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Impact of Early Clinical Exposure on Psychomotor Skills of Medical Students in Indian Medical Education Set Up

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Abstract

Introduction: Most attempts at early clinical experiences have been confined to limited patient contact in an introductory course on patient interviewing, a beginning physical examination skills course or elective opportunities. Early clinical exposure (ECE) and the accompanying knowledge and skill development does not replace the basic and clinical sciences but rather enriches and contextualises that learning and offers a wider variety of teaching and learning methods.

Material and Methods: This Cross sectional study carried for three years duration. In the present study 820 students participated. Voluntarily participated students were randomly divided into two groups viz. ECE exposed group (Group A) and Traditional teaching exposed group (Group B). We conducted Periodical sessions (Each duration: 60 minutes). Objective Structured Practical Examination (OSPE) tests were conducted towards end of every session.

Results: Comparing OSPE test ECE session results with traditional teaching methods found statistically significant in all colleges. (P value < 0.001) (Using Mann-Whitney Test). We found, Module wise comparing OSPE test ECE session results with traditional teaching methods found statistically significant in all modules except Module number five (P value < 0.001) (Using Mann-Whitney Test)

Conclusion: From these results it can be concluded that early clinical exposure is to be an important intervention for improving psychomotor skills of medical students.

Keywords: Early clinical exposure, medical education, psychomotor skills

Introduction

Most attempts at early clinical experiences have been confined to limited patient contact in an introductory course on patient interviewing, a beginning physical examination skills course or elective opportunities.¹ Early clinical exposure (ECE) and the accompanying knowledge and skill development does not replace the basic and clinical sciences but rather enriches and contextualises that learning and offers a wider variety of teaching and learning methods.²

ECE ensures well integrated knowledge of the basic sciences, clinical sciences and social sciences.³ Medical curricula across the world now strongly emphasise early clinical exposure with horizontal and vertical integration and contextual learning in the local setting. Different conventional and innovative teaching-learning methods have been used in teaching basic medical sciences (Anatomy, Physiology and Biochemistry) to the first year medical students so as to increase their interest and enhance their learning. Keeping in mind the implications of early clinical exposure MCI has recommended early clinical exposure in new proposed CBME (Competency

Based Medical Education) curriculum.⁴

Material and methods:

The present study was carried out in Department of Physiology, Rural Medical College, Pravara Institute of Medical Sciences (DU), Loni, India, in collaboration with Department of Medicine, Department of Surgery and in 5 other Medical Colleges from the Western Maharashtra. This was Cross sectional study carried for three years duration.

In the present study sample size was estimated by using Probability Proportionate Random Sampling (PPRS) technique (50% criteria) with the help of expert statistician. The study was approved by the Institutional Ethical Committee. Prior informed written consent was obtained from the participants after explaining the procedure and purpose of study.

In the present study 820 students were participated.

Voluntarily participated students were randomly divided into two groups viz. ECE exposed group (Group A) and Traditional teaching exposed group (Group B). We conducted Periodical sessions (Each duration: 60 minutes) Objective Structured Practical Examination (OSPE) tests were conducted following every session.

The present study included first year M.B.B.S. students from 2 government medical colleges, 2 private medical colleges and 2 deemed university medical colleges from the Western Maharashtra region.

List of participating medical colleges:

1. Byramjee Jeejeebhoy Government Medical College , Pune

2. Rajashree Chatrapati Shahu Maharaj Government Medical College , Kolhapur

3. Smt. Kashibai Navale Medical College and General Hospital , Pune

4. Dr. Vitthalrao Vikhe Patil Foundation’s Medical College and Hospital , Ahmednagar

5. Dr. D. Y. Patil Medical College, Hospital and Research Centre , Pimpri , Pune

6. Rural Medical College , PIMS (DU), Loni

Inclusion and Exclusion Criteria:

Inclusion criteria:

The present study included first year M.B.B.S. students from 2 government medical colleges, 2 private medical colleges and 2 deemed university medical colleges from western Maharashtra region who voluntarily participated after explaining necessary details of this work.

Exclusion Criteria:

The students not willing to participate were not being included in present study.

We used validated 10 point questionnaire for feedback collection.

ECE module - Measurement of Blood Pressure – in First visit was conducted in all 6 medical colleges.

Subsequently following six modules were conducted in our parent university.

List of modules and topic covered:

S. NO.	Module Title	Topic covered under module
1	Module 1) Ward and OPD visit	1. Working structure of OPD and ward in hospital 2. General examination of patient 3. Basic terms used in medicine
2	Module 2) Blood bank visit	1. Working structure of blood bank 2. Blood groups 3. Blood donation 4. Blood group matching

Cont... List of modules and topic covered:

3	Module 3) Cardiovascular system examination	1. Working structure of wards 2. Cardiovascular system examination 3. Blood pressure and Pulse
4	Module 4) Respiratory system examination	1. Working structure of wards 2. Respiratory system examination
5	Module 5) Nervous system examination	1. Working structure of wards 2. Central nervous system examination
6	Module 6) Community visit	1. Community – Health and disease 2. Communication skills 3. Doctor – patient relationship 4. Herd Immunity

In our present study we conducted thus seven modules in a hospital based setting as well as community setting, covering the majority syllabus of clinical physiology. We demonstrated clinical examinations to students in small groups. We motivated students to observe and to revise basic clinical examinations in wards. Faculties and residents supported students during these visits. We motivated students to active participation of students.

Data was pooled and tabulated for analysis using Microsoft -excel Sheet and analysis was done using SPSS [Statistical Package for the Social Sciences], IBM , version 23.0 software.

Results

In the present study 820 students were participated.

Table 1 : College wise results pattern:

S. NO.	Name of College	B J Medical College , Pune (Mean±SD)	Government Medical College , Kolhapur (Mean ±SD)	SKN Medical college , Pune (Mean±SD)	PVVPF Medical college , Ahmednager (Mean±SD)	DR DY Patil Medical College , Pimpri , Pune (Mean±SD)	RMC , Loni (Mean±SD)
1	ECE Group (OSPE) (N=10)	5.65 ± 1.55	5.73 ± 1.66	5.33 ± 1.77	6.11 ± 1.55	6.24 ± 1.75	5.95 ± 1.64
2	Traditional Group (OSPE) (N=10)	5.07 ± 1.31	4.91 ± 1.23	5.01 ± 1.32	4.78 ± 1.37	4.75 ± 1.31	4.69 ± 1.55

(N = Marks) (SD = Standard Deviation)

From the above table, it is observed that mean values of ECE exposed groups were higher than traditional teaching exposed groups in OSPE test results.

Table 2 | OSPE Test – Results

S.No.	Name of college	Mann –Whitney Test (P Value)	Results
1	B J Medical College , Pune (n=110)	0.02	Statistically significant (P value < 0.05)
2	Government Medical College , Kolhapur (n=104)	0.0001	Statistically significant (P value < 0.001)
3	SKN Medical college , Pune (n=120)	0.001	Statistically significant (P value < 0.001)
4	PVVPF Medical college , Ahmednager (n= 112)	0.0001	Statistically significant (P value < 0.001)
5	P DR DY Patil Medical College , Pimpri , Pune (n=181)	0.0001	Statistically significant (P value < 0.001)
6	RMC , PIMS , Loni (n=193)	0.0001	Statistically significant (P value < 0.001)

(n= Participated students)

Comparing OSPE test ECE session results with traditional teaching methods found statistically significant in all colleges. (P value < 0.001) (Using Mann-Whitney Test)

Table 3) Module wise study results :

Module (N)	Skill domain	Mean ± SD	Median	Normality by KS	95% CI		Mann-Whitney Test
					Lower	Upper	
No .01 (47)	ECE-OSPE	5.97 ± 1.53	6.00	Non-normal	5.52	6.43	P < 0.001; Significant
	Traditional-OSPE	4.85 ± 1.36	5.00	Non-normal	4.45	5.25	

Module (N)	Skill domain	Mean ± SD	Median	Normality by KS	95% CI		Mann-Whitney Test
					Lower	Upper	
No. 02 (47)	ECE-OSPE	6.02 ± 1.53	6.00	Non-normal	5.56	6.47	P < 0.0001; Significant
	Traditional-OSPE	4.74 ± 1.37	5.00	Non-normal	4.34	5.14	

Cont... Table 3) Module wise study results :

Module (N)	Skill domain	Mean ± SD	Median	Normality by KS	95% CI		Mann-Whitney Test
					Lower	Upper	
No. 03 (47)	ECE-OSPE	5.53 ± 1.82	5.00	Non-normal	4.99	6.06	P < 0.006; Significant
	Traditional-OSPE	4.40 ± 1.36	5.00	Non-normal	4.00	4.80	

Module (N)	Skill domain	Mean ± SD	Median	Normality by KS	95% CI		Mann-Whitney Test
					Lower	Upper	
No. 04 (47)	ECE-OSPE	5.68 ± 1.87	5.00	Non-normal	5.12	6.23	P < 0.03; Significant
	Traditional-OSPE	4.68 ± 1.25	5.00	Non-normal	4.31	5.04	

Module (N)	Skill domain	Mean ± SD	Median	Normality by KS	95% CI		Mann-Whitney Test
					Lower	Upper	
No. 05 (47)	ECE-OSPE	5.27 ± 1.79	5.00	Non-normal	4.75	5.80	P: 0.058; Non-Significant
	Traditional-OSPE	4.34 ± 1.32	5.00	Non-normal	3.95	4.72	

Module (N)	Skill domain	Mean ± SD	Median	Normality by KS	95% CI		Mann-Whitney Test
					Lower	Upper	
No. 06 (47)	ECE-OSPE	6.14 ± 1.84	6.00	Non-normal	5.60	6.69	P: 0.001; Significant
	Traditional-OSPE	4.80 ± 1.07	5.00	Non-normal	4.49	5.12	

[N= Participated students, SD = Standard Deviation]
 [P<0.05 = Significant, P<0.005 = Highly significant]

From these results, we found , Module wise comparing OSPE test ECE session results with traditional teaching methods found statistically significant in all modules except Module number five (P value < 0.001) (Using Mann-Whitney Test)

Comparing pretest and post test results (OSPE Test) found statistically significant (P value < 0.001) results in ECE sessions (Using Wilcoxon Matched Pair test)

Discussion

In traditional medical teaching pattern medical students has to spend the preclinical years in only classrooms and laboratories, memorizing body parts and

dissecting specimens, eagerly anticipating the clinical years when they would see and learn from patients.^{5,6} This division between preclinical and clinical years has been since a century ago providing a theoretical base for clinical practice.⁶ Thus in traditional curriculum the early years of medical education only engages medical students in classroom setting and makes abrupt entry in hospital setting from second year.⁷

When we tried to analyze the scientific base responsible for positive impact of ECE on all learning domains we found that ECE is complex multidimensional learning experience including visual as well as auditory learning inputs, verbal as well as nonverbal communications, group activity involving direct patient interaction experience and chance to perform clinical examination on live, leading activation of different groups of neurons.⁸ Secondly in ECE sessions learning increases direct involvement of students. On the basis of Kolb's learning theory, student's direct involvement in learning processes develop their ability to possess and active use of analytical skills improve their decision making skills. This direct involvement in learning and interest is responsible for positive outcomes.^{9,10,11}

Early clinical exposure makes overall impact on student's performance and confidence.¹² ECE is often defined as authentic human contact in a social or clinical context during the preclinical medical years.¹³ Due to working at an early stage with active interest improves psychomotor skills of students. Anatomy, Physiology and Biochemistry are the foundation subjects on which clinical medical education is built.¹⁴ These are considered a basic narrative science that introduces students to the terminology and basic concepts of modern medicine.^{13,1} This kind of learning is an active process and students who learn actively may learn better than passive learners.¹⁵ In conclusion, Anatomy and physiology is being the portal of entry to the medical curriculum and if we teach them with ECE sessions using spiral integrated model will be more beneficial.¹⁶ Worldwide in today's technology based decade number of newer hybrid applications, innovations, smart utilities are changing and enhancing our life making more simplified. Medical education sector is adapting these technologies with more intensify and core working model.¹⁷

Numbers of research studies have proved this fact in

various settings. **Sonia Littlewood *et al* (2005)** found, as part of a complex curriculum intervention early clinical experience helped recruit residents to rural primary care in the US.¹⁸ **Justin G. Peacock (2015)** found, introducing actual patients into a first-year, helped students to develop differential diagnosis formation, history-taking, and basic clinical decision-making skills at an early stage of undergraduate medical education.¹⁹ **BJ Medical College, Pune** implemented ECE model from 1989 as part of routine practical teaching in Physiology and in the long term found very positive results.

Motivation is an important component in any teaching and learning methodology which is also the highlight of our study. We found that students were highly motivated by using ECE sessions. Similar observations were noted by **Sawant *et al*, Chari S *et al*, Baheti S N *et al***, etc.^{20,21,22} The purpose, objective and importance of motivation should be clearly understood by the faculty. The fundamental aim of motivation is to stimulate and to facilitate learning activity.¹⁴² Learning is an active process that needs to be motivated and guided toward desirable ends.²³

A definite motive is very important in all work for best outcome. The greater the readiness, the greater will be the attention given to the work on hand and the sooner will the desired result be achieved.²⁴ Same is applicable for learning. Learning with motivation leads to improving psychomotor skills.

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Return to Work in Post COVID Phase in India: Media Reports Compilations

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Abstract

Summary: Ministry of Health & Family Welfare, Government of India (MOHFW, GOI) has published guidelines on preventive measures to contain spread of COVID-19 in workplace settings to respond in a timely and effective manner for detection and control of COVID-19 cases. It was first published on 17th March with subsequent revision on 15th April; 18th May and in June 2020. Despite timely and efficient implementation of the guidelines; there was a steep rise in COVID cases. This article attempts to review those guidelines holistically; to identify the gaps in them and the challenges in their implementation.

This study will address shortcomings in the guidelines and what can be done to rectify these shortcomings. There is a need for strengthening of current monitoring and evaluation system/ mechanism along with the provision of public health insurance.

Keyword: COVID, Policy, resuming work

Introduction

On 31st December 2019, health authorities in China reported to World Health Organization (WHO) a cluster of viral pneumonia cases of unknown cause in Wuhan, Hubei. In January 2020, WHO declared the outbreak of a new coronavirus disease in Hubei Province, China to be a Public Health Emergency of International Concern (PHEIC) (1, 2, 3). COVID-19 pandemic in India is part of worldwide pandemic of coronavirus disease caused by severe acute respiratory syndrome coronavirus -2 (SARS COV-2) (2,3). The first case of COVID-19 in India, having travel history from China was reported on 30th January 2020 (2, 3,4). Worldwide, countries have responded by implementing extensive contact tracing, vigorous testing, travel restrictions, lockdowns and facility closures to check exposure (4,5). Due to increase in number of COVID cases, India opted the strategy of lockdown and closure of facilities (6, 8). COVID 19 spreads as droplet infection through cough or exhalation, touching contaminated surfaces or objects. People with the age of ≥ 40 years, pregnant women, children aged < 5 years, persons with

immunocompromised conditions such as diabetes, heart and lung disease are more vulnerable and have high chances of developing complexities/ serious illness (2,7,8).

COVID pandemic of 2019 is responsible for largest global recession and has resulted in social and economic disruption worldwide (9, 10). Recommended patient specific health education strategies for disease prevention included hand washing, maintaining personal hygiene and social distancing (6, 9, 10). WHO has published guidelines on 3rd March 2020 for workplace readiness to tackle COVID situation (5, 11, 12). Those guidelines included simple ways to prevent the spread of COVID-19 in workplace, managing COVID-19 risks while ongoing community transmission (5, 6, 8, 9, 13). To prevent spread of COVID-19 in workplace, those guidelines advised on regular and thorough hand washing (10,14,16). WHO has advised responsibility of ensure supply and availability of hand sanitizers with employers. WHO clearly advised symptomatic patients to stay indoors (confined to homes/ healthcare facilities) (5, 12). Present document highlights the public health preparedness planning for tackling COVID

infection at workplace in India and how this would be done in better way.

Methodology: This review article has complied summary of all workplace related guidelines, SOPs published by government of India and related published articles during COVID epidemics. Effects of these guidelines on no of COVID Cases, strength and limitation of these guidelines are summarised. Along with how these can be addressed effectively has be suggested as well.

Government of India (GOI) Directives for resuming work during COVID^(5,6,7,8,9):

GOI has timely published guidelines for public health preparedness for tackling COVID infection at workplace. India opted with country wise lockdown on 24th March 2020. GOI issued guidelines for social distancing at offices, workplaces, factories and other establishments in a process of gradually resuming routine work services with multiple revisions. First draft was published on 17th March in with subsequent revision on 15th April, 18th May and June 2020 with detailed standard operating procedures (SOP). It also advised Work from Home (WFH) for private-sector employees in nonessential services interim period of this surge of COVID cases. SOP has been devised to ensure the safety of the employees and ultimately to check the transmission of COVID. Employers (Essential Goods & Services enterprises) are permitted to function during the lockdown with strict adherence to these Guidelines, focused on employee's health, workplace hygiene and safety of customers.

Following activities are part of the SOPs for resuming work:

1. PPE usage and hygiene measures: Every organisation must ensure employee wears facemask. Employers must supply hand-wash and sanitizers adequately, preferably with a touch free mechanism at all entry points and common areas. **Primary responsibility rests with Employers** for Intensive training and communication on good hygiene practices, **wearing of face masks in the company premises, etc.**

2. Physical distancing, Prohibition of Congregation: It has been advised that the distance

between employees should be more than 6 feet at workplace. **Employer shall arrange Special Transportation from home to workplaces and back** at 30%-40% of passenger carrying capacity of the vehicle. . Timings of lunch and other breaks must also be staggered. The staggered working hours must be implemented over at least three 1-hourly blocks. This allowed **permitting** only 2-4 people at a time in lifts (**elevators**); encouraged use of staircase, etc.

3. Sanitation/ Disinfection: All areas of workplace including entrance gate, cafeteria, lifts, washroom, walls and other surfaces must be disinfected every day every shift .All vehicles and machinery entering the workplace should be disinfected. Strict ban on tobacco products and spitting in company premises.

4. Policy changes: All employees above the age of 65; Persons with comorbidities and parents with children below the age of five were encouraged to work from home. Non- essential visitors prohibited from visiting company premises. Employers should provide insurance to its employees. Use of "Arogyasetu" app was recommended.

5. Personalised Screening: Mandatory temperature scanning (with a contactless thermal thermometer) of every individual entering and exiting the workplace.

List of services- was released by GOI and MOHFW Including all health services together with AYUSH; All agriculture and horticulture activities; Operations of the fishing (marine/inland); financial sector; social sector; Animal husbandry; Plantation activities such as tea, coffee and rubber to functional with 50% of workers; Public Utilises and MNREGA works (Watershed, Irrigation and Flood management works), Agricultural and Livestock related works, Fisheries and works in coastal areas and the Rural Drinking water and Sanitation related works. Following activities were allowed such as supply of essential goods, Movement of loading and unloading of goods/cargo (inter and intra) state; Online teaching/distance learning; Commercial and private establishments; Industries/Industrial establishments (both government and private); Construction activities; Private vehicles for emergency services, including medical and veterinary care and for procuring essential commodities and all personnel travelling to the place of work. Offices of the government of India and offices of

the state was allowed to resume activities.

These guidelines advise employers to provide PPEs, including masks and sanitizers to its employees in order to protect them from COVID. The low-cost measures under these guidelines certainly helped to prevent the spread of other infections in workplaces, such as cold, flu and stomach bugs, and protected employees against these seasonal, endemic morbidities. Provision of health

insurance shall be the responsibility of employer under this guidance document. These guidelines tried to address health; safety and financial security of employees.

Results

Major Milestones in relation to COVID cases statistics has been described in following table (**Source: WHO Coronavirus Disease (COVID-19) Dashboard and India Ministry of Health website**)

Table 1: Statistics of COVID cases in India and world with important milestones

Events	Timeline/ date published	COVID cases in India in world	COVID cases in World
First confirmed case of COVID in China	17/01/2020	0	5
First confirmed case of COVID in India	30/01/2020	1	7836
1st Draft of guideline/SOPs for workplaces to resume activity in COVID Situation resuming routine work services COVID	17/03/2020		191473
Lockdown imitated	24/03/2020	564	386969
Second draft revision of guidelines	15/04/2020	12,371	1921602
Third draft revision of guidelines	18/05/2020	90,927	4660870
‘COVID cases till First June	01/06/2020	190,535	6080983
Current COVID cases till date	15/07/2020	9,36,181	13,119,239

Indian economy has been gradually opened, and companies' has resumed work following these guidelines precautiously. Companies gradually started with workforce as minimum as 5% and scaled up to 50 %^(9,11,12). Despite implementing these guidelines, a steep rise in COVID cases (Table 1) was observed. This reflects some shortcomings in either formulation or implementation of these guidelines.

Challenges and recommendations to tackle the challenges:

1. Classification of activities: Essentialness of Workplace activities are not classified for resuming for work in this COVID pandemic phase⁽¹⁴⁾.

Classification of essential and nonessential work processes was needed to decide further continuation or suspension of activity. Active involvement of District and state level officials was needed for classification of activities for resuming in this pandemic phase and their monitoring and evaluation. This should be supervised with

help of existing OSH Audit mechanism.

2. Challenges regarding WFH provisions

^(14,15): Work processes allowed under WFH (“Work from Home”) criteria were not clearly defined in these guidelines. Employee and employers may have biased opinion for these classification, gatekeeping is must. Despite of permission to work from home for non-essential services, companies’ struggle to cope technologically and behavioural challenges for implementing WFH to make it a seamless experience.

3. Specification of insurance coverage:

Specification and details of health insurance coverage was not clarified in these guidelines. Workers from Unorganised sector, daily wage workers and / or part time workers were not documented for considering insurance coverage ⁽¹⁶⁾.

Workers from Unorganised sector, Daily wage workers’ or part time workers shall be included under insurance coverage. Daily log of these worker shall be maintained by HR. Health insurance coverage shall specify details such as inpatient, outpatient, intensive care admission and death benefit for family.

4. Leave Benefits: Employees infected with mild/ moderate symptoms requiring hospitalisation or employee needing to stay in home isolation; details of leave benefits were not specified in this SOPs

Employee needing to stay in home isolation shall be allowed to take sick leave. Infected employee requiring isolation shall be allowed to take paid hospitalisation leave.

5. Monitoring and evaluation: Details of Monitoring and evaluation of essential and nonessential works was not specified. No supervision or check on daily logs with employees was mentioned. No Supervision or monitoring pattern for physical distancing along with deviation from routines was not specified.

Companies shall consider giving additional responsibility of supervision for monitoring of social benefit to existing supervisors. Existing available monitoring and evaluation systems for workplace audits at district and state levels shall be utilised along with coordination of **Directorate General Factory Advice and Labour Institutes** (DGIFASLI), technical arm to

assist the Ministry in formulating national policies on occupational safety and health in factories and docks.

6. Emotional and Mental health: Post-COVID new realities of working from home with additional responsibility of managing home front is challenging situation. Especially, female employee with kids managing home front alone, in absence of domestic helper and child care has been additional burden to the employees. Another concern is to address fear of contracting the virus at workplace and during travel.

Adjusting to this new lifestyle changes after COVID pandemics; emotional support is an essentially a need of the hour. Dedicated mental health helpline and psychologist will be new alternatives to help stressed employees. Employers shall take responsibility of these alternatives.

Conclusion

Guidelines for returning to work has played important role in ensuring Health and safety of employees in Pandemic period. Monitoring and evaluation of these recommendations shall be implemented in coordination with Directorate General, Factory Advice and Labour Institutes (DGFASLI) with available existing system of evaluation. Employers need adapt policies fitting baseline working conditions ensuring health and safety of employee, leading uninterrupted work continuity and productivity at workplace. Each worker should take ownership of their own Health and safety along with their co-workers. Successful ownership from employee and employers are of paramount importance in Control of COVID in pandemic era.

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Epidemiology of Morbidity Profile among Population of Dehradun, Uttarakhand

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Abstract

Background: Health which is multidimensional in nature and difficult to measure, often captured through a range of indicators like mortality and morbidity. The data on morbidity is easy to collect but difficult to measure without subjective bias. A bulk of the research has been done for standardization of definitions of morbidity at National and local levels by various researchers.

Objective: This study attempts to find out the pattern of morbidity of people along with their age, sex, type of family and religion who are permanent residents of Dehradun, Uttarakhand.

Materials and Methods: This Cross-sectional study was done from December 2018 to February 2019 for a period of 3 months. A door-to-door survey was conducted amongst all residents of Raiwala and Rishikesh block, Dehradun, Uttarakhand. All residents were interviewed and data related to the socio-demographics characteristics, co-morbidities, alcohol consumption and tobacco use was collected. SPSS software was used for analysis.

Results: A total of 3198 were included in the study. The case rate was highest (86.7%) for ≥ 60 yrs age group. Among communicable diseases, upper respiratory tract infections (URTI) (6.71%) and acute gastroenteritis (5.8%) had maximum burden. Musculoskeletal pains (31.4%) and hypertension (8.1%) were the most reported diseases among non-communicable diseases. Females outnumbered males in most of the diseases.

Conclusion: The relatively higher burden of non-communicable diseases hints towards entering of the transition phase in India, an eye opener for the health planners to equip themselves against these diseases and develop appropriate health care policies and practices.

Key words: Morbidity, Mortality, Communicable diseases, Non-Communicable diseases

Introduction

Long term diseases are our own creation. The India is ageing, it is natural and inevitable so, the risk of having, at least, one chronic disease, such as hypertension, diabetes, arthritis, cancers, Tuberculosis, hypertension increases with age, this is not so much a function of chronological age per se but a reflection of the life-long accumulation of risk factors¹.

As Johansson (1991) points out, the concept of morbidity has more than one meaning and it is complex, multi-dimensional, difficult to define and measure because it has strong cultural character which permit their meaning to change over time and space².

Morbidity is measured by the World Health Organisation using DALYs (Disability Adjusted Life Years), the amount of life left due to disease or conditions. Globally, morbidity is higher in LEDCs than MEDCs. In MEDCs, the primary source of morbidity is from disease due to poor lifestyles and diseases from old age. The survival rate from these diseases is much higher in MEDCs too. The major sources of morbidity in LEDCs are prenatal conditions, Cancer, heart diseases,

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hypertension and Tuberculosis with much lower survival rates³.

Morbidity is affected by certain risk factors. In these factors are malnutrition, social diseases (i.e. Tuberculosis, AIDS), unsanitary hygiene & living conditions, a lack of clean water and poor living standards. In these main factors are high blood pressure, lack of physical activity and lifestyle choices such as a smoking, alcohol, tobacco and poor diets⁴.

Improving health status around the world today is an important social objective, which has obvious direct payoffs in terms of longer and better lives for millions and indirect payoffs through accelerating economic growth⁵.

Non-communicable diseases are increasing worldwide due to rapidly changing life style. NCDs kill 41 million people each year, equivalent to 71% of all deaths globally. Each year, 15 million people die from a NCD between the ages of 30 and 69 years; over 85% of these “premature” deaths occur in low- and middle-income countries. Earlier, burden of communicable diseases was much higher than non-communicable diseases. Due to rapid change in lifestyle, the gap has reduced drastically causing double burden of disease in developing countries such as India⁶.

In spite of the declining mortality and changing morbidity pattern, India still has the “unfinished agenda” of combating the traditional infectious diseases that continue to contribute to a heavy disease burden and take a sizeable toll⁷.

A constant watch on the changing pattern of the diseases provides us an opportunity for timely intervention as well as monitor the progress of the ongoing disease

control programs and helps in optimizing the allocation of the limited resources⁸.

With this perspective, the present research was undertaken to study the morbidity pattern and the socio-demographic profile among population of Dehradun, Uttarakhand.

Objective: To study the morbidity pattern and its socio demographic determinants among population of Dehradun, Uttarakhand.

Materials and Methods:

Study Design: The present study was a community based cross sectional study done in Raiwala and Rishikesh block of Dehradun, Uttarakhand.

Study Period: Three months from December 2018 to February 2019.

Study Settings: Rishikesh and Raiwala block of Dehradun, Uttarakhand.

Study Population: The People living in the area of Rishikesh and Raiwala block were included in the study.

Sample Size: House to house survey was done and we were able to collect demographic data on all residents, though some residents refused to undergo full assessment, making a total sample size of 3198.

Data Collection: Data was collected after taking informed verbal consent from the participants by means of a predesigned, pretested and semi-structured questionnaire covering information regarding socio-demographic factors, co-morbidities, and lifestyle.

Data Analysis: Data was entered and analyzed using SPSS software version 21 for windows.

Results

Table 1: Distribution of study population according to socio-demographic characteristics (N=3198):

Sociodemographic Characteristics	Variables	Male No. (%)	Female No. (%)	Total No. (%)
Age groups	0-14 years	354 (55.6)	283 (44.4)	637 (19.9)
	15-29 years	474 (48.9)	497 (51.1)	971 (30.3)
	30-44 years	434 (51.9)	402 (48.1)	836 (26.1)
	45-59 years	305 (58.5)	216 (41.5)	521 (16.2)
	≥60 years	164 (70.4)	69 (29.6)	233 (7.3)
Type of family	Nuclear	1172 (54.2)	992 (45.8)	2164 (67.6)
	Joint	350 (53.5)	304 (46.5)	654 (20.4)
	3 generation family	209 (55)	171 (45)	380 (11.8)
Religion	Hindu	1568 (54.5)	1311 (45.5)	2879 (90.1)
	Muslim	73 (45.1)	89 (54.9)	162 (5.1)
	Sikh	78 (60.5)	51 (39.5)	129 (4.1)
	Christian	12 (42.8)	16 (57.2)	28 (0.9)
BPL Card	Present	299 (51.2)	285 (48.8)	584 (18.3)
	Absent	1432 (54.7)	1182 (45.3)	2614 (81.7)

It was observed that majority of the study population were in the age group of 15-29 years (30.3%), belongs to nuclear family (67.6%), Hindu (90.1%) by religion and without having BPL card (81.7%). The prevalence of morbidity among study participants were 43.5%.

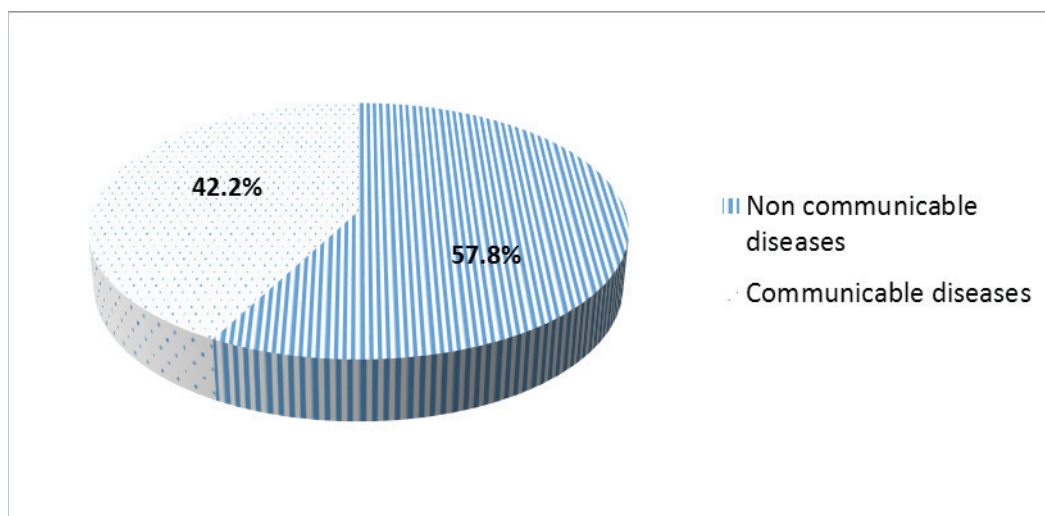


Figure 1: Prevalence of Communicable and Non Communicable diseases

Table 2: Association between socio-demographic characters and morbidity patterns

Sociodemographic Characters	Variables	Morbidity Present No. (%)	Morbidity Absent No. (%)	P Value
Sex	Male	707 (40.8)	1024 (59.2)	<.05
	Female	685 (46.7)	782 (53.3)	
Age Groups	0-29 years	336 (20.9)	1272 (79.1)	<.05
	30-59 years	854 (62.9)	503 (37.1)	
	≥60 years	202 (86.7)	31 (13.3)	
Type of Family	Nuclear	960 (44.4)	1204 (55.6)	>.05
	Joint	286 (43.7)	368 (56.3)	
	Three Generation family	146 (38.4)	234 (61.6)	
Religion	Hindu	1310 (45.5)	1569 (54.5)	<.05
	Muslim	46 (28.4)	116 (71.6)	
	Sikh	28 (21.7)	101 (78.3)	
	Christian	7 (25)	21 (75)	
BPL Card	Present	244 (41.8)	340 (58.2)	>.05
	Absent	1148 (43.9)	1466 (56.1)	

Table 2 shows that morbidities found to be more among ≥60 years (86.7%) hindu (45.5%) females (46.7%) who were living in nuclear family (44.4%) and had no BPL card (43.9%).

Discussion

This was a community based cross sectional study done to study the morbidity pattern and its socio demographic determinants among population of Dehradun, Uttarakhand.

The importance of the study lies in the fact that a constant watch on the changing pattern of the diseases provides us an opportunity for timely intervention as well as monitor the progress of the ongoing disease control programs and helps in optimizing the allocation of the limited resources.

The study confirms that burden of Non communicable diseases (57.8%) are more than that of Communicable diseases (42.2%).

Among Communicable diseases URTI (6.71%) contributed the most followed by acute gastroenteritis (5.8%). Similar results were found in a study done by Sharma MK et al⁹, Abhishek et al¹⁰ and Lamichhane DC et al¹¹ and contradicts the finding in an earlier study done by Kumari R et al⁸.

Our study reported higher proportion of musculoskeletal pain (31.4%) followed by hypertension (8.1%) and Diabetes mellitus (7.5%) among NCD’s. Results are comparable to other studies conducted by Jyvasjarvi S et al¹², Dharmaratne S et al¹³, Gupta A et al¹⁴, Shankar R et al¹⁵ and Lai MS et al¹⁶. However, a study done in Lucknow shows hypertension to be the major non-communicable disease followed by anaemia¹⁰.

In our study all most all the diseases were more common in females, a finding consistent with other

studies^{8,9,10}. This may be due to the fact that males are having more interaction with the social, economic and biological determinants of the health aspects and moreover females concern more with the health of family members rather than their own individual health.

It was observed that morbidities are more common in age group ≥ 60 years. This confirms the well-known fact that as the life years' increases, structural and functional changes is deteriorating with the old age. So, they are affected by chronic diseases more frequently than younger people.

Morbidities were reported higher among Hindus (45.5%). This may be due to the fact that Hindus forms the major proportion (90.1%) of study as compared to others religion.

Conclusion

The relatively higher burden of non-communicable diseases hints towards entering of the transition phase in developing country like India, the situation once faced by developed countries long back. This is an eye opener for the health planners to equip themselves against these diseases and develop appropriate health care policies and practices.

The high morbidity load among elderly in the present study stresses for efforts to provide better health care to them and thus ensure that they remain active members of our society.

Further multi-centric long term studies with wider coverage are desired for better understanding of the disease trend which will also act as a perfect tool for the health planners to plan better strategies.

Limitations of the study: As study was of shorter duration, so seasonal variation of morbidity pattern could not be assessed.

Conflict of Interest: Nil

Source of Funding: Nil

Ethical Clearance:

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Assessment of Nutritional Status of Underfive Children in a Low Socio-Economic Urban Community of Guntur city in AP State

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Abstract

Introduction: Under nutrition profoundly affects children's survival, growth and development. Various classifications of malnutrition in children use different cut off points for malnutrition making it difficult to compare data. The Composite Index of Anthropometric Failure (CIAF) is an alternative classification system which incorporates stunting, wasting and underweight. **Objective:** To identify malnutrition in underfive children in a low socio-economic urban area of Guntur city. **Methods:** This cross-sectional study was carried out during 2017 and 2018 at Israilpet in Guntur city of Andhra Pradesh. Weights and heights were measured for 740 underfive children (367 boys and 373 girls) according to WHO guidelines. The data collected was entered into MS Office Excel and analysed data is presented in the form of tables. Important findings are subjected to statistical tests at 5% Level of Significance. **Results:** Using WHO standards, 4.1% boys and 1.9 % girls are lesser than 3 standard deviations from the median and therefore can be considered severely malnourished. 10.4 % boys and 8.8% girls were moderately malnourished. Only 1 girl was more than +3 SDs and is obese. The infant age group has the highest prevalence of malnutrition (33.7%). Stunting is overall 10.0 % while wasting is 39.6%. Anthropometric failure taking into consideration all three aspects of malnutrition i.e. wasting, stunting and underweight is 53.9% (boys 54.2% and girls 53.7%) **Discussion:** The response to child under nutrition in India has been limited to food supplementation not taking into consideration the multidimensional nature of malnutrition. Stunting is a significant form of under-nutrition but goes largely unrecognized. CIAF could recognize more undernourished children than the z score-based classification. **Conclusion:** Using low weight-for-age as the only criterion may underestimate the true prevalence of under nutrition. It is also seen that under nutrition in the first year of life is significantly higher both in boys and girls.

Keywords: Malnutrition, stunting, wasting, underweight, anthropometric failure, CIAF

Introduction

Globally, almost 200 million underfive children suffer from stunting, wasting, or both. According to the UNICEF, there is 38% and 21% moderate to severe wasting and stunting respectively in underfives in India.¹ The National Family Health Survey - 4 showed that

38.4% of underfives are stunted (height for age), and 21% are wasted (weight for height).² Good nutritional status of pre-school children is the foundation for lifelong physical and mental health. Poverty, disease and malnutrition form important components of a vicious cycle.

Anthropometry is a practical tool for evaluating the nutritional status of children.³ Body measurements are sensitive over the full spectrum of malnutrition while biochemical and clinical indicators are useful only when a child is at least moderately malnourished.⁴ As weight is easy to measure it is the most common indicator used.

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To grade malnutrition, there are various classifications such as IAP and Gomez (weight for age), McLaren and Waterlows (weight for height). These classifications use different cut off points making it difficult to compare data. They do not address all the three indices of under nutrition i.e. stunting, wasting and underweight. Stunting is due to long-term nutritional deprivation. It results in delayed mental development and reduced intellectual capacity. Wasting is due to acute under nutrition, due to insufficient food intake or a high incidence of infectious diseases.⁵

Not only does nutritional status indicate the well-being of the child but also the overall development of the region.³ Anthropometric failure (AF) is represented by the conventional indicators of malnutrition i.e. stunting, wasting and underweight. When used individually or in combination, conventional indices fail to depict the overall magnitude of under nutrition. The Composite Index of Anthropometric Failure (CIAF) is an alternative classification system which includes all children with stunting, wasting and underweight and gives an overall prevalence of malnutrition.^{6,7}

Objective: To gather anthropometric measurements of underfive children in a low socio-economic urban area of Guntur city and identify the optimum classification of malnutrition.

Methodology

This cross-sectional study was carried out from 2017 to 2018 in the catchment area of the Urban Health Center (UHC) at Israilpet in Guntur city of Andhra Pradesh. Institutional Ethical Committee (IEC) clearance of the NRI Medical College was taken. A pilot study helped to design a semi-structured questionnaire for mothers of underfive children. A sample of 740 underfive children was taken based on the prevalence found in the pilot survey, NFHS 4 and DLHS 4 reports for Guntur District. A house to house survey was done and all the under five children available at the time of visit in 6 Anganwadi

areas were included in the study. Children's heights and weights were measured as per the WHO guidelines on anthropometry. Separate growth charts were used for boys and girls as per WHO guidelines.^{8,9} Data collected was entered into MS Office Excel and analyzed with Epi Info version 3.4.3. The data is presented in the form of tables and percentages. Significant findings are subjected to tests of significance to look for associations between variables at 5% Level of Significance.

Results

Using WHO weight for age standards, under nutrition (both <SD 2) was seen in 14.4% <5 boys and 10.7% <5 girls (Chi square 2.33, p 0.12). Severe malnutrition was seen in 4.3% boys and 1.9% of the girls (Chi square 3.13, p 0.07). Only 1 girl was more than +3 SDs and is obese. Malnutrition in infant age group (25.9%) is higher than all the other age groups (7.9%). This difference is statistically significant (Chi Square 42.2, p <0.000001). It is seen that there is a statistically significant difference in malnutrition (< SD 2) between male infants (33.7%) and female infants (16.4%) (Chi square 7.1, p 0.008) (Tables 1 & 2). Median weights are seen in 44.7% boys and 55.5% girls (Chi square 8.65, p 0.003)

Stunting is overall 10.0 % (8.9% mild, 0.9% moderate and 0.2% severe). Wasting is seen to be 39.2% (Mild 30.1%, Moderate 8.2% and severe 0.9%). The difference between boys and girls with stunting or wasting is not statistically significant.

Of the underfive children, it is seen that 53.9% (boys 54.2% and girls 53.7%) are in failure (Table 3). The WHO measurement shows the least amount of malnutrition while the CIAF model shows the most practical and relevant finding (Table 4). Looking at BMI in 406 children in the 3 years to 5 years age group, it is seen that a total 47.5% were below the 5th percentile (Table 5).

Table 1: Distribution of under nutrition by WHO classification in <5 Male children

Age in years	- SD3 (%)	- SD2 (%)	- SD1 (%)	Median	+ SD1 (%)	+ SD2 (%)	+ SD3 (%)	Total
1	14 (13.5)	21 (20.2)	23	40	5	1	0	104
2	1 (1.4)	2 (2.8)	22	39	5	2	0	71
3	0	6 (7.5)	39	34	1	0	0	80
4	0	7 (11.9)	23	28	1	0	0	59
5	0	2 (3.8)	26	23	2	0	0	53
Total	15	38	133	164	14	3	0	367

(Chi Square 45.38, deg of freedom 4, p <0.00000001)

Table 2: Distribution of under nutrition by WHO classification in <5 Female children

Age in years	- SD3 (%)	- SD2 (%)	< -SD 1 (%)	Median	> SD 1 (%)	+ SD2 (%)	+ SD3 (%)	Total
1	4 (3.6)	11 (12.4)	26	46	1	0	1	89
2	1(1.2)	3 (3.6)	26	51	2	0	0	83
3	1(1.2)	6 (7.2)	21	52	3	0	0	83
4	1 (1.8)	9 (16.1)	21	25	0	0	0	56
5	0	4 (6.5)	25	33	0	0	0	62
Total	7	33	119	207	6	0	1	373

(Chi Square 10.98, deg of freedom 4, p 0.027)

Table 3: Calculation of CIAF (Composite Index of Anthropometric Failure) in Boys and Girls				
Category	Type of Anthropometric Failure	Boys (%)	Girls (%)	Total (%)
A	No failure	168 (45.8)	173 (46.3)	341 (46.1)
B	Wasting only	122 (33.2)	126 (33.7)	248 (33.5)
C	Underweight & Wasting	7 (1.9)	9 (2.4)	16 (2.2)
D	Wasting, Stunting & Underweight	15 (4.1)	11 (2.9)	26 (3.5)
E	Stunting & Underweight	0	0	0
F	Stunting only	24 (6.5)	24 (6.4)	48 (6.5)
G	Stunting and overweight	0	0	0
H	Overweight only	0	1 (0.27)	1 (0.1)
Y	Underweight only	31 (8.4)	29 (7.8)	60 (8.1)
	Total	367	373	740
$CIAF = 1 - A / A + B + C + D + E + F + G + Y = 1 - A/1 = 1 - A$				
CIAF for Boys = 1 - 0.458 or 54.2% CIAF for Girls = 1 - 0.463 or 53.7%				
Overall CIAF = 1 - 0.461 = 53.9%				

Table 4: Comparing the different classifications of malnutrition (All grades)				
S.No	Classification	Boys (%)	Girls (%)	Both Boys & Girls (%)
1	IAP (mild, moderate & severe)	60 (16.3)	58 (15.5)	118 (15.9)
2	Gomez (mild, moderate & severe)	157 (42.8)	161 (43.2)	318 (42.97)
3	WHO < -2 Standard deviations	53 (14.4)	40 (10.7)	93 (12.6)
4	Anthropometric Failure - CIAF	199 (54.2)	200 (53.6)	399 (53.9)

Table 5: Distribution of >2 years children according to BMI and age

Age in years (Boys & Girls)	<5th percentile (%)	5th to 95th percentile (%)	Total
3	92 (56.4)	79 (43.6)	163
4	52 (45.2)	61 (54.8)	115
5	43 (37.4)	66 (62.6)	115
Total	187 (47.6)	206 (52.4)	393

Chi Square 5.65, deg of freedom 2, p 0.05

Discussion

In India, child malnutrition is mostly the result of high levels of exposure to infection and inappropriate feeding and caring practices.¹⁰ The existing response in India has been skewed towards food-based interventions with little emphasis on the multidimensional nature of malnutrition in children.¹¹ Underweight, stunting, wasting and overweight are indicators that are used to measure nutritional imbalance.¹² Sahu et al in a review showed that the prevalence of under-nutrition among under-five children in India was high and varied widely across the country.¹³

Bhandari et al state that almost 60% of children were below 2 standard deviations.¹⁴ Patnaik et al found that under-nutrition in Bhubaneswar was 28.2%.¹⁵ Srivastava et al found that 31.7% boys and 23.2% girls were underweight. Stunting was seen in 17.9 % boys and 20.1% girls.¹⁶ Thakur et al found an overall prevalence of malnutrition as 56.2%. (Boys 57.1 and girls 42.9%) They also state that all grades of malnutrition are more common in infants.³

Wasting in children is a symptom of acute under nutrition which also impairs the immune system leading to increased susceptibility to infectious diseases and increased severity and duration of disease.¹⁷ Stunting is a frequent form of under-nutrition, yet it is poorly recognized. 38% children under-five years in India are stunted.¹⁸ Stunting leads to decreased mental aptitude, decreased learning potential and poor school performance. There is also an increased risk of nutrition-related chronic diseases in the future. Preventing stunting

is essential in the long run to ensure healthy, educated and productive adults.

Seetharaman et al found 68.6% of the children to be in a state of anthropometric failure while the WHO and IAP scoring showed malnutrition as 49.6% and 51.4% respectively.¹⁹ Savanur et al found that prevalence of underweight, stunting and wasting was 35.7%, 33.8% and 18.5% respectively. However as per CIAF, 47.8% children were undernourished. Of these, a third of them had single anthropometric failure while half of them had dual failure and 17.1% had multiple failures.⁶ CIAF is useful in assessing the overall magnitude of under nutrition and identifying children with multiple anthropometric failures. In another study of slum children in West Bengal, the prevalence of low weight for age was 41.6%, whereas CIAF was 80.3%.²⁰ A study done in Raipur showed that by CIAF the prevalence of under nutrition was found to be 62.1%.²¹ In a study done in Yemen, CIAF identified under nutrition in 70.1% of underfive children, while conventional anthropometric indices revealed 55.1% underweight.²² Kaissie et al found 36.3 % stunting, 12.1% wasting and 24.9% underweight while the prevalence of total under nutrition in the children was 45.96%.²³

The multi-dimensional nature of malnutrition and the three anthropometric indicators of children are equally important. Short-term nutritional interventions are unlikely to succeed in an environment where the causes of malnutrition are multidimensional and interrelated. Focused interventions are needed for improving the nutritional status of underfive children to ensure ideal growth and development and also reducing

morbidity and mortality.²⁴ By using CIAF classification, undernourished children can be distributed into different groups to identify children with multiple anthropometric failures for and prioritized management.²⁵

Conclusion

Anthropometric failure takes into consideration all three aspects of malnutrition i.e. wasting, stunting and underweight. Using low weight-for-age as the only criterion may underestimate the true prevalence of under nutrition. It is also seen that under nutrition in the first year of life is significantly higher both in boys and girls. A relook at infant feeding practices is necessary.

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Comparison of Effectiveness of Chlorine Dioxide Mouthwash and Chlorhexidine Gluconate Mouthwash in Reduction of Oral Viral Load in Patients with COVID-19

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Abstract

Background: Air-borne droplets constitute the main route of transmission of COVID-19. Considering the exponential increase in number of cases, it has become the need of the hour to develop additional measures to limit the spread of infection.

Materials and Methods: 40 patients were provided with Chlorhexidine gluconate (0.2%) mouthwash and Chlorine dioxide (0.1%) mouthwash to rinse and gargle thrice a day for one week. The qualitative COVID antigen test confirmed by Qualitative PCR on an oropharyngeal swab collected from the patients was compared for both the groups at baseline and post-intervention levels.

Results: There was an improvement in symptoms such as cough, sore throat and bad breath in both the groups. The number of cases demonstrating reduction in intensity of symptoms as well as testing qualitatively negative for COVID-19 antigen were found to be greater in the group that was provided with Chlorine dioxide mouthwash.

Conclusion: Regular use of Chlorine dioxide could effectively reduce the symptoms and oral viral load, thereby subsequently reducing the symptoms and risk of transmission of COVID-19. Use of Chlorine dioxide mouthwash may be recommended as a part of health policies and preprocedural protocols.

Keywords: *Pandemic; Airborne spread; Oropharyngeal; Virucidal mouthrinses; Health policy*

Introduction

The cases of COVID-19 have been increasing ever since its inception and considering its alarming level of spread, it was characterized as a pandemic by WHO on 11th March, 2020 [1]. The virus is abundantly present in

the oropharyngeal region wherein especially high load has been reported in the saliva [2-3]. Airborne droplets generated during sneezing, coughing, breathing, and talking comprise the most common route of infection [4]. The aerosols generated by patient may permit COVID-19 to remain suspended in the air for about 3-4 hours and can spread up to a distance of 1 meter [5].

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Therefore, in order to limit the physical spread of the outbreak, various measures such as social distancing, lockdown, wearing masks and practicing sanitization are implemented. However, despite numerous efforts, the number of cases globally are exponentially increasing

day by day. It is, thus, imperative to find adjunctive measures that could aid in limiting the spread of the disease.

Chlorhexidine gluconate when used as a mouthwash has been proven effective in reducing oral viral load in 0.12% and 0.2% concentrations according to various scientific reports [6,7]. Yet another less commonly utilized mouthwash i.e. chlorine dioxide (0.1%) has been proven effective in reduction of viral load [8]. Its safety as a mouthwash for oral rinse and gargle has also been documented in scientific literature [9,10].

If the oropharyngeal viral load is substantially lowered by rinsing and gargling by a mouthwash having virucidal activity, it could play a pivotal role in curbing the number of cases during the pandemic. In this context, we have attempted to assess the effectiveness of chlorhexidine gluconate mouthwash and chlorine dioxide mouthwash in reducing the oral viral load of COVID-19 positive patients so as to reduce the risk of transmission.

Materials and Methods

Study sample and Grouping:

A sample size of 40 patients was determined for the pilot study. Patients confirmed as positive for COVID-19 antigen by means of Qualitative PCR test with age ranging from 19 to 49 years were included in the study. A detailed case history including their present symptoms were recorded at the time of selecting patients. Patients having medical history or family history of systemic disorders; or of allergic reaction to either components of the mouthwash; inadequate records or disambiguous history; those with severe symptoms in need of immediate critical care; non-compliant and not willing to participate in the study were excluded from the study.

Informed consent was obtained from the cases deemed as eligible for the trial and a randomly generated code was provided. On the basis of code generated, the participants were divided into two groups:

Control Group ($n=20$) à provided with Chlorhexidine gluconate (0.2%) mouthwash

Study Group ($n=20$) à provided with Chlorine dioxide (0.1%) mouthwash

Clinical Protocol:

Both the investigator and the participant were blinded with respect to the mouthwash provided. The participants were provided with either chlorhexidine gluconate (0.2%) mouthwash (Guard OR, Group Pharmaceuticals Ltd., India) or with chlorine dioxide (0.1%) mouthwash (Freshclor, Group Pharmaceuticals Ltd., India) depending on the group they were assigned to. Instructions to rinse and gargle with 10 ml of undiluted mouthwash, thrice a day – before brushing in the morning and after meals during afternoon and night for seven days were given and regular daily follow up was carried out.

Another swab test was carried out for the patient at the 8th day on which the patient would not use the mouthwash so as to eliminate temporary and mechanical effects of mouthwashes on the test results. Qualitative assessment of symptoms and oral viral load by RT-PCR test from each group were compared to the initial baseline and the results of each group were compared to each other.

Results

The number of cases remaining positive for COVID-19 antigen as tested by RT-PCR test after 1 week of mouthwash protocol have been illustrated in **Figure 1**.

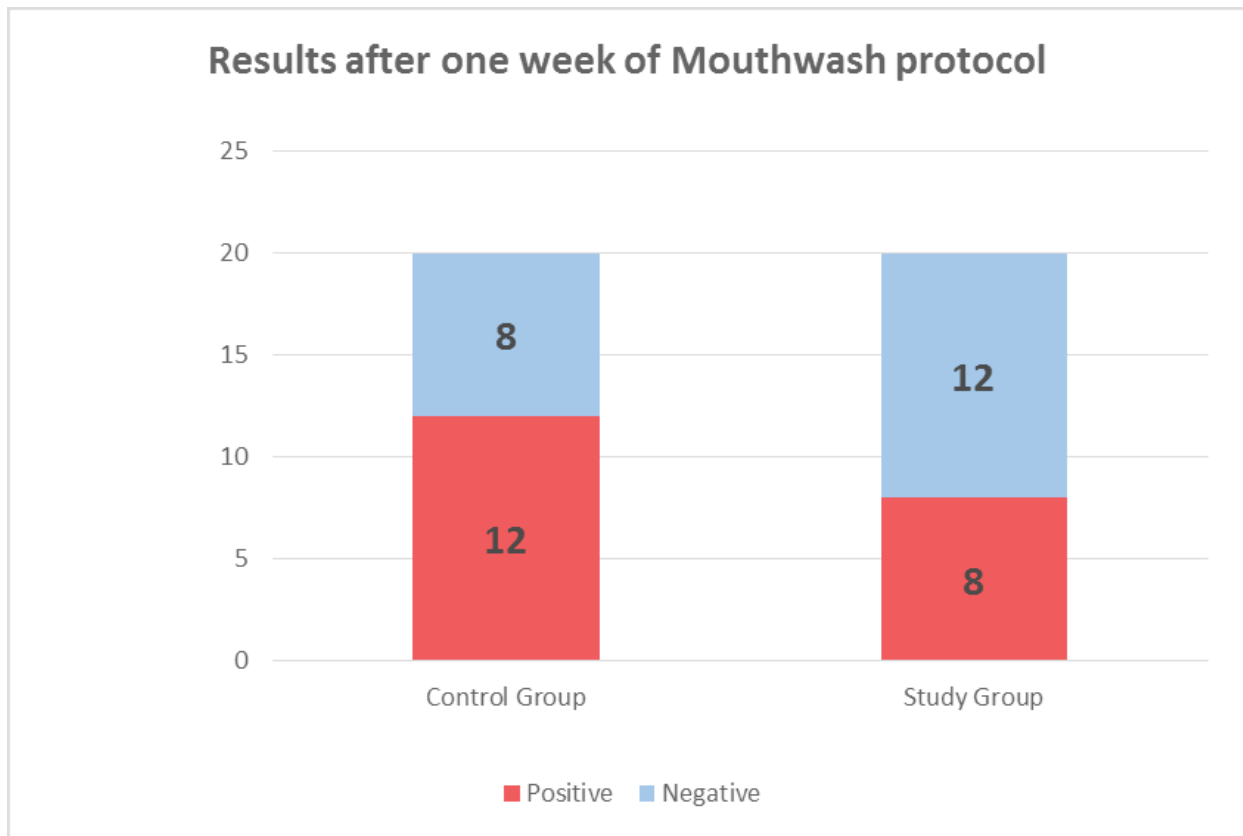


Figure 1 illustrates the resultant number of cases testing positive and negative for COVID-19 antigen by Qualitative PCR test after one week of mouthwash intervention in the control and study groups respectively.

Although the results could not be subjected to statistical analysis owing to the small sample size of the present pilot study, it was found that more number of patients recovered from the disease after one week of Chlorine dioxide mouthwash protocol along with routine therapy. Thus, it could be extrapolated from the results that Chlorine dioxide mouthwash could possibly prove more beneficial in reduction of oral viral load and subsequently limiting the spread of infection through oral droplets.

Furthermore, all the patients having cough, sore throat, bad breath and loss of taste showed rapid improvement in their symptoms. Patients with symptoms such as diarrhoea, cold and headache were more or less unaffected and any improvement could not be entirely attributed to mouthwash.

Discussion

Coronaviruses are a group of positive-sense single-stranded RNA viruses surrounded by a fatty layer, called

a “lipid envelope,” into which the spike glycoproteins required for infection are inserted. Disruption of the lipid envelope represents a viricidal strategy to target many coronaviruses [11]. Due to its positive charge, Chlorhexidine gluconate reacts with the negatively charged microbial surface, thus penetrating into the cell. It has been proven to effectively reduce the viral concentration of the lipid enveloped viruses [12]. A recent meta-analysis showed that chlorhexidine (rinse or gel) can reduce risk of ventilator-associated pneumonia in patients undergoing mechanical ventilation [13].

Chlorine dioxide (ClO₂) is an unstable gaseous compound. Therefore, salt of chlorine dioxide i.e. sodium chlorite is utilized which is termed as stabilized chlorine dioxide. Oral rinses containing ClO₂ are now utilized in dental practices as an anti-microbial mouthrinse for the oral cavity or for dentures [14,15]. Previous studies have suggested that ClO₂ and ClO₂⁻ are chemically reactive oxidants with powerful reducing capacity. Such oxidative mouthwashes are proven more effective

against coronaviruses.

In an in-vitro study, Noss et al found that chlorine dioxide reacted with viral proteins, namely cysteine, tyrosine, and tryptophan amino acid residues [16]. Ogata found that ClO₂ caused denaturation of viral proteins of influenza virus by oxidative modification of the tryptophan and tyrosine residues in hemagglutinin spike protein, thus abolishing its receptor-binding ability [17]. The spike protein of the new coronavirus SARS CoV-2 also contains 54 tyrosine, 12 tryptophan, and 40 cysteine residues [18]. Another mechanism involving antiviral activity of ClO₂ could be inducing the release of reactive oxygen species (ROS) which could be further enhanced with the use of antioxidants like Vitamin C and E [19].

COVID-19 positive tested patients can mainly spread the virus unknowingly during the subclinical period [20]. This can be tested by assessment of viral load in these patients. *Viral load* also known as viral burden or viral titer is a numerical expression of the quantity of virus in a given sputum or blood plasma [21]. Higher viral load of SARS-COV2 has been found in the saliva as compared to that of oropharynx. [3] The reason for higher transmission and viral load in saliva is related to the receptor binding tropism, SARS-CoV-2 binds to the angiotensin converting enzyme 2 (ACE2) receptor, which is present in abundance in the respiratory tract and the salivary gland duct epithelium [22,23].

This viral load can be reduced from the upper respiratory tract, which is quite accessible, by gargling of oral cavity with an antiseptic and use of nasal drops/tampons for nasal cavity.

A randomized controlled trial by Satomura et al found that regular gargling with drinking water containing 0.5 mg/L of chlorine was effective in reducing the effect of upper respiratory tract infections including influenza like viruses [24].

A virus ready to infect a cell is typically in aqueous phase, e.g., in a fluid droplet, or in the epithelial lining fluid covering the mucous membranes, the size of which is much larger than that of the virus. Therefore, in such cases, the rate-limiting step probably would be the diffusion of a substance, in this instance, chlorine dioxide in the water [25]. However, on rinsing with chlorine dioxide mouthwash, the gaseous compound

is released in the mouth Taking this into consideration Chlorine dioxide in the form of mouthwash would be an effective modality for reduction of oropharyngeal viral load.

Use as preprocedural mouthwash

A study found out that pathogenic microorganisms are present in patients' mouths from day one and show an increasing trend during hospitalization. [26] Chlorhexidine, being a gold standard mouthwash, has already been used as a preprocedural mouthwash for COVID-19 with varying concentrations in dental practice, that acts by reducing the systemic complications of the disease and accelerating the recovery process [27]. Chlorhexidine mouthwash has been reported as effective in reducing the incidence of ventilator-associated pneumonia in critically ill patients [28].

Chlorine dioxide has also been proven to be an effective antiviral mouthwash against various RNA and DNA viruses. As a disinfectant, it is more effective than sodium hypochlorite and chlorine alone which releases trihalomethane. [29]. As discernable from our results, inclusion of Chlorine dioxide mouthwash before dental procedures could further reduce the risk of infection by reducing the oral viral load.

However, due to limited budgeting and risk of infection, the sample size of the present study was limited and further studies with greater sample size and quantitative viral load estimation methods could be undertaken to ascertain the effectiveness of mouthwashes in reduction of oral viral load. Yet another limitation of the study was that the patients continued receiving routine treatment regimen for COVID-19 alongside the mouthwash intervention. Thus, all the results could not be attributed entirely to the mouthwash although patients had similar baseline variables such as location and treatment provided.

Conclusion

We cannot be sure that such a treatment would be enough to prevent the development and spread of the illness, as viruses living in other parts of the body can survive. However, inactivating part of the viruses and reducing their load in the oropharyngeal region using Chlorine dioxide mouthwash would definitely aid the

reducing the transmission of the disease through oral droplets along with the social distancing protocol. Chlorine dioxide mouthwash could augment the improvement of symptoms in COVID-19 patients as well. Thus, it should be recommended as an adjunctive measure by implementation of policies by health authorities and government bodies.

Ethical Clearance: The approval for trial was obtained from Medical Officer of Health, Department of Public Health, G/North Ward, Dadar, Mumbai before commencement of the study.

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Brain Waves and Emotional Competency: Mediating Role of Creativity

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Abstract

A general opinion is coming out among researches that brain waves are associated with cognition and emotion. Brain waves are tiny pulses of the electrical activity which are detected using sensor placed on the scalp. Our brain waves change according to what we are doing and feelings. The present study attempts to explore the possible role of creativity in explaining the relationship between brain waves and emotional competency. Thirty participants (18 graduate and 12 post graduate) were assessed on measures of EEG recording, creativity and emotional competency. Analysis revealed that alpha, beta and theta waves are positively correlated with all dimensions of emotional competency and creativity. The findings of stepwise multiple regression analysis revealed that alpha waves emerged as the best predictor of creative fluency, creative flexibility and originality followed by theta waves. To examine the meditational role of creativity in alpha – emotional competency relationship a meditational analysis was carried out. Finding revealed that the creativity significantly mediated this relationship. In the total sample, alpha waves predicted emotional competency in an initial regression model (beta = 0.64, $p < 0.001$). When creativity was added to the model, however, alpha waves – emotional competency relationship was attenuated less and insignificant (beta = 0.27, NS). A Sobel test of significance confirmed a mediated effect ($p < 0.01$). The results have been discussed in the light of available empirical researches.

Key words: Brain waves, creativity, emotional competency

Introduction

Brain networks have small-world attributes, and studying complex brain networks has become an important direction for brain waves research. Brain waves are generated by the building blocks of brain, the individual cells called neurons. Neurons communicate with each other by electrical changes. We can actually see these electrical changes in the form of brain waves as shown in an electroencephalogram (EEG). Brain waves are measured in cycles per second measured in Hertz (Hz). The Alpha wave (about 8-10Hz) occurs when brain activity slows just below the normal

waking state of Beta (11-25 Hz). In Alpha, the mind and body are relaxed but a level of focus is easily maintained. In this deeper brainwave state, information can be processed consciously without as much “mental activity” to interfere with it. There is also a greater link between the conscious and subconscious mind in Alpha, meaning that while one is consciously learning, their brain is also unconsciously processing what one is learning. Alpha waves have a positive relationship with cognitive performance^(1,2,3). Alpha is ‘the power of now’, being here, in the present. Alpha is the resting state for the brain. Alpha waves aid overall mental coordination, calmness, alertness, mind/body integration and learning. The beta brain waves frequency ranges from 13 Hz to 30 Hz and has been correlated with attention, high level of concentration, and solving of complex mental problems. It has been observed that an increase in beta power is related to increased tasks difficulty^(4,5). Beta brainwaves dominate our normal waking state of consciousness

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when attention is directed towards cognitive tasks and the outside world. Beta is a 'fast' activity, present when we are alert, attentive, engaged in problem solving, judgment, decision making, or focused mental activity. Theta brainwaves occur most often in sleep but are also dominant in deep meditation. Theta is our gateway to learning, memory, and intuition. In theta, our senses are withdrawn from the external world and focused on signals originating from within. It is that twilight state which we normally only experience fleetingly as we wake or drift off to sleep. In theta we are in a dream; vivid imagery, intuition and information beyond our normal conscious awareness. It's where we hold our 'stuff', our fears, troubled history, and nightmares^(6, 7).

Creativity is defined as the tendency to generate or recognize ideas, alternatives, or possibilities that may be useful in solving problems, communicating with others, and entertaining ourselves and others. The psychometric approach to creativity reveals that it also involves the ability to produce more. A focus on the nature of the creative person considers more general intellectual habits, such as openness, levels of ideation, autonomy, expertise, exploratory behavior, and so on. Guilford (1967) suggested that creative processes involve divergent thinking which allows an individual to break free from previous and the most obvious type of ideas⁽⁵⁾. This is then followed by convergent thinking which involves the process of narrowing down and choosing the best idea^(8, 9). Creativity, the ability to produce novel and useful work, is one of the most extraordinary capabilities of the human mind⁽¹⁰⁾. In particular, creative idea generation was associated with increased oscillation power in the alpha band in prefrontal and parietal cortical areas^(11, 12). Several research sources state the positive effects of a brainwave entrainment program. D. S. Foster (1990) defines Alpha brainwave entrainment as a consciousness management technique, implying a self-adjustment component⁽¹³⁾. Some researchers reported considerable decrease in anxiety levels and a raised level in the participants' life quality and overall wellbeing, following a brainwave entrainment program^(14, 15).

Human emotion is very difficult to determine just by looking at the face and also the behavior of a person. Although we all experience emotions, we markedly differ in the way we process them. Some

of us are able to identify our emotions, express them in a socially acceptable manner, and regulate them when they are inappropriate, others have a hard time interpreting their emotions and seem most of the time overwhelmed by them. Emotional Competency refers to individual differences in identifying, expressing, understanding, regulating, and using emotions^(16, 17). Brain rhythms act as a gate for information entering and leaving the mind. One of the most scientifically studied and proven benefits of brainwave entrainment is its ability to improve academic performance, increase IQ, and improve cognition, but which brainwave is best for studying? It hasn't cleared yet. Creativity, the ability to produce innovative ideas, is a key higher-order cognitive function that is poorly understood. Yet, the neural basis of creativity remains poorly understood.

It is evident from the review that the cognitive performances are related to the different brain waves^(18, 19). Particularly alpha brain wave is associated with enhanced creativity and emotional competency. It is very important to understand how brain waves contribute to the state of mind. This observation lends indirect support to our speculation that the beneficial effect of alpha brain waves may be mediated by creativity. There is shortage of literature in this area and most of the early studies on brain waves explain their dominant roles on cognition. So the present study will be modest attempt to examine the brain waves- emotional competency relationship in general population using physiological measures of brain waves through EEG and explore the relative significance of various brain waves in predicting creativity. It will also explore the potential mediating role of creativity in Alpha wave-emotional competency relationship.

Method

Sample: The present study was conducted on a sample of 30 subjects belonging to middle class from Noida and Delhi NCR with the help of randomized sample technique (age range 18- 45 years, Mean age 32.4 yrs.). With the help of EEG, 4 waves were taken for the study. No one had reported any history of chronic illness (hearing ability, mental state, and health conditions of the test subjects were normal). Furthermore, the test subjects had not undergone any EEG-related training. This study was designed in a controlled environment.

Tools

1. The electroencephalogram (EEG): It is a widely used non-invasive method for monitoring the brain. It is based upon placing metal electrodes on the scalp which measure the small electrical potentials that arise outside of the head due to neuronal action within the brain. The EEG signal that arises on the scalp is measured as a voltage in the time domain, with a wide number of potential signal morphologies present. Software Version 4.48, hardware version 3.2 was used in this study. It is a 24 Channel EEG, USB powered. Copyright © Clarity Medical Private Limited, C-84, Industrial Area, Phase-7, Mohali, Punjab (INDIA) – 160055. This EEG is characterized by dividing it into frequency bands, each given the name of a Greek letter: • Delta: Activity at less than 4 Hz • Theta: Activity between 4 and 8 Hz • Alpha: Activity between 8 and 13 Hz • Beta: Activity between 13 and 30 Hz

2. Verbal test of Creative thinking (20): It is a verbal test of creativity which evaluates the level of creativity on the basis of three domains. **(a) Fluency:** which represents the number of responses that are appropriate and not repeated, **(b) Flexibility:** represents the ability to produce distinct responses which differ in the trend of thought. The ideas expressed are limited to one category of classification, and **(c) Originality:** which is represented by uniqueness of the responses given by less than five percent of the normalized group.

The test-retest reliabilities of factor scores are as follows – 0.945 for fluency, 0.921 for flexibility, and 0.896 for originality.

3. Emotional Competence Scale (21): measures emotional competence on five dimensions, namely, adequate depth of feeling (ADF), adequate expression and control of emotions (ACCE), ability to function with emotions (AFE), ability to cope with problem and enhancement of positive emotions

Procedure

The participants were made to sign the consent and the confidentiality sheet to ensure that they are willingly participating in the research study. All the subjects were told to wash their hair the day before the test as, an oily scalp is a contra-indication for an EEG recording. The participants were then administered verbal test of creativity and emotional Competence along with the proper instructions. Their responses were recorded in an answer booklet. The participants were asked to solve the problems at their own preferred pace, without interruption. Next, the participants were asked to commence with their electroencephalogram recording as and when they completed filling the response sheet. The EEG recording was carried out by experienced technicians so that the data being collected has minimal artifacts. The scores of the test were later assessed. The average of the relative power of the brain waves present in all the lobes was then calculated and later correlated with the scores in the test.

Results

To examine the relationship of brain waves with all dimensions of creativity bivariate correlations were computed and obtained results have been displayed in table-1

Table1: Bivariate Correlation among the relative frequency of brain waves and scores of creativity.

Waves/Creativity	Total Alpha waves	Total Beta waves	Total Theta waves	Total Delta Waves
Fluency	0.743**	0.371*	0.482**	-0.641**
Flexibility	0.571**	0.365*	0.470**	-0.605**
Originality	0.668**	0.367*	0.348	-0.613**
Total creativity	0.755**	0.412*	0.481**	-0.696**

*p<0.05, **p<0.01

Inspection of the table-1 indicates that the sub-domain of creativity – Fluency, flexibility and originality as well as the total scores of creativity significantly and positively correlated with alpha, beta, and theta waves and negatively correlated with delta waves. It suggests that a correlation between an increase of alpha brain waves—either through electrical stimulation or mindfulness and meditation—and the ability to reduce depressive symptoms and increase creative thinking. Our various states of consciousness are directly connected to the ever-changing electrical, chemical, and architectural environment of the brain. Daily habits of behavior

and thought processes have the ability to alter the architecture of brain structure and connectivity, as well as the neurochemical and electrical neural oscillations of your mind. At the root of all our thoughts, emotions, and behaviors is communication between neurons. Brain waves are produced by synchronized electrical pulses from masses of neurons communicating with each other (22). To determine the relationship of brain waves with all dimensions of emotional competency bivariate correlations were computed and obtained results have been displayed in table-2

Table2: Bivariate Correlation among the relative frequency of brain waves and scores of emotional competency.

Waves/EC	Adequate depth of feeling	Adequate expression and control	Ability to function with emotion	Ability to cope	Enhancement positive emotion	Total emotional competency
Alpha	0.41*	0.60**	0.61**	0.58**	0.47**	0.64**
Beta	0.39*	0.59**	0.51**	0.32	0.38*	0.52**
Theta	0.16	0.21	0.19	0.09	0.25	0.22
Delta	-0.42*	-0.60**	-0.58**	-0.52**	-0.44*	-0.61**

*p<0.05, **p<0.01

Inspection of table-2 indicates that alpha and beta waves are significantly positively related with all dimensions of emotional competency whereas delta wave significantly negatively related. Pattern of this correlation suggests that thoughts and other mental activity play an essential role in the formation of emotional competency. When a person is happy he or she is very existed and full of energy, enthusiastic. When they are happy and are relax and do not have any sort of stress or very low stress alpha waves are seen (23). In

addition, previous studies on brain wave reported that the participants who have high EQ (over 110), had their entropy of Beta band increased significantly. In contrast, the subjects with the entropy of Alpha band in high IQ (over 120), decreased significantly (24). However, as relative significance of various brain waves in predicting creativity cannot be determined by simple bivariate correlation, a series of stepwise regression analyses was conducted using different brain waves as predictors and various dimensions of creativity as criterion variable. The result has been displayed in table 3.

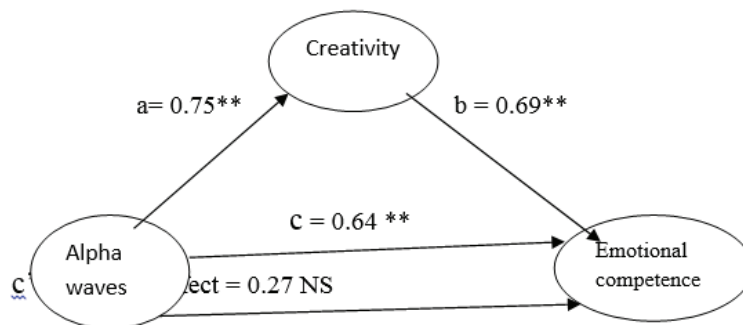
Table: 3 Step wise multiple regression analysis using brain waves as predictors and dimensions of creativity as criterion

Predictors	R	R2	R2 change	F change	B	Beta	T
Criterion variable (Fluency)							
Alpha	0.74	0.55	0.55	34.45**	0.05	0.66	5.51**
Theta	0.79	0.64	0.08	6.50	0.01	0.31	2.55**
Criterion variable (Flexibility)							
Alpha	0.57	0.33	0.33	13.57**	0.01	0.48	3.20**
Theta	0.66	0.44	0.11	5.19*	0.01	0.34	2.28*
Criterion variable (originality)							
Alpha	0.67	0.45	0.45	22.55**	0.04	0.67	4.75**

The results revealed that Alpha waves emerged as the best predictor of all dimensions of creativity (fluency, flexibility and originality) contributing 55%, 33% and 45% followed by Theta wave contributing 8% of fluency and 11% of flexibility. Beta indicates the significantly positive direction with fluency, flexibility and originality. Overall, the findings suggest that Alpha is ‘the power of now’, being here, in the present. Alpha is the resting state for the brain. Alpha waves aid overall mental coordination, calmness, alertness, mind/body integration and learning (25, 26). Several studies also indicate that EEG alpha activity is associated with cognitive performance (27, 28).

Present research study suggests that brain waves are associated with creativity as well as with emotional

competence. Furthermore, it is also evident from the results of the present study that power of creativity is positively associated with emotional competency. This pattern of relationship between alpha waves, creativity and emotional competence support this possibility that the emotional competency is likely to be mediated by the creativity. However, present research tried to empirically examine this creativity as a mediator between alpha waves and emotional competency. The mediation analysis was computed by running an Andrew Heys (2009) macro for estimating direct and indirect effects in single mediator models (29). For this analysis total scores on alpha waves was considered as predictor and the total scores of emotional competences was taken as criterion variable. The mediation relationship of alpha waves and emotional competence via creativity has been displayed in fig-1 along with path coefficient.



It is evident from fig-1 that the total effect of alpha waves on emotional competency (path $C=0.64$) reduced substantially after controlling the indirect effect of creativity resulting in a non-significant direct effect of alpha waves on emotional competency (path $C' = 0.27$ NS). It explains that alpha waves promote the emotional competence by increasing the creativity. Creative Behavior shows the power of emotional intelligence to make creativity happen. Alpha waves aid overall mental coordination, calmness, alertness, mind/body integration and learning. A series of studies explained the special role of alpha activity in creative cognition (30, 31, 32, 33, and 34).

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To Study Efficacy of Online Classes among Medical Students During Covid-19 Situation

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Abstract

Background- Education has changed dramatically, with the distinctive rise of e-learning, whereby teaching is undertaken remotely and on digital platforms during covid-19 pandemic. There is a need to monitor the implementation of online education closely, evaluate and review the method used in teaching and upgrade to maintain the quality of online education

ObjectiveS- To study the efficacy, to evaluate and compare of online class with traditional classroom learning among medical students during COVID-19 situation

Methodology- A Cross-sectional study was conducted during April 2020 to June 2020. Sample size was 1200 students. Sampling technique is convenient. Study place was Telangana and Andhra Pradesh .

Result- 78.5% students listen using mobile phones. For 65.5% students duration of online classes is 30-60 min. Majority of professors use PPT for teaching classes .57.6% of students can clarify their doubts partially only. 58.2% of students believe online classes might affect their eyesight, 58% students faced hearing issues using headphones. 55% students feel online classes are comfortable during pandemic situations. Rating of online class is very highly significant. There is association between type of college and method of teaching & feeling stressfulness by students during online classes.

Conclusion - Majority of professor's use PPT. Maximum students listen using mobile phones & use headphones For 65.5% student's duration of online classes is 30-60 min. Rating of online class is very highly significant. There is association between type of college and method of teaching & feeling stressfulness.

Key Words- PowerPoint presentation, students, mobile phones.

Introduction

The world, as we know, it has changed in the blink of an eye. The COVID-19 has resulted in schools and colleges shut all across the world. As a result, education has changed dramatically, with the distinctive rise of e-learning, whereby teaching is undertaken remotely

and on digital platforms. Suddenly, it was no longer a buzzword or a fancy Ed-tech term. Now everyone has to do it. ⁽¹⁾ It is undeniable that online education provides ample of benefits to young learners. Nevertheless, there are also many negative implications of online education. Limited collaborative learning, increase in time, and effort is the several negative implications of online education. ⁽²⁾ Furthermore, there is a need to monitor the implementation of online education closely, evaluate and review the method used in teaching and upgrade to maintain the quality of online education. Taking higher education online is much like taking up a sport such as a cricket, football or boxing online. One has not actually learnt the sport unless one has engaged with it in one's gully, stadium, field, or ring. In education, the classroom

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acts as space where skills such as dialogue, debate, disagreement and friendship are learnt and practised. A diverse and inclusive classroom is the best litmus test for any theory or insight. Multidisciplinary happens more through serendipity — when learners across disciplines bump into each other and engage in conversations. Classroom and campus spaces offer the potential for solidarity in the face of discrimination, social anxiety, and stage fear, paving the way for a proliferation of voluntary associations that lie outside the realm of family, economy, and state. In the absence of this physical space, teaching and learning would give way to mere content and its consumption. Without a shared space to discuss and contest ideas, learning dilutes to just gathering more information. This could also dilute norms of evaluation, whereby a “good lecture” might mean merely a lecture which “streams seamlessly, without buffering”. This is not an argument from tradition. One could think of greater value-sensitive and socially just architectures and technologies that further foster classroom engagement and make it accessible for students of various disabilities and challenges, thereby adding more value to the existing meaning of education. But public education modelled on social distancing is a functional reduction and dilution of the meaning of education. It could add value only as an addendum to the classroom. (3)

Aims and Objectives

ü To study the efficacy of Online Classes among medical stuents during COVID-19 situation.

ü Evaluation and Comparison of Online class with Traditional classroom learning.

Methodology

Type of Study: Observational study

Study design: Cross-sectional study

Study period: April 2020 to June 2020

Sample formulae: 4PQ/dXd

Sample size⁽²⁾: 1200 students

Sampling technique: Convenient

Study place: Telangana and Andhra pradesh

Inclusion criteria: Medical students who consented to Participate study conducted

Exclusion criteria: Students who were not willing to participate.

Data was entered into microsoft excel version 2019, and analysed with the help of Google forms ,Microsoft excel & SPSS trail version 20.0. Statistical tests used are descriptive statistics, one sample t test, Chi square test & Kolmogorov-Smirnov test.

Institutional ethical committee certificate was obtained prior to start of study.

Result and Analysis

This study was conducted with the help of a pre-designed, pre-tested web-based questionnaire in both states Telangana and Andhra Pradesh.

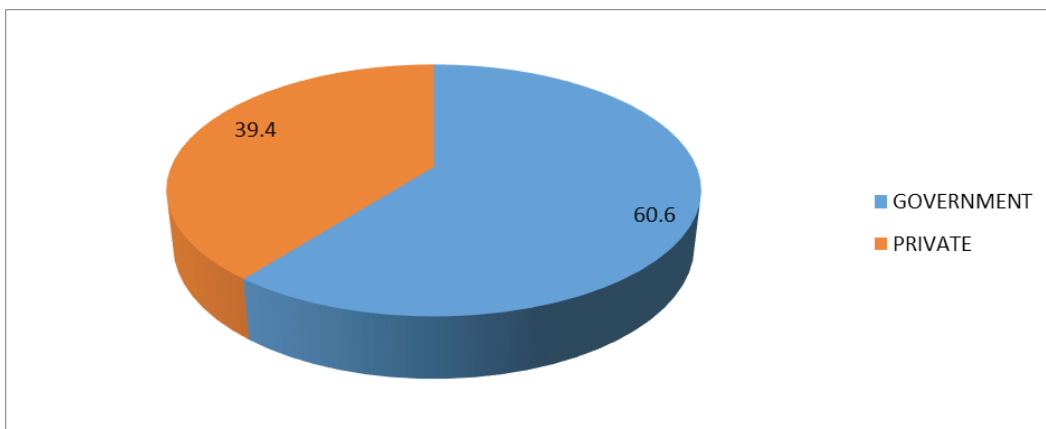


Figure 1 COLLEGE TYPE

A total of 1200 medical Undergraduates participated in the study in which 61% of students are from Government colleges, and 39% of students are from private colleges.

28.1% are from 1st year, 26.6% from 2nd year, 30.55% from 3rd year, 14.65% from final year. Among them, 48.5% of students preferred classroom learning, 22.3% of students preferred discussion with a small group, 10.6% of students preferred online learning and 18% students preferred both online and classroom learning. 78.5% students listen using mobile phones, 14.3% students listen using laptops, 5.2% students using PC and 5.2% students listen using other sources like Tabs etc., 46.6% students prefer mobile phones, 35.4% students prefer laptop, 14.1% prefer tab, 3.9% students prefer PC.

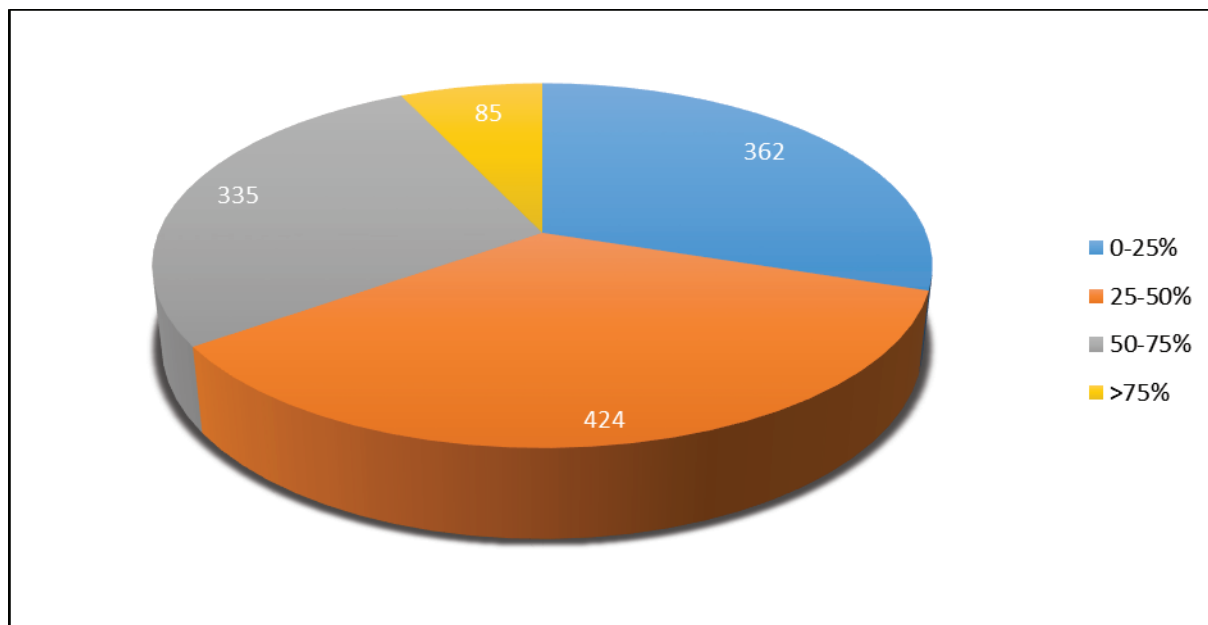


Figure 2 Percentage of grasping during online classes

According to the study grasping power of the students vary, but majority students (35%) says that they can grasp in between 25-50% only .29.9% students says that they can grasp only upto 25% from online classes .27.7% says that they can grasp up to 75% from online classes. Only 7% of students can grasp >75% from online classes.

But as per the study, 35.4% students prefer laptop so that they can have clear, bright and big screen compared to mobiles and Tab so that they can grasp as much as possible, but practically only 14.3% use laptops for listening classes so that overall grasping powering of students included in the study has been decreased. By this, we can say that a big-screen can increase the grasping

power of the students; this also signifies the importance of blackboard and PowerPoint presentation in traditional classroom learning. Questionnaire in between lectures also plays an important role in the professor how much a student can able to grasp from his lecture. But according to our study, Only 20.8% students carefully listen to each and every online lecture for other 68.8 % students many other factors determine their listening to lectures and 10.4% students not even listen to online lectures, only 27.8% students are able to answer the questionnaire asked by professor every time, 51.1% students say that they can answer only during some times, 15.7% students are completely not able to answer the questions, 4.6% students can't understand even questions too.

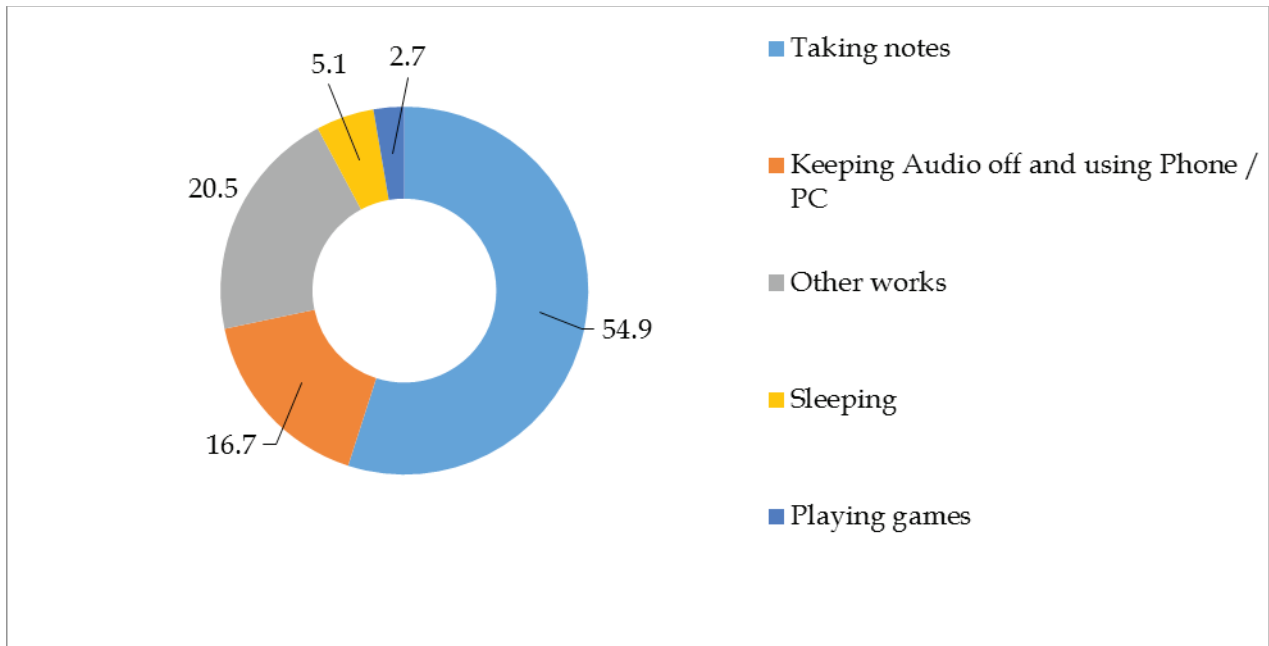


Figure 3. Students doing their actives during online classes

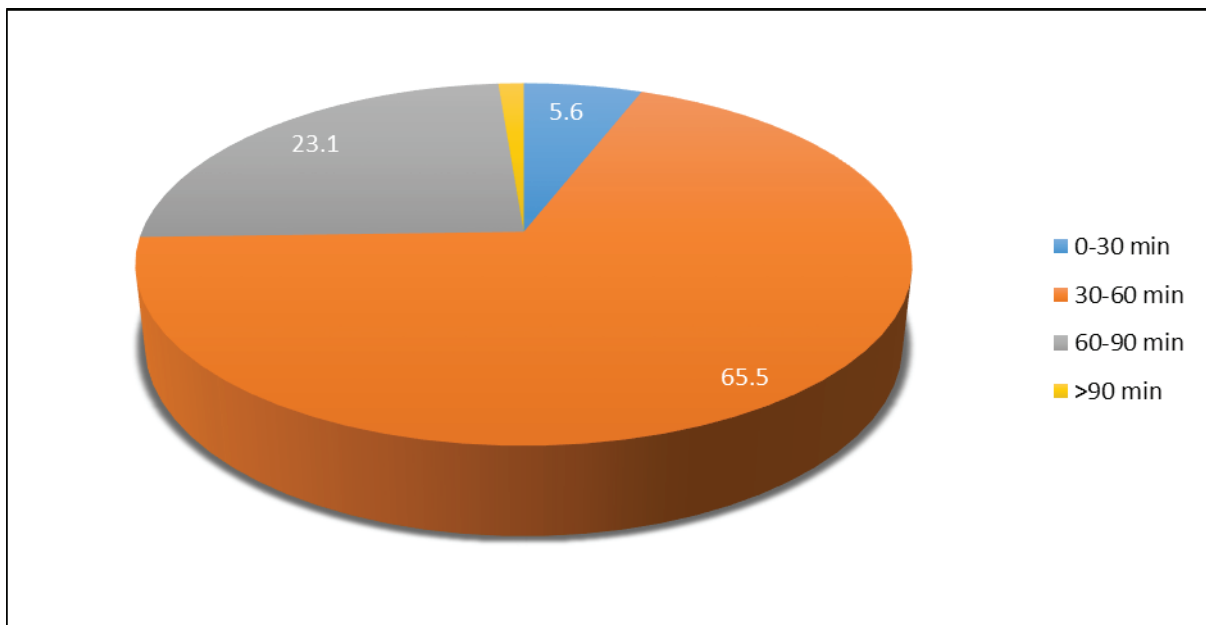


Figure 4 Duration of classes

The number of online classes also is a factor that affects learning, according to our study 50.5% students have 2-4 classes daily, 44.7% students have 1 or 2 classes daily, 2.7% have more than 4 classes daily, 2% students do not have any classes. As Number of classes per day increases Nowadays, students lose their patience and their grasping power gradually decreases, thus conducting an average of 3 classes can be better is the opinion given by the students in our study.

Giving Assignments after classes can also increase the learning time by the students, so some professor prefers giving assignments. According to our study assignments are given to students only if the topic is important (30.7% students opinion), another 30.1% says that no assignments are given to them, 19.9% says that they will get daily an assignment, 19.3% says that weekly once they will get assignments. Only 21.5% of students say that assignments are useful for them, 32.6%

of students say that assignments are useful during important topics only, 21.4% of students do assignments just for the sake of attendance. So giving assignments is also a helpful thing for students so that they can learn from assignments also.

Some professors want to know the learning status of the students, so they conduct tests for the assessment of students. During this Covid-19 situation, only online tests are possible, so 36.8% students don't have any tests, but 25.5% students have once in a week, 16.3% students have tests depending on the topic, 13.4% students have daily once, 8% students once in a month. But how can a Professor know that student has been attending test honestly is still a non-traceable thing. In our study 37% students answer the memory of the test from listening online classes, 28.5% students refer to books, 16.2% students from online reference, 7.5% students copying their friends answer sheets, 10.9% students say that they will not attempt the test. Conducting tests is an attempt made by a professor to know the standard of the student; this may help him to adjust his standard in teaching.

Majority of professors use PowerPoint presentation for teaching classes (92.5% students opinion), 4.1% of professors use discussion type for teaching, 1.8% staff teach orally, 1.6% Blackboard for teaching. So visibility of PowerPoint presentation, blackboard plays an

important role in the method of teaching, such technical issues like connectivity comes into the role, 49% students say the visibility of PowerPoint presentation, blackboard depends on signal, 45.9% students say there is a clear view of both PowerPoint presentation and blackboard, 4.3% students say they are not clearly visible, 48% students say that there is no change in teaching when compared with traditional classroom teaching, 34.5% students observed change in teaching style by their professor to some extent, 17.6% students have observed there is a complete change in the teaching style of a professor. 48.6% students observed that their professor could convey only upto some extent, 44.2% students say that their professor can convey what he wants to teach, 7.3% students are of the opinion that their professor can't convey what he wants to teach.

Doubt in a class/ discussion plays a role in gaining more knowledge for both students and staff. So in online classes, how a professor can clarify his /her doubts is also plays a role in the learning process. 57.6% of students can clarify their doubts partially only, 26.6% of students feel they can't clarify their doubts; 15.8 % of students can clarify their doubts completely. So clarifying doubts in online classes is also a disadvantage, which once again signifies classroom learning and teacher-student interaction. Teacher-student interaction plays a key role in moulding students interest in the subject, where it is less/minimal in online classes.

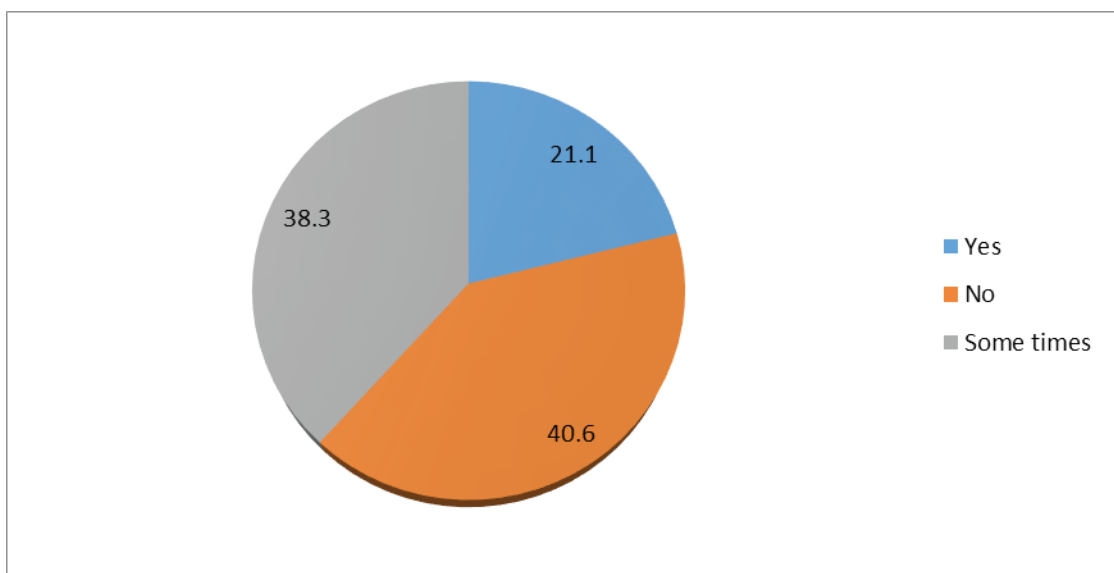


Figure 5 Stressfulness by Students

Continuous use of Laptop/ Mobile may cause the Dryness of the eye, 58.2% of students believe online classes might affect their eyeSight, 13.4% are not sure about that,42.9% Students show a change in their sleeping pattern, continuous use of headphones for hours may cause hearing problems, 58% students faced hearing issues using headphones,67.7% students use headphones during Online Classes, 24.3% students use speakers, 6% students mute the class. Using speakers and other devices may cause less damage to ears.

Technical issues like connectivity also determine the interest of student and his learning abilities. According to our study 15.7% students says there are no disturbances in connectivity,42.3%students say that there is little disturbances in connectivity21.1% students says that there are moderate disturbances in connectivity,20.9% students says that there are high disturbances in connectivity. So practically approximately an average of 30% can hear classes without any disturbances in connectivity. Moreover, people who are living in rural

areas experience connectivity problems frequently compared to people living in urban areas.

Disturbances in the normal classroom are common and little, but disturbances in online classes have been increased when compared with classroom learning. According to our study, 57.9% students say that there are no disturbances in classes,23.4% students blame others for disturbances,11.2% students say they will also involve in creating disturbances during sometime,7.5%students say that there are disturbances from the side of the teaching staff. When compared to Normal classroom learning disturbances in online classes has been increased, these may affect the grasping power of the students in online classes.

Referring to books, the Internet after classes improves knowledge of the student and helps to master the topic. According to our study, 41.9% of students refer to the books or PDFs after classes,35.6% of students refer only if any work is given, 22.5% students not even refer to the books.

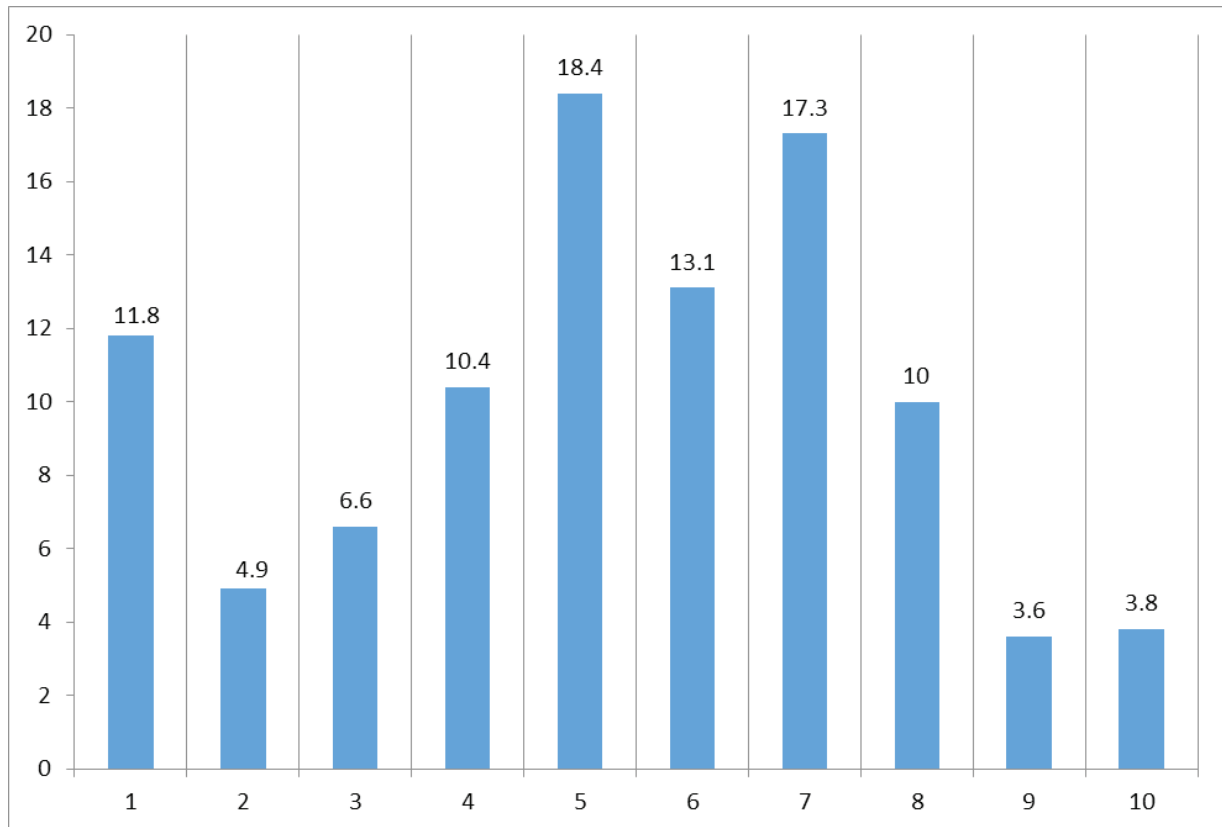


Figure 6 Percentage of the rating given by students for online classes

The opinion of parents also matter so we also collected opinion of parents about online classes 49.3% parents are of the opinion that online classes were good, Another 24% feel better on conducting online classes,7.1% parents

feel online mode of education is best, 19.6% parents feel not comfortable on conducting online classes. Opinion of students also taken into consideration, 55% students feel online classes are comfortable during pandemic situations, 15.1% students say online classes can be preferred, 20.1% say that online classes are not preferred, 9.8% students are of the opinion that online classes are not at all useful for studies.

There is a significant difference in mean rating of online by one sample t test ($p < .001$).

Phi Coefficient (0.335) suggests that there is only a negligible association between opinion of parents about online classes & feeling stressful during online classes.

Cramer's V (0.399) tells that there is weak association between teaching method of class & parent opinion about online classes.

According to chi-square test there is statistical significant association between type of college (Government/Private/others) & method of teaching ($p < 0.05$). Also statistical significant association between type of college (Government/Private/others) & feeling stressfulness by students during online classes. ($p < 0.05$). Chi square also states that type of college (Government/Private/others) is very highly significant with opinion of parents on online classes ($P < 0.001$). Kolmogorov-Smirnov test indicates that the rating of online classes is not normally distributed " $p < 0.05$."

Discussion

Large number of studies have been conducted showing effectiveness of online learning. In 1997 Gunawardena and Zittle found a strong correlation between learners' social presence and their overall satisfaction in the medium⁽⁴⁾, a study conducted by Navaro and Shoemaker in 2000 shows that student learning outcome for online learners were as good as or better than traditional learners regardless of background⁽⁵⁾. A study done by the Rovai and Jordan in 2004 examines the relationship of sense community between traditional classroom and the blended format, and they found that students in blended format had a stronger sense of community than the students in traditional format⁽⁶⁾. Vuopala et al indicates that developing and sustaining

a collaborative learning space within an e-learning environment is essential for maximizing the satisfaction of the participants⁽⁷⁾. In 2011 Allen conducted studies say that in order to enhance the productivity of the learners' long duration classes should be avoided and sufficient break should be given between two consecutive classes⁽⁸⁾. In Gourav Saikia's opinion, only online classes are not effective to cover the whole syllabus, it needs to be supplemented with offline classes⁽⁹⁾. Aljawarneh, et al study say that convenience and flexibility were identified as the strength of online classes.⁽¹⁰⁾ Bowen in 2012 students were randomly assigned to traditional format (control) and hybrid interactive online learning format that met once a week where students did most of the work online. They found that there are comparable learning outcomes for both groups and that there was a promise of cost savings and productivity gains over time for hybrid course⁽¹¹⁾.

Conclusion

- 1) Majority of professor's use PowerPoint presentation for teaching classes
- 2) 78.5% students listen using mobile phones.
- 3) 67.7% students use headphones during online Classes.
- 4) For 65.5% student's duration of online classes is 30-60 min.
- 5) According to our study, 57.9% students say that there are no disturbances in classes.
- 6) Rating of online class is very highly significant.
- 7) There is statistical significant association between type of college and method of teaching & feeling stressfulness by students during online classes.

Recommendations

- Ø Three classes /day is useful in reducing stress in students.
- Ø Break should be given in between continuous classes.
- Ø Separate sessions for doubt clarification will be helpful.

Ø Teacher-student relationship should be increased by interacting with the Students.

Ø 20-20-20 rule(Every **20 minutes**, take a **20-second break** and focus your eyes on something at least **20 feet away** prevents dryness of eye) is to be followed to prevent dryness of eye.

Ø Laptop /Tab/ Mobile should be kept at the level of the eye to prevent neck pain.

Ø Pronlonged use of headphones should be avoided.Less use of headphones and using speaker on phone and other devices like Bluetooth speakers will reduce risk of hearing problems.

Ø Use of good quality headphones and low sound hearing should be preffered.

Ø Use of teacher and student friendly platforms for online classes.

Conflict of Interest-NIL

Funding- Self

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A Cross Sectional Study on Stress and Quality of Sleep among Long Distance Truck Drivers in South India

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Abstract

Background: Truck drivers work in extremely tough situations away from home. In India, the existing literature on truck drivers was done focusing mostly on overall health aspects such as lifestyle diseases, but very limited studies done on mental aspects of truck drivers. **Objectives:** 1) To assess the stress among long distance truck drivers 2) To determine the quality of sleep among long distance truck drivers 3) To assess sleepiness among long distance truck drivers. **Methods:** A cross sectional study was conducted among truck drivers from the truck lay by areas on the Old Madras Road. Socio demographic data was collected with the help of a pre designed pretested semi-structured schedule. To assess stress Cohen's perceived stress was used and to assess sleepiness and sleep quality Pittsburg Sleep quality index (PSQI) and Epworth Sleepiness scale was used. **Results:** Among the total 117 truck drivers more than one thirds belonged to 28-37 years age group, majority (90.6%) belonged to private sector with mean years of experience in driving being 13.14±8.51 years. Only one fourth experienced excessive daytime sleepiness but majority of truck drivers had average stress. 7.8% had poor quality sleep. **Conclusions:** This study could be considered as the initial step towards detection of stress and quality of sleep.

Keywords: truck drivers, long distance, stress, sleep quality, scale

Introduction

In India, after agriculture the sector which generated maximum employment is the Transport sector. Among which, truck drivers play a major role in transportation system carrying goods and other crucial supplying across the length and breadth of our country thus playing a pivotal role. But truck drivers work in extremely tough situations away from home, under different climatic conditions and work stress. The stress of delivering goods on time so that to get any extra incentive or full

payment takes a heavy toll on their mental health. Some existing literature shows that they drive continuously for hours even without major gap in between^[1,2].

There would be various health issues due to working environment such as obesity, smoking, low physical activity, hypertension, diabetes mellitus, stress, sleep disturbances, poor quality of sleep, alcohol and many more. In HIV/AIDS, truck drivers are considered as bridge population as they are a critical group because of their mobility with HIV. Mental health is important especially for truck drivers. Long driving hours, disturbed sleep patterns, compelling duties can have impact on mental health. Mental fatigue can lead to loss of focus on driving leading to road traffic accidents^[3-5]. According to Road accidents in India report 2018, Trucks form the third-highest group of vehicles to be involved in road mishaps (around 12.3%) and road-accident fatalities (around 15.8%) published by the Ministry of road, transport and highways^[6]. Of 151,417 road-accident deaths recorded in 2018, 10% or 15,150

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victims were drivers or passengers in trucks, data show. This is a decline from 11.6% or 17,158 of 147,913 road-accident deaths in 2017 [6,7].

A research study done by Kantar IMRB in association with Castrol India was done to understand health issues faced by truckers in 2018. According to the study, more than 50% truckers faced driving related health issues such as physical stress, lack of sleep, obesity, back pain, joint pain, neck pain, eye sight issues, loneliness, breathlessness / breathing problems, mental stress. Other important findings were: unusually long working hours, long periods away from home and family, difficult road and driving conditions, all emerged as issues impacting their health and well-being. 50% of truck drivers had trips where duration is over 12 hours and 46% drove continuously for over six hours with no break. This brings to light the stressful lifestyle of long distance commercial drivers. Maintaining mental and physical fitness is of utmost importance in the trucking industry. And yet 62% drivers had not undergone a medical checkup in the past one year [8].

In India, the existing literature on truck drivers was done focusing mostly on overall health aspects such as lifestyle diseases, STDs including HIV/AIDS. Very limited studies done on mental aspects of truck drivers. This study was thus taken up focusing mainly mental aspects such as stress, sleep disturbances and sleep quality. The aim of the present study was to study about long distance truck drivers certain areas of Bangalore.

Objectives

- 1) To assess the stress among long distance truck drivers
- 2) To determine the quality of sleep among long distance truck drivers
- 3) To assess sleepiness among long distance truck drivers.

Material and Methods

Study Design

This was a cross sectional descriptive study.

General Setting

The study was conducted in Hoskote taluka of Bengaluru rural district of the state of Karnataka with a population of 66.8 million. Bengaluru rural comprises of 4 Talukas – Devenhalli (population - 2,09,622), Doddaballapura (population - 2,99,594), Hoskote (population- 2,70,818) and Nelamangala (population -2,10,889). The terrain of the district is mainly a plain area and population of 9, 90,923. MVJ medical College and research hospital is a teaching hospital situated in Hoskote, Bengaluru rural.

Specific Setting

The study was conducted among truck drivers from the truck lay by areas on the Old Madras Road at Hoskote, Tavarekere and on the Hoskote – Malur road and on national Highway connecting Hyderabad, Chennai via Bangalore and also Inter - state borders of Andhra Pradesh, Karnataka and Tamil Nadu. The study was conducted from September 2018 to January 2019.

Study Population

Study subjects were all the truck drivers from the truck lay by areas on the Old Madras Road at Hoskote, Tavarekere and on the Hoskote – Malur road and on national Highway connecting Hyderabad, Chennai via Bangalore and also Inter - state borders of Andhra Pradesh, Karnataka and Tamil Nadu. Both private and government truck drivers who gave consent for the study were taken.

Data variables, source of data and data collection

Socio demographic data was collected with the help of a pre designed pretested semi-structured schedule. Informed consent was taken prior to the start of the study.

The following 3 scales were used in our study:

To assess stress Cohen's perceived stress was used and to assess sleepiness and sleep quality Pittsburg Sleep quality index (PSQI) and Epworth Sleepiness scale was used.

The Perceived Stress Scale (PSS) is the most widely used psychological instrument for measuring the perception of Stress. It is a measure of the degree to which situations in one's life are appraised as stressful. PSS is a 10 item scale. Items were designed

to tap how unpredictable, uncontrollable and overloaded respondents find their lives. The scale also includes a number of direct about current levels of experienced stress. The PSS was designed for use in community samples. The items are easy to understand and the response alternatives are simple.^[9,10]

Epworth Sleepiness Scale (ESS) and the Pittsburgh Sleep Quality Index (PSQI) scales are utilized as general measures of sleep health and daytime dysfunction^[11,12,13]. Both the scales have been extensively used in wide range of studies.

Epworth Sleepiness Scale (ESS) is 8 item scale. It is scale to know how likely are people to doze off or fall asleep in some situation. It requires the respondents to rate on a 4-point scale (0-3) their usual chances of having dozed off or fallen asleep. The sum of scores can range from 0 to 24. The higher the score, the higher the persons average sleep propensity in daily life or their daytime sleepiness.

Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure the quality and patterns of sleep in the older adult. It differentiates poor from good sleep by measuring seven domains: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleep medication and daytime dysfunction over the last month. The client self rates each of the seven areas of sleep. Scoring is based on a 0 to 3 scale.

Data Analysis

Data collected was coded and then spread on Microsoft Excel 2010. Data was collected and. Statistical analysis of data was conducted by using Epi Info version 3.01. Descriptive data was presented in percentages & proportions. Associations between variables were done using chi-square test. The level of significance was established with p value less than 0.05 considered statistically significant.

Ethics approval

Ethics approval was obtained from the Institutional Ethics Committee of the MVJ Medical College and research hospital, Hoskote, Bengaluru, India. Informed consent was taken from all the study subjects.

Results

A total of 117 truck drivers were interviewed and assessed for stress and sleep quality during the study period.

Age wise distribution showed that majority (37.6%) belonged to 28-37 years age group followed by 38-47 years age group (26.5%), 17.1% to 18-27 years age group, 14.5% to 49-57 years and 4.3% belonged to more than 57 years age.

With regards to type of sector they are currently working with, majority 90.6% (n=106) belonged to private sector and rest (9.4%) government sector.

The mean years of experience in driving among truck drivers was 13.14±8.51 with majority (30.8%) having 4-7 years of experience.

Three fourth (76%) had mild excessive day time sleepiness, 16.2% moderate and 7.7% severe excessive daytime sleepiness. Majority of the truck drivers (89.7%) had average stress. Low and high stress was noticed in 5.1% each respectively. Sleep quality was assessed using Pittsburgh Sleep Quality Index (PSQI) and it was found that majority (92.3%) had good quality sleep and 7.8% had poor quality sleep.

Association between age and pattern of sleepiness, pattern of stress and sleep quality was not found statistically significant with p values being 0.3, 0.5 and 0.8 respectively.

Association between type of job and pattern of sleepiness, pattern of stress and sleep quality was also not found statistically significant with p values being 0.4, 0.09 and 0.8 respectively.

There is a general assumption that longer duration of driving experience might have a definite impact on pattern of sleep, pattern of stress and sleep quality as a whole but in the present study, there was no significant association with p values 0.3, 0.6 and 0.2 respectively. In the present study, there was a pattern of study population with average stress having moderate excessive day time sleepiness but when the association between sleepiness and stress was tested, there was no statistical association with p value being 0.09.

Association between pattern of sleepiness and sleep quality was not significant statistically with p value 0.6. Association between stress and sleep quality was significant statistically with p value 0.03 indicating that higher stress levels had a definite impact on the sleep quality.

Table 1: Pattern of sleepiness based on Epworth Sleepiness scale

Pattern of sleepiness	Frequency	Percentage
Mild excessive day time sleepiness	89	76.1%
Moderate excessive day time sleepiness	19	16.2%
Severe excessive day time sleepiness	09	7.7%

Table 2: Pattern of Stress based on Perceived Stress Scale

Pattern of Stress	Frequency	Percentage
Low stress	06	5.1%
Average stress	105	89.8%
High stress	06	5.1%

Table 3: Pittsburgh Sleep Quality Index (PSQI)

Sleep Quality	Frequency	Percentage
Good quality sleep	108	92.3%
Poor quality sleep	09	7.8%

Table number 4: Association between sleepiness and stress

Sleepiness	Stress			Total	P value
	Low	Average	High		
Mild	5	81	3	89	0.095
Moderate	0	18	1	19	
Severe	1	6	2	9	
Total	6	105	6	117	

Table number 5: Association between sleepiness and sleep quality

Sleepiness	Sleep quality		Total	P value
	Good sleep quality	Poor sleep quality		
Mild	82	7	89	0.616
Moderate	17	2	19	
Severe	9	0	9	
Total	108	9	117	

Table number 6: Association between stress and sleep quality

Stress	Sleep Quality		Total	P value
	Good sleep quality	Poor sleep quality		
Low	5	1	6	0.03*
Average	99	6	105	
High	4	2	6	
Total	108	9	117	

Discussion

The present study was done to throw some insights on pattern stress and quality of sleep among long distance truck drivers in Bangalore, Karnataka.

Among the total 117 truck drivers that were interviewed more than one thirds belonged to 28-37 years age group, majority (90.6%) belonged to private sector with mean years of experience in driving being 13.14±8.51 years.

Only one fourth experienced excessive daytime sleepiness but majority of the truck drivers had average stress. Emotional stress was seen in 11.1% in de Oliveira et al., 2015^[14] study. In Garbarino et al (2017)^[15] study, depression was seen in 9.2%. Another study by Shattell et al (2012)^[16] found that anxiety (14.5%), loneliness (27.9%), depression (26.9%) and other emotional problems in 13% of their study population. Our study dealt mainly on the pattern of stress and sleep, hence other mental or psychological disorders were not mentioned in the present study.

