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Healthcare Service Provision Seen through Villager's Lenses

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Abstract

Social health protection is an essential part of the welfare policy framework. This article discusses two components of Social health protection – direct provision of health care services by the government and NGOs; and micro health insurance for covering catastrophic health expenditures. The discussion sections start with the components of direct healthcare service provision at the village level: healthcare centers, free medicines, health camps, awareness campaigns and health talks and referral services. The article shows that if done properly, all these components are well appreciated by the villagers. They are seen to have no urge to use private facilities, if good facilities established by govt/NGO exist. NSS also shows that there is higher utilization of government health services than before.

The article shows that quality and affordable healthcare leads to better income, better school attendance, reduction in out of pocket expenditures and minimal dependence on informal health workers. However, the current healthcare service situation in rural India leaves much to be desired. There are problems of infrastructure, manpower, training, availability of consumables, and hence lack of trust in government services.

Reimbursement of health expenses can address some of these issues but the articles whos that there too, the progress is slow and not upto the mark yet. Therefore it is concluded that health care services in India need to be upgraded starting from providing very basic facilities like water and electricity.

Key words: *primary health care (rural); micro health insurance; subcenter.*

Background

Any health issues in a family causes distress and economic loss. Illness of the main earning member results into food insecurity for the entire family. Health problems in the dependent members of the family causes anxiety and hence productivity loss. If the dependent member has to be accompanied to the health facility, it also means loss of earnings for that period. The importance of giving security against such losses has been emphasized often in literature.

Cost of medical treatment is another important concern. The medical care costs have been rising

sharply all across the world. A single serious illness in a family can wash out all the savings. Most poor families end up in indebtedness and sink further into poverty with such health episodes. According to Khandheria¹ approximately 7% of Indian population annually plunges below poverty line due to health care costs.

Rising costs also make health services unaffordable. That results into deaths/disabilities for completely surmountable causes, making families unnecessarily sink into deep and irreparable mental and economic losses.

This is where social health protection comes in. It refers to measures that help in alleviating some of these distresses and losses. It can come in the form of direct health interventions like giving free medicines/vaccines or providing free hospitalization or in the form of health insurance enabling patients to seek health services by reimbursing the costs.

Social health protection is not only useful for better health and productivity but also in safeguarding education of the children. Without proper health care facilities, for small illnesses also, children have to remain absent from school for long. Even if health is an issue for some other family member, there is a possibility that the child will be withdrawn from school – boys to help in earning wages and girls to help in household work. Social health protection thus is necessary even for education. It is also important in addressing malnutrition because the deterioration of economic situation of the household due to catastrophic health expenditures results in hunger. Therefore, social health protection is identified as one of the important interventions by organizations like UNICEF and Save the Children.

Governments at all levels in India have emphasized the role of primary health care as an important tool to achieve social health protection. The Bhole Committee Report² was the first official document that recommended a 3-tier health infrastructure to provide basic health services. It referred to rural areas only but later the concept was extended to urban areas also, given that slum dwellers formed a substantial part of urban population. National Rural Health Mission (NRHM) reemphasized the importance of this 3 tier structure and sought to strengthen it. According to the goals of NRHM, the community level sub centers should be established within 5 km of distance from all villages. Noticing that government has not been able to provide initial health care in many pockets, NGOs have also tried to provide such services in rural and

urban areas (examples are SEWA in Ahmedabad and Uplift in Pune)

In last two decades, efforts have also been made to cover the underprivileged population through public health insurance. Rashtriya Swasthya Bima Yojana (National Health Insurance Program) which is now reintroduced as Ayushman Bharat covers expenses upto 5 lakhs for medical treatment for the BPL families. State governments also have introduced their own such programs like Arogyashri in Telangana and Andhra; Mukhyamantri Amrutam Yojana in Gujarat³. Many NGOs like SEWA, and Yashaswini have also successfully operated health insurance models. Uplift India Association came out with an interesting community based mutuals health insurance model that has received many positive reviews⁴.

The purpose of this paper is to report the situation on ground regarding primary health care services. Opinions of people regarding the positive impacts of the health services are listed together with the problems found. Secondary data of NSS 75 Round is combined with notes from focused group discussions conducted by the author in Dungarpur, Rajasthan for providing the insights.

Health services at the village level

Healthcare centers

At the village level centers (whether established by the government or NGOs), primary health care services are provided by the health workers. In government sub centers, at least one Auxiliary Nurse Midwifery (ANM) is supposed to be there⁵, who would have passed a 6 months' diploma course. S/he is helped by ASHA (Accredited Social Health Activists) and aganwadi workers. The latter two are supposed to have no educational background in health; they learn from the initial training given to them. In the NGO run health centers (the author has seen some NGOs of Gujarat and Rajasthan, the observations are based

on these. There is no claim made to have a blanket inclusion of all health care service types provided by various NGOs in India), usually a literate person (preferably has finished at least 10+2) would be trained for a short period to undertake the duties of a health worker.

As pointed out by Bajpai⁶, Rajasthan had 24% less subcenters than required and 34% less Primary Health Centres (PHCs) and Community Health Centres (CHCs).

Maybe for this reason, even when the villagers have to pay for availing the NGO health center services, we found in Dungarpur that women were ready to join the program. The program required women to pay Rs. 120 per year to get free primary health services and reimbursement of hospitalization expenses upto Rs 12000. The women reported that once there was some health episode in the family, they realized the importance of being a part of such health service program. They decided to join the program just for the benefits of receiving free medicines for small illnesses. We found that in Mada region of Dungarpur, because of positive experience of services provided by the NGO health workers, the increase in membership was 23% last year. This finding underlines the fact when government falls short in its provision of health services, NGOs can play a useful role.

However, neither the subcenters nor the NGO health service centers at the village level have a trained medical doctor. Existence of a private doctor is not guaranteed within even 15-20 km radius for backward regions of India. An MBBS doctor should be available at the closest PHC, according to the government guidelines. But due to many unfilled vacant posts, there is no guarantee that the doctor would be there in a PHC. No wonder then that the private doctors are the most used health service providers (table 1), even if they are much more expensive.

Free Medicines:

Essential drugs are provided free of charge by both public and NGO health services. The variety of drugs is supposed to be larger at the subcentre compared to the NGO health center. Wherever there was adequate provision of such health services and free drugs, almost all of our sample women utilized such services. The women informed us that dependence on quakes and priests was negligible and that too only under the condition when other remedies were not working. NSS 75th Round data confirms this finding: just 4.3% in rural areas and 0.9% in urban areas sought the health services of informal health workers (table 1).

Table 1: Treatment by type of healthcare service provider, India

Healthcare service provider	Percentage of treated ailments		
	rural	urban	all
Government/public hospital	32.5	26.2	30.1
Private hospital	20.8	27.3	23.3
Charitable/trust/NGO-run hospital	0.9	1.3	1.1
Private doctor/ in private clinic	41.4	44.3	42.5
Informal health care provider	4.3	0.9	3.0
All	100.0	100.0	100.0

Source: NSO: Key Indicators of Social Consumption in India: Health, NSS 75th Round⁷

Referral Services:

If the health worker comes across an episode that is beyond her capability, the patient is referred to the nearby PHC/CHC or district hospital by the sub-center. The health facility set up by the NGO sector would advise the patient to go to a known doctor/hospital. We found that the villagers would not necessarily go to the higher centers, as advised. The visits outside the village were made only if the health problem worsened. Also, these visits were made to the places that the villagers thought to be reliable, the choice was seldom based on the advice given by the local health center. In other words, the choice of specialized service provider depends on reputation of the place, unlike the choice of local health center which depends more on accessibility.

Health camps:

Considering non-availability of an MBBS doctor and absence of specialized services at the village level, and also lack of facilities for conducting diagnostic tests, health camps are organized by NGOs as well as government centers for the villagers. The simplest medical camp would have a general practitioner, giving consultations on all types of health issues to villagers. There would also be health camps for specialized as well as diagnostic services like eye camp or diabetes camp.

All such camps are well attended by the villagers, as reported by the women in Dungarpur. About 60% of our group members reported having utilized the services of such camps. The women reported that the tests undertaken in these camps have helped them in taking timely action for the diseases. But for such camps, they would have never undertaken any such tests.

Since such camps are required to be organized by the sub centers according to the government

guidelines, a fruitful partnership can be formed between government and NGOs. The NGOs, with their grassroot level contacts, can organize the camps, and the government center staff can provide the experts as well as equipment. In this way, NGOs do not need to raise funds for organizing such camps and government centers can meet their targets.

Awareness campaigns and Health talks:

The subcenter health workers are expected to undertake awareness campaigns for specific diseases like TB or covid and are also supposed to spread awareness about good sanitary practices. Awareness campaigns depend on availability of funds for the NGOs but they occasionally organize health talks by experts during the saving group meetings. The women of Dungarpur told us that they have learnt many desirable health and sanitation practices from the talks and appreciate the importance of such programs. We feel that saving groups can be used as vehicles by the government centers too for their awareness campaigns.

Positive impact of provision of local health services

a. Quick resolution of small health issues

The most important impact, the women of Dungarpur explained, was on their daily lives. Small health issues get quickly resolved when a good subcenter or NGO center is there. Prolonged discomfort due to non-treatment of a health problem gets eliminated. In the absence of a close by and reliable sub center/NGO center, the treatment was not done either because there was no money to pay for the fees of the private doctor or there was no reliable medical help available. Their general health, they report, has improved a lot with timely medicines. It has also led to increase in their productivity and incomes.

b. Better attendance at school

Women also reported that children have become more regular in schools when there are good primary health care services available in the village. When the medical services were not accessible easily, they would keep the sick child home till s/he felt better. In the absence of medicines, such absence from school could be long. With free and timely medicines provided by the NGO or ASHA workers, the children get better in a short time. The general improvement in their health level has improved school attendance.

Girl children were kept home if the mother was not well. With the improvement in health status of the mother due to timely medicines, we were told that girls also are able to attend school more regularly.

c. Reduction in out of pocket expenditure

According to NSS 75th Round, the charges of government centers are the lowest, availing services of private doctor costs 74% more. For secondary care, the costs are more than 300% for private hospitals (table 2).

Our interactions also show a similar result: where there are reliable health service centers by government or NGO, the out of pocket expenditure has substantially reduced because the services are provided free or at very reasonable rate. The presence of a reliable primary health center thus implies considerably less out of pocket expenses.

Table 2: Average medical expenditure, by types of service providers

Sector	Average medical expenditure (Rs.) per spell of ailment treated by					
	Govt/ Public Hospital	Private Hospitals	Trust and NGO hospitals	Private doctor/ clinic	Informal healthcare providers	All
Rural	325	1081	624	566	487	592
Urban	344	1038	863	714	1035	710
All	331	1062	732	624	552	636

Source: NSO: Key Indicators of Social Consumption in India: Health, NSS 75th Round⁷

Our FGDs showed that 60% of the hospitalization expenses came from borrowings, increasing the debt burden of already indebted families. But those who got and followed referral from the government/NGO health workers reported spending just 20% of what they would have spent at the private hospital. Thus reliable referral services also seem to be reducing the out of pocket expenditure substantially.

d. Health seeking behavior:

NSS 75th Round reports a heartening trend that 96% of treatment for ailments was availed from allopathy health workers. The health seeking behavior of Indian population has changed and improved considerably. The proportion of services availed from quacks and priests have declined to mere 0.1%. In our survey we

found that 100% of women were seeking treatment from allopathy practitioners. The accessibility to health services has ensured its utilization.

This has added one more dimension to the health issues though. Jana and Basu⁸ point out that since the services of medically qualified personnel was actively sought by all, people often travel to another place for getting treatment. Transportation cost is now an important part of the out of pocket health expenditure. That is the reason health service provision plans provide for transportation costs also. RSBY provided for it and so does Ayushman Bharat.

Problems on field for providing primary health care:

1. Availability not ensured

The health services in government subcenters should be available 24x7. However, studies have

reported widespread absenteeism in these centers. So the trek to the center by an unwell person goes waste. This discourages people from availing the services.

When the services are provided by NGOs, the health worker usually comes to the village just once in a few weeks. On other days, the health services are still located at a distance and hence are not easily accessible.

2. Lack of proper infrastructure:

In our experience of various regions in India, almost half of the subcenters do not have even running tap water and access to electricity. Lack of hygiene, leaking walls, absence of examination room/bed were some other complaints that we have encountered.

Because of National Health Mission, states have been made to evaluate their health service delivery systems. Table 3 shows the state of health centers in Dungarpur.

Table 3: Facility wise Score card of District hospital, CHC and PHC of Dungarpur District

	>80% (A+)	>70% - <=80% (A)	>60% - <=70% (B)	>50% - <=60% (C)	<50% (D)
District Hospital (1)					1 (42%)
CHC (15)		1	1	7	6
PHC (55)	5	9	9	9	23

Source: National Health Mission <https://nhm.gov.in/index4>⁹

The only proper hospital in the district is of D grade. Out of 15 CHCs studied, 13 CHCs (87%) are of inferior quality. Similarly, 62% of the PHCs were found to be wanting in quality services.

This can be one of the reasons that NSS 75th round finds that 61% of health care services are availed from private sector (private doctors and private hospitals). Only 37% of health services are availed from

government sector or informal providers (table 1). As reported earlier in Section I, if the services are good then we found that all our sample women were using the services of such health centers only.

Qadeer¹⁰ argues that a part of such deterioration found in many parts of India can be attributed to the change in the dominant paradigm of welfare state to liberalization and privatization. As the budget allotted

for health and education stagnated, there were scarce opportunities for significant gains.

However, there seems to be some effort to upgrade the health systems. Ayushman Bharat has re-introduced the concept of comprehensive primary health care and policies have been made to transform the subcenters into Health and Wellness Centres.

Primary health care centres mainly concentrate on just mother and child health care and population control at present. The scope of these centres is planned to be widened to cover non-communicable diseases too under the current health policy. It would be interesting to see how the policy gets translated into action.

3. Low pay for the staff

The aganwadi workers as well as the health workers employed by NGOs are paid very low wages. For years, the salaries were not raised nor any increment in other forms was provided. The helpers in aganwadi were paid Rs 1500 per month and the Sevikas (aganwadi workers) were paid Rs 3000. After Seventh Pay Commission's recommendation, the wages have changed, but only in some states like Kerala, Andhra and Telangana. Most states and central government are still continuing with the same low rates.

The ASHA is supposed to be an honorary worker, paid compensation only when she goes for training or when she gets involved with some procedure like immunization, antenatal services, etc. The pay thus remains a major issue with ASHA also.

As a result, the turnover rate in health workers is very high. Given the fact that the health workers gain most of the knowledge about health matters from field experience, such high turnover proves counterproductive in improving the health systems.

Another problem is, not many people are attracted to take up the position of para-medical and medical posts in government health centres because of the low pay. Bajpai⁶ reports that deficiency in specialists in Rajasthan was around 90%. Kumar¹² confirms that there is a great shortage of health care staff in Northern India. Quality of the services rendered by the staff is another important concern. Vij¹³ reports that in March 2018 only 8% sub centres, 12% PHCs and 13% CHCs met Indian Public Health Standards.

4. Referral services

The 12th pass health worker cannot be expected to understand complex medical conditions and advise the patient which doctor s/he can go to. Generally, the patient has to be referred to PHCs or private doctors for further referral. As mentioned earlier, there is no guarantee that a doctor will be available in PHC to guide the patient. So the patient will have to go to Community Health Centre or District Hospital. This means multiple trips for the villager before reaching a proper care facility.

The government guidelines mandate visit of a qualified doctor to each subcenter at least once in a month. A stronger integration of secondary and tertiary level services with the primary health care services is needed. For example, in a condition that requires urgent intervention, visit frequency of once in a month by the doctor will be of little use. This is where a case for telemedicine as well as helplines manned by qualified doctors is strong. Their presence is much needed in filling this gap.

The staff at the Sub Centre level is trained in addressing only "common diseases", but a whole range of diseases exist in rural and urban India. A qualified doctor is the only one who can be expected to deal with such range of diseases. Here also telemedicine and helpline are of high relevance.

5. Lack of proper training

If NGOs are running the health service centres, we found that there was no guarantee that the health workers were trained regularly. High turnover rate of the health workers also aggravates the problem of training. We had found that the health workers working with government subcenters in Andhra were sent for training at least once or twice in a year, but we do not know whether all states in India have a strong training component for their health program. Additionally, not much attention is paid to improving the number and quality of training schools so the knowledge imparted might also be of questionable quality.

Not just the health workers at the subcenter level, but the MBBS doctors also need to be sent for specialized training/workshops/conferences to keep abreast of the new developments in the field. This spirit of keeping up-to-date with the advances in the field is completely missing from government and NGO run programs.

6. Lack of consumables for diagnostic tests

It is mandated by National Health Mission that the ASHA workers should monitor the levels of non-communicable diseases like diabetes, hyper tension, etc. These tests, which are now easy to conduct with modern devices, are not being done much. The women at Dungarpur reported that no monitoring of communicable or non-communicable diseases is undertaken in their villages. It seems that only a few states undertake such monitoring and provision of medicines for non-communicable diseases. Even there, as we found from our consultancy experience, there is inadequate supply of consumables like the strips

for diabetes monitoring. Therefore the monitoring in these states also must be highly inadequate.

We feel that the sub centers should be given budget to buy such supplies on their own rather than depending on the approval by higher authorities. It would improve the services at least in those states that are trying to provide these monitoring facilities.

7. Poor service quality leads to high out of pocket expenditure

We found in Dungarpur that the out of pocket expenditure is very high because for even slightly complex health issue, people go the private hospitals across the border in Gujarat. This happens because the district hospital of Dungarpur is not considered good. The women in Dungarpur also told us that they prefer not going to the government run centres because the staff is very rude to them and do not treat them well. For other parts of India, long waiting period at the government hospitals is an important deterrent.

Doctors of Gujarat hospitals talked nicely but they charge exorbitant prices and often made people go through unnecessary treatments like treating the patient for glaucoma when the problem was simple cataract.

NSS 75th round shows that 55% of total hospitalization cases in the country are treated by private hospitals (table 4). The NSS data also notes that the cost of treatment in private hospitals is almost 8 times (800%) higher. If the quality of public health services improves and patients are guided to the right hospitals by the helpline/telemedicine, the out of pocket expenditure can reduce substantially.

Table 4: Hospitalization by Type of hospitals

Type of hospital	% share of hospitalization cases		
	Rural	Urban	Rural+Urban
Government/Public hospital	45.7	35.3	42.0
Private hospital	51.9	61.4	55.3
Charitable/ Trust/ NGO run hospital	2.4	3.3	2.7
All	100	100	100

Source: NSO: Key Indicators of Social Consumption in India: Health, NSS 75th Round⁷

8. Low utilization of services

We found that the footfall was barely 15 patients or so daily in some subcentres. In addition to the rudeness of the staff, it could be trust and reputation – the private doctor enjoyed better reputation and was “known to cure people”. Similar factors are mentioned by Anand et al¹⁴.

This means that most people either do not take any treatment at all or for persistent severe problems, avail the expensive services of private doctors. Efforts need to be put in to make the public health infrastructure better and then bring about change in people’s perception about such centers.

Micro Health insurance

It needs mention here that primary and secondary health care is not covered in most health insurance schemes. It covers only hospitalization expenses. But given the catastrophic impact of such expenses on household finances, micro health insurance assumes importance.

Government health insurance like Ayushman Bharat does not require any premium to be paid. Its predecessor, Rashtriya Swasthya Bima Yojana, required a payment of only Rs. 30. There are other state sponsored insurance schemes too that do not

require any premium payment. All these schemes allow the beneficiary to choose a hospital of their own choice for treatment.

Some NGOs have also started providing micro health insurance. The model that we mentioned before in Section on Health Services at Village Level, required an annual premium of Rs 120 to be paid per family member to avail of free medicines for small ailments and reimbursement of upto Rs 12000 for hospitalization. While Rs 12000 might seem very low, NSS 75th round has shown that the average hospitalization expenses in a public hospital would be around Rs. 4500 only⁷. There are many such insurance schemes introduced by NGOs in India.

However, we found that these health insurance schemes have not been availed much. According to NSS 75th round, only 13% of the patients used these schemes⁷. Majority of the health expenses were paid by the patients themselves. Our detailed discussions with the women of Dungarpur revealed some serious shortcomings of micro health insurance schemes.

Shortcomings of health insurance

i. Voluntary enrolment is low for insurance with premium

The concept of health insurance is very difficult to explain to the villagers. That they have to pay

the premium irrespective of any health issues in the family seems illogical to them. Very few people in India, even among the high income brackets, get health insurance. NSS 75th round shows that only 33% of the sample population from the fifth quintile (the highest income group) had health insurance.

Thus the only solution to saving people from catastrophic health expenses is to enroll them compulsorily. The government, PSU and private sector employers insure their employees compulsorily. The SHGs deduct insurance premium from members' accounts compulsorily. Schemes that try to enroll people voluntarily into health insurance meet with only limited success.

ii. Ignorance about being enrolled

Compulsory enrolment, as discussed in the point above, is the most viable way to get members. However, the danger with compulsory enrolment is that people would not be aware that they are covered under a health insurance; they will still spend money on hospitalization/costly treatment by borrowing money. Very few women from Durgapur reported claiming reimbursement for hospitalization expenses, although hospitalization cases were many. The whole purpose of micro health insurance was thus defeated.

iii. Sustainability of the program

It has been observed that as more and more people get to know about the health insurance program, the claims start rising. The claim:premium ratio was vastly negative for RSBY at 122%¹⁵. The insurance companies that insured the RSBY beneficiaries started inventing numerous excuses to dishonor the claims. Similarly, for the NGO run insurance schemes, those schemes that reimburse only a small part of the claim have remained sustainable. Most others have resulted into losses.

A scheme like Ayushman Bharat, wherein the government bears the whole medical expenditure, is sustaining now because very few people know about it. If all BPL patients start availing of expensive medical care that is provided free of charge, the scheme would soon become unsustainable, as USA and some European nations have found for themselves.

In such circumstances, a comprehensive scheme that provides for government facilities (that offer affordable care) for primary, secondary and tertiary care and also provides for affordable/subsidized medicines seems like a better solution than micro health insurance. This is because the pre-condition for micro health insurance to work is to have good hospitals that provide care to the poor at reasonable rates. Strengthening public health infrastructure can bring in many benefits.

Conclusion

This article shows that the provision of primary health care has improved in Indian countryside. The health seeking behavior of Indian population now largely excludes any space for the quacks and priests. The overall health status of the population has improved, as shown clearly by rising life expectancy figures in every census. Free medicines, health camps and talks by experts as well as awareness campaigns have also helped in making people more proactive on the health front.

Although private sector dominates the overall scene of health service provision, utilization of government hospitals and primary healthcare centers is on the rise especially in some southern and north-eastern states. Gaps in public sector health services are at times covered by NGO health workers.

However, the primary health care sector has still some glaring gaps at the field level, as highlighted by this article. Issues of bad infrastructure, high absenteeism among staff members, shortage of

consumables for tests, etc need urgent attention. India used to spend a mere 1.5% of GDP on health (with the covid vaccination that share must have increased). Investing in public health leads to many benefits as the literature shows and as shown by the discussions with the women in Dungarpur. India needs to invest more to improve the basic infrastructure of the health centers; it would lead to gains in national income also.

The article also shows that the prevalence of health insurance is very low and so is its utilization among the persons covered. It also highlights though that once the utilization of health insurance increases, it tends to become economically unviable. A better solution would be to invest in health infrastructure and provide quality services at an affordable cost.

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Association of Dietary Behaviour with Demographic and Socio-economic Factors and Physical Activity among Rural Adolescents: A Cross-Sectional Study

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Abstract

Purpose: This study aimed to investigate the association of dietary behaviour with demographic characteristics, physical activity and socio-economic variables among rural Indian adolescents.

Methods: A cross-sectional study was undertaken among 100 school-going adolescents (43 boys, 57 girls) of 13-17 years, residing in the rural area of Aligarh district (India). Dietary behaviour assessment was carried out using a pretested self-administered structured questionnaire. Food frequency questionnaire and 24-hour diet recall were used to collect data regarding food groups and nutrients intake. Binary logistic regression model was used for the association of dietary behaviours with demographic and socio-economic variables and physical activity.

Results: The mean age of participants was 14.78±1.26. Daily consumption of breakfast was associated with the structure of the family. Association between family type and preference for green leafy vegetables was observed. Liking for green leafy vegetables had an association with the occupation of the mother. Physical activity was associated with the dietary behaviour of having sweet after a meal. Inadequate intake of energy, iron, dietary fibre, and zinc was observed.

Conclusion: Dietary behaviours are associated with demographic variables such as the structure of the family, class, occupation of mothers and physical activity, but are not associated with socio-economic factors.

Keywords: Adolescent; Dietary behaviour; Food groups; Nutrients; Physical activity

Introduction

Adolescence is considered to be a crucial stage in human life. It is a transition stage, from childhood

to adulthood, between 10-19 years of age.¹ This is the formative period of life when maximum physical, cognitive, and socio-emotional growth occurs.² Such remarkable growth spurt significantly increases the demand for calories and nutrients such as iron, calcium and vitamins.³ Healthy dietary intake contributes to optimum physical growth and development but some inadequate dietary food habits such as having a nutrient deficient diet, skipping breakfast and not having timely meals, wide use of fast food and poor

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intake of vegetables and fruits, common among adolescents, can have negative consequences.⁴ These inappropriate eating behaviours are undesirably influenced by socio-cultural and biological factors, which can lead to increasing rates of malnutrition and early obesity.⁵⁻⁶ Several empirical studies conducted on nutritional status and diet quality have shown a high prevalence of adverse dietary patterns among adolescents. Mean intake of all major food groups, especially pulses, milk and milk products, sugar and jaggery was lower as recommended by Indian Council of Medical Research (ICMR).⁷ Intake of soft drinks and fast food was found to be very high whereas, consumption of fruits and vegetables was found to be very low.⁸⁻⁹ There was a huge variation in the intake of food groups among participants. The consumption of milk and milk products, beverages and energy dense foods were higher in boys than their girl counterparts. In contrast, the proportion of consumption of cereals, fruits, vegetables and nonvegetarian food products was found to be very high than boys.¹⁰ Overall, inadequate dietary habits in terms of excess intake of nonessential foods and omission of a variety of food groups from the diet may contribute to the progress of health-related problems among nutritionally vulnerable Indian adolescents.¹¹ Adolescents need a balanced, diversified and adequate diet for preventing and maintaining the long-term health consequences in later life.

Current data on dietary behaviour and food preference among Indian school going adolescents are limited. The present study in selected schools of rural areas of Aligarh city in the state of Uttar Pradesh, India, aimed to evaluate the association between demographic characteristics, physical activity, socio-economic variables, and dietary behaviours of Indian adolescents.

Methods

Study design and population

This community-based cross-sectional study was conducted among 100 school going adolescents (43 boys, 57 girls) of age 13-17 years, residing in rural areas of Aligarh district of Uttar Pradesh, India. The target population for the study was school going adolescents of class 9th to 12th from 2 private schools of the selected area. The sample was selected through simple random sampling method. All schools were randomly selected for this study. All data were collected after approval of the local Directorate of Education and school administration. The study was conducted in conformity to Ethical Guidelines on Human Subjects,¹² as per the revised Helsinki Declaration (2013).

Measurements and data collection techniques

Demographic and socio-economic variables

A pre-designed and pretested questionnaire was used to interview the subjects to elicit information on demographic variables, like gender, age, class etc. Information related to socio-economic variables was asked from parents using Kuppaswamy's socio-economic status scale.¹³

Dietary assessment

A pretested questionnaire based on existing relevant literature and questionnaires on adolescents' healthy eating habits was used to assess the habitual food intake of these adolescents. A total of 30 questions were asked on the consumption of breakfast, eating salad during the meal, skipping of meals, avoid eating fried foods, eating regular meals with your family at home, etc.

Dietary assessment was done using 24-hour diet recall and food frequency questionnaire (FFQ). In 24-hour diet recall, standardized measuring cups were used to remove all the ambiguity on the estimation of the average intake of food.¹⁴ After collecting dietary information from respondents all the recipes were

standardized in the food laboratory of Banasthali Vidyapith. Researcher entered dietary data directly into validated Nutrition Software of India- 'DietCal- A Tool for Dietary Assessment and Planning' version-8.0 (Profound Tech Solution; <http://dietcal.in/>). Nutrients were calculated using this software. The mean intake of these nutrients was compared with adolescent nutritional requirements.¹⁵ The Nutrient Adequacy Ratio (NAR) was calculated for seven nutrients, including energy, using 24-hour recall data. It was calculated by dividing the subjects' daily intake of nutrient by Recommended Daily Allowance (RDA).¹⁶ The Mean Adequacy Ratio (MAR) was calculated by dividing the sum of all nutrients by the number of nutrients. A value of 1 is considered ideal for both MAR and NAR, it reflects that the individual has taken nutrient in an adequate amount.¹⁷

A food frequency questionnaire was devised according to the food groups given in the nutritive value of Indian foods.¹⁶ It was used to elicit information on the eating frequency of a particular food item by participants.

Assessment of physical activity

Physical activity index was used to measure health related physical fitness of adolescents.¹⁸ It composed of three measures of physical activity patterns dealing with intensity, duration and frequency. Participants were asked to mark one category for each item. The score was computed by multiplying all these three values. A higher overall activity score (81-100) was reflective of a very active lifestyle and excellent physical activity level.

Statistical Analysis

After collection, all data were analyzed, and appropriate statistical tests were applied using M.S. Excel software and SPSS-20.0. $P < 0.05$ was considered statistically significant. Student's t-test was employed to evaluate the significant difference between the

mean intake of food groups and recommended dietary allowances.

In binary logistic regression models, we estimated odds ratios (ORs) with 95% confidence intervals (95% CI) for the association of dietary behaviours with demographic variables, physical activity and socio-economic characteristics, using the category of "male," "12 class," "nuclear family," "non-vegetarian," "working," "lower (V)," "poor" as a reference.

Results

Subject characteristics

A total of 100 adolescents with a mean age of 14.7 (SD=1.2) years participated and 57% of them were girls. The age of subjects ranged from 13 to 17 years. Majority of subjects (61%) were studying at the secondary level (classes 9th and 10th). Nearly a quarter of the heads of the family (26%) obtained high school education and majority of mothers (96%) were housewives, not engaged in any paid activity. In total, 46% of adolescents belonged to upper lower socio-economic status. A significant association ($\chi^2=20.30$; $p=0.000$) was observed between gender and physical activity. Active lifestyle and very good physical activity were reported more amongst the boys as compared to girls.

Association of dietary behaviours with demographic, socio-economic variables and physical activity

Table 1 shows the association between daily consumption of breakfast, consumption of snacks between main meals, junk food as an alternative to breakfast and factors such as age, gender, class, family type, eating habits, occupation of mother, socio-economic class and physical activity. Adolescents who belonged to the joint family were more likely to consume breakfast every day than those who were

belonged to the nuclear family (p=0.01). Adolescents who studied in 9th and 10th standard tended to prefer consumption of snacks between meals (p=0.00; p=0.02). Odds for adolescents who had a habit of consuming junk food as an alternative to breakfast were higher in the case of children who studied in 11th

standard (OR=3.56). Adolescents who belonged to the upper lower socio-economic class had increased odds of the consuming snacks between main meals (OR=2.52).

Table 1. Association between daily consumption of breakfast and consumption of snack between main meals and junk food as an alternative to breakfast and factors from logistic regression model

Variables	Daily consumption of breakfast		Consumption of snacks between main meals		Junk food as an alternative to breakfast	
	OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Age	0.76(0.51-1.14)	0.19	1.30(0.92-1.83)	1.34	1.19(0.74-1.91)	0.46
Gender						
Male	1.42 (0.53-3.80)	0.48	1.19(0.48-2.98)	0.69	1.24(0.37-4.09)	0.72
Female (ref.)	-	-	-	-	-	-
Class						
9	0.54(0.14-2.02)	0.36	0.14(0.03-0.54)	0.00a	1.68(0.30-9.38)	0.55
10	0.52(0.14-1.93)	0.33	0.25(0.07-0.86)	0.02a	0.78(0.17-3.57)	0.78
11	0.24(0.04-1.38)	0.11	0.40(0.11-1.48)	0.17	3.56(0.33-37.68)	0.29
12 (ref.)	-	-	-	-	-	-
Family type						
Joint Family	0.34(1.23-9.63)	0.01a	1.78(0.73-4.34)	0.20	1.12(0.34-3.73)	0.84
Nuclear Family (ref.)	-	-	-	-	-	-
Eating habits						
Vegan						
Lacto-vegetarian	1.50(0.16-13.8)	0.72	0.49(0.09-2.74)	0.42	6.00(0.87-41.21)	0.06
Lacto-Ovo-vegetarian	0.80(0.07-8.75)	0.85	0.47(0.07-2.98)	0.42	1.91(0.28-13.08)	0.50
Non-vegetarian (ref.)	-	-	-	-	-	-
Occupation of mother						
Housewife	NA	0.99	0.97(0.09-10.5)	0.98	2.33(0.22-24.28)	0.47
Working (ref.)	-	-	-	-	-	-

Cont... Table 1. Association between daily consumption of breakfast and consumption of snack between main meals and junk food as an alternative to breakfast and factors from logistic regression model

Socio-economic class						
Upper (I)						
Upper middle (II)	NA	0.99	0.42(0.02-9.36)	0.59	NA	0.99
Lower middle (III)	0.50(0.04-5.63)	0.57	0.70(0.06-7.70)	0.77	NA	0.99
Upper lower (IV)	1.18(0.11-12.42)	0.88	2.52(0.24-26.06)	0.43	NA	0.99
Lower (V) (ref.)	-	-	-	-	-	-
Physical activity						
High	NA	0.99	NA	0.99	0.15 (0.00-2.76)	0.20
Very good	0.35(0.09-1.33)	0.12	0.91(0.33-2.45)	0.85	1.30(0.31-5.35)	0.71
Fair	0.65(0.12-3.36)	0.60	1.89(0.51-7.03)	0.33	1.56(0.17-13.96)	0.68
Poor (ref.)	-	-	-	-	-	-

OR: odds ratio; CI: confidence interval

^aSignificant association

The results examining factors impacting preference to eat green leafy vegetables, skipping meals and enjoying something sweet after a meal are presented in table 2. Association between the family structure and liking for green leafy vegetables was found and presented as: adolescents who belonged to the joint family were more likely to prefer green leafy vegetables than those who belonged to the

nuclear family (p=0.02). Adolescents whose mother was housewife were more likely to prefer green leafy vegetables than those whose mother was working (p=0.02). Adolescents who fell in the fair physical activity category were more likely to enjoy something sweet after a meal than those who belonged to the high, very and poor physical activity category (p=0.03). Dietary behaviours had no association with socio-economic status of adolescents.

Table 2. Association between socio demographic variables and selected dietary behaviours from logistic regression model

Variables	Like to eat green leafy vegetables		Skipping meals		Enjoying something sweet after meal	
	OR (95% CI)	P	OR (95% CI)	P	OR (95% CI)	p
Age	1.04(0.70-1.55)	0.81	0.77(0.54-1.09)	0.14	0.77(0.56-1.06)	0.11
Gender						
Male (ref.)	-	-				
Female	2.4(0.81-7.51)	0.11	0.33(0.13-0.81)	0.16	1.70(0.76-3.78)	0.19

Cont... Table 2. Association between socio demographic variables and selected dietary behaviours from logistic regression model

Class						
9	2.28(0.53-9.83)	0.26	1.25(0.38-4.06)	0.70	3.20(0.91-11.14)	0.06
10	0.57(0.10-3.17)	0.52	2.49(0.72-8.61)	0.14	2.62(0.75-9.07)	0.12
11	1.33(0.25-6.94)	0.73	4.12(0.89-19.00)	0.69	2.80(0.72-10.75)	0.13
12 (ref.)	-	-	-	-	-	-
Family type						
Joint Family	0.21(0.05-0.78)	0.02a	0.80(0.33-1.91)	0.61	2.28(1.00-5.21)	0.49
Nuclear Family (ref.)	-	-	-	-	-	-
Eating habits						
Vegan	NA	0.99	NA	0.99	NA	0.99
Lacto-vegetarian	NA	0.99	0.56(0.06-5.18)	0.61	3.78(0.41-34.23)	0.23
Lacto-Ovo-vegetarian	NA	0.99	0.32(0.03-3.18)	0.33	7.08(0.73-68.6)	0.09
Non-vegetarian (ref.)						
Occupation of mother						
Housewife	0.6(0.00-0.68)	0.02a	0.81(0.81-8.11)	0.85	0.27(0.02-2.69)	0.26
Working (ref.)	-	-	-	-	-	-
Socio-economic class						
Upper (I)						
Upper middle (II)	9.00(0.56-143.88)	0.12	0.55(0.03-8.08)	0.66	1.00(0.09-11.02)	1.00
Lower middle (III)	0.50(0.04-5.63)	0.57	0.83(0.07-8.82)	0.88	0.82(0.10-6.43)	0.85
Upper lower (IV)	0.45(0.04-5.06)	0.51	0.84(0.08-8.89)	0.88	0.84(0.10-6.48)	0.86
Lower (V) (ref.)	-	-	-	-	-	-
Physical activity						
High	NA	0.99	0.37(0.02-6.30)	0.49	NA	0.99
Very good	1.33(0.43-4.13)	0.61	0.78(0.29-2.09)	0.62	0.83(0.34-2.06)	0.70
Fair	1.83(0.41-8.16)	0.42	0.99(0.23-4.21)	0.99	0.09(0.01-0.80)	0.03
Poor (ref.)	-	-	-	-	-	-

OR: odds ratio; CI: confidence interval

^aSignificant association

Dietary assessment

Nutrient intakes derived through the adolescents' diet are shown in table 3. Among adolescents, NAR of energy, protein, fat, calcium, iron and zinc were higher in boys than those in girls, while NAR of dietary fibre and vitamin C were lower in boys than

those in girls. NAR of calcium intake according to gender shows that boys had adequate intake, whereas girls had inadequate intake of calcium. MAR results are different by gender that boys had higher MAR than girls. MAR was found to be 1.07 which indicate overall nutrients adequacy in the diet.

Table 3. Nutrient Adequacy Ratio (NAR) of adolescents

Nutrients	Total (n=100)	Boys (n=43)	Girls (n=57)
Energy (kcal/d)	0.84±0.33	0.87±0.33	0.82±0.32
Protein (g/d)	1.39±0.47	1.66±0.87	1.33±0.64
Fat (g/d)	2.34±1.22	2.77±1.25	2.12±1.14
Calcium (g/d)	1.00±0.74	1.42±0.98	0.78±0.43
Iron (mg/d)	0.43±0.45	0.61±0.26	0.37±0.20
Dietary fiber (g/d)	0.68±0.28	0.66±0.27	0.70±0.29
Vitamin C (mg/d)	1.37±1.18	1.31±0.90	1.39±1.31
Zinc (mg/d)	0.52±0.18	0.58±0.18	0.49±0.16
MAR	1.07±0.60	1.23±0.63	1.00±0.75

Recommended consumption of cereals, pulses, sugar and fats and oils was different between age groups, whereas the consumption of fruits, vegetables and milk and milk products was similar. The average daily intakes of green leafy vegetables, roots and tubers and sugars were higher than the recommended dietary intake (RDI) in adolescent girls aged 13-15 years, whereas consumption of cereals, pulses, other vegetables, fruits and fats was lower than RDI in adolescent boys (13-15 years). Overall consumption of milk and milk products was found to be higher in boys than their girl counterparts. The deficit in the consumption of pulses, green leafy vegetables, fruits

was higher among girls, compared with boys (16-17 years).

The mean daily intakes of fats and oils and sugar in girls aged 16-17 years and roots and tubers and sugar intakes in girls aged 13-15 years were higher than the recommended dietary intake (RDI). In contrast, intakes of cereals and millets were much lower than recommended in all the age groups. It is worth noting that fats and oils, sugars, roots and tubers were the major food group categories in meeting the total energy. The mean intakes of milk and milk products in boys aged 13-17 years were much higher than the

recommended, whilst the intake of pulses was lower than the recommended among all the subjects. It can be stated that the higher contribution to total protein intake came from milk and milk products followed by pulses.

Discussion

Our findings, akin to the previous study¹⁹ inferred that there were family type-related differences in the dietary habit of daily breakfast consumption. Results showed that family type inequalities in daily breakfast intake exist in India with more likely to eat breakfast daily among adolescents living in a joint family. Our results indicated adolescents who enrolled in 9th and 10th standard were more likely to consume snacks between meals. Several researchers have evaluated different aspects of adolescents snacking such as snacking time,²⁰ snacking location,²¹ effects of snacking on academic performance.²² A previous study examined that consumption of snacks leads to higher total caloric intake, leading to a greater risk of overweight and obesity among adolescents.²³

As seen in this study, the structure of the family and occupation of the mother were associated with liking for green leafy vegetables among adolescents. Evidence highlighted that adequate consumption of green leafy vegetables is associated with improved mental health and lowered non communicable disease risk among adolescents.²⁴⁻²⁵ Our study found that adolescents who involved in fair physical activity tended to enjoy something sweet after having a meal compared with participants who involved in high and poor physical activity. A cross-sectional survey conducted among adolescents showed that adolescents who performed physical activity for more than 4 hours per week tended to consume more vegetables, beans, cooked vegetables, fruits and milk, but less consumption of sweets among adolescents.²⁶ Dietary behaviours were not found to be associated with the socio-economic status of adolescents. This

was in contrast to many studies including one in which Daeie-Farshbaf et al,²⁷ found a positive association of dietary pattern with socio-economic status.

The inadequate intake of nutrients such as iron, dietary fibre and zinc is quite evident in the present study. In line with this research, a study conducted among adolescents in Tanzania reported a low intake of micronutrients including vitamin C, calcium, iron and zinc.²⁸

Conclusions

Our results demonstrate that demographic characteristics such as types of family, class, occupation of mothers, physical activity are associated with adolescents' dietary behaviours. Daily intake of energy, iron, dietary fibre and zinc is lower than their respective RDAs in the diet of both the female and male adolescents.

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Association of Lipid Profile Ratios to Diabetes Mellitus and Hypertension in an Indian Population

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Abstract

Objective: Two lipid ratios (i.e. triglyceride (TG)/high-density lipoprotein cholesterol (HDL-C) and HDL-C/total cholesterol (TC)) along with other lipid levels have been considered as important measures of lipid profile and risk for developing coronary disease and type 2 diabetes (T2D). This paper investigated independent association between index of lipid measures with T2D and hypertension in a study of Indian population.

Methods: In this prospective study, 162 patients were selected and recorded their socio-economic and physical characteristics. Each participant was evaluated for lipid levels *i.e.* TC, TG, HDL-C, low-density lipoprotein cholesterol (LDL-C) and examined for T2D and hypertension. Multiple logistic regression was conducted to find odd ratios (ORs) between lipid measures and ratios with T2D and hypertension. Measures of each lipid and ratio were stratified into quintiles of the distribution and ORs with 95% CIs were estimated for each quintile with lowest quintile as reference. Receiver operating characteristic (ROC) curve was used to discriminate individuals with T2D or hypertension from individuals without T2D or hypertension.

Results: Patients with T2D and hypertension had higher TG/HDL-C and lower HDL-C/TC (p-value<0.01). T2D and hypertension shared an independent positive correlation with TC, LDL-C, TG, HDL-C/TC and TG/HDL-C. Significant increasing trends in OR for T2D and hypertension were seen in TG/HDL-C and TG (p-value<0.01). Comparing areas of ROC curves, TG/HDL-C played a more superior role in discriminating between participants with and without T2D, hypertension.

Conclusions: TG/HDL-C is strongly associated with T2D and hypertension and is a superior predictor to other lipid measures as a risk marker in this population.

Keywords: Triglycerides, HDL-C, Type 2 diabetes, Hypertension, Odd ratio, ROC curve

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Background

Type 2 diabetes (T2D) has become a common and serious lifestyle disease with chronic complications leading to cardiovascular disease, stroke, chronic kidney disease, etc. The prevalence and incidence of T2D and hypertension are also high in India, causing

millions of people suffering from it. Diabetes mellitus is a major cause of cardiovascular disease resulting in 75% of hospitalizations and 70-80% of deaths.^[1,2] Patients with diabetes have a two-to-four fold higher risk of chronic heart disease (CHD) mortality and incidence of nonfatal CHD events compared with patients without diabetes.^[3] T2D and hypertension are inter-related diseases and individuals with diabetes are expected doubled to have hypertension.^[4] Chen et al.^[5] stated that hypertension accounts for 30% of deaths in diabetes patients and for 25% of cardiovascular events in diabetes patients.

Abnormalities in lipid (dyslipidemia) have been identified as independent risk factors of hypertension giving rise to the term dyslipidemic hypertension.^[6-8] They have been commonly seen in patients with untreated hypertension and lipid levels increase as blood pressure increases.^[9] T2D is associated with dyslipidemia in the form of a reduced level of HDL-C and elevated level of TG.^[10]

Several studies have confirmed that T2D can be prevented by identifying and intervening in the development of risk factors.^[11-13] Incidence of T2D has been associated with traditional lipid measures, including TC, LDL-C, and TG.^[14,15] Some studies have reported that lipid ratios, such as TC/HDL-C, have shown a predictive value for cardiovascular disease.^[16,17] Ley et al.^[18] reported an association of the incidence of T2D with HDL-C and showed its superiority over LDL-C as a risk predictor in 606 diabetes-free participants. Hadaegh et al.^[19] reported an association of the incidence of T2D with lipid ratios TG/HDL-C and TC/HDL-C in a prospective study among Iranians.

This study considered two non-traditional lipid measures viz. TG/HDL-C and HDL-C/TC along with other lipid measures for possible association with T2D and hypertension and compared the superiority of these measures as risk markers in this population.

Hence, the aim of this study was to compare the independent association between different lipid indices with the incidence of T2D and hypertension in a cross-section sample of the Indian population.

Subjects and Methods

This study was conducted as a part of the out-patient survey in Dibrugarh Hospital, Assam. All patients were attendees at the out-patient department at the Hospital from Dibrugarh city and adjoining areas. A written well-informed consent was obtained from all patients and the study was performed according to the Declaration of Helsinki, 1975. The participants completed laboratory tests including fasting plasma glucose (FPG), fasting lipid profiles, and a questionnaire on their health & socio-economic status and on various potential risk factors for diabetes.

The baseline characteristics of individuals were recorded such as age, gender, residence, socio-economic (SE) status, physical activity, education level and history of diseases (hypertension and T2D) by providing a questionnaire to each participant. Clinical and laboratory measurements such as BMI, waist circumference (WC), waist-to-hip ratio (WHR), TC, LDL-C, HDL-C, TG, FPG and blood pressure levels were also measured by trained doctors and nurses. Mercury sphygmomanometer was used to measure the blood pressure of a participant. Systolic and diastolic blood pressures were measured two times with 5-min intervals having participants resting in a chair between measurements and the average of two readings was used for analysis. Hypertension was defined if systolic blood pressure ≥ 140 mmHg, diastolic blood pressure ≥ 90 mmHg. T2D was diagnosed if the participant had FPG level ≥ 126 mg/dl, or if it had a history of T2D or if it was under the treatment of T2D with insulin or oral hypoglycaemic agents.

This article studied two lipid ratio HDL-C/TC and TG/HDL-C besides common lipid measures of TC, LDL-C, HDL-C and TG, as it has appeared that people with high TG have low HDL's, which is unhealthy in protecting against heart disease. Since HDL-C is protective against heart disease, it is better to have a higher value of HDL-C/TC and lower value of TG/HDL-C.

Statistical Analysis

Statistical analyses were performed using R 3.3 software. Multiple logistic regression analyses for T2D and hypertension were conducted to find ORs (adjusted and unadjusted) between lipid measures and ratios with T2D, hypertension. Measure of each lipid and lipid ratio was stratified into quintiles of the distribution of each measure and ORs with 95% confidence intervals were estimated for each quintile, taking the lowest quintile as the reference group. Tests for trend were performed on chi-square distribution. The area under the receiver operating characteristic (ROC) curve was used to discriminate participants suffering from T2D and hypertension using different lipid ratios. All statistical tests were two-sided. A p-value <0.01 was considered statistically significant.

Results

Of the 162 participants, 76 (46.9%) and 55 (33.9%) were diagnosed with T2D and hypertension respectively. Compared with those without T2D, patients with T2D had higher TG/HDL-C and lower HDL-C/TC (p-value <0.01). Also, those who had hypertension, had a significant higher level of TG/HDL-C and lower level of HDL-C/TC compare to those who did not have hypertension (p-value

<0.01). Compared to male, female participants had a significant higher level of TG/HDL-C, HDL-C and lower level of HDL-C/TC.

Logistic regression for T2D and hypertension were conducted and OR (unadjusted and adjusted) for each of the measures of lipid and ratio are listed in Table 1 and Table 2 respectively. ORs were adjusted for age, sex, residence, SE status, physical activity, BMI and further for WC and WHR. In the fully adjusted model, an individual positive correlation was seen between TC, LDL-C, TG, HDL-C/TC and TG/HDL-C with T2D. Similarly, TC, LDL-C, TG, HDL-C/TC and TG/HDL-C had an individual positive correlation with hypertension.

The level of each lipid measure and ratio was stratified into quintiles of the distribution of these measures. OR and 95% CI for T2D (Table 3) and hypertension (Table 4) were computed for each quintile, using the lowest quintile as the reference group. The significant increasing trends in OR for T2D were seen in HDL-C/TC, TG/HDL-C and TG (p-value < 0.01). In the case of hypertension, significant increasing trends in OR were also seen in TG/HDL-C, LDL and TG (p-value < 0.01).

Fig. 1 shows the ROC curve of lipid measure and ratio to predict T2D and hypertension with their corresponding specificity and sensitivity. The cut-off values of TG/HDL-C and TG to predict T2D and hypertension were 4.65 and 4.53, 169.17 and 164.74 mg/dl respectively. Comparing ROC curves, TG/HDL-C played a more superior role in the discrimination of participants with T2D and hypertension.

Table 1: Logistic regression analysis of associations between measures of lipids and hypertension

	Unadjusted OR (95% CI)	Adjusted OR^a (95% CI)	Adjusted OR^b (95% CI)
TC	1.132 (0.929, 1.147)	1.463 (1.253, 1.927)	1.473 (1.138, 1.838)
HDL-C	0.826 (0.496, 1.376)	1.058 (0.617, 1.823)	1.025 (0.572, 1.754)
LDL-C	1.115 (1.01, 1.234)	1.726 (1.367, 1.992)	1.712 (0.128, 2.729)
TG	1.124 (1.053, 1.248)	1.326 (1.283, 1.827)	1.481 (0.119, 1.922)
HDL-C/TC	1.129 (1.028, 1.635)	1.364 (1.123, 1.934)	1.382 (1.381, 2.074)
TG/HDL-C	1.453 (1.129, 1.837)	1.583 (1.372, 4.273)	1.599 (1.262, 4.448)

^aAdjusted for age, sex, education level, SE status, physical activity, and BMI

^bAdjusted for age, sex, education level, SE status, physical activity, BMI, WC, WHR

Table 2: Logistic regression analysis of associations between measures of lipids and T2D

	Unadjusted OR (95% CI)	Adjusted OR^a (95% CI)	Adjusted OR^b (95% CI)
TC	1.045 (0.910, 1.151)	1.087 (0.928, 1.263)	1.123 (1.010, 1.251)
HDL-C	0.900 (0.520, 1.560)	0.910 (0.512, 1.620)	0.950 (0.520, 1.740)
LDL-C	1.108 (1.121, 1.256)	1.233 (1.091, 1.649)	1.298 (1.073, 1.564)
TG	1.105 (1.004, 1.321)	1.182 (1.112, 1.698)	1.219 (1.092, 1.742)
HDL-C/TC	1.118 (1.062, 1.573)	1.193 (1.092, 1.872)	1.253 (1.112, 1.825)
TG/HDL-C	1.233 (1.089, 1.646)	1.425 (1.125, 3.585)	1.502 (1.121, 4.278)

^aAdjusted for age, sex, education level, SE status, physical activity, and BMI

^bAdjusted for age, sex, education level, SE status, physical activity, BMI, WC, WHR

Table 3: ORs (95% CIs) by quintiles of measures of lipid for T2D with quintile 1 as reference

OR lowest to highest quintile						
	1	2	3	4	5	Test for trend ^a
HDL-C/TC	1	1.05 (0.29 – 3.77)	1.87 (0.49 – 7.10)	3.00 (1.01 – 12.66)	3.25 (1.08 – 17.09)	0.006
TG/HDL-C	1	1.47 (0.30 – 7.18)	1.52 (0.31 – 7.40)	1.96 (0.87 – 6.95)	2.44 (1.08 – 8.57)	0.003
TC	1	1.74 (0.19 – 16.03)	3.29 (0.37 – 29.08)	3.42 (0.38 – 31.08)	2.35 (0.25 – 21.83)	0.019
LDL-C	1	1.36 (0.21 – 8.72)	2.14 (0.38 – 11.85)	5.17 (1.04 – 25.66)	2.42 (0.43 – 13.44)	0.043
HDL-C	1	0.25 (0.07 – 0.90)	0.23 (0.27 – 4.86)	0.11 (0.02 – 0.60)	0.18 (0.04 – 0.81)	0.018
TG	1	1.75 (0.29 – 10.29)	1.80 (0.42 – 6.04)	2.16 (0.71 – 10.63)	6.30 (1.22 – 32.35)	0.008

^ap-value based on c² test.

Table 4: ORs (95% CIs) by quintiles of measures of lipid for hypertension with quintile 1 as reference

OR lowest to highest quintile						
	1	2	3	4	5	Test for trend ^a
HDL-C/TC	1	1.25 (0.41 – 3.77)	1.16 (0.41 – 3.29)	0.98 (0.35 – 2.72)	1.29 (0.45 – 3.66)	0.026
TG/HDL-C	1	1.47 (0.39 – 5.43)	2.72 (0.74 – 9.87)	4.78 (1.33 – 17.17)	15.62 (4.11 – 59.46)	0.000
TC	1	1.14 (0.21 – 6.13)	2.77 (0.51 – 14.91)	3.72 (0.67 – 20.63)	2.33 (0.43 – 12.69)	0.050
LDL-C	1	2.79 (0.92 – 8.47)	1.73 (0.59 – 5.06)	1.37 (0.45 – 4.15)	5.11 (1.79 – 14.56)	0.010
HDL-C	1	0.88 (0.34 – 2.23)	0.23 (0.07 – 0.69)	0.32 (0.11 – 0.91)	0.46 (0.17 – 1.29)	0.018
TG	1	3.38 (0.65 – 17.68)	7.91 (1.62 – 38.71)	7.33 (1.47 – 36.67)	52.00 (9.89 – 273.39)	0.000

^ap-value based on c² test.

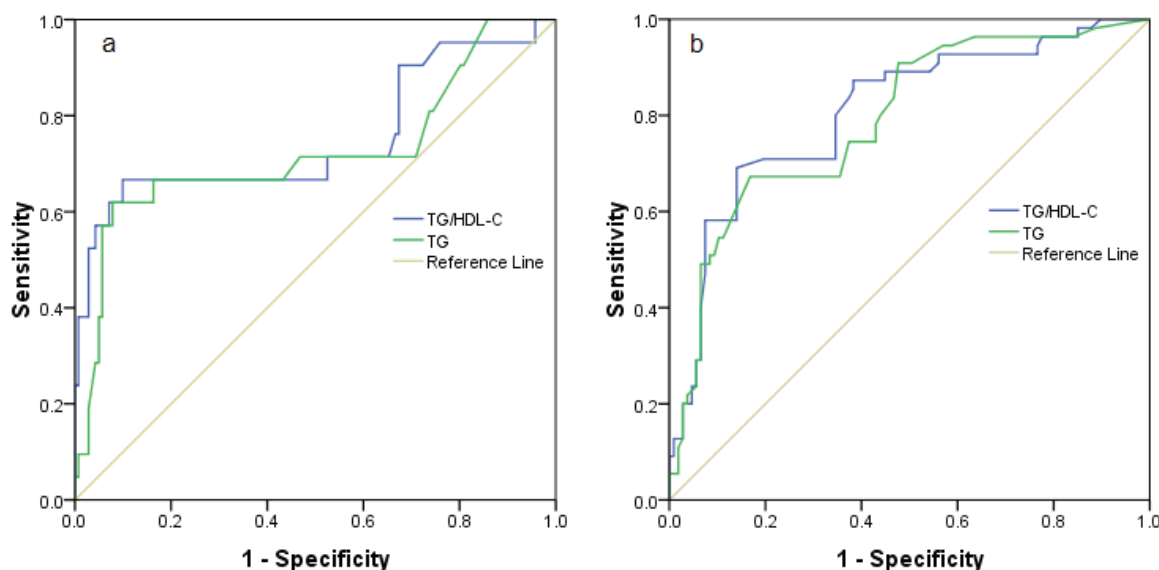


Fig 1: ROC curves for evaluating TG and TG/HDL-C to identify a) T2D and b) hypertension.

Discussion

The independent association between lipid ratios and incident vascular disease is well documented^[16,17] though there has not been enough study on the association of hypertension with lipid ratio of HDL-C/TC and TG/HDL-C. The current study showed an increased lipid ratio of HDL-C/TC and TG/HDL-C were strongly associated with T2D and hypertension. Moreover, the lipid ratio of TG/HDL-C and TG were superior markers of T2D and hypertension in this population from Assam.

A previous prospective study reported that the ratio of TC to HDL-C and ratio of TG to HDL-C are associated with the incidence of T2D among Iranian men and women.^[19]

In the current study, areas under ROC curves for lipid measure of TG and ratio of TG/HDL-C were 0.723 and 0.751, respectively, suggesting that TG/HDL-C might be a superior predictor of T2D compared with TG. Similarly, areas under ROC curves for lipid measure of TG and ratio of TG/HDL-C were 0.792 and 0.808, respectively, suggesting again TG/HDL-C as a superior predictor of hypertension. In a

study on Iranian men and women, Hadaegh et al.^[19] also reported the superiority of lipid ratios over lipid measures in association with T2D. However, Ley et al.^[18] reported an association of non-HDL-C with the incidence of T2D and superiority as a risk predictor over HDL-C. Ethnicity might be played as a crucial in the result obtained from different studies.

In the current study, comparing the area under the ROC curve, the relationship of incidence of T2D and hypertension with the lipid ratio of TG/HDL-C is stronger than TG. As a result, TG/HDL-C is appeared to be a better predictor of T2D and hypertension in our study population having different socioeconomic and lifestyle categories. The results of our study proved that there is a statistically significant influence of dyslipidemia in hypertension and T2D with elevated levels of TG/HDL-C and TG. Taking together, these findings suggest that these lipid abnormalities could play a significant role in causing of hypertension and T2D.

The results of our study have several strengths as well as limitations. The strengths of the study include information on potential determinants of T2D and

hypertension, and using the direct measurements of the anthropometric indices rather than self-reported data. However, the sample size is the weakness of the study.

Conclusions

HDL-C/TC and TG/HDL-C were strongly associated with T2D and hypertension, along with established independent lipid measures such as HDL-C and LDL-C in this population. Moreover, TG/HDL-C and TG appeared to be superior markers for predicting T2D and hypertension in this population from Assam. The results supported that using TG/HDL-C information which is available in the clinical setting, the progression of the disease of T2D and hypertension can be monitored. Therefore, TG/HDL-C can be incorporated into clinical decision making for the prevention of T2D and hypertension.

Compliance with ethical standards

Conflict of Interest: The authors declare no conflict of interest, as this research was undertaken solely for scientific purposes.

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Prevalence of Subclinical Hypothyroidism in Metabolic Syndrome and Correlation with Its Components

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Abstract

Aim: The aim of this study is to evaluate the prevalence of Subclinical Hypothyroidism in the patients with Metabolic syndrome. To find the correlation of Subclinical hypothyroidism with the various components of metabolic syndrome.

Methodology: Cross sectional study- a single centre observational study over 100 patients and 50 controls of the age group of 20 to 75 years.

Results: Observations for metabolic syndrome patients (cases) versus Healthy controls. Observations of thyroid function tests in Metabolic syndrome Vs Healthy controls. Observations for Subclinical Hypothyroidism in Metabolic syndrome Vs Healthy controls. Correlation of various components of MetS with Subclinical Hypothyroidism.

Conclusions: study clearly indicates and emphasizes a diehard need for investigating the presence of thyroid dysfunction while managing patients with MetS.

Keywords: thyroid, metabolic syndrome, syndrome X

Introduction

The “deadly quartet” constitutes of hypertension, high triglyceride levels, low high-density lipoproteins and abnormal fasting glucose levels in obese individuals. It is also referred as a “metabolic syndrome (MetS)” and “syndrome X”^{1,2} In this syndrome, mortality risk is getting doubled due to myocardial infarction and other cardiovascular risk factors. They have three times more risk to have stroke as compared to normal

population³ Insulin resistance is identified as the central pathophysiological phenomenon underlying this syndrome.⁴ Obesity, sedentary lifestyle, aging, dyslipidaemia, cardiovascular disease, lipodystrophy etc are some of the risk factors for developing metabolic syndrome.

In general, the prevalence of the MetS increases with age. It is also estimated that around 20- 25% of the world’s adult population has MetS and they are twice as likely to die from it and they are three times more likely to have a heart attack or stroke compared with people without the syndrome.⁵ As per the data of the National Health and Nutrition Examination Survey (NHANES) 2003–2006, the age-adjusted prevalence of the MetS in U.S. adults without diabetes is 28% for men and 30% for women. A very consistent

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finding in all of these studies is that the prevalence of the MetS is highly age dependent.⁶ Increases in waist circumference predominate among women, whereas increases in fasting plasma triglyceride levels, reductions in HDL cholesterol levels and hyperglycemias are more likely in men. 10 Indian studies among adults have reported prevalence varying from 13%-24.9% in northern India to 41% in southern India using different definitions.⁷

The prevalence of MetS is increasing all over the world with distinct evidence of high prevalence in India and other South Asian countries.⁸ Prevalence of MetS in USA has been found to be 23.7%.⁹

The correlation between Subclinical Hypothyroidism and MetS has not been extensively investigated in prospective controlled studies and only a few studies are available in the world literature. Besides there being a paucity of any further research on this subject in India, few studies have been done on North Indian Patients. Therefore, a study based on the prevalence of subclinical hypothyroidism in patients with MetS and its relation with the components of MetS holds importance and as per our knowledge no such type of study has been done earlier in this institution.

Methodology

The study was conducted in the medical outpatient departments and medical wards at the SGT hospital, Gurugram.

Study design: Cross sectional study- a single centre observational study

Sample size: 100 patients and 50 controls of the age group of 20 to 75 years who fulfilled the inclusion criteria and gave written informed consent for the study after due deliberation. Study duration: 18 months after ethical clearance from the institute ethics committee

Inclusion criteria

Patients with Metabolic Syndrome who fulfilled the Modified NCEP-ATP III (National

Cholesterol Education Program Expert Program and Adult Treatment Panel III) criteria for Asians proposed by AHA [American Heart Association] (3 out of 5 criteria positive) were included in the study;

1. Blood Pressure \geq 130/85 mmHg or on antihypertensive medications.
2. Fasting plasma glucose \geq 100mg/dl or on anti-diabetic medications.
3. Fasting triglycerides \geq 150mg/dl or under treatment.
4. HDL cholesterol $<$ 40 mg/dl in males and $<$ 50 mg/dl in females or under treatment,
5. Abdominal Obesity (Waist circumference): \geq 90 cm in South Asian men and \geq 80 cm in South Asian women will be included in the study group.

Exclusion criteria

The following patients were excluded from the study.

1. Patients with known case of hypothyroidism and under treatment for any thyroid related disorders.
2. Renal disorders and liver disorders
3. Congestive Cardiac failure.

Results

The study was performed at the department of Medicine in the SGT medical college, hospital & research institute, Budhera, Gurgaon, Haryana, India during December 2018 to May 2020. 150 subjects were included in the study – 100 patients of metabolic syndrome and 50 healthy controls. Data was retrieved

and analysed. The observations are presented under 4 sections.

Section 1. Observations for metabolic syndrome patients (cases) versus Healthy controls

Section 2. Observations of thyroid function tests in Metabolic syndrome Vs Healthy controls.

Section 3. Observations for Subclinical Hypothyroidism in Metabolic syndrome Vs Healthy controls.

Section 4. Corelation of various components of MetS with Subclinical Hypothyroidism.

Section 1. Observations for metabolic syndrome patients (cases) versus Healthy controls

The average age of patients with metabolic syndrome was higher than the controls (50.57 vs 42.64 years). The difference was statistically significant ($P=0.0007$).

The proportion of patients with age 40 years or more in patients with metabolic syndrome (78, 78%) was significantly higher than that in patients who were healthy controls (29, 58%).

The proportion of males and females in both the groups was similar with no statistically significant difference ($P=0.3355$).

Patients with metabolic syndrome had a higher systolic BP on average (138.20 mm Hg) compared to controls (122.04 mm Hg). The difference was statistically significant ($P<0.0001$).

The proportion of patients with systolic BP 130 mm Hg or more in patients with metabolic syndrome (92, 92%) was significantly higher than the proportion in healthy controls (2, 4%).

Patients with metabolic syndrome had a higher diastolic BP on average (89.36 mm Hg) compared

to controls (82.22 mm Hg). The difference was statistically significant ($P<0.0001$).

The proportion of patients with Diastolic BP 85 mm Hg or more in patients with metabolic syndrome (90, 90%) was significantly higher than the proportion in healthy controls (12, 24%).

The results were significant statistically ($P<0.0001$).

The fasting blood sugar levels were higher for the patients with metabolic syndrome (152.743 mg/dl) compared to 88.90 mg/dl in the healthy controls. The difference was statistically significant ($P<0.0001$).

The proportion of patients with FBS 100 mg/dl or more (84, 84%) was significantly higher than that in the healthy controls (0,0%).

The average HDL levels in patients with metabolic syndrome (40.33 mg/dl) was significantly lower ($P<0.0001$) compared to the healthy controls (53.33 mg/dl).

The proportion of patients with HDL levels below the prescribed limits for either gender was more in the patients with metabolic syndrome (68, 68%) compared to the healthy controls (1, 2%).

The average triglyceride levels were significantly higher in patients with metabolic syndrome compared to the healthy controls (212.311 vs 105.18, $P<0.0001$).

The proportion of patients with triglyceride levels 150 mg/dl or more than 150 mg/dl was more in the patients with metabolic syndrome (64, 64%) compared to the healthy controls (0, 0%).

The average waist circumference was significantly higher ($P<0.0001$) in the patients with metabolic syndrome (89.25 cms) compared to healthy controls (78.24 cms).

The proportion of patients with waist circumference above the prescribed limits was significantly higher in the patients with metabolic syndrome (91, 91%) compared to healthy controls (0, 0%).

Proportion of patients with hypolipidemic drug use in the group with metabolic syndrome (41, 41%) was significantly higher compared to healthy controls (0,0%).

Section 2. Observations of thyroid function tests in Metabolic Syndrome Vs Healthy controls.

The free T3 levels were lower in patients with metabolic syndrome compared to the healthy controls (2.97 vs 3.31 ng/dl). The difference was not statistically significant ($P=0.1751$).

The free T4 levels were higher in patients with metabolic syndrome compared to the healthy controls (2.03 vs 1.55 ng/dl). The difference was not statistically significant ($P=0.1751$).

Section 3. Observation for Subclinical Hypothyroidism in Metabolic syndrome patients Vs Healthy controls.

The proportion of patients with metabolic syndrome having subclinical hypothyroidism was higher (19, 19%) compared to the healthy controls (8, 16%). The difference in proportion was not statistically significant ($P=0.6532$).

Section 4. Correlation of various components of Metabolic Syndrome with Subclinical Hypothyroidism.

The average age of metabolic syndrome patients with subclinical hypothyroidism (50.31 years) was similar to the patients without subclinical hypothyroidism (50.62 years). The results were comparable with no significant difference statistically ($P=0.9669$).

Amongst the patients with metabolic syndrome, the proportion of females in patients with subclinical hypothyroidism (15, 78.94%) was significantly higher ($P<0.0001$) than that of females in patients with no subclinical hypothyroidism (47, 58.02%).

Discussion

Quartet of hypertension, high triglyceride levels, low high-density lipoproteins and abnormal fasting glucose levels in obese individuals is known as a “metabolic syndrome (MetS) “ and “syndrome X”. Insulin resistance is the primary pathophysiological process for developing this syndrome. It can develop cardiovascular disease and type 2 diabetes into these individual more as compared to normal population. Risk factors associated with MetS includes obesity, sedentary lifestyle, aging, dyslipidaemia, cardiovascular disease, lipodystrophy etc.

Hypothyroidism is also related with lipid abnormalities like high triglycerides levels, low high-density lipoproteins, weight gain, hypertension, glucose intolerance etc which are also part of MetS. Thyroid disease is associated with atherosclerotic cardiovascular disease. This association may be in part be explained by thyroid hormones regulation of lipid metabolism and its effects on blood pressure.

Thyroid hormones having multi systemic effects can affect the functionality of most organs. It can serve as a general pacemaker which enhance overall metabolic process and can be related with MetS. The correlation between Subclinical Hypothyroidism and MetS has not been extensively investigated up till now.

The present study was carried out in northern India to find out whether there is any correlation between Subclinical hypothyroidism with the components of MetS and aim to evaluate the prevalence of Subclinical Hypothyroidism in the study population of the patients with MetS.

The present study included 150 subjects and was conducted at the department of Medicine in the SGT medical college, hospital & research institute, Budhera, Gurgaon, Haryana, India during a period of one year. Cases which met all inclusion and exclusion criteria are included in this study. Key observations from this study are mentioned below.

Shrestha S. Sub clinical hypothyroidism prevalence in our study was found to be 19%. TFT was done in all patients so estimated higher prevalence could be due to the same.

The mean age of presentation was 50.31 ± 13.63 years in patients of metabolic syndrome patients with subclinical hypothyroidism. The maximum numbers of patients were in the age group of 60 years and above and were females in both the groups (78.95% & 58.02). The proportion of females in patients with subclinical hypothyroidism was significantly higher which is in concordance with a study conducted by Shantha GP et al where females were predominant as compared to males.⁶⁴ Also, a study by Sorkhou EI et al showed 28% prevalence in 40-55-year-old followed 57.8% in above 55-year-old patients.

Conclusion

Managing hypothyroidism in MetS patients is rewarding by improvement in the metabolic parameters as well as reducing the cardiovascular risk; thereby improving the quality of life of these patients. Prevention and treatment MetS should be a public health priority to reduce cardiovascular diseases. It indicates the need for thyroid screening of all patients of MetS at first diagnosis. Hence, this study clearly indicates and emphasizes a diehard need for investigating the presence of thyroid dysfunction while managing patients with MetS.

