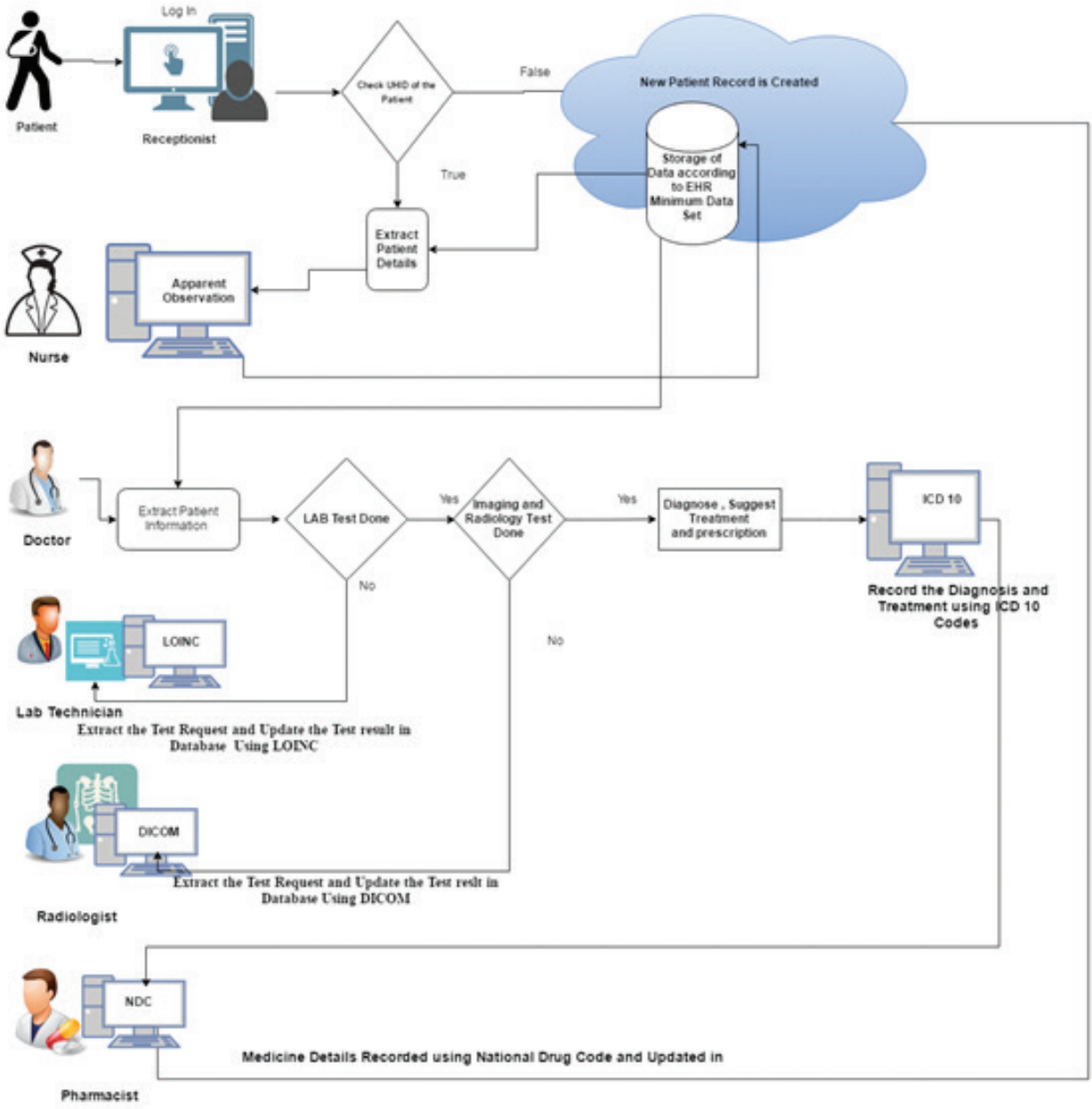


Figure 3: Electronic Health Record Generation Process

Figure 3 depicts the EHR generation process. When a patient arrives at the hospital at the registration desk, patient demographic details are collected using any standard and valid ID such as Aadhaar Card and authenticated. Once the registration process is complete, the patient moves to the nurse, where the basic vital signs are collected such as height, weight, blood pressure, etc. On completion, the patientis sent to the doctor. The doctor takes the history and physically examines the patient and suggests for the diagnostic test such as; Lab, Radiology or others depending upon the initial assessment and records the entire event in the EHR database. Data generated from the laboratory test is stored using LOINC, DICOM and recorded in the cloud-based EHR database. The patient data stored in the EHR database is made available to the doctor for further verification and care. Doctor confirms the diagnosis and enters the treatment details and symptoms into the EHR database using one of the classification standards like ICD or SNOMED-CT. The doctor then writes aprescription, and that data is transferred to the pharmacist for dispensing of medicine. The pharmacist verifies the prescription details and records the drug detail using National Drug Code (NDC) Database for further communication. If the patient visits the same healthcare

for the second time, using his/her unique identity, the doctors can retrieve the previous treatment history or medication for the patient care.

Proposed cloud-enabled standard Electronic Health Record (EHR) architecture

Current health care information systems of the hospitals are usually isolated from each other as most of the hospitals and healthcare institutions have their ownformat to create Electronic Medical Record (EMR) to serve the purpose of treating thepatient. But this approach does not support when the patient moves from one health care facility to another for care and consultation as the EMR in this institution are not built on similar architecture and integrated. Thislimitation calls for anElectronic Health Record (EHR) built on standard architecture and cloud enabled so that the health information generated at various location within and outside the institution can be captured without any difficulty.

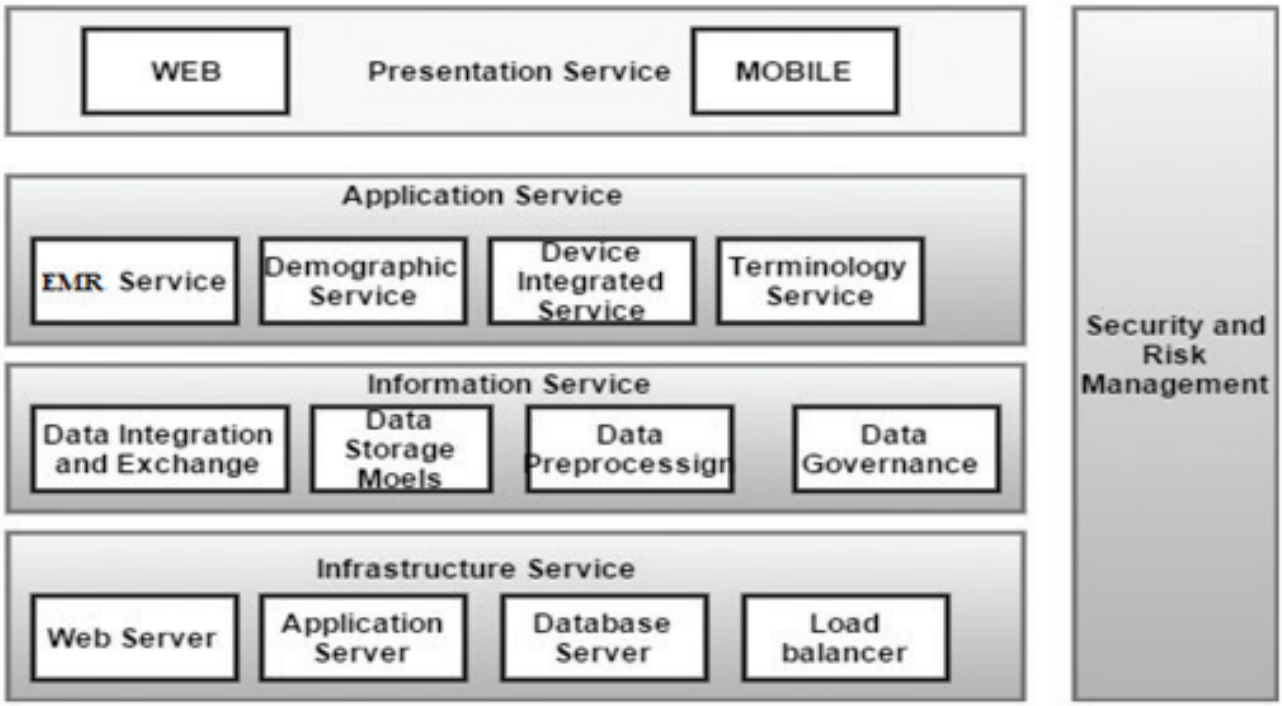


Figure 4: Layered Architecture for proposed cloud-based EHR

Figure 4 shows the layered architecture of the proposed cloud-enabled EHR system. The Infrastructure Services Layer (ISL) consists of the cloud instances on which the proposed EHR system is deployed. ISL layer mainly consists of Web servers, application servers, Database Servers and load balancer. Developed EHR application is utilizing the services of the application server and web server to communicate with the database server. The database server can host one database or more than one database such as Oracle, SQL Server, Mysql., Etc. The Information Services Layer (InSL) consists of a data integration engine (that allows acquiring medical data from different sources into the cloud) modules for data storage and clinical concepts and the data governance module. The Application Services Layer(ASL) provides various services such as EHR service, demographic service, device integration service, and terminology service. The Presentation Services Layer is mainly used for displaying the user interface and user interaction. HTML, CSS, JavaScript and Jquery are good scripting language for the presentation layer.

Figure 5 shows the cloud-enabled architecture for standard EHR. This architectureenables single format for all types of health care facility. In this,Cloud resourcesare shared with different healthcare sectors such as primary, secondary and tertiary. In each health care sector, data exists in various forms such as structured or unstructured or on different formats such as text,image and video. Each cloud serves its purpose of storing the patient record. Here, the primary level is again divided into sub-center, primary health center, and community health center. All the data captured from the each healthcare setting is finally storedin global cloud database called EHR database.

The EHR is designed using standard medical terminology and coding standard such as SNOMED-CT, ICD-10, LOINC, DICOM and NDC.Suppose apatientis admitted to theprimary healthcare facility, the patient demographic data, patient history, diagnosis information (CT scanners, MRI scanners) and pharmaceutical information is stored in the EHR database. In the diagnosis process, the doctors retrieve the health information of patients and analyze it to diagnose the illness. Doctors from primary healthcare can take expert advice from secondary or tertiary care specialists by sharing the information. Current model makes use of Role-Based Access Control (RBAC) in order access data from different levels of thehealthcare system. Using this approach, the three levels are given access criteria such that primary hospital doctor can see patientdata of primary hospital, secondary healthcare doctor can see both primary and secondary hospital data of the patient visitedand finally tertiary level care can see data from all hospitalsconnected to EHR database.

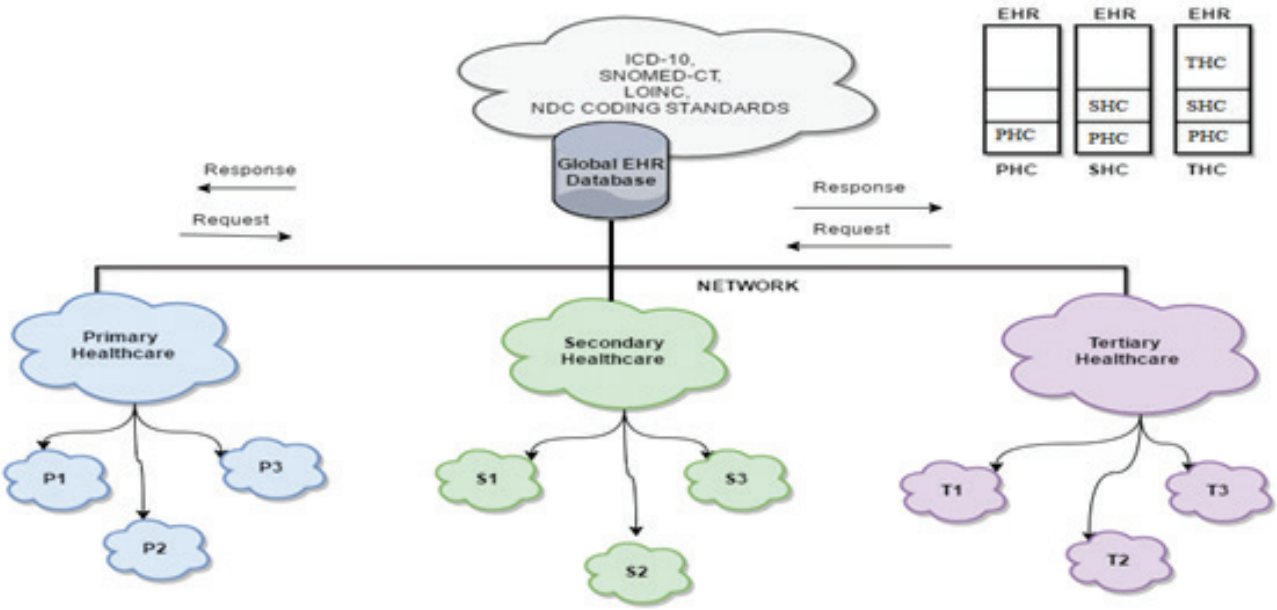


Figure. 5 Cloud-enabled architecture for standard EHR

The proposed EHR adopts Single Sign-On (SSO) for authentication. Electronic Health Record (EHR) is an integration of different health information services available in multi-tenantcloud environment. Healthcare users can access multiple health services after signing in only once. When user signs in, user identity is recognized and user neednot sign in again and again to access different types of health services.

BENEFITS OF PROPOSED CLOUD-BASED EHR ARCHITECTURE

Benefits of proposed cloud-basedEHR are as follows:

Consistent representation: Theproposed Standard Electronic Health Records uses harmonization process to integrate different representations of health care information into a consistent representation (Data Integration Engine) and maintain and update that consistentrepresentation over time.

Healthcare standards: The information stored in EHR allow meaningful retrieval and helps in preparing right retrospective reporting for research and management. Using standards in proposed architecture such asICD-10, SNOMED-CT and LOINC mainly helps in reducing the need for attachments to explain the patient's condition in more detail to the doctors. LOINC standards avoid duplicate testing and treatment when patient visits other healthcare services which helps in reducing the cost of healthcare events.

Reduced cost: Organizations moving to cloud is a transformational investment. Depending on the hospital requirement, services can be orderedwhich helps in reducing the capital expenditure cost and transforms to operational expenditure cost. The organization has to pay only for software maintenance and support cost. If an organization requires additional computing power for computing or processing patient query, during that time on demand service can integrate to the already available service.

Improved patient flow: Patient moves from the primary to the tertiaryhealth care system during which complete patient information will be available in tertiary care hospital. When a patient is admittedin primary health carecenter, his/her data is captured and stored in the EHR system. When the patient moves from one hospital to another hospital, prior history of the patient is made available at all higher healthcare levels.

Security model: SAML-SSO basedauthentication model improves user authentication by checking the identity of the user by using identity provider which increases the access speed by accessing all the integrated services by single sign in. Health care admin work is simplified by using active directory in healthcare organization which restricts the outside access of healthcare data for other purposes.

CONCLUSION

The proposed EHR uses layered approaches tointegratehealth information data from disparate data sources. Proposed architecture has a better interoperability, scalability, maintainability and reduced cost as compared to client-server based model. Cloud-enabled Standard Electronic Health Records uses thepatient-centric approach in which scattered patient health records are made available in an integrated and combined manner at episode of the care. Patient health data recording and reporting are done using standard codings such as SNOMED-CT, LOINC, DICOM and NDC. The healthcare standard and medical coding with cloud database enable connectivity between primary, secondary and tertiary levels to makepatient health data available all-timewhen required for his/her care. Security Assertion Markup Language-Single Sign On(SAML-SSO) authentication model adopted in EHR module to access multiple services of health information after signing in only once improves the security and increases the access speed of the health information service.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Mobile Text Messages-A Silent Revolution for A Sound Antenatal Care

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ABSTRACT

As a basic human right, every woman has the right to life, health, reproductive autonomy, equality and non-discrimination. Maternal health indicator reflects how well this right has been ensured for the women living in a nation. India is one of the developing nations which face a high maternal mortality rate. To address to the diversified and scattered populace of the country, and their varied health needs, India needs advanced connectivity for transforming the delivery of healthcare services. Given the consideration of cost, ease of use, asynchronous delivery, text messages are the most preferred m Health solution across the globe. An experimental study was conducted among the pregnant women visiting the Primary Health Centers in and around Coimbatore, Tamil Nadu, India. The objective of the study was to test the effectiveness of text messages in generating awareness on antenatal care and essential behavior change among the pregnant women. A pre test was conducted among the pregnant women and an intervention of text messages was sent to their mobile phone numbers for a period of one month. After the invention, a post test was conducted again to test the increase in their level of awareness on antenatal care. The results were analyzed using a paired sample's' test using SPSS. A substantial increase in the level of awareness on antenatal care was found among the participants. It can be found that the widespread penetration of mobile phones among the rural and marginalized people can be used for connecting them to the healthcare system.

Keywords: *Antenatal care, maternal mortality, mobile phones, pregnant women, text messages.*

BACKGROUND OF THE STUDY

Maternal healthcare is strongly associated with and highly reflective of the quality of health services in a nation. A woman, as a mother has to be protected in her own right. Furthermore, it should be understood that the status of women in a society is central to solving many of the economic, social and developmental challenges faced by the nation. In realization of the need for protecting the status of women and their health, Government of India, through National Rural Health Mission(NRHM) has spurred up several initiatives for providing quality antenatal care. Some of them include

- Early registration of pregnancy and ensuring minimum four ante natal care (ANC) visits.
- Immunization through minimum two tt injections.
- Supply of free iron and folic acid supplements
- Mother and child tracking system (MCTS), a name based tracking of pregnant women for provision of timely ANC, institutional delivery, immunization and other related services.
- Jananishishusurakshakaryakaram (JSSK) which entitles all pregnant women to deliver in public health institutions, absolutely free, including caesarean section. This initiative stipulates free drugs, diagnostics, blood and diet, besides free transport from home to institution, between facilities in case of a referral and drop back home
- Combating anemia through effective monitoring by medical officers and health workers.

It is estimated that nearly 27 percent of the global maternal deathswere happening in India during 1990 has been reduced to 16 percent now.Despite the incredible progress made in the provision of quality antenatal

care,nearly an estimated 47,000 mothers are reported to die due to preventable causes. The causes are not merely medical as many factors including illiteracy, low socio-economic status, traditional and cultural practices also contribute to low level of healthcare access.

India is the second largest mobile phones user with over 900 million users. The low pricing of both the mobile handsets and the tariffs associated with it has shown a glorious increase in the geographic coverage of mobile phone networks in India. These factors have resulted in a scenario where the rural people in India now have access to mobile phones and its myriad capabilities. These capabilities can be used for providing quality health care services to the under privileged and the people residing in the far and remote areas.

REVIEW OF LITERATURE

For the support of the study objectives and to obtain essential guidelines in the design of the study, a review of previous research studies on the use of text messages in health care was done. In a study by Ramachandran, et.al, in Orissa, it was found that use of mobile phones during health counseling improved the ability of the health workers to provide in-depth and effective counseling and indirectly influenced the women to take iron pills to avoid anemia and also save money for birth preparedness[1]. In another study by Pai, et.al., 2013, automated voice calls were found to be effective in reducing anemia among a low income group pregnant women in Mumbai[2]. The Government of Kerala had successfully initiated and is running the Dr.SMSprogramme, where the people can get any kind of information regarding access to health care services10. Khokar, 2008 found that the text messages were helpful in increasing the practice of Breast Self Examination (BSE) as a measure to reduce the risk of breast cancer among the women in New Delhi[3]. In a pilot qualitative study by Chandra et.al, (2014), text messages were found to be a culturally acceptable way to reduce and prevent the causes of mental health issues among young women in urban slums in India[4]. In a study among the diabetes patients in India, text messages were found to be acceptable and influential tool in send medication reminders to them and improving their health condition[5]. A cross sectional survey among the TB patients in South India revealed that Incentives like free talk time and short message service (SMS) will encourage patients to communicate frequently with health workers, thereby, increasing the chances of better adherence to DOTS. It was also found that SMS in regional languages will be more effective[6]. A near to complete compliance in antenatal visits through SMS reminders was found among pregnant women in Mali and rural Zanzibar[7,8]. Behavioural changes towards immunization and increased turnout to health facility for delivery was made possible through several maternal m health programmes in Bangladesh, India and South Africa[9].

OBJECTIVES OF THE STUDY

Based on the review of literature and the existing scenario of maternal healthcare in India, the objective of the study was identified as below:

- To test the effectiveness of text messages in generating awareness on antenatal care and essential behavior change among the pregnant women in Coimbatore.

MATERIALS AND METHODS

A pre experimental study using One Group Pre-test and Post-test design was employed to test the effectiveness of mobile text messages in generating awareness on antenatal care and essential behaviour change among the pregnant women in Coimbatore. This design includes a pretest measure followed by a treatment and a posttest for a single group.

Pretest
Questionnaire Survey
↓
Intervention
Mobile text messages
↓
Post test
Questionnaire Survey

On antenatal care

The study was conducted among the pregnant women visiting the primary health centers in the rural and semi urban areas of Coimbatore, Tamil Nadu, India. Coimbatore has a population density of 748 persons per sq.km and there is an equal percentage of male and female population with female literacy rate at 79.16%.

In the pretest stage, a questionnaire survey was administered among the volunteering pregnant women visiting the primary health centers. The pretest questionnaire consisted of items for collecting data on the socio-demographic profile, their mobile phones usage pattern, and their knowledge level on antenatal care. The sample size of the pretest stood around 397 participants.

The intervention consisted of 35 text messages on antenatal care which aimed at creating awareness on essential knowledge on antenatal care. The antenatal care text messages to be sent through mobile phone were designed based on the suggestions given by the Village Health Nurses, the pregnant women, Doctors. The content of the messages was framed based on the Guidelines for ANMs, prepared by the Ministry of Health and Family Welfare, Government of India[11]. After a peer review with the health department officials, the text messages were then translated into Tamil, the regional language. These messages were sent to the mobile phone numbers of the pretest participants for a period of one month. The messages focused on the key areas of antenatal care such as antenatal care visits, immunization, scans, birth preparedness, anemia, and gestational diabetes, nutritional aspects, taking iron and folic acid supplements and iodine supplements. (See sample messages in the Annexure 1).

After a period of one month a post test questionnaire was administered on the study participants. Due to potential loss to follow up, only 198 could be contacted for the post test. The post test questionnaire had two parts which reconfirmed the details collected in the pre test questionnaire and also had questions testing the knowledge on essential antenatal care.

SAMPLE POPULATION

Table No. 1 Demographic Profile of the participants

Demographic Factors		Frequency	Percentage
Age	19	11	5.6
	20	30	15.2
	21	22	11.1
	22	30	15.2
	23	28	14.1
	24	19	9.6
	25	13	6.6
	26	9	4.5
	27	14	7.1
	28	8	4.0
	29	3	1.5
	30	6	3.0
	32	3	1.5
	33	2	1.0
Education	Up to 10th standard	102	51.5
	Plus two	54	27.3
	Graduate	25	12.6
	Post Graduate &above	17	8.6
Occupation	Housewife	185	93.4
	Working women	13	6.6
Type of family set up	Nuclear	86	43.4
	Joint family	112	56.6

A non-probability purposive sampling method was used to identify the participants of the study. The sample consisted of 198 pregnant women from 19 to 33 years with a median age of 23 years, and most of the participants had an educational qualification of up to 10th standard only and the median family income group among the participants was Rs. 7,000/-. (Table No. 1)

Nearly all the participants possessed the knowledge to operate most of the functions of mobile phones. More than 50% of the participants were interested in using mobile phones for various purposes of m Health including appointment/ medication reminders and consultation with village health nurses/ doctors(51.5), health counseling(59.1%) and for availing emergency services (52%). Most of the participants were found to be using the mobile phones for not more than 2 years. It was very surprising to note that nearly 73.7% of the participants preferred receiving text messages more than the voice calls for accessing health care information.

RESULTS

The paired sample t-test using SPSS version 20.0 was used for analyzing the differences in the pre intervention knowledge level and the post intervention response levels of the participants and identify if there is a significant increase in the awareness level of the participants on antenatal care.

The mean difference in the paired sample t test statistics table (Table No. 2) indicates that the post test score of the various aspects of antenatal care knowledge is higher than the pre test score. The mean differences range from -.05 to - .74. It can be also seen that the statistical significance for all the aspects of antenatal

stands to be at p=.000. Hence, we can infer that the intervention messages had resulted in the increase in knowledge level of antenatal care among the pregnant women.

Registration and antenatal care visits: The registration of pregnancy and regular antenatal care visits are essential elements in the provision of quality healthcare to the pregnant mothers. It could be seen from the results of the study that there was an increase in the knowledge score on the need for registration and antenatal care visits after receiving the mobile text messages. Such improvements in the knowledge on the need for antenatal visits through mobile text messaging was also found among pregnant mothers in Mali and Rural Zanzibar7,8. Registration of pregnancy in a health facility is required to track the pregnant women and regular antenatal care visits will ensure the monitoring and provision of pregnancy care for the pregnant women.

Immunization, scans and iron and folic supplements: A pregnant woman is expected to be immunized withtt injections in the 2nd and the 4th month of her pregnancy. Similarly scans at required intervals are essential for identifying the presence of pregnancy complications. The participants have a statistically significant improvement in understanding the need for ttinjections and scans after the intervention of mobile text messages which was also evidenced among the pregnant women through several m health programmers for maternal health care[9].

However, the level of awareness on the importance of Iron and Folic Acid Supplements during pregnancy period was found to be less. This might be due to the socio cultural factors existing factors existing in the society, as many of the elderly parents have a feeling that having too many medicines will affect the health of the baby. Hence a separate study can be aimed to address to such challenges and issues.

Table No. 2 Paired Sample‘t’ test statistics on various factors of Antenatal Care Knowledge.

Paired Samples test								
Factors of Antenatal care Knowledge	**Paired Differences**					**t**	**df**	**Sig. (2-tailed)**
	Mean	**SD**	**Std. Error Mean**	**95% confidence Interval of the difference**				
				Lower	**Upper**			
Registration of pregnancy	-.364	.637	.045	-.453	-.274	-8.039	197	.000*
ANC visits	-.520	.576	.041	-.601	-.439	-12.702	197	.000*
Folic Acid Supplements	-.242	.662	.047	-.335	-.150	-5.152	197	.000*
TT injections	-.742	.450	.032	-.805	-.679	-23.224	197	.000*
Gestational diabetes	-.556	.583	.041	-.637	-.474	-13.416	197	.000*
Foetal movements	-.313	.647	.046	-.404	-.222	-6.805	197	.000*
Gap between pregnancies	-.192	.648	.046	-.283	-.101	-4.168	197	.000*
Emergency ambulance	-.056	.230	.016	-.088	-.023	-3.404	197	.001
Blood donor	-.515	.568	.040	-.595	-.436	-12.772	197	.000*
Iron supplements	-.652	.547	.039	-.728	-.575	-16.758	197	.000*
Iodine	-.662	.505	.036	-.732	-.591	-18.419	197	.000*
Anaemia	-.616	.518	.037	-.689	-.544	-16.743	197	.000*
Scans	-.460	.618	.044	-.546	-.373	-10.469	197	.000*
Institutional delivery	-.551	.565	.040	-.630	-.471	-13.699	197	.000*
Birth assistants	-.520	.594	.042	-.603	-.437	-12.331	197	.000*
Weight gain	-.369	.621	.044	-.456	-.282	-8.348	197	.000*

*Significance level at 0.001

Maternal anemia and gestational diabetes: Maternal anemia is found to be the most common cause for maternal death in many of the developing countries. The intervention of text messages through mobile phones has essentially improved the awareness of anemias and its ill effects. The need for regular intake of iron supplements along with the iron rich foods to combat anemias was realized by the presentstudyparticipants andalso among the tribalwomen in rural Odisha1. Though not identified as a major concern in maternal healthcare, gestational diabetes is another vital area of awareness for the pregnant mothers and was understood by the study participants with a statistically significant value.

Birth preparedness: Birth preparedness includes arranging transport facilities during emergency, identifying blood donors for emergency during delivery, presence of skilled birth attendants at the time of delivery, and most important delivery at a health facility. The present study participants were found to have shown statistically significant increase in their knowledge on the aspects of birth preparedness. Such an improvement was also witnessed among the women in rural Odisha who started saving money for their delivery expenses1.

General Issues: Issues like the minimum gap between two pregnancies, minimum weight gain during pregnancy for a healthy pregnancy are some of the concerns for which less attention is paid to. The participants of the study showed significant improvement in their knowledgelevels between pre and post test on these issues.

In–Depth Interviews: In addition to the quantitative aspect of the study, in order to understand if the text messages were able to bring in any changes in the behaviour of the pregnant women participated in the study, a focus group interview was carried out. Some of the responses in the words of the participants will enable to understand the usefulness of the messages.

"My parents advise me not to take too many tablets during pregnancy. After receiving the messages, I understood that taking iron and folic acid tablets are essential for a complete growth of my child. Now I have started taking iron tablets regularly".

"I actually forgot to take my 2nd dose of tt injections. The messages were a good reminder to take tt injections and also scan. Sometimes during the ANC visits we tend to skip several tests, which I am now doing it regularly."

"I am residing with my parents or elders to guide me through my pregnancy. This is my first pregnancy and I am so comfortably handling my pregnancy with the counseling from the VHNs and the text messages which I am receiving now right from my first ANC visit."

It can be seen that the text messages have been successful in not only increasing the awareness on antenatal Care but also in creating essential behavioural changes.

DISCUSSION

Information and Counseling on health issues are available in plenty across many websites and mobile apps. They are not very successful for several reasons including the prevalence of technical skills among the population, availability of suitable handsets, connectivity issues at rural and remote areas, cost of transmission, and more than anything the reliability of the content to be implemented. Hence not many a pregnant woman, especially in the rural areas do rely on their elders or the formal health system including doctors, VHNs.Closer to them are the VHNs who make frequent visits to their residence and also make a call during their hospital visits on every Tuesdays. There is an unknown bond between them and they request information from these VHNs on antenatal care.

The Central Government has made an attempt to send text messages in English to all the registered pregnant mothers through MCTS. However, owing to the low literacy level in English they are not able to comprehend the messages, which will be the case in most of the states in India as the native language is more predominant, naturally.

Though regular face to face counseling sessions occur during the ANC visits and the field visits by the VHNs, every pregnant mother tend to have an issue so very typical for her and she would need consultation during that moment. In addition, along with the sea of information shared during their visits, the pregnant women will be unable to remember the necessary information for her.

CONCLUSION

This attempt with text messages on health care for pregnant women proves that mobile phones and text messages can serve as a supplementary knowledge bank to the pregnant women at times of their need.

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ANNEXURE 1

Sample text messages(the messages were translated to Tamil, the regional language) sent to the mobile phone numbers of the study participants

1. Register your pregnancy with the ANM before 3 months or immediately when you know you are pregnant and receive a quality and safe pregnancy period.
2. A safe pregnancy is ensured by doing minimum 2 scans. 1st in 3rdmonth to detect any mis formation; 2nd in the 4 to 6 months to find out any anomalies and if needed in the term to find out the position of the baby.
3. Take minimum 100 folic acid supplements, with a daily dose of 400 µg folic acid. It will reduce the occurrence of birth defects of spine and brain in the first 3 months of your pregnancy.
4. Foetal movements, also called "quickening", begin at around 18–22 weeks of pregnancy. Check for the foetal movements of the baby. If it is below 10 in an average for an hour, refer to a health facility
5. Pregnant women should refrain from doing heavy work, especially lifting heavy weights as this can adversely affect the birth weight of the baby.
6. Low iodine level in the mother will cause deficiency in the thyroid hormones of the baby. Consume iodised salts every day
7. An amla/tomato immediately after your meal in the afternoon will enhance the iron absorption level, taking tea, coffee or milk within an hour after a meal, interfere with the absorption of iron.

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Towards Next Generation of Live Attenuated Viral Vaccines

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ABSTRACT

This mini-review aims to focus on the changing trend in the industry towards the type of cell substrates being used for viral vaccine production.

Most of the commercial live attenuated viral vaccines were developed in the mid twentieth century, when primary cultures were traditionally being used for routine production of vaccines. Vaccine strain development process then essentially involved multiple passages on various primary cultures derived from different tissues.

However, today in the twenty first century, the trend has seen a complete reversal. Established cell lines are being preferred over the primary cultures. Over the years, vaccine industry has learned the limitations of primary cultures as cell substrate. The industry and regulatory agencies have also understood the unique benefits offered by the established cell lines as substrates for vaccine production.

Measles and Rubella vaccines are being produced on the diploid MRC-5 cell strain. Production technologies for Rotavirus and Dengue virus vaccine are being established on Vero cells, an already approved cell line by regulatory agencies. Rabies vaccine production has seen a journey from usage of sheep brain, through human diploid cells to continuous cell lines as cell substrates.

Majority of commercially produced mumps vaccines are still dependant on primary culture of chicken embryo cells, derived from specific pathogen free eggs. Recently, mumps RS-12 strain has been reported to be established on human diploid MRC-5 cells. Other mumps vaccine strains such as Leningrad-Zagreb, also needs to be explored on the diploid or continuous cell lines to derive the benefits.

In conclusion, additional research efforts are needed towards adapting the vaccine viruses on established cell lines to produce next generation of live attenuated viral vaccines, which are anticipated to be at least equivalent in characteristics but more cost-effective, thus beneficial to the society.

Keywords: *Continuous cell lines, Diploid cell lines, Next generation viral vaccines, Primary Cultures.*

BACKGROUND

Human immunization history of more than 100 years could be categorized into few generations based on the milestone achievements in vaccinology. Viral vaccines developed and produced using animals and primary cultures could be viewed as first generation vaccines. Those produced using human diploid cells and continuous cell lines could be second generation and the ones being developed using stem cells and engineered cell lines could be the third generation.

The terminology, 'next generation vaccine' has been used in quite a few articles published in recent past, however the meaning of the 'next-generation' has been context specific expressing an additional work performed on one or more quality aspects of vaccine, encompassing wide areas ranging from vaccine design, its quality control to its delivery. This has been elaborated below with examples of few articles.

The need to improve the efficiency of the vaccine delivery systems by transforming the fundamental components of the vaccine supply chain management has been described as the next generation work in vaccinology[1]. The deep sequencing work done to improve the quality assurance of rabies vaccine's identity and stability has been reported as the next generation quality control of the vaccine[2]. An approach to developing a universal multivalent vaccine based on the next generation immunology has been outlined[3]. Human Papilloma Virus (HPV) vaccine developed by

generating virus-like particles (VLPs) of HPV through recombinant measles vaccine vector has been reported as next generation vaccine4. Usage of a cold-adapted, attenuated polio virus vaccine strain has been described as a next generation inactivated polio virus vaccine[5]. Development of a safer chikungunya vaccine with reduced probability of reversion has been described as the next generation sequencing approach to confirm lower frequencies of single nucleotide polymorphisms[6].

Chronologically smallpox vaccine was introduced first, followed by rabies vaccine and polio vaccine. Subsequently, live attenuated measles, mumps and rubella vaccines were introduced. Other licensed viral vaccines include varicella, rotavirus, influenza, yellow fever, Japanese encephalitis, human papilloma virus, hepatitis A and B and adeno virus vaccines. For other viral diseases like Human Immunodeficiency Virus, HIV, chikungunya, dengue and respiratory syncytial virus, safe and effective vaccines are under development[7].

Viruses being obligate intracellular parasites, suitable living host cells are required for their replication and propagation. Depending on their origin and characteristics, different cell substrates can be categorized as primary cells, diploid cells, continuous cell lines, stem cells and special purpose engineered cell lines.

In early days, primary cultures were preferred because of their closeness to the physiological conditions and their easy availability. However, later on, the importance of thorough characterization was realized by the cell culture scientists. Characterization of the cell substrate essentially involved establishment of its origin, identity, safety, purity and stability. Primary cultures derived from tissues of wild animals were thought to carry more risk of latent viruses than the primary cultures derived from tissues of animals bred in close colonies. Besides, embryonated chicken eggs and animal tissues such as sheep brain, various mammalian cells have also been exploited for growing viruses. Kidney cells have been particularly more exploited for virus research. These include baby hamster kidney, BHK-21cells[8,9,] rabbit kidney, RK-13 cells,[10] cells, dog kidney Medin Derby Canine Kidney, MDCK cells,[11,12,] bovine kidney Medin Derby Bovine Kidney, MDBK cells[13] as well as human embryonic kidney, HEK-293 cells[14], besides the most popular African Green Monkey Kidney, Vero cells. Other than kidney, lung and ovary cells have also been researched such as monkey fetal lung cells, Fetal Rhesus lung, FRhL-2[15], human embryonic lung cells, WI-38 and Walvax-2 female origin and MRC-5 male origin and hamster ovary, Chinese Hamster Ovary, CHO cells[16].

FIRST GENERATION VIRAL VACCINES

Most of the live attenuated viral vaccines were developed around mid-twentieth century. Attenuation strategy involved passaging the wild-type isolate of the virus multiple times in various cell substrates in vitro, as exemplified by the developmental work on the mumps vaccine described below.

Mumps virus, a paramyxovirus was isolated in the 1960s in Leningrad Russia. It was attenuated by passaging it 15 times in guinea pig kidney cell culture, followed by 6 more passages in Japanese quail embryo cell culture. After doing one more passage back in guinea pig kidney cell culture, it was further attenuated in Croatia by 3 serial passages in chicken embryo cell culture derived from specific pathogen free eggs, came to be known as Leningrad-Zagreb mumps virus vaccine strain[17]. Thus, the use of primary culture from different animals such as guinea pig, Japanese quail and chicken was evident in the development of the vaccine.

Mumps vaccine is a typical example of a live attenuated viral vaccine that is still being grown on primary culture of chicken embryo, CEC. Adequate and timely supply of specific pathogen free, SPF eggs is an important prerequisite for mumps production on CEC. Supplying certified SPF quality eggs requires maintaining generations of SPF bird flocks and rigorous monitoring of these birds and eggs for essential quality attributes[18]. Testing for the absence of specific avian viral pathogens is a complex task requiring a lot of planning and resources. SPF status is certified by testing the birds and eggs for almost thirty different adventitious pathogens, which includes viruses, bacteria and mycoplasma[19]. Not many vendors are available, who are capable of delivering SPF eggs. Safe and efficient transportation of the delicate eggs requires a lot of advanced logistics planning. With all these efforts, the CEC prepared is only a primary culture, which can not be banked. There are limitations on its characterization. Lot to lot variation, delicate and complex handling procedures, slower growth rates and mandatory usage

of antibiotics are the other few features, which restricts its usage to a situation where there is no alternative. Research efforts in adapting other mumps viruses such as Leningrad-Zagreb strain of mumps vaccine virus on the cell substrates other than CEC such as diploid or continuous cell lines will help us to overcome all the limitations of primary culture mentioned above. This is even more justified in a case, where mumps is a part of combined multi-component vaccine such as Measles, Mumps, Rubella, MMR and the other two components are already being produced on established bankable cell substrates. This will help to harmonize and simplify the MMR production process with the elimination of dependency on the external source of supply for SPF eggs, the most critical animal originated raw material.

In the 1980s, Mumps vaccine virus, strain Rubini was developed using human diploid cells, WI-38 and MRC-5[20]. It was used as a vaccine but discontinued later on because of inadequate long-term protection. Recently another mumps vaccine strain RS-12 was established to grow on the human diploid cells[21]. Its thermal stability in the lyophilized formulation was also reported[22].

Avian originated primary cultures are known potential sources of undesirable adventitious agents[23]. They are also reported to contain residual reverse transcriptase activity[24]. After ensuring that the safety profile of the selected cell substrate is satisfactory, one needs to focus on the homogeneity and stability of the cell line. Primary cells are direct explants from tissues or organs and hence often contain more than one cell types, leading to biological variations. Primary cultures are known to be heterogeneous and less stable compared to diploid cell strains. The degree of inherent biological variation is more in the case of primary cultures than diploid or continuous cell lines. Cytogenetic stability of the cultures is also important and should be monitored over the generations.

Thus primary cells from animals and humans, which more closely represent the physiological conditions, were extensively used during the developmental work. However, there was a constant fear of adventitious agents and oncogenicity associated with the use of primary cells and hence researchers were looking for alternative cell substrate for growing viruses.

In the 1990s, the MMR group of vaccines grown in chicken embryo cell culture were found to contain reverse transcriptase activity, suggesting contamination with retroviruses. However, upon detailed investigations, no infectious avian retroviruses could be detected or isolated from the vaccine, thus allowing continued usage of vaccines.

Mass protection of the society from morbidity and mortality associated with the viral diseases was of prime importance at the time of first generation vaccines. Sporadic adverse reactions or events associated with immunization were secondary in nature. However, later on, with increased understanding of viral pathogenesis, host immune responses together with advent and usage of molecular biology tools in research, it was possible to provide vaccines with improved quality standards not only in terms of safety but also the efficacy and stability.

SECOND GENERATION VIRAL VACCINES

Human diploid cell cultures with finite in-vitro lifespan were the next choice of cell substrate because of their bankability and full characterization. Immortalized cell lines were then explored as the cell substrates with their infinite proliferation capability and ability to grow as suspension cultures in bioreactors. However tumorigenicity and oncogenic potential of continuous cell lines needed to be thoroughly investigated. Specially designed cell platforms or expression systems are currently being evaluated as future cell substrates for manufacturing vaccines.

Scientist came across human diploid cells as a safer cell substrate for vaccine production because they were well characterized and susceptible to many viruses. Rubella vaccine can be viewed as an example which was attenuated using human diploid cells. Rubella vaccine strain RA-27/3 which was produced and characterized in the 70s represented an example of virus attenuation by cold adaptation on a single cell substrate[25]. Original virus was isolated from kidney tissue of an aborted fetus suffering from rubella infection. It was attenuated using human diploid cell strain, WI-38, which was the purest known cell substrate available at that time. During multiple passages on WI-38, the temperature of incubation was gradually reduced from 35oC to 33oC and finally to 30oC for the attenuation of the virus[26]. Edmonston-Zagreb measles strain and RA-27/3 rubella strains were also adapted to grow on human diploid cells in Europe since the 1980s. All these time-tested vaccines

are having good immunogenicity and safety record. The cell substrate chosen for growing vaccine viruses ultimately plays a major role in the characteristics of the final product. It is a constant endeavor of vaccine manufacturers and regulators to make the vaccine free of any risk. Based on the principles of quality by design, the cell substrate and raw materials used for vaccine production should be selected on the basis of the risk assessment with respect to the safety of the final product. As an example of animal origin raw material, fetal bovine serum is commonly used in cell culture stages of many viral vaccine manufacturing processes, without any contamination risk by the bovine origin viral agents or spongiform encephalopathy agents, because industry has learnt to mitigate this risk by implementing one or more measures such as extensive testing for extraneous agents, multiple sterilizing grade filtrations, radiation treatment of the raw material and sourcing the raw materials from countries which are certified by the regulatory agencies to be at negligible risk. Vaccine manufacturing industry's knowledgebase has matured over the years because of the past incidences, some of which are revisited below as important lessons to learn from.

Contamination of the poliomyelitis vaccine by Simian Virus, SV40 in the 1960s was a well-known historical incidence. The investigation had revealed the root cause to be monkey kidney cell culture that was being used for the production of poliovirus. In the 1970s, Measles, Mumps, Rubella, MMR live attenuated viral vaccines were reported to be contaminated with bacteriophage. Bovine sera used during the cell culture stages of vaccine manufacture were apparently responsible for the incidence. In 2010, the rotavirus vaccine was observed to be containing porcine circovirus type I, PCV-I and type-II, PCV-II DNA sequences, implying contamination of rotavirus vaccine by PCV-I and PCV-II viruses of swine origin. Apparently, the root cause was identified as porcine origin trypsin that was being used in cell culture stages of vaccine production. Fortunately, in all the above four cases of safety risk in viral vaccines, there was no product recall or interruption in vaccine supply, because the expert committee reviewed with due diligence the results of investigations and decided that the vaccines offered more measurable benefits than any potential theoretical risk[27].

Diploid cells have a finite in-vitro lifespan and tend to enter senescence after known number of population doublings. Senescent cultures exhibit altered morphology, reduced growth rate and abnormal changes in chromosomes, thus becoming cytogenetically less stable[28]. Human diploid cells are categorized as normal cells. Continuous cell lines such as Vero cells are categorized as immortal cells because they have infinite potential for growth and replication in vitro. Diploid cells are considered as one of the safest time-tested cell substrate, however, the stock of well-characterized diploid cells such as WI-38 and MRC-5 is limited and not freely available. Researchers, therefore are trying to establish new diploid cell lines such as Walvax-2 cell line for future usages[29]. Industry moved from diploid cells to continuous cell lines such as Vero cells, mainly because of the higher yields obtainable on Vero cells. Compared to human diploid cells, Vero cells could be easily grown to nearly ten times higher densities, making the bioreactor based scale up much easy. Vero cells could also be grown in serum free media and their population doubling time was lesser than that of the diploid cells. Simultaneously, the risk of oncogenic and tumorigenic potential of Vero cells was mitigated because of the thorough investigations and characterization studies done on these cells[30].

Vero cells, i.e. African Green Monkey Kidney cells were reported to be the most popular cell substrate used for growing various viruses[31,32]. Being a continuous cell line, they might express less stable characteristics after a certain number of passages, thus limiting the number of stable useful passages for the virus growth. Rabies vaccine, a virus from Rhabdoviridae family, represented a typical example of post-exposure prophylaxis. Having a history since Louis Pasteur's time in the 1880s, this vaccine had seen a lot of improvements over the century[33]. Nervous tissue based vaccine was long replaced by a cell culture based vaccine with better quality and higher titers. In the 1950s and the 60s, chicken and duck embryos were used to make rabies vaccine. During the 60s and the 70s, primary cultures from different animals such as a hamster, dog, duck and chicken were explored for making rabies vaccine. Hayflick et al developed human diploid cell strain, WI-38 in 1961, but it took more than 10 years to come up with HDC based rabies vaccine. WHO recommended the HDC based rabies vaccine as gold standard in 1974. Yasumura and Kawikata developed the Vero cell line in 1962, however, the Vero cell-based rabies vaccine was first licensed in 1985. Vero cell-based rabies vaccine grown in animal

component free media on microcarriers in a bioreactor was reported to have excellent productivity[34]. Vero cells therefore appeared to be the most popular cell substrate approved by regulatory authorities for the manufacture of different viral vaccines. Besides, rabies, Vero cells were reported to be used for the production of diverse viral vaccines such as influenza, rotavirus, dengue virus and even smallpox virus[31].

THIRD GENERATION VIRAL VACCINES

Search for an ideal cell line is continued till date and some of the promising cell substrates, specially designed and engineered are described below along with their desirable quality attributes. These can be used for the production of next-generation viral vaccines and other therapeutic biologicals. Some of these cell lines and their desirable features are briefly described below.

HEK293 cell line was established in the 1970s from an aborted, healthy human fetus. It was Frank Graham's 293rd experiment at University of Leiden, Holland which resulted in the name HEK293. Kidney cells were transformed by Adeno virus DNA to get this immortalized cell line. HEK293, having a modal chromosome number of 64, was shown to express neuronal markers suggesting derivation from neuronal cells. It was progressively adapted from the anchorage dependent mode to suspension culture mode, with desirable attributes such as ease of growth as suspension, short doubling time of 34 hr. and high transfection efficiency. Ad5 nucleotides 1 to 4333 were incorporated into the chromosome 19 of the human embryo kidney cells.

A proprietary cell line, EB66 was developed by Valneva from duck embryonic stem cells. It was shown to be highly susceptible to many human and animal viruses. It was also shown to possess desirable quality attributes like long-term genetic stability, indefinite cell proliferation, amenability to high-density suspension culture in chemically defined media and scalability in stainless steel or disposable bioreactors35. Marketing approval for H5N1 influenza vaccine grown on EB66 cell line was received in 2014 in Japan.

A proprietary cell line, PER.C6 was developed by Crucell, Holland. It was derived from human primary embryonic retinoblasts. Human embryonic retinal cells were transfected with Adenovirus type 5, Ad5 E1A and E1B genes to get the cell line37. It was shown to be neoplastic in nature, capable of forming tumors in immunodeficient nude mice at high dosages. However, its purified DNA or cell lysate was shown to be not inducing tumor formation in newborn hamsters or nude mice. A fully characterized cell line, standardized for influenza vaccine production, also being exploited for HIV type-I vaccine, was also shown to be capable of growing as the suspension culture in serum-free conditions as well.

In summary, the third generation viral vaccines are expected to be of the highest quality yet easily accessible and affordable to masses so that immunization coverage can be reached to the targeted, sustainable figure of more than 90% all over the world. This could be made possible by following the principles of quality by design and continuous improvement so that currently licensed viral vaccines will get a chance for up-gradation, irrespective of the generation they belong to today.

Ideally, therefore, there should be well characterized and qualified cell bank of a perfect cell substrate. This bank should be large enough to last for a few decades at least with consistent stable characters. The cell substrate chosen for the bank should not only pass all the regulatory acceptance criteria expected today but should be susceptible to and capable of growing many numbers of vaccine viruses. A multi-point characterization program should be undertaken for any such cell bank in order to have sufficient assurance about its quality, encompassing the aspects such as sterility, identity, stability, tumorigenicity, viability, cytogenetic attributes, oncogenicity and microbial adventitious agents[38]. Further, looking at the growing importance of PCR-based testing, regulators like WHO should make available updated international standard on this nucleic acid amplification based protocols[39].

CONCLUSION

Vaccines are known to be the most efficient health care intervention of the last century. It has resulted into eradication of smallpox, near elimination of polio and significantly controlled the morbidity and mortality associated with other viral diseases such as measles, mumps, rubella, influenza, hepatitis etc. Most of the developed countries are no more endemic to diseases against which sustained immunization with more than

90% coverage was maintained for years together. This goal could be realized in developing nations as well, if quality vaccines could be made available at readily affordable prices, which in turn could be achieved with the help of next generation vaccines produced using ideal cell substrates. Today majority of licensed viral vaccines are being produced as first or second generation viral vaccines. Vaccines produced on third generation cell substrate should not only be cost effective but are also expected to be of superior quality. Regulatory approval and availability of such next generation viral vaccines will help us to achieve the goal of disease free society on fast track. Although purpose built cell lines such as PER. C6 and HEK293 are available primarily for developing vectored vaccine such as AIDS vaccine, they are being now explored for producing other viral vaccines as well. Broadly speaking continuous improvement is needed on all the fronts of immunization, which includes developments in vaccine itself and betterments in accessibility, i.e. vaccine distribution and delivery systems. Developing countries need to be more and more self-sufficient with respect to making quality vaccines available to all that population which needs it the most.

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MicroRNAs in Determining the Subtype Specific Treatment Regimens for Breast Cancer

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ABSTRACT

Introduction: Micro RNAs (miRNAs) are a class of non-protein coding endogenous small single-stranded RNAs which were originally discovered in Caenorhabditis elegans. They are evolutionarily conserved in nature and are also found in eukaryotes including human. Depending upon the level of complementarity between the miRNA and its target mRNA there can be two regulatory mechanisms namely degradation of target messenger RNA or translational inhibition.

Various studies have shown that miRNAs serve as molecular signature to classify the subtypes of breast cancer. The intrinsic subtype properties of the primary tumor play a role in determining the treatment regimen for breast cancer.

Thus investigating the myriad of miRNA expression would enhance the understanding of the role played by specific miRNAs in breast cancer and those can be used as therapeutic targets for treating breast cancer.

Purpose: To determine the role played by particular miRNAs in regulating the molecular mechanism involved in breast cancer metastasis.

Research Design: Meta-analysis of previously published research data has been used to generate a comprehensive list of differently expressed miRNAs in various subtypes of breast cancer. "miRTarBase", "miRDB", "TargetScan" was used to identify the target genes of different miRNAs in breast cancer. Pathway analysis will be done using "Panther" and "KEGG".

Results & discussion: Various aberrantly expressed and subtype specific miRNAs in breast cancer metastasis with respect to their target genes were identified viz., let-7c-SUV39H2, miR-10a-HOXA3, etc. Further analysis of the signaling pathways will be carried out to understand the role of identified miRNA in defining breast cancer subtypes.

Research implications: Breast cancer subtype specific novel miRNAs exhibiting a differential expression pattern were identified which can have feasible applications in both basic and clinical research.

Novelty: Various novel miRNA-mRNA targets were identified which can be used as diagnostic markers for classifying breast cancer subtypes.

Keywords: *Breast cancer, MicroRNA, Subtype, Therapy.*

INTRODUCTION

Breast cancer is one of the leading cause of cancer related deaths among women[1]. The estimated number of new cases and deaths are 249,260 and 40,890 respectively[2]. Breast cancer comprises of molecular heterogeneity and exhibits biologically different entities with distinct pathological features and clinical implications[3]. Breast cancer is subdivided into intrinsic subtypes namely, luminal A-like type, luminal B-like type, hormone receptor positive and human epidermal growth factor receptor type 2 (HER-2) positive type (HER-2), hormone receptor negative and human epidermal growth factor receptor type 2 (HER-2) positive type (HER-2) and triple negative[4] (Table 1). Thus by identifying the cancer subtype, the specific tumor biology can be understood and the appropriate treatment regimen can be selected. Therefore specific and sensitive biomarkers are required to distinguish among the various breast cancer subtypes, from the clinical

standpoint. As it is shown by research breast cancer is not only a heterogeneous pathology but it also comprises of deregulated major pathways regulating fundamental cellular processes such as proliferation, differentiation, migration and death[5].

MicroRNAs are short, non-coding, evolutionarily conserved, single stranded, endogenous RNAs that were first discovered in *Caenorhabditis elegans*[6]. MicroRNAs are regulatory in nature and around 1-5% of the human genome is under its regulation[7]. The regulatory mechanism of miRNAs is of two types, they either degrade the target messenger RNA (mRNA) or bring about their translational inhibition, depending upon the level of complementarity between the target mRNA and miRNA,[8]. MicroRNAs can be readily detected from small amount of body fluids such as serum, plasma, sweat, tears, saliva, breast milk, urine and semen[9]. They can function both as an oncogene and as a tumor suppressor depending on the type and stage of cancer[10]. In addition to their high specificity and sensitivity, miRNAs exhibits robust stability even in stored RNA samples, fixed tissues and other body fluids[11]. All these features make miRNAs a potential biomarker candidate. Although expression profiles of miRNAs have been used to classify various cancers[12], classification of cancer into various molecular subtypes is also essential to shed more light into the discriminative signatures possessed by each subtype and in deciding the best treatment regimen.

Table 1: Breast cancer subtypes and their distinctive features

Subtypes	Characteristics	Hormone treatment	Frequency in population	References
Luminal A-like	ER and/or PR positive	Endocrine therapy alone	40%	3,4
Luminal B-like	ER and/or PR positive	Endocrine +/- cytotoxic therapy	20%	3,4
HR-positive and HER2-positive	ER and/or PR positive	Cytotoxics + anti-HER2 + endocrine therapy	10 -15%	3,4
HR-negative and HER2-positive	ER and PR negative	Cytotoxics + anti-HER2	10-15%	3,4
Triple negative	ER, PR, and HER2 negative	Cytotoxics	15-20%	3,4

Various groups have identified dysregulated miRNAs that are breast cancer subtype specific 13–15. However, the key enriched pathways and the gene ontology annotations exploited by each subtype based on the miRNA signatures associated with each subtype breast cancer has not been evaluated to the best of our knowledge. In this work, we have made a comprehensive list of dysregulated miRNAs that are specific to each subtype of breast cancer. Using *insilico* tools we have identified the targets of these miRNAs and have further tried to evaluate the signaling pathways being exploited by these miRNAs in each of these molecular subtypes.

MATERIALS AND METHODS

MiRNAs specific to each subtype of breast cancer: A comprehensive list of miRNAs specific to each subtype of breast cancer was prepared using existing literature(Blenkiron et al., 2007; Chen et al., 2016; Enerly et al., 2011; Hua, Li, & Zhou, 2013; Iorio et al., 2005; Kurozumi et al., 2016; Lowery et al., 2009; Mattie et al., 2006; Peña-Chilet et al., 2014; Sugita et al., 2016). Various databases such as PubMed, EMBRASE, Medline were searched with key words “microRNA”, “MiRNA”, “Breast cancer subtype”, in “and” and “or” combinations. Peer reviewed articles written in English with specific detailing and sufficient for our understanding was selected. Non-English articles and articles whose full text were not available and articles without complete data were excluded from the study.

Target Identification: The targets of the identified subtype specific miRNAs were screened using insilico tools viz., TargetScan, miRDB and miRTarBase. We have used these two tools because these are the most frequently updated ones 24. To further strengthen our target prediction we have used insilico tool for experimentally validated miRNA targets i.e miRTarBase. A comprehensive list of targets specific to each subtype of breast cancer was prepared followed by duplicate removal (Supplementary table1).

Molecular network analysis: To analyse the key enriched signaling pathways by these subtype specific miRNAs, we used bioinformatics tools that predicts molecular interactions viz., Kyoto Encyclopedia of Genes and Genomes (KEGG) (http://www.kegg.jp), Panther (http://www.pantherdb.org), GeneCodis (http://genecodis.cnb.csic.es/) and Reactome (http://www.reactome.org). KEGG includes manually curated signaling pathways that regulates fundamental cellular processes 25.s

MiRNAs specifying intrinsic breast cancer subtypes: Various studies have reported that the identified breast cancer subtypes exhibits different panels of dysregulated miRNAs[18,26,27]. We have identified 119 differentially expressed miRNAs and out of these 106 were upregulated and 13 were downregulated in breast cancer subtypes (Table: 2). This can further help in categorizing breast cancer subtypes based on biomarkers thereby help in deciding treatment regimen specific to each subtype.

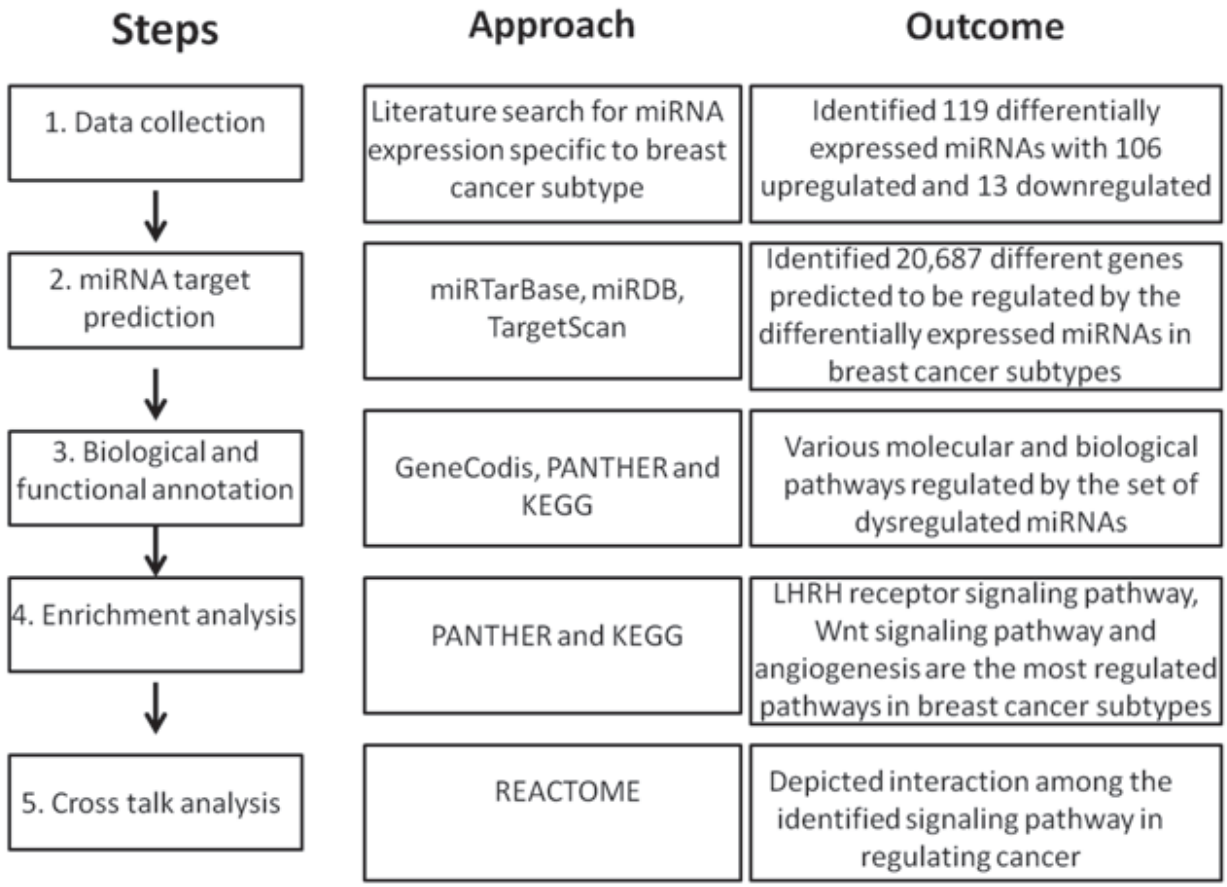


Fig. 1 Flow chart showing the steps for identifying enriched pathways in breast cancer subtypes

RESULTS

Table 2: Differentially expressed miRNAs in breast cancer subtypes

Breast cancer subtype	Up-regulated miRNAs	Down-regulated miRNAs	References
Luminal A-like	Let-7c, let-7f, miR-191, miR-10a, miR-26, miR-99a, miR-190b, miR-126, miR-130, miR-100, miR-136, miR-146b	Mir-15b, miR-103, miR-107, miR-206	16–18,20
Luminal B-like	miR15b, miR-103, miR-107, miR-342	miR-99a, miR-100, miR-126, miR-130, miR-136, miR-146b	17,19
HR-negative and HER2-positive	miR-142-3p, miR-150	miR-125a/b	17,18
Triple negative	miR-17-92, miR-18a/b, miR-93, miR-135b, miR-155	miR-29, miR-190b	18,20

Target prediction of the identified subtype specific miRNAs: Various *insilico tools* (TargetScan, miRDB, miRTarBase) were used to identify the targets specific to each subtype of breast cancer. TargetScan is a web tool that predicts miRNA targets based on the 3'UTR of the protein coding sequence by seed matching[24,28]. miRDB is a database designed for mature miRNA target prediction and also predicts targets based on the sequence complementarity between the guide miRNA and target mRNA and the free energy of the duplex[29]. The miRTarBase comprises of experimentally validated miRNA targets from 18 species and is linked to miRNase v20. [30]. Using these tools and after duplicate removal we have identified 20,687 genes in total that are predicted to be regulated by the miRNAs specific to each breast cancer subtype (Supplementary table1). Some of the important targets identified by our analysis are BCL2, HOXA13, CLOCK, DICER, BCL2, FZD-8, FZD-9, WNT-5A.

Biological and Molecular Functions: Using databases such as PANTHER and Genecodis tool-CSIC, we have identified various biological and molecular functions that are regulated by these set of dysregulated miRNAs with *P* value <0.05. In all the four subtypes, majority of the genes were involved in major biological and molecular processes that regulates cancer such as cellular process, metabolic process, protein binding affinity, catalytic activity, transporter activity, developmental process, angiogenesis. Showing a strong correlation between the regulated signaling pathways by these identified miRNAs and the cancer hallmarks.

Major signaling pathways regulated in each breast cancer subtype: By using PANTHER and KEGG functional enrichment tools, we have identified major signaling pathways being exploited by each subtype of breast cancer. In all the four subtypes, Gonadotropin releasing hormone receptor pathway (GO P06664: 86) and Wnt signaling pathway (GO P00057: 101), are the most dysregulated ones followed by angiogenesis (GO P00005: 61), MAPK signaling pathway, Neurotrophin signaling pathway, Integrin signaling pathway and TGF-beta signaling pathway.

Cross talk analysis: Reactome analysis further showed cross talk among the identified pathways viz., Gonadotropin releasing hormone receptor pathway (GO P06664: 86) and Wnt signaling pathway (GO P00057: 101), angiogenesis (GO P00005: 61), MAPK signaling pathway, Neurotrophin signaling pathway, Integrin signaling pathway and TGF-beta signaling pathway supporting our functional enrichment analysis. In addition, it also presented an array of other major deregulated pathways by the identified miRNA targets in breast cancer, namely chromatin organization, cell cycle, programmed cell death, DNA repair, diseases (signaling by Wnt in cancer), signal transduction.

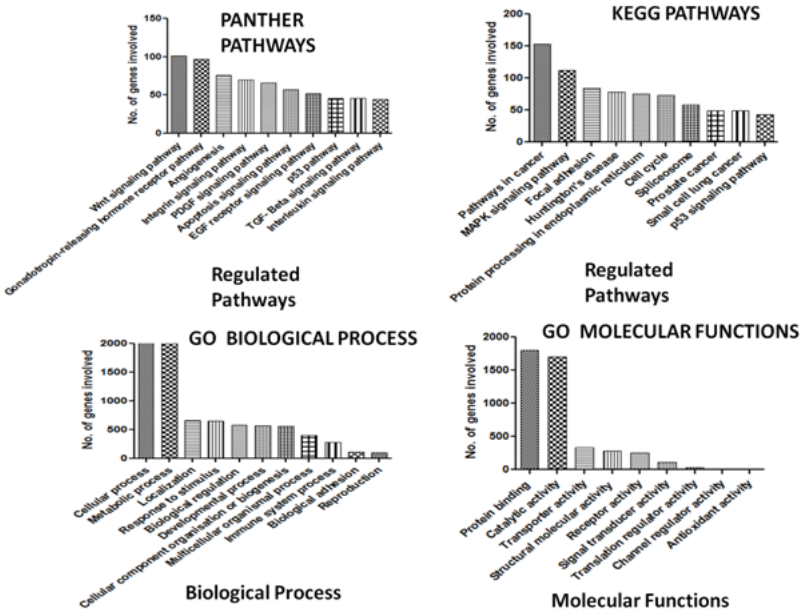


Fig.2Biological, molecular and signaling pathways regulated by dysregulated miRNAs in Luminal A subtype of Breast cancer.

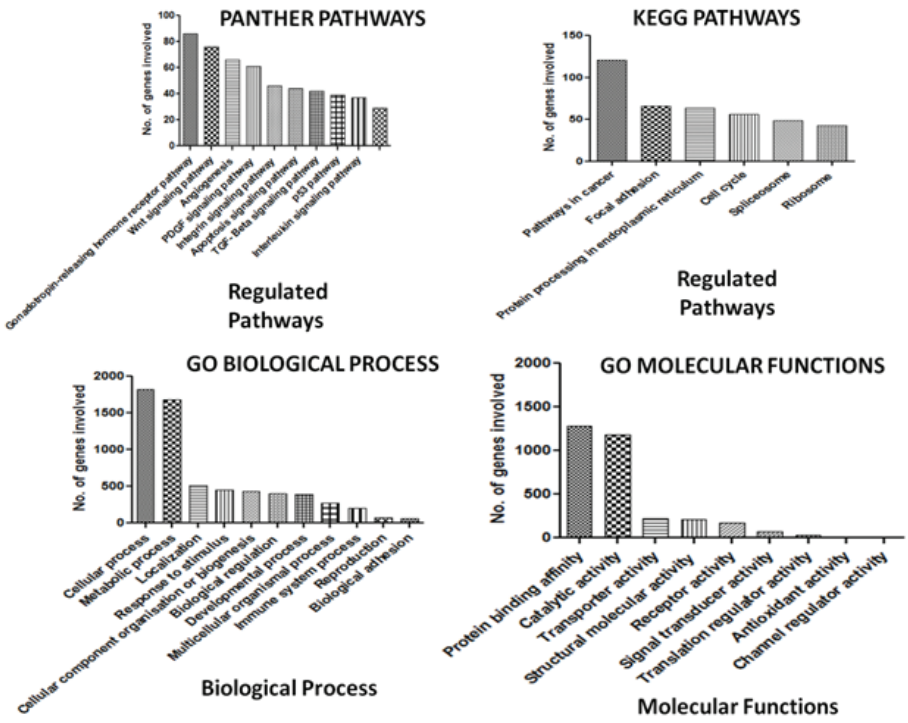


Fig.3 Biological, molecular and signaling pathways regulated by dysregulated miRNAs in Luminal B subtype of Breast cancer.

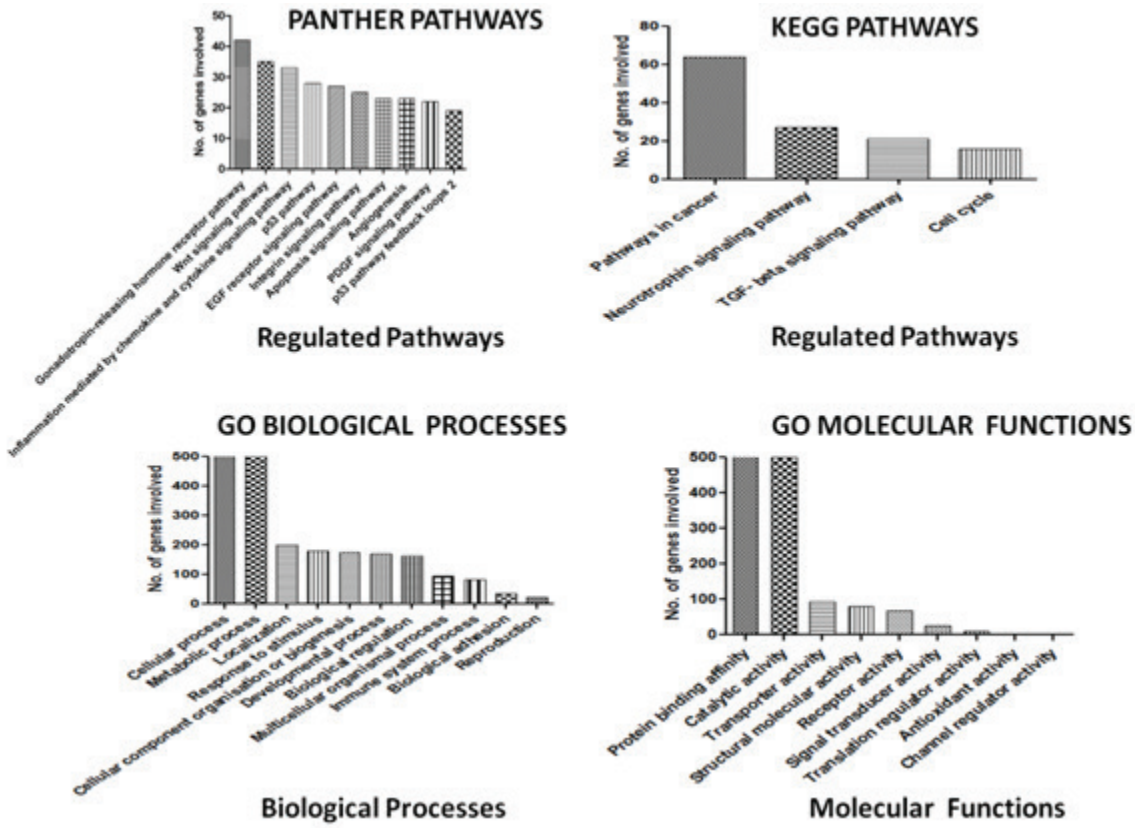


Fig.4 Biological, molecular and signaling pathways regulated by dysregulated miRNAs in HR-negative and HER2-positive subtype of Breast cancer.

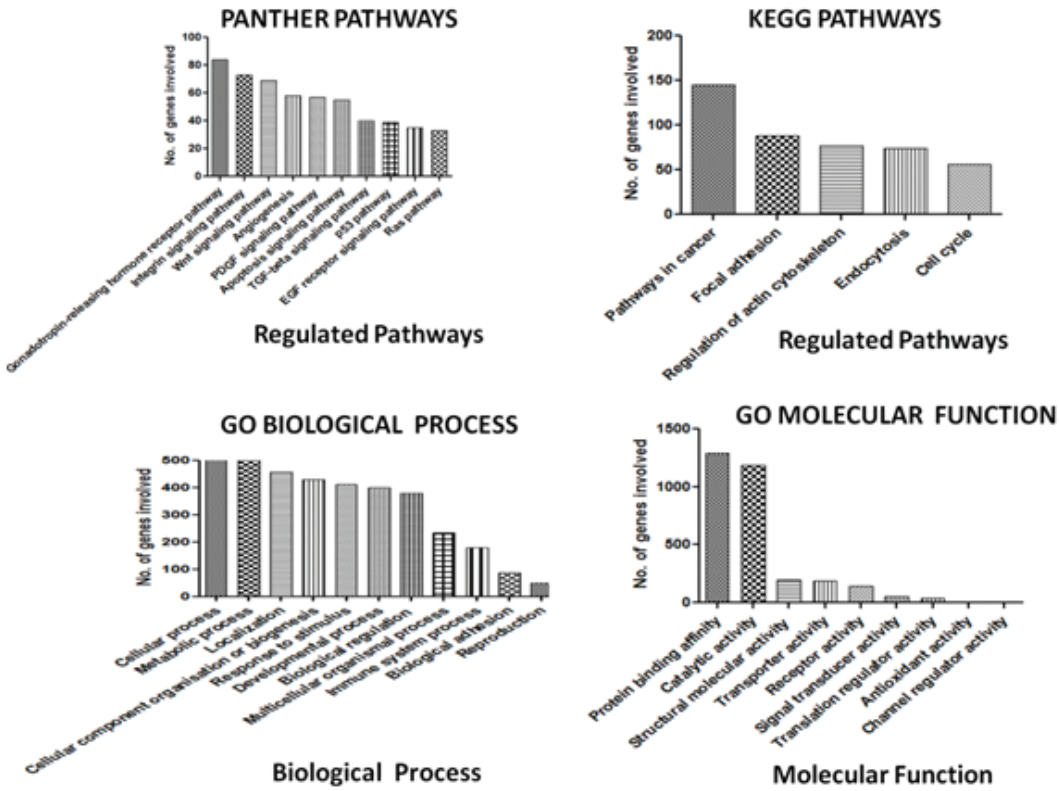


Fig.5 Biological, molecular and signaling pathways regulated by dysregulated miRNAs in Triple negative subtype of Breast cancer.

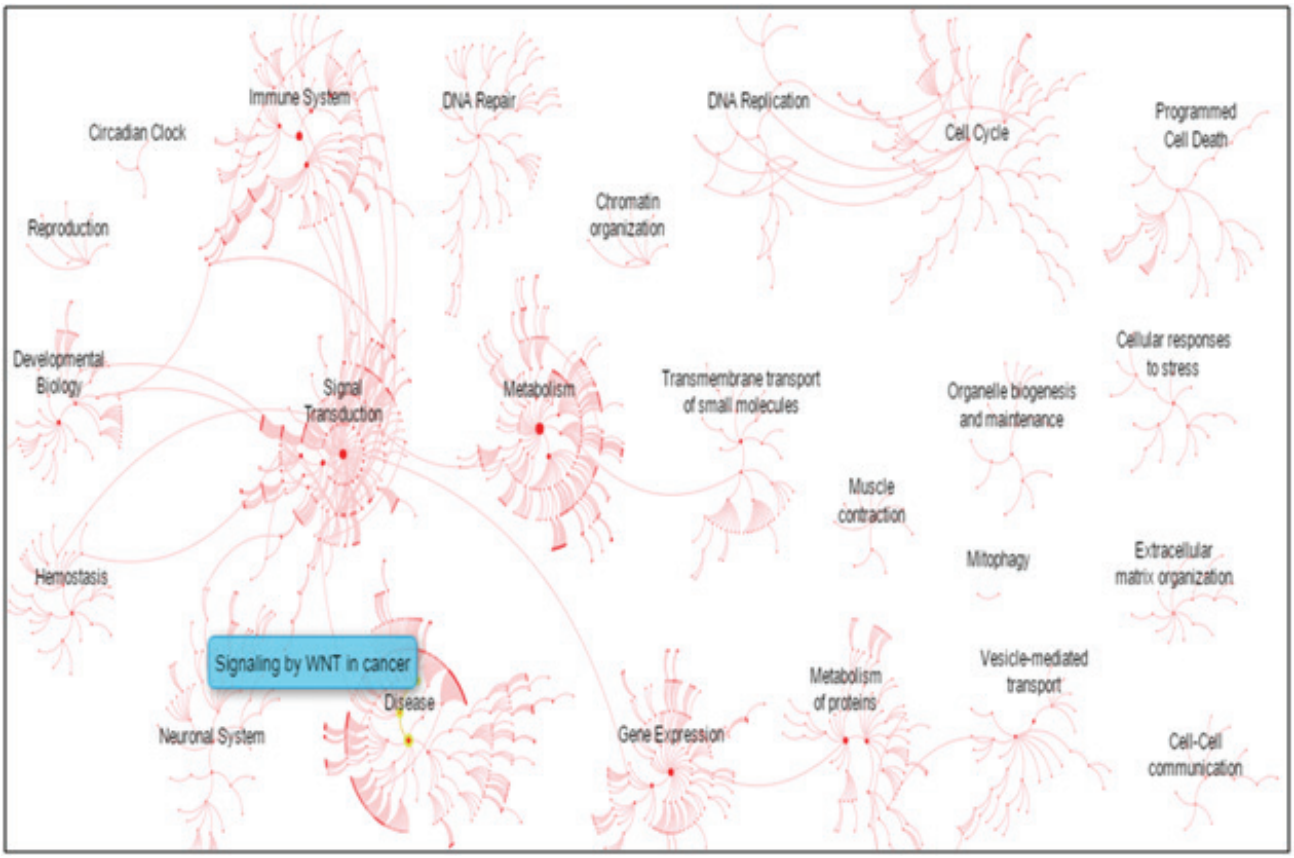


Fig.6 Reactome analysis showing cross talk between the major pathways regulated by identified targets.

DISCUSSION

Breast cancer being a heterogeneous disease with different molecular subtypes has drawn the attention of many researchers in better understanding the distinctive molecular feature associated with each subtype. Various efforts have been made in identifying signature miRNAs as specific biomarkers in categorizing breast cancer subtypes[15,22,31,32]. Here we have made a comprehensive list of dysregulated miRNAs in each subtype of breast cancer from the existing literatureand have further predicted their targets using *insilico* tools viz., TargetScan and miRDB. To further strengthen our analysis we have used TargetScan database, which is a web tool for experimentally validated miRNA targets and finally after duplicates removal made an exhaustive list of breast cancer subtype specific miRNAs.

Various novel targets have been identified in a breast cancer subtype specific manner which needs further validation, however, it opens a plethora of therapeutic interventions for breast cancer management in subtype specific way.

Key signaling enrichment analysis was performed using PANTHER, KEGG and Genecodis web tools unwinding significant insight on the different pathways regulated by the set of each subtype specific miRNAs in breast cancer and their target genes. Among the signaling pathways being exploited the most are the Gonadotropin releasing hormone receptor pathway, Wnt signaling pathway, Angiogenesis and Integrin signaling pathways. All these pathways have been reported to play a crucial role in cancer initiation and progression[33–35]. Further, functional and biological annotation study has shown various biological and molecular functions being regulated by the predicted targets that plays crucial role in cancer maintenance such as cellular process, protein binding and transcription.

Gonadotropin releasing hormone receptor pathway: Gonadotropin releasing hormone (GRH), also known as luteinizing hormone-releasing hormone, is the primary regulator of reproduction in mammals[36]. It sensitizes the gonadotropes via G-protein coupled receptor to stimulate synthesis and secretion of luteinizing hormone (LH) and follicle stimulating hormone (FSH) thereby regulating gametogenesis and steroidogenesis[35]. Research has shown that GRH analogs are used to regulate gonadotropin secretion from the hypothalamus and thus are used to hormone dependent neoplasms including breast cancer[37,38]. Its expression is reported to be higher in patients with triple negative breast cancer[39], highlighting its importance from the therapeutic point of view.

Our functional enrichment analysis revealed that Gonadotropin-releasing hormone receptor pathway (GO is the most deregulated signaling pathway in luminal B, HR negative and triple negative breast cancer subtypes and in the second most exploited pathway in luminal A-like breast cancer subtype. Several miRNAs are found to regulate this hormone receptor pathway including miR-103, miR-107, miR-126, miR-99a targeting HOXA13 and CLOCK.

Wnt signaling pathway: Wnt/β catenin signaling pathway is reported to play a major role in breast tumorigenesis (ref.[40] and regulate proliferation, migration and differentiation in many cancers including breast cancer. Different stages of mammary gland development is reported to be regulated by Wnt/β catenin signaling pathway[41]. Activation of Wnt/β catenin signaling pathway is associated with poor prognosis of breast cancer[42]. Moreover, Wnt signaling pathway is reported to inhibit breast cancer cell growth and metastasis by inhibiting breast cancer stem phenotype[43] and is reported to be associated with metastasis of triple negative breast cancer subtype to bone.

In our analysis, Wnt signaling pathway (P00057: 101) is found to be the second most dysregulated pathway in luminal B-like subtypes, triple negative breast cancerand was most significantly dysregulated in luminal A-like subtype of breast cancer with miRNA let-7c, miR-10a, miR-26 showed to target DICER, BCL2, FZD-8, FZD-9 and WNT-5A.

Angiogenesis: Angiogenesis is the formation of new blood vessels which aids in tumor metastasis, making cancer life threatening[44]. Angiogenesis is one of the crucial factors in sustaining tumor growth since it is essential for influx of nutrients to the cancer mass[45]. Among the crucial players of angiogenesis characterized so far are the vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF), placenta growth factor, transforming growth factor thymidine phosphorylase pleiotrophin and andrenomedullin that regulates both physiological and pathological angiogenesis[46–48]. Research has shown that breast cancer cells expresses these angiogenetic markers at different stages of tumor

development and exhibits different angiogenic profiles depending on the subtype and stage of breast cancer[49,50], indicating the necessity to use different angiogenic agents to treat different subtypes of breast cancer.

In our analysis, angiogenesis (P00005: 77) is the third most exploited pathway in luminal A-like and luminal B-like subtypes and is the fourth most statistically dysregulated pathway in triple negative breast cancer. Various genes are also identified by PANTHER such as fibroblast growth factor receptor substrate 2 (P00240), fibroblast growth factor receptor (P00186), fibroblast growth factor (P00213), focal adhesion kinase (P00209), VEGFR-associated protein (P00196), vascular endothelial growth factor (P00241).

CONCLUSION

Breast cancer being a heterogeneous disease with different molecular subtypes exhibiting a spectrum of different pathological features demands tailored treatment based on each subtype. In this work, we have highlighted the different miRNA signatures of each breast cancer subtype and eventually the various signaling and biological pathways being exploited by each subtype to different extends. Therefore the management of this heterogeneous form of cancer should be made based on the biological nature of the subtype under consideration after dissecting the clinical features associated with it. Thus miRNAs being specific to each intrinsic subtype may work as signatures to classify the intrinsic breast cancer subtypes and can be used as therapeutic targets in future for breast cancer management.

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Change in Completeness of Medical Records After Nabh Process in A Teaching Hospital

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ABSTRACT

Introduction: Comprehensive medical record is a cornerstone in the quality and efficiency of patient care during hospitalization and in subsequent follow-up visits, as they can provide a complete and accurate chronology of treatments, patient results and future plans for care. An incomplete medical record may reflect a poor and inadequate clinical care. It can also be used to support the allegations of negligence and fraud.

Purpose: To check the completeness of medical record/ IPD files in a teaching hospital in Pune.

Methods: The study was conducted at a teaching hospital attached to a medical college in Pune. Activities pertaining to NABH accreditation were conducted in October 2015 which were considered as intervention. A comparative study was done during January to May 2016 on the IPD records of September (Pre intervention) and December 2015 (Post intervention). Sample size was calculated to be 170 in each group. The IPD records of Pre and Post intervention period were analysed on the parameters in structured checklist. Data was analysed statistically by simple proportions using SPSS v20.

Results: As compared to the 78.75% completeness of IPD records in September, a significant increase of to 87.75% (p-value <0.01) was observed in December. Department wise participation was seen maximum of medicine (65/170 i.e. 38.24%) in September and of paediatrics (49/170 i.e. 28.82%) in December. Department wise average completion per cent of IPD records was best seen in psychiatry (97.06/100) in September and in December it was of ENT department (95.00/100). Maximum change was observed in ENT department.

Conclusion: Few activities pertaining to accreditation of the hospital to NABH improves the completeness of medical records.

Novelty: There is a paucity of existing data regarding the completeness of IPD records and measures to improve it.

Keywords: Completeness, Intervention, Medical Records, NABH

INTRODUCTION

Medical record is a clinical, scientific, administrative and legal document relating to patient care in which are recorded sufficient data written in the sequence of events to justify diagnosis and warrant treatment and end results. The medical record has a comprehensive purpose: "to recall observations, to inform others, to instruct students, to gain knowledge, to monitor performance, and to justify intervention"[1].

It is a virtual image of the patient created by a doctor at the moment of illness. Comprehensive medical records are a cornerstone in the quality and efficiency of patient care during hospitalization and in subsequent follow-up visits, as they can provide a complete and accurate chronology of treatments, results and future plans for care. An incomplete medical record may reflect a poor and inadequate clinical care. This can be used to support the allegations of negligence and fraud[2]. Medical record is now being employed to determine how well physicians in general are conforming to standards set by their peers[3].

With increasing pressure on physicians to provide cost effective and efficient care and the shortage of manpower, they tend to lack the completion of documentation. Also in developing countries like India

little priority is being given to the completion of the records. High income countries usually have a well advanced and extensive use of information technology to curb the problem[4].

Under the ambit of RTI act, CPA and Medical council act, it is the duty of the hospital to provide the medical records to the patients which are their right. This fact is rooted in Article 19 and 21 of Constitution of India ("Patients have right to get medical records from hospitals,says Law Ministry - timesofindia-economictimes")[5] Accreditation system helps to monitor the quality of hospitals and the standard of the treatment given to the patients. Under the aegis of Quality Council of India (QCI) and with the cooperation of Ministry of Health & Family Welfare, Govt. of India, National Accreditation Board for Hospitals & Healthcare Providers (NABH) was set up in 2006. It establishes and operates accreditation programme for healthcare organisations.

Purpose of the Study: The purpose of this study was to check the completeness of medical record/ IPD files in a teaching hospital in Pune. The results from this study will be used to further assess the potential of quality improvement in strengthening medical records management.

The objectives of this study were to determine the completeness of medical records and assess the change in the completeness after initiation of the NABH process in the hospital.

METHODOLOGY

A pre and post Intervention study was conducted at an 831 bedded multidisciplinary tertiary care teaching hospital located in Pune city, from January to May 2016. Figure 1 gives a picture of working of the Medical Records Department (MRD) of the hospital.

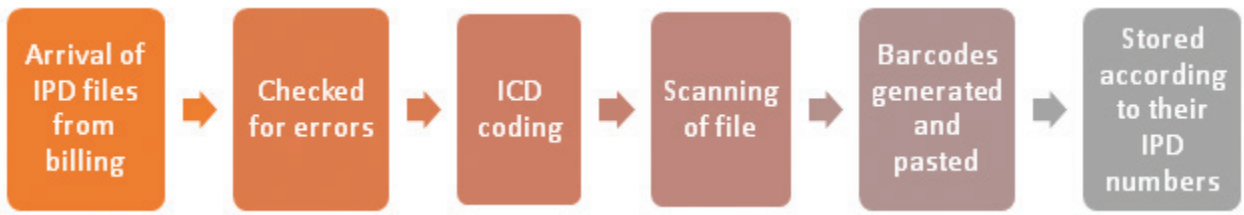


Figure 1. Functioning of the MRD

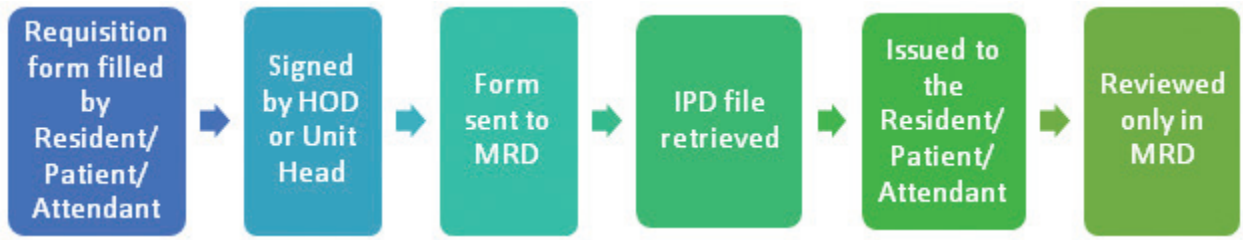


Figure 2. Retrieval of files

The hospital had initiated process for accreditation from NABH in October. Multiple activities were conducted to improve the quality of healthcare facilities. Few activities pertaining to the Medical Records Section are:

1. **Formation of IMS committee:** Information Management System Committee was formed, chaired by the NABH coordinator. The meetings were held fortnightly and the progress was discussed.
2. **MRD manual:** Standard Operating Procedures (SOP) were made on the guidelines issued by NABH.
3. **Training:** All the MRD staffs and hospital staffs were trained on the guidelines.
4. **Circulars:** Circulars are issued regarding
   (a) Sign, Name, Date and Time (SNDT)
   (b) Use of Stamps i.e. for Author of entry
   (c) Legibility
   (d) Continuation
   (e) MRD checklist
1. **Printing of various forms:** Various forms like initial assessment sheet, plan of care sheet, general and other consent forms were revised and issued again.
2. **Meeting and training at respective departments:** A meeting and training is conducted at every

department which includes the HOD, clinical and non-clinical staffs regarding the requirements of NABH.

3. **Audit:**
   - **(a) Active Audit:** The IMS Committee audits 10% of the files of each department. The mistakes were corrected there only and training was also given thereby. Audits are done quarterly.
   - **(b) Passive Audit:** MRD keeps a check on the IPD files. Their feedback and recommendations are collected frequently.

1. **MRD Committee:** A multidisciplinary committee was formed, chaired by the Medical Director. It included all the HODs, nursing supervisors and IT staffs. Their meeting was held quarterly.

2. **Quality Indicators:** Frequent revision of the indicators were performed. For entry level NABH, the following four indicators were monitored:
   - (a) Percentage of medical records not having discharge summary.
   - (b) Percentage of medical records not having ICD coding.
   - (c) Percentage of medical records having incomplete or improper consent forms.
   - (d) Percentage of missing medical records

All these activities were considered to be an intervention.

So the month of September 2015 was taken to be Pre- intervention group and December 2015 was considered as Post-intervention group. The records of September and December 2015 were analysed with a checklist which was prepared on the guidelines issued by NABH with the help of Medical Record Officer of the MRD.

A pilot study comprising of 10 samples in each group was done, the completeness was found to be 70% in September i.e. Pre- intervention period and 83% in December i.e. Post- intervention period. The sample size for comparing two proportions was calculated[6].

$$N = \frac{(Z\alpha + Z_{(1-\beta)})^2 \times (p_1q_1 + p_2q_2)}{d^2}$$

$p_1 = 70$, $p_2 = 83$, $q_1 = 30$, $q_2 = 17$

$$d = p_1 - q_1 = 70 - 83 = -13$$

$$= \frac{7.84\ [(70*30) + (83*176.5*93.5)]}{(-13)^2}$$

$$= 162.88 \sim 170$$

So for each group 170 IPD records were analysed. The records were selected by systemic random sampling method. The total number of admissions for the month of September and December 2015 were 2980 and 2819 respectively. To achieve a sample size of 170 per group every 17th IPD record was analysed.

Data Collection: Permission from Institutional Ethical Committee and MRD of the hospital was taken prior to study. The IPD records of the month of September and December 2015 were analysed on the parameters in the checklist. The checklist had 18 groups. Each group had a sub group ranging from 2 to 7 parameters. If all the parameters of the sub group were complete, a score of 1 was given else it was scored as nil. The obtained score was then converted out of 100. The percentage of completion of each record as well as for each group was calculated.

Completeness of medical record was calculated based on following equation:

$$\frac{\text{\% of completeness of IPD medical (Total Score(Marks given))}}{\text{(Number of parameters checked,applicable in the IPD record)}} \times 100$$

(Dima, 2014)

The records derived after the sampling technique were requested from Medical Records Officer (MRO). If the IPD file was not available the next file was taken into study. After the issue of IPD file from the MRD, they were analysed. The IPD files from September were analysed first. The scores derived were recorded in Microsoft Excel 2013. Patient confidentiality was maintained by assigning codes. The data was then analysed in Microsoft Excel 2013. For qualitative data various rates, ratios and percentage (%) were calculated. For quantitative data, mean, SD, median etc. were calculated. A two tailed test with P-value < 0.05 was considered as significant. Paired and unpaired t test were used to test the significance in the pre and post intervention periods. ANOVA was used to test the significance in between the departments.

RESULTS

A total of 340 IPD records were analysed - 170 in each group. The length of the stay of patients was of 2 to 23 days in September and 2 to 24 days in December. The mean length of the stay of patients was 5.39 ± 3.78 and 5.75 ± 4.28 in September and December respectively.

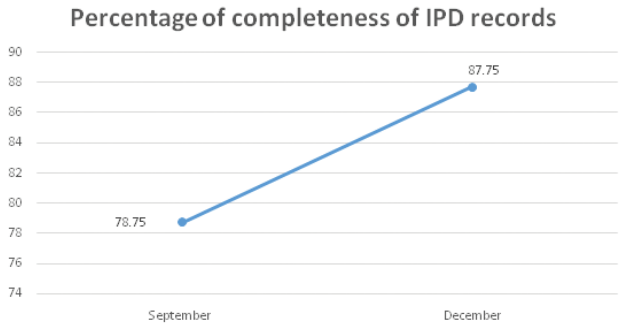


Fig. 3. Percentage of completion of IPD records in pre intervention and post intervention period.

In September i.e. the pre intervention period, the completeness of IPD records was found to be 78.75% and a significant increase in December i.e. post intervention, to 87.75% (p-value <0.01) was noted. Figure 4 depicts the increase in the completeness of IPD records.

Figure 5 elicits the department wise participation in the sample collected. In September i.e. Pre Intervention period, the maximum participation was of Dept. of Medicine (65/170 i.e. 38.24%) followed by Dept. of Paediatrics (40/170 i.e. 23.53%). Minimum participation was of Psychiatry (1/170 i.e. 0.59%).

In December i.e. Post Intervention period, the maximum participation was of Dept. of Paediatrics (49/170 i.e. 28.82%) followed by Dept. of Medicine (41/170 i.e. 24.12%). Minimum participation was of Dept. of ENT (2/170 i.e. 1.18%).

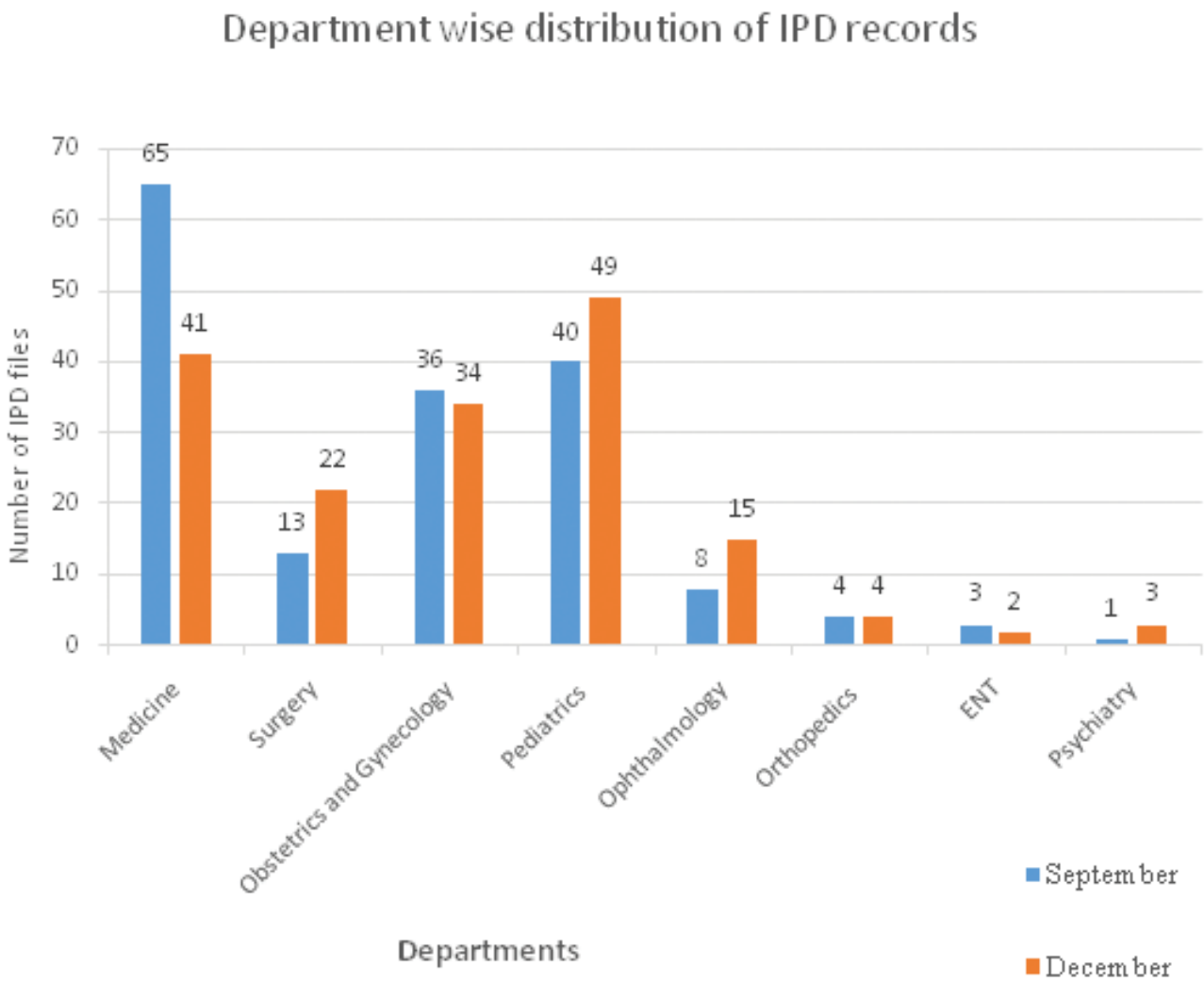


Fig. 4. Department wise distribution of the IPD records in pre intervention and post intervention periods.

Each department was considered as one subject and was evaluated. They were given scores based upon the completeness of their records. Subsequently t test was applied. Table 1 discusses the score of completeness of the IPD records for different departments. Department wise average completion score of IPD records was best seen in Dept. of Psychiatry (97.06/100) followed by Dept. of Obstetrics and Gynaecology (83.33/100) in September and it was highest for Dept. of ENT (95.00/100) followed by Dept. of Orthopaedics (91.85/100) in the month of December. Maximum change was observed in Dept. of ENT (76.35/100 to 95.00/100 i.e. 18.65). (Table 1)

Dept. of Psychiatry showed a negative trend (from 97.06 to 86.27) which might be attributed to its small sample size in the study.

The Dept. of Medicine, Dept. of Paediatrics and Dept. of Obstetrics and Gynaecology, which had the largest share in total number of participants in the study, showed an increase by 8.80, 10.09 and 5.29 respectively. (Table 1)

The increase in the completeness of IPD records of Departments of Orthopaedics, Ophthalmology, Surgery, Paediatrics and Medicine was found to be significant. It can be seen that the increase in Departments of Surgery, Paediatrics and Medicine was highly significant (p value≤0.01). (Table 1)

Table 1. Department wise completeness of IPD record

Department	Pre Intervention -September 2015		Post Intervention - December 2015		Change	p value
	Count	Average marks obtained for completion	Count	Average marks obtained for completion		
ENT	3	76.35	2	95.00	18.65	0.087
Orthopedics	4	78.27	4	91.85	13.58	0.003*
Ophthalmology	8	70.34	15	83.39	13.05	0.02*
Surgery	13	78.12	22	90.56	12.45	0.001*
Pediatrics	40	77.23	49	87.32	10.09	<0.001*
Medicine	65	78.16	41	86.96	8.80	<0.001*
Obstetrics and Gynecology	36	83.33	34	88.62	5.29	0.11
Psychiatry	1	97.06	3	86.27	-10.78	-

* - p value < 0.05 ~ Significant

Similar method for calculation was applied for evaluating the parameters. Each of the parameter was considered as a subject and was marked accordingly. Table 2 depicts the different parameters used to check the completeness. In the pre intervention period, the maximum completeness recorded was of TPR BP chart (99.41/100) and the minimum was pre-operative checklist (5.56/100).

In the post intervention period the maximum completeness was of diet chart which was recorded to be 100% complete (100/100) and the minimum was pre-operative checklist (54.76/100). (Table 2)

A significant change (p – value < 0.05) was found in the parameters of admission record, discharge card, progress sheet, input output chart, medication chart, general consent forms, pre anaesthesia check-up, pre-operative checklist, ICU monitoring and ICU discharge after the intervention. (Table 2)

It could also be noted that admission record, progress sheet, medication chart, general consent forms, pre-operative checklist, ICU monitoring and ICU discharge were having highly significant increase in the post intervention period. (Table 2)

Table 2. Parameters wise completion rate of the pre intervention and post intervention period

Parameters	Pre Intervention - September 2015		Post Intervention - December 2015		Change	p value
	Count	Average marks obtained for completion	Count	Average marks obtained for completion		
Admission Record	170	91.93	170	97.56	5.63	<0.001*
Discharge Card	170	83.65	170	88.59	4.94	0.048 *
Initial Assessment Sheet	170	61.18	170	65.15	3.97	0.43
Progress Sheet	170	61.18	170	87.65	26.47	< 0.001*
Physiotherapy Assessment	1	66.67	1	66.67	0.00	-
Diet Chart	3	66.67	3	100.00	33.33	0.23
Lab Reports	170	92.65	170	95.29	2.65	0.16
Input Output Chart	170	85.15	170	91.62	6.47	0.02*
TPR BP Chart	170	99.41	170	98.82	-0.59	0.56
Medication Chart	170	66.47	170	78.63	12.16	< 0.001*
General Consent	170	87.45	170	94.31	6.86	< 0.001*
Other Consents	23	94.20	27	97.53	3.33	0.39
Pre-anesthesia Checkup	25	79.33	39	94.87	15.54	0.006*
Pre-operative Checklist	27	5.56	42	54.76	49.21	< 0.001*
OT Record	28	74.05	41	80.41	6.36	0.30
ICU Monitoring	50	36.41	21	85.71	49.30	< 0.001*
ICU Discharge	22	20.00	21	68.57	48.57	< 0.001*

* - p value < 0.05 ~ Significant

Table 3. Department wise comparison for pre intervention period

Department	N	Mean	Std. Deviation	Std. Error	95% CI for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Medicine	65	78.16	9.58	1.19	75.78	80.53	52.38	97.06
OBGY	36	83.33	10.48	1.75	79.79	86.87	44.12	97.06
Ophthalmology	8	70.34	12.62	4.46	59.79	80.89	45.45	91.18
Orthopedics	4	78.27	2.72	1.36	73.93	82.60	75.47	81.13
Pediatrics	40	77.23	8.70	1.38	74.45	80.02	61.76	91.18
Psychiatry	1	97.06	.	.	.	.	97.06	97.06
Surgery	13	78.12	10.22	2.83	71.94	84.29	64.00	94.12
ENT	3	76.35	7.32	4.23	58.17	94.54	67.92	81.13
Total	170	78.75	10.02	0.77	77.23	80.26	44.12	97.06

p – value = 0.01 i.e. < 0.05 ~ Significant

Table 4. Department wise comparison for post intervention period

Department	N	Mean	Std. Deviation	Std. Error	95% CI for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
Medicine	41	86.96	7.63	1.19	84.55	89.37	67.16	100.00
OBGY	34	88.62	16.48	2.83	82.87	94.37	16.67	100.00
Ophthalmo-logy	15	83.39	8.00	2.07	78.95	87.82	76.00	100.00
Orthopedics	4	91.85	4.48	2.24	84.73	98.98	88.00	97.06
Pediatrics	49	87.32	10.08	1.44	84.43	90.22	58.82	100.00
Psychiatry	3	86.27	14.80	8.55	49.50	123.05	70.59	100.00
Surgery	22	90.56	8.95	1.91	86.60	94.53	65.91	100.00
ENT	2	95.00	7.07	5.00	31.47	158.53	90.00	100.00
Total	170	87.75	10.88	0.83	86.10	89.39	16.67	100.00

p – value = 0.557 ~ Not Significant

Table 3 and Table 4 depict the department wise comparison of pre and post intervention period respectively. ANOVA was used to test for significance. In the pre intervention period a significant difference is present (p value =0.01). In post intervention period p = 0.557 which is > 0.05. So no significant difference was noted.

DISCUSSION

One of the best ways to assess the implementation of the NABH guidelines is to check the completeness of medical records as other commonly used methods like interviewing the patients might not be as efficient. Evaluating the IPD records gives a dichotomous result which is independent from influence and is documented and accessible at all times.

The results which we achieved in this study of the completeness of medical records is comparable to the study done by Wong and Bradley in 2009. Their intervention included the following components: (1) a single point of entry for patient registration, (2) a custom-made MS Access-based computerized system for the master patient index and registration process, adapted to the unique needs of Ethiopia's language, culture, and limited computer skills, (3) standardization of medical records forms, (4) implementation of standardized procedures for medical record handling and filing, and (5) enhanced human resource training and supervision.

They found the completeness increased significantly from 6.5% to 45.7% i.e. by 39.2. This increase might be due to a shift from paper based to electronic medical record[4]. Roukema et al found that the paediatricians are documenting around 25% of all available patient information in paper records[7]. Here in this hospital, the records are filled by the residents, who are pursuing their post-graduation, supervised by faculty members and consultants of the respective department, and nurses, who are supervised by their senior nurses and faculty members of the respective department. Dima et al noted an increase in completeness by 73.6% after intervention. A gap between the pre and post intervention periods was of 10 months compared to our study which has a gap of 2 months. One can expect increase in completeness in subsequent month[8]. In a similar study conducted at a teaching hospital in Karnataka, India, all records were properly filled. 100% compliance was found in assembling and coding of the record[9].

After applying the sampling technique, the distribution pattern of participants give a general picture of the population of the patients visiting the different departments of the hospital. The picture is in line with previous records of patients admitted to the hospital in the past years.

The completion rate in pre intervention is already on a higher side than other studies. This might be attributed to the supervision of residents by their seniors, faculty members and unit in charge. The change in both the periods can be expected to increase with time and practice.

Major departments like Medicine, Paediatrics, Surgery and Orthopaedics showed a significant increase in the completion. Departments of Orthopaedics showed the maximum increase whereas Departments of Medicine and Paediatrics have, although significant, a relatively less increase which might be attributed to more work load on the residents and nurses who usually fill the records, which may contribute to delayed improvement. With time, more improvement can be expected.

Departments of ENT, Obstetrics and Gynaecology and Psychiatry didn't have a significant change. Department of ENT and Psychiatry have a small participation which might be the cause for it. It can be observed in Table 1, the completeness of Department of Obstetrics is already high (83.33/100) as compared to other departments. So they will need extra efforts as they might have reached the stage for hard core improvement. This extra effort will have to be made at all the levels in the administration.

Forms like initial assessment sheet, physiotherapy assessment, pre-operative checklist and ICU discharge summary were lagging in terms of completeness even after the intervention. ICU has a rotatory posting of the residents and nurses in the hospital. It might be possible the trained resident or nurse may have been shifted to different department in the hospital. This would call for increased frequency of training of the residents and nurses. A decrease in completion percentage is seen in TPR BP chart. No change was noted in physiotherapy assessment sheet.

A study by Owen et al. regarding the completeness and safety of medication lists recorded in outpatient notes, admission notes, and discharge summaries showed that 28.5% of notes were complete including a medication name, dose, route, and frequency. Discharge summaries had the highest rate of completeness 44.4% and admission notes had a lowest rate of completeness 22.9%[10].

It can be seen in Table 3 that a significant difference is present in between the departments with regards to the quality of completion of IPD records in the pre intervention period. In Table 2 it is observed that the completion rate has increased in nearly all the departments and 5 departments showed a significant increase in completion. Thus it can be deduced that the significant difference as depicted in Table 3 was removed post intervention and was not observed in Table 4. In other words the departments which were poorer in terms of completion in pre intervention period improved as did the other departments.

Accreditation is an incentive to improve the capacity of the hospitals to provide quality of care to the patients. It is an approach to improve the quality of hospitals.

It is expected that the biggest beneficiaries of accreditation are the patients. They start to receive high quality of care and safety. The staffs are trained and are present at their rightful job description in the hospitals with accordance to their background. The satisfaction of the patients are regularly evaluated.

The hospitals are benefited as the accreditation helps them to improve continuously. They aim not only

to provide quality care but also to reach the best of it. There is overall professional development of the staffs as they get an opportunity to work in a good working and learning environment.

After accreditation, certified information on facilities, infrastructure and level of care is provided. The accreditation is beneficial to insurance and other third parties as well.

We found that few interventions which were conducted to train for accreditation do increase the completeness of medical records. This will further improve the quality and performance of the hospital.

CONCLUSION

Few activities pertaining to accreditation to NABH improves the completeness of medical records in the hospital. It can also be noted that a short time has passed after the intervention. So increased completeness can be expected with passage of time. The simplicity and overall expense of the project produced results demonstrating a collective effort taken at all the levels regarding the medical records.

RECOMMENDATIONS

1. At the hospital, the interventions were done as per the requirement of accreditation of NABH. These activity should be done irrespective of accreditation requirement.
2. Frequent trainings of the residents and nurses should be scheduled – at the start of each academic year and repeated as per the need after audits.
3. Special attention can be given to departments like Obstetrics and Gynaecology, Ophthalmology, Medicine, Psychiatry for training.
4. Training emphasis can be given to filling forms of initial assessment sheet, pre-operative check list etc. which were lagging behind in terms of their completeness.
5. Frequent audits should be done to keep a check. Inadequacies can be corrected there on.
6. The hospitals can issue a medical record deficiency form, which can be filled by the resident/nurse, billing department and staffs of the MRD which can filter and guide about the deficiency in the IPD records.

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Evaluating the Performance of an Advanced Breast Cancer Diagnosis Unit in India

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ABSTRACT

Purpose: Breast Cancer (BC) is the most common cancer in India and has the highest mortality rates. Given the increasing BC burden, there exists a need to establish BC advanced diagnostic centres in India that deliver affordable services with global standards. To evaluate the performance of an advanced BC diagnosis facility in Pune, India

Methodology: Radio-diagnosis department at Orchids Breast Health Clinic (OBHC) in Pune is equipped with 2-D Full-field Digital Mammography (FFDM) with 3-D Tomosynthesis, Automated Breast Volume Scanner (ABVS) and precision biopsy devices (i.e. stereotactic, vacuum and mammotome). Breast radiologists, surgeons and radiographers follow NCCN guidelines and BIRADS lexicons for BC diagnosis based on ultra-sonography (USG) for women <40 years and FFDM for women aged 40 years and above. Suspicious cases undergo appropriate image-guided biopsies. Retrospective radiology and clinico-pathology data was collected from clinically annotated patient archives maintained at OBHC.

Results: During the period of 20 months (i.e. from February 2015 to October 2016), women walked into OBHC for their breast related symptoms or annual check-up or screening. Out of the total women who underwent imaging based diagnostics, 206 women had a breast biopsy. Among them, 96.8% women were diagnosed for BC on a tru-cut biopsy and 3.2% on a stereotactic biopsy.

Conclusion: Following the EUSOMA guidelines, OBHC has improved and advanced their diagnostic modalities, clinical team, paramedics, trainees and quality service for Breast Cancer care in India.

Keywords: *ABVS, BIRADS, Breast Biopsy, Breast Cancer, FFDM*

INTRODUCTION

Cancer is the leading cause of premature death and disability worldwide, especially in women[1]. Increasing cancer burden is a rapidly growing crisis in low-income and middle-income countries (LMICs)[2]. Breast cancer (BC) is one of the most common cancers diagnosed in women globally. With an estimated 1, 45,000 new cases detected and 70,218 deaths recorded per annum, BC stands as the most common cancer in India. It is estimated that 1 in 22 Indian women carry a lifetime risk for breast cancer[3].

BC has gained a predominantly urban profile and is the commonest cancer in urban Indian females, and the second commonest in the rural Indian women[4]. In urban India, the age standardised ratio (ASR), which is defined as the number of newly diagnosed cases per annum per 1, 00,000 population, is 33-35 in comparison to the rural ASR of 16[4]. India has the highest incidence-to-mortality conversion rate in the world (i.e. one death in every two women detected with BC in the first 5 years after diagnosis. Various factors contribute to the increasing BC disease burden which includes lack of awareness about the disease, lack of screening programs, late stage detection and poor treatment outcomes. In the Indian society, lack of awareness and education about BC has resulted in generation of numerous myths about the disease. This ignorance has led to the development of fear towards cancer screening; thereby, resulting in women detected with advanced stages of BC. Lack of appropriate treatment options and medical facilities in our country has contributed to poor compliance to BC treatment protocols and has thus, increased the disease-associated mortality.

In order to tackle the growing BC burden in India, women need to be made aware of primary early detection methods for BC such as breast self-examination every month (BSE), clinical breast examination (CBE) and screening mammography (SM).

CBE of both breasts is a cost-effective, systematic, visual and palpation method conducted in both sitting and supine positions by a doctor or trained primary health caregivers. While CBE has high specificity (94–99%) and low sensitivity (28–54%) a secondary diagnostic test involving analysis of biopsied breast tissue is often necessary to assess all the abnormalities identified through BSE and CBE[5].

With the projected increase in BC risk and disease burden in India in coming years, there is an exigent need to establish dedicated Breast Care units particularly in urban areas. Such Breast Care units should provide access to the best of diagnostics, treatment and rehabilitation facilities to all socio-economic strata of the society at affordable cost.

In year 2013, EUSOMA (The European Society of BC Specialists) published a Position Paper titled "The Requirements of a Specialist Breast Centre"6. The objective of this document was to define the organisational model for a speciality Breast Centre, with the appropriate standards for resources, clinical expertise and data management. Based on the guidelines published in this document, many dedicated Breast Care units have been created or upgraded in the European countries. Such Breast Care units provide all the necessary services in the BC domain, which range from community screening, preventive oncology, risk assessment, radiological diagnosis, surgery, chemotherapy, radiation oncology, psychological counselling, patient rehabilitation and follow-up services. A multi-disciplinary team of appropriately trained and experienced medical and allied health professionals are involved in the successful operations of such Breast Care units.

Despite the growing BC disease burden, the Indian healthcare system does not have many examples of such speciality Breast Care units. It is noteworthy that only a handful, large-sized regional cancer centres in various parts of the country have taken concerted efforts in this direction.

With this background, Prashanti Cancer Care Mission (PCCM), a public charitable trust in Pune has established Orchids Breast Health Clinic (OBHC) with a goal to emerge as a Centre-for-Affordable-Excellence in Breast Care.

This paper describes the operational model of the Radio-diagnosis department of this centre and evaluates its compliance to the recommendations of the EUSOMA guidelines.

METHODOLOGY

PCCM is an NGO in Pune, Maharashtra, India and functions as a registered public charitable trust mainly working in the area of providing affordable treatment and rehabilitation to cancer-affected women. PCCM is also mandated to undertake cancer education, training and research activities

Initiation of a BC Clinic: In the year 2009, PCCM established a dedicated Breast Cancer Unit– OBHC in Pune.

At present, OBHC comprises of a multidisciplinary team of Onco-surgeons, Medical and Radiation Oncologists, Radiologists, Clinical Scientists, Physicians, dieticians, nursing staff, paramedics and psychological counsellors.

Patient Flow: The general demography of women visiting the breast care unit includes women in the age group of 25-75 with breast related complaints, symptoms, or referrals from other doctors as well as for annual check-ups. The activities at the Radiology department generally follow the flow as depicted in Figure 2.

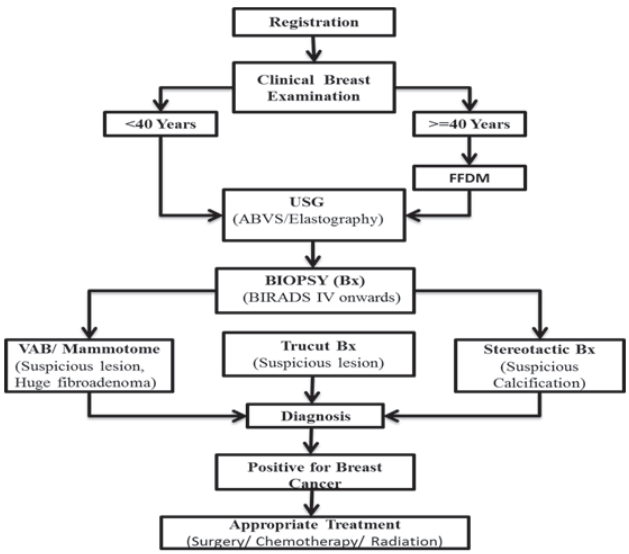


Figure 1: Schematic representation of patient's journey at Orchids Breast Health Centre

Registration: When a woman approaches OBHC, she is registered in the patient database with a unique patient identity number. Her personal details including past medical and family history is collected, and documented as per standard proforma.

Clinical Breast Examination: The onco-surgeon will examine the breast via clinical breast examination (CBE) with attention to enlarged lumps, nodules, swelling, skin changes or thickening that is unlike normal breast tissue. Depending upon the clinical findings and if indicated, the patient is advised further on an appropriate radio-diagnostic modality.

Radio-Diagnosis: Women above 40 years undergo a digital mammography and the women aged 39 and below are offered an ultrasound. However, women below the age of 40 will be offered mammography if they are symptomatic.

The radio-diagnosis department in OBHC is equipped with the following facilities:

Full-Field Digital Mammography (FFDM) with 3D Tomosynthesis: The 2-D FFDM with 3-D Tomosynthesis (Siemens Mammomat Inspiration™) at OBHC provides significant advances in BC diagnosis and the following benefits: less radiation dose, reduced breast compression pressure and improved breast cancer detection rates. Furthermore, this equipment quickly acquires digital images with high resolution, and increases diagnostic certainty, which helps the radiologist identify abnormal tissue and lesion morphology.

Digital Breast Tomosynthesis creates a 3D picture of the breast. Tomosynthesis is similar to a standard mammogram in that it uses X-ray technology and applies the same amount of pressure to the breast. But rather than providing two views-from top to bottom and side to side-the 3D approach captures multiple views from a variety of angles in few seconds. Once the digital images are acquired and transmitted to a high-tech digital mammography workstation, the radiologists view the images on the Siemens' *syngo*. Breast Care[TM] based acquisition workstation. These monitors have advanced visualization and 3-D features which brings better quality and efficiency to view, read and report image. The mammogram findings are further reported according to the Breast Imaging Reporting and Data System (BIRADS) lexicons.

Automated Breast Volume Scanner (ABVS)/ Ultrasound: Mammography may not be able to detect cancers in younger women due to the predominantly dense breast tissue. Ultrasonography (USG) has demonstrated the ability to detect cancers that are missed by mammography. ABVS (ACUSON S2000TM) is a 3D USG based diagnostic modality that offers great advantage in identification of suspicious lesions with reference to the anatomical context of the breast tissue. USG can also be used to precisely locate the position of a tumour in order to guide the onco-surgeon during a biopsy or aspiration procedure. The USG machine uses an additional, new technique called Elastography, which defines the elasticity of the breast tissue and has additional benefit of defining the lesion characteristics.

Biopsy Devices: A breast biopsy is performed to remove representative cells or bits of tissue from a suspicious lesion in the breast for further examination. This sample tissue is evaluated by a pathologist under a microscope and a cancer diagnosis is confirmed. Breast biopsies are performed surgically by a radiologist using a less invasive procedure that involves use of a hollow needle and image-guidance techniques. The biopsy procedures carried out at OBHC are as follows:

Vacuum Assisted Biopsy (VAB)*:* With a vacuum-assisted device, negative pressure is used to extract small amounts of tissue into the sampling chamber from the breast through the needle. Without withdrawing and reinserting the needle, the VAB device rotates positions and collects additional samples. Typically, eight to twelve slivers of tissue are collected from the lesion.

Stereotactic Biopsy*:* In stereotactic breast biopsy, a special mammography machine is used to help guide the radiologist's biopsy equipment to the site of the abnormal growth. A stereotactic biopsy is carried out when the radiologist finds a suspicious calcification in the mammogram. The procedure is carried out on the FFDM machine and the stereotactic biopsy device helps the radiologist to directly insert the biopsy needle at the exact area of concern, guided by an image and algorithm created by the machine.

Mammotome Biopsy*:* Mammotome breast biopsy devices are accurate to diagnose a variety of suspicious breast lesions, and are even used for the

excision of fibroadenomas with minimal scarring, without any stitches, and thereby ensuring an OPD-based procedure and immediate recovery. This is a minimally invasive biopsy technique and causes very little discomfort.

Data Collection: Data collection is the most important element in any healthcare set-up[7]. It is desirable that data is comprehensively stored and not kept separately across various repositories and locations. In order to analyse the functioning of an organisation at the macro and micro levels, healthcare providers have to envisage a comprehensive data management policy that includes clinical as well as administrative data. Meaningful data management allows clinicians and hospital staff to make informed decisions to constantly improve quality of care as well as undertake research activities.

Data Collection at OBHC: OBHC has established a Hospital Information System (HIS) and an Electronic Medical Recording (EMR) system that ensures streamlining the work flow of patients, easy capture, archival and retrieval of clinical data. HIS saves time with multiple users simultaneously operating the system in real-time and as well as the healthcare professionals for maintaining data quality and safety.

The conventional method of clinical data capture using paper-based forms is labour-intensive, time consuming, error-prone and requires additional man-power for converting manually collected data into an electronic format. Therefore, OBHC has implemented the use of Doxper™; a specially designed digital pen which when used on designed coded papers can convert handwritten data to digital format in real time. The extensively-designed patient case forms are filled using this digital pen. The corresponding data is stored in electronic formats and are readily available for online viewing that is made available by means of annotated excel sheets. This novel technology solution has been shown to save data collection time, reduce errors and eliminate the need for an additional human resource.

The radiology images from FFDM are visually analysed by experienced Breast Radiologists on a reporting system (syngo.via Acquisition Workstation) with resolution of greater than or equal to 3 mega-pixel (>=3). Sygno.via monitors have advanced visualization and 3-D features, which brings better quality and efficiency to view, read and report images. The sygno.via workstations are user friendly and can be accessed on mobile. It displays quantitative information such as the breast density or position and size of the lesion. All radiology images are stored in the Picture Archiving and Communication System (PACS) which allows for data retrieval from off-site locations via cloud based access.

Informed consent is obtained from patients undergoing the aforementioned radiological investigation for further use in research projects.

RESULTS

The present data pertains to a specific period of 20 months (i.e. from February 2015 to October 2016). This data represents radiological investigations performed during this period on women who visited OBHC for their complaints, symptoms, annual check-up and screening.

Out of all women who came to OBHC, 1405 women underwent a FFDM scan and 1393 women had an USG. The suspicious cases further underwent appropriate biopsy procedures with co-relation on FFDM and USG. (Table 1)

Table 1: Summary of radiological investigations at OBHC

Parameters	Total number of cases
FFDM	1405
ABVS	1393
Biopsies	209

Diagnosis: Of the 1405 women who were radiologically investigated, 209 women with suspicious mammogram and USG underwent a biopsy (i.e., rate of biopsy is 14.8%. Out of these 209 suspicious cases, majority (93%) women underwent a tru-cut biopsy (195/209), while only few (7%) had a stereotactic biopsy (14/209).

In reference to the total number of women who underwent radiology investigation, the rate of diagnosis was determined as 11% (126/1405). Of the 209 highly suspicious cases that underwent biopsies, 126 cases were diagnosed positive for BC after histopathological

analysis; (i.e. rate of histopathological diagnosis was calculated as 60%)

The majority of cases (122/195) diagnosed with BC had undergone tru-cut biopsy (i.e. 62.5% of cases where positive out of the total number of tru-cut biopsies). Only a minor number of cases had undergone stereotactic biopsies (4/14i.e. 28%) of cases were positive out of the total number of stereotactic biopsy procedures performed. The results are summarised in Table 2.

Table 2: Summary of Biopsy procedures at OBHC.

Type of biopsies (done with co-relation on FFDM and USG)	Tru-cut biopsy	Stereotactic biopsy
	195 (93%)	14 (7%)
Diagnosed positive for breast cancer	122/ 195 (62%)	4/ 14 (28%)

DISCUSSION

Global epidemiological data indicates predominantly high BC incidence in developed countries. The life-time risk of developing BC in western population (1 in 8 women) is much higher than in Indian women (1 in 22)[3]. However, unlike India, these developed countries have significantly low incidence-to-mortality conversion rates. In response to the high BC disease burden, the healthcare systems in such countries are adequately sensitized to create innovative models for early detection and treatment of BC. Such concerted efforts have resulted in successful establishment of national screening programs as well as specialty Breast care units across major medical centres in these developed countries.

The growing burden of BC in India is soon expected to become a major public health issue that will impact several domains in the healthcare sector. It is now widely believed that the high BC-associated mortality in India is a result of lack of awareness, lack of appropriate medical infrastructure and personnel and poor treatment outcomes. Indeed, there is an exigent need to create healthcare models in the country that will incorporate not only early detection me thods but also adequate treatment facilities.

A few dedicated Breast Care units have been established in regional cancer centres in India and have shown great value in BC management in the surrounding regions. It is noteworthy that in November 2017, Ministry of Health, Government of India has launched a national breast cancer screening program in 100 districts with help from the public healthcare set-ups. In concordance with these encouraging developments at the government level, the Indian healthcare scenario will largely benefit if like-minded individuals and medical organisations in the NGO and private sector also contribute to the BC management needs of our nation. Indeed, the National Comprehensive Cancer Control Program of India (NCCCPI) has recommended a significant role for NGOs in the battle against cancer affecting the Indian population.

The battle against BC in India will require a multi-pronged approach. Indian women should be educated about BC risks, detection methods and treatment options. Cost- effective early detection methods (SBE, CBE-based community screening) should be adopted by the community. Further, BC diagnostic centres should be established in tier II and III cities so as to ensure that women with breast abnormalities can undergo timely and accurate diagnosis. In addition, BC treatment centres should be available in such places with adequate medical facilities and trained personnel.

With this motivation, PCCM-an NGO working in Pune has established Orchids Breast Health Clinic (OBHC), a speciality breast care unit, as part of its social-impact projects.

Phases of Development of OBHC: Since its inception in 2009, OBHC underwent developmental phases as depicted in Figure 1.

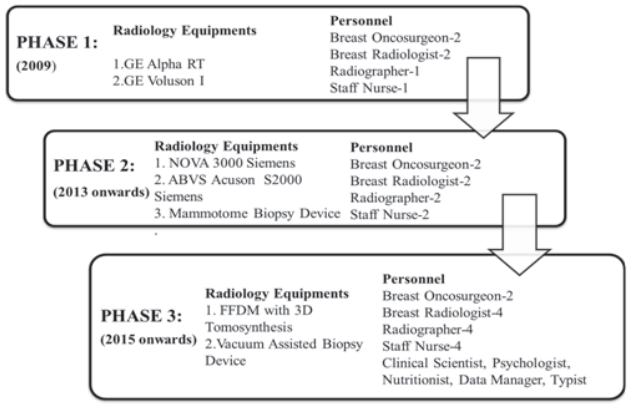


Figure 2: Phases of Development of OBHC

The European Society of Breast Cancer Specialists has published a EUSOMA paper[6], which depicts the

guidelines for establishment and operational model of a breast cancer units (Figure 3). This policy document has set a benchmark for many European breast care units who have created and upgraded their centres accordingly. Table 3 describes a summary of EUSOMA guidelines for creation of a Radio-diagnosis unit in a BC centre along with the compliance of OBHC to these guidelines

Table 3: EUSOMA Guidelines for Breast Radio-diagnosis Unit

PARAMETERS	GUIDELINES OF EUSOMA	OBHC COMPLIANCE
Examination & Procedures	● Clinical breast examination	Yes
	● Mammography	Yes
	● Ultrasound of the breast and axilla	Yes
	● Core Biopsy.	Yes
	● FNAC	Yes
	● Breast MRI	No(Referred to a diagnostic centre)
Equipments	● Mammography unit (Preferred Digital)	Yes
	● Stereotactic biopsy attachment	Yes
	● Ultrasound Unit	Yes
	● Core Biopsy Devices	Yes
Radiology Staff	Two dedicated Breast **Radiologists**	Yes
	● Dedicate 30% time in Breast Imaging.	Yes
	● Should report minimum 1000 mammography cases per year	Yes
	Two dedicated **Breast Radiographers**	Yes
	● Should perform minimum 1000 mammograms per year.	Yes
	● Should attend refresher training every 3 years.	Yes

Latest trends indicate increase in number of younger Indian women (i.e. age 35-45) diagnosed with BC. The density of breast tissue is this age group is higher than the women approaching their fifties. Also, it is reported that Indian women have higher breast density. In this scenario, the standard mammography-based diagnosis is not recommended due to radiation-associated risks and poor imaging outcomes, respectively. To overcome this limitation, OBHC has acquired a unique USG system namely Automated breast volume scan (ABVS), which evaluates the dense breast tissue and identifies lesions in women of the younger demography.

In addition to ensuring accurate BC diagnosis, the Radio-diagnosis Unit at OBHC has also been instrumental in the genesis of high-impact projects such a community screening, training workshops and research.

PCCM is running a 3-tier community BC screening program in Pune which involves:

(a) Education and awareness

(b) CBE and Screening mammography in a mobile diagnostic unit

(c) BC diagnosis and treatment.

In this project, the team of radiologists at OBHC play an active role in training of radiology technicians working in the mobile screening van, analysis of mammography images and diagnosis of screen-positive cases. In a span of one year in this project, 5040 women in Pune city were screened and 1892 mammographies were performed (37.5%). Of this pool of women who underwent mammography, 331 women were screened positive (17.5%) and underwent further diagnostic follow-up at OBHC with FFDM and/or ABVS. Further, 12 highly suspicious cases were biopsied of which 5 cases were confirmed as BC on histopathological

analysis. Therefore, it is apparent that the presence of an advanced BC radio-diagnosis unit at OBHC has made a significant impact on the on-going community screening project in Pune.

With ready access to advanced diagnostics technologies at OBHC, training programs for Onco-surgeons, Radiologists and Radio-technicians have been initiated. Onco-surgeons in India routinely visit OBHC to learn advanced biopsy techniques while trainee radiologists are mentored by senior radiologists by means of hands-on training workshops on breast imaging. Furthermore, radiology technicians also undergo training in various technical aspects of FFDM, ABVS and breast biopsies. It is noteworthy that OBHC has now been recognised as a practical training centre for Masters in Oncoplastic Breast Surgery program in India conducted by University of East Anglia, UK.

Availability of cutting-edge Breast imaging modalities at this centre has also resulted in genesis of Breast imaging-themed research projects. The radiology and clinical research team is currently maintaining a curated BC Radiology database with close to 5000 images generated from FFDM and ABVS. This database has enabled investigations of mammographic and USG-based features of various BC subtypes, particularly triple-negative BC (TNBC), a highly prevalent subtype in India. Studies are also on-going for identifying characteristic imaging features of various BC subtypes using the ultrasound-based elastography technique.

CONCLUSION

With the projected increase in BC incidence in India, there is an urgent need to upgrade the existing medical infrastructure and services for effective medical management. Therefore, establishment of dedicated Breast Care units that are equipped with advanced diagnostic and treatment facilities and situated in various geographical locations across India inclusive of tier II and III cities is the need of the hour. Such Centres should be modelled as per the EUSOMA guidelines to ensure that the services are patient-centric, affordable, and easily accessible without compromise on quality. Furthermore such Centres should also aspire to become Centres of Excellence that will also undertake training and research activities. The operational model and performance evaluation of the diagnostic unit at OBHC, Pune described in this paper may be considered as a representative example for future establishment of similarly themed units in other parts of the country.

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Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Prevalence and Health Seeking Behavior of Depressed Persons in India

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ABSTRACT

Depression is a significant contributor to the global burden of disease and affects people in all communities across the world. The objective of the study is to study the prevalence of depression and to find out the possible factors of depression in India and to study the unmet need for treatment among depressed people. Present study utilizing the secondary data from study on global ageing and adult health (SAGE), India. This is implemented in six states – Assam, Karnataka, Maharashtra, Rajasthan, Uttar Pradesh, and West Bengal. A separate bivariate analysis and multivariate logistic regression analysis are carried out to examine the socio-economic and demographic factors, risk factor, co-morbidities affecting the dependent variables used in the study i.e. depression. The study reveals that the prevalence of Symptom-based depression is high than self-reported. It is found to be highest in both less developed and more developed states Uttar Pradesh and Karnataka. It is found high in person with higher age, low educational level, poor, in currently married and widowed/divorced/separated. Unmet need for medication and treatment is found to be high for depression and it gets decreased as it co-morbid with other diseases.

Keywords: *Co-morbidity, Depression, Quality of Life, Unmet Need.*

BACKGROUND OF THE STUDY

Depression, the most common mental disorder, Global Burden of Disease study showed about 9.7% years lived with disability in 2010[1]. The World Mental Health Survey carried in 17 countries observed that on average about 1 in 20 people reported having depression[2]. Depressive disorders usually start at a young age; it reduces people's functioning and often is recurring. Due to these, depression is the leading cause of disability worldwide regarding total years lost due to disability[2]. Unipolar depression in South East Asia region ranked as the fourth leading cause of burden of all disease, accounting for 4.8% of total DALYs[3]. In India, many studies have estimated the prevalence of depression in community samples and the prevalence rates have varied from 1.7 to 74 per thousand population[4,5].Substantial evidence from India and other low and middle-income countries (LMIC) links socioeconomic deprivation with increased risk of depression[6]. Other groups which are shown to be at higher risk for depression in India are women, the elderly and urban dwellers and people who are divorced or widowed[7].

India's highly inequitable distribution of mental health resources means at least 90% of people with mental disorders (PWMDs) are undiagnosed and untreated[8]. Depression is responsible for the greatest proportion burden of disease which results in non-fatal health outcomes, producing for almost 12 percent of total years lived with disability worldwide[9]. Without medical treatment, depression has the tendency to assume a chronic course, be repetitive, and over time to be associated with increasing disability[10]. The comorbidity of depression with chronic physical diseases such as arthritis and diabetes are well recognized in developed countries. Several studies have shown that people with one or more chronic diseases, increases the risk of having major depression disorders[11,12]. With a growing elderly population, and the associated increase in the prevalence of chronic medical conditions, a concurrent rise in the prevalence of depression is to be expected. In fact, projections indicate that after heart disease, depression is assumed to become the second-leading cause of disease burden by the year 2020[13]. Depression is not only a common, often chronic, and recurrent disorder, but it is cardinally associated with significant impairment in

work and daily social and psychological well-being[14]. As reported in the Medical Outcome Study (MOS) of the United States, patients with depression were found to function at a lower level and to have poorer well-being compared to patients with other chronic conditions[15].

This study arises from the fact that in India we found a limited study done on depression. The available research comes from community-based research, research studies on depression shows a considerable amount of people are suffering from depression. If we see community, in-depth study on the national level about the exact situation of depression person is lacking, Well-designed, population-based analytical studies on the causation of mental disorders lack in India. This study presents the prevalence of depression, sociodemographic associations, Quality of life and Treatment-seeking behaviors of people with depression.

OBJECTIVES

- To study the prevalence and possible factors of depression in India.
- To investigate the quality of life of co-morbidities of depression and to study the unmet need for treatment among depressed people.

DATA SOURCES AND METHODOLOGY

The present study utilizes secondary data from Study on Global Ageing and adult health (SAGE) wave 1 which is sponsored by WHO. The implementation of SAGE Wave 1 was from 2007 to 2010 in six countries over different regions of the world (China, Ghana, India, Mexico, Russian Federation and South Africa). In India, a multistage cluster sampling design was used. The SAGE India sample is nationally representative and is implemented in six states – Assam, Karnataka, Maharashtra, Rajasthan, Uttar Pradesh, and West Bengal. A systematic random sample selection process was undertaken for the SAGE that included all states in India. SAGE India gathered evidence on a selected range of chronic diseases that contribute to a large portion of the burden of non-communicable diseases more widely prevalent among older adults.

Depression: For diagnosis of depression respondents were asked whether they had ever been diagnosed with depression, and whether they had experienced symptoms of depression in the past 12 months. The diagnosis of depression derived from the reporting of symptoms was based on the International Classification of Diseases, 10th Edition, and Diagnostic Criteria for Research (ICD-10-DCR).

Unmet need: Unmet need refers to the percentage of respondents who had not received medication or treatment in the previous 12 months, despite being diagnosed with the condition.

Study instruments

Quality of life: Evaluative well-being, or quality of life (QoL), is defined as individuals' perception of their position in life in the context of their culture and value systems and in relation to their goals, expectations, standards and concerns (WHOQOL Group, 1994). The Quality of life is assessed by perceptions about sufficiency of energy and money for daily needs and satisfaction about oneself, health and ability to perform daily activities, personal relationships, and living conditions. In SAGE, QoL was assessed by asking respondents to rate their satisfaction with different domains of their lives on a 5-point scale, ranging from very satisfied to very dissatisfied, as well as rating their overall life satisfaction. A composite score was created by summing the responses across the different questions and rescaling the responses from 0-100, where a higher score indicated better quality of life.

Survey data were analyzed using SPSS.20 separate bivariate analysis and multivariate logistic regression analysis were carried out to using all relevant socioeconomic, demographic and risk factor variables, and significant variable ($p<0.05$) were considered in the multivariate logistic regression analysis. The dependent variable was binomial as no depression=0 and depression=1.

RESULTS AND DISCUSSION

Table 1 shows that 14 percentages of the overall prevalence of depression. Stigmatization of mental illness like depression results in higher percentage of symptom-based (12.4 per) depression than Self-reported prevalence (3.4 per)[16]. According to various literature found that one of the major factors that affect depression is the age with increasing age (18-29 year 6.4 per and 50+ year 28.1 per) depression increases. Currently

married and widowed/divorced/separated female are more likely to have depression. Another risk factor for depression in this study is educational status; illiterate people were more depressed (17.5 per) than people with higher education (11.8 per). People who had not completed primary schooling had the greater risk of depression. Our results show a marked dose–response relationship: increasing years of education provide increasing protection. Increases opportunity to access resources, and to develop protective social and cognitive skills, and reduced risk for mental distress.

Table 1: Prevalence (in percent) of depression (age18+) by background characteristics of India, SAGE, 2007

Background characteristics	India
Age Group	
18-29	6.1
30-39	13.2
40-49	16.5
50-59	20.6
60+	26.4
Sex	
Male	14.0
Female	15.2
Marital Status	
Never Married	5.3
Currently married	14.3
W/D/S	27.1
Place of Residence	
Urban	14.2
Rural	14.7
Education	
Illiterate	18.4
Primary	12.4
Secondary	12.4
Higher	10.5
Caste	
Scheduled Caste	8.5
Scheduled Tribe	14.7
Others	15.2
Religion	
Hindu	14.3
Muslim	18.2
Others	9.7
Employment	
currently working	13.7
currently not working	18.9
never worked	14.1
Wealth quintile	
Poorest	15.2
Poor	16.4
Middle	15.5
Higher	15.9
Highest	9.7
Risk factors	
Tobacco	
current daily	15.7
current, not daily	21.4
not current	27.6
never used	12.9
Alcohol	
Life time abstainer	14.6
Non-heavy drinkers	15.9
infrequent heavy drinkers	21.3
frequent heavy drinker	5.2
Physical Activity	
Vigorous activity	14.0
moderate activity	14.3
light activity	13.2
no activity	17.7
Total	14.6
cases	1866

This study shows a much greater risk of depression in poorest persons (12.5 per). A systematic literature review in LMIC shows depression to be strongly associated with socioeconomic deprivation[17]. WHO Commission on Social Determinants of health concept supports mediating pathways that link poverty with lack of access to economic power and political recognition[18]. Many Indian studies also suggest socioeconomic factors as the key determinants of depression[19].

Table 2 presents the logistic regression showing the effect of background variables on diabetes. The analysis shows that northeastern state Assam and southern developed states Karnataka western state Maharashtra has more likely to have depression than less developed northern states Rajasthan in both male and female. Age has the significant effect on depression, as age increases

there is more likely to have depression. Sex is not showing any significant effect on depression. It is more likely to have currently married and widowed/divorced/separated as compared to never married and found to be highly significant. Scheduled tribe and other categories are more likely to have depression than scheduled caste. Muslims are more likely to have depression than Hindu. Currently not working are more likely to have depression than those who are currently working. Middle and highest wealth quintile groups are less likely to have depression than the poorest wealth quintile group. As the level of wealth quintile increases, it is less likely to have diabetes. In case of alcohol Nonheavy drinker male and infrequent heavy drinkers are more likely to have depression than lifetime abstainer of alcohol. According to various literature risk factors of depression are alcohol and tobacco and their consumption increases the risk of depression than non-tobacco and non- alcohol consumer. Physical activity is associated with a range of health benefits, and its absence can produce harmful effects on health and wellbeing, which can increase the risk for various chronic diseases various studies shown the physical inactivity may lead to development of depression, but study not showing any significant effect of physical activity on depression.

Table 2: Odds Ratio showing the effect of Background variables on Depression: Results from Logistic Regression Analysis

Background characteristics	Total
States	
Assam®	
West Bengal	1.654***
Maharashtra	1.518**
Rajasthan	2.095***
Uttar Pradesh	4.392***
Karnataka	7.578***
Age Group	
18-29®	
30-39	1.922***
40-49	2.414***
50-59	2.808***
60+	3.447***
Sex	
Male®	
Female	0.907
Marital Status	
Never Married®	
Currently married	1.792**
Widowed/Divorced/Separated	2.852***
Place of Residence	
Urban®	
Rural	1.219**
Education	
Illiterate®	
Primary	0.976
Secondary	0.925
Higher Secondary	0.764**
Caste	
Scheduled Caste®	
Scheduled Tribe	1.357*
Others	1.430**
Religion	
Hindu®	
Muslim	1.404***
Others	0.96
Employment	
currently working®	
currently not working	1.268**
never worked	1.076
Wealth quintile	
Poorest®	
Poor	0.818**
Middle	0.833*
Higher	0.673***
Highest	0.536***
Risk factors	
Tobacco	
current daily®	
current, not daily	1.971***
not current	1.773***
never used	0.918
Alcohol	
Life time abstainer®	
Non-heavy drinkers	1.252*
infrequent heavy drinkers	1.694**
frequent heavy drinker	0.739
Physical Activity	
Vigorous activity®	
moderate activity	1.03

light activity	1.041
no activity	1.187
Total	0.023***

Note: ®: Reference Category, ***: 0.01 level of significance, **: 0.05 level of Significance, *: 0.1 level of significance

Table 3 shows the relationship between depression and non-communicable diseases. The relationship between depression and chronic diseases can be bidirectional. Depression can be associated with physiological and hormonal changes in the organism that increase the probabilities of acquiring certain chronic diseases, i.e. depression would be a risk exposure for the development of other chronic diseases[20]. This study found a degree of association between depression and other chronic diseases. From the bivariate analysis between depression and chronic conditions shows the more than half depressed person having each chronic disease. Diabetes is not associated with depressed persons whereas a person with chronic lung disease is more likely to get Depression. Also stroke, cataracts, angina, hypertension and arthritis are significantly associated with depression.

Table 3: Prevalence (in percent) of depression among chronic diseases by India, SAGE 2007

Non-communicable Diseases	India	
	Yes	No
Angina	37.5	13.9
Hypertension	28.3	13.2
Stroke	26.6	14.5
Diabetes	31.3	14.1
Arthritis	30.8	12.9
CLD	37.0	14.0
Cataracts	24.8	13.9

Table 4 presents mean WHOQoL by disease in India. If we see WHOQoL persons with any of the chronic diseases or depression has the low mean score as compare to those without any morbidity (68.5 per). Persons with hypertension diabetes angina stroke and cataracts and arthritis has mean score 62.6, 62.5, 61.6, 60.9, 60.2 and 59.2 per respectively. Persons with alone one disease has nearly same mean score in them depression (58.0 per) Chronic lung disease (57.6 per) has the lowest score among alone chronic diseases. WHOQoL score ranges from hypertension (62.6 per) to depression plus Chronic Lung Disease (52.3 per). Single chronic disease having high WHOQoL than a comorbid condition with depression. Mean score of Hypertension and diabetes is found to be more affected by comorbid condition. When single chronic disease combines with depression the mean score decreases. These results show that comorbid depression is significantly associated with lower mean score in persons with chronic conditions in comparison to having chronic conditions. Depression lowers the quality of life of people than other chronic diseases. The co-morbid condition of depression more worsens the quality of life than depression alone. Depression produces the greatest decrement in health compared with the chronic diseases. The comorbid nature of depression incrementally deteriorates the health of person as compared to alone depression and with any of the chronic diseases alone.

Table 4: Mean World Health Organization Quality of life (WHOQol) for depression and co-morbidities by India, SAGE, 2007

Non-communicable Diseases	India
No morbidity	68.5
Hypertension	62.6
Diabetes	62.5
Angina	61.6
Stroke	60.9
Cataracts	60.2
Arthritis	59.2
Depression & Angina	58.4
Depression	**58.0**
CLD	57.6
Depression & Hypertension	56.8
Depression & Cataracts	55.9
Depression & Diabetes	55.3
Depression & Arthritis	55.1
Depression & Stroke	54.8
Depression & CLD	52.3
Total	66.7

Table 5 shows the unmet need for depression and comorbidities. The highest unmet need found in persons having depression (72.5 per). The lowest unmet need was observed in the comorbid condition of depression plus

diabetes. Unmet need for the single chronic diseases is found to be high as compare to their comorbid condition. The condition gets worsen when depression combines with other chronic diseases which indicate that people are not taking treatment because of depression they taking treatment because of the worse health condition which is a result of depression a nd co-morbid disease. The highest gap between the unmet need for single and chronic disease found in chronic lung disease. Where in arthritis it is found to be increasing as it combines with depression.

Table 5: Unmet Need for depression and comorbidities of India, SAGE, 2007

Non-communicable Diseases	India
Depression	72.5
Stroke	66.0
CLD	50.5
Depression & Stroke	43.6
Depression & Arthritis	35.5
Hypertension	31.3
Angina	29.2
Asthma	28.1
Arthritis	24.5
Diabetes	23.4
Depression & Asthma	19.4
Depression & CLD	9.9
Depression & Angina	7.8
Depression & Hypertension	7.0
Depression & Diabetes	6.5

CONCLUSION

Prevalence of depression was 14 percent in India, and it is more common in a person with higher age, low educational level, poor, in currently married and widowed/divorced/separated. This study shows that higher percentage of people i.e. more than 70 percent are not aware that they are having depression and those who know about their disease in them very fewer people taking treatment, and it gets decreased as it co-morbid with other diseases. Depression produces the greatest decrement in health compared with the other chronic diseases. The comorbid nature of depression incrementally deteriorates the health of a person as compared to alone depression and with any of the chronic diseases alone. the results show the urgency of addressing the issue of depression as a public health priority to reduce burden and disability and to improve the overall health of the population.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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A Prospective Evaluation of 150 Individuals to Analyze the Cause and Effect Relationship of Morbid Obesity towards Certain Co-Morbidities

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ABSTRACT

Purpose: People are unable to find a cause and effect relationship between obesity and its co-morbidities. This paper attempts to evaluate perception of morbidly obese Indian patients towards obesity and related disorders.

Methods: Data of 150 obese patients undergoing Bariatric Surgery of which 57 were males and 93 females, with a mean pre and post op BMI 46± 17 and BMI 39± 16 was evaluated prospectively with a questionnaire to see presence of commonly seen obesity related co-morbidities like Type II Diabetes, Hypertension, etc as induced by Obesity.

Results: Outof 150 patients 100% patients had one or more multiple co-morbidities.In the present study the % of patients who correlated these co-morbidities with obesity as a cause was 20%, 40%, 100%, 7%, 10%, 10%, 0%, 60%, 65%, 0%, 0%, 100%, 60%, 10%, 5%, 0% out of 100% for Type II Diabetes, Hypertension, DOE, Snoring, Acanthosis, PCOD, Migraine, Depressive Symptoms, Lethargy, Urinary Incontinence, Hirsutism, Joint Pain, Oedama, Varicose Veins, Gynacomastia and GERD respectively.

Conclusion: Many co-morbidities related to Obesity like Acanthosis, PCOD, Migraine, Varicose Veins, Gynacomastia and GERD (<50%), were not perceived by patients as induced by obesity. Even Depressive Symptoms, Lethargy and Oedama did not have 100% correlation in the patient's perception. There is a huge scope for educating population and creating awareness.

Keywords: *Bariatric Surgery; co-morbidities; cause-effect relationship; Morbid Obesity*

INTRODUCTION

The WHO defines obesity as excessive accumulation of fat that may possess a risk to the health of a person[1]. The incidence of obesity as a disease is increasing in the world and it is estimated to affect a population of 3.3 billion adults by the end of 2030,which are 57.8% adults in the world[2]. This is becoming a severe public health challenge. And in developing countries like India, it is like a dual burden where the country has to fight against under nutrition and over nutrition at the same time[3]. In spite of 250 million people below poverty line it is crushing to know that India is now the third most obese country in the world after China and United States of America[4]. Obesity is now defined as a disease by many healthy organizations. It is known to bring with it an array of diseases which affect almost every system of the body. Obesity is known to give rise to multiple co-morbidities like Type II Diabetes Mellitus[5], Hypertension[6], Cardiovascular Diseases[6, 7], dyslipidemia[8], various cancers[9], etc. In spite of the severe impact obesity has on one's health it is not perceived as a disease by most and more over many of the co morbidities are not understood by people as obesity induced co-morbidities and hence it creates a challenge for treatment of obesity.

Considering the above facts, this paper attempts to evaluate perception of morbidly obese Indian patients towards obesity and related disorders. Such evaluation

may be able to throw light on future steps in approaching the prevention or treatment of obesity at large: for the patients, clinicians as well as the society. This seems to be the first such study in morbidly obese Indian patients.

MATERIALS AND METHODS

In the present study 150 morbidly obese patients undergoing primary bariatric surgery at one unit from June 2014 to August 2014 were selected and were enrolled in the study. A two-point Likert scale with Agree and Disagree as options was administered to these patients at baseline (pre operative) and at one year after surgery. They were prospectively interviewed for their perception on the cause and effect relationship of various co-morbidities to obesity. 109 patients underwent Sleeve Gastrectomy and 41 underwent Gastric bypass. The patients were evaluated using the scale on their understanding of Type II Diabetes, Hypertension, Breathlessness (DOE), Snoring, Black pigmentation (Acanthosis), Irregular Menses/PCOD, Migraines, Depressive Symptoms, Lethargy, Urinary Incontinence, Hirsutism, Joint Pain, Edema, Varicose Veins, Gynecomastia and GERD and its correlation to obesity. These were the most common co-morbidities seen in clinical practice and hence considered. All the questions were administered by a qualified psychologist who explained the disease or its symptoms before administering a particular question to the patient and once the patient had understood the co-morbidity they were asked to answer the questions with Agree or Disagree.

Patient's BMI was recorded at baseline and at one year. Male to Female ratio was 57:93 with a mean BMI of 46+/- 17 at baseline. After being enrolled in the study at baseline all patients were encouraged to participate in a monthly Support Group meetings and education seminars where they could witness results of other patients and be better educated about obesity, related co-morbidities as well as about Bariatric Surgery.

RESULTS

In the present study, the mean BMI dropped from 46±17 to 39±16 at one year post bariatric surgery.

In the study each patient had one or more of the co-morbidities. Graphical representation was used to show how many patients had different co-morbidities.

The following graph shows the number patients and co-morbidities they had.

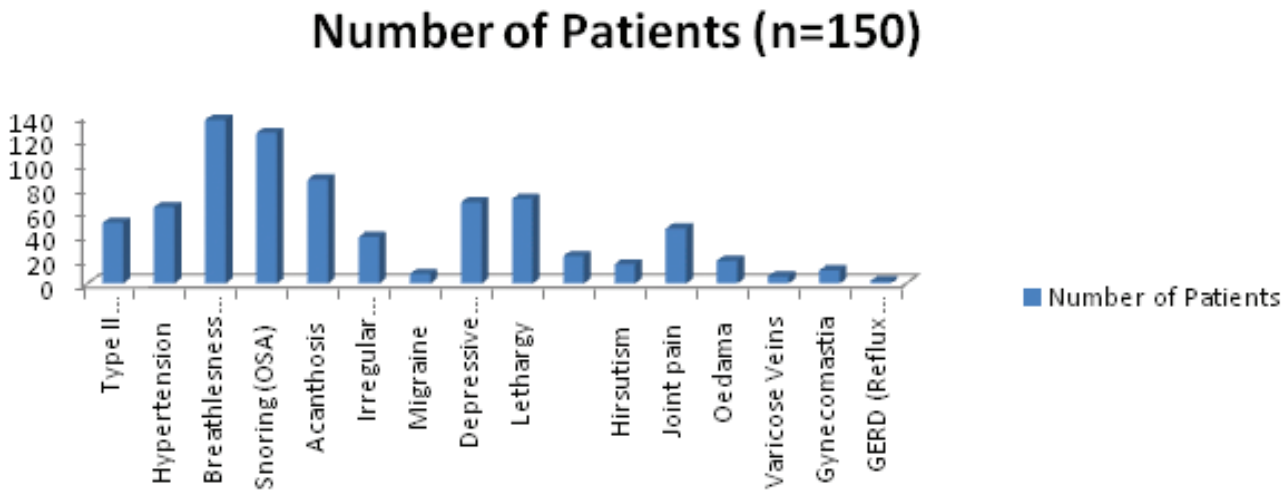


Figure 1: X-axis shows the co-morbidities commonly seen among patients and Y-axis shows the number of patients out of 150 who had one or more of these co-morbidities

The main aim of the study was to see the perception people had about obesity related co-morbidities and if they co-related these co-morbidities to obesity.

A table is used to show the co-morbidities that the patientshad the number of patients out of 150 who perceived that certain co-morbidity co-existed due obesity and the percentage of these patients.

Table 1: This table shows the number and percentage of patients who perceive certain co-morbidities occurring due to obesity at baseline (pre-operatively)

Co-morbidity	No. of patients (out of 150)	% of Patients
Breathlessness (DOE) and Joint Pain	150	100%
Depressive symptoms, Lethargy and Oedama	90	60%
Hypertension	60	40%
Type II Diabetes	30	20%
Black Pigmentation (Acanthosis)	15	10%
Snoring	11	7%
Irregular Menses (PCOD)	15	10%
Migraine, Unwanted Hair growth (Hirsutism) and Reflux Disease (GERD)	0	0%
Gynacomastia	8	5%
Varicose Veins	15	10%

Even though the main aim of the study was to see the co-relation that the patients made of the co-morbidities to obesity, as a part of the study we also studied the change in perception these patient had a one year as compared to baseline in the perception. A graphical representation was used to show this change in perception of the patients after they were psycho-educated about the disease of obesity and its related co-morbidities through support groups and educational seminars after undergoing bariatric surgery at one year.

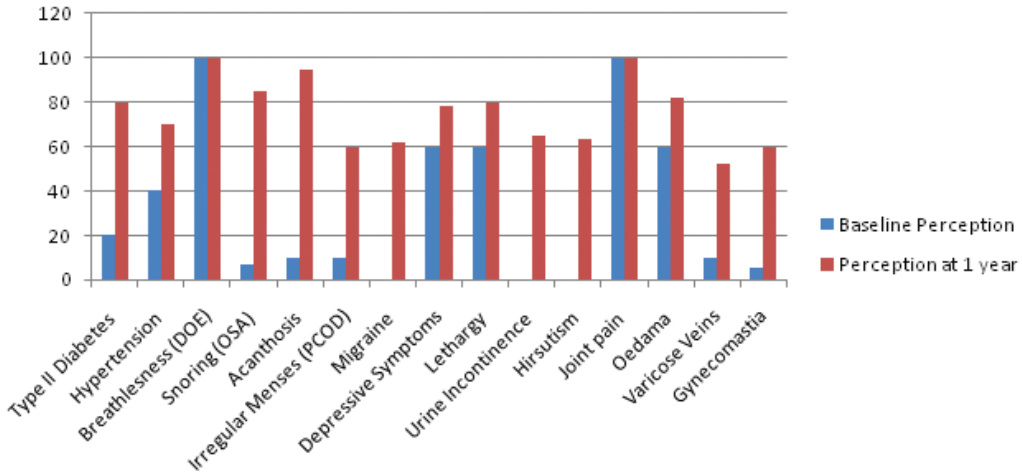


Figure 2: This graph shows the change in perception of the patients at baseline and at one year after surgery.

Even though co-morbidity resolution was not the primary aim of the study, we can see from the below table that the overall improvement in the co-morbidities was statistically significant at 0.02 at 95% level of significance. In the present study, statistical software SPSS 16.0was used to find the statistical significance with a paired sample t-test. Following are the tables showing the same:

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	VAR00001 & VAR00002	16	.719	.002

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	VAR00001 - VAR00002	-4.46875E1	26.60506	6.65126	-58.86434	-30.51066	-6.719	15	.000

Table 2: SPSS result table for statistical significance in improvement in co-morbidities.

Lastly, the in present study it was also seen that there was an improvement in the co-morbid conditions among the patients with resolution in the health problems at one-year post surgery. The table below shows the same.

Co-morbidity	No. of patients (out of 150) with co-morbid condition	No of Patients that showed resolution of the co-morbid condition
Type II Diabetes	51	41
Hypertension	64	40
Breathlessness (DOE)	137	106
Snoring	126	102
Black Pigmentation (Acanthosis)	87	38
Irregular Menses (PCOD)	39	31
Migraine	08	03
Depressive Symptoms	68	35
Lethargy	71	47
Urine Incontinence	23	11
Unwanted Hair growth (Hirsutism)	16	05
Joint Pain	46	24
Oedama	19	10
Gynacomastia	11	05
Varicose Veins	06	03
Reflux Disease (GERD)	02	01

Table 3: This table shows the co-morbidity and the number of patients who suffered from the co-morbidity at baseline and the resolution of the co-morbidity at 1 year post surgery.

There was a statistical significance in the two groups on the resolution of co-morbidities for the patients as compared to baseline. Data was analyzed using SPSS version 16.0 and the significance found was of 0.00 at 95% level of significance on a two-tailed test. Paired sample T-test was used to find the significant difference. Below is a table of the same:

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	VAR00003 & VAR00004	16	.967	.000

Table 4: SPSS result table for statistically significant difference in co-morbidities pre and post operatively

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	VAR00003 - VAR00004	1.70000E1	13.21615	3.30404	9.95761	24.04239	5.145	15	.000

These tables were inserted to understand if the presence of certain co-morbidity in the patient would affect their perception of the co-morbidity as arising out of obesity, which could be a further continuation of the study and another aspect which could be considered for future researches.

DISCUSSION

In the present study aimed at studying the perception of people towards obesity related co-morbidities and if they perceived certain commonly found co-morbidities of obesity to be occurring due to obesity. It was found in the study that a significant number of participants were unable to correlate the co-morbidities to obesity.

Type II Diabetes: According to a study done by Wild et al as many as 79.4 million Indians will be suffering from Diabetes Mellitus by the end of 2030[10]. 90% patients with Type II Diabetes Mellitus are known to be overweight or obese. Aggressive treatment for weight loss has always been a part of the treatment of Type II Diabetes Mellitus with the advice through dietary calorie restriction, however very few can achieve the same and maintain the weight loss in the long run. This leads to worsening of Type II Diabetes Mellitus and increased incidence of its complications. Various publications in the last two decades suggest that Bariatric Surgery can resolve or improve Type II Diabetes Mellitus, through weight loss as well as weight independent hormonal actions[11]. In 1995 Dr Walter Pories who quoted in his publication: Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus- with reference to results of Bariatric Surgery[12]. In the present study only 20% pts referred to obesity as one of the causative factors of Type II Diabetes, since a common man always thinks that it is an incurable disease of the pancreas. However witnessing the results of total remission of Type II Diabetes which means normalization of BSL without medications; their perception of relation of obesity and Type II Diabetes improved making them seek options for weight loss for treatment of their Type II Diabetes.

Hypertension: Research suggests that obesity is known to induce and aggravate Hypertension[13]. Weight loss with lifestyle change is known to improve Hypertension[14]. In the present study, 40% participants correlated obesity and hypertension at baseline. Hypertension was also thought to be a condition requiring lifelong medication by majority of the patients in the study. The patients were also unaware that weight loss after Bariatric Surgery would even resolve or reduce medications for hypertension. However at the end of one year 62.5% of patients could very comfortably appreciate the benefits of weight loss in improving hypertension.

Snoring and Lethargy: Majority of the patients in the present study (93%) perceived snoring as a habit or natural condition not requiring any significant treatment. Contrary to their concept snoring is known as a major respiratory disorder in morbidly obese individuals which may give rise to certain other co-morbidities[16]. Snoring is induced by a combination of low oxygen and high carbon dioxide during sleep and is known to affect deep sleep. Snoring can accelerate hypertension; heart disease and can induce lethargy or day time sleepiness which unfortunately is interpreted as laziness[16, 17]. In a paper published by New England Journal of Medicine by Yaggi et al demonstrated that snoring is a disorder called sleep apnea or obesity hypoventilation syndrome in morbidly obese persons and could prove to be fatal [18]. Various published papers have indicated that snoring and OSA (Obstructive Sleep Apnoea) as an indication for Bariatric Surgery since it is known to resolve snoring in the majority[19, 20]. Almost all patients in the present study appreciated rapid disappearance of snoring in a few weeks after surgery and appreciated that snoring is a sleep disorder induced by obesity and can be treated.

Acanthosis: Acanthosis is the black, hyper pigmentation of the skin usually found in the body folds especially in the neck, armpits, groin forehead and other areas, seen more commonly in age groups below 45 and also in patients with. Acanthosis signifies higher insulin levels in the blood stream and hence is one of the first warnings of a hormonal disorder of obesity[21]. However 100% of the patients in the present study were unaware of the above condition and were better educated at the end of the study.

Irregular Menses or PCOD: The Women Health Information Centre defines PCOS as a result of hormonal imbalance in the body. Weight gain and irregular menses could be the main symptoms[22]. Obesity and PCOS increase the risk of Diabetes Mellitus, Metabolic Syndrome and can affect reproductive functioning[23]. Only 10% pts in the study were aware of the above association and the understanding improved in 80% after interaction with pts suffering from PCOS and morbid obesity. Since incidence of morbid obesity and PCOS is on the rise there could be more focus on educating adolescents about prevention of obesity by lifestyle measures.

Migraine: It is a condition characterized by chronic or episodic headaches. Body Mass Index has a direct co relation with incidence and severity of headaches[24]. Obesity is known as an inflammatory disorder and studies suggest that neuro inflammation can induce migraine headaches. Migraine and BMI are known to be independent risk factors for CVD[25, 26]. In the present study it was unfortunate that none of the patients including those who were suffering from migraine co

related the two and hence did not seek any treatment for obesity as a treatment for migraine. Even family, friends (with a high BMI) of those who were suffering from migraine became ready for the treatment of migraine and obesity since headache was a very distressing symptom. 4 patients out of 8 in the present study suffering from Migraine had complete disappearance of headaches within a month of surgery which was also reported by a similar study done by Bond et al[27]. And it was maintained throughout the year. The study design itself could improve understanding of Migraine and morbid obesity in the present group. There is a rise leading to more scope for research in this field.

Urine Incontinence: It is characterized by leakage of urine on coughing or sneezing. Urine Incontinence, commonly seen in women is generally thought to be a purely urolological symptom most patients seek opinion form a gynecologist or urologist but never an obesity specialist. We found the same approach and interpretation of UI in the present study from all the patients.

In absence of an anatomical disorder of Urinary tract Urine Incontinence is caused by increase in intra abdominal pressure exerted by the fat inside the abdomen in morbidly obese women. It resolves in the majority after Bariatric Surgery[28, 29]. This association was well appreciated by majority of the patients since it gives complete relief from a socially distressing symptom which may affect psycho-social status of a lady. Bariatric Surgery is the best modality to treat Urinary Incontinence in morbidly obese women[30].

Gynecomastia: It is defined as proliferation of male breast tissue and is usually caused by increased estrogen activity and decreased testosterone due to obesity in a morbidly obese male[31]. It is mostly a benign condition but can induce sign anxiety or embarrassment. In spite of these 95% patients in the group were unaware that morbid obesity can reduce testosterone levels and can induce Gynecomastia[32]. Bariatric surgery is known to increase testosterone levels even though some patients may eventually need surgical correction for Gynecomastia[32]. The patients in the group learnt that if this association was known to a young male, their commitment towards treatment of obesity would be far more than otherwise.

Gastro Esophageal Reflux Disease (GERD): It is a condition where gastric contains and acid refluxes into the esophagus giving rise to burning in the chest and upper abdomen. Chronic GERD can induce esophageal cancer and hence needs attention[33]. The effect of weight gain examined in a study by Nilsson et al found that an increase in BMI of even 3.5 units there was a 3-fold increase in the risk of developing new reflux symptoms[34]. Bariatric Surgery has been suggested as a potential alternative treatment for GERD in those who are morbidly obese[35]. In the present study patients interpreted reflux (GERD) only as a condition of hyperacidity or stress and were unaware of the increased association with obesity. Obesity treatment in fact is an integral part of treatment of GERD and was better understood during the study.

Varicose Veins and Edema: It is a condition in which veins of the lower limb become unusually dilated or prominent giving rise to edema over feet, pain on walking, discoloration or an ulcer over the leg. Many obese people are unaware of this disease since the veins may not be seen because of the fat deposits till an ulcer is formed[36]. Obese patients are more prone for a clot in the deep veins, deep vein thrombosis, which is a potentially fatal condition[37]. Hence it needs attention. Majority of the patients in the group were unaware of the association and the risks associated. They felt better educated and appreciated the same being practically a life saving treatment for some.

Hirsutism: Hirsutism is commonly associated with PCOS and worsens with obesity due to hyperandrogenism (increase in male hormones) in women who are obese[38]. It induces lack of self esteem, affecting their psychological functioning[39]. Most of the times girls seek treatment for the same only from the cosmetologist and beauty clinics rather than a treatment for both PCOS and hirsutism. The entire group of participants in the present study was unaware of the association with obesity felt better educated at the end of the study and the perception drastically improved.

Depressive Symptoms: Various studies have shown a significant correlation to obesity and depression[40]. With a significant increase in the number of obese patients in the world there is going to be an increase in depression which will in turn affect and increase the burden of mental health. If there is no awareness among patients about the impact of obesity on mental health, like seen in the present study where only 60% of the

participants could correlate obesity and depression, it will only increase the burden of both the diseases. Much awareness and acceptance needs to be inculcated among people about both the sky-rocketing problems in order to treat and make people aware of the dual burden being created.

CONCLUSION

Obesity being a pandemic a lot of material is available and accessible in various media like print, digital publications as well as discussion among people. However it is ironical to note that in spite of all the resources and material available a vast majority of those who are suffering from these various obesity induced co morbidities are unfortunately, unable to link them to obesity as the main causative factor.This could be one of the challenges towards making people seek scientific treatment of obesity. To explain further it is frequently found that unlike any other diseases people seek treatment for obesity from non medical professionals. People even agree to attempt quack treatments advertised in media. This very much implies that they are unaware of the seriousness of the disease mainly because they do not correlate the serious chronic life threatening co morbidities as induced majorly by obesity.

This magnifies the scope of the study even on a wide scale to prevent obesity in the society or country. In the present study, it isinteresting to note that the perception of the same group of individuals changed drastically over a year, practically making them feel that they could have acted earlier. The importance of weight loss and its benefits was even appreciated by their relatives and friends seen as secondary observations during the study.

Morbid obesity is a disease giving rise to chronic, debilitating as well as life threatening conditions still needs better awareness. The sample size in the study is small compared to the magnitude of the overall incidence. But it can still provide leads to further and larger studies which eventually can help clinicians, government and other organizations working towards the treatment of obesity to understand and map a future path towards prevention of obesity as well as improve services offered for the prevention as well as treatment of these ailments. Better understanding of this subject would even improve reimbursement of treatments and resources directed towards obesity by a nation.

Role of a clinical psychologist in an obesity clinic is equally important since the patients do not correlate many comorbiditieswhich eventually have an impact on psychological status.We found that an interaction with a psychologist could make them express all comorbiditiesimpacting them. It was then for a psychologist to make them aware of the associations of all these to obesity. This may also suggest the need for a clinical psychologist trained in the field of obesity and Bariatric surgery as an integral part of every weight management unit to improve awareness as well as outcomes of treatment.

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Women's Education, Autonomy and Their Linkages with Contraception Use in India

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ABSTRACT

Fertility and use of contraception in developing countries have found to be linked with various markers of socioeconomic status, of which women's education is the most prominent, and it is also proposed that autonomy acts as a mediator link between literacy and contraception use. This study attempts to explore the relation between women's education and autonomy, which is taken through various dimensions with that of contraception use in India. For this study Indian Human Development Survey II, data has been used, in which married women aged 15-49 years was taken as a sample size (n=23,457.). Some socio-demographic variables were used to investigate the association between women's education, autonomy and use of contraception. It was observed that out of all the contraception methods sterilization is the most common method practiced and is seen high in 45-50 years' age group and women with no education. North-eastern states like Mizoram, Arunachal Pradesh, Assam, Tripura, and Nagaland are observed to be using modern contraception method which is unlikely in the northern states like Uttar Pradesh, Punjab where traditional methods are still in practice. Women's education was seen to have some association with the use of contraception, but when women's education combined with decision-making autonomy, physical movement freedom, and economic self-sufficiency, it did not show much significance. Women's dependence does not seem to have significance association with contraception use as that of women's level of education.