And with regards to quality of sleep, 7.8% had poor quality sleep. Bad sleep quality was found in 17.3% in study by Guglielmi et al. (2018)^[17]. In contrast to the present study, more than half the population (56%) experienced bad quality sleep in de Oliveira et al., 2015 study. In the study done by Krishnaswamy et al (2016)^[18] on night bus drivers found that only 2 (1.1%) had significant level of daytime sleepiness. However, 10 (5.6%) drivers confessed to feeling sleepy during the day while stopping in traffic and 103 (57.2%) drivers admitted to feeling sleepy while driving at night.

In the present study, no significant association was found between pattern of sleepiness, pattern of stress and sleep quality with age, type of job and years of driving experience. But there was statistically significant association between stress and sleep quality.

A descriptive review of the current evidence on sleep and mental health in truck drivers by Garbarino S et al (2018)^[19] concluded that awareness among truck drivers of the high risk for health and safety due to (often co-existing) untreated sleep and mental health problems

is critical. Alcohol and prescribed or illicit drugs are often misused to compensate for depression, anxiety, job strain, fatigue, and social isolation. Polypharmacy and dependence increase the chance of unsafe behaviors on the road.

Souza JC et al (2005) [20] on sleep habits, sleepiness and accidents among truck drivers found that 43.2% of the drivers drove over 16 hours a day, and 2.9% worked shifts. Mean number of sleep hours/day was 5.97±1.47; 23.8% slept <5 hours; 50.9% made use of alcohol, 95.6% of caffeine, and 11.1% of amphetamines. Mean PSQI was 4.95±2.56; 35.4% had a PSQI >5. Mean ESS was 6.56±4.2; 21.7% had a score >10.

Hence the present study findings were compared in detail with other studies; some of them were in concurrence and some in contrast to the present study findings. Limited studies were done in India concerned to stress and sleep quality in India, henceforth majority of the studies discussed were from other countries.

Limitations of the study: The questionnaire was translated into local language before applying it but the self-reporting format of the study might give an under estimate of the findings or not precise because there is lack of real time monitoring and no investigations being obtained. Information was not obtained on data regarding alcohol consumption behavior, number of accidents happened if any nor any other information on other mental health related issues such as depression.

Conclusion

The present study highlights the pattern of stress, pattern of sleep and sleep quality among truck drivers in India. This study could be considered as the initial step towards detection of stress and quality of sleep. A simple questionnaire like the one used in our study could be used in the pre-recruitment process of hiring long distance truck drivers. We strongly feel that this would be a step in the right direction towards reducing the number of road traffic accidents and the fatalities associated with them.

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The Effect of Lifestyle on Physical Conditions as Observed by CD4, SGOT, and SGPT of People Living with HIV: A Case Study at Dr. Iskak Hospital in Tulungagung Indonesia

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Abstract

HIV-AIDS, or Human Immunodeficiency Virus, which is the cause of AIDS ailment, or Acquired Immunodeficiency Syndrome, works by attacking white blood cells, which then leads to compromised immune system, making the person affected more susceptible to different other ailments. The virus can be found in semen, vaginal fluid, cervix, as well as blood, resulting in impairment of CD4+ as an effect of the HIV virus on human immune system. This study aims to identify and analyze the relationship between the pattern of the physical condition of people living with HIV with CD4+ indicator, SGOT and SGPT as well as a reference to improve knowledge about HIV in the laboratory. This research is experimental analytic done with the aid of Pearson statistical correlation test. The samples were thirty (30) HIV-AIDS patients at the Dr. Iskak Hospital in Tulungagung, Indonesia, who were being interviewed through a set of questionnaires given out between February to June 2013. For CD4+, the study result done using Pearson statistical correlation showed that P value is greater than α , namely $P = 0,854$, and, as such, it is concluded that there is a relationship between the lifestyle and the physical condition of patients living with HIV. However, for SGOT and SGPT, the P values are smaller than α , namely $P = -0,323$ for SGOT and $P = -0,073$ for SGPT.

Keywords: HIV, AIDS, lifestyle, physical condition, examination of CD4+ test, SGOT and SGPT

Introduction

This virus can be both found in and transmitted through semen, vaginal fluid, cervical fluid, and blood. Most patients who are diagnosed with HIV show psycho-social changes within themselves, e.g. suffering from depression, lack of social acceptance, and change in behaviour¹.

HIV virus attacks the organs responsible from immune system, such as T helper cell or CD4+, macrophage, and dendritic cells, which then causes the amount of CD4+ to decrease to be less than 200c/mm³. An acute infection of HIV will turn into a clinical latent infection, and early symptoms of HIV infection will eventually show and become AIDS as can be identified by the CD4+ test and Opportunistic Infection².

Health-related officials and society should ideally have a great understanding about care, support, and

treatment for people living with HIV-AIDS. To date, there is no cure for this virus. However, medicine to slow down the degenerative effect of the virus is at hand. Unfortunately, many people, especially those in rural areas, still have a misconception about this condition and, as such, avoid the people who live with HIV-AIDS³.

The number of HIV cases increase every year in Indonesia. As of June 2011, the reported case of HIV was 26,483 across 33 provinces and 300 cities/regencies. The most significant increase was seen in East Java Province with the additional 239 patients in the year of 2011 alone⁴.

According to the official data from Commission for AIDS Prevention and Treatment, there were 424 people living with AIDS as of October 2011 in Tulungagung alone, with 131 of amongst which passed away due to the ailment. As in the end of 2012, 153 people out of 617

reported cases passed away. To date, the reported case of HIV findings in Tulungagung is relatively high across East Java Province⁵.

The HIV patients who have learned to accept and cope with their condition tend to have better perceptible physical conditions than their other counterparts. To aid with their immune system and to slow down the progression of the virus, an Anti-Retro Viral, or ARV, is usually administered. Although ARV can increase the amount of CD4+, long-term ARV medication can affect liver enzymes and, thus, increase the SGOT (Serum Glutamic Oxal-acetic Transaminase) and SGPT (Serum Glutamic Piruvic Transaminase). However, it was found that there were some patients with decreasing values of SGOT and SGPT. This finding certainly needs further investigation⁶.

Methods

The populace was taken from the patients of HIV-AIDS who were being treated at Dr. Iskak Hospital in Tulungagung, East Java, Indonesia, whereas the sample was those in this populace who were willing to be respondents in the study. There were thirty (30) respondents in total. Each of these thirty respondents was given a set of questionnaires, which, amongst others, probed about their lifestyle and their physical conditions. The laboratory results of their CD4+, SGOT, and SGPT, paired with their questionnaire answers were then analysed

Examination of CD4+

Method : Flow cytometry

Goal : To determine the amount of blood cells (CD3+ dan CD4+)

Principle : Monoclonal Antibody (MoAb), which is coloured with a fluorescent chemical compound called fluorochrome, will create a bond with specific antigen, or Ag, on the surface of leucocyte. The Ag-MoAb complex can then be identified by its fluorescent glow when it is being passed under the laser light emitted by the flow cytometry.

Material : Blood taken from venae veins with anticoagulant Ethylene Diaminete Tetra

Acetate (EDTA)

Tools : - Pima Analyser

- Micropipette

- Yellow tip

- Cartridge

Workflow:

1. Turn on the Pima Analyser and press OK on the keyboard when the screen shows "Run Test, Press OK"

2. Before running the sample, do Pima bead standard (low bead and normal bead) running every morning or every time the tool is being moved by putting in the cartridge low or normal.

3. Wait for ten minutes for each bead standard and record the result (low bead or normal).

4. Take 25 uL sample with a pipette and put the sample into cartridge (sample collector). Avoid any bubble from forming.

5. Close the cartridge tightly.

6. Put in the cartridge (Pima bead sample) until you hear a click and Pima analyser automatically pull in the cartridge into the machine.

7. Enter the name of the operator and the name of the sample.

8. Wait for around twenty minutes for the process to take place, after which take out the cartridge and print the result by pressing the OK button

Examination of SGOT and SGPT

Method : IFCC (Enzymatic)

Goal : To determine the level of SGOT and SGPT

Principle : Kinetic determination

L-Aspartate + α - Ketoglutarate Oxaloacetate
+ L - Glutamate

Oxaloacetate + NADH + H⁺ L-Malate +
NAD⁺

MDH = Malate dehydrogenase

Material : Serum

Tools : - Selextra X and Cobas

- Centrifuge

- Cup sample

- Tube

Workflow:

1. Do control and calibration of the tool before running the sample

2. Reagent is being put in its respective place according to the user's wish

3. Write down the following data on the tool's label (laboratory number, medical record number, patient's details, and doctor's name)

4. Assign number to each sample and put them in their respective places

5. Start the tool and wait for the result (8-10 minutes)

Results and Discussions

From the study conducted between February to June 2018, data of CD4+, SGOT, and SGPT from thirty samples taken from HIV patients can be seen on table 1.

Table 1. Levels of CD4+, SGOT dan SGPT of thirty samples of HIV patients at Dr. Iskak Hospital in Tulungagung

No	Name	Age (year)	CD4 Normal Value (cell/mm3) 500 – 1500	SGOT/SGPT Normal Value u/L (0-40/0-41)	
1.	WST	42	194	27	25
2.	SYN	38	10	38	41
3.	GNW	49	179	25	29
4.	NYT	37	123	30	29
5.	KAL	42	29	42	38
6.	MRY	23	304	34	35
7.	ITK	24	192	29	32
8.	KDR	60	53	55	61
9.	EK	41	251	22	21
10.	AG	35	285	30	32
11.	KMJ	50	160	40	44
12.	SSD	42	296	28	30
13.	YLN	32	313	18	21
14.	HM	43	258	24	21
15.	KT	25	121	37	36
16.	SBR	50	138	40	39
17.	MJ	48	144	36	40
18.	SL	31	100	38	35
19.	WG	29	15	67	59
20.	WNS	32	221	27	31
21.	RN	32	127	27	26
22.	YN	41	66	46	45
23.	YLI	45	70	27	29
24.	TMJ	27	171	36	33
25.	ZZ	38	313	23	26
26.	PWT	43	184	29	32
27.	AF	26	114	121	166
28.	SAY	39	22	54	20
29.	BRY	34	40	40	35
30.	AN	39	247	17	8

Source : Primary Data for Examination of CD4, SGOT and SGPT

Note:

Most patients have age between thirty (30) to forty-five (45) year old, have CD4+ values which range between 70 – 300 cell/mm³ with normal value 500- 1500 cell/mm³, have values of SGOT dan SGPT range between 10 – 45 u/L, which is under normal category, i.e. 0 – 41 u/L.

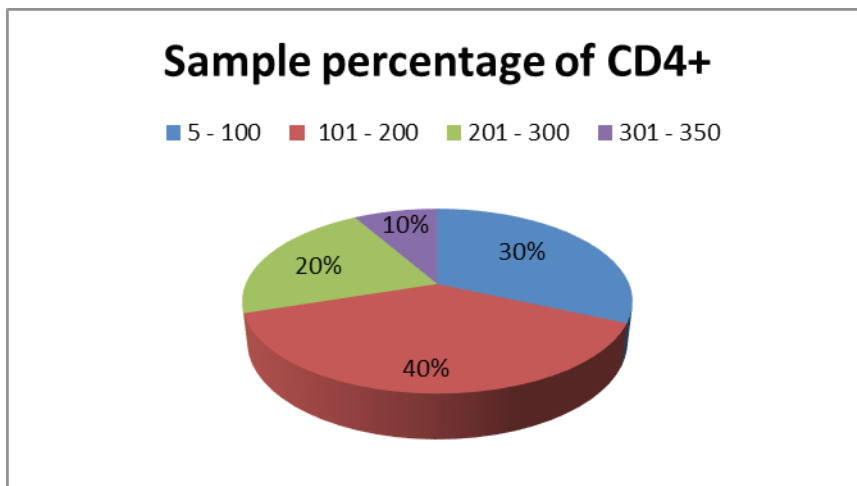


Figure 1. Sample percentage of CD4+

- a. 5 – 100 cell/mm³ : 9 patients = 30% , very low
- b. 101 - 200 cell/mm³ : 12 patients = 40%, quite low
- c. 201 - 300 cell/mm³ : 6 patients = 20% , low
- d. 301- 350 cell/mm³ : 3 patients = 10% , medium

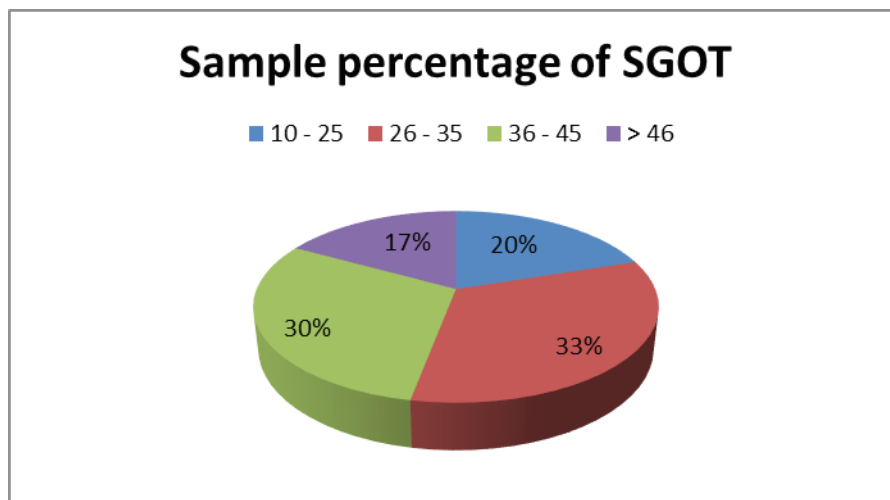


Figure 2. Sample percentage of SGOT

- a. 10 - 25 u/L : 6 patients = 20%
- b. 26 - 35 u/L : 10 patients = 33%
- c. 36 - 45 u/L : 9 patients = 30%
- d. > 46 u/L : 5 patients = 17%

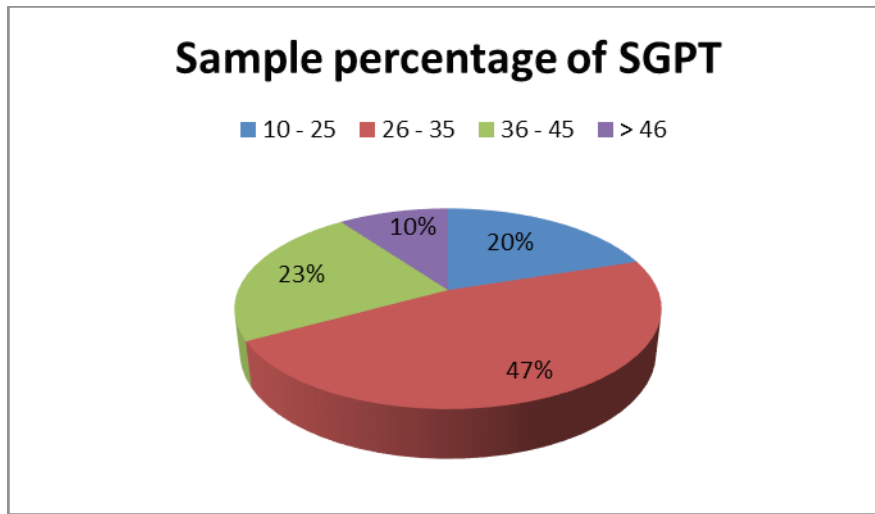


Figure 3. Sample percentage of SGPT

- a. 10 – 25 u/L : 6 patients = 20%
- b. 26 – 35 u/L : 14 patients = 47%
- c. 36 – 45 u/L : 7 patients = 23%
- d. > 46 u/L : 3 patients = 10%

Normality Test

First and foremost, *Kolmogorov-Smirnov* test was conducted to determine the distribution of the data. If the data has normal distribution, then a parametric test shall be conducted. Otherwise, a nonparametric one shall be conducted.

From *Kolmogorov-Smirnov* test, it was found that for CD4+, the p is 0.964; for SGOT, the p is 0.070 (which is more than α); for lifestyle, the p is 0.152 (which is more than α with $\alpha = 0.05$), whereas for SGPT, the p is 0.015 (which is less than α).

Conclusion: the data have normal distribution.

Pearson Correlation Test

To determine the relationship between lifestyle, physical condition of the patient, and their levels of CD4+, SGOT, and SGPT, Pearson correlation test was conducted with the following hypotheses:

Ho : There exists no relationship between lifestyle and physical condition of the patient according to their levels of CD4+, SGOT, and SGPT

Hi : There exists relationship between lifestyle and physical conditions of the patient according to their levels of CD4+

From the Pearson correlation test, it was found that $p > \alpha$ for CD4+ $p = 0.000$, with the correlation coefficient (r) being positive, i.e. 0.854, which indicates that there exists relationship between lifestyle and physical condition of the patient with the examined CD4+ as much as 85.4%; whereas the rest of 14.6% was due to other factor(s). For SGOT case, it was found that $p > \alpha$, i.e. 0.082, with the correlation coefficient (r) being negative, i.e. -0.323. For SGPT case, it was found that $p > \alpha$, i.e. 0.701, with the correlation coefficient (r) being negative, i.e. -0.073. These indicate that there exists no relationship between lifestyle and physical condition of the patient with the examined SGOT and SGPT values.

From the Pearson correlation test on CD4+ examination, it was found that (p) $< \alpha$ (0.000), which indicates that there exists a relationship between lifestyle and physical condition of the patient with the examined values of their CD4+. The positive correlation coefficient of 0.854 indicates that this relationship is a strong and positive relationship, which means that when the lifestyle and physical condition of the patient improves, their levels of CD4+ also improves.

However, for SGOT examination, it was found that (p) $> \alpha$ (0.082), which indicates that there exists no relationship between lifestyle and physical condition

of the patient with the examined values of their SGOT. The negative correlation coefficient of -0.323 indicates that this relationship is a negative one, which means that when the lifestyle and physical condition of the patient improves, their levels of SGOT do not necessarily increase.

The similar result was reflected from SGPT examination where it was found that $(p) > \alpha$ (0.701), which indicates that there exists no relationship between lifestyle and physical condition of the patient with the examined values of their SGPT. The negative correlation coefficient of -0.073 indicates that this relationship is a negative one, which means that when the lifestyle and physical condition of the patient improves, their levels of SGPT do not necessarily increase.

From the previous study in 2012 from North Sumatra University, entitled "Overview on the Lifestyle of Patients of HIV-AIDS Treated at RSUPH Adam Malik in Medan", it was found that the majority, i.e. 70.58% of the seventeen (17) respondents, led a poor lifestyle, as observed from their physical limitations, vitality, social functions, and mental health⁷.

However, this study did not indicate similar results as were shown in Tan Mei Kun's which may be due to the difference between the level of awareness of the patients of their own health condition. Lacking awareness of their condition, the patients at RSUPH in North Sumatra may not have taken care of their lifestyle as well as the patients at Dr. Iskak Hospital in Tulungagung did after their HIV diagnosis.

SGOT, or *Serum Glutamic Oxal-acetic Transaminase*, also known as *Aspartate Amino Transferase* (ASAT), can be found in cytoplasm and mitochondria of the cells of liver, heart, muscle, kidney, pancreas, and erythrocyte⁸.

SGPT, or *Serum Glutamic Pyruvic Transaminase*, also known as *Alanine Amino Transferase* (ALT) can be mainly found in cytoplasm of the cells of liver and some in kidney, heart, and muscle⁹.

It was found in this study that the SGOT and SGPT levels have yet to increase, which indicates that the liver cells have yet to deteriorate. When the cells of that organ have deteriorated, the levels of SGOT and SGPT in the

serum would accordingly increase^{10,11}.

Conclusion

There exists a relationship between lifestyle and physical condition of the patient with the examined CD4+. However, there exists no relationship between lifestyle and physical condition of the patient with the examined SGOT and SGPT.

Conflict of Interest Statement: The authors of this research declare that there is no conflict of interest related to this study

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Ethical Clearance: The ethical clearance of this research taken from Ethics Committee of Health Polytechnic Jakarta II – Indonesia (Ethical Approval LB.04.05/KE/30/503a/2018)

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Study to Assess the Knowledge, Attitude and Practice of Plastic Use among School students of Meerut, Uttar Pradesh

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Abstract

Back ground: Plastic is everywhere in today's lifestyle. Because of indiscriminate dumping of plastic bags on land, toxic metals such as cadmium and lead pigments percolate into underground water. Garbage mixed with plastic bags interferes in waste processing facilities and causes problems in landfill operations. Disposal of plastic through recycling, burning, or land filling is a myth because it does not undergo bacterial decomposition⁵. Due to non-biodegradable nature they cause hazardous negative impact on the environment. **Material & methods:** The present quasi-experimental study was conducted among school going students of class 11th and 12th of Satyakaam International School. Data was collected on predesigned semi structured questionnaire which included details of socio demographic variables like age, sex, parent's education and other details about knowledge, practice and attitude of school going children regarding plastic use. One week after the presentation again the knowledge of students regarding plastic was assessed on the same set of questionnaire. **Result:** knowledge of chemical nature of plastic before presentation was present in 64% students. knowledge regarding Non-biodegradable nature of plastic was present in 88% students. There was increase of 12% in knowledge regarding side effects of plastic on environment. 89% of the students support government on plastic ban. **Conclusion:** 16% samples that were unaware of the hazards of plastic use needed to be educated about them through means like pamphlets, health talks, advertisements and awareness programs.

Key word : Plastic, Knowledge, Practise, Biodegradation

Introduction

Plastic is everywhere in today's lifestyle. It's used for packaging, protecting, serving, and even disposing of all kinds of consumer goods. The Modern consumer is exposed to a wide variety of plastic and rubber products in his day to day life: at home, work, school, shopping, recreation, play and transport¹. As a material, plastic

has existed for just over a century and mass production began in earnest in the 1950s. By 1988, 30 million tons of plastic products were produced annually, reaching 265 million tons by 2010 and accounting for 8% of global oil production². Plastics are inexpensive, lightweight, strong, durable, corrosion-resistant materials, with high thermal and electrical insulation properties. The diversity of polymers and the versatility of their properties are used to make a vast array of products that bring medical and technological advances, energy savings and numerous other societal benefits. Consequently, the production of plastics has increased substantially over the last 60 years from around 0.5 million tonnes in 1950 to over 260 million tonnes today³.

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Plastic waste includes items as bags (44.6%), bottles/caps/lids (29.4%), and others (26%) and their life is approximately minimum 10 years to maximum 500 years or above⁴. Because of indiscriminate dumping of plastic bags on land, toxic metals such as cadmium and lead pigments percolate into underground water. Garbage mixed with plastic bags interferes in waste processing facilities and causes problems in landfill operations. Disposal of plastic through recycling, burning, or land filling is a myth because it does not undergo bacterial decomposition⁵. Due to non-biodegradable nature they cause hazardous negative impact on the environment. Disposal of plastic waste which is a major cause of environment pollution becomes carcinogenic to human, birth defects, impaired immunity, endocrine disruption, development and reproductive effect⁶. Our oceans have been used as a dumping ground, choking marine life and transforming some marine areas into a plastic soup. In cities around the world, plastic waste clogs drains, causing floods and breeding disease. Consumed by livestock, it also finds its way into the food chain⁷. Burning of plastics cause emissions of toxic gases and release a toxic carcinogen called dioxin. The dioxin affects the function of the reproductive and immune system. It is also associated with skin and respiratory problems resulting from exposure to and inhalation of toxic fumes, especially hydrocarbons and residues released during the process⁵.

Many attempts have been made to address the negative impacts of usage of plastics by recycling and banning of the production of one time use plastics. Recently, our honourable Prime minister started a campaign “Say No To Single Use Plastic” to address this problem. To create a better environment for all, it is important to realize the negative impacts of plastic, and limiting the use of plastic products in everyday life .What is the level of knowledge, attitudes and practise of using plastic?

This is the issue this study seeks to investigate. Knowledge affects attitude and attitude affect practice. With this back ground, the present study was conducted to assess the level of knowledge, attitude and practise related to plastic use among school students of class 11th and 12th standard and to study the percent change in their knowledge one week after one hour presentation.

Aim and Objectives

1. To assess the level of knowledge of students about plastic use and its effect on environment.
2. To assess the attitude of students towards plastic use.
3. To assess practise of students related to plastic use.

Material and Methods

Study setting: Satyakaam International School, Meerut UP

Study population: Students of class 11th and 12th

Study Design: Quasi-experimental

Sampling technique: Purposive sampling

Sample size: 100 students

Research tool: Self designed semi -structured questionnaire

Study Period: 3 months (October 2019- December 2019)

Inclusion Criteria: Both male and female students and Students who are present at the time of study were included in the study

Exclusion Criteria:

Students who were not willing or not present at the time of study

Dependent variables: Knowledge, attitude and Practice related to plastic

Independent variables: age, sex, mother’s and father’s education

Methodology: The present quasi-experimental study was conducted among school going students of of class 11th and 12th of Satyakaam International School, Meerut. Prior permission was taken from the concerned authority and arrangement was made to gather the students at pre decided date, time and place. The purpose and objective of the study was explained to the students prior to the data collection and they were assured about the confidentiality of the data . Data was

collected on predesigned semi structured questionnaire which included details of socio demographic variables like age, sex, parent’s education and other details about knowledge, practice and attitude of school going children regarding plastic use . Before filling the questionnaire, questions were explained to the students so that they could understand the questionnaire completely and could answer properly. Completion of questionnaire was assured at the time of collection. After collection of filled questionnaire a Power point presentation along with videos regarding various aspects of plastic was given to the students. one week after the presentation again the knowledge of students regarding plastic was assessed on the same set of questionnaire. The data was entered and analysed on SPSS.

Results

It is seen that in the study group 13% students were of 15 years of age, 40% of 16 years, 42% of 17 years and 5% of 18 years. Amongst the students 61% were male and 39% female, 57% were studying in class 11th and 43% in class 12th. 3% of student’s father was educated till high school, 21% were educated till intermediate, 49% were graduate, and 27% were post graduate. 3% of student’s mother educated till high school, 29% was educated till intermediate, 41% were graduates and 27% were post graduate.

Figure 1 shows that in our study group, knowledge of chemical nature of plastic before presentation was present in 64% students while it was 93% after presentation. There was increase of about 29% which was found to be statistically significant

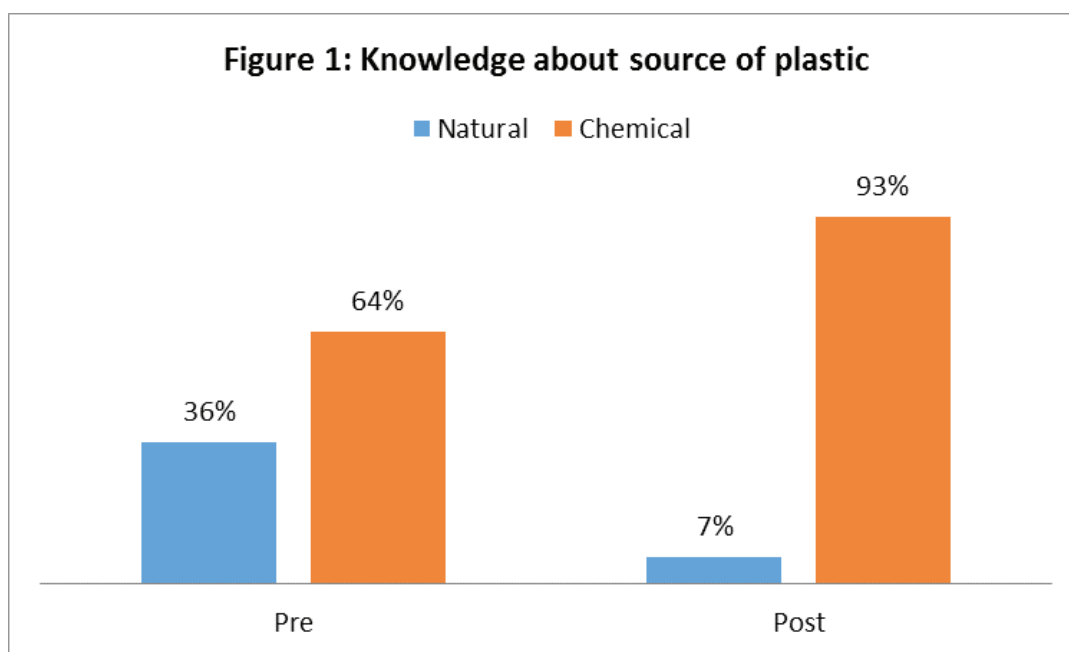
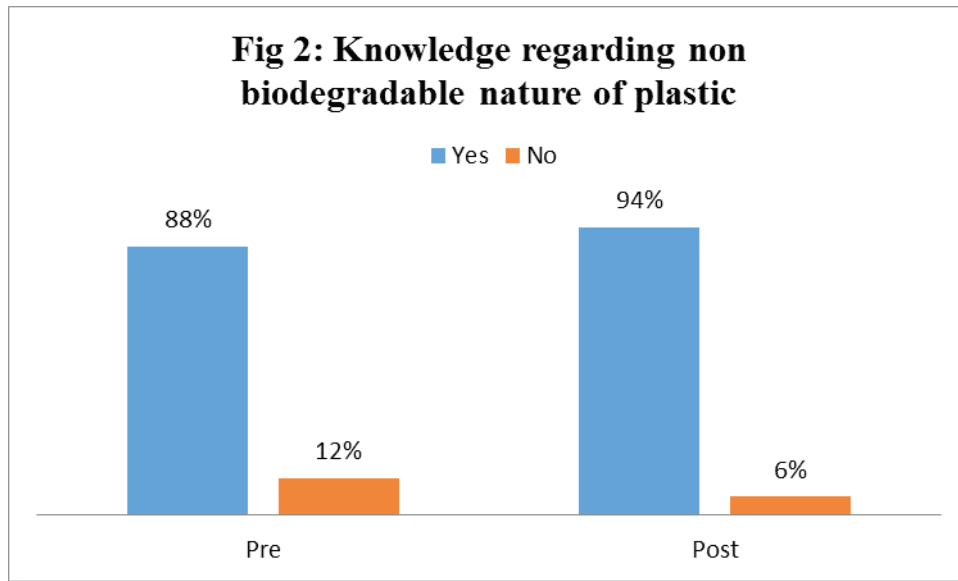


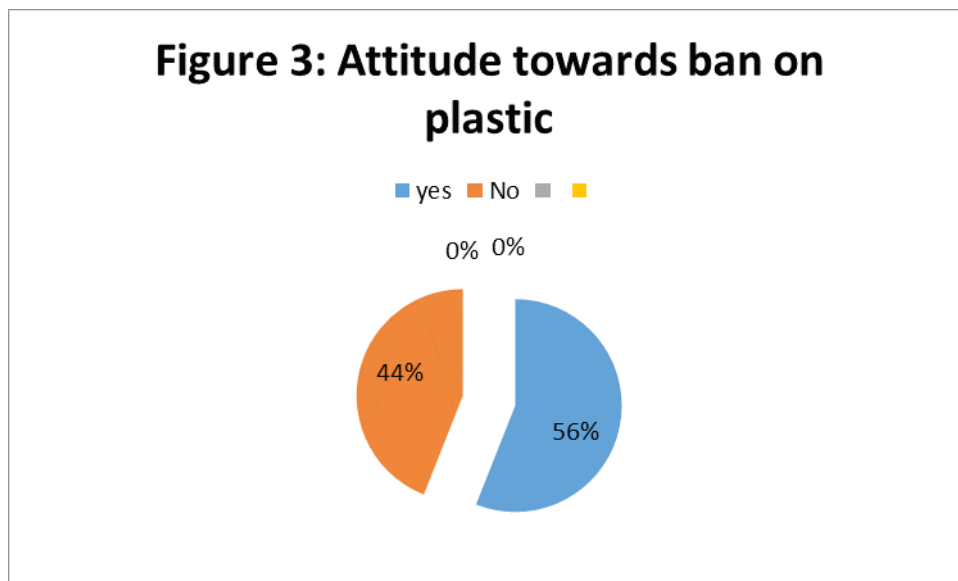
Figure 2 shows that in our study before presentation knowledge regarding Non-biodegradable nature of plastic was present in 88% students and it was 94% after presentation. There was increase of about 6% which was found to be statistically non-significant.



Knowledge of study subjects regarding recent campaign “NO to single use plastic”. Before presentation the knowledge of campaign was present in 64% students but after presentation it was 83% and the difference was found to be statistically significant.

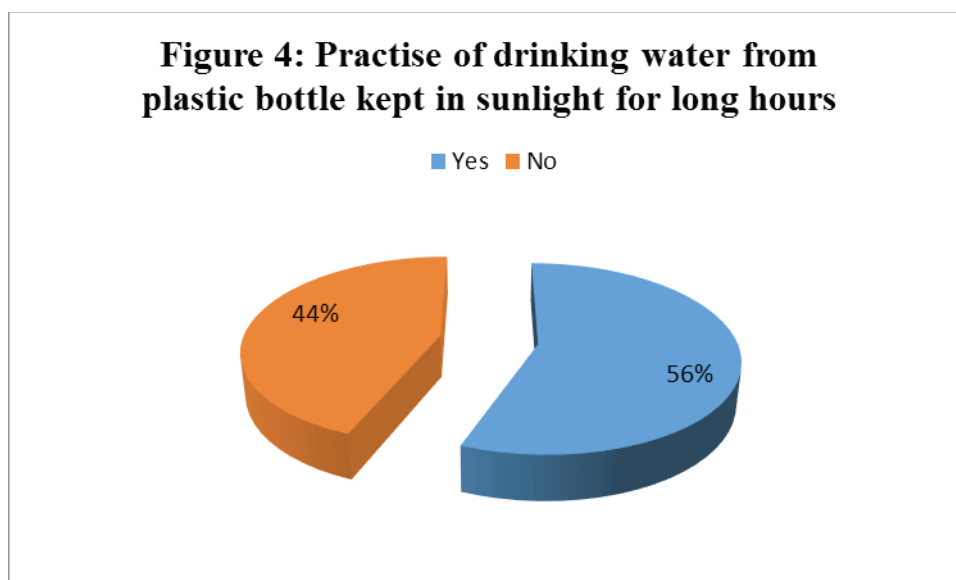
Knowledge of students before and after presentation. There was increase of 12% in knowledge regarding side effects of plastic on environment. The difference was not found to be statistically significant.

Figure 3 shows the attitude of students towards ban on plastic. According to the majority of the students (77%) ban on plastic is a great solution to the problem. In our study 89% of the students support government on plastic ban and 87% of the students say no to future use of plastic.



64% of the study subjects consume food that was microwaved in plastic utensils

Figure 4 shows distribution of students according to their practise of drinking water from plastic bottle kept in sunlight for long hours. 56% of the students drink water from the bottle that was kept for long hours in sunlight and 44% do not.



In our study nearly two third (66%) students used plastic bags when they went for shopping. Only 34% student used other bags like cotton bag, paper bag and cloth bags respectively.

Table 1 shows that slightly more number of males (88.52%) as compared to female (87.17%) students had knowledge of non- biodegradable nature of plastic. The difference was found to be statistically significant.

Table 1: Association between gender and knowledge about non-biodegradation of plastic

Gender	Yes (%)	No (%)	Total
Male	54(88.52%)	7 (11.47%)	61 (61%)
Female	34 (87.17%)	5 (12.82%)	39 (39%)
Total	88 (88%)	12 (12%)	100 (100%)
	X ² =0.0408	P value<0.05	

Table 2 shows the association between the gender and their attitude towards future use of plastic. In our study majority of the students (87%) denied the future use of plastic. Nearly equal number of male and female (86.88% and 87.17%) students said no to future use of plastic. The difference was not found to be statistically significant.

Table 2: Association between gender and their attitude towards further use of plastic

Gender	Yes (%)	No (%)	Total
Male	8 (13.11%)	53 (86.88%)	61 (61%)
Female	5 (12.82%)	34 (87.17%)	39 (39%)
Total	13 (13%)	87 (87%)	100 (100%)
	X ² =0.0002	P value= 0.966	

Discussion

In our study group the knowledge regarding source of plastic, non-biodegradable nature, recent campaign and various side effects of plastic on environment was found to be 64%, 88%, 64% and 72% respectively. With regard to the knowledge level as whole one of the study conducted in Shariah⁸ among school students show low level of knowledge as compare to our study (52%) while a study conducted in Singapur⁹ shows similar level of knowledge as compare to our study (70.9%). One of the study conducted in Tamil Nadu shows low over all knowledge of students related to plastic as compare to our study (42%) but better knowledge of students regarding ill effects of the plastic (M=10.49) which is similar to our study (72%)⁶.

In our study 77% of the study shows favourable attitude towards on plastic and thought that the ban is great solution to the problem. In our study 89% of the students support government on plastic ban and 87% of the students say no to future use of plastic. Similar favourable attitude (77.9%) towards ban on plastic was observed by Joseph et. al¹⁰ in their study. Whereas Kanagabala et al¹¹ in their study reported higher percentage of students (88.3%) who strongly favoured ban on plastic. In Oneof the study conducted among school going adolescents in Wardha, Maharastra 65.26% of the students agreed for ban on plastic bag usage¹².

In our study 66% students used plastic bags when they went for shopping. The practise of drinking water from the bottle that was kept for long hours in sunlight was observed in 56% students. While quite low practise of plastic was found in one of the study conducted in Tamilnadu⁶ where good practise related to plastic was present in only 22.7% students and moderate practise in 33.7%.

In our study significant difference was found in the knowledge of male as compare to female regarding non biodegradable nature of plastic. Slightly more number of female as compare to male was found to have positive attitude toward future non use of plastic. From a gender perspective similar findings were reported by Tanima Ferdous¹³ in her study among school students of Lalitpur district where female respondents had stronger attitudes than male partners.

Conclusion

The study concluded that the knowledge regarding plastic has increased significantly among students. More than half of the students microwave food in plastic container, drink bottle water kept in sunlight for long time and carry plastic bags for shopping. Knowledge regarding non-biodegradable nature of plastic was found to be more among male as compare to female. Majority of the students denied future use of plastic. These students having knowledge about plastic can bring about revolutionary change in the usage and disposal mechanism of plastic bags. Through their knowledge of hazards that are caused due to excessive and unwarranted usage of plastic bags and irresponsible dumping of them, they can limit use of plastic bags and also encourage the use of eco-friendly conventional carry bags, for e.g. cloth bag. The above findings also showed that the 16% samples that were unaware of the hazards of plastic use needed to be educated about them through means like pamphlets, health talks, advertisements and awareness programs.

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Conflict of Interest : None

Source of Funding : Self

Ethical Clearance: The study was approved by institutional ethical committee.

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A Systematic Review on Effectiveness of Botulinum Toxin in the Treatment of Frey's Syndrome

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Abstract

Background: The treatment of Frey's syndrome by using Botulinum toxin is both non-invasive, comparatively more long lasting and has a better prognosis compared to the other available treatment options to treat Frey's syndrome.

Aim: - The aim of the study is to undertake a systematic review and understand whether Botulinum Toxin is a feasible treatment choice for Frey's syndrome. .

Methodology:- The literature review was done using PubMed , Wiley online, science direct, CINALH, Cochrane library, gray literature, Prospero, OSF, Scopus and New England Journal of Medicine. The keywords were "Frey's syndrome" and "Botulinum toxin". A total of 1306 records were screened after quantitative synthesis four articles were finalized. Meta analysis was not done to be heterogeneity in the article included for final review.

Result: - Four studies were included in our systematic reviews which included. The studies performed in different countries to prove the role of Botulinum toxin for Frey's syndrome and suggest that is Botulinum Toxin is a safe and good treatment option for Frey's syndrome.

Conclusion: Treating the Frey's syndrome with good prognosis is always a challenging task to the dentist. Here the included studies have shown positive results for treatment of Hyperhidrosis or Frey's syndrome with Botulinum Toxin injections.

Keywords: - Botulinum Toxin, Frey's syndrome, treatment, systematic review

Introduction

Frey syndrome is a postoperative phenomenon following salivary gland surgery and less commonly neck dissection, facelift procedures, and trauma that is characterized by gustatory sweating and flushing¹. It may also be associated with other symptoms like pain, burning sensation, erythema, itching and even neuralgia. Hence it can cause discomfort and embarrassment to the patient. Following parotidectomy or surgeries related to the region, Frey's syndrome is observed to be an unavoidable result and has been reported as 100%².

Some of the commonly adopted methods for its management are topical application of anticholinergic

drugs, nerve resection and Botulinum Toxin -A injection (BoNT-A). Of these BoNT-A intradermal injection has been reported to be the most suitable treatment option³. Botulinum toxin is a neurotoxin produced by Clostridium Botulinum and can cause human and animal botulism with high fatality rates⁴. It has 8 subtypes from A to H out of which A and B subtypes are used in several aspects in the medical field such as ophthalmological disorders, movement disorders, pain disorders, hypersecretory disorders, neuromuscular dysfunction, muscle spasticity, ENT related disorders and cosmetic application^{5,6}.

Botulinum neurotoxin-A has a variety of clinical applications and has been popularly used in treatment

of Strabismus , protective ptosis, cerebral palsy, muscle dystonias, pain , spasticity, tremors, tics, urinary retention , chronic rhinitis , achalasia , gastroparesis , aesthetic correction and several more⁷. The present treatment modalities for Frey’s syndrome are Surgical correction like excision of the affected skin, interposition of fascia lata, muscle flaps (platysma), or silastic sheeting. Topical and systemic usage of anticholinergic and antihidrotics is also adopted⁸.

Although these methods are widely in use they are invasive and expensive procedures which not many patients may be able to prevail; topical and systemic drugs have presented with many cases of irritation and ADRs that tend to produce further discomfort to the patient. In addition all these methods are not long lasting and tend to revert back after some time. It has been reported that the treatment of Frey’s syndrome by using Botulinum toxin is both non -invasive, comparatively more long lasting, and has a better prognosis compared to the other available treatment options⁹. The aim of this article is to undertake a systematic review and to study the relationship between Botulinum toxin-A and Frey’s syndrome and to know its feasibility as a treatment option.

Methodology

Question Addressed

Is Botulinum Toxin -A feasible for the treatment of Frey’s syndrome?

Literature Searching

The literature review was performed using the search engines PubMed, Wiley Online, Scopus and New England Journal of Medicine. The search terms or keywords were “Frey’s syndrome” and “Botulinum toxin”. A total of 1306 records were screened of which 4 were finalized and used for this article that was related to the topic.

EXCLUSION AND INCLUSION CRITERIA

INCLUSION CRITERIA

1. Full text articles were included
2. Compulsory inclusion of Botulinum Toxin -A for the treatment of Hyperhidrosis
3. Only Randomized controlled trials were included.

EXCLUSION CRITERIA

1. Studies in which Botulinum Toxin had not been used for treatment for Hyperhidrosis were excluded.
2. Non-randomized control trials and other types of investigative studies were excluded.

Result

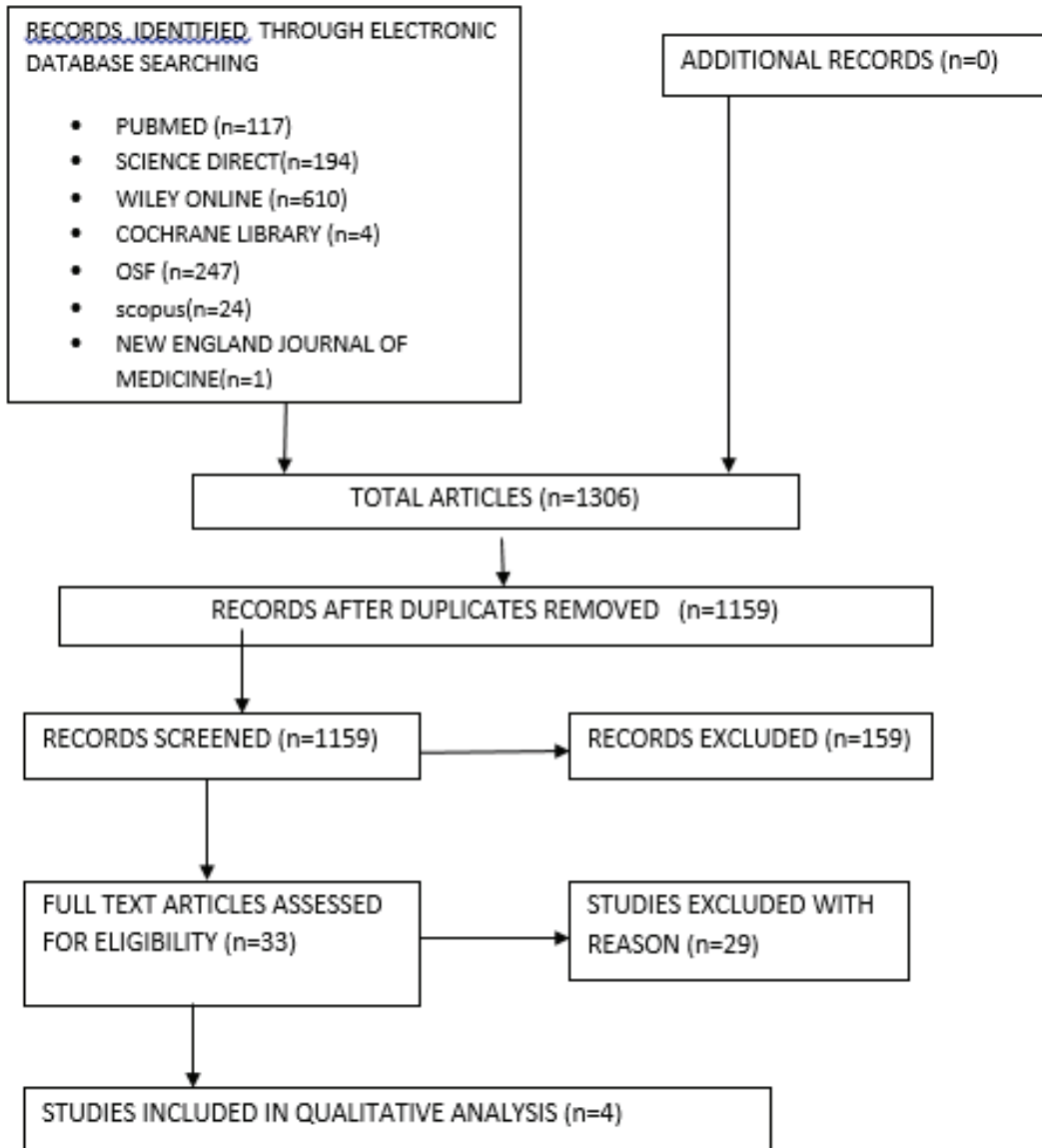


Figure 1: Flow Diagram Showing the Number of Studies Identified, Screened, Assessed For Eligibility, Excluded And Included In The Systematic Review

TABLE 1: CHARACTERISTICS OF THE INCLUDED STUDY IN THE SYSTEMATIC REVIEW

AUTHOR NAME	YEAR	SAMPLE SIZE	PATIENT CHARACTERISTICS	DURATION	NUMBER (CASE /CONTROL)
D. Nolte et al.[8]	2004	20	Patients with Frey's syndrome between the age group of 20 - 74 years were selected	12 months	Group 1 :- 10 individuals (2 MU/cm ² of intradermal Botulinum toxin A injection) Group 2 :- 10 individuals (3MU/cm ² of intradermal Botulinum toxin A injection)
Mark Heckmann et al.[6]	2001	145	Patients with sweat production of more than 50mg and were unresponsive to topical therapy with aluminium chloride for more than one year Average age =50	26 weeks	Axilla1 :- 200U Botulinum toxin A Axilla2:-placebo (human albumin + lactose) After 2 weeks:- Axilla that had received the placebo was injected with 100U of Botulinum toxin A
Orlando Guntinas-lichius et al.[10]	2002	40	Patients with gustatory sweating for more than 6 months, no prior treatment of the sweating, and unilateral evidence resulting from parotid gland surgery	12 months	Group 1 :- 10 individuals (10MU/0.1ml of Botulinum toxin A) Group 2 :- 10 individuals (20MU/0.1ml of Botulinum toxin A)
Pasquale Cappacio et al.[9]	2008	24	Patients within the age range of 24 to 86 years. Group1 :-Patients with other salivary gland disorders other than Frey's syndrome (salivary fistula, sialocele etc.) Group2 :- Patients with regular, often, or always present Symptoms in the Frey's questionnaire card game system. They gave a positive starch iodine test.	12 months	Group 1:- 12 individuals (25 to 60 MU BoNT type A) Group 2:- 12 individuals (2 MU BoNT type A)

TABLE 2:- OUTCOME DATA AS REPORTED IN INCLUDED STUDIES

AUTHOR NAME	YEAR	EFFECT MEASURE	RESULT
D.Nolte et. al.	2004	After 2 weeks the gustatory skin were decreased from 32cm ² to 14cm ² in Group A And 39cm ² to 3cm ² in Group B	Group A individuals showed a decrease in gustatory skin by 56% And Group B individuals showed a decrease by 97%
Mark Heckman et al.	2001	After 2 weeks the sweat production decreased from 164mg to 24±27mg in the BoNT-A treated Axilla and from 174mg to 144±113mg in placebo treated axilla	A 98% decrease in the sweat production was observed in BoNT-A treated Axilla compared to Placebo Axilla
Orlando Guntinas-lichius et al.	2002	After 10 months 85% patients in Group1 gave a Positive Starch - Iodine Test and 5% of the patients in Group 2 gave a positive Starch - Iodine test	The duration of effectiveness in Group 2 was twice longer compared to Group 1.
Pasquale Cappacio et al.	2008	After 2 months Group1:- partial or subtotal improvement was observed Group2:- complete recovery was observed in almost all cases	Group2 patients had a better response to the BoNT-A compared to Group1

A total of 1306 articles were selected using the keywords “Botulinum toxin” and “Frey’s syndrome”. After the duplicate articles were removed 1159 articles were obtained. 33 articles were selected from these based on the availability of full text articles. From these articles 29 articles were excluded as they were not RCTs and relevance to the topic. The 4 finalized articles were then studied and their characteristics and outcomes were tabulated

In Table 1 we see that all the 4 studies study the effect of Botulinum toxin on sweat production. In two of the studies of D.Nolte et al¹⁰; Orlando Guntinas et al¹²; different amounts of Botulinum Toxin were given to both the groups and their rates were observed. In the

study by Pasquale Cappacio et al one group was given BoNT-A while the other was given Placebo. Whereas in the study by Mark Heckman et al. the different rates of sweat production were studied by injecting one axilla with BoNT-A and the other with placebo.

In Table 2 we see that the outcome in all the four studies showed that there was a decrease in the rate of sweat production after intradermal application of Botulinum toxin. All the four studies have a p-value below 0.05. In the studies conducted by D.Nolte¹⁰ and Orlando Guntinas¹² it is seen that the group that was given higher concentration of BoNT-A had a longer and better prognosis than the one given lesser concentration of BoNT-A. In the study carried out by Cappacio et al¹¹ the prognosis of Frey’s syndrome patients was better than

other salivary gland and nerve regeneration patients. In the study carried out by Mark Heckman et al⁹, the axilla treated with BoNT-A showed almost complete remission compared to the placebo axilla in all the patients.

BIAS ANALYSIS AS INCLUDED IN THE STUDIES

The bias is assigned as; low risk (-), high risk (+), and unclear (?)

AUTHOR NAME. YEAR	RANDOM SEQUENCE GENERATION	ALLOCATION CONCEALMENT	BLINDING OF OUTCOME	INCOMPLETE OUTCOME DATA	BLINDING OF PARTICIPANTS AND PERSONELLE	SELECTIVE REPORTING	JUDGEMENTAL BIAS
D.Nolte et. al.	+	?	-	-	-	+	-
Mark Heckman et al.	-	-	-	-	-	-	-
Orlando Guntinas-lichius et al.	?	-	-	-	+	?	?
Pasquale Cappacio et al.	+	+	-	-	+	?	+

The sequence generation is high risk in the studies conducted by D.Nolte as the 20 patients were divided into two halves and assigned groups without any randomization method adopted. Similarly in the study conducted by Cappacio the patients were divided on the basis of the secretory disorder and not randomly. Again Allocation concealment was given a high risk in Cappacio's study as it was clear to the patient which group they would belong to as it was based on whether they suffered from Frey's syndrome or any other secretory or nerve regeneration disorder. Blinding of participants and personelle did not take place in the studies conducted by Guntinas and Cappacio the Blinding of participants did not take place and the participants were aware of the criteria on the basis of which they were assigned to their groups.

Discussion

In this research 1306 different articles were screened from various online databases from which after exclusion 4 were finalized. The articles were excluded based on whether they were RCTs, presence of full text articles and their relevance to the topic, i.e. treatment of Frey's syndrome using Botulinum toxin. In the research's carried out by D.Nolte et al¹⁰ and Orlando Guntinas et al¹², patients were divided into two groups and both groups the groups were given intradermal injection of BoNT-A in different concentrations. It was observed that the group that had received higher concentrations of BoNT-A had a better prognosis. The p value in the both these studies were below 0.05 and are hence statistically significant.

In his research, Pasquale Capacio et al¹¹, divided the patients into two groups ; Group 1 with patients

suffering from other salivary gland disorders, and Group 2 consisted of Frey's syndrome patients. Both the groups were injected with BoNT-A injection. Group 2 patients showed lower rates of reduction in Hyperhidrosis compared to Group 1. The value of this study as well, is below 0.05 and is hence significant.

Botulinum neurotoxin-A has a variety of clinical applications and has been popularly used in treatment of Strabismus, protective ptosis, cerebral palsy, muscle dystonias, pain, spasticity, tremors, tics, urinary retention, chronic rhinitis, achalasia, gastroparesis, aesthetic correction and several more¹³.

Several studies have shown the efficacy of Botulinum toxin -A in the treatment of other Hypersecretory disorders similar to Frey's syndrome, e.g.: Crocodile tear syndrome (CTS) or gustatory lacrimation¹⁴. In a case study carried out by D.E. Baranano et.al. BoNT-A was injected Transconjunctivally in the left palpebral lobe of the lacrimal gland of a CTS patient. This resulted in relief from the symptoms with no adverse effects and the patient required a reinjection only after 11 months¹⁵.

In a case study carried out showed the effectiveness of different treatment modalities for Frey's syndrome was studied. In this particular study they checked the pros and cons and overall effectiveness of surgical measures, topical drugs and BoNT-A intradermal injection. It was observed that the BoNT-A injection was the safest option with the least side effects and the longest period of efficacy without relapse¹⁶.

This article was not considered in this particular study as only RCTs have been included in this article, and this study only focuses on a particular case. In another case study carried out by Cantarella G et al¹³, BoNT-B was considered as an alternative treatment option for Frey Syndrome. This has not been used widely and works on a different mechanism than BoNT-A. Seven Frey syndrome patients were included in the study. All the participants reported reduction in the rate of sweat production post treatment. This study was not included as it focuses more on the action of BoNT-B compared to BoNT-A on Frey's syndrome. In a case study carried out by Aleissa M. et al; unilateral, focal facial Hyperhidrosis that occurred in a patient following internal carotid artery dissection was treated successfully with intradermal BoNT-A injection¹⁷. However, Clostridium Botulinum

is a known neurotoxin to humans and has several reported reactions. Local reactions to BoNT therapy include pain, oedema, erythema, ecchymosis, headache, and short-term hyperaesthesia. Certain systemic reactions after BoNT treatment have also been reported, and these may include nausea, fatigue, malaise, flu-like symptoms, rash, and a metallic taste. Allergic reactions to BoNT are rare.

In another case study conducted by Henry N. Et al.; which concerned the development of Frey's syndrome following a facial burn was treated using BoNT-A successfully, without any adverse effects. This case is of interest as development of Frey's syndrome following facial burns is extremely rare. In a study by Jigna S. Shah et al; they reported of a very rare development of a post-herpetic Frey's syndrome. The adopted treatment modality was Botulinum Toxin -A intradermal injection, which showed successful results^{18,19}. The aforementioned studies were not included as they are case studies and focus on rare particular cases which are not relevant to the purpose of this study.

Conclusion

All the four research articles considered for this systematic review have shown positive results for treatment of Hyperhidrosis or Frey's syndrome with Botulinum Toxin injections. In addition to this it has also shown minimal recurrence rates and adverse effect when compared with the other available treatment modalities. Hence, we conclude by stating that Botulinum Toxin Intradermal injection is a feasible and safe treatment modality for Frey's syndrome.

Ethical Clearance- Ethical clearance approval was taken from the institutional review board.

Source of Funding- Self funding.

Conflict of Interest- Nil

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Odontometric Analysis of Permanent Maxillary First Molar For Sex Determination

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Abstract

Introduction: Sex determination from skeletal remains forms part of archaeological and medicolegal examinations. Teeth, being the hardest and chemically the most stable tissue in the body are an excellent material in living and non-living populations for anthropological, genetic, odontological and forensic investigations.

Objective: The aim of this study is to assess and evaluate the sex discrimination potential of permanent maxillary first molar.

Materials and method: 100 subjects (47 males and 53 females) were selected from outpatient department of a private dental institution, with the age group of 10-40 years. The mesiodistal and buccolingual crown dimensions, cusps dimensions and diagonal dimensions of permanent maxillary right and left first molar were measured from the study casts with digital Vernier caliper. Sexual dimorphism in the left and right maxillary first molar was also calculated using formula. The data obtained were subjected to statistical analysis using paired and unpaired t-test.

Conclusion : Maxillary first molar shows significant sexual dimorphism and can be used as an adjunct along with other accepted procedures for sex determination.

Keywords: *Odontometrics, gender determination, maxillary molar.*

Introduction

Human beings are born with an identity. ^[1] In forensic practice the four main attributes that aid in biological identity for the dental anthropologists are the gender, age, stature, and ethnic or racial background of the individual. ^[2] Identifying the sex of skeletal remains is an important step during forensic investigations. This can result in a more accurate identification of the

deceased since the subsequent methods for age and stature estimation are often gender dependent. ^[3]

Measurements of the long bones, particularly those of the femur and humerus, provide highly accurate sex assessments. In forensic practice; dental indices have always been employed to determine sex. ^[4] Teeth, being the hardest and chemically the most stable tissue in the body are an excellent material in living and non-living populations for anthropological, genetic, odontologic and forensic investigations. ^[5]

Sexual dimorphism refers to those differences in size, stature, and appearance between male and female that can be applied to dental identification as no two mouths are alike. ^[6,7] Gender dimorphism in tooth size has been demonstrated by anthropologists and odontologists in bucco-lingual and mesio-distal dimensions of teeth

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(linear dimensions). [1,8,9,10] and diagonal measurements of tooth crowns. [11,12] The tooth size variations are influenced by both genetic and environmental factors. [6]

Many studies established that permanent mandibular canines exhibit greater sexual dimorphism but permanent maxillary first molars erupt early in the oral cavity at the mean age of 6–7 years and are less commonly impacted when compared to canines. [7] The odontometric features of permanent maxillary first molars that erupt at an early age can be of immense use in gender determination. [7,13] Hence the present study aims to assess and evaluate the sexual discrimination potential of permanent maxillary molar crown width and cusp dimensions.

Materials and Methods

Sample Design:

The present comparative cross-sectional study was conducted in the outpatient department of orthodontics from a private institution in Chennai with approval from the Institutional Review Board on 100 subjects (47 males and 53 females), aged 10-40 years. This particular age group was studied as ante-mortem insults like attrition and abrasion affecting occlusal and proximal tooth surfaces are minimal. The subjects were told about the aim and purpose of the study and only those who gave their voluntary consent participated in the study.

Inclusion criteria:

Fully erupted first permanent molar which are morphologically well formed

Healthy state of periodontium

Angle's Class I malocclusion

No history of orthodontic treatment

Caries free teeth

Presence of bilateral maxillary first molars

Exclusion criteria:

Missing teeth

Extracted teeth

Endocrine disturbances

Study Design:

Following informed consent, impressions of the maxillary arch were made with irreversible hydrocolloid (alginate) material and casts poured immediately in type II dental stone to minimize dimensional change. Maxillary permanent both right and left first molar was taken into consideration for this study.

Measurement of crown dimensions

The following parameters were measured on the study casts with digital Vernier caliper, calibrated to 0.01mm. Mesiodistal and buccolingual crown dimensions, cusps dimensions i.e. mesiopalatal cusp, mesiobuccal cusp, distopalatal cusp, and distobuccal cusp, and the diagonal dimensions i.e. mesiopalatal cusp to distobuccal cusp and mesiobuccal cusp to distobuccal cusp were measured by a single observer.

The mesiodistal and buccolingual dimensions were measured at the maximum contour of the tooth surface. The diameter of the individual cusps was determined by measuring the diagonal distance from the central pit to the outer margin of the relevant cusp.

All the data were recorded, tabulated in Microsoft Excel and subjected to statistical analysis.

Sexual dimorphism

Sexual dimorphism in the left and right maxillary first molar was calculated using the following formula. [14]

$$\text{Sexual Dimorphism} = \left(\frac{x_m}{x_y} - 1 \right) \times 100$$

Where x_m = Mean value for males, and x_y = Mean value for females

Statistical Analysis

The data obtained were quantified and analyzed statistically to determine the significance of differences between males and females using the SPSS (IBM SPSS Statistics for Windows, Version 23.0, Armonk, NY: IBM Corp. Released 2015). Normality tests Kolmogorov-Smirnov and Shapiro-Wilks tests were done, and the results reveal that all variables follow Normal distribution. Therefore, to analyse the data Parametric methods are applied. To compare mean

values between genders independent samples t-test is applied. To compare mean values between right and left maxillary dimensions student t-test is applied. To predict the gender Fisher’s linear discriminant function analysis was done with Significance level fixed as 5% ($P < 0.05$) and confidence interval of 95%.

Results

The descriptive statistics for crown width and cusp diameters for both right and left maxillary first molar are shown in table 1 and table 2 respectively. The mean values were significantly different between the males and females ($p < 0.05$), with male mean value exceeding those of females for distobuccal cusp dimension in relation to

left maxillary first molar(table 2). The percentages of sexual dimorphism among the cusp diameters revealed greatest dimorphism in mesiopalatal cusp for right maxillary first molar (Figure 1), whereas the distobuccal cusp showed the greatest dimorphism for left maxillary first molar (Figure 2).

On comparing the mean values for males between right and left maxillary first molar, the distobuccal cusp of left maxillary first molar showed a statistical significant difference than the right maxillary first molar($p < 0.05$) (table 3). On comparing the mean values for females between right and left maxillary first molar, there was no statistical significant difference observed (table 4).

Table 1. Independent samples T-Test to compare means of right maxillary values between genders.

Variables	Gender	N	Mean	Std. Dev	t-value	p-value
Mesio Distal	Male	47	9.753	.5187	0.729	0.468
	Female	53	9.660	.7236		
Bucco Lingual	Male	47	11.368	.7585	0.563	0.575
	Female	53	11.279	.8118		
Mesiobuccal cusp MB	Male	47	4.643	.3705	0.306	0.760
	Female	53	4.613	.5575		
Mesiopalatal cusp MP	Male	47	5.270	.5610	1.661	0.100
	Female	53	5.075	.6057		
Distobuccal cusp DB	Male	47	4.202	.3768	0.439	0.662
	Female	53	4.247	.6075		
Distopalatal cusp DP	Male	47	3.449	.4704	0.001	0.999
	Female	53	3.449	.5472		
MB – DP	Male	47	9.471	.7876	0.289	0.773
	Female	53	9.426	.7649		
MP – DB	Male	47	7.964	.9361	0.124	0.901
	Female	53	7.987	.9077		

Table 2. Independent samples T-Test to compare means of left maxillary values between genders.

Variables	Gender	N	Mean	Std. Dev	t-value	p-value
Mesio Distal	Male	47	9.712	.6296	0.438	0.662
	Female	53	9.657	.6262		
Bucco Lingual	Male	47	11.415	.7342	1.075	0.285
	Female	53	11.260	.7017		
Mesiobuccal cusp MB	Male	47	4.777	.4593	0.239	0.812
	Female	53	4.802	.5823		
Mesiopalatal cusp MP	Male	47	5.194	.4513	0.221	0.825
	Female	53	5.170	.6034		
Distobuccal cusp DB	Male	47	4.400	.5477	1.914	0.058
	Female	53	4.196	.5163		
Distopalatal cusp DP	Male	47	3.600	.6217	1.241	0.217
	Female	53	3.451	.5787		
MB – DP	Male	47	9.666	.6492	0.885	0.378
	Female	53	9.526	.8910		
MP – DB	Male	47	7.919	.6402	0.093	0.926
	Female	53	7.904	.9969		

Table 3. Student T-Test to compare mean values between right and left maxillary dimensions among males.

Variables	Maxillary Dimension	N	Mean	Std. Dev	p-value
Mesio Distal	Right	47	9.753	.5187	0.72
	Left	47	9.712	.6296	
Bucco Lingual	Right	47	11.368	.7585	0.76
	Left	47	11.415	.7342	
Mesiobuccal cusp MB	Right	47	4.643	.3705	0.12
	Left	47	4.777	.4593	
Mesiopalatal cusp MP	Right	47	5.270	.5610	0.46
	Left	47	5.194	.4513	
Distobuccal cusp DB	Right	47	4.202	.3768	0.04
	Left	47	4.400	.5477	
Distopalatal cusp DP	Right	47	3.449	.4704	0.18
	Left	47	3.600	.6217	
MB – DP	Right	47	9.471	.7876	0.19
	Left	47	9.666	.6492	
MP – DB	Right	47	7.964	.9361	0.78
	Left	47	7.919	.6402	

Table 4. Student T-Test to compare mean values between right and left maxillary dimensions among females.

Variables	Maxillary Dimension	N	Mean	Std. Dev	p-value
Mesio Distal	Right	53	9.660	.7236	0.97
	Left	53	9.657	.6262	
Bucco Lingual	Right	53	11.279	.8118	0.41
	Left	53	11.260	.7017	
Mesiobuccal cusp MB	Right	53	4.613	.5575	0.09
	Left	53	4.802	.5823	
Mesiopalatal cusp MP	Right	53	5.075	.6057	0.42
	Left	53	5.170	.6034	
Distobuccal cusp DB	Right	53	4.247	.6075	0.64
	Left	53	4.196	.5163	
Distopalatal cusp DP	Right	53	3.449	.5472	0.98
	Left	53	3.451	.5787	
MB – DP	Right	53	9.426	.7649	0.53
	Left	53	9.526	.8910	
MP – DB	Right	53	7.987	.9077	0.65
	Left	53	7.904	.9969	

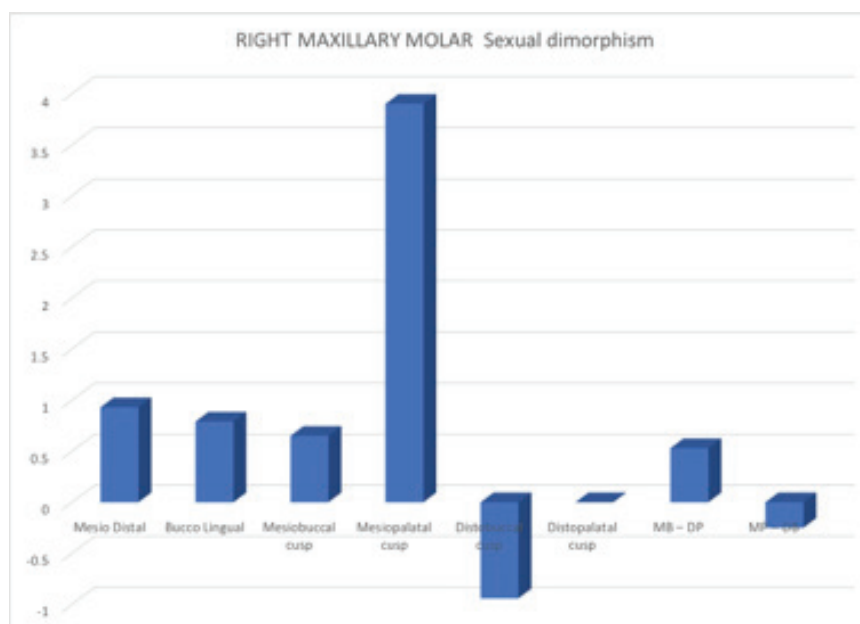


Figure 1: Sexual dimorphism for right maxillary molar

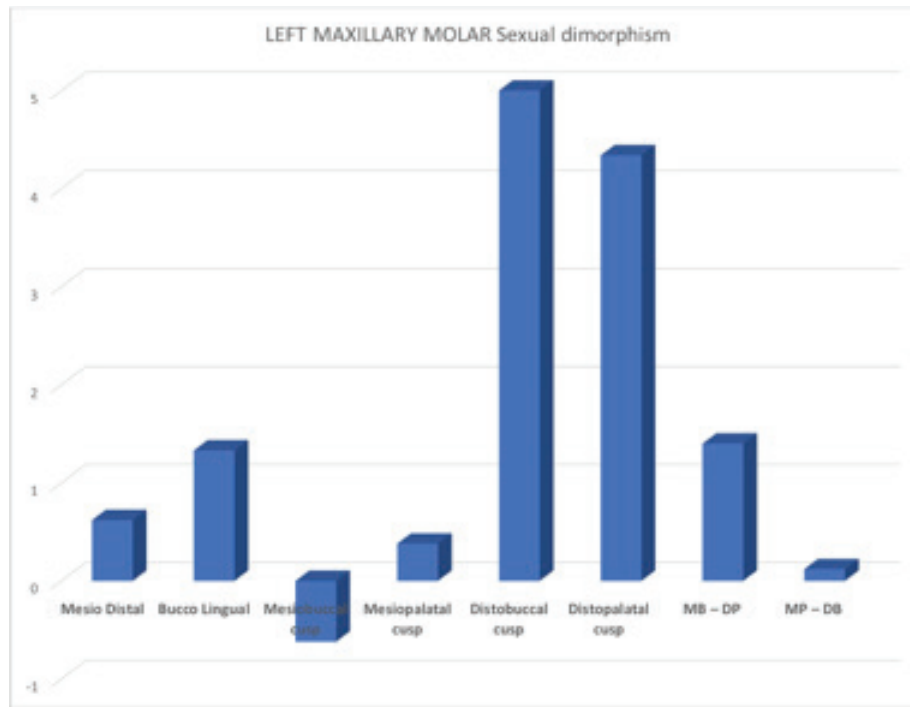


Figure 2: Sexual dimorphism for left maxillary molar

Discussion

Osteometry is considered as the most preferred technique for sex determination. [15] The determination of sex is one amongst the vital aspect of forensic odontology. Many authors have done the measurements of crown in teeth between males and females and found certain variations. Measurements of tooth dimensions are quick, less time-consuming, noninvasive, and can be easily performed compared to DNA technique. Rose JC and Ditch LE et al., were the first who advocated the use of tooth dimensions for identifying sex. [16] Since then several studies have quantified sexual dimorphism in permanent dentition.

Teeth form an excellent material in the living population for genetic, forensic, anthropological, and odontogenic investigations. Dimensions of teeth are used to establish the sex of a victim in major disasters/accidents, medico-legal cases, and natural disasters. In several instances, the dentition especially the anterior teeth might get fragmented by perimortem (e.g., trauma, burning) and/or post mortem (e.g., weathering, soil acidity) factors. Hence posterior teeth are generally considered in forensic investigations. [17]

The crowns of maxillary molars have four main cusps, namely the mesio-palatal, disto-palatal, mesio-buccal and distobuccal cusps. Each cusp has an independent growth pattern. The mesiobuccal is the first to appear both ontogenetically and phylogenetically and is regarded as the successor of the single cone of the reptilian haplodont dentition. The disto palatal tends to develop last in terms of ontogeny and phylogeny, and it differentiates from the lingual cingulum. Odontometric characteristics of each molar crown are thought to represent a cumulative effect of individual cusp dimensions, so analysis based on measurement of cusp dimensions promises to be more meaningful biologically than conventional measurements of whole crowns. [18]

The present study showed that dimensions of all permanent teeth on the left side were not the same on the right side in the upper jaw. The right and left differences may be attributed to dental asymmetry as perfectly bilateral body symmetry is a theoretical concept that seldom exists in living organisms. [7] On comparing the mean difference of mesiodistal and buccolingual parameters for both genders, permanent left upper first molar showed minimum mean difference, statistically suggestive of a better predictor of sexual dimorphism.

Similar results were found by Agnihotri and Sikri al.,^[19] Kumar et al.,^[13] Narang et al.,^[20] Suazo et al.,^[21] in their studies. For permanent left maxillary first molars the buccolingual dimensions in the present study was found to exhibit greater sexual dimorphism than mesiodistal dimensions which is in-agreement with the study done by Garn et al.^[22]

In the present study, the comparison of mean values of all parameters measured in left maxillary first molar between males and females, the distobuccal cusp showed statistically significant difference with $P < 0.05$. These results are not in agreement with the studies done by Sonika et al.,^[7]

Perzigian et al.,^[23] Ghose and Baghdady et al.,^[24] Stroud et al.,^[25] Hattab et al.,^[26] Rai et al.,^[27] and Ghodosi et al.,^[28] in which the authors have observed that mean values of all parameters measured between males and females showed statistically significant difference.

The dimensions obtained for the male teeth were larger compared to those for females; thus, exhibiting sexual dimorphism. The male teeth are usually larger in size as compared to the female teeth.^[19,29] The sexual dimorphism in tooth morphology is attributable to the Y-chromosome which increases the mitotic potential of the tooth germ and induces dentinogenesis; whereas the X-chromosome induces amelogenesis.^[7,29,22]

In the maxillary right first molar, sexual dimorphism was significant in mesiopalatal cusp and mesiobuccal cusp and not significant in the distobuccal and distopalatal cusp which is in accordance with the study conducted by Payal Sharma et al.^[17] In the maxillary left first molar, it was significant in distobuccal, distopalatal and mesiopalatal cusp but not significant in mesiobuccal cusp. In our study, the mesiopalatal cusp dimension in the right maxillary first molar and disto buccal cusp dimensions of the maxillary left first molar exhibited greater sexual dimorphism than other dimensions of the same teeth. This order has been found to differ among populations. In a study conducted by Agnihotri and Sikri on Jat Sikhs, the order in cusp size was found to be distopalatal > mesiopalatal > mesiobuccal > distobuccal.^[19] For the Japanese, Kondo et al.^[30] found the sequence to be: mesiopalatal > distopalatal > mesiobuccal > distobuccal. For American whites, Biggerstaff et al.

^[31] reported the order to be mesiopalatal > distobuccal > mesiobuccal > distopalatal. The apparent difference in the pattern of sexual dimorphism between these geographically disparate populations is likely due to a combination of environmental and genetic factors, given that dental sexual dimorphism is strongly influenced by sex-linked genes.^[32]

Conclusion

From the present study, it can be concluded that maxillary first molar show significant sexual dimorphism and can be used as an adjunct along with other accepted procedures for sex determination. Further investigations are desired with larger samples and in populations of varied ethnic origin in the direction of improving accuracy of using linear dimensions of teeth as a method of sex identification.

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Survival and Hospital Stay Characteristics of COVID-19 Patients in Karnataka, India

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Abstract

The rapid transmission of this virus from human to human made the World Health Organization (WHO) to declare this as the public health emergency of international concern and called it as global pandemic. As on July 21, 2020, globally 14562550 COVID-19 cases have been reported and caused 607781 deaths.²

The first case of the COVID-19 pandemic in India was reported on 30 January 2020. As on 22 July 2020, the MOHFW, Government of India has reported 411133 confirmed cases from 33 states with 28732 deaths and 753049 cured/discharged.

The case fatality rate was 1.9% and the recovery rate was 98.1% Following the test positivity, the mean length of stay among COVID-19 patients with definitive outcomes was 15.41 days COVID-19 cases with SARI at the time of admission and those with travel history had significantly lower length of hospital stay as compared to their counterparts. There was no difference in the length of hospital stay by gender and age .Among those without definitive outcomes (245/3162), the length of stay in the hospital following test positivity ranged from 40 to 114 days.

The Kaplan–Meier analysis showed an overall survival rate of 98.8% at 7 days and

98.1% at 14 days. The survival probability at 21 days is 98.5%.COVID-19 cases who were ≥ 60 years and who have presented with SARI had significantly higher risk of mortality when compared to the counterparts ($p < 0.001$). However, the risk of mortality did not differ much among male and female COVID-19 patient ($p = 0.88$).

Having SARI at the time of admission (adjusted hazard ratio: 0.07 (0.04-0.14); $P <$

0.001), being aged ≥ 60 years (adjusted hazard ratio: 0.2 (0.1-0.3); $P < 0.001$) and having travel history (adjusted hazard ratio: 3.7 (1.7-8.2); $P < 0.001$) were the significant predictors of mortality .

Key Words: COVID 19, Pandemic, Survival

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Introduction

Coronavirus or novel coronavirus which is taxonomically termed as SARS-CoV-2 and named by

World Health organization (WHO) as COVID-19 which emerged from Wuhan city, Hubei Province of China by the end of 2019 has caused unprecedented panic across the world. Positive cases of COVID-19 and

deaths due to this virus have been reported in almost every country in the world.¹ The rapid transmission of this virus from human to human made the World Health Organization (WHO) to declare this as the public health emergency of international concern and called it as global pandemic. As on July 21, 2020, globally 14562550 COVID-19 cases have been reported and caused 607781 deaths.²

The first case of the COVID-19 pandemic in India was reported on 30 January 2020. As on 22 July 2020, the Ministry of Health and Family Welfare, Government of India has reported 411133 confirmed cases from 33 states with 28732 deaths and 753049 cured/discharged. Karnataka reported its first COVID case on March 9, 2020. As of July 22, 2020, Karnataka has reported 71069 positive cases with 24549 discharges/cured and 1464 deaths.³

The available data show that the rate of fatal cases is not very high in the young population.⁴ However, older people (over 60 years) and people with co-morbidities (such as diabetes and heart disease) may be more vulnerable and mortality can be high in this population.⁵

As of now, there is abundant information on the descriptive statistics (confirmed cases, active cases, and death) of COVID-19 in India which provide only crude information. With the progression of global pandemic of COVID-19, the information on the duration of hospital stay and the survival of patients may be helpful in the planning of allocation of medical resources, improving treatment outcomes, and designing effective interventions.⁶ However, such information for COVID-19 have not been well described in the Indian context.

With this in background, we aimed to investigate the factors associated with hospital stay and death among COVID-19 patients for the entire state of Karnataka, India.

Materials and Methods

The retrospective cohort analysis was done using the health bulletin data on COVID-19 published by the Department of Health and Family Welfare, Government of Karnataka (GoK). Karnataka is a southern state in India with 30 districts and a total population of

6,10,95,297 which accounts for 5% of total population of India.⁷

The cohort for the study included all the COVID-19-positive cases that were published in the GoK media bulletin from March to May 31, 2020. Data from the health bulletin were entered into the excel sheet which formed our cohort database. The data included the variables on Patient Id, Gender, Age, Place of hospital admission, Place of residence, Exposure/Travel history, Severity of symptoms, Date of test positivity and Date of discharge/death.

Our fixed cohort was followed till 40 days (July 10, 2020) for definitive outcomes (death/discharge). Those patients without definitive outcome till July 10, 2020, were right censored.

Data analysis

Descriptive statistics were computed for demographic and clinical characteristics. The ttest was used to compare the differences in the length of hospital stay between the various groups of patients with definitive outcomes.

Kaplan–Meier method was used to estimate the survival probability of COVID-19 patients at 7, 14, and 21 days. The risk factors associated with COVID-19 mortality were assessed through the Cox proportional hazard regression. All analyses were performed using SPSS16 software.

Results

Of the total 3221 patients of our cohort across the entire state of Karnataka, 59 patients data was missing from health bulletin. So among 3162 cases, 2917 (92.25%) had definitive outcomes till July 10, 2020. Majority of the patients were male (60.8%) and belonged to the age group <60 years (93.6%). Among those with definitive outcomes, 51 (1.7%) had SARI at the time of admission [Table 1].

The case fatality rate was 1.9% (55/2917), and the recovery rate was 98.1% (2862/2917). Following the test positivity, the mean length of stay among COVID-19 patients with definitive outcomes was 15.41 days (SD: 6.55). COVID-19 cases with SARI at the time of admission and those with travel history had significantly

lower length of hospital stay as compared to their counterparts. There was no difference in the length of hospital stay by gender and age [Table 1]. Among those without definitive outcomes (245/3162), the length of stay in the hospital following test positivity ranged from 40 to 114 days.

The Kaplan–Meier analysis showed an overall survival rate of 98.8% at 7 days and

98.1% at 14 days. The survival probability at 21 days is 98.5%. COVID-19 cases who were ≥ 60 years and who have presented with SARI had significantly higher risk of mortality when compared to the counterparts

($p < 0.001$). However, the risk of mortality did not differ much among male and female COVID-19 patient ($p = 0.88$).

Having SARI at the time of admission (adjusted hazard ratio: 0.07 (0.04-0.14); $P <$

0.001), being aged ≥ 60 years (adjusted hazard ratio: 0.2 (0.1-0.3); $P < 0.001$) and having travel history (adjusted hazard ratio: 3.7 (1.7-8.2); $P < 0.001$) were the significant predictors of mortality among COVID-19 patients [Table 3]. Age had confounding effect on the severity of symptoms and survival as Model-1 and Model-2 were compared.

Table 1: Characteristics of COVID-19 cases by length of hospital stay

Variables		Frequency (%)	Mean Length of Hospital stay in days (SD)	t-test	
				t-value	p-value
Gender	Male	1774 (60.8)	15.48 (6.5)	0.758	0.45
	Female	1143 (39.2)	15.29 (6.5)		
Age (Years)	<60	2729 (93.6)	15.46 (6.4)	1.764	0.07
	≥60	188 (6.4)	14.59 (8.1)		
Travel history	Absent#	990 (33.9)	15.97 (7.3)	3.342	0.001
	Present	1927 (66.1)	15.12 (6.1)		
Severity of symptoms	SARI	51 (1.7)	9.73 (8.3)	6.285	<0.001
	Others	2866 (98.3)	15.51 (6.5)		
	Overall	2917 (100)	15.41 (6.5)		

Primary and secondary contacts

Table 2: Predictors of mortality among COVID-19 cases using univariate cox-proportional hazard regression

Variables	Categories	Univariate model	
		Unadjusted hazard ratio (95%CI)	p-value
Gender	Female	Reference	0.9
	Male	1.041 (0.6-1.8)	
Severity of symptoms	with SARI	Reference	<0.001
	No SARI	0.02 (0.01-0.03)	
Age (Years)	≥60	Reference	<0.001
	<60	0.06 (0.03-0.09)	
Travel history	Absent#	Reference	<0.001
	Present	9.7 (4.7-19.9)	

Primary and secondary contacts

Table 3: Predictors of mortality among COVID-19 cases using multivariate cox proportional hazard regression

Variables		Multivariate Model 1		Multivariate Model 2		Multivariate Model 3	
		Adjusted hazard ratio (95%CI)	p-value	Adjusted hazard ratio (95%CI)	pvalue	Adjusted hazard ratio (95%CI)	p-value
Gender	Female	0.9 (0.5-1.6)	0.83	0.9 (0.5-1.6)	0.76	0.9 (0.5-1.5)	0.71
	Male	Reference		Reference		Reference	
Severity of symptoms	No SARI	Reference	<0.001	Reference	<0.001	Reference	<0.001
	With SARI	0.02 (0.01-0.03)		0.05 (0.02-0.09)		0.07 (0.04-0.14)	
Age (Years)	<60	-	-	Reference	<0.001	Reference	<0.001
	≥60	-		0.15 (0.08-0.29)		0.2 (0.1-0.3)	
Travel history	Absent#	-	-	-	-	Reference	0.001
	Present	-		-		3.7 (1.7-8.2)	

*Model 1 included sex and severity of symptoms as predictors; Model 2 included sex, severity of symptoms, and age as predictors; Model 3 included sex, severity of symptoms, age, and travel history as predictors.

SARI: Severe Acute Respiratory Illness, CI: Confidence interval

Discussion

Karnataka reported the first COVID-19 death for India on March 13, 2020.⁸ The overall case fatality rate for our cohort with definitive outcome was 1.9%, and this was much lower than the overall national figure (7%) as on July 22, 2020.³ This might be because the cases and deaths reported from Karnataka increased drastically after lockdown release and our cohort represented data during lockdown.

COVID-19 patients who are ≥ 60 years and those with serious illness (SARI) at the time of admission were found to have poor prognosis, whereas gender had no effect on the mortality. Similar results have been reported by Mishra, *et al.*⁹ This stresses on the attention and additional medical resource allocation to be given to vulnerable elderly populations irrespective of the gender.

More importantly, the study emphasizes the need for reverse quarantine (protecting the highly vulnerable elderly population from the highly mobile younger population with a high prevalence of COVID-19).¹⁰

The mean length of stay reported in the present study was 15.4 days. Mishra, *et al.*⁹ reported a 17 days in their study in Karnataka. This was higher than that reported from China (14-days) and outside China (5-days).¹¹ This may be explained by the differences in early detection, severity, admission and discharge criteria, and different timing within the pandemic.¹¹

We reported the case fatality rate of 1.9%. Mishra, *et al.*⁹ reported 5.1%. We reported the survival rate of 98.8% at 7 days and 98.1% at 14 days whereas Mishra, *et al.*⁹ reported survival rate of 95.7% at 7 days and 95.5% at 14 days. This difference might be because of the difference in virility of the virus (higher during start of the pandemic).

Having SARI at the time of admission and being aged ≥ 60 years were the significant predictors of mortality among COVID-19 patients. Similar results have been reported by Mishra, *et al.*⁹

Systematic data collection, a cohort with large data on definitive outcome and robust analyses of survival characteristics were the strengths of the study.

Our limitations are few data which were missing from health bulletin were excluded from the study and also we could not analyze cause of death and comorbidities.

The overall picture of COVID-19 can be obtained only after the end of epidemic; however, these preliminary evidences would be sufficient for health resource planning and resource allocation

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Ethical Clearance: Ethical Committee BMCH

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Antimicrobial Resistance Pattern of *Escherichia Coli* From Urinary Tract Infections in Relation to ESBL and *pap* gene Production and Fosfomycin Sensitivity

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Abstract

Introduction: Urinary Tract Infections (UTI) is becoming increasingly difficult to treat due to emergence of multi-drug resistant uropathogens. Fosfomycin can be used as an alternative due to lack of cross-resistance. We aimed to evaluate in-vitro activity of fosfomycin against uropathogenic *E.coli*.

Material and Methods: The study period was September 2017 to August 2018. Two hundred and fifty two urine samples were collected from women having uncomplicated cystitis. Out of these 168 isolates was *E.coli*, Antimicrobial susceptibility testing was performed using the Kirby-bauer disk diffusion method. ESBL screening was done using the double disc synergy test. Fosfomycin susceptibility was determined by the disk diffusion method for *E.coli*. Prevalence of the *pap* gene among the isolates were checked using amplification.

Results: The study showed that among *E.coli* isolates frequency of ESBL producers were 30.95% while 4 % were identified as carbapenem resistant Enterobacteriaceae (CRE). Among the isolates, 84.50% were susceptible to fosfomycin. There was 92.0% fosfomycin susceptibility in ESBL producing *E.coli*, and 71.42% showed fosfomycin susceptibility in CRE. The overall *pap* gene prevalence was 18% and the expression was 22% among the ESBL isolates and 20% among the CRE.

Conclusion: The study demonstrates that, a considerable proportion (68%) of the multidrug-resistant *E.coli* with diverse resistance mechanisms, including ESBL and CRE. Fosfomycin resistance was low even among ESBL and CRE isolates. *Pap* genes were prevalent among the ESBL isolates. For the treatment of uncomplicated cystitis fosfomycin is a useful antibiotic agent.

Objective: The aim of this study was to establish *in vitro* susceptibility of uropathogenic *E.coli* to fosfomycin and to check the prevalence of the expression of *pap* gene a virulence determinant among the isolates from uncomplicated cystitis in females.

Keywords: *Escherichia coli*, ESBL, fosfomycin, CRE, *pap* gene, antimicrobial resistance.

Introduction

Urinary tract infections is a common infection and *Escherichia coli* is the most common pathogen encountered⁽¹⁾. The high rates of resistance exhibited by the uropathogens and particularly *E.coli* is alarming which necessitate the re-evaluation of old antibiotics⁽²⁾. Among UTIs, cystitis is a common infection. It affects mostly women of reproductive age, while incidence

declines after the age of 40⁽³⁾. Just as in other infections there is an alarmingly high rate of multi drug resistance and extensively drug resistant bacteria causing UTI especially when patients are with co morbidities and repeated antibiotic exposures⁽⁴⁾. Since carbapenems show excellent activity against uropathogens, they are the antimicrobial agents of choice for urinary tract infections (UTIs), especially those due to extended spectrum beta-lactamase producing *Escherichia coli*⁽⁵⁾.

The increase of multidrug-resistant (MDR) bacteria induced a renewed interest in old antibiotics, such as fosfomycin⁽⁶⁾. Because of its broad-spectrum activity, sustained urinary concentrations and its safety profile. Fosfomycin tromethamine a stable salt of fosfomycin is licensed for the single-dose treatment of acute uncomplicated urinary tract infections (UTIs) caused by susceptible organisms⁽⁷⁾. Fosfomycin, originally named phosphonomycin, was discovered in Spain in 1969. Fosfomycin inhibits phosphoenolpyruvate transferase, the first enzyme involved in the synthesis of peptidoglycan, inhibiting cell-wall synthesis. There are three forms of Fosfomycin : Fosfomycin tromethamine (a soluble salt) and Fosfomycin calcium for oral use, and Fosfomycin disodium for intravenous use. Fosfomycin, is a safe antibiotic with limited adverse events⁽⁸⁾.

80% of acute urinary tract infections are attributed to *E. coli*. The ability of the bacteria to adhere to the uroepithelial cell receptors through specific fimbrial adhesins is critical for the initiation of infections⁽⁹⁾. *E. coli* is a common inhabitant of the gastrointestinal tract of humans and animals⁽¹⁰⁾. Adhesive molecules and toxins of *E. coli* account for the most important mediators of pathogenicity⁽¹¹⁾.

E. coli most often expresses P Fimbriae or mannose resistant adhesin⁽¹²⁾. The *pap* (pyelonephritis associated pilus) operon mediates the binding of the galactosyl galactose specific P fimbriae to the epithelial surfaces of intestine, vagina, urinary tract and moiety of the P blood group by their tip adhesion molecule^(13–15).

Materials and Methods

Patients: Female Patients between 18 and 65 years of age with the diagnosis of uncomplicated lower UTI were included in the study. Ethical approval was obtained from the institutional Ethical Committee

Bacterial strains

A total of 168 uropathogenic *E. coli* (UPEC) strains were isolated from 252 urine samples during a 12 months period (between September 2017 and August 2018) from lower UTI cases, from tertiary care hospital. All patients were females, aged above 18 and had dysuria or problems with frequency or urgency in passing urine; had >20 leukocytes/mm³ in urine sediment and

E. coli urine culture (>10⁵ cfu/mm³) We excluded duplicate isolates, which were defined as isolation of the same bacterial species from the same patient with the same antibiogram.

Laboratory methods

For this study, midstream urine was collected from 252 suspected cases of UTI and inoculated into MacConkey agar and Blood agar. A colony count of 10⁵ was taken as significant bacteriuria⁽¹⁶⁾. From the samples 220 showed significant growth and 168 isolates were *E. coli*. We identified the species of *E. coli* by standard biochemical tests⁽¹⁷⁾. After characterization, the UPEC isolates included in the study were kept in Luria broth medium at -20°C.

Extended spectrum beta-lactamase production was confirmed by phenotypic testing a double disk synergy test according to Jarlier⁽¹⁸⁾. Identification of ESBL production was done based on the demonstration of synergy between clavulanic acid and broad-spectrum cephalosporins.

For genotyping bacteria was grown in Luria broth medium for 18 h at 37°C. For standardization of PCR conditions positive strains, kindly provided by Johnson lab & Brian J from Pathos pool were used. Positive control strains include J-96 Strain positive for *pap* and known negative control⁽¹⁹⁾.

Antimicrobial susceptibility testings

The disk diffusion method was used to test the antimicrobial susceptibilities for the commonly used antibiotics. We used the following antimicrobial agents ampicillin, cefazolin, cefuroxime, ceftriaxone, cefotaxime, ceftazidime, cefixime, ciprofloxacin, Levofloxacin, nitrofurantoin, gentamicin, amikacin, trimethoprim-sulfamethoxazole. Testing for carbapenem susceptibility was done with imipenem and meropenem discs and the results were interpreted as susceptible (S), intermediate susceptible (I) and resistant (R) following CLSI 2016. The breakpoints of these antimicrobial agents were using CLSI criteria⁽²⁰⁾.

With regard to the antimicrobial activity of fosfomycin, the CLSI-directed disk diffusion test for *E. coli* was used. *In vitro* sensitivity to fosfomycin was tested according to Clinical and Laboratory Standards

Institute(CLSI) guideline. Fosfomycin trometamol disk (200 µg fosfomycin/50 µg glucose-6-phosphate) (Hi media, Mumbai, India) was used to determine the susceptibility to fosfomycin and growth-inhibition zone was evaluated⁽²¹⁾.

Preparation of bacterial DNA.

DNA to be amplified released from whole organisms by boiling. Bacteria were harvested from 1 ml of an overnight broth culture, centrifuged pellet suspended in 200µl of sterile water, and incubated at 100°C for 10 min.

Primers: *pap*, forward and reverse primers obtained from *Eurofins Mwg*, Bangalore

Amplification Procedure

All amplification reactions performed in Applied Biosystem thermocycler. PCR amplifications consists of 1 cycle of 94°C for 60 s, 30 cycles of denaturation at 94°C for 60s , annealing at 63°C for 30 sec and extension at 72°C for 90 s followed by a final cycle of 72°C for 90s. The PCR products analyzed by electrophoresis in a 1.0% submersed agarose gel stained with ethidium bromide and visualized under UV light as described by Sambrook

*et al*²² .

Statistical Methods

Differences between non-continuous variables was tested by *Chi-square* test or two tailed fisher exact test as appropriate. All results will be considered to be statistically significant at P=0.05

Results

Antimicrobial resistance of *E.coli* isolates from clinical data of 252 eligible patients was analyzed. A positive urine culture was found in 87.3%. Within the 220 pathogens, *Escherichia coli* was most frequent (76.3%).

E.coli showed the highest rate of susceptibility to imipenem (94%) followed by fosfomycin(84.5%), nitrofurantion(83%) and amikacin(82.0%).The lowest rate was found for ampicillin(45.1%).

The *pap* genes(Figure 1)are associated with different forms of UTI. They are important in the pathogenesis of ascending UTI and pyelonephritis.*pap* gene coding for *pap* adhesin was present in 30 of the *E.coli* isolates.25 of these isolates were susceptible to fosfomycin

Table 1 Susceptibility to fosfomycin among ESBL and CRE

Fosfomycin	Escherichia coli	
	ESBL n=52	CRE n=7
Susceptible	42	5
Intermediate	08	3
Resistant	2	0
Total	52	7

ESBL: Extended spectrum beta lactmase CRE: Carbapenem resistant Enterobacteriaceae

Among the *E.coli* isolates, ESBL producers had a frequency of 30.95% (52/168) and 4%(7/168) were identified as Carbapenem resistant Enterobacteriaceae (CRE). Overall, 84.50% (142/168) isolates were susceptible to fosfomycin. There was 92.00% (48/52) fosfomycin susceptibility in ESBL producing *E.coli* and 71.42% (05/07) showed fosfomycin susceptibility in CRE.

Table 2 Demographic and clinical data of patients according to ESBL production. Fosfomycin, had good activity against gentamicin, ciprofloxacin and co-trimoxazole resistant *E.coli* with or without *pap* gene. The resistance rate of fosfomycin was significantly lower in gentamicin,ciprofloxacin, cotrimoxazole resistant *E.coli* isolates compared to isolates susceptible to antibiotics.

Characteristic Comorbidities, underlying condition	Total n=168 (%)	ESBL n=52(30.9%)	NonESBL n= 116 (69.1 %)
Previous use of antibiotics	60 (35.7)	29(56.6)	31(27.0%)
Type2 diabetes	56 (33.3)	22(41.4)	34 (29.3%)
Arterial hypertension	31 (18.4)	11(20.7)	20(17.2%)
Pregnancy	26(15.6)	4(8.3)	22 (18.9%)
ESBL, extended-spectrum beta-lactamase			

Resistance rate among *E.coli* to the trimethoprim-sulfamethoxazole was 48%, the resistance to cephalosporins ranged from 49% to 88%, ciprofloxacin 58.20%, levofloxacin 69%, imipenem 6 %. High frequency of resistance to ampicillin (72%) and moderate resistance (36.0%) to gentamicin was detected. 68% were found to be (multidrug-resistant MDR). Resistance rates lower than 20% were found for amikacin, nitrofurantoin, and fosfomycin. The overall *pap* gene prevalence was 18% and the expression was a 22% among the ESBL isolates and 20% among the CRE.

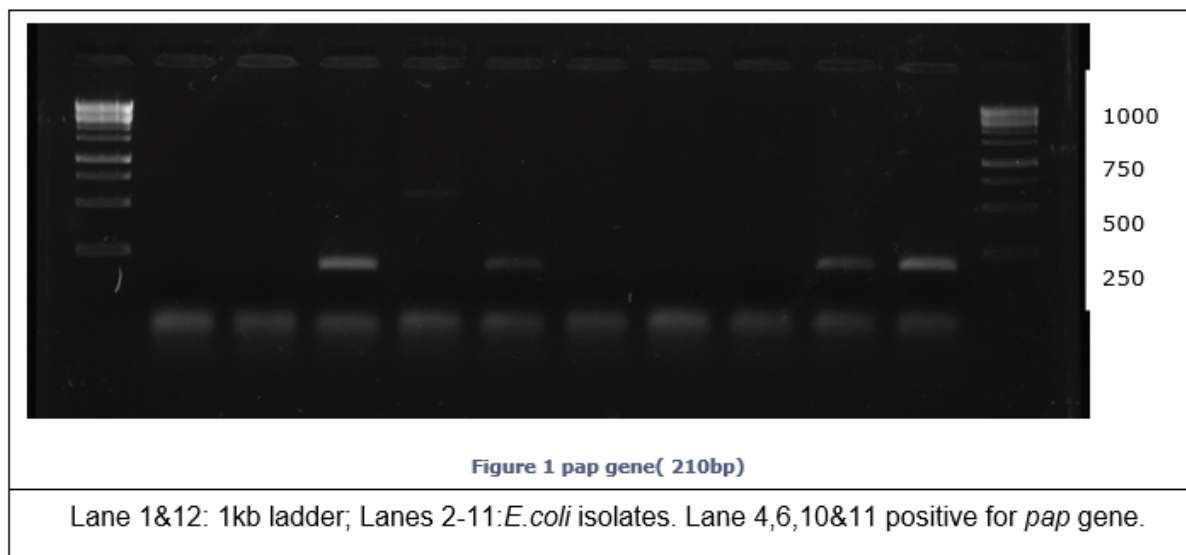
Table 3 Age Distribution of Uropathogenic *E.coli* isolates

Age distribution	female
>18-30	46
31-40	48
41-50	39
51- 60	18
above 60	17
Column Totals	168

There was significant difference between the different age groups namely (18-30), (51-60) and >60 among the patients.

Table 4 *pap* gene distribution

<i>pap</i> gene	absent	present	Total
case	138	30	168
Total			168



Discussion

The ability to adhere to epithelial surface has been shown to be a prerequisite for *E. coli* strains to colonise the urinary tract and cause UTI in the absence of urological abnormalities. *pap* is the pyelonephritis-associated pili. In this study we have looked at the sensitivity of the antibiotics with relation to *pap* genes and found its prevalence to be 17.8%. There is whole lot of difference in the frequency of *pap* gene among UPEC strains isolated from different region^(23–28). This could be because UPEC strains utilize a variety of adhesins to bind to the urinary epithelial cells and start the infection.

Ciprofloxacin has commonly been used as oral therapeutic option for ESBL producing isolates⁽²⁹⁾. The resistance rate of ESBL *E. coli* to ciprofloxacin was 58.2% in this study. ESBL-producing enterobacteriaceae have emerged in both the community and hospital settings in most countries, including India. Carbapenems are the drugs of choice for treating severe infections caused by the ESBL producing isolates⁽³⁰⁾. In our study, imipenem and meropenem were most actively against ESBL.

Trimethoprim-sulfamethoxazole is one of few oral therapeutic options for ESBL-producing isolates. But in this study, it was the not an active antimicrobial agent against ESBL producing *E. coli*. Ko et al showed that the resistance rates for trimethoprim-sulfamethoxazole among *E. coli* are rising accompanied with ciprofloxacin resistance and ESBL production⁽³¹⁾. In our study, a high percentage of strains susceptible to amikacin and nitrofurantoin were found 234 (99.5% and 92.1%, respectively). Nitrofurantoin is an old drug used for uncomplicated UTI, but its use is limited because of its nephrotoxicity. the potential role of nitrofurantoin for uncomplicated UTI in the growing resistance era has been mentioned by Kashanian et al⁽³²⁾. In our study, a high percentage of strains susceptible to amikacin and nitrofurantoin were found, amikacin(82.0%) and nitrofurantoin(83%) respectively).

Fosfomycin has been reported to have good potential in treating UTI caused by multidrug resistant *E. coli*.

Fosfomycin is well tolerated in humans and causes little nephrotoxicity. Fosfomycin-tromethamine, an oral form of fosfomycin, is also indicated for uncomplicated UTI^(33,34). In a systematic review, fosfomycin is found actively against Enterobacteriaceae producing ESBL, particularly *E. coli*^(35,36). In Switzerland and Italy, fosfomycin has been found to be the most active agent

against *E. coli*, presenting 100 and 98% efficacy, respectively^(37,38). Fosfomycin susceptibility rates in Sweden are high in *E. coli*, particularly in ESBL-producing strains (97–99%), supporting the replacement of antibiotics exhibiting reduced activity by fosfomycin⁽³⁹⁾. Our study showed that the activity of fosfomycin against ESBL isolates remained reliable even in

ciprofloxacin-non susceptible isolates. Ko et al has shown that fosfomycin does not have cross-resistance with other antimicrobial agents⁽⁴⁰⁾. This finding may be because of the unique antibacterial mechanism of fosfomycin.

This study has few limitations. First, only disk diffusion method was used to determine the fosfomycin susceptibility. Only women candidates from outpatient setting was evaluated.

Conclusion

Fosfomycin remains a viable option for the treatment of *E.coli* in uncomplicated UTIs; different susceptibility testing platforms can give very different results regarding the prevalence of fosfomycin resistance, with false positives being a potential problem that may unnecessarily limit the use of this agent.

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Assess the Knowledge and Practice regarding Self-administration of Insulin among Patients with Type -2 Diabetes Mellitus admitted in Medical ward at a Tertiary Care Hospital

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Abstract

Diabetes mellitus is a chronic disease in which the body's inability to produce insulin is decreased, resulting in impaired carbohydrate metabolism can leads to elevated glucose in the blood. Among the types of the Diabetes mellitus Type 2 diabetes mellitus, which is much more common, occurs when the body cannot produce enough insulin or the insulin is not working efficiently enough. Insulin is more important therapy for type 2 diabetes when blood glucose levels cannot be controlled by diet, weight loss, exercise, and oral medications. Most of the people are still visiting the physicians twice monthly and on maintenance drugs only. Hence a study was conducted to determine the level of knowledge and Practice regarding Self-administration of Insulin among patients with Type -2 Diabetes Mellitus. The objectives of this study were to assess the Knowledge and Practice Regarding Self-administration of insulin among the diabetes patient admitted in a Medical ward , to find out the association between knowledge and Practice with their selected socio-demographic variables and to find out association between knowledge and practice regarding self-administration of insulin. A non-experimental descriptive design was adopted and the study was conducted in medical ward , Sri Ramachandra Hospital, Chennai, Tamilnadu. 40 Type-2 diabetes patients on self-administration on insulin were selected for the study by using convenient sampling technique. The result suggests that there is an inadequate level of knowledge and the poor level of practice among Type-2 diabetes patients. There is a significant association between the level of knowledge and practice with the selected demographic variables among the Type-2 diabetes patient. Hence the Nurses play an vital role in building their knowledge and understanding the importance of prevention of complications of regarding self-administration of insulin. This can be facilitated by motivating the nurses to provide outpatient based education programme to improve their health.

Keywords: Knowledge, Practice, Type-2 Diabetes mellitus and self administration

Introduction

One of the greatest challenges faced by the modern world is Diabetes mellitus. Diabetes mellitus is a chronic disease and a growing challenge in India with estimated 8.7% diabetic population in the age group of 20 and 70 years. **Type 2 diabetes** is the most common type of diabetes, accounting for around 90% of all diabetes cases.

Diabetes currently affects more than 62 million Indians, which is more than 7.1% of the adult population. Tamil Nadu had the highest death rate from diabetes among Indian. Most people who are newly diagnosed with type 2 diabetes begin initial treatment with a combination of diet, exercise, and insulin therapy. Intensive insulin therapy is essential in the maintenance of strict glycemic control among insulin requiring patients with diabetes.

Comprehensive and awareness regarding diabetes mellitus is a necessary criterion for individuals and communities to take action for control of the disease condition. The major pharmacological intervention for

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diabetes included the administration of oral hypoglycemic agents and injectable insulin therapy. Insulin therapy requires crucial coordination and understanding of both the individual with diabetes and those responsible for diabetic care. Insulin therapy should be individualized to conform to the patient's lifestyle and body metabolism. Along with therapy, changes and modifications need to be implemented. Information and education regarding diabetes mellitus and its treatment provides improvement in knowledge, attitude and skill which consequently leads to better control of the disease. The objectives of this study were to assess the Knowledge and Practice Regarding Self-administration of insulin among the diabetic patient admitted in a Medical ward, to find out the association between knowledge and Practice with their selected socio-demographic variables and to find out association between knowledge and practice regarding self-administration of insulin.

Methodology

The research design chosen for this study was non-experimental descriptive design. The settings of the study were Medical ward of Sri Ramachandra Hospital, Chennai. Population of the study included is patients with Type -2 Diabetes Mellitus on self administration of insulin. The samples selected for the study were both male and female patients admitted in the medical ward. The sample size was 40 and the sampling technique used was convenience sampling technique. Inclusion criteria included patients with Type -2 Diabetes Mellitus on self administration of insulin, patients who belongs to the age of 18 to 60 years, who could understand Tamil or English and willing to participate. Exclusion criteria were those who were developed complications for insulin, not willing to participate, or suffering from any chronic illness or disability.

Description of tool SECTION A: Demographic variables of the patients with Type -2 Diabetes Mellitus

on self administration of insulin consist of age, education, locality, occupation, income, marital status, type of family, number of children, family history of diabetes mellitus, duration of diabetes mellitus, duration of treatment and duration of insulin etc. SECTION B: Semi structured questionnaire prepared by the investigator consisting 10 practices questionnaire regarding self-administration of insulin and **questions** on knowledge consisting 15 questions regarding self-administration of insulin. The tool was validated by the experts of Department of Medical surgical Nursing. The tool has got the following categories the questions related to the 8 questionnaire consists of Knowledge regarding Storage of Insulin, 4 questionnaire consists of Techniques of Insulin Administration and 3 questionnaire consists of Complication of Insulin Therapy and 10 questionnaire consists of Practice Regarding Self Administration of Insulin. Each knowledge and practice statement has got score for the right answer has 1 and 0 for wrong answer. The scoring has been interpreted as the score of 75 % as adequate knowledge and good practice. Data collection procedure the study was conducted for a period of 4 weeks. Permission to conduct the study was obtained through proper channel.

Patients with diabetes mellitus who met the inclusion criteria and those with the history of diabetes mellitus for more than 6 months were selected for this study. Using the tool, the data were collected from the patient to find out their knowledge and practice regarding Type -2 Diabetes Mellitus on self administration of insulin. The data were collected through structured interview method and data was analyzed with descriptive and inferential statistics.

Results

The major findings of the study are depicted below in tables and graphs.

Table 1: Frequency and percentage distribution of the demographic variables among patients with. Type -2 Diabetes Mellitus on self administration of insulin (n=40).

S. No	Demographic variables	Frequency	Percentage (%)
1.	Age in years		
	18-30	3	8
	31-45	7	17
	46-60	12	30
	>60	18	45
2.	Sex		
	Male	12	30
	Female	28	70
3.	Education		
	Illiterate	5	13
	Primary	7	17
	High school	20	50
	Graduate	8	20
4.	Occupation		
	Employed	22	55
	Unemployed	18	45
5.	Monthly income in Rupees		
	<5,000	7	18
	5,001 to 10,000	12	30
	10,001 to 15,000	13	32
	>15,001	8	20
6.	Type of Family		
	Nuclear	33	83
	Joint	7	17
7.	Place of living		
	Rural	18	45
	Urban	12	30
	Semi-urban	10	25
8.	History of co morbid illness		
	Hypertension	18	45
	Hypothyroidism	12	30
	Bronchial asthma	5	12
	Hyperlipidemia	5	13
9	Family history of DM		
	Yes	33	83
	No	7	17
10	Information about DM		
	Mass media	22	55
	Health personnel	11	28
	Relatives and friends	7	17

Table- 1: depicts the frequency and percentage distribution of the demographic variables of patients with Type

-2 Diabetes Mellitus on self- administration of insulin. Among which 18(45 %) of them belongs to the age group >60years and 28 (70 %) of them are female patients, and majority of 20 (40 %) had high school Education, 13 (32 %) are skilled labors with the income of Rs. 10,001 to 15,000 and 18 (45 %) are living in the rural area, 18 (45 %) has history of hypertension ,majority of them 33 (83 %) had family history of first degree relative with diabetes mellitus , 22 (55 %) has received information about diabetes mellitus through mass media.

Table 2: Frequency and percentage distribution of the clinical variables among patients with.Type -2 Diabetes Mellitus on self administration of insulin.

S. No	Clinical variables	Frequency	Percentage
11	Duration of Diabetes Mellitus		
	< 6months	22	55
	6-12 months	6	15
	13-18 months	5	12
	>18 months	7	18
12.	Duration of insulin therapy		
	< 6months	22	55
	6-12 months	6	15
	13-18 months	5	12
	>18 months	7	18

Table 2:depicts the Frequency and percentage distribution of the clinical variables among patients with. Type -2 Diabetes Mellitus on self administration of insulin. Among 22 (55%) of them were Duration of Diabetes Mellitus and insulin therapy for less than 6months

Table 3: Frequency and percentage distribution of the level of knowledge among patients withType -2 Diabetes Mellitus on self administration of insulin.

S.No	Level of knowledge	Frequency	Percentage
1	Inadequate Knowledge	32	80
2	Moderately Adequate Knowledge	04	10
3	Adequate Knowledge	04	10

Table 3: depicts that 32 (80 %) had inadequate knowledge and 4 (10 %) had moderately adequate and 4 (10%) only had adequate level of knowledge regarding self administration of insulin.

Table 4: Frequency and percentage distribution of the level of practice among patients with diabetes mellitus regarding self administration of insulin

S. No	Level of practice	Frequency	Percentage
1	Poor practice (1-3)	34	85
2	Average practice (5-7)	4	10
3	Good practice (8-10)	2	5

Table 4: depicts that 34 (85 %) of them had poor levels of practice; 4(10 %) and 2(5 %) had adequate and good levels of practice regarding patients with diabetes mellitus regarding self administration of insulin.

Table 5: Mean and standard deviation on the Level of knowledge and practice among patients with. Type -2 Diabetes Mellitus on self administration of insulin. (N= 40)

S.No	Variables	Mean	Standard deviation
1	Level of knowledge regarding self administration of insulin.	8.9	2.983
2	Level of practice regarding self administration of insulin	3.75	1.936

Table 5: depicts the mean and standard deviation of the knowledge variable is 8.9and2.98; practice is 3.75and 1.936 respectively.

Discussion

The descriptive statistics reveals that 32 (80 %) had inadequate knowledge and 4 (10 %) had moderately adequate and 4 (10 %) only had adequate level of knowledge regarding patients with diabetes mellitus regarding self administration of insulin. Similarly, 34 (85 %) of them had poor levels of practice; 4(10 %) and 2(5 %) had average and good levels of practice regarding patients with diabetes mellitus regarding self administration of insulin. The result suggest that the three topics on which the patient felt less informed were diet management ,exercise into daily life and periodic checkups of the blood sugar. Hence the nurse based education programme is crucial to improve their well-being. There is an significant association between the age, residence, sex, occupation and co-morbid illness with the level of knowledge and practice of patients with diabetes mellitus regarding self administration of insulin

Conclusion

The patients with diabetes mellitus on insulin therapy will have impairment in their physical, psychological and social dimensions. The findings of the present study suggest that even though the attending physician provides education to them during the consultation that is not enough for them to alleviate their myths. Hence separate education programme on the disease process is essential in order to avoid complications and improve

the quality of life among type 2 diabetes patients. The findings of the present study suggest that the nurse led education programme is essential key in the diabetes management plan and to improve their quality of life.

Ethical Clearance- Not appeared

Source of Funding- Self

Conflict of Interest – Nil.

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The Role of Life style Modification in Management of Polycystic Ovary Syndrome

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Abstract

Polycystic ovary syndrome is a common endocrine disorder affecting women of reproductive age group characterized by various metabolic and reproductive dysfunctions. There are evidences that environmental toxins play a potential role in disrupting reproductive health. In this review we summarized existing research on a variety of environmental factors involved in the etiology, prevalence and management of polycystic ovary syndrome. Pubmed, PsycINFO and Google Scholar were searched for the reviews and studies from last five years included in this study. All searches were limited to human studies. We concluded that symptoms of polycystic ovary syndrome are reduced with certain dietary supplement, restricted diet and exercise. Health related quality of life along with weight, body hair, infertility, acne score improves well with an intervention of about 24-weeks of lifestyle modification. That is why a healthy lifestyle is usually recommended to improve overall health and fertility.

Key words: Polycystic ovary syndrome, dietary habits and exercise

Introduction

Polycystic ovary syndrome is most common endocrine-metabolic disorders affecting 8% to 13% women of reproductive age group and is associated with ovulatory dysfunction, hyperandrogenism and cardiometabolic risk. Due to sedentary lifestyle and stress incidence of metabolic disorders like PCOS are increasing day by day. Polycystic ovary syndrome is characterized by insulin resistance, elevated circulating leukocytes, and hypothesized to have higher adipose tissue inflammation. The condition is marked by presence of cysts on the ovaries leading to their obstructed functioning. Amenorrhea, infrequent menstruation & anovulation, imbalanced hormonal levels, chronic pelvic pain and irregular bleeding are the common symptoms of Polycystic Ovary Syndrome. Women with polycystic ovary syndrome have higher prevalence of infertility compared with women without PCOS. 'The overweight-obese women having PCOS appears to have exacerbated reproductive dysfunction and cardio metabolic risk.¹ Early diagnosis and treatment may reduce the risk of long-term complications such as metabolic disorders,

obesity, diabetes, and coronary disease, and malignancies such as breast and endometrial cancer. Obesity worsens the presentation of PCOS and weight management is supposed to be an initial treatment strategy. Khademi 2010 et.al found that 'Obese PCOS women show more difficulty in losing weight by exercise than lean women with PCOS'.¹ Though this target can be achieved through lifestyle modifications, by incorporating restricted diet, exercise and behavioral interventions. That is why a healthy lifestyle is usually recommended to improve overall health and fertility.