Ethical Clearance- taken from institutional committee

Source of Funding- Self

Conflict of Interest – Nil

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Non Cirrhotic Portal Gastropathy: A Case Report

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Abstract

Idiopathic non-cirrhotic portal hypertension is a rare diagnosis caused by an unknown etiology with elevated intrahepatic portal pressures in the absence of underlying liver disease. We present a unique case of a 45-year-old male with non cirrhotic gastropathy with duodenal oedema with splenomegaly with MOD with ascitis with hypoalbuminemia. There is limited treatment available as management is primarily aimed toward preventing complications of the disease. This case highlights the need for further investigative research of this disease entity and its pathogenesis.

Keywords : non-cirrhotic portal hypertension, hepatic venous pressure gradient, endoscopy, left ventricular assist device

Introduction

Idiopathic non-cirrhotic portal gastropathy (INCPG) is a diagnosis of exclusion with increased portal venous pressure without cirrhosis, hepatoportal flow obstruction, splanchnic venous thrombosis, and other causes of liver disease.¹ INCPH accounts for 3% to 5% of portal hypertension (PH) cases and 14% to 27% of non-cirrhotic PH cases.² In Western populations, it predominantly affects males with a median age of 40 years; higher incidence at a younger age is seen in Eastern countries presumed to be due to socioeconomic disadvantages and poor living conditions.^{1,3}

INCPG presents as complications of PH including variceal bleeding, ascites, portal vein thrombosis, and hepatic encephalopathy.³ The underlying pathogenesis

remains unclear without specific diagnostic testing. An extensive workup is recommended including laboratory testing, hepatic imaging studies, and a liver biopsy to rule out underlying liver disease. INCPG is a diagnosis of exclusion.

Our case demonstrates the necessity of a thorough workup and the difficulties that occur in managing sequelae of INCPG. Unfortunately, because of unclear pathogenesis, it is difficult to treat, and overall prognosis is poor in the setting of liver failure. To our knowledge, this is the first case of INCPG in a patient with a left ventricular assist device with preserved right ventricular (RV) function.

Case Report

A 45-year-old male presented with weakness since one month, shortness of breath since one week, malena since 1.5 week, decrease in appetite since 7 days, and vomiting since 4 days. Examination was notable for decreased breath sounds. Laboratory tests were significant for anemia and transaminitis (aspartate aminotransferase 456 units/L and alanine aminotransferase 528 units/L). Chest X-ray showed

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right-sided pleural effusion; thoracentesis revealed transudative fluid and usg of whole abdomen revealed medical renal disease The patient was treated with diuretics and conservative treatment. To evaluate the anemia and melena, the patient underwent colonoscopy and enteroscopy revealing ileal and colonic arteriovenous malformations that were treated and grade 1 esophageal varices. The varices were suspected to be due to chronic liver disease secondary to passive congestion from underlying heart disease. The patient was stabilized and discharged.

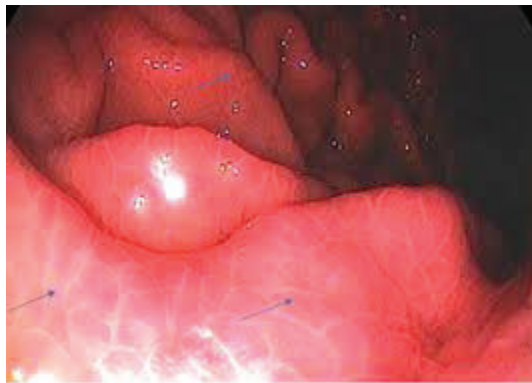


Figure:showing gastropathy

Discussion

The etiology of INCPG remains unknown; however, literature reports associations with immunological disorders, acute or chronic infections, medications and toxins, genetic disorders, and thrombophilia.^{1,2} These conditions are thought to cause portal venopathy from thrombosis or obliteration due to hypercoagulability, vascular remodeling, endothelial injury, or autoimmune injury from immune complex deposition, autoantibodies, or activated T-cells.⁴

Similar to our patient, the most common presenting sign of INCPG is gastric or esophageal variceal bleeding with preserved liver function.⁵ Due to intact hepatic function, the prognosis of variceal bleeding is improved; acute encephalopathy is a rare complication.^{2,5} Splenomegaly and ascites are found in approximately 95% and 50% of cases, and

correlates with poor prognosis. Portal vein thrombosis is relatively common and associated with 13% to 46% of cases.¹⁻³

The diagnosis of INCPG has no widely accepted criteria, is underdiagnosed, and commonly misdiagnosed as cirrhosis.^{1,2,6} Liver function tests are typically normal, hepatic and portal veins are unobstructed, and hepatic venous pressure gradient is elevated.³ Laboratory tests may show anemia and thrombocytopenia, secondary to hypersplenism.⁶ Viral hepatitis, alcoholic and nonalcoholic steatohepatitis, autoimmune hepatitis, hemochromatosis, Wilson's disease, and primary biliary cirrhosis must be ruled out via serology and liver biopsy.^{1,2,7} Histological findings are subtle and can be missed, but include dilated sinusoids, fibrotic degeneration of the venous wall, and dense portal fibrosis.

Conclusions

INCPG is a rare pathology that is difficult to diagnose and treat, especially in the setting of multiple medical comorbidities. Limited information is understood regarding this disease; only few studies have investigated INCPG pathogenesis, testing, and treatment. This case raises awareness of a rare disease entity and demonstrates the need for further studies to prevent poor outcomes.

Ethical Clearance- Taken from ethical committee of institution

Source of Funding- Self

Conflict of Interest – Nil

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Type of the Manuscript: Research Article

Study of Prevalence of Depression among XIth and XIIth Class Students of Medical Stream from Urban Schools of Punjab

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Abstract

Background: Depression during the teen years comes at a time of great personal change when boys and girls form their identity apart from their parents, grappling with gender issues and emerging sexuality, and make their own independent decisions for the first time in their lives. Purpose of this study was to estimate the prevalence of depression among XIth and XIIth class students of medical stream in urban schools of Ludhiana, Punjab. **Material and Methods:** Present study was Cross-sectional study, conducted in in students. Class XI and XII students of medical stream were interviewed. **Results:** Among 253 students studied, majority (71.1%) of the students were females, and about half of the total students were of 16 years of age. Out of total students 84.6% students were suffering from depression with 17.8% having severe depression. At 15 years of age students suffering from moderate to severe depression is 31% whereas at 18 years of age 57% students were suffering from moderate to severe type of depression. There was a significant difference of prevalence of depression in between males and females , with females(89.4%) outnumbering males (72.6%). Almost equal number of students in medical stream were studying in class XI and class XII, with slight over-representation (52.9%) of students in class XI. Out of 134 students in Class XIth 81.3 % had depression while 88.2 % of 119 students in class XIIth were depressed. **Conclusion:** The overall prevalence of depression in our study was 84.6% and it is a prudent reminder of the extreme pressure the adolescent face in this particular age. There was a significant difference of prevalence of depression as females (89.4%) outnumbering males (72.6%).

Keywords: depression, adolescent, medical stream, recreational activities, board exam.

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Introduction

Depression during the teen years comes at a time of great personal change when boys and girls form their identity apart from their parents, grappling with gender issues and emerging sexuality, and make their own independent decisions for the first time in their lives.¹ According to Diagnostic and Statistical Manual of Mental Disorders (DSM-V) (American

Psychiatric Association, 2013), depression is a mood disorder characterized by the presence of sad, empty or irritable feelings, accompanied by somatic and cognitive changes that significantly affect the individual's capacity to function.²

The prevalence of depression tends to increase during the age of 15 through 18 years,³ female students tend to suffer more from depression as compared to males.⁴ On the contrary it is seen that pre-pubescent males (53.7%) were more depressed as compared to females (46.3%). In this study it was further seen that out of 18% adolescents screened positive for depression, 41% reported low mood much of the time and 20% showed occasional mood disorder or more frequent self-harm.⁵

Adolescent depression not only interferes with emotional, social, and academic functioning but also is a proven risk factor for school absenteeism, educational under achievement, substance abuse and suicidal behavior. Various studies from India have tried to assess the prevalence of depression among adolescents. Results vary from around 11-15%.⁶ But scanty literature is available regarding the various social determinants that have an impact on adolescents' state of mental well-being.⁷

Given the said background, purpose of this study was to estimate the prevalence of depression among

XIth and XIIth class students of medical stream in urban schools of Ludhiana, Punjab and to compare the prevalence of depression between the two classes.

Material and Methods

It was a cross-sectional study, conducted in medical stream students, studying in urban schools of Jamalpur area, which is the field practice area of the Department of Community medicine, Christian Medical College, Ludhiana. The data was collected over a three-month period from August 2016 to October 2016, during this period students of both class XI and XII don't have any term examinations. This study was approved by institutional ethical committee.

After explaining the objectives to school authorities' permission was obtained to conduct study. The students were explained about the study and students who gave their consent for participation were included. Data was collected using predefined questionnaires. Data was entered into Epidata software version 3.1 and analyzed using Epidata Analysis software.

The study tool consisted of two different questionnaires. The first one was for eliciting general information from the students and their day to day activities and their pass-times. The second tool was PHQ-9 questionnaire.

Interpretation of Total Score:

Score	Depression Severity
1-4	Minimal depression / Normal
5-9	Mild depression
10-14	Moderate depression
15-19	Moderately severe depression
20-27	Severe depression

Sample size calculation:

The sample size was calculated using Open Epi, Version 3, open-source calculator--S. For a power of 80%- and two-sided alpha error level of 5%, assuming the prevalence of 15% in XIth standard and expecting the prevalence to be 30%in XIIth standard a sample size of 244, 122 in each arm was calculated which was rounded off to 250. The total number of students in the medical stream in all the schools was 253, so all of these students were included in the study.

Results

Out of 253 students studying, majority (71.1%) of the students were females, and about half of the total students were of 16 years of age (Table 1). Out of total students 84.6% students were suffering from depression and among them 17.8% had severe depression (Table 2). Furthermore

as the age increases the severity of depression in students also increases that is at 15 years of age students suffering from moderate to severe depression is 31% whereas at 18 years of age 57% students were suffering from moderate to severe type of depression

(Table 3). Moreover, there was a significant difference (p= 0.0015) of prevalence of depression in between males and females, with females (89.4%) outnumbering males (72.6%) (Table 4). Almost equal number of students were studying in class XI and class XII of medical stream, with slight over-representation (52.9%) of students in class XI (Table 5). Out of 134 students in Class XIth 81.3% had depression while 88.2% of 119 students in class XIIth were depressed, though the difference of levels of depression between two classes was not very significant i.e., Mann-Whitney U test was applied on the variables and the association between the two was not found to be significant (P-value = 0.436) (Table 6). Out of 253 students 95% students were satisfied with the stream they chose while 5% students were not satisfied and in those 5% students the severity of depression was more. Among 253 students 55% students like the way they were being taught the subject while 45% didn't like the way of teaching. Among 253 students 91.3% students didn't want to change the stream. Out of 253 students 60.9% observed change in their appetite over past two weeks and among 253 students 78.7 % experienced change in sleep patterns (Table 7).

Table 1. Age and gender distribution of students

Age (years)	Gender		
	Male	Female	Total
15	11 (15.1)	18 (10.0)	29 (11.5)
16	36 (49.3)	85 (47.2)	121(47.8)
17	17 (23.3)	67 (37.2)	84 (33.2)
18	09 (12.3)	10 (5.6)	19 (7.5)
Total	73 (100)	180 (100)	253(100)

Table 2. Distribution of students according to PHQ-9 Classification

Grading of depression	No. of subjects	Percentages
Normal	39	15.4
Mild depression	97	38.3
Moderate depression	72	28.5
Severe depression	45	17.8

Table 3. Depression according to Age

Age (Years)	Normal	Mild	Moderate	Severe	Total
15	06(20.7)	14(48.3)	07(24.1)	02(6.9)	29(100)
16	17(14.0)	43(35.5)	33(27.3)	28(23.1)	121(100)
17	14(16.7)	33(39.3)	25(29.8)	12(14.3)	84(100)
18	02(10.5)	07(36.8)	07(36.8)	03(15.8)	19(100)
Total	39(15.4)	97(38.3)	72(28.5)	45(17.8)	253(100)

$\text{Chi}^2 = 7.349$ $\text{df}(9)$ $p = 0.6008$

Table 4. Depression according to gender

Gender	Normal	Mild	Moderate	Severe	Total
Male	20(27.4)	30(41.1)	12(16.4)	11(15.1)	73
Female	19(10.6)	67(37.2)	60(33.3)	34(18.9)	180
Total	39(15.4)	97(38.3)	72(28.5)	45(17.8)	253

$\text{Chi}^2 = 15.395$ $\text{df}(3)$ $p = 0.0015$

Table 5. Distribution of students Class-wise

Class	Number of students	Percentage
XI	134	52.9
XII	119	47.1
Total	253	100

Table 6. Depression in class XI and XII

Class	Normal	Mild	Moderate	Severe	Total
XI	25(18.7)	42(31.3)	38(28.4)	29(21.6)	134 (100)
XII	14(11.8)	55(46.2)	34(28.6)	16(13.4)	119 (100)
Total	39(15.4)	97(38.3)	72(28.5)	45(17.8)	253 (100)

Percents: (Row) Mann-Whitney U test P-value = 0.436

Table 7. Distribution of students according to response to questionnaire

Questions	Response	
	Yes	No
Satisfaction with the stream	241 (95 %)	12 (5 %)
Satisfaction with teaching methods	139 (55 %)	114 (45 %)
Feel like changing the stream	22 (8.7 %)	231 (91.3 %)
Time for recreational activities	122 (47.9 %)	131 (53.1 %)
Liking extra-curricular activities	237 (94 %)	15 (5 %)
Change in appetite in past two weeks	154 (60.9 %)	99 (40.1 %)
Change in sleep patterns over the period of two weeks	199 (78.7 %)	54 (21.3 %)
Do you feel capable of taking decisions on your own ?	176 (69.6 %)	77 (30.4 %)

Discussion

The present study revealed a substantial prevalence of depression in medical stream students of urban schools of Ludhiana i.e. out of total students included in the study 84.6% students were suffering from different grades of depression with 17.8% suffering from severe depression. Majority (71.1%) of the students were females, and about half of the total students were of 16 years of age. The current study reported that as the age increases the severity of depression in students also increases, These results were similar to *Lamba R et al.*,⁸ who reported that highest psychiatric illnesses were in those who were 17 (20.4%) followed by 16 (15.2%) & 15 (14%) years of age respectively highest psychiatric illnesses were in the age group of 15 to 17 years..

*Ranney ML et al.*⁹ found that among 624 adolescents (88% response rate) meeting eligibility criteria, 22.8% (n=142) screened positive for depressive symptoms. This huge difference between this study and our study was because of the fact that they took adolescents of all ages while in our study we took into account only the students of classes XI and XII of medical stream.

*Math SB and Srinivasaraju R*¹⁰ conducted community-based epidemiological on mental and behavioral disorders and reported varying prevalence rates, ranging from 9.5 to 102 per 1000 population in the country. Till date, Indian studies reported prevalence rates of psychiatric disorders among children ranging from 2.6 to 35.6 percent.¹¹ *Bansal PD and Barman R.*¹² Showed that among 982 students, 199 (20.2%) had psychiatric morbidity. *Lamba R et al.*,⁸ found that out of total 257 respondents with response rate of 84%. Prevalence of psychiatric morbidity was 14.8% (38 cases).

*Ahmad A et al.*¹³ found the prevalence of the overall psychosocial problems to be 17.9%. *Hackett*

*R et al.*¹⁴ reported in a study which was done to find childhood psychiatric disorder in Calicut District, South India. Among 1403 children aged 8 to 12 years selected by random cluster sampling, a projected prevalence of 9.4% (95% CI 7.9-10.8%) was found. According to *Saluja G et al.*¹⁵ 18 percent of youths reported symptoms of depression out of these maximum were adolescents, which corroborated the fact that depression in adolescents was quite high like found in our study.

In our study majority students had mild depression (38.3%) followed by moderate depression (28.5%) and (17.8%) severe depression.. *Chauhan S et al.*¹⁶ found that among 360 students, the overall prevalence of depression among study subjects was observed to be 38% amongst which majority of subjects (75.7%) were having mild depression followed by moderate depression (23.5%).

In our study there was a significant difference in prevalence of depression between males and females, with females (89.4%) outnumbering males (72.6%) ($X^2 = 15.395$ df(3) $p = 0.0015$). While *Patil RN et al.*¹⁷ showed that prevalence of psychiatric morbidity was highest in children aged 8 to 11 years, in males than in females ($\chi^2 = 3.90$; df = 1; $P < 0.05$).

In our study we found depressive disorders are more than twice as common in girls as in boys by 14 years of age, showing that as the age increase and child reaches adolescents the trend of depression changes according to gender this is possibly because of differences in coping styles or hormonal changes during puberty. *Saluja G et al.*¹⁵ have also reported that a higher proportion of females (25%) reported depressive symptoms than males (10%).

Adolescent depressive disorders often have a chronic, waxing and- waning course, and there is a two- to fourfold risk of depression persisting into adulthood. Depression impacts growth and

development, school performance, and peer or family relationships, and it can be fatal. *Hackett R et al.*¹⁴ reported projected prevalence of 9.4% (95% CI 7.9-10.8%) was found which was associated with male sex.

*Ranney ML, et al.*⁹ noted that in logistic regression, depressive symptoms were positively associated with female gender (OR 2.84, 95% CI 1.78–4.51). *Kumar R et al.*¹⁸ found that female students scored higher than male students in all three variables i.e. depression, anxiety and stress, differences on all three variables were found to be significant at (0.05) level of significance. *Bhasin SK et al.*¹⁹ found that depression was significantly more among the females (mean rank 132.5) than the males (mean rank 113.2), ($p=0.03$).

*Trivedi D, et al.*²⁰ Found that girls were significantly more depressed ($P = 0.016$) and further found that out of 392 students they found that 88 (22.45%) students were depressed. There were 27 (6.9%) students with borderline depression, 35 (8.9%) with moderate depression, 16 (4.1%) with severe depression, 10 (2.6%) with extreme depression, and mood disturbances among 71 (18.1%). These studies corroborate the findings of our study which also show a high significance of females being more depressed than male adolescents.

Children who have depression are much more likely than their peers to have difficulty concentrating, completing assignments, paying attention, participating in class, achieving at grade level, feeling academically competent, persisting on tasks, and feeling motivated to perform. Socially, depressed children are more likely to be withdrawn, experience social skills deficits, and derive less enjoyment from their surroundings. *Salodia UP et al.*²¹ reported that factors associated with depression among the adolescents have indicated that the individuals known to suffer from depression in any form have are also associated with poor academic performance,

depression has been found to range between 18 and 50% among various study populations.

A major limitation of this study is that the prevalence estimation is through a screening tool rather than a definitive diagnosis by a psychiatrist. The cross-sectional study design qualifies only one time view of the relationships among all the variables that were determined, eliminating the ability to observe these associations over a longer period of time.

Conclusion

Present study highlights the prevalence of depression among adolescent studying in medical stream of urban schools of Ludhiana. It also identifies important positive and negative risk factors associated with adolescent depression. The overall prevalence of depression in our study was 84.6% and it is a prudent reminder of the extreme pressure the adolescent face in this particular age. Compared to other studies the percentage is alarmingly high. This is higher than those reported by several national, regional and international studies.

There was a significant difference of prevalence of depression in between males and females ,with females(89.4%) outnumbering males(72.6%). According to our study the students who carried out recreational activities had lower levels of depression which showed that carrying out recreational activities had a protective effect and may counter the stress of facing the board exam.

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Augmentation of Alderfer's ERG Needs Conducive in intent to Stay of Rural CHC Doctors in Tamilnadu: Structural Equation Modelling with Smart PLS

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Abstract

This research article examines how to motivate the doctors to stay in rural locations. The study observed the impact of ERG needs on CHC doctors' intent to stay in rural Tamilnadu. A connection was made between ERG needs and intent to stay. It is a cross-sectional analytical approach to collect primary data from 318 doctors using a standardized questionnaire with a 5-point Likert scale. 'Growth needs' was shown to be the most important predictor of rural CHC doctors' intent to stay. Researchers and practitioners of public health can utilize this validated ERG instrument to investigate doctors' motivation for rural posting in India.

Key words: Rural CHC doctors, ERG dimensions, Intent to Stay, structural equation modelling.

Introduction

Unequal health workforce distribution is a global issue. According to the Global Health Observatory, almost 40% of WHO member nations have less than ten medical physicians per 10,000 people, and 26% have less than three. India has less than ten physicians per 10,000 people.¹Tamilnadu is one of India's biggest states, with 97.35 percent of the land being rural and a rural population of 37229590 in 2011.²The aim of Health Sector 2023 is for Tamil Nadu to become India's leading state in increasing the standard of health care delivery by guaranteeing

universal access to health facilities, expansion of primary healthcare and upgradation of medical colleges to worldwide standards.³However building infrastructure without human resources is futile. The government approved more GDMOs to meet the rising population's healthcare requirements but the number of shortfall remain 179 in 2020.⁴The vacant posts in coming years are another paradox, as GDMOs have a state of the intent to leave CHCs once after completing their PG training.⁵It was spelt out by Bailey, PG education emerged as the crucial factor in career choices.⁶Another major challenge is massive shortage of specialists in CHCs. As per the Rural Health Statistics data 2020, there is a deficit of 1312 specialists in rural CHCS of Tamilnadu, despite one doctor per 253 people is accessible.⁶ states have more doctors than WHO 1: 1000 guideline and Tamilnadu has as high as 4 doctors per 1000 population, and in the first place. Skewed distribution of doctors is bigger problem than shortage.¹⁰ since

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doctors are largely concentrated on urban areas which result in shortages to rural areas. Subsequently, efforts to retain rural physicians continue to be a struggle. NHP 2015 emphasized the need of increasing rural medical students with the primary goal of returning to serve their community.⁷Also, the government took some compulsory measures for retention like mandatory rural postings.⁸But the data reveals that 250 doctors skip mandatory government service in Tamilnadu.⁹Hence, the applicability of the standards is a big challenge. Once the alarming facts of public healthcare system found from the sources, the study endeavor to identify the reasons of rural shortage of doctors in CHCs by exploring their motivational needs and its influence on their intent to stay.

Methodology

The aim of the study is to identify the dimensions of ERG (Existential, relatedness and Growth) needs from the Rural CHC doctor's perspective and to determine whether these needs having effect on Intent to stay.

To achieve the aim of the study, the specific objectives formulated are:

- a) To derive with the dimensions of ERG needs as perceived by Rural CHC doctors in Tamilnadu.
- b) To validate ERG needs dimensions for rural doctors working in Tamilnadu CHCs.
- c) To analyze the relationship between ERG needs and intent to stay as perceived by Rural CHC doctors In Tamilnadu.

Hypothesis:

- H01: There is no effect of Dimensions of ERG (Existential, relatedness and Growth) on intent to stay of Rural CHC doctors in Tamilnadu.
- H1: There is an effect of Dimensions of ERG (Existential, relatedness and Growth) on intent to stay

of Rural CHC doctors in Tamilnadu.

Questionnaire design:

§ **ERG Dimensions:** Structured questionnaire representing ERG needs was designed based on review of literature. The items relevant to ERG needs taken from 7 validated scales. In addition, 3 qualitative studies' themes itemized to form the questionnaire. After pilot study, the retained 37 items questionnaire on ERG dimensions measured the level of satisfaction towards the existential (13) relatedness (12) and growth needs (12). The Likert scale set for the independent variables i.e., ERG needs (1- Not at all satisfied, 2- Slightly satisfied, 3-moderately satisfied, 4-very satisfied, 5- extremely satisfied).

§ **Intent to stay:** Doctors' intent to stay was measured by the McCain Behavioral Commitment Scale with 5 items.¹¹The Likert scale set for dependent variable i.e., intent to stay (1-never, 2- Occasionally, 3- sometimes, 4- Often, 5-Always)

§ **Study design and sampling:** A cross-sectional analytical research design is used. The study population (N=2564) was all the doctors working in rural CHCs of Tamilnadu. Stratified sampling technique under probability method is used for this study. In total 56 CHCs among 4 Districts are selected, and the number of CHCs in every district is considered as strata. The available data from the respective districts are 93, 73,96 and 56 correspondingly. Hence, the reached sample size is 318.

Results and Discussion

Overall Reliability of the constructs in the questionnaire

Overall reliability of the questionnaire consisting of the dependent variable i.e., intent to stay comprising of five items and independent variables comprising of 37 ERG needs , constituting a total of 42 items was checked through Cronbach's α using SPSS software.

The reliability shown by Cronbach’s α value was 0.933, depicting a highly reliable questionnaire since it is well above the acceptable value of 0.5 as proposed by several researchers.

Test for sampling adequacy (KMO and Bartlett’s test of sphericity)

The sampling adequacy tested for this study through KMO and Bartlett’s test of sphericity through SPSS, the KMO value is 0.942, significantly greater than 0.5, indicating that a large enough sample size to access the factor structure, and the Bartlett’s test of sphericity with a significant value of 0.000, less than 0.05, indicating that the data collected for the dimensions of ERG were suitable for factor analysis.

Objective 1: To derive with the dimensions of ERG needs as perceived by Rural CHC doctors In Tamilnadu.

Exploratory Factor Analysis –The dimensions of ERG needs, which totaled 37 items, were factored using PCA (Principal Component Analysis) using the rotation technique with varimax and Kaiser normalization. The grouping of items under various

factors as per the rotated component analysis as follows: Through EFA, four components were extracted with a variance of 63.909%, and all the items were forced to form a single factor. The new extracted factors were: **Factor 1 (Existential needs: EN)** comprising of 8 items, **Factor 2 (Societal relatedness needs: RN_S)** entailing of 5 items, **Factor 3 (Family relatedness needs: RN_F)** involving of 5 items and **Factor 4 (Growth needs: GN)** residing of 6 items describing the variances of 19.078, 15.819%, 14.517% and 14.495% respectively.

Objective no2: To validate ERG needs dimensions for Rural doctors working in Tamilnadu CHCs.

Confirmatory factor analysis: The study used PLS technique and smart PLS software to get the findings of CFA. “Convergent validity refers to the degree of agreement between two or more measures of the same construct.”¹² It is assessed by individual item outer loadings, composite reliability, Cronbach’s Alpha scores, and Average Variance Extracted (AVE). Table 1 shows that ERG dimensions possessed convergent validity, except for the item GN3 (initial training for my learning, i.e., loading value less than 0.7) which was removed for further analysis.

Table 1: “Convergent validity of ERG dimensions”

	Constructs and associated items	Loading	Cronbach’s Alpha	Composite reliability	Average variance extracted
	Existential needs		0.911	0.93	0.653
EN1	Housing services	0.76			
RN2	Appreciation from patients	0.805			
RN3	Pleasant working climate	0.824			
EN2	Working conditions with light, heat, and ventilation	0.821			
EN3	Safe and attractive working environment	0.849			
EN4	Social benefits	0.802			
EN5	Satisfactory physical surroundings	0.796			
GN3	Initial training for my learning	0.633			
	Growth needs		0.86	0.895	0.588

Cont... Table 1: “Convergent validity of ERG dimensions”

Growth needs			0.86	0.895	0.588
GN2	Sense of value what I do	0.728			
GN4	Personal growth in my work	0.804			
GN5	Opportunities for advancements in my career	0.758			
GN6	Equal opportunities for promotion	0.788			
GN8	Promotion opportunities	0.736			
RN6	Status in the community as health care professional	0.784			
Family relatedness needs			0.833	0.883	0.602
GN9	Opportunity to expand the scope of practice	0.709			
RN11	Spousal fulfillments	0.844			
RN12	Finding spouse job	0.75			
EN12	Undisrupted family life	0.762			
EN13	School for children	0.806			
Societal relatedness needs			0.884	0.915	0.684
RN9	Interpersonal relationship	0.803			
GN11	Chance to paying back for public concern	0.796			
GN12	Chance to work for the poorest segments	0.844			
GN7	Chance to work for other people	0.829			
RN10	Social contact at work	0.86			

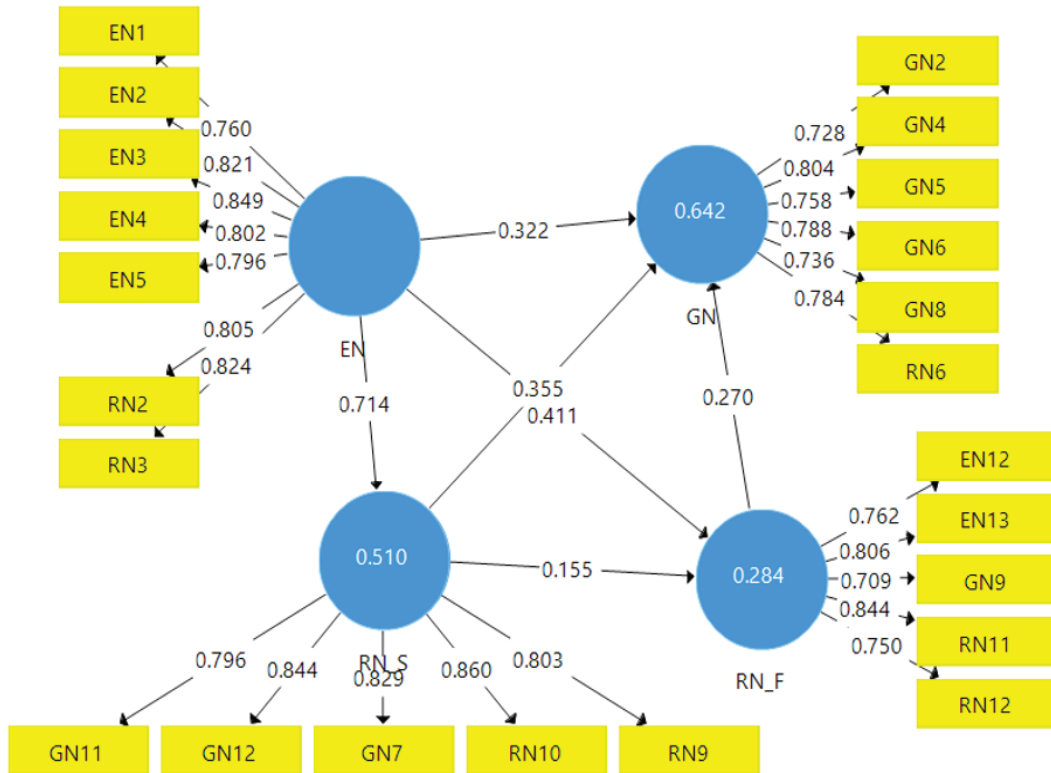


Fig 1: “Measurement model obtained after removing GN3”

Discriminant Validity : ‘Discriminant validity is the degree to which any single construct is different from the other construct in the model’. ¹²It is determined by Fornell-Larcker criterion and the Heterotrait-Monotrait ratio. Validity is established

when the diagonal elements in the relevant row and column values are much larger than the off-diagonal values. According to the findings (Table 2), all constructs show discriminant validity.

Table 2: ‘Fornell- Larcker Criteria for Discriminant validity’

	EN	GN	RN_F	RN_S
Fornell-Larcker criterion				
EN	0.808			
GN	0.716	0.767		
RN_F	0.522	0.597	0.776	
RN_S	0.714	0.706	0.448	0.827
Heterotrait – Monotrait ratio				
	EN	GN	RN_F	RN_S
EN	1.000			
GN	0.803	1.000		
RN_F	0.594	0.7	1.000	
RN_S	0.789	0.807	0.514	1.000

Objective no 3: To analyze the relationship between ERG needs and intent to stay as perceived by Rural CHC doctors In Tamilnadu.

Structural equation modelling: The study’s hypotheses were tested using Structural Equation Model in accordance with the objectives. It helps in complete model specification, estimation and assessment through an intuitive path diagram to bring out the hypothesis regarding the relationship amongst variables.¹³

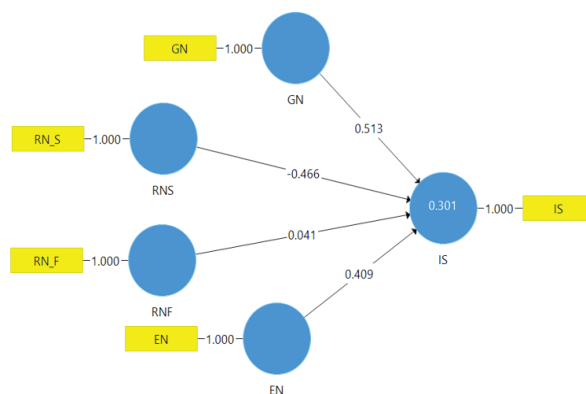


Fig 2: Structural Model 1: structural model of intent to stay with 4 derived ERG dimensions

Through structural equation modelling with Smart PLS software, Model 1 investigated the influence of

the aspects of ERG needs, including growth, societal relatedness, family relatedness, and existential needs. The link between the dimensions of ERG needs and Intent to stay in one direction has been established. As per the model estimates (Fig 2) the construct GN (0.513) has the greatest influence on IS with the p-value of 0.000, followed by RNS (-0.466) with the p-

value of 0.000 and EN (0.409) with the p-value of 0.001. But IS with RNF (0.041) having a very little effect with the p-value of 0.588. According to bootstrapping data, GN, RNS, and EN all have significant effects on IS, while RNF has no influence at the 5% likelihood of error level. Because of this, the study does not include family relatedness needs for further analysis.

Fig 3: Structural Model II: Model of intent to stay with 3 dimensions – after removing insignificant dimension

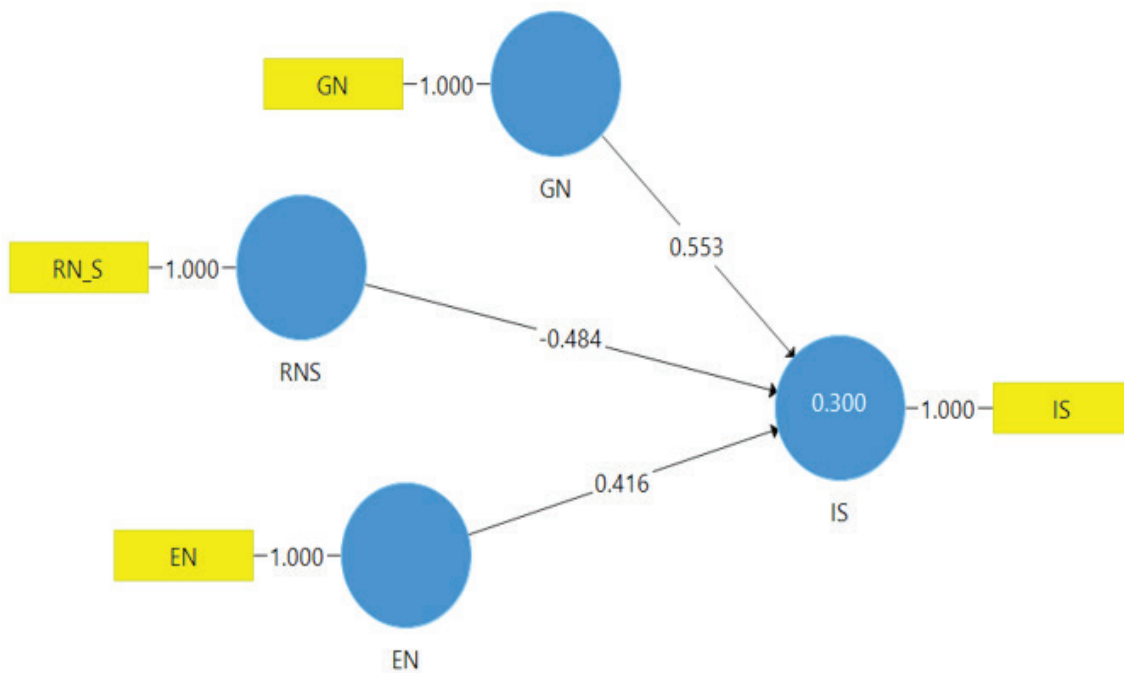


Table 3: ‘Path coefficients of the structural model II and model fit indices after removing insignificant dimension

	Beta coefficients	T Statistics	P Values	f ²	Q ²	R ²	NFI	SRMR
GN -> IS	0.533	4.334	0	0.08	0.288	0.30	1	0.000
RNS -> IS	-0.484	4.591	0	0.068				
EN -> IS	0.416	3.715	0	0.055				

The estimates in table 3 shows that all the dimensions i.e., Growth needs, Societal relatedness needs, existential needs concerning Intent to stay since the T- statistics value is 4.591, 3.715 and 4.334, hence

the dimensions have t- values more than 1.96, thus are considered significant. The p- values for these three dimensions are also highly significant i.e., 0.000.

Model fit indices: The key standards for the internal structural model evaluation are the determination coefficient R^2 , the path coefficient (β -value) and the T-statistic value, the impact size f^2 and the model's predictive significance Q^2 . Path coefficient and total effect were used to test the hypothesis. It is the most reliable source for examining multi-correlational variables.¹⁴ Furthermore, the t-value must be larger than 1.69 and the p-value must be less than 0.05.¹⁵ Cohen established that $R^2=2$ percent is categorized as a minor impact, $R^2=13$ percent as a median effect, and $R^2=26$ percent as a big effect in the field of social and behavioral sciences research.¹⁶ The R^2 score in this study is 30 percent, indicating that the model has big effect. Hair recommends the f-values 0.35 (strong effect), 0.15 (moderate effect), and 0.02 (weak effect).¹⁷ As per the study results the effect size is weak for GN, RNS and EN. Q^2 values greater than 0, 0.25, and 0.50, respectively indicate small, medium, and significant predictive significance of the PLS-path model.¹⁴ Table 3 indicates Q^2 value is 0.288; hence the model is having medium predictive power.

Assessing of model fit is ideal to obtain the important effect in the model. Furthermore, the SRMR was lower than the initially recommended criterion of 0.080, suggesting that the model fit was acceptable.¹⁸ The normed fit index developed by Bentler is one of the fit metrics suggested in the SEM literature; the closer the NFI to 1, the better the fit.¹⁹ NFI values greater than 0.9 generally indicate an acceptable fit.²⁰ In this study The SRMR i.e., 0.000 and NFI = 1, indicated the acceptable fit of the model.

Effect of the Significant Dimensions: All the dimensions of ERG needs were found significant with intent to stay, the influence of important dimensions' Beta coefficients derived from the Smart PLS output were considered. Results show that with every unit increase in growth needs, societal relatedness needs and existential needs, intent to stay is increased by

0.533, -0.484, 0.416 units and growth need was found to have maximum impact on the intent to stay of rural CHC doctors. Societal relatedness needs on the other hand, was found to have an inverse connection with doctors' Intent to stay. Hence it can be deduced there is a significant effect of dimensions of ERG with intent to stay for elements. So, the alternative hypothesis H1: ***There is an effect of Dimensions of ERG (Existential, relatedness and Growth) on intent to stay is accepted.***

The study has identified the essential dimensions of ERG needs lead to intent to stay. The dimension "Growth needs" having a high impact on intent to stay. The public health policymakers must identify a way to satisfy these needs to improve the retention of rural doctors. Right societal relatedness with community, patients and family, sufficient existential needs like water, transport, Communication are also crucial in determining rural retention. By observing the study results, the researchers put forward some ideal recommendations as follows:

Accurate and quick processes for receiving scholarships by performance level but not by time-bound compulsory rural postings are necessary to boost growth demands. To improve training quality, NHM should develop more in-depth training modules for future studies and redirect medical education to address rural health concerns. To progress doctor motivation, the Tamilnadu government should enforce procedural justice in determining promotion criteria. The study's findings favour rural upbringing; thus, government measures should be enhanced. Increased community involvement in communal health programmes is advised and private practise CHC physicians should be encouraged as they are fostering community connection. It's also vital to upgrade rural facilities. Public welfare and rural administrative services should work together in concert. Most doctors do not want their wards

admitted to rural schools. This eventually pushes these doctors to change. Improving rural education is critical to altering physicians' attitudes. This should be furthered by focusing on digital education and sophisticated curriculum that meets global demands. It is advised to inspect priority posts (specialists) and fill them as required by regions through yearly audit. Attractive incentives and promotion possibilities must be developed to recruit and retain urban doctors. The younger workforce has more hedonistic wants that are not met in rural areas. Salary and other fringe benefits must thus be structured to not only attract but also retain staff.

Conclusion

This study has several ramifications for Tamilnadu's public health system providers and policymakers. The "Growth requirements" component greatly influences retention. Thus, the study's findings would be useful in identifying growth requirements for Rural CHC doctors in Tamilnadu, such as career progression, education, and promotion. Adequate access to water, transportation, and communication are other important factors in rural retention. The study is of particular interest to doctors currently working in rural regions, as it seeks to assess their perceptions of a neglected facet of motivation. Researchers and public health practitioners can use the validated ERG to examine doctors' motivation for rural posting in India and enhance the insights provided by this study.

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Prevalence of Neuroleptospirosis in Pediatric Acute Encephalitis Syndrome Cases: An Experience of Northern India Tertiary Care Centre

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Abstract

Background: Acute encephalitis syndrome (AES) is a serious public health problem in Northern India. Neuroleptospirosis presenting as AES is well documented, so this study was planned to know the contribution of Neuroleptospirosis in AES, in children. Another gap in leptospirosis research is lack of studies on confirmed cases in children.

Aims: The aim of this study was to look for contribution of Neuroleptospirosis in Pediatric AES patients, in this part of the country.

Method: All children with AES-like presentations were included. Detailed history, clinical examination and appropriate lab investigations were done, to look for the cause of illness. For diagnosis of Leptospirosis, IgM, polymerase chain reaction (PCR), and Microscopic Agglutination Test (MAT) *Leptospira* was done.

Results: Among 100 AES children, 3 were diagnosed as neuroleptospirosis, the rest were 16 Scrub typhus meningoencephalitis, 20 Japanese, 14 dengue, 2 herpes, and 1 case of chikungunya encephalitis. 44 cases remain undifferentiated. Mean age at presentation for non-leptospirosis AES (NLAES) and Neuroleptospirosis was 75.4 & 96 months, 43% of NLAES were between 2-5 years while all neuroleptospirosis cases were older (> 8 years age). All neuroleptospirosis cases were, from a rural background, presented in rainy / post rainy season and fulfilled Modified Faine's criteria. Better Glasgow coma scale score, absence of seizure & focal neurological deficit, hypertonia among clinical findings, and high serum bilirubin, liver enzymes, and creatinine were other important observations, though only high serum bilirubin was statistically significant.

Conclusions: Neuroleptospirosis is uncommon but important treatable etiology for AES in children and should always be considered in differential while evaluating a child with AES.

Key-words: Neuroleptospirosis, Children, MAT, AES, Leptospirosis.

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Introduction

Leptospirosis (Weil's disease, icterohemorrhagic fever) is a neglected zoonotic disease with global distribution. It is caused by infection of spirochetes from the genus *Leptospira*. Infection results from

direct or indirect exposure to infected reservoir host animals that carry the pathogen in their renal tubules and shed pathogenic leptospires in their urine. Although many wild and domestic animals can serve as reservoir hosts, the brown rat (*Rattus norvegicus*) is the most important source of human infections¹.

Although leptospirosis usually presents as a mild, self-limiting febrile illness, severe cases with high mortality and morbidity might occur². It is now recognized as a disease of global distribution, the epidemiology of leptospirosis is mainly reported from developing countries in the tropics. An adult study from Chandigarh, India, concluded that there has been a rapid rise in the incidence of leptospirosis in north India³. Severe complications such as renal failure, respiratory failure, neuroleptospirosis, and disseminated intravascular coagulopathy are being seen with increasing frequency. The clinical manifestations of leptospirosis range from asymptomatic infection to severe, fatal illness. Increased awareness among physicians, and early diagnosis and treatment, may reduce mortality due to leptospirosis. Newer diagnostic methods like microscopic agglutination test (MAT) facilitate early diagnosis and antibiotic treatment. MAT requires advanced laboratory facilities and expertise and is not widely available in low- and middle-income countries where leptospirosis may be endemic. Consequently, leptospirosis may be overlooked as a cause of acute febrile neurological illness, and the burden of leptospirosis-associated morbidity and mortality remains poorly defined in many parts of the world⁴.

Another gap in leptospirosis research is lack of studies on confirmed cases in children. We, therefore, decided to look for this infection also in AES patients as well as children presenting with acute febrile illness in this part of the country.

Material and Method

This hospital-based prospective observational study was undertaken in the; Department of Pediatrics, King George Medical University (KGMU), Lucknow during the period September 2018 to August 2019. All Children aged 1 to 14 years of age admitted to Pediatrics wards or seen in Pediatric OPD with Acute febrile illness with altered sensorium or convulsions, were included. Children with obvious central nervous system disorder not related to *Leptospira* (i.e., Tumor, Neurocysticercosis, Epilepsy, etc.) were excluded. The sample size calculated based on the prevalence of 0.1 was calculated to be 140 patients¹. Detailed clinical history and examination evaluation done and appropriate laboratory investigations done to look for the cause of illness. For diagnosis of *Leptospira*; IgM *Leptospira* was done; using a *Leptospira* Direct kit marketed by Panbio Diagnostics, in the Department of Microbiology, KGMU, Lucknow as per the manufacturer's instructions. Test value of >11 PU was considered positive. Cross-check with PCR for the detection of leptospirosis: 16S r RNA amplification was carried out according to the method of Shukla et al (2003) with certain modifications⁵. Microscopic Agglutination Test (MAT) samples were sent to Indian Veterinary Research Institute, Bareilly according to standard methods. A titer of 1/100 or more was taken as significant criteria (Chirathaworn et al, 2014)⁶.

Results

Over a period of one year (From September 2018 to August 2019), a total of 100 patients with acute encephalitis syndrome (AES) were enrolled, 62% of them were male. The mean age at presentation was 75.4 months almost half of them (43%) were between 2-5 years. 59% of the AES cases were, from a rural background with 97% from upper lower and lower socioeconomic status as per modified Kuppaswamy scale (Figure 2)⁷. Three fourth of the cases were presented in rainy and post rainy season

months (June - November) (Figure 1). Among 100 AES cases 3 were diagnosed as neuroleptospirosis; rest were 20 cases of Japanese Encephalitis, 16 Scrub typhus meningoencephalitis, 14 dengue encephalitis, 2 herpes encephalitis, 1 chikungunya encephalitis. 44 cases remain undifferentiated. All 3 cases of neuroleptospirosis cases fulfilled Modified Faine’s criteria. The IgM Leptospirosis test was further supplemented by PCR and MAT for which samples were sent to Indian Veterinary Research Institute, Bareilly. Only one of the three patients was

positive for both PCR and MAT. Better Glasgow coma scale score, absence of seizure & focal neurological deficit, hypertonia among clinical findings and high serum bilirubin, liver enzymes and creatinine were other important observations, though; only high serum bilirubin was statistically significant. Neuroimaging (contrast-enhanced computed tomography scans) doesn’t show any remarkable findings. Overall outcome of the AES cases was good, 73% discharges and 14% mortality, (13 left against medical advice or absconded) while all neuroleptospirosis cases recovered.

Table 1: Clinical features of AES (N=97) & Neuroleptospirosis patients (N=3)

S. N.	Clinical features	AES (N=97)	Neuroleptospirosis (N=3)	p- value
1	Mean age Diagnosis (months)	75.4 ± 35.7	96.0 ± 12	0.323
2	Male Sex	62	2	0.870
3	Rural residence	59	2	0.790
4	Lower- lower socioeconomic status	85	3	0.468
5	September-November presentation	57	3	0.371
6	Exposure to flood water	0	3	<0.001
7	Duration of prodromal stage (in days) 1	3.3	4.6	0.362
8	Seizures	91	3	0.587
9	Type of Seizures			-
	Focal	6	0	
	Generalized tonic	28	0	
	Generalized tonic-clonic	57	3	
10	Altered sensorium	90	3	0.564
11	Headache	22	2	0.267
12	Vomiting	33	1	0.990
13	Diarrhoea	8	0	0.610
14	Rash	20	0	0.903
15	Bleeding	14	0	0.486

Table 1: Clinical features of AES (N=97) & Neuroleptospirosis patients (N=3)

16	Hepatomegaly	53	0	0.221
17	Splenomegaly	23	0	0.811
18	Mean GCS (Mean±SD) 1	8.1	10.3	0.170
19	Any meningeal sign	28	1	0.840
20	Increased muscle tone	44	3	0.183
21	Any focal deficit	13	0	0.504
22	Cranial nerve palsy	6	0	0.662
23	Extrapyramidal features	6	0	0.662
24	Signs of raised ICT	48	1	0.616
25	Signs of shock	23	1	0.677

Table 2: Laboratory parameters in AES (N=97) & Neuroleptospirosis patients (N=3)

Parameter	AES (N=97)	Neuroleptospirosis (N=3)	P value
	Mean ± SD	Mean ± SD	
Hemoglobin in gm/dl	9.7±1.8	8.00±0.62	0.107
Total leucocyte count/ cu mm	14019.7±6523.6	10200.00±3328.66	0.317
Platelets in lac/cu mm	1.25±0.76	1.30±0.62	0.911
s. Total Bilirubin (mg/dl)	0.61±0.33	2.06±1.02	<0.001
s. AST(IU/l)	121.9±165.5	167.33±137.6	0.639
s. ALT(IU/l)	81.8±66.5	108.66±73.1	0.493
s. Albumin (gm/dl)	4.6±0.87	4.53±0.66	0.891
International Normalized Ratio (INR) for PT	1.2±0.32	1.04±0.8	0.417
s. Urea (mg/dl)	45.2±45.4	79.7±17.7	0.194
s. Creatinine (mg/dl)	0.75±0.79	1.15±0.3	0.386
CSF cell count/ cu mm	17.9±16.2	12±7.2	0.532
CSF polymorphs %	22.3±12.9	21.7±7.6	0.937
CSF protein (mg/dl)	140.2±79.0	134.0±93.7	0.894
CSF sugar (mg/dl)	69.0±33.6	51.3±19.4	0.368

AST – aspartate transaminase; ALT- alanine transaminase; CSF- cerebrospinal fluid; MAT – Microagglutination Test ; PCR –Polymerase Chain Reaction; ¹ Number and percentage, PT Prothrombin Tim.

Discussion

Acute encephalitis syndrome (AES) is a serious public health problem in India, especially Uttar Pradesh. Japanese encephalitis (JE) was considered the major cause of AES in Uttar Pradesh since 1970. Acute encephalitis syndrome outbreaks in the monsoon and post monsoon season in the eastern districts of the state. Leptospirosis is another zoonotic disease which; can present as AES. Unlike most viruses, it is potentially treatable. Its presence has been recognized in many parts of the country but there are fewer studies from Uttar Pradesh, to assess the disease burden of leptospirosis in and around Lucknow among patients presenting with AES. All the conditions for the spread of Leptospirosis exist in eastern Uttar Pradesh. Therefore the main focus of this study was to look for Leptospirosis in patients of AES.

Among the clinical features of all AES patients enrolled, we find that seizures were present in the large majority of patients. Besides abnormal neurological features, rash, bleeding, and hepatosplenomegaly were common features in AES of non-leptospirosis (NLAES) etiology while older age, better GCS, longer prodrome, and hypertonia, favours the neuroleptospirosis (table 1). Among laboratory features, low mean hemoglobin, along with high Serum bilirubin, mean liver enzymes, and deranged serum urea and creatinine were the main differentiating biochemical parameters for neuroleptospirosis, though only serum bilirubin was statistically significant in this study (table 2). Neurological manifestations in patients with leptospirosis follows a pattern: the first phase is dominated by clouded sensorium and

meningism while the second phase is characterised by classical neurological features of central nervous system involvement; aseptic meningitis, encephalitis, intracranial bleed, cerebellitis, movement disorders or peripheral nervous system involvement flaccid paraparesis, mononeuritis or polymyositis⁹. Leptospire reach the CSF and brain as early as 48 hours after inoculation¹⁰. Mean CSF cell count was slightly raised and majority were lymphocytes. Mean CSF protein was also increased (table 2). The CSF findings are therefore suggestive of brain/meningeal inflammation. In Neuroleptospirosis cases, leptospiral cerebral arteritis and inflammation with uropod like cells and hybrid monocytes predominates (Zhang SM et al)⁸.

Neuroleptospirosis accounts for 10-15% of all forms leptospirosis presentations. Another common neurological presentation reported was aseptic meningitis⁹. Though we do not find any such presentations. Seizures are uncommon with neuroleptospirosis, hence one need to consider neuroleptospirosis in the differential diagnosis, whenever a diagnosis of viral encephalitis is made, especially in endemic areas with seasonal prevalence. Focal neurological deficits are also uncommon findings in Neuroleptospirosis¹⁰. The prognosis of neuroleptospirosis is largely unknown. Most of the adult studies report mortality rates for systemic leptospirosis, varying from 5-15 percent¹¹. In the study by Singh et al mortality rate was 24.1 per cent and the major cause of mortality was pulmonary involvement¹². In the study of Heath et al, which included patients with neurological and non-neurological manifestations, the mortality was 7 per cent¹⁰. In the current study all children have favourable outcome. Poor prognostic factors reported to be high CSF protein and low GCS at the time of admission (Mathew T et al)¹³.

Limitation of our study were that this being a hospital based study, the true burden of leptospirosis age and gender distribution and trends of leptospirosis in the community could not be ascertained, due to selection of cases only from the hospital. Secondly, this is a small study over a one year period only, so the desired sample size did not accrue for either AES or neuroleptospirosis.

In conclusion, current small hospital based study does confirm that Neuroleptospirosis has a small but definite presence in Uttar Pradesh, India. The prevalence of leptospirosis as well as neuroleptospirosis could increase dramatically in case of floods. Being a treatable condition with good outcome, Neuroleptospirosis should be in differentials, while evaluating every case of AES specially in rainy and post rainy season. Our results would be applicable to other locations in India with similar catchment populations.

Ethical Clearance: Approval was taken by Ethical Committee of King George Medical University, Lucknow.

Conflict of Interest: No

Source of Funding: NIL

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An Experimental Study to Assess the Effectiveness of Nesting on Physiological Parameters and Posture of Preterm Babies in A Selected Hospital, New Delhi

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Abstract

Preterm babies are physically immature and physiologically unstable. They cannot tolerate environmental stimuli. Due to immaturity, they often lack adequate muscle tone and are at the risk of developing an abnormal posture. Nesting helps maintain position, promote comfort and provide physiological, behavioural and postural stability to premature babies. The objectives of the study were: 1. To assess the effectiveness of Nesting on physiological parameters and posture of preterm babies. 2. To compare the effectiveness of Nesting on physiological parameters and posture of preterm babies in both experimental and control group. 3. To find out the association between the physiological parameters with the selected variables of preterm babies. 4. To find out the association between the posture with the selected variables of preterm babies.

The study was done at the Neonatal Intensive Care Unit of Kasturba Hospital and Hindu Rao Hospital, Delhi. A total of 60 samples were randomly assigned into 2 groups (30 in the experimental and 30 in the control group) through probability sampling technique (simple random sampling) using a chit method. A structured interview schedule, record sheet to assess the physiological parameters and Infant Positioning Assessment Tool were used to collect the data. Nesting was administered after a pre-test to the experimental group for 9 hours for consecutive 6 days, and routine care was given to the control group. Post-tests of physiological parameters were observed on the first day at the 3rd, 6th and 9th hour and post-tests of posture were assessed on the 2nd, 4th and 6th day of both the groups. The findings reveal that the calculated 't' values of physiological parameters (Heart rate) were 2.261 in post-test 3 and found significant at $p \leq 0.05$. In the respiratory rate, the calculated 't' value was 2, 2.079 in post-test and found significant at $p \leq 0.05$. In oxygen saturation, the calculated 't' value was 2, 3.28 in post-test and found significant at $p \leq 0.05$. In posture, the calculated 't' values were 3.644 in post-test 1, 9.917 in post-test 2 and 13.467 in post-test 3. The values were found to be significant in all the post-tests at $p \leq 0.05$. Thus, the study concluded that Nesting effectively stabilises the physiological parameters (Heart rate, Respiratory rate and Oxygen Saturation) and improves the preterm babies' posture, and it can be implemented as a useful measure.

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Keywords: *effectiveness, nesting, posture and preterm babies.*

Introduction

Background of Study

Preterm babies have poor muscle tone leading

to abnormal tone and consequent delay in motor development. The flexed posture reduces the surface area exposed to the environment, minimising heat loss which prevents enormous weight loss. It also affects neuro-behavioural development. Stable physiological parameters such as heart rate, respiratory rate and oxygen saturation are the indicators of good health and reflect the maturation of the central nervous system¹. Good posture can help to improve the circulation and digestion, enhance sleep and prevent cramping. It also enhances the quality of life and muscle control, physiological functioning and reduces stress. Many factors may combine to cause early birth. The causes of preterm babies are associated with maternal factors – malnutrition, hypertension, multiple pregnancies, polyhydramnios, placenta previa or diabetes, with behavioural and environmental factors – smoking, alcohol, domestic violence, stress, lack of social support. Foetal factors associated with prematurity area chromosomal abnormality, fetoplacental unit dysfunction, congenital anomalies and unknown factors. Due to immaturity, they often lack adequate muscle tone and are at the risk of developing an abnormal posture. A posture or alignment of various body parts in relation to one another as midline head position, neck slightly flexed forward, hands flexed and able to touch the face, rounded shoulders, hips, knees, ankle and feet aligned and softly flexed. Nesting is one of the methods that help maintain position, promote comfort and provide physiological, behavioural and postural stability to the premature babies.

Need of Study

A new born has so many adjustment problems soon after the delivery. When they were in the mother's womb, the temperature is maintained, and the flexed position provides much comfort to the baby. After delivery, there is an alteration in the posture and physiological parameters. Preterm babies

have poor muscle tone, and they lay with their arms and legs extended. Extended posture for a long time may lead to abnormal tone and consequent delay in motor development. In India, 6.4 lakh neonatal deaths occur per year – the neonatal mortality rate of 24 deaths per 1,000 live births in India (2019). India is the only major country to have higher mortality for girls than boys. Kerala, Goa and Delhi have neonatal mortality rates of 10 per 1,000 live births and Bihar and Uttarakhand stands at 44 per 1,000 live births¹.

Review of Literature

Gill Sandeep Kaur (2011)² conducted the study to assess and evaluate the effect of Nesting on physiological parameters (temperature, respiratory rate, oxygen saturation) and comfort behaviour of preterm infants admitted in NICU at Ambala. The sample was 30 preterm babies included for the experimental and control group. The findings of the study revealed that there was a significant effect of 'nesting' at 60th and 120th min on temperature ('t'(29)=7.86, 11.2), respiratory rate ('t'(29) = 6.43, 5.03), heart rate ('t'(29) = 6.61, 2.47) and comfort behaviour of preterm infants ('t'(29) = 22.48, 22.03). The results showed that Nesting was effective in significantly raising and stabilising the temperature of preterm infants and lowering and stabilising the mean respiratory rate and mean heart rate of preterm infants.

Mony K. (2013)³ conducted a study on the effect of Nesting on sleep patterns among preterm infants admitted in the NICU. Samples were babies born before the completion of 37 weeks of gestation. 21 samples were randomly assigned to two groups of nest and routine procedure. Sleep status was evaluated by using the neonatal sleep Assessment Scale. Duration of Total Sleep Time per cycle (TST) and duration of each stage, such as quiet sleep and active sleep indeterminate sleep, were recorded and analysed using a paired t-test. The result was that the total duration of sleep time showed that the mean value of

the entire course of sleep is significantly higher (113 min) among infants with Nesting than routine care (86 min). The study concludes that Nesting increases the sleep and duration of quiet sleep and aids in maintaining physiological parameters.

K. Prasanna (2015)⁴ conducted a quasi-experimental study on the effectiveness of Nesting on posture and motor performance among newborn babies. The sample size was 60 newborn babies, and purposive sampling was used for the selection of subjects. Questionnaire to obtain socio-demographic data of baby and mother and modified observational checklist Albert's Test of Infant Posture and Motor Assessment scale to assess the posture and movement of newborn babies. As a result, the post-test score mean was 18.8 with S.D. of 5.77, whereas in the control group, the post-test score mean was 13.5 with SD of 6.19. The calculated t-test value was 3.5, which exceeded the table value of 2.75 ($p \leq 0.01$). So, the study concluded that Nesting was an effective intervention in maintaining good posture and motor performance among newborns.

Problem Statement

An experimental study to assess the effectiveness of Nesting on physiological parameters and posture of preterm babies in a selected Hospital, New Delhi.

Objectives

1. To assess the effectiveness of Nesting on physiological parameters and posture of preterm babies.
2. To compare the effectiveness of Nesting on physiological parameters and posture of preterm babies in both experimental and control group.
3. To find out the association between the physiological parameters with the selected variables of preterm babies.

4. To find out the association between the posture with the selected variables of preterm babies

Conceptual Framework

The conceptual work adopted for the study was modified by Weidenbach's helping art of clinical nursing theory.

Methodology

Research design: It was a true experimental research design, consisting of physiological parameter record, structured interview schedule, physiological parameters and Infant Positioning Assessment

Setting: The present study was conducted in neonatal intensive care units in Kasturba Hospital and Hindu Rao Hospital, New Delhi.

Sample size: 60 preterm babies (30 in the experimental group and 30 in the control group) were selected.

Population: preterm babies admitted in neonatal intensive care unit in the selected hospital.

Sampling technique: the probability sampling technique (simple random sampling).

Tool: It consists of three sections:

Section 1 – Subject data to collect the demographic characteristics and clinical health data of mothers and preterm babies.

Section 2 – Record sheet to check the physiological parameters, watch, stethoscope and pulse oximeter.

Section 3 – Infant positioning assessment tool.

Validity: The tool was established by consultation with experts to calculate inter-rater observer reliability. The tool was found reliable with inter-rate reliability of 80%.

Pilot study: It was conducted on six preterm

babies in September to ascertain the feasibility of the study.

Data collection: A structured interview schedule, record sheet to assess the physiological parameters and Infant Positioning Assessment Tool were used to collect the data. On the first day before giving Nesting, the pre-test was done for the experimental and control group using the respective tool for physiological parameters (Heart rate, respiratory rate and oxygen saturation) and infant positioning assessment tool for assessing the posture of preterm babies and record on the record sheet. Nesting was done for the subject in the experimental group for 9 hours in 6 consecutive days. Post-test assessment of physiological parameters done on 1st day at 3rd, 6th and 9th hour and post-test assessment of posture was assessed with infant positioning assessment tool on 2nd, 4th and 6th day and recorded it.

Result

Section - I: Description of Demographic Data

(a): Assessment of demographic profile of the mothers of preterm babies in both experimental and control groups.

Out of 30 samples in the experimental group, the majority of 24 (80.0%) samples had a vaginal delivery, 5 (16.7 %) samples had caesarean section delivery, and 1 (3.3%) sample had assisted delivery. The majority of 24 (80.0%) samples did not have any complications, but 4 (13.3%) samples had pregnancy-induced hypertension (PIH), and 2 (6.7%) samples had diabetes mellites. None of the samples had any maternal unhealthy habits - 30 (100.0%) samples. A majority of 28 (93.3%) samples did not have any previous information on Nesting, and 2 (6.7%) samples knew about nesting.

Out of 30 samples in the control group, two-thirds of the total samples - 20 (66.4%) samples

had a vaginal delivery, 10 (33.3%) samples had a caesarean section with no assisted mode of delivery. A majority of 27 (90.0%) samples did not have any complications, but 2 (6.7%) samples had pregnancy-induced hypertension (PIH), and 1 (3.3%) sample had diabetes mellites. A majority of 29 (96.7%) samples did not have any maternal unhealthy habit, and 1 (3.3%) sample had a history of smoking and alcohol. A majority of 28 (93.3%) samples did not have any previous information on nesting, and 2 (6.7%) samples knew about nesting.

(b): Assessment of the demographic profile of the preterm babies in both experimental and control groups

Out of 30 samples in the experimental group, half of the total samples - 15 (50.0%) samples were between 32-34 weeks of gestation, 12 (40%) samples were between 30-31 weeks of gestation, and 3 (10.0%) samples were between 28-29 weeks of gestation. A majority of 29 (96.7%) samples had the vertex as presentation for the preterm, 1 (3.3%) sample had the breech presentation for the preterm. In terms of age, 27 (90.0%) samples were at 8-12 days, and 3 (10.0%) samples were at 17-21 days. Almost half of the total samples - 14 (46.7%) had birth weight between 1-1.5kg, 14 (46.7%) samples had birth weight between 1.5-2kg, and 2 (6.7%) samples had birth weight between 2-2.4kg. Almost two-thirds of the total samples - 19 (63.3%) samples were male preterm babies, and 11 (36.7%) samples were female preterm babies. A majority of 25 (83.3%) samples were fed with EBM, 4 (13.3%) samples were on breastfeeding, and 1 (3.3%) sample was having fed with formula feeding.

Out of 30 samples in the control group, a majority of 23 (76.7%) samples were between 32-34 weeks of gestation, 4 (13.3%) samples between 30-31 weeks of gestation and 3 (10.0%) samples were between 28-29 weeks of gestation. Five-sixths of the total samples -

25 (83.3%) samples had the vertex presentation for the preterm, 5 (16.7%) samples had the breech as a presentation for the preterm, and none of the samples had any other presentation. All the samples - 30 (100%) were at the age of 8-12 days. Almost one-third of the total samples -10 (33.3%) samples had birth weight between 1-1.5kg, 10 (33.3%) samples had birth weight between 1.5-2kg, and 11 (36.7%) samples had birth weight between 2-2.4kg. The number of samples was equal in terms of gender, 15 (50.0%) samples, i.e.

half of the total samples were male preterm babies and another half, 15 (50.0%) samples were female preterm babies. Almost two-thirds of the total samples, 21 (70.0%) samples, were fed with EBM, 9 (13.3%) samples were on breastfeeding, and none of them had formula feeding.

Section -II: Assessment of the Physiological Parameters and Posture in the Experimental Group and Control Group.

Table – 1: Comparison between pre-test and post-test of physiological parameters (heart rate) of preterm babies in the experimental group

n = 30

Physiological parameter	Experimental Group	Mean	Mean Difference	Standard deviation	Std. error mean difference	t – value		p -value
						Calculated	Tabulated	
Heart Rate	Pre-test	140.66	-	8.15	-	-	-	-
	Post-test	145.53	4.87	4.98	1.744	2.792*	2.05	0.002
Respiratory Rate	Pre-test	49.8	-	6.81	-	-	-	-
	Post-test	46.5	3.3	3.65	1.312	2.339*	2.05	0.009
Oxygen Saturation	Pre-test	95.53	-	2.56	-	-	-	-
	Post-test	97.06	1.53	1.70	0.561	2.727*	2.05	0.003

. *significant at $p(29) \leq 0.05$

The data represented in Table – 1 depicts that the mean score of the post-test of the experimental group was more than the mean pre-test score of the experimental group. In the post-test, the calculated 't' values were greater than the tabulated 't' value

of 2.05 at the 0.05 level of significance. The results indicate that Nesting effectively stabilised the heart rate, respiratory rate and oxygen saturation of preterm babies in the experimental group within 9 hours onwards.

Table – 2: Comparison between pre-test and post-test of the posture of preterm babies in the experimental group

n = 30

Experimental Group	Mean	Mean Difference	Standard deviation	Std. error mean difference	t – value		p -value
					Calculated	Tabulated	
Pre-test	7.7	-	1.54	-	-	-	-
Post-test	11.03	3.33	0.80	0.318	10.487*	2.05	0.0001

*significant at $p(29) \leq 0.05$

The data presented in Table – 2 depicts that the post-test mean score was greater than the pre-test score of the experimental groups. The calculated ‘t’ value of the post-test was greater than the tabulated ‘t’ value of 2.05 at the 0.05 level of significance. The result indicates that Nesting was effective in improving the posture of preterm babies in the experimental group after Nesting.

Table – 3: Mean, mean difference, standard deviation, standard error of mean difference and ‘t’ value of post-test score of physiological parameters (Respiratory rate) of preterm babies

n₁ + n₂=60

PHYSIOLOGICAL PARAMETER (POST-TEST 9 HOURS)								
Post-Test	Group	Mean	Mean Difference	Standard Deviation	Std. Error Difference	‘t’ – value		p-value
						Calculated	Tabulated	
Heart Rate	EXP	145.53	3.57	4.98	1.579	2.261*	2.001	0.011
	CON	149.10		7.07				
Respiratory Rate	EXP	48.63	0.61	4.27	1.026	2.079*	2.001	0.042
	CON	46.50		3.66				
Oxygen Saturation	EXP	95.37	1.53	1.87	1.533	3.284*	2.001	0.0017
	CON	96.90		1.75				

*significant at $p(58) \leq 0.05$

The data represented in Table – 3 depicts that the mean post-test score of heart rate and respiratory rate in the experimental group is higher than the mean post-test score of the control group. The post-tests’ calculated ‘t’ values were greater than the tabulated

‘t’ value at the 0.05 level of significance. The result indicates that Nesting effectively stabilised the heart rate, respiratory rate and oxygen saturation of preterm babies in an experimental group.

Table – 4: Mean, mean difference, standard deviation, standard error of mean difference and ‘t’ value of post-test score of the posture of preterm babies

$$n_1 + n_2 = 60$$

POSTURE (score)								
Post-Test	Group	Mean	Mean Difference	Standard Deviation	Std. Error Difference	‘t’ – value		p-value
						Calculated	Tabulated	
Post-test 1 (At 2 nd day)	EXP	8.80	0.6	0.664	0.165	3.644*	2.001	0.0001
	CON	8.2		0.610				
Post-test 2 (At 4 th day)	EXP	9.83	1.56	0.592	0.157	9.917*	2.001	0.0001
	CON	8.27		0.626				
Post-test 3 (At 6 th Day)	EXP	11.03	2.8	0.809	0.206	13.467*	2.001	0.0001
	CON	8.26		0.784				

*significant at $p(58) \leq 0.05$

The data represented in Table – 4 depicts that the mean post-test posture score of the experimental group is significantly higher than the mean post-test score of the control group with the ‘t’ value of 2.001 at the 0.05 level of significance. The result indicates that Nesting effectively maintains the posture of preterm babies in an experimental group.

Association between Pre-test Physiological Parameters and Selected Demographic Variable:

There was no significant association between

physiological parameters of heart rate, respiratory rate, oxygen saturation with the selected demographic characteristics like mode of delivery, maternal complication, unhealthy habits of the mother, the period of gestation, age of preterm baby, birth weight.

Association between Pre-test Posture and Selected Demographic Variable:

There was no significant association between posture and selected demographic variables like mode

of delivery, mother complication, mother habits, a period of gestation age of preterm babies and birth weight of preterm babies.

Discussion

The present study shows that Nesting effectively stabilises the physiological parameters and improves the posture of preterm babies compared to routine care. Physiological parameters like heart rate, respiratory rate, and oxygen saturation were stabilised, and posture improved after Nesting. The above study was consistent with the study finding of Nahed Saied Mohamed⁵, who reported the effectiveness of Nesting in stabilising the heart rate, respiratory rate and oxygen saturation. Another study supported by K. Prasanna and Radhika (June 2015)⁴ related to posture. This result indicated that Nesting effectively stabilised the physiological parameters and improved posture.

Conclusion

The following conclusions are drawn from the study. The study's finding proved that Nesting effectively stabilised physiological parameters and improved the posture in preterm babies admitted to the neonatal intensive care unit. Nesting intervention can be integrated with the nursing curriculum. The sample size was small to draw generalisations, and the time duration was limited.