Keywords: *Contraception Use, Decision Making, Economic Autonomy, Movement Autonomy, Women's Education.*

INTRODUCTION

India is in that state of demographic transition that exhibits strong spatial differences. Both Fertility and mortality have been declining in the recent years, from different levels and at different speeds from state to state. The high fertility rate leads to the rapid growth of country's population which is a significant obstruction in the development of the nation and so a quick and substantial reduction in fertility in the low-resource setting is a highly desirable goal. With this in mind, India was the first country to launch a well-defined family planning program in (1951) with the primary objective to balance the population with the resources available. India's current demographic phase was characterized by high fertility rate and moderate mortality rates. India's population is growing rapidly with about 18 million people being integrated into it annually, to give a 2.1 percent increase per year.

The Family Planning program is an easy way of making family life more content, tuneful and prolific. At present, the family planning program is also known as Reproductive and Child Health Programme (RCH). International conference on population and development gave the definition of reproductive health as the state of mental, physical and social well-being in all matters related to the reproductive system (UNFPA,1994). These changes were made to enhance the acceptance of family planning methods. The acceptance of family planning methods varies between and within the societies. There are many factors such as socio-economic environment, culture, education, etc. which are responsible for such disparity at community, family and individual level. A study from Rajasthan showed (60.8) percent had knowledge of family planning method, but only 19 percent were using them and that too irregularly.

Comparative studies have indicated that increased female literacy is correlated strongly with a decline in fertility[1]. Studies have shown that female literacy levels are an independent and strong predictor of the use of contraception, even when women do not have economic independence[2].

In some parts of South Asia, and elsewhere, women have considerably low social status and autonomy as compared to men and women's low status and independence were seen to be correlated with low-level control of fertility. Several reports have shown a constructive association between women's autonomy and contraception use. Improving women's education has been one way to improve their social status and dependence, and it has also been proposed that autonomy acts as a mediator of the link between literacy and contraception practice[3]. A large body of research has established beyond doubt that education is a strong determinant of fertility hence one pathway which had been suggested by many authors is that schooling may tend to improve women's autonomy which ultimately leads to lower fertility. However, there are very few quantitative evidence in support of a strong fertility-depressing effect of a strengthening of women's position with that of men and its importance as a mediating factor between education and fertility has not convincingly established[4].

Education, autonomy and contraceptive use: The inverse relationship between women's education level and fertility is universally recognized. There is also a common assumption that education leads to autonomy as it helps women to stand up to their husbands and provide them a forum to learn about fertility control and make use of the health care system[5]. Dyson and Moore defined autonomy as the technical, social and psychological ability to obtain information and to use it as the base for making decisions about one's private concerns and close relations. Women's autonomy is a broad concept that covers many different aspects of women's situation related to men. It can be loosely defined as their rights and freedom to act as they choose relative to that of men.

Some studies do indeed report that a women's education may have an impact on her autonomy along with other individual factors and community norms and institutional structures[5]. It had found an independent positive effect on women education with women's economic and decision-making autonomy. On the other hand, there are also some studies that show no effects or opposite effects, such as relatively little freedom of movement among the better educated[6]. Basu in the year (1996) argues that on the whole, there is little evidence in support of the idea that a woman's education unambiguously leads to increase in her autonomy and suggests that the education-autonomy relationship is not primary mode through which schooling leads to fertility change. Others have found that women's independence plays a significant role in the education-fertility relationships. For e.g. differentials in women's autonomy explained much of the education effects on contraceptive use in a study from Bangladesh[7].

Hence, India provides a setting for such an investigation. There has been widespread concern about the country's high fertility for half a century, although the policy has shifted its focus on demographic targets in recent years. According to the census (2011), the nation's total fertility has just dropped down to 2.4 percent. However, there are significant regional and socio-economic variations. Some states still have total fertility level above three, whereas in other states fertility is below replacement level. There is indeed room for educational expansion. As education is one of the key roles in determining women's status and social development, a large number of the Indian population has not completed even primary education, which the constitution grants them as their right. Several studies have found little evidence of a positive relation between women's education and their autonomy. In this paper, we tried to attempt to address these issues using Indian Human Development Survey data (2012), and the aim is to assess the relationship between women's education, autonomy and use of contraception. The present study is based on secondary data analysis of an existing dataset, and the choice of dimensions of women's autonomy in the study is therefore restricted to what was available in the dataset.

METHODOLOGY

For this study, (IHDS-II) data has used. Indian Human Development Survey (IHDS) is a national representative, multi-topic survey of (41,554) households in (1503) villages and (971) urban areas across India. The first round was conducted in (2004-05) and the second in (2011-12) in that survey sample size has taken about (N=42, 152). These data are mostly re-interviewed of households interviewed for (IHDS-I) in the year (2004-05). And it has covered topics on health condition,

education level, economic and employment status, marital status, fecundity, gender relations, social capital, village structure, and panchayat composition. Children aged (8-11) years completed short reading, writing and arithmetic tests. This survey has included number of questions about women's rights and opportunities that are meant to capture various dimensions of their autonomy

Measurements: The demographic background features were used in this analysis which includes the respondent's age (which are currently married and aged 15-49 years), Place of residence, Years of schooling, Religion, Caste, Children surviving and husband's education. In the present study, only three dimensions were used out of several other measures of women's dominance. This includes participation in household decision making (Decision autonomy), Freedom of Movement (Physical autonomy) and economic self-sufficiency. However, decision autonomy index was based on four questions such as (what to cook, buy an expensive item, number of children, buying or selling land/property).

Decision autonomy was measured from four questions (e.g. decision on what to cook, while purchasing an expensive item, no of children to have, buying or selling the property). Cronbach's alpha coefficient was used to assess the reliability, and theCronbach's alpha for participation in decision-making was 0.73. The movement autonomy scale was also based on four questions on whether permission was required to go to the local health centre, to the home of relatives or friends, to the Kirana shop or to travel for short distance. The Cronbach's alpha of these four subs –questions was 0.75, suggesting high internal consistency. Likewise, economic autonomy scale was also calculated based on three questions (have cash in hand, name on bank account, name on ownership or rental papers for home) and the Cronbach's alpha coefficient was 0.81

An overall autonomy score, combining all the three dimensions, was also calculated. However, the correlation between the three individual scores (Decision making, physical movement, and economic autonomy) was relatively less (0.4), possibly because of combining three different dimensions of autonomy which would have diluted the effects of each scale and therefore the overall score was not used in the final analyses.

Table1: Percentage distribution of the independent variable in married women sample, India, using (IHDS-II, 2011-12)

Background characteristics	Use of any contraception	
	Percentage	Total
Age of the respondent		
15-25yrs	48.5	2,726
26-35yrs	74.8	9,097
36-45yrs	80.3	9,315
46-49yrs	74.4	2,319
Place of residence		
Rural	69.7	15,263
Urban	76.2	8,194
Level of education		
Not educated	71.4	8,483
Primary education	74.3	5,978
Secondary education	70.6	7,405
Graduation and above	70.4	1,589
Religion		
Hindu	72.9	19,543
Muslim	64.6	2,517
Other	72.5	1,397
Caste		
General	72.9	6,977
OBC	72	9,575
SC	72.6	5,040
ST	64.9	1,834
Children surviving		
No children	13.5	263
1 Child	55.6	2,857
2 Children	80.2	9,058
3 & above children	80.2	11,276
Husband's education		
Not educated	70.6	4,573
Primary education	73.2	6,219
Secondary education	71.8	9,967
Graduation and above	72.6	2,618
Total	74.5%	23,457

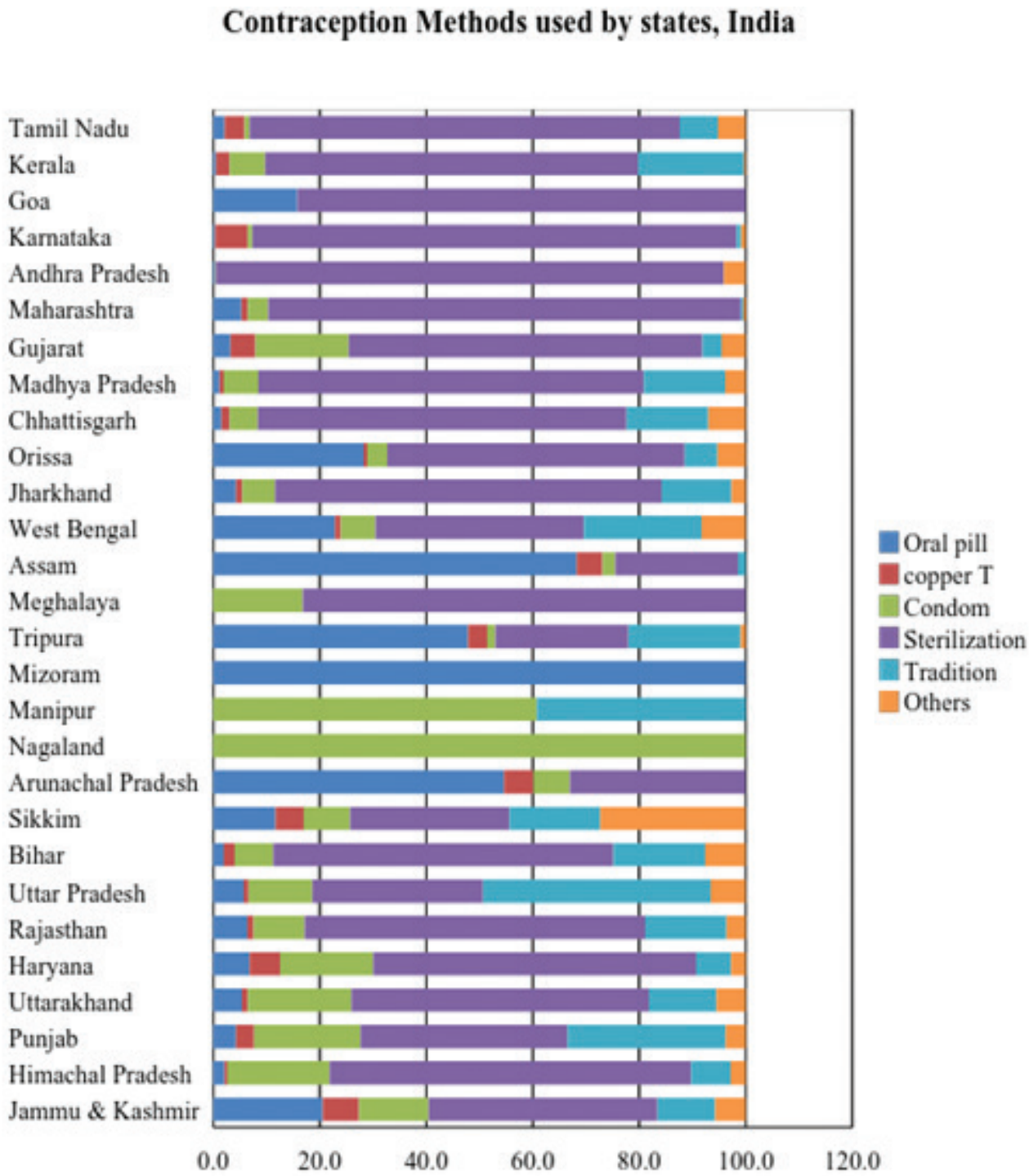

Contraception Methods used by states, India
Tamil Nadu
Kerala
Goa
Karnataka
Andhra Pradesh
Maharashtra
Gujarat
Madhya Pradesh
Chhattisgarh
Orissa
Jharkhand
West Bengal
Assam
Meghalaya
Tripura
Mizoram
Manipur
Nagaland
Arunachal Pradesh
Sikkim
Bihar
Uttar Pradesh
Rajasthan
Haryana
Uttarakhand
Punjab
Himachal Pradesh
Jammu & Kashmir
0.0
20.0
40.0
60.0
80.0
100.0
120.0
Oral pill
copper T
Condom
Sterilization
Tradition
Others

Table 2: Percent use of contraception by women's level of education and autonomy

Autonomy	Not educated	Primary education	Secondary education	Graduation & above
Decision making				
Less participation	71.0	74.5	70.7	69.5
High participation	73.1	74.2	70.9	73.9
Physical movement				
Less	74.3	76.5	72.2	71.9
More	72.1	75.1	72.4	72.3
Economic autonomy				
Low	73.7	74.0	67.4	64.9
more	76.4	78.4	76.1	72.9

Table 3: Odds ratio (95% confidence interval) of contraceptive use ever by socio-demographic variables, decision making, physical movement and economic autonomy

Contraception use	Odds ratio	[95% Conf. Interval]
Age of the respondent		
15-25yrs®		
26-35yrs	1.560***	(1.4-1.8)
36-45yrs	1.633***	(1.4-1.9)
46-49yrs	1.127*	(1-1.3)
Education status		
Not educated®		
Primary education	1.297***	(1.2-1.5)
Secondary education	1.256***	(1.1-1.4)
Graduation and above	1.404***	(1.2-1.7)
Religion		
Hindu®		
Muslim	0.513***	(0.5-0.6)
Other	0.685***	(0.6-0.8)
Caste		
General®		
OBC	0.973	(0.9-1.1)
SC	0.934	(0.8-1.1)
ST	0.721***	(0.6-0.8)
Children surviving		
No children®		
1 child	7.20***	(5.9-8.8)
2 children	22.21***	(18.1-27.3)
3 & more than three	25.84***	(20.9-32)
Husband's education		
No education®		
Primary education	1.119*	(1-1.3)
Secondary education	1.018	(0.9-1.2)
Graduation & above	0.9611	(0.8-1.2)
Participation in decision making		
Less participation in decision making®		
High participation in decision making	0.927**	(0.8-1)
Physical movement		
Low mobility®		
High mobility	0.952	(0.9-1)
Economic autonomy		
Low economically autonomous®		
High economically autonomous	1.029	(0.9-1.1)

Note-®:Referencecategory,*p<0.10;**p<0.05;***p<0.01.

RESULTS AND DISCUSSION

The various contraception methods used state wise. (See graph.1) It is seen that Sterilization (male/female) is the most common contraception method practiced in many states of India, but the prevalence was found maximum in Andhra Pradesh, Karnataka, Maharashtra, Goa, Tamil Nadu and so is the total fertility rate below replacement level in these states. The use of oral pill is observed high in most of the North-eastern states like Mizoram, Assam, Tripura and Arunachal Pradesh. The use of Copper-T is highest in Jammu and Kashmir, Haryana in the north Karnataka in south Sikkim, Arunachal Pradesh and Assam in the northeast. Moreover, the use of condoms is highest only in Nagaland and Manipur. States like Uttar Pradesh, Manipur, Punjab and West Bengal, are observed practicing traditional methods rather than using modern methods.

Descriptive statistics for married women sample for which some socio-economic variables thatare likely to be determinants or that may be spuriously linked with the use of contraception. Variables such as age, education religion and caste/tribe-membership are used. The urban/ rural nature of the place of residence is surely also, a strong determinant of contraception use and children surviving are taken. (See Table-1) It is observed that use of any contraception method increases in the higher age groups also the usage is slightly high in urban areas when compared to rural parts. The prevalence of contraception use is found to be more among uneducated, and it is low among Muslim women's and women belonging to ST as compared to other religion and caste. Contraception use increases as we go from women having no children to women having more than one or two children. With the increase in husband's level of education, the use of contraception is more or less the same.

It is found that the contraception use is slightly high among not educated women but are having strong participation in decision making on the contrary with an increase in education level and with more or less involvement in decision making the contraception use remains the same.(Table-2, which shows use of contraception by women's education level and autonomy) Also, the contraception use remains more or less the same among women who are educated or uneducated irrespective of their freedom of physical movement. In fact, the women who are uneducated and have less freedom of physical movement are more likely to use contraception than women who are educated and have more freedom of physical movement. When we move on to economic autonomy, it is observed that in the little financial independence setting with an increase in the level of education the use of contraception decreases. The uneducated with little economic independence women are more likely to use contraception than women with high education and low economic self-sufficiency. A reasonable explanation of this discrepancy pattern cannot be explained but at the same time it can be suggested that may be women with no education and with low autonomy may have opted for sterilization and so the increase in the use of contraception.

An inverse relationship has been observed between age and use of contraception as in the younger age there may be more demand for spacing and that with an increase in the level of education the use of contraception seems to be improving. (which can be seen in table-3 showing odds ratio) The Muslims women are less likely to use contraception as compared to women belonging to Hindu and other religions. The prevalence is low among Muslims women may be because of religious culture. Also, the women belonging to ST category are less likely to use contraception as compared to General, OBC, SC, and others. The ST Category women are the tribal people, and the less use of contraception may be because of the unmet need. The contraception use is more likely to increase among women with more number of children. As stated earlier sterilization is the most common practiced contraception method in India and women with more number of children who have attained the ideal family size seems to be opting for sterilization which accounts for increased use of contraception with increases in the number of children. The use of contraception is not highly significant, among the women with high participation in decision making. However, it showed no association with the women having more or less physical movement or high or low economic autonomy. From which it can be suggested that women's education has high significance with contraception use and on the contrary women's independence has no significance or no association with their contraception use.

DISCUSSION

In this secondary data analysis, it was observed that socio-demographic variables and women's autonomy was not significantly associated with contraception use and that autonomy did not show much association between women's education and contraception use. Literacy is relatively stable characteristic, unlikely to be affected by the Children surviving. Similarly, it is unlikely that dominance influences contraceptive use. The second probable limitation is the fact that we relied on secondary data in defining the autonomy variable. The dimension of women's status is composite8. With no consensus on definition and essential autonomy dimensions. Using only three dimensions, from some those that have been recommended9. Hence, the results confirmed the well-known effects of most aspects of the socio-economic environment on contraceptive use. The concentration of this analysis was on women's autonomy and contraception use, and by contrast, women's dominance which included participation in

decision making, Physical movement, and economic independence was not associated with contraception use. Finally, very few studies investigated the mediating effect of autonomy on education in individual level data, with contradictory results. While a study in Bangladesh, women's autonomy played a significant role7. The major analysis was done on Indian data; it found that autonomy did not intercede the link between education and use of contraception10. Even though the extraordinary women's independence is seen as required (although its significance may be different in various types of settings); however, the present study conclusions recommend that the influence of women's education on contraceptive use is self-determining of participation in decision making, also movement autonomy, and economic self-sufficiency.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Comparative Study of Nutritional Status of Preschool Children of Rural Area and Urban Slum

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ABSTRACT

Background: Malnutrition is a major public health problem in developing countries and in early stage of life affects growth and development of the child. The incidence and prevalence of malnutrition may differ among rural and urban population, due to a variety of factors.

Purpose: The present study aims to assess and compare anthropometric indices and dietary habits among preschool children in a rural area and in urban slum.

Research Design: A cross-sectional study was carried out to compare rural (n=40) and urban (n=40) children aged 2-5 years old from in and around Pune. Anthropometric indices weight-for-height (WHZ), weight-for-age (WAZ), height-for-age (HAZ) and mid-upper-arm circumferencewere used to estimate the children's nutritional status.

Results and Discussion: Prevalence of moderate wasting (WHZ<-2SD), severe stunting (HAZ<-3SD) and severe underweight (WAZ<-3SD) was higher in children from urban slums while prevalence of severe wasting (WHZ<-3SD) was similar in both the populations. Mid-upper-arm circumference (MUAC) revealed that 2.5 % children in urban slums were severely malnourished (MUAC< 115mm) which was not detected among rural children, more over percentage of children at risk of malnutrition was also found comparatively more in urban population. Dietary assessment revealed no difference in the consumption of cereals, legumes, bakery products in urban and rural populations but urban population consumed processed foods, sweets (chocolates/candies) and tea, in addition.

Research implications: The study would help to identify determinants for malnutritionand thereby appropriate measures to combat child malnutrition in rural as well as in urban set up.

Novelty: Present study investigated the extent of malnutrition and differences in food habits among children from rural and urban setting.

Keywords: *Nutrition status, Preschool children, Rural, Urban.*

INTRODUCTION

Preschool age is the most crucial stage wherein good nutrition is essential for the growth and development of a child. Growth of children is judged by nutritional status, which is influenced by their dietary intake[1]. India is home to 40 million stunted and 17 million wasted children[2].Continuous poor quality dietary intake is most commonly seen in children living in resource poor settings, resulting in low intake of micronutrients. This is the major cause of micronutrient deficiencies, notably vitamin A, iron, vitamin D and zinc, thereby resulting in improper overall growth and development of the child[3,4]. Further, poor dietary intake is the major contributing factor for malnutrition.Chronic malnutrition can impair cognitive development, memory and cause serious health impairments later in life that reduce the quality of life[5]. National Family Health Survey (NFHS-3) reported that almost 48% children under-five age are stunted and 43% are underweight. According to the Global Nutrition Report 2014, in India, between year 2006 to 2014 there was reduction in stunting rates from 48 % to 38 % among under-five age children, however child under nutrition rate is still high[6]. Thougha child's growth and health is directly influenced by diet,it is also greatly influenced by indirect determinants such as food

security, socio-economic status, environmental factors and available resources[7]. In a developing country like India, where poverty is still rampant, most of the poor rural households are landless and these people migrate to urban areas in search of jobs[8]. Due to rapid urbanization in rural areas, livelihood of the local population has changed drastically. These dynamics can also affect the dietary habits of the population in rural as well as urban areas thereby may influence the nutritional status of children. There are several programmes and policies in India to combat malnutrition, however, the utility and impact of these programmes varies across India. In order to develop effective strategies to combat malnutrition, there is aneed to generate data on the nutritional status of preschool children and their dietary habits in different geographical regions.This study aims to assess and compare the anthropometric indices and dietary habits of preschool children from rural area and urban slums in Pune.

MATERIALS & METHODS

A cross-sectional study was conducted from August 2016 to September 2016 in selected urban slums and rural areas located around Pune city. A total of 80 preschool children, i.e. (40) from rural and(40) from urban slumswere selected randomly. The data was collected by household survey wherein face-to-face interviewswere carried out with mothers after taking their informed consent. Socio demographic and other information was collected using a self-designed semi structured questionnaire.Socioeconomic index of study population was calculated by using Kuppuswami scale[9].

Anthropometric assessment: Anthropometric assessment is a widely accepted method to determine the nutritional status[10], we used this in our work. A trained researcher carried out anthropometric assessment. Measurementwas carried out in children with light clothes and without shoes. Body weight was measured with Tanita digital weighing scale Model HD 380 to the nearest 0.1kg, while height was measured with portable SECA Stadiometer Model 213 (SECA) to the nearest 0.1 cm. Mid upperarm circumference was measured with a flexible, non-elastic measuring tape Model 201 (SECA) tape to the nearest 0.1cm. MUAC was taken at midpoint between the acromion and the olecranon of child's non-dominant arm. All measurements were taken thrice and averages were calculated.

The nutritional status of children was determined by using three anthropometric indices such as height for age, weight for age and weight for height. These indices were expressed in Z score and these anthropometric indices were compared with cut off points given by WHO growth standards. As per WHO standards children whose height for age (HAZ) was below -2SD were considered as stunted and whose height for age (HAZ) was below -3SD were considered as severely stunted. Weight for height(WHZ) below -2SD was considered as wasted and weight for height (WHZ) below -3SD were considered severely wasted. Similarly children whose weight for age (WAZ)was below -2SD were considered as underweight and below -3SD were considered severely underweight11. Z scores for weight for age, height for age, and weight for height was determined by using WHO Anthro software version 1.0.3. MUAC cut offs 125 mm (12.5 cm) and 115 mm (11.5cm) was used to define moderate and severe acute malnutrition respectively[11].

Semi quantitative food frequency questionnaire was used to assess the dietary patterns of children by interviewing the mothers of children.The food items were grouped as cereals, pulses & legumes, poultry & meat, milk & milk products, vegetables, fruit, beverages, confectioneries & bakery products, and savory. Five frequency categories such asdaily, weekly, fortnightly, monthly and neverwere used.

Data was entered in MS excel sheet and analyzedusing SPSS software version 17.0. Descriptive statistics was expressed in percentages. Non-parametric tests Mann Whitney Test and Kruskal Wallis Testwere used for statistical analysis. P value of < 0.05 was considered statistically significant.

RESULTS

Majority of children from urban slums (67.5%) and (47.5%) children from rural areas belonged to upper lower socio-economic group. 17.5% children from urban slum belonged to lower socioeconomic class. Interestingly no one from rural areas belonged to this group. The total study population consisted of 57.75% boys and 42.5% girls. It has been found that more illiterate mothers were found inthe urban slums (20%) than in rural areas (17.5%). The study also observed that 60% families in urban slums were migrant. Almost

80% fathers from urban slums were engaged in unskilled occupations such as construction. (Table 1) illustrates the socio-demographic information of study population.

The magnitude of severe stunting (HAZ <-3SD) was significantly more in urban slums (27.5%) as compared to rural areas (18.5%), (P value = 0.03). Stunting among urban slum children was found significantly more in children belonging to lower socioeconomic group (P=0.0004). It was observed that stunting was significantly more amongst children of mothers who were illiterate or had only primary level education (P=0.003).Study also revealedthat prevalence of stunting was more among boys as compared to girls;however, this observation wasnot statisticallysignificant. Prevalence of severe underweight (WAZ<-3SD) amongst children belonging to migrant families was significantly higher (P value =0.009) in urban slums (22.5%) as compared to rural areas and it was also significantly more amongchildren belonging tolower socioeconomic status (P value= 0.0001). Prevalence of moderate wasting (WHZ<-2SD) was found more among urban slum children (20%) as compare to rural children. Prevalence of severe wasting (WHZ<-3SD) was found similar in both the populations. MUAC criteria revealed that 2.5% children in urban slums were severely malnourished (MUAC< 115mm) while this was not detected among rural children. The percentage of children at risk of malnutrition was also found to be comparatively more in urban population. Table II and III shows the nutritional status for the entire population.

Table I: Socio demographic characteristics of study population

Socio Demographic Correlates	Urban %	Rural %
Gender		
Female	37.5	47.5
Male	62.5	52.5
Education of Mother		
Illiterate	20	17.5
Primary	15	5
Middle School	57.5	57.5
High School	7.5	15
Graduate	0	5
Education of Father		
Illiterate	12.5	7
Primary	10	3
Middle School	60	52.5
High School	10	30
Graduate	7.5	7.5
Occupation of Father		
Skilled Worker	0	5
Semi-skilled worker	10	7.5
Unskilled	82.5	70
Unemployed	7.5	17.5
Socio-Economic Status		
Upper Middle Class	2.5	5
Lower Middle Class	15	47.5
Upper Lower Class	65	47.5
Lower Class	17.5	0

Table II: Comparison of Anthropometric Indices according to Geographic location

	Urban (%)	Rural (%)
HAZ Height For Age		
Severe Stunting	27.5	10
Moderate Stunting	37.5	35
Normal	35	55
Weight for Height- WHZ		
Severe Wasting	2.5	2.5
Moderate Wasting	20	7.5
Normal	77.5	90
Weight for Age-WAZ		
Severe Underweight	22.5	7.5
Moderate Underweight	25	30
Normal	52.5	62.5
MUAC Criteria		
Severe Malnutrition	2.5	0
Moderate Malnutrition	7.5	10
At Risk	37.5	27.5
Normal	52.5	62.5

Table III: Comparison of Anthropometric Indices according to Gender

	Male (%)	Female (%)
HAZ Height For Age		
Severe Stunting	15	3.75
Moderate Stunting	18.75	17.5
Normal	23.75	21.25

Weight for Height- WHZ		
Severe Wasting	1.25	1.25
Moderate Wasting	10	3.75
Normal	46.25	37.5
Weight for Age-WAZ		
Severe Underweight	8.75	6.25
Moderate Underweight	21.25	6.25
Normal	27.5	30
MUAC Criteria		
Severe Malnutrition	0	1.25
Moderate Malnutrition	5	3.75
At Risk	20	12.5
Normal	32.5	25

Fig.1 showsthe frequency of consumption of processed food and beverages among children from urban slums and rural areas. Dietary assessment revealedthat 45% children from urban slums consumedchocolates daily.The percentage of daily consumption of packaged foods like chips wasmore among children from urban slum. Percentage of children who consume biscuits daily was (40%) in rural and urban areas, 72.5% and 67.5% children from urban and rural area respectively consumed tea almost on a daily basis.

Figure 2. Shows the frequency of consumption of cereals, pulses, vegetables, fruits, milk and meat in urban slums and rural areas. Results show that there was no difference in the consumption of cereals among urban and rural population whilealmost more than 90% population consumed cereals daily as cereals form a part of the staple diet. Daily consumption of pulseswas found to be more among rural children (32.5 %) as compared to children from urban slums (27.5%). However, daily consumption of vegetables and fruits was very low among the total population; 32.5 % children from rural areas and urban slums never consumed fruits. There was not much difference in the percentage of children who consumed milk daily, moreover percentage of children who never consume milk is more among rural children as compared to children from urban slums. The study also found that weekly consumption of meat is more among urban slum children (57.5%) as compared to children from rural areas (47.5%).

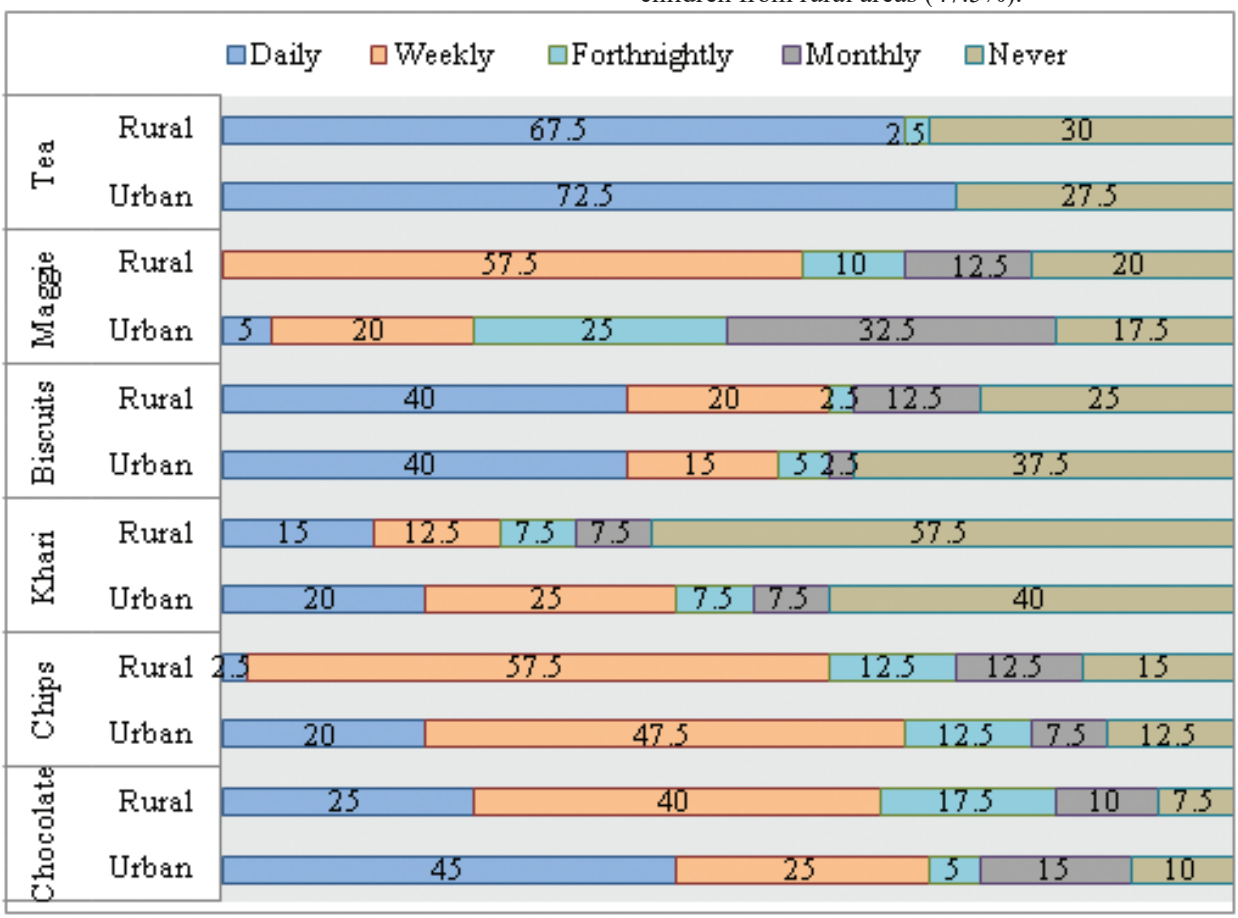


Fig. 1: Frequency of consumption (%) of processed foods and beverages among preschool children from urban slums and rural area.

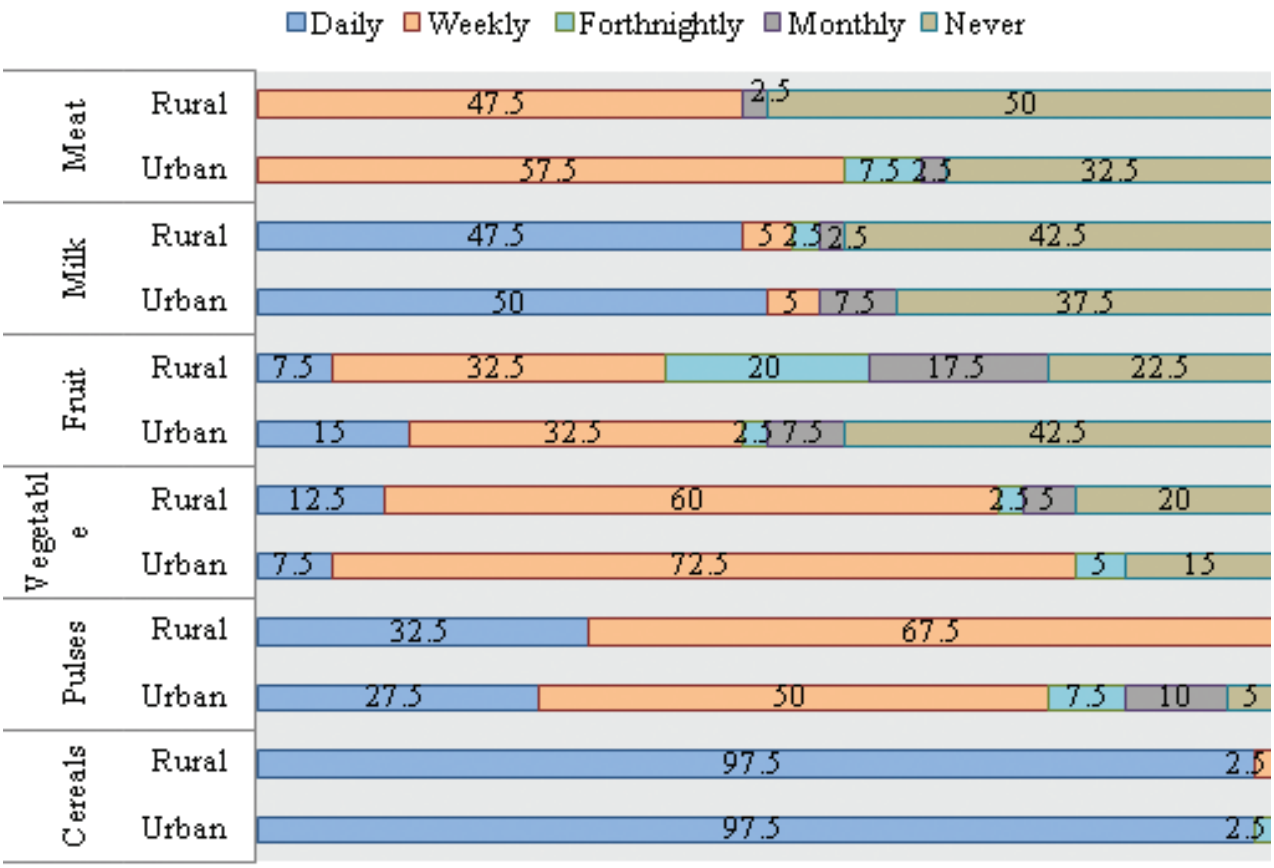


Fig. 2: Frequency of consumption (%) of cereals, pulses, vegetables, fruit, meat, milk in preschool children from urban slums & rural areas

DISCUSSION

According to NFHS 2015-16 reports for Maharashtra state, the prevalence of stunting among children below five years of age is 29.3% and 38.4% in urban and rural areas respectively[12]. These findings are consistent with another study conducted in central India, which reported 22% and 37% stunting in urban and rural area respectively[13]. However, the findings of the presentstudy are in contrast with the abovetwo studies and shows that the proportion of stunted children is more in urban slum (27.5%) as compared to rural area (10%). These findings are inline with the NFHS-3 2005-2006 fact sheet, which reported that 62.9% children from urban slum and 49.3% children from rural area were stunted[14]. A study conducted by Bentley et.al., in 2015 in Mumbai urban slums found that stunting was 56% among children < 5 five year old[15]. Stunting is seen to be more prevalent in urban slums;whichmay be because thecost of living in urban area is higher as compared to rural areas, resulting in lesser food buying capacity in urban areas. Moreover majority of urban population is migrantswho tend to be engaged in unskilled job which force them to live in food insecure situations (Varadharajan et al., 2013).

Weight-for-age (WAZ), which indicates acute and chronic malnutrition is considered as a composite index of height for age (HAZ) and weight for height (WHAZ)[5]. The current study finds 15% (8.75% boys and 6.25% girls) children of the total population were severely underweight. Similar studies also reported high prevalence of under nutrition among boys as compared to girls[16]. The exact reasonfor the above is not known, however, it is possible that this may be due to higher susceptibility of boys to environmental stress as compared to girls (Wamini et al., 2007). The present study reveals that the magnitude of moderate underweight is 30% and 25% among children from urban slum and rural area. These findings are consistent with the study conducted in Jabalpur[17].

A study conducted in Satara District showed that according to MUAC criteria, 3.2% girls & 6.3% boys were severely malnourished[18]. The present study however shows that, there is no severe malnutrition in boys and in case of girls only 1.3% have severe malnutrition. The present study also shows that while 57.5% of the child population is normal, 32.50% children are at risk and

1.3% children are severely affected. Another study in Bihar Singh and Mukherjee, 2015 however, reported that the rate of under nutrition among the preschool children from Bihar was comparatively much higher (24.9%) than the present study (1.3%), which was conducted in Pune[19]. Thesedata indicate a possible improvement in nutrition status in urban slums and rural areas in Pune when compared to other parts in the country.

With regards to WHZ, the NFHS 3, reported 6.8% and 8.3% severe wasting, and moderate wasting of 19.0% and 24.1% in urban and rural area respectively[5]. The present study reportssevere wasting in both urban and rural area to be 2.5%.As study conducted in West Bengal reported 2.7%severe wasting among preschool children and this result is similar to ours[20]. Moderate wasting in urban and rural areas is 20% and 7.5% respectively. The present study reports that overall prevalence of under nutrition is high in urban slums as compared to rural areas. The study finds that while there are no lower class families in rural areas, and the number of lower class families in urban slums is 17.5%. This can be one of the contributing factors to the high proportion of under nutrition in urban slums indicating that the economic status has a significant impact on the purchasing capacity of families.

The dietary assessment revealed that children from both regions predominantly consumed cereals and daily frequency of consumption of other food groups such as vegetables; fruits, pulses, milk and meat were found to be minimum. This may be because cereals are the staple food for all states and also the least expensive source of energy (Vecchio et al., 2014).Daily consumption of packed food items such as chips and chocolates was higher among children from urban slums. The study found that majority of preschool children from rural areas and urban slums consumed tea almost daily. A study conducted by Bentley et.al., in urban slums reported that children commonly consumed sugary snacks and salted snack foods, which, predisposes children to malnutrition and its associated deficiencies[15].

Mother's education and socioeconomic status are the key factors, whichhave animpact on the child's nutritional status. Anawarenessof child feeding practices and health seeking behavior of mother is very crucial for child development. Unfortunately sound child feeding practices as well as health seeking behavior is lacking in illiterate or poorly educated mothers which affects the nutritional status of children[21,22]. Mother's illiteracy could be one of the reasons for children's under nutrition as well as for children's indulgence in chocolates, processed food items and bakery products like biscuits. Employment of mother's may contribute to poor childcare and may result in poor dietary habits. This relationship needs to be further explored in the future research.

CONCLUSION

The present study concludes that despite the government's programmes to combat malnutrition, it is still widely prevalent in India. The data collected will help in identifying gaps in the existing programmes. The findings could contribute towards generating data on the required goals and targets to tailor made the current programmes. Therefore thiscalls for more effective strategies, which need to be better implemented to combat malnutrition. Nutrition education is fundamental in triggering changes in nutrition, cultural practices and diets over the long term, it is importantto increasethe public awareness of eating well for good health. In addition the study suggests the need to provide employment opportunities to migrants in order to enable them to sustain the economic challenges in urban areas.

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Effectiveness of Oral Health Education among Community Health Workers Based on Communication-Behavior Change Model

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ABSTRACT

The purpose of this study wasassess the effectiveness of health education based on Communication-behavior change model (McGuire, 1984) in improving the knowledge, attitude and practices of the ASHA and Anganwadi workers regarding oral health.

Methodology: A community randomized trial was conducted on ASHA and Anganwadi workers of Kaiwara and Chinnasandra, Primary health Centre based on Communication-behavior change model. They were provided with a self-administered questionnaire to assess knowledge, attitude and practices regarding oral health. This was followed by a 30 minute oral health education based on the Persuasive health message framework (Witte, 1995) using audio-visual aids. The ASHA and Anganwadi workers of Kaiwara PHC were randomly chosen to provide oral health information leaflet for reinforcement. After an interval of one month they were again given the questionnaires and the improvement in the knowledge, attitude and practices regarding oral health was assessed.

Results: 95 ASHA and Anganwadi workers participated in the study. The mean knowledge score before the intervention was 26.54 whereas after the intervention it increased to 29.77 and was statistically significant according to paired t-test.

Research implications: Community programs based on sound scientific models can be effective in bringing about behavior change in the community. The community health workers can be effectively used to reach the population who has limited access to dental services.

Keywords: *health education models, ASHA workers, Anganwadi workers*

INTRODUCTION

Effective public health, health education, health promotion, and chronic disease management programs help people maintain and improve health and reduce disease risks. They can improve the quality of life of individuals, families, organizations, and communities. Such a change requires behavior modification at many levels, (e.g., individual, community, policy). Not all health education programs are effective. Those most likely to achieve results are based on a clear understanding of targeted health behaviors, and the environmental context in which they occur. Practitioners and investigators use strategic planning models to develop and manage these programs, followed by meaningful evaluation. Health behavior theory can play a critical role throughout the program planning process[1].

The task of health education is to understand human behavior and to translate the knowledge acquired to bring about a change in attitude and practices of the population finally making a positive change in health behavior. Barriers to theory-led practice include the quantity of relevant theories, the nature of theoretical information, the way theory courses are taught, and the perspective on theory held by health education students and practitioners. The infrequency of theory-informed practice indicates that these barriers are sufficient to offset the potential benefits of such practice[1].

India is a country with majority of people living in rural areas. Following the Alma Ata declaration of 1978 on the appropriateness of "primary health care," rural health infrastructure has been designed to cover rural population through subcenters, primary health centers (PHC) and community health centers. As oral health is an integral component of general health, Oral health care of the necessity has to be delivered through primary health care infrastructure. Primary health care workers might play a key role in these areas where there is a deficiency of dental surgeons in providing oral health care services. (Nellore) Dental diseases in rural India are primarily due to socio-cultural factors, such as lack of knowledge about oral health and hygiene, inadequate or improper use of fluoride products, and systemic infrastructure deficiencies that prevent proper screening and dental care of oral diseases, especially in rural areas. 2 Ignorance about significance of oral health, lack of perceived needs, economic constraints, cultural and psychological barriers are few constraints to utilisation of dental services by the masses[2].

Hence a study was planned to assess the effectiveness of communication-behaviour change model to improve the knowledge, attitude and practices of the community health workers (ASHA and Anganwadi workers) regarding oral health.

MATERIALS AND METHODS

A community randomized trial was conducted to assess the effectiveness of oral health education based on Communication-behavior change model proposed by McGuire (1984) in improving knowledge, attitude and practices of community health workers of Kaiwara and Chinnsandra Primary Health Centers from April 2011 to July 2011. Ethical clearance was obtained from Institutional Review Board of M.S. Ramaiah Dental College and Hospital, Bengaluru prior to the start of the study. Permission was obtained from the Medical Officer of the respective Primary Health Centers. Informed consent was also obtained from the subjects to be a part of the study.

All the community health workers inKaiwara and Chinnasandra Primary Health Centre were included in the study. The community health workers who were absent on the day of the monthly meeting were excluded.

The study was conducted in two phases:

Phase I

Theoral health education module was based on Persuasive Health message framework proposed byWitte (2001) and included contents as in Table 1[3].

Table 1: Contents of the health message

1.	Human Biology	Anatomy of the tooth, types of dentition, functions of oral cavity and teeth
2.	Nutrition	Importance of nutrition in maintenance of oral health
3.	Diseases	Common diseases affecting oral health and the reasons for the same
4.	Treatments	The various treatment options available, the kind of treatment required based on the severity of the disease condition
5.	Prevention	Golden rules of dentistry, special emphasis on the prevention of early childhood caries (owing to the target group), demonstration of brushing technique.

A self-administered questionnaire was developed to assess the knowledge, attitude and practices of the community health workers. This tool had 18 items on the knowledge domain, 9 on attitude domain and 13 on oral hygiene practices domain. It was pre-tested and also underwent content validation by subject matter experts[4].

Phase II:

The study was planned and conducted based on the Communication-behavior change model proposed by McGuire (1984). The communication–persuasion model can be characterized as an input-output matrix that can be manipulated and measured to achieve a change[5].

Input factors

1. Source– A public health dentist
2. Message– based on the Persuasive health message framework
3. Channel– Type of media used was power-point presentation and information leaflets
4. Receiver– the community health workers (ASHA and Anganwadi workers) of Kaiwara and Chinnasandra
5. Destination– Immediacy/delay, prevention/ cessation

Output factors

1. Tuning in– Exposure to the health message in the Persuasive Health message framework
2. Attending– All the ASHA and Anganwadi workers who attended the monthly meeting were only considered
3. Liking– The ASHA and Anganwadi workers showed their Liking and interest by consenting for the study
4. Comprehending– ASHA and Anganwadi workers understood the message, if they had any doubts or did not understand a particular concept, they were allowed to ask clarifications at the end of the educational session
5. Generating– Related cognitions
6. Acquiring– The brushing technique was demonstrated to them and followed by individual demonstration by the community health workers
7. Agreeing– the ASHA and Anganwadi workers practiced the brushing technique also agreed on the information given to them
8. Storing– Message was saved to memory and this was assessed by checking it after 1 month
9. Retrieval– Retrieval of the message from memory was done in follow-up
10. Decision– Acting on the message was assessed based on the change in practices seen after 1 month
11. Acting– Performing the action
12. Post-action– Integration of the action into behavior
13. Converting– Being ASHA and Anganwadi workers, they serve the community and are in a position to advice others to behave likewise

The community health workers filled the KAP questionnaire prior to the intervention at baseline. Following which they were randomly divided into two groups. Flipping of coin was used to randomly divide them into two groups. One group which received the oral health education using the audio-visual aids and leaflets (Group I) and another group received only oral health education (Group II). Then the oral health education was delivered to the community health workers and oral health education leaflets were distributed to Group I. One month later the community health workers underwent the post-test. The time allotted to fill the questionnaire was 20minutes. (Figure 1)

Intervention–Oral Health Education: The oral health education was delivered using audio-visual aids. It was a 30 minutes' presentation which was followed discussion. The ASHA and Anganwadi workers of the Kaiwara PHC were randomly chosen (flipping of coin) to give the health education information leaflets for reinforcement. Wilcoxon Sign rank sum test was used to assess the difference between the two groups' pre and post-intervention and to assess the difference between the community health workers, pre and post-intervention.

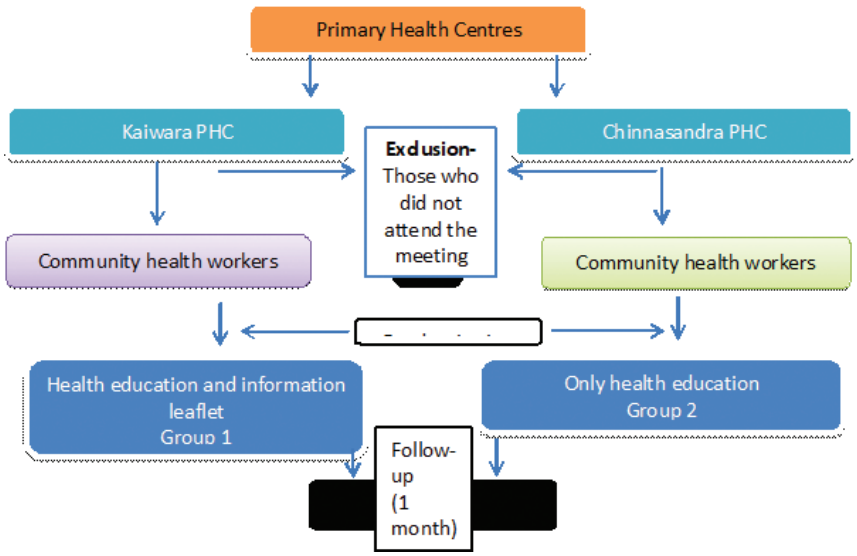


Figure 1- Flowchart depicting the community randomized trial

RESULTS

The community randomized trial included 95 community health workers, of which 62 were from the Kaiwara PHC and 33 from the Chinnasandra PHC. Of the 92 community health workers, 51 were Anganwadi workers and 44 were ASHA workers. The age-wise distribution of the study population shows that 42 (44.2%) of the community health workers were in the age group of 21-30 years, 43 (45.3%) were in 31-40 years, 7 (7.4%) were in 41-50 years and only 3 (3.2%) were 51-60 years. The educational level of the community health workers showed that only 1 (1.1%) was from secondary school, 72 (75.8%) had completed SSLC, 21 (22.1%) completed PUC and only 1 (1.1%) community health worker was a graduate.

18 questions were there in the knowledge domain, where it was observed that 100% of the respondents felt that the oral health is important for one's overall health, pre and post-intervention. Also it was observed that 40% of the community health workers considered that premature delivery can be a complication of gum diseases before the intervention, but after the intervention 80% were aware of this fact. Similarly, only 32.6% of the community health workers considered low birth weight babies can be a complication of gum diseases, before intervention but after that 71.6% were aware of it. 88% of them considered that they had got training in oral health after the intervention. 55.8% of the respondents considered that oral cancer shows early signs like white patch in the mouth and burning sensation before the intervention, but after that, 82.1% were aware of this fact.

In the attitude domain, there were 9 questions. It was observed that 92.6% would like to know more about dental health before the intervention and it increased to 97.9% after the intervention. 21.1% of the community health workers disagreed that dental problems affect the body as whole and this decreased to 5.3% after intervention. 98.9% of the ASHA and Anganwadi workers considered that they are a good medium to provide oral health education to the community after the intervention and 97.9% were ready to undergo oral health care training. 96.8% had an attitude that if adequately trained they are willing to educate people about oral health.

13 questions comprised the practice domain of the questionnaire. 91.6% of the community health workers used fluoridated toothpaste after the intervention. 10.5% of the community health workers brushed with horizontal technique before the intervention and after the intervention this reduced to 5.3%. 65.3% community health workers said they now visit a dentist if their gums bleed, also the number of community health workers reduced from 24.2% to 18.9% visit a dentist only in pain. The number of respondents visiting a dentist for regular check-up increased from 3.2% to 14.7%.

Wilcoxon Sign rank sum test was used to assess the difference between the two groups' pre and post-intervention. Knowledge showed statistically significant improvement but attitude and practice was not statistically significant. (Table 2)

Table 2: Comparison of the Knowledge, attitude and practices among the community health workers in the two PHCs

Village		Pre-test	Post-test	
Group I	Knowledge	26.24 (7.23)	30.06 (2.80)	0.000*
	Attitude	9.44 (2.95)	9.73 (1.36)	0.000*
	Practices	31.44 (5.711)	31.45 (4.58)	0.837*
Group II	Knowledge	25.18 (3.77)	29.21 (3.17)	0.000*
	Attitude	9.79 (0.85)	9.55 (0.83)	0.124*
	Practices	31.45 (4.58)	31.79 (4.14)	0.837*

*p<0.005-statistically significant (Wilcoxon Sign Rank test)

Wilcoxon Sign rank sum test was used to assess the difference between the community health workers, pre and post-intervention. Knowledge and attitude (Anganwadi workers) showed statistically significant improvement but attitude and practice was not statistically significant. (Table 3)

Table 3: Comparison of the Knowledge, attitude and practices among the ASHA and Anganwadi workers

		Pre-test	Post-test	
Anganwadi workers	Knowledge	24.55 (3.76)	29.27 (3.04)	0.000*
	Attitude	9.29 (2.75)	9.65 (1.49)	0.009*
	Practices	31.49 (3.84)	31.69 (4.01)	0.843*
ASHA workers	Knowledge	27.41 (8.02)	30.34 (2.75)	0.000*
	Attitude	9.86 (2.08)	9.68 (0.771)	0.771*
	Practices	31.39 (6.68)	31.25 (6.52)	0.876*

*p<0.005-statistically significant (Wilcoxon Sign Rank test)

DISCUSSION

Health promotion has become an important part of our efforts to improve health of the community. Goals of health promotion include the primary and secondary prevention of disease and health-compromising conditions. Behavioral and social science theories provides a platform for understanding why people behave in the way they do, and about their perceived health needs and behavior.

Theories do not identify an intervention to follow in particular. Instead they generate a series of ideas for a theory-led intervention to adopt. The purpose of theory is to enable the successful exchange of information and ideas between the investigator and the target audience (for example, the individual, group, population). Theory based health intervention allows practitioners to predict why the audience may not undertake a behavior no matter how much assistance or encouragement is available[5].

Rationale for using the communication-behavior change model: As per our literature search, the communication-behavior change model has not been used frequently in the dental faculty. The advantage of this model is that it has clear planning stages that can be followed in order to obtain an outcome.

Anadvantage of this module is that evaluation is included in the communication strategy as it is the part of the output factors. The model can also help practitioners to identify and consider channels and strategies that can influence the health outcomes. Given the emphasis on each stage, they can be examined for appropriateness and effectiveness[5].

This model has also been criticized for a number of reasons. These include having an overly restrictive number of steps in order for a behavior change to take place (Scholten 1996) – the Trans theoretical Model and the Process of Behavior Change have around half this number. McGuire (2001) himself considers that the matrix may restrict concentration on a single variable at a time, as they all interact with one another[5].

In our study, we used only one variable- oral health. Huhman (2004) suggested that as the audience processes a message, a percentage of this audience are lost at each step. Therefore, for this model to be effective high exposure, reinforcement and high awareness levels, are essential. The model lends itself therefore to more high-profile, high-level communication than smaller communication efforts[5].

Parle et al conducted a study using this model in cancer settings and saw that the preliminary results showed definite promise of this model in the communications research[6].

Rationale for using the Persuasive Health Message Framework: Although considerable laboratory research has shown that fear appeals (persuasive messages that arouse fear) motivate behavior change across a variety of behaviors, public health researchers and practitioners continue to contend that fear appeals backfire[3]. It is postulated that fear messages can influence health-related behavior under certain conditions such as when the health message is of high personal importance to the individual; if the individual is supplied with the alternatives; or if he or she feels in control or has the personal efficacy to change[7].

Hence the investigators decided to use the Persuasive health message framework to form an effective health message. This framework has shown to be effective in changing the attitude of the inner-city women when they were educated about smoking cessation. Participants reported a decrease in favorable attitudes toward smoking (P= 0.014) and an increase in cognitive change processes at follow-up (P = 0.037)[8].

Rationale for using community health workers as target population: The ASHA and Anganwadi workers have access to communities who can rarelyaccess dental services. According to the results of this study; they consider themselves to be an effective link between the dentists and the community. The target group they cater to is basically pregnant mothers, lactating mothers, women and children and hence the main focus will be primary prevention[9,10,11,12].

Literature has shown that Anganwadi workers have successfully embarked on different roles like providing information about breastfeeding and complementary feeding,identifying childhood disability and instituting immunization and supplementary nutrients,participating in rural newborn care programidentifying childhood blindnessand the study conducted in Chattisgarh has confirmed that after appropriate training they can be empowered to become an oral health guide[13]. An earlier study in Kerala they were found to conduct effective training in community oral health issues to mothers[9]. Raj et al.conducted a study to evaluate the impact of oral hygiene training package to Anganwadi workers on improving oral hygiene of preschool children and justified that the workers can be used for oral hygiene training[14].

ASHA could help government organizations, non-government organizations research investigators and private practitioners in bringing oral health to the grass root levels through various activities such as creating awareness on oral health, organizing oral checkups and outreach programs in addressing the oral health needs of the society. ASHA can disseminate information and knowledge through health education to strengthen the community's ability to deal with oral health problems. They may contribute to identify the most vulnerable group in the community in need of oral health services and can help improve access and utilization of primary care services thus preventing delayed dental care and emergency consultations. Improved knowledge about oral health in ASHA may play a key role in oral health promotion of the vast majority of the rural population[2].

CONCLUSION

It is no longer acceptable that health promotion campaigns are planned and implemented on an ad hoc basis and the application of theory to practice in interventions cannot be ignored. In order to promote health successfully and reduce ill health, investigators should use theoretical concepts to design all interventions for successful health promotion campaign[5].

In this study, it was observed that use of theoretical concepts made the health message effective and it had a better impact on the knowledge of the community health workers. But the attitude and practice of the community health workers did not change significantly, the reason for which could be related to lesser follow-up or requirement of more efficient reinforcement. Theory helps you ask the right questions, and effective planning lets you zero in on these elements in relation to a specific problem.

Theoretical models identify potential factors or leverage points that influence the decision that help change the behavior of the community even if it does not provide a full explanation of every factor in the behaviour change process. Critics of theoretical models should continue to debate not what is wrong with these models, but how they can be utilized or modified to bring about a positive change in the health behavior of the community or individual[5].

Although the results of this study look promising, it has certain limitations. The results are based on ASHA and Anganwadi workers of only one area. Recall period also has been relatively small. It would be imperative to study the knowledge retention of these participants after about a year. In addition, the ground reality about Anganwadi worker cannot be neglected. They are overloaded with excessive record maintenanceand are given inadequate reimbursement[15].Under these circumstances, training them to provide oral health education will be a challenging task. They need to be really motivated and provided with an incentive to create interest in undergoing the training session[13].

RECOMMENDATIONS

i. Incorporation of community health workers for the oral health education to the rural and disadvantaged communities'

ii. Integrate oral health and general health

iii. The use of health education models to improve the acceptance of oral hygiene practices.

Ethical clearance: No need

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Ayurvedic Ergonomics-Practical Solutions for Working Women in IT Sector

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ABSTRACT

Information technology is one of the fastest growing sectors of India. Women contributes a handy share of the growth. Working women at IT industry are at a herculean task of balancing work and family. Ayurvedic ergonomics can offer some practical solutions pertaining to daily routine food and sleep, which may help the women to remain healthy and deliver the maximum of potential wherever needed.

Keywords: *Ayurveda, Ergonomics, Women, Software sector*

INTRODUCTION

Information Technology sector has its inherent spill over benefit of creating employment potential for a large pool of educated unemployed youths including an attractive option for the women. The industry has now captured about 51 per cent of the world market women constitute 24 percent of total IT work force which is higher than participation in National economy as a whole[1]. Women in IT sectors have to meet up the tough demands of job along with balancing the home.

ERGONOMICS AND ROLE OF AYURVEDA

The success of any industry depends upon the quality of workers. Of the determinants of quality, the health of employees is as important as education skill and experience. the concept of occupational health acquires its relevance in this context. Ergonomics is a much-focused concept which attempt to make the worker fit to the job. In other words it is an art of designing the work to fit the worker. An ideal working environment is designed as per the work and the working condition.

Ayurvedic thought of ergonomics is a bit different. It is not always possible to bring an absolute change in working conditions. The science emphasizes on moulding the endurance of an employee to adapt to the work. Adhering to the basic principles of Ayurveda one can accomplish these motives through a series of health promoting practices[2]. The key intervening areas are

- Dinacharya-to create a healthy daily routine
- Ritucharya- to prevent undesirable bodily changes owing to seasonal variations
- Ahara-minimise the harmful effect of improper food habits by following the rules of dietetics in Ayurveda
- Vega Dharana: Avoiding deliberate suppression on natural urges
- Sadvritta: Following ethical code of conduct

Women and It Sector: Women employees in software sector have to fulfil multiple responsibilities as a professional and as homemaker. The target and performance based works imparts more stress while the busy schedule at home adds up to the physical and mental labour. Recent researches identifies an array of health issues-low back ache, stress induced ailments and eye problems are some of[3]. This paper attempts to analyse the difficulties faced by working women through the angle of Ayurveda Ergonomics.

METHODOLOGY

In order to have a clear understanding about the domains in which the general health of working women can be improved, an observational pilot study was conducted in 50 women working in different IT firms of south India. A questionnaire was prepared with important areas as daily routine, food habits, information regarding natural urges and work-home balance. Sampling method was convenient sampling.

RESULTS

1. **Age:** 46% of the responders were in age group of 25-30 years.40% were belonged to the age group of 30-35 and rest were of the age between 35 and 40.

Table 1: age range

Range	Number
25-30	23
30-35	20
35-40	7

2. **Work experience:** Half of the participants had a work experience between 5-10 years. 42% had an experience up to 5 years. 9% of the participants had experience more than 10 years.

Table 2: Work experience

Duration(years)	Number
0-5	21
5-10	25
10-15	4

3. **Shifts:** 44% had a night shift of their job and rest of them having only day shift.

Table 3: Shift

Type of Shift	Number
Only day shift	28
Day and night shift	22

4. **Working time:** 40% of the responders have a working time of up to 10hours, 48% work up to 12 hours and 12% work up to 14 hours.

Table 4: Working Time

Average working time	Number
8-10 hours	20
10-12 hours	24
12-14 hours	6

5. **Bowel Habits:** 14% of the responders presented with irregular constipated bowel.16% have an irregular loose bowel and 56% have a regular but constipated bowel.

Table 5: Bowel Habits

Bowel	Number
Regular loose	12
Irregular loose	8
Regular constipated	23
Irregular constipated	7

6. **Skipping of breakfast:**

Table 6: Skipping of Breakfast

Response	Number
Always	4
Often	19
No	27

7. **Intake of water:** 40% of the responders usually drink up to 4 glasses while 25% drank about 12 glasses of water

Table 7: Quantity of Water Intake

Quantity (Glasses)	Number
0-4	20
4-8	18
8-12	12

8. **Common eating place:** Majority of the participants had food prepared at home, while others preferred office canteen and other places like hotels and cafeteria

Table 8: Eating Place

Place	Number
From home	23
Office canteen	20
Others	07

9. **Exercise:** 58% of the responders do not had any regular exercise.

Table 9: Exercise

Regular exercise	Number
Yes	11
No	39

10. Routine after night shift: 24% followed a series of Bath-Eat-Sleep after the night shift while 22% followed Sleep Bath Eat series. 20% followed Sleep Bath Eat Format.

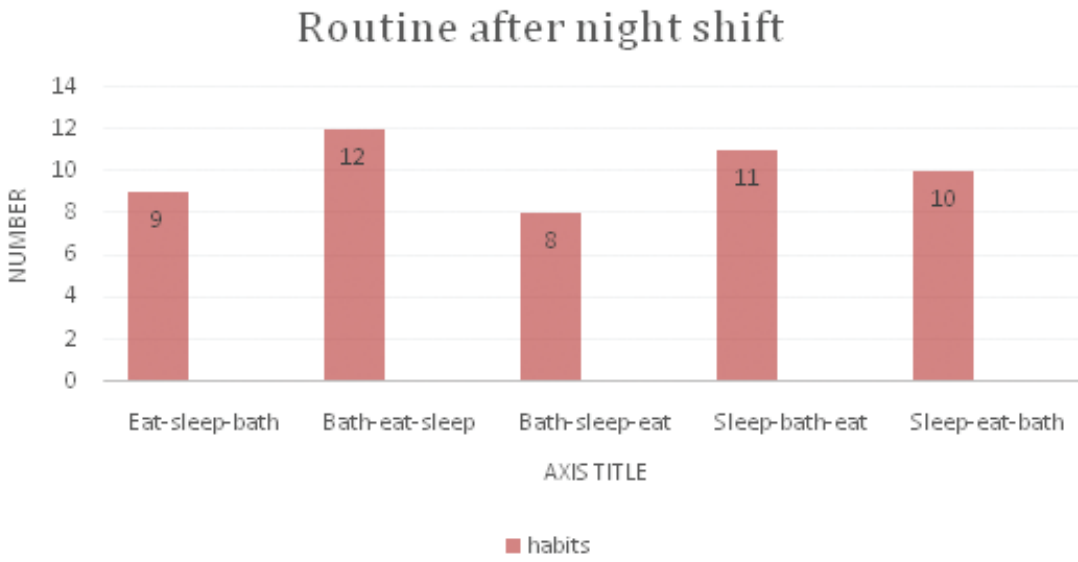


Figure 1: Routine after night shifts

11. Problems associated with menstruation: In the following survey only 16% were devoid of any king of menstrual problems others were suffering from cramps, mood swings, irregular menstruation, scanty menstruation and heavy bleeding

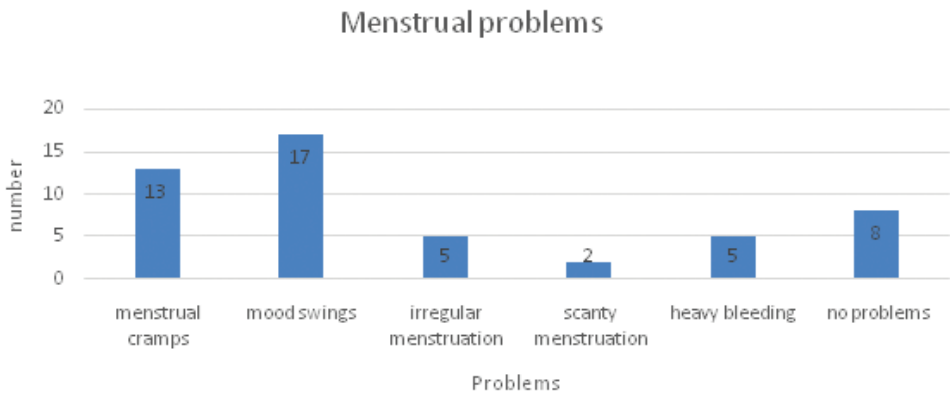


Figure 2: Distribution of menstrual problems

12. Suppression of urges: Defecation, urination, thirst and hunger are the most supressed natural urges, following are their pattern.

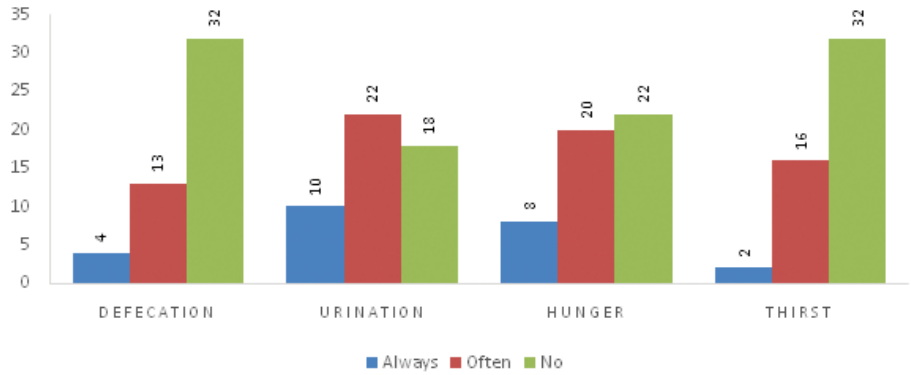


Figure 3: Distribution according to suppression of urges

13. **Balance between work and home:** Majority of the women found it difficult to balance between work and home

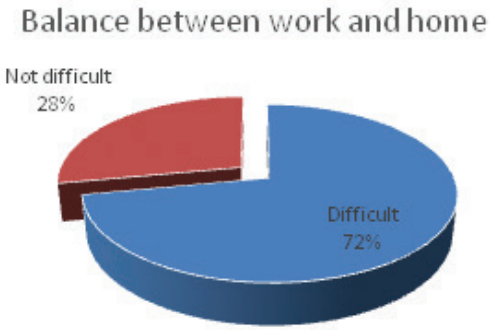


Figure 4: Balance between work and home

14. **Stress at office–losing temper and getting stressed out:** Most of the participants either always or often got stressed out easily

Table 11: Stress frequency

Response	Number
Always	16
Often	22
Rarely	12

From the above data is clear that positive interventions on food, daily routine and sleep can have a productive role in improving the health of women employees.

DISCUSSION

Proposal of an Ayurvedic Ergonomics model: The results of the observational study imply that a notable percentage of the employees are not following a healthy food sleep and daily routine. Job stress is an undeniable factor. Elimination of stress is not possible. Rather, enabling the individual to cope up with the stress is ideal. The elements of Ayurveda Ergonomics model can be subdivided as

1. **Daily routines**

   (a) **Wake up time:** Those who are managing the morning shift can rearrange the sleep-rise time 10 pm to 5 am. Ayurveda advises to wake up on Brahma muhurta-the auspicious time because of the natural action of the Vata, mind will be sharp ad attentive at that time[4,5].

   (b) **Analyse the body:** A quick analysis of one's body after wake up will increase the awareness[6]

   (c) **Bowel habit:** Majority of the participants in the survey had a regularly or irregularly constipated bowel. 34% of the participants supress the urge of defecation which may lead to muscle cramps recurrent headaches heaviness on chest.[7] Apana Vata has the function of regulating the micturition, urination and menstrual flow. Suppression of these functions leads to vitiation of Vata.

   Nasal instillation: Instillation of two drops of *anutaila* (a medicated sesame oil) daily in the morning will help to sharpen the eyes nose and ears, prevents premature greying and helps in preventing headaches[7].

   (d) **Gargling with Sesame oil:** Gargling or *gandusha* done with sesame oil increases the oral hygiene and contribute to gum and teeth health[10]

   (e) **Anjana-Collyrium:** Application of anjana help to sharpen the eyesight clears out the path of lacrimation[6]. Instead of using the artificial kajals, anjana prepared anjana (Vernonia cinerea and ghee) can be opted, which is cost effective, easy to prepare and healthy to the eyes

2. **Food:** It is not the quality of food alone that matters. The time, place ,amount along with the dietic conduct has a crucial role to play. 38% of the participants often skip their breakfast. Morning is one of the important food timing (*ahara kala*) as per Ayurveda. The quick alternatives like milk, banana, and sprouts can be consumed rather than skipping the breakfast. Hunger is also considered as a natural urge, the deprival of which may lead to severe systemic illness. Many a times a lot of water is taken in order to supress hunger. This in long run, is described as the one of the causes of ascites or Udara[12]

3. **Sleep:** 56% of the participants have disturbed sleep and of them, 20% are on medication to get the proper sleep. The sleep disturbance is more on the workers who are usually into night shifts, Night shift work may disrupt the normal nocturnal rise in melatonin, so could be an important risk factor to many cancers including breast cancer. Sleep deprivation may increase the mortality[6]. Sleep restrictions may alter metabolic and endocrine functions may lead to robust decline in immunity. So, proper sleep thus plays a crucial role in maintaining the health.

   There are many easy methods which will help to induce sleep. *Abhyanga* or massage helps to

pacify the Vata dosha, so that the total body get relaxed[13]. Some musical notations like neelambari and syama will relax the body and induce the sleep. Music therapy has proved beneficial in sleep disturbances.[14] Pranayama like nadisuddhi and chandranuloma improves sleep quality, fatigue and quality of life. Sleeping immediately after eating impairs digestive fire. A bath naturally increases digestive fire. So, the ideal regimen would be Bath, Sleep, Eat or Sleep, Bath and Eat.

The following regimens would be helpful

Table 12: Sleep Regimens

Procedure	Average time
Head and Feet massage	3 minutes
Oil massage	2 minutes
Cold water shower	5-10 minutes
Music	5-10 minutes
Pranayama	5-10 minutes
Chanting AA UU MM	5 minutes
Deep relaxation technique	10 minutes

CONCL0USION

Software industry is a sector which demands brainwork and creativity at its peak. One must have a sharp mind and supporting body to make the productivity reach a cent percent. Working women have to handle the pressure of home and work at the same time. This makes their body vulnerable to many weaknesses, which in turn may affect the mind.

Ayurvedic concept of Ergonomics is not just designing the work to fit the worker. It emphasizes on moulding the workers' endurance to adapt to the work in a healthy manner.

Altered daily routine, food habits sleep pattern and stress has been identifying as major risk factors for non-communicable diseases. The Ayurvedic intervention therefore focus on imparting mediated daily routine, healthy food, quality sleep and corrective measures for mental and social health, which can alter the health and quality of work of an individual. The concept of Ayurvedic ergonomics opens up a new dimension of compactible workers to any job.

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Effect of Pre-Treatment Bacillary Load on Treatment Outcome of New Pulmonary Tuberculosis Patients Receiving DOTS under Revised National Tuberculosis Control Programme

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ABSTRACT

Introduction: Under DOTS strategy, a high pre-treatment bacillary load may appear to be an important predictor for poor treatment outcome.

Purpose: To find out the treatment outcome of new smear positive pulmonary tuberculosis patients with various grades of sputum smear positivity

Materials & methods: A retrospective record based cohort study conducted among all new smear positive pulmonary tuberculosis patients registered during period of 1st January 2015 to 31st December 2015 in a TU of Pune. Smear positive patients under study was divided into two groups as per grading of sputum AFB: Group I High bacillary cohort (sputum 3+) and Group II Low bacillary cohort (sputum 1+ and 2+ combined).

Results: Sputum conversion rate at the end of 2 months' intensive phase and at the end of 3 months was significantly low in Group I as compared to Group II ($p<0.001$). Non adherence to treatment was significantly more among Group I in intensive as well as in continuation phase as compared to Group II ($p<0.001$). Unfavourable outcome was seen in 10(16.1%) and 7(2.8%) among Group I and Group II respectively ($p<0.01$). Odds ratio of unfavourable outcome was 6.62 (CI- 2.40-18.2) among Group I as compared to Group II.

Conclusion: From practical point of view, it would appear that grading of sputum need not be an academic exercise but instead help pinpoint a group of patients who are likely to have unfavourable outcome oftener than others and these patients need to be closely supervised.

Keywords: *DOTS, Pre-treatment bacillary load, Treatment outcome, Predictor*

INTRODUCTION

Under Revised National Tuberculosis Programme, all new smear positive pulmonary tuberculosis patients are given the same treatment regimen with same number of drugs and dosages, irrespective of bacillary load[1]. The absence of sputum conversion at two months is directly related to the initial bacillary load[2,3]. Absence of sputum conversion at two to three months of treatment has been found to be one of the strongest predictor for poor treatment outcome in various studies[4].

Rationale: Even under DOTS strategy, a high pre-treatment bacillary load may appear to be an important predictor for poor treatment outcome[1]. Where limited culture and drug sensitivity facilities are available, two and three month sputum microscopy is the critical discriminator of 'high' and 'low' risk patients for treatment failure[2]. Early identification of patients who have an increased risk of a poor outcome coupled with an intervention such as treatment modification could potentially reduce this burden. The present study was planned to know the effect of pre-treatment bacillary load on the treatment outcome of newly diagnosed sputum smear positive pulmonary tuberculosis patients with various grades of sputum smear positivity being treated with intermittent short course chemotherapy under direct observation based on WHO guidelines.

OBJECTIVES

1. To determine sputum conversion rate at 2nd and 3rd month in new smear positive pulmonary tuberculosis patients with various grades of sputum smear positivity
2. To find out the treatment outcome of new smear positive pulmonary tuberculosis patients with various grades of sputum smear positivity

METHODOLOGY

This was an observational Retrospective cohort study planned to be conducted among all new smear positive pulmonary tuberculosis patients who were registered in a Tuberculosis Unit of Pune corporation, Pune selected randomly by lottery method during the period of 1st January 2015 to 31st December 2015. A list of participants during specified period was obtained from Tuberculosis Register (TB Register) maintained at the Tuberculosis Unit. The Treatment cards of all these patients were filled and kept at the Tuberculosis Unit, were collected for study purpose. Information about their name, age, sex, address, initial sputum smear result, treatment category, date of start of treatment, co-morbidities, no. of missed doses, reasons for non-adherence, addictions, details of other investigations, sputum smear result during and at the end of their treatment and outcome was collected from the tuberculosis register and treatment cards maintained at the TU. Sputum smears were examined for Acid Fast Bacilli (AFB) by Ziehl-Neelsen staining method. The sputum smear results were graded as 1+, 2+ and 3+, scanty and negative as per National guidelines5. Smear positive patients under study were divided into two groups as per grading of sputum AFB: Group I High bacillary cohort i.e. exposed cohort (sputum 3+) and Group II Low bacillary cohort (sputum 1+ and 2+ combined) i.e. unexposed cohort.

The revised definitions given by WHO were used in this study to define the cases and treatment outcomes[6].

Sample Size: The parameter used to calculate sample size is the proportion of cure rate in exposed group (sputum 3+) and unexposed (sputum 1+ and 2+) which was 76.6% and 85.1% respectively according to a previous study[1].

The sample size was then calculated with following considerations[7]:

P1 = 76.6% (Exposed)

P2= 85.1% (Unexposed)

Confidence level = 95%

Absolute Precision = 14%

Ratio of exposed: ratio of unexposed = 1:4

Minimum sample size on each arm of study = 62 in Group I exposed (sputum 3+) and Group II non-exposed (sputum 1+ and 2+) = 248

So total 310 cases were enrolled in this study.

Patients with negative and scanty sputum were not included in the study.

Ethical considerations: Permission of Institute Ethical Committee was taken. Permission from the City Tuberculosis Officer was taken. As it was record based study, informed consent from the patients was not taken.

Statistical analysis: The data was tabulated and analyzed using SPSS version 23. The data was expressed by calculating percentages and Chi-Square test and Proportion test was used for categorical variable and Students t-test for the continuous variable. P-value below 0.05 was considered to be statistically significant.

RESULTS

Table1: Sociodemographic details of study subjects of high bacillary and low bacillary cohort

Sociodemographic characteristics	High bacillary cohort(n=62)	Low bacillary cohort (n=248)	p-value
1. Age(in years)			
<20 years	6(9.7)	39(15.7)	0.387
21-40 years	37(59.7)	140(56.5)	
41-60 years	17(27.4)	53(21.4)	
>60 years	2(3.2)	16(6.5)	
2. Gender			
Male	40(64.5)	140(56.5)	0.250
Female	22(35.5)	108(43.5)	
3. Residence			
Urban	48(77.4)	168(67.7)	0.138
Rural	14(22.6)	80(32.3)	
4.Occupation			
Employed	35(56.5)	126(50.8)	0.478
Unemployed	27(43.5)	122(49.2)	

Figures in parenthesis indicate percentages: Sociodemographic information of the study subjects such as age, gender, residence and working status were summarized in Table 1.The mean age of the patients among the high bacillary cohort(Group I) was 35.3 years+ 1.9 years and that for low bacillary cohort(Group II) was 34.6 years+ 0.92 years. Majority of the study subjects in both the group were from the most productive age group of life i.e. 21-40 years. The proportion of male patients was more in both the study cohorts as compared to female patients. 56.5% of Group I and 50.8% of Group II patients were employed in one or the other occupation. As shown in Table 1, the present study did not reveal any statistically significant difference in the sociodemographic profile of the study cohorts.

Table 2: Sputum conversion rate in high bacillary and low bacillary cohort at two months and three months of Intensive phase

Sputum conversion rate	High bacillary cohort (n=62) n (%)	Low bacillary cohort (n=248) n(%)	P value
At 2 months of IP	44(71.0)	239(96.4)	<0.001
At 3 months of IP (Extended IP)	52*(83.9)	246** (99.1)	<0.001

*3 deaths in high bacillary cohort
**1 death in low bacillary cohort

Sputum conversion rates at the end of two months intensive phase (IP) was 44(71%) among the high bacillary cohort and that of low bacillary cohort it was 96.4% (p<0.001). At the end of extended intensive phase (at 3 months), the sputum conversion rate for the high bacillary cohort was 52(83.9%) and for low bacillary cohort it was 246(99.1%) and this difference was highly significant (p<0.001).

Table 3: Patients showing non-adherence to treatment in high bacillary and low bacillary cohort

Missed dose	High bacillary cohort (n=62) Mean + SD	Low bacillary cohort (n=248) Mean+ SD	P value
Intensive phase	3.8+ 1.13	3.6 + 0.80	<0.001
Continuation phase	3.04+ 0.49	2.05+ 0.27	<0.001

Non adherence to treatment was summarized in Table 3. In high bacillary cohort, total 13(20.9%) patients missed their one or more doses in intensive phase while among the low bacillary cohort, 36(14.5%) patients missed their dose. During continuation phase, 24(38.7%) patients missed their dose among the high bacillary cohort and among low bacillary cohort it was seen among 34(13.7%) patients. When the mean missed doses among the two cohorts were compared, it was seen that significantly more no. of doses were missed in high bacillary cohort in intensive as well as in continuation phase as compared to low bacillary cohort (p<0.001).

Table 4: Treatment outcome in high bacillary and low bacillary cohort

Treatment outcome	High bacillary cohort (n=62)	Low bacillary cohort (n=248)	p-value
Unfavourable outcome	10(16.1%)	7(2.8%)	<0.01
Favourable outcome	52(83.9)	241(97.2)	

Proportion test applied for unfavourable outcome (Treatment failed, died, loss to follow up and not evaluated) against favourable outcome

Treatment outcome was classified as favourable outcome which includes cured and treatment completed and unfavourable outcome which includes Treatment failed, died, loss to follow up and not evaluated (Table 4). Unfavourable outcome was seen in 10(16.1%) and 7(2.8%) among High bacillary cohort and Low bacillary cohort respectively (p<0.01). Among the unfavourable outcome, in 4(6.4%) patients treatment was failed, 3(4.8%) patients died, 3(4.8%) were lost to follow up in High bacillary cohort while in Low bacillary cohort in 1(0.4%) patients' treatment was failed, 2(0.8%) patients died, 1(0.4%) were lost to follow up and 3(1.2%) patients the outcome was not evaluated. The mortality rate among High bacillary cohort was about 6.2 times higher than the Low bacillary cohort. Odds ratio of unfavourable outcome was 6.62 (CI- 2.40-18.2) among High bacillary cohort as compared to Low bacillary cohort.

Besides the sputum smear grading, by logistic regression analysis it was found that the missed dose in intensive as well as in continuation phase and sputum

conversion at the end of 2 months' intensive phase were also significant predictors of unfavourable outcome. In this study, 2(3.2%) were HIV positive in High bacillary cohort and 20(8.0%) were HIV positive in Low bacillary cohort and all these patients had favourable outcome.

DISCUSSION

Pre-treatment sputum smear grading is a direct measure of number of bacilli present in a smear and thus severity of disease which may affect the smear conversion and final treatment outcome. There are studies available which highlighted the importance of initial sputum smear grading and revealed that higher grades of smear positivity result in delayed smear conversion and poor treatment outcome[8]. The current study findings revealed the patients with high bacillary load showed significantly lower sputum conversion at the end of two months as well as three months (three months in patients where the intensive phase was extended by another one month because of persistence of sputum positivity) of treatment as compared to patients with low bacillary load. Non conversion of positive smears at the end of two months of treatment is one of the strongest predictors for unfavourable treatment[9]. Likewise, patients with high bacillary load showed a lower cure rate and a higher failure rate. The difference was statistically significant. Even the death rate was higher in this category of patients. The results of the present study were similar to another study reported recently from Delhi[10,11].

The grading of positive smears reflects the extent of lesion or size of cavitation as well as being directly proportional to the infectiousness of the case[10]. Reasons for poor treatment outcome in patients with higher bacillary load are not clear. Factors known to predict the outcome of treatment in tuberculosis patients include sputum conversion after two or three months of treatment, HIV status, drug resistance pattern, adherence to DOT regimen, malabsorption, cavitatory disease and bilateral disease. We assume that initial bacillary load may also be an important factor as is being observed by us. In this study, by logistic regression analysis it was observed that besides the sputum smear grading, missed dose in intensive as well as in continuation phase and sputum conversion at the end of 2 months' intensive phase were also significant predictors of unfavourable outcome. We observed significantly more no. of missed doses in High bacillary cohort; reasons are not clear but it has contributed to the result of our study. Similar findings were observed by a study conducted in Delhi[10] while in another study conducted by LRS Institute of Tuberculosis and Respiratory Diseases, New Delhi observed that non-adherence to DOT was not significantly different between High bacillary and Low bacillary cohort[1]. The findings of the present study, although with some limitations such as lack of knowledge on initial drug resistance pattern or initial chest radiograph findings, call for review of the current unified chemotherapy regimen prescribed for all newly diagnosed smear positive pulmonary tuberculosis patients irrespective of the bacillary load. As in this study, only 22(7%) out of total 310 patients were HIV positive and all of them had a favourable outcome. Hence, this may not be affecting much to the results of the current study. The available data in India, suggest that the level of multidrug resistance among patients with no history of previous treatment ranges from 1-3 per cent. Although the initial drug resistance pattern of the patients under study was not known, considering that the present study was done in freshly diagnosed sputum positive patients, the possibility of acquired drug resistance affecting the results is also unlikely.

CONCLUSION

A high pre-treatment bacillary load appears to be an important predictor for poor treatment outcome even under DOTS strategy. Further studies are required to investigate various issues discussed above. There is a strong reason to suggest that patients with high initial bacillary load to be considered for a more aggressive treatment and care as compared to patients with low bacillary load.

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Comparison among the EMG Activity of the Anterior Deltoid and Medial Deltoid During Two Variations of Dumbbell Shoulder Press Exercise

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ABSTRACT

Objective: To analyze the muscle activation of anterior and medial deltoid muscles while performing two different grip variations of dumbbell shoulder press.

Methodology: Ten healthy male participants (age = 20.9 ± 1.449 years, height = 1.71 ± .038 m, weight =69.65 ± 2.92 kg) from Lakshmi Bai National Institute of Physical Education (Gwalior, M.P, India) were recruited as a sample of the study. The participants performed 5 repetitions of two different grip variations of dumbbell shoulder press. The exercises were Arnold Dumbbell Press (ADP) and Overhead Dumbbell Press (ODP). Surface Electromyography (SEMG) was used to record the muscle activation and for measuring muscle electrical activity that occurs during muscle contraction.

Results: Paired t–test was used to detect mean differences between the two variations of dumbbell shoulder press. It was found that Anterior and Medial Deltoid muscles were more active while performing ADP (AD-1346.4292.495; MD – 827.5 146.426) as compared to ODP (AD - 1043.4 141.299; MD – 725.4 100.4). Also while performing both the exercises, the muscle activation of anterior deltoid was found to be much higher than Medial Deltoid.

Conclusions: Arnold dumbbell press was more effective exercise for the activation of Anterior and Medial deltoid muscles as compared to the Overhead Dumbbell Press. Anterior deltoid acts as primary muscle while performing both the exercises, as the muscle activation is much higher as compared to medial deltoid.

Keywords: *Anterior Deltoid, Dumbbell shoulder press, Electromyography, Medial Deltoid and Muscle activation*

INTRODUCTION

The shoulders are used in many daily life activities and it's a key to many full-bodied movements. The shoulder muscles always come into play while throwing, pushing, pulling or lifting[1].

Deltoids are the most important muscles of the shoulders to produce shoulder joint movements. Anatomically deltoids are divided into three different portions: anterior, medial and posterior. For developing its strength, each portion can be worked separately. Each of these portions has a different role of play. The anterior deltoids plays dominant role in lifting the arms forward, similarly the middle deltoids lift the arms sideways and the posterior deltoids lift the arms backward. Symmetrical development of each portion of the deltoids can be assured by the use of individual exercises that can be accomplished with the use of dumbbells. The strength, protection against shoulder injury, and a powerful upper body for participation in sports are some of the benefits of well-developed deltoid[2].

The dumbbell shoulder press is one of the popular exercises for the shoulders. While doing vertical press, dumbbells are the perfect tool for a several reasons. In dumbbell shoulder press the weight is pressed upwards, it allows the Gleno-humeral joint to follow a natural path, which is well suited to the anatomy of the shoulder. As compare to dumbbell press, in barbell Press the movement of the shoulder is limited by that of the other shoulder and the placement of the bar3. The dumbbell

shoulder press is also more effective for producing shoulder muscles hypertrophy. Dumbbells allow more freedom as compare to barbells but it also requires coordination. As compare to barbell, during the last phase of the press, dumbbells allow the arms to come closer that result in greater range of motion[4]. A twisting variation of the overhead dumbbell shoulder press (also known as basic shoulder press) is the Arnold dumbbell press. During this press, the range of motion increases at the starting position of the dumbbells, without altering the target muscles. The target muscles for both i.e. overhead shoulder press and the Arnold press are the front and side shoulder muscles[5]. Choosing the best exercise for developing the shoulder becomes really difficult due to the different portions of the shoulder muscles. One way to determine this is by checking the level of muscle activation associated with a particular exercise, through the use of electromyography (EMG).

Electromyography measures the electrical activity of the muscles tissues during muscle contraction and relaxation cycles. Apart from rehabilitation it is also used in many sports techniques and is an essential tool in physiological, biomechanical and biomedical assessments for performance enhancement in sports[6,7,8,9].

The purpose of the study was to analyze the muscle activity of anterior and medial deltoid during two different grip variations of dumbbell shoulder press.

METHODOLOGY

Subjects: Ten healthy male participants (age = 20.9 ± 1.449 years, height = 1.71 ± .038 m, weight =69.65 ± 2.92 kg) from Lakshmibai National Institute of Physical Education (Gwalior, M.P, India) were recruited as a sample to be included in the study. More specifically, each subject met our stringent requirement of at least 1 year of experience in their regular (i.e. at least thrice a week) weight training programs. Simple Random Sampling technique was used for the selection of the subjects. All subjects were free from injuries which would have limited their ability to perform the technique correctly. Each subject provided informed consent prior to participation in any testing procedures.

Experimental Approach to the Problem: To compare the EMG response between the two variation of Dumbbell Shoulder Press (DSP), subjects performed 5 repetition of Arnold Dumbbell Press (ADP) and Overhead Dumbbell Press (ODP), with surface electrodes positioned over the 2 muscle (i.e. Anterior Deltoid; AD and Medial Deltoid; MD). A familiarization session was carried out 2 weeks before testing for knowing 10 RM of the subjects. At the beginning of the session, the subjects were asked to warm up (jogging) for 3–5 minutes. Their 10 repetition maximum (10 RM) was determined by having the subjects lift approximately three to five sets of each exercise at increasing loads until they reach their maximum load for 10 repetitions. They were allowed to rest for 5 minutes between the sets, or until they felt sufficiently rested, and then they were asked to repeat the above steps (after two days) for determining 10 RM, this time performing the other variation. Surface ElectroMyoGraphy (SEMG) was used for measuring muscle electrical activity that occurs during muscle contraction and relaxation cycles. The SEMG signal generated by the muscle fibers is captured by the electrodes, then amplified and filtered by the sensor before being converted to a digital signal by the encoder. It is then sent (by optical fiber) to the computer to be processed, displayed and recorded by the Infiniti software. The MyoScan-Pro sensor's active range is from 20 to 500 Hz. It can record SEMG signals of up to 1600 microvolts (μV), RMS. A/D Converter (Encoder; ProComp Infiniti) has 2 channels (C and D) sampling at 256 samples per second.

Data collection: Biograph infinity version 5.0 was used to record muscle activation of Anterior and Medial Deltoid. Before placing the electrodes on the target muscles, an abrasive cream was applied to the electrodes. Then the EMG electrodes were placed parallel to the muscle fiber on two locations (i.e. channel C for Anterior Deltoid and channel D for Medial Deltoid). A 15 foot optic fiber wire was used for recording the muscles activation (Raw EMG signals), which is directly connected to A/C encoder. A 20 mega pixels extended video camera was synchronized with the EMG software (Biograph infinity version 5.0), to find out the muscle activation value of the selected muscles at the time of performing the exercises. Myoscan-pro sensor with triode electrode was used. The participants performed 5 repetitions (of 10RM) of each variation of dumbbell shoulder press one by one. To know the differences between the muscles activation in the Arnold dumbbell press and overhead dumbbell press, the amount of weight for the both the exercises was kept same. Sufficient recovery time was provided to the participants after completing each exercise. The mean value of 5 repetitions was recorded as a final score for each subject.

Statistics: For testing the assumption of normality and to know the nature of data different descriptive statistics

such as mean, standard deviation, skewness, kurtosis, normal probability plots and Shapiro–Wilk's test were used. All data are presented as mean with standard deviations. Paired t – test was used to detect mean differences between the two variations of dumbbell shoulder press. For this purpose Statistical Package for Social Science (SPSS) version 21 was used. The level of significance was set at 0.05.

RESULTS AND DISCUSSION

A deviation from symmetry can be indicated, if a skewness value is more than twice its standard error. As none of the variables' skewness is greater than twice its standard error, hence all the variables are symmetrically distributed. Similarly, the value of kurtosis for the data to be normal of any of the variable is not more than twice its standard error of kurtosis hence none of the kurtosis values are significant. In other words, the distribution of all the variables is meso-kurtic.

Further for testing the normality Shapiro–Wilks test was used. It compares the scores in the sample to a normally distributed set of scores with the same mean and standard deviation. If the test is non – significant (p>.05) it tells that the distribution of the sample is not significantly different from a normal distribution (i.e. it is probably normal) and vice–versa. Here from table-1 we can see that none of the variables' p – value is less than .05, hence the data is normally distributed.

Table 1: Descriptive Statistics and Test of Normality

Exercise	Arnold Dumbbell Press		Vertical Dumbbell Press	
Muscles	Anterior Deltoid	Medial Deltoid	Anterior Deltoid	Medial Deltoid
Mean	1346.40	827.50	1043.40	725.40
Std. Error of Mean	92.495	46.304	44.682	31.751
Std. Deviation	292.495	146.426	141.299	100.407
Skewness	.597	-.581	.223	.194
Std. Error of Skewness	.687	.687	.687	.687
Kurtosis	-.884	-1.295	-1.932	-.636
Std. Error of Kurtosis	1.334	1.334	1.334	1.334
Shapiro – Wilk (p-value)	.402	.103	.086	.872

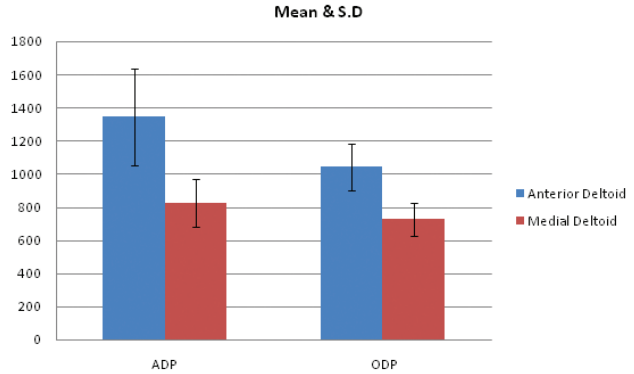


Figure 1: Mean and S.D value of muscles activation (Anterior Deltoid and Medial Deltoid) in Two Variations of Dumbbell Shoulder Press.

The above figure shows that the muscles activation of Anterior Deltoid and Medial Deltoid muscles in both the exercises were not similar. Arnold Dumbbell Press shows greater muscle activation in both Anterior and Medial Deltoid as compared to Overhead Dumbbell Press. To see whether these differences are significant paired t – test was used.

Table 2: A summary of the paired t - test

Muscles Pair		Paired Differences			t	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean		
AD	ADP - ODP	303	296.5854	93.78853	3.231	0.01
MD	ADP- ODP	102.1	105.5256	33.37013	3.06	0.014
ADP	AD - MD	518.90	276.98795	87.59128	5.924	.000
ODP	AD - MD	318.00	197.72427	62.52591	5.086	.001

*Significant at 0.05 level Degree of freedom= 9

Arnold dumbbell press found to be better exercise than overhead dumbbell press as significant differences shows higher muscles activation in both the muscles i.e. anterior and medial deltoid. In case of pairwise comparison between Anterior and Medial Deltoid muscle activation for each of the two exercises (i.e. ADP & ODP); significant differences were found in anterior deltoid muscle. This indicates that while performing ADP and ODP, anterior deltoid acts as primary muscle for both the exercises, as the muscle activation is much higher as compared to medial deltoid.

In the initial position of Arnold dumbbell press the elbows drop in front of the body, activates the anterior deltoid muscles to a great extent as compared to overhead dumbbell press. And as the dumbbell moves upward, the medial deltoids become increasingly engaged but not until the anterior deltoid initiate most of the movements[10]. Due to different movement patterns or the path, the Arnold dumbbell press is more effective for producing shoulder muscle (AD and MD) hypertrophy as compared to Overhead Dumbbell Press.

CONCLUSION

The purpose of the study was to analyze the muscle activity of anterior and medial deltoid during two different grip variations of dumbbell shoulder press. Due to greater range of motion Arnold dumbbell press was more effective exercise for the activation of Anterior and Medial deltoid muscles as compared to the Overhead Dumbbell Press. While performing both the exercises it has been concluded that anterior deltoid muscle acts as a primary muscle as the muscles activation is significantly higher than the medial deltoid, which means both the exercises are more effective for developing anterior deltoid than medial deltoid.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Effectiveness of Text Messages for Positive Change in Behaviour Amongst Young Adult Tobacco Users in Rural Wardha: Quasi Experimental Study

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ABSTRACT

Addictions developed in adolescence are likely to persist into adult life. The most susceptible time for tobacco use in India is during adolescence and early adulthood (15-24 years). Hence, an innovative community-based intervention for reducing primary uptake of tobacco among young adults is on priority. The objective of this study is to study the effectiveness of text messages for positive change in behaviour amongst young adult tobacco users in rural Wardha. A community based interventional study was carried out. All the young adults in the age group of 12-25years and willing to participate from selected village were enrolled in the study after informed consent. At recruitment, information like sociodemographic data, tobacco use pattern, addictions in family and peers was collected. The mobile numbers of the enrolled participants were taken and messages disseminating anti-tobacco health education were sent at fixed interval of time. The follow up was done at 3 months and 6 months. The effectiveness was measured on the parameters like reading the message, recollecting the most recent message correctly, understanding of the message and change in behaviour in terms of avoiding company of peers who consume tobacco and others. The results show the acceptability of the text messages by reading and recollecting the message at 6 months. But there was not a significant change in understanding the message and avoiding the company of peers. A formative research through Focussed Group Discussions was conducted which showed the feasibility and acceptability of text messaging to young adults in rural settings.

Keywords: *Young adults, Text messages, Wardha*

INTRODUCTION

Addictions developed in adolescence are likely to persist into adult life. Adolescence and early adulthood (15-24 years) is the time when the tobacco use starts in India. The Global Youth Tobacco Survey of 2009 showed that the current prevalence of tobacco use among boys and girls was 19.0% and 8.3% respectively. The current prevalence of smoking in boys is 11.2% and 3.7% in girls. 11.1% of boys and 6% of girls used smokeless tobacco[1]. Researchers have always found that tobacco is a major health issue in India.

Tobacco is used in a variety of forms in India; its use has been unfortunately well recognized in the adolescents. A Study by Dongre et. al. In 2008 from Central India showed commoner tobacco products used by young males as Kharra (79.2%), Ghutka (46.4 %), Khaini (32 %), Nus or Dry Snuff (25.6 %) and Bidi or Cigarette (4%)[2]. Thus, tobacco addiction in a large number of adults is initiated during adolescence. In India, although the community education program and awareness regarding the health hazards of tobacco use seems to have increased during recent times, scaling up of anti-tobacco initiatives to cover entire country is necessary[3].

The rapid development of mobile health technology (mHealth) provides a spectrum of opportunities to improve health services and to reach the people who are underserved. Mobile phone based short text messaging service (SMS) has the potential to deliver health education in a pattern and at regular intervals emphasizing on the importance of health. The low cost and relative ease of sending SMS to mobile phones make it an attractive and effective intervention for disseminating health education.

Studies have been undertaken in various parts of the World which provides support for the feasibility and acceptability of text messages program and with the

suggested improvements and technical improvements, the program may be promising. But countries like India, is still not using the mobile technology or m-Health to its optimum utilization4. The current study is thus planned to study the effectiveness of text messages for positive change in behaviour amongst young adult tobacco users in rural Wardha in the state of Maharashtra.

METHODOLOGY

Study Settings: Present Study was carried out in Wadgaon (Kala) Village with population of 1385 (as per 2011 census) Taluka Seloo, District Wardha which is an adopted village under the Department of Community Medicine, Jawaharlal Nehru Medical College, Sawangi(Meghe)[5].

Study Design: It is a Quasi-experimental study wherein pre-post comparison of intervention was studied.

Study Population: All the young adults in the age group of 15-24 years residing in the village who are not suffering from any pre-diagnosed respiratory health ailment.

Sample Size: Since the study is seeking for a behaviour change in adults, whole village adults as per the eligibility criteria were considered for interventions.

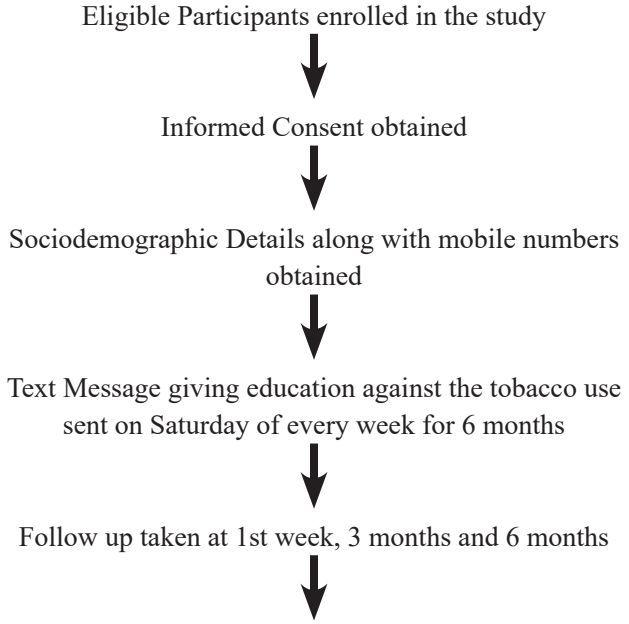
Data Collection Process: All the young adults in the age group of 15-24 were identified from the Village Level Grampanchayat and the baseline survey was done to obtain the sociodemographic details with the mobile numbers of themselves or any immediate family member whose mobile is accessible to the person. A pre-tested questionnaire was used to obtain the information like the use of tobacco and its products, the addiction in family and peers, etc.

Focussed group discussions were carried out with few representative adults in the village to know for feasibility and acceptability of text messages amongst the young adults, and also the problems we may encounter in bringing about this behaviour change among young villagers.

The text messages in the local language disseminating health education about the harmful effects to tobacco were pre-structured and validated by the subject experts and MPW from the department of Community Medicine for structure and content validity.

Interventions: Once the consenting participant is enrolled, the text messages educating about the harmful effects of tobacco were sent to each participant on their enrolled mobile number. This message was sent every Saturday of the week along the duration of 6 months. After the first message was sent, it was validated by collecting the information on the parameters like reading the message, recollecting the most recent message, understanding the message and avoiding the company of peers and family who use tobacco in any form. The data was obtained by calling the person individually in the second week itself. Similar data was obtained at the end of 3 months and 6 months.

Flowchart



Data analysis: Proportions from the intervention group were calculated at baseline, end of 3 months of intervention and end line 1.e. at end of 6 months of intervention and comparison of difference between proportions was made using z test for difference between proportions.

Qualitative data obtained from FGD was subjected to manual coding and manual content analysis was done for the same.

Ethical concerns: The research proposal was submitted to Institutional Ethics Committee and the approval was obtained. Pre-explained written informed consent was obtained from the participants in the local vernacular language.

RESULTS

Of the total 1385 population, 120 fell in the age group of 15-24 years. Of the 120, 102 could be interviewed to be the part of the study as the others were either unavailable at the time of interview or not willing to participate.

The socio-demographic profile of the participants is discussed in Table 1. Of 102 individuals, 59(57.84%) were in the late adolescent group and 43(42.16%) were in the early adult age group; 55(53.92%) were male and 47(46.07%) were female. Most of the participants have taken the education till Secondary school i.e. 46(45.09%). 42(41.17%) individuals are daily wage workers and as many as 78(76.47%) are under BPL. There is a history of addiction present in father in 66(64.7%) and in elder sibling in 26(25.49%).

Table 1. Socio-demographic Profile

Sr. No.		Total (n=102)
1.	**Age**	
	15-19years	59 (57.84%)
	20-24years	43 (42.16%)
2.	**Gender**	
	Male	55 (53.92%)
	Female	47 (46.07%)
3.	**Education**	
	Primary	24 (23.53%)
	Secondary	46 (45.09%)
	Higher Secondary	21 (20.58%)
	Graduate and Above	11 (10.78%)
4.	**Occupation**	
	Daily Wage Worker	42 (41.17%)
	Student	34 (33.33%)
	Others	26 (25.49%)
5.	**Tobacco use in any form**	
	Yes	76 (74.5%)
	No	26 (25.5%)
6.	**Socio-economic grade**	
	BPL	78 (76.47%)
	APL	24 (23.53%)
7.	**History of Addiction in Family**	
	Father	66 (64.7%)
	Elder Sibling	26 (25.49%)
	Others	10 (9.8%)

A focussed group discussion was carried out with 10 members of the sample group and the acceptability and feasibility of the text messages was sought for. Content Analysis was done for the results. The results are shown in the Table 2.

Table 2: Acceptability and Feasibility of Text Messages

Advantages of text messages:
Easy and Simple Method Not Time Consuming Individual connection established
Disadvantages of text messages:
Unreliable mobile networks Limit of words makes disseminating a lot of information difficult. No individual mobiles, hence difficulty in communicating the subject at times.
Opinion about acceptability of text messages
Most people accepted the method Some disagreed with the text messages A few gave a mixed response towards text messages

While most participants gave an opinion that the text messages are easy and simple method to disseminate health information, a few also said it is not a time consuming method and an individual connect with participants is established. The participants on asking about the disadvantages of the text messages said that the mobile networks are unreliable and the word limit for text message may pose as a challenge for the health education about tobacco consumption difficult. A few also said that since many people in the village don't have an individual mobile and have a common one for the family, it may lead to miss out of certain messages. When an opinion was taken on the acceptability of text messages among individuals, most of them accepted this as an effective method while just a few disagreed or gave a mixed response to it.

Of the 102 participants, 76 (74.5%) were found to be using tobacco in any form. The data was analysed and results were obtained for the 76 eligible participants; although the intervention was given to all 102 participants. The results for the variables were obtained at 3 months and 6 months are as follows in Table 3 and Table 4 respectively.

Table 3: Comparison of the baseline characteristics with the data at the end of 3 months

		Baseline (n=76)		3months (n= 74)		Z Value	p Value
		Yes	No	Yes	No		
1.	Reading the message	51	25	63	11	-2.585	0.0098
2.	Recollecting the message	26	50	31	43	-0.969	0.3320
3.	Understanding the message	20	56	26	48	-1.1711	0.242
4.	Avoiding the company of peers who use tobacco	32	44	35	39	-0.6395	0.5221

The baseline data was obtained after giving the intervention and at the end of one week. The data obtained at the end of 3 months showed a significant change (Z= -2.585, p Value= 0.0098) in reading the message. However, recollecting the message, understanding the message and avoiding the company of peers who use tobacco did not show much change.

Table 4: Comparison of the baseline characteristics with the at the end of 6 months

		Baseline (n=76)		6months (n= 71)		Z Value	p Value
		Yes	No	Yes	No		
1.	Reading the message	51	25	65	6	-3.6304	0.0002
2.	Recollecting the message	26	50	39	32	-2.5276	0.0114
3.	Understanding the message	20	56	29	22	-1.8674	0.0614
4.	Avoiding the company of peers who use tobacco	32	44	37	34	-1.2149	0.2262

At the end 6 months again the data was collected and was compared with the baseline. There has been an increase in all the parameters compared to 3rd month but not much. The parameter of recollecting the message showed a significant change at the end of 6 months (Z= -2.5276, p Value= 0.0114). However still understanding the message was low (Z= -1.8674, p Value= 0.0614) and avoiding the company of peers who use tobacco was not seen (Z= -1.2149, p Value= 0.2262).

DISCUSSION

The present study was aimed to assess the effectiveness of text messages for positive change in behaviour amongst young adult tobacco users in rural Wardha. This is a novel study as such type of study is not carried out in these settings before. We aimed at the adolescents in the age group of 15-24 years since they are the most vulnerable in falling for addictions. According to school-based GYTS in India, current use of any tobacco product among school children (13-15 years) was found to be 14.1% (17.3% boys, 9.8% girls). The prevalence was highest among male students in North East (34%) and the lowest was 4.9% among female students of western states. In Maharashtra, 12.9% adolescents (13-15 years) currently consumed any tobacco products1.

According to the Global Adult Tobacco Survey 2009-2010, urban tobacco users were more likely to be screened by healthcare provider for tobacco use as compared to rural tobacco users6. Hence we planned the study in the rural settings of Wardha to gain an insight more on the usage of tobacco and products in the rural areas.

The focussed group discussion conducted on the population showed that however much it is an easy and simple method for both, participant and researcher, it has its own set of disadvantages like unreliable networks and no individual mobiles. Hence this can be a limitation in the rural setups of India.

In the present study, in the comparison of baseline characteristics with the data at the end of 3 months and 6 months, we found that the acceptability of the text messages was seen with reading the messages and recollecting them. But they had difficulty in understanding the message. It may be due to the education as most of the participants were educated till Secondary school and a very few took education till graduation (10.78%). Another factor that may affect the results is that our sample size was small and so we recommend the study to be carried out at a larger scale for assessing the acceptability and feasibility.

In the adolescent age group, it is difficult for them to avoid the company of peers. In our study we found that the compliance of the participants towards avoiding the company of peers who consume tobacco. This can be due to various factors. Since it was a short duration study (6 months), the duration might be the one of the reasons for not being able to avoid the company of peers.

In the similar study conducted in Israel on Feasibility and Acceptability of a Text Messaging Program for Smoking Cessation the findings provided some support for the feasibility and acceptability of iStopSmoke; a program which was developed by the research team with assistance from InField Health, a US text messaging company that had the contract for SmokefreeTXT, the program upon which QuitNowTXT is closely modeled and, with the suggested improvements and technical improvements, the program may be promising[7].

In another study about the Mobile-phone text messaging (SMS) for providing oral health education to mothers of preschool children in Belgaum City, the authors have got the results that text messaging was more effective than pamphlets in improving knowledge, attitude and practices of mothers, but the comparative reduction in plaque score between groups was not significant. Text messaging appears to be an effective means of imparting oral health education8. However, this study has some limitations. The current study studies the effectiveness of text messages in the positive behaviour change amongst tobacco using adolescents. To be able to study the effectiveness on a larger scale, there is a need of comparison of the effectiveness of other interventions. Like in the BABEX Trial, Effectiveness of a brief community outreach tobacco cessation intervention in India, the authors have used the interventions like tobacco quit advice session and yogic exercises and found that the smoking cessation rate was higher with interventions in LMICS as compared to control group9. Hence newer measures of intervention needed to be explored and integration of mHealth is a newer approach towards healthcare.

RECOMMENDATIONS

Mobile based health education for promoting positive behavioural change is an effective means of imparting health education to Indian youth and should be promoted. Further studies of longer duration of intervention and bigger sample size are recommended to see the effect and impact of mobile based interventions.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Trends in Students' Outlook for Annual Health Checkup at an Indian University

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ABSTRACT

The annual health checkup programme is important for primary care and important concern for the healthcare professional to promote health. Health promotion professionals in higher education practice a process of prevention. To engage students in health promotion is the challenge for healthcare professionals in India. Formal evaluation of patient satisfaction should be a part of college health services as it is unclear whether the issue is being addressed in college health clinics. Hence, we conducted the study to understand students' perception from last three academic (2014-2017) years towards annual health check-up program and its aspects of conduct.

The availability of healthcare services at on-campus Health Centre and the process of conduct of health checkup was communicated and explained before the conduct of health checkup to students who participated in the annual health checkup programme. We selected alternate student to participate in this study and collected data from total 18127 students from last three academic years (2014-2017) about their views regarding health checkup programme schedule, conduct, hospitality and process along with their medical history and aliments.

From enrolled students, about 80% students attended annual health checkup every year. About 62 % from 2014-15 to 81% students from 2016-17 reported the need for health checkup. Last 3y trend showed increase from 85 percent to 96 percent students mentioned that they received all the requisite information about the health checkup procedures in time and in a friendly language. Thus, this suggest that there is improvement in communicating information about procedures which will facilitate conduct of checkup. More than 85% students reported that checkup was well-organized and felt that conduct and process was useful for them. About 1/4th of students reported that they diagnosed with some illness or medical disorder in the past where as 73 percent did not have any illness or disorder detected in past during 2014-15 annual health checkup while 14 percent students only reported that they diagnosed with any significant past medical history in 2016-17. Thus, during last 3y, there is about 9% fall in reported past medical history among these students.

Trend of last three academic year health checkup provided unique perspectives and guide healthcare professionals programming efforts to deliver healthcare services on university campus. Most importantly, it helped us to bring down the medical illness and aliments among these students. These trends suggest a need for continuation of existing as well new intervention strategies on university campus.

Keywords: *Trends, Annual Health Check-up (AHC), Student, Outlook*

INTRODUCTION

Annual screening of health can identify health problems before they start. By getting the right health services after screening and relevant treatments will have the healthier life. The annual health checkup is important for primary care and important concern for the healthcare professional to promote health. To engage students and academicians in health promotion is the challenge for healthcare professionals in India. College students do not appear to be well informed about healthcare & they are not very receptive to preventive programs, and they are neither worried nor knowledgeable about healthcare.[1]

The article reported students' participation in student health "programs" but provided no explanation of how

student participation was measured or defined. The visit to health Centre is not clear as a part of student health programs.[2] The paper presented at the 65th Annual Meeting of the American College Health Association, Chicago, IL, indicated that college students were optimistic about their own health. Academic pressure was the most significant contributor to stress, which students reported was their most serious health problem.[3]

To include student health centers at rural colleges in the national healthcare reform agenda otherwise closing schools' health centers could result in healthcare disaster for some students.[4] The 'on campus' health Centre is the nucleus of all the initiatives undertaken by a Health Promoting University. Therefore, available, accessible and affordable healthcare & utilization by stakeholder viz. student & their relationship with the healthcare provider is vital as regards health literacy and to consume health offerings on the university campus. Research is needed to clarify the mechanism through which literacy influences health status & health services utilization. Health promotion professionals in higher education practice a process of prevention, which is pre-diagnosis by definition.[5] The study reported that the formal evaluation system to be established to study evaluation of healthcare services and student satisfaction as a part of college health services.[6]

The results of the study presented as a set of principles that, if followed, should increase the likelihood that college health centers will be responsive to user needs.[7] The evaluation of health promotion is complex but it is possible to integrate health promotion into the University policies[8]. Health plays a critical role in student success, the availability of on campus health Centre, skilled healthcare professionals provides access to health and wellness services and address the unique health care needs of college students when they are on university campus. The importance of student community health, engaging students, faculty, and staff & determining whether more thorough, systematic, and intensive community health assessments or interventions are needed on campus settings.[9] The emergence of setting based approach and health promotion strategies for universities has its own challenges. There is a need to develop and establish framework suitable to universities in India, which will implement holistic and comprehensive approach to promote health[10].

The 'on campus' health Centre is the nucleus of all the initiatives undertaken by a Health Promoting University. Therefore, available, accessible and affordable healthcare & utilization by stakeholder viz. student & their relationship with healthcare provider is vital as regards health literacy and to consume health offerings on university campus. Research is needed to clarify the mechanism through which literacy influences health status & health services utilization.[11] The evaluation of health promotion is complex but it is possible to integrate health promotion into the University policies[12]. The emergence of setting based approach and health promotion strategies for universities has its own challenges. There is a need to develop and establish framework suitable to universities in India, which will implement holistic and comprehensive approach to promote health[13].

Formal evaluation of patient satisfaction should be a part of college health services as it is unclear whether the issue is being addressed in college health clinics[14]. In order to increase utilization, match services with student needs, and make maximum use of resources, the authors suggested that college health centers may need to develop and promote programs and services that better address student healthcare concerns.[15] Student satisfaction is an attitude subsequent to personal experience of healthcare perceived due to visit, infrastructure, services received by admin as well as medical professionals. The ability of doctor to communicate, inform & instill confidence in patients and convince the need of compliance for the advice offered make the difference between successful and unsuccessful treatment[16]. Satisfaction of beneficiary is linked to creating good interpersonal relationship, exchanging information, making treatment related decision and communicating after health checkup[17]. The study reported that General Practitioner (GP) plays a minor role in prevention use.[18] The present study is carried out to understand students' perception for continuous three (03) years towards comprehensive annual health check-up program conducted by Medical Officer, Consultant Physician, ENT Surgeon, Ophthalmologist, Dentist and basic lab investigation by pathologist (Haemogram and urine routine) and their views regarding various aspects of the conduct of health checkup program. The trend about students 'outlook about health checkup is an important element as regards healthcare services offered at the university.

Purpose: To study trends of students' outlook during 2014-15, 2015-16 & 2016-17 for AHC at an Indian University

RESEARCH DESIGN AND METHODS

The availability of healthcare services at on-campus Health Centre was communicated during induction program during 2014-15, 15-16 as well as 2016-17. The process of conduct of AHC is explained before the conduct of health checkup. An alternate student was randomly sampled for distribution of blinded questionnaire and responses were collected after AHC. Healthcare professionals planned and arranged checkup in coordination with academician therefore students are free from their academic engagements. A-10 statement questionnaire to study the trend of students' outlook regarding Health Checkup on parameters like regular to attend, information about the conduct, schedule, hospitality of staff, and preferred mode of health summery, advice offered was constructed and administered to all students after the conduct of annual health checkup for three (03) continuous year. 5735, 6227 & 6165 (Total 18127) no. of students submitted their responses after completion of checkup for all three consecutive years from 2014 to 2017.

Statistical methods: Data in tables are presented as frequency and percentages. Data were analyzed using Microsoft Excel to study trend of students' outlook for 03 years towards health checkup.

RESULTS

During academic year 2014-15, 2015-16, 2016-17 a total of 14,132, 14934, 15724 Students were enrolled respectively in an Indian University wherein research study conducted. Of them 11,471(81%). 12455 (83%) 12331 (78%) students underwent the annual health checkup program conducted by Health Centre at Pune, Nashik, Bangalore and Noida campus of University during 2014-15, 2015-16, and 2016-17

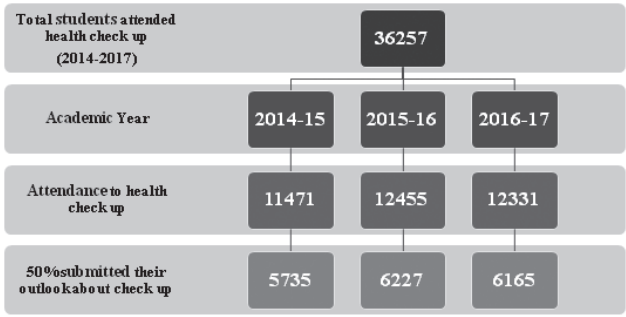


Fig. 1: Students Response to Annual Health Check up

Table 1: Status of students' attendance to Annual Health Checkup

YEAR	Admission to University	Attendance to AHC	Absentees to AHC
2014-15	14132	11471	2661
2015-16	14934	12455	2479
2016-17	15724	12331	3393

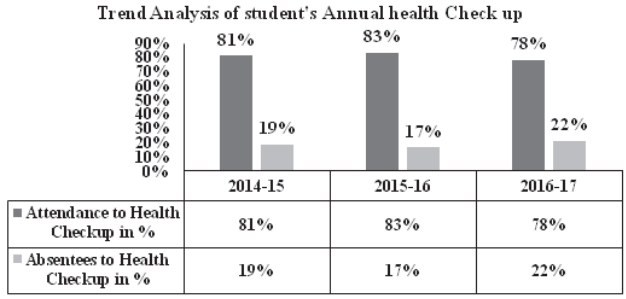


Fig.2: Trend Analysis of student's Annual health Checkup

Table 2: Trends in % for Students' outlook for Annual Health Checkup at an Indian University, 2014-15, 2015-16 & 2016-17

YEAR		2014-15		2015-16		2016-17	
Students' Perception		n	%	n	%	n	%
Attended Annual Health Checkup regularly	Yes	5672	91	5700	92	6127	98
	No	497	8	400	6	60	1
	Neutral	58	1	127	2	40	1
Attended health checkup because	Compulsory	2206	35	1260	20	1110	18
	Need For Health Check Up	3867	62	4867	78	5067	81
	Neutral	154	2	100	2	50	1

Received the information about checkup procedure	Yes	5297	85	5800	93	6000	96
	No	783	13	377	6	100	2
	Neutral	147	2	50	1	127	2
Health Checkup program	Well Organized	5290	85	5550	89	5777	93
	Needs Improvement	835	13	525	8	400	6
	Neutral	102	2	152	2	50	1
Health Checkup Schedule is suitable	Yes	5106	82	5200	84	5333	86
	No	1086	17	977	16	841	14
	Neutral	35	1	50	1	53	1
Health problems are diagnosed and addressed properly	Yes	5360	86	5220	84	5557	89
	No	707	11	907	15	620	10
	Neutral	160	3	100	2	50	1
Hospitality of Health Centre Staff	Good	5232	84	5500	88	5531	89
	Fair	953	15	724	12	676	11
	Neutral	42	1	3	0	20	0
Prefer health summery report by	Hard Copy	484	8	490	8	413	7
	Hard/Soft Copy	43	1	50	1	24	0
	Soft Copy	5603	90	5651	91	5772	93
	Neutral	97	2	36	1	18	0
Detected illness or disorders in past	Yes	1403	23	1000	16	870	14
	No	4713	76	5148	83	5269	85
	Neutral	111	2	79	1	88	1
Advice offered by consultant helped to improve health condition	Yes	2916	47	3000	48	3342	54
	No	2132	34	1920	31	2034	33
	Neutral	1179	19	1307	21	851	14

The trend of attendance is increased in 2015-16 & declined in 2016-17 for AHC. The inclination of students to attend regularly AHC is increasing from 91 % to 98 %. There is drop from 23 % to 14 % for students who had past medical history. Rise from 62 % to 81 % as students opined that there is a need for health checkup. The trend reported rise from 85 % to 96 % for students as they mentioned that they received all the requisite information about the health checkup procedures in time and in a user friendly language. Thus, this suggest that there is improvement in explaining/giving information about procedures which will facilitate sooth conduct of checkup. The trend analysis of 3 years conveyed that the student's outlook for health checkup is well-organized and percentage increased from 85 % to 93 % .There is an increase in students' outlook for suitability of health checkup schedule is increased from 82 % to 86 %. The trend of diagnosis of health problems and advice during health checkup is from 86 % to 89 %. Increase in outlook from 84% to 89 % students were happy with the hospitality offered by healthcare staff during students' visit to Health Centre. Almost, rise from 90% to 93% preferred soft copy of their Health Summery report via email.

However, being student population, we collected the information about the history and any illness or medical disorder. To our surprise, about 1/4th of students reported that they diagnosed with some illness or medical disorder in the past where as 73% did not have any illness or disorder detected in past during 2014-15 annual health checkup while 14% students only reported that they diagnosed with any significant past medical history in 2016-17.

While, 47% students reported that the medical advice & consultation received after the health checkup were helpful in 2014-15 and during 16-17, 54 percent students reported that the medical advice & consultation received after the health checkup were helpful.

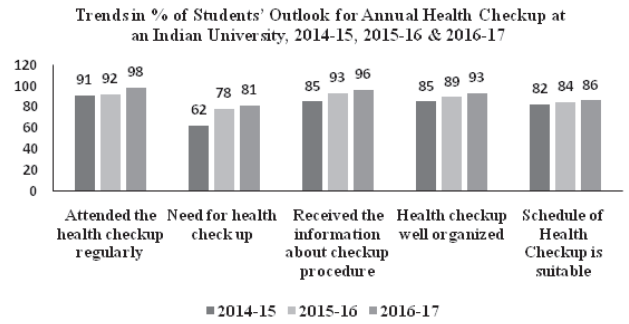


Fig 3 (A): Trend in % of students' outlook for annual health checkup at an Indian University 2014-15, 15-16 & 2016-17

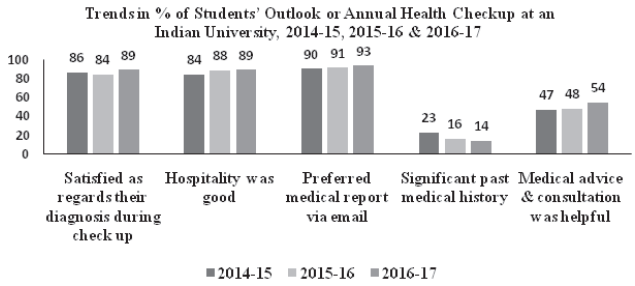


Fig 3 (B): Trend in % of students' Outlook for annual health checkup at an Indian University 2014-15, 2015-16 & 2016-17

DISCUSSIONS

The idea to invest in health is essential as health-promoting university & work towards cent percent students' attendance for the AHC. The results demonstrate the usefulness of AHC is to identify and assess health parameters. The trend reported fall in % towards attendance to health checkup. The students are addressed by healthcare professionals at the time of orientation/induction program & reiterated to the group of students during classroom induction. The flow of conduct of health checkup is explained by the healthcare professional at Health Centre. These trends suggest a need for continuation of existing as well new intervention strategies on university campus.

There is a need to explain the rationale of preventive care on campus its great benefits for health. The healthcare services are offered as the setting based healthcare system that moves beyond just looking at symptoms that brings students into clinics, instead, the focus is on prevention and act before they are sick as Health Promoting University (HPU).

Electronic Health Records (EHRs) are maintained to improve quality and efficiency in healthcare. The quality of change management played an important role in the success of EHR implementation at Health Centre. To address the challenge, a system based approach is adopted wherein all consultants are supported by healthcare professionals to collect, store & maintain electronic health records of every student in the cloud-based HIPPA compliant software application.

Healthcare professionals, consultants need to offer more time to communicate, explain advice to students & show genuine concern during the conduct of annual health check-up. This study is the evidence-based framework for the conduct of AHC & improve student satisfaction.

Most of the students were perceived satisfied for the health checkup program at Health Centre. However, there are opportunities for improvement to create awareness about the importance of health checkup annually wherein 100% student will attend annual health checkup, increase person to person interaction between student & healthcare professionals & consultants. The students will fully utilize the services offered by on-campus Health Centre if health screening program will be beneficial to the student community who rarely or never consult a physician without any illness. The qualitative data evaluation reinforced the findings from the analysis of the dataset.

Limitation & scope of further study:

- Attendance to AHC is less than 100% for three continuous years.
- To study strategies to maximize attendance to AHC, medical problems identified, outcome and benefit of screening of health checkup.

Research implications: The current study emphasizes the deployment of IEC strategies to create awareness for the importance of Health Checkup. The trend of Feedback analysis for 3 years as regards students' attendance to health checkup & outlook of the students for annual health checkup is critical in evaluating the quality of services rendered. Need and models of an ongoing training of the academic staff by healthcare providers focusing on promotional strategies would be useful for better acceptance to understand the importance of Health Promotion during academic lifecycle by the students. The author addressed 'Annual health checkup for student' as one of the health promotional strategies for establishing an HPU.

The trend analysis framework may be studied further to design adaptable framework for the higher educational institution for concepts of health needs, healthcare offerings, and resources as per campus population in India.

Novelty: The authors studied that more efforts to be taken by healthcare professionals in association with academicians to focus on prevention and promotion strategies as a Health Promoting University (HPU).

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Understanding Challenges and Opportunities Before Wellness Tourism in India

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ABSTRACT

Introduction: Make in India initiative of the present government has identified tourism & hospitality as one of the sectors for expediting the growth of Indian economy through generation of employment opportunities in the country. Adhering to the national call, author conducted a study on Health & Wellness Tourism (H& WT). H& WT is a travel associated with the quest for maintaining or enhancing one's personal wellbeing. In India this niche segment is still unexplored.

Purpose: The objective behind research in hand was to understand the challenges & opportunities before WT in India. It also studied the impact of changing family size, women's social roles and concern towards healthy lifestyles over H& WT.

Research Methodology: Research is based on both primary as well as secondary sources of information. The primary data was collected through a questionnaire survey of 300 people from Himachal Pradesh (Manali, Palampur & Dharamshala), India belonging to different income & age groups. In-depth interview of 6 hoteliers and tourist guides was also conducted. Analysis and interpretation of data was done through Graphs, ANOVA Test and Post Hoc Tests using SPSS.

Results & discussion: The changing demographic and economic environment has led to a significant change in the attitude of people towards tourism. People in the higher income group have started connecting tourism with wellness rather than the traditional cultural, sports or eco- tourism. Attributes such as availability of spa, gym and healthy food have started luring higher income groups.

Keywords: *Changing Demography, Changing Economy, Employment Generation, Wellness Tourism, Yoga.*

INTRODUCTION

Tourism earned third largest foreign exchange for country in the year 2012-13. In terms of international tourist footfall, India ranks 15th, bestowed with wide geographic diversity, it offers vide variety of niche tourism products ranging from aquatic adventures to mountain explorations; from medical to wellness; from rural to religious tourism[1].

Not much is known about H & WT. This paper is an attempt to understand the feasibility of the same in India. Before understanding the H & WT, it's important to understand the definition of health.

According to World Health Organization (1946), health is not merely about being free from any kind of mental or physical disease or disorder; it also includes one's social wellbeing[2]. In the light of this definition we may say that health tourism is a kind of tourism wherein tourists are motivated to visit different places to improve their health. The second word wellness attached to it means one's personal choice of lifestyle and self-care to enhance the quality of life. Visitors opting for wellness tourism are usually in good physical shape, but search for remedies to maintain this state of fitness. This may be achieved by visiting a place because it offers good spa, yoga-meditation center or arranges addresses by spiritual gurus.

REVIEW OF LITERATURE

The health and wellness industry primarily takes care of individual's health and well-being. Various factors like increasing life expectancy& improving economic conditions of the countries is making people concerned about their health & wellness[3]. This segment of people is ready to spend anything for enhancing their beauty, reducing their weight and feel fit both physically and

mentally. The nutritious food and anti-aging products and therapies also go well with this stratum.

Spas and the Spa Experience: The spa industry is offering them all these attributes and thus is the new love of people. The people today believe in the famous adage, "prevention is better than cure". They prefer H&WT for staying healthy and not for curing their ailments unlike medical tourism.

The International SPA Association (ISPA) (2010) defines Spas "as places devoted to overall well-being through a variety of professional services that encourage the renewal of mind, body and spirit" and include physical fitness training, wellness education and healthy cuisine[4].

Factors leading to the growth of Health & wellness tourism: Various scholars are of opinion that under the changing circumstances, wellness tourism is emerging as a niche market promising lot of scope for products and services maintaining health of the population[5,6]. The declining birth rate & death rate accompanied with increased life expectancy and better economy of the countries is gradually blending tourism and well-being generating avenues like spa tourism and other therapies like hydropathy[7,8,9,10].

H & WT targets people who are healthy, who wish to stay healthy and most importantly who have money and time to spend on Spa and other like wellness therapies. Social Media is playing a vital role in promoting this Niche tourism. Initially H & WT started as a part of medical tourism, but with the understanding that H & WT is for maintaining health of healthy people and medical tourism is for curing ailment, the H & WT established itself as an exclusive type of tourism across the globe[11]. H & WT includes retreat centers, rural or nature tourism, etc[12]. The concept of outdoors dates back to 1930s outdoor movement, also known as the open air movement, emphasizing the impact of outdoors and exercises on health[13]. This movement lead to the growth of exercises around the natural water bodies such as coasts, rivers etc.

Psychological & Social Well-Being: WHO's definition of health clearly indicates that health is not just about being free from physical and mental ailment, it also includes psychological & social well-being[14]. According to Nawijn (2010), well-being could be a general satisfaction with life or a specific one with respect to different facets, or realms of life[11].

Ferriss (2010) opined that people's perception of contentment and happiness depend upon various personal as well as environmental factors such as economic, geographical, socio-political and cultural variations[15].

It also depends upon individual's attitude towards his own physical and mental well-being[12].

The present day wellness tourism better known as well-being tourism is more related to subjective things like psychological and social satisfaction than objective things like physical fitness. Beauty enhancing, relaxing measures (body massage), work of art, music and the appreciation of nature are different facets of WT[16].

WT is also about enhancing the quality of life[17]. It led to the growth of cycleways, trekking routes, gym culture and other outdoor games in the UK (Cresswell, 2010).

RESEARCH OBJECTIVES

The objectives behind the research in hand are:

- To understand the concept of Health & Wellness tourism (H & WT)
- To understand the challenges & opportunities before H & WT in India
- To study the impact of changing family size over H & WT
- To study the impact of changing Women's status over H & WT
- To study the impact of rising middle income group over people's perception towards health & healthy lifestyles
- To study the impact of changing perception towards health & healthy lifestyles over H & WT

HYPOTHESIS

The following Hypotheses were tested at 5% Level of significance.

H1A: Changing family size has a significant impact over Wellness Tourism

H2A: The sudden rise in middle income group has a significant impact over people's perception of health & healthy lifestyles

H3A: Changing perception towards health & healthy lifestyles is encouraging Wellness Tourism

RESEARCH DESIGN & METHODOLOGY

Research was based on both primary as well as secondary sources of information. The primary data was collected through a questionnaire survey of 300 people from Manali, Dharamshala & Palampur in Himachal Pradesh visiting different health & wellness centers including *Bhagsu Yoga Institute* (Dharamsala), Holistic Massage Centre (McLeod Ganj), Buddha Hall (Dharamsala), Pure Ganga Yoga (Manali), TVA Spa by Tattva (Manali) and *Kayakalp*, Palampur: Himachal Pradesh institute of yoga and naturopathy@Palampur.

The age groups of the sample were 25 to 35 years, 35 to 45 years, 45 to 55 years and 55 years & above. The income groups included were less than 0.5 million, 0.5 - 0.8 million, 0.8 – 1.2 million and 1.2 million and above annually. In-depth interview of 15 hoteliers and tourist guides were also conducted.

The sample comprised of Indian tourists only, though the state receives significant number of foreign tourists and that too primarily from South East Asian & European countries. The objective behind this selection was to understand only the perception, attitude & behavior of Indian tourist towards H& WT. Sample was chosen through Stratified Random Sampling. Secondary information was collected through books, journals and articles. Statistical Analysis of data was done through Graphs, ANOVA Test and Post Hoc Tests using SPSS Software.

The test is reliable according to Cronbach's Alpha (α=0.857).

FINDINGS & DISCUSSIONS

The statistical analysis of data collected through primary research lead to the following results.

Impact of family size & dependency ratio over preference towards Health & wellness tourism

Family Size: Family size primarily means the number of people living in a house hold. The survey was conducted in Himachal Pradesh, India. The sample comprised of Indian tourists with three types of family size i.e., newlyweds; parents & children; and children, parents and grandparents. The grandparents in these different families were either working, pensioners or depended. The families where in grandparents were pensioners or working were relatively better placed than the other category wherein grandparents were either not working or did not have any pension. In the former case only children were dependents thus giving more financial freedom to the family. Where as in the latter category, the grandparents were also depended thus increasing the dependency ratio. Difference in the dependency ratio gave different responses for different groups. Other factors that influenced the dependency ratio were number of children in the house hold, the status of woman- whether working or not.

According to ANOVA test, (Table 1,2,3 & 4) Number of Children, Status of Women and Status of Parents showed Sig. value equal to 0.000 proving the acceptance of alternate hypothesis one i.e. (*H*1*A*) "Changing family size has a significant impact over Wellness Tourism."

Table 1: One-way ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Parents Status	Between Groups	10.417	2	5.208	2.624	.004
	Within Groups	589.583	297	1.985		
	Total	600.000	299			
Women Status	Between Groups	18.408	2	9.204	15.804	.000
	Within Groups	172.962	297	.582		
	Total	191.370	299			
Number of Children	Between Groups	17.443	2	8.721	7.244	.001
	Within Groups	357.557	297	1.204		
	Total	375.000	299			

Table 2: Post Hoc Tests Multiple Comparisons

Tukey HSD

Dependent Variable	(I) Preference towards health	(J) Preference towards health	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Parents Status	strong concern	neither agree nor disagree	.3154	.19544	.241	-.1449	.7758
		no concern	-.1581	.19737	.703	-.6230	.3068
	neither agree nor disagree	strong concern	-.3154	.19544	.241	-.7758	.1449
		no concern	-.4736	.21184	.067	-.9725	.0254
	no concern	strong concern	.1581	.19737	.703	-.3068	.6230
		neither agree nor disagree	.4736	.21184	.067	-.0254	.9725
Women Status	strong concern	neither agree nor disagree	.0561	.10586	.857	-.1932	.3054
		no concern	-.5198(*)	.10690	.000	-.7716	-.2679
	neither agree nor disagree	strong concern	-.0561	.10586	.857	-.3054	.1932
		no concern	-.5759(*)	.11474	.000	-.8461	-.3056
	no concern	strong concern	.5198(*)	.10690	.000	.2679	.7716
		neither agree nor disagree	.5759(*)	.11474	.000	.3056	.8461
Number of Children	strong concern	neither agree nor disagree	.5008(*)	.15220	.003	.1423	.8593
		no concern	-.0555	.15371	.931	-.4176	.3066
	neither agree nor disagree	strong concern	-.5008(*)	.15220	.003	-.8593	-.1423
		no concern	-.5563(*)	.16497	.002	-.9449	-.1677
	no concern	strong concern	.0555	.15371	.931	-.3066	.4176
		neither agree nor disagree	.5563(*)	.16497	.002	.1677	.9449

* The mean difference is significant at the .05 level.

According to Post Hoc Test, Table-2, mean difference is significant at the .05 level further confirmed that family size is influencing the Preference towards health.

Table-3: Oneway ANOVA
Women Status

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	18.408	2	9.204	15.804	.000
Within Groups	172.962	297	.582		
Total	191.370	299			

Table-4 : Post Hoc TestsMultiple Comparisons

Dependent Variable: Women Status
Tukey HSD

(I) Preference towards health	(J) Preference towards health	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
strong concern	neither agree nor disagree	.0561	.10586	.857	-.1932	.3054
	no concern	-.5198(*)	.10690	.000	-.7716	-.2679
neither agree nor disagree	strong concern	-.0561	.10586	.857	-.3054	.1932
	no concern	-.5759(*)	.11474	.000	-.8461	-.3056
no concern	strong concern	.5198(*)	.10690	.000	.2679	.7716
	neither agree nor disagree	.5759(*)	.11474	.000	.3056	.8461

*The mean difference is significant at the .05 level.

According to Post Hoc Test, Table-4, mean difference is significant at the .05 level further conformed that status of women is influencing the Preference towards health.

Impact of Income group over people's perception of health & healthy lifestyles: According to ANOVA test, (Table 5) Income group showed Sig. value equal to 0.000 proving the acceptance of alternate hypothesis one (*H2A*) "The sudden rise in middle income group has a significant impact over people's perception of health & healthy lifestyles"

Table 5: Oneway ANOVA

Income Group

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	61.059	2	30.529	32.623	.000
Within Groups	277.941	297	.936		
Total	339.000	299			

Table 6: Post Hoc Tests Multiple Comparisons

Tukey HSD

(I) Preference towards health	(J) Preference towards health	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
strong concern	neither agree nor disagree	.1398	.13419	.551	-.1762	.4559
	no concern	-.9268(*)	.13552	.000	-1.2460	-.6076
neither agree nor disagree	strong concern	-.1398	.13419	.551	-.4559	.1762
	no concern	-1.0667(*)	.14545	.000	-1.4093	-.7241
no concern	strong concern	.9268(*)	.13552	.000	.6076	1.2460
	neither agree nor disagree	1.0667(*)	.14545	.000	.7241	1.4093

* The mean difference is significant at the .05 level.

The Post Hoc Tests further confirmed that the mean difference is significant at the 0.05 level.

Impact of income group over leisure time spending behavior: According to ANOVA test, (Table 7) Income group showed Sig. value equal to 0.000 proving once again the acceptance of alternate hypothesis one (*H2A*) "The sudden rise in middle income group has a significant impact over people's perception of health & healthy lifestyles" and the same is also being reflected in their behavior of spending leisure time.

Table 7: Oneway ANOVA

Income Group

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	123.738	7	17.677	23.978	.000
Within Groups	215.262	292	.737		
Total	339.000	299			

Table- 8 Post Hoc Tests Multiple Comparisons

Dependent Variable: Income Group

Tukey HSD

(I) Leisure time	(J) Leisure time	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Jogging	spa	.8460(*)	.17078	.000	.3246	1.3674
	reading	.8182(*)	.26737	.049	.0019	1.6345
	nature lover	1.8182(*)	.25158	.000	1.0501	2.5863
	yoga	-.3485	.20692	.698	-.9802	.2833
	adventure sports	.1818	.21137	.989	-.4635	.8272
	gym	.8848(*)	.19678	.000	.2841	1.4856
	dancing/ singing	-1.1818(*)	.28943	.001	-2.0655	-.2982
spa	Jogging	-.8460(*)	.17078	.000	-1.3674	-.3246
	reading	-.0278	.23659	1.000	-.7501	.6945
	nature lover	.9722(*)	.21859	.000	.3049	1.6396
	yoga	-1.1944(*)	.16524	.000	-1.6989	-.6900
	adventure sports	-.6641(*)	.17078	.003	-1.1855	-.1427
	gym	.0389	.15234	1.000	-.4262	.5040
	dancing/ singing	-2.0278(*)	.26126	.000	-2.8254	-1.2301
reading	Jogging	-.8182(*)	.26737	.049	-1.6345	-.0019
	spa	.0278	.23659	1.000	-.6945	.7501
	nature lover	1.0000(*)	.30017	.022	.0836	1.9164
	yoga	-1.1667(*)	.26386	.000	-1.9723	-.3611
	adventure sports	-.6364	.26737	.255	-1.4527	.1799
	gym	.0667	.25599	1.000	-.7149	.8482
	dancing/ singing	-2.0000(*)	.33254	.000	-3.0152	-.9848

nature lover	Jogging	-1.8182(*)	.25158	.000	-2.5863	-1.0501
	spa	-.9722(*)	.21859	.000	-1.6396	-.3049
	reading	-1.0000(*)	.30017	.022	-1.9164	-.0836
	yoga	-2.1667(*)	.24786	.000	-2.9234	-1.4099
	adventure sports	-1.6364(*)	.25158	.000	-2.4045	-.8683
	gym	-.9333(*)	.23945	.003	-1.6644	-.2023
	dancing/ singing	-3.0000(*)	.31998	.000	-3.9769	-2.0231
yoga	Jogging	.3485	.20692	.698	-.2833	.9802
	spa	1.1944(*)	.16524	.000	.6900	1.6989
	reading	1.1667(*)	.26386	.000	.3611	1.9723
	nature lover	2.1667(*)	.24786	.000	1.4099	2.9234
	adventure sports	.5303	.20692	.174	-.1014	1.1620
	gym	1.2333(*)	.19199	.000	.6472	1.8195
	dancing/ singing	-.8333	.28620	.074	-1.7071	.0405
adventure sports	Jogging	-.1818	.21137	.989	-.8272	.4635
	spa	.6641(*)	.17078	.003	.1427	1.1855
	reading	.6364	.26737	.255	-.1799	1.4527
	nature lover	1.6364(*)	.25158	.000	.8683	2.4045
	yoga	-.5303	.20692	.174	-1.1620	.1014
	gym	.7030(*)	.19678	.010	.1023	1.3038
	dancing/ singing	-1.3636(*)	.28943	.000	-2.2473	-.4800
gym	Jogging	-.8848(*)	.19678	.000	-1.4856	-.2841
	spa	-.0389	.15234	1.000	-.5040	.4262
	reading	-.0667	.25599	1.000	-.8482	.7149
	nature lover	.9333(*)	.23945	.003	.2023	1.6644
	yoga	-1.2333(*)	.19199	.000	-1.8195	-.6472
	adventure sports	-.7030(*)	.19678	.010	-1.3038	-.1023
	dancing/ singing	-2.0667(*)	.27895	.000	-2.9183	-1.2150
dancing/ singing	Jogging	1.1818(*)	.28943	.001	.2982	2.0655
	spa	2.0278(*)	.26126	.000	1.2301	2.8254
	reading	2.0000(*)	.33254	.000	.9848	3.0152
	nature lover	3.0000(*)	.31998	.000	2.0231	3.9769
	yoga	.8333	.28620	.074	-.0405	1.7071
	adventure sports	1.3636(*)	.28943	.000	.4800	2.2473
	gym	2.0667(*)	.27895	.000	1.2150	2.9183

* The mean difference is significant at the .05 level.

Post Hoc Tests further confirms that the mean difference is significant at the .05 level.

Income Group vs. Concern towards healthy lifestyles: Table 9 below clearly shows that the Correlation between Income Group & Concern towards healthy lifestyles is significant at the 0.01 level (2-tailed). Meaning thereby that with the increase in the income, the population becomes more concerned towards their healthy lifestyles. The lower income group has low to negligible concern towards healthy lifestyles

Table 9: Correlations

		Income Group	Concern towards healthy lifestyles
Income Group	Pearson Correlation	1	-.268(**)
	Sig. (2-tailed)	.	.000
	N	300	300
Concern towards healthy lifestyles	Pearson Correlation	-.268(**)	1
	Sig. (2-tailed)	.000	.
	N	300	300

** Correlation is significant at the 0.01 level (2-tailed).

CONCLUSION

India in addition to housing beautiful geography, rich culture, variety of food, is the home of Ayurveda and Yoga. All these factors are bound to make India a favorable destination for H& WT. Economic growth of country in the past couple of years accompanied with the increased life expectancy; better standard of living; healthy environment; better governance; awareness among people of significance of being healthy, spread through various modes social media being the predominant one; access to wellness centers, through social media again, is promising a wonderful future for this sector of tourism in India.

The changing status of women in society, controlled number of children in each household, reduced dependency ratio, emerging middle income group is further going to harness a perfect ecosystem for the growth of H& WT.

Educated and working women are more aware. Their belief in the theory of, "Prevention is better than cure', is further inclining them towards H&WT. People in the higher income group have started connecting tourism with wellness rather than the traditional cultural, sports or eco- tourism. Easy access and awareness of spas, gyms and nutritive food have started luring higher income groups towards this segment. Sample also showed keen interest for attending yoga classes, meditation sessions or spiritual lectures as part of their tourism package. India the land of *Sadhus & Tapasvis* who have mastered the art of controlling one's mind, soul & body through Yoga; the country of Ayurveda & its unique Ayurvedic massage & other relaxation therapies; unique Meditation methods for calming brain & enhancing concentration are some of the obvious reasons for making India a favourite destination for H& WT.

Thus we may say, in pursuance of Prime Minister Modi's Dream of Make in India, the health & wellness tourism is going to play a vital role in expediting the growth of Indian economy through generating revenues and creating employment opportunities in the country.

Research implications: There is no doubt about the feasibility of H &WT in India. Results of this research can encourage people to invest in the area which is definitely going to boom. India in addition to housing beautiful geography, rich culture, variety of food, is the home of Ayurveda and Yoga. All these factors are bound to make India a favorable destination for H& WT.

It will help generate employment and earn revenue strengthening PM's Make in India Call.

Novelty/Originality: There has been an insignificant research in the field of wellness tourism in India. Research Outcome will be beneficial to the tourism industry and other support industries such as spa, yoga, meditation centers and spiritual gurus.

RECOMMENDATIONS

India in addition to housing beautiful geography, rich culture, variety of food, is the home of Ayurveda and Yoga. All these factors are bound to make India a favorable destination for H & WT provided we understand our strength and use it properly. We must

refine & tune up our ancient Indian mental & physical relaxation therapies and make world aware of it so as to generate huge revenues.

Government is offering incentives for installing projects in special areas such as the North-eastern states of India, Hill states of J&K, Himachal Pradesh and Uttarakhand. Interestingly these locations are blessed with natural beauty and also bear apt climate for wellness tourism. These states must make use of the natural, geographical, religious, rural and above all government policies for their growth.

Now the government has allowed 100% FDI in development of hotels, resorts and recreational facilities. (Make in India, 2016)[18]. People can make use of these incentives and in a symbiotic manner get incentivized along with aiding to the economic growth of country.

LIMITATIONS & FUTURE SCOPE

- Time was the biggest limitation. Human behavior may be mentioned here as another challenge.
- Researcher has carried out this research in Hill state of Himachal Pradesh; others may verify the results so obtained in other places like, Jammu & Kashmir, Northeastern States, Uttrakhand, southern parts of India such as Kerala.
- This empirical research is based on data collected from Indian tourists only. The results may further be verified with the foreign tourists.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Promoting Naturopathy in India

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ABSTRACT

The health condition of Indian is becoming an issue of concern, as number indicates India has maximum number of people suffering from many diseases. There are preventive as well curative ways to resolve it. Within this broad classification prevention and cure; multiple alternative health care systems are available. Allopathy has got maximum share of this market, but alternatives like Naturopathy which are equally effective as well as are economic has not been so popular. Naturopathy include nutrition, hydrotherapy, fasting therapy, yoga, behavioral therapy, and health promotion. It integrates the physical, mental, and spiritual aspects of human being and has the capacity to prevent and in some cases also cure the diseases.

The system need to promote its benefits to the public to attract them towards it. In the prevailing, situation efforts are being made by multiple stakeholders like the Government, private players as well as non-profit organizations, but effects are less than desired. The paper analyses the functioning of two organizations Nisargopchar Ashram and Kaivalyadhama Health and Yoga Research Center both of these organizations are working in Pune. The paper suggests maturity model to promote Naturopathy in India.

Keywords: *Naturopathy, India, Complementary and alternative medicine, Nisargopchar, Lifestyle disease*

INTRODUCTION

The cost of health services is becoming unaffordable for a large section of society and there are evidences of expenditure on health problem as a reason for being poor[1]. The recent trends of government to give more emphasis and space to private players have worsened the situation for the poor. But at the same time, India is witnessing a large number of medical tourist, coming here for treatment because it is comparatively cheaper to avail the medical services in India than developed countries. It has been made possible by innovative practices adopted by hospitals. The good quality services are being provided by the many Indian hospitals at fraction of price compared to the charges of the same services by hospitals in other countries[2].

The majority of the dialogue as far as medical services is concerned remain concentrated on allopathy. India has a long tradition of using alternative medical system like Ayurveda, Unani, Naturopathy and Homeopathy. But, over the period of time, it has lost its charm in the mind of consumers as well as policy makers. The humongous task of catering to huge population, and available number of allopathic facility warrants promotion of alternative therapy otherwise number of quacks would remain as they are in present situation.

There is increasing trend of access and use to health services in Urban India. The trend is similar in rural India, but their dependence on public hospitals are more than their urban counterparts (see, Table 1). Is it because of less number of private hospitals in the vicinity or lack of affordability or combination of both needs to be explored in detail?

Table 1: Health condition in India

Number per 1000 of persons hospitalized (excluding childbirth)			
	1995-96	2004	2014
Rural	13	23	35
Urban	20	31	44
Hospitalization in Public Hospitals			
Rural	44	42	42
Urban	43	38	32
Average hospitalization costs (in Rs.)			
Rural	3,202	5,695	14,935
Urban	3,921	8,851	24,436

Source: National Sample Survey Office, 2014

The cost of treatment rose at a double-digit pace of growth in both rural and urban India over the past decade (see, Table 1).

Table 2: Average medical expenditure per hospitalization at public and private hospital in 2014 (in Rs.)

	Public hospitals	Private hospitals
Rural	5636	21726
Urban	7670	32375

Source: National Sample Survey Office, 2014

The cost of access medical facility at private hospitals are more than four time costlier than accessing the same from public hospitals. Can this increased cost be justified by improved quality, is an answer which always may not be true. In addition to it, there is variation across states in terms of cost as well as access to health servicesfor both rural and urban areas.

The alternative therapy like Ayurveda, Homeopathy and Naturopathy has been cost effective as well as are more effective in certain types of ailment. The awareness of it need to be increased based on the results being achieved in this area by medical practitioners.

The Science of natural therapeutics is based on a use of the five elements, earth, water, ether, sunlight and air. These five elements constitute human body and naturopathy focuses on these five elements and their control in the treatment of the disease. It's also called as science of healthy living based on philosophy of natural healing. Naturopathy focuses on both measure i.e. corrective and preventive for healthy living. According to National Institute of Naturopathy, Pune (India), "Naturopathy is a rational and evidence based system of medicine imparting treatments with natural elements based on the Theory of Vitality, Theory of Toxemia, and Theory of Self-Healing Capacity of the body and the principles of healthy living."

The principles and practices of Naturopathy are integrated in the lifestyle of Indians which continues to grow and evolve, incorporating elements that advances the knowledge of the mechanisms of natural healing and therapeutics. Naturopathy is a cost effective drugless non-invasive healing system which has no side-effects

Mahatma Gandhi (M.K.Gandhi) added fasting and 'Ramanama' in nature cure because according to him living by obeying the laws of nature does not mean only proximity to five elements but it should lead to transformation of one's physical, mental, moral and social life through faith in the supreme power. Gandhiji's ideology on nature cure was mainly based on the suggestions by Adolf Just in his book called 'Return to Nature'.

LITERATURE REVIEW

The economic evaluation of alternative therapy helps in encouraging the policymakers to promote it in the masses by making appropriate changes in the policy. The value of these therapy are at multiple levels like patient empowerment, the operationalization of patient preference for a particular type of intervention, the length and process of the consultation, and still having treatment options open when other medical approaches have failed. While making any economic evaluation all these factors need to be included to provide it a level playing field[3].

The efficacy of Naturopathy is still not established in India. It needs a constant effort in terms of research and document the evidence of its effectiveness to convince the multiple stakeholders. The major reason for it can be attributed to lack of professional in the field4. There are evidence suggesting the effectiveness of alternative therapy, which can be used to resolve the problem of health services delivery in India.

Naturopathy in India, Current Status and Future Challenges: In India, Naturopathy has got support from multiple stakeholders. At the apex level, the government is trying to mainstream it. The importance of it can be seen by recent initiatives like forming a separate ministry to look after Complementary and alternative medicine. National Institute of Naturopathy (NIN), is an autonomous body under Ministry of Aayush, Govt. of India was established in 1986 with the objective to conduct, facilitate & encourage research activities to develop naturopathy as a system of medicine and as a way of life. The Central Council for Research in Yoga & Naturopathy (CCRYN), New Delhi is founded in 1978 with an objective to conduct scientific research in the field of Yoga & Naturopathy and to establish the efficacy of Yoga & Naturopathy in various disease

conditions. The Council runs its activities with the help of various schemes i.e. clinical research scheme, literary research scheme, running OPDs and conducting keep fit yoga classes for public. The Council provides financial assistance to premier Medical as well Yoga and Naturopathy Institutions in the country for undertaking research studies on these systems.

Table 3: Initiatives by various stakeholders

Stakeholders	Initiatives
Macro Level (Government, Regulators etc.)	Formation of separate ministry National Ayush Mission Opening up of Educational Institutions • National Institute of Naturopathy (NIN), Pune • Central Council for Research in Yoga and Naturopathy • Morarji Desai National Institute of Yoga (MDNIY)
Meso Level (Industry Association like International Naturopathy Organisation, Ayush Medical Association)	Organizing camps Conducting seminar and conferences
Micro Level (Organizations)	Creating Awareness Subsidized/cost-based treatment Publishing books, journals etc.

Source: Compiled by Authors

At the next level, there are association of organizations working for promotion of Naturopathy. They organize workshop, camps etc. for creating awareness about the benefits of this system among the people. In addition, to collaborate and update the existing knowledge base within the industry, seminar and conferences are also being conducted by these bodies. At Micro level, organizations working in the industry take effort at individual level to creating awareness as well as promote it.

In general use of Complementary and Alternative Medicine (CAM) is not so prevalent anywhere in the world and India is no exception. There are issues from supply as well as demand side (see Table 4) preventing the widespread adoption of these medicine. In India, CAM has been divided in Ayurveda, Unani, Siddha, Homeopathy, and Others. Naturopathy comes under others. The situation of Naturopathy is worse when one compares the different therapies available in CAM (see Table 5).

Table 4: Supply and Demand Side Barriers at Naturopathy

Supply Side Barriers	Demand Side Barriers
Number of Doctors	Lack of Awareness
Proper regulation	Belief in the system
Number of organizations	Mindset of spending on curative rather than preventive measure
Lack of Parity in salary structure and position	

Source: Compiled by Authors

Ecosystem for development and promotion of Naturopathy includes supply side i.e. government regulation, infrastructure, treatment centers etc. and demand side which consists of belief of the people in Naturopathy, awareness about it in them etc. The supply side barriers like less number of doctors, proper regulation, and parity in the salary structure can be resolved at the highest level by the government. Whereas, demand side barriers can be resolved by the organizations working in the industry as well as the government.

Table 5: Number of Ayush Hospitals and registered Practitioners (per crore) and Under-graduate (UG) colleges across the years

	2007			2011			2015		
	Hospitals	Practitioners (per crore)	UG Colleges	Hospitals	Practitioners (per crore)	UG Colleges	Hospitals	Practitioners (per crore)	UG Colleges
Ayurveda	2402	4030	240	2420	3547	260	2833	3120	279
Unani	262	414	39	258	408	40	265	374	43
Siddha	277	59	7	269	63	7	279	65	8
Homeopathy	234	1935	183	215	1853	183	212	2203	195
Others	32	NA	10	31	NA	14	43	NA	19

Source: Rural Health Statistics, 2014-15

Total number of primary health centers with Ayush facility is 10237, and there is variation across states. Although there are post graduate colleges are available for other system, but same is not available for Naturopathy.

RESEARCH METHODOLOGY

The study is based on case study method and analysis has been done by making comparison between cases. The information about the case study organizations have been taken from secondary sources. However, for better understanding of the functioning of these organizations a visit was made to these organizations. The interaction with the employees were generic in nature mainly concentrating on the functioning of Naturopathy. The organizations were chosen based on the popularity and access to the information. To avoid the temptation of getting diverted we made broad semi-structured questionnaire as well as probable probing questions related to it[5].We adopted multiple case studies, because single cases have limitation in terms of issues like generalizability and information bias and multiple cases helps in strengthening the quality and reliability of the study[6,7].

CASE STUDY

Nisargopchar Gramsudhar Trust: Gandhiji founded Nisargopchar Gramsudhar Trust on 1st April 1946, which worked under the dynamic leadership of Manibhaiji. Manibhai was instrumental in establishing it, and remain active and instrumental in its functioning till his death i.e.1993.

Over the years the Ashram has made remarkable progress and has set up the unique example in the field of Naturopathy.In addition to providing nature care for various ailments, it also spread awareness among the masses about the benefits of naturopathy as well as trains persons to spread the practice. It has the indoor capacity to cater 200 patients per day, which has the waiting period of 2-3 months. The indoor patients are mainly from urban area. The patients are mostly suffering from chronic problems; hence require stay at the Ashram compulsory to get the maximum benefit of the system. Doctors recommend minimum seven days of stay see the benefits of the therapy. Ashram also attracts good number of outpatients and it shows increasing trend (see Table 6). The number of indoor patients has the constraints of staying facility and Ashram also does not want to compromise on the quality of therapy by increasing the number of indoor patients. The current infrastructure is sufficient for catering the needs of these many patients.

Table 4: Number of outdoor and indoor patients at Nisargopchar Gramsudhar Trust

	Outdoor patients	Indoor patients
2003	951	3581
2004	942	3646
2005	1027	3988
2006	999	4524
2007	1174	4633
2008	1261	4572
2009	1317	4658
2010	1557	5064

2011	1544	5379
2012	1280	5251
2013	1524	5826
2014	1858	6119
2015	1967	6255

Source: Annual report of Nisargopchar Gramsudhar Trust (2015, 2014, 2013, 2012)

To compensate the constraint of infrastructure, Ashram promotes the Naturopathy among the people living in nearby area by conducting camps and workshops.

The Asham also has a good library on various subjects related to Naturopathy to cater the need of patients. The library has reading room facility for the patients and their relatives to increase awareness about the nature care. It has a book shop selling relevant books as per the demands of patients. Adjacent to the Ashram, there is one retail outset selling organic products made by self-help group members. Ashram has strong rules against the use of any intoxicating substance in the campus and follows a strictly laid down schedule for the patients (see annexure). Patient should strictly adhere to the diet and treatment regime prescribed by the doctor. To make it possible, patients get food from mess only after showing the prescribed food.

To spread the use of naturopathy in rural area, Ashram charges a nominal amount of money from the patients coming from rural area as consultation fee.

Table 5 : Consultation fees for outpatients at Nisargopchar Gramsudhar Trust

	Consultation fees (in Rs.)
Urban	250
Rural	60

Source: Nisargopchar Gramsudhar Trust

Treatment of patients happens through natural modalities like massage, mud therapy, hydrotherapy, and nutrition. In addition, physiotherapy, acupuncture and if required other branches of medicines are also referred for the treatment. The logo of Ashram is representative of five natural elements namely Space (Akash), Air (Vayu), Fire (Agni), Earth (Prithvi) and Water (Jala) which support life on Mother Earth.

Ashram has trained 2,222 people coming from different strata of the society in Naturopathy and Yoga, so that they can spread the practice of it among masses. They also conduct seminar on the topic related to Naturopathy. In addition Ashram also conducts Yoga Classes in rural areas, as many of them cannot come to Ashram.

The efforts of ashram have been recognized by various stakeholders and they have been awarded by various agencies. The Ashram has been recognized as a Centre of Excellence by the Ministry of Health and Family Welfare, Department of AYUSH. In addition, individual doctors of the Ashram have also got recognition and are part of many policy-making bodies, helping in spreading the reach of Naturopathy.

The patients are mainly from urban places and prefer staying for more than a week. The organization has a long waitlist for patients to get admitted. The most common ailment is Over-weight followed by Osteoarthritis and Cervical Spondylosis. The number female patients are more than their male counterparts. The maximum number of patients falls under the age category of 41 to 60 followed by 21 to 40 and 61 to 80. Ashram is engaged in research activity to create new therapy as well as provide evidence to increase the faith of patients in the system.

Kaivalyadhama: Kaivalyadham Yoga Institute was established in the year 1924 by Swami Kuvalyananda in 1924. Kaivalyadhama is engaged in the field of Yoga Research, Training and Therapy.

Three components of Yogic approach followed at Kaivalyadham are as follows.

(a) Practical Discipline: It involves the practice of Asanas, Pranayama, Kriyas and Meditation. All these practices induce increased awareness of physical and psychological processes.

(b) Regulation of diet and daily habits: It helps in removing imbalance in the functioning of body-mind complex.

(c) Changes in Life Style: It's concerned with changes in in one's attitude, behavior and life style.

As Yoga itself is focused on 'Integration' Kaivalyadham introduced separate Naturopathy way

in the year 1992. Now they have a Separate facility for Naturopathy treatments. As basic principle of naturopathy is 'to be one with nature' Kaivaalyadham introduced integrated packages where their participants can get better solution to health problems.

Kaivalyadham offerings: Kaivalyadham has 3 major packages which are offered to the participants for 7 days or 15 days residential treatment package at Lonawala centre. These packages are – i) Yoga and relaxation, ii) Yoga and Naturopathy, iii) Yoga and Ayurveda. It gives freedom to participants to choose the package as per their need.

Naturopathy centre has full time doctors (Naturopaths) who are qualified degree holders in Naturopathy. Participants on arrival visit the Naturopathy centre and doctors discuss their problems, suggests them certain tests if required and then different treatments in Naturopathy are advised and given at the centre itself. Treatments include Mud therapy, Hydro therapy, Steam bath, sun bath, Kati snan, Enema and a healthy diet as per need of the participant identified through diagnosis.

To spread awareness about Yoga and alternative therapy, Kaivalyadham organizes conferences at regular interval and proceedings of the same is available for general public for purchase. They have a book store having collection of books related to alternative therapy. To reduce the supply constraint of trained manpower, one college has been opened which is affiliated with University of Pune. In addition, to inculcate the practice of Yoga and alternative therapy at the earlier stage of life, organization has included the practice of it in the curriculum of the school run by them. Kaivalyadham also practices the use of renewable energy and have solar plat as well as windmill installed in the campus.

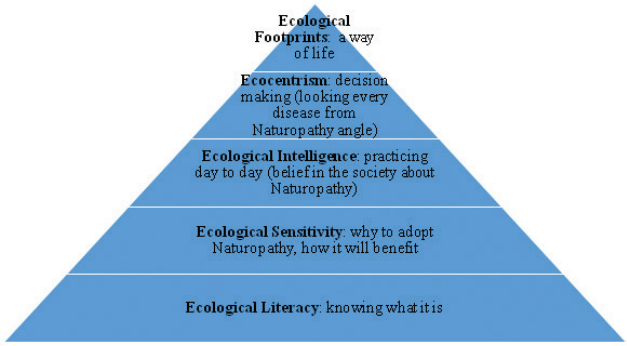
DISCUSSION AND CONCLUSION

Both organizations are well known in urban area specifically among educated population and have average waiting period of 2-3 months for the customers. But given the constraint of supply side and potential demand of Naturopathy, it becomes imperative to increase the penetration of it in the society.

Even in the present situation, there are many diseases where people prefer Naturopathy over allopathy. The different kind of diseases need to be identified and classified, then promoted accordingly. The classification can be made based on:

1. Preference of Naturopathy over other therapy
2. Just status quo is being maintained and no improvement from other medicine system
3. Not getting proper response from therapy
4. There is no cure in other system

Here, we need to make sure that cultural capital of the place is also being used properly[8]. In India, alternative therapy has been in practice for long time, only recently it has lost its charm in the society. The policy at national level with specific instruction about the licencing, registration, training of alternative therapy providers would help in establishing it in the medical industry[4].



Source: Adapted from Brahmankar and Dasika (2012)

We propose a maturity model as suggested by Brahmankar and Dasika (2012) for promoting Naturopathy in India9. Acknowledging the different level of appreciation among the consumer about the alternative therapy. Each level of understanding would require efforts from different stakeholders.

Table 6: Efforts required by stakeholders to promote Naturopathy

	Macro Level	Meso Level	Micro Level
Ecological Literacy	Including in the Syllabus of Schools and colleges	Conducting awareness camps	Conducting awareness camps
Ecological Sensitivity	Incentive for promoting Naturopathy,	making literature available	Highlighting the benefits of Naturopathy
Ecological Intelligence	Starting more colleges and infrastructure	Promoting evidences of benefits of Naturopathy	Changing the attitude of consumers
Ecocentrism	Providing Naturopathy doctors at every level (Competition or cooperation with other medicine)	Connecting to other stakeholders like government, insurance companies for promoting Naturopathy	Using principles of Naturopathy
Ecological Footprints	Treating naturopathy equal with other alternative medicine	Making resources available for day to day practice of Naturopathy for practitioners as well as patients	Inculcating the habit of practicing principles of Naturopathy

Source: Compiled by Authors

These two case study organizations (Nisargopchar Gramsudhar Trust and Kaivalyadham) are showing the way to practice Indian way of focus on preventive health care. Both of these organizations are functioning well and can act as an example for others to follow as role model to promote Naturopathy in consumer.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Reforms in Healthcare Management Education in India: A Symbiotic Approach

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ABSTRACT

Purpose: The main purpose of this paper is to discuss evolution of healthcare management education and an initiative to evolve a consensus between industry and academia with a view to produce a competent workforce.

Methodology: The study was cross sectional & descriptive. Data was obtained through questionnaire survey and one to one interactions with academicians and industry experts at various fora.

Results & Discussions: The study collates the lacunae as perceived by academicians and industry professionals and a consensus between the two as regards remedial strategies for reforms in healthcare management education in India.

Conclusions: Study highlights a consensus between academicians and industry professionals as regards lacunae in healthcare management education. There is a need for a paradigm shift through a symbiotic approach. An overarching accrediting body to ensure standardization and much needed reforms in healthcare management education and training is desirable.

Keywords: *Academia, Competencies, Healthcare, Industry, Management Education.*

INTRODUCTION

1.1 The growth of healthcare sector in India: Healthcare is one of the fastest growing sectors, both in terms of revenue and employment. From the current estimated size of US $35 billion, healthcare sector in India is estimated to reach US$ 280 billion by 2020 with a Compound Annual Growth Rate (CAGR) of around 22.87 %. Some of the factors contributing to this growth include growth in medical infrastructure (medicities), advances in medical tourism, emergence of public private partnerships etc. increasing coverage of services, a huge population with unmet healthcare needs, rising awareness as well as a capacity to spend on quality healthcare[1].

Primary stakeholders in this sector include hospitals/nursing homes, pharmaceutical industry, IT companies providing healthcare solutions, diagnostics, health insurance, medical equipment & devices, consultancies and other services (including training & education, non-governmental organizations, wellness sector etc.). Consequently, workforce requirements for this diverse healthcare sector are expected to grow from 35.9 lakh in 2013 to 74 lakh in 202[2].

With expanded reach of healthcare services, there is a substantial demand for high-quality and specialist healthcare services even in tier-II and tier-III cities[3]. This has resulted in a significant gap between the need (demand) for trained and efficient health care personnel and the supply of the same!

This growing sector with its ever increasing demand of quality services from current 'value conscious' patients necessitate the need to optimize systems & processes. An important aspect is that the healthcare sector today does not offer career options to medicos alone but also offers career

options to non-medicos too. Consequently, need for healthcare managers will almost double in the next 1-2 years' time[4].

1.2. Need of Manpower and the required skillset: As per WHO, India needs to add 1 million doctors, 2 million nurses and 3 million hospital beds to achieve the world average of 1.7 physicians, 3.3 nurses and 3.6 beds per 1000 population[5]. Hospitals today have become state-of-the-art healthcare facility providers. Further, technological advancements have and will make several jobs redundant while also creating new job roles, amply justifying need for highly skilled and trained healthcare management professionals who can thrive in a dynamically growing healthcare sector[6].

