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Pervelance and Risk Factors of Pem among Under Five Children in Urban Slum Areas of Kolhapur City

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Abstract

Background: PEM refers to an imbalance between the supply of protein energy and the body's demand for them to ensure optimal growth and function, According to WHO. It is a major public health problem in India & leading cause of death in children in developing countries. This affects the child at the most crucial period of time of development, which can lead to permanent impairment in later life. It includes kwashiorkor (protein malnutrition predominant) marasmus (deficiency in calorie intake) marasmic kwashiorkor (marked protein deficiency and marked calorie insufficient signs present, sometimes referred to as the most severe form of malnutrition.

Objectives: To assess the prevalence & risk factors of PEM among under five children's in urban slum areas of Kolhapur city.

Methods: A descriptive survey, one group pre test only research design was used, which was consisted a group of 210 samples that were selected by using probability simple random cluster sampling method. Data were collected by using nutritional assessment tool consisted of weight of the baby, degree of malnutrition and check list on risk factors of PEM. Data was analyzed and tabulated by descriptive statistics. An informational booklet was prepared and administered based on collected data.

Result: The result showed that, out of 210 under five children's, majority of participants 97 (46.19) were in 1st degree of malnutrition, minimum 1 (0.47%) were in 3rd degree & 55 (26.19%) were in 2nd degree of malnutrition and remaining 57 (27.14 %) participants were in normal degree of malnutrition. Majority of under five children's 18 (8.57%) were having poor sanitation condition as risk factor & minimum 1 (0.47%) were having more than 3 children's in family as risk factor.

Conclusion: The study concluded that, there is an emerging need to provide informational booklet on PEM to the parents of under five children's so as to prevent PEM.

Key Words: protein energy malnutrition, under five children, prevalence, risk factors.

Introduction

Malnutrition is a major health problem, especially in developing countries. It affects almost 800 million people. Prevalence rates vary among different continents of the world. PEM is undoubtedly the most serious nutritional problem affecting several thousand young children in India.¹

Today's children are tomorrow's world or tomorrow's father" this slogan is riding a massive

wave of concern throughout the world. But children, all over the world are deprived of many facilities. Hunger and malnutrition make them worst sufferers and these pose potential threats to mankind as a whole or to the civilization itself.²

According to World Health Organization estimates that globally, around 9.2 million under 5 children died. It is estimated that mortality of children aged less than 5 years is 68 per 1000 live birth 27%. 10 million children were dying each year, of which 40% were new born

in their first month. It concluded that majority of the children death resulted from infectious disease and malnutrition associated with more than 40% and 56% of all early deaths respectively.³

Need for the Study:

Nutritional status of children is an indicator of nutritional profile of the entire community. Studies conducted worldwide shows that 150 million (26.6%) are underweight, while 182 million (32.5%) are stunted all over the world. More than half of the worlds under nourished people live in India. 54% children are underweight, 52% are stunted, while 17% are wasted.⁴

The WHO estimated that malnourished children numbered 181.9 million (32%) in developing countries. In addition, an estimated 149.6 million children younger than 5 years are malnourished when measured in terms of weight for age. In south central Asia and eastern Africa, about half the children have growth retardation due to PEM. This figure is 5 times the prevalence in the western world.⁵

Problem Statement:

“A DESCRIPTIVE SURVEY TO ASSESS THE PREVELANCE AND RISK FACTORS OF PEM AMONG UNDER FIVE CHILDREN IN URBAN SLUM AREAS OF KOLHAPUR CITY, WITH A VIEW TO DEVELOP AN INFORMATIONAL BOOKLET.”

Objectives of The Study:

- 1) To assess the prevalence of PEM among under five children's in urban slum areas of Kolhapur city.
- 2) To assess the risk factors of PEM among under five children in urban slum areas of Kolhapur city.

Materials and Methods

A descriptive research design was used for the present study. This consisted a group of 210 participants that were selected on the basis of the sampling criteria

set for the study. Samples were selected by using probability simple random cluster sampling method. The tool was developed based on extensive review of literature and discussion with guide and experts. The content validity of the tool was done, which suggested that tool was reliable. Data was collected using Nutritional Assessment Tool & Check-list on risk factors of PEM among under five children's of urban slum areas of Kolhapur city. In order to fulfill the objectives, the data was tabulated and analyzed by using descriptive statistics. The descriptive statistics used were frequency and percentage distribution of samples characteristics of the prevalence and risk factors of PEM.

Results & Discussion

I. Findings related to distribution of socio demographic variables of under five children's.

Results indicated that, out of 210 under five children's, Maximum 90 (42.85%) under five children's belonged to the age group of 3-4 years, while minimum 26 (12.38%) belonged to the age group of 4-5 years. Maximum 121 (57.61%) were males and 89 (42.38%) were females. Majority of under five children's 102 (48.57%) had 2nd number among children's in home and minimum 6 (2.86%) had 4th number among children's in home. Majority of children's 66(31.42%) maternal education was illiterate & minimum of children's maternal education 29 (13.80%) were graduate. Majority of under five children's 91 (48.33 %) family income were between Rs. 5000 – 10000 & minimum 22(10.47%) were between Rs. 15000 – 20000.

The finding of this study are supported with the study done by Pius C Manyike et al, to assess the prevalence of malnutrition among pre-school children attending nursery and primary schools in abakiliki in Ebonyi state of Nigeria.⁶

II. Findings related to distribution of under five children's according to the degree of malnutrition.

Table 1 –Frequency & percentage distribution of under five children’s according to degree of malnutrition. (According to GOMEZ classification)

n= 210

Sr. No.	Degree of Malnutrition	Frequency (f)	Percentage (%)
1.	Normal	57	27.14
2.	1st degree	97	46.19
3.	2nd degree	55	26.19
4.	3rd degree	1	0.47

Table 1 indicates that,

Majority of under five children’s 97 (46.19) were in 1st degree of malnutrition, minimum 1 (0.47%) were in 3rd degree & 55 (26.19%) were in 2nd degree of malnutrition.

The findings of this study are supported with the study done by Laxmikant Purohit et al was conducted during January 2010 to December 2011 The results showed that 40.46% under five children were stunted, 38.15% were underweight, and 16% were wasted. ⁷

III. Findings related to distribution of under five children’s according to risk factors.

Table 2- frequency & percentage distribution of under five children’s according to risk factors of PEM.

n=153

Sr. No	Risk factor	Frequency (f)	Percentage (%)
1	Not breast fed since birth	9	4.28
2	Stopped breast feeding before 24 months of age	11	5.23
3	Lack of exclusive breast feeding (first month)	2	0.95
4	Initiation of complementary diet at 6 months	0	00
5	Pre-lacteal feed given	2	0.95
6	Bottle fed	16	7.61
7	Number of children greater than 3	1	0.47
8	Parental illiteracy	6	2.85
9	Socio economic status is low	5	2.38
10	Poor sanitary condition	18	8.57
11	Minimal medical attention	12	5.71
12	Frequent childhood infections	11	5.23
13	Worm infestation	6	2.85
14	Frequent episodes of diarrhea	15	7.14
15	Rice is the stable diet	6	2.85

Table 2 indicates that,

Majority of under five children's 18 (8.57%) were having poor sanitation condition as risk factor & minimum 1 (0.47%) were having more than 3 children's in family as risk factor.

The results were contrary to the findings of the study done by Ahmed M Hussein et al on 2012. The study revealed that most affected children were those whose families income per month was less than 250 SDG (18.5%), The prevalence of malnutrition increase among children there is mothers illiterate (13.4%).⁸

Nursing Implication:

The findings of the present study have served implications in different areas which are discussed in following area;

Nursing Education-

The finding of the study revealed that the prevalence & risk factors of PEM among under five children's is comparatively more. So stress should be made. The informational booklet can also be utilized by the students in community & hospital.

Nursing Practice-

Nursing practice includes preventive, promotive, curative and rehabilitative services. The present study shows that majority of under five children's having malnutrition. The use of informational booklet can be used during educational session, which helps in preventing or reducing PEM among under five children's. There was wide gap between existing and expected levels of knowledge of parents of under five year's children regarding PEM.

Nursing Administration

Nurses are vital source in educating the public on various health related issues. The informational booklet can be considered as an awareness program from anganwadi workers. The nursing administrator can use informational booklet, posters & charts regarding PEM & its prevention in hospitals with pediatric OPD & in patient ward facilities & community areas. In order to make the parents aware about the PEM & its prevention. The administrators can communicate these findings

to the parents of under five years children's. They can incorporate this in practice.

Nursing Research

The present study conducted by investigators can be a source of review of literature for others who are intending to conduct studies on PEM in under five children's. Evidence based practice improves the quality of life and this study focuses on prevalence and risk factors of PEM in under five years children's and provide information regarding PEM to parents, of under five children's

Limitations:

The limitations of the present study, is that no broad generation could be made due to small size of samples in limited area of research setting.

Recommendations:

The following recommendations were made,

1. Similar study may be undertaken with a larger sample to have a better generalization of the findings.
2. Pre-experimental study can be conducted to evaluate the effectiveness of informational booklet.
3. A correlation study can be conducted on the knowledge and prevention of the malnutrition of under five children's.

Conclusion

Based on the findings of the study the following conclusions were drawn, out of 210 participants 97 (46.19%) children's were in 1st degree of malnutrition. There is an emerging need to provide information booklet on PEM. It is high time we should understand that all the parents should know the need to prevent from malnutrition.

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Locked in: An Evidence based Study on Domestic Violence during COVID-19 in the Hilly Region of India

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Abstract

The study assesses the cases of domestic violence during Covid19 Lockdown in the Uttarakhand state of India. The Covid19 pandemic and subsequent lockdown has led to social isolation, curtailment of social support system and increased incidences of domestic violence against women in India and Uttarakhand in particular. Many steps have been taken by governments including helpline and counselling services. This article conducted follow up survey on 50 women to understand their experience of domestic violence in Uttarakhand. Since the implications of Covid19 is different than other emergencies so far, the reported cases of our study on domestic violence capture negative as well as positive consequences of it on individuals and families. The sociologist Marianne Hester argued that 'domestic violence goes up whenever families spend more time together'. As the National Commission for Women report suggests Uttarakhand has highest reporting cases of violence during lockdown. Our research finds that lockdown triggers the incidence of domestic violence in this state. Most of the women are burdened due to lockdown. Financial burden, anger, anxiety of husband has pushed the incidence of violence. Most of the men ventilates anger, anxiety on women without their fault.

Key words: Domestic Violence, Covid19, Lockdown, Uttarakhand, India

Introduction

Be it the Paleolithic age or the postindustrial society most of the women are forced to confine in home for their safety. Unfortunately, the safety bubble which is supposed to have the women unscathed costs more often becomes a large threat- "Domestic Violence"¹. As quoted by UN, Domestic abuse, also called "domestic violence" or "intimate partner violence", can be defined as a pattern of behaviour in any relationship that is used to gain or maintain power and control over an intimate partner. Abuse is physical, sexual, emotional, economic or psychological actions or threats of actions that influence another person. Globally, 1 in 3 women have experienced some form of physical and/or sexual violence with their intimate partner and 38% of murder are committed by a male intimate partner².

The onset of Covid-19 pandemic is not merely distress the global health, also the overall socio-economic condition in the globe³. Most of the infected countries went to sudden lockdown to stop the spread of virus including India⁴ operation entirely. Which further creates economic instability among the people⁵. The covid-lockdown came with social distancing, less social system support and eventually domestic violence against women⁶. Due to less social connection, there is no place to vent off steam outside of the house, as the situation remains precarious. In the wake of the pandemic the overall mental health has come under duress. According to sociologist Marianne Hester, "domestic violence goes up whenever families spend more time together, such as the Christmas and summer vacations". Violence can rather act as a catharsis to pent up feelings of anger, frustration, deficiency. In a household the women become the most obvious target due to the traditional

values the age-old structures of coverture in marriage, patriarchy and gerontocracy have established. These systems set the perfect stage for excusable reasonings such as “loss of control and violence” being innate to men’s natural being. The men who used to stay distant from the house for long durations are now holed up inside with the family members they barely might have interacted or spent hours at end, prior. Especially, the ones who do not have access to any modes of pastime- be it social media, television, group interactions or exercise are even more so struggling.

Intimate partner violence tends to increase during emergencies, including epidemics, and although robust data is still lacking, reports from China, the United States of America, and several European countries, point towards the same tendency concerning the Covid-19 pandemic⁷.

Around 243 million women with age 15-49 years have been reported physical and sexual violence in last 12 months and the number must have intensified due to Covid lockdown. According to UN report, since March 17 lockdown, around 30 per cent increase in the cases of domestic violence in France, in Cyprus and Singapore. Helplines have registered an increase in calls by 30 and 33 per cent, respectively and in Argentina emergency calls for domestic violence cases have increased by 25 per cent since March 20 lockdown. Besides, increased cases of domestic violence and demand for emergency shelters have also been reported from Canada, Germany, Spain, the United Kingdom and the United States. In South Africa before the Covid-19 pandemic, domestic violence was already alarming. In the first week of the lockdown, Police Minister Bheki Cele stated that police had received more than 87,000 gender-based complaints⁸. In the first week after the lockdown of India, the NCW (National Commission of women) of India recorded more than a two-fold increase in domestic violence and sexual assaults as well as three- fold rise in police apathy towards crimes against women⁹.

Domestic violence is an apparent problem in India. Around 37.2 percent women who have ever been married faced inter partner violence¹⁰. Further, out of the 37.2 percent only 2 percent sought help from the police. Patriarchy is a social organisation of violence against women in whole world. But, its intensity, the volume of

depiction, debates indicates the high crisis situation of Indian girls and women¹¹.

2. Rationale, Objectives and Framework

Home is considered as the safest place for anybody. A person lives with loved ones, share his/her joy, sorrow, anxiety of life. In this busy world, people always crave for time to spend with near and dear ones.

Covid-19 creates havocs in whole world since December 2019. The surge of Covid-19 drags most of the developed country into a breakdown point. Most of the countries went to sudden lockdown to reduce the spread of coronavirus along with India.

Despite of all the wrong reasons, the lockdown gives some people a break from their hectic life. A positive aspect is that the lockdown has resulted family time while maintaining social distancing. But, this opportunities can only be tapped and enjoyed by the people who are economically sound and secure for future. Of course, this pandemics has drained people in to anxiety, in security of job, financial concerns and social disconnection¹². This can lead to behavioral and psychological pressure of a person¹³. This burden must be equals for men and women. Most of the men ventilate stress through anger, conflict and violence⁶. According to Marianne Hester, domestic violence goes whenever families spend more time together⁶. But in India 37 percent married women have faced spousal violence¹⁰, whether she is working or not. The women already in abusive relationship may be more prone to exposed to violence as their family member cope with additional stress. Women’s mobility and contact with their family and friends have been restricted due to lockdown, physical and social distancing which may provide support and protection from violence. In India context, women are the prime bearer of managing household chores and kids. In an ideal condition, more people in house would have been helpful to the women in managing household chores. But in contrary, most of the Indian husbands are reluctant to share the burden of household and kids. And the workload have double up due to absence of maid or other household helpers. The additional pressure on women fuels the friction between the couple and lead to domestic violence¹⁴.

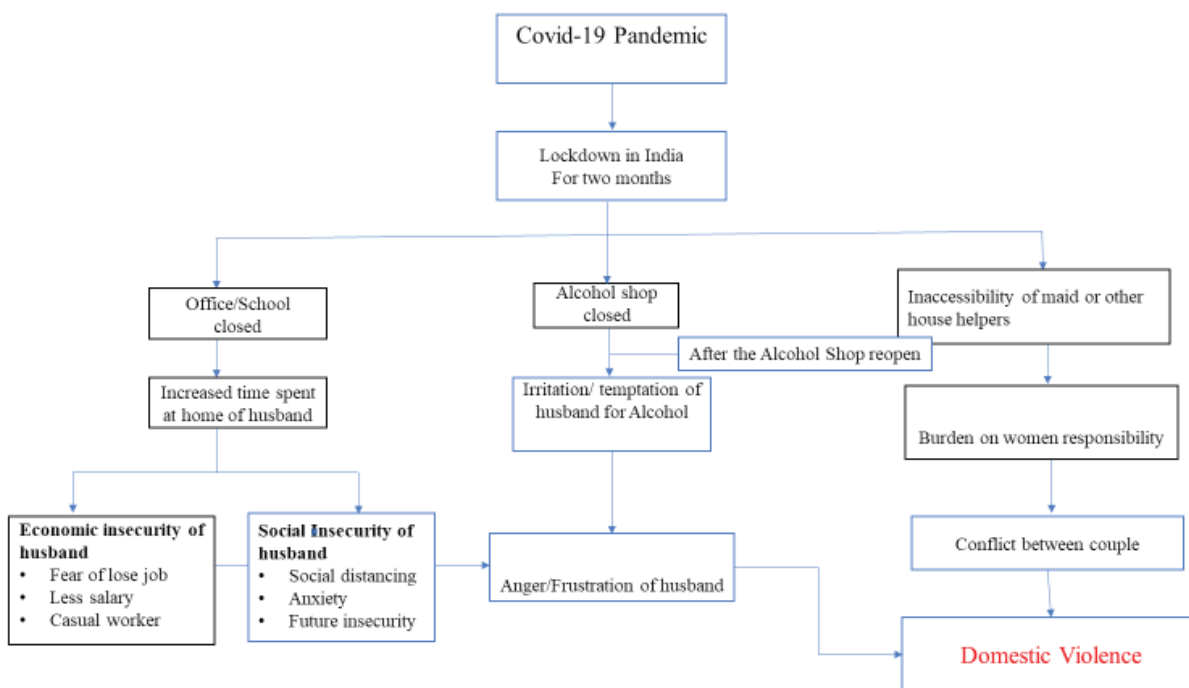
Several studies show that lower socioeconomic sections run a higher risk factor tendency towards abuse and violence during pandemic¹⁵. A history of exposure to violence, low education levels, alcohol/drug abuse, family violence and disposition to condones are major factors association with perpetration of violence¹⁶. Studies suggest that the factors most likely to amplify domestic violence are age of the women, poverty and unemployment, and alcohol and substance abuse^{17,18}. The antecedent of Covid have thumped the lower strata people mostly in India. So, the domestic violence situation among the poor is important to evaluate.

Education is the solution to every social problem in a society. Education substantially reduce the domestic

violence¹⁹. Education changes the socialisation process and understanding of men towards equity, respect and their acceptance of responsibility for their violence²⁰.

A study²¹ attempted to find out the correlation between IPV and physical health conditions among the sample with diagnosed alcohol use disorders (AUDs). The result showed odds of perpetrating IPV among participants with a physical health condition were 2.29 times larger than those among healthy participants. By considering 1445 Brazilian couples married or cohabitating, ²² showed that homemaker women were more prone to violence. Education, alcohol consumption and religion are other major cause of violence.

Figure 1: Conceptual Framework of the Study



The backdrop presented above not only explains the gravity of the situation, but also makes it evident that the issue needs more attention and proper redressal.

The metro cities and other developed areas in India have some basic facilities and access points for reporting cases of domestic violence and follow up procedures for the victims through government funded organizations or NGOs. However, the hilly areas being relatively less populated, and less accessible because of its geographic

contour, have always received much less attention from all corners. It is important to assess the prevalence of domestic violence in the hilly states of Uttarakhand at the first place. Often, the culture and customs in the hills tend to deviate from those observed in the plain areas. This makes it not only a curious case to be examined, but also may provide us with interesting observations about the unexplored areas.

The domestic violence complaints to National Commission for Women (NCW) rose to between 23 March and 1st April. As complaints surged, the NCW announced a WhatsApp number to receive complaints, to be more accessible to women who find themselves in abusive homes²³. As per the data, a total of 727 cases relating to Domestic Violence were reported to the Legal Services Authorities in total 28 states / UTs across the country for seeking legal aid and assistance. The highest number of cases were reported in the State of Uttarakhand (144) followed by Haryana (79), Delhi (63) as follows. The above report on NCW became upswing our ongoing research on domestic violence in Uttarakhand. There is a need of more robust data is still needed to define the impact of the Covid-19 pandemic, and each independent risk factor, on the prevalence and precipitation of IPV²⁴. Therefore, this studies justify as it tapped the actual experience of women in Uttarakhand. We aim to unpack the patterns of violence accounted and apply a multifaceted approach to delve into the backgrounds of the victims.

Methodology

There is an ongoing project on “Assessment of domestic violence and formulation of its preventive measures in region of Uttarakhand” funded by ICSSR to Dept. of management studies, IIT Roorkee. We had conducted several FGDs, in-depth interviews to assess the domestic violence in three districts of Uttarakhand. After the onset of coronavirus, we became curious to understand the situation of domestic violence during the lockdown. We have conducted a follow-up survey on the surveyed women in Uttarakhand. The women in the age group 15-49, who are ever married are sample for the paper. The respondents are from both region of Kumaon and Garhwal of Uttarakhand from different districts. Due to the incidence of coronavirus, direct interview with the respondents were not feasible. We have conducted individual in-depth interview with the through telephone and online. Also, the unstructured schedules are filled up by google survey form.

Sampling Techniques:

For the present study, we have used purposive sampling represents the surveyed **women under the project. It is a non-probability sampling technique** of different also known

as **judgmental, selective, or subjective** sampling, purposive sampling relies on the **judgement** of the researcher. When it comes to selecting the **units** the goal of purposive sampling is not to **randomly** select units from a population to create a sample with the intention of making generalisation.

The Research Methodology adopted in this study is comprised of exploratory research design, which is based on qualitative research approach for primary data collection and analysis. This study characteristically used ‘Reflexivity’²⁵ as a methodology for conducting primary research. The increasingly popular concept of reflexivity is used in variety of ways and emphasizes that “the researcher is part of the social world that is studied, and this calls for exploration and self-examination” and thus this study also would make an extensive usage of ‘a reflexive pragmatist approach’²⁵. The analysis of this work depends upon the major characteristics of the respondents with regards to the language barriers, cultural uniqueness, male dominated social structure, complacent nature, emotional-social organizational structure and so on would be done through qualitative methodology.

Samples: We have selected 50 ever married women aged 15-49 by following purposive sampling. Plight of women would not differentiate with increase of sample women. The samples of the study represent a major section of a society.

Schedule: The schedule for the present study is mix of “open ended” and unstructured questionnaire.

Techniques: The analysis for the present study is mostly innarrative form.

Domestic violence is a sensitive issue and many women prefer to maintain silence about it. We have initially established a healthy general conversation with them before asking about domestic violence. After establishing rapport, the topic of domestic violence was initiated. The broad included are: the prevalence of domestic violence by women before and after Covid19 lockdown, the factors leading to domestic violence, physical and psychological implications of violence and their view point on solution of the issue.

Analysis:

Domestic violence is not a new experience for the respondents. Most of the women have experienced violence ever in their lifetime. From the interviews of the key informants, it was highlighted that domestic violence against women was common among women.

Background Characteristics

It is very important to capture some background characteristics to understand its association with domestic violence. Education and income are the major role play in forming sustainability in life. All the participant in our study are educated at least up to primary level. Most of the husbands are engaged in casual work like, Hotelier, businessmen etc.

Covid Lock down and financial situation:

As we already discussed, how lockdown disturbs the financial condition of among the people. We have asked woman about their financial condition in post Covid lock down. The working women have reported no problem in financial disturbance during lock down. But the non-working women have reported major financial problem during lockdown as their husbands are mostly casual workers.

A 35-year housewife said, *“The lockdown affected my financial status as private sector were closed during lockdown”*.

Covid Lockdown and burden on women:

We have asked them about their extra burden in lock down as school and offices are close. Women have faced many difficulties as all the members are in the home. They have to always keep eye on the school going children due to closed school. They could not able to get any rest during lockdown due to constant engagement.

A 45 aged women replied *“Aajkal manage karnabohot difficult ho jatahai”*. It is very difficult to manage now a days.

We have also asked them about the attitude of their husband during lockdown. 20 women have reported their husband bad behaviour during lockdown, they later on address the financial stress is the major cause of this type of behaviour.

Domestic violence is a very subjective in nature. Sometimes women are not opened to share the sensitive issues. So, I tried to extract the information indirectly by asking *“Have you heard in your family and friends facing domestic violence during lockdown”*. All women have heard of somebody facing violence during lockdown. It is very evident that, women are eventually facing domestic violence during lockdown.

One woman should be voice of another in a family. We have asked whether *“they have mother in law in family”* and *“do you share your anxiety and sorrow with mother in law”*. Several women are reluctant to share their feeling with mother in law or any older lady in the family.

Domestic Violence:

Three types of domestic violence are included in this paper: Physical, Sexual and emotional.

Physical violence: Did you husband ever pushed, shook, or had something thrown to you, Slapped, punched with fist or hit by something harmful, twisted Arm or pulled your hair

Sexual Violence: Did your husband ever physically forced into unwanted sex, Forced into other unwanted sexual acts.

Emotional Violence: Did you husband ever humiliated, insulted and verbally abuse?

Around, 60 percent of the women reported that they faced either of violence at least once in their life by their husband. In terms of physical violence, all women have faced physical violence in their lifetime. Very few women mentioned being sexually abused by their husbands in their lifetime. The major concern witnessed was of forced unwanted unprotected sex by the husbands ending in unintended pregnancy and abortions. Overall, many women were being victimised by their husbands physically, mentally and/or sexually in their lifetime and, slapping appears to be the most common form of violence experienced by women.

Socio-economic characteristics always play a pivotal role in order to influence the occurrence of violence. It is important to categorise of women experiencing violence by age, marital duration, education and

occupation. The women in the age group of 31-35 are exposed to maximum violence of all sorts compared to other groups. In terms of marital duration, instances of physical and sexual violence are consistently higher for women married for more than 4 years. However, women married for four years or less and 10 years or more are found to have experienced more emotional violence.

4.1 Domestic Violence and Covid Lock down:

The responses clearly address the increasing incidence of violence during lock down. Although very few have experienced the violence first during lock down. Most of the women share their experience how husband ventilate their anger frustration on them during lock down. Our research outcome is validating the NCW report on domestic violence.

Case 1:

The girl narrated the atrocities to her parents and did not received full support from them initially, as the parents were also afraid of society's reaction once the news is out. The victim was determined not to go back and got emotional support from her younger sisters to report the instance. After knowing that a complaint has been made against them the in-laws and the husband made attempts to bring her back but the girl's fear can be seen in her comment that she mentioned during the counselling session, *"agar us din mohalle wale nahinhotetohshayad yeh log mujhejaan se maar dete"* *"had it not been for the presence of neighbours that day, these people might have killed me"*. Her determination to move out of the relationship was firm, the counsellor gave her a chance to rethink over her decision to take the complaint further by asking her that how she will survive once her parents are not there to support her emotionally. To which she responded, *"main mar jaungi per wapasnahinjaungi"* *"I will die but I will not go back there again"* she gets terrified recounting the horrors that she had faced, this was the third session for the couple and during the entire exercise the husband did not responded anything directly and his uncle who was a practicing lawyer was responding in his behalf in a rather intimidating way. The police officer and the legal expert might have sensed the same and assured the girl that if she wishes to proceed further with their complaint, she will get legal assistance and protection from police if required.

Case2:

Marital dispute, married for three years, one-year old child, wife left her husband's home with her child and staying with her parents for some time.

The couple had an arranged marriage, they were living in a joint family that included the in-laws and one unmarried brother. The husband runs a small shop, the earning from the shop is meagre and the family is majorly supported by father-in-law's pension. Husband claimed that the wife harassed him mentally and forces him to get his share from the parent's property and live someplace else, wife did not denied these allegations directly but expressed that she would be OK if the husband wishes to move out of the joint family but was concerned that how will the husband manage to provide for the family as his income was just for namesake. Husband told the panel that he has video evidence of the instances when the wife placed a knife on their toddler's neck warning him of consequences if he will try to stop her while she left the home, when asked to present the evidence before the panel the husband said he is not carrying it as of now. During the entire session the panel members tried to convince the girl to go back with her husband but she held her ground by stating that the husband does not have a suitable source of income to provide for her and the child. There was never an act or attempt of physical abuse by the husband on her wife, but from her statements it was evident that the husband did not want her to work and was also not earning sufficient money to provide for them, this could be categorised into economic abuse. The husband should not be blamed for the entire situation, as the girl's parents knew about the financial situation of the boy before marriage. It was irresponsible of the parents marrying the girl despite knowing the income status of the boy. We learned that the social pressure of marrying the girl as soon as she reaches the "marriageable age" and then "bear a child for the family" approach was a prime reason for the dispute, the husband was also clueless as his family also took the same approach with him. The husband was ready to take up any job to keep his wife and kids with him but the wife didn't saw any clarity or direction in her husband's plan of action and was perplexed herself to decide the future course of action. The counsellor tried to convince the girl to talk to her husband and try to find a way out, the husband agreed but with a condition that they

should be allowed to talk alone without their parent's intervention. They both went out for half an hour and told the panel that they will look for probable options and they asked for two weeks' time before they reappear in front of the panel.

Case3:

Marital dispute, married for one and half years, the case was referred for counselling by the court

Wife has filed a case in the court and seeks separation, the counsellors in the initial counselling The match was fixed through a marriage portal, it was an inter-religion marriage, wife accused the husband of not giving her enough freedom and a forced abortion while the husband accused the wife of mental harassment and physical violence and according to his statements was not aware of the abortion and denied it. The husband worked in a metro city and found the girl via a leading marriage portal, the boy was from Punjab and the girl was from Uttarakhand after few interactions online their parents met and fixed the marriage. Girl had a graduate degree and the boy was a postgraduate in management and worked in Delhi, before marriage the boy lived in a paying guest accommodation and soon after the marriage the couple shifted in a new rented accommodation. When they shifted to a 1 BHK rented accommodation, the husband called her mother from Punjab to help them setup things as the wife has never been to Delhi or outside her hometown before and as he used to work in night shifts he was concerned for the safety of her wife in the new locality also. The mother-in-law was elderly and a sciatica patient, the couple didn't have sufficient furniture in their new home, a double bed and a makeshift bed, as the husband used to return home by 3 AM the mother-in-law and the wife used to sleep in the double bed and the husband used to take the makeshift bed upon his return from office. The trouble started in the relationship as the wife started blaming the mother-in-law for deliberately distancing the couple, after few instances of heated arguments between the couple the mother-in-law expressed her wish to return back to Punjab and be with the boy's father who was dependent on wheelchair for most of his movements. Things were going well after that between the couple, as the husband's parents had limited earnings and the husband was their only child he often took care of some

of their expenses and used to order essential things for them online, this again became a bone of contention between the new couple and at times things went to such an extreme wherein the wife locked herself in a room and inflicted self-injuries and also attempted violence on the husband.

During the session the wife accused the husband of forcing her to drink alcohol without her consent in a family function, to which the police officer and the legal expert enquired and it was revealed by the wife herself that both of them are social drinkers and she admitted she consensually drank the alcohol in the said function. Husband accused the wife of cheating on him and claimed that when he confronted the wife with proof of the incident, she pleaded sorry and confirmed that such things will not happen in future. As per the husband, he wanted to give the relationship a fresh start, forgetting all the bitter experience of the past but things were never normal and later he came to know that the wife had an abortion, which the wife claimed as a forced abortion, the husband never accompanied her to the doctor where she had the abortion. The wife accused the husband of leading her to get the unborn child aborted by always telling her that currently the financial conditions are not as strong where they can afford the responsibility of being parents. The husband accepted that they had the financial condition and extending the family talks but was not aware of the abortion till she got the child aborted.

We observed that education gives the girl confidence to take a decision to report the case and pursue it, being fully aware of the social consequences and the result which may be stepping out of the marriage. Assessing the narratives of the females it was clear that in many cases lack of support from family is observed, however, upon pursual of the case by the victim family also supports in some cases but not initially. Not all cases that appear before the panel for counselling are of domestic violence, some of them are of dispute and not all cases have a female victim, highlighting the importance of making the domestic violence act gender neutral

Discussion

The propagation of male supremacy in many cultures also further the problem for females in a society. These notions privilege the men with unaccounted

anger, abuse, control, and dominance of anyone on the short end of the stick in distribution of power. In any household it is commonplace to see women being subjugated by the men in their lives, be it through father figures, older/younger brother, or husbands. This sets an exemplary norm for young girls who later might be dealing with abusive narcissistic husbands. From the unrestrained natural world to the sophisticated interiors of a household, the reigns of domination are vested in the hands of one powerful species- the Mankind. After its triumph over nature in ways of culture and technology, the second thing men like best to conquer is women.

Men have taken since the dawn on knowledge great prestige in their work. The realm of work defines one's identity and it is an implicit to earn extrinsic gratification through one's work along with wages. Now that the work has come to a halt, feelings of alienation and a loss of power and control runs a risk of diminishing masculinity. The costs of upholding the customary symbols of manhood have become flighty. Individualism and an isolation from domestic work which is one of the trademarks of men, are now endangered. With the added burden of a lack of household help the women have begun to seek assistance from other members of the family, and husbands are expected to partake as well.

Beliefs especially finding their ground concepts such as family honor, preferential treatment of boys, male privilege and entitlement, tepid sanctions to mistreatment and harassment of one gender make it even harder to conquer the battle against abuse and criminal offences against women. Despite there being enough social stigma around men victimization stemming from the standards set by hegemonic toxic masculinity men do suffer from violence simultaneously. But it doesn't come close to the extent of suffering inflicted of women.

It positively forecasts criminal behavior based on the antecedents like socio-economic challenges, pathological individual behaviour by studying personal histories and biological factors, social ties such as relation shared with family and peer, overall custom observed in the community, neighbourhood, work organisations as well as the legal framework established and at disposal.

This function comes in direct conflict with the traditional gender roles that men have performed that of a protector, procreator and especially provider.

Doing the measly chores, feeling disassociated from your identity tied to work are some of the psychosocial factors which may act as a catalyst to morbidly violent tendencies. Psychology today lists profile of an abuser and controlling behavior, isolation, forced sex, rigidity towards gender roles and jealousy are the primary markers.

6. Way forward:

Covid19 has created an unprecedented situation regards to everything most importantly to human relation especially with response to family and institution of marriage. This paper belongs to a detailed observation on the subject through the large and ongoing project and is based on an intricate that the subject of domestic violence. India society is vast and deeply embodied in the social structure, definitely would have impacted during the phase of where all the member bound to stay together. Logic suggest that when disaster of this magnitude comes, threaten the life in general than family become emotional strength for each other. But in contrary we find togetherness is a burden for women. The findings are eye opener where the most important learning is the basis of emotional base of family became liability than strength and becomes subject of violence by the male counterpart supported by elders and other family members. This may be suggested of new area of research that suggest logic of economic independence and total independence to choose to stay home or not. The fabric of family itself a question. The last sentence may be sound erratic view but require future in depth research.

Ethical Clearance- ICSSR, Govt. of India has given consent to study on this context and hence approval has been granted through project no. ICS-1215-MSD

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Conflict of Interest - nil

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Pattern of Mobile Phone usage and its Association with Stress among University Students in Delhi NCR

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Abstract

Background: There is a constant concern that the pattern of mobile phone usage may have harmful effects on physical and mental health of people. There is insufficient evidence regarding this potential risk. Hence, our objective is to study the pattern of mobile phone usage and its association with stress among university students.

Methods: A cross sectional study was carried out among 185 students in a private university in Noida, UP. Data was collected using a structured questionnaire. Perceived stress scale (PSS) was used for measuring stress level. Descriptive statistics was used to explore data. Chi-square test was used to study the association between categorical variable. A p-value of less than 0.05 was considered to be statistically significant.

Result and Conclusion: There were 62.2% females and 37.8% males. Low stress symptoms were reported by 17.8% students, moderate 74.6% and high stress in 7.6% students. We concluded that there was Asymptotic significance between stress and using mobile phone for more than 180 minutes in a day ($p=0.001$), checking phone in between sleep ($p=0.004$), burning eye sensation ($P=0.025$) and mobile phone addiction ($P=0.001$).

Key Words: Mobile Phone, Stress, University Students

Introduction

A mobile phone is a portable electronic device for communication purposes. It is considered as most amazing and versatile device of Information and Communication Technology^[1]. Nowadays mobile phones have become integral part of our daily lives. According to Telecom Regulatory Authority of India, the prevalence of active mobile phone user in India (2019) is 1191.81 million^[2]. Mobile phone have become a tool of learning in student's academic and personal well-being^{[3],[4]}. Some mobile phone applications like meditation, calm app are helping students suffering from stress^[5]. There are many cynics. Many believe that excessive use of Smartphones leads to physical and mental problems like stress, anxiety,

headaches, Neurovegetative dystonia and sleep disorders among university students^{[6],[7]}. Excessive use of social media, playing games, making frequent calls leads to addiction and other serious medical conditions like depression, anxiety, psychopathy^{[8],[9]}. There is dearth of studies in Delhi/NCR, showing the association of pattern of mobile phone usage and stress among university students. Thus, this study was conducted to estimate the prevalence of stress, explore the pattern of mobile phone usage and its association with stress among university students of Delhi/NCR region.

Methodology

A cross-sectional study was conducted among the students of Amity University, Noida campus. A

total of 185 student participants willingly underwent face to face interview using structured questionnaire between August to September 2019. Institutional ethical approval was taken. Information was collected on Socio-demographics characteristics, academic profile, health ill effects, and some general questions relevant to the topic. Stress was measured using Perceived stress scale(PSS)^[10]. The questionnaire was compiled and developed from different published sources regarding the manner, purpose and intensity of mobile phone use^{[11],[12]}. Descriptive statistics was used to explore

data. Chi-square test was used to study the association between categorical variables and stress. Ap-value of less than 0.05 was considered as statistically significant. The data was analyzed using SPSS Software (IBM SPSS statistics for windowArmonk ,NY:IBM).

Result and Discussion

A total of 185 university students participated in this study, predominantly females (62.2%). The age ranged between 17-35 years. The mean age was 21.97 years.

Table 01 shows Socio-demographics characteristics of the study population.

Table 01: Socio demographic characteristics of the participants (n=185)		
Characteristics	Number	Percentage
Sex		
Male	70	37.8
Female	115	62.2
Age		
17-20	68	36.7
21-25	94	50.7
26-30	21	11.4
31-35	2	1
Residence		
Day scholar	140	75.7
Hosteler	45	24.3
Native place		
Rural	34	18.4
Urban	151	81.6
Family income		
10,000-50,000	131	70.8
>50,000	54	29.2
Course		
Science	137	74.1
Commerce	48	25.9
Qualification		
UG	121	65.4
PG	64	34.6

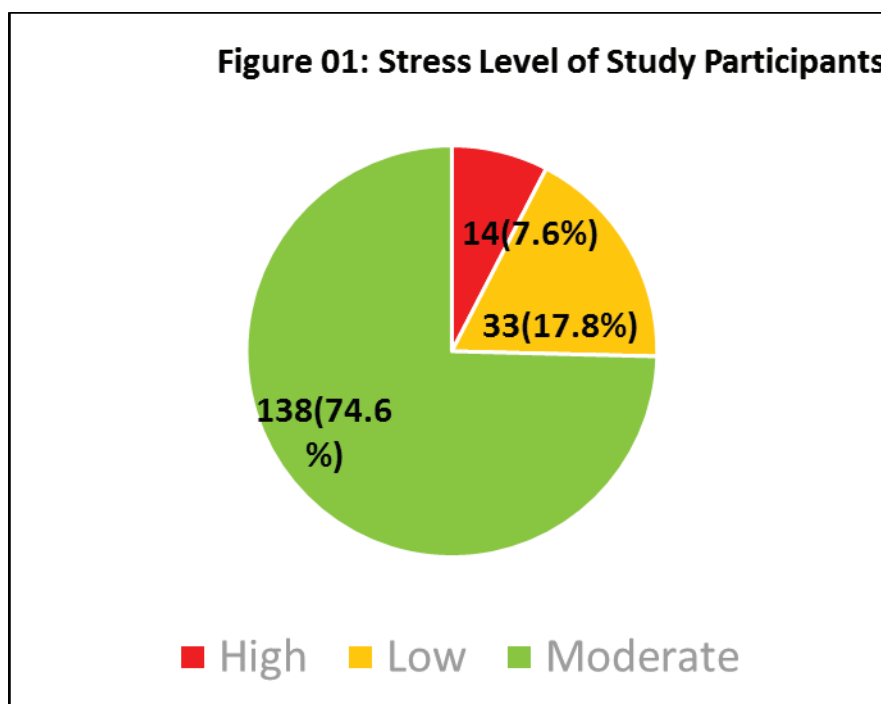


Figure 01 shows the Level of stress among university students.

Interpretation: From Figure 01, we observed that 14(7.6%) students were highly stressed, 138(74.6%) moderately stressed and 33(17.8%) were under low stress category.

Table 02 shows pattern of mobile phone usage among university students.

Table 02: Pattern of mobile phone usage among university students		
Pattern	Number	Percentage
Number of mobile phones		
1	155	83.8
2	30	16.2
Expenditure on Phone (INR)		
50-200	118	63.8
>200	67	36.2
Time spent per day (Minutes)		
≤180	89	48.1
>180	96	51.9
Checking phone in between sleep		
Yes	75	40.5
No	110	59.5

Frequently used Applications		
WhatsApp	141	76.2
Instagram	101	54.6
Facebook	71	38.4
Internet browser	34	18.4
PUBG	33	17.8
Linked In	31	16.8
Tik Tok	17	9.2
Others	26	14.1
Academic Purpose		
To login to academic portal	176	95.1
Downloading class material	170	91.9
Taking notes in the class room	154	83.2
Clicking pictures of black board	125	67.6
Recording class lecture	122	65.9

Interpretation: From Table 02, we observed that Majority of (83.8%) participants have only one mobile phone, 36.2% participants spent more than Rs 200 every month on their phones. Total 51.9% participants use their phones for more than 180minutes in a day and 40.5% participants accept that they check their phones in between sleep.

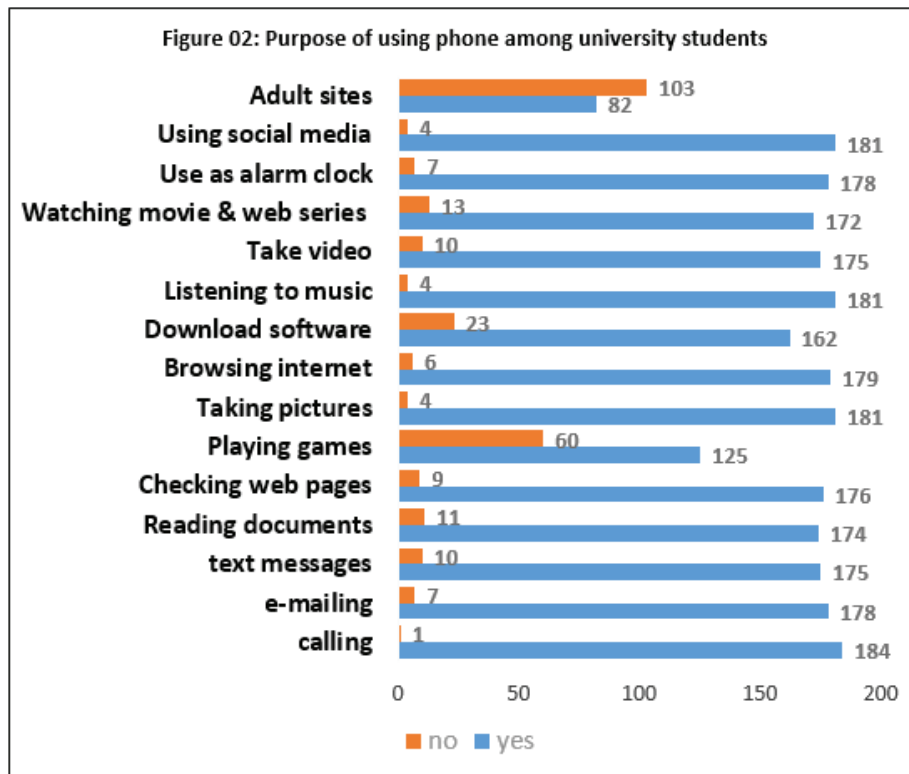


Figure 02 shows Purpose of using phone among university students.

Interpretation: From Figure 02, we observe that a majority of participants (184) use their phones to make calls, followed by 181 participants who use their phones for social media, music and for taking pictures. Only 82 participants accept that they watch adult videos on their phones.

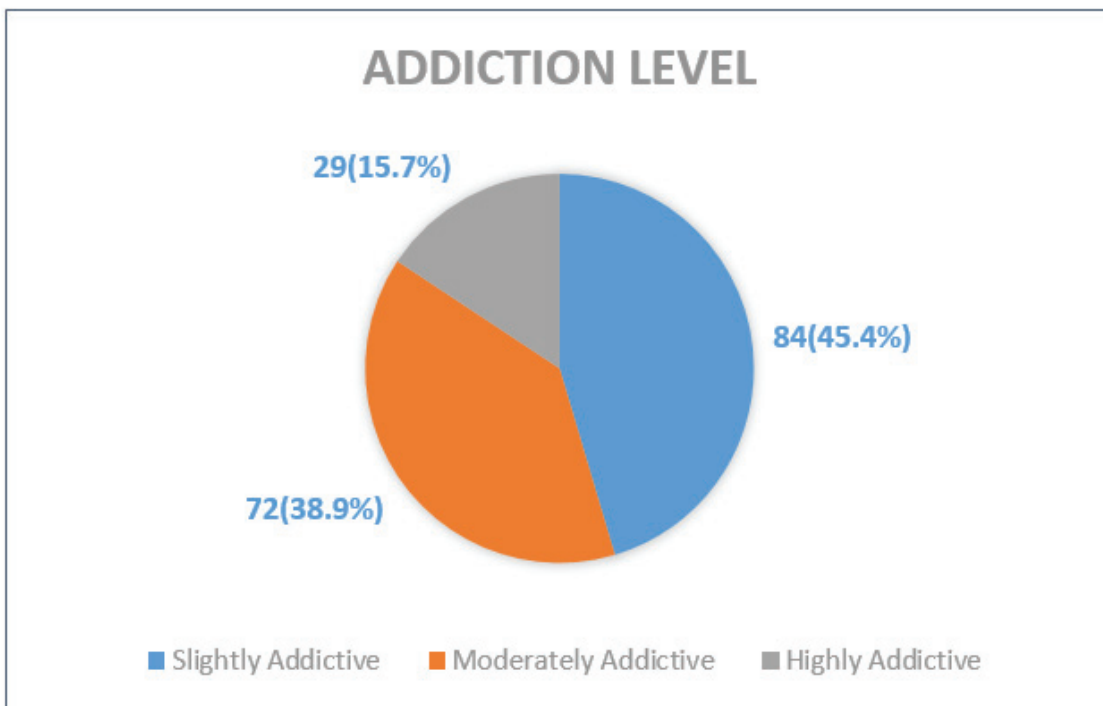


Figure 03 shows Smart phone Addiction among university students.

Interpretation: From Figure 03, we observed that 84(45.4%) feels slightly addictive for their mobile phones, 72(38.9%) feels moderately addictive and 29(15.7%) participants accept that they feel highly addictive for their mobile phones.

Table 03 shows effects of mobile phone usage among university students.

Table 03: Ill Effect of mobile phones usages on Health		
Health outcomes	Yes	No
Irritation without mobile phone	140(75.6%)	45(%)
Burning sensation on eyes	102(55.1%)	83(44.8%)
Headache	100(54%)	85(45.9%)
Difficulty in socializing with people	78(42.1%)	107(57.8%)
Insomnia	65(35.1%)	120(64.8%)
Pain on wrist/hand while using phone	61(32.9%)	124(67%)
Ear discomfort	52(28.1%)	133(71.8%)

Interpretation: From this Table 03, we observed various health ill effects due to mobile phones.

Table 04 shows the association of stress with pattern of mobile phone usage among university students.

Table 04: Association of Stress with respect to characteristics under study					
Characteristics	Total	Level of stress			Significance
		High stress	Moderate stress	Low stress	
Sex					
Male	70	4(5.7%)	53(75.7%)	13(18.6)	0.780
Female	115	10(8.6%)	85(73.9%)	20(17.3%)	
Current residence					
Hosteler	45	5(11.1%)	32(71.1%)	8(17.8%)	0.577
Day scholar	140	9(6.4%)	106(75.7%)	25(17.9%)	
Course level					
UG	121	7(5.8%)	94(77.7%)	20(16.5%)	0.290
PG	64	7(11%)	44(68.7%)	13(20.3%)	
Pattern of use: Time spent on phone (Minutes)					
≤180M	88	3(3.4%)	61(69.3%)	24(27.3%)	0.001**
>180M	95	11(11.6%)	76(80%)	8(8.4%)	
Pattern of use: Money expenditure					
<200 INR	118	6(5.1%)	88(74.6%)	24(20.3%)	0.152
>200 INR	67	8(11.9%)	50(74.7%)	9(13.4%)	
Pattern of use: Checking phone in between sleep					
Yes	75	7(9.3%)	63(84%)	5(6.7%)	0.004**
No	110	7(6.4%)	75(68.2%)	28(25.4%)	
Effect on health					
Insomnia					
Yes	48	5(10.4%)	39(81.3%)	4(8.3%)	0.055
No	120	7(5.8%)	85(70.9%)	28(23.3%)	

Cont... Table 04 shows the association of stress with pattern of mobile phone usage among university students.

Burning eye sensation					
Yes	102	6(5.9%)	84(82.3%)	12(11.8%)	0.025**
No	83	8(9.7%)	54(65%)	21(25.3%)	
Addiction					
Slightly addictive	84	6(7.1%)	55(65.5%)	23(27.4%)	0.001**
Moderately addictive	72	2(2.8%)	61(84.7%)	9(12.5%)	
Highly addictive	29	6(20.7%)	22(75.9%)	1(3.4%)	

Interpretation: From Table 04, we observe that there was Asymptotic significance between stress and using mobile phone for more than 180 minutes in a day(p=0.001), checking phone in between sleep(p=0.004), burning eye sensation(p=0.025) and mobile phone addiction(p=0.001).

Discussion

Excessive use of mobile phone leads to stress among students (Figure 01). Gladius Jennifer et al, shows similar findings where 70.4% medical students were categorize under moderate stress^[13]. Maya Sahu et al reported that 22.5% nursing students were under low stress, 67.7% under moderate stress and 9.8% under high stress due to mobile phone usage, hence showing similar findings^[14].

A total 51.9% participants use their phone for more than 180 minutes in a day (Table 02). Similar finding was reported in the study done by Dasgupta P et al^[15]. Prevalence of Checking phone in between sleep was 40.5% (Table 02). This finding was supported by a study conducted by Jilisha G. et al^[16]. Many students use Phone for academic purposes (Table 02). This indicates that mobile phone could be helpful for students in academics. This is supported by a study published by Md. Moyazzem^[17].

A majority of participants use phone for calling purpose(99.4%), followed by browsing internet (96.7%) and social media (97.8%) (Figure 02) and similar findings are reported inVasanthakumaran study^[12].

Our study revealed mobile phone addiction level among university students(Figure 03). Davey S et al reported smartphone addiction magnitude in India ranged from 39%-44% which was close to our findings^[18].Jain P et al showed the smartphone addiction prevalence as

24.65%, which is lower than our study finding^[19]. The likely reason for different finding could be that they use Smartphone addiction scale (SAS) to measure addiction whereas in this study the addiction level was self-reported by the students within the university.

Excessive mobile phone usage have ill effects on health (Table 03). Similar findings can be seen in P.Stalin et al study^[20]. Many other studies like Altalhi A. et alreported 62% participants suffer from burning eye sensation^[21]. Study by Logaraj M. et al presented 50% of female students complaints of headache due to CVS(Computer vision syndrome)^[22].Shantakumari N. et al reported 58.4% female students suffer from headache and 55.6% from burning eye sensation^[23]. Sharma N. et al in the study reported 73% of students feels irritated without their phones and 61% suffers from headache^[24]. Khan MN. et al presented that around 35-49% US population has sleep disorder like insomnia^[25]. Khilani et al showed that 38.3% participants were suffering from sleep disturbance^[26]. Another study by Althakafi KA. et al. reported (48.1%)early insomnia and (54.4%)late insomniaamong Saudi adult population^[27]. Likely reason for different findings could be that it was a nation-wide quantitative study including all population from age group 15-60 years whereas our study was conducted among university students.

Our study reveals a positive correlation between stress and using phone for more than 180 minutes

in a day. Deepali A et al showed a statistically significant correlation between mobile phone usage and stress($p=0.001$), irrespective of the cutoff for time spent on phone in a day^[11]. Thomée S. et al also showed similar findings^[28]. However They categorize excessive use of phone by number of phone calls and messages received in a day whereas we used categories of time to record the time of using mobile phones.

Another finding of our study was association of stress with checking phones in between sleep($p=0.004$) and burning eye sensation($p=0.025$) (Table 04). Several studies reported that checking phone frequently at night disturb sleep which cause burning eye sensation and eventually leads to stress. Prasad M. et al and Thomee S. et al reported that checking phone at night leads to sleep loss^{[29],[30]}. Thomee S. et al reported that students suffering from sleep problems considered as important factor leading to stress^[28]. Study by Basu S. et al revealed that reason for checking phone in between sleep could be text messages, checking social media to have conversation with friends^[31]. Altalhi A. et al and Shantakumari N. et al revealed that pattern of mobile phone usage cause health outcomes like burning eye sensation^{[21],[23]}. Study by Mork R et al reported that eye problems eventually leads to stress among students^[32].

Our study reveals a positive correlation between phone addiction and stress among university students (Table 04). Shokat S. stated in his study that people spend most of their time on their phones^[33]. This too much dependency makes us Mobile addictive. De-Sola Gutiérrez J et al reported that adolescents who are addicted to phone tends to use phone all the time which can lead to other health outcomes like headache, burning eye sensation, depression and Insomnia^[34]. These health problems in adolescents cause stress and anxiety. Dey M. et al and Alhassan AA. et al reported the same findings regarding association of phone addiction and stress^{[35],[36]}.

On the other hand, Jacob (2012) study's finding was contradictory with our findings ^[37]. He stated that, mobile phone allows the user to utilize more advanced functions such as video calling, internet browsing, e-mail handling, individualized application and so on and also presented that constant flow of information in smart phone reduce stressful situations at work place. This

study's targeted audience were working people whereas our study was on university students. This could be a possible reason for different findings on association of stress with pattern of mobile phone usage.

Strength: We were successfully able to accessed pattern of mobile phone usage, self-reported ill effects and mobile addiction as well as association between stress and various factors among university students.

Limitation: Present study was based upon smaller number of participants because of lack of time and resources, so larger studies are required to find the association between pattern of mobile phone usage and stress among university students. Also, results of this study cannot be generalized because study was conducted in only one college.

Conclusion

Based on limited sample size, our study indicates that pattern of mobile phone usage leads to stress and Ill health. If students follow healthy mobile phone usage patterns, like not checking phone in between sleep, not using phone for more than 180 minutes in a day can save students from stress and health issues caused by mobile phones.

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Source of Funding :Self

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A Cross-Sectional Study on Psychosocial Impact of Covid19 among Suspects

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Abstract

Background: COVID pandemic in India, like all the other affected countries, with its uncertainties affected the psychosocial impact of masses including the suspects. When the global focus has mostly been on testing, finding a cure and preventing transmission, people went through a myriad of psychosocial problems in adjusting to the current lifestyles and fear of the disease. However, only few studies have been conducted regarding the mental health of people amidst the pandemic. This study mainly explores the psychosocial impact of COVID19 among people including the suspects.

Methods: A cross sectional study was done over a period of 1 month to assess the psychosocial impact of Covid among suspects. The data was collected using predesigned, semi-structured questionnaire. It was circulated among general public, especially those residing in containment areas and those who are at high risk. The data compilation was done using Ms Excel and analysis was done using SPSS Statistics.

Results: There were a total of 230 responses from different parts of the country. The mean age of the respondents was around 21-30 years. Out of these, 25 respondents were suspects of COVID-19. A higher level (80%) of psychosocial distress was found among suspects.

Conclusion: The mental problems caused by COVID-19 lockdown not only impacted the psychosocial wellbeing of suspects but also individuals from the entire community including students, casual labourers, healthcare professionals and the general population. The study also showed that there was a higher level of fear and anxiety among the suspects when compared to the general public. In addition, constant mental pressure also eventually led to difficulty in sleeping among suspects.

Keywords: Cross Sectional, Psychosocial, Impact, Covid19, Suspect

Introduction

Since the first case of novel coronavirus disease 2019 (COVID-19) was diagnosed in Wuhan, China in December 2019, it has swept across the world. Due to this unexpected scenario, not only has the nation's response being observed, but also the mental health of

the public⁽¹⁾. The proliferation of fear is resulting in erratic behaviour among people since any among the gender irrespective of the socio demographic class can be infected⁽¹⁾. According to CDC (Centres for disease control and prevention), the best way to prevent illness is to avoid being exposed. Isolation and quarantine are regarded as one of the key pillars of COVID19 containment strategy⁽²⁾. Studies have shown that isolation has triggered a variety of psychosocial problems, such as panic disorder, anxiety and depression. It can also precipitate new psychiatric symptoms in healthy individuals and aggravate the condition of those with pre-existing mental illness. The ones who are sick or

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quarantined, may experience shame, guilt, or stigma⁽¹⁾. They fear contagion and infection to their family, friends and colleagues- thus feeling uncertainty⁽³⁾.

A research, done on mental health of people during 2003 SARS epidemic, indicated significant levels of psychiatric morbidity and stated the importance of evaluating the psychosocial impact of any emerging infectious disease on patients⁽⁴⁾. Many articles revealed that during the outbreak of Nipah virus encephalitis 2017, there was widespread psychosocial impact on people. The study stressed on a multifaceted approach to address the psychosocial consequences, to reduce vulnerability by enhancing better coping and resilience of people⁽⁵⁾.

Enhancing the psychological well-being, is crucial during this crisis⁽¹⁾. Thus, immediate research evaluating the mental health is needed to reduce unintended mental health issue, which can have long-term effects even after the disease has reduced. Such studies will bring clarity regarding psychosocial impact by comparing the lifestyles of the suspects⁽⁶⁾.

Objectives of the Study

- * To explore psychosocial behaviour of COVID19 suspects.
- * To measure prevalence of psychological distress among COVID19 suspects.
- * To compare the psychosocial characteristics of COVID19 suspects.

Material and Methodology

Type of study: Cross sectional study

Duration of study: 1 month (12th April- 9th May 2019)

Sample size: Reference for prevalence is taken from the article “Study on public psychological states and its related factors during the outbreak of corona virus disease (COVID19) in some regions of China”. The prevalence is taken as 18% and the required sample was calculated using the formula :

$n =$ sample size

$p =$ prevalence

$z = 1.96$

$d = 5\%$

Then, $n = 226.8080$, which is rounded off to 230

Sample method: Simple random sampling.

Inclusion criteria: (1) Participants giving their consent (2) Participants 18 years old and above.

Exclusion criteria: Persons who are chronically ill and those who do not give consent.

Methods of data collection and tools used: The Questionnaire was circulated among general public, especially those residing in containment areas and those who are at high risk. The study is conducted among the suspected patients of covid19 meeting the inclusion and exclusion criteria. The data will be collected using predesigned, semi-structured questionnaire. The entries in the survey will be kept confidential.

The questionnaire consists of 4 main sections:

- (1) General information that includes person’s age, sex, occupation, place, etc
- (2) Medical history
- (3) Psychological impact
- (4) Social impact

Statistical Analysis: The data compilation is done using Ms Excel and analysis is done using SPSS.

Results

There were a total of 230 responses from different parts of the country. The mean age of the respondents was around 21-30 years. Out of these, 25 respondents i.e., about 11% (Male=16 and Female=9) were suspects of COVID-19.(as seen in Table 1).Among the suspects,64% suspects i.e 16 of them were between ages 21-40yrs.Also among a total of 25 suspects,there were 16 male suspects and 9 female suspects.56% of the suspects i.e 14 of them resided in Karnataka region whereas 8 of them had travelled down from Maharashtra,1 each from Kerala,Chattisgarh and Rajasthan.Furthermore 56% subjects belonged to Hindu religion,40% subjects belonged to Muslim religion and others belonged to 4%.The study reveals that 11 suspects i.e., 44% of

the suspects were Undergraduates,6 completed post graduate,4 completed 12th std, 3 completed high school and 1 of them just completed primary education.Majority of the study participants(72%) as well as the suspects (75.7%) belonged to Upper class according to modified BG Prasad classification(as in figure 1).

Most importantly 52% suspects and 60.5% non suspects experienced behavioural changes in response to Covid19 pandemic whereas 84% suspects and 52.7% non suspects had fear regarding Covid pandemic.In addition to that it was found that 88% suspects and 32.2% non suspects felt anxious due to the lockdown imposed.48% of the suspects agreed to have experienced mental pressure during the lockdown whereas only 17.6% of the non suspects agreed.(as in table 2).An important fact to note here is that 44% of the suspects felt less

confident in themselves during this COVID19 pandemic whereas only 14.1% of non suspects felt less confident. 40.5% of the non suspects stated that they disagree to it.(as in Table 3). 32% of the suspects stated that they had difficulty in falling asleep as they had worries related to COVID19. 12% of the suspects strongly agreed to it. Whereas only 7.3% of non suspects agreed while 46.8% of non suspects disagreed to having difficulty in falling asleep due to worries related to COVID19(Table 4)

As social distancing was considered the norm, it was found that , 97.5% (200) of non suspects and 96% (24) of the suspects followed social distancing norms. (figure 2).Finally 68% (17) of suspects and 61.9%(127) of non suspects opined that the effect of COVID19 on their social life is not good.(figure 3)

TABLE 1: Distribution of the participants according to their age.

AGE(in years)	No	Suspected
<20	29	1
21-30	155	8
31-40	10	8
41-50	6	7
51-60	5	0
>61		1
Grand Total	205	25

TABLE 2: Table 2 shows mental pressure in response to Covid pandemic.

NON SUSPECTS (N= 205)		SUSPECTS (N= 25)	
FREQUENCY	PERCENT	FREQUENCY	PERCENT
36	17.6	12	48.0
70	34.1	2	8.0
65	31.7	5	20.0
20	9.8	6	24.0
14	6.8		

Table 3

Table 3 shows Frequency and percentage distribution of feeling confident in response to COVID19 pandemic among the participants.

	Non suspects (N= 205)		Suspects (N= 25)	
	Frequency	Percent	Frequency	Percent
Agree	29	14.3	11	44.0
Disagree	83	40.5	3	12.0
Neutral	71	34.6	7	28.0
Strongly agree	11	5.4	1	4.0
Strongly disagree	11	5.4	3	12.0

TABLE 4:

Table 4 shows Frequency and percentage distribution of difficulty in falling asleep in response to COVID19 pandemic among the participants.

	Non suspects (N= 205)		Suspects (N= 25)	
	Frequency	Percent	Frequency	Percent
Agree	15	7.3	8	32.0
Disagree	96	46.8	4	16.0
Neutral	38	18.5	8	32.0
Strongly agree	6	2.9	3	12.0
Strongly disagree	50	24.4	2	8.0

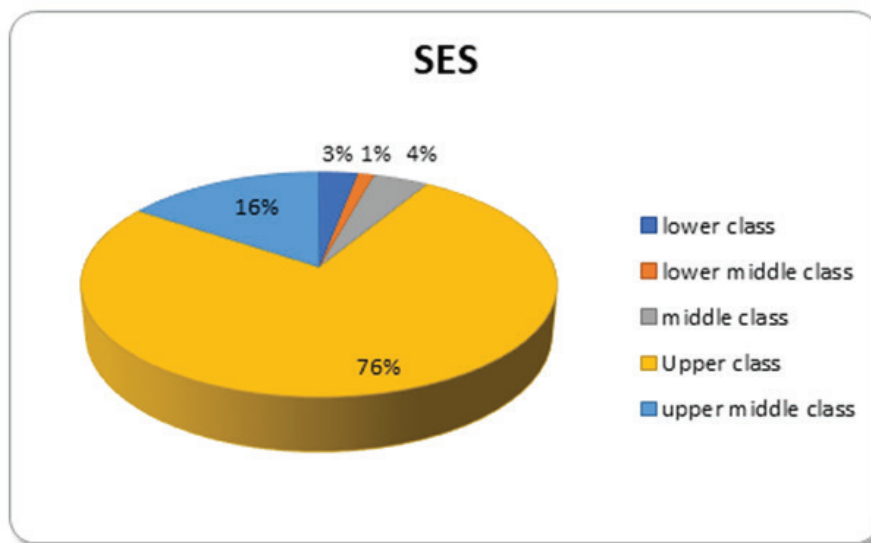


Figure 1: Shows socio economic classification according to modified BG Prasad classification of the study subjects

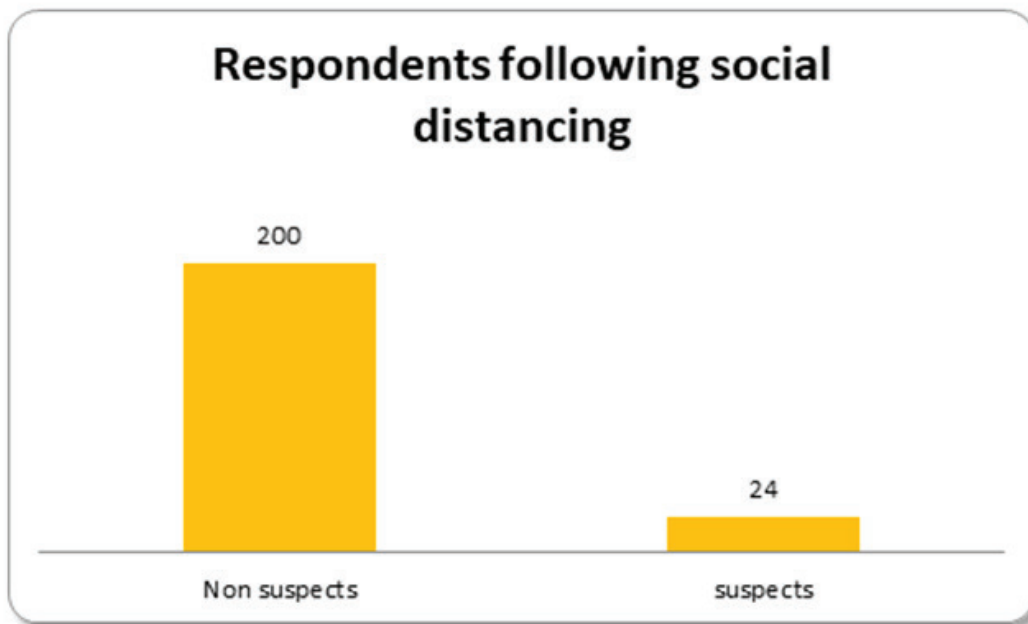


Figure 2 shows the number of participants and suspects following social disturbing norms.

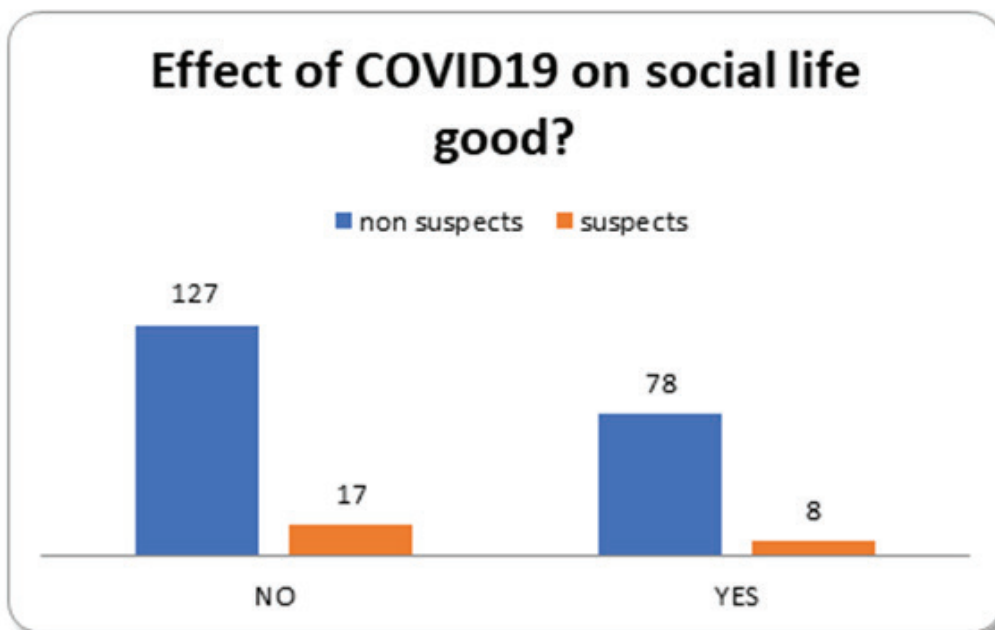


Figure 3 shows Distribution of the respondents according to their opinion on the effect of COVID19 on their social life

Conclusion

The mental problems caused by COVID-19 lockdown not only impacted the psychosocial wellbeing of suspects but also individuals from the entire community including students, casual labourers,

healthcare professionals and the general population. The study also showed that there was a higher level of fear and anxiety among the suspects when compared to the general public. In addition, constant mental pressure also eventually led to difficulty in sleeping among suspects.

Ethical Clearance: Not Taken.

source of Fund: Self

Conflict of Interest- Nil

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Nexus between Exposure to Mass Media and Health Care Expenditure: Empirical Evidence from India

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Abstract

Background: High Out-of-Pocket Expenditure (OOPE) on health care in India is a serious concern hitherto the low level of Government health spending and health pandemics. Personal savings are the only options left to the individual. This paper identifies the role of mass media use on OOPE on health care in India.

Methods: The analysis is based on the large scale nationally representative dataset (India Human Development Survey - IHDS – II, 2011-12) using the log-linear ordinary regression and multinomial logit regression models.

Conclusions: We observe the U-shaped relationship between Information and Communication Technology (ICT) use and health expenditure among Indian households. However, ICT use is corroborated with higher health expenditure since they belong to the higher strata of income quantile. Some specific policy-based recommendations on better dissemination of information through the appropriate use of ICT devices pertaining to health care have been suggested.

Keywords: *Healthcare expenditure, ICT, IHDS, Mass media.*

Introduction

Health care expenditure in India has been a matter of concern since a significant portion of this is Out-of-Pocket Expenditure (OOPE) along with low Government spending and lack of health insurance. OOPE is the direct burden of medical costs that households bear at the time of availing healthcare services. As per the National Health Account Estimates for India Report, 2015-16¹⁰, out of the current health expenditures of India, the share of households (including insurance) is about Rs 3,42,257 crores (i.e., 69 percent and OOPE being 64.7 percent). Also, the share of public spending on health care in India is just over 1 percent of gross

domestic product (GDP)¹. Thus, the prevailing health system in India is mainly dependent on OOPE on health care, unlike many countries in the world¹⁸. Therefore, the earnings of the household and their personal savings are the major sources of payment for illness in India⁹. But the marginalized section of the society, particularly low and middle-income categories, do not have adequate earnings nor savings. High health expenditure forces them into huge debt and, thereby, poverty². It is nearly eight percent of the population who are pushed below the poverty line in India because of the high burden of OOPE on health care alone⁸.

Literature suggests factors like education, age of the respondent, location of the respondent, corruption etc responsible for high OOPE on health care in India. Education plays an important role in determining the variation in OOPE¹³. The use of ICT in the classroom gives students a new method to learn and apply the skills required¹⁷. But poor people cannot afford a good education and thus have less knowledge about

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medical facilities and their availability. Also, the older population, particularly those living in rural areas, had higher OOPE on health care than urban areas¹³. In fact, location where the patients reside, signify their living conditions, and it has a linkage on medical expenses¹¹.

Doctors, both in government and private health care sectors, prescribe costly medicines and laboratory tests for their own financial commissions. Therefore, corruption is prevalent in the health care industry¹⁴, which is another reason for higher OOPE on health care. In fact, almost 63 percent of clinicians practicing in rural India have inadequate medical training¹⁶, and these have a significant bearing on the indirect cost of medical care. People from rural areas are compelled to go to urban cities to have better medical facilities. But it leads to higher transportation costs because of distance to hospitals. This increases the non-medical expenditure as part of OOPE on health care³.

Along with these important factors, access to information can help to reduce health expenditure⁶. But information differential is not given much attention in the context of health spending in India. Nonetheless, access to information is a major constraint for the marginalized sections of society, and they largely concentrated in rural areas. New technologies are majorly confined to urban areas⁷. Access to information related to health care improves both quality of care and the patient’s knowledge about health facilities⁶. Although several health schemes and facilities are presently operational in India by the government but those facilities are not being effectively accessed by the marginalized section of the society, precisely due to lack of information. Therefore, this paper finds the nexus between the use of mass media

and out-of-pocket expenditure on health care in India. It also identifies the socio-economic and information related covariates of OOPE on health care in India.

Poor have worse health conditions than non-poor as they lack access to resources, particularly monetary resources and low self- health awareness levels⁹. To increase awareness level related to health care spending, the spread of education, along with the use of ICT devices, is essential. Rural areas are deprived of new technologies⁷. Thus, urban people are more ICT friendly as compared to rural areas. One reason may be the expenditure involved in using ICT devices. Thus, specific studies on the impact of ICT devices, along with other factors, on OOPE on health care in the context of India is required.

Methodology

Data

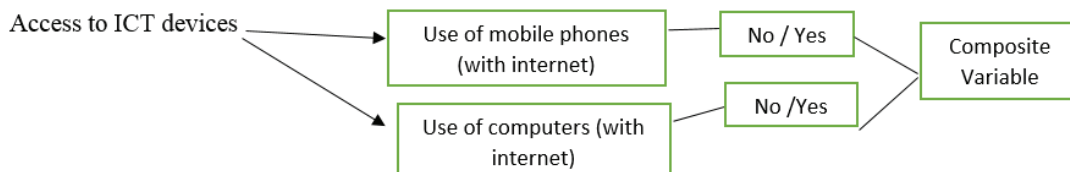
Data is extracted from the India Human Development Survey II (2011-12). In IHDS II, 42152 households (2,04,568 individuals) were interviewed.

Variables

In this study, access to computers and mobile phones is taken as a proxy for ICT devices. In model 1, the log-linear regression method is applied. Here mobile phones and computers are taken as independent variables in the model. In model 2, multinomial logit regression is applied to find out the OOPE on the health care of those who are using ICT devices differently (low, moderate, and high). For this, OOPE on health care is divided into three categories- Low, Mid, High.



Now, a composite variable of ICT is made, taking into account mobile phones and computers.



This composite variable is then added with the three categories of OOPE to generate a new variable ‘OOPE with ICT.’

OOPE with ICT= OOPE (divided into three categories) + Access to ICT devices (Composite Variable)

The variable ‘OOPE with ICT’ has three sub-categories: low level of access to ICT, moderate access to ICT, and a high level of access to ICT. Inferential statistics are derived using STATA 12. The dependent and independent variables are explained in the following table:

Table 1: Description of Variables

Variables	Description
Dependent variable (Model 1)	OOPE on health care is calculated by adding the variables medical out-patient (total value) and medical in-patient (total value) minus the health insurance. It is then divided by household consumption expenditure per capita (OOPE/TE). The variable is in log form. Here OOPE includes all individuals, irrespective of having or not having access to ICT devices.
Dependent variable (Model 2)	The dependent variable is OOPE on the health care of individuals having access to ICT. This variable is divided into three categories- low, mid, and high level of access to any of the ICT devices.
Independent variables	
Age group	It is divided into five equal categories taking twenty as the interval: (0-20) years, (21-40) years, (41-60) years, (61-80) years, and (81-100) years.
Location	Location is divided into two categories: Rural and Urban.
Education	It is divided into four categories: Primary (up to class 5), Secondary (up to class 10), Higher secondary, Graduate, and more.
Caste	Categories are Brahmin/General/forward, OBC, SC, ST, Others.
Gender Dummy	Male and Female.
Husband’s education	This variable is divided into four categories. Primary (up to class 5), Secondary (up to class 10), Higher secondary, Graduate, and more.
Access to mobile phones	This variable gives the number of individuals having access to mobile phones.
Access to computers	This variable gives the number of individuals having access to computers.
Treatment location	This is divided into four categories: same village/neighborhood, another village, other towns, and district town.
Confidence* in Government hospitals	The three categories are- Hardly any confidence, only some confidence, a Great deal of confidence.
Confidence in Private hospitals	The three categories are- Hardly any confidence, only some confidence, a Great deal of confidence.

Source: Authors’ calculation using India Human Development Survey II

Model Specification

We use log-linear regression in model 1 and the multinomial logit regression (MNL) technique in model 2. In the model 2, the error distribution (Kernel density function) doesn't follow a normal distribution and since this is categorical, the MNL regression is best fitted.

Model 1 (Log-Linear OLS using IHDS II)

$$\ln \text{OOPE}_{\text{II}} (2011-12) = A_0 + A_1 \text{AGE} + A_2 \text{LOCATION} + A_3 \text{MOBILE} + A_4 \text{EDUCATION} + A_5 \text{CASTE} + A_6 \text{GENDER} + A_7 \text{HUSEDU} + A_8 \text{CONFGOV} + A_9 \text{COMPUTERS} + A_{10} \text{CONFPVT} + A_{11} \text{TREATMENTLOCATION} + \epsilon_j$$

Model 2 (Multinomial Logit Regression)

$$P_{ij} = \text{Pr} (M_{ij} > M_{ik}), \text{ for } k \neq j, j=1,2,3$$

Where P_{ij} is the probability of i th individuals having access to ICT devices (j). They have three categories regarding the level of access to ICT- low (1), mid (2), and high (3). M_{ij} is the level of use of ICT devices ordered in three categories.

$$\text{OOPE}_{\text{ict}} = C_0 + C_1 \text{AGE} + C_2 \text{LOCATION} + C_3 \text{CONFGOV} + C_4 \text{EDUCATION} + C_5 \text{CASTE} + C_6 \text{GENDER} + C_7 \text{HUSEDU} + C_8 \text{CONFPVT} + C_9 \text{TREATMENTLOCATION} + \epsilon_k$$

Findings

Use of Mass Media and OOPE on Health Care

As of 31st December 2018, urban telephone subscribers are 666.28 million people, whereas rural telephone subscribers are 531.59 million people. In the case of internet subscriptions, urban internet subscribers per 100 population are 93.86, whereas rural internet subscribers per 100 population are 23.87 only. Also, urban teledensity is 159.98, whereas rural teledensity is 59.50 as of 31st December 2018¹⁹. These data show that urban people have more access to information as compared to people residing in rural areas⁷.

Here access to information includes reading the newspaper, listening to the radio, access to the internet, and having mobile phones. The figure depicts that as people have more access to information, OOPE on health care decreases.

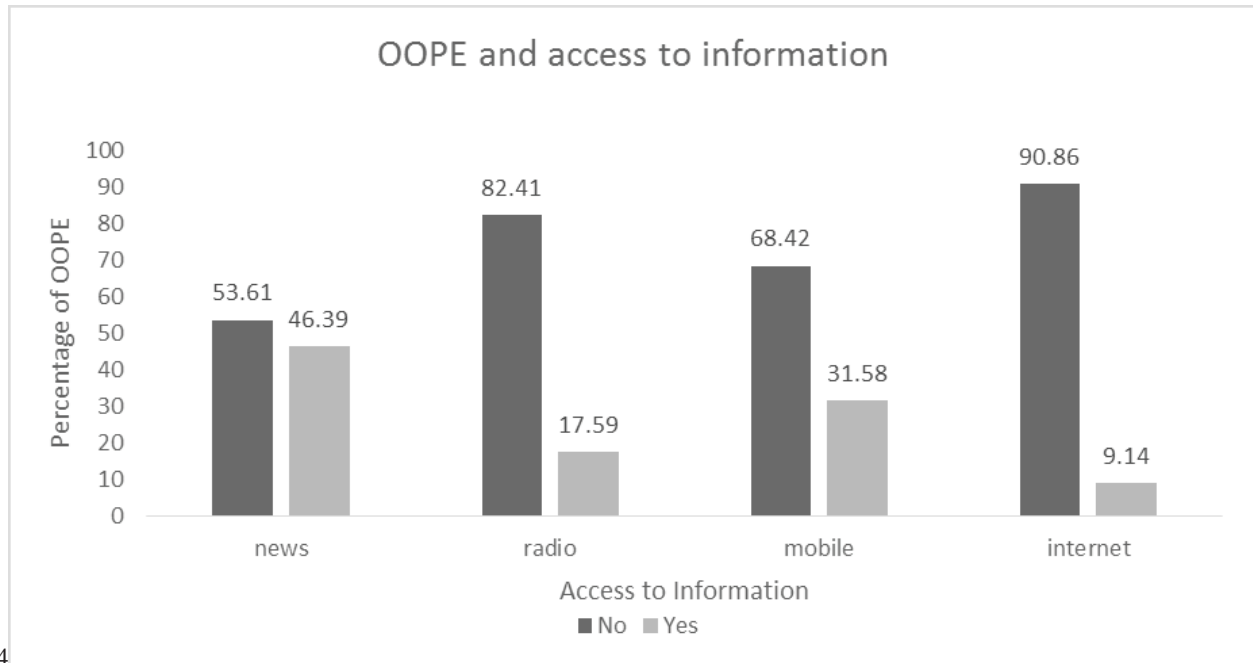


Figure 1: OOPE and access to information

Source: Authors' estimation using IHDS II

A newspaper is one of the major sources of information¹⁵. So, those reading newspapers have better access to information that helps in reducing OOPE on health care. Further, mobile phones, internet facilities, and listening to the radio also helps in the reduction of OOPE on health care.

Regression Results and Analysis

The regression models in this paper are well specified by including relevant variables. The interpretation of the slope coefficient of age, for age-group above 60 years,

shows a positive relationship with OOPE on health care and significant at one percent level. This indicates that the older population has a higher OOPE on health care, which is in line with the existing literature¹³. Location is another important control variable and significant at one percent level. People residing in urban areas have less OOPE on health care as compared to rural areas. This is because, in urban areas, private as well as higher quality health services are more easily accessible compared to the rural areas³. Also, there is considerable presence of heterogeneity in health and health care across states in India⁴.