Ethical Clearance: It was taken from the ethical committee of Holy family hospital with Kasturba Hospital and Hindu Rao Hospital. The final study was conducted at the Neonatal Intensive Care Unit of the hospital, and data collection was done in

December 2019 and January 2020. Eligible samples were randomly assigned to the experimental and control groups using the chit method's simple random sampling technique.

Source of Finding: Self

Conflict of Interest: Nil

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Eosinophilia Induced Acute Interstitial Nephritis: A Case Report

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Abstract

Introduction: This report presents the case of a patient with tubulointerstitial nephritis (ATIN) due to Eosinophilia, situation that has not been reported in India.

Case Presentation: A male patient with a history of pulmonary tuberculosis treated with ATT developed acute kidney injury. On admission, no evidence of abnormalities or history to explain the injury was found, but he did present tubular acidosis and associated Fanconi syndrome. The kidney injury was temporarily consistent with ATT use, and a kidney biopsy confirmed ATIN. The drug was suspended, resulting in improved kidney function.

Discussion: ATIN as a side effect of rifampin is a scarcely reported disease. The risk of developing this condition should be considered when starting and restarting treatments with this medication.

Conclusion: ATIN is one of the side effects of tuberculosis treatment. Albeit rare, it should be considered when starting tuberculosis medications.

Keywords: Nephritis; Interstitial; Acute Kidney Injury; ATT

Introduction

Rifampicin is a first-line anti-tuberculosis antibiotic drug used to treat *Mycobacterium tuberculosis*. It inhibits the P subunit of bacterial RNA polymerase with a consequent inhibition of messenger RNA¹; its use can generate side effects, including liver and gastrointestinal involvement and acute kidney injury, which was reported in 0.05% of patients in a retrospective study conducted between 1987 and 1995.² Factors associated with increased risk of kidney involvement were reintroduction and

intermittent use of rifampicin.^{2,3}

The onset of acute kidney injury in patients using rifampicin for the first time has been barely reported in the literature.⁴ These people have a favorable prognosis for recovery of kidney function, which can range from 73%⁵ to 96%², while mortality can reach up to 1.6%.²

Case Report

A 70-year-old male presented at the department of Medicine with fever since 3 months, generalized swelling since 2 months, cough with expectoration since 2 months and breathlessness since 2 months. Patient had history pulmonary tuberculosis and completed treatment of ATT for 9 months, 7 years back. The patient's kidney function was normal prior to antituberculosis management and he had no

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previous exposure to other medications, but given the abnormal results of laboratory tests regarding kidney function, he was referred to the emergency department. On admission, the patient was in good general condition; hydrated; without rashes, fever, dysuria, hematuria, abdominal pain, nausea, vomiting, fatigue, or decreased or increased amount of urine; he did not present any other symptoms on review of systems, nor manifested other relevant medical history. Physical examination revealed heart rate of 78 beats per minute, respiratory rate of 18 breaths per minute, and blood pressure of 118/68 mmHg. Fist percussion was negative and there was no abdominal pain, edema, or neurological abnormalities.

Creatinine test requested by the outpatient consultation service had values of 4.17 mg/dL. On admission, new tests were performed, which showed elevated azoids, proteinuria in non-nephrotic range and metabolic acidosis with increased anion gap; lactic acidosis and diabetic ketoacidosis were ruled out as causes of these symptoms.

Kidney and urinary tract ultrasound showed normal-sized kidneys with diffuse increase in echogenicity and no loss in corticomedullary differentiation.

The patient presented acute kidney disease KDIGO III⁷, glomerular filtration rate of 23.38 mL/min calculated by cockroft, proteinuria in the non-nephrotic range, high anion gap metabolic acidosis, urine sediment with glycosuria, positive urine anion gap and normal central glucose. All this led to consider that there was proximal tubular involvement compatible with Fanconi syndrome.

Considering the acute renal injury with proximal and distal tubular involvement, the history of tuberculosis and that rifampicin is the most frequently involved drug in kidney failure in this type of cases⁸, treatment was suspended and a kidney biopsy was

indicated to confirm the origin of the failure and plan a treatment. After the suspension of rifampicin, azotemias improved until creatinine was normalized. Kidney biopsy confirmed acute tubulointerstitial nephritis (ATIN) with inflammatory cells, eosinophils, and interstitial edema. The findings were also suggestive of drug hypersensitivity with associated tubular injury. Tubulointerstitial findings included: interstitial inflammation of the whole cortical area; presence of mononuclear inflammatory cells (+ + + +); eosinophils (++); plasmacytes (++); tubulitis (++) with focal rupture; degenerative changes of the tubular epithelium; detachment, flattening and cellular remains at intraluminal level with some neutrophils; extensive irregular vacuolization of the tubular epithelium; and irrelevant vascular findings that did not show sclerosis or hyalinosis.

Management with prednisolone at 1 mg/kg was initiated with stabilization of kidney function after 6 weeks. Once creatinine levels normalized (0.9 mg/dl), the patient was discharged; he continued with antituberculosis treatment and tests for follow-up of kidney function.

Discussion

ATIN is defined as an infiltration of inflammatory cells into the renal interstitium that leads to oliguric or non-oliguric kidney injury and causes up to 27% of sudden kidney failures.⁹ The causes may be allergic, infectious, autoimmune, systemic, idiopathic or drug-induced.^{5,10}

Drug-induced ATIN is the most common form found in practice (up to 1/3 caused by antibiotics) and is characterized by a classic clinical triad (rash, fever, and urine eosinophils), occurring in less than 10% of patients. When it only shows kidney manifestations, this infiltration has a worse prognosis and its diagnosis is late, so in most cases it requires treatment with steroids.¹¹ Therefore, when it is suspected, a kidney

biopsy, which is the gold standard for diagnosis, is necessary.^{8,12}

Rifampicin rarely causes ATIN and its onset is associated with irregular drug intake or systemic symptoms of hypersensitivity.⁹ On its physiopathological mechanism, antigen I, which is found in red blood cells and tubular cells, generates a response associated with immunoglobulin M and, to a lesser extent, with agglutination by immunoglobulin G in the presence of rifampicin. When the same response is obtained in vitro without the drug, such agglutination is not observed.¹²

Fanconi syndrome is an inherited or acquired disorder in the proximal renal tubules that results in excretion of amino acids, phosphate, bicarbonate and glucose.¹³ Urine anion gap is a useful tool to diagnose distal tubular involvement and to differentiate some of its causes, such as diarrhea, in patients with metabolic acidosis. It is calculated using the formula urine sodium + urine potassium - urine chlorine, and is considered positive when the value is between 20 and 90 ; in the reported patient, the value of this anion was 40.

Although the patient was asymptomatic, ATIN diagnosis was achieved based on the findings in urine sediment, the temporal relationship with the administration of anti-tuberculous drugs, and the fact that rifampicin is the drug most associated with this pathology.⁸

Some publications on this subject can be found in the literature. Chang *et al.*⁵, in a study conducted in Taiwan, studied acute kidney disease in patients treated with the four-drug tuberculosis regimen and found that it occurred in 7.1% of patients, of whom 11% developed the disease after first exposure to rifampicin. Muthukumar *et al.*³ published a case series of 25 patients with acute kidney disease secondary to the use of rifampicin; the patients presented with

oliguria, and the most common histological finding was ATIN, which might be associated with anemia (96%), hemolysis (17%) and thrombocytopenia (50%), and could help create a diagnostic approach and reach clinical suspicion.² Given that Bogotá is located more than 2600 meters above sea level, and that the reported patient was anemic, the associated physiopathology correlated with antigen I.¹² Finally, the study by Schubert *et al.*⁸, conducted between 1995 and 2007, evaluated the clinical features and complications of ATIN treated with the four-drug TB regimen, which was typically associated with re-exposure to the drugs; ATIN occurred in 5% of patients and had a presentation range of 1 to 21 days after the initiation of the treatment.⁸

The literature reviewed in PubMed and SciELO did not report any other cases of ATIN by rifampicin in Colombia, but there were contradictory results with respect to treatment for this disease with steroids. The review by González *et al.* suggests significant improvement in kidney function, while Effa *et al.* did not find any difference regarding the improvement of kidney function. No case reported the use of a defined dose of steroids, and the studies on which systematic reviews were conducted were very heterogeneous, mostly retrospective case reviews. In this patient, it was decided to start treatment with steroids for 6 weeks at 1 mg/kg, after which outpatient treatment was continued with complete recovery of kidney function.

Conclusion

Since there are few reported cases of ATIN in Latin America and it is a rare complication associated with rifampicin use, this case report is useful as it warns clinicians to suspect this disorder in patients who initiate or restart anti-tuberculous treatment and have subsequent kidney failure. To confirm the suspicion, further studies evaluating the effectiveness of steroids in ATIN by rifampicin at defined doses

in high-prevalence tuberculosis settings should be conducted in order to define the usefulness of steroid use.

Ethical Clearance- Taken from ethical committee of institution

Source of Funding- Self

Conflict of Interest – Nil

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Prevalence of Anaemia in Adolescence Females between Ages of 18-21 in Tamilnadu

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Abstract

Background: Anaemia is major problem faced by women now a days. The school students and colleges students under the age of 21 is highly affected by anaemia. This may due to improper nutritional supplements, diet system and physiological system. Care must be taken to control it at earlier state and it is also important to provide a healthy growth in adolescent so as to avoid any other complication in future.

Method: This study conducted for 35 adolescent college girls aging under the age of 21 with their parent and individual permission. Information including the symptoms, signs and diet system were gathered. Blood sample collected and Hb determined by Sahli's method.

Result: The prevalence of anaemia was found to be 66% which includes 22.8% of mild anaemia, 28.5% of moderate and 14% of severe anaemia. 70.5% of which anaemic patient followed vegetarian food. 65% of anaemic patient found non-vegetarian food. Hungriness (60.7%), tiredness (65.1%) and dizziness (52%) were found to more in anaemic patient.

Conclusion: Anaemia is seen more in girls between the ages of 18-21. Their diet system majorly affects their healthy state. The most of them experience the tiredness, dizziness and hunginess as the sign of anaemia. Iron rich food may be recommended to over the condition.

Key words: Anaemia, Sahls method, Adolesent girls, Blood sample and herbs

Introduction

Anaemia is defined as the decreased count of red blood cells than the expected level. It can also be defined as the inability of available red blood cell to fulfil the physiological needs ⁽¹⁾. Haemorrhage is one of the reason for anaemia. The blood loss from various body organs which lead to iron deficiency. Gastrointestinal bleeding could also cause anaemia. Anaemic is more common in women than in men, this is mainly due the menstrual cycle in women. Menstrual bleeding varies from normal range to 10ml - 250ml blood loss. Heavy

bleeding is also sign of anaemia, as the blood loss iron content also decreases ⁽²⁾. The common symptoms of anaemia includes tiredness, lethargy, fatigue, restless leg, shortness of breath and mild anaemia are mostly asymptomatic⁽³⁾. Normally anaemia is classified based on the Morphology, pathogenesis and clinical presentation. Based on pathogenic, it is classified into regenerative and hyporegenerative. Based on clinical presentation acute and chronic anaemia. In red blood cell morphology, based MCV parameter it is classified as Microcytic and macrocytic ⁽⁴⁾.Iron is important in production of haemoglobin. But iron can be depleted

by loss of blood, improper absorption or consumption⁽⁵⁾. Iron is essential for the blood production in human body two forms of iron is present one is heme iron and the other one non-heme iron. About 3-4 grams of iron present in the human body. The more of iron being lost from the body is more than the amount of absorption of iron leads to iron deficiency. If the iron deficiency increases it leads to anaemia. According to world health organisation haemoglobin values of less than 7.7mmol/l in men 7.4 mmol/l in women stated as anaemic persons⁽⁶⁾.

Materials and Methods

This study was made among college students in January 2020. The study conducted for 35 adolescent girls with their permission, with their parent's approval and the college permission. The private college students of various classes 1st, 2nd, 3rd year students with 12, 12, 11 students were selected respectively.

Inclusion criteria:

The study includes adolescent girls between the ages of 17-21. Students with good health condition are included. Students free from disease for past one month are included.

Exclusion criteria:

Students under age of 17 and above age of 21 were excluded.

Students suffering from illness and diabetic patient were excluded. Students consumed any medication for past one month.

Method

Haemoglobin level was determined by Acid haematin method also known as Sahli's method. The principle is based on the converting the haemoglobin present in the blood to haematin. The haemoglobin is colour producing substance present in the blood it is mainly due to the presence of chromophore group heme. The haematin acid produced is in dark brown colour and the colour is compared with standard colour present in the sahli's apparatus. The haematin group colour is correspondence with haemoglobin concentration in blood⁽⁷⁾.

Procedure:

The N/10 Dilute hydrochloric acid is taken in haemoglobin tube up to the 20 mark in yellow colour. Then the middle finger is sterilised with ethanol and punctured with lancet needle, the blood is pipetted up to 20µl in haemoglobin pipette. Blood removed is mixed with the diluted hydrochloric acid and it is further diluted with water to compare with standard colour in sahli's apparatus. According to the WHO guidelines person haemoglobin b count between 11-11.4 gms/dl were consider to be mild anaemic, 8-10.9 gms/dl is considered as moderate anaemic, less than 8 gms/dl is considered to sever anaemic and above 11.5 is considered as normal range. Results are represented in percentage.

Feedback form:

The feedback form from students under this study were collected. It is done to know their diet plan, weight, physiological problem they are facing (symptoms), Inheritance disorder, etc.,

Result

S.NO	Hb count (gms/dl)	Condition	Patient affected	Percentage
1	Above 11.4	Normal	12	34%
2	Between 11-11.4	Mild	8	22.86%
3	Between 8-10.9	Moderate	10	28.57%
4	Less than 8	Severe	5	14.28%

S.no	Condition	Normal	Anaemia	Total prevalence
1	Vegetarian	5	12	70.58%
2	Non-vegetarian/ Mixed	7	13	65%

Symptoms	Hungry		Tiredness		Dizziness		Breathing troubles		Leg cramps		Hair fall		Anxiety	
	Total	Anaemic	Total	Anaemic	Total	Anaemic	Total	Anaemic	Total	Anaemic	Total	Anaemic	Total	Anaemic
Presence	16	14 (60.7%)	17	15 (65.1%)	13	12 (52%)	8	5 (21.7%)	10	6 (26%)	17	12 (52%)	11	8 (34.7%)
Absence	19	9	18	7	22	11	15	18	25	27	18	11	24	15

The study carried for 35 students, from the table 1 it shows that twelve students (34%) have normal haemoglobin range (Above 11.4), eight students (22.86%) suffers from mild anaemia (Between 11-11.4), ten students (28.57%) suffers from moderate anaemia (Between 8-10.9) and five students (14.28%) suffers from severe anaemia (Less than 8). From the table 2 it shows the dietary plan, seventeen students (43.14%) following vegetarian diet out of that twelve students said to be anaemic (70.58%) and twenty students (56.86%) follows non-vegetarians dietary plans out of these twenty thirteen students are said to be anaemic (65%). From the table 3, it shows that anaemic patient experience hungry (60%), tiredness

(65%), dizziness (52%), breathing trouble (21%), leg cramps (26%), hair fall (52%) and anxiety (35%). 10% anaemic students experienced improper menstrual cycle.

Discussion

Anaemia is the condition where the amount of haemoglobin in the blood is less than the normal level. To diagnose the anaemic condition quantity of haemoglobin is necessary⁽⁸⁾. According to who guidelines, anaemia is classified into different levels based on haemoglobin concentration in (g/ dl) and the following cut-off, children 6–59 month: any anaemia < 11.0, mild 10.0–10.9, moderate 7.0–9.9, severe <

7.0. Non-pregnant women 15–49 year: any anaemia < 12.0, mild 11.0–11.9, moderate 8.0–10.9, severe < 8.0⁽⁹⁾. In recent systematic analysis of global anaemia, the prevalence of anaemia has been decreased from 40.2% in 1990 to 32.9% in 2010. The severity of anaemia is seen in females⁽¹⁰⁾. Numerous factors including age, sex, BMI, iron deficiency and pregnancy status influence haemoglobin concentration. Additionally helminthic infection, malarial infections were found to be some causes of anaemia⁽¹¹⁾. Some of the reasons for anaemia are insufficient nutrition, smoking. By taking iron rich food will raise the haemoglobin level⁽⁸⁾. The present study is done to know to prevalence of anaemia in adolescent girls aged between 17-21 the influence of diet and symptoms occurrence. The study included 35 students. The study made with concern permission from the college, parents and volunteers participated. The total prevalence of anaemia in my study in 66% and rest 34% are non-anaemic. The 22.8% suffered from mild anaemic, 28.5% suffered from moderate anaemic and 14.2% suffered from severe anaemia. The most of anaemic students experienced hungry, tiredness and dizziness. This results is similar to the results showed in the study made on Nepalese adolescent girls. It is prevalence of anaemia in semi-rural region where 209 participated showed 68%⁽¹²⁾. Comparing both the studies, our study is slightly lower than study made on Nepalese adolescent. The prevalence of anaemic survey study in adolescent girls, carried out between age of 10-19 in Rural Telangana state were nearly 59%⁽¹³⁾. The other study conducted in Delhi carried on adolescent girls which showed the prevalence of anaemia 59%. Mild anaemic (48%) are predominate cases found in those studies⁽¹⁴⁾. In the view of food supplements, girls following the vegetarian diet system exposed to anaemia more than the girls following the non-vegetarian diet system. 70% of vegetarian girls suffers from anaemia, where as 65% non-vegetarian girls suffers anaemia. This results similar to study carried

on Rajasthan women which says that vegetarian diet following women suffers from anaemia than the non-vegetarian diet following women⁽¹⁵⁾. The anaemic girls suffers mostly from tiredness, Hungry, Dizziness and hair fall. Other than these some girls suffers from anxiety, cramps and Breathing problem. This symptoms results are accepts with study made on Islamia university of Pakistan which shows that most anaemic persons suffers from tiredness, dizziness and fatigue⁽¹⁶⁾. Studies made on semi urban areas resulted the prevalence of anaemia to be 66%, the same way out study is based on the semi urban region, resulted in 66% anaemic⁽¹⁷⁾. Other study made on the Lucknow city with 400 participant showed the prevalence of anaemia nearly 56%, which is lesser than our study⁽¹⁸⁾. The prevalence of anaemia in all three areas (Rural, Semi-urban and urban) of Vododara district resulted 75%. All three region shows the same percentage of occurrence⁽¹⁹⁾.

Conclusion

Anaemia is one of world threatening problem. It seen more in women comparatively than men. The Girls in the adolescent age below twenty are mostly affected by anaemia. The care must be taken earlier to control the chronic stage. Good iron rich food supplement should be given to overcome this situation and further curative should be taken to control the anaemic condition.

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Social Cognition Theory and Physical Activity among Local Population: An Overview

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Abstract

Social cognition concerns the various psychological processes that enable individuals to take advantage of being part of a social group. Of major importance to social cognition are the various social signals that enable us to learn about the world. Such signals include facial expressions, such as fear and disgust, which warn us of danger, and eye gaze direction, which indicate where interesting things can be found. Such signals are particularly important in infant development. Social referencing, for example, refers to the phenomenon in which infants refer to their mothers' facial expressions to determine whether or not to approach a novel object. We can learn a great deal simply by observing others. Much of this signalling seems to happen automatically and unconsciously on the part of both the sender and the receiver. We can learn to fear a stimulus by observing the response of another, in the absence of awareness of that stimulus. By contrast, learning by instruction, rather than observation, does seem to depend upon awareness of the stimulus, since such learning does not generalize to situations where the stimulus is presented subliminally. Learning by instruction depends upon a meta-cognitive process through which both the sender and the receiver recognize that signals are intended to be signals. An example would be the 'ostensive' signals that indicate that what follows are intentional communications. Infants learn more from signals that they recognize to be instructive. I speculate that it is this ability to recognize and learn from instructions rather than mere observation which permitted that advanced ability to benefit from cultural learning that seems to be unique to the human race.

Keywords: *social, cognition, signals, meta-cognition, culture, observation*

Introduction

1. What is social cognition?¹

As currently used, the term 'cognition' refers to the many different processes by which creatures

understand and make sense of the world. The term does much the same work as was previously done by the term 'information processing' and is strongly influenced by developments in computing beginning in the 1940s. Perception, attention, memory and action planning would all be examples of cognitive processes. All these processes are important in social interactions and the study of information processing in a social setting is referred to as social cognition. 'The goal of social cognition is to provide mechanistic, process-oriented explanations of complex social phenomena' (Winkielman & Schooler in press).

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In this paper, I want to consider whether there are aspects of cognition that are specifically social and specifically human.

2. Social stimuli that tell us about the world²

(a) Avoiding danger

Physical disgust is an instinctive emotional reaction to sights and smells which helps us to avoid food poisoning or infection. The sight of someone with an expression of disgust is a signal that they are in contact with something that we should avoid. There is a mirror system for disgust (Wicker *et al.* 2003). When we see a disgusted face, we feel disgusted ourselves and may automatically take avoiding action before we consciously recognize the expression or discover the cause of the disgust.

(b) Learning which things are nice and which are nasty: social referencing

Closely related mechanisms can explain the phenomenon of social referencing (Feinman *et al.* 1992). Learning about the world from other people is particularly important during infancy when so much is novel. Confronted with a novel object or situation, the infant will look at his or her mother. A smile will cause the infant to approach while a frown will elicit avoidance. In this way, the infant can learn about a basic property of things in the world: whether they are nice or nasty. However, the infant does not learn about anything or from anyone. Through evolutionary history, the brain is pre-prepared to learn more rapidly about threatening stimuli, such as snakes (Mineka & Ohman 2002). Infant monkeys rapidly learn to fear snakes by observing fear in a model, but do not learn to be afraid of a flower by such observation (Cook & Mineka 1989). Initially, human infants learn about the world from observing their mothers, rather than strangers (Zarbatany & Lamb 1985). However, at 14 months, they will learn from a familiarized stranger (Klennert *et al.* 1986) and by 24 months strangers are

used as a source for learning (Walden & Kim 2005).

3. Social responses mirror social stimuli³

From a stimulus–response perspective, social cognition is very symmetrical. One person’s stimulus is another person’s response. This symmetry is most obvious in the various examples of the mirror system. I observe your fearful expression (a social stimulus), which causes me to make a fearful expression (a social response). Social interactions typically involve chains of such stimuli and responses. For example, Keltner & Buswell (1997) consider the case of the expression of embarrassment. Our protagonist has committed a social *faux pas* and his companions express anger. He responds by expressing embarrassment. His companions express sorrow as an empathic response to his discomfort. His appeasement has worked and every one expresses happiness.

4. Social signals that convey information⁴

We can use social signals to help us attain our goals. If I am looking for a drink at a reception I can use the density of people in different parts of the room or the direction of their movements as signals indicating the probable location of the drinks table. Most of the time we use such social signals emitted by people (our conspecifics). But we can also use such signals from species other than our own. We train dogs to point at quarry such as hares and game birds and the Romans famously used geese to warn them of danger. And it is not just us. Many species use signals from other species to help them achieve their goals (Danchin *et al.* 2004). The important aspect of these signals is that they are emitted by agents, rather than objects. It is therefore important to be able to detect agents.

5. Beyond stimulus–response psychology: goals and actions⁵

More recently, psychologists have started to

think that the interaction between the person and the environment should be described the other way round. Rather than starting from a stimulus in the environment, the starting point is inside me and concerns my goals. What is currently my most pressing goal? How can this goal be best achieved given my prior knowledge and the current context? On the basis of the answers to these questions, I perform an act upon the world (engineers call this the input). This act will cause new signals to strike my senses (engineers call this the output) and I will learn whether or not the act has brought me nearer to my goal. The difference between what I expected and what actually occurred is the error signal that drives the system and enables me to approach my goals (Sutton & Barto 1998). Within this framework also we can define subsets of processes with specifically social functions. In particular, we can define social goals. Social goals are shared goals and therefore involve at least two people. Shared goals are most obviously involved in joint action, when at least two people are required to perform a task or when a task can be performed better by two people than by one person on his own. Successful joint action benefits from communication and also from trust. A shared goal is also implied when one person works for the benefit of others. However, social goals can also be competitive, as when one person tries to deceive another.

6. The interpretation of signals⁶

(a) Learning by observation and learning by instruction

Most of the cognitive processes I have discussed so far function without awareness. People show emotional responses to fearful faces even though they are not aware of having seen the face (Morris *et al.* 1999). People also show emotional responses to untrustworthy faces even when they are attending to some other aspect of the face such as sex (Winston *et al.* 2002). We have also seen that the automatic

imitation that comprises the chameleon effect only works when the participants are unaware that they are being imitated (Lakin & Chartrand 2003). In all these examples, the participants are unaware that they are sending or receiving signals. Thus, many social processes can occur without conscious awareness. There is much less evidence, however, as to whether certain social processes cannot occur in the absence of awareness.

b) Deliberate signalling and knowledge transfer⁷

The same important distinction applies when we consider the sender of the signals. This is the contrast between signals that result from involuntary responses to the object and signals sent with deliberate communicative intent. For example, a mother might deliberately simulate fear she did not feel in order to keep the infant away from a dangerous object. However, in most cases, deliberate signals are not deceptive. When directed at infants, deliberate signals are usually intended to teach (Csibra & Gergely 2006).

Conclusion

These signals upon which we can reflect are not restricted to vocalizations or gestures. Marks and arrangements of inanimate objects can also be used as deliberate signals. In this way, material becomes part of culture. Perhaps it is this ability to reflect upon our own signals that provided the basis for the extraordinary achievements of the human race during the last few thousand years. This development did not depend upon changes in the basic cognitive apparatus present in the human brain, but on the knowledge acquired by others and passed onto us by deliberate instruction.

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Identify the Risk Factors of Osteoporosis Knowledge and Practices Regarding Prevention of Osteoporosis among Postmenopausal and Postmenopausal With Breast Cancer Women in Selected Tertiary Care Hospital

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Abstract

Background: Osteoporosis is defined as a decline in bone strength that raises the risk of fracture. Because the number of people in this area is so much higher than those in the osteoporosis range. More than 50% of the all the fractures among postmenopausal women, including hip fractures, occur in this group with low density. Due to the lack of awareness about osteoporosis, many post - menopausal women do not take preventative actions to protect the osteoporosis.

Materials and Methods: The study was conducted using an evaluative method and a non-probability purposive sampling technique. The study was conducted as a descriptive one. A tertiary care hospital was chosen for the investigation. 50 postmenopausal women 25 postmenopausal women and 25 postmenopausal women with breast cancer), they were included in the study.

Result : 14 (28.0%) were between the ages of 46 and 50 years. The high risk was 4 (16.0 %) and the moderate risk was 21(84.0 %) in women with breast cancer. The high risk is 1 (4.0 %) in women without ca – breast cancer, and the moderate risk is 4 (96.0 %). The majority of postmenopausal women with breast cancer had average knowledge, with 12 (48.0 %) having an average knowledge, 14 (56.0 %) had average knowledge, and 10 (40.0%) had poor knowledge. The knowledge for postmenopausal women without breast cancer (36.0%) were poor. 3 (12.0%) had good knowledge, whereas 2 (8.0%) had good knowledge. The overall mean percentage is (40.1%). The majority of postmenopausal women with breast cancer 18 (72.0%) and 20 (80.0%) had moderate practises for osteoporosis prevention, whereas postmenopausal women without breast cancer had moderate practises. The overall mean percentage is (58.1%)

Conclusion:The findings suggest that an awareness campaign should be conducted among women during the post-menopausal period to prevent complications arising due to osteoporosis.

Keywords: osteoporosis, postmenopausal women, breast cancer, risk factors, knowledge, practises

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Introduction

The right to health is a fundamental human right. It is central to the concept of general wellbeing. Health and its conservation is a considerable social

investment as well as a modern social priority. Health is a multifaceted construct. Indicators such as the death rate, infant mortality rate, and life expectancy can also be used to assess this health. Each set of information should, in theory, be meaningful by itself, although when integrated, should enable for a more comprehensive health profile of individuals and communities.¹

On October 20, World Osteoporosis Day provides an all-important focal point for informing and educating the general public and policymakers about the prevention of a disease that still suffers from poor general awareness. With the number of participating countries and scheduled events increasing steadily year by year, the impact of WOD has grown significantly.²

Early detection and treatments for breast cancer have significantly increased the 5-year survival rates of patients. Over 88% of women suffering from different stages of breast cancer survive. Cancer survivorship remains a challenge because patients do not return to a pre-cancer diagnosis state after completion of active treatment. Diagnosis and treatment of breast cancer are stressful events and may result in various physical, psychological, behavioural, social, and spiritual concerns, which are often experienced after treatment of Breast cancer survivors need not only medical therapy but also psychological, spiritual, and social support to cure the disease.

Osteoporosis is a systemic skeletal condition associated with varying degrees of bone loss. This is prevalent among postmenopausal breast cancer survivors, with prior reports of up to 80% of them experiencing a loss in bone density. Untreated bone loss can lead to significant morbidity due to the pain and fractures, as well as to death. Osteopenia is diagnosed among individuals with lower-than-average bone density, while osteoporosis is characterised by both low bone density and architectural deterioration of bone tissue. Among breast cancer survivors,

cancer-related risk factors for osteopenia and osteoporosis include both treatment and premature menopause. Importantly, the excess risk of osteopenia and osteoporosis among breast cancer survivors, particularly those of a younger age group relative to their cancer-free peers' remains unknown.⁴

Methods and Materials:

In this study, 50 postmenopausal women from the Dr. Vithalrao Vikhe Patil Memorial Hospital participated. Ahmednagar: A total of 50 postmenopausal women were included in the study (25 postmenopausal women and 25 postmenopausal women with breast cancer). They were selected using a non-probability purposive sampling technique and an evaluative approach. The study was conducted as a descriptive study. Exclusion Women who are postmenopausal and also have physical or visual impairments, or any disease such as HTN or diabetes, and third stage of breast cancer are not eligible. The study was performed after obtaining written informed consent from study participants. Age, religion, education, marital status, source of information, family history, hospital visit, type of treatment, identification of the risk factors check list on osteoporosis, knowledge score, and self-rating (observational check list) for osteoporosis prevention were obtained from a knowledge questionnaire and self-rating (observational check list). Descriptive and inferential statistics were used to analyse the data.

Statistical Analysis: Statistical analysis was done by the SPSS statistical package. The Chi-square test was performed to compare individual characteristics, and the t- test was performed to compare the two groups. Fisher's exact test P-value was considered statistically significant if it was 0.05. A Pearson correlation test was used to determine the significant correlations between variables.

In total, 50 postmenopausal women were studied, 25 were postmenopausal women without breast cancer and 25 were postmenopausal women with breast cancer. The analysis of the demographic data of the study samples gave an idea of the general characteristics of postmenopausal women at selected tertiary care hospitals.

Section I: Frequency and percentage distribution of socio-demographic variables of osteoporosis among postmenopausal and postmenopausal women with breast cancer

1. Age: The results show the age distribution of the study subjects, with 14 (28.0%) being between the ages of 46 and 50, 13 (26.0%) being between the ages of 40 and 45, 12 (24.0%) being between the ages of 51 and 56, and the remaining 11 (22.0%) being between the ages of 56 and 61.

2. Religion: According to the findings, 33 (66.1%) of the study subjects are Hindu, 10 (20.0%) are Christian, 4 (8.0%) are other religions, and the remaining 3 (6.0%) are Muslim religion.

3. Education: According to the findings, the study subject's education distribution was as follows: graduation and post-graduation were 7 (14%) participants, secondary education had 10 (20%) participants, primary education had 15 (30%) participants, and illiteracy was 18 (36%).

4. Marital status: Married individuals comprise 34 (68%) of the study population, widowed participants contribute 12 (24%) of the study population, single participants comprise 2 (4%) of the study subjects, and divorced participants constitute 2 (4%) of the study population, according to marital status.

5. Source of information: The finding shows the source of information distribution of the study subject where the 33 (66%) participants get information from doctors, family, 13 (26%) participants got information

from friends. Television is used by 3 (6%) of the participants to obtain information. 1 (20%) participant got information, and newspapers and the internet had 0 % get information.

6. Family history: This finding shows whether you have a family history of osteoporosis, breast cancer, or any other disease. The distribution of the study subjects were the 6 (12.0 %) participants having a family history, of osteoporosis or other diseases, and 44 (88.0%) of the participants having no history of diseases.

7. Hospital visit: The findings show the main reasons for the study subjects' hospital visits, with 4 (8.0%) participants having abnormal mammograms for themselves or first relatives, 4 (8.0%) participants having breast pain, 17 (34.0%) participants having breast lump, and the remaining 25 (50.0%) participants having other associated medical problems (DM, HTN, Gynaecological problems such as uterine prolapse, etc.)

8. Type of medical treatment: The distribution of the study subject's type of medical treatment they receive, shows that women with breast cancer 5 (20.0%) participants are on medical treatment and 20 (80.0%) participants are not receiving any type of medical treatment, while women with breast cancer 7 (28.0%) participants are on medical treatment in a with ca-breast and 18 (72.0%) are not receiving any type of treatment.

9. Age of menopause: The findings show the age distribution of the study subject where the majority, i.e. 33 (66 %) participants are aged 40 years, 16 (32.0 %) participants are aged 45 years, and 1 (2.0 %) participant is aged 50 years. Women have achieved menopause at an average age of 40 years.

10. Height and weight: The finding depicts the height distribution of the study subjects, with the majority, i.e., 19 (38%) participant height categories

between 135–145, the second group being 146–150, with a total of 13 (26.0%) participant height, the third (30.0%) participant height group being 151–155, and the last group being 156–160, with 3 (6.0%) participant height . The figure shows the weight distribution of the study subject where the majority, i.e. 24 (48%) participant weight categories between 41 -50 kg, the second group is 51 –60 kg, making a total of 12 (24.0 %)participant weight categories. 10 (20.0 %) participant weight categories is 30– 40 kg and the last group is 61 – 70 kg, which means 4 (8.0%) of the participant weight.

11. BMI: Findings show the BMI distribution of the study subjects, with the majority of 32 (64.0%) of participant BMI according to the BMI scale range of 18.5–24.9, the second 11 (22.0%) of participant BMI is 25–29.9, according to the BMI scale, 16.5–18.5 in that category is 2 (4.0%) of the study, and the final is 1 (2.0%) of the study.

SECTION :II : Description of risk factors for osteoporosis among post-menopausal and post – menopausal women with breast cancer :

TABLE 1 : Frequency and percentage distribution of risk score of postmenopausal &postmenopausal women with breast cancer

		Group			
		Post-menopausal With Breast Cancer		Post-menopausal With Out Breast Cancer	
		Count	Column N %	Count	Column N %
Overall risk score	High	4	16.0%	1	4.0%
	Moderate	21	84.0%	24	96.0%

The data in table 1 shows that the majority 14(16.0%) of postmenopausal women with breast cancer had a high risk and 21 (84.0%) had a moderate risk . Postmenopausal women without breast cancer were at a high risk of developing the disease 1 (4.0 %

), while 24 (96.0%) were at a moderate risk.

Section III: A description of the osteoporosis knowledge score of postmenopausal and postmenopausal with breast cancer women.

TABLE 2: Frequency and percentage distribution of osteoporosis knowledge scores among women in both groups

		Group				Total	
		Post-menopausal With Breast Cancer		Post-menopausal With Out Breast Cancer			
		F	%	F	%	F	%
Over all knowledge	Good	3	12.0%	2	8.0%	5	10.0%
	P Poor	10	40.0%	9	36.0%	19	38.0%
	Average	12	48.0%	14	56.0%	26	52.0%
Total		25	100.0%	25	100.0%	50	100.0%

The average knowledge of osteoporosis (56.0%) in women without breast cancer is higher than in women with breast cancer (48.0%), the poor knowledge of osteoporosis (40.0%) in women without breast cancer is higher than in women with breast cancer (36.0%), and the last good knowledge of osteoporosis is (12.0%) in women with breast cancer and (8.0%) in women without breast cancer.

Section IV: Self-rating scale description (adherence to osteoporosis prevention practices)

Table 3 shows the frequency and percentage distribution of women with osteoporosis' observation practises score.

		Group				Total	
		Post-menopausal With Breast Cancer		Post-menopausal With Out Breast Cancer			
		F	%	F	%	F	%
Over all Practices	Good	4	16.0%	1	4.0%	5	10.0
	Moderate	18	72.0%	20	80.0%	38	76.0
	Poor	3	12.0%	4	16.0%	7	14.0
Total		25	100.0%	25	100.0%	50	100

Table 3 demonstrates that good practise of osteoporosis prevention among postmenopausal women with breast cancer is 16.0 %, moderate practise is 72.0 %, and poor practise is 12.0%, whereas the second group of postmenopausal women without breast cancer (4.0%) had good practise ratings, (80.0%) had moderate practise scores, and (16.0%) had poor practise scores.

V: To compare the knowledge and practise scores of postmenopausal and postmenopausal breast cancer women.

Table 4 displays the compare knowledge and practise score among postmenopausal women with breast cancer.

Group	N	Mean	SD	Mean difference	SD difference	T value	df	P value
Knowledge Postmenopausal with breast cancer	25	8.32	3.881	0.600	1.030	0.583	48.000	0.583
Postmenopausal without breast cancer	25	7.72	3.385					
Practice Postmenopausal with breast cancer	25	19.84	4.140	2.36	1.21	1.95	48.00	0.06
Postmenopausal without breast cancer	25	17.48	4.408					

According to the findings, postmenopausal women with breast cancer have a higher mean of 8.32 SD 3.88 for knowledge than postmenopausal women without breast cancer. 3.72 SD 3.38 The P value is 0.583.

In comparison to postmenopausal women without breast cancer, postmenopausal women with breast cancer have higher practise mean scores (19.84), SD 4.14. The mean is 17.48, with a standard deviation of 4.40. The P value is 0.06.

Section VI: To determine an association between postmenopausal and postmenopausal women with breast cancer and their practises with demographic variables.

Association of practices among postmenopausal women with breast cancer with selected demographic variables :

The Fisher exact test was calculated to find out the association between practise score and selected demographic variables of women. Because the calculated value is greater than the table value at $p > 0.05$, there is no significant relationship between practise score and demographic variables. The practise score was unaffected by age, religion, education, marital status, source of knowledge, family history of osteoporosis, hospital visit, kind of medical treatment, age of menopause, height, weight, or BMI. As a result, the null hypothesis has been accepted.

Association of practices and selected demographic variables among post - menopausal women without breast cancer:

In that association with marital status, that practice score of postmenopausal women has a significant association with a group of women without ca – breast cancer. The calculated Fisher exact test value (0.007, P 0.05) was found statistically significant at the 5% level (i.e. p 0.05), rejecting the null hypothesis and accepting the research hypothesis.

Discussion: The results are consistent with the study conducted on Spanish women. The prevalence of osteoporosis risk factors was 67.6%. A high prevalence of women taking osteoporosis risk-related medication was observed in our study. There was a correlation between the menopausal symptoms' degree of severity and the risk of suffering from osteoporosis. ⁵

A study conducted on Israeli-Jewish and Arab women's findings revealed that women aged 45 and older had moderate to low levels of knowledge about osteoporosis. Expanding knowledge about osteoporosis may prove beneficial for increasing participation in preventive behaviour in both groups. ⁶

An study explores the connection with exercise habits and health concerns and knowledge regarding osteoporosis. To prevent osteoporosis, Study support the importance of early osteoporosis education and lifetime physical exercise. ⁷

These findings are in consistent with the report of an exploratory cross-sectional study performed among three age groups of Pakistani women. The findings revealed that younger women had a poor understanding of osteoporosis as compared to older women. Women with a higher socioeconomic status and a higher education level, irrespective of age, had slightly more knowledge of osteoporosis than those with a lower education. ⁸

Post-menopausal breast cancer women had higher rates of practice. Practice's score had a significant association with marital status .

Conclusion

Postmenopausal Women without breast cancer have a moderate risk of osteoporosis, whereas women with breast cancer will have a high risk of osteoporosis. Postmenopausal women with breast cancer have better osteoporosis prevention knowledge and practice.

Recommendations:

1. A descriptive study can be conducted among postmenopausal women .
2. A similar study can be replicated in other settings with different age groups
3. An experimental study can be conducted on effectiveness of calcium diet on the bone density.
4. A risk assessment study can be conducted among post – menopausal women by the help of bone mineral density .
5. A comparative study may be conducted between post- menopausal women and pre-menopausal women.

Limitation of the Study

Samples were from one Tertiary care hospital with a specific geographical area hence generalization to whole country is not possible, smaller sample size with purposive sampling technique. Self-reported data might have influenced the result through participants' bias.

Ethical Clearance- ethical Clearance was obtained from Institutional Ethics Committee of Dr. Vithalrao Vikhe Patil Foundation's Ahmednagar.

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Competing Interest : Authors have declared that competing interest exist.

Authors Contribution:

In the above study author 1. Designed the study proposal, conducted the study and statistical analysis, literature searches, and wrote the first draft of the manuscript. Author 2. Designed the study, Literature searches, reviewed and managed the analysis of the study, prepared and approved the final manuscript. Final Manuscript is finalized by both the author.

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An Outbreak of Measles among adolescents in a Health Care Setting, Bangalore, Karnataka, India

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Abstract

Background: Despite high immunization coverage, outbreaks of measles do occur, but occurrence of measles outbreak among adolescents in a health care institution setting in India, is rather unusual or unreported. **Methods:** On the 21st November 2013, cases of suspected measles among the students were reported at St. John's Medical College, Bangalore. The preliminary investigation using the epidemiological case sheet identified seven suspected cases of measles. This led to a detailed investigation for a suspected outbreak at the campus. The outbreak was notified to the government authority. A measles outbreak investigation case sheet was distributed among the students and a door to door survey was carried out. The laboratory confirmation of suspected measles cases was done at the National Institute of Virology, Bangalore by IgM test for measles specific antibodies, viral culture and RT PCR. **Results:** The outbreak occurred during the months of November and December 2013. A total of 13 confirmed cases of measles were identified with an overall attack rate of 2%. Five cases were confirmed by IgM test for measles antibodies, besides virus isolation and RT PCR was positive for two cases. More than half (54%) of the suspected cases were vaccinated for measles and the rest were unvaccinated (23%) or had an unknown vaccination status (23%). There were no complications or deaths due to measles. **Conclusion:** An outbreak of measles among a group of adolescents in a health care institutional setting who were mostly vaccinated raises a concern about the vaccine effectiveness and the duration of vaccine efficacy after immunization. Along with improving the immunization coverage of two doses of measles vaccine, research is needed to determine the most-effective timing of delivering the second routine dose to bring down the susceptible population.

Key words: *Adolescents, Health care setting, India, Measles outbreak, Outbreak investigation*

Background

Measles is an acute highly infectious disease caused by a specific virus of the group myxoviruses [1, 2]. It is endemic virtually in all parts of the world [3].

It tends to occur in epidemics when the proportion of susceptible reaches about 40 per cent [4]. Measles is the fifth highest killer disease among children under five years of age in the world [5, 6]. In India measles contributes significantly to the childhood morbidity and mortality. Measles vaccine was introduced into the Universal Immunization Program (UIP) of the country in 1985 and reported number of measles cases has come down from 252,000 cases in 1987 to 36900

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cases in 2007 [5]. Despite the fact that the number of cases and deaths due to measles are declining, it continues to occur both as sporadic cases as well as outbreaks even though scientific studies reveal that measles eradication is technically feasible with available vaccines [6]. The National Family Health Survey (NFHS) data show a gradual increase in the coverage of measles vaccine from 42.2-58.8% [7]. A nationwide coverage evaluation survey which was conducted by UNICEF in 2009 documented 74.1% coverage among children aged 12-24 months in India [8]. However it has not reached the elimination level and outbreaks of measles continue to occur and it is likely that the estimates are much higher as large numbers of cases go unreported. Some studies also show a change in epidemiological pattern of cases among older children because of increase in measles vaccine coverage [9].

In November 2013, suspected cases of measles were reported from St. John's Medical College campus in Bangalore among medical students who were adolescents or young adults. An extensive literature review revealed occurrence of measles outbreak among adolescents in an institutional setting in India, is rather unusual or unreported. Hence, the present measles outbreak investigation was carried out in a systematic manner to identify the high risk groups, to describe the changes in measles epidemiology, to assess the possible reasons for such an outbreak and to recommend control measures for preventing future outbreaks.

Methodology

St. John's Medical College is situated in Bangalore, Karnataka, India. At the time of this outbreak investigation there were 360 MBBS students, 240 Post Graduate Students, 120 Para Medical Students and 700 Nursing Students. The students who join the medical college are from all over India and mostly belong to a higher socio-economic status.

On the 21st November, 2013 cases of suspected measles among the first year medical students were reported to the Department of Community Health (DoCH) at St. John's Medical College. A preliminary investigation was carried out and seven suspected cases were identified using the Integrated Disease Surveillance Project (IDSP) case definition - "Any person with fever and maculopapular rash lasting for more than 3 days and cough or coryza (i.e. running nose) or conjunctivitis (i.e. red eyes)." Vaccination history based on respondent's parent's recall was also elicited. After the preliminary investigation, the suspected measles outbreak was notified to the Surveillance Medical Officer (SMO) of Bangalore Urban District. A laboratory confirmation of these cases was done at National Institute of Virology (NIV), Bangalore. Serological test was done to detect Measles specific IgM antibodies. The measles-specific immunoglobulin M (IgM) antibody assay, the test used most often, is almost 100% sensitive when done 2 to 3 days after the onset of the rash [10, 11]. Measles IgM antibody peaks at 4 weeks after the infection and disappears by 6 to 8 weeks. The students were within 3rd to 17th day of the onset of rash when their IgM test was done. The close contacts of these suspected cases also underwent IgM testing at NIV. Throat swab, urine and fluid from the rash were also collected from the students who were symptomatic at the time of investigation to do a viral culture.

As a next step in the outbreak investigation, an official notice was put up in the St. John's Medical College, St. John's Medical College Hospital, College of Nursing, and in the hostels to inform regarding the outbreak and preventive measures. The notice mentioned any faculty, staff or student with symptoms of fever with rash and cough, coryza or conjunctivitis; have to be examined immediately at the Staff and Occupational Health Services clinic at the hospital. A measles outbreak investigation case sheet was also prepared and was circulated among all the

undergraduate and postgraduate students including medical, paramedical and nursing courses to screen for any suspected cases.

While the survey was going on at the College, the government authorities {Bruhat Bengaluru Mahanagar Palike, (BBMP)} and the National Polio Surveillance Project (NPSP), decided to investigate this unusual outbreak. A field survey was carried out at ward 151, where SJMCH is situated and a population of around 30,000 was screened. It was carried out by 20 teams, each team consisting of a link worker and a medical officer from BBMP. A house-to-house survey was done to find clinical measles cases fitting the case definition that had occurred in the last 3 months and were listed down.

It was also decided that as a part of the protocol, a door-to-door survey would be carried out by BBMP, in the SJMCH hostels. The reason for screening the hostel inmates was that all reported cases of suspected measles was in the adolescent age group – i.e. among the students. A map of the SJMCH campus was prepared and all hostels were demarcated. The total number of hostel inmates was approximately 1500 out of which 1000 could be contacted after 3 visits to each hostels. This effort from government authority identified 6 more suspected cases with symptoms of fever and rash. For the completion of the outbreak investigation, an area inside the campus where the construction workers were residing and the SJMCH staff quarters were also surveyed. No suspected cases of measles were identified among them.

As a final step, the 6 newly identified suspected cases, and the students who screened negative for IgM initially, considering the probability of being in the convalescent period, were also taken to NIV for IgM test.

Results

Index case

The Index case was a first year MBBS student, who had probably acquired measles while traveling to Kerala and developed fever with rash on November 1st, 2013. He reportedly, had been immunized for measles during his childhood.

Clinical Picture

The illness was clinically compatible with measles. Typically, most cases had a 3 to 4 days prodrome with fever, coryza (runny nose), cough, and conjunctivitis (red, irritated eyes) followed by the appearance of a maculopapular (red spots and areas) rash. The temperature usually returned to normal 2 to 3 days after appearance of the rash, while the rash persisted for 5 to 7 days. The most commonly reported symptoms were fever, maculopapular rash, redevyes, cough and coryza and the least was presence of koplik spots. The other symptoms that were reported were vomiting, loss of appetite, fatigue, myalgia, joint pain and lymph adenopathy.

Description of the outbreak

The outbreak began on November 1st, 2013 and lasted till December 9th, a total of 39 days. Thirteen suspected cases were identified of whom 4 were laboratory confirmed by IgM test. One out of the 17 close contacts was also screened positive. Virus isolation and RT PCR was positive for two suspected cases. The rest were epidemiologically linked cases. Out of the thirteen suspected cases, 7(54%) were vaccinated, 3(23%) were unvaccinated and 3(23%) had an unknown vaccination status. All 5 screened positive for IgM were reportedly vaccinated. A total of 1000 students were screened among whom 370(37%) were vaccinated for measles in their childhood, 80(8%) were unvaccinated and the rest (55%) had an unknown status. The students were asked to confirm

their immunization status from their parents as immunization records were unavailable for most of them. The source of the outbreak remains unknown. The attack rate was 2% (Unvaccinated and those who had an unknown vaccination status were considered at risk). There were no complications or deaths due to measles reported. All except one reported seeking

medical treatment for their illness from SJMCH. The BBMP house-to-house survey of around 30,000 population identified 3 suspected cases of measles - a three year old, a ten year old and a twenty nine year old, among whom the ten year old child screened positive for IgM.

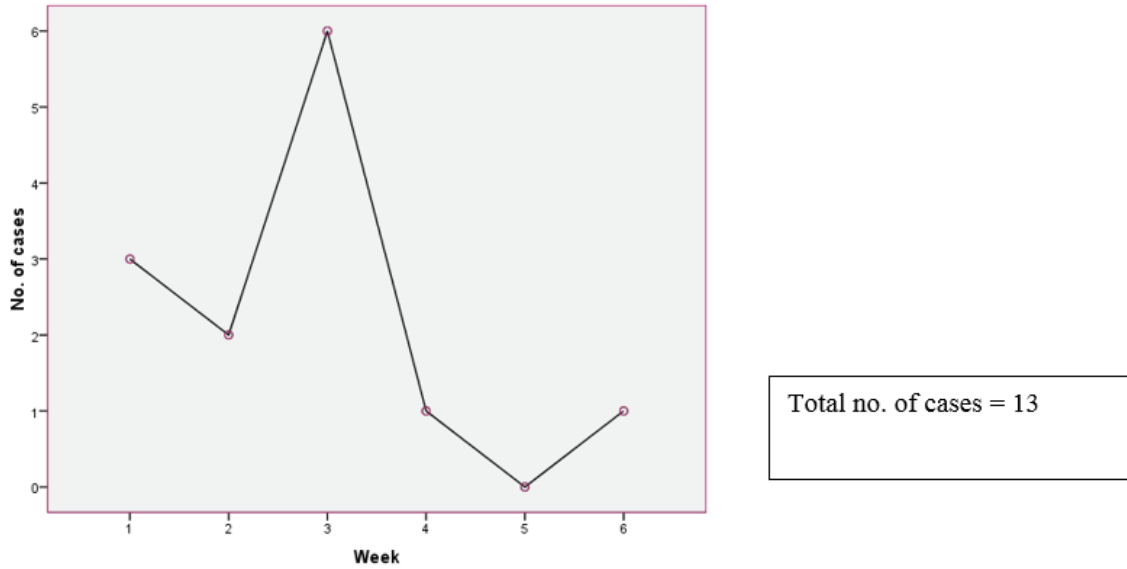


Figure 1: Epidemic curve

The epidemic curve showed that the outbreak started from the 1st week of November and continued until 2nd week of December. Peak of the outbreak was in the 3rd week. No further cases were reported after 2nd week of December.

Table 1: Laboratory tests done at NIV

Number of students tested for IgM antibodies against Measles	30 (13 suspects + 17 contacts)
Serology for IgM antibodies against Measles – Positive	2
Serology for IgM antibodies against Measles - Equivocal	3
Tested positive for Rubella	2
Tested positive for Chikungunya	1

Of the 5 who were screened positive for IgM, one was a close contact.

Discussion

Measles is seasonal. In temperate climates, outbreaks generally occur in late winter and early spring. In tropical climates, transmission appears to increase after the rainy season. In India, the epidemics of measles are more common in winter and early spring (January to April) [4]. This particular outbreak started in the month of November. There were no outbreaks of measles reported in and around the medical college campus during this period. Even the active case search by BBMP, did not identify any outbreak in this area. This leads us to the conclusion that the outbreak started within the campus itself.

The index case in this outbreak, as already mentioned, was a first year MBBS student, who did not report to have visited the hospital or to have had any close contact with a known case of measles during the possible exposure period. So the source of infection for the outbreak remains unclear. He probably would have acquired measles while traveling to Kerala.

While measles commonly occurs in the young child, a shift towards adolescent age group was a striking feature of this outbreak. Most of the cases were reported among medical students aged between 18 and 22 years, who were born between 1991 and 1995. During this period, measles vaccination had already been rolled out in the UIP of all states across India, though the reported coverage for measles vaccine based on the National Family Health Survey (NFHS) data during this period was only 42% [7]. However it is likely that most of these students (from a higher socio economic status) have received either the measles vaccine or the MMR vaccine in their childhood. The probable reasons for such an outbreak among the adolescent age group who had been immunized against measles could be the vaccine efficacy of only 85% for first dose of measles at nine completed months and the questionable duration of vaccine efficacy after immunization [12 - 15]. Most

countries in the African, American, and Asian regions including India are currently focusing on providing a first dose through routine immunization services and a second opportunity to receive measles vaccine through vaccination campaigns or administration of a second routine vaccine dose which provides immunity to 97%–99% of children [13, 14, 16–21].

Large college based outbreaks of measles have been reported from a few other parts of the world and they have implemented a standard policy of requiring proof of measles vaccination or immunity to measles at entry to the university [23,24]. To date, in India there are not many such outbreaks reported and there is no such policy in place. With decreasing susceptibility in younger age groups, there is a possibility of an increasing number of nationwide measles cases occurring in older adolescents and young adults. A first step in decreasing transmission in these age groups would be to ensure immunity in known high-risk groups, including medical college students.

Mass immunization with MMR when there is an outbreak in an institutional set up is much debated [23, 24, 25], but in the present outbreak, it was important to assess the cost benefit factors before taking such a step. The outbreak was reported only after 3 weeks of onset and low attack rates, no mortality and fewer complications indirectly reflected the mild nature of the outbreak. The success that could be achieved with outbreak response immunization at that time was questionable. Catch-up vaccinations for those who had not been vaccinated was also not done because of the inability to trace the immunization status of the at risk population.

In India, there is a need to strengthen the reporting system for diseases like measles, especially in private tertiary care institutions. Delayed reporting can result in late recognition of the outbreak and consequent delay in instituting containment measures. Experience from this particular outbreak investigation calls

for a critical need for setting an efficient measles surveillance system within the institution itself. Ongoing education is needed to prompt health care providers to have a high index of suspicion for measles in young adults presenting with rash illness and upper respiratory tract symptoms and also to report it to the government authority.

Certain limitations have to be considered while interpreting the findings of this outbreak. Some of the medical students did not know their vaccination history; therefore we were unable to correctly examine the role of vaccination in the outbreak and it was difficult to determine the precise attack rates, since the denominator which is the at risk population was uncertain.

In conclusion an outbreak of measles among a group of adolescents who were mostly vaccinated raises concern about the vaccine effectiveness and the duration of vaccine efficacy after immunization. Along with improving the immunization coverage of two doses of measles vaccine, research is needed to determine the most-effective timing of delivering the second routine dose to bring down the susceptible population.

Ethical Clearance: Written Informed consent was obtained from each study participants. Ethical clearance not obtained from Institutional Review Board.

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Conflict of interest: None declared.

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Microsponges: A Futuristic Approach for Oral Drug Delivery and Current Status

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Abstract

Microsponges are at the forefront of the field of new drug delivery technology, which is rapidly evolving. Microsponge drug delivery technology holds a lot of potential in terms of reaching the aim of controlled and site-specific drug delivery, thus it's gotten a great deal of interest from scientists. Microsponges are porous microsphere and biologically inert. Particle size of microsponges was 10-25 μ m. The Quasi emulsion solvent diffusion method was used to construct microsponges. It is a unique technique for controlled release formulation. This page gives an overview of the Microsponges delivery system, including the principles and methods of preparation. Particle size and distribution, surface morphology, porosity, and density are all considered as appropriate analytical methods for characterization of Microsponges. The advantages, drawbacks, and possible responses of microsponge drug delivery are also examined. The advantages, drawbacks, and alternative solutions of microsponge drug delivery are also explored. These microsponges are included in sunscreens, balms, ointments, and over-the-counter skin care products that are designed for external use. Microsponge drug delivery can provide increased efficacy for topically active agents with enhanced safety, extended product stability and improved aesthetic properties in an efficient and novel manner. They are mostly used for topical use and have recently been used for oral administration.

Keywords: *Microsponges, Controlled Release, Porous Microspheres, Oral Drug Delivery System.*

Introduction

Oral administration of traditional dosage forms releases active agent into the gastrointestinal fluid, and absorption from different parts of the gastrointestinal tract (GIT) is based on the physicochemical qualities of the drug. The gigantic preponderance of commercially available pharmaceutical formulations comprises immediate-release products that may result

in insufficient absorption of the active agent or the compound being cleared from the body before the next scheduled dose. As a result, these formulations may deprive consumers of the active agent's [1] medicinal benefits. Controlled drug delivery systems can help with these concerns by lowering dose frequency, permitting gastric bypass or site-specific distribution, boosting active compound efficacy, and improving safety through a reduction in side effects and breakthrough symptoms.[2]

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As a result of these efforts to design novel drug carrier systems, the microparticulate drug carrier technique was developed. Multiparticulate systems

are the most basic form of controlled drug delivery since they can control drug release in a variety of ways, such as rate control, site control, or both, and they are simple to create. Multiparticulate systems are supposed to be more uniformly dispersed throughout the absorption site^[3] thus ensure more homogeneous

drug absorption. Microparticles also generate an approach for chronotherapeutic drug delivery. Microspheres,^[4] microbeads,^[5] microcapsules,^[6] microballoons,^[7] and microsponges are just several of the microparticulate systems that have been produced and explored for this purpose.

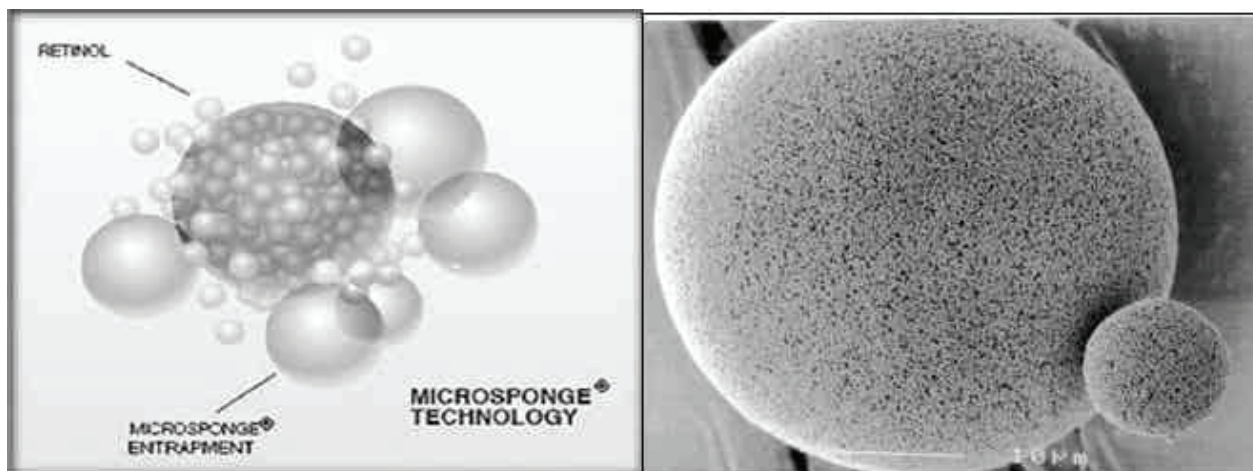


Figure No.1: View of microsp sponge

Defining microsponges

The Microsp sponge Delivery System (MDS) is a patented porous microsphere-based polymeric system. They're tiny sponge-like spherical particles with a plethora of interconnecting spaces within a non-collapsible structure with a wide porous surface that allows active ingredients to be released in a regulated manner.^[8] The microsponges range in size from 5 to 300 m in diameter, with a typical 25 m sphere having up to 250000 holes and an interior pore structure similar to 10 ft in length, providing a total pore capacity of roughly 1 ml/g and allowing for significant drug retention.^[9,10]

History of Microsponges

Won invented the microsp sponge concept in 1987, and Advanced Polymer Systems, Inc. was given the original patents. This company created a huge number of approach based, which are used in both cosmetic

and over-the-counter products (OTC) and prescription pharmaceutical products. This novel technology has recently been granted to Cardinal Health, Inc.^[11] for use in topical products. The internal structure of the microsp sponge particle is revealed by scanning electron microscopy as a "bag of marbles."^[12]

Characteristics

1. Microsp sponge stable at pH 1 to 11.
2. Their temperature stable up to 1300 degrees Celsius.
3. Microsp sponge formulations are self-sterilizing due to average pore size of 0.25m.
4. Compositions have a high entrapment rate, ranging from 50 to 60%.
5. Microsp sponge compositions are cost-effective and free-flowing.

6. Microsponge particles are too large to be absorbed into the skin, which adds a layer of safety to these microsponge materials by avoiding the microsponge adjuvants' adverse effects.

7. Microsponges can absorb 6 times their weight in oil without drying.

8. It has 12-hour continuous action period, i.e. extended release.^[13-15]

Advantages

1. These formulation are stable over range of pH1-11

2. These formulation are stable at room temperature up to 130⁰C

3. Most vehicles and chemicals are suitable with these formulas.

4. These are stabilizing as their average pore size is 0.25 µm where bacteria cannot penetrate.

5. These are non-irritating, non-mutagenic and non-toxic.^[16]

Table.1 LIST OF MARKETED PRODUCTS USING MICROSPONGES ^[17,18,19]

Product Name	Pharmaceutical Uses	Manufacturer
Ultra Guard	Protects baby's skin	Scott paper company
Retinol cream	Maintain healthy skin	Biomedic
Carac cream	Anti-Wrinkles	Avon
Lactrex TM 12%	Moisturizing cream	SDR pharmaceuticals, Inc
Salicylic peel 20	Excellent exfoliation	Biophora

Methods of preparation

This technology is simple to implement in the lab, but it has the potential to scale up to handle vast volumes of water.^[20]

Properties of the actives for the entrapment into the microsponge

Ø It should be fully miscible in monomer.

Ø It should be water immiscible or only slightly soluble.

Ø It must be monomer inert and not raise the viscosity of the mixture during formulation.

Ø It must also be stable while in contact with the polymerization catalyst and during polymerization conditions.

Ø The spherical structure of the microsponges should not collapse.^[21-25]

Liquid-liquid suspension polymerisation method

Liquid-liquid suspension polymerisation method contains two phases. In the first phase active ingredients form solution i.e., non-polar solution. The second phase (aqueous phase) is addition of surfactant or dispersing agents. In this method, the

first phase is dispersed in the second phase and this is done by polymerizations process with the help of catalyst, increased temperature or irradiation process. The steps involved include selection of active ingredients or monomers; formation of monomer chain as the polymerisation takes place; and formation of spherical particles of microspheres (agglomeration). This yields microsphere clusters, which are then combined to form microsponges.^[26-28]

Quasi-emulsion solvent diffusion method

Quasi-emulsion solvent diffusion method is a two-step process and increases the sensitivity of the drug release. This method uses different amounts of polymer. There are two phases to this, an interior phase

and an exterior phase. Polymer such as Eudragit RS-100 makes up the interior phase (low permeability). This cationic, non-biodegradable polymer was proven to enhance entrapment efficiency as the amount of Eudragit RS-100 was increased-100. The external phase consists of polyvinyl alcohol (PVA) with distilled water. Internal phase containing Eudragit RS-100 is dissolved in a solvent like ethyl alcohol at 35 °C under ultrasonication so that the internal phase is dispersed in the external phase containing PVA solution in water. The solution is stirred and 1 hour and is filtered to obtain the solid microsponges. This solid microsphere is dried in an oven at 35 °C- 40 °C for 12 hours. Before use^[29-31]

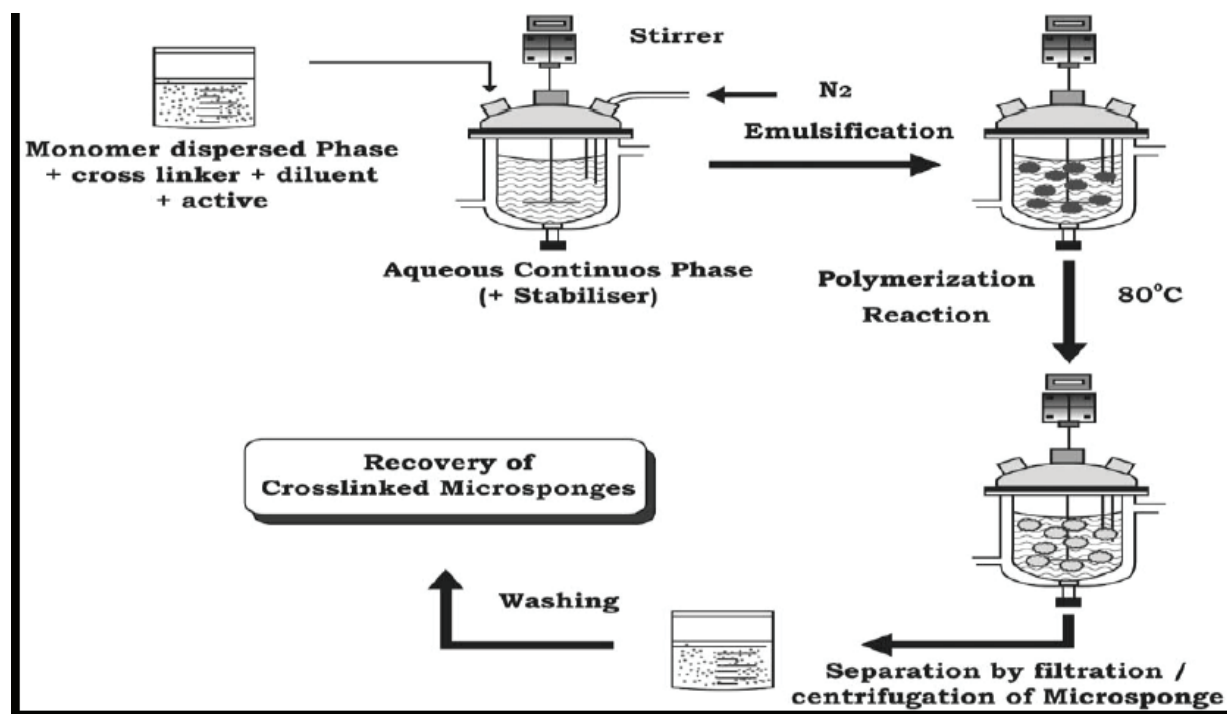


Figure 2: Suspension polymerization- system set up method

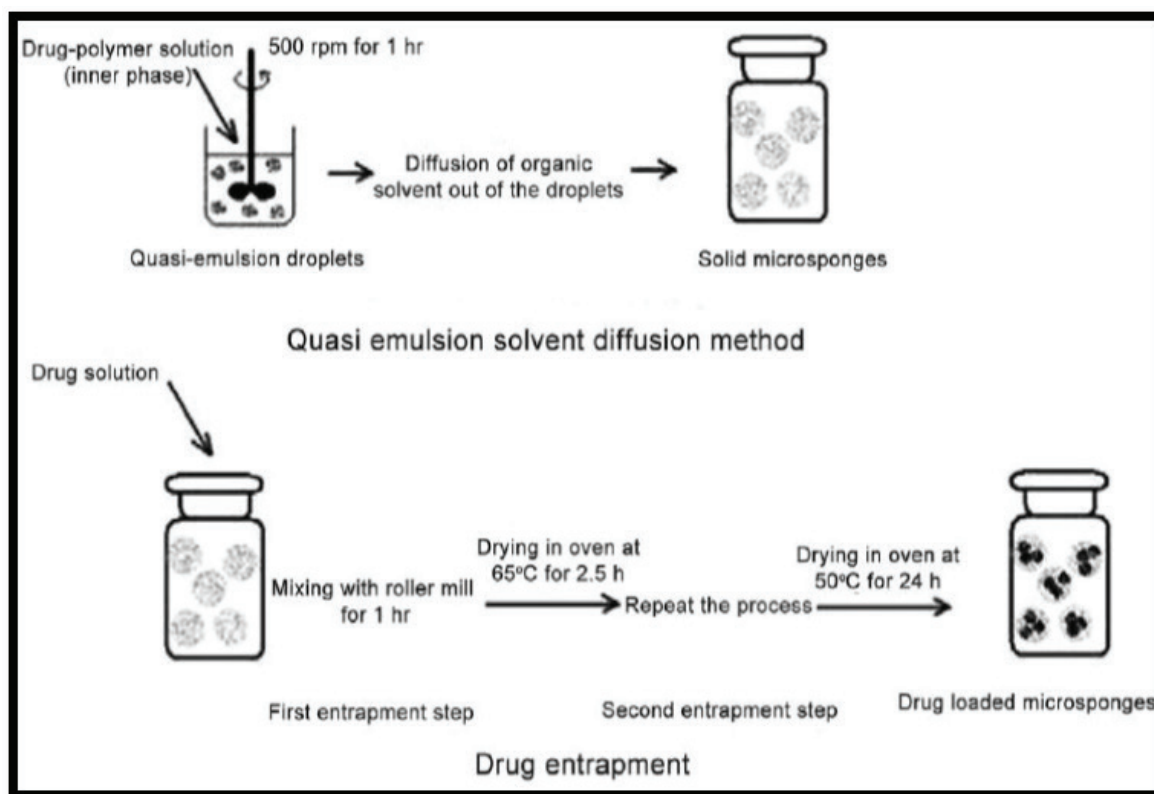


Figure 3:Preparation of microsponges by quasi emulsion solvent diffusion

Applications

S.No.	Applications	Advantages
1	Sunscreems	Long lasting product efficacy, with improved protection against sunburns and sun related injuries even at elevated concentration and with reduced irritancy and sensitization
2	Anti-acne e.g. Benzoyl peroxide	Reduced skin irritation and sensitization while maintaining efficacy.
3	Anti-inflammatory e.g. hydrocortisone	Long-lasting activity that helps to reduce skin allergies and dermatoses.
4	Anti-dandruffs e.g. zinc pyrithione, selenium sulfide	Reduced scent and irritation, as well as increased safety and efficacy
5	Antipruritics	Extended and improved activity.