In order to respond to the above mentioned growth spurt and to effectively and efficiently utilize the available resources and achieve realistic targets, the healthcare sector requires trained professionals in the broad area of management in healthcare, rather than the parochial hospital managers, since healthcare management is beyond hospital management alone and entails application of management principles to other verticals of the healthcare sector such as pharmaceuticals, healthcare IT/ medical equipment & devices companies, wellness establishments, consultancies etc. This concern forms the core of the study through which concerns related to knowledge, ability and skill sets required in a competent healthcare manager is explored.

Diversity of verticals as well as size of individual establishments entail diversity of operations, necessitating multi-sectoral coordination and strong managerial supports. The healthcare sector therefore provides an incremental demand for human resources across various cadres; from doctors, nurses, technologists to allied health professionals. One of the most important human resource in this entire chain is a professionally trained and qualified healthcare manager**.**

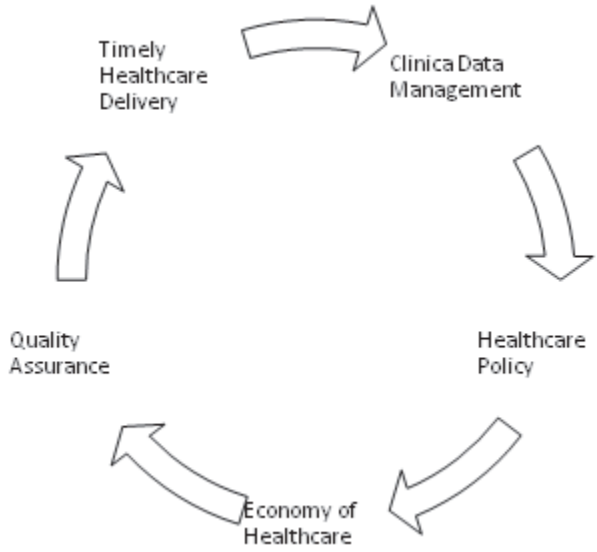


Fig 1: Diversity of Healthcare Verticals

(Source: India Education, Healthcare Management, 16 Feb 2015. Available at: http://www.indiaeducation.net/management/streams/healthcare-management.aspx.

With focus on the core areas as depicted in figure.1, a healthcare management professional is thus required to be proficient in various domains. To effectively comply with the multidisciplinary dimensions depicted above, it is necessary to train individuals to enable them to translate evidence into policies and to design, implement and evaluate programs. In spite of a growing focus on 'key skills', many researchers have suggested that graduate employability is a complex and difficult to precisely define and measure concept[7]. Healthcare management education, training and subsequently its application and practice in day to d ay life entails systematic planning, designing, delegating, coordinating, supervising and managing healthcare facilities to deliver quality healthcare services. In managing healthcare, besides having to work within the framework of professional, ethical & legal constraints, critically, one deals with the most important, non-negotiable commodity – HUMAN LIFE. The complex healthcare environment demands that its managers be suitably trained and equipped to manage the same in diverse settings. One therefore needs to understand the healthcare systems holistically and healthcare workforce at large. Several authors noted that the anticipated transfer of graduate skills to the job market occurs with *varying degrees of success*, depending on personality traits, the type of degree or subject studied, as well as the specific nature of workplace[8].

But there still exist a debate in the casual link between competencies and competence development on one side and managerial and/ or organizational performance on the other side[9]. Considering all the above aspects, it is evident that the healthcare sector needs professionally qualified, trained and competent managers to efficiently and effectively manage healthcare facilities to deliver quality healthcare services. While there may be various factors that are important for developing the required skills in the graduate to enhance their employability skills, the scope of this study at present is to understand the common competencies to make the specialized graduate programme more robust and standardized and to address the fact that there is no consensus on a common list of key skills[10].

With this backdrop, the present study aims at two research questions the first being identifying the gap between employers and academician's perception on the competencies that a healthcare management graduate should have and second being whether a competency model can be evolved with consensus from both the industry experts and the academicians.

METHODOLOGY

2.1 Study Design: The study conducted was cross-sectional and descriptive in nature. Data regarding academic institutes offering full time post graduate degree programme in healthcare management/ hospital administration & industrial organizations representing different verticals of the healthcare sector in the country were obtained using different strategies. The study proposal was tabled for ethical clearance.

2.2 Sample Population: For the purpose of the study two types of sample population were considered. This included the employers that employ graduates trained in healthcare management/ administration and the academic institutions which provide training and produce this trained manpower.

2.2.1. Healthcare Organizations: The details pertaining to healthcare organizations were obtained using the database that was made available through various online portals, magazines etc. and also the placement departments of some the top institutes which offer campus placements to their graduates. Randomly 100 top employers were selected. The employers were selected as they take these graduates for internship and also recruit them for managerial positions. The employers represented various verticals of healthcare namely hospitals, insurance, healthcare IT, healthcare consultancy, semi- government healthcare organizations and NGOs. This was done to obtain accurate assessment of the competencies needed to be possessed by these graduates.

2.2.2. Academic Institutes: The second group considered for the study was the academicians who are involved in teaching, training and grooming of graduates in the field of hospital & healthcare management/ administration. These academicians were selected from top 20 institutes offering full time post graduate degree programme in hospital management/ healthcare management/ administration, where all graduates from all fields are eligible for taking admissions. These institutes consisted approximately 50 full time teaching faculties which included assistant professors, associate professors and professors. The data of such institutes was obtained from three websites/ online forums and portals dedicated to higher education in field of management as well as medicine and allied health sciences. The selection criteria as stated above were made certain as. In two years the academicians work closely with their graduate students on various parameters to make them industry ready.

2.3 Research Instrument: To gain an in-depth insight into what are the essential and desirable knowledge, skills and attitude required from these graduates, an initiative in the form of consortium meet was convened of representatives of both from academic institutes as well as industry across verticals. The objective of this consortium was to evolve primarily a list of mutually agreed competencies with discussion touching on other aspects a s well like teaching pedagogies, importance of competency based education with the right blend of didactic and practical 'hands on' training and recommend reforms required to address the challenges and the gaps in skilling, training and education, thus '**HELPING BRIDGE THE SKILL AND CAPACITY GAP'.**

A list of commonly agreed competencies was arrived through this consortium as well as competency model of Saint Louis University and healthcare leadership alliance competency model was also referred and study instruments (both for industry and academicians) were developed, one for the academicians and the other for industry representatives, soliciting their opinion on key aspects related to the profession as well as on educational features existing and desired.

The questionnaires consisted of three parts, with the first part asking about the profile of the responders. The second part asked the responders to rate on the scale of 1 to 3 the competencies they rate as important to be possessed by students. Amongst the skills being assessed were combination of hard and soft skills like general and specific managerial skills, domain knowledge, presentation skills, etc. Finally, the third part asked the responders to comment and provide their views and opinions on the overall conduct of the programme with respect to teaching pedagogies, programme structure, experiential learning and their opinion on common centralized regulatory body for accreditation of such programmes.

2.4 Data Collection: Apart from the consortium meet which was aimed at collecting responses, the data was also obtained by mailing the questionnaires to the academicians of the selected institutes & industry representatives of organizations. Interaction during the consortium, emails & personal interaction at various fora were therefore the three sources of primary data. Responses were collected on 3- point Likert scale for close ended questions and views and opinions were solicited for open-ended questions. The study was spread over six months.

2.5 Data Analysis: Responses to all filled in questionnaires were collated. Questionnaires with more than 60 % unfilled data were rejected after repeat follow up. The base line variables and rating questions were summarized using SPSS version 21; valid percentage and frequency distribution was done along with Cramer's phi and independent 't' test.

RESULTS

Out of the 50 academicians contacted, responses were obtained from 33 and out of 87 industry experts contacted, responses were obtained from 60. This represents a response rate of (60%) & (68.9%) respectively. The demographic details of both the academicians and industry experts along with their profile are given in Table 1 & 2. In the academician's group, male (40.4%) and female (59.6%) distribution is fairly equitable; in the industry group, males (72.8%) outnumber the females (27.2%) significantly. An average of (82.5%) across both groups of the responders is in the prime and productive age group between 26 to 45 years of age. In the academician's group, (93%) of responders have a post graduate qualification. As regards teaching experience of academicians & work experience of industry responders, (79%) and (68%) respectively have between 4 to 12 years of experience which clearly reflects the mid-career profile of responders from both groups. (78.9%) of the industry responders were directly involved in the recruitment process. However, it is disappointing to note that (84.3%) of these individuals do not carry out a scientifically structured competency mapping exercise.

Table 1: Academician's demographic profile

Gender	
Male	40.4%
Female	59.6%
Age	
25 or less	3.5%
26-35	38.6%
36-45	49.1%
46 or more	8.8%
Academic Qualification	
Graduation	3.6%
Post-Graduation	93%
Ph.D.	3.4%
Teaching Experience	
1 year or less	2.3%
1-3 years	12.4%
4-7 years	57%
8-12 years	22%
12 years or more	6.3%

Table 2: Industry Expert's demographic profile

Gender	
Male	72.8%
Female	27.2%
Age	
25 or less	6.3%
26-35	46%
36-45	32%
46 or more	15.7%
Experience	
1 year or less	1.3%
1-3 years	22.6%
4-7 years	48%
8-12 years	20%
12 Years or more	8.1%
Directly involved in recruitment	
Yes	78.9%
No	21.1%
Do you carry out Competency Mapping?	
Yes	15.7%
No	84.3%

Phi and Cramer's V were also calculated to test the strength of association. Following competencies have shown significant association as given in Table 3.

Table 3: Strength of association amongst the competencies

Competencies	Phi	Cramer's V
Financial Management	.265	0.265
Performance Management	.211	.211
Legal Principles	.345	.345
Decision Making	.270	.270
Communication Skills	.271	.271

This is suggestive that the association is desirable as all the skills are required and are interdependent on each other. However, other domains where p- value was not found to be significant are also important as far as overall knowledge assessment of a candidate is concerned. Cross tabulation was carried out to examine the relation between importance of these competencies and its direct impact/relation in the recruitment process, as perceived by the recruiters at 95 % confidence interval; p – values ≤ 0.05 were considered significant. As depicted in Table 4, out of all the domains selected, financial management, performance management, legal principles, decision making and communication skills were found to be significant and these skills are considered by recruiters as essential (must know) competencies that a candidate must possess.

Table 4: Cross- tabulation results

Competencies	p- value	Competencies	p- value
Financial Management	0.04*	Health Policy	0.060
Performance management	0.054*	Legal Principles	0.011*
Project Management	0.451	Decision Making	0.005*
Organizational Management	0.087	Information Technology	0.063
Market Analysis	0.081	Database Management and assessment	0.891
Operation Assessment	0.924	Creativity	.0720
Strategic Management	0.078	Communication Skills	0.032*
Quality Assessment	0.074	Use of Statistical tools & techniques	0.427

*Significant p- values at 95 % CI

As presented in Table 5, industry experts and academicians were asked to rate the importance of competencies covered across all the semesters (in the two year programme) on a 3 point Likert scale of importance.

Table 5: Perception of importance of knowledge/competencies by industry experts and academicians

Knowledge/ Competencies	Industry Experts			Academicians		
	Very Important (n=60)	Important (n=60)	Somewhat Important (n=60)	Very Important (n=33)	Important (n=33)	Somewhat Important (n=33)
Financial Management	25%	56.6%	18.4%	83%	17%	-
Performance management	41.6%	50%	8.4%	15%	68%	17.00%
Project Management	31.6%	60%	8.4%	78%	20%	2%
Organizational Management	51.6%	45%	3.4%	88%	12%	-
Market Analysis	31%	38.3%	30.7%	96%	4%	-
Operation Research	41.6%	48.3%	10.1%	54%	40%	6%
Strategic Management	40%	42%	18%	52%	47%	1.00%
Quality Assessment	36.6%	41%	22.4%	56%	26%	18%
Health Policy	55%	40%	5%	87%	13%	
Legal Principles	26%	46.3%	27.7%	52%	44%	4%
Decision Making	61%	30.6%	8.4%	72%	28%	-
Information Technology	38.3%	45.6%	16.1%	87%	13%	-
Database Management and assessment	27.6%	36%	36.4%	34%	28.00%	38%
Creativity	23.3%	41.6%	35.1%	70%	30%	-
Communication Skills	73.3%	21.6%	5.1%	62%	38%	-
Use of Statistical tools & techniques	23.6%	49.3%	26.1%	66%	17%	17.00%

Perception of the importance of financial management draws parallel across industry experts (81.6%) and academicians (100%). This consensus across both cohorts amply justifies the importance and relevance of knowledge and competencies of financial management.

For, performance management, where (41.6%) of industry experts opined that it is 'very important'; only (15%) of academicians opine it to be 'very important'. Possible construal of this differential perception could be that academicians impart theoretical and didactic knowledge of performance management; it is the industry champions who actually assess the practical (translational) implications of this theoretical knowledge and therefore the difference. There is a consensus of opinion regarding the importance of project management (91.6% of industry experts & 98% of academicians), organizational management (96.6% of industry experts and 100 % of academicians), strategic management (82% in industrial group; 97% amongst academicians), Operation research (41.6% amongst industry & 54% amongst industry) and decision making (91.6% in industrial group; 100% in academicians).

Both groups (industry experts: 46.3% and academicians: 44%) comment similarly on the importance of knowledge of legal principals. Unfortunately,

quality assessment is only perceived as 'somewhat important' by both groups in equal numbers (22.4% by industry experts and 18% by academicians). Given the knowledge explosion, avenues of data generation, data analytics and the emerging importance of handling BIG DATA, it is rather surprising that only (27.6%) of industry experts and (34%) academicians rate database management and assessment as 'very important'. Data analysis, technology and numeracy are also becoming increasingly important in graduates as mentioned in similar studies [11]

Independent samples t-Test at alpha level 0.05 for differences in importance of competencies as perceived by industry experts and academicians was also conducted. The results are depicted in Table[6].

Table 6: Mean difference between the levels of importance of domain knowledge (Independent 't' test)

	Industry Experts		Academicians		
Domain	**Mean**	**SD**	**Mean**	**SD**	**Difference**
Financial Management	2.22	0.80	2.83	0.70	0.61**
Performance management	2.17	0.89	2.83	0.79	0.66**
Project Management	2.41	0.90	2.80	0.71	0.39**
Organizational Management	2.06	0.82	2.83	0.75	0.77**
Market Analysis	2.21	0.90	2.87	0.63	0.66**
Operation Assessment	2.10	0.85	2.90	0.76	0.80**
Strategic Management	2.47	0.57	1.70	0.86	0.77**
Healthcare Quality Management	2.06	0.82	2.83	0.75	0.77**
Health Policy	2.21	0.90	2.87	0.63	0.66**
Legal Principles	1.35	0.81	2.40	0.62	1.05**
Case Study Analysis	1.94	0.81	2.60	0.56	0.70**
Information Technology Management	2.27	0.89	2.57	0.63	0.30**
Database Management and Assessment	1.97	0.91	2.97	0.67	1.00**
Soft skills: Creativity, Communication Skills etc.	2.07	0.88	2.83	0.83	0.76**
Use of Statistical tools & techniques	1.42	0.81	2.30	0.70	0.88**

** Independent-Samples T test is statistically significant at 0.05 alpha level.

The results of the t- test generated from two different perspectives of industry experts and academicians are all statistically significant at 0.05 alpha level. This shows that both the groups rate these skills as 'must have' in a candidate; thereby mandating their inclusion in the academic curriculum to meet the industry requirements.

Additionally, views were collated on overall programme structure and teaching methodology, where (78 %) of academicians felt strongly for the need of a formal structured programme in healthcare management rather than having a programme in general management with some 'sprinkling' of the healthcare sector.

As regards the current programmes producing 'quality' candidates, (62.3%) industry professionals responded in the affirmative. This is further corroborated by (67.8%) of industry professionals opining that the syllabus covered is sufficient to impart desired competencies in the students to perform well in their profession. (82%) of experts (academicians as well as industry) opine that the major undesirable element of the education and training system is lack of stints of experiential learnings which help students attain and further develop certain important industry related skills. (72%) of academicians considered medical/life science graduates to be ideally suited for enrollment for a programme in healthcare management; whereas (64.2%) industry professionals opined that graduates from other streams but with relevant work experience are equally suitable. With respect to opinion of industry professionals, there was a consensus that the various training programmes do not include important courses such as public communication, bio-safety and bio-ethics, customer relationship management, disaster

prevention, mitigation and management and ability to foster an inter-sectoral coordination. Students passing out of these training programmes have more of the theoretical knowledge and are not abreast of current developments and trends. Whereas, the focus and stress of academic institutes is on knowledge, skills and attitudes (KSA); that of the industry is on attitude, skills and knowledge (ASK)!

From the results shown in table 8, it can be observed that the most preferred mode of engagement between academia and industry is having an industry representative as a 'guest speaker', followed by acceptance of students for summer internships and 'on job training'. On the other hand, collaborative research is not seen as a beneficial means of association. Same are the opinions on Corporate Social Responsibility (CSR) initiatives and on campus business incubator center.

Finally, all the responders unanimously agreed on having an overarching accreditation / regulatory body which will ensure academic delivery of a competency based curriculum in order to overcome the disparity between demand and supply of qualified and trained manpower.

DISCUSSION

The equitable distribution of males and females opting for a career in academics in contrast to the inequitable distribution for a career in industry could be reflective of the preference of females for academic careers over a career in the industry due to the demanding rigors of industry as compared to academia.

Majority of the responders (from both stakeholders) being in a productive age group is indicative of the tendency and trend of individuals to commit to a career in the healthcare sector. This in turn could be attributed to the wide scope that healthcare management industry offers due to the myriad career options available in the varied verticals of the healthcare sector.

The high percentage of qualified academicians denotes that professionals with domain specific knowledge are involved in capacity building. Needless to emphasize, such quality faculty will breed quality students. It can therefore be derived that the study has targeted faculty members who can groom and train students for developing the right employable competencies.

The questionnaire focused on relevance of the diverse and key managerial skill sets / competencies required for being a competent healthcare manager[12]**.** Given the diversity of operations which a healthcare manager is required to address, the exercise of competency mapping during and after recruitment should be mandatorily carried out in order to prevent *square pegs in a round hole!*

Overall, the consensus response from industry experts as regards the lack of practical knowledge on certain key aspects like project management skills, strategic thinking, presentation skills, use of analytical tools etc. underpin and reiterate the importance of '*hands on training'* on the latest technology in order to ensure 'industry ready' graduates.

This paucity of experiential '*hands on training'* is particularly worrisome. After all, *there is a difference between learning accountancy and actually maintaining accounts! OR learning surgery and actually performing an operation!* Hence, completion of successful internship should be one of the important criteria for getting certified. Further, assessments should also be conducted on the projects/ dissertations done during internships. This clearly reflects experiential learning as an integral part of the curriculum which should be taken seriously and sincerely by all the stakeholders involved.

Table 7: Mean difference between parameters of industry-academia interface

	Academicians		Industry		
Parameter	**Mean Score**	**SD**	**Mean Score**	**SD**	**Difference**
Guest/ visiting faculty from industry	2.9	0.63	2.3	0.67	0.6**
Acceptance of students for stints of experiential learnings e.g. Summer Internship Programme (SIP), On Job Training (OJT) etc.	2.7	1.10	2.3	0.87	0.4**
Conducting joint collaborative research	2.2	1.40	2.2	0.63	0

Participation of students in industry outreach programs (CSR or otherwise)	2.3	1.70	2.2	0.63	0.1
On campus business incubator center	2.5	1.30	2.3	0.67	0.2

**Independent Sample t- test is statistically significant at 0.05 alpha level.

Additional common areas of concern amongst academicians included absence of a standardization of the curriculum and its incoherence with the academic title awarded viz. Diploma / Degree. It is difficult, rather utopian to implement an academic programme, suited to the diverse requirements of the healthcare sector in a given limited time frame. Further, there is a dichotomy between various stakeholders as regards the priority of competencies to be taught. Globally health care faces a crisis of unsustainable economics, erratic quality, and unequal access. Those who educate and train health-care executives have before them a thrilling opportunity; yet a daunting task. This fact assumes particular significance, considering the myriad career pathways which the healthcare sector offers for individuals at different designations. Changing the way hundreds of educational programs operate can feel Sisyphean; but if academicians collaborate with each other and with industry professionals, restructure curricula to make it more current and relevant and use the academic tools known to be effective, they can educate leaders who are equal to the challenges of innovating 21st century health care. The reforms suggested by both groups correlate closely with the Dr. Shrikant Datar and his co-author's view point mentioned in *Rethinking the MBA* wherein Datar recommends a fundamental rebalancing away from 'knowing' and towards 'doing' and 'being.' "Without 'doing' skills, knowledge is of little value. Without 'being' skills, it is often hard to act ethically or professionally[13].

Interestingly, both the groups strongly agreed to the role of an overarching accrediting and regulatory body to attain the desired and much needed reforms in healthcare management education. There is huge increase in academic institutions all across the country. The quality of candidates produced at the end of 2 years' program is not the same across the country as there is no standardization. This has also given way to thought process where, the 'skills agenda' in higher education is challenged by many academics and there is some resistance to the growing influence of industry on higher education program content, design and policies [14,15].

In many other relevant studies, it is pointed out that Universities, as well as the graduates themselves, must undertake efforts to equip themselves with the requirements identified by industry, especially, with regard to employability skills. Similarly, universities must have consistent engagement with industries in understanding their evolving requirements with regard to what employability skills university graduates should possess. On the other hand, university graduates must also be proactive in identifying what is required by their potential employers. If this is happening, then, there is a bigger opportunity for the gap between universities, graduates and industries to be reduced in terms of what they can expect from one another. Hence, an overarching accreditation body is much the felt need of the hour. Since, youngsters on the threshold of their academic career make a conscientious decision to opt for a career in healthcare management, it behooves naturally on both these important stakeholders to design structure and implement a quality programme which is competency based and ensures a right fit of the individual to the institute/organization they choose to join.

CONCLUSIONS

The present study has identified a consensus between academicians and industry professionals as regards lacunae in the existing system of healthcare management education and training in India. The disparity between demand and supply of quality manpower is fundamentally due to a gap between the academicians' and the employers' perception on the importance of competencies expected of a healthcare management graduate. It is therefore a need for a paradigm shift through a symbiotic approach. Hosting a consortium thereby facilitating an open dialogue between these two most important stakeholders is critical to analyze this gap in order to raise a cadre of competent healthcare management professionals. Engagement of qualified faculty to create exciting and novel learning opportunities (pedagogy) and opportunities for experiential learning by industry professionals are crucial.

Ethical clearance: No need

Source of funding: Self

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Analysis of Attrition of Staff in A Multispecialty Hospital and Formulation of Retention Strategies

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ABSTRACT

Introduction/Background: The presence of experienced and skilled team is an asset for any industry to have, none more than the hospital. The cost and effort involved in hiring and training new employees is a not just a serious investment, but also a liability. In this study, we have analyzed the attrition rate of a multispecialty hospital quantitatively.

Purpose: As attrition is a serious concern for any hospital, it is necessary to find possible solutions to not just solve the problem but also to mitigate it.

Methodology: This was a cross sectional study conducted in a multispecialty hospital. The data was collected on a 5- point Likert type agreement-disagreement scale. Cronbach`s alpha was used to assess the reliability of the data.

Results & discussion/Findings &interpretation: Overall Cronbach`s α for instrument was 0.962 which showed high reliability of the instrument. Major reasons for employee attrition were Supervisor behavior (28.67%), Salary Issues (15.3%), Lack of Coordination (18.67%).

Research implications: The results presented in this study would serve as a useful resource for the hospital management to consider and potentially address the issue even before they start to occur.

Novelty/Originality: This is an original research done for studying the reasons of employee attrition in hospital.

Keywords: *Attrition, Behavior, Cronbach's alpha, Hospital, Retention.*

INTRODUCTION

Employee attrition is voluntary reduction in the manpower of an organization and has become the major concern of organizations.[1] Attrition happens through resignation, retirements and death out of which the first two reasons are the major causes for attrition as they have a direct relationship with the efficiency of the organization.[2] This is why the human resources department treats attrition as a very critical issue. It is a major loss to the organization when a well-trained and skilled staff leaves the organization as the cost of recruitment and training has to be borne once again.

Attrition is an undesirable but an unavoidable situation. Indian studies have found unfair compensation, lack of goal achievement, poor learning and development opportunities, etc. as the prime causes of attrition.[3] An organization cannot function with unhappy or unsteady employees, who are in constant search for new opportunities. However, attrition studies largely focus on the leaving employees. The present study has been done on existing as well as leaving or past employees to understand the reasons of attrition in the organization and formulate strategies for staff retention.

METHODS

This is an exploratory study that was conducted using quantitative tools on employees of a 100-bed super-specialty hospital in Pune during May- July 2015. All the data was collected after taking necessary permission from the hospital authorities and consent from the respondents of the study.

Study subjects included existing employees as well as the past employees of the organization. For existing

employees, the data was collected using qualitative and quantitative tools from 100 employees keeping in mind the most common issues pertaining to employee dissatisfaction leading to attrition in the hospital. A 14-item questionnaire was developed by consulting the Human Resources Manager and the General Manager of the hospital to identify the most common issues relevant to attrition and retention of hospital staff. The baseline data, of the employees included their Department, Designation, Age, Gender, Marital Status, Qualification and the Duration for which they have worked with the organization. The assessment of the employees was done based on Communication, career development, your role in organization, recognition and rewards, teamwork and cooperation, Organizational culture, relation with superior, Facilities, restrooms, recreation & welfare, and Training and development. Questionnaires with ≥5% missing data were excluded from analysis.

The baseline information as well as quantitative responses to questionnaires was summarized. Qualitative responses were transcribed and reported. The data was collected on a 5-point Likert type agreement-disagreement scale; 1 being the lowest rating depicting utmost dissatisfaction and 5 being the highest rating depicting utmost satisfaction. Mean and standard deviation (s.d.) are presented and Cronbach`s Alpha was used to test the instrument for reliability.

RESULTS

Existing employees: Out of 110 employees requested to participate in the study, a total of 97 respondents agreed to participate. Out of the participating subjects, 46 were from nursing department, 27 from customer care; 12 from administrative departments (like HR, finance, marketing and IT); and remaining 12 from support service departments. 67% of the respondents were males; 94% employees were in 21-34 year age group and remaining 6% in 35-44yrs. 83% respondents had work experience of less than one year and 17% between 1-2 yrs. 89% participants were in lower to middle positions like 7% were supervisors, and 4% were managers. The reliability analysis and the mean and s.d. of the score is given in table 1.

Table 1: Reliability analysis of the questionnaire (n=97)

Questions	Mean ± s.d.	Alpha if item deleted
Q1) Communication		
Q1 a) I am aware of the ongoing initiatives within the unit	2.42 ± 1.075	0.978
Q1 b) Communication from functional heads are frequent/transparent enough	2.52 ± 0.990	0.957
Q1 c) There is adequate communication between departments	2.46 ± 1.086	0.947
Cronbach's alpha(P value): 0.967(<0.01)		
Q2) Career Development		
Q2 a) I have a clearly established career path	3.88 ± 0.832	0.91
Q2 b) I have opportunities to learn and grow	3.82 ± 0.821	0.909
Q2 c) My last performance appraisal accurately reflected my performance	3.47 ± 1.396	0.862
Q2 d) The performance appraisal system is fair	3.54 ± 1.403	0.857
Cronbach's alpha (P value): 0.933(<0.01)		
Q3) Your role		
Q3 a) I am given enough authority to make decisions I need to make	2.91 ± 0.842	0.942
Q3 b) I feel I am contributing to organization's mission	3.32 ± 0.942	0.917
Cronbach's alpha(P value): 0.948(<0.001)		
Q4) Recognition and rewards		
Q4 a) I feel I am valued at Unit	3.51 ± 0.959	0.909
Q4 b) Unit gives enough recognition for work that's well done	3.48 ± 0.904	0.862
Cronbach's alpha (P value): 0.936(<0.01)		

Q5) Teamwork and Cooperation		
Q5 a) At work, I have a close friend for sharing work/personal related issues	3.78 ± 0.980	0.862
Q5 b) I feel part of a team working towards a shared goal	3.48 ± 0.967	0.857
Cronbach's alpha (P value): 0.982(<0.001)		
Q6) Organizational culture		
Q6 a) I believe my job is secure	3.41 ± 0.965	0.909
Q6 b) I can keep a reasonable balance between work and personal life	3.23 ± 1.043	0.862
Cronbach's alpha (P value): 0.958(<0.01)		
Q7) Your immediate Superior		
Q7 a) My superior treats me fairly & with respect	2.43 ± 1.008	0.947
Q7 b) My superior gives frank feedback at regular intervals	2.71 ± 1.066	0.921
Q7 c) My superior asks me for my input to help make decisions	2.42 ± 1.056	0.924
Cronbach's alpha (P value): 0.953(<0.01)		
Q8) Training and Development		
Q8 a) On boarding / Induction training is adequate	2.60 ± 1.271	0.921
Q8 b) Unit provides ongoing training as I need	2.60 ± 1.239	0.924
Cronbach's alpha (P value): 0.967(<0.01)		
Q9) Facilities, restrooms, recreation & welfare		
Q9 a) Employee dining	2.42 ± 1.075	0.967
Q9 b) Restrooms	2.40 ± 1.119	0.96
Q9 c) Welfare Activities	2.58 ± 1.056	0.952
Cronbach's alpha (P value): 0.962(<0.01)		

As can be observed from table 1, the mean scores (on a scale of 1-5) are largely on the lower side and in none of the questions the mean is 4 or above. Hence the current employees seem to score between low and moderate range on factors crucial for retention. Further, some factors had a marginally higher score like Career Development, Recognition and rewards and Teamwork and Cooperation, whereas remaining factors had a lower score.

The instrument was highly reliable with an overall Cronbach's alpha of 0.97 ($p<0.001$). All the questions were strong as shown by the alpha if item deleted values.

The satisfaction levels of the employees could be analyzed through the mean results. None of the results were strong enough stating their high satisfaction.

Past Employees: Exit interview data was obtained from the organization and analyzed for the 150 employees who had already left the organization. Out of these 150 employees, 65(43.33%) were males; 80 had worked in the organization for 3 months, 16 for 6 months, 22 for 1.5 years and remaining 11 for almost 2 years. The employees were working in different departments during their service like 19 in administration, 18 in customer care and 13 in Support services. The reasons mentioned by them in their exit interview are given in table 2.

Table 2: Department-wise reasons for leaving the organization

Reasons for leaving	Doctors and nurses	Administrative department	Customer Care	Support services	Total
Supervisor behavior	21	6	15	1	43
Better Opportunity	8	1	0	4	13
Lack of coordination, pressurized by organization	15	9	3	1	28
Salary issues	18	1	0	4	23
Extreme work pressure	5	2	0	0	7
Night shifts/odd duty timings	6	0	0	0	6

Bad accommodation	18	0	0	0	18
Personal reasons	5	1	0	3	9
Absconding	3	0	0	0	3
Total	99	20	18	13	150

From the above table it can be observed that maximum i.e. 43 employees left the organization due to their supervisor`s behavior. Only about 12 to 14 employees left the organization due work pressure and odd shift timings. Lack of coordination in the organization was another major reason for the employees leaving the organization. Hence it can be construed that employee dissatisfaction was majorly due to the lack of coordination and support from their supervisor.

DISCUSSION

This study demonstrates the various reasons for employee attrition in the organization. Supervisor behavior alone constituted 28.67% of the total people having left the organization, followed by lack of coordination which led to 18.67% of the employees to leave the organization. A previous study stated that 52% of the nurses left due to lack of support from the management.[4]

Turnover was highest in the nursing department and predominant reason was supervisor behavior. The results of above study revealed that management and supervision are the most important predictors of job satisfaction and organizational commitment of the employees towards the organization. Every organization needs to encourage its employees by offering them the salary of their worth. Salary issues were also one of the determining factors for employee attrition.

A failure to do so has been clearly one of the crucial reasons for an employee to leave the organization. A previous study[5] has shown that insufficient remuneration forces employees to look for better opportunities. Other reasons due to which employees left the organization included extreme work pressure, Night shifts/odd duty timings, accommodation issues and other personal/ family problems.[6]

We have observed that the employees were dissatisfied with the communication pattern, their supervisors' behavior and less focus by organization on their training and development. Similar observations have been reported by past studies done on employees leaving the organization.[7-9] The analyzed data shows a clear indication that it is important to retain the employees as the problems due to which they are leaving can be catered with understanding their needs and providing them with a necessary benefit.

Adhering to collective retention strategies the issues can be solved. These strategies may involve: Implementing appropriate salary and benefit programs, providing them with optimal workload, offering them flexible working hours, maintaining good working conditions by introducing positive work culture so that an employee is at ease and not stressed while working and good supervisor behavior.[10,11]

A regular check should be done to see that there is no miscommunication between the top management and employees because a wrong message is really dangerous. Regular and justified appraisal at the right time is one of crucial ways to retain an employee. If the employee feels recognized his or motivation increases and the organization benefits from this approach.

CONCLUSION

We conclude that an effective system to monitor the supervisor's behavior with the employees is an absolute must for the hospital. This will ensure that the employees are well behaved with and that they feel happy working for the organization. A complaints redressal committee should meet on a monthly basis to address the problems that the employees face. There should be an effective and regular training programme conducted for on board employees.

The hospital should come up with more employee engagement activities which enhances the team spirit amongst them. Employees at any level, wouldn't want to stay if they are not involved in decision making, especially if it is in their area of expertise. Thus, they should be asked for their opinions and be involved in the decision making process. Favoritism and partiality should not be encouraged whatsoever as it creates divide. There should be a better system of recognizing the employees for their work. 'Star employee' etc. should be practiced on a regular basis.

Ethical clearance: No need

Source of funding: Self

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Performance of CBE and Mammography for Breast Cancer Screening in Indian Setup

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ABSTRACT

Introduction: Detecting Breast Cancer (BC) early is critical for providing effective treatment, thereby, reducing the disease burden and mortality. Common methods used for BC screening are Clinical Breast Examination (CBE) and Screening Mammography (SM). CBE is affordable, but gives inconsistent results, while the expensive SM has better chances of detecting cancer at the early stage.

Purpose: To compare the performances of CBE and SM in an ongoing BC screening programme in Pune city

Methodology: We have created a Mobile Cancer Screening Unit which operates in Pune city with a team of trained health personnel who reach out to women in the community and impart awareness on BC. After obtaining consent and relevant clinical history, CBE and SM are performed on all eligible women aged between 40 to 70 years. While CBE findings are recorded on the spot, the SM images are made available to the radiologists at the center for reporting. All abnormalities detected are recalled to the center for further diagnostic follow-up. Retrospective data was collected for the period of June to November 2016 for this study.

Results: Among 852 total women who were screened for BC, 300 women were screened positive. Among which 117(13.73%) were CBE positive, 106(12.44%) were SM positive and 77(9.03%) were positive on both tests.

Keywords: *Breast cancer, CBE, early detection, mammography, screening*

INTRODUCTION

Breast cancer (BC) is one of the most common cancers found in women across the world. It is the second most common cancer across the globe with an estimate of 1.67 million new cases around the world in the year 2012 which constitutes 25% of all cancers (Ferlay *et al.*, 2012). In India, around 1.4 lakh new BC cases are diagnosed annually and around 70 thousand deaths occur due to BC each year (Ferlay *et al.*, 2012). BC accounts to one fifth of the cancer related deaths in India. Incidence rate of the breast cancer in India among the age group of 35-70 years is 40-50 per 100,000 women and rate of mortality is 15-20 per 100,000 women[1].

BC incidence rate in developing and developed countries is high and comparable. However, the incidence to mortality ratio in developing counties is more than that of developed countries (Ferlay *et al.*, 2012). For instance, the incidence-to-mortality ratio in India is 2:1, while that of USA is 4:1. This means in India, every alternate woman who is diagnosed with breast cancer succumbs to it within the first five years after diagnosis. The possible reason for this difference of incidence-to-mortality ratio between the developing and developed countries is attributed to inadequate medical infrastructure, particularly for early detection and management of BCs[2].

While most of the BC in the western population are detected in early stages (i.e, stage I or stage II), in India, BC are usually detected in advanced stages (stage III, or IV). BC detected in advanced stage are difficult to treat and less curable[3]. On the contrary, if BC is detected early, it is easily treatable with lesser treatment costs[2]. Furthermore, patients with BC detected early also have been shown to have better life expectancy than those detected in later stages[3].

The risk factors associated with BC can be classified as uncontrollable risk factors and controllable risk

factors. The uncontrollable risk factors are those which cannot be controlled or modified by a woman, include old age, menstrual status - early menarche and late menopause, family history of BC and genetic mutations (for e.g., in genes such as BRCA 1/2). The controllable risk factors are those which can be controlled or modified by woman, include pregnancy - late first pregnancy or no pregnancy, lactation - short duration of lactation or no lactation, use of hormone replacement therapy (HRT), high fat diet, sedentary lifestyle, high alcohol intake and obesity[2].

Increasing BC awareness and implementing BC early detection methods have been recommended by the WHO as effective means of tacking the disease. BC screening programs play an important role in early detection of the disease. In many cases, the BC lumps are painless and fixed to the chest wall and can cause skin thickenings due to which they are difficult to get noticed[2]. Therefore, a woman needs to be made aware of such symptoms and the various presentations of BC to be able to detect lump by breast self-examination (BSE) which will help detect cancer in its early stages.

The most popular community screening techniques for breast cancer are Clinical Breast Examination (CBE) and Screening Mammography (SM). CBE is a thorough and systematic visualization and tactile palpation of breast done by doctors or trained primary healthcare professionals. SM is an imaging technique which uses low energy x-ray photons to diagnose and locate tumors of the breast. The sensitivity of CBE is low (28-54%), but specificity is high (94-99%). Also, CBE is cost effective and does not require any specific instrument or device , but its contribution in mortality reduction is yet unknown[1,2].

It has been studied through randomized controlled trials, that on an average SM is known to reduce BC mortality by 23% in women, making it the only method shown to reduce mortality[4]. It has the ability of detecting non-palpable lumps at a very early stage. The sensitivity of SM varies from 64% to 90% and specificity from 82% to 93%. However, for dense breasts, the sensitivity of SM reduces[5], and hence in women with dense breasts, Ultrasonography (USG) or Magnetic Resonance Imaging (MRI) have been recommended. In India, MRI is a cost-prohibitive option for screening and based on the dismissal of writ filed in high court by Maharashtra State Branch of IRIA, ultrasound machine cannot be used as a portable device[6], thereby, making it unsuitable for a community based screening program.

The time interval between two subsequent breast cancer screenings can extend from one to three years. During this interval, slow growing or fast growing lumps may appear which may have a better or poor prognosis, respectively. Therefore, it is very important that women are educated about such issues and be given training of SBE during screening intervals.

Since preliminary evidence suggests downstaging of the disease after CBE-based screening, it is recommended that this screening modality should be considered for population based BC screening in low-resource setting along with diagnostic ultrasound. It is also recommended that when SM is a realistic option, it should be used in age groups where mortality reduction and relative-risk ratios are highest[1].

Prashanti Cancer Care Mission (PCCM) has been conducting a BC community screening program in Pune for the past one year. The 3-tier program involves BC education and awareness, screening via CBE and SM in mobile screening units, and appropriate medical follow-up for screen-positive women.

In this paper, we present the comparative pilot study of both CBE and SM in an Indian setup. It is expected that this study will provide insights in designing the suitable models for BC screening in India.

METHODOLOGY

Since February 2016, PCCM in association with Tata Trusts initiated a community screening project to screen women population in the areas of PMC and PCMC for BC. In this paper, we are presenting data from a representative period of six months from June 2016 to November 2016.

Each woman enrolled in this program underwent both the breast cancer screening tests, CBE and SM.

Inclusion Criteria: Women between age group of 40-70 years with intact breasts

Exclusion Criteria: Women below age 40 years, who are not menstruating, pregnant or lactating

This screening project was carried out on three different levels–

(a) Primary level: BC education and awareness in the community

The social workers of PCCM conducted awareness program for BC in the community. The women were informed about BC, its risk factors and were trained for performing BSE. They were informed about the techniques which are used for BC screening, following which they were invited for the BC screening camp.

(b) Secondary level: BC screening by CBE and SM

The BC screening camps were held in the community where a fully equipped mobile mammography van was employed. The mobile van was equipped with an analogue mammography unit (GE Alpha RT), a cassette reader (Carestream) and an examination table for performing CBE.

Women giving informed consent were invited to participate in screening camps and were assigned unique ID number. Relevant medical history was obtained from the participants that included reproductive history - number of births, duration since last pregnancy, period of lactation, history of breast surgery and family history of BC and/or other cancers. The screening tests, CBE and SM, were then performed by trained professionals according to standard operating procedures.

Technique of CBE: CBE involves visual inspection and palpation of the breasts. Visual inspection involve observations for any changes or deviations from normal including asymmetry; skin changes - dimpling/skin retraction, discoloration, ulceration and inflammation of skin; nipple inversion; and scarring tissue (figure1 (a)). Visual inspection is performed in three different sitting positions: (1) hands on hips; (2) hands on hip and leaning forward; (3) hands kept over the head.

After visual examination, the breasts are palpated (figure 1 (b)) when subject is in supine position and hands are kept over the head to flatten the breast to check for palpable lumps, tenderness, and axillary nodes. With the help of pads of middle three fingers the whole breast is palpated in a coin sized circular movement. A parallel pattern is followed starting from supra-clavicular region to inferior fold of breast and from mid-axillary line to sternum. Axilla is palpated for axillary nodes in sitting position and by raising arm till shoulder level (figure1 (c)). Nipples are checked for bloody or clear discharges by squeezing the breast and the nipple (figure 1 (d)).

Observations of CBE are documented and reported as normal (screened negative) or abnormal (screened positive).

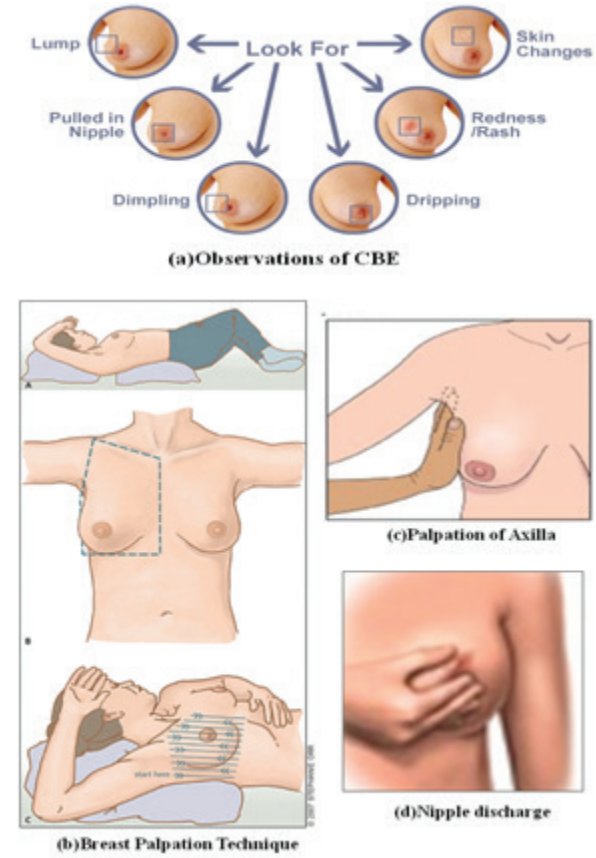


Fig. 1: Observations of Clinical Breast Examination (CBE) and palpation Techniques during CBE (Knutson et al., 2007, Kingcheta)

Technique of Screening Mammography (Figure 2): Only women above 39 years of age are screened with mammography by trained female mammography technologists on an analogue mammography unit (GE Alpha RT). Each mammography test comprises of four views, right cranio-caudal (RCC), left cranio-caudal (LCC), right medio-lateral oblique (RMLO), and left medio-lateral oblique (LMLO).

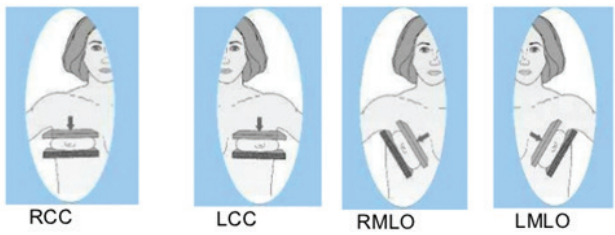


Fig. 2: Views of Mammography (Khare 2014)

Mammography images were acquired using cassettes. The intensifying screen of the cassettes was read by a cassette reader (Carestream) after exposure of x-rays and the image was displayed on monitor screen. These acquired images were then transferred to Orchids Breast Health Clinic (OBHC) for analysis and reporting by an expert panel of radiologists. Final reports were generated with appropriate BIRADS (Breast Imaging-Reporting and Data System) classification and follow-up advice. BIRADS is a risk assessment classification, widely used for reporting of mammography, ultrasound and MRI of breast. This system classifies the breast lesions into six categories[7]:

- BIRADS 0: Incomplete study, further evaluation needed
- BIRADS I: Negative/Normal
- BIRADS II: Benign findings
- BIRADS III: Probably benign
- BIRADS IV: Suspicious abnormality
- BIRADS IVa: Low level suspicion for malignancy
- BIRADS IVb: Intermediate level of suspicion for malignancy
- BIRADS IVc: Moderate level of suspicion for malignancy
- BIRADS V: Highly suggestive of malignancy
- BIRADS VI: Known malignancy proven by biopsy

Definition for Screened Positive Results: Presence of palpable lump, tenderness on palpation, inverted nipple, nipple discharge (serous/sticky and bloody), dimpling, discoloration on breast and palpable axillary nodes were considered as abnormal findings and reported as positive CBE (McDonald *et al.,* 2004). Cases with BIRADS 0, IV and V were reported as positive on mammography.

(a) Tertiary Level: Women screened positive on CBE and SM were recalled at OBHC for further investigations such as sono-mammography, 3D Tomography and additional spot-magnification views on mammography. All recalled patients were evaluated and consulted by a Breast onco-surgeon. If the lesion was benign, necessary intervention/ medications and follow-up was advised. Patients with suspicious lesions underwent biopsy and additional investigations as applicable. Cases that were diagnosed as malignant were given further line of treatment at OBHC.

Training and Quality Maintenance: All mammography technicians and nurses working on the project were trained for CBE using structured modules and artificial simulators (silicon breast models). After evaluating the performance of the screening project staff they were sent on the BC screening camps. Refresher trainings and re-assessments were carried out periodically. Quality control measures for mammography machine were carried out according to the standard recommendations of manufacturers.

RESULTS

In this paper, we present the interim data for the duration of 6 months (June 2016 to November 2016). During this period, 82 camps were conducted in which 852 women, aged between 40 to 70 years, were screened for breast cancer. As per medical guidelines, only women above 40 years of age are eligible for screening mammography. Therefore, the study population represents only those women above 40 years who have undergone both CBE and SM. Table 1 summarizes the medical, reproductive and lactating characteristics of the women who participated in breast cancer screening.

Table 1: Overview of medical history of the women who came for screening

Sr. No.	Parameter	Numbers	%
1.	Average age of women in the sample population	48.38 yrs	
2.	Average total number of births per woman	3	
3.	Average total number of pregnancies per woman	2	
4.	Lactation period: No breast feeding	68	7.98%
5.	Lactation period: Below 6 months	13	1.52%
6.	Lactation period: 6 months and above	771	90.49%

7.	Use of oral contraceptives	58	6.80%
8.	Use of Hormone Replacement Therapy	40	4.69%
9.	Women who underwent BC screening previously: CBE	134	15.72%
10.	Women who underwent BC screening previously: Mammography	85	9.97%
13.	Women who underwent BC screening for the first time	709	83.21%
11.	Family history of breast cancer in sample population	52	6.10%
12.	Family history of any other cancer in sample population	93	10.91%

According to this demographic report, average age of participating women was 48.38 years; average total number of births was three, and average total number of pregnancies was two. 1.52% women had breast fed for less than 6 months, whereas 90.4% of women breast fed for six or more than six months and 7.9% of women had never breast fed. Among the study population, 83.2% of the women underwent breast cancer screening for the first time and 15.7% and 9.9% had previously undergone CBE and SM respectively. Family history of breast cancer was seen in 6.1% of the women.

Results of the screening were recorded according to three classifications:

1. Screened positive on CBE only (i.e, abnormal CBE, normal SM);
2. Screened positive on SM only (i.e, normal CBE, abnormal SM);
3. Screened positive on CBE and SM (i.e, abnormal CBE and abnormal SM)

The data of screened positives from CBE and SM amongst the women screened in 82 camps is summarized in Table 2.

Table 2: Screened positives of Clinical Breast Examination (CBE) and Mammography

Total women screened: 852 **Age:** 40-70 years			**Period:** June – November 2016
Parameters	CBE	SM	Both tests (CBE+SM)
Screened positive/ recall rate	117	106	77
	13.73%	12.44%	9.03%
Cancer cases detected	0	0	1
	0%	0%	1.36%

Among 852 women screened for BC, 300 were screened positive (figure 3). Among the screened positive cases, 117 (13.73%) were positive on CBE, 106 (12.44%) were positive on SM and 77(9.03%) cases were positive on both tests. Among all these screen-positive cases, only one case was found to be positive for BC. This case was found to be positive on both CBE as well as SM.

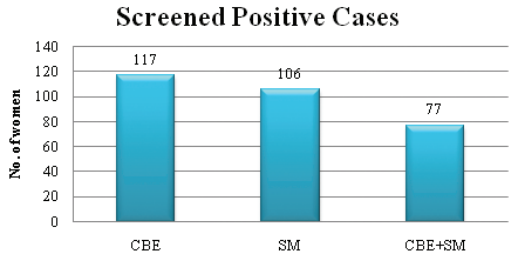


Figure 3: Results for screened positive cases of Clinical Breast Examination (CBE) and Screening Mammography (SM)

DISCUSSION

In India, incidence of BC is as high as 1.4 lakh per year with highest mortality conversion in the world of around 70,000 deaths. This is attributed to late-stage detection and poor treatment outcomes. World-over, BC mortality reduction has been shown by implementing early detection methods with help from appropriate screening techniques. Indeed, many countries have adopted national BC screening programs by employing the technique of CBE and SM. Mammography screening is recommended for every woman once she crosses the age of 40 years because of the increased risk of BC due to age related risk factor and also because of the density of the breast[1].

In Canada, BC screening programs involve use of both CBE and mammography. In a research study emerging

from the Canadian BC screening program, screening only with CBE detected 4.6-5.9% of BC, while 60-64% of BC was detected using mammography alone. Among those cancers detected by CBE, 83-88% was also detected on mammography. Similarly, 31-37% of BC detected on mammography was also detected on CBE[8].

In India, CBE-based community screening trials have shown low sensitivity and high specificity towards early detection of BC to CBE[1,9]. An ongoing study in Mumbai has demonstrated significant down-staging of the disease after CBE-based screening. However, the effectiveness of CBE in reducing BC mortality has not yet been established[1,2].

In India, most of the BC screening programs are based on CBE as the only screening modality[1,9]. To the best of our knowledge, the BC screening program in Pune is different as a combination of both CBE and SM is employed for community based BC screening in women above age 40 years. In this study, only 9.9% and 15.7% of women were reported to have previously undergone mammography and CBE, respectively. Thus, remaining 90% and 84.2% of women from sample population had never undergone mammography and CBE, respectively prior getting enrolled into this screening program. This indicates that 83.2% of women from study population were undergoing BC screening for the first time.

Invasive Ductal Carcinoma (IDC) represents a much-developed stage of BC in which the breast lump becomes palpable on CBE[3]. If BC is detected early, before it manifests as a palpable lump, it can be easily treated with lower medical costs. Such patients are also expected to have better quality of life and life expectancy. Screening mammography can detect ductal carcinoma *in situ* (DCIS), the non-palpable stage of BC, which if left untreated may or may not develop into IDC. Indeed, several reports based on RCTs have indicated that SM can reduce BC-associated mortality by about 30%. Twenty-two developed countries in the world have adopted national BC screening methods based on mammography.

However, mammography also has some disadvantages. A mammographically-detected DCIS may develop into an IDC or maintain the status quo as an indolent DCIS throughout the lifetime of the women. In the absence of other diagnostic or pathological tests to predict the trajectory of DCIS, all cases of DCIS have to be surgically treated and may need further medical management. Over diagnosis and overtreatment for mammographically-detected DCIS remains a major criticism against the use of this screening modality in BC screening[10].

Another drawback of mammography screening is its limitation in appreciation of dense breast tissue[2]. If the tissue is dense, the lumps cannot be appreciated well and could be missed out. Studies shows that around 3-45% of BCs were detected on CBE, which were missed out on a mammogram[8,11]. This limitation is particularly important in the Indian context as Indian women have been reported to have denser breasts as compared to other ethnicities.

Despite these disadvantages, there is no denying the impact of SM on mortality reduction. Indeed, SM has been the screening modality of choice in developed countries. For developing countries like in India, mammography based BC screening poses the problems of accessibility, feasibility and affordability[1]. In this screening program operational in Pune, at least one of the difficulties, i.e., accessibility was addressed and resolved. Mammography was made available to the women in the community at their door step through the mobile van. The cost-effectiveness and affordability of mobile mammography vans is being studied.

In general, it is recommended that BC screening programs should have maximum cancer detection and minimum recall rates[8]. In this study, we can see that the recall rates for CBE are higher than the recall rates of mammography. This data suggests that CBE alone as a screening modality may not be logistically effective for conduction of mass screening programs in settings where medical infrastructure is unavailable to handle the high load of patient recalls.

Few reports have debated the use of CBE complimenting mammography for early detection of breast cancer[8,9]. These studies have found minimal contribution of CBE towards increasing impact of mammography for early detection of BC. However, in this study we were able to identify one positive BC case out of 852 women screened. This case was identified as highly suspicious by both CBE as well as mammography indicating that both tests may complement each other.

The major limitation of this study was high drop-out rate for post-screening follow up. Carefully designed

protocols were implemented to ensure that screen-positive women were recalled to clinic for further investigations. However, many screen-positive women did not comply with the advice and did not undergo follow-up testing to further investigate the nature of breast abnormality observed during screening. Indeed, BC community screening programs in India will be successful only if public education and awareness components are embedded in the work-flow and logistics of such multi-step programs[2].

The current data represents a pilot study with limited duration and limited sample size. In order to substantiate our preliminary observations, further work will be needed. Further data collection and analysis is underway on this ongoing 2-year BC screening project in Pune city.

CONCLUSION

Despite their limitations, CBE and SM are the only available options for community BC screening in women above age 40 years. Mammographically-inaccessible lumps present in dense breasts can be identified by CBE. Small lumps which are not palpable by CBE can be identified by mammographic images. So to avoid missing out of any lumps both the techniques should be used for screening of breast cancer.

Thus, we can say that these two screening modalities can complement each other towards effective identification of BC-related abnormality. The potential impact of dual-modality of CBE and SM in BC community screening programs needs further exploration.

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Source of funding: Self

Conflict of Interest: Nil

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Understanding Impact of Unhealthy Lifestyle Choices and Cognitive Ability in College Going Students at an Indian Higher Education Institute

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ABSTRACT

Introduction : The growing problem of stress, obesity, insomnia and lethargy among young adults is a huge concern today. Unhealthy lifestyle choices are shown to cause adverse consequences on physical health. The cognitive ability of college students is also affected further as they indulge more into such activities.

Purpose: The present study attempts to understand the correlation between stress, sleep, exercise and diet on cognitive ability amongst the college students.

Research Design: A cross-sectional study was conducted amongst the college students in Indian setup for a period of one month. Random sampling was used to collect data from 60 samples. The questionnaire on lifestyle focused on factors such as exercise, diet, stress, smoking, drinking, sleep habits etc. as section A. Section B focused on certain typical questions related to ability to remember and applying simple logic. Quantitative and qualitative data analysis was done using SPSS version 21.

Results & discussion: It was observed that most of the students under study are in the normal stress range between 4 and 7{range included: 1-3, 4-7 and 7-10(low, moderate and high)}, maximum students get adequate amount of sleep depicting no case of insomnia. Further, students who get optimum sleep between 6 to 7 hours, are found to be in the stress range between 4 to 7. Relationship between stress and cognitive ability showed that low stress levels improves memory and thinking capabilities as the majority of the students in the low stress range scored the highest memory test points.

Research implications: Study shows a cumulative association of stress levels, sleep patterns, consumption of fruits and vegetables, low physical activity level with poor cognitive function, this can be further utilized to develop programmes focusing on improving the well-being.

Originality: Assessing relationship between diet, stress, sleep and cognitive ability

Keywords: *Correlation, stress, lifestyle, cognitive ability.*

INTRODUCTION

The growing problem of stress, obesity, insomnia, lethargy and susceptibility to infections among young adults is a huge concern in today's world. Unhealthy lifestyle choices such as poor diet, no physical activity, lack of sleep, stress, sedentary living etc. are shown to cause adverse consequences on physical health, including risk for obesity, type 2 diabetes, stroke, cholesterol, high blood pressure and cardiovascular disease[1]. In the recent past, these unhealthy lifestyle choices are found to also affect the brain health which includes risk of premature cognitive aging and also Alzheimer's disease. Unhealthy lifestyle and behaviour also include smoking, misuse of illicit drugs, excessive alcohol consumption, consumption of sugary foods and over-eating are most commonly used because they are effective in managing stress[2].

As per Fernand Gomez, diet, exercise and sleep have potential to alter our brain health". Other studies, also pin out that certain dietary deficiency in humans is associated closely with increased risk of several mental disorders.

Usually people find it very difficult to get rid of these behaviours as they can be very addictive. As a matter of fact, health factors and bad lifestyle choices

might not affect the brain and its functionality until their effects have accumulated for many years, but it is equally possible that early adoption of these choices may cause these effects to manifest earlier in life and also cause long term cognitive defects (UCLA, 2014) and since most of the college going students take their habits related to these primary functions very casually, there is a steep rise in such cases.

Studies have demonstrated that nutrition affects students' thinking skills, behavior, and health, all factors that impact academic performance. Research suggests that diets high in trans and saturated fats can negatively impact learning and memory, nutritional deficiencies early in life can affect the cognitive ability[3]. An important finding from a study conducted in US pointed out that individual's overall behaviour is result of its interaction in micro environment, which consists of workplaces, schools etc., in this case higher-education institute(college) and macro-environment which includes food- industry, government, society's attitude and beliefs.

Variables related to lifestyle:

- Lifestyle is defined as, 'a pattern of individual practices and personal behavioural choices that are related to elevated or reduced health risk[4]. Therefore, an active and healthy lifestyle is a pattern of individual practices that include good nutrition, regular exercise, adequate sleep and proper stress management.
- Memory is "process of retaining information over time[5].
- Physical activity - Regular exercise affects brain function by conveying beneficial effects on memory function independently of its intensity, possibly mediated by local gray matter volume and neurotrophic factors. Many studies have suggested that the parts of the brain that control thinking and memory (the prefrontal cortex and medial temporal cortex) have greater volume in people who exercise versus people who do not have any sort of physical activity[6].
- Sleep is the time of reduced physical activity wherein the bodies self-repair occurs and rejuvenation of cellular tissue takes place. It plays a crucial role in brain development and growth as memory consolidation occurs during sleep[7]. Sleep affects learning and memory. Studies have revealed that people who get adequate sleep at night are seen to perform better both at work and all other day to day tasks.
- Stress is also referred to as psychological distress or emotional distress. Severe stress lasting weeks or months can impair cell communication in the brain's learning and memory region. Increased stress hormones lead to memory impairment in the elderly and learning difficulties in young adults.

Thus, there are many factors that contribute in developing one's healthy/unhealthy habits leading to certain type of lifestyle. With this objective, the present study was conducted to understand what kind of unhealthy lifestyle choices the students have or pick up which may have an impact on their cognitive ability.

RESEARCH DESIGN

The questionnaire for the purpose of the study was prepared keeping in mind the day to day lifestyle choices and how they affect the memory in urban college students. The study was conducted for a period of one month from August 2016 to September 2016. Random sampling method was employed to collect data from the students and was assessed statistically to deduce a relation between bad lifestyle choices such as high stress level, fewer hours of sleep, no physical activity, etc. Total 60 students responded to the questionnaire. This was followed by 3 focus group interview to assess the impact on lifestyle choices and cognitive ability.

A structured questionnaire was developed to address the research objective. The students were being explained the objective and invited to participate voluntarily. Informed consent was taken from all the participants before inclusion in the study. The questionnaire had three sections apart from the baseline variable information which included gender, age, height, weight and body mass index (BMI). Section A had question on general health and eating habits, section B had questions on physical exercise and section C was on stress and sleep. For the stress criteria, students were asked to rate their stress level from 1-10, where 1 is the lowest and 10 is the highest. The ranges were given as 1-3, 4-7 and 7-10(low, moderate and high)

The focus group conducted concentrated on understanding habits of individuals and also to understand their cognitive ability and comparing vital activities like sleep, physical activities and memory recall with stress levels. Each student individually filled out the questionnaire and it was later on compiled and interpreted to give conclusive results. The data was collected, collated and summarized into a frequency table for interpretation and presentation. Comparison table of stress levels with sleep hours, physical activity and memory were also calculated and tabulated.

RESULTS AND DISCUSSION

A total of 60 students were included in this study, of them, as per table 1, (46%) were male and (54%) were female. All the study subjects were in the age group of between 18 and 26 years with mean age 23.4 years. (59 %) were undergraduate students and remaining (41%) were pursuing their post-graduation. About the dietary habit, (54 %) of the study subjects were non-vegetarian. (68 %) were hostellers along with (18 %) staying as paying guests. Further as per World Health Organization (WHO) classification of BMI for Asian adults, the responders were classified as normal (15%), slightly overweight (10.9%), overweight (25.2 %) and obese (12.6%).

Table 1: Socio-Demographic details of the respondents:

Sr. No.	Variables		% (n= 60)
1.	Age (yrs.)	18-20	6
		21-23	60
		24-26	34
2.	Gender	Male	46
		Female	54
3.	Education	Undergraduate	59
		Postgraduate	41
4.	Dietary Preference	Vegetarian	46
		Non-Vegetarian	54
5.	Current Residence status	Own House	14
		Hostel	68
		Paying Guest	18
6.	BMI	Normal	51.3
		Slightly Overweight	10.9
		Overweight	25.2
		Obese	12.6

Table 2: Lifestyle practices of students-self-perception

Sr. No.	Variables		% (n = 60)
1.	Overall health rating	Bad	3
		Fair	55
		Good	52
2.	Smoking	Yes	56
		No	44
3.	Frequency of smoking per day	1-5	78.4
		5-10	17.1
		More than 10	4.5
4.	Alcohol	Yes	67
		No	43
5.	Frequency of alcohol consumption	Once a week	10
		More than once a week	3
		Once a month	54
6.	Meals per day	Two	59
		Three	22
		>Three	19
7.	Eating out	Rarely	14
		Twice a week	34
		Once a week	26
		> two times a week	36
8.	Consumption of processed food	Daily	28
		Twice a week	42
		Once a week	30
9.	Consumption of fruits	Rarely	51
		1 per day	28
		2 per day	21
10.	Frequency of exercise	Daily	18
		3-4 days/wk	41
		Nil	27

Further the responders were asked about various parameters related to their lifestyle and their perception regarding the same as indicated in table 2. For this, (3%) believed that their overall health was bad whereas (55 %) believed it was fair and (52%) as good, this perception was based on their own perception, largely depending upon their frequency of falling sick. (56 %) were smokers while (44%) were non-smokers. Amongst the candidates who smoked (78.4%) smoked between 1-5 cigarettes per day, (17.1%) between 5-10 and remaining (4.5 %) smoked more than 10 per day. Regarding alcohol consumption, (67 %) consumed out of which (54 %) at least once a week followed by (3

%) once in 15 days and (10 %) once a month. The most common reasons for drinking alcohol were to drink with friends, for enjoyment and growing party culture where consuming alcohol is taken as a norm. Thus, social drinking and peer pressure could be an important factor for exposure to tobacco and alcohol (9). Majority of the subjects have poor dietary habits where (59 %) consume only two meals per day. It is also seen that tendency of consuming junk food is also high with (28 %) consuming it daily and (42 %) more than twice a week followed by low consumption of fruits by (51 %). For frequency of exercise, (27%) do not perform any exercise, however it is heartening to note that (18%) do exercise on daily basis and 41 % perform some or the other form of exercise for three days a week. Majority of the reasons stated for not performing exercise include lack of time and place.

Further, the responders were also asked to rate their stress level on scale of 1 to 10. Fig.1 depicts the distribution of range of stress from low {1-3}, moderate {4-7} to high {7-10}.

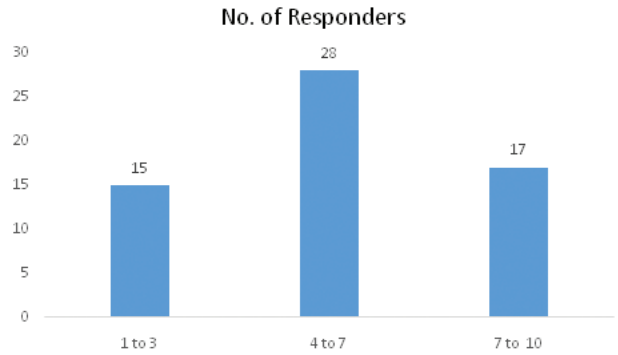


Fig.1: Stress levels among college students

As per fig.1, here the maximum numbers of responders (28 students) are in the intermediate stress level i.e. 4 to 7 that is considered a normal stress range. Low stress levels and high stress levels had 15 and 17 students respectively. It is evident from various researches that stress can have detrimental effects on both physical and mental health. Acute and short-term stressors, such as continuous loud noise, heat, and sleep deprivation, are known to impair a wide range of cognitive abilities, ranging from attention to implicit and procedural learning. Stress induced in college student and adult population increases interference from irrelevant information, impairing selective attention and working memory resulting in reduced ability to pay attention to, keep track of, or remember steps in the task at hand. The students having unhealthy lifestyles are more prone to arguments which also are a leading stress factor[8].

Similar to categorizing students based on their stress level, we can categorize students based on their sleep pattern i.e. the number of hours of regular sleep at night. The three categories of sleep hours that were given were - 6 to 7 hours, 3 to 5 hours and less than 2 hours. The range 6 to 7 hours of sleep is considered ideal for a healthy lifestyle. The data obtained was tabulated as follows;

Table 3: Distribution of number of hours of sleep

No. of hours of sleep	No. of students
6 to 7	35
3 to 5	20
Less than or =2	5

In various studies that were conducted, there seemed to be a distinct correlation between stress levels and sleep pattern. Thus in orders to prove a theory, the students were segregated based on their stress levels and their sleep patterns were evaluated.

Table 4: Comparison between stress levels and no. of sleep hours

Stress level	Total number of students	Sleep hours		
		6 to 7	3 to 5	< 2
1 to 3	15	10	5	0
4 to 7	28	17	10	1
7 to 10	17	8	7	2

In the stress range 1 to 3(low stress), there are no students who get less than 2 hours of sleep. Maximum numbers of students, who get optimum sleep between 6 to 7 hours, are found to be in the stress range between 4 to 7 that is optimum.

Further, regular physical activity is very essential for a healthy lifestyle, the data obtained was segregated based on their stress levels and were analysed to see whether or not the population under study include exercise in their day to day lifestyle.

Table 5: Comparison between stress levels and physical activity

STRESS LEVEL	YES	NO
1 to 3	11	4
4 to 7	15	13
7 to 10	5	12

It is seen from the graph that at low (1-3) and optimal stress level (4-7), the number of students that exercise regularly is more whereas at high stress levels (7-10) the number of students who exercise regularly is much less comparatively. Thus it can be inferred that regular physical activity causes lowering of stress levels which in turn drastically affects the overall health of the individual.

There are also evidences which show that practices such as smoking, less physical activity and dietary choice are associated with decline in memory. To assess this, a small memory test was also conducted with the responders. Visual memory test was used wherein first the students were asked to remember 5 symbols and then draw them after it is shown to them for about 5 seconds. These questions access how efficiently the student is able to follow instructions and recall. For Example, in the visual memory test if the student has recalled and drawn all the 5 symbols, he was awarded 3 points, if he drew 4-3 symbols he/she was awarded 2 points and if he has drawn 2-1 symbols he/she was awarded 1 point. This was further correlated to stress levels to test the effects of stress on memory. The results of the same are as shown in table no.6.

Table 6: Memory score sheet and stress levels

STRESS LEVEL	MEMORY SCORES		
	3 points	2 points	1 points
1 to 3	0	6	9
4 to 7	1	16	11
7 to 10	0	4	13

(40 %) from low stress level showed better performance with 2-point score, while (60 %) performed at average with 1- point score. For intermediate stress level nearly (58 %) performed well at memory test as compared to high stress levels where only (23.5 %) performed well scoring 2-point. Thus, the above table clearly indicates that at lower stress levels the students performed better that those students at higher stress levels.

In this study, it is evident that there is a high prevalence of physical inactivity and sedentary lifestyle among the study subjects and unfavourable attitude toward physical activity and could be a major challenge for improving the level of physical activity and healthy lifestyle. The majority of the subjects have poor dietary habit and low fruit and vegetable intake in their daily diet with frequent consumption of fast foods and carbonated soft drinks. There is low and inadequate intake of fruits and vegetables in the majority of the study subjects. As per the WHO recommendation on daily fruits and vegetable intake, we must take at least 3 servings/ day as part of our healthy dietary requirement. Key findings were that a consistently healthy dietary choice was associated with slower memory decline, and that consistently high or increasing physical was associated with lower stress levels.

CONCLUSION

In recent times there is a lot of effort that goes into keeping oneself healthy and fit in order to lead a healthier life. This realization has set in over the years due to influence of televisions, mobile phones, internet and various other social forums. But the mechanism by which healthy lifestyle choices affect cognitive fitness is least understood. In addition to causing obesity, heart disease, depression, diabetes, high blood pressure etc., unhealthy lifestyle also affects the proper brain functioning by affecting the health of the brain cells.

In this survey, only a population of 60 individuals has been considered for study. This conclusion holds good for the group of urban college students considered for this study. However, for larger groups of populations, results and conclusions may vary. For more efficient and accurate conclusions and results, a larger and more diverse group should be considered.

In this survey of comparison between Unhealthy lifestyle choices and cognitive ability in urban college students, students were segregated based on the various unhealthy lifestyle choices such as stress, inadequate sleep, no physical activity and low fruit intake. From “Segregation of population based on stress levels” it is seen that most of the students under study are in the normal stress range between 4 and 7 and from “Segregation of

population based on sleep patterns" show that maximum students get adequate amount of sleeping depicting no case of insomnia in this population. It is found that maximum number of students who get optimum sleep between 6 to 7 hours, are found to be in the stress range between 4 to 7. When these students segregated based on stress levels were assessed on their frequency of physical activity it was found that at lowered stress levels the number of students who have regular exercise is more. These results prove that stress, sleep, exercise and fruit intake are all interconnected and in turn affect the health of an individual.

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Circulating MicroRNAs as Novel Biomarkers for Type 2 Diabetes

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ABSTRACT

Type 2 Diabetes mellitus (T2DM) has become a global health burden. With urbanization, the burden of rapid increase of non-communicable disease such as T2DM has been observed in the recent years in India. T2DM remains asymptomatic and thus delays the actual diagnosis of the disease. MicroRNAs are the non-coding RNAs emerged as the post transcriptional regulators of gene expression and expressed differently under different pathophysiological conditions. They are remarkably stable in body fluids such as whole blood, plasma and serum. Recent evidences indicated that microRNAs are the potent micro-regulators of β-cell functions. The previous studies reported altered microRNA profiles in blood samples of T2DM patients than that of healthy individuals. The differential expression patterns of microRNAs have been reported in the blood samples of prediabetic, newly diagnosed T2DM patients and T2DM individuals. This novel class of non-coding RNA molecules can be considered as the clinically relevant biomarkers to detect diabetes in high risk population. The circulatory microRNAs can be used as novel biomarkers of T2DM and can be used to detect at prediabetic stage. This review aimed to summarize an account of circulatory microRNAs associated with T2DM.

Keywords: *Biomarkers, β cell, Circulating microRNAs, Type 2 diabetes*

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a complex, multifactorial, metabolic disorder characterized by hyperglycemia, relative insulin deficiency and increased insulin resistance. With rapid urbanization and sedentary lifestyle, there is an increased risk of T2DM in India with 65.1 million of diabetic individuals[1]. T2DM increases the likelihood of development of microvascular complications such as nephropathy, retinopathy, neuropathy and macrovascular complications such as cardiovascular diseases[2,3].

The delay in actual diagnosis of T2DM remains asymptomatic and this leads to delay in actual diagnosis of T2DM which elevates the propensity of developing future vascular complications in patients[4]. The existing classical biomarkers of T2DM such as fasting/ post-prandial plasma glucose, oral glucose tolerance test (OGTT), and glycosylated hemoglobin (HbA_{1c}) are used applicable for diagnosis of diabetes and not for prediction and probability of development of diabetes and associated risks in future[5]. Thus, there is an utmost requirement of innovative strategies and non- or minimally invasive blood based biomarkers for early diagnosis of T2DM.

Recent years have experienced the development and progress of microRNAs (miRNAs) as the potential biomarkers of different diseases such as cancer, cardiovascular diseases, and neurodegenerative diseases including T2DM[6]. MiRNAs can be considered as early biomarkers of T2DM that can be used for disease detection at pre-disease or pre-diabetic stage. This review aimed to summarize an account on circulatory miRNAs associated with T2DM and approaches to predict the novel biomarkers for the disease.

MiRNA BIOGENESIS AND FUNCTIONALITY

MiRNAs are the large class of non-coding RNAs comprising of 18-22 nucleotides, emerged as the key regulators of gene expression by either translational repression or target mRNA degradation. MiRNAs bind to their target mRNAs by complementary base pairing to 3' untranslated regions (UTRs) of the later[7]. The biogenesis of miRNAs has been described in figure 1. Briefly, miRNAs are transcribed by RNA polymerase II from introns of non-coding genes or from intergenic regions within the genome as the primary transcripts.

The primary transcripts of miRNAs also called pri-miRNAs are further processed by RNase III type enzyme Drosha and DGCR8/Pasha protein into hairpin shaped precursors called pre-miRNAs comprising of 70 to 100 nucleotides[8]. The pre-miRNAs are then exported to cytoplasm from nucleus by Exportin-5 and Ran-GTP, where the pre-miRNAs are cleaved by another RNase III type enzyme Dicer to generate a miRNA duplex of approximately 22 nucleotides[9]. Upon separation of two strands, the guide strand of mature miRNA binds to an Argonaute protein, assembled into RNA induced silencing complex (RISC), recognizes specific targets and repressing the gene expression of target mRNA. The binding of miRNA to target mRNA depends on the "seed region" which consists of 2-8 nucleotides of miRNA[10]. The passenger strand often gets degraded. A single miRNA can regulate up to 100s of mRNA targets[11]. The impaired biogenesis and functionality of miRNAs have crucial role in development of various diseases[12]. This novel class of non-coding RNAs instigated the researchers to find out their roles in development and pathogenesis of diabetes.

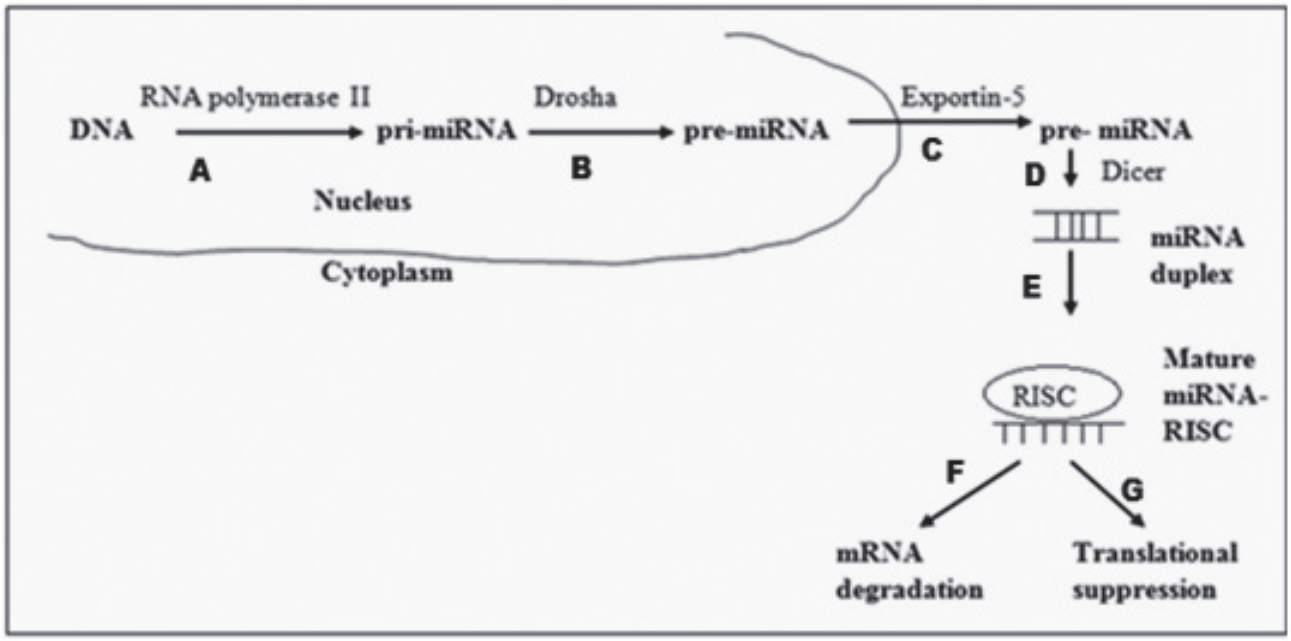


Figure 1: Diagrammatic representation of biogenesis and functionality of miRNA

A) The primary miRNA (pri-miRNA) is transcribed from introns of non-coding genes by RNA polymerase II. B) The pri-miRNA is then processed by RNase III like enzyme Drosha into precursor miRNA (pre-miRNA). C) The pre-miRNA is exported to cytoplasm by Exportin-5 and RanGTP. D) The pre-miRNA is further processed by another RNase III enzyme Dicer to form miRNA duplex. E) On separation of two strands of miRNA duplex, guide strand of mature miRNA is then loaded into RNA inducing silencing complex (RISC) and either F) degrades target mRNA or, G) represses expression of target mRNA.

MiRNAS IN β-CELL PHYSIOLOGY

The β-cells of pancreas play crucial role in pathophysiology of diabetes. Recent years have experienced enormous researches that reported regulatory roles of miRNAs in various cellular processes including development and activities of β-cells. The most highly expressed miRNA in pancreatic β-cells is miR-375[13]. MiR-375 is one of the most studied miRNA in β-cell biology, having inhibitory roles in insulin secretion[13] and compensatory proliferation of β-cells[14]. This highly abundant miRNA in α and β-cells of pancreatic islets[15], mouse insulinoma cells (MIN6 and INS-1)[13,16] however found to be down-regulated in certain types of cancers[17]. Increased expression of miR-375 reported to decrease glucose-stimulated insulin secretion (GSIS) in MIN6 cells[13]. Up-regulation of miR-375 observed to down-regulate the expression of its potential targets such as myotrophin (Mtpn), responsible for insulin exocytosis and phosphoinositide dependent protein kinase-1 (PKD-1), having role in insulin gene expression[18,19]. However, the deletion of miR-375 however resulted in β-cell mass reduction and severe state of diabetes[14]. There are certain β-cell specific miRNAs, such as miR-204 was reported to

have an important role in insulin production[20]. MiR-7a-2 observed to regulate negatively GSIS and β-cell specific deletion of this miRNA increased the insulin secretion[21]. Various other miRNAs reported to have regulatory roles in insulin biosynthesis, insulin secretion, β-cell survival and apoptosis[12] have been shown in figure 2.

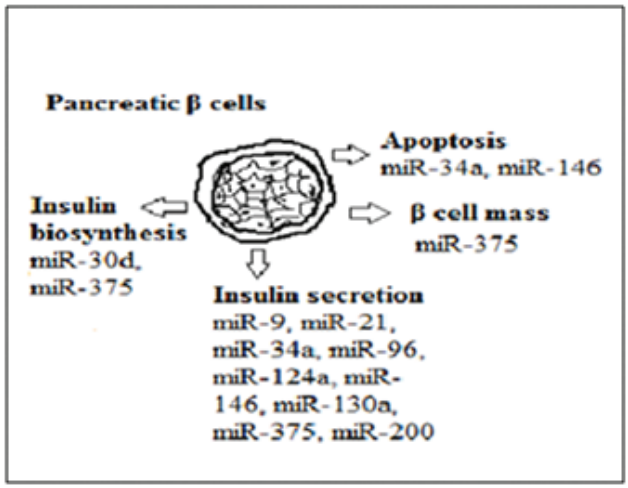


Figure 2: MiRNAs involved in regulation of functions (insulin biosynthesis, insulin secretion) and development of pancreatic β cells (development of β cells and β cell apoptosis)

CIRCULATING MIRNAS IN T2DM PATIENTS

Owing to their remarkable stability in body fluids such as whole blood, serum and plasma, miRNAs can be used widely as biomarkers of different pathophysiological conditions including T2DM[22,23]. The previous studies have reported differential miRNA profiles in the patients' blood as compared to that of healthy individuals[24]. The identification of miRNAs as novel biomarkers of T2DM can screen out individuals at increased risk of developing diabetes at later stage. MiRNAs can ideally diagnose T2DM at much early stage of the disease and may overcome the drawbacks of the existing biomarkers of T2DM in predicting future risk of T2DM complications.

Early diagnosis of T2DM and subsequent management of its pathogenesis can control diabetes worldwide. Recent years have experienced enormous studies on miRNAs in T2DM conditions in model animals, cell lines and human population. The first study in this line was by Zampetaki and co-workers[25], reported reduced expression of plasma miR-126 in T2DM patients. The down-regulated expression of miR-126 found to have role in endothelial dysfunction by targeting Sprouty related protein (SPRED-1)[26]. MiR-126 reported to increase in patients with cardiovascular diseases such as coronary artery disease[27] whereas, significantly down-regulated in T2DM patients with coronary artery disease[28]. The previous reports indicated differential miRNA signatures among pre-diabetics, diabetics, and newly diagnosed T2DM patients[29,30]. A summary of notable miRNAs with differentially expressed in T2DM patients, pre-diabetics and newly diagnosed T2DM patients have been explained in table 1.

Table 1: Differential expression patterns of blood based miRNAs in T2DM patients

Circulating miRNAs #	Sample type	Categories of T2DM patients	Sample size (n)*	References
miR-126 (↓)	Plasma	T2DM cases, T2DM susceptible cases	60	30
miR-146a (↓)	Peripheral blood mononuclear cells	T2DM cases without vascular complications	20	31
miR-146a	Plasma	Newly diagnosed T2DM cases	90	29
let-7a (↓), let-7f (↓)	Plasma exosomes	T2DM cases without vascular complications	18	32
miR-21 (↓), miR-126 (↓)	Plasma	T2DM cases with vascular complications	193	33
miR-103b (↓)	Platelet	Pre-diabetics, T2DM cases with complications, T2DM cases with coronary heart disease	127	34

*n= number of T2DM patients; #↑: Up-regulated miRNA; ↓: Down-regulated miRNA

APPROACHES TO DETECT MIRNAs

MiRNAs associated with the development and pathogenesis of T2DM can be obtained either by *in vitro* and *in vivo* strategies. The i*n vitro* strategies of understanding role of miRNAs in diabetes include exposure of cell lines or isolated primary cells to hyperglycemic condition. The method enables researchers to analyze the signaling pathways and regulatory miRNAs involved in T2DM pathogenesis. The expressions of these miRNAs, having crucial roles in initiation and progression of T2DM, have been widely studied in various model animals such as mice, rats. The most frequently used animal models of T2DM are the ob/ob mice and db/db mice lacking leptin receptors[35,36]. Mice or rats fed with high dietary fat for several weeks are also used as models to study T2DM pathogenesis[12]. Another popular model to study insulin resistance and T2DM is Goto-kakizaki (GK) rats, non-obese Wistar strains[37]. The alterations of miRNA expressions in T2DM condition have also been explored in human samples as described in the previous section.

The blood components are easy accessible sources of studying circulating miRNAs. Various commercial kits are available for extraction of total RNA including miRNAs from blood components. The commonly used miRNAs detection methods include checking of the level of expression of mature miRNAs either by determining the level of individual miRNA or by analyzing the expression profiles of several different miRNAs. The level of individual miRNA can be determined by real time RT-PCR, Northern blotting and in-situ hybridization (ISH), whereas, microarray analysis or miRNA PCR arrays or deep sequencing can be used for simultaneous determination of several miRNAs[38].

CONCLUSION

The current diagnostic techniques, although, are widely used for diagnosing T2DM but these modalities are insufficient to predict the probability of developing T2DM and future risk of vascular complications. The miRNAs have become potential as the micro-regulators of gene expression and are not limited to certain signaling pathways. They are important regulators of β cell physiology and functions. The circulating miRNAs owing to their remarkable stability in blood and differential expression patterns associated with diabetes pathogenesis have instigated them to consider as the potential biomarkers of diabetes. The researches on circulating miRNAs are at an elementary stage. The future work and strategies needs to develop to consider measurement of specific circulating miRNA or miRNA signatures to screen out individuals susceptible to develop T2DM and thus, preventing the development of diabetes.

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Maharashtra Emergency Medical Services Project- Assessment of Efficacy

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ABSTRACT

To reduce morbidity & mortality, Government of Maharashtra decided to offer Emergency Medical Services (EMS) in the state of Maharashtra. This study was aimed to assess efficacy of pre hospital care provided through situational analysis for period of 30 months from 01 January 2014 to 30 June 2016 across all districts of Maharashtra through the MEMS project.

Maharashtra Emergency Medical Services (MEMS) Project is a toll free '108' number based 24 x 7 hours' pre-hospital emergency medical services free of cost to entire population in the state of Maharashtra.

State of art Emergency Response Centre (ERC) is developed at Aundh Chest Hospital Pune. ERC operates 24 x 7 hours through a centrally operated toll free telephone number- 108 which can be dialed from any part of the state.

There is state of the art 937 ambulances (233 ALS and 704 BLS ambulances) operational across Maharashtra capable to provide competent care for the sick or injured in emergency medical settings.

Training was imparted to all Emergency Medical Services professionals (EMPs) working with MEMS by Symbiosis Institute of Health Sciences, a constituent of Symbiosis International University.

Purpose: This study was aimed to assess efficacy of pre hospital care provided through situational analysis for period of 30 months from 01 January 2014 to 30 June 2016 across all districts of Maharashtra through the MEMS project.

Methodology: This study was conducted **during** 01 January 2014 to 30 June 2016 across all 34 districts of Maharashtra. Emergency Medical Services Professionals (EMPs) working on 937 Ambulances respond to emergency calls, perform medical services and transport patients to appropriate hospital as required. Number and type of cases attended by these EMPs every month during the period of study are considered for analysis. Year and district wise data is represented by frequency and percentages. Incident types are represented by descriptive statistics and data is analyzed in SPSS (V.23).

Results: Maharashtra EMS receives on an average 25000 emergency medical calls every month.

The Clinical Incidents are relatively increasing throughout the years from 2014 to June 2016 and a total of 1100 cases were attended during two and half years.

EMS across 34 districts was provided to on an average 32 (min: 22, max: 61) clinical cases per district with incidents in Bhandara district being highest. Number of incident increases during the month of May to October perhaps due to rainy season.

More than 1000 cases of accidents, assault, burns, cardiac, fall, intoxication, labour utilized Emergency Medical Services.

Summary (Novelty): Emergency Medical Services professionals are immersed in the fast-paced service sector of saving lives in response to a wide variety of emergency medical situations. Duties include quickly assessing and prioritizing patient needs with the goal of providing life support in situations where trauma, respiratory, diabetic, behavioral, cardiac, allergic, poisoning, and childbirth emergency situations might exist.

Earlier EMS was fragmented and not accessible. In a short span of three years MEMS has shown commendable results. State wide 108 services cater to community at large with a definitive goal of reducing morbidity and mortality, thus confidence and trust among people is instilled to use 108 ambulance services during emergencies as shown by the increased utilization of the services

Keywords: *EMS – Emergency Medical Services, ERC – Emergency Response Centre, EMP's – Emergency Medical Services Professionals*

INTRODUCTION

Emergency Medical Services (EMS) is a branch of emergency services dedicated to providing pre hospital/ out-of-hospital acute medical care and/or transport to definitive care, to patients with illnesses and injuries which the patient or the medical practitioner believes constitutes a medical emergency. The goal of emergency medical services is to either provide treatment to those in need of urgent medical care, with the goal of satisfactorily treating the malady OR arranging for timely transport of the patient to the next point of definitive care. This is most likely a casualty/ emergency room at a hospital or another place where physicians are available.[1]

India is the second most populous country in the world. Currently, India does not have a Centralized body which provides guidelines for training and operation of Emergency Medical Services (EMS). Emergency Medical Services are fragmented and not accessible throughout the country[2]. Pre hospital care is being provided mainly by persons who are not trained in EMS. The ambulance service virtually has no emergency medical services professional(EMPs). Urban ambulance services are run by a multitude of organizations including governments, police, fire brigade's hospitals and private agencies with little coordination amongst them. Private hospital ambulances operate on strictly 'fee - for – service' basis. Ambulances are often used for internal hospital transport and non-emergency calls.

The World Health Organization National Commission on Macroeconomics and Health Report on India said that an average villager in India, who does not have a motor vehicle, needs to travel over two kilometers to get a tablet of paracetamol, over six kilometers for a blood test, and nearly 20 kilometers for hospital care[2]

In India, one person dies on the road every 4 minutes. While 7 to 10 percent are critically injured, 20 to 30 per cent are seriously hurt; of these about 30 per cent are disabled for life, either partially or totally[3]. The current growth in road accidents is expected to escalate to one death every three minutes by 2020**.**

MEMS PROJECT

To reduce morbidity & mortality, Government of Maharashtra decided to offer Emergency Medical Services in the state of Maharashtra.

Maharashtra Emergency Medical Services (MEMS) Project is operated by Bharat Vikas Group (BVG) India Limited. It is a toll free '108' number based 24 x 7 hours' pre-hospital emergency medical services, free of cost to entire population in the state of Maharashtra.

Emergency Medical Services Control Room: State of art Emergency Response Centre (ERC) is developed at Aundh Chest Hospital Pune. ERC operates 24 x 7 hours through a centrally operated toll free telephone number- '108' which can be dialed from any part of the state. This emergency toll free 108 number also serves as the point of first contact for police and fire related emergencies. Emergency Response Centre Physician (ERCP) provides On-line Medical direction for the doctors on ambulance during emergency calls. ERCP also provide on-line pre-arrival instructions to the callers or patients if needed. After timely pre-hospital care, patient will be admitted to most appropriate hospital as per the patient's need.

Maharashtra Emergency Medical Services Ambulance: There are 937 state of the art ambulances (233 ALS and 704 BLS ambulances) operational across Maharashtra capable of providing competent care for the sick or injured in emergency medical settings

Key Features of Ambulance

- First ambulance in the country to have Medical Oxygen Delivery System
- Best in the class equipment with defibrillator, ventilator, syringe pump, infusion pump etc.
- All the equipment's in the ambulance are EN 1789 & EN 1865 certified considering patient safety.

All Ambulances are manned by Doctors trained in Emergency curriculum who respond to emergency calls, perform medical services and transport patients to appropriate hospitals, as required.

Training: Training was imparted to all Emergency Medical Services professionals (EMPs) working with MEMS by Symbiosis Institute of Health Sciences, a constituent of Symbiosis International University from. The training center is well equipped with advanced training material, including state of the art infrastructure, simulated manikins and world class equipment. These professionals were trained to detect any emergency, respond immediately, report, provide on-scene care, en-route care and transfer to appropriate hospital; Training also includes reassurance to patients, relatives and bystanders prior to and during transportation to hospital casualty room.

OBJECTIVE

This study was aimed to assess efficacy of pre hospital care provided through situational analysis for period of 30 months from 01 January 2014 to 30 June 2016 across all districts of Maharashtra through the MEMS project.

METHODOLOGY

Training of EMPs and phase wise launch of Ambulances was initiated over a period of six months from 01 July 2013 to 31 December 2013. As state wide services were fully operational from 01 January 2014 this study was conducted for a period of 30 months during 01 January 2014 to 30 June 2016 across all 34 districts of Maharashtra. Emergency Medical Services Professionals (EMPs) working on 937 Ambulances respond to emergency calls, perform medical services and transport patients to appropriate hospital as required. Number and type of cases attended by these EMPs from pre-hospital care records (PCR*) response records and 48-hour follow-up records maintained by the emergency response officer every month during the period of study are considered for analysis.

This available Retrospective Quantitative data was collected, collated and analyzed for the purpose of accessing efficacy of Maharashtra Emergency Medical Services Project.

STATISTICAL METHODS

Data was analyzed by using descriptive statistics. Year and district wise data is represented by frequency and percentages. Incident types are represented by descriptive statistics and data is analyzed in SPSS (V.23).

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*PCR is emergency hospital care records maintained by the EMPs in the Ambulance.

RESULTS

Maharashtra EMS receives on an average 25,000 emergency medical calls every month.

Table 1 shows data regarding service area of Maharashtra EMS

Table 1: Maharashtra service area information

Area served	Maharashtra
Total districts served	34
Population served	12.13 crore
Type of services provided	Pre Hospital care
Number of Ambulances	937
Number of EMPs	3000

Below Table shows mortality and morbidity statistics in the state of Maharashtra.

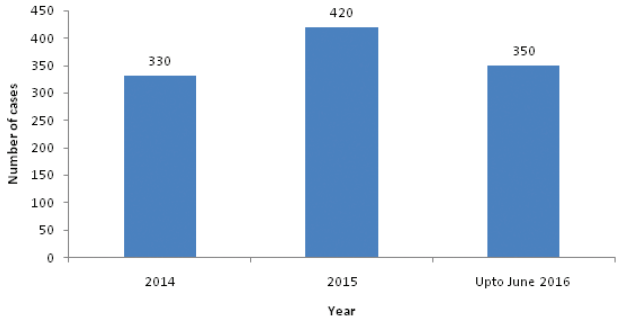
Table No 2: Mortality and morbidity statistics of Maharashtra State

Sr. No.	Cause	Mortality	Morbidity
1	Road accidents	13680	45374
2	Heart attack (Sudden Death)	5771	4163

3	Fire	5612	2058
4	Railway accidents	5024	3625
5	Drowning	4949	87
6	Poisoning (including snake Bite)	2393	7929
7	Fall from height	2235	1402
8	Epilepsy (sudden Death)	1958	420
9	Electrocution	1269	167
10	Alcohol (sudden Death)	1185	359
11	Others	16439	4895
	Total	60515	70479

Source: NCRB, Ministry of Home affairs, GoI. (2011)

Fig 1: Yearwise incident of clinical cases



The indications of clinical incidents as displayed in fig 1 depicts that the Clinical Incidents are relatively increasing throughout the years from 2014 to 2016. Thus a total of 1100 cases were attended during last two and half years.

Table 3 shows the district-wise distribution of clinical incidents during 2014-2016. Emergency Medical Services across 34 districts was provided to on an average 32 (min: 22, max: 61) clinical cases per district. Bhandara district, being a tribal area, clinical incidents are possibly more as compared to all other districts.

Table 3: District-wise distribution of clinical incidents, 2014-2016

District	Clinical incidents
Ahmednagar	32
Akola	32
Amravati	33
Aurangabad	33
Beed	31
Bhandara	61
Chandrapur	30
Dhule	32
Gadchiroli	30
Gondia	32
Hingoli	30
Jalgaon	32
Jalna	30
Kolhapur	33
Latur	31
Mumbai	32
Nagpur	33
Nanded	32
Nandurbar	30
Nashik	33
Osmanabad	30
Palghar	22
Parbhani	30
Pune	32
Raigad	33
Ratnagiri	33
Sangli	32
Satara	34
Sindhudurga	33
Solapur	32
Thane	32
Wardha	32
Washim	31
Yavatmal	32
Total	1100

The focus of EMS is to provide pre-hospital care and transport the patient to definitive care by monitoring and reporting clinical performance.

Fig 2: Month-wise Frequency of clinical incidents during Jan 2014-June 2016

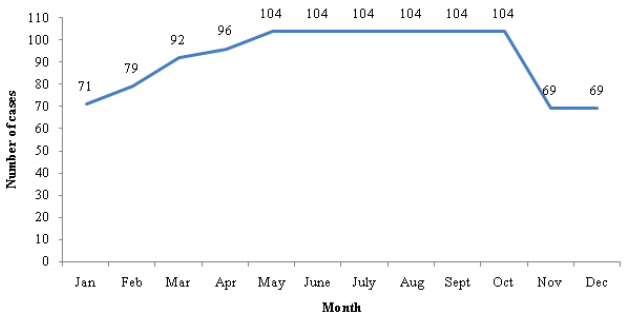


Figure 2 describes the month-wise number of incidents during 2014-2016.

This figure depicts that during 2014-16 on an average EMS was utilized for 91 cases every month. However, number of incident increases during the month of May to October. This might be due to rainy season.

Table 4: Distribution of type of incident treated during 2014-16

Incident type	Number	Percent (%)
Accident	1097	8.39
Assault	1052	8.04
Burns	1058	8.09
Cardiac	1025	7.84
Fall	1082	8.27
Intoxication	1083	8.28
Labour	1097	8.39
Lighting	803	6.14
Casualty	889	6.80
Medical	1100	8.41
Other	1095	8.37
Trauma	912	6.97
Suicide	785	6.00
Total	13078	100.00

Table 4 shows the frequency and incident type which clearly indicates that more than 1000 cases of accidents, assault, burns, cardiac, fall, intoxication and labour utilized Emergency Medical Services.

Table 4 shows the month wise distribution of clinical incident type during last two and half years.

Table 5: Month-wise distribution of incidents during 2014-2016.

Months	Jan (%)	Feb (%)	Mar (%)	Apr (%)	May (%)	June (%)	July (%)	Aug (%)	Sept (%)	Oct (%)	Nov (%)	Dec (%)	Total
Accident	70(6.4)	77(7)	92(8.4)	96(8.8)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	69(6.3)	69(6.3)	1097
Assault	70(6.7)	77(7.3)	85(8.1)	90(8.6)	97(9.2)	100(9.5)	100(9.5)	99(9.4)	101(9.6)	101(9.6)	65(6.2)	66(6.3)	1051
Burns	70(6.6)	73(6.9)	84(7.9)	92(8.7)	96(9.1)	99(9.4)	101(9.5)	101(9.5)	101(9.5)	103(9.7)	69(6.5)	69(6.5)	1058
Cardiac	68(6.6)	72(7)	79(7.7)	84(8.2)	91(8.9)	95(9.3)	101(9.9)	100(9.8)	102(10)	102(10)	66(6.4)	65(6.3)	1025
Fall	70(6.5)	77(7.1)	85(7.9)	95(8.8)	100(9.2)	102(9.4)	104(9.6)	103(9.5)	104(9.6)	104(9.6)	69(6.4)	69(6.4)	1082
Intoxication	70(6.5)	76(7)	85(7.8)	93(8.6)	102(9.4)	103(9.5)	104(9.6)	104(9.6)	104(9.6)	104(9.6)	69(6.4)	69(6.4)	1083
Labour	70(6.4)	77(7)	92(8.4)	96(8.8)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	69(6.3)	69(6.3)	1097
Lighting	42(5.2)	41(5.1)	54(6.7)	60(7.5)	82(10.2)	87(10.8)	86(10.7)	88(11)	88(11)	81(10.1)	50(6.2)	44(5.5)	803
Casualty	59(6.6)	60(6.7)	61(6.9)	74(8.3)	84(9.4)	83(9.3)	93(10.5)	88(9.9)	89(10)	79(8.9)	61(6.9)	58(6.5)	889
Medical	71(6.5)	79(7.2)	92(8.4)	96(8.7)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	69(6.3)	69(6.3)	1100
Other	70(6.4)	79(7.2)	92(8.4)	96(8.8)	103(9.4)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	104(9.5)	69(6.3)	66(6)	1095
Trauma	61(6.7)	63(6.9)	66(7.2)	78(8.6)	87(9.5)	86(9.4)	83(9.1)	87(9.5)	90(9.9)	89(9.8)	60(6.6)	62(6.8)	912
Suicide	58(7.4)	54(6.9)	68(8.7)	74(9.4)	71(9)	65(8.3)	75(9.6)	72(9.2)	75(9.6)	66(8.4)	49(6.2)	58(7.4)	785
Total	849	905	1035	1124	1225	1236	1263	1258	1270	1245	834	833	13077

Note: Values are n (%)

LIMITATIONS

Information on patient outcome, response time, is not available to make considered decisions

SUMMARY

Emergency Medical Services professionals are immersed in the fast-paced service sector of saving lives in response to a wide variety of emergency medical situations. Duties include quickly assessing and prioritizing patient needs with the goal of providing life support in situations where trauma, respiratory, diabetic, behavioral, cardiac, allergic, poisoning, and childbirth emergency situations might exist.

Earlier EMS was fragmented and not accessible. In a short span of three years MEMS has shown commendable results. State wide 108 services cater to community at large with a definitive goal of reducing morbidity and mortality, thus confidence and trust among people is instilled to use 108 ambulance services during emergencies as shown by the increased utilization of the services.

The structure, development, Function and performance in challenging environment lays the foundation for developing standardized state of the art pre hospital care services.

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Conflict of Interest: Nil

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High Flux Versus Low Flux Membranes: Adequacy of Hemodialysis

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ABSTRACT

Hemodialysis is the most widely used renal replacement therapy globally1. The dialyzer used in hemodialysis treatment is one of the important determinants of the effectiveness of dialysis 2. Three general types of dialysis membranes are available for hemodialysis procedure: unmodified cellulose (low flux; namely "bio incompatible" membranes), modified/regenerated cellulose (low flux or high flux; namely, "relatively biocompatible"), and synthetic membrane (low flux or high flux; namely "relatively biocompatible"). This study investigates the high flux versus low flux membranes for adequacy of hemodialysis. A total of 40 patients were included in the study of which 28 were males (60%). The mean age of the patients was 42 years. The mean Kt/V was 1.3 ± 0.3 in high flux membrane and 1.2 ± 0.2 in low flux membrane hemodialysis whose differences were statistically significant (P=0.05). The mean of URR was 64.2 ± 10.3 in high flux membrane and 61.1 ± 9.8 in low flux membrane HD whose differences were also statistically significant (P=0.05).

Keywords: *Flux membranes, Hemodialysis, Renal replacement, Dialysis, Chronic renal failure*

INTRODUCTION

Hemodialysis is the most widely used renal replacement therapy globally[1]. The dialyzer used in hemodialysis treatment is one of the important determinants of the effectiveness of dialysis [2]. Three general types of dialysis membranes are available for hemodialysis procedure: unmodified cellulose (low flux; namely "bio incompatible" membranes), modified/regenerated cellulose (low flux or high flux; namely, "relatively biocompatible"), and synthetic membrane (low flux or high flux; namely "relatively biocompatible")[3]. Hemodialysis using high-flux dialysis membrane can clear more middle molecular weight uremic toxins such as b2-microglobulin than hemodialysis using low-flux dialysis membrane because of its higher porosity[2] .Unmodified cellulosic membranes allow ultrafiltration (UF) rates of up to 5 to 6 ml/h/mmHg per m^2. Development of high-flux membranes has allowed higher rates over 20 ml/h/mmHg per m^2, favoring convection, while being thin enough to permit diffusion[4]. Compelling data from the Membrane Permeability Outcome Study suggest that high flux hemodialysis (HD) provides a survival benefit compared with low-flux HD, at least in patients with low serum albumin [4]. In patients with greater residual renal function, the beneficial effects of b2-microglobulin removal by high-flux dialysis may not be apparent, hence the beneficial effect of high flux dialysis on mortality may be different between patients with variable degrees of residual renal function [2,10]. Oates et al. compared the influence of high-flux and low-flux membranes in dialysis adequacy. The results showed no significant difference between the membranes[8]. Eknoyan et al. found that high-flux membrane improves the adequacy of dialysis in chronic renal failure [9]. Varying results of high flux HD versus low flux HD makes it imperative to compare the efficiency of low-flux versus high-flux membranes in patients with chronic renal failure to ensure better adequacy of hemodialysis.

MATERIALS AND METHODS

In this cross-sectional study, 40 patients who required dialysis for more than 6 months were evaluated for adequacy of hemodialysis. Two consecutive sessions of low-flux and high-flux membrane dialysis were performed on these patients. Demographic and clinical

data were collected at the time of enrollment. Assessment of Urea reduction ratio (URR) and Kt/V ratio were done.

Patient selection criteria included participants' age between 18 to 60 years, dialysis treatment for at least 6 months with conventional HD, using fistula or graft as vascular access, at least twice 4-hour dialysis sessions per week, consciousness for participation in study, hemoglobin ≥ 9 mg/dl and intradialytic weight gain less than 3 kg.

The exclusion criteria included hypotension (systolic BP ≤ 90 mm Hg), acute clinical conditions (myocardial infarction, congestive heart failure, recent surgery), dysfunction of vascular access during the study, discontinuation of dialysis less than 4 hours, reduction in patient's consciousness, patient's restlessness and agitation, severe nausea and vomiting during dialysis, smokers, patients on anti-inflammatory or antioxidant therapy and starting other treatments.

All the patients included were kept on conventional hemodialysis, 4-hour session, 3 times per week using hemodialysis machine (Fresenius Medical Care 4008B) with low flux polysulfone dialyzer (Fresenius F6). The standard dialysate consisted of sodium, 136mEq/L; potassium, 2mEq/L; calcium, 1.75mEq/L; and bicarbonate, 35mEq/L. These patients were switched to high flux polysulfone dialyzer (Fresenius F6) without changing any other dialysis prescription parameters except ultrafiltration to achieve estimated dry weight which is the normal weight without any extra fluid in the body. The patients were dialyzed 3 times/week using bicarbonate dialysate. Dialysate flow rate was 500 mL/min. The duration of each session varied from 4 - 5 hours. Blood flow rate ranged between 250–400 mL/min. Bicarbonate-based dialysate solutions were used in all patients using high-flux dialyzers. Blood samples were taken before the dialysis session of the high flux period (pre-high flux sample) as well as at the end of the session (post-high flux sample). The urea reduction ratio (URR) and the KT/V ratio markers were utilized to investigate the adequacy of dialysis. In KT/V ratio, K represents dialyzer clearance (mL/min), T represents time of dialysis (min), and V is the distribution of urea. The URR was estimated based on the calculation using, (urea pre-dialysis - urea post-dialysis)/ urea pre-dialysis x100.

The data collected were tabulated & analyzed using SPSS version 23.0. Quantitative variables were described by mean & standard deviation (X ± SD). Between the high flux and low flux membranes usage for hemodialysis procedure comparison of quantitative variables (Kt/V, URR & Blood Urea Nitrogen - BUN) were analyzed by using independent sample t test and paired-t test for comparison of pre-dialysis and post-dialysis BUN in high-flux and low-flux membranes.

The dialysis adequacy was classified into three groups: inadequate dialysis (KT/V ≤ 0.89, or URR ≤ 0.60); relatively adequate dialysis (KT/V = 0.90 to 1.29 or URR = 0.61 to 0.70); and the totally adequate dialysis (KT/V ≥ 1.3, or URR ≥ 0.70). Statistical significance was considered at P value < 0.05.

RESULTS

A total of 40 patients were included in the study of which 28 were males (60%). The mean age of the patients was 42 years. The mean Kt/V was 1.3 ± 0.3 in high flux membrane and 1.2 ± 0.2 in low flux membrane hemodialysis whose differences were statistically significant (P=0.05). The mean of URR was 64.2 ± 10.3 in high flux membrane and 61.1 ± 9.8 in low flux membrane HD whose differences were also statistically significant (P=0.05) (Table 1).

The mean of BUN prior to low flux hemodialysis was 124±34.61 mg/dL which significantly reduced to 48.73±21.5 mg/dL after low flux hemodialysis. Observed difference in values was statistically significant (P=0.05); whereas, the mean of BUN before high flux hemodialysis was 124±37.6 mg/dL which significantly reduced to 44.9±19.6 mg/dL, and was statistically significant (P=0.05) (Table 2).

The mean URR for patients in low flux hemodialysis was 61.1 ± 9.8 and the mean URR for patients in high flux hemodialysis was 64.2 ± 10.3. The adequacy of HD based on URR was higher in the high flux hemodialysis than the adequacy of low flux HD. The difference observed was statistically significant (P=0.05) (Table 3)

In high flux HD, the mean KT/V ratio was 1.3(±0.3) whereas the mean KT/V ratio in low flux HD was 1.2(±0.2).

These observations were statistically significant (P=0.05) which reveals the relative adequacy of high flux HD.

Table 1: Comparison of KT/V index in High and Low-Flux membrane

KT/V	High Flux No. of patients (%)	Low-Flux No. of patients (%)
0.5-1.19	8 (20)	13 (32.5)
1.2-1.39	7 (17.5)	14 (35)
1.4-2.19	25 (62.5)	13 (32.5)
Mean (±SD)	1.3(±0.3)	1.2(±0.2)
	P=0.05	

Table 2. Comparison of Pre-dialysis and Post-dialysis BUN in High-Flux and Low-Flux Membranes

Membrane	Pre dialysis BUN (mg/dL)	Post dialysis BUN (mg/dL)	Paired t Test
Low flux	124(±34.61)	48.73(±21.5)	P=0.05
High flux	124(±37.6)	44.9(±19.6)	P=0.05

Table 3. Comparison of URR in High-Flux and Low-Flux membranes

URR(Urea Reduction Rate)	High-Flux No. of patients (%)	Low-Flux No. of patients (%)
0.40-0.59	9 (22.5)	13 (32.5)
0.60-0.79	9 (22.5)	14 (35)
0.80-0.99	22 (55)	13 (32.5)
Mean(±SD)	64.2(±10.3)	61.1(±9.8)
	P=0.05	

DISCUSSION

The study was conducted to compare the effectiveness of high flux and low flux membranes for adequacy of hemodialysis in patients taking conventional hemodialysis treatment. The major findings of current study showed that hemodialysis using high-flux dialysis membrane (mean KT/V was 1.3±0.3) results into quality dialysis as compared to the hemodialysis using low-flux dialysis membrane (mean KT/V was 1.2±0.2). When comparing the result outcomes, it is indicative that high-flux dialysis impacts the adequacy differently according to residual renal function and that high-flux dialysis (mean URR is 64.2 ±10.3) is superior to low-flux dialysis (mean URR 61.1 ±9.8) in patients without residual renal function. Residual renal function inferred from adequacy of hemodialysis is linked to improved survival and clinical outcomes such as hospitalization, nutrition, anemia, and serum phosphorous control in hemodialysis patients[5]. One of the major factor that affect the adequacy of dialysis is the types of membranes used during hemodialysis procedure. High flux membranes capably remove the middle size and large size molecules such as $ß_2$ micro globulin, thus allows improved removal of a wider spectrum of uremic toxins which may improve the adequacy of patients on chronic hemodialysis[11].

The outcome of this study positively reinforces that the use of high-flux dialysis membranes for hemodialysis procedure improves adequacy of HD. The findings of our study are in association with the study of Maryam **et. al. who inferred that** to increase the dialysis adequacy, use of High-Flux membrane is a better choice than Low-Flux membrane[12]. The outcomes of this study are also in agreement with that of AR. Moslem et al who concluded that most patients who used High flux membranes had enough dialysis adequacy [7].

CONCLUSION

Having been resigned to the fate of chronic renal failure patients for many years, there is hope for better treatment outcomes in patients on hemodialysis using high flux dialysis membranes. High-flux dialysis membranes remove the middle-sized uremic toxins and improved the adequacy of hemodialysis. Using high flux hemodialysis thus allows better removal of a wider spectrum of uremic toxins which may improve the quality of life and adequacy of hemodialysis. Further studies with larger sample size are necessary to understand the short and long term clinical benefits of high flux dialysis in chronic renal failure population.

In developing countries, low flux membranes have been regularly used for dialysis patients because of its cost effectiveness[14]. This evidence based study promotes use of high flux membranes for efficient adequacy of dialysis and may be considered as a treatment management plan for chronic renal failure patients.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Role of Cardiovascular Technologists in Screening & Risk Profiling of Young Hypertensive at a Tertiary Care Hospital in Pune

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ABSTRACT

Hypertension is one of the most common lifestyle diseases today, and is a leading public health challenge globally due to its high prevalence and related morbidity and mortality. It is increasingly observed in young patients in the age group of 18 to 40 years and is a cause of concern worldwide. Risk factors like hypertension, smoking, alcoholism, dyslipidemia, obesity and diabetes mellitus magnify the risk of stroke, coronary heart disease and chronic renal failure. This study was done to explore the role of cardiovascular technologists in screening and risk profiling of young hypertensive patients that included identifying the common symptoms at presentation and detecting the risk factors like obesity, alcoholism, smoking, diabetes mellitus and dyslipidemia in the young hypertensive patients aged between 18 to 40 years at a tertiary care hospital. The cardiac investigations like measurement of blood pressure, performing electrocardiography procedure, conducting stress test and echocardiography including the interpretation of these tests were carried out by the Cardiovascular Technologists and the treatment of patients was managed by physicians and cardiologists. Thus, this paper is an evidence based research on the role of screening & risk profiling of young hypertensive by Cardiovascular Technologists providing relief in workload of the physicians and cardiologists and sparing them for more complicated cases.

Keywords: *Cardiovascular technology, Hypertension, profiling, Risk, Tertiary care*

INTRODUCTION

Hypertension is one of the most common lifestyle diseases today, and is a leading public health challenge globally due to its high prevalence and related morbidity and mortality[1,2,3]. Hypertension is increasingly observed in young patients [1,3] in the age group of 18 to 40 years and is a cause of concern worldwide [4]. Risk factors like hypertension, smoking, alcoholism, dyslipidemia, obesity and diabetes mellitus magnify the risk of stroke, coronary heart disease and chronic renal failure[1,3,4,5,6]. Majority of young (< 40 years) patients with high blood pressure have essential hypertension but many are diagnosed with secondary hypertension, the root cause of which can be eradicated [2]. Although a battery of investigations are available for diagnosing hypertension and its etiopathogenesis, clinical symptoms and signs serve as well-defined determinants for taking the best course of investigations in hypertensive patients [7], a role well played by practicing cardiologists.

Advances in technology and improved patient outcomes in cardiovascular illnesses is resulting in longer life-spans of cardiac patients with greater co-morbidity; further increasing the burden of cardiologists [8]. Pressure is being felt at every level of the health care delivery platform, from the community cardiologist to the subspecialist in a tertiary care centre comprising of physician shortages, excessive workloads and possible changes in the training of medical specialists [8]. Capacity building is vital and takes centre stage whereby the effectiveness of health work force is dominated by a skill mix, quality & opportunities for upgrading skills; leading to the evolution of training programs for Medical Technologists predominately in the Cardiovascular Technology domain [9]. Currently, there is a transformative trend from cardiologists and physicians; to trained cardiovascular technologists performing a key role in screening of cardiovascular diseases [10]; thus, giving doctors more time to devote their skills for complex tasks.

This study was done to explore the role of cardiovascular technologists in screening and risk profiling of young hypertensive patients that included

identifying the common symptoms at presentation and detecting the risk factors like obesity, alcoholism, smoking, diabetes mellitus and dyslipidemia [11,12,13,14] in the young hypertensive patients aged between 18 to 40 years at a tertiary care hospital.

METHODS

Preventive health check-up is routinely conducted at a tertiary care hospital centre in Pune city; whereby the patients attending these preventive health check-ups are investigated for blood pressure, height, weight, Body Mass Index (BMI), lipid profile, blood sugar level, Electrocardiography (ECG), Stress Test and Echocardiography.

50 adult patients aged between 18 to 40 years were enrolled in this prospective study, who came for routine preventive health check-up at Out-Patient Department (OPD) of this tertiary care hospital.

The selection of patients included in the study was based on asymptomatic patients of both genders, aged between 18 to 40 years.

The exclusion criteria included presence of any medical diseases, younger patients less than 18 years and elderly patients above 40 years, who had come for routine health check-up.

All the included patients underwent a medical examination and every participant's name, age, gender, clinical history, history of diabetes mellitus, smoking and alcohol was recorded. Blood pressure measurement examination was done in all patients with the use of aneroid sphygmomanometer for three consecutive days successively in supine and sitting positions by the cardiovascular technologists. Screening & risk profiling protocols of young hypertensives were applied to these individuals by cardiovascular technologists as per the criteria laid by Seventh Joint National Committee Criteria (JNC-7). The other screening parameters included in these patients were electrocardiography, stress test and echocardiography which were performed and assisted by cardiovascular technologists. The patients were further referred to the physicians for confirmation of diagnosis; and management of patients when required. The cardiovascular technologists assisted during patient's positioning and performed the procedures of electrocardiography, stress test and echocardiography. The patient preparation, data entry and selection of Bruce or Modified Bruce Protocol used for stress test was done by the cardiovascular technologists. Every hypertensive patient was evaluated for risk profiling like diabetes mellitus, obesity, dyslipidemia, smoking and alcohol consumption according to the guidelines for fasting glucose 102–125 mg/dl [6;] Body Mass Index was calculated according to WHO guidelines [14,15], the categories of BMI are shown in the (Table 1.) and Dyslipidemia was calculated according to the Adult Treatment Panel III (ATP III) classification of lipid profiles are shown in the (Table 2)[16].

Table 1: WHO Guidelines for Categories of BMI

Categories of BMI	
Underweight	Below 18.5 kg/m^2
Normal Weight	18.5–24.9 kg/m^2
Preobesity	25.0–29.9 kg/m^2
Class I Obesity	30-34.9 kg/m^2
Class II Obesity	35-39.9 kg/m^2
Class III Obesity	>40 kg/m^2

Table 2. ATP III Classification of Lipid Profiles

Lipid Profiles							
	Low	**Optimal**	**Near Optimal/ Above Optimal**	**Desirable**	**Borderline**	**High**	**Very High**
Total Cholesterol	-	-	-	< 200 mg/ dl	200-239 mg/dl	240 mg/dl	-
Triglycerides	-	-	-	< 150 mg/ dl	150-199 mg/dl	200-499 mg/dl	>500 mg/dl
HDL Cholesterol	< 40 mg/dl	-	-	-	-	>60 mg/dl	-
LDL Cholesterol	-	<100 mg/ dl	100-129 mg/dl	-	130-159 mg/dl	9 mg/dl	>190mg/dl

The laboratory reports for BSL and Lipid profiles were generated by the central laboratory of the hospital. Patients screened by the cardiovascular technologists diagnosed with hypertension having normal electrocardiogram, stress test and echo test were referred to the physicians for confirming the medical examination done; treating the patients if required. Hypertensive patients with either an abnormal electrocardiogram, positive stress test or with abnormal echocardiogram were referred to cardiologists for further management.

RESULTS

In this study, among the 50 asymptomatic patients, aged between 18 to 40 years that had come for preventive health check-up at a tertiary care hospital, it was observed that 32 (64%) were males and 18 (36%) were females (Table 3).

According to Joint National Committee VII criteria (Table 4,5,6) used by Cardiovascular Technologists, out of 50 patients, 10 (20%) were normotensive, 24(48%) were pre-hypertensive, 11 (22%) were Stage-I hypertensive, 05 (10%) were stage-II hypertensive.

Among the young hypertensive patients, abnormal ECG was detected in 25 (50%) patients, 16 (32%) patients had positive stress test and abnormal echocardiography findings were present in 09 (18%) patients.

Considering the risk factors, 11 (22%) patients were smokers, 5 (10%) patients were consuming alcohol, 6 (12%) patients had high cholesterol diet, 13 (26%) patients were obese ,7 (14%) patients were tested positive for diabetes mellitus and it was observed that 8 (16%) patients did not demonstrate any risk factor (Table 7,8).

Table 3. Distribution according to gender

Gender	Frequency	Percentage
Male	32	64.00 %
Female	18	36.00%
Total	50	100.00%

Table 4. VIIth Joint National Committee Guidelines for Classification of Hypertension

Classification	Systolic Blood Pressure (mm Hg)	Diastolic Blood Pressure (mm Hg)
Normal	<120	<80
Prehypertension	120–139	80–89
Stage I hypertension	**140–159**	**90–99**
Stage II hypertension	≥160	≥100

Table 5. Profiling according to gender and levels of hypertension

Levels of hypertension	Total Frequency	Male Frequency	Female Frequency	Total Percentage	Male Percentage	Female Percentage
Normotensive	10	03	07	20.00%	9.37%	38.8%
Pre-hypertensive	24	17	07	48.00%	53.12%	38.8%
Stage-I hypertension	11	08	03	22.00%	25.01%	16.68%
Stage-II hypertension	05	04	01	10.00%	12.50%	5.56%
Total	50	32	18	100.00%	100.00%	100.00%

Table 6. Age wise distribution of levels of hypertension

Levels of hypertension	Age Groups			
	18-23	24-29	30-35	36-40
Normotensive	02	02	02	04
Pre-hypertensive	01	05	11	07
Stage-I hypertension	00	05	03	03
Stage-II hypertension	01	01	01	02
Total	04	13	17	16

Table 7: Profiling according to risk factors

Risk factors	Frequency	Percentage
Smoking	11	22.00%
Alcohol	05	10.00%
High cholesterol diet	06	12.00%
Obesity	13	26.00%
Diabetes Mellitus	07	14.00%
No risk factor	08	16.00%
Total	50	100.00%

Table 8. Correlation of Levels of hypertension and risk factors

Levels of hypertension	Risk factors					
	Alcohol	Smoking	High cholesterol diet	Obesity	Diabetes Mellitus	No risk factor
Normotensive	-	01	01	03		05
Pre-hypertensive	05	06	02	06	03	02
Stage-I hypertension	-	03	02	04	01	01
Stage-II hypertension	-	01	01	-	03	-
Total	05	11	06	13	07	08

DISCUSSION

This prospective study was conducted to investigate the role of cardiovascular technologists in screening & risk profiling of young hypertensives at a tertiary care hospital in Pune city. In this study, it was observed that the cardiovascular technologists were able to apply JNC –VII criteria on the patients, identify risk factors and perform diagnostic investigations for cardiovascular system complications such as ECG, Echocardiography and Stress test and observed that 10 (20%) patients were normotensive, 24 (48%) patients were pre-hypertensive,11 (22%) patients had stage1 hypertension & 5 (10%) patients had stage 2 hypertension during routine preventive health check-ups. The cardiovascular technologist performed the risk profiling of these 50 patients enrolled for the study and the outcomes of this study was such that obesity was the commonest risk factor noted (28%), alcoholism (10%), smoking (22%), high cholesterol diet (12%) and diabetes mellitus (14%) and (16%) had no risk factors. The cardiovascular technologists were able to perform screening of hypertension according to JNC criteria VII. These cardiovascular technologists were thus able to minimize the work of cardiologists by screening and risk profiling young patients for hypertension who were symptomless when they had come for routine preventive health check-ups. This study proves that the cardiovascular technologists are a capable workforce that are able to reduce the workload of cardiologists. It is hence desired that more training institutes for cardiovascular technologists are established, for improving the healthcare services and preventing cardiovascular episodes in the youth.

CONCLUSION

The cardiac investigations like measurement of blood pressure, performing electrocardiography procedure, conducting stress test and echocardiography including the interpretation of these tests were carried out by the Cardiovascular Technologists and the treatment of patients was managed by physicians and cardiologists. Thus, this paper is an evidence based research on the role of screening & risk profiling of young hypertensives by Cardiovascular Technologists providing relief in workload of the physicians and cardiologists and sparing them for more complicated cases.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Healthcare Challenges in Rural India

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ABSTRACT

Purpose: Study was undertaken to understand the overall status of the healthcare scenario comprising of the healthcare infrastructure, availability of healthcare facilities and services and ascertain the health status of the rural population in a rural setting not very far from a metro city.

Design: It was a primary research undertaken in a real-life rural backdrop at village Kavnai, Taluka – Igatpuri, Dist. Nashik about 100 kms from Mumbai.

Findings: This study is an attempt to determine the overall healthcare scenario in a village setting. Although an allocation of a primary health centre had been made by the government it was non-operational. There was not a presence of a single medical store in this village. Overall there was a near absence of any health infrastructure or healthcare facilities /services in this village.

Conclusions: Local healthcare was almost non-evident in this village. There was a dependency for healthcare services and facilities like treatment for acute and chronic diseases/disorders, availability of medicines, basic diagnostic facilities on far-off towns or district place leading to severe hardships for the village population.

Keywords: *Rural, Healthcare, Infrastructure, Medicines, Services*

INTRODUCTION

India ranks 143/ 188 on a new health index[1]: A new index developed to assess each countries'achievement on a range of health indicators ranks India at 143 in a list of 188 countries, six places ahead of Pakistan and way behind countries like SriLanka(79), China(92), Syria (117) and Iraq (128)[2]

This is the first global analysis that assesses the countries of the globe on the Sustainable Development Goals (SDG) health performance published in The Lancet, Oct 2016. This study analysed an individual country's progress towards achieving health related SDG targets through the help of an overall SDG index score.Four out of eight UN Millennium Development Goals (MDG) are related to healthcare and health represents 12.4% of GDP in Organisation for Economic Cooperation and Development Countries(OECD) while in India health represents only 4%.[3]

The Indian healthcare system presents many challenges for the current government. As per the economic survey 2015-16, the government expenditure on health was 1.3% of its GDP.[4]

Some of the other healthcare challenges faced by India are:

(1) Urban versus rural divide: Around 70% of India's population lives in rural areas and they have very limited access to clinics and hospitals[5]

(2) Inadequate health infrastructure: India has 1 bed for every 1050 patients in contrast to Japan which has got one for 85 patients and the US which has one for every 350 patients. India's ratio of Doctors and Nurses to the population stands at 0.7 Doctors and 1.5 nurses per 1000 people which is much lower than the WHO average of 2.5 Doctors and nurses per 1000 people[6]

(3) Inadequate basic primary healthcare: There is a need for India to address its basic health concerns in the areas of TB, diarrhoea, malaria, HIV, sanitation and child malnutrition.

The Government of India spends only about 30% of the country's total healthcare budget on primary healthcare.(5)

(4) Low health insurance coverage: As per the national health profile 2015, compiled by the central bureau of health intelligence, only around 21.6 crore people, which is less than 1/5th of India's population is covered under any health insurance scheme.[7]

Because of the above factors and the low spending of the government on healthcare, this results in to a high burden on individual patients and families resulting in a very high Out of Pocket (OOP) expenditure rate, which is one of the highest in the world.

The government spends only around 4.3% of its total expenditure on health – the private sector contributes around 69.5% and the government contributes 30.5% of this health related expenditure. Out of the 69.5% contributed by the private sector, 87.2% is OOP. (3)

To overcome the above shortcomings ,India is poised to undertake transformation in healthcare through the introduction of various structural reforms and by devising new policies and programs for enabling access to healthcare and improving the quality of healthcare services.[8] This is evident from the manifesto of the Government of India's twelfth five year plan where the government wants to accelerate the reforms suggested by the World Health Organization [WHO] through the Universal Health Coverage. The aim of the Universal Health Coverage is to ensure that everyone and everywhere in the world can access quality health services without being forced into poverty, which was announced by a global coalition of more than 500 leading health and development organizations in December 2014. [9] This program was accepted by the Government of India. To achieve this objective, the government would require various new initiatives and also overcome the current lacunae in policy framing, program designing and implementation. This entails a lot many challenges which need to be overcome, one of which is the expenditure on healthcare as percentage of India's GDP - currently it is 3.8%. [10] This is the lowest amongst the BRIC countries and much lower than the developed countries. Reduced funding by the Indian Government has been attributed to historic failures on the part of the ministry of health and family welfare to spend its allocated budget fully. [6] The shortage of qualified medical professionals is one of the key challenges facing the Indian health care administrators. [6] There is an acute shortage of paramedical and administrative professionals thereby many patients especially those living in rural and semi urban areas are still receiving services from unqualified practitioners.[6.] India's density of doctors and nurses to the population is 0.7 doctors and 1.5 nurses per 1000 people, which is significantly lower than the recommendation of WHO which is of 2.5 doctors and 2.5 nurses per 1000 people. [6]. Also a big challenge for India is the healthcare in rural setting as rural India comprises around 70 % of the country's population. [5,12] Around the world, the health status of people in rural areas is generally worse than in urban areas. [13] The new government at the centre drafted the new health policy in Jan 2015 which has suggested programs to strengthen the primary health care network all over the country and consider health as a fundamental right of all citizens of the country. Against this background, this study has been undertaken with the objectives as follows:

RESEARCH OBJECTIVES

1. To understand the current levels of physical healthcare infrastructure and healthcare staff in a rural setting close to an urban city in India.
2. To understand the public health and sanitation scenario and identify the prevalence of communicable and non-communicable diseases in a rural setting.
3. To ascertain the important health parameters in the rural population and to determine the awareness levels of these amongst them.
4. To determine the access to and the availability of healthcare facilities /services to the rural population and understand their current practices for resolving their health care/medical problems.
5. To understand the functioning of the public health centres in a rural setting.
6. To identify the gaps in the health parameters with respect to the normal recommendations and the observed.
7. Collating the above to determine the contemporary challenges for healthcare in rural areas.

RESEARCH METHODOLOGY

(a) Study Design: A primary research study which was exploratory and descriptive in nature was undertaken by this group along with a medical

practitioner in a real life rural setting at a village Kavnai in Igatpuri taluka, Nashik district in the state of Maharashtra, 100km from Mumbai the capital city of the state. The study group undertook field visits to this village in the first half of the year 2016.

(b) Data collection: The team studied the health status of the village population and the healthcare infrastructure and availability of health related services in Kavnai. This included: interviews with the sample population and the office-bearers in the village, investigation and identification of their health status and the measurement of all important representative physical health parameters of this sample population from this village which included the measurement of height, weight, the BMI, random blood pressure, random blood sugar, pulse rate, waist hip ratio. The study group also investigated their historical disease profile, dental health, eye health, malnourishment in children, habits like smoking, chewing tobacco and betel nut, dietary habits, male to female ratio, average age of male and average age of females, number of children, per capita income, per capita expenditure on healthcare, occupation, healthcare facilities, number of geriatric patients, pregnant women, number of medical practitioners, presence of medical stores, vaccination status in children, potable water analysis, life expectancy level, death rates, infant mortality rate, maternal mortality rate, diagnostic services, and the literacy levels in the village. The overall findings have been collated to determine the contemporary healthcare challenges to be overcome in a rural area.

(c) Data collection tool: The data was collected through unstructured interviews, through one to one questioning.

The measurement of the physical parameters like height, weight, Random blood glucose, pulse etc was done with the help of a medical practitioner.

(d) Sampling strategy: Convenience sampling

FINDINGS

(I) Demographic details

- Total population of the village – 4,500
- Number of adult population – 3,500 [77.7 % of the total population]
- Number of children <12 years –around 1000 [22.2% of the total population]
- Number of women > 60 years – 50 % of the total population
- Occupation of the rural population – Agriculture
- Annual income of the village – Rs 25 lakhs approximately per year
- Literacy rate – 85 %
- Birth rate – 5 to 6 children per year
- Death rate – 7 to 8 per year
- Infant mortality rate – Nil
- Maternal mortality rate – Nil
- Rate of alcoholism amongst men-30 %
- Female education – up to H.Sc
- No NGO support for this village
- Villagers have Adhar cards, Television and Mobile phones
- The village gets Water from Mukha dam

(II) Current levels of physical healthcare infrastructure and staff: The study group during their visits observed near absence of healthcare infrastructure in the village and deficiency or near absence in primary (basic) and secondary speciality health care facilities and services along with absence of any professional healthcare service in this village.

The preliminary results demonstrated a very low awareness of their health status and government health schemes amongst the village population, deficiency in primary(basic) and secondary (speciality) healthcare facilities and services in the village and absence of any professional healthcare services. Although the Primary health care services existed, it was almost non-operational. None of the villagers in Kavnai were covered by health insurance schemes like Mediclaim, further the study group noted very low awareness of the health status amongst the village population. Although the primary healthcare services existed, it was almost non-operational.

(i) **Public health /sanitation scenario and prevalence of communicable and non-communicable diseases**: There were no public

toilets in this village neither awareness nor facilities to provide sanitation for women. The village women were unaware of the use of sanitary napkins and used cotton cloth instead of these. There was absence of any drainage system in this village. The diseases like Malaria was common amongst the villagers, the other disorders that were present in this village were diarrhoea, common cold and flu, deficiency in RBCs and WBCs, disorders of uterus in women and some cases of Malnutrition.

(ii) Health parameters of the village population

(a) Height: The average height observed amongst the village males was 159.40 cm and amongst village women was 148.37cm

(b) Weight: the average weight amongst the village males was 48.20kg and the amongst village woman was 43.27kg

(c) BMI: the average BMI amongst the village men was 18.48 and amongst the women was 18.87

(d) Random blood pressure: The average blood pressure amongst villagers was 118.78/74.25

(e) Random blood sugar: The average Random blood sugar of the villagers was found to be 133.63

(f) Pulse rate: The average pulse rate was found to be 89.51

Table 1: Physical health parameters amongst the rural population

S.n	Name	Age (yrs)	Sex	Wt (kg)	Height (cm)	BMI (kg/m2)	BP (mmHg)	Pulse per min	Random blood sugar(mg/dl)	WHR (cm)
1.	Venubai Santu Shirsat	65	F	42	147	19.44	160/100	84	102	
2.	Shivaji Laxman Shirsat	41	M	55	155	22.54	120/80	91	116	90/70
3.	Manisha Shirsat	27	F	53	166	19.27	130/80	80	111	87/68
4.	Nivrutti Dashrat Shirsat	32	M	44	172	14.91	110/70	81	112	80/66
5.	Sunil Shrsat	31	M	64	178	20.25	120/70	68	128	90/90
6.	Suman Rambhai Shirsat	50	F	64	160	25	130/70	110	308	103/87
7.	Roshan Navnath Shrsat	12	M	29	151	12.71	110/80	105	101	67/55
8.	Sarthik Navnath Shirsat	7	M	16	111	13	98/80	103	-	51/46
9.	Vaibhav Shirsat	22	M	51	174	16.88	130/70	78	121	84/74
10.	Balu Mahadev Shirsat	61	M	55	162	20.99	130/80	60	144	97/93
11.	Dashrat Shankar Shirsat	71	M	72	167	25.89	160/90	84	168	111/115
12.	Phulabai Laxman Shirsat	60	F	56	149	25.22	100/60	90	170	107/100
13.	Balu Nana Dhonde	49	M	65	168	23.04	140/80	92	181	90/94
14.	Valu kisan Sable	55	M	42	156	17.28	130/90	83	104	77/72
15.	Kishan Shankar Wagh	55	M	46	154	19.40	100/70	76	100	85/75
16.	Janabai Pandu Donde	70	F	53	158	21.28	160/80	76	97	86/93
17.	Minabai Sable	45	F	26	142	12.93	110/76	86	75	65/52
18.	Indubai Padekat	40	F	46	149	20.72	120/80	104	97	86/74
19.	Nivrutti Wagh	32	M	54	158	21.68	132/80	97	118	82/80
20.	Wadabai Kisan	50	F	43	144	20.77	14/100	86	123	86/75
21.	Lilabai Kondaji wagh	45	F	51	152	22.07	100/50	88	350	81/79
22.	Sandip Nimba Donde	34	M	49	165	17.94	120/90	94	89	83/71
23.	Rupali Dattu Muthye	17	F	41	155	17.08	120/80	90	111	77/68
24.	Karuna Bala Donde	16	F	54	163	20.37	120/70	98	179	89/71

25.	Varsha Padekar	16	F	51	151	22.36	120/70	91		76/71
26.	Aarthi Valu Sable	14	F	27	140	13.77	100/60	136		59/53
27.	Juoti Chandrakant Sable	13	F	34	146	15.96	100/60	98	90	
28.	Maya Chintaman Gulwe	12	F	33	130	17.36	100/60	97	134	64/55
29.	Anusaya Chandrakant Sable	27	F	33	142	16.41	100/50	89	128	69/60
30.	Sonali Chandrakant Sable	13	F	22	129	13.25	80/50	81	115	56/50
31.	Pratik Dhonde	13	M	31	143	14.83	110/60	94	116	69/61
32.	Vishnu Nagu Muthe	65	M	50	177	15.97	120/80	87	111	91/79

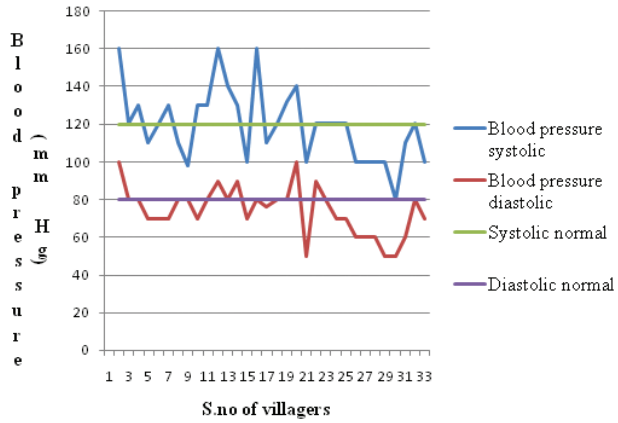


Figure 1. Blood pressure amongst the rural population

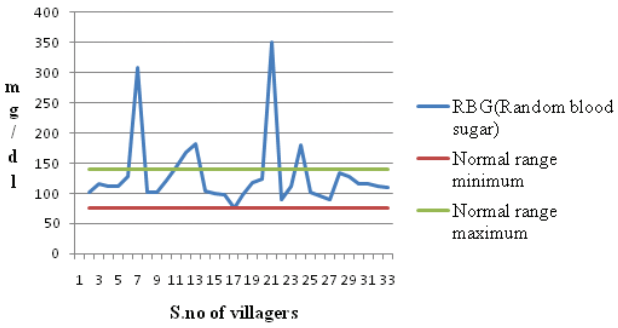


Figure 2. Random blood glucose levels amongst the village population

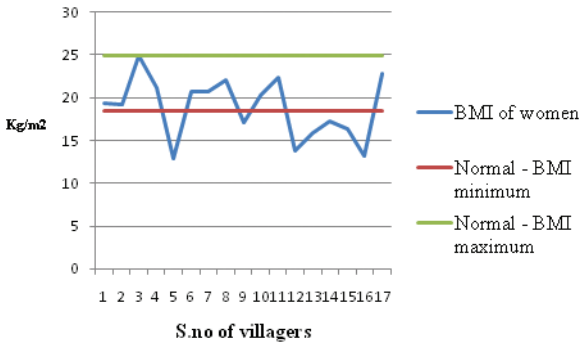


Figure 3. BMI of the village population [female]

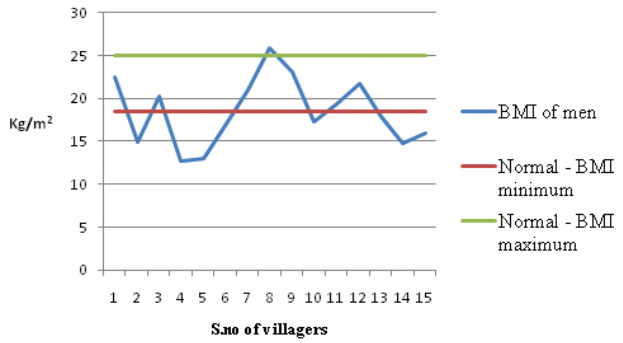


Figure 4. A graph showing the BMI of village men

Inferences from the measurement of physical health parameters

- 12% of the village population demonstrates high blood pressure
- 24% of the village demonstrate low blood pressure
- 9% of the village population have lower BMI
- 15% of the village population demonstrate high blood glucose, higher than the normal
- 15% of the village population demonstrated higher pulse rate
- Average waist to hip ratio was found to be 1.14, which is above the safe limit of 0.95 in males and 0.80 in females (as per WHO guidelines)

(III) Access to and availability of healthcare facilities/ services: There was one primary healthcare centre in this village. There were two non MBBS general practitioners practising from Monday to Friday. The village had one Ayurveda clinic which operated on all week days between 9.00am to 5.00 pm and not on Sundays.

There was no medical store in this village also this village did not have any dental clinic. There

were no maternity facilities nor the presence of any public toilets. Child delivery was conducted by old women in this village known as "Daiis". In emergency health situations the villagers had to travel to a nearby town which was around 9 km either by walking or hiring a private vehicle. This village also did not have any diagnostic facilities.

This village did not have any public tap water system but there was presence of public water system through hand pump.

(iv) Government health facilities: This village had a primary health centre which functioned irregularly

DISCUSSION

As per the World Health Organisation (WHO) health is, a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity. Therefore, health is at the heart of economic, political, social, and environmental prosperity. Globally the governments have subscribed to the thought that healthier citizens and prevalence of a society that is disease free is responsible for the economic growth of the country. Despite showing improvements in some of the health outcomes India demonstrates deficiencies and inefficiencies in health care. As per a PwC and CII publication around 30% Indians do not have access to primary health care facilities and 30% people in rural India do not visit hospitals fearing the expenses [3]. The same publication mentions that the rural India accounts for 70% communicable diseases and over 50% non-communicable diseases. As per a McKinsey- CII report on health care, the Indian health care sector face shortages of work force and infrastructure and India's infant mortality rate and maternal mortality rate lagged behind the low and middle income countries [(8)]. With this background, this study was undertaken with a purpose in a rural setting which was close to Mumbai -one of the biggest cities in India featuring advanced healthcare facilities. There have been some studies conducted to assess the challenges for health care in rural settings however, this study has been conducted very recently. This study reveals the status of health care infrastructure, availability of healthcare services and the health status of a rural population close to a metro city. There is a scope for future studies to be conducted to consider and overall health care perspective in a rural setting considering factors like analysis of the quality of potable water and analysis of the blood samples of the rural population. This study gives an overall direction to address the health care issues and problems faced by the rural population pertaining to healthcare. This should help the government to think of appropriate solutions with respect to improving the health care infrastructure services and solutions to the health related disorders / disease prevalent in the rural population. Factors such as poverty low health awareness, low educational levels coupled with lack of active government support could lead to poor health standards among the rural population. Importantly the measurement of various health parameters done in this study indicated the presence of various chronic disorders like hypertension, hyperglycaemia which can lead to cardio vascular complications, respiratory problems and severe complications such as loss of organ functioning, management of chronic disorders can lead to higher treatment costs and un awareness of the presence of these can result in higher rate of morbidity and mortality in the rural population. As observed by the study group, very poor health care infrastructure and unavailability of healthcare services in the village can lead to poor monitoring of health parameters by the rural population and a higher out of pocket expenditure to maintain normal health. As such 70% of health expenditure is contributed by the private sector, out of which 87% is out of pocket expenditure.[3]

Secondary expenditure on health such as transportation facilities, far off distances to neighbouring towns with better healthcare infrastructure can add to the burden of healthcare expenditure of the rural population. These could result in to loss of work days, decrease in productivity, lesser disposable income for meeting other personal needs and increase in expenditure leading to poor quality of life. It is the expectation of this study group that the policy makers and the ministry of health, Government of India would device various measures to reduce out of pocket expenditure on health care and strategies and programs for better healthcare within the existing rural setting and infrastructure.

CONCLUSION

This study is an attempt to understand the healthcare scenario in terms of the availability of private and public infrastructure and services in a rural setting not very far from a metro city and to know the levels of

health prevailing amongst the rural population. As per the United Nations, four of the eight UN Millennium Development Goals (MDG) are health care related. [3,11]

The study indicated poor levels of public and private health care infrastructure, facilities and availability of public healthcare facilities. The study indicates presence of high levels of chronic disorders amongst the rural population like hypertension and hyperglycaemia which if not managed can lead to various complications resulting in morbidity and mortality. Awareness on health related issues amongst the rural population was also low. It was observed that the village did not have any facilities for the supply of drinking water. The villagers were dependent upon hand pumps and a well for this purpose hence acute disorders and diseases like diarrhoea, malaria and flu were common.

Unavailability of healthcare infrastructure adds to secondary expenditure on health such as transportation expenses to distance towns and cities which adds to the burden of healthcare expenditure, loss of work days, decrease in productivity and further loss of income. The study also confirms the resultant of low spending on health related expenditure by the government of India which is not more than 5% of the nation's GDP.

LIMITATIONS

This study has endeavoured towards getting a holistic perspective of healthcare of the village which has been a self-funded project. However, some more studies /tests for the rural population which if undertaken would have fulfilled this objective. These include analysis of the blood samples of the rural population to reveal the presence of anaemia and other disorders/diseases, chemical analysis of the water consumed for drinking by the village population. Also certain other medical tests like bone density, visceral fat analysis would have given a better picture of the overall health status of the rural population.

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Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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A Study on Relevance of Professional Training to Healthcare Housekeeping Aide through SAP-LAP Inquiry

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ABSTRACT

Purpose: The purpose of this paper is to explore the need and relevance of professional training to Healthcare Housekeeping Aide. This would not only enhance their service delivery but also improve the quality of service delivery in Industry.

Design/methodology/approach: The foundation of the present study is based on extensive review of extant literature by authors and appreciative inquiry. Furthermore, keeping the purpose of the study in mind authors tested the relevance of training using situation–actor–process and learning–action–performance [SAP-LAP] technique of enquiry.

Findings: The study outcome has proposed the relevance of professional training to healthcare housekeeping aide in India. This can be further used for design of professional training modules for housekeeping aide in Healthcare for sustained and enhanced service delivery of the Industry.

Research limitations/implications: The study proposes need and relevance of professional training based on insights from AI and literature review; it needs to be further validated using various methods including empirical ones. Although, authors have interviewed few selected hospital administrators and housekeeping aide from respective hospitals based on their availability and willingness to contribute. The may induce high risk of bias and to further strengthen the present study, the similar study needs to be conducted on large scale. Since, housekeeping aide in healthcare in India primarily falls under unorganized sector with lack of awareness and unity among workers of the industry. However, interviewing the senior housekeeping aide provided diversified insights.

Practical Implications: The study recommendations are configurator outcome of literature review of extant literature, appreciative inquiry and SAP-LAP analysis. These recommendations would help industry and professionals to understand the prominence of such training and development to enhance service delivery and service quality of the Industry.

Social Implications: The study finding formed a basis for the subject to establish and to be picked up by researchers to validate further in another setup.

Originality/ Value: The present study ventures in to new domain i.e. it is one of the initial attempt to understand the relevance of training of Healthcare Housekeeping Aide in India.

Keywords: *Healthcare Housekeeping aide, Professional Training, Service Delivery, Service Quality, Profitability.*

INTRODUCTION

Over the years Healthcare services as a branch of study has witnessed the swift rise in research about healthcare professionals by eminent scholars across diversified domains of management i.e. recruitment and selection of Human resource, Operations management and Service quality of Service marketing[1,2,3,4.] In other domains of healthcare sector, prominent researches comprise patient care and management, training of junior and senior medicos along with nursing aide, palliative care, waste management and sanitization to medical tourism etc. Wherein there remains dearth of literature which point outs to formal training needs of housekeeping aide in healthcare segment. This

would lead to formal skill development and help to attain sustainable service quality and delivery. The housekeeping aides are the pillars of healthcare sector who play critical role in healthcare industry. Though India is emerging as promising hub of medical tourism but healthcare housekeeping here is still largely handled by unorganized sector. The same scenario prevails in developed nations as well.

In routine practice, housekeeping aide's responsibilities are restricted to cleaning of floors, carpets and garbage from the assigned area. Moreover, it also encompasses to keep things properly in place in holistic manner. Their responsibilities include changing linens, curtains, cleaning and sanitizing restrooms, closets, corridors, guest areas and stairwells. Other than domestic front medical and healthcare sector, hospitality and tourism, service apartments are prominent employers for majority of housekeeping aides.

There is no prerequisite of educational qualifications to housekeeping staff rather physical strength with stamina to work for eight to ten hours a day along with appropriate communication skills are preferred for employment. Under traditional approach even in developed nations like USA a housekeeping aide usually receives on-the-job training to prepare them for their duties i.e. they learn by assisting experienced housekeepers in their work.

Hospital housekeeping in specific is more crucial in nature. They play prominent role here that they offer helping hand to medicos and nursing staff to take complete patient care in hygienic and efficient manner. In order to create and sustain safe healthcare environment for patients and society, Infectious disease prevention is a vital challenge to healthcare segment. There the role of healthcare housekeeping takes lead than merely maintaining proper disinfectant and tidy environments. But they have to ensure proper disposal of contaminated supplies. The weak and flawed housekeeping in relation to equipment, surfaces and others may turn fatal and potentially life-threatening not only to patients but for mankind at large.

India with a growth rate of 7% is regarded as the fastest developing nation of the world. The service sector contributes to approx. 65 percent of GDP in India and out of that around 6.5% comes from healthcare segment which is likely to be 10% of GDP by 2020. Also, India is known for the quality healthcare services at affordable rates and thus emerging as hub for Medical tourism.

> **"One well-trained, conscientious housekeeper given the right tools and enough time will prevent more disease than a room full of doctors can cure."**

Most of the researches revolve around sanitation and hygiene in healthcare segment. In contrast, there is hardly any research which emphasizes the relevance of formal training and skill development of healthcare housekeeping aide. This problem has determined the need to create new ways to provide professional training to healthcare housekeeping aide in formal manner. Thus the present study is driven by this research gap and leads to following research objectives:

1. To analyze the duties and skills required by housekeeping aide in healthcare segment, as an integral component to develop sustainable quality service delivery;
2. To analyze relevance of professional training using SAP-LAP analysis so as to create a talent pool for healthcare housekeeping; and
3. To outline further research directions.

Since, Service delivery and Service Quality are two important domains of service marketing and today, the traditional approach to professional training to healthcare aide is obsolete. Thus above objectives are in synchronization with prominent but unfulfilled need of healthcare segment.

REVIEW OF LITERATURE

The objective of conducting literature relevance is to understand the relevance of professional training to healthcare housecleaning aide, thus identifying the research gaps in existing training mechanism to healthcare housekeeping aide.

2.1 Roles and Responsibility: In order to get the exhaustive idea about the roles and responsibilities of healthcare housekeeping aid we have endeavored a qualitative technic named appreciative enquiry [AI], which is an assimilation of elucidations, drives and motives of the people based on their experiences from the specific industry. Cooperrider et al. (1998) in their research

regarded it as one of the well regarded technique of qualitative research[5]. In order to get diversified views we focused to collect opinions from various locations of India, namely Indore, Lucknow, Mumbai, Noida and Pune. Our respondents include both management professional and practitioners along with actual housekeeping aide of respective organization from healthcare segments. The basic purpose behind collecting opinions from both was to understand the level of sync between top management's expectations and perceivance and understanding of housekeeping about their roles and responsibilities in respective hospital/pathology. In order to get fair picture, respondents were promised to keep their identity as anonymous. The coming paragraph here provides a summarized view of roles and responsibilities of healthcare housekeeping aide based on AI inputs and existing literature.

Housekeep aide's routine responsibilities are not just restricted to merely clean and sanitize designated areas, changing linens etc. They are also liable to perform some specific obligations like stains removal from floor, cleaning windows and mirrors and dusting and polishing of all furniture and accessories. They not only clean and sanitize bathing spaces, sinks and toilets but also vacuum, sweep and mopping. They routinely check for damages to company property and equip supervisor with reports. The housekeeping aide not only provides assistance to maintain adequate supply of supply carts items but they also needs to remain in constant and recurring touch with their staff supervisors and other allies.

The most prominent role played by the housekeeper or environmental cleaning personnel is critical due to its nature. Their actions are directed to their foremost objective i.e. to the rheostat and thwart infections especially in healthcare segment. Although in holistic approach, it is a solidarity effort to which every element ranging from doctors, nurses at the bedside, respiratory therapists, pharmacists, physical therapists, surgery technicians in the Operating Rooms, cooks in the kitchen and housekeepers etc. play a distinctive role through rigorous efforts so as to maintain a clean environment.

2.2 Training: The training aspect of the healthcare professions in specific has been studied by some researchers with different perspectives. The segment illustrates few of the prominent studies conducted are dimensions here. Boyce and Pittet (2002) have proposed Guideline to maintain "Hand Hygiene" in Health-Care Settings useful to healthcare workers [HCWs][6]. The study recommendations were based on review of literature related to hand-wash and hand antisepsis in health-care segment. The focus of study recommendations was to endorse hand-hygiene practices and in order to minimize the chances of transmission of pathogenic microorganisms to patients and personnel in health-care settings. It also studied the new proposition of alcohol-based hand rubs and their role in hand-hygiene practices. In order to broaden the scope of study they have also included wearing of artificial fingernails, use of surgical antiseptics and hand lotions or creams.

HealthForce Minesota (2011) under their research project titled "Best Practices in Education for Healthcare Professionals of the Future" compiled various future oriented techniques of oriented training especially for Healthcare professionals[7]. In their project they not only reviewed the prevailing finest practices but also proposed some practices with futuristic orientation to educate healthcare professionals and furthermore they proposed strategic opportunities for Hennepin Health Foundation to employ these techniques. They conclude better training develops greater adaptability in healthcare professionals to cope with dynamic market demand.

The healthcare workforce today is not prepared to counter the growing challenges put forth by volatile environment. According to *Daniel Perry, ''the lack of training in the professionals that govern the care and treatment of people constitutes an immediate and continuing crisis. Now is the time to coalesce our efforts.'' He proposed that instead of sitting idle or observing, industry leaders and practitioners should provide constructive contribution to the sector, they should develop appropriate training programs for professional training of staff.

Health Foundation (2012) researched about "Quality improvement training for healthcare

professionals" and their study prompted that healthcare industry putting[8]. It has revealed that healthcare sector is functioning with customer centric orientation today. They put major thrust on providing value for money to its customer i.e. patients and their families. The sector is concerned and working rigorously to ensure higher access with unmatchable quality services. Keeping the quality enhancement approach in mind, healthcare sector has devised multiple training programs for students and professional of healthcare sector. The disparity between the content taught and the actual need of professional sector is quite visible. The study prominently pointed towards paradigm shift in terms of understanding the volatility in the concept of quality improvement. But it is yet to be infused in current training programs and resulting wide scope of development and research in this domain.

Roberta E. Sonnino (2013) studied about formal leadership training needs of healthcare executives[9]. They proposed that such programs are of high efficiency though it is relatively a new phenomenon. Furthermore they recommended that there are major opportunities available for surgeons especially women to obtain formal and informal leadership training for careers healthcare administration.

Engstrom et. al. (2016) examined the role of post-graduation professional training and qualification courses in relation to public health and primary healthcare[10]. They proposed the need for development of competencies through professional training and at the same time they advocated to take into consideration about dynamic nature of industry and develop the content accordingly which will give value to the students.

2.3 SAP-LAP Analysis: SAP-LAP framework for inquiry was invention of Sushil (2000)[11]. It has emerged as popular tool for analytics and very soon numerous prominent studies employed this technique in vivid domains.

Table 1: Few prominent research studies employing SAP-LAP framework (Source: Authors' own compilation)

Author(s) / Year	Domain	Research Study
Sushil (2000)	Proposed SAP-LAP	SAP-LAP model of inquiry
Sushil (2001)	Advancement of SAP-LAP	SAP-LAP framework
Suri (2008)	Fertilizer Industry	Tactical E-governance
Banvet and Pramod (2010)	Flexible Management System	Strategic Change management
John and Ramesh (2012)	Disaster management	Humanitarian Supply Chain Management
Kabra and Ramesh (2015)	Humanitarian Supply Chain	ICT issues in Supply Chain
Venkatesh et. al. (2016)	Flexible Management System	Palliative care process

RESEARCH GAPS

To substantiate the findings from AI method, authors have conducted extensive review of extant literature. This procedure called our attention to an unexplored region which is starving to be picked up with uttermost attention by researchers. Over the years, healthcare as a segment is enriched with ample of research efforts in vivid dimensions by various authors. But, there is a dearth of literature which emphasizes the training needs of housekeeping aide in healthcare in developing nations especially in India. Thus, there exists an unrelenting demand to develop the appropriate training framework modules for healthcare housekeeping aide. This will make the sector ready to face the future challenges to enhance quality service delivery.

3.1 SAP-LAP Framework for relevance of formal training to healthcare housekeeping aide

3.1.1. Situation: As mentioned earlier, housekeeping aide is an integral constituent of healthcare industry. However, the industry is still waiting for the due attention toward the formal training needs of its housekeeping aide so as it would benefit the society at large.

India has emerged as a promising medical hub for providing world class services at affordable rates than the rates of developed nations. Thus, trained housekeeping aide will

significantly enhance quality service delivery and resulting profitability of the sector. Government and administrators of various healthcare organizations in develop nations like USA and UK are much aware about the relevance of professional training in healthcare sector and the sector has enriched through numerous researches. Even though, there is no prerequisite of educational qualifications to join as housekeeping aide in healthcare sector. Also, there is no provision of professional training in formal manner for such aide including both developed and developing nations. As a usual practice in healthcare, after joining for initial few months housekeeping aide receive on the job training [OJT] in the form of assisting their seniors and superiors and they develop desired skill set to perform regular duties. Only a handful of the players in healthcare sectors are paying attention to this unexplored area.

The present study is an attempt to highlight the unfulfilled and unsaid need of the sector so as to fetch attention of policy makers and researchers to work upon it. Introduction of formal training services would not only uplift the moral and satisfaction of housekeeping aide but it would also increase operational efficiency as well.

3.1.2. Actors: In India, Ministry of Health and Family Welfare of central and various state governments are policy formulators related to healthcare issues including training and development etc. Housekeeping workers unions may play the role of need generator and ensure uninterrupted implementation of policies and training of housekeeping aides. The major human force in rendering healthcare services are called as 'Clinicians' which include doctors, nurses at the bedside, respiratory therapists, pharmacists, physical therapists, surgery technicians in the Operating Rooms etc. Rest all other are housekeeping aide, they render assistance services to clinicians for smooth administrative and allied functions. Top management of healthcare industry as change agent may induce formal training policy and distinctive training program for housekeeping aide.

3.1.3 Process: Implementation of formal training procedure for healthcare housekeeping aide is necessary for to enhance service quality delivery. According to cleanlink.com portal, Healthcare housekeeping task is a blend of cleaning, disinfecting, infection prevention and sanitizing. It starts with the proper cleaning and putting entities as appropriate place. Later, objects are disinfected with the use of liquid chemicals called disinfectants. Infection prevention is the most crucial part of housekeeping here. This aspect not only identifies but also reduces the risks of infections from developing or spreading. There is constant threat of infection spread for both patient and his family along with healthcare staff. Healthcare centers have made special arrangement to reduce the high risk of infection. Through proper disposition of hazardous waste reduces the risk. Thus, trough effective formal training this risk can be minimized efficiently

3.1.4 Learning: There is an urgent need to develop a common understanding about training needs of housekeeping aide among all stakeholders of healthcare sector and devise comprehensive program to render formal training services. The need of proper training and motivation are the key areas of concern for housekeeping aide today. Unfortunately, the housekeeping aide in healthcare segment in India is completely unaware about their training needs. The service providers also overlooked this aspect. The training will not only boost the morale of existing aide and they would be in better position to perform their duties more effectively and efficiently. This would strengthen Indian healthcare segment in terms of service quality and service delivery and equip it with better competency among its contenders. Moreover, as an organized sector it will motivate the less educated and unemployed people to join the sector resulting it will reduce unemployment problem of India.

3.1.5 Actions: In order to achieve sustainable and competent service quality delivery, it is necessary to plan and devise a holistic service delivery system and all stakeholders are required to be integrated into a central system. Resulting housekeeping aide will get an integral position and keeping in mind the current and future training needs of housekeeping aide it requires a comprehensive training policy for every stakeholder in healthcare sector.

This will enable them to render nation-wide uniform service quality and delivery. Thereby Indian healthcare sector will not only achieve a distinct position but it will be future ready to compete with its competitors across the globe.

The housekeeping aide needs to be properly trained and developed on ways of delivering quality services in a holistic manner to achieve the organization objectives. The top management and government should join hands to implement all possible measures so as to ensure that customers receive housekeeping services of international standards in India. Training and development of housekeeping aide through interactive sessions should ensure continuous improvement in services

3.1.6 Performance (Expected): The systematic implementation of formal training procedure will boost the morale of all stakeholders including housekeeping staff, patients and society at large. It will reduce the risk of infection and ensure quality service delivery in empathetic manner. The Indian housekeeping aide will perform on world class standards. This will motivate them to learn continuously and keep them more informed to deliver high-quality service through training and development. Standard housekeeping practices and models can be developed to provide standard services to all and the same could be benchmarked to attain higher goals and quality. Ultimately, the goal of **'quality service and delivery with profitability' will be achieved.**

DISCUSSIONS AND RECOMMENDATIONS

The SAP-LAP analysis above clearly indicates how the formal training under moderation effect of government regulations and top management commitment can transform an untrained housekeeping aide into motivated housekeeping professionals. It can successfully help them to acquire desired skills and remain competitive in the market. The training can enable them to respond to volatile needs and challenges of the market. Thus, based on these premises, we offer the following recommendations so housekeeping aide can lead their life as a respected professional and they can be part of sustainable quality service delivery network.

1. First and foremost, the commitment and motivation from the top management officials from the industry acts like driving force to transform pool of skilled housekeeping aide. Keeping their contribution in mind top management may offer higher remuneration packages and perks to skilled aides to boost their moral.
2. Next, trainers must identify the personality traits and skill set desirable for housekeeping aide. Later, the training content must be developed in sync with their personality traits which results into transformed housekeeping aide for healthcare segment.
3. In order to offer due recognition to invaluable contribution of healthcare housekeeping aide, Indian Government and top management from the industry must come together and run the awareness campaigns in public. This will lead to establish healthcare housekeeping as a respectable profession in an organized manner.
4. Proper training has twofold advantages. It will not only motivate our less educated and unemployed people to pick it as career but also enhance service quality and delivery of healthcare industry in India.
5. In order to confront market volatility, the training content must be comprehensive enough i.e. it must equip housekeeping aide with appropriate methodological and behavioral competence. It must be inclusion of psychological, behavioral and scientific aspects wherein the method of training can be traditional mentor-mentee method or role play method etc. They may use the technological advancements like simulation and online training.

CONCLUSIONS

We have conducted extensive extensive literature review while keeping our first research objective in mind. Further, we have employed AI as a quasi-ethnographic approach to identify roles and responsibilities of healthcare housekeeping aide. In order to respond to our to our second research objective, we have employed SAP-LAP analysis which confirms the unfulfilled need of formal training and establishes its relevance in terms of enhancing the service quality and delivery to match with international standards. In healthcare segment in India, the current skill set of healthcare housekeeping aide is not appropriate to cope with future challenges of the industry. Since, our research findings are based on our pragmatic approach guided by extant literature and AI data thus need to be validated further.

6.1 Unique contributions: The present study is amongst one of the initial attempts to propose relevance of formal training to housekeeping aide for sustainable quality service delivery in healthcare sector in India. It has attempted to contribute to the existing body of knowledge. Though housekeeping has been integral element of healthcare segment, somehow it has received little attention from earlier researchers and industry personnel. Both, the industry professionals and previous researchers have overlooked the nexus between two important aspects i.e. desired skill sets and formal training needs of healthcare housekeeping. Based on AI and extensive literature review our study recognized the relevance of formal training to housekeeping aide in healthcare sector of India, thus contributing to service sector literature.

6.2 Managerial implications: The present study provides the comprehensive picture about the roles performed by healthcare housekeeping aide along with the unfulfilled training needs of the domain. It proposes the relevance of the same. This can grab the attention of policy makers and practitioners towards the relevance of formal training and they devise appropriate training modules for housekeeping aide so as to make it achievable the sustainable quality service delivery. It will transform the unorganized healthcare housekeeping in India into an organized one. This can generate significant employment to less educated and employed youth of India. Professional institutes like ITI's and NIOS can respond to our call by introducing formal training modules for housekeeping in healthcare sector. In order to take advantage of their vast experience senior and aged housekeeping may get recognition as trainers. These whole efforts will establish this into an organized industry. Also, to provide due recognition to the significant contribution of housekeeping aide in healthcare sector, Regulatory authorities and other members of professional institutions in healthcare must introduce a package inclusive of uniform pay scale and perks for them.

6.3 Limitations and further research directions: Nothing is perfect in this world and thus the present study has its own limitations but these limitations are stimulus for further research. The study proposes need and relevance of professional training based on insights from AI and literature review; it needs to be further validated using various methods including empirical ones. Based on availability and willingness to contribute we could interview few selected senior hospital administrators and housekeeping aide from respective hospitals. The may induce high risk of bias which can be eliminated by conducting the study on large scale. Also, the housekeeping aide in healthcare in India primarily falls under unorganized sector with lack of awareness and unity among workers of the industry. However, interviewing the senior housekeeping aide provided diversified insights.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Effectiveness of Training Provided to Emergency Medical Services Professionals Working with Maharashtra Emergency Medical Services Project

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ABSTRACT

Introduction: Maharashtra Emergency Medical Services (MEMS) is project of Government of Maharashtra under National Rural Health Mission (NRHM) and is operated by Bharat Vikas Group (BVG) India Limited in academic association with Symbiosis Institute of Health Sciences (SIHS) and United Kingdom Specialty Ambulance Services (UKSAS, United Kingdom). It is a toll free '108' number based 24 x 7 hours' pre-hospital emergency medical services free of cost to entire population in the state of Maharashtra.

Training was imparted to all Emergency Medical Services Professionals (EMPs) working with MEMS project by Symbiosis Institute of Health Sciences, a constituent of Symbiosis International University.

Purpose: The present study shows the analysis of performance of Emergency Medical Services Professionals (EMPs) before and after the training based on their Scores in Pre-Course Test, Post-Course Test and Skills Assessment.

Methodology: This study was conducted before providing the training and after training was completed during 01 July, 2013 to 31 January, 2015. Only BAMS and BUMS doctors were enrolled for the study. The participants with MBBS background were not included in this study. At the beginning of the training session, course test and skills test assessment of 100 points each was administered.

Total of 122h of theory and practical training programme was carried out for all participants.

After training session, course test and skill test assessment to 100 points each was again administered to determine the change. The questions used for assessment were pertaining to EMS and experience gained in EMS system.

Results: Total 3000 trainees attended the training during 01 July 2013 to 31 January 2015. Of them 38 participants submitted incomplete assessment at either time points and were not considered for final analysis. Thus the final analysis was carried out on 2962 participants

The average score of course tests and skill test assessment of participants before training was 53.1 (SD 10.9) and 52.1 (SD 10.5) respectively. The course test assessment showed that more than 1/3rd of the participant had score below 50% before the course test assessment and course skill assessments. Also 3/4th of the participants have score below 60 percent in course test assessment and almost 8 out of 10 participants have score below 60 percent in course skills assessment.

After training, the mean score of course test assessment was 77.0 (SD 9.3) and skill test assessment was 77.9 (SD 9.5). Thus there was more than 45 percent change from before training to after training in course test and skill test assessment of participants. This change was statistical significant ($p<0.0001$ for both test).

Research Implications: Looking at the average of the score of the Doctors in the Pre-Test and Skills Assessment and for the Post-Test and Skills Assessment after undergoing Training it can be concluded that the Training provided to the candidates has helped them improve their Skills and there has been up gradation in their knowledge.

Novelty: This is a significant observation and highlights importance of hands on training in building skills.

In order to do this well, doctors and nurses need to be trained to recognize the severity of illness and to categorize conditions in relation to the likelihood of treatment priority and the strategies most likely to maximize outcome.

Keywords: *EMP, EMS, MEMS.*

INTRODUCTION

Emergency Medical Service (EMS) is a branch of emergency services dedicated to providing pre hospital/ out-of-hospital acute medical care and/or transport to definitive care, to patients with illnesses and injuries which the patient or the medical practitioner believes constitutes a medical emergency. The goal of emergency medical services is to either provide treatment to those in need of urgent medical care, with the goal of satisfactorily treating the malady or arranging for timely removal of the patient to the next point of definitive care. This is most likely a casualty/ emergency room at a hospital or another place where physicians are available.[1]

In India, (one person dies on the road) every 4 minutes. While 7 to 10 percent are critically injured, 20 to 30 per cent are seriously hurt; of these about 30 per cent are disabled for life, either partially or totally[2].

To reduce morbidity & mortality, Government of Maharashtra decided to offer Emergency Medical Services across all districts of Maharashtra.

Maharashtra Emergency Medical Services (MEMS) Project is operated by Bharat Vikas Group (BVG) India Limited. It is a toll free '108' number based 24 x 7 hours pre-hospital emergency medical services free of cost to entire population in the state of Maharashtra. Training was imparted to all Emergency Medical Services professionals (EMPs) working with MEMS by Symbiosis Institute of Health Sciences, a constituent of Symbiosis International University.

The training center is well equipped with advanced training material, including state of the art infrastructure, simulated manikins and world class equipment. These professionals were trained to detect any emergency, respond immediately, report, provide on-scene care, en-route care and transfer to appropriate hospital; Training also includes reassurance to patients, relatives and bystanders prior to and during transportation to hospital casualty room.

Complete training program is conducted for a period of 122 Hrs. as shown in Table no. 01 below.

Table No. 01

Sr.	Module	Hours	Division (Theory + Practical) in Hours
1.	Basics of EMS including Medico legal and ethical issues.	36	14 + 22
2.	Medical Emergencies	24	9 + 15
3.	Trauma Emergencies	20	8 + 12
4.	Emergency Medical Services Officers operations	18	7 + 11
5.	Clinical Rotation	24	24 Hours Practical

AIM: To study the effectiveness of the training provided to the EMPs with Maharashtra Emergency Medical Services Project.

MATERIAL AND METHODS

This study was conducted before providing the training and after training was completed during 01 July 2013 to 31 January 2015. Only BAMS and BUMS doctors were enrolled for the study. The participants with MBBS background were not included in this study. At the beginning of the training session, course test and skills test assessment of 100 points each was administered.

Total of 122h of theory and practical training programme was carried out for all participants. The theory includes training on basics of EMS, medico-legal and ethical issues, medical and trauma emergencies, (Emergency Medical Service Officers) EMSO operations and clinical rotation. Electronic media, audio-visual

aids & Simulations based case scenarios were used for training. Discussions were carried out in smaller group of 10 participants in each group. Practicals were conducted on manikins and simulation based case scenarios.