The actual cause of PCOS is unknown but environmental factors such as dietary habits play an important role in prevention and treatment of this syndrome. 'Weight reduction even of about 5% can improve problems such as insulin resistance, high level of androgens, reproductive system dysfunctions in women with PCOS. Thus, lifestyle modification can be used as therapeutic strategies in these patients'.² Lifestyle intervention may improves secondary reproductive outcome, free androgen index, may reduce weight and BMI. Women inducing lifestyle intervention shows

significant improvement in cardio respiratory fitness and reduces resting heart rate. It may also be used for improvement of health related quality of life and other psychological complications in women with PCOS. This can make enormous difference and relieve symptoms like eating habits, participating in regular physical activity, maintaining healthy weight, reducing androgen level, reducing risk of DM and CVD. 'Lifestyle intervention helps improving body composition parameters including BMI, waist circumference, waist hip ratio, body fat, total cholesterol, C-reactive protein and peak VO₂ MD'.³ Knowledge about these interventions increases healthy eating, active living, health care satisfaction, feelings and experiences about intervention and health concerns.⁴ Losing just 5-10% of your body weight helps regulating menstrual cycle and improving symptoms of polycystic ovary syndrome. Thirty minutes of moderate to vigorous intensity exercise at least 4 days a week along with healthy diet can help women with PCOS lose weight.

Effect of Exercise on Polycystic Ovary Syndrome

Healthy lifestyle including nutritious and balanced diet, yoga & exercise are found effective in management of polycystic ovary syndrome. Weight loss programs hold promise and efficient hospital or community-based programs may prove beneficial in women with PCOS. Regular exercise also increases quality of life in these women. In overweight and obese women with or without PCOS exercise contributes to lower insulin and free androgen levels which helps restoring hypothalamic-pituitary-gonadal axis regulation of ovulation. The mechanism by which exercise affects ovulation is probably via modulation of hypothalamic-pituitary-gonadal axis. 'Despite various researches supporting weight loss as primary measure for PCOS management there is lack of studies comparing types of physical activity, intensity and settings. These gaps may be responsible for delaying an efficient and effective use of exercise as a therapeutic modality to treat anovulatory infertility including PCOS. Exercise with or without diet can lead to resumption of ovulation. Regular exercise for 30-60 min is associated with reduced risk of anovulatory infertility'.⁵ Moderate aerobic exercise intervention for more than or equals to a period of three months have favorable effects on various cardio-metabolic risk factors in women with polycystic ovary syndrome.

Some of these factors include total cholesterol level, fasting glucose, waist circumference and waist to-hip ratio, testosterone, sex hormone, C-reactive protein and systolic blood pressure.⁶ Continuous aerobic training and intermittent aerobic training both helps in reduction of anxiety and depression. After approximately four months or sixteen weeks of aerobic training significant reduction in testosterone level are found. 'CAT significantly increases the total score of Female Sexual Function Index, improves FSFI domains of satisfaction and pain and reduced WHR. Intermittent aerobic training increases total FSFI score and improves desires, excitation, lubrication, orgasm and satisfaction in women with polycystic ovary syndrome'.⁷ Beneficial effects of exercise are found for a range of metabolic, anthropometric and cardio respiratory fitness related outcomes. 'Short duration and aerobic exercise significantly affects fasting insulin level, total cholesterol, low density cholesterol, and triglycerides. Exercise also improves VO₂ max, waist circumference and body fat percentage'.⁸ Moderate intensity exercise independent of substantial weight loss improves endothelial function in women with PCOS by reducing circulating CD105+MP.⁹ Physical resistance exercise alone can improve hyperandrogenism, reproductive function, and body composition by decreasing visceral fat and increasing lean muscle mass. 'PRT reduces plasma testosterone and fasting glucose, increased androstenedione concentration and sex hormone binding globulin concentration decreases in women with PCOS'.¹⁰ Regular physical activity is associated with better anthropometric and androgenic profile in women with PCOS. As compared to sedentary women with PCOS active women have lower waist circumference, lipid accumulation product and low androgen levels.¹¹

When compared to oral contraceptives which treat hyperandrogenism and menstrual disturbances structured exercise training program is helpful in effective management of anthropometric measures, insulin sensitivity indexes, lipid profile, cardiopulmonary function, inflammatory marker and frequency of menstrual cycle in women with PCOS.¹² 'Obese adolescents having PCOS who have experienced childhood trauma can lose weight and acquire its health benefits when intervened with weight loss, mood, and sleep'.¹³ Weight loss, fertility hormones, FSH, prolectin, oestrogen, antral follicle count, baseline anti-mullerian

hormone and adiponectine are significantly correlated with reproductive function. Physical activity changes the level of anti-mullerian hormone and adiponectin. Moderate aerobic exercise for around twelve weeks had significant effect on reproductive functions by modulating adiposity, levels of adiponectine anti-mullerian hormones and fertility hormones. 'Participants who respond to aerobic exercise intervention show significant improvement in reproductive function, with lower baseline anti-mullerian hormone level, weight loss and increased adiponectine level. These women also shows significant improvement in ovarian process and a restoration of menstrual cycle'.¹⁴ Resistance training has beneficial effects on morphology of the ovaries and the glycemic index in women with PCOS. It has good effect on insulin resistance index, improves ovaries volume, body composition indices including weight, body mass index and body fat.¹⁵

Polycystic ovary syndrome is characterized by insulin resistance, elevated circulating leukocytes and more tissue inflammation. In obese individuals aerobic exercise reduces circulating leukocytes and improves insulin sensitivity. Women with polycystic ovary syndrome have higher circulating leukocytes. This condition can be reversed by aerobic exercise and is associated with improvement in insulin sensitivity. WBC is found higher and total adiponectin level is lower in PCOS women performing regular exercises. 'Regular aerobic exercise for four weeks reduces serum leptin; ratio of leptin to high molecular weight adiponectine after eight weeks and significantly increases serum dehydroepiandrosterone sulfate after sixteen weeks'.¹⁶ Exercise may normalize amino acid metabolite in women with PCOS. 'If regular exercise is performed, Leucine, glutamate, methionine, ornithine, phenylalanine, tyrosine and proline in women with PCOS may normalize and become equal to women without PCOS'.¹⁷

'Aerobic exercise increase vagal modulation, decrease sympathetic modulation and increases parasympathetic modulation, decrease resting heart rates and systolic blood pressure irrespective changes in BMI, fasting insulin and testosterone level'.¹⁸ Women with PCOS who meet department of health and human services guidelines for exercise have superior metabolic health parameters. Vigorous exercise is associated with reduced metabolic dysfunctions independent of age,

BMI and total energy expenditure. 'When compared with inactive women and moderate exercisers, it was found that vigorous exercisers had lower body mass index, higher level of HDL and sex hormone binding globulin and reduced prevalence of the metabolic syndrome'.¹⁹ Homeostatic assessment of insulin resistance improves after high intensity interval training, high density lipoprotein increases, endothelial function increases and body fat decrease.²⁰ Progressive aerobic exercise improves health related quality of life, cardio respiratory fitness and cardio metabolic profile of overweight/ obese women with polycystic ovary syndrome. While glancing psychological aspects 'exercise improves following domains of health related quality of life - physical functioning, general health and mental health'.²¹

Effect of Yoga on Polycystic Ovary Syndrome

Women with PCOS also suffer from emotional ill health, anxiety and depression. Medical yoga therapy is emerging as an effective modality in the management of much non-communicable disease. Yoga therapy also addresses psychological morbidity. Yoga has calming effect on the mind and body through balancing sympathetic and parasympathetic nervous system. Lifestyle modification including diet, exercise and weight loss is very important component of management of PCOS. 'Thus yoga results in multiple beneficial effects on neuroendocrine axis and facilitates adoption of healthier lifestyle addressing underlying hyperandrogenemia and insulin resistance in PCOS'.²² Due to disturbance in hypothalamo-pituitary-ovarian axis various symptoms like anxiety, depression, insomnia, loss of concentration, acne, infertility etc. appears in syndrome. It is a psychosomatic disorder too, so it is important to provide psychic and somatic treatment also. Yoga is the complete prescription for the healthy body and mind which deals with the root cause of this disorder i.e., obesity and stress. 'Daily yoga with for thirty minutes with four asans, four pranayam, meditation, and shavasana helps in weight reduction and stress management, thus normalizing hypothalamo-pituitary-ovarian axis and curing polycystic ovary syndrome. Asans like suryanamaskar, paschimottan asan, bhujangasan, shalabhasan etc. helps in weight reduction and toxin excretion from the body. Pranayam and relaxing yoga posture like Shavasana, makarasana etc. helps curing stress'.²³ Yoga and naturopathy therapy

for twelve weeks improves ovarian morphology and anthropometric measurements.²⁴ Regular mindful yoga practice can be used as complementary therapeutic option for women with PCOS. This lowers serum androgen (dehydroepiandrosterone) and free testosterone levels. Improvement occurs even in absence of weight loss and persists even if there is a lapse in practice.²⁵

Dietary Modification and PCOS

Overweight women with PCOS related infertility have eating behaviors inconsistent with achieving a healthy body weight. They have poor dietary intake, particularly related to whole grains, fiber and iron.²⁶ 'PCOS women consume high glycemic index food items and lower legumes and vegetables'.²⁷ There is high prevalence of overweight status, obesity, and increased visceral fat in these women. Diet quality is negatively associated with obesity. Two of the primary ways diet affect PCOS are weight management and insulin production and resistance. 'Diet therapy in these patients must reach specific goals such as improving insulin resistance, metabolic and reproductive function. Low-calorie diet can be used to achieve weight loss or maintaining a healthy weight. Diet must focus on limited intake of simple sugars, refined carbohydrates and intake food with low glycemic index, reduction of saturated and trans-fat. Attention must be paid to possible deficiencies of vitamin D, chromium and omega-3 fatty acid'.² Energy restriction and weight loss in PCOS improves ovulation rates, conception, hyperandrogenemia, glucose and insulin level, insulin resistance, and satiety hormones. Diet low in carbohydrate as compared to standard diet has 1-5% significant additional effect to caloric restriction in terms of weight loss.²⁸ Carbohydrates are the main stimulators of insulin release. Dairy products and starches elicit great postprandial insulin secretion than non-starchy vegetables and fruits. 'Eight week dietary intervention using a low starch/low dairy diet in women with PCOS is effective in reducing weight, BMI, waist circumference, waist to hip ratio, fasting insulin and homeostasis model assessment of Insulin Resistance (HOMA-IR), total testosterone, free testosterone, and ferriman- Gallwey score'.²⁹ High dietary GI and low fibre intake are associated with PCOS.³⁰ Low carbohydrate diet is more beneficial in weight loss, reducing insulin and serum testosterone. 'This diet when combined with exercise results in weight loss, decreased body fat,

increased insulin sensitivity, improved estradiol and LH: FSH ratio and other reproductive measures'.³¹ Dietary weight loss in adolescent women with polycystic ovary syndrome resulted in significant improvement in menstrual regularity, BMI, waist circumference, and hirsutism score.³² 'When these women are subjected to an anti-inflammatory hypocaloric diet with physical activity they show significant improvements in body composition, hormones, menstrual cycle, blood pressure, glucose homeostasis, dyslipidemia, C-reactive protein and serum amyloid acid and improved fertility with 12% spontaneous pregnancy rate'.³³ A proper low-calorie diet with low glycemic index should be recommended along with PA to improve psychological, reproductive, and cardiovascular parameters for women with polycystic ovary syndrome.

There is currently no standard diet for PCOS. However, a widespread agreement about food which seems to be beneficial for these women are: A) A low glycemic such as whole grains, legumes, nuts, seeds, fruits, starchy vegetables, unprocessed and low carbohydrate good. B) An anti-inflammatory diet such as berries, fish, green leafy vegetables, extra virgin oil etc. C) DASH (dietary approaches to stop hypertension) diet which includes poultry, fruits, vegetables, whole grain, and low fat dairy products. DASH diet reduces hypertension and risk of heart disease. Other foods that can be included in diet are: natural unprocessed food, high fiber food, fatty fish, salmon, spinach, dark red fruit, blue& blackberries cherries, broccoli and cauliflower, dried beans, lentil; healthy fats such as olive oil, avocados, coconut; nuts like walnut, almonds, pistachios; spices like turmeric and cinnamon; and dark chocolate. Food to be avoided is: sugary beverages such as sodas and energy drinks; refined carbohydrates such as pastries, cakes, white processed bread; processed meat etc.

Other beneficial dietary habits are including small frequent meals, consumption at regular times, majority of carbohydrates consumption at lunch time or equally distributed through out the day and drinking plenty of water.

Conclusion

Due to sedentary lifestyle and stress incidence of metabolic disorders like PCOS are increasing

day by day. Early diagnosis and treatment including lifestyle modification may reduce the risk of long-term complications such as metabolic disorders, obesity, diabetes, and coronary disease, and malignancies such as breast and endometrial cancer. Losing just 5-10% of your body weight helps regulating menstrual cycle and improving symptoms of polycystic ovary syndrome. Moderate to vigorous regular physical exercise along with healthy and restricted diet helps these women achieving healthy body weight, normalizing hormonal profile and improving metabolic and reproductive functioning. Including yoga in daily life routine helps in both mental and physical health maintenance. Lifestyle modification is thus an effective measure in improving mental and physical health of women with PCOS.

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Ethical Clearance- Not required

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Prevalence and Initiating Factors for Alcohol Use Disorder among Medical Students of Telangana

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Abstract

Introduction: alcohol use disorders (AUD) or alcoholism is a term for any drinking of alcohol that results in mental or physical health problems. alcoholism is a worldwide problem. it is known to have adverse effects on psychological and social health. **Objectives:** to study the prevalence of alcohol use disorder (AUD) among medical students. to study the initiating factors for alcohol use among study population.

Methodology: the present study is a prospective observational study done on medical students and internees (house surgeons) of telangana state government medical colleges with the use of pre-designed, pre-tested web-based audit (alcohol use disorders identification test) questionnaire with additional variables to determine the initiating factors of alcohol use. **Results:** in this study total 270 mbbs students were participated in those 141(52.22%) were boys and 129 (47.77%) were girls. majority study population belongs to 3rd mbbs 137 (50.74%) and less study population from internship 12 (4.44%). in the present study males 111 (41.1%) are under low risk, 30 (11.11%) are at risk among females 115 (42.59%) are under low risk, 14 (5.18%) are at risk. **Conclusion:** the overall prevalence was found to be 44 (16.29%).factors that seem to be enabling initiation of alcohol include male sex, curiosity, background of medical education, staying away from parents and an age group of 16-20 years.

Keywords: - alcohol use disorder (AUD), medical students, at risk, medical college.

Introduction

Alcohol use disorders (AUD) or alcoholism is a term for any drinking of alcohol that results in mental or physical health problems [1]. Alcoholism is a worldwide problem. It is known to have adverse effects on psychological and social health. Alcohol being easily available is one of the common substance to be abused and is also socially acceptable. Worldwide, 3 million deaths every year result from harmful use of alcohol [2], this represent 5.3 % of all deaths. Overall 5.1 % of the global burden of disease and injury is attributable

to alcohol, as measured in disability-adjusted life years (DALYs). Beyond health consequences, the harmful use of alcohol brings significant social and economic losses to individuals and society at large.

Alcohol is known to cause various accidents, cognitive Impairment, poor performance and behavioral changes. The mean age of initiation of alcohol has been declined in recent years [3]. College students are more vulnerable to alcohol abuse due to increased stress, peer pressure, change in social environment and curiosity. Medical students, in spite of knowing the ill effects of alcohol continue to abuse it. Higher prevalence of substance abuse was found among medical students than general population by some studies [4]. This is an area of concern since medical students, the future of our health care system is increasingly consuming alcohol and this may have an effect on healthcare system of our country.

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Objectives:

- To study the prevalence of alcohol use disorder (AUD) among medical students.
- To study the initiating factors for alcohol use among study population.

Methodology

Study design- The present study is a prospective observational study done on medical students and internees (House surgeons) of Telangana state government medical colleges with the use of pre-designed, pre-tested web-based AUDIT (Alcohol use disorders identification test) questionnaire with additional variables to determine the initiating factors of alcohol use.

Sampling- convenience sampling is used 270.

Inclusion criteria- All the students from all the medical colleges who consent to participate in the study will be included.

Exclusion criteria- students who are unwilling to participate in the study were excluded.

Approval from the institution will be taken and study is conducted and study will be conducted from May 2019 to July 2019 for a period of 2 months. Google

Forms will be used to create the Questionnaire online and the link to fill the form will be sent via social platforms. The participants will be asked for their consent. Only after they have given the consent, they will be eligible to take part in the study. Their personal data like Name and email id is not taken and the data collected is not revealed so it is anonymous and confidential. The data obtained will be analysed using MS-EXCEL 2016.

Questionnaire- The questionnaire used in the study is AUDIT questionnaire with additional variables. It is a 10- item questionnaire developed by WHO (world health organisation) to assess alcohol consumption and related problems [5]. Each question has a set of responses and each response has a score ranging from 0 to 4. A cut off score 8 will be taken as an indicator of Alcohol use disorder. The questionnaire contains questions related to their recent alcohol use, number of standard drinks, dependence symptoms and alcohol related injuries. Standard drink is a drink containing 10grams of absolute alcohol. That is 330 ml beer, 140ml wine, 40 ml distilled spirits (vodka, gin, rum, whisky) [6]. This will be informed to the participants in the questionnaire. The additional variables include Age, Gender, and Year of study, Age of initiation of alcohol, what made them to have their first drink, if they have any relative with a habit of drinking, weather they stay in hostel or at home. The data obtained will be analysed using MS-EXCEL 2016.

AUDIT (Alcohol use disorders identification test)

Risk level	Score	Intervention
Low risk	0-7	Alcohol education
Medium risk	8 to 15	Simple advice
High risk	16 to 19	Simple advice and continued monitoring
Addiction likely	20-40	Referral to a specialist for further evaluation

Results

TABLE 1:- DISTRIBUTION OF STUDY POPULATION ACCORDING TO YEAR OF STUDY AND SEX

Year	Male (%)	Female (%)	Total (%)
1st MBBS	36 (13.33%)	6 (2.22%)	42 (15.55%)
2nd MBBS	30 (11.11%)	3 (11.48%)	61 (22.59%)
3rd MBBS	55 (20.37%)	82 (30.37%)	137 (50.74%)
4th MBBS	11 (4.07%)	7 (2.59%)	18 (6.66%)
Internship	9 (3.33%)	3 (1.11%)	12 (4.44%)
Total	141 (52.22%)	129 (47.77%)	N=270

In this study total 270 MBBS students were participated in those 141(52.22%) were boys and 129 (47.77%) were girls. Majority study population belongs to 3rd MBBS 137 (50.74%) and less study population from Internship 12 (4.44%).

TABLE 2:-AGE AND SEX WISE DISTRIBUTION OF STUDY POPULATION

Age	Male	Female	Total
17-19	41 (15.18%)	22 (8.14%)	63 (23.33%)
20-22	86 (31.85%)	102 (37.77%)	188 (69.62%)
23-25	14 (5.18%)	5 (1.85%)	19 (7.03%)
Total	141 (52.22%)	129 (47.77%)	N=270

In this study majority study population were in the age group of 20- 22 that is 188 (69.62%) and only 19 (7.03%) from 23-25 age group.

Prevalence:

TABLE 3:- PREVALENCE OF RISK AMONG MALES AND FEMALES

Type of Risk	Male	Female	TOTAL
Low risk	111 (41.1%)	115 (42.59%)	226 (83.71%)
At risk	30 (11.11%)	14 (5.18%)	44 (16.29%)
Total	141 (52.22%)	129 (47.77%)	N=270

Chi-Square=4.6293, P=0.03, CI=95%

In the present study Males 111 (41.1%) are under low risk, 30 (11.11%) are at risk among females 115 (42.59%) are under low risk, 14 (5.18%) are at risk.

TABLE 4:- PREVALENCE OF RISK AMONG MEDICAL STUDENTS

PREVALENCE AMONG 1ST MBBS				
	Males	Females	Chi- Square	P value
At risk	3	0	0	1 (NS)
Low risk	33	6		
PREVALENCE AMONG 2ND MBBS				
	Males	Females	Chi-Square	P value
At risk	4	3	0.0021	0.9632(NS)
Low risk	26	28		
PREVALENCE AMONG 3RD MBBS				
	Males	Females	Chi-Square	P value
At risk	12	8	2.9351	0.0866(NS)
Low risk	43	74		
PREVALENCE AMONG 4TH MBBS				
	Males	Females	Chi-Square	P value
At risk	5	2	0.0486	0.8255(NS)
Low risk	6	5		
PREVALENCE AMONG INTERNS				
	Males	Females	Chi-Square	P value
At risk	6	1	0.1143	0.7353(NS)
Low risk	3	2		

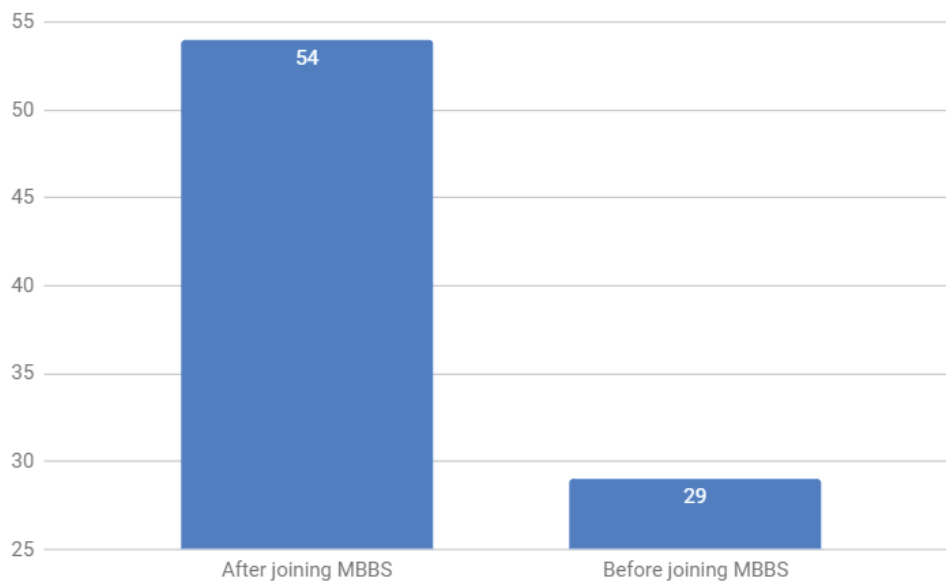
In the present study 3rd MBBS students are at risk when compare to other students in that 12 males are at risk and 8 females are at risk.

TABLE 5:- REASON FOR INITIATION ALCOHOL USE:

Factor	Number of responses
Curiosity	42
Accidental	12
Peer Pressure	9
Stress	6
Relationships	7
Other	7

In this study most common reason for initiation of alcohol is Curiosity (42), followed by Accidental (12), Peer Pressure (9), Stress (6), Relationships (7), Other (7).

TABLE 6:- INITIATION OF ALCOHOL BEFORE OR AFTER MBBS



In this study 54 students initiated alcohol consumption after joining MBBS and 29 students before joining MBBS.

Discussion

Medical students are generally more vulnerable to alcohol abuse because of the sudden change from their normal previous life style and increase in stress factors. several studies have shown that there is an increase of alcohol use among physicians^[7]. The use of alcohol has a potential to affect their careers and patient care. It is revealed that the overall prevalence of alcohol use disorder was 16.3% of which males taking majority

(68.18%). In this study, Majority of participants have said they had their first drink after joining medical college. 25 responders have said that they or someone else has been injured because of their drinking in the past year. 31 responders have said that they were not able to stop drinking once started which indicates they are likely dependant. 17 responders have said that they needed a first drink in the morning after a heavy drinking session which indicates that they are experiencing withdrawal symptoms. The prevalence of this study (16.3%) was

similar to other study conducted in India which showed a prevalence of 16.6%^[8]. overall male prevalence(21.2%) was higher compared to females (10.8%).Even though some studies have indicated a higher prevalence among female medicos, such a trend has not been observed^[9]. This can be attributed to different attitudes, cultures and low sample size.curiosity was found to be the most common initiating factor. majority of subjects have said that they have consumed alcohol at the ages of 16-20, while the legal age for drinking in Telangana is 21.

Conclusion

The overall prevalence was found to be 44 (16.29%). Factors that seem to be enabling initiation of alcohol include male sex, curiosity, background of medical education, staying away from parents and an age group of 16-20 years.

Recommendations:

- Counselling sessions explaining demerits of alcohol use to be conducted to people opting medical career.
- Enforcing strict laws to ban the sale of alcohol to the people below 21 years of age.
- Early identification and rehabilitation of addicted group.
- Moral and psychiatric help and education.
- Faculties of the medical colleges can play a role in counselling students
- Encouraging medical students towards participating in social medicine.

Ethical Clearance- Taken from institutional ethical committee

Source of Funding- Self

Conflict of Interest- Nil

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Is India Ready to Address COVID-19 Like Pandemics: A Perspective From Existing Public Health Acts

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Abstract

Background: There were three influenza pandemics during the 20th century (in 1918, 1957 and 1968) before 2019 the first of which killed at least 40 million people worldwide, exceeding the 8.3 million military deaths during World War I. Novel Coronavirus Outbreak (COVID-19) pandemic was a call for immediate action to be taken on by all countries in terms of stepping up treatment, detection, and reduction of transmission. **Objectives:** To review various existing public health acts in India. **Methodology:** The existing public health acts in the country was reviewed thoroughly from various sources and a summary was formed after review. Feedback about the existing public health acts from experts of different fields was also sought and incorporated into the review and finally components for a model public health act was summarized. **Conclusion:** The Pandemic responses would require strong community engagement using trusted individuals, inter-sectoral collaboration, the involvement of private health care providers, build on existing disease surveillance systems, and link with India's existing crisis management frameworks.

Keywords: COVID-19, Pandemics, Public Health Acts, Lockdown

Introduction

There were three influenza pandemics during the 20th century (in 1918, 1957 and 1968) before 2019 the first of which killed at least 40 million people worldwide, exceeding the 8.3 million military deaths during World War I. ¹ Novel Coronavirus Outbreak (COVID-19) pandemic was a call for immediate action to be taken on by all countries in terms of stepping up treatment, detection, and reduction of transmission. A total of about 2 crores confirmed cases with over 7 lacs 99 thousand deaths reported across the globe. Around more than 2900967 cases and 54948 deaths reported in India as on 20th August 2020. ²

Government of India initiated various Non-Pharmaceutical Intervention (NPI) to break the chain of transmission and prevent the spread of COVID-19, which included social distancing, and restricted public mobility like lockdown. ³ Whenever any such pandemic accelerates, it is factual that health care systems face tremendous workload in terms of a case seeking, testing and care. ⁴ To deal with such situations the country needs a correctly updated framework at national, state and district level which serves as a shield for the community against pandemic India's fight against COVID-19 has been guided by the following legislations:

The epidemic diseases act 1897 (EDA): It is An Act to provide for the better prevention of the spread of Dangerous Epidemic Diseases. ⁵ The 123-year-old act is India's solitary act that provides a framework for containing the spread of various diseases including Plague, cholera and malaria.

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The act describes the Powers of Central Government as “When the Central Government is satisfied that India or any part thereof is visited by, or threatened with, an outbreak of any dangerous epidemic disease and that the ordinary provisions of the law for the time being in force are insufficient to prevent the outbreak of such disease or the spread thereof, the Central Government may take measures and prescribe regulations as necessary.

The EDA has some constraints such as, the act does not define clearly about the nature of the disease if it is dangerous, infectious, or contagious up-to which extent. Also, it does not define the conditions in which a disease can be declared as an epidemic.

Also, the act does not explain the pharmacological (Treatment, drugs, vaccines) and non-pharmacological (Isolation/quarantine measures) interventions for the prevention of the spread of disease.

Preservation of fundamental principles of human

rights during an epidemic is the responsibility of the government which has not been addressed clearly in EDA-1897; instead, it only emphasizes the powers of the central and state governments. The three-tier health structure in India is excellent for primary and routine care and is the need of the country but also at present situation with such independent tiers; it is challenging to tackle the pandemic.

National Disaster Management Act 2005: The Government of India ordained the Disaster Management Act in December 2005, which envisaged the formulation of National Disaster Management Authority (NDMA) and State Disaster Management Authorities (SDMAs). The ministry of home affairs has developed a national disaster management framework. The framework comprehensively covers all aspects of disaster management, including the disaster prevention, legal and policy framework, institutional mechanism, early warning systems, disaster preparedness and human resource development.

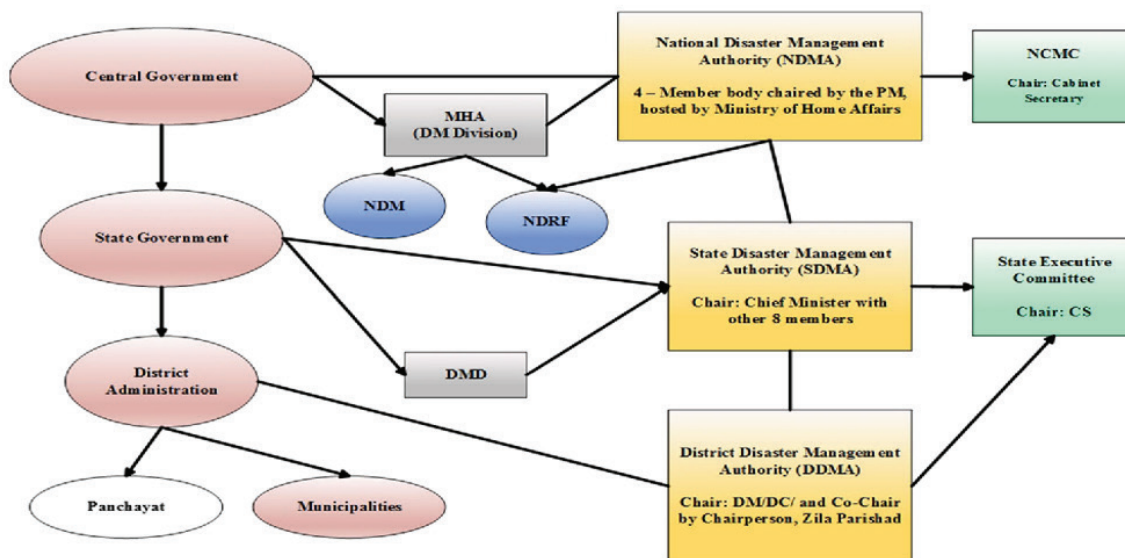


Figure-1: Institutional framework for disaster management in India (Source: *www.ndma.gov.in), MHA- Ministry of Home Affairs, NCMC-National Crisis Management Committee, NDRF-National Disaster Response Force, DMD-Disaster Management Department.

The NDMA framework divides the authority and power among the center, state and district. Each level has its disaster management cell and working committees to tackle the disasters at the local level. Due to the lack of a

stringent public health act, the country still is relying on the NDMA framed in 2005, which is more relevant for disasters other than disease pandemics.

The public health (prevention, control and management of epidemics, bio-terrorism and disasters) bill, 2017 : To provide for the prevention, control and management of epidemics, public health consequences of disasters, acts of bio terrorism or threats thereof and matters connected therewith or incidental thereto.

The Bill had a total of 5 chapters in which the second one deals with the public health measures in emergencies, like Isolation, Quarantine, Medical examination, Ban on the national and international travel and detention of the person/s not following the rules. The bill’s first schedule contains the list of epidemic-prone diseases including Bird flu (Sl.No.2), Influenza (Sl.no. 13), SARS (Sl. No. 27), Public Health Emergency of International Concern (Sl. No. 34), Any other disease to be notified (Sl. No. 35).⁶

The use of already established acts such as Municipal Acts, Clinical Establishment Acts by the state governments in a pandemic situation is not enough to

contain and mitigate the spread of disease. Instead it can be deduced that central public health legislation should be framed, empowering the Central government not the states separately. E.g., while the Delhi Municipal Corporation Act is quite detailed, whereas the Manipur Municipalities Act does not provide guidelines on the actionable measures during an epidemic.⁷

The Epidemic Diseases (Amendment) Ordinance, 2020: It was announced on 22nd April 2020 and mainly includes the violence against healthcare workers.

Public Health act: As a whole, a public health legislation is mainly concerned with the legal power and duties of the state to improve the health of the general population. It also deals with the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary or other legally protected interests of individuals for the protection or promotion of community health.⁸ The scope of public health law is as broad as public health itself, and both have expanded a lot to meet the needs of the society.⁷ The laws related to Prevent Epidemics and disaster Management, and Public Health Problems have been summarized in Table-1.

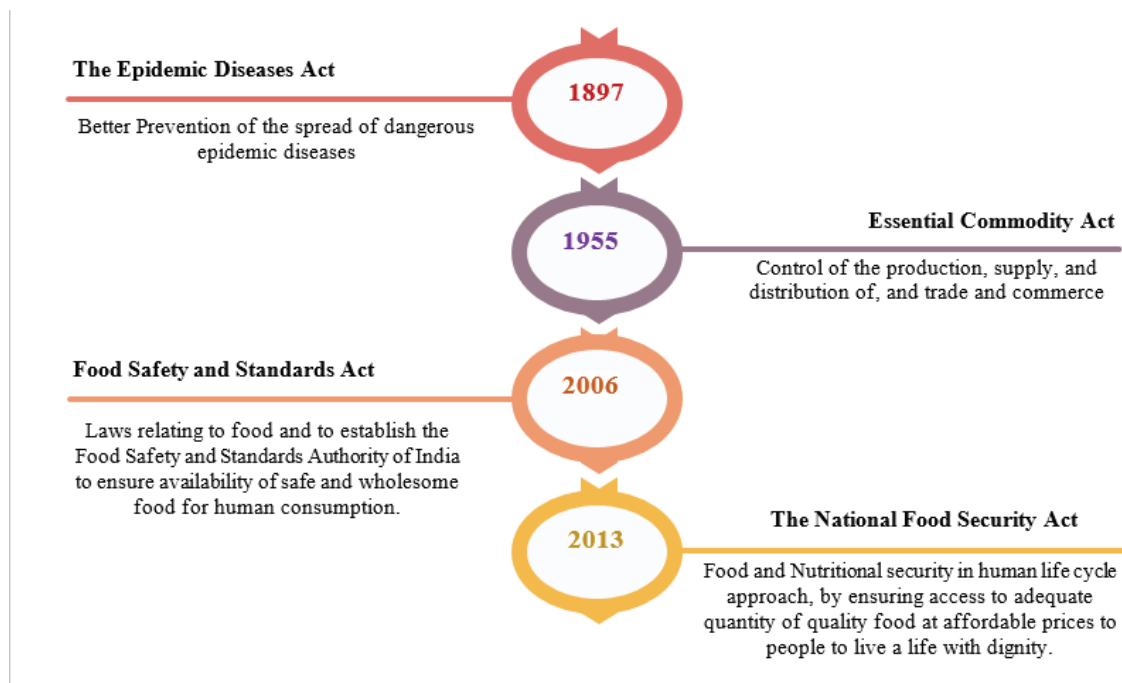


Figure-2: Laws related to Prevent Epidemics and disaster Management, and Public Health Problems.⁹ Preparedness in India:

India is a signatory to WHO's International Health Regulations 2005 and as per IHR 2005, which is a framework for strengthening capacity to detect, assess and respond to public health emergencies.¹⁰ Also on 4th September 2018, India signed the Delhi Declaration which aims in improving access to essential medical products in the South-East Asia region and beyond. It relates to the challenges in providing the right medical products at the right time to those in need and thus reducing the human suffering.¹¹

In December 2019, The Ministry of Health & Family Welfare (MoHFW) and World Health Organization (WHO) jointly hosted a meeting of lead experts from the fields of public health, epidemiology, surveillance, clinical medicine, virology, one health, disaster management, behavioural science, risk communication and defence sector to identify and address challenges that India would face during an influenza pandemic.¹²

In 2009 H1N1 influenza (Swine Flu) the control of the pandemic in India was done by the prompt and effective measures taken up by the Government of India. Isolation, categorization of cases, providing treatment to cases, public awareness, and other appropriate measures were very effective in due course of time. In addition to Govt. labs, several privately owned laboratories were also accredited for H1N1 testing.¹³ Similarly, when Zika virus outbreak occurred in India, Extensive state and national response efforts were implemented by the MoHFW. Suspected cases in the area were tested, including viral sequence analysis, and pregnant women were screened and made aware of Zika virus infection and prevention.¹⁴

Actions are taken by state governments: Many state governments took independent steps to mitigate and contain the spread of COVID-19 at the regional level. These actions were in addition to the guidelines issued by the Ministry of Home Affairs, GOI.

Table 01: Actions are taken by some state governments to prevent the spread of COVID-19 pandemic

State	Actions Taken
Kerala	The Kerala government has implemented an ordinance to give the state government several powers to deal with the coronavirus outbreak, including restrictions on essential services and the introduction of two-year imprisonment based on <i>The Epidemic Diseases Ordinance 2020</i> . ¹⁵
Rajasthan	Following were the measures taken by the Govt. of Rajasthan for control of the pandemic <ul style="list-style-type: none"> ● Industrial lockdown ● Hotels & hostels for quarantine centre ● Screening of 92% population ● Monitoring of quarantine suspects ● Contact tracing ● Aggressive testing
Delhi	The Delhi Epidemic Diseases, COVID-19 regulations, 2020 deals with various measures for the prevention and mitigation of COVID-19 such as screening, Isolation, testing, and treatment. ¹⁶

Cont.. Table 01: Actions are taken by some state governments to prevent the spread of COVID-19 pandemic

Bihar	<p>Under the EDA-1897 (Central Act 3 of 1897) the Govt. of Bihar issued “The Bihar epidemic diseases, COVID-19 Regulation 2020.” Which included¹⁷</p> <ul style="list-style-type: none"> ● Active and passive surveillance. ● Confidentiality of identity of the COVID-19 patients & treating doctors ● Financial assistance to pensioners and medical personnel’s ● Full lockdown in the state according to MHA, GOI guidelines ● District wise quarantine centre, sealing, barring entry, banning vehicles. ● Flu corner at every hospital for the screening of COVID-19 suspects
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A public health Act suitable for a Pandemic situation:

The public health bill, 2017, does not comprehensively talk about the pandemic situation and the available acts such as Municipal Acts, Clinical Establishment Acts, recently the Epidemic Diseases (Amendment) Ordinance, 2020 and individual acts by different state governments in a pandemic situation are not enough to control the spread of disease. In addition to the existing provisions in the public health acts/legislation that we already have, experts from different fields opine that comprehensive Public health legislation at the level of the central government is necessary. Under this act, the role of district hospitals & Public Health Institutions

should be mentioned. The act must talk about training a dedicated set of public health professionals, including field epidemiologists, disease control specialists, and community medicine experts as well. An appropriate measure for mitigation and prevention of the spread of pandemic should be given as an SOP to work together with accountability. Also, the act should commit to encourage and support research and development to cover emerging and reemerging diseases that continue to threaten the nation. There should be a clear-cut guideline for the provision of financial support to be sanctioned during necessary times. The bill should define the responsibilities of Civil Society Organizations (CSOs) also. Figure -2 explains the required Public Health Act with the related domains.

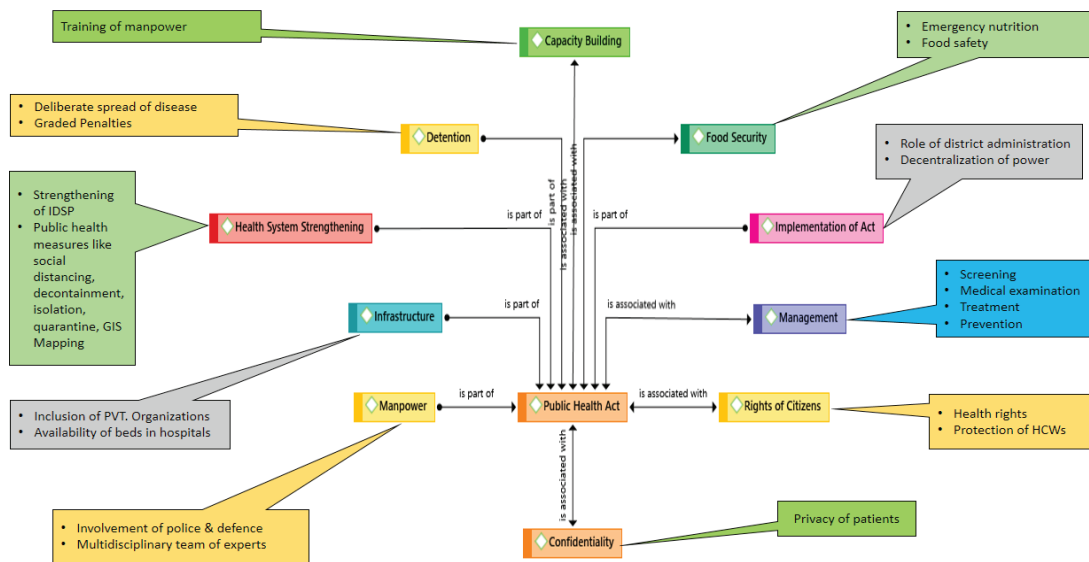


Figure No 03: Components to be included in a Public health Act

Conclusion: India has a rich history of successful public health responses, be it polio eradication or achieving more than 80% of Full immunization in most of the states, India has achieved even the most difficult of visions. The Pandemic responses would require strong community engagement using trusted individuals, inter-sectoral collaboration, the involvement of private health care providers, build on existing disease surveillance systems, and link with India's existing crisis management frameworks.

Thorough preparedness and response planning will help to strengthen the health system capacity of India to adequately respond to public health emergencies in line with the International Health Regulations, IHR (2005). WHO is also committed to continuing its collaboration with the Government of India; supporting the process to develop an updated national pandemic preparedness plan?

Ethical Clearance- Not applicable

Source of Funding- Nil

Conflict of Interest - None

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Covid-19 Crisis: Tackle Through Paradigm Shift Focus from Tertiary Care to Primary Care

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Abstract

To stress upon the primary level of prevention in fighting against the deadly Coronavirus(2019-nCoV) infection rather than tertiary care to increase the survival rate by stopping the spread of the pandemic and also this article describes elements of design of strengthening primary health care that is strengthening the health care delivery at the grass root level so as to decrease the burden of tertiary care in India. A Novel coronavirus (2019-nCoV) identified in Wuhan city of China capable of causing life threatening respiratory illness declared as a pandemic by WHO and has become a global fear among the community and healthcare professionals in 2020. All recent articles were given the priority, though the information on primary prevention focusing on delivering primary health care is in scarcity. An honest attempt to write a narrative review is made. The lack of prevention campaigns led to the increase in the death rate worldwide as the healthcare facility or tertiary care was incapable to handle such pandemic as great infrastructure is required. India is nonetheless different from other countries affected by COVID -19, as it is a developing nation and contributing just 5.3% of GDP to the health sector. Therefore, by strengthening robust primary health care delivery system in India can combat this pandemic.

Key words- covid-19, coronavirus, pandemic, prevention, primary health care

Introduction

Coronaviruses are a group of related viruses that have been known to cause diseases in mammals and humans. In the past, it usually manifested as a respiratory disease in humans ranged from a mild common cold to a fatal infection such as severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS)^{1,2}. An outbreak of viral pneumonia cases of unknown cause was reported by health authorities in Wuhan, the capital

of Hubei province, China on 31 December 2019³. Many of the reported cases mostly had links to the Huanan Seafood Wholesale Market, which also sold live animals; therefore, the virus is believed to have a zoonotic origin⁴. Since then, there has been a steady increase in the burden of COVID-19, with 20.9 million confirmed cases and 7,55,589 deaths globally and 2.4 million confirmed cases and 47,033 deaths reported in India, as of 8th August 2020. With cases emerging from as many as 29 countries, and travel-related importations also being reported, the global health security implications of COVID-19 have come to the fore^{5,6,7,8}. On 11-12 February 2020, WHO, in collaboration with the Global Research Collaboration for Infectious Disease Preparedness and Response (GLOPID-R-an international network of funders to facilitate coordination and information sharing), organized a Global Forum on research and innovation for COVID-19 ('Global Research Forum'). The goals of

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the meeting were two-fold: “To accelerate research that can contribute to containing the spread of this epidemic while integrating innovation fully within each thematic research area” and “To support research priorities in a way that leads to the development of global research platforms, aiding preparedness for the next unforeseen epidemic”⁹.

There is lack of prevention campaigns and is the main problem of concern. Our Indian system gives weightage to a health-care tradition that puts too much emphasis on treatment. The problem with this approach is that it misses important opportunities for risk reduction as it’s a important saying that “Prevention is better than Cure” and has been proved true in this serious pandemic of Covid-19. India is not among the worst-hit countries, but its grossly under-funded and patchy public health system, with huge variations between different states, poses special challenges for the country’s disease containment strategy¹⁰. There is a clear need for prevention of a disease developing in the first place and, once it has developed focus shifts from primary prevention to secondary prevention “early diagnosis and treatment”. “Earlier diagnoses have the potential to produce better treatment outcomes in such pandemic. This review is an attempt to discuss impact of COVID -19 infection spread in the community and how the levels of prevention could be achieved rather than providing treatment to Covid positive cases and thus preventing the daily loss of life years.

Material and Method

A writing search was performed to gather information about articles with respect to COVID-19 and primary prevention. A wide search was performed to cater as many sources so as to not to miss any relevant information. In this manner, no exacting consideration standards were applied. These sources included peer-reviewed literature publications from electronic databases such as PubMed and Google Scholar using the following search terms: “Coronavirus,” or “COVID-19,” or “SARS-CoV-2,” or “2019-nCoV,” separately combined with “prevention”, “primary health”. Exceptional reports and communications from significant bodies such as the Centers for Disease Control and Prevention (CDC), World Health Association (WHO) and significant national health bodies like Ministry of Health and Family

Welfare (MoFHW), National Health and Resource Center(NHSRC) were also referred.

Results

Because of the highly toxic and mutating nature of the disease and scientific evidence available is mainly narrative reviews, expert opinions, small cross-sectional studies. Therefore, recent and peer-reviewed studies were considered. As the evidence is still new and very limited in quality, a narrative synthesis was undertaken to provide a review on the prevention as majority of the data available is on the pathogenesis and treatment. Keeping in mind, the virulence of the virus, the only way to save the planet is through prevention till the vaccination is successfully introduced.

Discussion

COVID-19 is an unprecedented pandemic which has led to millions being affected and thousands dying every day across the world. Initially, the Government of India has announced a 21-day lockdown to prevent COVID-19 transmission in India and later extended till lockdown 4.0, mainly to buy time for health systems to be better prepared. While tertiary care systems are also being prepared it is important to ensure preparedness of Primary Health Centres. Towards this mammoth effort, the Indian medical and public health community is contributing in a big way. As of now however, the rate at which official figures of Covid-19 pandemic are rising, and some case histories seem to strongly indicate that community transmission has begun, In such a situation, the preparedness of government Primary Health Centres (PHCs) will be crucial in terms of their response to prevent the further transmission of COVID-19 with respect to screening of patients with symptoms, and in responding, either with treatment or referral. Investment in primary care is needed to manage the pandemic.

Importance of Primary Health Care

Why a renewal of primary health care (PHC), and why now, more than ever?¹¹ The immediate answer is the palpable demand for it as globalization is putting the social cohesion of many countries under stress, and health systems, as key constituents of the architecture of contemporary societies, are clearly not performing as well as they could and as they should. Few would disagree that health systems need to respond better –

and faster – to the challenges of a changing world and Primary Health Care can do that, therefore, focusing more on the concept from patient-centered care to the concept of community-focused care¹². India is also preparing for the eventuality where many people will be ill enough to require admission. Based on experience from China and Italy, we know that about 5-10 per cent of all infected patients will become severely ill and require admission. However, about 70 per cent of them would require supportive care and oxygen that could be easily managed by PHC's and the remaining 30 per cent might require more advanced critical care such as ventilator support and extracorporeal membrane oxygenation (ECMO).

While the States and the Central government are creating additional capacity in hospitals, there was a large-scale movement of migrants following the sudden lockdown, the disease may spread in rural areas. Rural populations live far from tertiary hospitals and any strategy of testing and management that is based on large hospitals is not likely to be effective or sustainable. In this scenario, the role of personal and community behaviour emerges as extremely critical for managing the pandemic. We know that physical distancing and hand-washing will have significant impact on slowing the spread of the epidemic. And this is propagated through establishing robust primary health care. There is a fear among the public health circles that excessive focus on managing coronavirus is likely to diminish care of people suffering from other health conditions, and result in higher mortality.

Primary health care in India

India has an extensive network of about 25,000 primary health centres and 5,300 community health centres spread across all regions and States. In addition, large numbers of private and non-governmental organisations provide primary healthcare in urban and rural areas. At this juncture, they can play a critical role in managing the epidemic and providing continuity of services.

How to strengthen Primary Health Care in India

An investment in strengthening primary healthcare

at these times will also go a long way in rejuvenating and creating resilient health systems.

Ø Recover at home: More than 90 per cent of all such patients could be managed at households with support of the primary health care providers. Primary healthcare providers can also triage the patients requiring tests or 'visit' the health centres over phone.

Ø Supportive care and oxygen: Standard protocols and oxygen would be essential for such care, and should be provided urgently. Regular availability of oxygen would save many lives from other respiratory or cardiac causes now and later.

Ø Expand detection: Primary healthcare providers can offer sample collection closer to families and communities. Such samples can be transported to the laboratories. It would require immediate training of primary healthcare staff in collecting samples and setting up a system for transportation.

Ø Provide continuity of healthcare: During the epidemic, there are early signs that outpatient and "routine" services are restricted within the public and private sector. Because of the lockdown, there is also a difficulty in accessing healthcare for many patients in rural areas. For those with chronic illnesses, such as tuberculosis, diabetes and hypertension, restricted access to drugs and services could be life-threatening. By the nature of being closer to the communities, PHCs and other primary care providers can significantly ameliorate the situation.

To perform all of the above functions, there is an urgent need for the States to ramp up the primary healthcare systems. It would go a long way in not only managing the epidemic but also strengthening the health systems in the long run and long past the rule has been passed to employ one dental surgeon along with the Medical and Ayush personnel but not implemented in many states eventhough a dental surgeon can contribute to an effective workforce in this pandemic crisis in the nation.

Preparedness within primary healthcare facilities (including PHC and sub-centre)¹³



Figure Adapted from online resources named Covid-19-PHC Action Group,2020.

For strengthening the primary health care delivery system in India to be strong enough to be active against the COVID 19 war, following key points should be considered.

1. Infrastructure, equipment and supplies- a designated hand-washing area/corner for all patients and health workers at the entrance or waiting area of the PHC, separate patient waiting area and consultation room for patients presenting with respiratory complaints and/or fever, hot water should be available for cleaning the health centre as per guidelines, PPE requirement for staff, have adequate stock for essential medicines, stock for hydroxychloroquine as per the ICMR chemoprophylaxis guidelines for health workers caring

for suspected or confirmed cases.¹⁴⁻¹⁷


2. Health Worker Safety- PHC staff should undergo training on modes of transmission, on the use of PPE and common myths/misconceptions about COVID19, PPE use guidelines (including hand washing) been printed and displayed in all relevant rooms at the PHC, the space in and around PHC should be divided into zones based on risk with restriction of outsiders and non-medical staff in the high-risk areas, an important way to assess staff and facility preparedness and training is by conducting mock drills for staff at the PHC and most importantly conducting periodic health-worker wellness and exposure checks of the health worker itself and the families of health workers^{18,19}.

PPE use: At the PHC, the main components of PPE used frequently are surgical masks, N95 masks and gloves. PPE must be worn in hospital depending on the risk of the health worker at that location²⁰

- Low risk areas/staff requiring surgical mask and gloves
 - Drivers of ambulances
 - Visitors accompanying young children (<5) and elderly (>60)
- Moderate risk areas/staff requiring N95 masks and gloves only
 - PHC entry screening area, health workers checking temperature, doctor outpatient chamber
 - Sanitary staff cleaning PHC waiting areas/toilets
 - Handling dead body at PHC
 - Attending emergency cases
- High risk areas/staff requiring full complement of PPE


Caring for the Carers: Promoting Mental Health of Frontline Healthcare Workers of COVID-19

The well-being of frontline healthcare workers may be one of the most essential factors in ensuring quality health care services. For healthcare workers themselves, responding to public health crises such as COVID-19 from the frontline can be rewarding, but it also can be extremely stressful. It becomes doubly important therefore, to pay special attention to their mental health and overall well-being.




Typical sources of stress for healthcare workers treating patients with COVID-19:

- High daily workload
- Feeling under pressure
- Being exposed to scenes of human suffering
- Dealing with difficult emotions like frustration, grief, guilt and fear
- Physical isolation and separation from family members (to be followed even after working hours)
- Constant vigilance and fear regarding possibility of infection (and implications for self and family)
- Inner conflict between duty towards public health and wanting to be with family
- Facing stigma & Discrimination




How can you care for yourself at work?

- Take brief breaks and avoid working long stretches
- Use relaxation exercises during breaks
- Work in teams / partnerships
- Access supervision from mentors and peer support from colleagues
- Discuss and share work experiences with each other
- Focus on what is in your control
- Check unhelpful self-talk such as: "Unless I work round the clock, my contribution won't matter."



How can you care for yourself after work hours?

- Seek social support and connect with family and friends; even if it is virtual
- Schedule time off-work on a daily basis to do something unrelated to it / something that you enjoy
- Maintain a healthy diet
- Make sure you're getting enough sleep
- Limit media exposure / getting constant updates
- Perform regular "self check-ins": monitor yourself for symptoms of burnout / distress such as difficulty sleeping or concentrating, sense of hopelessness, fatigue etc.
- Avoid/limit use of tobacco, alcohol or other drugs.
- Incorporate spiritual practices into your routine if they have been helpful for you



Finally, do not hesitate to seek professional help if you feel that your stress levels have been persistently high or feeling emotionally overwhelmed

Call: 9372048501, 9920241248, 83697 99513
Email: icall@tiss.edu
Chat: Download the nULTA app on your phone
Timings: Mon-Sat 10:00 am to 8:00 pm

Figure Adapted from online resources named Covid-19-PHC Action Group,2020

3. Patient Care²²⁻²⁴- planned and implemented a segregated patient flow based on symptoms at the facility entrance with appropriate signage, displayed screening, treatment and referral flowchart from guidelines for COVID-19 in the screening area and consultation room, printed a list and contact details of COVID-19 testing centres and designated COVID-19 hospitals in your district/neighborhood districts, have a plan for referral of suspected cases and patients presenting with SARI (Severe Acute Respiratory Illness) to the designated testing and/or quarantine facility identified for your

district as per district health authority guidance, have a follow-up plan for people identified at the PHC as being high-risk, have a strategy in place to minimise routine out-patient visits wherever possible, make teleconsultations feasible in your PHC area.

Strategies to minimise routine outpatient visits:
Consider tele-consultation, medicine drop-off at homes or proxy medicine pick-ups by younger or low risk family members for patients on monthly medication, home visits by ASHAs/health workers for chronically ill and antenatal check-ups.

A symptom checklist for COVID-19

S.No.	Symptoms	Yes	No	Remarks With Duration
1	Fever			
2	Cough			
3	Rhinorrhea/Runny Nose			
4	Sore Throat			
5	Body Pain			
6	Loss Of Appetite			
7	Diarrhea			
8	Lost Sense Of Smell			
RED FLAGS				
9	Difficulty Breathing Or Shortness Of Breath After Symptoms Set In			Immediate action
10	Persistent Pain Or Pressure In The Chest			
11	Increased Confusion Or Difficulty In Waking Up			
12	Bluish Lips Or Face			
13	Extreme Fatigue			

High contact risk checklist

S.No.	High Contact Risk Criteria	Yes	No	Within 14 Days Of Contact?
1	Contact with someone in the last 14 days having symptoms of severe respiratory illness/admitted for the same			
2	Caller in close proximity (within 3ft) of a conveyance with a COVID-19 symptomatic person			

3	Contact with someone in the last 14 days having tested positive for COVID-19			
4	Direct physical contact with the person being suspected to have COVID-19 including examining a person without PPE (personal protective equipment)			
5	Touched or cleaned the linen/clothes/dishes of a person suspected to have COVID-19			
6	Touched the body fluids (respiratory secretions, vomit, saliva, urine, feces) of a person with suspected COVID-19			

High Risk Conditions checklist

S. No.	High Risk Conditions Criteria	Yes	No
1	Above the age of 60 or under the age of 5		
2	Malnourishment		
3	Heart disease (such as congenital heart disease, congestive heart failure and coronary artery disease)		
4	Lung disease including asthma or chronic obstructive pulmonary disease (chronic bronchitis or emphysema), tuberculosis, occupational lung diseases like silicosis or other chronic conditions associated with impaired lung function or that require home oxygen		
5	Diabetes Mellitus		
6	Current or recent pregnancy in the last two weeks		
7	Compromised immune system (immunosuppression) (e.g., seeing a doctor for cancer and treatment such as chemotherapy or radiation, received an organ or bone marrow transplant, taking high doses of corticosteroids or other immunosuppressant medications, HIV or AIDS)		
8	Blood disorders (e.g., sickle cell disease or on blood thinners)		
9	On treatment for chronic kidney/liver disease		
10	On treatment for any chronic illness requiring care at home		

4. Biomedical Waste Management And Disinfection^{25,26}- disposal of infected waste (by incineration) as per state bio-medical waste management rules, staff should be fully aware of and complying with the bin colour codes depending on type of waste, PPE removal should be at/near the bin.

Ø Percent sodium hypochlorite solution is recommended. For surfaces that do not tolerate bleach

70% ethanol can be used (phones, computers, keyboards and other electronics).

Ø Instructions for disinfection: ● Spray 1% sodium hypochlorite working solution on all the surfaces (protecting electrical points/appliances).

● Then, clean with a neutral detergent that is used for removing traces of hypochlorite solution.

- While cleaning, windows need to be open .

- All frequently touched areas, such as all accessible surfaces of walls and windows, the toilet bowl and bathroom surfaces need to be carefully cleaned.

- All textiles (e.g. pillow linens, curtains, etc.) should be first treated with 1% hypochlorite spray and then packed and sent to get washed in laundry using a hot-water cycle (90°C) and adding laundry detergent.

- Mattresses / pillows after spraying with 1% hypochlorite should be allowed to get dry (both sides) in bright sunlight for upto 3 hrs each.

- Site of collection of biomedical waste should be regularly disinfected with freshly prepared 1% hypochlorite solution.

5. Health Information, Outreach And Communication- assess communication infrastructure (internet and phone availability) at your facility and your outreach points (sub-centre ANM, ASHA, AWW), the awareness material include a focus on countering possible stigma and discrimination due to quarantine status, contact exposure or test positivity at the PHC and community should be displayed, the state/district COVID-19 helpline number(s) prominently displayed at your PHC entrance and in all posters.

Posters to print and display the health centre

- Common symptoms
- Dos and don'ts
- National and state level helpline numbers
- When to seek medical attention (risk-factors/red flags as indicated above)
- Facility if any for tele-consultation in your PHC/ medicine pick-up
- Any other local information related to COVID

6. Monitoring And Reporting

Regularly Plan for meetings:

- Ø Plan for 30 min-1 hour meetings where at least the following can be discussed.

- Ø Discussing self/team's health status.

- Ø Assess latest information with health workers on disease prevention and transmission

- Ø Consider roster for health workers to limit exposure; provide periodic off-days to ensure health workers are well rested and motivated

- Ø Leadership by PHC medical officer: Health workers may be looking up for clarity of communication and leadership of the PHC medical officer.

- Ø Teamwork: Ensure coordinated response when positive cases are reported so that people or health workers do not panic.

Summary

During times of pandemics, as history tells us, there is a rise in stigmatisation of people; we together along with the government in this need of an hour can practice ways of prevention at individual level and as a primary health care giver so as to fight against the Covid -19 deadly pandemic affecting globally.

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A Study to Assess the Level of Test Anxiety among Senior Secondary School Students in Selected School of Haldwani, Uttarakhand

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Abstract

Introduction: Test anxiety is a combination of physiological over arousal tension and somatic symptoms along with worry, fear of failure and catastrophizing that occur before and during test situation this anxiety creates significant barrier to learning and performance. Researcher suggest that between 25-40% of student experience test anxiety. Directly or indirectly test anxiety affects the academic performance of student . Highly test-anxious score about 12 percentile points below their low anxiety peers. Test anxiety is prevalent amongst the student population of the world. Test anxiety prevalence has been reported as 10-41% in school age children. There are several different estimates for the prevalence of test anxiety with number ranging from 10-30% among high school and university students. The main objective of the study is to assess the level of test anxiety as measured by test anxiety scale among senior secondary school students.

Material and Methods : In the present study quantitative approach with non-experimental, “descriptive study design” was used. The study was done at selected school of Haldwani , Uttarakhand on 110 participants. The participants were selected through the random sampling technique. The researcher used test anxiety scale comprises of 25 statement with 4-point Likert scale, to assess the level of test anxiety among senior secondary school students

Result :The findings of the study show that 72 % of the participants having moderate test anxiety, 28% having severe test anxiety and no participants have mild test anxiety, when measured through the structured tool for assessing the level of test anxiety. And there was one significant association between test anxiety and one selected demographic variable i.e. occupation of father, whereas there is no significant association between other selected demographic variable.

Conclusion : The investigator observed that the level of test anxiety among senior secondary school students in selected school of haldwani, where 28% have severe anxiety and 72% have moderate anxiety.

Keywords: test anxiety, worry, high school students, senior secondary school students, academic performance.

Introduction

Everyone is afraid of something. Perhaps it's public speaking that quickens your heart rate, or walking home alone late at night. We've all felt anxious at one point or another. Yet, having an anxiety disorder is different¹. Teens and college students can easily feel anxious trying to juggle school, work, friends, and family while trying to figure out the rest of your life. Most of us bounce back. But frequent, intense, and uncontrollable anxiety

that interferes with your daily routines may be a sign of an anxiety disorder².

Anxiety disorders occur when anxiety interferes with your daily life, halting your ability to function, and causing an immense amount of stress and fear.³ Anxiety Disorders are one of the most common emotion characterized by an unpleasant state of inner turmoil, often accompanied by nervous behavior such as packing back and forth, somatic complaints.⁴ Anxiety among school going student interfere with social, occupational

and other area of functioning. It can also negatively affect physical health of children. Student can do worry and make themselves sick. Anxiety among school going student interfere with social, occupational and other area of functioning. It can also negatively affect physical health of children. Student can do worry and make themselves sick.⁵

It has been studied formally since the early 1950s beginning with researcher George Mandler and Seymour Sarason , Lrwin G. Sarason then contributed to early investigation of test anxiety clarifying the relationship between the focused effect of test anxiety other focused form of anxiety and generalized anxiety. Researcher suggest that between 25-40% of student experience test anxiety⁶. Student with disabilities and student in gifted education classes tend to experience high rate of test anxiety.⁷ Test anxiety prevalence has been reported as 10-41% in school age children.^{8,9} There are several different estimates for the prevalence of test anxiety with number ranging from 10-30% among high school and university student.¹⁰ Damer and Melendres found that 29.1% of undergraduate university fresher reported feeling heavily burdened by their school demands and this increasingly pressure a student may have an impact on test anxiety.¹¹

This study therefore investigated the relative and combined influences of test anxiety and motivation for examination among selected junior secondary school student.

Statement of the Problem

A study to assess the level of test anxiety among senior secondary school students in selected school of haldwani, uttarakhand.

Objectives

- 1) To assess the level if test anxiety among senior secondary school students
- 2) To find the association between level of test anxiety in selected demographical variable.

Material and Method

In this present study the investigator has selected quantitative approach with non-experimental, “descriptive study design”. The investigator has collected the date after obtaining necessary permission from authority. the participants were informed about the purpose of study and written consent was obtained from the participants.110 participants were selected randomly. Participants who were not studying in class 10th was excluded from the study at the time of data collection. The objective of the study was explained to the school students. The time taken for data collection was 1 day.

Part 1: consist of socio demographic variable

Part 2 : unstructured tool (test anxiety scale)

- The level of test anxiety was measured by assessment of test anxiety scale.
- It was 4-point Likert scale, containing 25 statements, for each statement there was response varying from mild to severe, and the score varying from 1- 4 respectively .
- Total score less than 30 indicate mild test anxiety, score 31 to 60 indicate moderate test anxiety, score more than 61 indicate severe test anxiety.

The study was conducted in May 2019. subsequent with coding the data, it was analysed and interpret accordance with objectives of study.

Table A: showing Percentage distribution of samples according to their demographic characteristics n =110

Sn	Variable	Category	Frequency	Percentage
1.	Age	a) 12 -14	07	6%
2.		b) 14- 16	10	9%
3.		c) 16-18	93	85%
4.		d) Above 18	00	0%

5.	Religion	a)	Hindu	109	99%
6.		b)	Muslim	00	0%
7.		c)	Christian	00	0%
8.		d)	Others	01	1%
9.	Occupation of father	a)	Govt Employee	32	29%
10.		b)	Private employee	50	45%
11.		c)	Businessman	10	9%
12.		d)	Daily wages	13	12%
a.		e)	No job	05	5%
13.	Family income	a)	Less than 5,000	15	14%
14.		b)	5,000- 10,000	26	24%
15.		c)	10,000- 15,000	38	35%
16.		d)	More than 15,000	31	28%
17.	Types of family	a)	Joint family	69	63%
18.		b)	Nuclear family	41	37%
19.		c)	Extended family	08	7%
20.		d)	Others	02	2%
21.	Number of siblings	a)	None	02	2%
22.		b)	One	29	26%
23.		c)	Two	45	41%
24.		d)	More than two	34	31%
25.	Previously Failed	a)	Yes	10	9%
		b)	No	100	91%
26.	Medium of education	a)	Hindi	50	45%
a)		b)	English	60	55%

In view of selected demographic variables revealed that majority of high school students 93(85%) were from the age group 15-16, 109 (99%) was Hindu and the father of majority of students 50(45%) were private employee, family income is more than 15,000 for 38

(34%) of students, majority of 45(41%) students were having two siblings and 100(91%) of students were not having any history of being failed in previous exams and majority of them 60 (55%) were from English medium.

Fig 1: Distribution of participants according to their level of test anxiety n=110

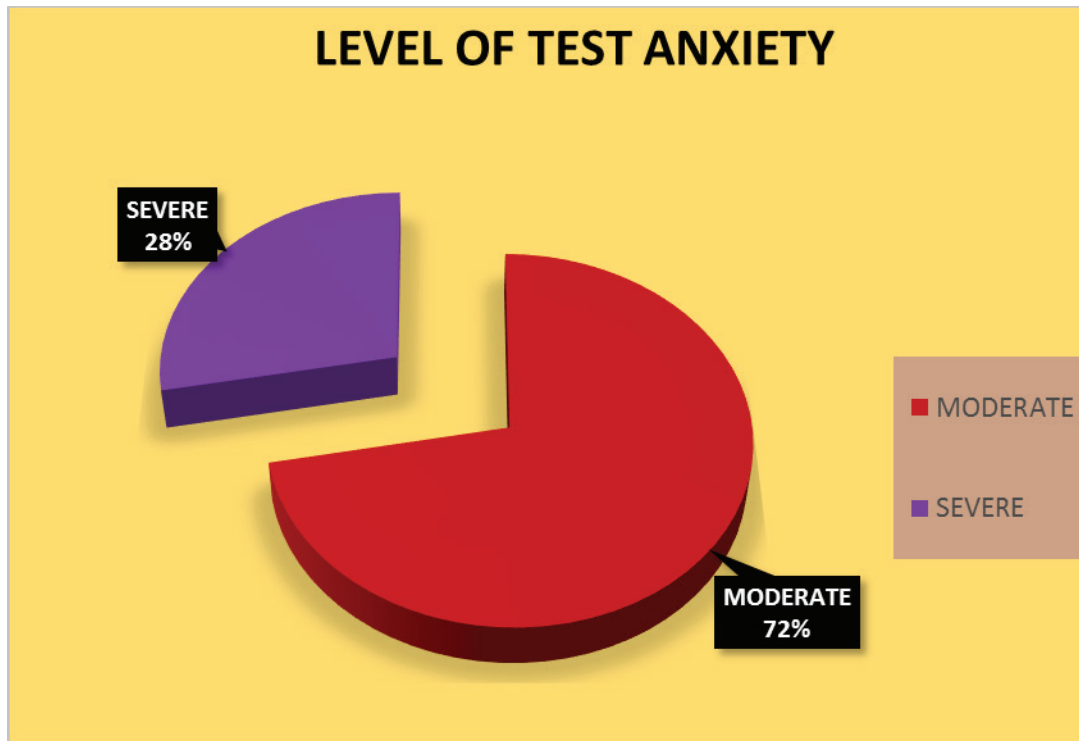


Diagram showing level of test anxiety among senior secondary school students.

above figure represent that majority of school students (72%) has reported moderate test anxiety, whereas rest 28% of the students has severe test anxiety , there was no students report with mild test anxiety.

Discussion

1. To assess the level of test anxiety as measured by test anxiety scale among senior secondary school students.

Based on the responses of the students over test anxiety scale , the level of test anxiety was calculated and categorized according to scores as mild, moderate and severe level. The findings of the study reveal that none of the senior secondary school students reported mild anxiety whereas 72% have reported majority of moderate test anxiety, and 28% were having severe test anxiety.

2. To find association between the level of test anxiety in selected demographical variable.

The association between level of test anxiety was calculated with the help of chi-square test , after calculating all the findings ,the Occupation of father

was significantly associated with level of test anxiety, somewhat similar result was found in a study which was conducted by Palermo (1959) and Durrett (1965) which included of 200 students (100 males and 100 females) studying in class 10 in different schools and their age range between 15 to 16 year. The subject was classified into 2 group in terms of economic status example 100 high and 100 low economic group subjects whose parent’s income was from 2000-10,000 per month and Rs 40,000 and above was placed into the category of low and high. The conclusion was that children of low economic status have a more exam anxiety¹².

Conclusion and Suggestions

The result of the study is suggestive assessment of level of test anxiety among senior secondary school students of Uttarakhand. Data is indicative that test anxiety is a type of anxiety that affects the performance of student. It was concluded that the ability of an individual to appropriately and successfully respond to different anxiety but this anxiety makes students nervous at the main point.

It may be required to give priority to this matter to conduct more studies and evaluate for the level of test anxiety among school students. So that we can improve the mental status of students and make them more confident, powerful and bold.

Conflict of Interest:

Source of Funding – Self Funded

Ethical Clearance: No Ethical Issue

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Existing Knowledge on COVID-19 Pandemic and Hygienic Practice Among South Indians

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Abstract

Introduction: Corona Viruses primarily cause enzootic infections in birds and mammals but, in the last few decades, it is being capable of infecting humans as well. World Health Organization announces newly emerging Corona virus disease 2019 (COVID-19) outbreak is a pandemic and major threats in mortality and economic crisis.

Objectives: To study existing knowledge, hygienic practice, their traditional food habits and cultural activity on the novel COVID-19 is every much essential among the general population to reduce further spread of disease and assimilate the impact for better standards of living.

Methods: A validated and pre-tested questionnaire on knowledge of pandemic COVID-19, hygienic practice, traditional food habits and cultural activities were assessed in 800 participants from both Urban and Rural area which includes aged 18 and above years of both male and female, having school and graduate education.

Results : This cross sectional study showed that average knowledge on COVID-19 was 68% (Mode of Transmission 94%; Affecting organ 79%; Morphology of Virus 33% and Symptoms 65%), 78% showed good Hygienic practice in which only 62% were using handkerchief while coughing and sneezing. An average of 77% consumed traditional foods (using banana leaves 58%; Rasam 80%; food ingredients like Turmeric, Ginger and Garlic 94%, lighting lamp and benzoin resin smoke 88%).

Conclusion: As till date there is no effective prophylaxis for COVID-19, which leads to the spread in an exponential way across the globe, but still in India tropical climate, existing knowledge on mode of the transmission of virus, good hygienics practices among the public as well as sensitized by the Government will combat the spread and death due to COVID-19 virus irrespective of dense population.

Key words: Corona virus; Pandemic; COVID-19, Hygienic Practice, Knowledge

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Introduction

Evolutionary factors that affect a pathogen's ability to infect a novel host. The emergence of human diseases from animal virus by switching hosts from animal to humans and was subsequently transmitted within human populations result in outbreak, mortality and economic

burden. Newly emerging viral diseases are major threats to global public health. The 75% of emerging human infectious diseases are of zoonotic, such that transmitted from animals to humans [1]. World Health Organization (WHO) announces COVID-19 outbreak a pandemic COVID-2019- “CO” stands for “corona”, “VI” for “virus” and “D” for “disease” 2019 – year of outbreak. Corona virus are enveloped single-stranded (SS), positive-sense RNA viruses named after crown-like surface projections seen under electron microscopy. Covid-19 spread fairly through air by coughing and sneezing from infected person through droplet nuclei results in the respiratory tract infection.

Symptoms include fever, tiredness, and dry cough, shortness of breath, breathing difficulties, persistent pain or pressure in the chest and in more severe cases may leads to pneumonia, severe acute respiratory syndrome, kidney failure and even death^[2]. Spreading of infection can be prevented by regular hand washing, covering mouth and nose when coughing and sneezing, thoroughly cooking meat and eggs, avoid close contact with anyone showing symptoms of respiratory illness.

Droplet nuclei transmission is possible for most of the respiratory infections and if microbes are also an airborne pathogen has a potentially huge impact on health status. A large fraction of the world’s illness and death is attributable to poor hygienic, lack of knowledge and awareness on communicable diseases, poor nutritional diets and low immunity. The present study was designed to explore the existing knowledge and hygienic practices related to COVID-19 pandemic, traditional food and cultural actives which states immune status among South Indian Population.

Methodology

The study was carried out during February 2020 in South India (Tamilnadu and Pondicherry which includes 4 Urban (Pondicherry, Chennai, Trichy and Thanjavur) and 4 Rural areas (Villianur, Mannadipet, Thuraiyur and Aranthangi) respectively. Institutional Ethics Committee (IEC/2020/008a) approval was obtained from Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry, India. Over all 800 participants which includes both male and female volunteers, aged in years between 18 to 40 and 41 and above, participated in this study after getting due consent. For data collection,

a closed-ended questionnaire were used and all the data were kept confidentially. Exclusion criteria was those who are not willing to participated and aged less than 17 years in this study. The questionnaire measured includes the sociodemographic data (Name, Age, Gender, Educational Level and habitat), knowledge on COVID-19 (Mode of transmission, Affecting organs, Morphology of Virus, Symptoms of COVID-19); Hygienic practice (Hand wash and using Face cover during coughing and sneezing) and traditional food and culture activities. The possible responses regarding knowledge on COVID-19, each YES answer was given ‘1’ Score and NO was given ‘0’

A pilot study [tested with a group of 50 people both Male(n 32) and Female(n 18)] was done to ensure applicability of the questionnaire and to estimate the time frame needed to complete it. The questionnaire (both in Tamil and English language) was validated by three experts in the microbiology, internal medicine, and biostatistics fields.

Statistical Analysis

Data were expressed in percentage data were categorized as urban and rural population, male and female, aging 18 to 40 and 41 and above, school and graduate for the analysis. For comparisons across the group, Chi-square test was used, for all comparisons $P < 0.05$ was considered statistically significant.

Result

In this study included 800 study participants, after approaching the consenting process and were completed the questionnaire. Overall results showed (Table no.1) that knowledge of COVID 19 was 68%, Hygienic practice 77%, consuming traditional food 77% and traditional activity 75%.

In the present study results (Table no. 2) of urban population (n 400, 50%) had good knowledge on COVID-19 mode of transmission (n 400, 100%) affected organs (n 400, 100%), Morphology of Virus (n 256, 64%), and symptoms of COVID-19 (n 362, 90.5%) significantly higher than rural population (n 400, 50%) knowledge in transmission (n 368, 92%) affected organs (n 232, 58%), Morphology of Virus (n 0, 0%), and symptoms of COVID-19 (n 182, 45.5%).

On Gender wise Knowledge in the study results (Table no. 2) showed male (n 492, 61.5%) were sound knowledge on COVID-19 mode of transmission (n 484, 98.4 %) affected organs (n 426, 86.6 %), Morphology of Virus (n 134, 27.2%), and symptoms of COVID-19 (n 321, 65.2%) significantly more knowledge than female (n 308, 38.5%) regarding mode of transmission (n 284, 92.2 %) affected organs (n 206, 66.9 %), Morphology of Virus (n 122, 39.6 %), and symptoms of COVID-19 (n 223, 72.4 %).

Further, aged (Table no. 2) between 18 to 40 years (n 453, 56.6%) person's knowledge were showed good knowledge of COVID-19 in mode of transmission (n 401, 100 %) affected organs (n 401, 100%) and symptoms of COVID-19 (n 317, 79.1%) significantly more knowledge than above 41 years old person (n 347, 43.4 %) in mode of transmission (n 367, 92 %) affected organs (n 231, 57.9 %), and symptoms of COVID-19 (n 227, 56.9 %), but knowledge in Morphology of Virus, aged 18 to 40 years (n 183, 45.6 %) of person knows less than aged above 41 years (n 73, 18.3 %),

Among population (Table no. 2) who studied up to school (n 578, 72.3%) education had significantly good knowledge in mode of transmission (n 549, 95 %) affected organs (n 413, 71.5 %), and symptoms of COVID-19 (n 336, 58.1%) than who completed graduation (n 222, 27.7 %) mode of transmission (n 219, 98.6 %) affected organs (n 219, 98.6 %), and symptoms of COVID-19 (n 208, 93.7 %). In contrast know of Morphology of Virus (n 130, 58.6 %), in graduate is greater than school completed population Morphology of Virus (n 126, 21.8 %),

The data of hygienic practice of COVID 19 showed in Table No.3. Hand wash practices and using face cover showed significantly higher in urban (n 390, 97.5% & n 347, 86.8 %), male (n 469, 95.3 % & n 264, 53.7 %), aged between 18 to 40 years (n 386, 96.3 % & n 259, 64.6 %) and school (n 530, 91.7 % & n 305, 52.8 %) educated person than the rural (n 362, 90.5 % & n 149, 37.3 %), female (n 283, 91.9 % & n 232, 75.3 %), aged above 41 years (n 366, 91.7 % & n 237, 59.4 %) and graduates (n 222, 100 % & n 191, 86 %) respectively.

Table. No.1. Average Existing Knowledge On Covid-19 Pandemic; Hygienic Practice, Traditional Food and Culture Acitivity Among South Indians

Knowledge on COVID-19	Overall %	Hygienic Practice	Overall %	Traditional Food	Overall %	Traditional activities	Overall %
Mode of Transmission	94	Hand wash with soap or sanitizer	93	Taken food in Banana leaf	58	Using oil lamp	88
Affected organ	79	Using Face cover or Hand kerchief while sneezing & Coughing	61	Food with Rasam	80	Benzoïn resin smoke	62
Morphology of Virus	33			Turmeric, Ginger & Garlic as ingredients in regular foods	94		
Symptoms of COVID-19	65						
Average	68	Average	77	Average	77	Average	75

Table. No. 2. Percentage of Existing Knowledge of Covid-19 Pandemic Among the Urban and Rural, Male and Female, Below and Above 40 years of age, Graduate and School completed South Indians

Charac-teristics	Total, n (%)	Mode of Transmission, n (%)		P	Affected Organs, n (%)		P	Morphology of Virus, n (%)		P	Symptoms of COVID-19, n (%)		P
		YES	NO		YES	NO		YES	NO		YES	NO	
Population													
Urban	400 (50)	400 (100)	0(0)	0.000	400 (100)	0(0)	0.000	256 (64)	144(36)	0.000	362(90.5)	38(9.5)	0.000
Rural	400(50)	368 (92)	32(8)		232(58)	168(42)		0(0)	400 (100)		182(45.5)	218(54.5)	
Gender													
Male	492(61.5)	484(98.4)	8(1.6)	0.000	426(86.6)	66(13.4)	0.000	134(27.2)	358(72.8)	0.000	321(65.2)	171(34.8)	0.035
Female	308(38.5)	284(92.2)	24(7.8)		206(66.9)	102(33.1)		122(39.6)	186(60.4)		223(72.4)	85 (27.6)	
Age group (yrars)													
18 to 40	453(56.6)	401(100)	0(0)	0.000	401(100)	0(0)	0.000	183(45.6)	218(54.4)	0.000	317(79.1)	84(20.9)	0.000
41 and above	347(43.4)	367(92)	32(8)		231(57.9)	168(42.1)		73(18.3)	326(81.7)		227(56.9)	172 (43.1)	
Education													
School	578 (72.3)	549(95)	29(5)	0.018	413(71.5)	165(28.5)	0.000	126(21.8)	452(78.2)	0.000	336(58.1)	242(41.9)	0.000
Graduates	222(27.38)	219(98.6)	3(1.4)		219(98.6)	3(1.4)		130(58.6)	92(41.4)		208(93.7)	14(6.3)	

Table. No. 3. Percentage of Hygienic Practices Among the Urban and Rural, Male and Female, Below and Above 40 years of age, Graduate and School completed South Indians

Characteristics	Hand Wash, n (%)		P value	Using face cover, n (%)		P value
	YES	NO		YES	NO	
Population						
Urban	390(97.5)	10(2.5)	0.000	347(86.8)	53(13.3)	0.000
Rural	362(90.5)	38(9.5)		149(37.3)	251(62.7)	
Gender						
Male	469(95.3)	23(4.7)	0.05	264(53.7)	228(46.3)	0.000
Female	283(91.9)	25(8.1)		232(75.3)	76(24.7)	
Age group (yrars)						
18 to 40	386(96.3)	15(3.7)	0.007	259(64.6)	142(35.4)	0.13
41 and above	366(91.7)	33(8.3)		237(59.4)	162(40.6)	
Education						
School	530(91.7)	48(8.3)	0.000	305(52.8)	273(47.2)	0.000
Graduates	222(100)	0(0)		191(86)	31(14)	

Discussion

Virus is an Acellular, obligate intracellular parasite contains either DNA or RNA nucleic acid bounded in a protein coat called capsid. DNA virus replicate in nucleus while RNA virus replicate in the cytoplasm. The capsid with nucleic acid is known as nucleocapsid, some of the viruses have an extra covering, which is the membranous envelope covering the capsid called enveloped virus^[3]. Single stranded RNA viruses are classified as negative-sense or positive-sense, or ambisense. The positive-sense viral RNA genome can serve as messenger RNA and can be translated into protein immediately in the host cell by which function both as a genome as well as messenger RNA and can directly cause infection^[4].

Emerging new viral diseases are often shift from its original host into a novel species must adapt to successfully infect a novel host like use of different cell surface receptors, to escape the host immune response and successfully replicate and transmitted to the new host. RNA viruses are the most likely group of pathogens to jump between hosts, possibly because of their ability to rapidly adapt to new hosts. RNA viruses have a broad host range being particularly prone to jumping between distantly related species. Lack of proofreading ability in RNA polymerases of RNA virus leads to mutations remain in the newly synthesized RNA is one of the major sources of diversity that allows viral evolution to take place at an unprecedented scale of viral antigenic drift were vaccine are ineffective. Further mediates cell-cell fusion between infected cells and adjacent, uninfected cells. This leads to the formation of giant, multinucleated cells, which allows the virus to spread within an infected organism without being detected or neutralized by virus-specific antibodies^[5]

Mostly Virus gains the ability to spread efficiently within a new host that was not previously exposed or susceptible. This may be achieved by either increased exposure or the gaining of variations that allow them to overcome barriers to infection of the new hosts, in these cases, outbreaks will be the result since that have the ability to spread efficiently between individuals in populations of the new host. Transferring successfully over great phylogenetic distances might be the reason for the novel SS positive sense RNA COVID-19 shift

to human form unknown host believed to be the result of Zoonotic transmission. Following a host shift favours mutations that allow utilising better cellular machinery, enhancing immune avoidance, replication, optimising virulence, and maximising the transmission potential might be the reason for pandemic outbreak. Overall globally 1,099, 960 cases were confirmed with COVID-19 infection in which 59,197 cases from India and death rises to of which 68 from India as on 4th April 2020^[6]. The percentage of death was greater in male gender (2.8%) than female (1.7%) this may be due to respiratory complications because of smoking. Further physically more active by male by which circulatory system cannot keep up with the available oxygen by the muscles. In order to maintain the energy level, muscles shift from aerobic to anaerobic metabolism by which break down of carbohydrates anaerobically to generate energy result in pyruvate metabolic products in the absence of oxygen converted into lactic acid. These modifications of the energy level utilization by the viral infected cells can increase available energy for viral replication^[7].

Most of the enveloped viruses are animal virus origin derived from portions of the infected host cell membranes with some viral glycoproteins which protect from the host immune system on the other hand enveloped viruses are easily destroyed by agents affecting lipids such as alcohols and high temperature^[8]. By which the enveloped COVID-19 are more susceptible to drying and easily destroyed during high temperature. WHO announces novel COVID-19 outbreak a pandemic as it spread in an exponential way but still in India the positive cases was only under limited numbers irrespective of dense population. This may be one of the reasons India's hot tropical climate which is average temperature of 35-45° C in current season.

The key to reducing loss of life, personal injuries, and damage during outbreak of infectious disease is widespread of public awareness and education. Public should need to be aware, in advance, of procedures to follow in a crisis that threatens to paralyze the entire community they serve, and they need to know how to communicate accurate information to combat against the outbreak. In this present study shows higher knowledge and hygienic practice among groups urban, male, aged between 18 to 40 and school education group than the rural, female, aged above 41 years and graduates. In

addition to that south Indian populations are following traditional food habit and also have traditional activity habits regularly.

In the present study knowledge on COVID-19 (Table no. 1) was assessed in which 94% of people aware that mode of transmission through droplet nuclei generated from infected persons and 79% aware which affect the respiratory tract. Regarding morphology of COVID-19 only 33% aware it's an enveloped RNA virus, and 65% of the studied population had knowledge on symptom of COVID-19 infection.

Though urban population showed higher percentage of knowledge on COVID 19 then rural population but still it is believed that less dense population in rural area may reduce the spread of COVID 19 virus. (Table No.2) Poor hygiene practices and inadequate sanitary conditions result in wide spread of communicable diseases. In the present study awareness of hand washing was assessed in which 93% of people are washing hands with soap before taking food and only 61% of people were using Handkerchief while coughing and sneezing warrant further sensitize (Table no.3). South India Greeting culture is by clasp vertically hands in front of the chest without any physical contacts and strictly restricted the footwear's away from the living area also plays an important role in control the transmission of contagious infection.

Many foreigners were wondered that South Indians have great respect for the therapeutic value of food as followed in Siddha and Ayurvedic principles in their everyday eating like served food on a banana leaf, daily intake of Pepper, Tamarid and turmeric powder added as an ingredients in most of the recipe in the South Indian dishes like Pongal, Rasam and Sambar recipes (Table no.1) which showed antiviral property by inhibiting the viral replication [9-11]. The present study showed 77% of the studied population used traditional food. As eating healthy foods not only regulate the immune system but also protect against infection. Further Ginger and garlic added in most of the South Indian recipes also reported to have antiviral property by increase the body temperature [12]. An increase in body temperature has been known since ancient times to be associated with infection and inflammation. Elevated body temperature stimulate more number of CD8 or cytotoxic T-cell" which capable

of destroying the intracellular parasite [13]. In the present study 86% of studied population had ancient style of traditional food (Table No. 1). Traditionally 88% of population use to light oil lamp and 62% of population use Benzoin resin smoke after Sun set which will act as an air purifier, remove moisture content and act as organic disinfectants that drive away insects and many pathogenic microbes of airborne [14].

India is a developing country were most of the Government hospitals are well ventilated and more number of open market (Sandhai) are available around the country. Well-designed natural ventilation systems can often be more effective than air conditioning in promoting effective infection control, by increasing the number of air exchanges [15]. Poorly ventilated buildings affect air quality have higher risks of infectious disease transmission for patients, workers, and visitors might be the reason for high number of COVID-19 positive cases observed in most of the developed countries.

Conclusion

Till date there is no effective line of prophylaxis for COVID 19 at least existing holistic approach in antiviral herbal drugs administered along with modern medicine to prevention intense spread of this virus. In addition overall the Indian climatic condition, good knowledge, traditional culture and food habit may reduce / slow down the spread of pandemic COVID-19 in India by which health care systems has sufficient time to prepare and assimilate the impact for better and healthy standards of living.

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Back Pain and Associated Risk Factors

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Abstract

Background: Musculoskeletal pain is a major health concern that is managed by physiotherapists across the country. Over the past decade, with increased urbanization, advances in technology and an increase in sedentary life styles there has been an advent in risk factors related to the incidence of musculoskeletal problems particularly back and neck pain. In order to better manage and address these problems within the current healthcare delivery system, it is important to objectively determine the spectrum of MS pain, their prevalence and associated lifestyle risk factors in an urban population.

Objective: To determine the prevalence of back and neck pain and its related risk factors in an urban population.

Methodology: A survey questionnaire was used to obtain data regarding prevalence and related risk factors of such pain from the participants.

Results: 46% of the sample reported musculoskeletal pain: low back (36%), neck (35%) followed by, Upper back (13%), arms (7%), legs (7%) and head (2%). Participants living in urban slums reported more pain (58%) than those living in urban areas (44%). Interestingly, pain prevalence was greater in young adults (more than 50%) than the in elderly, and pain was not associated with risk factors, like sleeping surface used, pillow, sleeping position, and medications.

Conclusion: Musculoskeletal pains, predominantly back pain remain a major problem. A poor association between pain and traditional risk factors, such sleeping surface, use of pillow, sleeping position was found.

Keywords: *Musculoskeletal pain, Neck Pain, Back pain, Prevalence, Risk factors*

Introduction

The integrity of the core or spinal musculoskeletal framework allows humans to perform day to day tasks in an efficient and skillful manner. With rapid Urbanization and advancing technology undue stresses are placed on these enabling structures leading to back pain and instability. This is a global health problem with a 75% prevalence of musculoskeletal pain, of which neck and back pain constitutes 37% and 39% respectively.¹ Pain is one of the main reasons for seeking medical attention as it primarily and significantly interferes with activities of daily living, which consequently causes worry, emotional distress and undermines confidence in a person's own health.

The point prevalence of LBP is 28.5% found in Asian countries. The prevalence of back pain in Indian population range from as low as 6.2% to high as 92% depending upon the population under study.¹ More than 100 risk factors for LBP have been identified ranging from individual factors like age, gender, BMI to work related occupational factors to psychosocial, lifestyle and environmental factors like sleep cycle, stress etc. In majority of cases, a combination of individual and work-related as well as non-work-related factors is likely to contribute to the development of such pains.²

Back and neck pain have been suggested to contribute significantly to a lack of sleep. A survey conducted by the National Sleep Foundation found that adults on average sleep for less than seven (7) hours per night, and that there was a decrement in quality of

life, social life and several psychological parameters in people that suffered from a lack of sleep.³ Furthermore, it has also been reported that sleep deficiency resulted in loss of work production, increased sick days, greater absenteeism, loss of productivity and higher injury rates.^{4,5,6,7}

Typically, it is observed that people with back and neck pain report a disturbance in their sleeping patterns, which then sets up a vicious cycle of pain – lack of sleep – more pain. A variety of treatment options are available for such pain, along with advice that ranges from the use of specific mattress, the type of pillow, sleeping position, room temperature etc. Significantly, in a comprehensive survey of orthopedic surgeons, 95% believed that a mattress played an important part in the management of low back pain and 75% recommended firm or hard mattresses for the relief of back pain.⁸ Similarly, patients are advised on the position one should sleep in, the ambient temperature of the room etc.

To compound the problem manufacturers of mattresses make false claims using medical jargon, usually with support from the medical fraternity, to the relative health benefits derived from using selected mattresses. These claims are also largely unsupported and not based on empirical research. Recent studies found that some mattress ads depict how the contour of the bed surface conforms to that of the body. However, the data suggests that there is no reliable evidence that the spinal curvature changes when sleeping on a hard or soft surface.^{9,10} Moreover, others have reported that changes in spinal curvature in the lying position does not concurrently increase or decrease EMG activity, and thus would not impact the level of spinal discomfort.¹⁰

Clinicians generally hypothesize, albeit with limited or no evidence, that different sleeping position and surfaces generate different contact pressure points, and consequently will generate differential stress areas on the body surface and or spine. The three basic sleep positions (supine, side, prone) thus, require unique qualities in the support and softness of mattress to dissipate focused areas of pressure and spinal stress. However, it is observed that typically a person who suffers from pain will adopt a unique sleeping position that is individualistic, and which will minimize the pain and discomfort.^{11, 12}

A review of the literature revealed a paucity of research on the prevalence of back pain and associated risk factors such as sleeping surfaces, positions, etc., particularly in the Indian context. In addition, given the lack of evidence with regards to risk factors that patients and more importantly clinicians associate with back pain, the objectives of this study were to (1) determine the prevalence of back and neck pain in an urban population, and (2) determine the commonly associated risk factors, such as sleeping positions, surfaces, etc. with back and neck pain in an urban population.

Method

Identification and selection of trials

1100 Subjects living in and around Delhi 18 years and older were asked to complete a self-administered questionnaire. The sample was a convenience sample. Subjects residing in the urban slums were recruited as volunteers, while those residing in urban areas were recruited from memberships of resident welfare associations and clinical OPD of Amar jyoti charitable trust.

Subjects who were pregnant, suffered from neurological conditions and or any other diagnosed systemic illness were excluded from the sample.

Data extraction and analysis

Survey Instrument

A questionnaire was developed. Each question was scored on a nominal scale. The following sub-scores were derived:

Prevalence: Prevalence of urinary incontinence was determined by calculating the number of 'yes' on question 7.

Risk factors: Questions 2, 3, 4 and 5 documented the Risk factors associated with spinal pain. In addition, the degree of risk is determined by adding the no of subjects who answered the above questions related to risk factors in the affirmative.

Awareness: Awareness was measured using question 11. This was an indirect measure of awareness to interventions and their use.

Study design- Descriptive study design

Procedure-

The questionnaire was administered by volunteers who were recruited from the community. They were trained in its administration by the principal investigators (PS) in the procedures on how to administer the questionnaire. The volunteers went to their assigned urban slum area and had a one to one interaction with people of the community at their respective homes. They explained the subjects about the survey and instructed the method to fill the questionnaire. In urban areas the Investigator themselves went to administer the questionnaire at various resident welfare areas and societies. The investigator instructed the subjects in the same way as the volunteers did in urban slums.

Ethical clearance- Amar Jyoti Institutional Review board- Ethical Committee.

Results

1) Demographic Data

1100 subjects including 200 from urban slums and 900 from urban areas participated in the study with age range 18-75 years, mean age 36 years.

2) Prevalence

It was observed that 46% of subjects sampled were having spinal pain of which 58% of subjects were living in urban slums, while 44% in urban areas.

It was also observed that the prevalence of spinal pain decreases as the age advances (figure 1).

Insert Figure 1 here

3) Risk for spinal pain-

As seen in figure.2, 3, 4 and 5 it was observed that subjects that the pain and no pain population showed almost similar results.

Insert figure 2 here

Insert figure 3 here

Insert figure 4 here

Insert Figure 5 here

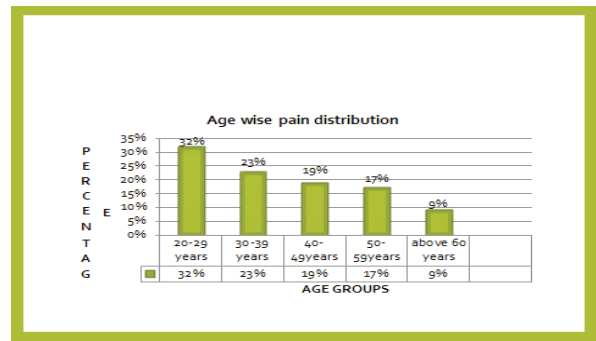


Figure 1: Showing age wise pain distribution

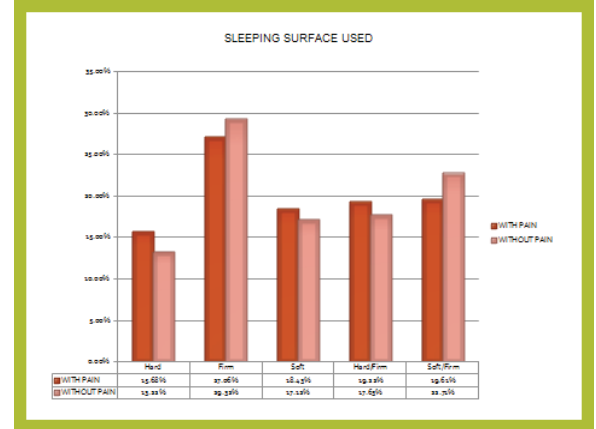


Figure 2: Percentage of sleeping surface used by the population

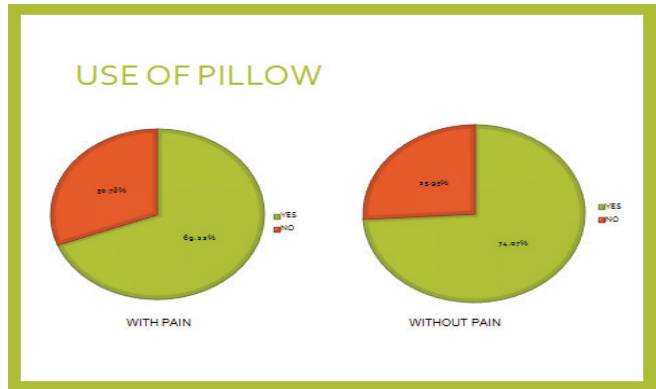


Figure 3: Percentage of pillow use by the population

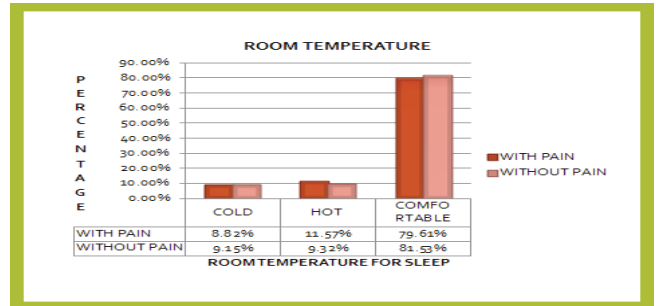


Figure 4: Percentage of room comfort reported by the population

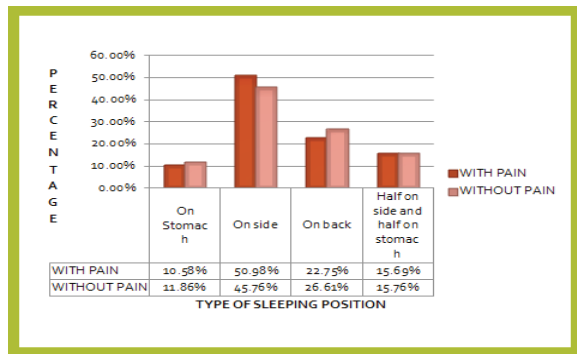


Figure 5: Percentage of sleeping position used by the population

Discussion

The prevalence of musculoskeletal pain in our study was observed to be 54%, which is much higher as compared with the other studies^{13, 14, 15,16}. In all these studies, the prevalence ranged between 15 and 25.9%. However, a study done in the general community in Cuba reported close results with a much higher prevalence of 43.9%.¹⁷

Our study reported almost similar prevalence among both genders with females having pain slightly more than males; however other studies reported that Females are more affected than males.^{14,15,18}

Pain was more prevalent in the urban slums with females more affected than males when compared with urban areas, more than half of the population in urban slums reported presence of pain. Similar results were found in a study by Chopra *et al.* the study reported urban prevalence of musculoskeletal (MSK) disorders. Another study on urban slums by Pingle and Pandit reported Prevalence of Musculoskeletal disorders as 18% with more in females (28.2%) as compared to males (8.1%).¹⁴

Prevalence of pain was seen more amongst young adults as compared to the older people. The reason may be that the younger population is involved more in energy intensive jobs or the ones requiring maintenance of typical postures for prolonged times.¹⁹ but as the age advances the physical stress of work decreases as people tend to settle in more comfortable jobs or retire. It is also speculated that older people also tend to get habituated or accept chronic aches and pains as a part of normal aging, which may be the reason for less reported pain in this age group. However studies report that prevalence increase

till 50 years and then decreases.^{13,14} The latter results were similar to our study as the prevalence decreased in the older age group. Only one study reported that the prevalence increased markedly with age.¹⁸

Our study is first of its kind to report pain in relation to sleeping surface characteristics. Maximum pain was reported with the usage of firm surface; however the interesting part of the result is, population without pain also maximally used the firm surface, suggesting that the firmness can be cause or reliever of pain or might not be related at all.²⁰ Though literature suggests that mattress of medium firmness improves pain and disability among patients with chronic non-specific low back pain. Levy and Hutton cited that in daily practice, physicians are frequently requested to counsel on the characteristics of beds and mattresses to lessen back pain. In a survey of orthopaedic surgeons, 95% believed that mattresses played a part in the management of low-back pain, with 76% recommending a firm mattress.²¹ However, evidence supporting this advice is lacking. The effect of mattress characteristics on low-back pain has been analyzed in a limited number of studies.²²

As, cited in the book “BACK AND BED Ergonomic Aspects of Sleeping” by Bart Haex When sleeping on too firm a mattress the spinal column is supported incorrectly; in the case of a lateral position, only places with a large body width—the shoulders and the hip zone—will be supported. The lumbar region will bend down, especially in people who have a more pronounced contour (e.g., women). In supine position the pelvis will cant forward under the influence of tension in the ilio psoas muscle; after muscle relaxation it cants backward as is the case on soft mattresses. The consequent flattening of the lordosis is less pronounced and more harmful.²³

These results null and void the typical question asked in the clinical assessment about the mattress used. Rather the type of mattress suggested by the clinician should be based on thorough physical assessment.

Though our study did not enquired for the type of pillow, but usage was asked and it was noted that the results were similar for population with and without pain. A similar study asked the respondents about the type of pillow and the usage²⁴. They concluded that ideal pillow should be soft and with good support for the neck

lordosis. A specially selected and individually tested pillow with good shape, comfort and support to the neck lordosis can reduce neck pain and headache and give a better sleep quality. They further reported that the usage is entirely an individualistic decision and does not affect the results.

The results suggested that subjects in the urban slums having pain were not using pillow whereas, subjects in the urban areas as result of affordability and accessibility used pillow. They also reported use of customized pillows. However, the results also indicate that the non-usage and usage of pillow was associated with pain. According to Haex, B, the pillow use depends on the condition of the patient, their neck posture and sleeping position.

This study related sleeping position with pain symptoms and report that maximum population chooses the side lying position for sleeping. These results are similar to study by Gordon *et al.*, which also state maximum usage of side lying position. However the present study reports that the pain population also uses side lying position, on the contrary the study by Gordon *et al* stated that the position not only reduces pain but also improves the sleep quality. Hence, is considered the best sleeping position for minimizing waking symptoms and maximizing sleep quality.

Conclusion

Musculoskeletal pains, predominantly back pain remain a major problem. A poor association between pain and traditional risk factors, such as and its prevalence tends to decrease with age, No association was found between pain and risk factors like sleeping surface, use of pillow, sleeping position etc.

Conflict of Interest: None

Source of Funding: Self

Ethical Clearance: Not Applicable

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Comparison of Bone Turnover Markers on Osteoporosis in Pre and Postmenopausal Women

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Abstract

Osteoporosis, a major public health problem, is becoming increasingly prevalent with the aging of the world population. Rapid bone loss occurs in postmenopausal women due to hormonal factors which lead to increased risk of fractures. Biochemical markers of bone metabolism are used to assess skeletal turnover. Bone formation markers (Total Calcium, Ionised calcium, Alkaline phosphatase), and bone resorption markers (Urinary Hydroxyproline) were analysed in pre and post menopausal women. A cross-sectional study of 200 pre- and post menopausal women was carried out at Sree Balaji Medical College and Hospital, Chennai. Bone formation markers (Total Calcium, Ionised calcium, Alkaline phosphatase), and bone resorption markers (Urinary Hydroxyproline) were analysed in pre and post menopausal women. Bone formation markers, Total and Ionised calcium were significantly decreased ($p < 0.001$) and Alkaline phosphatase was significantly increased ($p < 0.001$) in postmenopausal women compared to premenopausal women. Bone resorption markers, Urinary hydroxyproline excretion was significantly increased ($p < 0.001$) in postmenopausal women. The results from this study suggests that simple, easy, common biochemical markers such as age, years after menopause, urinary hydroxyproline, total serum ALP, total serum calcium and ionized calcium could be used as indicators of increased bone turnover, to enable early intervention so as to minimize fracture due to osteoporotic changes.

Key Words: Osteoporosis, Bone turnover, Alkaline phosphatase, Hydroxyproline, Osteopenia

Introduction

The word 'menopause' is derived from two Greek words, 'meno' (month) and 'pau' (to stop). Clinically, menopause is said to have occurred when menstruation has ceased for twelve months ⁽¹⁾. Physiologically, menopause is defined as the permanent cessation of menses resulting from reduced ovarian hormone

secretion that occurs naturally or is induced by surgery, chemotherapy, or radiation ⁽²⁾. The post-menopausal stage in women is essentially an oestrogen-deficient state ⁽¹⁾. Both menopause and aging are associated with an accelerated loss of bone mass. Menopause occurs when the balance between bone formation and resorption is upset and resorption is excessive, resulting in a negative remodelling balance ⁽³⁾.

Biochemical markers of bone turnover have been shown to provide valuable information for the diagnosis and monitoring of metabolic bone disease ⁽⁴⁾. They reflect the whole body rates of bone resorption (Resorption markers) and bone formation (Formation markers). Therefore they may provide a more representative index of the overall skeletal bone loss than would be obtained by measuring the rates of change in Bone Mineral Density (B.M.D) at specific skeletal sites ⁽⁵⁾. Osteoporosis is

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more common in post-menopausal women and not only gives rise to morbidity but also markedly diminishes the quality of life in this population. There is lack of information regarding the risk factors of osteoporosis in developing countries⁽⁶⁾. The occurrence of Osteoporosis in postmenopausal women is very common problem especially in India who are exposed to many of the risk factors like Family h/o osteoporosis, history of anorexia or bulimia, prolonged amenorrhea, low calcium diet, lack of exercise, Vitamin D deficiency. But there are very few Indian studies regarding the prevalence of osteoporosis in postmenopausal women and also regarding the biochemical markers which indicate bone turnover in our setup.

Osteoporosis is an important public health problem in middle-aged and older women. Until recently, the diagnosis and monitoring of treatment for osteoporosis has been confined to clinical assessment, radiography and bone densitometry. However, in recent years biochemical markers of bone formation and resorption have been developed to quantify bone turnover and remodelling, with possible applications in clinical practice. Osteoporosis is a major health and economic problem. An International consensus development conference has stated that osteoporosis is a systemic skeletal disease characterized by low bone mass and microarchitect deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture. This silently progressing metabolic bone disease is widely prevalent in India, and osteoporotic fractures are a common cause of morbidity and mortality in adult Indian men and women⁽⁷⁾. Osteoporosis has been linked to an increased fracture risk and subsequent mortality in the later life. Previous prediction models have focused on osteoporosis in postmenopausal women; however, a prediction tool for osteopenia is needed. Osteoporosis is a serious global health issue due to the rapid increase in the size of the aging population⁽⁵⁻⁶⁾ Osteoporosis related fractures have been found to be associated with significant costs, increased morbidity and mortality, reduced quality of life, and loss of independence⁽⁵⁻⁶⁾. The prevalence of osteoporosis increases with age for all sites, and by WHO definition up to It is important to think clearly about the 2 principle determinants in adult bone health (a) Maximum attainment of Peak bone mass (PBM) in young adulthood, and (b) the rate of bone loss with

advancing age. With the onset of menopause, rapid bone loss occurs which is believed to average approximately 2% to 3% over the following 5 to 10 yrs, being greatest in the early postmenopausal years⁽⁷⁾. Life time losses may reach 30% to 40% of the peak bone mass in women and 20% to 30% in men. The pathogenesis of postmenopausal osteoporosis involves the interplay of many factors- Nutritional, Environmental, Genetic factors⁽⁸⁾.

Total alkaline phosphatase activity in serum has been used commonly as a biochemical marker of osteoblast function, but lacks specificity because of the contribution of activity derived from the liver, in particular. Human alkaline phosphatases (ALP) are a group of enzymes of similar specificity coded for by at least four different gene loci that catalyse the hydrolysis of phosphate esters at an alkaline pH⁽⁹⁻¹¹⁾. The gene for tissue non-specific ALP encodes the isoenzymes expressed in liver, bone and kidney. In healthy individuals about half the activity of alkaline phosphatase in serum is derived from bone and the remainder from liver. The isoforms differ only in the degree of sialylation and glycosylation, reflected in differences in electrophoretic mobility, heat stability and precipitation by lectin. Methods to separate and quantify bone ALP in the presence of liver ALP, based on these properties, have not had sufficient specificity or sensitivity to be useful clinically. In the USA, the prevalence of osteoporosis in postmenopausal women aged 50 years has been found to be 15.8% in non-Hispanic whites, 7.7% in non Hispanic blacks, and 20.4% in Mexican Americans⁽¹²⁾. Among postmenopausal women, the average bone mineral density (BMD) was found to be highest among African Americans, followed by among Hispanics, native Americans, and Asians⁽¹³⁾. In Taiwan, the prevalence of osteoporosis among women aged 40 years has been estimated at 10.1% and 7.5% based on the BMD of the spine and femoral neck, respectively⁽¹⁴⁾. Despite the availability of diagnostic tools and treatment protocols, osteoporosis remains underdiagnosed and undertreated⁽¹⁵⁾. Women reach peak bone mass between the ages of 20 years and 30 years. Then, BMD decreases gradually and continues to decline rapidly after menopause⁽¹⁶⁾. Therefore, predicting the risk of osteoporosis at an earlier age (e.g., premenopausal) or a preclinical phase (i.e., osteopenia) is crucial for early prevention of osteoporosis.

Osteoporosis is more common in post-menopausal women and not only gives rise to morbidity but also markedly diminishes the quality of life in this population. There is lack of information regarding the risk factors of osteoporosis in developing countries⁽¹⁷⁻¹⁸⁾. Serum alkaline phosphatase (ALP) is the most commonly used biomarker of bone formation. ALP is a ubiquitous enzyme that plays an important role in osteoid formation and bone mineralisation. The serum ALP pool consists of several dimeric isoforms that originate from various tissues, such as the liver, bone, intestine, spleen, kidney, and placenta⁽¹⁹⁻²¹⁾. Thus, the aim of the present study is to evaluate the risk of accelerated bone mass loss by assessing bone markers, such as alkaline phosphatase (ALP) and serum calcium, in post-menopausal women.

Therefore, a tool that includes easily accessible factors may be a plausible approach to predict the risk of osteopenia. Some biomarkers (e.g., blood or urine markers) can easily be obtained during routine health checkups and improve the sensitivity in predicting osteoporosis at the preclinical phase (i.e., osteopenia). However, biomarkers are rarely included in the currently available prediction tools. Therefore, this study aimed to develop a simple and accurate prescreening tool for identifying premenopausal and early postmenopausal women (aged 40-55 years) with a high risk of osteopenia via the incorporation of biomarkers.

Thus, the aim of the present study is carried out to assess the clinical utility of biochemical markers of bone turnover, such as Total Calcium, Ionised calcium, Alkaline phosphatase in pre- and post menopausal women and to evaluate the risk of accelerated bone mass loss by assessing bone markers, such as alkaline phosphatase (ALP) and serum calcium, in post-menopausal women

Material and Methods

We performed a cross-sectional study of 200 pre- and post menopausal women, at Department

of Orthopaedics, *Sree Balaji Medical College and Hospital, Chennai*. The Institutional Ethical Committee approved the study and Informed consent was obtained from each participant in the study. The study group consisted of 100 Postmenopausal women in the age group of 46-65 years and 100 Premenopausal women in the age group of 25-45 years. All the participants were non smokers, non alcoholic and ambulatory. The women were neither pregnant nor on oral contraceptive pills. None of the postmenopausal women had suffered any fracture in the previous 1 year nor were they on Hormone replacement therapy or any other medication that might affect bone turnover. Based on time since menopause, 100 postmenopausal women were categorized into 2 groups. 30 women were in their early postmenopausal period (<5years) and remaining 70 women were in their late postmenopausal period (>5years). Height and Weight of all the participants were noted and Body mass index (BMI) was calculated using the formula = Weight (Kg) / Height² (m).

5 ml of random blood sample was collected in a plain bulb from each participant. Serum was separated immediately by centrifuging at 2000rpm for 15min and analysed for Total calcium, Ionised Calcium and Alkaline phosphatase. Random sample of urine was collected at the same time in a clean plastic bulb and analysed for Hydroxyproline and Creatinine immediately.

Statistical Analysis

The data were presented as Mean \pm SD. Statistical analysis were done by using Microsoft Excel and SPSS for windows version 11.5 (SPSS, Inc., Chicago). P value <0.05 was considered statistically significant.

Results

Table. I. shows the comparison of all the biochemical parameters estimated as their mean values.

Table. I : Comparison of markers of bone turnover in pre- and post Menopausal women (values expressed as mean ± SD)

Parameters	Pre menopausal women(n=100)	Post menopausal women (n=100)
Age	33.32±6.16	57.80±7.93**
Years after Menopause		11.72±7.84
BMI	23.42±4.57	25.68±5.76*
Alkaline phosphatase	2.42±0.56	3.49±1.09**
T.Serum Calcium (m.mol/lit)	2.241±0.25	2.099±0.18**
I. Serum Calcium (m.mol/lit)	1.39±0.24	1.38±0.26**
Urinary Hydroxy Proline (mg /g crt)	10.48±3.28	22.82±10.96**

*p<0.01 (significant), **p<0.001 (highly significant), (mg /g crt=milly grams per grams creatinine)

Table. II : Comparison of markers of bone turnover in Early (<5yrs) and Late (>5 yrs) post menopausal period (values expressed as mean ± SD)

Parameters	Early menopausal Period (n=30)	Post menopausal Period (n=70)
Age	49.9±4.47	59.9±12.4**
Years after Menopause	3.18±1.53	14.93±4.36***
BMI	25.8±4.38	25.73±5.79*
Alkaline phosphatase	3.83±1.16	3.45±1.37*
T.Serum Calcium (m.mol/lit)	2.091±0.17	2.36±0.48**
I. Serum Calcium (m.mol/lit)	1.17±0.14	1.27±0.24*
Urinary Hydroxy Proline (mg /g crt)	25.27±13.78	21.33±14.36*

*(not significant), **p<0.05 , ***p<0.001 (highly significant)

Table. 2. shows the comparison of all the biochemical markers of bone turnover on early and late postmenopausal periods.