Microsponge: as oral delivery system

Microsponges are frequently used for topical delivery. Due to their elegance these carrier systems also have applications in cosmetics [32] MDS were also studied for the peptide delivery

by varying ratio of polymers [33]. These microparticles possess potential for oral administration and pulmonary delivery. The potential of porous microsphere as injectable drug delivery system for controlled protein delivery using human serum albumin as model drug studied the potential of the porous microspheres of capreomycin sulfate for pulmonary use. Microsponge drug delivery system is suitable for drug delivery through oral route as these have the ability to increase the rate of [34] drug release of poorly water-soluble drugs by entrapping such drugs in the microsponge pore system. The microsponge particles bind to as a result of the rough surface of the intestinal mucosa, these carrier systems have the potential to increase bioavailability through with a combination of improved adsorption and dissolution rates.

Recent advances

Some researchers, pharmaceutical companies are developing advanced formulations. They're the following, and they're more stable than microsponges. [36]

Nanosponges:

This has been found to be a good carrier for gas delivery. When cytotoxic is combined with a nanosponges carrier system, the drug's efficacy is increased, allowing it to be utilised to target cancer cells. Crosslinking the -CD molecule with biphenyl carbonate produces -CD nanosponges. They can be utilised to make both hydrophilic and hydrophobic medicines. Flurbiprofen, dexamethasone, itraconazole, and other drugs were examined using

this advanced approach. [37]

Nanoferrosponges:

Nanoferrosponges are self-promising carriers with increased penetration towards a particular area due to an external magnetic reaction that allows carriers to penetrate deeper tissue before magnetic material is excluded and a porous system is left behind. [38]

Porous microbeads

Microspheres with better properties led to the development of porous microbeads. Polymerization and cross linking processes are utilised to create solid porous microbeads. The monomer used in the high internal phase emulsion approach has an exterior oil phase, an internal aqueous phase, and a cross linker. Topical, oral, and buccal medication delivery systems all use microbeads. [39]

Future prospects

Microsponge drug delivery system provides unique qualities such as enhanced product performance and elegance, longer release, improved drug release profile, reduced irritation, improved physical, chemical, and thermal stability, which makes it flexible to design novel product forms in the future. The real challenge in future is the development of the delivery system for the oral peptide delivery by varying ratio of polymers. [40] These microstructures have also been explored for drug delivery through the use of the pulmonary route, demonstrating that they can provide effective drug release even when resources are limited. As a result of the dissolving fluid, the colon is an effective site for medication release targeting. Alternative drug administration routes, such as parenteral and pulmonary. These particles can also be used as the cell culture media and thus can also be employed for stem cell culture and cellular regeneration in the body. These carrier systems have been used in cosmetics because of their

elegance. These formulation advances also open up new drug delivery options.^[41]

Conclusion

Microsponge technology and the versatility it provides have a lot of promise in the market because of the demand for novel and highly efficient Pharmaceutical and Cosmetic goods. Formulators can achieve the complete benefit of these unique materials as they investigate new and creative ways to administer actives, providing improved safety, improved stability, and decreased side effects actives, enhanced multifunctionality and improved ingredient compatibility.

Microsponge delivery technology. Microsponges offer a distinct advantage over existing traditional topical dosage forms for the treatment of tropical diseases; they are a one-of-a-kind technology for the controlled release of topical drugs that can also be used for oral and biopharmaceutical medication delivery. This product is superior to others since it is non-mutagenic, non-toxic, and non-irritant. As a result, the microsponge medication delivery system has a lot of potential and is still a new topic that require investigation in the future by the majority of researchers.

Ethical Clearance: Taken from institutional Ethics Committee of SRMS CET, Bareilly

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Effectiveness of Home Isolation in COVID-19 Patients

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Abstract

Background: The COVID-19 pandemic has created unprecedented disruption for the healthcare industry, forcing hospitals, organizations fighting infectious diseases, which has led healthcare workers to return up with other ways of delivering medical services while adapting to the new environment. Inadequate quarantine facilities and hospital beds are the major issues facing by the citizens due to sudden increase in cases.

Methods: This is statistical and descriptive study that was conducted at Healthcare at Home India Pvt. Ltd, which included patients enrolled for the home isolation programme from the June 2020 to January 2021.

Conclusion: This study is showing HIP is operative in the home setting for COVID-19 patients is an effective way of utilising less resources.

Keywords: COVID 19, Home Isolation, Hospitalization

Introduction

COVID-19 is reshaping the healthcare system by that specialize in healthcare safety and therefore the responsibilities of future healthcare leaders have increased twofold. HCAH performing on creating and nurturing a culture of safety, one that's aligned with a holistic, continuous improvement process and sustained through effective communication and education is not any longer a choice; it's now a requirement of all healthcare leaders, from the boardroom to the bedside. Studies on the feasibility of home isolation for COVID-19 patients are the necessity of the hour.¹

Recent studies on COVID 19 suggested that we can limit the spread of a contagious illness by the means of isolation and can be carried out voluntarily by

government authorities. Though isolation is different from quarantine and both the terms having different definitions, however due to lack of awareness and knowledge most of the time people wrongly use these terms interchangeably. Isolation refers to the people who have a specific infectious illness. Movements of these individuals are restricted, and they are separated from individuals who are healthy or asymptomatic.² A COVID 19 positive person can be isolated at home, in hospitals, or at another healthcare facility. Literature mentions that there are various challenges associated with Isolation such as compliance, cost, productivity, quality of life, etc.^{3,4}

Material & Methods

This is statistical and descriptive study that was conducted at Healthcare at Home India Pvt. Ltd, which included patients enrolled for the home

isolation programme from the June 2020 to January 2021. Laboratory confirmed COVID-19 patients were assessed during the enrolment for their eligibility for home isolation.¹

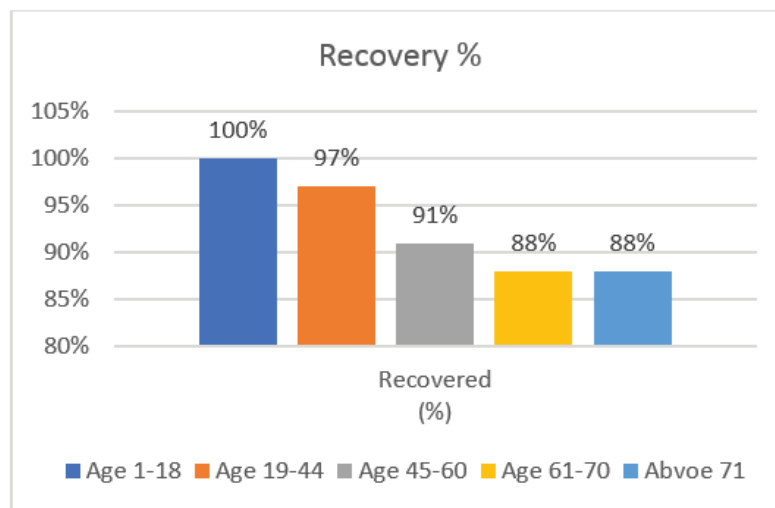
Only those who are asymptomatic or mild symptomatic were eligible to be in isolation at home. HCAH checks the eligibility of onboarding (i.e no dypnea, SpO₂> 90-94% on room air, Resp Rate≤24/min) and take the consent/undertaking on mail. Also confirm whether the patient have a room to isolate themselves from your family members. The enrolled patients were followed up by the Tele caller on a daily over a telephonic call (on a recorded line) with objective parameters like temperature, pulse rate, oxygen saturation, symptoms if any and fill the details in the assessment form. A dedicated tele-monitoring link had established for daily follow-up of the person during the entire period of home isolation. In case vitals were not stable then Tele caller informs the same to the patient or NoK that they will forward their call to clinical expert team. This Home Isolation program also included 4 doctor calls, 1 Dietician call, 1 Physiologist call and 1 Psychologist Counselling. According to the condition of the patient, he/she will be kept in the hospital or at home.

Patient under home isolation stand discharged and end isolation after 17 days had passed from onset of symptoms (or from date of sampling for asymptomatic cases) and no fever for 3 days. Discharge to only be permitted if patient has:

- No symptoms
- No fever recorded for 3 days (<= 99.5 F)
- Maintains saturation above 95% (self-reported by patient, wherever possible)^{4 567}

Results

During the study period from June 2020 to January 2021, there were a total of 500 patients and segregated the data into 5 age group i.e. age group 1-18 years (Group 1), age group 19-44 years (Group 2), 45-60 age group (Group 3), Age group 61-70 (Group 4) and above 71 (Group 5). Of those, 156 were female (31%) and 344 were male (69%). Of the total cases, 31 (6%) required hospital admission and the reasons like fever, Tachycardia, desaturation, and non-medical ones like anxiety regarding the disease. And majority 469 (94%) were continued in the home monitoring program till recovery. Mean age for hospitalization cases 57.8±15(SD) and mean age of oxygen required cases 69.6±11.0(SD).

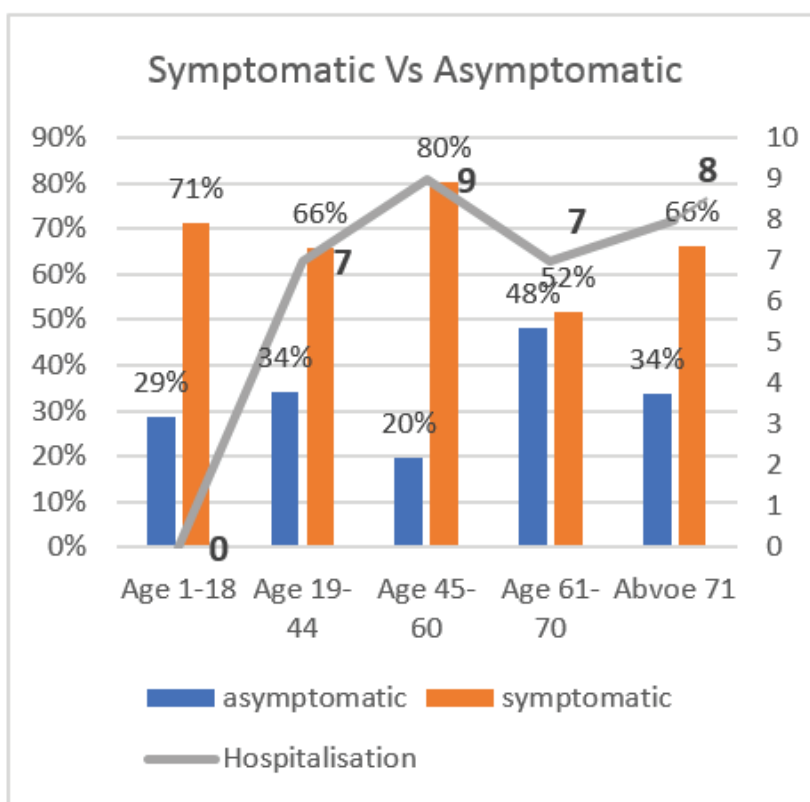


Graph 1 Recovery Percentage Table 1 Male Vs Female (%)

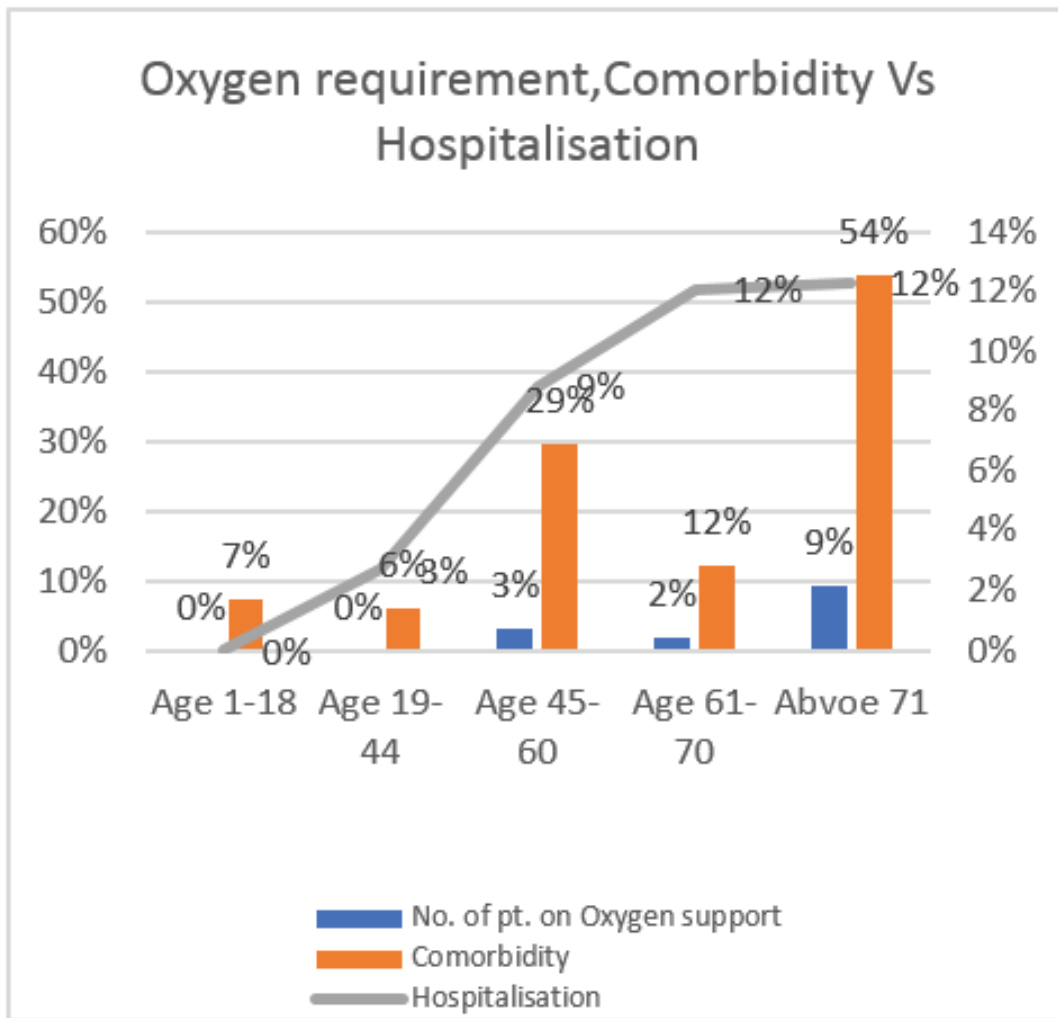
Age	Female	Male	Total Percentage
Age 1-18	64%	36%	3%
Age 19-44	24%	76%	52%
Age 45-60	36%	64%	20%
Age 61-70	53%	47%	12%
Above 71	25%	75%	13%

By the above graph, it is clearly showing that recovery is related with the patient age. As the age of patient increasing parallely recovery is decreasing. And it's high in Age group 1-18 and lowest in age group 61-70 and Above 71.

If we talk about the recovery percentage identified from COVID-19 patients data, so the highest recovery rate that is 100% found in age group 1-18 years (Group 1), followed by 97% in age group 19-44 years (Group 2), 91% patients recovered in the 45-60 age group (Group 3), and 88% COVID recovered in Age group 61-70 (Group 4) and above 71 (Group 5).



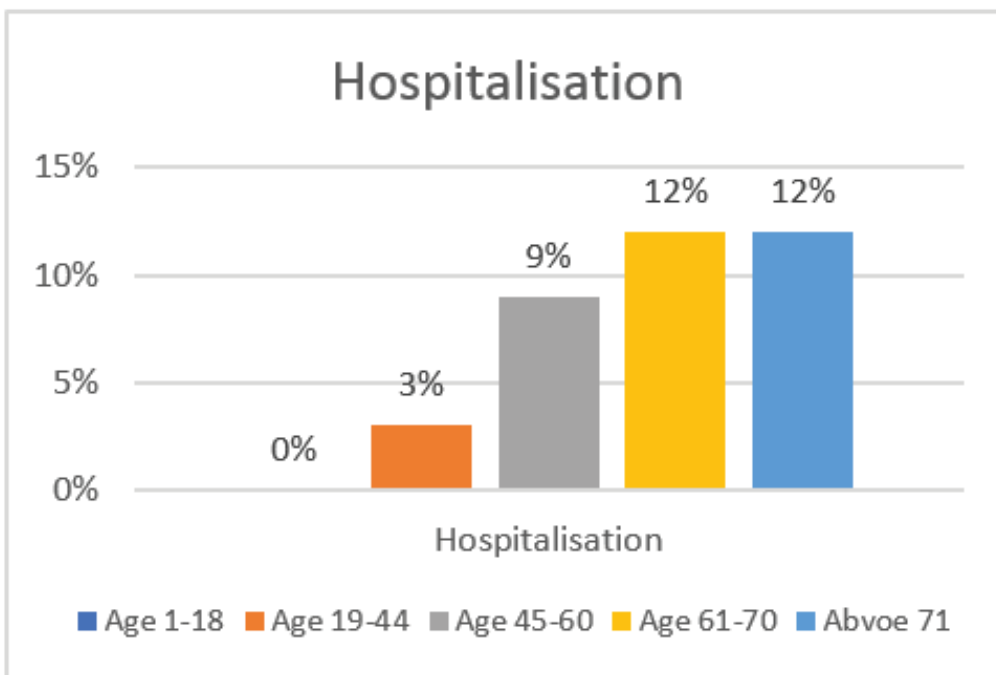
Graph 2: Symptomatic Vs Asymptomatic



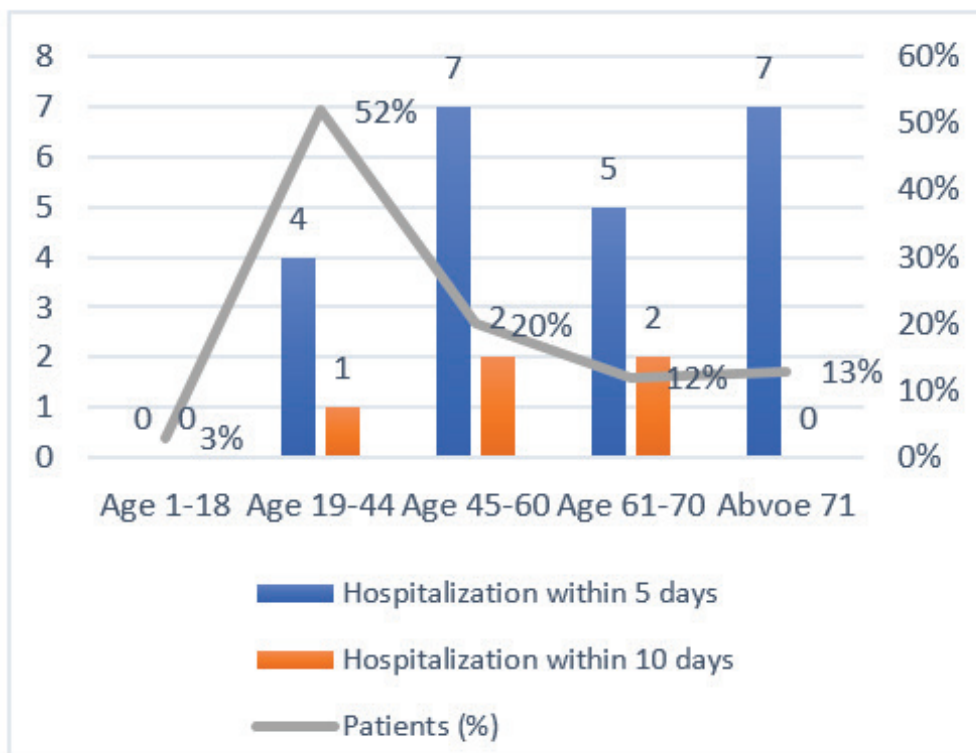
Graph 3 Oxygen requirement, Comorbidity Vs Hospitalisation

This graph is showing that symptomatic patients and hospitalization are high in Age group 61-70 and above 71 years and symptomatic cases are directly related to the patient age. It was found that 93% patients those hospitalized were the symptomatic cases and majorly falling under age group of 61-70 and above 71.

This graph is depicting that comorbidity is high in 3 age groups that is Age group 45-60, 61-70 and above 71 and number of patients on oxygen support are also high in the respective 3 groups where co morbidity are high in number. Age and the presence of comorbidities were directly related to the requirement of hospitalisation.



Graph 4 Hospitalisation



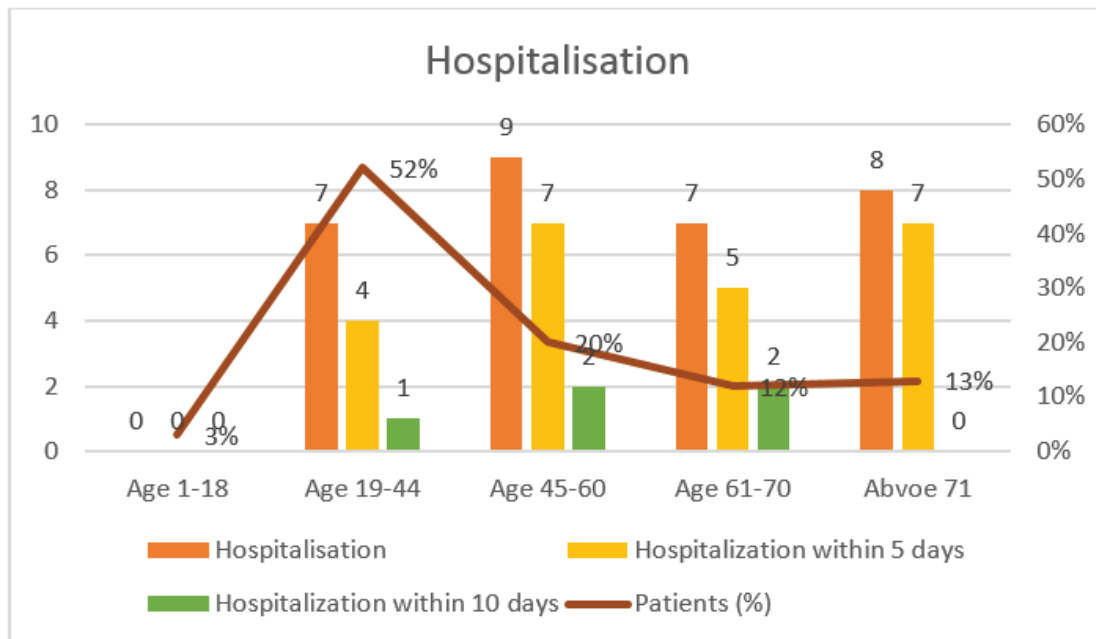
Graph 5 Hospitalization within 5 to 10 days

This is showing that hospitalization are there in every age group except Age 1-18 but the highest number of hospitalization is there in Age 61-70 and above 71.

This is also showing that Hospitalization within 5 days of home isolation is highest in the above mentioned two groups and this is also giving direct indication that hospitalization has correlated with the

age of the patients. As the age of the patients increasing number of hospitalizations is also increasing. And the reasons for hospitalisation are Fever, Tachycardia, Breathing difficulty and desaturation.

By conducting Chi square test, $p < 0.05$, the value of p is 0.004133 So, there is a significant relationship between age and hospitalisation.



Graph 6 Hospitalisation with patient %

The proportion of COVID-19 positive men was higher than that of women (69% vs 31%). Analysis of the data shows highest patients falls under 19-44 years age group i.e. 261 patients out of which 198 males and 63 females, second highest number of patients falls under 45-60 years age group i.e. 102 patients out of which 65 males and 37 females are there and the lowest count is there in 1-18 years age group i.e. 14 patients out of which 5 males and 9 females. However, the highest number of hospitalised patients falls under 61-70 and above 71 years age group. It

was showing that 82 patients were showing symptoms at the time of initiation of Home Isolation program in 45-60 years age group 3 which is the highest amongst all the groups, 10 patients were showing symptoms at the time of initiation of Home Isolation program in 1-18 years age group 1. Age and the presence of comorbidities were directly related to the requirement of hospitalisation. In 45-60 years age group (group 5), 9 patients were hospitalized and in ≥ 70 years age group 5, total 8 patients hospitalized during the tenure of their home Isolation Program.

Discussion

The findings were in accordance with results of other studies those have found that men are more commonly infected with COVID-19 than women. Patients with comorbidities, especially hypertension and diabetes, are more likely to contract the disease.⁷ The present study reflected that symptomatic patient; age and the presence of co-morbidities are directly related to the requirement of hospitalisation.

And the major reasons for hospitalisation were Fever, Tachycardia, Breathing difficulty and desaturation. No children required hospitalisation. There were no deaths. Home Isolation programme had been very well accepted and cherished by both patients and other healthcare workers. This isolation programme was more suitable for those who were low risk, especially when it comes to families with young children or elderly relatives. In this situation, being quarantined in a Care centre/facility can be very traumatic and challenging.

The present study had certain limitations, such as small sample size. Future research should focus on the relationship between symptomatic, asymptomatic and hospitalization.

Conclusion

This study is showing that this programme is operative in the home setting for COVID-19 patients is effective way of utilising less resources. And our study is proving that asymptomatic and mild symptomatic cases can be tackled without compromising the life of a patient.

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Conflict of Interest: The author declares that they have no financial or non-financial conflict of interest.

Source of Funding: No funding was provided to this research study.

Ethical Clearance: Ethical clearance was not required in this study.

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innovation in developing, maintaining, and

impacting the outcome of SARS-CoV-2 infected
patients, Travel Medicineand Infectious Disease
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Factors Influencing the Magnitude of Menstrual Problems among Married Pre-menopausal Women of Rural Puducherry District

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Abstract

Among rural women of India, the magnitude of menstrual problems is fairly large. Such problems will be still large enough among those who are at pre-menopausal ages. In view of this, we made an attempt here to understand the magnitude of menstrual problems among rural women and tried to identify the key factors influencing the same. The data has been collected from 780 married pre-menopausal women (aged 35–49 years), who are selected from 30 villages of five communes in Puducherry district. Descriptive and inferential statistics as well as linear regression technique adapted. Around 63.5 per cent of sample women perceived to be suffering from one or the other menstrual problems. Results of multiple linear regression analysis suggest that the likelihood of women suffering from menstrual problems is positively associated with current age, pregnancy wastage and ever used oral contraceptive pills or IUCD. Conversely, such probability is found to be negatively associated with years of schooling, family monthly income, grading of occupational status, menstrual hygiene and extent of freedom of movement. Efforts may be taken to improve the socio-economic conditions and imparting good menstrual hygienic practices among rural women through the Government resources, NGOs and Voluntary Organizations.

Key Words: *Menstrual Hygiene, Menstrual Problems, Multiple Linear Regression,*

Introduction

In India, rural women, to a large extent, suffer from one or more number of menstrual problems. This is mainly due to the fact that women first of all do not know whether the problems, which they perceive on symptomatic basis, are related to menstruation or

not. Further, even if they know, they many not take treatment at the earliest mainly due to ‘culture of silence’ as they are menstrual / gynaecological related. Under these circumstances, these simple problems would develop to complicated ones and also cause some more related problems. Another worth noting point here is that women who are in their later part of reproductive ages (say 35 years & above) are more likely to suffer from menstrual problems due to various reasons like irregular menstrual cycles due to nearing menopausal age, occurrence of secondary sterility, use of contraceptive methods (especially temporary), number of pregnancies and/or reproductive wastage

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(spontaneous / induced abortion, miscarriages and still births).

A number of studies,¹⁻⁴ at micro and macro level, have been carried out focusing on menstrual disorders and related aspects among women of reproductive ages and/or young married ones. Moreover, most of the studies collected and analysed the information as part of reproductive tract infections and/or gynaecological morbidities instead exclusively focusing on menstrual problems from which women suffered. Thus, studies exclusively on married pre-menopausal women are scanty or almost nil. Hence, this study aims to fulfil these research gaps.

Objectives

- To understand the prevalence of menstrual problems among the married pre-menstrual women (aged 35-49 years) residing in selected rural areas of Puducherry district, and
- To examine the various socio-demographic & economic and obstetric factors affecting the magnitude of menstrual problems among the sample women.

Materials and Methods

Study Population: This study was done as part of the doctoral research work on '*factors influencing gynaecological morbidity and treatment seeking-behaviour among married pre-menopausal women dwelling in selected rural areas of Puducherry district*'. The sample included was currently married pre-menopausal women (aged 35-49 years).

Sample estimation: The sample size was estimated using the Daniel's⁵ formula keeping 36% of RTI prevalence among reproductive women in India with assumption of 95% confidence interval (CI), 5% margin of error and 0.05 as absolute precision. Further, with design effect of 2.0 and to compensate for 10% of non-response rate of the determined sample, the

calculated final sample size arrived was 780.

Sample Selection: Multi-stage sampling was adapted for the selection of the sample women. At the first stage, based on probability proportionate sampling technique 30 villages out of 2 communes were selected from Puducherry district. Next, in each of these 30 villages, 100 households each (in which eligible women found) were selected through household survey, which formed as clusters or Primary Sampling Units for further selection of samples. Then, 26 sample women (respondents) were selected from each of these 30 clusters (or PSUs) based on simple random sampling. Thus, a sample of 780 women were selected and interviewed for this study.

Data Collection: Required data was collected from the respondents by administering a semi-structured schedule with the assistance of face-to-face interview method during January – April, 2021. All the women were asked to provide the details about the menstrual problems from which they suffered / experienced during twelve months prior to the survey period. This information was collected on the basis of self-reported symptomatic approach, which was widely used in different settings around the world.

Statistical Analysis: For the present paper, the dependent variable considered was 'the number of menstrual problems from which the women suffered during one year preceding to the survey', which ranges between '0' and '6'. Selected women's background characteristics have been considered as factors that are likely to influence (independent variables) the magnitude of menstrual problems. Frequency tabulations were done in the case of prevalence of menstrual problems as well as socio-demographic & economic and obstetric characteristics of women. Then the bivariate analysis was carried out to examine the associations (or differentials, if any, exist) between the mean number of menstrual problems (from which women suffered) across the background

characteristics of women and the levels of significance were assessed with one-way ANOVA / t-test. At the final stage, multiple linear regression analysis was done considering those variables (factors) that were found to be significant at 0.05 level or above in the bivariate analysis. All these analyses were executed through IBM-SPSS software (version 20.0).

Results

Prevalence of menstrual problems

On the whole, about 63.5% of the respondents (women) in rural areas of Puducherry district reported to be suffered from one or the other menstrual problems (during one year prior to survey). Lower abdominal pain (30%) and irregular periods (23%) are reported to be the major symptoms of menstrual problems, followed by itching during menstruation (15.4%), excessive bleeding (12%) and passes blood clots (11.4%). On the other hand, while about 26% of them suffered from one menstrual problem, 22% and 11% stated to be suffered from two and three menstrual problems, respectively.

Background characteristics of respondents

Among the sample respondents (Table 2), majority belonged to the age group 35-39 years (44.7%), educated up to middle school & high school level (25.9% & 28.6%, respectively) and homemakers & working as labourers (43% and 34%, respectively). Most of them belonged to families that have monthly incomes of ₹12,001-18,000 and ₹18,001-24,000 (28.3% & 27.7%, respectively). Two-thirds of respondents (66.7%) belonged non-scheduled castes / tribes. Little less than half of the respondents have had 3 or more pregnancies, whereas about one-third of them have had history of pregnancy wastage (spontaneous & induced abortions, miscarriages and still births) and just about one-tenth of them ever used oral contraceptives & IUCD.

In the present study, the freedom of movement of women has been measured based on the responses elicited from them for four common aspects of their movement from home to outside community / society and assigning the scores on the following lines: 'going to market', 'going to health facility' & 'going to outside village / community' (not at all = 0, with someone = 1 and alone = 2) and 'frequency of visiting parents' home' (Rarely / Once in a year = 0, Two or more times in a year = 1 and Often = 2). Then, the cumulative score for each respondent has been computed (ranges between 0 and 8), which indicates their extent of freedom of movement index and on the basis of this pooled score, a large number of them (70.3%; scores 5-8) are stated to be having 'higher' extent of freedom of movement (Table 2) and the rest have freedom of movement to a 'lower' extent (29.7%).

The menstrual hygiene index of the respondents is obtained on the basis of responses (and scores assigned) to the following eight menstrual practices. 'Frequency of cleaning perineum' (while taking bath only = 0, after voiding urine & defecation = 1 and whenever feel discomfort = 2), 'material used to clean perineum' (with cold water = 0, hot water = 1 and soap with cold / hot water = 2), 'procedure of cleaning perineum' (wash from back to front = 0, wash from back to front and front to back = 1 and wash from front to back = 2), 'type of perineum pads used' (old clean cloth = 0, old clean cloth & local made sanitary pads = 1 and sanitary pads = 2), 'frequency of changing perineum pads' (only once = 0, morning and evening = 1 and whenever pad is soaked = 2), 'procedure of disposing perineum pads after use' (wash and reuse it = 0, thrown into dustbin = 1 and burn / buried = 2), 'no. of times taking bath during menstruation' (one time = 0, two times = 1 and 3+ times = 2) and 'no. of days after menstruation participate in sex' (≤ 5 days = 0, 6-7 days = 1 and 8 + days = 2). The cumulative score for each respondent has been computed (ranges

between 3 and 15), which indicates their degree of overall menstrual hygiene followed (higher the score higher would be their menstrual hygiene). Based on this pooled score, majority of them (47%) are said to be practicing menstrual hygiene at a ‘fair’ extent (Table 2) followed by ‘poor’ extent (29%) and around 23% of them classified as ‘poor’ in their menstrual hygiene practices.

Cross-tabular analysis showed that the mean number of menstrual problems from which women suffered is appeared to be decreasing with their educational level, occupational status, monthly family income and menstrual hygiene index. It is further noted that the mean number of menstrual problems is found as lower among those women who belonged to non-Scheduled Castes / Tribes and also among those have ‘higher’ freedom of movement. Conversely, the corresponding mean has exhibited an increasing trend with their current age. On the other hand, the mean number of menstrual problems is observed as higher

among those women who had 3 or more pregnancies, pregnancy wastage and ever used oral contraceptive pills / IUCD than their counterparts. The one-way ANOVA / t-test results in all these regard turned out as statistically significant at different levels (Table 2).

The multiple linear regression analysis results (Table 3) highlight that the likelihood of experiencing from menstrual problems appeared to be strikingly decreasing with an increase in the current age of the women ($p < 0.001$) and such probability is also found as higher among women ever used oral pills / IUCD ($p < 0.01$) as well as among those who had the history of pregnancy wastage ($p < 0.05$). Conversely, the extent of women suffered from menstrual problems is observed to be decreasing with an increase in their menstrual hygiene practices index ($p < 0.01$), monthly family income ($p < 0.01$), years of schooling ($p < 0.05$), degree of freedom of movement index ($p < 0.05$) and the hierarchical order of occupational status ($p < 0.05$).

Table 1: Distribution of respondents by menstrual problems (N=780)

Menstrual Problems	%	n
Lower Abdominal Pain	31.2	243
Irregular Periods	23.6	184
Itching during Menstruation	15.5	121
Excessive Bleeding	12.3	96
Passes Blood Clots	11.4	89
Vaginal Irritation Often	9.1	71
Scanty Bleeding	8.6	67
Feeling of Heaviness Below	7.2	56
Frequent Vaginal Discharge	3.2	25
Suffering from any menstrual problems	63.5	495
<i>No. of menstrual problems from which respondents suffering</i>		
0	36.5	285
1	26.3	205
2	21.8	170
3	10.8	84
4	3.3	26
5	0.9	7
6	0.4	3

Table 2: Distribution of respondents and mean number of menstrual problems across their background characteristics

Background Characteristics of Respondents	%	n	Menstrual Problems		p
			Mean	SD	
Current Age (in Years)					
35 – 39	44.7	349	0.98	1.2	0.001
40 – 44	29.2	228	1.30	1.2	
45 +	28.0	203	1.55	1.3	
Education					
Illiterates	11.7	91	1.51	1.2	0.001
Primary School	14.2	111	1.50	1.2	
Middle School	25.9	202	1.24	1.2	
High School	28.6	223	1.14	1.3	
Higher Secondary School +	19.6	153	0.93	1.2	
Occupation					
Not Working / Homemakers	42.8	334	1.29	1.2	0.003
Agricultural / Non-Agri. Labourers	34.0	265	1.34	1.3	
Service / Skilled Workers	9.5	66	0.89	1.2	
Cultivation / Business	7.7	60	1.03	1.2	
Employees (Govt. & Private)	7.1	55	0.82	1.1	
Monthly Family Income (in ₹)					
12,000 & less	19.9	155	1.49	1.1	0.002
12,001 – 18,000	28.3	221	1.23	1.3	
18,000 – 24,000	27.7	216	1.22	1.3	
24,001 +	24.1	188	0.98	1.3	
Caste					
Scheduled Castes / Tribes	33.3	260	1.35	1.3	0.05
Non-Scheduled Cates / Tribes	66.7	520	1.16	1.2	
No. of Pregnancies					
≤ 2	51.7	403	1.11	1.2	0.01
3 +	48.3	377	1.34	1.2	
Pregnancy Wastage					
No	67.1	523	1.15	1.2	0.05
Yes	32.9	257	1.36	1.3	
Ever Used Oral Pills / IUCD					
No	89.9	701	1.18	1.2	0.01
Yes	10.1	79	1.56	1.4	
Freedom of Movement (Index)					
Lower	29.7	232	1.48	1.3	0.001
Higher	70.3	548	1.11	1.2	
Menstrual Hygiene (Index)					
Poor	28.8	225	1.47	1.1	0.001
Moderate	47.3	369	1.22	1.2	
Good	23.8	186	0.92	1.2	
Total	100.0	780	1.22	1.2	

Note: t-test of significance is computed for those variables which have 2 categories only.

F-test of significance is computed for those variables which have 3-4 categories.

Table 3: Multiple linear regression analysis of factors influencing menstrual problems

Explanatory Variables	β Co-efficient	t-value	p-Level
<i>Constant</i>	--	0.600	0.549
Current Age (<i>In Years</i>)	0.159	4.469	0.001
Educational Level (<i>Years of schooling</i>)	-0.074	-2.020	0.05
Occupation (<i>5 Categories</i>)	-0.071	-2.028	0.05
Monthly Family Income (<i>in ₹</i>)	-0.092	-2.579	0.01
Menstrual Hygiene (Index) (<i>Pooled Score</i>)	-0.104	-2.929	0.01
Freedom of Movement (Index) (<i>Pooled Score</i>)	-0.071	-1.997	0.05
Pregnancy Wastage (<i>Yes</i>)	0.080	2.326	0.05
Ever Used Oral Pills / IUCD (<i>Yes</i>)	0.095	2.758	0.01

Discussion

A large number of sample women of our study have suffered from one or more number of menstrual problems. Such large prevalence is relatively higher mainly due to the fact that the study women are in their later part of reproductive ages (35-49 years) and pre-menstrual women (who are more likely to be susceptible for infections related to menstruation), besides dwelling in rural areas who are less accessible to conducive environmental factors and health facilities. Added to these, the reference period for menstrual problems is little longer, i.e., 12 months, preceding the survey date. A study³ conducted among women living in slums of a city in Andhra Pradesh showed 66% of women (aged 15-49 years) reported to be suffered from menstrual problems, whereas such

prevalence is found as much less (10%) in an all India survey⁴ and also in another study in rural Haryana² (20%).

One of the major findings of this study is an increase in the prevalence of menstrual problems with women's age, which is supported by findings of a few studies conducted at different settings of India^{3,4,6}. Yet another striking finding observed here is that there is a consistent decrease in the magnitude of menstrual problems with an increase in the menstrual hygiene practices index. Several studies show that practicing of one or the other menstrual hygiene aspects (or management) significantly lessen the occurrence of menstrual morbidity not only among married women^{1,4,7,8}.

Our study further exhibited that the magnitude of women suffered from menstrual problems is significantly decreasing with an increase in their years of schooling and family monthly income, and grading of occupations in which they engaged. The role of education in reducing the occurrence of menstrual problems is supported from the findings of few studies from India^{1,3,4,9}. Likewise, while a micro-level study in Karnataka¹ women belonged to higher socio-economic class have exhibited lower prevalence of menstrual morbidity, the all India survey⁴ demonstrated such prevalence is higher among women those who possess below poverty line (BPL) card (lower in their family economic status). On the other hand, the study among rural married women of Haryana² noticed that the magnitude of menstrual problems as higher among housewives than among those who are engaged in different economic activities (working) for earning wages / income. Thus, women being educated, working (mostly outside home) and belonged to families have lesser risk of suffering from menstrual problems as such women are more likely to have greater awareness in preventive and curative health care aspects, besides adhering to better personal and menstrual hygienic practices. Added to these, as this study suggests women who have higher movement of freedom (to outside home / community / village), which is higher among those educated and engaged in different occupations, have demonstrated lesser prevalence of menstrual problems. Further, most of these women are belonged to non-Scheduled Castes / Tribes and also have lesser (≤ 2) number of children, which again exhibited detrimental effects on menstrual problems.

This study has also clearly demonstrated that the magnitude of menstrual problems is higher among those women who had history of pregnancy wastage and ever used oral pills / IUCD. These findings are also noted as analogous with the ones observed in a few studies^{1,4}. However, the study by Ahamed et al.²

showed that the prevalence of menstrual problems is significantly higher among those who ever not used any contraceptive method than those using any or the other method.

Conclusion and Suggestions

Overall, it can be stated that married pre-menstrual women (aged 35-49 years) in rural Puducherry district to large extent suffered from one or more menstrual problems. While the prevalence of menstrual problems appears to be positively associated with their current age, pregnancy wastage and use of oral pills / IUCD, similar prevalence is negatively associated with their good menstrual hygiene practices and better socio-economic conditions. Improving the socio-economic conditions of women and encouraging / motivating them to practice / maintaining good menstrual hygiene are to be taken care through various strategies and programmes not only by the Government concerned, but also by the NGOs / Voluntary organizations located in respective rural areas.

Ethical Considerations

The researcher read the statement of consent to all sample women highlighting the importance of the study and risks and benefits before starting data collection, and interviewed those who are willing to participate voluntarily by giving oral consent. They have been assured to keep their self-respect to privacy confidentiality of information provided, etc. Respondents were also informed about their full right to participate or withdraw from the study at any stage as well as skip or not to give information for any question(s) they feel embarrassed or willing to. The researcher also got appropriate ethical clearance approval from Institutional Research Board, IIHMR, Jaipur.

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interest

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Courveilhier Baumgarten Syndrome: A Rare Case Report

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Abstract

A 44 year old female had presented with history of abdominal distension of 20 days duration and on examination he had prominent abdominal vein and a venous hum with Ascites. He had no history of altered sensorium, melena. The clinical scenario was suggestive of Cruveilhier Baumgarten syndrome.

Keywords: ascites, altered sensorium, melena, case report

Introduction

The term Cruveilhier Baumgarten syndrome is used for cases of portal hypertension due to any cause in which a loud venous murmur can be heard over the upper abdomen. The Cruveilhier Baumgarten disease is reserved for cases with congenital patency of the umbilical vein associated with congenital hypoplasia of the liver and portal system and a venous murmur heard over the umbilical vein⁽¹⁾.

Case Report

44 years old married female, labourer by occupation presented to our out-patient department with complaints of suddenly progressive abdominal distension since 12 days, pain in lower abdomen since 4 days and lump on the anterior abdominal wall above the umbilicus which is bluish in colour. There is also history of one episode of black tarry stools two days back. Patient had similar complaints in the past 1.5 years back for which she was diagnosed with

Abdominal Koch's and took treatment for the same for 6 months. There is no history of altered sensorium or hematemesis.

On examination, patient is average built female and her vitals were stable (BP-128/82 mmHg, PR- 88/min, RR- 18/min and spo2- 98%) mild palor present with no obvious signs of hepatic failure. Abdominal examination revealed distended, soft shinny skin with visible prominent single vein over anterior abdominal wall above the umbilicus, non-tender with presence of shifting dullness and bowel sounds present. Chest examination was normal. Abdominal and pelvic sonography revealed cirrhosis of liver with portal hypertension with recanalized patent umbilical vein travelling along the anterior abdominal wall with mild splenomegaly and gross ascites.

Lab investigations were performed as : Hb-7.6, TLC-8400, platelet count-1.3 lacs, INR-0.9, Total Bilirubin- 1.4, Direct Bilirubin-0.5, Indirect Bilirubin-0.9, SGOT-50, SGPT-38, ALP-195, Total proteins-5.9, Serum Albumin- 2.5. Ascitic fluid analysis was also performed and Serum albumin ascetic gradient was 1.1 and viral serology was negative.

CT scan of the abdomen was done which showed cirrhotic changes in the liver, marked ascites with mild

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splenomegaly with portal hypertension and multiple porto caval vascular shunts as prominent patent umbilical vein in the falciform ligament, along lesser curvature of stomach, spleen and linorenal region.



Figure:showing ascites

Discussion

In 1833 Pegot reported a case of portal hypertension in which a loud venous hum was heard at the umbilicus. This case was elaborated by Cruveilhier. At autopsy it was found that the venous murmur was due to collateral circulation through a widely patent umbilical vein. The liver was hypoplastic. In 1908 Baumgarten reported a similar case in a 16 year old boy who died following a gastric haemorrhage. He believed that the widely patent umbilical vein, splenomegaly and atrophic liver were due to congenital hypoplasia of the liver. Since then several similar cases have been reported in foreign literature but the first complete review in the English literature was that by Neil Armstrong et al² in 1942. The portal circulation commonly decompresses through collaterals in the ligamentum teres. This usually echogenic structure becomes sonolucent centrally, producing a “bull’s eye” appearance in the transverse plane on ultrasound examination. A central vascular channel exceeding 3mm in diameter is a specific sign of portal hypertension. On longitudinal

scans, these recanalized paraumbilical veins can be followed caudally toward the umbilicus as a tubular lucency . A patent umbilical vein excludes an extra hepatic cause of portal hypertension because the umbilical vein arises from the intrahepatic portion of the left portal vein. This vein enables the formation of an anastomosis between the left branch of the portal vein and the veins of the anterior abdominal wall, creating a portal systemic bypass circuit known as the Cruveilhier Baumgarten syndrome. The vein may sometimes become aneurysm ally dilated and simulates a pancreatic pseudocyst, so Doppler scanning of cystic structures in patients with cirrhosis should be done before Biopsy. Doppler sonography can also be used to assess the hemodynamic significance of flow in paraumbilical vein. When hepatofugal flow in the umbilical vein exceeds hepatopetal flow in the portal vein, patients are less likely to have esophageal varices and bleeding. Although it occurs more commonly in patients with severe functional impairment, it may play a protective role against variceal bleeding.^(3,4,5)

Ethical Clearance- Taken from ethical committee of institution

Source of Funding- Self

Conflict of Interest – Nil

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Psychiatric Comorbidity in Dermatology Patients in a Tertiary Care Centre in Western U.P

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Abstract

Skin is an organ that has a primary function in tactile receptivity and reacts directly upon emotional stimuli. Dermatological practice involves a psychosomatic dimension. A relationship between psychological factors and skin diseases has long been hypothesized. Psychodermatology addresses the interaction between mind and skin. It is divided into three categories according to the relationship between skin diseases and mental disorders. This article reviews different dermatological conditions under each of the three categories namely psychosomatic disorders, dermatological conditions due to primary and secondary psychiatric disorders. Dermatological conditions resulting from psychiatric conditions like stress/depression and those caused by psychiatric disorders are discussed. This review intends to present the relationship between the 'skin' and the 'mind' specifically from the dermatology point of view. The effects on the quality of life as a result of psychodermatological conditions are highlighted. A multidisciplinary approach for treatment from both dermatologic and psychiatric viewpoints are suggested.

Keywords: *Liaison therapy, mind, psychodermatology, quality of life, stress*

Introduction

Skin has a special place in psychiatry with its responsiveness to emotional stimuli and ability to express emotions such as anger, fear, shame and frustration, and by providing self-esteem, the skin plays an important role in the socialization process, which continues from childhood to adulthood.^[1] The relationship between skin and the brain exists due to more than a fact, that the brain, as the

center of psychological functions, and the skin, have the same ectodermal origin and are affected by the same hormones and neurotransmitters.^[2] Psychodermatology describes an interaction between dermatology and psychiatry and psychology. The incidence of psychiatric disorders among dermatological patients is estimated at about 30 to 60%.^[3] Psychiatry is more focused on the 'internal' non-visible disease, and dermatology is focused on the 'external' visible disease. Connecting the two disciplines is a complex interplay between neuroendocrine and immune systems that has been described as the NICS, or the neuro-immuno-cutaneous system. The interaction between nervous system, skin and immunity has been explained by release of mediators from NICS.^[4] It has been reported that

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psychologic stress perturbs epidermal permeability barrier homeostasis, and it may act as precipitant for some inflammatory disorders like atopic dermatitis and psoriasis.^[5] Dermatologists have stressed the need for psychiatric consultation in general, and psychological factors may be of particular concern in chronic intractable dermatologic conditions, such as eczema, prurigo and psoriasis.^[6,7] Patients with psychocutaneous disorders frequently resist psychiatric referral, and the liaison among primary care physicians, psychiatrists and dermatologists can prove very useful in the management of these conditions. Thus consideration of psychiatric and psychosocial factors is important both for the management of psychodermatologic disorders and for some aspects of secondary and tertiary prevention of a wide range of dermatologic disorders.^[8] Regardless of psychiatric morbidity, skin diseases can greatly affect patients' quality of life.^[9] The drugs used in the treatment of dermatological diseases such as steroid and retinoid may lead to psychiatric symptoms.^[10] Not surprisingly, a relationship between psychological factors and skin diseases has long been hypothesized. There is a common opinion that many cases of skin disease are caused by psychological stress, or are related to certain personality traits, or represent a complication of a psychiatric disorder. Although the dermatologists awareness of the problem is increasing,^[11] co-occurring mental disorders go often unrecognized and are believed to be less frequent than they actually are in many skin conditions. There is a need for a biopsychosocial approach to patients with skin disease.^[12,13] Liaison therapy enables multidisciplinary approach with the cooperation of psychiatric and dermatologic terms and simultaneous diagnostic procedures and treatment of patients with psychodermatologic disorders.^[14]

Classification

Although there is no single universally accepted

classification system of psychocutaneous disorders and many of the conditions are overlapped into different categories, the most widely accepted system is that devised by Koo and Lee.

Psychodermatology is divided into three categories according to the relationship between skin diseases and mental disorders : 1) Psychophysiological (psychosomatic) disorders caused by skin diseases triggering different emotional states (stress), but not directly combined with mental disorders (psoriasis, eczema); 2) primary psychiatric disorders responsible for self-induced skin disorders (trichotillomania) and 3) secondary psychiatric disorders caused by disfiguring skin (of ichthyosis, acne conglobata, vitiligo), which can lead to states of fear, depression or suicidal thoughts.

Psychophysiological (Psychosomatic) disorders

Here psychiatric factors are instrumental in the etiology and course of skin conditions. The skin disease is not caused by stress but appears to be precipitated or exacerbated by stress.

Psoriasis

Psoriasis is a relatively common, chronic and inflammatory and hyperproliferative skin disease that occasionally requires systemic therapy. Stress has long been reported to trigger psoriasis. Psoriasis is associated with a variety of psychological difficulties, including poor self-esteem, sexual dysfunction, anxiety, depression and suicidal ideation. Psoriasis is associated with substantial impairment of health-related quality of life (HRQOL), negatively impacting psychological, vocational, social and physical functioning. The most common psychiatric symptoms attributed to psoriasis include disturbances in body image and impairment in social and occupational functioning. Quality of life may be severely affected by the chronicity and visibility of psoriasis as well as by the need for lifelong treatment. Five dimensions

of the stigma associated with psoriasis have been identified: (1) Anticipation of rejection, (2) feelings of being flawed, (3) sensitivity to the attitudes of society, (4) guilt and shame and (5) secretiveness. Depressive symptoms and suicidal ideation was frequently associated in psoriasis. In general, psychological factors, including perceived health, perceptions of stigmatization and depression are stronger determinants of disability in patients with psoriasis than are disease severity, location and duration. In a recent prospective study of patients with psoriasis, the frequency of psychiatric disturbance decreased with improvement in the clinical severity and symptoms of psoriasis. The emotional effects and functional impact of the disease are not necessarily proportionate to the clinical severity of psoriasis.

Atopic dermatitis

The onset or exacerbation of atopic dermatitis often follows stressful life events. Symptom severity has been attributed to interpersonal and family stress, and problems in psychosocial adjustment and low self-esteem have been frequently noted. Adults with atopic dermatitis are more anxious and depressed compared with clinical and healthy control groups. Children with atopic dermatitis have higher levels of emotional distress and more behavioral problems than healthy children or children with minor skin problems.

Psychosocial morbidity in atopic dermatitis

Psychological stress may be an acquired factor affecting the expression of atopic dermatitis.[35] Atopic individuals with emotional problems may develop a vicious cycle between anxiety/depression and dermatologic symptoms. In one direction, anxiety and depression are frequent consequences of the skin disorder. The misery of living with atopic dermatitis may have a profoundly negative effect on health-related quality of life (HRQOL) of children and their families. Teasing and bullying by children and

embarrassment by adults and children can cause social isolation and school avoidance. The social stigma of a visible skin disease, frequent visits to doctors and the need to constantly apply messy topical remedies all add to the burden of disease. Lifestyle restrictions in more severe cases can be significant, including limitations on clothing, staying with friends, owning pets, swimming or playing sports. The impairment of quality of life caused by childhood atopic dermatitis has been shown to be greater than or equal to that of asthma or diabetes.

Conclusions

Psychodermatologic disorders are conditions involving interaction between the mind and the skin. They fall into three categories; psychosomatic, primary psychiatric disorders and secondary psychiatric disorders. Atopic dermatitis, eczema, urticaria, psoriasis, herpes simplex, alopecia areata, rosacea, etc are regarded among dermatological psychosomatic disorders with psychogenic manifestation/exacerbation. It is suggested to use a biopsychological model, which takes into account the psychological (e.g. psychiatry comorbidity such as major depression and the impact of skin disorder on the psychological aspects of quality of life) and social (e.g. impact upon social and occupational functioning) factors, in addition to the primary dermatologic factors, in the management of the disease. The treatment of psychodermatological disorders should be carried out through the liaison therapy, which enables multidisciplinary approach, including family physician, dermatologist, psychiatrist and psychologist. It is very important to educate dermatologists in the diagnostic procedures and therapy of psychiatric disorders, which sometimes coexist with the skin disease. Majority of psychodermatological disorders can be treated with cognitive-behavioral psychotherapy, psychotherapeutic stress-and-anxiety-management techniques and psychotropic

drugs. Psychopharmacologic treatment includes anxiolytics, antidepressants, anti-psychotics and mood stabilizer. The cooperation of the dermatologist and a psychiatrist in order to increase the life quality of the patients is of utmost importance. A dermatologist's lack of knowledge on the psychiatric morbidity rates in dermatological diseases may delay the diagnosis of psychiatric condition and hinder the treatment, and hence establishment of separate psychodermatology units and multicenter research about the relationship of skin and psyche is necessary in the form of prospective case-controlled studies, and multisite therapeutic trials can provide more insight into this interesting and exciting field of medicine. The management of psychodermatologic disorders requires evaluation of the skin manifestation and the social, familial and occupational issues underlying the problem. Once the disorder has been diagnosed, management requires a dual approach, addressing both dermatologic and psychologic aspects. A mutual, respectful collaboration between dermatologists and mental health professionals might be of help for many psychiatric patients. Therefore, understanding of biopsychosocial approaches and liaison approach involving general practice, psychiatrist, dermatologist and psychologist treatment in this field is essential.

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Conflict of Interest – Nil

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Late Allograft Rejection: A Case Report

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Abstract

Recognition of donor antigens by recipient T cells in secondary lymphoid organs initiates the adaptive inflammatory immune response leading to the rejection of allogeneic transplants. We present a unique case of a 38-year-old male with late allograft rejection due to immunosuppressive cytotoxic therapy. There is limited literature available as well as management. This case highlights the need for further investigative research of this entity and its pathogenesis.

Keywords : immune response, cytotoxic therapy, immunosuppressive, allograft rejection

Introduction

Allorecognition relates to the detection of genetically encoded polymorphisms between individual organisms of the same species by the immune system. Allorecognition has been described in nearly all multicellular phyla, including invertebrates that are devoid of an adaptive immune system⁽¹⁾. Indeed, certain cells of the innate immune system such as NK cells and macrophages are capable of self–non-self discrimination^(2, 3). In vertebrates, the adaptive immune response to allogeneic cells is initiated through recognition of polymorphic proteins by T lymphocytes through their antigen receptors. Subsequent activation of pro-inflammatory allospecific T cells initiates a cascade of reactions leading to rejection of transplanted allogeneic tissues and organs. Alternatively, under particular circumstances, deletion or inhibition of alloreactive

effector T cells can result in allograft acceptance or tolerance^(4, 5). Seminal studies in skin-grafted rodents support the view that early after transplantation intra-graft dendritic cells (DCs) (passenger leukocytes) migrate through lymphatics to host regional lymph nodes (LNs)^(6, 7). Naïve T cells located in these LNs become activated through recognition of allogeneic MHC molecules displayed on these donor passenger leukocytes⁽⁸⁾.

Case Report

A 38-year-old male presented with fever since eight days, cough since 3 days, shortness of breath since 2 days with history of covid pneumonia, sepsis, CKD, HTN, post LRRT status 7 years back being father as donor and had taken tacrolimus 0.1 mg/kg modified as per levels as well as clinical course along with steroids prednisolone 40 mg/ dose decreased to 2.5 mg / day to 20 mg per day along with mycophenolate mofetil 500 mg 2 tab twice a day along with antihypertensives as well as antibiotics postoperatively and continued this immunosuppressive treatment and postoperatively serum creatinine was corrected around 1.3 mg/dl.

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But after 7 years patient presented with fever having serum creatinine levels of 4 mg/dl which raised to 7.7 mg/dl in 2 weeks and started on injection solumedrol 500 mg three doses were given and discharged on tab tacrograf 2mg , tab renodapt 500 mg and prednisolone 20mg.

After 9 months from last discharged patient presented with fever, covid pneumonia as well as deranged creatinine levels Examination was notable for decreased breath sounds and went through usg guided left kidney biopsy revealing grade 2 IFTA , grade 1 chronic active T-cell mediated rejection and usg revealed bilateral medical kidney disease. The patient was treated with injection remdesivir and discharged on conservative treatment of feropenem . linzolid, steroid , antihypertensive, and levera. The patient was stabilized and strict follow up for dialysis advised, his renal function improved and discharged.

Discussion

Allograft tolerance, defined as long-term survival of allogeneic transplants in the absence of ongoing immunosuppressive drug treatment, can occur *via* deletion or inhibition of alloreactive T cells. This process can occur naturally, as seen in the tolerance of paternal alloantigens expressed by the fetus during pregnancy . In addition, immune-privileged tissues such as the central nervous system and the testis are tolerogenic in that they elicit systemic tolerance to foreign antigens to which they are exposed . Various cells and mediators of the innate and adaptive immune systems have been implicated in the process of allograft tolerance . Among them, regulatory T cells (Tregs) play an essential role by suppressing inflammatory responses . Tregs are CD4⁺CD25^{high} T lymphocytes expressing FoxP3 transcription factor either constitutively (thymic Tregs or tTregs) or after peripheral recognition of antigens (peripheral Tregs or pTregs) . In addition to their role in self-antigen tolerance, both Treg subsets can suppress inflammatory

alloreactive T cells *in vitro* and *in vivo*. They inhibit alloreactivity in MLR *in vitro* and are thought to mediate transplant tolerance elicited *via* leukocyte costimulation blockade, donor-specific transfusion . This is supported by experiments in which inoculation of Tregs from tolerant mice to naïve mice could prolong allograft survival and even transfer tolerance Although activation of pTregs may be antigen specific, it is not clear whether their suppressive function follows the same rules. Therefore, both Treg subsets involved in allograft tolerance are presumably activated through recognition of peptides presented by self-MHC class II on recipient APCs, i.e., in an indirect fashion. However, the mechanisms by which they suppress alloreactive T cells and induce and/or maintain allograft tolerance are still unknown.

Conclusions

It is now firmly established that the mechanisms by which T cell recognize and respond to alloantigens greatly vary upon the nature of the transplanted organ or tissue, the site of anatomical placement, and the immunological status of the host. This explains why certain transplants, such as skin allografts, which induce potent inflammatory responses by both CD4⁺ and CD8⁺, activated directly and indirectly, are highly immunogenic and thereby resistant to tolerance induction. In contrast, corneal allografts that elicit only indirect alloresponses by CD4⁺ T cells are tolerogenic and often spontaneously accepted. On the other hand, early acute rejection of solid organ allografts such as hearts and kidneys is mediated essentially by T cells activated directly. While this immune response results in a potent inflammatory reaction, it is readily inhibited by calcineurin inhibitors. This explains why these drugs have been effective at achieving prolonged survival of organ allografts in patients. These treatments do not, however, efficiently suppress alloreactive memory T cells, thus precluding transplantation in patients sensitized to their potential

donors (10% of patients). Most importantly, many transplanted organs are progressively lost due to chronic rejection, a process presumably initiated by indirectly activated T cells and subsequent production of cytotoxic anti-donor antibodies. For reasons that are still unclear, this response is not always efficiently suppressed by current immunosuppressive drugs. Therefore, future challenges in clinical transplantation will be to suppress or eliminate allospecific memory T cells and to prevent the development of indirect alloresponses.

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Conflict of Interest – Nil

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Assessment of Services at Primary Health Center of Jaipur District as Per Indian Public Health Standards

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Abstract

Background: These standards are to underpin the delivery of quality services which are fair and responsive to client's needs, which should be provided equitably and which deliver improvements in the health and well-being of the population. **Aim and Objectives:** to identify the existing gap with respect to Indian Public Health Standards (IPHS) for availability of infrastructure, human resources, investigative services and emergency services at 24 × 7 primary health centers (PHCs) of Jaipur district of Rajasthan state. **Methods:** It is a cross-sectional quantitative study was conducted from March 2018 – March 2019 in Jaipur district of Rajasthan state. Jaipur is divided into 7 blocks, 73 PHC and 18 CHC. Out of these 7 blocks 3 blocks were selected by simple random sampling. From these 3 blocks 3 PHC from each block was selected by simple random sampling. 3 sub center from each PHC was selected by simple random sampling and then 30 households were selected from each Sub-centre by systematic random sampling. **Results:** In terms of staff availability found critical status, Essential services were adequate, but not at all PHCs, Infrastructure and facilities was satisfactory. **Conclusion:** Even after more than a decade of Indian Public Health Standards (IPHS) in place for the Public Health Facilities this study reveals a huge gap in the availability of the manpower (Medical, Para medical and support manpower), Services, Drugs, equipment, infrastructure and Quality control measures.

Keywords: Infrastructure, Manpower, Standards, Quality

Background

Health is a state of complete physical, mental and social well-being and not merely the absence of

disease or infirmity (WHO). Health is thus vital for contemporary and whole development for individual and community and socio economic development of whole country. Public health is the science and art of promoting health, preventing disease and prolonging life through the organized efforts of society (WHO). It is a political and social concept aimed at improving health, prolonging life and quality of life among population through disease prevention, health promotion and other health intervention. Under article 42 Indian constitution states, state shall regard raising

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level of nutrition, standard of living among its people and improvement of public health among its primary duties. Under article 42 it is considered that state shall make provision for just and humane conditions of work and for maternity relief. After independence government has formed various committees the recommendations of which have been used for the betterment of public health scenario in India. Even after 60 years of independence the health expenditure by the state is still just a miniscule proportion of GDP [1]. In India, PHCs are the cornerstone of rural health services – A first port of call to a qualified doctor of the public sector in rural areas for the sick and those who directly report or referred from subcenters (by health workers) for preventive, promotive, and curative health care. It acts as a referral unit for subcenters and refers out cases to community health centers (CHCs) and district hospitals.[2] The CHCs which constitute the secondary level of health care were designed to provide referral as well as specialist health care to the rural population. These centers are however fulfilling the tasks entrusted to them only to a limited extent.[3],[4] The Government of India recognized the importance of health in the economic and social development and improving the quality of life of our citizens, and launched the National Rural Health Mission (NRHM) on April, 12th 2005 to carry out necessary architectural correction in the basic health-care delivery system.[5],[6] The Mission covers the entire country with special focus on 18 states, where the indicators of health are below the acceptable level which include Himachal Pradesh.[7],[8],[9] Standards are a means of describing the level of quality that health-care organizations are expected to meet or aspire to. Key aim of these standards is to underpin the delivery of quality services which are fair and responsive to client's needs, which should be provided equitably and which deliver improvements in the health and well-being of the population. Standards are the main driver for continuous improvements in quality.[2]

Objectives:

The main objective of the present study is to identify the existing gap with respect to Indian Public Health Standards (IPHS) for availability of infrastructure, human resources, investigative services and emergency services at 24 × 7 primary health centers (PHCs) of Jaipur district of Rajasthan state.

Material and Methods

It is a cross-sectional quantitative study was conducted from March 2018 – March 2019 in Jaipur district of Rajasthan state. For the purpose of better health administration, Jaipur is divided into 7 blocks, 73 PHC and 18 CHC. Out of these 7 blocks 3 blocks were selected by simple random sampling. From these 3 blocks 3 PHC from each block was selected by simple random sampling. 3 sub center from each PHC was selected by simple random sampling and then 30 households were selected from each Sub-centre by systematic random sampling. The availability of staff was checked according to the IPHS standards and interview of staff as well as household was conducted using a structured questionnaire.

Results

Staff availability

Availability of medical officers as well as Ayush doctor is present in all selected PHC.

In case of Accountant/ Clerk cum Data entry operator only 5 PHCs had it. Pharmacist seat was vacant only in one PHC. Health worker male and female, Multi skilled worker were also less in number in all PHCs. 2 LHV seat were vacant in two PHCs. Laboratory technician were present only in four PHC. Sanitary workers were present in three PHCs only.

Essential services

ANC, PNC, new-born care, immunization,

management of RTI, facilities under JSY and family planning are available all PHC. MTP services are not provided in any of the PHC. AEFI reported in all the PHCs. Supervision found too poor in majority of the PHCs. Routine blood, urine and stool examination and blood grouping was available in all nine PHCs.

Sputum examination, BT/CT and rapid test for syphilis were done in only one PHCs. Blood smear examination for MP parasites, rapid test of pregnancy and rapid test for HIV were done in all PHCs. Diagnosis of RTI/STDs with wet mounting, grams stain was not done in any PHC. None of the PHC had the entire drug available according to the EDL.

Infrastructure and facilities

Only five PHC out of nine was not found at the correct location. Out of nine PHC only five had own designated government building. Only five PHC were found in full construction stage. Only six PHC had fully compound wall. General cleanliness was

not found in any of the PHC except one. Boundary wall with gate existed in two PHCs. Display boards regarding service availability in local language was found in seven PHC only. Registration counter was present in all PHCs. Separate public utilities were found in only three PHC. Suggestion box was not found in any PHC. OPD rooms were available in all PHCs except one. Family welfare clinic was present in four PHC. Waiting room was present in three PHC. Emergency room was not found in any of the PHCs. There were no separate wards for male and females in any of the PHC. Operation theatre was not found in any PHC. Labour room was found in all PHCs only. Nurses rest room and overhead tank and pump were not found in any PHCs. In two PHCs laundry facilities was not available and in Seven PHCs it was outsourced. Communication facilities were present in all PHC. Ambulance was available in all PHC. Store room was present in five PHC. Kitchen was not available in any PHC.