After training session, course test and skill test assessment to 100 points each was again administered to determine the change. The questions used for assessment were pertaining to EMS and experience gained in EMS system.

This available date from completed questionnaire was collated and developed expressively for the purpose of evaluating resuscitation skills and thus effectiveness of training.

STATISTICAL METHODS

Descriptive statistics was displayed for all documented and derived variables. Data in table is presented as number and percentages. For continuous data, the number of non-missing observations (n), mean, standard deviation (SD), minimum (min) and maximum (max) were calculated. Group comparisons were made using χ^2-test and paired t-test. Data with missing values are not considered for analysis. All statistical analyses were performed with SPSS, version 20.0.

RESULTS

A total of 3000 trainees attended the training during 01 July 2013 to 31 January 2015. Out of these, 38 participants submitted incomplete assessment at either time points and were not considered for final analysis. Thus, the final analysis was carried out on 2962 participants where data before and after providing training was available.

Table 2 shows the assessment score on participants who appeared for course test and skill test assessment before and after the EMS training.

Table 2: Percent distribution of test and skill assessment scores before and after training

	Course Test assessment (n=2962)		Course Skills assessment (n=2962)	
Marks categories	**Pre**	**Post**	**Pre**	**Post**
<50	1052 (35.5)	16 (0.5)	1115 (37.6)	20 (0.7)
51-60	1272 (42.9)	148 (5.0)	1366 (46.1)	148 (5.0)
61-70	489 (16.5)	358 (15.1)	350 (11.8)	320 (10.8)
71-80	136 (4.6)	1365 (35.9)	130 (4.4)	1100 (37.1)
81-90	13 (0.4)	1063 (46.1)	1 (0,03)	1360 (45.9)
91-100	--	12 (0.4)	--	14 (0.5)
Mean (+SD)	53.1 (+10.9)	77.0 (+9.3)	52.1 (+10.5)	77.9 (+9.5)

Note: values are n(%)

The average score of course tests and skill test assessment of participants before training was 53.1 (SD 10.9) and 52.1 (SD 10.5) respectively. The course test assessment showed that more than 1/3rd of the participant had score below 50% before the course test assessment and course skill assessments. Also 3/4th of the participants have score below 60 percent in course test assessment and almost 8 out of 10 participants had score below 60 percent in course skill assessment. Only about 5 percent scored above 70 percent before training.

After training, the mean score of course test assessment was 77.0 (SD 9.3) and skill test assessment was 77.9 (SD 9.5). Thus, there was more than 45 percent change from before training to after training in course test and skill test assessment of participants. This change was statistically significant ($p<0.0001$ for both test). After training, only 5 percent participants scored 51-60 percent, about half % of them scored between 61-80 percent and 45 percent participants scored more than 80 percent in course test and skill assessment.

The participants who scored less than 50 percent in either assessment were remediated. Thus, after the training program the participants achieved adequate knowledge regarding medical, trauma and other emergencies. Similarly, the participants also acquired the basic and advanced life-saving skills required to deal with any emergencies.

CONCLUSION

1. Few participants had prior knowledge of Emergency Medical Services and possess experience of managing emergency patients.
2. Participants were familiar with emergency service equipment and articles.
3. Cognitive objectives were achieved by lectures based on slide presentations, use of audio-visual aids and tasks or discussions carried out in smaller groups.
4. Skills outcome: At the end of this program, the students have acquired the basic and advanced life-saving skills required to deal with any emergencies.
5. Knowledge outcome: At the end of training program, the students have achieved adequate knowledge regarding medical, trauma and other emergencies.

Further a comparison of performance of Pre Test, Post Test including Skills Assessment for both tests was done for evaluating up gradation of skills.

The average score of doctors in Pre Test is 53.1 (SD±10.9) & Pre Course skill assessment is 52.1 (SD±10.5)

The average score of doctors in Post Test is 77.0 (SD±9.3) & Post Course skill assessment is 77.9 (SD±9.5).

Thus training provided to the candidates has helped in up gradation of knowledge and improved skills.

It is well known that improved training leads to an improvement in the standard of resuscitation attempts along with improved chances of survival for the patient[3].

Looking at the average of the score of the Doctors in the Pre-Test and Skills Assessment and for the Post-Test and Skills Assessment after undergoing training it can be concluded that the Training provided to the candidates has helped them improve their Skills and there has been up gradation in their knowledge.

This is a significant observation and highlights importance of 'hands on training' in building skills.

In order to do this well, doctors and nurses need to be trained to recognize the severity of illness and to categorize conditions in relation to the likelihood of treatment priority and the strategies most likely to maximize outcome.

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Mishandling of Medical Devices in Hospital ICU: Analysis of Causes, Revenue Drains and Training Needs of ICU Staff

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ABSTRACT

Introduction: Medical devices in hospital Intensive Care Units (ICUs) constitute a major investment center. Repair/replacement costs due to mishandling causes revenue drains which are largely avoidable. This study identifies the causes, cost incurred, lag time due to breakdown of medical devices in ICUs due to mishandling and training needs of ICU staff.

Methods: This observational study was conducted in a 550-bed hospital in Pune from Jan'2015-May'2016. Records of machine breakdown reports maintained by biomedical department were analyzed for cost incurred due to repair or replacement of devices/accessories/parts. Reasons for mishandling were enquired through questionnaire and short interviews of ICU nurses and biomedical staff. Machine breakdown due to unavoidable incidents were excluded. Further, we prepared Instrument handling guidelines; proposed an ergonomically sound patient bed area; and conducted training of ICU nurses. Subsequently a post training assessment was done.

Results: More than INR 4, 66, 000/- worth of accessories/parts/devices were replaced due to device mishandling. Monitors and syringe pumps were most prone to breakdowns due to mishandling. The average time lag for solving a breakdown problem was 24 hours (minimum=5 minutes, max=11 days, 3 hours). The leading causes for mishandling were ignorance, carelessness, lack of training, improper ergonomics and improper placement of devices, stress and fatigue. Post training assessment showed that mishandling incidents reduced to less than 50%.

Discussion & Conclusion: Regular training of ICU staff, and incorporating 'Instrument handling guidelines' as a part of induction program for new staff will reduce device mishandling. Unplanned expansions should be avoided and patient bed area should be properly planned.

Keywords: *Intensive Care Unit (ICUs), Medical devices, Training needs, Human factors, Mishandling*

INTRODUCTION

In today's scenario, tertiary care hospitals are increasing and existing tertiary care hospitals are expanding with the state of the art technology to serve the community. As a result of this a very high budget is spent on equipment purchasing and their maintenance. Though the hospitals are spending more money on advance technological devices and their maintenance, still hospitals are facing problems of equipment breakdowns. These types of equipment breakdowns are mainly related to mishandling of equipment, which leads to decreased machine life and unnecessary expenses to the hospitals. Further, the repair/replacement costs due to mishandling cause revenue drains which are largely avoidable.

It has been seen that, the mishandling of equipments is a major problem but, mostly neglected by the hospital management staff as they are unaware of the cumulative cost incurred in the device mishandling and sometimes the improper handling is unrecognizable or neglected because of involvement of small accessories and cheaper parts. But the range of breakdown problem occur from small part of the machine to breakdown of complete machine, and according to that cost of breakdown varies.

'The mishandling of device means to manage or deal with or to operate medical device in a wrong or ineffective manner'. This mishandling of devices hampers the capital cost invested in the machines and leads to breakdown of an equipment. In this study we are focusing on mishandling of medical equipments in ICUs, as medical devices in hospital ICUs constitute a major investment center.

This study identifies the cost incurred in ICUs due to mishandling of equipments, their causes, lag time due to breakdown of equipment, training needs of the ICU nursing staff, preparing guidelines on instrument handling, impact of staff training on the amount of reduction in mishandling cases and expenses in ICUs.

METHODOLOGY

This observational study was conducted in a 550-bed hospital in Pune from Jan'2015-May'2016. Included in the study were ICUs of the hospital namely, Neuro Trauma Unit (NTU), Cardiac Care Unit (CCU), Neonatal ICU and recovery rooms. Records of machine breakdown reports maintained by biomedical department were analyzed for cost incurred due to repair or replacement of devices/accessories/parts. Reasons for mishandling were enquired through questionnaire and short interviews of ICU nurses and biomedical staff. After analyzing the causes of machine mishandling, we prepared Instrument handling guidelines; proposed an ergonomically sound patient bed area; and conducted training of ICU nurses. Subsequently a post training assessment was done.

Avoidable breakdowns of devices occurred due to mishandling were included whereas, unavoidable breakdowns like due to electronic failure, manufacturing defects, and due to wear and tear were excluded. The respondents for questionnaire were nursing staff working in various types of ICUs mentioned above. The participating Nurses were both males and females and were in the age group of 22-62. They were interviewed regarding their information related to medical devices and reasons of mishandling.

The breakdown cost of medical equipments was calculated from breakdown reports of equipments maintained by the biomedical staff by cross checking price of the broken-down accessories/parts/device with the price list in the biomedical department. Observations were noted to understand device handling techniques of ICU nursing staff by regular visiting ICUs. For analyzing causes of mishandling we prepared questionnaire containing 15 questions. By identifying the causes of mishandling we prepared device handling guidelines for the instruments which are most prone to breakdowns and ICU nursing staff were trained using these guidelines after which a post training assessment containing 10 questions was conducted to evaluate the changes/improvements in device handling techniques. Along with the post training assessment, we designed an ergonomically sound patient bed area for better movement of staff and devices around the patient bed. Recommendations were given for better improvement in device break-down cost reduction.

RESULTS

In the year 2015, the expenditure on mishandling of devices of hospital was Rs. 14,13,474, including ICU expenditure of Rs 3,56,946 which was around 25% of the total breakdown cost of devices in the hospital. The study was further concentrated on ICU device mishandling for the period of January 2015 to May 2016 and it was found that the total cost incurred was Rs. 4,66,045. After bifurcating the total mishandling expenditure of devices occurred in critical care units, it had been seen that, NTU had highest amount of mishandling expenses on medical devices of Rs. 1, 63,288 (35%). ICU and CCU had nearly equal amount of mishandling expenses of Rs. 1, 38,477 (29.71%) and Rs. 1, 37,771 (29.55%) respectively. Recovery rooms and NICU had less amount of mishandling expenses consisting of Rs. 22,329 (4.5%) and Rs. 4240 (1%), shown in figure 1.

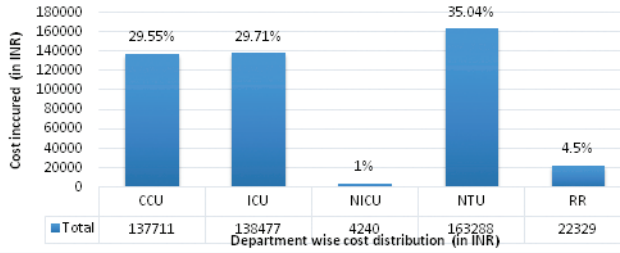


Figure 1: Expenses incurred due to mishandling of devices in ICUs

In figure 2, the pie chart shows that maximum mishandling was reported for monitors as it has many accessories attached to patients in addition to being handled by multiple users. Therefore it was the main pain area in mishandling of medical devices. This cost

was around Rs. 3,05,126 with 66% of mishandling breakdown cost. Another major amount of mishandling was found in Syringe pumps which cost around Rs. 97,674 with 21% of mishandling breakdowns. Ventilators are the lifesaving instruments showed 10% of mishandling breakdowns costs worth Rs. 47,955. ECG, Baby warmer, and other devices shared much lesser proportion of breakdown cost due to mishandling.

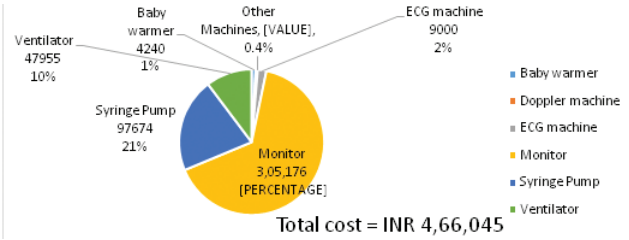


Figure 2: Pie-Chart of instrument wise breakdown cost occurred due to mishandling (cost in INR, %)

On an average monthly 3 breakdown calls occurred due to device mishandling in critical care units. So for the study period of 17 moths (i.e. January 2015 to May 2016), it was found that, the average monthly expenditure on mishandling of devices was Rs. 27,415.

The lag time found to solve the breakdown call was 24 hours depending upon the availability of accessories with critical care staff or in the biomedical department. The minimum time lag was 5 minutes, whereas maximum time lag was 11 days, 3 hours. Interviews of nursing staff and biomedical staff revealed 6 common reasons of mishandling at the user end. They are ignorance, stress, fatigue, multiple number of users, high employee turnover and poor patient space management.

Ignorance is the main human factor involved in a mishandling of devices. Ignorance is seen in ICU staff due to lack of knowledge or handling techniques about devices, emergency situations, hurry to do work, careless attitude and distraction in work. 86% nurses said that they feel stressed while handling the equipments as many of them are fresher (with 5 to 10 month experience). This is an occupational stress. 51% of the staff reported that cause of stress due to 'inadequate training' and 'handling of critical care equipments'. 39% staff reported that they feel stress while handling critical or restless patients, and 10% of the staff feels stress, due to their personal reasons.

17% of the staff reported fatigue due to overtime duties. 48% of employees feel fatigued due to heavy work load and 36% due to less manpower. Senior staff sometime feels fatigued because they are responsible for training and instructing the new/junior staff. Wrong placement of devices and other component of the patient bed area also created fatigue in staff.

There should be adequate space near patient bed. This space is necessary for movement of staff and instrument near the patient bed. Instruments require space for movement, air circulation to cool down and to avoid electric and magnetic noise of nearby devices. In NTU only 60 to 80 sq. feet space for patient bed area was available. In ICUs, users are more in numbers, their handling techniques are different and most of them are freshers. Therefore, breakdown of machines due to mishandling is more compare to single user devices.

If the patient is restless or rowdy he/she breaks the SpO2 probes by hitting it on hand rails of the patient bed or pulls off ECG cables or syringe tubes. So this causes breakdown of devices or accessories. 12 to 16% of breakdown of instruments is due to restless patient.

From the above calculated expenses, most of them were avoidable. For avoiding these expenses we designed the 'Instrument Handling Guidelines' for the devices which are regularly used and showing high mishandling cost in the expense sheet.. These guidelines are based on respective devices' manuals and SOPs defined by the biomedical department of the hospital. By considering human factors which were discussed previously we also redesigned ergonomics of the patient bed area. We gave training to 165 nursing staff on these guidelines and ergonomics because, training to staff was the best solution for avoiding such expenses.

From the results of post training assessment (fig. 3), it was found that staff had secured good score in the assessment. 83% staff had scored above 90% of marks. This indicated that they had understood the equipment handling guidelines and losses occurred due to mishandling of devices. And by analyzing the feedbacks received from nursing staff we can say that, 60% of the nursing staff said that, the training was useful to staff to solve their quarries related to handling of the devices. 70% the staff was satisfied due to their expectations about information of devices were quite met from this training session. After training sessions, the instrument handling of staff were observed for remaining days of study period and it was observed that, their handling techniques were improved. So we can conclude that the impact of training on nursing staff was good and it helped in their work.

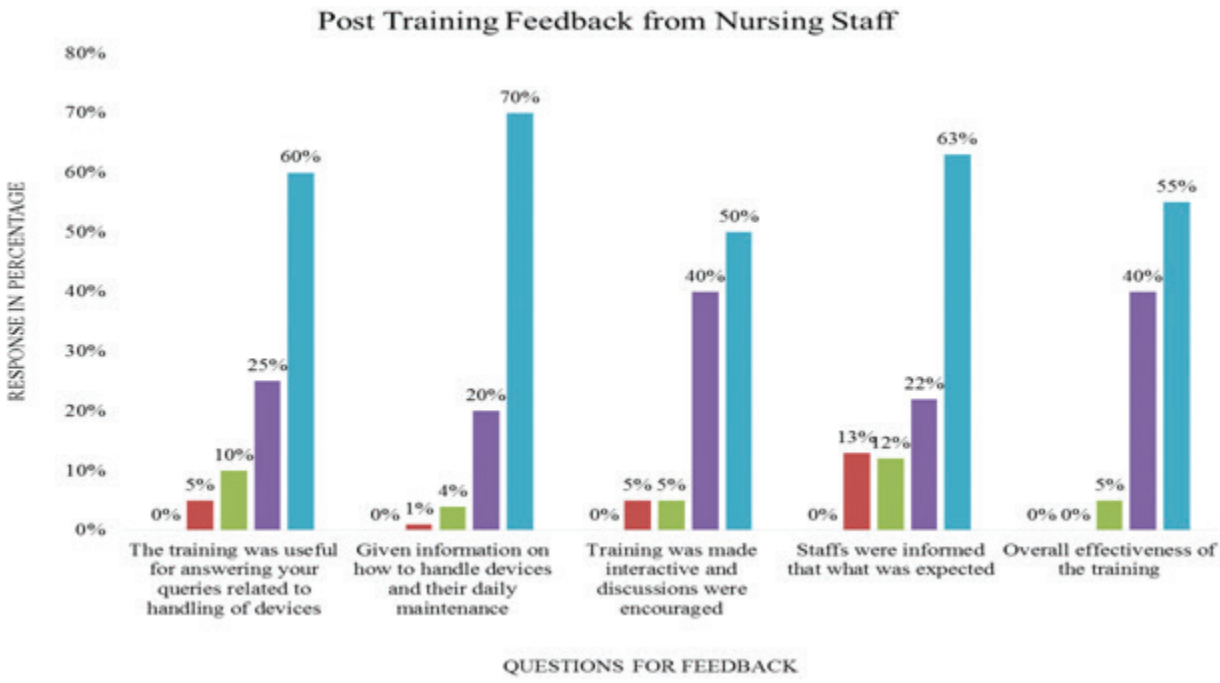


Figure 3: Post training feedbak from nursing staff

It has been observed that there were no complaints received in the month of June 2016 for device mishandling in biomedical department. But in July 2016 they received a complaint of syringe pump broken. On further investigation it was found that the clamp was broken due to improper handling and it cost around Rs. 4996. However, the cost was reduced to 18.22 % as compared to average mishandling expenditure. The incidence of mishandling cases dropped by 33.33% as compared to the baseline incidence of mishandlings.

DISCUSSION

The mishandling of a medical device means to manage or deal with or to operate medical device in a wrong or ineffective manner'. This mishandling of devices hampers the capital cost invested in the machines and leads to breakdown of an equipment and reduce life span of a medical device. A previous study showed that[1] for medical equipment failures, about 80% of all failure cases are caused by preventable factors. For instance, failures due to inadequate maintenance account for about 60% of all the failure cases. Most failures arise from deterioration of accessories and consumable components. The deterioration time of the accessories and consumable components can, however, be predicted by carrying out maintenance and inspection. Therefore, 60% of all these failures can be prevented by replacing such 'consumable parts' on a regular basis, or replacing them immediately when the equipment becomes defective. These are not real breakdowns of the equipment. In addition to this, failures due to inappropriate handling, environmental stress and wear-out account for about 20% of all the failure cases. Most of these can also be prevented by carrying out appropriate measures based on MMS. It can be said that 80% of medical equipment failures are, therefore, preventable.

In ICUs, the major mishandling happened with Monitors as it has many accessories attached to patient and has many users including doctors, nurses, and ward boys during transportation, therefore it is the main pain area in mishandling of medical devices costs around Rs. 3, 05,126 with 66% of mishandling breakdown. Another major amount of mishandling was found in Syringe pumps which cost around Rs. 97,674 with 21% of mishandling breakdowns. Ventilators are the lifesaving instruments showed 10% of mishandling breakdowns with amount of Rs. 47,955. ECG, Doppler machine, and Baby warmer showed lesser breakdown cost due to mishandling.

There were total 32 mishandling complaints received related to monitors. Most of them were of SpO_2 probes and ECG cables. 17 Out of 32 cases were related to breakage of SpO_2 probes (i.e. 50%). In that 16 cases, we found that, 6 times SpO_2 probe broken down due to wrong and forcefully insertion of probe into the machine. This is due ignorance of nursing staff. In 4

cases, probe was cut as it was jumbled or woven into the handrails of the patient bed. In 4 cases, patient trolley or bed moved over it and resulted into breakage. This happened due to ignorance or carelessness of nursing staff. Restless patients also pulled down the SpO_2 probe due to uneasiness that lead to breakage. This is a huge cost considering that each newly replaced SpO_2 probe costs around Rs. 17552.

It has been observed that, ECG cable was broken down 15 times out 32 incidents (i.e. 47%) due to forcefully being pulled off. In another case, saline solution had gone into the cable and resulted into short circuit of cable. One cable was broken down while shifting of a patient. There were 4 cases of breakage of ECG cable occurred due to restless patients. Each ECG cable costs around Rs. 5808. There were 2 complaints for missing of BP cuff and rectal probe.

In ventilators, we found that 85% of problems related to moisture trap breakage. This occurred during shifting or moving a ventilator from one place to another. During shifting nursing staff holds the moisture trap instead of handrails and it results breakage of moisture trap. The cost of new moisture trap is Rs.2415, and there were 11 such cases. Similar type of forcefully shifting resulted into the breakage of expiratory port of the ventilator, which is quite expensive, nearly worth Rs. 23,000. A total of 13 mishandling breakdown cases of ventilator occurred during study period.

In syringe pumps, it was found that around 86% of mishandling breakdown occurred due to fall on the ground. In that case its parts like plunger, syringe holder, drive, display etc. were broken down and sometimes whole assembly needs to be replaced.

The lag time found to solve the breakdown call was 24 hours. It was depending upon the availability of accessories with critical care staff or in the biomedical department. The minimum time lag was 5 minutes, whereas maximum time lag was 11 days, 3 hours. For minimizing this lag time of service, there should be adequate storage of accessories or parts which required on regular basis.

Our study showed that, 86% of staff nurse said that they feel stress while handling the equipments as many of them are fresher (5 to 10 month experience). The relationship between stress level and performance has also been confirmed through many researches. While high stress is something that everyone can relate to, it is important to recognize that low level stress also counterproductive, as this can lead to boredom and failure to attend to a task with appropriate vigilance[4]. 51% of staff reported that cause of stress due to 'inadequate training' and 'handling of critical care equipments'. 39% of staff reported that they feel stress while handling critical or restless patients, in this case breakdown of an instrument is happens if staff is treating the patient then unknowingly giving jostle to the equipment. And 10% of the staff feels stress, due to their personal reasons.

There is strong scientific evidence linking between fatigue and performance decrement, making it a major risk factor in patient safety[2]. Prolonged work has also shown to produce the same deterioration in performance[3]. This statement also applies to mishandling of equipments done at the user end, concluded from questionnaire filled by nursing staff. Nursing staff do their routine duty for 6-8 hours and night shift for 12 hours. ICUs have a 2:1 patient to nurse ratio which goes up at times and creates fatigue in staff. 17% of the staff reported fatigue due to overtime duties.

It has been observed that, the hospital have very high employee turnover rate. Critical care units had 59% fresher staff, average experience of staff was 12 months, and none of the fresher staff had received any training on biomedical equipment at the time of joining or when they were transferred to ICUs. Whereas 64% of the ICU staff got training related to medical devices during their job tenure and 75% of the staff reported difficulties while handling the equipments. 46% of the total staff have not read any manuals or information related to devices and its working. They totally depend on training given by biomedical staff or instructions from senior staff. We observed that employees work in the hospital for only 1 to 2 years. Every time institute receives unskilled worker, spends time on training, teach them but due to high employee turnover these efforts have less output. This situation increases mishandling of devices as the new employees are less acquainted with the devices.

Space is another important factor in handling the equipments. There should be adequate space near patient bed. This space is necessary for movement of staff and instrument near the patient bed. Instruments require space for movement, air circulation to cool down and to avoid electric and magnetic noise of nearby devices. As per ICU guidelines, the patient bed area should not be less than 100

sq. feet[5]. Except NTU all critical care units had sufficient space. NTU had 60 to 80 sq. feet. We also observed that there is no glass partition in between two patient beds as like other ICUs. That's why equipments connected to one patient are very close to equipments connected to other patient. For example, Monitor attached to one patient is very close to ventilator attached to another patient. Syringe pumps are also mounted to nearby these devices. Therefore there remains less space for operating equipment and staff movement which makes it crowded at times. This situation increases the chances of device fall and mishandling by the staff or patient.

Hospital equipment are usually single user handled or multiuser devices. Fewer (negligible) mishandling cases occur in single user device such as CT scan, MRI, and Ultrasound and so on because no. of users are less and devices are one hand use. Technicians are well trained to operate these instruments. In such cases mainly hardware or software related problems occur. Where as in OTs, ICUs, Wards, users are more in numbers, their handling techniques are different and most of them are freshers. Therefore, breakdown of machines in ICUs due to mishandling is much more compared to single user devices**.**

Instruments in ICUs are in direct contact with patients. Sometime patient feels irritation or uneasiness of accessories attached to him such as SpO2 probe or ECG machines of monitor or disposable syringe tubes of syringe pump. If the patient is restless or rowdy he breaks the SpO2 probes by hitting it on hand rails of the patient bed or pulls off ECG cables or syringe tubes. So this causes breakdown of devices or accessories. 12 to 16% of breakdown of instruments is due to restless patient. This type of breakdown of an equipment is not related with ICU staff and is avoidable.

The mishandling breakdown cost of hospital in the year 2015 was Rs.14, 13,474 which includes ICU's mishandling cost of Rs.3,56,946. This cost is equivalent to the cost of one anesthesia machine and one multipara monitor. These wasted expenses are mostly avoidable and it occurs mainly due to human factors, which are discussed previously. So, for avoiding these expenses training of staff on biomedical devices for creating more awareness is the best solution.

From the results of post training assessment, it was found that staff had secured good score in the assessment. 83% staff had scored above 90% of marks. This indicated that they had understood the equipment handling guidelines and losses occurred due to mishandling of devices. And by analyzing the feedbacks received from nursing staff we can say that, 60% of the nursing staff said that, the training was useful to staff to solve their quarries related to handling of the devices. 70% the staff was satisfied due to their expectations about information of devices were quite met from this training session. After training sessions, the instrument handling of staff were observed for remaining days of study period which showed that their handling techniques were improved. So we can conclude that the impact of training on nursing staff was good and it helped in their work.

CONCLUSION

The mishandling of equipments has direct impact on machine life as it deteriorates machine life and its efficiency, and it hampers the capital cost invested by the hospital on medical equipments. This breakdown cost of equipment is avoidable, if the devices are handled properly by the staff, then it results in accurate output and the cost of breakdown due to mishandling can be saved, which may be further utilized for preparing next term budget.

The major reason of this problem are human factors and lack of awareness about devices, which is found due to inadequate training. Therefore training of users on equipment creates awareness and reduces the equipment downtime. Another reason is improper ergonomics of patient bed area. It means crowding and wrong placement of equipments, which leads to obstructions in movements of devices and staff, unnecessary movements which results into fatigue, unknowingly fall down of equipments and reduced patient safety. By planning proper ergonomics, movement of staff and devices around patient bed can be improved and it facilitates good access to use devices. Restless patient may break cables or accessories of device but it found less times and it sometimes unavoidable.

Hence to reduce possibility of equipment malfunctioning of devices and their breakdown cost due to improper handling, adequate training of devices should be given to staff and the patient bed area should be properly maintained according to device use and their necessity.

Ethical clearance: No need

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Conflict of Interest: Nil

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Health and Fitness Articles on Facebook– A Content Analysis

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ABSTRACT

As per the statistics provided by Statista, Facebook holds 18% market share in the space of online and social media and has over 1,590 million active users worldwide (Chaffey, 2016). This statistic is interesting to analyze in the Indian context where the total internet penetration is about 28% which means 375 million active internet users, according to the 2016 report by *We Are Social.* The same report states that 48% of the Indian population uses the internet every day and Facebook is the most active social media platform with 13% of the total users. In this group, users in the age group of 20-29 years comprise 51% of the total users, with a further bifurcation of 38% male users and 13% female users. The aforementioned statistics build a very crucial context for investigating social media behaviors of Indian youth in general. This is also significant to explore the most important topics or subjects that this group engages with on a social media platform like Facebook.

This research paper will review popular Indian articles on health and fitness pages on Facebook and analyze the content that is posted about health and fitness. The aim of the research study is to find if the discourse on health and fitness is actually serious and informative or is just restricted to notions of attractive body and cosmetic benefits. The research paper will use a mixed methodology framework to conduct a content analysis of the discourse of these Facebook pages. This study is crucial since Facebook attracts a large number of young users, who may be develop very limited notions of health and fitness.

Keywords: *Social media, health and fitness messages, young users, content analysis*

INTRODUCTION

Media has substantial influence on public perceptions of health and fitness issues. While media are not merely neutral producers of information; they create/ re-create, reflect and reinforce societal understandings about health. In the mediated world, health may often be framed, defined, or examined via appearance. Therefore, a healthy body may be portrayed as one that is thin and attractive. This study aims to analyze the representation of health and fitness, as text and images, in popular articles of two leading Indian newspapers which were posted on their Facebook pages.

Review of Literature: The review of literature has been divided into the following sections – media & health messages; social media and health messages; methodological frameworks in studying media & health messages.

Media and Health Messages : The study by Conlin & Bissel (2014) is the first to examine both health/fitness magazines and beauty/fashion magazines to determine the framing of health-related messages sent to readers in editorial and advertising content[1]. Premised on the theory of media framing, the study chose magazines with the largest circulation (both print and online) that were representative of the beauty/fashion or health/fitness magazine category. Six magazines were selected in all. Since the study was limited to women's magazines, the coding categories included - Weight Loss: Diet, Weight Loss: Exercise, Weight Loss: Appearance, Weight Loss: Health, Appearance: Clothing, Appearance: Overall Beauty, Appearance: Attractiveness to Men. The study concluded that the messages in both health/fitness and beauty/fashion magazines contribute to a system of meaning that placed value on thinness and also the kind of body images propagated by celebrities. When looking at the different types of framing that exist in messages on women's magazine covers, health and fitness magazines were found to contain just as many appearance-related messages as health-related messages (p.18). Weight-loss

and body shaping messages account for almost one-fifth of all the editorial content in women's fitness and health magazines, where the emphasis of this content is placed on appearance rather than on health, and exercise rather than healthy diet (p.24).

> While beauty/fashion magazines are already well-known for presenting thin ideals to their audiences, it is surprising that health/fitness magazines are also featuring ultra-thin models, which seems to contradict their reported focus on health. This only further solidifies the notion that in order to be considered beautiful or attractive, one must also be thin, and it problematic because it marginalizes women who are fit but not thin, particularly women who participate in sports that require a muscular body. It was expected that the models used in the health/fitness magazines might be closer to average size or at least not conspicuously thin, because thin does not always equal healthy,57 but our findings did not confirm this expectation. (p. 13)

Roy (2008) argues that women magazines integrate the information from medical journals and other expert documents in a simple manner with certain representations of reality, hence creating a discourse on health which may reinforce oppressive gender norms[2]. According to this study, data from three magazines (issues between 1997 to 2000) generated the following themes –the discourses in the articles put the responsibility of health on women, not in physical but also in moral terms; high usage of militaristic language; reinforcement on call to action; focus on negative consequences of inaction; cautionary tales to put forth acceptable and non- acceptable health norms; inspirational stories. The most overarching theme of Roy's (2008) analysis was the importance of healthy physical bodies and she argues that the discourse on health in women's magazines is devoid of the social and political contexts. This may be understood as a discourse which exists therefore at a very superficial and cosmetic level. Roy (2008) states,

> Cultural products like women's magazines are created for someone, they have intended audiences reflecting producers' conscious and unconscious assumptions about who the audience is and what they want (p. 473).

Phul et al (2013) conducted a video content analysis of obese persons as portrayed on online news[3]. Their analysis found that 65% of the videos represented obese or overweight individuals by focusing on their individual body parts like the buttocks, stomach or portray a rear view of their body. They found that such bodily depictions were also portrayed in stigmatizing manner. Overweight individuals were shown to consume unhealthy food or beverages and were dressed in inappropriately fitting clothes. The authors state that negative depictions of obese people saturate online news media content. They argue that more positive images can mainstream the acceptance of overweight and obese representations. They also contend that weight stigma leads to more health problems (unhealthy eating, for example) and is therefore counterproductive. Hence the representation of thin body as normal may actually lead to unhealthy behaviours.

Social Media and Health Messages: Schein et al (2010) state that social media has become a very popular platform that is being used by health organizations to propagate health messages[4]. Social media is being used to amplify messages that are already present on traditional media like print, television or radio and also as a standalone platform that creates messages in accordance to the characteristics of its target audience, and additionally co-creates messages along with its target audience. The authors specifically discuss the case of tennagers and young adults, who they argue have become more open in terms of the ways in which they interact with experts on social media platforms. This study succinctly points out to the potential and popularity of social media to further health messages.

Laranjo et al (2014) conducted a study to evaluate both the utilization and effectiveness of social networking sites in bringing about a change in health behaviours[5]. Facebook emerged as the most utilized social networking site in this context. This meta-analysis study concluded that using social media as a platform was effective to propagate health behaviours. However, it also pointed out that the effectiveness is heterogeneous.

Carrotte et al (2015) conducted a study to investigate youngsters' motivations to like and follow certain health and fitness related pages on social networking sites[6]. They premised their study on the debate around the credibility of information regarding health and fitness on social media and umpteen popular claims that it

was misleading. One category of Facebook pages that the authors delved into were 'fitsipration' pages, which according to their review of past literature, were pro-thinness rather than pro-fitness and targeted more towards women. The authors also cited celebrity diet-foods as very popular content on social media, which had actually been criticized my experts. Additionally, they argue that despite credibility issues associated with health and fitness related information on social media, young adults find it most convenient and trustworthy as a source of information. This study categorized the consumers of three kinds of Facebook pages – fitspiration pages, detox pages and diet/finess plan pages. The study found that teenaged girls were the largest consumers of these pages. However the biggest gap of this study was that it did not conduct the content analysis of these pages.

Methodological Directions in Studying the Relationship between Media & Health Messages: Gannon et al (2012) state that discourses analysis is being increasingly used in studies related to health psychology[7]. They argue that people acquire a certain perspective on the world around them by participating in certain discursive practices that assign certain meanings to conversations, images and subjects. The authors carry forward this argument to the domain of health-related images and point out specifically to images of fit female bodies vis-à-vis unfit female bodies. Their research analyzed a corpus of 40 news stories with women and exercise as the central themes. Their coding sheet comprised the following parameters - name of target article, target audience, type of story, other stories and advertisements appearing on the page, content summary and lead paragraph; discursive strategies (e.g. metaphors and rhetorical strategies) and potential effects (e.g. ideological and behavioural).One of the major findings of this study was the concept of gendered exercises, which highlighted a discourse of exercise as beautification. This sidcourse analysis constructed the image of 'the ignorant or the irrational woman', as those who are unfit because they lack the knowledge as to how to exercise to attain a fit body. Gannnon et al (2012) state,

> "Within the exercise as beautification discourse, the expert ultimately holds the information, knowledge and power to give women more agency and control over their unfit bodies. The subject position of the expert creates a clear indication of who owns the knowledge (i.e. the fitness industry) and who does not (i.e. unfit women) within an exercise as beautification discourse". (p. 38)

THEORETICAL FRAMEWORK

Quoting Berger and Luckmann 1967), Adoni and Mane (1984, p.325) discuss the concept of sociology of knowledge. They state that everything in a society constructs social knowledge and therefore media play a significant role in the social construction of knowledge. Gamson et al (1992) also discuss media's role in the social construction of reality[8]. They replace the words 'facts and information' with 'images'. Media content forms a system of representations. Hall (2013) states that language is a representational system[9]. When language is replaced with images and sounds, they also form a representational system. It is in this representational system that meaning gets produced. Hall (2013) states sounds, words, images, notes, gestures, expressions, clothes – everything constitutes language and therefore constructs meanings and transmits them. Hall (2013, p.3-9) states that meanings are not simply found but socially constructed through representations. Social norms construct a certain version of the ideal body and form the crux of the media discourses on health and fitness. Hence the social construction of reality and Hall's conceptualization of representations become the guiding theoretical premise of this study.

RESEARCH METHODOLOGY

Sampling and Coding: This study used content analysis as the primary methodology. The sample consisted of 56 articles that were obtained through Facebook posts of Times of India and Indian Express between March 15, 2016 and April 15, 2016. The rationale for using this time period was that April 7 is celebrated as World Health day and the researchers assumed that health-related content would dominate social media posts during this period. By using health and fitness as keywords, a total of 56 Facebook posts became the sample for analysis. Purposive sampling was employed to zero in on the sample. Once the broad categories of representations emerged from the content analysis, the discourses of this representations was discussed.

DATA ANALYSIS

The following were the coding categories on which article was analyzed – type of story; target group;

context of the story; and accompanying image. Some stories could not be coded on each parameter. Three stories could not be coded on any parameter at all and hence the sample size consisted of 53 stories (in the form of Facebook posts) eventually.

Table I is the coding sheet for the 53 stories analyzed in this study.

Table I

Story No.	Type of Story	Target Group	Context of the Story	Accompanying Image
	Feature	Hindu Community	Festival Fasting Diet	Product/Dish
	Feature	Urban/Hindu	Festival Fasting Diet	Product/Dish
	Photo Story	Urban	Diet Festival	Food Products
	Photo story	Urban	Diet, Festival, Health	Food Product
	Feature	Age group - 20 to 50	Food tips, Age, Diet, World Health Day	-
	Feature	Men/women	Tips to stay healthy, Fitness	Picture of a woman (desire)
	General Story	Urban	Social Media's impact on audience's awareness about health	White woman
	Feature	Urban	Diet, Food	Food Product
	Feature	Youth	Lifestyle, Improving Sex-life, Health	White couple
	Photo Story	-	Health tips	White models (creating desires)
	Feature	Urban parents	Teen's health, Life style,	White woman
	Feature	-	Disease, Food, Health tips	Fish
	General story	Old age	Old age, fitness	Old woman
	General	-	Health, Diet,	White man
	Feature	-	Diet, Health tips, Food	-
	Photo story	-	Fitness advice	Young and Middle aged women
	Video	Youth	Fitness facts	10 images of white women
	Photo feature	Urban	Food	Indian food
	Feature	Women	Health, Disease, ways to fight a disease (migraine)	Indian Woman
	Professionals	Feature	Health tips, lifestyle	Image of woman
	Feature	Urban	Fitness, lifestyle, eating habits tips, health	-
	Feature	Urban	Couple, relationship, modern meditation techniques, rebonding through meditation	Indian meditation guru
	Feature	Women	Women health	Woman foreign doctor

	-	Youth	Celebrities, health, fitness	-
	Feature	Urban	health tips, diet	A woman
	Feature	Urban	Improving wrong habits, lifestyle	A woman's photo
	Feature	-	Disease, health, study on diabetes	-
	Feature	Urban	Food, healthy food tips for modern city people	Exotic food
	Feature	Working professional	Lifestyle	White couple
	Feature	Professional	Tips to improve brain function, health, lifestyle	Indian male and female
	Feature	-	Autism, world autism day, kids,	Kids
	Feature	Urban	Diet, fitness, health, celebrity nutritionist, urban die chart	Young woman
	Feature	Urban	Super hero, fitness	Batman and superman
	Feature	Urban	Tips to counter a depression, health	White woman
	Feature	Urban	Diet, health, food,	Image of a sausage
	Feature	Urban	Health tips,	Women
	Feature	Parents	Kids health, diet plan	Diet chart
	Feature	Women	Women's health, fitness,	White women
	Feature	-	Myths breaking awareness, health, disease, lifestyle	-
	Feature	-	Lifestyle, food, health	-
	General	-	Disease, health policy in India	Drug
	Feature	-	Lifestyle, health	Coloured pencils
	General	-	Awareness, health,	White woman
	Photo story	-	Healthy lifestyle,	Graphics
	Feature	-	Food tips, health, nutrition	Exotic food
	Feature	-	Health policy, medicines	Drug
	General	-	Policy, public health issue	Milkman
	Feature	-	Disease, awareness, celebrity	Woman
	Feature	-	Health tips, lifestyle, awareness	White man and woman
	Feature	-	Women's diet, health	White woman
	Feature	-	Products, lifestyle	Asian woman
	Feature	-	Therapy, health	Woman
	Feature	-	Fitness, health	Men and women walking

68% of the stories were feature stories. This clearly demonstrated that the stories were detailed and anecdotal. 10% of the stories were exclusively photo-stories and one of the stories was interestingly, a video story. Images of women dominated the content. While 20% of the images portrayed women, 13% of those images were of white women. Only 2 % stories had pictures of men and women together. Four stories had images of men and two of them showed men in a professional rather than a common-man role. What emerges is an inherent gendered focus in articles related to health and fitness. Women are both the subject and target audience for most of the health and fitness related posts on Facebook. In terms of the kind of stories, lifestyle and diet related topics formed majority of the content at 17% each. 7% of the stories were celebrity-centric and 13% stories were related to diseases. Only three stories out of the 53 were related to children. The target group of the stories was entirely urban and the discussions centered on more upmarket and elite concerns.

DISCUSSION AND CONCLUSION

Fit bodies are at the centre of the discourse on health and fitness as revealed in the analysis of 53 stories posted on Facebook by two of the leading national dailies of India. This finding resonates with similar findings obtained in other research studies internationally, as cited in the review of literature. Health is constructed on very physical dimensions in the social media narrative. The fact that this sample consisted of only two stories related to mental health and depression proves the aforementioned point even further. Roy (2008) argued that the discourse of health and fitness is constructed with women as the key focal point. This has been established beyond doubt in this research study as well. Women's health is a popular subject. However, the definition of health and fitness is delimited by concepts of thinness and beauty. The discourse is further misconstrued when health and fitness are discussed only in the context of specialized diets. The social media narrative is oblivious to the subject of children's health and fitness, which is another significant finding of this study. The literature review demonstrates, that teenagers and young adults have high engagement with social media. Hence this medium can be suitably employed to engage them with positive messages on health and fitness. Since anecdotal evidences in most of these stories discuss the cases of high-profile celebrities, somewhere this discourse becomes more cosmetic and aspirational.

Media have the potential to represent messages in meaningful ways. Media's framing of messages privileges a certain representation over another. This study establishes that health and fitness posts on Facebook privilege the concept of appearance rather than health messages to frame body-image. This is a skewed representation and it is definitely upon the media to introspect and revisit the narrative of these messages.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Maharashtra Emergency Medical Services Project: A Scalable Model

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ABSTRACT

Emergency Medical Services (EMS) is specialized field where emergency healthcare needs are addressed through well-defined care processes by trained EMS professionals. EMS includes early detection of any emergency, immediate response, reporting, on-scene care, en route care and transfer to appropriate definitive healthcare facility. This paper discusses in length the integrated scalable model pertaining to Maharashtra Emergency Medical Services Project.

Keywords: *Emergency Medical Services, Emergency healthcare, Scalable model, National Health Mission*

INTRODUCTION

Emergency Medical Services (EMS) is specialized field where emergency healthcare needs are addressed through well-defined care processes by trained EMS professionals[1]. Important aspect of EMS includes early detection of any emergency, immediate response, reporting, on-scene care, en route care and transfer to appropriate definitive healthcare facility[2].

Community needs including emergency care or EMS requirement during road traffic accidents, cardiac emergencies, fire emergencies and multi casualty incidents have been well articulated and partly served in urban areas. Whereas, rural community has poor access to such services during the time of greatest need. It is also identified that EMS need for stroke, respiratory emergencies, diabetic emergencies and several others have been unidentified and unserved in rural as well as urban communities[3]. It is well proven fact that an integrated approach by Medical, Police and Fire services is essential for effective delivery of emergency patient care.

Steps involved in EMS system:

1. Emergency Recognition
2. First aid/ Citizen access
3. Dispatcher
4. Basic Life Support (BLS)/Advanced Life Support (ALS)/ Fire/ Police/ rescue
5. Medical direction
6. Patient stabilization and transport
7. Handing over to hospital

Core components of emergency medical care: Emergency medical care has three components (fig 1): care in the community; care during transportation and care on arrival at the receiving health facility

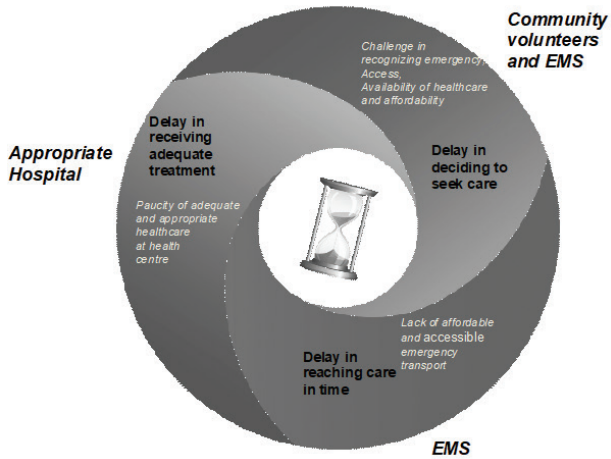


Fig. 1: Core components of emergency medical care.

(1) Emergency medical care in the community: The outcome of acute illness or injury is strongly influenced by early recognition of its severity and the need for medical intervention.

(2) Emergency medical care and transportation: An absence of emergency medical transport is a common barrier to care. This may arise because of any of several factors, including the lack of appropriate vehicles, the absence or inadequacy of roads, and the inability to pay for transport services. The consequences of a lack of transport can be grave.

(3) Emergency medical care at first-contact and referral facilities: The ready availability of treatment on arrival at a formal health care facility is the third component of emergency medical care. Health care facilities differ widely in respect of equipment, staff and resources, and they consequently possess varying capacities to provide emergency care.

India accounts for about 10% of road traffic accidents (RTA) fatalities worldwide. In terms of absolute numbers more people die in RTA in India than anywhere else in the world, including the more populous China. A significant burden of diseases in India is caused by time-sensitive illnesses and injuries, such as severe infections, hypoxia caused by respiratory infections; dehydration caused by diarrhoea, intentional and unintentional injuries, postpartum bleeding, acute myocardial infarction and Cerebro Vascular accidents[4].

Every 5 minutes one death happens on Indian road with the current growth in road accidents it is expected to escalate to one death every three minutes by 2020.

Maharashtra Emergency Medical Services: Maharashtra Emergency Medical Services (MEMS) is project of Government of Maharashtra under National Health Mission (NHM). Training is imparted to all the professionals working for MEMS in academic partnership with Symbiosis Institute of Health Sciences (SIHS). It is a toll free '108' number based Emergency Medical Services, free of cost to entire population in the state of Maharashtra, formally launched on 1st March, 2014. Objectives of the project are:

1. To provide 24 × 7 hours pre-hospital emergency medical service response services across Maharashtra, including disaster situations in the state.
2. To achieve 20% reduction in mortality & morbidity rate in an Emergency

The scope of the project is as below:

1. Develop & Operate Emergency Response service/ Ambulance Service to provide quality, reliable & trustworthy Emergency Response Service.
2. Developed a fleet of 937 Life Support Ambulances (233) Advanced Life Support + 704 Basic Life Support).
3. To provide 24*7 pre-hospital EMS across Maharashtra state.
4. Trained 5000 Emergency Medical Professionals.
5. Developed mechanism in consonance with Police & Fire Department operated through a single toll free number 108
6. Effective Logistics to maintain Response time below 20 minutes in urban & below 30 minutes in rural areas.



Fig 2: Significance of MEMS Logo

- **The star of life,** designed by Leo R. Schwartz is a blue, six-pointed star. In the center, it features a widely used symbol of medical care, a snake-entwined staff, known as the Rod of Aesculapius. This is named after a figure from Greek mythology, Aesculapius, the god of medicine and healing.

  The six branches of the star symbolize the six main tasks executed by emergency medical services rescuers all through the emergency chain:

1. **Detection:** The first rescuers on the scene, usually civilians or those involved in the incident, observe the scene, understand the problem, identify the

dangers to themselves and the others, and take appropriate measures to ensure their safety on the scene (environmental, electricity, chemicals, radiation, etc.).

2. **Reporting:** The call for professional help is made and dispatch is connected with the victims, providing emergency medical dispatch.
3. **Response:** The first rescuers provide first aid and immediate care to the extent of their capabilities.
4. **On-scene care:** EMS professionals arrive and provide immediate care to the extent of their capabilities on-scene.
5. **Care in transit:** The EMS professionals proceed to transfer the patient to a hospital via ambulance for specialized care, and provide medical care during transportation.
6. **Transfer to definitive care:** Appropriate specialized care is provided at the hospital.

- **Wheat Leaves:** Wheat is grown across India and considered as symbol of unity.

Project implementing organizations: MEMS Project is operated by BVG India Ltd. with United Kingdom Specialist Ambulance Services (UKSAS) as the consortium partner & Symbiosis International University as academic partner for providing training and certification to EMS professionals working with MEMS.

BVG India Ltd.

1. BVG started operations in 1998 to give employment to rural youth and also to cater to various service requirements of Industrial and Government establishments, keen on outsourcing and today has over 25,000 employees controlled by over 42 locations all over India providing different services across both Government and Private Sector.

United Kingdom Specialist Ambulance Service (UKSAS)

1. UK's largest private Emergency Ambulance Service provider.
2. Affiliated to NHS for responding to 999 calls.
3. Handles more than 7, 50,000 contracted patient journeys per year.

Symbiosis International University, (SIU)

1. Symbiosis International University (SIU) is one of the premiere educational institutes of India. Founded by Padma Bhushan Dr. S. B. Mujumdar sir in 1971. Symbiosis today consists of 45 institutions with 50,000 students across India and the world. Symbiosis is synonymous with quality education.
2. PGDEMS program of SIHS is University accredited academic program since 2002 under the aegis of SIU is recognized by the University Grants Commission (UGC), Ministry of HRD, Govt. of India
3. The Curriculum and its implementation is recognized by the Los Angeles Paramedic Training Institute and Department of Transportation, USA.
4. Symbiosis is the Institute in the country today with the coveted dual status of an International Training Centre (ITC) of the American Heart Association (AHA) and a "Chapter" status of the International Trauma Life Support Organization, USA.
5. Imparted EMS education to over 6000 students since last 15 years.
6. SIHS is recognized as approved site for conducting - Advanced Trauma Life Support® (ATLS®) - India Program Course of American College of Surgeons.

Training: Training is imparted to all the professionals including Doctors, Pilots (Drivers) and all other Emergency Response Centre (ERC-) personnel by Symbiosis International University, Pune. The training centres are equipped with advanced training material, including state of the art infrastructure, simulated manikins and world-class equipment's.

Key Features of MEMS training

- All the Emergency Medical Service Officers (EMSOs), Pilots, Managers, Supervisors, Emergency Response Centre Physician (ERCP), Control room staff are trained by Symbiosis International University (SIU)

- Instructors are certified by American Heart Association (AHA), USA & International Trauma Life Support (ITLS) organization, USA.
- Government of Maharashtra approved EMS protocols.
- Manual of Emergency Medical Services for training.
- Training schedule is focused on hands on training utilizing world class manikins.
- Training includes general principles, body systems & management of common emergencies, skills and procedures in Emergency and drugs in Emergency.
- All trainings are conducted as per protocol with Pre-test – Post Test, Skills- Theory evaluation and comparison
- Pilots are trained in Basic Life Support (BLS) and Emergency Medical Services (EMS) specific skills in driving.

Emergency Medical Services Control Room: State of art Emergency Response Centre (ERC) is developed at Aundh Chest Hospital Pune. ERC operates 24 x 7 hours through a centrally operated toll free telephone number-108, (fig. 3) which can be dialed from any part of the state. This emergency toll free 108 number also serve as the point of first contact for police and fire related emergencies. Emergency Response Centre Physician (ERCP) provides On-line Medical direction for the doctors on ambulance during emergency calls. ERCPs also provide on-line pre-arrival instructions to the callers or patients if needed. After timely pre-hospital care patient is admitted to most appropriate hospital as per the patients need.

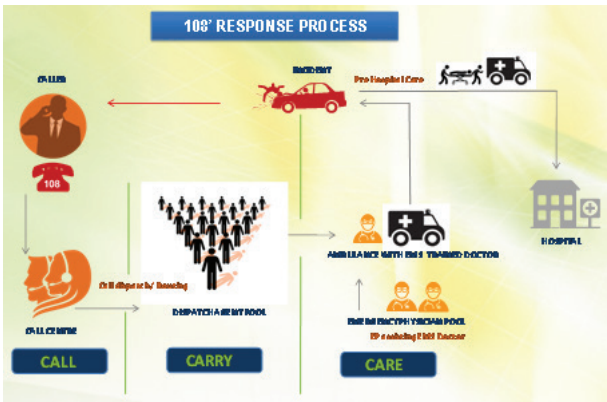


Fig 3: 108 emergency number response process

Key Features of EMS Control Room

- Segmentation- 6 Ambulance dispatch options for any emergency anywhere in Maharashtra
- Server Room with Pureflex System X servers from IBM, Voice Solution from Avaya
- Government of Maharashtra approved training curriculum for control room staff
- Seamless process of Ambulance and Hospital selection
- Dedicated Emergency Response centre Physician application

Maharashtra Emergency Medical Services Ambulance: There are a state of the art 937 ambulances (233 ALS and 704 BLS ambulances) operational across Maharashtra capable to provide competent care for the sick or injured in emergency medical settings. All Ambulances are manned by Doctors trained in Emergency curriculum who respond to emergency calls, performing medical services and transporting patients to appropriate hospitals as required. Key features of the ambulance are:

- First ambulance in the country to have Medical Oxygen Delivery System
- Best in the class equipment with defibrillator, ventilator, syringe pump, infusion pump etc.
- All the equipment's in the ambulance are EN 1789 & EN 1865 certified considering patient safety.

SUMMARY

Emergency Medical Services professionals are immersed in the fast-paced business of saving lives in response to a wide variety of emergency medical situations. Duties include quickly assessing and prioritizing patient needs with the goal of providing life support in situations where trauma, respiratory, diabetic, behavioral, cardiac, allergic, poisoning, and childbirth emergency situations might exist.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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An Analysis of Organizational Justice on Employee Engagement in Selected Healthcare NGOs in India

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ABSTRACT

Purpose: The purpose of the paper is to investigate the effect of organizational justice perceptions on engagement of employees in selected healthcare Non-Governmental Organizations in India.

Methodology: Colquitt's four construct model comprising of distributive, procedural, interpersonal and informational justice while engagement was measured through a 7 item scale. Quantitative data was analyzed through the use of questionnaires and statistical tool using SPSS.

Findings & interpretation: The study shows that distributive justice perceptions, procedural justice perceptions, interpersonal justice perceptions and informational justice perceptions have a significant relationship with employee engagement in health care non-governmental organizations in India.

Managerial implications: The management of health NGOs in India will significantly benefit from the findings in that it helps them appreciate the role of justice and its influence on engagement of employees. This study should lead to the development and application of appropriate human resource management practices in the Indian health care NGOs.

Originality: This study is one of its kinds in India which will help in the development of work place policies which would promote fairness in order to enhance employee engagement in Healthcare NGOs.

Keywords: *Human resources, Employee engagement, Organizational Justice, NGOs*

INTRODUCTION

A lot of literature emphasis that an organization puts a lot of importance to their core values and the culture to the organization (Collins & Porras, 1997). Justice in terms of fair treatment of employees is identified as one of those values and fairness as one of the fundamental bases in organizations (Cropanzo et al, 2007). Telling the Truth, keeping promise, fairness and transparency amongst employees, and respect for the individual are some of the key guiding principles of effective people management in many companies.

Organizational justice refers to employee perceptions of fairness in the workplace. These perceptions can be divided into four forms namely distributive, procedural, informational, and interpersonal. Justice perceptions can influence employees' attitudes and behaviour for good or ill, in turn having a positive or negative impact on their performance and the organization's success (Baldwin, 2006). Justice is therefore a basic requirement for the effective functioning of organizations and the personal commitment of the individuals they employ (McFarlin & Sweeney, 1992). Employee engagement which refers to a heightened emotional and intellectual connection that an employee has for his/her job, organization, manager, or co-workers that in turn influences him/her to apply additional discretionary effort to his/her work (Gibbons, 2006). The purpose of the paper is to investigate the effect of organizational justice perceptions on engagement of employees in selected healthcare

Employees who are engaged to their organization generally feel a connection with the organization, feel that they fit in it, feel they understand and are committed to the goals of the organization (Cohen et al., 2001). The added value of such employees is that they tend to be more determined in their work, show relatively high productivity and are more proactive in offering their support (Konovsky, et al, 2000). Meyer & Allen (1997) conceptualized employee commitment (organizational commitment) in three dimensions namely affective, continuance and normative commitments.

Justice Perceptions and Employee Engagement: Justice perceptions can influence employee attitudes and behaviour for good or ill, in turn having a positive or negative impact on individual, group and the entire organization's performance and success (Baldwin, 2006). Empirical evidence supports the notion that an employee's perception of organizational justice affects their attitude toward the organization (Konovsky, et al, 2000). If the perception of organizational justice is positive, individuals tend to be more satisfied and committed to their job (McFarlin & Sweeney, 1992).

Organizational justice impacts on employees in organizations since they are the subject of work place decisions virtually every day of their organizational lives (Cohen et al., 2001). Some of these decisions deal with the salaries individuals earn, the projects or programmes they implement while others deal with work place interactions. The importance of those consequences causes individuals to judge the decision making they experience from a justice perspective (Colquitt, 2001). According to Baldwin (2006) the term organizational justice refers to the extent to which employees perceive workplace procedures, interactions, and outcomes to be fair in nature. He concluded that these perceptions can influence attitudes and behaviours of the employees. Cropanzano, Bowen and Gilliland (2007) defined it as a personal evaluation about the ethical and moral standing of managerial conduct.

Extant literature on organizational justice identifies four different constructs; distributive justice, procedural justice, interpersonal justice and informational justice (Colquitt, Greenberg, & Zapata- Phelan, 2005). Distributive justice is the justice of an employee which he perceives as a result of comparing the commitments he makes to his work and the outcomes of these such as rewards, duties and responsibilities, compared to the commitments the other employees make and the outcomes of them (Colquitt,2001).

Procedural justice implies that, while evaluating the fairness of the organizational decisions, employees are not only interested in what these decisions are but also with the processes which determine these decisions (Folger & Cropanzano, 1998). Interpersonal justice refers to people's perceptions of the fairness of the manner in which they are treated by those in authority during the enactment of organizational procedures (Lind & Bos, 2002) while informational justice refers to people's perceptions of the fairness of the information used as the basis for making a decision (Gurbuz & Mert, 2009). Each of these forms of justice has been found to have different effects on employee commitment (Colquitt, et al., 2005).

Employee Engagement: Employees who perceive organizational decisions and procedures, treatment by others and informational basis of decision making as unfair are known to be less committed to the organization (Baldwin, 2006). They engross themselves with and engage in negative or unproductive psychological and physical withdrawal behaviour. Psychological withdrawal consists of actions that provide a mental escape from the work environment. It is manifested through such actions as daydreaming, socializing,looking busy, moonlighting and cyber loafing. Physical withdrawal behaviour consists of actions that provide a physical escape, whether short term or long term, from the work environment. These include tardiness, long breaks, missing targets, deadlines, meetings, absenteeism and quitting (Skarlicki & Folger, 1997).

Against this backdrop, changing employment landscapes have weakened employees' physical, administrative, and temporal attachments to organizations (Scott & Davies, 2015). Modern day employees are more mobile, more autonomous, and less dependent on their organizations for employment than ever before (Cascio, 2003). Long term employee commitment is less and less of a given. The idea that an employee will spend his or her entire career at one organization is long dead. To address these challenges, organizations are increasingly seeking to strengthen employees' attachments by cultivating commitment to the organizations (Mathieu & Zajac, 1990).

Employee engagement brings forth numerous advantages for the firm. Employee engagement is a tool which could be deployed in the organization so that the talent is appropriately deployed and harnessed effectively. It helps in building employee commitment and helps employees perform better in their roles. (Meyer & Allen, 2001It leads to focused efforts and better outcomes. It translates into greater innovation, commitment to organization, positive energy and higher productivity. It also leads to lower attrition levels and absenteeism. Engaged employees love their jobs, believe their employer, company goals and the manner in which they conduct their business (*Turgut, H., Tokmak, I., &*

Gucel, C. 2012). They exhibit high levels of passion and creativity and they believe they create value and management.

Employee engagement is an effective tool to help every organization to strive to gain competitive advantage over the others. People is one factor that cannot be duplicated or imitated by the competitors and is considered the most valuable asset if managed and engaged properly. This point has been emphasized by Baumruk (2004), in that employee engagement is considered to be the most powerful factor to measure a company's vigor. Katz and Kahn (1966) have referred to the concept of engagement in their work related to organizational effectiveness. However, it was mentioned in general as one of a number of needs to be developed to provide an innovative and co-operative work environment leading to performance and effectiveness. Kahn (1990) introduced the concept of employee engagement, giving his now famous definition quoted in the introduction, namely, "the harnessing of organization members' selves to their work roles; in engagement, people employ and express themselves physically, cognitively, and emotionally during role performances". Kahn added that three psychological engagement conditions are necessary for an employee to be rightly engaged meaningfulness (work elements), safety (social elements, including management style, process, and organizational norms) and availability (individual distractions).

There are numerous models available for employee engagement and different business firms have their own thought patterns around the same. For example, (Thelen 2002) also mentions that offering developmental opportunities is also one of the key ways for managing workforce. Motivating the key talent is one of the most important aspects of talent management. Employee engagement especially in an NGO to occur, there are two important aspects which need to be looked into. The first is enablement, which exists when employees have the necessary support and tools to work efficiently and effectively over time; the second is energy, which comes from a healthy work environment that supports employees' physical, social and emotional well-being.

Non-Governmental organizations: A Non-Governmental Organization (NGO) is defined as an independent organization that is neither run by government nor driven by the profit motive like private sector businesses (Lewis & Kanji, 2009). NGOs are one of the key actors in processes of development alongside the state, county government, foreign donors and private corporations (Willetts, 2002). NGOs are perceived to bring distinctive advantage in promoting development through efficiency and innovation, widespread participation and the ability to implement pro-poor projects (Nwaiwu, 2013). In terms of their structure, NGOs may be large or small, formal or informal, bureaucratic or flexible and in terms of funding, many are externally funded, while others depend on locally mobilized resources (Lewis, 2005). Some NGOs have highly professionalized staff, while others rely heavily on volunteers and supporters (Lewis, 2009).

Human resource management poses a critical management challenge in NGOs due to the multidimensional ways in which HRM issues manifest in the organization leading to a variation in application of HRM methods (Yassine, N., & Zein, R. (2016). It is for instance hard to justify and implement a reward based performance sys tem in an organization who solely relies on income from donors funds (Nwaiwu, 2013). Most NGOs work with a project orientation focus. A project, by definition, has a beginning and an end. Staff appointments are therefore project based, contractual, and for specified periods. The main implication of this practice on commitment is that employees have a start date and a known end date to employment. The second implication is that NGO organizations assign a very low priority for investing in nurturing human resource capacities and staff retention measures due to the short term nature of the projects (Gichira 2015). The programme or project based nature of work directs employees' focus towards the work and less to the organization. The nature of work also determines the forms of employment.(Yucel 2013)

RATIONALE OF THE STUDY

The rationale of the study was to understand the influence of organizational justice on employee engagement in Health NGOs in India.

OBJECTIVE OF THE STUDY

The objective of this study with a very special reference to the NGO workforce is to understand the impact of: Distributive justice on employee engagement of the NGOs employees

Procedural justice on employee engagement of the NGOs employees

Informational Justice support on employee engagement of the NGOs employees

Interpersonal Justice on employee engagement of the NGOs employees

Employee engagement is a state of mind where an employee enjoys and feels pride in his work. Employee engagement is one area where all the organizations struggle to find out, what keeps their employees committed, what factors influence their engagement levels.

HYPOTHESIS OF THE STUDY

H_0: There is no relationship between Distributive justice and employee engagement

H_1: There is a positive relationship between Distributive justice and employee engagement

H_0: There is no relationship between Procedural justice and employee engagement

H_1: There is a positive relationship between Procedural justice and employee engagement

H_0: There is no relationship between Informational Justice and employee engagement

H_1: There is a positive relationship between Informational Justice and employee engagement

H_0: There is no relationship between Interpersonal Justice and employee engagement

H_1: There is a positive relationship between Interpersonal Justice and employee engagement

Conceptual Framework: A conceptual framework is used in research to outline possible courses of action or to present a preferred approach to an idea or thought (Mugenda & Mugenda, 2008). The purpose of a conceptual framework is to clarify concepts and propose relationships among the concepts in a study. It provides a context for interpreting the study findings and to explain observations. The independent variable of the study is organizational justice perception represented by four constructs (distributive justice, procedural justice, interpersonal justice, and informational justice as exemplified by Colquitt (2001). The dependent variable is organizational commitment measured through three dimensions namely; affective, continuance, and normative commitment as construed by Meyer and Allen (1990).

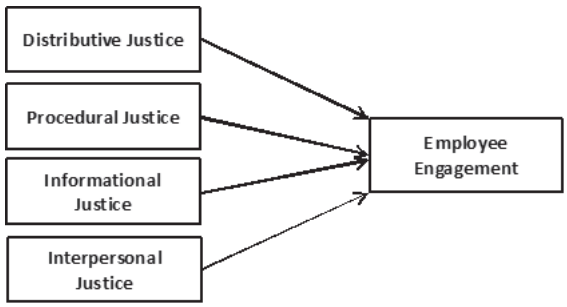


Figure 1 Factors impacting employee engagement (proposed model)

RESEARCH METHODOLOGY

A descriptive and correlation research design approach was adopted for this study based on the study objectives.

The sampling frame for this study comprised of 7 health sector non-governmental organizations based within Maharashtra. The following NGOs in and around Maharashtra were being studied for this research.

Table 1: Names of the Indian Health NGOs

Name of Organization	Sample Distribution
Society of Nutrition, Education and Health Care	12
Foundation for Mother/Child Health	11
Sneha	10
Smile Foundation	15
Give India	17
Plan India	18
Help Age India	19
Total	**102**

The study sought to measure employee perceptions using a five point multiple choice ordinal Likert rating scale measurement as propounded by Cooper & Schindler (2003). The reliability and validity of Likert attitude scales has been confirmed in past studies in various fields (Barford, I. N. 2014). The independent variable, organizational justice, was

measured using a scale adapted from Colquitts' 2001 version of the organizational justice scale. The scale has four dimensions: Distributive Justice (4 statements), Procedural Justice (7 statements), Interpersonal Justice (4 statements) and Informational Justice (5 statements).

Table 2: Organizational justice measurement scales

Variable	Total No. of items	Scales	Source
Distributive justice	4	Five Point Likert- type Scale (1-5)	Colquitt, (2001)
Procedural justice	7	Five Point Likert- type Scale (1-5)	Colquitt, (2001)
Interpersonal justice	4	Five Point Likert - type Scale (1-5)	Colquitt, (2001)
Informational justice	5	Five Point Likert - type Scale (1-5)	Colquitt, (2001)

The dependent variable, employee engagement was measured using a 7 item scale. Primary data was collected using self-administered questionnaires.

RESEARCH FINDINGS AND DISCUSSION

The study conducted a survey using a self-administrated questionnaire which was administered to 200 sampled respondents. 102 valid questionnaires were returned representing a response rate of 51 percent. A response rate of above 50% is considered adequate in social science research (Mugenda & Mugenda, 2008; Babbie, 2002).

The study tested the influence of distributive justice perceptions on employee engagement in Health Sector non- governmental organizations in India using regression analysis. In statistics significance testing the p-value indicates the level of relation of the independent variable to the dependent variable. The results indicate that the model was statistically significant. ($p<0.05$)

Correlation Analysis: The Correlation Analysis was performed to explore the association between all the four variables namely Distributive justice, Procedural Justice, Informational Justice, Interpersonal Justice and employee engagement. Co-relation simply tells us whether the two variables are related to each other i.e. Distributive justice, Procedural Justice, Informational Justice, Interpersonal Justice and Employee Engagement in this study. For each variable the results are discussed below.

Table 3: Co-Relation Analysis

Hypothesis	Method	Co-Relation Value	Result
H0: There is no relationship between Distributive justice and employee engagement H1: There is a positive relationship between Distributive justice and employee engagement	Co-Relation	.732	Reject Null Hypothesis
H0: There is no relationship between Procedural Justice and employee engagement H1: There is a positive relationship between Procedural Justice and employee engagement	Co-Relation	.656	Reject Null Hypothesis
H0: There is no relationship between, Informational Justice and employee engagement H1: There is a positive relationship between , Informational Justice and employee engagement	Co-Relation	.521	Reject Null Hypothesis
H0: There is no relationship Interpersonal Justice and employee engagement H1: There is a positive relationship between Interpersonal Justice and employee engagement	Co-Relation	.453	Reject Null Hypothesis

As seen from the above co-relation analysis Distributive justice, Procedural Justice are highly co-related to engagement and the other two factors' Informational Justice and Interpersonal Justice Regression Analysis are moderately related to Employee Engagement.

Multiple Regressions was used to study the impact of Distributive justice, Procedural Justice, Informational Justice, Interpersonal Justice on Employee Engagement. Multiple Regression was used to study the predictive ability of each of the independent variable separately. It

was used to predict the value of a dependent variable i.e. Employee Engagement based on the four independent variables i.e. Distributive justice, Procedural Justice, Informational Justice, and Interpersonal Justice. Multiple regressions also allowed determining the overall fit (variance explained) of the model and the relative contribution of each of the predictors Distributive justice, Procedural Justice, Informational Justice, Interpersonal Justice to the total variance explained.

Step wise multiple regression was used to study the variables.

The measurements independent variables viz Distributive justice, Procedural Justice, Informational Justice, Interpersonal Justice

Table 4: Model Summary of Regression Analysis

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics	
					R Square Change	F Change
1.	.953[a]	.808	.907	.33169	.908	3921.121
2.	.962[b]	.805	.825	.29907	.017	92.772
3.	.963[c]	.750	.727	.29384	.003	15.303
4.	.964[d]	.729	.728	.29184	.001	6.461

From the model summary table it can be seen that the step wise multiple regression analysis has produced 4 models.

Model 1: Predictor Distributive justice

R^2=0.808

This shows that Distributive Justice explain 80.8% of the variance of the dependent variable employee engagement

Model 2: Predictor Distributive justice and Procedural Justice

R^2=0.805 R^2Change = 0.017

Procedural and distributive justice can explain 80.5% variance of the dependent variable. The inclusion of procedural justice has increased the predictive ability of the model by 1.7% and this change is significant [F (1,398) =92.77 p =0.000]

Model 3: Predictor Distributive justice, Procedural Justice and Informational Justice

R^2=0.750 R^2Change = 0.003

This shows that Informational Justice and distributive justice and procedural justice can explain 75% variance of the dependent variable. The inclusion of informational justice has increased the predictive ability of the model by 0.3% and this change is significant [F (1,397) =15.303 p =0.000]

Model 4: Predictor Distributive justice, Procedural Justice, Informational Justice and Interpersonal Justice

R^2=0.729 R^2Change = 0.001

This shows that Interpersonal Justice, Informational Justice, distributive justice and Procedural Justice can explain 72.9% variance of the dependent variable. The inclusion of interpersonal justice has increased the predictive ability of the model by 0.3% and this change is significant [F (1,397) =15.303 p =0.000]

Table 5 ANOVA Table of Regression Analysis:

Model		Sum of Squares	df	Mean Square	F	Sig.
1.	Regression	431.383	1	431.383	3921.121	.000b
	Residual	43.896	399	.110		
	Total	475.280	400			
2.	Regression	439.681	2	219.841	2457.885	.000c
	Residual	35.598	398	.089		
	Total	475.280	400			

3.	Regression	441.002	3	147.001	1702.576	.000d
	Residual	34.277	397	.086		
	Total	475.280	400			
4.	Regression	441.553	4	110.388	1296.112	.000e
	Residual	33.727	396	.085		
	Total	475.280	400			

a. Dependent Variable: Employee Engagement

b. Predictors: (Constant), Distributive justice

c. Predictors: (Constant), Distributive justice, Procedural Justice

d. Predictors: (Constant), Distributive justice, Procedural Justice, Informational Justice

e. Predictors: (Constant), Distributive justice, Procedural Justice, Informational Justice, Interpersonal Justice

The Annova test measures whether the Regression model has significant predictive ability. From the Annova table it can be seen that all the four models are significant hence this proves that the regression model has the significant predictive ability.

Table 6: Coefficients Table of Regression Analysis

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1.	(Constant)	.096	.058		1.650	.100
	Distributive justice	1.000	.016	.953	62.619	.000
	(Constant)	.059	.052		1.132	.258
2.	Distributive Justice	.697	.035	.665	20.214	.000
	Procedural Justice	.326	.034	.317	9.632	.000
	(Constant)	.003	.053		.063	.950
3.	Distributive Justice	.641	.037	.611	17.417	.000
	Procedural Justice	.308	.034	.300	9.194	.000
	Informational Justice	.089	.023	.087	3.912	.000
	(Constant)	-.054	.058		-.935	.350
4.	Distributive Justice	.619	.038	.590	16.475	.000
	Procedural Justice	.267	.037	.260	7.217	.000
	Informational Justice	.080	.023	.079	3.532	.000
	Interpersonal Justice	.086	.034	.075	2.542	.011

For the Co-Efficient table it can be seen as follows

- Distributive Justice is a significant predictor of Employee Engagement
  [t=16.475, β=0.619, p=0.000] B=0.590
- Procedural Justice is a significant predictor of Employee Engagement
  [t=7.217, β=0.267, p=0.000] B=0.260
- Informational Justice is a significant predictor of Employee Engagement
  [t=3.532, β=0.08, p=0.000] B=0.0775
- Interpersonal Justice is a significant predictor of Employee Engagement
  [t=2.542, β=0.086, p=0.001] B=0.075

From the β values it can be seen that Distributive Justice is the strongest predictor of Employee Engagement followed by Procedural Justice, Informational Justice, and Interpersonal Justice. Based upon the above discussion the regression equation can be as follows

Employee Engagement=-0.054 + 0.619(Distributive Justice) + 0.267 (Procedural Justice) + 0.08 (Informational Justice) + 0.088 (Interpersonal Justice)

CONCLUSION

The overall objective of the study was to establish the influence of organizational justice on employee engagement in Health Care Non-Governmental Organizations in India. The results of the study revealed that organizational justice have a significant relationship with employee engagement. The study revealed that justice perceptions have a varied influence on employee engagement.

RECOMMENDATIONS

An engaged workforce is a necessary condition for the realization of organizations' strategic objectives. Employees who perceive unfairness in the workplace may exhibit varying degrees of negative behavior. It is therefore important for employers to provide employees with organizational justice in order reap the positive outcomes of highly engaged employees

The study findings suggest that employees' engagement with an organization could be significantly increased by enhancing organizational fairness, particularly procedural justice. NGO leaders and managers should look at the procedural justice and hence increase overall levels of perceived justice by involving employees in the procedures used in making decisions and allocating rewards. Procedural justice can be fostered further through employee involvement which gives them a voice during a decision-making process, influence over the outcome or by adherence to fair process criteria. The study findings indicate that there is a need to promote distributive justice amongst health NGOs. Distributive justice is enhanced through provision of timely and honest explanations to people on issues that affect them, their work.

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Animal Trials of *Carica Papaya* Leaf Extracts for Increasing Platelet Count

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ABSTRACT

Thrombocytopenia is defined as decreased platelet count. Thrombocytopenic disorders (dengue, chikungunea, malaria etc.) are spreading in urban area with the lightning speed. This is now endemic in more than 125 countries. The major mechanisms for a reduced platelet count are decreased production and increased destruction of platelets. Use of papaya leaf extract for increasing platelet count has been described by many scientists. The proposed research work has main aim to explore *Carica papaya* leaf extract for increase in platelet count in induced thrombocytopenic experimental animals and to study hematology and histopathology of various organs for any side-effects. So papaya leaves were extracted with n-hexane, acetone, ethanol and methanol using Soxhlet apparatus and distilled water using maceration for 8hours.and experiments on experimental animals to see increase in platelet count were carried out. Hematological and Histopathological studies on experimental animals may prove beneficial for toxicologists.

Keywords: *Carica papaya, extracts, organic solvents, platelet, Thrombocytopenia,*

INTRODUCTION

Thrombocytopenia is defined as a platelet count below the 2.5th lower percentile of the normal platelet count distribution. Results of the third US National Health and Nutrition Examination Survey (NHANES III) support the traditional value of 150 x 10^9/L as the lower limit of normal[1]. However, platelet counts between 100 and 150 x 10^9/L do not necessarily indicate disease if they have been stable for more than 6 months (R. Stasi et al 2006) and the adoption of a cutoff value of 100 x 10^9/L may be more appropriate to identify a pathologic condition[2]. Platelet counts above 200 x 10^9/L, clinical symptoms are often limited to easy bruising; however, below 100 x 10^9/L, the risk of spontaneous muco-cutaneous bleeding increases rapidly[3].

Thrombocytopenia is caused by two basic reasons; one is impaired platelet production and second is excessive destruction. Impaired platelet production occurs in BM failure, megaloblastic anemia, leukemia, myeloma, myelo-fibrosis, solid tumor infiltration, aplastic anemia and paroxysmal nocturnal haemo-globinuria (PNH) [4]. Excessive destruction occurs in autoimmune ITP, SLE, viral infections like EBV, dengue and HIV, DIC, TTP and in hyper-splenism[4]. Thrombocytopenia is the most common cause of defective primary hemostasis that can lead to significant bleeding. Significant quantitative or qualitative platelet dysfunction causes muco-cutaneous bleeding. The most common causes of thrombocytopenia are defective production of platelets by the bone marrow, diminished platelet survival and sequestration of the platelets by the spleen, leptospirosis, malaria and dengue associated with platelet destruction and bone marrow suppression and sepsis. A combination of above facts also can lead to thrombocytopenia[3]. It is now known that in many cases of Thrombocytopenia, such as primary immune Thrombocytopenia (ITP) and hepatitis C virus infection, multiple mechanisms may contribute to the development of Thrombocytopenia[5].

Carica papaya L. belongs to the plant family Caricaceae[6]. The different parts of papaya leaf contains various chemical constituents that has been proved for various medicinal activities like antioxidant, anti-hypertensive, wound healing, hepatoprotective, anti-inflammatory, antimicrobial, anti-amoebic, and anti-helminthic. Recent Phytochemical examination of plants has a suitable history of use in folklore for the treatment of thrombocytopenia. Research into phytotherapy of diseases is a current trend in the management of tropical diseases and genetic disorder like sickle cell anemia, with a view to finding cheaper, alternative medicines that the wide populace can have immediate access[7].

The rapid recovery of platelet counts was studied in children suffering from dengue. The boys, were administered a spoonful of ground papaya leaves paste every 04 hourly. A dramatic increase in platelet counts was observed within 12 h of initiating treatment, the count increased to 100,000 in one case and in the second case, it increased within 2 days to 250,000. Patients were administered fresh juice *C. papaya* leaves once a day 15 min after breakfast for 3 consecutive days. The study found that there was a significant increase in the platelet counts at the end of 40 h when compared to the counts 8 h after the intervention began[8].

A suspension of powdered crude *Carica papaya* leaves in palm oil when administered to experimental animal have shown the consistent rise of the thrombocyte counts in the treated group. The effect of papaya leaf formulations was higher and significant indicating a potential in the treatment of thrombocytopenic purpura[9].

Various clinical and pre-clinical studies conducted demonstrate the positive beneficial trend in increasing the platelets. Significant rise was observed on the fourth day of admission. However, large scale randomized clinical trials were suggested to further establish its pivotal role in the management of dengue.

The results of Zunjar et al (2016)[10] experiments, suggested that *Carica papaya* leaves decoction has very good anti-thrombocytopenic properties. It is predicted in the study that anti-thrombocytopenic property of *Carica papaya* leaves may be due to alkaloid. Additionally, no visible toxicity or any adverse effect was observed in animals,

The study of Gamulle (2012)[11] reiterated that the mature leaf *Carica papaya* concentrate (MLCC), has the potential to be developed as a plant based therapeutic agent for thrombocytopenia. It was also observed that the MLCC prepared by the mature leaves of *Carica papaya* can be orally administered, is safe (non-toxic), effectively increasing platelet, WBC and RBC counts in normal (non-thrombocytopenic) and thrombocytopenic rats.

Thrombocytopenic parameter of papaya leaf extract is studied with crude extract of water, followed by methanolic and ethanolic extract up to some extent. The current study detailed study of action of five different extracts of papaya leaf from polar to non-polar solvents.

MATERIALS AND METHODS

Sample preparation: The authenticated, disease free sapling of papaya plant of breed "Taiwan 786" was purchased from "Ram Biotech limited", Nashirabad, Maharashtra, India. These saplings were given organic manure with fifteen days interval.

Fifteen days old leaves were shade dried, powdered and used for extraction. 25 grams powdered plant materials (leaves) were soaked separately with 250 ml of each of the ethanol, methanol, n-hexane and acetone, and extracted in a Soxhlet apparatus for 6 hours at boiling point until complete extraction of the materials. Extracts were concentrated at room temperature in order to reduce the volume. In distilled water the same was soaked separately with 250 ml and macerated for 6 hours with some intervals. At the end of 6 hours, each extract was filtered through Whatman No.1 filter paper and filtrates were concentrated at room temperature in order to reduce the volume. These extracts were used for further analyses.

Animal experiments:

Experimental Design:

Phase-I:

Standardization of carboplatin doze: The dose of carboplatin was standardized to check the toxicity and lethalness of drug. Thrombocytopenia was induced in experimental Sprague dawley rats by a single intra-peritoneal injection of carboplatin (Fresenius Kabi Oncology Ltd). The dose of carboplatin was given in 50 mg/kg body weight, 100 mg/kg body weight, 150 mg/kg body weight concentrations to 12 Sprague dawley rats of either sex.

The dose of 50 mg/kg body weight of carboplatin was finalized as this dose was found to be suitable for induction of thrombocytopenia with no or very little toxic effects and non-lethal; while other two doses were found to be lethal.

Phase-II:

Standardization of extracts doze: Group of 06 animals (Sprague dawley rats) of either sex set was experimented to decide the doze of extract for 05 different solvents in 02 different concentrations of 100 mg/kg body weight and 200 mg/kg body weight, a set of standard

drug prednisilon (Intervet India Pvt Ltd). These results concluded without any rise in platelet count. So the new preclinical experiment was designed with double dose that was 400 mg/kg body weight. This doze gave results as per hypothesis showing rise in platelet count.

Phase-III:

Animal trials: A set of48 Sprague dawley rats was divided into seven groups of 06 (03 Males and 03 females) animals each. After inducing thrombocytopenia in all animals, on 6th day, the control group (group 0) was given 0.3 ml distilled water and experimental groups were orally treated with 400 mg/kg body weight of extracts (group 1 to 6). This was continued every alternate day from day 06 to 27. (Group1: hexane extract, 2: acetone extract, 3: ethanol extract, 4: methanol extract, 5: distilled water extract, 6: standard).

Blood Sample Collection: Retero-orbitally blood sample was drawn on day 6, 15, 25 for platelet count rise.

Platelet Examination: Induction of thrombocytopenia was established by determining platelet counts with the standard protocols as given in book name[12].

Histopathological studies: At the end of experiment animals were sacrificed for histopathological examinations of Liver, lungs, kidney, spleen, heart and intestine to check effect of extract on organs and its toxicity with the standard protocols[12].

Result and discussion: Animal trials were conducted on Sprague dawley rats to check the rise in platelet count as a result of extract treatment, after inducing thrombocytopenia with the help of carboplatin. Retero-orbitally blood sample was drawn, from rats of each group on day 0, on 6th, 15th, and 25th day of the experiment. Papaya leaf extracts of various solvents prevented fall in platelet count throughout the study period.

Before induction of thrombocytopenia in rats (day 0), the platelet count in control, n-hexane, acetone, ethanol, methanol and distill water extract and standard were found to be 8.83±103, 8.99 ±97, 8.90±104, 9.18±139, 9.40±129, 8.90±104, 9.68±145 × 10^5/ cmm respectively.

Carboplatin has been used to induce thrombocytopenia. It is a derivative of Cis-platin. It is a second generation platinum drug that is clinically effective in malignant tumors. It was chosen because it causes lesser side effects like toxicity, nausea and vomiting[13]. Carboplatin causes a rapid decrease in circulating platelet number[14] and it affects multi-lineage hemopoietic cell which are mature in nature and does not affect the stem cells[15]. After induction of thrombocytopenia with the help of carboplatin, the platelet count was reduced by 71.46%, 74.22%, 73.53%, 77.89%, 79.03%, 75.51%, and 75.10 % in control, n-hexane, acetone, ethanol, methanol and distilled water extract and standard respectively on day 06. From day 06 onwards on every alternate day till the end of the experiment, extract and standard were given as per decided doze and schedule. On 15th day the platelet count rise was observed by 18.19%, 42.49%, 42.26%, 49.92%, 60.10%, 70.97%, 139.94% in case of control, n-hexane, acetone, ethanol, methanol and distilled water extract and standard groups respectively. On 25th day increase in platelet count was found to be 126.52%, 166.36%, 178.94%, 181.20%, 190.36%, 216.96%, 303.66% in case of control, n-hexane, acetone, ethanol, methanol and distilled water extract and standard groups respectively. Fig. 1 and Table 1 represents percentage increased in platelet count and the number of platelets observed.

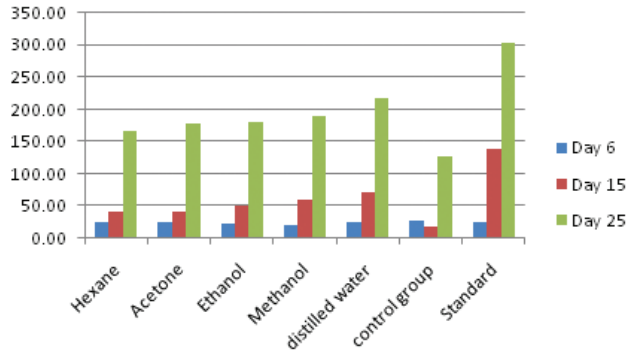


Fig.1: Percentage increase in the platelet count

Study reveals that difference between male and female animal platelet count was not significant.

Table1: Platelet Count × 105/ cmm Mean ± SD observed in various extracts treated rat groups.

Group name	Day 0	Day 6	Day 15	Day 25
Hexane	8.99 ±97	2.31±63	3.30±54	6.17.5±73
Acetone	8.90±104	2.35±84	3.35±78	6.57±64
Ethanol	9.18±139	2.03±112	3.04±95	5.70±52
Methanol	9.40±129	1.97±86	3.15±96	6.00±68
Distilled water	8.90±104	2.18±89	3.73±84	6.91±85
Control	8.83±103	2.52±75	2.97±84	5.70±28
Standard	9.68±145	2.41±62	5.78±112	9.73±130

Histopathological examination of the liver, lungs, kidney, intestine, heart and spleen of control and treated groups did not reveal any morphological differences or toxicity even after 27 days of treatment. This suggests that *Carica papaya* leaf extracts are safe and have no side effects as well as toxic effects. Figure 1 shows the representative histopathological images of the various organs.

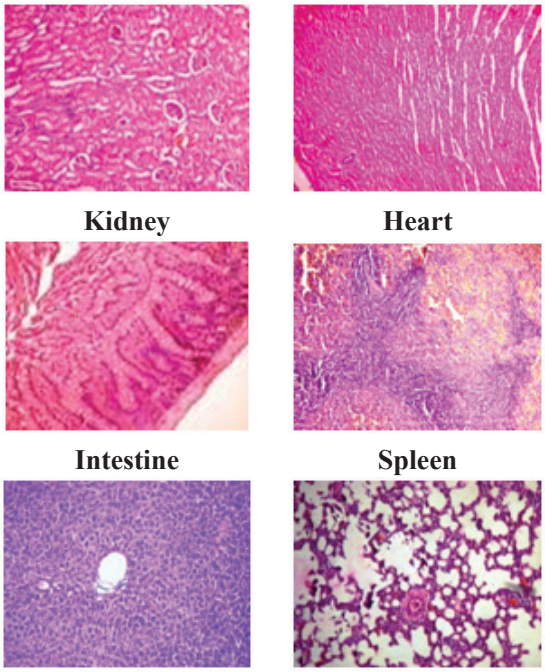


Fig. 2: Histopathological images of the various organs.

Platelet count was decreased after administration of carboplatin injection (50mg/Kg body weight). Maximum effect of the carboplatin was observed on 7th day and then increase in platelet count was observed.

Carica papaya leaf extracts prevented fall in platelet count throughout study period. Platelet count was found to be at higher level on day 7th, 15th and 27th in all experimental groups as compared to the same group at day 1 (Fig. 2). From the observations it is clear that not only fall in platelet count was prevented but count was also increased significantly above baseline. When platelet count in experimental groups was compared to the standard (Prednisolon) and control (Natural recovery), it was observed that increase in platelet count in standard group was rapid and at higher level as compared to experimental groups while platelet count in control group was found to be at lower level. Gender-wise difference in platelet count was not significant in all groups.

One animal study investigating effect of papaya leaf juice on platelet count on 5 healthy mice showed increased platelet count within hours, suggesting increase of platelets from bone marrow[16]. Gammulle et al (2012)[17] studied effect of papaya leaf juice on hydroxyl urea induced thrombocytopenia in rats. 7.2 ml/kg of juice given for three consecutive days increased platelet count by 76.5% as compared with control. Tahir et al (2014)[4] studied difference in effect of male and female *Carica papaya* tree leaf juice on platelet count. Difference between male and female plant was not significant while higher dose (10 ml/kg) produced significantly high response as compared to low dose (5 ml/kg). This is in concordance with our study.

Multiple mechanisms mediated by many active principles in papaya leaf juice may be responsible for increasing the blood cell counts. Papaya leaves contain active compounds papain, chymopapain, alkaloids, flavonoids, flavonaols, tannins and benzylglucosinolate. These compounds stimulate and/or improve the megakaryocytes to produce sufficient numbers of platelets to maintain a suitable platelet count in mammals, in particular during chemotherapy[4]. Biologically active compounds present in leaf are proteolytic enzymes, for example papain and chymopapain. As proplatelet formation is regulated by a caspase (protease) activation, protein digestion by these enzymes may increase platelet count[18]. The flavonols (such as kaempferol, quercetin, myricetin and fisetin), and flavonoids are used as ingredients in many pharmaceuticals composition. They are shown to have anabolic effect[19], which may be responsible for stimulant effect on blood cell production. Tannins are large polyphenolic compounds containing sufficient hydroxyls and other groups (such as carboxyl) to form strong complexes with proteins and other macromolecules. As retraction events release individual pro-platelets[18], the complex – forming properties of tannins may contribute to the positive effects on platelet count in blood.

At the end of experiment animals were sacrificed for histopathological examinations of liver, lungs, kidney, spleen, heart and intestine to check effect of extract on organs and its toxicity by the protocols given by Godkar and Godkar (2003)[12]. From histopathological studies it is clear that all extracts had no toxic effects on major organs like liver, lungs, kidney, spleen, heart and intestine. Hence these extracts are safe by oral route for increasing platelet count.

CONCLUSION

Papaya leaf extracts not only prevents fall in platelet count induced by carboplatin but also increases platelet count in a dose dependent manner without any toxic effects. On other hematological parameters, effect of extracts was insignificant and there was no significant effect of extracts on male and female rats. From this it is very much clear that *Carica papaya* extracts contain potential component(s) which is responsible to increase platelet count and so further studies on isolation, purification and characterization of such component(s) is required on urgent basis.

However, this is a primary study and more work is needed to isolate and identify the active bio-components of *Carica papaya* leaves to create a suitable formulation responsible for production of the platelets.

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Conflict of Interest: Nil

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Toxic Hexavalent Chromium Removal from Aqueous Matrices Using Passive Waste Biomass: Kinetics and Adsorption Isotherm Models

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ABSTRACT

Purpose: Hexavalent chromium is well known for its toxicity to all forms of living cells and therefore its removal from industrial waste matrices is the key. The main purpose of this study was - (i) to investigate the potential of some low-cost agricultural waste biomaterials for its efficacy to remove toxic hexavalent chromium from industrial effluents; and (ii) to study the kinetics and adsorption models.

Design/methodology/approach: Biomass collected from different sources was processed in laboratory to obtain sorbents for Cr(VI) sorption studies. Batch mode studies were performed to analyze the adsorption capacity and adsorption models like Langmuir, Freundlich and Tempkin were investigated from suitability aspects.

Findings: Among tested biomaterials, wood apple shell powder (WASP) and coconut shell powder biomass were found to be highly efficient biosorbent for removal of Cr(VI) from wastewater. Optimal pH for maximum sorption was at acidic pH. Kinetics showed that the time taken for maximum sorption was 60 min. Loading capacity of WASP was found to be higher than that of conventional activated charcoal. Sorption data obtained at various initial concentrations could be well fitted in the different adsorption models used and obeyed the principles underlying it.

Originality/Value: The research focuses attention on the use of waste agricultural biomass for the removal of non-renewable waste metal resource from wastewaters.

Keywords: *Biosorption, Hexavalent chromium, Low-cost biomass, Wood Apple Shell Powder*

INTRODUCTION

Chromium exists in environment both in trivalent and hexavalent form, of which the hexavalent form is approximately 500 times more toxic than trivalent one. Chromium is industrially crucial metal because of its distinctive properties of corrosion resistance, hardness and colour and therefore finds large applications in modern industries like chrome-plating, steel and alloy manufacturing, paints manufacturing, leather tanning, textiles and ammunition factories[1]. Many of these industries use hexavalent chromium [Cr(VI)] either in chromate or dichromate forms. These industries consequently, discharge large volumes of Cr(VI) effluents. Cr(VI) is a known mutagen and carcinogen[2], therefore the prevalent water pollution control laws in most countries require its complete removal from waste streams before discharge. The Indian Statutory Limits of Cr(VI) for industrial effluents discharge in inland surface waters is 0.1 mg/l. High atomic weight metallic element like mercury, chromium, cadmium, arsenic and lead can harm living forms at low concentrations and tend to assimilate in the food chain[3]. According to the report of WHO (2011)[4], chromium regulates the function of insulin in patients. In adults, the advice intake is 50-200 µg/day and higher concentration can be carcinogenic or mutagenic affecting skin, bones and teeth.

Numerous conventional processes are operated to cleanse chromate-bearing effluents. These processes include reverse osmosis, adsorption onto ion-exchange resins and reduction-chemical precipitation[5]. The latter process is used most widely. However, most of these this process is highly energy-intensive, consumes huge

quantity of chemicals and hence is not economically attractive. It is therefore imperative to seek for new practical and economic alternate treatment methods. Use of biological treatment methods is one such effective alternative[6]. Under the purview of biological methods, use of either live (active) or dead (passive) biomass could be employed. Significant work has been carried out on microbial reduction of chromium[7-8]. However, live biomass is subject to the toxicity and could only be used when chromium concentration is very low. Therefore, biosorption (passive biomass), a technically feasible and economical process has gained immense creditability during recent years[9]. Moreover, chromium being non-renewable and finite natural resource, the argument is not limited only to their removal from the effluents, but also extends to finding an efficient and economical ways of resource recovery and recycling. There are quite a few reports of chromium removal by employing passive biomass[10]. Biosorption demonstrates quite adequate process for the removal of heavy metal/metalloids ions from polluted waste water in a low cost and environment friendly manner. Biosorption is a passive process which employs cell wall of biomass to sequester the metal ions from aqueous solutions. The prime advantages of this method are cost-effectiveness, regeneration of biosorbents and possibility of metal recovery. In this paper, the researchers presents the findings concerning Cr(VI) removal from aqueous matrices using passive waste biomass along with their kinetics and adsorption isotherm models.

MATERIALS AND METHODS

Some agricultural waste biomass like coconut fibers, groundnut husk, rice straw and wood apple shell were collected from diverse sources. Samples were collected in polythene bags and brought to laboratory. The samples were washed several times with tap water followed by distilled water (DW) to eliminate the dirt and other impurities, if any. Later the samples were dried in oven at 60°C for 48-96 hours till the constant weight was obtained. The dried biomass was ground in order to obtain uniform particle size of ≤ 500 µm and stored in air tight glass bottles.

Batch experiments were conducted on biosorption of Cr(VI) using the waste biomass. 1 g of low-cost grounded biomass was contacted with 25 ml of 50 mg/l Cr(VI) of desired pH (4.0) in a set of 150 ml capacity Erlenmeyer flasks. The flasks were incubated on rotary orbital shaker at 100 rpm at 30°C for 1 hour, unless otherwise stated. After incubation the contents of the flasks were filtered out and analyzed for residual Cr(VI). The residual Cr(VI) was determined by diphenyl carbazide method using spectrophotometer[11]. Total chromium was also estimated by Atomic Absorption Spectrophotometer. All experiments were performed in duplicates and repeated twice to confirm the results. Appropriate controls were run simultaneously. Adsorbent like activated charcoal was employed as a reference material.

The adsorption yield or efficiency (Adsorption %) was computed using the following the relation

$$\text{Biosorption (\%)} = \frac{(C_i - C_f)}{C_i} \times 100 \qquad \text{Eqn. 1}$$

Where, Ci was the initial metal ion concentration and C_f is the residual metal ion concentration in solution at equilibrium in (mg/l).Parameters like contact time, pH and concentration of chromium solution was evaluated for the selected biomass.

The loading capacity of Cr(VI) [µmol Cr(VI) bound per gram weight of biomass] was determined by contacting 1 g of biomass several times with fresh batches of 25 ml of 50 mg/L Cr(VI) solution till saturation was achieved. The biosorption capacity at equilibrium was computed as follows:

$$Q = \frac{(C_i - C_f)V}{1000\ m} \qquad \text{Eqn. 2}$$

Where, Q was the Cr (VI) uptake (µmol per gram biomass); C_i was the Cr (VI) initial concentration (mg/l); C_f the final concentration (mg/l); V the volume of Cr (VI) solution (ml) used; m was the mass of biosorbent (g).

RESULTS AND DISCUSSION

The data in Table 1 depicts percent sorption of Cr(VI) at pH 4.0 using some agricultural waste biomass under study. It could be clearly seen that wood apple shell powder (WASP) biomass showed highest sorption, which was followed by coconut husk powder, groundnut shell, rice straw and cow dung. It was interesting to note that WASP showed higher biosorption compared to activated charcoal which was used as reference material. Control flask without sorbent showed no loss of Cr(VI) confirming that removal of target metal from aqueous matrices is due to passive biomass.

From the first screening experiment, WASP and Coconut husk powder (CHP) were selected to investigate their loading capacity as these two biomass were efficient sorbent for Cr(VI). As a reference material, loading capacity of activated charcoal was also determined. These experiments were conducted as optimal pH condition (i.e. 4.0). Table 2 illustrates the data on loading capacity at optimal pH. It could be clearly seen from the data that WASP showed the highest loading capacity form Cr(VI) compared to CHP and activated charcoal (reference material and control). Loading capacity of the biosorbent corresponds to the number of requisite sites present in the sorbent. Result of loading capacity has further narrowed down our study to WASP biomass for Cr(VI) concentration. Based on the results obtained further studies were focused on WASP.

Table 1: Sorption (%) of Cr(VI) using some agricultural waste biomass (at pH 4)

Sr. No.	Biosorbent/Biomaterials	% Biosorption
1.	Coconut husk powder	89.0*
2.	Cow dung	31.8
3.	Groundnut shells	48.4
4.	Rice Straw	40.2
5.	Wood apple shell powder	99.8
6.	Activated charcoal (Conventional sorbent as reference material)	98.0
7.	Control (without biomass)	0

*All the values mentioned in table are average of two readings

Table 2: Loading capacity of Cr(VI) at optimum pH

Sr. No.	Biosorbent/Biomaterials	Loading Capacity (mg/g)
1.	Coconut husk powder	22.43*
2.	Wood apple shell powder	25.30
3.	Activated charcoal (Conventional sorbent as reference material)	22.56

*All the values mentioned in table are average of two readings

Kinetics of Cr(VI) biosorption: Kinetics plays a significant role on the sorption rate of Cr(VI) on to the surface of biomass[12]. The experimental results presented in Fig.1 shows the biosorption of Cr(VI) as a function of time at various initial concentration. It was observed that no sorption increased with the increase in time upto 60 min after which no significant variation was observed. In the initial stages, the rate of sorption was found to increase. However, as the time elapsed a slow down towards equilibrium was observed. It is attributed to the fact that in the initial stages, more vacant sites are available on sorbent surface and high concentration gradient of Cr(VI) solution lead to rapid adsorption. Agitation on rotary shaker at 150 rpm lead to proper mixing and provides the necessary driving force for chromium to enter from bulk of solution to sorbents active sites. The energy generated on rotation help to reduce the resistance of mass transfer between sorbate and sorbent. 80 to 90% of sorption of Cr(VI) took place in first 45 min to 1 hour and equilibrium is established in one hour. As concentration increases the metal has to diffuse to the biosorbent surface by intraparticle diffusion. Being highly hydrolyzed diffusion of ions will be at slower rate. This shows the monolayer development of chromium ion on the surface of biomass[13]. In the reaction the rate limiting step is defined as the rate of the sorption which is concentration dependent. When the kinetics of the reaction is controlled by intra particle transport, variation in the reaction rate is not expected to be linear, whereas the rates of strictly adsorptive reaction and simple diffusion controlled process are expected to be proportional to the first power of the sorbate concentration.

The percentage removal was found to increase from 25% to 92.1%, 35% to 87% and 42% to 39 % for 10, 50 &100 mg/l respectively for 5 to 60mins of contact time for initial Cr(VI) concentration. With passage of time the rate of adsorption is equal to rate of desorption when the number of site on the sorbents are filled up. The remaining vacant surface site are difficult to occupy due to repulsive forces between the solute molecule on the solid and bulk phases. Rest of the batch experiments were carried out for 60mins of contact time.

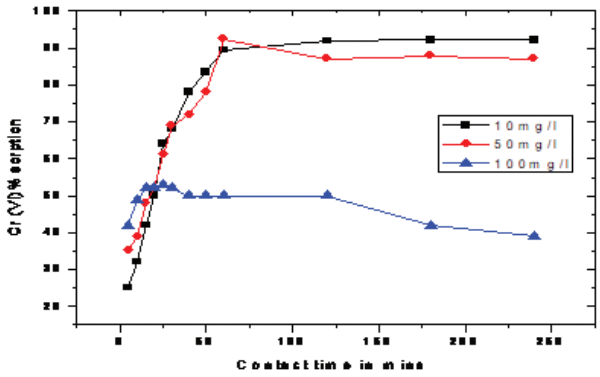


Fig. 1. Effect of contact time at pH 4 on the biosorption of chromium (VI) ions with initial concentration of 10 mg/L, 50 mg/L and 100 mg/L.

In the present study the equilibrium time required by the WASP was 60 mins which is less compared to the other bio sorbents reported in the literature. For industrial use and process applications equilibrium time is an important and significant parameters as shorter contact time influence the size of the equipment, capacity and operation cost as equilibrium time is one of the important considerations for economical water and wastewater applications. In process application, this rapid (or instantaneous) biosorption phenomenon is advantageous since the shorter contact time effectively allows for a smaller size of the contact equipment, which in turn directly affects both the capacity and operation cost of the process[14-15] reported that the available adsorption sites on the biosorbent are the controlling factor for metal uptake.

Biosorption of Cr(VI) was studied at various pH ranging from 2 to 9. It was found the pH of 4.0 was optimum for the removal of the target chemical species (>90%). With rise in pH, a decrease in removal efficiency was observed which may be due to competition between OH^- ion and CrO_4^- ion, and OH^- showing dominant effect.

The impact of initial sorbate concentration (C_0) on the sorption by WASP was examined by ranging the initial concentration from 10-500mg/L of 25ml volume. This study was conducted at solution pH 4, and time duration of 60 mins. Results showed that uptake of Cr(VI) increased with increase in Cr(VI) concentration. This may due to presence of large vacant sorbent site and high concentration gradient between the solution and solid phase. High initial concentration helps to overcome the resistance to the mass transfer of Cr(VI) between the aqueous solution and solid phase. Increase in concentration of Cr(VI) enhances the uptake. With passage of time a plateau is reached because of decrease in driving force and thus can be interpreted that sorbate has approached saturation level.

Adsorption Isotherm: Adsorption isotherms are mathematical models, to express the adsorption mechanism of sorption. Based on assumptions of adsorption isotherm the distribution of adsorbate in the adsorbent and solution can be explained. To explain the mechanism of Chromium (VI) adsorption onto WASP biomass, adsorption isotherm are important. To identify the best suited adsorption model, experimentally obtained equilibrium data was applied to three different models in the current study namely Freundlich[16], Langmuir[17] and Tempkin[18].

3.7.1 Freundlich isotherms: Freundlich isotherm is extensively practiced in heterogeneous system especially for organic compounds at present. The amount adsorbed is the summation of adsorption on all sites. The stronger binding sites are engaged first till the adsorption energy decrease upon the completion of adsorption process[19].

This empirical model described the non-ideal sorption on heterogeneous surfaces. It can be applied to multilayer sorption and is expressed by the following equation:

$$Qe = K_f C_e^{1/n} \quad \text{Eqn. 4}$$

Where, K_f = Freundlich constant expressed as $mg^{1-1/n}\ L^{1/n}\ g^{-1}$, n = adsorption intensity, Ce = the equilibrium concentration of adsorbate (mg/L), Qe = the amount of metal adsorbed per gram of the adsorbent at equilibrium (mg/g). K_f is a constant which indicate the relative adsorption capacity of the adsorbent. Whereas 1/n is a function of the strength of adsorption in the adsorption process

The plot of log qe vs log Ce (Fig. 2) gives a straight line which enable determination of the isotherm constant K_f and 1/n from the slope and intercept[12, 20]. The value of K_f and n are 1.77 and 1.38 respectively as listed in table 5. The R^2 value obtained from the model for WASP biomass is 0.9121which is lower than that of Langmuir isotherm model as shown in Table 3.

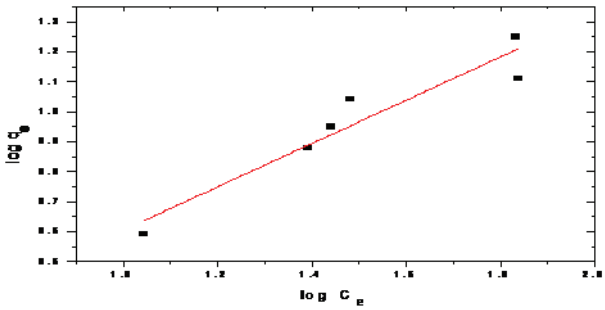


Fig. 2: Freundlich adsorption isotherm for Cr(VI) adsorption by WASP

The values of exponent "n" in general indicate the favorability of adsorption. n in the range of 2-10 represents good adsorption, 1-2 moderately difficult and less than 1 poor adsorption characteristics. 1/n value less than unity represent chemisorption process whereas above one indicate cooperative adsorption[21-22]. As the value of 1/n for WASP biomass is 0.72 which is less than unity shows that adsorption has chemisorption nature.

3.7.2 Langmuir isotherm model: Irving Langmuir in 1916 presented his model called as Langmuir isotherm for his investigations relating to surface chemistry. Langmuir adsorption isotherm was initially established to define gas-solid phase adsorption on activated carbon[21].

The Langmuir equation may be written as:

$$q_e = \frac{Q_0 K_L C_e}{1 + K_L C_e} \qquad \text{Eqn.5}$$

Linear form of the same equation is used for calculation as given in Table 3. Where q_e is the amount of solute adsorbed per unit weight of adsorbent at equilibrium in mg/g. Ce the equilibrium concentration of the solute in the bulk solution in mg/L, Q_0 the maximum adsorption capacity (monolayer coverage capacity) in mg/g. K_L is the Langmuir isotherm constant related to the free energy of adsorption in L/mg.

Table 3: Adsorption isotherm model: Linear equation Freundlich, Langmuir, Tempkin

Isotherm	Nonlinear form	Linear Form	Plot
Freundlich[16]	$q_e = K_F C_e^{1/n}$	$\log q_e = \log K_F + \frac{1}{n}\log C_e$	$\log q_e$ vs $\log C_e$
Langmuir[17]	$q_e = \frac{Q_0 b C_e}{1 + bC_e}$	$\frac{C_e}{q_e} = \frac{1}{bq_0} + \frac{C_e}{Q_0}$	$\frac{C_e}{q_e}$ Vs C_e
Tempkin[18]	$q_e = \frac{RT}{b_T}\ln A_T C_e$	$q_e = \frac{RT}{b_T}\ln A_T + \frac{RT}{b_T}\ln C_e$	q_e Vs ln C_e

The important features of Langmuir adsorption isotherm parameter can be used to predict the affinity between the sorbate and sorbent using a dimensionless constant called separation factor or equilibrium parameter, which is expressed by the following relationship[24-25].

$$R_L = \frac{1}{1 + bC_0} \qquad \text{Eqn. 6}$$

Where b is the Langmuir constant and Ci is the initial concentration. The parameters R_L indicated the type of Langmuir isotherm and the shape of the isotherm accordingly if,

$R_L > 1$ Unfavorable

$0 < R_L < 1$ Favorable

$R_L = 1$ Linear

$R_L = 0$ Irreversible[24-25]

The adsorption data for hexavalent Cr onto WASP were analyzed by the regression analysis to fit the linearized expression of Langmuir isotherm model. The value of Q_0 and K_L can be calculated from the intercept and slope of the graph between Ce/ qe versus Ce as represented in Fig 5. The experimental value obtained for Q_0 =17.39mg/g, K_L =0.03, R_L =0.86 and R^2 =0.9954 respectively for the linearized form studied is mentioned in table 5. The R_L values between 0 and 1 indicate favorable adsorption. The R_L value in the present investigation was found to be 0.86 to 0.9, representing that the adsorption of the Cr (VI) metal ion onto WASP is favorable. The high value of R^2 i.e., 0.99 obtained confirms monolayer adsorption of Chromium (VI) onto WASP biomass and also signify better fit between the experimental values and isotherm parameters.

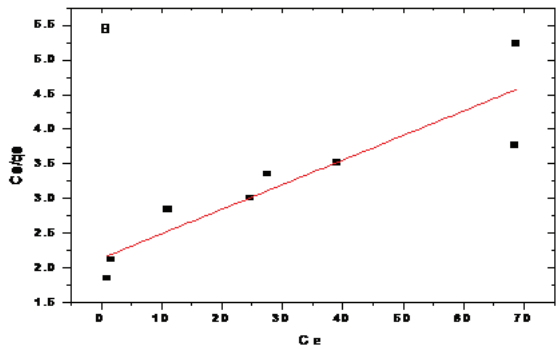


Fig. 3: Langmuir adsorption isotherm for Cr(VI) adsorption by WASP

Langmuir was more suitable for the experimental data than was the Freundlich isotherm because of the reasonably higher values of correlation coefficient (R^2).

3.7.3 Tempkin Isotherm: The Temkin model is given as

$$q_e = RT/b \ln (A_T C_e) \quad \text{Eqn. 7}$$

In the equation qe represents the fractional coverage, R = Universal gas constant (8.314 J/mol/K), T = absolute temperature (K), A_T = Temkin isotherm equilibrium binding energy constant (L/mg), b_T = Temkin isotherm constant (J/mol/K), B = Constant related to heat of sorption (J/mol)

The Temkin isotherm was exemplified by a linear plot of qe versus ln Ce using linear equation given in Table 1, from the slope and intercept of the plot the variation of adsorption energy (B) and the Temkin equilibrium constant (b_T) can be calculated. The sorption data were analyzed according to the linear form of the Temkin isotherm.

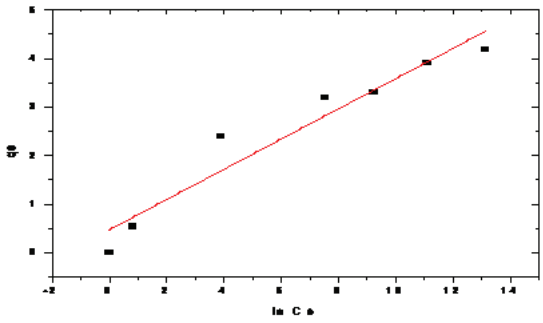


Fig. 4. Tempkin adsorption isotherm for Cr(VI) adsorption by WASP

Lower value of B in this study indicates weak interaction between adsorbate onto adsorbent, favouring the mechanism of ion exchange. In table 5, the parameters and the regression coefficient of Temkin models are presented. R^2 value is 0.93 which shows a good linearity regardless of the maximum capacity of adsorption used to calculate the coverage area. From the Temkin plot, the following values were estimated: A_T = 4.85 L/g, B=29.91J/mol which is an indication of the heat of sorption indicating a physical adsorption process.

Table 4: Adsorption isotherm constant values

Langmuir			
Q0(mg/g)	**KL (L/mg)f**	**RL**	**R²**
17.39	0.03	0.86	0.9954
Freundlich isotherm			
Kf (mg/g)	**1/n**	**n**	**R²**
1.77	0.72	1.38	0.9121
Temkin isotherm			
AT (L/g)	**bT (J/mol K)**	**B (J/mol)**	**R²**
4.85	8285	29.91	0.9276

Thus it could be concluded from the study of screening of different biomass that low cost biomass like wood apple shell powder was found to be highly promising biomaterial for removal of toxic hexavalent chromium from solution.

CONCLUSION

Kinetics of waste agricultural biomass (viz. wood apple shell powder) for the removal of Cr(VI) from aqueous solutions showed that equilibrium was reached within 60 min and the data obtained at different Cr(VI) concentration obeyed the principles of Freundlich, Langmuir and Temkin isotherm models (R^2 >0.90 in all three cases) thereby indicating that the biomass could be employed at industrial scale waste treatment.

Ethical clearance: No need

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Conflict of Interest: Nil

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Capital Structure Decisions of Indian Drugs and Pharmaceutical Firms

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ABSTRACT

Purpose: The study examines determinants of capital structure decisions of firms in the Indian healthcare industry, specifically in the Drugs and Pharmaceuticals sector. The paper further analyzes the trend in healthcare financing over a period of seventeen years from 2000 to 2016, and draws out the transformation in healthcare financing pre and post financial crisis of 2008.

Research Methodology: An empirical analysis of short term and long term leverage of pharmaceutical companies was undertaken. A panel regression model was used to incorporate factors that drive capital structure decisions of firms.

Results & discussion: The study finds that capital structure depends significantly on growth, profitability, non-debt tax shields and net fixed assets. It also finds that firms tend to maintain similar capital structures within the drugs and pharmaceutical industry in the long term. Financial crisis has significantly increased long term bank borrowing of firms in this industry.

Research implications: The research provides insights into capital structure decisions of firms and provides an understanding of factors determining those decisions.

Keywords: *Capital Structure, Financial Crisis, Financing, Healthcare, Leverage*

INTRODUCTION

Drugs and Pharmaceuticals in India has been one of the fastest growing Industries with a Compound Annual Growth Rate of 23.55% in terms of total asset growth from 2000 to 2016 (Figure 1). The market is expected to grow to US$ 50 Billion by 2020 and US$ 100 Billion by 2025[1].

The industry generated revenues of US$ 30 Billion in FY2015 of which approximately US$ 15 billion comprised of exports. India also ranked 3rd world-wide by volume of production and 14th by value, thereby accounting for around 10% of world's production by volume and 1.5% by value in 2015[2].

Government in India has been trying to boost the development in this sector through several reforms. Foreign Direct Investment (FDI) inflows in the period from April 2000 to March 2016 totalled US$ 13.85 Billion, of which US$ 3.53 Billion have come in the last three financial years[3]. FDI norms were revised to allow up to 74% investment in brownfield investment via automatic route and up to 100% via government approval route. 100%. FDI has been allowed under Greenfield investments through the automatic route. According to the earlier policy, up to 100 per cent was allowed under government approval in brownfield pharma and up to 100 per cent FDI under automatic route in Greenfield pharma[4]. This implies that more FDI inflows are expected in the near future as the Indian pharmaceutical industry outpaces the global industry. With more investments expected in this sector, financing decisions would become very important for existing firms in the industry. The way these firms have been raising funds over the years might help in understanding the future capital raising strategies.

The main objective of the study, therefore, is to help in understanding the capital structure patterns of the firms operating in the drugs and pharmaceutical sector

in India. The findings of the paper would be beneficial in knowing the main determinants of the financing decisions of the firms. We base our study on previous research work carried out across geographies and industries.

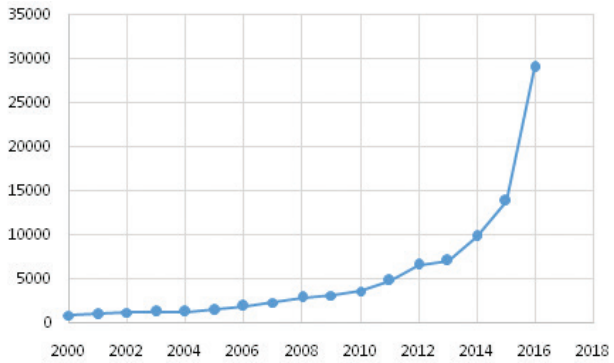


Fig. 1: Average Total Assets for all firms in the Time Series (INR Million)

Source: Authors' calculations using data from CMIE Prowess Database

REVIEW OF LITERATURE

Several studies have highlighted the importance of capital structure. Past researchers found that capital structure decision of a company was affected by both firm specific and country specific determinants[5,6,7,8,9].

Demirgüç-Kunt and Maksimovic (1994) found that in terms of relative explanatory power of the determinants of capital structure for both short-term and long-term, for most countries in the sample of ten emerging countries, the asset structure, liquidity and industry effects have more explanatory power than firm size, growth opportunities and tax effects[5]. Also Net fixed assets were positively related to long-term debt and negatively related to short-term debt. Firms with high market to book ratios had more debt. Firms with high non-debt tax shields had less debt. Rajan and Zingales (1995) found that at an aggregate level, firm leverage was more similar across the G-7 countries than previously thought, and the differences that existed were not easily explained by institutional differences previously thought important[10]. The factors identified by previous cross-sectional studies in the United States that found that capital structure was related to leverage, like tangibility of assets (the ratio of fixed to total assets), the market-to-book ratio (usually thought of as a proxy of investment opportunities), firm size, and profitability seemed similarly related in other countries as well.

Industry class was found to be an important determinant of financing structure, as financial structures differed across an array of industries. Firm size though important is not the primary factor contributing to the differences in leverage across industries[11]. It was found that firm fixed effects played a significant role in explaining capital structure variation. However, supply-side and financial contracting views suggested that debt structure and leverage were tightly linked and they should be considered as joint rather than sequential decisions[12]. Titman and Wessels (1998) found that debt levels were negatively related to the uniqueness of a firm's line of business, implying that firms that could potentially impose high costs on their customers, workers, and suppliers in the event of liquidation had lower debt ratios[13]. Short-term debt ratios were seen to be negatively related to firm size, possibly a result of the relatively high transaction costs faced by small firms while issuing long-term debt.

With respect to India, Kakani and Reddy (1999) using data for 100 firms for pre (1984-89) and post liberalization (1991-95) found that long term debt, short term debt and total debt were negatively impacted by profitability and capital intensity during both the phases[14]. During the 1984-89 period, regulated firms and growth-oriented firms had more total and long-term debt. In the liberalized era, the net exports of a firm seemed to have grown in importance in determining the long-term and total debt ratios. In addition, earnings volatility and non-debt tax shields were significantly negatively related to short-term and total debt of the firm. They concluded that liberalization affected the determinants of capital structure.

Subramaniam and Umakrishnan (2004) looked at different categories of debt for Indian firms[15]. Handoo and Sharma (2014) studied 870 Indian firms from 2001-2010[16]. They found that short term debt ratio was negatively impacted by profitability, size, tax rate and debt serving capacity and positively by tangibility. Long term debt ratio is negatively impacted by profitability, cost of debt, tax rate and debt serving capacity and positively by growth and, tangibility. Total debt ratio is negatively impacted by profitability, size, tax rate, debt serving capacity and age and positively by growth and tangibility.

Industry wise analysis of capital structure was done by several researchers. Aggarwal (1990) examined

the variations in capital structure across twenty Asian countries[17]. He found that country and industry factors influenced capital structure in Asia while size did not matter. India was identified to have moderate levels of leverage (on an average, an equity ratio of 30.55% for the years 1981 and 1982, 92 firms). Inter industry capital structure differences were evident for India when country level analysis was done. Sinha (1993) explained the variations in capital structure for different industries in India. He found asset type and profitability as significant factors[18]. Inter industry differences among twelve manufacturing industries pre and post liberalization were evident in a study by Das &Roy (2007)[19]. Firm size contributed to the variation but nature of industry played a dominant role, specifically, technology differences. Table 1 below presents some research studies highlighting industry differences.

Table 1: Review of Literature on Capital Structure Determinants of Indian Industries

Author(s)	Industry and Period	Findings
Guha-Khasnobis & Bhaduri, 2002[20]	697 Manufacturing firms (1990-1998)	Small firms depended on short term borrowings. Profitability showed negative relationship. Asset structure was positive and significant. Short term financial distress risk was negatively related to leverage.
Nagaishi, 2005[21]	3198 firms 1998-2000, 43 regulated firms	Findings indicated that in the context of Indian firms (i) regulation tended to create an incentive for regulated firms to increase their debt level, (ii) debt had a positive effect on the return on equity (ROE), and (iii) if a regulated firm's investment was relatively large, it was inclined to be highly leveraged.
Madan 2007[22]	Hotel Chains in India	Firms that have been moderately geared have been able to generate a good return on equity
Ali, 2011[23]	170 Textile Companies (2006-2010)	Size, non-debt tax shields and tangibility positively impacted leverage while growth and profitability had a negative impact.
Gill & Mathur, 2012[24]	Survey Based (Punjab Area, 600 small business service firms)	Capital structure was positively associated with CEO Duality, Board Size, growth and family.
Goyal, 2013[25]	Listed Public sector banks (2008-2012)	Positive relationship of short term debt with profitability and Earnings per share.

From the literature review, the research gaps identified were:

- Several sectors were covered for understanding Indian firms' capital choices but studies relating to healthcare sector have been scarce. These firms were covered in the overall India studies but findings were not analyzed distinctly. Hence the unique features of this industry could not be captured in the earlier studies.
- Past studies have not introduced economic shocks in their model. Some studies have looked at regulatory environment and the changes in it but financial crisis has not been covered for Indian firms.
- Looking at the gaps, this study formulated the following objectives:
- To understand the capital structure trends of the Drugs and Pharmaceutical sector for India from 2000 to 2016.
- To find the determinants of capital structure for the firms in Indian Drugs and Pharmaceutical sector
- To find if financial crisis has an impact on these firms' capital structure choices.

DATA AND METHODOLOGY

For this study, financial data has been collected for publicly listed Indian pharmaceutical firms from Centre for Monitoring Indian Economy-Prowess Database for the period 2000 to 2016. We used descriptive analysis on the dataset followed by regression analysis on a sample of 183 firms and 1762 observations. The number of observations changed as we added more explanatory variables in the study.

The dependent variables used in the study included Total Debt to Total Equity **(TDTE),** Bank Borrowing

to Total Equity **(BBTE),** Long Term Bank Borrowing to Total Equity **(LBBTE)** and Short Term Bank Borrowing to Total Equity **(SBBTE)**. We identified a list of independent variables from literature comprising of Net fixed assets divided by total assets **(NFATA)**, Depreciation by total assets **(DEPTA),** Annual Growth rate of total assets **(GROWTH),** Profitability **(PROFIT),** Market to Book Ratio **(BVMV),** Asset Turnover ratio **(NSNFA),** Non Debt tax Shields **(NDTS),** Size **(FSIZE)** and Age of the firm **(AGE)**. The definitions of the variables used are provided in the annexure.

A comparison of trend in Total debt, Bank Borrowings, Long Term Bank Borrowings and Short Term Bank Borrowings, all scaled by equity and across the time series is carried out. It is observed that a general upward trend in the Total Debt to Total Equity levels is reversed in the last four years implying the preference of equity over debt in recent times. Bank Borrowings to total equity (BBTE) have steadily increased over the time period apart from an exceptional spike in 2011 and 2012. The debt is primarily long term as observed by the next graph for LBBTE. Short term bank borrowings are relatively steady, which can be explained by ongoing operational requirements. (Figure 2 and Figure 3)

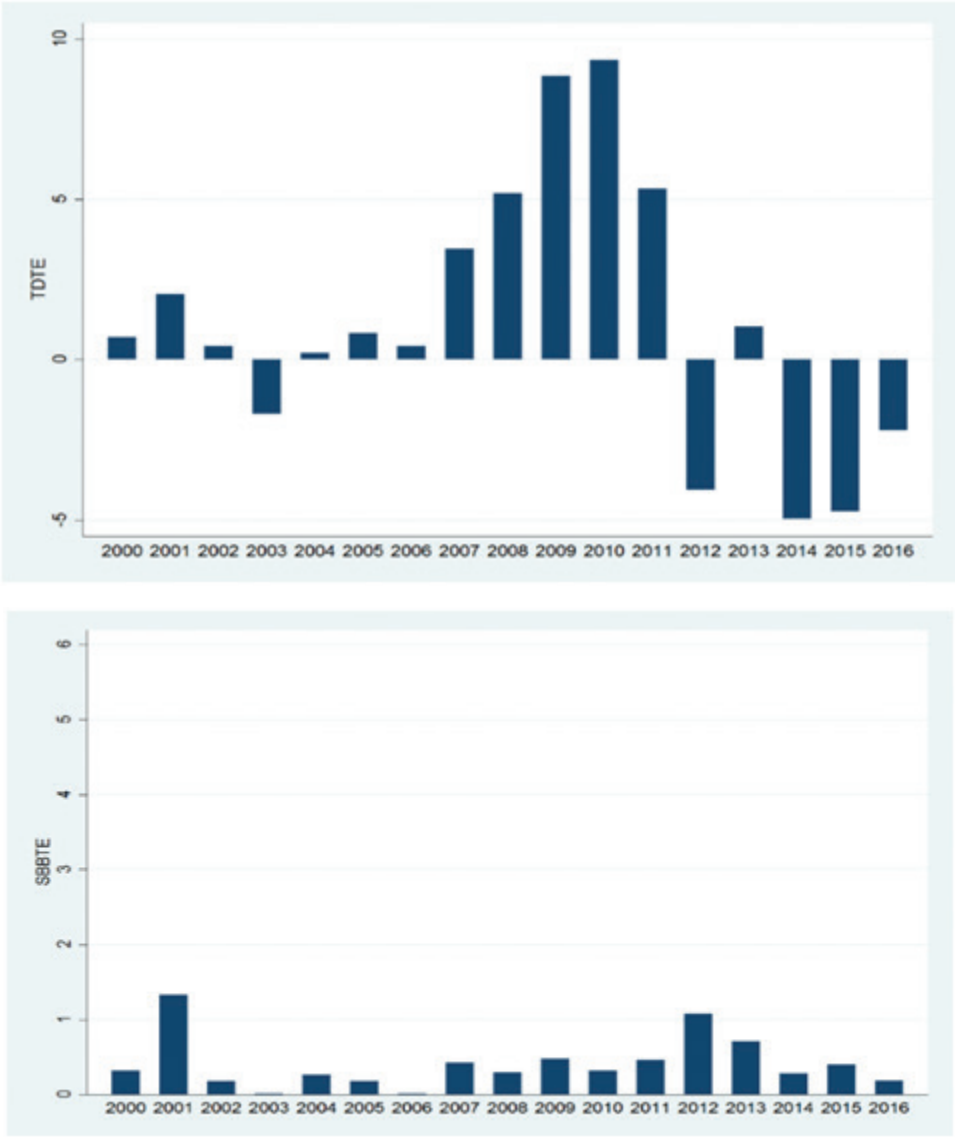


Figure 2: Average data of time series of total debt to equity and total bank borrowings to equity

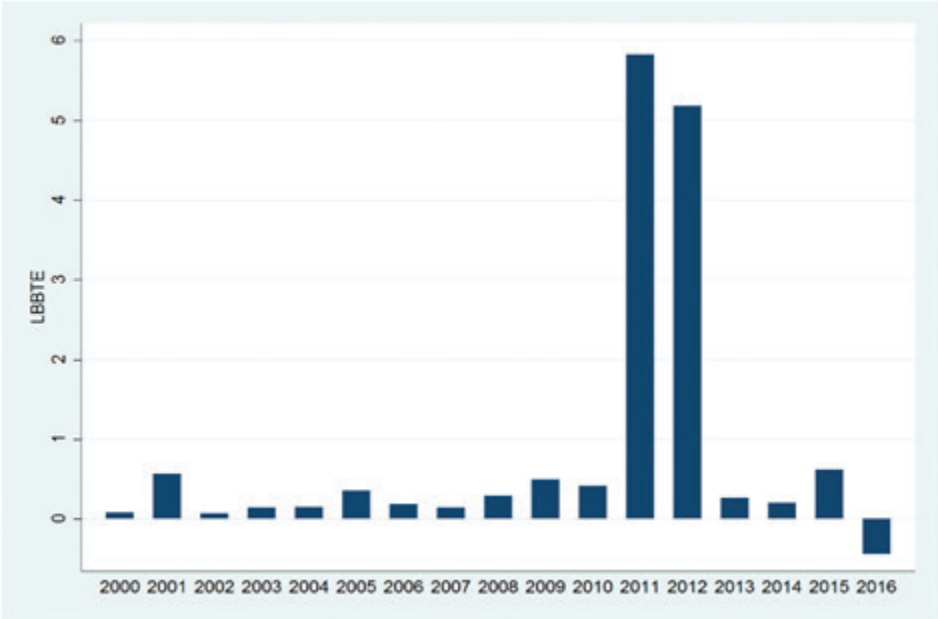


Fig 3: Average data of time series of long term bank borrowings to equity and short term bank borrowings to equity

Table 2: Average of values of the variables for all firms under consideration in the sample period

SQ	TDTE	BBTE	LBBTE	SBBTE	NFATA	DEPTA	GROWTH	PROFIT	BVMV	NSNFA	NDTS	AGE
1	-0.01	0.2	-0.16	0.37	0.4	0.05	0.56	0.18	0.28	5.82	-0.15	17.46
2	4.62	0.38	0.37	0.15	0.37	0.03	3.09	0.06	-0.32	7.49	0.02	19.49
3	1.3	2.69	2.93	0.6	0.35	0.03	6.91	0.08	0.65	11.39	0.05	23.26
4	1.23	0.79	0.47	0.46	0.33	0.03	138.18	0.11	2.01	4.57	0.09	30.63
TOTAL	1.86	1.12	1.09	0.41	0.36	0.03	40.39	0.1	1.04	7.41	0.01	22.72

Descriptive analysis of the variables is presented in Table 2 and Table 3. Firms were divided into Quartiles based on their Total Assets from the median where SQ1 – 0 to 86.9, SQ2 – 86.9 to 342.9, SQ3 – 342.9 to 1537.4, SQ4 – 1537.4 to 548369.3 respectively (INR Million). It can be observed that larger firms i.e. SQ4 prefer equity to debt, while a steady increase in debt levels is observed till SQ3.

In Table 3, GROWTH variable captured exceptional increase in total assets in 2012 and 2015. This is due to the spin-off of Sun Pharma Laboratories from Sun Pharmaceutical Industries Ltd. in 2012. In 2015, Jubilant Generics Ltd. issued equity shares, long term debentures and added long term loans which led to abnormal increase in both Current and Non Current Assets.

The model used for the analysis comprised of a panel regression. We ran the Hausman test to decide whether to use fixed effects panel regression model or random effects panel regression model.

The hypothesis for Hausman Test is as follows:

H_0 : Difference in coefficients is not systematic, i.e. use random effects model

H_a : Difference in coefficients is systematic, i.e. use fixed effects model

Hausman Test results ($Prob>chi^2 = 0.0007$) led to the rejection of our null hypothesis at 5% level of significance. Hence, we used the fixed effects regression model for our data.

We develop the hypotheses for each of our dependent variables and present the models in the following sub-sections.

(a) Dependent Variable – Total Debt to Total Equity (TDTE)

H_o1 : TDTE is independent of FSIZE, NFATA, DEPTA, GROWTH, PROFIT, BVMV, NSNFA, NDTS of firms

We specify the following fixed effects panel regression model:

$$TDTE_{kt} = \alpha_k + \beta_1 FSIZE + \beta_2 NFATA + \beta_3 DEPTA + \beta_4 GROWTH + \beta_5 PROFIT + \beta_6 BVMV + \beta_7 NSNFA + \beta_8 NDTS + e_{kt} \quad (1)$$

Where -

TDTE is the dependent variable where k is the entity and t is the time α_k is the unknown intercept for each entity k = 1, 2,…,n for n entities β_1 is the coefficient for FSIZE and similarly β_2 to β_8 for other variables e_{kt} is the error term

(b) Dependent Variable – Bank Borrowing to Total Equity (BBTE)

H_o2 : BBTE is independent of FSIZE, NFATA, DEPTA, GROWTH, PROFIT, BVMV, NSNFA, NDTS of firms

We specify the following fixed effects panel regression model:

$$BBTE = \alpha_k + \beta_1 FSIZE + \beta_2 NFATA + \beta_3 DEPTA + \beta_4 GROWTH + \beta_5 PROFIT + \beta_6 BVMV + \beta_7 NSNFA + \beta_8 NDTS + e \quad (2)$$

Where -

BBTE is the dependent variable where k is the entity and t is the time α_k is the unknown intercept for each entity k = 1, 2,…,n for n entities

β_1 is the coefficient for FSIZE and similarly β_2 to β_8 for other variables e_{kt} is the error term

Table 3: Average of values of the variables for all firms under consideration for each sample period

YEAR	TDTE	BBTE	LBBTE	SBBTE	NFATA	DEPTA	GROWTH	PROFIT	BVMV	NSNFA	NDTS	AGE
2000	0.70	0.34	0.08	0.32	0.36	0.03	.	0.08	0.69	7.80	0.02	19.54
2001	2.04	1.52	0.57	1.33	0.37	0.03	7.83	0.05	0.17	5.13	-0.06	19.93
2002	0.42	0.21	0.08	0.18	0.38	0.03	0.12	0.07	0.34	4.78	0.01	20.10
2003	-1.69	0.09	0.15	0.00	0.36	0.03	0.37	0.06	0.39	5.34	0.02	20.55
2004	0.21	0.33	0.15	0.26	0.35	0.03	0.22	0.10	1.24	5.57	0.06	20.51
2005	0.84	0.39	0.36	0.17	0.36	0.03	0.34	0.04	1.42	5.50	0.01	20.74
2006	0.43	0.13	0.19	0.00	0.36	0.03	0.85	0.10	1.95	4.99	0.07	20.59
2007	3.47	0.48	0.14	0.42	0.37	0.03	0.34	0.10	1.27	9.88	-0.02	21.21
2008	5.20	0.48	0.29	0.30	0.37	0.05	6.99	0.08	0.90	9.76	0.01	21.85
2009	8.86	0.81	0.50	0.48	0.38	0.03	1.51	0.13	0.15	4.90	-0.35	22.08
2010	9.34	0.61	0.42	0.32	0.37	0.03	1.03	0.39	0.99	9.86	0.28	23.11
2011	5.35	4.93	5.83	0.46	0.36	0.03	0.29	0.07	0.81	10.43	0.03	24.10
2012	-4.06	4.91	5.18	1.07	0.37	0.03	451.74*	0.07	0.60	8.22	0.00	25.46
2013	1.04	0.88	0.27	0.71	0.37	0.03	0.12	0.07	0.64	8.21	0.01	26.33
2014	-4.96	0.43	0.20	0.28	0.35	0.03	0.10	0.08	1.21	5.64	0.00	27.03
2015	-4.74	0.82	0.62	0.40	0.34	0.04	152.93*	0.06	2.55	9.67	-0.01	29.38
2016	-2.22	-0.12	-0.43	0.19	0.33	0.04	0.23	0.08	2.72	12.48	0.06	33.26
TOTAL	1.85	1.12	1.09	0.41	0.36	0.03	40.38	0.10	1.04	7.41	0.01	22.74

(c) Dependent Variable – Long term Bank Borrowing to Total Equity (LBBTE)

H_o3 : LBBTE is independent of FSIZE, NFATA, DEPTA, GROWTH, PROFIT, BVMV, NSNFA, NDTS of firms

We specify the following fixed effects panel regression model:

$$LBBTE = \alpha_k + \beta_1 FSIZE + \beta_2 NFATA + \beta_3 DEPTA + \beta_4 GROWTH + \beta_5 PROFIT + \beta_6 BVMV + \beta_7 NSNFA + \beta_8 NDTS + e \quad (3)$$

Where -

LBBTE is the dependent variable where k is the entity and t is the time α_k is the unknown intercept for each entity k = 1, 2,…,n for n entities

β_1 is the coefficient for FSIZE and similarly β_2 to β_8 for other variables e_{kt} is the error term

(d) Dependent Variable – Short term Bank Borrowing to Total Equity (SBBTE)

H_o4 : SBBTE is independent of FSIZE, NFATA, DEPTA, GROWTH, PROFIT, BVMV, NSNFA, NDTS of firms

We specify the following fixed effects panel regression model:

$$SBBTE = \alpha_k + \beta_1 FSIZE + \beta_2 NFATA + \beta_3 DEPTA + \beta_4 GROWTH + \beta_5 PROFIT + \beta_6 BVMV + \beta_7 NSNFA + \beta_8 NDTS + e \quad (4)$$

Where -

SBBTE is the dependent variable where k is the entity and t is the time α_k is the unknown intercept for each entity k = 1, 2,…,n for n entities

β_1 is the coefficient for FSIZE and similarly β_2 to β_8 for other variables e_{kt} is the error term

We ran the same model for TDTE, BBTE, LBBTE and SBBTE dependent variables with CRISIS as an added dummy variable to incorporate the Financial Crisis of 2008 into our study of the Drugs and Pharmaceuticals industry. CRISIS takes the value 0 if year 2000 to 2007 and 1 if year 2008 to 2016.

Results and Discussion are provided in the next section.

RESULTS AND DISCUSSION

The results of the panel regression models are provided in four sub-sections.

Model 1 corresponds to regression carried out across the time series without incorporating CRISIS dummy variable.

Model 2 corresponds to regression carried out with dummy variable CRISIS to split the time series into pre and post 2008 financial crisis.

(a) Results: Total Debt to Total Equity As Dependent Variable

The results are presented in Table 4.

Table 4: Panel Regressions Results for TDTE

Variable	Coefficients (MODEL 1)	Coefficients (MODEL 2)
FSIZE	0.0652	-0.1757
NFATA	0.2236	0.1010
DEPTA	-16.3903	-19.5461
GROWTH	-0.0804	-0.0457
PROFIT	-16.9792*	-16.1138*
BVMV	0.9785***	0.9830***
NSNFA	0.0028	-0.0017
NDTS	10.5522	9.6622
CRISIS		0.5643
N	1762	1762
R^2	0.3057	0.3067

* p<0.05; ** p<0.01; *** p<0.001

From the model results, we find that Total Debt to Total Equity is affected negatively by profitability and positively by Market to Book Ratio. Crisis did not have an impact on the Total Debt to Equity Ratio of the pharmaceutical firms.

(b) Results: Bank Borrowings to Total Equity As Dependent Variable

The results are presented in Table 5.

We find thatt profitability has a negative impact on bank borrowing as well while market to book ratio has a positive impact. Another variable which becomes positively significant is the Non-debt tax shields. The crisis variable is positive and significant for this variable which implies that crisis had a positive impact on bank borrowings of drugs and pharmaceutical firms.

Table 5: Panel Regressions Results for BBTE

Variable	Coefficients (MODEL 1)	Coefficients (MODEL 2)
FSIZE	0.1228	-0.1264
NFATA	0.3616	0.3161
DEPTA	-11.0799	-14.6197
GROWTH	-0.0894	-0.0481
PROFIT	-16.9643**	-16.2079**
BVMV	0.6523***	0.6576***
NSNFA	0.0040	-0.0002
NDTS	12.6610*	11.8794*
CRISIS		0.5823*
N	1661	1661
R^2	0.2642	0.2661

* p<0.05; ** p<0.01; *** p<0.001

(c) Results : Long Term Bank Borrowings to Total Equity As Dependent Variable

The results are presented in Table 6.

We analysed the long term bank borrowings of the firms. From table 6, we can see that net fixed assets to total assets positively impact the long term bank borrowings to equity ratio of pharmaceutical firms along with market to book ratio. For this variable also, crisis had a positive impact.

Table 6: Panel Regressions Results for LBBTE

Variable	Coefficients (MODEL 1)	Coefficients (MODEL 2)
FSIZE	0.0160	-0.1468
NFATA	1.7644*	1.7080*
DEPTA	-7.8478	-9.9539
GROWTH	-0.0389	-0.0139
PROFIT	0.3663	0.6211
BVMV	0.4524***	0.4549***
NSNFA	0.0108	0.0069
NDTS	-2.1356	-2.4384
CRISIS		0.3822*
N	1146	1146
R^2	0.4621	0.4644

* p<0.05; ** p<0.01; *** p<0.001

(d) Results : Short Term Bank Borrowings to Total Equity As Dependent Variable

The results are presented in Table 7.

We find that profitability has a negative impact on short term borrowings ratio while market to book and non-debt tax shields have a positive impact. Crisis does not come significant when firms decide about short term financing.

Table 7: Panel Regressions Results for SBBTE

Variable	Coefficients (MODEL 1)	Coefficients (MODEL 2)
FSIZE	0.0341	0.0341
NFATA	-0.9896	-1.0074
DEPTA	-3.3229	-4.5525
GROWTH	-0.0419	-0.0279
PROFIT	-23.4351***	-23.1125***
BVMV	0.2452***	0.2471***
NSNFA	-0.0011	-0.0026
NDTS	20.3268***	19.9922***
CRISIS		0.2077
N	1604	1604
R^2	0.0862	0.0862

Legend: * p<0.05; ** p<0.01; *** p<0.001

The negative relationship between profitability and capital structure is supported by pecking order theory which suggests that cost of financing increases with information asymmetry. Hence, managers first prefer internal source of funding followed by debt and then equity. As managers possess more information than external investors, cost of financing through equity is higher as investors are at an informational disadvantage. This negative relationship between profitability and capital structure is seen in the study carried out on Iranian pharmaceutical firms[26]. Although further research is required to establish the applicability of pecking order theory in the pharmaceutical industry, managers in the pharmaceutical industry do possess classified information. Internal information pertaining to R&D, development of new drugs and impact due to change in regulatory norms and licence agreements may alter revenue streams and profits extensively.

Looking at the results, it is evident that for the period under study, drugs and pharmaceutical firms in our sample, had reduced total debt to total equity ratios after 2012. However, firms with low profitability tend to have higher total debt to equity ratios and these are also firms with high market to book ratios. We found

that CRISIS is significant for bank borrowings, implying that the financial crisis played a significant role in long term bank borrowing for firms in the industry over the time period since the crisis. In particular, we find that bank borrowings increased on an average post the crisis period. As debt is less expensive to raise than equity, firms may have found it prudent post the crisis to take on a debt servicing burden rather than a more risky proposition of issuing equity and not getting the required amount of capital.

Today, as the drugs and pharmaceutical industry undergoes rapid growth, companies may need to turn towards increasing equity issuance to cater to expanding foreign markets. Foreign equity investments are likely to increase as the government has now relaxed norms for FDI investments in the industry. Also, increased equity issuance over debt will reduce debt servicing costs and repayment obligations for firms. The pharmaceutical industry has seen several successful IPOs in recent times viz. Syngene International - the research arm of Biocon, Dr Lal PathLabs, Alkem Laboratories among others[27].

CONCLUSION

The paper finds that capital structure of the firms in the study are significantly affected by several factors viz. growth prospects, profitability, non-debt tax shields and Net Fixed Assets and firms converge towards similar capital structures within the industry in the long run. GROWTH is negatively correlated, PROFIT is negatively correlated, NDTS positively correlated, NFATA is positively correlated to capital structure of the firms.

The 2007- 08 Financial Crisis has significantly affected Long term bank borrowing of firms. CRISIS is positively correlated to the dependent variables. The regression results imply that equity issuance must have fallen post the 2008 crisis which can be reinforced with low Deal Count and Deal Value of IPOs in the market.

This paper studies firm specific factors that affect the capital structure decisions of companies in the Drugs and Pharmaceutical Industry. External factors like market interest rates, economic environment, and maturity of the industry, government regulations, and export contract covenants among others are other likely factors that would affect capital structure choices.

ANNEXURE

Definitions of variables used in the study:

TDTE = Total debt to total equity

BBTE = Bank borrowings to total equity

SBBTE = Short term bank borrowings to total equity

LBBTE = Long term bank borrowings to total equity

NFATA = Net fixed assets divided by total assets

DEPTA = Depreciation divided by total assets

GROWTH = Annual Growth rate of total assets

PROFIT = EBIT divided by total assets

BVMV = Market value of equity minus book value of equity, divided by book value

NSNFA = Nets sales divided by net fixed assets

NDTS = (EBT – TAX/CTR)/TA; Non-debt tax shields equals earnings before taxes minus the ratio of corporate taxes paid to corporate tax rate, all divided by total assets

FSIZE = Log of total assets

AGE = Current year minus year of incorporation of firm

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Study on Applicability and Benefits of EOQ Lot Order Based Cost Optimization in an Apex Tertiary Care Government Hospital in India

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ABSTRACT

Introduction: Benefits of Economic Order Quantity are established worldwide. In India, limited studies on EOQ have been conducted in hospital setup. This study aimed to calculate benefits of EOQ and its applicability for A-class and AV-category items in hospital.

Methods: A cross-sectional descriptive study was conducted in medical store of an apex tertiary care hospital in New Delhi, India. ABC analysis was conducted using EXCEL and AV-items identified based on expert opinion for consumptions and hospital formulary for FY 2013-14. Traditional method of costing was used to determine carrying costs, ordering costs and EOQ levels for A-class and AV-items. Benefits of EOQ in reducing costs tied in inventory and opportunity costs were calculated. **Results:** A, B and C class items were 12%, 16% and 72% of inventory and accounted for 71%, 20% and 9% of expenditure (335940604 INR), respectively. AV category drugs were 16 (3%). Adopting EOQ method can result in reductions of costs tied in inventory and opportunity costs up to 62% in various groups of inventory items.

Implication: Without using EOQ method, costs tied in inventory and lost opportunity costs are high, there can be significant reductions in these if EOQ technique is used. Applicability of EOQ must be contemplated with caution with its assumptions fulfilled as a pre-requisite.

Keywords: *ABC-VED, AV items, ordering cost, Carrying cost, EOQ, Opportunity costs*

INTRODUCTION

It is projected that Indian pharmaceuticals market will grow to USD 55 billion by 2020 and hospitals segment will grow to 25 per cent of market[1]. In hospitals, the objectives of stores management are uninterrupted supply of items for patient care at the right time in right quantities while keeping inventory related costs low[2].

In the hospital under study, the stores section is responsible for procuring, temporarily storing and dispensing all items required for patient care services. Hospital stores account for a large proportion of the material and supply budget. Lead time based lot order quantity and frequency are the basic inventory techniques followed. Accordingly, requirement for three months are orders. The reorder levels and the buffer/safety stocks do not exist. Studies on ABC-VED analysis have been done but there are limited studies on EOQ in hospital settings in India. ABC-VED matrix analysis offers the advantage of addressing criticality in addition to high expenditure items. This involves not only the investment in terms of direct costs like the actual inventory costs but also indirect costs. Since costs are sacrifices, to be an efficient system these needs to be minimized. A common problem is the paucity of space in the stores where corridors and passages are full of cartons of items. Studies have shown that EOQ technique emphasises the optimization of the lot order size so that the costs tied in inventory are minimized.

This study aimed at determining the financial advantage of using EOQ and its applicability in a government hospital set up.

INVENTORY METHODS

Originating from Pareto's 80-20 rule and conventionally based on 'Annual Consumption Value', Always Better Control or ABC analysis[3] is a basic starting point of materials management[4,5,6].

It builds a base for cost reduction and facilitated decisions, easy surveillance and financial control[7,8,9,10].

ABC-VED (Vital-Essential-Desirable) analysis is a combined inventory method addressing criticality in addition to annual expenditure[6,9,11].

COSTS

Ordering costs are associated with processing orders, receiving goods, building and maintenance cost, electricity, depreciation on equipment & furniture, postage, telegrams & telephone bills, stationery and other consumables, fees due to legal matters arising out of purchase and tendering costs[9,12,13].

Carrying / holding are expenses of maintaining average inventory for one year costs[9,12,14]. It also includes the less obvious and often difficult to measure costs like opportunity cost and risk costs like obsolescence, damage, shrink, taxes and insurance[13]. Stock out costs are incurred for procuring out-of-stock item at a non-discounted price, includes patient dissatisfaction, loss of business to competitor and lost goodwill[11,12]. Opportunity cost is interest that is foregone by allocating resources to inventory[15].

Lead Time is the interval between placing an order and receiving it[13,16].

METHODOLOGY

The study was conducted in the Medical and Crystalloid Store of the hospital and procurement office.

ABC Analysis & AV items: To identify ABC class, retrospective study of medical store issue data from the ledgers for financial year 2013-14 was conducted for all items for their consumptions and unit costs were compiled from rate contract agreements. Annual and cumulative costs were calculated using EXCEL spread sheet and ABC items were identified. Due to limitations of time and uncertainty of the applicability of EOQ model, only A and AV category were studied. List of A-class drugs& crystalloid items were presented to expert clinical faculty members for classification into Vital, Essential and Desirable supplies in the hospital. Items having 50% or more concurrence among the faculty for vital items were classified as Vital amongst A-class items.

Calculation of Ordering Costs: Since basic function of stores is to make available items required for patient care services, storage being a temporary activity, all costs related to ordering office, drug and crystalloid areas were assigned to costs involved in ordering. Traditional method of costing was used to calculate all costs. These costs included one year depreciated (1% depreciation with useful life of 100 years) costs of construction and maintenance of building, calculated using CPWD manuals and factoring the cost inflation index for the financial year in 2013-14), human resource, utility and risk costs. Land costs were not considered as it was a government property. Depreciation costs on capital items were calculated using straight line depreciation method. To arrive at the costs per order the total costs were divided by the number of orders placed in FY 2013-14.

Since tendering involved hospital administrators and committees like Stores Purchase Committee, negotiations committee, etc., human resource costs of the same were also factored in based on hourly involvement, their salaries and level of attendance in meetings (for committees only). Costs per hour were calculated taking 22 full 8 hours' working days, 4 half-days and 4-5 leaves on an average in a month. Numbers of working hours in a month were hence taken as 192 hours per month. The salaries were divided by the number of hours and hourly costs per human resource were calculated.

Electricity Costs for hours of operation and load were considered to arrive at the annual electricity (in Kilo Watt Hours) consumed and annual cost @ Rupees 7/-per KWH were arrived at.

For calculations regarding telephone bills, total of monthly bill (10 Lakh/m) including rental for 15 Primary Rate Interface (@ INR 5000/- per PRI) was divided by 3000 (no. of extensions).There was no legal case related to medical store during the period of study. For calculation of advertisement costs, payments made on actuals were considered. Utilities costs of housekeeping and security were also accounted in it.

As a tender was valid for 2 years, this was divided by the number of orders placed in 2 years for the drug and crystalloid store items and added to the ordering costs per order. Similarly, the costs for temporary storage in the drugs and crystalloids areas were divided by the number of orders placed for these items in 2013-14.

Sizes and frequencies of purchase orders (PO) were obtained from ledgers at stores and PO records from dealing clerical staff.

Carrying costs: Risk costs which include obsolescence, damage/deterioration or shrink was taken as zero as no records of any write offs were available and near expiry items were returned to the vendors and replacements taken with no extra costs. Only six items were found to be not consumed at all during the study period which was negligible. Since the costs of storage are fixed irrespective of variation in inventory levels, the opportunity costs for the annual inventory values were considered. Any reduction in the inventory levels will lead to an excess balance in the treasury. This bears an approximate interest at 8%, it was considered as the carrying cost. The stock out costs were difficult to estimate, hence excluded.

EOQ: EOQ was calculated based on results of carrying & ordering costs:

$$Q^* = \sqrt{2 \times o \times D/HC} \quad \text{(Equation no. 1)}$$

o = ordering cost per order

A = Annual consumption

H = Holding cost

C = Unit cost

The existing average inventory value was calculated by taking the sum of month end inventory levels divided by twelve. Differences and ratios of average inventory values, opportunity costs (alone and combined with ordering costs) were calculated for the various classes of items.

Fixed Order Quantity with Safety Stock Model: Since in our study, demand was variable to avoid stock outs, the reorder point was calculated using safety stock (SS) model by using formula:

$$ROP = đ\, L + SS \quad \text{(Equation no. 2)}$$

SS is determined by variation in demand and desired service level (probability of having an item on hand when needed or 100 % - Stock out risk).

$$SS = z \times \sigma L \quad \text{(Equation no. 3)}$$

σ = Standard deviation of demand

L = lead time

z-value = number of standard deviations above the mean (1.28, 1.65, 2.33 and 3.08 at service levels of 90%, 95%, 99% and 99.9%).

RESULTS & ANALYSIS

On ABC analysis, 68 A-Class (12%), 90 B-Class (16%) and 402 C-class (72%) items accounted for 71%, 20% and 9% of expenditure (table 1 and figure 1).

Table 1: ABC analysis of drugs and crystalloids

ABC	No of items	Annual Value	Percentage value	Percent no of items
A	68	237201070	71%	12%
B	90	67735638	20%	16%
C	402	31003895	09%	72%
	560	335940604	100%	100%

Source: Author analysis of study data

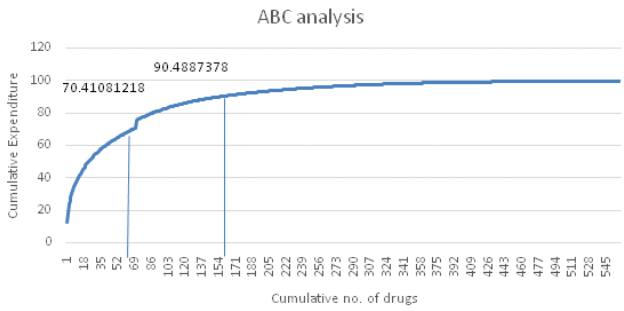


Fig. 1: ABC analysis cumulative graph

Ordering Costs (table 3): Total ordering cost for both drugs/crystalloids was found to be Rupees 6986/- per order (Table 2). Traditional costing for entire stores was done and divided by the number of total annual orders. For costs specific to the drugs and crystalloids areas, numbers of orders specific to these were accordingly taken as denominator.

Table 2: Ordering costs

Types of Costs	Crystalloid (96sqm)	Medical Store (222m²)	Office area (412 m²)
Building Construction cost1% of 100 years life @43825.43/- per m²	42072	97292	180560
Building Maintenance cost @ 100.61/- per m²	9658	22333	41450
Electricity cost @ Rs.7/-per KWH	136458	803754	330288
Telephone Bills @ 4200 per extension	4200	4200	12600
Stationery Cost	35000	100000	400000
Depreciation expense for capital items	25981	127469	213250
Advertisement Cost	NA	NA	1650000
Human Resource	2054000	2430792	7307880
Sub-total	2272369 (a)	3485840 (b)	10136028
		5758209 (a+b)	10136028
Total orders of drugs and crystalloids in the year	1371 (drugs & crystalloids)		4000 (overall items in store)
Cost per tender (drugs & crystalloids)	5758209/1371 = 4200 (c)		2534 (d)
Other HR costs in tender per order for drugs & crystalloids (meetings of committees)	691518/2742 (2 year purchase orders) = 252 per order		252 (e)
Cost per order			6986 (c) + (d) + (e)

Source: Author analysis of study data

EOQ levels: Appendix 1 shows the EOQs calculated for all the A-class

Table 3 shows the details related to the AV-items. The annual consumption, EOQ and average inventory levels can be seen before and after the EOQ lot order size calculations.

Table 3: EOQ-AV items

Name of the Molecules	Annual Consumption	Avg. Inventory level (units)	EOQ	Avg. Inventory level (units)
Paracetamol I.V. 1GMInj.	100796	10797	9934	4967
Human IV Gammaglobulins 5 gm 100 mlInj.	937	114	144	72
Cefoperazone 1gm + Sulbactam 1gmInj.	114550	42927	21109	10555
Meropenem 1gmInj.	19189	4560	3588	1794
Tigecycline Inj. 50mg	3254	484	631	315
Piperacillin 4gm.+Tazobactum 500mg. 4.5 gmInj.	55101	10134	10841	5420
Human rabies immunoglobulin 300IU/mlInj.	764	118	159	80
Amphotericin B Lipo 50mgInj.	1286	134	267	134
Glass Normal Saline (Sod. Chloride 0.9%) 500 ml	174751	3530	37204	18602
Teicoplanin 400mgInj.	7649	693	1641	820
Plastic Normal saline (Sod. Chloride 0.9%) (FFS) 500ml	211738	3548	48456	24228

Glass Normal saline (Sod. Chloride 0.9%) 100 ml	208166	9884	55851	27926
Imipenem 500mg + Cilastatin 500mgInj.	10759	2862	3038	1519
Voriconazole 200mgTab.	6554	1624	1874	937
Amoxycillin+Clavulanic Acid 1.2gInj.	44076	10660	13801	6901
Total parenteral nutrition solution 1850-2100 mlInj.	982	174	331	165

Source: Author analysis of study data

Cost reductions using basic EOQ model: The self-explanatory table 4 shows the comparisons and reductions in costs in various classes of items.

Table 4: Comparison of costs in various classes of items

Type		Average Inventory Value	Opportunity Cost	Opportunity Cost + Ordering Cost
A-class	**Existing**	55582769	4446622	5899710
	EOQ based	19855440	1588435	3176870
	n	53		
	p-value*	p = 0.05	p = 0.05	p < 0.05
	Diff	35727329	2858187	2722840
	US$	591316	47305	45065
	Ratio EOQ/ Existing	0.36	0.36	0.54
A-class crystalloids	**Existing**	1472165	117774	383242
	EOQ based	2179986	174399	348799
	n	6		
	p-value*	p > 0.05	p > 0.05	p > 0.05
	Diff	-707821	-56625	34443
	US$	-11715	-937	570
	Ratio EOQ/ Existing	1.48	1.48	0.91
A-class drugs	**Existing**	54110604	4328851	5516471
	EOQ based	17675456	1414038	2828071
	n	47		
	p-value*	p < 0.05	p < 0.05	p < 0.05
	Diff	36435148	2914813	2688400
	US$	603031	48243	44495
	Ratio EOQ/ Existing	0.33	0.33	0.51
AV-items	**Existing**	10904143	872331	1354365
	EOQ based	6805157	544413	1088826
	n	16		
	p-value*	p=0.0574	p=0.0574	p < 0.05
	Diff	4098986	327918	266539
	US$	67842	5427	4395
	Ratio EOQ/ Existing	0.62	0.62	0.8

Wilcox on rank-sum (Mann-Whitney) test applied

Source: Author analysis of study data

Lead time: Review of records for the year 2013-14 revealed that internal and external lead times were 22 days and 20 days, respectively.

Existing Reorder Points: An analysis of the existing reorder levels for AV items revealed that the reorders levels did not match the lead time requirements. For an estimated lead time of 42 days, the reorder levels would have lasted for only 26 days on an average and might have resulted in stock outs.

Table 5 shows the ratio of average inventory levels determined at different service levels based on reorder point using safety stock model of EOQ. Overall median ratio was calculated to be 2.6.

Table 5: Ratio of average inventory levels based on ROP determined using Safety Stock Model of EOQ

'z' value	Resulting Service Level	Ratio of New to Existing Average Inventory levels Median (Min-Max) n=16
1.28	90%	2.5 (0.8-20.6)
1.65	95%	2.6 (0.9-21.0)
2.33	99%	2.8 (0.9-21.8)
3.08	99.9%	2.8 (0.9-22.7)

Source: Author analysis of study data

DISCUSSION

An ABC analysis of different hospitals worldwide and in India (table 6) conducted over a period of time has shown that average items in A, B and C-class items are 12%, 17% and 71% which matches the findings of our study. The variation in per cent items in different classes in these studies is most likely due to differences in complexity and costs of medications based on case mix catered to. Per cent of AV category drugs (3%) in our study was also comparable to other studies except the ICU based study conducted by Basukala *et al* (2015) which again involved complex medications[17].

Table 6: Comparative table of the ABC classification in various studies

ABC	Our study	Dept. CM, Medical College in Delhi (T. Anand, 2013)18	Armed forces tertiary care hospital (Kumar S, Chakravarty A, 2015)19	Medical store of tertiary careneuropsychiatryhospital in Delhi (Khurana S., 2013)20	Hospital "X", Sukabumi, West Java, Indonesia (I.Junita, and R.K. Sari, 2012)21	Pharmacy store of PGIMER, Chandigarh (Devnani M. et al., 2010)22	Tertiary care hospital in Nagpur (Mahatme M.S., et al.,2012)23	ICU of a tertiary care hospital (Basukala et al, 2015)17	Mean %
A	12%	18.6%	6.77%	3.45%	7.74%	13.78%	14.55%	17%	12%
B	16%	24%	19.27%	6.9%	11.01%	21.85%	18.18%	20%	17%
C	72%	57.4%	73.95%	89.65%	81.25%	64.37%	67.27%	63%	71%
AV	3%		4%				3.64%	6.7%	

EOQ and its benefits: Inventory carrying fraction in our study was 8 % for the drug store. It was 15.18 % in a study in Khonkaen hospital, Thailand[24]. The carrying costs of drug store in refrigerator and drug store in room temperature was 1.25% and 1.20% of the average inventory value in a study in Ramathibodi Hospital in Thailand (Chuleeporn Laeiddee, 2010) although these have been found to be up to about 20% of the total amount invested in the inventory[11,14,25,26].

Van Der Linde, L. P. (1983) found ABC/EOQ inventory model led to a 46.5% reduction in standing inventory levels[27]. In the present study, statistically significant reductions in average inventory costs/ levels and opportunity costs to 36 %, 62 % and 33 % in A-class, AV-category and A-class drugs, respectively compared to the costs based on existing system. The A-class Crystalloids average inventory costs/levels and opportunity costs increased to 148% of existing costs which was statistically not significant.

Ballentine R, *et al.* (1976), found that most of the savings with the ABC-EOQ system occurred with the low dollar value items (B and C items) which were being purchased too frequently[28]. They demonstrated statistically significant mean annual savings of $4.13 +/- $0.36 (S.E.) in 10% sample of all items and statistically insignificant mean savings of $2.42 +/- $0.60 (S.E.) in a sample of 10% of the A items. In our study, combined opportunity and ordering costs were reduced to 54 %, 51% and 80% in A-class items, A-class drugs and AV-items, respectively and were statistically significant. In another study the overall cost savings were found to be 61%[29]. In our study, combined opportunity and ordering costs of A-class crystalloids were reduced to 90% but it was not statistically significant.

In our study, annual savings in terms of opportunity costs were 2858187/- INR (US$47305) and 327918/- INR (US$5427) for A-class and AV-category, respectively (Average $ value of rupees 60.42 in FY 2013-14). Sullivan, D.L. and Schommer, J.C., (1993) used EOQ model and found that potential yearly cost savings based on 8500 brand name stock-keeping units was $271,320 or $31.92 per product[30]. This was very similar to the findings of Vincent and Ranton (1984) with cost control for about $ 30.12 per annum from just one item-Ampicillin injection 250 mg from more than 800 of total drug items in the hospital using EOQ[31]. In our study cost savings were 53928/- INR or US$893 per A-class and 20495/- INR or US$339 in per AV-item.

CONCLUSION

The study classified the items into ABC classes and identified AV-class of items. The study concluded that there is a significant reduction in the costs if the EOQ model of inventory management is implemented for the A-class and AV-class of items. Although it appears that EOQ reduces the costs tied and opportunity costs, interpretation of these results must be done keeping in view the assumptions of the EOQ technique. In our study, it was found that the demand was variable and if firms are allowed the 45 days for delivery as per the terms of the tender, the total lead times become very long (at least 65 days). As EOQ lot quantity resulted in lowering the average inventory levels, in case the reorder points are not optimally determined to match the lead time requirements and adhered to (as found in our study), it may result in more frequent and prolonged stock outs with EOQ. Therefore, in this setting considering variable demands and long lead-times, a more complex EOQ based technique is required. EOQ with statistically determined reorder points and safety stock results in higher costs as calculated in our study. Further interventional studies aimed at reducing lead times first need to be done before the EOQ model can be adopted in our settings. Negotiations can be done with suppliers for frequent and small supplies and delivery on time can be ensured by measuring, monitoring and recognizing vendor performance. This may be incorporated in future tenders. Vendor managed inventory may also be studied. JIT inventory is already in place for the orthopaedic implants. Better communications in the supply chain can also lead to reduced inventory and duplicate safety stocks while maintaining the service levels. Costs can be decreased by improving forecasts accuracy and keeping it lower and variable.

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Equity Price Performance of the Pharmaceutical Industry- A Comparative Analysis of Select Global and Indian Companies Using Stock Market Indices

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ABSTRACT

Purpose: The purpose of this paper is to examine the equity price performance of selected Indian and multinational pharmaceutical companies operating in India.

Methodology: A quantitative analysis procedure was undertaken using stock market results and revenues details for the years 2011-16 for three Indian owned and three multinational pharmaceutical enterprises. The study concentrated on the using bench mark Bombay Stock exchange price fluctuations of pharmaceutical companies to understand their equity price performance.

Findings/Interpretation: The results indicate that over the past five years Indian companies have performed with high rate of financial returns compared to the MNE based companies. The multinational pharmaceutical companies in India hardly have any debt on their books of accounts because they do not have big research and development centers in India. They largely sell patented drugs at high margin niche market. This business model has in built cap on their funds requirements. The Indian pharmaceutical companies have large scale manufacturing capacities for Indian and export market. The level of activities involved requires the big amounts of funds. As Indian companies will start investing more funds in research and development to sustain them in the market, the debt equity ratio is further expected to increase.

Originality/Novelty: This paper analyses the three ratio to showcase the reason for better performance of share price of Indian pharmaceutical companies compared to multinational pharmaceutical companies.

Keywords: *Pharmaceutical industry, sustainability, stock markets, equity price performance, ESG*

INTRODUCTION

The Indian pharmaceutical sector is estimated to meet around 70 percent of the country's demand for bulk drugs, formulations, and injectable. In a liberalized economy the growth in the sector has surged with over 300 large units and about 8000-8500 small and medium enterprises involved in bulk drugs and specialized drug manufacturing[1]. Major government policies which have led to de-licensing of the Industry has meant that businesses have been able to develop products for the large Indian market with due approval of the drug control authority. Although, there are low costs of production and R&D costs, the financial performance of the industry has often been affected by various market, consumer and regulatory issues.

The stock market price performance is considered as barometer for the financial performance of a company. The current study is focusing on Indian and multinational pharmaceutical companies operating in India. The last couple of years have witnessed the patents of multi products have been lost. This has helped the generic drug maker companies of India. The revenue growth for Indian pharma companies should reflect in the profitability of these companies and the share price of these companies should also reflect this change. Does the theory stand true in the actual market? To answer that question analysis of share price movement of Indian pharmaceutical companies can be done compared with multinational pharmaceutical companies present in India. The comparison is based on the market capitalization of these companies reflected by the movement is stock price of these companies.

The early 1990s perhaps can be termed as a land mark decade in the history of mankind as it was the realization of some of the most important global environmental threats which were reviewed by the United Nations. It was also one of the decades when the entire issue of sustainability as a tool of corporate business practice became a reality with the involvement of major industry players, civil society, academic bodies, and the United Nations. In 1992, the United Nations meeting Rio de Janeiro, Brazil also popularly known as the Earth Summit (www.un.org) established three major International conventions namely:

- The Convention on Biological Diversity (CBD)
- The United Nations Framework Convention on Climate Change (UNFCCC)
- The United Nations Convention to combat Desertification (UNCCD)

The decades of the 1990's is perhaps the turning point in the history of governance, industry growth, sustainability and emerging business practices in India. The liberalization of the economy along with major global environmental actions and treaties saw the emergence of a new paradigm of sustainability as a broad concept from what existed earlier. While corporate philanthropy as a societal responsibility was a proven approach even several decades back, it was mostly restricted to CSR based local activities. The emergence of new global standards and models like CDP, GRI have seen a transformative change in corporate governance In recent times the advent of ESG as a disclosure benchmark, very few companies have seen the need to incorporate sustainability as a key factor in driving the industry's performance [2].

METHODOLOGY

– A quantitative analysis procedure was undertaken using stock market results and revenues details for the years 2011-16 for three Indian owned and three multinational pharmaceutical enterprises. Data was obtained from company websites, sustainability reports, equity based websites. The global reporting initiative[3], reporting framework was also used for data collection. The rationale behind selecting these companies was the performance of share price of these companies in last six years. The companies selected for the study were:

Indian pharmaceutical companies

- Alembic Pharmaceuticals Ltd.
- Natco Pharma Ltd.
- Ajanta Pharma Ltd.

Multinational pharmaceutical companies

- Abbott India Ltd.
- Pfizer Ltd.
- GlaxoSmithKline Pharmaceuticals Ltd.

RESULTS AND DISCUSSION

The equity price performance amongst pharmaceutical industry is largely a local phenomenon. Limited studies are available to analyze the financial performance of this industry which deal lt with in terms of Multivariate Discriminate analysis (MDA)[4] in Bangladesh, Dupont analysis[5] in India and other authors like Han et al, 2016 who have linked CSR to financial performance in Korea.

Equity performance: It has been observed that market capitalization of these companies grew at a rate which distinguishes them clearly between Indian and multinational pharmaceutical companies. The growth in market capitalization of Indian companies is way beyond to its peers. It has increased at an average rate of 2000%, whereas multinational companies' market capitalization growth has languished at an average of 200%. Table 1 shows the difference in the way Indian companies have performed versus multinational pharmaceutical companies.