Discussion

Current guidelines from the US Preventive Services Task Force recommend that women younger than 65 years be screened for osteoporosis using dual-energy X-ray absorptiometry (DXA) if their 10-year risk of a major osteoporotic fracture is greater than or equal to that of a 65-year-old white woman without additional risk factors ⁽²²⁾. Biochemical parameters can give an idea as to the rates of bone formation and resorption. High rate of bone turnover correlates with a low bone mass. Calcium salts in bone are embedded in collagen fibrils, 13% of which is mainly hydroxyproline. During bone loss, collagen fibrils are broken down and hydroxyproline is thus excreted in the urine. Urinary hydroxyproline(OHPr) is thus considered as an index of bone resorption and a major determinant of bone status ⁽²³⁾. In this study urinary hydroxyproline is expressed as mg of hydroxyproline per gram of creatinine, because creatinine is excreted in the urine in relatively constant amounts proportional to an individual's muscle mass, thus serving as a reference standard ⁽²³⁻²⁴⁾. In the present study there was a significantly increased urinary excretion of hydroxyproline (mg/g Cr) in postmenopausal women when compared to premenopausal women. Other potential uses of turnover markers include the ability to monitor drug efficacy, to predict increases in bone mass, and to assist in the selection of patients for treatment. Bone-turnover markers have little or no use in the diagnosis of osteoporosis, in the prediction of bone mass, and in the ability to monitor compliance.

Menopause is known to be associated with numerous physiological and biochemical changes affecting bone mineral metabolism. The results of various case control studies in pre- and post-menopausal women have shown that changes in the serum calcium levels in post-menopausal women are not statistically significant ⁽²⁵⁻²⁷⁾ ; however, in the present study, we found that the serum calcium levels were significantly reduced in the post-menopausal group ($p < 0.001$) when compared to the pre-menopausal group ($p < 0.0001$) Ashuma et al. reported that aging and menopause lead to a decline in oestrogen and progesterone production, which has been implicated in the increased calcium levels of post-menopausal women ⁽²⁵⁾. The response of markers of bone turnover may inform the physician about patient compliance, absorption of the bisphosphonate and the

effect of treatment. It has been suggested that markers of bone turnover could be used to predict the response of an individual (in terms of BMD) to bisphosphonate therapy. In general, women lose about 1% of their bone density per year during and after menopause. However, nearly 35% of women lose bone at a faster rate during the late perimenopausal period. Biochemical markers can detect women who are considered "rapid losers" that is, those who lose 3% to 5% of bone per year ⁽²⁸⁾.

The most common sources of elevated serum ALP levels are liver and bone. In bone, ALP is present on the cell surface of the osteoblasts and probably cleaved off from the membrane and released into circulation. In healthy individuals, about half of the serum ALP is derived from bone. Therefore, measurement of S-ALP, can be used as a bone turnover marker, but it lacks sensitivity and specificity, especially in conditions where there is only a small increase in bone turnover. Measurement of the bone-specific isoform, S-Bone ALP, has better sensitivity for detecting changes in bone turnover. However, currently available S-Bone ALP assays still have a crossreactivity of 15–20% with the liver isoenzyme. Serum alkaline phosphatase is the most commonly used marker of bone formation. ALP is a ubiquitous enzyme that plays an important role in osteoid formation and mineralization. The total ALP serum pool consists of several dimeric isoforms which originate from various tissues such as liver, bone, intestine, spleen, kidney and placenta. In adults with normal liver function, approximately 50% of the total ALP activity in serum is derived from the liver, whereas 50% arises from bone ⁽¹⁰⁾. In our study the total ALP levels were significantly high in postmenopausal women in comparison to premenopausal women. Bonespecific ALP level is a bone turnover marker that is associated with low BMD and fracture risk ⁽²⁹⁾. A previous Taiwanese study showed that serum total and bone-specific ALP levels slowly increased in women after the age of 40 years ⁽³⁰⁾. These two types of ALP have been found to have a linear association and a high level of correlation among people without bone diseases. ⁽³⁰⁾ Therefore, total ALP serves as a surrogate for bone-specific ALP level. Finally, the number of years since menopause was an important predictor of osteopenia. ALP level reflects the physiological status in the body, which is more sensitive than using weight or age for predicting subtle changes in BMD during the preclinical phase of osteoporosis. a

serum marker, total ALP level, which can be obtained during routine health checkups, significantly increased the sensitivity of the model for osteopenia prediction compared with the existing tools. Early prediction of osteoporosis has important public health and clinical implications, as osteoporosis usually has no symptoms until the occurrence of fractures. Conversely, the serum alkaline phosphatase (ALP) levels were significantly increased in the post-menopausal group compared to the pre-menopausal group ($p < 0.001$). It has also been shown that oestrogen deficiency, as occurs during menopause, induces the synthesis of cytokines by osteoblasts, monocytes, and T cells and thereby stimulates bone resorption by increasing osteoclastic activity. This action results in modification of the reabsorption, excretion, and resorption of calcium, which leads to increased circulating levels of this ion⁽³¹⁻³⁴⁾. Thus, we have reported a negative correlation between serum calcium and ALP levels in post-menopausal women. Several studies have reported no significant correlation between serum calcium levels and ALP when assessing various years since menopause⁽³⁵⁻⁴⁰⁾. However, contrary to these findings, higher levels of calcium and ALP have been demonstrated in early post-menopausal women compared with late menopausal women ($p < 0.001$)⁽³⁴⁾.

The ALP levels were high in women during their early postmenopausal period when compared to late postmenopausal period (Table II). Ionised calcium levels were found to be significantly decreased in Early postmenopausal women compared to late postmenopausal women.(Table II).This shows that the bone mass continues to decline with age but at a slower rate than during the early menopausal time. Annual change in ALP seems to indicate that bone resorption prevails on bone formation in early postmenopausal period. Total calcium and ionized calcium also the markers of bone formation were significantly decreased in postmenopausal women, when compared to premenopausal women.

Preanalytical variability is one of the limitations affecting the clinical interpretation of bone marker measurement. Level of markers are affected by diurnal, menstrual and seasonal variations, food intake, and the level of physical activity. Uncontrollable factors include for example age, gender, menopausal status, recent fracture, bed rest, metabolic bone disease, and renal

function. Bone turnover markers are highest in early morning and lowest in late afternoon and evening. The largest diurnal variation has been reported for urinary collagen crosslinks and crosslinked telopeptides. Serum levels of bone turnover markers are less affected⁽⁴⁰⁾.

The results from this study suggests that simple, easy, common biochemical markers such as age, years after menopause, urinary hydroxyproline, total serum ALP, total serum calcium and ionized calcium could be used as indicators of increased bone turnover, to enable early intervention so as to minimize fracture due to osteoporotic changes. These markers may help identify women at greatest risk for bone loss who would benefit most from therapeutic interventions. To the best of our knowledge, the OPAT is the first tool developed for predicting osteopenia in women aged 40 to 55 years. Integration of a serum marker, total ALP level, Calcium and urinary hydroxyproline which can be obtained during routine health checkups, significantly increased the sensitivity of the model for osteopenia prediction compared with the existing tools. More studies are warranted to validate this new tool for predicting osteopenia risk in women aged 40 to 55 years.

Although bone turnover markers have shown clinically interesting associations, currently available bone turnover markers also have some limitations. They reflect quantitative changes but do not provide information on structural abnormalities of bone or remodeling rate of different bone compartments. Some analytes have high variability or are not bone-specific. Recent progress in the identification of important pathways in bone physiology has led to the development of potential new biochemical markers. These include osteoclastic enzymes, regulators of bone cell activity, non collagenous matrix proteins, or their fragments, and markers of bone matrix properties.

Conclusion

Bone turnover markers, in particular those associated with bone resorption rate, have potential for clinical use in many applications related to skeletal disorders. Guidelines for their use are gradually becoming available. Novel, more specific markers as well as improvement and standardization of measurement techniques will enhance reliability and facilitate the use of bone turnover markers in practice. Therefore, an increase in

bone turnover accelerates bone mass reduction in post-menopausal women, whereas a decrease in bone turnover is associated with the preservation of bone mass.

In normal post-menopausal women, an increase in bone turnover accelerates bone mass reduction. The present study reveals that serum calcium levels are significantly reduced in post-menopausal women, whereas serum ALP levels are significantly increased. In addition, a significant negative correlation was observed between serum calcium and ALP levels in the experimental group. Measurement of bone turnover through urinary hydroxyproline, Alkaline phosphatase and Calcium could form a tool available to assist health care professionals to predict fracture risk. Early prediction of osteoporosis has important public health and clinical implications, as osteoporosis usually has no symptoms until the occurrence of fractures. *The results from this study suggest that simple, easy, common biochemical markers can still be used to assess the bone turnover in postmenopausal women and hence their risk of developing osteoporosis and fractures.* conclude that bone ALP is useful in monitoring alendronate treatment of patients with osteoporosis. It has better clinical utility for following both treatment groups and monitoring individual patients. The biochemical markers of bone turnover provide dynamic measures of bone remodeling and thus potentially useful in predicting the course of changes in bone mass. The inclusion of serum total alkaline phosphatase level in the model, which is easy to obtain from routine health checkups, significantly enhanced the sensitivity for detecting osteopenia in women aged 40 to 55 years.

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Promoting Health Worker Safety; A Priority for Patient Safety during COVID -19 Pandemic and Beyond

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Abstract

Background: As per World Health Organization, health workers accounted for over 1.4 million COVID-19 infections globally. This paper attempts to identify key risk factors for health worker infections in India, describe its impact on their wellbeing and the health systems, and derive lessons from other country experiences, that could be adapted to Indian context for strengthening health workers safety and preparing health systems for future waves.

Methods: A systematic review of existing published articles, government and media reports was undertaken. Online databases -MEDLINE, EMBASE, PUBMED and Google Scholar were searched using key terms related to COVID-19 infections in health workers. Thirty-four papers were included dependent on their relevance to research objectives.

Conclusions: The key risk factors for health workers infection were; unsafe exposure to patients infected with COVID-19, lack of adequate personal protective equipment, and suboptimal infection prevention and control measures and compliance. Health workers infection has impacted their health and psychosocial wellbeing and diminished healthcare system capacity to provide safe and effective healthcare. Safeguarding the health workers is critical, and requires multifaceted approach for strengthening infection prevention and control measures and supplies, strategic workforce planning, dedicated policies and capacity building interventions.

Key Words: COVID-19, Health worker, patient safety, Health system, Infection prevention and control, Psychological wellbeing

Introduction

When theme for the 2020 world patient safety day (17 September) was established as “Health workers safety: A priority for patient safety”, not many realized that it would be so pertinent in the era of Coronavirus Disease of 2019 (COVID-19). The Severe Acute Respiratory Syndrome- Coronavirus-2 (SARS-COV-2) that causes COVID-19 will continue to wreak havoc globally and in India, till the time effective vaccine or treatment is found.

The health workers (HWs) have emerged as the true heroes in battle against COVID-19. However over 1.4 million HW (nearly 10% of all cases) acquired COVID 19 and thousands have died¹. HWs infection and deaths lead to a huge knock-on effect; not only for their own health and psychosocial wellbeing, but also diminishing the health systems capacity to provide safe and effective patient care- both COVID-19 and non-COVID19 related. Therefore, to prevent avertable mortality and sustain an effective COVID-19 response, prevention and management of HW infections and preserving their psychosocial well-being is pivotal.

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In India, nearly 5% of all COVID-19 cases are detected amongst HWs². Given the rapid nationwide rise

in COVID-19 cases, we may soon be heading towards an outstripped health system, as India already grapples with chronic HW shortage. With this backdrop, this paper attempts to identify key risk factors for HW infections in India, describe its impact on HW health and wellbeing, and the health systems at large, and derive lessons and best practices from other country experiences that could be adapted for Indian context for strengthening the health worker safety and preparing health systems for future COVID-19 waves and pandemics

Materials and Methods

A systematic review of existing published and non-published articles and reports was undertaken and the four online databases -MEDLINE, EMBASE, PUBMED and Google Scholar, were searched covering the period after the first COVID-19 case was reported in the world - 1st January 2020 to 1 August 2020. The search strategy used variants and combinations of search terms related to COVID-19, HWs infection, Infection prevention and control (IPC), Health System. The retrieved studies were exported, and duplicate articles were discarded. Studies included could be in any setting, given these were in English language. We also included media articles and government reports that covered the COVID-19 pandemic and response in India in general. We excluded articles if they covered topics that were not relevant to India. We located 1286 articles, of which 66 were related to HWs during COVID-19 response, and of that 34 were considered relevant to this review. The Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR) guidelines was used to write and report the findings.

Findings

Key risk factors of SARS-CoV-2 infections amongst HWs in India

There were limited studies and data on HW infections in the Indian context. Only six articles identified the key reasons for HWs infections with SARS-CoV-2 at work place. The majority HW infections were due to 1) unsafe exposure to patients infected with COVID-19; 2) Lack of adequate of personnel protective equipment (PPE); and 3) suboptimal infection prevention and control (IPC) measures and compliance.

Unsafe exposure of HWs to the COVID-19 infected patients, especially with atypical symptoms or mild flu like symptoms was the most common risk factor³. A case control study of HWs across India, disclosed that the use of PPE was independently associated with the reduction in odds of getting infected with SARS-CoV-2⁴. Inadequate PPE use was mainly due to acute shortage of PPE to protect HWs during pandemic. Nearly 1 million PPE kits and 4.6 million N95 masks were available against the estimated requirement of 38 million masks and 6.2 million PPE kits.⁵ As a result, PPE were available only at 27% sites, N95 masks at 50% sites, and only surgical masks were available at 39 % sites according to a study conducted at 51 primary health centers across India⁶.

Limited knowledge and understanding about IPC measures such as appropriate PPE use particularly correct sequencing of donning and doffing of PPE and rapid triage were important risk factors for HW infections. Surprisingly, suboptimal hand hygiene among HWs was also reported as a vital factor for COVID-19 infection, with compliance rates sometimes dipping below 20%⁷. Lack of access to reliable and adequate alcohol-based hand rub (ABHR) is major challenge at some facilities⁸.

Three predisposing risk factors were identified for HW infections- 1) Workplace, 2) profession, and 3) pre-existing comorbidities. HWs working in certain high-risk departments such as emergency departments, COVID-19 wards, Intensive Care Units (ICUs) and Operation theaters acquired more infections compared to other departments^{9, 10}. Professional groups such as anesthetists, surgeons, and ophthalmologists had higher infection rates compared to other cadres, possibly due to prolonged exposure to infectious patients with high-viral load during aerosol generating procedures¹¹⁻¹³. HWs with pre-existing medical conditions (such as hypertension, diabetes mellitus, cardiovascular disease, chronic lung disease, and immune-compromised conditions)¹⁴. Most commonly affected age group was 26 to 41 years (61%)¹⁵ possibly due to highest proportion of HWs falling in this age group.

It also emerged that the actual number of HWs infected with COVID-19 could be higher than 5% of total COVID-19 cases, but this could not be substantiated due to paucity of available data. Although it also cannot be

ruled out that some HWs also acquire infections in the community rather than the healthcare settings.

Impact of HWs Infections

The COVID-19 infection has a huge impact on the health and psychosocial wellbeing of the HWs, as well as on the already overstretched health system for maintaining the COVID-19 and non COVID-19 related essential health services.

On Health and Psychosocial well being of HWs:

A study conducted at multi-healthcare centers across India, demonstrated that even without lab confirmation, HW's with symptoms resembling COVID-19 such as headache, throat pain, lethargy, fever and breathlessness, reported a higher rate of anxiety, stress, depression, and Post Traumatic Stress Disorder (PTSD)¹⁶. Another cross sectional study from eastern India, revealed that all frontline doctors regardless of specialty had higher stress levels during COVID-19 pandemic, however higher stress was significantly associated with females and unmarried individuals¹⁷.

Other causes that affected psychosocial wellbeing of HWs during pandemic were: fear of infecting their families, lack of PPE, loneliness, lack of support (food, lodging, transportation and childcare needs due to school closures), lack of access to up-to-date information about COVID-19, and growing incidences of harassment, violence and social stigma against them¹⁸. Finally, the anxiety and guilt associated with ethical decisions on prioritization of hospital bed allocation, ICU care - who to admit and who to refuse care, when health systems become overwhelmed limiting the resources¹⁹⁻²¹.

On Health Systems and continuity of safe patient care provision:

The staff shortage due to COVID-19 infections have led to work overload and longer duty hours for the remaining HWs, and thus leading to burnout and making them prone to medical errors putting their own and patient safety at risk. India with its density of physicians (7.8 per 10,000 population) and nurses (21.1 per 10,000 population) is already far below the WHO threshold of 45 HWs per 10,000²². The COVID -19 infections amongst HWs further exacerbated the staff shortages either directly due to HWs being infected themselves, or

having to quarantine being the close contacts of infected HWs, or some HWs just being too afraid to go to work.

The other essential health services too are disrupted especially the outpatient services related to non-communicable diseases (NCD), the antenatal care, TB treatment and immunization clinics have seen significant decline in patient footfall as also the use of clinical services including elective surgeries^{23 24}. This is partly due to reallocation of scarce HW's to COVID-19 care but also because high HW infections instilled a fear of hospitals amongst the patients, which has contributed to delay in care-seeking, that can have longer term health impacts²⁵.

Interventions to strengthen HW safety

The measures to strengthen HW safety are suggested based on the innovations and best practices seen in various countries including India, and as per the WHO guidance²⁶. The proposed interventions for the COVID-19 response and future waves and pandemics are broadly aimed at supporting HW safety and needs at three levels 1) individual, 2) institutional and 3) system wide.

Interventions and tools to support HWs at the 'individual level'

Building capacity and competencies:

Trainings and capacity building in Infection Prevention and Control(IPC) is the most critical intervention that must continue throughout the career. This needs to be followed up with on-job trainings specifically on handling patients with highly infectious disease, appropriate use of PPE, prevention and management of complications and septicemia, and patient safety incidents. Additionally, training on soft skills such as effective communication, teamwork as well as engagement of patients, their families and caregivers is vital²⁷.

The current online training resources on IPC, clinical management including ventilation, and logistics is available on Ministry of health and Family Welfare (MoHW) website, besides the Integrated Government Online Training (iGOT)-Diksha platform, that has been utilized to conduct uniform training to all cadres of HWs across country. Similarly, Online training and webinars

for Physicians and nursing personnel is conducted by AIIMS, New Delhi⁵. However, IPC training must be reinforced for those working on the frontlines of the COVID-19 response, especially among redeployed HCWs with little experience in the clinical management of infectious diseases.

Strengthening infection prevention and control (IPC), including provision and appropriate use of PPE:

The risk of HWs infection can be mitigated by strictly adhering to the most recent IPC guidelines of the MoHFW. Adequate precautions including maintaining physical distance, frequent hand washing or use of hand rub and respiratory etiquette must also be maintained in common spaces outside wards- such as the canteens, staff rooms and resting areas. Within healthcare facility, the appropriate use of PPE including a gown, gloves, facemask, and a face shield or goggles is essential. Adequate availability and access to IPC supplies (such as ABHR, soap, disinfectants, PPE), and preposition IPC supplies at point of entry and patient care also needs strengthening²⁸.

Psychosocial support for HWs:

In India, a dedicated toll-free helpline-08046110007 has been established for providing support to HWs. HWs are encouraged to practice stress management techniques and the training modules are available on MoHFW website. However, engaging psychology departments of universities and providing psychological support and counseling services using digital health tools could further help to address such a crisis²⁹. Additionally, provision of a rest area, care for basic physical needs such as food, group activities for stress reduction, leisure activities, and periodic visits by a counselor could be an option as successfully tried in China. India can consider experiences from African continent, where psychological support from retired nurses and HIV counselors and support among HWs through social media, such as the 'Vula' platform in South Africa or WhatsApp, which may also relieve stress, could provide advice on clinical decision-making, and can also be used to circulate messaging on psychological support³⁰. Visits by politicians, and other public figures and healthcare leaders or managers should to the hospitals to, acknowledge their commitment and Has also been quite successful in boosting HW morale as seen in Italy,

Spain and China³¹

Remuneration and incentives:

The MoHFW guidance mandates timely payment of frontline HWs such as ASHAs, other voluntary HWs and to those requisitioned from outside government sectors; recently lack of timely or adequate payment of HWs was primary cause of strikes³². Maintaining staff motivation may be especially challenging where levels of trust in the health system and in the government are low. Financial remuneration based on duties performed and risk allowances may be used for motivating and retaining HWs, although there might be jealousy, as other staff will continue to care for non-COVID-19 patients and hence miss out on these benefits. Risk allowances were used during the recent Ebola epidemic in Western Africa where the benefits were apparent, but also the jealousies of those not receiving these allowances³⁰.

Interventions at 'Institutional level'

Improve HWs availability through hiring, task shifting and rational distribution;

Recruitment of additional HWs with relevant skills such as HWs that are unemployed or retired, HWs from private sector, research institutes, military health workforce and Red Cross could be deployed on temporary basis. Reassign HWs with risk factors (due to pre-existing co-morbidities, immunosuppression) to non-COVID essential services and in telemedicine, non-COVID-19 outpatient clinics or administrative positions, and skilled and healthy HWs to COVID affected area. Singapore and South Korea deployed HWs from other disciplines and recent medical graduates, as well as China moved HWs to Wuhan from other provinces. Similar practices could be adapted in Indian context³³. Mobilizing existing CHWs and health volunteers is also important strategy utilized by China and could be key information source to dispel myths in the Indian community, but also perform symptom screening and contact tracing³⁴.

Decent working conditions- occupational health and safety, and manageable workload:

Implement triage in the hospitals and infectious-source controls including engineering controls such as adequate ventilation and access to water and sanitation

for health (WASH) services. Display of visual alerts (educational material in vernacular language) for family members and patients can also help reduce infection risk amongst HWs. Providing security that prevents harassment, stigma and violence against HWs including implementation of “Zero Tolerance” law passed by GoI against HWs attackers³⁵.

Providing manageable working hours and blame free environment where HWs have timely access to information on evolving situation, clinical protocols, guidelines and decision to ensure effective implementation³⁶. Provide briefings on rights, roles and responsibilities in context of COVID-19 response³⁷. Telemedicine and remote care such as *e-sanjeevani* OPD, could further help reduce workload as also the infections for HWs³⁸.

Interventions at ‘System wide level’

Strengthening information systems for HWs, including to track HWs infections:

Our study clearly highlights the lack of data regarding HW infections. It is pertinent to strengthen existing information systems for HWs for timely reporting of HW infections and deaths, monitoring and tracking HWs infections and surveillance mechanisms or to identify issues that warrant course correction. This is critical to inform and update COVID-19 response policies or guidelines and rapid decision-making based on evidence..

Licensing and regulatory reforms:

Testing of HWs is being done on priority basis in India. However, there is a need for universal guidelines for testing and reporting of infections in HWs. disability, death, return to work and recognition of COVID-19 infection as a professional exposure disease in certain occupational group.

Regulatory reforms are needed during COVID -19 response, allowing HWs to perform tasks for which they were not licensed despite having competencies and training, redeployment across different employers, public/private sector, geographic region.

Investing in health systems with multisectoral approach:

The government’s ‘*Aatmanirbhar Bharat*’ project to become more self-reliant is likely to augment building lifesaving equipment’s like PPE, ventilators, hospital infrastructure, ICU beds, oxygen supply in hospitals, strengthening of laboratories, hiring of additional human resources which were scarce before pandemic. All this will improve the health care system and facilities in India³⁹. Additionally, working with other sectors and communities to ensure adherence to non-pharmaceutical interventions and public health measures can contain COVID-19 pandemic thus putting less strain on HWs and health systems.

Discussion

The key risk factors for HWs infections at work place were unsafe exposure to infected patients with COVID-19, lack of adequate PPE and, suboptimal IPC measures and compliance. Similar finding were revealed in a multi-country rapid review conducted by Mhango et.al⁴⁰. Our review highlighted exposure to COVID -19 patients especially with atypical presentation as a risk factor, similar finding were observed in Thailand, a patient admitted with dengue fever also had COVID-19 and the treating HW also got infected with COVID-19⁴¹, that warrants full IPC precaution with all patients. Acute shortage of PPE was our review’s major finding, related outcome were also reported in prospective cohort study from UK and USA, where risk of COVID-19 infections were threefold in HWs without PPE in comparison with HW with adequate PPE⁴². Support from International donors may be beneficial, many European nations have received support in terms of human resources and PPE during COVID-19 from government of China. Furthermore, HWs in high risk departments and contaminated aerosol exposure (risk ratio of 13.2) were at greater risk⁴³, our review also presented similar results as risk factor, that necessitates full donning of PPE in these departments and taking adequate precautions while performing aerosol-generating clinical procedures. A review on physician deaths from Covid-19 showed, physicians 57 years and older with preexisting medical conditions accounted for three-quarters of Covid-19-related deaths⁴⁴. In our review most affected age group was 26 to 41 years, however due to dearth of adequate infection and mortality data amongst HWs, we cannot fully corroborate the findings

Lack of complete knowledge about IPC measures, poor hand hygiene and lack of availability of updated IPC guidelines were reported from mainly low income countries⁴⁵⁻⁴⁷. Our review has also showed low knowledge about IPC measures amongst HWs in various facilities across India. Hence continuous IPC training to all cadres of HWs is critical.

HWs infection has impact on their psychosocial wellbeing in our review, Similar conclusion was documented by Lai and colleagues who analyzed 1257 HWs psychological status exposed to COVID-19, where considerable proportion of HWs reported symptoms of depression (50.4%), anxiety (44.6%), insomnia (34.0%) and distress (71.5%) respectively⁴⁸. Support and new innovations in this field is highly recommended because India already have dearth of professionals in this area. HWs infections also stressed health system capacity in our review. Alike concern was also reported from Italy's overstrained health system workforce, Italian physicians have advocated a home based or community-centered care system for Covid-19 to not only decrease the workload on HWs but also reduces the HWs exposure and transmission of disease⁴⁹.

The key Interventions for HWs safety were strengthening IPC measures, improving availability and access to appropriate and adequate PPE, strategic workforce planning, dedicated policies and capacity building interventions as well as a system wide and multi-sectoral approach. Countries such as South Korea, Singapore and Hong Kong have tackled current crisis because of their strong investment in IPC and surveillance and response mechanisms. Surveillance and response measures are often missing in many health settings in India, these countries provide important lessons to invest more in these measures for appropriate response to future waves and pandemics⁵⁰.

Conclusion

The COVID-19 pandemic has highlighted the systemic challenges that compromise HW safety, which in turn has immense impact not only on health and psychosocial wellbeing of HWs but also on the health system's capacity to provide safe and effective patient care. Thus, safeguarding the health and wellbeing of HWs is an immediate and utmost priority that requires multifaceted approach including strengthening Infection

prevention and control, improving availability and access to appropriate and adequate PPE, strategic workforce planning, dedicated policies and capacity building interventions, as well as a system wide and multisectoral approach. It is only then India will be able to prepare a responsive and resilient workforce in face of the COVID-19 pandemic and emerging populations health demands. COVID-19 pandemic has put India's health systems to litmus test, yet has also offered several lessons for future- particularly on importance of building resilient health systems, effective governance, management of human resources for health, investing in infrastructure as well as use of health technology including telemedicine and digital health. While there may be many primacies for the COVID-19 response in India, we strongly urge governments, the private sector, and the general populace to pay concerted attention to HWs safety and wellbeing because "safe health workers are essential for patient safety".

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Development and Validation of Oral Cancer Health Literacy Tool

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Abstract

Introduction: Oral health literacy is vital to the decision making process for screening, prevention and treatment of oral diseases. Although there are several tools available for assessing oral health literacy, there is none to assess oral cancer health literacy. **Aim:** To develop and validate an Oral Cancer Health Literacy Tool (OCHLT).

Materials & Methods: The study was conducted in two phases- tool development and validation among the population. The Delphi method was adopted for content development of the tool. Fifteen experts were selected based on their expertise in the field, years of experience, number of specialties etc. The categories included in the tool were 'word recognition', 'functional health literacy' and 'information methods'. A convenient sample of 140 reporting to the OPD at the Faculty of Dental Sciences, MS. Ramaiah University of Applied Sciences, Bangalore, India were selected. The data thus obtained was assessed for the for reliability, criterion validity and construct validity.

Results: There were positive correlation between OCHLT scores and proxy measures number of years of education, satisfaction with oral health status and absence of tobacco related habits ($p=0.001$). The intra-class correlation coefficient of OCHLT was 0.849 and the Cronbach's α was 0.79. This resulted in a tool consisting of 32 items.

Conclusion: The final tool accounts for the multi- dimensionality of oral cancer health literacy showing acceptable psychometric properties.

Key-words: Health literacy, Delphi, Oral cancer

Introduction

Diseases and pathological conditions related to the oral cavity are among the most prevalent health problems witnessed in populations across the globe. Apart from being the target site for a range of highly prevalent oral diseases, the oral cavity also plays a vital role in an individual's general health, being the primary

gateway through which foreign matter can enter the human body. Consequentially, maintaining the health of the oral cavity becomes a crucial need that, in turn, is dependent on the degree of the individual's awareness about oral health. Oral health literacy (OHL) can hence be defined as the 'degree of an individual's capacity to obtain, process and understand basic oral health information and services needed to make appropriate health decisions' [1-3]. This ability to access and leverage oral health-related information and services serves as the most reliable indicator of oral health levels, since a high degree of OHL would correspond to a higher likelihood of good oral health being maintained. Being able to measure such an important indicator, therefore, would

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prove to be extremely valuable in assessing overall oral health levels of a given population.

There have been several methods and techniques proposed to measure the OHL levels of individuals as well as that of populations. The most reliable of them, till date, are oral health instruments/tools, which attribute quantitative values to oral health awareness levels of the respondents. A number of such tools, after conducting several studies on various populations, have been developed so far. The most widely used of them all is the Rapid Estimate of Adult Literacy in Dentistry (REALD-99) [4]; of which several variants have been subsequently developed. Other popular tools such as the Test of Functional Health Literacy in Dentistry (ToFHLiD) [5]; the Comprehensive Measure of Oral Health Knowledge (CMOHK) [6] and the Health Literacy in Dentistry (HeLD) scale [7] have also been greatly successful.

Arriving at an estimate of the respondents' OHL levels using these tools, however, depends upon testing their word recognition abilities and reading skills. In this regard, only a few tools have been developed till date that provide a comprehensive and comparable view of the respondents' overall level of oral health awareness.

Furthermore, there is a dire need for disease-specific oral health literacy assessment tools, as incorporating parameters that are based on disease-specific salient features in to a tool improves the level of its accuracy and provides better insights regarding the population.

Oral cancer is a substantial component of the global burden of cancer [8]. It affects 300,000 people worldwide annually, who constitute 2.1% of the total world population, with two-thirds of the occurrence being seen in men [9]. In India, it ranks amongst the three most common cancers and accounts for almost 40% of total cancer deaths in some areas. In most regions of the country, oral cancer is the second most common malignancy diagnosed in men and the fourth most common in women [10]. As a lack of health literacy is a potentially significant factor contributing to oral cancer among these people, it needs to be further explored. The present study, hence, was conducted to develop and validate an oral cancer literacy tool that detects and assesses poor health literacy.

Methods

Instrument Development

The Delphi method, consisting of three rounds, was used to develop the tool. The expert panel consisted of 15 members: four oral surgeons, three oral medicine specialists, four oral pathologists, two oncologists and two public health dentists. The selection of the members of the expert panel was based on their knowledge and expertise with respect to the study subject, i.e., oral cancer.

The first round began with a thorough literature search to evaluate existing data about oral cancer. An open-ended questionnaire was designed to solicit the experts for specific information related to oral cancer. Along with their responses, various oral cancer health educational materials and text types were used for generating the items. Following the first round, the tool was developed in three levels and the number of items in each level was:

1. Word recognition- 27 items
2. Functional health literacy- 6 items
3. Information methods- 5 items

The next two rounds constituted the quantitative phase, where the experts rated each item on a Likert scale to assess the level of agreement on them. In the third round, all items obtained an agreement mean value of more than 3 and the final tool thus developed, consisting of 37 items, was assessed for psychometric properties.

Participant Selection

The tool was tested on a convenience sample population reporting to the OPD at the institute. The study was conducted between May 2016 and August 2017, and was approved by the Institute's Ethics Committee. The participants included those who were aged 18 years or older and could read and write in English. A total of 140 participants took part in the study. The participants were asked to provide following details their demographic details, including sex, age, years of education, contact details, satisfaction with oral health status, tobacco-related habit and filled OCHLT. The duration for filling the tool ranged from 20 to 25 minutes. Two weeks later, 15 of the participants were contacted for a retest.

Assessment of Psychometric Properties

Content validity. The panel of experts responded to the following question for each item: “Is the skill or knowledge measured by this item ‘essential’, ‘useful, but not essential,’ or ‘not necessary’ to the performance of the construct?”, following which the Content Validity Ratio was evaluated as proposed by Lawshe^[11–13]. Five of the items had a value less than 0.49, and were hence eliminated. Upon completion of the content validation, the final OCHLT included 32 items.

Construct validity. Principal factor analysis was used to evaluate the construct validity. The Kaiser-Meyer-Olkin Measure of Sampling Adequacy determined that the patterns of the correlations are relatively compact and so factor analysis will extract distinct and reliable factors. The value of greater than 0.5 is considered as good^[14]. Bartlett’s Test of Sphericity tests that null hypothesis that original correlation matrix is an identity matrix. Here, it demonstrated that the correlation matrix ($p < 0.001$). An Eigen value greater than 1 was used as the criterion for factor inclusion, representing the variance accounted for by each underlying factor. As for the rotation, the method used was Direct oblimin^[15–17].

Criterion validity. It pertains to the evidence of a relationship between the attributes in a measurement tool with respect to its performance on some other variable that accurately measures the same phenomenon of interest^[13]. Due to the lack of a gold standard for measuring oral cancer health literacy, subjective proxy measures were used to measure the criterion validity.

Data for subjective proxy measures on the years of education, satisfaction with oral health status and tobacco-related habit status were obtained.

Reliability. Cronbach’s α (alpha) was used to measure the internal consistency (reliability) of the tool. Test-retest reliability was evaluated by means of intra-class correlation coefficient, using the data collected from the 15 participants.

Data were coded and analyzed using the Statistical Program for Social Sciences (SPSS) version 20.0 software.

Results

Content validity of OCHLT using Lawshe’s method

According to the content validity ratio (Lawshe’s method 1975); the minimum value of 0.49 was considered for the 15 panellists. Another five items from Level 1 — items numbered 1.5, 1.22, 1.23, 1.24 and 1.25 — had value less than 0.49 and, hence, were eliminated. Consequently, the final OCHLT comprised 32 items. Care was taken to include positively and negatively worded questions in the OCHLT to discourage respondent acquiescence.

Internal reliability and Test retest reliability of OCHLT

The Cronbach’s alpha value of the OCHLT was 0.849. The Cronbach’s alpha did not depict a significant increase upon deleting any of the items. All items were therefore retained.

Test-retest reliability was assessed using intra-class coefficient (ranged from 0.4 to 1.0), which resulted in an overall correlation of 0.79.

Criterion validity

There were statistically significant associations between the OCHLT scores and three of the proxy measures, with the former being directly associated with the number of years of education ($p = 0.001$), satisfaction with oral health status ($p = 0.001$) and absence of tobacco-related habits ($p = 0.001$). The proxy measures with respect to the predictor and criterion variables were correlated and the strength of this positive correlation substantially supports the extent to which the instrument accurately estimates performance on each criterion.

Table 1: Pearson’s correlation of OCHLT with years of education, satisfaction with oral health status and absence of tobacco related habits

Proxy measure	r	P value
Years of education	0.262	0.001
Satisfaction with oral health status	0.399	0.001
Absence of tobacco related habits	0.516	0.001
Note: Pearson Correlation was used (p<0.05- significant)		

Construct validity

Construct validity was evaluated using Principal Component Analysis. Assumptions in the correlation matrix were confirmed prior to the analysis. Table 2 demonstrates that Factor analysis of the 32 items yielded nine factors with Eigen values greater than 1 (9.151, 2.236, 2.048, 1.602, 1.394, 1.335, 1.230, 1.208 and 1.005), which explained 66.273% of the variance (28.596%, 6.987%, 6.399%, 5.005%, 4.357%, 4.172%, 3.842%, 3.775% and 3.141%, respectively). A rotated solution was then arrived at to simplify their interpretation, for which only those loading factors higher than 0.4 were considered as significant, based on the requirements of sample size.

Table 2: Item factor analysis results

Rotated loadings from the seven factor solution									
	1	2	3	4	5	6	7	8	9
Level 1.1	.872								
Level 1.2	.800								
Level 1.3	.889								
Level 1.4	.772								
Level 1.5		.527							
Level 1.6	.831								
Level 1.7		.832							
Level 1.8				.839					
Level 1.9	.598								
Level 1.10				.637					
Level 1.11								.680	
Level 1.12	.678								
Level 1.13		.413						.374	
Level 1.14	.595								
Level 1.15	.613								
Level 1.16	.853								
Level 1.17								.531	
Level 1.18								.806	
Level 1.19		.443						.516	
Level 1.20	.837								
Level 1.21						.502			

Cont.. Table 2: Item factor analysis results

Level 2.1					-.804				
Level 2.2			.666						
Level 2.3			.733						
Level 2.4			.530						
Level 2.5					-.388				
Level 2.6					.452			-.414	
Level 3.1							.757		
Level 3.2		.421							.522
Level 3.3							.601		
Level 3.4								-.815	
Level 3.5									.828

Note: Kaiser-Meyer-Olkin Measure of Sampling Adequacy- 0.858
Bartlett's Test of Sphericity tests- 0.001
Rotation Method: Oblimin

Annexure- Oral Cancer Health Literacy Tool (OCHLT)

Level 1- Word recognition			
If you are able to read and understand the following given words, kindly tick 'Yes' in front of each word or else tick 'No'.			
1. Smoking	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
2. Habit	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
3. Cigarette	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
4. Beedi	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
5. Betel nut	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
6. Tobacco	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
7. Betel quid	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
8. Spicy food	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
9. Alcohol	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
10. Sharp teeth	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
11. ill- fitting denture	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
12. Risk factors	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
13. Palate	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
14. Mouth	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
15. Ulcer	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
16. Swelling	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
17. Lump	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
18. Hoarse voice	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
19. Lymph nodes	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
20. Surgery	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
21. Chemotherapy	Yes	<input type="checkbox"/>	No <input type="checkbox"/>

	<p>Level 2- Functional health literacy</p> <p>Kindly read the following questions and tick the correct option given.</p>
1.	<p>“Green leafy vegetables and fruits are good for preventing oral cancer.”</p> <p>After reading the above sentence, answer the following question. Which one of the following is the best food to prevent oral cancer?</p> <p>1. Greens and apple <input type="checkbox"/></p> <p>2. Chocolate and ice cream <input type="checkbox"/></p> <p>3. Spicy curry <input type="checkbox"/></p>
2.	<p>If you observe an ulcer in your mouth that does not heal for more than 2 weeks, what you should do?</p> <p>1. Wait for it to heal <input type="checkbox"/></p> <p>2. Immediately consult the Dentist <input type="checkbox"/></p> <p>3. Buy over- the- counter medication and take it <input type="checkbox"/></p>

3.	<p>Blood report</p> <p>The normal range for haemoglobin for a female is 12.0 to 15.5 g/dl. Jaya’s haemoglobin is 9.7 g/dl. Is Jaya within the normal range?</p> <p>1. Yes <input type="checkbox"/></p> <p>2. No <input type="checkbox"/></p>
4.	<p>Patient’s name: Ramesh</p> <p>Age/Sex: 35/M</p> <p>Date: 20/09/2017</p> <p>R_x</p> <p>Tab. Lycopene (anti-oxidant) for 3 weeks (0-0-1) × 20 days</p> <p>Doctor</p> <p>Ramesh has to take medicine at what time of the day?</p> <p>1. Morning <input type="checkbox"/></p> <p>2. Afternoon <input type="checkbox"/></p> <p>3. Night <input type="checkbox"/></p>
5.	<p>A tumour biopsy is done to:</p> <p>1. Diagnose it <input type="checkbox"/></p> <p>2. Treat it <input type="checkbox"/></p> <p>3. Both <input type="checkbox"/></p>
6.	<p>Chemotherapy is given to oral cancer patients to</p> <p>1. Remove it <input type="checkbox"/></p> <p>2. Diagnose it <input type="checkbox"/></p> <p>3. Treat it <input type="checkbox"/></p>

Level 3- Information methods Kindly read the following questions and tick the correct option given.	
1.	Do you think TV, radio, newspapers are giving enough information about the effects of tobacco on oral health? 1. Yes <input type="checkbox"/> 2. No <input type="checkbox"/>
2.	Do you face any difficulty in understanding the information about oral cancer provided by Doctors in hospitals/ clinics? 1. Yes <input type="checkbox"/> 2. No <input type="checkbox"/>
3.	Do you think there are sufficient oral- cancer related patient education materials in regional languages in hospitals that you have been visiting? 1. Yes <input type="checkbox"/> 2. No <input type="checkbox"/>
4.	Do you fill your medical forms on your own? 1. Yes <input type="checkbox"/> 2. No <input type="checkbox"/>
5.	Do you take help from others to understand your medical prescriptions? 1. Yes <input type="checkbox"/> 2. No <input type="checkbox"/>

Discussion

The objective of this study was to develop and validate a new instrument to measure oral cancer health literacy for adults, and to complement other functional oral health literacy instruments that are currently available. In the OCHLT, items appropriate for studying oral cancer were generated using the Delphi method^[18]. One of the major advantages of the Delphi method is that all the experts had the same degree of impact on the consensus process and helped to ensure the validity of the study. The expert panel in the present study, although comprising participants with different fields of expertise, were treated as a homogenous group. In this respect, expert knowledge representing a variety of viewpoints can provide relevant inputs in the Delphi process, this can also help in minimising bias.

The OCHLT was modelled on a previously validated medical instrument which was developed to measure cancer health literacy among patients.^[19] The study also used a Delphi Panel to discuss domains of health literacy to develop a psychometrically sound

instrument designed to measure cancer health literacy along a continuum (CHLT-30). In China, Chinese-specific tool for paediatric nurses to assess risk of infection in oncology patients was developed using Delphi method. The authors in the study mention that the high response rate could be due to the authors' ongoing communication regarding the importance of each participant's contribution, continual reminders and a limit set at three rounds. It also reflects the experts' understanding of the importance of the study^[20].

OCHLT displayed high internal consistency with a value of 0.849 indicating how well the items on a tool fit together conceptually. A coefficient alpha of 0.70 is acceptable for new scales^[13]. Test retest reliability was evaluated after 2 weeks as it is the generally accepted time interval for retesting with intra class correlation value of 0.79. Similarly CHLT-30 also showed Cronbach's alpha internal consistency reliability of 0.88 and 2-week test-retest reliability of 0.90, and 6-month test-retest reliability of 0.92, all of which are indicative of a highly consistent measure of cancer health literacy^[19].

In recognition of the importance of oral health literacy, the measurement of health literacy has been an area of growing research. Various types of instruments have been developed to measure oral health literacy to direct test individual's oral health literacy abilities and self-report of oral health literacy abilities. But there are no oral disease specific tools.

Considering, oral cancer as a threat, it is estimated that around 43% of cancer deaths. Low-income and disadvantaged groups are generally more exposed to avoidable risk factors such as environmental carcinogens, alcohol, infectious agents, and tobacco use. [8] Another factor that possibly contributes to oral cancer may be low levels of health literacy. This study was an attempt to develop first tool on oral cancer to assess oral cancer health literacy in adult population.

One of the limitations of the study was the convenience sampling methods that may alter the psychometric properties of the instrument in a larger, more representative sample. Secondly, this tool was designed in English language and thus limiting its applicability on rural population of India where different regional languages are used.

Conclusion

OCHLT developed using Delphi method containing 32 items shows acceptable psychometric properties. The tool accounts for the multi- dimensionality of oral cancer health literacy by encompassing the domains of Word recognition, Functional health literacy and Information methods. It appears promising in planning appropriate strategic intervention for oral cancer by all stakeholders to address this emerging public health problem.

Future Recommendations

We would like to give few recommendations, based on the results of this study. The validity of the tool should be tested on other diverse populations, different age groups and environment. The tool should be considered for cross cultural validation.

Ethical Clearance- Taken from M.S Ramaiah University of Applied Sciences Ethics committee

Source of Funding- Self

Conflict of Interest - Nil

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Clinical Applications of Glass Fiber Reinforced Composites: A Case Series

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Abstract

Dental resin composites have seen a substantial improvement in terms of toughness, rigidity and flexural strength with the development of Fiber Reinforced Composite (FRC) Systems. Esthetic dentistry has seen a major leap in advancements with the beginning of the era of the FRC technology. The biocompatibility, translucency, ability to bond to tooth structure and the possibility of direct chair side application has made life easier for the dentist, providing improved results with ease and reliability. This paper attempts to showcase the versatility and applicability of this wonderful material (FRC) in day-to-day dental practice.

Keywords: FRC, Fixed partial denture, Post and core, core buildup, Splinting

Introduction

Fiber reinforced composite (FRC) technology has brought about great changes in the properties of dental resin based composites, including increased flexural strength, rigidity and toughness.^[1]

Various types of fibers and other materials including carbon, graphite, glass, Kevlar have been considered, and their technique of usage investigated, to provide this form of reinforcement.^[2, 3]

The fibers may be arranged in a unidirectional manner, with every fiber running in a single direction,

or, alternatively, may be present in a weave or meshwork pattern.

Various factors such as loading of fibers in the restoration, bond efficacy at the fiber-resin interface, orientation of the fibers and their position in the restoration may cause changes in the physical, mechanical, thermal and optical properties of the material.^[4]

Super-Splint is a reinforcement glass-fiber system composed of fibers that are arranged in a multidirectional leno-weave. This material has been developed as a reinforcement system, with the proposed advantage of being tear proof.^[5] Super-splint is bondable with all composite resin systems. As purported by the manufacturer, its biocompatibility is high.

Glass fiber ribbon can be used in the splinting of periodontally weak teeth, as endodontic post and cores, in the splinting of traumatized teeth, and as space maintainers.^[6] Reinforcement fibers have proven to prevent fractures that occur due to high masticatory stresses by increasing the fracture toughness and flexural strength of composite resins.^[7, 8]

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With the advantages of translucency, biocompatibility, bondability to tooth structure and direct chair side usability, this technology has greatly benefited the dentist with its ease of use and reliable performance. This paper shows the versatility and applicability of FRC in day-to-day dental practice.

Case reports

Case 1- FRC fixed partial denture

A 32-year-old female patient reported to the department with discoloration and mobility in her upper front tooth. Clinical examination revealed deep caries involving pulp and grade III mobility of the primary maxillary right lateral incisor.(Figure 1A ,1B) After clinical and radiographic examination, extraction of the primary tooth followed by a fixed partial denture with Super-Splint (Hager Werken, Duisburg, Germany) using composite as a pontic was suggested.

After etching and bonding was performed, the lingual and proximal surfaces of the abutments were

coated with a thin film of a flowable composite material (Filtek™ Z350 XT flowable restorative, 3M, USA), leaving the resin uncured.

A 10 mm strip of Super-Splint Glass fiber resin was placed on the lingual surfaces of the maxillary right central and lateral incisors, followed by the application of pressure using a hand instrument to obtain a close contact interproximally. (Figure 1C)

After removal of excess material, a light emitting diode (LED) Light curing unit (Bluephase, Ivoclar, Vivadent) was used to light cure the splint and resin for 20 seconds.

Following this, free hand light cured composite resin (Filtek™ Z350XT Universal Restorative, 3M, USA) build up was done to mimic a lateral incisor (pontic) which was then adapted to the splint using a flowable composite and cured for 20 seconds. After finishing and polishing of the restoration, an appealing result was obtained, which satisfied both the clinician and the patient. (Figure 1D)



Figure 1 A&B: Intraoral view showing retained deciduous maxillary right lateral incisor (labial and palatal view); C: FRC placed on the palatal surfaces of the maxillary right central and lateral incisors; D: FRC Fixed Partial Denture

Case 2- Endodontic post and core

A 40-year-old female patient reported to the department with a chief complaint of fractured upper front tooth. The patient gave a history of a root canal treatment performed on the tooth one year prior. There was no history of bleeding at the area of interest and the medical history was non-contributory. Intraoral examination showed a fractured maxillary right lateral incisor with less than half of remaining tooth structure. (Figure 2A) Radiographic examination revealed satisfactory obturation.(Figure 2B)

Since there was considerable tooth structure loss, the tooth was planned to be restored with Super-Splint in the form of an endodontic post.

A post space was prepared on the maxillary right lateral incisor (Figure 2C) after which etching (Eco Etch, Ivoclar, Vivadent, USA) was performed for 15 seconds. The etchant was removed with thorough water rinsing for 30 seconds and the tooth was air-dried. Paper points were then used for the drying of the canals. A micro-brush was used to apply two coats of an adhesive (Adper Single Bond 2, 3M ESPE, USA) following which the solvent was evaporated by gentle air-drying. Adhesive was then used to wet the Super-Splint and it was placed in the post space along with resin cement (Variolink, Ivoclar, Vivadent, USA) and cured with a light emitting diode (Bluephase, Ivoclar, Vivadent, USA) light curing unit(Figure 2D). Building up of the crown was done with a light cured composite material (Filtek™ Z350XT Universal Restorative, 3M, USA) to complete the procedure(Figure 2E & 2F).



Figure 2:A-Intra oral view showing fractured right lateral right lateral incisor; B-IOPA showing satisfactory obturation in incisor; C-IOPA showing post space preparation D- IOPA showing FRC as moldable post; E & F-Clinical and radiographic view showing composite build-up

Case 3- Splinting of traumatized teeth

A 35-year-old female patient was referred to the department two hours following a traumatic injury that resulted from a road traffic accident. On examination an Ellis class III fracture of the left maxillary lateral incisor

and moderate mobility of the permanent maxillary anterior teeth was observed. (Figure 3A) The decision was made to splint the maxillary anterior teeth for patient comfort using Super-Splint. After etching, rinsing and drying of the labial surfaces of the anterior teeth from the maxillary left canine to the right, a fifth generation

bonding agent (Adper Single Bond 2, 3M ESPE, USA) was coated on to the teeth and light curing was performed for 20 seconds using a light emitting diode light curing unit (Bluephase, Ivoclar, Vivadent, USA). A flowable composite was applied to the teeth, and Super-Splint was pressed into the composite and cured. An additional layer of flowable composite was then placed over the cured material and cured for another 20 seconds (Figure

3B). After two weeks, a diamond point was used to cut the Super-Splint at the interproximal areas. The splint was then removed using a scalpel blade, by inserting it in between the tooth and the splint on the distal-most end. A tungsten carbide bur in a low speed handpiece was used under a water coolant to remove the remaining material, and the tooth surfaces were then polished using disks

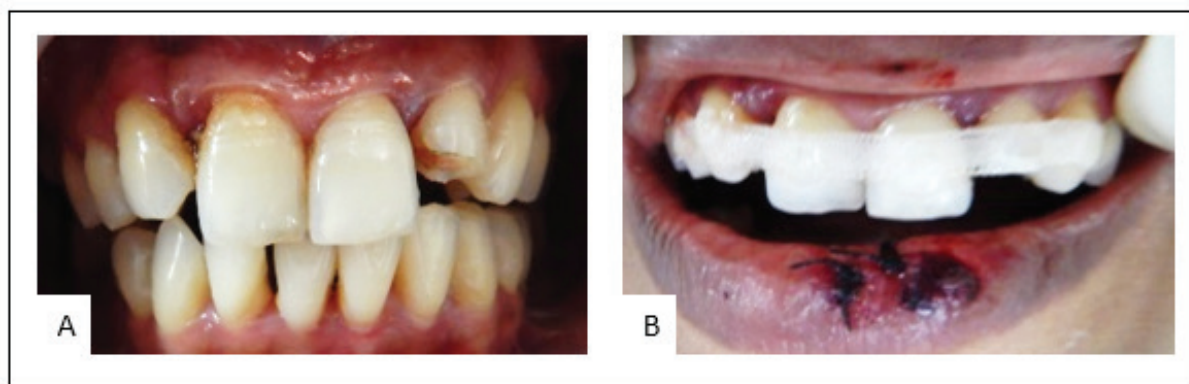


Figure 3 A- Pre-operative view; B-Post-operative view

Case 4: As a reinforcement of composite restoration

A 30 year old female patient reported to the department with a chief complaint of a broken filling in her left lower back teeth region. The patient gave a history of a root canal treatment performed on that tooth 1 year back. On clinical examination the mandibular left first molar showed a fractured post endodontic restoration. Radiographic examination revealed satisfactory obturation. The decision was made to restore the endodontically treated tooth by composite restoration reinforced by glass fiber ribbon.

The old restoration was removed, and the tooth was cleaned, dried, and etched with 35% phosphoric acid (Eco Etch, Ivoclar, Vivadent, USA) for 15 seconds. The teeth were then rinsed for 10 seconds and air-dried for 1-2 seconds. Subsequently, a single bottle total-etch adhesive system (Adper Single Bond 2; 3M ESPE, St. Paul, MN, USA) was applied and photocured using a light-emitting diode light curing unit (Bluephase, Ivoclar, Vivadent, USA) for 10 seconds. A glass-fiber ribbon saturated with bonding agent was placed in a bucco-lingual direction and cured for 20 seconds. A layer of nanocomposite was placed over the exposed fiber surface. Then another strip of fiber saturated with adhesive was placed in a mesio-distal direction and cured for 20 seconds. Finally, the occlusal surface of the tooth surface was built with light-cured composite.

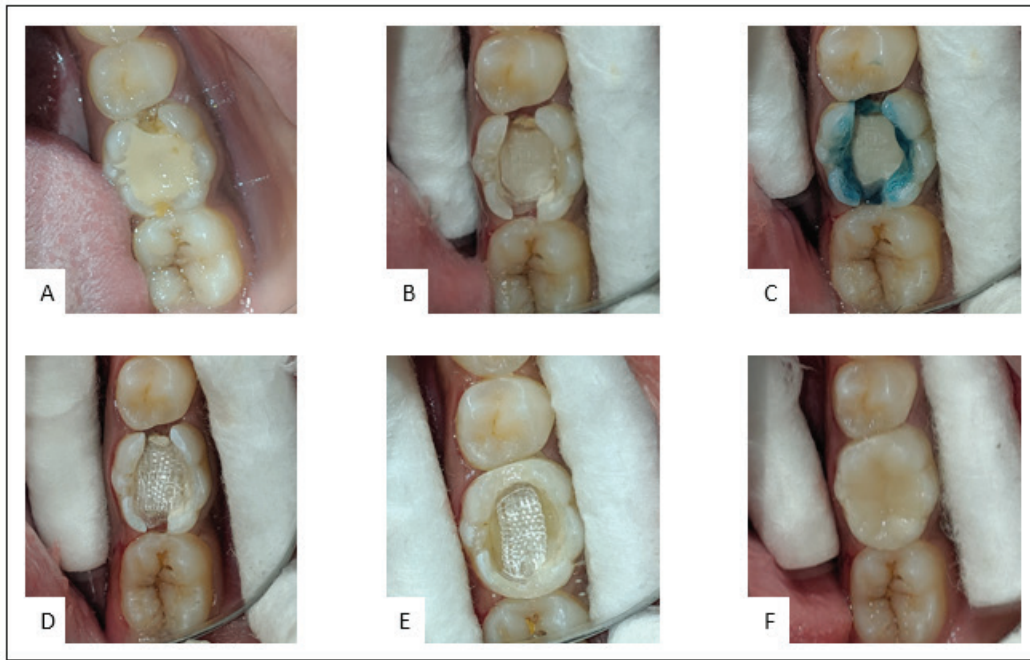


Figure 4: A- 36, Fractured post endodontic restoration; B- Removal of fractured post endodontic restoration and application of base; C- Etching with 37% phosphoric acid; D- Two fiber strips inserted inside the cavity and adapted over the pulpal floor in bucco-lingual direction using adhesive resin; E- Fiber strip placed mesio-distally before the final composite build up; F- Composite build up

Discussion

Fiber reinforcement has increased in popularity over the recent years, due to its versatile applications, which include Fiber reinforced composite bridges, periodontal splints, posts, as orthodontic retainers, and as FRC resins. These materials provide several mechanical advantages such as superior flexural strength, fatigue strength, bond strength and modulus of elasticity.

FRC fixed partial dentures have been suggested as esthetic and functional alternatives to conventional prostheses for the replacement of missing teeth.^[9] They are hygienic, non-irritating, and have been proven to provide more comfort to the wearer than the conventional removable appliances. They have the additional advantage of requiring no tooth preparation, and have the capacity to be modified, repaired, or removed, while causing minimal iatrogenic damage. The possible pontics for such FPDs include the patient's natural dentition, or teeth made of acrylic or composite resins. With proper etching and bonding procedures, FRC FPD's have proven to be reliable and clinically stable.^[10]

Endodontic post-and-core systems are designed to provide reinforcement in situations where insufficient tooth structure remains following endodontic therapy. Conventional posts are usually cast or prefabricated metal-based, requiring considerable tooth preparation of an already compromised tooth. Several FRC posts have been developed as alternatives, to support endodontically treated teeth.^[4] In the present case, Super-Splint was chosen due to its superior esthetics and the need for no further tooth preparation. FRC based posts may be individually formed or prefabricated posts. Additionally, an intra-radicular ferrule effect is obtained with the use of FRC posts.^[11]

Following traumatic injuries to teeth, which include sub-luxation, luxation, avulsion and root fractures, stabilization is performed with the use of splints. Dental literature includes various techniques for splinting.^[12, 13] In this case report, Super-Splint was selected for its use in the splinting of multiple teeth. It is also smooth, thin, less irritating to oral soft tissues like the lip, and is considerably esthetic. However, this material has the disadvantage of being comparatively expensive.

Direct composite resin restorations can be significantly strengthened by the use of reinforcement fibers.^[14] These fibers aid in the reduction of shrinkage strain and help to prevent fracture propagation. Holding the buccal and lingual cusps together with the placement of a fiber helps protect the cusps and increase the fracture resistance of the restored tooth.^[15, 16] This is especially imperative in endodontically treated molars, as these teeth are frequently structurally compromised, and technical failures like de-bonding and vertical root fractures are common in the post-endodontic restoration. Visser et al postulated that the presence of fibers, either embedded in the resin itself, or placed beneath the resin, significantly improved the fracture strength of dental restoratives.^[17]

Conclusion

Fiber-reinforced composites are developing as conservative and esthetic alternatives to conventional dental treatment procedures. The long-term use of these materials, however, is less known and requires further clinical studies for evaluation.

Ethical Clearance- Patient's consent was taken

Source of Funding- Self

Conflict of Interest - Nil

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Medication Adherence among Patients with Mental Illness Attending Psychiatric OPD & Ward in a Tertiary Hospital at South India

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Abstract

Background: The purpose of the study was to assess the medication adherence among patients with mental illness.

Methods: The present study adopted descriptive non experimental research design. A total of 70 patients with mental illness were recruited using a convenience sampling technique. In this study, the data was obtained through interview technique on demographic variables, medication related variables and medication adherence scale from samples who were satisfied the inclusion criteria.

Results: The study finding revealed that 20 (28.5%) patients had low medication adherence, 27 (38.5%) patients had medium medication adherence and 23 (33%) patients had high medication adherence level. There was a significant association between the level of medication adherence and the residence at the level of $p < 0.05$

Conclusion: Improving the support system by getting the family involved in the management of the patient, empowering them with educational, behavioral techniques and improving living condition of patient will improve medication adherence.

Keywords: Medication adherence, mental illness.

Introduction

Mental and behavioral disorders are common and affect more than 25% of all people at sometimes during their lives. 1 in our families is likely to have at least one member with a behavioral or mental disorder. People with mental disorders often cause distress among their family members. The family experiences financial hardship due to medical bills and the patient economic dependency, disruptions of household functioning, curtailment of

social activities and altered relationship with friends and relatives because of the excessive demands on caregiver¹. Medications can play a role in treating several mental disorders and conditions. They can reduce symptoms and prevent relapses of a psychiatric disorder².

Many people with mental illness who have taken psychiatric drugs as per doctor advice have found out the withdrawal effects of the drugs can persist for months, even years after they stop taking them. When their drug treatment is not restarted, **post withdrawal disorders may last several months to years**. Significant persistent post withdrawal emergent symptoms noted consist of anxiety disorders, including generalized anxiety and panic attacks, tardive [developing slowly] insomnia³.

Non adherence to treatment remains one of the greatest challenges in mental health care services. Adherence to psychiatric medications is a complex,

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dynamic behavior requiring patients to initiate treatment and continue to take their medications at the correct time, in the correct dose, for prolonged periods of time ⁴.

Non-adherence is likely to remain a major public health problem despite treatment advances. However, increasing knowledge about factors affecting adherence and leveraging novel technologies can enhance its early assessment and adequate management, particularly in patients with psychotic disorders ⁵.

Strategies focused on raising awareness of the importance of adherence are also warranted, with the aim of improving patient outcomes in psychiatric diseases. This made the investigator to take up the study and identify the level of medication adherence among patients with mental illness and help them in overcoming the withdrawal symptoms, relapses.

Methods & Materials

Research design and setting

A descriptive research design was adopted for this study. The study was conducted in outpatient and inpatient psychiatric department of Sri Ramachandra hospital, Porur, Chennai. It is a multi-specialty hospital with 1737 beds. The patients with mental illness attend psychiatric outpatient department to get consultation for their problems and have regular follow up. The psychiatric ward consists of 60 bedded where around 30 – 40 patients with mental illness get admitted and seek treatment for their problem.

Sample size and technique

The sample for the study includes 70 patients with mental illness who were available during data collection and who filled the inclusion criteria. It was estimated using previous literature ⁶ The sampling technique used for selecting participants was non probability convenience sampling technique.

Criteria for sample selection

Patients with mental illness who were in the age group of 20 to 60 years, of both gender, able to understand and speak Tamil or English, have insight level of V and VI according to Ahuja scale were included and Patients with mental illness who are not willing to participate in the study and with severe cognitive impairment. Were

excluded for the study

Description of the tool

The tool used for the present study has two sections

Section A: Background variables, it consists of Demographic information of patient with mentally ill such as age, gender, residence, education, occupation, monthly income, marital status, religion, duration of mental illness, types of mental illness and clinical variables - Medication related information of patient with mentally ill such as types of mental illness, duration of mental illness, types of drug prescribed and major side effects of drugs.

Section B: Morisky Medication Adherence Scale

It is standardized scale developed by D.E. Morisky in 1995 to screen the level of medication adherence. The tool has eight items with a scoring scheme of “Yes” = 0 and “No” =1.

Score interpretation

The scale has got a minimum score of 0 and maximum score of 8.

Level of medication adherence

- Low medication adherence - 0 to <6
- Medium medication adherence - 6 to <8
- High medication adherence - 8

Data collection procedure

The data collection procedure was carried out for one week from 7.11.16 to 11.11.16. The researcher obtained formal permission from the Principal, Faculty of Nursing, Chairman Ethics committee Sri Ramachandra university, Head of the Department of Psychiatry Sri Ramachandra Hospital, Medical superintendent of Sri Ramachandra Hospital, to conduct the study. Rapport was maintained, the purpose of the study was explained to patients and written consent was obtained from them before collecting the information. The researcher collected the data through interview technique on demographic variables, medication related variables and medication adherence scale from 70 samples who were satisfied the inclusion criteria. Confidential was

maintained throughout the study. The time taken for the data collection for each participant was about 15 – 20 minutes using English and Tamil language.

from English version to Tamil. The content validity of the tool was obtained from experts in the field of Nursing and Psychiatry. The tool was found to be reliable with r value of 0.83 for screening medication adherence.

Validity and reliability

The research tools used in the study were translated

Results

Table 1. Frequency and percentage distribution on the level of medication adherence among patient with mental illness (N=70)

Level of Medication Adherence	n	%
Low medication adherence 0 - <6	20	28.5
Medium medication adherence 6- <8	27	38.5
High medication adherence >8	23	33

In view of medication adherence 28.5% patients had low medication adherence, 38.5% patients had medium medication adherence and 33% patient had high medication adherence level, is provided in

Table 2.: Table 3. Mean score and Standard Deviation of Level of Medication Adherence among Patients with Mental Illness (N=70)

Variable	Mean	Standard deviation
Level of Medication Adherence	6.46	1.61

The mean score was 6.46 with standard deviation of 1.61 for medication adherence among patients with mental illness

Table 3. Association between the level of medication adherence and demographic variables among patient with mental illness.

Demographic variables	Level of medication adherence						X2-Value P value
	Low medication adherence		Medium medication adherence		High medication adherence		
	n	%	n	%	n	%	
Age in years							0.95 0.457 (NS)
a.20-30 yrs	6	8.57	5	7.14	3	4.28	
b.31-40yrs	6	8.57	11	15.71	8	11.42	
c.41-50yrs	8	11.42	7	10.0	9	12.85	
d. Above 50yrs	0	0	4	5.71	3	4.28	

Cont... Table 3. Association between the level of medication adherence and demographic variables among patient with mental illness.

Sex							
a. Male	11	15.71	14	20	10	14.28	0.63
b. Female	9	12.85	13	18.57	13	18.57	0.729 (NS)
Marital status							
a. Married	13	18.57	18	25.71	16	22.85	0.44
b. Unmarried	5	7.14	5	7.14	6	8.57	0.7793
c. Separated/widowed	2	2.85	4	5.71	1	1.42	(NS)
Education							
a. No formal education	4	5.71	6	8.57	4	5.71	0.36 0.9439 (NS)
b. Primary education	3	4.28	8	11.42	5	7.14	
c. Secondary education	5	7.14	6	8.57	7	10	
d. Higher education	2	2.85	2	2.85	3	4.28	
e. Graduate	6	8.57	5	7.14	4	5.71	
Occupation							
a. Retired	1	1.42	0	0	0	0	1.13 0.3445 (NS)
b. Employed	6	8.57	11	15.71	8	11.42	
c. Un employed	12	17.14	16	22.85	12	17.14	
d. Coolie worker	1	1.42	0	0	3	4.28	
Family monthly income in rupees							
a. <5000	10	14.28	7	10	10	14.28	0.81 0.5637 (NS)
b. 5000-10000	4	5.71	13	18.57	7	10	
c. 10000-15000	5	7.14	6	8.57	5	7.14	
d. >15000	1	1.42	1	1.42	1	1.42	
Residence							
a. Urban	12	17.14	14	20	16	22.85	* 0.01
b. Rural	8	11.42	9	12.87	11	15.71	0.99 (S)
Religion							
a. Hindu	15	21.42	23	32.85	20	28.57	1.25 0.2886 (NS)
b. Muslim	1	1.42	3	4.28	2	2.85	
c. Christian	4	5.71	1	1.42	1	1.42	
d. Others	0	0	0	0	0	0	

Cont... Table 3. Association between the level of medication adherence and demographic variables among patient with mental illness.

Duration of mental illness							
a.<6 months	1	1.42	2	2.85	4	5.71	0.88 0.5359 (NS)
b.6 months-1 yr	1	1.42	4	5.71	3	4.71	
c.1-3 yrs	7	10	8	11.42	2	2.85	
d.3-5 yrs	2	2.85	3	4.28	3	4.28	
e.>5 yrs	9	12.85	10	14.28	11	15.71	
Types of mental illness	10	14.28	10	14.28	7	10	1.31 0.2190 (NS)
a. Schizophrenia	5	7.14	7	10	7	10	
b. Depression	4	5.71	3	4.28	1	1.42	
c. Bipolar disorder	0	0	2	2.85	0	0	
d. Substance abuse disorder	0	0	2	2.85	0	0	
e. Other neurotic disorder	1	1.42	1	1.42	1	1.42	
f. Other disorder	0	0	4	5.71	7	10	
Types of drugs prescribed							1.16 0.3130 (NS)
a. Antipsychotic drugs	11	15.71	13	18.57	15	21.42	
b. Antidepressant drugs	7	10	8	11.42	6	6.57	
c. Antimanic drugs	0	0	3	4.28	1	1.42	
d. Antianxiety drugs	0	0	2	2.85	1	1.42	
e. Sedative & hypnotic drugs	0	0	1	1.42	0	0	
f. Other drugs	2	2.85	0	0	0	0	
Side effects of drugs							1.78 0.4160 (NS)
a. Taste changes	0	0	1	1.42	0	0	
b. Memory issues	0	0	0	0	0	0	
c. Frequent urination	0	0	0	0	0	0	
d. Drowsiness	2	2.85	3	4.28	7	10	
e. Nausea	0	0	0	0	0	0	
f. Sleep problems	1	1.42	3	4.28	2	2.85	
g. Weight gain	0	0	0	0	1	1.42	
h. Loss of appetite	5	7.14	2	2.85	1	1.42	
i. GI disturbance	2	2.85	3	4.28	2	2.85	
j. Weight loss	0	0	2	2.85	1	1.42	
k. Other side effects	0	0	0	0	0	0	
l. Nil	10	14.28	13	18.57	9	12.85	

S-Significant p<0.05. NS-Non-Significant.

There was a significant association between the level of medication adherence and the residence at the level of p<0.05

Discussion

The study finding revealed that 20(28.5%) patients had low medication adherence, 27(38.5%) patients had medium medication adherence and 23(33%) patients had high medication adherence level, (Table 2). The findings of the study revealed that the mean score was 6.46 with the standard deviation 1.61 for medication adherence among patient with illness (Table 3). A study done to examine the level of medication adherence on patients among a group of 95 outpatients participated in this study. The result showed that the eight items Morisky medication adherence scale indicated high adherence levels amongst 12.6%, moderate adherence levels amongst 50.8% and low adherence levels amongst 37% of participants⁷.

There was a significant association between the level of medication adherence and the residence at the level of $p < 0.05$. A study was conducted on factors affecting non-compliance among psychiatric patients at regional institute of Medical Sciences, Imphal, India. Using a non-probability sampling technique 50 patients were selected for the study. Data was analysis using SPSS for window 20.0 version. The study findings revealed that non-compliance to drug treatment was most common between 21-30 years of age groups, more in females (72%) than males (28%), high among married (60%) than single (40%), and with low education (28%) and low socioeconomic status (54%). There was a significant association between the level of medication adherence and the age, education among psychiatric patients at the level of $p < 0.05$ ⁸.

Conclusion

The study revealed that the majority of the patients had medium medication adherence level and there was a significant association between the level of medication adherence and the residence at the level of $p < 0.05$. Improving the support system by getting the family involved in the management of the patient, empowering them with educational, behavioral techniques and improving living condition of patient will improve medication adherence.

Nursing implications

The implications drawn for the study are of vital concern to clinical nurse practitioners, nurse

administrator, educator and researchers. Monitoring medication adherence among psychiatric patients is an important aspect in nursing practice. Improving adherence is an ongoing and dynamic process that requires the involvement of all health care professionals working with the patient. Nurses should be exposed to various strategies such as good communication, shared decision-making about medication, and specific but nonjudgmental inquiry about adherence to overcome or minimize this behavior and help the patients to adhere medication. The nursing faculty members should organize continuing nursing education programmes on medication adherence and teach the nursing students to motivate psychiatric patients towards medication adherence and also help them in prevention of relapses among psychiatric patients. The nurse administrator must periodically evaluate the nursing interventions used in the hospitals Nurse administrator should take an active part in conducting in-service education among students as well as the staff members to create awareness about the effect of medication non adherence among psychiatric patients. The nurse researcher can motivate the nursing students and nurses to conduct various projects by variety of methodology in overcoming medication non adherence among psychiatric patients.

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A Study of Platelet Indices in Patients with Metabolic Syndrome and Type 2 Diabetes Mellitus

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Abstract

Altered platelets have been reported in patients with diabetes mellitus and MS has been considered as a 'prothrombotic state' with enhanced platelet reactivity. They have been associated with increased risk of vascular complications in these patients. Platelet indices correlate with functional status of platelets and is an emerging risk factor of vascular complications in diabetes and MS. The study was undertaken to know the efficacy of platelet analysis in assessing the prognosis of diabetes mellitus and MS. Results of our study may lay a foundation for a discovery of new approaches for prevention and treatment of cardiovascular complications in MetS and DMT2 in early stages of metabolic disorders in patients. MetS is a proinflammatory and prothrombotic state, characterized by alteration of platelet indices. Plateletcrit is shown to be a significant biomarker along with other parameters, including waist circumference, SBP, and serum triglyceride levels. Platelet activation causes high risk of cardiovascular complications in MetS. T2 DM is associated with the changes in the intra cellular signaling systems regulating platelet functions.

Key words: Platelets, Metabolic Syndrome, Type 2 Diabetes Mellitus, Nitric Oxide, Hematological parameters, Triglycerides.

Introduction

Metabolic syndrome (MetS) and type 2 diabetes mellitus (T2DM) are the factors of cardiovascular risk. MetS comprises an array of pathogenetically interrelated metabolic and clinical abnormalities (insulin resistance, arterial hypertension, and dyslipidemia) and increases risk of atherosclerotic damage of blood vessels. Metabolic syndrome (MetS) is a combination of abdominal obesity, atherogenic dyslipidemia, elevated blood pressure (BP), and elevated plasma glucose

(1). Platelets play a key role in the development of atherothrombosis, a major contributor of cardiovascular events (1). The contribution of platelets to cardiovascular events has been noted for decades. Since then, there have been numerous studies underlying the importance of platelets in thrombotic complications (2). The importance of platelets in cardiovascular disease, medicines aimed at inhibiting platelet activity have been demonstrated to be very effective at decreasing myocardial infarction, stroke. Metabolic syndrome, a precursor to diabetes, is an independent predictor of cardiovascular events (3). Although several measurements of platelet activity have emerged as potential contributors to atherothrombosis, many of these measurements are time-consuming, expensive, use a high sample volume, or require specialty training (4-5). People with diabetes, exhibit increased platelet reactivity. Hyperglycemia contributes to greater platelet reactivity through direct effects and by promoting glycation of platelet proteins. Both insulin resistance and insulin deficiency increase

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platelet reactivity. Insulin inhibits activation of platelets. Therefore, relative or absolute deficiency of insulin would increase platelet reactivity⁽⁶⁾.

Recent studies on platelet volume indices in the spectrum of ischemic heart diseases show that all platelet indices—plateletcrit, mean platelet volume (MPV) and platelet distribution

width (PDW) were significantly raised in patients who had suffered from acute myocardial ischemia. A key component of vaso-occlusion is believed to be increased platelet activation and reactivity, and thus an increased platelet volume resulting in an elevated PDW. Also, higher concentrations of platelet microparticles have been detected in proinflammatory disorders such as sickle cell anemia. Studies on diabetes mellitus (DM), which too is considered to be a prothrombotic state with enhanced platelet reactivity, found a statistical rise in MPV and PDW, yet very few studies have been carried out regarding platelet indices for MetS patients.

MetS patients have been found to be at a greater risk for developing insulin resistance, visceral adiposity, atherogenic dyslipidemia, and endothelial dysfunction. Patients with insulin resistance tend to develop hypertriglyceridemia and are prone for developing atheromas in vascular lumen, leading to an increased incidence of coronary artery disease and stroke.⁸ Hypertriglyceridemia too leads to endothelial dysfunction that predisposes to the development of atherosclerotic depositions along vessel lumina. Visceral adiposity has been implicated in dysregulation of adiponectin levels, which too eventually causes vascular dysfunction.⁽⁷⁾ Metabolic abnormalities, associated with insulin resistance syndrome, significantly affect functional activity of platelets. Activation of platelets can play an important role in progression of heart failure due to a formation of the microthrombi in the myocardial microcirculation. Although several measurements of platelet activity have emerged as potential contributors to atherothrombosis, many of them are time consuming, expensive and use a high sample volume. Alternatively, MPV, PDW and P-LCR can be easily determined on routine automated hemograms available at low cost. Patients with larger platelets can easily be identified during routine haematological analysis and timely treatment could be undertaken.

Thus, in multiple recent studies, it has been shown that platelet indices are higher in patients suffering from DM, impaired fasting glucose, and dyslipidemia, as compared with MS. Thus, the aim of this study was to analyze the platelet indices in DM and MetS patients. To assess various platelet indices in MetS patients including plateletcrit, MPV, and PDW. To correlate platelet indices with other parameters of MetS, including waist circumference, BP, and lipid profile. The study also demonstrated an increase in the mean platelet diameter in T2DM patients. The effects of the pro inflammatory cytokines on functional activity of platelets are studied. The present study compares the hematological parameters between patients with diabetes and MS.

Material and Methods

The study was carried between January to December 2019 in Central Laboratory of Sri Lakshmi Narayana Institute of Medical Sciences, Puducherry, India. All the Samples were recruited and collected after informed consent and study was approved by Institutional Ethics Committee approval. Laboratory analysis The mean platelet volume (MPV), platelet count, and other blood cell indices were measured using a Study participants selected were 100 MetS patients aged between 25 and 60 years, attending the medicine OPD and/or admitted to the medicine ward/intensive care unit (ICU). A DM, non-MetS participants were chosen. On assessment of waist circumference, BP was the parameter assessed next. Mean SBP, mean DBP On assessment by Student's unpaired *t*-test, Lipid profile of patients was then assessed. Fasting blood glucose levels of patients was the subsequent parameter taken into consideration. Platelet indices of patients, comprising plateletcrit, MPV, and PDW, were then taken into consideration. The first parameter taken into consideration was the patient's plateletcrit. When mean plateletcrit of the two categories was Compared.

Statistical Analysis

Statistical analyses were carried out using inferential statistics, including chi-square test and Student's *t*-test. Software used for the analysis was SPSS version 11.5. $p < 0.05$ being considered as significant.

Results

This study assessed morphologic, hematologic, and

biochemical parameters of 100 Metabolic syndrome and Diabetes patients. Criteria assessed to make the diagnosis of MetS were the NCEP-ATP III criteria.

Table 1. Correlation of Waist circumference of study population in Metabolic Syndrome and Diabetes Mellitus. **Table 2** Correlation of systolic blood pressure

of study population in Metabolic Syndrome and Diabetes Mellitus. **Table 3** Correlation of serum triglyceride levels of study population in Metabolic Syndrome and Diabetes Mellitus. **Table 4:** Correlation of plateletcrit of study population in Metabolic Syndrome and Diabetes Mellitus

Table 1. Correlation of Waist circumference of study population in Metabolic Syndrome and Diabetes Mellitus

Category	N	Mean	Standard deviation	Standard error mean	t-Value	p-Value
Metabolic Syndrome	100	92.73	6.96	1.52	2.10	0.032
Diabetes Mellitus	100	83.78	5.18	1.40		

Table 2 Correlation of systolic blood pressure of study population in Metabolic Syndrome and Diabetes Mellitus

Category	N	Mean	Standard deviation	Standard error mean	t-Value	p-Value
Metabolic Syndrome	100	136.73	14.83	1.83	2.30	0.020*
Diabetes Mellitus	100	122.38	7.99	1.36		

Table 3 Correlation of serum triglyceride levels of study population in Metabolic Syndrome and Diabetes Mellitus

Category	N	Mean	Standard deviation	Standard error mean	t-Value	p-Value
Metabolic Syndrome	100	176.32	67.92	9.34	2.02	0.031*
Diabetes Mellitus	100	132.38	44.86	5.18		

Table 4: Correlation of plateletcrit of study population in Metabolic Syndrome and Diabetes Mellitus

Category	N	Mean	Standard deviation	Standard error mean	t-Value	p-Value
Metabolic Syndrome	100	0.23	0.07	0.012	2.42	0.016*
Diabetes Mellitus	100	0.20	0.02	0.002		

Discussion

On assessment by Student's unpaired *t*-test, no statistical significance was found in correlation of patients' age to their MetS status ($p < 0.05$). The findings we obtained in this study have been similar to those obtained by various other authors regarding work on both, MetS, and platelet indices in national and international literature. We obtained a significant, positive correlation of the MetS status of patients to their waist circumference, SBP, serum triglyceride levels, and plateletcrit, as confirmed using independent Student's unpaired *t*-tests. The role of platelet-activation pathways has also been widely studied in causation of complications in MetS. (8-9). Studies have shown that platelet aggregation is controlled by the activity of PDI. This relationship between PDI and platelet hyper reactivity in MetS and its role in the causation of insulin resistance and nitric oxide dysfunction were studied by previous study (10) Increasing plateletcrit acts as a predisposing factor to development of cardiovascular complications in MetS patients, and also noted an increased risk of developing MetS among patients with increased leucocyte and erythrocyte counts (11-12). Previous studies noted that elevated platelet indices correlated statistically with waist circumferences of patients and acted as a determinant of abdominal obesity, a major factor implicated in the development of MetS, with similar results shown by authors Barzin et al as well. (13-14)

Other platelet indices studied include platelet-to-lymphocyte ratio, which was found to be elevated in MetS patients, as well as shown be a marker for

cardiovascular dysfunction in MetS patients (15-16) Further pathophysiology of platelet dysfunction and other biochemical abnormalities in MetS patients was studied in a study who documented sex-based differences in cardiovascular risk factors and predisposition to DM. (17). Increase in blood glucose level is one of the factors that change the erythrocyte morphology. The extent of change in shape of erythrocyte depends on the level of blood glucose level. All this affects the flow property of blood due to alteration and deformation (18). The present study compares the hematological parameters between patients with diabetes and Metabolic Syndrome. Some studies performed a study on 170 diabetic patients to determine the relationship of glycemic control on hematological parameters in diabetes mellitus patients, reported that among hematological parameters MPV and PDW were significantly increased in diabetes patients (19). Significant difference was obtained for RCDW, PDW, MPV, PLT and PCT between patients with good, poor and uncontrolled diabetes mellitus ($p < 0.05$). Raised level of such indices can be utilized as the possible indicators for finding the risk of developing micro and macro vascular complication in diabetes patients (20) in present study total RBC, PVC and PLT were significantly high in patients with diabetes whereas RCDW was significantly high in Metabolic Syndrome patients. Some studies did not find any difference in haematological parameters except WBC count, all other parameters such as hemoglobin, platelets and haematocrit levels were similar in patients with and without diabetes which is in accordance with the present study findings (17). One study reported that platelet indices such as mean platelet volume and platelet distribution width were significantly

higher in diabetes patients, but in present study we found the contrary results⁽²¹⁾. Patients with diabetes had higher level of total RBC, PCV and PLT whereas patients with hypertension and diabetes were having higher values of RCDW. Hematological parameters such as RCDW, PDW, MPV, PLT and PCT were found. Present study recommends the screening for hematological parameters and RFT in patients with diabetes mellitus.

Several publications provide evidence of putative inter relations between the MetS components and blood platelet count. One study showed that blood platelet number in the individuals presented with three and more MetS components is significantly higher than in the presence of only one or two components or without MetS components at all⁽²²⁾. Diabetes mellitus is not a single disease entity but rather a group of metabolic disorders sharing the common underlying feature of hyperglycemia. The chronic hyperglycemia and metabolic dysregulation may be associated with secondary damage in multiple organ systems, especially the kidneys, eyes and blood vessels⁽²³⁾. Platelets from patients with type 2 diabetes mellitus have increased reactivity and baseline activation which are likely to play a key role in development and sustainment of vascular complications⁽²⁴⁾. Sustained hyperglycemia leads to a series of interrelated alterations that can cause evident endothelial dysfunction and vascular complications.

Human platelets are a nucleate discoid cells that circulate in the bloodstream and participate in hemostasis. In response to stimuli generated by the endothelium of blood vessels, platelets change shape, adhere to sub endothelial surfaces, secrete the contents of intracellular organelles, and aggregate to form a thrombus⁽²⁴⁾. There is evidence that spontaneous platelet aggregation, estimated based on the sizes of the formed aggregates, was significantly higher in MetS patients compared with healthy volunteers. The curves of the mean aggregate sizes and light transmission characteristics suggested that the rates of collagen-induced aggregation of isolated platelets in MetS patients significantly exceeded the corresponding values in group of healthy volunteers⁽²³⁻²⁴⁾. The very elevated glycosylation of the platelet membrane proteins, rather than molar ratio of cholesterol and phospho- lipids, can decrease platelet membrane fluidity in diabetic patients⁽²⁵⁾. Increased glycosylation of platelet proteins modulates cellular functions in diabetes.

In particular, possible glycosylation of calmodulin that modulates activity of nitric oxide synthase (NOS) results in the decreased synthesis of nitric oxide (NO). Some data suggest that hyperglycemia contributes to platelet aggregation whereas normalization of glucose concentration attenuates this process⁽²⁵⁾. High glucose concentrations hypothetically activate endothelial NOS in platelets via the osmotic mechanisms involving protein kinase C- β isoform and intracellular calcium increase.

The molecule of NO is a universal regulator in the cardio-vascular, immune, and nervous systems of the organism. NO is synthesized both in endothelial, neural, smooth muscle cells, and in platelets. This molecule there by mediates auto regulation of platelet activity. NO is a neutral radical with unpaired electron. This molecule has the highest diffusion coefficient compared with other molecules (O_2 and CO_2) in the organism and free lypenetrates cellular membranes⁽²⁵⁾. Activation of iNOS results in synthesis of high NO concentrations enough to stimulate T-cell-mediated immunity and exert cytotoxic effects. iNOS is identified in macrophages, neutrophils, keratinocytes, fibroblasts, chondrocytes, osteoklasts, neurons, astrocytes, various epithelial cells (respiratory, retinal, pigment, renal, tubular, and adeno carcinomatous), hepatocytes, pancreatic β -cells, endotheliocytes, endocardiocytes, and vascular smooth muscle cells. The enzyme is activated by cytokines or bacterial antigens in inflammation as well as by ultraviolet, ozone, nicotinic acid, and hormones affecting cAMP synthesis (adrenalin, glucagon). This NOS isoform generates manifold NO amount compared with other forms of NOSs and does not require Ca^{2+} for this process. Our study demonstrated an increased basal NO production by monocytes isolated from MetS patients perhaps due to the iNOS activation. There is evidence of decrease in the insulin stimulated NO production by the endothelial and smooth muscle cells in the presence of insulin resistance⁽²⁵⁾. India betes, platelet adhesion and spontaneous aggregation increase as well. Altered activity of NOS in platelets from patients with MetS can play the key role in onset of the platelet hyper activation and development of macro and micro angiopathies. Studies of NO production in the platelets showed decreased basal NO production in all groups of MetS patients compared with healthy donors. Moreover, the lowest rates of NO synthesis

were observed in patients with decompensated T2DM. There is reverse correlation between the NO mediated synthesis of cGMP in platelets and the levels of glucose and glycated hemoglobin in blood. Reduced basal formation of NO by the cells from MetS patients can be because by various reasons. The presence of hyperglycemia due to glucose autooxidation contributes to the formation of superoxide an ion interacting with NO and mediating formation of the peroxynitrite attenuating NO content. There is evidence that platelets express functional Ca²⁺-calmodulin dependent constitutive NOS. Glycosylation of calmodulin can cause reduction of basal NO secretion.

Human platelet aggregation is also modulated by NO and prostacyclin (PGI₂) released from the endothelium. Endothelial dysfunction, accompanying the insulin resistance syndrome, attenuates NO and PGI₂ production in the endotheliocytes. Effects of NO and PGI₂ on the platelets are mediated by the adenylate and guanylate cyclases that synthesize cAMP and cGMP. The adenylate and guanylate cyclases are regulated by prostacyclin and NO, respectively. Formed cGMP inhibits phosphodiesterases metabolizing cAMP. Degradation of cAMP and cGMP is mediated by phosphodiesterases⁽²⁶⁾. Abnormalities in cAMP/cGMP pathways can cause platelet hyperactivity. Platelets from patients with diabetes have decreased sensitivity to NO and PGI₂. In diabetes mellitus, the number of PGI₂ receptors is not decreased suggesting that the defect is downstream of the receptor. Previous studies⁽²⁶⁾ detected a decrease in G_i protein in the platelet membranes from T2 DM patients. Some studies demonstrated elevated activity of cGMP dependent phosphodiesterase eventually leading to decrease in sensitivity to NO. Homocysteine affects blood vessels through the active oxygen forms, decrease in endothelial NO production, and augmentation of smooth muscle cell proliferation. Homocysteine can decrease platelet NO production by several mechanisms. Striated that homocysteine causes atherogenic effects in diabetic patients due to decreased platelet NO production with following augmentation of platelet activity and aggregation. The effects of insulin on platelets in healthy individuals consist in the NO-mediated elevation of cGMP and cAMP, decrease in Ca²⁺ currents induced by Ca²⁺ mobilizing agents, decrease in agonist-induced aggregation, augmentation of platelet binding with anti aggregation prostanoids,

and suppression of platelet binding with catecholamines leading to adrenalin induced platelet aggregation. In insulin resistant patients, calcium content in platelets rises in response to stimulation by insulin, leading thereby to platelet activation and aggregation. The study of individuals with abnormal carbohydrate metabolism demonstrated augmentation of platelet activity and aggregation in response to an increase in content of cGMP exerting anti-aggregation effect. The authors assume that elevated platelet aggregation in these patients causes cGMP increase by the negative feedback mechanism.

Conclusion

Platelet activation causes high risk of cardiovascular complications in MetS. T2 DM is associated with the changes in the intracellular signaling systems regulating platelet functions. Due to the altered NOS expression and activity, platelets increase their prothrombogenic potential. The cGMP-mediated anti aggregational effects of insulin, involving NOS and NO-dependent mechanisms, become abnormal. The effects of aggregation triggering agonists are modulated by the proinflammatory factors. All these mechanisms of changes in platelets aggregation activity in MetS and DM T2 are caused by the metabolic disturbances including insulin resistance, hyperglycemia, and dyslipidemia.

Results of our study may lay a foundation for a discovery of new approaches for prevention and treatment of cardiovascular complications in MetS and DM T2 in early stages of metabolic disorders in patients. Patients with metabolic syndrome (MetS) and type 2 diabetes mellitus (T2DM) have high risk of micro circulation complications and micro angiopathies. Factors leading to platelet activation in MetS and T2 DM comprise insulin resistance, hyperglycemia, non-enzymatic glycosylation, oxidative stress, and inflammation. Decrease in a number and sensitivity of the insulin receptors on platelets in T2DM can cause platelet hyperactivation. These data suggest a potential role of platelet activity measurement in subjects with diabetes. Thus, platelet volume indices MPV, PDW and P-LCR provides an important, simple, effortless and cost effective tool which can be useful in predicting an impending thrombotic state and vascular complications of diabetes. Plateletcrit was shown to be a significant biomarker along with

other parameters, including waist circumference, SBP, and serum triglyceride levels. Early detection using these markers can lead to an overall decline in morbidity and mortality due to MetS. MetS is a proinflammatory and prothrombotic state, characterized by alteration of platelet indices. Plateletcrit was shown to be a significant biomarker along with other parameters, including waist circumference, SBP, and serum triglyceride levels.

Conflict of Interest: Nil

Source of Funding: Self/Diagnostic kits are provided by institution as on complimentary basis for research.

Ethical Clearance No: No.IEC/C:135/2019

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Musculoskeletal Pain and its Association with School Bag Weight and Diet Intake: A Cross-Sectional Study among School-Going Adolescents in Delhi

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Abstract

Background: Prevalence of musculoskeletal pain is increasing in adolescent school students. This study conducted to assess the role of heavy bag packs and faulty dietary habits in the causation of musculoskeletal pain.

Methods: The study was conducted in school going 1600 adolescent school students of Delhi, India from April 2018 to March 2019. The demographic profile, symptoms of pain in neck, shoulder and back was recorded through a validated questionnaire and the simplified dietary gap assessment tool was applied to assess the dietary habits. The weight of the school bag was measured. The prevalence of musculoskeletal pain was 56.8% among adolescent school students. The musculoskeletal pain was significantly higher in those students who were carrying bag weight 10-15% of their body weight and was two times higher than those students who were carrying bag weight less than 10% of their body weight. Students having dietary gap score of less than 5 out of 10 were more prevalent to get musculoskeletal pain than those having dietary score more than 8.

Conclusions: Carrying of heavy school bag weight and gap in the diet among the school going adolescents can lead to musculoskeletal pain.

Key-words: Musculoskeletal, Pain, Adolescent, Bag, Diet, School

Introduction

In childhood, pain is a common presentation which becomes disabling when it persists in adolescent stage.¹ Among the types of pains, around 64% are of musculoskeletal origin.² The symptoms of pain in school-going adolescents are more common in girls than boys³ and can be attributed to faulty and stationary

postures⁴, improper classroom furniture⁴ and excessive school bags load affecting the spine.⁵

Heavy schoolbags are a potential risk for musculoskeletal problems among adolescents.⁶ School bags heavier than 10% of one's own body weight may result in back and shoulder pains⁷, can affect the curvature of lumbar and sacral spine⁸ increases musculoskeletal injury risk and affects cardiopulmonary functions.⁹

Poorer general health is also associated with back pain in around 74.4% bag pack user adolescents.¹⁰ The adolescents continue to have unhealthy foods because of the gap in knowledge regarding the unhealthy food ill effects and lack of time.¹¹

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The present study was intended to evaluate the musculoskeletal pain association with bag weight and nutritional status.

Methods

The cross-sectional observational study approved by the Institutional Ethics Committee conducted between April 2018 to March 2019 in Government co-educational schools of south Delhi. The permission was granted by Directorate of Education, Government of Delhi in 101 schools and out of those, 23 schools were Co-educational Senior Secondary schools.

The sample size was calculated based on the referenced study which showed the prevalence of neck and back pain was in 50% of the young adolescent.¹² With the allowable error as 5% of prevalence, the sample size required was 1600. Principals of 16 schools were approached as per convenience sampling for the study out of which Principal of 10 schools with 7511 students accepted to be the part of the study. Total 3790 consent forms were distributed to the senior secondary students out of which 2083 students were eligible to participate in the study. 1600 students were randomised by the “Random number generator software -Stat Trek” to include in the study.

Data Collection

The students of class 6th to 12th standard of age group 10-19 years from both gender carrying regular school bags to school were included in the study. The students having a recent history of injuries in neck, shoulder or back were excluded from the study. The details of the procedure of the study was given and explained to all the students and written informed consents were taken indicating the voluntary participation. The pre-designed proforma was filled to capture the demographic details. The height and body weight of each student along with their school bag weight was measured. The weighing machine was calibrated and height was measured with a portable stadiometer. The questions related to the use of school bags and their type i.e. Side bags or bag backs were asked. The responses were collected in the proforma by asking the students to answer “yes” or “No” to the questions. The way of carrying the bag either in both or single shoulder or in hands, and any pain or discomfort in single, double and three sites in the neck, shoulder and back pain within 1 month due to the school bag carriage was noted.

The simplified dietary assessment tool¹³ was used to collect the dietary pattern of the adolescents. The questions were asked and scores were calculated as per their response in Table 1.

TABLE 1: Simplified dietary assessment tool developed by Chacko and Ganeshan 2018

S. No	Questions (based on Indian Council Medical Research/National Institute of Nutrition recommendations)	Response Score	
		Yes =1	No=0
1	Daily do you have 3 main meals of cereals?		
2	Do you have mid-morning and evening snack daily?		
3	Do you take at least one of these items along with your meals daily? pulses/ dhal/non-vegetarian food (fish, chicken, mutton, egg) daily?		
4	Do you take 3 cups of milk/coffee/tea/flavoured milk or 2 cups with curd daily?		
5	Do you take green leafy vegetables daily?		
6	Do you take other vegetables along with your meals daily?		
7	Do you take a fruit daily?		
	General faulty dietary habits: Reverse scoring	Yes=0	No=1
8	Do you skip any meal?		
9	Do you eat junk food		
10	Do you buy eatables from the street shops?		
	Maximum possible score =10		

Data Analysis

The descriptive statistics was applied to see the prevalence of musculoskeletal pain (neck/back/shoulder) both gender-wise and across the whole samples. The prevalence of pain was analysed for the students carrying bag weight more than 15%, 10-15%, and less than 10% of their body weight. The dietary intake of participants was scrutinised with simplified dietary gap assessment tool. The data obtained was subjected to the statistical analysis using Stata (Version 14). Chi-Square test was used to evaluate the risk of musculoskeletal pain among both genders, weight of the schoolbag and simplified dietary gap assessment tool. The variables with a significant association to musculoskeletal pain in univariate analysis were then included in a multivariate model. Logistic regression was used to determine

in the variables which had an independent effect on musculoskeletal pain.

Results

Sample Characteristics

There were 1600 students included in the study meeting the inclusion criteria out of which 745 (46.5%) were females and 855 (53.4%) were males. The mean age of the participants was (13.5 ± 2) years whereas the 68% (1089) students were underweight with BMI <18 kg/m². The mean bodyweight of the students was 41.1 ± 11.1 kg and the mean height was 151.5 ± 11.6 cm. The mean schoolbag weight for all of the adolescents was 4.3 ± 1.2 kg. Total of 1591 (99%) students carried school bags on both shoulders. The characteristics of the students are described in Table 2.

TABLE 2. Sample characteristics of the students

	Total Students (n=1600)	Male (n = 855)	Females (n =745)
Age in years (Mean ± SD)	13.5 ± 2	13 ± 2	13.4 ± 2
Height in cm (Mean ± SD)	151.5 ± 11.6	154.5 ± 12.6	147.9 ± 9.0
Weight (Kg) (Mean ± SD)	41.1 ± 11.1	42.12± 12.45	39.4 ± 9.1
BMI (Mean ± SD)	17.7 ± 3.4	17.58 ± 3.71	17.83± 3.2
Weight of school bag (Kg) (Mean ± SD)	4.3 ± 1.2	4.3 ± 1.2	4.4 ± 1.2

Neck, Shoulder and back pain

Out of 1600 adolescent students, 909 (56.8%) had musculoskeletal pain either single site (neck, shoulder, back), two sites (neck, shoulder or neck, back or back, shoulder) or three sites (neck, back and shoulder). The shoulder pains were reported in 570 (35.6%) while back and neck pain were reported in 68 students (4.2%) and 29 students (1.8%) respectively. Among all participants, 203 (12.6%) had complaints in two different sites and 38 students (2.3%) had complaints in three sites simultaneously. An overview of the prevalence of musculoskeletal pain in different sites is presented in Figure 1

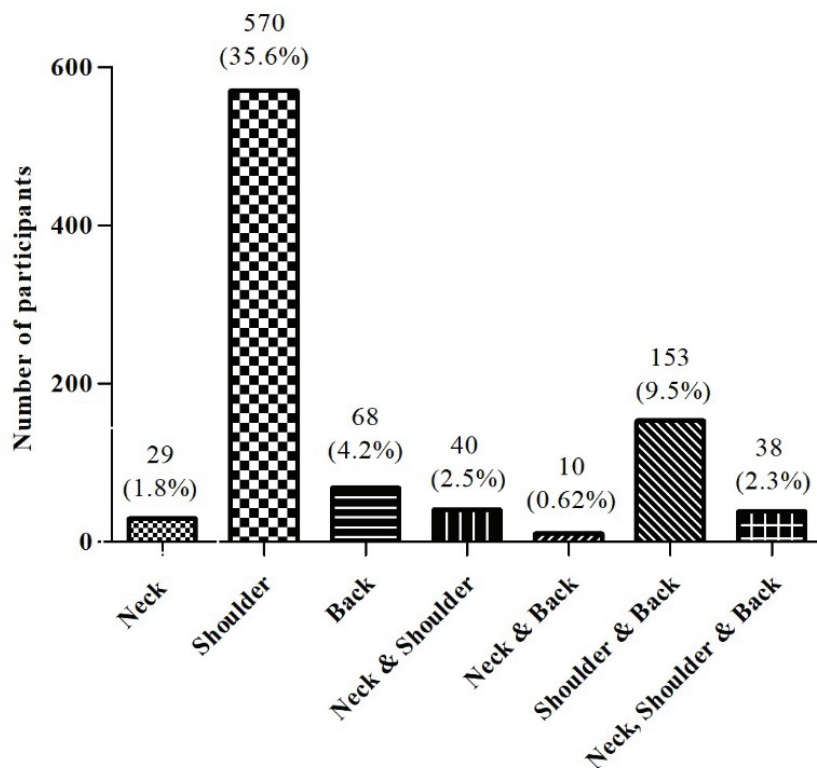


FIGURE 1. Frequency of Neck, Shoulder and Back pain as per single, two and three sites

The data analysis (χ^2) shown in Table 3 suggested that females have a higher prevalence of musculoskeletal pain than males ($\chi^2=27.41$ p value= $p<0.0001$). The musculoskeletal pain is more associated with the students who carry more than 10% of their body weight. ($\chi^2=33.97$ p value= $p<0.0001$). The association of pain was more common in the participants having dietary scores ≥ 5 out of 10. ($\chi^2= 8.4$ p value= 0.014*).

TABLE 3. Prevalence of musculoskeletal pain and their association with gender, bag weight and simplified dietary assessment score

Variables		Pain	No Pain	χ^2 P value
Gender	Male	434(50.76%)	421(49.21 %)	$\chi^2=27.41$ $p<0.0001^*$
	Female	475(63.75 %)	270 (36.24%)	
Carries Bag Weight	<10 % of body weight	419 (50.79%)	406 (49.21%)	$\chi^2=33.97$ $p<0.0001^*$
	10-15% of body weight	283 (59.08%)	196 (40.92%)	
	>15% of body weight	207 (69.93%)	89 (30.07%)	
Simplified dietary gap assessment tool score (Total score =10)	≥ 8	173 (52.58%)	156 (47.42%)	$\chi^2= 8.49$ $p = 0.014^*$
	6-7	484 (55.70%)	385 (44.30%)	
	≤ 5	252 (62.69%)	150 (37.31%)	

* $p<0.05$

The results of the univariate and multivariate logistic regressions are presented in Table 4 (Crude and adjusted odds ratios) and showed that musculoskeletal pain had a significant association with female gender, bag weight more than 10% of the body weight and Simplified dietary gap assessment tool score ≤ 5 out of 10.

TABLE 4. Risk factors associated with musculoskeletal pain among the study population using univariate and multivariate regression

Variables		Univariate Logistic Regression			Multivariate Logistic Regression		
		COR	95% CI	p	AOR	95% CI	p
Gender	Male Female	1.70	0.69-4.16	0.17	1.65	0.72-3.77	0.163
Carries Bag Weight	<10 % of body weight		1			1	
	10-15% of body weight	1.39	1.01-1.93	0.046*	1.29	1.05-1.58	0.025*
	> 15% of body weight	2.25	0.94-5.35	0.060	2.04	0.90-4.62	0.071
Simplified dietary gap assessment tool score (Total score =10)	≥ 8		1			1	
	6-7	1.13	0.87-1.46	0.33	1.10	0.68-1.78	0.59
	≤ 5	1.51	1.12- 2.03	0.006*	1.39	0.98-1.95	0.05*

*p<0.05

Discussion

The prevalence of musculoskeletal pain was 56.8% among the school going students of age between 10 to 19 years. In one study done in New Zealand, the musculoskeletal symptoms were reported by 77.1% of adolescent school students.¹⁴ The cross-sectional descriptive study involving 532 pupils from six primary schools with a mean age of 13.6 years suggested that about 35.4% of the children reported that carrying the schoolbag was the cause of their musculoskeletal pain.¹⁵

The present study revealed that there is a significant association of pain among female participants in the χ^2 analysis (p <0.0001). 63% of females reported musculoskeletal pain as compared to 50% males. However, with the multivariate regression model the gender-wise difference was not found to be significant

(p=0.163; OR1.65; 95%CI 0.72-3.77). In a community-based study in Maharashtra (India) conducted in children from various schools of the age group of 11 to 14 years, the musculoskeletal problems related to use of backpacks was more in females (66.53%) as compared to that of males (55.02%).¹⁶ Females tend to have a higher prevalence of back pain (30%) and neck pain (33.9%) compared to that of males (25.7% and 23.8%) respectively.¹⁷

In the present study, it was observed that only 51% of students were carrying bag weight less than 10% of their body weight. As per the recommendation of The National Commission for Protection of Child Rights, measures should be taken to reduce the weight of school bags which the children carry. The suggestions for the junior classes included making month-wise

books with relevant chapters of all the subjects that will be taught in a particular month. It also suggested making changes in the Right to Education Act, 2009, so that children can avoid carrying more than 10 per cent of their body weight as their daily school bag.¹⁸ A study involving Malta school students (aged 8–13 years), over 70% exceeded the recommended 10% bag weight to body ratio and out of which 32% complained of back pain, which was related to gender, body mass index and bag weight.¹⁹

The current study revealed that 29.9% students carried the bag weighing between 10-15% of their body weight have significant association of musculoskeletal pain than those students carrying less than 10% of their body weight in multivariate analysis. ($p=0.025$ OR 1.29 95% CI 1.05-1.58). The risk of getting musculoskeletal pain in the students carrying more than 15% of their body weight had two times higher than students carrying less than 10% of their body weight ($p=0.071$ OR 2.04 95% CI 0.90-4.62). This finding can be correlated with a similar study conducted in preadolescent children in Mangalore, India suggesting that bag pack weighing 15% of the bodyweight has an impact in the craniovertebral angle especially the head on neck angle, and head and neck on trunk angles affecting the posture.⁴

The overall data from the current study suggests that in single-site pain the shoulder pain 35.6% (570) was more prevalent whereas, in the two site pain complaints, shoulder and back 9.5% (153) was prevalent. Around 2.3% (38) participants complained of three site pains in neck, shoulder and back. The findings of single-site pain were similar with the studies conducted among children which also highlighted mostly the single-site such as most on shoulders (57.9%), followed by neck (44.3%), upper back (36.4%), lower back (35.0%), and rest arms, legs, knee and hip.¹⁴

In the present study, the dietary gap assessment tool¹³ effectively overcame the challenge among the adolescents to understand the complex concept of portion size and frequency of food intake. It was found that the students having more dietary gap tend to develop musculoskeletal pain. In our study, the students having dietary gap score ≤ 5 have more prevalence of musculoskeletal pain from those students who had dietary gap ≥ 8 ($p=0.05$; OR 1.39; 95%CI 0.98-1.95).

Similar Questionnaire-based studies in the form of Food frequency questionnaire is being used in one study conducted in Greece to assess the dietary calcium intake in common population.²⁰ Dietary gap analysis was conducted in Cameroon which can be of help in the development of strategies for both the supply and demand to achieve a healthy diet.²¹

Conclusion

The findings of the present study emphasised that the weight of the school bags needs to be restricted $\geq 10\%$ of the bodyweight of the student. The dietary modification may be made in the daily intake of the food items so that the nutrient gap in the daily diet of adolescents can be minimised.

Conflict of Interest: Nil

Source of Funding: Self

Ethical Clearance: The study was approved by:

Institutional Ethics Committee of All India Institute of Medical Sciences, New Delhi, India bearing number IEC/555/9/dated 22/11/2017

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Effect of Virtual Reality Training Using Leap Motion Controller on Impairments and Disability in Patients with Wrist and Hand Stiffness

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Abstract

Background and Purpose: Virtual reality (VR) training targets not only the musculoskeletal, but also the neurological system and has been successfully used in neurological rehabilitation. Our objective was to test whether there are any benefits of adding VR training with conventional physiotherapy on impairments and disability of wrist and hand stiffness, in patients with distal forearm fractures and early rheumatoid hand affection.

Methodology: In this experimental study, 50 patients suffering from wrist and hand stiffness were alternately allocated into either Conventional physiotherapy group and VR with conventional physiotherapy group. Both the groups completed 8-12 training sessions over a period of 4 weeks comprising of similar protocol of conventional physiotherapy with only the VR group receiving additional VR training. Patient was assessed on outcome measures pre and post treatment.

Results: All the outcome measures showed significant improvement in both groups. On between group comparisons, the VR group showed significantly greater improvements on the outcome measures of grip strength, dexterity (left hand and assembly), wrist flexion, ulnar deviation, forearm range of motion and work component of Michigan Hand Questionnaire when compared to the conventional group. There were no differences between groups on outcome measure of pain, wrist extension, wrist ulnar deviation and total disability score of Michigan Hand Questionnaire.

Conclusion: We conclude that, adding virtual reality training to conventional physiotherapy has benefits on outcome of grip strength, hand dexterity, work component of disability and direction specific improvement in the range of motion of wrist and forearm as compared to conventional physiotherapy alone.

Key Words: *Virtual Reality Training, hand rehabilitation, Gaming, distal end forearm fractures.*

Introduction

Human hand is a highly evolved distal functioning part of the upper extremity. Function of the human hand

is not only limited to prehension and manipulation of objects, but it also serves as a medium of interaction with the environment and tool for communicative gestures. This is possible due to the musculoskeletal system integrity coupled with a highly developed neurological system that controls hand function¹. Any injury to the forearm hand complex can adversely affect the hand function.

Impairments of pain, deficits in fine dexterity and reduction in grip strength persist in patients in the long

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term after distal end radius fracture^{2,3,4}. Functional impairments of hand stiffness and weakness were associated with difficulty in return to their work, even after one year in patients post distal radius fracture.⁵ Moore CM & Leonardi-Bee J, have demonstrated that moderate to very severe disability persists in patients up to one year post distal radius fracture.² Hence, it is important to provide appropriate rehabilitation to the patients presenting with hand conditions in order to lower the incidence of complications over a period of time.^{6,7}

A wide variety of exercises, addressing both impairments and functional deficits are utilised in hand rehabilitation. More recently, technology in the form of Virtual Reality (VR) based therapy has become an important medium of rehabilitation by physical therapists. Virtual Reality therapy refers to a broad class of interventions, but can generally be defined as technological interventions that alter properties of the physical world⁸. VR technologies have emerged within medical research in recent years for treating acute pain, and proved to be an effective strategy based on pain distraction^{9,10}. In neurological conditions, like Parkinson's disease treatment with VR training have demonstrated improvements in the motor learning¹¹. In musculoskeletal conditions, use of VR showed reduction in pain intensity and neck disability and improved cervical ROM in the short term.¹²

A number of VR gadgets are now available like Microsoft Kinect, Nintendo Wii-Fit etc., but they do not primarily detect fine hand and finger movements, and hence, would be of limited benefit in hand rehabilitation. The Leap Motion Controller (LMC) is a low-cost, marker-less motion-capture device that tracks the fine movements of fingers and hands using neither data gloves nor markers¹³. LMC device can track the movement of multiple hands and fingers, within sub-millimetre accuracy. The usability of the device in the early rehabilitative phase in stroke patients was good to excellent¹⁴. Virtual reality training with LMC device has been shown to facilitate motor recovery and dexterity of a paretic upper limb¹³. However this device is less explored with in hand conditions of musculoskeletal origin. Hence, the objective of our study was to assess whether adding Virtual Reality therapy has additional benefit over only conventional Physiotherapy on

impairments and disability in patients with wrist and hand stiffness.

Methodology

Study Setting and participants

The study was conducted at the D.Y. Patil Hospital & Research Centre, Navi Mumbai.

Ethical permission was obtained from the Institutional Review Board. Patients between the age of 18-70 years, with residual wrist and hand stiffness, post wrist fractures/ injury or due to rheumatoid arthritis were included in the study after obtaining an informed consent. The aetiology included distal end radius (DER), distal end ulna (DEU), mid-shaft radioulnar fractures with ORIF plating and Rheumatoid Arthritis presenting with wrist and hand pain but free of deformities.

Patients were excluded if they were suffering from any condition affecting the shoulder or elbow joint, having cognitive impairments or neurological conditions like Parkinson's disease Stroke, etc.. Pregnant women and patients with rheumatoid arthritis with hand deformities, and tendon injuries, nerve injuries of the upper limb were also excluded from our study.

Study Design

The study design was an intervention based parallel group study. The participants were alternately allocated using single blinding method into two groups: Experimental/Virtual Reality Training group (Group I) and Conventional group (Group II).

Group I included supervised virtual reality (VR) training combined with conventional physiotherapy and the Group II included only supervised conventional physiotherapy.

Outcome measures

Patients were then assessed by physical examination on the aforementioned outcome measures before and after intervention. Pain was measured with Visual Analogue Scale (VAS); wrist and hand range of motion (ROM) using the Universal Goniometer; Grip Strength using Jamar Dynamometer; Hand Dexterity using Perdue Pegboard and hand disability using the Michigan Hand Questionnaire (MHQ).

The Michigan Hand Questionnaire is a valid and a reliable tool used in the assessment of hand conditions incorporating components of pain, aesthetics, function, work and satisfaction.^{15,16} The grip strength measured using the Jamar Dynamometer has high inter-rater reliability, high accuracy and strong validity.¹⁷ Abundant research has been done in healthy population for hand dexterity using the Purdue Pegboard, a tool with well-established validity and reliability.¹⁸

Intervention

For *Group I*, treatment protocol consisted of 15-20 minutes of conventional physiotherapy, followed by VR training for 10-15 minute. Patient in this group, received 2 sessions/ week of training with VR.

The patient was seated on a chair with back rest and elbows supported. VR was delivered with Leap Motion Controller device (Leap Motion Inc, 2013) that consists of an optical sensor which works with computer interaction. Leap Motion Controller (LMC) is a motion based device specially designed for acquisition of 3D positions and orientations of hands and fingers. The device consists of two monochromatic IR cameras and three infrared LEDs giving the device a semi-spherical observational area with a distance of approximately 1 meter.¹⁹ There are more than 30 online free downloadable games that can be used for rehabilitation at the LMC gallery. We chose five games appropriate to our protocol. Each game used for the treatment purpose had a variety of levels and progression to the next level occurred only on completion of the previous level. If the patient was unable to progress due to discomfort or incompetency for the previous level, he/she would not be progressed to the next level.

Group II received conventional physiotherapy under the supervision of the therapist for 25 minutes/session. The

treatment protocol for the conventional physiotherapy included muscle stretching, joint mobilisation, range of motion and strengthening exercises for wrist and hand muscles, as per the impairments.

Patients of each group received a total of 8-12 sessions of treatment over a period of 4 weeks i.e. 3 sessions/week. The total number of sessions were same for both the groups. The patients in both the groups were assessed on outcome measurements pre-intervention and after 4 weeks of intervention.

Statistical analysis

The statistical analysis of the study was done using the “R Programming” software and 95% confidence level was used so that level of significance was set at $p = 0.05$, two-tailed. The distribution of the outcome measures was checked using the test for Normality - Kolmogorov-Smirnov test. The results showed that the data was not normally distributed and hence non-parametric tests have been used for further analysis of the outcome measures. Wilcoxon test was used to conduct within group analysis and Mann-Whitney U for between group analysis.

Results

Fifty participants with injury to forearm hand complex were alternately allocated to either conventional physiotherapy or VR group. The age of the patients matched at baseline between the two groups (p value = 0.992, which is >0.05).

Table 1 demonstrates patient characteristics in each group. Patients demonstrated moderate to severe pain, moderate to severe hand disability and dominant hand more affected than the non-dominant. There were no significant differences between the groups at baseline ($P > 0.05$) on demographics measures.

Table 1

Parameter	VR group	Conventional Group
Mean Age (years)	48.8	47.9
Gender – Male: Female ratio	10:15	10:15
Dominance - right: left	19:6	19:6

Cont... Table 1

Affected hand – right: left ratio	13:12	14:11
VAS	7.04	6.96
MHQ- Overall	40%	46%

Values are presented with numbers or percentage.

Tables 2 and 3 demonstrate within group change in outcome measures pre-intervention and post-intervention for VR group & conventional respectively with statistical analysis. Within group statistical analysis indicate that both the groups improved on all outcome measures (Table 2 & 3).