Table 2: Regression results [Model 1(Log-linear) and Model 2 (Multinomial logit)]

	Model 1 [Dep Var: Log (OOPE/TE)]	Model 2 [Dep Var: OOPE/TE (@low ICT use)]			
	Coef.	moderate use of ICT		high use of ICT	
		Coef.	Average marginal effect	Coef.	Average marginal effect
Age (0-20®)					
21-40	-0.208*** (0.013)	-0.386*** (0.019)	-.0325 (.0022)	-0.577*** (0.028)	-.0183 (.0013)
41-60	-0.193*** (0.016)	-0.688*** (0.020)	-.0743 (.0023)	-0.431*** (0.030)	-.0019 (.0016)
61-80	0.301*** (0.016)	0.717*** (0.029)	-.0760 (.0034)	-0.486*** (0.044)	-.0042 (.0023)
81-100	0.193*** (0.065)	0.221* (0.108)	-.0104 (.0129)	0.911*** (0.134)	.0589 (.0101)
Gender (Male®)					
Female	-0.105*** (0.011)	-0.129*** (0.016)	-.0160 (.0017)	-0.004 (0.023)	.0039 (.0011)
Location (Rural®)					
Urban	-0.303*** (0.013)	-0.046*** (0.019)	-.0311 (.0021)	0.754*** (0.027)	.0466 (.0015)
Caste (Brahmin®)					
OBC	0.290*** (0.013)	-0.684*** (0.019)	-.0793 (.0031)	-1.003*** (0.028)	-.0392 (.0016)

Cont... Table 2: Regression results [Model 1(Log-linear) and Model 2 (Multinomial logit)]

SC	0.003 (0.015)	-0.008 (0.0231)	.0094 (.0035)	-0.237*** (0.032)	-.0170 (.0020)
ST	-1.391*** (0.411)	-3.764*** (0.035)	-.3666 (.0028)	-2.947*** (0.056)	-.0770 (.0018)
Others	0.411*** (0.072)	0.649*** (0.127)	.1285 (.0188)	-0.384** (0.196)	-.0499 (.0075)
Education (Primary®) of the respondent					
Secondary	-0.039** (0.013)	-0.125*** (0.017)	-.0334 (.0019)	0.616*** (0.027)	.0352 (.0013)
Higher Secondary	-0.085*** (0.024)	0.179*** (0.035)	-.0420 (.0038)	1.638*** (0.041)	.1087 (.0033)
Graduate	-0.051* (0.028)	0.079** (0.041)	-.0529 (.0043)	1.597*** (0.046)	.1100 (.0038)
head/Husband's education (Primary®)					
Secondary	-0.120*** (0.017)	0.199*** (0.025)	.0104 (.0028)	0.434*** (0.032)	.0186 (.0017)
Higher Secondary	0.089** (0.040)	0.077 (0.063)	-.0065 (.0067)	0.466*** (0.071)	.0255 (.0038)
Graduate	-0.342*** (0.042)	-0.145** (0.064)	-.0229 (.0067)	1.597*** (0.046)	.0135 (.0035)
Access to Mobile	-0.176*** (0.016)	--	--	--	--
Access to Computer	-0.194*** (0.015)	--	--	--	--
Confidence in Government hospitals (Hardly any confidence®)					
Only some confidence	0.150*** (0.012)	-0.493*** (0.017)	-.0526 (.0020)	-0.355*** (0.025)	-.0041 (.0012)
Great deal of confidence	0.152*** (0.018)	0.501*** (0.029)	.0514 (.0037)	0.529*** (0.039)	.0133 (.0021)
Confidence in Private hospitals (Hardly any confidence ®)					
Only some confidence	0.034*** (0.014)	-1.393*** (0.018)	-.1599 (.0025)	-1.164*** (0.028)	-.0249 (.0013)
Great deal of confidence	0.084*** (0.030)	0.022 (0.047)	.0052 (.0067)	-0.045 (0.066)	-.0036 (.0034)

Treatment Location (Village/neighbourhood ®)					
Another village/ neighbourhood	-0.081*** (0.015)	-0.349*** (0.022)	-.0428 (.0034)	-0.421*** (0.036)	-.0132 (.0019)
Other towns	0.341*** (0.017)	-1.513*** (0.021)	-.1797 (.0030)	-1.238*** (0.033)	-.0274 (.0016)
District town	0.357*** (0.021)	0.327*** (0.034)	.0305 (.0052)	0.610*** (0.043)	.0306 (.0028)
	No. of observation= 115267 F(25,115241)=1342.76 R-squared=0.2256 Adj.R-squared=0.2254	Log Likelihood = -96423.427 No of observation= 182528 LR chi2 (46) = 100133.7 Prob>chi2= 0 Pseudo R2= 0.3418			

Source: Authors’ estimation using IHDS II

Education is found to be a significant variable. The regression result in table 2 (Model 1) finds a negative relationship between the level of education and OOPE on health care¹³. The variable ‘mobile phones’ and ‘computers’ are taken as a proxy for access to ICT devices. The regression result shows that those individuals who have access to mobile phones have less OOPE on health care as compared to those who do not have a mobile phone. The variable ‘access to computers’ also explains that those who have access to computers have less OOPE on health care than those who do not have. This indicates that access to ICT is important for the reduction in the cost of health spending⁶.

The variable ‘confidence in Government hospitals’ and ‘confidence in private hospitals’ matters in the variation of OOPE on health care. The doctors sometimes go to the extent of prescribing unnecessary medicines and laboratory tests¹⁴, which is another reason for higher OOPE on health care.

Model 2 however, investigates the OOPE on health care for people who have access to ICT devices. The result shows how differential in access to ICT affects OOPE on health care. Model 2 brings the discussion on

the relative use of ICT, given their OOPE as a percentage of total household consumption expenditure (TE). Here, the dependent variable is OOPE on healthcare subject to the nature of access to ICT. With reference to those having low use of ICT devices, how their socio-economic and other relevant factors explain the moderate and high level of ICT use. The variable location is significant in both the cases - medium and high level of ICT use. But with a high level of ICT use, the coefficient shows a positive relationship with OOPE on health care. This means, if an individual, living in urban areas along with high use of ICT devices, then their OOPE on health care increases as compared to those having a medium level of ICT use.

Similarly, in the case of education, we see that for the secondary level of education, people with a high level of ICT access have more OOPE on health care as compared to those having a medium level of ICT access. Thus, the use of ICT can reduce health spending⁶, but it depends on the level of ICT use since this incurs expenditure further.

It is interesting to note that the multinomial logistic regression results identify some coefficients which are quite different than the log-linear model, especially in case of social hierarchy (caste system in India). The ICT

access brings down the OOPE on health care though they belong to the bottom section in the caste hierarchy. Thus, policies should be framed to nurture the people in the lower caste in terms of access to ICT, which thereby bring down OOPE on healthcare. Similarly, results can be interpreted for the age group of individuals.

The variable 'confidence in Government hospitals' explains the OOPE on healthcare positively and significantly for the persons who access ICT. Treatment location also matters in the context of OOPE and ICT.

Robustness check of the model

We have checked the robustness through subsampling method at 25, 50 and 75 per cent of the sample used in the model 2. The results are still valid at subsample models and hence can be generalised.

Summary and Discussion

The findings in this paper confirm the nexus between use of mass media and expenditure on health care of the Indian households. Information access of the individual indeed influence the OOPE on health care. The regression results also show that age, location, education, caste, household head/husband's education, confidence in government/private hospitals are the significant determinants of OOPE on health care in India. Our results indicate that older people and health expenditures are positively related, which is found similar to the existing literature¹³. Similarly, variables like location and education also justify the existing literature^{11,13}.

Information differentials have not been paid much attention by the policymakers in India so far as an important factor. The multinomial regression results identify the U-shaped relationship between OOPE on health care and the level of ICT use. With a low level of information, OOPE on health care increases, however, as the level of information (through ICT devices) increases to a moderate level, OOPE on health care declines. Further, with a higher level of information, OOPE on health care again increases. Therefore, it is suggested that specific interventions like better ICT penetration and dissemination with health awareness are necessary to improve the information access through the appropriate level of ICT use in reducing the OOPE on

healthcare and quality care access in India.

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Ethical Clearance: The IHDS-II data used in this study is available in the public domain. IHDS followed ethical clearance guidelines and norms. No separate ethics statement and consent for publication was required for this study.

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Effect of Prolonged Upright Position during First Stage of Labour on Labour Outcome in Low Risk Term Nulliparous Women

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Abstract

Background: For positive childbirth experience, WHO recommends that women with low risk pregnancy should be encouraged to be ambulatory and assume upright position during labour. The aim of present study was to compare the effect of prolonged upright position during active first stage of labour with ambulation as per choice of the women, on the labour outcome. **Methods:** This was an interventional study conducted on 60 low risk nulliparous women. 30 women were assigned to upright position and motivated to remain in sitting, standing or walking position for atleast 60% of the duration of active first stage of labour and women in the control group were allowed to assume the position of their choice. Duration of labour, need for augmentation and mode of delivery in both groups were compared. **Conclusion:** In low risk nulliparous women, upright position during active first stage of labour is associated with frequent and stronger contractions in first 3 hours of active labour but does not have any significant impact on duration of labour, need for augmentation and mode of delivery. Therefore, nulliparous women during active first stage of labour can be allowed to be in position of their choice rather than imposing prolonged upright position.

Keywords: *apgar score, duration of labour, first stage of labour, mode of delivery, position during labour, upright position*

Introduction

The ideal maternal position during labour and child birth is debatable. In the past, women were encouraged to adopt various erect positions in labour to expedite the labour process. Since the twentieth century, and with western influence on our training, delivery and labour in the supine position have become the norm in hospital and domestic settings. Supine position helps the caregivers to exercise better control and improves monitoring of the labour process, administration of anaesthesia and

intravenous fluids. However in this position prolonged aortocaval compression by the term pregnant uterus leads to around one fourth decline in cardiac output that may cause a decrease in the utero-placental perfusion and foetal distress.¹⁻³

It is also proposed that in contrast with supine position, delivery in the upright and mobile posture uses gravity to aid descent of the fetal head into the pelvis. The rate of descent of fetal head therefore is faster with upright position due to improved alignment and gravitational pull, leading ultimately to shorter duration of labour.^{1,2,4,5} As the head is directly and evenly applied on to the cervix during this position, uterine contractions intensify in strength, regularity and frequency, and are less painful.^{6,7} Also there is lower incidence of non reassuring fetal heart rate due to decreased aortocaval

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compression in the upright position.^{8,9}

A 2013 Cochrane review studying effect of positions on labour found a significant decrease in the length of first stage of labour by one hour and twenty two minutes, reduction in operative vaginal delivery rate, and decrease in caesarean rate in upright position versus supine position in the first stage of labour.¹⁰ Therefore, all the recent guidelines, and those for the low middle income countries favour any position in labour that the patient is comfortable with to be adopted during labour.¹⁰ World Health Organisation 2018 guidelines on “Intrapartum care for a positive childbirth experience”, recommend that women with low risk pregnancy should be encouraged to remain mobile and assume an upright position during labour.¹¹ Despite these recommendations most of the women delivering at labour wards of the hospitals in India spend most of the time during labour in the supine position. Also there is paucity of literature on the duration for which upright position should be assumed for it to have greater impact on the labour outcome. Keeping these in mind, the present study was conceived to compare the effect of upright position for more than 60% of the first stage duration with position of women’s choice on the duration of first and second stage of labour, mode of delivery and need for labour augmentation.

Materials and Methods

This was an interventional study conducted in the labour ward of a tertiary care centre of North India over a period of 18 months. Low risk term nulliparous women with cephalic presentation admitted in early labour were informed and counselled about the study protocol. Those who consented to participate in the study and were willing to follow the methodology were recruited in the study. Ethical clearance was taken from the institutional ethical committee. Women with obstetric and medical

complications were excluded from the study.

All women received information regarding the possible benefits of erect position and were divided into study group and control group of 30 each by closed envelope method. The instructions to women regarding the position in first stage of labour were given by the same investigator. The women were given short and easy to understand instructions for assuming erect position (walking, standing or sitting) during the active first stage of labour for at least 20 minutes at a stretch. It was ensured that patients were adopting a sitting position on bed or stool or were walking for at least 60% of the first stage of labour. This arbitrary duration of 60% was taken as monitoring of women, assessment of uterine contractions and foetal heart monitoring was done over a period of 10 minutes every 30 minutes. Women in the control group were free to move around during labour as per their wishes. At 30 minutes interval the investigator recorded the time spent by the women in erect position by recall method, in both the groups.

The demographic profile and detailed history of the women was recorded in a pre-designed Performa. General physical and obstetric examination was done and labour was managed according to the institutional protocols. The duration of first and second stage of labour, need for oxytocin augmentation and mode of delivery was recorded.

Statistical Analysis

Statistical analysis was done using SPSS version 20.0. Data was represented as Mean and standard deviation. Numerical data was compared using t-test, non-parametric numerical data was compared using mann whitney test and nominal data was compared using chi square analysis. The p-value<0.05 is taken as significant.

Table 1: Demographic Profile of Women in Study and Control Group

Parameters	Study Group (N=30)	Control Group (N=30)	p Value
Mean age (years)	22.83	23.37	0.450
Booked	25	20	0.136
Employed	13	11	0.598
Rural residence	17	15	0.603
Mean period of gestation (weeks)	38.73	38.70	0.898
Time spent in erect position (minutes)	141.90	46.67	<0.001

Table 2: Frequency and Intensity of Uterine Contractions in Study and Control Group

Parameters	Study Group	Control Group	p Value	
Number of contraction per 10 minutes during active labour (mean)				
1st hour	2.87	1.57	<0.001	
2nd hour	3.81	3.21	0.424	
3rd hour	4.52	3.64	<0.001	
Intensity of uterine contraction during active labour				
1st hour	Mild	14 (46.66 %)	24 (80.00 %)	0.022
	Moderate	13 (43.33 %)	4 (13.33 %)	0.022
	Strong	3 (10.00 %)	2 (6.00 %)	0.022
2nd hour	Mild	0	9 (32.14 %)	0.002
	Moderate	18 (66.66 %)	16 (57.14 %)	0.002
	Strong	9 (33.33 %)	3 (10.71 %)	0.002
3rd hour	Mild	0	2 (8.00 %)	0.285
	Moderate	11 (52.38 %)	15 (60.00 %)	0.285
	Strong	10 (47.61 %)	8 (32.00 %)	0.285

Table 3: Comparison of Labour Characteristics in Study and Control Group

Parameters	Study Group (N=30)	Control Group (N=30)	p value
Mean duration of 1st stage of Labour (minutes)	221.60	273.67	0.144
Mean duration of 2nd stage of Labour (minutes)	41.79	48.70	0.291
Need of oxytocin for Labour augmentation (N)	3	7	0.166

Table 4: Mode of delivery in Study and Control Group

Mode of Delivery	Study Group (N=30)	Control Group (N=30)	p value
Normal Vaginal Delivery	27	26	0.839
Instrument Vaginal Delivery	2	2	
Caesarean Delivery	1	2	

Table 5: Foetal Outcome in Study and Control Group

Foetal Outcome	Study Group (N=30)	Control Group (N=30)	p value
Non reassuring foetal heart rate Number (%)	3 (10%)	4 (13%)	0.688
Meconium stained Liquor Number (%)	2 (6.66%)	3 (1%)	0.618
APGAR Score <7 at 5 minutes Number (%)	1 (3.33%)	6 (2%)	0.044
Mean weight (Kgs)	2.95	2.83	0.108

Discussion

In India traditional practice of ambulation in the first stage of labour is gradually declining due to shift towards institutional deliveries. The practice of institutional delivery significantly reduces the maternal and foetal morbidity and mortality. However, this improvement in maternal and fetal health is associated with increase in interventions during labour that are in the form of need for augmentation of labour and increased operative

deliveries.¹²⁻¹⁴ One factor that has been associated with more interventions required in low risk women is the position adopted during labour. Although women prefer adopting comfortable position during labour, it interferes with the monitoring of woman and the baby.

The present study was done at a tertiary care centre of North India to assess the effect of prolonged upright position (more than 60% of active first stage of labour) on labour outcome. Age, socioeconomic

status and employment status of women in both the groups was comparable, $p > 0.05$. The mean period of gestation of women in study and the control group was also comparable, 38.73 ± 0.980 and 38.70 ± 1.022 weeks respectively. The patients in study group adopted erect position for significantly longer duration of time in first stage of labour than the control group, 141.90 versus 46.67 minutes, $p < 0.001$, Table 1.

Significantly increased frequency of uterine contractions was observed in the study group during first 3 hours of active first stage of labour. In first 2 hours of active labour, the intensity of the contractions was significantly more in study group compared to the control group, $p = 0.022$. During third hour of active labour both groups had similar intensity of labour pains, Table 2. The first stage of labour was 52.07 minutes shorter in erect position as compared to supine position but this difference was not statistically significant ($p = 0.144$). The difference in mean duration of second stage of labour was also not statistically significant ($p = 0.291$), Table 3. Mode of delivery was comparable in both groups, $p = 0.839$, Table 4.

There was no statistically significant difference in incidence of meconium stained liquor and non reassuring foetal heart between both the groups, $p = 0.618$ and $p = 0.688$, respectively. A statistically significant difference in apgar score > 7 at 5 minutes was observed in the study group, $p = 0.044$, Table 5.

Upright position during first stage of labour has been reported to be associated with shorter duration of both first and second stage of labour.^{9,14-18} A systemic Cochrane review also reported shorter duration of the first stage of labour by one hour twenty-two minutes in women assuming upright posture during the first stage of labour as compared to recumbent position.¹⁰ Kumud Rana et al observed significant reduction in first stage of labour by 123.6 minutes in the erect position.¹³ However, our study did not report any significant difference in the duration of first stage of labour in women who assumed erect posture for an average 141.90 minutes in active first stage of labour as compared to 46.90 minutes in the control group. This difference could be attributed to the fact that women in the control group in our study were also allowed to ambulate as per their choice and most of the women assumed sitting position during contraction

and were lying in between contractions.

Previous studies reported that parturient who assumed upright positions had increased strength of uterine contractions compared to those assuming supine position in first stage of labour.^{5,10,13,19} We also found better intensity and frequency of uterine contractions in women who were in the erect position for longer duration during first stage of labour as compared to women in the control group.

More women in the control group required augmentation of labour with oxytocin but the difference was not statistically significant, $p = 0.166$, Table 3. Kumud, Bundsen and Chen also reported that majority of the women with upright position during first stage of labour did not require acceleration of labour as compared to the women in supine position group.^{13,20,21}

In Our study there was no significant difference in mode of delivery between the two groups. Most of the women had normal vaginal delivery. However, we expected a higher normal vaginal delivery rate in the study group as labour was hypothesised to be shorter with lesser incidence of exhausted women and instrumental deliveries. This could be explained by difference in the control group as women in our control group were also allowed to assume position of their choice rather than assume recumbent position. These findings are in contrast to Gizzo et al who observed normal vaginal delivery, operative vaginal delivery and caesarean delivery in 47.8% Vs 87.1%, 26.1% Vs 7.1% and 26.1% Vs 5.8% women in the recumbent group and group with sitting upright or squatting position, respectively.⁹ Kumud et al also found that 100% of women with upright position in the first stage of labour had normal vaginal delivery while in the supine position 26.7% women had instrumental delivery.¹³ However Cochrane review 2013, Mc Manus et al, Bloom et al and Savitha et al reported no difference in the mode of delivery with change of position in first stage of labour.^{10,22-24}

Present study found statistically significant ($p < 0.005$) number of babies with 5 minutes apgar score more than 7 in the study group as compared to the control group. Emam et al also reported improvement in Apgar score with upright posture in first stage of labour.¹⁴ However, Gizzo S et al and Lawrence et al found no significant difference in the Apgar score of neonates in

erect position.^{9,10}

Conclusion

The frequency and intensity of the uterine contractions in low risk term nulliparous women is significantly more if upright position was assumed for more than 60% duration of the first stage of labour without any impact on duration of first and second stage of labour and need for labour augmentation. There was significant improvement in the Agar score at 5 minutes if mother spent more than 60% time in erect position during first stage of labour.

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Psychological Problems Becoming Viral due to the Virus – Current Scenario in India

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Abstract

Background: Psychological health is a neglected health issue globally. Bereavement, isolation, loss of income and fear are triggering factors for disrupting mental well-being during COVID 19 pandemic.

Aim: To assess impact of COVID 19 pandemic on psychological health status of general population in India.

Methods: A descriptive study was conducted using questionnaire prepared through Google forms. A non-probability snowball sampling was used.

Results: We received 2131 responses of which, 42.3% of the population were frustrated due to the pandemic. 27.8% of the participants had negative and suicidal thoughts. 64.1% of the participants were frustrated due to social isolation from colleagues and peers. 44.4% of the participants feared job insecurity. Majority of the males and females (58.8% and 53.3%) were going to work against their will. 43.5% in the age group of 18-30 years were more frustrated. 58.6% of healthcare workers were separated from their loved ones and 60.1% suffered from anorexia nervosa. 56.2% of the total participants did nothing specific to combat frustration. 78% of the stressed respondents opined that stress-relief programs, online psychological health counseling is need of the hour in the pandemic period.

Conclusion: COVID 19 pandemic has led to panic and anxiety amongst the public globally and affected them psychologically. Government aided online psychological health counseling programs, motivational and awareness programs would prove to be reliable tools to combat psychological health problems in general public.

Key words: Psychological health, COVID 19, Anxiety, General public, India

Introduction

For many people, the lack of social interaction caused by the pandemic has had a profound effect on their mental health - Tedros Adhanom

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The outbreak of novel corona virus (COVID 19) in Wuhan, China was recognized by the World Health Organization (WHO) as a Public Health Emergency of International Concern (PHEIC) which risks the international public health.¹ COVID 19 is a highly contagious disease. India witnessed its first case of Novel Corona virus on January 30th 2020 in Kerala. The number of cases escalated during March, all over the country, most of which were linked to people with a travel history to affected countries.^{2,3} COVID 19 accounts for 8636011 infected cases and 127571 deaths till date in India and is still increasing and so is the fear of second wave.⁴

To control the spread of this pandemic, the government of India announced a countrywide Janata Curfew to break the transmission chain for slowing down the spread of COVID 19.^{5,6} Man being a social being, these isolation and quarantine measures led to various psychological health issues like stress and depression, unknown fear, anxiety, hatred and stigma among the population.^{6,7} Majority of the crowd was working from home which was challenging.⁸ A few had no technological knowledge and access to internet which contributed to the existing stress. Fueling to this anxiety was exposure to lot of myths and fake news from the social media. Section 66 A – Information Technology Act of 2000 was imposed by the Indian government to curb spread of fake news which had increased tension amongst the general public. World health organization was constantly providing the general public with authentic information.⁹ In spite of all measures taken, social isolation led to major psychosocial impact on economic, emotional and financial crisis.¹⁰

Systematic reviews were conducted by Pappa S et al 2020 and Xiong J et al 2020 to assess psychological status of Healthcare workers and general population respectively.^{11,12} High levels of distress, anxiety, depression were perceived in both the groups. Both the reviews lack the mental health scenario in Indian population. Hence this unique study was conducted with an aim to assess the impact of pandemic or quarantine periods on psychological health status of general public of India with the following objectives:

- 1) To assess knowledge, attitude and practices regarding COVID 19 Pandemic among the general public of India.
- 2) To assess association between socio-demographic factors like age, gender and profession and psychological status.

A self -designed questionnaire based on Beck Depression Inventory – II (BDI - II) questionnaire was employed to assess the psychological health status during social distancing and pandemic periods.^{13,14}

Materials and Methods

A descriptive cross-sectional study was carried out in the time period from 10th April to 20th September

2020. This study adapted the Snowball sampling technique to circulate online questionnaire in the form of Google form. The link of the questionnaire was sent through various social groups, social networks such as Whatsapp, Facebook, Messenger, Gmail, Twitter, LinkedIn, Outlook and Telegram. The participants were requested to roll out the questionnaire link to as many people as possible.

The 24-itemed, self-designed questionnaire was developed based on information on COVID 19 and its prevention from various factsheets, course materials, information leaflets and booklets developed by Centre for Disease Control and Prevention (CDC), National Health Service (NHS), WHO and Beck Depression Inventory – II (BDI - II) questionnaire.¹³⁻¹⁷ It comprised of total 8 questions assessing knowledge, attitude and practice component and total 16 questions assessing psychological status in the wake of COVID 19 Pandemic.

Pilot study was done on 15 participants to assess the flaw, feasibility and reliability of the questionnaire was assessed using Cronbach's α and was found to be 0.85. Validity of the questionnaire was done using face off validity which was found to be 0.84 % and content validity ratio was found to be 0.78.

The data collection was initiated on 10th April 2020 at 4 PM IST and closed on 20th September 2020 at 4 PM IST. Data was collected from various states of India. Descriptive statistics and chi square test have been employed in the study to analyze the findings.

Results

From the online survey a total of 2131 responses were recorded. The lowest education level was observed to be 12th pass and the highest were Post-graduates. The age groups of the respondents ranged from 18 to 65 years old and the major proportion (41.9%) belonged to 18 – 30 years age group. Among the participants, 42.5% were males and 57.5% were females. All the participants were of Indian origin and were from 20 states or union territories of the country with maximum participants from Goa, Karnataka, and Maharashtra. Majority of the participants were upper class and upper middle class. In the present study various social, personal, political aspects of participants are focused upon which may

have an impact on the psychological health status of an individual.

General information based upon knowledge, attitude and practice component:

Approximately all of the participants (95.6) were aware that COVID 19 is a pandemic (Table 1) 68.2 % of the respondents were at home, while 31.8 % of the respondents had to go for work or work from home. About 54.1% of the respondents stated their work does not come under essential services whereas 56.6% stated that they go to work against their will. (Table 1)

Psychological effect:

Around 42.3% of the participants were frustrated at home. Around 38.0 % of the participants were separated from their family, 30.5% of the people were agitated more than usual, and 22.5% of the participants stated that they were so restless that they had to keep moving or doing something. (Table 2)

32.6% reported they sleep more than usual, 21.1% reported that they sleep a lot more than before and 19.4% of the participants stated that they sleep less than usual. When asked about appetite, 21.5% declared that they had less appetite than before while 29.3 % of the participants had increased appetite than before. (Table 2)

Digging up on any negative or suicidal thoughts, 11.1% reported yes, while 16.7% reported they sometimes do have such thoughts. 64.1% stated that they miss their peers, colleagues and family. (Table 2)

43.6% of the participants strongly feared, 42.1% moderately feared while 14.3 % did not fear economic crises. 44.4% of the participants were of the opinion that they would probably lose their job due to crisis. (Table 2)

The cause of the frustration was 50.7% due to inability to go out, 20.2 % due to difficulty in maintaining social distancing everywhere, 9.8 % due to increased workload at office and schools while 19.3% were frustrated due to difficulty in working and learning from home. (Table 2)

Relief measures:

About 78.0 % of the respondents were of the opinion

that stress relief programs, online psychological health counseling should be employed in the pandemic period. Upon asking various methods to de-stress at home, 5 % of the participants reported they shout and quarrel with others, 12.4 % talk to themselves, 26.4% indulged in meditation and yoga while 56.2 % of the participants do nothing specific to combat frustration. Various methods that participants used to amuse themselves during this period were also recorded. 32.6% invested their time browsing internet, while 35.5% of the participants were nurturing their hobbies to remain positive and happy during the pandemic. (Table 2)

Association of gender, age, profession with psychological status of the participants:

It can be noticed that more of the male participants (74%) were not going to work in the wake of COVID 19 Pandemic. 59.3% of the male population did not do anything specific to deal with stress. 13.4% of Males and 11.1 % of females had suicidal thoughts while 13.1% of males and 22.2% of females revealed that they sometimes do get negative and suicidal thoughts. 41.6% of the male and 46.7% of the female population feared economic crises during the Pandemic. 42% of male and 48% of female population had fear of losing their job. 48.9% of males and 53.6% of females were frustrated due to inability to go out like before due to the stern measures adopted by the government. (Table 3)

About 43.5%, 42.2% and 14.3% of the population in the age group of 18-30 years, 31-50 years and above 50 years respectively were frustrated at home during COVID 19 Pandemic. Changes in sleeping trends were observed in all three age groups where 18-30 age group was the most affected. (p value = 0.008). 48.2% of the participants from this age group were sleep deprived while 46.3% of the participants observed increased sleeping hours. Maximum participants (46.8%) from 18-30 years of age expressed their willingness to meet family, colleagues and friends. 44.8%, 40.7% and 14.5% of population from 18-30, 31-50 and above 50 feared job insecurity. (Table 4)

52.3% of healthcare workers (HCW) and 47.7% of Non- healthcare workers (NHCW) served the nation by working during rough times of the pandemic. Most of HCW (49.7%) and NHCW (50.3%) did nothing specific to relieve their frustration. 58.6% of HCW and 41.4% of

NHCW were separated from their family due to COVID 19 Pandemic and social distancing norms. Increased frequency of crying was perceived in both the groups (p value = 0.003). 49.8% of HCW and 50.2% of NHCWs felt the urge of crying but could not cry. 60.1% of HWC revealed reduced appetite while 61.1% of NHCW craved for food all the time. 57.2% of NHCW and 42.8% of HCWs feared economic crises. (Table 5)

Options and suggestions:

There was one open ended question where the population projected their feeling of anxiety and fear in particular area which they were stressed about.

- Financial help for those people who work on daily wage basis.

They expressed their concerns by giving following suggestions.

- Sanitization of public places, strict social distancing, border sealing should be followed strictly.
- Strict actions against violation of any rules or harassment of medical staff and police.
- Penalizing customers and warning grocery outlet of fines for not obeying social distancing.

Table 1: Responses for the questionnaire based on Knowledge, attitude and practices component.

Type of question	Questions	Responses	Total Responses	%
Knowledge Q1	Are you aware of the COVID-19 pandemic spread worldwide?	Yes	2037	95.6%
		No	94	4.4%
Knowledge Q2	Are you aware of 21 days Lockdown declared by government	Yes	2065	96.9%
		No	66	3.1%
Knowledge Q3	Does your work come under essential service?	Yes	786	36.9%
		No	1153	54.1%
		Not sure	192	9%
Practice Q1	Are you going to work during lockdown period?	Yes	677	31.8%
		No	1454	68.2%
Practice Q2	Are you willingly going for your work?	Yes	924	43.4%
		No	1207	56.6%
Practice Q3	Did you participate in events like clapping to boost morals of health workers and lighting Diya to show solidarity?	Yes	1776	83.3%
		No	259	12.2%
		Not aware	96	4.5%
Attitude Q1	What was your view on this event?	Responsible leader	599	28.1%
		Was meaningful	313	14.7%
		Was waste of time	158	7.4%
		Showed unity	1061	49.8%

Attitude Q2	Would you like to have online health counselling programs or stress relief programs during pandemic?	Yes	1663	78%
		No	468	22%

Table 2: Responses of the participants based on psychological components.

Questions	Responses	Total Responses	%
Q1 Do you like spending time at home?	Yes	1286	60.3%
	No	255	12%
	Sometimes	590	27.7%
Q2 Are you getting frustrated at home?	Yes	901	42.3%
	No	1230	57.7%
Q3 How do you de-stress yourself if frustrated?	Nothing Specific	1197	56.2%
	Meditation	563	26.4%
	Shouting and getting angry	107	5.0%
	Talking to myself	264	12.4%
Q4 How do you amuse yourself at home?	Television	301	14.1%
	Sleeping	232	10.9%
	Phone calls	147	6.9%
	Surfing internet	695	32.6%
	Indulging in hobby	756	35.5%
Q5 Are you separated from your loved ones in this Lockdown Period?	Yes	809	38%
	No	1322	62%
Q6 Do you cry alone in the lockdown period	I don't cry	1193	56%
	I cry more than I used to	138	6.5%
	I cry over every single thing.	119	5.6%
	I feel like crying, but I cant	681	32%
Q7 Do you feel agitated in this lockdown period?	I am no more restless	1000	46.9%
	I feel more restless than before	651	30.5%
	I am so restless that I keep moving	480	22.5%
Q8 Do you have changes in your sleeping pattern?	I sleep a lot more than before	449	21.1%
	I sleep Less	413	19.4%
	I sleep somewhat more than usual	694	32.6%
	No changes	575	27%
Q9 Are you experiencing change in appetite?	Less than before	459	21.5%
	Greater than before	624	29.3%
	No appetite	40	1.9%
	Crave for food all the time	314	14.7%
	No change	694	32.6%
Q10 Do you get any negative/ suicidal thoughts	Yes	236	11.1%
	No	1539	72.2%
	Sometimes	356	16.7%
Q11 Do you miss your colleague, peers and want to meet them?	Yes	1367	64.1%
	No	291	13.7%
	Sometimes	473	22.2%
Q12 Are you afraid of economic crises?	I strongly fear	929	43.6%
	I Somewhat fear	898	42.1%
	I don't fear	304	14.3%
Q13 Do you feel that your job is in danger after lockdown?	Yes	946	44.4%
	No	1185	55.6%

Q14 What is most common thing that makes you frustrated	Inability to go out	1081	50.7%
	Difficulty in maintaining social distancing	430	20.2%
	Increased pressure from work	209	9.8%
	Work from home/ learning from home	411	19.3%

Table 3: Association between gender and mental health status/psychological impact due to COVID-19 pandemic

Question	Category	Male %	Female%	Total %	p-value
Going for Work during pandemic	Yes	25.8	41.1	31.8	0.000
	No	74.2	58.9	68.2	
	Total	100.0	100.0	100.0	
Work under essential service	Yes	33.6	42.0	36.9	0.000
	No	57.9	48.2	54.1	
	Not sure	8.5	9.8	9.0	
	Total	100.0	100.0	100.0	
Are you willingly going for your work?	Yes	41.2	46.7	43.4	0.012
	No	58.8	53.3	56.6	
	Total	100.0	100.0	100.0	
Participate in events like clapping, diya lighting to boost morals of health workers	Yes	87.9	76.3	83.3	0.000
	No	9.9	15.7	12.2	
	Not aware of such events	2.2	8.1	4.5	
	Total	100.0	100.0	100.0	
Would you like to have online health counselling programs or stress relief programs during pandemic?	Yes	81.9	71.9	78.0	0.000
	No	18.1	28.1	22.0	
	Total	100.0	100.0	100.0	
How do you de-stress yourself if frustrated?	Nothing Specific	59.3	51.3	56.2	0.000
	Meditation	24.8	29.0	26.4	
	Shouting and getting angry	3.8	6.9	5.0	
	Talking to myself	12.1	12.8	12.4	
	Total	100.0	100.0	100.0	
Do you get any negative/ suicidal thoughts	Yes	13.4	7.5	11.1	0.000
	No	73.4	70.4	72.2	
	Sometimes	13.1	22.2	16.7	
	Total	100.0	100.0	100.0	
Are you afraid of economic crises?	I strongly fear	41.6	46.7	43.6	0.000
	I Somewhat fear	46.0	36.1	42.1	
	I don't fear	12.5	17.1	14.3	
	Total	100.0	100.0	100.0	

Cont... Table 3: Association between gender and mental health status/psychological impact due to COVID-19 pandemic

Do you feel that your job is in danger after lockdown?	Yes	42.0	48.1	44.4	0.006
	No	58.0	51.9	55.6	
	Total	100.0	100.0	100.0	
What is most common thing that makes you frustrated	Inability to go out	48.9	53.6	50.7	0.000
	Difficulty in maintaining social distancing	24.0	14.2	20.2	
	Increased pressure from work	7.8	13.0	9.8	
	Work from home/ learning from home	19.4	19.2	19.3	
	Total	100.0	100.0	100.0	

Test applied – Chi-square, Significant $p < 0.05$

Table 4: Association between age and mental health status/psychological impact due to COVID-19 pandemic

Questions	Responses	18-30 years %	31-50 years %	> 50 years %	Total %	p-value
Are you getting frustrated at home?	Yes	43.5	42.2	14.3	100.0	0.008
	No	49.5	39.5	11.0	100.0	
	Total	47.0	40.6	12.4	100.0	
Do you have changes in your sleeping pattern?	I sleep a lot more than before	46.3	42.1	11.6	100.0	0.008
	I sleep Less	48.2	36.6	15.3	100.0	
	I sleep somewhat more than usual	49.0	37.5	13.5	100.0	
	No changes	44.2	46.3	9.6	100.0	
	Total	47.0	40.6	12.4	100.0	
Do you miss your colleague, peers and want to meet them?	Yes	46.8	41.1	12.1	100.0	0.026
	No	40.2	46.7	13.1	100.0	
	Sometimes	51.6	35.5	12.9	100.0	
	Total	47.0	40.6	12.4	100.0	

Cont... Table 4: Association between age and mental health status/psychological impact due to COVID-19 pandemic

Do you feel that your job is in danger after lockdown?	Yes	44.8	40.7	14.5	100.0	0.021
	No	48.7	40.6	10.7	100.0	
	Total	47.0	40.6	12.4	100.0	

Test applied – Chi-square, Significant p <0.05

Table 5: Association between profession and mental health status/psychological impact due to COVID-19 pandemic

Questions	Responses	HCW %	NHCW %	Total %	p-value
Are you going to work during lockdown period?	Yes	52.3	47.7	100.0	0.032
	No	47.3	52.7	100.0	
	Total	50.7	49.3	100.0	
How do you de-stress yourself if frustrated?	Nothing Specific	49.7	50.3	100.0	0.001
	Meditation	52.9	47.1	100.0	
	Shouting and getting angry	34.6	65.4	100.0	
	Talking to myself	57.2	42.8	100.0	
	Total	50.7	49.3	100.0	
Are you separated from your loved ones in this Lockdown Period	Yes	58.6	41.4	100.0	0.000
	No	45.9	54.1	100.0	
	Total	50.7	49.3	100.0	
Do you cry alone in the lockdown period	I don't cry	49.5	50.5	100.0	0.003
	I cry more than I used to	65.9	34.1	100.0	
	I cry over every single thing.	51.3	48.7	100.0	
	I feel like crying, but I cant	49.8	50.2	100.0	
	Total	50.7	49.3	100.0	
Are you experiencing change in appetite?	Less than before	60.1	39.9	100.0	0.000
	Greater than before	54.2	45.8	100.0	
	No appetite	52.5	47.5	100.0	
	Crave for food all the time	38.9	61.1	100.0	
	No change	46.7	53.3	100.0	
	Total	50.7	49.3	100.0	
Are you afraid of economic crises?	I strongly fear	42.8	57.2	100.0	0.000
	I somewhat fear	61.5	38.5	100.0	
	I don't fear	43.1	56.9	100.0	
	Total	50.7	49.3	100.0	

Test applied – Chi-square, Significant $p < 0.05$

Discussion

COVID 19 pandemic has led to panic and increased stress level amongst the general public. It has destroyed the wage earning opportunities of daily wage workers and to a great extent harmed the small scale industries due to fall in demand.

All the epidemics and pandemics possess unique features in terms of its outbreak, progression, spread and control measures. It is important to understand general public's awareness towards any pandemic so that appropriate actions could be taken to boost their knowledge in favor of control of disease.¹⁸

Majority of the participants in the present study were aware of the rapidly spreading pandemic and also rules imposed by the government body to prevent community transmission of the epidemic. A study conducted by Ilesanmi O et al during Ebola outbreak to evaluate the attitude, and perception of Ebola virus infection among secondary school children of Nigeria, reported that majority of the population had inadequate knowledge and carried a negative attitude towards the Ebola outbreak.¹⁹

When a larger population is affected by depression, fear and anxiety, people tend to be more aversive in nature. It can result in exhaustion of resources due to panic buying of groceries, medications, masks, sanitizers etc. Dietary modification, changes in lifestyle, changes in behavior are associated with anxiety. It can affect the psychological health status of an individual.

In our study, 94.6% reported changes in sleeping pattern, 53% were agitated and restless, 42.3% were frustrated, 67.4% experienced changes in appetite. (Table 2) These observations imply that majority of the population is dealing with lot of anxiety and stress. High anxiety levels among public were also seen in swine flu epidemic of 2009–2010, which was associated with high mortality globally.²⁰

Our study portrayed significant association between psychological status and socio demographic component like gender, profession and age. 74% of males were at home during lockdown. 87.6% males feared economic crises while 26.5% of the male population had negative

and suicidal tendencies. (Table 3) On the contrary, studies done by Ahmed et al., 2020; Gao et al., 2020; Lei et al., 2020 concluded that females were more vulnerable to develop the symptoms of various forms of mental disorders including depression and stress during the pandemic.²¹⁻²³ This may be attributed to the fact of being home bound without the regular work routine leads to remarkable rise in frustration and stress levels. This calls for initiation of online mental health counseling sessions and programs for uplifting mental health status which is easily accessible to the public.

Majority of psychological changes were perceived in 18-30 years age group. This age group represents young working group who would have just began their careers. Frustration levels were 43.5% in this age group. Major portion of this age group experienced drastic changes in sleeping pattern where 95.3% felt that they sleep more than before while 48.2% reported sleep deprivation. Greater portion of this age group (44.8%) also feared job insecurity. (Table 4) A study done in China by Huang and Zhao, 2020 also highlighted that individuals under 40 years old were associated with adverse psychological manifestations during the pandemic.²⁴

XXXIII. COVID-19 pandemic has significantly affected the psychological health of healthcare workers (HCWs) who are the frontline warriors of this crisis. Our study encompassed responses of around 52.3% of HCWs who were fighting the COVID 19 pandemic. Around 49.7% of HCWs did nothing specific to combat frustration. Around 58.6% of HCWs were separated from their family and loved ones. 49.8% of them felt the need of crying but they could not. Around 60.1 % of HCWs reported fall in their appetite. All these factors point to strong evidence of presence of depression, frustration and stress among HCWs. (Table 5) This may be due to strict norms of quarantine, self-isolation while treating the sick, lack of self-time, long patient monitoring hours while battling the pandemic. Our findings are similar to findings portrayed by Pappa S where prevalence of depression, anxiety among HCWs was high.¹¹

The present study also ascertained inclination of all the participants towards negative and suicidal thoughts. 27.8 % of the participants (Table 2) had negative thoughts and feelings which may be attributed to economic fallout and occupational deprivation. These

findings may ignite suicidal tendencies. Deena Dimple Dsouza et al delineated 69 cases of suicide associated with COVID 19 in India from March to May. These suicidal cases were linked to aftermath of COVID 19 pandemic such as phobia of acquiring infection, economic crises and distress.²⁸ However quite a lot of participants spent their time browsing internet. Surfing internet for longer hours in a day can have negative impact on psychological health and can trigger anxiety in participants.²⁶ Also it increases stress and fear when participants come across a lot of fake news and rumors which are being forwarded on social media.

In the present study, variations in anger, sleep, frustration, anxiety pattern were observed. Majority of the participants felt the need to have psychological health counseling and motivational programs. Maintaining psychological health status is as important as having COVID 19 free nation. Considering the present scenario of the pandemic, online free psychological health consultations approved by government authority would form the basis to attain a healthy stress free country.

Limitations

The study is limited to the participants who had access to various social media platforms. Majority of the participants were educated hence, the results cannot be generalized to the whole population of the country.

Conclusion

The Covid-19 pandemic has startled the entire world. It has alarming implications for people and overall health, psychological status and social functioning. There has been remarkable increase in fear, anxiety and worry among the general public towards COVID 19 pandemic. This calls for introduction of health awareness, motivational programs, government aided online psychological health counseling sessions to address psychological issues among general public and to promote their wellbeing.

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Conflict of Interest: Nil

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Skeletal Changes Accompanying Surgically Assisted Rapid Maxillary Expansion in Adults A Computed Tomography Evaluation

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Abstract

Background: Surgically assisted rapid maxillary expansion (SARPE) is a common procedure to correct maxillary transverse deficiency of >5mm in patients with closed midpalatal suture. The aim of this study was to three dimensionally analyze skeletal changes after SARPE.

Studydesign: Twelve adult patients (mean age 20 years) with a palatal transverse deficiency underwent SARPE. The surgical procedure consisted of a lateral osteotomy combined with an interradicular osteotomy between the roots of the upper central incisors. Measuring points were defined on the hard palate. Cone beam computerized tomography scans were performed preoperatively and 6-months postoperatively.

Results: Skeletal changes accompanying SARPE utilizing Hyrax appliance were analyzed.

Conclusions: Bilateral osteotomy combined with a sagittal osteotomy is a safe method of SARPE. The expansion was mostly achieved by maxillary expansion. The amount of dentoalveolar tipping was smaller than reported.

Key words: Cone beam computed tomography, CBCT, maxillary transverse deficiency, MTD, surgically assisted rapid maxillary expansion, SARPE.

Introduction

Surgically assisted rapid palatal expansion (SARPE) has become a widely used and acceptable means to expand the maxilla in adolescents and adult patients. The method has advantage of bone formation at the maxillary edges of the midline, while they are separated by an external force.⁽¹⁾

Maxillary transverse deficiency (MTD) is a dento-facial disturbance characterized by the presence of unilateral or bilateral posterior cross-bite, deep or high arched palate, anterior tooth crowding, dental tipping and difficult nasal breathing. The SARPE is a clinical therapeutic procedure used to correct this deficiency in

adult patient who have already completed ossification of the mid-palatal suture.⁽²⁾

Cone beam computerized tomography (CBCT) is a multi-planar imaging technique that allows visualization of slices as well as 3D reconstructions like medical CT scanning does, with a better resolution and a far lower ionizing radiation dose.⁽³⁾

Patients and Methods

Twelve adult patients (8 females and 4 males) having a MTD participated in this study. The patients attended the department of Oral and Maxillofacial Surgery for correcting their maxillary deficiency before undergoing

orthodontic treatment. The patient ages ranged from 16 to 29 years, with an average of 20 years. A pre-operative protocol including orthodontic photos, study models and CBCT was carried out for every patient.

Prior to surgery, a tooth-borne expander (*Hyrax appliance*) with a 13mm screw was prepared on the study model and cemented to the first maxillary premolars and first molars in all patients. The inclusion criteria for patient were: skeletally mature patients with a total bilateral transverse maxillary deficiency of more than 5 mm, without a history of trauma or any cranio-facial syndrome.

Surgical technique

SARME was carried out under general naso-endo-tracheal anaesthesia. The technique enclosed bilateral zygomatic buttress and mid-palatal osteotomies. The malar buttress osteotomy did not extend forward to the piriform aperture or posteriorly to the pterygo-maxillary fissure. It was about 2 cm in length and perpendicular to the outer surface of the bone. A fine osteotome was inserted into the midline of the maxillary alveolus and anterior nasal spine regions, through a small vertical incision at the midline, to separate the two maxillae. A finger was placed on the palate to protect the mucosa during separation of the palatal suture by gentle malleting of the osteotome. The surgical sites were irrigated copiously and sutured.

Expansion protocol

No expansion was attempted for 5 days postoperatively to facilitate patient comfort. There-after, all patients were instructed to turn the appliance a one-quarter turn (0.25 mm) twice daily, morning and evening (2 turns /day).

The expansion was finalized when an over-correction of 2 mm was achieved at the maxillary molar level on each side. Then, the appliance was secured in place for

3 months as a retainer. After 3 months, the appliance was replaced with a trans-palatal arch for an additional 3 months. Later on, patients underwent conventional orthodontic therapy.

Cone beam computed tomography

Using a cone beam computed tomography (A Scanora 3D, Soredex, Finland) was used to obtain all patient scans. The machine was set to capture axial and coronal images at the manufacturer's recommended settings of 15-mA and 85-kVp.

Every patient was scanned at two time intervals: T0 and T1. The first image (T0) was obtained prior to surgery. The second image (T1) was obtained immediately after removal of the trans-palatal arch at 6 months postoperatively.

I- Coronal measurements.

A- C-angle. It is the angle formed by intersection of two lines touching the inferior palatine margin of the alveolar process of the maxilla (C2) and the palatine process of the maxilla (Fig.1).

B- C1: It is measured at the level of the palatine process of maxilla (Fig.1).

C- C2: It is measured at the inferior palatine margin of the alveolar process of the maxilla.⁽⁴⁾

II- Axial measurements

A- A-angle

It is the angle formed by the intersection of two lines touching the greater palatine foramen and the greatest convexity of the medial wall of the maxillary sinus.

a-A1: It is a linear measurement at the level of the greatest convexity of the medial walls of maxillary sinus.

b-A2: It is the linear measurement at the greater palatine foramina.⁽⁴⁾

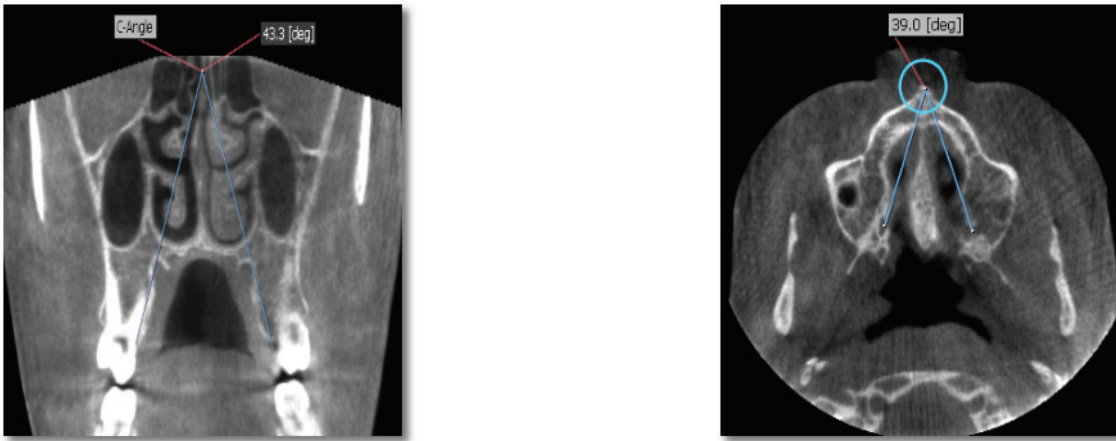


Figure 1: CBCT of axial and coronal cuts representing A&C angles respectively.

Table 1: The mean absolute and relative differences between preoperative and 6-months postoperative axial and coronal measurements.

Measurement (mm)	Preoperative	Postoperative	Mean of difference+SD	
			Absolute (mm or degree)	Relative (%)
A1	23 ± 2	27.6 ± 1.9	5 ± 1.8	20+8.6
A2	31 ± 2.1	32.5 ± 1.9	1.5 ± 0.7	4.8+2.5
C1	23 ± 2.1	27.8 ± 1.8	5 ± 1.6	21.8+8.6
C2	32.3 ± 3.1	38.9 ± 4.9	6.6 ± 5.4	23.2+17.1
A angle (degree)	39.7 ± 4.5	37.3 ± 4.3	-2.5 ± 1.1	-6.2+2.7
C angle (degree)	30.9 ± 8.1	37.0 ± 8.7	6.1 ± 2	20.8+7.9

Results

The measurements revealed that the greatest expansion occurred in the most inferior and anterior regions of the maxilla; where it was 6.60 + 5.4mm at C2 and 4.89 + 1.62mm at C1. Table (1) exhibits that, the means of absolute and relative maxillary expansion were higher at C2 than at C1, where they were 6.6+ 5.4mm(25.2+ 17.1%) and 5+ 1.6 mm (21.8 + 8.6%) respectively. This indicates tilting of the expanded segment outwards at C2 level. Also, the difference in maxillary expansion between C2 and C1 was 3.4 mm.

Table (1) exhibits that the means of the absolute and relative maxillary expansion at A1 (5+ 1.8mm, 20 + 8.6 %) were higher than at A2(1.5+ 0.7 mm, 4.8+ 2.5 %). This indicates tilting of the expanded segment outward at the A2 level. The difference in maxillary expansion between A1 and A2 was 3.5 mm (15.2%).

In addition, table (1) shows, also, that the means of the absolute and relative differences between preoperative and postoperative measurements of the C and A angles were 6.1+2°(20.8 +7.9%) and -2.5+ 1.1° (-6.2+ 2.7 %) respectively

The postoperative increase in the A angle and the decrease in the C angle indicate tilting of the expanded segment outward inferiorly and anteriorly in the coronal and axial images, respectively.

Discussion

SARME expansion provides a correction of maxillary transverse deficiency. The expansion device should separate the maxillary segments by a transverse distraction. SARME is advocated to overcome the fusion and resistance of the adult sutures to expansion.⁽⁵⁾

In skeletally mature individuals, the mid-palatal suture has fused and there is marked resistance to transverse expansion.⁽⁶⁾ The SARME is unavoidable where expansion of the maxilla is not possible orthopedically because of the patient's skeletal maturity.⁽⁷⁾

SARPE has been advocated in order to overcome the fusion of mid-palatal suture and resistance arising from the other maxillary articulations to expansion in the adult. The relative lack of complications, high effectiveness and the excellent stability are important reasons for considering this procedure.⁽⁴⁾

The bilateral zygomatic buttress and mid-palatal osteotomies are sufficient to achieve maxillary expansion in adults^(1,4), which is in agreement with Pogrel et al.⁽⁸⁾

The sagittal and skeletal displacement was greater posteriorly than anteriorly and this finding in accordance with similar studies on a tooth borne expansion device (Antilla et al 2004, Byloff and Mossaz 2004, Koudstall et al 2009 and Nada et al 2012).^{(1),(9),(10),(11)}

More skeletal displacements were found inferiorly than superiorly and more posteriorly than anteriorly. The superior landmarks in the maxilla were located at the zygomatic process and at the most lateral and inferior point of the nasal aperture and the anterior nasal spine. All these landmarks are validated and reliable for measurements in the maxilla (Moore-Jansen 1994 and Swennen et al 2006).^{(12),(13)}

Maxillary expansion at the midline was greater than that at the canines. Moreover, that greatest expansion had been occurred in the most inferior region of maxilla. This triangular pattern of maxillary expansion (the base

of this triangular at the dental level and the apex toward the nasal floor) might be due to anterior mid-palatal vertical osteotomy of maxilla during surgical operation.

The lateral outward tilting of the posterior bony segment of maxilla was significant. Byloff and Mossaz⁽²⁰⁰⁴⁾⁽⁹⁾ considered the "molar tipping" to be an undesirable dental side effects. In this study, the marked posterior tipping at the molars might be related mainly to the tipping of the whole posterior bony segment and to a lesser extent to tipping of teeth. Skeletal over-expansion would reduce the molar tipping which in agreement with Chung and Goldman (2003).⁽¹⁴⁾

As the greater palatine foramina are stable structures and unaffected by the surgical procedure, they are used for measuring the width changes in the posterior maxilla, being reproducible anatomical landmarks.

Conclusions

The study concluded that;

1. SARME is an extremely valuable operation that should be considered whenever maxillary expansion is needed with adults.
2. The relative lack of major complications and the excellent stability of the expanded two maxillary halves are significant reasons for considering this procedure.
3. During the activation phase for maxillary expansion, a mild diastema was observed that is decreased gradually till closure about two months.
4. A retention period of 6 months is recommended in SARME to allow consolidation of the expanded maxillary two halves by the new bone formation.

Conflict of Interest: Nil.

Source of Funding: Self.

Ethical Clearance: Department of Oral and Maxillofacial Surgery (by department's management board) followed by a second approval of board committee of the Faculty of Oral and Dental Medicine, Cairo University, Cairo, Egypt.

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Cephalo Facial Anatomy of the Simte Tribe of Manipur

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Abstract

Background: Present study aims at documenting a database of the cephalometric anatomical features of the Simte tribe of Manipur on one hand and comparing these features with the available data of other population of Manipur on the other.

Materials and Methods: A total of randomly recruited 300 subjects (123 males and 167 females) were subjected to analysis of six cephalometric measurements and three derived indices using appropriate statistical analysis.

Results: The findings of the study reveals that maximum head length falls within the ranges of ≥ 19.4 cm for males and ≥ 18.5 cm for females. Both the sexes have maximum head breadth and bizygomatic breadth falling under the category of medium category. Males have low morphological facial length in contrast to medium among the females. As regards nasal characters are concerned, Simte males have medium breadth while females have below medium breadth. However, both males and females have above medium length nose. Simte population of both sexes possesses Mesocephalic head; Mesoprosopic face and Mesorhinae nose. A comparative study with regards to indices, all the communities show similarity to the Simte except the Tangkhul on CI (Brachycephalic) and FI (Mesoprosopic) among males. Among females, all the constant measurements fall similar to the Simte people.

On inter community comparison, greatest statistical significant difference is observed within the inter-group Koirao-Purum and Kwatha-Purum, respectively. Highest similarity is observed between the pair Koirao-Kwatha whereas among the females highest similarity is displayed between Simte-Koirao (83.33%).

Conclusion: In all cephalometric measurements, the male populations have higher values compared to the female counterpart, which is the universal phenomenon of sexual dimorphism. In somatometric measurements and indices among the Simte, majority classification falls on medium and similar categories respectively. Significant variations are observed when compared between inter-groups. In both the sexes, statistical significant differences outnumbered over similarities.

Keywords: *Simte, Churachandpur District, Indices, Somatometry, Cephalometry*

Introduction

One of the basic objectives of somatometry-systematic metrical study of human body is to

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understand and examine the bodily dimensions of different populations. This type of study on the Indian populations started as early as in the early part of the 19th Century^{1,2,3}. The main emphasis on these studies was to classify the people of India into various 'racial types'. They recognised the existence of more than one 'racial type' and a great deal of anthropometric heterogeneity among the people across India. Later, several surveys and some of the exemplified works on the study of the

anthropometric variation were postulated from different populations of India. Majumdar and Sen (1949) worked among the people of Gujarat, followed by the population of Uttar Pradesh⁴, Karve and Dandekar (1951) among Maharashtra⁵, Majumder and Rao (1960) among Bengalese⁶, Malhotra et al.,(1981) among the people of in Tamil Nadu⁷ and among many others. Besides these, a good number of other studies are available numbering to about 1200 population groups reported by different authors listed by Bhasin, Walter and Danker-Hopfe (1992)⁸.

However, in Manipur only few scholars worked on anthropometric variations since the later part of the 20th century. Singh (1978) pioneered such a type of study among three valley population groups viz. Meitei, Ando and Khangabok and calculated genetic distance among them⁹. Later it was in the year that Singh (1986)¹⁰ examined the anthropometric variation between the hill Kabui tribe and their valley counterparts suggesting a microevolutionary trend because of environmental factors. Shah (1990) compared three different Muslim population groups of Manipur and reported a low degree of variation among them¹¹. Singh (1991) studied among the Meitei of Manipur and Assam focusing their differences in geographical and socio-cultural elements that ultimately demands biological variations between the two groups with a common ancestor, leading to the process of micro-evolution¹². Further, Devi (2002) worked on the morpho-genetical study of Kwatha Meite population settling in Chandel district of Manipur¹³. In the same year, Singh (2002) worked on the demography, culture and bio-anthropology of Kom tribe¹⁴. In an attempt to examine the micro-evolutionary trend Vokendro (2005) studied the anthro-po-genetics of the Purum tribe of Manipur from a diachronic approach¹⁵. Also, Singh (2008) and Kiranbala (2010) worked on Koirao¹⁶ and Tangkhul tribe¹⁷, respectively. Exhaustive study on secular trend on anatomical features of head¹⁸, face¹⁹ and nose²⁰ of the Meitei males of Manipur valley from a diachronic approach was carried out by Devi (2020)²¹ wherein she exclusively reported a secular trend in the cephalo-facial anatomy.

Though literature and database on cephalometric anatomy of few selected community as mentioned above are available, many of the communities still remain as virgin with regards to this aspect. Among the so many

untouched communities, Simte Tribe of Manipur is one. Keeping this in view, the present study is being attempted. Simte is one of the prominent tribe in the state of Manipur-a state strategically located in the north-eastern part of India. Simte people are concentrated in the southern part, i.e. Churachandpur District than elsewhere of the state Manipur. Etymologically, the term "Simte" is a combination of two words, 'Sim' which means South and 'te' the suffix to denote 'people'. Therefore, the term Simte implies the 'southerner or those who come from the south' (Lianzira, 2008)²². The origin of the term 'Simte' is little-known in oral tradition. It is said to be applied to them by others after they settled in Manipur since there was no reference found regarding the use of the word or term previously (Leivang, 2001)²³. They become recognised as one tribe among the Scheduled Tribes of Indian Union under the central Government of India, Order No. 1956 Vide SRO-24774 Gazetteer of India, Part-II Section-III, No.-316/A, and New Delhi, India and under the Indian constitution Article 330-342. According to the 2011 census²⁴, the total population is only 6728 individuals, and their language becomes endanger as the speaker falls below 10,000 individuals. Due to such reasons and the absence of literature demands for undertaking an immediate, exhaustive study of this population. However, covering the total aspect of anthropometric dimensions will be too extensive and beyond the purview of this journal, hence emphasis is given only to six cephalometric dimensions and three relevant indices. The most important body part that epitomises personal identification of individuals is head and face. Also, being an anatomical entity that arouses through biological processes during evolution and its structure is regulated by the same embryological, anatomical, physiological mechanisms that form all other parts of the body. The present study aims to know the natural constitution of the cephalometric anatomy of both the sexes of the Simte tribe. Also, the findings of the present study are being compared with the findings of the earlier workers who worked on different populations of Manipur.

Material and Method

A total of 300 unrelated individuals comprising of 123 males and 167 females constitute the sample size. The measurements were taken following the technique recommended by Martin²⁵ (as cited by Singh and

Bhasin, 2004). As far as possible, great care was taken to avoid instrumental, personal and parallax error in order to record accurate reading. The recording of data of all the measurements was made in centimeter. An

analysis is made according to Lebzetter and Seller. The name, abbreviation and landmarks of the anthropometric parameters selected for the present study are as follows.

Measurement	Abbreviation	Landmark
Maximum Head Length - straight distance between Glabella and Opisthocranion	MHL	Glabella (g)– prominent point in between two eyebrows just above the nasal root in mid sagittal line Opisthocranion(op) – most posterior point on the head in mid sagittal plane
Maximum Head Breadth – straight distance between Euryon to Euryon	MHB	Euryon (eu) - most lateral point on the lateral prominence of parietal bone
Morphological Facial Height - straight vertical distance between nasion and gnathion	MFH	Nasion (n) – the point on the root of the nose where it intersects with the mid- sagittal plane
Breadth of Bizygomatic Arch - straight horizontal distance between two zygia points.	BBA	Zygion (zy) – most lateral point on the lateral prominence of xygomatic process
Nasal Length - measured from nasion to subnasal	NL	Nasion (n) – the point on the root of the nose where it intersects with the mid- sagittal plane, Subnasal (sn) – the point at which the nasal septum merges with the upper cutaneous lip in the mid-sagittal plane.

Nasal Breadth - Straight horizontal distance between alare to alare

NB

Alare (al) – the point at the most laterally prominent point on the nasal wing

Based on the six measurements, the following four relevant indices were calculated.

1. Cephalic Index : $\frac{\text{Maximum Head Breadth}}{\text{Maximum Head Length}} \times 100$
2. Morphological Facial Height = $\frac{\text{Morphological Facial Height}}{\text{Breadth of Bizygomatic Arch}} \times 100$
3. Nasal Index = $\frac{\text{Nasal Breadth}}{\text{Nasal Length}} \times 100$

Results and Discussion

Based on the statistical analysis of the data on somatometric measurements (table 1), it is observed that the maximum head length falls within the ranges of ≥ 19.4 cm among males and $18.5 \geq$ cm among females. The maximum head breadth falls in the category of medium for males but broad for females. Both the sexes fall on

the ranges 12.1-13.0 cm in head height with very low percentages of 30.66 % males and 34.97% females. Males have low morphological facial length whereas females have medium. The parameter of Breadth of Bizygomatic arch shows medium category in both sexes. The nasal measurement of both the length and breadth is done according to Schlaginhaufen. The inference is

medium in case of males but below medium among females on the parameter of nasal length. However, the Simte has a broad nose as the inference of the nasal breadth is above medium in both the sexes.

Table-1: Cephalo-facial Dimensions of Simte Tribe of Manipur showing only the Highest Frequency Percent distribution

Parameters	Sex	Ranges (cm)	f	%	Inferences
Somatometric Measurements					
MHL	M	19.4-X	60/137	43.8	Very Long
	F	18.5-X	74/163	45.4	Very long
MHB	M	14.8-15.5	64/137	46.72	Medium
	F	15.0-15.7	73/163	44.79	Broad
MFH	M	11.2-11.7	64/137	46.72	Low
	F	10.8-11.3	58/163	35.58	Medium
BBA	M	13.6-14.3	96/137	70.07	Medium
	F	12.8-13.5	102/163	62.58	Medium
NL	M	5.0-5.4	83/137	60.58	Medium
	F	4.5-4.9	73/163	44.79	Below Medium
NB	M	3.5-3.9	87/137	63.50	Above Medium
	F	3.5-3.9	94/163	57.67	Above medium
Somatometric Indices					
Cephalic Index	M	76.0-80.9	61/137	44.53	Mesocephalic
	F	77.0-81.9	67/163	41.10	Mesocephalic
Morphological Facial Index	M	X-78.9	61/137	44.53	Hypereuryprospic
	F	81-84.9	50/163	30.67	Mesoprosopic
Nasal Index	M	70-84.9	96/137	70.07	Mesorrhinae
	F	70-84.9	100/163	61.35	Mesorrhinae

The statistical constant of three selected indices (table 1) to study head and face are calculated and classified based the conventional categories of Martin and Saller. Simte population possesses all type of head forms. High incidence of ‘mesocephalic’ head form is

observed in both sexes. It comprises 44.53% for males and 41.10% females. For Morphological facial index, males fall within the category of Hypereuryprospic and females in Mesoprosopic. The nasal index is in the middle ranges which is Mesorrhinae in both males and females

Comparative study:

Comparison of the mean values of cephalo-facial measurements and indices of the available populations of Manipur are presented in table-2. The findings reveal that among the males, highest mean values of maximum head length is observed among the Simte (19.1±0.11cm) followed by Koirao (18.64±0.03 cm), Purum (18.45±0.04cm) Tangkhul (18.39±0.08 cm) and Kwatha (18.32±0.10 cm) being the least. Among the females too Simte tribe possess the highest maximum head length (18.33±0.08cm) followed by Koirao (17.87±0.04 cm) and then Kwatha Meitei (17.71±0.09 cm). Similarly, the highest mean value of maximum head breadth is also observed among the Simte (15.33±0.07cm for males and 14.79±0.06 cm for females). Whereas the least mean are among the Kwatha Meitei for males (14.61±0.20 cm) and Koirao for females (14.25±0.03 cm). As for morphological facial length, Koirao tribe has highest mean value of 11.41±0.03 cm for males and 10.56±0.07cm for females and Simte tribe has the least for both the sexes i.e. 11±0.07cm for males and 10.54±0.05 cm for females. As regard Breadth of the Bizygomatic arch, Koirao (14.01±0.03cm) and Tangkhul (14.02±0.06cm) males have almost similar

mean values. The difference is only 0.1 cm. Interestingly, Kwatha and Purum males share the same mean value, of 13.66±0.14cm. Females mean distribution trend goes from highest to lowest among Koirao (13.31±0.03 cm), Kwatha (13.31±0.03 cm) and Simte (13.01±0.04 cm). The Tangkhul males have the highest nasal length (5.22±0.04 cm) and narrowest nasal breadth (3.66±0.03 cm) compared to other populations. Others populations have more or less similar mean distribution. In both the sexes, Koirao has the highest mean values in nasal breadth among males with a mean value of (4.99±0.02 cm for males and 3.49±0.01 cm for females

With regards to indices (table 2) among males, Length breadth index of the head or cephalic index that Tangkhul (81.46±0.63) shows the highest mean value while Kwatha (78.60±0.59) the lowest. Most of the populations subjected to study are 'mesocephalic' except Tangkhul who are 'brachycephalic'. With regards to Morphological Facial Index, the mean facial index shows that all are 'euryprosopic' suggesting broad face except Tangkhul who are 'mesoprosopic'. In respect to the nasal index, all populations under consideration show relatively medium type of nose i.e. 'mesorrhine'.

Table -2: Mean Values of different Cephalo-facial Dimensions of different Communities of Manipur

Parameters (in cm)	Sex	Simte (M-137; F-163)	Koirao (M-213; F-214)	Kwatha (M-58; F-58)	Purum (M-200)	Tangkhul (M-85)
Somatometric Measurements						
Maximum Head Length	M	19.1±0.11	18.64±0.03	18.32±0.10	18.45±0.04	18.39±0.08
	F	18.33±0.08	17.87±0.04	17.71±0.09	-	-
Maximum Head Breadth	M	15.33±0.07	14.79±0.03	14.61±0.20	14.69±0.04	15.02±0.08
	F	14.79±0.06	14.25±0.03	14.38±0.10	-	-
Morphological Facial Length	M	11±0.07	11.41±0.03	11.18±0.07	11.27±0.04	-
	F	10.54±0.05	10.73±0.03	10.56±0.07	-	-
Bizygomatic Breadth	M	13.8±0.06	14.01±0.03	13.66±0.14	13.66±0.04	14.02±0.06
	F	13.01±0.04	13.31±0.03	13.22±0.08	-	-
Nasal Length	M	3.66±0.03	3.77±0.01	3.76±0.03	3.69±0.02	5.22±0.04
	F	4.68±0.03	4.62±0.02	4.40±0.04	-	-
Nasal Breadth	M	4.94±0.03	4.99±0.02	4.82±0.05	4.67±0.03	3.66±0.03
	F	3.41±0.02	3.49±0.01	3.26±0.03	-	-

Cont... Table -2: Mean Values of different Cephalo-facial Dimensions of different Communities of Manipur

Somatometric Indices						
Cephalic Index	M	80.08±0.51	79.09±0.20	78.60±0.59	79.90±0.29	81.46±0.63
	F	81.11±0.44	79.85±0.23	80.24±0.59	-	-
Morphological Facial Index	M	79.81±0.56	81.23±0.24	83.05±0.92	82.65±0.36	84.38±0.52
	F	81.13±0.45	80.68±0.23	80.73±0.81	-	-
Nasal Index	M	73.99±0.54	75.50±0.39	76.64±1.08	79.54±0.60	70.74±0.85
	F	73.66±0.58	75.86±0.35	75.5±1.00	-	-
Sources		Esther Lalremkim (2015)	Singh, M. (2008)	Devi, R. (2002)	Vokendro, H. (2005)	Kiranbala, P (2010)

Among females, the cephalic index of all the three population falls under the class ‘mesocephalic’. Their mean values are 81.11±0.44 for Simte, 80.24±0.59 for Kwatha and 79.85±0.23 for Koirao. With regards to Morphological Facial Index, Simte (81.13±0.45) belong to ‘mesoprosopic’ while other two Koirao (80.68±0.23) and Kwatha (80.73±0.81) fall on ‘euryprosopic’ suggesting broad face. Similarly, the related nasal index of all three populations falls on ‘mesorrhinae’ which mean a relatively medium type of nose.

Test of Significant (t-test)

To ascertain the inter-group differences and similarities of the indices, t-test had been calculated from the mean value of cephalo-facial characters and their indices of the selected population. The calculated t-test values at 0.5% confidence interval of their respective degree of freedom are listed in table- 3 for cephalo-facial measurements and table- 4 for indices.

Table -3: Comparative study of Cephalo-matric mean distribution of different Communities using t-test

Popn	Sex	MHL	MHB	BBA	MFH	NH	NB	Total ‘+’	%
S-Ko	M	4.18*	6.75*	3*	5.13*	3.67*	1.67+	1	16.7
	F	5.11*	7.29*	6*	3.17*	1.5+	4*	1	16.7
S-Kw	M	4.88*	2.88*	0.93+	1.8+	2.5*	1.67+	3	50
	F	6.89*	3.15*	2.1*	0.22+	1.5+	3.75*	2	33.3
S-P	M	5.42*	7.1*	2*	3.38*	0.76+	6.75*	1	16.7
S-T	M	5.07*	2.82*	2.75*	-	31.2*	32*	0	0
Ko-Kw	M	2.91*	2.63*	2.19*	2.89*	0.33+	2.83*	1	16.7
	F	1.6+	0.81+	1.11+	1.89+	4.4*	7.67*	4	66.7
Ko-P	M	3.8*	2*	7*	2.8*	4*	8*	0	0
Ko-T	M	2.78*	2.56*	0.14+	-	36.25*	33.25*	1	16.7
Kw-P	M	0.59+	0.4+	-	1.13+	1.75+	3*	4	66.7
Kw-T	M	0.54+	1.86+	2.4*	-	29.2*	19.33*	2	33.3
P-T	M	0.67+	3.67*	5.14*	-	38.25*	25.25*	1	16.7

Key: - = Data not available; + = insignificant; * = significant

Abbreviations: S-Simte; Ko-Koirao; Kw-Kwatha; P-Purum; T-Tangkhul.

Abridge total:

Males: + = 14 (23.33%) ;*= 41 (68.33%); - =5 (8.33%)

Females: += 7 (38.89%) ;*= (61.11%); - =0 (0%)

The greatest statistical significant difference and similarity in selected head and face parameters is observed within the inter-group Koirao-Purum and Kwatha-Purum respectively. A quick glance of table-3 reveal that among males population, 68.33% of the inter group comparisons show significant difference in contrast

to 23.33% insignificant difference. However, 8.33 % of the parameters are not included due to non-availability of data. Similarly, among the females too statistically significant difference (61.11%) outnumbered the insignificant difference (38.89%). The highest degree of significant difference of males is observed among the pair Kwatha-Purum constitute 66.7% (4 out of 6 parameters) followed by Simte-Kwatha (50 %), Kwatha-Tangkhul (33.3%) and 16.7% each on Simte-Koirao, Simte-Purum, Koirao-Kwatha, Koirao-Tangkhul and Purum-Tangkhul. However, no statistical significance is observed among the group Simte-Tangkhul and Koirao-Purum. Among the females, with respect to inter-group comparison of indices, highest statistically significance is observed the inter-group of Koirao-Kwatha (66.7%), followed by the inter group Simte-Kwatha (33.3%) and Simte-Koirao (16.7%).

Table-4: Comparative study of mean distribution of different Cephalometric Indices using t-test

Indices	S-Ko		S-Kw		S-P	S-T	Ko-Kw		Ko-P	Ko-T	Kw-P	Kw-T	P-T
	M	F	M	F	M	M	M	F	M	M	M	M	M
CI	1.8+	2.52*	1.9+	1.18+	0.31+	1.7+	0.79+	0.62+	2.31*	3.59*	2*	3.33*	2.26*
MFI	2.33*	0.79+	3*	0.43+	4.23*	6.01*	1.92+	0.06+	3.3*	5.53*	0.4+	1.25+	1.63+
NI	2.25*	3.24*	2.19*	1.59+	6.85*	3.22*	0.99+	0.34+	5.61*	5.06*	2.34*	4.31*	8.46*
Total '+'	1	1	1	3	1	1	3	3	0	0	1	1	1
%	33.33	33.33	33.33	100	33.33	33.33	100	100	0.00	0.00	33.33	33.33	33.33

Key: - = Data not available; + = insignificant; * = significant

Abridge total:

Males: + =10 (33.33 %) ;* =20 (66.67%); - = 0 (0.00.%)

Females: + = 7 (77.78%); * = 2 (22.22%); - = 0 (0.00.%)

In the total mean distribution on three Cephalometric Indices on males, it is observed that statistical significant difference (66.67%) outnumber non-statistical difference (33.33%). Most statistical difference is seen in the population between Koirao-Purum and Koirao-Tangkhul (100% each). However, similarity (77.78%) outnumber difference (22.22%) among females. Statistical significant differences is found only among Simte-Koirao in MFI and NI.

Conclusion

It can be concluded that the present study will provide vital information and fill the gap of the literature of the Simte tribe of Manipur. Further, in all cephalo-facial measurements, the male populations have higher mean values compared to their female counterparts, which is the universal phenomenon of sexual dimorphism. The Simte falls in different range categories of somatometric parameters majority of which falling in medium range. One significant result is they have a large nose breadth as the inference of the nasal breadth is above medium category in both the sexes. The highest frequency distribution of indices of Simte population falls on Mesocephalic (CI); Hypereuryprospic (MFI) in males but females in Mesoprosopic (FI); and Mesorhinae (NI). A comparative study with regards to indices reveals that all the communities falls similar to the Simte except the Thankhuls who have CI (Brachycephalic) and FI (Mesoprosopic) among males. Among females, the indices inference is similar to the Simte. The closeness and similarity in Cephalo-facial measurements and indices may be due to factor influencing similar environmental condition and adaptation. Significant variations are observed when compared between inter-groups. Statistically significance difference outnumbered over similarity. It is believe that the variations observed are mainly as a result of exposure to different environmental conditions and not because of genetic factors. A quick glance on t-test reveal that male population ‘*’ (68.33% difference) outnumbered ‘+’ (23.33% similarities). Similarly, among the females too 61.11% of differences outnumbered the similarities (38.89%).

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Critical Review on Proposed Amendments to Food Safety and Standards Act 2006

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Abstract

Indian Food Safety and Standards Act 2006 (Act) came into force in the year 2011 and the Act is being amended further to bring animal feed into the ambit of Food Safety and also amending various sections of the Act and proposed to increase the penalties for not having license or registration under the Act. The present paper dwells only on the proposed definition of 'manufacturer' and also on the proposed penalties for not obtaining or renewing the License or Registration as per the provisions of the Act. The above amendments are examined from doctrinal research method and found that offences are not in compliances with the legal jurisprudence.

Key words :- Article 47 of constitution, FSSAI, Food Safety, Food Business Operator, License, Registration.

Introduction

Food is essential for mankind as it provides nutritional support to human beings; food contains essential nutrients like Vitamins, Fats, Carbohydrates, and Proteins etc. Food usually consists of either plant or animal origin. Food and mankind co-exists since the evolution of mankind on the planet.

Over the Centuries the process and procedures are developing for providing safe and wholesome food to the mankind. In India, the laws regulating the quality of food have been in force since 1899.

Article 47 of Indian Constitution, mandates the duty of the State to raise the level of nutrition and the standard of living and to improve public health.

Food industry mainly consists of milk and milk products, pulses, grains, fruits and vegetables, chocolates,

water, beverages, jams, bakery products, processed food, snacks, ready to cook and ready to eat foods etc., Food industry provides a vital intermediary between the Agriculture and manufacturer and consumers. Average food travels miles before it reaches your dining table. Sometimes it travels countries and continents also. It is expected that the food shall retain its quality and standards despite undergoing various stages like Storage, Transport and Distribution and finally reaching the shelves of retailers. In view of the importance of food in human life, the Government of India has legislated food laws from time to time. Article 47 enshrined in the Indian Constitution mandates the State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties. Until 1954 several states had their own food related laws. Thereafter Government of India had enacted central legislation called Prevention of Food Adulteration Act 1955, with an object to lay down the standards for food and rules for labelling and packaging. The Prevention of Food Adulteration Act 1955 was repealed in 2011 and the new law The Food Safety and Standards Act 2006 was enacted¹. Till the enactment of Food Safety and Standards Act 2006, multiplicity of laws like the Prevention of Food Adulteration Act, 1954 (37 of 1954), Fruit Products

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Order, 1955, the Meat food product Order, 1973, the Vegetable Oil Products (Control) Order, 1947, Edible Oils Packaging (Regulations) Order, 1998, the Solvent Extracted Oil, De-oiled Meal, and Edible Flour (Control) Order, 1967, the Milk and Milk Products Order, 1992, Essential Commodities Act, 1955 (10 of 1955) are in existence².

Food Safety and Standards Act 2006 came into force with effect from 5th August 2011 interalia prescribing the procedure for applying for license for manufacture and sale of food products and at the same time, regulate the quality of food in order to ensure that the food which is supplied to the consumers is safe and wholesome and also laying scientific based standards for the food. The Act also contains Rules and various Regulations like Food Safety & Standards – Licensing & Registarion of Food Business) 2011, Packaging and Labelling Regulations 2011, Food Products Standards and Food Additivites Regulation 211, Prohibitions and Restriction of Sales Regulations 2011, Containmants, Toxins & Residues Regulations 2011, Laboratory and Sample Analysis) Regulations, 201, Food Recall Procedure Regulations, 2017, Food Import Regulations, 2017, Health Supplements, Nutraceuticals, Food For Special Dietary Use, Food For Special Medical Purpose, Functional Food and Novel, Food Regulations 2016, Fortification of Foods Regulations 2018, Approval For Non-Specified Food and Food Ingredients) Regulations, 2017, Organic Foods Regulations, 2017, (Alcoholic Beverages) Regulations, 2018, (Advertising and Claims) Regulations, 2018 & Food Safety Auditing Regulations, 2018. In other words the regulations under the Act are covered the entire ecosystem of food business and its stake holders.

Proposed Amendments

Of late, Food Safety Authority of India has brought many regulations and also simplified the process of obtaining licenses and other compliances and became more interactive and communicative with all stakeholders. Further, any regulations proposed are being notified well in advance so that the Food Business Operators has sufficient time to get the infrastructure and material ready and equipped with the compliance. Now after 14 years from the drafting the current Food Law and after 9 years of operation of the Act, the Food Safety

Authority of India has proposed amendments to revamp some of the provision of the Food Safety and Standards Act 2006 (Act). Around 70 amendments are proposed to the Act which interalia includes bringing the animal feed into the ambit of the Act and enhances penalties, and proposing other changes by way of amending around 70 provisions of the Act.

Some of the highlights of the proposed amendment are not in line with the objectives of the Act or not in conformity with the just and equity and criminal jurisprudence. The manufacturers definition is widened and brought the Brand owner included in the definition of manufacturer, earlier manufacturer defined under Section 2(zd) of Food Safety and Standards Act 2006 as “as person engaged in the business of manufacturing any article of food for sale and includes any person who obtains such article from another person and packs and labels it for sale or only label it for such purpose” so manufacturers and repackers are covered under the earlier definition. Under the proposed amendments the “brand owner” is included in the definition of manufacturer.