Table 1: Comparison of Market Capitalization between companies

Company	Alembic	Natco Pharma	Ajanta Pharma	Abbott India	Pfizer Ltd	GlaxoSmithKline Pharmaceuticals
Market Capitalization	Rs. Cr	Rs. Cr	Rs. Cr	Rs. Cr	Rs. Cr	Rs. Cr
2010	909	375	212	1929	2856	19799
2017	11348	10209	15990	9874	8328	23142
Growth in % between 2010 and 2017	1147%	2620%	7409%	411%	327%	16%
Source: Bloomberg						

A look at Earnings per Share (EPS) can help in finding out the significant difference the change in market price and resultant change in the market capitalization.

Table 2: Earnings per Share of Multinational pharmaceutical companies

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Abbott India	55.06	56.66	64.81	75.32	93.39	107.75	122.26
Pfizer India	N.A	N.A	54.30	76.73	33.43	12.5	6.9
GlaxoSmithKline Pharmaceuticals	67.55	77.58	78.12	54.78	43.54	43.01	44.31

Source: Bloomberg

Table 3: Earnings per Share of Indian pharmaceutical companies

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Alembic Pharma	N.A	4.53	6.90	8.77	12.49	15.01	38.16
Natco Pharma	3.46	3.80	4.11	5.08	6.43	8.73	8.96
Ajanta Pharma	3.87	5.77	8.80	12.76	26.62	35.79	46.06

Source: Bloomberg

The EPS of Abbott has risen during 2010 to 2016, other two companies have shown declining trend in the EPS. The Indian companies have smaller EPS compared to their multinational peers but it is clearly on the rise. Among the analyzed companies Ajanta Pharma has shown the highest growth in EPS which has directly contributed in 7409% rise in the market capitalization. (Table 2 &3)

As it well known that Indian pharma companies focus on generic product development which has substantial market in India and the export potential of such products is immense the financial performance of these companies stand out compared to their global peers. The multinational pharmaceutical companies operating in India focus on high margin products with patents offer better margins.

The financial performance of a company can be analyzed through the DuPont analysis, which measures the return on Equity by considering the profitability, efficiency and financial leverage. These three ratios combined reveal the overall performance of the company. The financial performance indicators considered for this study are

1. Net profit margin (Profitability)
2. Assets Turnover ratio (Efficiency)
3. Debt Equity Ratio (Financial Leverage)

The comparison of these ratios should reflect the phenomenal growth in the share price of Indian pharmaceutical companies. Net Profit Margin is calculated by dividing net income by total sales of the company (Table 4&5)

Table 4: Net profit ratio of Multinational pharmaceutical companies

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Abbott India	5.88	8.08	8.97	9.13	0.00	10.00	9.88
Pfizer India	18.07	50.24	16.85	47.92	19.86	3.76	11.04
GlaxoSmithKline Pharmaceuticals	26.52	26.06	18.02	21.43	18.98	13.97	13.75

Source: Bloomberg

Table 5: Net profit ratio of Indian pharmaceutical companies

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Alembic Pharma	N.A	7.11	8.88	10.87	12.64	13.76	22.85
Natco Pharma	11.31	11.64	11.38	10.88	13.90	16.31	13.59
Ajanta Pharma	8.31	10.17	11.41	12.04	19.36	21.03	23.24

Source: Bloomberg

It can be clearly observed that the net profit margin of multinational pharmaceutical companies in India is decisively going down. On the other hand, the net profit margin of Indian pharmaceutical companies has been steadily growing.

The assets turnover ratio helps in understanding how efficiently is the company using its assets to generate revenue. The ratio is computed as sales revenue divided by total assets. (Table 6 &7)

Table 6: Assets turnover ratio of Multinational pharmaceutical companies

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Abbott India	2.29	2.41	1.89	1.74	1.99	1.82	1.75
Pfizer India	1.09	0.89	0.69	0.50	1.20	0.70	0.69
GlaxoSmithKline Pharmaceuticals	0.79	0.81	0.81	0.86	0.82	1.01	0.88

Source: Bloomberg

Table 7: Assets turnover ratio of Indian pharmaceutical companies

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Alembic Pharma	NA	NA	1.55	1.45	1.65	1.44	1.54
Natco Pharma	0.80	0.73	0.65	0.67	0.65	0.64	0.71
Ajanta Pharma	0.86	0.98	1.16	1.36	1.45	1.41	1.31

Source: Bloomberg

The assets turnover ratio is coming down in case of multinational pharmaceutical companies in India.

The debt equity ratio examines how much of external funding is required for the business. The higher the debt equity ratio higher is the requirement of funds for the business. Maturing business or low prospects business usually does not need more funds. (Table8 & 9)

Table 8: Debt Equity ratio of Multinational pharmaceutical companies

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Abbott India	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Pfizer India	0.00	0.00	0.00	—	0.00	—	0.13
GlaxoSmithKline Pharmaceuticals	0.00	0.25	0.23	0.21	—	0.17	0.14

Source: Bloomberg

Table 9: Debt Equity ratio of Indian pharmaceutical companies

	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Alembic Pharma	N.A	N.A	1.55	1.45	1.65	1.44	1.54
Natco Pharma	0.80	0.73	0.65	0.67	0.65	0.64	0.71
Ajanta Pharma	1.23	0.83	0.66	0.31	0.19	0.60	0.62

Source: Bloomberg

Sustainability performance: The performance of the pharmaceutical industry from a sustainability perspective is generally considered low with very little compliance toward formal environmental reporting standards like GRI, CDP etc[3,6]. In comparison to equity price performance for the six identified companies, it is interesting to note that the three multinational companies show very high standards of reporting and disclosures for environmental, social and economic dimension of their performance. In other words, the philosophy of triple bottom line is well entrenched in these companies through citizenship reporting, responsible business and product safety as well supplier social responsibility. Indian pharmaceutical companies selected in this study show no or little effort to report on sustainability as an integral part of their business and operations.

CONCLUSION

The multinational pharmaceutical companies in India hardly have any debt on their books of accounts because they do not have big research and development centers in India. They largely sell patented drugs at high margin niche market. This business model has in built cap on their funds requirements. The Indian pharmaceutical companies have large scale manufacturing capacities for Indian and export market. The level of activities involved requires the big amounts of funds. As Indian companies will start investing more funds in research and development to sustain them in the market, the debt equity ratio is further expected to increase.

The analysis of above three ratio showcase the reason for better performance of share price of Indian pharmaceutical companies compared to multinational pharmaceutical companies.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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The Relationship of Debt Management, Compulsive Buying Behavior and Financial Well-Being

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ABSTRACT

Purpose: Debt is an economic matter but its psychological aspect is not empirically tested in Indian context. The purpose of this paper is to examine the relationship of individual's attitude towards debt management financial well-being and the relationship of compulsive buying behavior with financial well-being.

Methodology: This research uses quantitative techniques to examine the relationship between individual's attitude towards debt management, compulsive buying behavior and financial well-being. This relationship was tested on a sample of 190 working professionals from age group of 22 – 60 years.

Results & Discussions: After applying suitable statistical tools, results indicated that higher the positive attitude towards debt, higher is the financial well-being. Compulsive buying behavior is negatively associated with financial well-being i.e individuals engaging in compulsive buying face financial distress. The respondents showed lack of awareness of the term "debt" and expressed their interest to increase their financial knowledge.

Research implications: The findings have empirical and applied implications. Empirically the study is an addition to the understanding of financial behavior. Psychological and economic aspects of one's daily life influences their attitude towards how they perceive financial stress vs well-being. Psychologists must focus more on how attitudinal aspects play an important role in an individual's financial and personal well-being.

Originality/value: The study highlights attitude towards debt management and compulsive buying as predictors to financial well-being. It is recommended in light of the findings mentioned above that it is important to create awareness of debt management and reduce the taboo that it is not a "bad" phase in your financial life; One must know how to manage debt.

Keywords: *Debt management, compulsive buying behavior, financial well-being*

INTRODUCTION

A crucial part of an individual's psychological well-being has been satisfaction with varied aspects of life[1, 2]. Financial situation is one such domain. Prior studies state that personal savings and personal debt are two main financial sources for individual households. The management of both these variables leads to effective financial management. With prior research undertaken in the area of personal saving, the concept of personal debt and how individuals perceive it has limited exposure. There are studies undertaken which correlate individual debt with psychological and social factors. However, these studies defined debt as involuntary inability to make and repay payments instead of credit use wherein postponement of payment is planned and agreed upon by the parties involved. Studies highlighted use of debt as a prosperity symbol and that households with higher income have a high rate of debt installments[3] stated than families with higher income have larger debt involvement rather than lower and middle income group families.

To explain the phenomenon of financial conditions of individuals and families, researchers have examined both objective and subjective measures. However, little agreement was arrived on which is the best measure for the construct. Objective measures like household income indicates the real financial condition rather than one's feeling of the situation. Objective indicators are used to predict individual's perception about financial well-being but these facets do not measure one's reaction or feeling

in depth. Researchers have also highlighted subjective measures can are a strongly used as a predictor for judgments about financial well-being. Few researchers examined subjective indicators like satisfaction with level of living and resources to predict one's perception of their well-being. Off the recent studies,[4] reported that subjective indicators like level of financial stress and tolerance to risk were related to financial well-being. Financial behavior is guided by attitude and personality. The options available to one, help them create their well-being. Two such predictors of financial behavior are attitude towards debt and compulsive buying behavior.

LITERATURE REVIEW

Compulsive buying is a psychological disorder which was studied and concluded that they may cause significant psychological, interpersonal & financial difficulties [5]. It was diagnosed that such features lead to a strong, irresistible impulse towards buying specially for personal use or consumer goods. Using Belk's (1985) three materialistic personality traits, studies found that "compulsive buyers were more jealous and non-generous". If a person is high on compulsive buying behavior, may show signs of low self-confidence and show compulsivity as an own trait and are more into imaginary world unlike other normal consumers. This behavior may lead to high debt, worry and defeat and a loss of wisdom. It's more of psychological and behavioral satisfaction which becomes the base for the compulsive buying rather than the economic benefit of buying goods.

To study the psychological and behavioral aspects of the compulsive buying behavior scales of [6] has been taken. Compulsive buying behavior is a widespread phenomenon. Compulsive buying behavior is also influenced by factors like gender, age, where women is much more affected by the compulsive buying than men. The difference of gender diminishes in youngsters. Although young consumers have more pronounced compulsive buying behavior[7].

In consumer oriented societies materialism expands the consumption levels and higher level of GDP, which gives an overall wellbeing to the society. Contrary to this studies also shows that consumers with high materialistic values endorses compulsive buying behavior. Supporting the statement consumers with high materialism are low on wellbeing. Research is also indicated individuals symbolically relate compulsive buying behavior with happiness and desire for material goods and motivated to buy and link this with compulsive buying.

The amount of money a person owns is directly related to the materialism. Also higher levels of materialism lead to higher level of financial stress [7]. It was found that materialism is a strong predictor of debt rather than income or money management skills. Opposing the fact [8] found out that financial cultural values like financial literacy are also the predictors of debt. [9] describes debt as "yesterday's spending taken from tomorrow's income" It has been seen that that if debt is under control than the consumers reasonably expects financial well-being to improve i.e. when they avoid paying late payments and are able to relocate income from making debt settlements to accumulate funds[10] after testing the model the variables personal characteristics, objective attributes, perceived attributes, and evaluated attributes measures the financial well-being[11] examines the effect of downturn or unemployment in the economy on the self-reported financial well-being (emotional sensitivity) of the individuals. Citizens of America reported severe drops in their life evaluation, severe rise in anxiety and strain, and drop in confidence.

Financially distressed shoppers often account low savings and high household debt. Financial distressed/ Financial well-being has been defined as judgments about and reactions to one's financial state [12]. There are subjective and objective measures of financial well-being, where former helps the researcher to examine the response towards the financial status of the consumer. Whereas the later takes into account the household debt, debt to income ratio etc. In another study [13] observed the effect of credit counseling and debt management made on the financial stressor events. Thus they found out the debt management counseling cuts the financial stressor events. Studies report that the individuals with higher financial well-being reported healthier health than those experiencing less financial well-being.

'Debt' implies an obligation that the borrower is either unable to discharge or is trying to avoid discharging, at least at the time when it should be discharged or he may be an unwilling donor unlike credit which means a willing donor. An unmanageable debt lead to the poverty and bankruptcy and there could be many causes and

consequence of such unmanageable debt are economic and psychological and one such psychological measure is attitude and psychological variables which differ from credit handling of the individuals. Current paper tries to test the relationship of attitude towards debt which acts as one of the variable of the debt with financial well-being. [14] had taken gender, age and religious affiliation as the contributing variables for attitude towards debt.

[15] captured to related attitude towards debt with the mental health a study done on the students. Although some denied the fact and found no relation between the stress level of students and debt. But later it has been seen that it's not debt which causes mental stress but the attitude towards the debt[8, A] study done on Brazilian – American women students, captured that interventions like financial knowledge help students to promote financial wellbeing and avoid debt.

A study on Australian workers found the factors of financial snags and discontent and the amount to which facing financial snags and discontent influence attitudes towards financial counseling. A Financial dissatisfied condition is derived by the money management and attitude towards the finances. Although there was no interrelation found between financial problems and dissatisfaction and attitude towards counselling for or handling finance[16].

[17] have found out geographical location did not acts as moderating affects for the financial attitude, although financial attitude and spending differ across the location. Study also revealed that higher financial achievement attitudes and power attitudes were associated with lower responsible spending behaviors. The study suggests that financial knowledge in a way targets particular financial attitudes specific to each different location[18]. The study done on the Canadian students investigated the relationship between anxiety sensitivity i.e. to spend in the moment with the compulsive buying. Study also reveals that females reported to have high anxiety while shopping but later they experience guilt (stress) relative to males while males report to experience stress about shopping.

To find the relation of the compulsive buying behavior or the attitude towards debt management on financial well-being literature provides studies which focusses on the students and their behavior. Thus a need felt to test these concepts on the working professionals.

OBJECTIVE OF THE STUDY

The aim of this research was firstly to test the relationship between attitude towards personal debt management and financial well-being. Secondly to test the relationship between compulsive buying behavior and financial well-being. Both the constructs were explored as predictors to financial well-being of an individual.

HYPOTHESES

The hypotheses proposed to be tested in the present study are:

H1: There is a positive relationship between attitude towards debt management and financial well-being

H2: There is a negative relationship between compulsive buying behavior and financial well-being.

METHODOLOGY

Sample: The target population for this research were working professionals working in private and public companies in Pune and Mumbai region. Table 1 represents a detailed description of the sample. Data was collected from total 191 working professionals (135males (70.68%), 56 females (29.31%)) from Pune and Mumbai region. The respondents for the study were selected randomly. The average age of respondents was 32.09 years ranging from 22 to 60. Of the sample, 120 respondents were graduates and 71 were post graduates. 59.68% of the respondents were married with 34.03% having their spouse also an earning member in the family while 27.22% of respondents did not have their spouse earning. 40.31% respondents were unmarried with making it not a applicable question for 38.74% of the sample. The personal income level of individual ranged from Less than 5 lakhs to Above 10 lakhs. Around 24.08% of the sample had an income less than 5 lakhs, 36.64% had a personal income ranging from 5lakhs-10lakhs and 39.26% had a personal income more than 10 lakhs. The total gross family income of respondents again ranged from less than 5 lakhs going upto 15 lakhs and above. While 7.85% of the sample had a family income less than 5 lakhs, 25.13% had a family income between 5-10lakhs and 41.36% of the respondents had a family income above 15lakhs. Total 250 questionnaires were distributed, 210 filled questionnaires were received out of which 19 responses were discarded due to missing data. The respondents were assured with anonymity of their responses. (refer table 1).

Table 1: Demographic details of the Sample

Variables	Frequency	%
Education		
· Graduate	120	62.82
· Post Graduate	71	37.17
Gender		
· Male	135	70.68
· Female	56	29.31
Marital Status		
Married	114	59.68
Unmarried	77	40.31
Spouse Earning	65	34.03
Yes	52	27.22
No	74	38.74
NA		
Personal Income		
Less than 5Lakhs	46	24.08
5Lakhs – 10Lakhs	70	36.64
Above 10 Lakhs	75	39.26
Family Income		
Less than 5Lakhs	15	7.85
5Lakhs – 10Lakh	48	25.13
10Lakhs – 15Lakhs	49	25.65
15Lakhs and above	79	41.36

Measures: The questionnaire was divided into three section. The first set of items were related to attitude towards debt management, second was related to compulsive buying and third was on financial well-being. Questions on demographic variables like age, gender, marital status, income, financial dependents were also seeked.

Attitude towards debt: The scale adopted for the study was developed by S.E.G Lea et al 1993. It was a 12 items scale to be answered on a 7 point Likert rating scale from "1" being Strongly Disagree and "7" being Strongly Agree. The questionnaire explored the general attitude of the respondents towards debt and debt management. The alpha value of the scale was .70, indicating an acceptable score for usability. Higher score represents positive attitude towards debt. Sample items include "I am careless with money" or "I do not like being in debt". There were five reverse key items in the scale.

Compulsive Buying Behavior (CBB): The scale adopted to measure CBB is an 11 item scale developed by D'Astous, Maltais, & Roberge, 1990. Internal consistency was high with α= .90. Responses were seeked on a 7-point rating scale ranging from "1" being Strongly Disagree and "7" being Strongly Agree. High scoring indicates greater tendency to compulsive behavior. Sample items include "I often have a real desire to go shopping and buy something.

Financial Well-being: The In Charge Financial Distress/ Financial Well-Being (IFDFW) is an eight-item scale developed by Prawitz et al 2006, indicating one's present state of financial distress/well-being. Items measured respondents current stage of being in financial distress with low level of financial well-being to high level of financial well-being with no distress. Sample items include questions like "How do you feel about your current financial situation?" There were four reverse key items in the scale. Initial scale was ten-point rating scale but in the present study the scale was modified. In the present study 7-point rating scale ranging from "1" being Strongly Disagree and "7" being Strongly Agree was used. The initial study reported α score of 0.956 and in the present study α was re-calculated and it reports to be 0.856 which showed high internal consistency of the scale.

Control variables: Demographic data was collected on factors like age, gender, total work experience, No of financial dependents, marital status was also collected. Respondents were asked to categorically respond to factors like Gender, Education, Annual personal income and family income was coded as categorical (Refer Annexure 1)

RESULTS AND DISCUSSION

Table 2 reports mean, SD and bi-variate correlations among all the studied variables. The results of correlation indicate significant positive relationship between attitude towards debt management and financial well-being (r=.398, p>.01). On the basis of the above finding, hypotheses 1 of the present study is accepted. Variables like work experience and personal income had significant effect on financial well-being of individuals. The more work experience and increase in income led to better financial confidence and less of financial stress. As the debt servicing ratio has reduced, individuals tend to borrow more[19]. This suggest that due to this phenomenon financial stress may is felt by some households. There are number of other factors like spouse earning in the family, No. of financial dependents which had a significant impact on debt management. It was found that multiple earning member in the family led to better debt management and financial well-being. The findings in previous researches showed that higher debt can be due to not managing money efficiently[14]. This study is one of the kind which measures individuals attitude towards debt and its association with financial well-being. It is an attempt to contribute to literature how working professionals in India feel about the term "Debt" and how that impacts their financial distress/ well-being.

Table 2: Descriptive Statistics and Correlations of variables

	Mean	SD	Work Exp	Edu	Gen	Marital	Spouse Earning	NoFD	Per Inc	Fam Inc	DM_ total	CB_total	FWB _total
Age	32.094	7.0875	.940**	.365**	-.010	-.589**	-.539**	.267**	.443**	.140	.195**	-.215**	.275**
Work Exp	9.387	6.5867		.282**	-.065	-.540**	-.476**	.292**	.460**	.150*	.160*	-.237**	.287**
Edu	2.414	.6421			.195**	-.247**	-.285**	.017	.170*	.137	.179*	.021	.130
Gen	1.293	.4564				.104	-.103	-.277**	-.197**	.031	.199**	.182*	.102
Marital	1.403	.4918					.857**	-.261**	-.431**	-.285**	-.048	.176*	-.155*
Spouse Earning	2.047	8540						-.058	-.333**	-.336**	-.086	.101	-.206**
NoFD	1.932	1.628 9							.266**	-.019	-.024	-.061	-.143*
Per Inc	2.335	1.0376								.689**	-.006	-.127	.285**
Fam Inc	3.005	.9921									-.021	-.070	.255**
DM_total	56.85	9.131										-.195**	.398**
CB_total	35.6283	13.11540											-.312**
FWB_total	36.5393	8.869 66											-

Notes: **Correlation is significant at the 0.01 level (two-tailed)

*Correlation is significant at the 0.05 level (two tailed)

It is also observed from table 2, that there is a significant negative relationship between compulsive buying behavior and financial well-being (r=-.312, p>.01). Higher the behavior for compulsive buying, lower is the financial well-being. The study measures that work experience was a strong predictor of compulsive buying behavior. Less years of experience, increased compulsive buying behavior leads to disturbance in the financial status of the individual. Dittmar, 2012 studied that mood and motives are likely predictors for individuals to engage in spending more money than they could afford. This study highlights that the association of compulsive buying behavior to financial well-being can be applied to research on debt (Refer table 2).

Table 3 reports the results of hierarchical regression where attitude towards debt management and compulsive buying behavior was treated as independent variable and financial well-being was the dependent variable of the study. All the demographic variables (Age, gender, total work experience) were treated as control variables. Results reported in Table 3 indicates that attitude towards debt management (β=.323, p>.01) significantly predicts financial well-being followed by significant role of compulsive buying behavior (β=-.211, p>.01).

Table 3: Hierarchical Regression Analysis of variables

Model	Step 1	Step 2
Age	-.015	-.120
WorkExp	.283	.257
Edu	.002	-.011
Gen	.078	.059
Marital	.084	.110
SpouseEarning	-.065	-.106
NoFD	-.235**	-.216**
PerInc	.207	.244**
FamInc	.067	.049
DM_total		.323**
CB_total		-.211**
R2	.195	.357
Adjusted R2	.155	.318
F value	4.88**	9.05**

DISCUSSION AND MANAGERIAL IMPLICATIONS

The study was aimed to test two objectives. First was to test the relationship between attitude towards personal

debt management and financial well-being. Secondly, to test the relationship between compulsive buying and financial well-being. Results obtained from the study suggests that individuals who have a positive attitude towards debt are likely to be sound with their financial well-being. Debt may include loans, credit cards, any other borrowing. Individuals who rated themselves low with debt management, witnessed financial stress. Results also suggested that individuals who engage in compulsive buying behavior are less likely to have a positive financial well-being. This depicts they are inversely related. In Indian context, debt is still considered as a risky proposition. As income increases, the capacity to be in debt increases. It was also found through the studies that individuals with income less than 5 Lakhs, had a negative attitude towards debt. Irrespective of the demographic variables, individuals engaged in compulsive buying, there was no pattern found.

It is recommended in light of the findings mentioned above, it is important to create awareness of debt management and reduce the taboo that it is not a "bad" phase in your financial life. Debt can be taken positively; one must only know how to manage it. The findings have empirical and applied implications. Empirically the study is an addition to the understanding of financial behavior. Psychological and economic aspects of one's daily life influences their attitude towards how they perceive financial stress vs well-being. Psychologists must focus more on how attitudinal aspects play an important role in an individual's financial and personal well-being. The findings of the study can be applied to financial consultancy, debt prevention measures, consumer consultancy, money management literacy more specific to the youth who are exposed to frequent materialistic objects which may add to their financial stress.

LIMITATIONS AND SCOPE FOR FUTURE RESEARCH

The study had certain limitations. The data was collected from working professionals based out of Mumbai and Pune. Hence the findings cannot be generalized. Future research can be undertaken on a larger sample size to confirm the relationship between variables of the study. The data was collected at a single given point of time future research could use longitudinal methods to broaden the understanding of the association between two different time periods. The study did not take into consideration what leads to compulsive buying behavior, is it materialism or personality factors. Future research can explore this area. How individuals manage their debt in response to their attitude of debt can also be a ripe area of research. In conclusion, individual's attitude towards debt can be witnessed by his money management skills and how aware he is about debt usage. The study highlighted attitude towards debt management and compulsive buying as predictors to financial well-being, however additional variables can be explored for future research.

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Effect of Community Level Communication on Community Participation in Public Health Research

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ABSTRACT

The term research in itself is a word that indicates continuous search for the betterment of humanity. Over a period of time research has evolved and has been providing answers to new questions. From a scientific standpoint, research is benefitting the academic community but translating this research into policy and practice is still a challenge faced in the domain of translational research. This gap is due to disconnect between the investigators, funders and decision makers as each has a different priority and perspective. For population health, it is the nonscientists usually outside the health professions who act as change agents to improving health behaviors, social and environmental conditions in the community. To bring about change in the society who are unaware about science, persuading such an audience is a task in itself. For promotion of population health, four elements play an important role. These elements are user needs based research, in depth knowledge on decision making environment, engagement of stakeholders and lastly strategic communication.

Keywords: *Community communication, Public health research, Research participants*

INTRODUCTION

The term research in itself is a word that indicates continuous search for the betterment of humanity. Over a period of time research has evolved and has been providing answers to new questions. From a scientific standpoint, research is benefitting the academic community but translating this research into policy and practice is still a challenge faced in the domain of translational research. This gap is due to disconnect between the investigators, funders and decision makers as each has a different priority and perspective. For population health, it is the nonscientists usually outside the health professions who act as change agents to improving health behaviors, social and environmental conditions in the community. To bring about change in the society who are unaware about science, persuading such an audience is a task in itself. For promotion of population health, four elements play an important role. These elements are user needs based research, in depth knowledge on decision making environment, engagement of stakeholders and lastly strategic communication[1]

Effective communication to uplift the population health is through interaction with the decision makers, stakeholders and the public itself. The primary communication channels for scientist are through journals and conferences which targets a small audience but this knowledge remains with the academicians and rarely disseminates to the general population which in turn keeps the knowledge cycle incomplete[1]

Knowledge, logical thinking, diversity in perspective and action along with acceptability to norms and suggestions are required to change attitude and behavior of the community for a better quality of life. Accepting norms and recommendations through knowledge and psychological adaptation is provoked by motivation. Hence motivation leads to active involvement and participation that develops a feeling of ownership that facilitates the change processes[2].

Education empowers individuals and communities by means of identifying and increasing their control over wide range of determinants of health. An imbalance in power relations and unfair structure can deter from achieving a positive social change, hence a balance is desirable. It is vital to know how health is conceived by the community in terms of cultural and social appropriateness while promoting health in order

to develop community capabilities. An understanding of potential barriers and opportunities in terms of community engagement is essential. The social, political and economic mechanisms by which health and literacy are influenced provides insights into the potential barriers and opportunities involved in community engagement that can help plan effective process [3].

In order to achieve effective and sustainable development, an integrated approach consisting of planning, implementation, monitoring and evaluation is essential. Integration involves coordination from the targeted audience, assimilation of values, cultures, approaches of organizations in the community and cooperation of the stakeholders for inter sectoral coordination. Organizations with an aim of integration disseminate its values to stakeholders and at the same time act to synergize efforts to improve health of the community. While intending to attain sustainable health promotion efforts, these cannot be achieved through force but is attained through a foundation based on mutual respect, trust and working in synergism to reach a common goal [2]

Researchers have the capability, position and power to make a difference in the population health by disseminating health issues and its solutions to the community through effective communication, capacity building, stakeholder involvement and community engagement. Community engagement being one of the most underrated mode of interaction is also an effective way to engage community in the research process. Appropriate communication informs, inspires and motivates individuals/ community thus widening the scope of application of communication in general for the health of the public and public health research[4]

Communication with the community for various purposes includes different modes ranging from traditional community meetings to technology based communication such as films and social media [5]. Every mode of communication has a different impact on the community in terms of understanding and participation in research activities.

Assessing the impact of communication would give insights on strategizing use of communication for community awareness and community participation in public health research.

Vadu Rural Health Program: Vadu Rural Health Program, KEMHRC Pune (VRHP) has been on a forefront of community health research since early 1970s with special focus on maternal and child health. The mission of the organization is to 'provide evidence-based, sustainable and rational health care solutions for the rural population using globally relevant community-based ethical research' thus emphasizing on the need of awareness and community participation in the research activities. The VRHP profile includes health programs and services accompanied by research focused on the community needs.

Vadu HDSS, a part of VRHP is an independent surveillance system initiated in 2002 that biannually monitors pregnancies, births, marriages, migrations, deaths and collects information on causes of deaths using verbal autopsies in a population that is currently 150000 residing in about 45000 households in 22 villages. The distribution of Vadu population in 2016 is shown in figure 1.

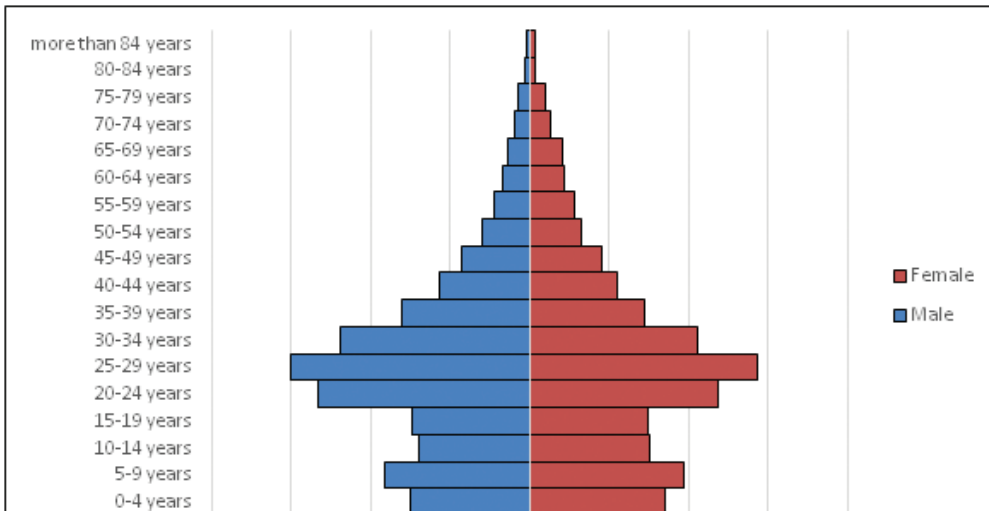


Fig 1: Vadu HDSS Population pyramid 2016

The population in Vadu has undergone significant transition in terms of socioeconomic status. The area around VRHP is rapidly industrializing thus resulting in in-migration of work force in the age group of 25-35 which is also indicated by the population pyramid. This transition of the area from rural to semi urbanized due to industrialization has also resulted in transition of socio economic status of the population. The comparison of information collected in 2004-5 and 2015-16 shows that the proportion of cultivators has reduced from 22.58% to 13.69% while that of agricultural landowners has decreased from 61% to 25% indicating reduction in proportion of people dependent on agriculture.

Moreover, the proportion of individuals working in small and medium scale industries has increased from 36% in 2004 to 44% in 2015. This indicates a trend in occupation, moving away from farming. The semi urbanization of this area is also indicated by the increase in use of flushed toilet facilities by 7% and increase in the use of electricity for lightening and other households by 11% in ten years. Additionally, proportion of households using LPG increased from 55% to 77.45% in last one decade. Urbanization in Vadu HDSS area is prominent owing to changes in occupation, and standard of living.

Changing trends and urbanization in Vadu is also applicable to the nearby areas as it represents many such areas. The changing population dynamics relates to the changing trends in the community and has seen a rapid change in the lifestyle of the population. This changing dynamics and trends eventually leads to access to variety of information through different modes. With varying and wide modes of communication available to the community, it is difficult to assess if the information and knowledge which reaches the community is correct and true. However, with all available communication resources, the community could easily be misdirected. These various modes of communication could also turn to be beneficial for knowledge distributions and spread of appropriate information.

With the rapid change in the mindset and lifestyle of the community, the research interest of the institution has also expanded from local needs to the globally relevant community requisites for healthy population. Research at Vadu in the late 80s was focused on maternal and child health with biomedical, epidemiological and social science research exploring low birth weight, child survival, maternal mortality, safe abortion, and domestic violence. The research portfolio has ever since expanded to include clinical research, disease burden studies, epidemiological surveys and social science research. Epidemiological studies conducted at Vadu have laid the foundation for a more evidence-based approach to resource allocation and to develop health promotion programs. It has also exemplified the feasibility of conducting non-communicable diseases risk factor surveillance in the low and middle-income settings by integrating it into existing HDSS data collection. As evident from the traditional practices of cooking, the scientists at Vadu have recently focused their research on Indoor air pollution and its effects through behavioral intervention approach. Social issues of adolescent girls, like sanitation practices and preparedness for marriage are addressed through qualitative research studies .Vadu's foray into large community based GCP compliant phase II/ III vaccine trials for meningitis, measles, typhoid and rota-virus are important contributions to national efforts in getting safe, highly efficacious yet affordable vaccines to licensure and use in India and globally.

Combining these two changes to successfully engage the population in the research arena needed special strategies. The community members who contribute as research assistants in VRHP are from local area. The FRAs' (field research assistants) working with VRHP are from the entire rural region. Due to this factor, it becomes very easy to implement a culturally appropriate recruitment strategy. Moreover, due to the surveillance system in place quite often, there is a sampling frame readily available for recruitment of participants in research studies in a scientific manner so as to ensure gender sensitivity and ethical balance in the sampling strategies. VRHP primarily engages the community in its research through the community based volunteers or field research assistants (FRA) by building their capacity to approach the community and conduct research. This strategy has been of prime importance when establishing trust of the participants in the research and community empowerment by providing employment and promoting further education of the FRA. Vadu Rural Health Program has been appointing field staff from the community ever since its inception. This environment boosts capacity building and sustainability. The FRA's from the community are in better position to explain and resolve queries of the community with regards to the research. This creates a strong bond between the research team and the community.

A recent analysis of self-reported progress among the local community staff members at VRHP shows drastic improvement in education and knowledge of the employees followed by the improvement in communication skills. This progress is also indicated by the contribution of many of our team members in local decision making and social activities in their respective work areas and villages of residence.

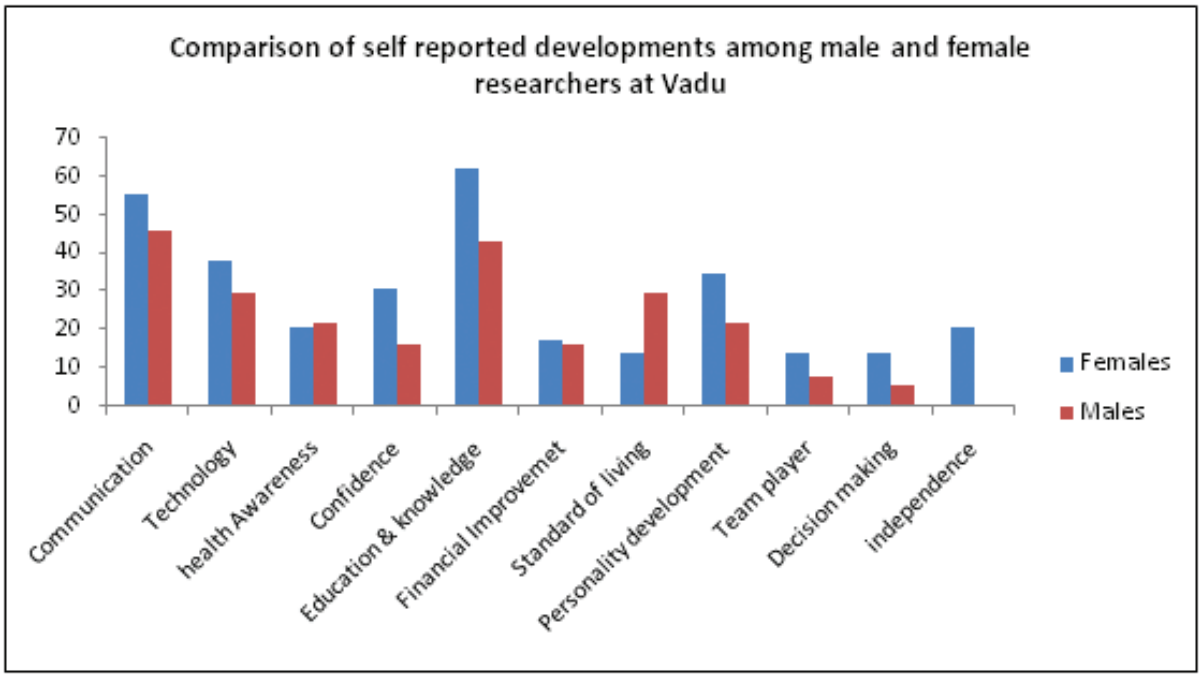


Fig. 2: Self reported developments of Vadu Researchers

The gradual progress of Vadu researchers in terms of education is shown in figure 3. Prior to joining Vadu Rural Health Program, approximately 46% of the FRAs' qualification was 12th standard while 29% had degree and 15 % had post-graduation degree. However, after being employed at VRHP, there is a gradual change in the educational level with 58% employees with a degree and 23 % with post-graduation degree as compared to the past. This highlights the change in outlook of the researchers with many understanding the value of education and VRHPs' motivation to bring about change in knowledge and promoting education for a better community and better research.

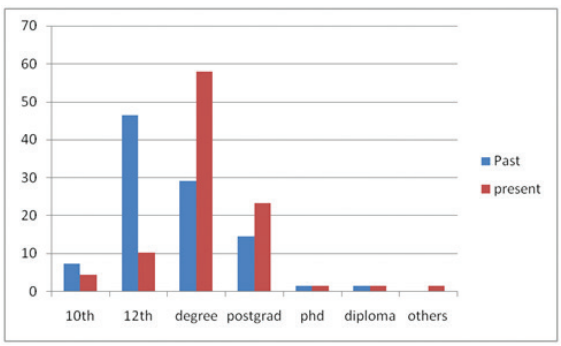


Fig. 3: Previous vs Current Educational status of Vadu Researchers

As literacy and employment is gradually improving among the Vadu populace and FRAs, it is slowly moving towards development of the community in terms of family welfare. With people taking education, it is more likely that parents will educate their children and hence lead to an overall growth of the family.

To attain highest quality of research that meets the national and international principles/guidelines at Vadu, community meetings are conducted by the study teams. These community meetings are conducted in consultation and cooperation with the local self-governments as also known as community decision makers. These meetings are conducted before the start of any study to provide information on the study and at the end of the study to disseminate the results of the study. These meetings are extremely useful to understand the community perspective towards research. These meetings also help the community to clarify their doubts about their contribution to research and access to healthcare facilities.

Questions related to ethical practices are also discussed to achieve highest level of mutual cooperation. This interaction in turn supports the research activities in

long run as it builds up trust and faith in the community. Moreover, encourages fearless and active participation of the community in future studies. This practice empowers the community in terms of knowledge regarding research and health. In case of vaccine trial research, the community is made aware of importance of vaccination, and vaccine preventable diseases. Due to which the immunization coverage in Vadu area is fairly high. The FRA's play a vital role as they also make the community aware of health centers in the area which also improves the access to health care in this region.

Vadu has been at the forefront to promote use of technology in research. With the help of IT department of Vadu, it has introduced tablets for collection of HDSS data in an effort to go paperless.

The FRAs are trained to use the tablets which serve as an example of comprehensive growth in terms of knowledge and capacity building. The community is aware of the work that the FRAs are doing; by sheer influence people are motivated to approach the centre for education and employment. Another development is the use of mobile technology for tracking the population to study their health care seeking behavior. This approach depicts multidimensional research using simple technologies. The Vadu team has conceived, and conceptualized the iShare initiative that enables research organizations to share their data on public domain. This initiative has put Vadu on the global map. This initiative is an example of reaching out to the public through scientific research. The need is to create scientific evidence that can be utilized for the up-liftment of the community. This is not restricted to only national level but also applies to the international level. Good research does not imply conducting only studies but a good application of those studies by the scientists and stakeholders.

Additionally, use of mobile technology for tracking population in studying their care seeking behavior has asserted the capacities of Vadu to conduct multi-dimensional research using simple technologies. Conceptualizing, conceiving and successful INDEPTH wide implementation of ***iSHARE-an initiative for enabling research organizations to share data in public domain*** (www.indepth-ishare.org) has helped Vadu to go global.

Recently, social media has made a great impact on the common people. It is useful means to spread messages, and scientific knowledge. Propelled by ground-breaking research, political unrest, and extreme natural disasters occurring worldwide, the popularity of the social media phenomenon is not waning - it is exploding. In short order, it has gone from functioning as a powerful influence over current events to a phenomenon that serves as a vital communications tool. To conclude not only are scientists utilizing social media to communicate their research, they must use this tool in structured fashion to reach maximum audience. The ability to communicate and dialogue with the masses via social media is critical to the distribution of scientific information amongst professionals, policymakers and the general population. Successful communication can only be achieved by employing the channels in which the general public is currently engaged.

In order to break the disconnect between scientific research findings and the community, KEMHRC Vadu has created a video which highlights the research conducted in Vadu and the value of participation of subjects from Vadu . This activity has shown a positive impact on research participation by the community. In the video clippings, the inception of Vadu Rural Health Program, projects conducted, advantages of the research to the community, facilities available at Vadu such as hospital facility, research Centre are shown. Moreover, the progress of FRAs'is shown in the form of how data is collected in HDSS rounds. Owing to this community approaches the Centre for employment and are willing to participate in research without hesitation. There is also a section in the video which asks the community members about their views and knowledge about the research conducted at the Centre. Importance of the research conducted is also depicted in the form of policy implications, immunization benefits to the community etc. With involvement of local self-governments, neighboring doctors and community engagement, KEMHRC has progressed in terms of supportive, ethical and equitable partnership with all sectors which ensures that encouraging recruitment is sustained in future as well. VRHP regularly conducts community meetings in the villages to interact with the population for understanding their perspective on research and update them about the research process and practices. A short film produced by VRHP and some documentaries are shown in community meetings for easy and effective communication with the population. The films are also circulated using electronic media such as WatsApp

KEM has been directly working with the government for effective implementation of many locally and nationally relevant public health programs. It is essential to translate research results into policy as well as conduct relevant research to answer questions posed by policymakers, hence, KEMHRC has always strived to communicate and interact with policy makers and support in whatever ways possible. KEMHRC has developed partnership with the state government health services for health care delivery in public health which has made it possible to conduct studies like Rotavirus vaccine study and management of PSBI. The PHCs and health work-force in the government setup have been trained such that the conduct of research studies is complementary to regular healthcare delivery.

CONCLUSION

Involving the local community as researchers itself is a technique of community communication which makes the community more informed about the way studies are conducted by Vadu (ethics, rights perspective in mind and dignity to the participants etc) which has often had a direct influence on participation in other studies by the population. Moreover, additional communication strategies such as video clippings and community meetings have helped in developing a rapport with the community. Encouraging local community researchers for further education and development of their skill has created a symbiotic environment of work at the centre.

The use of various communication modes in the community has resulted in engagement and continued support of population in various research studies. It has built capacities of volunteers and participants in terms of technology usage and knowledge. A mutual contribution to research in the form of community empowerment and participation would help in streamlining communication strategies.

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Source of funding: Self

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Developing A Family Version of the Cultural Formulation Interview

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ABSTRACT

Background: The Cultural Formulation Interview (CFI) in DSM-5 focuses on the cultural identity (CI) and illness explanatory models of individual patients. In India, clinicians frequently see patients with their family. A family version of the CFI is needed, especially in such family-centric societies like India.

Purpose: Plan development and testing of a family version of the CFI (CFI-F) based on the framework that has been validated internationally with a field site in Pune.

Approach: Review topical themes identified in the CFI Pune validation study and a follow-up study of cultural identity. Field-trial data of the CFI (n=36), and narratives of 460 clinic and community participants from study of cultural identity (CI) and its impact were reviewed. Experience from these studies guided development of proposed items and plans to validate the proposed CFI-F.

Results & discussion: The draft interview focuses on presenting problems of an index person in a family assessment, and it is designed to elicit consistent and divergent views among family members regarding illness explanatory models, cultural identity and the role of family in shaping problems, support and solutions.

Research implications: Experience with the CFI and study of cultural identity indicate the relevance of concepts of Hindu philosophy, changing cultural concepts of family and the influence of global values. The roles and responsibilities of various family members further explain their practical significance. This report presents the structure of the proposed CFI-F and plans for validating and using it for clinical care and community mental health.

Novelty/Originality: Symptom-based diagnostic assessment may fail to account for significant effects of cultural and family contexts that affect vulnerabilities and resilience to mental health problems. Development of the CFI-F provides a strategy that builds on achievements of the CFI by acknowledging the relevance of family relationships, which is particularly important in family-centric societies.

Keywords: *Cultural Formulation Interview, Family assessment, Cultural Identity, Cultural competence, Community mental health*

INTRODUCTION

Psychiatric medicine has evolved as a person-centred discipline to incorporate not only rigorous symptom based evaluation but also psychological and cultural evaluation. The primary focus of any cultural assessment is to elicit the individual's perception about their illness which is influenced by one's culture. However, standardized means for clinical evaluation of cultural aspects were not present before the Outline for Cultural Formulation (OCF) in the Diagnostic and Statistical Manual (DSM-IV). The OCF attempted to operationalize cultural assessment for clinical purpose. With further research and recommendation, the Cultural Formulation Interview (CFI) was incorporated in the fifth edition of the Diagnostic and Statistical Manual (DSM-5). Both the OCF and the CFI focus on the cultural identity (CI) and illness explanatory models (IEM) of individual patients.

The CI of an individual is operationalized as one's racial, ethnic or cultural background, language preferences, migration and other clinically relevant aspects which tend to impact the patient's distress. An IEM, on the other hand, elicits an individual's perception about one's illness with reference to name, cause, context, supports and help-seeking behaviour in past and present. The DSM-5 also provides supplementary modules for the CFI, which in addition to the core CFI help in venturing deeper into specific topics such as aspects of functioning, religion, social supports, modules for children and care-givers and even cultural identity.

Considering the importance of the relatives or informants as cause, context and support for any mental illness, a cultural assessment like the CFI cannot occur in isolation from assessment of the informants or relatives. Therefore, a special informant version of the core CFI has been published in the DSM-5 to help in eliciting CI and IEM of the patient's illness from the perspective of the informant. It has also been documented in the recent field study of the CFI that relatives provided highest ratings for the CFI in comparison to the patients and the clinicians[1]. However, the informant version does not aim to capture the complexities and dynamics involved among the family system in culture like India, where boundaries are enmeshed and roles are not defined clearly. Hence, we propose a new tool which could help in the cultural assessment of the family with reference to the CI and the IEM[2].

Therefore, the aim of the paper is to propose and plan the development of a method for testing a family version of the CFI (CFI-F) based on the framework that has been validated internationally with a field site in Pune.

METHODOLOGY

The proposed tool is developed from the review of identified topical themes in the CFI Pune validation study and a follow-up study with a new tool to assess cultural identity (CI-study). The samples reviewed consisted of 36 CFIs, and 460 narratives of clinic and community participants from the CI-study.

The CFI-field trial study involved debriefing interviews (including rating scales and narratives) with evaluation by the patients, accompanying relatives and the interviewing clinicians about the feasibility, acceptability and overall clinical utility after they were interviewed on the CFI[3].

The CI-Clinic-Community Study involved a semi-structured tool which elicited narratives and objectively recorded aspects of the CI in both clinic and community. For each factor of the CI, two objective measures were recorded: firstly, the way factor was reported - ***Spontaneous*** *(scored as 2),* ***Probed*** *(scored as 1),* or ***Denied*** *(scored as 0).* Secondly, the nature of impact that factor had over the person's life – ***Positive*** *(scored as +1),* ***Negative*** *(scored as -1),* and ***Both*** *(scored as 0)* or ***Neither*** *(scored as 0).*

Audio-recorded interviews from both the studies were made available on the MAXQDA software for qualitative analysis. MS Excel files for quantitative analysis were also prepared. For the CFI study, descriptive statistical analysis was computed, whereas for the CI-study there were two kinds of quantitative analyses were undertaken. Firstly, mean prominence for the way factor was reported was calculated and secondly, mean indicated the net impact was computed to understand the direction and intensity of the impact.

Experience from these studies guided development of proposed items and plans to validate the proposed CFI-F.

RESULTS

Brief review of the CFI-field trial study: The sample consists of 14 women and 22 males from varied socio-economic backgrounds. It can be seen that relatives gave higher ratings to the experience of the CFI in comparison to both the relatives and the clinicians.

Table 1: Feasibility, acceptability and utility showing the value of CFI rated by patients, clinician-interviews and relatives

Measures of value of CFI (mean)	Patients (DIP) n=36		Clinician interviews (DIC) n=36		Relatives (DIP-R) n=12		P value* MW test	P value† K-W test
	Mean	SD	Mean	SD	Mean	SD		
Feasibility	1.29	0.50	0.96	0.98	1.29	0.72	0.2998	0.4604
Acceptability	1.33	0.63	1.20	0.80	1.17	0.78	0.4989	0.7425
Clinical utility	1.26	0.51	1.01	0.84	1.08	0.85	0.1848	0.4354
Overall value	1.28	0.49	1.05	0.81	1.14	0.72	0.2500	0.5454
P value Friedman test	0.6186		0.0026		0.6095			

*Based on comparison of patient's and clinician interview's ratings only;
†Based on comparison of patient's, clinician interview's and relative's ratings. DIP – Debriefing interview of patient; DIC – Debriefing interview of clinician; DIP-R – Debriefing interview of patient's relative; CIF – Cultural formulation interview; MW test – Mann–Whitney test; K-W test – Kruskal-Wallis test

The qualitative narratives in both the content of the CFI and the debriefing interviews indicate importance of the family in both IEM and CI. Family is not restricted to the parents and siblings; it also extends to relatives. Also, the negative impact of the family is elaborated frequently and spontaneously, then the positive impact.

Consider the case of SJ, a 39 years-old *Sanyas* man who was distressed by ruminating thoughts and somatic complaints like digestion, acidity, and sticky stools. He explained cause, context and support of his problems sourced from family circumstances and sought help from the support of his wife.

> "My childhood was very sad. I was the only son. When I was in class 4 (about 10 years old), my parents got separated. My father had become an addict and so my mother left him. While my mother lived in the village at my uncle's home, I lived in a town with my other uncle. He was a political leader and a social worker. I spent my childhood working and I had no time to play. My aunt would treat me like an outsider, a pariah. Even if uncle gave me things, aunt would put a restriction on them. While today I use spirituality to deal with these memories, the thoughts still remain. To speak from a spiritual perspective, I must have done something in my last life time or this experience must be as a result of bad karma that I have to bear this psycho- physical stress… Since childhood there has been no relaxation for me. I had a lot of responsibilities like that of my three sisters' marriages, my own marriage, and of supporting my mother and maternal uncle. Due to this, I suffered from a lot of physical and mental exhaustion which is definitely a reason for my illness."

He speaks on the social support he received from his wife as follows,

> "My wife supported my renunciation in that she understood my problems and showed me the courage to live life alone. I renounced worldly pleasures at very young age and her (wife's) courage of being able to live alone, helped me."

Let's see another case of RK, a 46 year-old woman with bipolar disorder, who is heavily influenced by the dynamics at her in-laws and feels helpless even though they have physically shifted to another location. She explained,

> "Initially members of my husband's family were very abusive towards me… so much so that they would often hit me. That is one reason. They also speak with a sharp tongue. Now we live separately from my husband's family. But whenever I remember these things, I feel terrible and sad. I mean at that time, my mother's place was far away. She lived in Mumbai; no one from my side of the family would come and specially visit me. So it was only when I visited them that I would get to meet them. Basically because I endured and tolerated everything forever, I am

so troubled. I would just agree with anything anybody said, without voicing my views. Following these traditional (roodi) customs has led to my family troubling me. You know how society has a set of beliefs and customs… That no matter what, one has to endure and tolerate that which you are faced with; once you are married, it's done."

Brief review of the CI-Clinic-Community Study: Overall prominence for family as a feature of cultural identity was observed to be the highest amongst all 13 categories of the CI.

Table 2: Prominence of Family as a feature of CI in Clinic and Community

Setting	Type	Total	Percentage of responses		Prominence
			Spontaneous	Probe	
Clinic	Total	302	88.7%	9.9%	1.87
	Male	151	85. 4%	13.2%	1.84
	Female	151	92.1%	6.6%	1.91
Community	Total	163	57.7%	39.9%	1.55
	Male	83	51.8%	43.4%	1.47*
	Female	80	63.8%	36.3%	1.64

*For community males, the highest prominence was recorded for 'work as feature of CI', i.e. 1.72

As it can be observed, clinic and community participants tend to spontaneously identify family as part of their CI. The females in both the groups endured family as part of their identity more often than the males, more so amongst community participants. Also, community participants needed more probing than the clinic counterparts to acknowledge family as part of their CI.

Table 3: Net Impact of Family as a feature of CI in Clinic and Community

Setting	Type	N	Percentage of Responses				Net Impact
			Positive	Negative	Both	Neither	
Clinic	Total	302	49.7%	7.6%	41.7%	1%	0.42
	Male	151	54.3%	5.3%	38.4%	2%	0.49
	Female	151	45%	9.9%	45%	0	0.35
Community	Total	163	81%	1.6%	16.6%	1.2%	0.80
	Male	83	79.5%	1.2%	16.9%	2.4%	0.78
	Female	80	82.5%	1.3%	16.3%	0	0.81

The impact is perceived as less positive amongst the participants at clinic than the community participants. Community females had the highest net-positive impact of family on their lives as opposed to clinic females, who had the least net-positive impact of the family.

KJ, a 30 year-old married woman from the clinic, tried to explain the complexity about her parents and in-laws' family as part of her CI and wanting her children to not have a '*shadow'* of the same on their lives.

"(I have) no good memories from any family. I have only seen my parents fight and get separated. I was depressed when I got married to my husband. Even after knowing that he was already married, I married him because I wanted someone to take care of me. But that didn't happen. I did not get that satisfaction from him. Things started becoming very difficult for me but I tried adjusting where it didn't mean that I would spend all my life like that. I am 30 years old now, and I won't live the rest of my 30 years like this - sitting and crying on one side of the bed. I want to live a life and I want my children to live a life. Whatever I have gone through, I do not want my children to go through. This is the main reason that I've come here. I want to make my mind. I want to give them proper life and education. I want them to learn good

things. My eldest daughter is 11 years, second is 5 years and third is 4 years old…. But I am so frustrated with my fights with my husband that I happen to expel my anger on my daughters, which I do not want to do. I have come here because I want them and even myself to have a peaceful life. I regret getting married."

A young man from the community tried to make his focus of work as cultural identity and how providing for the family is only an outcome of his work-identity:

"I have a business, and my name is YN. I am into selling haar. Giving a particular introduction depends upon the person who asks us. Work is what I am linked to. I talk well with everybody. I do not create trouble or use bad words, etc. Family is important. What does one work for? One works for one's family. One should go home, look after children, what else is there?"

Brief Outline of the Family Version of the CFI: We propose that the draft interview will be a semi-structured one systematically assessing cultural factors influencing IEM with reference to the CI of each family member and relationship dynamics within the family. This interview is to be conducted with each family member of the patient. Following sub-sections can be conceptualized in the family version of the CFI:

1. Nature of relationship of the family member with the patient: Who is the family member? How are they associated?
2. Illness Explanatory Model: Perception of the family member about description, causes, contexts, supports, and help-seeking options in past and present.
3. Cultural Identity of the family member with reference to aspects of the identity helping the patient or creating a negative impact on them and vice versa.

An overall summary from all the family members shall elicit consistent and divergent views among family members regarding all the facets of the cultural formulation.

DISCUSSION

The dataset adequately highlights that patients and community participants are highly influenced by the family as a feature of their identity. However, the dataset also makes the earlier lacuna about enquiry into family dynamics and cultural identities clearer. For example, consider the case of KJ, manoeuvring through the spaces provided by both her families (which are a strong part of her CI). She is negotiating to create a desired personal identity in this space. In such a circumstance, it is necessary to analyse and interpret the cross-cutting CIs of the family members within the family members which are resulting in a 'distressed' KJ4. Therefore, restricting our inquiry into patients' and informants' perspectives of the IEM and CI through the CFI or CFI-Informant version is limiting the inquiry as compared to the information yielded from the family component of the CI.

The proposed family version of the CFI, would allow us to access the discourse, for example, of the wife of the Sanyasi man's about the relationship dynamics they shared, her own cultural identity and its impact on the patient and vice versa. These discourses of family members will bring together cauldron full of cultural and social factors to bring about a 'potion' explaining or situating the patient's distress. These explanations would be of key help in appropriately formulating patient- and family- centred treatment interventions[5].

In the long run, research data from such a tool will be able to highlight an intersectional view of the greater complexity of the Indian family in distress or around a locus of distress (patient), ergo, a cross-sectional social biography. This has great significance in India in building a family centric data point in cultural epidemiology for clinicians. 'While the focal point is, no doubt, the patient's distress and his/her perspective on it, this allows us to see how gender, caste, class, religion and social support interact as factors to create a particular subset of conditions around that distress. A result of this enquiry would be a wider local and national context to points of suffering.'

Any cultural formulation is highly mediated by the clinician's confluence of socio-cultural factors that affect their sense of self and their relationality/registry of those factors[6-7]. The idea that 'the best way to learn cooking is to cook' applies to the clinicians practicing cultural psychiatry and its assessment methods. It was experienced by the researchers in both the studies that greater sensitization to and awareness of certain social and cultural issues, for example, caste and gender discrimination, exclusion or bias, led to explorations

that yielded richer narratives in that domain, for that researcher[8]. Also, practice with the tool enhanced the clinician's experience with the participant and led to satisfaction. Therefore, we would recommend we involve a multi-disciplinary team encompassing clinicians (any professional who is in service to patients) who have the capacity to 'register' such nuances in the responses of the patient and their family members, when administering such methods and tools. Along with this, the clinicians should also possess qualities like sensitisation towards various socio-cultural factors, neutrality in 'excavating', critical thinking and reasoning, and varied life experience and an ethnographic approach. In short, the CFI-F promises to enhance cultural competence for practitioners as well as capacitate communities through relevant interventions.

RESEARCH IMPLICATIONS

The CFI-F has four major clinical and research implications:

1. Understanding the dynamics of the family and crosscutting influence of CIs of family members on the resultant distress and vice versa.
2. Designing a treatment plan
3. Generating empirical evidence on current and changing family-systems of India
4. Enhancing cultural competence

However, there are a few questions that need to be considered while developing the tool for clinical or research use:

1. Universal or selective use of the CFI-F
2. If the request to conduct family assessment is denied by a patient to protect confidentiality.
3. The role of the clinician in assimilating responses given by the participants is crucial.
4. The clinician's reflexivity is a crucial part of such assessments.

CONCLUSION

CFI-F has promising utility on both clinical and research front. Also, it has an academic value which promotes cultivating cultural competence and liaison with multiple disciplines to conduct and work with cultural assessments like the CFI-F.

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Comparing Family as A Feature of Cultural Identity in Clinic and Community Settings of Pune, India

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ABSTRACT

Background: Expression of cultural identity (CI) reflects personal and family values, which may have positive and/or negative associations. In clinical field trials of the Cultural Formulation Interview for DSM-5 (CFI) in Pune, respondents' difficulty understanding, and clinicians' difficulty assessing CI indicated need for improved assessment.

Purpose: Assess key features of CI and perceived positive and/or negative impact with a particular focus on the role of family, and compare accounts of CI among outpatient psychiatry patients and non-patient community residents.

Methodology: A semi-structured interview was used to examine 12 domains of CI. Prominence of each domain—ranging from 0 (not mentioned) to 2 (definite feature)—was analysed based on respondent accounts. Positive and negative impact of CI was also analysed. Thematic analysis was used for qualitative elaboration and comparison.

Results & discussion: Family was the most prominent domain of CI for clinic (n=302) and community (n=163) respondents. Themes of family identity focussed on the family name, respondent roles with reference to key relationships and responsibilities. Community respondents regarded the impact of the family more positively, though violence and deprivation were also acknowledged. Clinic patients had less positive views of family relationships, elaborated in accounts of criticism, neglect and exploitation.

Research implications: Family is the most prominent feature of CI, and in-depth assessment of CI helps both patients and community respondents understand and express features of cultural identity that are otherwise difficult to articulate spontaneously. Findings indicate that assessment and consideration of the role of CI and its impact are relevant for clinical care and for community mental health planning.

Novelty and Originality: Both assessing CI and considering implications for inking culturally competent clinical psychiatric services to culturally sensitive community mental health planning have been challenging goals. The approach to assessment and the clinic-community comparative design are unique contributions of this study.

Keywords: *Cultural Formulation Interview, Cultural Identity, Cultural Competence, Community Mental Health, Family Values*

INTRODUCTION

Cultural Identity (CI) and Illness Explanatory Models (IEM) are central to cultural assessments like the Cultural Formulation Interview (CFI). There is a lacuna of Cultural Epidemiological studies highlighting on patterns of CI in the general population and clinical population due to lack of objective tools[1].

Cultural Identity is conceptualized in the DSM-5 as an individual's racial, ethnic or cultural background, language preferences, migration and other clinically relevant aspects which tend to impact the patient's distress. Family plays an important part in the process of identity formation especially because they provide significant foundations for cultural impact[2]. Families also contribute significantly to pathology and support needed for recovery from it.

The qualitative findings from the clinical field trial of the Cultural Formulation Interview for the DSM-5 in Pune revealed difficulty of the patients in understanding questions on Cultural Identity. This motivated the next study to prepare a tool on cultural identity which is both qualitative and quantitative in nature. This study was carried out in both clinic and community settings.

The report will assess family as the key features of CI and perceived positive and/or negative impact, and compare accounts of CI among outpatient psychiatry patients and non-patient community residents.

METHODOLOGY

Two different sampling strategies were adopted for clinic and community to recruit participants between age group of 17 to 70 years of age. A consecutive sampling strategy was practiced in clinic to recruit patients, excluding patients in acute psychosis, intoxication, neurological and cognitive difficulties. A stratified random sampling was adopted in the community setting, wherein blocks of the community were randomly selected. A proportionate number of participants with reference to total sample desired were calculated for each block.

A semi-structured interview was used to elicit narratives which could be categorically coded as various dimensions of CI and quantified in terms of the spontaneity and the impact on life. The 12 domains of CI included family, profession, migration, religion, caste, affiliation with social groups, influence of political groups, being man or a woman, in-laws, art/literature, social status, being victimized and others if specified. Acknowledged features of the CI were coded as either reported spontaneously, probed or denied. Whereas, impact on life was coded as either positive, negative, both, or neither[3].

An XLS form was prepared for the interview schedule which was loaded into ODK-collect application an Android OS Tablet Computer. After the consent was obtained, the interview was audio-recorded and the form was filled on the application. The completed form was sent to a private and encrypted server. The server helped in downloading an excel file, which already had data entered according to the variables. After processing the raw-data file, two separate files were prepared for qualitative and quantitative analysis. Interviews were translated and filled in the qualitative analysis file. This file was imported into MAXQDA and analysed for deriving thematic content pertaining to each domain.

Prominence of each domain was calculated which ranged from 0 (not mentioned) to 2 (definite feature). A net impact was calculated which ranged from 0 to +/-2.

Results pertaining only to the domain of family are discussed here.

RESULTS

The clinic sample consisted of a total of 302 patients (50% of which were women), and the community sample consisted of 80 women and 83 men (total of 163 participants). The mean age of participants in the clinic was 37.44 years (SD 12.78) and in the community it was 33.21 years (SD 10.98). The most frequently encountered religion in both the setting is Hinduism; however, community setting has higher frequency of Muslim (30.7%) than in clinic setting (7.3%). Clinical setting had more open-category participants (77.8%) and community setting had more of SCs (30%). In both the settings, the most participants haven't secured education beyond high school. The income of the participants range only until Rs. 20, 000; whereas in the clinic, the range of income is beyond Res. 50, 000 as well. However, the maximum participants earn their personal income up till Rs. 5000 in both the settings; this is primarily due to

home-makers. However, participants in the clinic have also completed their university education. In clinic, the participants majorly belong to nuclear family type. In the community setting, there proportion of participants from both categories, nuclear and joint family, is similar (Joint family = 46.6%; Nuclear = 49.7%). The socio-demographics are summed up in table 1.

It can be noted from table 2 that in both the settings family has the highest prominence as a feature of one's CI. However, clinic participants report family as part of their CI more often than community participants. Also, community participants are more likely to report family as part of their CI when probed than the clinic participants. Overall, community men are less likely to report family as identity than rest of the participants. Also, community participants required more probing than the clinic participants to acknowledge family as a feature of CI.

The net impact of family (Table 3) is reported to be more positive amongst community participants than amongst clinic participants. Also, clinic females have the least positive impact of family on their lives and community females report to have the most positive impact. Very few participants (only males) in both the setting express to have no impact by their families on their lives.

Table 1: Socio-demographic characteristics of the sample in both Clinic and Community

Socio-demographic	Dimension	Clinic (302)		Community (163)	
		N	%	N	%
Marital Status	Married	176	58.3	103	63.2
	Never Married	87	28.8	48	29.4
Religion	Hindu	244	80.8	95	58.3
	Muslim	22	7.3	50	30.7
	Buddhist	16	5.3	14	8.6
	Christian	14	4.6	1	0.6
	Jain	4	1.3	0	0
	Other	2	0.7	1	0.6
	Undisclosed	0	0	2	1.2
Caste	OCs	185	61.3	38	23.3
	OBCs	60	19.9	25	15.3
	SCs	27	8.9	49	30.1
	Undisclosed	8	2.6	26	16.0
	STs	4	1.3	9	5.5
	Other	18	6.0	16	9.8
Language	Marathi	235	77.8	85	52.1
	Hindi	36	11.9	57	35.0
	Others	30	9.93	4	2.45
	Telugu	1	0.3	17	10.4
Education	Bachelors	136	45.0	20	12.3
	Secondary	68	22.5	73	44.8
	Masters	34	11.3	7	4.3
	Higher-secondary	29	9.6	25	15.3
	Diploma	10	3.3	1	0.6
	Primary	8	2.6	15	9.2
Personal Income	Up to 5000	159	52.6	86	52.8
	INR 5,001 to INR 10,000	32	10.6	97	59.5
	INR 10,001 to INR 20,000	29	9.6	11	6.7
	INR 20,001 to INR 30,000	25	8.3	0	0
	INR 30,001 to INR 40,000	15	5.0	0	0
	INR 40,001 to INR 50,000	10	3.3	0	0
	More than INR 50,001	19	6.3	1	0.6
	Cannot say/ NR	13	4.3	28	4.3

Family Type	Joint	82	27.2	76	46.6
	Nuclear	211	69.9	81	49.7
	Single Person Household	7	2.3	2	1.2

Table 2: Prominence of Family as a feature of CI in Clinic and Community

Setting	Type	Total	Percentage of responses		Prominence
			Spontaneous	Probe	
Clinic	Total	302	88.7%	9.9%	1.87
	Male	151	85. 4%	13.2%	1.84
	Female	151	92.1%	6.6%	1.91
Community	Total	163	57.7%	39.9%	1.55
	Male	83	51.8%	43.4%	1.47*
	Female	80	63.8%	36.3%	1.64

*For community males, the highest prominence was recorded for 'work as feature of CI', i.e. 1.72

Table 3: Net Impact of Family as a feature of CI in Clinic and Community

Setting	Type	N	Percentage of Responses				Net Impact
			Positive	Negative	Both	Neither	
Clinic	Total	302	49.7%	7.6%	41.7%	1%	0.42
	Male	151	54.3%	5.3%	38.4%	2%	0.49
	Female	151	45%	9.9%	45%	0	0.35
Community	Total	163	81%	1.6%	16.6%	1.2%	0.80
	Male	83	79.5%	1.2%	16.9%	2.4%	0.78
	Female	80	82.5%	1.3%	16.3%	0	0.81

Clinic males highlighted following aspects contributing to the negative family-identity included neglect, exclusion, and lack of support. However, positivity was reported regarding values imparted by family, status of family, responsibilities and support. Following are a few representative narratives:

> R: It is quite troublesome for me to identify with family. My father was an alcoholic and also a gambler. He would often lose money on gambling and on alcohol. So there were many problems. So I always felt bad. That part of my identity was awful... the fact that my father was an alcoholic and used to gamble and would cause ruckus... I never felt good about my parents.
>
> I: You always felt negatively about that, is it?
>
> R: Yes, always. I have not seen my father for last 15 years. He came when my uncle died. I saw him from over 50 feet. I don't want to see him. That much hatred is there inside me. When I was small he used to beat and torture me. He would threaten me with a knife as if he would kill me. – CLM001
>
> "My identity is related to my family and my parents as a 'good boy'. I follow the values they have taught. They like the way me and my brother behave... Mother said, ' If you are poor don't shy away and if you are rich don't drown in arrogance' Even my father always said, 'if you are hungry ask for food. Don't steal' I always keep that in mind. – CLM047

Women in clinic mostly expressed by relations they have in the family, for example, 'I am a wife', 'I have husband', etc. They also emphasize value of *samskara* inculcated by the family. These women seem to be juggling their family identity between their parents and in-laws. There is very less integration between their two families. Following are a few representative narratives:

> "I am NS so and so's daughter… so and so's wife… VP's mother… I attend a spiritual organization and I am the head of a savings-

group … When I got married I came to a conservative family that is why I could not do a lot of things plus I was the eldest daughter in law and I had to take responsibility of everything. At that time I needed my husband's support that I could not get. My cousin mother in law didn't behave well with me … I had a premature baby first time and the doctor literally saved me… because family was conservative, they did not have much knowledge and they didn't even know my blood group…" - CLF037

How will you introduce-(did not understand easily) I'm married, I have kids. What else? I have a home; I work there, where else can I go? There is nothing else to know about me. I have nothing else. One factor is because I got married to him (her husband). My kids make up my identity as well- I am their mother. Only mother was at home and dad used to be out working. My siblings were also younger to me. There was no scope to think in the house. Just went to school and came back. Do not remember much from before marriage. 2 years after marriage, gave birth to Autistic child- so could never go out. So he is my identity and I'm his. – CLF042

Community males reported aspects of family such as taking family responsibilities, values of family, status of family and mutual support. Marriage is reported to have positive impact on family as part of identity, especially with regard to responsibility. The negative influence of the family identity was elaborated as lack of resources for growth and fights within the family. A few representative narratives are elicited below:

"Of course, the status of one's family determines our identity. My parents and my friend circle have made an impact on me. Before marriage, I was not so serious. But after marriage, one tends to become serious." – CMM025

"Family had both positive and negative impacts. There are two sides to the coin. The family atmosphere was not good. Father was alcoholic would come home and beat mother, so that has had a negative impact. My brother was studying so he used to guide me well. So, that was a positive impact." – CMM034

"I have been living here since last 25 years. My parents migrated here. Parents worked as laborers, so i could not study. My children are studying but I could not. Our community is still lagging behind in development. So i am still doing this centering work. My parents came here to the city. So at least my children will study well." – CMM035

"My grandfather was educated and so was my father. My grandfather was much into social work. And I have imbibed many of his habits. I like studying and am interested in education. The benefits are many, I got higher education. And off course there are some negative experiences." – CMM053

"Yes, part of my identity. Whatever I am and my mental makeup is like this right from my childhood. If I want something or if I want to do something then no one can stop me. I am determined to get that. Since childhood, I have seen these clashes/fights between neighbours and I used to hate those scenes. So I decided that I must study and prove to them that we can also study and we can also earn good income. So I had decided this. We were brought up in a family where people would come and meet my parents, drop in for a chat. So I also became like that. I like to participate in social events, gatherings and am accommodative. I am social by nature" – CMM054

In community, the women identify with family as their identity as they have no work-identity to them, which is given higher status in their community. Also, relationships they live are seen as a major part of family-identity. There is also confusion at times when women see family-identity sourced from both their parent's family and in-laws family. Women find positive aspect of their identity when they fulfill roles and responsibilities of their family, and negative impact is elaborated when there is lack of support and fights within the family. Following are the representative narratives:

"We stay in this house. I am the elder daughter-in-law of GD family. Now I cannot speak of my father's house since I am married." – CMD001

"Name, I am "his (YH's) wife" and "their (LS's) Daughter-In-law. If I will work in something, that will also be a part of my identity. I am at home, so I have no identity of my own. Right now, I am only known by my husband's name

and by my Father-in-law and Mother-in-law's name. If I work, I will have some identity. I have a small kid. He does his mischief. I think that my son should be in a good environment so that he learns something. Then he will gain knowledge, he will study nicely. There is no good education in this area. My husband has not taken me out so I do not know about the other areas in Pune. But my son's brain is very powerful. His grasping power is great. He catches everything any language quickly. Now questions that you are asking me, if he would have been here he would have taken them? That's why I asked him to leave right now- otherwise he would start thinking and sit with it." – CMF024

"One exists because of the family. Our family got its roots because of our father in law. Elder people have to give their backing. Because of his name, people know us" – CMF045

"If you satisfy everyone at home, then there is satisfaction… If you fight, then there are fights… We should understand... Then everything will be good…" – CMF026

"100% part of identity. See, there are clashes, fights. But for the sake of our parents or children we have to handle these issues." – CMF074

DISCUSSION

Participants acknowledge the role of family as a feature of their CI prominently. The thematic content differentiates the narratives from the community and gender.

The distress from family is reported higher amongst the clinic than in community. This could be accounted by the approach into the settings. The patients came in the clinic with distress and hence the narratives could be skewed towards negative impact. The researchers approached the participants in the community, which would have led to defensive and positive responses[4].

Considering gender differences in the discourse of family as identity, there is a shadow of patriarchy in identity narratives of both the genders. The women in both community and clinic define family as primary source of their identity. They seem to have been groomed to believe and live a defined set of roles, that of 'wife', 'mother', 'sister', etc. However the impact of family differs among the community and the clinic. Though both of them source their support from the intangible 'values', the community females are able to also reinforce the sense of their identity by satisfaction derived from fulfilling their assigned duties[5]. However, the clinic females show resistance to such defined and groomed roles and they aspire for a change for their upcoming generations. Therefore, distress is breeding change and no-distress is reinforcing on-going structures[6].

The men also define their identity in form of the gender-enforced structures of being a provider to the family and sourcing their sense of self from the outside. Therefore, they seldom face negativity related to the family, especially amongst the community males[7]. Also, the clinic males talk about negative impact their family dynamics had on them during their childhood which is impacting them even in their current life.

The results have implication both clinically and in research. Clinically, the results indicate importance of also considering other avenues a patient for treatment plan or providing spaces to explore as a community mental health program. Also, considering special tool, which would probably assess family in greater detail would be necessary. From research point of view, a data like such would help in commenting changing and shifting social structures.

CONCLUSION

Exploring and studying the family as a prominent feature of CI has significant impact over distress and help sought, especially with reference to its differential impact on gender and setting. Not only does this impact influence treatment plan for an individual, it also impacts policy making for community mental health and a greater discourse of family systems of India.

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Rights of Children in Surrogacy and ART: Debating Challenges to Healthcare Justice

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ABSTRACT

Purpose: The authors propose to highlight here only those legal issues which may arise in determining parenthood of the child born to a surrogate through surrogacy arrangement.

Methodology: It will be predominantly doctrinal with primary data from various legal texts

Results, Implication and discussion: Authors will discuss assisted reproductive technology and types of surrogacy, issues arising out of surrogacy arrangement as regards determination of parenthood and legitimacy of the child born out of surrogacy arrangement. Drawing on Sen and Nussbaum's theory of justice as capability in *Frontiers of Justice* and John Rawls' justice as fairness, the authors would dwell on how the legislations of various countries have tackled the problem of determining the parenthood of the child born out of surrogacy arrangement. Further, the authors discuss the personal laws prevailing in India and the status of the child born to a surrogate along with judicial pronouncements of different courts of India and other countries. In India, the Assisted Reproductive Technology Bill, 2010, the current Surrogacy Bill are still a topic of discussion.

Novelty: The authors will critically evaluate these approaches and recommend reforms.

Keywords: *ART, Surrogacy, children's rights, determining parenthood, healthcare justice*

INTRODUCTION

Every human being has an urge to have a child. This urge, however, has been cursed by infertility. Today, modern science has equipped human beings with Assisted Reproductive Technology (ART) of reproduction for fulfilling their desire for children. ART has become a viable alternative for many infertile couples longing for children[1]. ART refers all techniques that attempt to obtain a pregnancy by handling or manipulating the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive tract of a woman[2]. There are many methods of ART. Surrogacy is one of them.

Surrogacy is an arrangement in which "a woman agrees to a pregnancy achieved through assisted reproductive technology in which neither of the gametes belongs to her or her husband, with the intention to carry it and hand over the child to the commissioning coupe for whom she is acting as a surrogate[3]. A surrogate mother is a woman who agrees to rent her womb to carry the pregnancy and deliver the child to the commissioning couple with whom she has entered into an agreement.

Surrogacy may be traditional or gestational. In traditional surrogacy, surrogate's own eggs are fertilized via AI and the surrogate mother is genetically related to the child. In gestational surrogacy, an egg of another woman is fertilized with sperm outside of the body to create an embryo, and then that embryo is implanted in a surrogate to carry the pregnancy.

What are the facets of healthcare justice? A survey of relevant literature shows predominant debates around the ideas and issues of universal access to health care, constitutionality of such access and the assurance of the government of such access to a reasonable array of health care services. Scholars argue that healthcare is identified as requirement of social justice while social justice itself 'is baked in different ways to serve different cakes'[4]. Such facets include, a. John Rawls' approach of

protecting opportunity applied to therapeutic healthcare, to infuse normal parenting capability and to treat it as fairness with claim to equal treatment. b. Dworkin's idea of treating people as equals in a context of equality of resources. c. Preventing any kind of harm by informing and facilitating choices. d. Nussbaum and Sen's ideas of justice to enhance dignity and ten central human capabilities.

Surrogacy and ART with the potential to heal childless parents, also raise legal challenges for the child. The ART science is galloping ahead where law is lagging behind. This has created a legal vacuum where the prevalent laws which were enacted long back do not address the challenges raised by the use of technology. This has created legal vacuum or uncertainty. Under such circumstances the state must protect the rights and interests of the surrogates and the children born through ART. In such cases, access to equality and access to justice, according to Rawls, are facets of justice as fairness. These cannot be limited to selective access to healthcare justice. Parents make the choice as healthcare seekers to enhance their quality of life and the wonders of health science facilitate such choices.

Thus, surrogacy involves the issue of health care justice for both surrogates and the children born out of surrogacy. Health includes the people's ability to live a life they value[5]. Ability to lead the life that one values improves one's mental health and well-being[4]. Conversely, the ability to make unhealthy choices can degrade one's health status[4]. As stated already, health care justice involves the issues of social justice[5-6]. Justice, according to Amartya Sen is about providing opportunities for people to develop and fulfil their own capabilities[7]. For Sen, people have freedom to determine their choices. Hence surrogate mothers cannot be prevented from pursuing their choices. However, their bargaining power in the surrogacy process needs to be enhanced with effective legal and institutional changes[4].

Issues related to healthcare justice arising out of the use of surrogacy for assisted reproduction in respect of surrogates: Different jurisdictions deal with the issue of surrogacy differently. Some jurisdictions allow only altruistic surrogacy while in some jurisdictions any kind of surrogacy is illegal[8-9]. Some jurisdictions allow even commercial surrogacy[10]. In some countries the surrogacy arrangement must be pre-approved[11]. In some countries parental orders have to be taken post birth[12].

In India where thousands of women die each year during pregnancy and childbirth, the practice of surrogacy often reflects blatant exploitation of vulnerable women, who are available for a fraction of cost charged by Western surrogates in countries where commercial surrogacy is permitted[13]. The evidence generated by journalists suggests that there is little evidence that Indian surrogate's human rights and physical and psychological health is adequately protected[4]. A surrogate may have to move away from home during the period of pregnancy. Uprooting a surrogate from her family and children during pregnancy may adversely affect her psychological health. In a research conducted by Centre for Social Research (CSR) 47% of the total respondents in Delhi and 41% of the total respondents from Mumbai experienced fear and anticipation before pregnancy on account of artificial procedure and because they had to stay away from their families for nine months[14]. Anecdotal evidence indicates that at least some surrogates suffer from post partum depression and a sense of emptiness as a result of being unable to breast feed their baby[15]. The bio-ethicists are concerned that Indian surrogates are being badly paid and working as surrogates in a country with a comparatively high maternal mortality rate[16]. In the research of CSR, 29% of the total respondents in Mumbai and 26% of the respondents in Delhi said that they have experienced some emotional difficulties, 23% experienced physical difficulties, 33.33% of the total respondents in Mumbai experienced some physical difficulties due to c-sections deliveries during surrogacy arrangements. Though the clinics/doctors/centres/agencies promised that they would help the surrogate mother if she faces any physical difficulties for lifelong with free health check-ups, in reality this is absent[17].

The surrogate is required to give the custody of the child born to her as a result of surrogacy agreement to the intending parents as well as to relinquish the parental rights over the said child upon birth. In surrogacy, the child is effectively handed over to the intended parents at or shortly after birth. The main reason behind hastening the process of taking the custody of the child from surrogate mother may be to avoid the emotional involvement of the surrogate mother with the child and the resulting custody disputes. In this hurried process of taking the custody of the newborn child, an important need of the surrogate as well as the child is overlooked, viz., the necessity of giving and taking the breast milk

by the surrogate mother and the child respectively. The newborn surrogate child is denied invaluable breast milk of her birth mother i.e. surrogate mother in the process of removing the child from her custody. For the first few months of a child's life the best possible protection which any mother can provide for the baby's normal health and growth is exclusive breast feeding[18]. Breast milk contains at least six anti-infective agents against some of the most common illnesses of infancy. It is also the most nutritious and hygienic food which any child can be given[4]. In the research of CSR, 86% of the total respondents in Delhi and 94% of the total respondents from Mumbai replied that the baby was immediately handed over to the commissioning parents which mean baby didn't stay with the surrogate mother at all[19].

Legal issues in respect of children born out of surrogacy: The uncertain legal status of the child created via IVF and surrogacy raises other legal, ethical, human rights concerns. One such concern is contraction of HIV by the pregnant surrogates. Potential surrogates are tested for HIV before the transfer of an embryo; however, if a surrogate were to be infected mid-term, it raises the possibility that the child may be abandoned, leading to host of other issues.

The uncertain legal status of children born as a result of a surrogacy arrangement is illustrated by the case of Manji Yamada. Manji was born to an Indian surrogate engaged by Japanese commissioning couple. However, before Manji was born the couple was separated and divorced and neither the commissioning mother, surrogate mother nor the egg donor wanted her. The Japanese genetic father was not allowed to return to Japan with her because under the Indian law he was not recognised as child's father. The authorities refused to issue a birth certificate for Manji. Eventually after a considerable media attention, Manji's grandmother was permitted to take her to Japan[20].

Before the advent of ART there was no problem in identifying the parents of the child. The woman who gave birth to the child was the mother and her husband was easily identifiable as the father. When a surrogate is engaged it is possible that three women may claim to be the mother of the child; gestational mother, i.e. a surrogate, commissioning mother and the genetic mother, if donated egg is used. Where donated sperms are used, three persons may claim to be the father of the child; the donor of sperms, the commissioning father and the husband of the surrogate, if married. A child produced through surrogacy arrangements may potentially have as many as six individuals as competing for parental claims: the surrogate, the surrogate's husband, the intending father, the intending mother, as well as possible outside donors. This fact makes the children vulnerable and their status uncertain if battle over their legal parentage and citizenship are contested. Many legal issues such as child's legal status, parenthood, name, legitimacy, custody, inheritance, citizenship, etc. arise.

The Kerala High Court and the Supreme Court of India held that, legitimacy is a matter of status[21]. For determination of status, the parenthood of the children has to be determined. There are various theories to determine parenthood of children[22].

Legal theories for determination of parenthood: The courts have adopted varying criteria including marital presumption[23], genetics[24] gestation[25] intention[26], etc. for determining parenthood.

Marital Presumption: As per common law, a man will be presumed to be the legal father of a child born during his marriage to his wife who gave birth to the child or within a defined period[27] following its termination, whether by death, dissolution or annulment (i.e. *pater is est quem nuptiae demonstarat*). This presumption is rebuttable. It is normally accepted that a man is married to the woman who gave birth to the child is presumed to be a natural father of the child.

As per this presumption, a surrogate and her husband would be the legal parents of the resulting child and not the intending parents engaging her. This common law presumption is incorporated in India, when there were no means of ascertaining the biological paternity of a child and sexual intercourse was a prerequisite for birth of children. With the ART and surrogacy coitus is not necessary for the birth of the child. A woman can be impregnated with the stored sperms in the absence of her husband. In such an eventuality it is easy to rebut the marital presumption and the husband may easily prove the child to be illegitimate.

If donated sperms are used by the wife to procreate the child it is possible to rebut this presumption by proving that the husband is not the genetic father of the child. The recent judicial trend is to allow the parties to take DNA test to determine if the child is biologically related

to them. Most legislation world over have extended the presumption of legitimacy by providing that a child born of artificial insemination with the consent of the husband and wife shall be deemed to be the husband's legitimate child, irrespective of biology.

Gestation: Generally the woman who gives birth to the child is the legal mother. Earlier it used to be that the maternity is conclusive whereas paternity is trust. However with the surrogacy this saying also becomes doubtful.

The legal parenthood or the status of the child born to a surrogate will depend upon whether surrogacy is allowed in a particular jurisdiction or not. Where surrogacy is banned, the gestational woman will be considered the mother of the child[28]. Where surrogacy is legal and valid, the gestational surrogate would not be the legal mother and the child born to a surrogate shall be considered to be the child of intending parents[29].

In Re Baby M, Mary Beth, a surrogate, was artificially inseminated with the semen of a man who was not her husband[30]. The surrogacy contract was held invalid and the natural mother i.e. surrogate retained her parental rights[31]. In Jan Balaz v. Anand Municipalty and others[32], when the German twins born to a surrogate mother in Gujarat were caught in a legal wrangle of nationality, the Gujarat High court held that the birth mother of the child will be the legal mother[4].

Gestational test is not relevant in the context of surrogacy. It would compel an unwilling surrogate to become a parent. If the surrogate is considered as a mother of the child, the commissioning parents would be required to indulge in unnecessary and expansive legal formalities to become a parent.

Genetics: As per the genetic theory, contributor of gametes is a parent. In the context of ART, a stranger donor of the gametes would be a parent, and not the intending parents. In a few cases the courts have relied upon this theory.

In Belsito v. Clark[33], Belsitos had the embryo consisting of their gametes implanted in a gestational surrogate and sought a pre-birth parentage order. The court relied upon genetic relation between woman and child for determination of legal maternity[4].

In Perry-Rogers v. Fasano[34] due to a clinic mix-up, two couples' embryos were implanted in Mrs. Fasano[35]. The Fasanos refused to give up custody of the child who was not genetically theirs. The appellate court in New York characterized Mrs. Fasano as a gestational surrogate, a stranger with no genetic connection, and therefore not a parent.

As per much legislation, genetic theory for determination of parenthood of child born through ART is not accepted as it is specifically provided that the donor of sperms is not father and the ovum donor is not a mother of the resulting child[36].

The recent technological advances have created the potential for a child to be genetically linked to two women through ooplasmic transfer, resulting in a baby that is genetically related to three people[4]. Even in "CAI" where sperms of two males are combined, the genetic test would result in having two fathers for the child.

Contract or Intent Theory: According to this theory one who intends to be the parent and takes steps in pursuance thereto shall be the parent of the resulting child. With ART, a child is procreated at the instance of the commissioning parents. It is they who had initiated the process of ART to procreate a child for themselves. Without the intention of the commissioning parents, the child would not come into this world. It is because of their desire, psychological involvement and financial investments that the child is born.

In Johnson v. Calvert[37] a gestational surrogate, who agreed to carry and deliver the genetic child of Mark and Crispina Calvert decided to keep the child she carried[38]. Court held on the basis of the surrogacy contract that only the wife was the child's mother, which entitled her to be recognized as the child's parent[39].

Acceptance of intent theory will bring certainty to the legal status and parent-child relationship from the moment of the birth of the child and shall avoid the claims/disputes over the child. There shall be certainty as to the persons against whom a child can claim his/her rights. The surrogate and the gamete donors shall also not be thrusted with unwanted parenthood.

General Concept of Legitimacy: Personal Laws in India and ART

(a) As per Hindu law, legitimacy is conferred upon the child by valid marriage only. Only legitimate relationship is recognised as to inheritance of the

property of a male Hindu[40]. The heirs related to an intestate by full blood shall be preferred to heirs related by half blood, if the nature of the relationship is the same in every other respect[41]. Hence the child born through donated gametes of strangers to a married couple may not be considered as their legitimate child not being genetically related to them. A child born to a surrogate may be considered as the legitimate child of the surrogate and her husband, if married, even though the gametes of the intending couple are used for procreation.

(b) Under Indian Succession Act 1925, child means a natural or legitimate child (born in lawful wedlock) – son or daughter-of the propositus[42]. The property of an intestate devolves upon wife or husband, or upon those who are the kindred of the deceased[43]. Kindred or consanguinity is the connection or relation of persons descended from the same stock or common ancestor[44]. Therefore only the child born to a wife, artificially inseminated with the sperms of her husband or embryo created with her eggs and sperms of her husband, shall be their legitimate child. Child born to a wife using donated gametes may not be considered as the legitimate child of the couple. The child born to a surrogate will not be considered as a legitimate child of the intending parents not having born in lawful wedlock nor will the child be considered as a legitimate child of the husband of the surrogate.

(c) According to Mohammedan law, children born outside the marriage or born of void marriages are illegitimate. Muslim law prohibits inheritance to property of the deceased by illegitimate children[45]. It adheres to the concept of '*Nullius Fillius*' or child of no one. Hence only the child born during valid wedlock, to the wife, who is artificially inseminated with the sperms of her husband or embryo created with her own eggs and sperms of her husband, shall be their legitimate child. In case where the child is born to a wife with the use of donated sperms or eggs, or to a surrogate, the child will be considered as the child of the gestational mother only under *Hanafi* law. The child is born to an unmarried surrogate will be *Nullius Fillius*.

Thus the personal laws are inadequate to address the problems of legal status and parenthood of the children born through ART or surrogacy.

In India presently there is no law governing ART and surrogacy. Various Bills are laid before the parliament in the year 2008, 2010, and 2014. Recently The Surrogacy (Regulation) Bill 2016 is introduced. Let us examine the provisions of the said Bills in the context of conferring legal status to the child born through ART.

Critical Appraisal of the ART Bill, 2010, 2014 and The Surrogacy (Regulation) Bill 2016: Sub section (1) of section 35 presumes that the child born to a married couple through the use of assisted reproductive technology to be the legitimate child of the couple. Whereas subsection (2) of section 35 states that a child born to an unmarried couple shall be the legitimate child of both parties. Sub section (3) of section 35 deals with a situation when a child is born to single man or woman through ART and it is stated that the child will be the legitimate child of the woman and in case of a single man the child will be the legitimate child of the man.

Similarly ART Bill of 2014 also presumes that a child born to a married couple to be the legitimate child of the couple. This Bill does not allow ART to be used by unmarried couple, single man or woman.

There is no provision in the said Bills providing that the child born to a surrogate shall be legitimate child of the commissioning parents. In the absence of such provision, the child shall be legitimate child of a surrogate and not commissioning parents.

The Surrogacy Bill of 2016 provides that any child born out of surrogacy procedure shall be deemed to be a biological child of the intending couple and the said child shall be entitled to all the rights and privileges available to a natural child under any law for the time being in force[46]. It is very surprising that the legitimacy is provided by way of a proviso to section 7 of the Surrogacy Bill 2016. It is necessary to make the changes accordingly in the ART Bills.

CONCLUSION AND RECOMMENDATIONS

The surrogate mothers and the children born out of surrogacy are the vulnerable components of the surrogacy process. We owe moral and legal duty to

provide basic human needs such as nutrition, health care and financial and emotional security on the globally comparable terms to surrogates and nutrition, legal status, parenthood, citizenship, etc. to the children born out of surrogacy. The research carried out by CSR demands post-natal care for the surrogate mother, central database or registration to maintain permanent address and details of children born, surrogate mothers and intended parents, provisions of dual citizenship for the children of surrogacy contracts[47]. Failure to make basic legal provisions for their protection will result into infringement of their human right.

There needs to be a right based legal framework from the point of view of surrogate mothers and children and research is required to be undertaken from the perspective of the rights of the surrogates and children. An empirical study is also required to be undertaken of the surrogacy agreements to examine whether the rights of the surrogates are actually protected and enforced without entangling into long fought legal battles, as surrogate may not have financial capacity for the same. A study on granting legitimate status in all the circumstances to all the children including the children born out of assisted reproduction needs to be undertaken.

The democratic law which we have been waiting for last 10 years must regulate the surrogacy in the country[48]. The surrogates and the children born out of surrogacy process are important components of not only the surrogacy process but society also. By denying them their basic rights, we kill their dreams and their future. There is no greater violence than to deny the dreams of children[49] or for that matter any members of the society. Let us vow to keep those dreams alive. While enabling and facilitating surrogacy and ART, the healthcare does not per se generate injustice. However, the disequilibrium caused by inadequacy or absence of entitlements to the surrogates as well as resulting children, as shown above, pose serious challenges to this miracle of health science. Is it the time for healthcare justice to discover its own new models?

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Regulations for Authentic Ayurvedic Healthcare Establishment

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ABSTRACT

Clinical establishment act was passed by parliament in 2010. Objective of this act is to prescribe basic minimum standards for different categories of clinical establishments for ensuring provision of proper healthcare. Ayurvedic practitioners are also contributing a part in Indian health care system. That's why it is utmost important to bring uniformity & validity in the structure of Ayurvedic hospitals. Hospital management is not a new term for Ayurveda. In Ayurvedic ancient text components related to medical services like hospital (*Aturalaya*) planning, location, space, equipment and material procurement (*Agropaharniya*), medical quality control (*Chikitsaa Chatushpaada*), human resource management and many other aspects of hospital management are described. Most of them are still applicable but some of them are quite difficult to follow in present era. So, implementation of instructions relevant to 21st century should be done, rather than following texts blindly. This can be done by formulating a structure considering references from different ancient texts which are relevant to today's era.

Keywords: *Ayurveda, clinical establishment act, human resources, space requirement*

INTRODUCTION

'The Right to Life' is the most fundamental of all rights. As human rights can only attach to living beings, the right to life is most primary right. 'LIFE' in Article 21 is not merely physical act of breathing but, it includes right to live with human dignity, right to livelihood, right to health, right to pollution free air etc. It is essential for our existence[1].

For maintenance of heath, healthcare industry is playing a crucial role. As time changes newer technologies are being added to the surgical & medical fields for diagnosis & treatment of variety of diseases. A uniform standard is required for delivering best facilities to the patients.

One big step in this direction is Clinical Establishment Act. Objective of this act is to prescribe basic minimum standards for different categories of clinical establishments for ensuring provision of proper healthcare. It leads to improvement of public health quality by eliminating quacks. Clinical establishment act was passed by parliament in 2010. This act has come into force in the states of Arunachal Pradesh, Sikkim, Mizoram, Himachal Pradesh & all union territories, Chandigarh, Dadra, Diu, Daman, except Delhi from March 2012[2].

As a country with a large population India is always facing a problem with health care sector especially in rural areas. Main support to healthcare system is given by Ayurvedic practitioners in those areas. Ayurveda system of medicine is also going to be a major area of solution in many conditions of medical treatment. Increase in lifestyle disorders & unique approach of Ayurveda towards the treatment of such aliments impart importance to ayurvedic clinic & hospital establishments. So, numbers of Ayurveda hospitals are increasing day by day. Which have made it crucial to take steps to bring uniformity & validity in the structure of Ayurvedic set ups. Draft for Development of Minimum Standards of Clinical Establishments Ayurveda is done according to CCIM (Central Council of Indian Medicine) norms, IPHS (Indian public health standards) guidelines and MSR for Ayurvedic hospitals in Gujrat[3].

Step has been taken through this article in exploring treasures of classical ayurvedic text. Which have not been taken previously regarding construction of different wards. Many articles were published previously regarding ethical principles and practices

in Ayurveda. But guidelines regarding construction of different rooms or wards are not studied thoroughly. Hospital management is not a new term for Ayurveda. Acharya Charak and Sushrutra both have clearly described about hospital (Aturalaya) planning, structure, equipment and material procurement (agropaharniya), medical quality control (Chikitsa Chatushpad), human resource management and so many aspects of hospital management at different places in their text i.e. Charak Samhita and Sushruta Samhita[4] (javed, October - 2015). we are trying to formulate a new structure for ayurvedic set ups. without disturbing guidelines given in the classical texts. Implementation of instructions relevant to 21st century should be done rather than following texts blindly.

Since this topic is very vast, we have tried to focus on only 2 aspects of ayurvedic set up namely space & human resources. Space for ayurvedic set up includes place where it should be built, dimensions, structure & instructions for interior. Human resources includes mainly Vaidya (Ayurveda Physician) & Paricharaka (attendant). According to different functions paricharaka are termed accordingly.

The main objectives of the present studies were: (i) To collect references for setting up an authentic Ayurvedic hospital with special reference to space & human resources; (ii) To analyse those references to determine their validity with current scenario & to determine their feasibility for application to practical purposes.

MATERIALS & METHODS

This study is of review type. Collection of data was done in the following steps:

- Three major classical texts i.e. Charak Samhita, Sushrut Samhita & Ashtang Hridaya & their commentaries were reviewed first to search references related to space & human resources.
- Review of recent guidelines for standard maintenance of hospitals were done
- Research papers & reports providing contemporary evidences were also reviewed
- Data was compiled & organised into a structured format.

Critical analysis:

- Data was sorted in 2 groups first viz. space & human resource
- Then data was analysed into qualitative & quantitative parameters.
- Feasibility & practical applicability of these references was also reviewed.

RESULTS

A literary review was done using ayurvedic classical texts, research papers and other net sources. Different references were found scattered all over the texts. Collection & sorting of these references were done in two categories, space & human resources.

Space: In the draft for clinical establishment act for Ayurveda, space is given according to no of beds in hospital for e.g. Clinic minimum 100 sq.ft, dispensary Minimum 100 sq. ft., therapy centre minimum 150 sq.ft, hospital with minimum 100 beds 100 sq.ft. OPD & IPD 500 sq.ft. etc.[5]. Separate bathroom & toilet for male & female should be there.

In classical Ayurvedic texts, various references are scattered related to space in form of **sutikaagar** (labour ward), **kumaragaar** (paediatric ward), **vranitaagaar** (ward for patients with ulcer or wounds) **bheshajagaar** (storage room for medicines). Specific space for OPD is not mentioned in ayurvedic texts, since in ancient time Vaidya used to visit patients at home for consultation.

Sutikaagaar: Sutikaagaar means place created for safe delivery of a lady where she can stay from beginning of ninth month. According to Charak, room should be built on the land free of bones & uneven pebbles. Wood should be used for construction of the room. It should be comfortable for all seasons. Door of the room should face north or east direction. The room should be well plastered. All necessary equipments, water storage, toilet, bathroom kitchenette should be present in the room[6].

According to Sushrut, inner dimensions of room should be 8 cubits (1 cubits = 45 cm or 1.5 foot) in length & 4 cubits in breadth. He has instructed to build this room according to social order on different coloured soil with different woods for each social order[7].

Kumaraagaar (paediatric ward): According to Charak, paediatric ward should have proper lighting, it should not be dark. It should be well ventilated but direct wind should not enter. It should be free of dogs, wild animals, mosquito, and rats. It should be well planned with toilet, kitchenette, and bathroom. Description of bedding is also given in details. Bedding should be clean & hygienic. Regular dhoopana should be done[8].

The dhoopa dhoopana dries up the intracellular fluid matrix in a bacterial cell. Drugs which are used for dhoopana are volatile in action and thus they keep the wound and surrounding of the wound, clean and clear of krumi. Dhup Dhoopana has showed remarkable sensitivity against Staphylococcus aureus, Salmonella abony and E-coli[9].

Plants like *Nimba (Azadirachta indica)*, *Guggulu (Commiphora mukul), Sarshapa (*Brassica nigra*), Ela (*Elettaria cardamomum*), Haridra (curcuma longa), Bhallataka (Semecarpus anacardium), Jatamansi (Nardostachys jatamansi), Nirgundi (Vitex nigundo) & Tulasi* (Occimum sanctum) possess potent anti-bacterial activity & therefore are successfully used in fumigation therapy both as mainline treatment & prophylaxis with minimal adverse effects[10]

Vranitaagaar: According to Sushrut, chamber or room for patients with wound or ulcer should be clean & spacious. It should have protection from excessive heat & strong gust of wind. The bed should be spread clean, ample & comfortable[11].

Wound healing is accelerated when the wound bed is kept warm at body temperature, therefore, frequent dressing changes should be avoided whenever possible. Evidence-based practice indicates that the natural healing process should be disrupted as little as possible[12].

Bheshajaagaar: According to Charak, there should be a separate room for the storage purpose of medicines. Door of this room should face north or east direction. It should be well ventilated. Herbs should be stored in containers according to their nature. It should be free of any pests, dogs & dust. Collected medicines should be kept suspended from wooden pegs[13].

According to Sushrut, medicinal storage of physician should occupy a commendable site & an auspicious quarter of sky i.e. north east direction. Collected medicines should be kept tied in pieces of clean linen or stored in earthen vessels or hollow tubes of wood. It should be suspended on wooden pegs[14]. WHO guidelines provide good manufacturing practices (GMP) about Storage areas which covers all ancient guidelines[15].

Room or ward for panchakarma (ward for purification procedures): Panchakarma is done to detoxify the body according to Ayurveda. The five procedures are claimed to eliminate the vitiated Doshas from the body. They are Vamana (Emesis), Virechana (Purgation), Nirooha Basti (Decoction enema), Nasya (Instillation of medicine through nostrils), Anuvasana Basti (Oil enema) & Raktamokshana (blood-letting)[16].

According to Charak, room for panchakarma should be spacious, well built. It should be well ventilated & free of smoke, dust. It should have attached kitchenette, bathroom & toilet[17]. This ward is used for vamana & virechana karma.

Charak have described special type of fomentations namely, *Jentaaka & Kuti Sweda* (fomentation). To perform these processes special rooms should be constructed. Following guidelines are given for construction of the rooms.

Jentaak Sweda[18]: Specifications are given about land where it should be built. Land should be in eastern or northern direction, auspicious, spacious, with black & sweet or golden soil. It should be at a distance of 3 meters from lake or pond. Room should face east or north. Height & area of thehouse should be sixteen *Aratni* (731.52 cm)House should be circular from all sides.It should be well plastered with mud & many windows. Inside this room a bench like extension of one *Aratni* (45.72 cm) in height & width should be provided all along the wall upto the door. At the centre, there should be an oven made up of woods from *Khadira* (Acacia catechu) tree etc. Dimensions of this oven should be four hasta in diameter (6 ft) & height of one *Purusha* (height of one man).

Kuti sweda: a cottage room should be constructed with walls, not very high & wide, circular, without any window & plastered with *Kushtha* (Sausurrea lappa) etc., furnace filled with charcoal should surround it[19].

Kuti (cottage) for rasayana chikitsa[20]: Kuti praveshika is a special type of *Rasayana* (rejuvenation) therapy mentioned in ayurveda, which requires isolation of the patient for certain time period. In this indoor type

of rasayana therapy a special cottage should be built in auspicious ground, facing east or north direction. It should have sufficient space, area & height. There should be three concentric chambers one after the other. Walls should be thick and with small pores and comfortable for all seasons. Walls should be impermeable for undesirable sound (sense object). It should be well equipped with all necessary accessories.

Human resources: Reliable and systematic data for health workers in India are difficult to obtain. Estimates for 2005 (based on the 2001 census) suggest that India had almost 2·2 million health workers, including about 6,77 ,000 allopathic doctors and 2,00, 000 practitioners of Ayurveda, yoga and naturopathy, unani, siddha, and homoeopathy[21]

In the draft for clinical establishment act for Ayurveda following human resources are mentioned according to the number of beds in hospital[22] for eg,

1. **for more than 100 beds:**
   Doctor – 5 - 10
   Pharmacist – 5
   Nurses - 5
   Attendant – 5
   Panchkarma technician – as per requirement
   Multipurpose worker-4
2. **for 26-50 bedded hospital:**
   Doctor – 3- 4
   Pharmacist – 1-2
   Nurses – 3
   Attendant – 2-3
   Multipurpose worker – 2

In Ayurveda, the success of Chikitsaa (treatment) depends totally upon four factors which are known as Chikitsaa Chatushpaada (chatu = four & pada = factors or pillars). These Chatushpaada includes Bhishag (Vaidya / ayurvedic physician), Upastha (paricharak / attendant), Rogi (patient) and Dravya (medicines)[23,24,25] .

According to Ayurveda, all Chatushpaada equipped with their sixteen qualities are responsible for the success in treatment. Still the Vaidya, by the virtue of his keen knowledge of medical science, administrative position and by prescribing capacity occupies the most important position among them[26]

Vaidya (Ayurveda physician): According to Sushrut, a physician should be well versed in the principles of science of medicine. He should have proper knowledge of Ayurveda[27].

A physician should study as many allied branches of sciences as possible. The physician who studies the science of medicine from the lips of his preceptor & practices medicine after having acquired experience in his art by constant practice is termed as a true physician[28].

Sushrut have devoted a complete chapter "Yogyasutriyam" (practical training) to make a student fit for surgical work. In the view of Sushrut, though the student has understood the element of the science fully, he must be made competent (Yogya). With this purpose, Sushrut explained and demonstrated different kinds of Yogya Vidhi[29]. For example,

- Practice of excision (Chhedana Karma) can be done on pumpkin (Pushpaphala) and cucumber (Trapusa)
- Scraping (Lekhana Karma) can be practiced using broad sheet of dead animal leather with hair
- Puncturing (Vedhana) can be practiced using veins of dead animal and stalk of lily plant
- Probing (Eshana Karma) can be practiced using holes in pieces of wood eaten by moths
- Suturing (Sivana Karma) can be practiced using thin and thick cloths
- Bandaging (Bandhana) could be using models or mannequins prepared from mud or clothes.

Thus, one who desires to become skilled in the use of instruments (Shastra), alkali (Kshara) and thermal cautery (Agnikarma), should practice on similar objects and become skilled in surgical art. Sushruta says that, in this way the intelligent, who has made fit himself by using methods and techniques suitable for practical training described in the texts, does not falter in his actions.

In general, simulators fall into the following categories: (1) mannequin-based, high fidelity, or realistic patient simulators, (2) partial or complex task trainers, (3) web- or screen-based computer simulators, (4) standardized patients, (5) crisis resource management or multidisciplinary team training, and (6) virtual reality[30].

Simulation is used as a tool nowadays for teaching & assessment as it helps to give training in all 3 domains. It holds great promise to improve physician training and, thereby, to impact patient safety and health care outcomes in a positive and significant way[31].

Sushruta have given guidelines for the physician to enter the profession. That physician should enter in the profession, who has completed the study of the texts, understood the interpretations, who has made himself thorough through practical training and recapitulating the teachings of the science always and obtained the permission from the king[32].

This is suggestive of the existence of the rules regarding the control and regulation of medical practice during ancient times, similar to registration of a medical practitioner of present days. "Don't behave like a quack." This is the warning given to the physicians to be always careful in conduct and behaviour with patient to avoid loss of reputation and respect in society.

Qualities of Vaidya:

- According to Acharya Charak, ideal physician should possess the following four qualities[33,34].
  1. Shastra (having detailed knowledge about diseases and the treatment)
  2. Drushtakarma (having extensive practical experience)
  3. Daksha (alert or Dexterity)
  4. Shuchi (purity of mind and body)
- According to Acharya Sushruta, A Vaidya (physician), who is well versed in the science of Ayurvedic medicine and drushtrakarma (who has attended to the demonstrations of surgery procedure), and who have seen the treatment being performed, and gained experience by doing it himself. He should also have qualities like, Shuchitwa (cleanliness), courage, Laghuhasta (firm and light in hand), Shaurya (brave). He should be fully equipped with medicine, surgical instruments and Visharad (who is intelligent to manage any critical situations), well read, and is a man of ready resources, endowed with all moral virtues, is alone fit to be called a Vaidya.
- According to Charak, clear picture of different types of physician such as Raja Vaidya (royal physician), Pranabhisara (an excellent physician), Bhishak chadhamchar (pseudo physician / who pose themselves as a physician), Siddhisadhit (feigned physician / who boast themselves as a successful physician) Vaidyagunayukta (genuine physician) and Murkha Vaidya are given[35].

Paricharak (attendant):

- According to Acharya Charak, the attendant attending on the patient should possess following four qualities[36].
  1. Buddhiman (Intelligent enough to understand the physician's instructions and act accordingly)
  2. Daksha (Alert or active)
  3. Anurakta (Affection or attachment towards patient)
  4. Shuchi (purity of mind and body)
- According to Acharya Sushruta ,A person is fit as a Paricharak (medical attendant) who is Snigdho (affectionate), desirous of protecting the patient, who is cool-headed and pleasant in his demeanour, does not speak ill of any body, Balwaan (strong) and attentive to the requirements of the patient and strictly and indefatigably follows the instructions given by the physician[37].
- According to sushruta, 4 elderly attendants should be present in sutikaagar. They should have own children & experienced for process. They should be able to give support lady in labour verbally also[38].
- According to Charaka , in panchakarma ward following different paricharak should be present:
  i. Soup odan pachak (cook)
  ii. Snapak (attendant for sponging or bathing patient)
  iii. Samvahak (attendant who rubs the limbs of patient)
  iv. Uthhapak (attendant who helps patient to get up or lifting of patient)
  v. Samveshaka (attendant who assist patient to lie down on bed)
  vi. Aushadha peshaka (attendant who prepares medicine in mortar & pastel)

They should also be able to entertain patient by singing, playing musical instruments, enchanting, and storytelling & by telling them incidences from history & *purana*.

DISCUSSION

Fusion of ancient science with available facilities will be golden mean. Ayurveda is ancient science, references available for planning of aturalaya in ancient texts still shows its validity. It is necessary now to formulate some guidelines for ayuredic set ups as their number is increasing. These guidelines should fulfil current requirements of maintaining standard care but at the same time should preserve the unique structure of ayurvedic set ups. Ayurvedic hospitals should have unique identity rather than following blind rules of allopathic hospitals. In the texts, some references are there which are not feasible to follow in present era. Avoiding these, some most important references should be followed for development of authentic ayurvedic hospitals. Some of the most important features of an ideal Ayurvedic hospital are the following:

We can prescribe some guidelines for location and general construction of hospital. These are as follows: In Ayurveda north and east directions are considered as auspicious directions. Wards should be constructed in such a manner that their doors should face one of these two directions. Land where hospital construction is going to take place should be even which will avoid any accidents during transportation of patients. Proper lighting and ventilation should be there which are important for maintaining clean air so as to prevent spreading of any infection. Rooms should be well equipped with all the necessary medicines, instruments and facilities for the preparation of medicines like decoctions. Emergency medicines and instruments should also be present in that room since panchkarma procedures can sometimes lead to complication like dehydration.

Now we will consider instructions for Specific different wards:

Sutikaagar: This is a room designed for care during 9th month of pregnancy. Its dimensions are mentioned as 12 ft in length & 6 ft in width. It should have even flooring & well plastered walls, which will protect the room from any reptiles which still cause for trouble in rural areas. For example in rural India snake bite or scorpion sting occurrence is still common where house are not well plastered. In the text four (Number) attendants should be there. The attendant should be elderly& should have own experience of delivering a child. This is emphasised specifically because if they have their own experience then only they can understand the intensity of labour pain and give right assurance and encouragement to pregnant lady in labour pain.

Kumaraagar: Kumar means son or baby. Kumaraagar is a place where care of babies was taken. Hence this is a room for paediatric patient. Here emphasis is given on hygiene, ventilation & proper lighting. Dhoopana karma is advised in this ward, which is a kind of hospital aseptic technique. It is also considered as measure to protect baby from krimi (Germs).

For creation of comfortable environment for child various types of safe toys should be there.

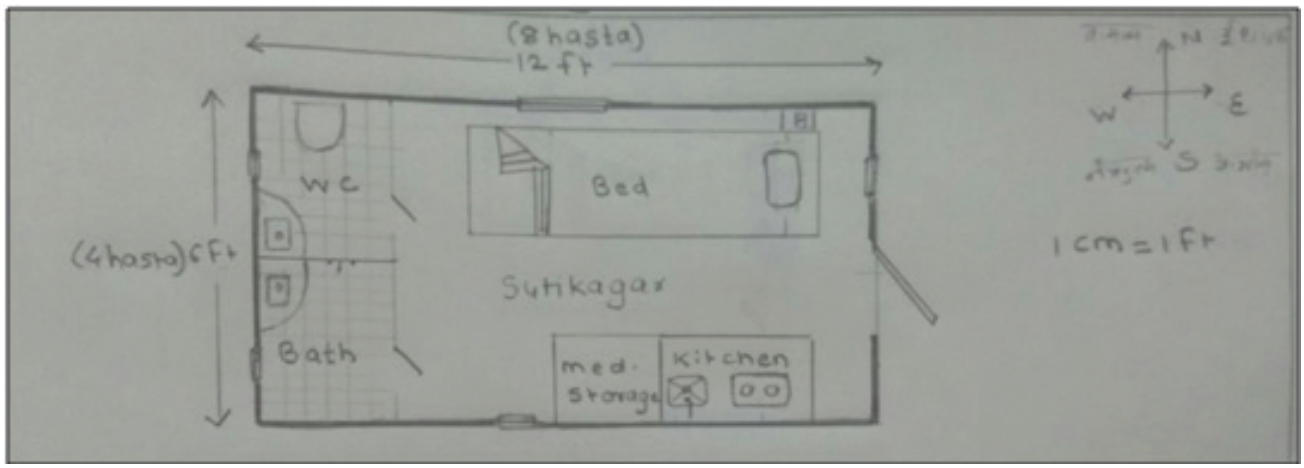


Figure 1: Room designed for 9th month of pregnant women

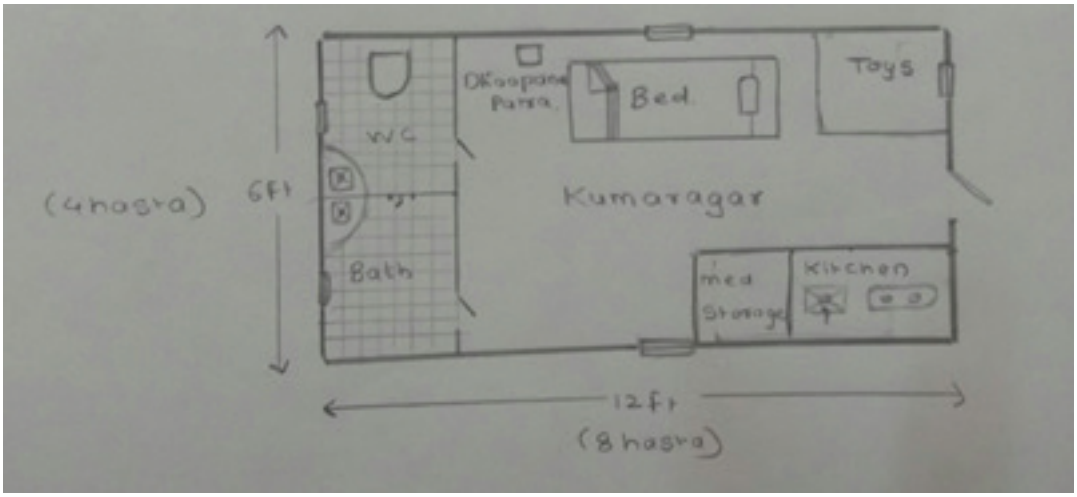


Figure 2: Room designed for paediatric patient

Vranitaagar: It is a ward for care of patients of wound or ulcer. Here, emphasis is given on maintenance of sterile conditions for better wound healing. It should be spacious. It should be warm.it should be designed in such a manner that wind should not enter directly, which may act as a carrier for organisms responsible for infection of wound.

Bheshajaagar: Every ayurvedic hospital must have its storage room for herbal medicines. They should be stored in such a way so as to protect them from pests, humidity or direct sunlight. If possible, plantation should also be there of herbs which are used usually in fresh condition for extraction of juice, decoction or for fomentation like, vasa (Adathoda vasika), tulsi (Occimum Sanctum), nirgundi (Vitex nigundo), Guduchi (Tinospora cordifolia) etc.

Panchakarma room: This room or ward should be planned in such a way that it should have facility for all types of karma. It should be spacious, properly ventilated. It should be well equipped for performing particular karma & its complications as well. Toilet & bathroom should be attached for post Panchkarma procedure. Special types of cottages are also mentioned in the texts like jentak sweda & kuti sweda. These structures can be incorporated in hospitals where sufficient land is available.

Kuti for rasayana: This special type of cottage can also be built where land is available & other necessary requirements related to patient can be fulfilled.

After considering qualitative parameters for these rooms. We will go through the quantitative parameters of these rooms.

Number of wards: There are 5 wards which can be constructed in hospitals. Structure described in texts are rooms for a single person. But we can modify these structures after taking sufficient measures. Protection of privacy and dignity of patients during making such changes in the structure should be kept in mind. Other 3 separate structures namely, jentaak sweda, kuti sweda and kuti for rasayana can be incorporated in the structure of hospitals where land is available and other instructions can be strictly followed.

Dimensions: Dimensions for these rooms are described as 12 feet in length and 6 feet in width.

Now we will look at the Specific instructions related to human resources:t

Vaidya: Vaidya is most important factor according to Ayurveda in case of treatment of any disease.

He should have proper knowledge of the texts as well as he should have practical experience for all the necessary procedures for treating a patient. This can be achieved by further improvement in education standards by applying newer technologies like simulation technique, audio visual aids.In the texts it is mentioned that he should have permission from king. Nowadays we require registration in central register after completing the course. Registration under Bombay nursing home act, 2012 is mandatory for hospitals.

Paricharak: In Ayurveda emphasis is given on qualities of paricharak. He should be affectionate. He should be well trained. Various attendants are described for specific purpose like cook, masseur, lady attendant, etc .He should be strong, alert, attentive and with pleasant

nature. In sutikaagaar four attendants should be there whereas in panchkarma ward 6 attendants should be there to look after the patient.

CONCLUSION

Clinical establishment act is aimed at bringing uniformity & improving quality of healthcare systems in India. Ayurveda as a system of Indian Medicine have established its importance in maintaining health of Indian population at primary care centres. It is possible to incorporate principles given in ayurvedic texts to today's era. We can establish a centre to provide authentic ayurvedic treatment where good standards can be maintained.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Globalization and Intellectual Property Rights: A Case Based Critique on Access to Medicines in A TRIPS Plus World

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ABSTRACT

The modern knowledge based economy thrives on innovation; which requires strong intellectual property protection. These intellectual property regimes differ across nations due to colonial history and differing stages of development. In the Free Trade Agreements (FTA) between countries, the intellectual property components can conflict with the local laws, the multilateral framework of TRIPS and affect access to health, innovation etc. These agreements, known as TRIPS Plus, involve extension of the patent term beyond 20 years, limits on compulsory licenses, restricting generics etc. Also, in the globalized era we see a phenomenon of a power shift from the government to transnational corporations capable of influencing policy. Implementation of such agreements in developing countries like India, wherein a significant section of the population lives below a dollar a day, can drastically impact their right to health and run contrary to the government policies of poverty reduction, access to health and the UN goal of sustainable development. This article will cover these developments based on various aspects including qualitative data from stakeholders.

Keywords: *Access to health, Globalization, Human Rights, TRIPS Plus*

INTRODUCTION

The modern era of globalization links countries that may otherwise be at the opposite end of the political spectrum. Innovation is the primary tool that helps countries project national power in the current era where the world is a global village. It helps countries maintain the competitive edge and keep them ahead. It is essential that to protect innovation there have to strong measures in the form of intellectual property laws. Economic growth by itself cannot be treated as in end in itself. The growth has to enhance the lives of all people and enhance the freedoms enjoyed.

The aim of intellectual property like any other resource is to enhance the well being of society. The IPR framework of a country and its innovation policies go hand-in-hand. They cannot exist without each other. How the IPR laws are framed can greatly affect fundamental rights of citizens like the right to health[3].

Globalization has brought in a uniform framework of intellectual property laws irrespective of social and economic parameters of a country known as Trade Related Intellectual Property Rights (TRIPS). Developing and least developed countries have had to strengthen their local laws to bring it at par with TRIPS.

TRIPS Agreement read along with the Doha Declaration, gave freedom to countries to give a priority to public health, public interest, public order and morality, gave options like compulsory licence etc. The member states were given freedom to modify their local laws by regulating patent grants and for enforcing higher standards for patent protection.

As the Indian legislature intended to harmonize our laws with that of various international commitments and to balance the obligation to protect and promote access to medicines for the citizens. As stated above, the Indian laws via various provisions of the Patents Act, for e.g. section 3(d), enforce a balance between the need for promoting research and innovation and the basic right to health of citizens.

However, many of the developed countries sought to dilute the multilateral framework and promoted a bilateral framework as explained below.

There is a need to study the effects of these agreements especially on developing countries with their implications and to find ways to protect the interests and human rights of their population and the interests of the local industry. As these agreements have the potential of significantly impacting access to health, innovation, technology etc. it is essential that such a study is conducted.

CONCEPT OF TRIPS PLUS

The TRIPS agreement attempted to bracket all countries into the same league irrespective of social and economic development, and enforce a uniform method for intellectual property rights. Although the TRIPS agreement and Doha Declaration gives freedom to countries to prioritize public health, many countries are under pressure to incorporate harsh legal measures in their respective systems.

Although there may be no overt obligation to do so, many developing countries in Latin America, Asia and Africa have implemented stringent provisions under pressure and as a part of FTA. These have had a negative impact on the right to health and access to medicines for their citizens. Examples of such provisions include extension of the patent term, extending patent terms to compensate for the regulatory delays, limiting compulsory licences, data exclusivity, and restriction of generics.

Companies get exclusive rights to the clinical trial data and can withhold the data from generic companies even after the expiry of the patent term. This article will primarily explore the implications of patent term extension and data exclusivity. The generic company will have to conduct the clinical trials again and as a result of the cost escalation, the prices will increase for the citizens and hamper access to medicine. It can be called a backdoor method to restrict competition and maintain a monopolistic position even after the patent has expired. The authors will draw upon the experience of Thailand and derive the possible implications for India.

EFFECT OF THESE PROVISIONS ON ACCESS TO MEDICINES AND HUMAN RIGHTS

A country that is a net exporter of intellectual property, has a high Human Development Index, High per capita income among other factors may be able to bear such stringent provisions. For developing and least developed countries that have a low GDP and are also lacking on social and human development parameters, such provisions will cripple the need for welfare of the poor and greatly hinder access to medicines.

There is a view that intellectual property rights should be read as a part of international instruments like UDHR and ICESCR. There could be a framework for xo-existence and not an either-or approach with regards to welfare and innovation. People should have access to various innovations while the innovators should be rewarded.

Implementing stringent agreement like TRIPS Plus could run contrary to the realization of economic, social and cultural rights. The study goes beyond the access to medicines interpretation of human rights and includes other aspects such as traditional knowledge and technology transfer. It also suggests methods such as judicial activism, sui-generis system, worldwide database, information disclosure etc. are used to balance human rights and development.

When the impact of these agreements was studied in Latin America, it was found that would lead to an increase in prices and negatively impact access to medicines and heath. It was found that price increases by greater than 100%.

There are other examples wherein companies appropriated the patent system for their own benefit and caused many patients to pay large sums of money way beyond their means. The Company Myraid, rushed to beat the human genome project in identifying BRCA genes related to breast cancer so that it could get patents and extract a large amount of money from people. Although the US Supreme Court struck down the patents of Myraid in 2013, until then many were forced to pay large sums of money.

Article 21 of the Indian Constitution has been judicially interpreted to include the right to health in various cases including Paschim Bangal Khet Mazdoor Samity case.

Generic medicines, primarily from India, have reduced the price of drugs in places like Sub-Saharan Africa to just around 1% of the cost a decade ago[1].

PRIMACY OF NATIONAL INTEREST IN HEALTH

The main objectives of India's patent laws, especially when it comes to pharmaceuticals, are mainly driven by a welfare motivation: "if knowledge that might save people's lives exists, it must be brought to bear; to the extent that such knowledge is in the private domain, the power of the state to make it public, at least in a limited way, must be used." These conditions similar to the power of eminent domain. As per the Title 28, Chapter 91, S 1498 of the US Code, a legal authority is given for any Federal Officer to utilize any patented invention with negligible restriction. The patent holder would be entitled to reasonable compensation.

Post 2005, India amended its patent laws and permitted product patents and amendments were also brought about in Section 3(d) so as to prevent ever greening of patents. In the case *Novartis AG v. Union of India & Others* the patent application for a drug was rejected as it did not conform to the standards of incremental innovation laid down in Section 3(d). Other developed countries do not place restrictions on ever greening of patents as in the case of India like Section 3(d).

FEASIBILITY OF STRONGER IP NORMS FOR DEVELOPING COUNTRIES

Third world countries lack in expertise or even social and educational development so as to effectively capitalize on embracing imported technologies for local uses. A research by the World Bank demonstrates that implementing international agreements such as the TRIPS Agreement enforces expensive application costs that undermine the policy of poverty reduction and furthering growth that is especially important to third world countries. In addition, estimates of a positive economic outcome that is associated with strong IP protection, results in welfare losses in the short term before the benefits can be realized.

HUMAN RIGHTS PROTECTION FOR CORPORATES

An emerging view holds that human rights should be made applicable even to corporate entities.In the case of *Anheuser-Busch, Inc v. Portugal*, the European Court of Human Rights sought to extend the coverage of Article 1, Protocol No. 1 and the term "possessions", in Article 1 of Protocol No. 1 has been interpreted the provision to include intellectual property rights.

While the new trend is to accord human rights protections to corporations for their inventions, a logical corollary would be to hold them liable for any violations of human rights.

CASE STUDY: THAILAND

It is said that people with the power to make policy decisions neglect their right to health duties towards the general population while discussing or applying stringent intellectual property rights. Thus policy makers need to ensure primacy of human rights duties while negotiating or implementing any legal framework.

In the 21st Century many developed countries particularly the United States and the European Union, are in favour of enforcing higher-level intellectual property in developing countries. Such protection is euphemistically called TRIPS-Plus. The Unites States has conducted FTA negotiations with several countries, including Bahrain, Chile, Morocco, and Thailand.

The Thai-US FTA encompasses various issues of trade in goods and services and investment. The potential implications of TRIPS-Plus on accessibility to essential medicines and the cost of medication in Thailand was done and it was found that the availability of generics would help save 104.5% of actual costs and accessibility would increase 53.6%.

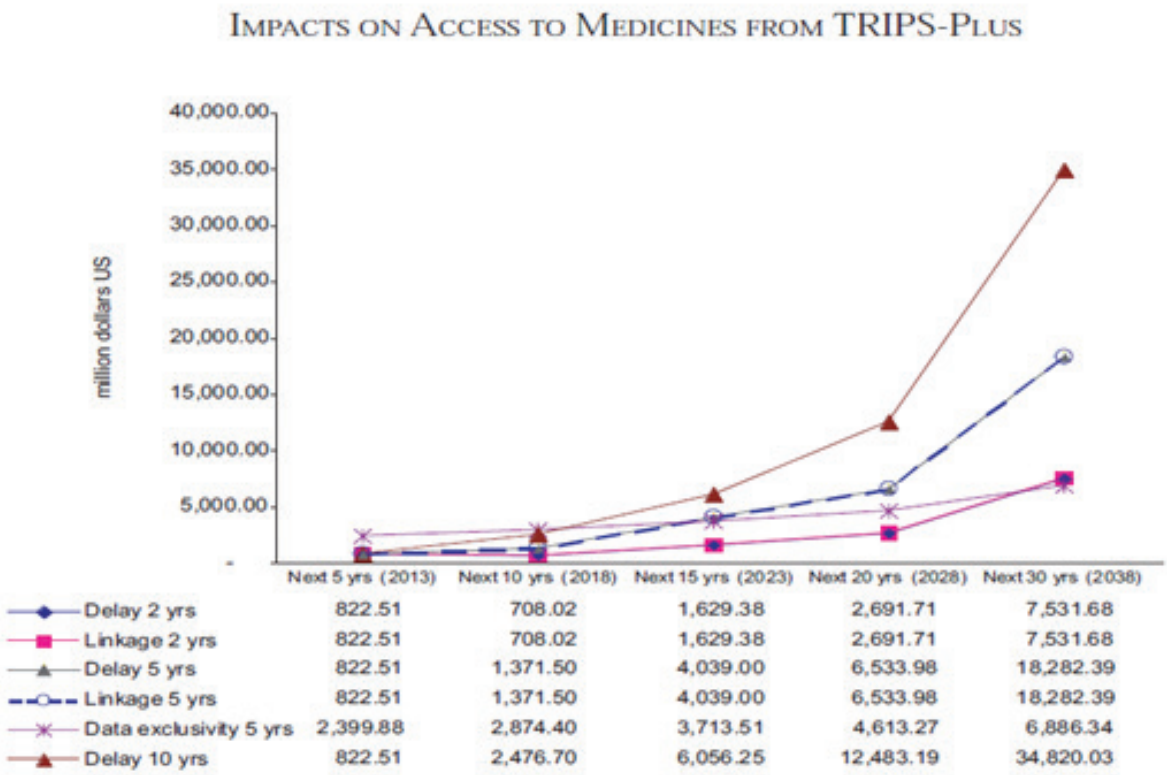
This study calculated the impact on access to medicines under the specific conditions, including extension of patent term for 10 years. The extension of the patent period could result from a delay in patent approval, drug registration and/or a link between the patent and drug registration

Some of the provisions warrant attention. Article 7 of the agreement required extension of the patent term to offset unreasonable delays in granting the patent or delays in approval for marketing. Article 4 of the agreement required the drug regulatory authority to notify the patent holder if anyone made an attempt to register a generic drug.

The agreement demanded Thailand to permit a period of data exclusivity for 5 years in pharmaceuticals and

10 years in agricultural chemicals. There was a visible negative impact on the pharma market, particularly for increasing drug costs, reduction in access to medicines, and dwindling of the domestic pharmaceutical industry. A 10 year patent extension would have the utmost negative impact. If that was done, medicine prices would increase by 67% from the baseline scenario.

The following graph shows a rise in costs and access to medicines if such stringent provisions are imposed.



Source: Kessomboon N, Limpananont J, Kulsomboon V, Maleewong U, Eksaengsri A, Paothong P. Impact on access to medicines from TRIPS-Plus: a case study of Thai-US FTA. Southeast Asian Journal of Tropical Medicine and Public Health. 2010 May 1;41(3):667.

Figure 1: Impact on access to medicines from TRIPS-PLUS

Although these could be simplistic assumptions many countries are engaged in negotiations to with regards to similar agreements. Such agreements have extensive implications and directly impact access to medicines. The TRIPS-Plus provisions undermine important safeguards that were the basic of the TRIPS agreement that developing countries sought to preserve. It will increase medicine prices, and delay or restrict the introduction of generics.

The experience in Thailand with regards to the free trade agreement and policy makers neglecting their duties is as follows as per another study:

"The first of these studies found that branded antiretroviral drugs in Thailand were two to ten times more expensive than generics, with generic medicines costing 40 to 448 Baht ($1.30-15) versus 252 to 791 Baht ($8.50-26.45) for branded drugs. The study further found that branded drugs cost approximately 1.5 to 4.7 times the daily minimum wage of 170 Baht per day ($5.60). The intellectual property rights section also explored a study estimating drug costs if patent terms or market monopoly was extended from one to ten years. The study found that a one-year patent extension would increase drug costs per item ten-fold, from 4.29 to 43.95 Baht ($0.14-1.46 per item), while a ten year extension would increase drug prices six-fold, from 181.10 to 1,116.16 Baht ($6-37)."[1]

It was also found that the free trade agreement would result in a decrease in the number of local pharmaceutical companies, hamper the research of local companies and permit conglomerates with better R&D capabilities and resources to monopolize the market.

INNOVATION AND STRONG IP LAWS

Proponents of stringent IP norms argue that strong IP regulations have led to an increase in innovation and that has been the popular belief. That however may not hold true.

It has been argued that an increase in the number of patents is primarily because of the quickening of the rates of innovation that would still exist with weak IP protection. This argument also says that growth in R & D spending predates the strengthening of the IP regime.

One author says that the current international framework for intellectual property rights like TRIPS limit domestic policy options to increase access to medicines that are affordable. Such rules may be contrary to the human rights narrative to increase access to affordable medicines, with harmful impacts on the health of the underprivileged population.

In the 18th century James Watt improved upon the steam engine and secured a patent. Due to the influence he had, this patent got extension by the England Parliament. After his patent expired, new developments increased 5 fold in the field. The patent was used to prevent further development and create an exclusive monopoly.

Misuse of intellectual property rights has a long history. In the last century, the development of two of the most important inventions, the automobile and airplane were impeded by IPR. For the automobile, although a patent was granted, it was an excessively generic patent. The owner of the patent did not have any intention of developing the automobile. He used the patent instead to form a cartel.

PRESENT INDIAN POSITION

The present Indian position does not favour the implemention of such provisions within the local laws[2].If implemented it would greatly impact our own generic companies and restrict them from acquiring the latest technologies at affordable prices. As India is a net importer of intellectual property, our local industry along with the rights of the citizens would be harmed if such provisions were implemented.

IMPLICATIONS FOR INDIA AND CONSULTATION WITH STAKEHOLDERS

Although India is yet to be a part of these agreements, the Indian judiciary is alert and critical with regards to the rights of citizens. As a part of the consultation with stakeholders, an interview of Dr. S. Sivaram, former Director of National Chemical Laboratory Pune, a well-known innovator and a Padma Shri awardee, was conducted.

An interview of Dr. R.A. Mashelkar, Padma Vibhushan, was conducted. Dr. Mashelkar was among the forefront in protecting and promoting Intellectual Property in India. His activism primarily began when he helped protected Indian indigenous knowledge intellectual property like turmeric and basmati and fought against their patents. He has been in various committees to advise the government and has also been in many international committees and is one of the main individuals who is involved with intellectual property rights protection and promotion in India.

He said that it is not necessary to be alarmist and take extreme positions on either side. It is not that we have to make a choice between social welfare and industrial/ scientific development. As per the current internationals norms it is possible than both can coexist. We can provide for a large part of our underprivileged population along with focussing on innovation and industrial growth. He talked about the flexibilities in the TRIPS agreement and also various other measures like differential pricing etc.

He also believes that we are moving towards an international understanding in solving many such intellectual property issues. Companies and the respective governments also can work together to ensure that while the intellectual property and revenue of the company is protected on one hand, equal access is ensured on the other hand.

Dr. Sivaram was of the opinion that in the modern age innovation is the only way we can move forward and not be dependent on foreign companies. He gave certain innovative solutions include like giving interest free capital, tax benefits through which the State can intervene and incentivize companies for pursuing fundamental research in developing indigenous drugs within the country itself along with known methods of differential pricing and exclusive marketing rights.

Another innovative solution that he gave was regarding funding original drug discovery through crowd sourcing.

An interview with a person in the top level management of an Indian pharmaceutical company was also conducted. He was also of the opinion that the government should bear some financial burden to spur innovation with regards to drug development, as innovation is the only way forward. We have to not only ensure access equality but also income equality so that everyone can benefit from the innovation. He is of the opinion that India cannot escape signing of agreements that enforce stringent IP measures. With regards to data exclusivity, he was of the opinion that in case of pharma products it will not be implemented in India as it could have a crippling effect for the domestic generic industry. However he was hopeful that with the increase in research within India it is only a matter of time before we begin developing drugs on our own.

OTHER LEGAL CONFLICTS BY ENFORCING TRIPS PLUS STANDARDS

TRIPS Plus provisions have given rise to certain legal problems[5]. These provisions relate to limits on compulsory licensing, parallel imports, etc. Most developing countries are opposed to an extension of TRIPS and the Doha declaration as that would significantly impact public health. These countries if they implement the stronger IPR provisions may be compelled to extend the same treatment to the other members of the WTO by virtue of Article 4 of TRIPS.

Additionally, with the ever increasing bilateral agreements, international agreements and local laws, the complexity and ambiguity of IP protection has significantly increased. One study has mentioned the example of Chile that has over a hundred such bilateral agreements besides its local laws. It is very likely many of the agreements differ amongst themselves and with the local laws which increases the problem of inventors and companies[6].

INVESTMENT AND STRONG IP LAWS

While it is believed that there is a correlation between investment, a strong economy and enhanced levels of IP protection that may not always be the case. Many African countries have the strongest IP laws but are still economically backward[3].

There is evidence that licensing of IP goods was unrelated to the strength or weakness of IP regimes and further that FDI was highest among the mineral rich war torn LDC's in Africa thereby further undermining the correlation between strong IP regimes and strength in attracting FDI in these economies.

Consolidating IP protection without simultaneously talking about the conditions associated with low economic growth in third world countries will not result in benefits that come with the strengthening the IP framework in countries where the right conditions for growth and development exist.

It has also been found that there are many other factors that influence FDI and technology transfer decisions, such as technology development policies, low level of corruption etc. It was also seen in the case of China that the growth of FDI did not seem to be correlated to increase in the level of IP protection or political reforms. In many cases, geopolitical or commercial considerations outweigh intellectual property concerns.

"POVERTY PENALTY" FOR PRIORITISING HUMAN RIGHTS

One author believes that developing nations have to face a "poverty penalty" for prioritizing their national responsibilities; even when they do not conflict with their international obligations (Ragavan, 2004). They may be threatened with economic repercussions for doing so. As we have seen earlier, TRIPS agreement provides sufficient flexibilities so that developing countries can provide reasonable access to medicines to their poor population.

Developed countries have been challenging all attempts by developing countries to invoke these provisions like compulsory licensing. However, when faced with a public health crisis, developed countries also resort to the same means. Imposition of indirect price controls were agreed to even in developed countries in case of exigencies. In some cases, the government moved towards issuing compulsory licenses.

The author says that ironically, this "poverty penalty" is not for deviating from the TRIPS norms but from attempting to fulfil it to further the objective of socio-economic welfare. Such situations will worsen with the implementation of norms that go beyond the TRIPS agreement and developing countries will continue to face further "poverty penalties". Developed countries

should not be able to unfairly use their economic clout to force the developing countries to neglecting their underprivileged population. Lives in developing countries are just as valuable as those of the developing countries.

INTERNATIONAL HUMAN RIGHTS LAWS: INCLUDING IPR AS A PART OF HUMAN SECURITY

The Universal Declaration of Human Rights (UDHR) recognises the right to freely participate in the cultural life of the community and the protection of interests arising from scientific, literary or artistic production. There are some human rights provisions that are noteworthy: Article 15(a) of the International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 15(c) of the ICESCR and Article 27 of the International Covenant on Civil and Political Rights (ICCPR).

As the concept of human rights is changing, a human being should be accorded with a good standard of living and be capable of sustaining himself and his family. Mere animal existence is not considered as human dignity. However, we also need to include provisions to enforce these rights (Palmer, 2007).

MAKING DEVELOPMENT SUSTAINABLE

The UN Sustainable development goals also list out health and innovation as being among the 17 priority areas[4]. However, the stringent TRIPS Plus bilateral framework can conflict with and also run contrary to these sustainable development goals. In the modern world, countries have to promote innovation to enhance the quality of life of its citizens. Such innovation however should not be at the cost of basic human rights. We have to study how the two can be reconciled.

The Third World Approach to International Law as a critical framework for this research will also be studied. It can provide a theoretical and conceptual framework in this study. This will include a way to promote the development of third world countries, while balancing it with the bilateral agreements that impose stringent IP norms.

The following model is proposed on the interconnection and prognosis of the interconnection between globalization, sustainable development and human rights.

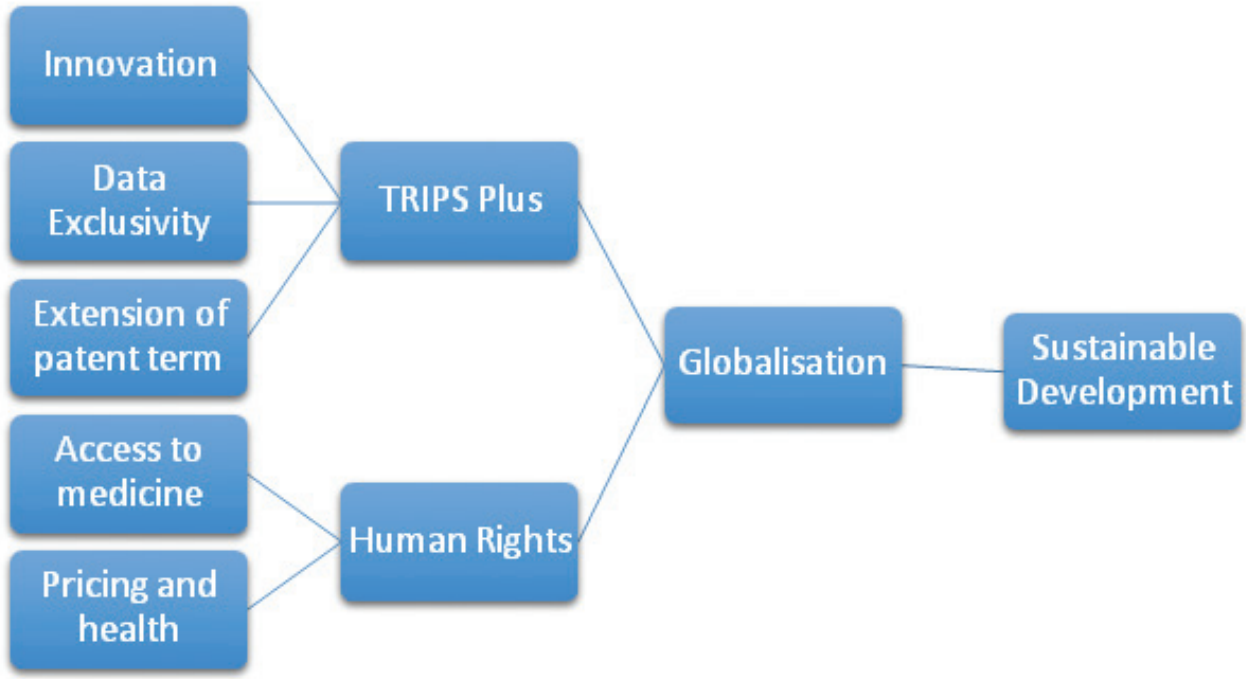


Figure 2: A model of interconnection between globalization, sustainable development and human rights.

CONCLUSION

Free trade is believed to lead to an increase in wealth and is thus defended (James and Patomaki, 2007). Those that are disadvantaged or socially excluded are often not a part of wealth and prosperity. Steps need to be taken for their benefit."Effective internationalization does not mean unmitigated laissez faire."

As we have seen there are various examples where harsh intellectual property measures can negatively impact the access to medicines and thereby the tight to health of common citizens. It has also been found that there is a negative effect on the local industry.If such provisions are enforced in India it would not only affect our citizens but have a direct impact on the rest of the developing world as Indian is a major source of generic medicines.

Developed countries have aggressively pushed the developing countries to enforce strict measures with regards to intellectual property. These agreements enforce standards that do not take into account the development and social indicators of the country. These agreements are often not viable. At the same time there has been a power shift from a state to a corporation. Activities that were the exclusive job of the state are now controlled by corporations. As a result corporations have become violators of human rights. Very often there seems to be a conflict between enforcing such measures and human rights. While we need to reward innovation, we have to balance innovation with the rights of the citizens so that there is equitable development in society.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Global Health Care: A Disregarded Domain

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ABSTRACT

Purpose: The main purpose of this paper is to analyse international legal framework, scrutinize and comment on the role of state, to evaluate role of WHO, UNDP and UNEP, to examine and comment on issues and challenges, and to recommend appropriate changes in the role of the state, legal framework, role of international organization relating to global healthcare.

Methodology: This paper follows doctrinal methodology. Approaches of research include interpretative, analytical and comparative. The inferences are deduced from logical examination of existing data and literature. The legal framework and working of organizations are scrutinized based on the rules of interpretation, logical analysis and existing literature. Induction method is used for arriving at findings.

Results & Discussion: This paper deliberates on current health care problems at global level vis-à-vis accountability of the State. The authors also have discussed analysed and interpreted present international legal framework. It identifies issues and provide appropriate recommendations/ suggestions. Findings can be useful in amending existing international legal framework, policies and programs.

Research implications: The findings are useful in interpreting, framing and implementing conventions, policies and programmes and ultimately will lead to protection of health care at global level.

Novelty/Originality: The paper is an attempt to provide novel recommendations relating to the existing issues and problems.

Keywords: *Global health care, Legal framework, Accountability, International organisations*

INTRODUCTION TO INTERNATIONAL HEALTH CARE: AN UNDERVALUED ARENA

Globalisation has integrated the world like never before. The easy flow of goods and services, trade, technology, information, population etc. has hurled success stories for all commercial industries since the last quarter of twentieth century. The underdeveloped or developing economies with rich resources were portrayed as promising markets with umpteen opportunities for capital growth. If the timeline of word affairs were given a look, world community could join hands together only in 1945 that marked not only the period of world wars but also the beginning of the most successful attempt of international coordination for peace and security. Post Second World War, the attention of international community was driven towards ensuring peaceful co-existence of States by dodging episodes of conflicts until 1970s, when the world awoke to the need for international coordination and this time it was not related to war or issues aftermath but for protection of human environment. Though national legislations on environmental protection existed in some States, the world community realised and acknowledged the need for 'common outlook and for common principles to guide the world in preservation of human environment' (Stockholm Conference, 1972). This phenomenal effort by world community later ushered the way for international treaties and conferences on environmental protection in the following years. Soon it was apparent that challenges to changing environment could not be dealt domestically and called for global law and regulations.

However, issues of health care did not meet similar fate. The history of international health diplomacy goes back to 1851 when Imperial powers of Europe assembled to deliberate coordination on epidemics prevalent in the then continent [David P. Fidler, 2001] in International

Sanitary Convention further culminating into treaties on infectious diseases starting from 1892. Significant development in international health governance was the creation of 'Office International d'Hygiene Publique' (OIHP) in 1907[2] that served as a forum for discussions and exchange of information on public health. However, this institution failed in its attempt to coordinate health issues followed by Health Office of League of Nation which crashed with the outbreak of Second World War. It was the formation of United Nations (UN) in 1945 that coordinated the efforts of international community, required for health governance. With protection of public health as one of the fundamental functions of UN, World Health Organisation (WHO) emerged in 1948 that acknowledged standard health as fundamental right of all humans and the same being instrumental in attaining the ultimate peace and security. It also recorded the need of corporation of not just States but also of individuals. Since the organisation enjoyed the power to frame regulations under Article 21, International Sanitary Regulations (ISR) 1951 later renamed as International Health Regulations (IHR) in 1969. These regulations like past, regulated the popular epidemics like Cholera, Plague etc. with little modifications in 1981.

These regulations by end of twentieth century were considered ineffective in terms of combating emerging challenges in epidemics like SARS, HIV/AIDS and Tuberculosis, measures of enforcing compliance by States and weak response strategies to transforming economic and technological environment[1]. Further the advent of SAARS in 2003 also questioned the incompetence of regulations to achieve the objectives of WHO. These developments ushered new IHR in 2005 that promoted protection of public health from emerging epidemics (EDP) by obliging States to enact laws that in tandem with its obligations under trade agreements.

In the same era, private entities had also increased their investments in health care institutions as part of globalisation strategy. The IHR 2005, were also truncated in the manner that regulated policies and imposed obligations to be fulfilled, by the Member States and no regulations or obligations on private players.

Further, though the Constitution of WHO empowers it to chart out conventions, ensure its adoption in Member States (Article 19), authorises to draft recommendations under Article 23 making it capable of attaining, in words of preamble, the highest possible level of health. The only convention on health so far has been in 2003 when Framework Convention on Tobacco Control (FCTC) was adopted which historically tuned into the most ratified treaty across the world (so far 166 States). It also spurred civil society organisations hold accountability of States in furthering the obligations under treaty such as taxation of tobacco goods, prohibiting advertisements and enactment of appropriate legislations. As proclaimed by WHO its goal is to build a future that is better, healthier for humanity (WHO website). This can be achieved only when efforts undertaken by other international organisations to combat risks on global health are synthesised together.

JOURNEY FROM INTERNATIONAL HEALTH CARE TO GLOBAL HEALTH CARE: NEED FOR PRAGMATIC APPROACH

For Aristotle, health was the first virtue that promotes a well-being of a human. His ideas on health, medicine and medical ethics have shaped the practices of healthcare that continue to take its form even in modern day healthcare practices. Even when world pledged in unison to mitigate situations that vitiate human rights in 1948, right to adequate health and wellbeing of self, family also found its place in the Declaration (Article 25), followed by another milestone in 1966 when twin covenants on civil and political rights (ICCPR) and social, economic and cultural rights (ICESCR) acknowledged right to physical health and mental to the highest attainable standard. These conventional developments recognised the right to health as crucial to civil, political social, economic and cultural rights of humans. This multi-dimensional approach in the recognition of right to health continued with United National Development Programme (UNDP), United Nations Environmental Programme (UNEP) that acknowledged the right to health and healthy and safe environment as human right respectively. Justice Weeramantry of International Court of Justice recorded in her dissenting opinion in the case of *Hungary v. Slovakia* [1997] ICJ Rep held that protection of environment is since qua non for enjoyment of right to health and life.

Historically, issues affecting health were discussed, resolved with regional cooperation by States. The globalisation network has brewed new challenges and issues for the world community pushing it towards the concept of global health governance. The rampant

mobility of people since last century is now one of the major reasons for widespread epidemics from one continent to another. A classic example is of SARS in 2002 that pulled attention of world towards the need for global coordination in matters connected to health that originated in China and later spread to 26 countries within the span of a year. Recently, the Ebola virus Disease (EVD) outbreak also alarmed the world of the new viruses originating from underdeveloped States and created havoc in other neighbouring States by causing deaths of 11,310. The WHO response to such epidemics has been in form of increased operations teams in the affected areas, mobilisation of Global Outbreak Alert and Response Network (GOARN), guidelines for experts etc have resulted in phenomenal contribution towards its control and prevention. If epidemics received media coverage worldwide, other issues subsisting like integrity of medical data, growing threat to right to privacy of medical data, medical tourism and drug access and affordability somehow escaped the response of WHO. These emerging issues have been continuing to create hurdles in the goal of global health care. Before dealing with the issues, let's understand the idea of global health care.

Until mid of twentieth century, health care was not paired up with the term 'global' but 'international' for health care issues comprised of only epidemics that were dealt with funding, foreign aid and expert assistance. The obligations so far have been equated to foreign assistance that aid in improving health care conditions[3] and have not taken shape of obligations on the international community as a primary concern in all leading policy developments and agreements. Thus, the philosophy fostered by global health care considers health as a shared global interest especially with respect to developing states who don't just bear duty to protect rights and create equity but are also right holders relying upon cooperation of international community for assistance in public health programmes and global challenges[3].

This global health care gives way to the global health governance contemplating health as a threat to not just national security but human security - a global public good[4]. Global health governance thus postulates global health as morally binding on the world community. It calls for a global health justice by way of global health law that governs the community at large idolising the duty to ensure 'health for all'.

INTERNATIONAL ORGANISATIONS AND GLOBAL HEALTH CARE:

It is now certain that globalisation approach has widened the gap between the rich and the poor in the developing and underdeveloped States. It is observed that the poverty is reducing at a rate much lower than anticipated, inequity in access to basic resources, transnational issue of epidemics have further aggravated the health care issues. Assessing the gravity of impact of poverty rate on global economy, WTO targets to eliminate extreme poverty by 2030.

Internationally, organisations like UNDP, UNEP and World Bank have undertaken projects that promote better health care conditions in the policy making process of developing States such as integrating norms that protect public health from HIV, Malaria, Tuberculosis etc. An example of such close association of UNDP in working with governments lies in the recent success story of Kyrgyzstan, where court of law upheld the human rights of a person affected by HIV when a doctor facilitated the broadcasting of patient's medical condition without his knowledge and impinged on his right to privacy. UNDP supported the litigation of the patient through legal aid measures. Efforts of UNDP are restricted not just to the HIV and diseases but to improve living conditions so as to enable the adaption of life to changing climatic conditions and thus increasing the short life span. In 2007, World Bank's Health Development strategy aimed at development of reproductive health of people and facilitated family planning measures. Other include Health project in Liberia that covers financial assistance for better maternal, neonatal health. Fourthly, the initiatives of World Health Organisation have been so far only on Emerging Infectious Diseases in the form of International Health Regulations from the year 1996 and latest being IHR 2015 as a response to Ebola virus in Afro and Asian Continent. The focus of IHR and WHO has been restricted to the control of proliferation of epidemics and EIDs[5]. Though the organisations have been working with overlapping objectives, the same have not been able to answer to the issues beyond infectious diseases. Challenges like growing inequity with respect to access to basic medicines, economic barriers to medical facilities and other issues that prevent poverty stricken people from availing health care benefits however have remained unattended by the international organisations.

RIGHT TO HEALTH- A RIGHT MORE THAN SOCIO-ECONOMIC ASPIRATION:

The debate in international law over right to health circles around two focal points of discussion. *First*, whether right to health is a justifiable human right like civil and political rights or mere justifiable aspirations like socio economic right? *Second*, the role of State with respect to the right. The role can be gauged only when the legal position of the right is clear and therefore it is significant to point out the *dichotomies* prevailing under the umbrella term of human rights. Civil and political rights entail right to life; right to self-determination; right against exploitation etc that as considered by liberalists are negative rights with States obligation of non-interference whereas social, economic and cultural rights cover privileges of positive nature rooted from morality for instance, education, food, shelter, health etc. Interestingly right to health is explicitly found under Article 12 of International Covenant[6] on economic, social and cultural rights, 1966 and not under Covenant on civil and political rights. The only mention of health under the latter is carved out in terms of the exception that allows State to restrict rights recognised under it. Since right to health encompasses of multiple facets like health care, access to medical facilities, securing social and economic conditions that promote health and existence of suitable environment, the fulfilment of these obligations are variably dependent upon the economic growth of the State. They come with heavy burden on the resources for if the right is made justiciable, demand for access to medical facilities may not correspond with the capacity of the State and thus it shall be held responsible for violations of human rights[7].

It is difficult to fathom how an individual will exercise his/her guaranteed liberty and life in absence of education, shelter, food, healthcare that enable a rational thinking and develop capacity to make just use of all negative liberties. An impoverished state of health makes concessions with people's liberty [Washington v. Glucksberg, 1997]. An individual's potential is nurtured with adequate health care, food, nutrition, a home for security and the education he/she receives. Thus, negative rights award an individual with life however, positive rights awards a meaningful life that an individual may really aspire[8]. The Supreme Court of India based on this rationale held in the case of *Consumer Education and Research Centre v. Union of India* [1995][9] that 'right to life under Indian Constitution envisages life as more than animal existence – a meaningful and purposeful life with dignity' and read right to healthcare and medical facilities as part and parcel of right to life under Article 21. Therefore, these rights are more than just justifiable aspirations that negative rights pursue. A classic example is of Indian State that has guaranteed positive rights with legislative protection; right to 'free and compulsory elementary education' to children in India under 'Right to Education act, 2009[10] and Right to food under 'National Food Security Act, 2013[11] to people living under poverty line. Statistics by World Health Organisation suggest that in 2015[12], of 56.4 million deaths throughout world, 54% were due to medical health issues. States in modern world are welfare States that govern themselves on socialist model working on egalitarian principle. The growing inequities in health care opportunities and poverty have emerged as the root causes of ailing health. Therefore, a welfare State cannot brush away its obligations towards health care of its people on the premise of justifiable aspirations. It is difficult to fathom a welfare State that does not support conditions that favour a better health of people. Health of an individual is of paramount significance and thus acquires precedence over all other human virtues endeavours[13]. All human endeavours are hollow without a healthy body which is an imperative of sustenance.

Poverty and growing inequity in distribution of resources have emerged as the priorities of global justice [Pogge, 2001]. Healthcare issues stemming from these are also thus a priority and in a globalised world a challenge can be dealt with only global collaboration. The burden on low and middle income groups due to health care inequity demands global health financing in order to secure sustainability and equity [Shared Responsibility for Health- 2014] as analysed[3].

EMERGING ISSUES *VIS-A-VIS* GLOBAL HEALTH CARE:

Right to Privacy of Medical Data- Analysis of Legal Framework: The modern day *Magna Carta*- UDHR under Article 12 declares that 'no person shall be interfered with his/her privacy *arbitrarily*'[6]. This statement explains that only arbitrary interference with privacy is prohibited and not reasonable interference. Invasion thus does not violate human rights as long as it's reasonable. The need to protect individual's right on one

hand and interest of society, nation and public interest has kept alive the tug of war between right to privacy and national and public interest. Paul Starr[14] describes it aptly as a *'Haystack in a Hurricane'*. Complete dominance of one over the other would impair the concept of a modern welfare State which involves the constant process of securing its national interest but also struggling to live up to the responsibility of protecting human rights of its citizens. Different interpretations have resulted in different laws relation to right to privacy with respect to medical data which amounts to informational privacy[15]. For instance, in United States understands national and public interest as superior to right of privacy especially in terms of medical data. In the case of *Board of Education v. Earls*[16], the school had mandated drug test on students to participate in any extra-curricular activities. The results of the tests were not managed properly by the school and that led to disclosure of medical information of some students. The measure in this case was the harm caused to students because of disclosure and not the fact that disclosure of information is in its state the actual harm[17]. Though the Health Insurance Portability and Accountability Act, 1996 prohibits use of medical data by insurance companies for use other than necessary for insurance coverage, treatment or health care[17].

European Commission on Human Rights while interpreting Article 17 of the Convention on Human Rights upheld respect for individual's self-realisation and autonomy as one of the goals of right to privacy. In the *T.V v. Findland*[18] case the European Human Rights Commission held that disclosure of personal medical data to prison staff will be justified only if staff maintains strict confidence of such information. However, in *MS v. Sweden*[19] a hospital communicated the information regarding medical data of the patient to an insurance company without the consent of patient and Commission held that such disclosure without consent of patient amounted to violation of right to privacy under Article 8. Unlike the United States Supreme Court in the case of Board of Education, Commission did not consider the harm caused to the patient due to disclosure of information to a government insurance authority but condemned the actual act of disclosure. These instances are indicative of the balanced approach adopted by EU to protect the right and maintain national or public security.

International Covenant on Economic, Cultural and Political Rights under Article 15 as well as the Article 15 of the European Convention on Protection of Human Rights and Dignity both codify the freedom to conduct research in biology and medicine as this research promotes innovation and scientific progress in the society and also fastens obligation on State to ensure environment conducive of such research[15].

Medical data like banking consumer data is the kind that requires utmost privacy[20]. The nature of relationship between patient and medical practitioner is that of trust and confidentiality. Physicians bear the duty to their patient and to the health of their communities. A breach of privacy is therefore breach of the fiduciary relationship. The rationale behind this confidentiality is that unless a patient is assured that his information will be kept private and his identity shall not be disclosed or published with medical information, he/she will never confide and reveal information crucial for diagnosis[14].

Medical Tourism and Global Health: The concept of medical tourism is based on the movement of people from their home country to another country for a health care treatment. This movement, until previous century involved citizens from developing country flocking to westerns States for the purpose of accessing advanced medical treatment facilities that lacked gravely in their home countries[Hill, 2012]. Since, the expense of medical treatment in the developed countries remained at high levels like in US and European patients strived for medical attention due to long tenure of intervals in treatments, private hospitals in developing world meanwhile ensured that physicians were trained under medical officers abroad and that's how developing countries became a big attraction for medical tourists[21]. In 2003, the then Minister of Finance, Shri Jaswant Singh announced the future of India as a major destination in global health[22]. The Recent liberal policy drive on visa undertaken by government in a magnetic attempt to draw tourists (medical) in India.

Since the sector remains unregulated in developing countries, a new trend is noticed in medical practitioners who, allured by high demand clubbed with fat income packages, are now oriented towards practising and specialising in treatment preferred by medical tourists. Government hospitals are the most affected by it as they are suffering from dearth of doctors. For instance, around 100 Primary Health Care centres in Odisha still await the presence of doctors with more than 1300 positions for government doctors lying vacant. The State of Gujarat

and Jammu and Kashmir suffers from same plight. Further, the Rural Health Statistics, 2016 by government of India revealed that depleting human resource in hospitals of rural areas is one issue not adequately addressed by government. In addition to this, though this industry promises economic surge to the destination States, they are burdened with greater responsibility of creating conditions that bloom the sector such as lease for land, subsidies, tax rebates etc along with the responsibility to eliminate the prevailing health inequity. This has produced disparity in terms of access to medical care of highest standard and contributed to polarization between rich and poor in developing country[23].

The second unaddressed area in medical tourism is the contract formulated between patient and the health care professional agencies. With the growing popularity of the concept, many websites, portals of such agencies contact patients and execute the agreement online keeping in mind their convenience. A patient's choice is usually truncated by barriers of costs. He/she is compelled to accept such offers and later in case of medical negligence on part of health professionals is prohibited to claim legal remedies due to such arbitrary clauses. Health is the top notch concern for an individual and any compromise with medical treatment is likely to produce barbaric consequences on an individual's life and other negative liberties. Therefore any exploitation on this basis must be condemned globally.

CONCLUSION

In addition to this, the emerging trend of medical tourism has surfaced new challenges. The issue of jurisdiction in respect of medical negligence on part of health care professionals of host countries, damages in case of infringement of privacy of medical data due to data transfer, increasing burden on host countries and growing disparity on terms of access to medical healthcare facilities by rich and poor have not been attended appropriately. The question of global justice with respect to health care issues continues to remain as a big question mark. In the light of the issues and challenges demonstrated above, the authors have recommended the following.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Medical Tourism: A New Challenge to Right to Health in a Globalised World

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ABSTRACT

This paper focusses on the medical tourism with special reference to various challenges to right to health in globalized world. Although there are few existing laws that prescribe standards of care by medical practitioners, there is a need to have and express law that protects and safeguards patient rights of those coming from other countries for treatment in India. While there are well developed malpractice laws in many developed countries in India the protection available is nowhere near. There is a need to provide more transparency in the health care sector from the government. Better regulation to help in the growth and sustenance of Medical Industry and trade in services through medical tourism.

Keywords: *Medical tourism, Right to health, Medical industry, Globalization*

INTRODUCTION

Opening of the national borders to international trade which includes trade in services has provided a new impetus to the health care sector in India. With healthcare becoming expensive in developed countries it is expected that India's medical tourism industry will double in size to around 8 billion dollars from its current size of 3 billion by 2020[1]. Globalization has taken medical services from being a regional and local matter to a global business. Cross border trade in services includes health care services and India is second only to Thailand in the number of medical tourists that it attracts every year[2]. Scores of people from developed countries travel to India for medical procedures that ranges from cosmetic surgeries to cardiac bypass surgery to Surrogacy and IVF treatments.

Eman Ahmed Abd El Aty, the Egyptian who weighed nearly 400 kg and was perhaps the world's heaviest woman is the most recent case of medical tourism in India where her sister brought her for bariatric treatment. She went back weighing approximately 175 kg less but with lot of disgruntle at the services she received while her medical treatment was underway in India.

Technological progress and advancement has further helped improving transcontinental medical consultations. Business Process Outsourcing (BPO) services in areas such as laboratory investigations, software development, medical transcriptions and telemedicine are provided by countries such as India, China, Korea, and Japan. Globalisation has opened markets as well as increased competition between different players and market. As a result health care sector and companies have become global players.

Tourism itself has been categorized as religious tourism, student tourism, medical tourism, health care tourism where healthcare tourism also includes within its purview travel to spas and wellness resorts and alternative therapies while medical tourism is limited to travel for the purpose of bio medical procedures. The term medical tourism was coined to show the growth in travelling across borders to other countries to get better medical care and facilities. There are many factors responsible for increase in medical tourism which includes cheaper tickets, communication channels, super specialty medical services, qualified medical practitioners and better affordability. Improvement in communication systems has also been a factor for increase in medical tourism[3]. Medical tourism is not a new phenomenon. Ancient Greeks used to travel to spas known then as *askepia* in the Mediterranean region for purification and spiritual healing. Romans had constructed the *aquae sulis* reservoir in the now British town of Bath to which foreign patients have travelled for healing for thousands of years[4]. Trade in health services has assumed significant importance especially for India

where the medical service is affordable and of good standards. India provides world class medical facilities with hospitals and specialized multi-specialty health centers providing their expertise in the areas ranging from cosmetic surgery, heart surgeries, kidney transplantation, IVF, Surrogacy etc. With the availability of excellent medical services India is becoming a much sought after medical tourism destination. There is a need to assess the regulatory framework currently in force in India. Last few decades has also seen an increased interest in alternative medicine and India with its Ayurveda, yoga and other forms of holistic treatment remedies. From an estimate in 2004 of 150,000 foreigners seeking medical treatment in India there has been a projected increase by fifteen percent annually for the next several years[5].

With the remarkable increase in the scale of the industry and increasing number of foreign nationals travelling as medical tourists to developing countries such as India there are a large number of legal and ethical concerns that have been raised in the last few years.

India and Medical Tourism: India provides world class medical services with multi-specialty health centres providing expertise. Although Allopathic treatment is widely prevalent in India and there is a huge amount of funds allocated for it in the health care budget, India is the birthplace of holistic treatment such as Ayurveda and yoga and it is an integral part of the Indian system which is gaining popularity with the western people[6]. People travel to India to experience the holistic medicine and the authentic experience which India offers. There are various reasons for medical tourism gaining popularity in India and this could attributed to long waiting lists for patients in developed countries, low costs of medical treatment in India, world class technology of medical services, affordable travel costs and advancements in mode of communications.

Medical tourism in India has provided the economic stimulus to geographical. It has improved jobs, income, quality of life and technology transfer in India. It has promoted infrastructure development to support the industry. It has also prompted continued education and training. India offers world class healthcare at costs substantially less than that in developed countries using same technology delivered by very competent medical practitioners. With the advantage of being an English speaking nation it encourages patients to come to India as a preferred destination for medical treatment. Indian hospitals don't lack technical skills but difficulty lies in leveraging the soft skills of employees. There is a need to create effective environment, building professional competence through competent health care managers.

Reasons for Growth of Medical Tourism in India: Coming to India for medical treatment provides a variety of advantages for the patients including financial cost savings and increased treatment access[7]. In a cost driven environment many uninsured and under insured patients travel to India to get good medical treatment and save costs. Patients urgently needing treatment and those unwilling to wait for long, travel to India where treatment is readily available[8]. Medical tourism in India is a manifestation of globalisation.

India has the advantage of lower labour and living costs. It also boasts of availability inexpensive medicines. India offers certain medical procedures at costs much lower than that in developed countries.

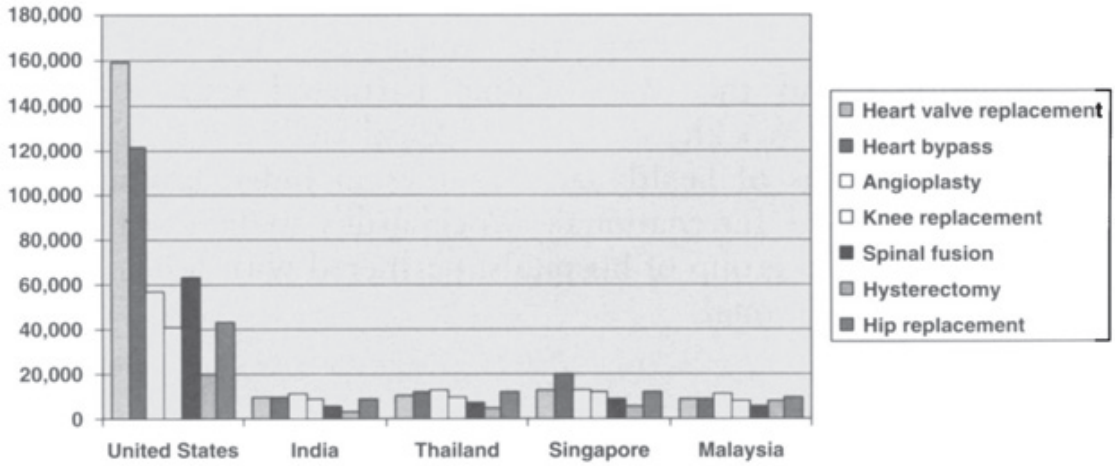


Figure 1: Comparative costs of selected medical services. Sources: ESCAP[9], York[10]

ISSUES IN MEDICAL TOURISM

Medical tourism highlights certain undisputable risks including risks of medical travel for patients, lack of information, unforeseeable costs that patients have to incur in destination countries, medical complications, and inadequate legal redressal forums for malpractice or death. Though medical tourism is linked to globalisation and trade, it is distinctive because it does not deal with manufactured goods but with human beings who are at times seeking lifesaving and essential treatments. It has far reaching impact on the meaning of human dimensions of care which is an integral part of medical care such as doctor patient relationship, communication between doctors and patients and the softer human side to the relationship.

Medical tourism carries with it many risks including those involving international travel both while travelling to the destination country or during the return travel. There may be issues in patient screening before and after the treatment and follow-up care may be inadequate due to the long distance relationship between the physician and the patient. Physical examination is not possible especially during the post treatment palliative care period especially if there are complications arising subsequently after the patient has returned to his/her home country. The quality of health care is not uniform between countries and varies significantly. Lack of centralized regulation of medical tourism and data collection makes it difficult to measure quality of treatment and aftercare services that are provided.

There is no international legal regulation of medical tourism. Every medical procedure may have an element of risk. The issue of legal recourse for substandard or unsatisfactory treatment across international boundaries is a legally vague issue.