Table 2: Within group changes in parameters in VR Group, presenting results of pre and post intervention

Outcome Parameters		Pre- intervention	Post- intervention	p value#
Pain (VAS)		7.04±0.89	1.76±1.13	.000*
Grip Strength (kg)		6.72±3.45	8.88±3.59	.000*
Swelling(cm)		41.68±3.56	38.96±2.86	.000*
Dexterity (Purdue Peg board)	Left	9.48±3.06	11.64±2.12	.000*
	Right	10.88±2.03	12.36±1.68	.000*
	Both	7.24±1.67	8.6±1.63	.000*
	Assembly	4.56±1.36	5.96±1.46	.000*
Disability (MHQ)	Overall	40.60±20.78	73.00±21.51	.000*
	ADL 1 hand	44.80±29.84	87.00±11.18	.000*
	ADL 2 hand	70.76±17.80	93.10±6.86	.000*
	ADL Overall	59.67±22.52	91.16±7.28	.000*
	Work	15.60±9.86	68.40±10.07	.000*
	Pain	52.60±29.62	8.80±7.54	.000*
	Aesthetics	38.49±23.30	86.22±12.90	.000*
	Satisfaction	46.37±27.36	85.97±6.90	.000*

Cont... Table 2: Within group changes in parameters in VR Group, presenting results of pre and post intervention

Wrist & Forearm ROM	Flexion	42.2±14.80	77.84±8.27	.000*
	Extension	33.20±20.51	63.12±11.79	.000*
	Ulnar Deviation	17.72±4.55	27.4±4.79	.000*
	Radial Deviation	16.28±5.91	26.48±5.04	.000*
	Supination	46±23.58	84.6±5.39	.000*
	Pronation	62.28±30.16	89.60±1.38	.000*

*significant #Wilcoxon Signed Ranks Test

Table 3: Within group analysis of changes in parameters in Conventional Group pre intervention and post intervention:

Outcome Parameters		Pre-intervention	Post- intervention	p value#
Pain (VAS)		6.96±0.84	2.16±1.49	.000*
Grip Strength (kg)		7.48±3.96	8.76±4.38	.000*
Swelling(cm)		40.88±2.99	38.64±2.74	.000*
Dexterity (Purdue pegboard):	Left	11.04±2.03	12.52±1.78	.000*
	Right	11.56±2.14	13.24±1.42	.000*
	Both	8.32±2.29	9.64±2.23	.000*
	Assembly	4.20±1.19	5.12±1.09	.000*
Disability (MHQ)	Overall	46.00±18.71	83.00±14.22	.000*
	ADL 1 hand	48.00±24.28	87.40±8.18	.000*
	ADL 2 hand	68.81±23.19	93.12±8.18	.000*
	ADL Overall	62.19±19.74	91.60±5.77	.000*
	Work	26.00±17.38	70.60±10.24	.000*
	Pain	47.40±23.59	7.20±7.08	.000*
	Aesthetics	49.48±26.82	86.00±10.70	.000*
	Satisfaction	49.41±19.14	87.15±9.00	.000*

Cont... Table 3: Within group analysis of changes in parameters in Conventional Group pre intervention and post intervention:

Wrist & Forearm ROM	Flexion	49.32±14.26	73.44±11.45	.000*
	Extension	39.08±17.23	63.12±16.00	.000*
	Ulnar Deviation	21.4±8.07	26.44±5.74	.000*
	Radial Deviation	14.56±4.63	23.16±6.32	.000*
	Supination	55.6±21.95	77.24±13.77	.000*
	Pronation	76.88±20.77	89.4±1.66	.002*

*significant #Wilcoxon Signed Ranks Test

On between group comparisons, the VR group showed significantly greater improvement in grip strength, dexterity, wrist flexion, ulnar deviation, forearm supination, forearm pronation, and the work component of the MHQ, when compared to the conventional group. Whereas, there was non-significant difference between the two groups on the other outcome measures i.e. pain; wrist swelling; dexterity of right and both hands; wrist extension; wrist radial deviation; components of MHQ (overall, ADL, pain, aesthetics and satisfaction) (Table 4)

Table 4: Between group changes in parameters post intervention

Outcome Parameters		VR Group Mean Difference (Pre- post treatment)	Conventional Group Mean Difference (Pre-post treatment)	P value
Pain (VAS)		5.28±1.40	4.80±1.71	0.217
Grip Strength(kg)		2.16±0.62	1.28±0.84	0.000*
Swelling (cm)		2.72±1.65	2.24±1.27	0.504
Dexterity (Purdue Pegboard)	Left	2.16±1.18	1.48±0.77	0.042*
	Right	1.48±0.77	1.68±1.28	0.663
	Both	1.36±1.22	1.32±0.80	0.830
	Assembly	1.40±0.82	0.92±0.70	0.014*
Disability (MHQ)	Overall	32.40 ±26.93	37.00±14.86	0.969
	ADL 1 hand	42.20±24.28	39.40±23.86	0.666
	ADL 2 hand	22.34±13.14	24.32±17.16	0.930
	ADL Overall	31.49±17.86	29.42±16.76	0.381
	Work	52.80±19.32	44.60±14.50	0.038*
	Pain	43.80±28.00	40.20±20.69	0.527
	Aesthetics	47.73±21.15	36.52±20.93	0.057
	Satisfaction	39.60±23.61	37.74±15.00	0.711

Cont ... Table 4: Between group changes in parameters post intervention

Wrist & Forearm ROM	Flexion	35.64 ±14.67	24.12±10.91	0.012*
	Extension	29.92±16.51	24.04±13.85	0.178
	Ulnar Deviation	9.72±4.39	5.04±4.94	0.002*
	Radial Deviation	10.2±5.28	8.6±6.24	0.234
	Supination	38.6±20.23	21.64±15.26	0.003*
	Pronation	27.32±27.10	12.52±20.83	0.045*

* significant change #Mann-Whitney U test

Discussion

The purpose of this study was to test whether Virtual Reality Training has any additional benefits over Conventional Physiotherapy on impairments and disabilities in musculoskeletal related wrist and hand stiffness.

In this study, female patients were more than the male patients (Table 1). This can be attributed to the fact that females being more prone to osteoporosis as a result of menopause and are more prone to fractures as compared to males.²⁰ Most of the patients included in the study suffered from distal end radius fracture. This can be explained by the overall high incidence and prevalence of upper extremity fractures in adults and distal end radius fracture constituted to 18% of all the fractures in the adult population.^{21,22}

Effect on Pain:

Patients in this study were suffering from moderate to severe pain post trauma or rheumatoid arthritis. The significant reduction of pain in both groups could be attributed to the exercises incorporated in protocol for both Groups (Table 2 & 3). Our results are in concordance with previous research reporting pain reduction with administration of exercises in patients with DER fractures^{23,24}.

It has been hypothesized pain reduction with VR occurs via distraction due to increased activity of the anterior cingulate cortex and orbitofrontal region of the brain, due to the high cognitive demand placed while playing the games. This is accompanied by a decreased activity of the pain matrix through attention, emotion

and other senses (e.g. visual, auditory) to modulate pain during distraction²⁵.

Effect on Swelling:

In within group analysis, a significant reduction in swelling was observed in both the groups. This is because the treatment protocol in this study involved exercises with the hand in an elevated position. Also, patients were taught hand exercises in elevation as a part of their home program in order to reduce the swelling.

Effect on Grip Strength:

While patients in both the groups had a significant increase in grip strength, there was significantly more increase in the grip strength in the VR group, as compared to Conventional group (Table 4). Although there was no real-world resistance during the VR training, it can be attributed to the neural facilitation that takes place in the early rehabilitative phase^{26,27} with the use of repetitive pinch and grip movements.¹³

Effect on Dexterity:

In within group analysis, a significant improvement in dexterity was observed in each group. Between group comparison, shows that there was a significant improvement in dexterity (left hand and assembly) in the VR group on comparison with the conventional group. This could be attributed to the intense, highly repetitive and task-specific movements required with VR training.²⁸ Repeated practise of the affected limb may lead to neural re-organisation²⁹ of the imitation-dependent cortex neuroplasticity through mirror neural networks³⁰. Additional improvements in dexterity can be attributed to the neural requirements such as having a

good attention³¹, hand-eye coordination, maintaining the position of the hand in space and performing fine motor movements while playing the VR based games.

Previous studies have demonstrated improvement in both dexterity and motor deficits after VR based training but in a different pathology i.e. stroke patients with neurological deficit in upper limb.^{32,33} We have observed similar benefits as reflected by significant improvement in dexterity in our patients with musculoskeletal hand affection.

Effect on Hand Function:

Post treatment there was a significant improvement in the hand function as measured using MHQ in both the groups. On between group comparisons, a significant improvement in the work component was observed in the VR group, which can be an incidental effect due to the higher percentage of working individuals in the VR group, as there was no significant difference on the total MHQ scores. In our study, 84% of the study subjects in the VR group were working as opposed to 75% subjects in the conventional group.

Effect on Wrist and Forearm Range of Motion:

Both the groups had a significant improvement in the wrist and forearm ROM is observed in the conventional and the VR group (Table 2 & 3). This improvement is in line with previous research which shows that joint mobilization helps in improving wrist range of motion³⁴.

On between group comparisons, significantly more improvement was observed in the VR group in the ROM of wrist flexion, ulnar deviation, forearm supination, forearm pronation with no difference on wrist extension and radial deviation. This could be due to the position adopted by the patient as per the requirement of the game. The games used in our protocol required the wrist to be in the flexed position and forearm in mid-prone or pronation for 10 minutes intermittently, with some other requiring to perform repetitive wrist radial and ulnar deviation.

Conclusion

Virtual Reality training and Conventional training are both individually effective in improving wrist range of motion, grip strength, hand dexterity and reducing and

pain disability in patients with wrist and hand stiffness post distal forearm fractures and early rheumatoid arthritis hand affection.

However, adding virtual reality training to conventional physiotherapy led to greater improvement in grip strength, hand dexterity, wrist flexion, ulnar deviation and forearm range of motion. There was an additional benefit on work component of disability with VR training, but not on overall disability in these patients. Whether direction specific movement improvement occurs with VR training can be explored in detail in future research.

Forthcoming studies can investigate the effect of virtual reality training as a home program treatment in patients with musculoskeletal involvement of wrist and hand.

Limitations:

The duration of treatment in the VR group was 10-15mins more than the conventional group, which could be reason of better outcome in VR group. Single blinding method was used in our study. Patients with two diverse pathologies i.e. distal forearm fractures and early RA affection were included in this study.

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Conflict of Interest: The authors declare no that there was no conflict of interest.

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Efficacy and Safety of Anti Snake Venom, used as per National Guidelines, at a Tertiary Care Centre in Puducherry

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Abstract

Aim: To study the efficacy and adverse events after use of Anti Snake Venom (ASV) and note its usage pattern

Methods: This prospective observational study included 97 cases of snake bite admitted to Indira Gandhi Government General Hospital and Postgraduate Institute, Puducherry from June 2016 to December 2017. Adverse reactions to ASV and clinical response parameters like number of vials of ASV needed, time to response, hospital stay were analysed

Results: Of the 97 cases enrolled and 96 analysable, 59 cases had hemotoxic, 12 neurotoxic, 9 a combination of both and 16 had local envenomation. The mean number of vials used (25.92 +/-12.97), time to control envenomation (35.48 +/- 22.03 hours) and duration of hospital stay (5.79 +/-4.89 days) was not significantly different for any particular type of envenomation

16 patients suffered 49 adverse events, 34 being mild, 10 moderate and 5 severe. The symptom cluster of itching, urticaria, was the most common, seen in 9 patients. This was accompanied by a permutation of tachycardia with colic, vomiting, nausea and diarrhoea. Most were managed by giving an additional dose of hydrocortisone or antihistamine or both. None had to be administered adrenaline.

Conclusions: The ASV brand used, was well tolerated, and the number of adverse events were less than those reported in earlier studies. Authors conclude that the National Guidelines are applicable in majority of the cases but due consideration must be given to the clinician's judgement in individual cases

Key words: Anti-snake venom serum, Pharmacovigilance, envenomation, hemotoxic, neurotoxic, national snake bite guidelines

Introduction

Snake bite is an unexpected life-threatening emergency. Snakebites are under reported as patients often use locally available traditional medicine of suspect efficacy, and many do not reach the treating centres at all. The million deaths study estimated about 45900 deaths annually due to snakebite in India¹.

ASV is a lifesaver in snakebites but being of animal origin, it can itself cause serious reactions, including fatal anaphylaxis. However, considering the risk associated with snake bite envenomation, ASV has to be

administered, sometimes with premedication, to prevent possibility of adverse reaction².

Various snakebite management guidelines recommend different schemes for administration of ASV. The Indian National Guidelines recommend up to 20 vials for neuroparalytic envenomation and up to 30 vials for hemotoxic envenomation³. Yet one finds that more than recommended number of vials are often used for snakebite management. Every institute has a protocol in slight variance with the guidelines; justifiably so, because it has been developed out of their own experience.

Premium Serums and Vaccines Pvt Ltd (PSVPL) have recently introduced their brand of ASV which was made available to us at Indira Gandhi Government General Hospital and Post Graduate Institute (IGGGH&PGI). We decided to conduct a post marketing study on this product with a dual purpose. Other than recording adverse events we decided to go by the recommendations and confirm whether they apply in our settings. The secondary objectives were to evaluate the correlation, if any, between various parameters like type of envenomation, time elapsed before ASV was started, time to stop ASV, duration of stay, number of vials used and number of patients experiencing side effects

Materials and Methods

This open label study was carried out from June 2016 to December 2017 at IGGGH&PGI after approval by the institutional ethics committee. Two out of the three medicine units participated in the study. Every patient of either sex, with snake bite, and a clinical envenomation serious enough to administer ASV was enrolled after obtaining informed consent from the patient or his/her legally acceptable representative.

Patients were treated as per standard of care adopted at the institute. Patients were not excluded because of any comorbid conditions or concomitant medications. Pregnancy was also not an exclusion criterion since ASV is lifesaving.

In a few earlier studies patients with known systemic diseases like pre-existing renal disease, uncontrolled chronic obstructive airway disease, congestive heart failure or previous myocardial infarction and those taking diuretics, anticoagulants and antiplatelet drugs were excluded^{4,5,6}. This was because these illnesses and medications could have altered the clinical and laboratory profile of patients with envenomation. We included all of such patients too since this was a study in real time.

Patients were categorised as neuroparalytic envenomation if they presented with ptosis, dysphonia, dyspnoea, dysarthria, diplopia, respiratory failure and head lag, Not being able to speak a complete sentence and a single breath count of < 30 numbers confirmed the diagnosis

Patient presenting with epistaxis, bleeding gums, vomiting, haematemesis, haemoptysis, bleeding from freshly healed wounds, acute abdominal pain along with

a (Whole Blood Clotting Time) WBCT >20 minutes were classified as hemotoxic envenomation.

Local swelling, blistering, necrosis, pain at bite site, severe swelling, absent pulse, lymph node enlargement selected itself as local envenomation on lines of the painful progressive swelling classification in National Guidelines³. If this was associated with symptoms of hemotoxic or neurotoxic envenomation it got classified under the larger head as in WHO as well as National Guidelines^{2,3}.

PSVPL supplied ASV in 20 ml glass vials with 10 ml sterile water for injection, as diluent. 10 vials were administered by slow IV or infusion over one hour. Pheniramine maleate 0.5mg/kg and Hydrocortisone 100mg were given to all patients prophylactically, five minutes prior to administration of ASV.

Following an adverse reaction ASV was discontinued. Hydrocortisone 100 mg iv and Inj Pheniramine 0.5 mg/Kg iv was repeated. Inj Adrenaline 0.1 ml of 1 in 1000 was given subcutaneously when required. Once the patients had recovered, ASV was restarted slowly keeping the patient under close observation.

ASV was repeated based on the WBCT findings after 6 hours. Antibiotics, neostigmine, atropine, renal and ventilatory support were administered as required

ASV was discontinued on WBCT reaching normal, no further bleeding or spreading cellulitis and no evidence of evolving acute kidney injury in case of hemotoxic envenomation. In case of neurotoxic envenomation clinicians waited till ptosis had resolved, patient could speak full sentences, count to more than 30 in each breath and could be weaned off the ventilator. In cases with predominance of local envenomation one had to wait till after active tissue damage was controlled.

Demographic information, nature of snake, time of snake bite, anatomical site of bite, time interval between snake bite and ASV administration, total quantity of ASV needed, laboratory investigations, comorbid conditions and concomitant medications was recorded on the Case Record Form.

Results were analysed using descriptive statistics, and parametric and non-parametric tests as appropriate

Results

97 cases of snakebite were enrolled in the study.

There were 70 males between 19 and 70 yrs (mean age 48.6 yrs), and 27 females between 16 and 77 years (mean age 40.3 yrs.). Data about occupation was recorded in 92 cases. 34 were involved in agriculture, 55 were pursuing other professions, 1 was a student and 2 homemakers. At the time of bite, from available records, 39 were walking, 32 working, 16 sleeping and 2 playing. 18 lived in RCC houses, 44 in semi built and 20 in thatched houses. Tourniquet was used in only 9% cases and 33% were immobilised. 64 cases were brought to the hospital and received the first dose of ASV within 6 hours.

One case came to the hospital after having received 20 vials of ASV elsewhere, which was followed by 20 more in the hospital. Since Premium Serum ASV was administered we considered the case for evaluation of adverse events but not for other analyses.

Envenomation was classified clinically before therapy. Distribution of different types of envenomation is shown in Table 1. The number of vials used for various types of envenomation, time to stop ASV and duration of hospital stay are also listed. There was no significant difference for any of these parameters across various types of envenomation.

Distribution of vial use is shown in table 2.

16 patients suffered 49 adverse events (table 3), 34 being mild, 10 moderate and 5 severe. The number of patients suffering ADRs did not vary as per envenomation (Table 1). 12 cases needed ventilatory support, 7 dialysis, 7 needed platelets and fresh frozen plasma due to coagulation disorders and 3 required surgical debridement.

Table 1: Distribution of envenomation types, mean number of vials of ASV used, duration of hospital stay, duration of ASV administration and number of cases with adverse events across envenomation

Envenomation	N =	Mean No. of vials used (SD)@	Mean duration of ASV use - hours (SD) #	Mean duration of stay - Days(SD) \$	No. of cases with ADRs**
Haemotoxic	59	26.44(13.36)	39.17(24.37)	6.12(5.66)	10
Haemo and neurotoxic	9	32.22(13.97)	38.22(9.64)	5.50(2.74)	2
Local	16	19.88(8.34)	27.25(17.11)	4.19(1.56)	4
Neurotoxic	12	26.67(13.03)	26.25(17.78)	6.5(4.6)	0
Total	96*	25.92(12.98)	35.48(22.03)	5.74(4.89)	16
f value		1.97009	2.11598	0.83654	

*Patient # 6 who had been administered ASV before admission, not considered

@ Mean number of vials, # Mean duration of ASV administration and \$ Mean duration of hospital stay across envenomation are not significant

** Number of patients with adverse events across envenomation is not significant as per Chi square

Table 2: Distribution of vial use

CATEGORY	FREQUENCY	Cumulative %
Up to 10	23	23.95
20	27	52.08
30	21	73.95
40	18	93.68
50	5	97.71
60	2	100
TOTAL	96	100

Table 3: AEs distribution in 16 patients

Event	Mild	Moderate	Severe	Total
Urticaria	5	2	2	9
Itching	7	3	1	11
Cough	1	1	1	3
Nausea	2		1	3
Vomiting	2	2		4
Abdominal pain	4	1		5
Diarrhoea	1			1
Fever	0	0	0	0
Tachycardia	6	1		7
Hypotension	3			3
Bronchospasm	2			2
Angioneurotic oedema	1			1
Total	34	10	5	49

Table 4: Duration of hospital stay across various envenomation and a bite to needle time of 6 hours

	Envenomation Type	Time to ASVS											
		Under 6 hours				More than 6 hours				Total			
		N	Mean	SD	ADRs	N	Mean	SD	ADRs	N	Mean	SD	ADRs
Duration of Hospitalization (Days)	Haemotoxic	39	6.36	5.58	6	20	5.65	5.94	4	59	6.12	5.66	10
	Neurotoxic	8	6.63	5.32	0	4	6.25	3.40	0	12	6.50	4.60	0
	Local only	9	3.56	1.33	1	7	5.00	1.53	3	16	4.19	1.56	4
	H+N	9	5.50	2.93	2	0	0	0	0	9	5.50	2.74	2
	Total	65	5.89	4.91	9	31	5.58	4.91	7	96	5.79	4.89	16

Dependent Variable	Source	Type III SS	df	Mean Square	F	p
Duration of Hospitalization (Days)	Envenomation	159.77	3	53.26	2.3	0.0823
	Time to ASV (6hr)	42.68	1	42.68	1.85	0.177
	Envenomation * Time to ASV (6hr)	85.49	3	28.5	1.23	0.3032

No of patients with ADRs vs 6 hrs bite to needle time not significant Chi square

Discussion

Due to variations in the snake toxin based on region and climate, one often encounters a mix of clinical signs and symptoms, making it difficult to precisely classify the patient into a particular type of envenomation category. In our case we had cases that were hemotoxic, or neurotoxic alone and also a combination of both. Many of these were accompanied with additional local or general signs and symptoms. Cases which showed exclusively local symptoms without change in WBCT or signs of neurotoxicity were classed in a different bucket.

Hemotoxic envenomation was controlled with a mean of 26.44 vials while neurotoxic required 26.67 vials. In India, out of “Big Four”, haemotoxic envenomation is caused by Russell’s vipers and Saw Scaled Vipers and Neurotoxic envenomation by Indian Cobra and Common Kraits.

Russell’s viper envenomation from Southern India and Sri Lanka also manifests neurotoxic symptoms, since Phospholipase A2 is the major class of toxin in South Indian Russel Viper venom [7]. The same has also

been mentioned in WHO-SEARO guidelines. It was seen in the present study that there were 9 patients (9.375%) with combined Syndrome of Haemotoxic and neurotoxic envenomation which has not been mentioned in National Guidelines. Five of these required ventilation and 2 needed administration of blood products. This category required the highest mean number of vials (32.22) to control envenomation

Our mean of 26.44 vials for haemotoxicity is well within the recommendation of National Guidelines. Out of the 59 cases, 4 cases needed renal support in the form of dialysis as well as substitution of blood products, and 3 each needed renal and hematological support alone. 3 cases had to be referred for surgical debridement.

In case Neuroparalytic poisoning we needed a mean of 26.67 vials, higher than national recommendations. In cases of Krait bite, since it is of the presynaptic variety, symptoms of paralysis take time to resolve. In the absence of knowledge about the biting species, clinicians tend to overdose. Out of the 12 neuroparalytic cases some were administered 40-60 vials, accounting for the variation.

In our study we noticed a group of patients who had only local manifestations without any bleeding or clotting disturbances or signs of neuroparalysis. WHO SEARO guidelines mention local involvement in 3 out of the 5 syndromes but always with bleeding, kidney or neural involvement. The Indian guidelines have a category of painful progressive swelling which is close. In spite of only local involvement these cases needed an average of 19.88 vials with a range of 8 to 60 vials.

Several species of Pit Vipers have been reported to cause bites in Southern India². The venom of Pit vipers rarely cause fatalities but can cause extensive local tissue degeneration exhibited by extensive local swelling⁸. The current ASV does not contain specific neutralizing antibodies against venom of Pit vipers and in the absence of any confirmatory tests for diagnosing offending snake species, may lead to administration of higher quantities ASV.

Overall, 51 % cases were managed with 20 vials, and 73% with up to 30 vials (Table 2). So, in a setting like Puducherry, even if we assume that there are local differences in presentation, the WHO and Indian guidelines^{2,3} do hold true. These numbers also compare favourably with findings in earlier studies.

Suchithra N et al⁶ mention that median number of vials used to control envenomation was 22 with a range of 3 to 62 vials. Bhattacharya P⁹ in his series of 13 neuroparalytic cases needed between 10 and 30 vials over two days. Amin MR et al⁴ in their study of neurotoxic poisoning used 10 vials per patient.

National Guidelines mention that if one waits for 6 hours for manifestations of envenomation to develop, it would result in systemic envenoming and high fatality³. Suchithra N⁶ also noticed that those patients who had a bite to needle time of greater than 6 hours has a higher incidence of complications. Mathivani et al¹⁰ observed that patients who had a bite to needle time of more than 8 hours had more complications. Assuming that complications would translate into longer hospital stay, we decided to divide the population into those who received the first dose of ASV within 6 hours of bite and those who received it later to compare the duration of hospitalisation. There was no significant difference in the duration of hospital stay across different types of envenomation. The number of patients suffering adverse events also did not vary based on the 6-hour cut off. (Tables 4)

Adverse Drug Reaction monitoring

16 cases experienced 49 adverse events after administration of ASV, all of which were expected as per the pack insert (Table 3). The symptom cluster of itching, urticaria, was the most common, seen in 9 patients. This was accompanied by a permutation of tachycardia with colic, vomiting, nausea and diarrhoea. Most were managed by giving an additional dose of hydrocortisone or antihistamine or both. None had to be administered adrenaline. These could be classified as early ASV reactions³. In the remaining patients the clustering occurred at random. There was no case of pyrexia.

Hemotoxic and hemotoxic with neurotoxic envenomation, accounting for 12 of 16 cases of ADRs while local envenomation accounted for 4. No patient with neurotoxic envenomation suffered an ASV related adverse event. These differences were however not statistically significant (Table 1).

Incidence of adverse events in only 16 of 98 (16.3%) is much lower than that seen in studies reported from India and other countries.

Amin MR et al during their prospective study in neurotoxic poisoning in Bangladesh, recorded anaphylaxis in 20 of 35 cases (57%). Patients had urticaria, itching, nausea vomiting, wheezing and rhonchi. Although they labelled these symptoms as anaphylaxis, only 2 cases had to be administered adrenaline. The rest were managed by steroids., very much like our cases⁴

In India Deshmukh VS et al¹¹, in their study on 50 cases of snake bite, reported adverse reactions in 62% i.e. 31 cases. There were 51 events reported of which 27 (53.94%) were of early anaphylactic type and 23 (45.1%) were pyrogenic in nature

Deshpande RP et al¹² studied snakebite cases over 2 seasons. Out of 164 patients who received ASV, 92 (56%) experienced adverse events. The most common presentation of reaction were chills, rigors (69.3%) followed by nausea and vomiting (41.3%). 15% patients suffered from moderate to severe reactions like hypotension and sudden respiratory arrest. There was a higher incidence of antivenom reactions in cases of vasculotoxic snake bites (52.17%) as compared to neuroparalytic snake bites (21.74%) similar to our findings.

Mathivani M et al¹⁰, in their yearlong study on hemotoxic bites noticed adverse events in 127 out of 212 (59.9%) cases. Most of them were early reactions occurring within a mean duration of 18 minutes of administration of ASV

Seneviratne SL et al¹³ in Sri Lanka reported that acute adverse reactions to ASV occurred in 102 (55.4%) patients given ASV. There was no significant difference in the rate of reactions whether premedication was given or not. Fan HW et al⁵ from Brazil, had similar findings about the use of prophylactics. They reported ADRs in 25 of 101 cases administered ASV, and there was no reduction after premedication with promethazine. In our study hydrocortisone and antihistamines were used as prophylactics but going by above findings we can assume that they were not the reason behind fewer adverse effects

Lower incidence of adverse events compared to earlier studies without a single case of pyrexia could be attributed to better manufacturing techniques as proposed by Kalyankumar et al¹⁴.

Conclusion

The findings of the study indicate that ASV manufactured by PSVPL was safe showing only expected AE's which could be well managed clinically. The ASV was also found to be effective, requiring average of 26 vials per treatment irrespective of the envenomation syndrome.

More than recommended vials were necessary if the patient has sought alternate means of therapy, or failed to identify the bite as in a krait biting a sleeping individual. More vials could also be needed if the species is a local variant and not fully covered by the available polyvalent serum and if the patient's renal functions are under stress. The national guidelines are certainly applicable in majority of the cases but due consideration must be given to the clinician's judgement in individual cases.

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Upper Extremities Fractures in Alnajaf/Iraq

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Abstract

Purpose To take an idea about the size of an important socioeconomically public health problem, which are fractures of the upper extremities

Material and Methods: All the patients who sustained upper extremities fractures in one year (between 1st Jan. till 31st Dec. 2018) included in this study. Data collected from the documents of alsader medical city in Alnajaf, it included the types of fractures, ages, gender, side of fracture, and causes. Analysis of these data was done and the results were demonstrated in tables.

Results : The total number of the patients were (3067), males 2231 and females 835. The number of fracture clavicle 168, proximal humerus 28, shaft humerus 163, supracondylar fracture 169, elbow fractures 85, forearm fractures 823, lower radius in children 292, wrist fracture 193, and hand fracture 310. People in the 1st decade were the most 1132 followed by the 2nd decade 949, 3rd decade 421, 4th decade 256, 5th decade 141, 6th decade 104, 7th decade 36, and above 70 (28) patient. The most common cause of the fractures was fall in 1263 patient followed by fall from height 810, sport (football) 292, direct hit 243, RTA 214, and fall of heavy object 155 patients.

Conclusion: Children and adolescent are mostly affected. Planes from all the government administrations showed decrease the occurrence of such injuries by learning programmes to avoid fractures in all ages, in order to decrease the socioeconomically burden on the community.

Key words (*upper extremity, fractures, upper limb, Alnajaf*)

Introduction

Trauma is becoming more common with the increase of speed and involvement of more people in sports. Fractures due to trauma is an expanding public health problem, serious fractures may lead to mortality and morbidity.^(1,2,3) Upper extremity injuries are common including soft tissue, joints and bones, fractures are the most common disorders.^(4,5) Upper limb fractures are more common among young and elderly people. In children and adolescent the increasing rate is because they are more active and involved more in sports, and also they are less skilled at risk assessment, while in aged patient the rate is increasing because of

the increasing population of aged and also those people have osteoporosis. Males are affected more than females except in elderly where the incidence is more in females.^(1,2,6,7) In US the number of osteoporotic –related fractures was estimated to exceed 2 million in 2005 with a total cost of \$17 billion.⁽⁸⁾

Little was written about upper extremities fracture in Iraq especially in Alnajaf city.

This paper is to discuss this problem from all sides regarding types of fractures, age groups and the causes. By putting the facts in front of the administrations we aim that they will start to put planes to decrease the rate

of occurrence of these fractures and to but solutions and improve the methods of early management to decrease morbidity among population.

Material and Method

This paper was conducted on patients attended the main hospital(Alsader teaching hospital) in Alnajaf city/Iraq in the period between the 1st of January 2018 to the 31st of December 2018.The data was collected from the documents of the outpatient clinic and from the emergency ward. The data include the age, gender, type of fracture, and the cause. For the age the patients were grouped according to the decades from one year old up to above 70 years old.

Regarding the types of fractures we started proximally from the clavicle, proximal humerus, shaft of humerus, supracondylar fracture (SCF), elbow fractures, forearm, lower radius and ulna, wrist fracture, and hand fractures. Elbow fractures (a part from SCF) include condylar fractures, fracture olecranon, epicondyle fractures, fracture head of radius and fracture neck of radius. Lower radius & ulna fractures in children include

metadiaphyseal parts. Wrist fractures in adult include all types of fractures of lower radius. Hand fractures include scaphoid fractures, metacarpals and fracture phalanges.

The causes of fractures include fall during walking or playing, fall from height (FFH), road traffic accidents (RTA), fall of heavy object (FHO), direct hit, sport mainly foot ball (FB), bullet injury, injury due to explosions, and machine injuries.

Statistical Analysis

Statistical analysis was done by using SPSS (statistical package for social sciences) version 20, in which we use frequency and percentage, mean and standard deviation as descriptive statistics. Chi square test used for analytic statistics.Pvalue <=0.05 regarded significant.

Results

The total number of the patients was 3067 in one year. The number of the males was 2231(72.74%) and the number of females was 855(27.22%).

Table one shows details of gender, age range, mean age, and the side of the fractures.

Table (1): types of fractures, gender, age, side

Fracture Type	Male No.&%	Female No.&%	Age: rang	Mean age	Right side	Left side	Total
Clavicle	168 75.33%	55 24.66%	1-60	18	142 63.67%	81 36.32%	223 7.27%
proximal humerus	28 66.66%	14 33.33%	4-75	37.6	31 73.8%	11 28.19%	42 1.36%
Humerus	163 67.35%	79 32.64%	2-109	27.8	149 61.57%	93 38.42%	242 7.89%
SCF	169 75.11%	56 24.885	1.5-16	7.3	73 32.44%	152 57.55%	225 7.335%
Elbow	85 65.38%	45 34.61%	4-61	9.12	52 40%	78 60%	130 4.23%
Forearm	823 78.45%	226 21.55%	1-83	16.85	514 48.99%	535 51.0	1049 34.20%
Lower radius&ulna	292 77.86%	83 22.13%	1-15	10.5	173 46.13%	202 53.86%	375 12.22%
Wrist	193 51.32%	183 48.67%	16-98	39.9	184 48.93%	192 51.06%	376 12.25%
Hand	310 76.54%	95 23.45%	20-60	24.6	329 81.23%	76 18.76%	405 13.20%
Total	2231 72.74%	836 27.26%	1-109	19.96	1647 53.70%	1420 46.29%	3067

The types of the common fractures of the upper limb starting proximally from the clavicle, proximal humerus, shaft of humerus, supracondylar fracture, other elbow fractures, forearm fractures, fracture lower radius and ulna in children, wrist fracture, and hand fractures. Regarding hand fractures it includes carpal fractures mainly scaphoid which represent about (12.84%) and metacarpal and phalangeal fractures (87.16%).

The table shows that the most common fracture was forearm fractures (34.2%). It also shoes that males affected more than females (72.74%) and (27.26%), ratio of 2.67:1. The mean age of the patients was (19.96) years. The right sides affected in fracture clavicle, proximal humerus, shaft of humerus, and hand fractures. The left side affected more in supracondylar fracture, elbow, and distal forearm fractures in children. Both sides are affected almost equally in forearm and wrist fractures.

Table (2): fractures /age groups & %

Fracture Type	Age group /No. & %								Total NO.
	1-10	11-20	21-30	31-40	41-50	51-60	61-70	>70	
Clavicle	131 58.74%	36 16.14%	17 7.62%	6 2.69%	12 5.38%	20 8.96%	1 0.44%	-	223 7.27%
proximal Humerus	7 16.66%	7 16.66%	4 9.52%	4 9.52%	7 16.66%	7 16.66%	-	6 14.28%	42 1.36%
Humerus	54 22.31%	76 31.40%	30 12.4%	32 13.2%	9 3.71%	7 2.89%	15 6.195	19 7.85%	242 7.89%
SCF	179 79.55%	46 20.44%	-	-	-	-	-	-	225 7.33%
Elbow	61 46.92%	38 29.23%	16 12.3%	9 6.92%	3 2.30%	-	3 2.30%	-	130 4.23%
Forearm	450 42.89%	338 32.22%	135 12.86	65 6.19%	26 2.47%	31 2.95%	1 0.09%	3 0.28%	1049 34.20%
Lower Radius&ulna	150 40%	225 60%	-	-	-	-	-	-	375 12.22%
Wrist	75 19.94%	75 19.94%	63 16.75%	54 14.36%	65 17.28%	28 7.44%	16 4.25%	-	376 12.25%
Hand	25 6.21%	108 26.66%	156 38.51%	86 21.23%	19 4.69%	11 2.71%	-	-	405 13.20%
Total	1132 36.96%	949 30.945	421 13.72%	256 8.34%	141 4.59%	104 3.39%	36 1.17%	28 0.91%	3067

This table shows that the most common age group affected are in the 1st and 2nd decade where they represent about (68%) of the whole group.

It also shows significant association between age and (supracondylar fracture and fracture lower radius)

where both occurs in children (p<0.05). In the 1st decade there is significant association with forearm fractures .In the 3rd decade there is significant association with hand fractures .In the 5th decade there is significant association with wrist fractures , while for people above 70 there is significant association with fracture humerus.(p<0.05).

Table (3); causes of fractures

Fracture type	Cause of fracture/No.& %									Total
	Fall	Fall from height	Road Traffic Accident	Fall of heavy object	Direct hit	Foot ball	Bullet	Explosion	Machine	
Clavicle	88 39.46%	73 32.73%	38 17.04%	5 2.24%	5 2.24%	14 6.27%	-	-	-	223 7.27%
proximal humerus	30 71.42%	8 19.04%	4 9.52%	-	-	-	-	-	-	42 1.36%
Humerus	66 27.27%	58 23.96%	72 29.75%	15 6.19%	-	-	-	14 5.78%	17 7.02%	242 7.89%
SCF	121 53.77%	90 40%	1 0.44%	4 1.77%	-	9 4%	-	-	-	225 7.33%
Elbow	69 53.07%	33 25.38%	4 3.07%	4 3.07%	16 12.305	4 3.07%	-	-	-	130 4.23%
Forearm	425 40.51%	320 30.50%	53 5.06%	48 4.57%	91 8.67%	73 6.95%	16 1.52%	13 1.23%	10 0.95%	1049 34.20%
Lower radius&ulna	142 37.86%	122 32.53%	19 5.06%	4 1.06%	4 1.06%	84 22.4%	-	-	-	375 12.22%
Wrist	229 60.90%	81 21.54%	14 3.72%	5 1.32%	5 1.32%	42 11.17%	-	-	-	376 12.25
Hand	93 22.96%	25 6.17%	9 2.22%	70 17.28%	122 30.12%	66 16.29%	14 3.45%	1 0.24%	5 1.23%	405 13.20%
Total	1263 41.18%	810 26.41%	214 6.97%	155 5.05%	243 7.92%	292 9.52%	30 0.97%	28 0.91%	32 1.04%	3067

This table shows that the most common cause of the fracture is fall (41.18%) followed by fall from height (26.41%). There is significant association between fall and fracture proximal humerus, and the same for forearm fractures ($p < 0.05$). Direct hit is significantly associated with hand fracture while sport mainly football is significantly associated with fracture of distal forearm fractures ($p < 0.05$).

Discussion

Fractures in general are a big medical problem all over the world. It has a huge socioeconomically burden on the community and on the health system for the high rate of morbidity. In general it affect young people who they are the most active regarding work and productivity..

In this study we found that (53%) of all patients who sustained upper limb fractures aged between 11 and 40 years. This result is comparable to that of Maryam et al. (5) where they notice that 57% of patient aged between 11 and 40 years.

However the most common group of patients in general is those in the first decade where in our study represent 36.96% of the whole group followed by the patient in the second decade (30.94%). These findings are correlated with the results from other papers. (6,7,9)

We found in general the most common cause of fractures of upper limb was fall which goes with findings in other studies. (3,5)

The male to female ratio differ between a study and another but as in this study all other studies from different countries concluded that males sustained more fractures probably because males involved in more activities and sports. (1,2,5,9)

In this study we found that fracture forearm bones were the most common fracture of upper limb especially in children. This is comparable with the findings of Wei et al. study. (4)

Fracture clavicle: It constitute (7.27%) of all upper limb fractures. People in the first decade are more prone for this fracture and they represent(58.74%) of the group of fracture clavicle. The mean age of the whole group is 18 years .It affect males (75.33%) more than females). The most common cause of the fracture was

fall (39.46%) followed by fall from height (32.73%), and the third cause is RTA(17.04%).

Postacnini et al. (10) also found that this fracture is more common in the first decade(88.2%). The males represent 68% of the group while females represent 32%.

They found that RTA is the most common cause in adults.

Callistus et al. (11) concluded that fracture clavicle is more common in young adults, and about 71% of patients were in the 3rd and 4th decade. The most common cause was RTA.

*Fracture of proximal humerus :*In this study it constitute about (1.36%) of upper limb fractures. It affects mostly people in the 1st and 2nd decade (33.33%) and people above 40 (47.7%) .Males affected more females and the mean age is 37.6 years. The most common cause is fall(71.42%).

Daniele et al. (12) found that the mean age of patient with fracture of proximal humerus is 61.2 years. Fall is the most common cause and there was high incidence in females and old ages. This difference in mean age between two studies may be due to the high percentage of old people in Italy in comparison to our country.

Fracture humerus: It constitute about 7.89% of the patients in our study. The mean age is 27.8 years and male affected more than females (67.35% and 32.64%) respectively. People in the 1st and 2nd decade represent more than the half (53.71%).The most common cause of this fracture is RTA (29.75%) followed by fall (27.27%) and fall from height (23.96%).

These findings differ from that of Ekholm et al. (13) where the mean age in their group was 62.7 years and females affected more than males (61% and 39%) respectively. The most common cause of the fracture was fall(68%) followed by fall from height(8%) and sports(7%)

Elbow fractures: represent 11.57% of the whole group. It include supracondylar fractures which represent (63.38%) of elbow fractures and other fractures around the elbow (36.62%) ,the most common of which is fracture lateral humeral condyle and fracture olecranon. Collectively the mean age was 8.21 years ,males affected

more than females (70.24%) and (29.76) respectively. The most common cause of the fracture was fall (53.42%) followed by fall from height (32.69%) Children in the 1st decade were mostly affected (63.23%) followed by those in the 2nd decade (24.83%) and 3rd decade(6.65%).

Maryam et al. ⁽⁵⁾ in their study from Iran found that SCF represent 54% of elbow fractures ,the mean age of the patients was(9.22).Males represent 68.1% and females 29.9%. These figures are comparable with our study. The same is for the causes were the main cause of elbow fractures in Iran was fall(59.7%) followed by fall ,from height (24.3%).People in the 1st decade are mostly affected (58.5%) ,in the 2nd decade are(18.13%) , and the 3rd decade (9.8%)[5].

Fracture forearm: constitute (34.2%) of whole fractures in our study. The mean age was(16.85) years , and males affected more than females(78.45%) and(21.55%)respectively. The main cause of the fracture was fall(40.51%) followed (by fall from height (30.50%). people in the 1st decade were affected more (42.89%) then in d decade (32.22%), and the 3rd decade (12.86%).

Maryam et al. ⁽⁵⁾ found that the mean age of those patients was (21.87) years which is higher than that in our series. Males affected more than females (75.1%) and (24.9%) respectively .Fall was the main cause of the fractures(63%). People in the 2nd decade were more affected (33.4%) followed by those in the 1st decade(27.03%) and in the 3rd decade (13.3%).

Fracture lower radius&ulna in children: This fracture occur mostly in the metadiaphyseal part of the forearm bones .It almost a fracture of adolescent and children where the mean age was 10.5 years. People in the 2nd decade were more affected 60% followed by those in the 1st decade(40%) .Males constitute (77.86%) while females constitute (22.13%). The main cause of the fracture was fall in(37.86%) then fall from height (32.33%) and sport injury especially football (22.4%) .This fracture is unique because it is midway between fracture lower shaft of radius and ulna and fracture wrist. There is no specific study about this unique fracture which we think that it needs further discussion.

Wrist fracture: it constitute about (12.25%) of the fractures of upper limb. The mean age of the patients was 39.9 years , males represent (51.32%) and females

(48.67%).The most common cause of the fracture was fall(60.9%) followed by fall from height (21.54%). People in the 1st and 2nd decades affected similarly (19.94%) and in the 5th decade (17.28%).

Regarding the mean age it is comparable with that of patient in M aryam et al. ⁽⁵⁾ series which was (36.88) years but males are more affected than females (75.4%) and (24.6%) respectively, while in our study males almost equally affected as females.

Regarding the cause of the fractures the figures are also comparable where the main cause was fall in (61.96%) and fall from height (16.96%).They found that (19.2%) of patients were in the 2nd decade and (15.9%) were in the 4th and 6th decade .

Kate et al. ⁽¹⁴⁾ found that (25%) of fractures in children involve wrist (distal radius), boys affected more than girls ,and the most common cause was sport.

Hand fracture: it account for 13.20% of all fractures of upper limb. It include carpal fractures mainly scaphoid(12.5%) and metacarpals and phalangeal fractures (87.16%).The mean age was (19.96) years ,males constitute (72.74%) and females (27.22%). The main cause of the fracture was direct hit (30.12%) followed by fall (22.96%) ,fall of heavy object(17.28%) ,and sport injury mainly football(16.29%).People in the 3rd decade were mostly affected(38.51%) followed by those in the 2nd decade (26.66%) and in the 4th decade (21.23%).

Lynne et al. ⁽¹⁵⁾ found that people between 15-40 are mostly affected ,and males affected more than females , which is comparable with our results. Mryam et al.[5] found that the mean age of the patients was (29.73%) years , males constitute (85.8%) and females (14.5%). They found that the main cause of the fracture was direct hit (58.7%) followed by fall (22.3%).The fracture were more frequent in the 3rd and 4th decade of life.

Conclusion

Fractures of upper extremities affect children and adolescents more than adults. Planes and measures to be taken by administrations like schools and media to teach people how to avoid trauma which may lead to fractures. Starting by home , the parents should do their best to protect their children by more supervision to

avoid more traumas. For sports it is necessary to prepare safe playgrounds to decrease trauma.

Conflict of Interest: No conflict of interest

Funding: Self Funding

Ethical Clearance: Compliance with ethical standards: this study was approved by the ethical committee of Alsader medical city /Alnajaf/Iraq

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Evaluation of Hepatotoxicity of Two Famous Antiepileptic Drugs Depakine[®] and / or Epanutin[®] in Male Albino Mice *Mus Musculus*: Integrated Biochemical and Histological Studies

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Abstract

Background: depakine and epanutin introduce useful tools in wide range of clinical issues. Liver is the local position for their metabolism and is susceptible for their influences.

Methods: forty-two male albino mice were divided into seven groups. control group injected with NaCl (0.9%) 1ml/kg, group 2 injected with depakine 25mg/kg/day, group 3 injected with depakine 50mg/kg/day, group 4 injected with epanutin 3mg/kg/day, group 5 injected with epanutin 6mg/kg/day, group 6 injected with (depakine 25 + epanutin 3) mg/kg/day and group 7 injected with (depakine 50 + epanutin 6) mg/kg/day. All animals were injected intraperitoneally, were fasted 12hours after last injection, were sacrificed via cervical dislocation and specimens were collected after one and two weeks for each dose.

Conclusions: human therapeutic doses range of depakine and/or epanutin produced elevation in the mean of liver aminotransferases enzymes levels in serum without dose or time depend and generate variable degrees of hepatotoxicity in mice according to dose and depend on time.

Keywords: aminotransferase, epilepsy, liver, phenytoin sodium, valproate.

Introduction

Epilepsy is an illness case targets a considerable percentage of total population without discrimination. It occurs as a result of abruptly and enormously depolarization of some or all encephalic neurons. This impact occurs in some neurons and causes local seizure or extends to all cerebral neurons cause generalized seizure. It is long-life curable disease [1]. valproate exists in several pharmaceutical forms to treat wide range of neurological disorders include epilepsy [2]. It generates several teratogenic effects [3] and psychiatric disorders [4]. Long term administration of valproate has adverse effects on brain mass [5], lower part of gastrointestinal tract [6], urinary system function [7], bone density [8] and liver enzymes [9]. Phenytoin is an effective antiepileptic drug [10], its effective dose differ individually from patient to another due to the polymorphism of hepatic

cytochrome responsible for its hepatic metabolism [11]. Phenytoin causes a group of teratogenic effects with defined phenotypes [12] and it enhances hepatotoxicity if co-administrated with paracetamol and its derivatives [13].

Materials and Methods

Current experiment was carried out on November 2019 at Ain shams university, faculty of education, biological and geological science department, Cairo, Egypt.

Drugs:

Depakine oral suspension 200 mg/1ml sodium valproate from Sanofi Aventis. Epanutin vail 250 mg/5ml phenytoin from El-Nile company for medicine

Industries. Drugs were diluted with saline to prepare all tested doses concentrations with fixed volume of 1ml/kg for each dose. All tested doses were derived from the human therapeutic dose [14].

Animals:

This study was applied on forty-two healthy and pure strain adult male mice (*Mus musculus*), (25 - 30 g) from animal house of research organization, Egypt. Mice were housed inside acrylic cages with base covered with clean sawdust under standard circumstances at 20°C, 12 hours of day/night cycle. Animals were nourished on commercial rodent grain and deionized water. Sawdust was changed daily to get rid of food and feces remnants and avoid contaminations. Mice handling and experimental steps followed the restricted guideline of Ain shams University ethics committee.

Experimental design:

Forty-two mice were equally distributed into seven groups (6 mice per group).

Control: injected with saline 1ml/kg.

2nd Group: injected with depakine 25 mg/kg/day.

3rd Group: injected with depakine 50 mg/kg/day.

4th Group: injected with epanutin 3 mg/kg/day.

5th Group: injected with epanutin 6 mg/kg/day.

6th Group: injected with (depakine 25 + epanutin 3) mg/kg/day.

7th Group: injected with (depakine 50 + epanutin 6) mg/kg/day.

All animals were injected via intraperitoneal route. Mice of all were selected randomly, sacrificed and

samples were collected after one and two week(s) for each dose.

A) Biochemical analysis

Blood serum is extracted after centrifugation of the blood at 2000 xg /10 minutes/ 5°C in tube without anticoagulant. Concentrations of AST (aspartate aminotransferase) and ALT (alanine aminotransferase) liver enzymes in serum were estimated by Randox kits (UK) with applying a specific methodology [15].

B) Histology

liver was isolated after dissection, rinsed with normal saline, fixed in 10% formalin/24 hours, dehydrated in ascending concentrations of ethanol, cleared in xylene, immersed in paraffin at 56°C/24hours, sectioned at 4 microns' thickness, mounted on glass slide, stained by hematoxylin & eosin and examined under light microscope [16].

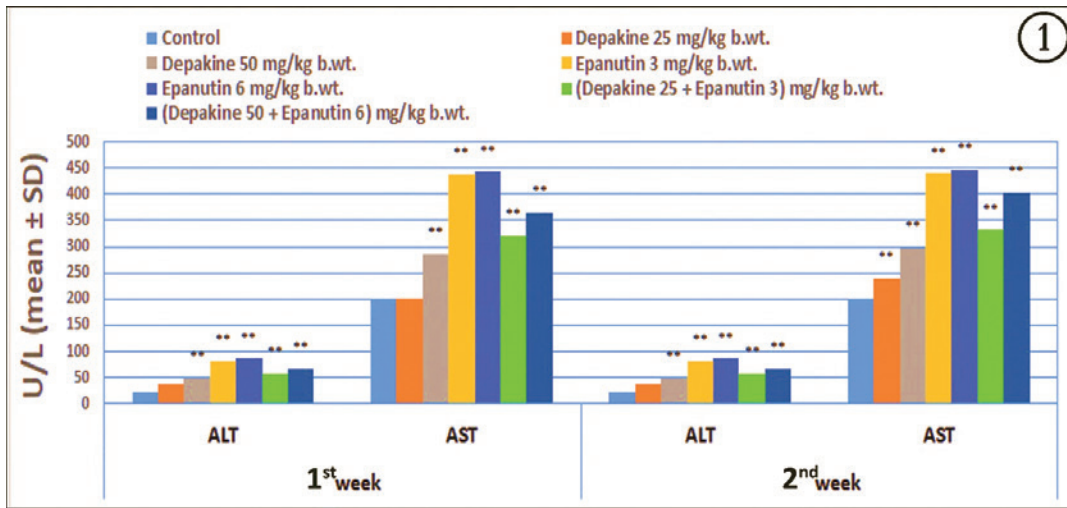
C) Statistical analysis:

Data were analyzed by version 16.0 of (SPSS). Results are expressed by means ± SD of three independent experiment. Statistical significance of difference was determined by T- test. A level of P <0.005 was defined as statistically significant.

RESULTS

A) Biochemical analysis:

As it was shown in figure 1 the mean of ALT or AST enzymes concentrations in serum exhibited high significant increase $P < 0.001$ in all treated groups except in groups that were treated with depakine 25mg/kg/day showed no significant results $P > 0.005$ in ALT concentrations even after one or two weeks of treatment and AST concentrations after one week only in comparison to control group.



** represented a highly significant $P < 0.001$.

Figure 1: Histogram represents the relationship between ALT and AST serum activity and the time of treatment in control group, groups treated with single doses of either depakine or epanutin and groups treated with combination doses of depakine in addition to epanutin.

B) Histological observations:

Hepatic histological alterations of male albino mice were observed in variable degree according to dose and time in all treated groups in comparison to control group. Treatment with depakine 50 mg/kg/day for two weeks resulted in hepatocytes cytoplasmic changes in the form of cloudy swelling figure 2. While, treatment with epanutin 6 mg/kg/day for one week caused hepatic histopathological alterations in the form of inflammation and congestion in central vein figure 3 and after two weeks of treatment with the same dose of epanutin

hepatic histopathological alterations were in the form of hepatocytes nuclear change in the form of pyknosis developed to appearance of large area of necrosis and central vein congestion figure 4. Moreover, co-treatment with (depakine 25 + epanutin 3) mg/kg/day for one week induced hepatic histopathological alterations in the form of congestion in portal vein with inflammation figures 5. While co-treatment with (depakine 50 + epanutin 6) mg/kg/day for two weeks exhibit hepatic histopathological alterations expressed by hydropic degeneration and and nuclear karyomegaly figure 6.

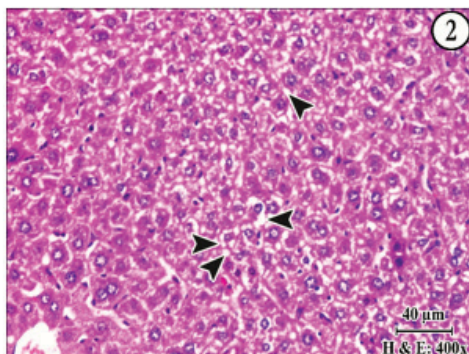


Figure 2: photomicrograph of C.S. in liver of male albino mouse treated with depakine 50mg/kg/day for two weeks showing hepatocytes cytoplasmic changes in the form of cloudy swelling with foamy appearance (arrows heads).

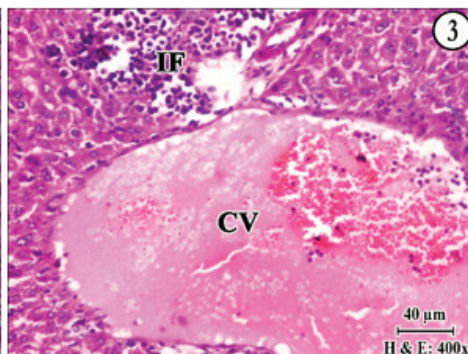


Figure 3: photomicrograph of C.S. in liver of male albino mouse treated with epanutin 6mg/kg/day for one week showing large area of inflammatory cells (IF), extensive congestion and dilation in central vein (CV).

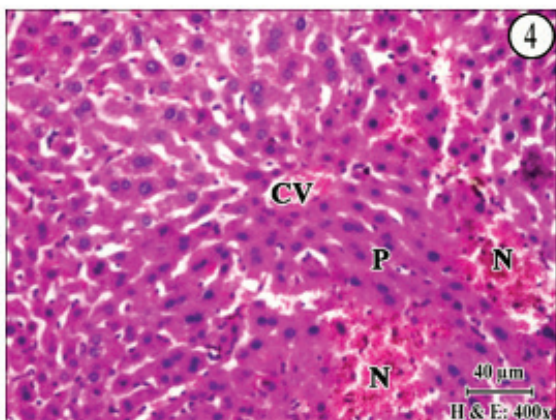


Figure 4: photomicrograph of C.S. in liver of male albino mouse treated with epanutin 6mg/kg/day for two weeks showing congestion in central vein (CV), large area of hepatocytes with pyknotic nuclei (P) and necrosis (N).

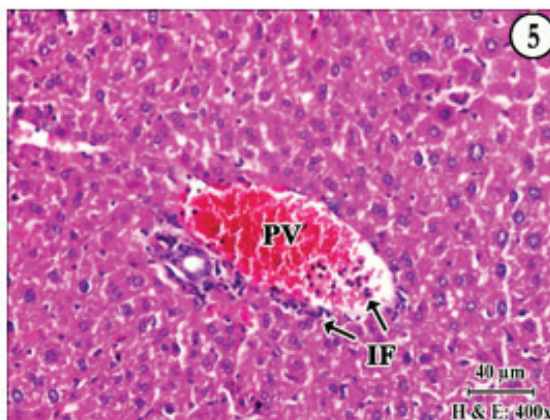


Figure 5: photomicrograph of C.S. in liver of male albino mouse treated with depakine 25mg/kg/day + epanutin 3mg/kg/day for one week showing extensive congestion in portal vein (PV) and inflammatory cells infiltration (IF).

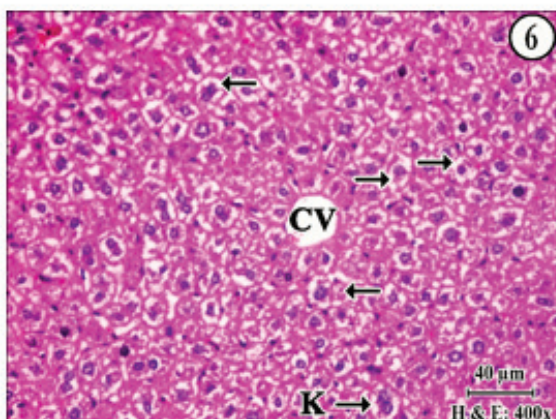


Figure 6: photomicrograph of C.S. in liver of male albino mouse treated with depakine 50mg/kg/day + epanutin 6mg/kg/day for two weeks showing normal central vein (CV), hepatocytes cytoplasmic changes in the form of hydropic degeneration (arrows) and hepatocytes nuclear change in the form of karyomegaly (K).

Discussion

Because liver is the target organ of many drugs metabolism [17], present work gave special attentions to hepatic histopathological changes in male albino mice resulted from treatment with depakine and / or epanutin to explain the results of ALT and AST concentrations in blood serum which are normally situated inside hepatocytes [18]. Current study observed that treatment with depakine and/or epanutin resulted in variable degree of histopathological alterations in the liver of male albino mice depend on dose and time compared to control group. Hepatic histopathological changes in depakine treated groups were in accordance with Ibrahim, (2012) [19] found that depakine induced reversible hepatotoxicity in albino mice depend on time. Hepatic histopathological changes in epanutin treated groups

were agreed by Saraswathy *et al.*, (2015) [20] declared that phenytoin causes injury in rat liver indicated with significant increase in concentrations of liver enzymes in serum. In the present work hepatic histopathological changes in groups treated with depakine and epanutin together are due to the toxic metabolites of either depakine [21] or immunoreactions of epanutin [22] in consideration with that depakine inhibits epanutin metabolism by removing it from the plasma binding site [23]. Inflammatory reactions that were observed in all treated groups are due to oxidative stress [24] which produced after the hepatic metabolism of either depakine [25] or epanutin [26]. Finding of biochemical analysis is occurred because inflammatory cells secret lipolytic enzymes that have a destructive effects on phospholipids of hepatocytes membrane [27] causes extracellular leakage of hepatocytes cytoplasm includes

aminotransferase enzymes. In addition, inflammatory reactions cause hepatocytes membrane permeability dysfunction through inhibition of energy metabolic enzymes [28] caused abnormal intracellular entrance of sodium ions with water and extracellular leakage of potassium ions resulted in observed cloudy swelling and hydropic degeneration in hepatocytes cytoplasm. In epanutin treated groups appearance of necrosis in the form of dark eosinophilic areas within parenchyma is due to the oxidative stress generates intracellular membranes damage and leakage of hydrolytic enzymes resulted in digestion of cytoplasmic contents [29]. Also, the oxidative stress resulted in hepatocytes nuclear changes in the form of karyomegaly and pyknotic nuclei through inhibition of spindle fiber formation and block anaphase [30] resulted in karyomegaly that is described as polyploidy [31]. also oxidative stress induces chromatin condensation and pyknosis [32]. In present study all treated groups showed variable degree of congestions in all parts of hepatic vascular system even portal vein or drain part of blood sinusoid and central vein. These congestions are due to the direct degenerative impacts of oxidative stress on the endothelial wall of hepatic sinusoids [33] leads to congestion in blood sinusoid extended to central vein [34] previous conditions collectively act as an obstacle for portal vein perfusion and portal congestion [35].

Conclusion

Administration of therapeutic doses of depakine drug and / or epanutin drug adversely induced hepatic injuries in male albino mice *Mus musculus* by dose and by time for each single or combination doses. It is recommended to utilize in human patient under restricted precautions.

Ethical Clearance: Taken from Ain shams University ethics committee.

Source of Funding: Self.

Conflict of Interest: Nil.

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Hormonal Contraception Use and Risk of Breast Cancer Relationship Among 25-64 Years Old Women in Urban Areas of Indonesia

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Abstract

Background: In 2013 in Indonesia, breast cancer was the second highest type of cancer after cervical cancer, with a prevalence of 0.5 %, or an estimated 61,682 patients. Hormonal contraception is one of the factors that can increase the risk of breast cancer, as excessive exposure to sex hormones such as estrogen and progesterone interferes with physiological processes in the body, including breast tissue. One example of the use of estrogen and progesterone is in hormonal contraception.

Methods: The study used NCD (non-communicable disease) research data from the Indonesian Ministry of Health Health Research and Development Agency, employing a cross-sectional study design. The data were collected from 34 provinces, consisting of 76 districts and cities in Indonesia, and 35,444 respondents were included in the study. Breast cancer was diagnosed by clinical breast examinations and confirmed by biopsy. Odds ratios and 95% CI derived from logistic regression were used to estimate the relationship between hormonal contraception and breast cancer.

Results: The results show that the incidence of breast cancer among 25-64 years old women in urban areas in Indonesia in 2016 was 0.2%. The multivariate analysis showed that women who used a combination of progestin and estrogen for hormonal contraception had a 2.178 (95% CI: 1.090-4.348) times higher chance of developing breast cancer than women who did not use hormonal contraception, after controlling for covariate variables. In line with this, women who had used hormonal contraception for ≥ 5 years had a 1.928 (95% CI: 1.019-3.647) times higher risk of developing breast cancer than women who had used such contraception for < 5 years, after controlling for covariate variables.

Conclusions: Hormonal contraception significantly increases the risk of breast cancer among 25-64 year old women in urban areas of Indonesia. Women who are exposed to estrogen over a long period will face a higher risk of breast cancer. Moreover, to reduce the risk of breast cancer it is important to reduce the duration of hormonal contraception use, or choose non-hormonal contraception for birth control.

Keyword: Relationship, Breast Cancer, Hormonal Contraception, Indonesia.

Background

Breast cancer can be interpreted as a malignancy in breast tissue, that can originate from the ductal

epithelium and lobules.¹ It is the most common type of cancer found in women in both developed and developing countries², specifically in 140 out of 184 countries worldwide.³ Breast cancer is also a common cause of death in women, with a total of 522,000 deaths in 2012.³ In 2012, globally 6.3 million women had been living with breast cancer over the previous five years³, a figure which had increased since 2008, when 5 million

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women had been living with breast cancer during the previous 5 years.⁴

In 2013 in Indonesia, breast cancer had the second highest prevalence rate after cervical cancer, with a rate of 0.5 % , or an estimated 61,682 patients. The highest prevalence of breast cancer in Indonesia is in the province D.I Yogyakarta, at 2.4 %⁵, whereas the highest number of patients is estimated to be in Central Java province, with an estimated 11,511 patients. Based on data from the Dharmais Cancer Hospital, from 2010 to 2013 breast cancer, cervical cancer and lung cancer were the three most common diseases at the hospital, with the number of new cases and of deaths continuing to increase.⁶

Hormones are one of the factors that can increase the risk of breast cancer¹, but more as a promoter than an initiator. Excessive exposure to sex hormones such as estrogen and progesterone interferes with physiological processes in the body, including breast tissue. In everyday life, the hormones estrogen and progesterone, or a combination of the two, are taken by many people, especially women. One example of the use of estrogen and progesterone is in hormonal contraception.⁷

This is a type of contraception that uses estrogen and progesterone together, or progesterone alone, to prevent pregnancy.⁸ In Indonesia, the use of hormonal contraception is quite high compared to non-hormonal contraception. According to 2013 Riskesdas data, the use of hormonal contraception in Indonesia was 51.8%, while those using non-hormonal contraception constituted only 7.5%.⁵

A study conducted on women in Dr. RSUP Sardjito Yogyakarta showed that women using hormonal contraception had a 2.378 (95% CI 1,282 - 4,412) times higher risk of developing breast cancer than women using non-hormonal contraception.⁹ A study conducted at Al-Ihsan Regional Hospital Bandung reached the same conclusion. The duration of hormonal contraceptive use can also increase the risk of breast cancer (OR: 9.06; 95% CI: 9.10–11.4).¹⁰

Methods

The study used a cross-sectional design and employed NCD (non-communicable disease) research data from the Indonesian Ministry of Health Health

Research and Development Agency. It was conducted between August and September 2016 in 34 provinces in Indonesia, including 76 regencies and cities, and focused on urban areas.

The 2016 NCD research sample was designed for presentation at the national level. The size of the sample was 70,000 respondents spread across 1,400 census blocks and 76 selected districts in 34 provinces throughout Indonesia. A total of 43,948 respondents were successfully visited and interviewed. 39,099 of the respondents had undergone clinical examinations, although 3,655 of these had incomplete data, meaning the total number of participants with complete data was 35,444.

Breast cancer was discovered from the results of the diagnosis in clinical breast examinations and biopsy, and confirmed by breast mammography/ultrasound examination and anatomic pathology (PA) examination conducted by the Health Research and Development Agency of the Ministry of Health of the Republic of Indonesia. Hormonal contraception was divided into no use of hormonal contraception, use of progestin only, and use of a combination of progestin and estrogen. The duration of hormonal contraception use was divided into <5 years and ≥ 5 years, while the use of DES (diethylstilbestrol) was divided into 'used' and 'never used'. The use of hormonal drugs for infertility was also divided into 'used' and 'never used', as was the use of hormone replacement therapy. Family history of cancer was represented by 'yes' or 'no', while education was categorized as 'low' (high school or below) or 'high' (university). Work status was divided into 'not working' and 'working'; marital status into 'married' and 'not married'; age into <40 years and ≥ 40 years; and socioeconomic into low (lowest to middle) and high (middle to highest).

Bivariate analysis was used to observe the relationship between hormonal contraception (use and length of use) and the incidence of breast cancer. Odds ratios (ORs) and 95% confidence intervals in multivariate analysis with logistic regression were employed to examine the relationship between hormonal contraception and breast cancer after controlling for covariate variables (use of DES, uses of hormonal drugs for infertility, use of HRT, family history of cancer, education, work status, marital

status, age, and socioeconomic status).

Results

Table 1. Incidence of Breast Cancer in Women Aged 25-64 in Urban Areas of Indonesia in 2016

Variable	N	%
Breast Cancer		
Yes	58	0.2
No	35.386	99.8

Table 1 shows that 0.2% of women aged 25-64 were suffering from breast cancer and 99.8% were not

Table 2. Characteristics of the Study Population and Hormonal Contraception Use

Variable	Breast Cancer		No Breast Cancer		P- value
	n = 58	%	n = 35,386	%	
Age					
≥40 years	38	0.2	21,623	99.8	0.580
<40 years	20	0.1	13,763	99.9	
Education					
Low (high school or below)	47	0.1	31,626	99.9	0.065
High (university)	11	0.3	3,760	99.7	
Socioeconomic status					
High	19	0.1	14,546	99.9	0.247
Low	39	0.2	20,840	99.8	
Work status					
Not working	20	0.2	12,667	99.8	0.943
Working	38	0.2	22,719	99.8	
Family history of cancer					
Yes	6	0.2	2,945	99.8	0.750
No	52	0.2	32,441	99.8	
Hormonal contraception use					
Combination of progestin and estrogen	43	0.2	21,323	99.8	0.034
Progestin only	5	0.1	3,638	99.9	0.512
No	10	0.1	10,425	99.9	
Duration of hormonal contraception					
≥ 5 years	46	0.2	23,666	99.8	0.061
<5 years	12	0.1	11,720	99.9	
Diethylstilbestrol use					
Yes	6	0.3	2,241	99.7	0.326
Never	52	0.2	33,145	99.8	

The variables of marital status, use of hormonal drugs for infertility, and hormone replacement therapy use are

not included in the table because it has an empty cell in the 2x2 table.

Table 2 shows that the proportion of breast cancer in those age ≥ 40 years was 0.2; low education level was 0.1%; high socioeconomic status was 0.1%; not

working was 0.2; family history of cancer was 0.2%; use of progestin only was 0.1%; use of a combination of progestin and estrogen was 0.2%; use of hormonal contraception for ≥ 5 years was 0.2%; and use of DES was 0.3%. There is a significant relationship between the incidence of breast cancer and use of hormonal contraception in the form of a combination of progestin and estrogen (P: 0.034).

Table 3. Relationship between Hormonal Contraception and the Risk of Breast Cancer in Women Aged 25-64 in Urban Areas of Indonesia

Variable	Crude Analysis		Adjusted Analysis*	
	OR	95% CI	OR	95% CI
Hormonal contraception used				
Combination of progestin and estrogen	2.102	1.056 - 4.185	2.230	1.117-4.455
Progestin-only	1.433	0.489-4.195	1.351	0.460-3.962
Not used	Ref	Ref	Ref	Ref
Duration of hormonal contraception				
≥ 5 years	1.898	1.005-3.585	1.967	1.040-3.721
<5 years	Ref	Ref	Ref	Ref

*Adjusted by use of DES, family history of cancer, education, work status, age, and socio-economic status.

Table 3 shows the relationship between hormonal contraception and the incidence of breast cancer in women aged 25-64 years in urban areas of Indonesia. From the results of the bivariate analysis of the relationship, the figures can be seen relating to women who used a combination of progestin and estrogen (OR: 2.102; 95% CI: 1.056 - 4.185); who used progestin-only (OR: 1.433; 95% CI: 0.489-4.195); and those who had used hormonal contraception for ≥ 5 years (OR: 1.898; 95% CI: 1.005-3.585).

The results of the multivariate logistic regression show a significant relationship between the use of a combination of progestin and estrogen and the incidence of breast cancer. Women who used such a combination for hormonal contraception had a 2.230 (95% CI: 1.117-4.455) times higher chance of developing breast cancer than women who did not use hormonal contraception, after controlling for DES, family history of cancer, education, work status, age, and socioeconomic status as covariate variables. In addition, women that used progestin were 1.351 (95% CI: 0.460-3.962) times more

likely to develop breast cancer than women who did not use hormonal contraception, after controlling for DES, family history of cancer, education, work status, age, and socioeconomic status as covariate variables. The multivariate analysis of the duration of hormonal contraception usage and the incidence of breast cancer produced significant results. Women who had used hormonal contraception for ≥ 5 years had a 1.967 (95% CI: 1.019-3.647) times higher risk of developing breast cancer than those who had used hormonal contraception for < 5 years, after controlling for DES, family history of cancer, education, work status, age, and socioeconomic status as covariate variables.

Discussion

The results show that the prevalence of breast cancer among 25-64 year old women in urban areas in Indonesia was 0.2%. The multivariate analysis shows that women who used a combination of progestin and estrogen for hormonal contraception were 2.230 (95% CI: 1.117-4.455) times more likely of developing breast cancer than women who were not using hormonal contraception. In addition, women who had used hormonal contraception for ≥ 5 years had a 1.967 (95% CI: 1.019-3.647) times higher risk of developing breast cancer than women who had used hormonal contraception for < 5 years.

A study conducted at Dr. Sardjito Yogyakarta obtained similar results, that women who used hormonal contraceptive as a combination of estrogen and progestin were 3.14 (95% CI: 1.68-5.86) times more likely to have breast cancer than those who used non-hormonal contraception. The study also mentioned that women who had used hormonal contraception for ≥ 5 years had a 3.55 (95% CI 1.70-7.40) times higher risk of breast cancer than those who did not use hormonal contraception.¹¹

The use of hormonal contraception for more than 4 years can increase the risk of breast cancer 1.52-fold. That happens because after 4 years the estrogen will accumulate and multiply, and excessive levels of estrogen in the body can be one of the risks of breast cancer. The growth of breast tissue is very sensitive to estrogen. Women who are exposed to it for a long time will have a greater risk of breast cancer. The occurrence of estrogen exposure can be caused by the use of hormonal contraceptives that contain a combination of

hormones, estrogen and progesterone. To reduce the risk of breast cancer due to the use of hormonal contraception, the American Cancer Society recommends reducing the duration of hormonal contraception use or choosing non-hormonal contraception for birth control. For example, a non-hormonal intrauterine device (IUD) is a reversible form of birth control that is not linked to breast cancer.^{12,13,14}

Conclusion

Hormonal contraception significantly increases the risk of breast cancer among 25-64 year old women in urban areas of Indonesia. Women who are exposed to estrogen for a long time will have a higher risk of breast cancer. To reduce the risk of breast cancer it is important to reduce the duration of hormonal contraception use or choose non-hormonal contraception for birth control.

Ethical Considerations: Ethical testing was conducted by the Health Research Ethics Commission of the Indonesian Ministry of Health Research and Development Agency No: LB 02.01 / 5.2 / KE / 154/2016.

Competing Interests: The authors declare that no competing interests exist.

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Association between Intimate Partner Violence and Mental Health Status During Pregnancy: A Survey among Pregnant Women in Calabar, Nigeria

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Abstract

Human pregnancy should be a safe and rewarding physiological process. However, violence-mediated distress may contribute to adverse fetomaternal effects. This study aimed at assessing relationship between intimate partner violence (IPV) and mental health status of pregnant women in Calabar, Nigeria. Composite Abuse Scale and Hospital Anxiety and Depression Scale questionnaires were used to assess IPV and anxiety and depression, respectively. Of 250 respondents surveyed randomly, 54.8% had at least one of the three types of abuse within the last 12 months, with common combination being psychological abuse only (16.4%), all three types of abuse (15.6%), and psychological and sexual abuse (10.8%). Anxiety and/or depression which was found in 48.0%, was more prevalent among respondents that suffered psychological (57.0% vs. 38.5%), sexual (64.4% vs. 41.2%), and physical (64.2% vs. 42.1%) types of abuse ($p < 0.05$). Findings suggest need to redouble effort at integration of gender into reproductive health in developing countries.

Key words: Intimate Partner Violence, Pregnancy, Anxiety, Depression

Introduction

Harmful physical, sexual, and psychological behaviour within intimate relationship referred to as Intimate Partner Violence (IPV), is a global public health problem. Females in developing countries are often worse hit, with an estimated one in three women experiencing at least one form of violence by males in their lifetime.¹ This menace is thought to have persisted in many developing countries, due to patriarchal sociocultural beliefs and norms, which support male dominance over women, amidst lack of interventions and weak legal systems.² The occurrence of IPV during pregnancy poses further risk of reproductive and mental health consequences to both mother and child.³ Sexual violence increases risk of unwanted pregnancy, while physical violence increases risk of antepartum

hemorrhage, induced abortion, low birth weight, and fetal distress.⁴ The presence of these complications in pregnancy, may further worsen the mental health state of anxiety and/or depression.⁵

Meta-analysis of 70 studies most of which were conducted in developed countries, found significant positive relationship between maternal abuse and prenatal depression.⁶ A survey among adolescent parturients in New York, USA, found 38.0% prevalence of IPV, with associated two to three-fold increased odds of depression among victims compared with non-victims.⁷ Similar study among Vietnamese pregnant women found 50.4% prevalence of emotional form of IPV which was associated with 3.15 times increased odds of post-natal depression.⁸ Also, a cross-sectional study in Brazil found significant difference in mental disorders comparing victims and non-victims of IPV (71.0% vs. 33.0%, $p = 0.00$).⁹ Systematic review of studies in low and medium income countries (LMIC) reported 1.69 to 3.76 times increased odds of antenatal depression among victims compared with non-victims

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of IPV during pregnancy.¹⁰

Tura et al., in their analysis of secondary data in Mozambique found 47.3% prevalence of IPV among 205 ANC attendees.¹¹ A cross-sectional study among reproductive-age women (15-49 years) in Ile-Ife, South West Nigeria, found 36.7% lifetime prevalence of IPV, associated with 17 times increased odds of anxiety.¹² Unfortunately, most studies on IPV in developing countries, including Nigeria, were conducted among non-pregnant women, or among pregnant women but without assessment of potential associated adverse outcomes. This study was therefore aimed at assessing burden and mental health impact of IPV among pregnant women in Calabar, Southern Nigeria.

Methods

Study design was cross-sectional descriptive, and study population comprised attendees of antenatal care (ANC) clinics in General Hospital and Police Clinic, as the two key secondary health facilities in Calabar Municipality. ANC attendance registers were used as sampling frame to recruit two hundred and fifty (250) consenting parturients, through systematic random sampling method. A 12-item Composite Abuse Scale – Revised Short Form (CAS_R-SF) questionnaire was used to assess psychological, sexual, and physical forms of intimate partner violence. Hospital Anxiety and Depression Scale (HADS) was used to assess presence of anxiety and depression. These validated instruments were pretested before use for interviewer-assisted quantitative data collection. Data was entered and analyzed using SPSS version 21.0. Pearson chi-square was used as inferential statistic, and p-value was set at 0.05.

Result

Data was obtained from two hundred and fifty (250) respondents with mean age of 29.7 ± 6.1 years, ranging from 18 to 46 years. Most respondents were young adults

within 18 to 34 years (74.4%), married (82.4%), had tertiary education (62.0%), and were traders/business women (57.2%). Mean parity was 2.3 ± 1.2 ranging from 1 to 7. Approximately one-tenth had childhood history of sexual abuse (11.6%), and was currently afraid of their spouse (9.2%).

Approximately half of respondents (51.2%) had had at least one form of psychological abuse within the previous 12 months (table 1). Commonly reported psychological abuses were blaming for violent behaviour (32.8%), following someone at home or work (28.0%), and saying one was crazy or stupid (24.0%). Sexual abuse was experienced by 29.2% of respondents. Approximately a quarter of respondents each, reported being made to perform undesirable sexual acts (27.6%), and had sex under duress (23.2%). Sixty-seven respondents (26.8%) had had at least one occurrence of physical abuse. Commonly reported physical abuses were shaking, pushing or grabbing (20.0%), hitting with fist (16.0%), and threatening with knife or weapon (13.2%). A little above half (54.8%) had had at least one of the three types of abuse within the last 12 months. The common combination of abuses was psychological abuse only (16.4%), all three types of abuse (15.6%), and psychological and sexual abuse (10.8%). One hundred and twenty respondents (48.0%) had abnormal mental health status, comprising anxiety only (12.8%), depression only (22.0%), both anxiety and depression (13.2%).

Table 2 shows relationship between type of intimate partner abuse and mental health status. Presence compared with absence of anxiety and/or depression, was significantly more prevalent among respondents that suffered psychological (57.0% vs. 38.5%), sexual (64.4% vs. 41.2%), and physical (64.2% vs. 42.1%) types of abuse ($p < 0.05$). Also, prevalence of anxiety and/or depression was significantly higher among respondents that suffered at least one type of abuse compared with those that were not abused (55.5% vs. 38.9%, $p = 0.01$).

Table 1: Frequency of intimate partner abuse, anxiety & depression during pregnancy (N=250)

Variable	Frequency (Yes)	Percentage
Psychological abuse		
Blamed me for causing violent behaviour	82	32.8
Tried to turn me against my family, children or friends that I am crazy	32	12.8
Followed me or hung around outside my home or work	70	28.0
Threatened to harm/kill me or someone close to me	30	12.0
Harassed me by phone, text, e-mail or using social media	51	20.4
Told me I was crazy, stupid or not good enough	60	24.0
Kept me from seeing or talking to my family or friends	33	13.2
Kept me from having access to a job, money or financial resources	33	13.2
Had at least one psychological abuse in last 12 months	128	51.2
Sexual abuse		
Made me perform sex acts that I did not want to perform	69	27.6
Forced or tried to force me to have sex	58	23.2
Had at least one sexual abuse in the last 12 months	73	29.2
Physical abuse		
Shook, pushed, grabbed or threw me	50	20.0
Used or threatened to use a knife or gun or other weapon to harm me	33	13.2
Choked me	27	10.8
Hit me with a fist or object, kicked or bit me	40	16.0
Confined or locked me in a room or other space	24	9.6
Had at least one physical abuse in the last 12 months	67	26.8
Had at least one form of abuse in the last 12 months	137	54.8
Number and type of intimate partner abuse		
None	113	45.2
Psychological abuse only	41	16.4
Sexual abuse only	3	1.2
Physical abuse only	2	0.8
Psychological and sexual abuse	27	10.8
Psychological and physical	21	8.4
Sexual and physical	4	1.6
All three forms	39	15.6

Cont... Table 1: Frequency of intimate partner abuse, anxiety & depression during pregnancy (N=250)

Mental health status categories		
Normal	130	52.0
Anxiety only	32	12.8
Depression only	55	22.0
Both anxiety and depression	33	13.2
Mental health status category		
Normal	130	52.0
Had anxiety and/or depression	120	48.0

Table 2: Relationship between type of intimate partner violence and mental health status (N=250)

Variable (occurring within last 12 months)	Had anxiety and/or depression			Chi-square (p-value)
	Yes n (%)	No n (%)	Total n (100%)	
Had at least one psychological abuse				
Yes	73 (57.0)	55 (43.0)	128 (100)	8.6
No	47 (38.5)	75 (61.5)	122 (100)	(0.00)
Had at least one sexual abuse				
Yes	47 (64.4)	26 (35.6)	73 (100)	11.1
No	73 (41.2)	104 (58.8)	177 (100)	(0.00)
Had at least one physical abuse				
Yes	43 (64.2)	24 (35.8)	67 (100)	9.6
No	77 (42.1)	106 (57.9)	183 (100)	(0.00)
Had at least one type of abuse				
Yes	76 (55.5)	61 (44.5)	137 (100)	6.8
No	44 (38.9)	69 (61.1)	113 (100)	(0.01)
Abuse category				
None (no abuse)	44 (38.9)	69 (61.1)	113 (100)	17.6
One type of abuse only	19 (42.2)	26 (57.8)	45 (100)	(0.00)
Two types of abuses present	27 (50.9)	26 (49.1)	53 (100)	
All three types of abuses present	30 (76.9)	9 (23.1)	39 (100)	

Discussion

This study found high prevalence of 54.8% of at least one form of IPV among pregnant women, which is towards the upper limit of the range of 9% to 65% reported in a recent systematic review of studies in similar Low and Middle-Income Countries (LMIC).¹⁰ Hence, this prevalence is lower than what was reported in similar studies in Jos, North-Central Nigeria (63.2%)¹³, but higher than most other studies including Mozambique (47.3%)¹¹, Egypt (30.6%)¹⁴, and South Africa (15%)¹⁵. Variation in prevalence rates may depend on methods of assessment of IPV, and effectiveness of legal system towards women's rights.²

In particular, the occurrence of IPV during pregnancy increases risk of fetomaternal morbidity and mortality.³ Resulting maternal morbidity includes impairment of mental health status, mainly anxiety and/or depression, which were found in 48.0% of respondents in this study. Systematic review of studies in similar settings reported prevalence of antenatal anxiety ranging from 15% to 65%, and depression ranging from 5% to 35%.¹⁰ These mental health effects often get worse or persist even after the abuse ends. Other untoward maternal effects, especially for sexual and physical forms of abuse include genital injuries, unwanted pregnancy, antepartum hemorrhage, pregnancy loss, fetal distress and premature labour.³

The main focus of this study was to identify possible association between IPV and mental health status during pregnancy. Presence of anxiety and/or depression was significantly more prevalent among respondents that suffered each of the psychological, sexual, and physical forms of abuse. Adverse childhood experiences (ACE) of respondents may have contributed to high prevalence of IPV, anxiety and depression found in this study.¹⁶ Parturients who may have had low levels of resilience to ACEs during their childhood period, may have had increased risk of IPV and its associated mental health effects. Resilience is thought to enable victims IPV as an effective coping strategy, especially against anxiety and depression.¹⁶ Since maternal mental stability is essential for provision of adequate nursing and child care, high prevalence of IPV-associated impairment in mental health status may potentially impair infant bonding.¹⁷

In this study, family and socioculturally-driven stigma and discrimination may have led to

underreporting of IPV during pregnancy. Respondents may have felt uncomfortable or insecure about sharing their personal experience of violence perpetuated by their intimate partners. On the other hand, perhaps due to the physiological and psychological demand of pregnancy, parturients' threshold for perception of abuse by their partners may be lower compared with their non-pregnant status, potentially leading to overreporting of IPV. Also, causality cannot be established between IPV and mental health status using cross-sectional study design. Assessment of changes in mental health status before, during, and after pregnancy, would have more appropriately identified causal relationship between these variables. Therefore, some amount of caution should be exercised in the interpretation and application of findings from this study.

Conclusion and Recommendation

This is one of few studies assessing burden as well as mental health effects of IPV among pregnant women in a developing country. High prevalence of all forms of violence and their significant association with anxiety and/or depression, may be indicating much unmet reproductive health needs of women in resource-poor settings. Continued neglect of IPV may be making significant contribution to maternal morbidity and mortality in developing countries.

Preventive strategies aimed at minimizing effects of IPV should also be explored. These include training of the girl-child (who are future mothers) to be resilient against their ACEs, since these have been linked to future occurrence of IPV and adverse mental health effects. Healthcare workers in maternity settings should also be trained and retrained to recognize, counsel, and provide linkage support to victims of IPV towards minimizing adverse effects. Further research in other developing country settings, including use of qualitative methods and follow-up studies is also recommended.

Conflict of Interest: There is no conflict of interest to declare

Author Contribution

OO – conceptualized the work, analyzed the data, and wrote the draft manuscript

AA – collected and entered data, reviewed draft

manuscript

NK – collected and entered data, reviewed draft manuscript

OF – reviewed draft manuscript

LA – reviewed draft manuscript

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Effectiveness of Sodium Reduction Program on Urine Sodium Output among a Community Population: Cohort Study

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Abstract

Aim and Objective: The effect of reducing sodium consumption has been examined in sodium reduction programs that were designed to fit each area, using individual level intervention, but some outcomes were inconclusive. This 6-month study aimed to reveal effects of the combined individual-family-community program for reducing the intake of sodium and its content in urine in a community population.

Materials and Method: This cohort study recruited 127 participants from the community. All of them completed a 3-month individual-family-community program within the 6-month period of the study. Outcome measures assessed at baseline and the 1st and 3rd month of the program, and 6th month of the study, showed sodium content in first-morning urine, blood pressure, risk of excessive sodium intake, knowledge and self-efficacy.

Result: The participants showed significant improvement in all outcomes at month 1 ($p < 0.05$) when compared to baseline of the program. Knowledge was the only outcome that showed significance at month 3 of the program and 6 of the study period. The combined individual-family-community program was effective in the reduction of sodium output in urine and blood pressure, and increase of knowledge and self-efficacy in the community.

Keywords: sodium consumption, sodium reduce program, community, knowledge, self-efficacy

Introduction

Non-communicable diseases (NCDs) are a major cause of death worldwide [1]. It is estimated that they can lead to 49% of coronary heart disease [2]. Increased blood pressure level and hypertension are important risk factors for cardiovascular disease. High blood pressure can cause stroke [2], which is associated with sodium intake. The World Health Organization (WHO) determined that sodium salt reduction is one of nine global targets for controlling NCDs [3], since the reduction of sodium intake could reduce blood pressure levels [4,5]. Systematic reviews also showed that reducing

sodium intake could reduce blood pressure and risk of cardiovascular disease [6-7]. Furthermore, the WHO is concerned about these significant problems and has set a national goal of reducing sodium intake in the global population by 30% by 2023 [8].

Previous studies have investigated the effect of programs for reducing sodium intake in normal populations. These programs had interventions that consisted of self-management, self-efficacy and self-monitoring. [9-11]. Although these studies showed good outcomes in reducing blood pressure and sodium intake after intervention, and the programs were designed to fit each area and use individual level intervention, some outcomes were inconclusive. Moreover, interventions such as educational programs and family and community level intervention were used rarely in previous studies. Hence, implementing the same programs for reducing

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sodium intake may not be utilized wholly in the general population.

Therefore, this study aimed to research effects of the combined individual-family-community program for the reduction of sodium intake and content in urine, blood pressure and risk of excessive sodium intake, and increase of knowledge and self-efficacy in the community.

Materials and Methods

Study design and Study population

This was a cohort study. A total of 127 normally healthy participants were recruited from a Chinese-Haw tribe in Pa Tueng, Mae Chan district, Chiang Rai province between January and December 2017. The sample size was calculated from the n4Studies app [14]. The inclusion criteria included participants with a urine sodium output of more than 2,400 mg/day and aged 30 years or older. The exclusion criteria included those who were diagnosed with hypertension, and heart and kidney disease. The one group pre-posttest design, derived from analysis of sodium content from first-morning urine, was examined by the Atomic Absorption Spectrophotometer (AAS) method, before using the formula for calculating 24-h Na excretion (mmol/day) [15].

Outcome measurements

Outcome measurements were assessed at baseline and the 1st and 3rd month of the program and 6th month of the study.

1. Self-efficacy [16] was assessed by a self-confidence questionnaire that determined the

ability of the participants to practice sodium reduction. Its validity and reliability was 0.73 and 0.83, respectively. Ten items had a core range of 0-10 points, with a cut-off point at 72 points.

2. The risk of excessive sodium intake was assessed by the Food Frequency

Questionnaire (FFQ) [17], with its validity and reliability valued at 0.76 and 0.80, respectively.

3. There were 10 questions for assessing dietary consumption over the previous 7 days. Original Bloom's cut-off points were used for assessing sodium consumption [18], with their validity and reliability being 0.76 and 0.89, respectively. Knowledge scores ranged from 1 to 15 points and were interpreted into two levels as follows: 1) Pass means total score was at least 50% or 8–15 points; and 2) not pass means total score of less than 50% or 0–7 points.

4. The sodium content in urine was assessed by the

AAS method. First-morning urine samples were used in this method for calculating sodium intake. They were kept in a freezer at minus 80 degrees Celsius before being sent to a standard laboratory. The value of urine sodium and creatinine was used in the formula for calculating sodium intake [15].

5. Blood pressure was measured by a sphygmomanometer (Terumo brand, serial number

ES-P370, Terumo Company Ltd., Japan).

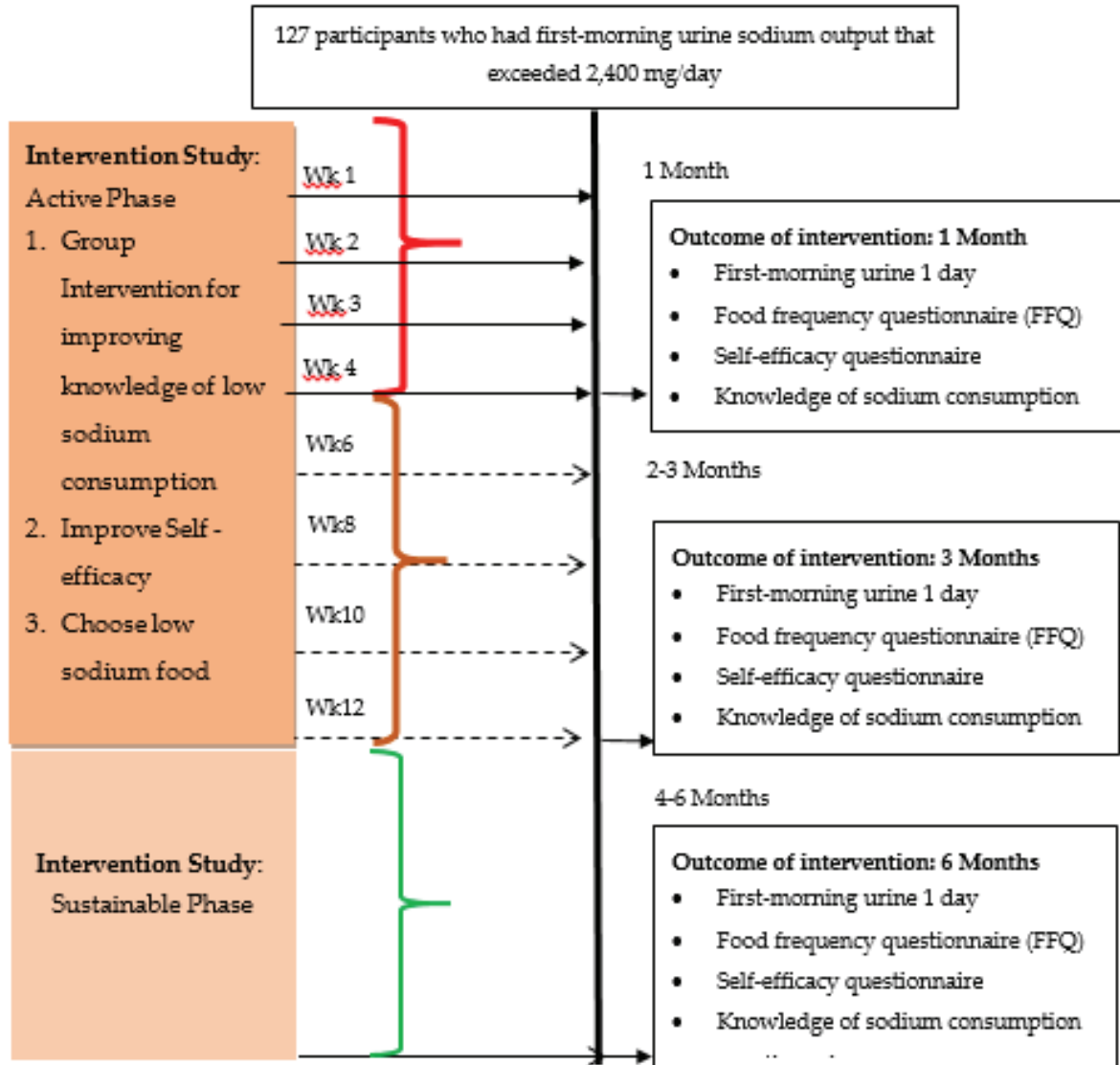


Figure 1: Flow chart of research intervention.

Intervention

The participants received the program for reducing sodium intake, which comprised individual, family and community level intervention.

Individual level: One hundred and twenty seven participants attended educational classes (knowledge and self-efficacy) once a week in the 1st month and every other week in the 2nd and 3rd month of the program.

Family level: Family members who cooked for the participants were invited to take part in a cooking training class for the first time in the 1st month of the

program.

Community level: The village headman announced basic knowledge of sodium and health once a week in the 1st month and every other week during the 2nd and 3rd month of the program.

None of the participants received any intervention after the 3rd month of the program (total program duration = 3 months).

Data Analysis

Data were analyzed using SPSS version 22 (SPSS

Inc., IBM Singapore Pte. Ltd., Changi Business Park Central 1, Singapore) [19]. The results were analyzed as mean, standard deviation (SD), median (Minimum-maximum), percentage and proportion. The paired t-test was used to compare each outcome within a group. A p-value of <0.05 was set as the level of statistical significance.

Results

A total of 127 participants were recruited into this study and assessed at baseline and the 1st and 3rd month of the program and 6th month of the study. All of them completed the study at month 6 and none of them dropped out. The mean age of the participants was 51.3±10.9 years and the majority were female (68.5%);

85.0% were married; 66.1% were agricultural workers; 86.6% were uneducated; and 82.7% had inadequate income and were unable to save money. The median of sodium in urine was 3,515.4 mg/day, with that of creatinine in urine valued at 95.56 mg/dl.

Table 1 shows proportion of the intervention result in reducing sodium intake by using the cut-off criteria in urine values of more than 2,400 mg/day. In almost all of the 127 cases, the variables were found to have decreased from the baseline data, except for self-efficacy that was found to decrease in the first month compared to baseline. Self-efficacy increased in value and then returned to a reduced value in the following measurements.

Table 1 Proportion of the intervention result in reducing sodium intake (n=127 cases)

Variables	Baseline n (%)	Follow-up		
		1 Month n (%)	3 Month n (%)	6 Month n (%)
Urine Sodium Cut off 2,400 mg/day				
< 2,400 mg/day	30 (19.10)	51 (32.50)	29 (18.50)	29 (18.50)
≥ 2,400 mg/day	127 (80.90)	106 (67.50)	128 (81.50)	128 (81.50)
2. Systolic Blood Pressure (SBP) cut off ≥ 140 mm.Hg				
< 140 mm.Hg	91(71.70)	124(97.60)	88(69.30)	97(76.40)
≥ 140 mm.Hg	36(28.30)	3(2.40)	39(30.70)	30(23.60)
3. Diastolic Blood Pressure (DBP) cut off ≥ 90 mm.Hg				
< 90 mm.Hg	114(89.80)	126(99.20)	115(90.60)	115(90.60)
≥ 90 mm.Hg	13(10.20)	1(0.80)	12(9.40)	12(9.40)
4. FFQ Score				
Low Risk (0 – 3)	80(63.00)	85(66.90)	104(81.90)	104(81.90)
Middle Risk (4 – 7)	36(28.30)	27(21.30)	21(16.50)	21(16.50)
High Risk (8 – 10)	11(8.70)	15(11.80)	2(1.60)	2(1.60)
5. Knowledge Score				
Pass ≥ 8 score	42(33.10)	92(72.40)	107(84.30)	96(75.60)
Not pass < 8 score	85(66.90)	35(7.60)	20(15.70)	31(24.40)
6. Self – Efficacy (Median score 72.00, rang minimum – maximum score 18 - 100)				
At least 72.00	58(45.70)	53(41.70)	61(48.00)	95(74.80)
Less than 72.00	69(54.30)	74(58.30)	66(52.00)	32(25.20)

Table 2 presents effectiveness of the intervention in reducing sodium intake and comparison of mean difference with baseline.

Sodium intake, as measured by AAS (first-morning urine sodium content of more than 2,400 mg/day), decreased at month 1 (-154.61), but rapidly increased at month 3 of the program (422.82) and 6 (577.15) of the study.

Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) levels were -9.19 and -6.40, 5.12 and -0.52, and 0.40 and -1.78 at the 1st and 3rd month of the program and 6th month of the study, respectively.

The average knowledge score measured by sodium consumption was found to increase to 3.08, 4.22 and 3.42 in the 1st and 3rd month of the program and 6th month of the study, respectively.

Table 2 Effectiveness of intervention in reducing sodium intake and comparison of mean difference with baseline (n=127 cases)

Variables	Baseline Mean (±S.D.)	Follow-up								
		1 Month			3 Months			6 Months		
		Mean (±S.D.)	Δ Mean (±SD)	P value	Mean (±S.D.)	Δ Mean (±SD)	P value	Mean (±S.D.)	Δ Mean (±SD)	P value
1. Urine Sodium, mg/day	3515.43 (±1065.77)	3360.82 (±1427.28)	-154.61 (±137.60)	0.26	3938.25 (±2008.91)	422.82 (±188.34)	0.03*	4092.58 (±2258.05)	577.15 (±220.84)	0.01**
2. SBP, Mean (±S.D.)	132.83 (±20.75)	123.63 (±11.99)	-9.19 (±22.81)	0.00**	137.83 (±18.15)	5.12 (±29.61)	0.50	133.24 (±18.32)	0.40 (±20.07)	0.81
3. DBP, Mean (±S.D.)	76.14 (10.72)	69.74 (±9.17)	-6.40 (±14.86)	0.00**	75.62 (±9.93)	-0.52 (±13.95)	0.67	74.36 (±11.62)	-1.78 (±11.20)	0.07
4. Knowledge Score (±S.D.)	7.92 (±2.14)	11.00 (±3.09)	3.08 (±3.61)	0.00**	12.14 (±2.92)	4.22 (±3.54)	0.00**	11.34 (±3.13)	3.42 (±3.30)	0.00**

Discussion

The participants of this research were selected from those having first-morning urine sodium samples of more than 2,400 mg/day, and most of them were female, married, lacked education, and had insufficient income. Nearly all of the participants cooked for themselves and their family.

The mean difference of knowledge score continued to increase throughout the research period. This was

consistent with Lara Nasreddine et al.^[24], who found the majority of their subjects had knowledge that high dietary salt might worsen health status. However, the findings of Leila Cheikh Ismail et al.^[25] indicated low salt-related knowledge scores among their students.

If people could reduce sodium consumption by at least 30 percent, they would reduce morbidity and mortality ^[17]. This study found that the sodium reduction program could reduce urine sodium output by 32.5 percent from baseline, which is in line with

previous studies^[9-11].

This research revealed that the mean difference between SBP and DBP levels were decreased. At the same time, previous studies showed evidence that substantial statistical heterogeneity of SBP and DBP were reduced in all intervention arms – normotensives^[9-11].

The risk of excessive sodium intake, as measured by the FFQ scores, showed decreased score in high- and moderate-risk groups, but increased score in low-risk groups at the 1st and 3rd month of the program and 6th month of the study. Similarly, Lara Nasreddine et al.^[24] found a high proportion of their participants reporting that they generally checked information on food labels, which affected their purchasing decisions. However, Durrajam Khokhar et al.^[26] found that about half of all parents in their study reported adding salt to their own food at the table, while about one third reported adding salt to the food of their child/children.

Self-efficacy score at baseline increased in the low self-efficacy group at the 1st and 3rd month of the program and 6th month of this study, which showed that the program could improve self-efficacy and be maintained throughout the 6-month period. Similar studies by Lu Hu et al.^[27], found that interaction between dietary self-efficacy and intervention had impact on the changes in dietary sodium density; and So-hyun Ahn et al.^[28], found that self-efficacy was the primary resource for stronger related intention to perform healthy eating practices than expected.

The strength of this study was the combination of 3 intervention levels (individuals, family and community), which could reduce sodium intake and sustain knowledge of sodium consumption. This study found that key success at the family level was housewives who cook for themselves and family at home. This was the key factor in changing cooking habits and reducing sodium ingredients in food for the family. However, the limitation of this study was no comparison group in the program. Therefore, it is suggested that further study should be designed to cover case and control for comparison, consistency and sustainability.

Conclusion

This program could be applied and extended to other groups who encounter sodium consumption problems beyond the standard criteria. The effects of this research model in reducing sodium intake, are seen through the effective frequency of activities that stimulate knowledge, self-efficacy and regulation of salty diets. Therefore, health volunteers who support health workers lead to sustainability.

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Conflicts of Interest: The authors declare no conflict of interest.

Ethical clearance: This study protocol was approved by the Committee of Research Ethics in the Faculty of Medicine, Chiang Mai University (Study Code No. COM-2559-03677/Research ID: 3677)

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- Title of the Manuscript:

A Study on Knowledge, Attitude and Practice Towards COVID-19 among the Population in Balod and Raipura Mahadev Ghat areas of Chhattisgarh State in India

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Abstract

Background: The coronavirus is a family of viruses, it can cause severe medical complications and lead to death in some people. Aim of the study was to assess the knowledge, attitude and practice towards COVID-19 among the population in Balod and Raipura Mahadev Ghat areas of Chhattisgarh state in India. **Methods:** A Cross-sectional study was conducted in selected areas of Chhattisgarh state during lockdown period from 23rd to 30th April 2020. A total of 151 responses were recorded online survey through Google Form. Data analysis was carried out using SPSS-21. Among the participants, considerably sound knowledge was present regarding the transmission of COVID-19 from human to human (100%), its causative agent (96%), at risk group for COVID-19 (91.4%), incubation period (90.1%). Almost all the respondents (98%) avoided stepping out of home and also maintained social distance and avoid gathering. All the participants used mask whenever they went out of home and 90.7 percent respondents had followed hand washing steps as suggested WHO. **Conclusion:** Health awareness has impact on knowledge, attitude and practice towards COVID-19. Moreover, regular educational interventions and awareness campaigns are still required in preventing the further spread of COVID-19.

Key words: COVID-19, knowledge, practice, social distance

Introduction

Corona virus is creating a scientific fire storm across the world, the virus that led to the global pandemic, now has created so much tragedy and deaths in India and all around the world. This expanding global outbreak of a respiratory illness caused by the SARS-CoV-2 has been named as COVID-19. While most COVID-19 cases were initially associated with travel, person-to-person spread is now being reported in all places. Corona viruses are a group of viruses that cause diseases in humans. Coronaviruses constitute the subfamily

Orthocoronavirinae, in the family Coronaviridae, order Nidovirales and realm Riboviria.^[1,2] Corona Virus are a large family of viruses that cause illness ranging from the common cold to more severe diseases and deaths. On 31st of December 2019, WHO was informed of cases of pneumonia of unknown cause in Wuhan city in China. A novel coronavirus was identified as the cause by Chinese authorities on 7th January 2020 and was named by COVID -19. The ongoing COVID-19 Pandemic has spread very quickly and had reached more than 180 countries. The WHO has declared the COVID-19 outbreak as a global pandemic on 11th March 2020.

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The risk of acquiring the infection increases when living with an infected individual or entering a health care setting. The virus is excreted through droplets where coughing and sneezing is likely to facilitate the transmission of the virus. Moreover, surfaces, objects and hands contaminated with the virus are suggested sources of transmission. Unwashed contaminated hands

increase the risk of infection when coming into contact with noses, eyes or mouths. Clinical presentation of the infection varies from mild flu-like symptoms to severe acute respiratory illness and death especially in cases involving co-morbidity.^[3]

India has recorded 33,050 confirmed cases, 1,074 deaths, 8,325 cured cases, according to the latest update released by the Union Ministry for Health and Family Welfare on Thursday morning 30th April 2020.^[4] Chhattisgarh State reported its first coronavirus case in a Raipur man on 19th March 2020. According to AIIMS-Raipur official, the patient has come back to India from overseas along with his family. As COVID-19 cases continue to pile up across the country, Chhattisgarh has emerged as one of the big states to have done well, at least till now, in checking the spread of the disease. According to the Ministry of Health and Family Welfare, as of April 27, Chhattisgarh had a total of 37 cases, of which 32 had recovered. The remaining 5 were in hospital and were showing signs of recovery. With no deaths, perhaps the best rate of recovery in the country (over 86%), and with 23 of the state's 28 districts unaffected, Chhattisgarh has emerged as the state with the largest area without COVID-19 cases as a percentage of the total area of the state.^[4]

Most people who fall sick with COVID-19 will experience mild to moderate symptoms and recover without special treatment. No vaccine has been developed or discovered so far in preventing the spread of highly pandemic deadly disease. The virus that causes COVID-19 is mainly transmitted through droplets generated when an infected person coughs, sneezes, or exhales. People can be infected by breathing in the virus if people are within close proximity of someone who has COVID-19, or by touching a contaminated surface and then your eyes, nose or mouth. Therefore, applying preventive measures to reduce the spread of the disease is of the utmost importance.^[5] The WHO and the Centre for Disease Control and Prevention (CDC) have published recommendations for the prevention and control of MERS infection in health care settings.^[6] This includes hand hygiene, wearing personal protective equipment, and patient placement.^[7] So, it has to be strengthen the preventive strategies for management of COVID-19 in Chhattisgarh State, there is an urgent need to understand the public awareness and to get

comprehensive approaches towards COVID-19. The aim of this study was to assess the knowledge, attitude and practices towards COVID-19 among the population in Balod and Raipura Mahadev Ghat areas of Chhattisgarh state in India

Materials and Methods

Study design

A Cross-sectional study was conducted in Balod and Raipura Mahadev Ghat areas of Chhattisgarh state during the lockdown period. Community based survey during lockdown period was not feasible, therefore, we conducted an online survey through Google Form for documenting and collecting the information from participants.

Study duration

This study was conducted from 23rd to 30th April 2020.

Study Population

Study participants were selected among rural and urban population both male and female aged 18 and above years.

Sampling Technique

Purposive sampling technique was applied for data collection with following Inclusion Criteria:

- Individuals aged 18 and above years and can read and understand English and Hindi.
- Individuals willing to participate and give their consent.
- Individuals who can provide data through digital media.

Data collection

We conducted an online survey through Google Forms to collect the data from the participants. Data were collected using a self-administered, closed-ended questionnaire. 200 questionnaires were distributed and a total of 151 responses were recorded.

Data Analysis

Data analysis was carried out using SPSS-21.

Categorical variables were presented as frequencies and percentages.

Results

Study was conducted an online survey through Google Form to understand the level of knowledge and practices towards COVID-19 among the population in the study area. Result shows that mean age of study population was 30.8 years [Table 1]. More than half of the participants were males (58.3%) and 62.9 percent of the participants resided in urban areas. [Figure 1 & 2]

[Table 2] shows that the level of knowledge and information regarding COVID-19. Considerably sound knowledge was present regarding the transmission of

COVID-19 from human to human (100%), its causative agent (96%), at risk group for COVID-19 (91.4%), incubation period (90.1%), potential to spread in hot and humid climate (92.1%) and 49.7 percent felt that it was a curable disease.

[Table 3] indicates that the attitude and practices of the participants towards COVID-19. Almost all the respondents (98%) avoided stepping out of home and also maintained social distance and avoid gathering. All the participants used mask whenever they went out of home, 90.7 percent respondents had followed hand washing steps as suggested WHO and 46.3 percent relied on traditional/herbal medicines for boosting their immunity.

Table 1: Age distribution of the participants

Age	Male	Female	Total
18-27	42(53.2)	37(46.8)	79
28-37	22(59.5)	15(40.5)	37
38-47	11(64.7)	6(35.3)	17
48-57	10(71.4)	4(28.6)	14
58+	3(75.0)	1(25.0)	4
Total	88(58.3)	63(41.7)	151

Table 2: Knowledge assessment about COVID-19

Sl.No	Questions	Frequency and (%) (N=151)	
		Yes	No
1	Causative Agent for COVID-19?	145(96)	6(4.0)
2	Is air a mode of transmission for COVID-19?	76(50.3)	75(49.7)
3	Can Covid-19 virus spread from human to human?	151(100)	(0.0)
4	Can COVID-19 be transmitted directly through contact with infected surfaces?	142(94)	9(6.0)
5	Can COVID-19 infection spread from animal to human	108(71.5)	43(28.5)
6	Can Covid-19 virus spread in hot and humid climates	139(92.1)	12(7.9)
7	Safe distance to stay apart from someone who is sick	90(59.6)	61(40.4)
8	Incubation period of COVID-19	136(90.1)	15(9.9)
9	High risk group for COVID-19	138(91.4)	13(8.6)
10	Is COVID-19 a curable?	75(49.7)	76(50.3)

Table 3: Attitude and Practices towards COVID-19

Sl.No	Questions	Frequency and (%) (N=151)	
		Yes	No
1	Prefer to avoid going out of home during lockdown	148(98)	3(2.0)
2	Prefer to eat home cooked food	142(94)	9(6.0)
3	Do you think one should wash hands at least for 20 seconds?	147(97.4)	4(2.6)
4	Do you think one should sneeze or cough flexing the elbow and avoid using hands	146(96.7)	5(3.3)
5	Even after lockdown, will you avoid physical contact while greeting?	140(92.7)	11(7.3)
6	Do you maintain social distance and avoid gathering	148(98)	3(2.0)
7	Due to COVID-19, do you pay more attention towards your personal hygiene	149(98.7)	2(1.3)
8	Do you use traditional/herbal medicines to boost your immunity?	70(46.3)	81(53.6)
9	Do you wear mask while stepping out of home?	151(100)	(0.0)
10	Do you perform hand washing steps as suggested WHO	137(90.7)	14(9.3)

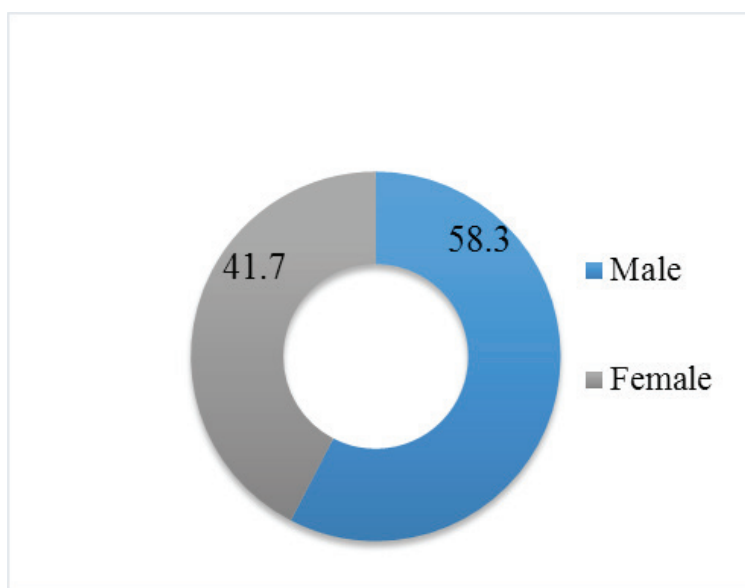


Figure 1: Sex distribution of the participants

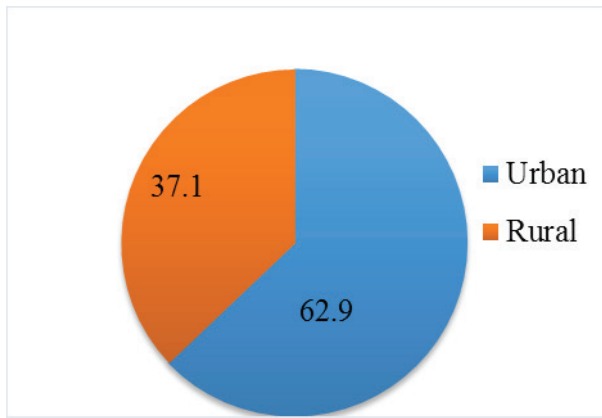


Figure 2: Residence of participants

Discussion

At presently, COVID-19 is a daily conversation subject in the mass media and among the public irrespective of rural and urban population. The outcome of the study may be useful when planning health education programmes for further action in preventing the spread of COVID-19. The evidence based information will be asset for health care providers and policy makers to take comprehensive strategy for preventing the spread of communicable disease at the very earliest.

A significant proportion of the participants were aware about the causative agent of COVID -19. Knowledge of the etiological agent is considered as the first step of public awareness. Once the people know the agent they are most probably understand how the disease is transmitted from one person to another and what are the preventive measures has to be taken for preventing the spread of COVID-19. Present research study reveals that people have had considerable sound knowledge regarding the transmission of COVID-19 from human to human (100%), its causative agent (96%). Other study shows that nearly 57 percent of the respondents were classified as knowledgeable about the disease and its management.^[8]

Another study conducted by Zahra Al-Muhafda, results showed that prior to the educational event, the majority of the recipients thought that they didn't have enough knowledge about MERS-Corona Virus (54.5%). The most recipients knew about the symptoms associated with MERS-Corona Virus in pre-test (51.5%), additively, the majority showed that they knew about these symptoms, but their knowledge improved compared to pre-test (90.9%), McNemar's Test

($P = 0.001$). When it comes to prevention, most recipients chose washing hands as preventive methods (33.3%) in pre-test.^[9] Another study stated that a vast majority of the participants were aware of the MERS-CoV in Saudi Arabia.^[10] Furthermore, females had more knowledge and better attitude than males. This study also showed a positive attitude and a higher level of proper hygienic practices among the population. These current results are in line with other studies' findings which showed a positive attitude of the public and among healthcare professionals specifically.^[10]

All the respondents reported in the present study the people themselves can act as a source of transmission of COVID-19 through connect with an infected people, touching surfaces contaminated with virus, confirming the good knowledge level about mode of transmission of COVID-19 infection among rural population in Chhattisgarh State. The most identified gap in knowledge among respondents was related to disease treatment domain. Half of the respondents replied that COVID-19 is not curable disease. Other study shows that, only 19% of participants believed that there is no treatment for MERS-CoV; however, (26.6%) agreed with using supportive treatment for MERS-CoV, and (31.1%) of the participants believed in the presence of a vaccine for preventing COVID-19. Actually, there is no treatment, and the infected people treatment depended on their immune system.^[11]

In the present study, almost all the participants (98%) had avoided going out of home and had maintained social distance and avoid gathering during lockdown period and also worried about COVID-19 for their family. Similar findings have been reported in many previous studies.^[12,13] This study identified precautionary measures against COVID-19 such as practice of hand washing, avoiding touching face. All the participants wear mask while stepping out of home and 90.7 percent followed hand washing steps as suggested WHO. The most commonly reported method of preventing transmission of COVID-19 is hand washing in the present study.