Section 3(z) defines labels which covers “brand” any mark, picture or other descriptive matter printed, stamped or marked on food package. However, brand owner is not defined in the existing Act or proposed amendment.

In the recent times, the business of franchising or outsourcing of manufacturing activity has gained momentum and most brand owners (corporates) in order to leverage their brand goodwill and reputation and to reach larger geographies enter into various modes of franchising and/or outsource their business of manufacturing to another party, so that they can offer substantial efficiencies in some of their operations and focus on their core expertise. The world’s major food brands has set up their operation in India through franchise models, to name some of them as Yum Restaurants (KFC, Pizza Hut), Mc Donalds, Dominos, Sub-way and some brands are conducting business through their Indian entities but the brand is owned by a parent company situated outside the India like Pepsi, Coca Cola, Cadburys etc.,

The Franchise business has emerged for easy and rapid expansion of the business where the brand owner grant license to the franchisee or the 3rd party to

manufacture on behalf of the brand owner and carry out production/manufacture of the food products and these franchisees exercise all their diligence, expertise and capabilities independently in manufacture and packaging of the food products. The sourcing of raw materials will be carried out directly by the Franchisee or he receives the raw material from the brand owner. The Franchisee is responsible for storage and conversion of the food products and he employs the machinery and the labour to facilitate the conversion. So the production is carried out purely by the 3rd party manufacturer or franchisee independently without any control of the brand owner.

Before we further debate on the subject let's understand the duties and liabilities of the manufacturer under the existing Act.

Section 26 of the Act casts a duty on the every Food Business Operator (FBO) to ensure and satisfy the requirements under the Act in all stages of production, processing, import, distribution and sale within the businesses under his control.

As per the Section 27 of the Act the manufacturer shall be responsible if the product does not meet the requirements as mentioned in the regulations or the Act i.e., the manufacturer shall be responsible for Misbranding, Sub-standard and for Unsafe food.

Section 3 (zf) "misbranded food" means an article of food –

(A) if it is purported, or is represented to be, or is being (i) offered or promoted for sale with false, misleading or deceptive claims either;

(a) upon the label of the package, or

(b) through advertisement, or

(ii) sold by a name which belongs to another article of food; or

(iii) offered or promoted for sale under the name of a fictitious individual or company as the manufacturer or producer of the article as borne on the package or containing the article or the label on such package

Section 3 (zx) defines "Sub-standard" an article of food shall be deemed to be sub-standard if it does not meet the specified standards but not so as to render the

article of food unsafe

Section 3(zz) defines "unsafe food" means an article of food whose nature, substance or quality is so affected as to render it injurious to health :—

(i) by the article itself, or its package thereof, which is composed, whether wholly or in part, of poisonous or deleterious substance; or

(ii) by the article consisting, wholly or in part, of any filthy, putrid, rotten, decomposed or diseased animal substance or vegetable substance; or by virtue of its unhygienic processing or the presence in that article of any harmful substance; or

(iv) by the substitution of any inferior or cheaper substance whether wholly or in part; or

(v) by addition of a substance directly or as an ingredient which is not permitted; or

(vi) by the abstraction, wholly or in part, of any of its constituents; or

(vii) by the article being so coloured, flavoured or coated, powdered or polished, as to damage or conceal the article or to make it appear better or of greater value than it really is; or

(viii) by the presence of any colouring matter or preservatives other than that specified in respect thereof; or

(ix) by the article having been infected or infested with worms, weevils, or insects; or

(x) by virtue of its being prepared, packed or kept under insanitary conditions; or

(xi) by virtue of its being mis-branded or sub-standard or

food containing extraneous matter; or

(xii) by virtue of containing pesticides and other containments in excess quantities specified in the regulations.

After going through the above definitions the duties of manufacturer and the brand owner cannot be equated as most of the cases the brand owner and the

manufacturer cannot be the same entity or same person. Many of the brand owners enter some arrangement with the manufacturer and lend their name in lieu of some consideration and these brand owners does not exercise the control and supervision over the manufacturing process or they have no role whatsoever in the manufacturing, sometime the brand owner may provide the specifications or even provide the raw materials but does not have any say on the production or the process of manufacturing. Even in some cases the brand owner does not have any entity or existence in the Country.

As per Section 27 of Food Safety and Standards Act 2006 the liability of the manufacturers or packers, distributors and the seller (retailers) are clearly demarcated in the existing Act considering their roles and responsibilities. However, this difference will be mitigated if the proposed amendment is goes through and become an Act.

Legal Jurisprudence

Under criminal jurisprudence *No one is to be held criminally liable for an act of another*. One party is not liable to the others criminal act unless if he is party to the act or part of the offence as originator, conductor or conspirator. Criminal law tends to stay away from vicarious liability, the Constitution Bench of Supreme Court of India held that the essential constituent of the vicarious criminal liability contemplated shall be as per the Section 34 of IPC i.e. of common intention³. However, the liability under the Food Safety Act 2006 is *strict liability* and *mens rea* is totally eliminated under the food laws.

Honourable Supreme Court of India in the *Shah Ashu Jaiwant vs State Of Maharashtra*⁴ held that mens rea in the ordinary or usual sense of this term is not required for proving an offence defined by Section 7 of the Prevention of Food Adulteration Act, 1954 (under old Act). It is enough if an article of food manufactured for sale, or stored, or sold or distributed in contravention of any provision of the Act or of any rule made there under shall be suffice to cast the liability. Nevertheless, the prosecution has to prove, beyond reasonable doubt, that what was stored or sold was 'food' in violations of the Act, rules or regulations.

Further, the mental element with an intention to commit offence and accused's participation in one form or other qua the crime is not required.

Section 26 of the Act earmark the liability of the food business operator at all stages of food ecosystem under his control and relying on this provision of the law, the party who has no control on manufacture, distribution and sale of the food product is not liable for the any offence.

Licenses

The proposed amendments also involves enhancement of penalties for various offences including carrying out business without License. As per Section 31 (1) No person shall commence or carry on any food business except under a licence. A petty manufacturer who himself manufactures or sells any article of food or a petty retailer, hawker, itinerant vendor or a temporary stall holder or small scale or cottage or such other industries relating to food business or tiny food business operator shall register with themselves under the Act. Earlier the under Section 63 the penalty was Rs. 5.00 lakhs (5.8K USD) and imprisonment upto 6 months and now it is proposed to increase the fine to Rs. 25.00 lakhs (34K USD) instead of Rs. 5.00 lakhs (5.8K USD) and the corporal punishment i.e. imprisonment upto 6 months is deleted. Decriminalisation is a welcome move but increasing fine by 500% will severely impact the small traders who by any chance fails to make application or even fails to make renewal in time. As per FSSAI fact sheet as on 30/09/2020⁵ in India there are about 7.67 lakhs State Licenses issued and around 40,000 Central licenses issued. As per the industry estimate there are more than 12 million kirana & small grocery stores in India and most of these stores are in rural area ad tier 2 or 3 cities, which are offering food & grocery business services⁶ and in addition there are around 10 million small food and beverage outlets across India. As per Food Safety and Standards License Regulations 2011 the shops or establishments whose turnover is more than Rs. 12 lakhs per annum and less than Rs. 20.00 Crores will come under State Licenses and above Rs. 20.00 Crores or operating in more than two states will come under Central license.

The FBO with central licenses are equipped for doing the necessary renewals but State Licenses not fully equipped for renewal in time. As per the Section 31 if the renewal application shall be submitted before the expiry of the validity of the license then the license shall continue to be in force till any other order is passed. Further, as per regulation 2.1.7 of FSSRs. (Licensing & Registration of Food Business) Any application for the renewal of a registration or license shall be made not later than 30 days prior to the expiry date. If failed to apply before the expiry of validity period, then a late fee of Rs. 100/- per day, however but not beyond 30 days. If the food business operator not applied for renewal then he/she shall stop the business activities at the premises and under the proposed regulation it will be a criminal offence and also huge penalty will be levied.

As per the above statistics there are considerable numbers of small food business operators who are yet to apply for the license will be severely impacted if penalty of Rs. 25 lakhs is levied against them. Honourable Supreme Court in *Alister Anthoy Pareria Vs State of Maharashtra*⁷ held that *the prime objective of the criminal law is imposition of appropriate, adequate, just and proportionate sentence commensurate with the nature and gravity of crime and the manner in which crime is done*. The courts have evolved the twin objectives of sentencing i.e. deterrence and correction. Thus the crime and punishment has direct relation and influence and it is settled that punishment shall not be disproportionate.

Conclusion

The framers of the legislation are well thought and given due consideration to the situation and demarcated the liability under the Act. Section 26 states that food business operator shall be liable for any violation under his control. Similarly, Section 27 also separate the liability of Manufacturer, Distributor and Seller. But, if the definition of the manufacturer is amended and Brand owner is included in the definition then brand owners will be responsible and liable for the any non-compliances under the Act & regulations and the same is inconsistent with the object of Section 26 & 27 of the Act.

Further as ordered by Honourable Supreme Court of India has ordered the Central and State Government to create awareness about adulteration of milk and

shall inform the general public of the nature of risk to health and create awareness of Food Safety and Standards. They should also educate school children by conducting workshops and teaching them easy methods for detection of common adulterants in food, keeping in mind indigenous technological innovations⁸. Similarly, FSSAI shall conduct an awareness programme with all the stake holders of food ecosystem and especially to conduct a drive for street food business operators and instantly grant the Licenses upon complying the basic requirement and to provide time for any other compliance as per the regulations, otherwise, the proposed amendments will fails to achieve the object of the Act.

Ethical Clearance- The research conducted on doctrinal method on review of the existing and proposed law, hence ethical approval is not applicable.

Source of Funding - Nil

Self Conflict of Interest - - Nil

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Original Research Article

Effectiveness of Informational Booklet on Knowledge Regarding Low Cost Health Mix on Nutritional Status of Under Five Children with Malnutrition among Mothers of Selected Areas of Bagalkot

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Abstract

Childhood malnutrition is a major public health concern, as it is associated with significant short- and long-term morbidity and mortality. This study aims to assess the knowledge regarding low cost health mix on nutritional status of under five children and with malnutrition and effectiveness of information booklet. **Methodology:** An evaluative approach with pre-experimental one group pre-test post-test design was used for the study. A structured interview schedule was used to collect the data. The sample includes 50 mothers of under five children residing at selected areas of Bagalkot with help of convenient sampling technique. **Results:** The mean percentage of knowledge scores of the mothers of under five children in the pre-test was 31.84 % with mean and SD (15.92±1.66), whereas the mean percentage of knowledge scores in post-test was 44.48% with mean and SD (22.24±1.64). Significance of difference between the pre-test and post-test knowledge scores was found to be highly significant [t= 20.68, p<0.05]. There was a significant association found between pre-test knowledge scores of the mothers and socio demographic variables like age ($\chi^2=3.86$; $P<0.05$), place of residence ($\chi^2=3.92$; $P<0.05$), exposure to mass media ($\chi^2=9.92$; $P<0.05$) and knowledge of low cost health mix ($\chi^2=3.89$; $P<0.05$). **Conclusion:** The study proved that information booklet was effectiveness in improving the knowledge of mothers on low cost health mix on nutritional status of under five children.

Keywords: Effectiveness, Self Instructional Booklet, Knowledge, Low Cost Mix, Under five Children, Malnutrition.

Background of the Study

Food means not only proteins, fats, minerals, vitamins and other nutrients- but much more; it is part of security and civilization. Nations and civilization are linked together not only by ideas, but also by bread. Hunger and malnutrition are problems everywhere and have harassed mankind and threatened peace throughout history. It is no wonder that the growing incidence of hunger and malnutrition should have come to the forefront of international concern.¹

In India, gross malnutrition is said to kill around 5, 00,000 of our infants and children every year. This quite understandable in view of the fact that around three-fourth of our pediatric population is suffering from one or another nutritional deficiency. Around 25% of the pediatric beds are occupied by patients whose major problem is malnutrition.²

Children of families with lower socio-economic standing are faced with sub-optimal growth. While children in similar communities have shown to share similar levels of nutrition, child nutrition is also

differential from family to family depending on the mother's characteristic, household ethnicity and place of residence. It is expected that with improvements in socio-economic welfare, child nutrition will also improve.³

A supplementary food based on a blend of roasted wheat flour (30 parts), green gram flour (20 parts), groundnut (8 part) and sugar or jaggery (20 parts) has been developed by National Institute of Nutrition, Hyderabad. The food contains about 12.5 percent proteins. A daily supplement of 80g of the Hyderabad mix food (providing 300kcal and 10g of proteins) has been found to bring about significant improvement in the growth rate of pre-school children.⁴ Studies have also shown that the formula advised by the National Institute of Nutrition, Hyderabad specially prepared protein mixtures provide an increase of weight after 22 days to 3 weeks or little later.⁵

The researcher's clinical experience, it was that there was a high prevalence of malnutrition among under five children at Bagalkot and so low cost mix such as Hyderabad mix is assumed to be the cheap and best supplementary food in treating the malnutrition which is introduced by National Institute of nutrition at Hyderabad, hence to decided to evaluate the effectiveness of information booklet on knowledge regarding the low cost mix for under five children with malnutrition among their mothers at selected areas of Bagalkot.

XXXIV. Statement of the Problem:

“EFFECTIVENESS OF INFORMATIONAL BOOKLET ON KNOWLEDGE REGARDING LOW COST HEALTH MIX ON NUTRITIONAL STATUS OF UNDER FIVE CHILDREN WITH MALNUTRITION AMONG MOTHERS OF SELECTED AREAS OF BAGALKOT”.

Objective of the Study

1) To assess the knowledge regarding low cost health mix on nutritional status of under five children with malnutrition among mothers of selected areas of Bagalkot.

2) To evaluate the effectiveness of information booklet on knowledge regarding low cost health mix on nutritional status of under five children with malnutrition among mothers of selected areas of Bagalkot.

3) To find the association between pre test level of knowledge with selected socio-demographic variables.

Methodology

Research approach: An evaluative approach was used for the present study.

Research design: Pre-experimental one group pre-test, post-test design.

Variables under the Study:

Dependent Variable: Knowledge of mothers regarding low cost health mix on nutritional status of under five children.

Independent Variable: Information Booklet on knowledge of mothers regarding low cost health mix on nutritional status of under five children.

Socio-demographic Variables: age, place of residence, exposure to mass media, knowledge of low cost mix.

Setting of the Study: The present study was conducted at selected areas of Bagalkot.

Population: The population for this study was mothers of under five children at selected areas Bagalkot.

Sample size: The sample for the present study composed of 50 mothers of under five children.

Criteria for Selection of Sample:

Inclusive criteria: The study includes the mothers;

1. Who are willing to participate in study.
2. Who are having under five children.
3. Who all are able to co-operate during the study.

Exclusive criteria: The study excludes the mothers;

1. Who are not interested to participate in study.
2. Who are not present at the time of study.
3. Who are ill at the time of study and unable to provide data.

Sampling Technique: Convenient sampling technique.

Description of the final Tool: **The structured interview schedule was used for this study which consists of two parts:**

- PART I: Items related to socio-demographic data of mothers.

- PART II: Knowledge Questionnaire regarding low cost mix.

Scoring of the Items: The maximum obtainable scores were 30. To find out the association between the selected socio-demographic variables and knowledge scores, respondents are categorized in to five groups.

Category	Score
Adequate	21-30
Average	11 - 20
Inadequate	0 - 10

Data collection procedure: Pretest was administered on day one. Then information booklet was administered on the same day after one hour of pre-test. On the 8th day after the administration of information booklet the post test was conducted using the same interview schedule.

Plan of Data Analysis: The data obtained was analyzed in terms of achieving the objectives of the study using descriptive and inferential statistics.

Results

Part I: Level of pre-test knowledge of the mothers regarding low cost mix.

Table 1: Percentage wise distribution of study subjects according to levels of knowledge in pre test.

N=50

Level of knowledge	Range of scores	Number of respondents	Percentage (%)
Inadequate	0 - 10	00	00
Average	11 - 20	50	100
Adequate	21 - 30	00	00
Total	0-30	50	100

Assessment of the level of knowledge of the mothers reveals that all (100%) of the mothers had average knowledge.

Part II: Significance of the difference between the pre-test and post-test knowledge scores of the mothers.

Table 2: Significance of the difference between the pre-test and post-test knowledge scores of the mothers.

Knowledge area	Test	Mean	SD	Paired t-value
Low cost mix	Pre test	15.92	1.66	20.68*
	Post test	22.24	1.64	

*Significant (p<0.05)

Findings reveal that the difference between mean pre-test (15.92±1.66) and post-test (22.24±1.64) knowledge scores of mothers found to be statistically significant at 0.05 level of significance [t= 20.68, p<0.05].

Part III: Association between the pre-test knowledge scores of mothers of under five children regarding low cost mix and selected socio - demographic variables.

Table 3: Association between the pre-test knowledge scores of staff nurses regarding Blood components transfusion and its complications and selected socio - demographic variables.

Sl. No	Socio-demographic variables	Df	Chi-square value	Table value	Level of significance
1.	Age	1	3.86	3.84	P<0.05 S
2.	Place of residence	1	3.92	3.84	P<0.05 S
3.	Exposure to mass media	1	9.92	3.84	P<0.05 S
4.	Knowledge on low cost health mix	1	3.89	3.84	P<0.05 S

Df – Degree of freedom *Significant NS – Not significant

Findings of the study revealed that there is significant association found between pre-test knowledge scores of the mothers with selected socio demographic variables such as like age ($\chi^2=3.86$; $P<0.05$), place of residence ($\chi^2=3.92$; $P<0.05$), exposure to mass media ($\chi^2=9.92$; $P<0.05$) and knowledge of low cost health mix ($\chi^2=3.89$; $P<0.05$).

Discussion

The findings of the study were discussed according to the objectives which were stated. The present study has showed that the difference between mean pre-test (15.92±1.66) and post-test (22.24±1.64) knowledge scores of mothers found to be statistically significant at 0.05 level of significance [t= 20.68, p<0.05].

These findings were supported, by the study conducted to find the effectiveness of structured teaching program on knowledge regarding Hyderabad mix among 50 mothers of under five children Kalburgi, where the overall pretest mean knowledge score was 23.45(sd=5.76), post test mean score was (sd=6.48) with paired t-value of 49.57.⁶

Conclusion

From the present study it was found that information booklet was very self learning method. The investigator as a nurse felt the need that mothers of under five children should be educated regarding the use nutritional supplementation for the under five children in order prevent the morbidity and mortality among the under five children.

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Conflict of Interest: Author has no conflict of interest.

Ethical Clearance: Ethical clearance was obtained from Institutional Ethical Clearance Committee, BVVS Sajjalashree Institute of Nursing Sciences, Bagalkot.

Funding: Nil

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Comparative Evaluation of Apically Extruded Debris with Hyflex Edm, MTWO and Self Adjusting File Systems; An In –Vitro Study

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Abstract

Aim of the Study: To compare and evaluate the amount of apically extruded debris with Hyflex EDM, Mtwo, and the Self-Adjusting File systems.

Materials and Methods: Sixty single-rooted human mandibular teeth with straight canals were selected and access cavities were prepared. All the teeth were mounted in the Eppendorf tubes after obtaining the initial weight of the empty tubes. Samples were then divided into three groups (n=20) according to the rotary system used and instrumented with Hyflex EDM, Mtwo, and SAF respectively. After washing the root surface with 1mL distilled water, the tubes were incubated for the next 5 days at 70°C. Then, the dry weight of the debris was calculated. Results were analyzed using ANOVA and post hoc Tukey's test.

Results: All the groups showed debris extrusion. The difference between the amount of apically extruded debris among all the groups was statistically significant ($P < 0.001$) with SAF showing the least debris extrusion, while Mtwo showed maximum debris extrusion.

Conclusion: Compared to other file systems, the SAF showed the least amount of apical debris extrusion and Mtwo showed the highest amount of extruded debris.

Key words: apically extruded debris, Hyflex EDM, Mtwo, SAF.

Introduction

Root canal preparation is one of the foremost vital stages in endodontic treatment that comprises complete debridement of the root canal system using instrumentation and irrigation which aims at successful treatment with resultant periradicular healing¹. Intracanal irrigants and debris containing microorganisms, dentine chips, pulpal fragments, and necrotic tissue may be apically extruded through the apical foramen during canal preparation and may cause postoperative pain, inflammation, flare-ups, and short- or long-term failure^{2,3}. As the clinical symptoms are so intense, the patient requires an unscheduled visit for emergency treatment⁴.

Currently, all the preparation techniques and instruments extrude debris periapically even after maintaining the preparation short of the apical terminus, and engine-driven rotary preparation produces lesser extrusion when compared to manual instrumentation². Development in rotary instruments have promoted and fastened the root canal procedures and resulted in a consistent and predictable root canal shaping, thus reducing iatrogenic errors⁵.

Mtwo files (VDW, Munich, Germany) have a double cutting blade with an S-shaped cross-section and has a positive cutting angle and a non-cutting safety tip, which renders the instrument more efficient for cutting dentin walls. In addition, these files have a space between the

blades that increasingly widens from the tip to the shaft, thus restricting the file from engaging in the root canal walls, eliminating threading and binding that can occur during continuous rotation, and reduces the transport of debris toward the root apex⁶.

Hyflex EDM one file (Coltene), features a tip size of 25 with a 0.08 taper. This new file is a multi-tapered rotary file. Its taper changes along the file shaft. The apical diameter of the file is 0.25 mm and the taper is a constant 0.08 in the apical 4 mm of the instrument but reduces consecutively up to 0.04 in the coronal portion of the instrument⁷. Hyflex EDM has three distinct cross-sectional zones over the full length of the working part which increases the fracture resistance and cutting efficiency of the file. Due to the proprietary manufacturing process and heat treatment, this file has increased cyclic fatigue resistance⁸.

The Self-Adjusting File (SAF) (ReDent Nova, Ra'anana, Israel) is the first endodontic file with a unique design that does not have a metal shaft⁹. It is a thin-walled, hollow file with an asymmetrically pointed cylinder with a 1.5 mm diameter made of a NiTi lattice with a rough outer surface that is compressible in a canal. The file operates using a handpiece that permits a vertical vibration with 3,000 to 5,000 vibrations per minute and a 0.4 mm amplitude conforms to the canal shape and allows uninterrupted irrigation all through the procedure via a silicon tube attached to the revolving hub on the shaft of the file¹⁰.

Thus, the aim of this investigation was to evaluate and compare in vitro the amount of apically extruded debris using the single file rotary system Hyflex EDM (Coltene), the multiple-file rotary Mtwo system (VDW), and Self Adjusting File system (ReDent Nova). The

null hypothesis is that there is no distinction between the amounts of apically extruded debris associated with these file systems.

Methodology

The study was conducted after obtaining clearance from the ethical committee. Sixty freshly extracted human mandibular premolars having single straight root canals with mature apices and the curvature measured <5 degrees according to Schneider method¹² were selected for use in the study and the external root surfaces were cleaned with a periodontal curette. A flat coronal reference point was gained by grinding the tooth to a total length of 18 mm. Access cavity preparation was done and working length (WL) was calculated by reducing 1 mm from the canal length (17 mm) with size # 15 K-File.

An experimental model described by Myers and Montgomery⁴ was used in this study (Fig:1). Stoppers were removed from the Eppendorf tube (Eppendorf India Ltd., Chennai, India) and an analytical balance (Navodaya medical college, Raichur) with an accuracy of 10-4 g used to measure the initial weight of the tubes. Three successive weights were obtained for each tube and the mean was calculated.

A hole was produced in each stopper, then the tooth was inserted into this up to the cemento-enamel junction and was sealed with cyanoacrylate resin. The outside and inside pressure of the tubes were balanced by inserting a 24-gauge needle alongside the stopper (Fig:1). A single operator performed the cleaning, shaping, and irrigation of every sample to eliminate the bias and to avoid variation in the study. Then, a second examiner, who was blinded by the assigned groups assessed the extrusion of debris.

Depending on the file system used for the root canal preparation, the teeth samples were assigned randomly into three groups.

Group	Sample size	Material used	Manufactured
A	20	Hyflex EDM	Coltene/Whaledent, Altstatten, Switzerland
B	20	Mtwo	VDW, Munich, Germany
C	20	SAF	ReDent Nova, Ra'nana, Israel

Group I: Hyflex EDM

Glide path was established using size #15 K-File. The HyFlex EDM file with the size of 25.08 was used in a gentle in-and-out motion operated at 500 rpm rotary motion and 2.5 Ncm torque (Fig:2). The total quantity of irrigant used was 20 ml of distilled water.

Group II: Mtwo

Glide path was established using a size # 15 K-File. With a gentle in-and-out motion, every Mtwo files (Fig:3) were used to the full working length of the canals with an endodontic motor (X-Smart plus; Dentsply Maillefer) operated at 400 rpm rotary motion with 2.5 Ncm torque. The instrumentation sequence was as follows: size 10/.04 taper, size 015/.05 taper, size 020/.06 taper, size 025/.06 taper, and size 030/.05 taper. 5 ml of distilled water was used after each file and the total quantity of irrigation solution used for each tooth was 20 ml of distilled water.

Group III: Self-Adjusting File system

Glide path was established using a size # 15 K-File, followed by size 20 K-File to the working length according to the manufacturer's instructions. Then the

SAF (Fig:4) (2.0 mm diameter, 21 mm length) was used in the canal till working length using RDT3 Nx handpiece head (Re Dent Nova, Ra'naana, Israel). With continuous irrigation of distilled water at a rate of 5 ml/min, SAF was used for 4 minutes in each canal. Thus, the total irrigation solution used for each tooth was 20 ml.

The entire stopper assembly was detached from the Eppendroff tube after completion of the instrumentation. 1 ml of distilled water was then used to wash the root surface to collect the adhered debris on the root surface. These tubes were then incubated at 70°C for the next 5 days to evaporate the distilled water. The second weighing was done by another examiner who was blinded to the various samples.

The ultimate weight of tubes inclusive of extruded debris was obtained by weighing the Eppendorf tubes using the same analytical balance. Three successive weights were established and the mean calculated. The weight of the empty tube was then subtracted from that of the tube containing debris to obtain the dry weight of extruded debris.

Statistical analysis of the results was then obtained using ANOVA and post hoc Tukey's test.



Fig 1: Tooth mounted on vial Fig 2: Instrumentation with Hyflex EDM

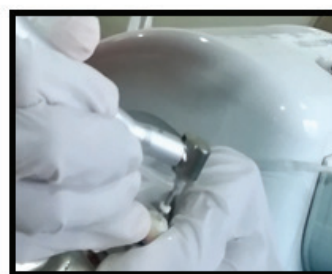


Fig 3: Instrumentation with Mtwo

Fig 4: Instrumentation with SAF

Results

The obtained results of the mean extrusion values (g), standard deviation (SD), and the range of debris extrusion (minimum and maximum values) for each group are presented in Table 1 and were subjected to ANOVA parametric statistical test. Graph 1 represents the mean extrusion of debris among all the groups.

A measurable amount of debris was extruded apically in every group and a significant difference in the amount of debris extrusion was noticed in the three types

of instrument groups. *Post hoc* Tukey’s test was used to obtain the comparison between the three experimental groups, in which SAF (0.00027 g) showed a significantly least amount of debris extrusion when compared with Hyflex EDM (0.00052 g) and Mtwo rotary files ($P < 0.001$). Mtwo (0.00091 g) showed the highest amount of extruded debris among all the groups and it was found to be statistically significant. The results were also statistically significant when comparing debris extrusion in Hyflex EDM with Mtwo rotary files ($P < 0.001$).

TABLE 1: Mean extrusion of debris in three groups based on weight in gms

Instrument group	N	Minimum	Maximum	Mean	S.D
Hyflex EDM	20	.00030	.00080	.00052	.000154
MTWO	20	.00050	.00130	.00091	.000229
SAF	20	.00010	.00040	.00027	.000103

TABLE 2: Comparison of the groups using anova

ANOVA	71.79
p value	0.00*

*significant

TABLE 3: Inter-group comparison using *post-hoc tukey* test

Groups	Mean difference	P value
Hyflex EDM * MTWO	-0.00039	0.00*
Hyflex EDM * SAF	0.00025	0.00*
MTWO * SAF	0.00064	0.00*

*significant

Discussion

Biomechanical preparation of the root canals causes extrusion of infected debris into the periradicular tissue space, which is one of the foremost causes of endodontic

flare-up that could end in acute periapical inflammation and post-operative pain⁴. It has been revealed that the manufacturing methods, pitch design of specific instruments, instrumentation technique, kinematics, and the number of files influence the amount of debris

extruded apically².

Straight and single-rooted mandibular premolar teeth were chosen in the study to omit the attainable complication. Myers and Montgomery have stated that, working length when kept 1 mm short of the respective canal length contributed to a very less debris extrusion. So, in the present study, to eliminate the variables which may affect the results, working length was maintained 1 mm short of the apex. The Myers and Montgomery methodology used in the study failed to resemble a closed system due to the absence of a physical back-pressure provided by the periapical tissues⁹.

Irrigation is an important phase in cleansing the canal and is unavoidable. The irrigant acts as a solvent, a lubricant, a disinfectant, a lavage, and flush, within the canal¹³. To avoid an increase in weight due to the crystal formation by NaOCl, distilled water was used as an irrigation solution in this study. The amount of irrigant used in all the three techniques was kept constant at 20 ml. According to Brown et al, apical extrusion of the irrigant is minimized with reservoir technique when compared with deep penetration of the irrigant¹⁴.

The crown-down technique pulls debris from the dentin into the flutes of the file and directs it toward the coronal part of the canal, which was already flared early. The rotatory motion directs debris toward the orifice. Thus, the crown-down technique combined with rotary instruments prevents compaction of debris in the root canal minimizing debris extrusion¹³. During the step-back technique, the push-pull or filing action pushes more debris apically, and also the file acts as a plunger in the apical third causing hydrostatic pressure to push the debris ahead of the file; thus leading to greater apical extrusion of debris⁹.

In the present study, all the instrumentation systems tested generated apically extruded debris in vitro, however, SAF (0.00027 g) showed statistically significant least amount of extruded debris when compared with Mtwo and Hyflex EDM, while Mtwo showed maximum debris extrusion. The present results may be explained by differences in the instrument design and movement kinematics between the different file systems. SAF is a single, hollow file system that has no cutting edge or flutes. The back and forth grinding motion combined with the continuous flow of the

irrigation solution from the SAF system efficiently clean the canals. Pressure build-up can be eliminated in the root canal space because the irrigant simply escapes through openings in the file lattice¹⁰. The elimination of positive pressure could favor a greater reduction of debris extrusion in the SAF group.

There have been various studies comparing the efficacy of SAF in extruding debris apically with V-Taper, ProTaper Next1, and with ProTaper Universal and WaveOne⁹, which showed least debris extrusion with SAF, wherein the findings of our study agree.

Hyflex EDM (0.00052 g) showed more extruded debris than the SAF. The unwinding of spirals while preparation of root canals is a well-known feature of Hyflex EDM file systems. Elmsallati et al (2009) concluded that the short pitch design instruments extruded less debris than the medium and long ones. The unwinding feature of the Hyflex instruments might be the reason for the greater extrusion of debris with the system¹⁵. Single file systems simplify the instrumentation protocol, minimize the operation time, and also result in less extrusion of debris which indeed supports our findings¹⁶.

The Mtwo multiple file system(0.00091 g) consists of four instruments to prepare the root canal to a size of 25, whilst only one instrument was used for Hyflex EDM. The varying number of files used in the different groups might have resulted in more debris production, due to the increased file insertion time³.

Conclusion

Within the limitations of this study, it can be concluded that apical debris extrusion was evident in all the groups yet the working length was maintained 1 mm short of the apical foramen. The SAF that used a vibratory motion with uninterrupted irrigation showed significantly less debris extrusion when compared to Hyflex EDM and Mtwo in the canal preparation of mandibular premolars. Among all the groups, Mtwo showed greater debris extrusion.

Conflicts of Interest: Nil.

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Assessment of Quality of Life and Activities of Daily Living among the Elderly Population of Rural Andhra Pradesh

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Abstract

Background: Elderly were facing heavy burden of sequel of long-term physical illness, as a result the ultimate effect was on quality of life. There is a need to highlight their medical and psychosocial problems and bring up strategies for improvement in their quality of life.

Methods: A community based cross sectional study was conducted among 100 elderly people, aged 60 and above, residing in a retirement home, present in the field practice area of RHTC, Anandhapuram, Visakhapatnam district, Andhra Pradesh, from October 2019 to December 2019. Data was collected by using the standard WHO BREF questionnaire for quality of life assessment and Katz index of ADL score for activity of daily living assessment. Majority of study population were females (53%) and majority was in the age group of 60-69 years (65%). Social support and relationship domain and environmental domain found with high mean quality of life scores (55.87+ 13.12 and 54.24 +10.12 respectively). 89% of the study population was found with full functional activity and only 1% with severe impairment.

Conclusion: Economical independence, social security and support by the family, regular health checkups and health seeking behaviour, legal security and special schemes for elderly will improve their quality of life and helps them to live longer and happier.

Keywords: *Quality of life, Retirement Home, WHO BREF, Katz index, Activity of daily living, Visakhapatnam*

Introduction

Today, most people could expect to live into their sixties and beyond. The one key factor, on which the increasing longevity would heavily depend on, was the health of the older populations. This increase in life expectancy was leading to significant changes in population structure – population ageing¹.

By 2020, the number of people above 60 years and older would outnumber the children younger than 5 years

and the proportion of the world's population over 60 was expected to double from 11% to 22% between 2000 and 2050² and the low and middle income countries were experiencing that greatest change, expecting by 2050, 80% of the older people would live in these countries.^{2,3}. In India, as per 2011 census, the population of 60 years and above was found to be 8.0 per cent⁴.

Elderly were facing heavy burden of sequel of long-term physical illness, as a result their ability to perform day-to-day activity often deteriorates. The physical dependency on others for performing activities of daily living deteriorates their mental health status and self-esteem. All these could lead to social disconnection and feeling of negligence by family members. As a result, the ultimate effect was on quality of life⁵. Quality of life is a broad ranging concept and was defined by the WHO as "individuals perceptions of their position in life in the

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context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns".⁶

There is a need to highlight the medical and psychosocial problems, which are being faced by the elderly people in India and strategies for bringing about an improvement in their quality of life. So, the present study has aimed to assess the quality of life and activities of daily living among the elderly population in a rural population.

Materials and Methods

A community based cross sectional study was conducted from October 2019 to December 2019 among the elderly population aged 60 and above, residing in a retirement home, present in the field practice area of our Rural Health Training Center, Anandhapuram, Visakhapatnam district, Andhra Pradesh. A sample of 100 people, representing 25% of the total residents of the retirement home was taken as sample size. Systemic random sample (k=4) was used and through random selection, every fourth person from the list of the residents which satisfied the inclusion criteria were chosen to participate in the research.

Inclusion criteria:

The individuals who aged 60 years and above and who were able to communicate and orient and were willing to participate were included in the study.

Exclusion criteria:

The individuals with any mental health issues, unable to respond, those who were bedridden and those not willing to participate were excluded.

Data was collected from individuals through face-to-face interview after explaining them about the study and informed consent was taken before questioning them with the questionnaire. Institutional ethics committee approval was taken.

The questionnaire includes three parts:

1. Personal information questionnaire

This includes the information related to their socio demographic characteristics i.e., name, age, sex,

education, and marital status.

2. WHOQOL-BREF questionnaire

It was developed by world health organization, to assess the quality of life. It is a 26-item Field trail version of WHOQOL-100. It includes 4 domain structures

- Physical domain
- Psychological domain
- Social relationship domain
- Environmental domain

Each domain includes seven, six, three and eight items respectively and 2 individual scored items that were examined separately on overall perception of quality of life and on overall perception on health. Each item in these domains was rated on a 5-point Likert scale and the domain scores were scaled in a positive direction (i.e. highest scores denotes higher quality of life). As per the WHO guidelines, domain scores for each domain was calculated by calculating the mean score of the items within each domain and that mean score was multiplied by 4, to make the domain scores comparable with the WHOQOL-100 scores and subsequently transformed to a 0-100 scale using the following formula.

$$\text{Transformed Score} = [\text{Domain score} - 4] \times [100 \div 16]$$

It was transformed to a score ranging from 0 to 100, where 100 is the highest value and 0 is the lowest value. The Mean score, domain score and transformed scores of each of the study participant was calculated.

3. Katz index of independence in Activities of Daily Living (ADL)

To assess the functional abilities in performing activities of daily living independently, Katz index of independence was used. This tool was developed by Hartford institute for geriatric nursing, New York University. It ranks the adequacy of performance of the elderly in six functions

- Bathing
- Dressing
- Toileting

- Transferring
- Contenance
- Feeding

For independence in performing each of these six functions, they were scored 1 for “yes” and 0 for “no”. Accordingly, based on there overall response, the individuals were scored. A score of 6 indicates Full function, 4 indicate moderate impairment and 2 or less than 2 indicates severe functional impairment.

Collected data was compiled into MS excel. Date was grouped and expressed in various variants

as frequency tables and summarized as means with standard deviations (SD). The correlation among quality of life and activity of daily living were analyzed by Spearman’s correlation coefficient using Epi-info statistical software package version 3.5.4. $P < 0.05$ was considered statistically significant.

Findings

Majority of the study participants were females (53%) and majority were in the age group of 60 – 69 years (65%). Considering their marital status, 60% were married and 36% were widowed. Majority (63%) of them were illiterate (Table 1).

Table 1: Socio-demographic characteristics of the study participants

Variables	Groups	Frequency N=100(%)
Gender	Male	47
	Female	53
Age	60-69	65
	70-79	26
	>80	9
Marital status	Married	60
	Unmarried	2
	Widowed	36
	Divorced	2
Education	Illiterate	63
	Primary School	28
	High School and Above	9

Quality of life is a multi dimensional aspect with involvement of many factors. For overall quality of life the total mean score with standard deviation was $51.68 + 10.14$ and among the different domain scores social relationship domain was found with highest mean score ($55.87 + 13.12$) followed by environmental domain ($54.24 + 10.12$)

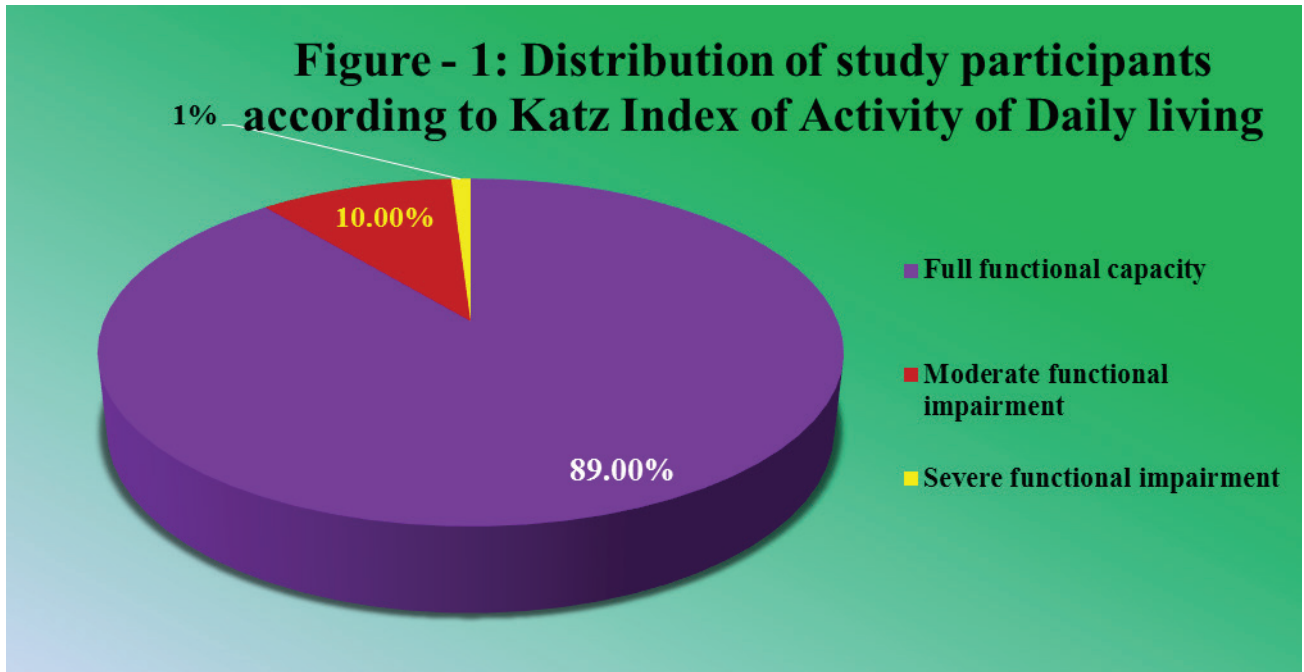
(Table – 2).

Table - 2: Mean quality of life scores of male and female for each domain

Domains	Male Mean + SD	Female Mean + SD	Total Mean + SD
Physical	48.58 + 11.13	49.62 +10.14	49.52 + 10.54
Psychological	46.60 + 13.22	46.82 + 13.49	47.12 + 13.23
Social relationships	54.12 + 12.89	56.63 + 13.26	55.87 + 13.12
Environmental	53.16 + 9.58	54.52 + 10.34	54.24 + 10.12

This indicates that the social support and relationship with their friends and relatives had a significant impact on their quality of life and also environmental factors were satisfactory.

There is a inverse relationship of age and quality of life with respect to, all the domains.



With respect to activity of daily living, majority (89%) of them were found with full functional capacity and 10% were found with moderate functional impairment. Only 1% had severe functional impairment. (Figure – 1)

Table - 3: Association between functional capacity and quality of life

Domains	Functional ability	Mean \pm SD	P value
Physical	Normal	52.08 \pm 9.13	0.001**
	Impaired	36.05 \pm 5.92	
Psychological	Normal	50.03 \pm 8.53	0.004**
	Impaired	38.24 \pm 9.96	
Social relationships	Normal	63.12 \pm 11.08	0.000**
	Impaired	45.24 \pm 11.32	
Environmental	Normal	48.82 \pm 11.89	0.000**
	Impaired	32.10 \pm 9.54	

(**- Highly significant)

Significant association ($p < 0.01$) was found among the elderly between the quality of life, with respect to all the four domains and their functional ability in performing their activities (Table 3)

Discussion

In the present study of assessment of quality of life among the elderly rural population, the mean scores for the social relationship domain was found to be high. In a similar study done by Ganesh Kumar et al., in urban Puducherry found that mean score for social relationship domain was lowest.⁵ This difference could be due to varied life style modification between the rural and urban population.

Also, there is an inverse relationship of age and quality of life with respect to, all the domains. Similar findings were observed in other studies done at Tamil Nadu and Karnataka.^{6,7}

With respect to functional disability, majority (89%) were found with full functional capacity. Similar findings were observed in other study done by KiranBala et al., in Jammu.⁸

Also, Significant association ($p < 0.01$) was found between quality of life and functional activity of daily living. Similarly, in a study done by Takemasa S et al, it was found among the elderly with poor quality of life had less activity of daily living score⁹.

Conclusion

The study says that the persons who are active have better quality of life. Even though ageing and disabilities of old age is universal and non-preventable we should learn the art of making it healthier through multidisciplinary measures. Economical independence, social security and support by the family, regular health checkups and health seeking behaviour, legal security and special schemes for elderly will improve their quality of life and helps them to live longer and happier.

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Source of Funding: Self

Ethical Clearance: Institutional ethics committee approval was taken.

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Outcome of Non Descent Vaginal Hysterectomy in Benign Gynecological Condition

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Abstract

Background: The most common gynaecological surgery is hysterectomy which is indicated mostly in DUB, fibroids, adenomyosis to malignancies. The various procedures range from laparoscopic to vaginal hysterectomies in non- descent cases. Vaginal Hysterectomy appears to be, relatively advantageous or superior procedure in terms of patient safety, cost-effectiveness, faster recovery (short hospital stay), and dreaded complications. It is the only surgery which has a very good cosmetic benefit that is without any visible scar.

Aim: To study the outcomes of Non-descent vaginal hysterectomy in benign gynaecological conditions.

Objectives:

1. To assess the outcome of Non- descent vaginal hysterectomy for benign Gynaecological conditions in terms of intra operative characteristics.
2. To assess the postoperative outcome in Non-descent vaginal Hysterectomy.

Materials: This prospective observational study was conducted between November 2018 to October 2020. The study was done among 100 women who fulfilled the inclusion criteria. Details regarding indication, size of the uterus, operation time, mean blood loss ,hospital stay and intraop and post op complications were noted.

Results: The mean age was 46.05 ± 5.413 . The mean operating time was 58.46 ± 17.75 minutes, the mean blood loss was 91.79 ± 27.18 ml and the mean hospital stay was 4.24 ± 0.63 days. Majority (57) of the patients indication of surgery was DUB. 47% of the patients had normal uterine size, 23% and 27% had less than 8 weeks and between 8-12 weeks uterine size respectively. Only 3% subjects had uterus size between 12-36 weeks. Majority subjects had no postoperative complications, whereas other complications like fever , UTI , vaginal bleeding and need for blood transfusion were found in 06,04,03 ,04 subjects respectively, and none of them had any intra op injury.

Keywords: Non- descent vaginal hysterectomy, DUB and Fibroid

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Introduction

Hysterectomy is a surgical procedure which involves uterus removal usually indicated in > 40 years of age woman, multiparous woman or when associated with benign or malignant conditions¹. Hysterectomies performed for leiomyomas (most common indication),

abnormal uterine bleeding, endometriosis, benign ovarian masses and uterine prolapse have decreased over time.⁵ Due to unavailability of information by large-scale (like whole country wide representative surveys), Data Evidence on prevalence of hysterectomy in India is sparse till recent years. A cross-sectional prevalence survey in 2015-2016, National Family Health Survey-4 collected the data on epidemiology of hysterectomy and self-reported reasons for undergoing the procedure for the first time (number of women included in survey -699,686) who were in the reproductive age⁶. The state wise data shows Andhra Pradesh being 22.4% followed by its neighboring state Telangana which was 20% were recorded as highest hysterectomies and Lakshadweep, Assam (3.0%) were lowest hysterectomy surgery performing states⁶. Women in India, removal of uterus is happens at an early age. As per the first prevalence study of India, NFHS-4 (2015-2016), 3.2 per cent women, between 15-49 years had a hysterectomy. Age-specific prevalence of hysterectomy was 0.36% among women aged 15-29, in women aged 30-39 years, it was 3.59% and in 40-49 years, it was 9.20%.⁶ Hysterectomies types are broadly divided Abdominal or vaginal based on route of surgery. These two varieties can be further divided into many types based on the route and surgical procedure options like, abdominal/vaginal hysterectomy, total Laparoscopy / laparoscopic assisted vaginal hysterectomy, and robotic assisted laparoscopic hysterectomy, etc^{1,2}. Abdominal hysterectomy was criticized for, high mean blood loss, morbidity, hospitalization period, and recovery time over other procedures². World health organization, Reproductive health library) Summaries based on Cochrane review as, vaginal hysterectomy (VH) showed shorter hospital stay compared to conventional abdominal hysterectomy (AH) and laparoscopic operated hysterectomy (LH). When compared to AH, both VH & LH had statistically equal shorter time to return to normal daily activities.⁸ Vaginal Hysterectomy appears to be, relatively advantageous or superior procedure in terms of patient safety, cost-effectiveness, faster recovery (short hospital stay), and dreaded complications. It is the only surgery which has a very good cosmetic benefit that is without any visible scar.²

Aim: To study the outcomes of Non-descent vaginal hysterectomy in benign gynaecological conditions.

Objectives:

1. To assess the outcome of Non- descent vaginal hysterectomy for benign Gynaecological conditions in terms of intra operative characteristics.
2. To assess the postoperative outcome in Non-descent vaginal Hysterectomy.

Material and methods

Study Area

The study was conducted among patients attending department of department of obstetrics and gynecology, Sri Siddhartha medical college and hospital research centre, Tumakuru.

Study Design

Prospective observational study

Study Period

November 2018 to October 2020

Ethical approval

Institutional ethical committee approval was obtained prior to the initiation of the study

Study Population

All cases with benign gynaecological conditions as per the inclusion and exclusion criteria, attending the OPD or admitted under OBG department, Sri Siddhartha Medical College Hospital and Research center, Tumakuru

Inclusion Criteria

1. Uterine size not more than 16 weeks
2. Adequate vaginal access
3. Good uterine mobility

Exclusion Criteria

1. Uterus with restricted mobility
2. Proven malignancy
3. Complex adnexal mass
4. Uterus size more than 16 weeks

5. Nulliparity, PID, previous LSCS

Sampling method: Simple random sampling

Sample Size

Considering the prevalence of NVDH as 37.68% the sample size was calculated for our study using the formula

$$N = 4pq/L^2 :$$

$$\emptyset \quad p = 37.68\%$$

$$\emptyset \quad q = 62.32 (100-p)$$

$$\emptyset \quad L = 25\%$$

Sample size works out to 109 subjects with the above formula and with a dropout rate of 5%- 8% the study was rounded off to 100 subjects.

Study Tools: Pre-designed pre-tested questionnaire.

Data Collection Methodology

The subjects were included in the study after their consent. Details were noted and in detail history was also noted. A complete clinical examination was done. Blood and urine samples were collected.

A written informed consent from all patient after explaining the procedure and special consent for conversion to abdominal hysterectomy were taken from the patients. All cases were performed under appropriate anesthesia. All cases were reassessed in operation theatre after anaesthetized to see size of the uterus, mobility of the uterus, laxity of pelvic muscle. If at any time uterine size did not allow an easy exteriorization then debulking techniques like morcellation, bisection, myomectomy or a combination of all this method were done. Intra operative blood loss and post-operative complication like fever, UTI, vaginal cuff cellulitis and vaginal bleeding noted.

Procedure

After painting and draping, anterior lip of cervix is held with velsellum. Curved transverse incision

is taken on anterior vaginal wall at the lower limit of bladder wall and anterior vaginal wall is pushed up. Pubo-cervical ligament is cut and bladder is pushed up. Incision is extended posteriorly, posterior vaginal wall is separated. Anterior UV fold and posterior cul-de-sac opened. Uterosacral and cardinal ligaments are clamped, cut and ligated bilaterally. Then uterine vessels are clamped cut and ligated bilaterally. Depending on the size of the uterus various debulking procedures are used to deliver the uterus. Final clamp were applied to round ligament, fallopian tube and ovarian ligament together, cut transfixed and ligated. Infundibulopelvic ligament is clamped if oophorectomy is done. Then vaginal vault is closed by continuous interlocking sutures.

Data Analysis

The collected data was collected, coded, entered into Microsoft excel work sheet and exported to SPSS. Data was analyzed using SPSS version 21. Data is presented as percentage in categories and then presented as tables.

Results

Table 1 depicts that for majority (57) of the patients indication of surgery was DUB ,whereas for 08 patients it was Endometrial hyperplasia, 1 patient had cervical fibroid, 7 had adenomyosis, for 22 patients indication was fibroid, 1 had endometrial polyp and 1 had FIB+PMB and 01 of them had cervical elongation. According to the above table 2, 47% of the patients had normal uterine size, 23% and 27% had less than 8 weeks and between 8-12 weeks uterine size respectively. Only 3% subjects had uterus size between 12-36 weeks. Table 3 explains shows that out of 100 patients were 13 of them were between 35 to 39 years, 22 were 40 to 44 years and 35 were 45 to 49 years and 30 were above 50 years. The mean operating time was 58.46 ± 17.75 minutes, the mean blood loss was 91.79 ± 27.18 ml and the mean hospital stay was 4.24 ± 0.63 days. Table 4 depicts majority subjects had no postoperative complications, whereas other complications like fever , UTI , vaginal bleeding and blood transfusion were found in 06,04,03 ,04 subjects respectively, and none of them had any intra op injury.

Table 1: Indication of NDVH

Indication	Number of patients	Percentage
DUB	57	57%
Endometrial hyperplasia(aub E)	08	8%
Cervical Fibroid	01	1%
Adenomyosis	07	7%
Fibroid	22	22%
Endometrial polyp	01	1%
Fibroid + Endometrial hyperplasia	02	2%
Cervical Elongation	01	1%
Fibroid + PMB	01	1%
Total	100	100%

Table 2: Distribution of patients according to uterus size

Size (in weeks)	Number of patients	Percentage %
Normal	47	47%
< 8 weeks	23	23%
8-12 weeks	27	27%
12-16 weeks	03	3%
Total	100	100%

Table 3: Comparison of the present study with other studies

	Present study	Gayathri et al	Chandana et al.	Dewan et al	Saha et al.	Thulasi et al
Age						
35-39	13%	28.5%	6%	12%	30%	6%
40-44	22%	59%	55%	54%	40%	55%
45-49	35%	10%	25%	20%	10%	25%
>50 years	30%	2.5%	14%	14%	20%	14%
Indication	DUB (57%) Fibroid (22%) Endometrial hyperplasia (8%) Adenomyosis (7%) PMB (1%)	DUB (50%) Endometrial hyperplasia (40%) PMB (9.5%)	DUB (32%) Fibroid (43%) Adenomyosis (9%)	DUB (20%) Fibroid (68%) Adenomyosis (6%)	DUB (26%) Fibroid (46%) Adenomyosis (24%)	DUB (32%) Fibroid (43%) Adenomyosis (9%)

Cont... Table 3: Comparison of the present study with other studies

Mean operation time	58.46±17.75 mins	90 mins	70 mins	54.5 mins	120 mins	70 mins
Mean blood loss (ml)	91.79±27.18 ml	100 ml	150 ml	290 ml	205 ml	150 ml
Mean hospital stay	4.24 ± 0.63 days	3 days	-	-	-	-

TABLE 4. Post-operative complications:

Type	Number of patients	Percentage
No complication	83	83
Fever	06	6%
UTI	04	4%
Vaginal bleeding	03	3%
Blood transfusion	04	4%

Discussion

Non descent vaginal hysterectomy describes a vaginal approach that can be undertaken in absence of uterine prolapse. It is performed entirely through vaginal route and its advantage over abdominal and laparoscopic hysterectomy is well documented. Outcome data of the procedure in a local setting would be helpful for both clinician and patient to consider vaginal approach of hysterectomy. The present study shows 35% of the patients were between 45 to 49 years, 30% were above 50 years and 35% were between 35-44 years, a study by Gayathri et al ⁶ showed majority of the subjects, 59% were between 40 -44 years followed by 28.5% between 35-40 years. Another study by Chandana et al,⁷Dewan et al,⁸Saha et al ⁹ and Thulasi et al ¹⁰ showed majority i.e 55%, 54%, 40, and 55% subjects were between 40 to 44 years respectively. The most common indication observed in the present study was DUB (57%), fibroids (22%) and adenomyosis (7%). Studied by Gayathri et al ⁶ showed 50% of the patients indicated was due to DUB, 40% due to endometrial hyperplasia and 9.5% was PMB. Chandana et al,⁷Dewan et al,⁸Saha et al ⁹ and Thulasi et al ¹⁰ suggested 32%, 20%, 26% and 32% patients indication was DUB, 43%, 68%, 46% and 43%

for fibroids and 9%, 6%.24% and 9% was adenomyosis respectively. This study showed 475 subjects had normal uterus size 23% < 8 weeks, 27% uterus size was between 8-12 weeks and 3% had uterus size between 12- 16 weeks. Gayathri et al ⁶ showed 27.5%, 49.5%, and 12% respectively and also reported 10.5% had uterus size above 16 weeks. The mean operating time in the present study was 58.46±17.75 minutes were as Gayathri et al,⁶Chandana et al,⁷Dewan et al,⁸Saha et al ⁹ and Thulasi et al ¹⁰ reported 90, 70, 54.5, 120 and 70 minutes respectively. The present study mean blood loss was 91.79±27.18 ml which was close enough to the study done by Gayathri et al that reported 100ml blood loss. The other studies by Chandana et al,⁷Dewan et al,⁸Saha et al ⁹ and Thulasi et al ¹⁰ reported 150 ml, 290 ml, 205 ml and 150 ml respectively. The mean hospital stay was 4.24 ± 0.63 days were as Gayathri et al ⁶ reported a mean of 3 days hospital stay. In this study majority subjects had no postoperative complications, whereas other complications like fever , UTI , vaginal bleeding and blood transfusion were found and there was no intra op complications. Other study conducted by Arifa et al¹¹ there were minor complications of the procedures like UTI, vaginal cuff infection, blood transfusion ,bladder injury. Also in a study conducted by Elizabeth et al¹²

there were postoperative complications with 02, subjects had UTI, 09 subjects had perioperative blood transfusion and 01 patient having bladder injury

Conclusion

The results obtained from this study showed majority of subjects were 65% were above 45 years. The most common indication was DUB followed by fibroids, endometrial hyperplasia and adenomyosis. The uterus size was normal in 47% subjects. The mean operating time was 58.46±17.75 mins, the mean blood loss was 91.79±27.18 ml and mean hospital stay was 4.24 ± 0.63 days. It can be concluded also concluded Vaginal Hysterectomy is least invasive route and it is associated with rapid postoperative recovery. Less intraoperative blood loss, less duration of surgery and less duration of hospital stay depicts that vaginal route should be the choice of operation in non descent cases.

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Role of Percutaneous Tracheostomy in COVID-19 Patients on Ventilator

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Abstract

The pandemic caused by novel coronavirus (SARS-CoV 2) with respiratory and multiorgan dysfunction needing prolonged mechanical ventilation. Tracheostomy reduces ventilator support time. The study was done on 23 patients and role of PCT was observed. A recovery rate of 8.77% was observed and no significant change in mortality rate was observed with even after better airway management.

Keywords: COVID-19, tracheostomy, PCT, Ventilator

Introduction

Coronavirus disease 2019 (COVID-19) is defined as illness caused by a novel coronavirus now called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; formerly called 2019-nCoV), and was first identified amid an outbreak of respiratory illness cases in Wuhan City, Hubei Province, China. [1] It was initially reported to the WHO on December 31, 2019. On January 30, 2020, the WHO declared the COVID-19 outbreak a global health emergency. [2, 3] On March 11, 2020, the WHO declared COVID-19 a global pandemic, its first such designation since declaring H1N1 influenza a pandemic in 2009.

Illness caused by SARS-CoV-2 was termed COVID-19 by the WHO, the acronym derived from "coronavirus disease 2019" [4,5]. With presentations ranging from asymptomatic/ mild symptoms to severe illness with involvement of lungs, heart, pancreas and kidneys with multiorgan dysfunction.

Tracheostomy is one of the oldest and most commonly performed procedures in critically sick

patients. Surgical tracheostomy (ST) was first described by Jackson in 1909. Percutaneous dilatational tracheostomy (PDT) over a guidewire was invented by Ciaglia in 1985. PDT has now become the standard of care in ICU and has replaced ST in this subset of patients to a large [6]

PCT involves blunt dissection of pretracheal tissues followed by dilatation of trachea over the guidewire and insertion of tracheal cannula using Seldinger technique.

Prolonged ventilator stay is the most common indication of tracheostomy in critically ill patients. Up to 24% of mechanically ventilated patients in ICU undergo tracheostomy. Tracheostomy has been conventionally recommended for patients requiring ventilator for >21 days, and endotracheal (ET) intubation is recommended if ventilator stay is <10 days. This was as per the first consensus on artificial airways published in 1989, for patients on mechanical ventilation. [7] Most of the recent guidelines have found insufficient evidence to make any concrete recommendations in this regard. [8] When compared to trans-laryngeal intubation, tracheostomy is associated with less sedation, better patient comfort, reduced work of breathing aiding in faster weaning from ventilator.

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Use of tracheostomy can facilitate weaning from ventilation and potentially increase the availability of much needed intensive care unit (ICU) beds, however this being a high aerosol generating procedure it does put the health care worker to risk of transmission. [12]

The past year has been difficult due to spread of the pandemic and the healthcare systems all over the world have been facing unprecedented challenges. These challenges are most for the Intensive Care Unit/ High Dependency Units to manage the critically ill patients.

Reports show that 5–15% of patients with COVID-19 are critically ill and need mechanical ventilation^[9,10,11]. Many of these patients need extended period of ventilation where tracheostomy is a common procedure for mechanical ventilator support. Use of tracheostomy can facilitate weaning from mechanical ventilation and potentially increase the availability of intensive care unit beds.

Material and Methodology

Prospective observational study. Series of 23 patients admitted in Subharti Medical College in COVID- ICU, during the period of 3 months from July 2020 to September 2020. Percutaneous Tracheostomy were done by dilatational method bedside

Inclusion criteria: RT-PCR positive for COVID-19, patients on mechanical ventilator support

Exclusion criteria: patients not on ventilator support

Materials: ICU setup, Tracheostomy tube, injectable anaesthetic agent, surgical blade, dilator, tracheostomy set, mechanical ventilator

Procedure

Position: The patient's neck is extended over a shoulder roll (unless there is a contraindication). The anaesthesiologist stands at the head end of the bed. All personnel were equipped with the proper personal protective equipment (including an N100 equivalent half face gas respirator, eye goggles, transparent full-face shield, gown, and sterile double gloves.)

- Before the procedure, patients were anesthetized with 2% lidocaine with adrenaline injected in the neck at the site of planned PCT. The soft tissue till trachea was instilled and 2 minutes was given.

- The sedative agent – most commonly fentanyl used as an infusion of 20-40 mcg/hour- was given as a bolus 30-50 mcg, 10 min before the procedure.

- Skin incision made and the pretracheal tissue cleared with blunt dissection.

- Endotracheal tube was withdrawn, placing the cuff at the level of the glottis. A 3.8 mm bronchoscope (3.8 or 5.0mm bronchoscope inserted through suction port of T connector of ventilator circuit) was used and was placed at the end of the ET.

- Surgeon enters the tracheal lumen below the second tracheal ring with an introducer needle, the same was confirmed by the bronchoscope and a guidewire was placed. Needle and bronchoscope are removed after successful placement of the guidewire.

- The tract between the skin and the tracheal lumen was then serially dilated over a guidewire.

- With the help of Griggs forceps the trachea was entered over the guidewire and the opening dilated

- A tracheostomy tube was placed over a dilator.

- The cuff was inflated. The position was confirmed by reduction of tidal volume generated through ET to zero and then generation of TV through the TT.

- The ET was now removed after deflating the cuff and proper suctioning.

- Tube was secured to the skin with sutures and the tracheostomy tape

Observation:

- Total patients on Ventilatory support: 114 (without PCT)

- Patients with PCT: 23

Duration after admission when PCT was done patients

0 to 5 days	15 patients
6 to 10 days	7 patients
>10 days	1 patients

Days on Ventilatory support post PCT

≤2days	13patients
>2 days	10 patients

Duration of Ventilatory support after which PCT was done

0 to 3 days	15 patients
4 to 6 days	6 patients
>7 days	2 patients

Total ventilator days: 133. (5.78 mean)

Antiviral drugs: out of 23 patients, 19 were on Remdesvir, 5 on Oseltamivir, and 1 on Favipivir

- 7 patients were given Ulinastatin concurrently
- 18 patients were given dexamethasone and 18 low molecular weight heparin
- Mean time of PCT post intubation: 2.47 days
- Mean time of ventilator support post PCT: 3.30 days

Antibiotic coverage was given by ceftriaxone in 13 patients, Piperacillin and tazobactam in 7 patients. 6 patients were given a combination of other drugs.

Hydroxychloroquine: 2

Ivermectin:1

The indication to upgrade antibiotics were; a raised PCT level, culture report or new onset fever (after 4 days of ventilation) with falling cardiovascular parameters

Summary of our experience with ventilation of

- Total patients on ventilator: 114
- Total patient days on ventilator: 730
- Average: 6.403 days
- Total no. Of patients successfully weaned off ventilator support: 10

(8.77% recovery from ventilator)

- Pressure control ventilation in: 111
- Volume control ventilation in: 3

Most common cause of death:

- 50%- bleeding from respiratory passage, either TT or ET despite all bleeding parameters being normal.
- 30%- ARDS with MODS with falling BP despite triple inotropes.

Conclusion

Although doing a PCT decreased the number of days on ventilator support, no advantage was seen in the mortality rate. In COVID-19 critically ill patients, a modified PT technique, did not lead to improvement or prolongation of life as compared to endotracheal tube even though it ensured a better airway management for suctioning and respiratory function, patient comfort, reduced need of patient sedation and great safety for the staff.

Survival did not improve even after early PCT and ventilation.

Ethics: clearance from University Ethics Committee (Medical), Subharti University

Conflict of Interest: Nil

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Comparative Study of Pap Smear Verses Visual Inspection with Acetic Acid in Screening for Cervical Cancer

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Abstract

Background: Carcinoma of cervix is 2nd most common cancer globally . India accounts for 4th global burden . Pap smear is screening method in developed countries .VIA can be an alternative screening method to pap smear in developing countries as it is low cost, simple administration, real time screening of results .

Aim of Study : To compare pap smear and VIA in screening for cervical cancer.

Objectives of the Study:

1. To find out the specificity , sensitivity, PPV , NPV of pap smear for detecting carcinoma of cervix
2. To find out the specificity sensitivity PPV, NPV of VIA detecting carcinoma of cervix.
3. To compare the cost effectiveness of performing pap smear and VIA

Methodology : Informed oral consent taken .Cervix is to be visualized using a cuscus speculum .Ectocervix and endocervix samples taken and fixed with cytofix and sent for pathologist .TZ is visualized and 3% acetic acid is applied for 1-2 min . If aceto white areas seen it is positive test . colposcopic guides biopsy done for women with any one test positive .Correlation of the above two tests is done by HPE .

Results: The sensitivity, specificity, PPV, NPV of pap smear 70.83% , 55.56% ,45.95% , and 78.13% .

The sensitivity,specificity, PPV, NPV of VIA 87.50% , 31.11% , 40.38% , 82.35% .VIA is more cost effective than Pap smear test .

Conclusion : Cervical cancer has a long precancerous stage . VIA is more sensitive compared to pap smear. It is simple, safe , cost effective test requires less training. VIA can be used as an alternative screening test.

Keywords : Pap smear , VIA. Cancer cervix, screening

Introduction

Carcinoma of cervix is 2nd most common cancer globally ¹. India alone accounts for one fourth of the

global cervical cancer burden. ¹Lack of resources screening programme and poorly organized health systems for detecting precancerous condition are the reasons for increased incidence in India .²

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Ca cervix can be prevented through primary prevention and early detection and treatment can be done for precancerous lesions before it progresses to invasive cancer .²

The advantages of pap smear is its safe , simple, non invasive and effective method for detection of precancerous ,cancerous, and non cancerous changes in cervix and vagina².

Visual inspection with acetic acid has been advocated as an alternative screening method to PAP smear in developing countries ².

The advantages of VIA include low cost, simple administration, real time screening and donot need lab facilities hence it is more beneficial to developing countries ² ..

Many developing countries do not have ample resources to implement cytology based prevention programs .³

Pap smear screening has markedly reduced mortality from cervical cancer ⁴

Every year around 1.23 lakh women are diagnosed with cervical cancer and 67,500 of women die of the disease in india .⁵

Aim of study : To compare pap smear and visual inspection of acetic acid in screening for cervical cancer.

Objectives of the study:

1. To find out the specificity , sensitivity, PPV , NPV of pap smear for detecting carcinoma of cervix
2. To find out the specificity sensitivity PPV, NPV of Visual inspection with acetic acid for detecting carcinoma of cervix.
3. To compare the cost effectiveness of performing pap smear and visual inspection with acetic acid.

Methodology

Study Population : The study will be conducted on all married women of general population attending pap smear screening camp at various rural areas of Tumkur district.

Study Design: Camp based Population based cross sectional study

Sampling Method : General population

DURATION: 18 MONTHS .

Sample size: 1000

Inclusion Criteria:

- AGE GROUP: All married women with or without risk factors like
- Early marriage
- Early pregnancy
- Multiparity
- Sexual activity at early age .
- Multiple sexual partners.

Exclusion Criteria

- Unmarried women
- Women below 18yrs
- Patient having bleeding PV or active infection during examination
- Women with frank invasive cervical carcinoma
- Post hysterectomy status.
- Women who do not give consent.
- Pregnant women .
- Seriously ill patients.

A cross sectional study will be carried out of general population of various rural areas of Tumkur District .

Patient to be screened will be explained about the procedure to be performed oral informed consent is to be taken a relevant obstetric and gynecological history is to be taken with the patient being reassured that the procedure is painless and effective in screening of carcinoma .

Firstly the cervix is to be visualized using a cuscus speculum or using anterior vaginal wall retractor and Sims vaginal speculum . A pap smear will be taken with Ayer spatula and cytobrush . Pap smear is taken from two samples from ecto and endo cervix . Ectocervix samples is to be taken using the ayers spatula and Endo cervix samples is to be taken using Cyto brush. The pap

smear slide is to be immediately fixed with a mixture of 50% ethyl alcohol and 50% ether (cytofix).

After taking Pap smear cervix is to be washed with normal saline. The slides are to be stained using papanicolaou stain and reporting is to be done according to Bethesda classification.

The VIA is to be performed using a cotton swab soaked in 3% acetic acid for 1 to 2 min and then the cervix is to be carefully inspected for any aceto white lesions, particularly in the transformation zone. The test outcome is considered positive if any distinct acetowhite lesions areas is to be detected on the cervix. If no acetowhite lesions is detected or if the whitish appearance is to be doubtful or faint the test was scored negative.

Colposcopic guided biopsy was offered for women who had positive VIA test or positive pap smear test and the sample was procured for Histopathological examination.

Cervical cytology and VIA results were correlated with histopathological finding which were taken as gold standard. CIN 1 or higher grade lesions diagnosed by histopathology were taken as true positive cases.

Statistical Analysis

Data was entered in excel and analysis was carried out using SPSS (Version 20). Descriptive statistics was performed for socio demographic variables. Categorical variables were expressed as frequencies and percentage. Quantitative variables were tested for normality using Kolmogorov Smirnov test. Present age, age at the time of marriage were expressed in Median and Inter Quartile Range. Setting Histopathological results as gold standard, Sensitivity, Specificity, Positive predictive value, Negative Predictive Value and Accuracy of Pap Smear and VIA were computed and compared. Kappa statistic was also calculated.

Results

Age distribution of study subjects :

In our study 358 women (35.8%) were in the age group between 31 – 40 years.

Median of age at marriage and duration of married life of study subjects :

Mean age of the population in the present the study was 40 years.

Mean age at marriage of the population in our study was 20 years.

Mean of married life of women in our study was 20 years.

Occupations of women in the study :

In the present study 371 women 37.1% of women were laborer by occupation, 344(34.4%) women were house wife.

Cytology results of women in the study :

In our study 925 women (92.5%) were negative for intraepithelial lesion or malignancy. 42 women (4.2%) of women had low grade squamous intra epithelia lesion on cytology.

21 (2.1%) women had high grade squamous intraepithelial lesion. 11 (1.1%) women showed ASCUS. 1 (0.1%) Women has SCC on pap smear.

Distribution of neoplastic lesions based on cytology :

In our study 63 (6.3%) had premalignant and malignant changes on pap smear. Out of which 41 (66.13%) had Low grade squamous intraepithelial lesion, 21 (33.87%) women had high grade squamous intraepithelial lesion, 1 (1.59%) had squamous cell carcinoma on pap smear.

Comparison of Cytological diagnosis with Histopathological Diagnosis :

In our study 4 out of 9 cases of CIN1 were correctly diagnosed as LSIL on cytology. Pap smear missed 3 HSIL. One case was diagnosed as squamous cell carcinoma on both cytology and histology.

Diagnostic accuracy of cytology in neoplastic lesions :

In our present study, the diagnostic accuracy of cytology for low grade squamous intra epithelial lesion was 44.4%. It was 78.6% for high grade lesions and 100% for squamous cell carcinoma.

VIA pattern in study subjects :

In our present study VIA was positive in 161 (16.1%) women .

Final Diagnosis of Histopathology :

Final diagnosis by histopathology was taken as gold standard . Only 69 women were willing for biopsy for Histopathological examination . Out of this 69 women 25 (36%) women were negative for intra epithelial; lesion 20 (29%) women had chronic cervicitis , 9 (13%) had CIN 1 , 7 (10%) women had CIN11 , 1 women had squamous cell carcinoma .

Comparison of Pap smear with biopsy examination in the diagnosis of cervical neoplasm:

In our study 24 out of 69 were true positive for presence of pre malignant and malignant lesions. Pap smear picked 17 out of 24 cases , 7 cases were missed on pap smear .

Sensitivity analysis of Pap smear :

In our study the sensitivity of pap smear in detecting pre cancerous and cancerous lesion was 70.83%. Specificity was 55.56% , Positive predictive value is 45.95% , negative predictive value 78.13% . The overall diagnostic accuracy was 60.87% .

Comparison of VIA with biopsy examination in the diagnosis of cervical neoplasm :

In our study , VIA was positive in 21 out of 24 true positive cases , 3 cases were missed on VIA.

Sensitivity analysis of VIA :

In our study Visual inspection with acetic acid was more sensitive test than pap smear , where as pap smear was more specific test compared to visual inspection with acetic acid .

Cost Effective Analysis of Pap Smear vs VIA:

In our present study the cost per pap smear test was 300 rupees , the cost per VIA test was 30 rupees.

37 women underwent pap smear and colposcopic guided biopsy for HPE total cost was 41,400 rupees .

52 women underwent VIA and colposcopic guided biopsy for HPE total cost was 22,770 rupees .

Discussion

Comparison of age distribution with other studies :

In our study 35 .85 % of women were in the age group of 31 – 40yrs , Our study was similar to the study done by Niyodusenga A et al ⁶ 32.3% of women were in age group 41- 50 yrs . By a study done by Zahan .N et al ⁷ 25 .7 % women were in the age group of 26-30 years .

Comparison of age of marriage in years with other studies:

In present study age of marriage was < 20 yrs in 57.1 % of women . Our study was similar to the study done by Nath JD et al ²⁰ age of marriage was < 18 yrs in 82.3% . A study done by Rashid MH et al ¹⁶ 45 % of women were married at the age < 15 years .

Comparison of Duration of marriage / Married life in years with other studies

In the present study duration of marriage / married life was in the range between 11- 20 yrs . Our study was similar to study done by Nakash .A et al⁸ . A study done by Nath .J.D et al ²⁰ , 50 % of women in the study were married for > 20 yrs .

Comparison of Occupation of women with other studies : 37.1% of women in our study were labourer by occupation , 34.4 % of women were house wife .

A study done by Rashid MH et al¹⁶ 91.5% of women were home makers and 4.5% of women were govt employee .In a study done by Nakash A et al ⁸ 80.10 % of women were house wife and 10.90% of women were teacher by occupation

Table 1: Comparison of Cytology/ Pap smear results with other studies :

Cytology	Percent
Sinha .S 9 et al 2020	
NILM	91.5%
HSIL	3.5%
LSIL	5 %
Squamous cell carcinoma	0 %
Sinha P et al 12 2018	
NILM	89.66%
HSIL	0.6%
LSIL	3.6%
Squamous cell carcinoma	1.6%
Abiodun A et al 13 2017	
NILM	95.9%
HSIL	1.25%
LSIL	2.8%
Squamous cell carcinoma	00
Nakash .A et al 8 2017	
NILM	56.40%
HSIL	5.2%
LSIL	13.4%
Squamous cell carcinoma	1.20%
Verma A et al 14 2017	
NILM	92%
HSIL	2.5%
LSIL	5.5%
Squamous cell carcinoma	00
PRESENT STUDY	
NILM	92.5%
HSIL	2.1%
LSIL	4.2%
Squamous cell carcinoma	0.1%

Our study was similar to study done by Sinha .S et al , Our study results were also similar to the study done by Abiodun A et al and Verma A et al .

In our present study the ratio of premalignant to malignant lesion was 62:1 .

Our study is similar to study Sökkary H.H i.e 49:1 .

Comparison of Different Cytologic Categories with Other Studies :

Table : 2 Comparison of Distribution of Neoplastic Lesions with Other studies :

STUDY	LSIL	HSIL	CARCINOMA	TOTAL
Niyodusenga . A et. al 6 2020	20 (25.3%)	6 (7.5%)	53 (67%)	79
Sinha. P et al 12 2018	11(61.1%)	2(11.1%)	5(27.7%)	18
El Sökkary HH 10 2017	36 (72 %)	13 (26%)	1 (2%)	50
Nakash .A et al 8 2017	21 (67.7%)	8 (25.8%)	2 (6.4%)	31
Present study	42 (66.13%)	21 (33.87 %)	1(1.59 %)	64

Our study was similar to the study done by Nakash .A et al .

Table 3: Comparison of Diagnostic accuracy of cytology for cervical cancer with other studies :

Study	Diagnosis based on HPE	Diagnosis based on cytology	Percentage
K.pushpalath et al 11 2017	4	4	100 %
El Sökkary HH 10. 2017	1	1	100%
Nakash .A et al 8 2017	2	2	100%
Mohamed KA15 et al 2016	13	16	81.25%
Present study	01	01	100 %

The diagnostic accuracy of our study was 100 % , all other studies have similar results except Mohamed KA et al where the diagnostic accuracy is 81.25% , this can be attributed to sampling errors .

Comparison of Diagnostic accuracy of cytology for HSIL with other studies: The diagnostic accuracy of cytology for HSIL in our study is 78.6% . Our study results were similar to study done by Mohammed KA (73.86%) .

In the present study the diagnostic accuracy of cytology for LSIL IS 44.4% .

Our study results were similar to the study done by M Mrudula D.M. with the diagnostic accuracy of cytology for LSIL is 52.3% .

Comparison of Diagnostic accuracy of cytology for LSIL with other studies :

Table 4 :Comparison of Proportion of Women Screened Positive with VIA and Pap smear with Other studies :

STUDY	VIA POSITIVE	PAP SMEAR POSITIVE
Niyodusenga .A et al 6 2020	94 (47.47%)	79(39.89%)
Vahedpoor Z et al 17 2019	92(21%)	22 (50.5%)
Mrudula .DM et al 182018	156 (31.2%)	110 (27.7%)
Sinha P et al 12 2018	38 (12.6%).	31 (10.3%)
K.Pushpalath et al 11 2017	29(5.34%)	417 (76.8%)
Mohamed KA et al 15 2016	200 (6%)	164 (5%)
Present study	161 (16.1 %)	64 (6.4%)

In our study the proportion of women screened positive with VIA was 161 (16.1%) and for pap smear was 64 (6.4%) .Our study results were similar to the study done by Sinha p et al .

.Table 5 : Comparison of Diagnostic value of VIA and Pap Smear with Other Studies :

STUDY	SCREENING TEST	SENSITIVITY	SPECIFICITY	PPV	NPV
Sinha .S 9et al 2020	VIA Pap Smear	88.23% 88%	78.68% 52.63%	53.57% 47.05%	96% 90.9%
Niyodusenga .A et al 6 2020	VIA Pap Smear	88.5% 80.45%	84.68% 91.89%	81.91 % 88.6%	90.38% 85.71%
Sinha P 12 et al 2018	VIA Pap smear	93.3% 93.8%	60% 72.9%	36.8% 48.4%	97.3% 97.7%
EI Sokkary HH et al 10 2017	VIA Pap Smear	66.7% 83.3%	91% 90.7%	46.1% 50.8%	95.9% 97.9%
Present study	VIA Pap Smear	87.50% 70.83%	31.11% 55.56%	40.38% 45.95%	82.35% 78.13%

A study done by Niyodusenga et al showed similar results as our study .

Table 6 : Comparing the cost effective analysis with other studies :

	PRESENT STUDY (N= 1000 women)	Lince-Deroche N19 et al 2015 (N = 1202 women)
Cost per pap smear test	300 Rupees	US \$ 130 .63
Cost per VIA Test	30 Rupees	US \$17.05
Cost of true positive cases with pap smear and Colposcopic guided biopsy	10, 200 Rupees	US\$ 38, 915
Cost of true positive cases with VIA and Colposcopic guided biopsy	6930 Rupees	US \$ 4383

Our study was similar to the study done by Lince-Deroche N et al , which concluded that VIA was more cost effective than pap smear .

Conclusion

Cervical cancer is second most commonest cancer among women in India .

Cervical cancer has a precancerous stage and takes long time to progress from precancer stage to cancer stage .

Pap smear has been successfully used as a screening test to prevent cancer cervix in developed countries . Such screening has been less successful in developing countries because of complexities involved with the procedure .

In this study we found that VIA is more sensitive compared to pap smear. It has advantage of being simple , safe , cost effective test .VIA requires less training even health workers can do it . Any screening test which has high sensitivity is good screening test . Hence we recommend the use of VIA as an alternative screening test for diagnosing precancerous lesions of cervix .

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Study on Association between Vitamin D and Essential Hypertension at a Tertiary Care Centre in Udaipur

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Abstract

Introduction: Vitamin-D has very important role in calcium metabolism and optimum bone health. Vitamin-D is derived from endogenous UVB (Ultraviolet-B) which induces vitamin D synthesis in the skin. Currently very high prevalence of vitamin D deficiency in India can be attributed to the lifestyle changes and low sunlight exposure. Identification of the vitamin-D receptor (VDR) in almost every human cells, suggest a role in extra skeletal diseases. Various studies have shown that vitamin D deficiency is an independent risk factor for essential hypertension.

Aim: To evaluate the association between vitamin D and essential hypertension among people coming for out patient department at a tertiary care centre of Udaipur.

Materials and Methods: Study was carried out as a cross sectional study at a tertiary care hospital of Udaipur. Participants (259) were both males and females (134 males and 125 females), between the age group of 20-60 years attending the OPD clinic of our tertiary care hospital.

Statistical Analysis: Appropriate Statistical test was done using latest version of SPSS.

Results: It is found that severe vitamin D deficiency is highly prevalent in people with hypertension as compare to people without hypertension (P value <0.001).