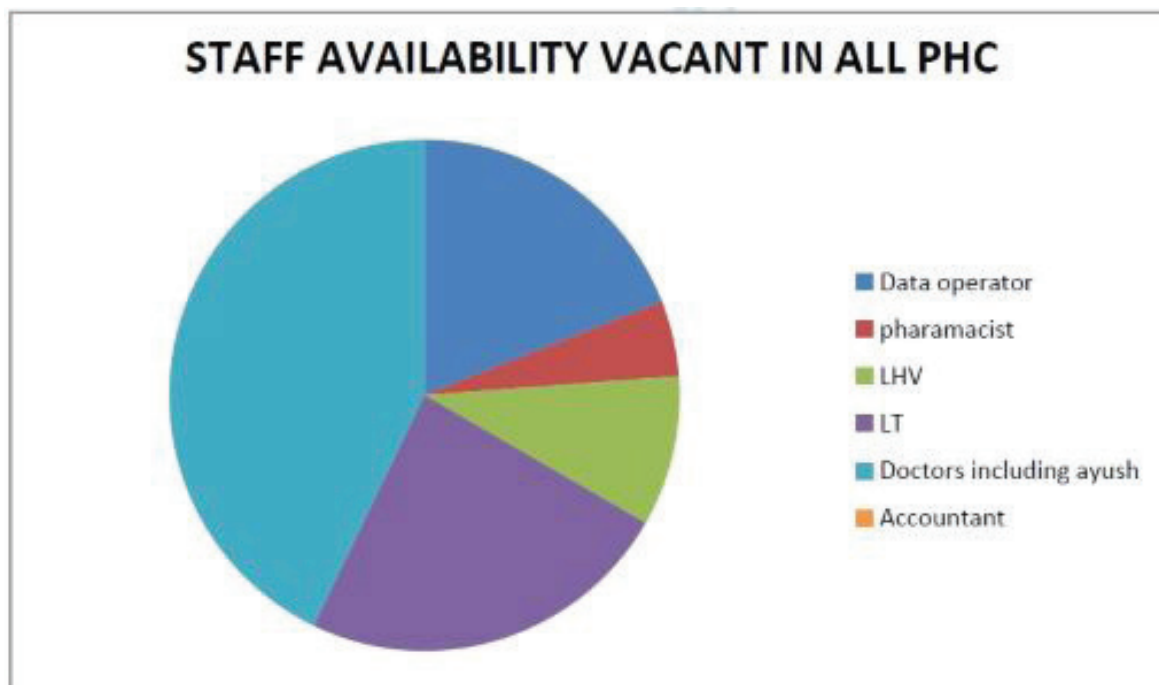


Figure 1:

Figure 2 :

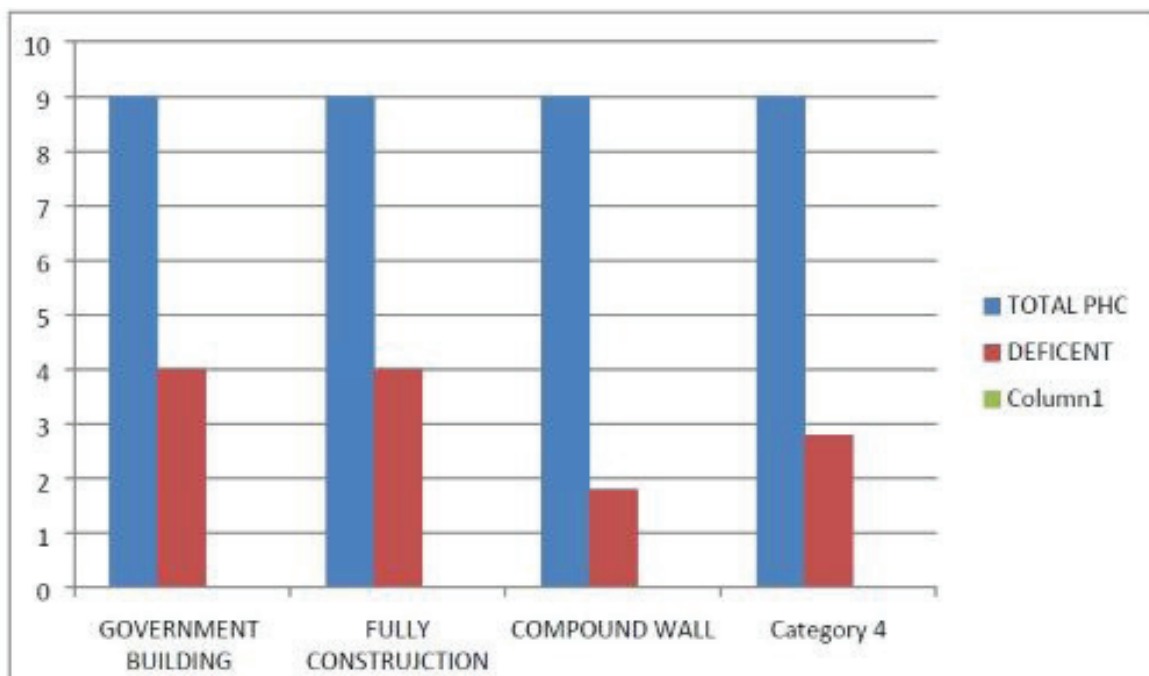
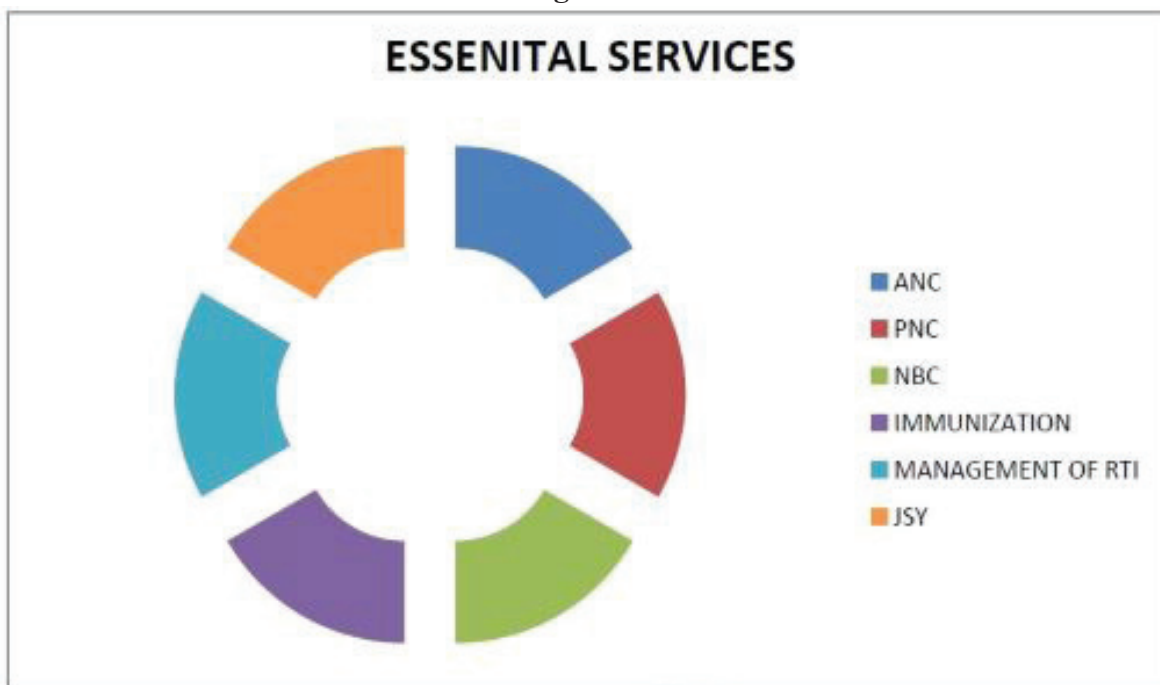


Figure 3: Infrastructure and facilities

Discussion

The study shows that doctors are posted at all PHCs of the selected blocks of Jaipur district, which were included in the study, but paramedical staff was deficient, in the PHCs. A study conducted in

Gujarat showed that the post of Medical Officer was filled in 80% PHCs whereas in 20% PHCs the post was vacant.^[10] In a study conducted in Riyadh, Saudi Arabia (1996), it was found that the staff was 100% complete for physicians, nurses, and clerks only as per standard no for each center, which was similar to

this study. Centers did not meet requirements from the Ministry of Health for technicians, pharmacists, health workers, social workers, and health inspectors.^[11] Findings of the Programme Evaluation Organization study stated that the adequacy of doctors against their sanctioned posts seems to be encouraging, as 75% of doctors are in a position in assisted PHCs, whereas 96% of them are found in a position in non-assisted PHCs.^[12] The focus of the government seems to be on posting doctors in the rural areas, but the paramedical staff is not being posted to the same extent. The absence of paramedical staff makes it very difficult for the doctors to work in rural areas and it also dents their morale as they do not have support. The focus should be on posting all kind of staff, i.e., laboratory technicians, health workers, health supervisors, staff nurses also along with the doctors in CHCs and PHCs. This will not only support the doctors but also will motivate them to work better. Residential accommodation for the doctors and other staff is provided by majority of the CHCs and only two PHCs. A report on the study conducted in subcenters, PHCs and CHCs revealed that residential accommodation for health staff at all levels seems to be a problem. It is either not available, or if available, it is not conducive for habitation or it is located in an isolated area.^[13] Residential facilities for staff (Medical Officers, pharmacists, and nurses) were lacking in a study conducted by Akhtar in Empowered Action Group (EAG) and non-EAG states.^[14] This could be due to the lack of capital investment for strengthening health services. Provision of proper accommodation will not only encourage the staff to stay at the center, but it would also be an important step for the provision of 24-hour emergency services. The provision of 24-h delivery services at PHCs is an important component under the IPHS. This can improve by posting the recommended paramedical staff along with the doctors at the PHCs. As JananiSurakshaYojna has shown that provision of incentives to the patient has

improved the institutional deliveries, incentives should also be given to the provider of delivery services. The study revealed that laboratory is present in all PHCs but it was properly functional in only five PHCs. Laboratory is there in all PHCs. OT is not present in any PHCs. A report on the study conducted in subcenters, PHCs, and CHCs revealed that while half of the sampled PHCs have labour rooms and laboratory facilities, only one-third have OTs.^[13] In a critical review conducted by Ray in West Bengal, it was found that out of 10 PHCs studied there were separate OTs in eight PHCs. However, there was major shortage of equipments.^[15]

Conclusion

Health is something that should be provided to every person irrespective of the ability to pay for it as health is a state subject. The majority of the population in India lives in the rural areas. They do not get access to most basic health services. After the launch of NRHM there were some major changes brought in the rural areas to address the pathetic health conditions of the rural people. Even after more than a decade of NRHM and Indian Public Health Standards (IPHS) in place for the Public Health Facilities this study reveals a huge gap in the availability of the manpower (Medical, Para medical and support manpower), Services, Drugs, equipment, infrastructure and Quality control measures. The concept of quality in health care is essential to the subject of providing services to the rural people at the PHC. The fact that services required in rural area are basic services and do not require for high technical excellence. So it is being labelled as sub-standard service. This needs rigorous scrutiny so that marginalized people have access to good quality health care. There should be more transparency in the system and community participation should be apart of the planning process. Planning should be based on the needs of the people and not according to the needs of the donors.

Recommendations

To ensure the availability, adequacy, and functionality of health infrastructural facilities including the medical and paramedical staff in PHCs, there is an urgent need to emphasize the systemic mechanism of supervision, monitoring, and review of the functioning of primary health-care institutions. This will not only help improve the quality of health delivery system but also ensure optimum use of public resources. Another approach which can be tried on a pilot basis is outsourcing of primary health care in a particular area to an NGO. This method of public-private partnership can be very useful in improving primary health care at rural level.

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Effect of Buerger Allen Exercise on Lower Limb Tissue Perfusion among Patients with Type 2 Diabetes Mellitus

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Abstract

Background: Diabetes mellitus is one of the leading causes of death and disability worldwide. It can lead to both macro and microvascular complications. Peripheral artery disease which is slow and progressive in nature is one of the microvascular complications of diabetes mellitus. It is recognised that the collateral blood flow to the legs and the heart can be restored through regular lower limb exercises. The current study aimed to evaluate the effect of Buerger Allen exercise on lower limb tissue perfusion among patients with type 2 diabetes mellitus.

Materials & Methods: A facility based pre-test and post-test comparison group design was adopted to evaluate the lower limb tissue perfusion using Ankle-Brachial Pressure Index from sixty type 2 diabetes mellitus patients who attended the non-communicable disease clinic of a primary health centre. The samples were recruited using purposive sampling.

Results: The post-interventional mean score level of the ABPI score was statistically significant with a t value of 4.580 at p 0.05.

Conclusion: Buerger Allen exercise was found to improve the lower limb tissue perfusion among type 2 diabetes mellitus patients.

Keywords: Buerger Allen exercise, lower limb tissue perfusion, ABPI score, type 2 diabetes mellitus

Introduction

Diabetes mellitus [DM] is recognised as one of the prime non-communicable diseases [NCD]

as well as the leading cause of death and disability worldwide. In 2019, 463 million people had diabetes; 88 million people in the Southeast Asia region were diabetic, of which 77 million belonged to India [1]. By 2045, about 123 million people in India and 700 million people in the world will be affected by DM [2]. Diabetes can lead to both microvascular and macrovascular complications, resulting in organ and tissue damage [3]. The differentiation between the pathogenic mechanisms of micro-vascular and macro-vascular complications of diabetes and the varied responses to therapeutic interventions is blurry [4].

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Diabetes Mellitus is a significant risk factor for peripheral arterial disease (PAD), which is an atherosclerotic occlusive disease affecting the lower extremities. Patients with PAD have an increased risk of MI, stroke, and death [5]. The risk of PAD is 3–4 times higher in patients with type 2 diabetes mellitus (T2DM) compared to those without DM [6]. Most cases of PAD are asymptomatic and may lead to significant disability and limb loss [7]. PAD can be detected using the ankle-brachial pressure index [ABPI], which is a non-invasive test [8,9].

Buerger Allen Exercise (BAE) is an active postural exercise that promotes collateral circulation in the lower extremities [10]. But its’ application to managing patients with diabetes foot is very rare [11].

The current study was to evaluate the effect of Buerger Allen exercise on lower limb tissue perfusion.

Materials and Methods

A pre-test post-test comparison group design was adopted in the study among 60 T2DM patients of the

age group 30–60 years with a disease duration of 5 years and an ABPI score of 0.81–0.9 and who attended the non-communicable disease clinic in a primary health care setting in Kerala. The samples recruited were assigned to experimental and comparison groups in equal numbers (30 each in groups). Those with critical illness, foot ulcers and gangrene, and those on treatment for deep vein thrombosis were excluded from the study. The basic data of the samples, which included age, gender, educational status, food pattern, types of activity, duration of illness, BMI, smoking habit, and presence of chronic co-morbidity, were obtained through a structured questionnaire and recorded. ABPI was measured using a calibrated sphygmomanometer in both the groups before intervention, and its score was calculated using the equation:

Ankle/Brachial: The highest systolic reading in the ankle (mmHg)/The highest systolic reading in the arm (mmHg)

The ABPI score is interpreted as below.

Resting ABPI	Severity of PAD
>1.3	Calcification/Monckeberg’s sclerosis may be suspected
>0.9	No PAD
0.81-0.9	Mild PAD
0.5-0.80	Moderate PAD
<0.5	Severe PAD
<0.4	Critical limb ischemia

(courtesy: Guttormsen& Smith,2016)[12]

Fig.1 explains Buerger Allen exercise, an active three-step postural exercise, which includes elevation, dependency, and horizontal positioning of lower limbs

for a total of 15 minutes. It was administered to the experimental group four times a day for two weeks.

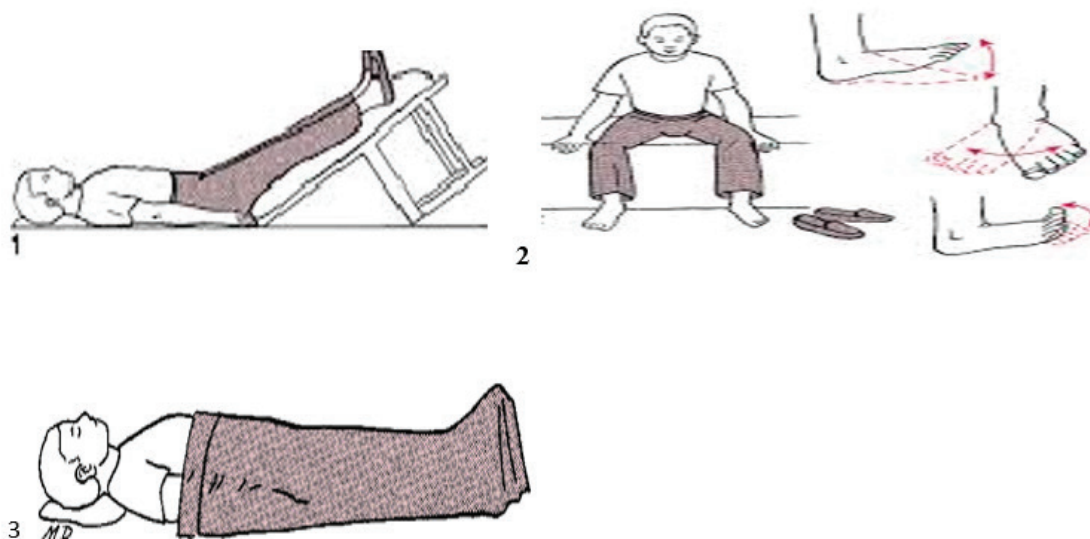


Fig.1.Steps of Buerger Allen Exercise (source: Black and Matassarini-Jacobs, 1997)

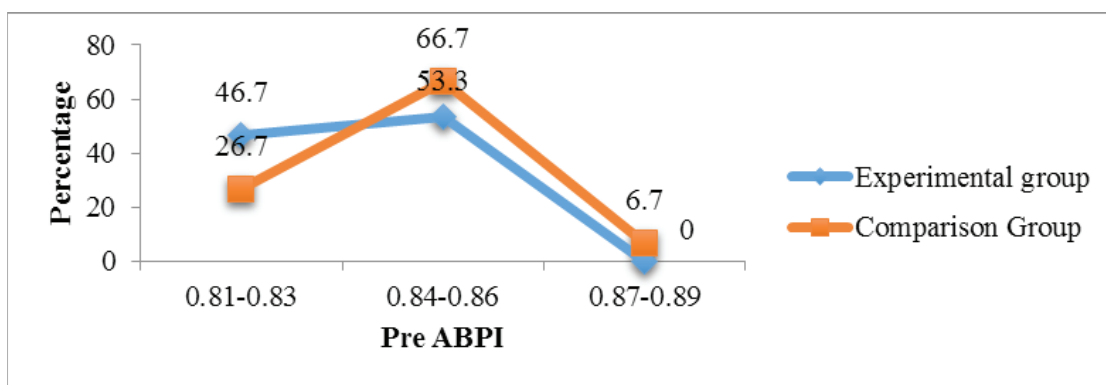


Fig. 2: Percentage distribution of study participants based on pre interventional ABPI score.

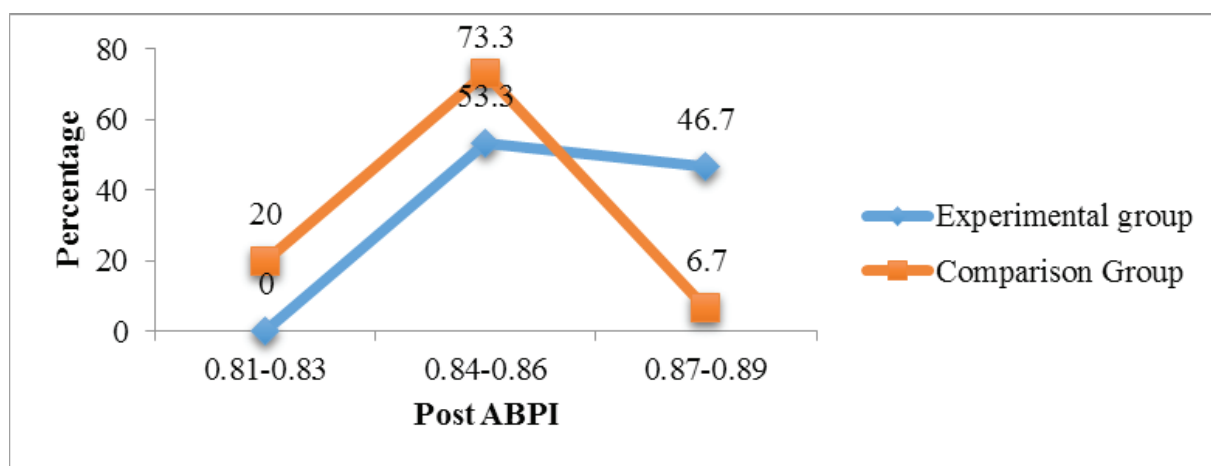


Fig. 3: Percentage distribution of study participants based on post intervention ABPI score.

1. In the first step, the lower extremities were elevated to a 45-90 degree angle and supported in the same position for 5 minutes until the skin became pale.

2. In the second step, the patients were made to sit in a relaxed position with their feet and legs rested below the level of the remaining parts of their body and performed individual foot flexion/extension and then pronation/supination for 5 minutes until redness appeared.

3. The third step was horizontal positioning, and the patient was asked to lie down quietly for 5 minutes with both their legs rested on the bed .

The experimental group was regularly monitored throughout the study period. ABPI was measured after four weeks of intervention in the samples.

Results

Participants' sociodemographic and clinical profiles

Table 1 shows the background variables of the participants of the study. The majority of the respondents in both the experimental (76.7%) and comparison group (66.7%) were in the age group of 56–60 years. Males out rated females in both the groups (63.3% of participants in the experimental group and 66.7% in the comparison group). 73.3 % of study participants in the experimental group and 90.0 % of the comparison group had primary education. 83.3 % in the experimental group and 73.3 % in the comparison group consumed non-vegetarian diets. The majority of participants (56.7% in the experimental group and 60% in the comparison group) were sedentary workers.

Table 2 The clinical variables of the study participants when analysed revealed that 96.7% of the study participants in the experimental group and 100.0% in the comparison group reported having T2DM for more than five years. The majority of study participants in both the groups (63.3% and 70%) had normal BMI. 46.7% in the experimental group and 60% in the comparison group did not have the habit of smoking, whereas 36.7% in the experimental group and 33.3% in the comparison group were ex-smokers. Hypertension was the most commonly reported co-morbidity among the study participants in both groups (63.3% & 73.3%)

Percentage distribution of participants based on pre and post-interventional scores of ABPI

Analysis of the percentage distribution of participants based on the pre-interventional score of ABPI (Fig.2) shows that 46.7% and 53.3% of T2DM patients in the experimental group had an ABPI score of 0.81-0.83 and 0.84-0.86, respectively, whereas in the comparison group, 26.7% and 66.7% had the same score. 6.7% of the comparison group had an ABPI score of 0.87-0.89

When the post-interventional ABPI score was examined, it was discovered that 53.3% and 46.7% of participants in the experimental group had ABPI scores of 0.84-0.86 and 0.87–0.89, respectively. 20.1% and 73.3% of the participants in the comparison group had an ABPI score of 0.81-0.83 and 0.84-0.86, respectively; 6.7% of the comparison group had an ABPI score of 0.87-0.89 after the intervention.(Fig 3)

Comparison of pre and post interventional level of ABPI score among the study participants

Table 1: Comparison of the pre and post interventional level of ABPI score among the study participants

Groups	observation	Mean	SD	t value	p value
Experimental group	Pretest	0.8403	0.01608	20.149	0.000**
	Posttest	0.8667	0.01900		
Comparison group	Pretest	0.8473	0.01484	-1.439	0.161
	Post test	0.8470	0.01535		

The paired “t” test analysis reveals a significant difference in the experiment group’s pre and post interventional mean ABPI score (t = 20.149, p = 0.000) at p 0.05.

Table 2. Comparison of post interventional level of ABPI score between the study participants

Groups	‘t’ value	p value
Experimental Group	4.580	0.000** S
Comparison Group		

A significant difference in the post-interventional level of ankle brachial pressure index (ABPI) score between the study groups (t = 4.580, p = 0.0001) was noticed using the unpaired “t” test.

Further chi-square analysis identified that there was no association between the post-interventional level of ABPI score of the study participants and any of their socio-demographic or clinical variables.

Discussion

The study assessed the effect of Allen Buerger exercise on lower limb perfusion in T2DM patients. The result revealed that 46.7% and 53.3% of T2DM patients in the experimental group had an ABPI score of 0.81-0.83 and 0.84-0.86, respectively, before the Buerger Allen exercise. After intervention, 53.3% and 46.7% of study participants had an ABPI score of

0.84-0.86 and 0.87-0.89, respectively.

In the comparison group, 26.7%, 66.7%, and 6.7% had an ABPI score of 0.81-0.83, 0.84-0.86, and 0.87-0.89, respectively, before the exercise. Their post-interventional score shows that 20%, 73.3%, and 6.7% had ABPI scores of 0.81-0.83, 0.84-0.86, and 0.87-0.89, respectively.

A significant difference in the level of ankle brachial pressure index (ABPI) score between the study groups was identified in the post interventional period (t = 4.580, p = 0.000), which explains that Buerger Allen exercise improved the lower limb perfusion in the experimental group. The above finding is supported by a similar study conducted among clients with diabetes mellitus admitted to selected hospitals in Tamilnadu, which also showed a significant improvement in the level of lower limb

perfusion in the experimental group after Buerger Allen exercise [13]. The findings of another hospital-based study conducted in Haryana also showed an improvement in lower limb tissue perfusion among T2 DM patients who had undergone the intervention [14].

Conclusion

From the present study, it is concluded that Buerger Allen exercise is effective in improving the peripheral circulation of the lower extremities among patients with type 2 diabetes mellitus. It is a non-invasive as well as cost-effective means of detecting PAD in patients with diabetic mellitus and even preventing complications of the foot. As it is rarely applied in clinical care, awareness regarding the same among nurses may improve the care rendered to patients in preventing peripheral arterial diseases. However, more studies can be replicated in building up evidence for best practices.

Conflict of Interest: The authors have no conflicts of interest.

Source of Funding: It was a self-funded study.

Ethical Consideration: A written initial approval was obtained from the institutional ethical committee and study setting. Written informed consent was obtained from each patient after explaining the nature and purpose of the study. Patients were informed that participation in the study was entirely voluntary and they could unconditionally withdraw from the study at any time. Anonymity and confidentiality of the data were also assured

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Know Case of Hyperthyroidism with Newly Diagnosed Adult Onset Still's Disease

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Abstract

To our knowledge, the possible unveiled interaction between adult-onset Still's disease (AOSD) with autoimmune thyroid disease (AITD) has never been reported although it is well established that systemic autoimmune disease may usually occur in relation to AITD. As increasingly clear links of AITD with other autoimmune disease such as systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), and primary Sjögren's syndrome (pSS) have been reported, and the incidence of AOSD concurrent AITD draws our attention rapidly. In this study, we searched relevant literatures published in the past 30 years to explore that condition.

Keywords: *Adult-onset Still's disease, thyroid disease.*

Introduction

Adult-onset Still's disease (AOSD) is a rare systemic autoimmune syndrome of unclear etiology. In 1971, fourteen adults with arthritis and systemic symptoms in accordance with the features of juvenile rheumatoid arthritis or Still's disease were described by Bywaters. From then on, AOSD was regarded as a different disorder gradually by us [1], which was characterized by spiking fever, pruritic or nonpruritic evanescent rash, arthritis, pharyngitis, leucocytosis and lymphadenopathy, and less frequently, hepatitis and polyserositis [2]. There is no single diagnostic test for AOSD and it is mostly based on clinical and laboratory criteria with the exclusion of other autoimmune diseases, neoplasms and infection. With

several diagnostic criteria developed over the years, Yamaguchi's criteria has been the most widely used as a result of higher sensitivity (96.2%) and specificity (92.1%) [3]. Thyroid disease of autoimmune origin is a frequent condition affecting 1% to 5% of general population, especially mostly seen in women of their third to fifth decades. Autoimmune thyroid disease (AITD), usually includes Graves' disease (GD) and Hashimoto's thyroiditis (HT), which are the most common reasons for thyroid disorders. An interplay among some conditions such as immune mechanism, environmental (for example, infection, iodine and stress), genetic and constitutional factors contributes to the mechanism of AITD. GD, the most common cause of thyrotoxicosis, is more prone to a family history with thyroid disease, especially with GD. GD can be incited by the combination of autoantibodies with TSH receptor which is activated then to stimulate thyrocyte growth and function.

Case

A 23-year-old male patient without evident disease previously presented to our hospital with a 2

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years of intermittent wandering arthralgia on the left side, and also with spiking fever (the highest body temperature up to 103°F), thoracalgia, sputum rashes over chest and upper back for 3 months. According to the examinations of the local hospital, X ray of the chest showed left sided pleural effusion leading to oppressive lung parenchyma; mild inflammatory infiltration of both lungs; and swelling lymph nodes on the right cardiophrenic angle. Distinctive laboratory findings, easily played a role in establishing the following diagnoses: chronic symmetrical inflammatory polyarthritis with appendicular involvement and no axial involvement with systemic manifestation of fever, anemia, hepatomegaly, lymphadenopathy and hyperthyroidism. On physical examination, he appeared irritable, general fatigue and underweight. And palpable lymph nodes at bilateral inguinal region and supraclavicular fossa were also found. According to the laboratorial results of the local and our hospital, hyperthyroidism was diagnosed. An abdominal ultrasound revealed normal study. Thyroid ultrasonography revealed heterogeneous in echogenic distribution and rich blood perfusion. According to the laboratory results, imaging studies, necessary exclusion and Yamaguchi *et al.* criteria, this case fulfilled the 1, 2 and 4 items of major criteria and 2 and 4 items of minor criteria. AOSD was therefore diagnosed.



Figure : Showing rashes over limb

Discussion

As far as we know, the association between thyroid disorders and AOSD has never been reported. Nonetheless, the association of AITD with rheumatoid arthritis, systemic lupus erythematosus, Sjögren's syndrome and Myasthenia gravis has usually been reported [4-6]. And the systemic autoimmune disease related to AITD has been widely known. Moreover, AOSD is considered as a variant of rheumatoid arthritis, so the similar condition of thyroid disorders with AOSD may exist. In our study, coincidental link could not be ruled out.

In this case, the examination outside our hospital showed hyperthyroidism and anti-thyroid drugs were prescribed, which led to the normal FT3, FT4, TT3 and TT4 level and decreased TSH in our hospital. Therefore, the anti-thyroid drugs were discontinued. But the spiking thyroid hormone changes occurred during hospitalization. Two explanations might be correlated to this relapse. Firstly, methimazole was stopped and the recurrence happened; secondly, AOSD and thyroid gland might interact with each other. An early report by Chen *et al.* was similar to our case. In Chen's case, elevated thyroid hormone concentrations and a palpable goiter had not been observed prior to admission. Although hydroxychloroquine was prescribed, Graves' disease appeared on the ten-day hospitalization and during the course of the disease, the hyperthyroidism had been aggravated whenever AOSD was in active stage.

So far, only a few reports have discussed the coexistence of AOSD and thyroid disorders. Literature research revealed five relevant reports (one in Chinese, one in French and one in Japanese, and two in English). Among them, two studies disclosed AOSD and thyroid disorders were diagnosed simultaneously; two indicated AOSD which was found before thyroid dysfunctions; one did not provide more information. In addition, only two reports provided the definite

types of ITD but the remaining three studies had no information of detailed type of AITD and we also failed to obtain the type from the relevant antibodies level. As a result, from the three reports we only diagnosed hyperthyroidism or hypothyroidism. At present, we only believe the two diseases can interact with each other by their shared pathogenesis; however, the clear link between them fails to demonstrate the coexistence of AOSD and ITD is rarely published. With an eye to the limitation of this study, it would be better that when physicians diagnose their patients as one of the two, screen the another. Then we will have more chances to explore the correlation further and with the implementation of large-scale trials, it will be greatly advanced our understanding of the interplay and therapy.

Conclusions

In conclusion, coexistence of AOSD and ITD is so rarely published that the explicit relationship is hard to acquire, but we can believe they could interact with each other through their common pathogenesis. As more cases are reported, the hidden association will become clear. Polyserositis is very scarce in the manifestation of AOSD. When, we, physicians encounter this sign, it becomes necessary to screen the relevant laboratory and imaging abnormalities. Circumstances permitting, a thyroid gland screening is recommended, especially in female patients. Finally, it is reasonable to reconsider the various manifestations of AOSD.

Ethical Clearance- Taken from ethical committee of institution

Source of Funding- Self

Conflict of Interest – Nil

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Pleural Effusion in Limited Cutaneous Systemic Sclerosis : A Report

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Abstract

Systemic sclerosis (SSc) is a chronic autoimmune multisystem disorder characterized by endothelial dysfunction and fibroblast dysfunction, which results in progressive fibrosis of the skin and internal organs more frequently the lungs and gastro intestinal tract. Pulmonary involvement is common in the course of SSc, with Interstitial Lung Disease (ILD) and Pulmonary Arterial Hypertension (PAH) along with pleural effusion being the leading causes of death. Here we report, case of an elderly male patient presenting with cutaneous SSc with multiple uncommon pulmonary manifestations like ILD with right sided pleural effusion with hepatic cyst.

Keywords: Interstitial lung disease, Pulmonary arterial hypertension, Scleroderma, Usual interstitial pneumonia

Report

A 55-year-old male presented to the Department of Medicine, SGT Medical College and Hospital, with complaints of generalized swelling with myalgia since 2 months, stiffness and darkening of skin with rash since 15 days, cough with expectoration and progressive breathlessness since three months, difficulty in swallowing, and loss of appetite. On examination- Scleroderma involving both the upper limbs, face, trunk and lower limbs was present. Sclerodactyly of all fingers was present with salt and pepper appearance of skin over the scalp, forehead, upper back, chest, trunk and limbs (figure) and

bilateral basal crackles were present. Abdomen was soft and non-tender with hepatomegaly as well as splenomegaly. Routine lab investigations revealed- Hb of 9.1g%, total count- 10,000 cells/ cumm, platelets- 2.4 lac cells/ cumm, RBS- 147 mg/dl, LFT's, RFT's and serum electrolytes within normal limits. Chest X-Ray showed right reticulo-nodular opacities with basal predominance. Spirometry showed restrictive defect with an FEV1/ FVC of 88, FEV1= 70% and FVC= 60%. Two dimensional ECHO revealed normal chambers with LVEF 55%. CECT showed mild hepatomegaly with hepatic cyst with right pleural effusion with small retroperitoneal lymph nodes. Connective tissue profile was sent. ANA and Anti Scl-70 were positive, whereas RA factor, anti- RNP, anti-Sm, c-ANCA and p-ANCA were negative. Skin biopsy (right arm lesion)- Dermis showed homogenous appearing thickened collagen bundles, consistent with scleroderma.

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Figure: sclerodermal changes over limbs.

Discussion

Systemic Sclerosis (SSc) is a connective tissue disorder of unknown aetiology affecting arterioles, micro vessels and fibroblasts resulting in vascular obliteration, collagen accumulation, scarring (fibrosis) and abnormalities of immune system [1]. SSc is more commonly seen in middle aged females between 45-55 years of age. It's prevalence in Asia is between 20-50 million [2]. Lung involvement is common in course of the disease, with ILD and pleural effusion being most frequent. The other pulmonary manifestations are aspiration pneumonia, pleural effusion, spontaneous pneumothorax and malignancy [2]. SSc patients with ILD and pleural effusion have a 5 fold increase in mortality rate. The prevalence of SSc-ILD with PAH is 18-22% [3]. SSc-ILD usually presents with Non-specific interstitial pneumonia (NSIP) pattern, but diffuse SSc showing UIP pattern is uncommon with an incidence of only 11%. The occurrence of pleural effusions is also rare and has been reported in only 7% of the cases [4].

Depending on the degree and extent of skin involvement SSc can be classified as:

Limited cutaneous (Lc SSc): Skin thickening restricted to sites distal to the elbows and knees, but may involve face and neck.

CREST syndrome: Subset of limited cutaneous SSc with prominent calcinosis, Raynaud's phenomenon, esophageal dysmotility, sclerodactyly and telangiectasia.

Diffuse cutaneous (Dc SSc): Skin thickening over the trunk and proximal extremities in addition to distal extremities and face.

Overlap SSc: Skin changes and other characteristic features of SSc coexisting with features of another connective tissue disease, such as systemic lupus erythematosus, rheumatoid arthritis, dermatomyositis or Sjogren's syndrome.

SSc sine scleroderma: Characteristic internal organ complications like pulmonary fibrosis or renal, cardiac or gastrointestinal disease, but no apparent

skin involvement [5].

Criteria for classification of Systemic Sclerosis:

1980 Systemic Sclerosis (Scleroderma)

Classification Criteria: These criteria were established in 1980 by the American Rheumatism Association (now known as the American College of Rheumatology) [6].

Requirements: Either the sole major criterion or two or more of the minor criteria.

Major Criterion: Proximal scleroderma: Symmetrical thickening, tightening and induration of the skin of the fingers and the skin proximal to the metacarpophalangeal or metatarsophalangeal joints. These changes can involve the entire limb, face, neck and trunk.

Minor Criterion: Sclerodactyly: Induration and tightening of the skin of the fingers.

Digital ischemia: Manifested by digital pitting scars or atrophy of finger pads.

Bibasilar pulmonary fibrosis: Reticular or reticulonodular densities most pronounced in the basilar areas of the lungs on chest X-ray (CXR). This may produce the appearance of “honeycomb lung” and must not be due to a primary pulmonary disease.

But the 1980 ACR criteria were not sensitive enough to identify patients with early disease or limited cutaneous SSc. To address this issue, a newer classification criterion was developed in 2013 by the joint ACR-EULAR committee [Table/Fig-6]. Based on the newer criterion- Skin thickening of the fingers extending proximal to the metacarpophalangeal joints is sufficient for a patient to be classified as having scleroderma. If this is not present, seven other additive items are considered, with varying weights or scores for each. Patients with a total score of ≥ 9 are classified as having definite scleroderma [7].

Investigations in systemic sclerosis are pulmonary function test which shows restrictive pattern and high resolution computerised tomography (HRCT) – NSIP pattern is most common. However, a UIP pattern showing peripheral and basilar predominant reticulation and honeycombing without significant ground glass opacities, can also be seen, but is more common in patients with LcSSc [8]. Immunosuppressants are the main stay of treatment for SSc. Cyclophosphamide, Mycophenolate Mofetil, Corticosteroids (usually in combination with the above drugs) are the preferred drugs. Other therapies under investigation are Bosentan (Endothelin receptor antagonist), Imatanib (tyrosine kinase inhibitor), Rituximab (a monoclonal antibody directed against the CD20 antigen on the surface of B lymphocytes) and Stem cell transplant [9]. Lung transplantation is considered in very rare cases.

Conclusion

We have thus presented a case of cutaneous systemic sclerosis (cSSc) with multiple uncommon pulmonary manifestations like right sided pleural effusion. The diagnosis of systemic sclerosis may at times be difficult, due to the overlapping features with other connective tissue diseases. There is also increased risk of organ damage early in the course of the disease even when the patient is asymptomatic. Hence, timely diagnosis and management is of utmost importance.

Ethical Clearance- Taken from institutional committee

Source of Funding- Self

Conflict of Interest – Nil

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COVID-19- Effects on Primary Health Care Services in Urban Field Practice Area of KIMS, Hubballi –A Cross-Sectional Study

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Abstract

Background:- The nationwide lockdown due to COVID-19 pandemic has impacted the global population in drastic ways. It was a health emergency in health care services impeding a lot of other services specially primary health care services and issue of proper referral of patients for adequate care.

Methodology:- A cross-sectional study was conducted for duration of one month during August-September 2021 among 200 participants aged more than 18 years visiting Urban Primary Health Centre at Old Hubballi, selected by random convenient sampling. Data collected was entered in MS Excel and analyzed using SPSS version 25.

Results:- 72.5% respondents preferred PHC over government hospital or private clinics for their treatment. 15% respondents were not satisfied with the services provided in PHC due to COVID pandemic. The average number of OPD cases was reduced by 50% and routine immunization by 80% during lockdown. The routine laboratory investigations fell by 33% of the pre-COVID time.

Conclusions:- The country's primary health care system suffered a major setback in terms of its routine services like providing treatment, routine immunizations etc. as the concentration shifted to pandemic control. And now with time, as the country's health care system is recovering, the progress is slow.

Keywords: COVID-19, PHC (Primary Health Centre), Pandemic, Lockdown

Introduction

COVID 19 PANDEMIC CURRENT SITUATION:-

India has seen a sharp increase in COVID-19 cases in the past 3 months, i.e., April to June 2021. As of December 20, 2021-Coronavirus Cases: 34,746,838, Deaths: 477,554, Recovered: 34,187,017 were reported from 36 states/union territories¹. Along with the nationwide lockdown imposed to limit the transmission, India has increased its testing rate and

has markedly reinforced the health care sector to fight COVID-19. The first case of COVID-19 in India was reported on January 30, 2020. Subsequently, more cases came to the forefront in the month of March and there has been an increase in the number of cases since the latter half of April 2020. The cases came to control during latter half of the year 2020. But India was hit by another wave of COVID 19 during the month of April 2021, taking lives of lakhs of people.

PRIMARY HEALTH CARE

The primary health care has been defined by the Alma-Ata conference as an essential health care made universally accessible to individuals and acceptable to them, through their full participation and at a price the community and country can afford.

Before Alma – Ata declaration, PHC was regarded as synonyms with “basic health care”, “first contact case”, “easily accessible care”.²

Primary health care is also defined by the World Health Organization (WHO) as a whole-of-society approach to health and well-being that is focused on the needs and preferences of individuals, families, and communities. It is an integral part of country’s health system with the following essential components like education regarding the prevailing health problems and the methods of preventing and controlling them; proper nutrition and Promotion of food supply; adequate supply of safe water and basic sanitation to the people; Maternal and child health care services which includes family planning methods; Vaccination against major infectious diseases; prevention and control of locally endemic diseases like Malaria, Dengue etc. Adequate treatment of common diseases and injuries; and delivery of essential drugs. Equitable distribution, Community Participation, Intersectional coordination and appropriate technology are the basic principles of Primary health care².

In recent years, there has been an increase in the worldwide burden of emerging illnesses, as well as the occurrence of outbreaks. However, none of the outbreaks reached the same pandemic proportions as the Covid-19 disease. Pandemics are extensive outbreaks of infectious disease with high burden of morbidity and mortality over a wide geographic area and cause significant economic, social and political disruption.

The main reason for quick spread of these pandemics are globalization with increased global integration, travel, urbanization, and greater exploitation of natural environment. Pandemics have had major social and economic cost to humankind over times in history. The COVID-19 (Corona Virus Disease -19) pandemic, which is caused by the SARS Corona Virus-2 (SARS CoV-2), is the deadliest of all pandemics we have experienced in our lifetimes³.

The COVID-19 pandemic has impacted the global population drastically over the past few weeks. It is critical for people to approach the health-care services during the pandemic for both emergency and primary health care. A lot of patients who previously would have sought health advice have been hesitant to seek help from health-care professionals either because of anxiety about contracting COVID-19 disease or concern about unnecessarily taking up valuable professional time⁴.

Access to healthcare is a basic human right; yet, COVID-19 has had a significant impact on the delivery of primary healthcare services worldwide, affecting many people who seek these services. COVID-19 emerged as a health emergency that has additionally hindered provision of primary to tertiary health care services. The problem stems from a lack of continuity of care, which begins with prenatal care and continues with neonatal immunization, eventually leading to a lack of care for chronic noncommunicable diseases. During the COVID-19 lock down, routine health care services at the facility level, as well as correct referral, have been serious challenges for the health care system³. Hence this study was done with the following objectives:

1. To study about the Primary Health Care services during and after the COVID lockdown.
2. To determine the patient satisfaction with the services provided in the Primary Health Centre.

Methodology

A Community based, Cross sectional study was done for a period of one month from 19th Aug 2021 to 15th Sep 2021 at the Urban primary Health centre, Banatikatta, Old Hubballi. The study population were individuals above 18 years of age visiting the Urban Primary Health Centre. Exclusion criteria included people less than 18 years of age and those who are not willing to take part in the study. Convenient sampling technique was used to collect data and a sample of 200 was achieved. Institutional Ethical approval was taken. Consent was taken from the participants and confidentiality was maintained.

Study tools: - A semi-structured, pretested questionnaire was prepared. Pilot study was done on 10 participants and required modifications were done.

*It included questions related to patient satisfaction regarding OPD services in primary health centre during COVID 19 pandemic and lockdown.

Other information of the PHC services were asked from the participants. It consisted of 3 sections

- Section A: -Details on impact of COVID 19 on OPD services in PHC.

- Section B: -Details on impact of COVID 19 on lab investigation in PHC.

-Section C: -Details on impact of COVID 19 in immunization in PHC.

Data collection: - The information for patient satisfaction was collected by interviewing the individuals visiting UPHC and recorded their information in Google forms and information regarding the services provided at PHC was collected by interviewing the staffs (for e.g.:- Doctors, lab technicians, pharmacists etc.) and clerks and recorded their information in word document.

Data analysis: - The data was entered into Microsoft excel sheet, tabulated and analyzed using statistical programs for social sciences (SPSS) version 25 and represented in the form of tables and charts .

Statistical tests of significance was applied where required.

Results

Our study revealed the following -Among the 200 participants, 104 respondents are male and remaining 96 are female. 190 of them belong to urban area and 10 belong to rural area. Among 200 respondents, 145 preferred primary health centres, 27 preferred government hospitals and 28 preferred private hospitals to get their disease cured.

Patient satisfaction with the PHC services: Between the 200 participants, 170 were satisfied with PHC services given now and the remaining 30 respondents were not satisfied. 61 were satisfied with PHC services before COVID 19 pandemic and 103 were not satisfied and 36 respondents maybe satisfied. 167 of the study participants got enough time from the doctor in consultation and 9 respondents didn't get enough time and 24 of them felt they may have got enough time. 165 respondents got complete checkup in PHC and 158 of them got drugs prescribed to them in PHC. 70 were afraid to come to the PHC. 153 respondents got their tests ordered to them in PHC, 91 people felt that the PHC was understaffed during COVID 19 lockdown. (Table no 1)

Reason for being afraid to come to PHC-

Among 70 participants who were afraid to visit the PHC, 6 of them thought that the doctor may have COVID and 29 were of opinion that the staff maybe infected and 34 were afraid of overcrowding and 1 respondent was afraid of spread of COVID infection.

PHC visits and its effectiveness among the participants during /after lockdown-

Out of 200 participants, 131 got cured in single visit to the PHC and 28 didn't get cured in a single visit to PHC. Amongst the participants who visited PHC- 6 didn't get complete checkup and 7 people didn't get the prescribed drug and 6 of them were prescribed drugs from outside the pharmacy and 15 were given only half of the drugs prescribed to them and 5 gave other reasons. Totally 140 were satisfied with the services given at PHC before COVID 19 pandemic and 25 respondents were not satisfied with the services of PHC and 35 respondents maybe satisfied with the services of PHC. (Table no 2)

Consultation outside the PHC- 166 people of 200 consulted outside the PHC and 34 of them preferred PHC consultation. Out of 166 who consulted outside the PHC, 158 got their disease cured there and 8 respondents didn't get their disease cured.

Among 200 participants who visited the PHC- 94 were referred to the higher centres from the PHC during COVID 19 pandemic for further treatment or management.

PHC Data collected before, during and after the lockdown-

A.OPD Cases-There has been a significant observable drop in OPD cases from 2019(pre- COVID) to 2020(COVID). After removal of lockdown in 2021, the numbers of OPD cases have returned to almost same level as in 2019.

b. Laboratory investigations-There was also a decline in the total number of laboratory investigations recorded from the year 2019 to year 2020 because of COVID 19 pandemic and lockdown in the year 2020. As there were no cases of COVID 19 in most of 2019, so COVID 19 swab collections were almost nil in 2019 and then the swab collections increased in the years 2020 and 2021 as the COVID cases increased. And most of the other lab investigations started coming back to pre- COVID levels.

C.Routine immunizations- A decrease in routine immunizations was also noted in the year 2020 because of COVID 19 pandemic and lockdown. And now the numbers of immunizations are returning to pre-COVID levels. (Table 3)

Average number of Outdoor camps conducted by the PHC during the pandemic has been shown below. (Table no 4). There was also a decrease noted in the average larva surveillance conducted monthly by PHCs during lockdown.

Association between PHC visit and disease getting cured- It was seen that 65.5% of them who visited PHC only once said that their disease got cured ,among these people 60% felt that PHC visit was effective before the pandemic. Around 14% felt their disease was not cured on a single visit during pandemic and 20.5% felt that their disease might have got cured. This was found to be statistically significant .(Table no 5)

Table no 1: Patient satisfaction regarding the PHC services

Patient satisfaction of PHC services		Frequency(n)	Percentage (%)
1.Satisfied with the services given in PHC Now	Yes	170	85
	No	30	15
2.Satisfied with the services given in PHC Before Covid pandemic	Yes	61	30.3
	No	103	51.5
	Maybe	36	18.2

Cont... Table no 1: Patient satisfaction regarding the PHC services

3. Whether the patient got enough time from the doctor in consultation	Yes	167	83.5
	No	9	4.5
	Maybe	24	12
4. Complete checkup of respondents in PHC	Yes	165	82.5
	No	35	17.5
5. Availability of prescribed drugs in PHC pharmacy	Yes	158	79
	No	42	21
6. Whether the respondents are afraid to come to PHC	Yes	70	35
	No	130	65
7. Availability of all the tests ordered by the doctor in PHC	Yes	153	76.5
	No	47	23.5
8. Whether the PHC was understaffed during lockdown	Yes	91	45.5
	No	109	54.5

Table no 2: Visits to PHC and its effectiveness among the participants during or after lockdown

Number of PHC visits		Frequency(n)	Percentage (%)
Disease or condition got cured in single visit to PHC	Yes	131	65.5
	No	28	14
	Maybe	41	20.5
Reasons for not getting their disease cured in a single visit to PHC	No complete check up	6	15.4
	Drugs prescribed are not available	7	17.9
	Drugs from outside pharmacy were prescribed	6	15.4
	Only half drugs are given	15	38.5
	Others	5	12.8
Effectiveness of single visit to PHC before covid pandemic	Yes	140	70
	No	25	12.5
	May be	35	17.5

Table no 3:-Data from the PHC before and after Lockdown

OPD CASES	2019	2020	2021
June	4000	2000	2985
July	3900	2800	3200
August	3828	2985	3925
LAB INVESTIGATION	2019	2020	2021
NTEP- sputum	60	3	21
Hb	186	23	107
Blood group	97	18	48
Blood smear malarial parasite	532	109	531
Widal test	358	12	34
Random blood sugar	202	27	92
HIV	82	19	52
HBsAG	41	24	61
VDRL	47	19	51
Urine sugars	66	15	44
UPT	29	5	24
COVID 19- Swab	0	57	174
ROUTINE IMMUNIZATION	2019	2020	2021
BCG	42	3	29
IPV	74	2	55
ROTA	90	2	71
PENTAVALENT AND POLIO	105	4	74
MR	83	2	64
JE	102	1	59
DPT BOOSTER	97	2	69
TT	41	4	28
ANC TT	58	3	39

Table no 4:-Outdoor camps conducted from PHC during COVID-19 pandemic

Outdoor camps	2019	2020	2021
Average larva surveillance	1650	1117	2350
Average outdoor Camps conducted	4	4	4

Table no 5: Association between single PHC visit and disease getting cured.

Single visit to PHC and if disease got cured in single visit		Was single visit to PHC effective before the COVID pandemic ?			Total
		Maybe	No	Yes	
Did the disease get cured in a single visit ?	Maybe	23(11.5%)	7(3.5%)	11(5.5%)	41(20.5%)
	No	5(2.5%)	14(7%)	9(4.5%)	28(14%)
	Yes	7(3.5%)	4(2%)	120(60%)	131(65.5%)
Total		35(17.5%)	25(12.5%)	140(70%)	200(100%)

Chi-square value=112.88 ,P value=0.0001 ,extremely significant

Discussion

Our study done to assess the patient satisfaction in view of PHC services during this pandemic revealed some of the important results which could be compared with studies done in other parts of the country or outside. However very few studies were available in this regard as this is one of the untouched topics of this area.

In the study done on “Primary health care and COVID 19 pandemic” by R Deepthi et al, the findings were suggesting a 53% decrease in the diagnosis of TB whereas our study revealed a 63% reduction in

sputum collection for diagnosis of TB³.

Our study showed that about 35% of the sample population were afraid to get medical services at PHCs but in the study done in rural China on “Impact of COVID 19 on primary health care and antibiotic prescribing” by Tingting Zhang et al revealed that patients were afraid of being infected with COVID 19 and most patients said they would avoid visiting places which could have a high transmission risk like health institutions⁵.

In the study done in Singapore on “childhood vaccination: Hidden impact of COVID 19 on

children” by Y Zhong et al showed significant drop in total immunization during year 2020, similarly our study also revealed remarkable decline in the number of vaccinations in children below 14 years of age from year 2019 to year 2020⁶.

“Impact of COVID-19 on routine primary healthcare services in South Africa” by Y Pillay et al, a study done in South Africa showed that the responses to the COVID-19 pandemic, including different levels of lockdowns, the limitation of health services, lack of staff as a result of COVID-19 infection, and fear and stigma, resulted in a reduction in access to routine health services which is in coherence with our study as well⁷ and also this was similar to a study done by Pillay Y in South Africa⁸.

Association between PHC visit and disease getting cured- It was seen that 65.5% of them who visited PHC only once said that their disease got cured, among these people 60% felt that PHC visit was effective before the pandemic. Around 14% felt their disease was not cured on a single visit during pandemic and 20.5% felt that their disease might have got cured. This was found to be statistically significant in our study. This indicates that the PHC services need to be improvised especially in times of crisis so that the general public could avail the best of the services available.

Conclusions

The study regarding health care facilities delivered by PHCs during COVID-19 pandemic suggests that there has been disruption in various facilities as below:-

1. A 50% reduction in average monthly OPD cases was observed.
2. Routine lab investigations were recorded 1/3rd of that of previous years.
3. The national programmes for health saw drastic

effects eg:-NTEP (sputum collection in 2020 was only 5% of that of year 2019).

4. Routine immunization of children fell down by 80%. The numbers are improving slowly but they are still not of the level of pre COVID time.

5. About half of the study subjects were not satisfied by the services provided by the PHC.

Limitations: - The study time was limited (one month) and was limited to only one PHC. Proper and complete morbidity and mortality records are not available in PHCs.

Recommendations:-

1. Large scale study of all rural and urban PHCs in each district should be done.
2. Maintenance of proper, complete and up to date records in all PHCs.
3. Increasing or making service areas inside PHC to avoid chaos and overcrowding.
4. Asking the patients a meagre amount for consultation and treatment so that the money can be utilized in making the PHCs more efficient.

Declarations:

Funding: No funding sources

Conflict of Interest: None declared

Ethical approval: Study was approved by the Institutional Ethics Committee.

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Conventional Viva and Structured Viva — Comparison and Perception of Students

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Abstract

Background- Viva-voce is used mainly to test the cognitive domain and is a part of assessment process. But the reliability of the conventional viva may be affected by various factors, such as the anxiety of the candidate, inconsistency of the examiner, various situational factors. It is fraught with subjectivity and has been found to have poor validity, reliability and objectivity.¹

Objectives: - Primary : • To compare the inter-rater reliability of conventional viva and structured viva among III year MBBS students.

Secondary • To explore the perceptions of the students and teachers regarding the conventional and structured viva.

Materials and Methods: The study was approved by IEC, MVJMC & RH. The study subjects were 130 students of III year part 1 who gave consent for the study. The process of structured viva and conventional viva was explained to the faculty and the students. Each student had to undergo conventional viva and structured viva for a topic to all the four examiners.

Structured Viva- 10 sets of questions were set which was used by all the examiners. They were 1 mark and 2 marks each. (Recall = 4 marks, reasoning = 6 marks). Each student picked up any one viva card by lottery method and the time given was 5 minutes.

Results: The scores awarded for viva were analyzed and reliability factor was calculated using Cronbach alpha. The conventional viva had 0.5 α and structured viva had 0.8 α . Feedback about the viva processes was collected both from the students and the faculty by focus group discussions.

Feedback – Faculty found conventional viva easier to conduct but they agreed that assessment may not be fair. They found structured viva reduces bias and assessment is fair but monotonous and lot of prior work. Students found structured viva fairer than the conventional viva.

Keywords- Conventional, structured, viva, subjective

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Introduction

Viva-voce is used mainly to test the cognitive domain and is a part of assessment process.¹

But the reliability of the conventional viva may be affected by various factors, such as the anxiety of

the candidate, inconsistency of the examiner, various situational factors.

It is fraught with subjectivity and has been found to have poor validity, reliability and objectivity.²

Evaluation is the process of determining whether pre-determined educational objectives have been achieved. In the present pattern of Graduate Medical Examination a student is evaluated through Theory examination, Practical/Clinical Examination, Internal Assessment and viva-voce Examination¹.

Oral examination or viva-voce is used mainly to test the cognitive domain and is conducted with the aim of evaluating the qualities like depth of knowledge, ability to discuss and defend one's decision, attitudes, alertness, ability to perform under stress and professional competence².

The Conventional Viva-voce examination (CVE) is fraught with subjectivity and has been found to have poor validity, reliability and objectivity. New teaching and assessment methodologies have been introduced in medical education in last two decades.

Since late 1990's, more emphasis has been placed on outcome based education and curriculum has become multidisciplinary to maintain the effectiveness of problem-centred and competency-based medical education (CBME).³

We expect medical graduate to integrate knowledge, advocate health issues, communicate well, take care of patients as well as society and become a lifelong learner. Each competency usually involves more than one domain of learning and comprises a number of small tasks forming specific learning objectives.³ For these objectives to be achieved, the importance of an assessment tool with characteristics of validity, reliability, feasibility, and higher educational impact cannot be over emphasised.⁴

Though many researchers have been trying to identify the best alternative for assessing medical teaching but none has come with a clear cut answer, as different levels of knowledge and skill domains are assessed better by different types of assessment methods.⁵

Assessment is a goal oriented process and is most effective when it reflects a multi-dimensional integrated learning and compares educational performance with educational purposes and expectations. It works best when it is continuous, formative, and summative and judges' goals, objectives, course content and teaching-learning strategies.

Viva Voce has been an old traditional method of examining student's knowledge, basic concepts, comprehension level and also communication power in 'question and answer' format.

Students develop ability to be methodical, logical, and analytical, motivated and acquire problem centred approach. Thus learners construct their own knowledge on the basis of what they already know, making judgment about when and how to modify knowledge (constructivism).⁶

The assessment process itself should be evaluated and refined in light of emerging insights. Thus feedback regarding students' experience about the curricula, teaching and kind of students' efforts that lead to particular outcome should be assessed.

Objectives

Primary

- To compare the inter-rater reliability of conventional viva and structured viva among III year MBBS students.

Secondary

- To explore the perceptions of the students and teachers regarding the conventional and structured

viva.

Materials and Methods

The study was approved by IEC, MVJMC & RH. The study subjects were 130 students of III year part 1 who gave consent for the study. Based on the syllabus and after due weightage to the various topics as per the curriculum, questions were framed. The questions were developed with graded levels of difficulty for different topics of the examination. Topics were categorized as major and minor based on its public health importance. The questions were subjected to peer review and finalized with approval of head of the department. Cards were designed with questions written on them. The process of structured viva and conventional viva was explained to the faculty and the students. Each student had to undergo conventional viva and structured viva for a topic to all the four examiners.

Structured Viva- 10 sets of questions were set which was used by all the examiners. They were 1 mark and 2 marks each. (Recall = 4 marks, reasoning

= 6 marks). Each student picked up any one viva card by lottery method and the time given was 5 minutes. The student began from any of the major categories and randomly chose a fixed number of cards from each topic sequentially and attempted to answer the same. Depending on the initial response of the student, he/she was encouraged to respond to questions of lower or higher level of difficulty as the case maybe so as to assess the level of students' knowledge.

In case the student failed to answer any question totally, he/she was allowed one to two attempts to select other cards. The marks obtained by the various students were analyzed by using various statistical methods.

Focused group discussion were carried out among the students and the teachers to get their feedback about both the processes and analyzed.

Results

Marks obtained by all the students (N=130) in 2 exams i.e. conventional viva & structured viva were analyzed & compared.

Table 1:- Range of marks obtained in both method of viva, mean & Standard deviation

VIVA	MEAN	S.D
CONVENTIONAL	5.5	1.01
STRUCTURED	6.5	2.08

p value= 0.0002 (significant)

Marks obtained in conventional viva ranged from 2-8 (out of 10 marks allotted for this viva) with a mean of 5.5 & in structured viva ranged from 4 to 9 (out of 10) with a mean of 6.5. Mean of marks in conventional viva was less than structured viva.

Table no 2- Level of performance of students

Performance	Conventional Viva	Structured Viva
>70%	15 (12%)	44(34%)
50-70%	101 (78 %)	78 (60%)
< 50 %	14 (10 %)	8 (6 %)

P= 0.05

The level of performance in the structured viva was better compared to the conventional viva. It may be due to non-uniformity of marking system in conventional viva. Marking system is effected by many objective & subjective factors. In structured viva objective & subjective bias in marking is minimized.

The scores awarded for viva were analyzed and reliability factor was calculated using Cronbach alpha. The conventional viva had 0.5 α and structured viva had 0.8 α .

Table no 3: Reliability Factor

Cronbach alpha	Conventional viva	Structured Viva
(α)	0.511	0.880

The correlation coefficient was calculated and compared

Correlation coefficient - 0.539 ($p < 0.001$) showing statically significant showing structured viva is more reliable and uniform method of assessment

Feedback about the viva processes was collected both from the students and the faculty by focus group discussions.

Feedback – Faculty found conventional viva easier to conduct but they agreed that assessment may not be fair as the questions asked were not of the same difficulty level. They found structured viva reduces bias and assessment is fair and the students seemed to be more confident

But structured viva is very

- Monotonous - can be avoided by creating more such sets of questions.
- Cannot discriminate the toppers from other students.
- Time consuming
- Lot of prior work.

Students found the following disadvantages in the conventional viva

- Assessment is not fair.
- Anxiety levels are high
- Time allotted is not uniform.
- Lack of uniformity in asking questions.
- Focuses on one topic more especially of their interest.
- Examiners can be moody affecting performance
- Questions are predictable for subsequent students

Students found that structured viva fairer than the conventional viva. It eliminates subjective bias. Time allotted is uniform to all the students irrespective of their roll nos. and the syllabus covered is good. Hence it is a comprehensive evaluation. It also reduces chances of repetitive questions for subsequent students. Students also expressed that it helps maintain chain of thought because of sequential questions

Discussion

Viva is an assessment tool that evaluates communication skills, power of explanation, interpretation, and confidence level and retention

abilities of students. In viva-voce examination there is bound to be subjectivity and a likelihood of judgment of examiners being influenced by various factors. To overcome these factors viva examinations too can be standardized.

The following properties of structured viva was studied

- **Objectivity- Yes**
- **Inter rater Reliability- Good ($\alpha = 0.8$)** $\{0.7 \leq \alpha < 0.9$ -Good}
- **Feasibility- Requires lot of preparation**
- **Validity- Yes as the process tested what was supposed to test.**

The result shows that objective structured practical examination increases the objectivity and reduces subjectivity compared to conventional viva. Performance of same student is improved when the method was standardized. The difference in marks was found statistically significant, showing structured viva is more reliable & uniform method of assessment of students. Once we overcome these problems we can conduct ideal examination to achieve effective results. This is an evaluation system that has demonstrable reliability. Improved result of the students in structured viva shows students are more comfortable in structured viva & also due to uniformity of questions & marking objective bias of conventional viva, is removed to a large extent. Similar results have been seen in the studies conducted by Shah et al¹ and Rehana et al³. Since the results quoted are based on only a few examinations at a single medical school, generalizations are not justified. Thus, we conclude that although the objective structured examination provides useful tool further studies in different institutes is required to justify. A comparative evaluation of the various methods for assessment of professional competence at undergraduate level

should also be done. For generalization of results a large population of students must be considered.

Though Graduate Medical Regulations 1997 have streamlined medical education in the country the element of subjectivity in the evaluation process was not addressed. The MCI task force in its recommended curriculum for MBBS has emphasized the need for introducing structured viva-voce examinations for all subjects so as to have objectivity in the evaluation process.

In that case, first and foremost the examiner has to have the openness to re look into the CVE and accept that there is a need for introducing objectivity into the system and be willing to work towards standardization of the system thus providing the student a fair chance and effective form of evaluation through Oral examination.

Feedback is an evaluative response which gives information on all aspects, experiences, difficulties, interpretations and proposals from learners.⁵ The perception of students can be used for a series of reforms in the process of improving the quality of teaching and assessment methods.⁶ This can thus be employed, to improve educational programs, in order to facilitate in-depth learning and satisfaction amongst students, for better university ranking and standards. Researchers have rated it as a reliable, effective, useful, interesting and challenging examination which decreases mental and physical exertion. The feedback response from students on perception of both tools of viva, structured viva to be a better and unbiased system of examination as it is neither stressful nor dependent on mood and fear of examiner.

Experiential learning is continued throughout clinical practice in professional life of medical students, hence effective and accurate evaluation of student performance in practical settings must be ascertained by an updated system of examination. The main objective

of medical education is to develop effective learning tools to understand physiological alterations that form the basis of a disease process.

Conclusion

Viva Voce is the assessment tool that evaluates communication skills, power of explanation, interpretation, and confidence level and retention abilities of students. To overcome the factors like subjectivity viva examinations too can be standardized and structured. However integrated teaching has transformed VV in a tool that is not just a recall of theory but empowers students to critically appraise new information, identify their own knowledge and skill gaps and reflect critically on their learning process and outcomes, thus covering both cognitive and effective domains.⁶

Ethical Clearance – Institutional Ethical Committee of MVJMC & RH gave approval for the same

Source of Support: Nil

Conflict of Interest: None

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Mobile Phone Usage Pattern and Incidence of Self-Reported Health Problems among a Selected Population of University Students in Sri Lanka: A Cross Sectional Study

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Abstract

Background: Excessive use of mobile phones has become an emerging challenge to the public health worldwide. The purpose of this study was to assess mobile phone usage pattern and incidence of self-reported health problems among a selected population of university students in Sri Lanka.

Methods: A descriptive cross-sectional study was conducted among a random sample of 2nd and 3rd year undergraduates (n=372) of University of Sri Jayewardenepura, Sri Lanka. Self-designed, pre tested self-administered questionnaire was used to collect data. Association between categorical variables were tested using Pearson chi square test and effect size was tested by means of Cramer's V.

Results: Majority of the students were using their mobile phones for 1 to 5-year duration (61.3%) and 1-5-hour duration per day (56.5%). Majority of the participants (83.1%) were moderately addicted to their mobile phones while 5.1% were severely addicted. Significantly higher mobile phone addiction level was associated with incidence of self-reported headache, body ache, ear ache, eye strain, irritability/restlessness, sleep disturbances, hearing defects while or after using mobile phone ($p<0.01$) and phantom vibration among the participants ($p<0.05$).

Conclusion: It is a timely need to educate especially vulnerable groups such as young adults and adolescents to depend less on the device or to take measures to prevent from the associated health hazards of problematic usage of mobile phones.

Key words: Health problems, mobile phone usage, undergraduates, Addiction

Introduction

Problematic use of mobile phones has been reported substantially among people during the COVID-19 pandemic over last two years with sudden shifting of day to day activities from natural style

to more technology-based style. "A recent global survey reported that approximately 70% of internet users especially the young generation were using their smart phones or mobile phones as a direct result of lockdown, due to corona virus outbreak¹. In fact, the mobile phones have enabled people to maintain their social connectedness despite physical distancing during the COVID-19 pandemic.

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Even though the mobile phones are useful for people to make interactions with each other through communication, excessive and compulsive use of mobile phones is similarly associated with negative health consequences both physical and mental². Even though there is widespread use of mobile phones, many users are unaware of the potential health risks associated with over and unsafe use of mobile phones³.

Number of recent research studies have found that there are associations between certain health problems including headache, earache, hearing problems, warmth sensations around the ear, eye strain, concentration difficulties, mood swings, memory loss, symptoms of depression, sleep disturbances, stress, ringxiety (phantom ringing/ ringing delusion) and musculoskeletal symptoms such as pain in hands or arms (due to intensive texting) along with over usage of mobile phones².

A study conducted in Saudi Arabia among female university medical students revealed that there were substantial number of students who reported side effects with use of mobile phones including recent memory impairment (45.8%), prolonged sleep (31.7%), insomnia (30%), Chronic headache (22.5%) and concentration problems (22.5%)⁴.

It was observed eye symptoms (63%), headache (40%), and feeling irritable (25%) as the most common perceived ill health effects due to mobile phone usage in a study conducted among people in the community in India. In addition to that, neck pain (21%), lack of sleep (24%), ear pain (15%), digital thumb (8%), elbow pain (9%) and feeling depressed (11%) were prevalent substantially among the same study participants⁵.

In a study done in Italy, reported that the percentage of adolescents who were addicted to their smart phones was increased from 26.1% to 46.7% over the course of COVID-19 pandemic⁶. A similar study

done in Egypt among university students, revealed that approximately 59% of university students were addicted to their smart phones irrespective of their gender difference. Smart phone addiction was significantly associated with incidence of depression, anxiety, sleep disturbances, smoking and suicide among university students⁷.

Rapid development of mobile phone technology has been contributed to the learning process of students and might be improved their academic performance especially during the COVID 19 pandemic all over the world in which the time that restricted physical classroom learning. However, apart from the benefits for academic activities, mobile phones can be influenced in developing negative health consequences with its continuous usage among the most frequent mobile phone users such as university students. Thus, it is an intended need to assess the magnitude of the problem related to excessive use of mobile phones and increase the awareness of negative health effects of excessive mobile phone use among frequent mobile phone users. Therefore, the current study aimed to assess the mobile phone usage pattern and incidence of self-reported health problems among a selected population of university students in Sri Lanka.

Materials and Methods

The study was a descriptive cross-sectional study which was conducted among a selected population of 2nd and 3rd year undergraduates in University of Sri Jayewardenepura, Sri Lanka. The study group included 372 university students. The sample was selected by simple random sampling method from each faculty of the university among 2nd and 3rd year undergraduates who were willing to participate in the study. Pre tested self-administered questionnaires were administered to the study participants which included socio demographic data, items assessing problematic mobile phone use based on problematic use of mobile phone

scale (PUMP Scale) and questions on adverse health effects of excessive mobile phone usage. Evaluation of mobile phone addiction level was carried out with considering the scores obtained from the items of PUMP Scale⁸. The original PUMP scale was first developed and validated by Merlo et al. considering the substance disorder criteria in the Diagnostic Statistical Manual of Mental Disorders (DSM-V) in United States of America. The PUMP scale is a highly reliable instrument to determine the level of mobile phone addiction in which has demonstrated excellent internal consistency across all the items with Cronbach's alpha =0.94⁸. The judgmental validity (Face and content validity) of the items of PUMP scale of the current study was assessed by the experts of the research field and group of university students. Out of the items of PUMP scale, 12 items were used to assess the level of mobile phone addiction among university students in the current study considering the cultural and content relevance of the items of the original scale. The items of the PUMP scale included degree of impact of mobile phone usage with regard to the day to day activities. Responses for each item in the PUMP scale were ranged from 1 = strongly disagree to 5= strongly agree. Total scores yielded from 12 item scale was ranged from 12 to 60 marks. The students who responded to every question as agree or strongly agree were categorized as individuals with high level of mobile phone addiction (more than 48 marks), and who disagreed with every question were categorized as individuals with low level of mobile phone addiction (less than 24 marks). Students who gained marks in between (25-47 marks) were categorized as moderate mobile phone addiction. As there was no universally accepted cutoff values in determining level of mobile phone addiction in previous literature, present study presumed as the high score yielded from PUMP scale denoted to high level of mobile phone addiction while lower scores to less addiction.

Before starting to collect data, Pretesting of the questionnaire was done by group of university students (n=5). Required approvals were obtained from the Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka. Informed written consent was obtained from all the participants before starting the data collection of the study. Privacy and the confidentiality of the participants were ensured during all steps of the study. The statistical analysis was carried out using International Business Machines Corporation (IBM) statistical package for social sciences (SPSS) version 21.0 software. Descriptive statistics including numerical tools (frequencies, percentages, mean, median and standard deviation) were used to present the results of the current study. Chi square test was used to determine association between two categorical variables and Cramer's V was used to test the strength of association between categorical/nominal variables. Significant level of the associations was predetermined at p value <0.01 and p value <0.05.

Results

Socio demographic characteristics

In total, the sample included 372 participants comprising 121 males (32.5%) and 251 Females (67.5%). The age range of the population was 20-26 years with a mean age of 23±1 SD year. The majority of the participants (57.8%) were residing in hostels (Table 1).

Mobile phone usage pattern among university students

Majority of the students were using their mobile phones for 1 to 5-year duration (61.3%) and 1-5-hour duration per day (56.5%). Majority of the students mentioned that they receive 1-10 calls per day (79.6%) and most of them were receiving 1-10 text messages per day (43.1%). Most of them were occasionally awakened at night using mobile phones

(47.6%) and majority were used vibration method during both day and night (60.5%) as the mostly used ringing mode. Majority of the participants (87%) used

to keep mobile phone next to the ear while calling and most of them used to keep mobile phone near the head on the bed while sleeping (48.1%).

Table 1: Socio demographic characteristics of the study group

Characteristics	Category	Frequency	Percentage
Age	20-23 years	287	77.2%
	24-26 years	85	22.8%
Gender	Male	121	32.5%
	Female	251	67.5%
Marital status	Married	10	2.7%
	Single	362	97.3%
Academic year	Second year	226	60.8%
	Third year	146	39.2%
Residence	Home	67	18.0%
	Hostel	215	57.8%
	Boarding place	83	22.3%
	Annex	7	1.9%

Problematic mobile phone usage among university students

Problematic mobile phone usage among participants were assessed based on the PUMP scale item analysis (Table 2). Majority of the students (60.2%) indicated that it is difficulty to give up using the mobile phone. A considerable percentage of students (39%) agreed that the mobile phone disturbed to their other important work such as studying,

working, sleeping or eating while 7.8% students strongly agreed with the same. More than 50% of the students agreed that they have given up, delayed or reduced their day to day activities such as academic activities and sleeping due to mobile phone use.

Mobile phone addiction level

Mobile phone addiction level was determined among university students based on scores yielded

from the items of PUMP scale developed by Merlo et al. including all the items given in table 2. Mean problematic mobile phone use (addiction) score among university students was 33.24±8.71SD. Based

on the scores yielded from PUMP scale, majority of the university students (83.1%) were moderately addicted to their mobile phone device while 5.1% were reported high level of addiction (Table 3).