Courts are usually unwilling to assert jurisdiction over doctors who neither reside nor practice within their jurisdiction. Even though the long-arm statute is usually available to patient back in their countries, medical-tourism plaintiffs most of the time face an uphill battle on the jurisdictional front. In case if there is any malpractice or negligence on the part of the health care providers in India the forum state does not have jurisdiction over a nonresident physician simply because the plaintiff does not reside there. However courts have held that the place where the patient resides is inconsequential in a jurisdictional inquiry because medical services are "directed to no place but to the needy person herself"[11]. However, medical-tourism plaintiffs can sue in their home states if the courts where they bring their actions make out the "continuing tort" theory of jurisdiction where a plaintiff's home state court can apply jurisdiction over a nonresident physician whenever the effects of the physician's tortious act continues to be felt by the person after returning to her home state. There could be a possibility of the continuing tort theory being rejected on the ground of public policy as it could inhibit non- resident patients from getting health care facility abroad with doctors becoming wary as defending cases in foreign jurisdiction could be extremely difficult just as it is difficult for patients to institute suits in foreign jurisdictions.

Even if the aggrieved patient can show personal jurisdiction over the medical practitioner who is now a foreign defendant, the court is likely to dismiss the matter for lack of convenient forum (*forum non conviniens)* if the defendant can show that there exists alternate forum in the destination country. Further damage recovery may be difficult and less favourable to patients as compared to recovering them in their domestic countries.

Medical tourism could be categorized into services that are illegal in both countries ie the destination country where the patient comes for medical treatment and the country to which the patient belongs, were the services are illegal in the country that the patient belongs but not illegal in the destination country and cases where the services are legal in both countries. In the first two categories there is a direct negative impact on the country where the patient comes for medical treatment and also raises ethical issues and its impact on the people of the country which provides such medical treatment.

Many a times the foreign patients medical costs are covered by insurance companies which raises concerns for the patients from substandard quality of medical care, de facto waiver of rights as provided in the policy in case of medical malpractice and right to compensation for medical errors which may have occurred during treatment and laxity in providing medical care as a dynamic effect. There may be a need to structure fair health insurance policies and plans which will take care of patient protection.

Growing Concerns in Destination Country: The growth in medical tourism has been an advantage and boon for many who prefer India as a travel destination for their medical treatments there have been concerns that have been raised regarding the interests of those in India who are unable to get the much needed medical assistance for various reasons. While enormous medico-industrial multi-specialty hospitals complete with the best of the facilities and technology is available in the country to provide for the wealthy medical tourists there are many who are dying in the country because they are unable to garner financial resources for even more common ailments such as malaria, tuberculosis, AIDS and cancer. It is an irony when a country goes extra miles to provide for wealthy patients from within and beyond the borders but allows those who are poor to fight destiny. Medical tourism brings out the lack of parity in the quality of care and malpractice recovery[12]. Without proper regulation which is absent today the higher payer patient souk will result in health care providers to focus more on these wealthy patients shifting away from treating patients from lower paying bracket.

Medical tourism also encourages higher salaries being provided to the health care professionals who in turn may discourage access to poor natives and instead of improving social development it may aggravate existing inequalities and further polarize people. This will also promote doctors and other medical staff to move from government hospitals to private hospitals which cater to the rich. Medical Tourism leads to medical migration, medical outsourcing and research tourism. There is also a benefit that Pharma companies may derive from medical tourism.

OBSERVATIONS AND SUGGESTIONS

India's private hospitals have gained international repute in providing excellent health care with its state of art facilitates and unmatched skills. International patients can combine leisure with treatment facilities available in the country. There is a need to regulate medical tourism in India in order to promote this service sector which has a very high potential for growth in India with its many advantages. Currently, medical tourism industry is a highly unregulated sector. There are a few regulatory frameworks that are in existence however they differ in effectiveness and are inadequate to deal with the unique challenges of the industry.

The Confederation of Indian Industry has done considerable work on providing guidelines for medical tourism in India. Under the Incredible India - The Global Healthcare Destination initiatives an Incredible India brochure has been released by CII / IHCF along with Ministry of Tourism for promoting India's healthcare sector at international stands. The brochure showcases the India Advantage as a health destination not only in the area of Holistic Approach & Wellness but in specialties such as Cardiology, Orthopedics, Minimally Invasive Surgery, and Cosmetology. The brochure also gives information about the Medical Visa issued by the Government and contains a list of Indian hospitals. CII has also come out with a Price Band Report which gives an insight of the price packages offered by Indian Hospitals. The committee has also been actively Partnering with the Ministry of Tourism for branding India's healthcare sector globally at eminent international events like New York Times Travel Show, WTM, ITB etc. A lot of initiatives are also being taken by the committee to work in tandem with the tour operators in the area of medical tourism[13].

There should be regulations framed which will provide a positive incentive to public health care facilities. A physician or other health care providers who benefit from medical tourism - in terms of economic benefit or human resource development in the form of trainings, should be incentivized for treating the poor and the needy. There needs to be regulations that force them to treat the poor. Most cases private hospitals do not honor the promise of treating the poor in spite of subsidies received by them in the absence of a forceful enforcement mechanism.

We may promote medical tourism with the hope that the trade in services through medical tourism will have a trickledown effect in the destination country but unfortunately internal problems such as corruption or the fact that a facility is largely owned by a foreign sector may make such targets impossible to achieve.

There are medical tourist firms that have set shops who help patients with all requirements and facilitate the process and these firms could also take the responsibility to assist in case of any legal complications[14].

Multilateral trade agreements initiatives can be undertaken to promote and improve trade in health care sector providing for mutually agreed quality of standards

for medical care and protection of patients although it may be argued that such agreements could be ineffective as agreements usually restrict rather than facilitate and enhance trade. Medical tourism can be regulated through GATS as it regulates cross border movement of tourists.

CONCLUSION

Although the Indian Medical Council (Professional conduct, etiquette and ethics) Regulation, 2002 and Indian Medical Council Act 1956 are few existing laws that prescribe standards of care by medical practitioners, there is a need to have and express law that protects and safeguards patient rights of those coming from other countries for treatment in India. While there are well developed malpractice laws in many developed countries in India the protection available is nowhere near. There is a need to provide more transparency in the health care sector from the government. Better regulation to help in the growth and sustenance of Medical Industry and trade in services through medical tourism.

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Conflict of Interest: Nil

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Need for Design Intervention Towards Building Conducive Patient Friendly Intensive Care Units for the Critically Ill in India

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ABSTRACT

Hospitals in India are equipped with medical facilities unparalleled compared to that in the west. New equipment is added to hospitals at lightning speed. Least contact methods are being attempted in special surgeries. Specialities are increasing and research in medical science is reaching a pinnacle with private drug companies chipping in for clinical research. Mortality rates in three top rated private hospitals has seen a rise in the last five years (according to two intensivists and one Male Nurse).

Despite all efforts to make the humankind free of disease, deaths due to disease are recorded in Intensive care units. Designing care units of Hospitals in India, is ignored. Design detail at System level as design intervention would reduce inconveniences that are encountered by people using the services of the hospital.

Patients discharged from ICU, relatives of the diseased and several people connected with hospital have been interviewed. Problems are highlighted by the subjects interviewed, in the hospital the care units. In order to counter some of the highlighted negative aspects of the care units from a design perspective some recommendations are provided with evidence.

The care systems in hospitals in India need to treat people holistically in some cases and the business has to empathise with relatives of patients.

Keywords: *Alternate Therapy, Care givers, Design Intervention, Healing, Hospital ICU.*

INTRODUCTION

Facts about private hospital systems are presented herein on interacting with Ten patients from five multi-speciality hospitals across the country, relatives of patients, relatives of the diseased, Five ward boys, Twenty Nurses, Two intensivists, three Aayas (helpers), one Bio medical equipment supplier and three Bio medical engineers. Personal experience by visiting hospital about 15 times has prompted the author to ponder on recommending design intervention and proposing solutions to the prevalent problems identified in Hospitals.

Private hospital is essentially a company; "A system that provides services to people in need services and pay for services provided". In the literal sense the prime focus of the hospital is generating monetary profit and hence private hospital is a business. Essentially with service comes a huge responsibility towards individuals who avail the services. The systems involve people and lives that depend on the quality of service provided by people in the hospital. Despite having the best equipment, patients do not like getting admitted in the intensive care units[1-2].

METHODOLOGY OF CONDUCTING THE STUDY

Data was collected by Informal interactions and recorded on interaction. One doctor from a private hospital, willingly participated in answering questions by telephone. The doctor from a local hospital talked in person during a visit to the intensive care unit. Male nurse from a private hospital willingly spoke on telephone. The other nurses talked in person. Data was collected from the patients on personal interaction[3].

- One patient terminally ill with cancer, likes the care unit and he requests admission into the ICU. He vouched that he is "taken care" of well. All other patients have innate fear of being admitted to the intensive care unit.

- Relatives of the patients made the following statements: "cannot see the person", "they want only money", "they don't care", "let my dear one get well soon".
- Nine out of ten patients used the following words to describe the ICU: "hate ICU", "scared", "feel lonely", "feel I am dying", "other patient died", "doesn't feel like home", "cannot make out the time", "staff unfriendly", "doctors are nice"
- The comments of all the nurses interviewed are: "we are doing our duty according to patient care charts", "patients demand too much", "patients want attention", "you cannot expect much recovery of old patients" "patients act crazy at times" "ICU psychosis? … these patients only "ACT". there is no such a thing as this".
- The responses from doctors is: "let us wait and watch", "time will tell", "we are not God".
- Responses from the bio-medical engineer and supplier: "doctors and staff do not know about personal care equipment that a patient has. They do not know to set them or do not know the use of these equipment" [4-5].

ANALYSIS

From the interactions it is found that people an innate fear of the hospital care units. People avoid going to doctors and self-medicate. This behaviour is observed among most people for the fear of being admitted into hospitals for healing a disease/condition. ICU Psychosis is not addressed by the staff and doctors in India. The hospital care units are run like a business life and death are treated as an "ON-OFF" mechanisms akin to switches in a circuit. Indian society is culturally rich. Sentiments of the people must be taken into account whilst designing systems. Geriatric patients do not get the respect they desire. Change in condition to the worse in the geriatric patients is more often treated as expected outcome of age. There are instances where the change in condition of the patient is not observed by the staff in the care unit and is reported to the intensivist by the attendant, who is a family member of the patient.

Some of the factors that contribute to healing a patient are

(a) Environment in which the patient is being treated.

(b) Psychological state of mind of the patient.

(c) Emotional state of the patient.

(d) Skill of staff attending the patient.

(e) Equipment used in treating the patient.

(f) Medicines used to treat the illness/condition of the patient.

(g) Alternate therapy to heal comatose patients.

Each of these factors is taken up from the designer's perspective and probable solutions are highlighted as an immediate necessity towards an efficient system design for a conducive patient friendly intensive care units [6-8].

Problems in the Intensive care units and Probable Solutions as recommendations:

(a) Environment in which the patient is being treated - The environment of Intensive care unit is unfamiliar to a patient and the family attending the patient.

(a1) Difference between Day and night cannot be distinguished inside the ICU. The lights are bright due to which the patient is deprived of sleep and sleep pattern is erratic. In one instance the erratic sleep pattern was construed as a disorder.

(a2) The environment and décor of the ICU is very depressing to the patients as the interior has curtain partitions and the colour of the curtains is monotonous. There is no entertainment for the patients to divert their mind from illness and surroundings.

(a3) For the family of the critically ill, the seating is secluded most often they are not fully aware of the efforts that are taken to treat the condition of the patient.

(a4) The temperature inside the ICU is too low 19°C-20°C. The human body temperature ranges from 36.5°C -37.5°C. For running biomedical equipment low temperature is ideal, but a human body finds it difficult to acclimatise to low temperature. When the patient is discharged the body is subjected to a wide variation of temperature differences suddenly. Sudden variation in temperate causes "fever" and sometimes re-admission into the ICU [9].

There may be multiple solutions to making the environment patient friendly. The colours of the ICU cannot be changed or modified.

A mini entertainment pad/console by the bed side with head phones can be installed by the bedside. This console attachment can be a feature in the bed or a separate unit by itself. If the patient can watch some entertainment programs or play a game. The console plays music if the patient desires and can be therapeutic.

The console can act as an indicator of time and date.

The Biomedical equipment can be housed in a separate cabinet at a lower temperature and the temperature of the ICU can be regulated.

(b) Psychological state of mind– A patient and their attendant a family member often come with a preconceived notion about the ICU. They are opinionated by the experience of other patients or individuals. Environment of the ICU and unfamiliar surrounding coupled with the medical jargons used by the staff, create an innate fear in the patient who is conscious. The family of the patient who are attending the patient in the hospital are subject to this torment. As internet is a vast resource, patients and their attendants are well informed of the disease and condition of the patient. In the Care unit they are not informed of the hourly changes in the condition of the patient. The attendants and the patient are totally demoralised and feel helpless. They develop loathe the entire system [10-12].

To Counter psychological effect on the patient, the attendant who is familiar to the patient must be allowed to be by the bed side of the patient.

The relatives of the patient must have accesses to the care chart and line of treatment. The relatives must have a visual display of the care console when they are in the waiting area outside the ICU.

(c) Emotional state of the patient: Emotional needs of the critically ill are often ignored in hospitals. Indian families are close knit and culture plays an integral part in the lives of most people. Many people are attached to children, pets, parents, spouse, siblings or friends. People are casual in meetings in real life and socialise informally. Patients in the ICU miss all social and cultural commitments and events in life. When isolated from society the patients are emotional and this has a negative effect on healing and in some cases cause depression, outbursts and feeling of helplessness [13].

In order to counter the effect of the emotions on the mental health of the patient it is recommended that:

A bedside entertainment console can be a transmitter and receiver from and to home enabling a personal connection to the home and loved ones. This set would give the patient will power to heal and to integrate with society through a virtual medium.

(d) Skill of staff attending the patient– Hospitals provide training to caregivers and helpers. Attendants and helpers in Mumbai live in shanties. They cannot cope the pressures of training. In one particular case 75-year-old female patient in ICU developed UTI. Her family member in the medical profession found out how exactly it happened. The helper was cleaning her faeces from the anal end she was moving her hand towards the urinary end because of this cleaning method the faces was entering the urinary tract causing infection. This was brought to the notice of the ICU intensivist. As an outcome of the complaint the relative was asked not to come inside the ICU [14].

The solution to this problem is that ICU staff must be open to constructive criticism and only a relative of the patient would be extremely vigilant to the care given to a patient. In cases where the patient is alone, the care givers must be trained to support the treatment by following the right procedures imbibed during training, imparted by the hospital.

(e) Equipment used in treating the patient - Patients have their personal equipment for use like a BIPAP or CPAP in these cases the hospitals do not have a bio medical in-charge to set up the machines to suite the requirement of the patient.

Relative or the care giver who is familiar with the patient's equipment must be beside the patient. The relative of the patient who monitors this machine on a daily basis is the best person to handle the setting of the machine.

(f) Medicines used to treat the illness/condition of the patient – In one particular case heparin was administered on trial to prevent speculated pulmonary embolism in a COPD patient. When the patient started bleeding from eye, and nose the ICU nurses refused to stop the heparin. The relative of the patient called the doctor in charge and finally the drug was stopped and the bleeding stopped. The male nurse attending the patient said "so what if she bleeds? its age related and happens commonly here ". Medicines are administered without correlating symptoms to the root cause of the symptoms. Nurses and care givers must be trained to discuss the case with doctors [15-18].

The above case establishes that care giver, a relative of the patient or a person familiar with the patient must be allowed to be by the side of the patient at all times. The care giver who knows and understands the patient will be sensitive and observant to report any change in condition of the patient.

In case of COPD repeated ABG tests are done twice a day that require drawing 5 ml blood each time for the number of days in ICU. The most disturbing fact is: to regenerate 5ml of blood in an old person at the age of 75years is impossible. In a situation, if the patient is hospitalised for 10 days in the ICU 50 ml of blood is drawn over 10 days. At the age of 75 years it is an alarming quantity of blood to loose.

This problem can be solved only by designing a small device that will monitor the ABG. There are no ABG monitoring meters are available in the market at present. **Instead of drawing blood for testing on a daily basis, a BIPAP machine must be continuously used till the other symptoms disappear (like nails turning to normal colour from black).**

(g) Alternate therapy to heal comatose patients: Patients in Coma sometimes respond with right inputs. In one case in 2010, when a patient was in Comatose state for three days, the relative took permission to try music therapy. The neurologist said the ear pod should not be used as there could be damage to the nerves and head phones could be used. The relatives took a bold stand of using ear pods. The doctors had given up on the patient so using ear pods or head phones would not make a difference to someone in a vegetative state. The relatives of the patient tried to experiment with music and dolphin screeches. There was no change in the patient. Next experiment was music alternating with the voice of her grandchild calling with a usual daily request. The music kept changing and the child's request changed. On the third day her condition reversed and asked to see the grandchild. The ICU staff was willing to allow the child inside [19].

Documented alternative therapies must be tried with the permission from the patient's family when medical science fails to heal the patient.

Need for Design intervention – At a system level design intervention is inevitable but at a micro level several smaller components need redesign.

(h1) Hospital Bed: The hospital bed needs to be re-designed. The mattress used on the bed is made of Rexene in India. The back of the bed is movable and needs to be tilted at an angle of 45- 60 degrees at times. During this time the patient slides down from the ramp [20]. The patient literally has to be dragged up and positioned in the desired angle. The patient repeatedly slides.

To counter the problem of patient sliding from the angular tilt of the bed, a movable and adjustable foot rest as in fig(a) must be provided so that patient can stop sliding down. In severe cases of comatose patients at present straps are used the foot rest could be an additional feature along with the straps.

(h2) Interface on the medical equipment is not visually ergonomic and gives rise to errors. The digital Blood Pressure monitors are not accurate. Blood Pressure is not monitored manually. There is always an error in the readings due this fault

The display of the Biomedical equipment and Blood Pressure monitors meters must be at the

eye level. Blood pressure must be monitored manually twice a day and values must be cross checked with the digital meter.

(h3) Sensors of various biomedical equipment cause injury on the skin due to suction pads and gel.

The sensors can be re-designed to be a wear on jacket with contact straps. This particular solution falls in the purview of Bio-medical equipment design.

(h4) Height of the food tray according to patients should be adjustable.

Adjustable trolleys can be designed to be used as an accessory to the hospital bed.

(h5) Hand written charts are hung at the foot of bed and the history of the medications and the history of the illness is recorded they are shabby as several people write on it.

As an alternative Care monitors can be provided to digitally record the data. Patient care monitors must be installed at the foot of the bed. Care monitors give the entire history of the patient. The patient data must be made available to the patients and the care giver on demand. This will help a patient to seek second opinion and enable transparency of the system[21-24].

CONCLUSION

From all the above cases problems sited are documented and design recommendations are suggested for the factors affecting the healing process of the patient.

It is essential that a relative is with the patient at all times during the treatment. Relative can be trained to be less demanding and stay by the side only for the psychological comfort and personal assistance to the patient.

Helpers must be trained adequately to manage critically ill patients. In addition to medicine the care of loved ones is essential in the full recovery of a patient.

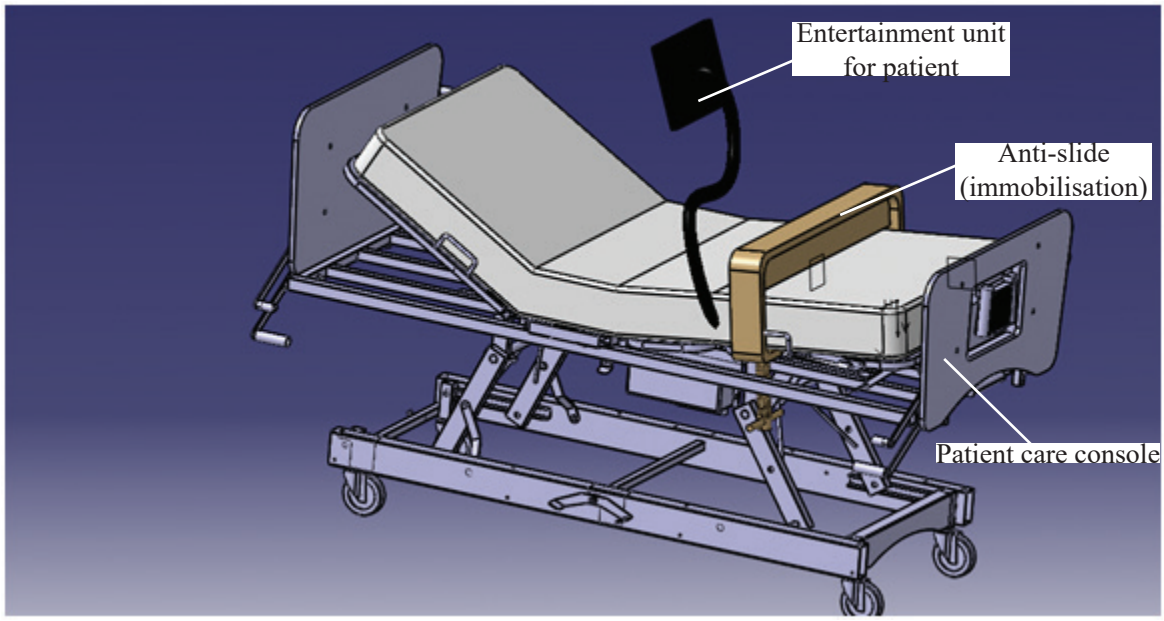
Transparency in the treatment procedure is essential at all stages of a patient in the ICU.

Design intervention with interdisciplinary approach, at every stage in the hospital care system will help redesign the care unit to make it conducive towards building a patient friendly intensive care unit.

Table 1.1. Patient responses to questions

Patient or Relative	Fear of ICU	Care in ICU	Temperature inside ICU	Social interaction with family/friends	Feeling	Entertainment and phone needed?	Need relative near you?
1.	No	Yes	Too cold	Don't care	Happy	Yes to attend business calls	No
2.	Yes	No	Too cold	Desire but Not possible in ICU	Depressed isolated	Yes to talk to family	Yes
3.	Yes	No	Too cold	Desire but Not possible in ICU	Depressed feeling of death	Yes to talk to family	Yes
4.	Yes	No	Too cold	Desire but Not possible in ICU	Depressed isolated scared lonely	Yes to talk to family	yes
5.	Yes	No	Too cold	Desire but Not possible in ICU	Depressed isolated	Yes to talk to family	Yes
6.	Yes	No	Too cold	Desire but Not possible in ICU	Depressed lonely scared	Yes to talk to family	Yes
7.	Yes	No	Too cold	Desire but Not possible in ICU	Depressed scared	Yes to talk to family	Yes
8.	Yes	No	Too cold	Desire but Not possible in ICU	Depressed scared lonely	Yes to talk to family	yes

9.	Yes	No	Too cold	Desire but Not possible in ICU	Depressed isolated scared	Yes to talk to family	Yes
10.	yes	no	Too cold	Desire but Not possible in ICU	Depressed scared lonely	Yes to talk to family	Yes



Fig(a) Anti Slide patient immobilisation device

This anti-slide immobilisation accessory is designed by Poornima Sajive Nair

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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A Time Motion Study in The Immunization Clinic of A Tertiary Care Hospital, BJGMC Pune

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ABSTRACT

Introduction: A time and motion study is used to determine the amount of time required for a specific activity, work function, or mechanical process. In the immunization clinic, time motion study helps to know time taken in different service delivery points in the immunization clinic.

Purpose: To determine the activity time at the service points in the immunization clinic

Material and methods: The present observational cross sectional study was done in the immunization clinic of BJ Medical College, Pune over a period of 1 month. The Study population was all the beneficiaries attending immunization clinic during study duration. Pre-synchronized stopwatches were used to record service delivery time at the different activity points.

Result: The total median duration for immunization was 61 mins. Of this, maximum median time i.e. 15 mins each was required for initial registration and for immunization registration (history, Treatment and HMIS entry) and the vaccination and post vaccination advice took comparatively less time (5mins and 2mins respectively).Median time for pediatric reference(if required)was 9 mins. Maximum median time spent on the vaccination was on Friday (68 mins).

Conclusion: A simple time and motion study of an OPD system and suitable inexpensive interventions can go a long way to improve the efficiency of a hospital. Separate arrangement for immunization OPD registration and up-gradation and increase number of computers for fast HMIS entry and prescription.

Keywords: *Time motion study, Immunization clinic, Tertiary care hospital.*

INTRODUCTION

A time and motion study (or time-motion study) is a business efficiency technique combining the time study work of Frederick Winslow Taylor (1881 A.D) with the motion study work of Frank B. Gilberth and his wife Lillian Gilbreth (1885A.D). It is a major part of scientific management (Taylorism) [1]. A time and motion study is used to determine the amount of time required for a specific activity, work function, or mechanical process. Motion study is designed to determine best way to complete a repetitive job while the time study measures how long it takes an average worker to complete a task at a normal pace. Historically the two studies are discussed individually; today they generally are discussed as one. The two techniques became integrated and refined into a widely accepted method applicable to the improvement and upgrading of work systems. This integrated approach to work system improvement is applied to determine schedules and planning of work in industrial as well as service organizations, including banks, schools and hospitals[2]. The objective of the Time and Motion Study is to determine a 'normal' or average time for a job, by using observers to record exactly how much time is being devoted to each task. With this objective, time and motion studies can be effective for performance evaluations as well as can be used for planning purposes[3,4].

During the last decade, the number of patients seeking Outpatient Department (OPD) services has increased many folds, but the facilities in the OPD have not increased at the same rate. The outpatient department thus requires a systematic study of its services for its efficient management and function. It is therefore imperative that a simple time and motion study of an

OPD system and suitable inexpensive interventions can go a long way to improve the efficiency of a hospital[5]. Thus, as the name suggests "time motion study" is concerned primarily with increasing performance by measuring and then minimizing the time taken to perform various operations without compromising the quality of services[6].

Few such studies have been reported in the outpatient department of hospitals, and such studies base exclusively on immunization clinic of an institute is a rarity. Immunization is considered as one of the most cost effective public health intervention which directly or indirectly prevents the bulk of mortalities in under-five children[7]. Hence, this present study was carried out in the immunization clinic of a tertiary care hospital, with the objective of determining the activity time at the service points in the immunization clinic, as such clinics dealt with the most vulnerable and sensitive section of the population, for whom satisfactory preventive and promotive care was essential.

MATERIAL AND METHODS

This was an observational cross sectional study done in the immunization clinic of B. J. Medical College, Pune over a period of 1 month (1st December-31st December 2016). The month of December was selected randomly to carry out the study. The study population included mother/caregivers attending the immunization clinics with their children. The total sample was 399. Before starting the study, ethical clearance for conducting the study was taken from the Ethics Committee of B. J. Medical College, Pune. Every mother/caregiver registering in the immunization clinic on the day of study was selected; the number of working days in the month of December was 26. Informed written consent was taken from every mother/caregiver selected for the study beforehand. A predesigned and pretested schedules were used to record time and other information, and pre-synchronized stopwatches were used to record total activity time(which included waiting time + service time). The immunization clinic was located in Pediatric OPD building (OPD No. 29, 30). The immunization clinic was open from 9.00 am till 1.00 pm an all working days from Monday to Saturday except on Friday OPD timings were from 9.00am to 2.00pm; reason being neonatal OPD was there from 1.00pm to 2.00pm. Data collection started at 9.00 am on all working days.

Time was recorded at the following points:

(a) Entry at hospital (OPD case paper+ waiting) in main OPD building

(b) Entry at Pediatric OPD (OPD No. 29, 30)

(c) Table 1- Nutritional Assessment (Entry time and Exit time)

(d) Table 2- Pediatric referral (if any) (Entry time and Exit time)

(e) Table 3- Immunization registration (History taking, Treatment and HMIS entry) (Entry time and Exit time)

(f) Table 4-Vaccination Proper (Entry time and Exit time)

(g) Table 5-Postvaccination Advice (Entry time and Exit time)

The following activities (Figure 1) were carried out in the respective immunization tables: At immunization table 1, nutritional status like anthropometric parameters i.e. Height and weight of all patients attending immunization OPD were done and according to growth chart patient was categorized for malnourished or not. At immunization table 2, patient was assessed for any medical complaints; accordingly patient was referred for pediatric opinion if required before immunization. At immunization table 3, vaccines scheduled according to age of patient were prescribed by doctor and HMIS entry was done on computer and order of paracetamol syrup if required for patient was done online. At immunization table 4, proper vaccination of patient is done with entry in the immunization card. At immunization table 5, post vaccination advice was given by nursing staff to mother/caregiver of child regarding post-vaccination care of child (regarding common side effects of vaccine and when to seek medical attention), nutrition of child, further immunization date for follow up and how to give paracetamol syrup prescribed by doctor to child was given to mother/caregiver.

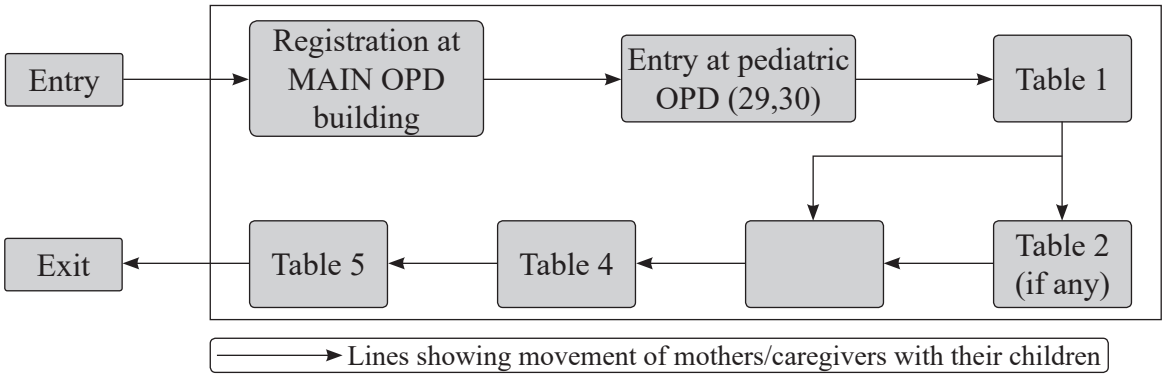


Figure:1Outlay of the immunization clinic at BJGMC, Pune

Motion of every mother/caregiver selected for the study was followed from the entry till exit from the immunization clinic in the above sequence, and time spent in the above mentioned activity points was recorded.

Statistical analysis was done by using Microsoft Excel 8.0 and using SPSS version 21. Time has been expressed as median (in minutes) and inter-quartile range (IQR) was calculated for each activity. Data was compiled and analyzed by using Kruskal Wallis test.

RESULTS

The study population belongs to 0-6 years age group; out of which maximum (63.6%) were infants (<1years) and 50.6% are female. Maximum of study population (72.2%) belonged to class II i.e. upper middle socioeconomic status according to Modified Kuppuswami scale; adjusted to price index December 2016.63.9% were from nuclear family,95.2% were from urban area and73.7% were Hindu by religion.

Table 1: Service Delivery time at different activity points

Sr. No.	Activity Points	Median time (in min)	% of total activity time	IQR (Q3-Q1)
1.	Registration at hospital (OPD case paper+ waiting)	15	24.59	20
2.	To reach at Pediatric OPD	10	16.39	5
3.	Table 1-At Nutritional Assessment	5	8.19	2
4.	Table 2-At Pediatric referral (if any)	9	14.75	4
5.	Table 3-At Immunization registration (History taking, Treatment and HMIS entry)	15	24.59	11
6.	Table 4-Vaccination Proper	5	8.19	5
7.	Table 5-Postvaccination Advice	2	3.27	1
8.	Total activity time	61	100.0	30

The service delivery time at the different activity points was presented in Table 1.

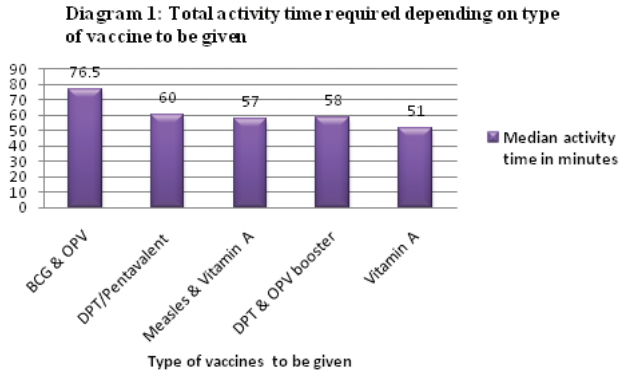
In the initial registration at OPD main building, the median time taken was 15mins (IQR-20mins).The median time taken to reach pediatric OPD was 10 mins (IQR-5mins). The median time taken for nutrition and health assessment was 5mins (IQR-2mins). If any child requires pediatric referral, the median time taken was 9 mins (IQR-14.75). At Table 3 where immunization registration (history taking, Treatment, HMIS entry) was carried out, required median time of 15mins (IQR-11mins). Vaccination advice at Table 4, took median time of 5mins with IQR-5mins while post-vaccination advice at Table 5 took median time of 2 mins (IQR-1min).Thus total median time required form entrance to exit from hospital is 61 mins. Maximum time taken was registration at hospital OPD main building i.e. 24.59% and Immunization OPD registration i.e. history taking, HMIS entry and vaccination prescription (24.59%) and least time was required for post-vaccination advice (3.27%).

Table 2: Service Delivery time in relation to day of visit

Sr. No	Day	Number of beneficiaries (n=399)	Total Activity Median Time (in mins)	IQR(Q3-Q1)
1.	Monday	64	58.5	24.75
2.	Tuesday	65	59	27
3.	Wednesday	57	40	25
4.	Thursday	48	65	22.5
5.	Friday	107	68	31
6.	Saturday	58	45.5	21.25

Table 2 shows the time (median time in minutes) required for different service delivery points in relation to day of visit. It was found that the maximum beneficiaries were on Friday and total activity time required was also more as compare to other days with median time 68 min(IQR-31) and minimum medium time was on Wednesday was 40 mins(IQR-25mins). This difference of median time among the days of week was statistically highly significant ($p<0.0001$).

Diagram 1 shows total activity time in relation to type of vaccine to be given. Maximum median time 76.5 mins was required for BCG vaccination and minimum time 51 mins was for Vitamin A.



DISCUSSION

The outpatient department is the point of contact between the health care facility and the community. The problems of OPDs of developing countries are long waiting time, long queues, inefficient staffs, absence of staffs, etc. The problem is graver when the OPD deals with pediatric patients like in the immunization clinics. Different components of work require varying time to complete the task. By finding the time required for individual subcomponents, suitable measures can be explored to complete the task in lesser time[7].Only one comparable time motion studies carried out in any other immunization clinic have been found, but other time motion studies have been carried out in relation to surgical interventions, nursing activity monitoring.

In present study, maximum time was required for initial OPD registration and registration at pediatric OPD (history taking, prescription, HMIS entry) i.e.24.59% each with minimum time for vaccination and post-vaccination advice with 8.19% and 3.27% respectively. Maximum number of beneficiaries and maximum time required for activity was on Friday may be because of special neonatal OPD on Friday in this Institute and heavy rush on that day. In a study from immunization clinic of Kolkata, West Bengal[6] maximum time required was for vaccination and post-vaccination table(46.3%) and maximum number of beneficiaries were on Monday and maximum activity time on Monday. In this study maximum median time required was for BCG vaccination (median time-76.5 mins); as BCG vaccination session was carried out first in newborn babies in PNC ward of this Institute and after that given to beneficiaries coming to immunization OPD by same staff after returning from PNC ward. So this waiting period was included in this activity time; as actual BCG vaccination time took only median time of 5 mins. Such bottlenecks identified may have relations to number of staff present on the particular day of study, unequal efficiency of the members of the staffs, pattern of arrangement of activity Tables in the immunization clinic, availability of vaccines uniformly, varying number of participants in relation to different days etc. However, these variations need to be studied in depth. Again, factors affecting waiting time and service time in different Tables may be studied separately for further future discussions.

This study represents one of the very few time and motion studies of functioning of immunization clinic in developing countries, and as such, provides a useful baseline for future studies. By identifying the bottlenecks and constraints in the system, the quality and efficiency of immunization services can be improved. Perhaps, we think that this study will helping the

initiation of further in-depth analysis of constraints and bottlenecks in implementation of immunization program in developing countries and in providing guidelines for optimal functioning of the system.

The study also has some limitations in itself being an observational study design. The results of the study can not be generalized since the data was collected from single immunization clinic attached to a Tertiary health care centre in Pune, India. The study can be done on a wider area and further research can be done to evaluate the effectiveness of integrating the time and motion model into the existing immunization program and subsequent remedial steps for optimal functioning of the program.

CONCLUSION

Efficient functioning of immunization clinics is essential for achieving universal immunization against all vaccine preventable diseases and also in achieving millennium development goals. Management of time at various levels of health care system should be recognized so that necessary remedial actions can be initiated for optimal functioning of the healthcare system. This study aimed to initiate an effort to study the utilization of time at the immunization clinic setting. Separate arrangement for immunization OPD registration in pediatric building itself and up-gradation and increase number of computers for fast HMIS entry and prescription will help in future to reduce the time spent on immunization service. Additionally, results of this study will guide public health decision-makers at all government levels in planning and implementing immunization programs and also during other public health interventions.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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EEG Based Epileptic Seizure Detection Using Empirical Mode Decomposition and Hidden Markov Model

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ABSTRACT

Epilepsy is a chronic neurological disorder which is indicated by recurrent seizure. According to World Health Organization about 50 million people worldwide and 80% people with epilepsy belongs to low or middle income group. Two million new epilepsy cases occur each year globally as estimated by world health organization. Present method of seizure detection is manual making the process time taking and doctor dependent. The proposed algorithm automatically detects seizures with higher accuracy. Hidden Markov model (HMM) based classification approach is proposed for epileptic seizure detection. Electroencephalogram (EEG) signal was decomposed using empirical mode decomposition. Higuchi's fractal dimension and Shannon, collision, minimum entropy features were extracted from six intrinsic mode function and average feature values were used for classification. Features extracted from the signals were efficient in differentiating seizure, healthy and inter-seizure EEG signals. K means clustering algorithm was used for generating symbol sequence. Baum-Welch algorithm was used training HMM model. Viterbi algorithm was used to find the state sequence for each observed sequence obtained after manual clustering of test signal features. Maximum accuracy of 99.16% was observed for healthy-seizure, 95.00 % for seizure-Interseizure and 50.62 % for healthy-Interseizure EEG signals classification.

Keywords: *Epilepsy, EEG, Empirical Mode Decomposition, HMM, Least Square Support Vector Machine Classifier*

INTRODUCTION

Seizure is defined as sudden electrical spark in neurons in particular area of brain. Epilepsy can affect any lobe of brain. Seizure can last for seconds to minutes and in some cases can last for 30 minutes. Depending on spread of seizure it can be partial seizure or generalized seizure. According to symptoms it can be tonic, clonic, tonic-clonic, myoclonic and absence seizure. Person of any age may suffer from epilepsy. Recent technique used for seizure detection is manual and efficiency of epilepsy detection depends on doctor's experience. Knowledge of seizure's start, end and intermediate stage can help doctors to predict seizure and take immediate step to minimize seizure effect. Various methods are being evaluated to classify epileptic seizure. For signal decomposition mostly used techniques are ensemble empirical mode decomposition (EMD) and wavelet decomposition. Azadeh Kamali Tafreshi *et al*[1] used EMD for decomposition of EEG signal for classifying preictal and interictal seizure period and accuracy achieved was 89.68%. Mean frequency components in multichannel EEG recordings, using the multivariate empirical mode decomposition (MEMD) algorithm was found efficient in differentiating ictal and healthy EEG signals[2]. Statistical features along with complete ensemble empirical mode decomposition achieved good accuracy in classification[3]. Bessel k form probability function and normal inverse Gaussian probability density function along with EMD found efficient in differentiating healthy and seizure EEG signal[4,5]. Ensemble EMD was also evaluated for seizure detection. Marginal spectrum extracted from each intrinsic mode function (IMF) along with k means clustering classifier achieved 98.00% accuracy in seizure detection[6]. EMD with modified peak selection along with features such as energy, sum of amplitude, sparsity of amplitude spectrum and sum of derivative of amplitude spectrum were used for seizure detection. Maximum accuracy of 100% is achieved for healthy and seizure classification[7]. Farhan Riaz *et.al* [8] proposed EMD, temporal and spectral features based seizure detection. Higher classification rate achieved compared to other state of art methods.

Wavelet transform was evaluated in seizure detection. Stationary wavelet transforms and HMM classifier was used for classifying seizure EEG signal[9]. Overall sensitivity and specificity achieved is 96%. A kumar *et al*[10] proposed technique with discrete wavelet transform[11], zero crossing rate, energy, variance and fractal dimension and support vector machine classifier resulted in sensitivity of 98%. Apart from decomposition, non linear features such as sample entropy, Lempel ziv complexity and symbolic entropy were directly extracted from EEG signal for seizure classification[12].

In the present research work data driven technique empirical mode decomposition was used. Initial 6 IMFs were used for feature extraction. Higuchi's fractal dimension and Shannon, collision, minimum entropy features were extracted from each IMF segments. HMM classifier was used for classification as seizure is a dynamic system and it transit from healthy to seizure to interseizure state. Accuracy of HMM is compared with least square support vector machine (LSSVM) classifier.

PROPOSED APPROACH

Figure 1 represents the training algorithm for generating HMM model for different EEG signals. Initially signal was band pass filtered using Butterworth band pass filter in frequency range 0.2-60 Hz. IIR notch filter was used to remove 50 Hz power line interference in the EEG signal. Higuchi's fractal dimension and Shannon, collision and minimum entropy features were extracted from initial 6 IMFs obtained after EMD. K means clustering was used for generating symbol sequence which is used for training of HMM model for seizure, interseizure and healthy EEG signals. Models were generated for seizure-healthy, healthy-interseizure and seizure-interseizure EEG signals. Figure 2 represents flowchart for proposed testing approach. Manual clustering was done to find the symbol sequence for testing EEG signal. Viterbi algorithm was used to find the state transition for the obtained symbol sequence. Last state indicated as the class of the test EEG signal.

Empirical Mode Decomposition: EMD technique[13] is used to decompose non-stationary signal into finite set of orthogonal intrinsic mode function. EMD is adaptive and data driven approach. One of the requirements of Fourier transform is linearity of signal while most of the real world signals are non-stationary. EMD decomposition is based on extreme points and zero crossing points. Basic steps to analyze non-stationary signal is decomposition should be complete, orthogonal, local and adaptive. EMD satisfies all above conditions. Condition of a signal to be IMF:

1. Number of extreme points and number of zero crossing must be equal or maximum differ by one.
2. Mean value of envelop defined by local minima or local maxima must be zero..

Steps of EMD are as follows:

EMD Algorithm

1. Input: signal x
2. Find the minima and maxima points of input signal
3. Find upper envelop e_{max} and lower envelop e_{min} of the signal by Spline interpolation
4. Find mean of the envelop $m = (e_{min} + e_{max)} / 2$
5. Subtract mean from original signal x to get first component. H=x-m
6. H is IMF if it satisfies the IMF condition mention above. Otherwise H is further decomposed to get the IMF.
7. Steps 2-6 are repeated to get more IMFs. Process continues till stopping criteria in not fulfilled. (Stopping Criteria: Standard deviation between two consecutive IMFs should be between 0.2-0.3)
8. Output: Decomposed IMFs

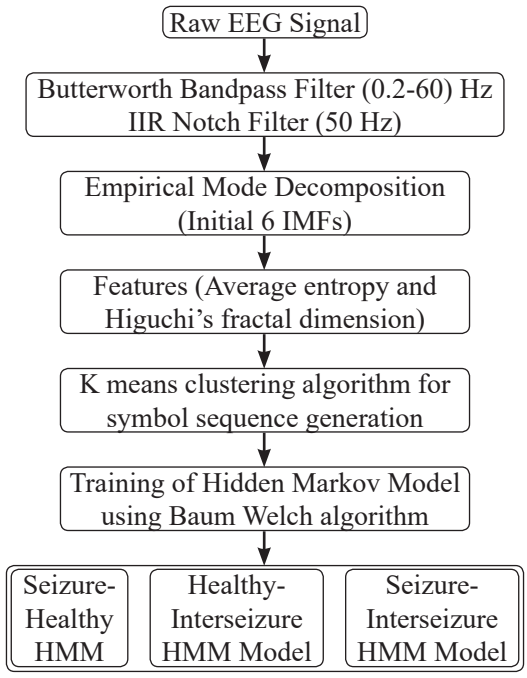


Fig. 1. Flow Chart of proposed approach for training of HMM model

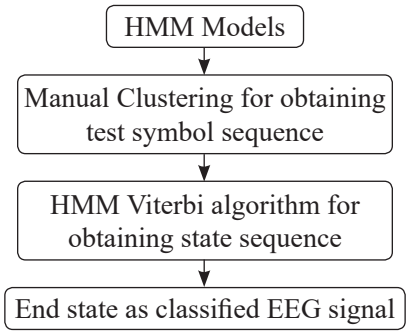


Figure 2: Flow chart of proposed testing approach

Features Extracted

Higuchi's Fractal Dimension: Term Fractal in time series implies data correlation between different parts of the signal[14]. It is a quantitative measure of the complexity of the signal. Higuchi's method of fractal dimension measures the change in signal amplitude while sampling the signal at increasing longer interval. Subset of signal was constructed as shown below.

$$x_m^k = [x(m), x(m+k), x(m+2*k), \ldots, x\left(m + \frac{N-m}{k}\right)] \quad \ldots(1)$$

Where k is the delay constant, N is the total sample and m is the initial time index. For each average length is computed.

$$L_m^k = (N-1) * \sum_{i=1}^{\frac{N-m}{k}} \frac{x(m+i*k) - x(m+(i-1)*k)}{\frac{N-m}{k} * K} \quad \ldots(2)$$

Total average length is calculated by

$$L_k = \sum_{m=1}^{k} L_m^k \quad \ldots(3)$$

This process is repeated for k=1 to $k=k_{max.}$ The slope of least square fit of the curve ln(L(k)) to the ln(1/k) is the higuchi's fractal dimension.

Entropy Features: Shannon entropy, collision entropy and minimum entropy features were extracted from 6 IMFs and averaged to get average entropy features. As can be seen in the seizure and healthy EEG signal, signal is more random for healthy subjects compared to seizure signal. In seizure activity group of neurons fire synchronously resulting in synchronous EEG signal. Mathematically these features can be defined as:

$$\text{Shannon entropy} = -\sum_i p(i) * \log(p(i)) \quad \ldots(4)$$

$$\text{Collision Entropy} = -\log(p(i)^2) \quad \ldots(5)$$

$$\text{Minimum Entropy} = -\log_2(\max(p(i))) \quad \ldots(6)$$

Where *p(i)* indicates the probability of the occurrence of a data point in an array.

K Means Clustering: K means clustering is a data partition technique and based on minimum distance between data points. Here k indicates the number of clusters to be created. The detail algorithm is explained below.

K Means Clustering Algorithm

1. Input: Data *x* and define the number of cluster *K*
2. Select an observation *o* from the dataset *x* and set it as centroid *c*
3. Compute distances from each observation to centroid c. Distance is denoted by *d(x,c)*
4. Next centroid is selected at random. Distance is calculated for each observation from centroid
5. Select each subsequent centroid with a probability to the distance from itself to the closest center that you already chosen
6. Repeat step 5 till the pre assigned cluster points are matched with centroid. Data points closer to centroid are assigned in same group.
7. Output: Partitioned data points in k clusters In this research numbers of clusters are selected to be 4 based on number of features used. Seizure and healthy EEG signals are clustered in different group indicating significance of features. But there was overlap between features of healthy and interseizure EEG signal. This technique was used for generating symbol sequence for each signal.

Manual Clustering: After training, during testing to generate symbol sequence for test signals, manual clustering was used. Euclidean distance from test feature vectors to the training feature vectors was calculated. The feature having minimum distance was assigned with index number generated during training phase.

$$\text{Distance} = \sqrt{\Sigma i\,(x_i - X)^2} \quad \ldots(7)$$

Where X is the training features and x_i is the each training feature vector.

$$\text{Training symbol sequence} = \text{index}(f_{min}) \quad \ldots(8)$$

Where f_{min} is the training feature vector having minimum distance from the test feature vector

Hidden Markov Model Classifier: HMM [15,16] is a time sequential classifier based on markov chain rule. Markov chain rule is defined as:

$$P(X_n = x_n|X_{n-1} = x_{n-1}, X_{n-2} = x_{n-2}, \ldots, X_0 = x_0) = P(X_n = x_n|X_{n-1} = x_{n-1}) \quad \ldots(9)$$

Probability of present state given all previous state is equal to probability of present state given only the past one state. Other state probabilities can be neglected. Markov chain is used to generate probability model of certain activity or signal. In HMM the states are considered as hidden state with only information about the symbol emitted from the states. In his research Baum-Welch algorithm is used for training of HMM and Viterbi algorithm is used for finding the state transition for the given state sequence. The Baum Welch and Viterbi algorithm are explained below.

Baum Welch Algorithm

1. Input: transition matrix a_{ij}, emission matrix b_{jk}, initial probability $\alpha_j(0)$ and symbol sequence v^T
2. Calculated forward probability

$$\alpha_j(t) = \begin{cases} 0, & t = 0 \text{ and } j \neq \text{initial state} \\ 1, & t = 0 \text{ and } j = \text{initial state} \\ \sum_{i=0}^{N} \alpha i(t-1) * a_{ij}] * b_{jkv(t)} & \text{Otherwise} \end{cases}$$

3. Calculate Backward Probability

$$\beta_i(t) = \begin{cases} 0, & \text{if } w_i(t) \neq w_0 \text{ and } t \neq \text{T} \\ 1, & \text{if } w_i(t) = w_0 \text{ and } t = \text{T} \\ \sum_{j=0}^{M} \beta_j(t+1) * a_{ij}] * b_{jkv(t+1)} & \text{otherwise} \end{cases}$$

4. Calculate the probability of being in state s_i at time t, and state s_j at time $t + 1$, given the model (θ) and observation sequence (v).

$$p(q_t = s_i, q_{t+1} = s_j|v, \theta) = \vartheta_{i,j}(t) = \frac{[\alpha_i(t-1) * a_{ij} * b_{jkv(t)}] * \beta_j(t)}{p(v^T/\theta)}$$

5. Update the emission and transition probability

$$a_{ij} = \frac{\sum_{t-1}^{T} \vartheta_{i,j}(t)}{\sum_{t-1}^{T} \sum_{k=0}^{n-1} \vartheta_{i,k}(t)}$$

$$b_{jk} = \frac{\sum_{t=1}^{T} \sum_{l=0}^{n-1} \vartheta_{jl}(t)}{\vartheta(t) = \vartheta(k)} \quad \sum_{t=1}^{T} \sum_{l=0}^{n-1} \vartheta_{jl}(t)$$

6. Repeat process 2 to 5 with updated matrix till maximum number of iteration

RESULTS AND DISCUSSION

Experimental database: A total of three sets of EEG data segments each containing 100 single channel EEG signal of 23.6-sec duration were used in this research [17]. These segments were selected and cut out from continuous multi-channel EEG recordings after visual inspection for artefacts. The sampling rate of the data is 173.61 Hz and the spectral bandwidth of the acquisition system is 0.5 Hz to 85 Hz. Sets A and B consist of segments taken from surface EEG recordings of five healthy volunteers in relaxed condition with eyes open and closed condition. EEG signals from five patients were selected. Set E contains seizure EEG signal and set C, D contains interseizure EEG segments.

ANOVA Test Results: In this research features such as higuchi's fractal dimension, Shannon entropy, collision entropy, minimum entropy and differential entropy features were extracted. Analysis of Variance (ANOVA) test was performed between features to test the feature differentiating ability. F value indicates the ratio of between groups to sum of within groups variance. P indicates the probability value calculated from ANOVA table. Detail analysis of ANOVA is shown in Table 1.

Table 1: ANOVA Test Results for Different Features

Class	Features	Higuchi's Fractal Dimension	Shannon Entropy	Collision Entropy	Minimum Entropy
Healthy-Seizure	F Value	183.15	3096.63	2280.01	2216.61
Healthy-Interseizure		172.03	1.85	27.46	62.16
Seizure-Interseizure		703.44	1749.69	1740.73	1072.36

Higuchi's fractal dimension is an efficient feature for differentiating healthy, seizure and interseizure EEG signals. As shown in Table 1 it differentiates seizure and Interseizure EEG features with higher accuracy. In entropy features, Shannon entropy achieved highest differentiation for healthy-seizure EEG signal. But the differentiation capability of healthy-interseizure was low for Shannon entropy as indicated by F value of 1.85. Collision entropy and minimum entropy were good features to differentiate seizure, interseizure and healthy EEG signal. Maximum F value was obtained for healthy-seizure EEG features.

Table 2: ANOVA Test Results for Combined Feature

Class		F	P
Healthy-Seizure	Combined Features	389.84	1.79*10-32
Healthy-Interseizure		6.88	8.8*10-5
Seizure-Interseizure		338.59	2.44*10-72

As shown in Table 2 the feature set has higher differentiation ability for healthy-interseizure after combining entropy and higuchi's fractal dimension features. Shannon entropy feature is not significant in differentiating healthy-interseizure EEG signal but has good separability in other classes and so considered in feature set for classification. ANOVA mean comparison for combined feature for all classes is shown in figure 3. As can be seen in the figure, mean value for healthy and seizure EEG signal is distinct and widely separated. Mean value for healthy EEG features and interseizure EEG features are significantly different but are close as compared to other classes.

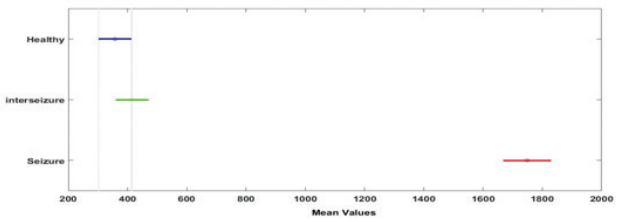


Fig. 3: Mean plots for combined features for healthy, interseizure and seizure EEG signals

HMM Model and Classification: Code book was generated for different EEG class features using k means clustering algorithm. All features are combined and clustered to get the symbol sequence for different classes. Features of healthy and seizure classes are grouped in different cluster but healthy and interseizure class features grouped mostly in single cluster. Baum Welch method was used for HMM training purpose. Three different HMM models were evaluated between three classes. Transition model was initialized for healthy-seizure, seizure-interseizure and healthy-interseizure EEG classes. Figure 4 shows the initial transition matrix.

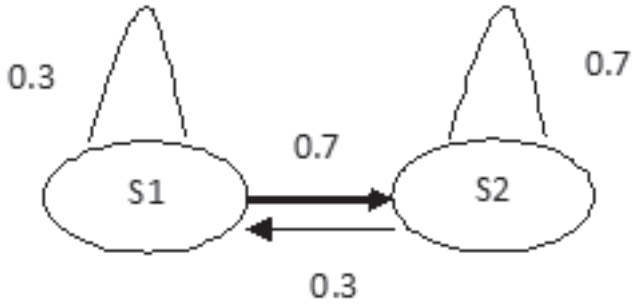


Figure 4: HMM initial transition Matrix

Initial emission matrix was calculated based occurrence of the symbol in symbol sequence obtained after k means clustering. Trained HMM models are shown in Figure 5 (a), (b) and (c). Healthy-seizure HMM model indicates that probability of signal to be in healthy state is 0.9947 where as transition to seizure is 0.0054. But once transition is done, probability of signal to remain in seizure state is 0.9946. Other HMM models also followed similar trend.

Viterbi algorithm was used for evaluating the state transition in different HMM model for the test symbol sequence. Last state of model is defined as the test signal class. Detail analysis of classifiers is shown in table 4. Different factors such as accuracy, sensitivity, specificity, positive predictive rate and negative predictive rate were evaluated. Mathematically they can be evaluated by:

$$\text{Accuracy} = \frac{TP + TN}{TP + TN + FP + FN} \quad \ldots(10)$$

$$\text{Spicificity} = \frac{TN}{TN + FP}, \text{Sensitivity} = \frac{TP}{TP + FN} \quad \ldots(11)$$

$$\text{PPV} = \frac{TP}{TP + FP}, \text{NPV} = \frac{TN}{TN + FN} \quad \ldots(12)$$

Where TP=true positive, TN=true negative, FP= false positive and FN=false negative

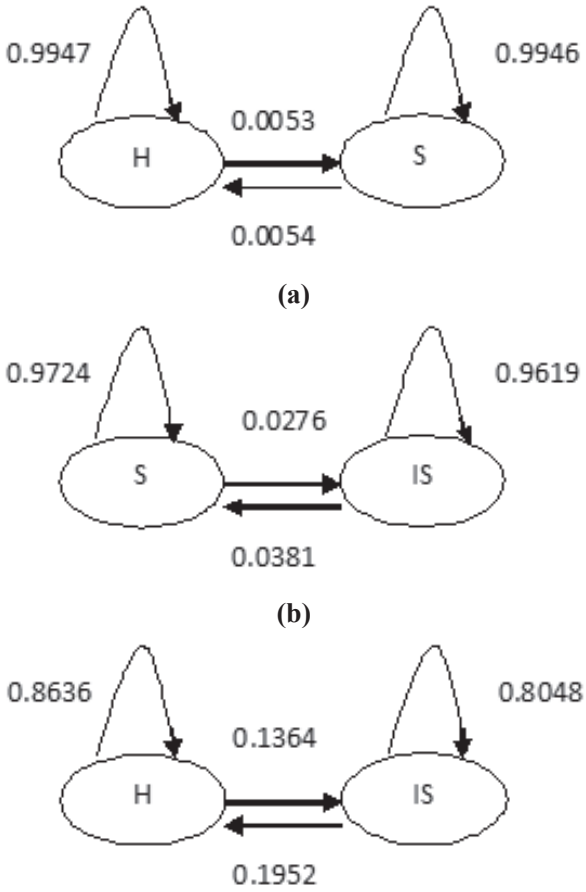


Figure 5 HMM Model for (a) Healthy (H)-Seizure (S) (b) Seizure (S)-Interseizure (IS) (c) Healthy (H)-Interseizure (IS) EEG signal

Table 3: Classification Accuracy for HMM classifier

Class	Accuracy (%)	Specificity (%)	Sensitivity (%)	PPV (%)	NPV (%)
H-S	99.16	97.50	100	98.76	100
S-IS	95.00	97.50	93.75	98.68	88.63
H-IS	50.62	46.25	55.00	50.57	50.68

Sixty EEG signals were used for training purpose from each set and 40 EEG signals were used for testing purpose. Maximum accuracy of classification was achieved for healthy-seizure classification. In any classification problem it is important to get less false negative that is good sensitivity. In the table shown above healthy-seizure classification achieved 100% sensitivity showing good classification accuracy. Classification between seizure-interseizure achieved 95.00% accuracy with 93.75% sensitivity. The lowest accuracy was achieved for healthy-interseizure classification. Features obtained in both classes were significantly different but still there was overlapping between the features. Here the accuracy of classification also depends on k means clustering performance in generating symbol sequence. As similar features grouped on same cluster the misclassification rate increased. Entropy features are good as a measure of randomness but not sensitive enough to differentiate nearly similar signals. Entropy features such as sample entropy and approximate entropy may be useful to differentiate healthy-interseizure EEG signals in present algorithm.

CONCLUSION AND FUTURE SCOPE

EMD and HMM based seizure detection method is proposed. Higuchi's fractal dimension, Shannon, collision and minimum entropy features were found significant in healthy, seizure and interseizure EEG signal classification. Accuracy achieved for seizure detection was 99.16%. The performance of proposed algorithm is comparable to other state of art methods. In future different features such as sample and approximate entropy's performance will be evaluated in seizure detection. Performance of EMD and Wavelet decomposition for seizure detection will be evaluated. Different probabilistic classifier such as Bayesian classifier and artificial neural network[18] will be evaluated for detection and seizure prediction. Present method is evaluated for single channel EEG signal. In future proposed approach will be extended for multichannel EEG signal.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Functional Clothing for The Differently Abled

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ABSTRACT

Disability may be broadly defined as a physical or mental condition that limits a person's movements, senses, or activities. Functional clothing is essentially designed to fulfil special requirements of the wearer including body disproportions or impairment. It also may affect a person's emotional wellbeing. This is an exciting field of study where opportunities of research, design and development of clothing for differently persons are being explored all over the world. Research and development of functional clothing in India is a relatively new field. This paper traces outstanding global advances in the field of functional clothing for the differently abled. Disabilities are of many types and functional clothing for each type of disability has entirely different requirements. Persons who are wheelchair bound, those who are bed ridden, persons who are spastic, autistic etc. all require different kinds of functional clothing. Clothing should be aesthetically appealing and should follow current fashion trends wherever possible; they should be easy to wear by themselves; they should be easy to care for and also provide the wearers with a sense of physical and mental comfort. Special requirements which arise from disabilities require the application of design and development to address the physical, physiological and mental issues for the differently abled. Global standards in quality, aesthetics and convenience should be followed so that such persons do not feel uncomfortable in any way. The paper introduces readers to new and exciting developments in the field of functional clothing for the disabled.

Keywords: *body features, clothing, differently abled, disability, functional*

INTRODUCTION

Disability is an impairment that may be cognitive, developmental, intellectual, mental, physical and sensory or a combination of these that substantially affects a person's everyday activities. A disability can be present from birth or can occur during a person's lifetime.

Any clothing that is specially designed to fulfil specific requirements of the wearer would be categorized as functional clothing[1]. These might also include clothing that is used in hazardous situations at work and special sporting requirements. Functional or adaptive clothing is special clothing that is essentially designed for persons with physical or mental disabilities. Differently abled persons often experience difficulties in wearing clothes by themselves. This is mainly due to difficulty in fine motor movements while fixing closures on the garment, or due to a limited range of movement of limbs due to physical impairment. The need for special clothing for the differently abled was identified in the early 20th century. Since then, there has been much advancement in this area with respect to design, materials used, finishes applied, ease of wearing, functionality for specific requirements, aesthetics, accessibility, durability, manageability, affordability etc.

This paper focusses on clothing that is specially designed keeping persons with disabilities in mind.

METHODOLOGY

This paper traces outstanding global research in the field of functional clothing for the differently abled through rigorous literature review. For this, twenty websites and online web pages have been studied to compile a thorough list of all such new developments. A list of general considerations while designing clothing for the differently abled has also been compiled.

REVIEW OF LITERATURE

Disability: The International Classification of Functioning, Disability and Health (ICF) (17) advanced the understanding and measurement of disability. In the

ICF, problems with human functioning are categorized in three interconnected areas:

Impairments are problems in body function or alterations in body structure–for example, paralysis or blindness;

Activity limitations are difficulties in executing activities–for example, walking or eating;

Participation restrictions are problems with involvement in any area of life–for example, facing discrimination in employment or transportation. Disability arises from the interaction of health conditions with contextual factors –

environmental and personal factors as shown in the figure below.

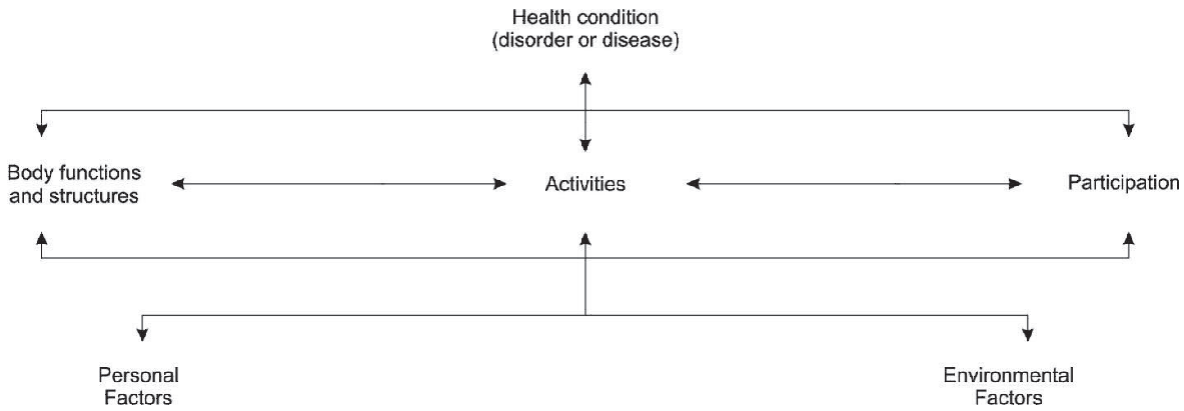


Fig. 1 International Classification of Functioning, Disability and Health2

Census of India 2011 has revealed that over 26.8 million people in India are suffering from one or the other kind of disability. As per the census data, 5.4 million people in India are movement disabled followed by hearing impaired (5.07 million) and visually impaired (5.03 million).

Disabled Population of India by Type of Disability

Disabled Population by Type of Disability India : 2011			
Type of Disability	Persons	Males	Females
Total	**26,810,557**	**14,986,202**	**11,824,355**
In Seeing	5,032,463	2,638,516	2,393,947
In Hearing	5,071,007	2,677,544	2,393,463
In Speech	1,998,535	1,122,896	875,639
In Movement	5,436,604	3,370,374	2,066,230
Mental Retardation	1,505,624	870,708	634,916
Mental Illness	722,826	415,732	307,094
Any Other	4,927,011	2,727,828	2,199,183
Multiple Disability	2,116,487	1,162,604	953,883

Figure 2 C-Series, Table C-20, Census of India 2011[3]

Further, the Census of India 2011 identifies 2.5% of the total population of Maharashtra, Andhra Pradesh, Odisha, Sikkim and Jammu and Kashmir to being disabled, while Tamil Nadu and Assam are among those where the disabled population is less than 1.75%.

Proportion of Disabled Population India and States/UTs

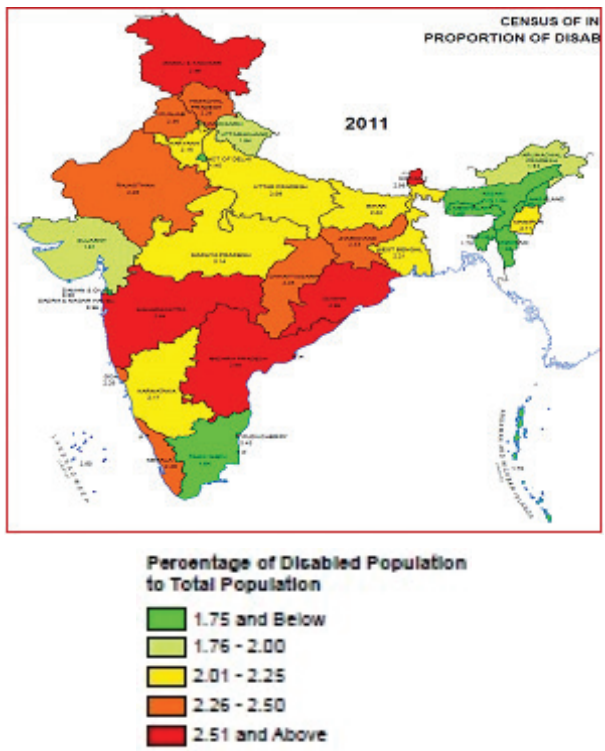


Fig. 3 DATA ON DISABILITY C-Series, Table C-20, Census of India 2011[3]

There are a large number of persons with different types of disability in India as evident from the data above. The requirement of adaptive or functional clothing for this slice of population is thus consequently huge.

Adaptive Clothing: Disability affects people in many ways and at different levels. There is a wide array of problems to be considered while designing clothes for the disabled. For the clothing to be practical and aesthetic, a detailed understanding about the body features of disabled people – shape, size, degree of mobility etc. needs to be considered before design development. Design considerations must also include quality, price point as well as the psychological and social needs of the disabled. While people with disabilities can live independently, they would be greatly helped if they found clothing that met their needs[4].

The disabled or the care givers find the mechanical aspect of getting dressed extremely demanding. Positioning and type of fastenings, fabric texture and type, positioning of seams etc. present challenges for those who live independently. They face considerable amount of hindrance in finding clothes that fit due to a mismatch between body proportions and clothing available. People with lower limb disability who commute with the help of wheelchairs often have shirts and jackets riding up at the back. Clothing which looks and feels good can go a long way in improving the quality of life of the disabled.

The words fashion and functional or adaptive clothing appear self-contradictory. Most of us regard fashion as a quirk, but for disabled people, it is an important part of their lives. Fashion is all about creating a socially acceptable or even desired image; while functional or adaptive clothing is about trying to achieve the exactly opposite effect – trying to camouflage. Clothing not only needs to take care of the physiological comfort but psychological requirement too. In order to maintain the same psychological characteristic as normal people, fashion needs to be used as a tool to cover up their disability and enhance self-confidence.

Adaptive clothing has been found to be a useful medium to satisfy the needs of the wearers and designing them in collaboration with them yields more satisfactory results[5]. Though most people are of the view that fashion is a whim, it still forms a significant part of the lives of disabled people[6]. People with special needs should select clothing that looks good, fits well, feels comfortable, helps one be more independent, and makes the wearer look as 'normal' as possible[7].

Clothing affects a person's physical, psychological and social comfort[7]. As per Kabel, Dimka and McBee-Black, the lack of attractive, functional clothing can be detrimental to overall well-being if individuals are unable to present themselves according to personal standards[4]. Designing functional clothing for the disabled aims to encourage health recovery, improve living style, realize personal expectations, allow the users to lead a life of self-respect and facility and enable them to mingle with family and society to a greater extent[8].

In order to fulfil the needs of persons with disabilities, functional clothing should be comfortable, easy to put on and take off, durable, simple to maintain and also rightly priced[9]. The design and manufacturing of specialized functional clothing is impacted by the understanding of the anthropometric, biomechanical and ergonomic expectations of the disabled consumer[10]. A smart combination of human ergonomics, textile material and apparel technology shall lead to the development of more inclusive functional clothing[8].

People with disabilities are often treated differently or given special attention. While this may be helpful in some situations, it may also alienate them from their peers. Such people do not wish to be regarded as being different from everyone else and may also react in a negative manner to clothing which has been specially modified to suit their needs[11]. Such persons look at clothing as an aid to independence while being a means of blending-in with their peers, asserting their identity and confront prejudice[6].

One of the objectives of this paper is to study the primary requirements that clothing needs to fulfil to be considered adaptive for persons with disabilities. It also traces the recent developments in adaptive clothing available globally.

Considerations in Garments for the Differently Abled: Limitations in range of physical activity often leads to requirements of functionality in clothing and other textile products[12]. While designing garment for persons with disabilities, one has to bear in mind the difficulties in movement, decreased range of reach and overall physical, psychological and social awkwardness that these persons battle with on an everyday basis. Many persons with disabilities use assistive devices like canes, casts, braces, walkers, scooters, and wheelchairs; modifications have to be made in clothing to accommodate such devices. Physical disabilities may often be accompanied by incoordination, sensory loss and imbalance. Many persons may also use catheters or urinary pouches which require more leg room in pants and skirts. Also,

most conventional clothing does not accommodate for the bends in the hips and knees or abnormal body shape due to deformities. Persons with irritable skin have to wear clothing with non-intrusive seams and soft, breathable material[13]. This too has to be taken into consideration while designing clothing for persons with disabilities.

Some innovations that have been used by the designers in apparel for the differently abled are front closing brassiere with Velcro fasteners, Velcro fasteners, big buttons - buttonholes, large zipper-pulls, open back blouse, shirts, capes, snap back shirt, expandable neck openings, cut out back shirt, Velcro opening pants, side opening pants, half open back dress, kimono or raglan sleeves, tops with action pleats in sleeves & back, Wheel chair cape, Zip up tie, Zip up sneakers amongst others[7].



Figure 4 Care Zip pants[14]



Figure 5 Low front high back jeans with side zipper openings[15]



Figure 6 Open-back pants for wheelchair users – IZ Adaptive[16]



Figure 7 Wrap-back top[17]



Figure 8 Pants with Velcro fastening [17]



Figure 9 Jeans with full side zipper - IZ Adaptive[16]



Figure 10 Front closing bra[18]



Figure 11 Back-open vest[18]



Figure 12 Wheelchair cape[19]



Figure 13 Zipper Tie[20]

Significant Global Advances made in this field: Merchandise available for the disabled is limited and isn't always in sync with the current fashion trends. In the recent years, a few designers have taken notice of the gap and created functional adaptive clothing, to meet those needs. Industry experts agree that the ultimate goal is increased independence at home, in the work place and at school. Some of the significant advances in this field are listed below.

According to a recent report, apparel manufactures play a vital role in helping people with disabilities by providing more appropriate clothing for social engagements, work and exercise. The lack of attractive functional clothing keeps differently abled people away from weddings, school dances, funerals, baseball games and graduation, homecoming. This research supports the need for new clothing designs to help eliminate the clothing-related barriers for people with disabilities[21].

Fashion designer Mindy Scheir of Runway of Dreams in collaboration with Tommy Hilfiger unveiled the new 'Tommy Hilfiger adaptive clothing line for kids' in February 2016. According to the brands website, the line is "a very special collection addressing the challenges the differently-abled community faces each day when getting dressed." The line features 22 pieces from size 4 to 18 for girls and 4 to 20 for boys. The look and feel and price point of this new adaptive line is similar to the TH kid's collection. The bottoms feature closures on legs and fly and also allow low waist and length adjustability[22]



Figure 14: Tommy Hilfiger adaptive clothing line for kids[22]

Runway of Dreams has come up with a technique of replacing buttons, zips and hooks and clips with the highly innovative Magna Ready magnets and closures. The brand also explores the creation of fully adjustable sleeve and pant lengths for those with limb differences and low muscle tone.



Figure 15 MagnaReady shirts with magnetic closures[22]

Lucy Jones won the Parsons graduate prize in 2015 for a clothing collection for people in wheelchairs. The collection focused on minimal and elegant clothes for wheel chair users, taking into account the need to be permanently seated and the challenges of wearing clothes when one is physically impaired. Jones has explored changing the proportions of clothes for those in a wheelchair and how the proportions of "seated clothes" differ to "standing clothes." She has also focused on improved ways to take pieces on and off for those in a wheelchair[23].



Figure 16 Parsons student Lucy Jones's "Seated Collection[22]



Fig. 17 Parsons student Lucy Jones's "Seated Collection[22]

Los Angeles-based jeans brand **ABL Denim** has created stylish yet practical jeans for those in wheelchairs. The waistbands of the jeans are set high to avoid the creep down effect of jeans when seated. They are also aiming to create jeans with weights to act as therapy for certain sensory disorders[24].



Fig. 18 Denim collection for men, women, and children with disabilities[24]

Toronto designer, **Izzy Camilleri**, founder of IZ Adaptive Clothing uses unique design techniques which includes a pitch in the back so there are no wrinkles in the front when sitting down, not having any back

pockets to avoid pressure sores and designing the cut of jackets and coats to be in an L shape so they don't look folded over in the wheelchair[24].



Fig. 19 Izzy Camilleri's IZ Adaptive Clothing [24]

Powered Clothing by Superflex addresses the challenges faced by the elderly or differently abled people who are too weak to walk up stairs or even get out of a chair. The line resembles science fiction power suits. Yves Béhar collaborated with Superflex to design the clothing, which was unveiled in concept form at the London Design Museum's exhibit devoted to design innovations in aging[25]. The prototype suits will be turned into consumer product and debut in 2018.



Fig. 20: Powered clothing by Superflex[25]

Care and Wear has designed a line of Zip-Open Shirts which have openings at strategic locations for access to medical ports for administration of medical drugs and chemotherapy[26].

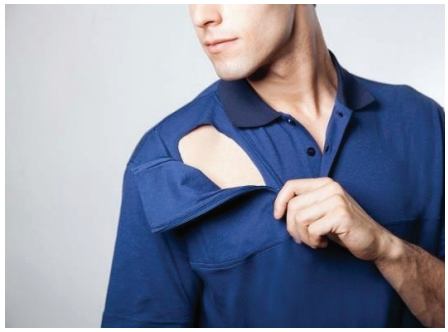


Fig. 21: Access Polo Shirt[27]

Nike has come up with a pair of special shoes at the behest of a child with cerebral palsy who had trouble wearing and taking off his shoes. Thus, in consultation with this teenager Nike produced their LeBron Zoom Soldier 8 Flyease shoes which zip open like an orange peel and can be closed with one hand[26].



Fig. 22 Nike's LeBron Zoom Soldier 8 Flyease basketball shoe

Shalini Visakan of Suvastra Designs, Chennai has recently launched her line of adaptive clothing for persons with disabilities. Her innovations include attaching sturdy loops to trousers for assistance in lifting a wheelchair bound person and a pre-stitched one-piece saree with an attached blouse and tops with detachable sleeves. She has also designed bridal wear and party wear for her special clients[28].

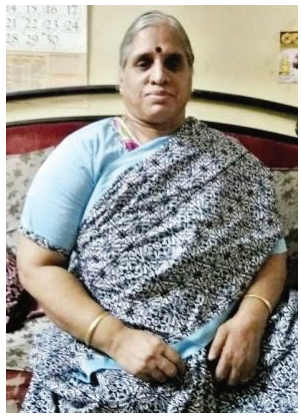


Fig. 23: Pre-stitched saree with attached blouse

Sanjay Dattatri, Director of Old is Gold store in Chennai launched their own brand of adaptive clothing 'Cocoon' in 2015. Their innovations include the use of Velcro and zips in their *veshtis* and *dhotis* apart from stocking easy to wear cotton clothing for the elderly[29].

Delhi based designer duo Shivan and Narresh, developed an interesting piece of clothing which they called the 'Mastectomy Blouse'. This blouse was designed for women who suffer from a feeling of great inadequacy and low confidence after undergoing mastectomy. Apart from a high end version priced at Rs. 15,000, they have also developed a blouse at Rs. 2000 which they hope to distribute to cancer survivors through NGOs[30].

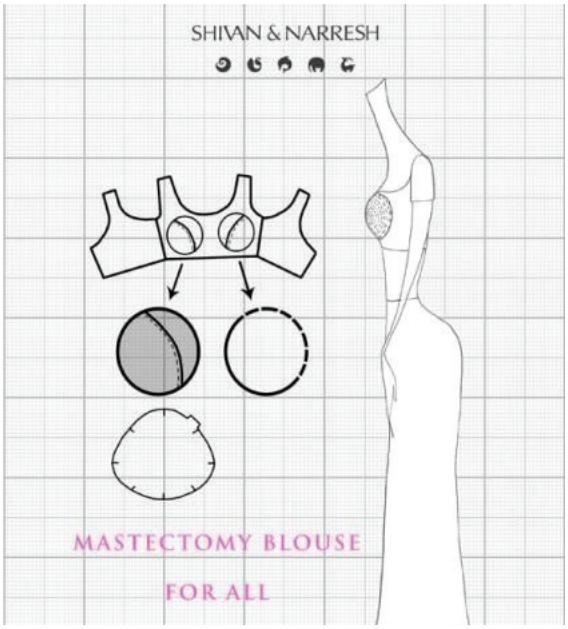


Fig. 24: Mastectomy Blouse by Shivan and Narresh[31]

Nidhi Munim, a Mumbai based designer has also launched a line of mastectomy swimwear using silicone implants imported from Italy; which she retails at half the price of her regular line. According to her, the demand for mastectomy clothing is steadily rising among women cancer survivors[29].

RESULTS AND DISCUSSION

After studying more than 30 websites featuring adaptive clothing, it was realized that all the sites were selling only in the United States, United Kingdom, Europe and in some cases even in China. Indian sites offering clothing for the differently abled are nonexistent except for Chennai based Old is Gold which also has very limited offerings. The survey of the websites also showed that, shirts with magnetic closures, zip open flaps, jeans with high waist at back and no back pockets for comfort, jeans with wrap waist and full side zippers, zip-up sneakers and zip-up hooded sweatshirts with hidden pockets to hold surgical drains put in place after surgery are just some of the recent developments in the field of fashion for the differently abled.

CONCLUSIONS

Many individuals all over the world are doing their best to address the problems faced by persons with disabilities through adaptive clothing. Sensitivity towards the physical, physiological and psychological difficulties faced by such persons is crucial in this case. In the Indian context, there seems to be an abysmal lack of initiative taken by leading clothing brands to address this very real issue with only a small handful of individual designers leading the way, that too in a limited manner. This situation needs to be effectively addressed, especially considering the huge numbers of disabled persons currently in our country. Special attention should also be paid to the socio economic strata that maximum of these persons belong to in terms of affordability, durability, functionality and ease of maintenance of such clothing.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Smart Supply-Chain Management Learning System for Homeopathy

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ABSTRACT

Research based on confluence of incremental-learning, homeopathy, microcontrollers, Cloud to Dew Computing technology is discussed in this paper. Dew computing based mobile system allows homeopath to identify/locate, retrieve required medicine bottle immediately. Medicine bottles arrangements are recommended iteratively based on incremental-learning of prescription and seasonality analytics. Quick and accurate medicine identification saves lot of quality time of patients & doctors and gives "feel good" factor, always; which is a necessary part of this research as homeopathy works both on physical and psychological levels. Microcontrollers/sensors attached to medicine bottle safely react to mobile signals to locate prescribed medicine bottle from the stack. Once located, medicine information is stored in database of patient for future reference. The paper proposes intelligent, efficient and automated exploratory medicine handling scheme for homeopathy clinic.

Keywords: *Learning system, Smart supply chain, Homeopathy, Dew computing, Microcontrollers*

INTRODUCTION

The system proposed in this paper is embedded ARM cortex based system for effortless and automatic identification of medicine bottle(s). The specific row columns arrangement of the configurable output ports identifies the bottle and its location in the medicine tray by mapping the doctors input prescription. This mapping is based on text mining algorithms along with sensor detection techniques. The system is also capable of maintaining the log records of the quantity and the availability of the medicines, for automated order-processing. Further the information regarding the diagnosis and prescription can be added to patients' available database for future ready reference.

This would not only save both doctors and patients valuable time but provide the doctor with easy access to patients' complete history anytime-anywhere, using Cloud Computing platform. Soft form of patients' history enables homeopath to analyze the case better, without maintaining hard copies of details.

RESEARCH METHODOLOGY

The Smart Supply Chain Management (S^2CM) system plays vital role amalgamating with the technology for homeopathy[1,2,10] clinical discrepancies and management of stress related concerns for latency scheduling in patient caring.

In a homeopathy clinic, all the medicines are generally compartmentalized in three categories. These categories are normal, severe and chronic diseases. Also there are potencies trays for a predictive homeopathy. In predictive homeopathy[11,16] the main intention and focus is the identification of a health problem well in advance or at primary stage and treating it before it penetrates deeper. This prediction is based on symptoms at present and patients history. There are two challenges at this stage; one is collecting enormous information for all the patients and second is maintaining the record or history, along with prescribed medicines, time to time / season-wise. When it comes to finding the record of required patient, at any moment, on the time line, it is not only laborious / slow but also very tedious and complex task

of equal importance. Based on the popularity of doctor, with increasing number of patients, locating required patients data, its prescribed medicines takes time. IT based solution helps in emergency situations also. In case patient needs doctors' help urgently, when doctor is not in clinic, then making use of Cloud[12,13] based solution like S2CM, doctor will be able to provide help immediately. Hence S2CM is very effectually solution, without consuming any time of all involved entities and also speeds up the treatment. Especially in case of longer treatments it is very difficult to repeat such tasks. In later scenario doctor and the assisting staff can concentrate more on the symptoms and the treatment instead of searching for history of the patient and the location of the medicine in the medicine and potencies trays.

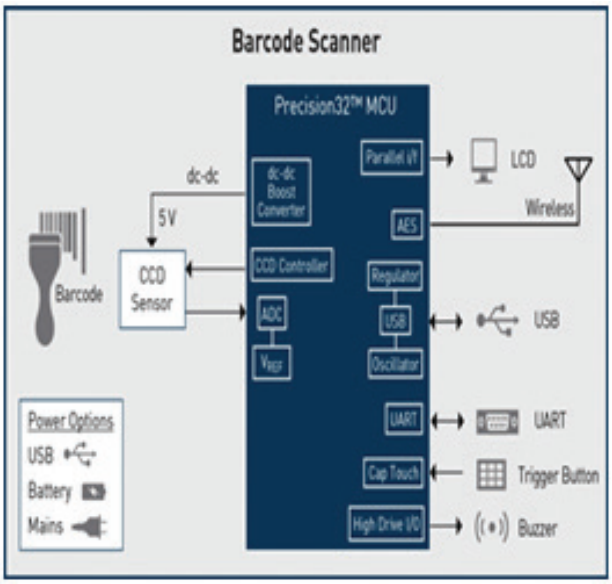


Fig. 1: shows the schematic details of microcontroller based barcode reader[17].

If it is compartmentalized modeling of medicine trays containing bottles with potencies arranged in a specific manner, the electronic system is designed in two parts and they are:

1. Front end design
2. Microcontroller based multitasking.

In front end engineering solution, the symptoms, diagnosis and the patients' history become available for the doctor on a click along with the previous diagnosis. This also helps in focusing on finding the root cause of the health problem as all the symptoms, diagnosis and treatment will be to the doctor altogether.

In different kinds of scenarios, the same system can make the information available to the doctor in his/her absence in the clinic. Access to the stored information can facilitate the treatment remotely. Computing the location and accessing information necessitates dealing with internet, cloud and GPRS. In microcontroller based multitasking environment the code readers are interfaced to the input ports of microcontroller to identify the location of the medicine bottle. The bar codes can be generated clinic specific or general considering cloud environment and as per the requirement of S^2CM.

The arrangement of the medicines is based on the requirement frequencies, symptoms, contents of the medicine and seasonal usage. The thought process extends itself to the severe and chronic rays as also to the potencies trays. Considering minimum size of a tray as let 25*10 the generalized block diagram for the microcontroller system is as shown in fig.1. Along with the identification of the location the system saves the doctors efforts of searching for the specific medicine. Even in the small tray of 25*10, one needs to scroll through 250 options which is not only time taking but also a stress developing exercise for patient and doctor in crowded clinics. The provision to add intelligence to this tray makes the place in supply chain management for clinic and connected clinics also. Transmitting the data to the cloud becomes necessary for the remote access to the medicines tray.

Further if the bottles are equipped with weight or level sensing solution can monitor the quantity of the available medicine and maintain the record of the same. This further can be interfaced to the information on cloud and supply chain management for automatically placing the order to procure the medicines.

Entire architecture of the proposed system will be fabricated using MATLABs SimEvent module[3,4], the initial phase of S^2CM model is shown in figure 5. The proposed system is built in two phases:

- Only soft form of the system, in the form of mobile app to hunt for bottle location virtually and perform all functionalities related to bottle from stack, including suggesting re-arrangements of bottles season-wise, frequency of usage-wise, faith-wise (varies from practioner to practioner) etc.
- Two phase system connecting mobile device to bottle locate concept physically and other functionalities.

The detailed steps of S^2CM algorithm is given below:

Smart Supply Chain Management (S^2CM) about Homeopathy medicines, algorithm steps:
Input:

- Doctors, Patients, Medicines, Suppliers, Manufacturers: 1 to n
- Data stored on Cloud Computing environment, accessed via Dew Computing
- Data of tags stored at back end on Cloud/Mobile systems to fetch when required, dynamically, with positions which keeps changing periodically.

Algorithm:

1. Homeopathy doctor prescribes medicines to patients
2. Use mobile device or iPad to prescribe medicine and other history related to patients
3. Text mining applied to cluster data based on season, health-condition, other details
4. Clustered data is stored on cloud for anytime reference by doctor
5. Clustered data can be fetched anytime by doctor using Dew Computing based on mobile communication network
6. Prescribed medicines can be located using mobile phone and bar code / RFID tags on bottles
7. Frequency of location of medicine bottle is captured and stored for incremental learning
8. Frequently used bottles based on season can be relocated at the prime / first row
9. Absolutely not fetched bottles can be kept at the last row
10. Frequency of bottles is captured and stored in database to be shared with medicine supplier
11. Medicine supplier further utilizes this database for orders from wholesaler and in turn manufacturer
12. Steps from 7 to 11 are repeated to form S^2CM for homeo medicines
13. This S^2CM includes doctors per area, suppliers from various cities and manufacturers i.e. steps from 1 to 12 are repeated for every doctor

Learning outcomes include:

14. Patients:
    (a) Quick / fast doctors visit
    (b) Availability of doctor anytime virtually (due to availability of data with doctor)
    (c) Better healing experience
    (d) Better trust on doctor
15. Doctors:
    (a) Easy of data access, no need to recollect
    (b) Anytime availability as data is easily fetched using mobile devices
    (c) No need to maintain files physically/static
    (d) More patients, more benefits (time, quality, access, supply etc)
    (e) Easy to access/locate medicine bottles
    (f) Seasonality specific bottles arrangements
    (g) Predictions per patients, age wise, disease wise etc
16. Suppliers
    (a) Predictions of requirements of frequency of medicines per doctor, per area, per city etc
    (b) Beneficial, quick, effective
    (c) Stocks maintained easily, supplied easily online
    (d) Full proof transactions automated
    (e) Can work with homeo, flower remedy and other related medicines too
    (f) Can be extended to other medicine branches too

Mind-map of S²CM distributed system is as follows:

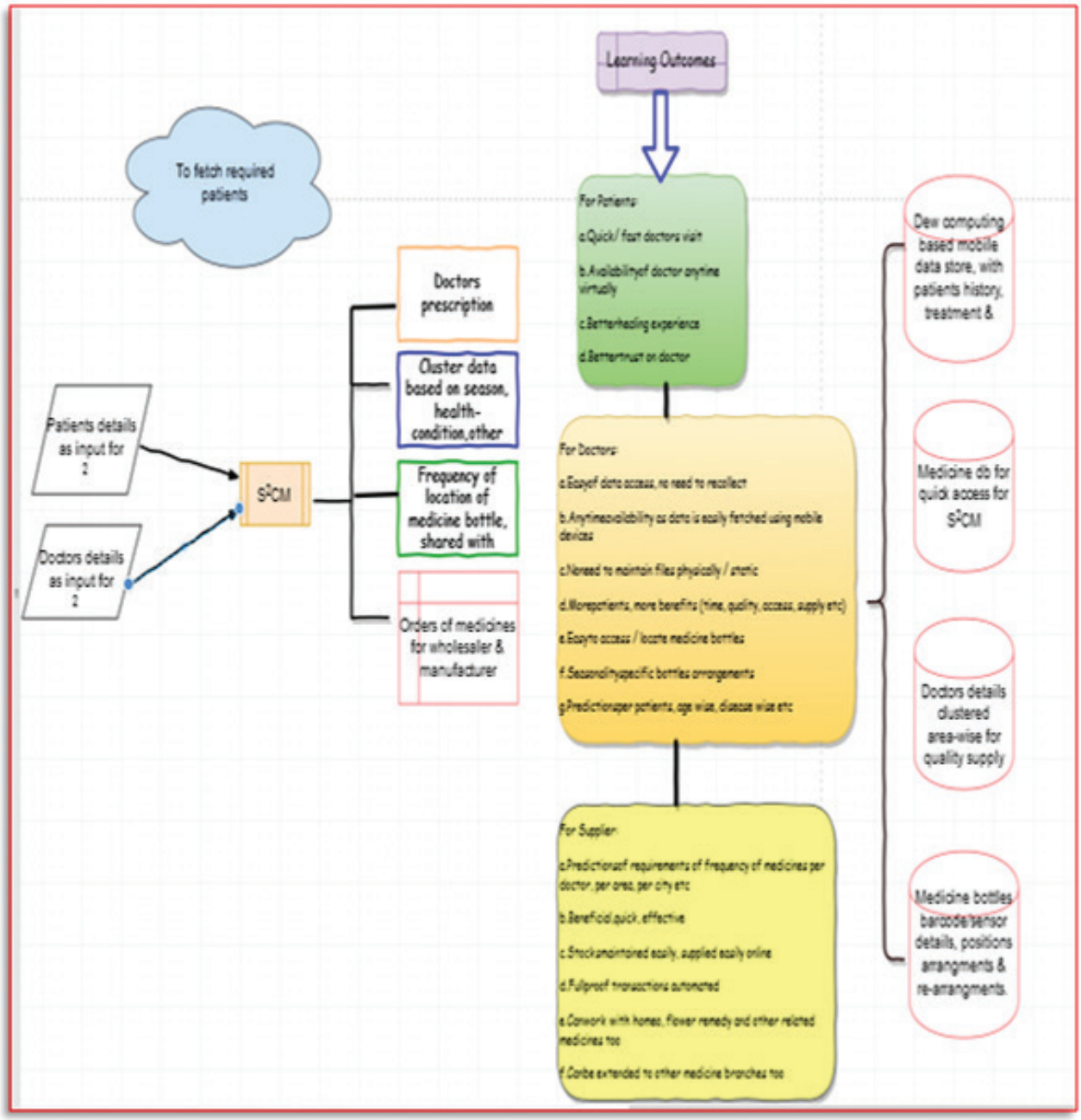


Fig 2: shows the detailed mind-map of S²CM, flow of functionalities, databases etc.

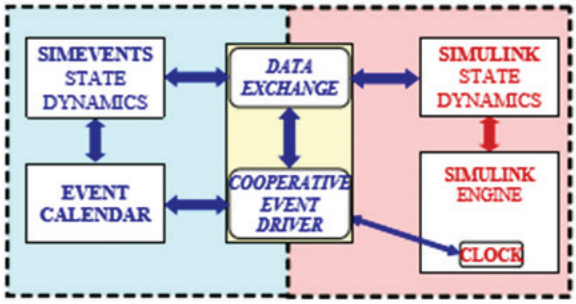


Fig. 3: shows MATLABs SimEvents block diagram proposed and implemented in S²CM³

MATLABs SimEvents offers model simulation services which are thoughtfully incorporated to model S²CM. This model simulation is at infant stage and supported with the programmable approach for results verification on sample set of data. 25 allergy medicine bottles were selected effectually from a doctor for this study. The odd number gave an opportunity to create a slot for unused medicine from the rack. This input about unused medicine also plays an important role in Supply Chain Management. Out of these 25 medicines it is observed that a doctor generally prescribes few medicines having faith on it, as an outcome of his experience, over the years related to various patients and their allergies, as shown in graphs 7a to 7h. Fig 3 shows the block diagram of SimEvents, Fig 4 shows SimEvent model of a subsystem created by researcher related to SCM³ and Fig 4,5 shows the initial phase model created using SimEvents for S²CM.

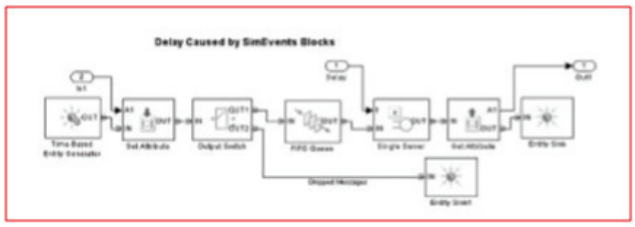


Figure 4 shows SimEvent model of S²CM [source M.Clune 2006 et al.]

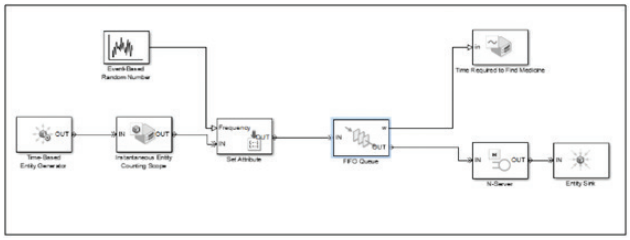


Fig 5 shows the SimEvent screen shot showing utilization of servers, cloud, mobile device (Dew Computing) etc.

RESULTS

This section of the paper depicts the virtual rack representation made available with doctors mobile phone. This virtual presentation shows the rearrangements of medicine bottles season-wise recommended by S²CM system.

29	30					
28	27	26	25	24	23	22
15	16	17	18	19	20	21
14	13	12	11	10	9	8
1	2	3	4	5	6	7

Fig 6a shows original medicine slots,

29	30					
28	27	26	25	24	23	22
15	**16**	17	18	**19**	**20**	21
14	13	12	11	10	9	8
1	2	3	**4**	**5**	6	7

Fig 6b shows frequently used medicines, season 1-wise

2	30					
28	27	26	25	24	23	22
15	16	17	18	3	6	21
14	13	12	11	10	9	8
16	**29**	**19**	**4**	**5**	**20**	7

Fig 6c relocation of frequently used medicines.

29	30					
28	27	26	**25**	**24**	23	22
15	16	17	18	19	20	21
14	**13**	12	11	10	9	8
1	2	3	4	5	6	7

Fig 6d shows frequently used medicines, season 2-wise

2	30					
28	27	26	7	8	23	22
15	16	17	18	3	6	21
14	**13**	12	11	10	9	**25**
16	**29**	**19**	**4**	**5**	**20**	**24**

Fig 6e relocation of frequently used medicines

2	30					
28	27	***26***	***7***	***8***	***23***	***22***
15	16	17	18	3	6	21
14	**13**	12	11	10	9	**25**
16	**29**	**19**	**4**	**5**	**20**	**24**

Fig 6f non-frequently used medicines shown in *bold italics* at the last row.

It is visible from the above tables (fig 6a-6f) which are outcomes of MATLAB's SimEvents. The frequency of medicines used during various seasons is noted in database and look-up table is used to compare different available medicines. Frequency count increases the moment medicine is prescribed by the doctor, identified/ located using the proposed system. This frequency count of medicine is considered per month/every month and per season as accumulated data. The re-positioning of medicine bottles for quick locate is decided by this frequency count.

Additional use of this frequency count is to know the details of non-frequently used medicines too. Based on which S²CM can predict about the life of those medicines.

Doctors' mobile phone contains part of system and software details including soft form of / virtual medicine bottle arrangement, look up table with medicine id, name and location details, text mining algorithm steps to locate prescribed medicine swiftly, and incremental learning code to learn about all involved entities.

Once the medicines are prescribed by doctor per patient, learning about medicine, patients starts at the doctors' end of system. Periodically incremental clustering[5,6] is applied based on either heuristic search (initial phase) followed by brute-force search (incremental phase) for forming clusters. Search is carried out in frequently used clusters only. This search from selected clusters is based on the approach used by www.clusty.com search engine, which is cloud based clustered solution / search engine online.

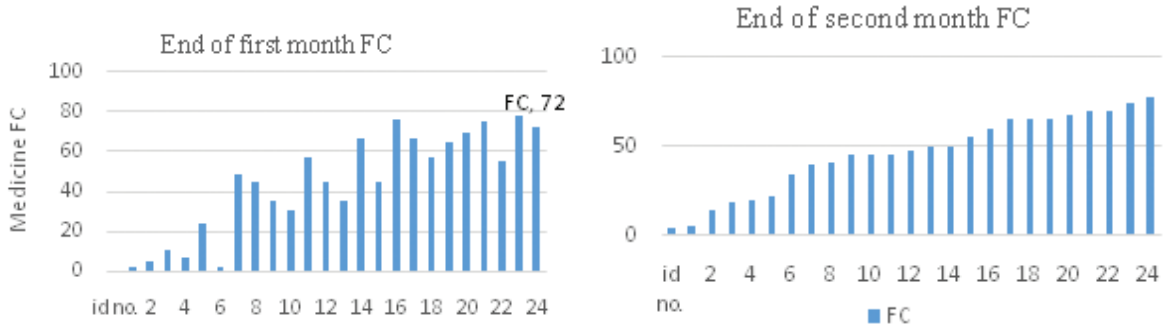


Fig 7a and 7b shows Frequency Count (FC) related to use of prescribed medicines by a doctor for first two months. A sample of 25 medicines related to allergies were considered for this case study.

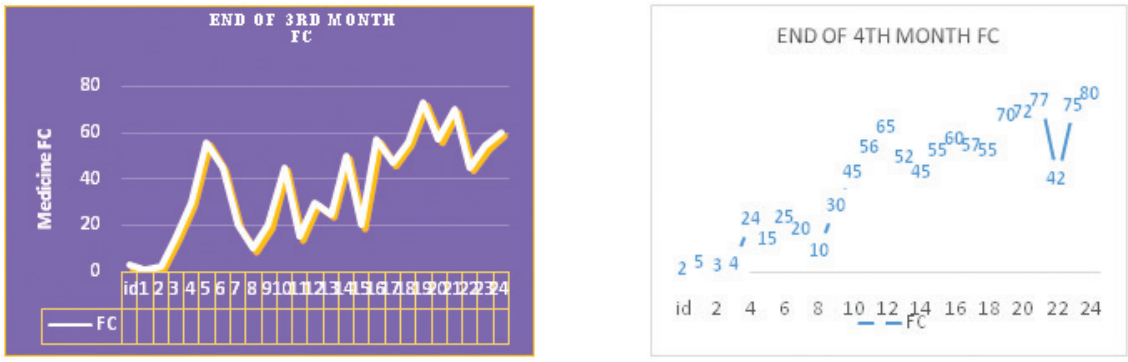
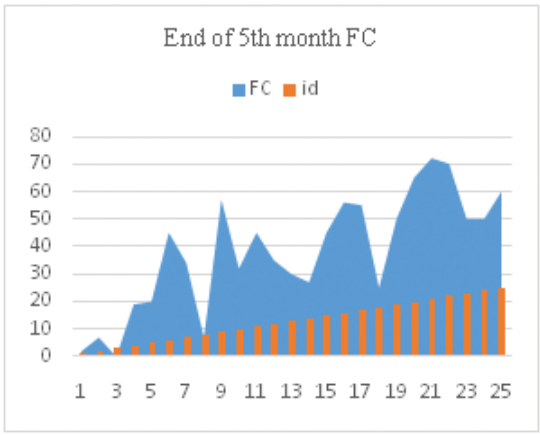


Fig 7c and 7d shows Frequency Count (FC) related to use of prescribed medicines by a doctor at the end of third and fourth month respectively. An important part of this research is to understand the "faith" of a doctor on certain set of medicines. It is observed that this doctor has a faith on medicines 25 and 24, as it is visible via programming output that this doctor have prescribed this medicine most often.



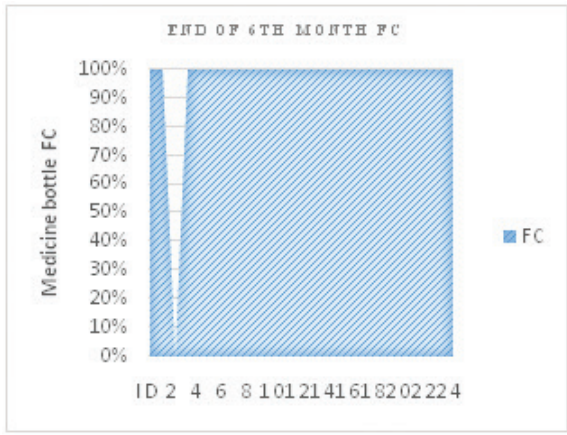
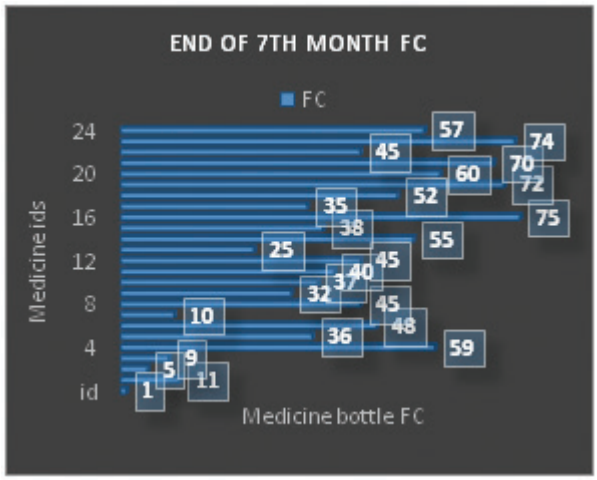


Fig 7e and 7f shows the FC related details in 5th and 6th month as a part of incremental learning. Following table 1 shows the changes over the period of 8 months about frequency of medicine bottles used (in turn prescribed by a doctor), to handle season-wise allergies.



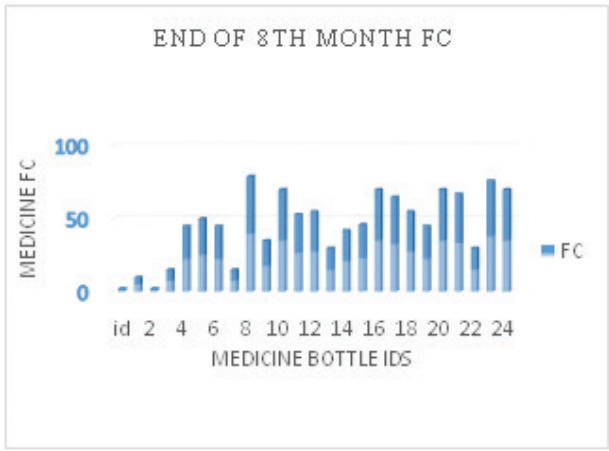


Fig 7g and 7h shows FC count related details about same set of allergy related medicines in the next season. Only 8 months were considered for this case study as it is observed that the medicines and FC is repeated in remaining months for a doctor.

Now this data of FC of medicine usage given by S²CM is available via designed distributed system for suppliers and manufacturers to use, including all homeopaths from various areas or cities.

TABLE 1 SHOWS THE MOST FREQUENTLY AND REPEATEDLY PRESCRIBED MEDICINES BY A DOCTOR, AS AN OUTCOME OF GRAPHS SHOWN IN FIGURES 7A-7H.

- id 24 is most frequently used
- id 25 is most frequently used in addition to id 24
- id no. 20 is most frequently used in addition to 25,24
- id no. 22 is most frequently used along with 25,24,20
- id no. 22 is most frequently used again along with 25,24,20
- id no. 22 is most frequently used along with 25,24,20
- id no. 17 is most frequently used along with 25,24,20,22,21
- id no. 24 is most frequently used again along with 25,22,20,17

Related Work

Amalgamation of Cloud to Dew Computing, Mobile Communication concepts, thin clients, homeopathy medicines, sensors / barcode / RFID and SCM[7,9,15] is proposed in this research. While working on this system, various research papers were surveyed for producing quality work.

David et.al. (2016)[10] have developed e-SCM for all types of eBooks including ePub, PDF, Kindle and AudioBooks too. This concept is also based on text mining and other machine learning algorithms to identify correct required version of book, place order as required and other technical billing details.

AYUSH is the most important initiative of Govt of India to accelerate medical records and patients facility details related to alternate medicines which are widely preferred in India by massive number of patients.

AYUSH system in mainstream health care system in India. Focused on cultivation of medicinal plants / herbs and encouraged good manufacturing systems of medicines, as a part of AYUSH.

Skala et. al. (2015)[13] developed scalable distributed computing system by amalgamating Cloud, Fog and Dew computing environments, which is effectually proposed in S2CM.

In the existing computing hierarchy, the Dew computing is positioned as the ground level for the cloud and fog computing paradigms. Compared to fog computing, which supports emerging IoT applications that demand real-time and predictable latency and the dynamic network reconfigurability, Dew computing pushes the frontiers to computing applications, data, and low level services away from centralized virtual nodes to the end users.

Forecasting[8,14] of medicine usage per doctor, per specific area / city, state is essential for computational details of supply chain management. Learning incrementally will provided timely forecast about all medicines for supplier and also for the manufacturer. Based on empirical patients data via S^2CM, even doctors will be able to plan their financial year, based on forecasting of patients visits, medicine requirements etc.

MARG is one of the ISO 9001:2008 certified inventory management software especially designed from the point of view of Ayurveda and Homeopathy medicines. The silent features of MARG includes: modular and scalable architecture, simple user interfact, Ekatm approvals from mail, reports generation, multiuser, multiplant functionality, data import/export in excel and other formats, integration with SAP, Oracle etc. The other useful features of MARG are:

- All Books of Inventory
- Brand, Group & Category Wise Inventory
- Stock Valuation on Multiple Methods
- Item Wise Gross Profit
- Primary and Alternative Unit for Each Item
- Party-wise Price Structure for Items/Groups
- Multiple Prices Lists of Items
- Sales & Purchase Order Processing
- Batch/MRP/Size/Shade/Reference/Serial No. Wise Inventory

tFrom the previous research work it is visible that lot of work is carried out related to SCM, eSCM etc. including billing and manufacturing of medicines, but adding doctors prescriptions, season-wise medicines relocation and learning, locating medicines bottles from rack, and use of distributed system all together in one system is hence proposed in this research.

Summary & conclusion: Incremental exploratory learning about patients, doctors, suppliers and manufacturers of homeopathy medicines via S^2CM is achieved with ease and based on incorporation of various technologies, entities and functionalities to achieve *Internet-of-Everything (IoE)* concept. Mobile signals are effectually used to trace decisive medicine bottle from larger stack, apply clustering to re-arrange bottles based on frequency of usage, allergies, seasonality and belief of practioner. IT enabled techniques really make the system learn over time about various entities of this proposed system which benefits the entire SCM users effectually. Accumulated learning outcomes can be used further for upcoming homeopaths as grand inputs in addition to traditional training.

Future Directions: The scope of this work is extended further out of homeopaths clinic to storage of medicines having larger size bottles, virtually using everyday device, Mobile phone.

Other medicine branches also utilize this IoE concept for locating required medicines such as Ayurveda and Allopath.

One of the simplest future directions of this system can be in every kitchen, library to name a few, to take care of the entire S^2CM virtually.

Frequency count of patients is also need to be considered as one of the important extensions of this research, to know how frequently patient visits, why, when, seasonality changes etc. to plan the financial perspective per doctor from individual city, state etc. This frequency count is further used by suppliers of medicines and manufacturers too.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Study of Potential Risk of Dengue Outbreak Using Spatial Modeling Based on Socioeconomic Parameters

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ABSTRACT

Dengue is the most important vector borne virus disease in the world with 50-100 million cases reported globally every year. Rapid urbanization, increasing population movement and lifestyles that contribute to the proliferation of man-made larval habitats of the mosquito are the exacerbated factors for the increasing number of the dengue incidences. The aim of this study was to model areas with humans at risk of dengue prevalence using multicriteria modeling depending on the spatial relationship between dengue fever cases and different socioeconomic parameters for the year 2012. The risk map of dengue incidences were classified as high, medium and low social risks. The developed dengue risk map was then verified by using reported cases in the year 2012 obtained from the municipality health department and it was found that more than ninety percent of the case samples were in the "medium" and "high" categories where most of the victims were found to have lived in the urban and sub-urban areas of the municipality. We have applied spatial statistics method Moran's I and kernel density estimation together with spatial analysis in the GIS environment to examine spatial clusters in order to identify and visualize areas giving different hotspot regions of the studied area. The output of the results indicated that the dengue cases were clustered ($p<0.01$) when analyzed using Moran's I with Z score 3.10. Descriptive statistical analysis was used to characterize dengue fever (DF) victims and it was observed that DF was more prevalent in adults between the age group from 15 to 55 accounting for approximately 82% of all the reported cases in 2012. Entomology index measured high with higher dengue incidence in humans; hence it is a robust measure of entomological risk for transmission of dengue virus. This study would be useful for decision makers to strategize and create preventive action plans to control the dengue transmission effectively.

Keywords: *Dengue, Disease Mapping, Geographic Information System (GIS), Hot Spot Analysis, Public Health, etc.*

INTRODUCTION

Dengue is considered as the most important arthropod-borne viral threat to public health[1,2] and it is estimated that 50-100 million cases are reported globally every year[3,4,5]. Dengue virus, a flavivirus with four antigenically distinct serotypes (DENV-1 to -4) cause a broad spectrum of clinical manifestations comprising asymptomatic infection, undifferentiated fever (UF), dengue fever (DF), dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS)[6,5,7,8,9,10]. The dengue distribution is associated with complexity of factors including climatic, socioeconomic, demographic and immunological variables[11, 12,13]. The reasons for the resurgence of dengue epidemic are global trade (transport of the mosquitoes), increasing international travel (movement of viremic people), urban crowding (favoring human vector contact) and ineffective vector control strategies all supporting the spread of the disease[14,15,16,17]. Unfortunately, no vaccine or specific therapy exists to treat the disease. Therefore, current disease control measures focus on the suppression of mosquito populations to reduce virus transmission. In order to effectively implement control strategies timely, reliable epidemiologic and entomologic information is essential to support decision making for public health agencies. The development of technologies such as the Geographical Information System/Global Positioning System (GIS/GPS) enables the participation of the spatial component in studies of vector-borne diseases[18,19].

A number of studies have been performed to assess and identify the possible risk factors involved in dengue transmission[3,20,21,22,23,24,25,26,27,28,28,30,10,31].Thus, the aim of this study was to identify the pattern of dengue incidence distribution then to analyze the hotspots locations of the dengue incidences and finally mapping the geographic distribution of dengue incidences in Pune Municipal Corporation (PMC) for the year 2012 using spatial statistics.

Fig. 1 Location of Pune city

METHODOLOGY

2.1. Study area: This study was conducted in Pune city which encompasses the extent of latitude from 18°27'20.96"N to 18°35'3.02"N and longitude from 73°45'39.57"E to 73°55'48.97"E. Pune city, situated near the western margin of the Deccan Plateau is the second largest city in the state of Maharashtra, India with estimated population 31,15,431 inhabitants. The city has a hot semi-arid climate with average temperature ranging between 20°C to 28 °C and average annual precipitation varies from 1500 mm to 2500 mm. Fig. 1 shows the location of Pune city, with a total area of 243.84 km². The restricted military area has been clipped due to non-availability of data.

2.2. Data collection: Epidemiology dengue data & demographic data for each ward were obtained from Pune Municipal Corporation (PMC), Pune. The entomology index data i.e. Aedes Aegypti mosquito rate was obtained from National Institute of Virology (NIV), Pune. A field survey was carried out with National Institute of Virology (NIV), Pune staff at locations where maximum dengue incidence cases were reported for the year 2012.

2.3. Data analysis

2.3.1. Disease mapping: Disease mapping has long been performed [32] and has been expanding with the advent of increase in the availability of spatially referenced data as well as the development of methodological spatial analysis and statistical analysis tools within Geographic Information System (GIS), which made it possible to uptake mapping technology for use relevant to health [33,34,35].There are a number of methods used to map the distribution of dengue fever[36]. A considerable number of approaches are based on spatial relationships measures[3,18,37]. A number of studies have used remotely sensed data in combination with different modeling approaches including logistic regression and multinomial models[38,39,40] and non-linear discriminant analysis[35]. Other approaches include utilizing indices of probability of case-occurrence, transmission intensity and mean duration of epidemic waves[41], computer simulation models based on climatic variables[42, 43,44], geographically weighted regression[45] and species distribution modeling[46,47,48].In present study socioeconomic parameters were used to identify the areas most suitable for dengue fever using weighted overlay technique. Weighted overlay technique is usually used for applying a common measurement scale of values to diverse and dissimilar inputs in order to create an integrated analysis.

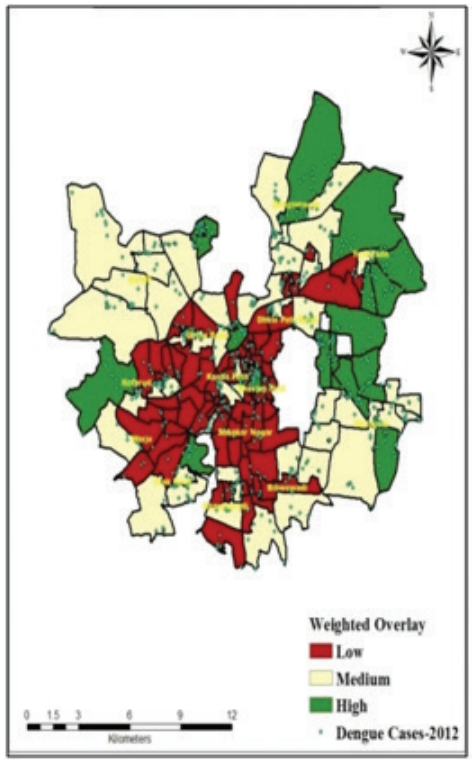


Fig. 2: PMC dengue risk map

2.3.2. Spatial clustering: We have applied the Moran's I to determine the spatial clusters of dengue incidence cases and used the kernel density to detect the spatial patterns of hotspots within PMC area. Moran's I measures spatial autocorrelation based on both feature location and feature values simultaneously. Kernel density estimation is an effective tool as it helps to precisely identify the location, spatial extent and intensity of dengue disease hotspots by producing a smooth and continuous surface that defines the level of risk for that area.

RESULTS

3.1. Spatial modeling for dengue risk map generation: The socioeconomic parameters such as total population, population density, total slum population, slum population density, dengue cases-2012, total slums and total gardens were identified as indicator factors of dengue outbreak in PMC. For dengue risk map generation, firstly from each of these socioeconomic parameters mentioned above seven spatial layers were created then all these layers were reclassified individually using reclassify tool and finally each of these reclassified layers were tested using the weighted overlay function technique in ArcGIS 10 software. Fig. 2 shows the dengue risk map with the point locations of the dengue incidence cases-2012 as a verification of the dengue risk map areas and that the highest Aedes risk was identified in the central areas of the municipality, while sub-urban areas and the peripheral areas of the municipality were identified as medium and low risk areas respectively.

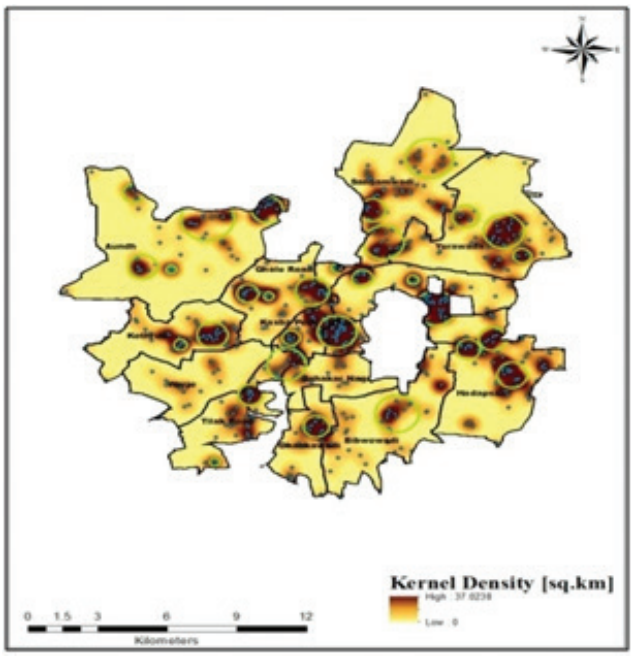


Fig. 3 Spatial autocorrelation report

3.2. Spatial clustering of dengue cases: Moran's I test on dengue incidence cases-2012 for PMC indicated that there was positive spatial autocorrelation among dengue incidence cases within the municipality as shown in Fig. 3. The Moran's I for dengue cases is 0.057 ($p<0.01$) while the z-score is 3.10 ($p<0.01$).

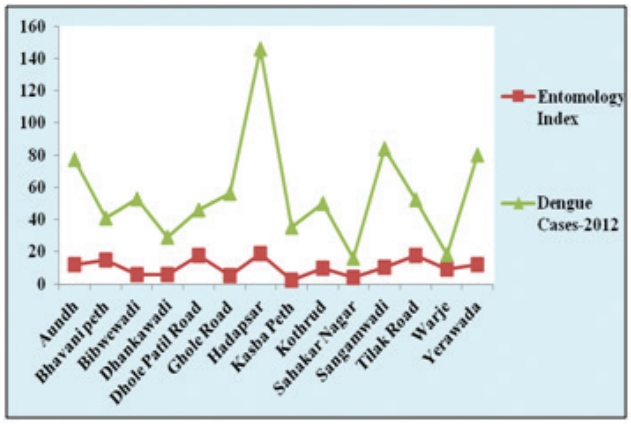


Fig. 4 PMC hotspots of dengue cases-2012

The encircled dark brown color shaded areas in Fig. 4 are the hotspots identified with maximum dengue incidence cases density. The kernel density map shows the overall picture of dengue density variation within PMC for the year 2012.

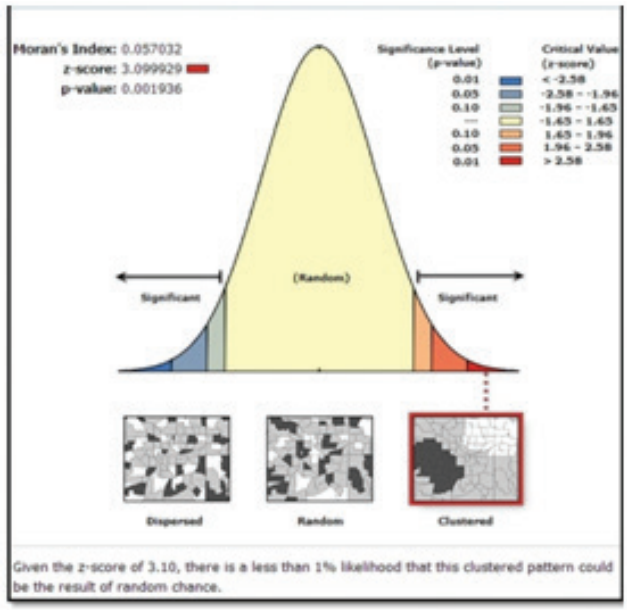


Fig. 5 PMC age group distribution of dengue cases-2012

3.3. Descriptive statistical analysis: Fig. 5 shows the overall age group distribution of reported DF cases during the year 2012. The age range with the highest number of dengue incidence cases was 15 to 24 for males and 24 to 35 for females, while age range with the lowest number of cases was > 55.

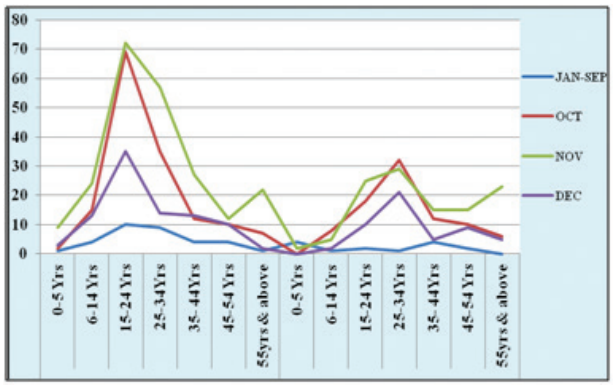


Fig. 6 PMC ward-wise distribution of entomology index and dengue cases-2012

Fig. 6 shows that the entomological index decreased with decrease in dengue cases and increased with increase in dengue cases for the year 2012.

DISCUSSIONS

The dengue risk map generated as described above was classified as "Low", "Medium" and "High" risk potential areas of having the dengue outbreak. A low value means the sub variable had a low intensity influence; a medium value equated to a greater risk influence to the outbreak and a high value equated to a very significant influence on the dengue outbreak pattern. The results shows that most of the dengue incidences had occurred in the high risk areas categorized in the dengue risk map generated from the socioeconomic parameters. The dengue risk map shows that 62.86 km² (25.55%) area is falling within high risk zone, 110.36 km² (45.42%) area in medium risk zone and 70.60 km² (29.03%) area in low risk zone of dengue fever prevalence. This finding is very encouraging as it validates the accuracy of the generated dengue risk map when compared with the reported dengue cases-2012 within the municipality area of Pune city. This novel approach allows the identification of interactive spatial risk characteristics opposed to the traditional use of case numbers. From the spatial autocorrelation report generated it can be concluded that the null hypothesis is rejected because the spatial distribution of dengue cases in the municipality is more spatially clustered. Most of the hotspots with the highest dengue cases and high risk levels were identified in central and northeastern part of PMC. The locations and distributions of hotspots occurred in areas of the highest population densities. Hence, with the help of dengue density map it was easy to target specific areas within PMC showing highest incidence cases. From the descriptive statistical analysis, it was observed that DF was more prevalent in adults between the age group from 15 to 55 accounting for approximately 82% of all reported cases in 2012. This could be explained by movement and travelling of adult age group that facilitated the spread of dengue, however further epidemiological investigation and entomological data may help in elucidating this trend. The data obtained from entomology index were related to dengue cases for the year 2012 and it was observed to have significant influence over ward-wise distribution of dengue prevalence. Thus, it can be widely employed in planning and undertaking dengue surveillance and control activities. A field survey of PMC area was carried out and it helped in collecting and gathering information at the local level. The field visits to each of the dengue risk areas as per the analysis were carried out to make the study more realistic.

CONCLUSIONS

This study shows that GIS can play a critical role for the development of dengue risk areas, improving the quality of dengue control management, preventive strategies and understanding the dynamics of dengue mosquito prevalence at spatial scale. This method incorporates a large number of socioeconomic parameters which are essential in understanding the process underlying the abundance of the mosquito and the changes in risk levels in the study area as a whole. The results of this analysis indicate that dengue cases for the year 2012 in PMC were spatially auto correlated through Moran's I index and clusters of dengue cases were found in some sectors of central and northeastern PMC, which are identified as hotspots by means of kernel density estimation. The dengue incidence cases for the year 2012 at ward level revealed that dengue generally occurred in areas with high population density, low socioeconomically life standards with limited access to public utilities and home gardens respectively. Hence, these areas should be under continuous monitoring and treatment to avoid any spread in the future. The statistical analysis revealed that dengue fever prevalence was found to be more in adult age group; hence there is need for an intensive educational program on dengue fever prevention and control using different types of media. Similar programs can easily be targeted in schools for

children, especially those between 5 to 15 years of age group. The preventative measures in domestic settings include water storage containers and ground level water storages to be treated and monitored to kill the eggs and larvae of Aedes mosquitoes to reduce the mosquito abundance. Hence, provision of urban services such as piped water, sewage and waste removal should be provided to reduce mosquito breeding sites. The low income communities were observed to have higher risk of disease due to less sanitary environments resulting due to inconsistent or nonexistent refuse collection, hence measures like access to water supply and infrastructure and receive more support for buying protective equipment such as door and window screens as well as netting should be provided to members of the household. This valuable information would strengthen the public health authorities for planning policies, prevention of future DF occurrences and spread.

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Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Predictive Analysis of Increased Adherence Level and Improved Health Conditions of Patients Through Mobility and Web-based IT Solutions

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ABSTRACT

Purpose: Regular adherence to medication can help improve the health conditions of a patient, enhance patient engagement and superior care coordination. Hence this paper tries to analyse the factors affecting the medication and consultation adherence level of the patient using or who may wish to use new age mobility and web-based technology solutions.

Research Methodology: Primary research survey was conducted on 158 patients with chronic ailments as well as non-patients who are willing to adopt technology. Data was analysed using SPSS and statistical methods like Factor analysis and multiple regression analysis.

Findings: The study proposes a significant model with good predictive power for future use of healthcare service providers. It predicts the value of the dependent variable i.e. adherence level on the independent variables of time, cost, convenience and regularity which contribute to encourage the patients to embrace new age technology transformation.

Research implications: This study will help healthcare service providers to provide better solutions for improved healthcare. This technology transformation will benefit millions of patients who do not have access to healthcare by providing healthcare service on time and at affordable cost.

Keywords: *Healthcare-IT, M-health, Mobility-solutions, Web-based-IT solutions, Predictive analysis.*

INTRODUCTION

The present day healthcare industry is witnessing a major paradigm shift in the information management from over the past decade, instigated by the advancement of mobile technology. This new world of electronically entered and stored medical information has addressed many shortfalls of the world of folders and paper medical records. This shift in information management is ongoing, accompanying the new focus on qualitative, affordable, high quality and timely patient-centric healthcare, resulting in a high level of patient experience satisfaction.

Health care reforms arise when there is a need to control cost without sacrificing quality. Societies of abundance like ours now have an entirely different illness profile than they used to. Long-term conditions emerging from lifestyles, like cardiac disease and diabetes are some of the major chronic diseases of the present day society. Studies state that around 70% of the nation's disease burden is preventable if a proper action is taken on time. With the advent of mobile phones and connected devices, mobile technology has increasingly become integrated into every facet of our day-to-day lives. As these technologies continuously grow at a rapid pace the major challenge is to meet the demand while controlling the costs. That is why mobile healthcare—or m Health—is redefining patient-centric care.

mHealth makes use of mobile phones and other wireless technology to educate consumers on preventive health care services and also aids in providing medical services to the patients. The mobile healthcare technology opens up new methods of providing clinical and critical care in ways that may help to improve the patient experiences. The main idea behind mHealth is to connect with patients and help them track their recovery with remote monitoring tools and follow what the doctor has prescribed. Patient reminders and

notifications on a regular basis can help individuals manage their health and health care. These reminders alert people to schedule medical visits and screenings and also remind them on how to take complex medical regimens. New communication modalities like text messaging, email, social media that are being adopted by the general mass could allow for the provision of timely and effective healthcare reminders and notifications that are seamlessly integrated into patients' day-to-day lives.

LITERATURE REVIEW

Healthcare sector in India: In the present day, timely service of healthcare is indispensable in order to improve the quality and prevent people from getting prone to any sort of disease. The primary task of health centers is to improve and deliver good quality services to patients [1]. The Indian health sector has reached the age of providing tremendous amount of growth in terms of physical size, expenditures, investments and service utilization [2]. Government authorities are advocating mobile technology as a potential tool for developing and improving the livelihoods of the people, which indirectly leads to growth in the mHealth industry[3].

With the fast adoption of mobile technology in the rural areas of India as a dependable and effective channel, the quality of services offered can be improvised by making use of prompts as well as reminders via voice calls as well as SMS for the patients. Refinements in terms of data quality and data timeliness will go a long way in helping the healthcare systems to manage the delivery and promotion of the healthcare functions[4]. Mobile apps, which are accessible, comprehensive and instantaneous, have the potential to optimize people's self-regulatory skills in meeting their goals. The mobile healthcare technology can aid in easily managing and supporting healthcare transitions as patients move from or to acute, emergency or chronic care[5]. Mobile solutions can play a vital role in supporting the healthcare services by making use of various applications and thus easing the life of chronically ill patients, as well as physicians[6].

In India, the mobile technology is growing rapidly due to the advancement in technologies, ease of use, broad network coverage and the falling costs of devices. This helps to make mobile an appropriate and adaptable tool to bridge the digital divide and opens up huge opportunity to provide services that would trigger development to improve the quality of life of people [7]. As a result of the wide usage of mobile phone, many mobile vendors have begun embedding eHealth care services in their mobile devices[8]. Unimpeded by the geographical boundaries, the surge in computing power and mobile connectivity with smartphone-linked wearable sensors built around real-time data streams has transformed the mode and quality of health care on a global level [9].Improvising the patient safety, reduction in cost and time that is taken for access as well as updates of the most important data, are the most important driving force for the m-Health development[10].

But despite all these factors, the various projects and studies done in areas of poor resource settings have emphasized the effectiveness and importance of the mhealth sector. Certain technological and programmatic challenges impede the adoption of mHealth in large scale across the health system[4]. The health planners and policy makers fail to get a holistic picture of the highly complex health sector network in the country[2]. Other challenges of the health sector in the developing nations include the lack of evidence to support the claim of the impact by the technology in the field, as research and development in the field is only in the starting phase[3]. Even though researches confirm the point that by the advancements of mobile technology, acquisition and processing of data via mobile applications, mHealth area is in expansion, challenges exist with the lesser battery life of the devices on using such apps regularly[11]. Studies also show that dissatisfaction with the e-health records with respect to few service providers remains a major hurdle in achieving the requisite potential of mhealth[12].

Wireless technology in Health care: As wireless technology continues to evolve, many new capabilities in form of innovative wireless business applications are constantly getting introduced to the once ignored or less efficiently addressed areas. The niche mHealth segment that appears to be poised to benefit by adopting wireless solutions proposes to radically change the way of present health care, by making use of wireless technology to raise the quality of patient care which will result in operational efficiencies in the healthcare sector[13]. With a regular use of wireless technologies that can offer early detection of health problems it will be easier to provide better results that may enable users to have lengthier and more satisfied lives. Telemedicine can help patients suffering from chronic diseases to lead normal personal

as well as work-life thus enabling them to stay in their own home setting rather than move around to various institutional settings[14].

Drivers of adherence levels: There are steep expectations from mHealth to transform health into a system which is not only prevention based but also sustainable. Unfortunately, it has yet to reach a large scale adoption due to the existence of many barriers[15]. Studies show that health telematics is showing a vital improvement on life of patients, especially those who are elderly and chronically ill. ICT improvements, along with the use of mobile Internet, offers anywhere and anytime connectivity and provides modern healthcare solutions. mHealth solutions addresses a variety of problems on healthcare services, which includes the growing number of patients with chronic diseases, high costs of existing healthcare services, and the need to provide a direct access to health services, regardless of the time and place[16]. By converging unobtrusive sensing, wireless communication, ubiquitous computing, connectivity and social networking, mHealth solutions can be used for diagnosis, therapy and monitoring of health conditions and can bring improvements in quality, convenience, reliability and cost of care to patients anytime and anywhere while they lead their normal daily life. Thus, by making use of mHealth solutions to manage chronically ill patients' in the developing countries, tremendous promises can be made to increase the reach and reduce cost, while improving quality of care to increase sustainability[17]. There are several barriers in adopting of mHealth services like time, convenience, cost and reliability as reported by several authors[14,18-22].

HYPOTHESES FORMULATION

In the hypotheses formulation, a combination of four factors has been considered. Time as a factor: (patients ailing from chronic disease prefer to adopt technology care provider highly to reduce the time consuming consultation process which can be related to the increased level of adherence to medication of the patient as they are able to consult frequently with their care provider regarding the change in medication dosage anytime).Cost as a factor: (patients has affinity towards cost effective ways of approaching the care provider, benefitted through adhering to regular medication intake and in turn improve their health conditions).

Convenience as a factor: (technology care providers can only promise convenience to their consumers where in this case its patients and in turn making consultation and treatment as the easiest process).Regularity as a factor: (patients with chronic ailment follows a routine to visit doctors, change their medication and consult about the changes in the health conditions and get prescribed with new set of medication which makes studying regularity with respect to increased level of adherence to medication of the patient a most important factor). Final hypothesis shows the significant relationship with the increased level of adherence to medication to use of technology in the context of healthcare related consultation (Figure 1).

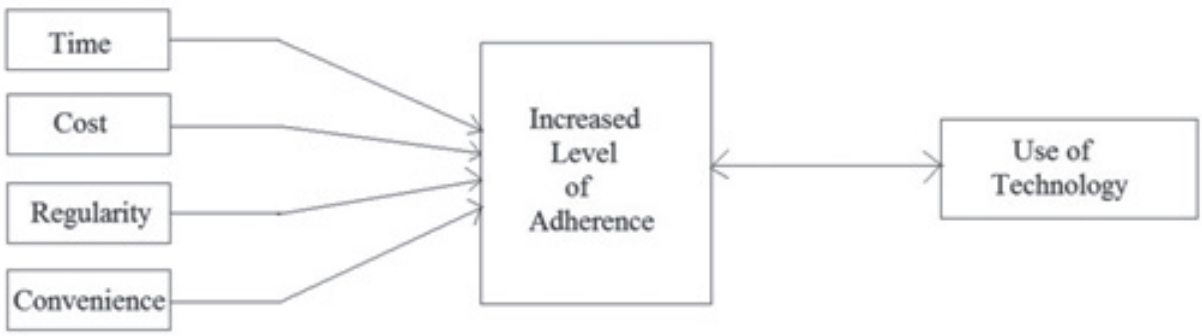


Figure 1: Conceptual framework

Based on the conceptual framework the following hypothesis has been formulated:

H1: Time factor has a significant relationship in impeding the increased level of adherence to medication of the patient.

H2: Cost factor has a significant relationship in impeding the increased level of adherence to medication of the patient.

H3: Regularity factor has a significant relationship in impeding increased level of adherence to medication of the patient.

H4: Convenience factor has a significant relationship in impeding increased level of adherence to medication of the patient.

H5: Use of technology in the context of healthcare has a significant relationship with increased level of adherence to medication of the patient.

RESEARCH METHODOLOGY

Research Design: This study aims at predicting the factors which impedes as well as improves the patient's level of adherence to medication which in turn is useful in improving the health condition of the patient ailing with chronic disease.

In order to carry out such a study, exploratory research design was used by the researcher. The main objective of this study which involved an exploratory survey and extensive literature review was to comprehend which factors affect the patient's level of adherence to medication and these impediment factors can be completely eliminated from the path of patient journey and the factors which contributes to the improvement can be added to the path of patient journey with the help of technology care provider.

Primary Research and Sample Size: Primary survey was administered to a sample size of 158 patients ailing from chronic disease as well as non-patients who may be directly supporting such patients or the mobile application users in the City of Delhi and City of Pune, Maharashtra. This was done through a structured questionnaire. A set of 17 parameters or attributes were considered for record purpose and response were measured on an importance scale. Additional relevant information was also recorded for the purpose of study.

ANALYSIS

Factor analysis was used to group the sixteen attributes of impediment and improvement factors that affect the patient's increased level of adherence to medication influencing the technology care providers. The responses collected on the 16 parameters of impediment and improvement factors (on a scale of one to five) were converted into "factors" or "constructs" that influence patient's level of adherence to medication. Moreover, for every respondent a "factor score" was created using factor analysis. The initial extracted factors went through varimax rotation. After which the 16 attributes in the questionnaire grouped into 4 factors.

Regression analysis was further carried out to confirm the relationship of the patient's increased level of adherence to medication with the four factors time, cost, convenience and regularity also with the usage of technology in the context of healthcare consultation. Regression analysis was done to confirm that a linear relationship exists between patient's increased level of Adherence to medication and the identified impediment and improvement factors. The results of Factor analysis and Regression analysis was used to validate the above stated Hypotheses which helped in arriving at appropriate conclusions.

Outcome of Factor Analysis

Principal Component Analysis: Based on factor analysis outcome, *Factor 1 (Time factor)* comes out as the most critical factor that explains 19.33% of the total variation (Table 1). This is followed by *Factor 2 (Cost factor)* that describes 16.21% of the total variation (Table 1). This is followed by *Factor 3(Regularity factor)* which explains 13.25% of the total variation (Table 1). *Factor 4 (Convenience factor)* which describes 11.28% of the total variation (Table 1).

Secondly, all the four statistically significant factors explain 60.09% of the variation. (Table 1)This indicates that 60.09% of the influence of impediment factors (four factors) on patient's level of adherence to medication towards addressing the impedance with the help of technology enabled care providers. Factor scores of most attributes are more than 0.7 which indicates that they are highly significant (Table 2).

Table 1: Total Variance Explained

	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
Component	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	5826	36413	36413	5826	36413	36413	3094	19335	19335
2	1417	8857	45270	1417	8857	45270	2595	16218	35553
3	1198	7487	52757	1198	7487	52757	2121	13256	48809
4	1174	7337	60095	1174	7337	60095	1806	11285	60095

Table 2. Rotation Matrix:

	Component			
	1	2	3	4
Adherence H1	.733	.351		
T1	.796			
T2	.563		.351	.436
T3	.653		.407	
T4				.849
T5	.650		.319	
C1			.643	
C2		.411	.319	.504
C3	.305	.332	.310	.301
R1			.685	
R2	.408	.460	.555	
E1		.617	.351	
E2		.685	.317	
E3	.516	.480		
E4		.719		
E5		.493		.528

Extraction Method: Principal Component Analysis.

Rotation Method: Varimax with Kaiser Normalization.

Rotation converged in 13 iterations

Scale Reliability Test: Cronbach Alpha coefficient was used to test the reliability of the 5 point scale used to obtain the results. The Cronbach Alpha test validates the reliability and consistency of the questions to measure the results. A Cronbach Alpha score of .07 or more is considered as good reliability of the scale. We have achieved the Cronbach Alpha for the importance scale as 0.877 (Table 3) which indicates a very good reliability of the scale.

Table 3. Scale Reliability Test:

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.877	.878	16

Statistical outcome of Regression Analysis 1: In this research study, patient's level of adherence to medication is identified as the dependent variable and the 16 identified attributes are called as independent variables. The model summary shows that R value in this study is 0.822 (Table 4) which signifies that 82% of the variation was explained by the impediment factors. As this is between 0 and 1 R square value is significant. As per table 5, The F statistic is 0.000 which is significant at less than the criterion alpha level (p = 0.01). This signifies 99 per cent confidence in the ability of the model to explain the dependent variable; hence we can conclude that the regression equation as computed is statistically significant. The table Coefficients provides information on the confidence with which we can support the estimate the p value of time factor and cost factor is 0.000 (Table 6) which is less than 0.01 signifying 99% confidence in the value of the estimated coefficient. The p value of convenience factor is 0.33 (Table 6) which is less than 0.4 signifying 67% confidence in the value of the estimated coefficient. The p value of regularity factor is 0.08 (Table 6) which is less than 0.10 signifying 90% confidence in the value of the estimated coefficient. The results of factor and regression analysis helped to validate the above stated hypotheses and arrive at appropriate conclusions.

Table 4: Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. error of the Estimate	Durbin-Watson
1	.822a	.676	.661	.361	1.552

(a) Predictors: (Constant), REGR factor score 4 for analysis 1, REGR factor score 3 for analysis 1, REGR factor score 2 for analysis 1, REGR factor score 1 for analysis 1,

(b) Dependent Variable: AdherenceH1

Table 5: Anova Output

Anova[a]

Model	Sum of Squares	df	Mean Square	F	Sig.
Regression	22.831	4	5.708	43.811	.000b
Residual	10.944	84	.130		
Total	33.775	88			

(a) Dependent variable: AdherenceH1

(b) Predictors: (Constant), REGR factor score 4 for analysis 1, REGR factor score 3 for analysis 1, REGR factor score 2 for analysis 1, REGR factor score 1 for analysis 1,

Table 6: Co-Efficient

Coefficients[a]

Model	Unstandardized coefficients		Standardized Coefficients			Model	95.0% Confidence Interval for B	
	B	Std. Error	Beta	t	sig		Lower Bound	Upper Bound
(Constant)	4573	.038		119.524	.000	1 (Constant)	4.497	4.649
REGR factor score 1 for analysis 1	.454	.038	.733	11.802	.000	REGR factor score 1 for analysis 1	.378	.531
REGR factor score 2 for analysis 1	.217	038	.351	5.652	.000	REGR factor score 2 for analysis 1	.141	.294
REGR factor score 3 for analysis 4	.037	038	.060	.966	.337	REGR factor score 3 for analysis 4	.039	.114
REGR factor score 4 for analysis 1	.067	038	.109	1.753	.083	REGR factor score 4 for analysis 1	.009	.114

Statistical Outcome of Regression Analysis 2: Regression analysis has been carried out to confirm that there exists a significant relationship between patient's increased level of adherence to medication and the usage of technology by the patient in the context of healthcare consultation. Previously regression analysis has been conducted to show that there exists a significant relationship between the patient's increased level of adherence to medication and the four impediment and improvement factors.

The model summary shows that R value in this study is 0.857 (Table 7) which signifies that 85.7% of the variation was explained by the use of technology factor. As this is between 0 and 1 R square value is significant. The table Coefficients provides information on the confidence with which we can support the estimate the p value of use of technology factor is 0.000 (Table 8) which is less than 0.01 signifying 99% confidence in the value of the estimated coefficient.

Table 7 Modal Summary of Regression Analysis II:

Model Summary

Model	R	R Square	Adjusted R Square	Std Error of the Estimate
1	.857[a]	.734	.731	.209

Predictors: (Constant), REGR factor score 1 for analysis 1

Table 8: Co-efficient of Regression Analysis II

Coefficients[a]

Model	Unstandardized coefficients		Standardized Coefficients			Model	95.0% Confidence Interval for B	
	B	Std. Error	Beta	t	sig		Lower Bound	Upper Bound
(Constant)	4.798	.022		216.087	.000	1 (Constant)	4.754	4.842
REGR factor score 1 for analysis 1	.346	.022	.857	15.501	.000	REGR factor score1 for analysis 1	.302	.391

Dependent Variable HImprovement (Q17)

HYPOTHESES TESTING USING FACTOR AND REGRESSION ANALYSIS

H1: Time factor has a significant relationship in impeding the increased level of adherence to medication of the patient.

H2: Cost factor has a significant relationship in impeding the increased level of adherence to medication of the patient.

H3: Regularity factor has a significant relationship in impeding increased level of adherence to medication of the patient.

H4: Convenience factor has a significant relationship in impeding increased level of adherence to medication of the patient.

H5: Use of technology in the context of healthcare has a significant relationship with increased level of adherence to medication of the patient.

The output of the factor analysis with respect to four underlying factors as: Time impeding factors, Cost Consumption factors, Regularity related factors and Convenience related factors. The extracted four factors explain 60% (Table 1) of the variance cumulatively. This pinpoints that there are four basic factors which patients evaluate while going for healthcare consultation. Explanation of total variance validate the four constructs thus specifying patient's level of adherence to medication are very much related to and depends on managing these factors. Addressing these factors effectively will help the patient improve their health condition and can be done with the help technology enabled care providers.

According to the statistical factor analysis output, Factor 1, Time Consumption factors (19.33% variance) (Table 1) came out as the most important factor impeding the patient's increased level of adherence to medication influencing technology enabled care providers. Regression output shows that the p value of this factor is 0.00 (Table 6) which is less than 0.01 (Table 6) signifying 99% confidence in the value of the estimated coefficient. This signifies acceptance of the 1st hypothesis *H1: Time factor has a significant relationship in impeding the increased level of adherence to medication of the patient.*

Factor 2, Cost Consumption related factors (16.21% variance) (Table 1) came out as the second most important factor impeding the patient's increased level of adherence to medication. Regression output shows that the p value of this factor is 0.00 (Table 6) which is less than 0.01 signifying 99% confidence in the value of the estimated coefficient. Moreover, these two factors account for 36% of the total variation (60%). This signifies acceptance of the 2nd Hypotheses that *"Cost factor has a significant relationship in impeding the increased level of adherence to medication of the patient."*

The other two factors, (Regularity and Convenience factors) account for the remaining variation 25% of the total variation. The p value of regularity factor is 0.08 (Table 6) which is less than 0.10 signifying 90% confidence in the value of the estimated coefficient. The results of factor and regression analysis helped to validate the acceptance of the 3rd hypotheses that *"Regularity factor has a significant relationship in impeding the increased level of adherence to medication of the patient".*

The p value of convenience factor is 0.33 (Table 6) which is less than 0.4 signifying 67% confidence in the value of the estimated coefficient. The results of factor and regression analysis helped to validate the acceptance of the 4th hypotheses that *"Convenience factor has a significant relationship in impeding the increased level of adherence to medication of the patient".*

The output of regression analysis shows that R square of the attributes of use of technology factors in this study is 0.857 (Table 7) which signifies that 85.7% of the variation was explained by the factors contributing to use of technology. As this is between 0 and 1 R square value is significant. The table Coefficients provides information on the confidence with which we can support the estimate the p value of use of technology factor is 0.000 (Table 8) which is less than 0.01 signifying 99% confidence in the value of the estimated coefficient. This signifies the acceptance of the 5th Hypotheses which is" *Use of technology in the context of healthcare has a significant relationship with increased level of adherence to medication of the patient*". Technology Enabled care providers can easily eliminate the impeding factors from the path of patient journey adding value by improvement factors providing excellent care coordination and patient experience*".*

MANAGERIAL IMPLICATIONS

The findings of this research on the factors impeding and improving the patient journey with the help of technology gives a strong message to the technology care

providers who cater to patients with chronic ailments and who need to stick to a daily routine of medication. The technology care providers can enhance their position in the market with new disrupting technologies related to healthcare using this research. This study can be used to promote healthcare through technology especially can help in converting patients who is on a back foot in terms of accepting the technology in such a data sensitive sector like healthcare. The main goal of the management of any organization should be to exploit the opportunity thereby increasing the profit and earn the trust of more and more patients. Our study will help patients understand the importance and convenience of using technology in terms of healthcare which ensures improved health conditions of the patient.

CONCLUSION

The study recommends that the use of mobile and web-based IT solutions in the context of healthcare consultation and follow up can improve the health condition of the patient with chronic ailments providing a new dimension to patient engagement and care coordination in the Indian healthcare industry. Other studies can be further conducted in the same sector and should consider all other categories of patients also in the industry.

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Measuring the Impact of Technology Trends and Forecasts in Sugar Industry Towards Sustainable Health-Care Services

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ABSTRACT

Purpose: The purpose of this paper is to measure the impact of technology trends and forecasts in agrobased industry towards sustainable health-care services.

Methods: Hundred sugar factories were surveyed from the four regions of Maharashtra. At the same time health status was studied through census data report in Maharashtra and neighbouring state Gujarat. All items included in the survey has been pretested to ensure precise operationalization of the variables for measuring technology trend and health care. Levene statistics and ANOVA table was used to see the trends.

Findings & Interpretation: The results shows that there was upgradation in the technologies employed from 2000 to 2015. However, there is no variation in the change in technology in the regions of Maharashtra. These trends have reflected upon sustainable health care services in and outside the factory. The effect of the user friendly technologies can be seen in the decreasing respiratory problems over Maharashtra and Gujarat. The population has been increasing every year yet the number of respiratory problems has reduced. The impact of technology trends has been measured significantly with the respiratory problems of the factory workers and surroundings.

Implications & originality: The authors have forecasted the use of various technologies in sugar factories. The study has interlinked the technology practices with a sustainable health care service

Keywords: *Technology impact, Sugar industry, Healthcare services, Sustainability*

INTRODUCTION

Sugarcane is known as an important crop in the tropical and sub-tropical zone contributing to Indian Economy and Employment generation. Of the total cane production 12% accounts for seed production, 5% for chewing and juice extraction, 25-30 % for khandasari and jaggery and the remaining 60 % is used for sugar production. The sugar industry is the second largest industry in India after Textile Industry. Almost fifty million people depend on sugar industry for their livelihood. More than 50 % of ethanol production comes from sugar. Brazil uses 60% of the sugarcanes for production of ethanol. Commercialization of sugar ethanol production process raises the demand for sugar thereby increasing the price. Modernization and up gradation in technology are continuous exercise for obtaining economies of scale and cost cutting. The future of Sugar Industry is moving towards cost minimization and is technology driven. The technology up gradation in sugar industry is therefore very important to ensure global competence and has to be a continuous process. The key drivers in technology use are improvements in Capital Output Ratio, efficiencies of the sugar plant, energy Conservation, optimizing cost of consumables and impact of the quality of sugar on price realization[1,2]. These key drivers are nothing but paths leading to sustainability. The technology up gradation in sugarcane industries has impacted in reduction of environment pollution positively. The reusability and recycling management of waste produced in sugarcane industries helped to reduce the same[3,4,5,6,7]. Sugarcane industries in India also has been using different technologies in controlling the environmental pollution[8,9,10,11,12]. The technology up gradation not only helped in environmental pollution reduction but also the reduction in pollution also has benefited the health impacts on human being.

Figure 1 shows the technology up gradation done by the sugarcane industries for reducing the pollution and in turn reducing its impact on the health.



Figure 1: Technologies used in Sugarcane Industries

There is a rich body of literature which shows technology role in industries and its impact on environment pollution reduction but there has been a dearth of literature on the impact of changing technology trends on the workers and people living in the surrounding areas of the sugar factory. Driven by the requirement of study we have come up with a research question What is the impact of changing Technology Trends on workers and people living around the factory? To address this research question we have come up with the following objectives:

- To study the technology trends in the four region of Maharashtra
- To study the impact of technology trend on health care

Technology Used in Sugar Factories

Sugar Industry has come up with several kinds of technology. Few of them and their benefits for health are listed below:

Cultivation Technology: For rapid multiplication of good planting material and quality seed production technology is required. In Maharashtra sugarcane requires efficient facilities of irrigation. Green whole-cane Harvesting Initiatives helps in harvesting of the canes and the leaves. GPS guidance system have been in use to track during harvesting, using telemetry to log harvesting, operation and progress. Large bins helps in the transportation of large biomass to the mill. There are large cane bins and automatic trapping system for transporting the whole crop material efficiently. Automated tarpaulin systems prevent the leaf material from blowing from the truck in transportation. Cane pad initiatives helps to optimize the cane pad location for reducing the average haul distance for in field transporters.

Growing Technology: Recently, there have been rapid advances in the equipment, systems and process designs which the industry should evaluate and adopt to be cost effective. Collective use of the technologies can optimize the plant capacity and lead to sustainability. Earlier the sugar plants were based on steam and required coal, wood and furnace oil as extra fuel for meeting the energy requirement. With time at present large number of sugar plants are electrically driven having optimum steam consumption and are self sufficient in fuel in the form of bagasse. With rising price of bagasse it is the source of extra income after being reused or recycled. The present average levels of power is 35 kW/Ton Cane and process steam consumptions is 480 Kg/Ton cane in a modern plant.

The following targets for energy consumption of Power Consumption 27-28 kW/Ton cane and Steam Consumption 400-420 Kg/Ton cane can be achieved in future through the use of modern technologies like use of falling and climbing film evaporators, Planetary Gear Boxes, Plant and Process automation, use of efficient motors and pumps and others as listed above.

RESEARCH METHODS

In this research we have used survey based technique. A questionnaire was prepared with measurements of technologies in sugar industry. The technologies used and their benefits have been drawn from the literature. Few interviews have also been taken to measure the change in health status of the workers with time. The indicators of health care in sugar factory have also been adopted

through current literature. Hundred sugar factories have been surveyed from the four regions of Maharashtra and the health status has also been studied through census data report in Maharashtra and the neighbouring state Gujarat. All items included in the survey has been pretested to ensure precise operationalization of the variables for measuring technology trend and health care. Levene statistics and ANOVA table has been used to see the trends.

RESULT AND DISCUSSION

The data has been collected on several changing technological aspects from the sugar factories in the four regions of Maharashtra. The data was used to analyse the trend of any technology updates from 2000 to 2015.

Technology Trend Analysis of Sugar Factories in Maharashtra: Hundred Sugar factories from four regions of Maharashtra have been taken for survey. These regions are Marathwada, Western, Khandesh and Southern region. About 100 sugar factories has been selected for the study from the four regions. A structured questionnaire has been prepared regarding the upgradation of technology yearwise from 2000 to 2015. The questionnaire is attached in the annexure at the end. The technology trends has been taken in terms of partial modification, two roller mills, cane separation system, membranes for juice purification, short retention clarifier, Film type sulphur burners, continuous pans, Decanters, Multijet condenser, Advanced condensing, High gravity centrifugals, Equipments, Boiler, Turbo generator, Tissue culture Technology, Automatic Traupallin system, Distillery, cogeneration and any other new technology upgradation. Sugar factories do not upgrade their technology every year, therefore the trend has been analysed since last fifteen years. The sugar factories have upgraded their technology in last fifteen years due to new innovations. This has led the factory to move towards sustainability. The details of the benefits of the new upcoming technologies have already been discussed in the earlier section. The table 1 gives the description of the technology up gradation in the sugar factories in the four regions of Maharashtra. The table 1 shows that technology has been upgraded in every four region from the year 2000 to 2015. The year 2014 and 2015 has shown higher technology up gradation due to installation of Distillery and cogeneration plant in most of the sugar factories.

Table 1 : Description of Technology Trends in the four regions.

		Mean	Std. Deviation
year2001	1.00	1.51	1.325
	2.00	2.29	1.604
	3.00	1.25	.866
	4.00	1.69	1.377
	Total	1.58	1.299
year2002	1.00	1.84	1.788
	2.00	1.86	1.069
	3.00	1.58	1.505
	4.00	1.31	.751
	Total	1.70	1.518
year2003	1.00	1.54	1.556
	2.00	1.00	.000
	3.00	1.33	1.155
	4.00	1.62	1.557
	Total	1.46	1.399
year2004	1.00	1.89	1.868
	2.00	1.00	.000
	3.00	1.00	.000
	4.00	1.00	.000
	Total	1.48	1.431
year2005	1.00	1.70	1.714
	2.00	1.00	.000
	3.00	1.83	1.946
	4.00	1.00	.000
	Total	1.52	1.511
year2006	1.00	1.19	.877
	2.00	1.00	.000
	3.00	1.00	.000
	4.00	1.00	.000
	Total	1.10	.645
year2007	1.00	1.16	.688
	2.00	1.00	.000
	3.00	1.00	.000
	4.00	1.00	.000
	Total	1.09	.507
year2008	1.00	1.62	1.705
	2.00	1.00	.000
	3.00	1.00	.000
	4.00	1.54	1.330
	Total	1.43	1.388

year2009	1.00	1.19	.660
	2.00	1.71	1.890
	3.00	1.42	1.443
	4.00	1.00	.000
	Total	1.25	.961
year2010	1.00	1.51	1.541
	2.00	1.00	.000
	3.00	1.00	.000
	4.00	1.31	1.109
	Total	1.33	1.223
year2011	1.00	1.11	.458
	2.00	1.00	.000
	3.00	1.83	1.946
	4.00	1.15	.555
	Total	1.23	.926
year2012	1.00	1.57	1.501
	2.00	1.71	1.890
	3.00	1.42	1.443
	4.00	1.38	.961
	Total	1.52	1.421
year2013	1.00	1.00	.000
	2.00	1.00	.000
	3.00	1.42	1.443
	4.00	1.92	1.891
	Total	1.25	1.049
year2014	1.00	1.89	1.807
	2.00	2.43	2.440
	3.00	3.08	2.575
	4.00	1.00	.000
	Total	1.99	1.936
year2015	1.00	2.29	1.922
	2.00	1.00	.000
	3.00	2.67	2.462
	4.00	2.46	2.295
	Total	2.25	2.030

Null Hypothesis

Ho: There is no change in technology upgradation in the regions of sugar factories in Maharashtra in last fifteen years.

The table 2 shows the homogeneity of variance. The significance level of the table 2 is seen. This shows that if the significance value is greater than 0.05 then there is little evidence that variances are not equal and the homogeneity of variance may be reasonably satisfied. The table 2 shows that the variances in technology upgradation are not equal for the year 2002, 2003, 2006, 2007 and 2012 in the sugar factories since the significance value is more than 0.05. The rest years shows that the variance in technology upgradation is equal among the sugar factories.

	Levene Statistic	**Sig.**
year2001	2.178	.099
year2002	1.998	.123
year2003	1.717	.172
year2004	13.649	.000
year2005	5.981	.001
year2006	2.077	.112
year2007	2.584	.061
year2008	4.473	.006
year2009	4.782	.005
year2010	3.449	.022
year2011	11.512	.000
year2012	.560	.644
year2013	14.717	.000
year2014	16.531	.000
year2015	11.402	.000

The table 3 shows the analysis of variance in technology upgradation among sugar factories in last fifteen years. The significance value of the year 2001 to 2010 shows significance value more than 0.05 therefore we fail to reject the null. There has been no change in technology upgradation in the regions of sugar factories in Maharashtra for these years. However, the table shows that the significance value of the year 2004, 2011, 2013and 2014 less than 0.05 therefore we reject the null hypothesis. Therefore the technology trend has shown variation in sugar factories in the regions of Maharashtra for the four years. This has been because of awareness practices and change in the firm's process and positions.

Table 3 Analysis of Variance Output

		Sum of Squares	**F**	**Sig.**
year 2001	Between Groups	5.121	1.011	.393
	Within Groups	109.691		
	Total	114.812		
year 2002	Between Groups	3.039	.429	.733
	Within Groups	153.570		
	Total	156.609		

year 2003	Between Groups	2.227	.368	.776
	Within Groups	130.933		
	Total	133.159		
year 2004	Between Groups	13.650	2.355	.008
	Within Groups	125.568		
	Total	139.217		
year 2005	Between Groups	7.821	1.150	.336
	Within Groups	147.396		
	Total	155.217		
year 2006	Between Groups	.614	.481	.697
	Within Groups	27.676		
	Total	28.290		
year 2007	Between Groups	.451	.574	.634
	Within Groups	17.027		
	Total	17.478		
year 2008	Between Groups	5.023	.864	.464
	Within Groups	125.933		
	Total	130.957		
year 2009	Between Groups	2.791	1.007	.395
	Within Groups	60.021		
	Total	62.812		
year 2010	Between Groups	3.264	.718	.545
	Within Groups	95.512		
	Total	98.776		
year 2011	Between Groups	5.363	2.196	.009
	Within Groups	52.927		
	Total	58.290		
year 2012	Between Groups	.714	.113	.952
	Within Groups	136.503		
	Total	137.217		
year 2013	Between Groups	8.972	2.952	.039
	Within Groups	65.840		
	Total	74.812		
year 2014	Between Groups	28.787	2.757	.049
	Within Groups	226.199		
	Total	254.986		
year 2015	Between Groups	13.638	1.109	.353
	Within Groups	229.612		
	Total	243.250		

Null Hypothesis: There is no change in technology with change in the regions of Sugar Factories

The table 5 shows the test of homogeneity of variance for technology upgradation in the four regions of Maharashtra. The significance value is less than 0.05. This means that we reject the null hypothesis. There is equal varaiance in the sugar factories in four regions of Maharashtra.

Table 5 Test of Homogeneity of Variances

Levene Statistic	df1	df2	Sig.
3.220	3	156	.028

The table 6 shows a significant value of more than 0.05 which means that we reject the null hypothesis. As a result, we can say that There is change in technology trends in sugar factories in the four regions of Maharashtra.

Table 6 ANOVA

	Sum of Squares	**Df**	**Mean Square**	**F**	**Sig.**
Between Groups	2.786	3	.929	.741	.05
Within Groups	81.504	156	1.254		
Total	84.290	159			

From the above result it can be concluded that there has been change in technology trends since last fifteen years with variation in technology within the four regions of Maharashtra except for the year 2004, 2011, 2012 and 2013.

Table 7 Performance of Cooperative Sugar Factory

Particulars	**As on 31st march 2013**	**As on 31st march 2014**	**Percentage Change**
Registered Sugar Factories	202	202	0
Factories in Production	108	96	-11.11
Members (’00)	24500	26340	7.5
Share capital of State Govt. (` crore)	1211.69	1244.30	2.7
Average capacity (TCD # lakh MT)	3.34	3.22	-3.6
Sugarcane crushed (lakh MT)	504.63	486.72	-3.6
Average sugarcane price (`/MT)			

a) Purchased (FRP)	1700	2100	23.5
b) Actual paid by factories	2450	2467	0.7
Sugar produced (lakh MT)	58.4	56.52	-3.2
Average extraction (per cent)	11.57	11.61	0.3
Molasses (lakh MT)	36.4	27.05	-25.7
No. of factories having :			
a) Distillery plants	68	69	1.5
b) Co-generation plants	39	46	18
Electricity generated (Million units)	628	827	31.7
Factories in loss (no.)	38	NA	-

Source : Economic Survey of Maharashtra 2014 – 2015 from https://www.maharashtra.gov.in/Site/upload/WhatsNew/Economic%20Survey%20of%20Maharashtra...pdf as accessed on 7th February, 2017[13]

The table 7 shown above clearly depicts that technology has been upgraded even from year 2013 to 2014. The distillery plants has increased by one and the cogeneration plants have increased from 39 to 46.

Technology Trend and Sustainable Health Care: Sugar firm workers have a high tendency of occupational accidents, exposure to high toxic pesticides, chronic and respiratory infections. Bagassosis is a problem regarding exposure to bagasse. Bagassosis is a problem specific to sugar factory due to excessive exposure of factory workers to bagasse[14]. It has been reported by Patil et al., 2008 that workers exposed to sugarcane dust are often suffering from lung dysfunction[15]. Hearn, 1968 has also reported that with reasonably consistent exposure to bagasse leads to diffusion of pulmonary fibrosis giving rise to lung disorders[16]. Bagasse control can be made by keeping the moisture content more than 20% and spraying 2% propionic acid a fungicide. Rao ,2015 reported in his study that hypertension, sleep disturbance and headache are commonly related health hazards among the workers in the industry. Spentwash of a distillery process has been a threat to environment. With the help of technology, the concentrated spentwash is sprayed in a furnace with support fuel bagasseand is then burnt in boiler[17]. Spentwash concentration and Iccineration technology simultaneously generates steam and power for the process and ethanol plant (http://environmentclearance.nic.in/writereaddata/Online/TOR/0_0_26_Feb_2016_1242439201PFR.pdf).

Null Hypothesis

There is no association between Technology Trends and Sustainable Health Care Services

Health and welfare is one of the factors in social sustainability. However there is very little research done in social sustainabilitymodern[18]. Sugar Industry workers have a high level of occupational accidents. Bagassosis is a problem regarding exposure of excess bagasse. Workers may also get affected by chronic respiratory infections. Dust particles also leads to this problem. Workers are often suffered with hypertension, sleep disturbance, headache and other commonly related health hazards.

Table 8 Health Status

Year	Death Rate in Rural	Death Rate in Urban	Number of Respiratory Problems
2001	8.5	5.9	7.5
2007	7.3	5.7	6.6
2008	7.4	5.6	6.6
2009	7.6	5.5	6.7
2010	7.5	5.3	6.5
2011	7.3	5.1	6.3
2012	7.3	5.0	6.3
2013	7.1	5.0	6.2

Source :Economic Survey of Maharashtra 2014 – 2015 from https://www.maharashtra.gov.in/Site/upload/WhatsNew/Economic%20Survey%20of%20Maharashtra...pdf as accessed on 7th February, 2017[13]

The table 8 and table 9 explains that the number of respiratory problems have slightly decreased in Maharashtra as compared to the year 2001. The percentage shows only a slight decrease due to the increase in the number of population every year.

Table 9 Causes of Death in major regions of Maharashtra and Gujarat

Year	Respiratory Disease %	Tuberculosis %	Respiratory Infections %	Ill Defined %
2001-2003	8.80	6.2	4.3	4.1
2004-2006	7.6	6.5	4.3	7.9
2007-2009	10.3	5.10	8.1	8.5
2010-2013	8.2	4.9	3.7	12.5

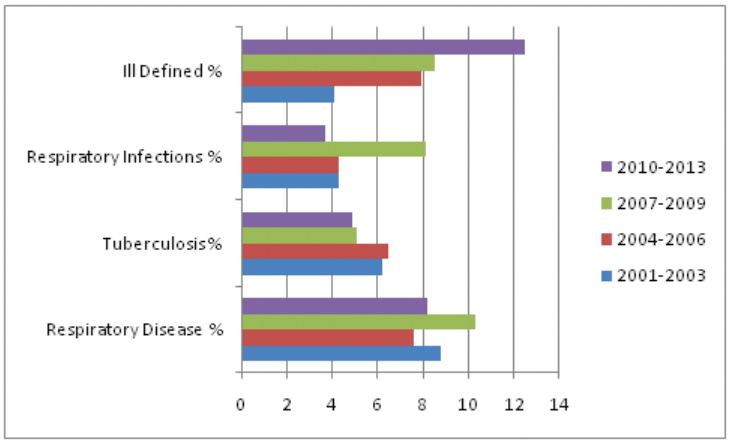


Figure 2 Health data from year 2001 to 2014

Figure 2 shows that the technology has been upgraded since last fifteen years. The percentage of patients suffering from respiratory disorders in Maharashtra and Gujarat has also reduced. However we can not say that sugar factories are solely responsible for respiratory disorders. Similarly there has been reduction in the percentage of patients suffering from tuberculosis. The workers of sugar factories mostly suffer from bagassosis which later leads to tuberculosis. The number of respiratory disease has also reduced in 2013. However, the figure shows that the percentage of ill defined patients have increased. This may be due to other factors like climate change or pollution.

CONCLUSION

The changing trends of technologies have been used in several factories. The results shows that the technologies have shown upgradation from the year 2000 to 2015. However there is no variation in the change in technology in the regions of Maharashtra. These trends have reflected upon sustainable health care services in and outside the factory. The effect of the user friendly technologies can be seen in the decreasing respiratory problems over Maharashtra and Gujarat. The population has been increasing every year yet the number of respiratory problems has reduced. The impact of technology trends has been measured significantly with the respiratory problems of the factory workers and surroundings. The authors have forecasted the use of different technology in the sugar factory. The study has interlinked the technology practices with a sustainable health care service. The research is limited to the sugar factory belt of the country and can be further implied to other agro based industries.

Ethical clearance: No need

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Conflict of Interest: Nil

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Diagnosis of Vascular Cognitive Impairment Using EEG

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ABSTRACT

Dementia or Major Neurocognitive disorder is the second most burdensome chronic condition in which 11.9 percent live with disability and 1.1 percent lost their lives, and their numbers will be doubling every 20 years to 65.7 million by 2030, and 115.4 million by 2050. Dementia due to vascular diseases is the second most common cause of dementia after Alzheimer's disease and 28 to 36 million people worldwide with dementia are undiagnosed[1]. Vascular Dementia is characterized by distinct aspects of impaired consciousness and such an impairment is indexed by declined performances at controlled cognitive tasks. It is related to reduced brain metabolic activity in a network of frontal, posterior associative, and limbic regions due to the occurrence of multiple mini/major strokes or other conditions that affect blood vessels and nerve fibres deep inside the brain. Diagnosis of Vascular dementia in its preliminary stages is a very complex task as it requires screening, Neuro-cognitive testing, and brain imaging evidence usually CT Scan or MRI. Sometimes cause of mild impairment cannot be diagnosed by brain Imaging. EEG based diagnostic approaches are promising tool in case of differentiating diverse types of dementia. Portable EEG with its high temporal resolution property is an economical solution for the many undiagnosed people with dementia in the low and middle income countries. This paper reviews EEG analysis approaches to diagnose vascular mild impairment and dementia as a future diagnostic tool in the healthcare sector.

Keywords: *Vascular Dementia, EEG, MNCD, MCI*

INTRODUCTION

Dementia is a general term for any neurodegenerative disease which causes long term or short term cognitive impairment and decrease motor response at later stages in adults. Dementia is defined as major neurocognitive disorder (MNCD). It is broader term which widely used for all subtypes and individuals but dementia is referred as a group of symptoms that usually affect older adults. There are more than 10 causes mentioned in diagnostic and statistical manual of mental disorders fifth edition, DSM-5 (Association, 2013) and out of them only five or six causes are renowned in older adults such as Alzheimer's disease (AD), vascular dementia (VD), frontotemporal dementia and Lewy body dementia and sometime mixed dementia. It is generally attributed to AD but recent studies showed that it has many causes in which VD is second most common cause of dementia after AD. VD is caused by problem in brain supply to the brain typically by series of minor stroke and sometimes larger stroke proceeded followed by other many smaller strokes. Many studies and survey believe that VD remains undiagnosed alike AD, even though it is recognized as common. Referred to DSM-5 (Association, 2013), AD and VD have most confusing symptomology as they have lots of similarities in diagnostic criteria and early symptoms, yet they are different due to different disease in the brain. The Table 1 shows comparison between AD and VD (Association, 2013). Basically, VD is caused by small vessel disease in which small blood vessels get weaken with old age and associated with poor blood pressure. It has two pathological factor; one is loss of elastin in the wall of arteries which help in arterial contraction. Second is build-up of fibrin in micro vessels in the brain. These two factors usually increase after age of 60 years. The two main arteries internal carotid artery and vertebral artery supply blood to the brain and reaches to the white matter with the help of branch of small arteries, Figure 1 shows name and territories area of small vessels network in the brain. It is clear from the Figure 1 that three branch of arteries shared an area which is called as subcortical watershed

area. It is specific area where small vessel disease causes ischemia. Further, it will result in series of small strokes in the brain. Consequently, it leads to frontal-executive function impairment and decline in different cognitive domain. At the later stage of dementia or after the major stroke, person deteriorate significantly in more than one cognitive domain which make him/her disable to perform life's everyday activities. Sometimes, stroke stimulates seizures in the brain which is the most common cause in the elderly persons. Stroke that obstructs the required amount of oxygen to the brain can be a cause of seizure. 10% and 22% of stroke survivors experience seizures. A seizure is caused by intracranial haemorrhage in 30% cases out of 1000 patients. Seizure detection may also help detecting of intracranial haemorrhage[2].