Conclusion: Since India is a tropical country, it was assumed that vitamin D deficiency and its ill effects are less common. But it is found that, vitamin D deficiency is highly prevalent in people with hypertension at Udaipur, attributed to the need of early vitamin D supplementation. Therefore, to reduce cardio-vascular events early identification of vitamin D deficiency and appropriate vitamin D supplement may be of very important in population with high prevalence.

Keywords: Essential Hypertension, OPD (out Patient Department), vitamin D level, vitamin D receptor

Introduction

Vitamin-D deficiency is having very important and of great public health interest in India. Many of the musculo-skeletal disorders are directly associated with vitamin-D deficiency.^[1-3] Vitamin-D supplementation is recommended to prevent rickets and osteoporosis,^[4-6]

Vitamin D has essential role to regulate the bone and mineral metabolism by calcium absorption in gut and providing calcium for mineralization.^[7] Vitamin D receptor (VDRs) are present in all human cells.^[8] Studies have shown association of vitamin D deficiency with a variety of chronic musculoskeletal diseases.^[9-15] Here in our study the aim was find Association between vitamin D and essential hypertension in People approaching to OPD at a tertiary care Centre in Udaipur.

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Association between vitamin D levels and essential hypertension

Vitamin D plays an important role in the pathophysiology of arterial hypertension. Vitamin D receptor knockout mice showed an increased renin expression and arterial hypertension. [16-18] Vitamin D exerts its effect on the renin angiotensin-aldosterone system (RAAS). [18] Increase in PTH levels, a hallmark of vitamin D deficiency, may also increase blood pressure. [19] Studies show a positive association between PTH levels and blood pressure. [19] In the cardiovascular system, PTH receptors are present and PTH infusions increase blood pressure. PTH is therefore an independent risk factor for cardiovascular events. [19] Nephroprotective actions of vitamin D have also been proved. [20] These involve anti-inflammatory actions of vitamin D, by suppressing nuclear factor- κ B (NF- κ B). [20] Increase in sodium intake increases urinary calcium loss, affecting the metabolism of vitamin D. [21] High salt intake can cause adverse effects on vitamin D status and its metabolism, by increased urinary loss of vitamin D metabolites. [21] Calcium is involved in the regulation of peripheral vascular resistance by modulating contractility of vascular smooth muscle cells. Vitamin D has got a direct effect on the vasculature. [22] Antiatherosclerotic effects of VDR activation has been studied. [22] These include vitamin D induced decrease of endothelial adhesion molecules, increase in nitric oxide (NO) production, and inhibition of macrophage to foam cell formation. Relationship between vitamin D deficiency and endothelial dysfunction has been studied. So, several patho physiological mechanisms exist between vitamin D deficiency and arterial hypertension.

Materials and Methods

Study was done as a cross sectional study at a tertiary care center of Udaipur . We have taken 259 participants coming for out patient department of general medicine. were both males and females (134 males and 125 females), between the age group of 20-60 years attending the health check up clinic of our hospital for a period of 4 months. Each subject was interviewed and a standardized questionnaire was computed, containing information on demographics, anthropometric profile, individual characteristics associated with major risk factors for cardiovascular disease, past medical history,

details of sun exposure (type of job and average time of sun exposure in a day), and biochemical parameters. Hypertension was identified from self reports or doctor measurement on the baseline and follow up measures or questionnaires meeting at least one of three JNC8 criteria: systolic blood pressure (SBP) \geq 140 mmHg, diastolic blood pressure (DBP) \geq 90 mmHg, or use of antihypertensive medicines. Incident hypertension was defined as newly developed hypertension among those free of baseline hypertension. The definition of incident hypertension is patient self report or doctor measurement. All participants gave their written informed consent to participate in the study that was approved by the institution ethics committee..

Sample size

A total of 259 patients were selected for the study. Assuming the prevalence of Vitamin D deficiency 60% (P) in *n* population, the sample size was calculated by applying the formula

$$n = Z_{\alpha/2} \times P \times (1 - P) / L^2$$

$$n = 256$$

where $Z_{\alpha} = 1.96$. $P = 60\%$. $L =$ Absolute allowable error (6%).

Considering a 10% attrition rate initially a total of 283 patients were selected by systematic random sampling. Among those attending medicine OPD, every 10th patient was selected as a sample in a specified weekday, every week. Data collection was done from September 2020 to December 2020. Among those selected, 20 were excluded from the study due to calculated GFR <60 ; one having pregnancy induced hypertention and three did not give consent. Hence, the final number of the sample we got 259.

Inclusion criteria

- Age group—20-60 years
- Both Sex- male & female
- Newly diagnosed patients of hypertension or on antihypertensive medications.

Exclusion criteria

- Age group <20 years and >60 years

- People with chronic hepatic, cardiac, renal, gastrointestinal, skeletal, endocrine diseases, diabetes, acute critical illness, and pregnancy
- People on calcium or vitamin D supplementation.

Biochemical Analysis

For assessment of vitamin D levels, 2 ml peripheral venous blood samples were collected from all the participants. Serum was separated by centrifuging at 3,000 rpm for 5 min. Vitamin D remains stable up to 72 hours in room temperature and up to 10 years if stored in -20 degree. The minimal detectable limit of vitamin D assay is 3 ng/ml. Participants were classified as vitamin D deficient, insufficient, and sufficient on the basis of vitamin D concentration of <20 ng/ml, 20-30 ng/ml, and >30 ng/ml, respectively, according to recent consensus. Vitamin D deficiency can be classified as severe (<10 ng/ml) and mild-moderate deficiency (10-20 ng/ml) depending on the vitamin D levels. The quantitative estimation of 25-OHD3 is done using ARCHITECT 25-OH assay, which is a Chemi-luminescent Micro particle Immuno Assay (CMIA). The estimated vitamin D is a sum total of both vitamin D2 and vitamin D3.

Statistical Analysis

Appropriate Statistical analysis was done by using latest SPSS version. For all variables, Chi-square

test was applied to test the relationship between two categorical variables. *P* value of <0.05 were considered as statistically significant.

Results

A total of 259 subjects [134 (51.74%) males and 125 (48.26%) females participated in the study [Figure 1]. 29.83% were below 40 years and 70.17% were above 40 years. Among hypertensive patients, 27.3% (60) were below 40 years and 72.7% (160) were above 40 years [Table 1]. Among total participants (259), 83.4% (216) had vitamin D deficiency, 7.34% (19) had vitamin D Insufficiency, and 9.26 % (24) had vitamin D sufficiency [Table 2]. Prevalence of severe and mild to moderate vit-D deficiency in hypertensive patients were 78.2% (172) and 8.2% (18), respectively. Prevalence of severe and mild-moderate vitamin D deficiency among non hypertensive was 23.1% (9) and 12.9% (5), respectively. Prevalence of vitamin D insufficiency and sufficiency in hypertensive patients were 6.36% (14) and 7.24% (16), respectively. Prevalence of vitamin D insufficiency and sufficiency among non hypertensive were 23.2% (9) and 40.8% (16), respectively (*P* value < 0.001) [Tables 3 and 4]. Among 220 hypertensive patients, mean vitamin D level in people with severe deficiency was 4.48 ± 1.50 and among 39 non hypertensive, mean vitamin D level in people with severe deficiency was 5.56 ± 1.12 (*P* value <0.005) [Table 5].

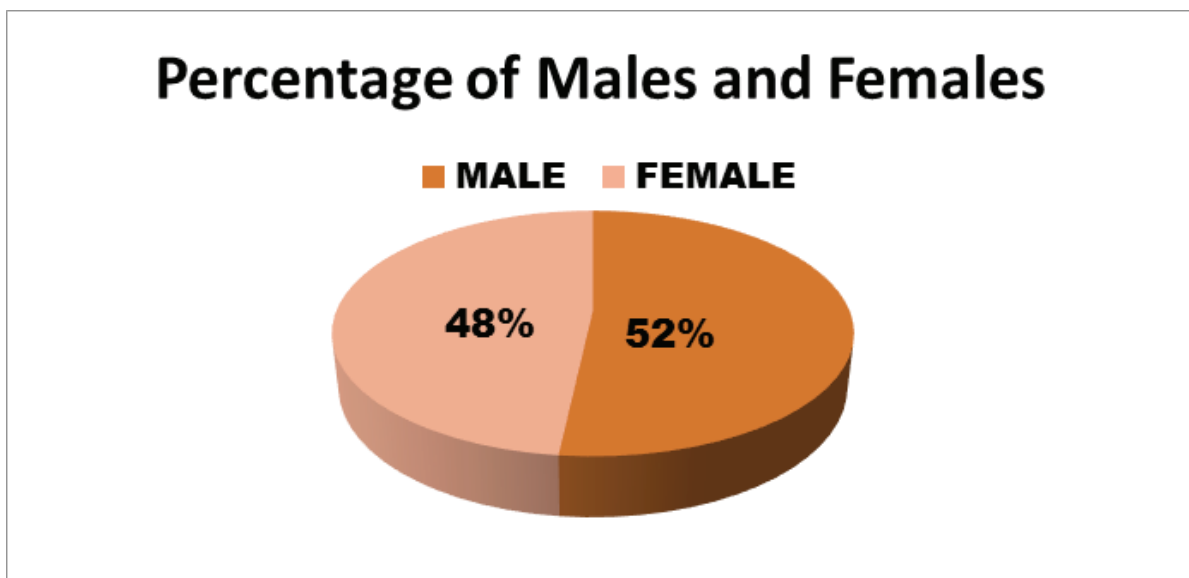


Figure 1: Percentage of males and females

Table 1: Distribution of age category among hypertensive

Age	Frequency	Percent
<=40 years	60	27.3%
>40 years	160	72.7%

Table 2: Prevalence of vitamin D deficiency, insufficiency, and sufficiency

Vitamin D status	Frequency	Percent
Vitamin D deficiency	216	83.4%
Vitamin D Insufficiency	19	7.34%
Vitamin D sufficiency	24	9.26 %

Table 3: Prevalence of severe, mild-moderate vitamin D deficiency, vitamin D insufficiency, and vitamin D sufficiency among hypertensive

Vitamin D status	Frequency	Percent
Severe deficiency	172	78.2%
Mild Moderate deficiency	18	8.2%
Insufficiency	14	6.36%
Sufficiency	16	7.24%

Table 4: Comparison of vitamin D status among hypertensive and non hypertensive

Variable		Vitamin D levels				P
		Severe no. (%)	Mild-mod no. (%)	Insufficiency no. (%)	Sufficiency no. (%)	
HTN	YES (220)	172(78.20%)	18 (8.20%)	14 (6.36%)	16 (7.24%)	<0.001
	NO (39)	9 (23.10%)	5 (12.90%)	9 (23.2%)	16 (40.8%)	

Table 5: Comparison of severe vitamin D deficiency among hypertensive and non hypertensive

Hypertension	Severe vitamin D Deficiency (NO)	Mean±Standard deviation	P
HTN (+)	172	4.42±1.52	<0.005
HTN (-)	9	5.48±1.12	

Discussion

Arterial hypertension is a significant risk factor for cardiovascular disease. The incidence of hypertension is increasing and there is large hypertensive population at risk for cardiovascular morbidity and mortality in India. Recent studies shows that vitamin D plays a key role in parameters that regulate high blood pressure via proliferation of vascular smooth muscle cells, endothelial cell function, regulation of renin-angiotensin pathway, and in regulation of blood pressure via increased intracellular calcium leading to decreased renin activity. In our study, prevalence of hypertension was 84.95%. Prevalence of severe vitamin D deficiency in hypertensives was 78.2%. Prevalence of vitamin D sufficiency in hypertensives was 7.24%. Prevalence of severe vitamin D deficiency in nonhypertensives was 23.1%. Prevalence of vitamin D sufficiency in nonhypertensives was 40.8%. Hypertensives had very low levels of vitamin D compared with nonhypertensives (P value <0.001). A study on 25 hypertensive patients by Duprez *et al.* [23] showed that vitamin D levels inversely associated with SBP. Studies have shown that incidence of hypertension increases with higher latitude. Blood pressure recordings in winter months showed higher values and blood pressure increases by 2.5 mm of Hg, for each 10° North or South shift of the equator, and prevalence of hypertension increases by 2.5%. A study by Tomaschitz A. *et al.*, [24] showed that both 25(OH)D and 1,25(OH)D were inversely associated with plasma renin and angiotensin II concentrations. Retrospective studies have shown a significant inverse association between vitamin D and SBP [24] Prospective study in 1,448 women [25] demonstrated a 2.21-fold increase in hypertension in people with vitamin D deficiency versus

control group. A study comprising of 613 men from health professionals follow-up study and 1,198 women from nurses health study [25] showed that lower serum 25(OH) vitamin D levels of 15 ng/mL (<37 nmol/L) increased the relative risk for hypertension by 6.13 in males and 2.67 in females when compared with vitamin D sufficient population (>75 nmol/L). NHANES 3-Third national health and nutrition examination survey study, a large cross-sectional study involving noninstitutionalized 12,644 patients aged more than 20 years, was used to evaluate the relationship between serum 25(OH) vitamin D and hypertension. The mean blood pressure varied inversely with serum 25(OH) vitamin D levels, with the association remaining significant after adjustment for age, gender, race, ethnicity, and physical activity. Women's health initiative (WHI), the largest trial till date, done on nonhypertensive subjects, failed to show any significant impact of a small dose of vitamin D (400 IU) with calcium 1,000 mg/day on SBP or diastolic blood pressure after a mean follow-up of 7 years in post-menopausal women. In a randomized controlled trial on 148 elderly women, demonstrated that a modest amounts of vitamin D (400 IU) with calcium given over 8 week period, significantly reduced SBP by 9%. A cross-sectional study [26] conducted on 4,125 subjects showed a significant association between vitamin D deficiency and hypertension. In the narrative review conducted by Kheiri *et al.* in 2018, vitamin D deficiency was associated with an increase risk of cardiovascular disease risk factor, especially hypertension In a study conducted by Suzanne E. Judd *et al.* in 2016, there was an increased risk of incident stroke in people with vitamin D deficiency. [27] In a study conducted by Delen and Sahim, vitamin D levels were lower in people with

resistant hypertension. [28] In a prospective study and meta-analysis conducted by Dan *et al.* in 2017, lower levels of vitamin D in people with hypertension were found. As far as India is concerned, India is a vast tropical country extending from 8.4° N latitude to 37.6° N latitude and majority of the population lives in areas with abundant sunlight. Staple diet is rice. Diet is also not rich in vitamin D. This finding of high prevalence correlates very well with other studies done in various parts of the world. There are studies which showed widespread prevalence of vitamin D deficiency in India. Poor sun exposure due to modern lifestyle, vegetarian diet, skin pigmentation, and cultural practices like *parda* and *burka* may be the reasons for this high prevalence in our population. Vitamin D is synthesized when the UV rays from the sun fall on the skin. Till recently, it was believed that Indians had sufficient amount of vitamin D. Since Indians are now confined to more indoor jobs, and thus less sun exposure, most of us are now vitamin D deficient. Absence of sunlight hits production of vitamin D in the body, adversely affecting blood pressure. Salt intake, smoking, obesity, and heredity are now considered as the contributors for HTN. In the coming years, vitamin D deficiency may be included as a fifth contributor for HTN. Early identification of vitamin-D deficiency and appropriate intervention may be of primary importance in a population, especially like ours, having high prevalence, to prevent one of the cardiovascular disease risk factors like hypertension.

Conclusion

We concluded from the present study that there was higher prevalence essential hypertension among people with severe Vitamin-D deficiency. Vitamin-D deficiency was associated with an increased risk of essential hypertension in this demographic group. There is need of awareness of Vitamin D supplementation among individuals with essential hypertension as well as other cardiovascular morbidities.

Ethical Clearance – Taken from ethical committee at tertiary care centre at Udaipur where study was done.

Source of Funding - Self

Conflict of Interest- Nil

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Geomedical Assessment of Areas Having Varying Groundwater Fluoride Levels in Rudraprayag District, Uttarakhand

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Abstract

Background: Fluorosis is a public health problem caused by excess intake of fluoride through drinking water. Groundwater around the rocks composed of fluoride-rich compounds may have a high concentration of fluoride. Thus, analyzing the geology of the area may serve as a guide for easy surveillance of fluorosis disease. **Methods:** The geological maps of the district were analyzed to develop a fluoride risk map for the occurrence of fluorosis i.e., the district was divided into three geological categories; high risk, intermediate, and low-risk areas. This map was correlated to the groundwater fluoride levels and prevalence and severity of dental fluorosis in the population of the corresponding area. A cross-sectional study was conducted using a purposive cluster sampling method, a total of 12 villages were selected from the district. Dental fluorosis was recorded in 558 children and 36 groundwater samples of these villages. **Results:** Fluoride contamination was almost nil (< 0.6ppm) in the areas composed of quartz and limestone which also showed an absence of fluorosis in the dependent population. It was moderate (0.6-1.5ppm) in areas of augen gneiss, porphyritic gneiss with mica schist which showed around 59.9% prevalence of fluorosis. Whereas, heavy contamination of fluoride (> 1.5ppm) was seen where granite was the main soil-forming parent rock and around 93% of the related population was affected by fluorosis. **Conclusions:** This study confirms the positive association between the presence of fluoride-rich rocks around the water source and the prevalence of fluorosis in the population of the area. Based on the finding of this study, geological maps of each district of the state may help in indicating the higher chances of occurrence of fluorosis in the respective districts.

Keywords: Fluorosis, Geology, Geomedical assessment, Community Fluorosis Index

Introduction

Fluorine is a trace element in the Earth's crust, constituting about 0.06–0.09 % of it. The concentration of fluoride in the ground principally depends on the geology of the area.⁽¹⁾ It occurs in combined form in rocks and soil. There are certain types of rocks like

the alkalic rocks (1000 ppm), rapakivi granites (2680 ppm), phenolites (930 ppm), granites and granodiorites (810 ppm), and shales (800 ppm) which are known to have a higher amount of fluoride in comparison to other rocks like limestone (220ppm), dolomite (260ppm) and sandstone (180ppm).⁽²⁾ Both surface and groundwater may have high fluoride concentration in a particular area, but the magnitude is often higher in groundwater than the surface water. When groundwater percolates through rocks composed of fluoride-rich compounds, fluoride leaches out and its concentration in water may increase above the safe level.⁽³⁾ Thus, the geology of an area may be related to fluoride concentration in groundwater of that area.

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Fluoride is considered to be caries protective and has an important role for growth, provided it is taken in optimal amount. If drinking water has fluoride concentration above 1mg/l, it shows many deleterious effects on human health causing dental, skeletal and, non-skeletal fluorosis.⁽⁴⁾ Fluorosis is a public health problem caused by excess intake of fluoride predominantly through drinking water over a long period of time. Dental fluorosis is characterized by staining and pitting of teeth and in more severe cases brown discoloration and, disfigurement of teeth presenting a corroded-looking appearance.⁽⁵⁾ Skeletal fluorosis causes pain and damage to bone and joints, which may go on to cause severe disability and handicap.

Fluorosis is one of the major public health problems in India impacting two-third of the states of the country and influencing the life of around 60 million people nationwide.⁽⁶⁾ A national program for the prevention and control of fluorosis was started in 2009. Over the years, the program has covered nearly 200 districts in 17 states with increased diagnostic activities, treatment, and rehabilitation at a village level. Even now, continuous identification of additional habitations affected by groundwater fluoride is in progress.

Uttarakhand is a state in northern India with difficult geographical terrain and climatic conditions. There are a total of 13 districts, Rudraprayag is situated in the upper Himalayan region of the state. Most of the population in this district resides in villages with scarce education, health, and livelihood facilities. For improving the health status of the population, and building good quality healthcare services in the state, it is important to know the current status of various diseases and their determinants, which is still lacking in the state, especially in geographically difficult terrains. Due to the aforementioned scenario, till date problem of fluorosis has not been recognized in the state. Although the central water board report of 2009 stated high fluoride concentration, more than the permissible limit of 1.5 mg/l in some parts of Rudraprayag district.⁽⁷⁾

Medical Geology can be defined as the branch of geology dealing with the relationship between natural geological aspects and health in organisms, trying to determine the influence of ordinary environmental factors on the geographical distribution of health issues.

⁽⁸⁾The geological analysis of a state may serve as a guide for easy surveillance of fluorosis disease. Hence considering the above issues, this research paper aims at presenting the analysis of the fluoride water concentration and the geological conditions of the selected areas and to analyze the association between community fluoride index and geology of the area around their drinking water source. This analysis may provide a guidance for researchers and decision-makers to start surveillance in other possibly affected areas.

Materials and Methods

Rudraprayag district lies in the northwest direction in Uttarakhand state within the Himalayan ranges. It covers an area of 2,252 sq. km and the average elevation ranges from 800 to 8000 m above the mean sea level.⁽⁹⁾ The total population of the district is around 242,285. Alaknanda and Mandakini are the two main rivers in the district. Groundwater mainly occurs in form of natural springs which may be perennial or seasonal and few wells and, handpumps can be seen in some villages of the district.

The geology and geomorphology map of the Rudraprayag district was digitized and prepared using the map of the district published by the Geological Survey of India (GSI). These maps were effectively analyzed to develop a fluoride risk map of the district for fluorosis i.e., certain lithologies would map as high risk, others intermediate, and another low risk. So, the district was divided into three geological categories:

1. *High-risk area*: main rock types were Granites and granodiorites, where high water fluoride level and high prevalence of fluorosis was indicated
2. *Intermediate risk area*: main rock types were granitic gneiss, augen gneiss and, garnet mica schist
3. *Low-risk area*: main rock type limestone and quartz, where low fluoride concentration in water and absence of fluorosis was indicated

A cross-sectional study was conducted in Rudraprayag district, using a purposive cluster sampling method, 4 villages were randomly selected from each geological category area. So, a total of 12 villages was selected from the district (Figure 1). This map was correlated to the groundwater fluoride data

and prevalence and severity of dental fluorosis in the population of the corresponding area.

Fluoride level assessment in groundwater:

Groundwater samples (36) were collected to explore the geochemical relationship between groundwater and local geology and to test our hypothesized geological control. Water samples were collected randomly from 3 different water sources in each selected village. Samples were transported and stored at 4°C till analysis. The concentrations of F⁻ [mg/L] were measured by the ion-selective electrode (Orion company A324pH benchtop model) using the EPA-approved ISE test procedures.

Dental fluorosis assessment in population:

Children belonging to age 6-19 years, who were residents of selected villages in their first 8 years of life were enrolled for the study. Door to door survey was done, every house of the village was visited and one eldest child in each house was included in the study. Thus, a total of 558 children was examined and dental fluorosis was recorded using the Deans Fluorosis Index (DI). The clinical examination of children was done in the presence of parents/guardians. Consent was taken from the parents/guardians of the children after explaining the procedure and importance of the study.

Results

The district has hilly terrain characterized by moderate to steep slopes that are intervened by narrow valleys. The topography of the region appears to be controlled by structural and lithological factors. Rudraprayag district comprises diverse rock types ranging in age from Palaeoproterozoic to Mesoproterozoic age.⁽¹⁰⁾ Two rock sequences are observed in the district namely

1. Lesser Himalayas- rock sequence between North Almora Thrust and Main Central Thrust
2. Higher Himalayas- rock sequence north to the Main Central Thrust

The geological map of the district shows, that in the higher Himalayas central crystalline rocks comprise of low, medium, and high-grade rocks that have been intruded by both acidic and basic rocks. The main rock types present in this area were granitic gneiss, augen gneiss, garnet mica schist, calc zone, and amphibolites.

⁽¹¹⁾ These areas were included in the *Intermediate-risk category*.

The rocks of the lesser Himalayas consist of low-grade metasediments. The major proportion of district population residences in this area. Main rocks observed in the area include phyllite, quartzite, limestone, slate, granite, and meta basics. Among them, limestone and quartz rocks were the most widespread. Villages in this part of the district constituted a *Low-risk category*. But in some pockets, this area has been intruded by granite e.g., area around the villages Chinka and Toneta. Here Granite 500 is the parent rock, forming soil and lithology of the area. And the granite in Toneta is of tourmaline variety which was at place chlorite rich also.^(12,13) The villages in these areas constitute *High-risk areas*.

The tectonics of the area has a substantial impact in enhancing the fluoride concentration in water. The groundwater zones with high fluoride concentration are mostly associated with some kind of tectonic zones. Rudraprayag is tectonically composed of Garhwal and the central crystalline geological units. These are geological units are unstable showing frequent movements leading to frequent landslides and earthquakes too. The rocks in the district have been originated through various phases of geotectonic movements and evidenced by faults, folds, thrusts, and lineaments. Such weathering of rocks has a significant influence in increasing fluoride leaching to groundwater.

Geological pattern and fluorosis

In the district groundwater is the prime source of drinking water which mostly occurs as localized, disconnected bodies such as natural springs (46.71%). Other 45% of the population caters its water requirements through the river and its streams, and seasonal local water bodies (commonly called Gadera). Fluoride contamination was commonly observed in the springs situated in areas of fluoride-rich rocks. The concentration of fluoride in the groundwater samples of the district ranged from 0.03 to 2.03 mg/l with an average of 0.55 mg/l. High concentrations of naturally occurring fluoride in the groundwater in some areas of the district make it inappropriate for drinking and there is no alternative source of drinking water available, hence severe dental fluorosis hazards prevalent in these areas.

The study shows that fluoride concentration in drinking water showed a positive association with the prevalence of dental fluorosis in the population. In the places, with <0.7mg/L fluoride in drinking water only 1% of children were affected by fluorosis, whereas at >1mg/L fluoride about 92% of children suffered from dental fluorosis ($p < 0.001$) (table.1).

There was a close correlation between the geology of the district with prevalence and, the severity of fluorosis in the corresponding population.

The villages with the low-level of fluoride in water (< 0.6ppm) were mostly observed in the areas of rocks composed of quartz and limestone (*the low-risk area*). The population around this area showed an absence of fluorosis.

The villages in which moderate water fluoride level (0.6-1.5ppm) was observed, were mostly located in Higher Himalayas and the rocks observed in this area were granite gneiss, augen gneiss, and porphyritic gneiss with mica schist (*intermediate risk area*). This part of the district showed around 59.9% prevalence of fluorosis with only 3.2% children affected by severe grade fluorosis DI(5). The mean community fluorosis index of these areas was 1.05 (Table.2).

Whereas, heavy contamination of fluoride (> 1.5ppm) was seen in the areas where granite was the main soil-forming parent rock-like in Toneta and around Chinka (*high-risk area*). Moreover, a major part of the population (93%) residing in this area was affected by fluorosis with around 25.9% of children affected by severe DI(5) grade fluorosis (Table.3). And community fluorosis index for these villages reached up to 2.59.

Discussion

The level of chemical contamination of the groundwater is mainly dependent on the geochemistry of rock and soil through which water flows while reaching the aquifers. The main domestic water source in the hilly area were springs. They are the highly weathered and immensely fractured geological system that allows a rapid transit of water through them under gravitational force. Thus, fluoride contamination was commonly observed in the water from the springs situated in areas of fluoride-rich rocks. The study shows that fluoride

contamination was almost nil in the areas composed of quartz and limestone, moderate around porphyritic gneiss with mica schist and granite.⁽¹⁴⁾ Whereas, heavy contamination of fluoride was seen where granite was the main soil-forming parent rock. Moreover, the presence of anion like chlorite further increases fluoride concentration in water as observed in Toneta.⁽¹⁵⁾

Similar results were observed in studies in other parts of the world, a study in Iran⁽¹⁶⁾ also signified that water-rock interaction and influence of clay minerals is a geochemical mechanism responsible for fluoride augmentation in groundwater. Other studies, in Ghana⁽¹⁷⁾, Pakistan and even in eastern parts of India⁽¹⁸⁾ underlined that the high fluoride-prone areas were located in close vicinity of granitic rocks and as the distance increases fluoride level in water decrease. According to a recent review, granites and gneisses are the main sources of fluoride in groundwater in India. It reveals that the lithology and geology of the aquifer that holds groundwater in the subsurface is the governing factor leading to groundwater fluoride contamination.

In a study conducted in Turkey⁽¹⁹⁾, the geo-medical map was prepared that demonstrated that medical and hydrogeological evidence were compatible with each other. It can be seen clearly from the map that the high prevalence of fluorosis among the population overlaps strongly with regions where the water fluoride concentrations were high and there was geological evidence of fluoride-rich rocks. Another study was done by Shekhar⁽¹⁵⁾ in the Palau district of Jharkhand also signified the contribution of geo-medical maps for indication of the occurrence of fluorosis.

The Community Fluorosis Index (CFI) is a mode of measuring the burden of dental fluorosis in a population. Instead of just measuring the overall prevalence of fluorosis (i.e. percentage of people who have fluorosis), it takes into consideration the severity of the fluorosis that is occurring in the population. The study shows that the highest CFI is recorded in the area where fluoride-rich rocks like granite were present around the water source whereas low CFI was recorded in the area composed of limestone and quartz-type rocks. Increased severity of fluorosis can also be observed from the increased proportion of children affected by the severe grade of fluorosis in high-risk areas of the district. Thus, in areas

where granite-type rocks were the main geological component both, the prevalence and severity of fluorosis were high.

To determine the severity of dental fluorosis as a public health problem, Dean categorized the community fluorosis index (CFI). When the CFI index was <0.4 Dean considered it of little or *no public health concern*. In areas of the district with rocks like quartz and limestone fluorosis is not of public health concern. Whereas in areas of granitic, gneiss, augen gneiss, garnet mica schist rocks, it is of *medium public health concerns*, CFI index between 1 to 2. But, in areas with granite rocks, it is a *notable public health issue* with a CFI index of more than 2.

The population clusters selected in the study belonged to almost the same cultural and ethnic group. Thus, their life-style habits, food habits, and socioeconomic status were also similar. But these clusters were residing at different elevation levels. Earlier studies have revealed a positive correlation between fluorosis and altitude. (20) The results of this study also indicate a relationship between altitude and fluorosis. It was reported that at a fluoride concentration of around 0.8ppm, 66% of the children at a height of 1467m suffered from dental fluorosis, as compared to 71.2% living at a height of 1800m. Moreover, a similar prevalence (95%) of dental fluorosis was seen in the cluster with a fluoride water concentration of 1ppm at 2392m elevation and the cluster with a fluoride concentration of 2 ppm at 1061m elevation, showing that more children were affected by fluorosis at higher altitude even at less water fluoride concentration.

One limitation of the study is that there should be a complete chemical analysis of water to observe the influence of pH, temperature, and presence of other ions on the level of fluoride leaching from the rocks to groundwater. The analysis of the corresponding soil in the area may also help in generating better geological maps of the area. To further confirm the results of this study it should be done in a large area.

Recommendations:

Through the guidance of geological maps, in regions where such problems occur or are likely to occur, the drinking water should be analyzed by a portable fluoride-

meter device before fluorosis diagnosis. Along with this, governments should encourage that the drawing of such multi-thematic maps which can be used to predict the possible negative effects of natural resources on human health and biological life becomes part of the development and health policy of the state.

Further studies can be carried out by colleagues, related to this issue by increasing the scope of the medical geology map presented in this study as well as by including other variables also that can be beneficial in the short, medium, and long-term policy making against this disease.

Conclusions

This study confirms the positive association between the presence of fluoride-rich rocks around the water source and the prevalence of fluorosis in the population of the area. Furthermore, based on the finding of this study, geological maps of each district of the state may help in indicating the higher chances of occurrence of fluorosis in the respective districts.

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Japanese Encephalitis and Other Acute Encephalitis Syndrome in the Khurda, Odisha, India

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Abstract

Background: Japanese Encephalitis (JE) is caused by Japanese encephalitis virus (JEV), a mosquito-borne flavivirus (family *Flaviviridae*, genus *Flavivirus*). In India a large number (10-15%) of cases of Acute Encephalitis Syndrome (AES) is due to Japanese encephalitis with a case fatality rate of 18%. In Odisha, sporadic cases of JE/AES cases have been reported since 2011. A case-control study was conducted in Khurda district of Odisha to assess the burden of Japanese encephalitis and the associated risk factors.

Methods: A probable case of AES/JE is defined as any child of 0-15 year age with onset of illness between September 1-December 31, 2017, residing in the Khurda district of Odisha, presenting with an “acute onset of fever, change in mental status (such as confusion, disorientation, delirium or coma) and/ or new onset of seizures”.. A 1 to 2 age matched case-control study was conducted. Data was analysed using SPSS version 15.0.

Results: We enrolled 13 cases and 26 controls between September 1-December 31, 2017. People living in close proximity to the agricultural fields (OR:15.63) rearing livestock at their house and having animal shed at proximity (OR:3.02 and 6.57 respectively) are at higher risk of getting the disease. Presence of waterbodies within 200-meter distance of the household (OR: 9.05) and stagnant water in the surrounding of the houses (OR: 12.38) were at higher risk of getting AES/JE. People using peri-domestic space for toilet (OR: 3.6) and having Practice of open air defecation (OR: 12.38) were are at higher risk of getting the disease.

Conclusion: Improvement of water and sanitation practices among the community by empowering the village water hygiene and sanitation committee and village gram panchayat. That will also involve building of toilets in the houses. Vector control activities like insecticide fogging, IRS spraying and distribution of long lasting insecticide treated nets are to be taken into consideration, especially in the rural parts of the district where it is not done regularly. Vaccination coverage of Japanese Encephalitis vaccine is to be increased.

Key Words: *Japanese Encephalitis, Acute Encephalitic Syndrome, Risk factor*

Background

Japanese Encephalitis (JE) is caused by a mosquito-borne flavivirus (family *Flaviviridae*, genus *Flavivirus*), which is related to dengue and West Nile viruses and found across most of south and East Asia. It contributes to with an estimated 30 000–50 000 cases and 10 000–15 000 deaths annually worldwide.¹ In India a large number (10-15%) of cases of Acute Encephalitis Syndrome is

due to Japanese encephalitis.² Clinically cases of JE are presented with high grade fever, altered sensorium, seizure, headache and vomiting.³ Case Fatality Rate due to JE can be up to 18%.⁴

According to World Health Organisation, in the South-East Asia, 24 countries along with the Western Pacific regions are endemic to JEV transmission, exposing more than 3 billion people to risks of infection.⁵

The National Vector-borne Disease Control Program (NVBDCP), India has reported >60,000 cases of acute encephalitis syndrome (AES) across the country in 2010–2016. In India, 8 states including Assam, UttarPradesh, WestBengal, Odisha, TamilNadu, Karnataka, Manipur, and Tripura accounted has historically reported JE/AES cases.⁹ In 2014, the total numbers of AES cases and deaths reported were 10,853 and 1717 respectively and JE alone contributed to 1657 (~15%) cases and 293 (~17%) deaths respectively across the country.¹⁰

In Odisha, sporadic cases of JE/AES cases have been reported since 2011 from certain districts. In 2015 during September to November, a viral encephalitis epidemic among children was reported from Mayurbhanj district, Odisha.¹¹

Methods

Review of Records

The study was conducted from January-June, 2018 in Khurda district, Odisha. First the Line-listing was collected from State VBDCP, Odisha,. After removing those not falling into inclusion criteria, final list was prepared. From the line listing the addresses of cases were used to locate them in different parts of the district.

Case Definition

A probable case of AES/JE is defined as an individual with onset of illness between September

1-December 31, 2017, residing in the Khurda district of Odisha, presenting with an “acute onset of fever, change in mental status (such as confusion, disorientation, delirium or coma) and/ or new onset of seizures”. The age group from 0-15 years was included.

Case Control Study

A case-control study was conducted, where the controls were age matched from the same locality of cases between September 1-December 31, 2017 without any signs and symptoms of JE/AES. Cases and Controls were selected in a time frame from September 1-December 31, 2017 to avoid recall bias. The field visits were conducted in co-ordination with the Multi purpose health worker (MPHW) under State VBDCP, Odisha. The MPHWS of that area were informed beforehand of the visit. Household of each case and control were visited by the Investigator. Maximum three attempts were done for each household; in case of non-availability of the respondent. After taking written informed consent from each respondent, a pre-structured questionnaire was administered by the investigator. Demographic table was used to describe categorical variables in terms of frequency and percentage and Odds ratio was used to explain the relevant risk factor of the disease. Data analysis was done using SPSS software of statistics version 15.0.

Results

Table 1 Distribution of Cases according to demographic profile (n=13).

Variable	Categories	Frequency	Percentage (%)
Gender	Male	7	53.84
	Female	6	46.15

Table 1 shows among 13 cases; 53.84% cases were male and 46.15% were female.

Table 2 Mean age among the cases.

Age of the cases in terms of completed years	
Mean age	4.283

Table 2 shows the mean age of the enrolled cases was 4.283 years.

Total population of the district Khurda = 2,251,673¹²

Children in the age group of 0-15 years constitute 24.6% of the total population.¹³

Incidence of cases of JE/AES between 1st of September to 31st of December was 29.

Taking the average, approximate incidence per year is 87.

Population 0-15 years = 2251673*24.6 = 553,911.55

100

So, the burden of the disease was calculated to be **15.7 cases per lakh per year.**

Table 3 Occurrence of symptoms among the cases.

Symptoms	Frequency	Percentage (%)
Fever	13	100
Loss of consciousness	10	76.9
Rolling Of eye ball	12	92.3
Stiffness of neck	2	15.3
Vomiting	12	92.3
Cough	3	23
Abdominal Discomfort	2	15.3

Table 3 shows symptoms like fever (100%), loss of consciousness (76.9%), rolling of eyeball (92.3%), stiffness of neck (15.3%), vomiting (92.3%), cough (23%), abdominal discomfort (15.3%) were prevalent among the cases.

Table 4 Impact of housing on Acute Encephalitis Syndrome or Japanese Encephalitis

Risk Factors	Case	Control	Odds Ratio	P value
People have house at the periphery of town or village	6	2	10.29	0.005
People not having toilet in their house	5	3	4.79	0.04

Table 4 shows people having houses at the periphery of the town or village were 10.29 times at higher risk of AES/JE and People not having toilet in their houses were 4.79 times at higher risk of getting the disease.

Table 5 Impact of various environmental factor on Acute Encephalitis Syndrome or Japanese Encephalitis.

RISK FACTORS	CASE	CONTROL	ODDS RATIO	P VALUE
People living in houses surrounded by peri-urban shrubbery	8	10	2.5	0.17
People living in proximity to agricultural fields (<100 meters)	5	8	15.63	0.004
People having livestock at the house	8	9	3.02	0.1
People having animal shed with in<10meters of the house	6	3	6.57	0.015
People having water bodies within 200 meters from their houses	10	7	9.05	0.002
People having stagnant water in the surrounding of the house	9	4	12.38	0.0007

Table 5 shows different environmental risk factors associated with AES/JE. People living in houses surrounded by peri-urban shrubbery were at 2.5 times higher risk of AES/JE. People living in close proximity to the agricultural fields i.e. <100 meters distance were at 15.63 times higher risk of AES/JE. People rearing livestock at their house and people having animal shed at <10-meter distance from their houses were at 3.02 and 6.57 times higher risk of getting the disease respectively.

Presence of waterbodies within 200-meter distance of the household increased the risk of getting the disease by 9.05 times.

People stagnant water in the surrounding of their houses were at 12.38 times higher risk of getting AES/JE. People living in proximity to the waterbodies cover by Water hyacinth and other floating weeds were at 5.33 times higher risk of getting AES/JE.

Table 6 Impact of various water and sanitation practices on Acute Encephalitis Syndrome or Japanese Encephalitis.

RISK FACTORS	CASE	CONTROL	ODDS RATIO	P VALUE
People drinking water without any treatment	7	5	4.90	0.02
People using peri-domestic space for toilet	6	5	3.6	0.07
People having Practice of open air defecation	9	4	12.38	0.0007

People lacking water sanitation or drinking water without any pre-treatment are at 4.9 times higher risk of getting the disease. People using peri-domestic space for toilet and having Practice of open air defecation are at 3.6 and 12.38 times higher risk of getting the disease respectively.

Table 7 Impact of Vector factor on causal of Acute Encephalitis Syndrome or Japanese Encephalitis.

RISK FACTORS	CASE	CONTROL	ODDS RATIO	P VALUE
People living in houses where mosquitos were seen during the day time	12	10	19.20	0.001
Presence of sand fly around the house	5	1	15.63	0.004
People having Rodents inside or around the house	12	11	16.36	0.002
People those never have IRS sprayed inside or around the house	12	13	12	0.009

Table 7 shows People living in houses where mosquitos were seen during the day time are at 19.20 times higher risk of getting the disease. Presence of sand fly around the house and Rodents inside or around the house increases chances of getting the disease by an odds ratio of 15.63 and 16.36 respectively. People those never have IRS sprayed inside or around the house are at 12 times higher risk of getting the disease.

Discussion

This study was conducted to estimate the burden of JE/AES and various risk factors associated with the disease in the district Khurda, Odisha. 13 cases were enrolled in the study, among them 53.84% were male and 46.15% were female, belonging to different blocks of Khurda including urban and rural area. Mean age of the cases was 4.28 years. According to census 2011, Population of Khurda district is 2,246,341. 24.6% of the population is between ages 0-15 years. So, the burden of JE/AES is 16 cases per lakh per year. (12) Symptoms like fever (100%), loss of consciousness (76.9%), rolling of eyeballs (92.3), stiffness of neck (15.3%), vomiting (92.3%), cough (23%) and abdominal discomfort (15.3%) was reported among the cases.

A total 13 cases and 26 matched controls from nearby locality were enrolled in the study. Odds ratio was calculated for each anticipated risk factor keeping

the CI 95%. P value < 0.05 was considered significant. Environmental factors like vegetation, distance from agricultural field, socio-economic factors like housing, water and sanitation, sanitation practices and entomological factors like mosquito breeding sight, mosquito density are taken into account. Also, emphasis was given on type of animal rearing, proximity of the inhabitant to animal sheds.

Japanese Encephalitis virus exist in zoonotic transmission cycle. *Culex tritaeniorhynchus* mosquito acts as the vector for the disease. Pigs, water birds and other animals serve as amplifying host. It is transmitted to human by accidental mosquito bite during the blood meal.⁶Khurda is a district where farming and livestock are the major livelihood in the rural area. The average temperature of the district is 27.4 degree centigrade with a humid climate throughout the year. Cultivation chiefly consists of rice followed by vegetables. Livestock as livelihood chiefly consists of cattle, goats, sheep, pigs, poultry and ducks. The study showed People living in close proximity to the agricultural fields and rearing livestock at their house or having animal shed at close proximity(<10metres) to their houses were at higher risk of getting the disease. Different studies have shown, Paddy fields and irrigated lands are favourable for the vector growth. Close inhabitant to the paddy field and piggery are at higher risk of getting infected with the virus.⁶It has been seen JE transmission is not only

prevalent in rural settings but also in peri-urban areas.¹⁶ It has been seen that the People living in houses at the periphery of the town or village were at higher risk of JE/AES with an odds ratio of 10.29.

The study showed People living in houses where mosquitos were seen during the day time are at higher risk of getting the disease. In optimum temperature, humidity and environment the mosquito density can raise up to four folds. In India, it is being observed that *Culex. tritaeniorhynchus* feed on cattle, between 85% and 98% and <10% on pigs.⁷ So the cattle- pig ratio is high which indirectly plays a role to reduce the incidence of the disease as cattle is a dead-end host for JE virus. Though the vector here is exophilic in nature, during the peak season the high rate of multiplication of the vector can increase the density inside the house too. Also keeping the animal shelter in proximity to human dwelling increases the chances of man-vector interface.⁸ It has been seen that abundance of animal has played a key role in high incidence of JE in peri-urban areas.¹⁶

In many studies it is found that water bodies near to human habitant and presence of stagnant water acts as vector breeding sites. (14,15) It was observed that houses of the cases were nearest to water bodies like ponds, ditched, pool, canals. Presence of waterbodies within 200-meter distance of the household increased the risk of getting the disease by 9.05 times. It was found people having stagnant water in the surrounding of their houses were at 12.38 times higher risk of getting JE/AES.

Accidental Finding

There were four cases of laboratory confirmed Scrub typhus among the AES cases. This might have contributed to a higher odds ratio of 16.23 to the presence of rodents inside or outside the house. But this was beyond the scope of the study and this needs further investigation to establish any fact.

Limitation:

But the study has few limitations as there is a time gap between the incidence of cases and the interview, that might have caused recall bias. In the study pre-structured questionnaire was used, that provided limited options for participants to answer.

Conclusion

Rice field, leafy cultivation, irrigated fields are considered to be favourable sites for breeding of *Culex tritaeniorhynchus* mosquito. Waterbodies are home to various water birds. Animals, pigs and water birds acts as amplifying host of the disease which can contribute to maintaining of transmission chain. Proximity of the house to the agricultural fields, waterbodies and animal dwellings increases the chances of the disease significantly among the people living in them. Poor vector control such as lack of IRS spaying inside or outside the house was seen to cause with increased risk of getting the disease, as mosquito net use was ubiquitous among the cases. Various campaigning can be organized to strengthen the awareness regarding Acute Encephalitis Syndrome and JE among the high-risk population. Improvement of water and sanitation practices among the community by empowering the village water hygiene and sanitation committee and village gram panchayat. That will also involve building of toilets in the houses. Vector control activities like insecticide fogging, IRS spraying and distribution of Long lasting insecticide treated nets are to be taken into consideration, especially in the rural parts of the district where it is not done regularly. Vaccination coverage of Japanese Encephalitis vaccine is to be increased.

Ethical Clearance- Taken from Institutional Ethics Committee.

Source of Funding- Self Funded

Conflict of Interest - Nil

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Gauging of Social Media Usage and Its Impact on Social Media Consumers: A Survey Study with Reference to Pandemic Disease Covid-19 in India

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Abstract

Background: Information and news reports on coronavirus disease (COVID-19) were published in the first few months of 2020. Quickly published and shared on social media and social networking sites. There is limited evidence, however, as to whether and how social media has been used and impact on social media consumers.

Aim: This study aims to assess the usage of social media and its impact on social media consumers during pandemic disease covid-19 in India.

Methods: An online questionnaire was prepared and conducted to study in India with a total of 210 social media consumers. This study used a Quantitative data analysis method. As a result, data were analysed using Microsoft Office Excel.

Results: Participants showed that Social media play an important role to deal with the pandemic disease. Whatsapp and Instagram were the most used social media platform for getting and sharing information about covid-19. We found a weak statistical correlation between social media impact on frequently usage of social media during covid-19 ($R=0.215825619$). Social media had equally impacted on gender group during the Covid-19 situation in India.

Conclusions: During Covid-19 Pandemic, people are using social media platforms to get and share information about Covid-19. Social media has no negative impact on social media consumers. Social media has an important role to deal with Pandemic disease conditions in India.

Keywords: Social media, Covid-19, Usage, Attitude, Impact

Introduction

In December 2019, there occurred a novel coronavirus (coronavirus disease 2019 [COVID-19])

outbreak in Wuhan, China, which rapidly spread worldwide. The outbreak was declared as “a public health emergency of international concern” by the WHO on January 30, 2020, and as a pandemic on March 11, 2020.^[1] The first case of COVID-19 in India was reported on January 30, 2020, with origin from China. As of October 16, 2020, there are 8,04,528 active cases in India with 1,12,161 deaths.^[2] In Gujarat, there are currently 14,782 active cases (till October 15, 2020) with 3,606 deaths as reported by the Ministry of Health and Family Welfare Department of Gujarat.^[3] During sudden outbreaks, the

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public needs access to timely and reliable information about the disease symptoms and its prevention.^[4] There is an ongoing increase in the use of social media globally, including in healthcare contexts.^[5] Nowadays, social media are often seen as fast and effective platforms for searching, sharing, and disseminating health information among the general population.^[6] The use of social media is prevalent across all ages and professions and is pervasive worldwide. Across India, there are 687.6 million internet users in India (till January 2020). There are 400 million social media users in India, The number of social media users in India increased by 130 million (+48%) between April 2019 and January 2020.^[7] Of all the social media available in India, the most popular social networking sites are YouTube and Facebook followed by What's App, Instagram, Twitter, and LinkedIn.^[8] In the environment in which people are born, live, study, work, play, worship, and age are social determinants of health, which are the factors that influence a wide variety of health outcomes, risks, and overall quality of life.^[9] Based on these determinants health care organizations and public health professionals enormously used social media for health guidance and any disease prevention. Several hospitals, medical practitioners, and health agencies have opened Youtube, Facebook, and Twitter pages to get access to their patients.^[10] An increase in health literacy has benefits such as the adoption of disease prevention methods and adherence to and understanding of treatments leading to improved health. Health literacy enables through a medium like newspapers, magazines, blogs, apps, social media and more can all be utilized to promote content related to general well-being as well as disease-specific guidelines gaining momentum in India.^[11]

At this time, when no other ways available to cure or manage Covid-19 other than social distances and public health awareness.^[12] Social media has become a strong platform for spreading public health awareness and advocacy regarding public health issues.^[13] Social networking sites serve as a way for disaster management, outbreak prevention, and emergency response staff to easily communicate and access critical information collected by organizations like the WHO and the Centre for Disease Control.^[14] A study shows that in 2016, when the WHO declared Zika virus as a danger to the world, social media monitoring and prevention awareness messages played a lifesaving role in enhancing risk

control and disease management.^[15] Studies reported that peers are one of the most important sources of information that influences one's actions and decisions when facing a health matter.^[16] July 2020 saw a rise of 10.5% in social media usage, compared with July 2019, according to a GlobalWebIndex survey. Some 46% of women and 41% of men said they've spent more time on social media during the pandemic, making it the second-most popular digital activity.^[17] With limited activity out of home, Indians are reportedly reading, contributing, and influencing on social media. According to Nielsen, the total volume of Covid-19 related conversations reached 22.3 million on March 24 in the country.^[18] However, Social media (e.g. Facebook, Twitter, and Instagram, etc.) had been recognized as an important strategy for health-promoting practice in public health. While social media use is widespread in the general population, but little is known about the effect of social media use on health promotion during the pandemic outbreaks.^[19] Hence, the present study was planned with the objective of assessing social media usage and its impact on social media consumers during pandemic Covid-19. This is important to establish whether social media improves preventive behaviours of social media consumers during covid-19.

Methods

In this study, we used a quantitative survey methodology to obtain data from Social media users in India. The online questionnaire was prepared in the English language and 210 social media users were sampled to collect the data. Quantitative data analysis was used to analyze the data. Microsoft office excel was used to categorize and test the results. The social media users participated in a random, which aimed to determine social media usage and its impact on social media consumers during the Covid-19 outbreak worldwide.

Results

The study shows [Table 1], that out of 210 participants, 179 participants had used social media for updating the information about the Covid-19 outbreak, 64 participants had used social media for sharing information about covid-19, 9 participants had not used social media for update and sharing information of Covid-19. 143 participants had used social media for getting information about preventive measures of

covid-19, 109 participants had used social media for sharing preventive measures information of Covid-19, 149 participants had used social media for getting information related to immunity promoting measures for self-care during Covid-19, 87 participants had used social media for sharing information related to immunity promoting measures of Covid-19, 149 participants had used social media for getting information of Lifestyle changing measures during Covid-19, 81 participants had used social media for sharing information of style changing measures during Covid-19. 120 participants had used social media for getting information about the supportive line of treatment used in Covid-19, 59 participants had used social media for sharing information about the supportive line of treatment used in Covid-19. Social media consumers had used Social media majorly for updating and sharing information related to the covid-19 outbreak as well as promoting health behavior changes to deal with the covid-19 outbreak.

According to the results shown in [Figure 1], the majority of participants (n=88, 41.9%) had used Social media platforms one time a day to get the update of Covid-19, while few participants (n=58, 27.6%) had used Social media platform two times in a day. Social media consumers have frequently used Social media platforms to get the update of covid-19 in India.

The study revealed in [Figure 2] shows that 27.1% of the participants were think that social media platforms were played extremely important roles in Covid-19. 40.5% of participants feel social media have a fairly important role to deal with Covid-19. 24.3% of participants saw Social media had a somewhat important role in Covid-19. 5.7% of participants thought that social media had the least important role in Covid-19. The majority of Social media consumers were on the opinion

of Social media were play an important role to deal with pandemic disease conditions in India.

[Table 2] illustrates that responses to the question “How your habits and routines (Life) have got affected due to social media usage during Covid-19?”, out of 210 participants, the majority of Social media consumers shown some extent changes in their Hygiene, Exercise, and Food habits as well as mental health, health information, social networking, and social relationship during Covid-19. Social media platforms had change social media consumers’ habits and routines (Life) during the Covid-19 situation.

According to the results shown in [Figure 3] , 12.4% of participants said that social media had a highly positive impact on them, 36.7% of participants believed that social media had a positive impact on them whereas 44.8% of participants remained neutral and 6.2% of participants on the opinion that social media had a negative impact. The majority of social media consumers were on an opinion that social media had no negative impact on them during pandemic disease conditions in India.

It is noted from [Table 3] that a social media impact is not independent of gender group (mean value of Male 3.5 is equal to the mean value of Female 3.5). during Covid-19 situation in India. This illustrates that social media has equally impacted on the gender group during Covid-19 situation in India.

[Table 4] shows that there is a weak correlation ($R=0.215825619$) between how social media has impacted social media consumers on the frequency of their usage of social media platforms during the Covid-19 situation in India. This illustrates that social media has the least impact on the frequency of usage of social media platforms during Covid-19.

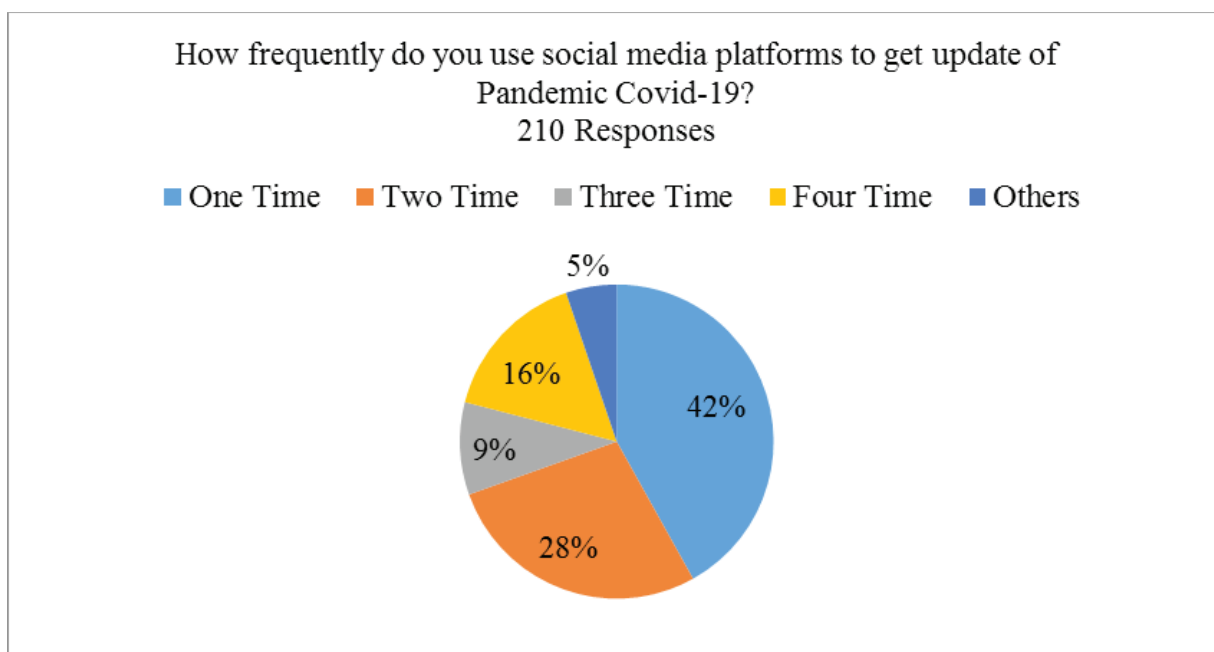


Figure 1, The Social media platforms frequency usage in a day during Covid-19

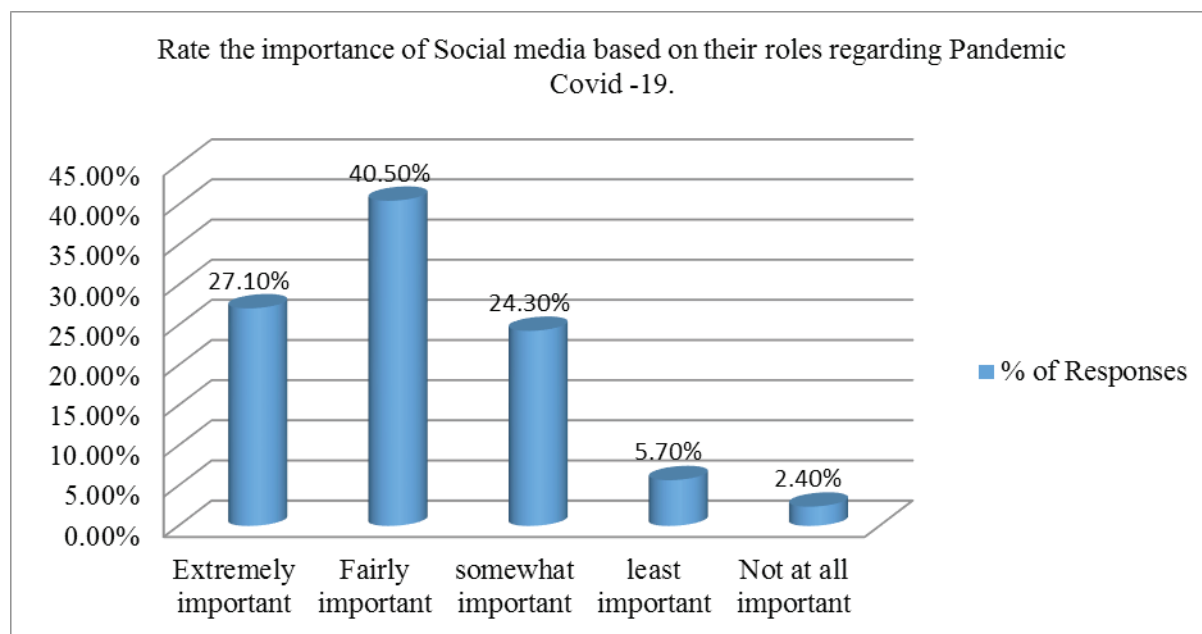


Figure 2, Social media importance during Covid-19

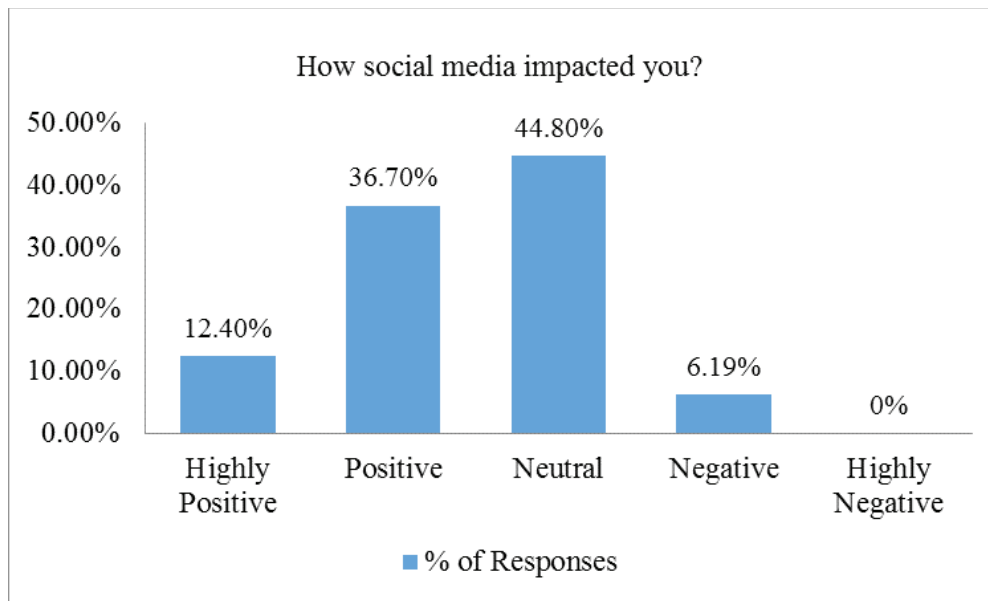


Figure 3, Social media impact on Social media consumers

Table 1. Social media usage classification in times of Pandemic Covid-19

Social media usage classification	Participants, (N=210), n (%)		
	Getting	Sharing	Neither sharing nor sharing
Updating with Covid-19 outbreak	179, (85.23)	64, (30.47)	9, (4.28)
Preventive measures of Covid-19	143 (68.09)	109,(51.90)	13, (6.19)
Immunity promoting measures for self care during Covid-19	149, (70.95)	87, (41.43)	14, (6.66)
Life style changing measures	149, (70.95)	81, (38.57)	17, (8.09)
Supportive line of treatment in Covid-19 positive case	120, (57.14)	59, (28.09)	23, (10.95)

Table 2. The social media impact on habits and routines of social media consumers during Covid-19

Variable	Not much, n (%)	Some extent, n (%)	Large Extent, n (%)	Total
Hygiene habit	68 (32.38)	78 (37.14)	64 (30.48)	210 (100.00)
Exercise habit	57 (27.14)	96 (39.52)	57 (35.24)	210 (100.00)
Food habit	53 (25.24)	83 (39.52)	74 (35.24)	210 (100.00)
Mental health	56 (26.67)	98 (46.66)	56 (26.67)	210 (100.00)
Health information	49 (23.33)	93 (44.29)	68 (32.38)	210 (100.00)
Social Networking	53 (25.24)	82 (39.05)	75 (35.71)	210 (100.00)
Social Relationship	70 (33.33)	85 (40.48)	55 (26.19)	210 (100.00)

Table 3. T test relationship between Social media impact perception on gender group during covid-19

Ho: A social media impact is an independent on gender group		
H1: A social media impact is not an independent on gender group		
Paired t-test		
Alpha	0.05	
Hypothesized Mean Difference	0	
	Male	Female
Mean	3.587301587	3.5
Variance	0.74031746	0.445783133
Observations	126	84
Observed Mean Difference	0.035714286	
Variance of the Differences	1.143287435	
df	83	
t Stat	0.306128594	
P (T<=t) one-tail	0.38013665	
t Critical one-tail	1.663420175	
P (T<=t) two-tail	0.7602733	
t Critical two-tail	1.988959743	

Table 4. Correlations between Social media impact and frequency of use of social media platforms during Covid-19.

Correlations	Frequency of use	Social Media Impact
Frequency of use	1	
Social Media Impact	0.215825619	1

Discussion

Overview

As social media professionals in India, we conclude from the results that social media has played an important role during the Covid-19 situation. The correlation analysis of the study indicates that there is a weak

statistical correlation ($R=0.215825619$) between social media impact on frequent usage of social media during covid-19. We can even see that it some extent change the habits and routine (life) of social media users.

The present study shows that out of 210 study participants, (60%) were male and (40%) were female. Most of the participants (95.7%) were aged 15-43 years.

Those who were 44 years and older made up only 4.3% of the participants. The participants were divided into four categories based on their scientific qualifications. The most common scientific qualifications were a Post-graduation degree (54.76%), Graduation degree (39.52%), while the least common were a Under graduation degree (3.33%) and Ph.D Degree (2.38%).

The majority of participants (96.7%) have Whatsapp , (n=172, 81.9%) Instagram, (n=165, 78.6%) Facebook accounts. The platforms Twiter, Linkedin, Hike, Telegram were among the lowest account.

The highest portion of participants (89.5%) had used for Entertainment, (53.3%) for Heath, while the lowest portion of participants had used for auto information (0.5%).

The study shows that most of the respondents (57.6%) were used Instagram to collect the information about Pandemic Covid-19. Whatsapp (55.6%), Youtube (48.8%), Facebook (36.1%), and Twitter (22%) were used to collect information of Covid-19. The platforms Snapchat, Linkedin, and Spinchat were lowest used for collecting information

Many respondents (80.6%) were used Whatsapp to share the information about Pandemic Covid-19. Instagram (55.2%), Facebook (34.8%), Youtube (17.9%), and Twitter (13.9%) were used to share information of Covid-19. The platforms Snapchat, Telegram, and Spinchat were the lowest used for sharing information. Instagram and Whatsapp are at the top most social media platforms used in India.

The study shows that attitude towards several social media platforms during Pre Covid-19 situation, (39%) participants show no change in their attitude towards Social media platforms before Covid-19. (34.8%) participants show favourable attitude towards Social media platforms, (18.1%) highly favourable attitude towards Social media platforms, while 6.2% (n=13) shown the least favourable attitude towards Social media platforms during Pre Covid-19. The majority of Social media consumers had favourable attitude towards Social media platform use before the Covid-19 situation.

The study indicates the attitude towards several social media platforms during Post Covid-19 situation,

(41%) participants show no change in their attitude towards Social media platforms in Post Covid-19, (36.7%) show favourable attitude towards Social media platforms, (14.8%) show highly favourable attitude towards Social media platforms, while (4.8%) show the least favourable attitude towards Social media platforms during Post Covid-19. The majority of Social media consumers had favourable attitude towards Social media platform used in Post Covid-19 situation.

Social media consumers are getting and sharing information about Covid-19 from their preferred social media than from any other sources instead of governmental sources. It is important to communicate this to health professionals to work with social media professionals to disseminated true health information through social media platforms to deal with such pandemic disease conditions in the future. This pandemic has helped the authors to identify the role of social media in public health.

Limitation

There were some research limitations, importantly these are electronic data from limited participants, and the lockdown period was a constraint to gather more participants' data. It was difficult to find participants who wished to participate in this study.

ConclusionsAs study results show that young age group of people are getting information from social media and then share the update, preventive, Immunity promoting, lifestyle - changing measures to their family and friends during pandemic disease covid-19. Social media are used majorly for entertainment, sports, and health information in general. Social media has changed people's habits & routines during covid-19. Majority of social media consumers feels that social has an important role to deal with a pandemic disease condition. We can say overall that there is no negative impact of social media has on social media users during pandemic disease conditions.

Conflict of Interest: Nil

Sources of Funding: Nil

Ethical Clearance: Institutional Ethical Committee (IEC) of Parul Institute of Public Health has approved the research entitled "Gauging of social media usage and

its impact on social media consumers: A survey study with reference to pandemic disease covid-19 in India” for the research activity.

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A Study on the *Culex quinquefasciatus* Say, 1823 Control Potentiality of *Colisa fasciata* (Bloch & Schneider, 1801) in Laboratory Condition

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Abstract

Colisa fasciata consumed significantly more *Chironomus ramosus* larvae as compared to *Culex quinquefasciatus* larvae and pupae when those were offered separately. In paired experiment it consumed significantly more *C. ramosus* larvae than *C. quinquefasciatus* larvae. When habitat was modified by incorporating sand and gravels on the floor of the aquarium, *C. fasciata* consumed significantly more *C. quinquefasciatus* larvae as compared to *C. ramosus* larvae. Chesson's food preference index also confirmed these findings. The larvicidal efficiency therefore not only depends on the availability of alternative prey but also on the micro-habitat condition.

Key Words: Biocontrol, *Colisa fasciata*, *Culex quinquefasciatus* larvae and pupae, *Chironomus ramosus* larvae, dietary preference, larvivorous fish.

Introduction

The use of fish in mosquito control has been well known for more than 100 years. Petr¹ reported that the use of larvivorous fish for vector control is simple, inexpensive and should be given preference. However, use of exotic fish has raised environmental concern because this leads to the elimination of native fish very significantly² and have some adverse effects on biodiversity causing degradation in fresh water ecosystem³. The indigenous larvivorous fishes coexisting in the mosquito larval habitat, naturally offer an alternative in this regard. Rama Rao⁴ & Krishna et al.⁵ have listed *C. fasciata* as a larvivorous fish and Das et al.⁶ opined that *C. fasciata* falls in the most efficient category of larvivorous fishes. Phukon & Biswas⁷, Bano & Serajuddin⁸ in India and Oo et al.⁹ in Myanmar have investigated the larvivorous efficiency of *C. fasciata*. In the present study biocontrol potentiality of *C. fasciata*, a common fish in Purba Medinipur district has been studied by conducting predation experiments on *C. quinquefasciatus* larvae and pupae in the presence of

an alternative prey *C. ramosus* larvae, under different habitat condition in laboratory.

Materials and Methods

Fish were trapped using gill net / hand net from pond / fresh water lotic system/ paddy field from the locality. They were gently placed in glass aquarium (60 × 30 × 30 ft) containing water from where those were collected and were acclimatized for a fortnight before the experiment. Mosquito larvae were collected from the drainage system of Tamluk municipality region. The larvae were captured by using hand net (mesh size 200 µm). Collected larvae were transported to the laboratory and kept in an aquarium (size 60 × 30 × 30cm) filled with drain water. *Chironomus ramosus* Choudhuri et al., 1992 were collected from drainage system of Tamluk municipality region along with the sediments were then transported and stocked in the laboratory.

Three glass aquaria (30 × 20 × 24 cm) were filled with 6 lit of pond water from where fish were collected after passing through a plankton net (mesh size 62

µm) the day before every experiment. Acclimatized fish of approximately similar weight (7.74 – 7.80 gm) and length (7.25 – 7.5 cm) were placed, one in each experimental tank and starved for 24 hours. The experiment commenced at 6 am in the next morning and continued for 24 hours.

Predation efficiency and prey preference were studied by offering prey separately and in paired combination. In the first series, in first set only *C. quinquefasciatus* larvae were given as prey and in the second set only *C. quinquefasciatus* pupae were given as prey, in the third set only *C. ramosus* larvae were given as prey. In each experimental aquarium one fish was placed as predator. Each experiment was repeated for three times.

In the second series, in the first set *C. quinquefasciatus* larvae and pupae were given together as prey in 1:1 ratio, in second set *C. quinquefasciatus* larvae and *C. ramosus* larvae were given together as prey in 1:1 ratio in simple glass bottom habitat and in third set *C. quinquefasciatus* and *C. ramosus* larvae were given together as prey in 1:1 ratio in an altered habitat by adding sand and gravel at the substratum of aquaria. Here also experiments were repeated for three times.

Collected data were analysed by using MS-Excel 2013 and IBM SPSS version 25 software. Dietary preference index was computed using the formula of

Chesson¹⁰.

$$\hat{\alpha}_i = \frac{\hat{r}_i}{\hat{n}_i} \left[\frac{1}{\sum (\hat{r}_j / \hat{n}_j)} \right]$$

[Where, α_i = Manly’s alpha (preference index) for prey type i; r_i, r_j = Proportion of prey type i or j in the diet (i and j = 1, 2, 3..... m); n_i, n_j = proportion of prey type i or j in the environment; m = number of prey types possible]

Result

When prey were offered separately *C. fasciata* consumed significantly more (t = 132.37, p < 0.001) *C. ramosus* larvae as compared to *C. quinquefasciatus* larvae or pupae in course of 24 hours (Figure 1). However, the fish hardly exhibited any preference for either larvae or pupae in the absence of alternative prey. The difference in number consumed being insignificant (t = 4.37).

When *C. fasciata* was offered larvae and pupae of *C. quinquefasciatus* together, it showed a significance preference for pupae over larvae as it consumed significantly more pupae as compared to larvae and this finding also confirmed by the preference index (Table 1).

Table 1. Consumption by *C. fasciata* when prey were offered together along with preference index.

Prey	<i>C. quinquefasciatus</i> pupae consumed	<i>C. quinquefasciatus</i> larvae consumed	t
Mean ± SE (Range)	308.33±3.61 (296-327)	236.56±2.92(228-250)	22.37*
Preference Index	0.57	0.43	22.30*

*(p< 0.001)

When *C. quinquefasciatus* larvae and *C. ramosus* larvae were offered together, *C. fasciata* consumed significantly more *C. ramosus* larvae as compared to *C. quinquefasciatus* larvae and showed a significant preference for *C. ramosus* larvae as revealed by preference index (Table 2, Figure 2).

Table 2. Consumption by *C. fasciata* when prey were given together along with the preference index.

Prey	<i>C. ramosus</i> larvae consumed	<i>C. quinquefasciatus</i> larvae consumed	t
Mean ± SE (Range)	670.78±3.21 (656-684)	231.22±2.46 (223-140)	132.85*
Preference Index	0.74	0.26	139.77*

*(p< 0.001)

When *Culex* and *Chironomus* larvae were offered together in an altered habitat with sand and gravel added to the substratum of the aquarium the fish consumed significantly more *C. quinquefasciatus* larvae as compared to *C. ramosus* larvae and the food preference shifted in favour of *C. quinquefasciatus* larvae as revealed by the preference index (Table 3, Figure 2).

Table 3. Consumption by *C. fasciata* when prey were given together in altered habitat along with the preference index.

Prey	<i>C. quinquefasciatus</i> larvae consumed	<i>C. ramosus</i> larvae consumed	t
Mean ± SE (Range)	432.44±4.57(417-460)	284.44±3.94(264-298)	29.06*
Preference Index	0.60	0.40	28.06*

*(p< 0.001)

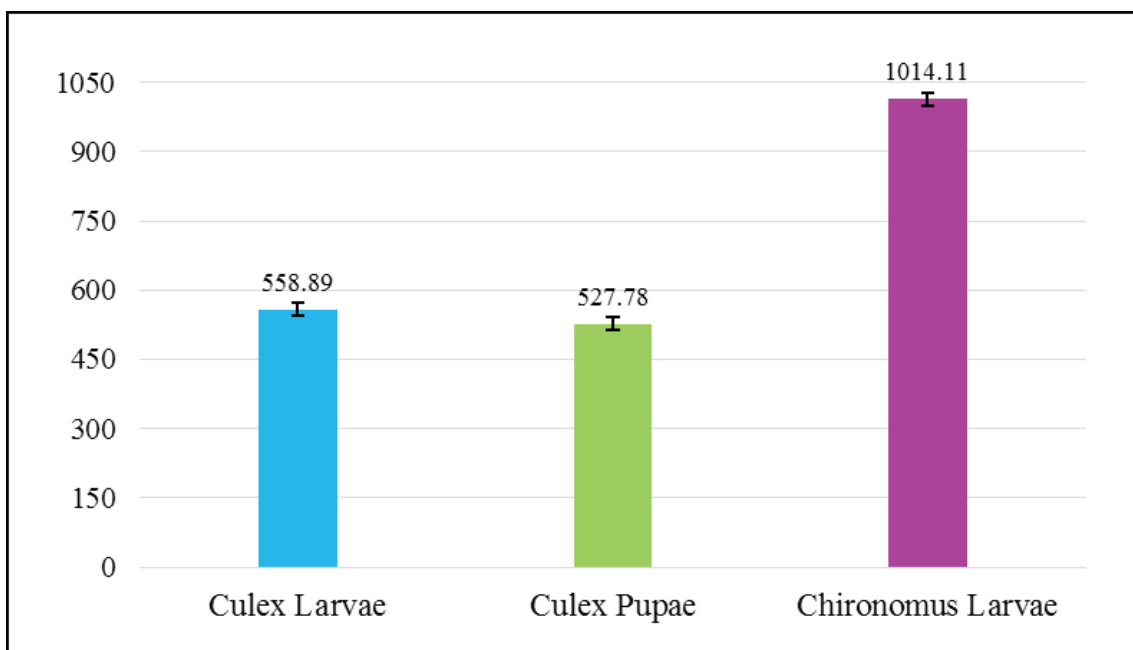


Figure 1. Consumption by *Colisa fasciata* when prey were given separately.

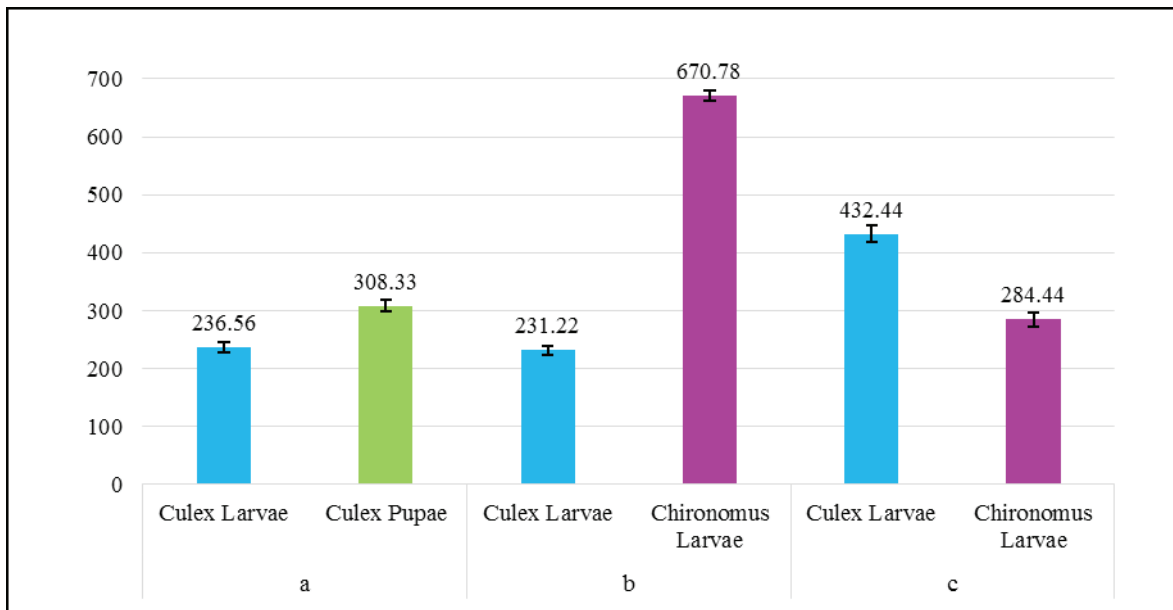


Figure 2. Consumption by *C. fasciata* when prey were offered together; a) *Culex quinquefasciatus* larvae and pupae, b) *Culex quinquefasciatus* and *Chironomus ramosus* larvae, c) *Culex quinquefasciatus* and *Chironomus ramosus* larvae in altered substratum.

Discussion

C. fasciata exhibited a more or less similar consumption preference for both larvae and pupae of *C. quinquefasciatus* but consumed significantly more pupae when both were simultaneously available as food. However, irrespective of the presence or absence of *C. quinquefasciatus* larvae, *C. fasciata* consumed significantly more *C. ramosus* larvae. Phukon & Biswas⁷ and Bano & Serajuddin⁸ opined that *C. fasciata* is an efficient consumer of mosquito larvae. However, they did not mention genus and species of mosquito. Oo et al.⁹ studied the larvicidal efficiency of *C. fasciata* on *Aedes* larvae in Myanmar. The rate of mosquito consumption in 24 hours in the present study is considerably more than the findings of the Phukon & Biswas⁷. In their study Manna et al.¹¹ observed that another larvivorous fish *Poecilia reticulata* exhibited a definitive preference for *Chironomus* larvae over *C. quinquefasciatus* larvae. Devi and Jauhari¹² and Barik et al.¹³ on the contrary observed that *Aplocheilichthys panchax* and *Puntius tetrazona* consumed more mosquito larvae even in presence of alternative prey, the chironomid larvae. Larvivorous predators have a wide range of prey choice and presence of alternative prey influence the target prey consumption¹⁴. Relative abundance of

alternative prey may also alter the consumption rate of the mosquito larvae^{15,16}. In presence of alternative prey biocontrol potentiality of hemipteran bugs¹⁷ and odonate naiads¹⁸ decreased considerably. Therefore, presence of alternative prey poses an adverse effect on elimination of target prey.

Present investigation reveals that when habitat was altered by providing sand & gravel bed in the aquarium, then *C. fasciata* consumed more *C. quinquefasciatus* larvae than *C. ramosus* larvae. Unlike mosquito larvae, which live mostly at the water surface in stagnant water, chironomid larvae live at the bottom or on submerged plants and objects¹⁹. Thus not only alternative prey but the habitat structure also changes the prey preference of the predator. Similar observation has also been made by Pahari et al.²⁰. In natural condition, column-surface feeding fish like *C. fasciata* will always prefer to consume suspended mosquito larvae rather than the chironomid larvae.

As such it may be concluded that *C. fasciata* is an effective biological control agent for mosquito larvae. This species may be cultured in aquaria & tanks in large scale and could be used in eradication of mosquito borne disease successfully.

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Ethical Clearance: No ethical issues were involved. No fish was sacrificed.

Conflict of Interest: Nil

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Subtotal Nephrectomy as a Model of Chronic Kidney Disease: A Systematic Review

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Abstract

Background: Subtotal nephrectomy (5/6 nephrectomy) is one of the most widely used animal models for modifying chronic kidney disease. Animal models of kidney disease play an important role to understand pathophysiology, progressivity, and therapies for the disease. The development of animal models that mimic the conditions in human disease is still a challenge.

Methods: We conducted a systematic search in the main biomedical databases MEDLINE (PubMed) and the Directory of Open Access Journals (DOAJ)

Conclusion: The subtotal nephrectomy procedure is a good model for chronic kidney disease. The kidney damage on this model most closely mimics with kidney damage in humans. This procedure used to remove or destroys 5/6 parts of the kidney, leaving only 1/3 of the kidney mass. There are variations to this procedure. Variations included in the type of incision, the location of the uninephrectomy, the type of ligase/ablation, the operation stage (one or two steps), the length of time between 2 operating procedures, the length of time for observation, and the type of animal used. Variations procedure in subtotal nephrectomy model have different effects on biochemical parameters, morphology, and markers of kidney damage.