Table 2: Problematic mobile phone use scale item frequency analysis

	Item	Strongly Disagree	Disagree	No idea	Agree	Strongly Agree
1.	Less satisfied when decreasing the time spending on the phone	10.8%	35.2%	12.9%	36.6%	4.6%
2.	Very difficult to give up using the mobile phone	7.5%	26.6%	5.6%	47.3%	12.9%
3.	Disturb the other important work	10.2%	37.9%	5.1%	39.0%	7.8%
4.	Spend too much time on mobile phone	11.0%	44.1%	5.9%	32.0%	7.0%
5.	Have gotten into trouble at work or university because of cell phone use	16.7%	55.9%	5.4%	19.1%	3.0%
6.	When not using the phone, thinking about it and plan to do it next	15.6%	37.9%	6.5%	34.9%	5.1%
7.	Feeling anxious if haven't received a call or message for some time	14.0%	39.8%	6.2%	33.3%	6.7%
8.	Have ignored the people or disturbed relationships due to use of mobile phone	10.5%	43.8%	7.3%	33.1%	5.4%
9.	Have use mobile phone when knowing it was dangerous to do so	10.8%	41.4%	5.6%	34.1%	8.1%
10.	Day to day activities are given up, delayed or reduced due to mobile phone use (Academics, sleeping)	8.1%	30.6%	4.3%	47.0%	9.9%
11.	Have almost cause an accident due to mobile phone use (road traffic accidents, day to day injuries)	26.3%	56.2%	4.3%	9.9%	3.2%
12.	Have used cell phone even when someone asked to stop it	19.9%	47.6%	6.2%	22.8%	3.5%

Table 3: Mobile phone addiction level among university students

Category	Score	Frequency	Percentage
Severe addiction	>48	19	5.1%
Moderate addiction	25-47	309	83.1%
Less addiction	<24	44	11.8%
Total		372	100.0%

Prevalence of self-reported health problems related to mobile phone use

Proportion of university students who had self-reported health problems related to usage of mobile phones is presented in figure 1. Self-reported health

problems such as phantom vibration (61.6%), phantom ringing (53.5%), hearing defects (60.8%), sleep disturbances (57.8%) and warmth sensation around the auricle (51.9%) were highly prevalent among university students due to usage of mobile phones in the present study.

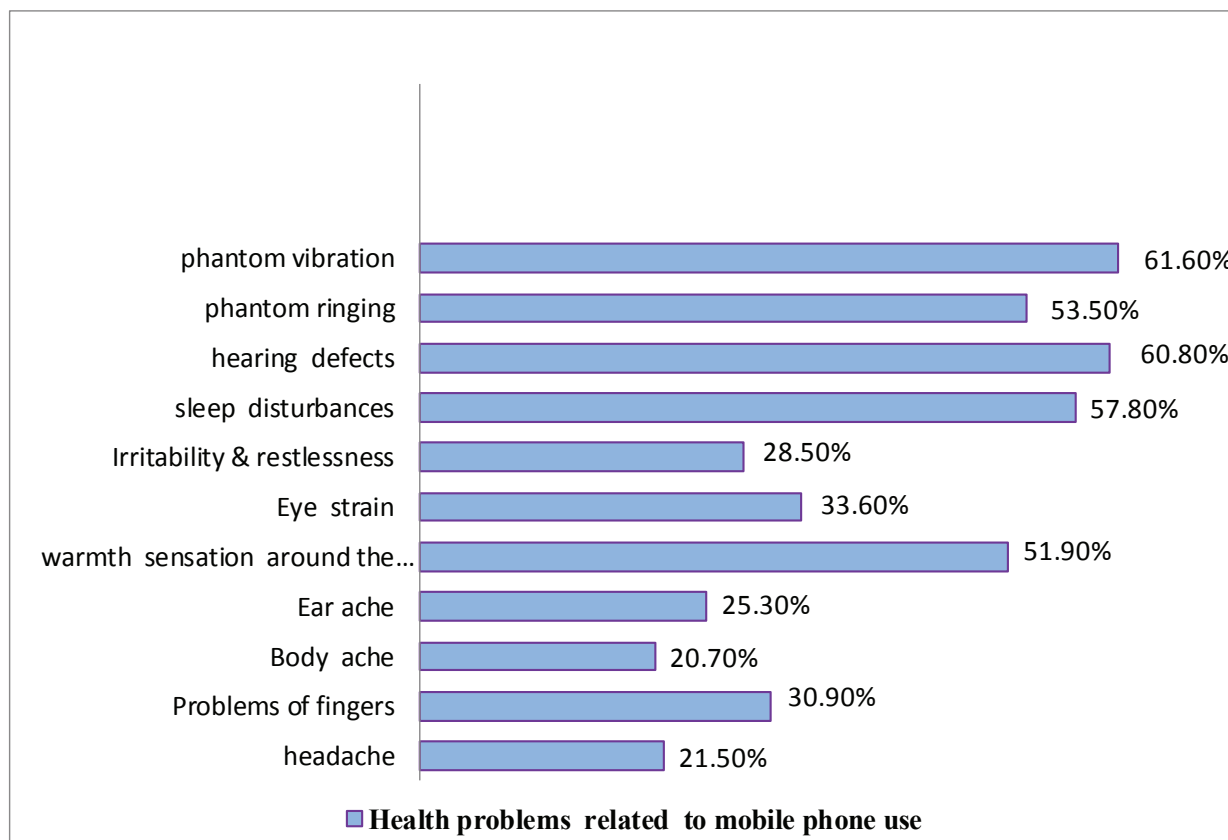


Figure 1: Self –reported health problems related to mobile phone use

Association between Mobile phone usage pattern and incidence of self-reported health problems

Students who used vibration mode as mostly used method in both day and night (60.5%) showed significant relationship with experiencing phantom vibration syndrome [Pearson $\chi^2 = 25.928$; $P=0.000 < 0.05$; Cramer's $V=0.264$]. The incidence of headache ($\chi^2=22.05$; $p=0.001<0.01$; Cramer's $V=0.172$), body ache ($\chi^2=0.98$; $p=0.02<0.05$; Cramer's $V=0.163$), warmth sensation around the auricle ($\chi^2=10.2$; $p=0.017<0.05$; Cramer's $V=0.166$), eye strain ($\chi^2=11.17$; $p=0.01<0.05$; Cramer's $V=0.173$), feeling irritable or restlessness ($\chi^2=22.54$; $p=0.000<0.01$; Cramer's $V=0.246$), Sleep disturbances ($\chi^2=29.35$; $p=0.000<0.01$; Cramer's $V=0.281$), hearing defects while or after using mobile phone ($\chi^2=22.49$; $p=0.000<0.01$; Cramer's $V=0.246$), phantom ringing($\chi^2=14.27$; $p=0.003<0.01$; Cramer's $V=0.196$) and phantom vibration ($\chi^2=14.03$; $p=0.003<0.01$; Cramer's $V=0.194$) were significantly associated with increased number of hours using mobile phone per

day by the university students. Awakening at night using mobile phones by the university students was significantly associated with incidence of stiffness, tremors or pain in fingers ($\chi^2=15.2$; $p=0.002<0.01$; Cramer's $V=0.202$), body ache ($\chi^2=20.02$; $p=0.000<0.01$; Cramer's $V=0.232$), warmth sensation around the auricle ($\chi^2=15.87$; $p=0.001<0.01$; Cramer's $V=0.207$), eye strain ($\chi^2=15.49$; $p=0.001<0.01$; Cramer's $V=0.204$), feeling irritability or restlessness ($\chi^2=12.04$; $p=0.007<0.01$; Cramer's $V=0.18$), phantom ringing ($\chi^2=15.71$; $p=0.001<0.01$; Cramer's $V=0.206$) and phantom vibration ($\chi^2=13.95$; $p=0.003<0.01$; Cramer's $V=0.194$).

According to the results of present study, significant relationships were observed between student's high level of mobile phone addiction and incidence of self-reported health problems such as headache, body ache, ear ache while/ after using mobile phone, eye strain, irritability or restlessness, sleep disturbances, hearing defects while or after using mobile phone ($P < 0.01$) and phantom vibration ($P < 0.05$) (Table 4).

Table 4: Association between mobile phone addiction level and self-reported health problems due to mobile phone usage

Self-reported health problems		Addiction category			Chi square value	P value	Cramer's V	Strength of Association
		High level of addiction	Moderate level of addiction.	Less addiction.				
Headache	80/372	12	64	4	24.04	0.000	0.180	Weak association
Body ache	77/372	12	61	4	24.65	0.000	0.257	Weak association
Ear ache	94/372	11	74	9	11.53	0.003	0.176	Weak association
Eye strain	125/372	10	110	5	13.39	0.001	0.190	Weak association
Feeling irritable or restlessness	106/372	13	88	5	21.03	0.000	0.239	Weak association
Sleep disturbances	215/372	17	188	17	31.17	0.000	0.289	Weak association
Hearing defects	226/372	17	192	17	15.85	0.000	0.206	Weak association
Phantom vibration	229/372	15	194	20	7.44	0.024	0.141	Weak association

Discussion

The results of the present study were compared with certain studies which have been done in other countries such as in India, Iran, Korea, United States, Pakistan, Saudi Arabia, Sweden and Finland. In many studies, same age range young adults (20-26 years) were assessed for problematic use of mobile phones as this is a vulnerable population and due to their tendency to indulge in more usage of mobile phones compared to that of the other age groups.

The adverse health problems related to mobile phone usage were found to be high among young population according to the previous studies. It was reported that headache was the commonest symptom seen in 51.47% college students in India due to use of mobile phones² and considerably higher percentage of study subjects (63.3%) were observed with headache in a study in Saudi Arabia among university students⁹. A research study that was conducted in Korea observed that 18.9% of study subjects suffered from headache with the use of mobile phones¹⁰. Similar to the previous studies, headache was prevalent among university students in the present study with considerable percentage (21.5%). The students who diagnosed to have migraine and other frequent types of headaches were excluded when assessing headache caused by mobile phone use in the present study to minimize the extraneous variables that can cause headache. The participants who mentioned that they get headache due to mobile phone use in the present study were further analyzed for the quality of the headache. Eighty students presented with headache while or after using mobile phone, out of them only forty-four students indicated the quality of headache they experienced. Out of the study subjects who reported the quality of headache, 38.6% were experienced unilateral headache at the side of mobile phone use. 18.18% students were presented with unilateral, burning type headache. Another, 13.3%

of study subjects mentioned that it was only burning type of headache and can't mention the definite place of it. However, the exact cause of headache while or after using of mobile phones is not established till the date but it may be due to diversifying circumstances during mobile phone use like radiofrequency fields, psychological factors, changes in local temperature, vibrations, cacophony and amalgamation of these various factors¹⁰.

Phantom vibration syndrome (Intermittent perception of vibration of mobile phone when it actually hasn't) was found to be the commonest health problem (61.6%) among participants in the present study. The incidence of phantom vibration syndrome among study participants was significantly associated with using vibration method on their mobile phones as mostly used ringing mode (both day and night) ($P < 0.05$). Phantom ringing (Intermittent perception of ringing of mobile phone when it actually hasn't) was experienced by 53.5% students in the present study and the prevalence is high when compared to a study which was carried out in India (34.5%)¹¹. The findings of the present study analogous with another study conducted in India which assessing prevalence and pattern of phantom ringing and phantom vibration among medical interns due to smart phone use¹². According the Mangot et al., 40% medical interns were reported problematic smart phone use while 60% were experiencing Phantom vibration and 42% were experiencing phantom ringing. Both Phantom vibration and ringing were significantly associated with high frequency of mobile phone use and use of vibration mode similar to the present study¹².

In addition, 60.8% students mentioned that they need to increase the volume of the mobile phone than previous occasions to hear the other partner's voice clearly. It may be due to the use of high volume on mobile phone when talking for a prolonged period of time. Considerable percentage (57.8%) of study

subjects had sleep disturbances due to being awoken at night with calling, texting and using social media (face book). Sleep disturbances may also cause among the university students due to stress of academic activities, doing part time jobs, long hours travelling as well as medical problems. These factors should be strictly addressed in future studies to minimize extraneous variables causing sleep disturbances. Some students may use to listen loud music using headsets during the night while sleeping. Perhaps they forget to remove their headsets until they wake up in the next day.

In addition, as the major reason causing sleep disturbance at night due to mobile phone usage was identified as blue light emitted by screens of mobile phones which decrease production of melatonin, the hormone which controls the sleep/wake cycle or circadian rhythm of the human body¹³. Negative physical health symptoms such as eye strain due to continuous usage and staring at the screen (33.6%), earache (25.3%), body ache due to use of same posture for a long period of time when calling or texting (20.7%) and problems in fingers such as stiffness, tremors or pain (3.7%) due to intensive texting, continuous usage of fingers especially thumb on small key pad were prevalent among the study participants. In fact, the present study observed wrist pain and stress as new negative health complains among university students when they were using mobile phones for a long period of time.

The present study has a few limitations. The first limitation was there was lack of validated and Sinhala translated PUMP scale in the present study and there were no universally accepted cutoffs to determine the level of mobile phone addiction. The second limitation was the health problems related to over usage of mobile phones were self-reported by the study participants and were not based on clinical diagnosis.

Conclusions

This study serves as an evidence-based background to make the public aware regarding the potential health risks related to excessive usage of mobile phones and the need to educate the public to depend less on the device especially during COVID-19 pandemic and post pandemic time in which the people more attach with their mobile phone each other. Further studies should be carried out to examine prevalence of health problems related to over usage of mobile phones among young population with a control group who are very less addicted to the device. Precautions such as minimizing call frequency and duration/ day, using hands free devices to hold the mobile phone as much as away from the body and head, using correct body postures while calling or texting for a long period of time, avoiding use of mobile phone during sleeping hours can be implemented to minimize possible adverse health effects due to mobile phone use. Further studies are required to develop diagnostic criteria for accurate diagnosis of the symptoms that occur due to mobile phone usage.

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CO₂ Laser Haemorrhoidectomy for Treatment of Grade IV Haemorrhoids

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Abstract

Background: symptomatic haemorrhoids are a common problem. While many treatment options are available, none have shown clear superior results. Pain, recurrence rates and potential complications are the main considerations when choosing the optimal treatment for haemorrhoids. **Methods:** We evaluated post operative pain using a visual analogue at one and four weeks post operatively in patients undergoing Milligan-Morgan haemorrhoidectomy using CO₂ laser. We also recorded any unplanned re-presentations and complications during a 24 months study period. **Results:** There were 77 patient who underwent CO₂ laser haemorrhoidectomy during the study period. Post operative pain was low (mode=1, mean=3) in the majority of patients. Those who developed a complication had higher post operative pain scores at one week compared to those who did not. All patients were pain free at four week follow up. **Conclusion:** Overall we found CO₂ haemorrhoidectomy to be a safe procedure which is well tolerated in the vast majority of patients.

Key words: CO₂ laser, Haemorrhoids, Coloproctology, Surgery

Introduction

Symptomatic haemorrhoids are a common problem across the world with up to half of adults thought to be affected at some stage in their lives [1,2]. They are the most common anorectal disorder and are frequently seen in general practice, emergency departments, gastroenterology units and both general surgical and colorectal clinics across the world [3,4]. Initial management of haemorrhoids is conservative with use of analgesics, stool softeners and topical agents. In those who remain symptomatic despite these measures, rubber band ligation or injection sclerotherapy may be indicated. However, despite

such conservative treatments, many patients remain symptomatic with their haemorrhoids and will ultimately require surgical intervention. The likelihood of failure of non-operative management is higher in patients with grade IV haemorrhoids.

While many techniques have been described for operative management of haemorrhoids, there is no consensus on which procedure is the ideal, as each is associated with its own risks, complications, post operative pain and recurrence rates. Excisional techniques such as Milligan-Morgan haemorrhoidectomy are thought to have lower recurrence rates, however they are often associated with significant post operative pain, and risk of post operative bleeding [3-4]. The use of diathermy for dissection allows for better haemostasis, but in the sensitive anoderm any heat spread and excessive

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tissue destruction will increase the risk of infection, the risk of sphincter weakness, post operative pain and time to full recovery. In contrast, use of cold scalpel minimizes tissue injury but does not itself allow for haemostasis, and can increase the risk of post-operative bleeding.

The use of CO₂ laser allows for meticulous haemostasis with minimal heat spread and tissue destruction. For this reason, we adopted its use in performance of Milligan-Morgan haemorrhoidectomy. In this study we aimed to evaluate outcomes of CO₂ laser haemorrhoidectomy for grade IV haemorrhoids. The primary end-point was recurrence rate, with secondary end-points of pain and complication rates.

Methods

All patients presenting with symptomatic grade IV haemorrhoids between January 2013 to January 2015 were included in the study. Symptomatic haemorrhoids were defined as haemorrhoids associated with bleeding, discharge, pruritus, pain recurrent thrombosis and infection. Those under the age of 45 years underwent flexible sigmoidoscopy and those over the age of 45 years a full colonoscopy prior to surgical intervention for their haemorrhoids. All patients were initially treated with four weeks of conservative treatment in the form of stool softeners, dietary advice and topical ointments and those who remained symptomatic offered surgery. Patients with underlying inflammatory bowel disease were excluded. Those with pre-existing perianal sepsis at time of presentation, had treatment of the sepsis and allowed time to recover prior to any treatment for haemorrhoids.

Patients who opted for surgery underwent CO₂ laser open Milligan-Morgan haemorrhoidectomy of all three haemorrhoidal columns (3, 7 and 11 O'clock position). The procedure was performed by the same surgeon under general anaesthesia in lithotomy

position, using a theatre that is well specialised for laser surgery. Using unfractionated CL20 CO₂ laser of wavelength 10600nm in continues mode with power of 5-8 Watts is enough to do good slow cutting with less harmful effect to the tissue and allows meticulous haemostasis. This is achieved by using the defocus technique of the laser beam with avoidance of diathermy. The depth of the cut is less than 2mm on the tissue which makes it safe to the tissue and the sphincter. The cut and the dissection is done by the laser with non-touch technique (the hand piece is 2cm away from the tissue) and avoidance of scissors or scalpel during the dissection. The haemorrhoidal pedicles were suture ligated with 2/0 vicryl. A local anaesthetic, Marcaine 0.5% was injected around the area of intervention. The wounds were covered with 2% lignocaine gel on a small sponge for a few hours only with no internal dressing.

Post-operative analgesic regimen included single dose intramuscular diclofenac 50mg prior to discharge with a prescription for 1g paracetamol QDS and 50mg Tramadol orally to be taken at home as PRN. All patients were given Bisacodyl 5mg once daily for ten days with advice to increase to 5mg twice daily if needed to ensure one soft bowel movement daily. They were also prescribed ciprofloxacin 500mg BD and Flagyl 400mg TDS for five days post operatively. The patients were advised to wash the area with soap and water twice a day after removal of the covering dressing.

Normal diet was resumed immediately after recovery from anaesthesia with advice to avoid spicy food. All cases were performed as day case operations. Patients were reviewed in the out-patient clinic at 7 and 28 days post procedure.

Data were collected on patient demographics, post operative complications necessitating unplanned out-patient visit and degree of post operative pain which was measured on day 7 and 28 using a visual

analogue pain scale (0-10).

All patients consented to undergo the proposed CO₂ laser open haemorrhoidectomy and the study was approved by the Al Salam Teaching Hospital surgical ethics committee.

Results

There were in total 88 patients eligible for the study having presented with symptomatic grade IV haemorrhoids during the study period. Of those, 11 patients did not proceed with surgery after endoscopic examination, leaving 77 patients who underwent CO₂ laser haemorrhoidectomy and were included in the study. Table 1 outlines patient characteristics.

Table 1: Patient characteristics.

Total number of patients	77	
Male	63	
Female	14	
Age	Mean 46 (34-56)	
Presenting complaint*	70	
	Bleeding	57
	Pain	25
Pruritis		

*patients often presented with more than one symptom

The mode pain score at day seven post surgery was one with mean pain score of 3. There were five patients complaining of 10/10 pain at seven days, however at four weeks follow up all patients were pain free.

There were seven recorded complications of surgery, which included perianal infection (n=6) and

anal stenosis (n=1). All infections had resolved after four weeks follow up and the patient with stenosis was treated with further surgery. The pain scores of the patients who developed post-operative infection were higher than those without infection at day seven. Diagram 1 outlines the post-operative pain scores at one week follow up.

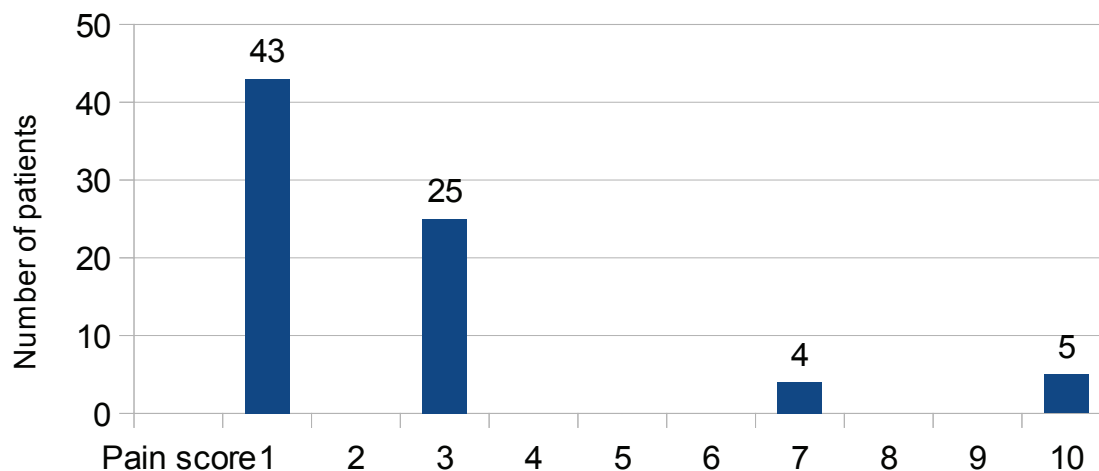


Diagram1. Post-operative pain score as reported by patients at one week post surgery.

All patients were asymptomatic from their haemorrhoids and pain free at four week follow up visit, with complete healing of wounds in all cases.

Discussion

The ideal treatment for haemorrhoids remains elusive. While techniques such as stapled haemorrhoidopexy and doppler guided haemorrhoidal artery ligation were introduced with the hopes of reducing post operative pain with similar outcomes to the well established existing treatments, there remains lacking data to support these methods as superior. In fact, initial enthusiasm has been superseded by guarded endorsement in selected cases^[5-8].

In this study, we highlight that excisional haemorrhoidectomy can be performed with low post-operative pain and complications as a day-case using CO₂ laser. This echoes findings of previous studies^[9, 10], but shares many of the same flaws. As a prospective observational study, there was no comparative group in our study to assess difference in pain scores and complications. However, Milligan-Morgan haemorrhoidectomy is long established as an extremely painful procedure, often needing several

days in-hospital stay with opiate analgesia^[11-13]. It is the authors belief that minimizing trauma to the anoderm results in less post operative pain. While such trauma is partly dictated by severity of haemorrhoidal disease, inevitably some of the trauma must be attributed to method of dissection and haemostasis. The CO₂ laser allows for excellent haemostasis with minimal heat spread and therefore limits tissue trauma and injury, it is for this reason we believe it superior to other energy devises in performing Milligan-Morgan haemorrhoidectomy.

Conclusion

Milligan-Morgan haemorrhoidectomy can be safely performed as a day-case using CO₂ laser. In our experience it is associated with low reported post operative pain score and complications. More comprehensive evaluation of post operative pain, complications and cost with CO₂ laser compared to other energy devises is needed.

Ethical Clearance: Al-Salam Teaching Hospital surgical ethics committee

Source of Funding: no funding received

Conflict of Interest: The authors have no conflicts of interest to declare

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The Effect of Semi Fowler's Position in Sleep Quality among Heart Failure Patients

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Abstract

Background: Coronary heart disease is one of the leading causes of death worldwide. Many cases of coronary heart disease can lead to heart failure. In patients with heart failure, sleep disorders are often found, one of which is paroxysmal nocturnal dyspnea (PND). Paroxysmal nocturnal dyspnea can cause a person to experience shortness of breath while sleeping. This symptom will worsen the condition of heart failure patients because patients will wake up from sleep and experience long-term anxiety and fatigue.

Aim: This study aims to determine the effect of Semi Fowler's Position in sleep quality among heart failure patients.

Methodology: The design of this study was pre-experimental which involved one group pre-test and post-test design approach, using Pittsburgh Sleep Quality Index (PSQI) instrument. The study was conducted at Indonesian Red Cross Hospital in Bogor City with a total sample of 32 heart failure patients. The data analysis techniques used were univariate and bivariate with Sample Paired T-Test.

Result: Out of 32 participants, 32 participants (100%) had bad sleep quality before intervention with Semi Fowler's Position and 29 participants (90.6%) had good sleep quality after practicing Semi Fowler's Position.

Conclusion: There was a significant effect of Semi-Fowler's Position in sleep quality among heart failure patients.

Keywords: Heart Failure, Paroxysmal Nocturnal Dyspnea, Semi-Fowler's Position, Sleep Quality

Introduction

The largest contributor to cardiovascular disease

deaths is coronary heart disease and approximately two-thirds of patients with coronary heart disease develop heart failure⁽¹⁾.

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Heart failure is a major public health problem worldwide. Heart failure is the final stage of heart disease after the myocardium has used up all its reserves and compensatory mechanisms⁽²⁾.

World Health Organization (WHO) recorded 17.5 million people in the world died from cardiovascular disorders. The number of heart disease cases in the United States was 136 per 100,000 people in 2016. The number of heart disease cases in Asia such as in China was found as many as 300 per 100,000 people, while in Indonesia 371 per 100,000 people and this made Indonesia included in the group with the highest number of cases⁽³⁾.

Based on Basic Health Research Data(2017), the prevalence of heart failure cases in Indonesia was 0.13% or an estimated 229,696 people. Based on the diagnosis and symptoms, the highest estimated number of patients with heart failure was in West Java Province with a total of 96,487 people (0.3%). Meanwhile, based on health data from Bogor Regency in 2017, number of patients with heart failure was 1,427 people (2.59%)⁽⁴⁾.

Heart failure causes various clinical symptoms including dyspnea, orthopnea, and the most frequently encountered symptom is Paroxysmal Nocturnal Dyspnea (PND) or shortness of breath at night, which appears suddenly and causes the patient to wake up⁽⁵⁾. The emergence of various clinical symptoms in patients with heart failure will cause nursing problems and interfere with basic human needs, one of which is sleep disorders⁽⁶⁾.

Nurses as health care providers could facilitate patients to solve problems through independent and collaborative actions⁽⁷⁾. Nurses can help to identify symptoms that appear in patients with dyspnea or changes in breathing patterns and give preliminary interventions by providing oxygen and practice Semi-Fowler's Position⁽⁸⁾. According to Javaheri (2016), the Semi-Fowler's Position will affect the state of cardiac output and development of the patient's lung cavity, so that shortness of breath is reduced and optimize the patient's sleep quality. The development of the chest cavity and lungs will cause oxygen intake to improve

and the respiration process will return to normal⁽⁹⁾.

Adjusting the patient into Semi-Fowler's Position at an angle of 45 degrees will help reduce oxygen consumption and increase maximal lung expansion as well as overcome impaired gas exchange associated with changes in alveolar membranes and produce good quality sleep⁽¹⁰⁾. Shahab S, Fvuzan S, and Budiharto I. (2016) revealed that the Semi-Fowler's Position with an angle of 45 degrees resulted in better sleep quality for patients with heart problems⁽¹¹⁾.

Methodology

Based on the preliminary study that has been conducted at Indonesian Red Cross Hospital in Bogor City through patients' medical record data, there were 94 patients diagnosed with heart failure from January to December 2020. It has recently been reported that out of 8 patients diagnosed with heart failure, 6 patients experienced sleep disorder and 3 patients had uncomfortable sleeping position.

This type of research used pre-experimental design, with one group pre-test and post-test design. The population in this study were patients with heart failure with a sample of 32 participants.

The study inclusion criteria were heart failure patients, in conscious state, and cooperative. Meanwhile, the exclusion criteria were patients who had decreased consciousness or unwilling to be a participant. The sampling technique used was Quota Sampling (Judgment Sampling)⁽¹²⁾. After the number of samples was identified, then steps were taken for the first participant who was given code 1 and followed by other participants until it reached code 32.

Researchers submitted a research permit issued by Wijaya Husada Health Institute Bogor to the head of the Indonesian Red Cross Education and Training Hospital. The Head of the Education and Training Division of Indonesian Red Cross Hospital in Bogor

City gave permission to researchers for conducting this study. After obtaining research permit, researchers met the head of the Intensive Care Unit to ask for permission and explained the instruments to be used for the research. Types of data collected in this study were primary data through observation and questionnaires, and secondary data through medical records to determine the number of heart failure population.

The questionnaire contained personal identification and the Pittsburgh Sleep Quality Index (PSQI) questionnaire. The nominal dispatch scales for

sleep quality is categorized as follows:

1. Good sleep quality (total score 0-5)
2. Bad sleep quality (total score 6-21)

The magnitude of the effect is determined by Sample Paired T-Test.

Results

This research was conducted in April 4-20, 2021. The participants aged more than 40 years old was 29 participants (90.62%), while 25 participants (78.12%) were female and 28 participants (87.5%) had high school level education.

Table 1: Normality Test of Sleep Quality Among Heart Failure Patients

Group	Shapiro-Wilk		
	Statistic	df	Sig.
Pre-Test	0.925	32	0.150
Post-Test	0.947	32	0.125

Based on Table 1, the data were normally distributed and the *p-value* in the pre-test and post-test groups was significant (>0.05).

Table 2: Homogeneity Test of Sleep Quality Among Heart Failure Patients

	Levene Statistic	Sig.
Based on Mean	1.416	0,164
Based on Median	1.286	0.187
Based on Median and with adjusted df	1.239	0.165
Based on trimmed mean	1.235	0.182

Based on Table 2, it can be seen that that the data is homogeneous (0,164>0.05).

Table 3: Frequency Distribution of Sleep Quality Among Heart Failure Patients Before Intervention with Semi Fowler’s Position

Sleep Quality	Total	Percentage (%)
Bad	32	100
Good	0	0
Total	32	100

Based on Table 3, most of the participants experienced bad sleep quality with a total of 32 participants (100%).

Table 4: Frequency Distribution of Sleep Quality Among Heart Failure Patients After Intervention with Semi Fowler’s Position

Sleep Quality	Total	Percentage (%)
Bad	3	9.34
Good	29	90.6
Total	32	100

It can be seen from table 4 that most of the participants experienced good sleep quality with a total of 29 participants (90.6%).

Table 5: Effect of Semi Fowler’s Position in Sleep Quality Among Heart Failure Patients

Paired Differences					
	Mean	T	Df	Correlation	Sig. (2-tailed)
Pre-test – Post-test	6.7333	18.802	31	0.3581	0.000

Table 5 shows that the p-value = 0.000, which means p-value < 0.05 and H₀ was accepted. This hypothesis shows that there is a significant relationship between Semi Fowler’s Position and sleep quality among heart failure patients.

Discussion

A. Sleep quality of heart failure patients before intervention with Semi Fowler’s Position

Based on the frequency distribution of the sleep quality in heart failure patients before intervention with Semi Fowler’s Position, the majority of

participants had bad sleep quality with a total of 32 participants (100%).

This study is in line with research conducted by Puspita Dewi (2017) which states that around 68% of heart failure patients have problems with bad sleep quality⁽¹³⁾.

The short-term effects of impaired sleep quality are increased response to stress, somatic pain, decreased quality of life, emotional distress, mood disturbances, cognitive impairment, and memory⁽¹⁴⁾. While the long-term effects that arise are hypertension, dyslipidemia, heart disease, weight problems, metabolic syndrome, type 2 diabetes, and colorectal cancer⁽¹⁵⁾.

A person who experiences sleep disorders often shows an inadequate response to external stimuli and difficulty concentrating, due to limitations in the quality and quantity of sleep, thus interfering with their ability to carry out activities⁽¹⁶⁾.

B. Sleep quality of heart failure patients after intervention with Semi Fowler's Position

Based on the frequency distribution of the sleep quality in heart failure patients after intervention with Semi Fowler's Position, the majority of participants had good sleep quality with a total of 29 participants (90.6%).

This study is in line with research conducted by Iyonu's (2014) which stated that the provision of a 45-degree Semi Fowler's Position had a significant effect in improving the sleep quality of heart failure patients⁽¹⁷⁾.

Position is an important component in critical care to optimize ventilation status and increase the effectiveness of gas exchange in the lungs. The Semi Fowler's Position of 45 degrees has an effect on oxygenation and blood gas parameters with oxygen saturation, partial pressure of oxygen and a decrease in carbon dioxide pressure, also increases

tidal volume by means of the diaphragm and alveolar expansion⁽¹⁸⁾. Thus, the Semi Fowler's Position will reduce shortness of breath in heart failure patients and improve sleep quality⁽¹⁸⁾.

C. The effect of Semi Fowler's Position in sleep quality among heart failure patients

Based on Table 5, p -value=0.000, which indicated that there was a significant effect of Semi Fowler's Position in sleep quality of heart failure patients at Indonesian Red Cross Hospital in Bogor City.

This study is in line with research conducted by Wijayati S, Ningrum DH, and Putrono P (2019) which stated that a change in Semi Fowler's Position has a significant effect in the sleep quality of heart failure patients⁽¹⁰⁾.

This fact is also supported by research conducted Javaheri S, Blackwell T, Ancoli-Israel S, Ensrud KE, Stone KL, Redline S (2016) which described that 45-degree Semi Fowler's Position will affect the state of cardiac output and the development of the patient's lung cavity, hence shortness of breath will be reduced and sleep quality of heart failure patients will be improved⁽⁹⁾.

Conclusion

There was a significant effect of Semi Fowler's Position in sleep quality among heart failure patients at Indonesian Red Cross Hospital in Bogor City, West Java, Indonesia.

Ethical Clearance: Ethical clearance was not required hence was not obtained.

Source of Funding: Self-funded.

Conflict of Interest: There was no conflict of interest in the research.

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The Effect of Fasting during Pregnancy on Brain-derived Neurotrophic Factor Expression in *Cerebrum* and *Cerebellum*

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Abstract

Background: Fasting for pregnant women is still a debatable issue among society and clinicians. Fasting done by pregnant women causes brain neurons to receive more energy thus increases the connection between the neurons. A brain hormone called Brain-derived Neurotrophic Factor will be affected during fasting. Brain-derived neurotrophic factor (BDNF) plays an important role in neuronal survival and growth, serves as a neurotransmitter modulator, and participates in neuronal plasticity, which is essential for learning and memory. Brain-derived Neurotrophic Factor (BDNF) has an important role in brain development, namely in the formation of new nerve cells and cognitive processes inside the brain which helps to optimize cognitive, learning, and memory functions. Fasting during pregnancy will influence fetal brain cells due to increase in the body's metabolic system which is delivered to *cerebrum* and *cerebellum* neuron cells. The objective of this research is to analyze the effect of fasting during three trimesters pregnancy on Brain-derived Neurotrophic (BDNF) factor expression in *cerebrum* and *cerebellum*.

Method: The design of this research is true experimental laboratory post-test with control group design. The research samples are rats (*Rattus norvegicus*) which consists of 3 groups and 1 control group. First group (X1) was the rats born from mother with 2 days fasting during first trimester pregnancy, second group (X2) was the rats born from mother with 2 days fasting during second trimester pregnancy and third group (X3) was the rats born from mother with 2 days fasting during third trimester pregnancy. The control group (X0) was the rats born from mother without fasting during the whole pregnancy. Brain dissections of new born rats were taken and the brain-derived Neurotrophic Factor expression was studied within munohistochemistry.

Conclusion: Brain-derived Neurotrophic Factor expression in *cerebrum* and *cerebellum* was examined with immunohistochemical method. Data from each sample was assessed using the Remmele Scale Index method (Immunoreactive Score). There was significant *cerebrum* Brain-derived Neurotrophic Factor expression mean found in third trimester (3.90 ± 2.403) with p-value = 0.008 ($p < 0.05$). There were no significant *cerebellum* Brain-derived Neurotrophic Factor expression differences found in all trimesters. Fasting during pregnancy is safe for both mother and children. Fasting during pregnancy will increase the Brain-derived Neurotrophic Factor expression so that the brain function will improve as well.

Keywords: Brain-derived, Fasting, Neurotrophic, *Rattus norvegicus*, Pregnancy

Introduction

Fasting is characterized by a series of coordinated metabolic changes designed to save carbohydrates and increase dependence on fat as a substrate for energy supply.¹⁸ Calorie restriction or dietary restrictions are the methods used by limiting the amount of consumed food. Diet retraction is also interpreted as reducing the number of calories that enter the body (about 20-40% of the daily intake that is normally consumed) while maintaining adequate nutrition needed by the body.²⁰ There are various methods of dietary retention, including alternate-day fasting, that is one day consuming food without restrictions (can be given twice the usual intake) and on a full day the food is reduced.²⁰ Another method is to try to satisfy animals (not given any food) for several hours with different duration of fasting.

During fasting, the body will signal hunger and stimulate the desire to eat. However, hunger will be halted so that the process of adaptation to the lack of energy sources will occur and energy needs will still be met.⁸

Fasting for pregnant women is still a controversy issue in the community. The public assumes that fasting during pregnancy will pose risks to pregnancy, including intellectual disorders in children, low birth weight, increase *hyperemesis gravidarum*, urinary tract infections, and trigger a decrease in fetal movement in the uterus.⁶

Brain-derived Neurotrophic Factor (BDNF) is one of the neurotrophic factors that support differentiation⁷, maturation¹ and survival of neurons in the nervous system¹¹ and shows a *neuroprotective* effect under adverse conditions, such as glutamatergic

stimulation, cerebral ischemia, hypoglycemia, and neurotoxicity¹². Brain-derived Neurotrophic (BDNF) stimulates and controls growth of new neurons from neural stem cells (neurogenesis)⁵.

A study showed that fasting could increase Brain-derived Neurotrophic Factor (BDNF) formed in the brain, which helps the body to produce more brain cells, which could increase the fetus brain function³. During fasting, the number of mitochondria in each neuron cell of the brain increases. *Mitochondria* causes the brain cells to increase which will affect the brain to be more durable to absorb memories¹⁹. Duan *et al.* showed that the levels of Brain-derived Neurotrophic (BDNF) was significantly increased in the hippocampus, cerebral cortex, and striatum of rats maintained on a dietary restriction (DR) regimen compared to controls.

Brain-derived Neurotrophic (BDNF) has important role in the formation of new neuron cells and cognitive process in the brain. The brain has few main parts, such as: *cerebrum*, *cerebellum* and brainstem. Functions of the *cerebrum* include: initiation of movement, coordination of movement, temperature, touch, vision, hearing, judgments, reason, problem solving, emotions and learning. While the function of *cerebellum* is to coordinate voluntary muscle movements, maintain postures, balance and equilibrium. The previous studies in this field have been conducted using blood samples of fasted humans or on animals without measuring the level of Brain-derived Neurotrophic (BDNF) expression during pregnancy in the *cerebrum* and *cerebellum*. This study is aimed to analyze the effect of fasting during three trimester pregnancy on Brain-derived Neurotrophic Factor (BDNF) expression in *cerebrum* and *cerebellum*.

Materials and Methods

The study design of this research is true experimental laboratory post-test only with control group design. The subjects in this research are divided into 4 random groups, consisting of 3 groups which fasted during Trimesters I, II, and III, and 1 control group which did not fast. Fasting during pregnancy

is an activity without the consumption of food and drinks with calories for 14 hours (17.00-07.00) with the normal food composition of 70-100/kgbody weight/day. Brain-derived Neurotrophic Factors (BDNF) is defined as a member of the neurotrophin family which has a main function to modulate neuron survival and apoptosis neuron plasticity. Immunohistochemistry method was used to assess the Brain-derived Neurotrophic Factor (BDNF).

The population of this research are mature female *Rattus norvegicus* aged 2-3 months with weights 130-170 grams which were obtained from laboratory and research center at Gadjah Mada University (LPPT UGM). The subjects on this research were young *Rattus Norvegicus* (young rats) with the inclusion criteria: newborn rats from healthy pregnant mother rat (active movements, shiny eyes, soft and thick fur, and has a normal weight), *Rattus norvegicus* mothers which have never been pregnant, and adult *Rattus norvegicus* aged 2-3 months. The total amount of subjects in this research was 32, which were divided

into 4 groups, each group consisted of 8 rats, namely : Control Group X0 which was given standard food and water , Group X1 fasted during trimester I for 2 days (Days 5 and 6, week 1 of pregnancy), Group X2 fasted during trimester II for 2 days (Days 11 and 12, week 2 of pregnancy), and Group X3 which fasted during trimester III for 2 days (Days 17 and 18, week 3 of pregnancy).

Sample collection was done immediately after the *Rattus norvegicus* was born, and then brain samples from the newborn rats were taken for immune on *histochemistry* check to measure the Brain-derived Neurotrophic (BDNF) expression of each sample.

Brain-derived Neurotrophic (BDNF) expression of each sample was graded semi-quantitatively in accordance to Remmele Scale Index (Immuno Reactive Score), which is taking into account the percentage immunoreactive cell percentage score (A) with the color intensity score (B). Field percentage is seen through a microscope with the magnification of 400X and counted per 100 cells divided by total cells, multiplied by 1000.

Table 1: Semi-quantitative Immunoreactive Score (IRS) in which the final results correspond to the product of two variables (AxB) (Madej et al., 2014)

Point Score	A	B
0	No cells with positive reaction	No color reaction
1	≤ 10% cells with positive reaction	Low intensity of color reaction
2	11%-50% cells with positive reaction	Average intensity of color reaction
3	51%-80% cells with positive reaction	Intense color reaction
4	>80% cells with positive reaction	

To see the difference in Brain-derived Neurotrophic (BDNF) expression in the cerebrum and cerebellum of *Ratus norvegicus* children in the fasting and control groups, normality test will be conducted first. If the data were normally distributed ($p > 0.05$) then the Shapiro-Wilk test was used followed by the analysis of variance test (ANOVA). However, if the data is not normally distributed then the Kruskal-Wallis test will be conducted. This study used p-value of 0.05 with 95% confidence level. All data analysis then statistically counted with statistical package for the social sciences (SPSS) for Windows 23.

Results

Brain-derived Neurotrophic (BDNF) expression in cerebrum was analyzed through immunohistochemical examination. Data from each sample was assessed using the Remmele Scale Index (Immunoreactive Score/IRS). Normality test of Brain-derived Neurotrophic (BDNF) expression in cerebrum of newborn *Rattus norvegicus* was obtained with the result of normal distribution between the control and treatment groups ($p < 0.05$). Then homogeneity test was performed which produced inhomogeneous data with $p\text{-value} = 0.04$. Since the data were not homogeneous, the Kruskal-Wallis test was performed.

Table 2: Brain-derived Neurotrophic (BDNF) Result in cerebrum of newborn *Rattus norvegicus* with Shapiro-Wilk Test

Group	n	p-value	
		Shapiro-Wilk	Levene's test
X0 (Control)	6	0,19	0,004
X1 (Fasted Trimester I)	6	0,07	
X2 (Fasted Trimester II)	6	0,16	
X3 (Fasted Trimester III)	6	0,20	

Table 3: Brain-derived Neurotrophic (BDNF) Result in cerebrum newborn *Rattus norvegicus* with Kruskal-Wallis Test

Group	n	Mean \pm SD	p-value
X0 (Control)	6	1,30 \pm 0,27	0,008
X1 (Fasted Trimester I)	6	1,77 \pm 1,19	
X2 (Fasted Trimester II)	6	2,20 \pm 0,35	
X3 (Fasted Trimester III)	6	3,90 \pm 2,40	

Based on table 3, there were significant differences in Brain-derived Neurotrophic (BDNF) expression in cerebrum of the four groups (p-value < 0.05), thus

further T-test was performed. The result of T2 free sample test showed that X0 group was different than X2 and X3 groups.

Table 4: Brain-derived Neurotrophic (BDNF) Expression in Cerebrum of X0 and X1 Groups

Group	n	Mean ± SD	p-value
X0 (Control)	6	1,30 ± 0,276	0,374
X1 (Fasted Trimester I)	6	1,767 ± 1,196	

The result of T2 free sample test showed that there was no significant Brain-derived Neurotrophic (BDNF) expression difference in the *cerebrum* between control group and fasted trimester I group (p-value>0.05).

Table 5: Brain-derived Neurotrophic (BDNF) Expression in Cerebrum of X0 and X2 Groups

Group	n	Median (min – max) Mean ± SD	p-value
X0 (Control)	6	1,30 ± 0,276	0,001
X2 (Fasted Trimester II)	6	2,200 ± 0,358	

The result of T2 free sample test showed that there was significant BDNF expression difference in the *cerebrum* between control group and fasted trimester II group (p-value<0.05).

Table 6: Brain-derived Neurotrophic Factor (BDNF) Expression in Cerebrum of X0 and X3 Groups

Group	n	Mean ± SD	p-value
X0 (Control)	6	1,30 ± 0,276	0,045
X3 (Fasted Trimester III)	6	3,90 ± 2,403	

The result of T2 free sample test showed that there was significant Brain-derived Neurotrophic (BDNF) expression difference in the *cerebrum* between control group and fasted trimester III group (p-value<0.05).

BDNF expression in *cerebellum* was analyzed

through immunohistochemistry examination. Data from each sample was assessed with Remmele Index Scale (Immunoreactive Score/IRS). Normality test of Brain-derived Neurotrophic (BDNF) expression in *Rattus norvegicus* cerebellum was performed using Shapiro-Wilk test.

Table 7: Brain-derived Neurotrophic Factor (BDNF) Result in *cerebellum* of newborn *Rattus norvegicus* with Shapiro-Wilk Test

Group	n	p-value
X0 (Control)	6	0,139
X1 (Fasted Trimester I)	6	0,077
X2 (Fasted Trimester II)	6	0,002
X3 (Fasted Trimester III)	6	0,085

Based on table 7, there was abnormality in distribution of BDNF expression in Group X2 (fasted trimester II) with p-value=0.002 (p-value<0.05). Thus, Kruskal-Wallis test should be done following the previous test.

Table 8: Brain-derived Neurotrophic Factor (BDNF) Result in *cerebellum* of newborn *Rattus norvegicus* with Kruskal-Wallis Test

Group	n	Median (min – max)	p-value
X0 (Control)	6	2,3 (1,0 – 6,4)	0,524
X1 (Fasted Trimester I)	6	2,2 (0,8 – 6,4)	
X2 (Fasted Trimester II)	6	2,8 (2,2 – 6,8)	
X3 (Fasted Trimester III)	6	2,2 (1,2 – 8,4)	

Based on the table 8, there was no significant difference on Brain-derived Neurotrophic (BDNF) expression of the 4 groups in *cerebellum*, with p-value=0.542 (p>0.05).

Discussion

There are reports indicating of a correlation between fasting and Brain-derived Neurotrophic Factor (BDNF) levels during fasting. One of the most comprehensive studies addressing this correlation was carried out by Krisztina Marosi and his colleagues. Their investigations showed that fasting/food deprivation can also induce Brain-derived Neurotrophic (BDNF) expression in neuronal circuits involved in cognition by increasing their activity, and by shifting cellular energy substrate utilization from glucose to ketones. They also added that intermittent fasting and exercise

through Brain-derived Neurotrophic (BDNF) induce the *neurogenesis*, by promoting the differentiation of neurons from stem cells, and the survival and synaptic integration of newly generated neurons¹⁷. There also are several investigations, which indicate that the calorie restriction has beneficial effects on neurotrophic factors such as Brain-derived Neurotrophic (BDNF) in the brain and that the elevation of this factor can improve the neuro generation in the nervous system^{2,10,16}.

During fasting, there is a shift in the utilization of brain cell energy substrate from glucose to ketones

3-hydroxybutyrate (3OHB). 3OHB can protect neurons against oxidative stress. *3-hydroxybutyrate* metabolism increases mitochondria which encourage changes in brain expression derived by Brain-derived factors (BDNF) in the cerebral cortex of neurons. The mechanism that induces *3-hydroxybutyrate* and Brain-derived *Neurotrophic* (BDNF) expression involves ROS (Reactive Oxygen Species) and activation of NF- κ B transcription factors. Since Brain-derived *Neurotrophic* (BDNF) plays an important role in synaptic plasticity and stress resistance, 3OHB (*3-hydroxybutyrate*) can mediate the adaptive response to neurons when fasting.¹⁷

Brain-Derived *Neurotrophic* Factor (BDNF) is a member of *neurotrophin* which functions to modulate endurance and play a role in the development, maintenance and synaptic plasticity.¹⁷

Consequently, Brain-derived *Neurotrophic* Factor (BDNF) is located in the cortex and basal cerebrum in the hippocampus which is a process for thinking, memory and recollection. Brain-derived *Neurotrophic* Factor (BDNF) is synthesized as pre-*neurotrophin* which is divided into pro BDNF and BDNF maturity. Pro Brain-derived *Neurotrophic* Factor (BDNF) is converted to mature BDNF which is active with the help of pro-hormone convertase such as proteases. Pro Brain-derived *Neurotrophic* Factor (BDNF) is also produced by neurons that are changed by tissue plasminogen activator (tPA) or plasmin to Brain-derived *Neurotrophic* Factor (BDNF).¹⁷

Brain-Derived *Neurotrophic* Factor (BDNF) is a protein expressed in the brain that covers the areas of the frontal cortex, parietalis, cingulatus, temporal, retrosplenial, piriform, hippocampus, entorhinal cortex, brain stem and cerebellum.⁴ In addition, Brain-derived *Neurotrophic* Factor (BDNF) concentrations in each area in the brain is different and the highest concentration is in the hippocampus.⁷

According to Manuaba (2010) that, during the first trimester of pregnancy there will be physiological adaptations resulting from hormones in pregnancy and metabolic changes are including a rise in basal metabolism by 15-20% from before pregnancy. During the first trimester of pregnancy the nutrients that enter the body tend to decrease, because the body is still adapting to pregnancy hormones. With poor nutrition during fasting, oxidative stress will be reduced so that the utilization of *3-hydroxybutyrate* will decrease. This might explain the reason there was no significant difference on BDNF expression in trimester I in both *cerebrum* and *cerebellum* in this study.

Cerebellum is the center of the body in controlling the quality of movement. The *cerebellum* also controls many automatic functions of the brain, including: regulating posture or body position, controlling balance, muscle coordination and body movements.⁹ In second trimester, body organs have formed, so the metabolic basal requirements will also increase and the need for protein used for fetal growth and development will also rise. In this trimester the body can adapt to changes in pregnancy hormones.¹³ During the second trimester, the amount of nutrients entering the body starts to increase, while the body's metabolic needs also grow in this period. This process will lead to rise in oxidative stress in the body, but the body has a mechanism to deal with this, namely through *3-hydroxybutyrate*s that enter the mitochondria and make deacetylation of ROS (reactive oxygen species) molecules such as SOD (superoxide dismutase) enzymes, causing Brain-Derived *Neurotrophic* Factor (BDNF) to increase in the cerebrum during second trimester pregnancy. In this study, there is no significant BDNF expression difference in *cerebellum* due to the different function of the *cerebellum*. BDNF is related to cognitive function while *cerebellum* is linked with balance and coordination.

In third trimester pregnancy, the mother's body needs more nutrients for fetal growth and development. Thus, the nutrients that enter the body increases which will elevate the oxidative stress and make the body use more ketones (*3-hydroxybutyrate*). In this study, there was significant difference of Brain-derived Neurotrophic (BDNF) in the *cerebrum* between the control group and fasted third trimester. While in the cerebellum there was no significant Brain-Derived Neurotrophic Factor (BDNF) expression difference between the control group and fasted third trimester group. This condition is due to the fact that the highest Brain-Derived Neurotrophic Factor (BDNF) concentration is located in the hippocampus.

Conclusion

In conclusion, fasting for pregnant women is safe. Fasting during pregnancy will increase Brain-derived Neurotrophic (BDNF) expression and improve brain function. As pregnancy age increases, Brain-derived Neurotrophic (BDNF) will also increase. However, there is still much that needs to be investigated to better understand the effect of fasting since this study was done on *Rattus norvegicus* that could only be fasted for few hours.

Conflict of Interest: There is no conflict of interest in the research.

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Ethical Clearance: All the clinical procedures were carried out following the protocols approved by the Ethics and Review Committee of Wijaya Husada Health Institute.

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CO₂ Laser Therapy for Chronic Anal Fissure Resistant to Non-Invasive Treatment: A Single Centre Experience

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Abstract

Background: The treatment of chronic anal fissure is predominantly conservative. However, failure of conservative measures obliges the use of more potent treatments, such as Botulinum Toxin (BT) injections to relax the internal anal sphincter. Furthermore, surgical intervention represented by lateral internal sphincterotomy (LIS) is used to treat resistant cases but imposes the risk of faecal incontinence. The aim of our study is to assess the degree of post-operative pain, recovery time and the rate of post-operative faecal incontinence in patients where CO₂ laser is used to perform LIS.

Methods: 236 patients clinically diagnosed with chronic anal fissure through 2012-2014 were included in the study. The selected patients were those who did not benefit from conservative treatment. The approach we took starts with Examination Under Anaesthesia (EUA), followed by excision of the fibrotic anal fissure using CO₂ laser on continuous mode with defocus technique for haemostasis. Wound healing was induced by secondary intention. The follow-up period extended for 2 years post-operatively.

Results: The effectiveness of laser LIS was tested over two domains, pain score and post-operative complications. On a pain scale of 1-10, all patients had a pain score of one or less on day seven. Three patients (1.27%) had recurrent pain and bleeding within two years and were treated conservatively. No patients had incontinence at the last follow-up. Six patients (2.5%) developed minimal mucus discharge for three months post operatively.

Conclusion: The treatment of resistant chronic anal fissure with CO₂ laser shows promising outcomes when compared to conventional LIS. Laser surgery offers the advantage of being a minimal surgical intervention in addition to a reduced risk of incontinence and recurrence when compared to other methods such as BT injections and conventional LIS.

Keywords: *Chronic anal fissure, CO₂ Laser, Lateral internal sphincterotomy*

Introduction

Anal fissure is defined as the presence of a

longitudinal tear in the distal anal canal which can be classified as acute and chronic [1,2]. Anal fissure is a common proctological condition with a cumulative lifetime incidence of 11% in the general population [3]. The pathophysiology of chronic anal fissure is not well established but it is thought that strained evacuation of hard stool, low-fiber diet and hypertonicity of the

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internal anal sphincter significantly increase the risk of developing anal fissure [1,4,5].

Conservative measures such as the use of analgesics, local vasodilators and laxatives are the first line treatment and is effective in healing anal fissure in the majority of cases [1]. The second line treatment is Botulinum Toxin (BT) injections which aims to reduce the sphincter tone thus, promoting the healing process.

If the above treatments fail, patients are offered operative measures, specifically, lateral internal sphincterotomy (LIS). A review of studies published between 1993-2011 comparing BT injections to surgery concluded that LIS is more effective and is associated with significantly lower rate of recurrence [5]. However, LIS are associated with a higher rate of faecal incontinence post-operatively [5].

In the last decade, CO₂ laser has been utilised in surgeries of the neck to remove malignant tumors due to the advantages of laser when used in the removal of malignancies such as tonsillar carcinomas, glottic cancer and hypopharyngeal carcinomas [6-8]. Similarly, laser surgery for anal fissure is associated with reduced post-operative pain, shorter recovery time and less operative complications [10].

In this study we aim to further validate the effectiveness of using CO₂ laser in the management of chronic anal fissure not responsive to conservative treatment. Despite that fissurectomy as a surgical technique may not be widely used nowadays, we introduce a new technique for the excision of chronic fibrotic and symptomatic fissures using CO₂ laser due to its gentle effects on the tissue, favourable healing rate and absence of major side-effects.

Materials and Method

A total of 236 patients clinically diagnosed with chronic anal fissure between January 2012 and

September 2014 were selected for the study [Table 1]. The diagnosis was based upon the presentation of chronic anal pain and a long history of per rectum (PR) bleeding, with chronic use of ointments, including Glyceryl Trinitrate (GTN) ointment without achieving symptomatic relief. Furthermore, all included patients complained of chronic constipation for a minimum of 3-6 months. On examination, all patients had a skin tag and PR bleeding indicating chronic fibrosis. Four patients presented with perianal abscess and two patients presented with perianal fistula. Those who had abscess (n=2) were treated with incision and drainage along with Metronidazole 500 mg three times daily for 5 days (n=4) before laser treatment, which took place three weeks later. All patients received prophylactic Ciprofloxacin 400 mg and Metronidazole 500 mg on induction.

Procedure:

All operations are performed as day cases. Patients receive general anaesthesia followed by positioning to lithotomy position. The perineal area is disinfected using Betadine 100mg/ml followed by classical draping. The surgeon uses the hand piece of CO₂ laser machine (CL20 with wavelength of 10 600 nm) utilising a power of 4-6 Watts on 'continuous mode' and adopting a non-touch technique with 2-cm distance from the skin. With the assistance of the red light pointer in the hand piece, the surgeon starts cutting the skin down to the subcutaneous tissue by holding the sentinel skin tag with tissue forceps or tooth forceps. Then, the dissection continues superiorly by the laser, passing the muco-cutaneous junction caudally under the fibrotic fissure. This continues until reaching a healthy anal mucosa then transfixing the proximal end of the mucosa using 3/0 Vicryl suture. Haemostasis of the raw area under the fissure is achieved by defocus technique, making the distance between the hand piece and the skin 3-4 cm.

Operations are done in a well isolated theatre room specialised for laser use. The surgeon, the assistant, the anaesthetist, and the theatre nurses wear protective glasses for the full duration of the procedure.

Prophylactic antibiotics were given for five days post-operatively. The choice of antibiotic was oral Metronidazole 500 mg 8-hourly. The analgesic

regimen involved Diclofenac 50 mg IM once only followed by topical Xylocaine gel (2%) and oral Paracetamol 500mg as required. Patients were advised to apply daily wash with water and cleaning soap and to rest for five days post-operatively. Follow-up was conducted in the outpatient clinic at three days, one and three weeks then one year and two years after surgery.

Results

Table 1. Patient Characteristics

	N=236
Age	42.7 ± 8.8 *
Gender	173:63 (M:F)
Pain	236 (100%)
Bleeding	176 (74.6%)
Constipation	142 (60.2%)
Pruritus	74 (31.4%)
Symptom burden (n from 4)	2.7 ± 0.8 *
	* mean ± standard deviation

Pain scores were registered three days post-operatively on a scale of 1-10, one being the least pain and 10 being the severest pain (Fig 1). 182 patients (77.11%) reported pain scores of 1-2 three days after surgery. 230 (97.45%) patients were healed,

asymptomatic, and able to resume their activities of daily living (ADL) at seven days post-operatively. Figure 1 demonstrates pain scores on day 3 post-operatively.

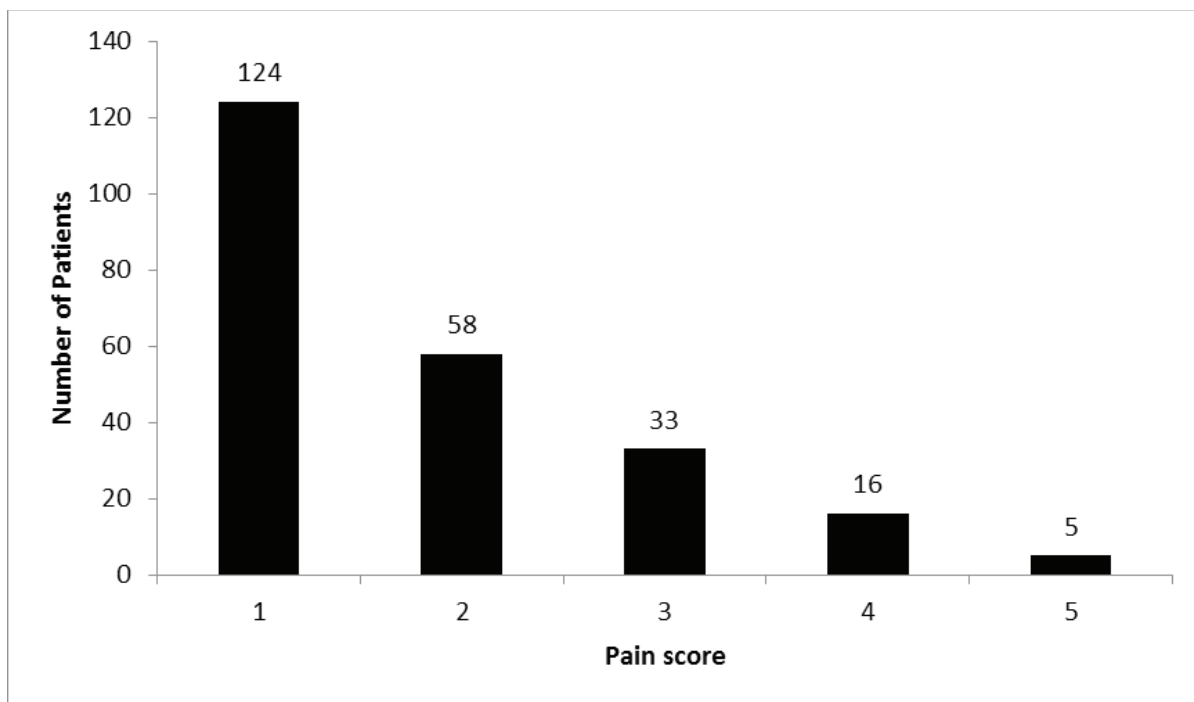


Fig 1. Pain scores on Day 3 post-operatively.

Six patients (2.54%) had persistent mucous discharge and itching after three weeks, with no pain or PR bleeding. Five patients continued to have a minor discharge for 3 months. One patient had persistent mucopurulent discharge and itching for three weeks and continued to have pain with intermittent PR bleeding for three months even after the use of antibiotics with Procto-Glyvenol suppository, Xaluron and GTN ointment. This patient underwent another EUA with biopsy of the ulcer which was reported as tuberculosis (TB) by histopathology and culture. The patient was referred to a TB clinic and received anti-TB regimen for six months. Which resulted in complete healing after three weeks of treatment without residual evidence of any fissuring or grooving.

Within the first year of follow-up, three patients presented with recurrent symptoms of PR bleeding and pain. They were treated conservatively with Ciprofloxacin 500mg twice daily and Metronidazole 500mg three times daily for seven days as they displayed signs of infection on clinical assessment. Additionally, they received Proctoglyvenol suppositories and laxatives. Their symptoms resolved within two weeks of treatment. There were no further recurrence symptoms reported during the second year of follow-up. In general, manometric studies were deemed unnecessary as no patients complained of faecal or gas incontinence. Table 2 demonstrates the follow-up findings.

Table 2. Follow-up findings for 24 months following operation.

	N=236		
	No. of Patients, at 3 weeks	No. of Patients, at 12 months	No. of Patients, at 24 months
Parameter			
Incontinence	0	0	0
Mucous discharge	6 (2.54%)	0	0
Pain	0	3 (1.27%)	0
Itching	6 (2.54%)	0	0
Bleeding	0	3 (1.27%)	0

Discussion

Treatment choices for chronic anal fissure are variable and include both conservative and surgical options depending on the severity of symptoms and the limitation of ADL. While conservative treatment is considered the first line therapy, resistant anal fissures require more invasive treatment. Surgical treatment, although not currently used as a first line, appears to be the most effective treatment. Ebinger et al., concluded that the overall healing rate of LIS is 93.1%^[3]. However, LIS has a considerable disadvantage represented by an incontinence rate of 9.4%^[3].

Minguez et al., conducted a long-term study to follow the efficacy of BT injections^[12]. The results showed that the recurrence rate following BT injection was 41.5%. This shows that the effect of BT is temporary in a significant proportion of patients. Furthermore, the incontinence rate following BT management is marked at 4.1%^[3]. On the other hand, patients treated with GTN report a wide range of side

effects that include headache, anal burning sensation, bleeding, wound infection and incontinence^[13]. Additionally, the effects of GTN take 6-8 weeks to appear while the cure rate does not exceed 60%^[13].

Our study shows that when compared to GTN, BT injection and LIS, laser surgery result in better outcomes. Only three (1.3%) patients had recurrence after 24 months of follow-up. This is less than the recurrence rate of BT injection and LIS which has been reported at 41.5% and 2.5% respectively⁽¹⁴⁾. Adverse effects such as bleeding, pruritus and wound pain were not reported by any patient. However, six patients (2.5%) experienced chronic minimal mucous discharge for three months postoperatively. Furthermore, no patient experienced any episode of incontinence after 12 months of follow-up. Our outcomes compare favourably to existing published data^[11].

These outcomes suggest that laser surgery may have the least risk of incontinence and other

complications compared to other routinely available treatments for chronic anal fissure.

Moreover, this study shows that the use of CO₂ laser in the treatment of chronic anal fissure combines the advantages of conservative, chemical and surgical treatments with a reduced recurrence rate of 1.3%. The advantages include no use of diathermy, minimal levels of post-operative pain, minimal risk of infection, and no risk of incontinence. Hence, we suggest that the use of laser surgery as an alternative to conventional surgery in patients who do not benefit from conservative management is well justified by its low-complication profile.

Conclusion

Treatment methods of anal fissure is controversial and the search for the most effective treatment has been ongoing for years. This study further presents an approach to the treatment of chronic anal fissure by CO₂ laser in one of the largest studies by case volume to date. We have shown that the use of CO₂ laser in surgical treatment of chronic anal fissure offers the advantage of being a minor surgical intervention and avoids the disadvantages of LIS and BT injection in addition to being cost effective. In combination with previously published literature, this study shows that laser therapy warrants serious consideration for routine inclusion as an option available to patients in treating this condition, particularly in patients who do not benefit from less invasive treatment.

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Ethics (IRB) statement: Ethical approval was granted by the local hospital board. No unique patient identifiers were gathered. The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki.

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Association between Hypertension with the Incidence of Type 2 Diabetes Mellitus in South Kalimantan

(Data Analysis of Indonesia Family Life Survey 5 Year 2014)

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Abstract

Background: South Kalimantan is the 3rd highest prevalence in Kalimantan, which is 1.8% and there is an increase in prevalence compared to the results of the 2013 Riskesdas study of 1, 4% (an increase of 0.4%). The purpose of this study was to know the association between hypertension and the incidence of diabetes mellitus. This study used a cross sectional design. The sample was 1,423. The analysis carried out was univariate, bivariate and multivariate.

Finding: Multivariate analysis showed hypertension is risk factor to experience diabetes mellitus (p-value 0.011). Hypertension has a 1.46 times greater risk of developing diabetes mellitus.

Conclusion: It is hoped that this research will serve as input for determining policy directions to educate the public so that they can prevent and control blood pressure levels so as not to cause hypertension which can lead to diabetes mellitus.

Keywords: Hypertension; IFLS-5; South Kalimantan; Type 2 Diabetes Mellitus.

Introduction

In the past two decades there has been a significant shift from communicable disease problems to noncommunicable disease threats not only around the world but also in Indonesia. NCDs tend to keep growing and have been a threat from an early age. The main non-communicable diseases include diabetes mellitus, high blood pressure, cancer, and chronic obstructive pulmonary disease (COPD)¹.

Diabetes Mellitus (DM) is a disease in which the patient cannot control the level of glucose in his blood. The pancreas gland in a healthy body functions to easily release the hormone insulin which is in charge of transporting sugar through the blood to muscles and other tissues for energy supplies. While DM is a metabolic disorder in the distribution of sugar in the body².

Based on data from the World Health Organization (WHO), the number of people with diabetes has increased from 108 million in 1980 to 422 million in 2014 globally. The prevalence of diabetes in adults over 18 years of age increased from 4.7% in 1980 to 8.5% in 2014³.

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The results of Riskesdas 2018, the prevalence of being diagnosed by doctors aged 15 years is 2% and in the Kalimantan area, South Kalimantan is the 3rd highest prevalence after North Kalimantan and East Kalimantan which is 1.8% and there is an increase in prevalence compared to the results of the 2013 Riskesdas study of 1.4% (0.4% increase)⁴.

In addition to insulin resistance, which acts as a pathogenesis factor for DM, there are many other factors that play a role in interfering with insulin hormone metabolism in the blood, thereby increasing the risk of DM⁵. One of the factors that play a role is hypertension. Hypertension is a factor that causes diabetes mellitus. Hypertension and DM are health problems that are closely related and both need to be handled carefully. Death caused by diabetes and cardiovascular disease, one of the factors that play a role in increasing both diseases is hypertension⁶.

Based on the above background, the researcher will conduct an analysis to determine the effect of hypertension on the incidence of diabetes mellitus in South Kalimantan.

Materials and Methods

This research is an analytical quantitative observation with a cross sectional design. Cross sectional studies study the relationship between risk factors and outcomes in the form of a particular disease or health status, all of which refer to the same time point. This study can assess the prevalence of a disease^{7,8}.

Researchers took data from secondary data sources, namely IFLS-5 2014. IFLS is an ongoing longitudinal survey in Indonesia. This survey has been reviewed and approved by Institutional Review Boards in the United States and in Indonesia at Gadjah Mada University for IFLS3, IFLS4 and IFLS5⁹. This research was conducted in June-August 2021.

The researcher determines the research sample by counting from the population aged 15 years in South Kalimantan Province who are the respondents of the Indonesia Family Life Survey-5. The inclusion criteria in this study were respondents from South Kalimantan or long-standing domicile in South Kalimantan. The exclusion criteria were incomplete data. The minimum sample size in this study uses the sample size formula as follows⁷:

$$n = \frac{(z_{1-\frac{\alpha}{2}}\sqrt{2P(1-P)} + z_{1-\beta}\sqrt{p_1(1-p_1) + p_2(1-p_2)})^2}{(p_1 - p_2)^2}$$

n = minimum number of samples

$z_{1-\frac{\alpha}{2}}$ = z value based on the degree of confidence 95%=1,96

$z_{1-\beta}$ = z value based on test power 80%= 0,84

p_1 = proportion of type 2 diabetes mellitus in people who have hypertension

p_2 = proportion of type 2 diabetes mellitus in people who do not have hypertension

$$P = \frac{p_1 + p_2}{2}$$

Calculation using proportion based on hypertension factor. This sample research is 1,423.

Researchers conducted data analysis through three stages, namely: univariate analysis, simple relationship analysis (bivariate), and multivariate analysis with the help of data analysis program applications. The results of data analysis are presented in the form of tables.

Results

In this study, most of the respondents had diabetes mellitus by 19.75%, hypertension by 28.39%, age 35 years by 51.37%, lack of physical activity by 33.66%, smoking status by 27.97% , not working by 18.90%, women by 46.24%, less consumption of vegetables and fruit by 64.79%, and abnormal nutrition by 44.83% (Table 1).