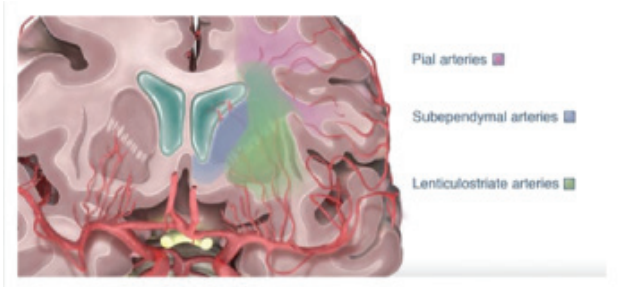


Figure. 1: Classification of small arteries in white matter.

Table 1: Comparison between AD and VD (Association, 2013)

Major Neurocognitive Disorder		
Subtypes	**AD**	**VD**
Diagnostic criteria	Insidious onset and Steadily progressive, gradual decline in cognition without extended plateaus Evidence of causative AD genetic mutation from family history or genetic testing.	Stepwise onset of the temporally cognitive impairment is related to one or more cerebrovascular events. Presence of cerebrovascular disease from family, physical examination, or Neuroimaging.
Symptomology	At mild phase, memory, and learning impairment, sometimes loss in executive function, apathy, and depression. Perceptual motor ability and language will be impaired at major phase. Social cognition suffered at later stage of disease.	Prominent decline in complex attention, processing speed, frontal executive function, and prominent mood fluctuations. For mild VD, Single stroke or extensive white matter disease reported in history. For major VD, two or more strokes, a strategically placed stroke, or a combination of white matter disease and one or more lacunas.
Neuropathology	Cortical atrophy, amyloid-predominant neuritic plaques and tau-predominant Neurofibrillary tangles only confirmed via post-mortem examination.	Cerebrovascular disease, single infarcts in critical regions, or more diffuse multi-infarct disease
Diagnostic Markers	amyloid beta-42 deposition in the brain and amyloid imaging on brain positron emission tomography (PET) scans Reduced levels of amyloid beta-42 in the cerebrospinal fluid (CSF) may have diagnostic value. Signs of neuronal injury on a magnetic resonance image scan or PET scan Evidence for raised total tau and phospho-tau levels in CSF	Structural neuroimaging, using MRI or CT, has a significant role in the diagnostic process. There are no other recognized biomarkers of major or mild VD.
Prevalence	In the USA, Between 65-74 years-7 % Between 75-84 years- 53% 85 years and above- 40%	In the USA. Between 65-70 years-0.2 % Between 70-80 years- 16% 80 years and above- 44.6% Higher prevalence has been reported in African Americans compared with Caucasians, and in East Asian countries. Prevalence is higher in males than in females.

Proportion of cases	60%–90%	20%–30%
Risk and prognostic Factors	Traumatic brain injury Age is the strongest risk factor for Alzheimer's disease. Increase in the genetic susceptibility polymorphism apolipoprotein E4 Individuals with Down's syndrome (trisomy 21) Multiple vascular risk factors	Hypertension, diabetes, smoking, obesity, high cholesterol levels, high homocysteine levels, other risk factors for atherosclerosis and arteriolosclerosis, atrial fibrillation, and other conditions increasing the risk of cerebral emboli. Cerebral amyloid angiopathy is an important risk factor in which amyloid deposits occur within arterial vessels. Hereditary condition cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy.
Cultural issues	Older adults face fewer cognitive demands in everyday life, very low educational levels pose greater challenges to objective cognitive assessment.	Neuroplasticity factors influence the neurocognitive outcomes of vascular brain injury such as education, physical exercise, and mental activity
Comorbidity	Cerebrovascular disease	Alzheimer's disease and depression

Mild cognitive impairment (MCI) or mild neurocognitive disorder define as evince of moderate level of cognitive decline based on concern of individual, informant, or clinician from the earlier year's cognitive performance, which is recognised by neuropsychological testing. The neuropsychological assessments are done by experienced professionals, psychologist, and therapist, but it contains long evaluation sessions and cannot confirm early onset of dementia, in addition it fails to distinguish correctly various cause of dementia at early stage. Moreover, histo-pathological analysis of the brain requires establishing unambiguous diagnosis of MCI and developing an accurate biological marker for early diagnosis remains as a challenge. For early diagnosis of dementia, quantitative electroencephalogram (QEEG) has emerged as a prominent technique. The EEG signal of a MNCD patient demonstrates the functional changes in the cerebral cortex. The symptoms of MNCD develop slowly in the initial stages and are often confused with impairments due to normal ageing with aetiologies. The symptoms become more apparent as MNCD progresses and it results in a decline in cognition which is interference with functional ability in normal or working life of the sufferer. It is difficult for any general practitioners (GP) or psychologist to differentiate early symptoms from ageing. Estimation of dementia is difficult due to the progressive nature of dementia and it is unpredictable in case VD as it has step wise progression. The symptoms of all types of dementia are kind of similar, but these expressions differ from person to person specially at the beginning. These expressions diminish the possibility of differentiating MNCD from other types of dementias[3]. Statistic showed in World Alzheimer Report 2009 that dementia people are doubling in every 20 years worldwide from 35.6 million to 65.7 million by 2030, and 115.4 million by 2050 because of the ever-increasing rise in the number of elder population every year. 58% dementia belong to low and middle income countries and their number also expected to be increased to 71% by 2050 (Prince & Jackson, 2009). The diagnostic ratio is lesser in low and middle income countries like India, and worldwide reports showed that around 28 to 36 million people are underdiagnosed for dementia. Thus, they are not reachable to treatment and care[1]. Early dementia diagnosis assists the patients to get proper information, resources, and care and it also supports in elucidating the condition of the patient to their family and carer. It helps to increase the quality of life and better benefits of the treatments. Further, it also aids to plan the future life of the patient and avoid redundant accidents.

EEG-based approach for diagnosing dementia: There are many interdisciplinary approaches to diagnose MNCD or VD at later stage as brain lesions or stroke are quite visible on PET/MRI or other imaging tools for neuroscientist. Some of the neurological biomarker are discussed in Table 1, which involves some neurobiological and neurochemical biomarker such as neurofibrillary tangles, senile plaques, amyloid beta-42, gamma-aminobutyric acid and N-acetylaspartate.

Either, these are examined by visual markers (such as CT, PET, or MRI scan) or in post-mortem studies. For this reason, these are not supportive at the early stage of disease, and it is difficult to conclude one of them as potential marker[4,5,6]. The visual marker approach is analytical models for anatomical and functional brain images[7,8,9]. These techniques are widely used in diagnostic of dementia and neurological disorders. However, neurologists are unable to diagnose early cognitive changes in brain due to progression of VD or AD using brain scan alone where neurological markers are invisible. Besides, imaging technique involves expense of specialised expertise and equipment, and it is not feasible for neurologist or physician to take scans on regular interval. Therefore, EEG-based diagnostic is non-invasive, less expensive, and portable, and it is also feasible with prosthetic implants. In case of AD, seizure and NCDs diagnosis, EEG studies show comparable sensitivity and specificity in comparison to imaging studies[10,11,2,12]. EEG based diagnostic approach involves three stages, pre-processing of signals, analytical feature extraction techniques for EEG and classification techniques for positive identification of dementia, which is shown in Figure 2.



Figure. 2: EEG-based approach dementia diagnosis[13]

Pre-processing: Pre-processing of signal is required to eliminate or reduce the noise factors and most artefacts overlap with the frequencies of the EEG signal. The biological artefacts are due to muscle activities, eye blinking, heart, respiration, perspiration, tongue. Non-biological artefacts are due to power line interference noise and electrode, movement, induction from nearby equipment[14]. Various signal pre-processing techniques are used to disregard the noise from a recorded EEG signal in which adaptive filtering and independent component analysis (ICA) are relatively effective and advance methods[15,16]. ICA is a special case of blind source separation. ICA is a computational method for extricating a multivariate EEG signal into additive subcomponents. This is done by, if the subcomponents are non-Gaussian signals and they are statistically independent from each other. One study showed that ICA based pre-processing improves the classification results for Alzheimer's disease (Melissant *et al.*, 2005). There are many toolbox can be used to remove the artefact in which EEGlab is most common toolbox[17].

Feature Extraction: Dementia mainly observed by three parameters; 1) EEG slowing, 2) reduction in complexity and 3) synchronisation using EEG signal[18] and these parameters are measured by linear and non-linear features of EEG signal. classification of nonlinear and linear feature based on three diagnostic parameters are mentioned in Table 2[13]. The linear relationship between the electrodes in case of NCDs is studied by distinct types of feature such as EEG relative power, coherence, and Granger causality. In addition, AD and VD can be differentiate by EEG spectral features such as alpha power, alpha dispersion frequency[19].

Table. 2: Three Diagnostic parameters with classification of EEG features

Parameters	Approach	Features
Slowing of EEG	Linear	Fourier, power, time frequency spectral analysis21
Reduced complexity	Nonlinear	Entropies, mutual Information34/ permutation conditional mutual information35, fractal dimension21,36/ correlation dimension (CD)/ Lyapunov exponent33
Perturbed synchronisation	Linear/nonlinear	Coherence32,34, Granger causality, State space synchrony, Stochastic event synchrony37, Graph theory

Classification: During the classification process, the main aim is to classify MCI and MNCD separately with high accuracy which is also very important for any diagnostic tool. There are few classifiers which are known for detection of MCI or AD such as linear discriminate analysis (LDA), support vector machine (SVM) and Neural Network (NN). SVM is widely used classifier for EEG signal processing till now to classify neurodegenerative disorders and brain disorders like epilepsy[2,20]. It showed better accuracy (78%) than NN (60–66%) in a study for the diagnosis of AD[21], whereas in one study, the NN accuracy was around 71%[22]. It is currently emerging research topic in this area. one study, which aimed to automatic distinguish between AD and MCI, showed 92.33% accuracy with proposed technique compared to blind source separation and wavelet pre-processing technique which showed 80.43% accuracy[22]. Despite these, there are many classifiers successfully used in other domain like Bayesian classifier, hidden Markov model[24,25,26], which can be used in detection of NCD in future works.

EEG-based proposed model: Every disease has different treatment, intervention, and cure. Therefore, diagnosis of early dementia requires multidisciplinary approach, which can involve cognitive screening tools like MMSE and Cognitive performance with EEG analysis[13]. Cognitive screening tool is very helpful in case of subject identification from the mass population before its proper diagnosis have been done and is an economical solution to save cost of failed diagnosis[27]. It requires the least assistance of clinical person and care taker or relatives to evaluate the condition of demented person from time to time. Sideways this, EEG analysis helps to investigate the brain activation during cognitive task performance, which is not feasible with imaging techniques. Meanwhile, Emerging technologies are playing key role in making neuro-psychological test more user friendly and less time consuming such as android or iOS apps. And this tool will be economical, portable and can be used to diagnose mass population. Thus, diagnoses of NCDs require a combination of extensive cognitive assessment and the screening of probable causes along with real time EEG analysis which provides promising complete neurological examination.

DISCUSSION

Most of the studies showed EEG as a potential diagnostic tool for MNCD. However, the NCD means cognitive decline and that is why conventional method of detection was neuropsychological test batteries which fail to diagnose NCD alone due to lack of cross validation with physiology. And many studies proved that EEG recording with cognitive task gave better detection result than steady state EEG signal. One study with MCI patient investigated that during working memory task, coherence and power are higher in patient[28]. The old studies have already explained age-related changes in EEG study during cognitive tasks which showed significant changes between healthy young and healthy elder[20]. Similarly, EEG with a combination of cognitive task can improve the accuracy in detecting several types of NCD because every subtype has different early signs of cognitive decline as mentioned in Table 1 like AD showed memory impairment first while VD affects executive function. Other hand, fronto-temporal dementia shows behavioural variant. Sometime patients also suffer from mixed type dementia[30]. There are many recent researches that explain the diagnosis of AD and other type of NCD is possible via EEG analysis and this analysis also proved its significance in early dementia diagnosis and other brain disorders. But, higher accuracy is still an unanswered question in the case of MCI where anatomical changes in the brain are diminish. And it is not feasible to measure cause of cognitive decline in MCI which some time confused with normal subjects. Even though, if there are probable changes of any neuro-degenerative diseases because it is not necessary, every MCI person gets dementia. MCI is an intermediary state of neurodegenerative disorders or NCD. Some studies worked on the same problem to differentiate progressive and stable dementia[31]. Still, there is need to develop a more accurate and a psycho-physiological tool for specific disorders after considering all the challenged involved in the diagnosis.

CONCLUSION

Diagnosis of Vascular dementia is very complex task and requires multiple testing. EEG based diagnostic approaches are promising tool in case of differentiating diverse types of dementia. Portable EEG with its high temporal resolution property is an economical solution for the many undiagnosed people with dementia in the low and middle-income countries. EEG analysis can act as a future diagnostic tool in the healthcare sector.

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Resource Based View of Innovative Strategies in Sugar Industry and Their Effects Towards Healthcare

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ABSTRACT

Purpose: The main purpose of this paper was to empirically study the resource based view of innovative strategies in sugar industry and their impact on healthcare.

Methods: Structured questionnaire was pretested for the content validity from experts. The questionnaire was circulated to 100 respondents from sugar factories. The dependence relationship in the framework was checked through data analysis in SPSS. Multiple regression method was used to check model fitness and individual construct fitness.

Findings & Interpretation: The data showed the reliability of the items for each construct. It was found that physical capital resources comprises of technology, geographical area and availability of raw materials. Human capital resources and organisational capital resources leads to the development of innovative strategies. Innovative Capability is based on reinforcing the firm's practices and processes. Reinforcement of new practices and process leads to proper health care. Healthcare is maintenance or improvement of health via diagnosis, treatment and prevention, illness, injury, and other physical and mental impairments in human beings.

Implications & Originality: This paper discusses the development of resource based innovative strategy for the improvement healthcare environment in agrobased industry.

Keywords: *Resource, Innovative strategy, Sugar industry, Healthcare environment*

INTRODUCTION

Sugar Industry has been a sign of high alert in terms of its presence since past. The innovative strategies have led the industry to reinforce its practices with the available resources. Sugar industry is well known in the country for high sugar production. The industry today is not only well known for producing sugar but also it leads to the production of spirit, distillery, petroleum, paper, fertiliser and electricity. Therefore, with several innovative strategies the industry has become a useful source of resources. The purpose of the article is to relate both innovative strategies and health care factors. Resource based perspective has been taken to see the sugar firms as bundles of resources. Resource means the strength of the sugar firm which may be tangible like technology and financial assets or it may be intangible like management capability. These resources in sugar firms help in reinforcing the innovative practices and process. The change in the process ultimately affects the health care impact of employees and employers. The objective of the study is as given below: (i) To construct a theoretical framework, (ii) To empirically validate the framework.

BACKGROUND AND THEORETICAL DEVELOPMENT

Resource Based View: Resource based view posits that in order to maintain competitive advantage, firms need to have certain unique tangible or intangible resources. Resources include financial, physical, human, technological and organizational resources[1]. Resource based theory includes Physical capital resources, Human

capital resources and Organizational Capital Resources. The physical capital resources comprises of physical technology used in a sugar factory, it's geographical locations and the availability of raw material. The human capital resources include training and insight of individual managers and workers in a firm. Organizational capital resources include planning, coordinating and controlling of system as well as informal relations among groups within and outside the firm. Resource based view comprises of all the assets a firm constitutes[2]. Sugar firms have the physical resources in the form of technology. These technologies are boilers, rotary filters, pan boilers, molasses storage tanks, Cane Separation System, Short Retention Clarifier, Membranes for juice purification, Film Type Sulphur Burners, Continuous Pans, Decanter, Multijet Condenser, Advanced Condensing and Cooling System, High Gravity Centrifugals, Equipment and Process automation , Boiler, Turbo generator, Boiling House Equipment, Tissue Culture Technology, Automated tarpaulin systems, Distillery and Cogeneration. The sugar firms are located in the rural areas due to availability of sugarcane. This also reduces the transportation cost. The Human resource capital in sugar firms comprises of proper training given to the employees. This also constitutes of proper insights given from the management. Sugar firms generally have seasonal workers therefore they should be trained properly and remuneration should also be given to them. The third part of resource based view comprises of Organizational Resources. This includes proper planning, controlling and coordination in the firm.

Innovative Strategy: Innovative strategy can be classified into three

- Sugar breeding leads to high yield and high sucrose. Genetically modified sugarcane varieties.
- Agriculture practices in production: crop rotation, water management, soil management, nutrient management, mechanism, optimisation model and geographic information system.
- Processing and byproducts: Energy saving and cogeneration of electricity results in cost saving. This leads to better utilisation of waste product.

Innovative Capability leads to product development in a firm. For a better positioning in the market a firm needs innovative capability for better product development[3]. The process of innovation helps to convert knowledge into social good and economic wealth. Innovation is defined as the introduction and application of ideas, products, services, processes or technologies which are either new or are improvements of current system that benefit individuals and group of society as a whole. Innovation differentiates between a leading industry and a following industry. Innovative strategies are based on reinforcing the firm's practices and processes. Several changes in the practices of sugar industry have led it to become a good source of resources. The innovative capability have left the industry not only to produce sugar but also it leads in the production of distillery, spirit, ethanol, alcohol, fertiliser, electricity and paper. Recruitment of staffs with skills in mathematics, Operations, Agronomy and Crop Physiology helps in enhancing the expertise. For sustainability the resources must be maintained and the impact on ecosystem should be minimised. Use of limited irrigation water is also an innovative approach for growing sugarcane. Upgradation in the sugar bag experimental database system ensures the user friendly packaging system in sugar industry. Vision of sugar industry reflects the aspirations of it's stakeholders namely farmers, millers, consumers and government. The vision is to achieve high economy, minimise risks, enhance relationship between farmers and millers, meeting domestic demand and contribute to food and energy needs[4]. According to this report export of ethanol will increase from 6.5 billion litres to 50 to 200 billion litres by the year 2020. The cogeneration plant helps in reducing the deficit of energy in the country. Sugar Industry should be located near sugar farms because sugarcane is perishable in nature. This adds high value from the byproducts. Variety in the form of sugar, alcohol, electricity generation and fertiliser leads to product innovation. Most of the loan is taken for modernisation and rehabilitation. In 2017 the potential of exportable power from cogeneration plant is about 9700 MW. The decentralized generation of power could also help in rural electrification. Use of high pressure with investment in boilers and turbine will benefit the plant. The transformation of the industry has led to several opportunities for both public and private partners. Industries in few countries have a long and strong collaboration therefore they have high technical inputs while industries in others have relatively weak collaboration tending to less technical service[5]

Health Care: Raising economy, increase in income level and changing lifestyle to health care. Innovation is

needed for improving healthcare. It is a possible solution to ensure efficient method for addressing healthcare needs. The occurrence of disease can be prevented by social factors like hygiene, water, education, sanitation and living space (https://www2.deloitte.com/content/dam/Deloitte/in/Documents/life-sciences-health-care/in-lshc-innovative-healthcare-noexp.pdf). Sugar firm workers have a high tendency of occupational accidents, exposure to high toxic pesticides, chronic and respiratory infections. Bagassosis is a problem regarding exposure to bagasse. Bagasse control can be made by keeping the moisture content more than 20% and spraying 2% propionic acid a fungicide. Rao et al. (2015)7 reported in his study that hypertension, sleep disturbance and headache are commonly related health hazards among the workers in the industry6. Twenty one working days on full pay is given for sick leave and 12 weeks leave on full pay with 800ml of milk per day during 3 months is given as maternity benefit.

THEORETICAL FRAMEWORK AND HYPOTHESIS DEVELOPMENT

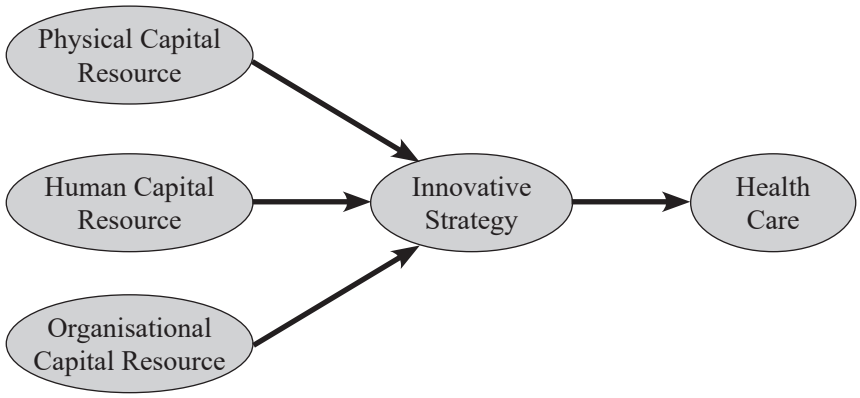


Fig. 1: Theoretical Framework

Hypothesis Development

H1 : Physical capital Resource leads to Innovative Strategy

H2 : Human capital Resource leads to Innovative Strategy

H3 : Organizational capital Resource leads to Innovative Strategy

H4 : Innovative Strategy leads to Health Care

Table 1: Definition of the Constructs used in the Theoretical Framework

S. No.	Constructs	Definition	Reference
1.	Physical Capital Resources	Physical Capital Resources comprises of Technology, Geographical Area and Availability of raw materials	Barney, 19911
2.	Human Capital Resources	Human Resources refers to the training, experience, judgment, relationship, intelligence and insights of individual managers and workers	Barney, 19911
3.	Organisational Capital Resources	Organisational Capital Resource comprises of Planning, Controlling and Coordinating	Barney, 19911
4.	Innovative Strategies	Innovative Capability is based on reinforcing the firm's practices and processes	Lawson and Samson 20017
5.	Health Care	Healthcare is maintenance or improvement of health via the diagnosis, treatment, and prevention of disease, illness, injury, and other physical and mental impairments in human beings	https://en.wikipedia.org/wiki/Health_care8

Table 2 Items of the Constructs used in the Theoretical Framework

S. No.	Constructs	Items
1.	Physical Capital Resources	Technology Geographical Area Availability of raw materials
2.	Human Capital Resources	Training Insights of individual Managers Workers
3.	Organisational Capital Resources	Planning Controlling Coordinating
4.	Innovative Strategies	Vision and Strategy Harnessing the competence Creativity and Idea Management Organisational Intelligence
5.	Health Care	Respiratory Disorder Sleeplessness Headache Occupational Accidents

RESEARCH METHODS

The article focuses on health care factors for the employees in the industry. Structured questionnaire has been prepared. The questionnaire has been pretested for the content validity from five experts. The questionnaire has been then circulated to 100 respondents from sugar factories. The dependence relationship in the framework has been checked through data analysis in SPSS. Multiple regression method has been used to check the model fitness and individual construct fitness.

RESULTS AND DISCUSSION

Instrument Reliability: The reliability of the instrument has been checked through cronbach alpha. The table 3 shows the reliability of the items of each construct. It has been found that the cronbach alpha is greater than 0.7 which means that the data is reliable for study. The cronbach alpha of Physical Resource is found to be 0.819. Human Capital Resource consists of four items and the cronbach alpha is 0.831. Organisational Capital Resource has four items and the cronbach alpha is 0.90. Innovative Strategy constitutes of five items with cronbach alpha 0.733 and the last construct healthcare has five items with cronbach alpha of 0.90.

Table 3: Reliability Test

Construct	Variable	Number of Items	Cronbach alpha
Physical Capital Resource	Availability of good Sugarcane results in lowering costs and improving quality with innovative methods	5	0.819
	Implementation of technology results in building creativity		
	Sugar Factory near to the sugarcane field results in saving of time		
	Good recovery of juice from cane leads to more sugar production		
	Better technology leads to better work		
Human Capital Resource	Proper Training results in better machinery work	4	0.831
	Good Management leads to better innovative methods		
	Commitment of work by the workers is responsible for efficient work		
	Training about new technologies leads to ulfil the mission of the factory		
Organisational Capital Resource	Proper planning results in efficient sugar production	4	0.90
	Proper controlling leads to organization intelligence		
	Coordination in work is important for efficient firm process		
	Planning of work saves time		

Innovative Strategy	Our factory has a program for dealing with loss situations	5	0.733
	Our factory takes continuous efforts in lowering costs and improving quality with innovative methods		
	Our factory has better equipment		
	Our firm has a process to apply new technologies		
	Our factory is competent to change and improve it's process		
Health Care	Our factory has an objective to reduce accidents with machines	5	0.90
	Our factory provides resources for employee development (resources such as education, healthcare, housing, safety etc.)		
	We have a reasonable and just working environment		
	Our factory monitors working environment towards safety, wellbeing of our employees and community around our business		
	Our factory has reduced the level of Sickness, headache and sleeplessness among the workers		

Instrument Validity: The validity of the data is checked through AVE and SCR scores. Convergent Validity refers to the extent to which there is consistency in measurement across multiple operationalization's[9]. From the Table 4 given below, we can see that the constructs of the theoretical framework possess convergent validity as we can see that the standardized factor loadings of the items are mostly greater than 0.7 and not less than 0.5. The Scale Composite Reliability (SCR) is found to be greater than 0.7, where the threshold limit of SCR should be greater than 0.7 and Average Variance Extracted (AVE) is found to be greater than 0.5.

Terms and condition for Convergent Validity are: Average variance extracted (AVE). Commonly used measure of convergent validity is average variance extracted. AVE is a convergence summary measure between set of questions for a latent construct. It is the average percentage of variance explained by indicators of the given construct. Following is the formula of AVE and the calculations are shown in Table 4.

Factor Loading (λ) should be > 0.5

Error = 1- (λ)^2

SCR = (summation of λ ^2) / {(summation of λ ^2) + summation of error}

The expected AVE is 0.5 or more (Hair, Black, Babin, & Anderson, 2010). AVE scores of

Since average variance extracted (AVE) scores for constructs of delivery gap and design gap are smaller than expected score of 0.5, other construct validity measure of factor loading and construct reliability are studied.

Explanation. Considering low score of AVE of delivery gap and design gap another measures of convergence validity; factor loadings, and construct reliability are studied. Both these measures indicate good convergence validity for the constructs.

Factor loadings. For a better convergent validity all standardized factor loadings should be significant and more than 0.5 or 0.7 or higher. The Table 4 presents value of factor loadings (λ) for items and corresponding to seven constructs under study.

Standarsized Factor Loadings > 0.5 or 0.7 and higher

Explanation. Construct reliability of all latent variables is in around 0.8 suggesting a good construct10 See Table 6.50.

Table 4: Validity

Construct	Variable	Factor Loading	AVE	SCR
Physical Capital Resource	Availability of good Sugarcane results in lowering costs and improving quality with innovative methods	0.80	0.6	0.75
	Implementation of technology results in building creativity	0.74		
	Sugar Factory near to the sugarcane field results in saving of time	0.93		
	Good recovery of juice from cane leads to more sugar production	0.78		
	Better technology leads to better work	0.80		
Human Capital Resource	Proper Training results in better machinery work	0.82	0.75	0.87
	Good Management leads to better innovative methods	0.87		
	Commitment of work by the workers is responsible for efficient work	0.93		
	Training about new technologies leads to ulfil the mission of the factory	0.98		
Organisational Capital Resource	Proper planning results in efficient sugar production	0.70	0.70	0.85
	Proper controlling leads to organization intelligence	0.96		
	Coordination in work is important for efficient firm process	0.98		
	Planning of work saves time	0.95		
Innovative Strategy	Our factory has a program for dealing with loss situations	0.90	0.6	0.89
	Our factory takes continuous efforts in lowering costs and improving quality with innovative methods	0.86		
	Our factory has better equipment	0.93		
	Our firm has a process to apply new technologies	0.88		
	Our factory is competent to change and improve it's process	0.90		
Health Care	Our factory has an objective to reduce accidents with machines	0.88	0.78	0.90
	Our factory provides resources for employee development (resources such as education, healthcare, housing, safety etc.)	0.92		
	We have a reasonable and just working environment	0.89		
	Our factory monitors working environment towards safety, wellbeing of our employees and community around our business	0.93		
	Our factory has reduced the level of Sickness, headache and sleeplessness among the workers	0.76		

Normality: The normality of the data has been checked through skewness and kurtosis. The value of skewness range from +2 to -2 and the value of kurtosis ranges from +7 to -7. The table 5 depicts the value of skewness and kurtosis of all the items. The data shows that they are normally distributed.

TABLE 5 NORMALITY

	N	Skewness	Kurtosis
	Statistic	Statistic	Statistic
PCR1	100	-1.228	1.272
PCR2	100	-.168	-.878
PCR3	100	-1.179	.217
PCR4	100	-1.179	.217
PCR5	100	-.875	.396
HCR1	100	.072	-1.013
HCR2	100	.072	-1.013
HCR3	100	-.232	-1.104
HCR4	100	-.251	-1.113
OCR1	100	-1.102	1.010
OCR2	100	-1.102	1.010
OCR3	100	-1.102	1.010
OCR4	100	-1.102	1.010
IS1	100	-1.102	1.010
IS2	100	-1.102	1.010
IS3	100	-.414	-.503
IS4	100	-.414	-.503
IS5	100	-.414	-.503
HC1	100	-1.116	.649
HC2	100	-1.116	.649
HC3	100	-1.116	.649
HC4	100	-1.116	.649
HC5	100	-1.116	.649
Valid N (listwise)	100		

REGRESSION TEST

Physical Capital Resource and Innovative Strategy: The table 6 shows that Physical Capital Resource leads to Innovative Strategy. The significant value as shown in the ANOVA table is less than 0.05 which shows that the alternate hypothesis is accepted.

Table 6 ANOVA[a]

Model		Sum of Squares	Df	Mean Square	F	Sig.
1	Regression	25.433	4	6.358	7.482	.000[b]
	Residual	80.727	95	.850		
	Total	106.160	99			

a. Dependent Variable: IS

b. Predictors: (Constant), PCR

Human Capital Resource and Innovative Strategy: The table 7 shows that Human Capital Resource leads to Innovative Strategy. The significant value as shown in the ANOVA table is less than 0.05 which shows that the alternate hypothesis is accepted.

Table 7 ANOVA[a]

Model		Sum of Squares	Df	Mean Square	F	Sig.
1.	Regression	4.919	1	4.919	4.762	.031[b]
	Residual	101.241	98	1.033		
	Total	106.160	99			

a. Dependent Variable: IS

b. Predictors: (Constant), HCR

Organizational Capital Resource and Innovative Strategy: The table 8 shows that Organizational Capital Resource leads to Innovative Strategy. The significant value as shown in the ANOVA table is less than 0.05 which shows that the alternate hypothesis is accepted.

Table 8 ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1.	Regression	59.118	1	59.118	136.894	.000b
	Residual	42.322	98	.432		
	Total	101.440	99			

a. Dependent Variable: IS

b. Predictors: (Constant), OCR

Innovative Strategy and Healthcare: The table 9 shows that Innovative Strategy leads to health care. The significant value as shown in the ANOVA table is less than 0.05 which shows that the alternate hypothesis is accepted.

Table 9 ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1.	Regression	7.773	1	7.773	7.084	.009b
	Residual	107.537	98	1.097		
	Total	115.310	99			

a. Dependent Variable: HC

b. Predictors: (Constant), IS

CONCLUSION

Physical Capital Resources comprises of Technology, Geographical Area and Availability of raw materials. These are an important resource in any agro based industry. Human Resources refers to the training, experience, judgment, relationship, intelligence and insights of individual managers and workers. Organisational Capital Resource comprises of Planning, Controlling and Coordinating. Proper Physical Capital Resources, Human Capital Resources and Organisational Capital Resources leads to the development of Innovative strategies. Innovative Capability is based on reinforcing the firm's practices and processes. Reinforcement of new practices and process leads to proper health care. Healthcare is maintenance or improvement of health via the diagnosis, treatment, and prevention, illness, injury, and other physical and mental impairments in human beings.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Role of microRNA in EVI1 Expressing Acute Myeloid Leukemia (AML)

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ABSTRACT

Acute Myeloid Leukemia (AML) is a blood disorder which can be identified by the accumulation of somatic gene mutations. AML is characterized by formation of immature myeloid blasts in bone marrow and blood. Micro-RNAs (miRNAs) are 18-22 nucleotides, non-coding RNAs that play an important role in normal hematopoiesis. Aberrant expression of miRNA has been observed in leukemia and other diseases. One of the genes associated with AML is *EVI1* (Ecotropic Viral Integration Site-1). Over expression of *EVI1* is an indication of leukemic disease prognosis and *EVI1* associated AML has been deemed as poor prognosis. Ectopic expression of *EVI*1 in AML regulates the expression of miRNAs, which eventually alters the functional properties of leukemic cells. In this review, we will discuss the role and importance of miRNA in cancers especially in leukemia. We also discuss the role of oncogene *EVI1* in leukemia and its expression affecting the miRNA status of leukemic cells. In this review, we suggest that miRNA can be used as tools for cancer therapy and diagnosis. MiRNAs have been used in classifying cancers which has eased the efforts of medical practitioners to develop a strategy for cancer treatment. However, further insights in miRNA's cellular function would provide us with more options in treating cancer.

Keywords: *Acute Myeloid Leukemia (AML), MicroRNA (miRNA), Ecotropoic Viral Integration Site-1 (EVI1), Therapeutic Biomarkers.*

INTRODUCTION

MicroRNAs (miRNAs) are 20-23 nucleotides, endogenous single stranded RNA molecules expressed in the nuclear region and matured in cytoplasm of a cell. MiRNAs are known to be crucial regulators of gene expression that control pathological and physiological process of development and cancer[1]. MiRNA, Lin-4 and Let-7 which were first discovered in *C. elegans* were found to control the timing of nematode development via incomplete base pairing of the 3'UTRs of the target mRNA to inhibit translation[2].

It has been shown that miRNAs regulate the process of hematopoiesis; as a consequence miRNA dysregulation leads to haematological malignancies including leukemia. MiRNA involved in leukemogenesis can have dual role i.e. oncogenic or tumour suppressive[3]. Several miRNAs which are related to AML disease pathogenesis provide valuable information about prognostic outcome of the disease[4]. Primary factors responsible for dysregulated miRNA expression are: (i) under or over-expression of certain miRNA controlling genes, (ii) Epigenetic regulation of miRNA genes or (iii) transcriptional alterations of miRNA genes. MiRNA profiling of leukemic cells may help to reveal the insight of disease pathogenesis[5]. Such information justifies the role of miRNAs to be used as prognostic markers in leukemogenesis. Complete understanding of the regulation of miRNA expression in normal as well as in disease stages will be immensely helpful for both diagnosis and treatment purpose.

EVI1 (Ecotropic Viral Integration Site-1) gene encodes of transcription factor associated with human myeloid leukemia. Cell line and bone marrow studies have shown that *EVI1* represses terminal differentiation of bone marrow progenitor cells in erythroid lineage cells[6]. *EVI1* is also known to favour hematopoietic differentiation of the megakaryocytic lineage[7]. Expression of *EVI1* gene in AML patients is associated to poor prognostic outcome suggesting the function of this gene in genomic instability in the disease[7].

In this review article we summarize the recent findings regarding miRNA in relation to *EVI1* expressing AML. We also discuss the difference in miRNA profile in different leukemia and cancer. At the end we have shared some information on the miRNA expression with respect to a single oncogene, *EVI1* in leukemia.

MIRNA: BIOGENESIS AND FUNCTION

MiRNA Biogenesis pathway can be divided into two events on the basis of location of maturation of the miRNA molecule. Diagramatic representation of the same is depicted in Figure 1.

Nuclear Processing: The first processing event occurs in the nucleus, where nascent miRNA transcripts (pri-miRNAs) are transcribed by RNA polymerase from the miRNA encoding gene. Majority of the miRNAs are known to be transcribed by RNA polymerase II (Pol II). However, RNA polymerase III (Pol III) is also known to contribute to generate the transcripts of a subset of miRNAs. MiRNA genes are classified on the basis of their location on the DNA. Intragenic miRNAs (located within gene clusters) on the same strand as their host gene are co-transcribed by Pol II while intergenic (located within introns) miRNAs are transcribed from their own Pol II and Pol III promoters.

A typical pri-miRNA is a 33-35bp, terminal loop, single stranded RNA segment. The pri-miRNA is processed (cleaved) by a microprocessor complex consisting of Drosha (RNAse III enzyme) and it's essential cofactor DGCR8 (Di George critical region 8) to form double stranded, 70 nucleotide, stem looped pre-miRNA. Drosha is a nuclear protein (160kD), belonging to RNAse III type endonuleases which is known to contain two tandem RNase-III domains and a dsRNA-binding domain[8]. Drosha contains a helicase domain, DUF283, a PAZ (Piwi-Argonaute-Zwille), two tandem RNAse III domains and a ds-RNA binding domain. The RNAse domains functions to cleave the 3'strand of the stem of pri-miRNA and 5' end to produce a staggered end with two nucleotide long 3' overhangs. DGCR8 stabilises and helps Drosha in recognition of the pri-miRNA binding sites[9].

The last step of the nuclear event of miRNA biogenesis is the export of pre-miRNA into the cytoplasm. This step is mediated via nuclear membrane protein karyopherin exportin 5 (EXP5) and RAN-GTP complex. EXP5 functions as a recognition molecule for ds-miRNA with a short 3'overhang. RAN (RAS associated nuclear protein) is a GTP (Guanidine triphosphate) binding protein, which binds to the EXP5 to form a nuclear heterodimer with pre-miRNA to channelize the export process. After translocating the ds pre-miRNA through the nuclear pore complex, GTP is hydrolysed to disassemble from the RAN-GTP complex and release the pre-miRNA into the cytosol[9].

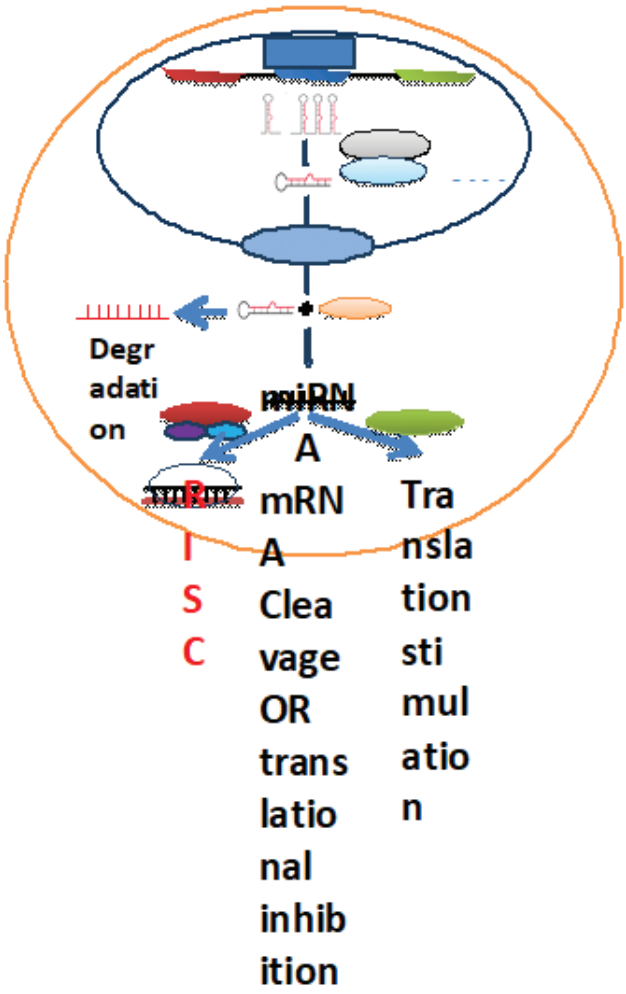


Figure 1. miRNA Biogenesis pathway

Cytoplasmic pre-miRNA Processing: After they enter they the cytoplasm, the pre-miRNA hairpin precursor is cleaved by Dicer into imperfect dsRNA duplex (Star (*) miRNA). *-miRNA is the non-functional part of the duplex and is degraded in the process. Dicer as similar to Drosha is a RNase III enzyme. Functionally, Dicer cleaves the 5' phosphorylated end of pre-miRNAs and generates a 22 nucleotide mature miRNA molecule. Cleavage by Dicer is regulated by TRBP (TAR RNA

binding proteins) which is a dsRBD (double stranded RNA binding domain) protein. TRBP molecule helps in processing pre-miRNAs and ultimately affects the length of mature RNA[9].

The RNA duplex which is formed after Dicer cleavage is subsequently loaded onto an argonaute protein (AGO) to form RISC (RNA induced silencing complex). The RISC assembly consist of two steps: loading of RNA duplex and unwinding of the duplex into a guide miRNA and a passenger miRNA. The passenger strand gets degraded and the guide strands gets loaded onto the AGO proteins to form the RISC. The loading of RNA duplex onto the RISC is an active process which requires ATP, where as the release of passenger strand is an ATP-independent process[9].

After the functional strand (guide miRNA) loaded together with AGO proteins into the RISC complex, it targets the mRNA where it carries out targeted cleavage or translational repression or mRNA deadenylation.

MiRNA and target gene interactions follow two notable steps for miRNA mediated targeted gene regulation: (1) miRNA targets the 3'UTR sites on the target genes, (2) for efficient repression of miRNA target mRNA, multiple target sites are required[5]. MiRNA-mRNA binding is commonly known for gene silencing and repressing protein expression. Apart from translational silencing, miRNA also promotes expression of target genes. MiR-328 promotes differentiation of myeloid cells by regulating the expression of master regulator of myeloid differentiation C/EBPα) via scavenging of translational inhibitor hnRNP E23. This interface between miR-328 and hnRNP E2 was independent from miRNA seed sequence, Dicer and Ago proteins and prevented hnRNP E2 from repressing C/EBPα translation. This also suggests that miRNAs can control the gene expression by interfering with the function of regulatory translational factors.

ROLE OF MIRNA IN CANCER

Over the past decades it has become evident that miRNA regulation and/or miRNA deregulation plays a vital role in tumour generation and metastasis. The downstream mechanism varies viz. chromosomal abnormalities, transcriptional control switches, epigenetic changes and defects in miRNA biogenesis machinery.

MiRNA expression is highly conserved process and takes place in each cell in all conditions (diseased/normal). We have reviewed miRNA expression of prominent cancers like glioblastoma[10,11], retinoblastoma[12,13], oral cancer[14,15,16], breast cancer[17,18], colorectal cancer[19,20] pancreatic cancer[21,22], hepatocellular cancer[23,24], renal cancer[25,20,26] prostate cancer[27,28,29] and melanoma[30]. Table 1 shows different cancers and the related miRNA expression.

Table 1: miRNA expression in different cancers

Cancer	miRNA Involved
Glioblastoma	miR-10b, miR-96, miR-182, miR-21, miR-542-3p, miR-132, miR-128, miR-181a, miR-181c
Colorectal cancer	Let-7, miR-17–5p, miR-20a, miR-29a,, miR-181b, miR-203
Breast Cancer	miR-146a/b, miR-106b, miR-128, miR-17-5p, miR-20a, miR-21, Let-7, miR-125a/b, miR-760, miR-626
Hepatocellular cancer	miR-221, miR-21, miR-93, miR-26, miR-130a
Melanoma	Let7a/b, miR-155, miR-126, miR-144, miR-20a, miR-141, miR-200c
Leukemia	miRNA-125b-1, miR-342 (AML), miR-193a, miR-196b, (ALL), miR-10a, miR-150 and miR-151 (CML), miR-155, miR-146a, miR-29 (CLL)

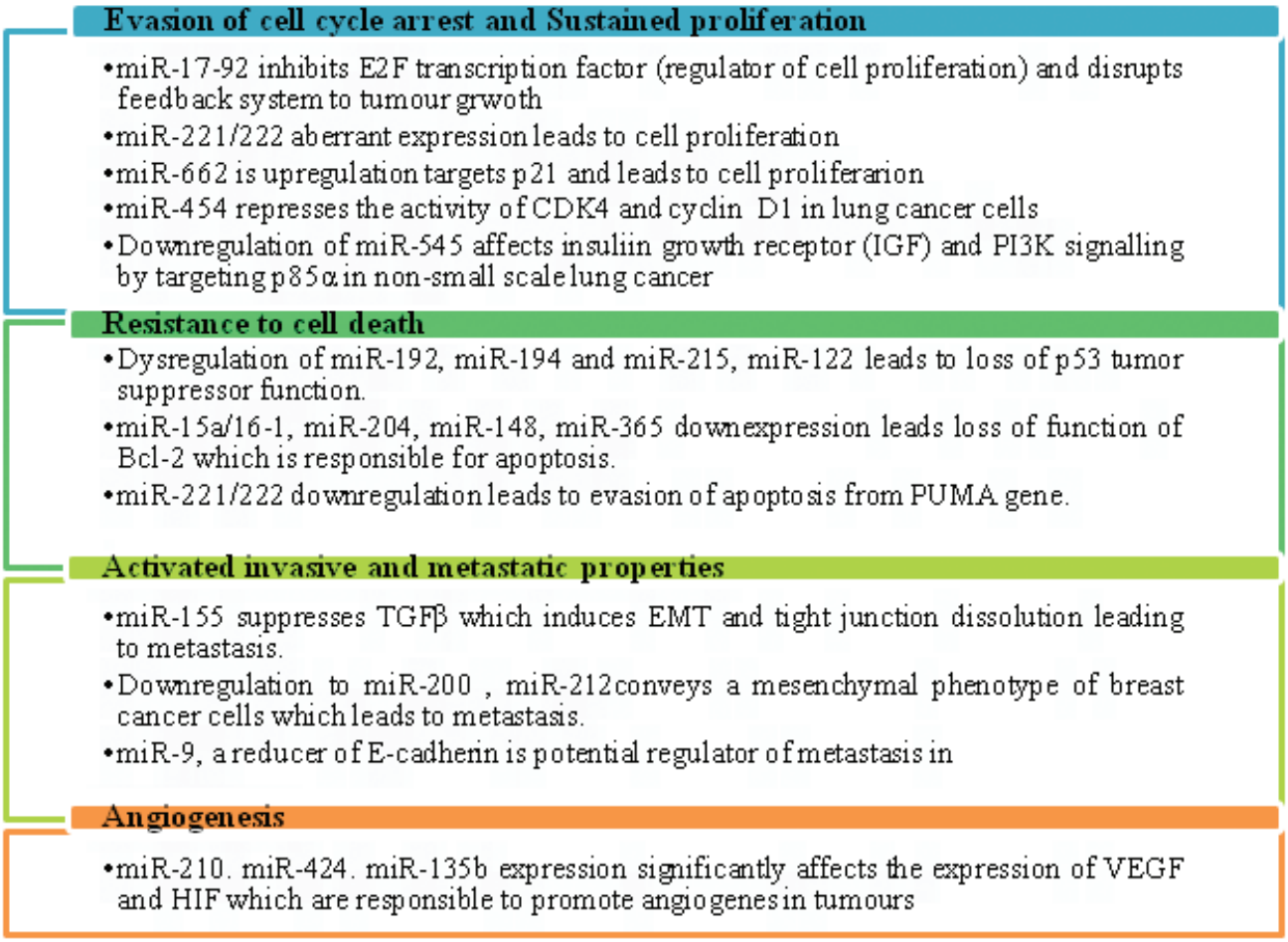


Figure 2: Significance of altered miRNA expression in cancer cells

It has been observed that many miRNAs are involved in each of these cancers. These various miRNAs have different functional and biological impact on diverse cellular functions and gene regulations, mentioned in figure 2. Some of the miRNAs functionally affect the cell proliferation pathways and deregulation of such miRNAs is responsible of evading growth suppressive signals and leads to sustained cell proliferation. Apoptosis evasion is another hallmark of many tumours, which is shown to be regulated by many miRNAs. Recent work also highlights the active role of miRNA in the process of EMT (Epithelial to mesenchymal transition), which is considered to be crucial step in initiation of metastasis by loss of cell adhesion[31,32]. MiRNAs are known to repress cell adhesion molecules and activate genes such as ZEB, SNAIL and TWIST which are associated with migration and invasion. TGF-β mediated miRNA regulations are known to induce EMT which further leads to apoptosis.

Deregulation of miRNAs in haematopoiesis and leukaemias: MiRNAs are known to be crucial players in hematopoiesis and regulate lymphoid and myeloid development. It is therefore very obvious that when dysregulated, these miRNAs will be responsible for disease pathogenesis and underlying mechanism. Prominent pathways that control the developmental and oncogenic processes are affected by the regulatory functions of miRNAs1. MiRNAs have dual abilities of being as tumor suppressors and as an oncogenic (oncomirs). Many studies have correlated miRNAs and leukemias thus suggesting possible roles for miRNA in hematopoiesis and tumourigenesis. The human miR-15a/miR-16 cluster, located at chromosome 13q14 is a region with regular chromosome deletions that are associated to majority of B-cell chronic lymphocytic lymphoma (B-CLL) and multiple myeloma5. MiR-15a and miR-16 are deleted or down-regulated in majority CLL cases implying that miRNAs play an important role as tumour suppressors on leukemia. The first link between miRNA expression and cancer was established upon the discovery of downregulated miRNAs miR-15a amd miRNA16-13. Deletion of miR-145 and miR-146a genes

on chromosomes 5q is connected with myelodysplastic syndrome (MDS). These findings exemplify that dysregulation of miRNA contributes to leukemogenesis by hampering the control of normal hematopoietic processes which eventually leads to cancer3. Different studies have shown that leukemic cells of acute myeloid leukemia patients have varied miRNA expression patters than normal hematopoietic cells (HSCs). Studies have proved that leukemic cells of B-ALL patients have different miRNA expression profiles as compared to the samples of normal bone marrow cells. Moreover, miRNAs are significantly different between T-ALL and normal thymocytes. Cytogenetic and molecular subtypes in acute leukemia have altered miRNA expression characteristics. 11q23/MLL-rearranged B-ALL cases display down-regulation of miR-708 and up-regulation of miR-196b and t (12:21)/TEL-AML positive B-ALL cases show up-regulation of miR-383, miR-125b, miR-99a and miR-100. This study shows that miRNA expression can be correlated with molecular sub-types in leukemia, mutational status and associated gene expression3. Studies regarding functional role of miRNA in cancer provide wonderful opportunity to provide targeted cancer treatment strategies. MiRNA profiles associated with cytogenetic aberration and mutational status of protein coding genes and prognosis may help to decipher the biology of different leukemia types. Novel miRNA are differentially expressed between cytogenetic subtypes of ALL and between ALL and normal cells. Such differential expression gives away for further studies for their potential role as prognostic markers in leukemogenesis. Such studies imply that miRNA have the potential to differentiate patients according to their respective leukemia can benefit from precise treatment options. Alteration of miRNA expression by anti-miRNA molecules or miRNA inhibitor drugs or tissue directed viral delivery is also promising therapeutic option.

EVI1 EXPRESSION IN AML

Many cancers, including leukemia are caused by chromosomal deformities such as inversions, translocations, deletions, or duplication. The study of aberrant chromosomes in leukemia has identified multiple regions of chromosomes that are likely to contain genes which are responsible for hematopoietic differentiation or for normal tissue and organ development. *EVI1* (Ecotropic Viral Integration site 1) gene is one of such genes associated with human as well as murine myeloid leukemia. *EVI1* was first identified as a common locus of retroviral integration in myeloid tumors found in AKXD mice[7,33]. *EVI1* gene encodes a transcription factor with two zinc finger domains. Expression of *EVI1* gene is constitutively activated by retroviral insertion in a region spanning 15 kilobases (kb) in the 5' region of the gene.

Expression of *EVI1* is observed during early embryonic development as well as in early myeloid cells. Regions in the embryo that are known to express Evi-1 consist of the urinary system, mullerian ducts, bronchial epithelium of the lung, focal areas within the nasal cavities, the endocardial cushions and truncus swellings in the heart, and the developing limbs. In hematopoietic system although expression of Evi-1 is low in early myeloid cellular differentiating cells, its level dramatically increases at the promyelocytic stage, and then decreased to the undetectable levels during G-CSF-induced differentiation of CD34 positive human myeloid precursors. Such a diverse expression of Evi-1 suggests an important role of this gene in organogenesis, morphogenesis, cell proliferation and differentiation of early embryonic cells and hematopoietic cells[7].

Evi1 gene in mouse and humans consists of two zinc finger domains at the amino and carboxyl terminal ends. The two zinc finger domains of EVI1 are known to recognise certain consensus DNA sequences (TGACAAGATAA & GAAGATGAG respectively). EVI1 exists in at two or more alternatively spliced forms. One is a 727 residue protein which lacks the zinc fingers 6 and 7 as well as the adjacent C-terminal amino acids. the next one has a different transcription initiation site and thus has additional 188 amino acid residues of alternative exons, which is also designated as MDS1 or PR domain, at the 5' end of the previously reported EVI1 protein[7].

EVI1 has been shown to be influenced by number of transforming oncogenes which raise the activity of AP-1 transcription factor, by transactivating the c-*fos* promoter. This process is known to be carried out by the second zinc finger domain. EVI1 is also known to inhibit the transforming growth factor thereby opposing the growth inhibitory effect of TGFβ pathway. This repression is brought about by the zinc finger domain-1 by interaction with Smad3, suppressing the transcriptional activity of Smad3, an intracellular mediator of TGFβ signalling[7].

Dysregulated expression of *EVI1* in hematopoietic stem cells results in cancer of myeloid lineages viz. acute myelogenous leukemias and myelodyplastic syndromes. *EVI1* gene is transcriptionally activated by translocations and inversion involving chromosome 3q26. The most frequent alteration include inv (23) (q21; q26) and t (3:3)(q21; q26) (Hirai, 1999). Most patients with 3q26 arrangements display overexpression of *EVI1* gene. Survival studies of AML patients having *EVI1* over expressed show that elevated level of *EVI1* is associated with poor survival outcome of AML34. Apart from unfavourable prognosis, *EVI1* activation leads to a particular aggressive form of acute myeloid leukemia[35].

MiRNAs with respect to EVI1 expression: Although overexpression of *EVI1* gene has been reported in a variety of acute myelogenous leukemias or myelodyplastic syndromes, very fewer studies have been carried out elucidating the relationship between the miRNA syntheses with *EVI1* overexpression. Also, not much has been described about the downstream targets and pathways involving *EVI1*. Thus new insights into molecular pathogenesis of EVI1 related leukemias are needed to understand the functionality of *EVI1* in AML. MiRNA deregulation has been known to be major contribution to cancer and leukemogenesis and hence a malignant phenotype of *EVI1* expressing leukemia can be partly explained through deregulation of miRNA(s) critically involved in oncogenesis (De Weer *et al*., 2011). It has been reported that transcription of miR-1-2 and miR-133a-1 was directly regulated by EVI1[34]. Further experiments revealed that miR-1 increased AML cells proliferation. MiR-133 exerted anti-apoptotic properties in leukemic cell. Treatment of miR-133 to AML cell lines increases their drug sensitivity to anticancer drug doxorubicin[34]. Since miR-133 dysregulates oncogenic function of EVI1 in AML, it can be used as a promising target in Evi-1 overexpressing AML patients[34]. Regulation of three miRNAs (miR-449A, miR-181-A1, and miR-107) resulted in decreased cell viability and increased apoptosis. Further analysis revealed that after switching off the *EVI1* expression, downregulation of miR-449A was observed[34]. In another study, induced EVI1 expression in murine MDS model and in cell line silenced the expression of miR-124. These studies show that miR-449A and miR-124 are direct transcriptional targets of *EVI1* gene in AML[36]. Another study demonstrated that *EVI1* exerts its proliferative properties to AML cells via miR-1-2[35]. Studies in *EVI1* overexpressing leukemia cell lines have shown that EVI1 silences miR-124 by DNA methylation. Consistent with these results expression of EVI1 in AML patients was shown to decrease the level of miR-124, suggesting that EVI1 plays an important role in transcriptional regulation of miRNAs[37]. MiR-9 is a critical regulatory organ developer, which is detected in hematopoietic stem cell differentiation. *EVI1* gene is known to down regulate miR-9, which leads to delay or blockage of myeloid differentiation by DNA hypermethylation[38].

Table 2: MiRNAs and its specific role in regulating cellular functions in EVI1 expressing leukemias

Micro RNA	Effect in the cells	Reference
miR-449A	Rescued *EVI1*-rearranged leukemic cells via NOTCH and BCL2. Increases rate of apoptosis in AML cells. Direct transcritiptional target of *EVI1*	De Weer *et al*., 2011[36]
miR-133	Increased drug sensitivity of *EVI1* expressing leukemic cells.	Yamamoto *et al*., 2015[34]
miR-1-2	Proliferation of AML cells	Gomez-Benito., 2010[35]
miR-124	Silenced by EVI1 in AML cells by demethylation by targeting CDK6	Vasquesz *et al*., 2010[37]
miR-9	Blocks myeloid differentiation by DNA hypermethylation by upregulating FoxO3 gene	Senyuk *et al*., 2012[38]

MIRNA AS BIOMARKERS AND PROGNOSTIC TOOL IN CANCERS

Genome wide profiling of miRNA expression in cancer including leukemia shows that miRNA expression is associated with tumour type, tumour grade and with immense clinical significance. Hence, miRNA could be used as potential biomarkers, prognostic markers, therapeutic targets or tools. Biomarkers are biological entities used to measure a biological state. miRNA are endogeneous coordinators of gene expression which can be used as an effective tool to judge the state of cells[39]. Harnessing the potential of plasma and serum

level miRNAs can empower us to detect diseases and cancers at early levels. It has been shown that circulating miRNAs, serum miRNAs are used as biomarkers in cancer diagnosis and prognosis. MiR-25 and miR-223 have been recently been proven to be upregulated in non-small scale lung cancer, suggesting their potential use for early diagnosis of lethal neoplasms. Traditionally, serum PSA (Prostate specific antigen) was used for screening patients with prostate cancer. After significant research on miRNA, miRNA-141 has been reported to be sensitive biomarker for Pca (prostate cancer). Urine levels of miR-107 and miR-574-3p were observed too high in Pca patients and can be used as biomarkers[40]. Circulating miRNAs from serum, plasma, whole blood and urine reflects not only the presence of ovarian cancer but also histology, stage and prognoses of ovarian cancer patients. Identification of tumour type is highly crucial for patient treatment and survival. Differential expression pattern of miRNA in individual tumour can help this classification. miRNA in breast cancer vary according to breast cancer subtype[39]. Renal tumours with different genetic background can be classified on the basis of differential miRNA expression level which has helped classify different renal cell carcinoma (RCC) among four subtypes [RCC clear cell RCC (ccRCC), papillary RCC (pRCC), oncocytoma and chromophobe RCC (cRCC)][39]. Keeping in view the above findings about miRNA biomarkers in clinical applications, miRNAs expression profile of different leukemia has been less explored. Despite of extensive research in identifying miRNA in leukemia of different cell lineages (myeloid or lymphoid), further steps of validation and accurate standardization needs to be carried out to venture into clinical use of these leukemic biomarkers.

CONCLUSION

Cells with abnormal miRNA expression are associated with sustained proliferation, evasion of growth suppressors, acquired invasive properties and angiogenesis. This suggests that miRNA functions as either tumour suppressors or oncogene under specific conditions. Although miRNA have multiple targets, their functions are exerted by regulation of few target genes. Hence, a challenge lies to identify critical target genes. A limited number of studies have highlighted the biological functions of miRNAs and also packaging of extracellular miRNAs needs to be evaluated and determined it's potential as therapeutic biomarkers.

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Assessment of Healthcare Utilization in a Community-Centric Model of Primary Healthcare for Rural Populations

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ABSTRACT

This study is an effort to assess the health service utilization of one such community-based clinic facility, as measure of its ability to meet community health needs. The study was based on retrospective analysis of administrative data relating to patient encounters, including data on chief complaints, clinical diagnosis. We analyzed the data of 16487 clinical visits from the year 2011 till 2016. The visits were classified based on clinical diagnosis into eight system organ classes (cardiovascular disorders, respiratory disorders, gastrointestinal disorders, urinary disorders, metabolic disorders, Skin disorders, musculoskeletal disorders and trauma or injury). The service utilization trends for cardiovascular disorders and metabolic disorders exhibited a liner increase utilization with the odds of 10.18(P Value- 0.001) and 8.80 (P Value – 0.001) respectively. While the service utilization trend for Gastro Intestinal disorders, Respiratory disorders, Skin disorders, Musculoskeletal disorders, Kidney disorders, Trauma or Injury were 0.54 (P Value- 0.012), 0.12(P Value- 0.001), 0.5 (P Value- 0.15), 1.26 (P Value- 0.001), 0.22 (P Value- 0.001), 0.38 (P Value- 0.003). When looked for service penetration, the cumulative service penetration till 2016 was 72%. This study has demonstrated the successful uptake of chronic care management program of our model and also pointed out the need to reinforce the primary care model with better interlinking to the community needs.

Keywords: *Healthcare assessment, Community-centric model, Primary healthcare, Rural population*

INTRODUCTION

Public health infrastructure in rural India is based on Health Sub centers (HSC) and Primary Healthcare Centers (PHC) as the first point of access for care seekers[1]. While the Indian healthcare industry is destined to grow at a staggering compound annual growth rate (CAGR) of 22.9 per cent during 2015-20, the growth is restricted to urban demographics with private tertiary care sector accounting for 74% of all the estimated growth [2]. This inequity in growth will cause tremendous stress on public health infrastructure in rural India which is already battling with inadequacy of well trained staff, poor funding and infrastructure challenges [3]. Under the "Universal Health Coverage" mantle, the Government of India and the State Governments have been working to provide free and universal access to healthcare services whilst ensuring that there shall not be any denial of healthcare directly or indirectly to anyone, by any healthcare service provider, public or private, by laying down minimum standards and appropriate regulatory mechanism.[4,5]Planning Commission of India constituted a high level expert group (HLEG. Despite these efforts, 823 million (69%) of population in rural India, largely struggles to meet the basic health care needs[6], access to the healthcare service providers still remain the major barrier to quality care. While Health Sub-Centers, that are accessible at a little over 3 km commute, have no physician access and offer little proactive risk screening/ curative services, PHCs (first point of physician access) require an average of >7Km commute, threatening rational care seeking and long-term adherence[7]. These challenges are exacerbated in the face of an unfinished communicable disease agenda and a fast rising non-communicable disease burden in these communities; thus calling for an urgent need for innovations in the area of community-centric, quality primary care delivery.

The IKP Primary Healthcare model was operationalized in rural Thanjavur, through SughaVazhvu Healthcare (SV) – a not-for-profit social enterprise delivering primary care and chronic disease management services in rural communities. The model

promotes the use of innovative technology products suited to low-resource settings to improve care delivery; evidence-based treatment protocols to standardize care and use of human resource alternatives (ex: AYUSH physicians) to overcome physician shortfall. The health services vertical of IKP includes a community-centric clinic set up in a rural village of 4000 residents since 2009. The clinic is located in Alakkudi Chief Village, in Thanjavur district, Tamil Nadu, India. The clinic is staffed by an AYUSH physician trained with evidence-based primary care protocols and a Health Extension Worker (HEW) sourced from the local community; and offers consultations and diagnostic services for a set of acute primary care conditions as well as NCD services. Population-level screening, enrollment, patient visit management and supply-chain management are facilitated through a cloud-based Health Management and Information System (HMIS) – IKP-TechPrima [7,8], developed by the IKP Centre for Technologies in Public Health (ICTPH), and deployed at SughaVazhvu clinics.

The Alakkudi clinic was setup with an objective of providing basic primary care services to the Alakkudi village, and also offers membership-based services for Diabetes, Hypertension and Hyperlipidemia, in an effort to improve patient follow-up and treatment adherence as well as to aid physicians in providing managed care to the chronic care patient cohort within the community with the help of technology. All the services offered by this clinic are free to all, in line with universal health coverage objectives. This study is an effort to assess the health service utilization of our community-based clinic facility in Alakkudi, as measure of its ability to meet community health needs

OBJECTIVE

The primary objective of the study is to assess the community level service utilization pattern at the SughaVazhvu healthcare facility.

METHODS

The study was based on retrospective analysis of administrative data relating to patient encounters, including data on chief complaints, clinical diagnosis. Special attention was taken to delink all the patient identifiers from the data and the analysis was performed on the basis of unique ids allotted to each unique clinical visit.

Study Population: The study population was the individuals form Alakkudi village, who had been visiting SughaVazhvu Healthcare center located in Alakkudi village from year 2011 to 2016. The eligibility criteria were the individual should be the resident of the Alakkudi Village. By resident we meant the individuals and families whose houses were located in the administrative boundary of Alakkudi gram-panchayat as of 2011 census. The non-resident individuals who accessed the SughaVazhvu Healthcare clinic in Alakkudi during the study duration were excluded from the analysis.

Sample Size Calculation: We included the entire data set from 2011 to 2016 and the entire households within the Alakkudi grampanchayat.

Statistical analysis: Our study includes the descriptive analysis of 16487 clinical visits made from Jan 2011 to Dec 2016. The demographics include mean age, proportion of male and female visits. Based on age, we stratified the visits as made by Children (<15 years) Adults (15 to 59 years) Elderly (>59 years) as the healthcare needs varies with each age group. We used the clinical diagnosis reported by clinician as the main factor for visit and classified the clinical diagnosis into eight system organ classes (cardiovascular disorders, respiratory disorders, gastrointestinal disorders, urinary disorders, metabolic disorders, Skin disorders, musculoskeletal disorders and trauma or injury) based on Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class (SOC) terminology. We also broadly classified the type of visits into infectious diseases and non-communicable diseases for understanding the trends of infectious diseases and non-communicable diseases over five years in our healthcare facility. We standardized the number of visits per year using village population of 4000 as of 2011 census as standardized population and calculated rate per 1000 individuals for each year and each SOC based disorder. We also looked at the number of visits per year, number of unique individual visits. The unique individual visits per year were presented as proportion and plotted year wise to understand percentage of village population utilizing health care service form our clinic.

RESULTS

From 2011 till 2016 total 16487 individual visits were made to our healthcare facility in Alakkudi, from the local community. Of these, 2535 (15.37%) visits

were made by children less than 14 years, 9276 (56.26%) were by Adults aged 15 to 59 years, 4677 (28.37%) were made by elderly aged 60 years or more. When stratified by gender, for males age group <14 years constitutes 24.10%, age group 15 to 59 years constituted for 49.84% visits and the age group >60 years constituted for 26.06% vists. For females age group <14 years constituted 11.12% visits, age group 15 to 59 years constituted for 59.39% visits while age group >60 years constituted for 29.49% visits. Observing at aggregate statistics for the 5 year period Respiratory disorder (45.13%) were the leading cause of visits in age group <14 years. For the age group of 15 to 59 years Skeletomuscular pain (Knee pain, Lower back pain, and Neck pain) (22%) and respiratory disorder (21.50%) was leading cause of visits. In case of >60 years age group Skeletomuscular pain (29%) and Metabolic disorders (Diabetes) (19%) were the leading causes of clinical visits (Table 1).

Further stratifying the data for annual utilization trends of clinic for above specified SOC's with population standardized rates Table 2 we were able to determine that there was increase in service utilization rates of all the above SOC's. Figure 1 graphically presents the population standardized rates of each with relation to time. Looking at the service utilization trends cardiovascular disorders and metabolic disorders exhibited as liner increase utilization with the odds of 10.18(P Value- 0.001) and 8.80 (P Value – 0.001) respectively. While the service utilization trend for Gastro Intestinal disorders, Respiratory disorders, Skin disorders, Musculoskeletal disorders, Kidney disorders, Trauma or Injury were 0.54 (P Value- 0.012), 0.12(P Value- 0.001), 0.5 (P Value- 0.15), 1.26 (P Value- 0.001), 0.22 (P Value- 0.001), 0.38 (P Value- 0.003). We plotted Figure **2** to broadly look at the service utilization pattern in terms of number for visits made for infectious diseases and number of visits made for non-communicable diseases. To understand the percentage of village population utilizing health care service form our clinic, we identified the number of unique individual visits per year. Table 3 and Figure 3 Presents the year wise classification of service penetration. The cumulative service penetration till 2016 was 72%. When the visits were stratified year wise the percentage of unique visits has seen rise in 2015 with 33% visits highest penetration followed by 2013 with 32%. 2016 with 19% has seen fall in unique individual visits.

Table 1. Aggregate five years demographics and reasons for clinical visits

Variable	n = 16487 (%)		
	Age <14 years	Age 15 to 59 years	Age >60 years
Age	2535 (15.37%)	9276 (56.26%)	4677 (28.37%)
Males	1301 (24.10%)	2691 (49.84%)	1407 (26.06%)
Females	1233 (11.12%)	6585 (59.39%)	3270 (29.49%)
Reason for Clinic visits stratified by age group			
Cardiovascular disorders	0 (0%)	345 (3.72%)	549 (11.74%)
Gastro Intestinal disorders	242 (9.55%)	845 (9.11%)	425 (9.09%)
Respiratory disorders	1144 (45.13%)	1969 (21.23%)	540 (11.55%)
Metabolic disorders	0 (0%)	1244 (13.41%)	867 (18.54%)
Skin disorders	106 (4.18%)	382 (4.12%)	138 (2.95%)
Musculoskeletal disorders	33 (1.30%)	1879 (20.26%)	1339 (28.63%)
Kidney disorders	21 (0.83%)	258 (2.78%)	32 (0.68%)
Trauma or Injury	223 (8.80%)	475 (5.12%)	116 (2.48%)

Table 2. Year wise numbers and standardized rates for SOC's (Direct standardization using village population of 4000)

SOC	Year					
	2011	2012	2013	2014	2015	2016
Cardiovascular disorders (n)	12	60	110	138	177	399
Cardiovascular disorders rate/ 1000 visits	3.00	15.00	27.50	34.50	44.50	99.75
Gastrointestinal disorders (n)	79	303	272	295	391	172
Gastrointestinal disorders rate/ 1000 visits	19.75	75.75	68.00	73.75	97.75	43.75
Respiratory tract disorders (n)	162	868	733	782	894	214
Respiratory tract disorders rate/ 1000 visits	40.50	217.00	183.25	195.50	223.50	53.50
Metabolic disorders (n)	35	313	349	229	351	834
Metabolic disorders rate/ 1000 visits	8.75	78.25	87.25	57.25	87.75	208.50
Skin disorders (n)	17	108	103	165	200	33
Skin disorders rate/ 1000 visits	4.25	27.00	25.75	41.25	50.00	8.25
Musculoskeletal disorders (n)	106	490	537	704	931	483
Musculoskeletal disorders rate/ 1000 visits	26.50	122.50	134.25	176.00	232.75	120.75
Kidney disorders (n)	15	108	60	48	67	13
Kidney disorders rate/ 1000 visits	3.75	27.00	15.00	12.00	16.75	3.25
Trauma or Injury (n)	72	162	166	137	164	113
Trauma or Injury rate/ 1000 visits	18.00	40.50	41.50	34.25	41.00	28.25



Figure 1: SOC wise standerdized service utilization trends from June 2011- June 2016

Table 3. Year wise service penetration

Year	N	2011	2012	2013	2014	2015	2016
Total number of Visits	**16487**	**671**	**2924**	**2764**	**3269**	**4305**	**2554**
Year wise number of Unique Individuals visits	4000	438 (11%)	1287 (32%)	1051 (26%)	1113 (28%)	1341 (33%)	777 (19%)
Unique individuals (cumulative) n (%)		438 (11%)	1542 (39%)	1995 (50%)	2367 (59%)	2760 (69%)	2887 (72%)

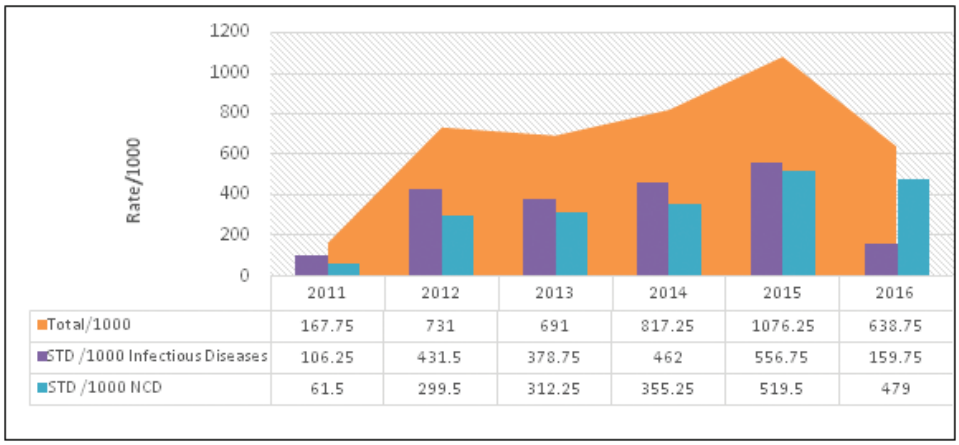


Figure 2: Standardized disease trends for infectious diseases and NCDs

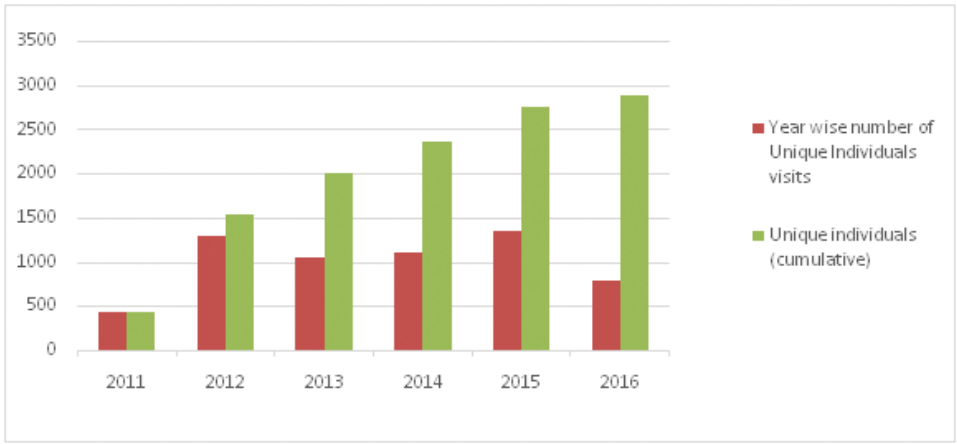


Figure 3: Year wise service penetration

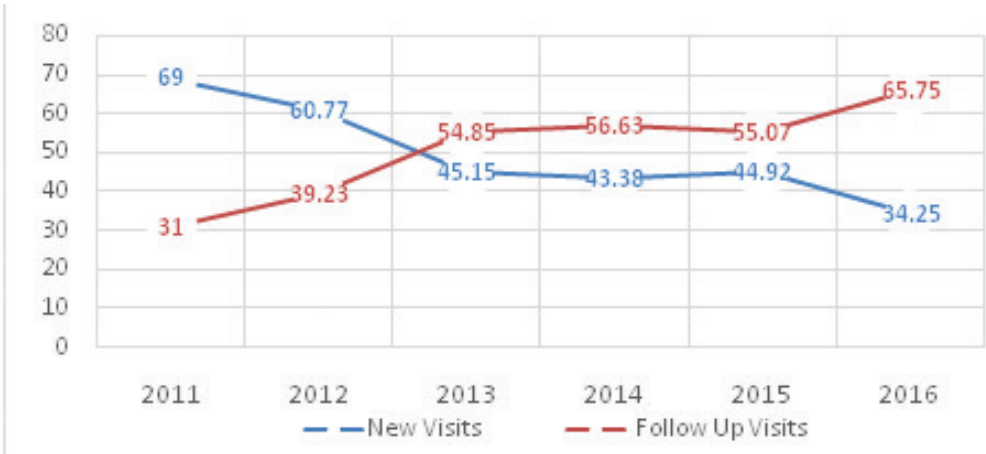


Figure 4: Year wise follow up visits

DISCUSSION

The present study investigates the primary healthcare utilization patterns from a healthcare systems perspective, in a low-resource setting. Through the primary healthcare clinic designed and implemented by ICTPH and SughaVazhvu, a model has been presented for a provision of accessible preventive, curative and early stage NCD management services, at the level of health sub-center by leveraging technology and process innovations and standard treatment guidelines.

The clinic visit data indicates robust utilization of the clinic, especially among access-restricted, dependent groups, such as women and the elderly. While the initial clinic utilization was higher for acute care related services, the data indicates an increase in chronic disease utilization – corresponding to the launch of focused membership-based interventions for early stage diabetes, hypertension and hyperlipidemia management.

The data from the initial years (2011, 2012) as in Figure 4 demonstrates the higher percentage of new visits which corresponds to comparatively higher cases of infectious diseases in Figure 3. While the year 2013 marked the equal percentage of new visits and follow up visits, proceeding years were marked with eventual rise in follow-up visits which coincides with liner rise of chronic diseases in Figure 3. The data trends are clinic specific and represent the pattern change within the community up to certain extent, but they specifically point out at the change in community perception of the clinic and services offered.

The launch of focused disease management interventions for diabetes and hypertension at SughaVazhvu, while timely given the increasing evidence of high disease burden in rural communities for these conditions, was based on our experiences in these communities, that led to the understanding that (i) lack of disease awareness and knowledge and (ii) access barriers and associated loss of wages, were primary factors that impacted treatment follow-up adherence. In addition, the complex nature of disease management, which required multiple and frequent touchpoints with the health system, and a patient-centric approach, led to the launch of this intervention in the Alakkudi clinic. The increasing utilization trends with respect to chronic care services can be attributed to factors like

1. Single point interface for consultation, diagnostics and medications
2. Zero commute time and associated wage loss for access to medical services
3. Proactive patient follow-up and reminder services made possible through TechPrima

The system organ class wise trends for 2016, indicates population standardized rates for cardiovascular disorders, metabolic disorders is on rise while respiratory disorders, musculoskeletal disorders, skin disorders, gastro intestinal disorders were on the fall. These could be attributed to an increasing perception among the community of the clinic as a "sugar clinic", or the requirement of higher levels of care for services related to pain management, etc.

CONCLUSION

The public health system in India is faced with the dual challenges of preventing and managing infectious and non-communicable diseases. Rural communities, where 70% of India's 1.2 billion population reside, are primarily served through the county's public health infrastructure, historically focused on infectious diseases and maternal health services. There is an urgent need to strengthen these facilities to make basic curative care components more accessible to the community, supported through capacity building of front-line workforce, use of strong evidence based guidelines and leveraging technology innovations. This study has demonstrated the successful uptake of chronic care management program of our model and also pointed out the need to reinforce the primary care model with better interlinking to the community needs.

Ethical clearance: No need

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Menstrual Hygiene in Rural India

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ABSTRACT

Menstruation, a phenomenon unique to women of reproductive age is marked by the discharge of blood and other materials from the lining of the uterus at intervals. A key sign of reproductive health and a normal biological process, yet menstruation, a taboo across the globe continues to be a topic that is less talked about. In a country of contrasts, India, menstruation and its practices are clouded by socio – cultural misbeliefs. The lack of appropriateness of practices of utilization and disposal of menstruation absorbents in rural setting as compared to urban setting can be attributed to the various psychosocial and economic factors that confine women to a state where they are unable to prioritize the health and hygiene needs over other issues. Various initiatives have been taken at the grass root level on usage of menstrual absorbents and menstrual hygiene management. Regardless of the usefulness of the interventions, governance challenges hinder successful implementation of the same across the country. The present article discusses the various aspects of menstrual hygiene in rural India that are less focused upon and the need to end the hesitation.

Keywords: *rural India, menstrual absorbents, menstrual hygiene, menstrual waste*

INTRODUCTION

Menarche, the onset of menstruation and part of a girl's transition from childhood to adolescence, is a critically important but under-recognized issue concerned with public health[1] Approximately, half of the global population is of reproductive age (26% of the total population), menstruating for between two and seven days each month. Good hygiene is an essentiality during menstruation that is characterized by use of use of most suitable menstrual absorbent, adequate washing and cleaning of genital area[2]. The misconceptions and ignorance of scientific facts and hygiene practices of menstruation, sometimes, result in adverse health outcomes[3]. Hence, appropriate knowledge about menstrual hygiene is vital.

Menstrual Hygiene Management (MHM) is a culmination of various strategies adopted by women to maintain cleanliness, acquire appropriate menstrual absorbents, use them, clean & safe reuse and appropriate disposal during menstruation. Menstrual Hygiene depends upon these strategies adopted during monthly periods. The methods girls and women have developed for management of menstruation varies across as well as within countries. The variations can largely be attributed to an individual's personal preferences, availability, accessibility, affordability, local traditions, cultural beliefs, and most importantly knowledge[4] Interplay of a multitude of factors channelizes the appropriateness of choices made by women. Studies in three Low & Middle Income Countries (LMICs); Nagpur district of India, Western Ethiopia and rural Nepal have reported low level of hygiene practices despite of existing knowledge[5] A comparative study in Nagpur district further revealed a statistically significant difference between hygiene practices in rural and urban setting with it being more satisfactory in urban setting[6]

MENSTRUATION IN INDIA

Deep engrained social stigma of menstruation impacts the menstrual hygiene practices of the women of the country. Menstruation and related issues are clouded by taboos and thus are rarely discussed by parents and the society. This hinders the flow of appropriate information, especially in the rural areas[7] The various stigmas clouding menstruation violate several human rights, especially the right to human dignity. Cultural restrictions and discriminatory gender roles further exacerbate women's difficulties during menstruation[8].

There is a blurring of the boundaries between cultural ethics and religious beliefs regarding menstrual hygiene. There is a difference in the MHM practices among communities of the same religion largely due to geographical and socio-economic variance. [8]. Girls, in Indian society during the periodic menstrual cycle face many restrictions such as refraining visits to place of worship, kitchen, eating separately, sitting separately from other household members, not being allowed to touch special foods, attend social functions, so on and so forth. Owing to the age – old unfounded myths and inhibitions towards discussing the topic results in girls and women having little knowledge of the actual facts of menstruation.

KNOWLEDGE AND PRACTICES REGARDING MENSTRUAL HYGIENE

Pre-menarche awareness: It is ideal for each and every girl child to be aware about menstruation, which is an important event at the inception of adolescence and most importantly before the attainment of menarche[9]. Contrary to this, studies have revealed lack of sufficient appropriate knowledge about menstrual[10] A Meta – analysis of menstrual hygiene management among adolescent girls in India reported pre – menarche awareness to be 48% with it being affected by setting, region and year of study with significantly higher awareness over time in the East and West of India as compared to the North, and lower awareness in slum settings[11]. In a comparative study on menstrual hygiene among Rural and Urban adolescent girls in Nagpur, it was found that 63.38% of girls in urban area and 47.57% in rural area were aware of menstruation prior to menarche with a statistically significant difference between urban and rural girls[6]. A cross – sectional community based study in Vijayawada reported that mothers were the primary informants about menstruation (64.22%)[14]. While, in a similar study in Varanasi, sisters were found to be the primary informants (55%)[12]. According to the same study, role of level of education in following appropriate practices was found to be statistically significant.

The first modern disposal pads were produced in 1890's and menstrual tampons in 1920's in America[13]. Since the introduction, the usage of these products has continued to increase both in Low and Middle Income Countries. Lack of menstrual hygiene, prolonged use of a sanitary napkin in a day, and reutilization of inadequately cleaned and improperly dried cloth napkins result in harboring of micro-organisms causing vaginal infections. Addressing the need to resolve the issue of unhygienic and unsanitary menstrual practices in LMIC's like India, Arunachalam Muruganantham, India's menstrual man had developed and patented a machine for manufacturing low – cost sanitary pads in early 2000s for a cost that was less than a third [13] Women can then buy these machines to make and sell the pads as alternative sources of income. This movement has sparked success across the country and the world.

Preferred menstrual absorbents: A Meta–analysis of menstrual hygiene management among adolescent girls in India found that there was a striking difference in the type of menstrual absorbent used with disposable sanitary napkins being more common in use in urban settings and reusable cloth pads being more common in rural settings[11]. This difference is attributable to the underlying socio–economic factors, such as; lack of knowledge, high cost of the pad, shyness, misbeliefs and lack of disposal facilities with the economic factor being the prime determinant. The same study also reported an increase in the use of sanitary napkins over the time. A study conducted in among adolescent girls in Saoner of Nagpur District reported that 30.82% of girls in rural areas used Sanitary napkins, and 62.33% used old cloth pads while only 6.85% used new cloth pads. Also, the study reported a statistically significant difference regarding the use of sanitary napkins among urban and rural areas, with 30.82% of rural and 60.58% of urban girls using sanitary napkins(Thakre et al., 2011)have reinforced a negative attitude towards this phenomenon. There is a substantial lacuna in the knowledge about menstruation among adolescent girls. Good hygienic practices such as the use of sanitary pads and adequate washing of the genital area are essential during menstruation. Menstrual hygiene and management will directly contribute to the Millennium Development Goal (MDG. A similar study in Udupi Taluk reported that among rural adolescent girls, 65% used sanitary napkins, 30.4% used both cloth pad and sanitary napkin and 3.9% used a new cloth pad while 0.7% used old cloth pads[7]

Availability of Sanitary napkin is a boon to present day women but whether they are easily accessible or not still remains an aspect which has to be more focused upon. Thus there are many fall-outs too.

Utilization of absorbents and cleaning practices: Cleaning of the genital area is an essential element for maintaining hygiene during menstruation. A cross–sectional study conducted in Vijayawada reported that while 63.33% girls used soap and 16% used antiseptic along with water, 20.67% cleaned using only water [14]. Similarly, a study in Nagpur district concluded that 56.16% used soap, 46.47% used only water whereas only 1.37% used antiseptic for cleaning (Thakre et al., 2011)have reinforced a negative attitude towards this phenomenon. There is a substantial lacuna in the knowledge about menstruation among adolescent girls. Good hygienic practices such as the use of sanitary pads and adequate washing of the genital area are essential during menstruation. Menstrual hygiene and management will directly contribute to the Millennium Development Goal (MDG. A comparative study conducted in Maharashtra reported that while 31.86% of urban girls had satisfactory cleaning practices (cleaning external genitalia twice a day), only 16.67% of rural girls followed satisfactory practices[6].

In addition to regular cleaning of external genitalia, periodic change of the absorbent is a major determinant of hygiene. Lack of private places, toilet facilities, adequate water are few of the major reasons for infrequent change practices. Lack of these basic facilities results in both school absenteeism and drop out among girls. A study regarding menstrual hygiene in Udupi taluk of Manipal reported an uncomforting feeling and shyness to be a prominent reason for not changing the absorbent (72.6%). Lack of water and disposal facilities, followed by unhygienic conditions of toilets were found to be the most stated reasons among rural participants of the same[7]

Disposal of absorbents: Along with the proper utilization practices, disposal practices are also important for adequate menstrual hygiene. The after usage aspect of sanitary napkins is often a neglected issue. With a plethora of taboos associated with menstruation, women avoid disposing the waste properly and rather hide it or dispose it in a way that can be detrimental. In rural areas, poor availability and accessibility of disposal facilities result in girls and women disposing the sanitary waste in open fields, garbage dump or small water bodies. Further, according to a study conducted by UNICEF in schools of few rural parts of West Bengal, it was revealed that out of the 48% who preferred sanitary napkins as an absorbent, 78% of them disposed the used napkins by burying in or alongside ponds while bathing while 2% of them burnt the pads [15.] On the contrary, a study conducted in rural parts of Hooghly district of West Bengal revealed that 57% disposed the used sanitary absorbent appropriately by wrapping in paper and dumping in a place for solid waste disposal [3]. AC Nielsen's study on 'Sanitary Protection: Every Woman's health right' reports that around 36 million women in India use sanitary napkins; which makes it 12% of 300 million women in the age group of 15-54 years. A woman uses around 10,000 pads, on an average, in her entire lifetime for around 30-40 years; this sums up to 58,500 million pieces per year[16]

The disposal practices adopted vary across populations depending on knowledge and attitudes. With the government promoting usage of sanitary napkins in rural areas for appropriate menstrual hygiene management to reach 100% from the 12%, the burden of menstrual waste in India and its impact on health in the coming years would increase in the absence of appropriate disposal practices.

PROGRAMS AND INITIATIVES

The National Rural Health Mission (NRHM), under the Ministry of Health and Family Welfare (MoHFW) recognizes adolescent health an important part of the Reproductive and Child Health (RCH) Component. The existing national health programmes such as the Adolescent Reproductive and Sexual Health (ARSH) and the Adolescent Education Programme (AEP) include a range of interventions for adolescent girls and boys who are in school and out of school. With a thought that for women and girls to live healthily and with dignity menstrual hygiene is important, the Menstrual Hygiene promotion scheme strengthens interventions for adolescent girls by facilitating discussions on menstrual health and hygiene, and distribution of sanitary napkins (NRHM Operational Guidelines: Promotion of Menstrual Hygiene among Adolescent Girls (10-19 Years) in Rural Areas, 2012). This scheme provides a package of health and supply of sanitary napkins through the involvement of local women's groups, Accredited Social Health Activists (ASHAs) and Auxiliary Nurse Midwifery (ANMs). The scheme ensures provision of sanitary napkins under the brand name "Freedays" of National Health Mission at a nominal cost of Rs. 6

for a packet of 6 pads by the ASHA [18]. The operational guidelines for promotion of menstrual hygiene among rural adolescent girls has been laid that directs the states to bring about convergence with other existing programs like the Total Sanitation Campaign and Sarva Shiksha Abhiyan for facilitating infrastructural improvement[16]

WaterAid, a global network has been working in the WASH (Water, Sanitation and Hygiene) Sector for the last four decades across the world. WaterAid India since 1986 has been working nationally and in the states in the country, recognizing the importance of menstrual hygiene in the lives of women [24]. In 2014, the Centre for Action Research and Management in developing attitude, knowledge and skills in Human Resources- CARMDAKSH, a Civil Society Organization in Chhattisgarh launched a rural campaign to provide comprehensive information about MHM to couples through means of counseling to sensitize the involvement of men 13.

Jatan Sansthan, a not for profit organization in the districts Rajsamand, Udaipur, Jhalawar and Bhilwada of the state of Rajasthan initiated the Safe Menstrual Campaign for empowering women, girls and youth on menstrual matters through means of research, male sensitization and development of reusable, washable, low cost sanitary napkins – UGER for making the practices more hygienic. Many such organizations; the Self – Employed Women's Association (SEWA) in Gujarat, Eco – Femme and Aakar (Anandi Pad), to name a few, are successfully working towards ensuring appropriate Menstrual Hygiene through provision of low cost reusable sanitary napkins and awareness campaigns.

CHALLENGES

The review of literature led to identification of several challenges persistent in context of menstrual hygiene management. Firstly, there is lack of adequate baseline data about MHM. Despite of the operational guidelines laid by the Government, implementation of the same has not been done. The various norms for facility provision are not adhered to. Secondly, MHM among adolescent girls has extensively been studied, but the same among women in rural areas has not been studied much. As the adult female members of the family, precisely mothers serve to be the first point of contact for the girls, knowledge and practices regarding MHM should be studied more among women especially in rural areas. Thirdly, while there are methods through which adequacy of access to facilities for MHM at schools can be assessed, there is a lack of well laid guidelines for assessing the same at households. Fourthly, there is a need for a measure of degree of appropriateness of knowledge of trainers and surety of it reaching the population. Training of the trainers is an often neglected aspect that should be emphasized upon. Fifthly, there is a lack of consolidation of activities of WASH sector and governance. Last but most importantly, gender sensitization is lacking. There is not much emphasis laid upon the gender based outlook towards MHM. Considering the decision making dynamics at household, the men need to be informed of the various aspects MHM adequately.

DISCUSSION

Lacking information, infrastructure, economic means and confidence to manage menstrual hygiene, the 355 million of reproductive women in the country are struggling to have their menstrual needs met. Many of these women are subjected to discrimination on the social front and they tend to lose out several educational and economic opportunities.

On the Cultural front, there is a need to sensitize men towards the issue. In a patriarchal society like ours, decision making power majorly rests with the men of the family. With them being negligent towards the subject, it is difficult to significantly change the current scenario. Counseling men in a comfortable environment is one of the most impactful ways of breaking the silence.

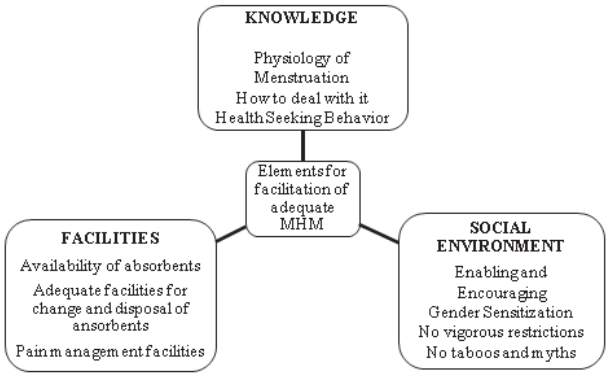
On the Educational front, firstly, educating the girls before the onset of menarche can be seen as the window of opportunity. With prior knowledge, the first experience at menarche does not shock the girls at the tender age. Second, schools should provide with enabling environment that can facilitate discussion about the topic. Mere presence of infrastructural facilities like toilets and incinerators would not effectively serve the purpose. There should be a room for counseling and informative sessions across all age groups. Third, with mothers being the primary source of information in majority of cases, it is essential to educate them about the subject. When in school, teachers could be the primary contact source if the mothers have inadequate knowledge but owing to the high drop - out rates from school, mothers have a significant role to play.

Menstruation being a taboo topic even restricts those who are responsible for spreading awareness from having the correct information. Henceforth, it is essential to train and update the trainers like the community health workers, ASHAs, ANMs, teachers about the best practices of menstrual hygiene.

On the Economic front, widespread inaccessibility and poor affordability of commercial menstrual products results in 88% women of the menstruating group refraining from using them and makes it necessary for them to be informed about the alternatives. Despite of the provisions made by the Government by means of various schemes, there is a lacuna of awareness about the same and also a gap between demand and supply. Reaching the last mile population should thus be prioritized.

Health seeking behavior should be promoted by means of Behavior Change Communication (BCC) activities, adequate use of media and participatory approach especially targeted at the mass before menarche as that is the golden window of opportunity. Undoubtedly, it is not an easy task to bring about change in behavior but this has to be promoted to bring about a steady and gradual change.

Elements for Facilitation of adequate MHM [11]



In many LMICs, sectoral monitoring systems are weak or absent. There may be a track of facilities in numbers but information about the functionality or utilization of the systems remains a lacuna. Evaluating the impact of any intervention based on easy tangible statistics often paves way to neglect of a few indicators. Thus, development of a comprehensive operational strategy through the involvement of all stakeholders for the Monitoring and Evaluation component with a focus not just on the availability of menstrual hygiene facilities but primarily on the accessibility of the same should be worked upon. For a better implementation of MHM interventions, engaging the local decision makers of the community; the men, older women, and panchayat leaders is critical. One of the major challenges on the way for successful mobilization of a community for achieving better MHM is lack of awareness. Intensive mass awareness campaigns accompanied by regular events and meetings can resolve the issue. Any intervention should be specific to the needs of the target population based on age, gender, setting and region. At the same time, there is no denying the fact that Menstrual Hygiene Management remains a matter of concern across the world. There is therefore a need for coming together of the local and global stakeholders for collaboration and strengthening of research capacity on Menstrual Hygiene Management to critically elaborate on the existing areas of action and identify newer ones. With most of the research studies targeted at the adolescent age group, considering it to be a milestone in the lives of young girls, it cannot be neglected that there is a need to understand the same subject among women.

Ultimately, prioritization of Menstrual Hygiene Management by all stakeholders and fading of the hesitation associated with a sensitive subject is the need of the hour.

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

The authors conceptualized the article. Ms. Vasudha Katti drafted an initial version. Dr. Yatin Pimple and Dr. Abhay Saraf provided extensive edits. All authors have read and approved the final manuscript.

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An Adaptive Index Associated With Community Ownership and Preparedness for The HIV Prevention Program in India

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ABSTRACT

Community-based groups (CBGs) are a frequent feature of community mobilization. In HIV/AIDS prevention programs in India, CBGs and networks are seen as a vehicle to strengthen demand for services and manage programmatic activities. Community mobilization is an important component of a participatory approach to health and development interventions.[1] and[2] have developed a methodology for measuring community mobilization score using community ownership preparedness index (COPI). These authors further use COPI to assess the effectiveness of the community mobilization in a 10-year, large-scale HIV Prevention intervention program, viz., "Avahan, the India AIDS Initiative". The COPI was calculated as a weighted average of 22 sub index scores, where the weights are based on the domain knowledge (or perception). In this paper, we attempt to develop a new data-driven (adaptive) composite index to measure the community mobilization score of a CBG. The suggested data-driven composite score index has been calculated using multivariate statistical methods such as principal components and factor analysis. The nearness of the suggested index to COPI has been established, thus justifying the use of COPI as a community ownership and preparedness index. The effectiveness of the program over the period of evaluation can be clearly seen from the improvement in the adaptive scores during the period 2009 to 2012

Keywords: *Adaptive index, Community ownership and preparedness index, Factor analysis, HIV prevention intervention program, Principal component analysis*

INTRODUCTION

In 2003, Bill and Melinda Gates Foundation launched the 'Avahan India AIDS Initiative', which support groups that are most vulnerable to HIV-infection, including sex workers (FSW), their clients and partners, high-risk men who have sex with men (MSM), and injecting drug users (IDU). In the first five year phase (2004-2008), 'Avahan' successfully built a large-scale HIV intervention programme in six states of India, viz., Maharashtra, Karnataka, Tamil Nadu, Andhra Pradesh, Manipur and Nagaland that accounted for 83 per cent of the country's HIV infections. In the second and last phase of this project (2009-2013), 'Avahan' aimed to hand over the programme to its "natural owners", like the Government of India and Community-based Groups (CBGs) that work locally with these communities. Thus, it was essential to judge the effectiveness and preparedness of these CBGs based on various aspects, before such hand over.

[1] and [2] (referred as TN hereafter) have developed an integrated set of measures to assess the effectiveness of the community mobilization and organizational development status of CBGs that are part of the 'Avahan Program'. For the computation of these measures, baseline data were collected from 36 CBG's in 2009 and annual re-measurements have been done until 2012, for a sub-set of all the CBGs. The measurement instrument incorporates a theory of what aspects of organizational development are important. It is expressed by paying attention to some aspects of organizational behavior, and ignoring others, which are unimportant. It is also expressed in the weightings used to help generate composite performance scores (on each "parameter") out of many subsidiary measures ("indicators"), a natural tool to construct a score or an index.

The collected data finally condensed to 22 indicators, which represent the traits that a CBG should posses. These 22 indicators are later pooled into 8

parameters, depending on their properties. These eight parameters are, *Leadership*, *Governance, Decision-making, Resource Mobilization, Community Networks Project Risk Management, Engagement with State* and *Engagement with other Influencers*. More details and explanations about these indicators and parameters are available in TN. The values for the 22 indicators are computed using the weights assigned to the categories and answers. These weights represent the percentage of importance given to a particular indicator. The weights are decided based on the pilot study and the opinion from various domain experts. Subsequently, TN have come up with percentage scores (out of 100) for each CBG, named as community ownership and preparedness index (COPI) and the Transition Readiness Scale, 1 to 4, based on COPI. These scales signify the transition readiness status of the CBGs in terms of basic, foundation, promising and vibrant.

The questions that we tried to address in this paper are (i) Can the weights be determined adaptively (from the data itself)? (ii) If yes, how do they compare with the existing weights or ranks of CBGs using the existing weights? (iii) Is the program effective? In this paper, our aim is to address these three questions. Towards this, first we develop an adaptive score for CBGs, based on twenty two indicators measured by TN in their paper. Subsequently, we statistically examine the agreement of the scores based on this new adaptive composite index with that based on the COPI of TN. Lastly; we study the effectiveness of the program by statistically verifying the improvement in the adaptive scores.

We use multivariate statistical techniques such as principal components and factor analysis for this purpose. This new adaptive composite index can also measure the transition readiness of the CBGs. It is found that the COPI suggested by TN and the new composite index suggested in this paper are in good agreement and provide almost similar rankings of CBGs. This claim is statistically verified here using the Cohen's Kappa statistic. We have also established that the program was effective, as the adaptive scores were improved during 2009-2012.

Several research papers have been published in the literature, which deal with the problem of construction of composite indices. Recent empirical literature has seen many multidimensional indices such as, well-being or poverty measures, which are, in particular derived from the principal components and various latent variable models like the factor analysis. Most of the research is done to develop indices for human development, poverty, child health etc. for example, [3] have developed a single comprehensive index of child mortality for longitudinal assessment of health status of children, using factor analysis techniques. [4] have studied specific features of the Indian socio-economic environment, the health and family welfare service facilities and the programmatic efforts by constructing several composite indices using principal component analysis technique. [5] considered the problem of poverty measurement based on asset index, using factor analysis and principal component analysis. [6] have constructed human development index (HDI) and human poverty index (HPI) for all the states of India and performed multivariate statistical analysis on the indicators used in the calculation of HDI and HPI. Some other related references are, [7] [8] [9] [10] [11] and [12] This is not an exclusive list of related references. However, we feel that it is for the first time that community based groups are being evaluated based on statistically constructed adaptive composite indices.

The paper is divided in to four sections.. In Section 2 of the paper, we describe the methodology, followed by results and findings in Section 3. Some conclusions are mentioned in Section 4.

METHODOLOGY

In this section we describe the methodology used in this paper to define an adaptive index for community mobilization and its comparison with COPI proposed by TN. For a theoretical development of multidimensional data analysis and index construction, we refer [13], [14] [15] [16] [17] [18] [19] and [20]

Initial tests: The suitability of the data for the application of factor analysis (or factorability) needs to be tested first, before applying the factor analysis. There are two methods for determining the factorability. These are Bartlett's test of sphericity and Keiser-Meyer-Olkin measure of sampling adequacy. The Bartlett's test examines whether the correlation matrix between the twenty two indicators is an identity matrix or not, which would test the appropriateness of the factor model. Here the null hypothesis is H_0: the inter-correlation matrix comes from a population in which the variables are non-collinear (i.e., an identity matrix). The test statistic is given by

$$[(n-1)-1/6(2p+1+2+/p)]-\left[\ln|S|+p\ln(1/p)\sum_j I_j\right]$$

where, p = number of indicators, k = number of components, I_j = jth eigen value of the correlation matrix S and n = number of CBG's. The degree of freedom of the approximate chi-square distribution is given by $(p-1)(p-2)/2$. More theoretical details of this test statistics can be found in[22] and[20]

The Kaiser-Meyer-Olkin measure (KMO) compares the value of the partial correlation coefficients against the total correlation coefficients. If two indicators share a common factor with other indicators, their partial correlation (a_{ij}) will be small, indicating the unique variance they share. The measure is defined by the formula

$$\text{KMO} = \left(\sum_{ij} r_{ij}^2\right) \Big/ \left(\sum_{ij} r_{ij}^2 + \sum_{ij} a_{ij}^2\right)$$

where, r_{ij} = simple correlation coefficient between the i[th] and j[th] indicator, a_{ij} is the partial correlation coefficient between the i[th] and j[th] indicator assuming the remaining indicators to be constant. The maximum value of KMO measure is 1. A value between 0.90 to 1.00 is considered as 'marvelous', between 0.80 to 0.89 is considered as 'meritorious', between 0.70 to 0.79 is considered as 'middling', between 0.60 to 0.69 is 'mediocre', between 0.50 to 0.59 is 'miserable' and anything less than 0.49 is treated as 'non factoring'. [13] and [20] give more details about this measure.

Principal component and factor analysis: Next we describe the methodology related to principal component analysis (PCA). From an initial set of correlated indices, PCA creates uncorrelated indices or components, where, each component is a linear weighted combination of the initial indices. For example, from a set of indices I_1 through I_{22} of the Avahan data, the method readily identifies 'm' indices viz., PC_1, PC_2,…, PC_m, which are linear combinations of I_1 to I_{22}.

Here we can fix the value of '*m*' as any integer between 1 to 22, depending on how much is the cumulative percentage of variation explained by the PC's, starting from highest to lowest. The weights (l_{ij}' *s*) of each principal component are given by the eigenvectors of the correlation matrix between the indices I_1 to I_{22}, or if the original indices were standardized, the co-variance matrix. The variance of principal component is given by the eigen value of the corresponding eigenvector of the covariance matrix. The second component PC_2 is totally uncorrelated with the first component PC_1, and explains additional but less variation than the first component. Subsequent components are uncorrelated with previous components; therefore, each component captures an additional dimension in the data, while explaining smaller and smaller proportions of the variation of the original indices. The higher the degree of correlation among the basic twenty-two original indices in the data, the fewer components required to capture common information. Thus, any application of PCA generally starts with a suitability study of that data by using certain other tests or measures. [16] provide for more theoretical as well as application details on principal component analysis.

The idea of factor analysis is to derive new indices called factors, which will help to construct a single unified index from a multidimensional data, thus giving better understanding of the data. The factor analysis requires a proper statistical model. It deals more with explaining the covariance structure of the indicators rather than with explaining variances. Factor analysis attempts to identify the underlying variables or factors, which explain the pattern of correlation within a set of observed variables. The main application of factor analytic techniques is to reduce the number of variables and to detect structure in their relationships. In factor analysis, each factor reveals the set of indicators having the highest association with it. The idea here is to account for the highest possible variation in the indicators set using the smallest possible number of factors. Therefore, the index no longer depends upon the actual dimensionality of the dataset but it is rather based on the "statistical" dimensions of the data.

The orthogonal factor model may be explained as follows. Let X is the observable random vector with p components has mean μ & covariance matrix Σ. The factor model postulates F_1, F_2… , F_m called common factors and p additional sources of variation ε_1, ε_2… ,ε_p called errors or specific factors. The factor analysis model is:

$$X_1 - \mu_1 = l_{11} * F_1 + \ldots + l_{1m} + \varepsilon_1$$
$$X_2 - \mu_2 = l_{21} * F_2 + \ldots + l_{2m} + \varepsilon_2$$
$$\vdots$$
$$X_p - \mu_p = l_{p1} * F_p + \ldots + l_{pm} + \varepsilon_p$$

l_{ij} = loading of the i^{th} variable on the j^{th} factor. In matrix notation, we may write

$$X_{(p \times 1)} - \mu = L_{(p \times m)} * F_{(m \times 1)} + \varepsilon_{(p \times 1)}$$

Here F and ε are such that (i) F and ε are independent, (ii) E(F) = 0, Cov (F) = I and (iii) E(ε) = 0, Cov (ε) = ψ, where ψ is a diagonal matrix.

While carrying out factor analysis, it is generally assumed that,

(a) The correlation matrix should not be an identity matrix i.e. there should be a dependency structure between the indicators.(usually tested by Bartlett's test of sphericity)

(b) The variables used in factor analysis should be linearly related to each other, i.e., one indicator can be expressed in terms of the remaining indicators. (tested by KMO statistics)

Here, the factors have been obtained using the principal component analysis method. Under this approach, the highest possible variation in the indicators set using the smallest possible numbers of factors are generally extracted out. Each factor reveals the set of indicators having the highest association with it.

An orthogonal transformation of the factor loadings, as well as the implied orthogonal transformation of the factors, is called factor rotation. There are various types of factor rotation available in the literature. Here we use the Varimax Rotation developed by Kaiser in 1960. With this rotation, each factor tends to load high on a smaller number of variables and low on other variables. The varimax rotation is used to minimize the number of indicators that have a high loading on the same factor. We refer to [16] for more details on this aspect.

Adaptive CBG Scores: The proposed adaptive composite index uses the factor scores obtained from the factor analysis and the percentage of variation explained by each factor. The adaptive composite index for the jth CBG is defined as:

$$I_j = \sum_k S_{jk} f_{jk},$$

where, f_{jk} = factor scores that are estimated values of the common factors and S_{jk} is the percentage of variability explained by the k-th factor F_k. The value of the index I_j can be positive or negative. Hence for comparison purpose, standardize them to a 0 to 100 scale as follows:

$$C_{Ij} = \frac{(I_j - I_{\min})}{(I_{\max} - I_{\min})}$$

The adaptive CBG scores have been obtained using the composite index quoted above. These scores will be relative to the minimum and maximum of the data.

Agreement of indices: Cohen's Kappa statistic has been used to check the agreement between the newly proposed adaptive composite index and the COPI. Kappa measures the percentage of data values in the main diagonal of the table and then adjusts these values for the amount of agreement that could be expected due to chance alone. Cohen's kappa measures the agreement between two raters who each classify N items into C mutually exclusive categories. The formula for Cohen's Kappa statistic is given by

$$K = \frac{[\Pr(a) - \Pr(e)]}{[1 - \Pr(e)]}$$

where, Pr(a) is the relative observed agreement among both the methods and Pr(e) is the hypothetical probability of chance agreement. A kappa value less than 0.20 is considered as a poor agreement. Between 0.20 to 0.40 is 'fair', between 0.40 to 0.60 is 'moderate', between 0.60 to 0.80 is 'good' and between 0.80 to 1 is 'very good' agreement. For more details on Cohen's Kappa statistics, we refer to the original paper of [21]

RESULTS AND DISCUSSION

For the Avahan data corresponding to year 2009, the Bartlett's statistic and the KMO measure turned out to be 825.318 and 0.706 respectively. With 231 degrees of freedom, the Bartlett's statistic 825.318 can be found to be highly significant and thus we reject the hypothesis of identity correlation matrix. That is, since the p-value = 0, which is less than 0.05, we conclude that the Bartlett's test reject the null hypothesis at 5% level of significance, that is, the correlation between the indicators is highly significant and hence they share common factors. This can also be verified from the correlation matrix. The KMO measure 0.706 comes under 'middling' category. Hence from both Bartlett's test and Kaiser– Meyer–Olkin (KMO) measure, it is clear that, this set up is ideal for performing a factor analysis on the indicators at hand. Therefore, for the subsequent years, we adopted the same procedures.

We have selected the factors, so as to contribute minimum 75 per cent of the variation in the data. It

was found that for each year, eight factors explained minimum 75 per cent variation of the data. Table 1 describes the percentage and cumulative percentage of variation for all the years 2009-2012. Note that a factor can be expressed in terms of the factor loadings corresponding to different indicators.

Table 1: Percentage of variation by leading factors: 2009-2012

Factors	Cumulative per cent variation (2009)	Cumulative per cent variation (2010)	Cumulative per cent variation (2011)	Cumulative per cent variation (2012)
F1	12.3	13.3	13.5	15.2
F2	24.2	25.2	25.2	26.7
F3	34.6	36.2	35.6	37.9
F4	44.5	45.8	45.4	48.7
F5	52.8	54.2	54.0	56.9
F6	61.0	62.6	62.2	64.9
F7	68.5	70.7	69.2	72.7
F8	75.8	77.9	76.0	79.4

The factor analysis is useful in identifying which indicators play a major role in explaining variation in the data. It turns out that indicator I1 (Strategic needs of community served), I19 (Legal and financial risk minimization) and I20 (Financial and administrative systems) played a significant role in all the four years. Also, indicator I2 (Need for collective action internalized), I4 (Solidarity during crisis), I9 (Defined system for decision making), I11 (Crisis and advocacy committees), I13 (Quantum of resources mobilized) and I15 (Increase in outreach) play an important role in three years out of 4. These indicators are significant in explaining approximately 31-35% variation of the data (35%, 34%, 31% and 34% for 2009, 2010, 2011 and 2012 respectively). Structure of the system is so complicated that, it seems if one chooses only few variables, it is not possible to explain significant variation of the data, which further means that it is difficult to conduct such a study with less number of indicators.

Adaptive composite CBG scores: In Table 2 (given in Appendix), we present the adaptive CBG scores CI_j for the year 2009 along with COPI. Similar scores have been obtained for other years too, however, they have not reported here. CBG names have been replaced herewith serial numbers, for not revealing the identity. From Table 2, it can be observed that the ranks of 21 CBG's are identical by the two methods. For the other CBG's the difference in ranks appears to be negligible. Thus, the newly suggested adaptive composite index matches with the COPI suggested in TN. For transition readiness, we have considered only two classes, viz., promising and foundation, as most of the other classes were not representative in 2009. The new index classified 14 CBG's as Promising and 22 CBG's as Foundation on the Transition Readiness Scale. The computation of the Cohen's Kappa statistic for Avahan data is as follows.

Table 2: Contingency table of two indices

		COPI		
		Promising	**Foundation**	**Total**
CI_j	Promising	11	3	14
	Foundation	0	22	22
	Total	11	25	36

From Table 3, it may be observed that 11 CBG's are classified as promising and 22 CBG's as foundation by both COPI and the suggested adaptive composite index. Thus, the observed percentage agreement is Pr(a) = (11 + 22)/36 = 0.11. To calculate Pr(*e*), we note that the COPI classifies 11 CBG's as "Promising" and 25 CBG's as "Foundation". Therefore, the percentage of promising is (11/36) *100 = 30.55%. Also, the percentage of foundation = (25/36)*100 = 69.44%. By the proposed adaptive composite index, we have classified 14 CBG's as "Promising" and 22 CBG's as "Foundation". Therefore percentage of promising = (14/36) *100 = 38.88% and percentage of foundation = (22/36)*100 = 61.11%. Therefore, the probability that both the methods would say "Promising" randomly is 0.3055*0.3888 = 0.1187 and the probability that both of them would say "Foundation" is 0.6944*0.6111 = 0.4243. Thus, the overall probability of random agreement is Pr(*e*) = 0.1187 + 0.4243 = 0.543. Hence the Kappa statistics is

$$K = \frac{[\Pr(a) - \Pr(e)]}{[1 - \Pr(e)]}$$

$$= [0.91 - 0.543]/[1 - 0.543]$$

$$= 0.803$$

This Kappa value 0.803 indicates a very good agreement between the scores obtained using COPI and the suggested adaptive index.

The proposed adaptive composite index has been computed for the years 2010-2012 for all the CBGs in the sample. However, for an year-wise comparison, we report only the adaptive composite index for the cohort group. (Table 3).

Improvement in performances between 2009 and 2012: To study the improvement in performance from the year 2009 to 2012, the indicator scores were considered. For each CBG, difference between indicator scores were computed, i.e.,

Table 3: Adaptive scores of cohort group of CBGs for 2010-2012

CBG	2010	2011	2012
1	61.67	57.94	57.55
2	59.45	27.96	86.81
3	46.02	72.36	95.03
4	47.20	69.85	69.56
5	31.23	57.72	33.51
6	78.10	95.03	31.04
7	11.37	47.03	57.60
8	21.30	39.76	73.31
9	75.57	52.70	100.00
10	37.80	68.39	69.40
11	65.92	65.22	0.00
12	23.07	69.34	41.12
13	16.31	61.84	66.98
14	50.19	44.58	80.23
15	100.00	21.97	38.68
16	0.00	88.51	56.62
17	40.41	43.47	34.02
18	9.95	22.40	52.15
19	49.74	24.22	81.72
20	43.42	23.30	46.61
21	53.06	0.00	97.05

This serves as a measure of improvement in performance. There are only 21 CBG's which are common in years 2009 and 2012. Since for each indicator, number of observations (CBGs) are only 21, t-tests were used, to examine whether the improvement is significant or not, i.e., where, . The t-test can be applied when data comes from normal distribution. Therefore the normality of improvement scores for each indicator is examined first. The test of normality was accepted for all indicators, except for indicator 6 and therefore, the t-test was used for each indicator except indicator 6. For indicator 6, Wilcoxon signed rank test have been (which is a non-parametric equivalent of t-test). It turns out that for the indicators I5 (Strength in community mobilization), I6 (Participatory selection process for the leadership), I7 (Leadership accountability to community) and I11 (Crisis and advocacy committees) the null hypothesis is not rejected i.e., for these indicators, there has not been any significant change in their scores from 2009 to 2012. For all other indicators, the improvement is found to be significant. This clearly indicates the effectiveness of the program over the period of evaluation.

CONCLUSION

In this paper, an adaptive composite index is suggested for measuring the transition readiness of the CBGs, based on statistical techniques such as PCA and factor analysis. Using factor analysis we have traced the indicators which explain the variations in the CBG scores. This study clearly indicates that it is possible to design an adaptive index to assess the complex components of community mobilization, incorporating the community's own perspective on the relative importance of various components.

In the case of COPI, the design team arrived at these eight parameters through consultations with community leaders across five districts, followed by consultations with primary user [23] and other community mobilization experts. The adaptive index suggested in this paper using statistical modeling explains that all eight parameters, on its own, are significant to any inference on transition-readiness of a CBG.

For most of the indicators, there was a significant improvement over the period of evaluation. This clearly indicates the effectiveness of the program over the period of evaluation.

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New Product Development and Innovation for Sustainable Profitable Businesses of Indian Small and Medium Scale Industries (SMEs) and Startups

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ABSTRACT

While current products of a firm continue to be top priority for business, the importance of new products increases over time and they may have to replace current products. Every firm has own way to sustain current products and make efforts to develop new product in order to show their strong presence in the market and stay ahead of competition. To augment new products, firm has to continue work on new product development and innovation. The critical success factors triggering innovation and new product development are - customer inputs, market feedback, changes in customer or consumer patterns, environmental changes, regulations, direct & indirect competition, product and process quality, things gone right, things gone wrong and supplier end developments. Firms have to nurture new ideas generated from these triggers, systematically, to fulfill their objectives. Firms have, to identify touch points and, to deploy mechanisms to collect ideas, feedback & suggestions. The significant contribution to Indian economy is done by small & medium scale industries and startups. Therefore, a study is undertaken to understand the current process of new product development and innovation in Indian SMEs and startups, to find out gaps to identify triggers and define a framework, which will give future insights to firms in Indian context.

Keywords: *Framework, Innovation, Indian SMEs, New Product Development, Profitability*

INTRODUCTION

In the current Indian scenario, in most of the industries, firms are developing new mechanisms to deliver new products. Some of these products are approaching end of product life cycle. As per the Boston Consulting Model, it is important to have product mix, to prepare to take on the competition, to show the strong presence in the market, to reap the benefits due to strong hold in the market and to discontinue some products, which have become obsolete. While businesses are focusing on sustaining the growth through current products, new products are required to continue and stay ahead of the competition.

The example from the automobile industry explains the necessity of new product development process. Ambassador car was most trusted vehicle in India. Government agencies were using Ambassador cars, as a safe vehicle, starting from Prime Minister of India, because of the brand image. However, the company had to close their operations since they are not able to sustain themselves in growing competition in Automobile Industry.

The other example is Kodak[1]

- There was a time when Kodak labs were at every corner
- People used to stand in queue at kiosk to get the photographs developed
- This resulted the trigger to preserve digital memories, editable & printable
- Kodak could not move ahead and think ahead to keep the market

Why this is happening? Because there is no robust process of new product development, organizations cannot cope up with the demands of the customers in the market. There is a need of running new product development program by each firm in parallel to conducting day-to-day business. Each firm can adapt it in order to meet specific company resources and needs[2].

PURPOSE OF REASEARCH

There has to be a framework to follow for each & every business to capture the correct feedback. This effort is to find out and identify touch points, which gives the essence of the feedback, to deploy correct mechanism collecting vital information for the business. The framework defined during this study, will further give the clarity on running new product development and innovation process. Firms have to keep on hunting new avenues of product development during business process. This will provide them future insights to grow the business and stay ahead in the competition.

LITERATURE REVIEW

Many times, companies copy & partially cover product concepts and solutions. Managers always plan and avoid unsuccessful products. New products are outcome of systematic planning or sometimes by chaotic means. Strategic activities of big organizations are by – stimulated or autonomic. Stimulated behaviors are in accordance with traditional concept of strategy. Through different administrative mechanisms, top management can influence operatives and middle management and in accordance with current strategy of organization. Line mangers believe that possibilities in the market are different from the current strategies. The leading products show the current strategy of the organisations[3].

New Product Development: All the concepts, captured through future insights, to be expanded in the product definition and final plan for the product development to be laid.

New product Development and Innovation is a systematic process, by which new products are conceived/developed/tested/validated and launched in the market place.

During the development process, going back to the customer or consumer and asking for their approval becomes important. This is to capture if there is any change happened in customer preferences. New product development is multidisciplinary process[4]. To compete with the large players, small and medium sized enterprises (SMEs) often try to assert themselves through new product developments[5].

To provide the guide path for new product development, triggering innovation in small businesses in Indian industry, current market condition study is more important.

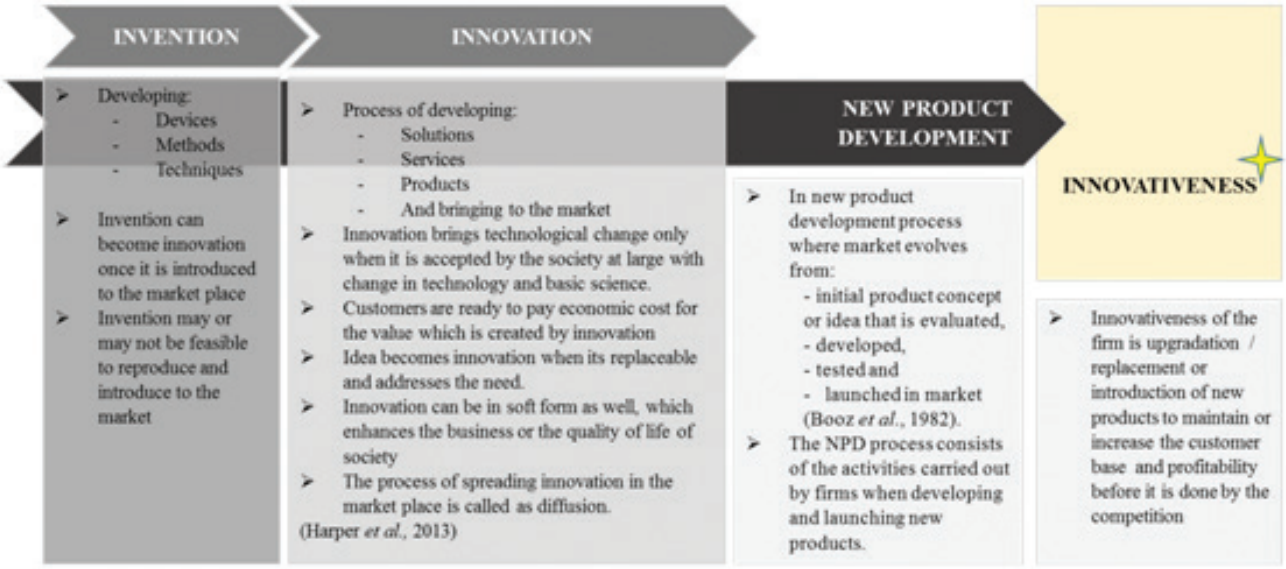


Fig. 1: Innovation, Invention, Innovativeness, and New Product Development – Definitions analysis

Innovation is often a driving force behind the long-term success of certain businesses and other organizations. Innovation allows an organization to introduce or use something new, such as new products, services, or manufacturing processes.

McAdam and Mcconvery observed that, in small and medium enterprises, deficiencies in innovation lead to difficulties to grow and export, which leaves them out of successful production chains[6]. Harper et al., shown the importance of understanding the innovation

by researchers that which are those innovations which are easily adopted by the customers[7]. Oliveira and Carlos Kaminski says innovation results from pressure, necessity or even adversity[8].

In this study, touch points are defined and broadly described in the next section. The literature here gives how they are individually important as innovation input factors.

Benchmarking competition - As competitors' strategies and customers' preferences change over time in a competitive environment, firms must be able to acquire knowledge about those changes and then adopt their efforts to respond to those changes by developing more products and deliver those products in a timelier manner[9]. Lack of qualified competitors is one of the reason concerning to strategic management of technological innovation. Salavou et al, studied 150 SMEs in Greece and concluded that the companies, which are with market orientation and continues learning, when facing competition, tend to become more innovative[10].

Customer Inputs – Customers play important role in both manufacturing and service organisations[11].

In-house process enhancement - Lucas Jr and Goh, have discussed employees in organisation who have dynamic core capabilities and others for who core capabilities have become core rigidities[12]. Core capabilities are firm's internal abilities to integrate, build internal capabilities to address rapidly changing environments[13]. Managers have to develop a strategy that emphasizes the response to a disruptive technology, and they must communicate this strategy throughout the firm[14]. When confronted with a rare, discontinuous change from technology, senior management in a firm faces the daunting task of changing the organisation to embrace the new technology. Change depends on convincing management ranks that the threat is serious; after a long period of success, core competencies become core rigidities, making change that much more difficult[12]. In 3M, employees can spend their 15% of time in pursuing ideas of their own choice. They are free to look for in expected breakthrough innovations that have potential to expand the pie. 3M targeted thirty percent of yearly revenues from new products launched in last 4 years[10].

Changes in customer / consumer patterns – In recent times, due rapid changes in business environment, there is change in customer/consumer patterns. Information technology such as data mining techniques helps to tap these patterns. Hung and Kui studied and found if such knowledge is not used, marketing managers may use outdated strategies for their products or services[10].

Supplier end developments - Calderini and Cantamessa, in their study concluded there are evidences that the essence of the innovation process in small and medium enterprises, at the stage of product design & development will depend on their ability to be flexible in their integration, both with customers and suppliers or partners[12]. Integration of suppliers may result in reduced costs, improved costs and quality, reduced product development time and better access to application technology[11].

Quality – Cameron (1994) argued that there are four building block of quality – continuous improvement, systematic perspective, and teamwork and customer orientation. The potential customer involvement conceptualized in creating competitive quality[13].

Small and Medium Enterprises: In India, as per the Micro, Small and Medium Enterprises Development Act of 2006, micro, small and medium enterprises, classified in two classes: manufacturing enterprises and service enterprises. The enterprises, engaged in the manufacturing or in the production of goods, defined in terms of investment in plant and machinery.

Small & Medium scale Enterprise (SME) definition - based on turnover/size/man-power/fixed investment/sales volume/worth of assets. Classification - Manufacturing and service enterprises:

- Small Scale Industry - Plant and machinery value from 25L to 5Cr;
- Medium Scale Industry - P&M from 5Cr to 10Cr

Narayanan found that formal structures and decentralization affects negatively on the innovation. Schumpeter's two phase innovation theory - Both formality and informality are important for manufacturing SMEs[19]. For entrepreneurial innovation SME to be informal, while as for managed innovation it can be formal to bring in cost effectiveness and increase efficiency.

Research Objective: Based on this study, a framework of new product development and innovation will be devised in the context of Indian small-scale industries. This will provide way forward / guide path for such businesses and startups. It will provide an idea, as to what is to be followed by such industries, to stay up-to-date and develop products to sustain the business.

RESEARCH DESIGN & METHODOLOGY

The research framework will attempt to answer the questions, which are arisen in our mind. The attempt is to understand the existing practice of SMEs and go from the idea generation up to the market. This will systematically provide us the gaps. Firm has to work on all aspects and broad level feasibility is to be done based, on which a call is to be taken to move forward.

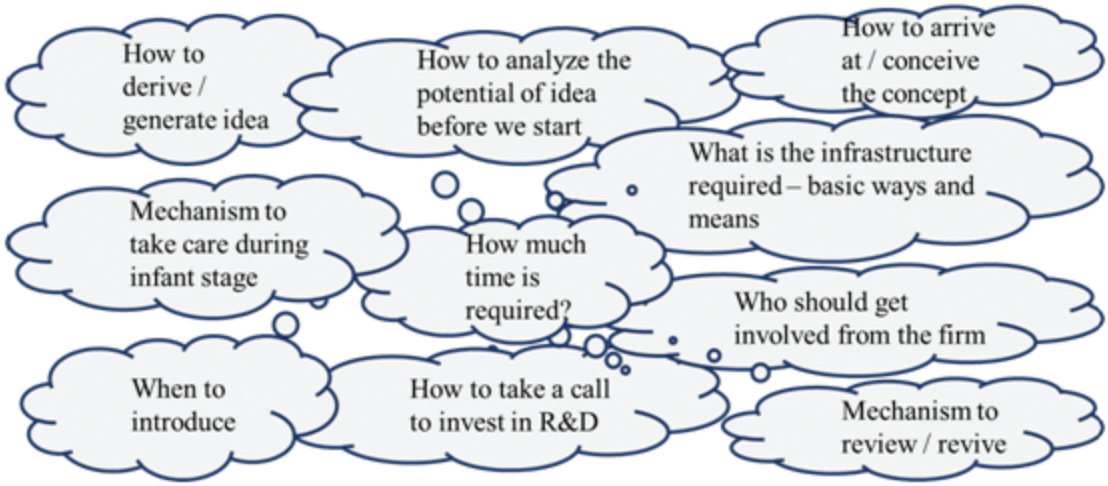


Fig. 2: Questions arisen

Future insights: Every organization should be ready with their minimum five-year plan, in terms of new product development. This includes short term and long-term plan to deliver products. There are ways of innovating new products.

These are critical success factors, which triggers new product development. There is a need to keep a log of these events.

These are considered as constructs for the study and while defining a framework.

These parameters are described in two sections, customer & competition side and product side as below:

Customer & Competition Side:

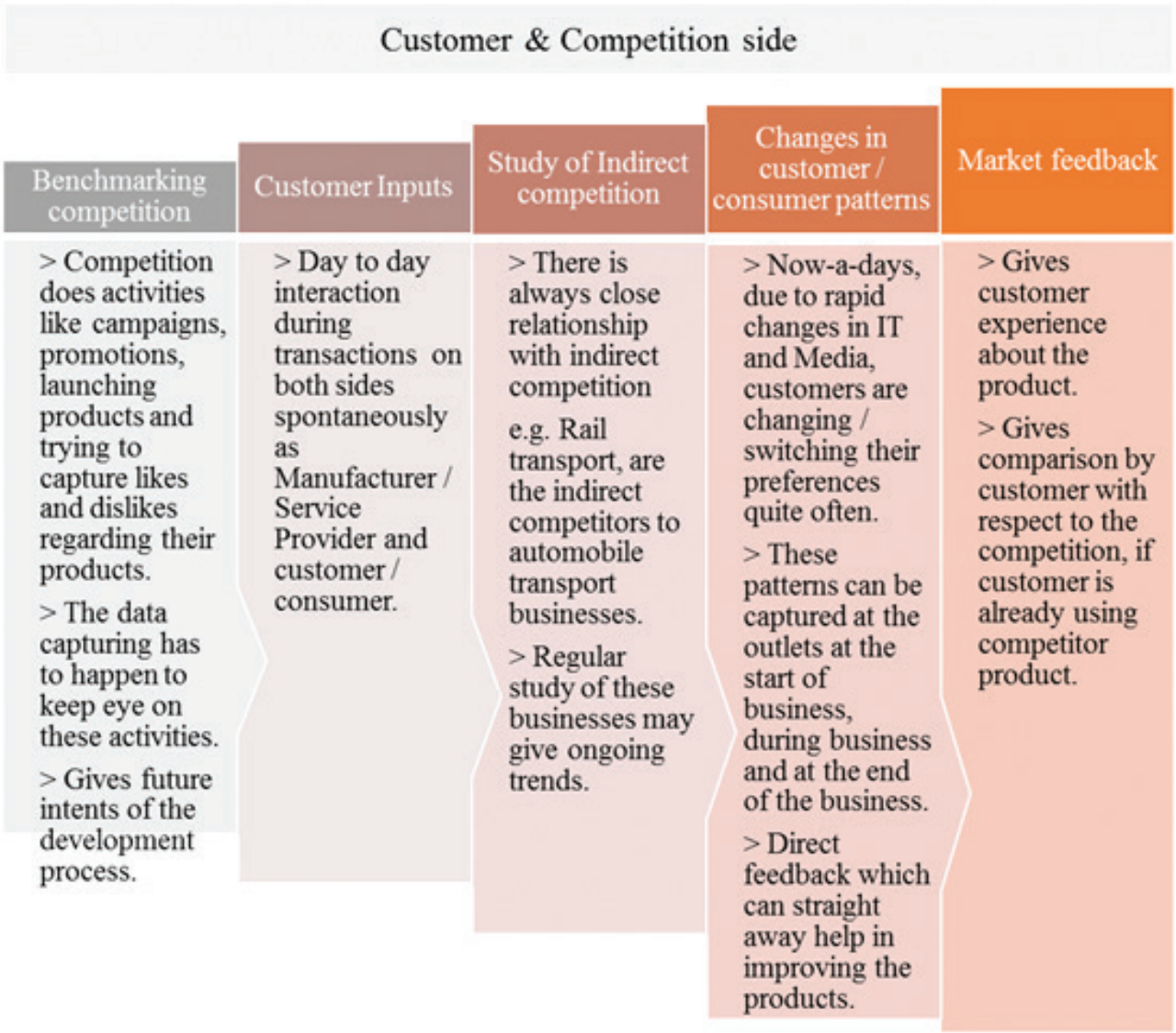
1. **Benchmarking competition:** There are competitors for every business. They are doing activities like campaigns, promotions, launching products and trying to capture likes and dislikes regarding their products. The data capturing has to happen to keep eye on these activities. This tool gives lot of future intents of the development process.
2. **Customer inputs:** During day-to-day transactions with number of customers, businesses are doing interactions. These interactions are done from both sides spontaneously as Manufacturer/Service Provider and customer/consumer.
3. **Indirect competition:** There is always close relationship with indirect competition. For example, shipping, rail transport, are the indirect competitors to automobile transport businesses. Regular study of these businesses may give ongoing trends.
4. **Changes in customer/consumer pattern:** Now-a-days, due to rapid changes in IT and Media, customers are changing / switching their preferences quite often. These patterns can be captured at the outlets at the start of business, during business and at the end of the business. This is the most important and direct feedback which can straight away help in improving the products.
5. **Market feedback:** After sales feedback given by the customers, provide customer experience about the product. This gives comparison by customer

with respect to the competition, if customer is already using competitor product.

Product Side:

6. **Environmental changes:** Changes due to demographic, economic, political scenarios in the market place, may give impact on the products. This is to be studied and monitored for future product development.
7. **Upcoming regulations:** Changes in regulations and new norms by regulatory authorities in the area of business may demand changes in the direct product.
8. **Supplier end developments:** The suppliers to business such as raw material suppliers, semi-finished goods suppliers can also trigger new product development.
9. **Quality:** Customers are expecting the quality in their products as hygiene factor. They cannot compromise on quality aspects of the product. To maintain quality, new ways in design, process and handling is required to be implemented.
10. **In-house process enhancement:** Brainstorming by employees in the organization: It is important to have this communication in structured manner to get the intent of the Employees/customer/ Market & competition. The firm should be able to understand difference between dynamic capabilities, core rigidities and managerial propensities.

Firm has to work on all aspects and they have to do broad level feasibility. Based on which, a call is to be taken to move forward.



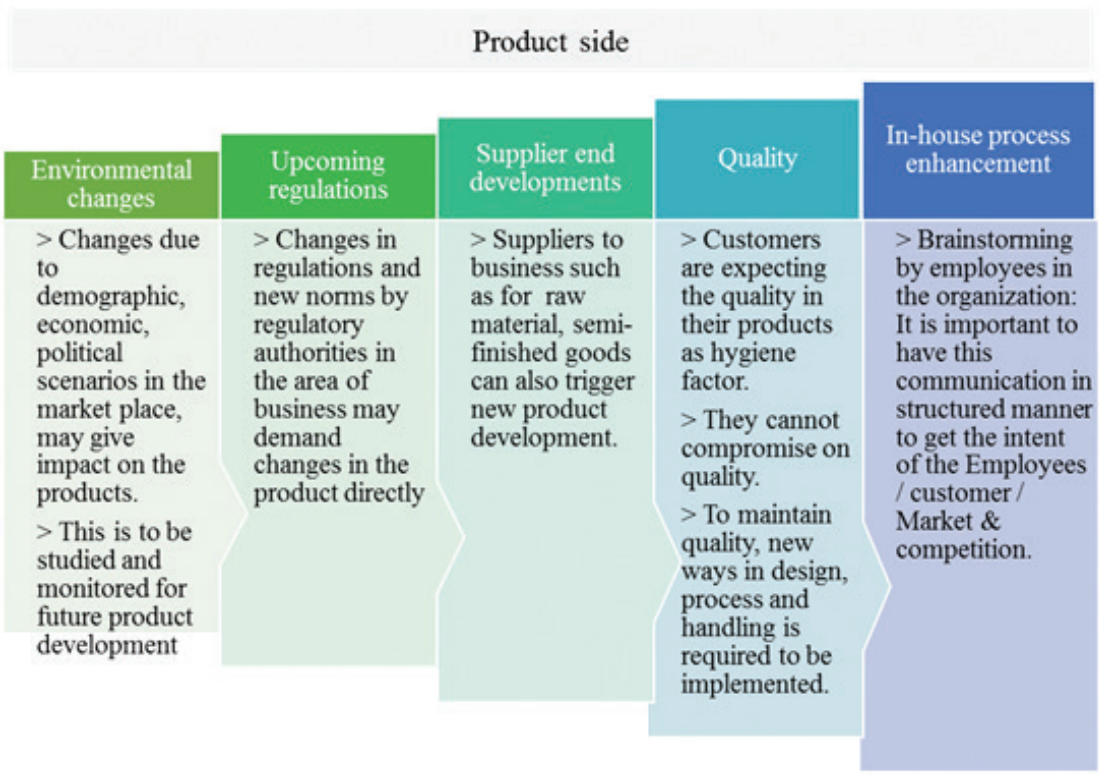


Fig. 3: Future Insights

It is planned to take up study in SMEs in selected areas, to understand the current process of new product development and identify the gaps.

Conceptual framework: The research method is defined with a conceptual framework to understand the study at a glance. The framework will be further fine-tuned with time during the research study.

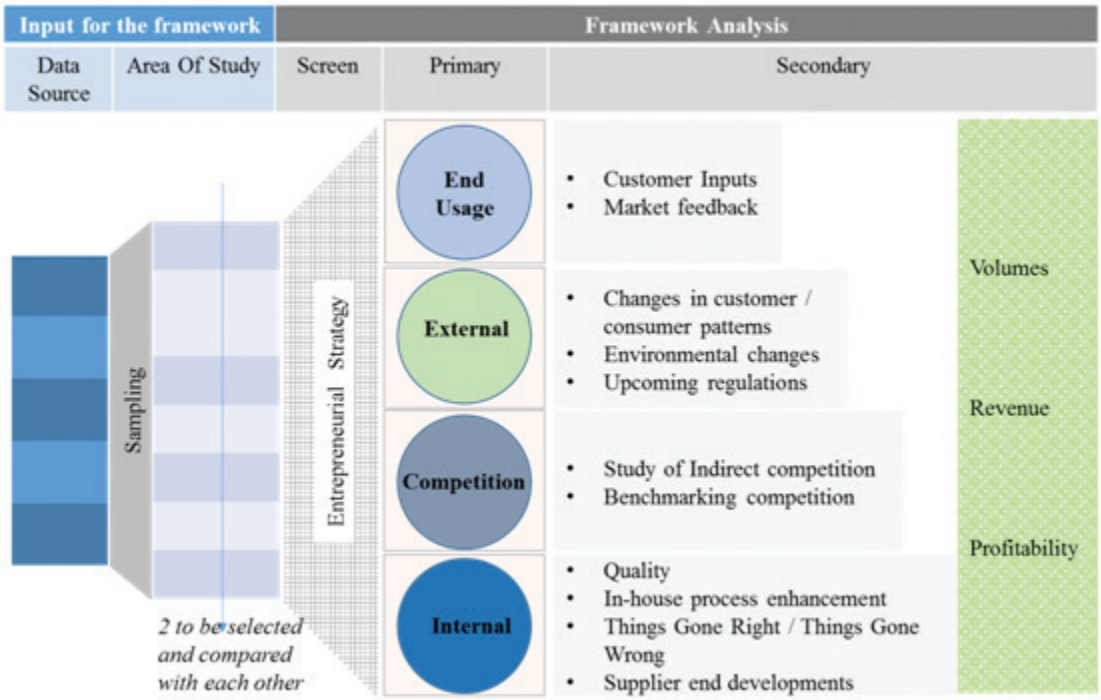


Fig. 4: Conceptual Framework

The research is to be conducted in Indian context taking samples from SMEs in selected areas. This will provide the cut section of Indian industry to understand and analyze the current scenario. Samples are to be selected for above said areas and detailed study to be conducted to understand the current process being followed by them.

The SMEs will be identified by using secondary data from sources based on the criteria as per SME guidelines. The selected enterprise will be contacted. The data collection method used by Eric, et al., is interview of project leader and written surveys from other departments. Similar approach planned for this study[20]. The data collections will be done by conducting interview of senior management to understand the environmental changes and future strategies while as questionnaires will be used to collect data from all other respective departments of the firms.

Secondary parameters as explained in the conceptual framework analysis will be further expanded to design the questionnaire. Calder et al,, Estman et al, studied to explore the relationships between the proposed constructs in the SME in emerging economy context and not to provide point and interval estimates of population parameters[21,22]. This study will also try to find out the relationships between the constructs as defined to build framework.

CONCLUSION

This paper explores the ways and means to find out the triggers of new product development and innovation concerning SMEs in Indian context. Customer & competition side and product side are two areas, which give origin of these triggers. The study planned is further supported with the help of conceptual framework and its outcome. Primary and secondary framework analysis firms up the origin of triggers. The gaps identified are further magnified to reach to the right solution to the customer and market demands. Product line strategy and future market opportunities are based on the success factors described in this study. Capturing the right kind of triggers give the spur to the new development and innovation and contributes to the profitability of SMEs and sustainability in the market place. The conceptual framework provides an idea, as to what is to be followed by firms, to stay up-to-date and develop products to sustain the business.

NOVELTY/ORIGINALITY

The literature review shows that the work has happened on the firm growth, development time but no work found on this area of research in Indian context. This study will be unique which will focus on parameters of new product development & innovation how SMEs can increase profitability with new product development and innovation and further sustain their businesses.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Is Digital Stress a Matter of Concern in Academic Productivity?

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ABSTRACT

In today's competitive and dynamically changing world, an individual's contribution and productivity in his/her profession is affected by various types of anxieties and stresses. One of these stresses arises from the use of digital technologies and communication at workplace. The significance of health and happiness is not just relevant for individuals but also for organizations. It is seen that group cooperation and participation is facilitated by increase in positive emotions[1]. Thus, job related stress can result in undesirable consequences for the organization and the individual since it can potentially lower motivation levels and preempt job turnover[2]. Similarly, academicians, who are vital stakeholders in the education system, and use digital technologies, can be subjected to its adverse consequences. Thus this research focuses on academicians and their use of digital technologies. This paper examines whether use of digital technologies and communications at the workplace can lead to stress among the academicians; and its effect on their productivity.

Keywords: *Happiness, Mental well-being, Productivity, E-stress*

INTRODUCTION

The advancement intechnology, globalization of economies and rate of new institutional products and processes, have triggered significant changes and increased stakes. The shifts in the nature of institutionsis expected to result in more stressful environments at work. This can potentially manifest in multiple forms. Information and communication technology (ICT) is now an integral part ofeveryday lives. The ever-increasing use of internet throughout the world from all age groups is proof of this. People have access to and are connected withavariety of online content and communication[3]. Several studies show benefitsof online communication and use of interactive media towards psychological healthandwell-being. Acquisition of online social capital[4] and satisfaction of intrinsic needs[5] are some of them. However, the very ways that lead enhanced productivity may also lead to undesirable effects of information overload and in extreme cases, could damage psychologicalwell-being.

Stress is, today, normally occurring part of life and job. In today's competitive and dynamically changing world, an individual's contribution and productivity in his/her profession is affected by various types of anxieties and stresses. One of these stresses arises from the use of digital technologies and communication at workplace. The significance of health and happiness is not just relevant for individuals but also for organizations. It is seen that group cooperation and participation is facilitated by increase in positive emotions[1]. Job stress refers to situations wherein factors related to job interact with an individual tothe psychological and/or physiological condition such that the person is forced to deviate from normal performance[6]. Thus, job related stress can result in undesirable consequences for the organization and the individual, as it can lead to lower motivation levels and or raise the intentions to quit[2]. Various types of pressures have been identified as "psychosocial stressors". These can raise the risk of some physical and psychological problems like high blood pressure, anxiety, depression, heart disease, burnout, absence, fatigue, accidents, substance misuse, physical disorders, work-family conflict and others[7]. These are undesirable outcomes for employers and can result in lower productivity, lower morale, higher turnover, absenteeism, conflicts and lower participation.

Similarly, academicians, critical stakeholders in the education system, who are usersof digital technologies, are not spared from its adverse consequences. Overuse

of these technologies can disrupt schedules and lead to working longer hours. Moreover, social pressures can lead to negative physical and psychological effects on health in the form of stress. To study this in further detail, this research focuses on academicians and their use of digital technologies.

Happiness and mental wellbeing have become crucial in such a stressful environment. Humanity has been striving to attain happiness since ages, and in several different ways. The Buddha and Aristotle were among the early happiness philosophers. It is widely accepted that happiness is derived more from spiritual enlightenment and less from material gains and from giving rather than getting. Happiness is subjective and the final judge is the "person who lives inside one's skin"[8]. Ancient philosophers believed that happiness was god's gift and could not be achievedorattained. As thought progressed, this gave way to the proposition that happiness was less a god's gift than a self-evident truth. Many thinkers believed that it could be attained. If one was not happy, it was considered imperative to alter one's behavior through beliefs, customs and living conditions. Happiness is popularly considered to be about feeling "good" - it is about vacations and a leisurely materialistic life. It is deeper than intense pleasure, which is a shallow concept.

Michael Fordyce's research in early 1980's, conducted empirical researchto increase happiness with his 14 "fundamentals for happiness." This was probably psychology's first understanding of volitional activity on happiness. He reported the importance of social relationships and their maintenance apart from positive thinking and occupancy with variety of jobs that would lead to enhanced feeling of happiness.

In the current study, we explore the various effects of digital stress and the ways to overcome it byfocusing on emotional intelligence and emotional vitality in order to bring in happiness in the lives of academicians and hence improve their productivity.

CONCEPTUAL AND THEORETICAL FRAMEWORK

Digital Stress: The stress as been defined by scholars is associated with one's psychological well-being. It's "a state of psychological and physiological imbalance resulting from the disparity between situational demand and the individual's ability and motivation to meet those needs" There have been many causes for stress, one of which is Occupational demands that is a kind of institutionalstress which gives birth to digital stress in today's dynamic environment, and this in turn is also a part of personal life stress that leaves one in deprived state of life. The happiness and productivity of an individual are affected due to this new emerging stressful life.

Stress mayarise from one's social network of numerous friends, feeling jealous of their well-projected lives, the demands of replying to the text messages, the addictive allure of pictures of amazing crafts on pintrest, to keep up with the status updates on twitter and the 'fear of missing out' on activities in the lives of friends, colleagues, bosses, family, relatives, even socialites and politicians.

To understand the digital stress, aterm technostress needs to be understood. This widely recognized term was first coined by clinical pscychologist Dr.Craig. The term is being defined as "modern disease of adaptation caused by an inability to cope with new computer technologies in a healthy manner. It manifests itself in two distinct but related ways: in the struggles to accept computer technology, and in the more specialized form over identification with computer technology" and as a "state of arousal observed in certain employees who are mostly dependent on computers in their work"[9]. We are trying to socialize by an unfeeling entity that isin turnsuppressing the feelings and emotions while shaping human minds: thecomputer.

Anxiety and negative impacts on attitudes and behaviors are observed under technicalstress, where a person is hasto handle technology[10]. Researchers[11] suggest that technostress could be a problem of adaptation when a person reduces his inability to cope with information and communication technologies (ICT). They also identifies the originators, or the five components of technicalstress. They are:

1. Overload due to technology: where computer users are forced to work faster and longer.
2. Invasion due to technology: where technology users feel that they can be reached anytimewhich can lead to reduced distinction between professional and personal contexts.
3. Complexity due to technology: where technology users feel a lack of skills in face of complexity

of advancement. Consequently, they are forced to spend time and efforts to gain additional skills and knowledge of the Information and Technology.

4. Insecurity due to technological advancement: where technology users fear that they a job loss or being replaced with persons having better competencies.
5. Uncertainty due to technology: where the technology user isuncertain and unsettled due to the continuously changing technology and upgradation of skills which it may require.

In psychological research, variables that drive the stressful experience have been well researched[12]. As observed in the transactional theory of stress[13-14], stress reactions are due to interaction of personaland environmental variables. Stress is "an unfavorable person environmentrelationship"[12] Stress is felt when thesituation demandsexceed the capabilities of the individual. It is suggested that cognitive appraisal is a mediator between stress reactions and environmental demands. This refers to the process where individuals "constantly evaluatethe significance of what is happening for their personal wellbeing"[12]. This study suggests that perceived stress can pose a crucial risk for undesirable psychological health outcomes. Stress is strongly and consistently associated with burnout, in a meta-analysis[15]. Stress has also been linked to a state of depression andanxiety at work and in social environments.

Psychological well being: Managing stress effectively and pursuing a purpose in life are the two activities most closely-associated with mental well-being. Socializing with friends and family, learning new things, getting enough sleep, reading, and eating a healthy diet, are also consistently linked to mental well-being. Psychological well-being denotes a state of mental health, joy, happiness, personal satisfaction and quality of life. Although mental health is a crucial component of well-being, psychological well-being is also determined by other variables that may not be related to mental health directly. In recent times, positive mental health and well-being haveare considered important predictors of overall health and longevity. This implies 'feeling good' and 'functioning well' includesoptimism, happiness, self-esteem, resilience, good relationships with others. There are many effects of ill mental health that are related one's physical health and economic status that may lead to more stress as it costs you time and money apart from relationships. Some researchers suggest that the economic benefits of promoting positive mental health are many. Mental well-being now is a matter of great importance in mental health and public health policies for the government as well. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) is a measure used to monitor mental well-being in the English public health outcomes framework and the Scottish Government's Mental Health Indicators data set.

In contrast to psychological ill-being, positive psychological well-being reflects the positive components of psychological health that characterize individuals who live a quality healthy life. The concept of Well-being is a broad one which includes theoretical approaches like hedonic well-being, eudemonic well-being and social well-being[16]. Every approach focuses on different facets and has different variables. Eudemonic well-being stresses functioning and employs variables such as purpose inlife and optimism. Hedonic well-being focuses on cognitive and affective evaluations of life and employs satisfaction in life and positive feelings as the variables. Social well-being is about functioning in the social world and assesses social integration and social contribution. There could be different approaches for the description of studies of well-being, herein we look towards the aspect of the individual performance, contribution and productivity in an institution to enhance satisfaction and happiness. Therefore, happiness and mental wellbeing are evaluated in this study through an integrated approach.

Emotional Vitality: Emotional Vitality (EV) is defined as an active engagement with society, effective regulation of emotions and a sense of well-being. Emotional Vitality is completely dependent on how an individual separates mind, emotions and body. Good EV is about an up-beat attitude, such that of being happy, optimistic, peaceful, enthusiastic and joyful. Then only one can be able to deal with various problems and stress that may hamper life of a person. Then one can strengthen emotions to deal with problems. One can increase emotional endurance and stamina to be able to maintain a positive outlook for a longer period of time. The topic of emotional vitality has become increasingly popular in most institutional human resource circles – and the consensus is that work place related stress

often damages an individual's emotional vitality. The downside of the hyper connectivity is the combination of globalization and technological developments which can make employees drained out. Some employee engagement surveys suggest that people face stressful challenges can lead to ill health anderosion of emotional vitality.

The concept of vitality develops on the self-determination theory and suggests a measure of subjective vitality, defined as a positive feeling of aliveness and available energy to oneself. Vitality is diminished in situations wherean analysis of social contacts intrudes the personal zone, or an event is missed out, or a feeling of disconnection or being controlled. Few researcher focused on certain psychological factors in their theory of emotional vitality which they defined as sensinga happy life, personal mastery and low symptoms of depression and anxiety[17].

Vitality is also expressed by intent to live happilyin lifein spite ofshortcomings. Another concept of life alludes to feelings of engaging in activities and social relationships which seek pleasure and joy. This concept is developed in individuals undergoing physical rehabilitation[18-19]. Therefore, it is suggested, that emotional vitality will increase in presence of social support which can beget belongingness and increased feelings of recognition.

As social groups may have an information provision, include practical advice and could lead to boosting morale, it follows that the individual may report more vitality because of the confidence it can beget. This could trigger an increasein one's beliefs in self efficacy. Research also confirms relatedness to others or social support, can affect vitality levels. Similarly, some studies suggest that increased participation in social activities can result in a feeling of wellbeing. This is seen asrelatively higher levels of vitality. In addition, research also indicates that the methods used to cope with individual stress may also be a critical factor which leads to improving vitality.

As workplace demands increase, energy and enthusiasm are seen to reduce. These are important for vitality and corporate resilience. Over working and attending to every message on phone and computers is not a way of improving productivity. On the contrary, we lose the natural rhythm of our lives and work. This can result in disappearanceof emotional resilience. Additionally, we lose times of reflection, ideation, contemplation, and playfulness. Vitality is the realization of physical, mental and emotional vigor and is the capacity for survival of a meaningful or purposeful existence. Having good vitality means one is energetic, lively and forceful that is essential to well-being.

Have Selye pioneered stress research, where he described adoption energy as a limited resource required for resilience to stress. It fosters abilities to keep emotions under control. The capacity of depleting individual's levels of dealing with stressful life events are one of a number of circumstances of behavior that can thwart vitality. A checklist by Robert Thayess Activation-Deactivation Adjective (ADACL) measures a state of calm energy, which in contrast to tense energy reflects a feeling of vigor & positive energy. McNair & colleagues also did research on profile of mood states (POMS) that assessed a state called vigor and positive energized mood.

Ryan and Frederich, the pioneers of the concept designed a subjective vitality scale (SVS) that looks into Individual's outlook towards concern, control, confidence and curiosity for tasks that contribute to vocational development.

Some suggests 'planned happenstance' a term which he describes as an experience resulting from a willingness to view unplanned events as opportunities. Adoptability, engagement & openers to planned happenstance promote a ready stance toward an ever-changing world and using these skills allows the individual to answer & find meaning in multiple challenges across a lifetime[20].

LITERATURE REVIEW

Although it is now popular that stress is a genuine problem for all kinds of occupations, very few researches have been found to be done in India specifically for academicians. However, there is substantial body of research in the international arena. The literature review considers technical stress and coping mechanisms in various kinds of audiences.

A 2015 study, "How to Cope with Digital Stress: The Recommendations Adolescents Offer Their Peers Online," examines comment threads shared among adolescent peers to better understand how young people

advise each other when it comes to online bullying. The study recommended some coping up strategies for different experiences of socio-digital stress and the digital challenges faced by youth affecting their relationships.

Another study on theme "Digital Stress: How to cope with it?" was done to understand the concept of digital stress. To identify the causes and finding out the strategies to overcome the digital stress. Prior research findings have shown that emotionally intelligent employees are optimistic and can control organizational and work related pressure positively that has been discussed by Goleman, D (1998) in the paper "Working with EI: Why it can matter more than IQ".

Technostress is studied in detail by Brod in his book "Technostress: The human cost of the computer revolution" that identifies different types of technostresses that have to be dealt with in a lifespan.

Hence it can be observed that there has been an increase in the use and influence of digital media which can affect productivity. The study examines following questions considering the context for academicians:

- Does digital media usage lead tostress?
- Does this effect productivity of the academicians?
- Can Emotional intelligence improve their happiness and productivity?
- Can Emotional vitality and well being be managed effectively for academicians?
- Based on the question above, the study will attempt to achieve following research objectives:
- Studying the factors that can cause digital stress and exploring the possible solutions
- Developing an integrated framework to understand the relation between Emotional Intelligence, Emotional Vitality and Digital Stress to enhance productivity of academicians
- Suggesting a communication strategy to overcome digital stress and bringing happiness in the work environment

RESEARCH METHOD

To address the research objectives formulated above, our research incorporates these strands:

According to researchers, qualitative examination through narratives is best suited to study a reaction to digital stress as these reactions are subjective by nature. These qualitative methods enable a deeper understanding of the lived experiences of the respondents. Thus as per the recommendations of the previous researchers this study used in-depth semi structured focused group interviews for analyzing digital stress.

We also reviewed the available literature in order to collect currently available evidence about the digital stress factors, Emotional intelligence and vitality and its relation at workplace to analyze productivity. At times, the environment and individual coexist in a dynamic relationship, where stress as a emotional and psychological is internally represented as a vital element of this stressful transaction. This type of relationship as a Cognitive-Relational approach in which copying and appraisal are two key concepts[21.]. Cox's transactional model of work stress is closely related to the model proposed by Lazarus and colleagues having similarities at various stages and processes. But Cox's model focus largely on individual differences and occupational health and has a clear structure[22].

The major digital stressors identified are: public sharing and humiliation, Mean and harassing personal attacks, Smothering, Impersonation, Breaking and entering and Pressure to comply[23].

Emotional Intelligence is primarily a combination of four factors self-management, relationship management, self awareness and social awareness.

Emotional vitality comprises of Joyfulness, engagement, optimism and vigor.

Some Strategies to overcome digital stress that have been identified are:

- Switching off from work
- Have important conversations face to face
- Be selective with your contacts
- Don't feel presumed to have it all
- Have a digital detox

These can be studied in relation to EI and EV components to develop an integrated framework for academicians

We use multivariate regression approaches to investigate the determinants of digital stress at workplace leading to productivity loss. These analytical methods enable us to look at associations between the happiness and its determinants, such as Emotional Intelligence, Vitality, optimism of academicians.

DISCUSSION AND FINDINGS

In this study, respondent's views about their usage of messenger apps and social networking sites was asked: Researchers asked academicians frequency of using different social networking platforms, such as Watsapp (used by 85% respondents), Facebook (used by 71% respondents), LinkedIn (22%), Pinterest (21%), Twitter (18%) and Instagram (17%).

As Watsapp and Facebook were most popular, researchers asked specific questions about users' networks and usage of platform. These questions are mentioned in the below table.

Table 1: Questions to respondents

Sr. No.	Questions	Average
1.	How many friends does user have	329
2.	What is the frequency of status updates in a month	8
3.	What is the frequency of "Liking" other people's content in a month	34
4.	What is the frequency of commenting in a month	22
5.	How often they send private messages in a month	35
6.	How often they engage in group activity in a month	50
7.	How often they respond to friends in a month	30
8.	How many digital pictures they share online in a week	4
9.	How many people they email in a day	9
10.	How many emails they send and receive in a day	25
11.	From their mobile phone how many messages they text in a day	32
12.	How many pictures they share via whatsapp in a day	2
13.	With how many people they exchange message via whatsapp in a day	4

Given the major differences in stress levels based on their academic career, age, interests, job involvement and interest, researchers used regression analysis for controlling these factors. Regression analysis helps in determining the degree of association between stress and type of technology use by keeping demographic variables constant.

CONCLUSION

This study was conducted to examine the relation between happiness, productivity and digital stress considering the Emotional Intelligence and vitality of academicians. It was established that academician experience the "digital stress" due to a sense of insecurity and invasion of personal life in this rapidly changing environment. Digital stress may significantly negatively affect happiness, innovation, commitment, and productivity. This subsequently leads to unhappiness, health problems and promotes low productivity in Indian academic organizations. The research provides various recommendations provided in this research may provide an avenue for academic institutions to address digital stress. Given the fast changing technological trends and an increasingly faster-paced stressful work environment, it seems reasonable to develop effective training and wellness programs to decrease academicians stress levels and to enhance their sense of technological mastery and personal value in Indian condition. Finally, as a result of this study, the following recommendations may be made in accordance with previous studies to enhance their productivity and happiness in academics at workplace.

1. Establishment of healthy environment to ensure academicians involvement in all the academic activities.
2. Ensuring that the academician gets involved in some physical and sports activities to relieve stress from time to time.
3. Involve them in creative works with students to unleash their potential, spare time for their hobbies as recreational activity on regular basis.
4. Organize camps/ sessions which help them with digital detox and other identified stress reliving activities.
5. Establishment of time management and healthy environment to ensure the acceptance and

acknowledgement of technology as a vital aspect of academic life, treating it as an assistance and not burden as stress over health and happiness.

6. Creating the awareness of new technological developments from time to time and ensure use of these technologies through seminars, training, courses etc.

Since happiness is found to causing successful outcomes (e.g., recognition, supportive social networks, good physical health and productivity) policy-makers should make appraisal and promotion a priority. Researchers should isolate the effects of individual predictors and concentrate on well-being. Lastly, the research on happiness will advance by using statistically sophisticated and methodologically proven techniques such as analytic techniques such as multilevel modeling, experience sampling procedures and multivariate replicated single-subject repeated measures designs.

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Impact of Microbiome Studies on Human Healthcare

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ABSTRACT

Background: Although distinct microbial communities inhabit all body surfaces most of them are located in the intestine. Genome of these microorganisms collectively forms microbiome; of which gut microbiome plays a vital role in human well-being by contributing to metabolism, immune system development, and pathogen regulation. It is also influenced by age, dietary habits, socio-economic status, geographic location, genetic makeup of individuals and varied states of dysbiosis, i.e.., microbial imbalance which leads to a myriad of changes throughout the lifetime. For developing microbiome-based therapies, it is crucial to deduce the relationship between different microbes in an intestinal ecosystem.

Purpose: Advancement in the sequencing technology has made it easier to identify the bacterial population residing in an ecosystem at a given time but the evaluation of varied degree of complex interactions between different bacteria is still in its infancy. A study of such kind will provide a systematic approach for further scientific investigations.

Approach: Researchers have studied human microbiome by employing next generation sequencing platforms; findings from these studies provide the basis to formulate the network of microbial interactions; while its validation may demand experimentation.

Findings: Study focusing on diet and geography by Bhute, *et. al.*, suggests the enrichment of *Prevotella* and *Megasphaera* in Indian population - *Prevotella* is known for degrading complex plant polysaccharides and *Megasphaera*can produce short chain fatty acids. There exist a plethora of such observations on association of bacteria in healthy and dysbiosis states like IBD, asthma, insulin resistance, obesity, etc.

Research implications: Network stimulations holds great promise for researchers from diverse disciplines and particularly so to the healthcare professionals.

Originality: Bioinformatic tools address the bacterial interactions merely on the basis of numbers but our approach of systematic incorporation of data will provide better insights on such interactions.

Keywords: *Dysbiosis, Human microbiome, Next generation sequencing, stimulation models.*

INTRODUCTION

Humans are referred to supra organisms, comprises of microbial elements. In fact it was projected that an individual contains as high as triple the number of microbial cells to the human cell[1]. These microbial communities can be found on various body sites including the largest organ i.e. skin surface, gastrointestinal track, reproductive and respiratory organ, etc[2]. Such huge assemblage of various microbes acts as ecosystem[3] by their own and depicts the high variability of community composition with associated functional potentials[4]. This myriad of microbial composition and functions could evident the complex interactions to the host physiological, anatomical and immunological attributes. Ley *et al*., (2006) describes these complex host-microbial interactions as part of ecological phenomenon of mutualism and pathogenesis which governs the turnover rate of microbial population under the comprehensive evolutionary selection pressures. The persistence of microbial population demands instant and effective response to external stimuli which can be of

host or microbial origin. In case of gastrointestinal (GI) track acidic secretions by host play a major barrier for adherence and proliferation of microbial population but adaptive strategies evolve by many of the microorganisms help them survive these adverse events[5].

In continuation to the observation of adaptive nature of microbes in GI track, the unconditional residence is greatly depended on the potential of these microbes to synthesize different vitamins, branched chain amino acid, antibiotics against the pathogenic invaders, degradation of complex macro molecules in to their simpler forms, initiating the immunogenic response, etc[6]. These different functional attributes of microbes, a resilient of human host along with its genome form the microbiome[7]. Gut microbiome has its superiority in terms of complex community structure and the ability to govern the biological cycling of macro to micro molecules inside the GI track make them out number compared to any other sites. This attribute motivated to initiate Human Microbiome Project and Metagenomics of the Human Intestinal Tract (MetaHIT) project[1,8]. Previous studies have shown the susceptibility of microbes to even a small alteration to their ecosystem which holds true for the gut microbiota as it is influenced by age, dietary habits, socio-economic status, geographic location, genetic makeup of individuals [8,10,11,12,13,14,15,16] and varied states of dysbiosis, i.e., imbalanced microbial makeup in response to undesirable changes in the host physiology. The state of dysbiosis can be reestablished depending on the severity of physiological alterations, age of an individual, mode of treatment, etc. The prolong perturbations to gut microbiota increase the risk of multiple infections to host by the commensal or facultative pathogenic microorganisms[17]. Characterizing these underlying mechanisms of mutualism and pathogenesis requires dissecting the structure of microbial population residing under particular physiological condition along with the microbe-microbe interactions and accompanied functional challenges. Deducing these crucial host-microbe and microbe-microbe interactions in a gut ecosystem will be a gateway to microbiome-based therapeutics. Advancements in the technology allow us to search for these clues using the modern molecular approaches such as high throughput sequencing, functional metagenomics, stimulation models, ect[18].

Improvisation in the sequencing technologies from Sanger's dideoxy chain termination method to the latest next generation sequencing platforms such as MiSeq by Illumina holds up a great promise investigating the microbial population residing at particular ecological niche[19,20,21]. The NGS allows us to generated higher data output with lower cost and time, in comparison to traditional approach of uncultured diversity by cloning 16S rRNA gene. Characterizing millions of such small oligonuclotide pose a critical challenge due to degeneracy in the available nucleotide databases. Advancement in sequencing technology has also enforced the researchers to develop Greengenes, SILVA and EzTaxon databases[22,23,24] for accurate taxonomic assignments. Currently 97% cutoff value for 16S rRNA gene is used as a threshold[2] for the discrimination between different microbial species. Further, the positioning of 9 variable regions in the 16S rRNA gene increases the resolution of taxonomic assignments [25] but with available sequencing techniques it difficult to sequence such a large gene fragment which raise another important challenge of convincing and synchronizing the use of specific variable region. Target a specific variable region is practically impossible as these different variable regions have a varied resolution so researchers have made it open to use either of these variable regions. Alike the critical issue we had some years ago about the lack of genetic information associated with trunked of nucleotide sequences, similar observation was made regarding the information generated through the microbiome studies. Characterizing the microbial sequences and assigning taxonomy or merely describing abundances or the presence/absence of different microbial communities doesn't hold much. In fact, studies have already proven the involvement of microbial consortia and not an individual microbe to drive complex interactions.

Microbial ecologists have always followed the typical strategies of microbial adaptations, in same regard they went forward for the development of bioinformatics tool providing functional insights using *insilco* approach. But these predictions are on the basis of the available genomic sequences so it is again a subject to validation. Now a day's studies have also opted for validation using qPCR methods[26] *in vitro* and *in vivo* experimentations. Using this approach we can predict the role of microbial assemblages at a particular niche but determining the various microbial interactions such as predation, competition and mutualism is still in its infancy[27]. In addition to these functional prediction tools, researchers have also tried to develop stimulation models

which can be employed to study the interaction between different microbes by considering not only the presence/ absence and abundance but also the metadata factors such as blood sugar level, vitamin B12, HDL and LDL level (during the type 2 diabetes) which might have great impact on the microbial colonization and interactions as well. These stimulations would enable the identification of factors driving the microbial communities along with the metabolic potentials across the time.

Stimulation models can be classified into microbial co-association networks and metabolic network models[28].The co-association networks describes the response of microbial communities in response to environmental perturbations, it also represents the impact of external stimuli on the composition and dynamics of microbial communities. The metabolic networking allows understanding the shared metabolic functionalities and interactions based on the putative functional attributes. The stimulation model might not be the true representative of the cellular interaction or metabolic potentials but will underscore the microbial relationship by reducing the probable number interactions to a reasonable limit, which make the validation more feasible and to further implicate it for the improvement of agriculture, human health, waste water treatment, etc[29,30,31,32,33].Networking models apply different strategies to best represent the microbial antagonistic, competitive and mutualistic interactions, the method used for the modeling categorize it under correlation and regression, graphical, local similarity, Bayesian modeling and mutual information based model[27,28,34,35]. Consequently these approaches generate co-relation matrices using statistical frame to indentify keystone species, and its interactions under particular environmental perturbation shaping the community structure, while metabolic network illustrates the species dependent metabolic contributions and commonalities regulating the community dynamics[28]. Undoubtedly, the network models are savior with wide range of applications however at later stages it is quite difficult to prove or superimpose such complex network predictions with the lab experiments. Here, we propose an approach of systematic reference based microbial networking (reMiNET).

Reference based microbial networking (reMiNET): reMiNET is a reference based microbial networking model which initially rely on the "reference based" followed by *"denovo*" stimulations to best represent the complex microbial interactions. Initial phase of reference based network re-construction involves the searching secondary dataset (published research articles) to trace back the specific interaction evolved by microorganisms to function under particular physiology of health or disease. Instead of plotting the obtained data from the reference based re-construction, it is treated as the metadata influencing the interaction; as it might squ the *denovo* networking. Finally the *in-silico* network construction tools will be employed to generate valid networking data frame which can be statistically tested and graphically interpreted using R workspace (Fig1). Network construction using reMiNET might sound laborious but it allows administering and curetting networking profiles by adding secondary value from the literature which will eventually act as a feedback. In contrast the available networking tools fail to provide any valedictory feature other that the statistical stimulation. Alike metabolic networks reMiNET *al*so demands the huge metadata information, consequnetly it substantially increases the accuracy of network reconstruction. Here describe the working of reMiNET by considering the type 2 diabetes (T2D) data from the study of Bhute *et al*., (2016)[36]. As we know that microbiome is susceptible to the dietary habits and the meal of average Indian population comprised of high fiber content which put them at highest risk of developing T2D[37]. The higher fiber content in a meal corresponds to high glucose release leading to glucose intolerance resulting into T2D. If we construct the microbial network with available information from the high throughput sequencing efforts we will be able generate a microbial clustering with varied node and edge scores. But these node and edge scores don't speak for themselves. In order to dig out the keystone species we need to validate this cluster. Bhute *et al*., (2016) have showen the persistence of *Prevotella* and *Megasphaera* in Indian population[36]. This enrichment can be supported by the functional potential of *Prevotella* for degrading complex plant polysaccharides and *Megasphaera* to produce short chain fatty acids. Further a plethora of such observations are available in association with bacteria in healthy and dysbiosis states like IBD, asthma, insulin resistance, obesity, etc. which can be utilized for the generating information on microbial interactions. Therefore elucidating such complex interactions can provide us different targets for the development of therapeutics based on microbiome assemblage and potential functioning. Popularization of probiotics is one of such initiative.