Conclusion

The previous and current decades witnessed the emergence of new viral diseases that threaten the health of the people across the world. Levels of knowledge and understanding about a particular communicable disease

can be influenced by the spread of the disease, incidence of morbidity and mortality, incubation period and methods for sharing and propagation of knowledge and it varies from person to person. A Health authority in Chhattisgarh State has taken substantial and continuous efforts in order to control the spread of disease through various measures. Public awareness on COVID-19 is considered as one of the effective measures that can help in the control of infectious diseases. A significant proportion of the participants were aware about COVID-19 and they were well understood how to maintain proper precautionary measures both in and outside the home. All the participants wear mask while stepping out of home and follow the hand washing steps. It is recommended that increase the knowledge, attitude and practice towards COVID-19 by utilizing the available social mass media, through this continuous endeavour authority can promote public health education for entire population in order to control COVID-19. Regular educational interventions and awareness campaigns are still required in preventing the further spread of COVID-19.

Acknowledgement

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Conflict of Interest : Nil

Source of Funding : Nil

Ethical Clearance: Institutional Ethical Committee (IEC) of Parul University has approved the research entitled “A Study on Knowledge, Attitude and Practice towards COVID-19 among the population in Balod and Raipura Mahadev Ghat areas of Chhattisgarh state in India” for the research activity.

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Literature Review : Dental Practice Management in the New Normal Era and Prevention Measures Regarding Dental Bioaerosol in Indonesia

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Abstract

Coronavirus 2019 (COVID-19) commonly spreads through droplets from the respiratory tract or contacts with contaminated surfaces. Risks of being infected with COVID-19 in work is mostly caused by close contacts less than 1 meter with people who are infected with COVID-19 and contact with contaminated surfaces and objects. All dental practitioners have a high risk of being infected with SARS-CoV-2 for face-to-face communication and saliva, blood droplets as well as other body fluids and the use of sharp instruments. To identify the procedures of dental practice management and prevention measures of dental bioaerosol in the new normal era of COVID-19. The descriptive analysis was done through a literature review. The data were from secondary data. Coronavirus is an RNA virus with a particle size of 120-160 nm. This virus mainly infects animals, including bats and camels. Some prevention measures applied by dental practitioners were wearing Personal Protective Equipment (PPE) level 3 with proper procedures of removing PPE, washing hands with soap by following six steps of handwashing suggested by World Health Organization, using a dental aerosol suction machine to reduce the aerosol concentration in rooms with poor ventilation, sterilizing all dental equipment with autoclave, disinfecting surfaces reached by patients and dentists, and having a protective vaccine for health workers, for example protecting vaccine. During the COVID-19 pandemic, nearly all dental practitioners are being at risk of transmitting and being infected with the SARS-COV-2 virus since the viral load is dominated by the aerosol in patients' mouths. Some prevention measures in the new normal era could be done by wearing Personal Protective Equipment (PPE) level 3 with proper procedures of removing PPE, washing hands with soap by following six steps of handwashing suggested by World Health Organization, using a dental aerosol suction machine, sterilizing all dental equipment with autoclave, disinfecting reachable surfaces, and getting the protective vaccine. The new normal era demands changes in behavior in daily activities by following the health protocols to prevent the spread of COVID-19.

Keywords: COVID 19, Dental bioaerosol, New Normal, Health Protocol

Introduction

In late December 2019, countries around the world were astounded by a new pneumonia epidemic that first emerged in a group of patients treated at hospitals and initially diagnosed as having pneumonia of unknown

etiology in Wuhan, Hubei Province. This case started spreading quickly to most of countries and territories. Firstly, this disease was temporarily given a name as 2019 novel coronavirus (2019-nCoV), but then World Health Organization announced its new name called Coronavirus Disease (COVID-19) which was caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2)¹. A letter from the Faculty of Medicine, University of Indonesia mentioned that Indonesia was ranked fifth with the highest Case Fatality Rate (CFR) in the world and with CFR 8-10%². In March 2020, the

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Indonesian Government announced COVID-19 firstly spread in Indonesia and was considered a national non-natural disaster³. COVID-19 generally spreads through droplets from the respiratory tract or contact with contaminated surfaces. Risks of being infected with COVID-19 at work are mostly caused by close contacts less than 1 meter with people who are infected with COVID-19 and contact with contaminated surfaces and objects. The risk levels are divided into three categories which can evaluate the risks of COVID-19 infection in the workplace, for example, low, medium, and high exposure risk. Low exposure risk occurs when a job does not contact closely and frequently with the public and other colleagues, visitors, clients, and other confirmed and suspected COVID-19 people. People with medium exposure risk work in an environment that closely and frequently contact with the public and other colleagues, visitors, clients or customers, or contractors, and other suspected COVID-19 people. While high exposure risk is experienced by people who have potential high and close contact with confirmed and suspected COVID-19 people and contaminated surfaces and objects^{4,5}. There are four basic spreading routes of pathogenic microorganism in dental clinics, for example, passing through the blood of infected patients, saliva or aerosol droplets of infected patients, gingiva secretion, periodontium, and teeth, aerosol droplets in handpieces in the dental unit, and finally direct contact with patients and contaminated equipment⁶. All dental practitioners have a high risk of being infected with SARS-CoV-2 for face-to-face communication and saliva, blood droplets as well as other body fluids and the use of sharp instruments⁷.

According to the Circular Letter Number 2776/PB PDGI/III-3/2020 concerning guidelines of services, dentists are asked to delay treatments to people without symptoms, elective treatments related to aesthetic treatment using a dental bur, scalar or suction during the COVID-19 pandemic⁷. However, the Indonesian Government now regulates the citizen's lives to be normal again, and this later condition is called the new normal. The term "new normal" emphasizes more on changes in the community's culture to practice healthy behavior. New normal is a change in culture, such as practicing hygiene and a healthy lifestyle, wearing masks when going outside the home, washing hands, and so on⁸.

Since dentists have high exposure risk to COVID-19 transmission, COVID-19 articles published in 2020 were under review. Several questions arose from this study was how dental practice management in the new normal era is (applied by operators, such as dentists and dental assistants) and patients and what prevention measures are used to prevent dental bioaerosol. These questions were based on the idea that dentists always have contact with bioaerosol which may transmit COVID-19 through droplets.

Materials and Method

The method used in this research is the study of literature, which is the study of the object of research in the form of scientific journals, books, articles in mass media, or statistical data. The literature will be used to examine research problems and how to deal with them. The nature of the study conducted is descriptive analysis which is to give a picture to the reader so that it can be a medium of public education. The type of data used is secondary data. The articles reviewed in the discussion were published from September 2005 to March 2020.

Results and Discussion

Coronavirus Disease (COVID-19) and Its Transmission. Coronavirus, an RNA virus, has a particle size of 120-160 nm. This virus primarily infects animals, such as bats and camels. Before the COVID-19 pandemic, there are 6 types of coronavirus which can infect humans, for example, alphacoronavirus NL63, betacoronavirus OC43, betacoronavirus HKU1, SARS-CoV, and the Middle East Respiratory Syndrome Coronavirus (MERS-CoV). Coronavirus was named for its crown shape with spikes on the surface. The virus will enter the susceptible cells to the body through nose, mouth, or eyes, and they will attach to respiratory tract cells which produce ACE2 protein⁹. The preliminary study showed oral cavity has high potential risks of the coronavirus confinement. Based on the existing data, comorbidities such as hypertension and diabetes mellitus, male subjects, and active smokers are the risk factors of SARS-CoV-2 infection. The disease distribution mostly occurs to males because they have a high prevalence of active smokers. In smokers and people with hypertension and Diabetes Mellitus, the expression of ACE2 receptor assembly increases. Besides, >65-year-old people with asthma, chronic lung disease, cardiac arrest, obesity,

immune system disorder, and liver problems have a high risk of SARS-COV-2 infection.

Personal Protective Equipment (PPE) for Dentist

PPE is obligatory for dentists and dental assistants. Recommendations of PPE use based on the protection level are divided into three levels, such as level 1, level 2, level 3. PPE level 1 consists of a 3-ply surgical mask, disposable latex gloves, and scrub suit. Surgical masks only give partial protection to people from bio aerosol. Health workers who work in the dental public practice which does not have high risks and aerosol will wear PPE level 1. While PPE level 2 includes an eye protector, a surgical mask, eye goggles, disposable latex

gloves, and a gown. The PPE level 2 should be worn by health workers, doctors, nurses, and laboratorians who work in inpatient rooms, where non-respiratory specimens are taken, and in laboratories. Whereas, the PPE level 3 consists of an eye protector and face shield, an N95 mask or equivalent, disposable latex gloves, eye goggles or head cape, all cover gown, apron, and boots. PPE level 3 should be worn by health workers who have direct contact with suspected and confirmed COVID-19 patients and who give a surgical treatment that generates aerosol¹⁰. However, another study found an N95 mask is not enough to protect people from droplets, thereby wearing PAPRs (Powered Air-Purifying Respirators).

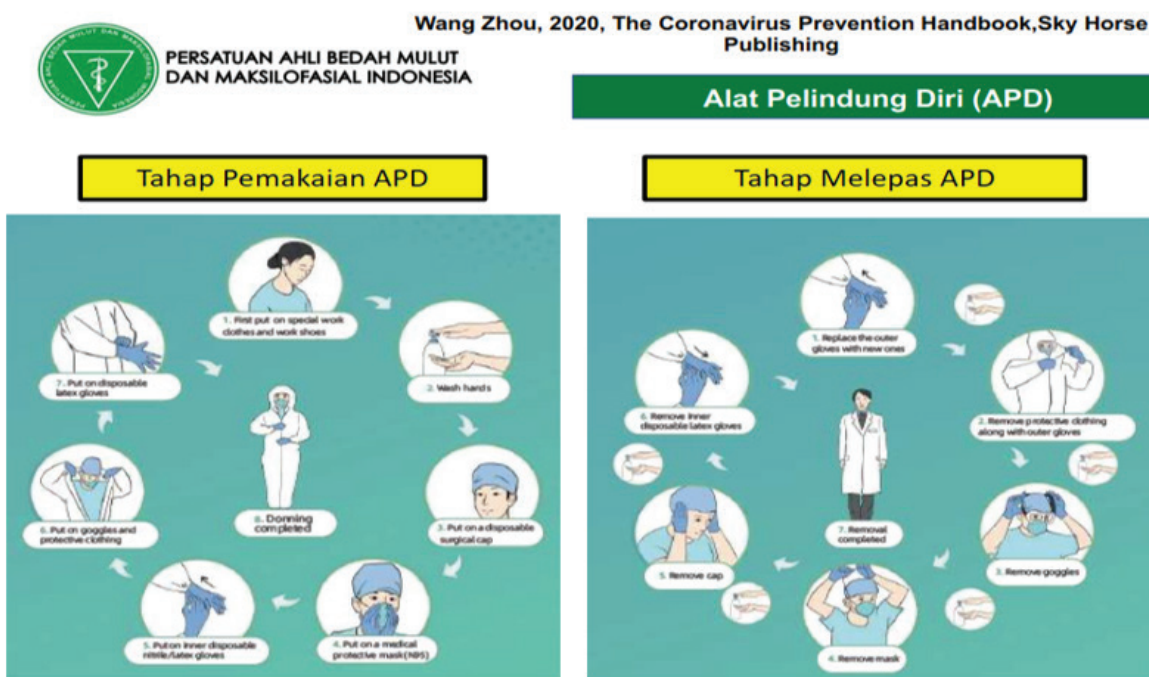


Figure 1. How to take off and use Personal Protective Equipment

Procedures for putting on PPE include wearing a scrub suit, removing all jewelry or accessories, handwashing prior and after putting on PPE, putting on and removing PPE in the Antero room, and taking a bath after removing PPE¹¹. Whang Zhou (2020) stated the above figure was based on the Coronavirus Prevention Handbook. Some procedures for wearing and putting on PPE were entering the Antero room after putting on a scrub suit in the fitting room, checking PPE in good condition, and washing hands with soap or hand sanitizer

in six steps, and then putting on boots. If health workers wear sneakers or other covering shoes, they shall wear shoe covers protecting the outer part of their shoes and pants by firstly putting feet in, covering sleeves and tightening coverall over the body by zipping it to the neck and letting hood or head cape of the coverall open behind the neck. Then, health workers should wear a surgical mask by putting in front of the nose and mouth by pulling two sides of straps and fastening it to the backside. Next, they put on a head cape that covers

the head and ears thoroughly and wears goggles with a tightening cover throughout the eyes. Finally, they need to cover the gown sleeves, and PPE is ready to wear¹².

While procedures for removing PPE range from standing in the unsterile area, removing hood or coverall head cape by removing the head cape from the head to the front until it is released. Health workers then shall remove the coverall gently by opening the zipper from the top to bottom and gently pull the inner front part of the coverall to the front part of the body. At the same time, hands slowly remove gloves and parts covering feet by flipping the outer part inside. During removing the coverall, always keep a distance from the health workers' body. After that, the coverall is thrown to an infectious waste container. Then, disinfect hands with hand sanitizer in six steps. Remove goggles by putting down the head a little bit and pull the left and right side of the goggles at once. Then, remove it from the face and throw the goggles into a secured box. Remove the surgical mask by slowly pulling mask straps and throw it into an infectious waste container. Disinfect hands with hand sanitizer in six steps. After removing scrub suit, health workers should shower and then wear casual clothes^{11,12}.

Procedures in Health Facilities

Proving washbasin or hand sanitizer is useful for everyone who enters a room and is required to wash their hands. Besides, using a thermometer infrared before entering a room can check the body temperature of people in the room. If someone's body temperature is suspected to 38oC, he will not be allowed to enter the room. Then, an anamnesis of whether the symptoms are COVID-19 or not was done. Furthermore, proper management of ventilation is significant. Good working ventilation will reduce the concentration of airborne microbes and avoid microbiologically contaminated air circulation. Avoid using split/central Air Conditioning and commercial windows except being equipped with High-Efficiency Particulate Air (HEPA) filter. Natural ventilation and mechanical ventilation in exhauster are recommended to use¹¹.

Purification of microbes pollutants in the air can be done by using a dental aerosol suction machine that can absorb droplets and aerosol up to 99%. The machine has 62 dB sound equivalent to the sound of a hairdryer

with little noise which does not disturb operators and patients. Carbon activation filtering and HEPA filter can result in a 0.3-micron filter, with the SARS-COV-2 particle size of 0.06 to 0.14 micron¹³. Use rubber dam tape when health workers wear a highspeed handpiece. Until now, further studies have not differentiated the use of aerosol suction machines and rubber dam to fight against aerosol. Both types of equipment are useful to avoid aerosol in the oral cavity. When using four-handed dentistry, dentists and dental assistants face patients in the supine position. Coordination between dentists and dental assistants is the key factor to implement the best practice, do sterilization, and save time spent during the procedures¹³.

Sterilizing dental equipment uses autoclave, especially B-class autoclave for handpieces or scalar (before and after its usage) by ensuring the inner and outer parts. The use of an N-class autoclave is not recommended in dental practices. Regularly disinfecting medical equipment at clinics is required when health workers start working and having contact with patients. The clinical contact surface can be contaminated through patients in forms of spray or sparks during the dental procedures or through contaminated gloves. Places that need to be disinfected are handle, dental lamp, radiography tools, dental chair, and cuspidor. Use a protector to avoid contamination of surfaces to clean and disinfect enclosed surfaces among patients¹⁴. Always do routine hygiene to the surfaces, such as floors, walls, and sink with detergent and water or the disinfected surfaces. Finally, health workers should do protective vaccines of Dental Health Care Personnel Safety, such as the BCG vaccine, influenza vaccine, meningitis vaccine, MMR vaccine, and varicella vaccine.

Preventive Measures for Patients

Some procedures need to be done when patients come to healthcare facilities especially dental clinics are firstly always wearing a sheet mask in the waiting room. Do physical distancing especially in the waiting room. Lastly, gargling with antiseptics before dental procedures. It is recommended to apply antiseptics for gargling with 1% of hydrogen peroxide (H₂O₂) and 0.2% of povidone-iodine. The Vice of General Secretary of Indonesia Dental Association (PDGI) drg. Iwan Dewanto, MMR, Ph.D. based on the research done,

stated that the use of 0.23% of povidone-iodine in 2 minutes can control the quantity of SARS-CoV-2 until the concentration of the virus is not detected anymore. While, the use of povidone-iodine has been proven to reduce up to 99.9% of the concentration of other types of coronavirus, such as Mers-CoV when it is used for 30 seconds.

Conclusion

During the COVID-19 pandemic, nearly all dental practices are at the risk of SARS-COV-2 transmission since aerosol from patients' oral cavity is dominant. Teeth bioaerosol could not stop thoroughly, but it can be reduced significantly by taking some preventive measures in the new normal era. These include wearing PPE level 3, frequently washing hands with soap in 6 steps as suggested by WHO, using a dental aerosol suction machine to reduce the concentration of aerosol in a poorly ventilated room, sterilizing all dental equipment by using autoclave, disinfect surfaces accessible to patients or dentists, and getting a protective vaccine, such as BCG vaccine, influenza vaccine, meningitis vaccine, MMR vaccine, and varicella vaccine. New normal means changing behavior in doing the daily activity by following health protocols to prevent COVID-19 transmission. Even though dentists and patients are now in the new normal, dentists and patients have to follow preventive protocols.

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Conflict of Interests : Nil

Ethical Clearance: This study utilizes secondary data that has been published. So there is no need for ethical clearance

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A Pharmaceutical Importance of *Murraya Koenigii*- A Complete Study

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Abstract

Murraya Koenigii is a multipurpose plant. Its belong to the rutaceae family. The plant is commonly known as Curry Leaf/Kari pataa or Meethi neem. The plant is a native of India. It is distributed/found in tropical and sub-tropical regions in the world. All parts of plant is useful for treat and cure various diseases and useful for preparation of pharmaceutical formulations, cosmetic preparation. The plant contains many major phytochemical compounds, Vitamins, Nutrients. it is also a rich source of nutrient and minerals (K, S, Ca, Zn, Fe, Mg) due to the presence of these major chemical compounds the plant contains many pharmacological activity like anti-inflammatory, anti-pyretic, hypoglycaemic, anti-ulcer, wound healing, hypocholesterolemic, anti-oxidant, useful for memory enhancing and some other uses includes insecticidal, anti-microbial, anti-fungal etc. The main goal of this study was to convey the information about plant benefits/use for pharmacological and nutritive purpose.

Key words:- *Murraya Koenigii*, Pharmacological uses

Murraya Koenigii is commonly known as Curry Leaf/Kari pataa or Meethi neem. Its belonging to Rutaceae Family ⁽¹⁾. The plant is an Native of India, Sri Lanka and some other countries ⁽²⁾. It is widely distributed and cultivated in India and also found in Assam, Bengal, Himalaya's, Uttarakhand, Thiru-Kochi (state of India) and some other Regions like western Ghats, Moist forests of Asian Regions, Bhutan, Nepal, Thailand, Pakistan etc ^(1,3). The plant possess a aromatic odour. It contains a small shrub or the plant height up to 6 m ^(4,5). It is a fast growing plant and contains a dark green colour leaves. Curry leaves contains a many chemical constituent which possess a many pharmacological/biological activity, nutritive property, aromatic property. Some chemical constituents are- α - caryophyllene, δ - elemene, β - elemene, α & β - phellandrene due to the presence of these compounds the plant ability to prevent food spoilage. some other compounds includes cis- β -

ocimene, cis-Piperitol, Linalool, γ -Terpinene, Terpinyl acetate, m-Cymene, α -Terpinene, β -Myrcene, Camphene, α -Thujene, Eucalyptol, Caryophyllene oxide. The plant also in rich source of girinimbiol, girinimbine (carbazole alkaloids), koenine, koenigine, koenidine, calcium, phosphorus, iron, thiamine (vitamin B1), riboflavin (vitamin B2), niacin (nicotinic acid), sitosterol, carotene, 1,4 methanoazulen-9-ol, Caryophyllene oxide, Phytol, pinene, phenolic compounds etc ^(3,6,7).

The plant leaves is widely used in Indian culture for cooking Purpose (used as a flavouring agent in curry, chutney, pulse etc), useful for its aromatic property. The plant parts (Leaves, root, seed) from centuries year ago beneficial for traditional medicinal use such as useful for bite of poisonous animal, tonic used as stomachic, leaves and roots useful to cure external eruption/wound, blood purifier, dysentery ^(3,8). According to various research reports *Murraya koenigii* roasted leaves are used as a anti emesis, the paste of the leaves mixed with buttermilk and daily consumed orally for stomach-ache. The plant parts is also beneficial for the treatment of deficiency of calcium and vitamins due to the presence of vitamins (vitamin A, vitamin B & C), Calcium source, Iron in plant. The leaves paste is apply on the boils/furuncle

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(painful pus filled bump in skin) for reducing pain and Inflammation, Prevent cataract, curry leaves is also useful for retained black colour in hair. Juice of roots is useful to cure Renal/Kidney pain ^(1,9).

Numerous researchers study Reported the Plant are useful to cure and treat various diseases because all parts of plant contains a many Important chemical constituent which exhibit many pharmacological activity such as the Raw leaves of plant is useful to cure diarrhoea, vomiting, stomach pain, Leaves and root of plant are used to treat and cure Piles, anthelminthic, leucoderma (white patches in

skin), blood disorder and also possess anti-inflammatory property, analgesic property, antibacterial property, anti cancer, antimicrobial activity, anti oxidative property and useful for reducing cholesterol level (hypolipidemic activity), anti hypertensive activity and also possess anti-diabetic property etc^(10,4). According to researchers study shown the plant also useful for making some important medicinal drug such as vinblastine, vincristine (drugs useful for cancer treatment), aspirin, quinine (used as a anti-malarial drug) ^(2,11).

Taxonomical/Scientific Classification of *Murraya Koenigii* ^(12,13,14)

Category	Botanical description
Kingdom	Plantae
Subkingdom	Tracheobionta (vascular plant)
Superdivision	Spermatophyta (seed plant)
Division	Magnoliophyta (flowering plant)
Class	Magnoliopsida
Subclass	Rosidae
Order	Sapindales
Family	Rutaceae
Genus	Murraya
Species	Murraya Koenigii

Vernacular name of *Murraya koenigii* (12,13,15)

English	Curry leaves
Kannada	Karibevu
Hindi	Karipatta, Mitha neem
Tamil	Kariveppilai
Malayalam	Kariveppu
Marathi	Kadhilimb
Sanskrit	Girinimba
Telugu	Karepeku
Tulu	Bevusoppu
Russian	Listya karri
Spanish	Hojas de curry
Italian	Fogli di Cari
French	Feuilles de Cari
German	Curryblatter
Guajarati	Mitho limado
Danish	Karry bald
Dutch	Kerriebladeren

Morphological characteristics of plant parts (13,15,16)

Plant Parts :- Bark, Leaves, Fruit, Flowers, Root, Seeds etc.

1) **Bark:** - The Main Bark of the plant is dark brown in colour and the longitudinal bark is peeled off and the bark colour is white in beneath. The plant contains a height up to 6m long and diameter is 15-20 cm.

2) **Leaves:** - The plant leaves exhibits very strong aromatic odour, leaves are dark green in colour, leaves are 2.5-4.5 cm long, lanceolate ovate shape with oblique base, Each rachis of leaf is 15-30 cm long and each rachis contain 11-24 leaflets. the plant leaves are arranged in bipinnately.

3) **Flower:** - The plant contains a small white flower, which arranged in a small panicles, funnel shaped, exhibits aromatic odour. Each terminal cyme carry 60-90 flowers. Flower diameter is 1-1.2, long up to 1.4-1.6 cm and the plant flower is bisexual.

4) **Fruit:** - fruit are oblong/ovate in shape, 1.4-1.6 cm long, diameter is 1-1.2 cm. The fully ripe fruit of plant are black in colour with shining surface and the no. of fruits per bunch/cluster differ from 32-80.

5) **Seed:** - The plant each fruit contains a seed which colour is spinach green, long up to 11mm, diameter is 8mm.

Flowering time & Fruiting time: - The flowering time of plant is April- last May and the fruiting time of plant is July- August⁽¹⁷⁾

Phytochemistry and Uses of *Murraya koenigii* plant part^(17,12)

All parts of this plant contains a major bioactive compounds which is beneficial for the medicinal/ pharmacological activity, nutritive property, used as a flavouring agent and prevent food degeradation (used as a food preservative) detailed discussed in below:-

Part used:- Leaves, root, bark, fruit, seed etc

1) **Leaves:-** leaves of the plant contains many bioactive chemical compounds which possess many useful effect for treat and cure various diseases. Some important chemical constituent are:- **Calcium, Oxalic acid Glycosides, Carbazole alkaloids like koenigin,**

girinimbin, mahanimbin, koenine, koenimbine, O-methyl murrayamine, O-methyl mahanine, iso mahanine, bis mahanine, bis pyrayafoline, murrayazoline, murrayazolidine, Euchrestine, Tannins, Tocopherol, Lutein and leaves of plant also a rich source of **protein, carbohydrate, fibers, vitamin (vitamin A, B, C), minerals, phenolic compounds, steroids, saponins, Flavonoids** etc due to the presence of these compound plant possess many pharmacological uses such as Anti-oxidant, anti-ulcer, anti-diabetic, ant-tumour, anti-cancer, anti-asthmatic, anti-inflammatory, neuroprotective, memory enhancing, anti emesis, larvicidal, insecticidal, used as a flavouring agent etc.

2) **Root:-** Root extract of this plant also contains many phytochemical compounds which is beneficial for its pharmacological and nutritive activity. some important phytoconstituents are:- **carbazole alkaloids** such as **murrayanol, mahanine, murrayagetin, bismahanine, mahanimbin** etc. Root extract is used as a stimulant and anti inflammatory etc.

3) **Bark:-** Bark of the murraya Koenigii plant contains various chemical constituents such as **murrayanine, girinimibine and mahanimbine, murrayazolinine, murrayazolidine, murrayacinine, mukonidine, mahanimbinol, murrayazolinol, carbazole alkaloid, girinimbinol and mahanimbilol and carbazole carboxylic acids (mukoeic acid & mukeic acid)** and the presence of these chemical compounds the bark of plant is also useful for treat various diseases such as **Ulcer, Apoptotic, Cancer, Tumour, used as anti-oxidant** etc.

4) **Fruit:-** Fruit contains many chemical compounds includes **Carbazole alkaloids (Isomahanine, murrayanol, mahanimbine and girinimbine, murrayazolidine, koenimbine and mahanine), niacin, leucin, alanine** and the fruit pulp contains **Sugar (reducing sugar), Tannins, vitamin C, minerals (potassium, magnesium, calcium, iron), proteins** etc. It possess many pharmacological activity **hypoglycaemic activity, apoptotic activity**, such as fruit pulp of plant exhibits **Free radical scavenging property** etc.

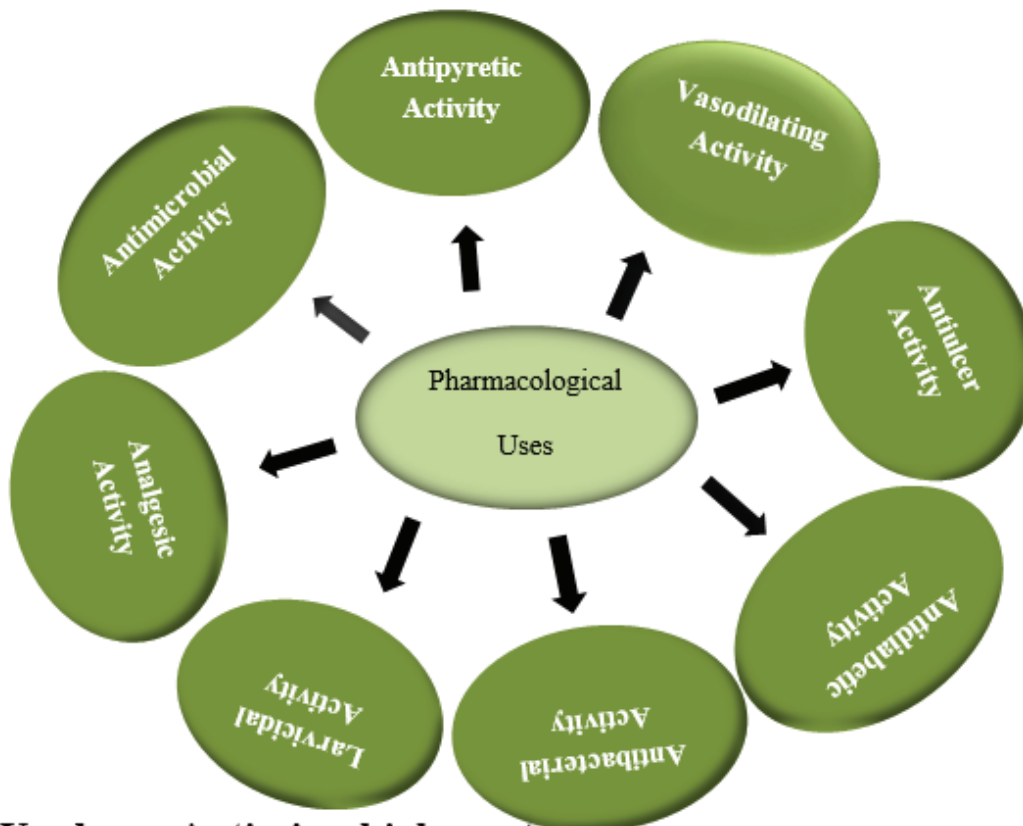
5) **Seed:-** seed of the plant contains various carbazole alkaloids includes **mahanimbine, girinimbine, isomahanine, mahanine, kurryam,**

koenimbine and lipids and it is useful in the treatment of diarrhoea etc.

Pharmacological use of *Murraya Koenigii*

The plant parts also possess various pharmacological activity/Medicinal property discussed below:-

Ø Used as a Antimicrobial agent



➤ Used as a Antimicrobial agent

The root extract of *murraya koenigii* with hexane, methanol, chloroform extract are tested against some microbes such as *Escherichia coli (E.coli)*, *Staphylococcus aureus*, *Bacillus subtilis*, *Salmonella typhi* and strain of *Candida albicans*, *Trichophyton rubrum*, *Aspergillus niger*. Results shown the hexane, methanol, chloroform extract of root of this plant possess anti-microbial activity. The study also shown the methanol extract of root of this plant more effective against microbes compare to other extract compounds and possess maximum inhibitory activity on microbes such as *Staphylococcus aureus*, *Trichophyton rubrum*.

In another study shown that the aqueous extract of the root of this plant are not effective against micro-organisms⁽¹⁴⁾.

Ø Plant possess Antipyretic activity

The ethanolic leaves extract of *murraya koenigii* also exhibits antipyretic activity. The study found to the ethanol extract of leaves is more beneficial compare to other extract such as petroleum ether, chloroform extract of leaves⁽¹⁴⁾.

Ø Used as a Antidiabetic Agent

The Petroleum ether extract of *Murraya Koenigii* contains mahanimbine chemical compound. In study the mechanism of mahanimbine shown it is useful for reduces the blood sugar level and potentiate/increase the level of insulin by improving the pancreatic secretion of insulin from β - cells. Another research study shown that the mahanimbine chemical compound also exhibit inhibitory effect against α -amylase in compared to

acarbose (anti-diabetic drug) ^(12,18).

Ø Useful to prevent Alzheimer disease/dementia

Numerous study shown that the plant leaves contain many alkaloids. These alkaloids useful for maintaining the anti-oxidants include glutathione peroxidase, glutathione reductase, superoxide dismutase, catalase in brain.

In another study shown the plant also beneficial for decreases the lipid peroxidation and nitric oxide. And induce ACH/Acetylcholine (Chemical messenger) secretion and reduce anticholinesterase (decreases breakdown of ACH). According to this study the researchers proved that the plant is useful for prevent the neurodegenerative diseases includes Alzheimer disease etc ⁽¹⁹⁾.

Ø *Murraya koenigii* plant possess Hypocholesterolemic activity

The ethanolic extract of plant leaves contains various major phytochemical compounds (Carbazole alkaloids) which is useful to cure and treat various diseases and the ethanol extract also exhibit hypocholesterolemic property (reduce level of cholesterol) which was studied in elder mice they observed the level of cholesterol is reduced in mice and also found the 500mg/kg dose is more effective compare to the hypocholesterolemic drug such as simvastatin ⁽¹²⁾.

Ø Plant is useful to prevent cardio vascular diseases

According to study the plant contains a various major bioactive chemical compounds includes carbazole alkaloids due to the presence of these compound the plant possess a vasodilating activity, hypocholesterolemic activity and anti-oxidant activity. Leaves of the plant is useful for prevent the cholesterol oxidation from bad cholesterol/LDL (low density lipoprotein) and helpful for induce the level of good cholesterol/HDL (high density lipoprotein) due to this pharmaceutical activity the plant is useful for protect body against atherosclerosis (cardio vascular disease) ⁽²⁰⁾.

Ø Useful for Skin pigmentation

The leaves oil of this plant possess sun protection factor (SPF) property (useful for protect skin against

sun burn), cream of the *murraya koenigii* plant useful against skin pigmentation, erythema (skin redness). And cosmetic industries also use of this plant for making formulations such as cream, lotion, soap and add some other additives for enhance/increase product efficacy ⁽¹²⁾

Ø Plant possess Antiulcer property

According to the researchers reports study shown that the aqueous extract of leaves of this plant effective against gastric ulcer in rats models (induced gastric ulcer in rat by using ethanol, aspirin, cold restrain, pylorus ligation(stimulation of acid output in rat) etc) and the animal is pre-treated with the aqueous extract of ethanol the evaluation shown the significant reduction of ulcer activity in rats ^(12,21).

Ø Plant exhibits Anti-diarrhoeal property

The n-hexane extract of the seeds of *murraya koenigii* plant contains many major bioactive compounds such as carbazole alkaloids, kurryam, koenimbine, koenine etc. These compounds exhibit inhibitory effect/activity against diarrhoea (induced by castor oil & PGE 2/Prostaglandin 2) in rats. The charcoal meal test shown the compound also useful for the decrease/reduced motility in GI in wister rats ⁽¹²⁾.

Ø Used as a Antibacterial agent

Murraya koenigii plant extract possess anti-bacterial activity against some bacteria includes *Bacillus cereus*, *Escherichia coli* (*E.coli*), *Staphylococcus aureus*, *Salmonella typhi* (*S.typhi*). The ethanol, methanol and acetone extract of plant shown the significant effect against these bacteria strain.

The acetone extract of plant shown maximum effect against *Bacillus cereus* and the methanol extract shown high inhibition efficacy compare to ethanol extract. Moreover, methanol extract shown less inhibition efficacy against *E.coli*, while acetone extract shown higher inhibitory effect compare to methanol extract ⁽²²⁾.

Ø Useful for Wound Healing

The Ethanol leaves extract of plant possess wound healing property. The researchers study has found in albino rat, male albino rat is sacrificed and applied the extract in wounds after some day the study showed decrease the wound affected inflammation in day by

day. Hence, the study proved that the plant leaves extract exhibit wound healing activity⁽²²⁾.

Ø *Murraya koenigii* possess Analgesic activity

The methanol extract of leaves of this plant possess analgesic property, According to numerous researchers study, The inflammation is induced in rat by using formalin (formaldehyde solution is subcutaneous injected in rat paw to induce pain/inflammation). Methanol extract of leaves were taken in different doses (100mg/ml, 200mg/ml & 400 mg/ml) and the 400mg/ml (dose) shown significant effect against pain/inflammation. Hence the study proved that the methanol extract of leaves of *murraya koenigii* plant exhibit analgesic activity⁽²²⁾.

Ø Plant possess Antiprotozoal and anti-hypertensive activity

Murraya koenigii ethanol leaves extract of plant possess antiprotozoal & antihypertensive both activity. The study shown that take the variety of extract of these plant such as extract A (contains whole plant except roots) and extract B (contains only roots of plant). And after evaluation of extract the study found extract A possess anti protozoal activity against *Ent amoeba Histolytica* in ileum of guinea pig, while extract B exhibits both activity such as antihypertensive activity and antiprotozoal activity in cat or dogs^(16,23).

Ø *Murraya koenigii* useful for Haematological property

The whole plant is useful for the haematological study. According to researchers study that found the normal human intake dose administered in rat and after administration the study not shown any adverse effect and no adverse effect on counts of RBC, WBC, haemoglobin, total serum protein, Fibrin level, blood urea and no any histopathological (disease on tissue/cell) changes in rat liver. Hence, the study proved that the plant possess no any adverse effect⁽⁷⁾.

Ø Useful for treatment of Respiratory diseases

The plant contains major bioactive chemical constituents with piper plant extract useful for the treatment of respiratory/bronchial disorders⁽¹⁶⁾.

Other Important uses of *Murraya Koenigii*

Ø *Murraya koenigii* Useful for Larvicidal (Kill larvae) activity

The Acetone and petroleum ether extract of plant leaves take a 250-900ppm concentration range possess larvicidal activity against *A.aegypti*⁽¹⁶⁾.

Ø Plant is a rich source for nutrition

The plants parts is a rich source of minerals, vitamins, Proteins, Carbohydrate, carbazole alkaloids and amino acids etc. The plant leaves also contains a Nitrogen, phosphorus, sulphur, potassium, sodium and also contains polyunsaturated fatty acid (linoleic acid).

Numerous researchers report shown that the leaves extract of plant contains a significant amount of fibers, calcium, iron, phosphorus and The plant green leaves also used in deficiency of micronutrient because its contains a considerable amount of micronutrient⁽²⁴⁾.

Ø Used as a Food Preservative

Murraya koenigii plant berry extract contains a many bioactive compounds (carotene, flavonoids, phenolic compounds) which possess a anti oxidative property and due to the presence of these compounds the plant prevent the oxidation process in food and also useful for maintain the quality for food includes flavour(used as a flavouring agent in meats, curries), texture of food, prevent rancidity, exhibits antimicrobial property. Hence, its proved the plant is useful for prevent food deterioration⁽²⁴⁾.

Ø Ethno botanical use of *Murraya Koenigii*⁽¹⁵⁾

· The fresh leaves or leaf powder is used as a flavouring agent and prevent degradation in curries, meats, soups, dishes etc. and the leaves of plant also useful for decoration of dishes.

· Boil the fresh leaves with coconut oil is used as a hair tonic. useful for hair growth and retain its black colour.

· The leaves oil is useful in cosmetic industry for making soaps, perfumes, other cosmetic products.

· The fresh leaves plant is apply on skin inflammation, Rashes, wounds for prevention.

The extract of leaves is possess antiemetic property and the leaves and plant possess many pharmacological activity includes anti-inflammatory activity, blood purifier, anti- hypertensive activity, hypoglycaemic activity, useful for renal pain, stomach ache etc brief discussed in above.

The fresh leaves paste is applied on animal bite from the body for remove poison and inflammation.

Conclusion & Discussion

The Present study/review describe that *Murraya Koenigii* Plant contains many phytochemical chemical constituents and also a rich source of nutrients, minerals and vitamins. which is beneficial for treat and cure several diseases or disorder and due to the presence of major bioactive compound Plant exhibits many major pharmacological activities such as hypolipidemic activity, anti-hypertensive activity, anti-diabetic property, anti-inflammatory activity, analgesic activity, antibacterial activity, anti- diarrhoea property etc. It is a multipurpose evergreen medicinal valued plant. It is a native of India. The plant leaves is widely used in Indian culture for cooking Purpose.

Ethical Clearance- Taken form JPCP Institutional Committee.

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Conflict of Interest- Nil

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Polymorphism gen Follicle Stimulating Hormone Receptor Ala307 Thr (rs 6165) and Ser 680 Asn (rs 6166) Related to Polycystic Ovary Syndrome with Insulin Resistance

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Abstract

Follicle stimulating hormone (FSH) has an important role in female reproduction, follicular development and ovarian steroidogenesis, through binding to FSH with its receptors in ovarian granulosa cells. The study design used was a study with an observational approach with a cross sectional approach, which is a group of cases originating from subjects with Polycystic Ovary Syndrome (SOPK). Wahidin Sudirohusodo and hospital education network and private hospitals. there was no significant relationship between the occurrence of FSHR Ala307Thr gene polymorphism with the incidence of insulin resistance Odd Ratio, 95% Confidence Interval 0.69 (0.23-2.12) with a value of $p = 0.518$. The same was also found in the Ser680Asn FSHR gene polymorphism with the incidence of insulin resistance Odd Ratio, 95% Confidence Interval 0.70 (0.27-1.84) with a p value = 0.470, as well as the polymorphism of the G935A LHR gene with the incidence of insulin resistance Odd Ratio , 95% Confidence Interval 2.24 (0.88-5.73).

Keywords: Ala 307Thr, Ser 680 Asn, Restensi insulin, SOPK

Introduction

Polycystic ovary syndrome (PCOS) is an endocrinopathic disorder that most often occurs in women of reproductive age with an incidence of 4 to 20%. Follicle stimulating hormone (FSH) has an important role in female reproduction, follicular development and ovarian steroidogenesis, through binding to FSH with its receptors in ovarian granulosa cells¹.

Other genetic factors that play a role in SOPK are LHB and LHCGR polymorphisms. Some studies want to prove this but have opposite results with each other. Bassiouny and friends first demonstrated the link between LHCGR G935A SNP and PCOS in women

in Egypt. El-Shal AS and colleagues succeeded in proving the linkage of gene polymorphisms (LHB G1502A and LHCGR (G935A and ins18LQ) and SOPK events Research that evaluates the relationship of these polymorphisms to the occurrence of PCOS is still very limited, but it is very important to continue evaluating the occurrence of SOPK^{2,3,4}.

Research conducted on SOPK research samples showed a wide variety of polymorphisms of A307T, 56% N680S, 30% S680S and 14% N680N. reported the presence of FSHR Ala307Thr polymorphisms and Ser680 Asn in PCOS women in ^{5,6,7}.From a meta-analysis of several studies, Seoul totaling 235 PCOS patients and 128 control patients, they found that Ser 680Asn from FSHR was significantly associated with PCOS, it turns out that also studies in South Korea from 377 PCOS samples and 388 controls found a significant association of Ala307Thr gene polymorphism and

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Ser680Asn with SOPK. Research in Turkey shows a significant relationship, whereas in caucasian women there is no meaningful relationship^{8,9}.

Insulin resistance and hyperinsulinemia are key factors in the pathogenesis of ovulation disorders and hyperandrogenism in PCOS. Increased adrenal activity is thought to cause insulin receptor phosphorylation which causes insulin resistance. Hyperinsulinemia also decreases the production of sex hormone binding globulin (SHBG) in the liver so that free testosterone levels will increase^{10,11,12}. Hormonal abnormalities are associated with carbohydrate imbalance, hyperinsulinemia and insulin resistance, with consequences developing into type 2 diabetes and impacting approximately 50% in PCOS patients both obese and thin^{13,14}. A meta-analysis of 28 studies found lower insulin sensitivity in women with PCOS^{15,16}.

Considering SOPK can occur with insulin resistance and without insulin resistance as well as several studies on the polymorphism of the Ala 307Thr gene (rs 6165) and the Ser680Asn gene (rs 6166), so it is necessary to know whether this insulin resistance is related to polymorphisms in these genes. Insulin resistance and hyperinsulinemia are key factors in the pathogenesis of ovulation disorders and hyperandrogenism in PCOS^{17,18,5}. In the ovary, high insulin levels will stimulate the enzyme 17 α -hydroxylase which will increase the process of converting progesterone to androstendione. Hyperperulinulinemia will increase the activity of the pituitary-pituitary-adrenal axis. Increased adrenal activity is thought to cause insulin receptor phosphorylation which causes insulin resistance. Hyperinsulinemia also decreases the production of sex hormone binding globulin (SHBG) in the liver so that free testosterone levels will increase^{19,20}

Materials and Methods

The study design used was an observational approach with a cross sectional approach, which is a group of cases originating from subjects with Polycystic Ovary Syndrome (PCOS).

The location of the study was conducted at the RSUP dr. Wahidin Sudirohusodo and hospital education network and private hospitals. Sampling was carried out in Prodia clinical laboratory, for examination of fasting blood glucose and fasting insulin in the calculation of HOMA-IR and NECHRI Laboratory of Hasanuddin University Makassar for examination of FSH receptor polymorphisms and LH receptors.

The study was conducted in January 2019 - February 2020 study sample that is all female sex patients aged 25 to 40 years, the selection method until is by consecutive sampling. the number of samples was 23 research samples for each group, namely 23 groups with HOMA-IR ≥ 2 and 23 groups with HOMA-IR < 2 .

PCR Real Time Checking

Genomic DNA was extracted from peripheral blood samples with the DNA Wizard Purification Kit (Promega, Madison, WI). Allelic discrimination is carried out using the MGB-NFQ primer / TaqMan probe assay on the ABI Prisma 7500 real-time PCR system (Applied Biosystems, Foster City, CA, USA). Plug pairs and probes for FSHR p. Thr307Ala and FSHR p. Asn680Ser is assays-on-demand, C-2676873_30 (Applied Biosystems), and assays-on-demand, C-2676874_10 (Applied Biosystems), respectively. The PCR mixture consists of 10 μ L from TaqMan Universal PCR Master Mix 2 \times (Applied Biosystems) and 25 ng DNA. The PCR cycle consists of one 2-min cycle at 50 $^{\circ}$ C, and 1 10-min cycle at 95 $^{\circ}$ C, followed by 40 cycles at 95 $^{\circ}$ C for 15 s and 60 $^{\circ}$ C for 1 minute.

Data processing and analysis

In this study primary data were obtained using questionnaire, on the sheets provided, then record the results of physical and laboratory examinations on the sheets provided. Polymorphism of FSHR 307, 680 and LhR 935 and HOMA IR were examined. After the primary data is collected and recorded, the data obtained is organized and processed using the SPSS computer program.

Result

Tabel 1. Characteristic of Responden

	N	Result
Age in a year (mean, SD)	83	27.9 ± 3.9
Age (N, %)		
≥ 30 Year	23	27.7
< 30 Year	60	72.3
Weight in kg (mean, SD)	83	65.5 ± 8.5
Height in cm (mean, SD)		
High mass indeks cm (mean, SD)	83	157.2 ± 5.7
Body Mass indeks (mean, SD)	83	26.5 ± 3.0
Body Mass indeks (N, %)		
Obesity	46	55.4
Non obesity	37	44.6
Polimorfisme gen (N, n%)		
Ala307Thr	83	15 (18.1)
Ser680Asn	83	23 (27.7)
G935A	83	56 (67.5)
Dosis (median, interquartile range)		
Fasting Sugar (mg/dl)	83	90 (84-98)
Insulin (µU/ml)	83	10.2 (5.3-16.8)
HOMA-IR	83	2.4 (1.1-4.1)

Table 1, shows that the mean age and standard deviation (SD) is 27.9 ± 3.9 which found 23 people (27.7%) in the age group ≥30 years and in the age group <30 years as many as 60 (72.3%) people, then the mean and sd for body weight and height respectively mean ± sd 65.5 ± 8.5 and mean ± sd 157.2 ± 5.7. From a total of 83 samples, there were 46 (55.4%) samples that resulted in Body Mass Index (BMI) in the obesity category while non-obese were 37 (44.6%) samples. The mean and standard deviation for BMI of the whole sample is mean

± sd 26.5 ± 3.0. the results of Body Mass Index (BMI) in the category of obesity while non-obese as many as 37 (44.6%) samples. The mean and standard deviation for BMI of the whole sample is mean ± sd 26.5 ± 3.0

Based on the examination of fasting blood sugar, fasting insulin and IR HOMA obtained median and interquartile range (IQR) respectively 90 (84-98) mg / dl, 10.2 (5.3-16.8) µU / ml and 2.4 (1.1- 4.1)

Table 2: Content HOMA IR with Polimorfisme gen Ala307Thr, And Ser608Asn FSHR

	N	HOMA-IR (median, IQR)	p-value*
FSHR Ala307Thr			
Negative	68	2.57 (1.11-3.96)	0.519
Positive	15	1.98 (1.16-4.30)	
FSHR Ser680Asn			
Negative	60	2.57 (1.12-4.05)	0.472
Positiv	23	1.98 (1.13-4.27)	
Positive	56	2.76 (1.17-4.38)	

IQR: interquartile range, *Uji Mann-Whitney

There was no significant difference in IR HOMA levels between polymorphisms and without polymorphisms in all FSHR genes namely Ala307Thr (p = 0.519) and Ser608Asn (p = 0.472)

Table 3. : Relationship of FSHR Ala307 Thr polymorphism, And Ser680Asn to insulin resistance

	n	n (%)	OR [95% CI]	p-value
FSH Ala307Thr				
Negative	68	38 (55.9)	reference	0.518
Positive	15	7 (46.7)	0.69 [0.23-2.12]	
FSH Ser680Asn				
Negative	60	34 (56.7)	reference	0.470
Positive	23	11 (47.8)	0.70 [0.27-1.84]	

^aassociation based on univariate logistic model. The number of positives (n) of the total population examined (N). OR: Odds ratio, CI: Confidence intervals.

Table 3 shows that there is no significant relationship between the occurrence of FSHR gene Ala307Thr gene polymorphism with the incidence of insulin resistance Odd Ratio, 95% Confidence Interval 0.69 (0.23-2.12) with a value of p = 0.518. The same was also found

in the Ser680Asn FSHR gene polymorphism with the incidence of insulin resistance Odd Ratio, 95% Confidence Interval 0.70 (0.27-1.84) with a p value = 0.470, as well as the polymorphism of the G935A LHR gene with the incidence of insulin resistance Odd Ratio , 95% Confidence Interval 2.24 (0.88-5.73).

Table 4.: Multivariate analysis between polymorfisme FSHR Ala307Thr, FSHR Ser680Asn to resistensi insulin^a

	adjusted OR [95% CI]	P-value
Polimorfisme FSHR Ala307Thr	0.69 [0.18-2.70]	0.590
Polimorfisme FSHR Ser680Asn	0.57 [0.17-1.92]	0.367

^aMultivariate model. CI: Confidence intervals.

In multivariable analysis of these two polymorphisms it was found that the FSHR polymorphism both Ala307Thr with an odds ratio of 0.69 and Ser680Asn with an odds ratio of 0.57 had nothing to do with the incidence of resistance

Discussion

FSH receptor position codon 307 is clearly known that plays an important role for ligand receptor interaction, whereas position 680 which is located intracellular is involved in transduction of the FSH signal. (Lussiana C et al., 2008) This was proven by Valkenburg and colleagues in 2009, the polymorphism of the Ser 680 allele had low estradiol levels when stimulated with FSH when undergoing assisted reproductive technology programs.

This shows that the polymorphism that occurs in the FSH receptor can cause a decrease in the sensitivity of the receptor to the FSH hormone. (Laen JS, 2019). San Millan and colleagues report that in PCOS with insulin resistance there is a ApaI polymorphism in genes that encode insulin-like growth factor (IGF-2) which is thought to stimulate androgen secretion.

The results of his study in Italy in reporting from 40 samples contained 26 (65%) Ala307Thr FSH receptor gene polymorphisms, Wu Xue-qing and friends in 2014 in North China reported from 215 samples there were Ala307Thr gene polymorphisms and Ser680Asn FSH receptor respectively. as many as 95 (44.2%) and 94 (43.7%), Sujatha T and colleagues in 2016 in India reported from 204 samples with PCOS that occurred Polymorphism of Ser680Asn 99 (48.52)%.

LHR gene polymorphism can cause an increase in receptor bioactivity or overexpression of the LH hormone, this is according to research by Joanes and colleagues reported by Azziz R (2016). Significant abnormality in the LH hormone can have an increased androgen production in PCOS and cause anovulation. (El-Shal A et al., 2015)

Some things that can be a cause of SOPK at a younger age include because of an increasingly unhealthy lifestyle, an unbalanced diet, passive physical activity, so that more and more at risk of becoming obese and metabolic syndrome. (P. Tsikouras et al, 2015) This study found related to this, from the sample group with age <30 years there were 41 obese samples namely BMI ≥ 25 kg / m², whereas BMI <25 kg / m² were 19 samples from 60 total samples from that group. And from the obese sample group there were 26 samples with IR HOMA ≥ 2 and 15 samples with IR HOMA <2.

Insulin resistance and hyperinsulinemia are key factors in the pathogenesis of ovulation disorders and hyperandrogenism in PCOS. In the ovary, high insulin levels will stimulate the enzyme 17 α -hydroxylase which will increase the process of converting progesterone to androstendione. In the adrenal gland, hyperinsulinemia will increase the activity of the pituitary-pituitary-adrenal axis. Increased activity of the pituitary-pituitary-adrenal axis increases the activity of the enzyme 17 α -hydroxylase which converts the compound 17OH Pregnenolone to Dehydroepiandrosteronesulphate (DHEAS). Increased adrenal activity is thought to cause insulin receptor phosphorylation which causes insulin resistance. Hyperinsulinemia also decreases the production of sex hormone binding globulin (SHBG) in the liver so that free testosterone levels will increase.

(Andon et al, 2016)

Conclusion

There is no correlation between Ala307Thr polymorphism and Asn680Ser gene follicle stimulating hormone receptor to the incidence of SPOK with insulin resistance.

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Conflict of Interest- None of the authors has competing interests

Ethical Clearance- This research was approved by the Research Ethics Commission of the Faculty of Medicine, Hasanuddin University Makassar, (No. 1140/UN4.6.4.5.31//PP36/2019), and all research subjects gave written informed consent.

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Knowledge and Attitudes of Breast Cancer, Breast Self-Examination and Mammography among Female Students in Saudi Arabia

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Abstract

Background: The purpose of this study was to assess the knowledge and attitudes of Breast cancer, Breast self-examination (BSE) and mammography among female students in the College of Applied Medical Sciences.

Methods: The study was conducted at College of Applied Medical Sciences in University of Hafr Al-Batin. after being approved by the local research Ethics committee. The sample was consisted of 200 undergraduates' female students from third and fourth academic year. The questionnaire consists of four sections: demographic data, knowledge of BC, BSE and mammogram (21 questions), knowledge of risk factors (7 questions), and attitudes (17 items). The findings revealed that 71% of the respondents had good knowledge of breast cancer, 63% had satisfactory level of breast self-examination, and 53% had poor level of mammogram. Furthermore, 72% and 59% of respondents had positive attitude towards BC and BSE respectively, while 69% of them had negative attitude regarding mammogram.

Conclusion: Lack of knowledge and attitudes about BSE and mammogram practice among female students may due to their beliefs that young women are not at risk and do not need to be aware with all breast cancer screening methods.

Key words: Breast cancer, Breast Self-Examination, Mammography

Introduction

Cancers in all forms are responsible for about 13% of deaths throughout the world ¹. Globally, breast cancer (BC) is the most frequent cancer among women, affecting 2.1 million women each year, and causes 627,000 deaths a year worldwide. In Saudi Arabia, the World Health Organization (WHO) (2018) documented that the cancer mortality profile in females is 4,300

deaths; including 18.7% for breast cancer that is ranked first among all cancers ².

BSE is a cost-effective method of early detection of BC especially in developing countries ^{3,4}. It is a process of examining women's breasts regularly to detect any abnormal swelling or lumps in order to seek prompt medical attention. It carried out once monthly, between the 7th and 10th day of the menstrual cycle, goes a long way in detecting breast cancer at the early stages of growth when there is low risk of spread, ensuring a better prognosis when treated ⁴.

Mammography is the most valuable tool for detecting BC in the earliest possible stages, before the cancer has metastasized compared to BSE or CBE. It is a specialized medical imaging, which uses a low-dose x-ray system for early detection and diagnosis

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of breast diseases in women ⁵. The decline in breast cancer mortality has been largely attributed to regular mammography screening practice. The American Cancer Society (ACS) recommends that women aged 40 and over should have a screening mammogram every year and should continue to do so for as long as they are in good health. Mammography screening can lower the mortality risk, but it is still under-used among minorities. A cross sectional study among women in the United Arab Emirates showed inadequate knowledge about BSE and mammography which resulted in abstaining from such examinations ⁶

The current study investigates the levels of knowledge and attitudes among female students regarding breast cancer, BSE and mammography at the College of Applied Medical Sciences, University of Hafr Albatin.

Materials and Methods

The descriptive cross-sectional research was utilized in this study. The study was conducted in College of Applied Medical Sciences in University of Hafr Albatin (UHB) after obtaining ethical approval from the local research ethics committee. The sample included of 200 undergraduates' female students who

accepted to participate in this study from third and fourth academic year. The inclusion criteria for selection of sampling excluded all students who were below 18 years and those who were not willing to give consent. A self-administered questionnaire was developed by the researchers to assess the knowledge and attitudes of BC, BSE and mammography based on through extensive literature search. The questionnaire consists of four sections. The first section includes demographic data such as age, marital status, academic year, family income, and family history of breast cancer. The second section involves closed-ended questions, which measure knowledge about BC, BSE and mammogram. It contains 21 correct responses; each correct response was given a score of one and a wrong response a score of zero. The third section includes seven items about knowledge regarding risk factors of breast cancer. The fourth section includes the attitudes (beliefs and feeling) of the respondent regarding BC, BSE and mammogram.

The value of Cronbach's coefficient alpha test was equal 0.72 and the value of test-retest reliability was equal 0.81. Responses were transformed to SPSS Statistics version 21 for further statistical analysis. The Mean, Standard Deviation (SD) and the Range (Maximum – Minimum) used to describe quantitative variables.

Results and Discussion

Table 1: Participants' knowledge of Breast cancer, Breast self-examination and Mammogram

Items	Yes	No	Don't know
	N (%)	N (%)	N (%)
	(n=200)		
BC (5 questions)			
Is Breast cancer common in this environment?	140 (70%)	22 (11%)	38 (19%)
Does Breast cancer lead to death?	124 (62%)	40 (20%)	36 (18%)
Is Breast cancer a congenital disease?	124 (62%)	40 (20%)	36 (18%)
Does early diagnosis of Breast cancer increase chances of survival?	144 (72%)	50 (25%)	6 (3%)
What are the warning signs of Breast cancer?			
ñ Exit secretions or blood from nipple	150 (75%)	16 (8%)	34 (17%)
ñ Lump or swelling in the breast or arm tip	186 (93%)	4 (2%)	10 (5%)
ñ Change in the skin of the breast	132 (66%)	48 (24%)	20 (10%)

Cont... Table 1: Participants’ knowledge of Breast cancer, Breast self-examination and Mammogram

BSE (6 Questions)			
Does BSE is an important way for early diagnose of disease?	72 (37%)	102(51%)	24 (12%)
Does BSE cause significantly harmful side effects?	6 (3%)	186 (93%)	8 (4%)
Does male only should perform BSE?	0	154 (77%)	46 (23%)
Does female only should perform BSE?	152 (76%)	26 (13%)	22 (11%)
Do both males & female should perform BSE?	48 (24%)	52 (26%)	100 (50%)
How many times should BSE to be done?			
ñ Daily	22 (11%)	178 (89%)	0
ñ Weekly	48 (24%)	140 (70%)	0
ñ Monthly	114 (57%)	86 (43%)	0
ñ Yearly	16 (8%)	184 (92%)	0
Mammogram (6 Questions)			
Is Mammogram the best way to diagnose undiscovered breast cancer?	96 (48%)	4 (2%)	100 (50%)
Does Mammogram has serious side effects?	54 (27%)	26 (13%)	120 (60%)
Is Mammogram a painful procedure?	30 (27%)	40 (20%)	130 (65%)
Do Mammogram need hospital admission to be performed?	24 (12%)	86 (43%)	90 (45%)
Should Mammogram be done once in a life?	42 (21%)	64 (32%)	94 (47%)
Has Mammogram only indicated for women with breast problem?	62 (31%)	58 (29%)	80 (40%)

Regarding BSE, more than half (51%) of participants knew that BSE is not an important way for early diagnose of disease and 93% of them knew that BSE does not cause significantly harmful side effects. Furthermore, (89%, 70% & 92%) of respondents reported that BSE should not be performed daily or weekly or yearly respectively, while 57% of them reported that BSE should be performed monthly.

On the other hand, (50%, 60% & 65%) of participants did not know that if mammogram is the best way to diagnose breast cancer or it has serious side effects, or it is a painful procedure respectively. Additionally, 45% of them thought that mammogram do not need hospital admission to be performed, and 47% of them did not know that if mammogram should be done once in a life or no. See Table 1.

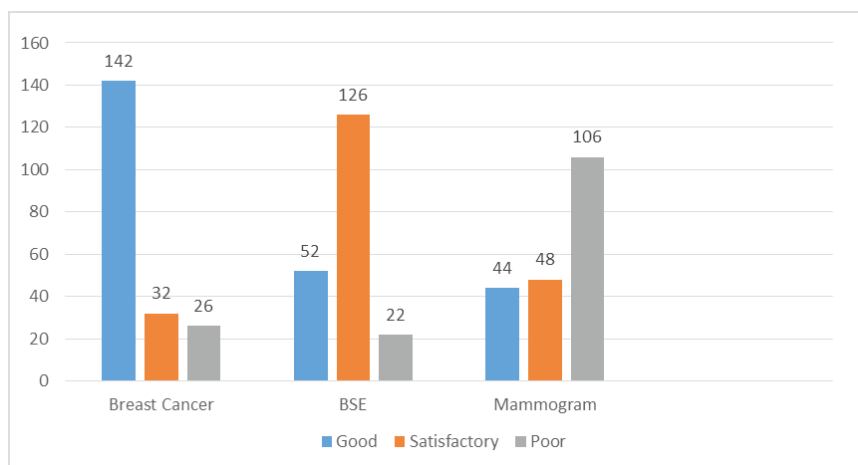


Figure 1. Total Participants’ Knowledge Levels Regarding Breast Cancer, Breast Self-Examination, and Mammogram

As shown in Figure 1, 71% of the respondents had good knowledge and the rest (29%) had satisfactory to poor knowledge regarding BC. According to BSE knowledge, only 26% of participants had good level, 63% of them had satisfactory level and 11% of them had poor level. Pertaining to mammogram, 53% of respondents had poor level, and the rest of them had satisfactory to poor knowledge.

Table 2: Participants’ attitudes of Breast cancer, Breast self-examination and Mammogram

Items	Agree N (%)	Disagree N (%)	Unknown N (%)
BC (3 Questions)			
Breast cancer patients should be isolated.	14 (7%)	148 (74%)	38 (19%)
Breast cancer patients should be allowed to live freely in the community.	132 (66%)	18 (9%)	50 (25%)
Breast cancer patients need for emotional support with home care.	196 (98%)	0	4 (2%)
BSE (9 Questions)			
Doing BSE is embarrassing.	168 (84%)	32 (16%)	0
Doing BSE is not interesting.	62 (31%)	84 (42%)	54 (27%)
Doing BSE applicable only for women with breast problem.	78 (39%)	88 (44%)	34 (17%)
Doing BSE not applicable for healthy women (women with normal Breast).	58 (29%)	112 (56%)	30 (15%)
Doing BSE will take too much time.	32 (16%)	138 (69%)	30 (15%)
Doing BSE is not necessary.	42 (21%)	130 (65%)	28 (14%)
Doing BSE need for privacy.	192 (96%)	8 (4%)	0
Doing BSE need for training.	52 (26%)	106 (53%)	42 (21%)
Doing BSE is very exhausted procedure.	26 (13%)	174 (87%)	0
Mammogram (5 Questions)			
Mammogram is very costly.	180 (90%)	4 (2%)	16 (8%)
Mammogram can be carried out in any clinics.	34 (17%)	110 (55%)	56 (28%)
Mammogram need for advice or consultation from physician.	122 (61%)	72 (36%)	6 (3%)
Mammogram cannot detect breast cancer in early stage.	18 (9%)	156 (78%)	26 (13%)
Mammogram is very exhausted.	98 (73%)	18 (9%)	84 (42%)

In the above Table, the majority (74%) of female students disagreed that breast cancer patients should be isolated, while (66% & 98%) of them agreed that breast cancer patients should be allowed to live freely in the community and need for emotional support with home care. The highest percent (84% & 96%) of respondents agreed that doing BSE is embarrassing and need for privacy.

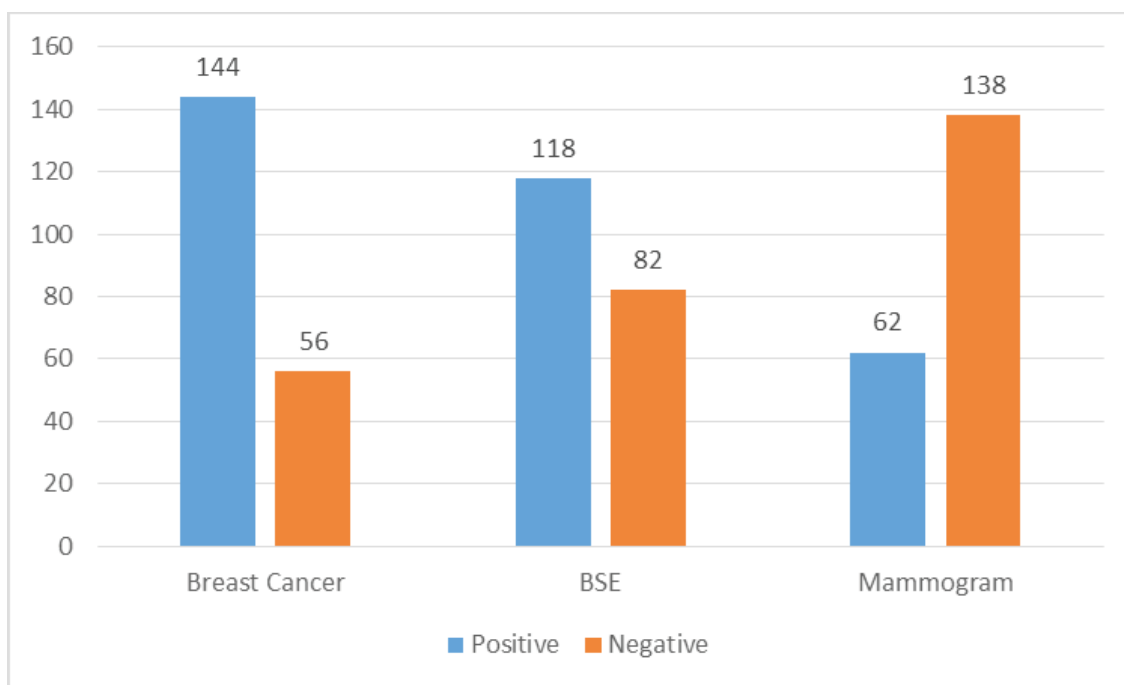


Figure 2. Total Participants' Attitudes Regarding Breast Cancer, Breast Self-Examination and Mammogram

As shown in Figure 2, 72% and 59% of respondents had positive attitude towards BC and BSE respectively, while 69% of them had negative attitude regarding mammogram.

In the current study, almost majority of female students reported that breast cancer is a common disease in this environment, congenital, leads to death and early diagnosis can increase chances of survival. The highest percentage of respondents informed that the warning signs of breast cancer involve exiting of secretions or blood from nipple, lump or swelling in the breast or arm tip and change in the skin of the breast.

Similarly, Ansari, et al.⁷ reported that medical students have high level of knowledge of Breast cancer. Contradictory for this finding, some research studies found that that the young women had very low levels of knowledge and understanding about Breast cancer^{8,9}. Moreover, the finding of Suleiman¹⁰ revealed that Jordanian women had worryingly poor levels of knowledge of breast cancer.

Furthermore, the participants' responses informed that family history was the most risk factors for increasing incidence of Breast cancer, followed by the age above 45, then using contraceptive and finally obesity. While,

the female students reported that breast-feeding decrease the chance of Breast cancer.

In this regard, Morimoto et al¹¹ found that obesity was associated with an increased risk of postmenopausal breast cancer only among women who have never taken hormone replacement therapy. While the study of Johnsona and Dickson-Swifta¹² had only identified two main risk factors, age and family history, and believed in common myths such as being hit in the breast causing breast cancer. Furthermore, Gabriel et al.¹³ mentioned that increasing age and current use of oral contraceptive pills are mostly identified risk factors, followed by family history of breast cancer, early age at menarche and late age at menopause.

According to the results, most of participants knew that BSE does not cause significantly harmful side effects, however they decided that it is not an important way for early diagnose of disease. The highest percent of them answered that the female gender only should perform the BSE and should be performed monthly, not daily, weekly, or yearly. It is apparent that the female students had satisfactory level of knowledge regarding BSE. Accordingly, Faronbi & Abolade¹⁴ mentioned that the majority of the teachers had poor knowledge of BSE,

while on contrary Odusanya & Tayo¹⁵ found out that nurses possessed adequate know ledge of BSE. In this aspect, Temiz et al¹⁶ illustrated that although educated and professional women in the field of medicine and nursing had greater knowledge of BSE, the majority of them did not perform BSE.

Based on these findings, the researchers stated most of participants thought that mammogram does not need hospital admission to be performed. The female students in the present study did not know if Mammogram is the best way to diagnose breast cancer, if it has serious side effects, or it is a painful procedure. They also do not know if mammogram should be done once in a life or indicated only women with breast problem. This study revealed a poor knowledge pertaining to mammography screening for breast cancer among female students. In fact, there is a great need to disseminate the information on the indications, side effects, procedures and advantages of mammography among public.

This finding supported by Rosmawati¹⁷ who conducted his study about the usage and knowledge of mammogram among women in sub-urban area, found seriously unaware and poor knowledge regarding mammogram and low percentage of women ever performed mammogram. In contrast, Ansari et al.⁷ stated that most medical students knew the importance of mammography in diagnosing breast cancer and most of them would recommend mammography for any women greater than 40 years old.

In this study, the respondents agreed that mammogram is very costly, need for advice or consultation from physician, and is very exhausted. They disagreed that mammogram can be carried out in any clinics and cannot detect breast cancer in early stage. The findings displayed that 69% of respondents had negative attitude about mammogram. In this regard, Temiz¹⁶ mentioned that although mammography remains the most valuable tool of screening in detection of breast cancer in the earliest possible stages and reduces mortality by up to 20% in women over 50 years, but it is beneficial only if done at regular intervals. According to the mammography side effect, Sharp et al.¹⁸ reported that the highest level of pain was resulted from the compression of the breasts, in which 72% of women gave the pain score ranked 4 or less on a scale of 0 to 10.

Conclusion: Although, the present study involved the responses of well-educated female students from third and fourth academic year, it was expected that they would have greater awareness and knowledge levels of breast cancer than the general population. Nevertheless, the study's findings were disappointing because they did not translate their knowledge into positive attitudes. This study revealed poor knowledge and serious negative attitudes pertaining to mammography screening for breast cancer. These results feel that they are away from the risk and it cannot happen to them.

Ethical Clearance- Taken from the Local Research Ethics Committee at the College of Applied Medical Sciences, University of Hafr Albatin.

Source of Funding- Self funding

Conflict of Interest- Nil

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Assessment of Pyogenic Granuloma of the Gingiva in Iraqi Patient

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Abstract

Pyogenic granuloma is smooth or lobulated mass that is usually pedunculated, while some lesion are sessile. Usually it enlarge until complete its size within weeks or months and rare does exceed 2.5 cm in size. Oral pyogenic granuloma, which in reality is the most common gingival tumor, shows a striking predilection for the gingival accounting for 75% of all cases. **Material and Method:** The data of this study was collected from oral pathology lab at dentistry college/ University of Baghdad, all cases from 2014 to 2018 were reviewed and the pyogenic granuloma cases were recorded after preparing a pathological report for each patients the clinical parameters regarding the age, sex, code, site, anatomical location of lesion were recorded. **Results:** The total number of pyogenic granuloma cases were 119, 76 cases were pyogenic granuloma of the gingiva. Number of female equal to 71 while number of males is 48. The highest number 26 patients was recorded in association with 11- 20 years group and lowest was in 71- 80 years group(only 2 patients).Maxilla is more affected by pyogenic granuloma (66%) than sites in mandibular arch (34%). **Conclusion:** The clinical, demographic and pathological features of oral pyogenic granuloma in the Iraqi population in this study were similar to those in studies of populations from other countries. The predilection site of pyogenic granuloma was the gingiva.

Key word: pyogenic granuloma, gingiva, health; patents; highly dosage.

Introduction

Enlargements of soft tissue of the mouth usually present a diagnostic challenge because a wide group of pathologic processes can produce these lesions. An enlargement may involve an inflammation, developmental anomalies, cysts, variation of normal anatomic structures, and neoplasm. Inside these lesions is a group of reactive hyperplasia, which growth in response to an excessive tissue repair response or chronic, recurring tissue injury that stimulates an exuberant. Pyogenic granuloma (PG) is the most common entities responsible for causing enlargements of soft tissue. Oral Pyogenic granuloma, which in reality is the most common gingival tumor ,shows a striking

predilection for the gingival accounting for 75% of all cases, where they are presumably caused by calculus or foreign material within the gingival crevice. The tongue, buccal mucosa and lips are the next most common sites. These lesions are more common on the gingiva in maxilla than the mandibular gingiva; anterior areas are more affected than posterior areas. Also, these lesions are much more found on the facial aspect of the gingiva than the lingual aspect; some time extend between the teeth and include both the facial and lingual gingiva ⁽¹⁾. Many “etiologic factors” such as injury, trauma to a primary tooth, hormones, chronic irritation, drugs, pre-existing vascular lesions, gingival inflammation, chronic irritation due to exfoliation of deciduous teeth, permanent teeth eruption , defective fillings in the region of tumor, periodontitis, food impaction, toothbrush trauma, etc. have been proposed as causative factors where patients presented with these findings ⁽²⁾. The PG is a lobulated or smooth mass that is usually pedunculated, while some lesions are sessile. The colour of its surface ranges from

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pink to red to purple and it characteristically ulcerated, according to the age of the lesion. Young PG are usually highly vascular in appearance while the older lesions that more collagenized and pink⁽³⁾. Clinical development of the lesion is slow, painless and asymptomatic but it may grow rapidly. Usually PG reaches its full size within weeks or months and seldom does exceed 2.5 cm in size. Identical mucosal lesions may occur spontaneously through pregnancy (granuloma gravidarum). In the mouth, the majority of PG occur on the gingiva; however, it can occur at any mucosal location of acute or chronic trauma, or infection⁽⁴⁾.

The surface is characteristically ulcerated and friable which may be covered by a yellow, fibrinous membrane and its color ranges from pink to red to purple, depending on the age of the lesion. Young PGs are highly vascular in appearance because they are composed predominantly of hyperplastic granulation tissue in which capillaries are prominent. Thus, minor trauma to the lesion may cause considerable bleeding, due to its pronounced vascularity⁽⁵⁾. The aim of this study was to evaluate the prevalence of pyogenic granuloma of the gingiva in Iraq and describe the clinical distribution of pyogenic granuloma of the gingiva among Iraqi patient.

Material and Method

The oral pathology lab archive at college of Dentistry/ Baghdad University was used to collect the data of this study. All cases from 2014 to the end of 2018 were review and the cases of pyogenic granuloma were recorded .After preparing a pathological report for each patients the clinical parameters including the sex, age, code, anatomic location of lesion, site and their initial clinical diagnosis of all cases of pyogenic granuloma were recorded.

This data was organize by using SPSS version 14 and all data had been being calculated and arranged in figures.

Result

The total number of pyogenic granuloma cases took from the archive of oral pathology lab in College of dentistry Baghdad university during five years period (from 2014 to 2019) were 119 cases, 76 cases were pyogenic granuloma of the gingiva. table1-Showed the Percentage of patients according to gender . Number of females equal to 71 (60%) while number of males is 48 (40%) with an overall female: male ratio of 1.47 :1 .

Table 1-distribution of cases according to gender

Gender	Frequency	Percent
Female	71	60
Male	48	40
Total	119	100

Age of patient were ranged from 3years to 73 years with mean age of 34.6 year .Frequency distribution of patients according to age groups were shown in fig. 1 -The highest number (26) patients was recorded in association with 11-20 years group and the lowest was in 71-80 years group (only 2 patients).

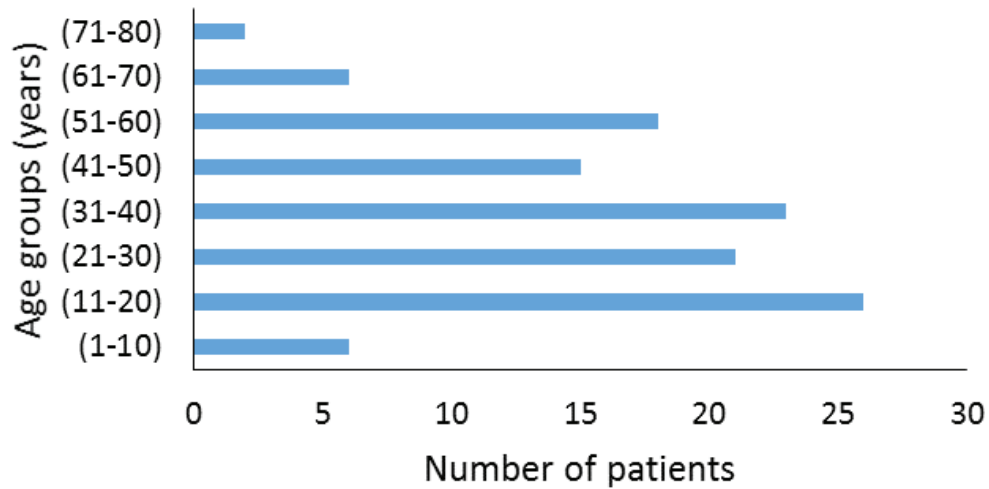
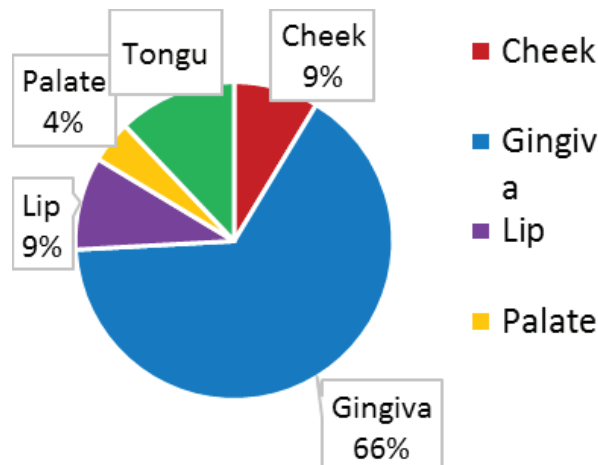


Fig 1 - Frequency distribution of patients according to age groups.

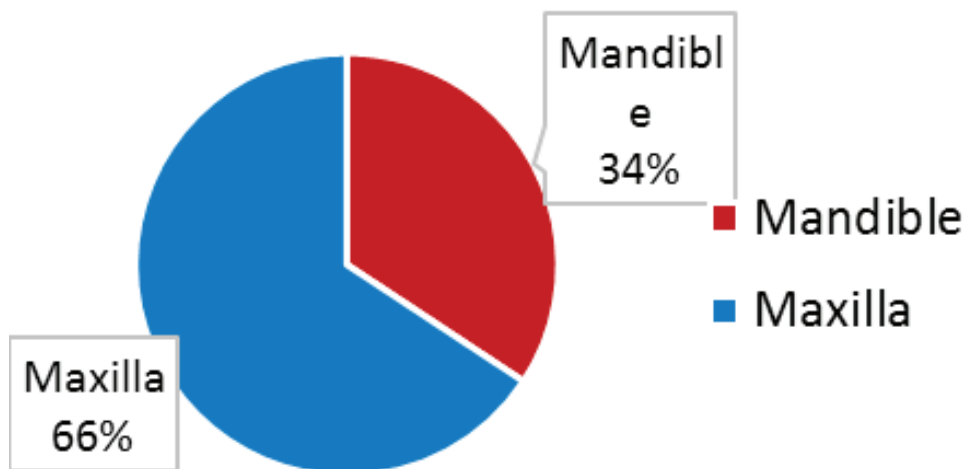
Table 2-Distribution of cases according to age group

Age group	Frequency	Percent
1-10	6	5
11-20	26	22
21-30	21	18
31-40	23	19
41-50	15	13
51-60	18	15
61-70	6	7
71-80	2	2
Total	119	100

As shown in Fig.2 , The Percent of sites affected by pyogenic granuloma The gingiva is the most affected site (66%) of the cases followed by tongue, cheek, lip, and palate representing 12, 9, 9, and 4% respectively.



Maxilla is more affected by pyogenic granuloma (66%) than sites in mandibular arch (34%) as shown in Fig 3.



Distribution of pyogenic granuloma according to tooth type showed that the anterior area of the jaws were the most common site. Upper anterior teeth were the most highly affected (40%), followed by the lower anterior teeth 19%. while the lowest teeth involved were lower premolar and molar (about 6%).

Table 3-distribution of P.G cases of the gingiva

Tooth type	Frequency	Percent
Upper anterior	32	40
Upper premolar	10	13
Upper molar	13	16
Lower anterior	15	19
Lower premolar	5	6
Lower molar	5	6
Total	80	100

Differential diagnosis of the cases indicated that the majority (67%) were initially diagnosed as pyogenic granuloma.

Discussion

The results of pyogenic granuloma in this study showed that female: male ratio was 1.47: 1, this is harmony with the result of Alkhateeb 2003⁽⁶⁾ who stated that female: male ratio was 1.7: 1, similar study done by Gordon- Nunez et al 2010⁽⁷⁾ showed that female: male ratio was 2.3: 1.

Regarding the age incidence, pyogenic granuloma in this study presented with mean age of 34.6 year, this is in harmony with Al Khateeb 2003⁽⁶⁾ who stated that

the mean age was 30 years. While Gordon- Nunez& Carvalho et al 2010⁽⁷⁾ demonstrated mean age was 27 years. (1.7%) of the lesion occur in the first five years of life, in contrast with Stephen& Patrice 1991⁽⁸⁾ who stated that (42%) of pyogenic granuloma occur in the first five years. The highest number(26) patients was recorded in association with 11- 20 years group this accordance with Ujwala 2018⁽⁵⁾ who showed that maximum cases were seen in the second (36%) and third decades (46%).

According to the distribution of site, the predilection site of pyogenic granuloma was the gingiva. Pyogenic granuloma tend to be localized on the gingiva in (66%) of cases, this was in harmony with other study Gordon-Nunez et al 2010⁽⁷⁾ which demonstrated that the most frequently involved site was the gingiva (83%). And (Akyol et al., 2001; Neville et al., 2016)^(9, 3) whom stated that oral pyogenic granuloma show a striking predilection for the gingiva. And also similar study Al Khateeb 2003⁽⁶⁾ showed that the most frequently involved site was the gingiva (44.4%). In contrast, (Mills, Stacey E. M.D 1980)⁽¹⁰⁾ stated that the lip was the most common site (38%).

Newadkar et al 2018⁽¹¹⁾; demonstrated that the gingiva was involved (90%) followed by the lip (6%) and ventral surface of the tongue (4%). Facial surface of gingiva involvement was more than that of the lingual or palatal surface.

Gingival pyogenic granuloma were more prevalent in the maxilla than in the mandible, with the anterior region of both jaws being more commonly affected. Comparable results was found in the study done by Al Khateeb 2003⁽⁶⁾ who also stated that the labiobuccal gingiva of both jaws was more commonly affected.

Ethical Clearance: The Research Ethical Committee at scientific research by ethical approval of both MOH and MOHSER in Iraq

Conflict of Interest: Non

Funding: Self-funding

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Factors Influencing Early Onset of Menarche Among School Children A Case Control Study

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Abstract

Introduction: Menarche is the appearance of first menstrual bleed. Many factors leads to early onset of menarche, of which physical factors, genetic factors, environmental factors, nutritional factors and family factors play a pivotal role. **Objectives:** The present study titled “Factors influencing early onset of menarche among school children” was an attempt to assess the mean age at onset of menarche and to determine the factors influencing early onset of menarche among cases and controls. **Methods:** A case control study was adapted to identify the factors influencing early onset of menarche among 411 (137 in cases and controls 274) children who were aged between 8-12 years. The schools were selected by simple random sampling technique and subjects by purposive sampling technique. **Results:** The study identified the mean age at onset of menarche among school children (including cases and controls) was 10.81 ± 0.821 years. Mean age at which siblings attained the menarche for controls were at 12 ± 1.697 years and controls was at 13 ± 1.697 years. The study also revealed statistically significant association between factors like consumption of fast food ($\chi^2= 1.250$, $p<.001$), knowledge about menarche ($\chi^2= 8.588$, $p =.003$) and excessive exercise ($\chi^2= 11.387$, $p<.001$) and onset of menarche. The chance of having early onset of menarche was 60.4% i.e. $(1- .396* 100)$ times more among cases who took nutritional supplements regularly. **Conclusion:** The study concludes that physical and nutritional factors needs parenteral control in order to remain fit and healthy.

Key words: Menarche, early onset, factors influencing, school children, nutrition, physical, environmental.

Introduction

Menarche is the time of first menstrual bleed. The first menstrual bleed is often not associated with ovulation. It is caused by the effects of estradiol on the endometrial lining. Menstrual bleeding in regular menstrual cycles after maturity is caused by the interplay of estradiol and progesterone produced by the ovaries¹.

There are many factors that leads to early onset of menarche, of which physical factors²⁻⁶, genetic factors⁷, environmental factors, nutritional factors and family factors play a pivotal role^{7, 8-11}. Early onset of menarche

results in behavioural problems, physical problems, teenage pregnancy, obstetrical problems etc. ^{7,12-18}

Identifying these factors from school children enables the health professionals, teachers and parents to promote awareness programmes in schools and community which has increased benefits in later part of their life.

The objectives of the study were to identify the age at onset of menarche and to compare the factors influencing early onset of menarche among cases and control group of school children.

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Materials and Methods

The study was carried out in the selected schools of Udupi District, Karnataka among school children who

were aged between 8-12 years. The total sample size was 411 (137 in cases and controls 274) based on the findings of previous study and sample size calculation. The schools were selected by simple random sampling technique and subjects were selected by purposive sampling technique. Data was collected from school children who attained menarche (cases) and those who did not attain menarche (controls) by administering the demographic proforma, physical measurements like height, weight, hip circumference, waist circumference were also assessed by the researcher and structured tool (that consisted of dichotomous question and rating questions) to assess the factors influencing early onset of menarche. The content validity of the tools was established by giving the tool to seven experts and Inter-rater measurement of reliability of the tool was $r=.97$

The study protocol was approved by Institutional Ethics Committee of the institution (IEC 742/2017). In addition the study was registered under Clinical Trial Registry of India (CTRI/2018/02/011701). After handing over subject information sheet to the participants, consent was taken from their parents. Tool was administered to the children and their mothers filled the data collection tool.

The data was analysed using Statistical Package for the Social Sciences (SPSS) version 16.0. Descriptive and inferential statistics was used for data analysis. Binary logistic regression was used to analyse the factors influencing early onset of menarche.

Results

The description of sample characteristics in mean and Standard Deviation (SD) [Table1], study results shows that out of 411 school children, the overall mean age (cases and controls) was 10.81 ± 0.821 years. The mean age at onset of menarche among cases was $11.598 \pm .492$ years. The mean height of the cases were 141.28 ± 4.66 cm and for controls it was 143.20 ± 7.91 cm. The mean weight of cases were 41.42 ± 7.72 kg and controls 33.65 ± 7.57 kg. Comparing the mean BMI, cases was 20.8 ± 1.83 kg/m² and controls were ranged on 16.4 ± 1.45 kg/m². Mean hip circumference for cases was 30.13 ± 2.17 inches and controls were 28.17 ± 1.27 inches. Mean age at siblings attained the menarche for cases was 12 ± 1.697 years and controls was at 13 ± 1.697 years.

Table 1: Description of sample characteristics in Mean and Standard Deviation (SD)

N=411

Variables	Cases n=137		Controls n= 274	
	Mean	SD	Mean	SD
Age at onset of menarche (in years)	10.81	0.821		
Age of cases (in years)	11.598	0.492		
Age of control (in years)			11.019	0.733
Height (in centimetres)	141.28	4.66	143.20	7.91
Weight (in kilograms)	41.42	7.72	33.65	7.57
BMI (kg/m2)	20.8	1.83	16.4	1.45
Hip circumference (in inches)	30.13	2.17	28.17	1.21
Age at siblings attained menarche (in years)	12	1.697	13	1.697
Age at mother attained menarche (in years)	14	1.11	14	1.11
Birth weight of the child (in kilograms)	2.94	.48	2.85	.51
Duration of pregnancy (in months)	>8	.313	>8	.313

Therefore difference was observed in height, weight, BMI, hip circumference among children in cases group which might be positive indicators for early menarche among them.

Table 2: Description of association of factors influencing early onset of menarche (cases and control)

N=411

Factors	Response	Cases		Control		X ²	df	p value
		f	%	f	%			
Nutritional factors								
Eats vegetables everyday	Y	73	53.3	171	62.4	3.152	1	.076
	N	64	46.7	103	37.6			
Eats fruits everyday	Y	94	68.6	198	72.3	0.591	1	.442
	N	43	31.4	76	27.7			
Drinks milk and milk products every day	Y	107	78.1	230	83.9	2.110	1	.146
	N	30	21.9	44	16.1			
Eats fast food items everyday	Y	56	40.9	31	11.3	49.806	1	.001
	N	81	59.1	243	88.7			
Family factors								
Staying with your parents	Y	134	97.8	274	100	1.545**	1	0.226
	N	3	2.2	0	0			
Parents separated	Y	134	97.8	274	100	1.620**	1	.339
	N	3	2.2	0	0			
Have an elder sister	Y	47	34.3	84	30.7	0.560	1	.454
	N	90	65.7	190	69.3			
Father more concern about your activities	Y	135	98.5	274	100	4.020**	1	.111
	N	2	1.5	0	0			
Mother more concern about your activities	Y	136	99.3	274	100	2.005**	1	.333
	N	1	.7	0	0			
Mother least bothered about you	Y	1	0.7	0	0	2.005**	1	.333
	N	136	99.3	274	100			
Environmental factors								
Family subscribes news paper	Y	81	59.1	120	43.8	8.588	1	.003
	N	56	40.9	154	56.2			
Family subscribes magazine	D	22	16.1	45	16.4	0.647	1	.724
	W	29	21.2	49	17.9			
	O	86	62.8	180	65.7			
Reads newspaper every day	Y	35	25.5	61	22.3	0.550	1	0.458
	N	102	74.5	213	77.7			
Attended any sexual awareness programs	Y	132	96.4	255	93.1	1.792	1	.181
	N	5	3.6	19	6.9			
Migrates from other places	Y	28	20.4	76	27.7	2.572	1	.109
	N	109	79.6	198	72.3			
Physical factors								
Follows regular exercise	Y	44	32.1	136	49.6	11.387	1	.001
	N	93	67.9	138	50.4			
On regular medications	Y	9	6.6	14	5.1	0.368	1	.544
	N	128	93.4	260	94.4			
Had any childhood illness	Y	11	8	19	6.9	0.162	1	.687
	N	126	92	255	93.1			
* = level of significance < .05, **cells <5, Fishers Exact test was interpreted, Y= yes, N= no, χ^2 = chi-square test								

Data showed in Table 2, reports statistically significant association between consumption of fast food ($\chi^2= 1.250$, $p < .001$), knowledge about menarche through newspaper, television, internet ($\chi^2= 8.588$, $p < .003$), among children who did not follow regular exercise pattern ($\chi^2= 11.387$, $p < .001$) and onset of menarche among cases than control.

Table 3: Association of Factors Influencing Early Onset Of Menarche Among Cases and Controls

N=411

Variables	Response	Cases		Control		χ^2	df	p value
		f	%	f	%			
Nutritional factors								
Skips breakfast more than 3 times in a week	R	67	48.9	134	48.9	0.000	2	1.000
	S	63	46	126	46			
	M	7	5.1	14	5.1			
Skips lunch more than 3 times in a week	R	100	73	218	79.6	5.938*	2	.051
	S	36	26.3	48	17.5			
	M	1	0.7	8	2.9			
Skips dinner more than 3 times in a week	R	90	65.7	197	71.9	1.794	2	.408
	S	36	26.3	61	22.3			
	M	11	8	16	5.8			
Eats sweet items everyday	R	29	21.2	56	20.4	9.456	2	.009*
	S	48	35	136	49.6			
	M	60	43.8	82	29.9			
Eats non- vegetarian items	R	27	19.7	47	17.2	10.044	2	.018*
	S	67	48.9	175	63.9			
	M	36	26.3	42	15.3			
	No	7	5.1	10	3.6			
Drinks beverages more than 2 times in a day	R	45	32.8	91	33.2	.205**	3	.977
	S	51	37.2	98	35.8			
	M	37	27	75	27.4			
	No	4	2.9	10	3.6			
Drinks aerated drinks	R	55	40.1	91	33.2	5.968	2	.051*
	S	63	46	159	58			
	M	19	13.9	24	8.8			
Takes nutritional supplements	R	91	66.4	135	49.3	12.322	3	.006*
	S	12	8.8	37	13.5			
	M	34	24.8	97	35.4			
	No	0	0	5	1.2			
Environmental factors								
Watches TV more than 3 hours in a day	R	33	24.1	77	28.1	14.058	2	.001*
	S	52	38	140	51.1			
	M	52	38	57	20.8			
Daily use of internet	R	47	34.3	150	54.7	17.389	2	.001*
	S	67	48.9	102	37.2			
	M	23	16.8	22	8.0			
Use of mobile	R	37	27	109	39.8	11.707	2	.003*
	S	73	53.3	139	50.7			
	M	27	19.7	26	9.5			
Use of internet other than study purpose	R	63	38.7	146	53.8	18.223	2	.001*
	S	59	43.1	112	40.9			
	M	25	18.2	16	5.8			
Physical factors								

Cot... Table 3: Association of Factors Influencing Early Onset Of Menarche Among Cases and Controls
N=411

Practices any form of dance	R	54	39.4	87	31.8	2.436	2	.296
	S	52	38	120	43.8			
	M	31	22.6	67	24.5			
Plays for more than 2 hours in a day	R	44	32.1	75	27.4	1.528	2	.466
	S	60	43.8	137	50			
	M	33	24.1	62	22.6			
Rides bicycle everyday	R	50	36.5	85	31	7.243	2	.065
	S	58	42.3	111	40.5			
	M	27	19.7	57	20.8			
	No	2	1.5	21	7.7			
Walks more than 3 km in a day	R	76	55.5	151	55.1	0.535	2	.765
	S	42	30.7	78	28.5			
	M	19	13.9	45	16.4			
Prefers reading story books during leisure time than physical activities	R	57	41.6	86	31.4	4.226	2	.121
	S	51	37.2	118	43.1			
	M	29	21.2	70	25.5			
Sleeps for more than 6 hours in a day	R	34	24.8	73	26.6	1.505	2	.471
	S	35	25.5	82	29.9			
	M	68	49.6	119	43.4			
Sleep disturbance	R	91	66.4	179	65.3	0.117	2	.943
	S	32	23.4	64	23.4			
	M	14	10.2	31	11.3			
<p>*= level of significance < .05,**cells <5, Fishers Exact test was interpreted. R= rarely, S= sometimes, M = most of the time, χ^2= chi-square test, df= degree of freedom</p>								

Data in table 3, reports that there was a significant association between nutritional factors like consumption of sweet items every day ($\chi^2= 9.456$, $p = .009$), drinking aerated drinks ($\chi^2= 10.044$, $p = .018$), eating non-vegetarian foods ($\chi^2= 5.968$, $p = .051$), taking nutritional supplements ($\chi^2= 12.322$, $p = .006$) and early onset of

menarche among cases. Also, environmental factors like excessive use of mobile ($\chi^2= 11.707$, $p = .003$), internet and usage of television ($\chi^2= 17.389$, $p = .001$) were also responsible for early onset of menarche among cases than controls.

Table 4: Odds Ratio and 95% CI Reporting Factors Influencing Early Onset of Menarche N=411

Factors	df	OR	95%confidence interval		Sig (p)
			Upper limit	Lower limit	
Eats fast food items everyday	1	.162	.391	.067	.001*
Family subscribes to newspaper everyday	1	.874	1.61	.400	.737
Follows regular exercise	1	1.005	1.67	.576	.985
Takes nutritional supplements	1	.396	.161	.576	.021*
Watches TV more than 3 hours in a day	1	.818	1.35	.496	.433
Daily use of internet	1	1.07	2.11	.547	.839
Use of mobile	1	1.01	1.87	.550	.958
Use of internet	1	.921	1.70	.498	.792

*= level of significance < .05 df= degree of freedom OR= odds ratio

Logistic regression analysis of factors influencing early onset of menarche in Table 4 shows that the cases who ate fast food everyday had 83.8% (OR .162, 95% CI [.067-.391]) p < .001 more chance of having early onset of menarche than controls. The chance of having early onset of menarche was 60.4 % (OR .396, 95% CI [.576 - .161]) more among cases who took nutritional supplement like iron tablets which were distributed in the government schools.

Table 5: Logistic Regression Analysis of Factors Influencing Early Onset of Menarche N=411

Risk factor	df	χ ²	OR	95%confidence interval		Sig (P)
				Lower limit	Upper limit	
Place of residence	1	6.152	.616	1.477	.257	.277
Occupation of father	1	16.525**	1.616	2.256	1.158	.005
Income of the family	1	7.982	0.434	.835	.226	.012

*= level of significance < .05 df= degree of freedom OR= odds ratio **cells <5, Fissures Exact test was interpreted

Data in Table 5 shows, that the chance of having early onset of menarche was 1.616 times more among cases whose father had better occupation [OR 1.616 (CI 1..158-2.256)], p < .005 than controls. The chance of having early onset of menarche was 56 % (OR .434, 95% CI [.226 - .835]) p < .012, more among cases whose family income ranged between Rs.10,000-50,000 than controls.

Discussion

Mean age at onset of menarche

The results of the present study showed that, the mean age at onset of menarche among 137 children aged between 8-12 years were 10.81± .821years. The mean age at onset of menarche in this study is however lower

when compared to other reports.^{10, 19-20}

In this study, mothers age at menarche for cases and controls were at 14 ± 1.11 years, which showed a decline in the age at onset of menarche in children, which was similar to studies conducted by Gujar, Kini, & Rani (children 11 ± 909 years, mothers $14 \pm .910$ years)²¹ Kolarov, et al[22] (children $12.17 \pm .95$ years, mothers 13.08 ± 1.32 years), Dundar, Hulya, Pinar²³ (children $12.6 \pm .03$ years, mothers $13.4 \pm .65$ years)

There was a relation between sibling's age at menarche and participants age at onset of menarche. It was observed that, the mean age at sibling's attained menarche among cases was 12 ± 1.697 years and controls was 13 ± 1.697 years, which was supported by a similar study, conducted among athletes with their sisters²⁴.

Present study found that lowest age at onset of menarche was 8 years 6 months. This finding is in agreement with the studies where 15.1% of girls attained menarche before reaching 11 years)²⁵, 11.8% attained before leaving VII standard²⁶, 18.2% attained menarche before 12 years of age¹⁹, 29.5% before 11 years of age^{2,12}.

Physical characteristics and age at onset of menarche

Physical parameters such as height, weight, BMI, mid upper arm circumference, hip circumference, waist circumference, status and bi-iliac breadth has a strong relation with onset of menarche^{2,5,6,8,27-28}. The present study showed significant difference in physical features and onset of menarche among cases and controls i.e., mean height 141.28 ± 4.66 centimetres and 143.20 ± 7.91 centimeters, mean weight 41.42 ± 7.72 kilograms and 33.65 ± 7.57 kilograms, mean BMI 20.8 ± 1.83 and 16.4 ± 1.45 , mean hip circumference was 30.13 ± 2.17 inches and 28.17 ± 1.27 inches. The results showed that short and fat girls attained menarche earlier than others.

Socio economic status and age at menarche

Present study showed that the chance of having early onset of menarche was 1.616 times more among cases whose father had better occupation OR 1.616 (CI 1.158-2.256), $p < .005$. The chance of having early onset of menarche was 56 % (OR .434, 95% CI [.226 - .835]) $p < .012$, more among cases whose family income

ranged between Rs.10,000-50,000. Similar results were observed by Radha S, Chellappan V²⁵, Bagga and Kulkarni¹⁹, Reddy and Radhika²⁹, Ghimire M, Sharma³⁰

Nutrition and age at onset of menarche

The present study results showed that, cases who ate fast food everyday had 83.8% (OR .162, 95% CI [.067-.391]) $p < .001$ more chance of having early onset of menarche than controls. The chance of having early onset of menarche was 60.4 % (OR .396, 95% CI [.576 - .161]) more among cases who took nutritional supplements than controls. The findings of the study supported by other reporters³¹⁻³⁵.

Conclusion

Menarche is the first menstrual period generally occurring in early stages of adolescent girls. It is a part of the maturation process and an important milestone of puberty for most women in adolescent girls. Age at onset of menarche and associated factors were assessed for 411 adolescent girls who were aged between 8-12 years. The study found that mean age at onset of menarche among cases was $10.81 \pm .821$ years. The present study concluded that nutritional status, physical activity and socio economic factor have a major role in onset of menarche.

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Iron profile and Hepcidin Associated with Oxidative Stress and Metabolic Disturbances in Pregnancy

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Abstract

Background: A common problem during pregnancy is anemia and to reduce its prevalence the WHO and national guidelines recommend a prescription of 30 to 60 mg of iron/day. The aim of this study was to evaluate the association of iron profile, hepcidin and oxidative stress in pregnant women prescribed with iron as a probable cause of metabolic disorders.

Method: In this cohort study two groups were followed: A) women with low-risk pregnancy (WLRP), B) women with high-risk pregnancy (WHRP): women with metabolic disorders (dyslipidemias, GDM and high blood pressure). Oxidative stress enzymes, iron profile and hepcidin were measured in the second and third trimesters.

Results: There were significant differences in hepcidin levels between WLRP and WHRP in 2nd (3.6 ± 4.2 vs 4.69 ± 3.23 $P=0.005$) and 3rd trimester (3.65 ± 3.44 vs 6.84 ± 5.14 $P=0.02$). The serum iron concentration had a negative relationship with catalase (-0.599 ; $P=0.04$) and a positive relationship with glutathione peroxidase (0.729 ; $P=0.007$).

Conclusion: The iron serum levels increase could induce oxidative damage in pregnancy. Increased hepcidin is a useful biomarker for determining iron availability in pregnancy and its association with antioxidant systems.

Key words: hepcidin, iron, oxidative stress, pregnancy,

Introduction

Between 2% and 5% of pregnancies in women older than 30 are associated with metabolic disorders¹ and 40.1% are related to anemia-associated nutritional deficits, being 50% of these due to iron deficiency.² Therefore, the prophylactic prescription of iron

supplements has become routine in the gestational period,³ recommending from 30 to 60 mg of iron/day as a prophylactic dose during pregnancy to avoid anemia.⁴

The Mexican Institute of Social Security (IMSS) defined in 1959 a standardized supplemental dose of 60 mg of elemental iron, generally supplied as 200 mg of ferrous sulfate/day based on estimates of pregnancy iron requirements between 3.5 to 4 mg/day. Moreover, the Mexican government recommends the administration of iron and folic acid as prophylactic prescription.²

It is well-known that iron participates in the generation and propagation of reactive oxygen species (ROS) and lipid hydroperoxides, which play an

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important role in the pathophysiology of diseases such as gestational diabetes mellitus (GDM) and preeclampsia.⁵

It is recognized that, to guarantee an absorption of between 4 and 7 mg/day of iron, at least 20 mg/day of this element should be consumed in the diet (20% bioavailability), and adding 60 mg/day of supplemented iron, a pregnant woman would receive 80 mg/day of which 16 mg/day would be absorbed, which implies a dose 4 to 8 times higher than the minimum requirement amount, leading possibly to an iron overloading exposition in the gastrointestinal system. Hence, iron overload results in an increase in total body iron stores, a situation that could favor oxidative stress in any system and in the body in general.

Hepcidin peptide plays an important role in iron homeostasis since it regulates both iron absorption in the duodenum and its recycling process from senescent erythrocytes.⁶ The aim of this work was to evaluate the correlations among serum iron levels, hepcidin and oxidative stress in pregnant women with or without metabolic disorders.

Methods

Study design

This cohort study, carried out at the “Mónica Pretelini Sáenz” Maternal Perinatal Hospital (HMPMPS), Health Institute of the State of Mexico (ISEM), Toluca, Mexico, included pregnant women divided into two groups: A) women with low-risk pregnancy (WLRP), B) women with high-risk pregnancy (WHRP): women with metabolic disorders (dyslipidemias, GDM and high blood pressure).

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 22 subjects per group were necessary to recognize as statistically significant a difference greater than or equal to 3 units for hepcidin levels with a common standard deviation of 3.5.

The protocol was reviewed and approved by the HMPMPS Ethics in Research Committee (number: 2018-10-608) and the volunteers signed an informed consent letter. All the procedures were conducted in accordance with the Declaration of Helsinki (Fortaleza, Brazil) and the General Health Law of Mexico.

Inclusion and exclusion criteria

The inclusion criteria were pregnant women between 18 and 40 years old in the 2nd trimester of gestation prescribed with ferrous sulfate (60 mg/day), presence of metabolic alterations for the risk group pregnancy (previously diagnosed by the treating physician based on: hypertension: systolic blood pressure (SBP) \geq 140 mmHg and/or diastolic blood pressure (DBP) \geq 90 mmHg); GDM; glucose $>$ 130 mg/dL; dyslipidemia: cholesterol $>$ 200 mg/dL and triglycerides $>$ 150 mg/dL) or women with Low-Risk for control group. Pregnant women with congenital heart defects, uterine abnormalities, chronic degenerative diseases, pregnancies with congenitally abnormal fetuses, pregnancies with assisted reproductive technologies, history of smoking, type 2 diabetes mellitus (T2DM) and infectious, inflammatory or autoimmune diseases were excluded. Volunteers who abandoned the study or who were lost to follow-up were discarded from the final analysis.

Data Source

A questionnaire completed by all the patients gathered their health status and sociodemographic data including information of weight, height, blood pressure, blood chemistry (glucose, cholesterol and triglycerides) and blood biometry.

Blood samples were obtained in the 2nd (14-27 weeks of gestation) and 3rd trimester (28-42 weeks of gestation). The antioxidant activity was evaluated through the enzymatic quantification of catalase (CAT), superoxide dismutase (SOD) and glutathione peroxidase (GPx) using the methods of Radis et al.⁷ Misra, et al.⁸ Paglia et al.⁹ respectively, as well as lipid peroxidation (LPOx) levels (Buege method).¹⁰ The iron profile included serum iron, total iron-binding capacity (TIBC), unsaturated iron-binding capacity (UIBC) and iron saturation (%S). Ferritin was also measured by chemiluminescence and hepcidin quantification was done by sandwich ELISA (LifeSpan BioSciences, Inc.)

Sociodemographic data was analyzed by descriptive statistics. The medians of the biomarkers under study were compared using the Mann Whitney U test and in order to analyze the correlation among biomarkers, a Spearman correlation was performed. The IBM STPSS Statistics 22 program was used, setting a P value \leq 0.05

as statistically significant.

Results

Of 106 patients who met the inclusion criteria in the 2nd. trimester of gestation, 42 were discarded, 20 did not want to sign the informed consent and 22 had inconsistent information. 64 volunteer patients, 23 in the WLRP group (mean age 23.8 ± 4.5 years, range: 18-31) and 41 in the WHRP group (27.0 ± 5.8 years, range: 18 to 31) participated in the study. Table 1 shows the population characteristics.

In relation to blood chemistry (Table 2), glucose levels were significantly higher by 7.93% in the WHRG group compared with the WLRP group only in the 2nd trimester. Cholesterol values in the WHRP group were significantly higher in the 2nd and 3rd trimester compared with those obtained in the WLRP group, by 19.7% and 17.3%, respectively.

The triglyceride values in the 2nd and 3rd trimester of the WHRP group were 1.67 and 1.65 times higher than those of the WLRP group. In the WLRP group, 26% exceeded the reference values for cholesterol in the 2nd trimester and 47.8% in the 3rd trimester. The triglyceride levels of 26% of the WLRP group were higher than 200 mg/dL in the 2nd trimester and 73.9% in the 3rd trimester. The WHRP group exceeded the 73.2% reference value for cholesterol in the 2nd trimester and 78.0% in the 3rd trimester. Likewise, for triglyceride, these percentages were 87.8% and 97.46%.

The results of the oxidative stress biomarkers show that SOD activity increased significantly between the 2nd and 3rd trimester in both groups (WLRP 26% and WHRP 21.9%); the increments for GPx in the same order

were 23.7% and 23.2%. Finally, LPOx levels increased 34% in the WLRP group, but only 8.5% in the WHRP group without being significant.

Regarding iron profile, there was no significant difference between the study groups, nor between the trimesters of pregnancy. Notwithstanding, a higher hepcidin concentration was obtained in the WHRP group compared with the WLRP group for both the 2nd and 3rd trimester (23.2 and 46.6%, respectively). TIBC in the 3rd trimester of the WLRP group and in the 2nd and 3rd trimester of the WHRP group were higher than the reference values (240 to 450 $\mu\text{g/dL}$).

To analyze the results of the iron profile, the groups were formed as follows: WLRP (n = 11) and WHRP (n = 12) (since only these volunteers had all the determined parameters). A significant difference between the groups was observed only for iron saturation in the 3rd trimester (Table 3).

Finally, Spearman’s correlation (Table 4) showed as main results that serum iron concentration had a significant negative relationship with CAT (-0.599; $P=0.04$) and positive with GPx (0.729; $P=0.007$). A positive correlation was obtained between SOD and LPOx (0.395; $P=0.007$), being lower for the WLRP group (0.481; $P=0.24$). It was also observed that at a lower hepcidin concentration, the SOD activity in the 3rd trimester of the WLRP group was higher (-0.6; $P=0.050$), and in the WHRP group the behavior was the opposite in the 2nd trimester of pregnancy. Interestingly, when the hepcidin concentration increased, the SOD activity also increased (0.615; $P=0.033$). For GPx activity, the correlation was negative with hepcidin (-0.636; $P=0.026$).

Table 1. Population characteristics

Variable	WLRP (N = 23) Mean \pm SD		WHRP (N = 41) Mean \pm SD	
	2nd trimester	3rd trimester	2nd trimester	3rd trimester
Age (years)	23.8 \pm 4.5	-	27.0 \pm 5.8	-
Height (m)	1.58 \pm 0.07	-	1.57 \pm 0.07	-
Weight (kg)	66.7 \pm 11.1	70.3 \pm 11.05	72.4 \pm 14.8	75.2 \pm 14.6
BMI (kg/m ²)	26.4 \pm 3.9	27.8 \pm 3.7	29.2 \pm 5.02	30.4 \pm 4.94
Gestation (weeks)	22.8 \pm 3.9	32.7 \pm 2	23.2 \pm 3.9	32.6 \pm 2.1
Systolic Blood Pressure (mm Hg)	103.3 \pm 8.4	106.9 \pm 7.0	111.4 \pm 13.5	111.9 \pm 10.0
Diastolic Blood Pressure (mm Hg)	63.6 \pm 8.2	63.9 \pm 5.8	66.7 \pm 9.6	69.5 \pm 9.5

Abbreviations: BMI: Body Mass Index, WLRP: Women with Low-Risk, WHP: Women with High-Risk Pregnancy.

Table 2. Means of the results of blood chemistry, oxidative stress and hepcidin (N = 64)

Variable	WLRP (N = 23)		WHP (N = 41)		Mann Whitney U test			
	2nd trimester	3rd trimester	2nd trimester	3rd trimester	*	†	‡	§
Glucose (mg/dL)	83.7 ± 10.8	87.1 ± 11.4	91 ± 15.9	89.2 ± 13.5	0.206	0.026	0.568	0.711
Cholesterol (mg/dL)	187.5 ± 19.67	206.1 ± 37.9	233.5 ± 51.6	249.1 ± 62.4	0.15	<0.001	0.297	0.002
Triglycerides (mg/dL)	144.5 ± 33.71	193.5 ± 57.8	242.8 ± 72.6	318.8 ± 98.9	0.002	<0.001	<0.001	<0.001
SOD (µmol/g Hb)	470.2 ± 293.63	635.7 ± 253.4	432.2 ± 264.6	553.3 ± 274.3	0.049	0.68	0.043	0.26
CAT (nmol/g Hb)	570.1 ± 265.53	580.2 ± 314.2	475.8 ± 262.9	549.4 ± 295.1	0.852	0.177	0.301	0.828
GPx (µmol/g Hb)	14.0 ± 6.2	18.4 ± 7.9	13.3 ± 6.6	17.3 ± 6.2	0.049	0.45	0.007	0.506
LPOx (nmol/g Hb)	313.7 ± 185.25	475.5 ± 238.4	375.1 ± 156.7	410.1 ± 159.9	0.024	0.173	0.537	0.367
Hepcidin (ng/mL) n = 38	3.6 ± 4.2	3.6 ± 3.4	4.7 ± 3.2	6.8 ± 5.1	0.806	0.005	0.199	0.02

Abbreviations: CAT: catalase, GPx: glutathione peroxidase, LPOx: lipid peroxidation, SOD: superoxide dismutase, WLRP: Women with Low-Risk, WHP: Women with High-Risk Pregnancy.

* WLRP 2nd trimester vs. WLRP 3rd trimester.

† WLRP 2nd trimester vs. WHP 2nd trimester.

‡ WHP 2nd trimester vs. WHP 3rd trimester.

§ WLRP 3rd trimester vs. WHP 3rd trimester.

Table 3. Means of the results of iron profile and hepcidin (n = 23).

Variable	WLRP (N = 11)		WHRP (N = 12)		Mann Whitney U test			
	2nd trimester	3rdtrimester	2nd trimester	3rd trimester	*	†	‡	§
Iron (µg/dL)	78.53 ± 33.73	86.54 ± 32.38	64.43 ± 18.75	69.6 ± 19.76	0.438	0.487	0.514	0.316
TIBC (µg/dL)	439.35 ± 80.58	437.15 ± 81.58	463.47 ± 98	460.23 ± 97.85	0.949	0.487	0.799	0.525
UIBC (µg/dL)	356.45 ± 94.19	358.54 ± 90.45	397.4 ± 90.73	392.9 ± 92.83	0.898	0.19	0.843	0.288
Iron saturation (%)	16.9 ± 7.12	20.35 ± 6.81	14 ± 4.26	15.08 ± 5.33	0.217	0.169	0.478	0.016
Ferritin (ng/mL)	15.98 ± 12.45	18.92 ± 14.97	9.62 ± 2.94	11.55 ± 3.4	0.519	0.413	0.198	0.288
Hepcidin (ng/mL)	2.61 ± 3.12	3.38 ± 3.72	4.64 ± 3.69	7.17 ± 6.43	0.519	0.104	0.478	0.118

Abbreviations: TIBC: total iron-binding capacity, UIBC: unsaturated iron-binding capacity, WLRP: Women with Low-Risk pregnancy, WHRP: Women with High-Risk Pregnancy.