Table 1. Proportion of Independent and Confounding Dependent Variables

Variable	Total	
	N=1,423	(%)
Diabetes Mellitus Type 2 (Dependent)		
Diabetes Mellitus	281	19.75
No Diabetes Mellitus	1,142	80.25
Hypertension (Independent)		
Yes	404	28.39
No	1,019	71.61
Covariate		
Age		
≥35 years	731	51.37
< 35years	692	48.63
Lack of Physical Activity		
Yes	479	33.66
No	944	66.34
Smoker Status		
Yes	398	27.97
No	1,025	72.03
Job Status		
Does not work	269	18.90
Work	1,154	81.10
Gender		
Women	658	46.24
Men	765	53.76
Less Consumption of Vegetables and Fruits		
Yes	922	64.79
No	501	35.21
Nutritional Status		
Abnormal	638	44.83
Normal	785	55.17

In this study, there was a relationship between hypertension, age, and employment status with diabetes mellitus. However, there was no relationship between gender, smoking status, lack of physical activity, less consumption of vegetables and fruit, and nutritional status with diabetes mellitus (Table 2).

Table 2. Association of Hypertension and Confounding Variables with Diabetes Mellitus

Variabel	DM				POR	95% CI	p-value
	Yes		No				
	n	%	n	%			
Hypertension (Independent)							
Yes	108	38.43	296	25.92	1.78	1.341-2.367	<0.0001
No	173	61.57	846	74.08	ref		
Covariate Variable							
Age							
≥35 years	181	64.41	550	48.16	1.95	1.475-2.581	<0.0001
< 35years	100	35.59	592	51.84	ref		
Lack of Physical Activity							
Yes	160	56.94	605	52.98	1.17	0.895-1.542	0.233
No	121	43.06	537	47.02	ref		
Smoker Status							
Yes	65	23.13	204	17.86	1.38	0.992-1.914	0.043
No	216	76.87	938	82.14	ref		
Job Status							
Does not work	68	24.20	330	28.90	0.79	0.572-1.070	0.116

Cont... Table 2. Association of Hypertension and Confounding Variables with Diabetes Mellitus

Variabel	DM				POR	95% CI	p-value
	Yes		No				
	n	%	n	%			
Work	213	75.80	812	71.10	ref		
Gender							
Women	107	38.08	372	32.57	1.27	0.960-1.682	0.080
Men	174	61.92	770	67.43	ref		
Less Consumption of Vegetables and Fruits							
Yes	189	67.26	733	64.19	1.15	0.862-1.530	0.334
No	92	32.74	409	35.81	ref		
Nutritional Status							
Abnormal	131	20.53	507	79.47	1.10	0.834-1.433	0.502
Normal	150	19.11	635	80.89	ref		

In the final model of multivariate analysis using logistic regression test, it can be seen that hypertension is a risk factor for the incidence of diabetes mellitus. The results of the analysis show that people with hypertension have a 1.46 times greater risk of developing diabetes mellitus (Table 3).

Table 3. Final Model Multivariate Analysis

Variable	POR	95% CI	P-Value
Hypertension	1.46	1.092-1.961	0.011
Age	1.72	1.292-2.297	<0.0001

Note: Adjusted by age

Discussion

The objective of this study is to know association of hypertension with the incidence of type 2 diabetes mellitus through a cross-sectional design. The use of design in this study has weaknesses due to temporal ambiguity such that the incidence of diabetes mellitus and its predictive variables may precede each other, giving rise to unclear aspects of the concept of causality. Furthermore, the causal model that this research design uses could not provide the most accurate picture to predict diabetes mellitus because it uses a cross-sectional design, so in this study it is possible that someone with diabetes mellitus may be at risk before the factor. However, this design is suitable for defining risk factors as a basis and reference for future research, as it is more efficient and effective than other designs.

In this study, it was found that there was a significant relationship between hypertension and the incidence of diabetes mellitus. In this study, it can be seen that there is a tendency that those aged 35 years who have hypertension have more diabetes than those aged <35 years.

The prevalence of DM with hypertension in Indonesia tended to increase with age. Most NCDs are more likely to have a positive linear association with aging due to metabolic pathways or biological changes during aging that can be positively or negatively influenced by lifestyle risk factors such as diet, smoking, physical activity and alcohol consumption¹⁰.

Hypertension is a factor that causes diabetes mellitus. Hypertension and DM are health problems that are closely related and both need to be handled carefully. Death caused by diabetes and cardiovascular disease, one of the factors that play a role in increasing both diseases is hypertension⁶. Based on JNC*VIII, blood pressure is expected to be controlled based on

the following populations, namely 60 years < 140/90 mmHg, > 60 years < 150/mmHg, chronic kidney disease and diabetes < 140/90 mmHg¹¹.

Hypertension has been shown to cause microvascular dysfunction, which can lead to the pathophysiology of the development of diabetes. Endothelial dysfunction associated with insulin resistance is also closely associated with hypertension, and endothelial dysfunction biomarkers were found to be an independent predictor of type 2 diabetes^{12,13}. Insulin resistance is a residual for hypertension, type 2 diabetes and cardiovascular disease. Thus there could be another potential relationship between hypertension and type 2 diabetes¹³.

According to Marewa (2015) high blood pressure (hypertension) is one of the factors that can cause beta cell damage due to insulin resistance¹⁴. Chou's research (2015) states that people with hypertension have a 1.60 times greater risk of developing DM¹⁵. Research by Zou Disha et al (2017) states that people with hypertension will have a 1.61 greater risk of developing DM¹⁶. Insulin resistance can be detected for several years in advance onset of T2D. It is associated with obesity, especially central obesity, but may be present in lean individuals with hypertension¹⁷.

Hypertension occurs in two thirds of DM patients, and its development coincides with the occurrence of hyperglycemia. The mechanism underlying the relationship these include insulin resistance in nitric-oxide pathways; stimulatory effect of hyperinsulinemia on sympathetic drive, smooth muscle growth, sodium-fluid retention; and the excitatory effect of hyperglycemia on the renin-angiotensin-aldosterone system¹⁸. Diabetes mellitus and hypertension are among the most common diseases and cardiovascular risk factors, respectively, worldwide, and their frequency increases with age. Elevated blood pressure (BP) values are a common finding in patients with type 2 diabetes mellitus (T2D)

and thought to reflect, at least in part, the impact of underlying insulin resistance on blood vessels and kidneys. In contrast, accumulated evidence suggests that carbohydrate metabolism disorders are more common in hypertensive individuals, thus suggesting that the pathogenic relationship between diabetes mellitus and hypertension is actually two-way¹⁹.

Hypertension usually occurs when blood pressure exceeds 140 mmHg (systolic) and 8590 mmHg (diastolic). The effect of high blood pressure on the incidence of DM is caused by the thickening of the arteries, which causes the diameter of the blood vessels. This interrupts the process of transporting glucose out of the blood. The higher prevalence of high blood pressure in diabetics requires special treatment for diabetics who also have high blood pressure. Management is controlling blood pressure to keep it within normal limits (below 120/80 mmHg) through a healthy lifestyle²⁰.

There are several factors that contribute to a greater coexistence of DM and arterial hypertension. The incidence of obesity in children and adolescents in industrialized countries has exploded in recent decades, with a threatening parallel increase in the incidence of arterial hypertension and DM^{21,22}.

High blood pressure is a powerful independent risk factor for cardiovascular disease and chronic kidney disease (CKD), and when hypertension is associated with DM, the risk increases even further^{23,24}. Although there is controversy about the optimal goal to reduce blood pressure^{24,25,26}, it remains clear that constant control of blood pressure in patients with DM is important to prevent and delay micro and macrovascular complications^{27,28}.

This study was conducted cross-sectional so it cannot ensure a definite causal relationship between the independent and dependent variables. However, in this study, the hypertension variable can be assumed

to occur earlier than the incidence of diabetes mellitus. Diabetes mellitus can occur due to the influence of hypertension or not a person's hypertension plus the age variable which further encourages the influence of hypertension to occur in diabetes mellitus.

Conclusion

Most of the respondents had diabetes mellitus and had hypertension. Age over 35 years is more likely to have hypertension than age less than 35 years. Hypertension is a risk factor for diabetes mellitus. Hypertension has a 1.46 times greater risk of developing diabetes. It is hoped that this research will serve as input for determining policy directions to educate the public so that they can prevent and control blood pressure levels so as not to cause hypertension which can lead to diabetes mellitus.

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Conflict of Interest: Nil

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Self Perceived Health Status, Medical Care Seeking Behaviour And The Preference of Telemedicine among Non-Communicable Disease Patients During the COVID-19 Pandemic Lockdown Period

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Abstract

Background: The coronavirus disease (COVID-19) is a highly transmittable and pathogenic viral infection caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV2). **Methodology:** A cross-sectional study was done to ascertain the self-perceived health status, medical care seeking behaviour and the preference of telemedicine among non communicable disease (NCD) patients who did not come for their periodic review during the COVID lockdown period in Kerala state of India. **Results:** The mean age of the study population was 62.42±12.8 years and the mean duration of the non communicable disease (NCD) were 6.6±7.8 years. 49.1% of the study participants did not come for review to the hospital due to fear of contracting COVID-19 and 35.6% due to lack of conveyance. On analyzing the association between the fear of COVID-19 with various factors, age was found to be of significant association **Conclusion:** The study showed that majority of the patients did not come for review to the hospital due to fear of contracting COVID-19 and owing to lack of conveyance during lockdown period. Patients who opted for telemedicine 60% showed willingness to continue with telemedicine in future.

Key words: COVID-19, Telemedicine, Non communicable disease, Pandemic, Lockdown

Introduction

Noncommunicable diseases (NCDs) kill 41 million people each year, equivalent to 71% of

all deaths globally. ¹. non-communicable diseases (NCD) like diabetes, hypertension, coronary heart diseases are the leading cause of death and people living in low and lower middle income countries (LLMICs) are 1.5 times more likely to die prematurely from these conditions than those living in high-income countries. ². Thankappan KR et al ³ estimated prevalence of hypertension and diabetes in Kerala were found to be 36.2% and 20.6%. Care-seeking behavior has been found to have strong influences on health outcomes among individuals with chronic diseases ⁴. In a study

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done in Kerala in 2017 by Vijayakumar G et al⁵, the prevalence of chronic kidney disease (CKD) among type 2 Diabetics was found to be 27.3%, 45.3% and 50% in 40-50 years age group, 50-60 and 60-70 age groups, respectively. The prevalence of bronchial asthma in Kerala is estimated to be in 4.45%⁶ and that of COPD was found to be 4.2%⁷.

The COVID-19 is a highly transmittable and pathogenic viral infection caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which emerged in Wuhan, China in December 2019 and was declared a disease of Public Health Emergency of International concern on 30th January 2020. India reported the first case of COVID 19 from a student who returned from Wuhan to Thrissur district of Kerala state. The state government declared an emergency on 4th February which was later scaled back on 8th February as the threat of community outbreak and surge in cases was not expected to rise but the state of high alert was reinstated after increase in number of cases mainly imported from Gulf countries and Italy. 23rd March the state government imposed a lockdown 1 day prior to the National announcement. Since March 8th when the high alert was reinstated there has been a substantial decrease in the number of NCD in-patients and out patients in our hospital. There is mounting evidence that in COVID-19 patients the morbidity and mortality are higher among geriatric patients and people with preexisting NCDs^{8,9}. Utilization of telemedicine and telecare could protect these vulnerable groups from coming into contact with COVID-19 patients especially in hospital settings and journey in public transport. Elevated levels of patient and health professional satisfaction have been reported in urban, rural and remote areas when consulting with a specialist from a tertiary teaching institution¹⁰. Due to the fear of COVID-19 we expected the patients to be more receptive and acquiescent to telemedicine and will continue to utilize it in future after the pandemic.

Materials and Methods:

Study design – Cross sectional

Study Period – April – May 2020

Study setting – Jubilee Mission Medical College and Research Institute, Thrissur, Kerala state

Study participants

Inclusion Criteria – All patients diagnosed of Diabetes mellitus, Hypertension, Coronary artery disease, Bronchial Asthma, COPD, stroke admitted in the hospital between 1st November 2019 and March 7th 2020 were included in the study

Exclusion criteria - All patients diagnosed of Diabetes mellitus, Hypertension, Coronary artery disease, Bronchial Asthma, COPD and Stroke admitted in the hospital between 1st November 2019 and March 7th 2020 but came for review during the first lockdown period that is from 8th March 2020 to 20th April 2020 were excluded.

Sample size –The total number of NCD patients admitted in the institution during November 2019 to February 2020 and did not come for review during the first lock down period was 3888 (N). A Pilot study of 30 patients was done and the non-responder rate was found to be 25%. The sample size was calculated to be 569 rounded off to 600 using the Slovincs formula

$$n = N / (1 + N e^2) \text{ where}$$

$$N = 3888$$

$$e = \text{margin of error } 5\%.$$

Taking into consideration the non-response rate of 25% we interviewed 750 patients so as to attain the calculated sample size of 600.

Sampling Method - The patient record was arranged in alphabetical order. The study participants were randomly selected using a computer generated

random number table.

Study tools and data collection

The information regarding the number of all patients diagnosed with Diabetes mellitus, Hypertension, Stroke, Coronary artery disease, COPD, Bronchial Asthma and Chronic Kidney Disease admitted in our institution between November 1st 2019 and February 29 2020 was collected from medical records department using ICD codes. These patients would then be crosschecked, using the in-house software (muziris), with patients who had come for review between March 8th and April 20th 2020 to capture those who did not turn up for review to the hospital. The patients were interviewed telephonically, after obtaining an verbal informed consent, using a semi structured questionnaire (**validity**) regarding their current state of health, medical care seeking behaviour, reasons for not coming for review and their preference of telemedicine for their periodic consultation. Data was analysed using SPSS version 25.

Results

Of the 750 patients who were contacted over telephone only 638 responded ie; a non-responder rate of 14.9%. The reasons of non-response included wrongly entered mobile numbers in medical records, unwilling to be interviewed, incomprehension of the questions asked through telephone and migration. The mean age of study population is 62.42 ± 12.8 years. 638 study participants who had not turned up for their review in our hospital, majority 328 (51.4%) were in the age group 61-80 years. 397(62.2%) were males, 241(37.8%) were females and 468(73.4%) participants were unemployed. The socio-demographic profile of the study participants is depicted in Table 1. The mean duration of the NCD was 6.6 ± 7.8 years. Majority, 237(37.1%) had been diagnosed with disease in the past 5 years. Among those NCD patients who had not come for regular follow up to the hospital, 21.6% was

having coronary heart disease, 8% diabetes, 5% each having hypertension and COPD/Asthma. 0.6% of the study participants suffered from more than three comorbidities (DM+HTN+CHD+Stroke). (fig1)

Substantiable number of study participants 85(13.3%) gave history of new symptoms during this period. Generalized weakness (2.4%) and breathing difficulty (2.2%) were the most common complaints reported. 612(96%) study participants were taking their prescribed medicines regularly, while 26(4%) were not taking their medicines regularly during this period. Among those who were regularly taking medications, majority, 413(64.7%) were taking medications according to the previous prescriptions from our hospital, 159(24.9%) were consulting a nearby doctor and 40(6.3%) were using telemedicine for consultation and continuing their regular medications. Among those who were not taking their prescribed medicines regularly (n=26), 4(14.3%) practiced self-medication, 6(21.4%) resorted to Ayurveda/alternate system of medicine and 14(57.1%) did not take any modality of treatment.

It is evident from the above table that majority, 313(49.1%) of the study participants did not come for review to the hospital due to fear of contracting COVID-19 and 227(35.6%) due to lack of conveyance during lockdown period. (Table 2) On analyzing the association between the fear of COVID-19 with various factors, age was found to be of significant association, with 175(54.9%) in the age group 61-80 years having fear of contracting COVID -19. Majority of the study participants, 543(85.1%) preferred to return to our hospital for their regular follow up visits as soon as the lockdown is lifted, while 95(14.9%) preferred to continue with the current treatment which they adopted during the period. Of the 40 subjects who opted for telemedicine 24(60%) showed willingness to continue with telemedicine in future. Among the various socio-demographic factors age

was found to be the only significant factor in taking regular medication. The elderly were found to be more compliant with medication. On analyzing the association between the method of treatment adopted during lockdown period and the socio-demographic variables, none of the variables were found to have significant association.(table 3)

In our study, it was found that among patients who were continuing their treatment, those who

had diabetes mellitus and hypertension, preferred to continue purchasing medications using previous prescriptions from our hospital rather than consulting a nearby practitioner or using telemedicine, and this difference was statistically significant. Those who were suffering from less than three comorbidities also preferred using previous prescriptions to continue treatment during the lockdown period. (Table 4).

Table 1: Socio-demographic profile of the study participants

Variables	Frequency(n)	Percentage %
Age		
<40	32	5.0
41-60	234	36.7
61-80	328	51.4
>80	44	6.9
Sex		
Male	397	62.2
Female	241	37.8
Distance from hospital		
≤ 10 km	135	21.2
11-30 km	229	35.9
31-50 km	161	25.2
51-80 km	99	15.5
>80 km	14	2.2
Occupation		
Employed	170	26.6
Unemployed	468	73.4
Education		
Illiterate	26	4.1
Below Secondary	219	34.3
Secondary	278	43.6
Plus Two	51	8.0
Degree and Above	64	10.0

Cont... Table 1: Socio-demographic profile of the study participants

Socio-Economic status		
BPL (Below Poverty Line)	199	31.2
APL (Above Poverty Line)	439	68.8
Marital Status		
Married	560	87.8
Unmarried	27	4.2
Widow	51	8.0

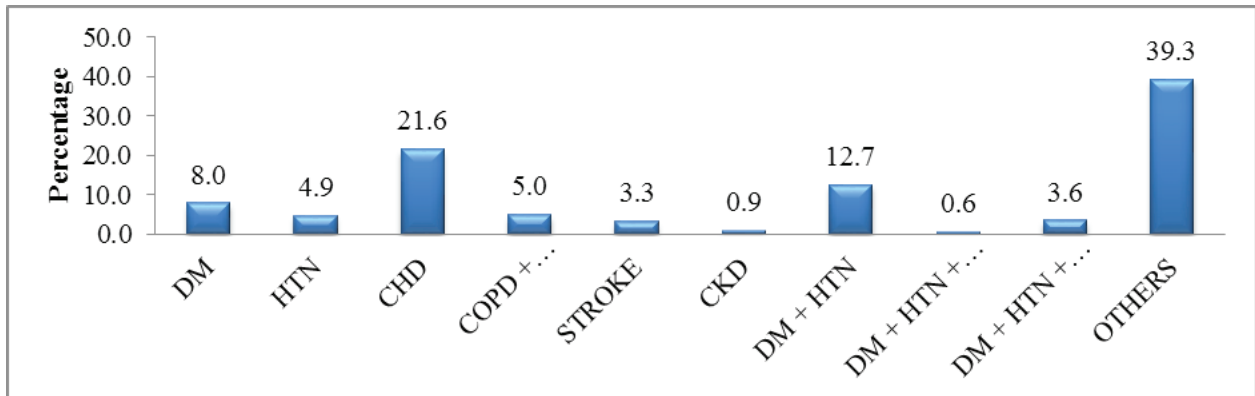


Fig1: Distribution of study participants according to their morbidity status

Table 2 Reason for not coming for regular follow up to the hospital during lockdown

Reason for not coming for regular follow up visit	Frequency(n)	Percentage(%)
No conveyance	227	35.6
Fear of COVID 19	313	49.1
Poor economic status	34	5.3
Lack of caretakers to accompany	33	5.2
Others	31	4.8
Total	638	100

Table 3 Association between socio-demographic variables and the method of treatment adopted during lockdown

Variables	Modality of treatment			Total	p Value
	Old prescription n (%)	Visited Nearby doctor n (%)	Tele consultation n (%)		
Age					
<40	13 (50.0)	11 (42.3)	2 (7.7)	26	0.471
41-60	159 (71.0)	52 (23.2)	13 (5.8)	224	
61-80	211 (66.1)	86 (27.0)	22 (6.9)	319	
>80	30 (69.8)	10 (23.3)	3 (7.0)	43	
Gender					
Male	267 (69.5)	95 (24.7)	22 (5.7)	384	0.320
Female	146 (64.0)	64 (28.1)	18 (7.9)	228	
SES					
BPL	123 (64.1)	59 (30.7)	10 (5.2)	192	0.160
APL	290 (69.0)	100 (23.8)	30 (7.1)	420	
Hospital Distance					
≤ 10 km	96 (74.4)	26 (20.2)	7 (5.4)	129	0.080
11-30 km	127 (59.6)	72 (33.8)	14 (6.6)	213	
31-50 km	109 (68.6)	36 (22.6)	14 (8.8)	159	
51-80 km	72 (74.2)	21 (21.6)	4 (4.1)	97	
>80 km	9 (64.3)	4 (28.6)	1 (7.1)	14	

Table 4 Association between the type of disease and preference of treatment during lockdown period

NCD	Old prescription n (%)	Visited Nearby doctor n (%)	Tele consultation n (%)	Total	p Value
Diabetes mellitus					
Present	192 (61.3)	99 (31.6)	22 (7.0)	313	0.003
Absent	221 (73.9)	60 (20.1)	18 (6.0)	299	
Hypertension					
Present	171 (62.0)	88 (31.9)	17 (6.2)	276	0.010
Absent	242 (72.0)	71 (21.1)	23 (6.8)	336	
Coronary Artery Disease					
Present	226 (71.3)	74 (23.3)	17 (5.4)	317	0.102
Absent	187 (63.4)	85 (28.8)	23 (7.8)	295	
Asthma/COPD					
Present	369(68.3)	137(25.4)	34(6.3)	540	0.46
Absent	44(61.1)	22(30.6)	6(8.3)	72	
Stroke					
Present	66 (74.2)	18 (20.2)	5 (5.6)	89	0.341
Absent	347 (66.3)	141 (27.0)	35 (6.7)	523	
Chronic Kidney Disease					
Present	43 (64.2)	21 (31.3)	3 (4.5)	67	0.486
Absent	370 (67.9)	138 (25.3)	37 (6.8)	545	
Number of Co-morbidities					
<3	319 (69.5)	107 (23.3)	33 (7.2)	459	0.025
≥3	94 (61.4)	52 (34.0)	7 (4.6)	153	

Discussion

To the best of our understanding, there is paucity of studies on Self perceived health status, medical care seeking behavior and the preference of telemedicine among NCD patients during the COVID 19 Pandemic and this study has major public health importance as these patients have a bad prognosis. Healthcare systems in LLMIC countries are especially challenged because of the effect of pandemic will have on the already weak health systems in these countries.^{11,12,13}

In a survey done by World Health Organization on rapid assessment of service delivery for NCDs during the COVID-19 pandemic, found that the pandemic has dramatically curtailed the provision of health services for these diseases and poorer countries were the most likely to report disrupted services and nearly 94% of responding countries had reassigned health ministry staff from work on NCDs to dealing with the pandemic. In rural India, 30% fewer cardiac emergencies reached health facilities in March 2020 than the previous year. Hypertension treatment has been partially or completely disrupted in 53% of the countries surveyed, diabetes treatment in 49%, cancer treatment in 42%, and cardiovascular emergency responses in 31%. In the survey WHO's director general stated that many people who need treatment for diseases like cancer, cardiovascular disease, and diabetes mellitus have not been receiving the health services and medicines they need since the pandemic began. It's vital that countries find innovative ways to ensure that essential services for NCDs continue, even as they fight covid-19^{14,15}. The impact of COVID-19 measures on NCDs is multifaceted. Social distancing or quarantine can lead to poor management of NCD behavioral risk factors, including unhealthy diet, physical inactivity, tobacco and substance abuse¹⁶. Evidence from this and previous pandemics suggests that without proper management, chronic conditions can worsen

due to stressful situations resulting from social and travel restrictions, insecure economic situations, and changes in normal health behaviors¹⁸.

In a study done by K Yuvraj et al¹⁷ on the prevalence of medication adherence and its associated factors among patients with NCD in rural Puducherry, South India, found that majority of the study participants (42.7%) belonged to elderly age group, and 70% were unemployed which is consistent with our finding. Kerala is the south Indian state with a high burden of Cardio-vascular disease¹⁹. A study done by Krishnan et al in 2012 established the prevalence of coronary artery disease in Kerala had increased nearly 3 times since 1991 without any rural urban difference²⁰. Although the number of COVID-19 cases and deaths is lower in LLMIC countries compared to high-income countries, we predict a potential shift towards a higher mortality rate in these countries due to poorer control of NCDs, despite the corresponding younger demographic structure²¹.

In our study 96% study participants were taking their prescribed medicines regularly, during lockdown period. Hitherto no studies have reported the adherence to medications of NCD patients during lockdown period. A study done by K Yuvraj et al¹⁸ on the proportion of individuals adherent to medication and its associated factors among patients with NCD reported that almost one-third of the study participants were non-adherent. Patients in the elderly age group and those of the female gender were found to be the determinants of non-adherence. In the face of the current pandemic, many countries had to make tough decisions in order to safeguard its people. These decisions include lockdowns and restrictions on people's movement and mobilization of health personnel to the front-line of the COVID-19 infection. This may be a major problem for patients with chronic diseases requiring revisits, follow-ups, check-ups and prescription refills since access to health facilities

and their attending physicians may be denied. As the pandemic continues to extend, the widespread demand on physicians has led to the postponement of routine patient reviews and hospital visits for patients with chronic diseases. Patients who would have required changes to their medications have been left with old prescriptions to refill and patients who required minor procedures may require medications to stabilize their condition until the procedure can be carried out²². In a study done by Hans Henri P Kluge et al conclude that a streamlined response to COVID-19 in the context of NCDs is important to optimise public health outcomes and reduce the impacts of this pandemic on individuals, vulnerable groups, key workers, and society²³.

Conclusion

The study showed that majority of the patients did not come for review to the hospital due to fear of contracting COVID-19 and due to lack of conveyance during lockdown period. Substantiable number of study participants gave history of new symptoms during this period. Majority of study participants were taking their prescribed medicines regularly, while a small proportion was not taking their medicines regularly. Based on these findings we recommend that patients with NCD have to be made aware of the importance and benefits of telemedicine during their first visit in the outpatient department in order to increase its utilization. This has to be conveyed by the treating physician and later on reinforced at the registration counter and the pharmacy. During teleconsultation an appointment should be given for the next session. Patients should be reminded through SMS 1 day before about the scheduled appointment. Those patients who were continuing with the previous prescriptions must be motivated to adopt teleconsultation before taking medications. Diabetics and hypertensive patients should be encouraged and educated to self-monitor their blood sugar and blood

pressure the day before the appointment.

Acknowledgement: Nil

Conflict of Interest : Nil

Ethical Clearance: Not taken because ethical committee couldn't assemble due to lockdown and at that time online mode was not popular. we have taken informed verbal consent from all the participants.

Source of Funding: Nil

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The Effect of Banana and Strawberry Juice in Increasing Hemoglobin Levels in Pregnant Women with Anemia

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Abstract

Background: Herbal therapy for food resources with high vitamin C dose is in demand by the public due to its safety natural materials and easy accessibility. When there is vitamin C deficiency, then the amount of absorbed iron will be reduced and lead to anemia. Bananas and strawberries are fruits that have high nutritional content. Bananas contain vitamin B6, vitamin C, potassium, fiber, phosphorus, protein, fat, calories, iron, folic acid and water, while strawberries contain anthocyanins, ellagic acid, vitamin C, vitamin A, vitamin B1 and minerals. Pregnant women are encouraged to eat healthy and nutritious food, including those that contain vitamin C. Adequate Vitamin C intake will reduce the pregnancy complications such as anemia, pre-eclampsia, and having low weight baby.

Objective: The purpose of this study was to determine the effect of banana and strawberry juice in increasing Hemoglobin levels in pregnant women with anemia.

Methodology: The type of research is analytic. The research was carried out at Rose Health Center, Bogor City. The number of participants was 16 pregnant women with anemia with one pre-test and post-test group and purposive sampling. The instrument used was an observation sheet and data analysis used a hypothesis test (Paired T-test) with SPSS 22.

Result: Before drinking banana strawberry juice, there were 11 (68.8%) pregnant women experienced moderate anemia and 2 (12.5%) pregnant women experienced heavy anemia. After intervention with banana strawberry juice, only 1 (6.3%) participant encountered heavy anemia while 12 (75%) participants had mild anemia.

Conclusion: There was a significant effect of drinking banana and strawberry juice in increasing Hemoglobin levels in pregnant women with anemia at Rose Health Center, Bogor City.

Keywords: anemia, banana strawberry, hemoglobin, pregnant women

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Introduction

According to WHO (*World Health Organization*), the prevalence of anemia in pregnant women worldwide is 41.8%. The prevalence of anemia in pregnant women is estimated 48.2% in Asia, 57.1% in Africa, 24.1% in America and 25.1% in

Europe.¹ The prevalence of iron deficiency anemia in Indonesia according to Basic Health Research is 31.7%.² Changes in the immune system that occur during pregnancy can make pregnant women more susceptible to bacterial and virus infection and more at risk of experiencing other severe diseases. In addition, high fever that occurs due to viral infection in the first trimester of pregnancy can increase the risk of birth defects in children.³

Pregnant women require higher oxygen level. This condition triggers an increase in erythropoietin production. As a result, plasma volume increases and red blood cells level (erythrocytes) increase. However, the increase in plasma volume occurs in a greater proportion when compared to the increase in erythrocytes so that there is a decrease in hemoglobin concentration due to hemodilution.⁴ The cause of anemia in pregnancy is due to the threefold increase in iron requirements for fetal growth and development. needs of pregnant women. During pregnancy, the mass of red blood cells increases by about 18%, so that sufficient iron is needed to form red blood cells.⁵

Herbal therapy that contains vitamin C is usually in great demand by the public, apart from its safety because it is made from natural ingredients. If there is a lack of vitamin C, the amount of absorbed iron will be reduced and lead to anemia.⁶

According to Wiyani (2018), banana is one of fruits that contains vitamin B6, vitamin C, potassium, fiber, phosphorus, protein, fat, calories, iron, folic acid and water which can also increase hemoglobin levels in pregnant women.⁷

Strawberry fruit also has high nutritional contents. Strawberries contain phytochemical compounds, namely: anthocyanins, ellagic acid, vitamin C, vitamin A, vitamin B1 and minerals. One piece of banana consists of 100 grams vitamin C and one piece of strawberry has 60 grams vitamin C.⁶

The purpose of this study was to determine the effect of drinking banana and strawberry juice in increasing Hemoglobin levels in pregnant women with anemia.

Materials and Methods

The research was conducted from January to September 2020 at Rose Health Center, Bogor City. The number of samples in this study were 16 participants obtained by purposive sampling technique. The inclusion criteria in this study were pregnant women with moderate anemia, pregnant women without comorbidities, pregnant women willing to be participants, and regular visitors of Rose Health Center, Bogor City.

Researchers asked the participants to sign the informed consent prior to the study. Participants' hemoglobin level was assessed using the Easy Touch tool before drinking banana and strawberry juice. Participants were given bananas and strawberries for two weeks. Participants had to drink the juice for two times in a week. Each participant was given 2 banana combs and 1 kg of strawberries every week along with the recipe for making banana and strawberry juice: mix 200 grams strawberries, 2 bananas and 400 ml water. In 100 grams of banana (1 fruit) contains 73.8 g of water, 0.5 mg of iron, 9 mg of vitamin C, 0.05 mg of vitamin B1, 0.8 mg of vitamin B2, 0.1 mg of vitamin B6 and 28 mg of phosphorus.⁸ While in 100 grams of strawberries contain 58.8 mg vitamin C.⁹

Statistical analysis used Sample Paired t-Test. The level of significance obtained $p < 0.05$.

Results

Hypothesis testing in this study was determined based on the results of the data normality test. The test showed that the $p\text{-value} = 0.00$, which means the data in this study has an abnormal distribution. So that the data analysis in this study used a test non-parametric with the help of SPSS 22.

Table 1. Frequency distribution of Hemoglobin levels in pregnant women with anemia before drinking banana and strawberry juice at Health Center Rose, Bogor City

PreTest	Frequency	Percentage (%)
Mild	3	18.8%
Moderate	11	68.8%
Severe	2	12.5%
Total	16	100 %

Based on Table 1, out of 16 participants, 11 participants (68.8%) experienced moderate anemia and 2 participants (12.5%) had severe anemia.

Table 2. Frequency distribution of Hemoglobin Levels in Pregnant Women with Anemia After Consumption of Banana and Strawberry Juice at Health Center Rose, Bogor City

PostTest	Frequency	Percentage (%)
Mild	12	75.0%
Moderate	3	18.8%
Severe	1	6.3%
Total	16	100%

Table 2 showed that out of 16 participants, 3 participants (18.8%) experienced moderate anemia while 1 participant (6.3%) had severe anemia after drinking banana and strawberry juice at Rose Health Center, Bogor City.

Table 3. The Difference for Before and After Drinking Banana and Strawberry Juice at Rose Health Center, Bogor City

Variable	Mean	N	P-value
Pre-test	8.544	16	0.000
Post-test	10.044	16	0.000

Based on Table 3, the mean for pre-test group (before drinking banana strawberry juice) was 8.544 while the mean for post-test group (after drinking banana strawberry juice) was 10.044. The obtained *p-value* = 0.000, which means there was a significant effect of drinking banana and strawberry juice in increasing Hemoglobin levels in pregnant women

with anemia at Rose Health Center, Bogor City.

Discussion

a. Frequency Distribution of Hemoglobin Levels in Pregnant Women with Anemia Before Drinking Banana and Strawberry Juice at Rose Health Center, Bogor City

Based on the results of statistical tests, it is known that out of 16 participants, 11 pregnant women (68.8%) were found with moderate anemia. Anemia is a decrease in hemoglobin levels below normal as a result of iron metabolism disorders consisting of absorption, transportation, storage, utilization and expenditure.¹⁰ Iron nutritional anemia occurs because the iron content in the consumed food does not meet the needs. In general, efforts are being made to treat cases of anemia in pregnant women by consuming iron supplements to increase hemoglobin synthesis for both mother and fetus. However, the fulfillment of iron needs with oral iron has many side effects, such as nausea, dyspepsia, and constipation that will lead to discomfort in pregnant women. One alternative is to consume bananas every day to meet iron intake for anemic patients. Moreover, bananas contain folic acid which is easily absorbed by the fetus through the uterus.¹¹

Hemoglobin is a protein in erythrocytes that functions as a carrier of oxygen from the lungs to the rest of the body. Hemoglobin also transports carbon dioxide back to the lungs to be removed from the body. In pregnant women there is an increase of 30% to 40% of plasma volume in the blood, resulting in blood thinning (hemodilution).¹² The increase in blood plasma volume occurs before the production of red blood cells. This condition causes a decrease in hemoglobin and hematocrit levels in the first and third trimesters.¹³ An increase in blood plasma volume in pregnant women causes hemodilution which is physiologically aimed at increasing the work of the mother's heart. Hemodilution occurs from 10 weeks of gestation and reaches its peak at 32-36 weeks of gestation. In pregnant women, anemia can lead to miscarriage, low weight baby, bleeding before or during delivery, and maternal death.¹⁵

In developing countries, including Indonesia, public awareness to consume supplements is still very

low. Supplemental deficiency during pregnancy is one of the indirect causes of maternal and child mortality that can still be prevented.¹⁷ Anemia is greatly affected by frequent pregnancy and childbirth. The more often a woman experiences pregnancy and childbirth, the more she is at risk of experiencing anemia due to iron loss of previous pregnancy and childbirth.

b. Frequency Distribution of Hemoglobin Levels in Pregnant Women with Anemia After Drinking Banana and Strawberry Juice at Rose Health Center, Bogor City

Based on the results of study, it is known that the frequency distribution of hemoglobin levels in pregnant women with anemia. showed the results of 12 pregnant women (75%) with mild anemia. In addition to pharmacological therapy, non-pharmacological therapy can also be given. Giving vitamin C in the form of tablets or high vitamin C food can increase the absorption of iron in pregnant women.¹⁸ Banana fruit is one of the non-pharmacological therapies that is consumed as a staple food in the tropics. This banana is fortified with iron which is effective for controlling iron deficiency and almost entirely can be absorbed by the body. Bananas also contain vitamin C which can help increase iron absorption.

Bananas contain iron which will stimulate the production of hemoglobin in the blood and also help prevent anemia, because vitamin C contained in bananas also increases iron absorption and increases blood formation.⁶

The results of this study are in accordance with the results of Achmad Abdul's research (2019) which showed that the average hemoglobin level of pregnant women in the third trimester before being given bananas was 9.333 g/dl and after taking Ambon bananas was 10.933 g/dl. The results of this study are in line with research on the effect of banana consumption on anemia in pregnant women in the first

trimester at the Simpang Empat Care Health Center.²⁰

The results of this study are in line with research regarding the effect of giving strawberry juice on hemoglobin levels in third trimester pregnant women at Bujel Pustum, Kediri City (2018).⁷

The hemoglobin of pregnant women is not only influenced by Fe supplements alone but also is supported by food consumption which contains substances needed in the synthesis of hemoglobin. Bananas contain vitamin B6 and B12 which are needed in the synthesis of hemoglobin.²¹ Bananas contain lots of folic acid and water-soluble vitamin B6, which are needed to make nucleic acid and hemoglobin in red blood cells. The content of vitamin B6 and vitamin C and iron in bananas can help produce antibodies, metabolize fat, red blood cells, and stimulate the production of hemoglobin in the blood of people with anemia.²² Vitamin C contained in bananas is also good for health to help rebuild the immune system.²²

Strawberry is a fruit that is rich in its content. Strawberry contains vitamin C so it can be used as an antioxidant and increase endurance. The high vitamin C in strawberries can help absorb iron so that it can increase hemoglobin levels in the blood.²³

Conclusion

There was a significant effect of drinking bananas and strawberries juice in increasing Hemoglobin levels of pregnant women with anemia at Rose Health Center, Bogor City.

Source of Funding- Self

Conflict of Interest- None

Ethical Clearance: This research was approved by the Ethics Committee of Wijaya Husada Health Sciences Institute. All participants were briefed regarding the purpose of the study and the voluntary nature of their participation and that they could

withdraw from the study at any time. They all signed written consent before participating and were assured of the anonymity and confidentiality of their personal data.

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Differential Effects of Heated Tobacco Products and Conventional Cigarettes on Cardiovascular System

A Systematic Review of Randomized Trials

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Abstract

Background: Heated tobacco products (HTP) are alternative forms to traditional cigarettes. Harmful components contained in HTP tobacco aerosol are in lower amounts than those in smoke from traditional cigarettes. That's why HTP are believed to reduce the burden of smoking related-diseases. However, due to its potentially toxic chemicals and the increased concentration of nicotine, HTP devices may not be as safe as the industries claim. This review was completed to summarize effects of HTP on user's health, in particular on cardiovascular system.

Methods: A systematic search of the literature in PubMed database was performed to identify significant articles published from 2015 to 2021. For this review we selected randomized clinical trials that explore the effects of heat-not-burn cigarettes on the cardiovascular system. Independent and sponsored studies by the tobacco industry were included.

Conclusion: The analysis of biomarkers of biological effect, such as those for oxidative stress, platelet activation, endothelial dysfunction, inflammation, antioxidant reserve and others showed differences between smokers and people using heated tobacco products in favor of the latter. However, studies comparing the acute effects of different tobacco products on arterial stiffness, heart rate and myocardial function indicated no relevant differences between IQOS and traditional cigarettes.

So, Heated Tobacco Products appear less harmful. Nevertheless, due to conflicting information and the restricted knowledge of IQOS exposure, further long-term human studies are needed to assess the potential benefit and risk of heated tobacco products.

Keywords: *Heated Tobacco Products; Cardiovascular system; Adverse effects*

Introduction

Heated tobacco products (HTP) are alternative

forms to traditional cigarettes⁽¹⁾. Harmful components contained in HTP tobacco aerosol are in lower amounts than those in smoke from traditional cigarettes⁽²⁾⁽³⁾. Tobacco heating systems release nicotine at lower temperatures (240–350 °C), without fire and smoke, while traditional cigarettes heat tobacco more than 600 °C⁽¹⁾. During the heating process generated aerosols have 90–95% lower levels of harmful substances than traditional cigarette smoke: affirm tobacco industries⁽⁴⁾

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(5)(6)(7). Some independent studies have also confirmed that the amount of toxic compounds contained in HTP aerosol is lower than that generated by conventional cigarettes (8)(9)(10). That's the rationale behind the belief that use of HTP will result in reduction of the burden of smoking related-diseases.

However, due to its potentially toxic chemicals and the increased concentration of nicotine, HTP devices may not be as safe as the industries claim (3)(6)(11)(12)(13)(14)(15)(16)(17).

Due to conflicting information and the restricted knowledge of IQOS exposure, we completed this review to study effects of HTP on user's health, in particular on cardiovascular system.

Objective of the study

The objective of the study is to evaluate whether the use of heat-not-burn cigarettes lead to a decreased cardiovascular risk, compared with the risk of combustible cigarettes.

Materials and Methods

Protocol and registration

We developed this systematic review using the criteria of the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) (18). The study's protocol was submitted to an international prospective register for systematic reviews (PROSPERO registry) and currently waits for approval under the number ID288674.

Information sources

A systematic search of the literature in PubMed database was performed to identify significant articles published from 2015 to 2021, during which smoke-free products were used more often.

Search strategy and selection of the studies

For our search we included keywords related

to the potential effect of heated tobacco products on cardiovascular system. Relevant results were identified using the following search terms with their possible alternatives: heated tobacco product, IQOS, cardiovascular system, adverse effect. Selected terms were used both as keywords and medical subject headings (MESH terms). The reference lists of the selected articles were subject to a hand search to find additional studies.

For this review we selected randomized clinical trials that explore the effects of heat-not-burn cigarettes on the cardiovascular system. Independent and sponsored studies by the tobacco industry were included.

The studies on animals, experimental in vitro studies and articles in a language other than English were excluded.

In total 195 articles were found as a result of our search. They were all checked for eligibility by two independent researchers. First all articles were explored by title and abstract. The majority of articles did not meet the inclusion criteria for our study and were excluded. Two abstracts without a full text version were excluded too, because of lack of information on bias risk. The remaining 8 articles were subject to a full-text review. The search strategy and selection process are presented in details in PRISMA flow diagram.

Risk of bias in individual studies

We assessed the risk of bias of the selected individual studies using The Cochrane Collaboration Risk of Bias Assessment 2.0 tool for individually randomized parallel group trials (19). The assessment was done on a study level and was based on five main domains (bias arising from randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, bias in selection of the reported result).

Results

Some of the selected studies explore the potential effects of tobacco and alternative tobacco products on cardiovascular system by evaluating the amount of biomarkers of potential harm (BOPH) that increase the cardiovascular risk, while the others evaluate their direct effects on cardiovascular system.

Two similar randomized studies were conducted in Japan in 2016 and in the United States in 2018, which compare the effects of menthol cigarette and Tobacco Heating System (THS) 2.2 on oxidative stress, endothelial dysfunction, platelet activation and lipid metabolism⁽²⁰⁾⁽²¹⁾.

In both studies participated one hundred and sixty healthy adult smokers. All subjects were randomized in a 2:1:1 ratio to menthol Tobacco Heating System 2.2 (mTHS), menthol cigarette, or smoking abstinence for 5 days in confinement and 86 ambulatory days. The study in Japan showed that switching from menthol cigarettes to Tobacco Heating System was associated with statistically significant improvements in clinically relevant risk markers, such as high density lipoprotein (HDL-cholesterol: marker of lipid metabolism), intercellular adhesion molecule 1 (s-ICAM 1: marker of endothelial dysfunction), 8-Epi-Prostaglandin F2 Alpha (8-epi-PGF_{2α}: marker of oxidative stress), and white blood cells (WBC: marker of inflammation)⁽²⁰⁾. The improvements in these markers approached those detected in the smoking abstinence group. In USA statistically significant changes were observed only for s-ICAM-1 and 8-epi-PGF_{2α}. Here further favorable, but statistically not significant changes were observed in high sensitivity C-reactive protein (hs-CRP), total cholesterol, HDL, low-density lipoprotein, Apo B and Apo A1 ($p > 0.05$)⁽²¹⁾.

Another multi-center, randomized trial of smokers switched to tobacco-heating cigarettes, snus or ultra-low machine yield tobacco-burning cigarettes

(50/group) was conducted in 2015⁽²²⁾. An additional group of no smokers was included for baseline comparisons. Several biomarkers of biological effect including those for oxidative stress and inflammation, hypercoaguable state, endothelial dysfunction, insulin resistance, DNA damage and lipid/cardiac risk markers were analyzed. In the baseline comparisons statistically significant differences between smokers and no smokers were detected only in half of measured biomarkers (in particular in intercellular adhesion molecule 1 (s-ICAM1), white blood cells (WBC), oxidized low density lipoprotein (OxLDL), hemoglobin (Hgb), homocysteine, hematocrit (HCT), and sister chromatid exchange in peripheral lymphocytes (SCE)). Smokers, who were switched to tobacco-heating cigarettes have statistically significant improvements in some biomarkers, such as platelets, intercellular adhesion molecule 1 and WBC. S-ICAM1 was significantly reduced also in the smokers switched to snus or to the ultra-low yield tobacco-burning cigarette⁽²²⁾.

In 2019 another randomized, independent cross-over trial in 20 smokers was conducted, which compared the acute adverse effects of heat-not-burn cigarettes (HNBC), electronic vaping cigarettes (EVC) and traditional cigarettes (TC) on oxidative stress, antioxidant reserve, platelet function, flow-mediated dilation and blood pressure⁽²³⁾. All types of the mentioned products were used by each participant, with one week intercycle washout period. The biomarkers were explored after a single use of each mentioned product. Compared to traditional cigarettes, HNBC had statistically significant less impact on oxidative stress markers (such as soluble Nox2-derived peptide, H₂O₂, H₂O₂ breakdown activity, 8-iso-prostaglandin F_{2α}-III), vitamin E, soluble P-selectin, flow-mediated dilation, and blood pressure⁽²³⁾.

In another randomized trial the effects of Heat-not-Burn cigarette (HNBC) on coronary, arterial and myocardial function, as well as on platelet activation and oxidative stress were compared to those of tobacco cigarette (Tcig) ⁽²⁴⁾. In the acute study, 50 subjects smoked either a single Tcig or a HNBC and after 60 min were crossed-over to the alternate smoking. The amount of malondialdehyde (MDA), exhaled carbon monoxide (CO), thromboxane B2 (TxB2) and pulse wave velocity (PWV) were assessed before and after each smoking. The acute study showed that significantly smaller increase of PWV was caused by HNBC smoking compared to Tcig smoking, without change in biomarkers and CO in contrast to traditional cigarettes. In the chronic phase 50 smokers started to use HNBC for one month and were compared with an additional group of 25 cigarette smokers. The amount of malondialdehyde (MDA), exhaled carbon monoxide (CO), thromboxane B2 (TxB2), pulse wave velocity (PWV), as well as myocardial work index (GWI), global longitudinal strain (GLS), coronary flow reserve (CFR), wasted myocardial work (GWW), flow-mediated dilation (FMD) and total arterial compliance (TAC) were assessed in the chronic study. Switching to Heat-not-Burn cigarette for 1-month improved CO, FMD, CFR, TAC, GLS, GWW, MDA, TxB2 compared to traditional cigarettes. So, this study shows, that puffing of HNBC has less acute adverse effect on arterial elasticity compared to Tcig and did not cause a further increase of platelet activation and oxidative stress burden in contrast of tobacco cigarette. Improvement in oxidative stress burden and endothelial function, reduction of platelet activity, as well as improvement in coronary flow reserve and myocardial work efficiency were observed when switching from Tcig to HNBC for one month ⁽²⁴⁾.

Two similar randomized studies, which compared the effects of different smoking products on arterial stiffness were performed in 2020 ⁽²⁵⁾⁽²⁶⁾.

In the first study 22 current smokers smoked randomly HNBC (IQOS) heat stick, a standard tobacco cigarette and a sham cigarette on three separate visits. Heart rate, blood pressure (both brachial and aortic), augmentation index corrected for HR (AIx@75), carotis-femoral PWV and brachial-ankle PWV were assessed before and immediately after smoking, and then at 5, 10, 20 and 30 minutes. No differences in all baseline measurements were observed between the three sessions. All the mentioned parameters were increased significantly after HNBC (IQOS) heat stick and a standard tobacco groups compared with sham smoking ($p < 0.05$). Although HNBC resulted in less potent numerical increases of examined parameters compared with tobacco cigarette, the observed differences between 2 types of smoking products were not significant. So according to this study HNBC is similarly impactful to tobacco cigarette for aortic stiffness and central haemodynamics ⁽²⁵⁾.

In the second study 20 active healthy smokers have to smoke HTP 2.2 (IQOS), a tobacco cigarette (Cig), e-cigarette with nicotine (ECig(+)), and e-cigarette without nicotine (ECig(-)) on four separate visits with interperiod wash-out of at least 48 hours. According to this study peripheral systolic blood pressure (SBP), mean arterial pressure (MAP) and heart rate (HR) increased significantly within the Cig, ECig(+), and HTP groups ($p < 0.05$). The augmentation index, adjusted for a HR of 75 bpm (AIx75), increased significantly in the Cig group after 5, 10, and 15 minutes and in the HTP group after 5 minutes. In pulse wave velocity (PWV) statistically significant alteration after 15 minutes was seen only for the Cig group ($p < 0.05$), whereas statistically insignificant trend was shown for ECig(+) ($p \approx 0.072$) and HTP ($p \approx 0.066$) groups ⁽²⁶⁾.

Another study, completed in 2020, compared myocardial systolic and diastolic function within transthoracic echocardiography in the acute phase after

IQOS smoking and cigarette smoking⁽²⁷⁾. Heart rate, systolic and diastolic blood pressure before and after smoking of each product were assessed too. Twenty-seven healthy IQOS smokers participated in this prospective study. Measurements were performed for each participant before smoking any tobacco product, after IQOS smoking and after cigarette smoking. The study showed, that in comparison with non-smoking status, LV global longitudinal strain (GLS), LV global circumferential strain (GCS), as well as RV longitudinal strain (GLS) decreased significantly after IQOS and cigarette smoking ($p < 0.05$). HR increased significantly after using of both products in comparison to nonsmoking status, whereas systolic and diastolic blood pressure increased significantly only after cigarette smoking⁽²⁷⁾.

Discussion

The impact of HTP on human health is still not well established. Studies evaluating the adverse health effects of HTP are rare and mostly conducted by tobacco industry. Implemented in vitro tests showed that HTP aerosols contain lower amount of toxic substances compared to traditional cigarette smoke. However, no sufficient amount of longitudinal studies on human are available to argue that switching from cigarettes to IQOS can lead to a reduction in exposure of toxic substances comparable to smoking abstinence.

Studies included in our systematic research indicated decreased amount of biomarkers of biological effect in individuals switched to IQOS smoking. The biomarkers include those for oxidative stress, platelet activation, endothelial dysfunction, inflammation, antioxidant reserve and others. Studies that assess the acute effects of different types of tobacco products also indicate lower amount of biomarkers after using a single heating tobacco product compared to traditional cigarette. The validity of the chosen end points is well established. Indeed,

systematic oxidative stress, downregulation of the antioxidant system, endothelial dysfunction and platelet activation play a fundamental role in vascular damage, atherogenesis and thrombosis. Higher levels of the mentioned biomarkers are surely associated with increase of the risk of cardiovascular events.

Despite growing evidence of potential favorable effects of heating tobacco products on cardiovascular system, studies comparing the acute effects of different tobacco products on arterial stiffness, heart rate and myocardial function indicated no relevant differences between IQOS and traditional cigarettes. The reason for this might be that IQOS delivers nicotine to organism in a similar way and quantity, as conventional cigarettes and this factor also needs to be studied further. Given the predictive role of arterial stiffness and myocardial function for cardiovascular events, the above mentioned findings born doubt on the advocating of smoking IQOS as a less risky product for the prevention of cardiovascular diseases.

Conclusion

It is clear that due to conflicting information and the restricted knowledge of IQOS exposure further long-term human studies are needed to assess the potential benefit and risk of heated tobacco products. However, available evidence is still in favor of HTP.

Limitations

The first limitation of included studies is the relatively small sample size of the selected population and the limited period of exposure. The next limitation is that the trials studied effects of different tobacco products only on apparent healthy subjects, and there is no evidence about users who have chronic cardiovascular diseases. The absence of a control group, not receiving any tobacco product, was a limitation of most of the included studies. Different levels of user's compliance with study products possibly affected the results too. However, according

to Cochrane Collaboration's R.O.B. 2 assessment all the studies showed low risk of bias, which is a major strength of this review.

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Conflicts of Interest: The authors declare no conflict of interest.

Ethical Clearance : Taken from Nork-Marash Medical Center ethical review board.

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The Incidence of Musculoskeletal Manifestations among Patients with COVID 19 Infection

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Abstract

Background- Patients with COVID-19 may manifest musculoskeletal symptoms; myalgia is frequently detected in COVID-19 infected patients. The study aims to examine the incidence of musculoskeletal manifestations in the Iraqi Kurdistan Region and its correlation with the disease severity, and the patient's outcomes. Further, it attempts to correlate the disease severity with the smoking.

Method- A sample of one thousand (1000) COVID-19 infected patients from the Iraqi Kurdistan Region, were examined in an observational cross-sectional study to obtain relevant data for the patients treated in the COVID-19 care centres in Erbil city. The study lasted from 15 August 2020 to 15 June 2021.

Conclusion- The study shows that the musculoskeletal manifestations are frequent in COVID-19 infected patients; 79.4% of patients had fatigue, 66.8% had myalgia, 56.9% had backache, and 41.5% had arthralgia, fatigue is the most common symptom. The smokers manifest severe or critical conditions of the disease.

Keywords- COVID-19, musculoskeletal symptoms, smoking, blood group, Iraqi Kurdistan Region.

Introduction

The first case of the 2019 corona virus (COVID-19) was detected in Wuhan, China on 31 December 2019, and World Health Organization (WHO) deemed it as a global pandemic on 11 March 2020. By the end of April 2020, the virus had spread worldwide with fear-evoking death reports¹. In early March 2020, the Kurdistan Regional Government's Ministry of Health announced the first confirmed cases of COVID-19 in

the Iraqi Kurdistan Region².

Myalgia, defined as muscle pain, has been frequently reported in COVID-19 infected patients with a prevalence range from 11 to 50% in large cohort studies³. Arthralgia has also been reported in 2.5% of patients⁴; meanwhile, fatigue is the most common musculoskeletal symptom reported in 63%, followed by back pain 50.5% in patients with COVID 19⁵. As such, the musculoskeletal symptoms reported in early stage of COVID-19 infection may also be reported in patients, who needed intensive care unit⁶.

Evidence on smoking impacting the disease progression and death in COVID-19 infected patients is still conflicting⁷. Furthermore, some studies reported no relation between active smoking and COVID-19

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severity, whereas others reported that smoking was associated with severity and mortality^{8,9,10}.

Material and Methods

Study Design and Participants- The study is an observational cross-sectional study, the data conducted from COVID-19 infected patients in the Iraqi Kurdistan Region; the participants were either treated at COVID-19 care centres in Erbil city, such as Rizgari Teaching Hospital, West Erbil Emergency hospital and in some private hospitals. Based on a Google Forms survey conducted by the study, the participants were either from inside or outside Erbil city (Duhok and Sulaimani). Confidentiality of the survey data was guaranteed. The Epi info 7 computer program was used for sample size estimation¹¹, then the following information were entered into the program: Population size (estimated number of COVID-19 cases during the study period in Kurdistan) 185716 patients², the estimated prevalence of musculoskeletal manifestations was set at 85.3%¹, absolute precision was set at 2.5%, and the confidence level was set at 95%. Accordingly, the estimated sample size was 768. For convenience and to overcome the possibility of non-response, Therefore, 1000 patients were included in the study between the 15 August 2020 to 15 June 2021.

Questionnaire Design and data collection- the study researchers developed a paper based and an online questionnaire through using Google Forms link shared on specific Facebook pages and via popular messaging applications in Iraq. The research team members reviewed, and pilot tested the questionnaire segments, the questionnaire covered the contact detail, demographic characteristics, comorbidities, current medications, and outcomes.

Inclusion Criteria- both genders, age between 18 to 80 years, the patients who confirmed to have COVID-19 infection based on one or more of the

followings - Real Time Polymerase Chain Reaction (RT-PCR) by nasopharyngeal swab, CT scan of the chest, clinical sign, and symptoms of COVID-19 as well as serological tests.

Exclusion Criteria- Pregnant women, patients with malignancy, and those who were on invasive ventilation.

Statistical Analysis- The study utilized the Statistical Package for Social Sciences (SPSS, version 25) application to analyse the outcome data. The variables were coded and analysed for socio-demographics; Chi square test of association was used to compare proportions. Fisher's exact test was used when the expected frequency (value) was less than 5 of more than 20% of the cells of the table. The P value of ≤ 0.05 was considered as statistically significant.

Result(s)

One thousand patients with COVID-19 infection were included in the study their mean age \pm SD was 46.5 and \pm 14.9 years, with their real age data ranging from 19 to 78 years old; the median was 44 years. The study has also found that only 11.3% of the patients were aged less than 30 years, and 9% were aged ≥ 70 years (see Table 1 below).

Additionally, the study analysis found that more than half (58.9%) of the patients were females. In terms of the participants' blood groups, 29.5% as the largest proportion of the study sample was O+ blood group, 25% was A+ blood group, and 20.5% was B+ blood group. Based on the study analysis, the most common symptoms included 80.5% malaise, 77.3% fever, and 75.2% headache.

Since it was based on clinical findings in 32% of the patients, the diagnosis depended on the results of PCR alone in 33.2% of the patients and on CT scan images alone in 8.9% of the patients. The mentioned methods were used to diagnose the rest of the patients;

around half of the cases were either severe (41.5%) or critical (2.7%). The co-morbidities, 63.1% of the patients had no co-morbidity, 10.5% had hypertension, and 5.6% had diabetes (see Table 1).

Table 1: Basic Characteristics of the Study Sample

	No.	Percentage (%)
Age (years)		
< 30	113	(11.3)
30-39	271	(27.1)
40-49	254	(25.4)
50-59	122	(12.2)
60-69	150	(15.0)
≥ 70	90	(9.0)
Gender		
Male	411	(41.1)
Female	589	(58.9)
Smoking		
Yes	184	(18.4)
No	816	(81.6)
Blood group		
A+	250	(25.0)
A-	31	(3.1)
B+	205	(20.5)
B-	46	(4.6)
AB+	118	(11.8)
AB-	20	(2.0)
O+	295	(29.5)
O-	35	(3.5)
Method of diagnosis		
PCR	332	(33.2)
CT	89	(8.9)
Clinical	320	(32.0)
All	259	(25.9)
Severity		
Mild	303	(30.3)
Moderate	255	(25.5)
Severe	415	(41.5)
Critical	27	(2.7)
Co-morbidities		
None	631	(63.1)
Hypertension (HTN)	105	(10.5)
Diabetes (DM)	56	(5.6)
Ischemic heart disease (IHD)	20	(2.0)
HTN+DM+IHD	139	(13.9)
Rheumatic disease	6	(0.6)
Others	43	(4.3)
Total	1000	(100.0)

*More than one symptom may emerge in one patient.

Figure 1 shows that the majority (95.8%) of the patients had at least one musculoskeletal symptom, 79.4% of them had fatigue, 66.8% of them had myalgia, 56.9% with back pain, and 41.5% had arthralgia.

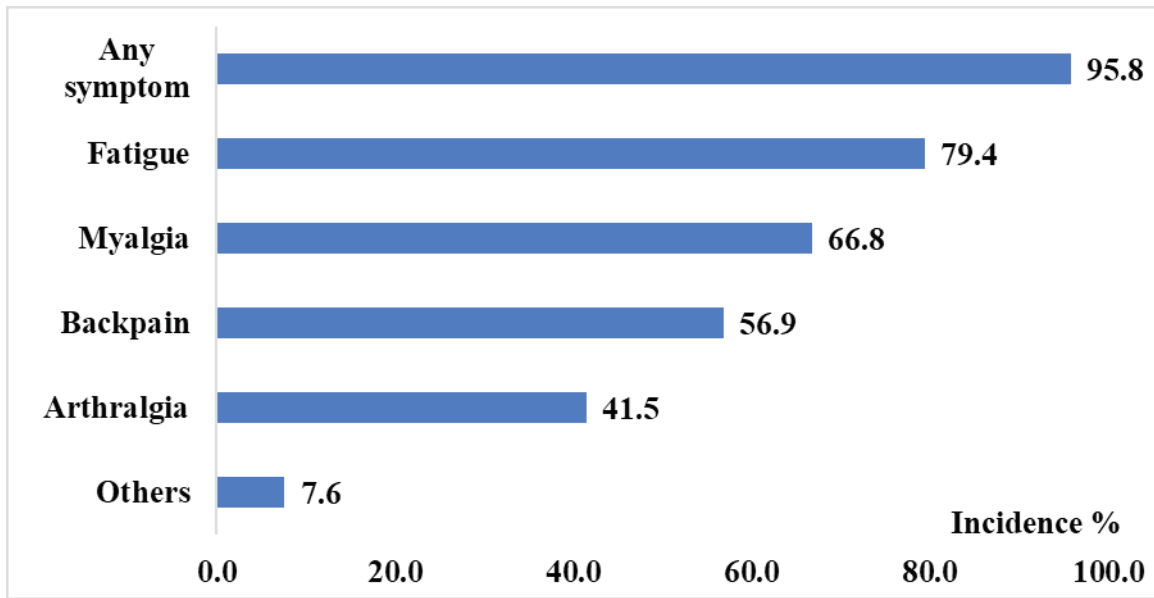


Figure 1: Incidence of Musculoskeletal Manifestations

Furthermore, significant differences were detected between the degrees of COVID-19 severity and the incidence rates of back pain, fatigue, and myalgia. These rates didn't obviously correlate with the grades of severity, i.e., the occurrence rates wouldn't steadily increase with the increase of the disease severity. See Table 2 below showing that no significant association was detected with arthralgia ($p = 0.083$).

Table 2: Association between the incidence of Musculoskeletal Symptoms with the Disease Severity

	Severity of COVID-19				P
	Mild (n = 303)	Moderate (n = 255)	Severe (n = 415)	Critical (n = 27)	
	No. (%)	No. (%)	No. (%)	No. (%)	
Backache	166 (54.8)	159 (62.4)	238 (57.3)	6 (22.2)	0.001
Fatigue	223 (73.6)	206 (80.8)	347 (83.6)	18 (66.7)	0.003
Arthralgia	113 (37.3)	121 (47.5)	172 (41.4)	9 (33.3)	0.083
Myalgia	176 (58.1)	190 (74.5)	285 (68.7)	17 (63.0)	< 0.001

In addition, no significant association was detected between the outcome of COVID-19 with back pain ($p = 0.058$), fatigue ($p = 0.248$), arthralgia ($p = 0.610$), and myalgia ($p = 0.455$) (see Table 3).

Table 3: Association between the incidence of Musculoskeletal Symptoms with the Disease Outcome

	Outcome of COVID-19			P
	Recovered (n = 939)	RCU (n = 48)	Died (n = 13)	
Back pain	530 (56.4)	34 (70.8)	5 (56.9)	0.058
Fatigue	743 (79.1)	42 (87.5)	9 (69.2)	0.248
Arthralgia	389 (41.4)	22 (45.8)	4 (30.8)	0.610
Myalgia	623 (66.3)	36 (75.0)	9 (69.2)	0.455

Moreover, over half of the smokers had either severe disease (51.1%) or critical disease (3.3%) compared with 39.3% and 2.6% among the non-smokers ($p = 0.015$) respectively.

Table 4: COVID-19 Severity per Smoking Status

Severity	Smoker		Non-smoker		Total		P
	No.	(%)	No.	(%)	No.	(%)	
Mild	41	(22.3)	262	(32.1)	303	(30.3)	
Moderate	43	(23.4)	212	(26.0)	255	(25.5)	
Severe	94	(51.1)	321	(39.3)	415	(41.5)	
Critical	6	(3.3)	21	(2.6)	27	(2.7)	0.015
Total	184	(100.0)	816	(100.0)	1000	(100.0)	

Discussion

Our study conducted among COVID-19 patients the median age of the participants were 44 years old, more than 55% of the patients were female. Among the most common symptoms observed and found in the patients were malaise followed by fever and headache (80.5%). In a comparison to a study that conducted by Wang D et al, the participants' median age was 56

years old among 138 hospitalized patients; 54.3% of the patients were men and 45.7% were female. The most common symptoms regardless of the disease's severity was as follow: fever 98.6%, fatigue 69.6%, dry cough 59.4%, myalgia 34.8%, and dyspnoea 31.2% respectively¹².

According to a study by Sansin Tuzun et al that examined 150 COVID-19 infected patients, the most

common musculoskeletal symptoms were 85% fatigue followed by 68% myalgia¹³. Their study's findings were close to our study, which shows that the most common symptoms were 79.4% fatigue, followed by 66.8% myalgia. Moreover, our study revealed that 56.9%, 41.5%, and 7.6% of the patients had back pain, arthralgia, and other symptoms respectively (see Figure 1).

The mortality rate as revealed in our study was 13 (1.3%) deaths out of 1000 participants, which was less than the mortality rate (2.6%) found in a study conducted in Korea that included 18 deaths out of 694 patients¹⁴.

Furthermore, debates have been made whether smoking is associated with increased risk of COVID-19 infection and related mortality⁷. A study conducted by Albert Pratis UB et al reported that there was no association between COVID-19 infection and smoking¹⁵. However, in our study half of the smokers had either severe disease (51.1%) or critical disease (3.3%) and it was statistically significant. These findings may come handy in future to assess the correlation of COVID-19 severity with smoking and the need for further research (see Table 4).

During the severe acute respiratory syndrome coronavirus (SARS-CoV-2) pandemic, several observations suggested that ABO blood type may contribute to the disease¹⁶. The study conducted by Göker H observed that blood group A was more frequent, and the blood group O was less frequent in COVID-19 patients¹⁷. Moreover, the higher proportion of our study sample included (29.5%) blood group O+ (see Table 1). In the Middle East countries like Iraq, blood group O is the most common even globally followed by A, B, and then AB blood groups¹⁶. This might also explain why the blood group O in our study result was more frequent in the COVID-19 infected patients.

The limitations of the study

The study had faced some limitations despite good efforts to eliminate them. The use of online-based questionnaires to collect data posed limitation to the study. We anticipated that rural inhabitants with poor to low education level wouldn't afford Internet connectivity, leading to insufficient response to the online survey.

Conclusion

The study shows that the musculoskeletal manifestations are frequent in COVID-19 infected patients; 79.4% of patients had fatigue, 66.8% had myalgia, 56.9% had backache, and 41.5% had arthralgia, fatigue is the most common symptom. The smokers manifest severe or critical conditions of the disease.

Ethical Clearance- taken from the Ethics and Scientific Committees of Kurdistan Board for Medical Specialties.

Source of Funding: self

Conflict of Interest: nil

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Public Health in the Rural Areas of India - A Privilege?

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Abstract

Background: Everything is a public health issue, from climate change to geopolitical threats to food safety to healthcare-associated infections. It is the most required and the most important service in the world right now. Despite public health being the fundamental human right, we can see how it is being denied to millions of individuals from the underprivileged communities especially the rural areas of the country. Hence a study explaining the critical need of public health and an analysis of the current public health issues in today's world is greatly needed.

Method: A cross-sectional study has been conducted for a period of 2 months among 100 low-income families in Kammavaripalem region of Nandigamamandal, Krishna district, Andhra Pradesh. This article specially focusses on riveting issues such as domestic abuse, menstrual hygiene and illiteracy which are the most immediate public health issues that needs to be addressed. The questionnaire concentrates on how the limited resources affects the public health status of the families. The data has been collected using a pre-tested and semi-structured questionnaire through face-to-face interview method.

Conclusion: The survey showed results that clearly depict a critical need for public health attention in these rural areas. Considering what were found the root causes of these issues, initiatives are suggested in these areas; educating women about their rights with regards to domestic abuse and giving them better employment opportunities, awareness among women about menstrual hygiene practices and a necessary cost effective alternate to commercial pads and a system to make the parents learn the importance of education in order to decrease the school drop-out rate.

Keywords: *Public health, low-income families, rural areas, menstrual hygiene, domestic abuse, illiteracy*

Introduction

Public health is defined as the art and science of preventing disease, prolonging life, and promoting health through the organized efforts of society. The above statement encompasses the outlook of the definition from the world health organization (Acheson, 1988; WHO).⁽¹⁾

The vision of public health is to promote the physical, emotional, and psychological well-being of an individual while reducing socioeconomic disparities

in a sustainable way. Despite its importance, public health has been the most neglected field in the last two decades and the consequences of this neglect are nothing short of calamitous.

India is the one of the most populated countries in the world and statistics show that 65.07% of the population lives in rural areas with limited access to fundamental needs such as nutrition, access to healthcare, and education. Women and children continue to remain as the most vulnerable part of

the population. Statistics also claim that around 70% to 90% of women in rural India experienced sexual abuse and the shocking fact is that around 55% of them believe that it is normal. The recent figures state that About half of rural children are too short for their age (stunting) and 21% have low weight for height (wasting). Domestic abuse rates have also increased at an alarming rate in the last two years, especially because of Covid lockdowns. Overall, these statistics are just an example of how the public health situation in India has deteriorated due to years of ignorance.

Aim

24) To study the immediate public health issues in the rural areas of India

25) To identify the root-cause of these issues

26) To quantify the need of action to address these issues

Materials and Methods

Across-sectional study has been administered among 100 low-income families for a period of 2 months using convenience sampling method from 8th of July to 11th of September. The data was collected using a pretested and semi structured questionnaire through face-to-face interview method after informing the participants about the nature of study. After collecting the data, analysis has been done using excel and the outcomes are interpreted in the form of graphs

and tables.

The questionnaire majorly revolved around the immediate public health issues like domestic abuse, menstrual hygiene and illiteracy which are recurrent in the rural areas of India. The following sections would include the detailed aftermath of the study.

Findings and Discussion

1. 42% of the married women in the survey mentioned domestic abuse incidents from their husbands, among which 7% filed a complaint and 21% approached for help from their trusted ones or NGOs. The data showed a direct relation between employment and the probability of a domestic abuse cases as represented in Figure 1 and 2, analysing that 68% of the unemployed women faced domestic violence versus the figure of 9% in the case of employed women, which clearly shows the psychological empowerment brought to the women in their households by being an earning member of the family⁽²⁾⁽³⁾⁽⁴⁾. Also, 27% of unemployed men were accused of domestic violence while the number significantly rose to 44% in the case of employed men. This indicates a familiar trend of employment carrying a sense of entitlement in men capable of domestic violence. Moreover, similar trend exhibited by spouses with habits like alcoholism⁽³⁾ and gambling continue to raise concerns as they can be observed in 74% of the accused versus the figure was significantly less in spouses not accused i.e. 26%.