Keywords: *chronic kidney disease, subtotal nephrectomy, animal model, procedure*

Introduction

Chronic kidney disease (CKD) is still a worldwide health problem with high morbidity and mortality rates. The prevalence of CKD stage 1-5 was reported to be 18.2% and 44% of people had CKD but were not diagnosed.¹ Many in vivo study has focused on developing appropriate animal models of CKD that can mimic kidney damage as occurs in humans. This animal model plays an important role to understand the physiology of the kidney, the pathophysiology of kidney damage, the specific mechanisms involved in this process, and the investigation of potential new therapies for the improvement of the kidney condition.^{2,3}

Generally, animal models of CKD are grouped into 3 main categories, namely spontaneous models, genetically engineered models, and acquired models. Acquired models are the most frequently used models and classified into immune-induced models and non-immune-induced models.⁴ Non-immune induced models include 5/6 nephrectomy,^{5,6} radiation nephropathy, unilateral ureteral obstruction (UUO),^{4,7} puromycin aminonucleoside nephrosis (PAN) and adriamycin nephropathy,⁸ folic acid nephropathy, CyA nephropathy, and deoxycorticosterone acetate (DOCA)-salt nephropathy.⁴

Of these animal models, the 5/6 nephrectomy model is the animal model that most closely mimics the progression of kidney damage in humans, after loss of renal mass in human.^{3,9,10} Therefore, this model is widely used in several studies that will assess the effect of a

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substance or drug on CKD. This literature review aims to review and analyze the use of 5/6 nephrectomy as an animal model of CKD in terms of several aspects such as procedures, types of experimental animals used, and effects on the kidneys.

Methods

Selection Criteria

We conducted a systematic search in the main biomedical databases MEDLINE (PubMed) and the Directory of Open Access Journals (DOAJ) starting October 7, 2020, until October 13, 2020. In a first phase,

we use specific keywords: “subtotal nephrectomy” [Title] OR “5/6 nephrectomy” [Title] OR “5/6 subtotal nephrectomy” [Title] AND “mice” [Title/Abstract]. We found 27 articles on Pubmed and 10 articles on DOAJ. After further selection regarding publication date (10 years) and text availability in full text, 7 articles were excluded. On the next step, we removed duplicated citations and content. In this step, 14 articles were excluded. The eligible content of the articles was selected based on information obtained from the title, abstract or full text, if necessary. We focus on the article with a specific effect of 5/6 nephrectomy on the kidney.

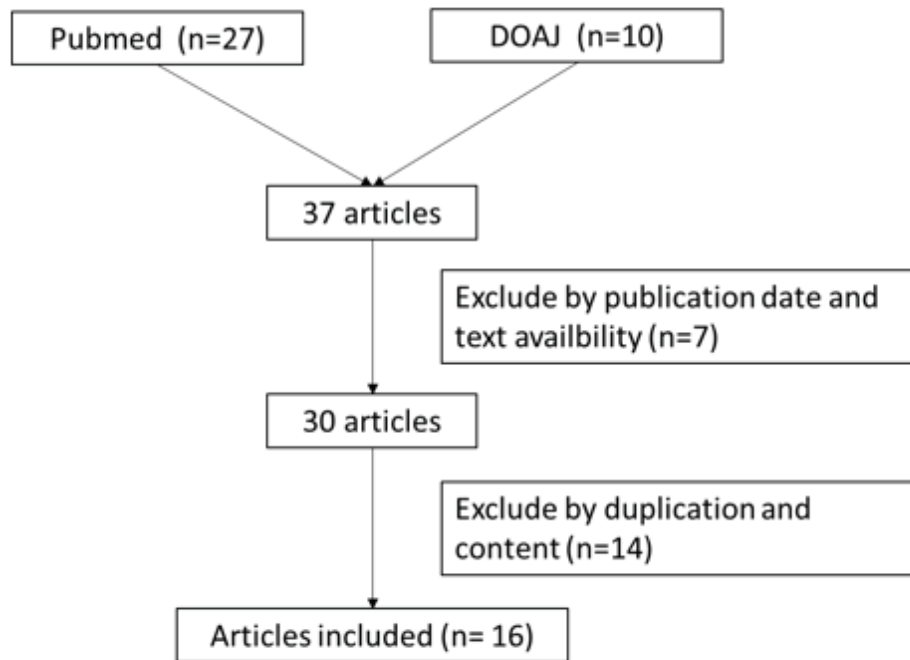


Figure 1. Flowchart of the selection process for the review

Results and Discussion

Subtotal Nephrectomy Procedure

Subtotal nephrectomy (5/6 nephrectomy) is a surgical procedure that removes or destroys 5/6 parts of the kidney, leaving only 1/3 of the kidney mass. This procedure can be done in 2 ways, by surgery or ligation. The ligation procedure is to ligate (tie) the blood vessels of the kidneys to cause necrosis or damage to the distal part of the kidney. The surgical procedure is to remove

part of the kidney by ablation of one kidney (unilateral nephrectomy) and ablation of the superior and inferior poles of the other kidney. This procedure is also known as the renal ablation model (model of kidney ablation) or remnant kidney model.² Ablation procedures are more likely to cause bleeding than ligation procedures. Animal mortality is often the result of bleeding and infection.⁹

There are variations of the 5/6 nephrectomy procedure, ranging from differences in the incision

locations, differences in the kidney that experienced unilateral nephrectomy (right or left kidney), differences in the duration of the first and second surgery (when using 2 stages of surgery), and differences in the length of observation before the animal was terminated (Table 1). Incisions can be in the form of a laparotomy,^{11,12} dorsal,^{13,14} and an incision in the flank region.^{6,9,10,15-17}

The majority of surgical procedures are carried out in 2 steps, although there are studies that are carried out in 1 step.¹⁵ When performed in 2 steps, the period between the two surgical procedures also varies between 1-2 weeks. However, some are only 1 day away.⁶ The length of treatment time also varies depending on the effect to be assessed.

Table 1. Variations of the 5/6 nephrectomy procedure in several studies

Study	Procedure
Hamzaoui et al.11	The left kidney was accessed by a laparotomy. The adrenal gland is separated from the left kidney, followed by the cauterization of both kidney poles. After 1 week, a nephrectomy was performed on the right kidney. Animals were terminated 12 weeks after the nephrectomy procedure.
Renczés et al.5	The procedure is carried out in 2 steps with 2 weeks interval. In the first step, the superior and inferior poles of the left kidney are excised. In the second step, the entire right kidney was removed.
Zhu et al.; Jin et al., 13,14	The two poles of the left kidney were removed. After 1 week, by a dorsal lumpectomy, the right kidney was removed. Animals are terminated after 4 weeks
Tan et al.9	Uninephrectomy on the right kidney through an incision in the flank region. After 1 week, continued by cutting the superior and inferior poles of the left kidney. Animals are terminated on 1, 4, and 12 weeks.
O'Sullivan et al.15	Surgery procedures are carried out in 1 step. The animal is positioned left lateral, incised on the flank to access the right kidney. The adrenal glands are set aside so they are not cut. The right renal pediculus was clamped and a nephrectomy procedure was performed. The clamp is removed and assessed for signs of bleeding. In the left kidney, the renal artery and vein are clamped for 5 minutes, and the renal poles (about 2/3 mass) of the kidney is removed. The clamps are then removed and the remaining kidney is inserted into the abdomen.
Rempelet al.12	Ventral laparotomy was performed to remove the right kidney and ligate 2 or 3 branches of the left renal artery, triggering infarction in 2/3 of the left kidney.
Nishiyama et al.16	A right dorsolateral incision was performed to access the right kidney. The hilum was ligated and the right kidney was removed. After 1 week, a left dorsolateral incision was performed, the renal blood vessel was clamped and the caudal part of the kidney was cut, leaving only 1/3 of the kidney. Then the clamp is removed. Animals were terminated 5 weeks after the last procedure.
Rosendahl et al.17	Incisions are made in the left flank region to access the left kidney. 2/3 of the kidneys are removed. 14 days later followed by uninephrectomy on the right kidney. The animals were terminated 12 weeks after the last procedure.
Cahyawati et al.6	The incision is made in the flank region. Unilateral nephrectomy was performed on the right kidney. One day after 1 day after that, ablation was performed on the superior and inferior poles of the left kidney (2/3 of the kidney). Animals are terminated after 2 weeks.
Saracyn et al.18	The animal is positioned in the pronation position. The incision is made in the lumbar region. The left kidney is completely removed after ligation of the blood vessels and ureters. After 2 weeks, a second operation was performed to remove the superior and inferior segments of the right kidney.
Oosterhuis et al.19	A retroperitoneal incision is used to excise the right kidney. After 1week 2/3 of the left kidney is removed. The experimental animals were terminated after 4 weeks.
Mirzoyan et al.10	The capsule of the right kidney is removed and cut through an incision in the flank region. Furthermore, the upper and lower poles of the left kidney are resected, by first removing the kidney capsule and preventing damage to the ureters and adrenal glands. The experimental animals were terminated after 5 months.

Animal species

The choice of animal species in a study is determined by the purpose of the research. Rodents are the type of animal that most widely.^{3,11} In the 5/6 nephrectomy model, animal strains also affect the results of the study.¹¹ Previous studies reported that C57BL/6JRj mice had a lower grade of CKD compared to other mice, such as 129/Sv and CD-1, after undergoing a 5/6 nephrectomy procedure.^{11,20} This result in line with the results of epidemiological studies that found there is a close relationship between genetic factors and the progression of CKD. However, the genes that contribute to this condition are unclear. The Ckdp1 locus on chromosome

6 that corresponds to the regions on chromosomes 2 and 3 in humans is thought to be associated with CKD progression.²¹ Table 2 describes several animal species used in the 5/6 nephrectomy procedure based on previous studies.

In general, male mice are the animal species that most frequently used. The age of the animals used was between 6-12 weeks. The age factor must be determined carefully so that the animal can survive until the end of the study. Male mice or rats were often selected to reduce hormonal factors that may affect the results of the study. However, another study reported that female FVB/N mice were more susceptible to developing towards CKD.¹⁰

Table 2. Characteristics of Animals in the 5/6 Nephrectomy Study

Study	Species	Strains	Age (week)	Gender
Hamzaoui et al.11	Mice	C57BL/6JRj and 129/Sv	8	Male
Renczés et al.5	Rat	Wistar	12	Male
Zhu et al.; Jin et al.13,14	Mice	C57/BL6	10	Male
Tan et al.9	Mice	C57BL/6	8	Male
O'Sullivan et al.15	Mice	129S2/SV	6-8	Male
Rempelet al.12	Rat	Munich-Wistar	-	Male
Nishiyama et al.16	Mice	C57BL/6	8-9	Male
Rosendahl et al.17	Mice	wildtype DBA/1J and recombination-activating gene-1 (RAG-1) deficient	10-12	Male
Cahyawati et al.6	Mice	Swiss	12	Male
Saracyn et al.18	Rat	Sprague-Dawley and Wistar	10	Male
Ismail et al.22	Rat	Sprague-Dawley	-	Male
Oosterhuis et al.19	Mice	wild-type (WT) immunocompetent CD-1 and athymic (AT) immunodeficient CD-1 Nude	9-10	Male
Mirzoyan et al.10	Mice	FVB/N	8	Female

Effects on kidneys

After undergoing the 5/6 nephrectomy procedure, there will be hemodynamic changes, especially in the renal nephrons. This procedure causes damage not only to the glomerulus but also to the tubules.^{10,23} Initially, there will be an increase in glomerular flow and pressure, which will trigger an increase in the glomerular filtration rate. However, chronic hyperperfusion, hyperfiltration, and hypertension will lead to nephron damage and a progressive decrease in glomerular filtration rate. This condition is known as glomerular hyperfiltration. This condition is the cause of the occurrence of CKD.²³

The mechanism of kidney damage as a result of the 5/6 nephrectomy procedure is still being studied. Several theories are believed to be based on it. The postoperative reduction in kidney mass results in a decrease in the number of functional nephrons in the kidney. The remaining nephrons will perform a heavy filtration function. The initial compensation that occurs in the glomerulus is glomerular hypertrophy. However, this compensation ability is limited. The continuous increase in urine flow will increase the mechanical stress on the glomerulus. This condition will affect the glomerular (intraglomerular) filtration structure and the post-filtration structure.^{23,24}

In the intraglomerular structure, the glomerular basement membrane and podocyte cells are the most affected. The podocyte foot processes will be able to attach from the glomerular basement membrane. This condition will impair the filtration function. Protein and

albumin will be able to pass into the tubule and cause proteinuria. This proteinuria will be able to trigger an inflammatory response and mediator of fibrosis.^{24–26} Initially, there will be an expansion of mesangial cells and deposition of collagen in the glomerulus. This will lead to glomerulosclerosis.²⁷

Furthermore, high pressure on the post-filtration structure will also cause dilatation of the renal tubules. This high pressure will make the contact between the albumin that passes to the proximal tubule will be limited, so that albumin reabsorption will be reduced (in the early stages). However, at the advanced stage, the megalin and cubilin receptors found in proximal tubular cells will be able to assist protein reabsorption through endocytosis.^{25,26} Hypertrophic proximal tubular epithelial cells will increase sodium reabsorption due to increased sodium transporter. The number of amino acids and glucose that pass into the tubule will also activate glucose transporter to increase glucose reabsorption. This condition will cause activation of protein kinase C (PKC), mammalian target of rapamycin (mTOR) pathway, and transforming growth factor-beta (TGF- β), which triggers tubular hypertrophy, tubulointerstitial inflammation, and fibrosis.²³ TGF- β can cause a feedback mechanism that can increase albumin filtration and inhibit megalin- and cubilin-mediated albumin, thereby increasing albuminuria.²⁶ Increasing the albumin concentration can also suppress protein kinase B (PKB) which triggers the activation of proinflammatory/fibrogenic genes and cell apoptosis.^{24,25} Apoptosis of tubular cells is what triggers atrophy in the renal tubules.²⁴

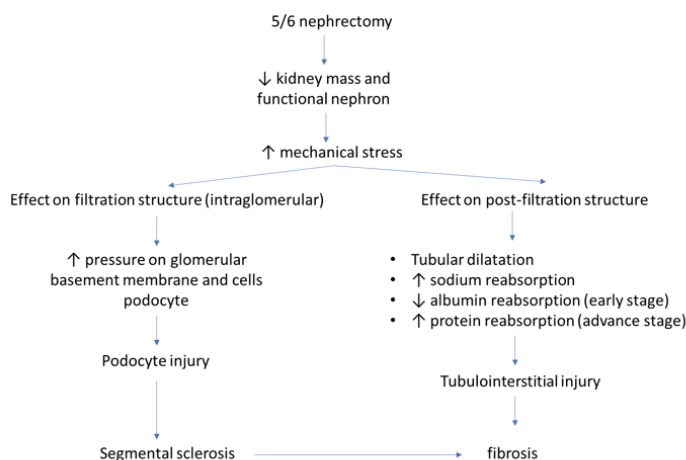


Figure 2. Mechanism of renal fibrosis as a result of the 5/6 nephrectomy procedure

Decreased in renal function in the 5/6 nephrectomy model can be seen through an increase in serum creatinine, phosphate, and urea in the blood.¹⁵ The accumulation of metabolic waste products in the blood over a long period will lead to uremia. The high levels of protein and albumin detected in the urine also indicate a defect in the glomerular filtration function. This decrease in GFR is a consequence of progressive loss of kidney mass, mesangial cell hypertrophy, and fibrosis in the glomerulus and renal tubules.^{27,28}

Based on several studies, the time it takes to cause this damage varies. These varying results occur due to variations in the methods used. Increases in serum creatinine, BUN, and proteinuria were reported to occur 4 weeks after surgery,⁹ but another study reported occurring 12 weeks after the procedure.¹¹ The fastest increase in serum creatinine was reported to occur 2 weeks post-surgery.^{6,27} Increased urinary albumin: creatinine ratio (ACR) also depends on the animal species.¹¹ An increase

in systolic blood pressure was reported to have occurred 2 weeks post-surgery.²⁷ However, another study reported that it only happened 8 weeks post-surgery.¹¹ Increased blood pressure can accelerate the progression of renal dysfunction that worsens glomerular damage and proteinuria.²⁷ An increase in systolic blood pressure is what generally occurs as a result of this procedure.²² This condition probably occurs due to peripheral resistance and stiffness in the aorta.²⁷

Morphological damage on the kidney occurred 1-week post-surgery. The damage will get worsen in line with the length of the observation/research.⁹ The damage is characterized by an increase in the degree of fibrosis,^{6,9,11} glomerulosclerosis,^{6,10,11} and the expression of α -SMA,^{6,9} and TGF- β .⁹ Besides that, the expression of adhesion molecules such as ICAM-1 and the presence of macrophage infiltration of cells will also increase.²⁹ Table 3 describes some of the effects on the kidneys as a result of the 5/6 nephrectomy procedure.

Table 3. Effects of the 5/6 nephrectomy procedure on the kidneys

Study	Effects on The Kidneys
Hamzaoui et al.11	↑ serum creatinine, urinary aldosterone, glomerulosclerosis, tubular injury, interstitial fibrosis, perivascular fibrosis, and vascular thickening
Zhu et al.14	↑ molecular expression of MHC II, CD80, and CD86 on endothelial cells of the glomerulus
Renczés et al.5	↑ BUN, creatinine, and ACR
Jin et al.13	↓ eNOS, ↑ COX-2, prostacyclin dan thromboxane A2 on renal arteries
O’Sullivan et al.,15	↑ serum creatinine, phosphate, urea, and ACR
Rosendahl et al.17	↑ albuminurin, urea-N plasma, NGAL, PAI-1, Serpine1, Lcn2, Ccl2, Il6, Cxcl1
Cahyawati et al.6	↑ serum creatinine, glomerulosclerosis, tubular injury, interstitial fibrosis
Ismail et al.22	↑ systolic blood pressure, plasma creatinine, albuminurin
Mirzoyan et al.10	↑ albuminurin, tubulointerstitial fibrosis, glomerular hypertrophy, LPA, NGAL, KIM-1 COL I, COL3 and cell surface glycoprotein F4/80 ↓ LPP (1, 2, and 3), nps1 (nephrin) and nps2 (podocin)
Gava et al.27	↓ GFR, creatinine clearance ↑ uremia, proteinuria, glomerular hypertrophy, mesangial cell expansion, and collagen deposition

Major histocompatibility complex II (MHC II), cluster of differentiation (CD), Blood urea nitrogen (BUN), albumin:creatinine ratio (ACR), endothelial nitric oxide synthase (eNOS), cyclooxygenase-2 (COX-2) neutrophil gelatinase-associated lipocalin (LGAL), plasminogen activator inhibitor-1 (PAI-1), lysophosphatidic acid (LPA), lipid phosphate phosphatase (LPP), kidney injury molecule-1 (KIM-1), collagen type 1 (COL1), collagen type 3 (COL3), glomerular filtration rate (GFR)

In conclusion, subtotal nephrectomy procedure is a good model for chronic kidney disease. Variations procedure in subtotal nephrectomy model have different effects on biochemical parameters, morphology, and markers of kidney damage. The choice of animal species can be one of the factors that affect the outcome of this procedure.

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Lamellar Ichthyosis: A Case Study

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Abstract

Lamellar Ichthyosis is a rare genodermatoses that appears at birth and continues throughout a person's life with an autosomal recessive mode of inheritance. At birth, most affected infants present as collodian babies, and after shedding the membrane, develop scaling over the body in the localized or generalized pattern. It has an equal incidence in males and females and is estimated to occur approximately 1 in 300,000 live births in the United States. Here, we describe this rare condition of Lamellar Ichthyosis in a 5 month old male baby who was admitted in hospital with the diagnosis of Sepsis. The purpose of reporting this case is to bring clinical understanding of this rare disorder and reviewing the current emerging knowledge about it.

Key words: Genodermatosis, Lamellar Ichthyosis, collodian babies, autosomal recessive

Introduction

The epidermis is a multi-layered, stratified epithelium that provides a physical barrier and protects from pathogens and dehydration. It's continuously regenerated by differentiated keratinocytes that migrate from the basal layer to the outer cornified layer during the process of cornification. In several genetic disorders, such as Ichthyosis, the cornification process is altered due to mutations in key components of the keratinocytes differentiation machinery¹.

The word Ichthyosis comes from the greek word "Ichthys", meaning fish, referring to the cutaneous scaling resembling the scales of a fish². According to the "first Ichthyosis Consensus Conference" in Soreze in 2009, in which the nomenclature and classification of inherited Ichthyosis were revised, the disease is clinically and genetically identified including Harlequin Ichthyosis, Lamellar Ichthyosis (LI), Nonbullous Congenital Ichthyosiformis and Congenital Ichthyosiformis³.

Epidemiology

According to the Foundation For Ichthyosis and Related Skin Types, autosomal recessive congenital ichthyosis- Lamellar ichthyosis type affects approximately 1:200,000 in the united states. The most frequently reported prevalence is 1:200,000 – 300,000¹. Consanguinity of parents is present in about 8% of cases. Premature birth occurs in 25% of individuals and 51% of siblings are affected. Lamellar Ichthyosis is most commonly inherited as an autosomal recessive trait, but autosomal dominant transmission has been observed⁴.

Pathogenesis

The majority of cases of lamellar Ichthyosis are caused by Transglutaminase- 1 deficiency resulting from mutations in both copies of the gene on chromosome 14. Transglutaminase -1 is expressed in the upper layers of the epidermis, facilitating the formation of the stratum corneum through cross- linking structural proteins and attaching the lipid envelope⁴. This ineffective barrier, in a means to correct itself, stimulates epidermal hyperplasia and hyperkeratosis. Hence, the clinical phenotype of lamellar Ichthyosis is a reflection of the underlying physiologic cascade in the epidermis in an attempt to normalize barrier function⁵.

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Genetics

Lamellar Ichthyosis is most commonly inherited in an autosomal- recessive manner. The parents of the affected individual must carry a mutant allele. A sibling has a 25% chance of being affected, a 25% chance of being unaffected, and a 50% chance of being a carrier. The offspring of an affected individual is a carrier, unless the partner is also a carrier, in which case the offspring has a 50% chance of being a carrier or a 50% chance of being affected. Young adults who are affected, any person identified as a carrier, or any person at risk for being a carrier should be offered genetic counseling. Furthermore, the availability of prenatal testing can be discussed if a patient is considering reproduction⁶.

Clinical Findings

Neonates with Lamellar Ichthyosis typically present with a collodion membrane at birth. The membrane dries and peels away within the first few days to weeks of life. The skin then develops diffuse, large, brown, polygonal scales over the entire body. The skin manifestations are unremitting and persist throughout life. Ectropion, Eclabium, Scarring Alopecia, Palmoplantar keratoderma with hyperlinearity, dystrophic nails, and crumpled ears can be seen in severe cases. Erythroderma is mild if at all present⁶. Hypohidrosis is not uncommon and temperature regulation/ monitoring is critical. During the neonatal period, they can have significant transepidermal water loss, fluid and electrolyte disturbances, and are at increased risk for infection and sepsis⁶.

Ophthalmologic involvement is a significant comorbidity among lamellar ichthyosis individuals. Ocular manifestations can include exposure keratitis secondary to ectropion, unilateral megalocornea, enlarged corneal nerve, blepharitis, absent meibomian gland, trichiasis, madarosis, and absence of lacrimal puncta. Corneal ulceration can occur. With prolonged excessive dryness, patients can develop bilateral cicatricial ectropions with subsequent contracures. Late presentation can lead to severe, sight- threatening complications⁷.

Hypovitaminosis D in individuals with ichthyosis and other disorders of keratinization have been reported, which is consistent with the case we present, and is most likely due to the impaired synthesis in the skin. Vitamin

D is essential for a healthy skeleton. Deficiency can lead to rickets in children and osteoporosis in adults. Vitamin D has also been shown to be potent antiproliferative and prodifferentiation mediator⁸. One study involving children with ichthyosis showed improvement of skin with topical application of calcipotriene, a vitamin D analog. Their systemic vitamin D deficiency, however, did not improve. Similarly, systemic medication that resolved vitamin D deficiencies did not improve skin findings⁹.

Diagnosis

The diagnosis of lamellar Ichthyosis can be established by a thorough history and physical examination. Skin biopsy is not necessary to establish the diagnosis⁶. Histologic findings in Lamellar Ichthyosis are nonspecific with massive compact hyperkeratosis covering an underlying acanthotic epidermis⁴. The Ichthyosis Consensus Conference stated, "diagnosis is based on dermatologic evaluation, careful family and medical history, and can be strongly supported by directed morphologic examinations and other special analyses. If available, molecular analyses are suggested to confirm diagnosis, and allow for testing of family members and prenatal diagnosis."³

Case Report

A 5 month old male baby known case of Lamellar Ichthyosis since birth presented to the Shri Maharaja Gulab Singh Hospital (SMGS) with the chief complaints of fever (4 days), fast breathing (1 days), excessive crying (1 days) and refusal to feed since afternoon on the day of admission. Patient was in usual state of health 4 days back when he started with sudden onset of fever which is continuous and high grade in nature, non- documented by parents and is temporarily relieved on medication.

The baby was fully term born in SMGS hospital with normal vaginal delivery. He was kept in the NICU for clinical stability and was diagnosed with lamellar Ichthyosis at that age, as per their history. The baby is the only child of consanguineous parents. There was no recollection of any family members with ichthyosis or any other skin conditions. His mother described the classic presentation of a collodion membrane at birth in baby. His mother stated that the layer peeled away within a week, and then the boy had a very thick pale skin

with deep red fissures. After several weeks, they began to develop the classic dark brown scales covering the entire body. His mother stated that the baby had a very difficult time with feeding and growing with subsequent hospitalizations.

Physical examination revealed that patient was febrile to touch with sick general appearance. Chest examination showed bilateral air entry present, which is equal in both sides and is clear with no chest retractions but respiratory distress is present. In cardio-vascular examination, both S₁ and S₂ sounds are present. On abdominal examination, liver was 4cm Below Costal Margin and was soft with no distension and tenderness. The vitals of the client are: Temperature: 101⁰F, Heart Rate- 180 beats/ min., Respiration rate- 90 breaths/

min. and SPO₂ is 98%. The weight of the client is 7kg, occipito- frontal circumference(OFC)- 42cm, length- 58cm, CRT< 3sec. and mid upper arm circumference (MUAC)- 13cm.

Physical examination also revealed a generalized distribution of large, dark, brown, polygonal, adherent scales without apparent underlying erythema (figure 1). The palms and soles demonstrated hyperkeratosis and hyperlinearity (figure 2). Facial skin was taut with significant scales. Bilateral congenital ectropions (figure 3), scarring alopecia(figure 3 and 4), dystrophic nails (figure 1) and crumpled ears(figure 4) was also present. The various laboratory examinations have been performed with normal ranges except increased WBCS count and CRP which was positive. The blood sugar random was 108 mg/dl.



FIGURE:1



FIGURE :2



FIGURE: 3



FIGURE: 4

Management

Bathing is recommended at least once daily. Exfoliation should be done after soaking with sponge, microfiber cloth, or pumic stone. Propylene glycol, vitamin E, and glycerol are emollients that should be reapplied throughout the day. Pure sodium bicarbonate has been successfully used as a bath additive to mechanically remove scale¹⁰. During the neonatal period, temperature, fluids, and electrolyte need to be regulated. Risk of infection should be closely monitored. Environment need to provide humidity/ moisture. Urea cream is commonly avoided in neonates. Dexpanthenol 5% is an alternative to urea that is safe to use during infancy. Salicylic acid is contraindicated in neonates or infants¹⁰.

In children and adults, keratolytic agents such as urea, lactic acid, salicylic acid, and alpha- hydroxyl acid may help thin the stratum corneum and induce peeling. Topical or oral retinoid therapy is recommended for those with severe skin involvement. Acitretin is efficacious, especially in lamellar ichthyosis and congenital ichthyosiform erythroderma. Isotretinoin may be preferred in female patients due to shorter duration of teratogenicity risk after taking the medication¹⁰. For individuals with ectropion, prevention of cornea dessication is through use of lubrication with artificial tears or prescriptions ophthalmic ointments⁶.

An upcoming treatment is the new class of retinoic acid metabolism- blocking agents (RAMAs). They inhibit catabolism of endogenous all- trans- retinoic acid. The effects of retinoic acid on epidermal growth and differentiation are indirectly achieved and with better tissue specificity. Therefore, the retinoic acid metabolism- blocking agents offer the possibility of reduced side effects and reduced potential for teratogenicity when compared with synthetic retinoids¹¹. A recent phase II/III, randomized, double- blind, controlled study indicated that Liarozole at a daily dose of 150mg is equally effective as treatment with Acitretin. In a study involving patient with Lamellar Ichthyosis treated with Liarozole 150mg daily, significant reduction in scale was noted. Liarozole has been granted orphan drug status for the treatment of congenital Ichthyosis by the European medicines agency and the US FDA¹⁰. Such drugs as Liarozole may become the treatment of choice

for cases of ichthyosis that warrant systemic therapy.

Another medication of interest is the compounded combination of topical 10% N-acetylcysteine and 5% urea emulsion. A report of five children with lamellar ichthyosis being treated with this medication describes marked overall improvement in the appearance of their skin with noteworthy reduction of scale. N-acetylcysteine has been shown to inhibit the proliferation of keratinocytes, and when combined with a commonly used keratolytic such as urea, significant benefit was noted with effectiveness that was greater than that seen with each entity separately. The emulsion was applied twice a daily for 2 weeks and then continued once daily. The drug was well tolerated, efficacious, and safe¹².

Genetic counseling should be offered to affected individuals and their families. Genetic testing and counseling enables patients to seek answers to their many questions regarding the nature of the disorder, inheritance pattern, and probability of affected family members or offspring³. Further information can be found at the Gene Tests Clinic Directory Website, www.ncbi.nlm.nih.gov/sites/genetests/clinic⁶. The Gene Tests clinic Directory is a voluntary list of United States and International genetics clinics.

In my client who is 5 month old male baby known case of lamellar ichthyosis was firstly treated for sepsis. He was managed with injectables like inj Ceftriaxone 250mg – IV- BD, Inj. Amikacin 105mg in 30cc NS – IV- OD, intravenous fluid with N/2 DNS 30CC/ hour. Client was also advised to use coconut oil and Fusidic acid cream- BD. Client has received treatment for 7 days and after the recovery from illness he was planned to discharge on follow up basis. During the discharge, parents were advised to assess the fluid and electrolyte needs. Risk of infection needed to be monitored closely. Environment needs to provide humidity/ moisture. Parents were advised to use certain medications like Physiogel- AI lotion – BD, Fusidic acid cream- BD, Apitol drops – 7 drops- BD, Syp Vit.D3 – 400IU- OD and Coconut oil. They were also advised to take ophthalmic consultation and come for routine checkup after every 3 weeks on followup basis.

Conclusion

Classic lamellar Ichthyosis is most notably due to

mutations in the transglutaminase- 1 gene. This is most likely the situation in this case we report. TGM1 is crucial for the formation of the cornified cell envelope. Current treatment is symptomatic and is largely directed towards improving the appearance of the skin by reducing scaling. Significant research of the underlying genetic and biochemical mechanisms has led to a greater understanding of this disease, furthering the progress and development of more targeted therapies¹³.

Ethical Clearance: For this case study we have taken the consideration of ethical issues. No significant ethical concerns were raised during the study. Ethical clearance was obtained from the HOD of pediatrics department. Consent was obtained from the parents of patient and they were assured about the confidentiality of the data obtained from them.

Source of Funding: Self

Conflict of Interest: Nil

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Comparative Study of Self-Demonstration Versus Video based Education on Level of Anxiety and Self-Efficacy in Patient Undergoing Cardiac Surgery: A Double-Blinded Randomized Controlled Trial

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Abstract

Aim: To compare the effect of self-demonstration versus video based education in reducing anxiety and improving self-efficacy of a patient undergoing cardiac surgery.

Methodology: A Double Blinded, Randomized Control Trial conducted at Dr. Vikhe Patil Memorial Hospital. Study duration was 12 months. A total number of 58 patients were included in this study. The patients divided into two groups. Group I which receives self-demonstration and Group II which receives video based demonstration by simple random sampling using chit method.

Outcome Measures: Primary outcome measure is Self-efficacy questionnaire. Secondary outcome measure is Hospital Anxiety Depression Scale.

Result: Within the group analysis, Group I and Group II showed that there was significant difference between pre and post intervention anxiety and depression. Between the group analysis, there was no significant difference found for anxiety (P=0.4925) and depression (P= 0.9441). In Group I and Group II there was no statistical significant difference for Score of Self Efficacy Questionnaire (P=0.6970).

Conclusion: Our study concluded that Self-Demonstration and Video Based Education both are equally effective in reduction of anxiety. Similarly the study supports equal effectiveness of above techniques in term of self efficacy post operatively.

Keywords: Cardiac Surgery, Self Efficacy, Pre Operative Education, Anxiety and Depression

Introduction

Cardio vascular diseases (CVDs) is the greatest cause of mortality in India and an important cause of morbidity and economic loss^[1]. Non-surgical management of cardiovascular disease involves Lifestyle changes

and drug treatment^[2]. Surgical Management involves opening of the thoracic cavity to repair or replace valve defects, or to perform coronary artery bypass graft surgery^[3].

Patients hospitalized in the Coronary Care Unit (CCU) are prone to hemodynamic instability and impaired cardiac output, electrolyte abnormalities and frequent occult infections on one hand and on the other hand, they are vulnerable to ICU Psychosis and pulmonary complications^[4]. The reported incidence of pulmonary complications is in the range of 20-90%^[5].

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Pre-operative education of the cardiac surgery patient plays a vital role in the patient's post-operative care and helps in faster recovery process^[3]. Studies show that preoperative physical therapy prevents postoperative respiratory complications like atelectasis, pneumonia, and reduces the length of hospital stay^[6]. Preoperative physiotherapy for cardiac surgery patients may include a variety of treatment techniques: Breathing exercise, coughing/huffing techniques, incentive spirometry, early mobilization techniques for getting in and out of bed, shoulder exercises, Ankle toe movement, and lower limb exercises^[7].

A variety of methods like written education materials, individual demonstration or self demonstration of exercises or group instruction classes, telephonic intervention, video education using CD-ROM or Internet are used for providing pre-operative physiotherapy education^[3,8]. Out of all these, use of self demonstration of exercise is the commonly used method. But now a days video based education also used to demonstrate the exercise and it is getting more preferred because it provides the learner with realistic experience that capture their attention, stimulate thinking and help in better understanding of the treatment protocol^[9].

So this study is mainly to find out the effectiveness and comparison between the two techniques, self demonstration and video based demonstration, on patient's level of anxiety and patient understanding or we can say patient self efficacy.

Materials & Methodology

The study was approved by the Institutional Research & Ethical Committee and CTRI registration was also obtained for the study. This study conducted over a period of 12 months from March 2017 to Feb 2018. The location of this study was Dr. Vikhe Patil Memorial Hospital. The study inclusion criteria were as follows: Age 18 – 60 years, either gender, patients undergoing cardiac surgery, Patients willing to participate. Patients who have diagnosed cognitive, visual or hearing impairments and not able to read and understand Marathi language and unwilling to participate were excluded from the study.

Procedure

Study is divided into two phase.

Phase I

The construct and content validation of Cardiac Self-efficacy questionnaire for post-operative cardiac surgery patients was done in the following way-

i) The questionnaire with a validation request and a grading sheet, sent to a team of five members who are experts in the field of cardiac surgery and rehabilitation with an experience of more than ten years in order to grade each item as relevant, appropriate and accurate along with any suggestions for modifications/comments.

ii) To ascertain content validity, the percentage of agreement among experts was calculated. The criterion for retaining an item was set above 75% agreement in terms of relevancy, accuracy and appropriateness.

iii) The comments were reanalyzed by the investigator to determine the modifications required for the formation of a revised questionnaire.

iv) Forward-backward translation of the revised questionnaire was done from English to Marathi language by sending it to senior physiotherapy faculty from Maharashtra domicile, with mother tongue Marathi.

For the validation of video clip, informed consent from the patient appearing in the clip was taken. The video clip was sent for content validation to a team of five members who are experts in the field of cardiac surgery and rehabilitation with an experience of more than ten years. Their suggestions were statistically analyzed. The video will contain information on post-operative complications and its prevention by performing exercises which were demonstrated by the patient along with instructions given postoperatively day wise as per protocol. Voice over is given in Marathi.

A pilot study was then be conducted using the revised questionnaire and the final video clip to evaluate the minimal clinically important difference of the outcome measure, for calculating the sample size.

Phase II

58 Patients undergoing cardiac surgery were recruited from cardiac ward and written consent was taken. Patients were randomly divided into two groups: Group I which receives self-demonstration and Group II which receives video based demonstration by simple

random sampling using chit method. Both the groups were assessed for anxiety and depression preoperatively. Group I received pre-operative education in the form of self-demonstration two days prior to surgery. Group II received pre-operative education in the form video two days prior to surgery. Pre-operative information consists of exercises like Ankle Toe Movements, Shoulder Movements, Breathing Exercises Incentive Spirometer, Huffing and Coughing Technique & General Bed Mobility Exercises. Both the groups were assessed for anxiety and depression post Video based education and self demonstration preoperative. Same post operative cardiac rehabilitation phase I protocol was given to both the group. Post-operatively on 4th day patients were given self-efficacy questionnaire to measure his/her level of self-efficacy. Another investigator, who is blinded to the study, was given a checklist of post-operative exercises which every patient is expected to perform. He also evaluated the patient’s efficacy in performing the exercises.

Outcome Measures:

Self Efficacy Questionnaire, in this researcher are interested in knowing about what patient will and will not be able to do after operation while in the hospital. This questionnaire consist of 5 domain i.e. Breathing exercises, Airway clearance, General mobility exercises, Ambulation and Posture. Using 0-4 scale i.e. 0=Not Confident with supervision, 1= Not confident without supervision, 2= Neutral, 3= Confident with supervision, 4= Confident without supervision, the number next to each component that shows patient’s confidence to do that particular activity during hospital recovery. There are no right or wrong answer. Total score for questionnaire are 40.Higher the score higher the self Efficacy.

The Hospital Anxiety and Depression Scale (HADS) is self-administered tool for measuring the levels of anxiety and depression consists of 14 items divided equally between the following 2 subscales: anxiety and depression, Cut-off scores: 0–7 = no depression/anxiety; 8–10 = borderline depression/anxiety or borderline abnormal; 11-21 = severe depression/ anxiety or abnormal^[10].

Result

The collected data were analyzed statistically using **SPSS Version 16.0**. Normal distribution of data was found out by **Kolmogorov-Smirnov Test**. Non-parametric test, Wilcoxon signed rank test was used for within the group analysis of Hospital Anxiety Depression Scale. Non-parametric test, Mann-Whitney U test was used for between the group analysis of Hospital Anxiety Depression Scale and Self Efficacy Scale. A p-value of ≤ 0.05 was considered as statistically significant. Baseline Characteristics of Patients in Group I and Group II showed there was no statistical significant difference between demographic data (p>0.0.5) (**Table no.1**). Within the group analysis, Group I showed that there was significant difference between pre and post intervention anxiety (p< 0.0001) and depression (p< 0.0001), and Group II showed that there was significant difference between pre and post intervention anxiety (p<0.0001) and depression (p<0.0001) (**Table no.2**). Between the group analysis outcome measure which showed that there was no significant difference found i.e. p value is 0.4925 for anxiety and p value is 0.9441 for depression (**Table no.3**). In Group I and Group II there was no statistical significant difference (μ Value=395.0, p Value=0.6970.) for Score of Self Efficacy Questionnaire (**Table no.4**).

Table No.1 Baseline Characteristics of Patients in Group I and Group II

Characteristics	Group I (n=29)	Group II (n=29)	P Value
	Mean ± SD	Mean ± SD	
Age	49.58621 ± 11.07932	44 ± 12.79788	0.1088
Depression	5 ± 2.9277	5.172414 ± 2.891724	0.8273
Anxiety	3.793103 ± 2.690981	3.896552 ± 2.820142	0.9441
Gender	Male:19 Female:10	Male:15 Female:14	

Within Group Analysis

Table No. 2) Pre and post Intervention Anxiety and Depression in Group I and Group II

		Pre Intervention	Post Intervention	W Value	p Value	Result
Group I	Anxiety	3.79310 ± 2.6909	3.27586 ± 2.20221	55.0	0.0010	Significant
	Depression	5 ± 2.9277	4.17241 ± 2.4358	105.0	< 0.0001	Significant
Group II	Anxiety	3.89655 ± 2.8201	2.93103 ± 2.21892	120.0	<0.0001	Significant
	Depression	5.17241 ± 2.89172	4.10344 ± 2.22557	153.0	<0.0001	Significant

Between Group Analysis

Table No.3) Comparison between Group I and Group II – Anxiety and Depression

	Group I	Group II	μ Value	P Value	Result
Anxiety	3.275862 ± 2.2022	2.931034 ± 2.2189	376.0	0.4925	Not Significant
Depression	4.17241 ± 2.43587	4.10344 ± 2.22557	415.50	0.9441	Not Significant

Table No.4 Comparison of Post Operative Score of Self Efficacy Questionnaire between Group I and Group II

Group I	Group II	μ Value	p Value	Result
35.89655 ± 3.58911	35.68966 ± 3.392254	395.0	0.6970	Not Significant

Discussion

Regarding comparing the baseline data between Group I and Group II, we found that they are equally and properly distributed. Statistical analysis for all baseline characteristics shows p value > 0.05 i.e. non-significant, it means baseline characteristics are equally distributed between both the groups.

Non-parametric test, Wilcoxon signed rank test was used for within the group analysis of each outcome measure. In **Group I** for Anxiety and Depression, within the group analysis showed that there was significant difference between pre and post intervention anxiety

and depression. These results suggest that providing preoperative self demonstration to the patients is effective in increasing knowledge about post-operative complications and its prevention by performing exercises, helping them to feel secure, and reduce their anxiety^[11].

In the literature review by Anne Scott it is stated that Pre-operative information provision can make a valuable contribution to reduce anxiety in elective surgical admissions in ICU^[12].

In **Group II** for Anxiety and Depression, within the group analysis showed that there was significant

difference between pre and post intervention anxiety and depression group.

These result suggested that preoperative video based education is effective in reducing anxiety and also it is an efficient and convenient way to inform patients [13]. This provides clear cut idea about the topic [14]. Video information is very useful for them to clarify their doubts and it gives the exact idea about the post-operative complications and its prevention by performing exercises [15].

The present study findings are supported by a study done by Doering S.(2000) to assess the videotape preparation of patients for hip replacement surgery. The result revealed that videotape preparation decreases anxiety, stress and was able to cope better with postoperative pain among experimental group patients [16].

In between the group analysis outcome measure which showed that there was no significant difference for anxiety and depression.

Result shows that both self demonstration and video based education significantly reduce the anxiety level. As self demonstration helps patient to manage their conditions; it has also provided the opportunity for the patient to ask questions, and the patient could discuss any question concerning the issue to, and modified inaccurate beliefs and information in their mind. So, it reduced the patient's concerns; on the other hand, the educator was assured about his understanding of information by face to face contact with the patient and a dynamic relationship is made between the patient and the educator [17]. Video based education basically is effective and convenient [18]. It provides the learner with realistic experience that capture their attention, stimulate thinking and help in better understanding of the treatment protocol [19].

Similar result found by P Akkamahadevi who investigated the efficacy of different methods of pre-operative counselling on perioperative anxiety in patients undergoing regional anesthesia. Their result showed that Personal interview, brochure and video are good at alleviating the anxiety throughout the perioperative period [19].

For between the group analysis of Score of Self Efficacy Questionnaire. In **Group I** and **Group II** for Score of Self Efficacy Questionnaire, showed that there was no statistical significant difference.

In the current study Comparison of post-operative score of self efficacy questionnaire of patients receiving self-demonstration to those who receiving video based education was also not significant in both groups. It means both methods i.e. self demonstration and video based education are equally effective.

Result of the present study are in accordance with the study done by Masumeh Hemmati Maslakpak et al. 2015. They concluded implementation of the face to face and video education methods improves the quality of life in hemodialysis patients [20].

Similar result found by Panagiota Nikopoulou-Smyrni and Christos Nikopoulos 2010, data from study provided an objective illustration that short video-based lectures can be at least as much effective as the standard teaching methods [25].

So in this study, there was significant reduction in anxiety by preoperative physiotherapy treatment. As in our study, we have two types of preoperative methods one is self demonstration and other is video based demonstration. But when we analyzed the result statistically, we found that both the techniques were statistically significant individually for reducing the pre-operative anxiety. But comparison between both the groups i.e. Self demonstration and video based education are not significant. Same way post operative self efficacy also shows statistically non significant as both the techniques were effective preoperatively.

Conclusion

Our study concluded that Self-Demonstration and Video Based Education both are equally effective in reduction of anxiety. Similarly the study supports equal effectiveness of above techniques in term of self efficacy post operatively.

Conflicts of Interest: There were no conflicts of interest in this study.

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A Study on Maternal and Perinatal Outcome in Pregnant Women Presenting with First Trimester Vaginal Bleeding and Ultrasonographic Evaluation

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Abstract

This study is an analysis of five cases of orbital trauma causing proptosis, paralysis of extraocular muscles with or without associated visual failure. All the cases were treated by a ENT and Neurosurgical team. Either a frontal craniotomy or a lateral orbitotomy was performed. Plain X-rays of the skull and Computerised Tomography (C.T. Scanning) were the main investigations. Results were encouraging both functionally and cosmetically. Early diagnosis and an aggressive approach to orbital decompression can achieve good results.

Keywords: Head Injury, Proptosis, Head injury complications, Post traumatic blindness

Introduction

First-trimester bleeding is normal complications during pregnancy, nearly for 16- 25% in all births.^{1,2}In this domain four major causes include miscarriage (threatened, inevitable, incomplete or complete), ectopic pregnancy, implant bleeding and cervical pathology.³Multiple analyses reveal that vaginal bleeding doubles the possibility of pregnancy complications.^{4,5}

In general first trimester vaginal bleeding patients are mostly unaware of their pregnancy status. 20-25% of pregnant women experience any degree of bleeding during the early months of pregnancy

The relevance of bleeding in an early pregnancy can vary from uncertain occurrences to life-threatening emergency.⁷Differentiating between ectopic pregnancy and abortion, the most frequent forms of first trimester bleeding is important to avoid life threatening complications.⁶

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Mostly it has been accepted that the outcome of pregnancy is linked with first-trimester vaginal bleeding. For patients and obstetricians the result of continuing pregnancy after the first trimester bleeding is important for planning maternal treatment and health procedures throughout pregnancy. Whatever the type of therapy used, the prediction of a threatened abortion is very uncertain. Because awareness of increased risks associated with first trimester bleeding, it may improve management of pregnancy, place and timing of delivery that eventually enhance neonatal outcomes.

Material and Methods

STUDY AREA:- The study was conducted at Department of Gynaecology and Obstetrics, Saraswathi Institute of Medical Sciences, Hapur.

STUDY POPULATION:- Women attended antenatal clinic and emergency with first trimester vaginal bleeding and also normal pregnant women without history of vaginal bleeding in first trimester as control population.

SAMPLE SIZE:- 100 pregnant women presented with vaginal bleeding and 100 pregnant women without bleeding history in first trimester.

STUDY TYPE:- Comparative cohort study.

METHODS OF STUDY:- Our study was conducted in the Dept of Obst&gynae , Saraswathi Institute of Medical Sciences , Hapur among 100 pregnant women presented with vaginal bleeding in first trimester and 100 pregnant women without bleeding history in first trimester as control group. This control group was taken from onset of second trimester of pregnancy onwards without any history of vaginal bleeding in first trimester, then maternal and perinatal outcomes were compared between two group.

Ultrasound study of every patient of both group were done. The characteristics of all the patients related to their age, gravida, parity, period of gestation at the time of bleeding and maternal and perinatal outcome determined and data collected through self-administered structured questionnaire, outcome data was obtained from hospital data and confirmed by telephone follow up wherever necessary. Potential confounding factors identified and adjusted in statistical model.

Ultrasonography for fetoplacental profile were done for every study women to evaluate the condition. After that proper management was given to every mother and if pregnancy continued proper antenatal follow up were done in our hospital set up. Sonography was performed at 8 to 10 week interval to detect pregnancy complication earlier.

DURATION OF THE STUDY:- From November 2018 to October 2020.

INCLUSION CRITERIA:-

- 1) All pregnancy confirmed women within 12 weeks pregnancy with vaginal bleeding.
- 2) Pregnant women without history of vaginal bleeding in first trimester.

This control group was taken after completion of first trimester of pregnancy.

EXCLUSION CRITERIA:-

- 1) Women with chronic medical complication including diabetes, hypertension and history of trauma, hematological disorder
- 2) Women with multiple pregnancy.

- 3) Women who willing to terminate the pregnancy.

Result

MEAN AGE, GRAVIDA AND PARITY DISRTRIBUTION BETWEEN CASE AND CONTROL

For age category the mean age is found to be 28.72 and 31.48 for cases and control respectively. For gravida the mean is found to be 1.82 and 1.75 for cases and control respectively and for the case of parity it is .48 and .66. Overall, statistically significant difference been found in age and parity category since the P value is found to be less than 0.05 level.

As 27 patients in case are primigravida and 35 case in control are primigravida so history of bleeding and history of abortion in previous pregnancy are not taken from them.

DISTRIBUTION OF HISTORY OF BLEEDING IN PREVIOUS PREGNANCY AND ABORTION BETWEEN CASE AND CONTROL

For the history of bleeding in previous pregnancy 42 cases were there in case category and 10 cases were there in control category. Statistically significant difference been found in history of bleeding in previous pregnancy since the P value is found to be less than 0.05 level.

For the case of history of abortion 28 cases been found in case category and 8 cases been found in control category. Overall, statistically significant difference been found in history of abortion since the P value is found to be less than 0.05 level.

DISTRIBUTION OF ABORTION IN PRESENT PREGNANCY

For case category 18 patients been found and for control 2 cases been found where abortion was present. Overall, statistically significant difference been found in abortion in present pregnancy since the P value is found to be less than 0.05 level.

DISTRIBUTION OF APH BETWEEN CASE AND CONTROL

For case category 10 patients been found and for control 3 cases been found where APH was present.

Overall, statistically significant difference been found in APH since the P value is found to be less than 0.05 level.

DISTRIBUTION OF PPROM BETWEEN CASE AND CONTROL

For case category 16 patients been found and for control 2 cases been found where PPROM was present. Overall, statistically significant difference been found in PPROM since the P value is found to be less than 0.05 level.

DISTRIBUTION OF FGR BETWEEN CASE AND CONTROL

For case category 5 patients been found and for control 1 case been found where FGR was present. Overall, statistically significant difference been found in FGR since the P value is found to be less than 0.05 level.

DISTRIBUTION OF PRETERM DELIVERY BETWEEN CASE AND CONTROL

For case category 20 patients been found and for control 3 cases been found where preterm delivery was present. Overall, statistically significant difference been found in preterm delivery since the P value is found to be less than 0.05 level.

DISTRIBUTION OF MODE OF DELIVERY BETWEEN CASE AND CONTROL

For case category 52 patient had CS and 30 patients had VD, while for control category 23 patients had CS and 75 patients had VD. Overall, statistically significant difference been found in mode of delivery since the P value is found to be less than 0.05 level.

DISTRIBUTION OF VAGINAL DELIVERY WITH OR WITHOUT COMPLICATION BETWEEN CASE AND CONTROL

For case category 20 patients been found and for control 90 cases been found where complications were present. Overall, statistically significant difference been found in vaginal delivery with/without complication since the P value is found to be less than 0.05 level.

DISTRIBUTION OF 5 MIN APGAR MORE THAN 7 BETWEEN CASE AND CONTROL

For case category 58 patients been found and for

control 92 cases been found where score was more. Overall, statistically significant difference been found in distribution of 5 min APGAR more than 7 since the P value is found to be less than 0.05 level.

MEAN BABY BIRT WEIGHT BETWEEN CASE AND CONTROL

For case category mean weight calculated is 2.88 while for control mean birth weight is 2.83. Overall, statistically non-significant difference been found in mean baby birth weight since the P value is found to be more than 0.05 level.

THE STILL BIRTH BETWEEN CASE AND CONTROL

For case category 4 patients been found and for control 1 case been found where the still birth has taken place. Overall, statistically significant difference been found in distribution of still birth since the P value is found to be less than 0.05 level.

THE NEO NATAL DEATH BETWEEN CASE AND CONTROL

For case category 4 patients been found and for control 3 case been found where the neo natal death has taken place. Overall, statistically significant difference been found in distribution of neo natal death since the P value is found to be less than 0.05 level.

THE NEO NATAL COMPLICATION BETWEEN CASE AND CONTROL

For case category 11 patients been found and for control 5 case been found where the neo natal complications has taken place. Overall, statistically significant difference been found in distribution of neo natal complication since the P value is found to be less than 0.05 level.

Discussion

It is already known that up to 15-25 percent of all births are affected by first trimester vaginal bleeding⁷ and 50 percent of affected women have reported spontaneous abortion and 50 percent of them have proceeded their pregnancy.⁸ These statistics indicate that the risk of miscarriage is not only related to miscarriage, but also to detrimental effects of pregnancy.

These results show that threatening miscarriage is not only related to abortion, but also to adverse outcomes of pregnancy⁹ low placenta lying¹⁰ placental abruption¹¹ rupture of premature membrane¹² low birth weight of baby.

The relatively high rate of abortion and complications in threatening miscarriage suggest the need for appropriate treatment and cure programming and also to inform women at high risk. Significant data suggest persistent placental disorder that may occur in later pregnancy via a number of adverse effects that have also been attributed to placental dysfunction is confirmed by the outcome of this research.

Yakistiran et al¹³ observed in an analysis that the mean maternal age of the risk group was greater than the control group 28.8, 33.5 year respectively. The statistically relevant value of this disparity was <0.001. Mean gravid was more in the threatened abortion category than the control group in this sample. This variation was non - significantly different. But in the control group, mean parity was more than a threatened group. This discrepancy was relevant statistically. From another study, Agarwal S et al¹⁴ found that there was no considerable difference in age and gravidity between women in the two groups.

For case category mean weight calculated is 2.88 while for control mean birth weight is 2.83. Overall, statistically non-significant difference been found in mean baby birth weight since the P value is found to be more than 0.05 level. In the case of distribution of 5 min APGAR more than 7 between case and control. For case category 58 patients been found and for control 92 cases been found where score was more. Overall, statistically significant difference been found in distribution of 5 min APGAR more than 7 since the P value is found to be less than 0.05 level. In this respect, Nandish et al¹⁵ reported an increased risk of low birth weight (< 2500 gm) for women affected by vaginal bleeding. Saraswat et al²⁰ also found that women with a history of bleeding from early pregnancy were more likely to give birth to babies with an APGAR score of < 7 5 minutes after birth. In the case of Yakistiran et al,¹⁶ the fetal weight was also lower than that of the control group. But they did not discover an APGAR score relationship between the control group and the threatened group.

The drawbacks of our research are that the number of cases and control was very few out of a vast number of patients attending early trimester bleeding.

Conclusion

In summary, given by the results of our first trimester study, vaginal bleeding may be an indicator of adverse maternal and child outcomes. In this respect, it is appropriate to improve the expertise of pregnant women for close monitoring. Also, because in these high-risk births, the professional involvement of a conscientious obstetrician plays a significant role not only in the continuity of pregnancy, but also in reducing fetal abnormalities.

For patients, continuous encouragement and a compassionate attitude and follow-up treatment are critical. This requires a conciliatory description of the pathological mechanism and, when pregnancy is viable, a positive prognosis. It is noted that early and adequate prenatal treatment can to some degree minimize the risk of threatening abortion. Enhanced antenatal monitoring could therefore classify women who are at increased risk within this category. Awareness of this elevated risk can also promote management, mode, location and time of delivery decision-making that will ultimately promote the consequence of pregnancy.

Ethical Clearance- Taken from ethical committee of institution

Source of Funding- Self

Conflict of Interest – Nil

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Effect of Aqueous Extract of Mentha Arvensis on Candida Albicans and Lactobacillus Acidophilus

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Abstract

Introduction: Orthodontic patients have an increase in the microorganisms because of the active sites for the plaque accumulation. Pudina (Mentha arvensis) which is a perennial plant has antimicrobial property and can be used as a mouth wash for these patients.

Aim: To evaluate the efficacy of aqueous extracts of Pudina (Mint) on Candida albicans and Lactobacillus acidophilus by evaluating their zone of inhibition and determining their minimum inhibitory concentration.

Methodology: This method consists of usage of aqueous extract of pudina and 0.2% of chlorhexidine is used as a positive control. The results are then quantified.

Results: The results showed that there is an increase in the inhibition zone diameter with the aqueous extract of pudina.

Keywords: Orthodontic patients, Candida albicans, Lactobacillus acidophilus, Pudina, inhibition zone

Introduction

Orthodontic appliances act as an active site for the attachment of food particles and subsequently microorganisms which later cause caries and periodontal diseases. Streptococcus mutans are strongly associated with the occurrence of caries. Patients with orthodontic brackets often have a large number of retention sites for plaque. There are studies confirming that after insertion of fixed orthodontic appliance, the levels of both the species have been increased despite a pre treatment oral hygiene education and training.^{1,6} Many plants exhibit potent antimicrobial activity against various microorganisms.² Many infectious diseases are known to be treated with herbal remedies throughout the history of mankind. The World Health Organization reported

that 80% of the world's population rely chiefly on traditional medicine and a major part of the traditional therapies involve the use of plant extracts or their active constituents. They have no side effects and act against and modulate the factors that are crucial for microbial survival or their activity.³ Pudina (Mentha arvensis), a perennial aromatic herb belonging to the family Labiatae and genus Mentha is an important culinary plant with immense medicinal use. The antibacterial effect of pudina has already been proven against Streptococcus mutans.^{4,5} This study is aimed at evaluating the efficacy of extracts of Pudina (Mint) on Lactobacillus acidophilus and Candida albicans by evaluating their zone of inhibition and determining their minimum inhibitory concentration

Materials and Methods

Pudina was obtained, air dried and then powdered (fig 1). Different concentration of pudina extract was prepared.(i.e) 5 g in 100ml, 10g in 100ml, 15 g in 100ml, 20g in 100ml and 25 g in 100ml (5%,10%,15%,20%,25%), it was then individually heated at 40°C for 5-10 mins.

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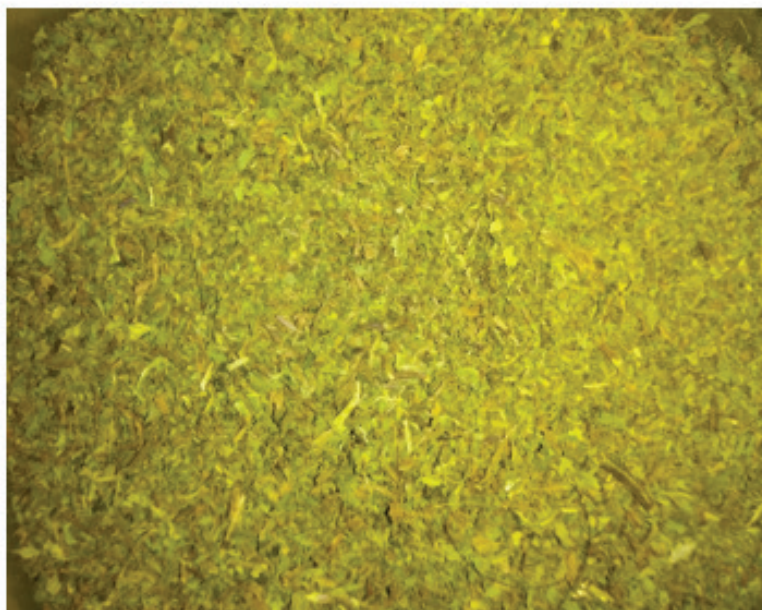


Fig – 1: Pudina powder



Fig – 2: Filter

The preparation was then incubated overnight at 37°C and then filtered (fig 2) using sterile whattman filter paper no 1, then the preparation was re- filtered using 0.45 micrometer filter paper and stored at 4°C in separate containers (fig 3).

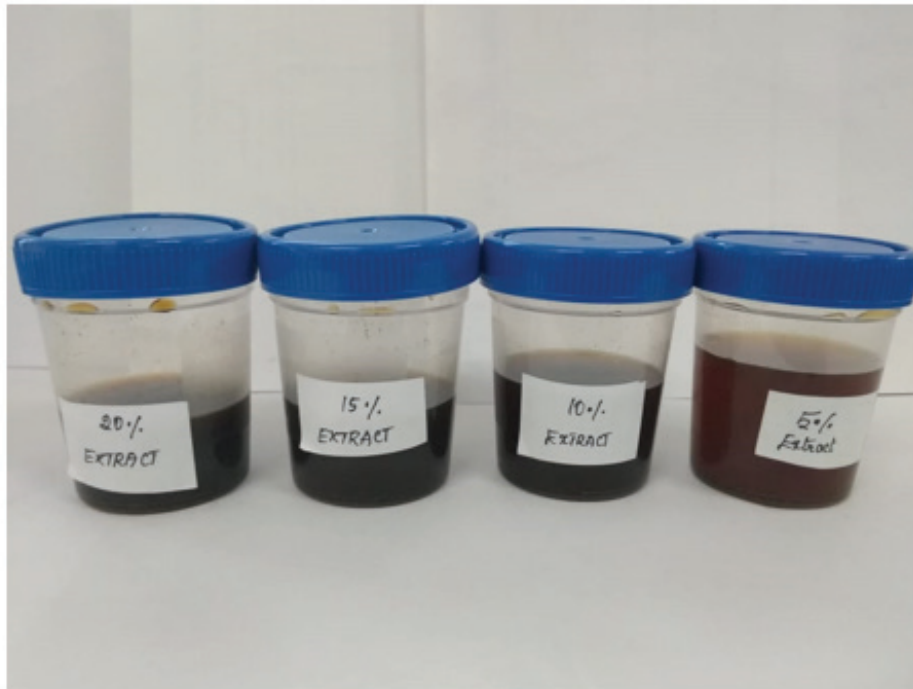


Fig – 3 : Prepared extract with distilled water

Cell suspension with 10^8 cells was prepared using lactobacillus acidophilus (NCIM 5306) and candida albicans (NCIM 3665) (fig – 4,5).⁷



Fig – 4 : Candida albicans culture

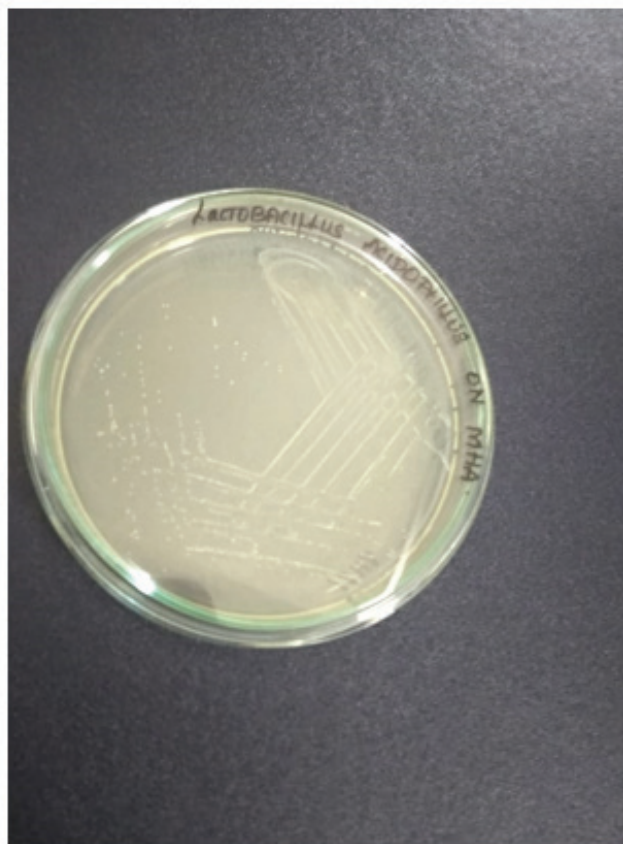


Fig – 5: Lactobacillus acidophilus culture

Using sterile micro tip, wells were made which was about 7- 8mm in diameter. Lawn culture was made on appropriate media. Then preparation with different concentrations were added on to the wells and observed for zone of inhibition after incubation at 37°C for lactobacillus acidophilus and 25°C for Candida albicans (fig 6)

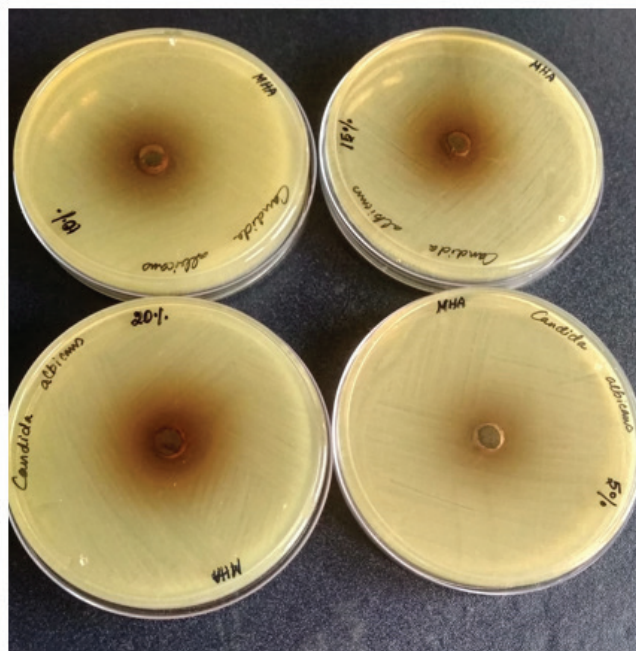


Fig – 6 : Inhibition zone with aqueous extract of pudina on Candida albicans

Results

Method – 1

Candida albicans: Partial zone of inhibition was present.

- 5% - No zone of partial inhibition
- 10% - 0.3mm
- 15% - 0.7mm
- 20% - 0.8mm

Lactobacillus acidophilus:

No zone seen in all the concentrations

Discussion

The medicinal plants have been used for the treatment of medical ailments for a long time. Many plants have been proven to have antibacterial properties. The composition of pudina (*Mentha arvensis*) is highly complex with many nutrients and biologically active substances, the amount of which may vary with different concentrations of pudina. The therapeutic properties of pudina is because of the presence of the menthol in it. It is largely used in the treatment of liver and spleen diseases. It is also used to treat asthma and jaundice.⁷

The other main constituents of pudina include 4.5 to 10% esters-menthyl acetate and 15 to 20% of ketones. The antibacterial effect of pudina is because of these constituents. The menthol in the pudina is more soluble in alcohol than in the water.⁵

Most orthodontic patients have lots of retention sites this leads to the number of *S. mutans* during active orthodontic therapy. The levels of *S. mutans* have been increased significantly in the carious than in the carious free orthodontic patients and studies have proven that the orthodontic treatment have increased the occurrence of carious lesions. There is an increase in the level of *Lactobacillus acidophilus* in patients treated with orthodontic appliance.^{1,6}

There has been studies by Hibino et al (2009) and Wisam Alhamadi et al (2017) that proves that there has been an increase in *Candida albicans* levels in orthodontic patients after the initiation of treatment.

This study was done to prove whether Pudina is effective against the *Candida albicans* and *Lactobacillus acidophilus*. The study proves that aqueous extract of pudina was effective against the *Candida albicans*. Hence the pudina mouthwash can be used for the patients being treated with orthodontic appliance. The pudina mouthwash can be used daily along the course of the orthodontic treatment for about 1 ½ to 2 yrs while the chemical preparations cannot be used for such a long time.

Conclusion

Candida albicans are opportunistic fungi and there is an increased quantity of *Candida* in orthodontic patients and this study has proven that aqueous extract of pudina is a good inhibitor of the *Candida albicans*. Hence it can be seen that pudina is a good alternative for the chemical mouthwash which has many side effects.

Conflict of Interest : Nil

Ethical Committee Approval: not needed since patients are not involved

Source of Funding: Self

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Relationship between Ocular Side Effects and Dental Local Anesthesia - A Review

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Abstract

Ophthalmological complications are infrequent problems due to dental local anaesthesia, diplopia being the most common among them. The intravascular injection of anaesthetic, since the cause of the problem and therefore it should be avoided in order to prevent accidents at ocular level.¹ Ophthalmologic complications take place as a result of maxillary and/or mandibular injections.^{2,3} The most commonly encountered complications affecting the eyes including blurring of vision, diplopia, mydriasis, palpebral ptosis and amaurosis (temporary or permanent).^{4,5} The dentist should be aware of these complications to avoid being perplexed by this unexpected circumstance, thus adversely affecting the doctor-patient trust.⁶ Herewith we discuss the association between the ocular side effects and dental local anesthesia.

Keywords: Anaesthesia, Complications, Diplopia, Nerve block, Ophthalmology.

Introduction

Local Anaesthesia has been defined 'as loss of sensation in a circumscribed area of the body caused by a depression of excitation in nerve endings or an inhibition of the conduction process in peripheral nerves'.⁷ Intraoral administration of local anaesthetics is one of the most common dental procedures. Ocular complications can occur after maxillary as well as mandibular local anaesthetic injections and may be under-reported and sometimes mis-interpreted.³ Unintended intravascular injection from inferior alveolar nerve blocks can result in frustrating distant complications affecting structures as the middle ear & eyes.⁸ The purpose of this article is to create awareness among dental practitioners the events that occur following the intravascular injections of local anaesthetics.⁹

LOCAL ANAESTHESIA AND ITS OCCULAR SIDE EFFECTS:

Complications which possibly affect the eyes include blurring of vision, diplopia, mydriasis, palpebral ptosis and amaurosis (temporary or permanent).⁴ The effect occurs a few minutes after injection of the anaesthetic, followed by complete resolution without sequelae on cessation of the anaesthetic effect.⁵ Among the maxillary anaesthetic injection techniques, posterior superior alveolar nerve block believed to be the major cause.^{1,2,5} and among the mandibular injection techniques, inferior alveolar nerve block^{1,4,6} and Gow – Gates technique⁸ are believed to be the major cause.

PATHOPHYSIOLOGY:

Here we present Pathophysiology of certain eye complications occurring as a result of dental local anaesthesia.

DIPLOPIA:

By giving mandibular injection, due to the vascular anatomy of middle meningeal artery there is chance for lateral rectus muscle paralysis which results in strabismus and eventual diplopia.¹⁰ By giving maxillary

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infiltration, via Autonomous Nervous System, there is a chance of diplopia.¹¹

LOSS OF VISION:

From maxillary injection, there is backflow of anaesthetic solution into the middle meningeal artery where it anastomosis with ophthalmic artery which passes via recurrent meningeal branch of lacrimal artery and reaches the central artery of retina which results in blindness.¹² From PSA, when large amount of LA under great pressure diffuses through inferior orbital fissure which touches optic nerve resulting in temporary blindness.¹³ From mandibular injection there is atrophy of optic nerve leading to permanent ipsilateral vision loss.¹⁴

OPHTHALMOPLEGIA:

From inferior alveolar nerve block, there is lateral rectus and levator muscle palsy which causes ophthalmoplegia.¹⁵ From mandibular and maxillary injection there is lateral rectus muscle palsy resulting in ophthalmoplegia.³ Fig 1 represents Lateral rectus muscle palsy, inability to move eyeball.¹⁶



Figure 5. The effects of an abducens nerve palsy on the left-hand side. The subject, due to a palsy of the lateral rectus muscle, has unopposed action of the medial rectus, with a resultant medial deviation of the eye at rest.

FIG-1-Lateral rectus muscle palsy, inability to move eyeball.¹⁶

Discussions

Here we discuss literature reports of cases of ocular complication due to dental local anesthesia.

Tomazzoli-Gerosa L , Marchini G , Monaco A presented a patient who had sudden permanent loss of ipsilateral vision with subsequent atrophy of the optic nerve with a mandibular nerve block.¹⁴ J. K. Scott, B. J. Moxham, I. P. Downie reported a patient of transient left lateral rectus nerve palsy, following an inferior alveolar nerve block for the permanent mandibular left third molar tooth removal.¹⁷ Fotios H. Tzermpas, Alina Cocos, Matthaios Kleftogiannis, Marissa Zarakas, Ioannis Iatrou presented a patient with temporary complete paralysis of cranial nerves III, IV, and VI, after a Gow-Gates injection. In this technique the paralysis occurred as a result of the proximity of the internal maxillary artery (accessory and middle meningeal) and the pterygoid plexus of veins and quick anaesthetic injection. Henceforth, it is necessary to perform careful aspiration before the local anaesthesia administration & injections should be on or within 1 mm to 2 mm of the condylar neck.¹⁸

Spierer A , Spierer S reported two children who had dental treatment under inferior alveolar nerve block. They developed lateral rectus muscle palsy and levator palpebral muscle palsy. Both cases were reported to be recovered spontaneously after a short period of time.¹⁵ Rodney E. Steller , E. Anthony Petrelli reported a 42 year old woman patient who developed transient partial third cranial nerve palsy after a supraperiosteal injection in the area of the middle superior alveolar nerve with mepivacaine HCl for dental anaesthesia. This effect may have been resulted by direct extension through a bony defect rather than by inadvertent intravascular injection of the anaesthetic.⁸ Leander Duboi, Serge A. Steenen , Peerooz Saeed , Jan de Lange did a review of the literature from the years 1936-2011 reported 131 cases with complication of right lateral rectus muscle palsy and blurred vision after bimaxillary anaesthesia.³ J.H. Kronman, S. Kabani reported a case with diplopia which resulted as an effect secondary to maxillary infiltration anaesthesia.¹¹ Michael Prakasm, Anil Managutti, R. S. Dolas, M. G. Agrawal reported ophthalmic complications arising from Posterior superior nerve block with the dilatation of pupil and ptosis of eye

lids.¹⁹Prilocaine Plain, an amide local anaesthetic (LA), is somewhat less potent than lidocaine and considerably less toxic after injection into peripheral tissues. Clinically, it is reported to produce less vasodilation and is similar to other amide LA in relative freedom from allergic reactions. It has been reliably used in a plain solution for cardiac patients receiving short procedures.²⁰

Conclusion

Every day in dentistry thousands of local anaesthetic injections are administered to patients, but the literature reports only a few ocular complications which require recognition to enable the practitioner to reassure the patient. Those complications due to the local anaesthetic solution itself demand knowledge of the pharmacology of the drugs and an understanding to obtain an accurate medical history.¹⁶Proper attention should be paid during the administration of the anaesthetic solution. Standard precautions like aspiration, slow injection, and continuous monitoring of the patient possibly will minimize side effects.²¹We conclude that the best way of avoiding the appearance of complications, both ocular and clinical, is to examine the patient and use a careful and correct technique, especially being careful to avoid intravascular injection of the anaesthetic.¹By knowing such incidents, dentists who find themselves in similar situations will be able to act accordingly.¹⁶

Source of Funding - Nil

Conflict of Interest- Nil

Ethical Clearance not required as it is a review article

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Effect of Mulligan's Mobilization with Movement and Post Isometric Relaxation Technique on Pain, Range of Motion and Functional Outcome in Subjects with Adhesive Capsulitis

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Abstract

Mobilization techniques and soft tissue techniques are widely used in managing Adhesive Capsulitis. Among various researches on different mobilization, the study results showed that the clinical concepts of Mulligan's Mobilization with movement is good. The results of various studies on different soft tissue techniques concluded that post isometric relaxation technique of Muscle energy technique is better. The aim of the study was to compare the effect of Mulligan's Mobilization with movement and post isometric relaxation technique on pain, range of motion and functional outcome in subjects with Adhesive Capsulitis. 30 subjects were selected and divided into 2 groups of 15 subjects in each group by purposive sampling method. Subjects in Group A received Mulligan's Mobilization with movement and conventional management, subjects in Group B received post isometric relaxation technique and conventional management for 4 weeks. Numerical Pain Rating Scale, Universal goniometer and Shoulder pain and disability index were used to measure pain, range of motion and functional outcome. There was a significant difference between the within group and between group in all parameters following intervention. However, Mulligan's group has shown significant improvement in all parameters (using unpaired 't' test, the calculated 't' value for pain is 10.27, $p < 0.05$ and the 't' value for ROM is 22.45 for external rotation, 14.95 for abduction, $p < 0.05$ and the 't' value for functional outcome is 6.71, $p < 0.05$). This study concludes that the Mulligan's mobilization with movement is more effective in reducing pain, improving range of motion and functional outcome in subjects with Adhesive Capsulitis.

Keywords: Adhesive Capsulitis; Functional outcome; Mulligan's Mobilization with Movement; Post isometric relaxation technique; Range of motion.

Introduction

Shoulder joint is the most important functional joint involved in the daily routine activities. Adhesive Capsulitis is a self – limited inflammatory process that affects shoulder capsule, characterized with progressive pain and decreased range of motion of the gleno – humeral joint in both active and passive movements¹. The incidence of Adhesive capsulitis in diabetic population is 17.9% and in non diabetic population is 7%. Women are more prone than men to get Adhesive

capsulitis. Adhesive Capsulitis is of two types. Primary Adhesive capsulitis occurs spontaneously whereas secondary adhesive capsulitis occurs after any injury or fracture to the shoulder. There will be capsular pattern of restriction in Adhesive capsulitis where external rotation is greatly restricted followed by abduction and internal rotation.

Stages of Adhesive Capsulitis are painful or freezing phase typically lasts for 10 to 36 weeks, with spontaneous onset of shoulder pain, which is often

severe and disturbs sleep. Stiffening or frozen phase may last for 4 to 12 months with restricted range of motion in a characteristic capsular pattern. Thawing or recovery phase is characterized by the gradual recovery of the range of motion, which may last an average of 5 to 26 months and is reportedly directly related to the length of duration of the painful phase². Pain is usually localized to the antero – lateral aspect of the shoulder joint.

Common functional limitations / disabilities seen in Adhesive Capsulitis are inability to reach overhead, behind head, out to the side and behind back thus having difficulty in dressing, reaching hand into back pocket to retrieve wallet, self – grooming and bringing eating utensils to the mouth³.

Multiple interventions have been described for the treatment of Adhesive Capsulitis such as Non steroidal anti – inflammatory drugs, local anesthetic and corticosteroid injections, distension arthrography, closed manipulation under anaesthesia, surgery, subject education, physical therapy modalities, cryotherapy, moist heat, joint mobilizations, stretching exercises, pendular exercise, scapula thoracic strengthening exercises⁴. Various physiotherapy treatment techniques include mobilization techniques like Maitland, Mulligan, Kaltenborn, soft tissue techniques like Muscle Energy Technique, Myofascial Release, PNF techniques, moist heat therapy, cryotherapy, ultrasound therapy, short wave diathermy, interferential therapy, transcutaneous electrical nerve stimulation, range of motion exercises, capsular stretching exercises and pendular exercises.

Brain Mulligan's technique known as Mobilization with Movement for peripheral joints combines sustained manual application of “gliding” force to a joint by the therapist while the restricted upper limb movement is performed actively or passively by the subject to restore the reduced accessory glide and the result should be a pain free movement. It helps in repositioning the bone positional faults⁵.

Muscle energy technique was developed by Dr. Fred Mitchell Snr. It is a non – invasive technique which can be used to stretch or lengthen muscle and fascia that lack flexibility. Post isometric relaxation technique of MET targets the soft tissue primarily, but it also makes a major contribution towards joint mobilization which not only increases range of motion of joints, but also increases

the extensibility of muscle by means of a mechanism expressed as “increased tolerance to stretch”⁶.

Materials and Methods

This experimental study was conducted on 30 subjects at the Department of Physiotherapy, K.G Hospital and Outpatient Department, K.G College of Physiotherapy, Coimbatore. This study has been approved by the Institutional Review Board. A clear explanation was given to every subject about the procedures and a written consent was obtained from them. The subjects were included based on the inclusion criteria [both genders with age ranging from 45 to 60 years, subjects with stage II idiopathic / primary adhesive capsulitis, subjects with unilateral involvement having painful stiff shoulder for more than 3 months without any shoulder trauma, pain in the shoulder should be ≤ 7 in numeric pain rating scale, subjects with adhesive capsulitis of capsular pattern of restriction (Rotation > Abduction > Flexion), subjects with more than 50% loss of both active and passive range of motion of the involved side when compared with the uninvolved side of the shoulder] and exclusion criteria [subjects with secondary adhesive capsulitis, rotator cuff tears, fractures or dislocations, history of any recent shoulder surgeries to the involved side, diabetic subjects, subjects with cardiovascular impairments, subjects with neurological impairments, malignancy, unwilling and uncooperative subjects]. Subjects were divided into two equal groups based on the purposive sampling method.

Group A - Mulligan's Mobilization with movement along with conventional management. Mulligan's mobilization with movement is performed for shoulder external rotation and abduction as described by Mulligan. 3 sets of 10 repetitions with 1 minute rest between sets, 3 times a week for 4 weeks are performed.

Group B - Post isometric relaxation technique along with conventional management. Post isometric relaxation technique of Muscle energy technique is applied for shoulder external rotators and abductors as described by Chaitow L. Post isometric relaxation technique is applied for 5 sets of 5 repetitions, 3 days a week for 4 weeks with each repetition maintained for 7 – 10 seconds.

Conventional management includes the application of moist heat therapy, capsular stretches and active

range of motion exercises. Each capsular stretch is maintained for 30 seconds with 30 seconds rest between stretching episodes and repeated for 10 times a day, 4 days a week for 4 weeks. Active range of motion exercises include, Codman’s pendular exercise, finger ladder exercise, pulley exercise, marine wheel exercise and towel exercise. Each exercise is performed for 2 sets of 15 repetitions with 2 minutes rest between each sets, twice daily, 4 days a week for 4 weeks.

The study was carried out for 6 months and baseline characteristics were similar in both groups. Pre and post test evaluation of pain, range of motion and functional outcome were measured.

Results

At baseline, the Numerical Pain Rating Scale scores of the two groups were similar (Table 1). A comparison of the Numerical Pain Rating Scale scores measured at the baseline and during the final treatment session in both groups revealed that the Mulligan’s mobilization

with movement decreased pain significantly compared to Post isometric relaxation technique (p<0.05) (Table 2) (Figure 1). A significant (p<0.05) decrease in pain was observed by the end of the treatment in both the groups.

The shoulder abduction and external rotation range of motion were similar in both the groups at the initial assessment (Table 1). Both abduction and external rotation range of motion increased significantly in Mulligan’s mobilization with movement group than the post isometric relaxation technique group (p<0.05) (Table 2) (Figure 2). The range of motion increased significantly from baseline to the final treatment session in both the groups.