* WLRP 2nd trimester vs. WLRP 3rd trimester.

† WLRP 2nd trimester vs. WHRP 2nd trimester.

‡ WHRP 2nd trimester vs. WHRP 3rd trimester.

§ WLRP 3rd trimester vs. WHRP 3rd trimester.

Table 4. Correlation of biomarkers of iron profile and hepcidin with blood chemistry and oxidative stress

Variables	WLRP and WHRP (N = 23)		WLRP 2nd trimester (N=11)		WLRP 3rd trimester (N=11)		WHRP 2nd trimester (N=12)		WHRP 3rd trimester (N=12)	
	r	P value	r	P value	r	P value	r	P value	r	P value
Iron - TIBC									0.608	0.036
Iron - UIBC	-0.325	0.028								
Iron - %S	0.815	<0.001	0.918	<0.001	0.9	<0.001	0.76	0.004	0.579	0.049
Iron - Ferritin			0.818	0.002	0.818	0.002				

Cont... Table 4. Correlation of biomarkers of iron profile and hepcidin with blood chemistry and oxidative stress

Iron - CAT							-0.599	0.04		
Iron - GPx							0.729	0.007		
%S - TIBC	-0.407	0.005								
%S - UIBC	-0.646	<0.001	-0.683	0.02	-0.691	0.019				
%S - Ferritin			0.782	0.004	0.745	0.008				
%S - Glucose					-0.627	0.039				
%S - Triglycerides							-0.643	0.024		
Ferritin - UIBC			-0.756	0.007	-0.645	0.032				
Ferritin - Cholesterol					-0.645	0.032				
Ferritin - Triglycerides			0.645	0.032						
Ferritin - CAT	-0.332	0.024								
Ferritin - LPOx									-0.632	0.028
TIBC - UIBC	0.92	<0.001	0.902	<0.001	0.845	0.001	0.839	0.001	0.734	0.007
TIBC - Cholesterol					0.8	0.003				
TIBC - Triglycerides									0.651	0.022
UIBC - Cholesterol					0.673	0.023				
UIBC - Triglycerides							0.58	0.048		
Hepcidin - SOD					-0.6	0.05	0.615	0.033		
Hepcidin - CAT	-0.316	0.032								
Hepcidin - GPx									-0.636	0.026

Abbreviations: CAT: catalase, GPx: glutathione peroxidase, LPOx: lipid peroxidation, SOD: superoxide dismutase, TIBC: total iron-binding capacity, UIBC: unsaturated iron-binding capacity, %S: iron percentage saturation, WLRP: Women with Low-Risk pregnancy, WHRP: Women with High-Risk Pregnancy.

Discussion

The results of this study showed a similar increase in cholesterol and triglycerides in both groups of volunteers from the 2nd to the 3rd trimester of pregnancy. Similar results to previous published information.^{11,12,13} In this survey, 34.1% of pregnant women in the WHRP group

were hypertensive and 51.2% were dyslipidemic.

On the other hand, SOD and GPx levels increased significantly from the 2nd to the 3rd trimester of pregnancy, in both groups, probably to offset the effect of lipid peroxides and other free radicals produced by abnormal lipid metabolism and inflammation processes

present when metabolic disturbances occur during pregnancy.¹²

Regarding the iron profile, it was found that the volunteers of both groups presented normal serum iron levels (60 to 170 µg/dL). However, the TIBC in the 3rd trimester of the WLRP group and in the 2nd and 3rd trimester of the WHRP group were higher than the reference values (240 to 450 µg/dL),¹⁴ which would indicate the absence of iron deficiency in both groups, and that by increasing the serum iron concentration, it also increases the binding capacity of transferrin and binding sites. This hypothesis is reaffirmed by the positive relationship between serum iron and iron saturation values,¹⁵ as well as a negative relationship between UIBS and iron saturation.

Overall, the positive relationship between iron levels and TIBC in the 3rd trimester in the WHRP group would indicate a probable iron overload when the binding capacity with transferrin saturates, leading to non-transferrin-bound iron being internalized in tissues,¹⁶ where the ROS would increase, unbalancing the antioxidant systems, reflected in the negative relationship between serum iron with CAT and the positive relationship with GPx, as well as the formerly described increase in GPx, affecting insulin secretion and lipid oxidation, resulting in increased sensitivity to insulin and predisposition to GDM.¹⁷

It is worth noting that excess free iron can accept and donate electrons not only to catalyze the Fenton and Haber-Weiss reaction, but also to propagate free radical chain reactions, acting as an oxidative substance with a role in endothelial destruction, and thus participating in the pathogenesis of preeclampsia or GDM,¹⁸ pathologies present in the WHRP group. Usually, efficient iron mobilization of reserves is reflected by lower concentrations of ferritin in the 3rd trimester of pregnancy,¹⁹ contrary to our results in both groups, in which we found an increase, although not significant.

When analyzing hepcidin levels, a significant increase from the 2nd to the 3rd trimester, in both groups, was found, data consistent with those reported early in high-risk pregnancies associated with inflammatory conditions (GDM or preeclampsia), in which hepcidin rises compared with healthy pregnancies, suggesting a probable iron accumulation as a result of the sulfate

ferrous prescription, since when finding a state of poor iron in pregnancy low levels of hepcidin have been found,²⁰ being the lowest during the 3rd trimester compared with the 1st and 2nd trimester, allowing maximum iron transfer to the fetus.²¹

The previous result points to the relevance of measuring hepcidin during pregnancy. For example, finding low levels of it could identify pregnant women who need iron supplementation before other iron status parameters, like hemoglobin change.¹⁹ Conversely, in this cohort, the two patients with the highest values of hepcidin developed preeclampsia.¹⁹

In support of the notion of the importance of hepcidin is the finding of a negative relationship between this hormone and SOD in the WLRP group, reflecting the increase in hepcidin expression due to the increment in systemic iron, which in turn helps to reduce iron-mediated oxidative stress by increasing SOD activity,¹⁴ causing an increase of LPOx levels, without implying metabolic damage when negatively related to glucose.

In the WHRP group, antioxidant activity was affected by iron, a situation reflected by the positive relationship of hepcidin with SOD, causing greater metabolic damage in the 3rd trimester of pregnancy when presenting an increase in the levels of GPx described before, a positive relationship between cholesterol with GPx and LPOx, as well as glucose levels with triglycerides, coinciding in part with a previously reported relationship between triglycerides and SOD in patients with preeclampsia where it would increase the risk of vascular disorders that trigger endothelial dysfunction, atherosclerosis and thrombosis,¹² so that oxidative stress and insufficiency in antioxidant defense systems could be factors that lead to an increase in lipid peroxidation in metabolic diseases such as preeclampsia and GDM,²² in addition to previously described elevated serum concentrations of ferritin and hepcidin, which lead to insulin resistance due to sensitization of peripheral glucose receptors.²³

A previous study in Mexico evaluated the intake of 60 mg of iron, finding that it caused elevations in hemoglobin, serum ferritin, iron, and LPOx, demonstrating that excessive iron intake during pregnancy could be one of the causes of cellular damage.²⁴ Iron overload has also been evaluated in mouse studies, demonstrating that it can generate a pathology similar to that observed in

T2DM, leading to hyperglycemia, hyperinsulinemia, lipid synthesis induction and insulin resistance, as well as increased production of proinflammatory cytokines, such as interleukin (IL)-6, which induces the hepcidin gene transcription.²⁵

It can be concluded from this study that in both circumstances, High-Risk and Low-Risk pregnancies, an increase in systemic iron levels can occur due to an overload induced by iron supplements without a confirmed diagnosis of anemia. The possibility exists that in women with Low-Risk, despite the fact that the antioxidant enzyme systems are responding to the presence of ROS, they are not totally effective since there is a significant increase in LPOx of the 2nd to the 3rd trimester of pregnancy.

A limitation of this study is the small number of patients. Notwithstanding, a final important message is that hepcidin measurement in pregnancy is important as it is the regulating hormone of iron homeostasis, and may be a useful biomarker to determine the availability of iron in pregnancy and its association with antioxidant systems could establish whether the increase in serum iron is one of the factors that lead to the development of metabolic disorders such as preeclampsia, GDM and dyslipidemia.

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Minimizing the Risk of COVID-19 in Pediatric Dialysis Center in Baghdad/IRAQ

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Abstract

The current Coronavirus Disease-19 pandemic represents a global challenge for citizens, health systems, local, and national governments. Since no previous experience has prepared the scientific and medical community to face such as widespread and rapid clinical emergency, local experiences can be of help in defining management strategies.

In this commentary, we briefly represent our approach to prevent and mitigate the risk of COVID-19 in hemodialysis pediatric patients, that we implemented at our Dialysis center, located in Baghdad, Iraq.

Keywords: COVID-19. SARS-CoV-2. Pandemic.

Introduction

Novel coronavirus disease (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)¹. On 31 December 2019, a cluster of pneumonia of un-known origin was reported in Wuhan City, Hubei Province of the People's Republic of China. On 11 March 2020, the World Health Organization's (WHO) announced that the pathogen known as the Coronavirus Disease 2019 (COVID-19), constituted a pandemic^{1,2}.

According to data released by the World Health Organization, as of 1 July 2020, the COVID-19 has affected 10,321,689 people across 216 countries and territories and 507,435 people have died from the disease³.

The first recorded case of COVID-19 was recorded in Iraq on 24-February, in the city of Najaf⁴. By 13 March, WHO reported that the increase in cases of COVID-19 in the Eastern Mediterranean region, including Iraq². And with the start of the second wave of pandemic, Iraq has reached one of the highest rate of death among Arabic countries³.

The Iraqi government authorities, to help stop transmission, had implemented bans on travelers from countries with significant COVID-19 outbreaks from entering Iraq and ordered to close the schools, universities

, some public spaces like malls, museums, businesses, and plans every day is a critical element in "social distancing," a powerful tool to restrict transmission of this disease. Once the pandemic was established, efforts switched from prevention to mitigation to minimizing the risk for transmission of COVID-19 among individual patients, the community, and health care workers⁴.

All age groups are susceptible to the SARS-CoV-2 infection, while the risk is increased in children because of their respiratory tract characteristics, their immature immune system. The main infectious sources are not only patients infected by SARS-CoV-2 with clinical symptoms but also infected individuals without clinical symptoms as well^{5,6}. Children seem to be less severely affected as compared to adults⁷.

One of the most critical challenges in such pandemic was in a highly specialized field as pediatric nephrologists caring for children with kidney transplants, receiving dialysis, or being treated with immunosuppressive therapy for kidney disease⁸.

In turn, the factors associated with an increased risk for contracting SARS-CoV-2 infection among pediatric chronic dialysis patients, especially those who receive in-center HD, include the following: (a) compromised immune system (the result of long-term malnutrition, uremia, and/or immunosuppressants); (b)

close proximity to other patients during treatment in a confined HD unit; (c) frequent contact with healthcare workers, who may be asymptomatic but infected while caring for a variety of other patients; (d) a need for the presence of parents or other relatives during the treatment, which increases the risk of cluster infection; and (e) non-adherence to, or a break in, implementation of recommended infection prevention practices⁸.

We as pediatric nephrologists, in Al-Zohoor hemodialysis center in the Central Teaching Hospital of Pediatric which is the major pediatric hospital in Al-karkh District in Baghdad, Iraq that provides hemodialysis services for about twenty five children from Baghdad and nearby provinces. It is an in-center dialysis for outpatient children with end stages renal disease, in addition to cases of acute kidney injury of different etiologies. Our patients must come together for three to four hours thrice weekly and may travel to and from these treatments, increasing possible exposure. So we tried to incorporate new safety measures and changes in routine clinical care to prevent infection from a highly contagious and deadly virus.

All the medical staff should follow the hospital, local public health, WHO and CDC recommendations for the use of safety guidelines during their interactions with patients.

Interaction with COVID team in our institution was highly recommended for recognition of suspected cases those may have one of the following epidemiological criteria⁹:

A. A history of travel or residence in areas with a wide spread diffusion of COVID-19 within 14 days prior to the onset of symptoms.

B. Direct contact with SARS-CoV-2-infected individual (positive nucleic acid test) within 14 days before the onset of symptoms.

C. Direct contact with a patient who has symptoms of fever and/or respiratory infection from areas with a wide spread diffusion of COVID-19 within 14 days prior to the onset of symptoms.

D. Cluster onset.

Or those who met these clinical manifestations:

a. Fever and/or respiratory symptoms. b. Pulmonary imaging with signs of COVID-19. c. Laboratory tests suggesting early stage of disease: total white blood cell count normal or decreased with decreased lymphocyte count.

Confirmed case: Suspected case with RT-PCR positive detection of SARS-CoV-2 nucleic acid⁹.

Continuous and effective education about COVID-19 is required for health-care workers and patients. Crucially, the basics of hand and respiratory hygiene as well as coughing etiquette with attention to using terminology that is consistent with their health literacy and avoiding medical jargon. Educated for the medical staff for the use of personal protective equipment (PPE) and should practice putting it on and taking it off correctly. Create backup lists if staff becomes sick.

Group activities, as we are in a teaching hospital for medical students, including group rounds, group studies, and case discussions, were minimized. Minimize face-to-face physician rounding, Distance health care workers during team rounds.

Patients feeling unwell are stimulated to discuss symptoms by phone and not to come to the dialysis unit to discuss, if this happens on a non-dialysis day and followed by phone call.

Patients were advised to use private transportation as much as possible and to reduce the number of patients per vehicle, protecting the patients and society.

One child should be accompanied by only one caregiver. Keeping the same person is recommended. Other accompanying person should remain in the waiting area. All should wear a disposable general medical mask or a surgical mask, hair covers and shoe covers, and follow all the instructions. Fixed shift is also advisable for individual patient to limit contact between different individuals.

During the dialysis, reducing movement in and out of the isolation room is also crucial to minimize contamination and avoiding possible additional equipment contamination. Unnecessary talking or eating is to be avoided during dialysis and in the waiting room. The accesses to dialysis center were locked to reduce the improper transits of unauthorized people. In addition

closure of the waiting room.

Information on travel, occupation, contacts, and history of each dialysis patient, their family members, collected and updated regularly. This is may be one of the hardest things since our societies are deniable in some sort to the nature of the disease itself and its severity despite education and announcement of social media and ministry of health. Except in urgent situations, transferring patients to different other units was avoided as much as possible .

Proper design of HD unit layout with the separation between two HD beds/chairs should be at least 1.5-2 m. Separate rooms with the door closed are used with special rooms used for treatment of patients with hepatitis B and C. All rooms in are fitted with a water tap and drainage infrastructure to facilitate HD at the bedside.

Fixed dialysis machine If possible, one child should use the same dialysis machine at every treatment .

Documentation of dialysis flow sheets is also strictly performed inside the rooms and kept in there.

All of the necessary equipment such as a sufficient number of sinks with soap dispensers, paper towels, hand lotions, and alcohol-based hand rubs placed at each patient station, beside every door and in the waiting room.

Hand Hygiene as recommendations from WHO should be performed: (1, 2) before and after every patient contact, body fluid exposure or risk, touching a patient's immediate environment, and before clean/aseptic procedures. Hand hygiene should be performed using soap and water when hands are visibly soiled with contaminants, and if not, using alcohol-based hand rub sanitizer for 20–30 s. It should also be performed even when wearing gloves for procedures. Hand hygiene is the most critical infection prevention measure.¹⁰

Upon discharge of the patient, the dialysis machines are thoroughly wiped down with 70% ethyl alcohol wipes before use for the next patient. Disinfection measures should be performed between each shift of dialysis and after all patient treatments for all the items and floor after dialysis. Also we used a 500- mg/L chlorine-containing disinfectant should be utilized to thoroughly wipe and disinfect the dialysis machine, first disinfecting

the clean surface and then the contaminating surface for more than 30 min. If any surface is contaminated by blood or any other secretions, a 2000-mg/L chlorine containing disinfectant should be used for more than 30 min. 1%povidone-iodine and hydrogen peroxide were also be used^{11,12}.

We make a local decision to change filters more than the recommended 72 h. All disposable equipment and consumables should be carefully discarded as per the local hospital policy or CDC recommendations. Equipment disinfection is essential to prevent potential iatrogenic COVID-19 transmission.

Fortunately, with these strategies to decrease infection, we had only3 suspected cases of COVID-19 in our center from the start of the pandemic till the 15th of August 2020. All of them had negative PCR detection of SARS-CoV-2 nucleic acid.

Conclusion

Situation due to the COVID-19 pandemic is unprecedented. Despite limited resources and query pandemic, we can mitigate risk of COVID-19. In order to protect your patients, you need to install plans in advance, to discuss with other stakeholders, with nursing staff, and perhaps most importantly, involve the patients and their families.

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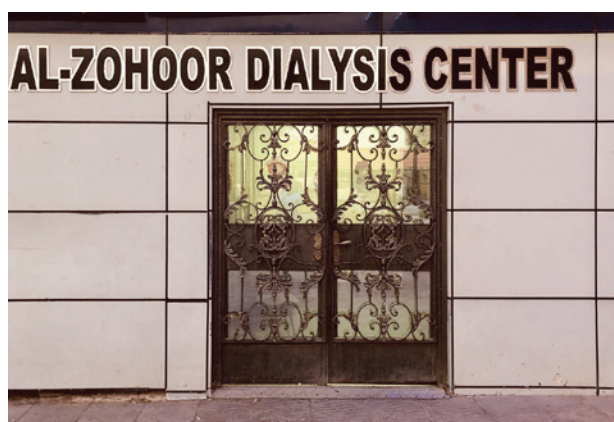




Fig 1-3: photos from Al-Zohoor pediatric dialysis center in Baghdad/IRAQ

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Ethical Clearance: All the strategies that we had followed were approved by the administration of our hospital and were carried out in accordance with the WHO and the CDC guidelines.

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The Covid-19 Outbreak in Algeria: What is the university Youth Help in Fighting the Epidemic?

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Abstract

The purpose of this short study is to discover the helping behavior among Algerian students during the confinement of the coronavirus epidemic in Algeria. Data was collected using a questionnaire submitted to 592 people in different regions of Algeria from June 21st, 2020, to determine the helping behavior of the Algerian people towards the negative consequences of the COVID-19 pandemic.

The results of the present study show the contribution of young students to provide significant participation to cope with the effects of confinement due to the coronavirus in Algeria through activities to raise awareness of the dangers of the coronavirus, support for families and health managers and the distribution of means of protection.

The need to establish volunteer work for youth, especially in times of crisis, is compulsory as society is in great need of them.

Keywords: help behavior; confinement, COVID-19, epidemic, student.

Introduction

The COVID-19 pandemic was having many negative effects in all areas of daily life around the world. This has forced governments to think about how to mitigate the impact of this epidemic to protect citizens, especially in the context of home confinement, which has defeated psychological and social pressures, but also economic and health needs, threatening the balance of psychosocial health.

The COVID-19 pandemic has left many damages, especially from the interactive psycho-social aspect, so the Turkish study has shown that that 64.1% of the total

participants experienced physical and mental fatigue¹. Moreover, the results show that the incidence of anxiety was 25% (95% CI: 0.19–0.32) and the incidence of depression was 28% (95% CI: 0.17–0.38)². Also, the mental health of Spanish people during the COVID-19 which was marked by the use of anxiolytics was significantly associated with higher emotional distress among the elderly compared to the younger generation³.

According to social cognitive theory, helping behavior is similar to any other behavior affected by individual perceptions, and in this context the results of his study⁴.

The results of the qualitative study which was conducted on a sample of 150 students in Dhaka, and Bangladesh showed that social behavior skills and helping behavior and cooperation contribute to academic achievement⁵.

At the organizational level, managers need to be sufficiently aware of the need for help behavior and how to motivate employees with this behaviour based

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on accurate knowledge of the characteristics of workers who can ask them for help⁶.

Helping behavior is linked to the number of social behavior assessments, where individuals receive comparisons about their social behavior in the form of reactions, the latter helps them choose to help or refrain from helping others⁷.

It is clear from the above that the behavior of aid intersects with different human activities at the level of certain sectors, including school and employment, and it is strongly influenced by the lack and quantity of social skills and the desire to assist others.

Helping behavior must be urgently needed in times of crisis, such as what the world is experiencing today with the Covid-19 pandemic, especially by young academics who have the active and driving force in social life. Therefore, the present study aims at analyzing the helping behaviors among young academics in Algeria during the period of home confinement.

Matetials and Methods

A field survey was planned to discover the helping behaviors among Algerian university students during the period of home confinement due to the COVID-19 pandemic; therefore, we adopted a widely distributed online questionnaire. The sampling strategy is based on the snowball method, and this sampling made it possible to obtain a total of 592 respondents living during the confinement of the coronavirus epidemic (COVID-19) in Algeria. The study sample consists of 55.7% women and 44.3% men, and the age of the sample ranged between 18 and 25 years, that is, the youth stage.

The current questionnaire is composed of nine items built from a review of the theoretical literature and was designed online to facilitate its rapid dissemination to have immediate answers during the period of home confinement. The questionnaire was designed based on Likert scale. The coefficient of reliability Alpha Cronbach was calculated (0.657), This result indicates reliability in the results of the questionnaire. The data were processed using software (SPSS 22) with descriptive statistics (frequency, percentage, mean and standard deviation, and relative weight).

Results

Table 1. Descriptive statistics of helping behavior among Algerian students (COVID-19) during the epidemic COVID-19 in Algeria (n = 592).

Items	N= 592			Mean	Relative weight	Range
		n	%			
I participated in the solidarity of families during the Coronavirus	StronglyDisagree	15	2,5	3,72	74,40	07
	Disagree	42	7,1			
	Neutral	171	28,9			
	Agree	230	38,9			
	StronglyAgree	134	22,6			
I contributed to solidarity with health workers during the period of the Corona epidemic	StronglyDisagree	12	2,0	4,11	82,20	02
	Disagree	5	,8			
	Neutral	81	13,7			
	Agree	302	51,0			
	StronglyAgree	192	32,4			

Cont... Table 1. Descriptive statistics of helping behavior among Algerian students (COVID-19) during the epidemic COVID-19 in Algeria (n = 592).

I contributed to the solidarity of the families victims of the coronavirus epidemic	StronglyDisagree	15	2,5	4,03	80,60	03
	Disagree	27	4,6			
	Neutral	77	13,0			
	Agree	281	47,5			
	StronglyAgree	192	32,4			
I contributed to the distribution of means of protection of coronavirus	StronglyDisagree	15	2,5	3,90	78,00	05
	Disagree	25	4,2			
	Neutral	134	22,6			
	Agree	246	41,6			
	StronglyAgree	172	29,1			
	Disagree	125	21,1			
	Neutral	261	44,1			
	Agree	99	16,7			
	StronglyAgree	51	8,6			
I have helped students with tips for further distance learning via social media	StronglyDisagree	5	,8	4,34	86,80	01
	Disagree	16	2,7			
	Neutral	48	8,1			
	Agree	229	38,7			
	StronglyAgree	294	49,7			
I helped young people to understand the dangers of coronavirus	StronglyDisagree	00	00	3,64	72,80	08
	Disagree	77	13,0			
	Neutral	154	26,0			
	Agree	268	45,3			
	StronglyAgree	93	15,7			

Cont... Table 1. Descriptive statistics of helping behavior among Algerian students (COVID-19) during the epidemic COVID-19 in Algeria (n = 592).

I helped my family members during home confinement	StronglyDisagree	5	,8	3,76	75,20	06
	Disagree	87	14,7			
	Neutral	90	15,2			
	Agree	273	46,1			
	StronglyAgree	137	23,1			
I contributed to national efforts to fight coronavirus by adhering to the confinement instructions	StronglyDisagree	27	4,6	3,97	79,40	04
	Disagree	21	3,5			
	Neutral	76	12,8			
	Agree	286	48,3			
	StronglyAgree	182	30,7			
I have helped families to get their daily needs during the period of home confinement	StronglyDisagree	25	4,2	3,58	71,60	09
	Disagree	97	16,4			
	Neutral	46	7,8			
	Agree	355	60,0			
	StronglyAgree	69	11,7			

Source: Authors using SPSS version 22.0

The findings in the table show that young students are primarily targeted at encouraging students at all ages to master distance learning techniques (M = 4.34), with the use of blogs, social networks, and other digital media.

Secondly, university students helped health executives (M = 4.11), including doctors, nurses and all health specialists, as they felt they had a great role in the fight against Covid-19, where the support was often morally thanks to social networks and various tools to boost the morale of health professionals.

Third, young students seek to support families who had lost one of their members due to the coronavirus (M = 4.03), and above all with the social stigma towards families affected by COVID-19.

Fourthly, young students were aware that the greatest support for young people was to sensitize them to

strictly respect the home confinement (M = 3.97), so that the coronavirus does not spread widely to compromise stability and the efficiency of the health sector.

Fifthly, young scientists have worked actively to help prevent the spread of coronavirus (M = 3.90), in particular by distributing masks and sterile goods, and by arranging social gatherings in public places such as post offices.

Sixthly, the support activity for young academics is concentrated in the family setting (M = 3.76), by raising awareness of the need to respect preventive measures for home confinement. Also, try to solve the problems that result from social interactions within the family.

Seventh, young academics also participated in solidarity aimed at low-income families (M = 3.72) through the distribution of food products and the various

needs of daily life, which enabled families to make a considerable effort to accept home confinement.

Eighth, the supportive behavior of young universities focuses on making young people aware ($M = 3.64$) of the seriousness of the coronavirus and the importance of respecting preventive measures, in particular by respecting social distances, by wearing masks and avoiding social gatherings and collective interactions.

In the ninth place, young university students help families who are struggling to meet their daily needs ($M = 3.58$), such as the elderly and the disabled, who live in isolated areas of the city.

Discussion

The present study has shown that young academics in Algeria are an important part of the strategy to combat epidemic coronavirus by:

-Help and support students so that they become attentive and focus on distance education to maintain the continuity of the learning and teaching process.

-Educate people to be aware of the need to comply with the instructions for confinement at home and with all preventive measures, in particular about wearing masks and social isolation⁸. Certainly, with the use of social networks for this purpose, especially since young people often use them.

-Participate in solidarity actions towards medical personnel or families.

-Participate in solidarity actions towards medical personnel or families affected to preserve the stability and social cohesion that help to breathe well into the coronavirus, since COVID-19 has short and long term impact on societies, health systems, workplaces and workers in many professions who are at high risk of becoming infected⁹.

Helping behavior is linked to social behavior assessments, where individuals receive comparisons about their social behavior in the form of reactions, the latter of which helps them choose to help or refrain from helping others⁷. Thus, individual behavior will be crucial in controlling the spread of COVID-19. Knowing how to maintain early self-isolation, consult a doctor remotely, the measures taken to prohibit mass gatherings are

important, as the presence of good diagnostic facilities and health advice accessible remotely can play an important role. In addition to this, using communication actions to keep the public informed about the best way to avoid infection is essential, as it is an additional support to manage the economic downturn¹⁰.

Conclusion

When the society suffers from serious crises, such as what it is experiencing today with the COVID-19 pandemic, the state must join the efforts of society as a whole, in particular young academics who become involved in a global strategy to fight against the coronavirus in Algeria through awareness and solidarity activities in various fields and with all categories of society, and this required the state to help and supervise these efforts to deal with crises and to strengthen social vigilance.

Funding: This research received no external funding.

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Ethical Clearance: not applicable, participants were invited to participate in the online survey, they had the choice of answering or not. The introduction of questionnaire informed that this is part of academic research and all responses were anonymous.

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Gravity Index of the COVID-19 pandemic in the first deconfinement phase in Algeria

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Abstract

This article aims to discover the risk index of the spread of coronavirus COVID-19 in Algeria, in particular with the procedures of partial deconfinement and its consequences which can be dangerous. Therefore, it is necessary to focus on objective statistical index to allow building effective knowledge and practices in the post-Coronavirus phase with more caution and prevention.

By using this index, countries can know the ideal moment to go towards deconfinement.

Keywords : gravity Index, COVID-19 pandemic, deconfinement.

Introduction

The World Health Organization (WHO) has reported 3 175 207 people infected and 224 172 deaths worldwide on May 1st, 2020, by COVID-19¹. The virus spreads quickly by respiratory droplets and also with direct contact, due to its nature and the difficulties in identifying the people affected to take care of them. So, this epidemic has a short and long-term impact on societies, health systems, workplaces and individuals^{2,3,4}. To avoid these effects, containment measures applied in Wuhan to ensure preventive social distancing and avoid displacement at the start of the epidemic in the affected area have enabled China to control the spread of the coronavirus in 2 months^{5,6,7}. On this basis, confinement should remain a priority for the moment in the affected countries since the short-term cost of containment is lower than the long-term cost of non-containment, especially since the number reached (COVID-19) doubles in 6.4 days.^{8,9}. Thus, the risk of

the spread of COVID-19 is significant and varies from one country to another. Algeria which applied total and partial containment on March 23, 2020¹⁰, recorded 4,154 people infected and 453 deaths because of this virus as of May 1, 2020,¹¹.

Many countries, including Algeria are thinking of deconfinement to revive their economy and return to normal life. This pandemic has caused significant damage to the economy as in the case of China, which recorded a fall of 13.5% in its industrial production during confinement¹². However, the risk of deconfinement on the population must be measured to better manage the post-COVID-19 phase. This study aims to determinate the statistical indices over two different periods, one from April 6th to 23rd, 2020 during containment, and the other from April 24th to May 3rd, 2020, during partial deconfinement. For the sake of monitoring the risk of spread of the pandemic during the application of partial deconfinement measures in Algeria, and allowing health authorities to better measure the risks and plan for deconfinement.

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Statistics on the evolution of the epidemic situation (COVID-19) in Algeria.

Table 1. Infected, deaths and cured patients during the (COVID-19) pandemic in Algeria (April 06 to May 03, 2020)

Date	New infected	Deaths	Cured patients
06-avr	103	21	90
07-avr	45	20	113
08-avr	104	12	237
09-avr	94	30	110
10-avr	95	21	58
11-avr	64	19	55
12-avr	89	18	131
13-avr	69	18	10
14-avr	87	13	91
15-avr	90	10	17
16-avr	108	12	75
17-avr	150	16	111
18-avr	116	3	53
19-avr	95	8	153
20-avr	89	9	52
21-avr	93	8	53
22-avr	99	10	52
23-avr	97	5	151
24-avr	120	8	53
25-avr	129	4	71
26-avr	126	6	29
27-avr	135	7	50
28-avr	132	5	93
29-avr	199	7	51
30-avr	158	6	51
01-mai	148	3	42
02-mai	141	6	51
03-mai	179	4	64
Total	3154	309	2167

Source: the authors` based on the data (MSPRH, 2020)

Table 1 shows the statistical evolution of the Coronavirus epidemic through the number of infected, deaths and cured cases, because these data are important to build a preliminary vision around the pandemic.

The number of healing cases was high at the beginning before entering a decreasing process, for this is the proof of the activity of the virus during this phase. As

the number of newly infected cases increases irregularly, this may be linked to a lack of rigorous commitment by the citizens to house confinement. The number of deaths has decreased during this period, which may indicate the effectiveness of the chloroquine treatment protocol used by Algeria in hospitals at the start of the epidemic.

The number of deaths by age variable from the start of the epidemic to May 2, 2020.

Table 2. Distribution of coronavirus deaths by age variable since the start of the first injury in Algeria.

	Less than 1 year	5-14 years old	15-23 Years old	24-44 years old	45-59 years old	Over 60 years old	Total
Number of deaths	0	1	1	37	75	344	459
Percentage	0	0,33 %	0,33 %	08,06 %	16,34 %	74,94 %	100 %

Source: the authors` based on the data (MSPRH, 2020)

According to Table 2, we note that 74.94% of deaths are over 60 years old and that 16.34% of deaths are between 45 and 59 years old.

This means that the elderly were the most affected by COVID-19 in Algeria, because of their fragile state of health. This situation requires serious care for the elderly during home confinement.

Coronavirus Gravity Index (COVID-19) (CGI)

CGI inf : this means the gravity index of infections of coronavirus, and it is calculated by dividing the number of deaths (ND) by the total number of infected (NI).

$$CGI_{inf} = \frac{ND}{NI}$$

With the percentage we find the following relation:

$$CGI_{inf} = \frac{ND}{NI} \times 100$$

When the mortality index is high, the higher the risk of COVID-19, as long as the value of the indicator is

away from zero, and this indicates a danger.

CGI cur: this means the index of cured cases of the coronavirus, which is calculated by dividing the number of cured patients (NCP) by the total number of infected (NI).

$$CGI_{cur} = \frac{NCP}{NI}$$

With the percentage, we find the following relation:

$$CGI_{cur} = \frac{NCP}{NI} \times 100$$

Thus, when the index of cured cases of the coronavirus is greater than 50% and close to 100%, this indicates control of the epidemic and its severity. So, it is very important to follow the evolution of the coronavirus through its severity indicators, in order to take the appropriate health measures at the right time and avoid the upsurge in the epidemic.

Table 3. Calculate the index of gravity coronavirus in Algeria in the period April 6 - May 03, 2020.

	From 06 until April 23rd, 2020			From 24 until May 03rd, 2020		
	New infected NI	Deaths ND	Cured patients NCP	New infected NI	Deaths ND	Cured patients NCP
	1687	253	1612	1476	56	555
CGI_{inf}	14,99%			03,79%		
CGI_{inf total}	09,76%					
CGI_{cur}	95,55%			37,60%		
CGI_{cur total}	68,51%					

Source: the authors` based on the data (MSPRH, 2020)

Table 3 shows the following results of the indices of the severity of the development of (COVID-19) in Algeria:

The index of death obtained during the first phase before the lifting of the home confinement went from (14.99%) to (3.79%) in the second phase after the start of partial deconfinement from April 24th, 2020, while the total percentage of the complete period is estimated (9.76%). This result can be explained by the effectiveness of the chloroquine therapeutic protocol in reducing the number of deaths, knowing that Algeria was one of the first implementing this treatment protocol. Otherwise, the statistics presented in table 3 indicate a considerable drop in the index of cured cases from (95.55%) to (37.60%) in the second phase of partial deconfinement. This result reveals the great increase of the infected with (COVID-19). Admittedly, the lack of monitoring of preventive measures is reflected in social behavior, direct contact and the neglect of wearing a mask. This will certainly lead to the spread of the pandemic.

Conclusion

It is necessary to take the maximum precautions when lifting the partial containment, which must be

progressive and considered with the imposition of preventive measures, such as the wearing of masks, and social distancing in all public places.

So we recommend the following:

-Monitoring the evolution of the epidemic through objective statistical indices is linked to its severity.

-Partial deconfinement with strict preventive measures, the establishment of an epidemiological surveillance system and an effective screening process.

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Conflicts of Interest: The authors declare no conflict of interest.

Ethical clearance: not applicable.

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Validity and Reliability of Indonesian Languages Version of Zung Anxiety Self-Assessment Scale Questionnaire for Pulmonary Tuberculosis Patients

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Abstract

Background: Patients with chronic disease, including tuberculosis, often get anxiety in their daily life. Valid and reliable instrument needed to detect anxiety in Tuberculosis patients in Indonesia. Therefore, Zung Anxiety Self-Assessment Scale questionnaire in the Indonesian language version should be validated and proved as a reliable instrument.

Objective: The purpose of this research is to validate and to get the scientific evidence of reliability on Indonesian language version of Zung Anxiety Self-Assessment Scale questionnaire.

Methods: The design of this study is cross sectional. Zung Anxiety Self-Assessment Scale questionnaires that have been translated to Indonesian language are given and filled by 129 pulmonary tuberculosis patients. We used Corrected Item-Total Correlation table for validity test and Cronbach's Alpha value for reliability test.

Results: Almost all of the questions (19 questions) are valid because Corrected Item-Total Correlation values for all the questions are more than r table ($>0,174$). One question, question number 17, is not valid and was deleted because had negative r value. The questionnaire is also reliable with r Alpha value (Cronbach's Alpha) 0,892.

Conclusion: Indonesian language version of Zung Anxiety Self-Assessment Scale questionnaires is a valid and reliable instrument to be used for detecting anxiety in adult pulmonary tuberculosis patients.

Keywords : *Validity, Reliability, Anxiety, Pulmonary Tuberculosis.*

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Introduction

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium Tuberculosis* which most often attacks the lungs. This disease can be treated and can be prevented.¹ Furthermore, Tuberculosis is also a contagious lung infection which is still a health problem in the world, especially in developing countries.²

According to World Health Organization (WHO), TB is a disease that occurs throughout the world. In 2018, TB cases were most prevalent in Southeast Asia with 44% new cases, followed by African countries with 24% new cases and West Pacific 18%. 87% of new TB cases occur in 30 countries with high number of TB cases. Eight countries accounted for two-thirds of new TB cases including India, China, Indonesia, the Philippines, Pakistan, Nigeria, Bangladesh and South Africa.¹ In Indonesia, the number of new cases was 420,994 cases in 2017.³ The number of deaths due to TB has reached 1,8 million in 2018.¹

Besides that, MDR TB cases from year to year are estimated to continue to increase. Multidrug-resistant tuberculosis (MDR-TB) caused by bacteria that are not responsive to isoniazid and rifampicin, the two most powerful first-line anti-TB drugs. In 2018, MDR-TB remains a public health crisis. WHO estimates that there are 484,000 new cases with resistance to rifampicin - the most effective first-line drugs - 78% of them have MDR-TB. Multi Drug Resistant (MDR-TB) is the biggest problem in the prevention and eradication of TB worldwide. Indonesia is ranked 8th out of 27 countries with the most MDR-TB in the world.⁶

Walker, et al. mentioned the high prevalence of mental disorders among individuals diagnosed with physical illness. This is related to worse mortality and morbidity, medication adherence, health care and quality of life.⁴ Anxiety is one aspect that affects quality of life. Quality of life according to WHO is a person's perception in the context of culture and norms in accordance with the person's place of life related to goals, expectations, standards and care throughout his life.⁵ Some social problems that are often the main concern of MDR-TB patients include: social stigma and discrimination; fear and guilt associated with serious risk infections, socio-economic and psychological burdens due to suffering from chronic life-threatening illnesses, increased dependence on others, some treatment failures and being told at health centers that there are no more therapies available, loss of family members and poverty.⁷

Research in the United Kingdom found that there are 30-34% of TB patients with mental disorders. Research in New York noted that there are 20-50% of TB patients who do not comply with medication because

they have psychological problems. Whereas the research by Tuahta (2006-2007) in TB patients showed that the majority of psychiatric disorders were depression by 58.3%, dystymia by 8.3% and general anxiety disorders by 8.3%.⁸

A valid and reliable instrument is needed to detect anxiety in TB patients in Indonesia. Thus, the language used in questionnaire should be in accordance with Indonesian culture and mother tongue, that it can be better understood. Therefore, the Zung Anxiety Self-Assessment Scale questionnaire should be translated into Indonesian language and the Indonesian language version must be validated and proved as a reliable instrument.⁹

Materials and Methods

This study was approved by Pelita Harapan University Ethical Committee. The design of this study is cross sectional by giving . Zung Anxiety Self-Assessment Scale questionnaires that have been translated to Indonesian language to pulmonary tuberculosis patients. Zung Anxiety Self-Assessment Scale questionnaires was translated from original English version to Indonesian language version by one psychiatrist and one clinical psychologist. After being translated from English version, the Indonesian language version was reviewed by one medical doctor with master degree of psychology. The Indonesian language version that has been reviewed then was given to Cultural and Science Faculty of Universitas Indonesia (Lembaga Bahasa Internasional Fakultas Ilmu Pengetahuan Budaya Universitas Indonesia) to be back translated to English version. The result from back translate process was reviewed once again and compared with the original English version to make sure that the back translate version has the same meaning as the original English version. After the reviewer stated that the back translate version has the same meaning as the original English version, the Indonesian language version was given to the pulmonary tuberculosis patients to be tested for validity and reliability.

Participants included in the validity and reliability test for the Indonesian language version of Zung Anxiety Self-Assessment Scale questionnaires were 129 patients with pulmonary tuberculosis that were treated as outpatient in Siloam General Hospitals Lippo Karawaci,

Puskesmas Kutai and Puskesmas Curug from March to April 2018. The sampling method used was consecutive sampling. Every patient came to the outpatient department was included until we got 129 patients. Informed consents were given and Indonesian version of Zung Anxiety Self-Assessment Scale questionnaires were filled by patients that have agreed to be participated in this study after they were explained about how to fill the questionnaire.

Inclusion criteria for the patients included in this study are 17 – 66 years old male or female patients with lung tuberculosis who stay in Tangerang and are receiving Tuberculosis drugs regiment therapy. Exclusion criteria in this study are male or female patients who did not agree to participate in this study, and also pregnant female patients. Other data collected from the patients were gender, age, weight, height,

educational status, and marital status. All data collected by interviewing the patients.

The data were then analyzed using Statistical Package for the Social Sciences (SPSS) version 23. Numeric variable of characteristics of the population were presented as mean and standard deviation, meanwhile categoric variable of characteristics of the population were presented as percentage. Validity test was done to assess the construct validation. Each question will be declared as a valid question if the corrected item-total correlation value is higher than r table value, so that the validity test result was presented as Corrected Item-Total Correlation table. For reliability test, the internal consistency was evaluated using Cronbach’s Alpha value. The internal consistency will be considered as internally consistent if the Cronbach’s Alpha value is 0.7 or higher, so that the result was presented as Cronbach’s Alpha value.^{10,11}

Results

A. Characteristics of Population

Table 1. Characteristics of The Patients.

		Mean + Standard Deviation (years)
Age		47.73 + 8.50
		Number of patients (%)
Sex	Male	89 (69)
	Female	40 (31)
Marital Status	Single	8 (6,2)
	Married	121 (93,8)
	Widower	0 (0)
Education	Elementary School	62 (48,1)
	Junior High School	24 (18,6)
	Senior High School	22 (17,1)
	Diploma	10 (7,8)
	Bachelor	11 (8,5)

From Table.1, we can see that the average age of the population in this research is 47.73 ± 8.50 years old. Almost all have married (93,8%). Most of them are male pulmonary tuberculosis patients (69%), and only graduated from elementary school (48,1%).

B. Validity Test Result in Patients with Pulmonary Tuberculosis

Table 2. Corrected Item-Total Correlation of Each Questions in Patients with Pulmonary Tuberculosis

	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
P1	.702	.868
P2	.665	.868
P3	.594	.871
P4	.691	.867
P5	.397	.876
P6	.437	.875
P7	.590	.870
P8	.650	.869
P9	.569	.871
P10	.703	.867
P11	.646	.868
P12	.508	.873
P13	.445	.875
P14	.187	.883
P15	.440	.875
P16	.320	.879
P17	-.071	.892
P18	.540	.872
P19	.465	.874
P20	.376	.877

Validity test was done with significance level $\alpha=5\%$. From r table we can find that r table value with significance level (alpha) 5% and degrees of freedom (df) 127 (n-2) is 0,174. Table 2 second column shows the Corrected Item-Total Correlation values for every question. We can see that almost all Corrected Item-

Total Correlation values are more than 0,174 except question number 17 (P17). The Cronbach's Alpha is 0,879. Question number 17 has negative Corrected Item-Total Correlation values and the Cronbach's Alpha if Item Deleted highly increased from 0,879 to 0,892. We should delete question number 17. We can see the result after we delete question number 17 in table 3 below.

Table 3. Corrected Item-Total Correlation of Each Questions in Patients with Pulmonary Tuberculosis

	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
P1	.666	.883
P2	.651	.883
P3	.579	.885
P4	.694	.881
P5	.388	.891
P6	.457	.889
P7	.620	.883
P8	.634	.883
P9	.574	.885
P10	.701	.881
P11	.639	.883
P12	.502	.887
P13	.461	.889
P14	.227	.895
P15	.443	.889
P16	.344	.892
P18	.548	.886
P19	.457	.889
P20	.378	.891

We can see in table 3 that almost all Corrected Item-Total Correlation values are more than 0,174.

C. Reliability Test Result in Patients with Pulmonary Tuberculosis

Table 3. Cronbach Alpha Value in Patients with Pulmonary Tuberculosis

Cronbach's Alpha	N of Items
.892	19

Table 2 shows the r Alpha value (Cronbach's Alpha) is 0,892. This value is higher than 0.7 (>0.7).

Discussion

Tuberculosis is still a global health problem, including in Indonesia. The high prevalence of TB in Indonesia, causing some TB patients easily experience anxiety. Anxiety is one of the psychological responses that the patient feels in dealing with his illness.¹² Anxiety in TB patients is related to a feeling of excessive worry about the disease. Patients diagnosed with TB will experience anxiety and fear in themselves which can include fear of treatment, death, side effects of drugs, transmitting the disease to others, losing their jobs, being rejected and discriminated.¹³

Anxiety in these TB patients should be diagnosed as early as possible. Zung Self-Rating Anxiety Scale questionnaire is one of the questionnaires that can be used to detect anxiety in TB patients, but this questionnaire is only available in English. Thus, the language used in questionnaire should be in accordance with Indonesian culture and mother tongue, that it can be better understood.¹⁴ so this questionnaire cannot be used for them. Therefore, the Zung Self-Rating Anxiety Scale questionnaire must be translated into Indonesian and also be assessed for its validity and reliability so this questionnaire can be used by the wider community. The validity and reliability test of the Zung Self-Rating Anxiety Scale questionnaire was obtained by testing this translated questionnaire for 100 pulmonary TB patients.

Based on the results of this study, it can be seen that the average age of patients is 47.73 ± 8.50 years. This is consistent with data from the Ministry of Health which states the prevalence of pulmonary TB patients is above the age of 15 years.¹ This is also in line with the study of Hendrawati et al in 2018 which states there is a relationship between age and anxiety levels. This happens because of lack of attention from their closest people. Age is one of the internal factors that contribute

to the emergence of anxiety in the elderly.¹⁶

Based on data from this study, 121 patients (93.8%) were married and only 6.2% were single. Other studies indicate that 61% of patients with TB are married people.¹⁷ Research conducted in Surabaya showed 66.67% of patients with pulmonary TB were married.¹⁸ This showed that most pulmonary TB patients were married.

This study also showed that 89 patients were male. Data from WHO in 2018 states that men have a three times greater risk of becoming infected with pulmonary TB compared to women.¹⁵ This is in line with research by Sartika et al. that showed the majority of patients with pulmonary TB were 40 people (53.3%) male sex and 35 women (46.7%).¹⁵ However, it was different from Hendrawati, et al who mentioned that TB patients who experience anxiety are mostly women.¹⁶ Women tend to be more prone to anxiety than men. This is because women are more sensitive to problems, so women's coping mechanisms are less good than men.¹⁵

Many of the TB patients are elementary school graduates (48.1%), 24% are junior high school graduates, 22% are high school graduates, 11% are Diploma, and as much as 8.5% are undergraduate. Other studies have shown that low levels of education are a risk factor for pulmonary TB. According to research from Priyatin (2007), there is a strong and significant relationship between education and anxiety. The higher a person's level of education, the less they experience severe anxiety because the more knowledge they have. Otherwise, lack of education will hamper the development of one's attitude towards newly introduced values to deal with a problem.¹⁰

The total correlation value for each question in this study was more than 0.174 except question number 17. And the R Alpha value for the Zung Self-Rating Anxiety Scale questionnaire was 0.879. For question number 17, because the correlation value is less than 0.174, then it must be removed from the question column, and must be repeated for the correlation test. After question number 17 was deleted, the total correlation value on all questions in this study was more than 0.174. This means that the Zung Self-Rating Anxiety Scale questionnaire has good reliability and can be used generally by the wider community.

The limitation of this research are 1) in this research the translated Zung Self-Rating Anxiety Scale questionnaire only tested in 100 pulmonary tuberculosis patients, so that the adequacy of the sample can be ranked as poor, 2) there was a possibility that the unhealthy patients were too lazy to answer the questions seriously too weak to concentrate, although this possibility had been reduced by giving them informed consent and slowly detailed explanation about how to fill the questions before they started to fill the questionnaire, 3) the questionnaires were given to the patients and filled in the busy and noisy outpatient departments that can distract patient's concentration in understanding the real meaning of the questions.

Conclusion

The translated Indonesian version Zung Anxiety Self-Assessment Scale questionnaires is a valid and reliable instrument to detect anxiety in adult pulmonary TB patients with different educational status.

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Study the C/T Single Nucleotide Polymorphism at Tyrosine Kinase Domain of Insulin Receptor Gene in Patients with Polycystic Ovary Syndrome in Babylon Province

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Abstract

Polycystic ovary syndrome (PCOS) is the commonest gynecological endocrinopathy, is characterized by chronic anovulation and hyperandrogenism and is also associated with increase insulin secretion and metabolic disease and insulin resistance. Present study aims to examine the association between the single nucleotide polymorphism (rs1799817) of exon 17 of the insulin receptor (INSR) gene and polycystic ovary syndrome (PCOS) in a Babylon women. Fifty women with PCOS and fifty healthy Iraqi women, age and BMI matching were achieved between study groups. Biochemical parameters that estimated were fasting glucose, fasting insulin, luteinizing hormone, testosterone. His 1058 C/T polymorphism at the tyrosine kinase domain in the INSR gene was analyzed by restriction fragment length polymorphism (RFLP-PCR). Significant increase in the levels of fasting glucose fasting insulin, HOMA-IR, LH, testosterone were noticed in patient when compared with control. TT genotype frequency was higher in PCOS patients whereas CC genotype was higher in control women. All parameters that estimate in this study were higher in TT genotype of patient group. In conclusion there are an association of C/T polymorphism at His1058 of INSR in patients women with PCOS in Babylon Province. Insulin resistance in PCOS patients might differ from these that result from obesity.

Keywords: *Polycystic ovary syndrome, insulin resistance, insulin receptor, tyrosine kinase domain, His 1058 C/T.*

Introduction

The present concept of polycystic ovary syndrome (PCOS) is a disorder that has ovarian dysfunction and endocrine issues and is also associated with increase insulin secretion (hyperinsulinaemia) and metabolic disease⁽¹⁾. PCOS was noted for first time by Stein and Leventhal in modern medical literature in 1935, they described seven women have amenorrhea, hirsutism, and magnify ovaries with multiple cysts⁽²⁾.

PCOS is a very prevalent and complicated endocrine disease of females⁽³⁾, affecting 4-18% of females of reproductive age, based on the diagnostic criteria used

⁽⁴⁾. PCOS is the most common cause of oligoanovulatory infertility which is characterized by insulin resistance (IR), while hyperinsulinemia is observed in 50–70 % of women diagnosed with PCOS⁽³⁾. The cause of polycystic ovary syndrome remains unknown, although, like most complex heterogeneous diseases⁽⁵⁾.

The pathophysiology is complicated and is thought to be a yield from interactions between genetics, epigenetics, ovarian dysfunction, endocrine, neuroendocrine and metabolic alterations, amongst other changes⁽⁶⁾. IR is a hallmark of the classic and the ovulatory phenotypes of PCOS⁽⁷⁾. IR can be present in 60%-80% of all females with PCOS and present in 95% of obese female with PCOS, IR is not the only metabolic disorder present in PCOS patients; there is also an high rate of impaired glucose tolerance, gestational diabetes (GDM), as well as T2DM⁽⁸⁾. Insulin resistance may result from any functional and structural defects in

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insulin receptor might impair the biological response to insulin, The human insulin receptor INSR gene is found on short arm of chromosome 19 (19p13.2) . Its long about 120,000 bp, composed of 22 exons and 21 introns. It plays an important role in insulin metabolism⁽⁹⁾. The INSR gene has several genetic polymorphisms and was recognized to be associated with PCOS and insulin resistance (IR)⁽¹⁰⁾. One of these polymorphism is single nucleotide polymorphism at (rs1799817) His1058⁽¹¹⁾, which encodes the partial tyrosine kinase domain containing the ATP binding site of INSR⁽¹²⁾.

Materials and Methods

Current study is case control study includes 100 females, which were divided into two groups, the 50 females with PCOS and 50 apparently healthy females, the age was ranged between (17 - 35) years. Assessment of obesity status of all female was done by the body mass index (BMI), [BMI= weight (kg) / height (m)²] and select just normal weight and overweight(BMI < 30)⁽¹³⁾.

Four ml of venous blood were drawn from all participants at second day of menstrual cycle by using disposable syringe. All participants were fasting during the time of blood samples collection.

The blood specimen was divided into two tubes (2 ml blood in EDTA tube for genetic study and 2ml blood in gel tube). The latter two ml of blood were centrifuged at 2000 rpm for 15 minutes, then the serum are divided into two parts in labeled Eppendorf tube and given serial number with patient's name then stored at -20 °C.⁽¹⁴⁾

Fasting serum glucose was analyzed by spectrophotometer. Fasting serum insulin, LH, testosterone were analyzed by enzyme linked immunosorbent assay kit (ELISA kit). Insulin resistance was calculate by homeostasis model assessment insulin sensitivity index (HOMA) as fasting insulin x fasting glucose /405

Genetic Analysis

Genomic DNA extracted from whole blood sample were collected in EDTA tube, its extracted by using gene extraction kit supplied by intron biotechnology company (Korea). Exon 17 was amplified using the following primers for forward and reverse respectively: 5-CCAAGGATGCTGTGTAGATAAG-3 and 5-TCAGGAAAGCCAGCCCATGTC-3 according to Siegel *et al.*⁽¹¹⁾. A total volume of 50 µl containing genomic DNA 10 µl was used as template in the reaction mixture, 6 µl of each primer and 25 µl of green master mix (Promega, USA), amplification condition was 94 °C for 5 minute to initial denaturation, 35 cycles with 94°C for 45 seconds, 55 °C for 40 seconds, 72 °C for 60 seconds, and 72 °C for 10 min. PCR products (317-bp) digested with *PmlI* (Thermo Scientific, USA) for 3 hours at 37 °C. A 2% agarose gel containing ethidium bromide was used to electrophoresed the digested DNA fragments and visualized by UV trans-illuminator spectroline (USA). Hence, the CC genotype represented by a single 317-bp band indicates homozygosity. TT genotype represented by two fragments, 274-bp and 43-bp bands, indicates homozygosity. The presence of three fragments, 317-, 274-, and 43-bp bands, indicates heterozygosity for the CT genotype, as shown in Figure 1.

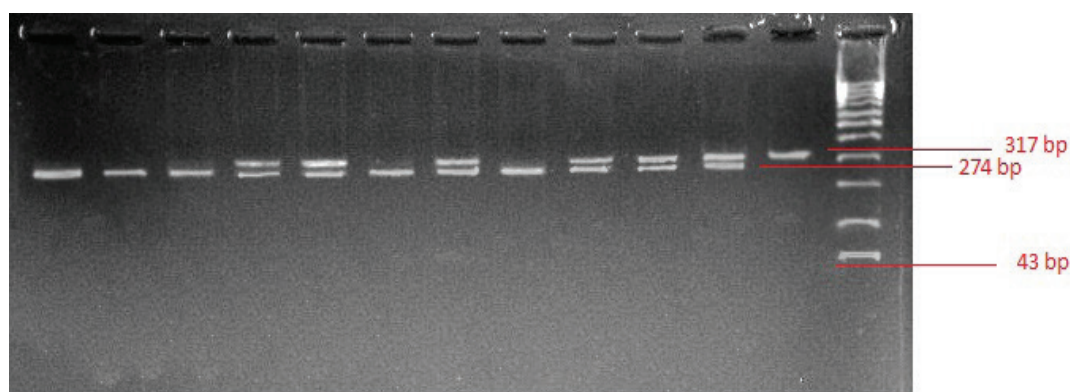


Figure 1 : Restriction fragment length polymorphism analysis of the C/T polymorphism of exon 17 in the INSR gene. Agarose gel (2%) electrophoresis after *PmlI* digestion of the PCR.

Results

Age and BMI matching between patient and control group were achieved to eliminate difference in parameter between group, so there were no significant difference in BMI, age as shown in Table 1.

Table 1 Age and BMI of Studied Groups

Variable	Study groups	N	Mean ± SD	Range	P-value
Age (years)	PCOS	50	26.42 ± 3.94	(17-35)	0.396
	control	50	25.52 ± 4.36	(18-36)	
BMI (kg/m ²)	PCOS	50	25.35 ± 2.13	(19.74 – 29.39)	0.713
	control	50	24.00 ± 1.98	(20.31 – 28.6)	

Biochemically, there were significant difference (p<0.05) in mean of fasting blood glucose, fasting insulin, HOMA in patient groups in compare with control groups, also significant difference in mean of LH, testosterone levels between patient and control groups as shown as in Table 2.

Table 2 Fasting Blood Glucose, Fasting Insulin and HOMA index, Luteinizing hormone, Testosterone hormone of Studied Groups.

Variable	Study groups	N	Mean± SD	P-value
Fasting glucose level (mg/dl)	PCOS	50	115.84 ± 13.09	0.036*
	control	50	90.70 ± 9.23	
Fasting insulin level (ng/ml)	PCOS	50	11.08 ± 1.81	0.001*
	control	50	7.03 ± 1.11	
Insulin resistance (HOMA)	PCOS	50	3.16 ± 0.72	0.001*
	control	50	1.57 ± 0.26	
LH	PCOS	50	7.150 ± 2.159	0.002*
	control	50	3.230 ± 1.394	
Testosterone	PCOS	50	1.622 ± 1.045	0.001*
	control	50	0.733 ± 0.346	

*significant

The frequency of the CC, CT, and TT genotypes of the INSR His 1058 C/T single nucleotide polymorphism, in patient TT genotype is common one, whereas CT genotype is common in control, as shown in Table 3.

Table 3 Genotypes of the INSR 1058 C/T Single Nucleotide Polymorphism, in Patients and Control groups

	CC	%	CT	%	TT	%
Patient n= 50	9	18 %	20	40 %	21	42 %
Control n=50	11	22 %	36	72 %	3	6 %

In Table 4, the frequency of the C allele (i.e., the CC, CT genotypes) was significantly increased in patients with PCOS compared with controls. Thirty-one (62%) of patients with PCOS but only twenty- two (42 %) of controls.

Table 4 Number and Percentage of Alleles Frequency in both Patient and Control Group.

Allele	Patients		Controls		OR(CI)	P-value
	Count	Proportion	Count	Proportion		
T	31	62%	21	42 %	2.25 (1.01 - 5.01)	0.04
C	19	38%	29	58%	0.44 (0.19 to 0.98)	

The correlations among studied parameter with genotyping of patient group and control groups were shown in Table 5.

Table 5 Correlation between Luteinizing Hormone, Testosterone and Insulin Resistance Using HOMA-IR Index Results in Each Genotype of Patient and Control Groups.

Parameter	Groups	CC	CT	TT
LH	Patient	7.25 ± 1.58	5.93± 1.73	8.45 ± 1.726
	Control	3.39 ± 0.808	3.36 ± 0.233	2.74 ± 0.422
Testosterone	Patient	1.10 ± 0.53	1.35 ± 0.90	2.21 ± 1.231
	Control	1.49 ± 0.97	1.58 ± 0.29	1.55 ± 0.20
HOMA-IR	Patient	2.54 ± 0.61	3.04 ± 0.65	3.54 ± 0.63 *
	Control	0.66 ± 0.34	0.77 ± 0.35	0.55 ± 0.75

Discussion

Most of patient with PCOs were young because of typical PCOS appeared to diminish with increasing age. Similarly, menstrual cycles of PCOS women become normalized with increasing age⁽¹⁵⁾. The blood glucose that not utilized by all tissue leading to hyperglycemia⁽¹⁶⁾, PCOS is associated with pre-diabetes, GDM (with around a 2-3 fold risk, independent of obesity), T2DM (4-6 fold risk independent of obesity) and these occur at a younger age⁽¹⁷⁾.

Hyperinsulinemia means a constant high level of plasma insulin in the fasting condition⁽¹⁸⁾, Hyperinsulinemia can result from a decrease in insulin clearance as well as from increased insulin secretion⁽¹⁹⁾. It is believed that hyperinsulinemia result from insulin resistance when β -islets try to control of blood glucose by produce a large amount of insulin⁽¹⁸⁾.

The common feature of PCOS is IR, its affect about 50–80% of patients. IR have clearly relationship with obesity, IR in lean PCOS women may cause by genetic disorders⁽²⁰⁾, IR, a substantial etiological factor of PCOS, was traditionally refer primarily to obesity. Moreover, insulin-signaling abnormalities is one of evidences that support the presence of an intrinsic IR in PCOS, independent of obesity⁽¹⁵⁾.

Common feature of PCOS disorder is LH excess and a high rate of PCOS patients have an elevated LH/follicle stimulating hormone (FSH) ratio perhaps due to elevated levels of LH. LH is important for the expression of gonadal steroidogenic enzymes⁽²⁰⁾, ovarian theca cells need High LH levels to synthesis androgen. reduce in oestradiol synthesis through the conversion of androgens and High LH combined with low FSH levels lead to anovulation due to the absence of a dominant follicle⁽²¹⁾.

Biochemical feature of PCOS is hyperandrogenism. About 80–90% of women with PCOS have elevated circulating androgen levels. derangements of androgen production and metabolism lead to hyperandrogenism⁽²⁰⁾, through several mechanisms the insulin resistance might contribute to hyperandrogenism and gonadotropin abnormalities⁽⁵⁾.

The frequency of the T allele (i.e., the TT, CT genotypes) was significantly increased in patients with

PCOS compared with controls. Thirty-one (62%) of patients with PCOS but only twenty- two (42 %) of controls, so this support that there were association between pathogenesis of PCOS and His 1058 C/T polymorphism at the tyrosine kinase domain of the INSR gene, similar to finding of a studies done by Siegel, Sheera, *et al.* 2002⁽¹¹⁾, Kashima, Katsunori *et al.*⁽²²⁾, Mutib, Manal T, *et al.* 2014⁽²³⁾, Mukherjee, Srabani, *et al.* 2009⁽¹²⁾. While Lee, Eung-Ji, *et al.* 2006 reported no association in Korea population⁽²⁴⁾. There are difference in result between researches, this difference can be attribute to ethnic difference, lifestyle and environment between the group that been studied.

Conclusions

In conclusion current study was noticed that there are an association between C/T polymorphism at His1058 of exon 17 of INSR and PCOS and may paly role in pathogenesis of this disease in share with other factors. Women who have T allele may be susceptible to development PCOS more than others who have C allele. Insulin resistance in PCOS might differ from these that result from obesity.

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Conflict of Interest: The authors declare that they have no conflict of interest.

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The Relationship of Environmental Factor with Incidence Rate of Dengue Fever in Municipality of Jember in 2016

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Abstract

Dengue fever can be infected in all parts of Indonesia, especially in dense population area including East Java. Jember is the Municipality in East Java which experience dengue fever cases. In 2016, Dengue fever IR in Jember Municipality is 53.66 per 100.000 populations. The purpose of this study was to see the distribution and analyze the relationship of environmental factors with the incidence rate of dengue fever in Jember Municipality.

The type of research used was observational research with the ecological study approach in Jember Municipality with a sample size of 52 villages/sub-districts. The dependent variable is the incidence rate of dengue fever and the independent variable is the altitude, senior high school and above education, poor household and ABJ. The results were analyzed using correlation test.

The results of the research showed that there is the proportion of senior high school and above education is almost similar and most of the proportion is low because <50%, most of low poor household proportion and most of low ABJ proportion and have not reached target, which is still <95%. The correlation results showed that the variables of senior high school and above education (p -value = 0.007; r = -0.373) and ABJ is correlated with the dengue fever incidence rate (p -value = 0.001; r = -0.434).

The conclusion of this research is there is correlation between factors of senior high school and above education an ABJ with dengue fever incidence rate while the village altitude and poor household factors are not correlated.

Keywords : Incidence Rate, Dengue fever, Environmental Factor

Introduction

The dengue fever disease is an infectious disease in tropical and subtropical areas that is often misdiagnosed because dengue disease is asymptomatic⁵. This disease has the tendency of increasing patients and widespread distribution and in the last 50 years, there has been a 30 fold incidence of dengue fever with increasing geographical expansion to new countries. Asian countries are ranked first with the highest number of dengue fever patients annually in the world and Indonesia is the country with the highest dengue fever case in Southeast Asia since 1968 to 2009¹⁶.

The dengue fever case in 2015 in Indonesia was increasing, from the dengue fever incidence rate (IR)

of 39.8 per 100,000 populations in 2014 increasing to 50.75 per 100,000 populations in 2015. This number is still below the target of national dengue fever illness (< 49 per 100,000 populations). Dengue fever can be infected in all parts of Indonesia because the virus and the mosquito which transmitting dengue fever are widespread. Currently, either in the city and villages in all provinces of Indonesia have contracted the disease especially in areas with dense population and one of them is East Java Province⁷.

In 2014, there is a decrease in the IR of dengue disease in East Java that is in 2013 of 39 per 100,000 population but decreasing to 24.1 per 100,000 population in 2014.³ However, East Java Province is ranked first with the largest number of deaths due to dengue fever in

all provinces in Indonesia, which is 283 deaths⁷.

There are several municipalities/cities in East Java Province that experienced an increase in dengue fever cases one of them is Jember Municipality. Jember Municipality is one of dengue fever endemic areas with high prevalence in East Java. The Dengue fever IR in Jember Municipality in 2015 was 39.96 per 100,000 population increased to 53.66 per 100,000 population in 2016. This number is still below the national IR target of dengue fever which is <49 per 100,000 population. In addition, dengue fever cases are always exists every year at each community health center in Jember Municipality. In 2016 the community health center, 28 out of 50 community health center had dengue fever IR > 49 per 100,000 population⁴.

Dengue fever is a disease which causes are very complex, means that it caused by various factors both in terms of population and in terms of individuals and one of the causes is environmental factors. The purpose of this study was to look at the distribution and analyze the relationship of environmental factors with the incidence rate of dengue fever in Jember Municipality in 2016.

Material and Methods

The type of research used was observational research with ecological study approach conducted in Jember Municipality in July 2017. The unit of analysis in this study was 52 villages or sub-districts in Jember Municipality drawn by simple random sampling. The dependent variable was the dengue fever incidence rate and the independent variables were the village altitude, high school and above education, poor household and ABJ. The data used were secondary data sourced from Central Bureau of Statistics of Jember Municipality, Jember Municipality Health Office and Community Health Centre of each village or sub-district which becomes the research sample. The results were analyzed using correlation test.

Findings

Village altitude

Of 52 villages or sub-districts samples, no village/

sub-district has altitude of 1000 mdpl. Most of the village/sub-district altitude <100 mdpl is located at an altitude of 100-500 mdpl that is as many as 19 villages or sub-districts and a small part is at an altitude of 500 - 1000 mdpl, that is 3 villages or sub-districts. In addition, the incidence rate of Dengue Fever in Jember

Municipality spreads throughout the village or sub-districts in both low and high plains.

Senior High school and above education

The proportion of Senior High school and above education in Jember Sub-district is almost the same and most of the proportion is low because <50%. Village or sub-districts with the highest proportion of senior high school and above education is found in Klompangan Village (39.02%) and the lowest is in Sempusari Sub-district (4.91%). In addition, the incidence rate of dengue fever is mostly spread in villages or sub-districts where the proportion of senior high school and above education is low.

Poor Households

The proportion of poor households in the village or sub-district in Jember Municipality in 2016 varies with low poor households proportion (4.93% - 24.04%) of 18 villages or sub-districts and the rest is in proportion between 24.04% - 41.08% and 41.08% - 97.24%, respectively of 17 villages or sub-districts. In addition, the incidence rate of Dengue Fever is spread across villages or sub-districts in either villages or sub-districts with high and low poor households proportions.

Larvae-Free Number (ABJ)

ABJ in Jember Municipality in 2016 is mostly low and has not reached the target of <95%. A total of 46 villages/sub-districts have ABJ between 75-95%. In addition, the incidence rate of dengue fever is mostly spread in villages or sub-districts with low ABJ proportion (<95%).

Correlation of Environmental Factors with Incidence Rate of Dengue Fever

Table 1. Correlation Test

Variable	r	p-value	N
Village Altitude	-0.037	0.792	52
Dengue Fever Incidence Rate			
Senior High school and Above education	-0.373	0.007	52
Dengue Fever Incidence Rate			
Poor Households	-0.229	0.103	52
Dengue Fever Incidence Rate			
ABJ	-0.434	0.001	52
Dengue Fever Incidence Rate			

Based on the result of correlation test, it was found that the factors of high school and above education and ABJ have significant correlation with the incidence rate of dengue fever because p-value <0.05, while the variable of village altitude and poor household is not significant (p-value > 0.05). The direction of the relationship between high school and above education and ABJ with the incidence rate of dengue fever is negative, which means that if the proportion of senior high school and above education and the proportion of ABJ increase it will decrease the incidence of dengue fever.

Dengue-transmitting mosquitoes are found throughout Indonesia, except in areas more than 1000 meters above sea level⁵. The correlation test results showed that there is no significant correlation between village altitude and incidence rate of dengue fever. This study was in line with research conducted in Brazil showing that there is a correlation between the altitude of the site and the incidence of dengue fever¹³. This is because based on the results obtained that in JemberMunicipality there is no village or sub-district that has an altitude of >700 mdpl so as to enable dengue fever mosquitoes to survive. In addition, it can also be caused by global warming to make mosquitoes survive in hot areas¹.

In addition, dengue fever has been found in the highlands due to population mobility. Jember Municipality is one of education area, so it is possible for people coming from outside of JemberMunicipality

to bring dengue fever virus into JemberMunicipality. Humans infected with dengue fever virus are carriers and will become the major replicating virus and become a source of virus for uninfected mosquitoes. Viruses circulate in infected human blood for two to seven days, at about the same time that they have a fever then Aedes mosquitoes acquire a virus when they bite an infected person during that period¹⁷.

High school and above education will make someone easily absorbing information so as to change into a better behavior. Based on correlation test results, it was obtained that there is a significant relationship between high school and above education and the incidence of dengue fever. This is in line with the research conducted by Sayavong that there is a significant relationship between the level of knowledge of respondents with the behavior of respondents in the prevention of dengue fever (p-value = 0.0001)¹². The senior high school and above education variable is related to the incidence rate of dengue fever because based on the results obtained, most of the incidence of dengue fever spread in areas with low proportion of high school and above education. A highly educated person will have a broader way of thinking than a lower educated person. Education increases knowledge and understanding of health¹⁰.

Poverty causes a person unable to meet the needs of a decent and healthy home⁸. People with low incomes tend to be at risk of dengue fever because the population tends to have water container such as pots and vases

that can become a breeding ground for mosquitoes. The correlation test results showed that there is no significant relationship between poor households with dengue fever incidence rate. This study is not in line with the study of systematic review which shows that there is strong evidence that dengue fever is also caused by the large number of poor people⁹. There is no significant relationship because the result obtained is that dengue disease is spread evenly in villages or sub-districts that have a small proportion of poor households.

The density of larvae is closely related to PSN behavior by the community. The higher the role of the community in terms of prevention of dengue fever, the value of ABJ will be bigger. Correlation test results showed that ABJ correlated with the incidence rate of dengue fever in Jember Municipality. This is in line with the research conducted by Sakdiah in 2008 that ABJ is correlated with IR dengue fever with $r = -0.622$ and $p\text{-value} = 0.041$ ¹¹ but this study is not in line with research conducted by Sitorus (2011) which states that there is no relationship between ABJ with dengue fever incidence rate of ($p\text{-value} = 0.051$)¹⁴. The results showed that most of the villages or sub-districts with high dengue fever incidence rate have low ABJ (<95%). Furthermore, the correlation test result also obtained the negative relationship between ABJ with dengue fever incidence rate in Jember Municipality. The low ABJ indicates the high probability of dengue fever spreads in the surrounding environment since the radius of dengue fever transmission is 100 meters from the patient.

One factor of low ABJ is ineffective monitoring by larvae monitoring officers. The larvae monitoring officers should be equipped with sufficient knowledge about dengue fever that includes the prevention and control of dengue fever¹⁵. Based on the results of interviews with dengue fever program officers at the community health center there are some larvae monitoring officers who only perform larva monitoring without providing education to the monitored community.

Conclusion

1. The village altitude has no significant relationship with the incidence of dengue fever in Jember Municipality

2. High school and above education have a significant relationship with the incidence rate of dengue fever in Jember Municipality

3. Poor households do not have a significant relationship with the incidence of dengue fever in Jember Municipality

4. ABJ has a significant relationship with the incidence of dengue fever in Jember Municipality

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Interactive Content Development for First Aid and Home Treatment e-Book

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Abstract

“First Aid and Home Treatment Interactive e-Book” is a novel interactive e-book that can be viewed by the public who are frequently carry out their activities at home area. It consists of four modules of common accidents that will occur at home area, which are ankle sprain, hot water burn, animal bites and infant choking. Due to the lack of first aid knowledge in some people and less attraction on conventional approach in giving first aid information such as books, flyers and videos, this interactive e-book helps the reader to learn some basic knowledge on first aid to treat the most frequent basic medical problems. The objectives of this project are to identify the common injuries and the first aid knowledge for the treatment of the injuries, in addition to integrate the basic first aid knowledge and finally, to develop an interactive book that give understanding to the readers about the first aid and home treatment. Furthermore, the project aims to evaluate the acceptance of the interactive book for first aid and home treatment with the medical practitioners and other target users. The methodology of this project consists of five phases which are analysis, design, development, implementation and evaluation. It is envisaged that the interactive e-book are attractive, easy to understand and enable the users to apply the treatment to the real situation.

Keywords: *E-learning, First Aid, Home Treatment, Interactive e-Book.*

Introduction

First aid aims to help a sudden sick or injured people by giving them an instant or temporary treatment to promote the recovery and prevent the condition from becoming worse. According to American Safety and Health Institute ^[1], injuries and illnesses kill more than 2.2 million people in the world each year at work. This is the same as at home when people do not know how to take the right action for the injury. Thus, the knowledge of the basic medical assistance on first aid is important for everyone to learn and to prevent further injuries or illnesses.

This project aims to create a “First Aid and Home Treatment Interactive e-Book”, in an interactive approach which suitable for the public. “First Aid and Home Treatment Interactive e-Book” is an electronic book that consists of the basic medical assistant to get the immediate treatment for injury. The interactive e-book is full of interactive elements and is easy to learn.

It is recommended to view the file in Adobe Acrobat or Adobe Reader with at least Acrobat 9 or Reader 9 or later.

There are two problem statements that contribute to the development of this project, which are the lack of medical assistance knowledge and the conventional approach in conveying medical assistance information. According to Harvey^[2], a minority of people living in New South Wales know the optimal time for cooling a burn injury and other appropriate first aid steps for burns. It shows that most of the people still do not know how to treat the burn injury. In addition, Khatatbeh^[3] revealed that the first aid knowledge among students at Yarmouk University was considered to be insufficient, as there was only 11 percent of the participants knew about the correct respiratory rate.

In this project, an application “First Aid and Home Treatment Interactive e-Book” was created for the

public who are frequently carry out their activities at home area with three main objectives. The first objective is to educate public on first aid treatment using e-book approach, secondly, to develop an interactive book that give understanding to the readers about the first aid and home treatment and finally, to integrate the basic medical assistance on first aid in treating the most frequent basic medical problems. There are four modules covered in this project, which are ankle sprain, hot water burn, animal bites and infant choking.

The process of creating this electronic book is by implementing five phases which are, analysis, design, development, implementation and evaluation. The main software used to create this interactive e-book project is Adobe InDesign. Some basic medical assistance is applied to the real situation through this first aid and home treatment interactive e-book. The final product is an interactive e- book that will be used by the public who want to learn some basic medical assistance and apply to the real situation through the development of this first aid and home treatment interactive e-book.

Related Work

An e-book can be defined as electronic book which is a digital form of book that require a reader or device. According to Shiratuddin and colleagues^[4], the paper books had been converted into a digital format through digitizing processes to form an e-book and allow them to be displayed on computers. In the report by Leaf^[5], the definition of the e-book is an online version of printed books that accessed via the internet.

E-book consists of hardware and software as its basic components, where the hardware is the reader. Tosun^[6] stated that e-books can be displayed on many reading devices and tools, such as Kindle, Iriver eBook Reader, eInk, as well as desktops, mobile phone, iPads or tablets. Brajković ^[7] claimed that the electronic book consists of various types of media, such as text, images, video, audio and animation, and those contents are called software components in the e-book. Munawwarah and colleagues^[8] developed an interactive e-book of teaching material for electrochemistry, which consists of animation, task and quizzes that involved the interaction of students directly. An e-book can be interactive by having the interaction between user and the e-book, which called interactive e-book. A recent

report by Woodward ^[9] claimed that the multimedia and interactivity of an interactive e-book is a further area for delivery of content and innovative design. This is a way for the users to improve their experience of engaging with texts by accessing to interactive images or any functionality that make interactive between the user and the e-book.

One of the advantages of using e-book is it is easily readable. It is an ideal format for those who have seeing difficulty by zoom in on the specific sections or alter the size of the font^[7]. In addition, e-book can have interactivity, which enable users to interact with the storyline in touch, sight and sound to enhance their reading and learning experience. E-book is also environmentally friendly compared to the paper books, where it helps reduce the paper consumption. Trollope and others^[10] claimed that e-books have several advantages compared to conventional paper textbooks, including portability and being able to incorporate interactive mediums, such as sound and video. Ebied et al.^[11] agreed that using multimedia within e-book, provides an easy access, organization, easy to return to titles and texts in the e-book, besides the capability to load the book on tablets and mobile phones, which makes it much easier to use at anytime and anywhere.

On the other hand, e-book has brought some disadvantages as well. E-book can cause eyestrain, where human eyes will feel tired when looking on the display screen for a long time because the resolution of the display screen is less than the printed books. Another disadvantage is e-book needs power supply. Without power supply or the batteries die, the user will unable to read the e-book. Some of the formats of the e-book are incompatible with the reader, where some of the format can only be read by specific reader like ePub format, which can be viewed by Apple devices.

The dangerous situations or medical emergencies can happen all the time even at home. If people know how to deal with the situation before an assistance like ambulance arrives, it can make any home a safer place, as people can act quickly when any accident occurs at home. It means that the first aid skills can be applied at home. First aid knowledge aims to save people's life. The advantage of having the first aid knowledge is to minimize the effects of illnesses or accidents and give

the instant treatment to the injury.

There are several related existing systems developed. They are a book named “First Aid Manual”, a printed book that endorsed by St Andrew’s First Aid, St John Ambulance and the British Red Cross^[12], a first aid 2D animation video named “First Aid Animation”^[13] and an e-book entitled “First Aid and Management of Minor Injuries”, which is written by Dallimore^[14].

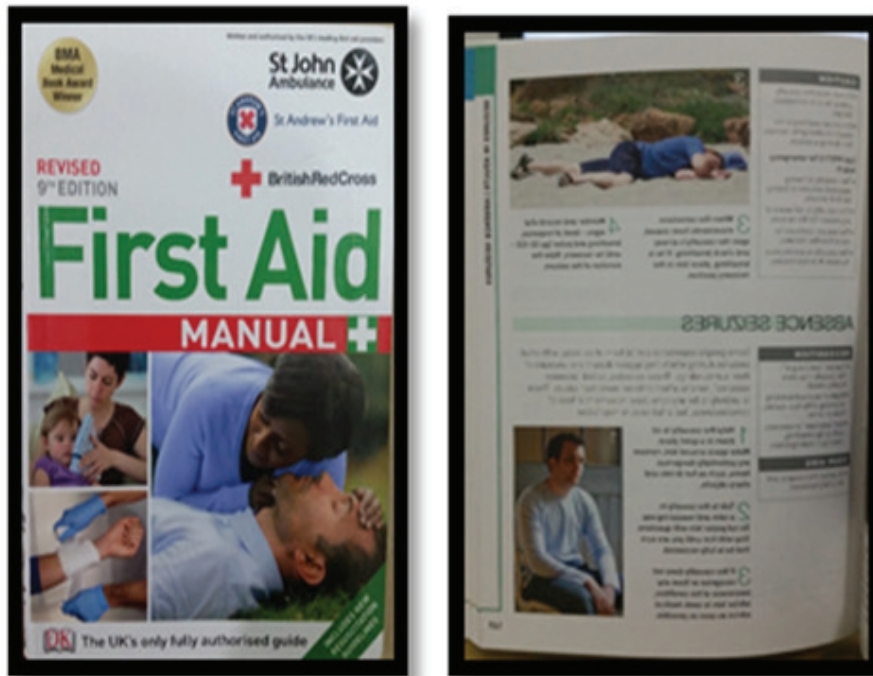


Figure 1: First Aid Manual by St John Ambulance ^[12]

Figure 1 shows the example of how the “First Aid Manual” looks like. It is a printed book that endorsed by St Andrew’s First Aid, St John Ambulance and the British Red Cross, published in 2010. It includes step-by-step first aid advice and used as the official training manual for UKs leading first aid organizations’ courses.



Figure 2: First Aid Animation by xKlaw ^[13]

Figure 2 shows “First Aid Animation” which is a 2D animation video that posted on the YouTube. It is a short animation video that explaining the basics of first aid and the immediate treatment that can be taken.

The video length is 5 minutes and 4 seconds.

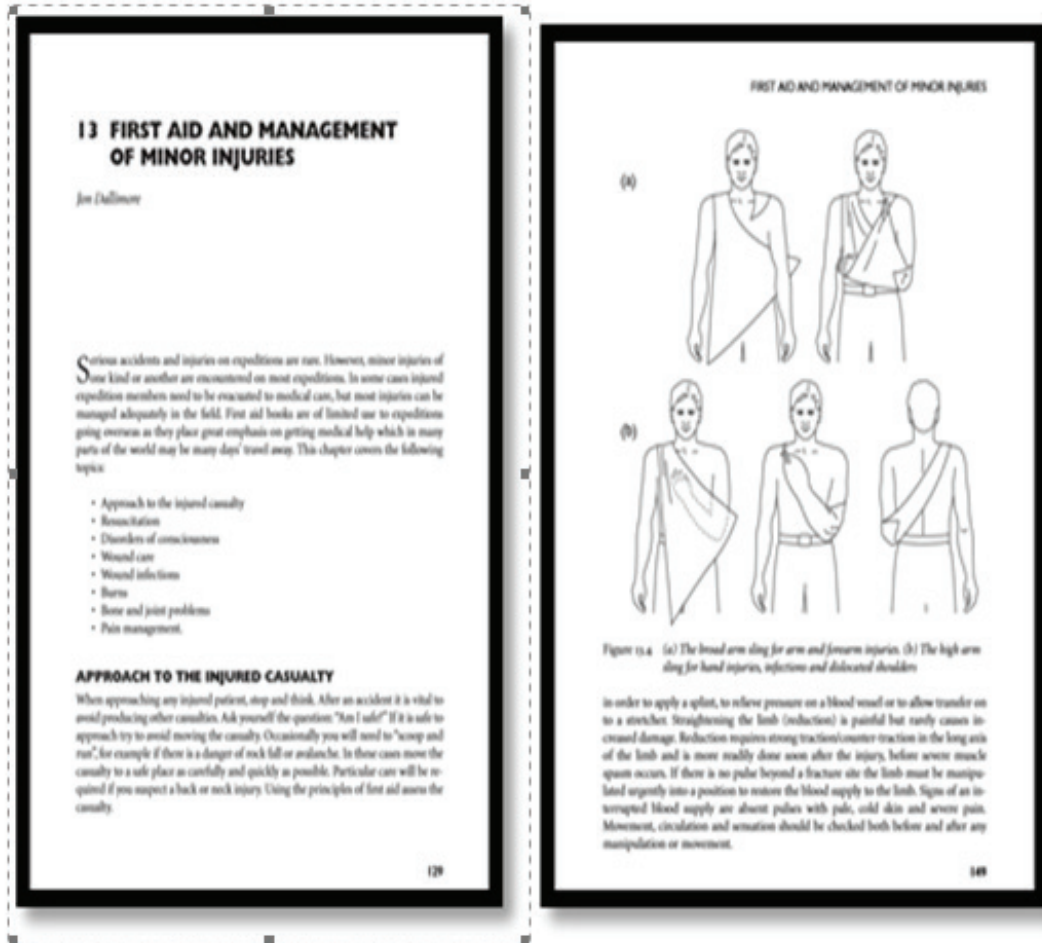


Figure 3: First Aid and Management of Minor Injuries by Jon Dallimore [14]

Figure 3 shows “First Aid and Management of Minor Injuries”, which is a pdf format e-book written by Jon Dallimore. This e-book explains about the minor injuries and its treatment that can be used. It is able to be read by the reader in Windows.

Methodology

The requirement analysis is crucial to the success of a development project. In this section, all requirement will be further analyzed in detail.

Data Collection/Information Requirement

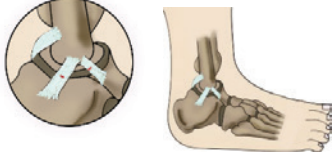



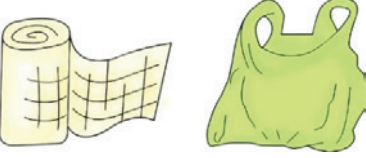
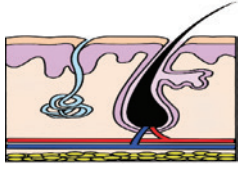


The data was collected through the interview session with the medical doctors at the Universiti Teknikal Malaysia Melaka (UTeM) Health Centre. There are four modules covered in this project, which are ankle sprain, hot water burn, animal bites and infant choking,

which have been confirmed by the medical doctor at UTeM Health Centre that these four selected modules are among the common accidents occur at home area.

Design

During the design phase, the project is designed to fulfill the requirements that identified in the previous analysis phase. In this phase, the design for the interactive e-book such as the cover, layout, and interactive elements are created. Storyboards also the content and media selection are performed in this phase. All the content assets that are created in the design phase will be assembled in the development phase. Meanwhile, Table 1 shows some of the character profile of models for each module used for this e-book.

Table 1: Model Design

Item/Model	Character
	Ankle Sprain
Ankle	
Bandage	
	Animal Bites
Injured hand	
Sterile and clean pad	
	Hot Water Burn
Gauze and plastic bag	
Skin	
	Infant Choking
Back blows	
Chest thrusts	

The content for each of the element in the e-book is discussed below:

Introduction : Briefly explain the product.

Content/Main Menu : A table of content with hyperlink.

Ankle Sprain, Hot Water Burn, Animal Bite and Infant Choking : Selection of modules.

Definition : Explain what is the meaning of the particular module.

Cause : State the cause that happened in the particular module.

Symptoms : List all the symptoms of the particular module.

Treatment : State the treatment steps of the particular module.

Quiz : Test the user’s knowledge on the particular module.

Development

Text is used to give the information and explanation of each of the modules. The fonts used in this interactive e-book are Hobo Std and Estrangelo Edessa for headers/ titles and contents, respectively. Most of the graphics or images used in this project are in Portable Network Graphics (PNG) format, which offers the ability to preserve transparency for the background. All the images are in 2D form. Those vector images have been drawn and edited by using Adobe Illustrator and Adobe Photoshop.

Meanwhile, the audio is generated by using a Text To Speech (TTS) service^[15]. It has been exported into a MP3 format. The video demonstration for ankle sprain treatment has been edited by using Adobe Premiere Pro. The video duration is about one minute and it is exported in FLV format. The animation in this interactive e-book is created by using Adobe Flash. Quiz is one of the animation for each of the modules. All the animations are exported in SWF format.

The integration process of all the multimedia elements was done by using the Adobe InDesign. The final product was exported as an interactive pdf. Figure 4

shows some interfaces of the product, including the main interface, ankle sprain treatment video demonstration interface and quiz interface.



Figure 4: Interactive e-Book Interfaces

Discussion

The strength of the project is this interactive e-book consists of many multimedia elements, such as video, text, audio, graphic and animation, in addition to interactivity, which can attract the attention of the reader. The interactive e-book can engage with the readers by using buttons and quizzes. Moreover, readers can click on the button to see the further information and also answer the quiz to test the understanding of their knowledge on ankle sprain, hot water burn, animal bites and infant choking after reading the interactive e-book.

Conclusion

This paper covers the concept of development of a novel “First Aid and Home Treatment Interactive e-Book”, starting from analysis to implementation phase. The “First Aid and Home Treatment Interactive e-Book” has been developed for public who are frequently carry out their activities at home area. The readers can gain the general medical information on how to treat the ankle sprain, hot water burn, animal bites and infant choking through an interactive book method. The testing phase will be conducted in order to evaluate the acceptance of the application with the medical practitioners and other target users. The interactive e-book also will contribute to the UTeM Health Centre for future use. All the multimedia elements in the interactive e-book is mainly to help the user enhance their knowledge on how to treat the common injuries.

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Source of Funding: Self

Ethical Clearance: Nil

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Prevalence of Loneliness and Depression among Elderly in South India

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Abstract

Introduction: ‘Old age’ considered as the least desirable phase of the life cycle and is characterized by financial, health, social and other problems. About 10% of the people over 65 years in community have signs of depression. The most common emotional disorder in the elderly population is depression, mostly caused due to loneliness, which is often overlooked by health care professional and family members.

Objectives: The objectives of the study were to assess the prevalence of loneliness and depression among elderly and to associate the selected background variables with loneliness and depression.

Methods: The research design adopted for this study was descriptive study design. The study was conducted among 300 subjects to assess the prevalence of loneliness and depression among elderly.

Findings: The study results revealed that majority of elderly 43.3% had experienced moderate loneliness, 41.3% of elderly severe loneliness and 15.3% of elderly had mild loneliness. With regard to level of depression among elderly 52.0% had mild depression, 40.0% had severe depression and 8.0% of elderly had no depression. A statistically significant association was identified between the loneliness among elderly with regard to age, marital status, education, living status, economic dependency and between the depression among elderly with regard to age, education, living status and economic dependency at $p < 0.001$ level.

Conclusion: This study brought into light that majority of the rural elderly population experienced mild loneliness and depression. Thus, active measures have to be initiated among family members and health care professionals to combat this dual problem of loneliness and depression among elderly population and aid them to live a life with happiness and satisfaction.

Key words: elderly, prevalence, loneliness, depression.

Introduction

‘Old age’ considered as the least desirable phase of the life cycle and is characterized by financial, health, social and other problems. About 10% of the people over 65 years in community have signs of depression. Whereas 30-50% of senior citizens living in residential care is found to be depressed. The most common emotional disorder in the elderly population is depression, which is

often overlooked by health care professional and family members. Depression among elderly adult has become a major public problem, associated with mortality and suicidal behaviour, because it is either undiagnosed or misdiagnosed and subsequently, left untreated.

Inventions in the field of medicine and improved social conditions have increased the life span of human. The expectation of life at birth in developed countries is over 70 years. In the year 2002, there were an estimated 605 million old persons in the world, of which 400 million were living in low-income countries. By 2025, the number of elderly people is expected to rise more than 1.2 billion with about 840 million of these in low-income countries. In India, For the year 2010 the

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estimates are 8 per cent of total population were above the age of 60 years, and is likely to rise to 19% by 2050. This profound shift in the share of older Indians, brings with it a variety of social, economic and healthcare policy challenges [1].

The risk of depression among elderly women is two to three times higher than that of elderly men. Additionally, elderly adults, residing in long-term care facilities, are at an even greater risk for developing depression. Depression in elderly adults can be debilitating and can affect functional, cognitive and emotional health. This increases risks for infections, falls, injury, and poor nutrition. The elderly person represents a store house of knowledge and experience and reservoir of wisdom but is a highly vulnerable group in society. Their vulnerability increases with age. The vulnerability lies mainly in lack of employment, financial uncertainty, ill health and abandonment by society. Any system of social security of the elderly should address all these vulnerabilities. Community surveys carried out in different parts of India have revealed that depression is the most common psychiatric disorder in late life.

Loneliness is defined as a feeling of emptiness, deprivation or sadness. As our population ages, more and more senior citizens suffer from loneliness. This sense of isolation is felt even more during holidays, although it can also be present on a daily basis. Loneliness should not be taken lightly since it can lead to serious consequences like loss of independence, eating disorder, increased stress & anxiety, depression, sleep problems, suicidal thoughts and higher risk of chronic diseases.

Loneliness is a human has been understood as a discrepancy between desired and real social relations. The impact of loneliness over physical and mental health has been evaluated in many studies across the globe. Data from the western counselling suggest that although loneliness is prevalent across all age group, it is more distinctive in the geriatric population. It is suggested that as the age advances, elderly persons often tend to lose the active role they used to play and enter into a passive role which makes them feel insufficient and they develop a sense of alimantation and a sense of losing in dependance and resultant loneliness. Available data also suggest that aging alone is not responsible for developing feelings of loneliness, rather several other factors such as gender,

marital status, level of education, being employed or not or being financially stable or not and living environment also play a significant role in the development of loneliness in elderly individuals. All these issues faced by the elderly prompted the investigator to take up this study to identify the prevalence of loneliness and depression among elderly residing in South India.

A cross- sectional study was conducted on depression among 450 elderly in rural population of Tamilnadu, India revealed that the prevalence of depression among elderly males was found to be 56.8% and among females was 79.2% and recommended a need to improve geriatric health care services combined with proper monitoring and evaluation^[2]. A community based quantitative, descriptive, cross-sectional and explorative study on prevalence of loneliness and its determinants among geriatric population was conducted among 370 elderly population in Bengaluru city, using UCLA Loneliness questionnaire. Result of the study highlighted the prevalence of loneliness was 37.6% among the elderly population and females were affected more when compared with males and the factors influencing loneliness were older age group, illiterates, not living with spouse, only person in the family aged 60 years and above, family size more than five and presence of daily activity disability ^[3]. A comparative study was conducted among 100 elderly to assess the prevalence of depression and loneliness among institutionalized and non- institutionalized elderly in selected community in Amaritsar and Tarntaran and the results revealed that depression and loneliness were found to be more among institutionalized elderly as compared to non-institutionalized elderly ^[4]. A community based cross-sectional study to determine depression among 150 elderly persons residing in urban areas of north Karnataka showed that the prevalence of depression in elderly persons was 37.1%, amongst which 24.7% were mildly depressed and 9.3% were severely depressed ^[5].

Materials and Methods

Ethical issues

Ethical clearance was obtained from institutional ethical committee (Human studies) of Sri Ramachandra Institute of Higher Education and Research institute (DU) after obtaining prior approval from Principal, Faculty of Nursing and Medical Officer, RHTC, Vayalanallur.

The purpose and nature of the study was explained to the elderly and written consent was obtained from them.

Study design and Setting

A descriptive study design was used to assess the prevalence of loneliness and depression among the elderly people. The study was conducted at selected villages under Rural Health & Training Centre of SRMC, Vayalanallur which included Annaikattucherry, Sorancherry and Amudurmedu villages, Thiruvallur district. These villages are administered by village panchayat and village members where mostly Hindus and few where Christians and Muslims. These villages are situated at distance of about 5kms away from RHTC, Vayalanallur.

Sample size calculation

Sample size was calculated based on power analysis and effect size ($\alpha = 5\%$ and $1-\beta = 80\%$). The sample size estimated was 283 elderly, to achieve 80% power at a 5% level of significance. Considering the chance of attrition, an increase of 10% was done and the obtained value was rounded to 300.

Sampling criteria

Purposive sampling technique was used to select 300 elderly people residing at Annaikattucherry, Sorancherry and Amudurmedu villages. The following elderly were included in the study, elderly residing at selected villages, elderly who can able to speak, understand Tamil or English, willing to participate in the study and available during data collection period. Elderly with severe mental illness were excluded from the study. The Demographic variables of the elderly were age, gender, marital status, education, living status, economic dependency, type of family and co-morbid conditions. The Geriatric Depression Scale was used to measure the level of depression. The tool consists of 30 items. Individual scores on the Geriatric Depression Scale can range from 0 to 30 with higher scores indicating higher levels of depression. The Scoring and interpretation are as follows: 0-9 - Normal, 10-19 - Mild Depression and 20 - 30 - Severe Depression. University of California, Los Angeles Loneliness scale was used to measure the level of loneliness among elderly. The tool consists of 20 items and the total score ranges from

0 - 60. The questionnaire was used to measure one's subjective feeling of loneliness as well as feelings of social isolation. The Scoring and interpretation are as follows: <20- Mild loneliness, 21 to 40- Moderate loneliness and 41 to 60 severe loneliness.

Data collection procedure

Ethical permission was obtained from institutional ethical committee of Sri Ramachandra Institute of Higher Education and Research (DU), IEC No: CSP/19/JAN/75/62. Permission obtained from Principal, Faculty of Nursing and Medical Officer, RHTC, Vayalanallur. The data were collected from elderly residing at selected 3 villages which includes Annaikattucherry village, Sorancherry village and Amudurmedu village . Each day around 45-50 elderly were interviewed and data were collected. Participants were selected according to the inclusion criteria. Informed consent obtained from all the study participants, assessment of the prevalence of loneliness by University of California, Los Angeles Loneliness Scale (UCLA) and depression by Geriatric Depression Scale (GDS) was done.

Findings

Among 300 elderly selected for the study majority of them 96 (32.0%) were in the age group of 65-69 years, 170 (56.7%) were females, 129 (43.0%) were living with spouse and children and with regard to economic dependency of elderly 104 (34.7%) were totally independent on their children, 100 (33.3%) were partially dependent and 96 (32.0%) were dependent. In relation to co-morbid conditions among elderly only 43 (14.3%) were found not suffering from any diseases, 97 (32.3%) had diabetes mellitus, 81 (27.0%) had hypertension, 27 (9.0%) had asthma, 25 (8.4%) had other diseases, 18 (6.0%) had arthritis and 9 (3.0%) suffered from heart disease.

The study results revealed that majority of elderly 43.3% had experienced moderate loneliness, 41.3% of elderly severe loneliness and 15.3% of elderly had mild loneliness [table 1]. With regard to level of depression among elderly 52.0% had mild depression, 40.0% had severe depression and 8.0% of elderly had no depression [table 2]. A statistically significant association was identified between the loneliness among elderly with regard to age, marital status, education, living status,

economic dependency at $p < 0.001$ level [table3]. The study also showcased that there is a statistically significant association identified between the depression among elderly with regard to age, education, living status and economic dependency at $p < 0.001$ level [table 4].

Table -1 Frequency and percentage distribution of level of loneliness among elderly (N=300)

Level of loneliness	N=300	%
Mild Loneliness	46	15.3
Moderate Loneliness	130	43.3
Severe Loneliness	124	41.4

Table -2 Frequency and percentage distribution of depression among elderly (N=300)

Level of Depression	N=300	%
No Depression	24	8.0
Mild Depression	156	52.0
Severe Depression	120	40.0

Table -3 Association between level of loneliness with selected demographic variables among elderly (N=300)

Demographic variables	Levels of loneliness						Chi Square & p-value
	Mild		Moderate		Severe		
	N	%	n	%	N	%	
Age in years							37.599 .000***
60-64	22	25.0	44	50.0	22	25.0	
65-69	16	16.7	46	47.9	34	35.4	
70-74	8	11.9	27	40.3	32	47.8	
Above 75	0	0.0	13	26.5	36	73.5	
Marital status							37.130 .000***
Single	3	21.4	2	14.3	9	64.3	
Married	41	19.2	106	49.8	66	31.0	
Divorce	0	0.0	1	20.0	4	80.0	
Widows/Widower	2	2.9	21	30.9	45	66.2	
Economic dependency							22.358 .000***
Independent	13	13.5	41	42.7	42	43.8	
Partially dependent	28	28.0	43	43.0	29	29.0	
Totally dependent	5	4.8	46	44.2	53	51.0	

*** $p < 0.001$

Table -4 Association between level of depression with selected demographic variables among elderly (N=300)

Demographic variables	Levels of depression						Chi Square & p-value
	No		Mild		Severe		
	N	%	n	%	N	%	
Age in years							43.963 .000***
60-64	7	8.0	26	29.5	55	62.5	
65-69	10	10.4	45	46.9	41	42.7	
70-74	5	7.5	46	68.7	16	23.9	
Above 75	2	4.1	39	79.6	8	16.3	
Living status							43.979 .000***
Alone	0	0.0	38	73.1	14	26.9	
With spouse	10	13.2	35	46.1	31	40.8	
With spouse and children	10	7.8	48	37.2	71	55.0	
With other individuals	4	9.3	45	81.4	4	9.3	
Economic dependency							24.966 .000***
Independent	7	7.3	39	40.6	50	52.1	
Partially dependent	11	11.0	43	43.0	46	46.0	
Totally dependent	6	5.0	74	71.2	24	23.1	

***p<0.00

Discussion

This study revealed that majority of elderly 43.3% had experienced moderate loneliness. About 41.3% of elderly had experienced severe loneliness and only 15.3% of elderly had mild loneliness. The study findings were well supported by a study done by R.Anil, (2016) at Bengaluru city, Karnataka, India which revealed that 37.6% of the elderly had loneliness, females were affected more, the factors influencing loneliness are older age group, illiterates, not living with spouse, only person in the family aged 60 years and above, family size of more than five and presence of daily activity disability^[3].

This study revealed that majority of elderly 52.0% had mild depression. About 40.0% of elderly had experienced severe depression and only 8.0% of elderly had no signs of depression. This study was well supported by a study conducted by Lilian D Souza (2015) at urban slum of Bangalore. The study revealed, the gender based distribution of depression in the elderly

males is 33.02% and females is 71.15%. some of the chief causes of depression were loneliness, health issues, financial insecurity, no social interaction and lack of a geriatric friendly environment ^[6].

This study revealed that there is a statistically significant association identified between the loneliness among elderly with regard to age at p < 0.001 level, were the level of loneliness among elderly increased constantly with their age. This study also showcased that female gender suffered more due to loneliness than males which was not statistically significant association was widowers suffered more from loneliness than those living with their spouses. This study brought into light that the elderly who were living alone were suffering more from loneliness than the other elderly who were living with their spouse or children, which was statistically significant at p < 0.001 level. With regard to economic dependency those elderly who were totally dependent on others had more signs of loneliness, when compared to those who were independent economically, which was found to be statistically significant at p <

0.00 level, were the level of depression among elderly increased constantly with their age. This study also showcased that female gender suffered more due to depression than males which was not statistically significant. A statistically significant association was identified with relation to depression and education at $p < 0.001$ level, as the non-formal education suffered more from depression than the literate

Conclusion

This study brought into light that majority of the rural elderly population experienced mild loneliness and depression. Due to shift in priority from geriatric to paediatric population in our country, most of the elderly are left neglected. Some of the symptoms of loneliness and depression is thought as common problems due to ageing and family members often fail to seek medical attention. Thus, active measures have to be initiated among family members and health care professionals to combat this dual problem of loneliness and depression among elderly population and aid them to live a life with happiness and satisfaction.

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Need for Octopace Culture to Promote Strategic HR Climate in Healthcare Sector

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Abstract

Purpose: The main purpose of this paper is to study the Openness, confrontation, Trust, Autonomy, Pro-action, Authenticity, Collaboration & Experimenting (OCTAPACE) Culture among nurses from five different hospitals

Methodology: A sample of 314 nurses from 5 hospitals in Udupi and Manipal were administering OCTAPACE profile instrument developed by Udai Pareek to study the cultural ethos at the selected healthcare organizations.

Findings: The results indicate that there is a gap between desired and actual levels of OCTAPACE Culture. Organizations despite providing comparatively higher salaries and a host of welfare measures seem to be possessing an average level of HRD Climate. Factors like lack of top management initiative in identifying and developing nurse's potential, nurses not taking the given feedback seriously and similar reasons contribute to this situation and hence offers a lot of scope for improvement.

Key words: HR Climate, OCTAPACE Culture., Healthcare sector.

Introduction

Culture is made up of or includes symbols, myth, ideational system (ideology), and ritual. It has also been expressed as a group's operative communication rules. The culture of an organization influences every aspect of organizational life and behavior as it affects the five basic processes of an organization: communication, cooperation, commitment, decision making, and implementation, but the members of the organization may not be aware of these shared assumptions that guide thought and action as they are taken for granted. The pervasiveness of culture can be understood from two of its major elements: the strength of the culture that determines the efficiency of an organization and the

content of culture that determines effectiveness because content determines the direction in which culture influences behavior.

Literature Review

HRD CLIMATE

Human resource development climate is an integral part of organizational climate. It can be defined as perceptions the employee can have on the developmental environment of an organization. This developmental climate will have the following characteristics:

A tendency at all levels starting from top management to the lowest level to treat the people as the most important resource; Perception that developing the competencies in the employees is the job of every manager/supervisor; faith in the capability of employees to change and acquire new competencies at any stage of life; a tendency to be open in communications and discussions rather than being secretive (fairly free expression of feelings); encouraging risk-taking and experimentation; making

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efforts to help nurses reorganize their strengths and weakness through feedback; a general climate of trust; a tendency on the part of nurses to be generally helpful to each other and collaborate with each other; team spirit; tendency to discourage stereotypes and favoritism; supportive personnel policies; supportive human resource development practices including performance appraisal, training, reward management, potential development, job-rotation career planning etc. [8].

HRD is the process of improving, moulding and changing skills, knowledge, creative abilities, aptitude, attitude, values, commitment, etc., based on present and future job and organizational requirements. HRD Climate is a measure of the perceptions about the prevailing nature of HRD [9].

Market-share, sales-turnover and profitability are lagging indicators of organizational performance. On the contrary, organizational climate is a leading indicator of organizational performance. Functional organizational climate leads to enhancement of personal, role and organizational effectiveness. Understanding the determinants of organizational climate is helpful in finding ways and means for strengthening the functional climate and de-emphasizing the dysfunctional climate [12].

HRD climate is an integral part of the organizational climate. It contributes to the overall health and self-renewing capabilities of the individuals, dyads, and team of the entire organization. The top management of the company must emphasize on the quality of work life and welfare measures for employees, which can infuse in them the team spirit and sense of belongingness. Management of the organization must ensure healthy and friendly working climate and fine welfare measures for the employees at all levels [4].

Organizational climate depends on the perception of the organizational members. Perception is influenced by the personality of the perceiver, his upbringing, education, and experiential learning. Personal variables would, therefore, qualify as some of the determinants of organizational climate [11].

HRD Climate is extremely important for the ultimate achievement of the business goals. It is a phenomenon experienced by employees and often referred to by expressions like 'environment', 'atmosphere' and so on. Climate at the individual level is a summary perception of

the organization's work environment that is descriptive rather than evaluative in nature, HRD climate has a definite impact on job satisfaction, attitude towards work and role efficacy which in turn gives impetus to the overall functioning of the institution [1].

A congenial HRD climate is essential for sharpening competencies as well as motivating employees to perform exceptionally [6].

Octapace Culture

Openness, confrontation, Trust, Autonomy, Proaction, Authenticity, Collaboration & Experimenting (OCTAPACE) culture is essential for facilitating HRD. Openness is present when employees feel free to discuss their ideas, activities, and feelings with each other. By confrontation, problems and issues are brought out into the open with a view to solving them rather than hiding them for fear of hurting or getting hurt. Trust is taking people at their face value and believing what they say. Autonomy is giving freedom to let people work independently with responsibility. Proactivity is encouraging employees to take initiative and risk. Authenticity is the tendency on the part of the people to do what they say. Collaboration is to accept interdependencies, to be helpful to each other, and work as teams [7].

There is a need for conducive HRD climate which is a sum of perceptions of members about the organization and its HRD philosophy, systems and practices, prevalent in the form of values of openness, confrontation, trust, authenticity, pro action, autonomy, collaboration, experimentation. In the presence of these values, there exists harmony for the conduct of HRD practices, which are strategically evolved. HRD instruments if implemented properly should lead to OCTAPACE Culture, which in turn results in more competent, satisfied and committed people, thereby making the organization grow [6].

Past research studies done by [10, 2, 3 & 5] and reveal that the congenial OCTAPACE culture is extremely important for promoting the organizational effectiveness and good Governance.

Employees have attitudes or viewpoints about many aspects of their jobs, their careers, and their organizations. Greater insights on the relationship between employee attitudes and business performance will assist HR professionals as they strive to enhance

the essential people side of the business in a highly competitive, global arena. Employee surveys, used effectively, can be catalysts for improving employee attitudes and producing organizational change [9].

Openness: The spontaneous expression of feelings and thoughts, giving and receiving feedback are the outcomes of openness.

Confrontation: It is defined as facing rather than shying away from problems. Deeper analysis of interpersonal problem is also confrontation.

Trust: It is defined as maintaining the confidentiality of information provided by others and not misusing it.

Authenticity: Congruence should be there in what one feels, says, and does.
Proaction: It means taking the initiative, preplanning, and taking preventive actions.

Autonomy: It means using and giving freedom to plan and act in one’s own sphere.

Collaboration: Collaboration is giving help to others and asking for help and working together.

Experimenting: This means using and encouraging innovative approaches to solve problems, encouraging creativity, and taking a fresh look at things.

OCTAPACE culture is essential for facilitating human resource development. Openness is present when employees feel free to discuss their ideas, activities, and feelings with each other. Confrontation involves bringing problems and issues into the limelight with a view to solving them, rather than hiding them for fear of hurting or getting hurt. Trust is taking people at face value and believing them. Autonomy is the freedom to allow people to work independently with responsibility. Productivity is encouraging employees to take initiative and risks. Authenticity is the tendency of interdependencies, to be helpful to each other and work as teams. Collaboration is required so the employees can cope up with the changes and upcoming trends in an organization.

Keeping in view the immediate priority of human resources to learn more about the needs, requirements, and responsibilities of the healthcare organizations and how it fits into global operations and customer satisfaction, the present study focused on the need for promoting favorable OCTAPACE culture in healthcare organizations especially among nurses. Towards this objective and based on the literature review the OCTAPACE culture dimension of HRD Climate have been taken for detailed study and a conceptual model has been developed as indicated in figure 1

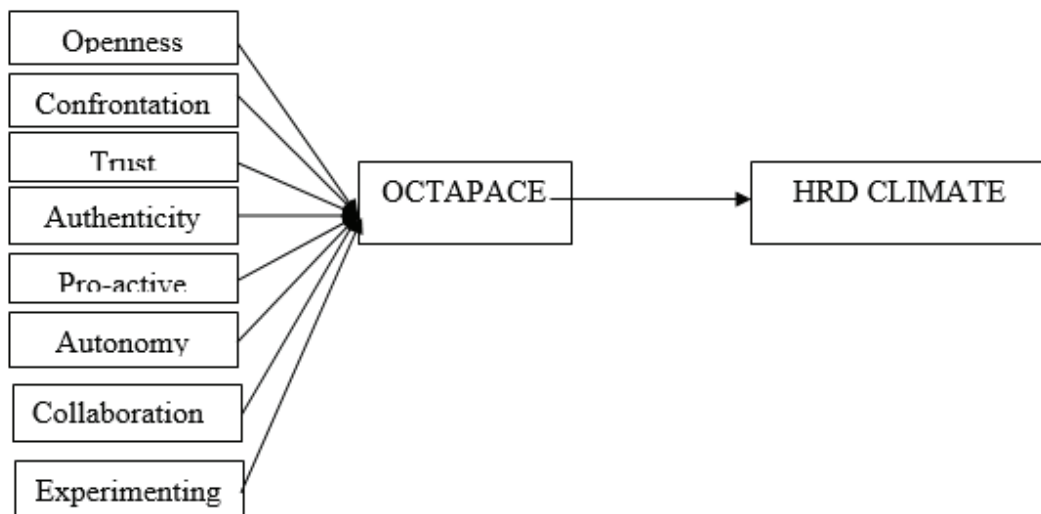


Figure 1 Conceptual Model of the study variables

Research Questions

1. What is the overall level of HRD climate prevailing in hospitals?
2. How are the hospitals faring in terms of OCTAPACE Culture?
3. What is the relationship between OCTAPACE Culture and HRD Climate at the overall level and at individual factor level?

Methodology

This study is descriptive in nature. Based on the literature review and keeping in view the topic selected for study namely HRD Climate in hospitals. A representative sample of 314 nurses from five hospitals in Udupi and Manipal was selected for study.

The data collection took place in the period November 2019 to February 2020. Data collected was then checked for completion of details and wherever required additional information was requested and recorded. The collected information was processed through SPSS package and the following tools namely Mean, Standard Deviation and Co-efficient of Variation for selected variables were employed to assess the degree of representation and variation. The researcher also used SEM modeling to validate the result.

This present study has been done by administering the Questionnaire developed by [7]. Human Resource Development (HRD) Climate is a concept proposed by [7] to explain the environment provided by organizations for the learning and development of its employees. This includes items both on the policies and practices for HRD in an organization. This instrument is developed to measure the HRD Climate consisting of 38 items by dividing them into three categories i.e., the first category is General Climate, second one is OCTAPACE Culture the third category is HRD mechanisms. It covers all aspects of HRM such as training, performance appraisal, potential appraisal, organization development, feedback, and performance coaching, career planning, rewards, employee welfare, quality of work life and human resource information systems.

The essence of the HRD climate can be well gauged from the amount of importance that is given to the development of OCTAPACE culture in the Organization. T. V. Rao introduced the concept of OCTAPACE culture as a good progressive way of

building organizations. Udai Pareek and T.V. Rao pioneered the concept of HR Culture and propounded the OCTAPACE Culture comprising seven factors namely, Openness, Confrontation, Trust, Autonomy, Pro-activity, Authenticity and Collaboration. An E for Empowerment and Experimentation was later added, and it became OCTAPACEE.

RESULT ANALYSIS AND DISCUSSION

Table 1 CATEGORY-WISE HRD CLIMATE

Category	Mean	Std. Deviation
GENERAL HRD CLIMATE	3.32	0.60
OCTAPACE CULTURE	3.30	0.63
HRD MECHANISMS	3.26	0.63
OVERALL HRD CLIMATE	3.29	0.61

The category wise mean scores presented above in table 1 indicates mean score of around 3.3 showing a moderate tendency on all three dimensions. Since the questionnaire used 5-point scale, Scores around 3.3 indicate the existence of a just above average degree of HRD Climate. Hence, the overall HRD Climate mean score of 3.29 and the standard deviation of the same at 1.05 reveals that the HRD Climate in the select organizations is just average and there is huge scope for improvement. Hence the organizations should take the perception of nurses about HRD Climate seriously and strive to fill the gap since there is huge scope for improvement.

INDIVIDUAL DIMENSIONS OF OCTAPACE CULTURE

Among the seven dimensions of OCTAPACE Culture, as far as this study is concerned, Autonomy scores the highest followed by proactivity, collaboration, trust, and authenticity. Openness and confrontation both score at the same level and are at the lowest level.

OPENNESS

In the present study, the mean scores of four items of Openness vary between 3.22 and 3.40, with an overall average of 3.27 indicating a medium level of openness existing. The nurse's willingness to share their

feelings among themselves and subordinates seems to be greater than that of their sharing with superiors. Hence there is a need for improving the superior sub-ordinate relationships which takes care of most of the day to day problems.

CONFRONTATION

The mean scores of the four items concerning confrontation between 3.18 to 3.40 with the overall score of 3.27 indicate the existence of average confrontational climate. While open discussion and problem-solving environment scores the lowest, nurse sharing the feelings with their subordinates scores the highest.

TRUST

Observation of mean scores of three items of trust that ranges between 3.17 to 3.48 and the overall score of 3.33 highlights the fact a climate of trust exists to a reasonable level although not very high. While the nurse’s trust in each other scores high, the support from supervisors in needy situations seems to be low.