Table:1: Distribution of responses among the married women (N=100) in 100 families regarding domestic abuse against the below criteria

Criteria	N=100
Have been victims to domestic abuse	42
Have suffered the frequency of more than 1 incident a week	12
Suffered domestic abuse and were unemployed (out of 56)	38
Suffered domestic abuse and were employed (out of 44)	4

Cont... Table:1: Distribution of responses among the married women (N=100) in 100 families regarding domestic abuse against the below criteria

Accused spouse who were unemployed (out of 11)	3
Accused spouse who were employed (out of 89)	39
Accused spouse with a problem of alcoholism or gambling (out of 42)	31
Spouse not accused and has a problem of alcoholism or gambling (out of 58)	15
Have suffered domestic abuse and reported it to authorities	3
Have suffered domestic abuse and approached for alternate help	9

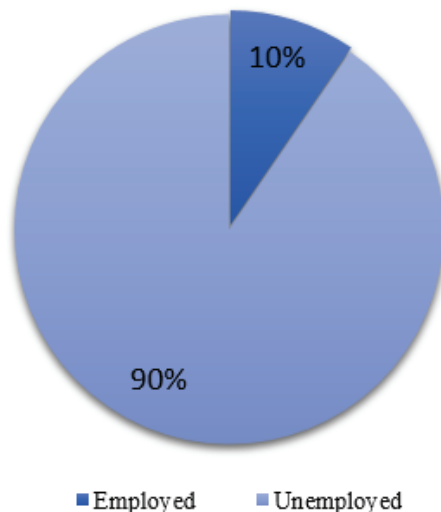


Figure 1: Women who suffered domestic abuse

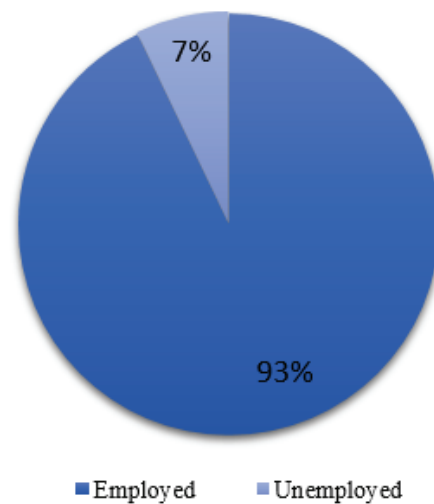


Figure 2: Accused Spouse

2. The survey showed that even the most basic menstrual health practices were known to only 65% of the respondents, with only 25% practicing proper cleaning of their external genital area⁽⁶⁾. Hence a shocking figure of only 26% of the female respondents using commercial sanitary pads and other 74% used homemade cloth pads. Most disturbing, however, was the lack of awareness to use them as 32% of the women using commercial pads didn't change it more than once a day and 23% of the women using cloth pads didn't change them more than once a day on most of the days of use. Being in a rural area only 41%

of them answered yes to if they have toilet facility at home. Also, superstitions⁽⁵⁾⁽⁷⁾ around menstruation hindered the daily life of many of these women including female minors not being sent to school during their cycle, not being allowed to play outside and in some cases, even food intake restrictions⁽⁵⁾ were seen with the percentages of respondents as 21%, 31%, and 5% respectively. Figure 3 shows the data for the sources from where the respondents acquired their elementary knowledge of menstrual health and hygiene. Represented data clearly shows how that schools contributed to educating only 12%

of the respondents about menstruation health and how there is also a shortage of awareness programs for menstrual education which contributed to only 5% of the total figure. 31% and 17% figures correspond to acquirement of knowledge from their female family members and internet or friends respectively, which forms the combined majority of the total women who had some prior idea about it. This indicates the need of a structured education and awareness system for mensural health and hygiene⁽⁶⁾ in rural areas to abolish the superstitions around it and build a clear picture of right practices⁽⁵⁾.

Table:2: Distribution of responses among menstruating women (N=166) in the 100 families regarding their menstrual hygiene and practices

Criteria	N=166
Have at least elementary knowledge about menstrual health and hygiene	108
Source of knowledge:	
1. School	20
2. Awareness programs	9
3. Internet and friends	28
4. Female family member	51
Used homemade cloth pads	123
Among which who changed it only once a day (on most days)	28
Used commercial pads	43
Among which who changed it only once a day (on most days)	14
Cleaned their external genital area properly twice a day	42
Toilet facility available at home	68
Female minors not allowed to attend school during menstruation (out of 58)	12
Female minors not allowed to play outside during menstruation (out of 58)	18
Women who followed food restrictions imposed under superstitions	8

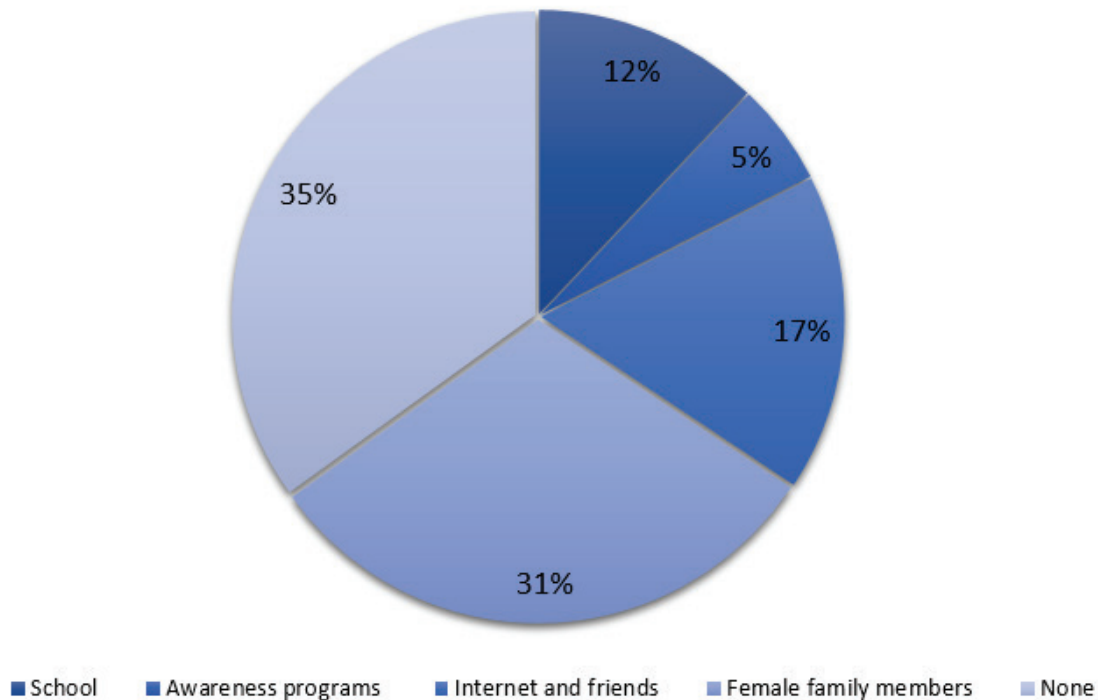


Figure 3: Distribution of responses regarding the source of attainment of awareness on menstrual health and hygiene

3. The total percentage of minors going to school was found to be 78% among which 74% attended government schools and the other 26% attended private schools. This was mostly governed by the family income. There was a drastic gap between statistics of female and male children going to school⁽⁹⁾ ⁽¹⁰⁾ as 88% of the male children attended school versus only 62% of the female children. Added to that 93% of those kids attending private school were males, which showed how quality education was considered necessary only for boy child. 22% of the kids were not attending school and the reasons for their drop-out or not enrolling in school are presented in Figure 4 and 5. These reasons varied with gender the analysis indicted that the major reasons for girl child⁽¹²⁾ were household responsibilities (21%) and education not considered necessary by their parents (23%). This data also highlighted some important issues in our government school structure in rural areas, as 15% of them don't attend school because of the lack of proper

sanitary facilities in the premises and 13% of them were not being sent to school because either there was no female teacher, or it was simply considered unsafe. In the case of boy child, the major reasons for not attending school were responsibility to contribute to family income and learning a new skill or trade, each forming 31% of the answers from the respondents. This indicates the still prevailing unawareness about the need and power of education towards a bright future of the child and family. It also indicated how in many cases minors must take the burden of the family responsibilities at an early age. Here too 15% of the responses stated their primary reason that their parents simply don't consider education necessary. 36% of the children's parents were both uneducated and lacked the awareness about the importance of education. The responses also revealed the reality of early marriage⁽¹⁰⁾ as it formed 10% and 8% of the responses in the case of female and male child respectively, this data also contained the responses of

children who had to leave school as their legal age of marriage was approaching. Lastly, another failure of the government schools surfaced as 15% and 5% of girl and boy child respectively stated their reason being unsatisfactory teaching in the government schools⁽¹³⁾. This data highlights the urgency of how we must relook into our rural school teaching system

and that we still need to eliminate many orthodox perceptions of people which keep their children away from schools. The survey also pointed out the need for the better penetration of social help to these rural areas, as only 26% of the respondents reported having been approached by an NGO trying to help in increasing literacy rates.

Table 3: Distribution of responses among children between the age of 4-18 years (N=212) in the 100 families

Criteria	N= 212
Attending school	165
Attending government schools	122
Attending private schools	43
Number of boy child going to school (out of 109)	96
Number of girl child going to school (out of 103)	64
Boys among the kids going to private school	40
Children with one parent educated	112
Children with both parents educated	23
Children with neither of the parents educated	77
Reason for drop-out or not enrolling for male child (13):	
1. To contribute to family income	4
2. Early marriage	1
3. Unsatisfactory teaching in government schools	2
4. Education not considered necessary by parents	2
4. To learn a skill or a trade	4
Reason for drop-out or not enrolling for female child (39):	
1. To contribute to family income	5
2. Early marriage	4
3. Unsatisfactory teaching in government schools	2
4. Education not considered necessary by parents	9
5. Lack of proper sanitary facilities at school	6
6. Household responsibilities	8
7. Not safe or (and) no female teacher at school	5
Approached by NGOs for help	55

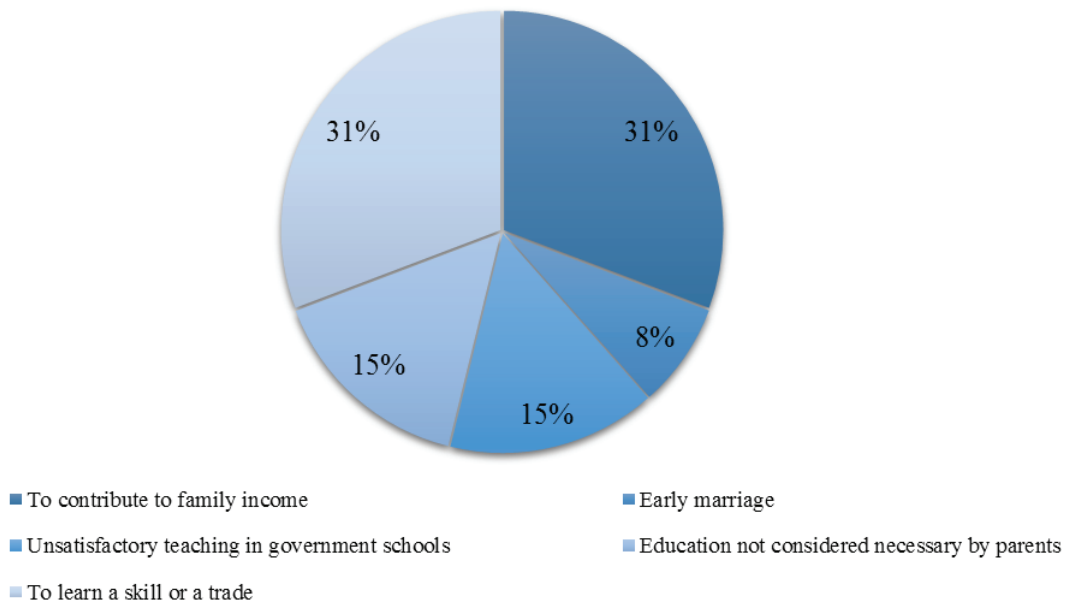


Figure 4: Distribution of responses regarding the major reasons of dropping out or not enrolling in the school for male child

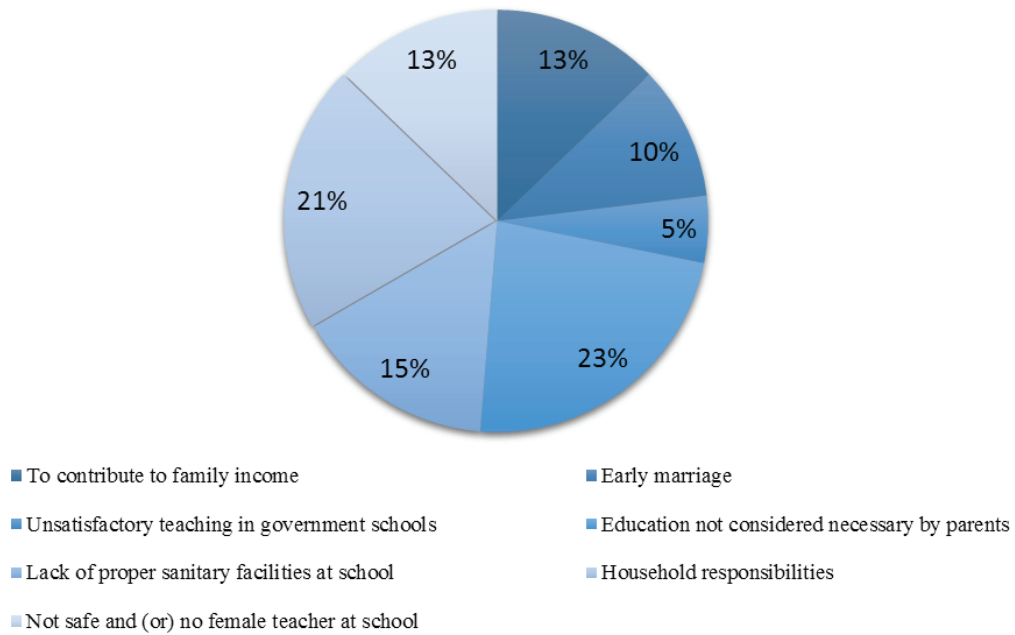


Figure 5: Distribution of responses regarding the major reasons of dropping out or not enrolling in the school for female child

Conclusion and recommendations:

The observed data indicates that increasing the employment opportunities for women in these rural areas is going to help with reducing the number of domestic violence cases.⁽²⁾⁽³⁾⁽⁴⁾ Also, as only 21% of them talked about their abuse to someone, there is a need for awareness programs to educate them about finding help⁽⁴⁾. This can be done by advertising the helpline numbers on telecom channels and even through education in school which the children can carry home.

Similarly, there should be menstrual health programs in action on ground and school level to educate women about the menstrual hygiene practices.⁽⁵⁾ Government should take up a project to necessarily provide cheaper alternatives to present commercial pads. Companies like Jayaa Shree Industries manufacture production machines which would make sanitary pads for 80% less the cost than the average market price⁽⁸⁾.

Along with this, there is a serious need to monitor the school drop-out rates⁽¹¹⁾ and construct a system to have one on one discussions with the parents of a child about to drop-out, as most of the reasons are governed by the decision of the parents⁽¹²⁾. Overall, the teaching in government schools⁽¹³⁾, hygiene and a safe environment should be provided and kept in check, door to door counselling can be a great source of encouragement with regards to education for the children, especially the female child⁽¹⁰⁾ as only 62% of them are in schools at present⁽¹²⁾.

Ethical Clearance: Not applicable.

Source of Funding: Self-funded.

Conflict of Interest: Nil.

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A Qualitative Study to Assess the Perceptions of the Nurses and Accredited Social Health Activists (ASHAs) Regarding the Prevention of Female Feticide in a selected District of Haryana

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Abstract

Objective: The objective of the study was to assess the perceptions of the nurses and Accredited Social Health Activists (ASHAs) regarding the prevention of female feticide.

Methods: The study was conducted in Public Health Centres and Community Health centres of Faridabad district, Haryana. An in-depth interview was conducted by using semi-structured interview schedule in order to assess the perceptions of the nurses and ASHA workers regarding the different aspects of female feticide. The recorded data were transformed into verbatim written accounts. Thematic analysis was done and it followed a five-phase process. In phase I, transcripts were read fully without coding the data to gain an overall sense of the views of the study participants. In phase two and three, more detailed transcript review to identify key phrases and words, followed by coding and data reduction was done. In phase four, another researcher individually coded the transcripts and compared those findings to reach a consensus about the explanations.

Conclusion: Qualitative analysis of nursing personnel and ASHAs regarding their perception about female feticide provided deeper insights into the problem of female feticide and its consequences in the society. And it reveals that they are sensitized about this pressing issue and are ready to become the channel of communication to the public for the prevention of the female feticide. It is very necessary that the government and NGOs should systematically organize and orient several programmes to tackle this critical social issue.

Keywords: *female foeticide, ASHAs, perception, nursing personnel, ASHAs, prevention.*

Introduction

Everyone in India claims that the country has come a long way since its independence more than half a century ago. Indeed, the country has made significant scientific and technological progress and churn out some of the brightest minds every year in every area possible. But when the country hears of female infanticide and female feticide, let alone the gender

discrimination everywhere else or when the statistics presents the skewed sex ratio, it makes one think that all this progress is absolutely worthless⁹. In this age, when human rights have been in focus internationally, with significant developments made in India as well, it is tragic that gendercide continues unchecked. The constitutional guarantee of equality of the right to life, and its faith in the dignity of every human being seem

so futile, when the parents themselves do not want to protect their child and educated doctors do not have any qualms in flagrantly violating the law¹.

Sex ratio is a sensitive social indicator of development and it shows the status of women in a country. Prenatal sex determination tests followed by quick abortions eliminate thousands of female fetuses. This is due to a mentality that looks down upon the female child as a burden. The fear of dowry on the one hand and losing property in inheritance, on the other, are the major irritants in the acceptance of a girl child². Indicating a continuing preference for boys in the society in India, the child sex ratio has dropped into 914 females against 1000 males³. The sex ratio at birth is the most relevant indicator for examining the magnitude of sex-selective abortions¹⁹. In some parts of the country, the sex ratio of girls to boys has dropped to less than 800:1000. The United Nations has expressed serious concern about the situation⁴.

The Indian Medical Association (IMA) estimates that five million female fetuses are aborted each year, and estimated in 1999 that India had approximately 20,000 ultrasound clinics, most unregistered and staffed by unqualified doctors. In the Indian states of Punjab, Haryana and Uttar Pradesh, mobile vans take sex-detection clinics to outlying villages. "You will find an ultrasound machine even in a village which has a road over which only a bullock cart can go, and electricity to run the machine and nothing else," said one ultrasonographer, as reported in *The Hindu*, a national newspaper⁵. The problem of female feticide requires urgent attention of all the parliamentarians, the government, the judiciary, the media and the public at large. There is an urgent need to embark on a massive nationwide sensitization and advocacy campaign with specific focus on the importance of girl child to reinforce the view that she is an asset not

a burden⁶. The qualitative analysis will help to assess the perceptions of nursing personnel and ASHAs regarding the problem of female foeticide which will be helpful for the planning of intervention for the prevention of female foeticide.

Materials and Methods

Research approach: The qualitative research approach is used to analyze the perceptions of the nursing personnel and ASHAs regarding the prevention of the female feticide. **Thematic analysis research design** is used to analyze the perceptions of the nursing personnel and ASHAs regarding the female feticide. Thematic analysis is applied to information gained from the interviewing participants transposed to interview transcripts. It emphasizes pinpointing, examining, and recording patterns/themes within the data⁷.

The study was conducted in the Public health Centres (PHCs) and Community Health Centres (CHCs) of Faridabad district of Haryana. Purposive sampling technique was used for selecting the sample and the sample size for thematic analysis was 16, which included 12 ASHA workers and 4 Auxillary Nurse Midwives (ANMs).

Development of tools

A semi-structured interview schedule was developed by the investigator and it consisted of 12 open ended questions and an in-depth interview was conducted for the participants in order to analyze the perceptions related to female feticide. The content was recorded; transcribed and thematic analysis was done. **Braun & Clark's (2006)** step-by –step guide for thematic analysis was used for analyzing the content of interview in order to analyze the perceptions of the nursing personnel and ASHAs regarding female feticide.

	Phase	Description of the process
1	Familiarize with the data- re-listen to audio and read transcripts a few times	Transcribing data (if necessary), reading and rereading the data, noting down initial ideas.
2	Generate initial code	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3	Discovering the themes or searching for the theme	Collating codes into potential themes, gathering all data relevant to each potential theme.
4	Reviewing the themes	Checking if the themes work in relation to the coded extract (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5	Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6	Writing the analysis/producing the report	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis of the research questions and literature, producing a scholarly report of the analysis.

Braun & Clark's (2006)

The tool was sent to the experts for validation. Experts were requested to give their opinion on the adequacy, relevance and appropriateness of each item. Based on the opinion from the subject experts, content validity index of each item and for the total instrument were calculated. The item with content validity index more than 0.8 were selected. The Content Validity Indices of semi-structured interview schedule was 0.8

Data collection procedure

Formal permission was collected from State Appropriate Authority-cum-Director General, Health services, Haryana. Formal permission has also been collected from District Appropriate Authority (PNDT) –cum-Civil Surgeon, Faridabad. The data was collected after obtaining ethical clearance from the institutional ethical committee of St.James

College of Nursing, Chalakudy. Written informed consent was obtained from all the participants before data collection and was assured that the information obtained would be kept confidential and used only for the research purpose. After obtaining the formal permission, an in-depth interview was conducted for the participants. The participants gathered in the hall attached to the primary health centre for data collection. Interview lasted for about 15-45 minutes, depending on the participant's ability to express themselves. All interviews were recorded. The interview was video recorded .

Results and Discussion

The recorded data were transformed into verbatim written accounts. Analysis followed a five-phase process. In phase I, transcripts were read fully without coding the data to gain an overall sense of the views of the study participants. In phase two and three, more detailed transcript review to identify key phrases and

words, followed by coding and data reduction was done. In phase four, another researcher individually coded the transcripts and compared those findings to reach a consensus about the explanations.

Description of the participants

There were sixteen participants and all of them were females. Among the participants, twelve were

ASHAs and four of them were ANMs. The number of participants from each health centre depended on the total number of samples is as follows: Kaurali CHC-5, Mohanna PHC-3, Chaiinsa PHC-4 and from Dayalpur PHC-4. Participants readily spoke about the topics raised in the interviews.

Table.1.Opinion regarding the female feticide as stated by the nursing personnel and ASHAs

n=16

Sl.No	Suggestions	f	%
1	Female feticide should stop at any cost	9	56.25
2	It is a big sin	3	18.75
3	Female feticide is wrong	3	18.75
4	Gives bad effect on women and society	3	18.75
5	It is a big crime	1	6.25

The immediate response of 56.25% (9) of participants towards female feticide was that it should be stopped at any cost. And 18.75% of the participants opined that it is a big sin, it is wrong and it gives bad effect on women and society.

A few verbatim observations of in-depth interview are as follows:

Female feticide is a sin; if we kill the girl baby,

then how can we worship Devi? Now I became deeply aware about the facts of female feticide because of this movie and class.

Today, the status of girls have increased and they are educated than boys; hence we need to discourage the female feticide. In my family, there are five girls and one brother. My father educated us and we all are living happily.

Table 2. Reasons for the preference for sons as stated by nursing personnel and ASHAs

n=16

Sl.No	Suggestions	F	%
1	Boy carries the name of the family	16	100
2	Boy can take care of the assets	4	25
3	Support provider in old age	2	12.5

Cont... Table 2. Reasons for the preference for sons as stated by nursing personnel and ASHAs**n=16**

4	Earns the money	2	12.5
5	Girl will go to her husband's house	2	12.5
6	Effect of culture	1	6.25
7	Perform the last rites	1	6.25

During the interview, all the participants had the opinion that the main reason for the preference for a son is that the “boy carries the name of the family,” though they are not convinced with the answer. It is clear from the response of one ASHA worker: “Since girls only can give birth to a baby, how can we say

boys carry the name of the family?” Four (25%) of the participants expressed the reason that the boy takes care of the assets. One ANM added along with this answer, “*People think only a boy can take care of the assets- land, building, agriculture; but girls also can manage that.*”

Table 3. Reasons for the female feticide as stated by the nursing personnel and ASHAs**n=16**

Sl.No	Suggestions	f	%
1	Dowry	8	50
2	Poverty	3	18.75
3	Compulsion from husband and in-laws	3	18.75
4	Availability of ultrasound scan	2	12.5
5	Lack of education	2	12.5

The spontaneous response of 50% (8) of the participants for the reason for the female feticide is dowry, followed by poverty (18.75%) and compulsion from husband and in-laws (18.75). The response of

one ASHA worker is noted: “*Today, we can't marry a girl without dowry; if there is no adequate money, it creates problems in both the families.*”

Table 4. Perception of nursing personnel and ASHAs about dowry**n=16**

Sl.No	Suggestions	f	%
1	Should stop dowry system	13	81.25
2	Cause for many family problems	8	50
3	Husband's family demands more and more	5	31.25
4	Burden for the parents	4	25
5	Cause for the female feticide	4	25

It is noted that 81.25% of the participants responded that dowry should stop at any cost. The following verbatim reveals the mindset of the ASHA worker: "I don't accept the boy who demands dowry. During my proposal time, one boy demanded dowry; I just refused that boy." Another ANM responded: "People think if there is no girl, no need to educate her and no need to give dowry also."

The present study supports the observations made in the study done in Mandya district about the disappearance of daughters and the intensification of gender bias. The study reports:

Boys' parents consider it is their right to collect dowry. They never think about the economic position of the girls' parents. No marriage in this village has

taken place without giving gold and cash to the boys' family. I don't want daughters. Even if I spend Rs 5,000 for abortion; it is better than spending Rs 500,000 on dowry⁸.

Another study done by Saroja Krishnaswamy in Dharward city contradicts the present study where the majority of married group of respondents were found to have significantly more favourable attitude towards dowry than unmarried women. In addition, as the educational level increased the attitude of women became increasingly favourable toward dowry. Moreover as the income of their parents increased, the attitude of both married and unmarried women became increasingly favourable. These findings imply the need to search for social and psychological factors which defeat all the efforts to eradicate dowry⁹.

Table 5. The consequences of the female feticide as stated by the nursing personnel and ASHAs**n=16**

Sl.No	Suggestions	f	%
1	Men won't find wives	09	56.25
2	Sexual violence and crimes will increase	09	56.25

Cont... Table 5. The consequences of the female feticide as stated by the nursing personnel and ASHAs**n=16**

3	Normal existence of the community will affect	03	18.75
4	Man cannot carry the name of the family without woman	02	12.5
5	Women go back to their own houses	01	6.25
6	No respect to woman	01	6.25
7	Family members torture the women	01	6.25

Among the participants, 56.25% (9) of them cited two main consequences: Man cannot find wives and sexual violence and crimes will increase. Today, generally the women in the society are so much anxious about the sex of the baby, in spite of the parity of the mother. It is clear from the following statement of an ASHA worker.

If there are 2 boys also, some couples wish third baby also to be a boy. Five days before, I met one antenatal mother with third pregnancy. She is scared about the sex of the baby and she took *Halathi* powder and some Ayurvedic medicine. But it was not get aborted and now the pregnancy is going on.

The data regarding the multitude of reasons given by the respondents which they feel would help in dealing with this social issue are as follows: Among the 16 participants, 14 (87.5%) expressed the need for providing awareness to women. 9 (56.25%) of them added the importance of education to women to deal with the present situation which is evident in the following verbatim: “Actually, boys are not studying well and they are failing in most of the subjects; girls are doing well. I feel girls are more capable than boys.”

With regard to the role of Doctors for preventing the female feticide, 87.5% of the participants opined that doctors should stop the detection of the sex of the baby. The role of doctors was expressed by an ASHA worker in one sentence: “Doctors are the main people

who do the ultrasound scanning, doing the abortion and taking the money. So first, doctors should get awareness about the seriousness of the problem.” Similar findings were reported in a study conducted in Delhi to assess the knowledge and the attitude of medical students and interns about female feticide. The participants included 62 interns and 39 IV year MBBS students and the data collected regarding the suggestions pertaining to arrest the declining gender ratio include: stricter punishment for doctors conducting illegal medical termination of pregnancy (15%), stricter punishment for doctors conducting illegal ultrasounds (26%), stricter punishment for a woman seeking abortions (14%) and stricter punishment for such a woman’s family (56%)¹⁰.

In the present study, according to 43.75% of the participants the regular follow up of pregnant mothers in the village is considered as one of the important roles of the ASHA workers. And 43.75% suggested the nurses should organize the training programme with movies to sensitize the people. Another study conducted in Ludhiana to assess the awareness and perceptions of school children regarding female feticide posed an open ended question in the questionnaire: “How this social evil can be stopped?” The respondents suggested the following answers: by increasing awareness in the society and parents, by giving equal status to girls, by giving punishment to people and doctors involved, by enforcing strict

law and by enforcing law against prenatal sex determination¹¹.

Have you come across any woman with history of female feticide?

The responses were as follows: Yes

I have come across about 15-20 cases during my seven years of experience. After the registration of pregnancy, when the woman is not coming for check up, I enquire about it and then I come to know the reality.

One ASHA worker explained:“In most of the cases, the reason was that it was second pregnancy with a girl baby and they wanted a boy baby.” Other two instances which the ASHA worker related are like this:

One woman registered for the second pregnancy; first child is a girl baby; when I went to her house to inform about vaccination, she is not pregnant. I asked her what happened. While she was doing some work, she slipped off and baby got aborted. Mother said. Later I came to know that it was lie; actually she had done female feticide.

Last year, I met one lady who was pregnant for the third time and has two girls already. And she was confused and was scared about the sex of the third baby and wanted to do abortion without doing scanning itself. I discouraged her saying that what surety she has about the sex of the baby. Anyway, she continued her pregnancy and it was a boy baby.

Another ASHA worker shared her experiences:

One lady, pregnant for the fourth time; already three girls; her husband wanted to do scanning and abortion; Doctor informed them that it's a girl baby; by the time five months were over. She shared her experience with me. I said: If you kill this baby, how can you be happy in life? You also will have

complications, even death; anyway she continued her pregnancy and gave birth to the fourth girl child.

In my village, I know one pregnant lady; I requested her to come for Inj.T T, but she did not come; when I enquired, I came to know that she has aborted her child. After that she has never become pregnant, even though she wanted a child.

Conclusion

Qualitative analysis of the nursing personnel and ASHAs regarding their perception about female feticide reveals that they are sensitized about this pressing issue and are ready to become the channel of communication to the public for the prevention of the female feticide. It is very necessary that the government and NGOs should systematically organize and orient several programmes to tackle this critical social issue.

Ethical Clearance: Formal permission was collected from State Appropriate Authority-cum-Director General, Health services, Haryana. Formal permission has also been collected from District Appropriate Authority (PNDDT) –cum-Civil Surgeon, Faridabad. The data was collected after obtaining ethical clearance from the institutional ethical committee of St.James College of Nursing, Chalakudy. Written informed consent was obtained from all the participants before data collection and was assured that the information obtained would be kept confidential and used only for the research purpose.

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Differential Effects of Heated Tobacco Products and Conventional Cigarettes on Cardiovascular System

A Systematic Review of Randomized Trials

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Abstract

Background: Heated tobacco products (HTP) are alternative forms to traditional cigarettes. Harmful components contained in HTP tobacco aerosol are in lower amounts than those in smoke from traditional cigarettes. That's why HTP are believed to reduce the burden of smoking related-diseases. However, due to its potentially toxic chemicals and the increased concentration of nicotine, HTP devices may not be as safe as the industries claim. This review was completed to summarize effects of HTP on user's health, in particular on cardiovascular system.

Methods: A systematic search of the literature in PubMed database was performed to identify significant articles published from 2015 to 2021. For this review we selected randomized clinical trials that explore the effects of heat-not-burn cigarettes on the cardiovascular system. Independent and sponsored studies by the tobacco industry were included.

Conclusion: The analysis of biomarkers of biological effect, such as those for oxidative stress, platelet activation, endothelial dysfunction, inflammation, antioxidant reserve and others showed differences between smokers and people using heated tobacco products in favor of the latter. However, studies comparing the acute effects of different tobacco products on arterial stiffness, heart rate and myocardial function indicated no relevant differences between IQOS and traditional cigarettes.

So, Heated Tobacco Products appear less harmful. Nevertheless, due to conflicting information and the restricted knowledge of IQOS exposure, further long-term human studies are needed to assess the potential benefit and risk of heated tobacco products.

Keywords: *Heated Tobacco Products; Cardiovascular system; Adverse effects*

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Introduction

Heated tobacco products (HTP) are alternative forms to traditional cigarettes⁽¹⁾. Harmful components contained in HTP tobacco aerosol are in lower amounts than those in smoke from traditional cigarettes⁽²⁾⁽³⁾. Tobacco heating systems release nicotine at

lower temperatures (240–350 °C), without fire and smoke, while traditional cigarettes heat tobacco more than 600 °C⁽¹⁾. During the heating process generated aerosols have 90–95% lower levels of harmful substances than traditional cigarette smoke: affirm tobacco industries⁽⁴⁾⁽⁵⁾⁽⁶⁾⁽⁷⁾. Some independent studies have also confirmed that the amount of toxic compounds contained in HTP aerosol is lower than that generated by conventional cigarettes⁽⁸⁾⁽⁹⁾⁽¹⁰⁾. That's the rationale behind the belief that use of HTP will result in reduction of the burden of smoking related-diseases.

However, due to its potentially toxic chemicals and the increased concentration of nicotine, HTP devices may not be as safe as the industries claim⁽³⁾⁽⁶⁾⁽¹¹⁾⁽¹²⁾⁽¹³⁾⁽¹⁴⁾⁽¹⁵⁾⁽¹⁶⁾⁽¹⁷⁾.

Due to conflicting information and the restricted knowledge of IQOS exposure, we completed this review to study effects of HTP on user's health, in particular on cardiovascular system.

Objective of the Study

The objective of the study is to evaluate whether the use of heat-not-burn cigarettes lead to a decreased cardiovascular risk, compared with the risk of combustible cigarettes.

Materials and Methods

Protocol and registration

We developed this systematic review using the criteria of the PRISMA statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)⁽¹⁸⁾. The study's protocol was submitted to an international prospective register for systematic reviews (PROSPERO registry) and currently waits for approval under the number ID288674.

Information sources

A systematic search of the literature in PubMed

database was performed to identify significant articles published from 2015 to 2021, during which smoke-free products were used more often.

Search strategy and selection of the studies

For our search we included keywords related to the potential effect of heated tobacco products on cardiovascular system. Relevant results were identified using the following search terms with their possible alternatives: heated tobacco product, IQOS, cardiovascular system, adverse effect. Selected terms were used both as keywords and medical subject headings (MESH terms). The reference lists of the selected articles were subject to a hand search to find additional studies.

For this review we selected randomized clinical trials that explore the effects of heat-not-burn cigarettes on the cardiovascular system. Independent and sponsored studies by the tobacco industry were included.

The studies on animals, experimental in vitro studies and articles in a language other than English were excluded.

In total 195 articles were found as a result of our search. They were all checked for eligibility by two independent researchers. First all articles were explored by title and abstract. The majority of articles did not meet the inclusion criteria for our study and were excluded. Two abstracts without a full text version were excluded too, because of lack of information on bias risk. The remaining 8 articles were subject to a full-text review. The search strategy and selection process are presented in details in PRISMA flow diagram.

Risk of bias in individual studies

We assessed the risk of bias of the selected individual studies using The Cochrane Collaboration Risk of Bias Assessment 2.0 tool for individually

randomized parallel group trials⁽¹⁹⁾. The assessment was done on a study level and was based on five main domains (bias arising from randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, bias in selection of the reported result).

Results

Some of the selected studies explore the potential effects of tobacco and alternative tobacco products on cardiovascular system by evaluating the amount of biomarkers of potential harm (BOPH) that increase the cardiovascular risk, while the others evaluate their direct effects on cardiovascular system.

Two similar randomized studies were conducted in Japan in 2016 and in the United States in 2018, which compare the effects of menthol cigarette and Tobacco Heating System (THS) 2.2 on oxidative stress, endothelial dysfunction, platelet activation and lipid metabolism⁽²⁰⁾⁽²¹⁾.

In both studies participated one hundred and sixty healthy adult smokers. All subjects were randomized in a 2:1:1 ratio to menthol Tobacco Heating System 2.2 (mTHS), menthol cigarette, or smoking abstinence for 5 days in confinement and 86 ambulatory days. The study in Japan showed that switching from menthol cigarettes to Tobacco Heating System was associated with statistically significant improvements in clinically relevant risk markers, such as high density lipoprotein (HDL-cholesterol: marker of lipid metabolism), intercellular adhesion molecule 1 (s-ICAM 1: marker of endothelial dysfunction), 8-Epi-Prostaglandin F2 Alpha (8-epi-PGF₂ α : marker of oxidative stress), and white blood cells (WBC: marker of inflammation)⁽²⁰⁾. The improvements in these markers approached those detected in the smoking abstinence group. In

USA statistically significant changes were observed only for s-ICAM-1 and 8-epi-PGF₂ α . Here further favorable, but statistically not significant changes were observed in high sensitivity C-reactive protein (hs-CRP), total cholesterol, HDL, low-density lipoprotein, Apo B and Apo A1 ($p > 0.05$)⁽²¹⁾.

Another multi-center, randomized trial of smokers switched to tobacco-heating cigarettes, snus or ultra-low machine yield tobacco-burning cigarettes (50/group) was conducted in 2015⁽²²⁾. An additional group of no smokers was included for baseline comparisons. Several biomarkers of biological effect including those for oxidative stress and inflammation, hypercoagulable state, endothelial dysfunction, insulin resistance, DNA damage and lipid/cardiac risk markers were analyzed. In the baseline comparisons statistically significant differences between smokers and no smokers were detected only in half of measured biomarkers (in particular in intercellular adhesion molecule 1 (s-ICAM1), white blood cells (WBC), oxidized low density lipoprotein (OxLDL), hemoglobin (Hgb), homocysteine, hematocrit (HCT), and sister chromatid exchange in peripheral lymphocytes (SCE)). Smokers, who were switched to tobacco-heating cigarettes have statistically significant improvements in some biomarkers, such as platelets, intercellular adhesion molecule 1 and WBC. S-ICAM1 was significantly reduced also in the smokers switched to snus or to the ultra-low yield tobacco-burning cigarette⁽²²⁾.

In 2019 another randomized, independent cross-over trial in 20 smokers was conducted, which compared the acute adverse effects of heat-not-burn cigarettes (HNBC), electronic vaping cigarettes (EVC) and traditional cigarettes (TC) on oxidative stress, antioxidant reserve, platelet function, flow-mediated dilation and blood pressure⁽²³⁾. All types of the mentioned products were used by each

participant, with one week intercycle washout period. The biomarkers were explored after a single use of each mentioned product. Compared to traditional cigarettes, HNBC had statistically significant less impact on oxidative stress markers (such as soluble Nox2-derived peptide, H_2O_2 , H_2O_2 breakdown activity, 8-iso-prostaglandin $F2\alpha$ -III), vitamin E, soluble P-selectin, flow-mediated dilation, and blood pressure⁽²³⁾.

In another randomized trial the effects of Heat-not-Burn cigarette (HNBC) on coronary, arterial and myocardial function, as well as on platelet activation and oxidative stress were compared to those of tobacco cigarette (Tcig)⁽²⁴⁾. In the acute study, 50 subjects smoked either a single Tcig or a HNBC and after 60 min were crossed-over to the alternate smoking. The amount of malondialdehyde (MDA), exhaled carbon monoxide (CO), thromboxane B2 (TxB2) and pulse wave velocity (PWV) were assessed before and after each smoking. The acute study showed that significantly smaller increase of PWV was caused by HNBC smoking compared to Tcig smoking, without change in biomarkers and CO in contrast to traditional cigarettes. In the chronic phase 50 smokers started to use HNBC for one month and were compared with an additional group of 25 cigarette smokers. The amount of malondialdehyde (MDA), exhaled carbon monoxide (CO), thromboxane B2 (TxB2), pulse wave velocity (PWV), as well as myocardial work index (GWI), global longitudinal strain (GLS), coronary flow reserve (CFR), wasted myocardial work (GWW), flow-mediated dilation (FMD) and total arterial compliance (TAC) were assessed in the chronic study. Switching to Heat-not-Burn cigarette for 1-month improved CO, FMD, CFR, TAC, GLS, GWW, MDA, TxB2 compared to traditional cigarettes. So, this study shows, that puffing of HNBC has less acute adverse effect on arterial elasticity compared to Tcig and did not

cause a further increase of platelet activation and oxidative stress burden in contrast of tobacco cigarette. Improvement in oxidative stress burden and endothelial function, reduction of platelet activity, as well as improvement in coronary flow reserve and myocardial work efficiency were observed when switching from Tcig to HNBC for one month⁽²⁴⁾.

Two similar randomized studies, which compared the effects of different smoking products on arterial stiffness were performed in 2020⁽²⁵⁾⁽²⁶⁾.

In the first study 22 current smokers smoked randomly HNBC (IQOS) heat stick, a standard tobacco cigarette and a sham cigarette on three separate visits. Heart rate, blood pressure (both brachial and aortic), augmentation index corrected for HR (AIx@75), carotis-femoral PWV and brachial-ankle PWV were assessed before and immediately after smoking, and then at 5, 10, 20 and 30 minutes. No differences in all baseline measurements were observed between the three sessions. All the mentioned parameters were increased significantly after HNBC (IQOS) heat stick and a standard tobacco groups compared with sham smoking ($p < 0.05$). Although HNBC resulted in less potent numerical increases of examined parameters compared with tobacco cigarette, the observed differences between 2 types of smoking products were not significant. So according to this study HNBC is similarly impactful to tobacco cigarette for aortic stiffness and central haemodynamics⁽²⁵⁾.

In the second study 20 active healthy smokers have to smoke HTP 2.2 (IQOS), a tobacco cigarette (Cig), e-cigarette with nicotine (ECig(+)), and e-cigarette without nicotine (ECig(-)) on four separate visits with interperiod wash-out of at least 48 hours. According to this study peripheral systolic blood pressure (SBP), mean arterial pressure (MAP) and heart rate (HR) increased significantly within

the Cig, ECig(+), and HTP groups ($p < 0.05$). The augmentation index, adjusted for a HR of 75 bpm (AIx75), increased significantly in the Cig group after 5, 10, and 15 minutes and in the HTP group after 5 minutes. In pulse wave velocity (PWV) statistically significant alteration after 15 minutes was seen only for the Cig group ($p < 0.05$), whereas statistically insignificant trend was shown for ECig(+) ($p \approx 0.072$) and HTP ($p \approx 0.066$) groups ⁽²⁶⁾.

Another study, completed in 2020, compared myocardial systolic and diastolic function within transthoracic echocardiography in the acute phase after IQOS smoking and cigarette smoking ⁽²⁷⁾. Heart rate, systolic and diastolic blood pressure before and after smoking of each product were assessed too. Twenty-seven healthy IQOS smokers participated in this prospective study. Measurements were performed for each participant before smoking any tobacco product, after IQOS smoking and after cigarette smoking. The study showed, that in comparison with non-smoking status, LV global longitudinal strain (GLS), LV global circumferential strain (GCS), as well as RV longitudinal strain (GLS) decreased significantly after IQOS and cigarette smoking ($p < 0.05$). HR increased significantly after using of both products in comparison to nonsmoking status, whereas systolic and diastolic blood pressure increased significantly only after cigarette smoking ⁽²⁷⁾.

Discussion

The impact of HTP on human health is still not well established. Studies evaluating the adverse health effects of HTP are rare and mostly conducted by tobacco industry. Implemented in vitro tests showed that HTP aerosols contain lower amount of toxic substances compared to traditional cigarette smoke. However, no sufficient amount of longitudinal studies on human are available to argue that switching from cigarettes to IQOS can lead to a reduction in

exposure of toxic substances comparable to smoking abstinence.

Studies included in our systematic research indicated decreased amount of biomarkers of biological effect in individuals switched to IQOS smoking. The biomarkers include those for oxidative stress, platelet activation, endothelial dysfunction, inflammation, antioxidant reserve and others. Studies that assess the acute effects of different types of tobacco products also indicate lower amount of biomarkers after using a single heating tobacco product compared to traditional cigarette. The validity of the chosen end points is well established. Indeed, systematic oxydative stress, downregulation of the antioxydant system, endothelial dysfunction and platelet activation play a fundamental role in vascular damage, atherogenesis and thrombosis. Higher levels of the mentioned biomarkers are surely associated with increase of the risk of cardiovascular events.

Despite growing evidence of potential favorable effects of heating tobacco products on cardiovascular system, studies comparing the acute effects of different tobacco products on arterial stiffness, heart rate and myocardial function indicated no relevant differences between IQOS and traditional cigarettes. The reason for this might be that IQOS delivers nicotine to organism in a similar way and quantity, as conventional cigarettes and this factor also needs to be studied further. Given the predictive role of arterial stiffness and myocardial function for cardiovascular events, the above mentioned findings born doubt on the advocating of smoking IQOS as a less risky product for the prevention of cardiovascular diseases.

Conclusion

It is clear that due to conflicting information and the restricted knowledge of IQOS exposure further long-term human studies are needed to assess the potential benefit and risk of heated tobacco products.

However, available evidence is still in favor of HTP.

Limitations

The first limitation of included studies is the relatively small sample size of the selected population and the limited period of exposure. The next limitation is that the trials studied effects of different tobacco products only on apparent healthy subjects, and there is no evidence about users who have chronic cardiovascular diseases. The absence of a control group, not receiving any tobacco product, was a limitation of most of the included studies. Different levels of user's compliance with study products possibly affected the results too. However, according to Cochrane Collaboration's R.O.B. 2 assessment all the studies showed low risk of bias, which is a major strength of this review.

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Ethical Clearance : Taken from Nork-Marash Medical Center ethical review board.

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Separation Anxiety Disorder among Preschool Children in Baghdad / Iraq

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Abstract

Background: Separation anxiety disorder (SAD) is a condition in which a child becomes fearful and nervous when away from home or separated from parent or another caregiver whom the child is attached to⁽¹⁾. Some children may develop physical symptoms, such as headaches or stomachaches when thought of being separated⁽²⁾. The fear of separation causes great distress to the child and may lead to interfere with their normal activities like going to kindergartens or playing with other children⁽³⁾. Few publishing on preschool SAD in Iraq. This was the impetus to carry out this work.

Key words: *Separation Anxiety disorder, fearful emotion, preschool children.*

Objective

Enhancement the attendance care of mental health of preschool children.

Materials and Methods

A total of 423 preschool children were included in the study. They were recruited from public and private kindergartens. The sample was selected by multistage random sampling. Al-Resafah selected randomly from the two sides of Baghdad. Al-Resafah Al-Thanih directorate was selected randomly from 3 educational directorate in Al-Resafah side of Baghdad. The selected kindergartens were Four private and four public kindergartens randomly from directorate.

Spence child anxiety scale-parent version (SCAS-P) was used. The SCAS-P is with good psychometric properties⁽⁴⁾.

Socioeconomic status was determined according to the recent published data⁽⁵⁾. Anxiety was dichotomized (Anxiety and no Anxiety). The data was collected by direct interview with one parent, usually

the mother. Chi square was used to test the impact of independent variables on dependent variable and Fisher's Exact test when recommended. P value < 0.05 was considered significant.

Results

Out of total, 101 (23.9%) were with SAD. It was 33 (21.0%) at age 5 years old while at age 4 and 6 years old very closely rate 33 (25.6%), 35 (25.5%) respectively. There was no significant association between Separation Anxiety and age of preschool children ($\chi^2 = 1.1$, d.f.=2, p=0.5). P value > 0.05.

Separation Anxiety was mainly in male 67 (33.7%) while 34 (15.2%) in female children. There was significant association between Separation Anxiety and sex of preschool children ($\chi^2 = 19.8$, d.f.=1, p=0.0001). P value < 0.05.

Separation anxiety was 67 (31.8%) at public kindergartens while 34 (16.0%) at private kindergartens. There was significant association between separation anxiety and type of kindergartens

($\chi^2 = 13.4$, d.f.=1, p=0.0001). P value < 0.05. High percentage of Separation anxiety with low socioeconomic status was 50 (48.1%) while middle socioeconomic status there was 42 (18.6%) children and the lower percentage with high socioeconomic status 9 (9.7%). There was significant association between separation anxiety and SES ($\chi^2 = 47.3$, d.f.= 2, p=0.0001). P value < 0.05.

Undergraduate fathers of children with Separation anxiety were 24 (38.1%) while graduate fathers were 61 (22.0%) and the lower percentage with postgraduate fathers 16(19.3%). There was significant association between Separation anxiety and paternal education according to Chi square test (P value =0.01). P value < 0.05.

There are 31 (44.9%) children had Separation anxiety with undergraduate maternal education while graduate mothers there were 60 (22.5%) children and the lower percentage with postgraduate mothers 10 (11.5%). There was significant association between Separation anxiety and maternal education according to Chi square test (P value =0.0001). P value < 0.05.

There were high percentage of Separation anxiety with children caring by one parent 76 (78.4%) while there were 10 (18.2%) with children caring by grandparents and there were 15 (5.5%) children had GA caring by both parents. There was significant association between Separation anxiety and care giver of children ($\chi^2 = 209.5$, d.f.= 2, p =0.0001). P value < 0.05.

Distribution of Separation Anxiety Disorder with determinant factors:

variable	total	SAD		Chi square χ^2
		No.	%	
Age 4	137	35	25.5	$\chi^2 = 1.1$, d.f.=2, p=0.5
5	157	33	21.0	
6	129	33	25.6	
Sex female	224	34	15.2	$\chi^2 = 19.8$, d.f.=1, p=0.0001
male	199	67	33.7	
Kindergarten public	211	67	31.8	$\chi^2 = 13.4$, d.f.=1, p=0.0001
private	212	34	16.0	
SES Low	104	50	48.1	$\chi^2 = 47.3$, d.f.= 2, p=0.0001
Middle	374	42	18.6	
High	93	9	9.7	
Paternal education Postgraduate	83	16	19.3	$\chi^2 = 8.5$, d.f.= 2, p=0.01
Graduate	277	61	22.0	
Undergraduate	63	24	38.1	

Cont.... Distribution of Separation Anxiety Disorder with determinant factors:

Maternal education Post graduate	87	10	11.5	$\chi^2 = 24.4, d.f.= 2, p =0.0001$
Graduate	267	60	22.5	
Undergraduate	91	31	44.9	
Caregiver One parent	97	76	78.4	$\chi^2 = 209.5, d.f.= 2, p =0.0001$
Both parent	271	15	5.5	
Grandparent	55	10	18.2	

Discussion

Separation anxiety experience extreme distress when they are separated from parents and caregivers (6). DSM-5 provides 11 different anxiety disorder, and only 4 for preschool (GAD, SA, Social anxiety and specific phobia) (6).

The separation anxiety disorder rate was 23.9% while in other literature may show lower rate 12.3 %. Children who faced traumatic event may show increase rate of SAD (7). Also, this might be attributed to employed mothers i.e., usually employed parents leaves their children in the kindergartens when they went to work and they worry about the effects of daily separation on their children (8).

Male children show high rate 67 (33.7%) while 34 (15.2%) female children among kindergartens. Literatures shows high rate of SAD among male children (9)(10).

SAD has significant association with type of kindergartens p value <0.05. This might due to good care of children, good building and they provide all playful tools in private kindergartens while the public usually old building and a smaller number of teachers so the care for children will be less efficiency.

Low socioeconomic status has significant affect

on increase rate of SAD among children. Also, literature might show the same effect (11).

Children cared by one parent were significant higher complain of SAD (p = 0.0001). This might attribute to increase in stress on child by absence of one parent. It is in agreement with that reported in other countries (12).

This study shows significant association between the paternal and maternal education and the anxiety of children. SAD of children increased with parents have undergraduate education (secondary school or less). This might be due to the education of parents plays important role in upbringing of the children (13).

Conclusion

A higher rate of SAD among preschool Iraqi children.

Conflict of Interest: Nil

Source of Funding: Self-Source

Ethical Clearance:

1. The approval of scientific board of community medicine –ethical committee will be obtained.
2. The official agreement will be obtained from the Research Ethical Committee in ministry of health

–Iraq.

3. The official permission will be obtained from the ministry of education.

4. The collection of data will be kept confidential and not be divulging.

5. A written consent will be taken from the parents for participating in this study and the manager of kindergarten.

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Effect of Pranayama (Ancient Indian Breathing Techniques) in Laparoscopic Cholecystectomy Patients: A Prospective Randomized Control Trial

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Abstract

Pranayama is an art of prolongation and control of breath, which helps the person to bring his conscious awareness in breathing; to reshape his breathing habits and patterns these in turn produce various biochemical and physiological changes in the body milieu which need no proof.

Materials and Methods: A total of 40 patients having cholelithiasis which consisted 34 females and 6 males (All were nonsmoker) with age varying from 18years to 82years were recruited from our hospital, Uttar Pradesh University of Medical sciences, Saifai. Etawah.

Results: In our study we found that the mean alertness level at 1 hour post op in subject groups was 7.2 in respect to 5.8 in the control group, which has a significant value.

Keywords- Pranayama, Laparoscopic Cholecystectomy patients, Breathing, Physiological environment, Stress

Introduction

Yoga is one of the most ancient Indian science as well as the way of life, which includes practice of specific postures (asanas), regulated breathing (pranayama) and other austere Vedic practices including dietary and life style modifications and regulations. Breath is the dynamic bridge between body and mind and pranayama (breathing techniques) is one of the most important yogic practices, which produces different physiological responses in the practitioner. Pranayama is an

art of prolongation and control of breath, which helps the person to bring his conscious awareness in breathing; to reshape his breathing habits and patterns these in turn produce various biochemical and physiological changes in the body milieu which need no proof. The mental changes modify the practitioners physiological responses to various trauma and also alters the pain tolerance threshold. The persistent conditioning of breathing pattern of pranayama increases the pulmonary function, improves other physiological hemodynamic functions, besides improving the physical and mental status of the individuals¹.

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Though, there are various pranayama: yogic practices, the Bhramari Pranayama (humming bee

breath) is one of the yogic practice, which involves sitting in Sukhasana position (ease pose the subject should inhale through both nostrils and while exhaling produce sound of female humming bee Combination of A, U (O) and me..." OM" is one of the fundamental symbols used in the yoga tradition, which symbolizes the three states of consciousness i.e., waking state, dream ate and deep sleep. Though, the sound of OM presents a vibration and the OM chanting is an important exhalation exercise.^{2,3}

There have been tremendous studies on yoga and its effects on physical functions, autonomic variables, stress etc on healthy individuals, the popularity of yogic pranayama is increasing astonishingly in the past few years⁴ both in the Indian sub-continent and abroad. However, there is lack of documented studies on pranayama (yogic breathing exercises) and its effects on patients experiencing stress the present study entails surgery as a form of physical stress. To the best of our knowledge there is limited randomized control trial representing the effect of pranayama on patients undergoing surgery(Cholecystectomy), which made us to select this present study with the aims and objective to evaluate the effect of Pranayama and Anulom –Vilom (a yogic breathing practice and exercise) in post op Patients:

Technique

Nadhi - Sodhana/ Anulom -Vilom also known as alternative nostril breathing, is a very relaxed, balancing breath that is used to help calm the nervous system and aid in a restful night's sleep. By increasing the amount of oxygen taken into the body, it's believed that this breath can also purify the blood, calm the mind, reduce stress, and promote concentration and alters the Practioners physiological response to stress which include

greater tolerance to pain, emotional trauma and maintaining the body vitals within normal physiological limits despite stress.

We advised patients Nadhi - Sodhana (a yogic breathing practice and exercise) which can be done seated or lying down. To start, empty all the air from your lungs. Using the thumb of their dominant hand, block their right nostril and inhale through their left nostril only. Be sure to inhale into their belly, not their chest. Once they are full of breath, seal their left nostril with the ring finger of the same hand, keeping their right nostril closed, and hold the breath for a moment. Then release their thumb and exhale through their right nostril only. Seal both nostrils once they have inhaled on the right side and exhaled through the left side. A complete cycle of breath includes an inhalation and exhalation through both nostrils. This was taught to the patient by physical demonstration by the doctors of our team, who were well trained in this yogic breathing exercises

We advised the patients to perform up to ten cycles of this breathing exercises and notice how their body responds in respect to a generalized feel of well-being.

Patient were monitored at 3 day interval regularly.

Materials and Methods

A total of 40 patients having cholelithiasis which consisted 34 females and 6 males (All were nonsmoker) with age varying from 18years to 82years were recruited from our hospital, Uttar Pradesh University of Medical sciences, Saifai. Etawah. Though, the patients were from different background they all were managed in the similar atmosphere, diet and treatment. As laparoscopic

Cholecystectomy is the gold standard^{5, 6} for the treatment of Cholelithiasis. We decided to conduct a study of, yogic breathing techniques pre operatively 2 weeks prior to the surgery and postoperatively on patients undergoing elective laparoscopic cholecystectomy. Out of 40 patients, 36 were unaware of breathing techniques and were termed as non-yoga practitioners, 2 patients were self-inherited practitioners of yoga who picked it up by watching television and two were practitioners who did not practice since 6-7 months with reasons not documented. The study was conducted in the Department of Surgery in our University of medical sciences and hospital. The study was explained to all subjects and their written informed consent had been obtained. The sample size was determined based on the number of subjects who volunteered to participate in the trial.

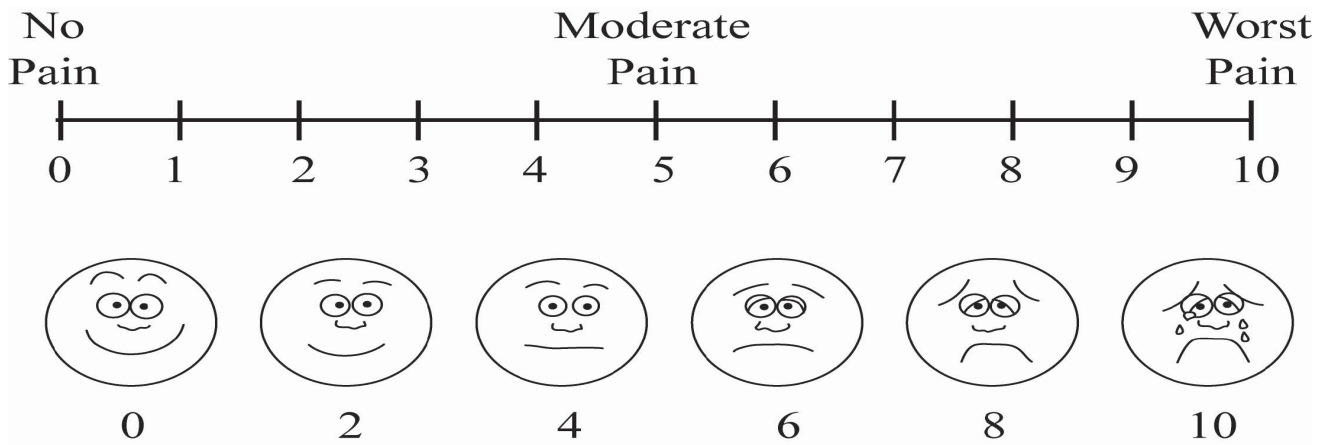
The cohort of 40 patients was divided into the subject of 20 patients and 20 patients as the control group, which was randomly assigned by the computer generated software system. Note of comorbid condition was also made. In our institution, the average waiting time from reporting to the OPD to undergoing the knife is around 2 week the control group was taught about the technique of *Nadhi sodhana/ anulom vilom* for around 5 minutes by the doctors of our team who were aware of these techniques and practicing it for around 4 to 5 years. The patient of the subject group were advised to do these breathing exercises 10 minutes each every day. When they were admitted for surgery 48 hour earlier as per our institutional protocol.

They performed these exercises twice daily for 10 minutes each. Under supervision of the surgical staff. On the day of surgery also, they should practice it for 20 minutes before the surgery. All the 40 patients were operated by a same operating unit/ teams and the same anesthetic team, with an aim of minimizing the bias. The preoperative and postoperative care was provided by the same team which includes JR, Intern and Paramedics. In the Postoperative period, the subject group was advised for gentle deep breathing exercises for 10 minutes at 2 hrs, then next 4 hrs and then next 4 hour, and from the next day *Anulom Vilom*, was also encouraged as a routine in morning and evening till discharge. The patients were also followed 10 days after the surgery at the time of suture removal for the assessment of any complication, generalized well-being and other parameters.

Exclusion criteria; patient with type II diabetes mellitus and neurological problems were excluded because of altered perception to pain.

Results

The results are evaluated in a tabular form .The tolerance of pain at 2,6 and 10 hours in postoperative period was also tabulated and it was analysed that there was no significant difference in the first 2 hour of assessment, but at the end of 6 hour there was a significant difference in the two group respectively, with the study group reporting less pain and consequently the analgesic requirement was lessened. At the end of 10 hour there was a marked difference in the pain score. Pain assessment was done as per Visual Analog Scale⁷.



Control group

Mean weight (kg)	Mean age(year)
71.4	37.30

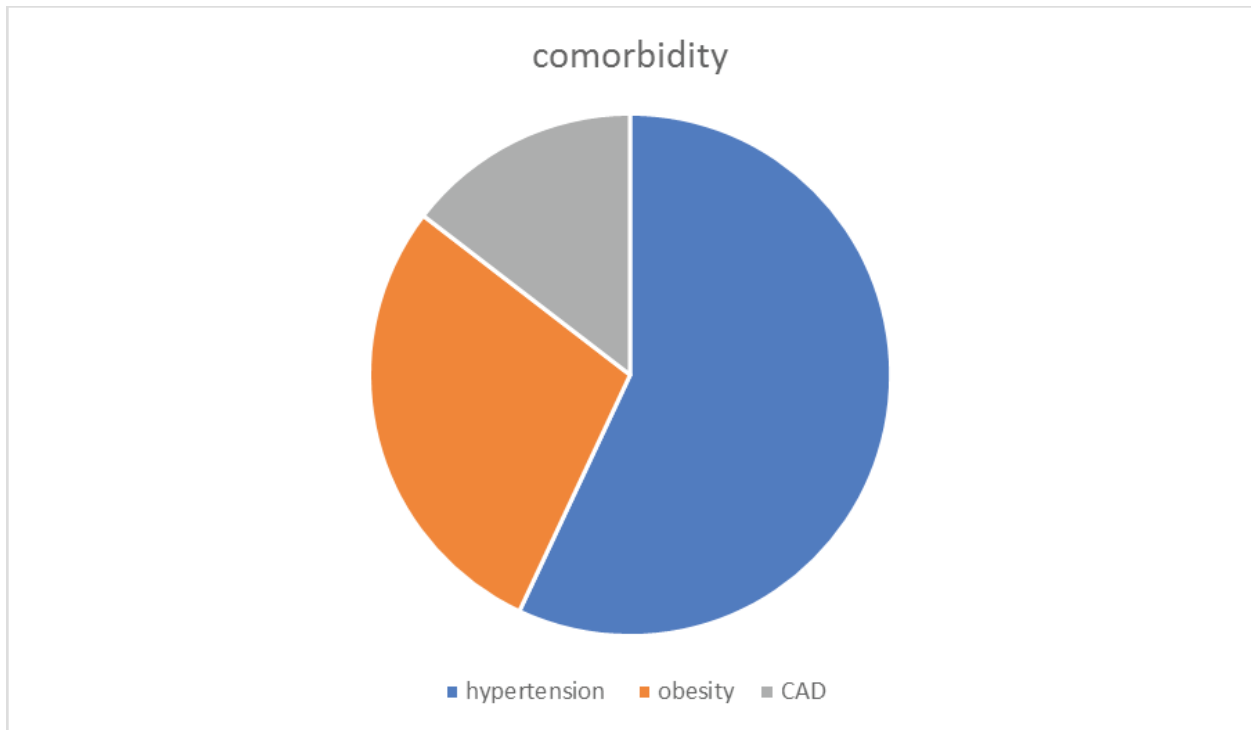
Subject group

Mean weight (kg)	Mean age (years)
76.55	35.45

Male to female ratio;

	Control group	Subject group
Male	3	17
Female	3	17

The most common comorbidity associated was hypertension accounting for more than half of the comorbidities (57.14%, approximately 17.5%) of the patients are having comorbid conditions



The return of the bowel sound in the both group assessed by auscultation for 2 to 3 minutes of the abdomen was recorded and it was found that mean time for return of bowel sound in the study group was 5 hour and 57 minutes which has a significant value in comparison to 8 hour in the control group.

	Mean time for return of bowel sound
Control	8 hours
Subject	5 hour 57 minutes

In the post-operative chest auscultation, air entry was found normal in all the patients. In association the postoperative fluctuation in the BP and RR in the HDU ward was observed to be less in the subject group in contrast to the control group.

ensuring similar modified Aldrete score in the post op patient. In our study we found that the mean alertness level at 1 hour post op in subject groups was 7.2 in respect to 5.8 in the control group, which has a significant value.

The level of alertness was evaluated by the standard P strike test, which was done after

MODIFIED ALDRETE SCORE

Criteria	Point value
Oxygenation	
SpO2 > 92% on room air	2
SpO2 > 90% on oxygen	1
SpO2 < 90% on oxygen	0
Respiration	
Breathes deeply and coughs freely	2
Dyspnoeic, shallow or limited breathing	1
Apnoea	0
Circulation	
Blood pressure ±20 mmHg of normal	2
Blood pressure ±20–50 mmHg of normal	1
Blood pressure more than ±50 mmHg of normal	0
Consciousness	
Fully awake	2
Aousable on calling	1
Not responsive	0
Activity	
Moves all extremities	2
Moves two extremities	1
No movement	0

	Mean alertness level 1 hour postop
Control	5.8
Subject	7.2

s. no	age/sex	weight(kg)	Comorbidity	operating time(min)	chest auscultation	alertness level	pain at 2/4/8 hours	return of bowel sound(hours)	complications
1	24/f	56	-	15	0	6	8,7,4	4	Nil
2	23/f	49	-	15	0	7	8,6,4	6	0
3	34/f	59	-	16	0	8	8,7,6	6	0
4	78/m	68	Hypertension	17	0	7	8,7,7	7	0
5	31/f	83	-	15	0	8	8,6,4	5	0
6	49/f	94	-	15	0	9	8,8,6	8	0
7	23/f	58	-	14	0	7	8,6,5	5	0

8	20/f	56	-	17	0	8	8,6,4	6	0
9	35/f	69	-	15	0	7	8,6,4	6	0
10	51/f	86	Obesity	18	0	6	8,6,3	8	0
11	18/f	64	-	16	0	6	8,6,4	8	0
12	76/f	68	HTN	18	0	7	8,7,4	8	0
13	33/F	65		14	0	6	8,3,3	7	0
14	21/F	56	CAD	16	0	7	8,6,4	6	SEROMA
15	32/F	35	-	15	0	7	8,6,4	7	0
16	42/f	67	-	18	0	6	8,6,4	7	0
17	38/f	65	-	15	0	7	8,6,6	6	0
18	29/F	76	-	16	0	7	8,6,4	7	0
19	20/f	54	-	18	0	7	8,7,5	6	0
20	32/F	64	-	18	0	5	8,6,3	6	0
21	20/F	48	-	19	0	5	8,6,3	7	SEROMA
22	23/F	66	-	20	0	6	8,7,5	7	0
23	29/M	72	-	20	0	5	8,6,4	7	0
24	54/F	75	HTN	22	0	5	8,7,7	7	0
25	53/F	71	0	25	CREPTS	4	887	7	0
26	65/F	69	-	20	0	5	886	7	0
27	20/F	48	-	14	0	6	865	6	0
28	38/F	78	-	18	0	7	866	7	0
29	30/M	88	-	17	0	6	863	7	0
30	23/F	88	-	19	0	7	864	7	0
31	31/F	71	-	17	0	5	864	8	0
32	51/F	69	-	20	0	7	863	7	0
33	37/F	74	-	25	0	7	866	7	0
34	82/F	77	HTN	22	0	8	864	6	0
35	69/F	69	OBESITY	23	0	8	864	7	0
36	29/F	81	-	22	0	8	863	7	0
37	19/F	80	-	25	0	7	863	7	0
38	29/F	79	-	22	0	8	863	8	0
39	21/F	69	-	23	0	7	866	8	0
40	23/M	79	-	23	0	8	863	7	0

Master chart

Discussion

In the modern Era, there has been tremendous research work done for the better outcome of post op patients, but the effectiveness of yoga and its role in postop recovery has been sparingly documented, hence this study is devoted to correlate and pass on the benefits to the patients.

Our study was very simple and cost effective, it required no specialized training or equipment or technique, and only requirement was motivation of the patient and his /her commitment.

In our scenario, training was provides by trained members of our team, the learning phase is also very short and better patient compliance hence

making the study more feasible. No specialized equipment are required. The parameter for training are replicable and doable without any absolute contraindications.

In our study the mean age of the patient undergoing Laparoscopic Cholecystectomy matches with standard literature and irrespective of the comorbid conditions. Yogic exercises commenced preoperatively definitely improved the post-operative alertness level of the patient. Thus, configuring the advantage of aspiration pneumonitis, perception of pain in the subject was significantly reduced in comparison to the control group and it helps in reducing the administration of analgesics to the patients.

Table 1 Post-operative analgesia requirement (injection diclofenace 75 mg IM)

Analgesia requirement	2 hour	4hour	8hour
Control	90%	85%	55%
Subject	80%	60%	25%

Thus, saving the patients of the ill effects of the analgesic agent and statistically reducing the cost component, besides reducing the workload of already overburdened nursing staff.

Table 2 comparison of post-operative pulse rate in control and subject

Pulse rate	2 hour		4 hour		8 hour	
	control	subject	control	Subject	control	Subject
>100/min	20%	15%	10%	5%	5%	0
90-100 /min	35%	25%	25%	15%	15%	10%
<90/min	45%	70%	75%	80%	80%	90%

Table 3 comparison of post-operative systolic blood pressure

Systolic blood pressure	2 hour		4 hour		8 hour	
	control	subject	control	Subject	control	Subject
Variation of +/- 20 mmHg from preoperative values	30%	15%	15%	5%	5%	0

Table 4 comparison of post-operative diastolic blood pressure

Diastolic blood pressure	2 hour		4 hour		8 hour	
	control	subject	control	Subject	control	Subject
Variation of +/- 5mmHg from preoperative values	20%	5%	5%	0%	0%	0%

The variations of the vitals like blood pressure, pulse and bowel sound in the study group was significant better than the control group. In the long term follow up, the patient in the study group practicing yogic exercises, reported a generalized feeling of well-being and besides lesser requirement of dosage for drug for blood pressure control and better sleeping pattern without any drug dependency and better digestive systems. The physiological body function was also better in the study group after a period of 10 days, Thus, the study concludes that preoperative breathing yogic exercises two weeks prior to surgery has a positive impact in the outcome of surgery. This study has opened a vista for further undertaking research on long term effects on control of obesity, coronary artery disease, pulmonary functions and generalized well-being in post-operative patients the authors have been convinced by these encouraging results and are now actively practicing yogic breathing

exercises.

Ethical Clearance- Taken

Source of Funding- Self

Conflict of Interest - Nil

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