The Shoulder pain and disability index score for functional outcome were also similar at the baseline (Table 1). The Shoulder pain and disability index score increased significantly after the treatment in both the groups (p<0.05) and a significant difference between the groups (p<0.05) was observed at the end of the treatment (Table 2) (Figure 1).

Table 1: Comparison of demographic characteristics of subjects in the Mulligan and Post isometric relaxation group

Subject Characteristics	Mulligan’s mobilization with movement group Mean ± Standard Deviation	Post isometric relaxation group Mean ± Standard Deviation
Age (years)	54.67 ± 3.81	52.73 ± 4.83
Weight (kg)	69.73 ± 3.47	66.53 ± 3.93
Gender	8 females, 7 males	9 females, 6 males
Dominant arm	13 right, 2 left	12 right, 3 left
Affected arm	10 right, 5 left	11 right, 4 left
Symptoms duration (months)	4	4
Numerical Pain Rating Scale	6.20 ± 0.77	6.47 ± 0.52
Shoulder Abduction Range of motion	88.93 ± 2.87	88.73 ± 2.46
Shoulder External rotation range of motion	39.60 ± 3.78	39.60 ± 3.46
Shoulder pain and disability index	81.20 ± 3.36	79.40 ± 3.36

Table 2: Comparison of the outcome variables between the Mulligan and post isometric relaxation group using the independent t-test

Variables	Mulligan’s mobilization with movement group Mean ± Standard Deviation	Post isometric relaxation group Mean ± Standard Deviation
Numerical Pain Rating Scale	2.13 ± 0.74	4.53 ± 0.52
Shoulder Abduction Range of motion	167 ± 1.65	158.07 ± 1.62
Shoulder External rotation range of motion	80.13 ± 0.83	68.27 ± 1.87
Shoulder pain and disability index	19.53 ± 4.07	27.47 ± 2.1

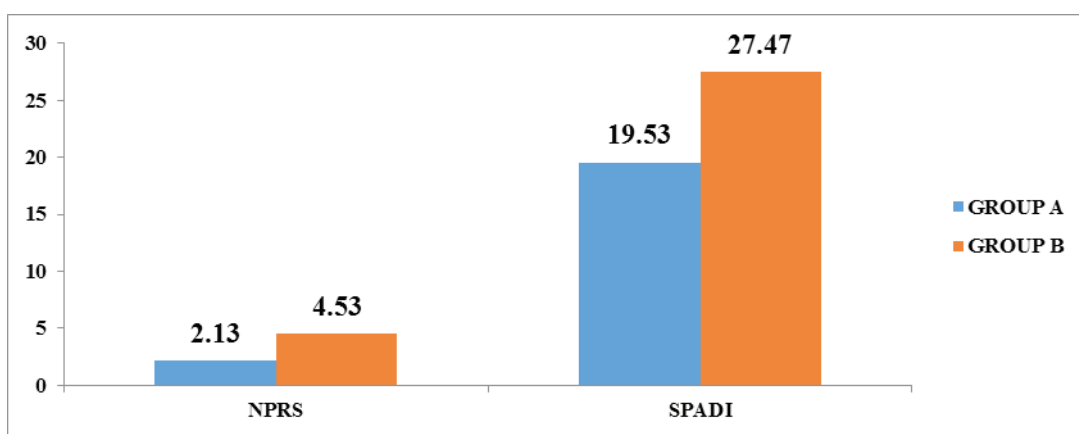


Figure 1: Comparison of the post test values of pain & functional outcome of Group A and Group B

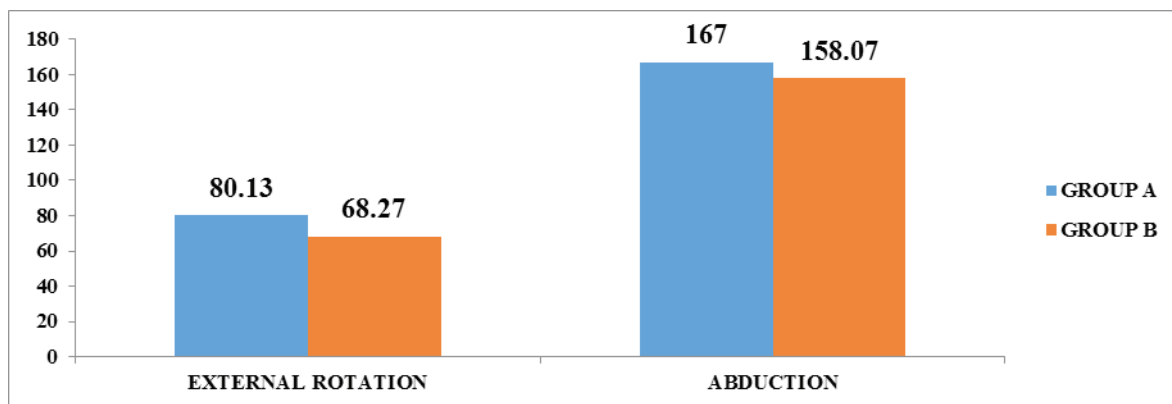


Figure 2: Comparison of the post test values of range of motion of Group A and Group B

Discussion

Mulligan’s Mobilization with Movement consists of patient generated active physiological movement along with accessory mobilization done by the therapist. Initial pain relief may be achieved by the

stimulation of joint mechanoreceptors and inhibition of nociceptors. Later the pain relief may be achieved by the stimulation of periaqueductal grey region which in turn causes the descending pathways to influence the inhibitory interneurons and may also be achieved by

dynamics of the synovial fluid during mobilization. Both physiological and accessory movement associated with MWM may correct the joint positional fault or movement fault, which causes the pain and disability. It might have stretched the tight capsules, broken the adhesions and regained the normal tissue extensibility.

MWM technique is found to be effective by neurophysiological mechanism of production of initial hypoalgesia based on stimulation of peripheral mechanoreceptors and the inhibition of nociceptors⁷.

The active participatory nature of this technique stimulates proprioceptors and inhibits pain⁸. The biomechanical effect of Mobilization With Movement is to correct the positional faults by repositioning the joint, causing it to track normally⁹. The active movement in this technique stimulates the proprioceptive tissues, such as the Golgi tendon organ by tendon stretch¹⁰. The mechanical benefits may include breaking up of adhesions, realigning collagen or increasing fiber glide when specific movements stress the parts of the capsular tissue. Other beneficial effects of Mulligan technique are improving the normal extensibility of shoulder capsule, stretching the tight soft tissues and normalization of scapulohumeral rhythm⁹.

The improvement in shoulder function seen in subjects within the Mulligan group could be a direct effect of pain relief associated with technique, which encouraged subjects to use their affected arms in activities of daily living¹¹.

Post isometric relaxation technique in MET may induce pain relief by stimulation of mechanoreceptors and inhibition of nociceptive impulses. Later pain relief is also achieved by the stimulation of periaqueductal grey region which acts on descending pathways and modulates pain. The range of motion may be increased by trigger of Golgi tendon organ following isometric contraction, while afferent impulses from the Golgi tendon organ interacts with inhibitory motor neuron, thereby stops efferent impulses and leads to relaxation and lengthening of agonist muscles.

The shoulder capsule consist of contributions from the rotator cuff muscles. Post isometric relaxation technique of MET is applied to the shoulder external and internal rotators, abductors and flexors in the restricted

range. It involved isometric contraction at restricted range followed with achievement of new available restricted range while relaxing and it goes on until maximum range that could be achieved. This could have broken the adhesions and stretched the tight capsule with tensile load to increase the tissue extensibility.

Pain reduction by muscle energy technique was due to centrally mediated pain inhibitory mechanism and neuronal mechanism in dorsal horn is by neurological and tissue factors such as stimulation of low threshold mechanoreceptors which leads to possible gating effects and effect of rhythmic muscular contraction on interstitial and tissue fluid flow^{12,13}.

Post isometric relaxation technique of MET is a manual therapy that uses the gentle muscle contractions to relax and lengthen muscles and normalize joint motion¹². The mechanism behind increase in range of motion by Muscle energy technique is that muscle contraction against equal counterforce triggers the Golgi Tendon Organ. The afferent nerve impulse from the Golgi tendon organ enters the dorsal root of the spinal cord and meets with an inhibitory motor neuron. This stops the discharge of the efferent motor neurons impulse and therefore prevents further contraction, the muscle tone decreases, which in turn results in the agonist relaxing and lengthening, so there is an increase in range of motion¹⁴.

Application of moist heat therapy prior to mobilization and exercises may be beneficial because it soothes and relaxes the joint and muscles and increases the tissue extensibility. Exercises may induce pain relief by activation of mechanoreceptors and increased fluid dynamics.

Mulligan's Mobilization with movement involved passive accessory glide and active physiological movement that could have directly stimulated the mechanoreceptors in articular cartilage and stretched the periarticular soft tissues more than the Post isometric relaxation technique where the mechanoreceptors are stimulated and periarticular soft tissues got stretched indirectly with only 20% of active muscle contraction. Even though both techniques worked significantly, Mulligan's Mobilization with Movement has shown significant improvement both clinically and statistically than Post isometric relaxation technique on pain, range

of motion and functional outcome. The limitations of this study are as follows. First, purposive sampling was used in this study, so the results could not be generalized to the entire population. Second, sample size is small. Third, long term follow up was not done. Future studies are recommended to include diabetic individuals, subjects with other stages of adhesive capsulitis can be included and other parameter like muscle strength can also be included.

Conclusion

In conclusion, Mulligan's mobilization with movement is more effective in reducing pain and improving range of motion and functional outcome than Post isometric relaxation technique of Muscle Energy Technique.

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Birth Preparedness and Complication Readiness among Antenatal Mothers Attending Tertiary Care Hospital

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Abstract

The most joyful moment for every mother is her pregnancy period. However, almost many mothers face unexpected complications during their pregnancy period which may lead to the death or injury to the infant or herself. Birth preparedness and complication readiness is a strategy developed and approved globally that encourages pregnant women along with their families to plan for birth and to be prepared if any emergency occurs.

Aims: To assess the knowledge of birth preparedness and complication readiness among antenatal women.

To find the association of sociodemographic and obstetric characteristics with maternal knowledge

Settings and Design: A facility based cross-sectional study was undertaken for a period of four months from May to August, 2019 in a tertiary care hospital, Sivagangai district, South Tamil Nadu

Methods and Material: A pretested semi-structured questionnaire was prepared to collect data. The study participants were selected by convenient sampling technique.

Statistical analysis used: Microsoft Excel was used to enter data and SPSS version 21.0 was used for analysis. Univariate and bivariate analysis was computed. Chi-square value was calculated and statistical significance was considered when p-value was <0.05.

Results: The overall study participants who were well prepared was 48.8%. The level of knowledge about danger signs during pregnancy, postpartum and newborn periods were 32.4%, 23.5% and 18% respectively. The association between baseline characteristics and maternal knowledge revealed significant association of maternal age, socioeconomic status, parity, gestational age with maternal knowledge on BPCR

Conclusions: Providing health education on pregnancy and its complications and birth plan during their antenatal visits would increase birth preparation and complication readiness plan.

Key-words: Birth preparedness, Complication readiness, Obstetric danger signs, maternal mortality

Introduction

Every mother has the right to have an unfathomable euphoria when an infant is set on the arms. However, for

several women in India this moment has become scary¹. worldwide estimate of maternal death is around 2,95,000 in 2017². Common factors influencing maternal mortality in developing countries are lack of institutional delivery, inadequate birth preparedness, poor competence of healthcare providers, lacunae in emergency obstetric services at facilities and weak referral systems³⁻⁶. Birth preparedness and complication readiness focuses on two components, planning for a normal birth and getting prepared for any emergency to come. This in turn

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also promotes timely utilisation of skilled maternal and neonatal care^{7,8}. This strategy has been approved globally as essential components of safe motherhood program⁹.

Complication readiness ensures to provide antenatal women knowledge on all obstetric complications. So that, the women will be able to recognise the complication at the earliest and seek care from qualified health care providers at the facility¹⁰.

In many sectors of the world due to cultural beliefs and inadequate awareness no action/preparation are taken prior to delivery. Many women do not know to recognise danger signs of complications, due to which there is delay in timely intervention in terms of getting organised for arranging money, transport and reaching appropriate referral facility¹¹⁻¹³. There is limited number of comprehensive studies to assess the knowledge of antenatal mothers on birth preparedness and complication readiness in the southern part of India. Hence the current study was undertaken to assess the knowledge of birth preparedness and complication readiness among antenatal women of any gestational age and the association of sociodemographic, obstetric characters of the study population with maternal knowledge.

Subjects and Methods

This study was conducted in Government Medical College, Sivagangai, a tertiary care hospital located in Sivagangai, Southern Tamilnadu. This facility based cross sectional study was conducted for a period of four months from May to August of the year 2019. The study included all antenatal women who visited antenatal clinic during the period of study regardless of their gestational age. They were explained about the purpose of the study and those who gave oral consent for the study were serially enrolled by convenient sampling technique.

A pretested, semistructured questionnaire was used to collect data from the study participants. Questions included identification details, details on sociodemographic profile, maternal knowledge on danger signs during pregnancy, puerperium period, danger signs for neonates, awareness on birth preparedness and complication readiness.

John Hopkins Bloomberg school of public health has developed birth preparedness and complication readiness index which has been used for studies conducted worldwide. This includes percentage of women who know about more than half of the danger signs of pregnancy, percentage of women who know about the transportation provided by Government, who identified skilled birth attendant for delivery, percentage of women who identified mode of transport, percentage of women who saved money for expenses and knowledge on financial assistance provided by government in Janani Surekha yojana. In the current study respondents who were able to say four, out of the eleven danger signs during pregnancy, post-partum and neonatal period were considered to have adequate knowledge on danger signs. Those respondents who were able to mention more than three out of the five components of birth preparedness and complication readiness were considered to have "well prepared". Respondent's age, socioeconomic status, gestational age, parity, previous history of stillbirth was considered as independent variables while maternal knowledge on each criteria was considered dependent variable.

Questionnaire was checked for completeness daily by the primary investigator. Data was entered in Microsoft excel, statistical package for social science windows version 21.0 was used for analysis. Univariate analysis was done using descriptive techniques and bivariate analysis using Chi square test for independence. Factors with p value <0.05 were considered to have statistically significant association with maternal knowledge.

Results

In this study a total of 451 antenatal women were interviewed. About 242 (53.7%) of the respondents were in the age group 21 to 25 years. Most of the respondents 385 (85.4%) were Hindu by religion. Table 1.

Of the total eleven danger signs those who were aware of at least four were considered knowledgeable. Thus 32.4% of the study participants had adequate knowledge about danger signs in antenatal period. Out of the 451 respondents, 353 (78.3%), 171 (37.9%), 148 (32.8%), 125 (27.7%) mentioned vaginal bleeding, severe abdominal pain, severe weakness, premature rupture of membrane respectively as pregnancy danger signs.

With regard to serious health problems that can occur during postpartum period, only 110 (24.4%), 51 (11.3%), 50 (11.1%) of the study participants mentioned high temperature, malodorous vaginal discharge, convulsions as postpartum danger signs, respectively.

From all the 451 respondents 204(45.2%), 154(34.1%), 119(26.46%) and 131 (29.7%) mentioned yellow skin/eye, small for date baby, poor feeding, difficult/ fast breathing as danger signs respectively.

If an antenatal mother reported at least three of the five components given in table 3, was considered as well prepared. Overall, 220 (48.8%) of the study participants were considered well prepared.

From table 4, it is observed that maternal age, socioeconomic status, gestational age and parity had statistically significant association with maternal knowledge on birth preparedness and complication readiness.

Table 1: Distribution of Sociodemographic and Obstetric variables of respondents (N=451)

Variables	Frequency (n)	Percentage (%)
Age group (in years)		
<20	51	12.2
20-25	242	53.7
25-30	137	30.4
30-35	17	3.8
Religion		
Hindu	385	85.4
Christian	37	8.2
Muslim	29	6.4
Socioeconomic status		
Upper middle	77	17.1
Lower middle	203	45
Upper lower	171	37.9
Gestational age		
First trimester	23	5.1
Second trimester	119	26.4
Third trimester	309	68.5
Parity		
Primi	307	68.1
Multi	144	31.9
History of still birth		
Yes	69	15.3
No	382	84.7

Table 2: Awareness about danger signs in pregnancy, postpartum and neonatal period(N=451)

Component	No. of women Aware	Percentage (%)
Knowledge about danger signs in pregnancy	146	32.4
Knowledge about danger signs of postnatal period	106	23.5
Knowledge about danger signs of new-born	81	18
Knowledge about BPCR	220	48.8

Table 3: Distribution of respondents according to their knowledge on birth preparedness and complication readiness (N=451)

Component	Adequate knowledge	Percentage (%)
Identified mode of transport	320	71
Saved money in case for emergency	370	82
Identified blood donor	120	26.6
Identified skilled birth attendant	17	3.8
Identified place of delivery	274	60.8

Table 4 : Factors associated with birth preparedness and complication readiness (N=451)

Factors	Knowledge		Chi-square	p value
	Adequate	Inadequate		
Age group (in years)				
<20	0	55	16.955	<0.001**
20-25	42	200		
25-30	13	124		
30-35	0	17		
Socioeconomic status				
Upper middle	22	55	29.838	<0.001**
Lower middle	26	177		
Upper lower	7	164		
Religion				

Cont... Table 4 : Factors associated with birth preparedness and complication readiness (N=451)

Hindu	48	337	0.067	0.714
Christian	3	34		
Muslim	4	25		
Gestational age				
First trimester	7	26	8.981	<0.05*
Second trimester	17	102		
Third trimester	31	278		
Parity				
Primi	23	284	19.863	<0.001**
Multi	32	112		
History of still birth				
Present	8	61	0.027	0.87
Absent	47	335		

**Significant ($p < 0.05$)

Discussion

The current study was conducted to assess the level of birth preparedness and complication readiness and associated factors among antenatal women and associated factors among antenatal women.

The level of knowledge on danger signs during pregnancy among the study participants was 32.4% which was consistent with the studies conducted in Adigrat town which included 562 recently delivered mothers and found (31.9%) to have adequate knowledge, another study conducted among four hundred pregnant women in Osun state, Nigeria revealed the level of knowledge as 28.3%.^{14,15} This was inconsistent with the 18.6% knowledge level observed among 2022 pregnant women at Rewa District, Madhya Pradesh¹⁶.

The most common cause of maternal mortality in India are postpartum haemorrhage and anaemia respectively. Identification of a compatible blood donor to be available in case of emergency is essential. In the

current study only 120 (26.6%) had identified blood donor. However, few other studies have reported similar results. This might be due to the lack of insufficient knowledge on the complication of blood loss during pregnancy or delivery period. This might also be due to their previous pregnancy which required no blood transfusion^{17,18}.

In the current study awareness on difficulty in breathing or fast breathing in newborn was found in 131 (29.7%) antenatal mothers. This was in line (24.3%) with the study conducted in Manipal by Gurung et al, among 320 pregnant women but significantly low compared to the observation done by Lliyasa et al., in Nigeria, were 49.7% of the respondents identified difficulty/fast breathing as a key danger sign in newborn^{17,19}.

The present study reveals that only 17 (3.8%) of the respondents have identified the skilled birth attendant. Similar study conducted among 417 antenatal attendees at a primary health center, Palam, New Delhi highlighted that 32 % of the respondents were aware of having a

skilled birth attendant.²⁰ The present study observation is also much lower compared to the studies conducted by Jayate Gurung et al, who revealed that about 99% of the respondents had identified skilled birth attendant for childbirth¹⁷.

Identification of health facility by antenatal women were found to be 274(60.8%). This was consistent with the results obtained in a study result from Rewa district of Madhyapradesh(63.8%)¹⁶. However, a study done by Anita Shankar Acharya et al, in new Delhi highlighted that 81.1% of their study participants had identified a skilled attendant at birth²³.

The present study found out that only about 220 (48.8%) seemed to be well prepared for birth preparedness and complication readiness. This is nearly similar to the study conducted by Jeyata et al, were 157 (51.47%) respondents seemed to be prepared for BP/CR in the study area¹⁷. The prevalence of BP/CR in the current study is higher than that reported by Hailu and Berhe in Southern Ethiopia, Kushwah et al. in madhyapradesh, India, Kabakyenga et al. in Uganda but lower than the observed results of Karkee et al. in Nepal.^{16,20-22} The variations in the birth preparedness maybe due to the variation in determining what constituted being “well prepared” because it is not same in all studies.

The study revealed statistically significant association of maternal age, parity, gestational age and socio-economic status with maternal knowledge. These findings were consistent with the findings of a study conducted in a primary health centre, Delhi which found parity, younger age, education, joint family system, and husband’s education and occupation to be associated with having a birth plan²⁰.

Conclusion

Although awareness on the concept Birth preparedness and complication readiness was not poor(48.8%), recognition of at least one danger sign during all pregnancy, postpartum and neonatal period was not satisfactory. Hence antenatal mothers could be provided with health education on birth planning, danger signs throughout pregnancy and puerperal period.

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Conflict of Interest -Nil.

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Role of Topical 5-Fluorouracil Combined with Microneedling in Stable Vitiligo

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Abstract

Background: Vitiligo is a chronic acquired disorder characterized by the development of depigmented macules which slowly enlarges with the concurrent appearance of new lesions.

Aim: The aim is to study the efficacy of treating vitiligo by microneedling followed by application of 5-fluorouracil on vitiligo patches.

Materials and Methods: This study was conducted in a tertiary hospital from March 2019 to August 2019. For this study, we selected about 50 patients in the age group of 10–50 years who had been taking treatment for vitiligo for 2–3 years without much improvement. We suggested them about needling with 5-fluorouracil application over vitiligo patches. The procedure was performed at a gap of 2 weeks on vitiligo patches of various patients for about 3 months.

Result: After about 1 month of this procedure, we noticed an improvement in about 40% of patients with some erythema and hyperpigmentation developing on the margins of vitiligo patches. Gradually more than 50% of patients had similar improvement by the end of 2 months. After 3 months, about 60% of patients had hyperpigmentation in the vitiligo lesions with almost complete pigmentation in very small patches; larger ones had less pigmentation and 40% did not have any pigmentation from the previous state.

Conclusion: 5-fluorouracil is a simple and effective method for treating small vitiligo patches (< 5 cm diameter generally) with no major side effects. It is a cost-effective procedure in treating a very resistant disease, i.e., vitiligo, especially for small lesions.

Key words: 5-fluorouracil, Microneedling, Pigmentation, Vitiligo

Introduction

Vitiligo is a common form of localized depigmentation. It is an acquired condition resulting from the progressive loss of melanocytes. It is characterized by milky white sharply demarcated macules. According

to a recent Vitiligo Global Issues Consensus Conference, the term “vitiligo” can be used as an umbrella term for all non-segmental forms of vitiligo (including acrofacial, mucosal, generalized, universal, mixed, and rare variants of vitiligo).¹

It is stated that vitiligo affects 0.5–1 % of the world’s population.

It can begin at any age, and the prevalence is probably the same in sexes. Various theories have been suggested for the etiology of vitiligo; the autoimmune theory is currently the leading hypothesis and is supported by strong evidence. It is based on the clinical

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association of vitiligo with a number of disorders also considered to be autoimmune or autoinflammatory. Among autoimmune diseases, the strongest association is with thyroid disease. Histochemical studies show a lack of dopa-positive melanocytes in the basal layer of the epidermis. Electron microscopic studies confirm the loss of melanocytes. In inflammatory vitiligo, where there is raised erythematous border, there is an infiltrate of lymphocytes and histiocytes. Medical treatment is the primary mode of therapy to achieve repigmentation. However, in patients recalcitrant to medical treatment alone, various surgical therapies can be used either alone or in conjunction with medical treatment to achieve repigmentation provided that the disease is stable. Needling followed by topical application of 5% 5-fluorouracil is a recent advancement to the treatment modality of vitiligo. In the present case series, we report some cases of vitiligo who had no or minimal repigmentation of the achromic patches with conventional therapy and responded to addition of needling with the application of topical 5-fluorouracil treatment leading to significant repigmentation.

Materials and Methods

This study was conducted at Saraswati Institute of Medical Sciences, Hapur, Uttar Pradesh, from March 2019 to August 2019. For this study, we selected about 50 patients in the age group of 10–50 years who had been taking treatment for vitiligo for 2–3 years without much improvement. Some were taking NB-UVB therapy also along with oral and topical medication. Their disease was stable for 3–4 months on an average. We suggested them about needling with 5-fluorouracil application over vitiligo patches. The procedure was performed at a gap of 2 weeks on vitiligo patches of various patients for about 3 months. They were explained about the side effects which might occur and asked to sign on the consent form for the procedure. We tried to take those patients only who had small patches of vitiligo to avoid discomfort and better assessment. 5-fluorouracil, available in cream form, is needed along with 26G needle and gloves. Under aseptic precautions, microneedling was done on the patch followed by application of 5-fluorouracil in minor operation theatre (OT). The patients were made to sit for 1 h after application so as to check for any side effects.

Result

After about 1 month of this procedure, we noticed an improvement in about 40% of patients (20) with some erythema and hyperpigmentation developing on the margins of vitiligo patches. Gradually more than 50% of patients (25) had similar improvement by the end of 2 months. After 3 months, about 60% of patients (30) had hyperpigmentation in the vitiligo lesions with almost complete pigmentation in very small patches; larger ones had less pigmentation and 40% (20) did not have any pigmentation from the previous state.

Discussion

More than 90% of patients had pain during the procedure; only a few had burning and erythema; no serious side effect was observed. This study shows that for small lesions of vitiligo, 5-fluorouracil application after needling is a cost-effective, safe, and easy method of treatment with minimal side effects although it is not reasonable for larger patches of vitiligo. It is comparable to a study by Sethi et al. in which dermabrasion was combined with 5-fluorouracil where erythema and serous discharge were noted in all patients.² A similar study was reported by Shashikiran et al. Efficacy of topical 5% fluorouracil needling in vitiligo, where more than 75% repigmentation was noted in 49% of the patches, 50–75% repigmentation was seen in 26% of the patches, 25–50% repigmentation in 11% of the patches, whereas 14% of the patches responded poorly with less than 25% repigmentation (their study considered the number of patches and not the number of patients for assessment). Application of 5-fluorouracil after therapeutic wounding, as a treatment for vitiligo, was introduced by Tsuji and Hamada in 1983.³ A strong inflammatory reaction is seen after needling followed immediately by application of topical 5-fluorouracil. Due to this, there is local edema, which increases the intercellular spaces of the basal layer for a long time. Active melanocytes with frequently vacuolated cytoplasm are found migrating from the pigmented to the achromic epidermis through these enlarged intercellular spaces. Further, the inflammatory mediators such as leukotrienes C₄ and D₄ are locally released, which would stimulate melanocyte proliferation and migration. The metalloproteinase-2 synthesized by the keratinocytes during the epidermis remodeling process

has been found to help in melanocyte migration. This favorable milieu, which persists for a long time, could explain the successful migration of melanocytes from the pigmented area to the achromic area.⁵

Conclusion

5-fluorouracil is a simple and effective method for treating small vitiligo patches (< 5 cm diameter generally) with no major side effects. It is a cost-effective procedure in treating a very resistant disease, i.e., vitiligo, especially for small lesions. We can say that 5-fluorouracil is a cost-effective way of treating vitiligo in patients with resistant patches of long duration.

Ethical Clearance- Taken from ethical committee of institution

Source of Funding- Self

Conflict of Interest – Nil

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A Study on Patient Safety Culture among the Health Care Providers in a Tertiary Care Hospital

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Abstract

Introduction: Patient safety emphasizes reporting, analysis and prevention of medical errors that often lead to adverse health events.

Aim: To observe the Patient Safety Culture among the Health-care Providers in a selected area of a tertiary care centre.

Methodology: A cross-sectional study was conducted in a specific area of a tertiary care hospital from January 2020 to March 2020 to study the Patient Safety Culture among the Healthcare Providers. Data was collected by using a stratified random sampling method using a validated questionnaire. Written informed consent was taken from all the participants. Data was analyzed by using the Statistical Package of Social Sciences (SPSS), Version-22.

Results: 102(50.5%) of the respondents belonged to the medical/surgical units, followed by 79(39.1%) other patient care units, 13(6.4%) from administration/management, rest belonged to miscellaneous groups/support services. 146(72.35%) of the participants strongly agreed that they worked together as an effective team. 131(64.9%) participants strongly agreed that their supervisors/clinical leaders consider improving patient safety. 93(46%) participants responded that they were always informed about errors in their unit, and 94(46.5%) responded that when errors happened in their unit, they often discussed the ways to prevent them from happening again. As far as staff position in the hospital was concerned, the excellent rating was given by others (83.3%) followed by Medical staff (73.7%). The study revealed a statistically significant (p-value <0.05) relationship between the position/primary unit in the hospital with respect to patient safety.

Conclusion- The study findings suggest that there is correlation between the position/primary unit in the hospital and perception about patient safety.

Keywords: patient safety, health management, patient safety culture,

Introduction

Patient safety can be defined as the prevention of errors and adverse effects associated with patients'

health care (WHO, 2017). Patient safety in health care includes the safety of both patients (clients) and health-care providers (HCP). It is a clinical, economic, managerial, and organizational concern in the health-care system. Patient safety culture is a crucial driver of health-care quality. Patient safety emphasizes reporting, analysis and prevention of medical errors that often lead to adverse health events¹.

Most of the adverse events are preventable and occur due to defect in system or organization design rather

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than poor performance of HCP. Clients are harmed by the misuse of technology and could be harmed by poor communication between different HCP or in rendering treatment². Unsafe medical care is a significant source of morbidity and mortality throughout the world. Although estimates of the problem's size are imprecise, millions of people likely suffer disabling injuries or death directly attributable to medical care (WHO, 2008).

Lack of trained staff, lack of policies, procedures, and a safety culture rank high among priority areas for improving patient safety and have massive implications for health care delivery and health systems in developing countries.

Several studies on medical errors report that one in ten patients are harmed while receiving hospital care³. Estimation from global studies reported the rate of adverse events as 3.2–16.2 per 100 hospital admissions. The rate of adverse events to patients varies with different states in the US; it ranges between 3.2% and 5.4%, it is 11.7% in the UK, and 9% in Denmark⁴. Safety culture differed significantly not only between hospitals but also within the institutions⁵.

Need for the study:

The European Society for Quality in Healthcare has defined a culture of safety in the context of patient safety dynamically as “an integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the processes of care delivery”. Measuring safety culture provides a tangible indicator of organisations' status and progress over time and teams implementing improvements.

A safety patient culture strategy starts with an evaluation of the present safety level in an institution (safety precautions implemented without proper

assessment may be costly with unpredicted new risks)⁶. With this background, a study to observe the Patient Safety Culture among the Health-care Providers in a selected area of a tertiary care centre was undertaken.

Methodology: A cross-sectional study was conducted in a specific area of a tertiary care hospital from January 2020 to March 2020 to study the Patient Safety Culture among the Healthcare Providers. The data was collected by stratified random sampling method using a validated questionnaire. The questionnaire, Hospital Survey on Patient Safety Culture (HSOPSC) that has been developed by the Agency Healthcare Research Quality, United States, was used.

The questionnaire has two main components. The first component relates to designation and area of work. The second component relates to unit, supervision, communication, patient safety event reporting, safety rating, about the hospital, and some background questions are asked. Most of the responses were recorded on a Likert scale having 1-5 scoring (Strongly disagree-strongly agree).

The questionnaire was distributed to different healthcare providers using stratified random sampling method. The study population included different cadres of healthcare staff like nursing, medical, managerial/supervisor and others.

Written informed consent was taken from all the participants. Data was analysed using the Statistical Package of Social Sciences (SPSS), Version-22.

Results- The study revealed that most 99(49%) of the participants were from a medical background, followed by nursing 81(40.1%), supervisor/leader 9(4.5%), others 6(3%), other clinical positions 4(2%) and support staff 3(1.5%). (Figure-1)

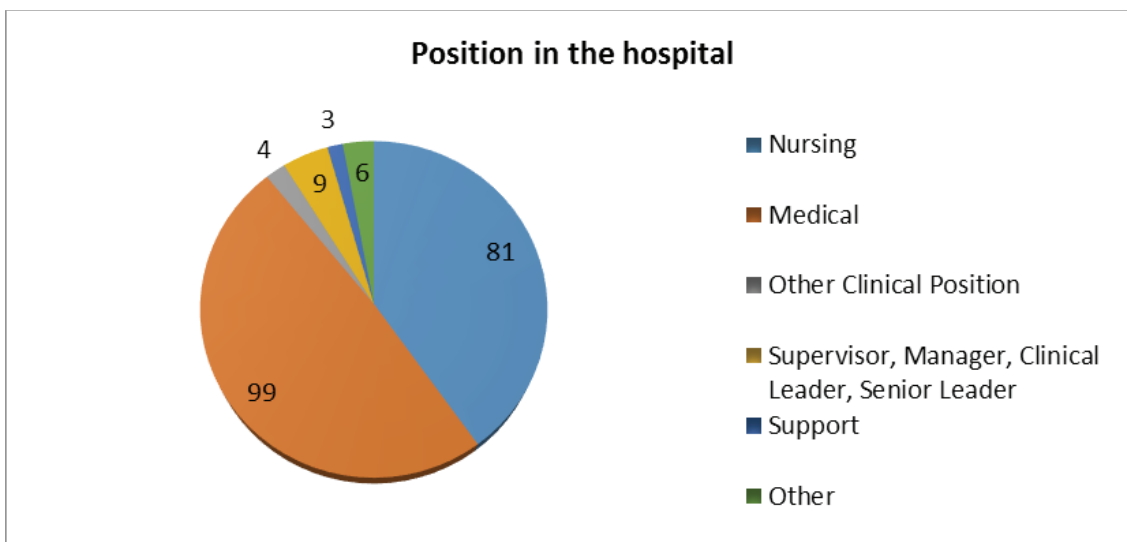
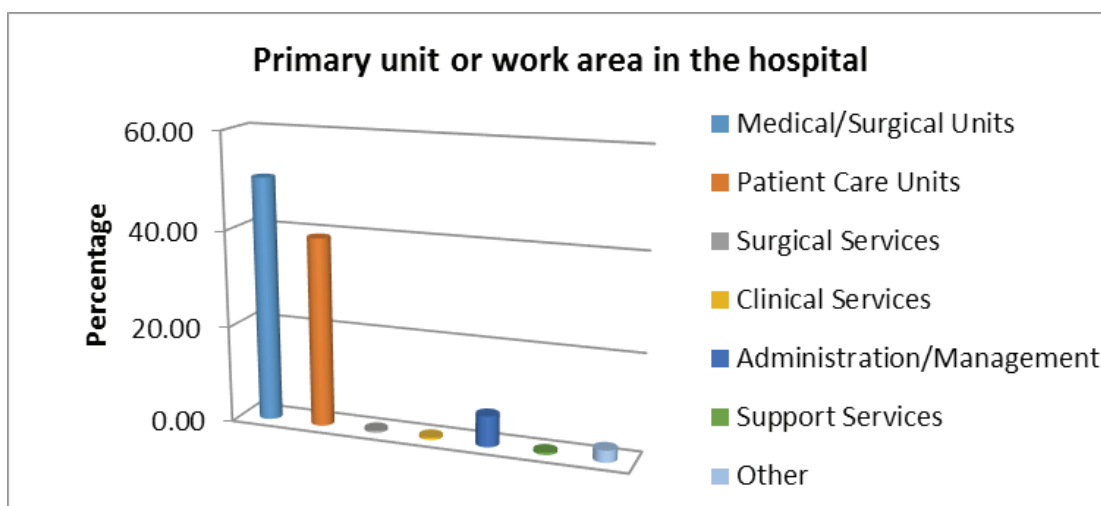


Figure-1 Posting in the hospital

102(50.5%) of the participants belonged to the medical/surgical units, followed by 79(39.1%) in other patient care units, 13(6.4%) from administration/management, and res from from clinical, surgical and support services. (Figure-2)



24(11.9%) respondents had work experience <1 year followed by, 1-5 years 90(44.6%), 6-10 years and >11 years 44(21.8%) respectively.

39(19.3%) responded that they were working in the same unit for <1 year, followed by 1-5 years 107(53%), 6-10 years 37(18.3%) and >11 years 19(9.4%). 164(81.2%) of the participants responded that they worked for >40 hours per week and 194(96%) of them responded that they interacted directly with the patients. (Table-1)

146(72.35%) of the participants strongly agreed that they worked together as an effective team. 78(38.6%)

of the participants agreed that they had enough staff to handle the workload. 114 (56.4%) participants agreed that their unit regularly reviewed work processes to determine if changes were needed to improve patient safety. 118(58.4%) strongly disagreed that they relied too much on the temporary staff and 84(41.65%) disagreed that staff felt like their mistakes were held against them. 124(61.4%) strongly agreed that the unit staff helped each other during busy times. 104(51.5%) agreed that when staff made errors, their unit focused on learning rather than blaming the individuals. 89(44.15%) of them disagreed that the work pace in their unit was so rushed that it negatively affected the patient safety.

107(53%) of the participants agreed that their unit evaluated the changes required to improve patient safety from time to time. 79(39.15) strongly disagreed that there was a lack of support for staff involved in patient safety errors, and 123(60.9%) strongly disagreed that the same patient safety problems kept happening.

131(64.9%) participants strongly agreed that their supervisors/clinical leaders considered patient safety as an important area for improvement. 93(46%) participants strongly agreed or agreed about the fact that their supervisor, manager, or clinical leader took action to address patient safety concerns brought to their attention.

93(46%) participants responded that they were always informed about errors in their unit, and 94(46.5%) responded that when errors happened in their unit, they often discussed ways to prevent them from happening again. 90(44.65) respondents opined that they were informed about changes made based on event reports. 87(43.1%) responded that most of the time they speak up if they see something that may negatively affect patient care. 119 (58.9%) opined that the staff were not afraid to ask questions when something does not seem right.

95 (47%) opined that when a mistake was caught and corrected before reaching the patient, this was reported most of the time. 49(24.3%) of the staff opined that in the past 12 months, most of the times patient safety events had been reported. 129(63.9%) of the staff rated the patient safety as excellent.

114(56.4%) strongly agreed that hospital management’s actions showed that patient safety was a top priority to them, and hospital management provided adequate resources to improve patient safety.

108 (53.5%) out of 202 participants disagreed about the fact that while transferring patients from one unit to another, important information was often left out. 104(51.5%) disagreed that during shift changes, important patient care information was often left out and 100(49.5%) strongly agreed that during the shift changes, there was adequate time to exchange all critical patient care information.

The excellent rating was given by others (83.3%) followed by Medical staff. In the primary unit of work, the excellent rating was given by Medical/Surgical Units followed by others. 53.8% of Administration/Management gave a fair rating. **None of the staff members gave a low rating to patient safety.**

Chi-square test was applied to see the relationship between the position/primary unit in hospital and patient safety. The study revealed a statistically significant (p-value <0.05) relationship between the position/primary unit in the hospital with respect to patient safety. One-way ANOVA test revealed that there is statistically significant (p-value <0.05) difference that is present in the mean scoring among the positions in that hospital with the patient safety. (Table-2)

Table1 - Satisfaction questionnaire

Think about your unit/work area:	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. In this unit, we work together as an effective team	0(0)	0(0)	2(1)	54(26.7)	146(72.3)
2. In this unit, we have enough staff to handle the workload	11(5.4)	37(18.3)	16(7.9)	78(38.6)	60(29.7)
3. Staff in this unit work longer hours than is best for patient care	14(6.9)	56(27.7)	69(34.2)	43(21.3)	20(9.9)

Cont... Table1 - Satisfaction questionnaire

4. This unit regularly reviews work processes to determine if changes are needed to improve patient safety	3(1.5)	3(1.5)	15(7.4)	114(56.4)	67(33.2)
5. This unit relies too much on temporary, float, or PRN staff	118(58.4)	51(25.2)	10(5)	13(6.4)	10(5)
6. In this unit, staff feel like their mistakes are held against them	58(28.7)	84(41.6)	44(21.8)	11(5.4)	5(2.5)
7. When an event is reported in this unit, it feels like the person is being written up, not the problem	54(26.7)	95(47)	37(18.3)	13(6.4)	3(1.5)
8. During busy times, staff in this unit help each other	0(0)	4(2)	3(1.5)	71(35.1)	124(61.4)
9. There is a problem with disrespectful behavior by those working in this unit	87(43.1)	78(38.6)	22(10.9)	7(3.5)	8(4)
10. When staff make errors, this unit focuses on learning rather than blaming individuals	2(1)	8(4)	23(11.4)	104(51.5)	65(32.2)
11. The work pace in this unit is so rushed that it negatively affects patient safety	67(33.2)	89(44.1)	24(11.9)	13(6.4)	9(4.5)
12. In this unit, changes to improve patient safety are evaluated to see how well they worked	0(0)	9(4.5)	23(11.4)	107(53)	63(31.2)
13. In this unit, there is a lack of support for staff involved in patient safety errors	79(39.1)	73(36.1)	30(14.9)	13(6.4)	7(3.5)
14. This unit lets the same patient safety problems keep happening	123(60.9)	51(25.2)	14(6.9)	14(6.9)	0(0)

Cont... Table1 - Satisfaction questionnaire

Your Supervisor, Manager, or Clinical Leader	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. My supervisor, manager, or clinical leader seriously considers staff suggestions for improving patient safety	4(2)	3(1.5)	11(5.4)	53(26.2)	131(64.9)
2. My supervisor, manager, or clinical leader wants us to work faster during busy times, even if it means taking shortcuts	60(29.7)	117(57.9)	14(6.9)	8(4)	3(1.5)
3. My supervisor, manager, or clinical leader takes action to address patient safety concerns that are brought to their attention	0(0)	3(1.5)	13(6.4)	93(46)	93(46)
Communication	Never	Rarely	Some-times	Most of the Time	Always
1. We are informed about errors that happen in this unit	0(0)	2(1)	26(13)	81(40)	93(46)
2. When errors happen in this unit, we discuss ways to prevent them from happening again	0(0)	3(1.5)	30(14.9)	94(46.5)	75(37.1)
3. In this unit, we are informed about changes that are made based on event reports	1(0.5)	7(3.5)	34(16.8)	70(34.7)	90(44.6)
4. In this unit, staff speak up if they see something that may negatively affect patient care		2(1)	39(19.3)	87(43.1)	71(35.1)
5. When staff in this unit see someone with more authority doing something unsafe for patients, they speak up	3(1.5)	9(4.5)	32(15.8)	103(51.0)	55(27.2)
6. When staff in this unit speak up, those with more authority are open to their patient safety concerns	1(0.5)	4(2)	34(16.8)	100(49.5)	63(31.2)
7. In this unit, staff are afraid to ask questions when something does not seem right	119(58.9)	55(27.2)	15(7.4)	9(4.5)	4(2)

Cont... Table1 - Satisfaction questionnaire

Reporting Patient Safety Events	Never	Rarely	Some-times	Most of the Time	Always
1. When a mistake is caught and corrected before reaching the patient, how often is this reported?	1(0.5)	5(2.5)	30(14.9)	95(47.0)	71(35.1)
2. When a mistake reaches the patient and could have harmed the patient, but did not, how often is this reported?	1(0.5)	10(5)	55(27.2)	103(51)	33(16.3)
	None	1-2	3-5	6-10	>11
3. In the past 12 months, how many patient safety events have you reported?	29(14.4)	39(19.3)	40(19.8)	45(22.3)	49(24.3)
Patient Safety Rating	Poor	Fair	Good	Very Good	Excellent
1. How would you rate your unit/work area on patient safety?	0(0)	17(8.4)	18(8.9)	38(18.8)	129(63.9)
Your Hospital	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. The actions of hospital management show that patient safety is a top priority	0(0)	0(0)	11(5.4)	77(38.1)	114(56.4)
2. Hospital management provides adequate resources to improve patient safety	1(0.5)	6(3)	17(8.4)	63(31.2)	115(56.9)
3. Hospital management seems interested in patient safety only after an adverse event happens	5(2.5)	47(23.3)	43(21.3)	60(29.7)	47(23.3)
4. When transferring patients from one unit to another, important information is often left out	68(33.7)	108(53.5)	14(6.9)	10(5)	2(1)
5. During shift changes, important patient care information is often left out	75(37.1)	104(51.5)	21(10.4)	1(0.5)	1(0.5)
6. During shift changes, there is adequate time to exchange all key patient care information	3(1.5)	2((1)	25(12.4)	72(35.6)	100(49.5)
Background Questions	<1 year	1-5 years	6-10 years	>11 years	
1. How long have you worked in this hospital?	24(11.9)	90(44.6)	44(21.8)	44(21.8)	
2. In this hospital, how long have you worked in your current unit/work area?	39(19.3)	107(53)	37(18.3)	19(9.4)	
	<30 hrs/wk	30-40 hrs/wk	>40hrs/wk		
Typically, how many hours per week do you work in this hospital?	8(4)	30(14.9)	164(81.2)		
	Yes	No			
In your staff position, do you typically have direct interaction or contact with patients?	194(96)	8(4)			

Table-2 Association between position, primary care units with respect to the patient safety -

		How would you rate your unit/work area on patient safety?					CChi-square, p-value
		Ppoor	Ffair	Ggood	VVery Good	EExcellent	
Position in hospital	Nursing	0.0%	8.6%	8.6%	23.5%	59.3%	67.266, 0.00001
	Medical	0.0%	2.0%	7.1%	17.2%	73.7%	
	Other Clinical Position	0.0%	50.0%	25.0%	0.0%	25.0%	
	Supervisor, Manager, Clinical Leader, Senior Leader	0.0%	66.7%	22.2%	0.0%	11.1%	
	Support	0.0%	0.0%	33.3%	33.3%	33.3%	
	Other	0.0%	0.0%	0.0%	16.7%	83.3%	
Primary unit or work area in hospital	Multiple Units, No specific unit	0.0%	0.0%	0.0%	0.0%	0.0%	68.713, 0.00001
	Medical/Surgical Units	0.0%	4.9%	6.9%	15.7%	72.5%	
	Patient Care Units	0.0%	5.1%	8.9%	24.1%	62.0%	
	Surgical Services	0.0%	0.0%	0.0%	100.0%	0.0%	
	Clinical Services	0.0%	0.0%	100.0%	0.0%	0.0%	
	Administration/Management	0.0%	53.8%	15.4%	7.7%	23.1%	
	Support Services	0.0%	0.0%	100.0%	0.0%	0.0%	
	Other	0.0%	20.0%	0.0%	20.0%	60.0%	

Discussion

Most of the staff ranked/perceived their patient safety rating as excellent. As per unit or work area, most of the participants agreed that they worked as an effective team, had enough permanent staff, and were not dependent on the temporary staff. It also revealed that the unit regularly reviewed work processes to determine if changes were required to improve patient safety, which is indeed a healthy sign for a healthcare manager and any organization.

Another important finding was that if an event was reported, the staff was not usually blamed; instead,

the management highlighted the problem and tried to learn from the errors. This result is contrary to a study conducted in the Beni-Suef University Hospital, Egypt⁷, which revealed that Healthcare workers appeared to have a lower perception of patient safety culture. They were used to play the blame game in case of any events occurred. The authors of that Egyptian study opined that patient safety needs were not incorporated into health professionals' education across the spectrum of healthcare. They also recommended that there should be a blame-free system for identifying threats to patient safety, sharing information, and learning from events.

When it comes to supervision, most of the participants strongly agreed that their supervisors/clinical leaders considered suggestions and quickly addressed the patient safety concerns for improving the patient safety, instead of adopting any shortcuts in the busy hours. Similar findings were observed in a study conducted in the Tanta University Hospitals, Egypt⁸. The study found that a non-punitive work environment is essential to facilitate patient safety culture change. Blameless reporting helps better detect and manage adverse events. Adequate supervision is only possible when effective communication takes place. Most of participants responded that they are always well informed about the errors that occurred and discussed the preventive measures for future recurrence. It was observed that all staff, irrespective of their hierarchy had liberty to speak about any errors/wrong happening, which is a good sign of transparent organizational work culture. A similar finding was observed in a study conducted in Southern part of India⁹. It was revealed by the survey that dimensions such as “hand-off and transitions,” frequency of events reporting,” and “communication openness” are the essential areas where further improvement assures more patient safety.

The study revealed that top management gave top priority to patient safety management, and provided adequate resources to fix the issues that arose. Most of the respondents gave excellent ratings regarding patient safety issues. Interestingly none of the staff members presented a low rating regarding patient safety in the hospital. This finding is important because it was anonymous.

The study revealed a statistically significant (p-value <0.05) relationship between the position/primary unit in the hospital with respect to patient safety. A statistically significant (p-value <0.05) in the mean scoring was observed among the hospital’s patient safety positions.

Conclusion

The study findings suggest that there is correlation between the position/primary unit in the hospital and perception about patient safety.

Limitations- In this study, complete blinding was not practiced, which can invite bias. The sample size was small as only a part of tertiary care center was

considered so we cannot generalize the findings.

Conflict of Interest- Nil

Funding- Nil

Ethical Clearance- Not required.

Consent- Taken

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Effect of Support Surface Quality for the Squat Exercise on Vertical Jump Performance

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Abstract

Background: This study investigated the effect of support surface quality, stable vs unstable, for 6-week long squat exercise program on vertical jump performance.

Method: The subjects were 24 healthy students who agreed to participate in this study. They divided into stable support surface group and unstable support surface group randomly. The squat exercise was performed three times of a week for 6 weeks. The height of each jump was measured by the height marked on the grid paper with the middle finger of the subject. Muscle strength was used to measure maximum voluntary isometric and isotonic contraction during knee extension. Balance (eyes-opened and eyes-closed one-leg standing balance tests) was performed alternately on the right and left legs.

Results: Vertical jump was significant difference stable support surface group with unstable support surface group.

Conclusion: These results indicate that vertical jump of stable support surface group was more improved than unstable support surface group.

Key words: Vertical jump, Squat exercise, Muscle strength, Balance

Introduction

Muscles strength in the lower extremity is an important factor for adults in managing their activities of daily living.^{1,2} Weakening of the leg muscles is reported to be associated with declining functional abilities, including unstable gait, while also having an impact in falls.^{1,2} The muscle that move the leg play an essential role in sports activities and activities of daily living since they provide stability to the hip, knee, and ankle joints by controlling external forces.³⁻⁵ Several existing studies mention the importance of leg muscle strength, an example of physical exercise aimed at building leg muscle strength are the closed kinetic chain (CKC) exercise. CKC exercise involves simultaneous application of resistance to proximal and distal areas while the distal area is immobilized.⁶ The squat, which is one type of CKC exercise, is a basic exercise that trains the hip, thigh, and trunk muscles, which play a

key role in running, jumping, and lifting. In addition, these exercises also effectively stabilize the hip and knee joints by activating the knee extensor and hip extensor muscles, while strengthening bone density, ligaments, and tendons simultaneously.⁷⁻¹¹ In particular, the squat is reported to significantly impact the strength of the vastus medialis, vastus lateralis, and gastrocnemius.¹²

Balance, which refers to the ability to maintain the body's center of gravity within the supporting surface, is a fundamental element so humans can respond to changes in their surroundings and perform intended activities.¹³ Balance control requires the interaction of the nervous and musculoskeletal system and contextual effects.^{13,14} Exercising on unstable support surface is reported to increase nerve activity to the muscles and synchronizes the motor units, while promoting activity from muscle synergism and stability in areas surrounding multiple joints.¹⁴ Moreover, muscle strength increases

from greater recruitment of muscle fibers.¹⁴ This also increases muscles activity levels and coordination, which can also lead to increased endurance.¹⁵

Previous studies have continuously reported that exercising on unstable support surfaces contributes to improved muscle strength and endurance.^{16,17}

However, studies on the direct effects of muscle strength training on unstable surfaces, such as balance pads, on vertical jump are lacking. Accordingly, the present study aimed to investigate the effects the vertical jump, performed on stable and unstable support surfaces, may have on vertical jumping ability, in addition to its effects on static and dynamic muscle strength and balance in healthy subjects.

Subjects and Methods

Study population and study design: The present study selected 24 healthy adults who attend University who voluntarily provided consent to participate in the study. Males and females were selected in equal ratio (12 males and 12 females) and were randomly assigned to the stable support surface group (SSG) and the unstable support surface group (USG) (12 in each group). The mean age, height, and weight of the SSG group were 22.83±4.16 years, 167.58±7.10 cm, and 64.76±10.81 kg, USG were 21±4.21 years, 169±4.12 cm, and 65±8.73 kg. The exclusion criteria consisted of those with congenital leg impairment, those with musculoskeletal and/or neurological lesions, and those who regularly perform leg exercise.

Experimental procedures: The SSG did not use any instruments between the subjects' feet and the support surface while the USG used a balance pad between the feet and the surface. Both group performed the exercise in comfortable clothing. Squats were performed with "shoulder stance" as the basic stance, by referencing the leg width for squat used in a study by McCaw and Melrose¹⁸.

Squat exercise were performed three times a week for six weeks: five sets of 15 reps in the 1st week; five sets of 20 reps in the 2nd week; five sets if 25 reps in the 3rd and 4th weeks; and five sets of 30 reps in the 5th and 6th weeks, with a one-minute break between sets. Static stretching was performed for five minutes before

the main exercise, and stretching with the use of a foam roller was performed for five minute as the cool down exercise.

Measurement: The subjects performed standing vertical jumps, as high as possible, using their arm and legs, with grid paper taped to the side wall. The height of each jump was measured by the height marked on the grid paper with the middle finger of the subject, which had red stamping ink on it. The measured value was calculated as the height reached subtracted by the height of the subject. This method was repeated three times, and the mean value of the three measurements was recorded.

To determine leg muscle strength, BTE (Primus RS, Hanover) was used to measure maximum voluntary isometric and isotonic contraction during knee extension. Knee extension of the right and left legs were measured three times each and the mean value of the measurements was recorded.

Balance measurements were taken with the subjects barefooted and in comfortable clothing. Two tests (eyes-opened and eyes-closed one-leg standing balance tests) were performed alternately on the right and left legs, and the time was measured.

Data Analysis

IBM SPSS Statistics Version 24 was used for data processing in the present study, where the mean and standard deviation were calculated for each group. A t-test was performed to determine homogeneity between the groups. Meanwhile, the Mann-Whitney U test was used for comparative analysis between the two groups, sine the sample size was small and data did not show normal distribution. The statistical significance level was set to $p < 0.05$.

Results

Pre and post-intervention performances of SSG and USG were assessed through vertical jumps (Table 1). The results confirmed homogeneity in the initial height id the two groups, and that both groups showed improvement in vertical height after the intervention ($p < 0.05$), with SSG showing significantly greater improvement ($p < 0.05$).

Pre and post-intervention maximal voluntary isometric and isotonic contraction of SSG and USG were assessed using BTE (Table 2). The results confirmed homogeneity in the initial maximal voluntary isometric and isotonic contraction of the two groups, and that both groups showed significant improvement in the maximal voluntary isometric and isotonic contraction ($p < 0.05$), with no significant difference between SSG and USG ($P > 0.05$).

The pre and post-intervention balance of SSG and USG were assessed through a stable balance test (Table 3). The results confirmed homogeneity in the initial values of the two groups, and that, both groups showed improvement in both eyes-opened and eyes-closed one-leg standing balance tests after the intervention ($p < 0.05$), with no significant difference between SSG and USG ($P > 0.05$).

Table 1. Comparison of vertical jump before and after exercise between stable unstable group (cm)

Variables	Stable (n=12)	Unstable (n=12)	p
	Mean±SD	Mean±SD	
pre	77.52±21.31	78.94±12.52	0.02**
post	83.41±21.52*	81.91±14.53*	

Significantly different of before and after intervention in one group ($p < 0.05$)

** : Significant difference between stable group and unstable group ($p < 0.05$)

Table 2. Comparison of muscle performance before & after exercise between stable & unstable group

Variables			Stable (n=12)	Unstable (n=12)	p
			Mean±SD	Mean±SD	
Isometric (N)	Rt.	pre	463.37±117.34	463.41±111.45	NS
		post	589.65±56.74	579.35±158.32	
	Lt.	pre	462.43±59.41	468.31±153.44	NS
		post	532.43±64.24	523.25±148.74	
Isotonic (W)	Rt.	pre	71.64±35.89	75.85±32.26	NS
		post	114.23±35.21	106.09±36.73*	
	Lt.	pre	68.26±28.25	63.24±22.82	NS
		post	94.21±36.24*	87.53±36.23*	

* : Significantly different of before and after intervention in one group ($p < 0.05$)

Table 3. Comparison of balance before & after exercise between stable & unstable group

(sec)

Variables			Stable (n=12)	Unstable (n=12)	p
			Mean±SD	Mean±SD	
EO	Rt.	pre	132.43±98.31	97.20±51.25	NS
		post	232.42±86.59*	195.73±72.25*	
	Lt.	pre	125.53±64.31	93.14±39.85	NS
		post	234.59±66.45*	189.18±51.21*	
EC	Rt.	pre	55.39±55.53	55.56±35.38	NS
		post	101.38±66.63*	85.72±53.43*	
	Lt.	pre	51.24±44.22	43.87±30.32	NS
		post	112.48±68.22*	97.39±52.16*	

EO : Eye Open, EC : Eye Closed

* : Different of before and after intervention in one group (p<0.05)

Discussion

Measurements of maximal voluntary isometric and isotonic contraction of knee extensors for investigation of knee extensors for investigation of improvements in leg muscle strength showed increased values in both left and right legs in both stable and unstable surfaces. Such findings were consistent with the existing literature, reporting that exercise on an unstable support surface has no particular advantage over exercising on a stable surface in terms of building muscle strength.¹⁹

Vertical jump is a field test commonly used to measure explosive muscle strength in the legs.²⁰ Generally, when performing a vertical jump, mechanical power is generated by muscle elasticity and contraction from instantaneous full extension of the muscles in the supporting leg.²¹ Increasing the strength in lower body muscles can improve exercise abilities, including vertical jump, which involves the use of the lower body muscles.²²

Vertical jump measurements showed an increase in values of both the stable and unstable surface groups. While SSG showed a greater increase than USG, with the difference between the groups being significant. These findings were consistent with the results reported by a previous study, where performing squats on a stable surface versus unstable support surface did not show difference in muscle activities, but performing squats on an unstable surface had a greater effect on trunk and hip muscle activities than on leg muscles.²³ Based on these findings, it is believed that performing squats on a stable surface had a greater impact on vertical Jump by triggering greater leg muscle activity than when performing squats on an unstable surface.

The results from the eyes-opened and eyes-closed one-leg standing balance tests to examine the improvement of balance ability between the two groups showed an increased value in both SSG and USG, but the difference was not significant. The weak effect on balance found in the present study can be explained

by the results from a previous study, which found that exercising on the balance ability of adolescents and young adults than in the elderly.²⁴ These results indicate that vertical jump of stable support surface group was more improved than unstable support surface group.

The limitations in the present study included the fact that the sample size was small, limited to only some students attending K University who satisfied the selection criteria. Therefore, the findings may not be generalized. Moreover, because the study was conducted in healthy adults, the findings may not be applied to people with impairment in their ankle joints. Furthermore, interaction effects between the tests influenced the results, and intervention on exercise speed could not be applied consistently.

Although the present study used a balance pad to provide an unstable support surface, future studies should use other tools to provide more diverse supporting surfaces.

Conclusion

These results indicate that vertical jump of stable support surface group was more improved than unstable support surface group.

Conflicts of Interest Disclosure: The authors declare that there is no conflict of interest statement.

Ethical Clearance: The present study was conducted with the approval from the Institutional Review Board of Department of Physical Therapy at Kangwon National University.

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Effect of Suryanamaskar on Stress Levels in SSC Students

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Abstract

Background - Suryanamaskar is a popular traditional Indian yogic practice. According to studies, it was found that stress was higher in students appearing for the SSC board exam. Non-pharmacological management of stress includes yogasana practice.

Methods and Materials – A total of 120 adolescents studying in 10th standard (Age 16 to 18 years) from schools in Pune were approached. The initial screening was done by using Smith Stress Symptoms Inventory (SSSI). A total of 50 out of 120 students who were identified as high stress on SSSI were included in the study. Subjects completed the suryanamaskar program of 13 cycles for 2 weeks (14 sessions) and were assessed pre and post-intervention by using Smith Relaxation Dispositional Inventory.

Result – A highly significant improvement was noted in components of smith stress symptom inventory on mental quiet, ease/peace, love and thankfulness, somatic stress, worry, and a significant reduction was seen in components like sleepiness, mystery, disengagement, and negative emotions.

Conclusion – This study concludes that suryanamaskar intervention is effective in reducing the stress of SSC students.

Keywords – SSC Students, Stress, Suryanamaskar, Smith Stress Symptoms Inventory (SSSI)

Introduction

Stress may be defined as a psychophysiological process usually experienced as a negative emotional state⁽¹⁾. Stress is experienced as a response to a range of physical, occupational & emotional stimuli. Continued exposure to stress can lead to physical and mental disorders⁽²⁾. Stress is a part of every student's life. As a student, the origin of stress may be related to academics, social situation, environment & lifestyle. Adolescents comprise about 1/5th (21.5%) of the total Indian population⁽³⁾. According to the studies it was found that stress was higher in SSC board class (10th) students

(53.52%). It was also found that the prevalence of stress was more in students who felt overburdened with the schedules, academic works, late-night studies, etc due to which they are not able to concentrate properly^(4,5). A 2012 lancet report also quoted that the 16 to 18 age group bracket in India has the highest rate of suicide in the world⁽⁶⁾.

Teenagers, especially those who are students always face learning problems, career management, and also problems in solving personal and social matters. These are the factors that contribute to stress in life⁽⁷⁾. This is the period of development where the academic stress of students is found to be a considerable factor influencing both the academic achievement and health status⁽⁸⁾.

To overcome the stress in SSC students different non-pharmacological therapies like yogaasan, meditation, physical exercise can be used to calm their

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minds and to reduce the stress.

Yoga is an ancient physical & mental activity that affects mood & stress. Yoga is essentially acclaimed to be the science of holistic living. It is an effective method for improving health in addition to the prevention and management of the disease. Suryanamaskar is a popular traditional Indian yogic practice. It is a set of sequential yogic postures which are called asanas. Past literature suggested that yoga may be equally effective or better than exercise at improving a variety of health-related outcome measures. It has a positive effect on mood states such as anxiety, stress, and depression, through physiological and biochemical mechanisms, including endorphins, mitochondria, neurotransmitters, and the hypothalamic-pituitary-adrenal axis.

Past research documents suryanamaskar as an effective intervention for college students has been effective in improving the psychological variables like a sense of wellbeing and feeling of relaxation. A study revealed that yoga and relaxation training reduced stress and competition anxiety and increased mental toughness among tennis players (3). A study “Effect of Suryanamaskar on stress level” concluded that it plays a positive and significant role to decrease the stress level of the subjects (4).

Hence the purpose of this study was to see the effect of suryanamaskar on stress levels in SSC exam going students.

Material and Methodology

Students were selected between the age of 16 to 18 years, had scored above 75% on a minimum of 4 out of 6 subscales of SSSI and those who were not participating in any other exercises/sports activity. Students with any musculoskeletal disorders which do not allow them to perform suryanamaskar were excluded from the study.

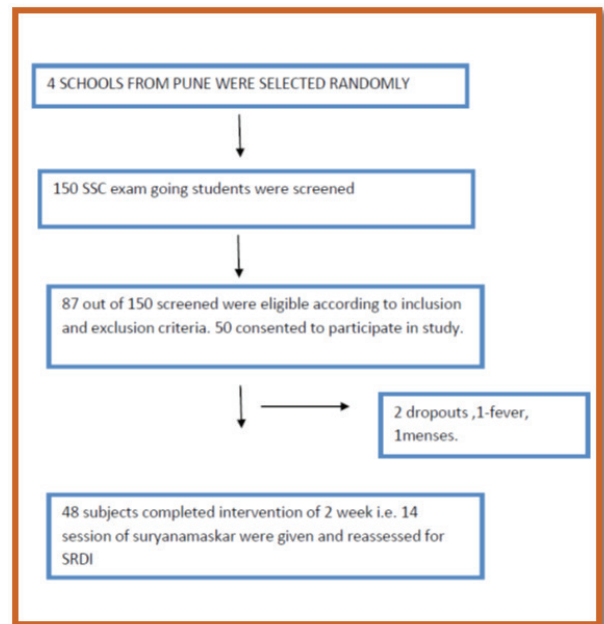
After approval from the Institutional ethics committee of M. A. Rangoonwala College of Physiotherapy & Research, the study was conducted in a school setting. Appropriate permission was obtained from the principals of selected schools. Students were selected based on inclusion and exclusion criteria. The procedure was explained and demonstrated to the participants and written consent was taken from them.

The initial screening was done by using Smith Stress Symptoms Inventory(SSSI). A total of 120 students were screened out of which 50 were included according to inclusion and exclusion criteria. Two students dropped out one due to fever and other due to menses.

It is seen in literature that the stress of SSC students was maximum before the final exam so intervention was planned in such a way that it would coincide with timing after the preliminary board exam and before the final board exam.

The suryanamaskar activity was conducted on the school terrace in the morning session. Students were informed to carry comfortable clothing (track pant) for suryanamaskar session. All the sessions were observed by the therapist.

Some discomfort due to physical activity was there which was informed to the students prior. If the musculoskeletal pain was not relieved until the next session, they had been asked to discontinue the protocol. The attendance records for all the students were maintained and the reasons for participants who discontinued were recorded. No student discontinued protocol due to residual body pain.



Intervention-Students received suryanamaskar session for 14 days. The everyday suryanamaskar session included warm up, 13 rounds of suryanamaskar with breathe controls and cool down. Proper instructions were given throughout the session.

Suryanamaskar (steps)-

Results

The statistical software IBM SPSS statistics 20.0 Descriptive and Inferential statistical analyses were carried out in the present study. The level of significance was fixed at $p < 0.05$ and any value less than or equal to 0.05 was considered to be statistically significant. The scale used in this study was SSSI. This is a scale

with 30 questions and these questions are grouped in 17 subcomponents. These sub-components are further classified in R-dispositions (Relaxation) and stress S dispositions. It is hypothesized that suryanamaskar group will be higher on R-dispositions and lower on stress dispositions compared with the control group⁽⁹⁾.

Since observation was on the ordinal scale, we have used Wilcoxon Signed Rank Test to test the efficacy.

Table 1: Shows Results For Stress S Dispositions.

	Median		Wilcoxon Signed Rank Z Value	P-Value	% Effect	Result
	Pre	Post				
Sleepiness	7	3	-5.948a	0.000	45.60	Significant
Disengagement	6	4	- 6.222a	0.000	33.33	Significant
Mystery	4	3	-4.388a	0.000	23.75	Significant
Timeless	3.5	2	-6.122a	0.000	52.98	Significant
Somatic stress	9	5	-6.165a	0.000	47.92	Significant
Worry	3	2	-6.181a	0.000	51.81	Significant
- ve Emotion	10	7	-6.110a	0.000	37.71	Significant

Results show that sleepiness, disengagement, Timeless, Worry, Mystery, Somatic stress and negative emotions were reduced significantly. The reduction was more than 30% except for mystery which was less but still statistically significant.

Table 2 shows results for Relaxation R dispositions.

	Median		Wilcoxon Signed Rank Z Value	P-Value	% Effect	Result
	Pre	Post				
Physical Relaxation	2	4	-6.002b	0.000	35.50	Significant
Mental Quiet	3	7	-6.145b	0.000	55.03	Significant
At ease/peace	3	9	-6.158b	0.000	63.49	Significant
Rested& Refreshed	2	3	-5.475b	0.000	38.52	Significant
Strength& Awe	4	7	-5.612b	0.000	37.39	Significant
Joy	4	6	-6.164b	0.000	37.60	Significant

Cont... Table 2 shows results for Relaxation R dispositions.

Love & thankfulness	4	6	-6.078b	0.000	53.75	Significant
Playfulness	2	4	-6.158b	0.000	55.88	Significant
Child like behaviour	1	2	-4.768b	0.000	33.33	Significant
Awe& wonder	4	7	-5.612b	0.000	37.39	Significant

Table 2 shows that Physical Relaxation, Mental Quiet, At ease/peace, Rested& Refreshed, Joy, Strength& Awe, love and Thankfulness, Playfulness, Child like behaviour, Awe& wonder which are components of R dispositions improved significantly. Overall improvement was more than 30%. Especially improvement in At ease/peace, Mental Quite, Love and thankfulness and playfulness improved more than 50%.

S dispositions reduced and R dispositions improved which suggests that stress reduced and relaxation improved

Discussion

An adolescent is a transitional stage where a teen experiences extreme stress in almost every sphere of life. Stress sets in motion a series of adaptive or defensive physiological reactions in the body and mind. Several studies indicate that the prevalence rates of individual disorders: stress, depression, and anxiety are growing among adolescents. For relieving stress yogic exercises are beneficial, as it promotes calmness of mind and subsides stress and anxiety level.

The present research aimed to study the effect of suryanamaskar on stress levels in SSC students. Table one two highly significant difference was seen in mental quiet, ease/peace, love, and thankfulness Rested& Refreshed, Joy, Strength& Awe, Playfulness, and Childlike behavior, Awe& wonder. These are R depositions which suggest relaxation was improved. The possible reason behind this could be suryanamaskar a yogic practice improves relaxation through reducing sympathetic activity and improves the sense of general well being by increasing parasympathetic activity ⁽¹¹⁾. The regular practice of yogasana has seen to affect the nervous system. Alternate deep breathing during asana

seemed to cause mild sympathetic stimulation thereby may increase the capacity of the sympathetic nervous system (SNS) to respond to acute stressors without rapidly exhausting its reserves ⁽¹²⁾. This affects the experience of calmness and relaxation combined with increased vigilance and attention.

Many studies have shown that suryanamaskar exerts positive effects on both the physiological and psychological variables ^(13,14). Brown RP, Gerbarg PL 2005 studied the effect of yogic exercise on stress, anxiety, and depression. They explained in their study that yogan and deep breathing exerts its endocrine effect by modulating the hypothalamic-pituitary-adrenal (HPA) axis, which is essential for fight and flight response. It increases the quantity of good mood and neurotransmitters like serotonin. The increase in the coordination of the body and mind is good for the feel good. This feel-good helps with reducing disengagement and sleepiness ⁽¹²⁾.

Suryanamaskar involves forming various body postures, slow stretching movements, breathing exercises. Regular practice/training of suryanamaskar improves the flexibility of body muscles especially leg, back, and chest. Z. Radak et al (2008) suggested in their study physical activity is aimed at improving muscle tone (suppleness) and plasticity of muscles and joints ^(15,16). Rhythmic stretching of muscles of the body leads to its increase in the strength of muscle spindles. It also increases the suppleness and plasticity of the muscles. Suryanamaskar with their rhythmic, mechanical stimulation of connective tissues and muscular fibers lining cause an improvement in their muscle tone and contractile power which in turn improves their functional capacity. This adequate muscle length leads to reduced muscle work leading to less fatigue during

ADL. This particular leads to progressive relaxation. The salutation to the sun may be regarded as the meditation in the movement of the body as it enhances the mental concentration improving relaxation and reduces depression, anxiety, and stress. Results of this study are in consensus with a study done by A. malathi* and a. damodaran in 1999 where they studied Stress due to exams in medical students - the role of yoga and dr. ashoke mukherjee and dr. Jayarajan David ⁽¹⁴⁾ where they studied the Effect of yogic practices in mental stress management of school teachers.

Yogasan is seen to affect the HPA axis. Cortisol, a stress hormone and an end-product of the HPA axis, has been reported to be flattened with yogasan practice. Improvement in HPA axis deregulation, fluctuations of cortisol has been shown to cause down-regulation of the immune response as a result of stress. ^(17, 18)

Due to the activation of parasympathetic activity, it is seen to reduce resting heart rate, deep breathing in each position of cycle leads to increased lung capacity and improved breathing pattern. Calm breathing ultimately leading to the reduced respiratory rate at rest. These all regulations are related to stress so improving those leads to a reduction in stress. One of the symptoms of stress is increased muscle tension. With alternate postures and stretching, rhythmic change in positions improves blood supply to muscles, suppleness of muscles leading to reducing tension on muscles hence reducing stress.

Sleepiness, disengagement, Timeless, Worry, Mystery, Somatic stress, and negative emotions were the subcomponent in stress dispositions. With increased lung capacity and more oxygenation at rest, sleepiness is reduced. Somatic stress is persistent physical complaints of subclinical origin. Its characterized by variation in symptoms with thoughts but physical pain is real. Stretching of muscles, strengthening of muscles, is going to improve blood supply leading to a washout of pain-producing P substance leading to a reduction in somatic stress. Which ultimately relieves stress.

Exercise and physical activity may help improve mental health by improving self-confidence, self-concept, cognition, and other psychological variables reducing stress.

Conclusion

Our study concluded that the 2-week intervention of Suryanamaskar has made a significant difference in reducing stress dispositions and improving R dispositions. This all together reduced stress in SSC students so could be used as an effective non-pharmacological tool in SSC students who are experiencing increased stress.

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Conflict of Interest: NIL

Ethics committee Clearance: Ethics clearance was availed from Institutional ethics committee of M.A. Rangoonwala College of Physiotherapy And Research, Pune.

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Effects of Laptop use on Wrist in Students and Teachers of Different Universities during Covid-19

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Abstract

The wrist is an ellipsoidal type (condyloid) of articulation synovial is permitting movements at two axes. The anatomical name of the joint is the radio-carpal joint [1-5]. It presents a sinuous opposing. The concave proximal articular surface is formed by the lower end of the radius and the articular disc of the inferior radio-ulnar joint. The reciprocally convex distal articular surface is formed by the scaphoid, lunate and triquetral bones from lateral to the medial side. The joint capsule surrounds the wrist and is attached to the distal ends of the radius and ulna and proximal rows of carpals excluding the pisiform. Strong ligaments strengthen and stabilize the joint from the sides, and on the ventral and dorsal surfaces. Repeated episodes of mechanical stress can cause the event of repetitive motion injuries or overuse injuries, which when including poor posture and biomechanics put much strain on the joints. They usually develop slowly over an extended period of your time. Wrists are one of the foremost common sites of repetitive motion injury. Therefore this research was designed to study the effect of laptop usage among physiotherapists (students and teachers). This study may give awareness to the individual to avoid or minimize the overuse of laptops and therefore the complications by breaking bad habits, practicing recommended/approved posture while using the laptop, and modulating the planning of the keyboards. Due to covid 19 era, the use of laptops and computer has significantly increased among students and teachers of different universities for teaching purposes. Therefore the study was designed to study the impact of laptop use on the wrist in students and Teachers during covid 19.

Objective: To find the impact of laptop use on the wrist in Physiotherapist during covid 19

Keywords: Wrist pain, laptop, students and Teachers, Online classes, Covid-19

Introduction

Coronavirus disease (COVID-19) is a disease caused by severe acute respiratory syndrome (SARS-CoV-2). It was first identified in December 2019 in Wuhan, Hubei, China, and has resulted in an in-progress pandemic. The outbreak of the coronavirus pandemic has created immediate and unprecedented challenges in different companies, governmental and non-governmental organizations, and in the field of

education. With work-from-home mandates continuing at most workplaces, typing away at your laptop for long hours (sans an ergonomic set-up) can leave your arms, back, and neck susceptible to pain and damage. Sounds familiar? Putting pressure on the wrist while typing, when exacerbated by postural issues, can cause the event of carpal tunnel syndrome (CTS), a painful issue that may put you out of commission for longer than you'd like^[2,3,5]. Keyboarding and mousing might not be considered strenuous activities, but if done incorrectly over time, they will damage the wrist and hand as surely as a nasty fall onto concrete^[12]. CTS is one of the musculoskeletal disorders that's often described as a hazard, including occupations involving computer use.

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Due to Covid 19 era students and teachers of different universities are using laptops at a large scale for teaching purposes. Therefore the study aims to find the effects of laptop use on the wrist in Physiotherapists during Covid 19.

Data collection:

We have made a consent form and privacy statement for all the subjects and the questionnaire were given to the subject had simple questions with their explanation in simple English and the queries related to the questionnaire were answered by the investigator.

Material and Methods :

1. Type of Study – survey
2. Sampling method - Convenient sampling
3. Sample size - 255
4. Sample was taken from different colleges of different cities like Rohtak, Hissar, Panipat and few are collected from Delhi
5. Patient-Rated Wrist Evaluation scale was to conduct the survey

Sample Selection:

Criteria Inclusion Criteria

1. Physiotherapist
2. Age 20-35
3. Individual with Non-specific wrist pain

Exclusion Criteria

1. Age above 35
2. Any recent injury of upper limb
3. Malignancy
4. History of significant injury to the neck or upper thoracic region
5. History of thoracic or cervical spine surgery
6. Pregnancy

Methodology:

Information regarding neck pain and computer usage was collected through questionnaires. It includes;

1. Individual demographic characteristics.
2. Work environment factors.
3. Information using PRWE Questionnaire
4. Total duration of daily sitting at work.

Patient-Rated Wrist Evaluation

The PRWE may be a 15-item questionnaire designed to live wrist pain and disability in activities of daily living. Developed in 1998 for clinical assessment and is employed for specific wrist problems. It is one of the reliable upper extremity outcome instruments.

The PRWE allows patients to rate their levels of wrist pain and disability from 0 to 10, and consists of two subscales:

1 Pain scale contains 5 items each of which is further rated from 1-10. The maximum score during this section is 50 and minimum 02 Function subscales: contains a total of 10 items which are further divided into 2 sections i.e specific activities (having 6 items) and usual activities (having 4 items).

The maximum score during this section is 50 and the minimum 0.

Measure the function score of all the ten items and divide it by 2

Total Score = Sum of pain+ function scores (Best Score = 0, Worst Score = 100)

Less score = better outcome

Data Analysis:

Data was analysed by IBM SPSS version 20 In this research we have used the 254 subjects in all.

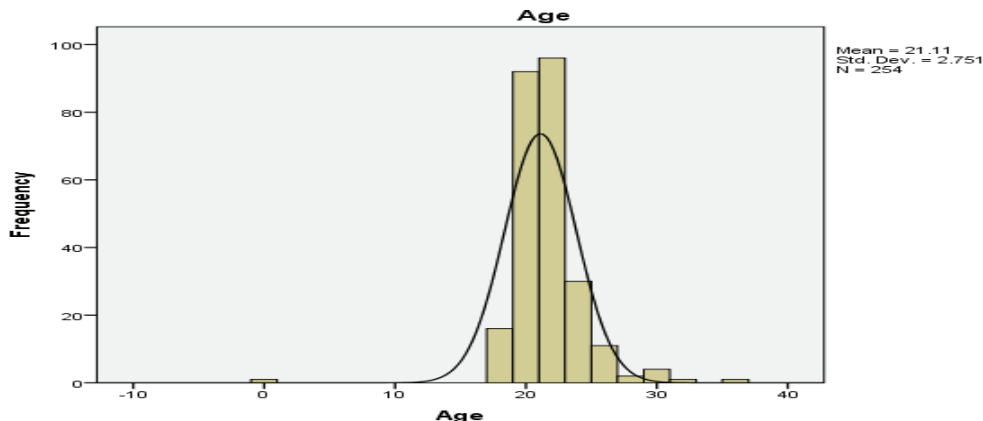
Out of which we have 179 female and 75 males.

Out of which we have 23 married and 231 unmarried cases

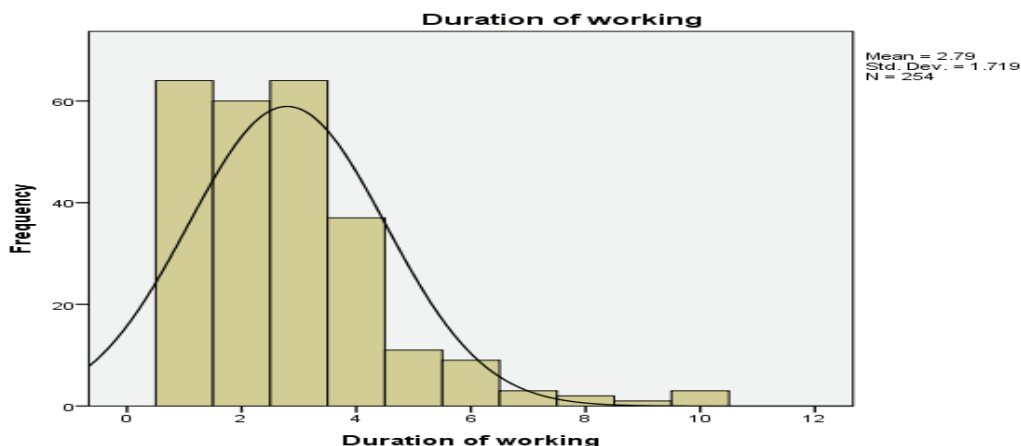
Result Analysis:

We have taken the age group of 20 to 35.

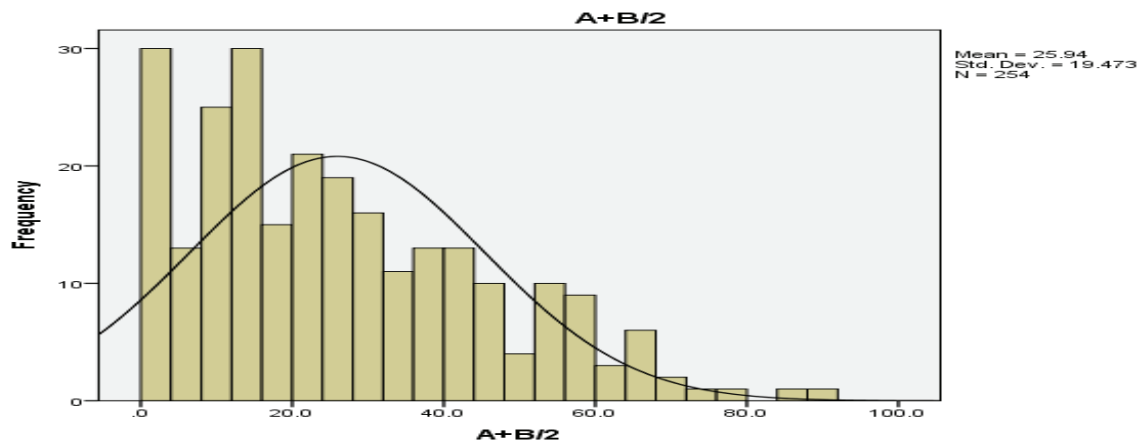
Having the mean age as 21.11.