AUTONOMY

As far as this study is concerned, an overall mean score of 3.38 indicates that the nurses are given a reasonable level of autonomy in their roles. The five items of autonomy possess average mean scores between 3.24 and 3.58, with the opportunities for implementation of learned things scoring low and avenues for experimenting with new methods and creative methods scoring high. Delegation of authority to juniors, encouragement for individuals taking responsibilities and juniors using the provided autonomy scores in between.

PROACTIVITY

The three items covering proactivity has mean scores between 3.05 and 3.58. While encouragement for nurses to experiment and innovate scored high, the top management’s efforts in utilizing the potential of nurses scored low with opportunities for nurses to do things on their own scoring in between. The overall mean score

of 3.35 shows that the company is providing a climate which promotes proactivity although at an average level.

AUTHENTICITY

The overall mean score of 3.29 shows that authenticity is existing to a reasonable extent. While the nurses are taking the opportunities for learning seriously, their seriousness towards accepting behaviour feedback scores low.

COLLABORATION

Analysing the mean scores of three items contributing to collaboration which varies between 3.22 and 3.40 and the overall mean score at 3.34, the collaboration among the nurses and with their supervisors seems to be happening at satisfactory levels. Team spirit seems to be scoring better than helping nature among nurses while seniors helping their juniors to take up future roles seem to be faring lesser.

EXPERIMENTING

The overall mean score of 3.15 shows that experimenting is existing to a reasonable extent.

Table 2 Summary of the study variables

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.964(a)	.929	.928	.15853

a Predictors: (constant), collaboration, proactivity, confrontation, trust, authenticity, openness, autonomy.

In the above table 2 the R square value is .929, we can conclude that there is significant impact of OCTAPACE Culture on HRD Climate on overall level which is as high as 93%. This highlights the importance of good OCTAPACE Culture which in turn contributes to better HRD Climate.

Table 3 Analysis of variance of the study variables

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	100.901	7	14.414	573.526	.000(a)
	Residual	7.691	306	.025		
	Total	108.592	313			

a Predictors: (constant), collaboration, proactivity, confrontation, trust, authenticity, openness, autonomy.

b Dependent variable: HRD climate.

From the above table we can interpret that the impact created by OCTAPACE Culture on HRD Climate is positively significant.

Table 4 Coefficient correlation of the study variables

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta	B	Std. Error
1	(Constant)	.274	.053		5.200	.000
	OPENNESS	.101	.021	.128	4.829	.000
	CONFRONTATION	.156	.019	.196	7.996	.000
	TRUST	.165	.017	.196	9.529	.000
	AUTONOMY	.127	.026	.179	4.888	.000
	PROACTIVITY	.182	.023	.243	7.940	.000
	AUTHENTICITY	.064	.018	.090	3.521	.000
	COLLABORATION	.117	.016	.177	7.114	.000
	Experimenting	.045	.010	.121	2.459	.210

a Dependent Variable: Overall HRD

Looking at the above table, we can once again reassure that the correlation between variables of OCTAPACE Culture and HRD Climate is significant since the T Value is above 5 generally. Openness and autonomy which are close to 5 and authenticity which is very low, the other four variables are significantly correlated with HRD Climate. Except for experimenting variable which is insignificant.

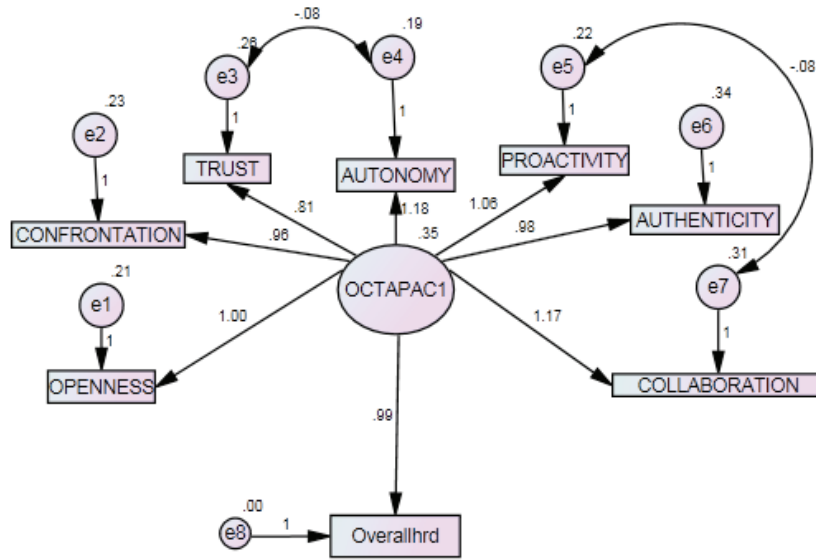


Figure 2: Model validation of the study variables

Table 5 Result of SEM path model

	Observed Vale
Chi Square	126.74
D.F	18
P value	0.000
CMIN/DF	3.546
RMR	0.039
GFI	0.825

Table 6 Regression weights of the study variables

			Estimate	S.E.	C.R.	P
OPENNESS	<---	OCTAPACE1	1.000			
CONFRONTATION	<---	OCTAPACE1	.956	.062	15.475	***
TRUST	<---	OCTAPACE1	.806	.060	13.463	***
AUTONOMY	<---	OCTAPACE1	1.180	.067	17.705	***

Cont... Table 6 Regression weights of the study variables

			Estimate	S.E.	C.R.	P
PROACTIVITY	<---	OCTAPACE1	1.060	.065	16.414	***
AUTHENTICITY	<---	OCTAPACE1	.982	.071	13.892	***
COLLABORATION	<---	OCTAPACE1	1.169	.074	15.862	***
Overall HRD	<---	OCTAPACE1	.985	.044	22.405	***

The above tables and SEM Model further validates that there is significant correlation between OCTAPACE Variables and HRD Climate both at individual level and overall level where chi square is 126.74 with degrees of freedom (df) at 18 and p value less than 0.05. Further the root mean square residual (RMR) of the model 0.039 and Goodness-of-fit statistic (GFI) is closer to 0.9 which indicates a good fit of the conceptual model.

HRD MECHANISMS

In case of HRD Mechanisms the overall mean stands at 3.26 with a standard deviation of 1.06 indicating average degree of implementation. While employee's seriousness towards training scores highest, the seniors helping juniors in utilizing career opportunities scores low. Other mechanisms like: Performance Appraisal, rewards, mentoring, training, feedback etc., show average mean scores highlighting the fact that HRD mechanisms are just working right even though they are not creating very high impact.

IMPLICATIONS OF THIS STUDY

The objective of this study is to reiterate the need for a conducive HRD Climate in terms of OCTAPACE Culture in healthcare industry in the context of increasingly complex business environments which magnify the challenges of human resource management in hospital settings. Collaboration between the hospital management and human resources is critical for the success of both. Hence this study on HRD Climate in carefully select sample of healthcare organizations serves as an indicator to understand the trends based on employee perceptions about HRD Climate in general and OCTAPACE Culture in particular.

Analysis of overall picture shows that only an average HRD Climate exists in these organizations leaving a huge scope for improvement. Category wise implementation of HRD mechanisms seems to be less prevalent while General HRD Climate is more prevalent and OCTAPACE culture is in-between.

Detailed item wise analysis of the findings of the present study has the following implications for the top management and the supervisors:

The top management must concentrate more on proper identification and utilization of employee potential, providing scope for experimenting innovative ideas and extending a helping hand to the juniors in learning the job. The management should educate the supervisors and other management staff on the future of the organization so that they can develop the juniors accordingly.

There is an urgent need to promote the culture of openness where nurses can freely discuss their problems whether personal or official with their supervisors and get help when needed. Supervisors must respond in a matured and understanding manner when nurses commit mistakes by not victimizing them instead extending a helping hand and improving trust. They should provide nurses with authentic feedback on their behaviour.

Nurses should be prompted to voluntarily approach the supervisors to find out their strengths and weaknesses and strive for personal development accordingly. Nurses should be given a sense of autonomy so that they grab the opportunities to shoulder higher responsibilities and prepare themselves for future roles in the organization.

This study highlights the need for more transparency and efficiency in HRD Mechanisms to allay fears of

nurses regarding bias in promotions, ensure appreciation from immediate bosses in case of good work by nurses, gentle way of feedback to nurses on their shortcomings, mentoring of juniors by seniors on career growth opportunities utilization and implementing employee welfare measures to an extent that nurses can concentrate their full energies towards the organizational goals while at work.

Conclusion

The findings of the study highlight the existence of average HRD Climate inspite of reasonable pay, welfare schemes, training programmes and a host of other employee friendly initiatives that too in reputed companies. This study underlines the need for more involvement of top management's time and other resources towards employee development, more transparent HRD mechanisms, an open climate which promotes communication and trust between workmen and superiors need to involve workmen more and more to make them strive for their own development and achievement of organizational goals.

The findings of the study are in line with the existing knowledge of HRD Climate and the present state of affairs in the industry especially regarding attraction of talent, Education and training for executives, keeping pace with technology; and succession and career planning.

The findings also indicate certain positive trends like nurses freely discussing among themselves to solve problems and taking training programs seriously for learning. The top management must make use of them and supplement with required involvement and support. While there is belief in top management about the human resources in their organizations and believe they can be changed at any point of time, there is not enough efforts and action to replicate the same in practice.

This study reiterates the fact that much more can be done by organizations for development of HRD Climate by top management's further involvement in employee development, supervisors showing more concern and maturity in handling nurses and guiding them, seniors mentoring juniors in career development and fine tuning HRD Mechanisms.

The present study has certain limitations that offer scope for future research.

This study has been based on perceptions of nurses of representative sample of healthcare organizations and hence may not be applicable to other types of organizations. Further, the sample consisted only of nurses and further research may be conducted among other groups. The data is based on individual opinion, which may bring in some bias. To improve the acceptability of the results, it needs to be extended to other sectors and public limited companies. The findings of the study are based on the perception of nurses and hence can be used by employers, HR practioners and scholars to know the current trends and further their understanding of HRD Climate existing in healthcare organizations. The study helps the organizations to know and focus on factors they need to address for improvement of HRD Climate. The study while reinforcing the findings of earlier studies also enriches the knowledge on the subject with additional findings and adding current trends.

Ethical Clearance- Taken from research committee of Manipal Academy of Higher Education (MAHE).

Source of Funding- Self

Conflict of Interest - Nil

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Comparative Analysis of Bioactive Molecules in Areca Nut Sourced in Andaman islands and Main Land India

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Abstract

Introduction: Increased prevalence of tobacco related products has been observed in the island territory of Andaman & Nicobar Islands. Chewing tobacco related products is more common than smoking. The predominant component of chewable form is areca nut. Increase in addiction than the population in mainland India could be attributed to the differences in chemical composition of areca nut. The present study intends to delineate the differences in the chemical constituents of areca nuts sourced from Andaman Islands and nuts sourced from India.

Methods: Alcoholic extract of areca nuts sourced from Mettupalayam, India and Port Blair, Andaman & Nicobar Islands were prepared. Bioactive constituents were assessed using Gas chromatography-Mass Spectrometer.

Results: Chromatogram obtained from GC-MS analysis of the areca nuts sourced from Mettupalayam, TamilNadu, India & Andaman Islands revealed peaks for 13 and 3 bioactive chemical compounds respectively.

Conclusion: Remarkable differences have been noted in areca nuts sourced from Andaman Islands with significant increase in the content of arecoline. Increased arecoline content could be the basis for increased addictive nature

Keywords: GC-MS, Andaman, tobacco, areca nut, psychoactive substance

Introduction

Areca nut is the seed of the areca palm commonly known as the betel nut. It is widely used as a chewable product along with various substances depending on the sociocultural and geographic background.¹ The psychoactive substances present in areca contribute to its addictive nature. Areca is native to South Asian countries. Areca catechu species has different varieties exhibiting variable nut characters as shape, size, and attachment to spadix, taste, texture, bearing period and yield.^{2,3}

In a recently conducted study on tobacco related habits in Andaman islands, it was found that the prevalence was significantly high similar to a previous report of 40.9% of population.⁴ This data is much higher than in mainland India. Habituation to tobacco is due to multifarious reasons and there is a complex sociocultural reciprocity. Increased prevalence in the island territory has been attributed to the laidback attitude and easy availability of wild type of areca nuts. Smokeless tobacco consumption is widespread, leads to oral submucous fibrosis which is a long lasting and devastating condition of the oral cavity with the potential for malignancy.⁵

Considering the increased addiction to chewing habits, the core ingredient areca was thought to play a key role. Arecoline present in areca nut is the main psychoactive substance responsible for addictive nature. Its ability to stimulate the nicotinic receptors in brain has been found to be similar to nicotine present in tobacco.⁶ Local environmental conditions could contribute to

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differences in composition of areca nuts. The present study intends to delineate the differences in the chemical constituents of areca nuts sourced from Andaman Islands and nuts sourced from India.

Materials

Areca nut samples were sourced from Andaman Islands and from plantations in Mettupalayam, Tamil Nadu, India. The nuts were powdered using an electric blender without generation of excess heat during the grinding process. Recommendations from CORESTA guidelines were followed during sample preparation.

Methodology

Sample Preparation Procedure:

1. Samples obtained were stored in appropriate conditions as per CORESTA guidelines.
2. Samples were ground using an electronic grinder. About 3grams of tobacco sample were weighed in an analytical weigh machine and was added to 10 ml of distilled water.
3. Samples were filtered using a filter paper after sufficient grinding and then transferred to falcon test tube.
4. 3ml of the sample was stored in ethyl alcohol as preservative before further analysis.
5. Prepared samples were then subjected to Gas Chromatography – Mass Spectrometry Analysis (GC-MS).

Bioactive constituents were assessed using Gas chromatography-Mass Spectrometer at the Sophisticated Analytical Instrument Facility, Indian Institute of Technology, Chennai. The GC-MS analysis was performed using the instrument Agilent 6890N

Gas Chromatography equipped with Jeol GC Mate II spectrometer. Mass spectrometry in conjunction with Gas Chromatography has been reported to be a powerful tool in biological and chemical studies. The Jeol GC Mate II GC-MS with data system is a high resolution double focusing instrument. Maximum resolution: 6000 Maximum calibrated mass: 1500 daltons. Source:

Electron Impact (EI).

GC-MS PROCEDURE:

Gas chromatography (GC) analysis was done using Agilent 6890N gas chromatography equipped with mass selective detector coupled to front injector type 1079. The chromatograph was fitted in HP 5 MS capillary column (30m X 0.25mm i.d., film thickness 0.25m). The injector temperature was set at 220 ° C and the oven temperature was 50° then programmed to 250°c at the rate of 10° per minute and finally held at 250 °c for 5minutes. Helium was used a carrier gas in the flow rate of 1.5ml per minute. 1microlitre of the sample

(diluted with acetone 1:10) was injected to the split mode in the ratio of 1:100. The percentage of composition of the areca nut was calculated using GC peak areas. The mass spectrometer was set at an electron impact mode of 70eV. Ion source and transfer line temperature was set at 250 ° C. The mass spectra were obtained by centroid scan of the mass ranges 40 to 1000 amu. The compounds were found based on the comparison of their retention indices (RI), retention time (RT), mass spectra (MS) of WILEY, NIST library data of GC-MS system and literature data.⁷

Results

Chromatogram obtained from GC-MS analysis of the areca nuts sourced from Mettupalayam, TamilNadu, India & Andaman Islands revealed peaks for 13 and 3 bioactive chemical compounds respectively. (List of samples – Table 1 & Table 2)

Table 1: Compounds estimated in Areca Nut – Tamil Nadu by GC-MS

S.No	PEAK NAME	RT	PEAK AREA	PERCENTGE %	FORMULA	MOLECULAR WEIGHT(g/mol)
1.	3-pyridinecarboxylic acid, 1,2,5,6 tetrahydro 1 methyl methyl ester	9.8	1974308	1.80	C8H13NO2	155.1943
2.	oxacyclotetradeca-4, 11dyine	12.12	5835148	5.34	C13H18O	190.2814
3.	1H-Pyrrollo[2,3-c] pyridine-3- proponic acid 5[4H]-oxo 6,7 dihydro- methyl ester	14.22	1220216	1.11	C11H14N2O3	222.24046
4.	E 9 Tetradecenoic acid	15.05	4033840	3.67	C14H26O2	226.355
5.	Hexadecanoic acid,14- methyl,methy ester	16.3	4033708	3.67	C18H36O2	284.4772
6.	Pentadecanoic acid 14 methyl, methyl ester	17.23	12311688	11.20	C17H34O2	270.4507
7.	Hexadecanoic acid, ethy ester	17.88	5974040	5.43	C18H36O2	284.4772
8.	3 Octadecenoic acid,methyl ester	18.95	26812072	24.40	C19H36O2	296.48794
9.	Heptadecanoic acid , 9 methyl , methyl ester*	19.17	20557160	18.70	C17H34O2	270.4507
10.	E 9 - Octadecenoic acid ethyl ester	19.55	12727000	11.58	C20H38O2	310.5145
11.	10Hydroxy 5,7-dimethoxy- 2,3-dimethy-1,4- anthracenedione	19.77	9685064	8.81	C18H16	312.317
12.	Dasycarpidan 1 Methanol acetate	21.35	2125056	1.93	C20H26N2O2	326.43264
13.	2,7 Diphenyl -1, 6-dioxypyridazino pyrrolo pyridazine	23.32	2636616	2.40	C20H13N5O2	355

Table 2: Compounds estimated in Areca Nut – Andaman by GC-MS

S.no	PEAK NAME	RT	Peak area	Percentage	FORMULA	MOLECULAR WEIGHT
1	3 Pyridinecarboxylic acid, 1,2,5,6 -tetrahydro-1 methyl, methyl ester	9.87	3811804	61.32	C ₈ H ₁₃ NO ₂	155.1943
2	Bicyclo(7.7.0) hexadec-1(9)-ene	16.1	1753382	28.2	C ₁₆ H ₂₈	220.39352
3	Glycine, N-phenylacetyl, ethyl ester	17.72	650386	10.46	C ₁₀ H ₁₁ NO ₃	193.19924

Peak area of each compound in the Chromatogram were calculated. The percentage of each compound was also determined in each sample. The plotted chart shows the percentage of each compound in the chromatogram at different retention time.

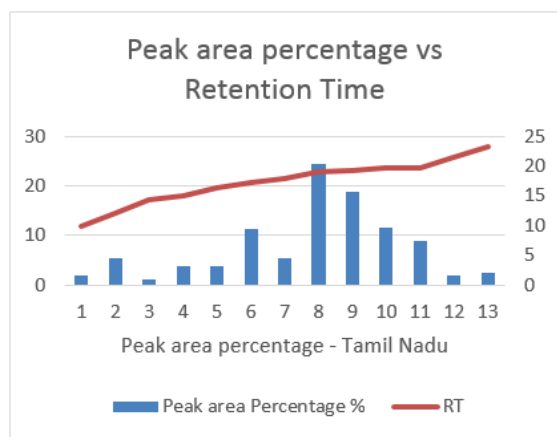


Chart 1: Peak area of areca nut sourced from Tamil nadu

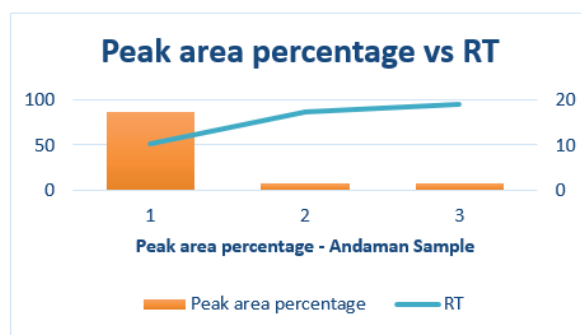


Chart 2 : Peak area of areca nut sourced from Andaman

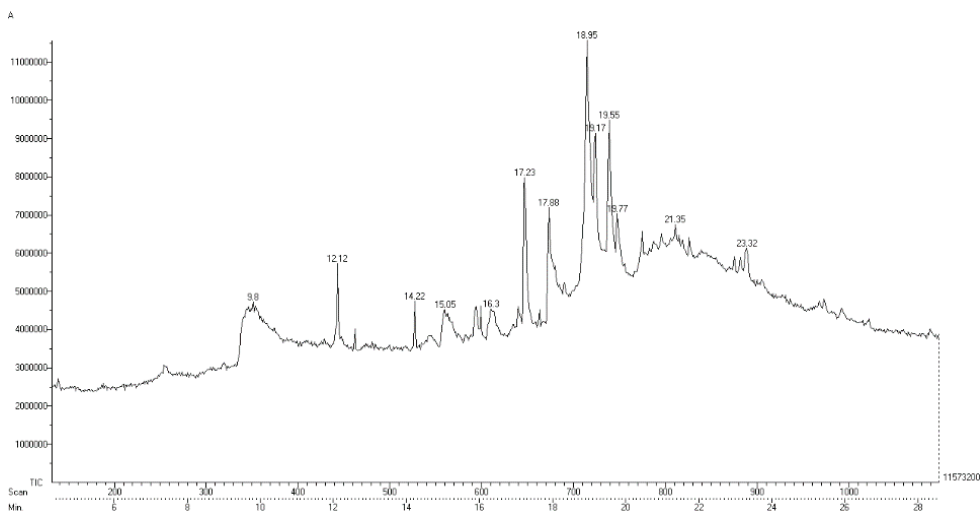


FIG 1 : GC MS of Areca Nut from Tamil Nadu

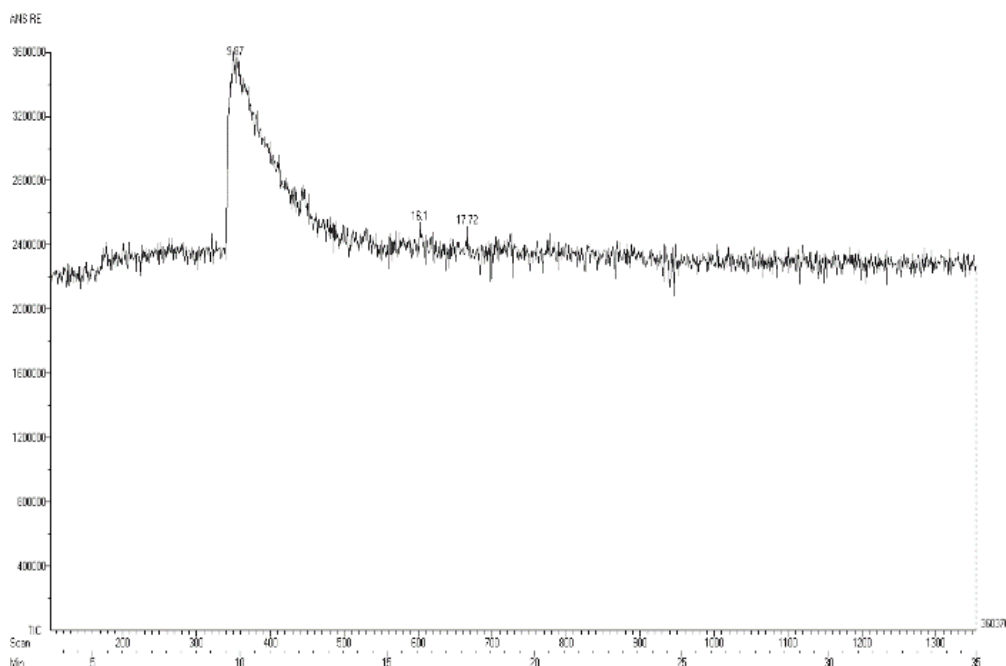


FIG 2: GC MS of Areca Nut from Andaman

Discussion

Areca nut is widely used as for chewing and medicinal purposes. The tree areca catechu grows in tropical climate and is commonly seen in South East Asia. Chewing areca in different forms, betel quid or commercially produced pan masala or gutkha is a common habit in many parts of Asia^{8,9}. And this leads to a variety of negative health outcomes, to the extent of Oro-pharyngeal cancers. Due to the presence of psychoactive substances areca nut chewing is addictive in nature. There are numerous varieties of areca nut in different geographical locations of South East Asia. Therefore, variations in the levels of areca could potentially contribute to the difference in addiction and also carcinogenic potential of the product.¹⁰

Andaman and Nicobar Islands is a union territory of Indian Nation, consisting of more than 500 islands and islets located 1200 km away from main land India. In a recently conducted study on tobacco related habits in Andaman Islands, it was found that the prevalence was very high similar to a previous report of 40.9% of population. The rate of tobacco related dependence was much higher than those reported in India.¹¹ However unlike India, tobacco usage is in the form of chewing rather than smoking. Chewing habits mainly pertain to arecanut. Though chewing habituation occurs due to a variety of reasons, the addictive nature of areca which grows in the island territory needed to be assessed in

comparison with the areca grown in mainland India.¹²

GS-MS analysis conducted with areca sourced from the respective regions revealed differences in bioactive chemical compounds (Chart/Figure 1 and 2). Significantly higher percentage of 3 Pyridinecarboxylic acid, 1,2,5,6 -tetrahydro-1 methyl, methyl ester was found in areca sourced from Andaman Islands. Two other compounds Bicyclo(7.7.0) hexadec-1(9)-ene, Glycine, N-phenylacetyl, ethyl ester were also found only in areca sourced from Andaman islands.

Pyridinecarboxylic acid, 1,2,5,6 -tetrahydro-1 methyl, methyl ester (Ethyl nicotinate) has peripheral vasodilator actions, Bicyclo(7.7.0) hexadec-1(9)-ene (Hexalen) has anticancer properties and Glycine, N-phenylacetyl, ethyl ester (Noopept) has nootropic actions. The bioactive chemicals present in areca sourced from Andaman Islands could have a synergistic addictive action more than the areca sourced from mainland. In another study reported recently wherein they had used liquid chromatography – tandem mass – spectrometry (LC- MS) method for quantification of areca alkaloids showed variations in the levels of alkaloids and the most abundantly found compound was guvacine followed by arecoline, arecaidine etc.¹³ The only common compound with regards to our study is arecoline. This major variation in the compounds could be the reason for the total alkaloid content in each product. These differences in results emphasizes the need for several such studies

and also close observation of the constituent levels of such products is necessary.

Conclusion

Remarkable differences have been noted in areca nuts sourced from Andaman islands with significant increase in the content of arecoline. Increased arecoline content could be the basis for increased addictive nature. However a more detailed study with other modes of areca would help further justification of increased addictive potential of wild type of areca nut sourced from Andaman Islands.

Conflict of Interest: NIL

Source of Funding: Self

Ethical Clearance: Taken from Institutional Review board (IRB) committee of SRM Dental College.

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Relationship of Predisposing and Enabling Factors with Unsafe Action of Nurse in the Inpatient Unit I of Rsud Dr. Saiful Anwar Malang

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Abstract

One of the factors causing occupational accidents and illnesses that occur in nurses in hospitals is a behavioral factor. The study was conducted to study the relationship between Predisposing, Enabling and Reinforcing factors with unsafe behavior of nurses in the inpatient room 1 Dr. Saiful Anwar Malang “. This type of research is a quantitative research with analytic observational design with cross sectional approach. The sample in this study were nurses in Inpatient Room I as many as 42 nurses were analyzed using the *Chi Square Test* and *Fisher Exact*. The method used is to use a questionnaire, observation and interviews. Chi Square test results showed $p = 0.818 > 0.05$ that there is no relationship between knowledge and unsafe actions. Fisher’s exact test results show $p = 0.481 > 0.05$ that there is no relationship between the Occupational Safety and Health policy with unsafe actions, Fisher’s exact test results show $p = 1,000 > 0.05$ that there is no relationship between Standard Operational Procedure and no action safe, Fisher’s exact test results show $p = 0.158 > 0.05$ that there is no relationship between Safety Training and occupational health with unsafe actions. Conducting routine socialization related to Operational Standards Procedures for how to appoint patients, conducting routine supervision related to unsafe actions of nurses when lifting patients, implementing reporting systems related to complaints of low back pain, implementing a reward system for workers who behave safely and punishment for workers who acted insecure.

Keywords: *Relationship, Predisposing, Enabling, Unsafe Behavior, Nurse*

Introduction

The hospital is a public service institution that has a high complexity, both in terms of personnel, services and equipment. The most important element in a hospital is a nurse. Nurses are those who care for or maintain, help, and protect someone because of illness, injury, and the aging process. For nurses, the hospital is one of the dangerous places because it can be infected with various types of risk of occupational diseases and injuries. Hospital leaders as managers must know, understand, and carry out protection for workers who are mostly nurses

One of the factors causing the high number of accidents and illnesses due to work at nurses in hospitals is the behavior factor. Unsafe behavior at work contributes significantly to accidents¹. 64.26% of occupational diseases and work accidents are caused

by low knowledge, understanding and awareness about occupational safety and health². Research which shows that 96% of work accidents are caused by unsafe behavior and 4% are caused by unsafe conditions³

Nurses in carrying out their activities, often do not pay attention to important things that are risk factors for occupational diseases. Occupational diseases can occur while doing work activities. Of the many occupational diseases, musculoskeletal complaints are the most frequently reported complaints. According to WHO the incidence of musculoskeletal diseases is the most common disease and is estimated to reach 60.4% of all occupational diseases. There are several things that cause nurses at risk of developing musculoskeletal disorders (MSDs) namely, nurses often do bending movements in handling patients (repositioning, transferring), helping lift patients with varying body weight without using assistive devices, then how to lift

and transport incorrectly so that it can cause sprains, and sit for too long in a position that is not ergonomic Indonesia, especially in the clinic at Siaga Raya Hospital, an average of 10 nurses per year came to the clinic with complaints of musculoskeletal injury, which is caused by pushing, lifting or transferring patients⁴. Various physical activities of work in nursing care such as frequent bending (twisting) and twisting (twisting), moving or changing the position of patients identified as having a risk that can cause low back pain⁵

Dr. Regional General Hospital Saiful Anwar (RSSA) functions to provide health services to the community, especially to patients in the inpatient ward 1 RSSA which is supported by more than 250 nurses. The results of initial observations and interviews with several nurses at the Regional General Hospital Dr. Saiful Anwar (RSSA) Malang in the inpatient room, there are nurses who experience complaints of back pain when providing services to patients, because of the work factor that is still manual handling, namely lifting patients with varying patient weights, thus requiring over exertion to be able to lift patients .

Conditions like this that can cause musculoskeletal disorders in nurses. This unsafe work behavior, if continually carried out by nurses, risks a serious work accident. Therefore, one of the efforts to prevent work accidents whose biggest cause is unsafe action or unsafe behavior is to implement a Behavior Based Safety (BBS) program as a process of increasing safe work behavior.

Based on this background, the researchers wanted to find out the relationship between Predisposing and Enabling factors with the action element (how to lift patients from a wheelchair to bed) on nurses in the inpatient room of Dr. RSUD. Saiful Anwar (RSSA) Malang.

Material Dan Methods

This research was conducted at Dr. Saiful Anwar (RSSA) Malang in the Inpatient Room I. The data collection process was carried out in January-May 2017. This type of research is a type of quantitative research with an analytical observational design using a cross sectional study approach. The sample in this study were nurses in the inpatient room I at Dr. General Hospital Saiful Anwar Malang as many as 42 nurses. The method used is by questionnaire, observation and interview.

The dependent variable in this study is unsafe behavior (how to lift patients from a wheelchair to bed) in nurses in the inpatient room I. The independent variables in this study are predisposing factors (knowledge), enabling factors (Occupational safety and health policy, standar operational procedure (SOP) and Occupational safety and health training). Data analysis techniques using the *Chi-square test* and *Fisher's exact test*. This study was approved by the ethics committee of RSUD Dr. Saiful Anwar Malang. All subjects received complete information about the procedures and objectives of this study and each subject before the study signed the consent form

Findings

The following are the results of the research presented in tabular form.

Table 1:Relationship Knowledge with Unsafe Action

Knowledge	Unsafe Action				N	Total	p-value
	Safe		Unsafe				
	N	%		%			
Good knowledge	8	40	100%	0,818	20	100%	0,818
Enough knowledge	7	31,8	100%	68,2	22	100%	

Based on table 1.1 shows p-value > 0.05, meaning that there is no relationship between knowledge and unsafe action (unsafe action). There were 15 study subjects (68.2%) who acted unsafe (unsafe action) which were categorized with sufficient knowledge. Research subjects with good knowledge category still acted unsafe (unsafe action) of 12 (60%).

Tabel 2: Relationship Occupational Safety and Health Policy with Unsafe Action

Occupational safety and health Policy	Unsafe Action				N	Total	p-value
	Safe		Unsafe				
	N	%	N	%			
There is a policy	10	32,3	21	67,7	31	100%	0,481
No Policy	5	45,5	6	54,5	11	100%	

Based on table 1.2, the p-value > 0.05 is obtained. This means that there is no relationship between K3 policy and unsafe action (unsafe action), as many as 21 research subjects (67.7%) who say there is a occupational safety and health policy but still take unsafe actions when lifting or moving patients from a wheelchair to bed. Research subjects who said there was no occupational safety and health policy but their actions were safe when lifting or moving patients from a wheelchair to bed were 5 respondents (45.5%)

Tabel 3: Relationship standar operational procedure (SOP) with Unsafe action

Standar Operational Precedure	Unsafe Action				N	Total	p-value
	Safe		Unsafe				
	N	%	N	%			
There are SOP	12	35,3	22	64,7	34	100%	1,000
No SOP	3	37,5	5	62,5	8	100%	

The results of the analysis of the relationship between SOP and unsafe action in table 1.3 show that p-value > 0.05, meaning that there is no relationship between standard operating procedure (SOP) with unsafe behavior (unsafe action) when moving or lifting a patient from a wheelchair to bed. Research subjects who

considered that there were standard operation procedures (SOP) but did not perform safe actions as many as 22 respondents (64.7%). Research subjects who said there were no SOPs with the category of safe action were 3 respondents (37.5%). A valid SOP will not guarantee that research subjects will take safe action.

Tabel 4: Relationship Occupational Safety and Health Training with Unsafe Action

Occupational Safety and Health Training	Unsafe Action				N	Total	p-value
	Safe		Unsafe				
	N	%	N	%			
Have attended training	9	29	22	71	31	100%	0,158
Never attended training	6	54,5	5	45,5	11	100%	

Based on table 1.4, $p\text{-value} > 0.05$ shows that there is no relationship between K3 training and unsafe behavior (unsafe action). Research subjects who had attended OSH training but whose actions when lifting or moving patients from wheelchairs to unsafe beds were 22 respondents (71%). While research subjects who have never attended OSH training in the safe action category were 6 (54.4%)

Discussion

The following is a discussion of the results of statistical tests related to the relationship of independent variables with independent variables.

Relationship Knowledge with Unsafe Action.

The results of this study indicate that there is no relationship between knowledge and unsafe actions (unsafe actions), research subjects who have good knowledge and who have sufficient knowledge mostly do unsafe actions. The better a person’s knowledge, then does not indicate the better one’s actions. Increasing someone’s knowledge does not always cause changes in worker behavior, because in the process many people know but few implement it in real form. This is influenced by the habits and culture of each individual.

Research subjects in the category of good and sufficient knowledge actually most of the unsafe actions (unsafe action). Based on observations, this is because respondents already know that the work they do is not safe, but they still do that on the grounds they are familiar with the condition even though in an unsafe way. The results of this study are in line with the results of previous studie⁶ “Analysis of Behavioral Safety Program with Unsafe Action in the Production Department 11 PT. Petrochemical Gresik “. The results of the analysis of the influence test show that the value of $p > 0.005$, meaning that there is no influence between knowledge and unsafe

action. A good level of knowledge does not guarantee that someone will behave safely.

These results are not in line with existing theories that behavior based on knowledge will be more lasting (long lasting) compared to behavior that is not based on good knowledge. Knowledge is one of the predisposing factors related to the motivation of individuals or groups to act.⁷

Relationship Occupational safety and health Policy with Unsafe Action.

The role of management has a direct bearing on occupational health and safety because management has control and provides work instructions. Management is required to be able to guide and control health and safety issues in the workplace⁸. One way is to form policies and regulations.

The majority stated that there was a occupational safety and health policy made by the hospital but still unsafe action (unsafe action). The existence of a Occupational safety and health policy will not necessarily increase safe actions on research subjects. The OSH policy made by the hospital is not to improve behavior. The OSH policy in writing is to set forth a hospital policy regarding the implementation of OSH in an organization whose function is to provide information to hospital workers, hospital visitors, and those who collaborate with hospitals. The written OHS policy is not intended to improve behavior about OHS

but is informational.

Based on observations in Irna 1 room at Dr. Saiful Anwar Malang, there are some rooms where the Policy is not posted in an easily visible place. Based on the results of the interviews, it was found that there was a policy, but for information documents such as SOP and policies, it was stored on a shelf because there were too many documents if they were posted on the wall, so that many did not know about them.

Relationship Standard Operational Procedure (SOP) with Unsafe Action.

Availability of facilities/ infrastructure and regulations are enabling factors for the formation of behavior⁹; by implementing SOP, the organization can ensure that an operation runs according to existing procedures and if the SOP is implemented properly, the organization will get many benefits from the application of the SOP¹⁰. Therefore, SOP plays an important role in meeting work standards that are organized, with the achievement of the objectives of implementing SOP the better the performance and quality of the organization.

Research subjects assessing that there are SOP lifting or transferring patients from wheelchairs to beds in the category of unsafe acts. This is based on the observation that when lifting or moving a patient from a wheelchair to bed, there are still many research subjects who do not carry out or refer to the correct SOP, so it is possible to act unsafe when providing services to patients.

The results of the interview by the head of the inpatient room 1, found information that there are standard operating procedures (SOP) in inpatient room 1, but there are still those who say that there are no standard operating procedures (SOP), this indicates that there is still a lack of socialization by parties management related to standard operating procedures (SOP) in each room. SOP storage in the form of documents in each room causes some research subjects to not know the existence of the SOP. The SOP is stored in a rack.

Relationship Occupational safety and health Training with Unsafe Action

Research subjects who said they had attended OSH training, with the category of still acting unsafe. The training that has been obtained by nurses will not necessarily improve one's behavior, this is because the

training is held to fulfill the hospital's accreditation only. However, that does not mean that training is not needed to increase knowledge and encourage workers to act safely. The training provided by the RSUD Dr. Saiful Anwar Malang to nurses, especially to new nurses, one of which was the training of patients for the purpose of fulfilling hospital accreditation.

One of the biggest causes of safety training cannot run properly because there is often no match between the requirements for training success and the training provided, safety training programs are often not in accordance with the needs of trainees¹¹. One reason is that training time is not enough to guarantee understanding complex issues. Effective safety training is important to educate employees how to prevent accidents and identify potential hazards in their work. Therefore training and education programs play an important role in increasing safety awareness^{12 13}

Conclusion

There is no relationship between predisposing factor (knowledge) with unsafe action (how to appoint patients) to nurses in the inpatient room 1 of the Regional General Hospital Dr. Saiful Anwar Malang (RSSA) “.

There is no relationship between enabling factors including (policies, SOPs and training) with unsafe actions for nurses in the inpatient ward 1 Regional Hospital Dr. Saiful Anwar Malang (RSSA) “.

Conflict of Interest: None

Source of Funding: Source of Funding-self

Ethical Clearance: The study was approved by the ethical committee of Hospital Dr. Saiful Anwar Malang. 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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Assess the Effectiveness of Information Module on Awareness of cervical cancer among women residing at Loni Bk village

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Abstract

Introduction: Cervical cancer a major problem in developing countries. Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Cancer is caused by both external factors (tobacco, infectious organisms, chemicals, and radiation) and internal factors (inherited mutations, hormones, immune conditions, and mutations that occur from metabolism). The study was carried out to determine the effectiveness of Information Module on awareness of cervical cancer among women.

Material and Methods: Using a Quasi experimental study, pre-test post-test design without control group approach was used. Non Probability sampling technique was used for selecting 380 women at Loni (Bk). Data was collected with help of pretested dichotomous questionnaire on knowledge on cervical cancer and after collecting the base line data and pretesting, the information module were provided to the participants followed by the post test was carried out on 10th day. The collected data were organized, tabulated and analysed by using descriptive and inferential statistics methods wherever required.

Results: Socio-demographic Characteristics Showed that maximum numbers of 182 (45.50%) women were from age group of below 35 years, 182 (45.5%) had a primary education, 301(75.25%) of women are Hindu, 348(87%) women live in nuclear family, 380(95%) of women are married, 374(93.5%) of mothers were house maker, 353(88.25%) of women have monthly family income of 3.5,547 – 9,248 Rs, 171(42.75%) women have menarche age of 13 year, 380(95%) of women were married at the age of 18-25, 245(61.25%) women conceived for the first time at the age of 18-25. The mean post test score 22.18(SD=2.23) was higher than the mean pretest score 11.6(SD=2.5) .The computed t-test statistic value is 65.94, Corresponding p-value was 0.000, which is small (less than 0.05). It shows that the information module was effective method for improving the knowledge of women regarding cervical cancer. Association between the awareness on cervical cancers with their selected socio demographic variables results showed that p value is less than 0.05 there was no significant association between the awareness on cervical cancers with their selected socio demographic variables of women.

Conclusion: Majority of women had poor knowledge. This study highlighted the importance of awareness creation, increasing knowledge, promoting active searching for health information and experiences of receiving information from any information sources regarding cervical cancer.

Key terms: *Effectiveness, Information Module, Awareness, cervical cancer, and women*

Introduction

Cancer is a group of diseases characterized by uncontrolled growth and spread of abnormal cells. If the spread is not controlled, it can result in death. Cancer

is caused by both external factors (tobacco, infectious organisms, chemicals, and radiation) and internal factors (inherited mutations, hormones, immune conditions, and mutations that occur from metabolism). These causal factors may act together or in sequence to initiate or

promote carcinogenesis. Ten or more years often pass between exposure to external factors and detectable cancer. Cancer is treated with surgery, radiation, chemotherapy, hormone therapy, biological therapy, and targeted therapy.¹

The current Indian population is 1.27 billion. The incidence of cancer in India is 70-90 per 100,000 population and cancer prevalence is established to be around 2,500,000 with over 800,000 new cases and 5,50,000 deaths occurring each year.²

Incidence of cervical cancer is still very high in India as compared to western countries. It is the commonest genital malignancy and leading cause of women's mortality. It is very unfortunately to see so many cervical cancer patients in India when there are preventive and screening methods available. The screening method is cheap but still not used as a national screening method in our country.³

In India, cervical cancer is one of the most common causes of cancer-related deaths. According to National Institute of Cancer Prevention and Research, one woman dies of cervical cancer every 8 minutes in India.⁴

According to the ICMR (2012-2014), the annual percentage change (APC) over time in incidence of cervical cancer in Bengaluru at 2.26%, Bhopal(-1.81%), Chennai(-.48%), Delhi(-2.73%) and Mumbai(-1.99%). All these regions showed a significant decrease for annual average rate for 3-5 years.

A study done by Koshy G, Gangadharan V, Naidu .on assess the knowledge and attitude of female graduate students on cervical cancer According to present study, 93% of medical, 75% of nursing and only 29% of engineering students and 9 % of other students were actually even aware of the term cervical cancer. Assessment of knowledge regarding the risk factors of cervical cancer revealed that 13 medical, 9 nursing, 75 of engineering and 85 of Other Graduates weren't aware of any risk factor that causes cervical cancer. As regards to attitude of the students towards cancer, present study revealed 4 medical, 23 nursing, 10 engineering and 9 general public women think that it is incurable and leads to death.⁵

A study done by Ashok Kumar on Effectiveness

of an Informational Booklet on Prevention of Cervical Cancer in Terms of Knowledge and Attitude of Female College Students.. According to present study findings suggest that the mean post-test knowledge score (25.9) was significantly higher than mean pre-test knowledge score (20.2) at $p < 0.05$. The subjects after exposure to the informational booklet gained a significantly higher attitude score (96.56 versus 68.11 at $p < .05$.) The study concluded that informational booklet was effective in enhancing knowledge as well as modifying the attitude of female college students on prevention of cervical cancer.⁶

Materials and Methods

Study Setting and Design: In view of the nature of the problem selected for the study and objective to be accomplished evaluative research approach was considered. A Quasi experimental study, pretest-posttest design without control group approach was used. Independent variable of the study was information module for a woman regarding cervical cancer, and knowledge scores as measured by structured questionnaires was dependent variable. Study was done in the Loni Bk village, Rahata Taluka, Ahmednagar District, Maharashtra, India.

Sample Size, Sampling Technique, Study duration and Study Population:

Expected proportion of women was taken. The sample of the study and taking absolute precision of 9% and Confidence interval of 95% the sample size was found to be 380. The study participants were selected by Non-Probability sampling method by convenience sampling. During the study period 380 consecutive women who consented for the study were enrolled. Ethical approval from the Institutional ethics committee of PIMS-DU, Loni (BK) was obtained (**Ref. No: PIMS/CON/2016/132**). After an extensive review of literature and with the help of experts structured knowledge questionnaire was prepared to assess the level of knowledge of women regarding the cervical cancer.

The tools consist of two sections:

Section I: Demographic characteristics of cervical cancers among the women

Section II: Dichotomous Questionnaire on

Knowledge on Cervical Cancer

Data Collection

Prior approval was obtained from the Institutional Ethics/Research Committee of PIMS (DU), written permission was sought from Sarpanch, Gram Panchayat, Loni (Bk) and the informed consent were obtained from the participants. Day 1st Data collection was done by using Dichotomous Questionnaire On Knowledge On Cervical Cancer and after collecting the base line data and the pretest; the information module were provided to the participants followed by the posttest on day 10th. Women actively participated and cooperated during data collection.

Data Analysis

The data obtained was analyzed in terms of the objective of the study using descriptive and inferential statistics. The plan of data analysis was developed under the excellent direction of experts in the field nursing and statistics.

The plan of data analysis was as follows:

1. Organization of data in a master sheet.
2. Tabulation of data in terms of frequency, percentage, mean, standard deviation (SD), median, and range to describe the data.
3. Classifying knowledge scores using mean and standard deviation (SD) as follows:

$$(SD+X) = \text{Good}$$

$$(SD+X) - (SD-X) = \text{Average}$$

$$(SD-X) = \text{Poor.}$$

A score of one was awarded to all correct answers while score of zero was awarded to all incorrect answers of structured questionnaire.

1. Inferential statistics were used to draw the following conclusions: Paired t-test was used for testing effectiveness of information module on knowledge of women, and Chi-square test was used to find association.

Results

Section A: Distribution of women according to socio-demographic variables.

The distribution of women according to socio-demographic variables, data shows that maximum numbers of 182 (45.5%) women were from age group of below 35 years, 182 (45.5%) had a primary education, 301(75.25%) of women are Hindu, 348(87%) women live in nuclear family,380(95%) of women are married, 374(93.5%) of mothers were house maker, 353(88.25%) of women have monthly family income of 3.5,547 – 9,248 Rs, 171(42.75%) women have menarche age of 13 year, 380(95%) of women were married at the age of 18-25, 245(61.25%) women conceived for the first time at the age of 18-25.

Section B: Distribution of women according to knowledge scores on cervical cancer.

Figure: 1. Pre test and post test score regarding awareness on cervical cancers among the women.

Above figure shows that in pre-test majority 4 (1.05%) woman had good knowledge and 333(87.63%) had average knowledge, respectively, and 43 (11.32%) had poor knowledge regarding cervical cancer. Where as in post-test majority 368 (96.84%) woman had good knowledge, 12 (3.16%) had average knowledge and 0 (0%) women had poor knowledge regarding cervical cancer.

Section C: Testing of Hypothesis (H1) for evaluation of the Effectiveness of Information Module on Awareness among women regarding cervical cancer.

Table No 1

Knowledge level	Mean	SD	t-value	P-Value	Remark
Pre-Test	11.62	2.52	65.94	<0 .00001	Significant
Post-test	22.18	2.23			

Table No 1. Pre test and post test mean score after intervention

Above table shows that there was a significant increase in post-test scores of women. The mean post-test knowledge score 11 ± 2 of women was significantly higher than their pre-test knowledge score 22 ± 2 . The computed t-test statistic value is 65.94, Corresponding p-value was 0.000, which is small (less than 0.05), and the null hypothesis is rejected. It shows that the information module was effective method for improving the knowledge of women regarding cervical cancer.

Section C: Association between the awareness on cervical cancers with their selected socio demographic variables. Chi-square test was used to find the association between the awareness of cervical cancer with their women with selected socio demographic variables. The results showed that p value is less than 0.05 there was no significant association between the awareness on cervical cancers with their selected socio demographic variables of women.

Discussion

This study was a quasi-experimental study; pretest-posttest design without control group approach was used to assess the Effectiveness of Information Module on Awareness among women regarding cervical cancer. The mean post test score $22.18 (SD=2.23)$ was higher than the mean pretest score $11.62 (SD=2.51)$. The computed t-test statistic value is 65.94; Corresponding p-value was 0.000, which is small (less than 0.05). It shows that the information module was effective method for improving the knowledge of women regarding cervical cancer.

A same study was conducted by Ms. S. Shakila, Dr. S. Rajasankar, Dr. N. Kokilavani. A study to assess the Knowledge regarding Cervical Cancer among Women. The study design was univariate research design was used for the study. An objective for study is To assess the level of knowledge regarding cervical cancer among women and to find out the association between knowledge score regarding cervical cancer with selected demographic variables of women. The study was conducted in Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research. Kanchipuram district. Univariate research designs were adopted for this study. The convenient sampling technique was used to select the

fifty samples. The data were collected by administering the structured knowledge questionnaire on cervical cancer to assess the level of knowledge among women. The result showed that majority 35(70%) had inadequate knowledge of 15(30%) had moderately adequate knowledge regarding cervical cancer among women. It was statistically proved that education, religion and source of information are significant association ($P < 0.05$) with knowledge score of women. There by H1 is accepted for selected demographic variables. The demographic variables like age, occupation, income, and number of children, are not significant association at ($P > 0.05$). Hence H0 is accepted. The study finding revealed that it's the responsibility for the health professional to create awareness to all women regarding cervical cancer and to develop desirable attitude to practice healthy behaviour and will help to reduces the morbidity and mortality rate of cervical cancer. Factors like education and source of information helps to develop desirable attitude and knowledge regarding cervical cancer. The study stated that knowledge level and understanding of cancer as well as its preventable nature should be improved consisting nurse education may strengthen cervical cancer screening programme Health care professional has to create awareness of disease can educate masses and increase health seeking behaviour women.⁷

Conclusion

Results of the study conclude that awareness of women on cervical cancer was inadequate in pre-test but then after the administration of information booklet there was an increase in the awareness about cervical cancer, so STP was effective in increasing the awareness of women regarding cervical cancer.

Source of Funding: Self

Conflict of Interest: None

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Longitudinal Study of Systolic and Diastolic Blood Pressure among Hypertension Population Aged 26-59 years in West Java Province, Indonesia

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Abstract

Background: The untreated and/or uncontrolled hypertension will be dangerous, because of the leading cause of the increasing morbidity and mortality. Other determinant factors for reducing blood pressure besides antihypertensive medication are expected to have an impact on the hypertensive population, but little has been achieved in the understanding of dynamics of changes in blood pressure on a population level.

Objective: To investigate the dynamics of changes in systolic and diastolic blood pressure among hypertension population aged 26-59 in Kebon Kalapa Village, West Java Province, Indonesia for 3 years' observation (year 2015-2017).

Methods: This study used secondary data from the 'Cohort Study of Non-Communicable Disease Risk Factors' conducted in Kebon Kalapa Village-West Java Province in 2015-2017. The population in this study was taken from individuals with hypertension wherein year the 2015 aged 26 to 59 years, and total sample obtained for analysis was 208 respondents.

Results: In This study, 87% hypertensive people were pre-elderly. The variable of age, BMI, sodium intake and stress the simultaneous influence of SBP and DBP changes ($p < 0.05$). The increasing age of 1 year will increase DBP of hypertensive people aged 26-59 years by 1 mmHg after multivariable adjustment. Meanwhile, the increase of SBP by age could not statistically be predicted by fixed effects regression models. The magnitude association between BMI and blood pressure shown a one unit BMI increase was associated with 2,47mmHg SBP and 1.03mmHg DBP after multivariable adjustment.

Conclusion: For Indonesian, our analysis suggests for including the information about the BMI changes in the hypertension monitoring reports, as indicators of early awareness of risk factors and prognostic factors for increased blood pressure.

Keywords: *longitudinal, systolic, diastolic, hypertension.*

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Introduction

Hypertension (HT) known as high blood pressure, is a condition in which the systolic blood pressure equal to or above 140 mm Hg and/or diastolic blood pressure equal to or above 90 mm Hg¹. The untreated and/or uncontrolled HT will be dangerous, because of the leading cause of the increase of cardiovascular risk,

onset of vascular and renal damage, and mortality². The number of important causal factors for HT complication have been identified, such as obesity, excess sodium intake, unhealthy diet, family history of hypertension and low socioeconomic status^{3,1}.

Worldwide, hypertension is estimated to cause 7.5 million deaths, about 12.8% of the total of all deaths. Complications of hypertension account for 9.4 million deaths worldwide every year. Hypertension is responsible for at least 45% of deaths due to heart disease, and 51% of deaths due to stroke¹. In Indonesia, prevalence of hypertension increased from 25.8% in 2013 to 34.1% in 2018. The prevalence of hypertension is highly age dependent. A prevalence of 13.2percent among adults 18–24 years of age rises to 45.3percent among pre-elderly⁴. Hypertension and its complications are the 5th leading cause of death for all ages in Indonesia⁵.

Treating systolic and diastolic blood pressure to achieve the normal level is associated with a decrease in cardiovascular disease complication. In the clinical trial study, antihypertensive therapy has been associated with reduction in heart failure (averaging more than 50%), stroke incidence (averaging 35-40%), and myocardial infraction (averaging 20-25%). It is estimated that in patients with stage one hypertension and additional cardiovascular risk factors, achieving a sustained 12 mmHg reduction in systolic blood pressure over 10 years will prevent 1 death for every 11 patients treated. In the added presence of cardiovascular disease or target organ damage, only 9 patients would require such blood pressure reduction to prevent 1 death³.

Other determinant factors for reducing blood pressure besides antihypertensive medication are expected to have an impact on the hypertensive population, but little has been achieved in understanding of dynamic of changes in blood pressure on a population level. In Indonesia, longitudinal study that focuses on the dynamics of changes in blood pressure in a hypertensive population as a treatment strategy for controlling blood pressure is not much. The objective of study was to investigate the dynamics of changes in systolic and diastolic blood pressure among hypertension population aged 26-59 in Kebon Kalapa Village, West Java Province, Indonesia for 3 years' observation (year 2015-2017).

Methods

This study used secondary data from the 'Cohort Study of Noncommunicable Disease Risk Factors'

conducted by the National Institute of Health Research and Development, Indonesian Ministry of Health in Kebon Kalapa Village-West Java Province in 2015 until 2017. The population in this study was taken from individuals with hypertension where in the year 2015 aged 26 to 59 years who enrolled in the cohort study (N = 389). The reproductive woman who used hormonal contraception (n = 131) and whose data were not available at the follow-up in three years (missing data, n = 50) were excluded from the study sample. Thus, the total number of individuals included in this study was 208.

Hypertension status assessed through systolic blood pressure (SBP) ≥ 140 mmHg, and/or diastolic blood pressure (DBP) ≥ 90 mmHg, and/or diagnosis of hypertension by a health professional, and/or undergoing treatment for hypertension. Blood pressure (SBP and DBP) was considered as the dependent variable. The number of SBP/DBP are mean by double measuring the SBP/DBP within 5 minutes under appropriate condition. The independent factors were age, nutritional status, sodium dietary intake, and mental health status/stress. Sodium dietary intake was obtained using 24-hour recall. The nutritional status was measured with a body mass index (BMI) parameter. BMI was calculated as body weight in kilograms divided by the height in meters squared. Mental health status/stress assessed using a self-report questionnaire. Data processing involved cleaning and transforming data and was performed by univariate, bivariate using ANOVA or Friedman test, and multivariate using panel data regression.

Results

The characteristic of adult and pre-elderly with hypertension

The sociodemographic, health and nutrition characteristic among hypertensive adult (aged 26-44years) and hypertensive pre-elderly (aged 45-59years) in the first observation (year 2015) present in Table 1. The result shown that pre-elderly has the highest proportion of hypertension population (87%) compared to adult (13%). Generally, characteristic among hypertensive adult and hypertensive pre-elderly are similar, where most of them are female, employment, obese, diastolic blood pressure above 90 mmHg, sodium intake was normal, and not stress. Meanwhile, for the level of education and systolic blood pressure show different. Most of hypertensive adult had higher

education and systolic blood pressure below 140 mmHg, but characteristic of hypertensive pre-elderly show vice versa.

The observational data on SBP, DBP, BMI, sodium dietary intake and mental health for three years (year 2015-2017) presented in Table 2. It was shown that all means of SBP were above 140mmHg, all means of DBP were above 90 mmHg, all means of BMI were in the overweight category ($>25\text{kg/m}^2$), all of SRQ score means were less than 6 (in not stress category), and means of sodium intake in the year 2015 until 2016 shown $\leq 2300\text{mg/d}$ (normal sodium intake), while in the year 2017 the mean shown $>2300\text{mg/d}$ (excessive sodium intake). The mean difference between time observation was proved statistically significant only for variable DBP, sodium intake and scores of SRQ (p value <0.05).

The pattern of SBP and DBP changes

The pattern of SBP among the hypertensive population, according to age shown tendency to increase with age. The mean SBP was 127.42mmHg among hypertensive people aged 26-30 years, and the mean

SBP increase to 151.05 mmHg in hypertensive people aged 61-65years. Whereas for the mean DBP seen to increase until the age of 41-45 years (97.51 mmHg) and thereafter seen to decrease to 91.26mmHg in aged 61-65years (Picture 1.a). According to BMI level, the pattern of SBP and DBP changes tend to increase with increasing BMI level (Picture 1.b). Mean SBP and DBP in lean hypertensive people were 142.04mmHg and 82.86mmHg respectively. The highest mean SBP and DBP were seen among obese hypertensive people, i.e. 150.23 mmHg and 95.86mmHg respectively. The similar pattern was also seen in DBP changes according to sodium dietary intake, which tendency to increase with increasing amount of sodium dietary intake, meanwhile the pattern for SBP seen fluctuate, decline in the amount of 75-1500mg/d sodium intake and then slight increase in the higher amount of sodium intake (Picture 1.c). The fluctuate pattern of SBP and DBP changes according to the score of SRQ can be seen in Picture 1.d. SBP seen the decrease in SRQ score 6-10, but thereafter seen to increase with the increasing SRQ score, in DBP changes also seen a decrease in SRQ score 6-10, and then increase in SRQ score 11-15, and after that sharply decrease in SRQ score 16-20.

Table 1. Characteristic of hypertensive adults and pre-elderly in years 2015

Variable	Hypertensive Adults (N=27)		Hypertensive Pre-Elderly (N=181)		
	n	%	n	%	
Sex					
Male	11	40.7	62	34.3	
Female	16	59.3	119	65.7	
Education Level					
Low (no education-junior high school)	9	33.3	124	68.5	
High (high school-college)	18	66.7	57	31.5	
Employment status					
Unemployment	2	7.4	8	4.4	
Employed	25	92.6	173	95.6	
Nutritional Status					
Lean ($<18.5\text{ kg/m}^2$)	0	0.0	3	1.7	
Normal ($18.5\text{-}25.0\text{ kg/m}^2$)	7	25.9	61	33.7	
Overweight ($25.1\text{-}27.0\text{ kg/m}^2$)	0	0.0	40	22.1	
Obese ($>27.0\text{ kg/m}^2$)	20	74.1	77	42.5	

Cont... Table 1. Characteristic of hypertensive adults and pre-elderly in years 2015

Systolic Blood Pressure					
≥ 140 mmHg	13	48.1	136	75.1	
<140 mmHg	14	51.9	45	24.9	
Diastolic Blood Pressure					
≥ 90 mmHg	20	74.1	95	52.5	
<90 mmHg	7	25.9	85	47.5	
Sodium intake					
Normal (≤ 2300 mg/d)	16	59.3	139	76.8	
Excess (> 2300 mg/d)	11	40.7	42	23.2	
Mental Health Status					
Stress (SRQ <6)	2	7.4	25	13.8	
Not stress (SRQ ≥6)	25	92.6	156	86.2	

SRQ=self-report questionnaire

Table 2. Mean of SBP, DBP, BMI, sodium intake, score of SRQ in years 2015-2017

Variable	Year	N	Mean	Min.	Max.	P value
SBP (mmHg)	2015	208	149.39	99.00	237.50	0.416
	2016	208	147.39	94.50	231.50	
	2017	208	148.73	103.50	228.50	
DBP (mmHg)	2015	208	90.98	65.50	121.00	0.0001*
	2016	208	94.54	64.50	134.50	
	2017	208	93.86	70.00	136.50	
BMI (kg/m ²)	2015	208	26.91	16.08	40.59	0.316
	2016	208	27.05	15.83	41.59	
	2017	208	26.95	13.97	42.39	
Sodium Intake (mg/d)	2015	208	1831.64	96.00	8354.00	0.0001*
	2016	208	1770.86	190.53	8598.09	
	2017	208	2340.79	206	6843	
Mental health (A score of SRQ)	2015	208	2.54	0	18	0.013*
	2016	208	1.84	0	12	
	2017	208	2.13	0	15	

SBP=Systolic blood pressure; DBP=diastolic blood pressure; BMI=body mass index; SRQ= self-report questionnaire

*Significant at P value <0.005

SE=standard error; Prob.=probability; BMI=body mass index.

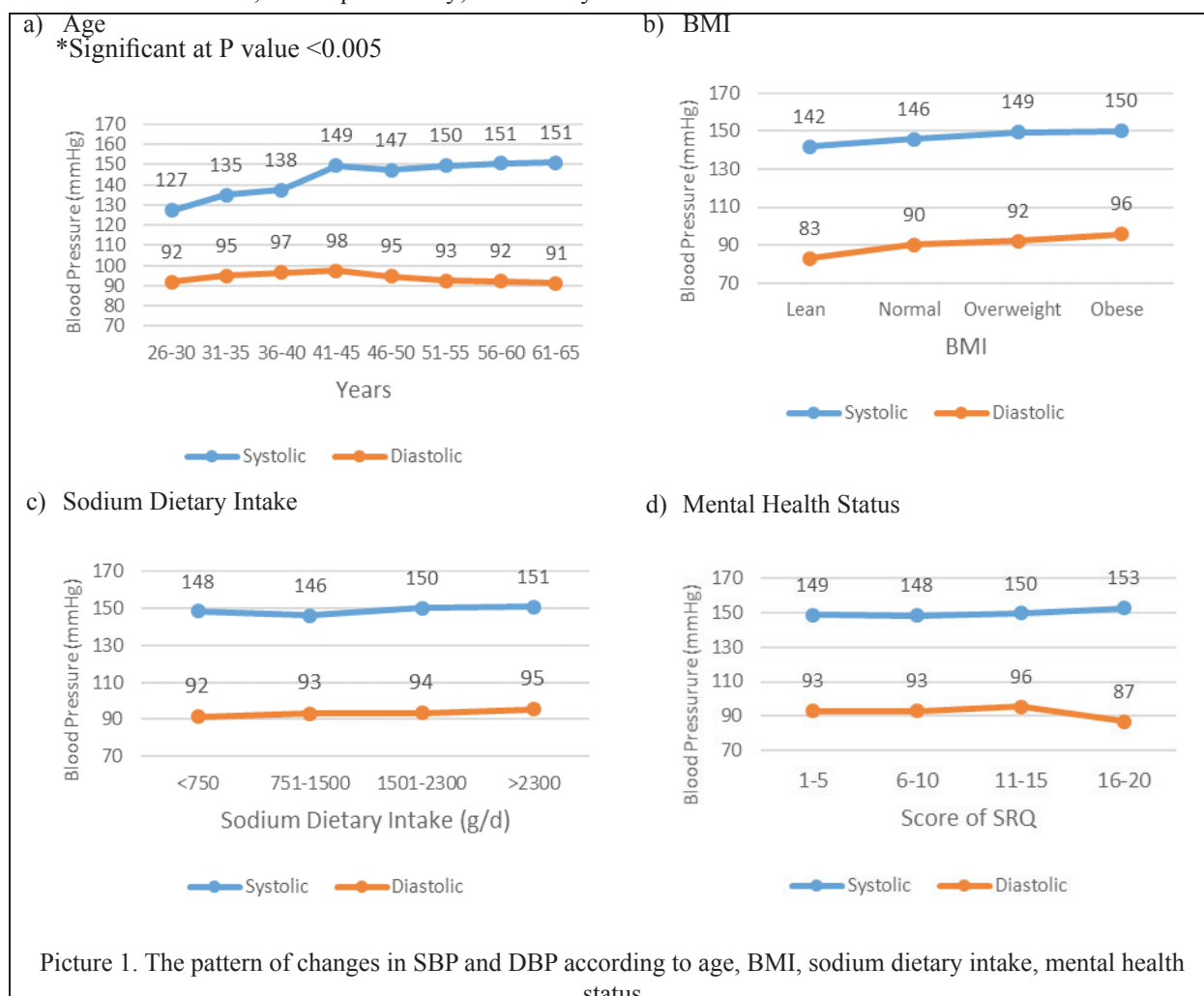


Table 3. Fixed effect model of systolic/diastolic blood pressure with age, nutritional status, sodium intake and stress

	Coefficient	SE	Prob.	Prob. (F-statistic)	Adjusted R2	R2
Systolic blood pressure						
Constanta	113.328	38.43	0.0034*	0.0001*	54,86%	0,70
Age	-0.646	0.67	0.3335			
BMI	2.472	0.60	0.0001*			
Sodium Intake	0.001	0.00	0.0564			
Stress	0.113	0.29	0.6997			
Diastolic blood pressure						
Constanta	-7.589	21.12	0.7195	0.0001*	55,41%	0,71
Age	1.379	0.37	0.0002*			
BMI	1.027	0.33	0.0020*			
Sodium Intake	0.000	0.00	0.4876			
Stress	0.089	0.16	0.5789			

The dynamic of changes in systolic blood pressure and diastolic blood pressure

To quantify the relationship between independent variables and dependent variable we were using regression panel data. Panel data is better suited than cross-sectional data for studying the dynamic of change of blood pressure (SBP and DBP). Based on the result of the Hausman test (SBP: p value = 0.0134; DBP: p value = 0.0009), the best model to describe the changes of SBP and DBP was fixed effect model (FEM).

The result of FEM to describe the dynamic of SBP changes shown in Table 3, it indicated that variable of age, BMI, sodium intake and stress are simultaneous influence to SBP proved statistically significant ($p < 0.05$). The magnitude of influence was 54.86%, while the remaining 45.14% was the influence of other factors outside the model, and the ability of the predictor variable is strong in explaining the change of systolic blood pressure ($R^2 = 0.7$). Based on the panel data regression equation (**SBP = 113.33 - 0.65 Age + 2.47 BMI + 0.001 Sodium Intake + 0.11 Stress**), it can be interpreted that if BMI increases by 1 kg/m², the systolic blood pressure will increase by 2.47 mmHg after adjusting for age, sodium intake and stress.

Table 3 also presented the dynamic of change of DBP was the simultaneous influence of variable of age, BMI, sodium intake and stress, it proved statistically significant ($p < 0.05$). The magnitude of influence was 55.41%, while the remaining 44.59% were influence by other factors outside the model, and the ability of the predictor variable is strong in explaining the change of diastolic blood pressure ($R^2 = 0.7$). The panel data regression equation (**DBP = -7.59 + 1.38 Age + 1.03 BMI + 0.00 Sodium Intake + 0.09 Stress**), can be interpreted that if BMI increases by 1 kg/m², the diastolic blood pressure will increase by 1.03 mmHg, after adjusting for age, sodium intake and stress. The regression equation also shown if age increases by 1 year, the diastolic blood pressure will increase by 1.38 mmHg, after adjusting for BMI, sodium intake and stress.

Discussion

Blood pressure is a variable that is always changing in individuals during the follow-up period⁶. The relationship between blood pressure level and mortality has been investigated in many studies^{7,8,9}. Our study confirmed the previous findings for a number of important causal factors for blood pressure changes,

namely age¹⁰, BMI^{11,12}, sodium intake¹³ and mental health status/stress¹⁴. Those factors proved statistically significantly simultaneously influencing the changes of SBP and DBP. Actually, the blood pressure regulation originates from a complicated interaction of genes and several environmental risk factors, including the factors previously mentioned (aging, elevated BMI, elevated sodium intake, and stress)¹⁵.

Some genetically related factors could include inappropriately high activity of the renin-angiotensin-aldosterone system and the sympathetic nervous system as well as susceptibility to the effect of dietary salt on blood pressure can be one of the causes of hypertension¹⁶. Many studies have documented that dietary salt intake level positively associated with the blood pressure level^{17,18}. A high salt intake induces a slight increase in $[Na^+]_p$ and/or $[Na^+]_{csf}$ which, when sensed by the lamina terminalis sodium/osmoreceptor, triggers, in susceptible individuals, the hypothalamus neuromodulatory signaling chain, activating the sympathetic nervous system. An increased activity of the sympathetic nervous system in the kidneys results in increased renin secretion and renal tubular sodium reabsorption and, consequently, in a shift to the right of the pressure natriuresis relationship is due to an increased activity of the renal sympathetic nerves, and ultimately can increase blood pressure¹⁹. In this study, although the pattern of SBP and DPB mean showed an increase with elevated sodium intake (Picture 1.c), however the increase in blood pressure of sodium intake could not predict statistically with a fixed effects regression model. The magnitude of the relationship between stress and blood pressure also cannot be predicted by the fixed effects regression model.

Blood pressure increases with age²⁰, this is another common cause of hypertension and mostly related to changes in arterial and arteriolar stiffness²¹. An age-related increase in systolic blood pressure is primarily responsible for an increase in both incidence and prevalence of hypertension^{3,20}. Correspondingly, the results of this study indicate that the proportion of hypertensive pre-elderly (87%) were higher than hypertensive adult (13%). Diastolic blood pressure also increases with age but may even fall at late ages²⁰, in this study, DBP mean shown decrease at the age of 46-50 years (Picture 1.a), the decrease of DBP may cause by the process of large arterial stiffness due to atherosclerotic structural alterations and calcification²². The prediction of the increase of DBP by the age shown

in the result of fixed effects regression model that DBP of hypertensive people aged 26-59 years predicted will increase by 1.38mmHg if age increases by 1 year after multivariable adjustment. Meanwhile, the increase of SBP by age could not statistically predicted by fixed effects regression models.

A significant positive correlation between BMI and blood pressure are well documented^{23,24}. The mean of SBP and DBP among different BMI categories was evaluated, it was found that mean SBP and DBP increased with increasing BMI from lean category/lowest BMI to the obese category/highest BMI (Picture 1.b). The potential mechanisms linking increasing BMI to elevated blood pressure include many factors such as dietary factors, endothelial and vascular dysfunction, metabolic, proteinuria, sodium retention, neuroendocrine imbalances, glomerular hyper filtration, and maladaptive immune and inflammatory responses²⁵.

Our analysis of the magnitude association between BMI and blood pressure is higher than other studies in China and Europe, in this hypertensive population study, a one unit, BMI increase was associated with 2.47mmHg SBP and 1.03mmHg DBP after multivariable adjustment. In China, the association between BMI and BP in subgroup were not taking antihypertensive medication ranging from 0.8 to 1.7mmHg/(kg/m²), and substantially higher compared with subgroup were taking antihypertensive medication ranging from 0.2 to 0.6 mmHg/(kg/m²)¹². In line with the study in China, the study in Europe among the untreated people, a one-unit, BMI increase was associated with 1.27 mmHg SBP after multivariable adjustment²⁶. The limitation of our analysis that we could not adjust for the intake of fruit, vegetables, antihypertensive medication, and also other confounders that might have implications for blood pressure changes, which those factors might have some effects on our results.

Conclusions

The uncontrolled hypertension can cause very expensive health care burden. The annual global direct health care costs attributable to uncontrolled blood pressure were estimated at US \$372 billion, representing about 10% of the world's overall health care expenditures²⁷, and improved blood pressure control at population level could have a positive impact in decreasing morbidity and mortality²⁸. For Indonesian, our analysis suggests for including the information

about the BMI changes in the hypertension monitoring reports, as indicators of early awareness of risk factors and prognostic factors for increased blood pressure.

Conflict of Interest Statement: There are no conflict of interest.

Ethical Clearance: This research has received ethical approval from "The Research and community engagement Ethical Committee Faculty of Public Health Universitas Indonesia", Ket- 432/UN2.F10/PPM.00.02/2019.

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Impact of Sesame Oil for Abrogating Hepatic Oxidative Stress Actuated by Aluminum Chloride in Male Rats

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Abstract

The hepatoprotective effect of sesame oil (SO) was evaluated against aluminum chloride (AlCl₃) induced hepatic tissue damage in male rats. A total of twenty four male rats were used and grouped into four groups of six rats each. AlCl₃ induced hepatic tissue damage, marked by increased the activities of aspartate transaminase (AST), alanine transaminase (ALT), alkaline phosphatase (ALP), lactate dehydrogenase (LDH), and bilirubin levels, and a significant decrease in total protein and albumin levels when compared with the normal control. Also, the level of malodealdehyde (MAD) in the liver tissue was significantly increased. Whereas, the activities of superoxide dismutase (SOD), glutathione (GSH) and catalase (CAT) enzymes were markedly decreased. Supplementation of AlCl₃ treated rats with SO could improve most of the biochemical alterations. The results of the present study prove that SO has a potent hepatoprotective effect against AlCl₃ induced oxidative stress injury in hepatic tissues of male rats.

Key-words: aluminum chloride, antioxidants, hepatic tissues, sesame oil.

Introduction

Human exposure to chemicals, most particularly aluminum (Al) occurs through natural procedures, for example, weathering of rocks and erosion¹. It is one of the highly abundant elements in the environment and the most basic metal and the third most elements in the earth crust². Its compounds are widely utilized in medications as³, tooth paste and food additives⁴ and water purification agents⁵. It is used commonly in making various kinds of household cookware and storage utensils⁶. During ordinary breathing, at least 1.4 µg of Al in particulate was reported to be breathed every day⁷. With a noteworthy Al load, the excretory limit of the kidney is surpassed prompting deposition of the minerals in various tissues including the liver and resulting in hepatotoxicity¹. The toxic effects of aluminum are attributed to intercession by reactive oxygen species (ROS) generation⁸.

Sesame seed (*Sesamum indicum*, Linn, Pedaliaceae) has long been utilized broadly as a traditional health food in the orient⁹. Sesame seeds are composed of 43% - 50% lipid, 15% - 20% protein, 10% - 15% carbohydrate, 5% - 6% moisture, 5% - 6% ash and 4% - 5% fiber¹⁰. The oil consists of glycerides of oleic, linoleic, stearic palmitic, and myristic acids and contains also, a crystalline substance, sesamin, sesamol, sesaminol, and a phenolic substance sesamol¹¹. Sesamin and sesamol have shown antioxidant¹² and increasing the oxidation enzymes of hepatic fatty acid¹³.

The present study investigates whether AlCl₃ induces the liver tissue oxidative stress, and whether such oxidative stress could be improved by using SO as a natural antioxidant.

Material and Methods

The present work was carried out on twenty four adult male albino rats, weighing 130-140 g. The rats were obtained from the animal house of Theodor Bilharz Research Institute (TBRI), El-Giza, Egypt and were housed in plastic cages, two animals/cage. The adult rats were preserved under laboratory standard conditions with a 12 h light/dark cycle, temperature range of 25 ± 2 °C, and relative humidity of 55 ± 5% throughout the

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experimental period.

Aluminum chloride powder (AlCl_3) was purchased from El Gomhoreya Company and dissolved in distilled water. Sesame oil (SO) was purchased from ELBARKA Company.

The animals were divided into four groups of six rats each. They were treated daily for four weeks as follows:

Group I (control group): Rats were received 1 ml/kg b.w of distilled water daily through oral gavage.

Group II (AlCl_3 group): Rats were received 10 mg/kg b.w in 0.2 ml of AlCl_3 once daily through oral gavage¹⁴.

Group III (SO group): Rats was received 5 ml/kg b.w SO¹⁵.

Group IV (AlCl_3 + SO group): Rats were treated with the combination of AlCl_3 (10 mg/kg b.w.) plus SO (5 mL/kg b.w) daily through oral gavage.

At the end of the experimental period, all the animals were fasted overnight and then anaesthetized by a slight exposure to diethyl ether. The blood samples were collected from each rat by cardiac puncture procedure using sterile disposable syringes and the serum was separated by centrifugation at 1600 g for 10 min and stored at -80°C for biochemical analyses and the liver of each rat was dissected out. The liver of each rat was homogenized in phosphate buffer solution (pH 7.4) and centrifuged at 5000 rpm, and the supernatant was stored at -80°C for biochemical assays.

Serum aspartate transaminase (AST) and alanine transaminase (ALT) activities were measured according to King¹⁶, the activity of alkaline phosphatase (ALP) was measured according to Englehardt¹⁷, lactate dehydrogenase (LDH) according to Scientific Committee¹⁸, and the determination of bilirubin was carried out according to Tietz¹⁹, total protein by the Biuret method²⁰, and albumin concentration according to Doumas et al.²¹.

Lipid peroxidation in liver tissue homogenates was estimated according to Ruiz-Larrea et al.²², and

superoxide dismutase (SOD) activity was determined by the method of Sun et al.²³. Liver reduced glutathione (GSH) was measured according to Weckbercker and Cory²⁴. Catalase (CAT) activity was determined as described previously by Aebi²⁵.

The obtained results were statistically analyzed by using SPSS program²⁶. Significant differences among groups were determined by one-way analysis of variance (ANOVA). The statistical significance of the data was evaluated by ANOVA using the SPSS/16.0 software and was expressed as mean \pm SEM of 6 rats per group. This was followed by post hoc test using Duncan to compare significance between groups when p-value <0.05 .

Findings

The data of the present study showed that the animals administered with sesame oil (SO) in normal conditions; for a period of four weeks, did not show significant changes in all the estimated parameters, (Tables 1-3). Whereas, the activities of aspartate transaminase (AST), alanine transaminase (ALT), alkaline phosphatase (ALP) and lactate dehydrogenase (LDH) enzymes showed a significant rise the sera of of AlCl_3 treated rats comparing with control or SO treated rats (Table 1). This effect was significantly ameliorated by administration of SO with AlCl_3 (Table 1). Also, the rats treated with AlCl_3 revealed a significant reduction in total bilirubin, total protein and albumin, as compared to the control or SO treated rats. The coadministration of SO and AlCl_3 , showed a significant increase in the levels of these parameters as compared to AlCl_3 treated group (Table 2).

The results of the present also revealed that the treatment with AlCl_3 induced a significant decrease in the antioxidant enzymes activities, superoxide dismutase (SOD), glutathione (GSH) and catalase (CAT) content, while the level of malodealdehyde (MAD) revealed a significant increase when compared to control and SO groups as revealed in Table (3). On the other hand, our findings revealed that the treatment with SO and AlCl_3 significantly ameliorated the alternations induced by

AlCl₃ in hepatic antioxidant levels (Table 3).

Table 1. Effect of sesame oil Supplementation on the liver enzymes in serum of aluminum chloride treated rats.

Groups Parameters	Control	AlCl ₃	SO	AlCl ₃ + SO
AST (IU/L)	35.92 ^a ± 0.25	60.53 ^b ± 0.45	33.01 ^a ± 0.24	40.2 ^d ± 0.51
ALT (IU/L)	25.98 ^a ± 0.12	44.62 ^b ± 0.36	23.3 ^a ± 0.23	30.05 ^d ± 0.35
ALP (IU/L)	50.48 ^a ± 0.4	88.95 ^b ± 0.45	49.5 ^a ± 0.33	55.85 ^d ± 0.38
LDH (IU/L)	200.8 ^a ± 0.81	251 ^b ± 0.73	197.82 ^a ± 0.65	219.32 ^c ± 2.02

Values are expressed as mean ± S.E (standard error) of six rats in each group. Different letters indicate significantly different means p-value < 0.05. Same letters indicate non significant changes.

Table 2. Effect of sesame oil Supplementation on total protein, albumin and total bilirubin levels of aluminum chloride treated rats.

Groups Parameters	Control	AlCl ₃	SO	AlCl ₃ + SO
Total bilirubin (mg/dL)	0.47 ^a ± 0.02	0.69 ^b ± 0.013	0.44 ^a ± 0.014	0.56 ^c ± 0.02
Total protein (g/dl)	6.8 ^a ± 0.13	4.5 ^b ± 0.14	6.9 ^a ± 0.15	5.7 ^c ± 0.152
Albumin (g/dl)	4.22 ^a ± 0.12	2.9 ^b ± 0.04	4.1 ^a ± 0.1	3.6 ^c ± 0.1

Values are expressed as mean ± S.E (standard error) of six rats in each group. Different letters indicate significantly different means p-value < 0.05. Same letters indicate non significant changes.

Table 3. Effect of sesame oil Supplementation on on hepatic MDA level, SOD, GSH and CAT activities of aluminum chloride treated rats.

Groups Parameters	Control	AlCl ₃	SO	AlCl ₃ + SO
MAD (n mol/g)	6.03 ^a ± 0.11	13.5 ^b ± 0.18	6.09 ^a ± 0.07	7.47 ^c ± 0.14
SOD (Unit/mg Protein)	10.66 ^a ± 0.12	7.45 ^b ± 0.16	10.83 ^a ± 0.08	8.92 ^d ± 0.13
GSH (µg/ g wet tissue)	15.14 ^a ± 0.12	9.84 ^b ± 0.23	15.6 ^a ± 0.21	12.5 ^c ± 0.21
CAT (Unit/mg protein)	29.49 ^a ± 0.39	20.19 ^b ± 0.29	30.1 ^a ± 0.31	26.06 ^d ± 0.22

Values are expressed as mean ± S.E (standard error) of six rats in each group. Different letters indicate significantly

different means p-value < 0.05. Same letters indicate non significant changes.

Discussion

Liver, one of the biggest organs in the body ²⁷, assumes an unquestionable role in catabolic and anabolic processes, storage, synthesis and detoxification ²⁸. The present work aimed to investigate the potential protective effects of sesame oil (SO) against the hepatic damage induced by AlCl₃. Activities of ALT, AST, ALP and LDH are very sensitive markers of liver injury and have been seen as critical in the evaluation of hepatic damage ²⁹. Raised activity of serum enzymes in intoxicated rats by AlCl₃ can be credited to the damaged structural integrity of the liver because these are cytoplasmic in nature and are discharged into the circulation after cellular damage ³⁰. Whereas, the coadministration of SO and AlCl₃ could suppress the elevated serum markers of these enzymes activities, may be due to the potent hepatoprotective influence of SO that play role in structural integrity preservation of hepatocellular membrane. AlCl₃ caused a significant increase in the bilirubin level comparing with control rats. SO treatment showed a protection against the injurious effects of AlCl₃. This restoration may be due to the inhibitory effects on cytochrome P450 or/and promotion of its glucuronidation ³¹, resulting in the returning bilirubin level like control value. The alleviating total serum protein and albumin levels that were observed in rats treated with AlCl₃ returned to the normal values by SO administration with AlCl₃. The inhibitory effect of AlCl₃ on protein profile is in agreement with the previous findings ³² that could be attributed to the decrease in the number of hepatocytes, which in turn may result in the decreased hepatic capacity to synthesize protein and a reduction in protein synthesis capability of the liver ³³, or may be mainly ascribed to the destructive impact of AlCl₃ on liver cells as reflected in the elevated activities of AST, ALT, ALP and LDH enzymes as reported in our results.

The present study revealed that AlCl₃ treatment caused decreasing antioxidant enzymes activities like superoxide dismutase (SOD), glutathione reductase (GSH) and catalase (CAT). The reduction of these enzymes activities reflect the reduced synthesis of these enzymes due to higher intracellular concentrations of aluminum (Al) and/or accumulation of free radicals or declining the expression of mRNA of endogenous antioxidants ³⁴. At the same time, the level of lipid peroxidation (LPO) was increased by AlCl₃

administration. These results confirmed that Al has a potential of hepatotoxicity, which may be intervened by free radical generation and antioxidant enzymes alterations ³⁵, leading to hepatotoxicity ³⁶. However, SO could improve the oxidant/antioxidant balance when combined with AlCl₃ that reflected by the decrease in MDA level and the stimulation of the the antioxidants enzymes (SOD, GSH and CAT) in the liver tissue indicating that SO may exert antioxidant activities and protect the tissues from LPO.

Conclusion

The results clearly showed the hepatoprotective effects of SO in AlCl₃ treated rats. Further studies on improving the liver functions against the hepatotoxicity of AlCl₃ are recommended.

Conflict of Interest : No

Source of Funding: Self

Ethical Clearance : The rats for the study were humanely handled in accordance with the Ethics and Regulation guiding the use of research animals as approved by the University.

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Prevalence and Predictors of Glycemic Control in Hospitalized Patients with Diabetes

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Abstract

Objective: To assess the level of glycemic control among type 2 diabetic patients and to evaluate the factors associated with glycemic control in hospitalized patients.

Method: The current prospective study included type 2 diabetes patients who were admitted into cardiology and medical wards in King Abdulaziz Medical City in Riyadh from October 2016-February 2017 for at least 3 days and followed for a maximum of 10 days or until discharge. Patients were classified into good glycemic control (average FBG<140mg/dl), or poor glycemic control (average FBG>140mg/dl). Data on demographic and clinical factors were gathered. Predictors of glycemic control were identified using multivariate logistic regression.

Result: A total of 158 patients were included. Average \pm SD age was 69.2 ± 11.4 years, with 54% females and average \pm SD HbA1C was $8.8\% \pm 2.0$. Thirty-seven patients (23.4%) had average FBG controlled. Results from multivariate regression showed that higher likelihood of poor glycemic control was significantly associated with use of steroids (OR = 5.56, $p = 0.039$), use of Aspart (OR = 2.86, $p = 0.012$) and Human regular 70/30 (OR = 5.88, $p = 0.029$). Patients with uncontrolled HbA1C had poor glycemic control (OR = 2.34, $p = 0.047$).

Conclusion: Poor glycemic control appeared to be significantly associated with uncontrolled HbA1C, patients receiving steroids, aspart or human regular insulin. Further studies are warranted to confirm this finding.

Keywords: Diabetes, Glycemic Control, Uncontrolled Blood Glucose.

Background

Diabetes has become one of the major health problems worldwide. In Saudi Arabia (SA), recent studies found that 13.4% of Saudis aged 15 years or older have diabetes⁽¹⁾. This number is alarming as it indicates a total

of 1,745,532 diabetics in Saudi Arabia. Patients with diabetes are admitted frequently to the hospital to treat conditions other than diabetes. Improvement of diabetes management requires an understanding of the predictors of uncontrolled diabetes in hospitalized patients which include patient related factors and treatment factors.

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People with diabetes are admitted to the hospital more frequently. A study of 10,135 patients with diabetes showed that 25% of type 1 and 30% of type 2 had a hospital admission within one year⁽²⁾. Blood glucose level is likely to be unstable in these patients and the reasons for this uncontrolled blood glucose are unclear. Several explanations have been considered such as stress, changes in dietary intake, and interruption of the patient's usual antihyperglycemic agents⁽³⁾.

Many studies showed that uncontrolled blood glucose is associated with increased risk of mortality, morbidity, cost and length of hospital stay⁽⁴⁻⁶⁾. A study of 6374 patients in non-critical care setting, evaluating the effect of hypoglycemia in people with diabetes, indicated that hypoglycemia is associated with increased length of stay and inpatient mortality⁽⁴⁾. In a retrospective review of 1886 hospitalized diabetic patients, hyperglycemia increased the mortality by 2.5-fold⁽⁵⁾. Another study evaluated intensive insulin therapy versus conventional treatment in adults admitted to intensive care unit showed that maintaining blood glucose level at 110 mg/dl or below reduces in-hospital mortality by 34%. It also, lowers acute renal failure requiring dialysis by 41%, sepsis by 46%, and blood transfusions by 50% in patients receiving intensive insulin therapy⁽⁶⁾.

A large number of studies demonstrated that diabetes is a risk factor for complications following different medical and surgical conditions. In patients admitted with acute myocardial infarction (MI), hyperglycemia is a predictor of mortality in patients with and without diabetes^(7,8). This result was driven by a prospective cohort study of MI patients that was done in 2002. Furthermore, a meta-analysis of 15 studies, evaluating the risk of congestive heart failure and in-hospital mortality after MI in patients with and without diabetes, found that blood glucose level more than 110 mg/dl increases the risk of mortality and the rates of congestive heart failure⁽⁹⁾.

Diabetes and postoperative hyperglycemia are independent predictor of infections in patients undergoing a cardiac surgical procedure⁽¹⁰⁾. Adequate control of blood glucose level decreases the incidence of deep wound infection in patients undergoing a cardiac surgery⁽¹¹⁾. A cohort study of 275 patients who underwent peripheral vascular surgery found that 31% of patients with high blood glucose level in the first 48 h after surgery developed infections⁽¹²⁾. The study conclude that post-operative hyperglycemia appears to be an independent risk factor for infections after vascular surgery. Stryker et al. found that greater risk for wound complications in patients undergoing arthroplasty surgery with postoperative blood glucose level more than 200 mg/dL⁽¹³⁾.

According to the patients with acute ischemic stroke, persistent hyperglycemia increases the risk of infarct expansion, poor functional outcomes, in-hospital mortality and hospital cost⁽¹⁴⁻¹⁶⁾. In addition,

a retrospective study by Gentile et al. reported that normalization of blood glucose level in patients with ischemic stroke during the first 48 hours of hospitalization was associated with a strong survival benefit⁽¹⁷⁾. In patients with acute lymphocytic leukemia (ALL), hyperglycemia is considered an independent predictor of adverse outcomes. A study involved 278 patients with ALL showed that hyperglycemia during induction chemotherapy decreased the complete remission duration, increased the risk of complicated infections and overall mortality⁽¹⁸⁾.

Gopinath et al. studied the factors associated with uncontrolled blood glucose level in Type 2 diabetic patients. In this study, male gender and hypertriglyceridemia were significantly associated with poor glycemic control in type 2 diabetic patients⁽¹⁹⁾. A retrospective study of 2,970 diabetic patients with poor glycemic control showed that duration of diabetes, age, number of medications, morbidity, and type of insurance coverage are associated with poor glycemic control⁽²⁰⁾.

Although glycemic control is crucial in hospital setting to avoid any complications, there is a limited data regarding the predictors of uncontrolled diabetes in hospitalized patients. The aim of this study is to assess the level of glycemic control among type 2 diabetic patients and to evaluate the factors associated with glycemic control in hospitalized patients.

Methods

This is an observational prospective study that was conducted at cardiology and medical wards of King Abdulaziz Medical City/ National Guard Health Affairs in Riyadh. Medical charts were reviewed of all non-critical care adult inpatients with type 2 diabetes who were admitted to ward of internal medicine and cardiology from October 2016-February 2017 for at least 3 days and followed for a maximum of 10 days or until discharge. Data were extracted from the electronic health records (Best Care®) and included age, gender, height, weight, BMI, admission date, length of stay, history of diabetes (duration of diabetes, past and current antihyperglycemic agents), treatment protocol for diabetes, admission diagnosis, other diseases, systolic blood pressure (SBP), diastolic blood pressure (DBP), and current medications. Lab data were also collected including glycosylated hemoglobin (HbA1c), 1st blood glucose level, fasting blood glucose level (FBG), random blood sugar (RBG), and fasting lipid profile. Data on presence of diabetic

complications (cardiovascular disease (CVD), stroke, retinopathy, neuropathy, nephropathy, foot problems) were also gathered.

Patients were stratified by mean blood glucose level into: good glycemic control (FBG<140mg/dl), RBG<180mg/dl) or poor glycemic control (FBG>140mg/dl, RBG>180mg/dl) ^(21,22). Glucose results were calculated as mean Fasting blood glucose per hospital duration.

Statistical Analysis: Descriptive statistical analyses are performed for the study sample. For continuous variables, measures of central tendency (e.g. mean, median) and standard deviation are provided. Proportions are used for categorical variables.

Patients were compared by glycemic control status in terms of demographic and clinical characteristics. Categorical data were analyzed using the Chi-square test. The distribution of all continuous data were examined. For continuous variables with normal distribution, a t-test was used for comparisons. If there is evidence against normality, the non-parametric Mann-Whitney U test was utilized. Univariate logistic regression models were employed to identify factors associated with poor glycemic control. Demographic and clinical factors significantly associated with glycemic control were examined in a multivariate logistic regression model. The backward elimination procedure was used to obtain the final model where the effect of all significant variables in the univariate models were examined in the multivariate model. Variables showing no further significant improvement to the model fit were removed. Statistical significance is considered as p<0.05. All statistical analyses were performed using SPSS 21.0 version [Release 21.0.0.0].

Results

A total of 158 patients were included. Average age was 69.2 (SD = 11.4) years, with 54% females (Table

1). Average HbA1C level was 8.8% (SD = 2.0). The majority of patients were overweight or obese (74%), 6% were extremely obese, 18% had normal BMI and only 2% were underweight. While most patients were non-smokers, 58% had cardiac disease, 37% dyslipidemia, 24% had renal disease and 25% had infections. Out of the 158 patients included in the study, 37 (23.4%) had their average FBG is controlled (Figure 1) and 52 (32.9%) had controlled A1C levels (Figure 2).

Table 1: Profile of Respondents. N = 158.

Factor	Value
Gender n (%)	
Male	73 (46.2%)
Female	85 (53.8%)
Age (years) mean ± SD	69.2 ± 11.4
median (IQR)	70 (60 – 67.3)
A1C (%) mean ± SD	8.8 ± 2.0
median (IQR)	8.5 (7.3 – 10.3)
BMI n (%)	
Underweight (<18.5)	3 (1.9%)
Normal (18.6 – 24.9)	29 (18.4%)
Overweight (25 – 29.9)	50 (31.6%)
Obese (30 – 39.9)	67 (42.4%)
Extremely obese (>40)	9 (5.7%)
Smoking n (%)	
No	141 (89.2%)
Yes	7 (4.4%)
Missing	10 (6.3%)
Renal disease n (%)	38 (24.1%)
Cardiac disease n (%)	91 (57.6%)
Dyslipidemia n (%)	59 (37.3%)
Infections n (%)	39 (24.7%)
Systolic BP mean ± SD	131.1 ± 15.4
median (IQR)	130 (120.8 – 143)
Diastolic BP mean ± SD	66.1 ± 8.0
median (IQR)	67 (61 – 71)

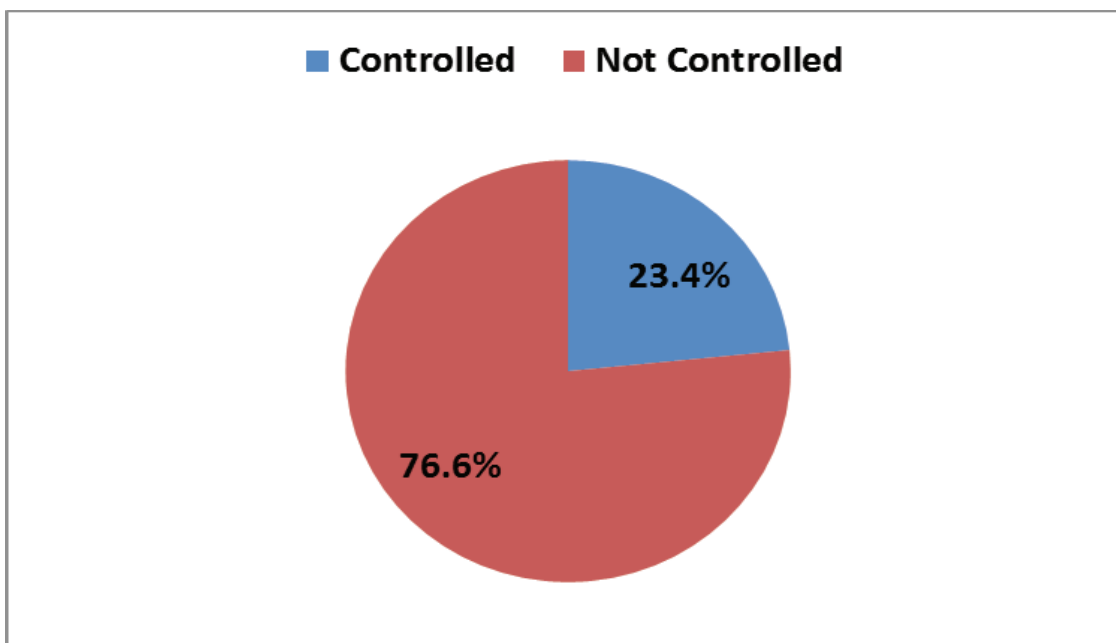


Figure 1: Fasting Blood Glucose Control Status

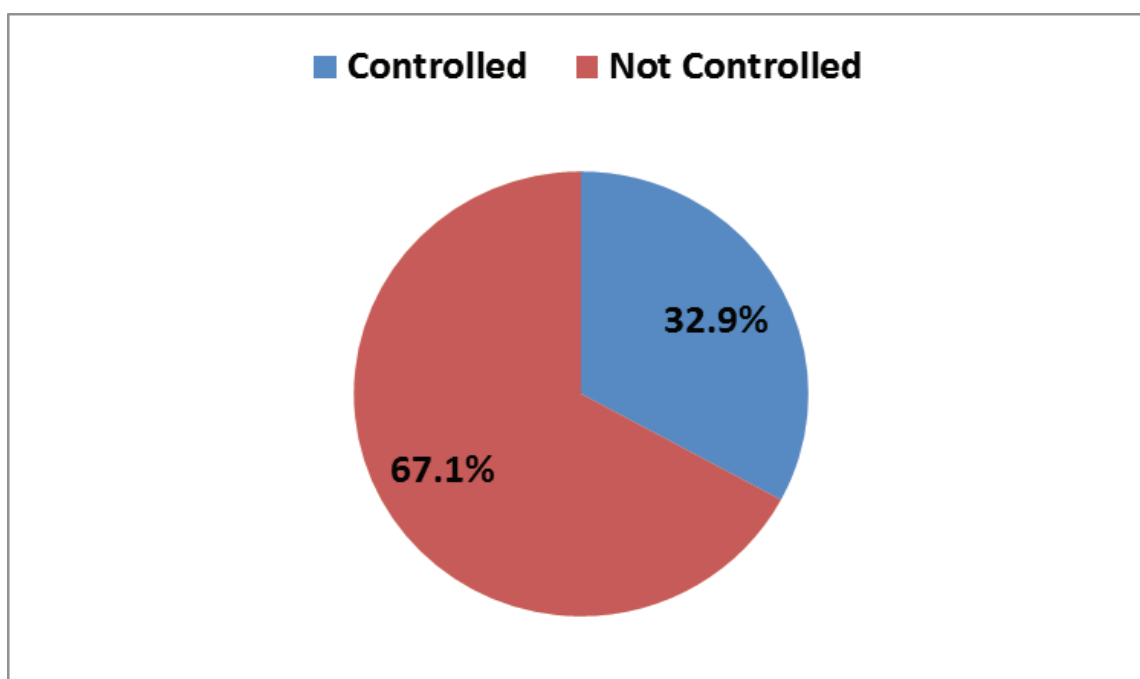


Figure 2: Glycemic Control Status (based on HbA1C)

Patients were receiving a variety of anti-diabetic medications including metformin (27%), Gliclazide (15%), Sitagliptin (8%), Glibenclamide (3%), Aspart (51%), regular insulin (18%), Human regular70/30 (11%) or glargine (56%). Other medications included diuretics (48%), beta-blockers (57.6%), steroids (11%) and antipsychotic medications (4%). Median length of hospital stay was 12.5 days (IQR: 8-21.8).

Results from multivariate logistic regression analysis (Table 2) showed that higher likelihood of poor glycemic control was significantly associated with use of steroids (OR = 5.56, p = 0.039), use of Aspart (OR = 2.86, p = 0.012) and Human regular 70/30 (OR = 5.88, p = 0.029). Patients with uncontrolled HbA1C had a higher likelihood of poor glycemic control (OR = 2.34, p = 0.047). Normal BMI patients were more likely to

have poor glycaemic control, however this result did not reach statistical significance. None of the other demographic or clinical factors were associated with glycaemic control.

Table 2: Multivariate Logistic Regression Model for Uncontrolled FBG

Factor	Mean or percent	OR	95% CI	p-value
Age (per 10 years)	69.2	0.74	(0.51,1.06)	0.10
BMI (normal vs. overweight/obese)	18.4%	2.63	(0.89,7.69)	0.080
Beta-blockers (yes vs. no)	57.6%	1.79	(0.79,4.00)	0.16
Steroids (yes vs. no)	11.4%	5.56	(1.09,25.00)	0.039
Aspart (yes vs. no)	50.6%	2.86	(1.27,6.67)	0.012
Human regular 70/30 (yes vs. no)	11.4%	5.88	(1.19,33.33)	0.029

OR: Odds Ratio

Discussion

Our study demonstrated that higher likelihood of poor glycaemic control appeared to be associated with use of steroids, use of Aspart and Human regular 70/30. Few studies have focused on the factors that associated with poor glycaemic control in hospitalized patients with Type -2 of diabetic ^(23,24).

According to the study that has been done in San Diego, California, the use of steroids was significantly associated with poor glycaemic controlled in hospitalized patient with diabetic type1 and 2 ⁽²³⁾. Developing a special treatment therapies that are tailored to patient that will administered steroids during their hospitalization may be consider to improve the glycaemic status in these patients .

In the current study, normal BMI patients were more likely to have poor glycaemic control but the result did not reach statistical significance. However, as reported by cross-sectional study that have been done in Tanzania, patients with normal BMI were tending to have poor glycaemic control. This might be clarified by the fact that patients with poor glycaemic control usually lose their weight due to disease process ⁽²⁴⁾ .

In this study, beta-blockers was associated with poor glycaemic control, However, the result was not statistically significant. Another study, that examined and compared the effect of beta-blockers (Metoprolol

VS Carvedilol) on glycaemic control using HbA1c, found that metoprolol was associated with significant increase of HbA1c. Despite that, this study was done to evaluate long term effect using HbA1c, while our study used FBG as marker for control ⁽²⁵⁾. Another review article, was done to evaluate the effect of beta-blockers on glucose metabolism, concluded that non-vasodilating beta-blockers (propranolol, atenolol, pindolol, metoprolol) was associated with worsening glycaemic control ⁽²⁶⁾. This could be a clue that beta-blockers can affect blood glucose during hospitalization.

The lack of meaningful relationship between age and poor glycaemic control in this study is not consistent with the findings of many studies ^(20,27,28). which showed that younger age was significantly associated with poor glycaemic control. Despite that, these studies main concern of glycaemic control were on HbA1c to define the glycaemic control and our study was done based on FBG.

Our study is a relatively small study, and a future study should be conducted including a larger and more representative sample from both the inpatient and outpatient setting with more variant demographic and clinical characteristics. However, this study is considered to be one of the first prospective studies that are done to evaluate the factors that are associated with poor glycaemic control in inpatient setting in patient with Type -2 Diabetes in Saudi Arabia.

Conclusion

In this study, higher likelihood of poor glycemic control appeared to be associated with uncontrolled HbA1C. Patients receiving steroids, and patients using aspart or human regular insulin were significantly more likely to have uncontrolled glycemic levels. Further studies are warranted to confirm this finding and explore other patient and diabetes related factors.

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Ethical Clearance: Our present study got ethical clearance from King Abdullah International Medical Research Center (KAIMRC) RC15/078/R .

Abbreviations:

HbA1c = Glycosylated hemoglobin, FPG = Fasting Plasma Glucose, RBG = random blood glucose level, DM = Diabetes mellitus, CVD = cardiovascular disease, MI = myocardial infarction, ALL = Acute Lymphocytic Leukemia, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure, CI = Confidence Interval, BMI = Body Mass Index , OR= Odds Ratio, IQR = interquartile Range

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Awareness About FMST- A Pre-Seasonal Screening Protocol among the Physiotherapists and the Coaches of South Indian Professional Soccer Teams/Clubs- A Cross-Sectional Study

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Abstract

Background: The Functional Movement Screen™ (FMS™) is a screening instrument that tests specific fundamental patterns of movement to assess possible risk of injury. The aim of the study was to find the awareness about FMST as a pre-seasonal screening protocol among the physiotherapists and the coaches of south Indian professional soccer teams/clubs.

Material and method: This is a cross sectional study conducted for duration of 6 months among the physiotherapists and coaches of the professional soccer team or clubs across south India. Study included 29 licensed coaches and chartered physiotherapists of senior rank (above 19 yr players) professional are teams or clubs after obtaining the informed consent.

Results: A total of 29 physiotherapist/coaches participated in this study out of which 20(69%) responded. Half of the participants were aware about the FMST as a pre seasonal screening protocol. All the participants had responded the questionnaire which was sent them via mail. 50% of the participants were aware about the FMST protocol and rest had no clue of it, among them 20% were following the FMST protocol. 42.9% responded that using FMST will benefit by reducing the injuries in players.

Conclusion: FMST's level of awareness among physiotherapists and South Indian professional soccer teams / clubs coaches is inadequate and more awareness programs should be conducted to raise awareness of the value of FMST in soccer as a pre-seasonal screening protocol.

Keywords: Functional Movement Screen, Soccer, Injury Risk, Athletic Performance.

Introduction

In order to prepare an sportsman for the wide range of activities required to engage in or return to their sport, the study of fundamental movements should be integrated into the screening to assess who possesses or lacks the ability to execute those important moves Soccer being is one of the world's most common sports, played by over 200million registered players. It's not just a game but for many around the world it's become

a profession. Soccer is a dynamic, high intensity contact sport with long lasting exercise cycles. Because of the game's character a significant number of players are vulnerable to injury during training or during a match.⁽¹⁾

Screening is a very useful method for detecting possible injury and illness, as well as other risk factors such as serious musculoskeletal disorders, heart disease and head injury.⁽²⁾ Many sports embrace the worldwide screening procedure as pre-participation or pre-seasonal screening. In literature several measurements and categories were used as screening methods. It includes measures such as ECG, strength checks, laboratory-based study of movement, musculoskeletal system and

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may also include medical questionnaires, food intake and fitness levels. Musculoskeletal screening is a significant part of the screening program and includes a thorough review of the joint range of motion, flexibility, strength, proprioception and balance of the player.^(3,4)

The sports physical therapist (SPT) has special credentials to engage in the delivery of preparticipation physical examination (PPE). The PPE is recommended and required by many jurisdictions before athletic participation.⁽⁵⁾ FMST (functional movement screening tool): Cook et al⁽⁶⁾ discovered the value of functional testing to determine the ability to execute activity or sport-specific functional movements. Functional activity screening is used internationally as a procedure, with athletes involved in different sports and competitive levels.

The aim of the study was to find the awareness about FMST as a pre-seasonal screening protocol among the physiotherapists and the coaches of south Indian professional soccer teams/clubs

Material and Method

This is a cross sectional study conducted for duration of 6 months among the physiotherapists and coaches of the professional soccer team or clubs across south India. Study included licensed coaches and chartered physiotherapists of senior rank (above 19 yr players) professional are teams or clubs. Professional soccer club coaches and physiotherapists of under 19 yr players and of non-professional clubs and unlicensed professionals were excluded from present study.

For the study, a total of 20 physiotherapists and coaches from different professional soccer clubs / teams in South India were recruited with informed consent. After gathering the baseline data, all participants were given a self-administered questionnaire by sending in the form of Google Forms in English via e-mails and internet links.

FMST includes the following 7 tests:⁽⁶⁾

- i. Deep squat.
- ii. Hurdle step (right & left).
- iii. Inline lunge (right & left)
- iv. Rotatory stability (right & left).
- v. Shoulder mobility (right & left).
- vi. Trunk stability push ups.
- vii. Active straight leg raise (right & left).

Each player is given 3 trails of each of the 7 tests and scored on a scale of 0-3, where; 0-indicates pain during the movement, 1-indicates failure to complete the movement, 2-indicates completion of the movement with compensation, 3-indicates performance of the movement without any compensation. Maximum score which can be obtained is 21 and the test is done bilaterally. A score of 14 or below is suggested to indicate elevated risk of injury. Hence functional movement screening tool (FMST) gives a clear image of an individualized training program which can be used to avoid or modify abnormal movement patterns, rather than focusing on the rehabilitation of the condition or injury,⁽⁷⁾ FMST is a highly reliable test battery for functional movement analysis, demonstrated among physical therapist in soccer players(0.95).⁽⁸⁾

Statistical analysis: all the data is collected and documented in Microsoft excel sheet and summarized using the descriptive statistics as mean, SD, frequency and percent. The obtained data was analysed using descriptive statistical tests. P value less than 0.05 was considered as statistically significant.

Result

A total of 29 physiotherapist/coaches participated in this study out of which 20(69%) responded. Half of the participants were aware about the FMST as a pre seasonal screening protocol.

Table 1. Questions related to injury and its impact on soccer player

Sl. No	QUESTIONS	YES	NO
1.	Do you think that maintaining a physical profile of a soccer player is essential in India?	20(100%)	0(0%)
2.	Do you think that injuries will affect the career of soccer players?	20(100%)	0(0%)
3.	Will a player's injury have an effect on the team's performance?	18(90%)	02(10%)
4.	Is it possible for an injured player (sprain/strain injuries) to continue with the training on the next day?	02(10%)	18(90%)
5.	Do you think mild injuries can affect the whole season of the player?	07(35%)	13(65%)
7.	Do you feel an early prediction of injuries in soccer is important?	20(100%)	0(0%)

Table 2. Injury prediction practice and awareness related to FMST among Physiotherapist and Coaches.

Sl. No.	Question	Yes	No	Other
1.	Is there any protocol that you are following for predicting injuries?	03(15%)	17(85%)	-
2.	Are you aware about any pre-seasonal screening protocol?	12(60%)	08(40%)	-
3.	Are you aware about functional movement screening tool (FMST)?	10(50%)	10(50%)	-
4.	Are you following FMST?	04(20%)	16(80%)	-
5.	Are you getting any benefits using the FMST protocol?	06(42.9%)	07(50%)	01(7.1%)
6.	If you are not following FMST, are you following any other protocol for screening?	04(23.5%)	13(76.5%)	
7.	Is the other protocol that you follow helpful in injury prevention?	07(50%)	07(50%)	

Fifty per cent know the FMST protocol and the rest don't. Of those who know, FMST is followed by just 20 per cent and the rest are not. However, those who obey do not use any of the FMST but using a portion of it. They (42.9 percent) have indicated that the benefits are obtained by using FMST participants, which indicates that FMST could help to minimize injuries (Table. 2).

Table 3. Questions related to risk factors, frequency of screening, problems faced during the screening and the opinion about FMST.

Questions	Options	Responses
Among the following, which factors do you think can be a risk factor for causing an injury during training or during the match?	Age	08(40%)
	Playing Surface	17(85%)
	Skill of The Player	03(15%)
	Previous Injury	15(75%)
	Gender	02(10%)
	Muscle Flexibility	13(65%)
	Physical Fitness	14(70%)
	Joint Laxity/Instability	10(50%)
	Protective Equipment	10(50%)
	Lack of Experience	07(35%)
	Aggressive Play	13(65%)
	Other	02(10%)
How often do you repeat the screening of players?	3Months	05(41.7%)
	6Months	06(50%)
	9Months	0(0%)
	1Year	01(8.3%)
	2Years	0(0%)
	Other	0(0%)
How often do you repeat the other protocol?	3Months	04(50%)
	6Months	03(37.5%)
	9Months	0(0%)
	1Year	01(12.5%)
	2Years	0(0%)
	Other	0(0%)
According to you what are the problems faced during pre-seasonal screening protocol?	Expensive	02(10%)
	Time Consuming	09(45%)
	Lack of Availability Of Staff	08(40%)
	Limited Time Period During Season	11(55%)
	Lack of Availability Of Players	02(10%)
	Lack of Proper Equipment	08(40%)
	Management of the Team Related Problems	05(25%)
	Other	0(0%)
Do you think FMST can be useful for your team?	Yes	13(65%)
	No	01(5%)
	May be	06(30%)
	Other	-

Risk factors selected by team physiotherapists / coaches that may result in injury during training or soccer match, the majority said playing surface (85%), prior injury (75%), physical strength (70%), muscle endurance and rough play (65%). Often the causes of injury are joint laxity and protective gear (50 percent), age (40 percent), and lack of experience (35 percent). Player and gender expertise are the least significant factors in injuring 15 percent and 10 percent respectively. Two replied that power, proprioception and BMI are also the risk factors for soccer injuries (Table. 3).

Discussion

The present study was done to find information among South Indian professional soccer teams / clubs about FMST as a pre-seasonal screening protocol among the physiotherapist and coaches. A total of 29 physiotherapists / coaches participated in this survey, 20 (69 per cent) of which responded. Half of the participants were aware of the FMST as protocol for pre-seasonal screening.

Mild injuries affect the soccer player, it affects working time on the field but it does not affect the whole season of the club. If the injuries are predicted it will also individually assist the team and the player. (Table. 1)

Several research indicated that player screening should be conducted before the start of the season, so screening protocols or assessments should be performed as pre-seasonal screening tests.^(7,9,10) Other screening tests and pre-seasonal protocols have different benefits.^(11,12) 50% Participants said they don't get any benefits in avoiding injury. And the rest of them said it's helpful in injury prevention (Table. 2). It could be assumed that FMST has not yet been published in India or widely used in India, so FMST awareness among Indian soccer teams is important. FMST details should be included in Indian Football Curriculum. Pre-seasonal data can be used to identify talent, specialized skills and include predictive data after injury for returning to soccer. Therefore FMST is important not only to reduce the risk of injury but also to develop programs for the prevention of subsequent injury.^(3,4,6)

Majority (55 percent) participants indicated that a short time period during the season was the key problem for performing a pre-seasonal screening followed by time consuming (45 percent), lack of personnel and equipment (40 percent). Some (25 per cent) stated that

team-related problems management is also a obstacle in screening players. 10 per cent say it's costly and player quality isn't enough. Studies show that FMST is helpful and appropriate in soccer and is very easy to perform and the above problems will not be found in FMST.^(4,8,9) As FMST as a pre-seasonal screening technique, the time constraints do not affect the testing.⁽⁶⁾

During the analysis, opinions of physiotherapy / coaches regarding the FMST were registered. Most (65 percent) of the participants agreed that FMST could be useful to their team and 30 percent said that it could be beneficial to the team because they are not positive about FMST's outcomes. Those who agreed on its usefulness claimed that it could aid in the prevention of accidents as well as offer an indication of which region they should work on. FMST will help the coach, physiotherapist and player themselves become more conscious of the training session and raising the possibilities for injury. It will help prevent injuries and help improve the performance of the player and staff.⁽¹³⁾ Some said that FMST hasn't met India widely; team coaches and physiotherapists are prepared to enforce the protocol during their training period if sufficient information and knowledge are given.

Limitations of study were, data collected was from very small group of participants from south region of India. Only coaches and physiotherapist associated with sports soccer was used. We recommend conducting more awareness programs about the importance of FMST as a pre-seasonal screening protocol among the physiotherapists and the coaches of Indian professional soccer clubs and across various sports.

Conclusion

FMST's level of awareness among physiotherapists and South Indian professional soccer teams / clubs coaches is inadequate and more awareness programs should be conducted to raise awareness of the value of FMST in soccer as a pre-seasonal screening protocol.

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