In summary, reMiNET holds a great promise could be employed to elucidate the microbial interactions especially co-occurrence and co-exclusion under specific physiological condition considering the information from the secondary databases, which will help to project the possible metabolic capabilities of microbial communities at given set of condition. The available set of projections can be considered to target a specific microbial population or inhibiting the limiting factors to prevent the adverse situations. Reconstruction of microbial network using reMiNET might be considered as key to map and overcome the unfavorable conditions but it also requires extensive lab work and validation to confirm its working and the stimulation outcomes. Due to its dependency on the secondary databases, exploded research on microbiome and the stimulation modeling using reMiNET would provide deeper knowledge on the microbial interactions. Further, we would need to question its accuracy and efficiency using larger dataset and multiple factors.

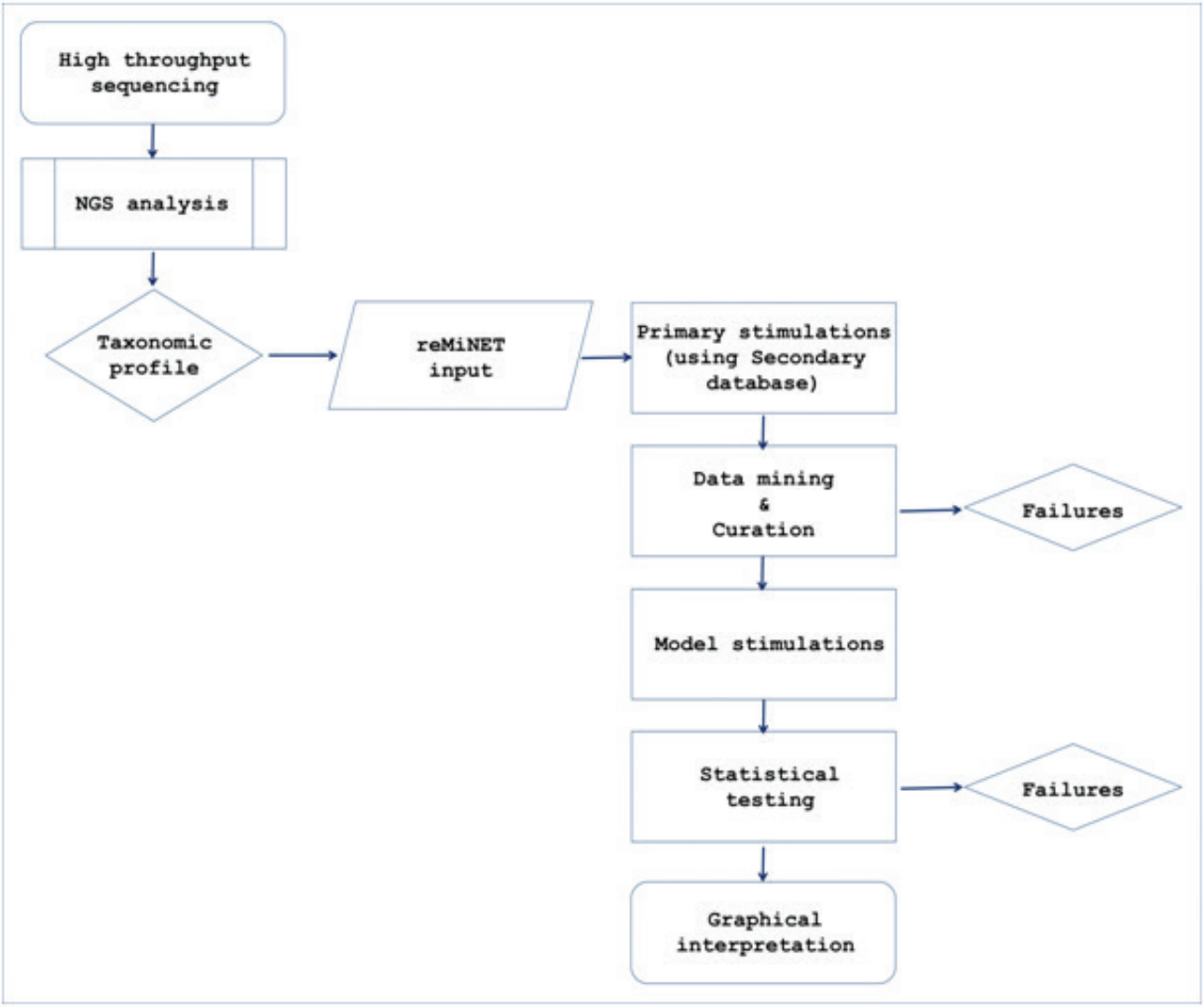


Fig. 1: Working of reMiNET. Shows the steps involved in modeling and reconstruction of microbial interactions using reMiNET.

CONCLUSION

In conclusion, microbiome studies provide a new target for the development of therapeutics under particular state of dysbiosis. Metagenomic analysis provides the taxonomic identification and probable functional contribution. Further insight into the complex ecological interactions played by microbial populations will prove to target the key stone species or the co-existing species. Use of reMiNET for recreation of microbial network will prove to be important tool, validating the interactions by employing a biosensor (positive control); but reMiNET demands more extensive work to validate its outcome.

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Just the Two of Us: Involuntary Childlessness, Causes and Consequences

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ABSTRACT

In the recent decades there has been a growing trend towards controlling fertility yet the desire to have at least one child seems overwhelmingly universal. Involuntarily childless couples undergo trauma and face stigma. Causes of infertility are linked with physiological malfunction. Studies have shown that, social change and its subsequent change in lifestyle along with other social cultural factors are linked to menstruation, conception and carrying the pregnancy full term. The present qualitative study included in-depth interviews with couples experiencing involuntary childlessness, gynaecologists and infertility specialists from Pune city. Majority of the respondents seeking medical assistance belong to the age group of 20-35 years. The causes of infertility can be categorized into genetic, physiological and lifestyle related. The common problems observed in males are lack of sperm motility, count or complete absence of sperm, whereas in females it is obesity and polycystic ovaries syndrome which can be a consequence of erratic and stressful lifestyle. The present research will help trace the socio cultural causes of infertility and the socio cultural pressures of the couples seeking treatment. If along with medical treatment, they are helped to deal with socio cultural circumstances then it may help to mitigate their circumstances.

Keywords: *Infertility, Involuntary childlessness, Socio-cultural, Causes, Life style*

INTRODUCTION

Radical changes in the thinking of today's society have led to phenomena such as live-in relationship and voluntary childlessness. These are just emerging trends and not very common. The age old tradition of getting married and having children is still a dominant practice. Motherhood is culturally and traditionally seen to be natural. Feminine identity is seen as synonymous with motherhood and mothering (Gillesple, 1999)[1]. It is encouraged in the personality of a girl from childhood itself. Newly married girls in India are often given blessing by elders to produce many children. Motivations for childbearing are assumed not to be entirely unique for the individual but to consist of a substantial component of culturally influenced desires. Other than biological continuity, social and economic reasons have also been described prominently for having children. Frequently citied reasons for having children generally fall into 3 categories social security, social perpetuity and social power desires (Balen, Inhorn, 2002)[2].

In a pro-natalist country like India a couple who is unable to have children undergoes trauma and faces stigma from the society. Indian rituals and culture showers special honour on women with children and in contrast excludes childless women. So the inability to bear children, involuntary childlessness, takes a toll on individuals and relationships.

Childlessness has various physical, psychological and social consequences. Prolonged treatment takes a toll on the health of women whereas psychologically the couple may face anxiety, depression with every failed attempt, helplessness and guilt. Lowered life satisfaction, economic hardships, marital problems, dissolution of marriage, stigma and loss of social status are the social repercussions. The objectives of the study were to document the treatment pattern of the couples facing involuntary childlessness as well as the physical, emotional and social stress faced. The present paper will help trace the socio cultural influences on causes of infertility, and the socio cultural pressures of the couples seeking treatment. If along with medical treatment, they are helped to deal with socio cultural circumstances then it may help to mitigate their circumstances.

METHODOLOGY

The present qualitative study included 47 in depth interviews with couples experiencing involuntary childlessness, gynaecologists and infertility specialists from Pune city. Seven clinics were selected on the basis of popularity and later by snow balling technique.

Respondents were selected by purposive sampling technique. Clinic based interviews were conducted with patients identified by doctors. Consent was taken at two levels. First, the fertility expert/ gynaecologist/ the person authorized by the doctor, talked to the patient about the study and obtained initial oral consent. Later a written consent was obtained from the couple being interviewed.

Interviews were conducted in the private cabins in the clinics. They were conducted in Marathi, Hindi or English as per the convenience of the respondent. They were recorded for further analysis and transcribed. Translation was skipped to avoid data loss.H The transcribed interviews, typed in Unicode, were analyzed using NVivo qualitative analysis software.

Limitations of the study: Though the consent was obtained for multiple interview sessions most of the respondents did not agree for repeat interviews citing that such interviews might jinx their chances of conception. So most of the interviews are conducted in one session, which was difficult since proper rapport could not be established before touching the main topic.

Infertility being a sensitive and personal issue, the interviews were emotionally laden and disturbing for the respondent as well as the interviewer. Training in counselling helped to deal with the distress of both.

Theoretical framework: Causes of involuntary are mostly linked with physiological malfunction like issues with sperm count, hormonal imbalance, amenorrhea, tubal damage, polycystic ovaries to name a few[3-4]. Studies have shown that, social change in general and its subsequent change in lifestyle along with various other social cultural factors are linked to biological processes like menstruation, conception and carrying the pregnancy full term[4].

Now-a day assisted reproductive technologies are readily available in order to help those suffering from problems in conception. There has been a rise in the 'medicalization' of the fertility problem where the process of conceiving a baby becomes more and more unnatural, intrusive, painful and difficult with every advancement in treatment. Though it provides an opportunity to overcome the problem of infertility, at the same time it is expensive and takes a toll on the couple's physical and mental health.

Several authors[3-5] suggest how the social change in general and the subsequent change in lifestyle has had an effect on the childbearing practices and overall biological processes like healthy menstruation, conception, and successful pregnancy and childbirth. The following concept map at a glance shows how the review of literature points at this. The theoretical map highlights how change in lifestyle has triggered different disorders which have in turn affected the fertility of couples.

Precedence to careers, work pressures, stringent deadlines make the jobs extremely demanding and in turn exerting tremendous stress on the individuals. Running behind deadlines and work pressures make the individuals lead an unhealthy lifestyle with lack of exercise, untimely eating habits and sedentary lifestyle. These ways of life may act as a trigger for various lifestyle disorders such as diabetes, obesity and cardio vascular diseases. These may lead to other complications such as cysts in ovary, annovulatory cycles, irregular periods etc. A term that encompasses all the above mentioned symptoms is polycystic ovaries syndrome (PCOS). This syndrome can cause severe problems in conception.

The different occupational avenues that opened for men included chemical industries, automobile industries work in IT industry, night shifts in BPOs etc. Some of these jobs were not only stressful but they also increased their exposure to various chemicals such as DDT and other industrial compounds such as phenols and dioxins which affect sperm quality[6]. Working in extreme heat conditions in automobile factories may lead to decrease in sperm count and quality. This may led to male infertility.

As men and women delay marriages the society has seen a steady increase in premarital sex. Lack of awareness, Knowledge and the need to keep it a secret may lead to unsafe sex practices. Sexually transmitted diseases are commonly seen. These infections may remain untreated due to the secrecy around it. If these infections worsen then it may lead to tubal blockages. Unwanted pregnancies are a common outcome of unsafe sex. Abortion of first pregnancy may lead to sticking of the walls of the uterus. All these infections and pregnancies may lead to problems in conception.

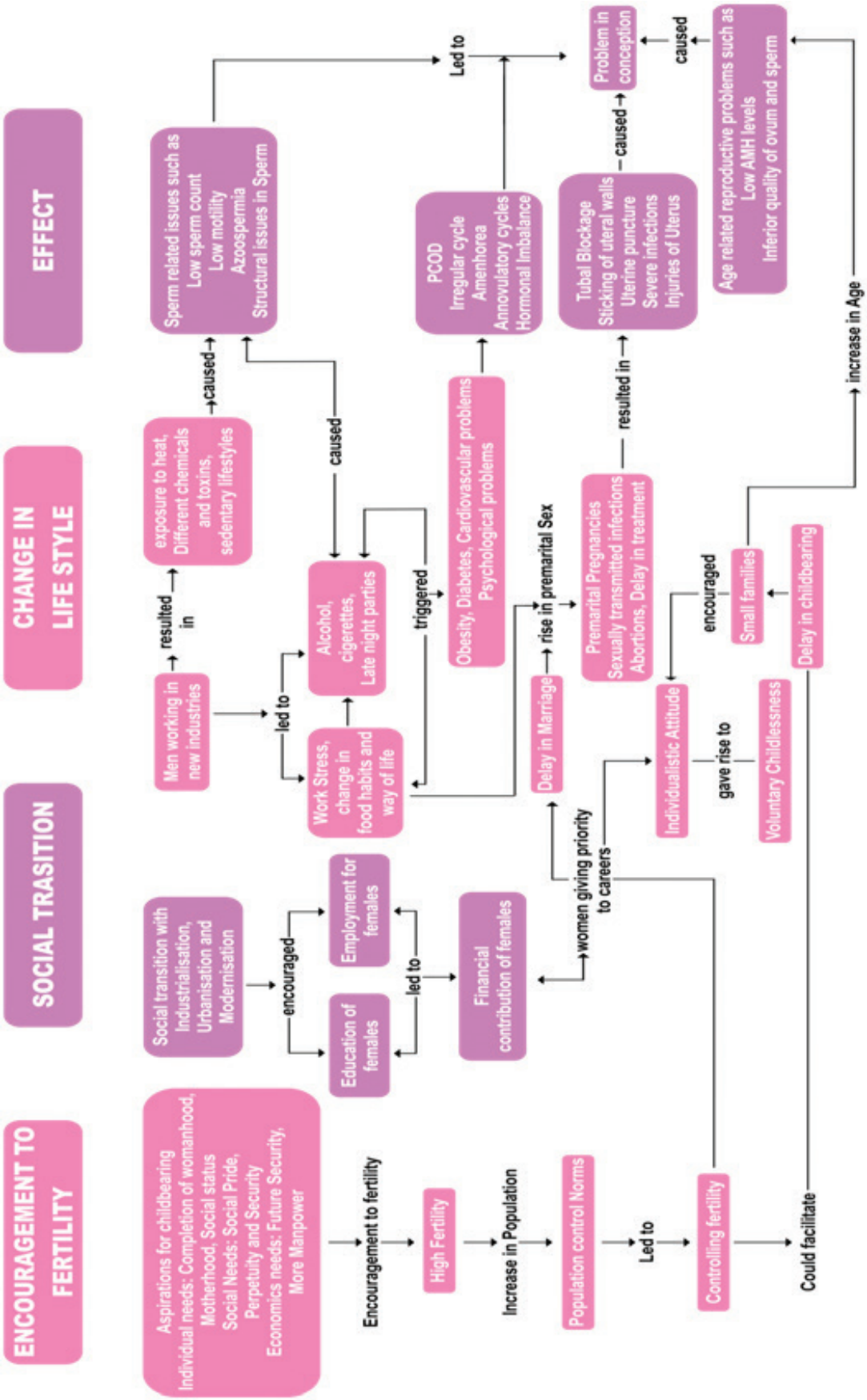


Figure 1: Theoretical Framework

FINDINGS AND DISCUSSIONS

1. Profile of the respondents

Table 1: Education profile of respondents

Education profile of respondents			
Sr. Number	**Education Bracket**	**Number of respondents**	
		Males	**Females**
1.	Primary	2	2
2.	Secondary	16	13
3.	Graduate	18	19
4.	Post graduate	9	11
5.	Above PG	2	2
	Total	47	47

Table 2: Education profile of respondents

Age of female respondents		
Sr. Number	**Age bracket (in Years)**	**Number of respondents**
1.	18-20	6
2.	21-25	16
3.	26-30	22
4.	31-35	3
	Total	47

Table 3: Economic profile of respondents

Economic profile of respondents		
Sr. Number	**Economic bracket**	**Number of respondents**
1.	10,000-50,000	15
2.	50,001-1 lac	10
3.	1 lac-1.5 lac	3
4.	1.5 lac & above	6
5.	Undisclosed	13
	Total	47

Women from the sample are more educated than the men. The graduates from the sample are trained to be doctors, teachers or engineers. Most of the women from the sample are housewife, with a few working as IT professionals and doctors. Men are IT professionals, government servants and businessmen. Most of them are middle class with family income of Rs 20,000-1 lakh per month. On the present day all the respondents belong to the age group of 25-45 years. But one should focus on the fact that the majority of them are undergoing treatment for the past 3-14 years without a single viable pregnancy. With this in mind, if we look at the age at which the respondents started treatment; one can see that most of them are in the age bracket of 18-30 years.

The relationship between marriage age and fertility through fecund ability is contingent on other social factors. With industrialization, modernization and urbanization followed social change which let women to be a part of the work force. This and many other factors related to social change led to increase in the age at marriage. Since most of the childbearing occurs in marriage, a rise in the age of marriage can affect world fertility[7]. Looking at the above figures though one can see that most problems in fertility occur in the peak reproductive age of 18-30 years. It highlights that increase in age at marriage may just be one of the reasons for fertility decline. Girls who got married at an early age are also commonly facing the problem of difficulty in conception. This compels us to look at other causes of involuntary childlessness.

2. **Causes of involuntary childlessness:** From the total number of respondents half had women diagnosed with problems in fertility and the remaining half included males, both males and females and sometimes no particular diagnosis of infertility.

   Causes of infertility are generally linked with physiological malfunction. Many a times this malfunction can be an outcome of either genetic or congenital causes or sometimes may be related to the changing way of life of young individuals. Following table shows the main causes of male and female infertility observed n the study, categorized in three main groups: as physiological, genetic/congenital and lifestyle triggered.

Table 4: Infertility problems in males and females

Sr. No.	**Problem seen in**		
	Females	**Males**	**Both Males and females**
	23	8	8

Table 5: Causes of infertility in males and females

Sr No	Physiological causes (13)		Genetic/ Congenital Causes (7)		Life style triggered (16)	
	Males	**Females**	**Males**	**Females**	**Males**	**Females**
	Blocked Vasa Differentia	Fallopian Tubal Blocks	Azoospermia	Chromosomal Abnormalities	Oligospermia	Hormonal imbalance
		Premature Menopause/ Low AMH levels	Absence of testicles	Tubes absent	Asthenozoospermia	Polycystic Ovaries
		Absence of fallopian tubes/ovaries		Small/inverted uterus	Diabetes	Diabetes
		Structural problems		Low AMH levels		
		Infections like TB, Chlamydia trichomis				

The data highlights that most of the respondents were told to make simple lifestyle changes in order to increase their chances of conception. These changes include exercise to control obesity which subsequently leads to polycystic ovaries and diabetes, timely eating habits, less stressful jobs, meditation to calm self etc. Patients who were advised such measures to overcome their problems are categorized under lifestyle related causes. They form more than half of our sample. One can clearly see the association of lifestyle changes and decrease in fertility in the empirical map seen below.

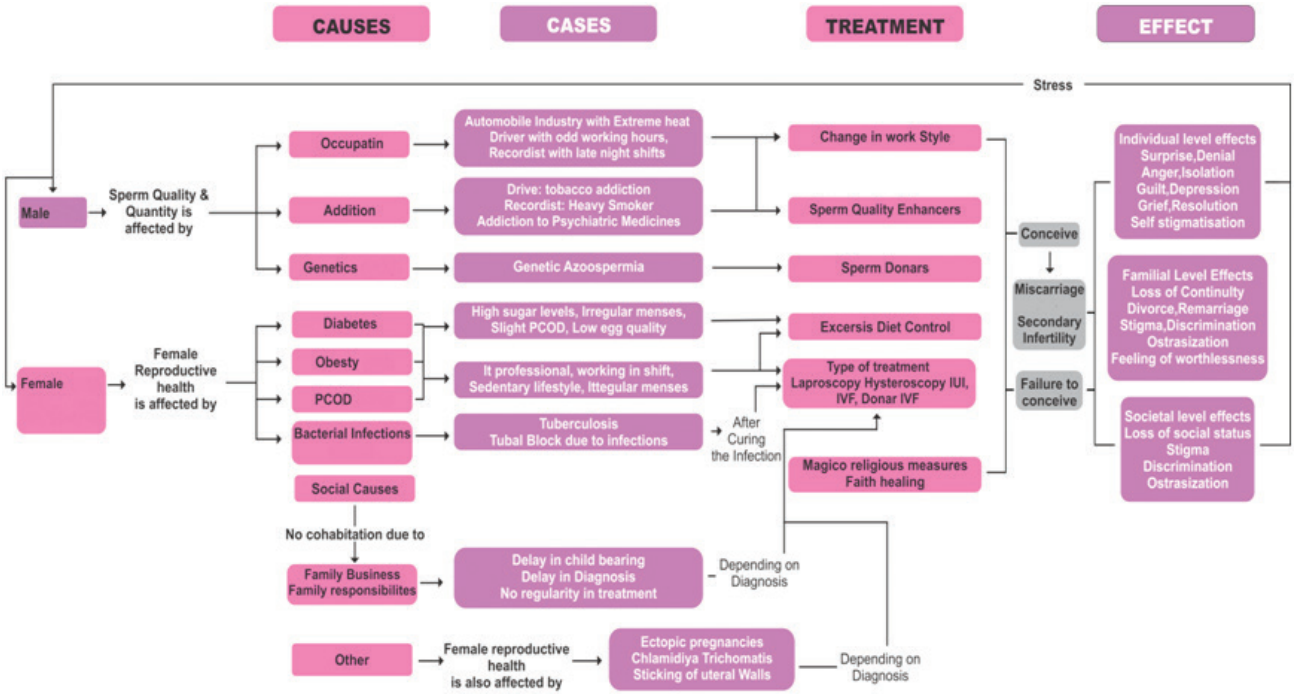


Figure 2: Empirical map

3. Consequences Of Involuntary Childlessness:

Individual level: The treatment for infertility can take a toll on a woman's health. It is tedious, long and a painful process which may or may not lead to a positive outcome. In the total sample of 47, the women have undergone total of 128 intra uterine inseminations and 21 in vitro fertilization cycles with no positive results till date. The highest number of treatment cycle for one individual is 21.

An individual faces anxiety during each cycle and intense depression after every failed treatment. Individuals report crying, rage, helplessness and extreme sadness during this period. They also report guilt, that they cannot fulfil the most natural process for a woman.

If the woman in the couple is the one with a diagnosed problem she lives in self stigma. She thinks people blame her for being unable to produce an heir for her family. If the spouse shows concern and care during treatment, she feels indebted. She feels obliged that he is not asking her to move out, or proposing remarriage. According to her it will not be wrong if the husband or the in laws trouble her over this matter.

Cases illustrating cultural pressures

Case 1:

The case highlights the cultural expectations on a daughter in law to produce children. This is a pressure felt by only son's wives who views it as a cultural binding on them. The respondent thinks that if they were in a western country where such expectations are not laden on a woman, she would have preferred to stop her treatment. Not having children has made her feel stuck in life. Cultural expectations and subsequent comparisons with cousins of her age make her feel better off alone.

"Suppose If I were living in the US, I would have never wanted to go through such a procedure. If I leave it people will say I did not take any effort. I am doing this for other people." says Sarika, a 29 year old Gujarati girl who is undergoing treatment for the past 2 years. Her husband is an only son, so she feels that being the only daughter in law she has to bear children to carry on the family name. She feels that the treatment is too taxing and does not allow her to lead a normal life. She has left her job as she cannot manage the doctors' appointments while working full time. She does not visit her native place as she feels that she has not progressed in life as her cousins because of her childlessness. Only because of her problem she feels isolated and says has stopped living her life. Given a choice she would not live her life this way.

Marital Life: Mostly, women list their husband as their main support in the experience of infertility, but feel that their relationship is affected negatively due to problems in conception. They report that their sexual life has been majorly hampered due to performance pressure, lack of desire to have sex and other side effects of the treatment. The wives' say that the treatment leaves them feel bloated and unattractive with no desire to have sex. To top that the treatment is extremely painful so one does not feel like having sex. Also, the compulsion to be intimate while trying for a child makes sex mechanical and less intimate. Also, some feel that if sex is not going to lead to conception then it is useless. On the other hand some couples also think that after everything they have been through together, their bold has become extremely strong. They can face any challenge now if they are together.

Cases describing marital distress

Inability to conceive naturally can make the couples feel that sex is redundant. Irrespective of who has a medical problem, majority of the treatment of infertility is carried out on the females. Treatment is long, rigorous and physically taxing. It also has side effects such as bloating, hair loss, hormonal imbalance etc. which have far reaching effects on their marital lives.

Case 2

Kartiki, a 36 year old primary school teacher has been on infertility treatment since the last 14 years. She had suffered from Tuberculosis of the uterus because of which both her fallopian tubes are blocked. She has undergone 8 IVF cycles and 4hysterectomies. Fed up with the side effects of the treatment and the physical damage it caused, she had also opted for surrogacy twice. Unfortunately both the cycles were negative. She says," "14 years of treatment have had many side effects. I have lost hair and then started feeling ugly. I don't feel like having sex."

Case 3

Pradnya is a 32 year old, 10th pass house wife. Her Husband is a MSEB worker and works in shifts. She has been on some or the other form of treatment since the past 12 years. Due to financial scrunch they could not opt for advanced technologies sooner but they have been following timed intercourse method every

month for the past 12 years. She says, "…It has been compulsory for the past 12 years, every month, because that was our aim. Now (I) don't want to have sex for the next 12 years."

Case 4

Donor IUI is a common medical treatment for patients suffering from Azoospermia, i. e complete lack of sperm. Sharada, a 27 year old hospital maid, has opted for donor IUI as her husband suffers from Azoospermia. As she works in a maternity hospital her treatment is carried out free of cost. The couple has hidden the disorder from their family members for 2 reasons. One that the husband will be taunted and 2nd if they tell the family, that child from a donor will not be accepted. She has been trying for a baby through natural conception for past 8 years. Now she says, *"Sex is useless because of Azoospermia"*

Family Life: Most of the respondents think that having children will have a positive effect on their status in their family. Not only will they earn respect, but also their opinions and views will be taken into consideration in their family. In general they think that their family will be happier. One case talks about fear of abandonment from the family and husband's remarriage. She feels that since no treatment is showing a positive result, her mother in law has started suggesting her husband's remarriage.

Having said that, most of the respondents think that their childlessness does not have an effect on their family relationships. Family is a closed knit bond where the members care for each other. The parents in law are supportive and sometimes also pay for the treatment. Sometimes, there can be taunting from the mother in laws. The respondents think that that is expected as they themselves are at fault and some tiffs are ok.

Cases describing familial stress

Family is always described as the main support in the treatment process. Women feel that they are not completely accepted by the in laws family till they bear a child. Women feel that if the problem lies with their husband, then the in laws family is more accepting of the situation.

Case 5

Shraddha, a 39 year old housewife has been undergoing treatment for conception for the past 10 years. Her husband suffers from low sperm count and she has hormonal imbalance. She had stopped treatment in 2011 as they didn't have money. Then she resumed t after 2 years after saving sufficient money. Presently she is undergoing IVF.

She lives in a nuclear family. Her in laws live in their native village. She says, "No one asks for our opinion at home if we do not have children."

Case 6

Shahida, is a housewife. She has recently discovered that she is pregnant after 10 years of marriage and 7 years of treatment including 3 IUI and 1 IVF. She lives in a nuclear family in Pune and her in laws live in Mumbai in a big joint family. They have 8 grandchildren from their other children. Shahida thinks that because of this, her in laws do not miss her children and are not concerned about her conception. As a result they are not very supportive about the treatment and she thinks that they are not concerned about her, She says, "They will look at us as 'baal bachche wale, wont point fingers if we have kids'

Case 7

Savita is a nurse in a maternity home. She has had an abortion in the first year of her marriage as there was no fetal growth. Now her husband is suffering from low sperm count. She thinks that her family members do not say anything to her about her childlessness as they know that the problem lies with their son. So they are more tolerant of her situation. Still she says "The family does not accept us completely till we bear a child"

Social Life: Majority of the respondents feel that having a child has a positive effect on their status in society. They say that they are viewed as a complete woman, their importance n rituals increase and they receive more respect in the society. They feel that people point fingers at childless couples, feel that they must be unsatisfied with their lives. Those who differ from this opinion feel that it is in the minds of childless women that people talk about them, when in reality it is not the case.

Case 8

Sneha, is a Software engineer, with irregular periods and PCOD. Her husband is a smoker.

She has had one ectopic pregnancy so only one working fallopian tube. She has undergone 6 IUI and 1 IVF. In the past 8 years. She saystthat usually she avoids going to any family functions and gatherings in order to avoid discussion regarding her childless status. She feels that since she herself feels inadequate everything seems negative to her. She says, "*I think more than they saying anything it is me who interprets it in a certain way because I always have it in my mind."*

Case 5

"Where ever we go, people always ask about our children, not about our job/ money." says Shraddha a 39 year old old housewife has been undergoing treatment for conception for the past 10 years.

CONCLUSIONS

Other than the physiological and genetic factors causing involuntary childlessness, the lifestyle factors form a major reason for it. These factors can be easily avoidable in the long run for couples who wish to conceive. The most important recommendation from the study is counselling as a part of therapy for patients of involuntary childlessness as well as their family members. Socio-cultural pressures, exerted by self, by the family and the society in general, are commonly describes by patients suffering from involuntary childlessness. This makes the process of childbearing more of a compulsion than a voluntary choice.

According to the ICMR guidelines given in the Assisted Reproductive Technologies (Regulation) rules of 2010, a counsellor is compulsory in the staff of the infertility clinics. This is not followed by all the clinics and generally the gynaecologist acts as a counsellor for the patients. The counsellor can also help educate the patients regarding healthy lifestyles, stress management and coping with the effects of treatment. It can also help for the family members of the patients. It is clearly seen from the discussion above that support from the family will help reduce a major stress factor of the patients. A counsellor can help psycho educate the family about the suffering of the patients and may be also educate them about adoption and its acceptance in chronic cases.

The society in general should be made aware of the suffering of the patients suffering from infertility. A sensitive and empathetic society will help the patients to better accept and cope with their situation.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Exploring Dietary Practices and Food Habits: A Focus Group Study among Rural Women in Mulshi, Pune

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ABSTRACT

Purpose: To study current food habits of rural population across SCOPE villages in Pune through qualitative research and educate them regarding the healthy dietary choices.

Methodology: Phase I: 7 Focus Group Discussions (FGDs) among 7 target groups (infancy to geriatrics -10 respondents each) for duration of 1-2 hours were carried out. Phase II: the reported recipes were developed; nutritive value of each recipe was calculated and compiled into a booklet.

Results & discussion: Mothers of infants/toddlers routinely fed their children with regular family diet indicating the unawareness of weaning to be initiated at 6 months and ignorance towards significance of special foods needed for growth and development. Nutritional knowledge and practices among pregnant, lactating and menopausal women was limited due to poverty and lack of awareness. Interestingly, geriatrics believed that engaging in physical activity and eating preparations made of millets is a key to good health.

Research implications: Nutrition education in schools and communities would help in addressing gaps in nutrition knowledge/practices.

Novelty/Originality: Development and compilation of recipe booklet as a key tool for nutrition education.

Keywords: *Focus Group Discussion, Recipes, Nutrition education, Dietary practices*

INTRODUCTION

The Indian government took several measures towards improving food and nutrition security of the households through planned socioeconomic development and public health interventions[1].Adequate nutrition has been recognized as a key prerequisite in improving family diets and children's nutritional status globally[2]. However, malnutrition in the world still remains unacceptable as 795 million people suffer chronically from hunger[2]. Under nutrition contributes to one-third of the global total of childhood deaths estimated at 2.6 million deaths of children under five each year and finally, 66 million primary, school-aged children across the developing world attend classes hungry (with 23 million in Africa alone) affecting their ability to learn [3]. The six global nutrition targets (World Health Assembly) were suggested to be used globally to track progress in reducing malnutrition[4].

There is a real need for nutrition education programmes in schools and in communities in order to promote a balanced diet approach to further improve the eating habits among vulnerable groups, specifically children[5]. A small study was carried out among vulnerable groups of people in SCOPE village with the aim of understanding the food habits of people in the SCOPE villages. Recipes are known to be popular vehicles in nutrition education. Significant time and resources are devoted to identifying, developing and distributing recipes in Extension nutrition education programs[6]. A qualitative review of the existing food habits of the various vulnerable groups such as infants, toddlers, school children, adolescents, pregnant and lactating women, geriatrics, menopausal women was carried out by qualitative research.

METHODOLOGY

Study Setting: The study was carried out in the seven villages of Mulshi taluka, under the guidance of a social worker, who works for SCOPE (Symbiosis Community Outreach Programme for Education). SCOPE is an

organization which helps the primary healthcare centers reach out for basic medications and nutritional guidance. They also have a vehicle which functions like a mobile medical store and provides medication which is not readily available at the primary healthcare centers. SCOPE works through joint initiatives undertaken by the university to impact the community positively. Family Doctor Clinic and Medical Mobile Unit work alongside SCOPE and cater to the healthcare needs of the community.

Methodology: This research study employed focus groups for data collection for the following groups. Focused Group Discussions (FGDs) is a loosely structured discussion among six to ten individuals that is used to gather information and perspectives on certain issues[7]. The participants are usually selected for their homogeneity on some factor important to the research, such as age, sex or profession. Discussions are 'focused' on the topic of interest to the researcher[8]. Focus groups are ideal for this research as they capture real-world perspectives on topics where data are limited[9,10]. The target groups selected for the study were infants, toddlers, school children, adolescents, pregnant and lactating women, women of menopausal age and geriatric women, who were gathered at the Primary health Centre for the FGDs. The Symbiosis Centre for Health Care (SCHC) contacted the Anganwadi teachers and informed them of (FGDs). In preparation for FGDs, separate 'theme guides', which listed the themes/topics around which the discussions would focus, were evolved from a review of literature, preliminary discussions with nutrition experts in the field. The broad areas of discussions for each FGD are shown in table 1.

Table 1: Themes used to elicit discussion during the Focus Group Discussions

Target groups	Themes
Infants	Concept of weaning Age of commencing weaning Sources of food which constitute the weaning diet Quantity and frequency of consumption Source of information for awareness and preparation of weaning foods Recipes
Toddlers	Concepts of feeding Toddlers Anganwadi Meal administered Health problems Recipes
School going children	Food cooked in the school Mother's recipes
Adolescents	Brief dietary recall Local foods available Foods consumed on special occasions Pre-menstrual symptoms and remedies taken Recipes
Pregnant and Lactating Women	Regular dietary habits Foods avoided during pregnancy/ lactation Food cravings Specific practices Recipes
Menopausal women	Concept of menopause Foods consumed to maintain good health Awareness on foods which are beneficial during menopause Menopausal symptoms Recipes
Geriatric women	Habitual Dietary pattern Health problems Home remedies for various illnesses Recipes

The FGD was conducted by a team consisting of a moderator and a notes taker, who were trained to conduct focus groups in a standardized way[11]. The discussions were conducted in Marathi (the local language) and were recorded using smart phones with the permission of the respondents. The recorded discussions were transcribed into individual scripts. A content analysis approach was used to analyse the data collected from the focus groups[12,13]. Content analysis is a method for uncovering patterns in participants' accounts to identify trends. All audio recordings were transcribed in English for analysis. The transliterated scripts were compiled into individual reports organizing raw data into conceptual categories or codes as per methods suggested by Newman 1995 by including suitable comments from the participants for analyzing the data. Then, separate documents were produced for each discussion containing the comments in response to the themes raised during the discussion/ interviews[11]. These reports were read independently by the Nutrition and Dietetics Faculty who agreed on the interpretations.

RESULTS

FGD among infants: The role of good nutrition has wider implications over a person's lifetime because infancy is when the groundwork for dietary habits and nutritional adequacy is laid[14]. Therefore, there is a need for appropriate food and nutrition during infancy, which contributes towards proper physical growth, mental development and a healthy immune system[15] (WHO 2001). FGD consisting of 10 women (mothers of infants) from Rihe village (Pune, Maharashtra) was carried. When enquired about their awareness on complementary feeding practices of infants, 80% of these mothers reported feeding their infants with the regular family diet as they were totally unaware about the concepts of complementary feeding. This came out clearly in the discussions: *"I give milk, fruits and biscuits to my child" (Mother of an8 months old baby).* "*I don't prepare any special recipe for my child, she eats rice and dal and I do not get time to make any other special food."(Mother of a 10 months old baby).* In 2001, after carefully reviewing the available evidence, the World Health Organization (WHO) made a global recommendation that all infants should be exclusively breastfed up to 6 months of age and partially breastfed thereafter up to 2 years of age[16].

When asked about the need for complementary feeding, only one mother (10%) mentioned that complementary feeding should be initiated early on so that the child develops a taste for other foods. However almost 100% of the mothers believed that babies should be exclusively breast fed up to the age of 1 year following which complementary feeding should be initiated. As one mother says, "*We have no concepts like complementary feeding and when it should be started because once babies start consuming rice, chapatti etc., we feed them the same foods as for the rest of the family and hardly ever make any special preparations for infants*'. This lack of awareness may be attributed to a recent study which showed that complementary feeding practices are often inadequate in developing countries, resulting in a significant nutritional decline between 6 and 18 months of age[17]. When asked about the food sources for making dishes for children they mentioned that they make use of locally available food sources like jowar, milk, ragi, green leafy vegetables and fruits grown in their fields.

"I give him one boiled egg every Sunday"(Mother of a 10 month baby). Most of the mothers said that they can't afford all pulses and non-veg foods like chicken, meat, fish because of their high cost. Most commonly used cereals were jowar and ragi and animal origin foods which were commonly given to children were egg and milk. They preferred jaggery over sugar and most commonly used oil was groundnut oil. When enquired about the quantity and frequency "It's not like that I give him a fixed amount at a time. He eats according to his appetite". (Mother of a 16 months baby) "Generally she eats her food 4-5 times in a day" (Mother of 10 months baby). The mothers were not much aware about the portion and serving sizes. Mothers were neither unconcerned about the quantity of milk consumed by the baby during breast-feeding nor the quantities provided during complementary feeding. This has been observed in a study carried out in South Africa wherein mothers only looked into the happiness and physical appearance of the child were their main concerns[18]. All the mothers in the group said that they had an exposure to the aspects of weaning food previously by the Anganwadi worker and by nurses at the PHC. "Didi told us to feed our babies with new foods after 6 months only but somehow were not able to manage or the child was not eating properly" (Mother of a 10 month baby). Recent research has shown that when these learned healthful habits and preferences are carried into adulthood, the likelihood of productivity, health and well-being are increased, and infectious and chronic disease risks are reduced[19].

FGD among toddlers: An FGD was carried out among a group of 12 women (18-25 years) who were mothers of toddlers from Rihe village. When asked about their knowledge on the concepts of feeding, only 16% of the women were in the practice of preparing meals (including greens, legumes, rice and chapattis, a form of Indian bread) for their toddlers with less spice in order to make it palatable and acceptable by the child. The remaining 84% routinely provided the children with the same meals cooked for the rest of the family. Interestingly, one respondent reported that 'We don't feed them, they are on their own'. A majority of the mothers (84%) habitually took their children to the Anganwadi centres in order to avail the facility of feeding their children with the nutritious combinations of rice and dal –khichdi (rice-pulse combination), sweet dishes such as shira [made of semolina, ghee and sugar] and lapshi [made of broken wheat ,jaggery and milk], ground nut ladoos ,sprouts of chana etc. that were provided as part of the Anganwadi meals. Only one child

was observed to demonstrate signs of malnourishment (having greater head circumference). The child was two and half years old exclusively fed on breast milk. Discussions with mothers revealed a passive approach towards weaning foods. Toddlers are known to be a group that is vulnerable to undernutrition, and therefore require special attention. Data from NNMB (National Nutrition Monitoring Bureau) surveys indicate that, over the past four decades, there has been a sustained reduction in undernutrition rates among preschool children owing to the improvements in access to healthcare and the consequent reduction in the nutrition toll of infections[1]. However, the findings of the present study indicate the need for educating women on weaning practices.

FGD among school age: The FGD was held at the primary school in Rihe village in Mulshi Taluka, Pune. When asked what kind of food was provided in the school from home, a majority (65%) reported of preparing rice with green leafy vegetables like Fenugreek (Methi) and Amaranth (Chawli leaves) or sprouts of Moth beans), Cow pea (Chawli sprouts) for lunch. Along with it they provide different preparations made of lentils such as Pigeon pea (Toor dal) Green gram(mung), Split red lentil (masur dal). It was observed that the students were provided with appropriate amount of cereals, pulses, legumes and sprouts but they were not provided with fruits at school. Interestingly food safety was being practiced and the students were trained in practicing hand washing. When asked about the source of information for them to prepare foods, mothers of the students mentioned that they very often acquired their knowledge about recipes from their mothers and grandmothers. Indian bread like Chapati with vegetables (vegetables included okra, cluster beans, potatoes and tomatoes) curry were habitually (60%) prepared for breakfast. Green leafy vegetables were not preferred by a majority (70%) of the children, which were included by 25% in preparations like parathas, a type of Indian bread that were served with curd. The remaining 40% of women who were employed in fields reported of providing chapatis with tea for breakfast due to lack of time but they managed to provide variety of cereal pulse combinations in the form of idlis, dosas at least once a week along with poha and upma as breakfast items. One of the respondents (Mother of a 6-year-old) informed that her son preferred tea but at least twice a week she gives milk with almonds as advised by the Anganwadi worker. Meat is eaten twice a week in their household which includes chicken, mutton and fish preparations. Dal recipes like aamti and saar were commonly prepared by the respondents. An interesting finding of this group showed that 22% of children expressed a liking for some foods mainly savouries and sweets prepared by their grandmothers depicting that traditional tastes and recipes were still preferred. When asked about the recipes procured from their mothers and family members, 50% reported of the mothers informed that they prefer providing home cooked foods as they are rich in nutrients as told to them by their mothers. It was interesting to know that they still practiced all the old remedies. Almost all vegetables were cultivated in their own fields and those vegetables that are not available are bought from nearby market.

Another traditional recipe popularly prepared by the respondents was chutneys. When the prepared meals are not readily consumed by the children, these chutneys are prepared and served along with the food which encourages the children to consume that particular food. For example: dry coconut chutney with any type of parathas (Indian bread). Amaranth ladoo, Semolina laddoo, Bengal gram (besan) ladoo are brought readymade. “Bhakriis” are made out of Ragi, Pearl millet and Sorghum. In Rihe the villagers also prepare rice flour bhakris. Different kinds of flours are bought readymade from the market especially by the working mothers.

FGD among adolescents: An FGD was carried out among a group of ten adolescents (13-19 years) in Rihe village. The girls were engaged in a vocational course in sewing. The discussion initiated with a short recall of the foods they routinely consumed on a daily basis. About a majority (95%) said that they consumed only 3 meals in a day, which consisted of whole wheat flour rotis in the morning along with some vegetable, and the same meal was also consumed in the afternoon while for dinner, they consumed either rice flour bhakris or sorghum flour bhakris with a vegetable curry. A majority (60%) consumed tea twice a day while 40% reported of consuming milk at bedtime. The same 40% also reported of consuming non-vegetarian foods like chicken, mutton and eggs once a week.

The fruit consumption revealed that though fruits like banana, mangoes (during summer), Indian blackberry (jamun), guava and apples were available, they were not always consumed (80% of adolescent

girls) indicating the need to educate adolescent girls in making healthy choice of foods. There were no specific dietary practices followed during the menstrual cycle but a few (20%) reported of consuming black pepper in tea to obtain relief from the symptoms.

FGD among pregnant women: The FGD with pregnant women (10 women) revealed that 85% consumed the same meals as the rest of the family members, which included non-vegetarian food (eggs and chicken and local fish like 'chilapi' and fresh water crabs, including pulses and cereals, which were consumed throughout the pregnancy. Based on the availability of fruits they prefer apples and coconut water. Local greens like 'shendvel' 'kartula' 'alu cha deth' were consumed and were found best in the rainy season. The food fallacies and myths revealed an avoidance of papaya, banana, pumpkin as it provides heat which may prove to be harmful for the baby. Spicy foods were avoided. On asking about special occasions as fasting they said "we continue with our religious fasts". About cravings nothing unusual was seen. Sour sweet foods were craved for. They liked to eat raw mangoes and tamarind. There was no note of any kind of nausea.

FGD among lactating women: The FGD (10 women) revealed that there was not much difference in the diet patterns pre and post pregnancy. When enquired about their specific practices, they revealed that they do not consume chapattis for the first two months. Bhakris are preferred. They avoid spicy food. Intake of leafy vegetables is increased as they believe it helps in the child's brain development. Spinach along with Sorghum (jowar) bhakris is consumed as it helps in increasing the breast milk production. Barnyard millet, dry fruit ladoos, Semolina preparations, and ghee are consumed on daily basis as it is beneficial for the mother's health as well as the child's health indirectly. Among the non vegetarian foods eggs and fish, specifically Bombay duck are thought to be very good for the milk production. It also nourishes the child with necessary nutrients. Eggs are eaten without the yolk. Other foods like black eyed peas (chavli), lima bean (pavta) and certain types of daal are avoided for the first 5 to 6 months as it affects the quality of milk. Plain rice or rice with milk is consumed. Salt consumption is not preferred for a week after giving birth. Water is boiled, then cooled and given to the baby as a measure to prevent cold. Most women (60%) consumed stale food to prevent food wastage.

FGD among menopausal women: Most women (90%) were totally unaware about the concept of menopause, which was evident as they consumed same diet as prior to the menopause. *"I eat gulavni (jaggery preparation with milk)"* (Women aged 60 years). *"I don't prepare any special recipe during my menopause, I eat rice and dal and I cannot afford."*(Woman aged 47 years)

Majority (85%) at Andgaon village said that they eat normal food like rice, dal and bhaji owing to lack of availability and poverty conditions. *"We eat lot of leafy vegetables because we grow them in our farms."*(Woman aged 55 years)

Many women (75 % said there no special recipes and only thing which keeps them healthy is eating simple food and working hard in the farm. *"I like eating bhoplyachipoli/ gharge (pumpkin sweet with jaggery)"* (Woman, 55 years). Cereals like jowar and ragi and animal origin (mutton and eggs) were commonly consumed. Jaggery was preferred to sugar. Women reported that mood swings was a major symptom along with excessive sweating and pain in the joints. Many (90%) informed that they traditionally followed the advice of their grandmothers and family members. Food preferences revealed that 45% reported habitually consumed leafy vegetables (fenugreek leaves, spinach, Celery leaves, (chaakvat), shepu, colocasia leaves and amaranth leaves). In addition, they liked pulse vegetable preparations such as moth beans with potatoes, broad beans i.e vaal, brinjal and ladies finger. 25% reported of consuming fish and chicken. Traditional sweets were consumed only during festivals. Only 30% reported of consuming fruits like Indian blackberries (jaamun), karvande (bush plum) and bananas. A majority (72%) reported of having back pain, cervical problems, knee pain which they attributed to the heavy work they do on the farms. Interestingly 10% of the women (supposedly having diabetes but did not show any clinical reports) reported of not consuming sweets/fruits like mangoes as they were concerned about the impact of these foods on blood sugar levels.

DISCUSSION

The objective of the FGD with various groups was to understand the dietary practices of the community at household and individual levels. FGD with mothers of infants revealed that 80% of the mothers were in the

habit of feeding their infants with the regular family diet mentioning that they were not aware complementary feeding. It is well known that breastfeeding is one of the key determinants of child survival, birth spacing, and the prevention of childhood infections. However, the beneficial effects of breastfeeding depend on its initiation, duration, and the age at which the breastfed child is weaned. The present study showed that mothers of infants did not pay attention to key issues such as concept of exclusive breastfeeding, frequency of feeding their babies as well as the quantities of food provided during complementary feeding. A study by Mahmood *et al.* 2012 revealed that despite higher rates of early initiation of breastfeeding and exclusive breastfeeding, awareness of the benefits of exclusive breastfeeding was low[20]. On the contrary, the present study showed the early introduction of complementary feeding thereby indicating the need to promote awareness on appropriate practices of infant feeding and care of the newborn. Creating an awareness of the advantages of exclusive breastfeeding will further strengthen and support this common practice in rural communities and avoid an early introduction to complementary foods for sociocultural reasons.

The FGD among toddlers showed a similar trend wherein 84% of the mothers routinely provided the children with the same meals cooked for the rest of the family. However, a majority of these mothers were in the habit of taking their children to the Anganwadi centres to avail the foods provided as part of the Mid-Day Meal (MDM) programmes. India's MDM scheme is one of the more "successful" (in terms of regularity and scale) food security programmes initiated by the Government of India which provides food to more than 12 crore children every day. Studies show that it has a significant impact on enrolment of children, especially those from disadvantaged groups[21]. Mothers of school children were also in the habit of largely relying on MDM provided in schools due to their poor socio economic status. Interestingly mothers informed that the MDM programme helped in imparting nutrition education as well as inculcating hygiene habits (such as washing hands before eating).

The FGD among adolescent girls revealed that 95% of the respondents consumed only 3 meals a day (rotis, bhakris or rice with vegetable curry), which did not comprise of a variety of foods suggesting that there was a need to educate adolescent girls on making a healthy choice of foods. A majority were not in the habit of consuming green leafy vegetables, fruits, nuts and flesh foods. Although this group had a high intake of cereals (consumption of energy and protein was better) but they were habitually consuming inadequate amounts of micronutrient such as iron, vitamin A, niacin, vitamin C and riboflavin[25]. The FGD among pregnant women reported that 85% consumed the same meals as the rest of the family members showing that this group did not pay attention to the additional nutritional requirements during this crucial phase of life. A similar trend was observed among the lactating women showing that no specific dietary guidelines were followed by these women during both the physiological conditions. Despite Anganwadi workers trying to create awareness on the dietary practices to be followed during pregnancy and lactating, it was observed that many pregnant and nursing women were not taking interest in improving healthy dietary habits, which could be due to poverty[23].

The FGD among menopausal women interestingly showed that a majority (75%) said there no special recipes and only thing which keeps them healthy is eating simple food and working hard in the farm. Although foods such as cereals, pulses, other vegetables, milk, oil and sugar were eaten everyday by these women however, perimenopausal women. Only 45% and 30% of the respondents consumed green leafy vegetables and fruits, suggesting the need to educate this group on consumption of adequate amounts of fruits and vegetables rich in antioxidants, calcium rich food and to eat food rich in isoflavones such as soyabeans[24].

CONCLUSIONS

This qualitative research aimed at studying current food habits of rural population in western regions of Maharashtra. Diets of infants and toddlers were same as the regular family diet suggesting the need to create awareness and ensure proper weaning practices. MDM schemes have been successful in providing meals to school going children. The food habits of adolescent girls showed the need to educate this group on the proper selection of nutritious foods in order to meet the increasing needs. Similarly nutritional knowledge and practices among pregnant, lactating and menopausal women was found to be limited due to lack of awareness. Interestingly, geriatrics believed that engaging in physical activity and eating preparations made of millets is a key to good health.

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Breast Cancer Biobank: A Novel Resource for Translational Research

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ABSTRACT

Introduction/Background: Current Breast Cancer (BC) knowledge has primarily emerged from translational research in western populations. Given the genomic and population diversity, mere extrapolation of this knowledge to BC in Indian women is incorrect. Hence, Indian-population specific research resources are needed.[1] Herein, we describe the creation of a pilot BC BioBank as a repository of clinically annotated bio-specimens from BC patients at our clinic.

Purpose: To establish a BC Biobank for collaborative translational research

Methodology: Given its high prevalence in India, our pilot study focuses on a BC subtype named Triple Negative BC (TNBC). Retrospective data (i.e., medical history, clinico-pathology, imaging, surgery, chemotherapy and post-treatment status etc.) was collected after informed consent from TNBC patients. Formalin-fixed paraffin-embedded *(FFPE)* tissue from post-surgery samples was also collected. In addition, Radiology images of TNBC were analyzed to identify unique imaging characteristics.

Results and Discussion: Out of 115 registered TNBC cases at our clinic, a pilot BioBank was generated with clinical data and FFPE blocks of 44 samples. Clinico-pathology details and medical history were meticulously collected for this study cohort. From these cases, extensive radiology imaging analysis was performed on 25 cases to identify unique Mammography or SonoMammography features of TNBC in Indian women.

Research Implications: The DNA from FFPE blocks of TNBC tumors is being used to identify mutational patterns in cancer-specific genes. The TNBC Imaging database has generated collaborations with imaging scientists to identify unique radiological features of Indian TNBCs.

Novelty/Originality: In this project, we have created a novel research repository for TNBC-themed research in Indian women. This unique project is acting as a driver for multidisciplinary research collaborations with scientists from academic and private sectors.

Keywords: *Biobank, Triple Negative Breast Cancer, Translational Research*

INTRODUCTION

The incidence of Breast Cancer (BC) is on the rise in Indian women and it is estimated that the current life-time risk for developing BC in urban Indian women is 1 in 22 (ICMR Reports, 2009-11). Half of the women with a diagnosis of BC are under the age of 50, which is a decade earlier than that seen in the West, and the Age-Standardized-Ratio (ASR) is 33 per 1,00,000 population [1]. India has the highest BC incidence-to-mortality conversion rate in the world mainly attributed to late-stage presentation and hence, poor treatment outcomes[2]

Based on the presence of specific protein biomarkers, BCs are immunohistochemically sub-divided into clinical subtypes namely Hormonal (i.e., presence for estrogen receptor (ER), progesterone receptor (PR)), HER-2 positive (i.e., presence of Human Epidermal Growth Factor Receptor-2) and Triple Negative BCs (TNBCs). TNBC represents a clinical subtype of breast carcinomas defined by the absence of expression of three main predictive biomarker namely ER, PR and HER-2[3]

Importantly, the prevalence of TNBC subtype in India (at 30%) is twice as much as the reported levels

in Western cohorts[4], [5] Due to its aggressive nature and the lack of effective targeted therapies, patients with TNBC generally have a poorer prognosis (at least 10% lower disease free 5-year survival rate) vis-à-vis other BC subtypes[4]. Despite an initial favorable response to chemotherapy, disease recurrences are all too common within the first 3 years after initial therapy[6]. The majority of TNBC tumors are highly malignant with aggressive behaviour and most importantly presented among young women. Moreover, the high likelihood of visceral metastasis and shorter disease free survival in subgroups of TNBC patients is a matter of major concern for oncological outcomes[6].

Current chemotherapy regimens are prescribed empirically without *a priori* determination of the optimal combination of anti-cancer drugs owing to the absence of validated companion diagnostics. In addition, the identification of the TNBC subtype by a negative definition without a corresponding set of positive criteria has led to the grouping of what is clearly a very heterogeneous sub-[8 9]. Attempts over the past 5 years to dissect the heterogeneity have provided interesting leads [10] which as in the cases of many other human diseases, may or may not hold true for Indian populations. Furthermore, despite intense scrutiny by the scientific community and varied attempts by clinicians, there has been no major break-through in the clinical management of TNBC patients. Observations in several BC clinics in India and abroad have corroborated the underlying difficulties in treating this aggressive disease.

Notwithstanding the demographic differences, the relative contributions of genetic and behavioral factors (including nutritional and reproductive) of the Indian population to this higher TNBC incidence are yet to be established. There is also a need to systematically examine the correlation between clinico-epidemiological factors such as parity, BMI, T2DM and the TNBC sub-type in Indian women. Thus, there exists a clear unmet medical need to understand the biological and clinico-epidemiological characteristics of TNBC disease in the Indian context and a distinct opportunity to improve clinical outcomes by personalizing chemotherapy regimens. In addition, the unrestricted availability of data from multi-platform-omics analysis of hundreds of TNBCs (for e.g., databases such as TCGA 2015, METABRIC) makes this an opportune point-in-time to perform in depth focused clinical validation of rationally chosen molecular signatures and more extensive cross-ethnic comparisons [11] Modern-day Translational Cancer Research has immensely benefited by creation of Cancer BioBanks. BioBanks are ethically developed repositories of clinical data from patients and meticulously annotated biospecimens (for e.g., primary tissue, formalin-fixed paraffin blocks (FFPE), blood, urine, saliva, DNA, RNA etc.). Such repositories established in major cancer centers all over the world have provided invaluable information to cancer researchers in the design and development of predictive and prognostic biomarkers as well as new therapeutics [12]

In this paper, we describe a pilot project aimed at creation of a single institution TNBC BioBank aimed to serve as a research repository of Indian women affected by this disease.

METHODOLOGY

Study Population: This study is based on a retrospective and prospective data and biospecimen collection strategy conducted after approval of an Independent Ethics Committee. The study population includes TNBC patients registered at Orchid Breast Health Centre (OBHC), Pune and its allied centers. The inclusion criterion includes women diagnosed with TNBC who were willing to share their clinical history and FFPE blocks alongwith informed consent.

TNBC Clinical Management: Clinical protocols for TNBC diagnosis and management at OBHC were based on the National Comprehensive Cancer Network (NCCN) guidelines. Briefly, following the clinical breast examination by Breast Onco-surgeon, suspected cases were investigated by Radiologists using imaging modalities namely Full Field Digital Mammography (FFDM) with 3-D Tomoynthesis or Automated Breast Volume Scanner (ABVS) with an age cut-off of above 40 years and below 40 years, respectively. Thereafter, suspicious cases underwent precision biopsies either by use of Mammotome Biopsy, Vacuum-assisted Biopsy or Tru-Cut biopsy. Biopsied tissue samples and/or lymph nodes from suspected cases were sent to NABL-accredited pathology labs for further histopathological investigations inclusive of Nottingham Score and Immunohistochemistry (IHC) for determination of ER, PR and HER-2 receptor status. On IHC, ER and PR were considered positive if >1% tumor cell nuclei

were immunoreactive and negative if found otherwise. To establish HER-2 status, FDA test guidelines (0 and 1 is negative, 2+ is borderline, 3+ is positive) were used. Samples that were HER-2 negative on immunohistochemistry were further analyzed using Flourescence In-situ Hybridization (FISH). Based on immunohistochemistry findings the BC cases were divided into respective clinical subtypes.

Confirmed BC cases underwent appropriate BC surgery (e.g., modified radical mastectomy or breast oncoplastic surgery) at a network hospital site. The surgically excised healthy and BC tissues from the operative patient are then sent to NABL-accredited partner pathology labs for further investigations. Based on the clinical staging of the disease, standardized chemotherapy regimens as per NCCN guidelines were applied either prior to surgery (neoadjuvant chemotherapy, NACT) or post-surgery (adjuvant chemotherapy, ACT) under the supervision of a Medical Oncologist at the chemotherapy daycare facility of the OBHC. Furthermore, for margin-positive and multiple-lymph node positive BCs, a standardized radiation therapy protocol was utilized under the supervision of a Radiation Oncologist at the partner hospital site as per NCCN guidelines.

BioBank Protocols: Patient clinical registry was maintained at OBHC as part of Medical records. After a counseling and questionnaire session for study participants by clinical research staff, informed consent was obtained. The clinical data generated included demography (age, menopausal status), medical data (e.g., radiology imaging data, FNAC or biopsy, HPE with grade, surgical HPE, TNM staging, chemotherapy, radiation therapy) and survival status (e.g., follow-up, disease recurrence, local or distant metastasis, death due to disease or other than cancer, death due to treatment toxicity, last follow-up, loss to follow-up, shifted to other hospital or city for treatment etc.). Clinical data was stored in appropriate Hospital Information Management System (HIMS) by de-identifying the patient name.

For this pilot study, clinical data and post-surgery FFPE tumor blocks were collected both prospectively and retrospectively only from TNBC patients who gave informed consent in local language. If the patient agreed to participate in the study, appropriate provisions were made for collecting the FFPE blocks without causing travel inconvenience to them. To ensure privacy and confidentiality, appropriate sample codes were generated which were only accessible to the senior researchers on the study. Every tissue block was collected along with the histopathology report and stored in a cool dry place under lock and key. A separate log book is maintained for the tissue storage. These TNBC BioBank samples and clinical data were further used for research studies initiated by OBHC.

TNBC Radiology Database: From the study population of histopathologically-confirmed TNBC cases, Radiology image analysis was carried out on archived databases. FFDM (Siemens Mammomat Inspiration ™) and SonoMammography (Siemens S2000 ™) images were analyzed using BIRADS lexicon. Data on Sonomammography images, Color Doppler studies and Strain and Shear elastography were available for all cases. Masses were evaluated for size, shape, margins, density, posterior acoustic features, presence or absence of calcification. Other associated features such as architectural distortion, skin thickening, nipple retraction and status of axillary lymphadenopathy were analyzed.

Data Analysis: Preliminary statistical analysis was performed based on proportion of cases (from pilot study) identified with features of interest. Appropriate statistical tools (MS-Excel) were used for data management and analysis.

RESULTS

Clinico-Pathological Characteristics: During the period of January 2012-January 2017, 115 histopathologically confirmed TNBC cases were registered at OBHC and its allied centers. Out of this patient pool, we could establish contact with only 65 patients willing to participate in the study. Of the 65 cases, 44 subjects could share their complete clinical history as well as the FFPE blocks. Thus, this pilot study was restricted to a sample size of 44 cases which included TNBC cases ranging from early to advanced stage, NACT and ACT as well as radiation therapy.

The mean age of the patients was 49.7 years with a range of 31-78 years. 23 cases (52%) were postmenopausal while 21 (48%) were premenopausal. Analysis of the histopathology grade and Nottingham Scores indicated that this TNBC study population had higher number of cases of IDC Grade II (i.e. 21 /44;

48%). More than half (23/44; 53.5%) cases had a tumor size in between 2-5 cm indicating a predominantly T2 status of these tumors (Figure 1 A-D - Data represents actual numbers from study cohort of 44). 25% cases (11/44) were found to be node-positive (N1 status). 15 of the 44 (34%) cases indicated clinical staging of the disease as Stage IIA suggestive of loco-regional, early disease status. A majority of these cases (34/44; 79%) underwent NACT while the 21% cases (9/44 cases underwent ACT with NCCN-recommended regimens. The most commonly used NACT and ACT regimens were FEC (5-FluoUracil, Epirubicin and Cyclophosphamide) and CAT (cyclophosphamide, Adriamycin and Paclitaxel) respectively. Survival analysis indicated that majority (83%, 36/44) of TNBC patients in this study pool were alive. Oncological outcomes indicated that 6/44 (13.6%) cases had progressive disease with distant metastasis. Recurrent disease was not found in this TNBC study cohort.

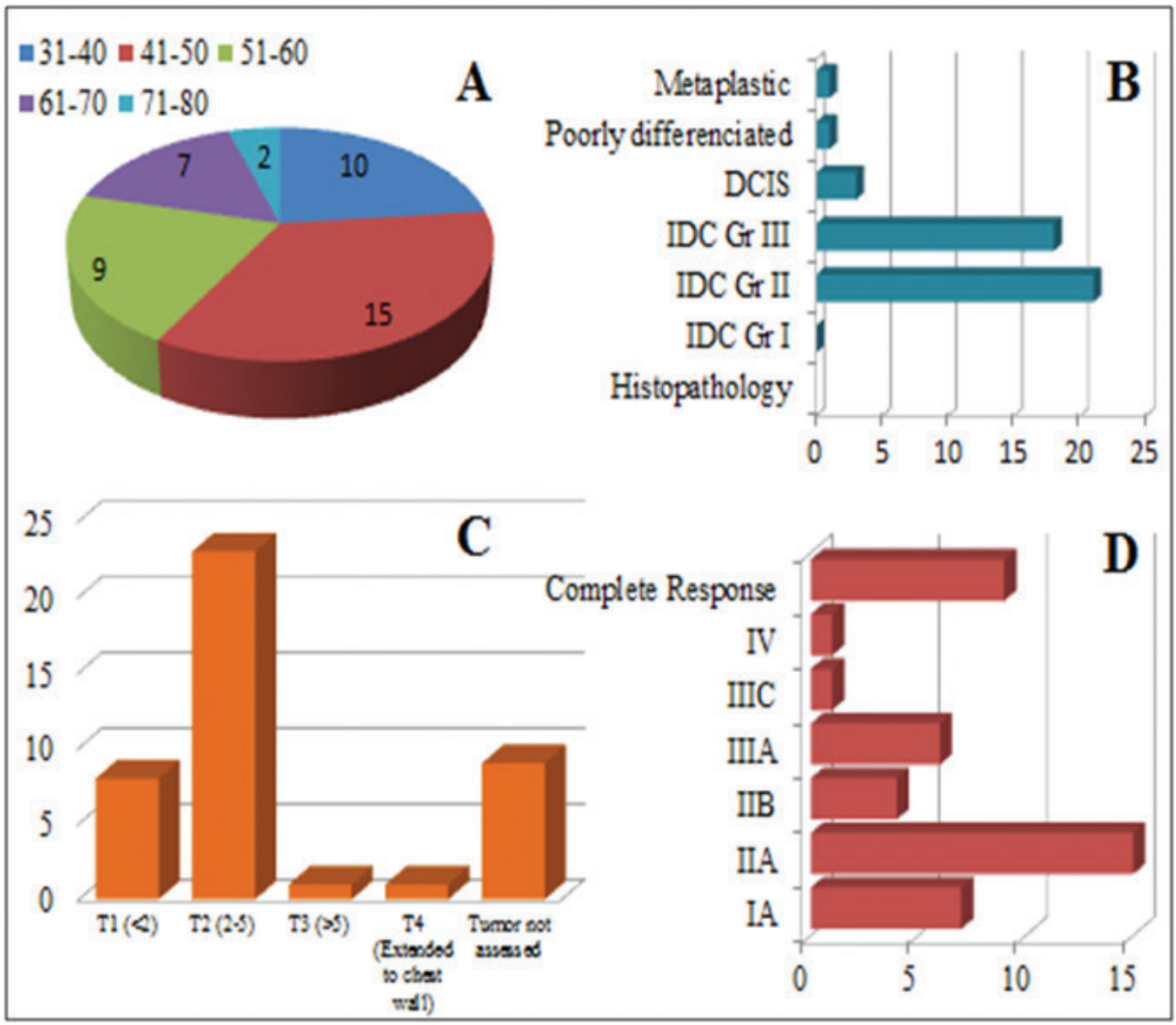


Figure 1: Clinico-Pathological Characteristics of Pilot TNBC BioBank
A: Age Distribution, B: Grade of Disease, C: Size of Tumor (in cm), D: Clinical TNM staging

Radiological Characteristics: Out of 44 cases in the TNBC BioBank, 25 cases were included for the Radiology image analysis study. FFDM images with Digital Breast Tomosynthesis were available in 22 out of 26 patients. Mammographic images indicated that 30 lesions were masses. While no asymmetries were found, one lesion was grouped as microcalcification without discrete mass. 85% masses had irregular shape Table 1).

Table 1: Mammographic Characteristics of TNBC

22 patients with 31 tumors		
Parameters	**Number (Total), Out of 31**	**%**
Appearance		
Mass	30	96.8
Focal Assymetry	0	0
Isolated Calcification	1	3.2
Architectural Distortion	0	0
MicroCalcifications		
Absent	25	80.6
Amorphus	1	3.2
Coarse Heterogeneous	0	0
Linear Branching	1	3.2
Fine Pleomorphic	4	12.8
Associated Features	**Number Total, Out of 22**	
Architectural Distortion	5	22.7
Skin Thickening	4	18.2
Oedema	4	18.2
Nipple Retraction	2	9.1

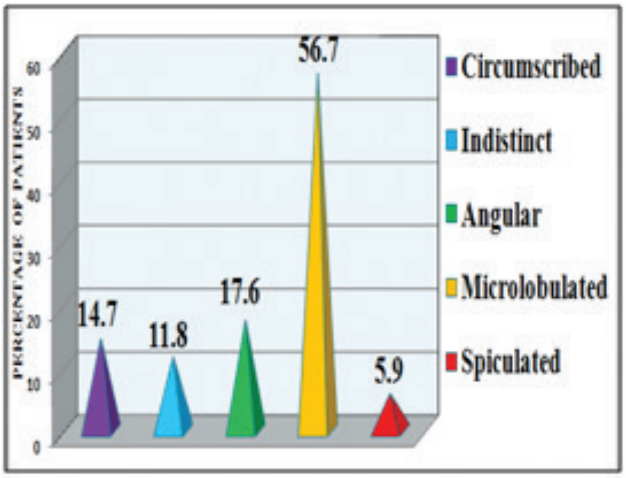


Figure 2: Sono Mammography Features of TNBC (Margin of Masses)

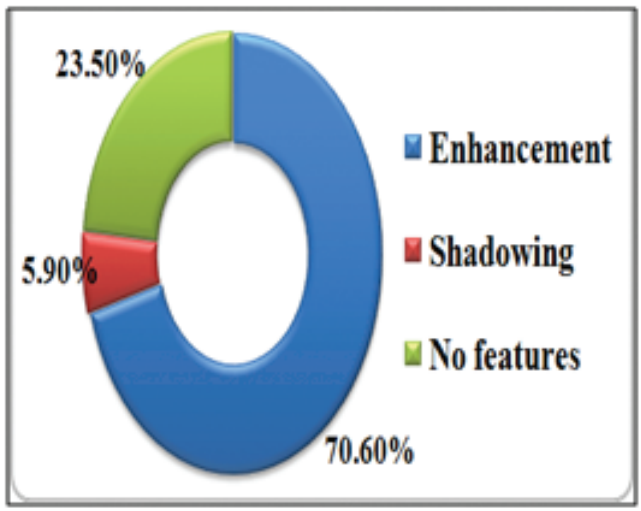


Figure 3: Sono Mammography Features of TNBC (Posterior Acoustic Features)

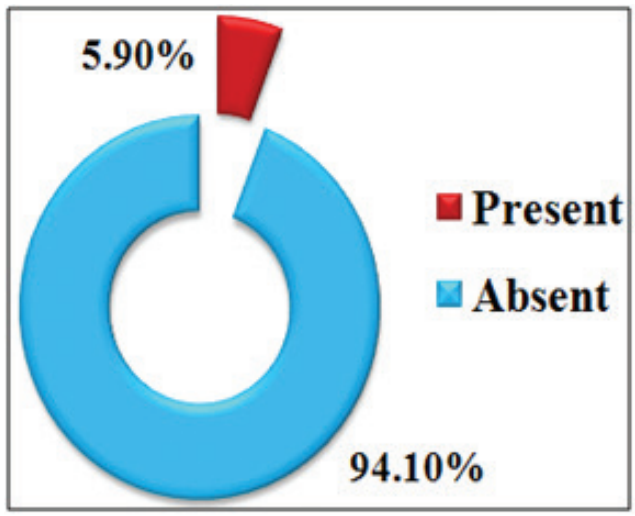


Figure 4: Sono Mammography Features of TNBC (Perilesional Echogenic Halo)

Tumor margins were most often partially circumscribed and partially obscured on mammography (38%) followed by microlobulated (19%) on SonoMammography. Spiculated margins were found only in 3 of 26 masses. Only 3 masses had intralesional microcalcification. Architectural distortion, skin thickening & nipple retraction were found in only 10-20% cases. On SonoMammography, microlobulated margins were most common (57%) followed by circumscribed (10%). Posterior acoustic changes were most commonly seen as enhancement (70%). Perilesional echogenic halo was present in only 2 masses. Preliminary comparisons between case studies representing TNBC images with other BC subtypes and breast abnormalities indicate that TNBC may appear similar to benign lesions (Figure 3).

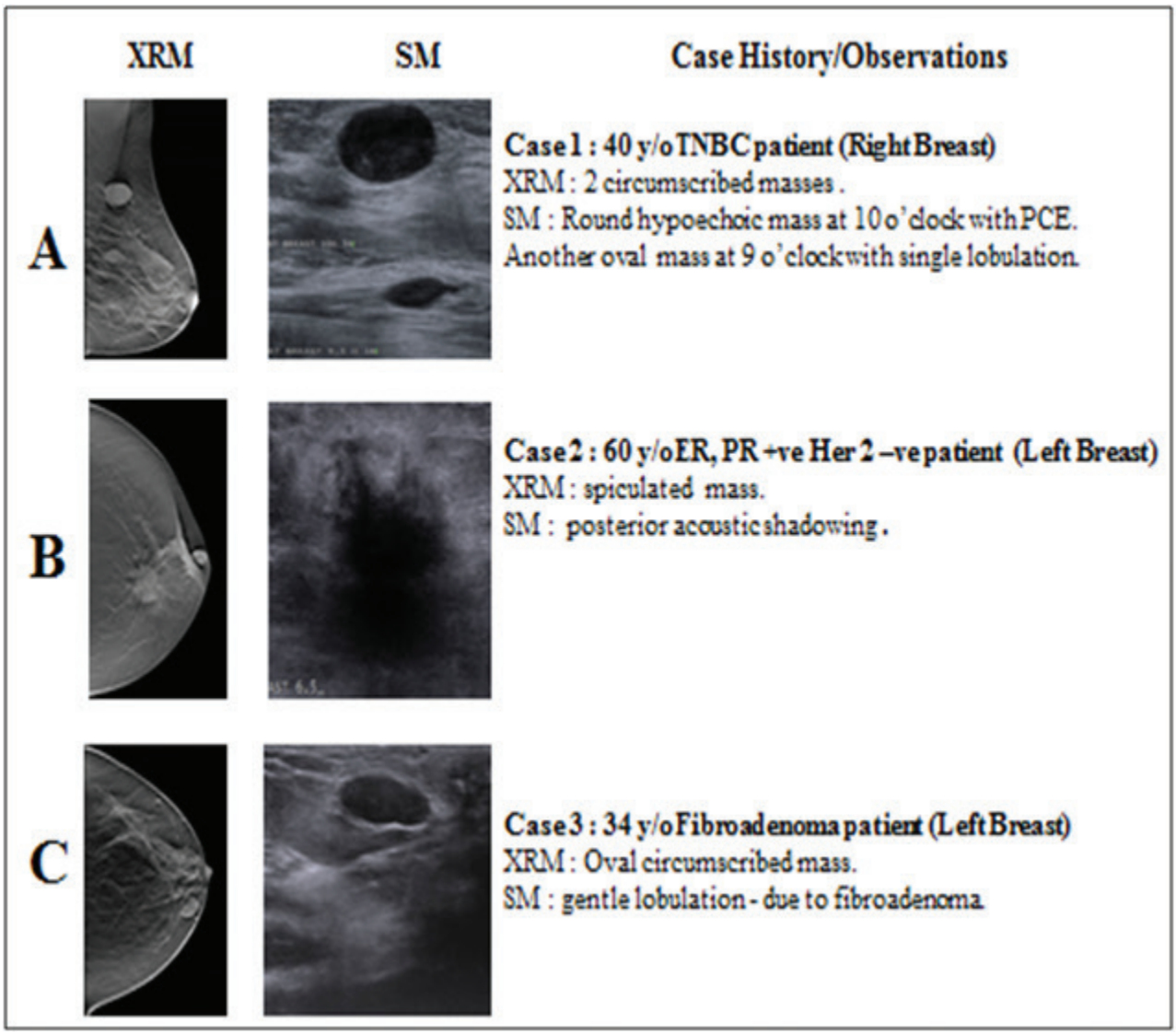


Figure 5: Comparative Analysis of TNBC tumors on Radiology Imaging
A: TNBC Case, B: HER-2 positive case, C: Fibroadenoma,
XRM: Mammography, SM: SonoMammography

DISCUSSIONS

TNBC represents a clinical BC subtype with aggressive biology, difficult clinical management, high risk of recurrence and hence, high mortality (Kreike et al., 2007). Thus, this disease remains a key focus area for of many BC researchers.

Translational Cancer research aims to apply findings from fundamental biology research into medical practice and meaningful health outcomes. Even though several translational TNBC research programs are active, breakthroughs in understanding the TNBC molecular profile that may influence clinical management of the disease are eagerly awaited. Interestingly, such intensive research efforts focused on understanding TNBC biology has identified the complex heterogeneity of this cancer along with novel predictive and prognostic biomarkers which are being explored for clinical drug development[10]

Most of the translational research that has influenced the guiding principles of modern-day TNBC clinical management has emerged from studies on western populations.[13], [14] Several studies have indicated that African American women have a higher propensity towards TNBC as compared to Caucasian women [15] Importantly, the prevalence of TNBC in Indian women is highest in the world (30% as compared to 10-15% in the west) [16], [5]. The etiological reasons underlying the increased TNBC risk burden in Indian women

are expected to be different from that in the western populations. Indeed, it is a well-documented fact that the global diversity in populations arises due to socio-economical, psychological, physiological and biological differences across ethnicities [17] Therefore, it is incorrect to simply extrapolate the research findings and TNBC management guidelines from western societies and apply to the Indian context. The lack of similar research in Indian women signifies a knowledge gap which can be only bridged by undertaking India-specific research programs in TNBC focused on the local context and population.

World-over, translational BC research has largely benefited from BC BioBanks which have provided invaluable clinical data and biospecimens for comparative studies between clinical subtypes as well as healthy women [18]. However, limited efforts have been noted in Indtia towards undertaking similar BC BioBanking approaches. With this background, OBHC has embarked on the creation of a pilot BC BioBank at our institution with focus on TNBC data collection.

Although limited in its scope and sample size, the present data has revealed few interesting observations. Close to 60% TNBCs patients diagnosed in our study cohort had age less than 50 years with a tumor size between 2-5 cm (T2 status). Majority of TNBCs appear to be of Grade II with clinical staging of Stage IIa representing locally operable BCs. In the past few years, TNBC imaging analysis in comparison to other BC subtypes has been an active area of Radiology research[19],[20]. Interestingly, our radiological imaging study on a subset of TNBC tumors has identified potential differentiating characteristics that may aid in the visual analysis by Radiologists. We observed that TNBCs lack typical radiological features of BC namely spiculated margins, posterior acoustic shadowing and microcalcification [21], [22] [23] In contrast, TNBCs show circumscribed margins and posterior acoustic enhancement. The comparison of our findings with reference to literature studies is presented in Table 1.

This pilot study aimed at creating a TNBC BioBank has inherent limitations. Despite the interesting findings, the current BioBank-initiated study with limited sample size is not qualified to make any major conclusions on the unique clinic-pathological or radiological characteristics of TNBCs in India women. Further, being a single-institutional study, the data collection may reflect investigator bias. Given the high loss-to-follow-up rates in the study cohort, there is scope for improvement of clinical data management protocols at OBHC to ensure up-to-date maintenance of case record forms of patients visiting the clinic. Innovative methods such as maintaining regular contact with BC patients treated at the clinic (via pink-ribbon patient support groups) are being undertaken so that patients are sensitized to timely follow-up thereby, ensuring lower dropout rates. Our observations also indicate that the FFPE blocks collected from patients are either from different pathological laboratories or not well maintained by TNBC patients. Thus, this sample non-uniformity will create variability in the data collection envisaged for the TNBC BioBank. Clearly, these limitations can be overcome by continuous commitment to improving and standardizing the existing protocols for data collection, storage and retrieval.

Table 2: Comparison of TNBC Radiological features with Literature

FEATURE	LITERATURE REVIEW	CURRENT STUDY, % Distribution
Age	Younger age	>50% cases <50 years
Appearance	Masses (Common). Interval cancers common due to rapid growth.	Masses (96.8%)
Margins	Circumscribed, microlobulated margins (Common) Smooth /pushing border (rapid tumor growth and absence of infiltrating margin). TNBC mimic benign lesions leading to its delayed diagnosis.	Microlobulated (56.7%), Circumscribed (15%), Spiculated (5.9%)
Posterior Acoustic Features	Enhancement most common (like benign lesions). TNBC: Syncytial growth pattern (good propagation of ultrasonic waves). Non-TNBC : Trabecular growth pattern(shadowing)	Enhancement (70.6%)
Perilesional Halo	Absent. Echogenic halo seen (inflammation and desmoplastic reaction in ER, PR +ve tumors).	Absent (94.1%)
Micro-Calcifications	Rare. Low incidence of in situ stage, Rapid carcinogenesis leading to IDC status	Absent (80.6%)
Histo-Pathology	Grade III tumors most common	Grade III (46.2%), Grade II- (42.3%)

Nevertheless, the pilot version of this unique TNBC BioBank has shown promise for conducting hypothesis-driven translational research in Indian women. OBHC has undertaken efforts to populate the TNBC BioBank and radiology database with more cases from our clinic as well as from other BC diagnostic centers. The availability of well-curated Radiology database has enabled initiation of interesting collaborations with imaging scientists. These projects will be focused on the development of predictive machine learning based algorithms for comparing radiological features of TNBCs with other BC subtypes, non-cancer breast diseases or health breast tissue.

Furthermore, as part of its future BioBanking initiative, OBHC will expand its biospecimen collection by inclusion of FFPE blocks representing other BC subtypes as well as other biospecimens such as primary cancer tissue, blood, urine, saliva , DNA etc. It is interesting to note that the TNBC FFPE block collection at OBHC has resulted in the genesis of collaborative research projects with like-minded BC translational researchers in India and abroad. We have initiated a project aimed at understanding the mutational hotspots in well-studied cancer-related genes from Indian TNBC patients. High-quality DNA isolated from tumor-rich regions of TNBC FFPE blocks in our BioBank is being subjected to next-generation sequencing (NGS). Such study in Indian TNBCs has not been undertaken previously and is expected to reveal novel insights in TNBC biology. It is possible that identification of actionable mutations in molecular signaling pathways can pave the way for future anti-cancer drug discovery and development.

In conclusion, the pilot study aimed at creation of TNBC BioBank at OBHC has facilitated the creation of a novel repository of clinical data and biospecimens. This unique research database has generated a novel model for fostering multi-disciplinary research collaborations

with like-minded scientists interested in BC research from India and abroad.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Maternal Perceptions On The Health Seeking Behaviour During Childhood Illnesses - A Mixed Method Study From Rural Patna, Bihar

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ABSTRACT

Purpose: Despite the massive efforts undertaken by various national and international agencies, childhood malnutrition remains as a major public health challenge in Bihar. Often childhood illnesses are aggravated due to the existing malnutrition, poor care and management, and the challenges experienced by the mothers in accessing healthcare facilities. The present study aimed to understand health seeking behaviour of mothers during illnesses of their children aged less than 2 years and the factors influencing the same.

Methods: Cross-sectional study was conducted in 4 blocks of Patna district, Bihar. Mothers of children (n=71) aged less than 2 years were recruited for the study. Information on socio-demographic factors, infant and young child feeding practices and health seeking behaviour during illness was collected from mothers using a pretested interviewer administered questionnaire.

Results: There were about 73 children (including two pairs of twins) in the study malnourished (n=56) and normal (n=17). The majority of children (93%) were having common childhood illnesses such as diarrhea, fever, common cold or measles. Of the 56 malnourished children, 73% (n=41) were not exclusively breastfed. The mother's health seeking behaviour was majorly influenced by perceived severity of the disease, consultation fees charged by service providers and flexibility in payments.

Keywords: *Health seeking behaviour, child, illnesses, consultation fees*

INTRODUCTION

In 2015, 5.9 million of children under 5 years of age died globally and almost half of these deaths could be attributed to infectious diseases such as pneumonia, diarrhea, malaria, meningitis, tetanus, measles, sepsis and AIDS[1]. India ranks number one in death due to pneumonia & diarrhea[2]. Cognitive and physical development of children is effected by both the severity and frequency of these illnesses episodes. The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) have emphasized the importance of seeking early care during illness[3]. On the another front IMNCI (Integrated Management of Newborn Childhood Illness) guidelines developed by WHO and UNICEF, focused on both preventive and curative practices for family and community to improve child health and decrease mortality due to these preventable causes[3]. The first point of action is the crucial part of managing childhood illnesses which is primarily governed by health seeking behaviour of the care givers. Thus, a proactive behaviour is necessary for proper wellbeing of children and their overall development[4]. Maternal perception of illnesses directly influences their health seeking behaviour. The WHO has prioritized the research on identification of barriers for access and seeking healthcare services using the methodology of the 'Child Health and Nutrition Research Initiative (CHNRI)'(Chandwani & Pandor 2015)[3].

Health seeking behaviour by mothers is governed by many social factors some of which are the perceived severity, socio-economic status of family, and access to health care provider. Framework developed by Kroege take into account the major underlying factors that govern the health seeking behaviour (Kroeger 1983)[5].

The present study was carried out to understand the perspectives of mothers on the illnesses of their children

below two years to get the qualitative perspective of their health seeking behaviour and factors governing it. The objective of the study was to determine the possible factors that affect the health seeking behaviour of mothers with regard to their children in rural Patna district.

METHODS

Study setting and participants: Patna, the capital and largest city of the state of Bihar in India with a population of 1.68 million in 2011 (Census, 2011) [6]. About 49.2 % of children below five years of age were reported to be underweight in rural Patna district (NFHS, 2015-2016) [7]. The study was conducted in 4 blocks- Maner, Bihta, Paliganj and Massuhari and 3 villages from each block were randomly selected using a lottery method (Dahibatta, Kariyawagarh, Harwanshpur, Swarmarwa, Madhupur, Pahila, Lalganj sehra, Sandosh, Mahabalipur ,Bela, Dumri and Nathupur). In population area of each Anganwadi centre (AWC), an index household was marked on the day of data collection and every third household was included. Data was collected through house to house visit by the investigator in a clock-wise manner to ensure saturation of the whole area of the respective AWC. The study was explained to the participants and a verbal informed consent was taken from the participants before the interview. Precautions were taken to ensure privacy during the interview. Children with critical illnesses were excluded from the study. A total of 73 children under 2 years of age and their mothers were included in the present study.

Study design: A community based cross-sectional study.

Study tool and technique: A pre-designed and tested semi-structured questionnaire was used in the present study to conduct personal interviews of mothers. The questionnaire was developed based on the literature review and the group consensus. The tool aimed at obtaining details about the health seeking behaviour of mothers for their children (under 2 years of age) during illnesses (Illness was defined as any common childhood illnesses- Diarrhea, ARI, Fever and Measles suffered by child in past 14 days from the day of data collection). Each interview lasted for about 30 minutes. Data was analyzed using EXCEL program, and proportions and frequencies were determined.

RESULTS

Characteristics of children: There were 73 children (including two pair of twins) in the study, of which 56 were malnourished and 17 were normal. Of the 56 malnourished children, 46.4% (n=26) children were severely malnourished, and 53.6% (n=30) were moderately malnourished. Of the 73, children of 0-5 month constituted 25% (n=18), 6-11 month constituted 48% (n=35) and 12-24 month constituted 27% (n=20) [Fig.1].

Most of the children 94% (n=69) were having common childhood illnesses such as diarrhea (n=13), fever (n=5), cold and cough (n=2), measles (n=5) and combination of these illness was analyzed as one separate group and was referred to as case of diarrhea and fever, diarrhea and cold or cough, fever and cold or cough (n=44) [Fig 2].

Mother's health seeking behaviour during childhood illnesses: Of all women (n=71), 64% (n=47) belonged to lower socio-economic status and 34% (n=24) belonged to middle socio-economic status. Mothers were asked information on first point of contact to health provider for advice/treatment. About 83% (n=39) of the women belonging to low socio-economic background reported that they approached Non-Qualified Quacks at first for advice or treatment. The major reasons for visiting quacks were immediate relief from the symptoms, sense of trust, flexibility in payment and no additional consultation fees. All (n=24) the women of middle socio-economic status reported to visit private practitioners as first point of action [Fig.3].

Cross cutting issues: Consultation fees charged by private practitioners was the main reason given by women of low socio-economic status for not visiting them at first. But, all (n=47) reported that if health condition of the child worsened after 2 days with Quack's treatment, they visited a private practitioner.

About 80% (n=57) of the mothers perceived monthly meetings at the AWC were more effective than home visits for generating health awareness regarding sanitation, hygiene, feeding practices. For health communication and promotion, AWCs are used as one of the platform for awareness generation and bringing positive behaviour change in community. In Bihar context, these meetings at AWC are in the form of

Annprashan divas, Viridhi nigrani divas, Village Health Sanitation and Nutrition Day and other such meetings. This could be due to its participatory and interactive approach, understanding from other's experiences and efficient use of Information Education Communication IEC material used for health education.

Consultation fees and its effect: Women belonging to the middle class families sought private practitioners help for treatment, even when it was chargeable (INR= 200) as a separate consultation charge in addition to the cost of medicines. Whereas, women of low socio-economic class generally approached quacks as first line of advice. There were no separate charges for consultation and within 100 INR they also received medicines. As mentioned by the mothers, Quacks give medicines for 2 days per consultation visit. In case of persistent illnesses and health conditions, (Lethargy, drowsiness, irritable) of the children after consultation with the quacks, the mothers visited the private practitioners despite being chargeable. Information gathered from interviews also reflected that, quacks were only approached for common illnesses like diarrhea, fever, persistent vomiting etc. Other reasons that were reflected from the data were: round the clock availability of the quack in the village and a sense of trust that was established from prior events.

Nominal user fee has been charged by government for provision of primary health at the Primary Health Centre (PHC). Even then, approach to these facilities for the treatment of common illnesses was not preferred for several reasons: lack of supplies of basic medicines, long queues for making Out Patient Department (OPD) card and disrespectful behaviour of medical officers on duty on clarification of doubts. Moreover, mothers also perceived that going to PHC's out of their busy schedule and spending resources on transport, standing in long queues for receiving a prescription and buying medicines themselves as a less feasible and unrealistic solution. Such reasons may have also influenced their decision on seeking health care from quacks.

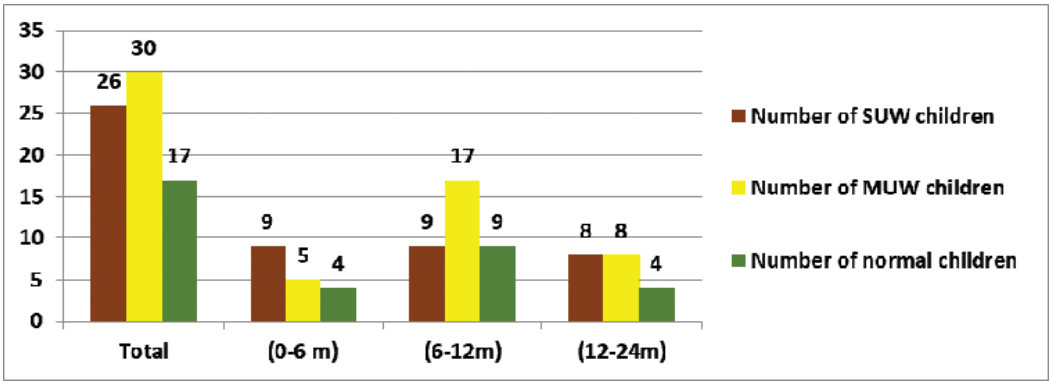


Fig. 1: Age wise categorization of SUW, MUW and normal children, N= 73

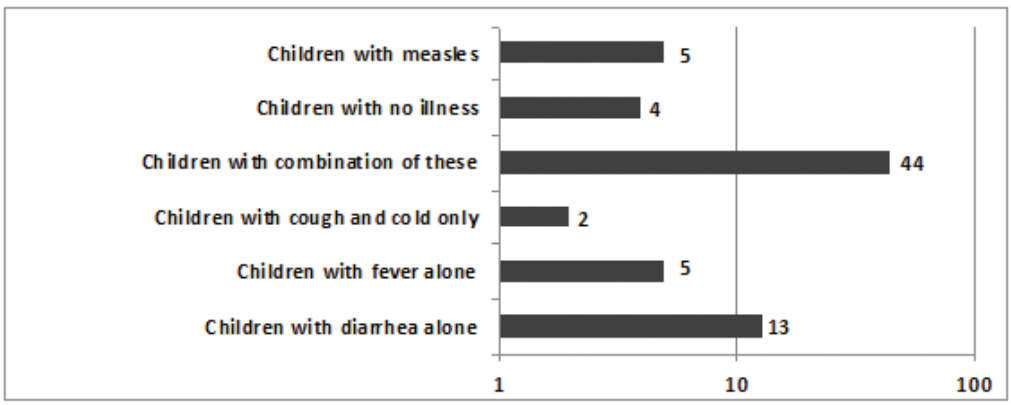


Fig 2: Illness distribution in children, N=73, combination refers to case of diarrhea and fever, diarrhea and cold or cough, fever and cold or cough

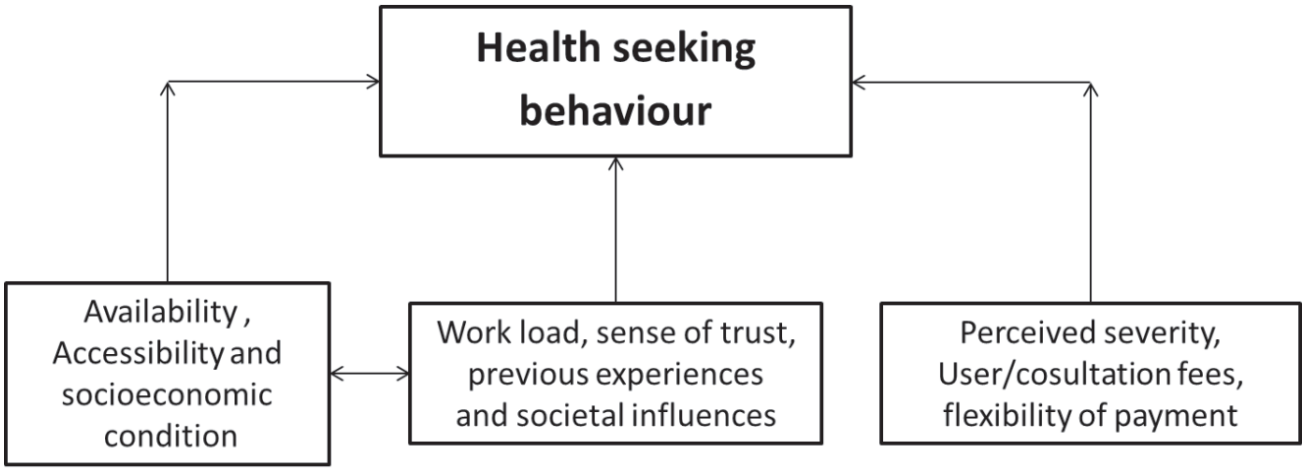


Fig 3: Factors influencing health seeking behaviour

DISCUSSION

The present study was aimed to understand the maternal perception of the illnesses of their children and their health seeking behaviour during childhood illnesses. Information showed that multiple factors influenced their decision on health seeking behaviour. Perceived severity of the disease was one of the major reasons that influenced the health seeking behaviour. Usually mothers wait for a day before seeking healthcare but if the child suffers from higher body temperature (fever) or vomiting, an immediate treatment was sought the same day as it was perceived as an alarming condition. Consultation fee charged by healthcare providers, was another major factor that influenced the maternal decision. Mothers belonging to lower socio-economic status preferred low cost alternative treatments at the initial stages. When the health condition of children worsened, the monetary aspects no longer influenced their health-care seeking behaviour. Mothers perceived a higher opportunity cost due to finding time out of their routine schedule, unavailability of basic medicines at the PHC and lack support from the healthcare workers to clarify their doubts.

Also, of all platforms used by AWWs, monthly meeting was preferred as the most effective way for generating awareness through interactive sessions. This could be due to interaction of majority of the mothers of the village at AWC, efficient use of Information Education Communication (IEC) material present at AWC such as posters, booklets, pamphlets etc and multimedia-based education used by AWWs. Discussion over common issues such as sanitation, nutrition advice, hygiene and its role for disease prevention was preferred by the mothers and were found to be efficient during these sessions. Additionally, such sessions provided an opportunity to have positive deviance and learning from other perspectives.

CONCLUSION

To conclude, perceived severity of the illness and consultation fees charged by the healthcare providers were the major factors that influenced the mother's decision for heath seeking behaviour during the childhood illness. Monthly meetings were found to be a preferred platform for awareness generation and inculcating positive behaviour change in mothers of these villages.

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Conflict of Interest: Nil

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HIV/AIDS Initiative in India: Community Mobilization and Sustainability of Health Care

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ABSTRACT

Community mobilization can lower the risk of HIV infection and help enhance and sustain the HIV/AIDS prevention program. Its applicability has been proved valuable while working with the sex workers and other high risk groups affected by HIV/AIDS infection. The challenges to community mobilisation basically include the absence of a sense of shared identity. Although the Community Mobilization (CM) approach is used in HIV/AIDS intervention programs, it fails to address structural barriers and related policy implications. A specific and in-depth analysis of community mobilisation relevant at the individual group level was conducted among two community based groups (CBGs) in Maharashtra using focused group discussion and participatory research methodology. The findings highlight that CM through these CBGs successfully implements the existing government programs among high risk groups but faces structural barriers while dealing with vulnerable groups. The finding introduces the community mobilisation group (CMB) models into our health policy ensuring that communities address prevention of disease and related challenges among stigmatized groups thereby enabling subsequent policy changes to overcome structural barriers. Considering the limited availability of healthcare resources, this method can optimize the program by strengthening the performance and elevating the sustainability levels thereby encouraging its inclusion in policymaking.

Keywords: *CBOs, Community mobilization, HIV/AIDS, Health care, High risk group, Targeted intervention*

INTRODUCTION

As per UNAIDS report on global AIDs epidemic, with 2.1 million people living with HIV and with an HIV prevalence rate of 0.26%, India ranks third, after South Africa and Nigeria, among the countries with the largest number of HIV-infected people. Through diverse HIV/AIDS Intervention programs, India has shown a downward trend in HIV epidemic with a 32% decline in new infections (86,000) in 2015 and a 54% decline in AIDS related deaths between 2007 and 2015. In India, one of the major causes of HIV/AIDS transmission is unprotected heterosexual intercourse, which accounts for 87% of the transmission. Other reported factors include parent to child transmission (5.4%) and high risk individuals and groups comprising Injecting drug users (IDU 9.2%); men who had sex with men (MSM-7.3%) and women sex workers (4.9%). Besides these risk groups, the large pool of migrant labourers and truckers act as the connecting link between the high risk groups and the general population.

The HIV/AIDS prevalence rate among antenatal clinic attendees is merely 0.48%. Much of the HIV/AIDS related focus has been on services rendered in marginalised societies due to which the interpersonal dynamics as well as political and socio-economic transformations in dealing with the epidemic is largely ignored. People are considered as entities located in isolated spheres requiring control by external agents. The target oriented approach is one in which people are targeted without considering their experiences and sufferings which are difficult to measure quantitatively. When we target communities and vulnerable groups, we subject them to "profound ill effects of structural violence and pathologies of power". But the communities mobilised for HIV/AIDS prevention in India, identified the communities not only as targets but also as partners in the development process. In India, as in other countries, community mobilization had proved valuable in working with sex workers and other high risk groups as an approach that can reduce the risk of HIV infections and enhance program relevance and sustainability[1] In 2010, under Bill and Melinda Gates Foundation (BMGF) Initiative in India[2], 140 community groups or organizations were formed, some of which are legally registered and charge nominal membership fees.

This enhanced scope of the programme complements the National Aids Control Program III, which also aims to strengthen participatory programming to build community networks[3-5].

The National AIDs Control Program of India (2007-12) was launched to provide prevention, care, support and treatment with an objective of reducing the infection by 60% in high prevalence states[6]. During the course of this phase, AVAHAN transferred the Targeted Intervention programme to its natural stakeholders, the Government of India and communities. For community members, NACO proposed that targeted Intervention through Community Based Organisations (CBOs)/ Non-Governmental Organisation (NGOs) will continue to emphasize and focus on the six elements of prevention, four being behavioural change, Sexually Transmitted Infection (STI) services; condom and needle syringe provision and linkages to care and support to address the proximal causes of HIV[7-9]. The other two components include CBO ownership and creating an enabling environment to address the distal causes. As far as ownership building is concerned, NACO envisages that the existing targeted intervention will adopt a rights based approach to ensure the empowerment of the communities and their ownership of the programme. Therefore, developing leadership skills and management capacity among such CBOs/NGOs will be accorded priority. Towards creating an enabling environment, NACO designed a project to empower the communities to provide crisis intervention services. The collectivization of the community was undertaken by AVAHAN with the help of NGOs and the Government to guide them to reduce social maladjustments and violence in the community. The project focused on disease prevention activities of the community, on identifying the social causes and on creating awareness among the community on sexually transmitted and reproductive tract infections (Reproductive Tract Infections (RTIs). Sexually transmitted infections (STIs) and HIV/AIDS are being increasingly recognised as a serious public health problem[10-13].

The term community was understood as those sharing a common identity linked to common life situations and practices such as homosexuality, sex work and drug use which, perceptibly, put them at a higher risk of HIV/ AIDS as compared to the surrounding populations. This model is based on the indispensability of community ownership for long term project sustainability[14]. The program strategy of build and operate, replicate and transfer is ideal and the AVAHAN program aimed to offer support for community mobilisation and ownership of the program. The program aimed at transitioning the targeted intervention project to its own owners for disease management and control through the sustainable model of community participation and to take ownership of the agenda of change[15]. Different parameters were developed to assess the community mobilisation initiatives and for the monitoring of the project in consultation with the community members in a dialogic way by enabling them to raise objections. The parameters of community preparedness include leadership, governance, decision-making, resource mobilisation, community collective networks, project risk management, engagement with the state and other key stakeholders, with the dimension of internal organisational strength, sustainability of the mobilisation efforts and capacity to manage and own targeted intervention and ability to influence and engage with the larger society and state[16-18]. The purpose of this study is to assess the success level of community ownership model and to identify the challenges of its positive implementation in India, with special reference to Maharashtra.

METHODOLOGY

A detailed analysis of community mobilization at the level of individual groups was conducted among two Community-based groups (CBGs) operating in Maharashtra using focused group discussions involving participatory research methodology (PRM). Leaders, officer bearers and members of the community in which the project was conducted, participated in the discussion. The researchers acted only as facilitators by allowing the community to participate freely in the discussions. The NGOs supporting these CBOs also participated in the focused group discussions along with community members. The purpose of this current research was stated and the consent of the participants were taken before the discussions. The questions were based on the perception of community members about the working of community based organizations in prevention of HIV/ AIDS, the rendering of support and service and their progress from being 'users' of HIV services to 'owners 'of these services and from being 'aware' of their rights and entitlements to actually 'claiming' them. Each question was initiated with the main question, "To what

degree do you think that the community ownership of the initiative is successful in achieving the objective of sustainability. The follow up questions were based on: 1) The communities' perception of the internal governing system and accountability of the leadership in the CBOs. 2) The communities' perception of the capacity of the CBOs to monitor and strategize service delivery for HIV reduction 3) The attitude of communities about the competence of CBOs in addressing violence and vulnerabilities and their networking skills with other groups and the state; 4) The communities' perception of hindrance to community ownership of the project. The definition of community ownership was not narrow and the discussion motivated the participants to share their experiences and opinions about the local factors affecting the community ownership of HIV/AIDS interventions[19-20]. The focused group discussions were analyzed by using the thematic analysis approach which involves generating a list of codes, applying them to the transcripts and obtaining a thematic framework by identifying recurring themes through tabulation.

RESULTS

From the analysis of the interactions with the two community based organizations in Maharashtra and the supporting NGOs, two themes were identified (i) encouraging factors of community ownership and (ii) challenging factors of community ownership the details of which are as follows:

Encouraging factors: The participants perceived that the targeted interventions through CBOs created leadership in the community, which enabled to mobilize the communities with specific visions, missions and clear objectives. This facilitated the development of leadership capacity among the community members to set the community agenda independent of any outside agency or interventions. The leadership component in CBOs helped in mobilizing and uniting the community through common cohesion and consciousness as well as in internalizing the community's vision and creating solidarity among its members. However, both the CBOs mentioned that the existing leadership failed to create a second line leadership or a new leadership, which is a core element in the empowerment of the community, based organizations. A majority of the participants confirmed that the community mobilization and targeted intervention helped them to take rational and quick strategic decisions, which are crucial in identifying emerging risks as well as finding solutions together as a group. The participants articulated that project assisted communities to associate, network and engage with wider civil society groups in a cohesive manner for information and resource sharing from which the communities benefited enormously. Participants expressed that their capacity in asserting their identity with the general population, gatekeepers, opinion makers and moral guardians widened through this process, which is anti-discriminatory and empowering to the communities. Networking also increased awareness of the communities towards their situations which equipped them to be prepared for their future course of action through experience sharing. Community based organizations also made the individuals in these communities responsible and accountable not only for their own lives but also for those of their community members which vitalized the interpersonal dynamics of the community as a whole.

Challenging factors: Most of the participants in both CBOs opined that their capacity to mobilize resources seems to be the core challenging factor in continuing with their program. Over the years, the knowledge of the multiple resource mobilization resources is negligible and the quantum of amount mobilized is meager and the overall resource mobilization capacity as well as the ability to create corpus is shrinking. Resource crunch is adversely affecting the community initiatives and program implementation. In the mobilized communities, governance appears to be another major challenge as per this study. The participants involved in this study identified the chief barriers in CBOs as lack of institutionalization of the system, lack of participatory selection/election process of leaders and board members, unavailability of established rules, procedures, duties and responsibilities of committee members and the absence of accountability of the leaders towards the community and a lack of inclusiveness in leadership training. Even though the focused group's discussion clarified that the project facilitated the networking and outreach activities and information sharing with multiple stakeholders, most of the participants agreed that the engagement with the state deteriorated over the period. As per the participants as well as the leaders of the CBOs, the capacity or bargaining power of the CBOs as well as their knowledge and awareness of the laws pertaining to their rights and entitlements decrease over a period

of time. There is a strong need felt for understanding the processes to be followed, to claim rights for CBOs as informal organizations and networking with the state for the strengthening of CBOs. Overall development of the communities through innovative policies and legal interventions to reduce stigma, discrimination and despair is possible only through interaction and interface with the state machineries. Another obstacle in community ownership pattern appears to be the project management by the CBOs, which seems unsatisfactory and ineffective in operational level. Awareness of the legal and statutory requirements and the attitude and skills required to manage the collective group is feeble in the CBOs concerned. CBOs strength in managing the administrative system and financial resources is meager and skills development through training in this area is crucial in the success of the community ownership of the program. Another factor in the journey towards empowerment of the communities is negotiating with the wider community in overcoming stigma and discrimination and to include them as equal partners and participants in the wider community, society and state.

DISCUSSION

The research findings reflect that community mobilization initiatives in India successfully enable capacity building and transferring of ownership to the community thereby bringing behavioural changes in the lives of the people[21]. It is an effective model in health service delivery pertaining to targeted groups through a shift in approach from being 'users' of HIV services to 'owners 'of these services, and from being 'aware' of their rights and entitlements to 'claim' their rights and entitlement[22-25]. Leadership, decision making skills, networking with society are the positive traits of community health mobilization initiatives highlighted through this study. Community ownership needs to be sustained in targeted group intervention to facilitate sustainable developments, skills development, capacity building in these community based organisation. Community preparedness to impart development is practical, only if the communities themselves are equipped to assess themselves and their readiness to govern. This study recognized resource mobilisation, project management and engagement with state as barriers to community ownership[26-28]. It is a well appreciated fact that data creation and utilization by the CBOs to analyse their progression and organisational development level will make them accountable. It will ensure capacity building activities to develop themselves, instead of depending on the outside agencies from getting involved in preparing and monitoring the project using their own parameters. Along with the formal system of assessment with a specific framework, the impressions of the members of the community about the way in which the CBO is progressing in the midst of their daily work is worth analysing. The ability of the CBOs to meet deadlines, organise meetings, their relationship with fellow organisations and informal social networks as well as other support structures is relevant to check whether they judge their progression based on fixed variables depending on empirically observable data. Readiness to unlearn, to be flexible and to adapt to the differences according to the changing context with deeper and comprehensive learning of the self-monitoring process is vital to ease the revision of benchmarks in response to diverse contexts[29].

CONCLUSION AND SUGGESTIONS

Community mobilization has been found to be the best available option for HIV/AIDS related health delivery, disease control and treatment in developing countries and is the accepted model as far as sustainability of development is concerned. Creation of community based organizations in India as a part of the targeted intervention is commendable. However, the community's preparedness to continue the initiative on their own without external support and to own their intervention independently has still not been achieved across all the CBOs. Governance issues, Resource mobilization, project management, engagement with state to own their rights and entitlements are the main challenges confronting some CBOs and preventing them from becoming formal sustainable organisations[30]. Capacity building and facilitation in terms of resource mobilisation and management is vital in order to prepare the community based organisations to manage on their own. Community ownership can be introduced by setting up clear rules, enabling best practices, training in advocacy to engage with the state in protecting and promoting their rights and entitlements through effective leadership. Different organizations plan and implement specific community intervention activities differently due to the structural barriers involved in the community

based organisation model[31]. These CBOs operate with little legal awareness, ineffective advocacy to ascertain their rights and entitlements, scarce availability and accessibility of health care facilities and lack of equality. In a social system where the health care staff, the police, lawyers, counsellors, state officials and the community at large looks down upon these CBOs instead of as equal partners in a democratic set up, they are labelled as a liability to the social system.

In order to follow the CBO model in the sustainability of HIV/AIDS programmes, healthcare facilities must warrant expanding and strengthening of services in terms of timings, facilities and other mental health needs. Support of the civil society and the state needs to be provided while working with the general public to implement the educational and sensitisation programs to reduce stigma and discrimination associated with HIV/AIDS, same sex groups and transgender communities. As an integrated health care approach of different stakeholders is essential to make health care sustainable for all, NGOs must engage with the CBOs as guides and facilitators rather than donors, a change makers or leaders. Another challenge is the target-driven approach, which targets people without looking at their experiences and suffering merely to achieve verifiable quantitative data. Caution be taken to ensure that the target approach does not cause a backlash to the ongoing HIV/AIDS management program. The pyramid-like structured program with the peer educators as soldiers set to meet the targets without proper wages, will not serve the purpose. If the community-based organisations are viewed as the vehicles for targeted interventions program and to equip the communities to take care of their own affairs, they then require system support not only from the government and the NGOs, but also honest efforts from the wider society. Support is also required from health care services, counsellors, lawyers, the neighbourhood, educational and employment institutions and from the media who view these CBOs with respect and understanding as equal partners in the development of the society and not as vulnerable groups. NGOs in India still have to play a vital role in developing and empowering these CBOs through capacity building workshops since the then acquired expertise through this training will create new NGO-CBO dynamics. If the CBOs established through these targeted interventions comprise community members equipped with the skills of monitoring, interpretation, planning, resource mobilisation and networking, the supporting role of NGOs will decrease gradually. The monitoring scores of the CBOs in terms of fixed variables and parameters may be exaggerated to put their best foot forward in terms of judgements by external stakeholders[31].

Monitoring mechanisms encouraged documentation, expertise in paper work, and a good input for planning for the next interventions. Valuing the performance for internal consumptions encourages self monitoring framework which promotes discussions among themselves rather than creating data, which act as an important vehicle for learning, a tool for critical reflection and a vital resource for learning and action. The increasing systematisation of CBOs raises the question of the extent to which the CBO leaders are rooted in the communities they represent in order to avoid the emergence of an elite class of CBOs emerging out of it. The required model is one in which there is openness to community leadership, the weak are respected and listened to, allowed self-appraisal and analysis along with taking care of their own priorities so that they show capabilities beyond what many development professionals perceive. Power relations have to be reversed which demands moving away from institutional commitment through top- down reporting and meeting accountability demands of the donors, for empowering those who are powerless on the economic, social, political, and spatial margins, through participation, which is both indispensable and cost-effective. In the short run, participation pays by challenging the existing data, questioning the culturally created myths and discrimination based on identity and related internal power dynamics within the sector, which elevate critical thinking opening the pathways for deepening the democracy. CBOs, however, should not be burdened with shouldering all the major responsibilities of the State such as ensuring the right to health and health care. Community participation approach will assist in removing the barriers such as discriminatory practices, inequity manifested in policies, pro-rich schemes, plans, nexus of the powerful leading to focus on their profits and corruption in ideas, thoughts and practices, which will generate an alternative approach in goal setting in the health care sector.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Prevalence of Mental Disorders in Clinical Settings of Pune City

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ABSTRACT

There's no health without mental health. It was unheeded field earlier in India. So, prioritizing and studying current scenario of mental illnesses is essential. Many community studies were conducted in India but little is known about prevalence of mental disorders in hospitals. Providing accurate data about it is vital in policy-making to plan and provide effective treatment services. Purpose of study was to report prevalence of mental disorders among sociodemographic characteristics of patients. The study was conducted in 2 hospitals (n=431) in Pune. Permissions were taken from medical officer and psychiatrists. Data was obtained from case files of patients who registered between January-March 2014. Interviews were conducted with 2 senior psychiatrists. Multinomial logistic regression model was constructed to predict prevalence of mental disorders and its determinants relative to sociodemographic characteristics. Three disorders were found highly prevalent: Neurotic, stress-related & somatoform disorders (34.3%); highest in unmarried patients (36.2%). Schizophrenia, schizotypal & delusional disorders (27.1%); highest in unmarried patients (40%). Mood disorders (25.8%); highest in age group 56-85 (41.3%). Female & unmarried patients and the one's in age group of 56-58 years are likely to suffer from Schizophrenia, schizotypal & delusional disorders.

Keywords: *Hospital, Mental disorders, Prevalence, Sociodemographic characteristics*

INTRODUCTION

In India, over the last several decades' encouraging advances have been made to overcome the problems in health care service delivery. But health is not strictly restricted to physical health. There exits this ever-broadening area of mental health which was a much unheeded field earlier in India[1]. Although it is a known fact that mental health issues exist so prioritizing and studying current scenario of mental health and illnesses is essential.

Mental health and its issues vary across time and populations in terms of quantity and quality which continue to contribute to the burden of disease. India ranks second and solely constitute fifteen per cent of the global mental, neurological and substance-use disorder burden. Even after several strides have been made to provide top medical care, mental health and psychiatric services hugely lack attention and priority in both the national and district level health policy-making. One of the reasons for this is insufficient data and discrepancies in the existing data on the distribution and determinants of mental disorders which is a nightmare for all policymakers[3].

This burden of mental disorders will sharply keep growing and it is likely to increase by twenty-three per cent between 2013 and 2023[2] mainly because of three facts: a) the existing gaps in estimating the extent and severity of mental disorders, b) the unmet needs of the mental health community and c) the dynamic nature of mental health issues that impact not only in planning and funding but also in the healthcare service delivery. The need of the hour is to move forward to actualize thoughts into actions that call for prioritizing, investing and improving the mental health services in India[3].

Many community-based psychiatric epidemiological studies are available in India but the region-specific clinical picture remains in the dark and little is known about it[4]. Providing accurate data about the extent of mental disorders in health care settings is vital in policy-making to further plan and provide effective treatment facilities and services as well as to allocate resources[4]. On the other hand, there are certain kinds of group of

individuals who are more likely at risk to develop mental disorders than others[5]. Many research studies have shown that these characteristics are factors that enhance or threaten an individual's or community's health status. Lack of identification of these determinants may contribute to increase the vulnerability of these individuals or groups to develop mental health issues. Also, lack of awareness about these risk factors may affect individuals help seeking behavior related to mental health[5].

Hence, the purpose of this study was to understand the types, extent and sociodemographic characteristics of patients suffering from mental disorders, who reported at Psychiatric OPD of private hospital settings in Pune city of Maharashtra state as well as to predict the likelihood of prevalence of mental disorders relative to the sociodemographic characteristics of the patients. It also aimed to assess the need to raise awareness about the determinants of mental illnesses among the community and to explore suggestions to improve the mental health care facilities. This study attempted to understand the needs of the mental health community at the district level.

METHODOLOGY

Study area and duration: This was a retrospective study conducted at Pune city of Maharashtra state. Due to limited resources of time, funds and grant of permissions, the study focused solely on the data collected from two private hospital settings of the city which provide psychiatric aid and services. Both quantitative and qualitative methods were used to obtain data.

Study sample: This study was undertaken among two private clinical settings (n=431). All new patients who were 18 years and above of age and had registered between January and March 2014, in the Psychiatric OPD of both the clinical settings were included in this study. Primary diagnosis concluded by the Psychiatrists appointed in the hospitals was considered and classification of the diagnosis categories was made based on Chapter V (F) of International Classification of Diseases, Tenth Edition[6].

Study procedures: A list of all major hospitals and clinics which provide psychiatric aid in Pune city was obtained via the Internet. Out of ten major hospitals in the city, only two granted approval. Prior to the study, permission was taken from the medical officer and the senior psychiatrists, for the data collection from the hospitals and to conduct interviews with their senior Psychiatrists respectively.

Post grant of permission, secondary data viz. full record and profile of the patients was obtained from the case files stored at the administration department of one hospital and similar data was extracted from the computer software at the second one. Data of follow-up visits, missing case records and the case records which had incomplete patient information were not included in this study. Primary data was obtained through the semi-structured interviews conducted with two senior Psychiatrists engaged in clinical practice in both the clinical settings. Interviews were conducted after the completion of the secondary data collection, using the 'Guidelines for Interview of Psychiatrists' which was developed with the help of the research guide, a mental health professional and a qualitative research expert. The responses of the interviewees were noted in written format during the interview and were later transcribed and translated.

Data analysis: The prevalence of mental disorders was calculated in terms of percentages. Chi-square test of independence was applied on categorical variables to test the association of socio-demographic characteristics viz. age, gender and marital status with the type of mental disorders. Multiple multinomial regression model was constructed to predict the likelihood of prevalence of mental disorders relative to the sociodemographic characteristics among the patients. The results of the multiple multinomial regression model are presented in the form of adjusted odds ratios, along with the corresponding 95% confidence interval (95% CI) and p-value of 5% which was considered significant. All analyses were done using IBM SPSS version 20.0 for Windows (SPSS Inc., Chicago, IL).

RESULTS

Socio-demographic characteristics of patients: Out of 431 patients studied, about half of the patients (47.8%) were in the age group of 18-35 years i.e. young adulthood, 37.6% were in the age group of 36-55 years i.e. middle adulthood and only 14.6% were in the age group of 56-85 years i.e. old adulthood. More than half of the patients were male (53.8%) and little less than

half were female patients (46.2%). About two-third patients were married (68.4%), one-fourth patients were unmarried (24.4%) and 7.2% patients were widowed/ divorced/ separated.

Prevalence of mental disorders: Figure 1 presents the per cent distribution and 95% CI range of the prevalence of three highly occurring mental disorders among the patients. 34.3% (95% CI: 30.012% to 38.942%) patients were suffering from Neurotic, stress-related and somatoform disorders. 27.1% (95% CI: 23.163% to 31.533%) patients were suffering from Schizophrenia, schizotypal and delusional disorders. 25.8% (95% CI: 21.853% to 30.084%) patients were suffering from Mood (affective) disorders.

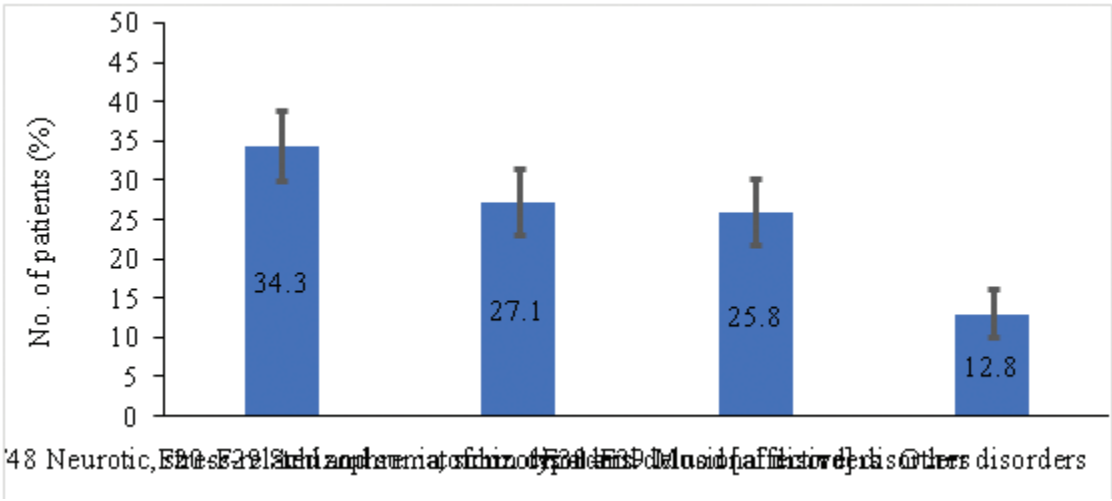


Figure 1: Prevalence of mental disorders, Pune city, India

Table 1: Percent distribution of mental disorders by socio-demographic characteristics, Pune city, India

Socio-demographic characteristics	No. of patients (N)	F00-F09 Organic, including symptomatic, mental disorders (%)	F10-F19 Mental and behavioural disorders due to psychoactive substance use (%)	F20-F29 Schizophrenia, schizotypal and delusional disorders (%)	F30-F39 Mood [affective] disorders (%)	F40-F48 Neurotic, stress-related and somatoform disorders (%)	F50-F59 Behavioural syndromes associated with physiological disturbances and physical factors (%)	F60-F69 Disorders of adult personality and behaviour (%)	F70-F79 Mental retardation (%)	F80-F89 Disorders of psychological development (%)	F90-F98 Behavioural and emotional disorders with onset usually occurring in childhood and adolescence (%)
Age											
18-35 years	206	1.0	5.8	30.1	18.0	35.9	0.5	4.4	3.4	0.5	0.5
36-55 years	162	0.0	3.7	28.4	29.6	34.6	0.6	2.5	0.6	0.0	0.0
56-85 years	63	9.5	3.2	14.3	41.3	28.6	0.0	3.2	0.0	0.0	0.0
Gender											
Female	199	3.0	0.0	28.1	29.1	33.7	0.5	4.0	1.5	0.0	0.0
Male	232	0.9	8.6	26.3	22.8	34.9	0.4	3.0	2.2	0.4	0.4
Marital Status											
Unmarried	105	0.0	1.9	40.0	11.4	36.2	1.0	1.9	5.7	1.0	1.0
Married	295	2.0	4.7	23.7	30.5	34.2	0.3	4.4	0.0	0.0	0.0
Widowed/ Separated/ Divorced	31	6.5	12.9	16.1	29.0	29.0	0.0	0.0	6.5	0.0	0.0
Total	431	1.9	4.6	27.1	25.8	34.3	0.5	3.5	1.9	0.2	0.2

Table 1 presents the per cent distribution of mental disorders by sociodemographic characteristics among the patients. The most prevalent condition was Neurotic, stress-related and somatoform disorders (34.3%); it was highest in the age group of 18 to 35 (35.9%), among male patients (34.7%) and unmarried patients (36.2%). The second prevalent condition was Schizophrenia, schizotypal and delusional disorders (27.1%); it was highest in the age group of 18 to 35 (30.1%), among female patients (28.1%) and unmarried patients (40%). The third prevalent condition was Mood (affective) disorders (25.8%); it was highest in the age group of 56 to 85 (41.3%), among female patients (29.1%) and married patients (30.5%). 1.9% patients were suffering from Organic including symptomatic, mental disorders and Mental retardation. The former condition was highest in the age group of 56 to 85 (9.5%), among female patients (3%) and Widowed/Separated/Divorced patients (6.5%). It was absent among the age group of 36 to 55 and unmarried patients. The later condition was highest in the age group of 18 to 35 (3.2%), among male patients (2.2%) and Widowed/Separated/Divorced patients (6.5%) followed by Unmarried patients (5.7%). It was absent among the age group of 56 to 85 and married patients.

Multiple multinomial regression model: In multiple multinomial regression model, other mental disorders were considered as reference category. Among socio-demographic characteristics, 'the age group of 56 to 85', 'male' and 'married' were considered as reference categories. Table 2 presents the results of multiple multinomial regression model.

Table 2: Multinomial logistic regression model predicting prevalence of mental disorders by socio-demographic characteristics, Pune city, India

Socio-demographic characteristics	No. of patients (N=431)	F20-F29 Schizophrenia, schizotypal and delusional disorders vs Other disorders (Reference category)		F30-F39 Mood [affective] disorders vs Other disorders (Reference category)		F40-F48 Neurotic, stress-related and somatoform disorders vs Other disorders (Reference category)	
		AOR (95% CI)	p-value	AOR (95% CI)	p-value	AOR (95% CI)	p-value
Intercept		0.703	0.482	2.127	0.069	1.592	0.281
Age							
18-35 years	206	1.048 (0.352, 3.119)	0.933	0.392 (0.151, 1.016)	0.054	0.877 (0.338, 2.279)	0.788
36-55 years	162	**4.201 (1.366, 12.917)**	**0.012**	1.516 (0.567, 4.052)	0.407	2.540 (0.927, 6.957)	0.070
56-85 years (Reference category)	63	1.000		1.000		1.000	
Gender							
Female	199	**3.049 (1.449, 6.413)**	**0.003**	**2.936 (1.396, 6.175)**	**0.005**	**2.379 (1.165, 4.857)**	**0.017**
Male (Reference category)	232	1.000		1.000		1.000	
Marital Status							
Unmarried	105	**3.114 (1.306, 7.426)**	**0.010**	0.778 (0.292, 2.072)	0.616	1.642 (0.712, 3.789)	0.245
Widowed/ Separated/ Divorced	31	**0.180 (0.050, 0.652)**	**0.009**	**0.233 (0.075, 0.724)**	**0.012**	**0.249 (0.081, 0.76)**	**0.015**
Currently married (Reference category)	295	1.000		1.000		1.000	

Pseudo R-Square: Cox and Snell=0.116; Nagelkerke=0.125; McFadden=0.046, AOR: Adjusted odds ratio, CI: Confidence interval

*Other disorders included F00-F09 Organic, including symptomatic, mental disorders; F10-F19 Mental and behavioural disorders due to psychoactive substance use; F50-F59 Behavioural syndromes associated with physiological disturbances and physical factors; F60-F69 Disorders of adult personality and behaviour; F70-F79 Mental retardation; F80-F89 Disorders of psychological development and F90-F98 Behavioural and emotional disorders with onset usually occurring in childhood and adolescence, †p-values are generated using Chi-square test of independence, CI: Confidence interval

Age: As compared with patients belonging to the age group of 56 to 85 years, patients in the age group of 36 to 55 years will be four times more likely to suffer from Schizophrenia, schizotypal and delusional disorders significantly (AOR: 4.201; 95% CI: 1.366 to 12.917) than other mental disorders. Mood [affective] disorders will be more prevalent in the age group 36 to 55 years (AOR: 1.516; 95% CI: 0.567, 4.052) and Neurotic, stress-related and somatoform disorders (AOR: 2.540; 95% CI: 0.927, 6.957) but not significantly as compared to any other disorders. Patients in the age group of 18 to 35 years (AOR: 1.048; 95% CI: 0.352, 3.119) are also likely to suffer from Schizophrenia, schizotypal and delusional disorders but not significantly as compared to other disorders.

Gender: As compared with male patients, female patients will be significantly two to three times more likely to suffer from Schizophrenia, schizotypal and delusional disorders (AOR: 3.049; 95% CI: 1.449 to 6.413), Mood [affective] disorders (AOR: 2.936; 95% CI: 1.396 to 6.175) and Neurotic, stress-related and somatoform disorders (AOR: 2.379; 95% CI: 1.165 to 4.857) as compared to any other mental disorders.

Marital status: As compared with married patients, unmarried patients will three times more likely to suffer from Schizophrenia, schizotypal and delusional disorders significantly (AOR: 3.114, 95% CI: 1.306 to 7.426) followed by Neurotic, stress-related and somatoform disorders not significantly (AOR: 1.642; 95% CI: 0.712, 3.789) as compared to any other mental disorders. As compared with their counterparts, Widowed/Separated/ Divorced patients were significantly less likely to suffer from any type of disorders.

DISCUSSION

We have estimated the prevalence of mental disorders relative to the sociodemographic characteristics of patients suffering with mental disorders. The major limitation of this study was that the sample was not representative of the entire community, because the study was conducted in the Psychiatric OPD of the private hospital settings in the city. But this challenge opened two pathways for exploration: a) to understand factors which contribute to the prevalence of mental disorders as estimated in the clinical settings and b) to understand predictors and risk factors which influence mental illnesses. We have attempted to study these factors as closely in context of the findings observed in the current study.

Contributing factors to the prevalence of mental disorders in clinical settings: Prevalence of mental disorders among new patients visiting the Psychiatric OPD every day may depend on multiple factors such as prevalence rates of mental illnesses among the community, changing trends and mental health literacy, referrals of pathways to health care services, availability, accessibility and affordability of mental health care facilities.

Incidence and prevalence in community: Report and analysis of the current study suggested that patients highly suffered from Neurotic, stress-related & somatoform disorders (34.3%), Schizophrenia, schizotypal & delusional disorders (27.1%) and Mood disorders (25.8%). Whereas, findings of a recent community-based psychiatric epidemiological survey suggested that out of all the diagnosable mental disorders the overall lifetime prevalence of Depression (3.14%) was the highest followed by Substance use disorder (1.39%) and Panic disorder (0.86%)[7].

Surprisingly, the proportion of people who seeked treatment for suffering from Neurotic, stress-related & somatoform disorders and Schizophrenia, schizotypal & delusional disorders was higher and Mood disorders was lower in clinical settings as compared to the diagnosable proportion of ill people as seen among the community. Visible somatic symptoms, significant underlying distress and increase in awareness is associated with neurotic, stress-related & somatoform disorders which make patients seek treatment immediately to relieve their distress[8]. Whereas, patients with schizophrenia,

schizotypal and delusional disorders undergo significant distress due to psychotic symptoms and diminishing executive functioning which gets worst and may get violent with time hence these patients seek treatment at initial stages and are usually referred for treatment in severe cases by a family member or friend.

Notably, the proportion of people who seeked treatment for mood disorders was found to be lower in clinical setting as compared to the diagnosable mentally ill proportion present in the community. It is a known fact that among all mental disorders, mood disorders particularly depression is a major cause of mental health burden and the leading cause of disability worldwide. Depressive disorders accounted for 37% of burden among all mental, neurological, and substance use disorder in India[2]. Most of the ill people fail to acknowledge their need for treatment due to lack of mental health awareness and stigma among community reduces the ability of depressed patients to seek the much-needed care[7]. These problems are discovered at a terminal stage when the emotional problem manifests into a physical problem[5]. The alert of budding physical symptoms with the combination of emotional burden beholds serious life threats and become severe with time, which is when treatment is finally sought[9]. This calls for more attention and concentrated efforts to be invested in this vulnerable group[10].

Mental disorders which were reported are differentially distributed across the population with different sociodemographic characteristics such as age, gender, marital status, education, socioeconomic and employment status. For instance, the community study found a strong association between people in the age group of 35-49 years, male gender, illiteracy, poverty, low socioeconomic status, employment, marriage and poor mental health[7]. In comparison to this study, the findings of the current study determined an association among patients in the age group of 18-35 years, male gender, marriage and poor mental health. The difference in the age groups may be due to different study settings as well as various other factors such as barriers in seeking help such as mental health literacy, social and family support system, and severity of the illness, availability, accessibility and affordability of mental health care facilities.

Trends and mental health literacy: In our study, the senior Psychiatrists working at the clinical settings in Pune City share their viewpoints on this subject matter. In the opinion of Psychiatrist 1 the trends in seeking help for treatment of mental illness clearly were affected by increasing awareness among the people, he affirmed this as he exclaimed that, "*Earlier there were fewer patients and now the number of patients visiting has increased. A patient who seeks treatment and experiences fruitful outcomes, guides by informing another potential person who might be suffering from similar problems, to the doctor s/he received treatment from and that person visits that doctor. So, if the trends have increased because of this or anything else is something I can't really say."* Whereas, Psychiatrist 2 shared an opposite point of view that present awareness doesn't affect the trends observed in the clinical settings, *"Trend is not changing. It has been almost the same more or so. But awareness is present in the public."*

These findings are also supported by other studies done earlier. A usual trend was observed of 50 to 60 patients on an average visit the OPD per day, who are attended by only one doctor. This sheds light on the deallocation of resources especially insufficient facilities which is the major challenge encountered by the clinical community today[7,11]. Increase in mental health literacy contributes to higher recognition of problems and immediate seeking of treatment[5,8].

Referral pathways to health care services: Many patients suffering with mental disorders do not seek immediate treatment due to lack of awareness about mental health care services and fear of stigma associated with treatment[5]. Culture plays an important role which can affect the morbidity pattern of mental illnesses in community settings that inversely affect the prevalence observed in the clinical settings[8]. Many times, patients and their care takers approach alternative service providers such as traditional faith healers, general physicians, family doctors prior to seeking help from a professional psychiatrist, psychologist or counselor. Factors such as trust, easy availability and accessibility of services, referrals of significant others and family and community belief in supernatural influence in causing mental illnesses influence the extent to which problems are perceived as disorders and may determine the choice of pathways adopted by these patients and their families[5,7]. Hence, we need to be mindful of these pathways while planning integrative mental health programs in the community[9,12].

Facilities: Shortage of mental health services, medicines and qualified professionals are other major barriers in help seeking behavior and the treatment gap[7]. Both the Psychiatrists 1 and 2 agreed.

Availability and accessibility: In India, as compared to urban regions, fewer health care facilities are available in rural and sub-urban regions, which are provided by the government that often lack mental health services[13]. So, often patients and their care takers have to travel long distances to reach health care facilities[8]. Hence, in the urban health care setups we see a mix of urban, rural and sub-urban populations seeking mental health care. Often these journeys are exhaustive, distressing and for some it means losing a daily wage because the often take leave of absence from work leading to financial strains. The commotion caused by these factors in the lives of those who seek health care leads to withdrawal from treatment or seek new services[14].

Affordability: Increased financial costs of treatment for mental disorders have adverse consequences on people belonging to poorer economic backgrounds which negatively affect access to health care[5]. There were two accounts that support and assert this observation in our study given by Psychiatrist 1 and. Psychiatrist 2 (statement not shown).

Predictors of mental illness and sociodemographic determinants: A report by WHO on 'Risks to Mental Health: An overview of Vulnerabilities and Risk Factors' discusses the determinants and risk factors associated with mental health and mental illness. It reported that poor mental health is influenced by three factors: individual attributes such as genetic & biological factors including poor physical health, life habits such as substance use, lifestyle choices such as getting married, divorced or remarried and individual behaviors such as low self-esteem, insecurity, hopelessness, shame, guilt, trauma, perceived crisis, cognitive, emotional & social immaturity. Environmental factors such as poor living conditions, poor access to basic civil services, stigma & discrimination, gender inequality, social injustice, intolerance & exclusion, adverse learning environment and media influences, physical insecurity due to exposure to natural and man-made disasters. All these risk factors present themselves over the life course as they interact with age and time (World Health Organization, 2012). As per the current study, the determinants of mental disorders were people in the age group of 36 to 55 years, belong to female gender and those who are unmarried.

Adulthood is one of the most critical age group especially in a developing country. It is a period during which an adult makes vital choices which concern their well-being such as being married, separated, divorced or remarried, forced marriages, bearing and raising children, rigidity in attitudes and habits, engaging in substance use. They also face multiple challenges such as being widowed, loss of a loved one, bereavement, empty-nest syndrome, being unemployment, in case of employment- finding the work-life balance, managing stress and anxiety while working and caring for others, operating in a difficult work environment, financial strain, living in debt or impoverishment conditions and discrimination[15].

Patel and Klienman have reported plausible evidence that life stresses faced by women especially the adversities associated with poverty and gender inequality such as less access to education, spouse and family abuse, forced marriages, stigma for failing to produce a son, limited job opportunities, limitation of participation in outdoor activities, sexual harassment and trafficking, migration of husbands to urban areas for employment heavily influence females to fall at risk to develop mental disorders[16].

Many cross-section studies have shown that married people have better mental health than unmarried ones[17]. Being unmarried can be both a function of life course choice such as not finding the right person, focusing on one's career and adverse circumstances such as demands of a particular time. Family responsibilities are often central in the lives of unmarried individuals particularly never married women whose roles include caring for parents and being a surrogate parent to one's younger siblings[18]. On the other hand, longitudinal studies support the alternative social-selection hypothesis that physically and mentally ill people are less likely to get married. Reverse causality is also likely to be a factor[20]. Other commonly observed reasons of diminished mental well-being among unmarried individuals are gender inequality, lack of support and rejection from family and extended family, stigma and discrimination, workplace discrimination, social exclusion and isolation, physical and economic insecurity, sexual vulnerabilities, feelings of loneliness, poor self-esteem and self-perception.

Although the current study did not address the determinants and risk factors of mental illnesses on such a broader level, hence further work is required in this

context. It is of utmost importance to not only focus on the needs of people suffering with mental illnesses but also to protect and promote the mental health and welfare of these people by building a comprehensive plan of action which is inclusive not only of early identification, prevention and care but also to consider and assess risks, vulnerabilities and determinants of both mental illness and health to build a stronger foundation for developing appropriate and effective mental health and social strategies[13,15].

CONCLUSION

The current study holds importance because it provides useful information about the most prevalent mental disorders in the clinical settings. Findings suggested that there is a need to increase mental health care infrastructure and facilities, along with health care providers and customized intervention programs to fulfill the needs of district level clinical community. Also, regular inspections of these facilities should be conducted by the supervisors for catering quality care to the people who seek help. This study also highlights the need to study other risk factors that include individual attributes, socio-economic factors, cultural and environmental factors associated with mental disorders to develop comprehensive and effective mental health and social plans and programs.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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Health Status and Treatment Seeking Among Elderly in India

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ABSTRACT

The study lights on the health status and treatment seeking, as the older people mostly have incomplete recovering abilities and are more susceptible to disease, syndrome, and sickness as well affected by the several social issues. The NSSO, 71st round (2014) used to assess the objectives of the study, whereas Statistical software used to analyse the data. Therefore, elderly has higher health problems especially most of them suffer from chronic ailments and their treatment seeking is hindered by various socio-economic factors. With this backdrop, it is worth studying the number of hospitalized person and their treatment seeking behaviour as well as nature of ailment they have and which type of care they are providing as per their economic status and perception towards their health conditions. During the 365 days preceding the survey and significant risk factors associated with the prevalence of any chronic ailment are increasing age, literacy status, caste, region and perceived poor health status. The strengths of this study are it provides an update on the status of elderly health and treatment seeking in the country, which is important for policy and program perspective, especially given the fact proportion of elderly in India, is growing considerably.

Keywords: *Elderly, Health Status, Socio-Economic Factors, Treatment Seeking.*

INTRODUCTION

Aging as a demographic process is happening all over the world and is simultaneously drawing increasing attention on elderly health especially health seeking behavior. The global phenomenon of population aging is directly related to a fundamental health transition means changes that include a shift from high to low fertility, steady expansion of life expectancy at birth and old ages, and a transition from common diseases to the chronic diseases. In recent time, a remarkable improvement in child and adult health status and declining fertility led to population aging in India. The proportion of elderly in India has increased to (103.8 million in 2011) that account for (8.6%) of the Indian population as against (76.6 million in 2001), which was (7.4%) of the Indian population. Moreover, the older population of India is projected to reach (19% in 2050), according to United Nations Population Division. It is evident that rising elderly population raises critical issues related to social security, economic security, and health care.

REVIEW OF LITERATURE

Elderly health studies show that older people have limited regenerative abilities and are more prone to disease, syndromes, and sickness. Multiple diseases are very common in elderly. The average number of illness is reported to be (2.6) per person[1]. Another study found that multiple ailments are common in elderly with locomotive disorders being the most common, followed by respiratory disorders, and hypertension. The majority of the elderly treated with allopathic medicines. However, only (39%) were reported to comply with the treatment. Half of them stated that it was not needed to take medicine. Non- availability of drugs was the main reason cited while the high cost of treatment and forgetfulness were other causes for non-compliance to treatment[1]. Another study in rural Varanasi found that (88.8%) of the elderly were considered to suffer from one or more sickness at the time of the survey. Also, the morbidity was directly proportional to the age. The most common morbidity was arthritis with an overall prevalence of (57.08%) followed by cataract (48.33%), hypertension (11.25%). However, the prevalence of old age-related morbidities increased with advancing age. Compared to married people a higher percentage of widow /widower (91.5%) suffered from old age-related morbidities[2]. The prevalence of most diseases is high in persons over 65. Hypertension being the most frequently reported disease of the persons over 65 years

old. Moreover, also more than (75%) are known not to have one of the chronic diseases, but of the more elderly patients who do have one of these diseases, (16%) has more than one chronic illness[3]. Among the inpatients of 65 years and older the higher frequency of co-morbidity is found in patients with diabetes mellitus. The second most frequent chronic disease is diabetic, followed by hypertension (19%). One fourth of the elderly in India perceive their current health status as poor compared to only (6%) who feel their health condition is excellent[4].

Another study exploring the health problems of senior citizens, found high prevalence of hypertension (29.3%), diabetes mellitus (8.3%), arthritis/joint pain (24.8%), eye problem (19.0%), hearing problems (3.3%), oral health problems (17.5%), digestive system problems (17.8%), respiratory problems (11.0%), heart disease (3.8%), renal problem (5.3%), skin diseases (7.5%), tuberculosis (3.0%). Faith healers were the first treatment choice (97.2%) irrespective of age, gender or ethnicity[5]. The study by Barik (2009) using NSSO 60th round data found that (MPCE) and place of residence influence treatment seeking behavior of elderly aged 65 & above are expected triple from (5% in 2005) to (15% by 2050)[6]. Age structure transition the annual rate of increase the elderly population (2.8 until 2050). Elderly of age 65 years and above are less likely to receive treatment than those in the age group 60-64 years. Another study found Poverty as a major determinant of health-seeking behavior and treatment considered a waste of money followed by a poor attitude of health worker[5]. With this backdrop, it is worth studying the number of hospitalized person and their treatment seeking behaviour as well as nature of ailment they have and which type of care they are providing as per their economic status and perception towards their health conditions.

Broadly, the present paper aims to understand the health status and treatment seeking behaviour of the elderly in India. The specific objectives are - (i) to understand the prevalence of any chronic illness & hospitalization and its associated risk factors among elderly; (ii) to study the pattern of treatment seeking and its associated factors among elderly hospitalized one year preceding the survey, and (iii) to understand the perceived health status and its associated factors among elderly.

Data and Methods: The present paper has used the data from 71st round of National Sample Survey (NSS), Scheduled No. 25.0 'Social Consumption: Health' conducted during January to June 2014. NSS is a nationally representative survey carried out with specific objectives during different rounds. The 71st round aimed to generate necessary quantitative information on the health sector. One of the vital components of the schedule was dedicated to collect information that was relevant to the fortitude of the prevalence rate of different diseases among various age-sex groups in altered parts of the country. Further, measurement of the extent of the degree of use of health facilities provided by the Government was a necessary component of this exercise. Particular attention gives the hospitalization or medical care received as an in-patient of medical institutions.

The ailment for which such care sought, the extent of use of government hospitals as well as different (lower) levels of public health care systems, and the expenditure incurred on treatment received from the public and private sectors, investigated by the survey. The break-up of cost by various heads estimated for expenses on medical care received both as inpatient and otherwise. Moreover, this study provides information about the socio-economic status of the elderly. Moreover, their economic situation, the perception of health status, details of ailments from which they are suffering, whether they have any chronic illness, whether they hospitalized and taken any treatment before hospitalization, the nature of treatment if any and level of care. This paper specifically used the data of (30012) people aged 60 and above.

Statistical analysis: Both bivariate and multivariate analysis have been carried out to fulfill the study objectives. The bivariate analysis had been done to show the level and differentials of the chronic ailment, hospitalization, hospitalization by nature of the sickness, treatment on medical advice before hospitalization, and perceived health status of the elderly by various socio-economic and demographic characteristics. Chi-square Test used for to show the test of significant and the difference in variables. Multivariate analysis (binary and multinomial logistic regression) had been done to explain the factors affecting the prevalence of any chronic ailment, hospitalization, and treatment before hospitalization and perceived health status of the elderly. STATA (SE.13) has been used to analyse the data with a significance level of (5%).

Dependent variables: The dependent variables included in the analysis which are as following: whether hospitalized (1-Yes, 0-No), suffering from any chronic Ailment (1-Yes, 0-No); Nature of Ailment for hospitalization (1-Infection/Injury, 2-Diabetes, 3-Cardio Vascular, 4-Respiratory, 5-Musculoskeletal, 6-Others); also the treatment related indicators are Nature of cure (1- Allopathy, 2-Indian System Medicine, 3-Others), and Perceived health status (0- Poor, 1-Excellent, 2-Good).

Predictor variables: The independent variables included in the analysis which are as following: Age group (60-64, 65-69, 70-74, and 75+), Sex (1-Male, 2-Female), Education (1-Not literate, 2-Literate), Marital status (1-never married/divorced, 2-currently married, 3-widowed); Religion (1-Hindu, 2-Islam, 3-Others), Social group (1-ST, 2-SC, 3-OBC, 4-General), Region (1-North, 2-Central, 3-East, 4-North-East, 5-West, 6- South), Economic Independence (1-Independent, 2-Partially Dependent, 3-Fully Dependent), and lastly Perceived Health Status (1-Excellent, 2-Good, 3-Poor).

RESULTS AND DISCUSSION

Prevalence of any chronic illness and hospitalization among elderly: A quarter of the aged is suffering from any chronic ailment in India (Table 1). As far as the prevalence of any chronic ailment by background characteristics is concerned, it is found that it varies by different individual and community level characteristics. A Higher percentage of elderly who are literates, those older from the non-Hindu/Islam category, and those elderly entirely dependent on others economically have any chronic ailment than their respective counterparts. Among the social groups, aged from SC (21%), OBC (25%) and General (29%) category have any chronic ailment compared to those from ST (11%). Only three percent of the elderly from Northeast have any chronic disease as against (43%) of those from the southern region. Prevalence of any chronic sickness increases with higher age. As may be evident, (22%) of the senior aged 60-64 have any chronic illness compared to (29%) of those aged 75+ years. Ten percent of the elderly with perceived superior health status have any chronic diseases. The corresponding figure is (40%) among those perceived to have poor health status.

About (11%) of the elderly found hospitalized for any ailment during the 365 days preceding the survey, and the hospitalization pattern varies by different individual and community level characteristics (Table 1). A Higher percentage of elderly who are literates, those aged from the non-Hindu/Islam category and those elderly entirely dependent on others economically hospitalized than their respective counterparts. Among the social groups, old from SC (8%), OBC (11%) and General (10%) category are hospitalized for any ailment compared to those from ST (5%). Only five percent of the elderly from Northeast hospitalized during last one year as against (15%) of those from the southern region. Hospitalization for any ailment increases with higher age. As may be evident, (8%) of the elderly aged 60-64 have any chronic ailment compared to 15% of those aged 75+ years. Four percent of the elderly with perceived great health stat hospitalized for any illness. The corresponding figure is 7% among those with perceived good health status and 19% among those perceived to have poor health status. Among the elderly hospitalized for any ailment during 365 days before the survey, 23% are found to be hospitalized for infection/injuries (Table 2). The other diseases leading to hospitalization are cardiovascular (18%), respiratory (8%), musculoskeletal (6%) and diabetes (4%). Another 41% elderly have cited any 'other' ailment for their hospitalization.

Factors affecting prevalence of any chronic illness & hospitalization among elderly: It is found that controlling the effects of other variables in the model age, literacy status, caste, region and perceived health status are found to be significant predictors of any chronic ailment among elderly in India (Table 7). Literate old are 1.7 times more likely to have any chronic disease than their illiterate counterparts (OR-1.776, CI- 1.666-1.893). The likelihood of any chronic illness is significantly high among women from General category compared to ST category (OR-1.666, CI-1.456-1.906). The chance of any chronic disease is more among the elderly aged 75 and above years than those aged 60-64 years, and the association is statistically significant (OR-1.164, CI-1.069-1.267). The likelihood of any chronic ailment is significantly higher among elderly from southern (OR-3.981, CI-3.635-4.360), western (OR-1.641, CI-1.480-1.820). Moreover, eastern region (OR-1.246, CI-1.128-1.376) than those from the north of the country. Partially dependent are less likely (OR-0.907, CI: 0.831-0.991) to have any chronic ailment than those economically independent. Elderly with perceived poor health status are 8.434 times (CI: 7.104-10.011) more likely to have

any chronic illness than those with perceived first health condition. So far as the factors affecting hospitalization are concerned, female elderly are 0.21 times (CI: 0.7445-0.847) less likely to be hospitalized than males (Table 7). Older with 75 and above years of age are 1.26 times (CI: 1.267-1.372) more expected to be hospitalized than those aged 60-64. Literate people are 1.30 times (CI: 1.228-1.385) more liable to be hospitalized than non-literate. Among religious group elderly from Islam are 0.077 times less likely (CI:0.846-1.006) and others are 1.110 times (CI:1.004-1.229) more liable to be hospitalized than those from Hindu religion. The general group is 1.32 times (CI: 1.177-1.479) more likely than ST elderly to be hospitalized. Old from The West region are 1.39 times (CI: 1.265-1.537) more likely, and those from the south region are 1.42 times (CI: 1.304-1.551) more liable to be hospitalized than those from North region. Economically fully dependent elderly are 0.109 times (CI: 0.829-0.958) less likely to be hospitalized than those independent people. Old with perceived poor health status are 8.14 times (CI: 6.944-9.550) and those with perceived good health status are 2.61 times (CI: 2.243-3.049) more likely to be hospitalized than those elderly with recognized top health condition.

Pattern of treatment seeking among elderly hospitalized last year: The question asked to elderly hospitalized for any ailment during 365 days before survey about the source of care as inpatients. Nearly two-thirds of the older found to have availed the services from private hospitals while one-third of them have accessed it from public hospitals. About three percent of the elderly have availed it from a PHC/Dispensary/ CHC/Mobile unit (Table 3). About 71% of the literate elderly have availed the services from a private hospital compared to 58% of the non-literates. More than half (54%) of the elderly from ST category have utilized the services from the public hospital, which used by less than 30% of those from OBC or General Category. A higher percentage of elderly from East and Northeast have utilized the services from the public hospital while it is the opposite in all other regions. It is worth mentioning that almost all (99%) the elderly hospitalized during last one year preceding the survey have undergone allopathic treatment (figure not shown).

Among those elderly treated on medical advice before hospitalization, 46% were treated in private hospitals followed by another 26% availing medical information from a private doctor/clinic. Twenty-three percent of the elderly availed the medical information from public hospitals while another four percent have accessed the medical advice from PHC/Dispensary/ CHC/Mobile unit and one percent from HSC/ANM/ ASHA/AWW (Table.4). Among the literates, 49% have availed the advice from a private hospital, 25% from a private doctor/clinic and 20% from a public hospital while the remaining from other public facility/provider. The corresponding figures among illiterates are 45%, 26%, 23% respectively. A relatively higher percentage of the elderly with financial independence have availed the services from a private hospital (47%) than those who are economically dependent on others (44%).

Factors affecting treatment before hospitalization: Elderly females are significantly more likely to have treatment before hospitalization that their male counterparts (OR-1.222, CI-1.004-1.255). The chances of receiving treatment before hospitalization is significantly more among those literate compared to those non-literates (OR-1.390, CI-1.254-1.540) General elderly are 1.28 times (CI:1.049-1.560) more likely to be treated before hospitalization than ST people. Elderly from western region are 1.46 times (CI: 1.232-1.738) more liable to be dealt with before hospitalization than those from The North region. Those from north-east are 0.324 times (CI: 0.550-0.831) less likely to be treated before hospitalization than those from North region. As per economic independence, entirely dependent are 1.14 times (CI: 1.007-1.289) more responsible for being considered before hospitalization than those economically independent. Those with perceived poor health status are 1.40 times (CI: 1.035-1.907) more accountable to receive treatment before hospitalization than those with perceived loftier health position.

Perceived health status of elderly: About 70 percent of the elderly perceived their health status is good compared to only 7 percent who feel their health is excellent and another 23 percent seen to have poor health status (Table 5). The perceived health status varies across background characteristics. As the age increases the status of health decreases in the age group 60-64 the exceptional, perceive health status was 10 percent, and 75 percent people has right perceived health situation, and that is 15 percent in the poor category. The poor health status increases with increasing age. Female elderly has recognized adverse health status

as compared to their male counterparts. The education level of old has an active relation with applicable state of health. Widowed have most dangerous relative health condition than currently married elderly. As per religion elderly following Islam has nastiest health status than Hindu elderly and others. In social groups, ST people has 5 percent excellent health status as compared to SC, and General has 7 percent excellent health status and good and poor condition are nearly same in all social group. Elderly in The East region is perceived to have worst health status while those in West region have the best health status. People who fully dependent on others have most dangerous health condition compared to those financially independent people.

Factors Affecting Perceived Health Status of Elderly: Multinomial logistic regression shows the relative risk ratio of co-occurrence of excellent and good health status groups by age, sex, education, marital status, religion, social group, region, economic independence (Table 6). It found that age was significant level decreasing with increasing age associated with both excellent and good health status. The relative risk ratio of good was significantly higher among female compared to the male. The relative risk ratio of 1.39 times more likely than not literate in excellent as compared to 1.09 times more in good than illiterate people. In religion relative, the risk ratio of excellent as well as right category 0.442 times less likelihood in Islam than Hindu. In social group relative risk ratio good health status increased in SC, OBC than ST category and the proper category also the same result found. As per region, wise relative risk ratio is 4.09 times more likelihood than the north of the country and i.e. 1.04 times more likelihood in good health status compare to poor health status. In financial independent relative risk ratio significantly less likelihood in excellent as compared to weak category and good health status as compared to poor that is less likelihood.

Table 1: Percentage Distribution of Elderly Suffering from any Chronic Ailment and Hospitalized for any Ailment during Last 365 Days Preceding the Survey by Background Characteristics in India, 2014

During Last 365 Days

Background Characteristics	Whether Suffering From any Chronic Ailment (%)	Total	Whether Hospitalized For Any Ailment (%)	Total
Age*(###)**				
60-64	22.2	10230	8.0	10633
65-69	24.1	8136	10.4	8459
70-74	25.4	5313	12.3	5618
75+	29.3	4897	15.3	5303
Sex*(###)				
Male	24.5	14081	11.5	14835
Female	24.6	14494	10.1	15177
Education*(###)**				
Not Literate	20.1	16516	8.2	16516
Literate	30.7	12059	11.4	12059
Marital Status*(###)**				
Never Married/Divorced	29.6	289	19.1	289
Currently Married	23.9	18128	9.4	18128
Widowed	25.6	10158	9.6	10158
Religion*()**				
Hindu	23.4	23823	9.3	23823
Islam	27.7	2837	9.9	2837
Others	34.2	1915	12.7	1915

Social Group*(###)**				
Scheduled Tribe	11.0	2129	5.3	2129
Scheduled Caste	20.7	4479	7.9	4479
Other Backward Class	25.2	12503	10.5	12503
General	28.6	9465	10.1	9465
Region*(###)**				
North	17.9	3832	9.6	3974
Central	12.7	5699	8.5	5984
East	21.6	5779	7.9	6089
North-East	3.0	851	4.8	902
West	18.3	4066	11.9	4269
South	42.9	8349	14.9	8794
Economic Independence*(##)**				
Independent	23.1	8061	8.8	8061
Partially Dependent	23.4	5721	9.1	5721
Fully Dependent	25.8	14781	10.2	14781
Perceive Health Status*(###)**				
Excellent/V. Good	10.0	1923	3.9	1923
Good/Fair	20.9	20049	7.0	20049
Poor	39.8	6592	19.1	6592
Total	**24.5**	**28575**	**10.8**	**30012**

Note- (*) means-chronic ailment and (#) means-whether hospitalized for any ailment

p<0.001, **p<0.05, *p<0.01 ***and ###p<0.001, ##p<0.05, #p<0.01

Table 2: Percentage Distribution of Elderly Hospitalized by Nature of Ailment in India, 2014

Background Characteristics	Nature of Ailment						
	Infection/Injuries	Diabetes	Cardio-Vascular	Respiratory	Musculo-Skeletal	Others	Total
Age* **							
60-64	25.1	3.7	16.6	6.4	7.5	40.9	2512
65-69	24.1	4.5	15.2	8.0	6.4	41.9	2599
70-74	20.5	3.4	21.4	11.0	5.1	38.7	2036
75+	21.7	5.0	18.7	8.9	5.7	40.0	2386
Sex* **							
Male	22.0	3.6	19.9	9.5	4.6	40.5	5019
Female	24.1	4.8	15.4	7.3	8.1	40.4	4514
Education* **							
Not Literate	25.3	3.0	13.8	8.9	8.1	40.9	4165
Literate	22.7	4.8	19.4	8.0	5.9	39.3	4235
Marital Status* **							
Never Married/Divorced	24.7	3.8	4.9	2.7	0.3	63.7	169
Currently Married	22.5	4.1	17.1	8.5	7.0	40.8	5243
Widowed	26.4	3.5	16.4	8.7	7.4	37.6	2988

Religion* **							
Hindu	23.7	3.7	15.0	8.1	7.1	42.3	6796
Islam	27.3	3.6	20.1	10.0	4.2	34.9	858
Others	22.0	6.3	27.8	7.6	9.6	26.7	746
Social Group***							
Scheduled Tribe	26.7	0.3	20.3	6.9	6.9	38.9	348
Scheduled Caste	26.5	5.0	14.1	8.3	5.5	40.5	1091
Other Backward Class	24.2	3.7	15.6	8.5	7.2	40.8	4023
General	22.3	4.2	18.5	8.5	7.3	39.2	2938
Region* **							
North	20.2	2.8	23.0	11.8	5.9	36.3	1125
Central	23.1	3.6	12.2	9.2	7.0	44.9	1499
East	24.8	1.4	18.4	7.4	5.4	42.5	1419
North-East	24.8	3.7	20.8	14.4	7.4	29.0	127
West	21.5	4.7	17.2	7.0	5.9	43.7	1495
South	23.5	5.6	18.2	8.0	6.4	38.3	3868
Economic Independence* **							
Independent	25.4	3.2	16.4	6.2	6.9	42.1	2174
Partially Dependent	21.8	3.3	17.3	8.6	8.0	41.1	1602
Fully Dependent	24.0	4.4	16.5	9.4	6.7	38.9	4623
Perceive Health Status* **							
Excellent/V. Good	17.7	2.4	14.5	4.0	1.6	59.7	231
Good/Fair	25.0	3.8	18.0	7.3	6.7	39.2	4300
Poor	23.2	4.1	15.2	9.9	7.6	40.0	3868
Total	**23.0**	**4.2**	**17.8**	**8.4**	**6.2**	**40.5**	**9533**

***p<0.001, **p<0.05, *p<0.01

Table 3: Percentage Distribution of Elderly Hospitalized for any Ailment by Level of Care in India, 2014

Level of Care

Background Characteristics	PHC/Dispensary/CHC/Mobile Unit	Public Hospital	Private Hospital	Total
Age				
60-64	2.8	33.2	64.1	2512
65-69	3.0	31.8	65.1	2599
70-74	2.9	30.6	66.5	2036
75+	2.6	36.3	61.2	2386
Sex* **				
Male	1.9	33.3	64.8	5019
Female	3.8	32.7	63.4	4514
Education* **				
Not Literate	4.3	37.7	58.0	4165
Literate	1.8	26.8	71.4	4235

Marital Status* **				
Never Married/ Divorced	4.6	10.5	85.0	169
Currently Married	2.8	31.6	65.6	5243
Widowed	3.4	34.5	62.1	2988
Religion* **				
Hindu	3.4	31.7	64.9	6796
Islam	0.9	40.5	58.7	858
Others	2.8	27.6	69.7	746
Social Group* **				
Scheduled Tribe	15.1	53.7	31.3	348
Scheduled Caste	5.7	46.1	48.2	1091
Other Backward Class	2.7	28.6	68.7	4023
General	1.2	29.5	69.3	2938
Region* **				
North	2.5	47.0	50.5	1125
Central	2.1	28.8	69.1	1499
East	5.3	51.0	43.7	1419
North-East	9.6	72.7	17.8	127
West	2.9	19.4	77.7	1495
South	2.0	28.0	70.0	3868
Economic Independence* **				
Independent	2.0	26.8	71.1	2174
Partially Dependent	3.8	35.0	61.2	1602
Fully Dependent	3.3	33.8	62.9	4623
Perceive Health Status* **				
Excellent/V. Good	1.7	14.7	83.6	231
Good/Fair	3.2	30.6	66.3	4300
Poor	3.0	35.1	61.9	3868
Total	**2.8**	**33.0**	**64.2**	**9533**

***p<0.001, **p<0.05, *p<0.01

Table 4: Percentage Distribution of Elderly Treated on Medical Advice before Hospitalization by Level of Care in India, 2014

If Treated on Medical Advice before Hospitalization Level of Care

Background Characteristics	HSC/ANM/ASHA/ AW W	PHC/Dispensary/ CHC/Mobile Unit	Public Hospital	Private Doctor/Clinic	Private Hospital	Total
Age						
60-64	2.1	4.1	21.8	26.6	45.4	1650
65-69	1.0	5.0	24.2	23.2	46.7	1784
70-74	0.2	4.8	21.2	25.4	48.5	1377
75+	0.9	3.8	25.2	27.9	42.3	1564

Sex*						
Male	1.2	4.3	22.9	26.4	45.2	3402
Female	0.9	4.6	23.5	24.9	46.1	2973
Education* **						
Not Literate	1.3	5.5	27.3	25.6	40.3	2579
Literate	0.3	3.9	19.7	27.0	49.1	2954
Marital Status* **						
Never	0.0	2.6	4.2	15.4	77.8	120
Married/Divorced						
Currently Married	0.6	4.6	21.6	26.7	46.4	3490
Widowed	1.1	4.8	27.3	26.4	40.4	1923
Religion* **						
Hindu	0.8	4.6	22.8	26.9	44.9	4512
Islam	1.1	3.8	30.9	26.8	37.5	536
Others	0.2	5.8	18.3	21.4	54.4	485
Social Group* **						
Scheduled Tribe	3.6	20.2	36.0	17.8	22.3	180
Scheduled Caste	1.5	6.8	35.3	24.6	31.8	694
Other Backward Class	0.5	4.2	21.8	26.2	47.3	2716
General	0.6	3.1	19.7	28.0	48.6	1943
Region* **						
North	0.9	3.3	37.0	21.0	38.0	711
Central	2.7	3.2	23.1	40.9	30.0	959
East	2.2	6.3	26.7	41.8	23.0	988
North-East	1.4	15.3	51.0	24.8	8.0	79
West	0.6	3.6	13.3	22.9	59.7	1117
South	0.2	4.5	21.4	16.3	57.6	2522
Economic Independence **						
Independent	0.8	3.9	22.4	26.4	47.0	1421
Partially Dependent	0.6	6.0	24.4	23.6	45.4	1018
Fully Dependent	0.8	4.6	23.2	27.3	44.2	3094
Perceive Health Status* **						
Excellent/V. Good	1.1	3.0	11.1	13.7	71.1	182
Good/Fair	0.8	4.3	20.3	27.3	47.3	2645
Poor	0.8	5.1	26.9	26.3	40.9	2706
Total	**1.1**	**4.4**	**23.2**	**25.7**	**45.7**	**6375**

***p<0.001, **p<0.05, *p<0.01

Table 5: Percentage Distribution of Elderly by Perceive Health Status in India, 2014

Background Characteristics	Perceive Health Status			
	Excellent	Good	Poor	Total
Age* **				
60-64	10.1	75.0	15.0	10226
65-69	6.9	74.1	19.0	8131
70-74	3.7	68.0	28.3	5311
75+	2.8	56.2	41.0	4896
Sex* **				
Male	8.2	71.0	20.8	14075
Female	5.3	69.4	25.3	14489
Education* **				
Not Literate	4.8	68.8	26.4	16510
Literate	9.3	72.1	18.6	12054
Marital Status* **				
Never Married/ Divorced	17.0	62.6	20.4	289
Currently Married	7.6	73.4	19.1	18120
Widowed	5.0	64.7	30.3	10155
Religion* **				
Hindu	7.0	70.4	22.6	23816
Islam	3.9	68.9	27.2	2836
Others	7.8	69.3	22.9	1912
Social Group* **				
Scheduled Tribe	5.4	70.8	23.8	2126
Scheduled Caste	7.0	70.4	22.7	4477
Other Backward Class	6.7	70.3	23.0	12500
General	7.0	68.8	23.2	9461
Region* **				
North	7.8	72.7	19.5	3831
Central	4.8	70.8	24.4	5697
East	3.9	65.8	30.3	5777
North-East	5.4	69.0	25.6	847
West	15.7	71.0	13.3	4065
South	5.4	71.4	23.3	8346
Economic Independence* **				
Independent	12.1	75.0	13.0	8061
Partially Dependent	6.8	75.5	17.7	5721
Fully Dependent	3.8	65.5	30.7	14781
Total	**6.7**	**70.2**	**23.1**	**28564**

***p<0.001, **p<0.05, *p<0.01

Table 6: Factors Affecting the Perceived Health Status of Elderly, India 2014

Background Characteristics	Multinomial Logistic Regression Showing Relative Risk Ratio	
	Excellent	Good
Age		
60-64®		
65-69	0.614***(.538, .700)	0.834***(0.774,0.899)
70-74	0.284***(0.239,0.338)	0.581***(0.536,0.630)
75+	0.147***(0.120,0.181)	0.384***(0.354,0.416)
Sex		
Male®		
Female	1.017(0.889,1.164)	1.145***(1.073,1.222)
Education		
Not Literate®		
Literate	1.399***(1.235,1.584)	1.098***(1.032,1.168)
Marital Status		
Never Married/Divorced®		
Currently Married	0.763(0.489,1.190)	0.763(0.489,1.190)
Widowed	0.715(0.454,1.127)	0.715(0.454,1.127)

Religion		
Hindu®		
Islam	0.558***(0.459,0.678)	0.558***(0.459,0.679)
Others	1.176(0.968,1.43)	1.176(0.968,1.430)
Social Group		
Scheduled Tribe		
Scheduled Caste	0.638***(0.500,0.813)	0.638***(0.500,0.813)
Other Backward Class	0.784**(0.635,0.969)	0.784**(0.635,0.969)
General	0.855(0.692,1.056)	0.855(0.692,1.056)
Region		
North®		
Central	0.671***(0.547,0.824)	0.812***(0.738,0.893)
East	0.467***(0.379,0.576)	0.625***(0.570,0.686)
North-East	1.071(0.845,1.359)	0.867**(0.766,0.982)
West	4.094***(3.409,4.916)	1.420***(1.275,1.580)
South	0.659***(0.545,0.799)	0.820***(0.749,0.897)
Economic Independence		
Independent®		
Partially Dependent	0.479***(0.410,0.560)	0.775***(0.707,0.850)
Fully Dependent	0.183***(0.159,0.212)	0.427***(0.394,0.462)

Total Number of Observations = 28564

® means reference category; ***p<0.001, **p<0.05, *p<0.01

Table 7: Factors Affecting Hospitalized and Chronic Ailment Cases of Elderly in India, 2014

Background Characteristics	**Hospitalized**	**Chronic Ailment**
	Odds Ratio	**Odds Ratio**
Age		
60-64®		
65-69	1.081**(1.008,1.159)	1.005(0.933,1.082)
70-74	1.204***(1.114,1.302)	1.167***(1.074,1.269)
75+	1.267***(1.170,1.372)	1.164***(1.069,1.267)
Sex		
Male®		
Female	0.794***(0.745,0.847)	1.058(0.988,1.133)
Education		
Not Literate®		
Literate	1.304***(1.228,1.385)	1.776***(1.666,1.893)
Marital Status		
Never Married/Divorced®		
Currently Married	0.980(0.764,1.258)	0.910(0.699,1.185)
Widowed	1.063(0.827,1.367)	0.922(0.707,1.204)

Religion		
Hindu®		
Islam	0.923*(0.846,1.006)	1.258***(1.150,1.375)
Others	1.110**(1.004,1.229)	1.56***(1.402,1.746)
Social Group		
Scheduled Tribe®		
Scheduled Caste	1.187***(1.047,1.346)	1.332***(1.151,1.543)
Other Backward Class	1.175***(1.049,1.317)	1.322***(1.156,1.512)
General	1.320***(1.177,1.479)	1.666***(1.456,1.906)
Region		
North®		
Central	0.942(0.856,1.035)	0.850***(0.765,0.945)
East	0.932(0.848,1.024)	1.246***(1.128,1.376)
North-East	1.017(0.901,1.149)	0.210***(0.173,0.256)
West	1.395***(1.265,1.537)	1.641***(1.480,1.820)
South	1.422***(1.304,1.551)	3.981***(3.635,4.360)
Economic Independence		
Independent®		
Partially Dependent	0.970(0.894,1.052)	0.907**(0.831,0.991)
Fully Dependent	0.891***(0.829,0.958)	1.009(0.935,1.089)
Perceive Health Status		
Excellent®		
Good/Fair	8.143***(6.944,9.550)	8.434***(7.104,10.011)
Poor	2.615***(2.243,3.049)	2.852***(2.418,3.364)

Total Number of Observations = 28564

® means reference category; ***p<0.001, **p<0.05, *p<0.01

CONCLUSION

To conclude there is a high prevalence of chronic ailment among elderly and a sizable percent of the elderly have undergone hospitalization during one year preceding the survey. Moreover, a significant percent of elderly has not taken any treatment on medical advice before hospitalization. There are regional differentials in the prevalence of chronic ailments, hospitalization, and treatment seeking before and during hospitalization. The results suggest the need for new/ strengthening the existing geriatric policy/programs to meet the health care need of the elderly. Any government initiative such as health insurance of elderly care will undoubtedly enhance the health care utilization of the elderly.

Ethical clearance: No need

Source of funding: Self

Conflict of Interest: Nil

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