Outcome denotes that the data is more deviated towards the positive side that means the frequency distribution is more towards the positive side.



We have tried to find the working hour of the subject as the duration of working. Mean duration of working is found to be 2.79. Though it varies from one hour of the general working period to the maximum of 10 hours.



Discussion

Musculoskeletal disorders have been observed and experienced widely at workplaces where the computers are frequently used. Increase in the number of employees working with computer and mouse coincides with an increase of work-related musculoskeletal disorders (WRMSDs) which affects the physical health of workers and pose financial burdens on the companies, governmental and non-governmental organizations. So, this survey was also conducted to investigate the effect of prolonged use of laptops on wrist of physiotherapist during covid 19 era.

Conclusion

In this research we found that the pain and disability increase from 5 to 30 that is alarming sign. So it's time for the physiotherapist to act on that situation and decrease the pain and disability. As we know Covid 19 effects the whole world. And we also concluded that besides the symptoms of this disease we found other symptoms in the human body which affect the Adl's of human beings and also created a challenging life style to overcome.

Ethical Clearance- There was no conflicts of interest in this study.

Source of Funding- Self

Conflicts of Interest- Patient consent was taken.

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Effects of Aerobic and Resistance Exercises on Selected Physiological Biochemical and Anthropometric Variables among Type 2 Diabetic Patients in Dilla, Ethiopia

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Abstract

The purpose of this study was to evaluate the impact of aerobic, resistance combined aerobic and resistance exercises on some specific physiological, biochemical, and anthropometric variables among type 2 diabetic patients. The study participants were 24 adult group patients with type 2 diabetes mellitus selected among the permanent follow up subjects of Dilla University Referral Hospital (DURH) clinic of diabetes care center in Dilla, Ethiopia. The randomly assigned subjects were allocated to experiment group such as aerobic exercise group (n= 6), resistance exercise group (n=6), combined aerobic and resistance exercise group (n=6) and the control group (n=6).total. The training period was 16 weeks. The Physiological and biochemical tests as well as anthropometric measurements were examined during pretest and posttest of the study. To compare means and mean difference of pretest and posttest of each exercise group, pair sample t test was used. To get a significant ANOVA by comparing the changes among groups, Tukey post hoc test also used. After sixteen weeks of regular exercise training glycosylated hemoglobin level (HbA1c), Fasting blood sugar level (FBS), blood pressure (systolic and diastolic), Heart rate (HR), and percentage of body fat (BF %) were significantly improved in the groups of exercise intervention. This was combined aerobic and resistance exercise alone followed by resistance exercise alone, and aerobic exercise alone. However none were significant in the control group. Thus, our study concluded that combined aerobic and resistance exercise alone has more beneficial than resistance exercise alone and aerobic exercise alone for the selected physiological, biochemical and anthropometric variables for patients with type 2 diabetes.

Keywords: Aerobic exercise, Resistance exercise, Type 2 diabetes mellitus

Introduction

Diabetes is a chronic metabolic disease characterized by high levels of glucose in the blood¹. It occurs either because the pancreas stops producing the hormone insulin (Type – 1 diabetes), or because of the inefficient use of insulin by the muscles (type – 2 diabetes)² (OECD, 2013). Regardless of the type of diabetes the disease affects the blood vessels and nerves causing several complications included in Microvascular and Macrovascular³.

There are a number of factors that increase the risk of developing type 2 diabetes mellitus (T2DM) including being overweight or obese, familial history, low physical activity and ethnic background⁴. Obesity is one of the

main risk factors and is related to an inactive life style and having an unhealthy diet⁵.

The Prevalence of type 2 diabetes mellitus is now increasing rapidly around the world and emerging as a global health problem that is expected to reach pandemic levels by 2030⁶. Africa's is highly populous countries contemporary approximation of people with diabetes include: Nigeria (3.9 million), South Africa (2.6 million), the United Republic of Tanzania (1.7 million), and Ethiopia (1.9 million) in these countries diabetes cases and diabetes related deaths accounts high rank from age 20 to 79⁷. Therefore, developing countries in Africa are vulnerable to diabetes epidemic and the disease is projected to become one of the world's main

killer within the next twenty-five years⁸. Like other developing countries high urban growth rates, changes in dietary habits, reduction in physical activity, and increasing obesity have become prevalent in Ethiopia⁹. According to 2000 GC World Health Organization's estimations, the country had about 800,000 diabetic patients and the number is expected to increase to 1.8 million by 2030¹⁰.

Prevention of complications due to type 2 diabetes mellitus is always related to improvements in dietary intake, physical activity and medication¹¹. With regard to physical activity, the incidence of diabetes is three times complex in individuals with light physical activity compared to those having substantial physical activity¹². For this reason Physical inactivity is a significant risk factor for type2 diabetes by leading to a decreased sensitivity to insulin however it can be prevented through exercise training combined with dietary guidelines¹³.

Exercise is extremely important in diabetes management because of its effect on lowering blood glucose and reducing cardiovascular risks¹⁴. And it has both a short- term and a long term effects that enhances insulin sensitivity and prevents type 2 diabetes mellitus¹⁵. Furthermore, regular exercise have improved blood lipid profile predominantly in the skeletal muscles, which leads to a reduced need for insulin¹⁶. Among regular exercises, regular aerobic exercise is an acknowledged therapeutic strategy for type2 diabetes because it has valuable effects not only on glycemic profile, but also on decreasing metabolic risk factors for cardiovascular diseases as well as insulin resistance¹⁷. On the other hand, resistance training is recommended to improve glycemic control and insulin sensitivity moderately via similar mechanistic pathways to aerobic training¹⁸. The combination of aerobic and resistance exercise rises endothelial vasodilator function to improve blood flow and glucose uptake in active muscle beds¹⁹.

Since there was no similar study in the area of three regular physical exercise interventions (aerobic, strength, and combined aerobic and strength exercises) by acquiring physiological, biochemical, and anthropometric variables in the management of type 2 diabetes mellitus among type 2 diabetes mellitus patients in Ethiopia, this information gap will be answered by this study.

Methods

Area and Design of the study

The research was carried out at Dilla University Referral Hospital (DURH). It is found in Gedeo Zone, Ethiopia particularly located to Nairobi-Kenya road from South of the capital city; Addis Ababa to Dilla town at a distance of 365 Kms. Randomized Parallel group control Trial design was employed.

Subjects

Study participants were 24 randomly selected patients with T2DM in middle age group of 40 - 64 and who were diagnosed as well as seen at the diabetic clinic of care at DURH. Consent was justified by those patients who needed to be joined in the study during data collection were randomly allocated to aerobic exercise program group (n = 6), strength exercise program group (n = 6), combined aerobic and strength exercise program group (n = 6) and control group (n = 6). Study participants gender distribution revealed 16 were men and 8 were women.

Eligibility criteria

Inclusion and exclusion criteria were used for the selection of study participants.

Inclusion criteria

1. T2DM Patients between one to ten year duration with oral hypoglycemic agents' treatment only
2. Sedentary middle aged (40-64) years old adult groups
3. Body mass index no more than 35 kg/m², and with HbA1c level <12%
4. Study groups who were following physician check up in the clinic of endocrinology unit of the hospital.
5. And, those who would gave their consent to participate in aerobic exercise and in strength exercise according to ADA and ACSM protocol that Dilla university community gymnasium (DUCG) was using, were included in the study.

Exclusion criteria

1. Severe mental health problems
2. Musculoskeletal problems
3. Hearing impairments
4. Increased likelihood of CVD (Cardio Vascular Disease)
5. And/or that might contraindicate certain types of exercise or predispose to injury, such as:
 - Severe autonomic neuropathy
 - Severe peripheral neuropathy, and
 - Pre-proliferative or proliferative retinopathy.
6. And/or any other severe health problems and those patients who were incapable to provide the relevant information will be excluded.
7. Patients with type 1 diabetes mellitus, pregnant women with and without gestational diabetes and other specific types of diabetes mellitus and who were participating in another research study were excluded in this study.

Ethical Considerations

Before carrying out the study, Health Research and Ethical Review Committee of Mekelle University was approved ethical clearance for the study with registration number of ERC0776/2016. And, again DURH department of internal medicine accepted this ethical clearance and disseminated the letter of permission to the diabetic clinic care and laboratory technicians to perform all the required tests and examinations for our study.

After permission was taken from the concerned authorities, written informed consent was provided and given to the concerned study participants with information about the objective of the study, and all agreed subjects were gave back the written informed consent to participate in our study. To guarantee confidentiality, we (the researchers) were used medical record number instead of name of the participant for our study.

Administration of the Test and Collection of the Data

The study investigators were supervised all intervention programs whether fitness center professionals gave appropriate exercise programs according to exercise recommendations for patients with T2DM or not. In addition, medical checkup of the permanently follow up study participants with T2DM in Diabetic clinic of Dilla University Referral Hospital was supervised. Following exercise, the study investigators were also supervised checkup of blood pressure level of the study groups by the concerned nurses in the diabetic clinics. Following ethical clearance attainment for the purpose of data collection, necessary information was explained to participants. Blood samples of study groups were given to laboratory technicians of DURH during pre and post intervention of sixteen weeks of exercise program. Blood samples for laboratory analysis were drawn early in the morning only at baseline (fasting) by making the subjects sit on the chair. Glycosylated Hemoglobin (HbA1c) was tested using Architect 4000 machine whereas Total Cholesterol (TC) level, HDL-c, LDL-c, Triglyceride (TG), and Fasting Blood Glucose (FBG) were analyzed using Blood chemistry analyzer (minder 200E) ,and Glucometer (i-QARE) by taking venous blood for these measurements. The test was done in the morning after and between eight to twelve hour fasting which is overnight fasting and without doing any physical exercise prior to testing. On the other hand, measurements of Herat Rate(HR) using count the beats for 15 seconds, percent body fat (BMI using stadiometer and weighing scale, and skin fold measurements using base line® skin fold caliper with its serial number of 12-1110, made in New York 10602 - USA) were taken prior to the exercise program of the first week and after the last week of the sixteen week exercises program. These measurements were performed by well-trained fitness professional of Dilla university community gymnasium (DUCG).

Exercise intervention (training) protocol

Aerobic exercise comprised aerobic dance, and stationary bicycle without load. The aerobic exercise group performed exercises up to 55 minutes per day, 4-5 times per week with no more than a day after one day between bouts of exercise, and intensity was set using Rate of perceived exertion (RPE) whereas resistance exercise comprised chest press, shoulder press, leg press, leg extension, and free weight (biceps & abdominal).

The resistance exercise group performed exercises up to 40 minutes 3 times per week with nonconsecutive days, and resistance exercise training load was set using a percentage of 1RM in which our study was used for assessing each individual per exercise. whereas combined aerobic and resistance exercise group performed exercises up to 37 minutes, 3-4 times per week, and the above aerobic exercises were followed by resistance exercises, which were set by Dilla University Community Gymnasium (DUCG) professionals. On the other hand, the control group was maintained as standard control (follow up clinical case living with daily routine) within 16 weeks. Each exercise administered session which included warming - up using stretching, brisk walking, jogging, and stationary bicycle for 10 minute in different periods were performed in the gymnasium. After warming- up the main work out was followed by a 5 minute cool down with slow waking and stretching that each exercise group was performed.

Statistical Analysis

To compare means and mean difference of pretest and posttest of each exercise group, pair sample t test was used. To get a significant ANOVA comparing the changes among groups, Tukey post hoc test was also used. Data are expressed as mean \pm SD. The level of significance was set at $P < 0.05$. Statistical analyses were performed with SPSS version 20 software.

Results

Table 1 shows the comparative values of physiological (SBP(mmHg),DBP(mmHg),HR(bpm)), biochemical (HbA1-c (%), FBS (mg.dl⁻¹)), and anthropometric (BF(%)) parameters of the allocated four groups pretest and posttest showed significant changes in three intervention groups while no significant change was observed in the control group. The comparison of changes in variables is shown in Table 2. As presented in this table Glycosylated hemoglobin (%) Fasting blood sugar (mg.dl⁻¹) blood pressure (systolic and diastolic) (mmHg), Heart rate (HR) (bpm) and percentage of body fat showed significant changes while no significant change was observed in the control group. On the other hand, Total Cholesterol (TC), Trigl (Triglyceride), HDL-c, and LDL-c showed no significant changes in all allocated groups. Inter-group comparisons of significant variables in the four allocated groups' results of the

Tukey post hoc test are shown in Table 3. These results report that HbA1-c (%), FBS (mg.dl⁻¹), Diastolic Blood Pressure (DBP) (mmHg), HR (bpm), BF (%) in the three intervention groups shows significant differences. But, combined aerobic and resistance exercise group shows ($p=0.054$) for percentage of body fat compared with the control group in these parameters. In addition, the aerobic exercise group shows a significant difference on Systolic Blood Pressure (SBP) (mmHg) compared with resistance exercise group ($p < 0.05$) and control group ($p=0.001$). But no significant differences were observed in between other groups.

Discussion

Regular aerobic and resistance exercises are recommendations from the current guidelines of the American Diabetes Association, the European Association for the Study of Diabetes, and the American Heart Association for people with type 2 diabetes without major complications²⁰. (Bweir et al., 2009). Therefore, various studies have evaluated the effects of these exercises training impact on glycemic control. Still the comparative beneficial effects of aerobic and resistance exercise have not been well identified in Ethiopia's context. The current study was designed to assess the impact of aerobic, resistance, and combined aerobic and resistance exercises on some specific physiological, biochemical, and anthropometric variables among type 2 diabetic patients of middle aged adult groups.

Biochemical tests

To maintain the target level of blood glucose control and improvement of insulin resistance is considered critical for the treatment of Type 2 diabetes²¹. Thus, the current study on the combined aerobic and resistance exercise training group showed that, it was effective in improving HbA1c followed by resistance exercise, and aerobic exercise as compared to the elevation in the control group. This findings is supported by the findings of Zanusso and others researchers²² and Sgnal and others researchers²³ stated that combined exercise training resulted in higher change in A1c values compared with aerobic exercise alone or resistance exercise training alone. FBG levels were significantly decreased in the three exercise intervention groups, although the decrease detected in the combined aerobic and resistance exercise group was followed by resistance exercise training

alone and aerobic exercise training alone. This finding is consistent with the reported changes in the study of Alam and others researchers²⁴ and Stefano Balducci and others researchers²⁵.

Physiological tests

In the findings of the current study, the three exercise intervention programs were found to be effective in the improvement of blood pressure (Systolic and Diastolic) among patients with Type 2 diabetes. However, no significant change was observed in the control group. This is consistent with the study of Maiorana and others²⁶ on the combined aerobic and resistance exercise. The significant reduction of systolic blood pressure in aerobic and resistance exercise groups were found

²⁷. Our findings are consistent with the results of this study as well. Heart Rate values were also improved in the intervention exercise groups compared with no significant change was observed in the control group²⁸ supports our findings and advocate that aerobically well-trained individuals present a lower resting-HR, suggestive of higher parasympathetic activity or lower sympathetic activity.

Anthropometric tests

The findings of²⁹ support our results on exercise intervention reduces percentage of body fat (BF %) of groups with type 2 diabetes (P=0.001).

Table 1 Comparison of pre exercise intervention and post exercise intervention values of tested

variables (Means ± SD).

Variables	AEG	p	REG	p	COM	p	CG	p
Biochemical								
HbA1-c (%)								
Pre-test	8.3±2.2	.013	8.7±1.5	.003	7.8±1.4	.001	8.8±2.1	.296
Post-test	7.7±1.9		8.1±1.2		7±1.3		9.2±2.1	
FBS(mg.dl⁻¹)								
Pre-test	151.3±45.6	.033	162.5±22.4	.002	161.3±23.3	.000	137.2±36.7	.157
Post-test	134.7±32.3		142.7±17.6		134.3±21.2		204.2±115.4	
TC(mg.dl⁻¹)								
Pre-test	248.2±123.6	.181	201.8±30.1	.204	200±140.1	.682	108.3±45.8	.109
Post-test	159.3±28.6		156.2±64.9		180.5±59.2		147.3±9.5	
Triglyceride(mg.dl⁻¹)								
Pre-test	241.7±120.2	.404	221.2±118.2	.352	308.2±246	.080	165.3±136	.295
Post-test	198.3±53.3		166.0±56.9		151±93.9		224.8±125.7	
HDL-c(mg.dl⁻¹)								
Pre-test	55.8±28.5	1.000	58.2±13.3	.074	74.7±18.4	.317	49.8±22	.244
Post-test	55.8±11.3		50.2±9.1		62.3±16.9		40.8±11.6	
LDL-c(mg.dl⁻¹)								
Pre-test	76.0±50.8	.579	89.7±27.4	.935	84.2±52.9	.990	64.3±19.1	.578
Post-test	63.7±25.5		88.3±31.6		84.0±42.6		71.3±23.4	
Physiological								
SBP(mmHg)								
Pre-test	133.3±17.5	.015	130.0±8.9	.025	131.7±9.8	.001	126.7±15.1	.363
Post-test	111.7±7.5		123.3±8.2		120±11		128.3±16	
DBP(mmHg)								

Cont... Table 1 Comparison of pre exercise intervention and post exercise intervention values of tested variables (Means ± SD).

Pre-test	81.7±4.1	.025	83.3±5.2	.042	81.7±4.1	.025	75±8.4	.175
Post-test	75.0±5.5		75.0±5.5		75±5.5		78.3±11.7	
HR(Bpm)								
Pre-test	87.8±10.2	.036	86.8±8.5	.017	94.3±9.7	.044	76.5±9	.122
Post-test	79.2±5.3		78.8±7.9		85.7±6.3		81.3±13.2	
Anthropometric								
BF (%)								
Pre-test	37.9±2.9	.030	38.7±5	.031	38.7±7.7	.000	38.8±8.2	.118
Post-test	37.4±2.9		36.5±5.4		36.9±7.5		41±6.4	

Note: p value is set at <0.05; AEG: Aerobic exercise group; REG: Resistance exercise group; COM: Combined Aerobic & Resistance Exercise Group; CG: Control group; p : p - value

Table 2. The comparison of changes in variables during sixteen weeks in the four allocated groups of type 2 diabetes mellitus (Mean± SD)

Variables	AEG	REG	COM	CG	p-value
<i>Biochemical</i>					
HbA1-c (%)	-0.53±0.34	-0.58±0.27	-0.88±0.33	0.42±0.88	.002
FBS(mg.dl ⁻¹)	-16.67±14	-19.83±7.86	-27±8.17	67±98.57	.012
TC(mg.dl ⁻¹)	-88.83±139.95	-45.67±76.53	-19.5±110	39±49.2	.196
Trigl(mg.dl ⁻¹)	-43.33±116.37	-55.17±131.84	-157.17±175.68	59.5±124.67	.095
HDL-c(mg.dl ⁻¹)	+0.00±18.01	-8±8.71	-12.33±27.18	-9.0±16.69	.711
LDL-c(mg.dl ⁻¹)	-12.33±50.98	-1.33±38.02	-0.17±29.65	7±28.87	.849
<i>Physiological</i>					
SBP(mmHg)	-21.67±14.72	-6.67±5.16	-10±6.3	1.67±4.08	.002
DBP(mmHg)	-6.67±5.16	-8.33±7.53	-6.67±5.16	3.33±5.16	.010
HR(BPM)	-8.67±7.47	-8±5.59	-8.67±7.94	4.83±6.37	.006
<i>Anthropometric</i>					
BF(%)	-0.52±0.42	-2.12±1.74	-1.77±0.51	2.22±2.88	.001

Note: p value is set at <0.05; HbA1-c – Glycosylated Hemoglobin, FBS – Fasting blood Sugar, TC – Total Cholesterol, Trigl – Triglyceride, HDL-c – High Density Lipoprotein, LDL-c – Low Density Lipoprotein, SBP – Systolic Blood Pressure, DBP – Diastolic Blood Pressure, HR – Heart Rate, BF – Body Fat. Reading measurements of Parameters are: % (percent), mg.dl⁻¹ (milligram per deciliter), mmHg (millimeter mercury), BPM (beats per minute).

AEG: Aerobic exercise group; REG: Resistance exercise group; COM: Combined Aerobic & Resistance Exercise Group; CG: Control group

Table 3. Inter-group comparisons of significant variables in the four allocated groups results of the Tukey

post hoc test for significant ANOVA

Comparison between Groups		HbA1-c (mg.dl-1)	FBS (mg.dl-1)	SBP (mmHg)	DBP (mmHg)	HR (bpm)	BF (%)
AEG	REG	.998	1.000	.033	.960	.998	.392
	COM	.650	.984	.124	1.000	1.000	.595
	CG	.022	.041	.001	.036	.014	.054
REG	COM	.748	.994	.908	.960	.998	.984
	CG	.015	.033	.366	.012	.021	.002
COM	CG	.002	.019	.124	.036	.014	.003

Note: p value is set at <0.05; AEG: Aerobic exercise group; REG: Resistance exercise group; COM: Combined Aerobic & Resistance Exercise Group; CG: Control group

Conclusion

Even though, in our study, the three exercise training interventions did not show remarkable changes in total cholesterol, triglyceride, high density lipoprotein, and low density lipoprotein among patients with Type 2 diabetes after sixteen weeks, combined aerobic and resistance exercise intervention alone has more beneficial effects on glycosylated hemoglobin, fasting blood sugar, blood pressure (systolic and diastolic), heart rate and percentage of body fat, followed by resistance exercise alone, and aerobic exercise alone, as they were compared with the control group. Thus, regular aerobic and resistance exercise training may give additional contribution next to pharmacological treatment to the prevention and control of Type 2 diabetes mellitus.

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Prevalence of Diastolic Dysfunction among Asymptomatic Normotensive Diabetics

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Abstract

LV diastolic dysfunction is one of the earliest signs of myocardial involvement in diabetes and hence, an important component in diabetic cardiomyopathy. It is also an important predictor of heart failure and long-term mortality. Diabetics have a 2.5 fold increased risk of heart failure. It is suggested that early detection of diastolic dysfunction by echocardiography can lead to institution of early measures for prevention of heart failure. The aim of this study is to find the prevalence of diastolic dysfunction in asymptomatic diabetic patients by echocardiography.

Key words: *Diastolic dysfunction, diabetes mellitus*

Introduction

Type 2 DM leads to a variety of subclinical target organ impairment that result in an increased incidence of cardiovascular disease. An important example is diabetic cardiomyopathy where heart failure occurs in the absence of coronary artery disease or hypertension. In this entity, diastolic dysfunction appears long before systolic dysfunction.¹ The prevalence of heart failure in diabetes is to the tune of 30%.² Diastolic dysfunction is present in about 50% of adolescents or young adults with diabetes of duration about 10 years. It has been seen that of diabetic patients with systolic dysfunction, 83% had impaired diastolic function, whereas only 30% of diabetic patients with diastolic dysfunction had systolic dysfunction.

Unrecognized diabetic cardiac impairment³ is identified from, among other findings, echocardiographic evidence of diastolic dysfunction.³ A close evaluation of diastolic function is necessary for identification of patients in the presymptomatic phase and subsequent close follow up and treatment.

Materials and Methods

100 consecutive asymptomatic patients of diabetes attending the outdoor patient department of MKCG Medical College, Berhampur were included in the study. The control group consisted of 50 healthy persons. All

patients were subjected to lab investigations including complete blood count, fasting and postprandial blood sugar, HbA1c, renal function test, liver function test and lipid profile. A resting ECG was recorded. BMI was calculated as weight in kg divided by height in metre (squared).

Transthoracic echocardiography (TTE) was performed by an experienced cardiologist using Philips HD7XE echocardiography machine with 3.5 MHz transducer probe. Echocardiography was performed on all participants and assessment of both systolic function and diastolic function was done. The parameters assessed were peak E velocity, peak A velocity, E/A ratio (normal 1-2), isovolumic relaxation time (IVRT) (normal 60-100 ms), deceleration time (DT) (normal 150-220 ms). E/e' was also assessed using Tissue Doppler imaging.

Diastolic dysfunction was categorised into grade 1 (delayed relaxation), grade 2 (pseudonormalisation), grade 3 (reversible restrictive) and grade 4 (irreversible restrictive).

Exclusion Criteria:

Patients of hypertension and known heart disease such as coronary artery disease, valvular heart disease and other causes of diastolic dysfunction such as constrictive pericarditis and restrictive cardiomyopathy were excluded from the study.

Results

Out of 100 diabetics, 68 were male and 32 female whereas out of 50 controls, 25 were male and 25 female. The mean age of diabetics was 42.7 years whereas the mean age of controls 37.3 years. 6 patients had type I diabetes. The duration of diabetes was less than 1 year in 10 patients, 1 to 5 years in 36 patients and more than 5 years in 54 patients. 76 patients had normal BMI, 20 patients were overweight and 4 were obese. HbA1c <7, 7-8 and >8 was observed in 74, 20 and 6 patients respectively.

Diastolic dysfunction was observed in 68 out of 100 diabetics but in only 6 out of 50 nondiabetics ($p < 0.05$).

Table 1 Comparison of E/A ratio between diabetics and nondiabetics

	Diabetics	Nondiabetics
E/A > 1	68	6
E/A < 1	32	44

Discussion

Diabetic cardiomyopathy is considered to be a unique entity with multiple putative mechanisms such as microvascular disease, autonomic dysfunction, metabolic disorders, and interstitial fibrosis. LV diastolic dysfunction may represent the first stage of diabetic cardiomyopathy.⁴ Diabetes causes diastolic dysfunction by derangements in myocardial relaxation and increased stiffness due to metabolic abnormalities and ultrastructural changes, largely due to circulating advanced glycation end products (AGEs).

The current study found the mean age of diabetics to be 42.7 years. Indians are known to develop diabetes 10 years earlier than their western counterparts with 46% of patients being under 40 years of age. The average age of onset of diabetes is 42.5 years. Also, a WHO report estimated that in developing countries including India, the largest number of diabetics is in 41-60 years age group.⁵ The number of people with diabetes in India has increased from 26 million in 1990 to 65 million in 2016.

In our study, 68 patients were male and 32 were female. The study by Kabeer et al found 64% males and 36% females.⁶ Increased prevalence in males was also shown by Patil MB et al who showed 56% males and 44% females in study population.⁷

The percentage of overweight and obese individuals in our study was 20% and 4% respectively. Vasanthakumar reported the prevalence of overweight in diabetes to be 19%.⁸

As in previous studies, an E:A ratio value of 1.0 was arbitrarily chosen as the lower limit to detect impaired relaxation.⁹ In our study, diastolic dysfunction was seen in 68% patients. In a study of 127 asymptomatic patients of diabetes, Patil et al reported the incidence of diabetes to be 54.33%.⁷ Burji et al found diastolic dysfunction in 32 (64%) of patients.¹⁰ Senthil et al reported the prevalence to be 30% as did Zarich et al.^{11,12} Pourier et al studied 46 normotensive men with diabetes and found diastolic dysfunction in 28 (60%).¹³ Fawad Randhawa et al studied 150 diabetics with normal blood pressure and found the prevalence of diastolic dysfunction to be 48%.¹⁴

Conclusion

Asymptomatic diastolic dysfunction is found in 68% of diabetics as compared to 6% of nondiabetics. Early diagnosis and institution of treatment is likely to improve both morbidity and mortality related to heart failure.

Conflict of Interest: None

Source of Funding: Self

Ethical Clearance: from MKCG Medical College Ethical Clearance Committee

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Junk food Consumption Pattern by Undergraduate Students of Dayalbagh Educational Institute, Agra

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Abstract

Background -Junk food is the food that can easily and quickly prepared, rich in calories but deficient in most of nutrients. Due to increased urbanization, globalization and commercial advertisements as well as abundant junk food outlets, college going students are getting indulge in eating these types of food. In recent researches, it is clear that fast food is the one of the reasons for metabolic disorders such as obesity, diabetes and heart diseases etc. Present survey was there fore conducted to check the consumption pattern of junk food by university students of Dayalbagh Educational Institute.

Methodology—Among all the university undergraduate students,198 undergraduate students (68 boys and 130 girls) were randomly selected and assessed by self-administration of structured questionnaire.

Results and Conclusion – Present study revealed that about 51% students regularly consume fried/high fat food in the form of kachori, samosa, pizza, pasta, chole bhature etc. and almost 31% students regularly consume high sugar-based food like cold drinks, ice-cream, donuts, pastries and cakes etc. Most of the students revealed that taste of fast food is the sole reason for consumption of fast food. Present study also revealed that about 23% students were having adequate knowledge about effect of fast-food consumption on health whereas 42% students was having inadequate knowledge about ill effect of fast-food consumption on health. It is therefore necessary to create awareness about ill effects of fast food and benefits of balanced diet to the college going students.

Keywords – *Fast food, junk food, nutritional awareness, general health, Unhealthy food*

Introduction

Junk food is the food that is served at fast food outlets, quickly and easily processed and prepared but lack in essential nutrients with dense in calories.Manufacturers set low prices with high marketing for selling fast food at high pace. Due to low in nutrient level, junk food does not contribute in maintaining health.^[1]

Environment in the college influence the behavior of students. Students are indulging into fast food to curb their hunger, social gathering with peers, save time as well as junk food give them a sense of pleasure. Due to low price and affordability, they consume junk food as alternative of home food.^[2] Due to rich in calories and salt, excessive consumption of junk food is major causative factor for non-communicable diseases such as

obesity, high blood pressure, high cholesterol and high glucose level in blood. Poor handling of food during preparation can cause microbial contamination resulting gastro-intestinal problems. It is proved that energy content of junk food is higher than the recommended dietary allowances and micronutrient level is much lower than the recommended dietary allowances that lead to osteoporosis and other diseases.^[3]

Present study was therefore planned to know the consumption pattern and factor associated with high consumption of fast food so that preventive measures can be taken to reduce consumption of junk food.

Objective of the Study

To assess the consumption pattern of fast food by

the undergraduate students of Dayalbagh Educational Institute (D.E.I), Agra.

Methodology

Cross sectional survey was conducted to assess the junk food consumption pattern among undergraduate students of Dayalbagh Educational Institute, Agra. List of undergraduate students was obtained from each faculty office of Dayalbagh Educational Institute. Simple Random sampling was used and every fifth student was selected as sample for the study. Total sample size was 198 students in which 34 were boys

and 65 were girls. To assess the consumption pattern of fast food by undergraduate students, self-structured questionnaire was constructed and sent to experts for opinion. Suggestions given by experts were incorporated and pilot study was conducted. On the basis of pilot study final questionnaire was finalized. Permission from ethical committee of the institute was obtained and data was collected during free period in the classroom.

Results and Discussion

All participants filled the questionnaire. For data analysis mean, standard deviation, percentage and Pearson correlation was used using SPSS version 23.

Table 1: - Distribution of students according to Age

Age group	Number (n=198)	Percentage
17-20 year	108	55%
21-24 year	74	37%
25-30 year	16	8%

As shown in Table 1, according to age, students were distributed into 3 groups. 55% students belong to 17-20 age group, 37% students belong to 21-25 age group and 8% students belongs to 25-30 age group. Age plays a important role in consumption of junk food as most of the students in undergraduate classes are at their late adolescence or in early adulthood. In this period, college gathering among peers or classmates are on regular basis also college students receive more pocket money from parents that influence junk food consumption.^[4]

Table 2 – Distribution of Students according to Gender

Gender	Number (n=198)	Percentage
Male	68	34%
Female	130	66%

As shown in Table 2, according to gender, approximately 66% students were female and 34% students were male students. In past researches it was observed that male consume more fast food than females as male students take advantage of their liberty and often go with friends, colleagues or classmates for outing, parties, get together or any sports activities that influence their consumption of outside food.

Table 3 – Distribution of Students according to Physical activity

Activity	Number (n=198)	Percentage
Sedentary	44	22%
Active	154	78%

As shown in Table 3, 78% students were having active lifestyle whereas 22% students were having sedentary lifestyle. Most of the college going students assessed was active as they were essentially engaged in some sort of physical activities per day such as running, jogging, playing sports (Badminton, Football, Cricket)

with their peers after college time. Physical activity also impacts the junk food consumption as during or after playing with friends they mostly indulge in fast food sold by street side vendors that increment in their consumption of fast food.

Table 4 - Distribution of students according to Weight

Weight	Number (n=198)	Percentage
Underweight	9	5%
Normal	79	40%
Overweight	69	35%
Obese	41	20%

As shown in Table 4, 40% students were having normal bodyweight, 35% students were overweight, 20% students were obese and 5% students were underweight. Junk food directly affects the weight of the individuals due to high salt content that led to water retention as well due to high fat content that is not fully utilized by the body deposit in adipose tissues of the body causes gaining in weight.

Table 5 – Distribution of students according to family history

Family history	Number (n=198)	Percentage
Yes	105	53%
No	93	47%

As shown in Table 5, 53% students were having family history of non-communicable diseases such as heart disease, diabetes etc. whereas 47% students responded as “No” for any family history of non-communicable diseases. It was observed that students with family history of non-communicable diseases was aware of ill effects of unhealthy eating therefore they keep check on amount of fast-food consumption.

Table 6 – Percentage distribution of students according to high fat/high sugar food

Consumption	Regularly (%)	Occasionally (%)	Never (%)
High Fat	51	48	1
High Sugar	31	60	9

As shown in Table 6, 51% students regularly consume high fat/fried food in form of chole bhature, samosa, kachori, poori, pizza, pasta, noodles, chowmine, golgappe etc. while 48% students occasionally consume high fat food. As shown in above table, 60%

students occasionally consume high sugar-based food like cold-drinks, pastry, donut etc. whereas 31% students consume these foods regularly. These foods are readily available in college canteen/cafeteria and fast-food outlets. Students during college hours or in get together

with peers consume mostly.

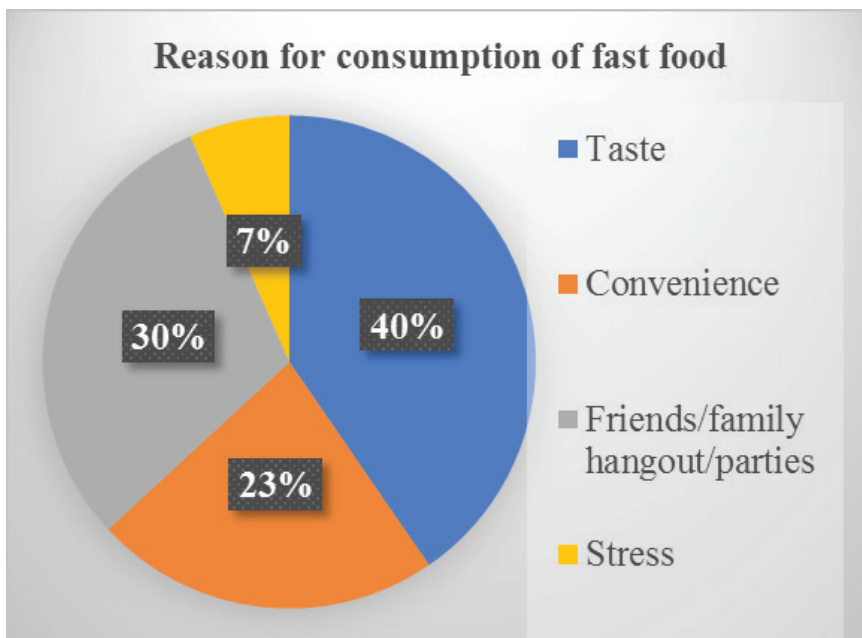


Figure 1 –Percentage distribution of students according to reason for consumption of fast food

As shown in figure 1, 40% students consume fast food due to taste whereas 30% students consume fast food in parties with family or friends. 23% students responded that fast food is easily available everywhere like canteen etc. thus freedom from carry food from home whereas 7% students responded that to relieve stress they indulge in eating fast food.

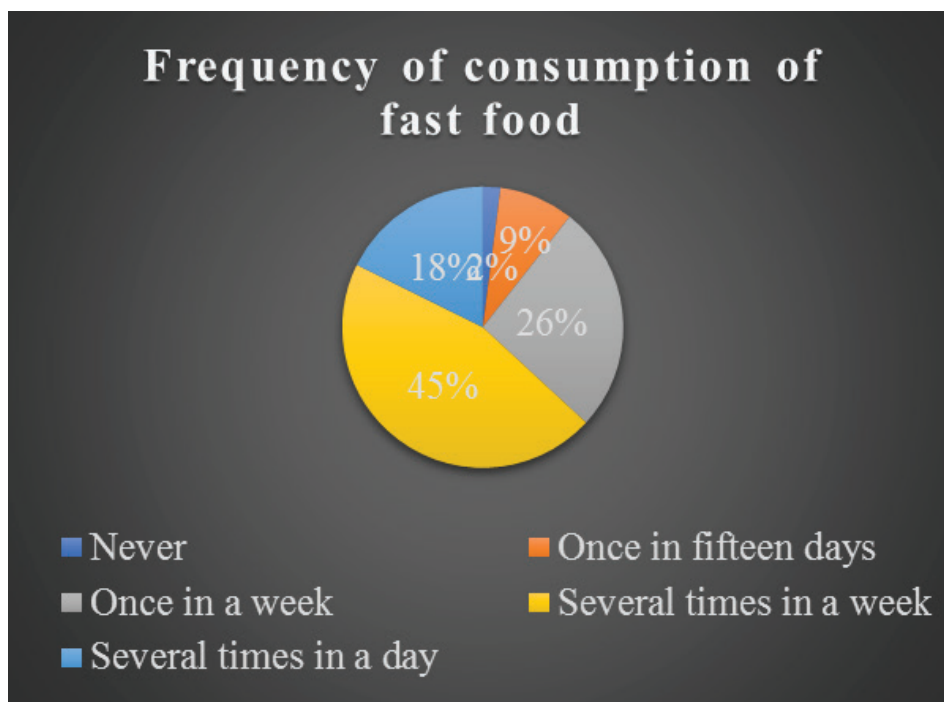


Figure 2 – Percentage distribution of students according to frequency of consumption of fast food

As shown in figure 2, 45% students were consuming fast food several times in a week whereas 26% students were consuming once in a week. 18% students reported consumption of fast food several times in a day whereas 9% students reported consumption of fast food once in fifteen days.

Table 7 – Awareness about junk food in university students

Awareness level (n=198)				
	Additives	Calories	Metabolic diseases	Freshness
Mean	1.6465	1.2677	1.4394	1.5657
Std. Deviation	.47928	.44387	.49757	.49693

As shown in Table 7, students were highly aware about addition of additives in junk food and least aware about calories present in fast food. Students were also aware about un-freshness of junk food than its linkage to metabolic diseases but because of taste, convenience and availability at gatherings or parties they consume it.

Table 8 – Pearson Correlation among awareness about calories, BMI of students and frequency of fast-food consumption

Correlations among awareness about calories, BMI of students and frequency of fast-food consumption (n=198)				
		Calories	BMI	Frequency
Calories	Pearson Correlation	1	.841**	.609**
BMI	Pearson Correlation	.841**	1	.778**
Frequency	Pearson Correlation	.609**	.778**	1
**. Correlation is significant at the 0.01 level (2-tailed).				

As shown in Table 8, there was significant correlation obtained among BMI of the students and frequency of consumption of junk food and calories present in junk food. With increment in frequency of high calorie food that is not utilized by the body ultimately deposited as fat in adipose tissue that led to increment in BMI. Although other factors are also responsible for BMI of the students other than junk food that is not covered in present study due to limitations.

Table 9 – Correlations among awareness about high calories in fast food, BMI and physical activity

Correlations among awareness about high calories in fast food, BMI and physical activity (n=198)				
		Calories	BMI	Activity
Calories	Pearson Correlation	1	.841**	.167*
BMI	Pearson Correlation	.841**	1	.278**
Activity	Pearson Correlation	.167*	.278**	1
**. Correlation is significant at the 0.01 level (2-tailed).				
*. Correlation is significant at the 0.05 level (2-tailed).				

As shown in Table 9, there is significant correlation among student’s physical activity, BMI and calories present in junk food. As per National institute of nutrition, India “Calorie in = Calorie out = Weight Maintenance” and if “Calorie in > Calorie out = Weight gain “therefore physically active students showed weak correlation with BMI and Calories.

Conclusion

Malnourishment in terms of obesity is the current vital health problem of the youth that leads to increased medical expenses. Various researches have shown that university or college students mostly consume food in high calories in terms of fried, packaged or high sugar food and least interested in consuming fruits and vegetables.^[5] In present study students reported that taste and convenience was the primary factor for junk food consumption. Other than taste other reason was frequent hangout with friends or family. Students who were aware about calories and ill effects of junk food having normal BMI in comparison of unaware students. Similar results were obtained by Shami and Fatima (2017) ^[2] in the study to know the trends of fast-food consumption by college going girls. Fast food junctions mostly target the young generation and environment of college, influence their behavior of students to make social interaction with peers and to satisfy taste buds and hunger. Study conducted by Vani et al (2016) ^[6] concluded that 71% students were consuming frequent fast food and taste was the primary reason for consuming junk food. Junk food contains high amount of fat, sugar and salt more than recommended by National institute of nutrition (NIN) and world health organization (WHO). In present study, there is significant correlation obtained among BMI, Junk food frequency, physical activity and awareness. It is therefore necessary to organize the nutrition education programme in colleges as well as in schools to prevent young generation from addiction of junk food so that non-communicable diseases like obesity, Diabetes, Cardiovascular disease etc. can be prevented.

Source of Funding - Self

Conflict of Interest - Nil

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The Relevance of Social Work Professionals in the Promotion of Occupational Health and Safety among Healthcare Workers

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Abstract

Background: In the global era, occupational health and safety (OHS) is becoming a major concern. In the domain of health, healthcare workers are at the risk of occupational exposure due to their working pattern. Aim: To investigate the relevance of social work professionals in the promotion of OHS. Design: Exploratory research design. Method: 34 medical social workers and counsellors of GMCH-32 and PGIMER, Chandigarh were interviewed. The mean and percentage were used for the analysis. Findings:-About 76.5% respondents considered physical, biological and social aspects of workers' wellbeing in the context of OHS. 41.2% respondents were suffered from occupational exposure. 85.3% respondents recognized the role of social work professionals in the promotion of OHS. Conclusion: The role of the professional social worker can be proved significantly with the use of professional skills and techniques. There is a need of training and awareness among professionals for the promotion of OHS.

Keywords: Occupational Health, Prevention, Risk, Safety, and Social work practice

Introduction

In the contemporary world, the prevention of occupational health (injury and disease) and promotion of workers' safety is becoming a global concern. Globalisation has brought substantial changes in the employment, job insecurity, condition of work and life of worker, particularly as a consequence of increased competition, deregulation, privatisation, restructuring corporate and introduction of new technology^{1, 2}. Major occupational hazards can be categorized as machinery related accidents, noise, dusts, poor ventilation, exposure to toxic chemicals and radiation which affect the health of the workers. And the mental stress has further added risk to the health of worker³. According to the report of joint committee of International Labour Organization (ILO)

and World Health Organization (WHO) in 2003, about 1.9 to 2.3 million work related death occurred globally every year. There were around 355,000 workplace accidents, 1,574,000 were occupational diseases and 158,000 were commuting accidents recorded. It was estimated that the cost of occupational diseases and accidents were about four percent (4%) of the World's GNP⁴.

Primary health care and medical education are two aspects of occupational health and safety in India. The Director General of the Factory Advisory Services and Labour Institutes (DGFASLI) reported that there were 1,509 fatal and 33,093 non-fatal injuries in 2009. The statistical data is under-estimated due to huge workforce in unorganized sector, the large number of unreported occupational illness, infrastructure problem and delay in the implementation of national policy on occupational health and safety⁵. There are four sectors- Mining, factories, port and construction where safety and health statutes function to regulate occupational health and

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accidents among workers. The Factories Act (1948), the Mines Act (1952) and the Dock Worker Act (1986) are some legal provisions in India relating to working hours, conditions of services and employment⁶. Many occupational diseases and accidents are preventive in nature and can be prevented at workplace by applying few safety measures. Maintenance of personal protective equipment, early detection of occupational disease, availability of curative and rehabilitation facilities and provision of primary health care are some of the measures to prevent occupational disease and accidents^{7, 8}.

Occupational Health and Safety (OHS):

‘Occupational Health and Safety’ is a branch of occupational medicine with an aim of maintaining worker’s mental, physical and social wellbeing⁹. According to WHO (2001), occupational health is defined as a multi-disciplinary activity for the promotion of the worker’s health and prevention of occupational disease and accidents. The term ‘occupational safety’ is defined as risk identification and preventive measures taken to reduce the hazards that may lead to accidents at workplace. Occupational disease and injury has had direct and indirect influence on the pocket of individuals, the expenditure for the treatment may be extended upto out of pocket. It has also impacted the families of worker, employing organisation and ultimately to the society at vast level¹⁰.

Individuals working in transportation industries, glass industries, power plants industries and textile industries are prone to affect with noise air pollution and vibration. Working in mines may be resulted in eye strain, fatigue defective illumination, skin diseases and increased rate of accident. A worker of fertilizer industry may be exposed to poisonous gases that affect the health of workers. Exposure to heat, noise, radiation, chemicals, pesticides and heavy metals fosters serious illness or hazardous to health and unsafe environment of the workplace. Repeated activity, improper designed workplace, less wages, long duration of the job and other work condition also affect the physical, mental and social wellbeing of individual^{9, 10}. The affected workers and their families have to face emotional and financial constrains. The employing organisation has to pay money as compensation, suffer the losses in

production, employ new workers and provide training to them which has an extra burden on the employer. The government needs to allocate extra fund in the health budget for the treatment of diseases and accidents related to occupation⁵. Comprehensive approach is required to prevent occupational disease and injury among workers as it encompasses all aspects of the workplace. These aspects are social, psychological, health, economic, political and environment⁹.

Occupation disease and injury (ODI) among healthcare professionals:

The healthcare workforce shows 12% of the global working population¹¹. Healthcare workers, such as doctors, nurses, technicians, medical social workers, counsellors, etc. work as a multidisciplinary team to assure equity in treatment and care among patients¹². They are at the risk of exposing with microbial agents such as bacteria, viruses, parasites and fungi through the contact with blood and body fluid of infected patients. Working in blood banks, tuberculosis centres and laboratories is more likely to result in contacting infections like tuberculosis, HIV/AIDS and Hepatitis B & C due to work related activities¹¹.

Approximately 5.6 million healthcare workers are at the risk of exposing with disease and injury related to occupation. Over 5000 manual disorder reported each year due to the handling of patients¹³. More than three million occupational injuries like a needle or sharp object penetrates the skin, occur annually¹⁴. Nearly, about 37% of the hepatitis B among health workers is due to occupational exposure. Although the exposing with hepatitis B is 95% preventive, yet only 20% of healthcare workers are immunized. Approximately 95% HIV occupational exposure can be prevented through practical and low cost measures¹³.

Whenever, any communicable disease outbursts in the society, healthcare workers are deployed to fight against the deadly disease. This will create a problem in hospital management and safety of personnel exposed to infected patients. It was observed that when an Ebola virus out broke among the general population in 2013-2016; over 890 healthcare workers were infected^{14, 15}.

Social work professionals in OHS:

Social work as a practice-based profession and discipline promotes social change and development in society. Principles of social justice, human right, collective responsibility and respect for diversity are central feature of social work. Social work professionals apply social work practices (values, principles and techniques of social work) to perform different roles like a facilitator, advocacy, intervention, prevention and social control in public and private agencies of society¹⁶. Social work professionals are working in different areas of health, such as HIV/AIDS, substance abuse prevention, mental health, maternal and child care, etc. The main focus of medical social worker is on the promotion of a healthy lifestyle among the public, the enhancement of the environment and the avoidance of risks. They are trained to provide intervention and prepare infected individuals, families and group at the time of traumatic events and disasters. They inform and educate community about health issues through social planning, organisational development and social marketing principles¹⁷.

The study of Moshe et al. (2017) supported the need of social work professionals in OHS by showing the positive impact of the social work service within the public health system of Israel. Patients had a high level of satisfaction with social work services¹⁸. The professional social workers can endeavour to reduce the risk of occupational diseases with the use of skills and techniques.

The present study was conducted among medical social work professionals, working in Government medical college and hospital (GMCH), sector 32 and Post Graduate Institute of Medical Education and Research (PGIMER), Sector 12, Chandigarh. The purpose of the study was to observe the relevance of medical social work professionals in the prevention of occupational hazards and promotion of OHS.

Objective of the Study

- To describe the awareness level among medical social work professional in the context of occupational hazards in health setting

- To explore the role of medical social work professionals in the realm of OHS

- To suggest social work practice to reduce the incidence of ODI

Methodology

An exploratory research design was applied to explore the relevance of social work practices in the prevention of occupational disease or injury occurring in the hospital. About 34 social work professional comprised of medical social workers and counsellors were selected through snowball sampling technique for the study. Interviews were carried out from November 2018 to January 2019 in GMCH, sector 32 and PGIMER, Sector 12, Chandigarh. The schedule composed of five sections i.e. socio-demographic profile, awareness about OHS, attitude towards OHS, description of occupational exposure and relevance of social work practice in OHS. Questions in these sections were consisted of both open and closed ended. The descriptive analysis like mean, median, etc. was done in the study. The mean and percentage was used for the analysis of data.

Results

Table 1 displayed the socio-demographic characteristics of 34 respondents, comprising 15 males and 19 females. Respondents belonged to different age group from 25 to 49 years (mean age 34.97, median 33.50, mode 30 and SD 5.579). There were 25 medical social workers and nine counsellors. Out of 34, 31 respondents were post-graduated and three respondents had done M. Phil/ Ph.D. There were 13 respondents who had the experience of 11-15 years. Only three had more than 16 years of experience in the domain of health. Respondents posted in different departments like emergency, radiation oncology, ophthalmology, etc. as a medical social workers or counsellor.

Table 1: Socio-demographic detail of respondents (n=34)

	Frequency	%age
Gender		
Male	15	44.1
Female	19	55.9
Age		
<= 25	1	2.9
26 – 30	9	26.5
31 – 35	11	32.4
36 – 40	7	20.6
41 – 45	5	14.7
46 – 50	1	2.9
Educational qualification		
Post graduation	31	91.2
Above Post graduation	3	8.8
Designation		
Medical Social worker	25	73.5
Counsellor	9	26.5
Professional experience in health		
1-5 years	9	26.5
6-10 years	9	26.5
11-15 years	13	38.2
16-20 years	3	8.8

In *Table 2* respondents were asked questions related to their understanding about OHS. About 76.5% respondents replied that occupational health and safety encompassed physical, biological and social aspect of workers' wellbeing in the workplace. There were 52.9% respondents who believed that healthy and safe environment, social environment and productive capacities were the aim of OHS. All respondents believed that both workers and employers suffered due to occupational disease and accidents. In regard to worker, pain and suffering (52.9% respondents),

expenditure (23.5% respondents), burden on family (17.7% respondents) and loss of income or job (5.9% respondents) were accepted as hazards. While for an employer, negative effect on other workers (41.2% respondents), has to pay compensation (29.4% respondents), appoint a new worker (17.6% respondents), and defame the company (11.8% respondents) were accepted as hazards. All respondents understood the meaning of the term 'Occupational disease'. While only eight respondents were aware about the agency, such as DGFASLI, working in the domain of OHS.

Table 2: Understanding and awareness about OHS (Occupational Health Services) (n=34)

	Frequency	%age
OHS (Occupational Health Services)		
Physical aspect of health and safe environment of workplace	6	17.6
Biological aspect of health and safe environment of workplace	0	0.0
Social aspect of health and safe environment of workplace	2	5.9
All the above	26	76.5
Aim of OHS		
Maintaining a healthy and safe environment of workplace	11	32.4
Enhancing social environment of workplace	2	5.9
Increasing productive capacities of workers	3	8.8
All the above	18	52.9
Importance of OHS		
Direct effects to worker	0	0
Indirect effects to worker	0	0.0
Affects to employer	0	0.0
Both worker and employer affects	34	100.0
Occupational hazards for worker		
Pain and suffering due to disease or injury	18	52.9
Expenditure in medical treatment	8	23.5
Lose of income or job	2	5.9
Burden on family member	6	17.7
Occupational hazards for employer		
Has to pay compensation to affected worker	10	29.4
Appoint new worker in place of affected worker	6	17.6
Defame the company	4	11.8
Negative effect on the morale of other workers	14	41.2
Occupational disease		
Any disease of general public	0	0.0
any disease of worker	0	0.0
Any disease of workers due to the working pattern	34	100.0
Awareness about any agency for OHS		
Yes	8	23.5
No	26	76.5

Attitude of medical social work professionals towards ODI in the health setting was illustrated in **Table 3**. Among the respondents, 88.2% accepted that working in a hospital was prone to occupational disease and accident, while 5.9% replied in no and 5.9% did not know. Expose to infectious disease and needle stick injury were major hazards that occurred in the hospital. Mental stress and sleeping disorder were other hazards from which healthcare workers also suffered. The exposure to infectious disease was the most common hazard. Using personal protective equipments, like wearing gloves, gown, etc. were considered the most important measure for universal safety against occupational disease and accidents. Cleaning and disinfection, respiratory hygiene, not skipping meals

and proper management of bio-waste materials could be used as alternative measures for universal safety. Lack of awareness and negligence in adapting universal safety measures were the foremost hurdle in the prevention of occupational disease and injury. Lack of training and skill among healthcare workers and lack of infrastructural management was other obstacles in this context. Development of infrastructural arrangement and management of affected healthcare worker and provide training to healthcare workers were the most favourable intervention to reduce the risk of occupational disease and injury. Compliance with universal precaution and availability of safety equipment were other suggested ways to promote OHS.

Table 3: Attitude towards occupational disease and injury in the health setting (n=34)

Detail	Frequency	%age
Working in hospital prone to OHS		
Yes	30	88.2
No	2	5.9
Do not know	2	5.9
Occupational disease and injury (ODI)		
Expose to infectious disease	9	26.5
Work related mental stress	3	8.8
Sleeping disorder	2	5.9
Needle prick	10	29.4
All the above	10	29.4
Universal safety precaution		
Using protective equipment	23	67.6
Cleaning and disinfection	2	5.9
Respiratory hygiene	1	2.9
Not skipping the meal	0	0.0
Proper management of bio-waste	0	0.0
All the above	8	23.5
Hurdle in OHS		
Lack of awareness among healthcare professionals	12	35.3
Lack of training and skill of health care professionals	4	11.8
Lack of infrastructural management	3	8.8
Negligence in adapting universal safety measures	10	29.4
All the above	5	14.7

Cont... Table 3: Attitude towards occupational disease and injury in the health setting (n=34)

Interrupt the risk ODI		
Compliance with universal precaution	4	11.8
Provide training to healthcare professionals for universal precaution	8	23.5
Availability of safety equipment	3	8.8
Development of infrastructural arrangement	14	41.2
All the above	5	14.7

Table 4, portrayed the responses on the exposure of ODI among respondents. About 41.2% respondents out of total respondents replied that they suffered with any infectious disease, needle stick injury, mental stress and accidents due to the working condition of hospital in the past. Among affected respondents, there were six (6) respondents who took the precaution, four (4) respondents who adapted the pattern of working, two

(2) respondents who advocated the issue with higher personnel and two (2) respondents who involved themselves in any recreational activities to prevent occupational disease and injury in the future. Among the respondents, 47.1% were hepatitis immunized. Out of 34 respondents, 41.2% respondents tested more than year, 29.4% respondents tested six months ago, 5.9% respondents tested three months ago and 23.5% never tested for HIV.

Table 4: Type of ODI and intervention taken among respondents (n=14)

Intervention	What kind of disease or injury				Total
	Infection	Injury	Accidents	Mental stress	
Recreational activities	0	0	0	2	2
Advocacy	0	0	1	1	2
Adaptation	0	0	0	4	4
treatment and precaution	5	1	0	0	6
Total	5	1	1	7	14

Table 5 displayed the responses of respondents on the exposure of ODI among their colleagues. About 52.9% respondents replied in no about the exposure of ODI among their colleague, while 35.3% respondents replied in yes about the exposure of ODI among their colleague. A total of 11.8% respondents did not aware

about the exposure of their colleagues. There were 11 respondents who counselled their colleagues to get blood tested for knowing about their HIV, Hepatitis status, regarding PEP (post-exposure prophylaxis) and to take precaution in the future.

Table 5: ODI among their colleagues and intervention taken by respondents (n=12)

What kind of disease or injury	Intervention		Total
	Counselling	no action	
Infection	6	1	7
Needle prick	5	0	5
Total	11	1	12

In **Table 6**, the relevance of social work practice was illustrated in occupational health and safety within the hospital. Among the respondents, 85.3% respondents recognized the significance of social work practice like awareness, guidance, counselling, liaising and research in the prevention of occupational disease and injury among healthcare professionals. Spread awareness was foremost suggested social work practices in the context of OHS among healthcare professionals. Guidance & Counselling, liaising and research were other social work practices to promote occupational health and safety in the health setting. Only 5.9% respondents showed a negative response on the relevance and 8.8% did not know the significance of social work practice in the context of occupational health and safety among healthcare professionals.

Table 6: Relevance of Social work practice in OHS within health setting (n=29)

Kind of social work practices	Frequency	%age
Awareness	19	55.9
Guidance and counselling	4	11.8
Liaising	0	0.0
Research	2	5.9
All the above	4	11.8

Discussion and Conclusion

The term ‘occupational health and safety’ is an interdisciplinary activity which requires coordination among different professionals, such as doctors, nurses, medical social workers etc. to prevent occupational disease and injury in the hospital^{12,19}. There are five routes of transmission of occupational disease or injury among healthcare workers. Blood borne (HIV, Hepatitis B and C etc.), droplet (Influenza etc.), airborne (Chickenpox, Tuberculosis etc.), fecal-oral (Rotavirus) and contact route (Scabies, Herpes simplex virus 1 or 2)

are routes of transmission²⁰.

The present study demonstrates that occupational disease or injury can be prevented through the adoption of universal safety measures among healthcare professionals. There are various strategies to reduce the risk of occupational exposure among healthcare workers. These are identification of high risk activities, training, precaution, efficient of disposal system, management of occupational exposed healthcare workers and counselling²¹.

There is an urgent need for training among healthcare professionals and developing infrastructural arrangement for practicing universal precaution and providing care to affected healthcare professional. Subramanian et al. (2017) described that lack of experience, lack of awareness and ignorance about polices were reasons behind occupational disease and injury. There was a need of continuous awareness activities to promote safety among healthcare workers²². Ngatu et al. (2017) also showed that there was a need to strengthen the health care system and improve occupational safety equipments in health setting¹⁵. Auta et al. (2017) also addressed the requirement of the staff shortage and highlighted the requirement of training among healthcare workers for the promotion of occupational health and safety¹⁴.

The findings of present study show the indifferent attitude towards OHS and ODI among respondents. There is a need to sensitize social work professionals about the issue and promote a safety culture among them. There is also a call for restructuring the responsibility of medical social work professionals in the context of OHS. Medical social work professional as a counsellor, facilitator, caregiver and researcher can be proved effective in sensitizing about the issue and providing care to healthcare workers in the hospital.

Chandrika (2015) underlined the services which social work professionals provided in the arena of public health, acute and chronic care system. These services were health education, crisis intervention, supportive counselling and case management¹⁷. There is also need of adequate use of social work methods, such as social research, social welfare administration etc. and adequate training²³.

Due to the constraint of time and resources, the researchers were unable to conduct a detailed study on different aspects of OHS within the context of hospital setting. In future, there is a need to carry out a qualitative and in-depth study regarding the relevance of social work skill and techniques in reducing the risk of occupational hazards.

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Ethical Clearance: This is not institutional based study or not belongs/represents to any particular institute. So, the ethical clearance is not applicable.

Conflict of Interest: No conflict of interest.

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A Study of Physical Activity Behaviour During the COVID-19 Pandemic

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Abstract

Background- The COVID-19 restrictions curtailed various physical activities whose effects are unfortunate because daily exercise may help combat the disease by boosting our immune systems and counteracting some of the co-morbidities that make us more susceptible to severe COVID-19 illness. **Objectives-** To study the physical activity behaviour, levels and its relationship with personal variables during COVID 19 lockdown, and to explore the differences between the inactive and active group respondents in terms of physical activity preferences, motivating and restricting factors. **Materials and Methods-** Cross sectional descriptive online survey (google forms) design was used and snowball sampling method was used to reach the respondents. Questionnaire consisted of four parts; 1) Demographics, 2) Occupation, Screen and Sleep behaviour, 3) Physical Activity behaviour, 4) Preferred physical activities, restricting and motivating factors to do any physical activity. To study the TPA OPA, MV-LTPA and HHPA were considered. **Results and Discussion-** A total of 400 respondents (male 56.2, female 43.2%) were eligible for the analysis, majority (93.6%) of them were young adults (18-38) involved in sedentary to light occupation (95.3%). Sedentary behavior in occupation was doubled (80%) as compared to pre COVID situation (42.5%). Majority of the respondents reported an increase in screen and sleep time. On calculating TPA ~33% of the respondents were found in each group; inactive, active and very active. Majority of them were performing pa for <150m/w in each domain i.e. OPA, MV-LTPA and HHPA. Significant difference was found between male and female, of all the three domains, in their physical activity group whereas no significant difference was found in their TPA group. Significant association was found between physical activity groups in terms of considering physical activity benefits, change in post COVID physical activity, and their self reported type of physical activity. Significant association was found between male and female respondents in terms of their BMI and perceived Body weight whereas no association was found between physical activity groups in terms of their BMI and body weight perception. Family/friends and health benefits were the most motivating factors for the majority of respondents whereas social distancing norms and lack of motivation were reported as restricting factors in doing physical activity. **Conclusion-** It can be concluded that physical activity among people was low even before the COVID-19 pandemic, this pandemic acted as a catalyst in promoting sedentary behavior.

Keywords: Physical activity, Physical health, COVID-19

Introduction

We are living in an unprecedented difficult time created by the COVID-19 pandemic throughout the

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world. The virus, which originated as an unexplained case of pneumonia in Wuhan China, was officially designated as COVID-19 by the World Health Organization¹. The highly contagious nature of the virus forced the governments of most of the countries to take extreme steps of announcing complete lockdown with different levels of restrictions. The lockdown brought India to a standstill as people were asked not to step out from their homes, all the transport services rail, road and air, were

suspended, educational institutions, places of recreation (swimming pools, gymnasiums, theatres, entertainment parks, bars, auditoriums and assembly halls) and gatherings of any kind were totally prohibited from March 25th 2020 to 14th April 2020 which was further extended till 3rd May 2020. Only essential services like Banks, grocery, medical, media, telecommunication, etc. were permitted. Later on it was extended in phases with certain relaxations in every successive phase². The total lockdown from March 25th to 3rd May, 2020 posed serious challenges of survival to many and issues of mental and physical health to almost everyone. Although lockdown 2.0 and 3.0 gave some relaxations but till 31st May no significant change was seen in the mobility of people³. The public health recommendations (i.e., stay-at-home orders, closures of parks, gymnasiums, and fitness centres etc.) to prevent SARS-CoV-2 spread have the potential to reduce daily physical activity (PA). These recommendations are unfortunate because daily exercise may help combat the disease by boosting our immune systems and counteracting some of the comorbidities like obesity, diabetes, hypertension, and serious heart conditions that make us more susceptible to severe COVID-19 illness. As this virus strain is novel to the human immune system, we are dependent on aspects of our innate immunity to deal with the initial infection⁴. Till date, no data is available whether the level of physical fitness affects the progress of SARS-CoCV-2 infections. However, it is well documented that regular exercise induced-adaptations enhance the effectiveness of the immune system⁵. In a time when vaccination for SARS-CoCV-2 infection is unavailable one feasible alternate option is to increase the effectiveness of the immune system⁶.

Stressing the importance of physical activity, especially during the COVID-19 pandemic, WHO re-emphasized guidelines of global recommendations on physical activity for health specifying time duration for doing various kinds of physical activities by different age groups (6-65 yrs). According to the recommendation adults of age group 18-64 should do at least 150 minutes of moderate-intensity physical activity throughout the week, or do at least 75 minutes of vigorous-intensity physical activity throughout the week, or an equivalent combination of moderate- and vigorous-intensity activity. For additional health benefits, adults should increase their moderate-intensity physical activity to 300

minutes per week, or equivalent. Muscle-strengthening activities should be done involving major muscle groups on 2 or more days a week⁷. During the pre COVID times, WHO found that globally, 1 in 4 adults is not active enough⁸. Various studies^{9,10,11} have shown that at least 60% immigrant South Asians of Canada, UK and US are comparatively inactive than the native white population. While in South Asia itself more than 75% respondents were found inactive in their leisure time¹². Even in India in a study conducted by Indian Council of Medical Research-India Diabetes¹³ it was found that more than 50% respondents were inactive while 31.9% were active and only 13.7% were highly active. In a study conducted by Kantar IMRB (2018) it was found that in the last one year one third of the respondents had not done any physical activity and also that they considered lack of time as the major constraint for the same¹⁴. Several studies^{6,15,16,17} have supported the theory that physical activity boosts our immune system, so it becomes imperative to study the physical activity behaviour of people especially during such a pandemic. Although several studies have been conducted with respect to lockdown and its impact on mental health, physical health has not been a much discussed issue in Indian context. In order to fill that gap this study is an attempt to study the physical activity behaviour of people and various factors affecting it during this pandemic. Objectives of the study were to study the physical activity behaviour, levels and its relationship with personal variables during COVID 19 lockdown, and to explore the differences between the inactive and active group respondents in terms of physical activity preferences, motivating and restricting factors.

Materials and Methods

Sample and design: Cross sectional descriptive online survey design was used in the study. Data was collected using Google forms. Snowball sampling method was used to reach the respondents as both the researchers of this study circulated the questionnaire through their social media platforms (whatsapp, facebook, emails, etc) requesting everyone to circulate it further. While selecting the responses for analysis age of the respondents (above 18 yrs) their literacy level (middle school and above) and nationality (Indian) were considered. Considering these three criteria out of 434 responses 400 responses were finally selected for

analysis.

Measures: The survey link was circulated between 1st June 2020 and 30th June 2020. It consisted of four parts; 1) Demographics, 2) Occupation, Screen and Sleep behaviour, 3) Physical Activity behaviour, 4) Preferred physical activities, restricting and motivating factors to do any physical activity.

Physical activity: Physical activity is defined as any bodily movement produced by skeletal muscles that require energy expenditure. Popular ways to be active are through walking, cycling, sports and recreation, and can be done at any level of skill and for enjoyment (WHO,2018).

All the physical activities were self reported by the respondents and to calculate the total physical activity (TPA) self reported occupational physical activity (OPA), household physical activity (HHPA) and leisure time physical activity (LTPA) were considered. Total physical activity (TPA) minutes were calculated as sum of OPA {Moderate/2*vigorous OPA min/week}, MV-LTPA {moderate physical activities min/week+ 2*(vigorous physical activities) min/week} and household physical activities min/week.

OPA was measured by questioning respondents about their occupational physical activity type i.e sedentary (mostly sitting)/light (sit and stand)/ moderate (mostly walking)/vigorous (carrying heavy loads) during COVID 19 lockdown and if they were involved in moderate/vigorous OPA then its duration in minutes/week was asked. LTPA was measured by questioning respondents about their involvement, in minutes per week, in moderate physical activities such as yoga, dance, brisk walk, bicycling, games etc. and also in vigorous physical activities such as weight training, aerobic exercise, running/jogging etc. HHPA was measured by questioning respondents about their involvement, minutes per week, in household chores such as mopping/sweeping/cleaning/cooking etc.

Respondents who reported TPA for less than 150 mins/week were considered to be inactive. Similarly, people who reported at least 150 mins/week of TPA were considered to be active. Active category was further categorized into two parts i) moderately active, performing TPA for 150-300 mins/week, ii) very active,

performing TPA for >300 mins/week.

Statistical Analysis

Descriptive information including demographic characteristics of the respondents, occupational, screen time and sleep behaviour during COVID-19 lockdown, physical activity levels (inactive, moderately active, very active) in different domains were summarized and split by sex only, whereas BMI and physical activity behaviour of the respondents were split by sex and physical activity level. Data was reported as means+SD for continuous variables and as frequency and percentages for categorical variables. Independent sample t test/one way ANOVA and chi square test were used to assess the difference between male and female respondents for both continuous and categorical variables. Preference of leisure time physical activities (LTPA) and motivating and restricting factors in doing physical activity were analysed and on this basis the respondents were split into active (>150 min/week) and inactive (<150 min/week) groups. Comparative analysis was done using chi square tests and frequency and percentages were calculated to see differences between active and inactive groups. All statistical tests were performed using IBM SPSS Statistics 21 and significance was set at $p < 0.05$.

Results

The result has been discussed under four categories: 1) Demographics, 2) Occupation, Screen and Sleep behaviour, 3) Physical Activity behaviour, 4) Preferred physical activities, restricting and motivating factors to do any physical activity. Each category deals with a different aspect of this study.

1.Demographics

A total of 400 respondents (male 56.2%, female 43.2%) were selected for the analysis. Majority of the respondents (93.6%) were between the age group of 18-38 years (mean age 28.4 + 7.3) and were unmarried (67.2%) with education level of graduation and above (91.5%). Most of the respondents (87.2%) were Hindu. Majority of the respondents were involved in light occupation (52.8%) followed by sedentary occupation (42.5%) while only 4.2% were involved in moderate occupation¹⁸. In order to categorize the location of the respondents all the Indian states were divided into five zones viz. North, South, East, West and Central. It

was found that half of the respondents were from the Northern zone (49.8%) followed by eastern (28.9%) and few were from Southern (8.7%), Western (8.5%) and Central zone (4.8%). Age, occupation and religion were significantly associated with sex ($p < 0.05$) whereas education, monthly family income, marital status and location were independent of sex ($p > 0.05$).

2. Occupation, Screen and Sleep behaviour

Table 1 summarizes the occupational, screen and sleep time behavior of respondents, during the COVID19 lockdown, split by sex. Among the working respondents (n=309), a significant difference was found between male (n=178) and female (n=131) in their mode of working as well as in their OPA during COVID 19 lockdown. Out of working respondents half of them were working from home, 25% were working with following social distancing norms and only 15%

were working as before. During COVID 19 lockdown sedentary behavior in occupation was doubled (80%) as compared to the pre COVID situation (42.5% from Table 1). While working from home 30% of the working respondents took not so frequent breaks and most of them were female (43.1% vs. 19.8%). Average total screen time was 9.2 ± 3.6 hours/day work related average screen time was 5.9 ± 3.4 hours/day and recreational average screen time was 3.4 ± 3.5 hours/day. An increase in screen time, during the lockdown, was mentioned by majority of the respondents (53.5%) and this increase was slightly more in female respondents (58.4%) than in male respondents (49.8%). Sleeping hours of ~40% respondents had increased during the lockdown while it remained the same for 45.8% and decreased for ~15% of the respondents. There was no significant difference found between male and female respondents in terms of their sleeping hours, total screen time or change in screen time.

Table 1: Occupational, screen and sleep time behavior during COVID 19 lockdown

Factors	Total	Male	Female	p-Value
Current working situation				
Not Working	91 (22.8)	49 (21.6)	42 (24.3)	
Working	309 (77.2)	178 (57.6)	131 (42.4)	<.001*
Working as before	46 (15)	26 (14.6)	20 (15.3)	
Working from home	156 (50)	91 (51)	65 (49.6)	
Working with following social distancing norms	77 (25)	55 (31)	22 (16.8)	
Household Chores	30 (10)	6 (3.4)	24 (18.3)	
Occupational PA during COVID				
Sedentary	324 (81)	183 (80.6)	141 (81.5)	<.001*
Light	63 (15.7)	33 (14.5)	30 (17.3)	
Moderate	13 (3.3)	11 (4.8)	2 (1.2)	
Frequency of breaks while working from home				
Total	156	91	65	
Every 30 min	17 (10.9)	11 (12)	6 (9.2)	.047
Every hour	38 (24.4)	23 (25.3)	15 (23)	
Every 2 hour	40 (25.6)	29 (40)	11 (17)	
Every 4 hour	7 (4.5)	5 (5.5)	2 (3.1)	
Not so frequent	46 (29.5)	18 (19.8)	28 (43.1)	
Not applicable	8 (5.1)	5 (5.5)	3 (4.6)	
Work related screen time(0-16)	5.9 ± 3.4	6.2 ± 3.4	5.6 ± 3.4	.079^

Cont... Table 1: Occupational, screen and sleep time behavior during COVID 19 lockdown

0	24 (6)	13 (5.7)	11 (6.3)	
1-4	119 (29.8)	60 (26.4)	59 (34.1)	
5-8	169 (42.2)	98 (43.2)	71 (41.0)	
9-12	82 (20.5)	54 (23.8)	28 (16.2)	
>12	6 (1.5)	2 (0.9)	4 (2.3)	
Recreational screen time (0-16)	3.4+3.5	3.2+2.3	3.6+2.3	.114 [^]
0	8 (2)	5 (2.2)	3 (1.7)	
1-4	302 (75.5)	182 (80.2)	120 (69.4)	
5-8	74 (18.5)	33 (14.5)	41 (23.7)	
9-12	12 (3)	5 (2.2)	7 (4.0)	
>12	4 (1)	2 (0.9)	2 (1.1)	
Total screen time (0-18)	9.2+3.6	9.3+3.6	9.1+3.6	.565 [^]
0-4	42 (10.5)	24 (10.6)	18 (10.4)	
5-8	136 (34)	69 (30.4)	67 (38.7)	
9-12	147 (36.8)	94 (41.4)	53 (30.6)	
>12	75 (18.8)	40 (17.6)	35 (20.2)	
Change in screen time				
Increased	214 (53.5)	113 (49.8)	101 (58.4)	.071
Decreased	40 (10)	28 (12.3)	12 (7)	
Remained same	146 (36.5)	86 (37.9)	60 (34.6)	
Sleeping hours during covid				
Increased	158 (39.5)	87 (38.3)	71 (41.0)	.258
Decreased	59 (14.8)	29 (12.8)	30 (17.3)	
Remained Same	183 (45.8)	111 (48.9)	72 (41.6)	

The p-values represent chi-square tests of independence indicating associations between sex and categorical variables,

[^]t test was computed for various screen time variable, unit for screen time was hours/day

*represents significant association/difference between categorical variables and sex

3. Physical Activity behaviour

Table 2 shows the physical activity levels in three domains i.e. OPA, MV-LTPA and HHPA as well as its total, all split by sex. During COVID-19 lockdown only 3.3% (Table 1) respondents were involved in moderate

OPA that too for <150min/week. Total Physical activity score was independent of sex whereas OPA, MV-LTPA and HHPA were having significant association with sex. Majority of the respondents were doing OPA (100%), MV-LTPA (58%) and HHPA (80%) for <150min/week and thus were called inactive in respective domains. In the present study, on considering domain-wise, more male respondents (51%) were participating in MV-LTPA for >150min/week than female respondents (30%) whereas the case was reversed for HHPA. In terms of TPA almost 1/3rd of the respondents were in each group (Inactive 34%, MA 33.5%, vs 32.5%). However, the percentage of male respondents was slightly higher in the very active group (>300min/week).

Table 2 Physical activity levels in different domains split by sex

Domain/ Activity levels	Inactive	Active		p-Value
	IA (<150) N (%)	MA (150-300) N (%)	VA (>300) N (%)	
OPA (400)	400 (100)	0	0	<.001*
Male (227)	227	0	0	
Female (173)	113	0	0	
MV-LTPA (400)	232 (58)	103 (25.8)	65 (16.2)	<.001*
Male (227)	111 (48.9)	63 (27.8)	53 (23.3)	
Female (173)	121 (70.0)	40 (23.1)	12 (6.9)	
HHPA (400)	320 (80)	72 (18)	8 (2)	<.001*
Male(227)	193 (85.0)	31 (13.6)	3 (1.3)	
Female (173)	127 (73.4)	41 (23.7)	5 (3)	
TPA (OPA+MV-LTPA+HHPA)	136 (34)	134 (33.5)	130(32.5)	.078
Male (227)	70 (30.8)	73 (32.2)	84 (37.0)	
Female (173)	66 (38.1)	61 (35.3)	46 (26.6)	

*The p-values represent chi-square tests of independence indicating associations between sex and categorical variables

Table 3 shows BMI, perceived body weight and physical activity behavior of the respondents split by sex and physical activity level. Physical activity level has been categorized as Inactive, Moderately Active and Very Active. Although no significant difference was seen in the physical activity levels in terms of BMI and perceived body weight there was a significant difference in BMI and perceived body weight of male and female respondents. Higher percentage of female respondents perceived themselves as overweight than they actually were (41% vs 22.5%) whereas a lesser number of male perceived themselves as overweight than they actually were (26% vs. 34.4%). However, more number of male

perceived themselves as underweight than they actually were (7.5% vs 2.6%) while lesser females perceived themselves as underweight than they actually were (9.2% vs 15.6%) as per their BMI. No significant difference was seen either between male and female respondents or physical activity levels in terms of change in leisure time physical activity (LTPA) and with whom they were staying. Increase in LTPA was seen sex-wise as well as across the groups i.e. inactive, moderately active, and very active. Highest increase in LTPA was among the respondents of the very active group (56.9%) followed by moderately active group (48.5%) and lowest increase (39%) among the respondents of inactive group. In terms of considering the benefits of physical activities sex-wise

no significant difference was seen whereas, significant difference was seen among the groups (IA, MA, VA) for the same. Higher percentage of active group respondents (65% MA, 68.5% VA) considered PA as beneficial (very to extremely) than inactive group respondents (41.2%). Sex-wise no significant difference was seen in terms of changing their physical activity behavior in post lockdown times whereas physical activity level wise a significant difference was seen. Physical activity level wise, more than 50% respondents of each group tend to

increase their PA in post COVID lockdown times. Sex-wise as well as physical activity level wise a significant difference was seen in type of physical activity that the respondents were doing. More male (33.5%) than female (19.6%) respondents accepted doing moderate to vigorous physical activity (MVPA). It was found that the majority of the active group respondents (MA 55.2%, VA 44.6%) preferred moderate physical activity whereas majority of inactive group respondents (44.8%) preferred light physical activity.

Table 3 BMI and Physical activity behavior split by and sex and physical activity levels

	Male N (%)	Female N (%)	p-Value	IA (<150) N (%)	MA (150- 300) N (%)	VA (>300) N (%)	p-Value
Total	227(56.7)	173(43.3)		134(33.5)	136 (34)	130(32.5)	
^BMI	24.5+3.9	22.4+3.6	<.001*	23.5+3.7	23.9+4.8	23.3+3.2	.551
Underweight (<18.5)	6 (2.6)	27 (15.6)		8 (5.9)	14 (10.4)	11 (8.5)	
Normal (18.5-24.9)	143 (63)	107 (61.8)		90 (66.2)	73 (54.5)	87 (66.9)	
Overweight (>25)	78 (34.4)	39 (22.5)		38 (30)	47 (35.1)	32 (24.6)	
Body weight perception							
Underweight	17 (7.5)	16 (9.2)	.003*	11 (8.1)	9 (6.7)	13 (10)	.120
Normal	151 (66.5)	86 (49.7)		78 (57.4)	73 (54.5)	86 (66.2)	
Overweight	59 (26)	71 (41.0)		47 (34.5)	52 (38.8)	31 (23.8)	

Cont... Table 3 BMI and Physical activity behavior split by and sex and physical activity levels

Change in LTPA							
Increased	100 (44)	92 (53.2)	.121	53 (39)	65 (48.5)	74 (56.9)	.055
Decreased	68 (30)	49 (28.3)		47 (34.5)	41 (30.6)	29 (22.3)	
No change	59 (26)	32 (18.5)		36 (26.5)	28 (20.9)	27 (20.7)	
PA beneficial							
Not beneficial	29 (12.8)	27 (15.6)	.564	35 (25.7)	8 (6)	13 (10)	<.001*
Slightly beneficial	59 (26)	52 (30.1)		45 (33.1)	38 (28.3)	28 (21.5)	
Very beneficial	86 (37.9)	60 (34.7)		40 (29.4)	56 (41.8)	50 (38.5)	
Extremely beneficial	53 (23.3)	34 (19.6)		16 (11.8)	32 (23.9)	39 (30)	
Change in post COVID PA							
Will increase	139 (61.2)	97 (56.1)	.327	86 (63.2)	82 (61.2)	68 (52.3)	<.001*
Decrease	7 (3.1)	2 (1.1)		3 (2.2)	4 (3)	2 (1.5)	
Continue with same	61 (26.8)	54 (31.2)		27 (19.9)	33 (24.6)	55 (42.3)	
No thoughts	20 (8.8)	20 (11.6)		20 (14.7)	15 (11.2)	5 (3.8)	
Self reported type of physical activity doing							
Light (106)	47 (20.7)	59 (34.1)	<.001*	61 (44.8)	29 (21.6)	16 (12.3)	<.001*
Moderate (184)	104 (45.8)	80 (46.2)		52 (38.2)	74 (55.2)	58 (44.6)	
MVPA110	76 (33.5)	34 (19.6)		25 (18.4)	29 (21.6)	56 (43.1)	

Cont... Table 3 BMI and Physical activity behavior split by and sex and physical activity levels

Staying with							
Family	175 (77.1)	143 (82.6)	.127	112(82.4)	102 (76.1)	104 (80)	.486
Friends	17 (7.5)	15 (8.7)		12 (8.8)	12 (8.9)	8 (6.1)	
Alone	35 (15.4)	15 (8.7)		12 (8.8)	20 (14.9)	18 (13.8)	

The p-values represent chi-square tests of independence indicating associations between sex and categorical variables, and physical activity levels and categorical variables

^BMI p values: *t* test was used when split by sex and ANOVA was used when split by physical activity levels

*represents significant association/difference between categorical variables and sex and physical activity levels

4. Preferred physical activities, restricting and motivating factors to do any physical activity

Frequency and percentage of various physical activities done by the respondents of active (>150min/week) and inactive group (<150min/week) was calculated and a significant difference among them was found (p<0.05). Percentage-wise participation in all the physical activities (yoga, dance, brisk walking, playing games, bicycling, weight training, aerobic exercise, running/jogging, household work) was higher for the active group respondents(73.1, 28, 82.2, 35.2, 20.5, 35.2, 66.7, 58.7, 78.4) as compared to the inactive group respondents (52.2, 20.6, 58.8, 17.6, 8.1, 4.4, 33.8, 17.6, 63.5). It is concluded that household work and brisk walk were the top two activities done by both the groups whereas weight training for inactive group (4.4%) and bicycling for active group (20.5%) respondents was reported as the least preferred physical activity.

The motivating (family & friends, online community & videos, health benefits, more free time, government initiatives, nothing and normal routine) and restricting (nothing, COVID 19 social distancing restrictions,

lack of motivation/interest, lack of equipment/space/ instructor and time constraint) factors in doing physical activity were also studied. Family/friends (34.8%) and health benefits (33.3%) followed by their normal routine (29.8%) acted as motivating factors for the respondents to be physically active. Overall (3.8%) as well as across the groups (Inactive 4.4%, active 3.4%) government initiative was reported as the least motivating factor. In terms of motivating factor in doing physical activity a significant difference was found between the active and inactive group (p<0.05). Although family/friends was one of the common motivating factors in both the groups (almost 35%), health benefits played an important role for active group respondents (38.6%) as compared to the inactive group (22.8%). In the active group majority of respondents (93.2%) were motivated by one or other factor to take up any physical activity whereas in the inactive group nothing could motivate its 19.1% of respondents to take up any physical activity during this lockdown.

It was found that 30% of the total respondents reported nothing as the restricting factor in doing physical activity during COVID 19 lockdown. Of the remaining respondents (70%) most of them (33.3%) reported COVID 19 social distancing restriction followed by lack of motivation/interest (29.7%) as the barriers in doing any physical activity. Higher percentage of inactive respondents (34.6%) than active respondents (13.6%) pointed out COVID 19 social distancing restrictions as a barrier in being physically active. However, lack of

motivation had almost equal percentage (~12%) of the respondents in both the groups. There was a significant difference in the active and inactive group's respondents in terms of restricting factors ($p < 0.05$).

Discussion

In the present study majority of the respondents were young adults (18-38yrs). All the respondents were literate and their occupational behaviour varied from sedentary to light. As 75% of the working respondents were working from home their occupational sedentary behaviour has increased, posing a threat to their health. Not only this, increased screen time and sleeping hours along with not so frequent breaks during work has been found leading to an increase in sedentary behaviour which is directly related to various musculoskeletal disorders¹⁹. In the present study only 10.9% of the respondents took a break every 30 min in compliance with WHO guidelines. Similar results were found in the study conducted in Italy as only ~10% of the working respondents took a break every 30 min in compliance with WHO guidelines²⁰. It was found that during COVID 19 lockdown sedentary behaviour in occupation was doubled (80%, Table 1) as compared to pre COVID situation (42.5%). This is an alarming result as studies have shown that lack of OPA can be associated with increase in obesity, larger waist and hip circumference; and poor performance in most of the fitness test²¹. Similar results were found in the Hong Kong study where both the sedentary behaviour and sleep duration increased significantly during COVID 19²². Majority of the respondents were doing OPA (100%), MV-LTPA (58%) and HHPA (80%) for <150min/week and thus were called inactive in respective domains. Earlier studies have shown that among the various domains of physical activity, involvement of people was highest in the occupational physical activity (OPA)¹³. Particularly in developing countries, occupation and transportation activities represent a substantial proportion of an individual's total physical activity²³. But in the present study occupational physical activity and travel is almost negligible and it can't be denied that COVID-19 restrictions might be the reason for it. In the ICMR-INDIAB¹³ study it was found that respondents, who were involved in recreational physical activities (6.2%), were spending less than 20min/day for the same. Results of present study clearly shows that active involvement

of both male and female in the MV-LTPA is low but in comparison to female respondents male respondents are more active in doing MV-LTPA. Several studies^{10,13,24} found similar results which concluded that male were more physically active than females. More female respondents were involved in HHPA for >150min/week than male respondents. Lockdown restrictions might be one of the reasons for low OPA and MV-LTPA so people should indulge themselves more in HHPA to compensate for the loss of physical activity in other two domains. Although 66% respondents of the present study were achieving the goals set by WHO in terms of PA but only 1/3rd of them will reap its health benefits as only they are doing it for >300min/week. In the World Health Survey, conducted almost a decade ago, only 17.7% respondents (19.8% female & 15.2 % male) were found inactive¹². While in a study conducted worldwide in 2012 it was found that 31.1% of adults were physically inactive. In India <19.9% respondents were found to be inactive²⁵. In light of these studies it can be said that inactivity among people has increased over the time.

When body-weight perception was explored it was found that females perceived themselves as overweight even when they were normal as per their BMI whereas this situation was totally reversed for male. This behaviour can be seen among people irrespective of their age group as was seen among adolescent respondents in the study conducted in Thailand²⁴. In present study no significant association was found between respondents BMI as well as perceived body weight to their physical activity level. Almost half of the respondents reported an increase in their LTPA during the COVID-19 lockdown but no significant difference was found between male, female and their physical activity levels in terms of change in their LTPA. This finding is in contradiction to the study conducted in Hong Kong in which majority of the respondents (72.3%) mentioned decrease in their LTPA and only 16.5% mention increase in their LTPA²¹. Whereas Similar results were seen in the Canadian study where physical activities increased more among the active respondents (40.3% vs. 33%) and decreased more among the inactive respondents (40.5% vs. 22.4%)¹⁰. Majority of the respondents tend to increase their LTPA in post COVID-19 times and this percentage was high for the inactive group and male respondents. Major concern drawn from these results is that 20% of the inactive respondents tend to continue with their physical

activity for <150min/week which yields no health benefit. Higher percentage of active group respondents (65% MA, 68.5% VA) considered PA as beneficial (very to extremely) than inactive group respondents (41.2%). However attention needs to be focused on that 25% of inactive respondents who consider physical activity not beneficial at all. Despite the fact that most of the respondents considered PA to be beneficial their involvement in MV-LTPA is quite low and involvement of females in MV-LTPA is even lower than male. Unawareness of benefits of physical activity might be one of the reasons for considering it not beneficial at all and that's why efforts should be made to make people more and more aware about the benefits of physical activity. Both sex wise and physical activity level wise significant difference was found in the self reported type of physical activity. Majority of inactive respondents were involved in self reported light physical activity whereas majority of active respondents were involved in self reported moderate physical activity.

On analyzing the type of physical activity done by the respondents it was found that household work and brisk walk were the top two activities done by both the active and inactive respondents. Walking was also the common physical activity for active and inactive groups among the Canadian respondents and participants of inactive groups were more involved in walking (57.2%) than the active group (19.7%)¹⁰. It was family/friends and health benefits that motivated the respondents of present study to involve in physical activity. It was social distancing norms and lack of motivation that acted as a barrier for respondents in doing physical activity. Similar results i.e. lack of motivation and lack of time were reported as the two most common barriers in doing physical activity by the adults of Barranquilla, Colombia²⁰.

Conclusion

It can be concluded that physical activity among people was low even before the COVID-19 pandemic, this pandemic acted as a catalyst in promoting sedentary behaviour. Both the sexes are ignoring their physical health but this ignorance is higher among females. They need to be made aware about the benefits of physical health which will act as an intrinsic motivation. Government needs to intervene extensively in promoting physical health especially in times of such pandemic which will

have long lasting effects on behaviour of people. As we can see that as far as possible work from home culture is being promoted due to this pandemic. In such scenarios the onus of keeping themselves physically active lies mostly with the people. Those who are not following the guidelines of WHO on physical activity needs to take it seriously and should involve themselves in LTPA at least as per the norms. People need to control their prolonged sedentary behaviour specifically screen time as it will have a long lasting ill-effect on our physical as well as mental health. We have seen studies which reflected that physical health and mental health are intertwined. So, it becomes a prerequisite for people to be physically fit in order to survive during and also after this pandemic.

Ethical Clearance: The authors declare that the study has been conducted following all the research ethics. Consent of respondents to participate in the study was taken.

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Occupational Health and Safety of Health Care Professionals During Pandemic COVID-19

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Abstract

The study is based on online survey, including the occupational health and safety of health care professionals. The study was conducted in the tertiary health care centres of Chandigarh (UT), India by applying snowball sampling technique. There were 69 health care professional included from different occupational category, i.e. medical staff, paramedical staff, nursing staff and helpers. The study was conducted to underline the different components of occupational health and safety during Covid-19 pandemic. Another scenario of study was to discuss various view points of healthcare professionals on epidemic.

Keywords: COVID-19, Healthcare professionals, Occupational Health, Prevention, Safety.

Introduction

Since ancient times, human civilization has been a victim of various types of ‘Pandemics’ in which millions of the population have lost their lives and money in different countries within few months or years. There is a mention of numerous ‘Pandemics’ in the history. *Prehistoric epidemic: Circa 3000 B.C., Plague of Athens: 430 B.C., the Black Death: 1346-1353, Cocoliztli epidemic: 1545-1548, Great Plague of London: 1665-1666, Philadelphia yellow fever epidemic: 1793, Flu pandemic: 1889-1890, American polio epidemic: 1916, AIDS epidemic: 1981-present day, H1N1 Swine Flu pandemic: 2009-2010, West African Ebola epidemic: 2014-2016 and Zika Virus epidemic: 2015-present day* and so on are some epitome of a pandemic ¹.

The contemporary world confronts with a novel pandemic ‘Corona-virus disease 2019 (COVID-19)’ which is caused by the virus named ‘Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)’.

As a matter of fact, the corona-virus is not a new virus and it belongs to the family of ‘Coronaviridae’ which can infect both animal and human being. The symptom for COVID-19 is considered in the range from mild (dry cough, sore throat and fever) to severe (organ failure, septic shock, pulmonary edema, severe pneumonia and acute respiratory distress syndrome). COVID-19 disease is considered more dangerous for elderly people, infants or small children, pregnant ladies and people with weak immunity or any medical condition, such as diabetes, hypertension, cardiovascular disease and any other chronic or respiratory disease²⁻⁴. The first case of COVID-19 is reported in the Wuhan City, China in the month of December 2019². The COVID-19 has the capacity to transmit in a community through a personal contact with a person or object infected with the coronavirus^{4,5}.

Despite of the developed economy and sufficient healthcare facilities, more or less 216 countries encounter health, social and economic crisis with the outbreak of COVID-19 which requires urgent political responses⁶. The government of Italy, China and other countries have adopted the ‘national lockdown’ to prevent the spread of COVID-19. Restriction on transportation or mobility, massive quarantine, public health measures,

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tourism, public gathering and other economic activities like constraint on retail, trade fairs, event cancellation, etc. is disrupting the production, global supply chain, consumption and stock market⁷⁻⁸. This has created numerous economic and social problems for people and country for example, loss of job by five (5) million people in China, production of car suspended in Europe, poor performance of stock market in the UK and German, expected 3% decrease in the GDP of US etc⁸. Along with the social and economic crisis, mortality and morbidity due to COVID-19 become a global concern that requires the collaboration among government of different countries and between countries and International agencies like WHO, OCHA (United Nations Office for the Coordination of Humanitarian Affairs), World Bank, etc².

According to World Health Organization (WHO, 2020), a total number of 6,194,533 COVID-19 cases were confirmed, including 376,320 deaths worldwide (till 4th June 2020)⁶. According to Ministry of Health

and Family Welfare (2020), India stood seventh (7th) in ranking among highest confirmed cases countries with 207,615 number of cases and 5,815 deaths recorded till 4th June 2020. Approximately 294 cases of COVID-19 were confirmed in Chandigarh, including about 82 active cases, 214 cured/discharged/migrated cases and 5 deaths (till 4th June 2020)⁹.

A total of 6,520,011 confirmed cases of COVID-19 were recorded worldwide, including 384,861 deaths and 3,102,908 recovered cases. About 4,427,362 cases of COVID-19 and 269,834 deaths were confirmed only in top ten (10) infected countries out of them. Approximately 67.90% of globally confirmed cases and 70.11% worldwide deaths were recorded in top ranked ten countries (**Table 1**)¹⁰. WHO (2020) considered the outbreak as the Public Health Emergency of International Concern on 30th January 2020 and suggested measures to interrupt the spread of COVID-19 pandemic. These measures were early detection, treating cases, isolation, contact tracing and social distancing². **Table 1: Top 10 countries with maximum COVID-19 infected cases**

Table 1: Source: https://www.worldometers.info/coronavirus/?utm_campaign=homeAdvegas1?¹⁰					
Top 10 countries with corona infected cases (till 11:55 pm IST, 4th June 2020)					
Sr. No	Countries	Number of Confirmed Cases	Number of Deaths	Number of testing done	Total Population of Countries
1	USA	1,890,947	108,599	18,874,077	330,854,064
2	Brazil	560,737	31,417	930,013	212,442,762
3	Russia	432,277	5,215	11,426,045	145,929,848
4	Spain	287,406	27,128	4,063,843	46,753,443
5	UK	279,856	39,728	4,786,219	67,858,826
6	Italy	233,836	33,601	3,999,591	60,468,295
7	India	216,769	6,088	4,103,233	1,378,937,377
8	Germany	184,228	8,682	4,348,880	83,763,806
9	Peru	174,884	4,767	1,092,646	32,934,728
10	Turkey	166,422	4,609	2,155,349	84,267,248
Total		4,427,362	269,834	55,779,896	2,444,210,397

**Data taken on above mentioned time & date, as the data is changing every day so it may vary accordingly with the increase in number of cases*

In the absence of a vaccine and optimum treatment for COVID-19, the focus is given on the symptomatic treatment to manage the symptom of the COVID-19 infected patients^{3, 11}. Clinical trials are still going on in the development of vaccine for treating COVID-19. This creates a burden of providing treatment to patients infected with COVID-19 and having an adverse effect on healthcare professionals in the global healthcare system¹². They are at the risk of exposing hazards, such as pathogen exposure, long working hours, psychological distress, fatigue, occupational burnout, stigma, and physical and psychological violence¹³. There is also a risk of transmission the infection to the family members of healthcare professionals¹². The first case of infection in healthcare professional was reported in 20th January 2020 while providing care to COVID-19 patients¹⁴.

WHO (2020) considers measures to reduce the risk of infection or hazard exposure among healthcare professionals. Measures like an adequate supply of personal protective equipment (PPE) or other required items for sanitation, screening and treatment of patients; cooperation between management and health workers; compensation, rehabilitation, and curative services; access to mental health and counselling services etc. are considered. Healthcare professionals should follow the protocol of safety while treating patients infected with COVID-19 in the environment of dignity and respect¹².

Literature Review: WHO (2020) gives priority to the safety of health workers during the outbreak of COVID-19. The ‘occupational health’ services play a vital role in the protection of health workers from occupational hazards which ensure the continuity of healthcare services¹⁵. The ‘Occupational Health and Safety (OHS)’ is a sub-discipline of occupational medicine, which has a motive to sustain the mental, physical and social wellbeing of a worker¹⁶. WHO (2001) defined the ‘Occupational Health and Safety’ (OHS) as an interdisciplinary activity to reduce occupational diseases or injuries and promote health and safety among workers through risk identification and preventives measures¹⁷. On the occasion of the ‘World Day for Safety and Health at Work’ on 28 April, International Labour Organization (ILO, 2020) addresses the need of preventing occupational accidents and disease at workplaces globally during the pandemic COVID-19¹⁸. Emergency response workers provide essential services

which are necessary for the health, safety, and welfare of the community as a frontline response for the outbreak. These workers are healthcare workers, police officers, civil protection personnel, military personnel, and other workers in the area like transportation, fire, electricity, water supply, food, banking, telecommunication, marine services, and administration during an emergency situation¹⁹.

Healthcare professionals, such as doctors, nurses, paramedics and support staff consider as a frontline to provide treatment and care to COVID-19 infected patients in the response of the outbreak of COVID-19¹³. Approximately 12% of the global working population was represented in the domain of healthcare workforce²⁰. Healthcare workers function as a multidisciplinary team to ensure equity in the treatment of patients²¹. Nearly 5.6 million healthcare workers are vulnerable to the exposure with disease and injury related to occupation²². The occupational disease or injury can be spread among healthcare workers through five routes, such as blood borne (HIV, Hepatitis B and C), droplet (Influenza), airborne (Chickenpox and Tuberculosis), fecal-oral (Rotavirus) and contact route (Scabies, Herpes simplex virus 1 or 2)²³. More than 890 healthcare workers were infected during the outbreak of Ebola virus among the general public from 2013-2016²⁴⁻²⁵.

According to WHO (2020), more or less 35,000 healthcare professionals were infected with corona virus during the outbreak of pandemic COVID-19 (as on 21 April 2020). This number may be larger than the reported cases because of underreporting²⁶. According to International Council of Nurses (2020), more or less 90,000 healthcare workers reported to be infected with COVID-19 and more than 260 nurses died due to COVID-19²⁷. Between 8% and 38% of healthcare professionals suffer physical and verbal violence as well as social stigma due to their work. Apart from these hazards, they also confront psychosocial hazards, such as fatigue, occupational burnout, distress or declining mental health which affect their health and quality of work. Delay in recognition or suspicion of COVID-19 in patients, working in risky environment, long duty hours and sub-optimal adherence to preventive measures (hand hygiene practices and improper use of PPE) are some of the identified occupational risks for COVID-19 infection among health workers. There are others factors

also, such as insufficient training, inadequate supply of PPE, long exposure with COVID-19 infected patients, shortage of staff and resources²⁶.

Subramanian et al. (2017) discussed the reasons for occupational disease and injury among healthcare workers, such as lack of experience, lack of awareness and ignorance about polices. Constant awareness activities could promote protective measures among healthcare workers against infection or injury²⁸. Ngatu et al. (2017) underscored the requirement of strengthening the health care system and advancing the occupational safety equipments in health setting²⁵. Auta et al. (2017) also emphasized the shortage of staff and the requirement of training among healthcare workers to promote OHS²⁴. In the context of COVID-19, various strategies are underlined to reduce the risk of occupational exposure among healthcare workers. These are an identification of high risk activities, training, precaution, efficient disposal system, and management of occupational exposed healthcare workers and the service of counselling²⁶. WHO (2020) has a concern to supply adequate PPE or other materials, provide training, availability of sufficient human resources, employment injury benefits (compensation, rehabilitation, and curative services), access mental health services and psychosocial support for health workers^{9,11}.

The present study aimed at describing the 'Occupational Health and Safety' in healthcare setting and at outlining the viewpoints of healthcare professionals on different concerns related with pandemic during the outburst COVID-19.

Method and Material

The study adopted the cross sectional and descriptive research design. In this study, an online survey was conducted in order to avoid the risk of spreading the infection during COVID-19. The participants of the study were healthcare professional in the tertiary healthcare centres of Chandigarh (UT), India. A questionnaire was developed with the help of Google form which comprised of both open ended and closed ended set of questions. Using a snowball sampling technique (non-probability sampling), the questionnaires were sent and study conducted via E-mail, social media and telephonic interviews. The duration of data collection was 10 day from 18th May 2020 at 12 noon (IST) and closed on

27th May 2020 at 12 noon (IST). Out of 107 healthcare professionals, the 69 (64.5%) participants gave their consent and participated in the study.

The questionnaire comprised of three sections: The *first section* delineated the socio-demographical profile of the participants. The *second section* encompassed the existing circumstances in the healthcare setting and described the exposure of occupational hazards that healthcare professionals confronted due to the outbreaks of COVID-19. The *third section* illustrated the viewpoint of healthcare professionals towards different aspects of the pandemic COVID-19.

After the collection of data, the Ms-excel sheet was used for data recording and coding. The sheet imported to the platform of IBM SPSS (Statistical Package for Social Sciences) version 20, employing T-test, Karl Pearson's correlation and Spearman's correlation, Reliability test, Cronbach's Alpha test. The confidence interval was 95% included and less than 5% was considered statistically significant. The format of 5-point Likert scale was used to describe Opinion {ranging from Strongly Disagree (1) to Strongly Agree (5)} and Level of satisfaction of participants on different components of COVID-19 {ranging from and Strongly Dissatisfy (1) to Strongly Satisfy (5)}. The data were computed using descriptive statistical analysis, such as measures of central tendency (mean, median and mode), dispersion measures (standard error and standard deviation) and association measures (correlation). Percentages, frequency tables, cross tabulation and a discussion as another example of descriptive analysis was also applied to encapsulate and display the data.

Results and Discussion

The study was conducted among n=69 (100%) health care professionals, 30 (43.5%) Male and 39 (56.5%) Female ($Mean=1.57$ $SD=0.499$, $SE\ mean=0.060$, $T=26.037$ $Skewness=1.060$, $SE\ Skewness=0.289$). There were 24 (34.8%) medical staff, 33 (47.9%) para-medical staff, 05 (7.2%) nursing staff and 07 (10.1%) helpers of tertiary care setting of Chandigarh ($Mean=1.93$, $SD=0.913$, $SE\ mean=0.110$, $T=17.544$). Among them 45 (65.2%) were post-graduates, followed by 15 (21.7%) graduates, 08 (11.6%) had secondary level education and only 01 (1.4%) was Ph.D. degree holder, ($Mean=2.57$, $SD=0.717$, $SE\ mean=0.086$,

$T=29.719$). The mean age was 35.13, Median=32 Mode=30, $SD=8.992$, $SE\ mean=1.082$, $T=32.454$, and the maximum respondents were belonged to 30-34 years of age category i.e. 23 (33.3%), followed by 17 (24.6%) were 25-29 years of age group, 10 (14.5%) were 35-39 years of age group, 06 (8.7%) were 50-54 years of age group, 03 (4.3%) were above 55 years 02 (2.9%) were ≤ 24 years and 08 (11.6%) were from 40 to 49 years of age group respectively. The results calculated statistically and it was significant $P\ value \leq 0.05$.

WHO (2020) considered the consistent and correct practice of hand hygiene, sanitation, cleaning surfaces and proper bio-waste management as an essential practice to prevent the spread of corona virus among healthcare professionals, patients and their caregivers in the health setting²⁹. Correspondingly, this study also found significant changes in the hospital, particularly in hygiene and sanitation practices during the outburst of COVID 19. The more focus was emphasised on the sanitization practice in the hospital premises. Out of total 249 multiple response sets, the 56 participants {20 (8%) medical staff, 25 (10%) para-medical staff, 04 (1.6%) nursing staff and 07 (2.8%) helpers, $SD=0.394$ } responded to this. The 64 participants {24 (9.6%) medical staff, 29 (11.6%) para-medical staff, 05 (2%) nursing staff and 06 (2.4%) helpers, $SD=0.261$ } observed the second change in the hospital staff i.e. they were more inclined towards personal hygiene practice. The 51 participants {17(6.8%) medical staff, 25 (10%) para-medical staff, 04 (1.6%) nursing staff and 05 (2%) helpers, $SD=0.442$ } observed the change in the habit of cleaning their accessories for e.g. cell phone, pen, watch, keys, glasses, etc., among the hospital staff. The 38 participants {11(4.4%) medical staff, 19 (7.6%) para-medical staff, 04 (1.6%) nursing staff and 04 (1.6%) helpers, $SD=0.501$ } observed the reduction in the habit of spitting here and there by patients inside and outside the hospital premises. The 33 participants {12 (4.8%) medical staff, 14 (5.6%) para-medical staff, 03 (1.2%) nursing staff and 04 (1.6%) helpers, $SD=0.503$ } observed the habit of changing the clothes frequently after going back to home from duty. The 07 participants {01(0.4%) medical staff, 05 (2%) para-medical staff and 01(0.4%) helpers, $SD=0.304$ } observed that people following the social distancing, avoiding crowded places, wearing a masks at public places and even also following at workplaces. While checking the reliability

of responses it was statistically significant, the $P\ value \leq 0.05$.

Out of total $n=69$ (100%) participants, 52 participants (75.4%, $SD=0.434$, $Skewness=1.204$, $SE\ Skewness=0.289$) responded that the working hours and burden was increased during this pandemic, because the only 33% staff attendance was allowed every day during the lockdown to maintain the physical distancing at workplace. Out of total 69 (100%) participants, the 37 (53.6%, $SD=0.502$, $Skewness=0.149$, $SE\ Skewness=0.289$) attended the Covid-19sensitization training. Out of total 69 (100%) participants, the 36 (52.2%, $SD=0.503$, $Skewness=0.89$, $SE\ Skewness=0.289$) had performed the Covid-19screening duty. The data were calculated statistically and it was significant, the $P\ value \leq 0.05$. The study of Wang et al. (2020) also found that phenomena, such as long exposure to the large number of infected patients, pressure of treatment, work intensity and lack of rest could increase the risk of infection among healthcare professionals during pandemic COVID-19³⁰.

Out of total 266 multiple response sets, the participants responded that they had applied the following protective measures to protect themselves from Covid-19in the hospital, such are as 58 (21.8%, $SD=0.369$) responded that they frequently clean their hands with soap and alcohol based hand sanitizer, followed by the 61 (22.9%, $SD=0.323$) avoid touching door handles, walls, switches on public places, etc., 24 (9%, $SD=0.480$) adopted wearing mask, 43 (16.2%, $SD=0.488$) used mask and gloves both, 24 (9%, $SD=0.480$) used PPE kit during duty, and 56 (21.1%, $SD=0.394$) replied that the maintained social distance at work place. The results were calculated statistically and it was significant, the $P\ value \leq 0.05$. Similarly, Feng et al. (2020) found that the use of medical mask among healthcare professionals became a ubiquitous. PPE should be rationally used in healthcare settings and supply chains should be effectively managed. WHO (2020) estimated that 89 million medical mask, 76 million gloves, 1.6 million goggle could be used in each month. It also called to increase the production of protective equipment, including face mask at 40%³¹⁻³².

While performing duty, around 17 (24.6%) participants replies 'YES', 32 (46.4%) participants

replied ‘NO’ and 20 (29%) participants replied to ‘NOT SURE’ regarding the contact with COVID infected patients. Around 07 male & 10 female health workers (04 medical staff, 10 para-medical staff, 01 nursing staff and 02 helpers, $T=23.052$, $SD=0.736$) came into contact with Covid-19 suspected or confirmed cases. According to World Economic Forum (2020), 1 out of 10 healthcare professionals are likely to get infected with coronavirus while treating COVID-19 infected patients in some countries³³. Delay in recognition of COVID-19 patients, lack of skill in dealing with this pathogen, exposure to large patients and lack of PPE and preventives measures are some reason for vulnerability of healthcare professionals^{26, 33}.

After came into contact, 02 male & 02 female (01 medical staff, 02 para-medical staff, and 01 helper, $T=4.544$, $SD=0.795$) discussed with family, colleagues, friends, etc., 05 male & 04 female (01 medical staff, 05 para-medical staff, 01 nursing staff and 02 helpers, $T=4.391$, $SD=0.685$) consulted to the health care professionals, around 04 male & 09 female (03 medical staff, 08 para-medical staff, 01 nursing staff and 01 helpers, $T=4.384$, $SD=0.577$) was also quarantined with medical advice, and 05 male & 03 female (03 medical staff, 03 para-medical staff, and 02 helpers, $T=4.413$, $SD=0.709$) among them took decision for self-isolation. The results were calculated statistically and it was significant, the P value ≤ 0.05 .

As a frontline support, many health care professionals faced the occupational hazards during working Covid-19 pandemic. Various studies (Pfefferbaum & North, 2020; Rana et al., 2020; Shanafelt et al. 2020) found that healthcare professionals were more vulnerable for emotional and mental distress during the outbreak of COVID-19. Reasons, such as, risk of exposure, longer working hours, concern about family members, scarcity of PPE and other resources, economic loss, stigma associated with quarantine and involvement in difficult decisions on resource allocation were identified³⁴⁻³⁶.

Table: 2 Occupational hazards faced by health care professionals (Multiple response set).

Occupational Hazards (Table 1)	N	Percent
Pathogen exposure	26	17.9%
Psychological distress	39	26.9%
Fatigue	14	9.7%
Occupational burnout	14	9.7%
Stigma	12	8.3%
Physical violence	5	3.4%
Psychological violence	9	6.2%
Long working hours	19	13.1%
Not any	7	4.8%
Total	145	100.0%

The participants faced the one or more occupational hazard while working, around 39 (26.9%, $T=23.867$, $X^2=1.174$, $SD=0.499$) had psychological distress during performing duty, followed by 26 (17.9%, $T=27.622$, $X^2=4.188$, $SD=0.488$) faced pathogen exposure, 14 (9.7%, $T=36.849$, $X^2=24.362$, $SD=0.405$) faced fatigue, 14 (9.7%, $T=36.849$, $X^2=24.362$, $SD=0.405$) occupational burnout, 12 (8.3%, $T=39.728$, $X^2=29.348$, $SD=0.382$) faced stigma, 09 (6.2%, $T=45.777$, $X^2=37.696$, $SD=0.339$) faced psychological violence, 19 (13.1%, $T=31.838$, $X^2=13.928$, $SD=0.450$) worked for long hours, 07 (4.8%, $T=36.849$, $X^2=24.362$, $SD=0.405$) not faced any occupational hazard and 05 (3.4%, $T=51.854$, $X^2=43.841$, $SD=0.304$) faced physical violence (Table 2). The results were calculated statistically and it was significant, the P value ≤ 0.05 .

In order to support frontline healthcare professionals, Government of India in collaboration with academia developed the *Arogya Setu App* in the month of April 2020. It can help in tracing the Covid-19 cases and also provides the necessary information, updates, alerts, etc., to the users related with Covid-19. The app incorporates mix responses, such as positive and negative³⁷. As per the study conducted, out of 69 (100%) respondents only 55 (79.7%, $T=24.66$, $Mean=1.20$, $SE Mean=0.049$,

$SD=0.405$, $Skewness=1.511$) had downloaded the *Arogya Setu App*. According to the *Arogya Setu App*, approximately 12.87 crore people downloaded the app³⁸. The usage frequency ($T=9.991$, $Mean=1.93$, $SE\ Mean=0.193$, $SD=1.603$, $Skewness=0.431$) of app by respondents as follows, Once in a day 24 (34.8%), Twice in a day 04 (5.8%), Often use 11 (15.9%), Once in a week 12 (17.4%) and Not using 04 (5.8%). The results were calculated statistically and it was significant, the $P\ value \leq 0.05$.

The Government of India recognises that the outbreak of communicable diseases like COVID-19 can create fear and anxiety among general public due to misinformation about virus and fake news, which is further responsible for prejudice, social isolation and stigma against frontline workers, such as healthcare workers, police and sanitary workers³⁹. The government, media, doctor, police, celebrities and other stakeholders have been continuously making an appeal to avoid public gathering among the general public. Despites of this, the attitude of people is indifferent towards preventive measures and the incidence of ignoring the significance of social distancing is found⁴⁰. Along with government initiatives, there is also a need of a responsible citizen, healthcare professionals, other frontline workers, essential service providers and support of family and society in order to counter these problems in the outburst of COVID-19³⁹.

While performing the Covid-19 related duty, there were 20 (29%) respondents faced misconduct or stigma, 46 (66.7%) didn't face any misconduct or stigma, 03 (4.3%) didn't wanted to disclosed ($T=27.695$, $Mean=1.75$, $SE\ Mean=0.063$, $SD=0.526$, $Skewness=-0.215$). After facing the misconduct or stigma during performing duty, 10 (14.5%, $T=4.899$, $Mean=0.43$, $SE\ Mean=0.089$,

$SD=0.737$, $Skewness=1.366$) respondents discussed with colleagues and higher authorities, 02 (2.9%, $T=5.1798$, $Mean=0.55$, $SE\ Mean=0.106$, $SD=0.883$, $Skewness=1.028$) took legal action against misconduct or stigma, and 13 (18.8%, $T=4.859$, $Mean=0.39$, $SE\ Mean=0.081$, $SD=0.669$, $Skewness=1.474$) tried to explained about their duties and responsibilities to violators. The results were calculated statistically and it was significant, the $P\ value \leq 0.05$.

Around 08 (11.6%, $SD=0.675$, $Skewness=-0.486$, $Median=02$, $Mode=02$) health care professionals accepted that the post Covid-19infected patient visited to the department for other chronic disease treatment, 30 (43.5%) responded that they had 'No Idea' and 31 (44.9%) replied to 'No'. When Post Covid-19patient visited to the departments of participants, they had took various safety steps, such as follows, 04 (5.8%) took necessary safety precautions, 02 (2.9%) done screening for initial symptoms, 01 (1.4%) treated the patients with proper safety protocols and 01 (1.4%) propagated the telemedicine option ($SD=0.704$, $Skewness=3.826$). While attending the chronic disease patients in emergency and special OPD's, around 37 (53.6%, $SD=0.502$, $Skewness=0.149$, $Median=01$, $Mode=01$) of respondents accepted that if patients coming for treatment, they had sent the patients for Covid-19screening first. Nearly around 59 (85.5%, $SD=0.355$, $Skewness=2.062$, $Median=01$, $Mode=01$) participant accepted that their department followed the proper protocol, while attending the patients.

The personal opinion of respondent **Table 3** about Covid-19lockdown situation was measured on Likert Scale, Reliability test applied to check the validity of scale, $Cronbach's\ Alpha\ Test=0.935$, $Grand\ Mean=3.92$, and it was significant $P\ value \leq 0.05$.

Table 3: The personal opinions of respondents about the situation during Covid-19 lockdown

Covid-19 an occupational disease for health care professionals			
Likert Scale	N	Percent	SD=1.223, Median=4.00
Strongly disagree	04	5.8	
Disagree	10	14.5	
Neutral	13	18.8	
Agree	21	30.4	
Strongly agree	21	30.4	
Total	69	100.0	
Healthcare professionals are more vulnerable for the exposure of corona virus			

Cont... Table 3: The personal opinions of respondents about the situation during Covid-19 lockdown

Likert Scale	N	Percent	SD=1.098, Median=4.00
Strongly disagree	04	5.8	
Disagree	02	2.9	
Neutral	10	14.5	
Agree	25	36.2	
Strongly agree	28	40.6	
Total	69	100.0	
Did the government have taken the decision of lock-down timely?			
Likert Scale	N	Percent	SD=1.196, Median=4.00
Strongly disagree	04	5.8	
Disagree	09	13.0	
Neutral	09	13.0	
Agree	26	37.7	
Strongly agree	21	30.4	
Total	69	100.0	
The government had rightly taken the decision of increasing the lock-down			
Likert Scale	N	Percent	SD=1.098, Median=4.00
Strongly disagree	03	4.3	
Disagree	04	5.8	
Neutral	12	17.4	
Agree	23	33.3	
Strongly agree	27	39.1	
Total	69	100.0	
COVID-19 has increased the economic burden of the country			
Likert Scale	N	Percent	SD=1.105, Median=4.00
Strongly disagree	03	4.3	
Disagree	04	5.8	
Neutral	11	15.9	
Agree	22	31.9	
Strongly agree	29	42.0	
Total	69	100.0	
Frequency of using digital technology for payment should be increased			
Likert Scale	N	Percent	SD=1.007, Median=4.00
Strongly disagree	03	4.3	
Disagree	02	2.9	
Neutral	11	15.9	
Agree	30	43.5	
Strongly agree	23	33.3	
Total	69	100.0	
General public should follow safety measures to reduce the number of COVID-19			
Likert Scale	N	Percent	SD=1.271, Median=5.00
Strongly disagree	05	7.2	
Disagree	06	8.7	
Neutral	05	7.2	
Agree	17	24.6	
Strongly agree	36	52.2	
Total	69	100.0	

Cont... Table 3: The personal opinions of respondents about the situation during Covid-19 lockdown

The lock-down should increase to further more days			
Likert Scale	N	Percent	<i>SD=1.264, Median=4.00</i>
Strongly disagree	02	2.9	
Disagree	17	24.6	
Neutral	11	15.9	
Agree	16	23.2	
Strongly agree	23	33.3	
Total	69	100.0	
Online training or teaching is one of the best alternative for education			
Likert Scale	N	Percent	<i>SD=1.096, Median=4.00</i>
Strongly disagree	02	2.9	
Disagree	10	14.5	
Neutral	15	21.7	
Agree	25	36.2	
Strongly agree	17	24.6	
Total	69	100.0	
Hygiene practice should be followed in a long term approach			
Likert Scale	N	Percent	<i>SD=1.069, Median=5.00</i>
Strongly disagree	03	4.3	
Disagree	02	2.9	
Neutral	09	13.0	
Agree	18	26.1	
Strongly agree	37	53.6	
Total	69	100.0	
Physical distancing is an effective measure to prevent communicable diseases in future			
Likert Scale	N	Percent	<i>SD=0.991, Median=5.00</i>
Strongly disagree	02	2.9	
Disagree	01	1.4	
Neutral	12	17.4	
Agree	17	24.6	
Strongly agree	37	53.6	
Total	69	100.0	

The satisfaction level of respondents **Table 4** about the situation lockdown during the Covid-19 pandemic, it was measured on Likert Scale. Reliability test applied to check the validity of the scale, *Cronbach's Alpha Test=0.808*, *Grand mean=3.23* and it was significant *P value ≤ 0.05*. **Table 4: The satisfaction level of participants about the situation during Covid-19 lockdown**

Maintenance of social distance during lock-down by public			
Likert Scale	N	Percent	<i>SD=1.194, Median=3.00</i>
Strongly dissatisfy	08	11.6	
Dissatisfy	20	29.0	
Neutral	14	20.3	
Satisfy	21	30.4	
Strongly satisfy	06	8.7	
Total	69	100.0	

Cont... Table 3: The personal opinions of respondents about the situation during Covid-19 lockdown

Supply of sanitation products		
Likert Scale	N	Percent
Strongly dissatisfy	02	2.9
Dissatisfy	11	15.9
Neutral	13	18.8
Satisfy	37	53.6
Strongly satisfy	06	8.7
Total	69	100.0
<i>SD=0.964, Median=4.00</i>		
Regularity of PPE kit		
Likert Scale	N	Percent
Strongly dissatisfy	08	11.6
Dissatisfy	16	23.2
Neutral	17	24.6
Satisfy	24	34.8
Strongly satisfy	04	5.8
Total	69	100.0
<i>SD=1.138, Median=3.00</i>		
Number of testing for COVID-19		
Likert Scale	N	Percent
Strongly dissatisfy	10	14.5
Dissatisfy	19	27.5
Neutral	14	20.3
Satisfy	21	30.4
Strongly satisfy	05	7.2
Total	69	100.0
<i>SD=1.207, Median=3.00</i>		
Behaviour of general public towards corona warriors		
Likert Scale	N	Percent
Strongly dissatisfy	04	5.8
Dissatisfy	18	26.1
Neutral	17	24.6
Satisfy	21	30.4
Strongly satisfy	09	13.0
Total	69	100.0
<i>SD=1.141, Median=3.00</i>		
Government's strategies on issues		
Likert Scale	N	Percent
Strongly dissatisfy	12	17.4
Dissatisfy	16	23.2
Neutral	14	20.3
Satisfy	22	31.9
Strongly satisfy	05	7.2
Total	69	100.0
<i>SD=1.243, Median=3.00</i>		
Aarogya Setu App is helpful for public in updating about COVID-19		
Likert Scale	N	Percent
Strongly dissatisfy	04	5.8
Dissatisfy	10	14.5
Neutral	32	46.4
Satisfy	17	24.6
Strongly satisfy	06	8.7
Total	69	100.0
<i>SD=0.980, Median=3.00</i>		

Role of forces in maintaining the situation		
Likert Scale	N	Percent
Strongly dissatisfy	02	2.9
Dissatisfy	04	5.8
Neutral	18	26.1
Satisfy	25	36.2
Strongly satisfy	20	29
Total	69	100.0
Role of media in entertainment or spreading awareness during lockdown		
Likert Scale	N	Percent
Strongly dissatisfy	06	8.7
Dissatisfy	05	7.2
Neutral	14	20.3
Satisfy	26	37.7
Strongly satisfy	18	26.1
Total	69	100.0

SD=1.014, Median=4.00

SD=1.198, Median=4.00

The respondents had given some valuable suggestions during the study considering the situation of Covid-19 lockdown. The suggestions were given by the various health care professionals of different categories. Around 33 (47.8%) suggested that it was necessary to ensure occupational health and safety of health care workers, 12 (17.4%) suggested that the burden of patients should be reduced, 8 (11.6%) suggested that the preparedness for treating Covid-19 patients with adequate testing and screening, 04 (5.8%) the lockdown should be unlocked step-by-step, 07 (10.1%) suggested that the alternative treatment should be encouraged, 08 (11.6%) suggested that the awareness and training should be encouraged, 31 (44.9%) suggested that the safety measures and precaution should be strictly followed by the general public, 01 (1.4%) suggested to increase the health care budget and 06 (8.7%) suggested to developed the infrastructure for future.

Similarly, the study of Wang et al. (2020) suggested that there should be increased in capacity; management of patients, visitors and staff; a separation of staff as per their duty in the care of COVID-19 infected patients and other patients; used of alternative source of communication and treatment like social media and telemedicine; training; adequate use of PPE; and consistent use of mask and gloves. Apart from these, the modification of infrastructure, process of infection prevention strategies and clinical recommendation could be effective in the preparation for the pandemic. These could be indispensable to optimize the quality of care provided to COVID-19 patients as well as to prevent the risk of transmission among healthcare professionals and

other patients⁴¹. Shanafelt et al. (2020) consider the need to address the concern of healthcare professional, provide training, reduce the risk of infection, acknowledge the limitation of healthcare professionals as human and provide holistic support. These can be proved effective measures in the reduction of anxiety among healthcare professionals³⁶.

The participants also had given their personal opinions about the current situation during Covid-19 pandemic. Around 31 (44.9%) said that the safety measure should be practiced after a specific interval in daily life but not only in the emergency situation, 13 (18.8%) gave opinion towards the spread of awareness and understanding the epidemic situation in regular life, 04 (5.8%) gave opinion that the supply of safety material shouldn't be interrupted and ensured the availability of equipment regularly, 04 (5.8%) strongly said the lockdown should be increased and it shouldn't be uplifted so soon, 10 (14.5%) said that it should be strict restrictions on tourism and mobility and 16 (23.2%) said the government should ensure the safety of healthcare workers and other public or government.

Limitation: The study could not help in determining the causal relationship and inference due to adoption of cross sectional and descriptive study. The study was limited to those healthcare professionals having a Smartphone, an email id and access to internet. Repeated requests were made to participants for completing the questionnaire. Participants could be annoyed with investigators by repeated requests. There was a chance of biasness in the selection of sample and low rate of

responses with the use of web-based survey method. Finally, the findings could not be generalized to a larger population due to the sample size of the study.

Conclusion: The agenda 2030 Sustainable Development Goal 8 (8.8), recognized the significance of OHS to promote safe working environment for all workers in the sustainable society⁴². Despite of international commitment of ILO, WHO and other organizations, many workers report the undue risk in the workplace. Healthcare workers are considered the frontline of any epidemic because they spread treatment and prevention to the community. The most recent pandemic Covid-19 put pressure on healthcare services⁴³. This study endeavours to delineate different components of OHS in the healthcare setting during the outbreak Covid-19 as well as underscores the viewpoints of healthcare professionals on various concerns related with pandemic. The Covid-19 is a new pandemic to the world, so there was no treatment protocol developed, as well as no immunization available, no medicine available and only symptomatic treatment is followed in every country. Mostly preventive measures are following by the general population, like wearing masks & gloves, frequent hand wash or use of alcohol based sanitizer, avoiding crowded places, physical distancing and other.

According to this study, healthcare professionals observed the various changes at their workplaces, e.g. the sanitization practice is following more than earlier and people are become much aware about personal hygiene. The working hours are increased and people are become much responsible at work places as well as their home. In the hospitals, the trainings were organized to sensitize the staff about safety or precautionary measures. These days most of the people are adopting

digital services e.g. payment of bills, online classes or training, telemedicine, and etc. The *Arogya Setu App* was developed by Government of India for corona updates, but according to the participants, the *Arogya Setu App* requires to modify and many other services may include in this application.

It is significantly proved that by following the safety or precautionary measures most of the staff members are still safe and even though they performed the screening duty safely for Covid-19. In some hospitals the Emergency Services, including Oncology OPD, Obstetrics' OPD, and Neonatology OPD are functioning. It has greater chance that the Covid-19 infected suspects may visit to these emergency departments. Is thermal screening enough to identify the positive Covid-19 cases? So, that the preventive measure should be strictly followed by healthcare professionals and it is the duty of concerned department to enforce the safety protocols strictly. The impact of this pandemic may reduce if every country, every professional, every citizen works together effectively. During the Covid-19 epidemic, there are many limitations observed, such as follows, there is a need to increase the health budget, researches should be more initiated, social media should be controlled in such kind of emergency as it may use for spreading fake news, much focus on recruiting the health care staff as well as building up the new hospital should be the target, and it was observed that the labour class or migrants were highly exploited in this pandemic but now government suggesting the states to arrange the employment for them at their places like MNREGA. Lastly, people should change their personal attitude towards the Covid-19 and follow the precautionary methods to stay safe till the discovery of treatment and vaccine.

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Ethical Clearance: This is not institutional based study or not belongs/represents to any particular institute. So, the ethical clearance is not applicable.

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Current and Future Trends for COVID-19: A Case Study of Vadodara, India

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Abstract

Background: COVID-19 has been a pandemic and global disaster since the beginning of 2020. However, there is a lack of city/locale based studies on status and trends of COVID-19 in India.

Aim: The study aims to report the tests, total cases, cases per age group, zone wise confirmed cases and the status of hospitalization / home quarantining for COVID-19 for the smart city of Vadodara.

Methods: A retrospective secondary data analysis conducted on all the COVID-19 cases reported from 3rd April to 15th September 2020 for the city of Vadodara. Data were accessed through the Website of Vadodara Municipal Corporation and analyzed on cumulative number of tests, positive cases, deaths and patients' recovery for comparison of Vadodara with the State, National and International statistics.

Results: COVID-19 was found to be more prevalent among males. The age group of 51-60 years had the highest number of cases. The number of deaths was highest in the age group of 61-70 years. Nonetheless, case fatality rate was highest in the age group of 71-80 years. Vadodara also has shown a steady decrease in test positivity rate and fared better in terms of recovery rate as compared to Gujarat, India and the world. However, 15 day moving average of positive cases and deaths indicated that there will be an increase of the cases in near future.

Conclusion: Vadodara showed positive trends in managing the COVID-19 pandemic. Vadodara administration had managed to reduce the case fatality rate as compared to Gujarat, India and rest of the world.

Key Words: COVID-19, Virus, Pandemic, Smart City, Vadodara

Introduction

The current Corona virus disease 2019 (COVID-19) pandemic has led to more than 29,727,390 cases and 939,289 deaths globally as of September 15, 2020.^[1]

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Although most infections are self-limited, about 15% of infected adults develop pneumonia that requires treatment with supplemental oxygen and an additional 5% progress to critical illness with hypoxemic respiratory failure, acute respiratory distress syndrome, and multi-organ failure that necessitates ventilator support, often for several weeks. ^[2-4] At least half of patients with COVID-19 requiring invasive mechanical ventilation have died in hospital, ^[4,5] and the associated burden on health-care systems, especially intensive care units, has been overwhelming in several affected countries.

Till date there is no proven treatment and availability of vaccine for COVID-19 hence clinicians and public health experts are focusing on preventive measures till vaccine and effective anti-viral drugs are available for everyone.

On 15th September 2020, India ranked 2nd in the list of countries having most cumulative cases with 4,938,293 active cases and 3rd in cumulative deaths (82,066).^[6] The situation poses a grave challenge for India because of high population density.^[7] There are several variables that are central, such as age, comorbidity, amount of virus exposure, etc., which may assess the seriousness of the infection and the rate of infection recovery.^[8] The higher rate of disease transmission further increases the risk especially for urban population. Hence, India went into a lockdown state for 68 days from 25th March to 1st June 2020 and since then India has begun its unlocking phase.^[9] Few studies have shown that the testing rate has increased drastically after the 68 days of lockdown in India. The last day of lockdown had 2,708 tests per million population, which had increased to 16,947 tests per million by first week of August.^[10]

COVID-19 is probably one of the most dreadful words in the lexicon of Gujarat, especially in Vadodara where people equate it with death because of its upward curve towards case fatality rate during initial phase of the epidemic. The panic affected behaviour not only from closing the schools but also people become xenophobic.

Few studies have been conducted on the effectiveness of the lockdown and unlock phases^[10, 11] as well as on the current mortality statistics and trends in India^[12] and state wise also.^[13] Kapasa N et al, and Mahato S et al, have analysed the impact of the lockdown on education and pollution across states and cities.^[14, 15] But very few studies have looked at city/district wise statistics and trends, especially after the start of the unlock phase. City/town based studies have also not been conducted on future prediction on the spread of the disease. This study thus will aim to look at the statistics of a smart city Vadodara of Gujarat State in terms of tests, cases, and cases per age group, zonation of confirmed cases within the city and the status of hospitalization / home quarantining in the city. The trends were studied independently for the smart city of Vadodara and results

were compared with the status of the Gujarat as well as with the Indian data.

Methods

Study Area:

Vadodara is the third largest city in the state of Gujarat and located 140 kilo meter South of the State capital Gandhinagar. It is well connected by air, rail, and road. Vadodara city is a metropole with 2.1 million population governed by Municipal Corporation. Vadodara Municipal Corporation (VMC) reported first diagnosed COVID-19 case on 18th March 2020; a businessman who had a travel history to Spain, Dubai, and Mumbai.^[16] VMC area reported first COVID-19 death on 2nd April 2020. The deceased has history of travel to Sri Lanka from where he had most likely contracted the COVID-19 infection.^[17]

Study Design:

A retrospective secondary data analysis conducted on all the COVID-19 cases reported in from 3rd April to 15th September 2020 for the smart city of Vadodara.

Data Sources:

The secondary data obtained from the public domain sources like Vadodara Municipal Corporation website,^[18] the Gujarat State Government COVID-19 dashboard^[19] the Government of India COVID-19 dashboard,^[20, 21] and Worldometer global corona virus database.^[22] The information collected for the study includes daily updates as well as cumulative statistics. The information collected for Vadodara includes number of tests carried out on suspected patients for diagnosis of COVID-19, demographic profile of the cases, total number of positive tests, number of patients recovered, number of active cases, and number of deaths in Vadodara city. This analysis considered the data available on the website from April 03, 2020 till September 15, 2020 i.e. of 166 days. For comparison of Vadodara with the State, National and International statistics, data has been taken on cumulative number of tests, positive cases, deaths, active cases and patients' recovery.

Ethical Clearance: The study has utilized existing (secondary) data available in the public domain, and therefore, no direct interaction was made with any

human beings. The data do not have any identifying information (anonymous in analysis).

Statistical Analysis: Data were processed in Microsoft Excel and analysed through Excel 2013 and SPSS (20.0). Data for age, sex, location, tests, confirmed cases and mortality were analyzed and percentages for categorical variables were calculated. The 15-day moving average was also calculated and predictions were made on the trends of number of tests, number of cases and number of deaths for smart city of Vadodara.

Results

Of 122,104 individual were tested for COVID-19 during the study period, 9,918 were positive. There were 6,506 (66%) male and 3,412 (34%) female cases.

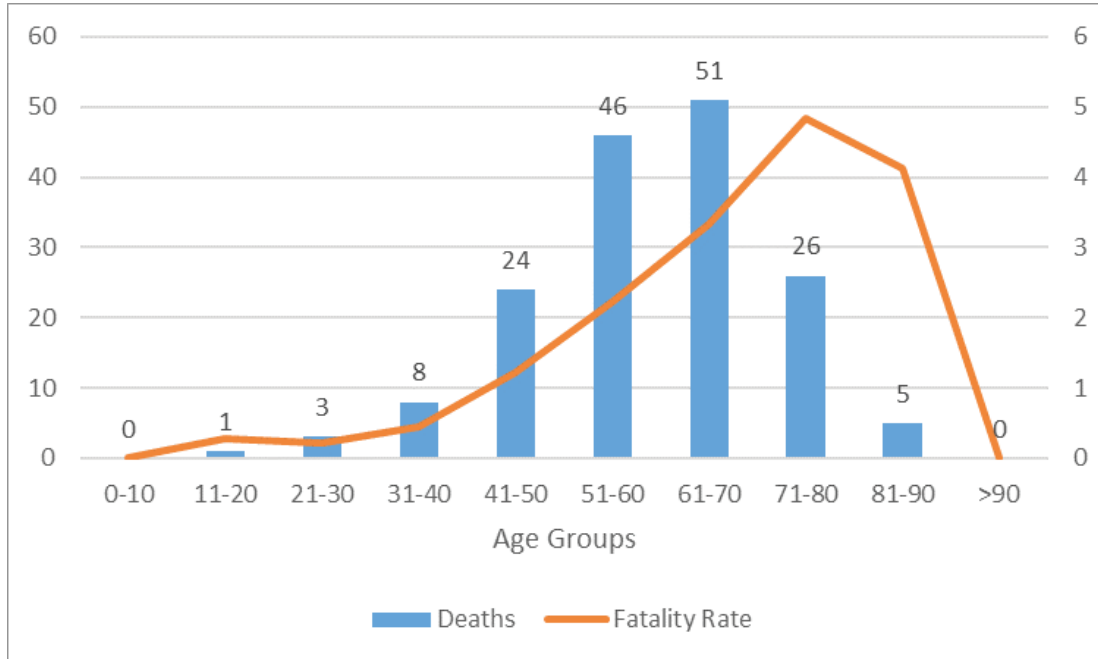


Figure 1: Age Distribution of Deaths due to COVID-19 in Vadodara, India

Figure 1 depicts the age and case fatality rate wise distribution of the COVID-19 in Vadodara. A total of 164 deaths have occurred during the study period of 166 days. While the number of deaths is highest between the age group of 61-70 years, but the case fatality rate (CFR) is highest in the age group of 71-80 years.

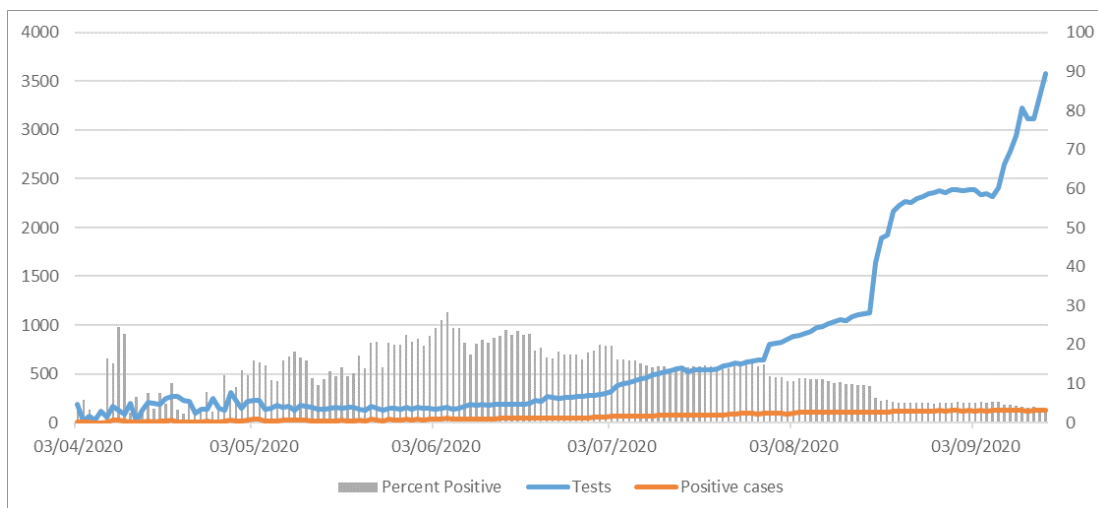


Figure 2: No. of tests, no. of test positive and positive cases % per day

The tests carried out and number of positive samples for COVID-19 have been increasing over the period but the percentage of positive cases per day were in decreasing trend. There was a gradual increase in percentage of positive cases against test carried out per day till first week of June 2020. Twenty-eight per cent of the laboratory samples tested positive for COVID-19 on 5th June 2020, then there is a gradual decline in percentage of positive samples which is around 3.5% as of 15th September 2020 (Figure 2).

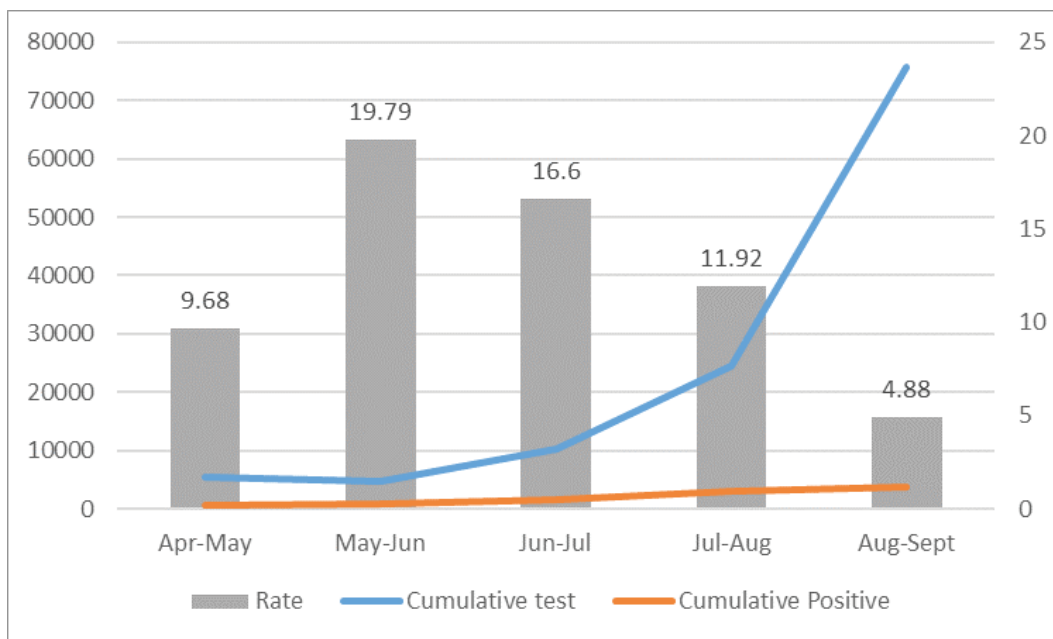


Figure 3: Monthly Tests and Positivity Trends

Figure 3 shows the cumulative tests and rate of positivity. The trends show a spike in the month of May-June but there has been a steady drop since then with the current positivity rate at 4.88% in the month of August-September.

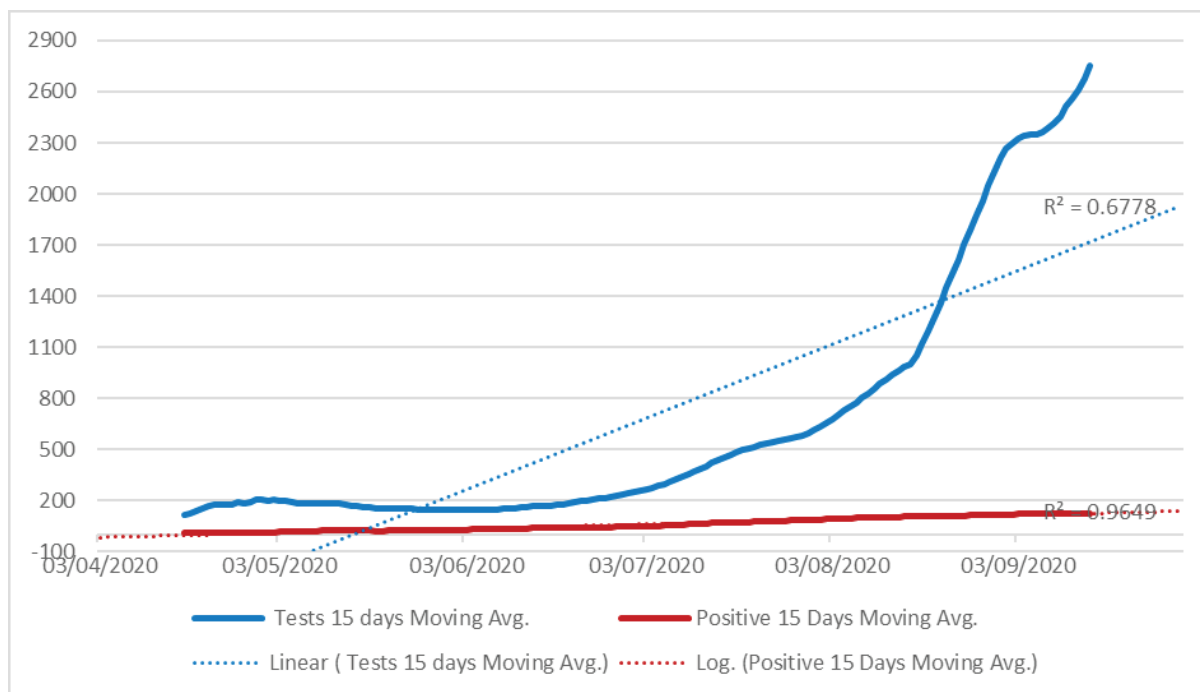


Figure 4: Fifteen (15) Days moving average of positive cases and deaths by COVID-19 (Linear scale)

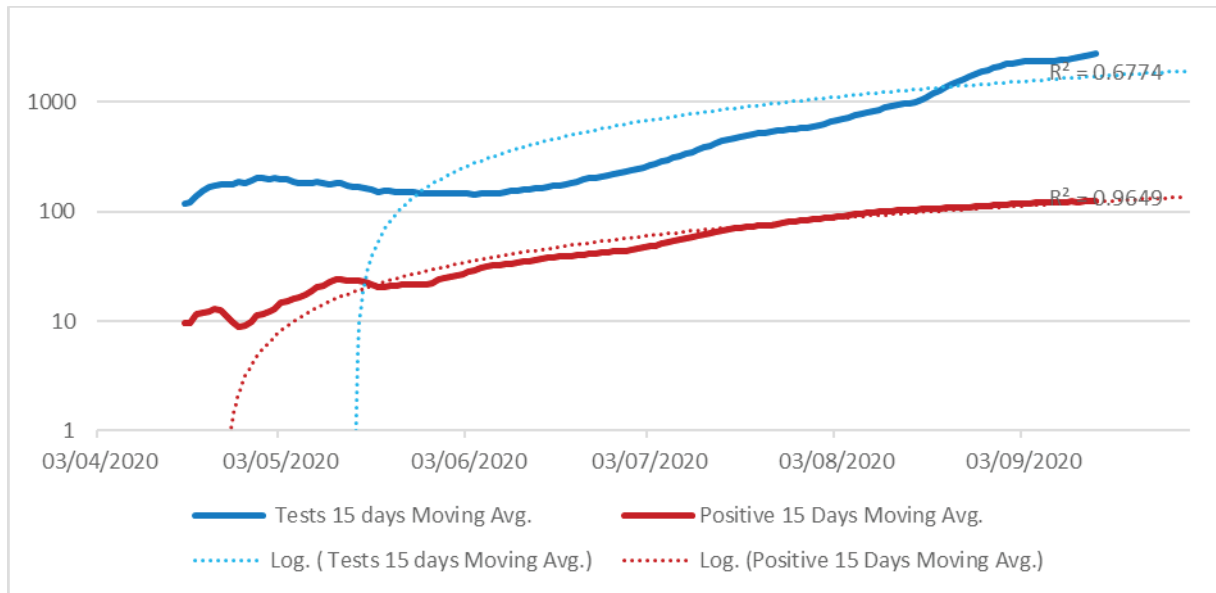


Figure 5: Fifteen (15) Days moving average of positive cases and deaths by COVID-19 (Logarithmic scale)

Figure - 4 and 5 depicts that the fifteen days moving average of positive cases is showing upward trend in the forecast best fit trend line. The occurrence of deaths in COVID-19 patients is also slightly above the forecast best fit trend line.

Table: Distribution of the COVID-19 cases, CFR and recovery rate (15th September 2020), Vadodara, India

Variable	Number of Cases	Percentage
Age (yrs) Group wise distribution*		
0 – 10	138	1.39
11 – 20	350	3.53
21 – 30	1423	14.35
31 – 40	1792	18.07
41 – 50	1953	19.69
51 – 60	2065	20.82
61 – 70	1529	15.42
71 – 80	538	5.42
81 – 90	121	1.22
> 90	9	0.09
VMC Zone wise distribution*		
East	1,613	16.26
West	1,602	16.15
North	2,352	23.71
South	1,935	19.50
Rural	2380	24.00
Outside (VMC limit)	36	0.36

Hospital wise cases*		
GMERS Gotri Medical College Hospital	245	17.68
SSGH (Sir Sayajirao General Hospital)	320	23.10
Private Hospitals	245	17.68
Home Isolation	474	34.22
COVID-19 Care Centre (CCC)	101	7.29
Total Tests Conducted**		
Vadodara	122,104	100.00
Gujarat	3,436,069	100.00
India	59,429,115	100.00
Test Positive (Test Positivity Rate)**		
Vadodara	9,918	8.12
Gujarat	116,345	3.38
India	5,020,359	8.44
Case Fatality Rate (CFR)**		
Vadodara	164	1.65
Gujarat	3,244	2.78
India	82,066	1.62
World	939,289	3.15
Recovery Rate		
Vadodara	8,369	84.38
Gujarat	96,582	83.00
India	3,942,360	78.52
World	2,15,46,861	72.46

*Till 15th September 2020

**On 15th September 2020

Table shows that almost 88% of the COVID-19 cases were in between ages of 21 to 70 years. However, highest number of COVID-19 cases was in the age group of 51-60 years. It also shows that the Rural zone has higher number of cases (24%) followed by the North zone, while West zone has lowest percentage of cases on 15th September 2020. On the day of 15th September 2020 only 34.22% of the patients were in home isolation, 17.68% patients were treated for COVID-19 in private hospitals while 40.78% were treated in Government Hospitals. The COVID-19 Care Centre in Vadodara is handling only 7.29% cases. COVID-19 Test positivity rate for Vadodara is lesser than India but higher than

Gujarat State. The CFR for Vadodara is almost aligned with the national level but it is significantly lower than the Gujarat state as well as for the whole world level. The recovery rate for Vadodara is higher than Gujarat, India as well as for the world (Table).

Discussion

The pandemic of COVID-19 posed a serious threat to the population. Currently it is a cause of great concerns of various health organizations and Governments and given the sleepless nights to health and other administration officials. The handling of COVID-19 outbreak has been a critical issue ever since its inception. To the best of our knowledge, this kind of report is the first from smart city of Vadodara, so we are unable to compare the results of this study with other Indian

studies. Vadodara was chosen as the study area because of the readily available data in the public domain. More so VMC has shown many positive adjectives in handling of the COVID-19 epidemic.

The difference in sex distribution of COVID-19 is significant in Vadodara with the male population having almost double the number of cases than the female population is consistent with State and National level data. This could be possibly explained that because of work / job and movement in the community due to social obligations made the male population more vulnerable to contract the infection than the females. The age distribution shows that the working population has been more affected due to their exposure to the infection. However, the CFR is higher for the age group of 71-80. This finding concurs with the earlier COVID-19 study that higher age and co-morbidities results in more deaths among COVID-19 victims.^[23] The zonal distribution have shown a need for better attention towards the North, South and Rural zones as these have the higher percentages of cases.

The results have shown an increase in the number of tests since April 3rd and an increase in number of daily cases, however, daily test positivity rate has decreased after a huge spike in June 2020. The results have also shown that Vadodara has around 1.65 per cent CFR which is significantly lower than Gujarat, signifying that Vadodara has outperformed the State. This may be due to the innovative measures like COVID-19 management protocols and the untiring efforts of VMC officials. The overall test positivity rate of below 5 percent and a fatality rate of less than 1 percent show that a city, state or country has a grip over the pandemic. However, the test positivity rate is still near the national level which is around 8 per cent but much higher than Gujarat (3.38%). Vadodara has a better recovery rate as compared to the state of Gujarat, India and the World. The current recovery rate is almost 12% more than the international average as on the 15th of September 2020. The continuous streak of very high levels of recoveries is the testimony of the effective clinical management and treatment protocols active in Vadodara. Hence, it is clearly evident that VMC is doing fairly well in terms of handling COVID-19 epidemic. However, cases may rise in near future as per analysis of 15 day moving average of positive cases and deaths.

Limitations:

Some limitations of the study need to be acknowledged.

- The main limitation of the study is that it couldn't include the daily tests and daily results of Gujarat and India from 3rd April 2020 because of the unavailability of the data in the public domain. The availability of daily data for Gujarat and India could have helped in a better comparative analysis for Vadodara.

- This analysis used cumulative data which limited the findings.

Hence, there will be limitation to generalization of observation and results.

Conclusion

The study analyzed COVID-19 situation for the smart city of Vadodara using data on daily tests and cases and compared the data of Vadodara with the state of Gujarat, India and the world. The study has shown that Vadodara has done a good job in containing the spread of the COVID-19 pandemic. As of 15th September 2020, the number of cases in Vadodara stands at 9,918 and the total number of tests stands at 122,104. There is a decrease in percentage of positive cases from around 28 per cent to 3.5 per cent. In terms of mortality and recovery, Vadodara has performed better than the average of Gujarat, India and the rest of the world. The recovery rate is higher as compared to State, National and International, however, the CFR is higher than the Gujarat and the world but almost similar to the India level.

Finding of the study also shows that there will be increase in cases in near future though percentage of test positive and the case fatality rate are in declining trend. The increase in cases would increase the burden on the VMC administration, health infrastructure and resources. Authorities need to reassess the availability of beds, intensive care facility, oxygen supply, medicines particularly required to treat COVID-19, medical and nursing staff in view of increase in the cases.

Recommendations:

The findings from this study may lead to further studies in Vadodara in understanding and dealing the

COVID-19 pandemic at local level. The findings can further lead to nationwide adoption of the measures and help in flattening the COVID-19 curve.

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

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Response to the Precautionary Measures to Prevent Coronaviruses-19; after Decline of the Pandemic, Taif City, KSA

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Abstract

Introduction: In spite of regression of pandemic curve in the Kingdom of Saudi Arabia there is fears of second wave especially during this winter.

Objective: This study aims to explore the public commitment to COVID-19's precautionary measures after the dropping of the cumulative curve towards regression, and to determine the role of society culture in the compliance with these preventive procedures.

Methodology: This is a descriptive cross-section survey conducted in Taif city, Saudi Arabia. Using a convenience sampling method.

Results: The score of society compliance with precautionary measures after regression of curve towards flat line was (3.72±0.47/) which considered high. There was a significant relationship between nationality and the precautionary measures to prevent COVID-19 ($t=-2.34$, $p<0.05$, $\beta = 0.02$), the mean score of non-Saudi (3.88±0.36), which exceeded Saudi mean scores (3.70±0.48). Few participants thought that there was overstatement against COVID-19's precautionary measures.

Conclusion: After regression of COVID-19 curve towards flat line, the level of society commitment to the preventive measures was still high. Most responders adhere to kept a distance from a person who has signs of SARS-CoV-2.

Keywords: COVID-19, precautionary measurements, response, curve regression.

Introduction

The coronavirus (COVID-19) is pandemic disease of which, recently, there have been 56,623,643 confirmed cases of (COVID-19) worldwide, including 1,355,963 deaths.¹ In Saudi Arabia the total confirmed case was 354,813 people.² Therefore, many countries took the initiative to impose precautionary measures to limit the spread of this pandemic, when the first wave of the SARS-CoV-2 (COVID-19) swept around the globe.

The level of rigorousness of these measures was varied; most countries enforced a complete lockdown, physical spacing and isolation of infected persons,^{3,4} while other countries were neglectful and delayed the application of these precautionary measures.

Saudi Arabia is considered to be one of the first countries to impose these precautionary measures,⁵ in which the level of commitment of society members in implementing of these precautionary measures was high.^{6,7}

The history of application of public precautionary measures to prevent and control infectious diseases dates back to 100 years ago when it was applied to control the spread of the Spanish flu which swept almost European countries.⁸ In recent history the preventive measures were applied to control the spread of swine and bird flu.^{9,10}

The best method to prevent SARS-CoV-2 infection is the practicing of physical distancing,¹¹ which refers to the maintenance of a safe distance between people who

are not from one home.¹²

Social distancing includes the practice of staying at home and compliance with at least 1-metre space. People who engaged in dynamic public regime are the most likely to violate social distancing processes.¹³

Another measure that is not less important than physical distancing in limiting the spread of the COVID-19 is to practice hand hygiene with soap and/or alcohol.¹⁴ Hand hygiene is considered one of the main non-pharmaceutical behaviours implemented widely to control the spread of previous pandemics and the COVID-19 pandemic. With regard to the wearing of face masks to prevent the spread of COVID-19, there is discrepancy in this issue.

Wearing masks was not recommended by world health organization for the public, while the Centers for Disease Control and Prevention (CDC) recommended wearing fabric masks for society in crowd settings.¹⁵ In Saudi Arabia fabric masks were recommended for the public.

People assumed or confirmed SARS-CoV-2 can decrease the spread of infection by adhering to face mask wearing while they are in close contact with other persons. The public masking is recommended if COVID-19 spread in the society. Masking also advising for further community sector personnel who have close contact with people such as postal transfer, receivers of community services, educators, store persons and food dispensers.¹⁶

The family of the virus that COVID-19 belongs to is thought to be transmitted commonly through inhalation of the droplets liberated from infected persons through coughs or sneezes. Because these droplets are large, they can likewise attach on shells and people can catch them with their hands and become infected.¹⁷

In light of clear laxity, will the governments need to use a punishment for those who violate the commitment to precautionary measures, or use the motivational approach and intensify awareness campaigns through various media to reduce the occurrence of the second wave of the COVID-19; or just follow the reports and the cumulative curve of the pandemic? Up to now there is no evidence on the global database to answer these

questions.

Up to now there has been no study carried out in Saudi Arabia to assess the response of the public to these preventive measures after the pandemic curve has dropped towards regression, so this study was conducted to explore the response of the public to these COVID-19 precautionary measures.

Now the cumulative curve of the pandemic is going towards a regression in Saudi Arabia. The peak rate of COVID-19 confirmed cases was between May and August 2020, then the rate of cases started declining. However, there is a fear of a second wave that may be more ferocious than the first. In order to maintain the regression of the curve, evaluation of society's response to the precautionary measures is crucial. Therefore, this study aimed to assess the community commitment to the precautionary measures after the decline of the cumulative curve towards a flat line, as well as to determine the role of Saudi culture in the compliance with COVID-19 preventive guidelines.

Method

Study Type and setting

This is a descriptive cross-sectional survey conducted among society in Taif city western Saudi Arabia, it's one of the cities that were affected by the COVID-19 pandemic at early phases. The total of population living here are around 500000 people.

Study Population

The sample used in this study is non-probability convenience sampling which obtained from general society accommodate in Taif city, both Saudi and non-Saudi, male and female, for those 18 years and over.

Data Collection

This study used an electronic questionnaire. These questionnaires designed on google forms which was shared on WhatsApp and twitter. These social media are one of the most favorable social media used by Saudi society, to obtain a high participation rate. The data was collected from December to January 2021.

Collection Instrument

The electronic questionnaire consists of two sections: the first section includes the agreement to participate and biographic data; the second section involves information about the precautionary measures of SARS-CoV-2.

Data Analysis

Data was analyzed using SPSS version 23.0. The frequencies, percentage, mean and standard deviation were computed for the scale and for demographic factors. One-way ANOVA, independent t test and Pearson correlation were used to test relationships between the scales of the socio-demographic information. A *p* value less than 0.05 was considered statistically significant. One-Sample Kolmogorov-Smirnov Test was used to test the data normality. The precautionary measures to prevent COVID-19 Scale was measured using the 5-points Likert scale from Always = 5 to Never = 1. The level of range was calculated using the following formula: Interval level = (biggest number –smallest number) / (number of points). Interval level = (5-1)/5=0.80, so the level was presented from very high(4.20-5) to very low(1-1.79).

Ethical Aspects

This study was approved by the Research Ethics Committee of Taif university, Saudi Arabia (Application code: 42-0079).

Results and Discussion

191 people participated in this survey, including 162 (84.8%) male and 29 (15.2%) female; 118 (61.8%) were married, 65 (34%) were single and only 8 (4.2%) were widowed. 164 (85.9%) were Saudi, and 27 (14.1%) were non-Saudi. 135 (70.7%) were employed in the government sector, 25 (13.1%) were in self-employment work, 16 (8.4%) worked in the private sector, and 8 (4.2%) were retired. The mean age of the participants was (33.43±10.38). 163 (85.3%) reported that they did not have chronic disease, and 50 (26.2%) were smokers. 113 (59.2%) were worried about the risk of catching the COVID-19 infection.

As shown in Table 1 the precautionary measures to prevent COVID-19 Scale were analyzed using descriptive analysis (the frequencies, percentage, mean and standard deviation).

The overall mean score was (3.72±0.47/High). Item (8) ‘You are keen to escape from a person who has COVID-19 signs’ achieved highest mean score (4.60±0.74/Very High), and item (20) ‘Do you think the precautionary measures against COVID-19 are exaggerated?’ got the lowest mean (2.23±1.19/Low).

Table 1: Descriptive analysis of the precautionary measures to prevent COVID-19 Scale

Statement	Never	Rarely	Sometimes	Frequently	Always	Mean±SD / level
Are keen to sleep early?	23	18	55	51	44	3.39±1.27
Are you keen to stay in home?	1	5	17	59	109	4.41±0.80
you are keen to hand washing	0	3	18	59	111	4.46±0.73
You are keen to be a meter or more away when mixing with others	1	7	19	83	81	4.24±0.82
You are keen to adhere to coughing technique	5	7	27	46	106	4.26±1.01
During sneezing, you are keen to use a tissue or sneeze on the elbow	3	2	22	43	121	4.45±0.86
You are keen to put the used tissue in a closed basket	8	5	22	47	109	4.28±1.05
You are keen to escape from a person who has COVID-19 Signs	2	2	11	41	135	4.60±0.74

Cont... Table 1: Descriptive analysis of the precautionary measures to prevent COVID-19 Scale

You are keen to participate in social events (wedding, and etc...)	82	36	31	24	18	2.27±1.37
You are keen not to touch the mouth, eyes and nose	8	11	40	72	60	3.86±1.06
Take the initiative to contact the health workers or go to the hospital when you feel symptoms of Corona	5	9	16	46	115	4.35±1.00
You are Keen to eat foods that strengthen the immune system	4	5	36	62	84	4.14±0.95
When meeting with relatives and friends, you are keen to initiate a handshake	66	38	35	26	26	2.52±1.43
When going to public places, you are keen to wear gloves	17	8	38	53	75	3.84±1.24
When going to public places, you are keen to wear face mask	22	26	35	26	82	3.63±1.44
When returning home, you are keen to embrace your children and those in the house	86	29	29	24	23	2.31±1.45
You are keen to follow the news of COVID-19	10	7	29	60	94	4.25±0.88
You are interested to follow rumours related to COVID-19 news	74	38	32	21	26	2.41±1.44
You are keen to tell your family members the necessity to adhere to COVID-19 preventive measures	1	3	15	42	130	4.55±0.75
Do you think the precautionary measures against COVID-19 are overstated?	90	29	27	29	16	2.23±1.39
Mean ± SD/Level3.72/0.47 /High						

Table 2 shows that the associations between the precautionary measures to prevent COVID-19 Scale and socio-demographic factors were conducted using independent t test, one-way ANOVA and Pearson correlation at 0.05.

Table 2: Associations between the precautionary measures to prevent COVID-19 Scale and demographic factors

Variables	M±SD	Statistic /p
Gender Male Female	3.72 (0.48%) 3.71 (0.42%)	t=0.12 (0.90%)
Marital statue Single Married Widow	3.63 (0.50%) 3.76 (0.44%) 3.85 (0.56%)	F=1.96 (0.14%)
Nationality Saudi Non Saudi	3.70 (0.48%) 3.88 (0.36%)	t=-2.34 (0.02%)
Work statue Government Private Free work Retired House wife	3.68 (0.47%) 3.77 (0.51%) 3.88 (0.45%) 3.75 (0.45%) 3.74 (0.43%)	F=0.97 (0.43%)
Do you have any chronic disease? No YES	3.70 (0.46%) 3.82 (0.50%)	t=0.12 (0.90%)
Are you smoker? No YES	3.72 (0.47%) 3.73 (0.46%)	t=0.12 (0.90%)
Are you worried about the risk of catching the Corona virus? No YES	3.71 (0.50%) 3.73 (0.44%)	t=0.12 (0.90%)
Age	33.43 (10.38%)	r=0.21** (0.004%)

** is significant at (0.05)

The result shows that there was a significant relationship between nationality and the precautionary measures to prevent COVID-19 ($t=-2.34$, $p<0.05$, = 0.02), the mean score of non-Saudi (3.88 ± 0.36), which exceeded Saudi mean scores (3.70 ± 0.48). There was a positive significant relationship between age and the precautionary measures ($t=0.21$, $p<0.05$, = 0.004), which means that older people take more care and pay more

attention to the coronavirus atmosphere.

The sliding of the COVID-19 curve towards a flat line does not mean that the pandemic has gone away, therefore the higher the rate of commitment with preventive guidelines, the less chance of a second wave. The findings of this study was in line with the results of others studies,^{6,7} which shows that the level and response of Saudi community to health guidelines to

prevent COVID-19 was high.

Attending social events, such as weddings and funerals, and embracing friends and relatives are well-established in Arab cultures, the COVID-19 pandemic has examined to what extent Arab society adheres to these cultures; thus it can be said that society has succeeded to a high degree in relinquishing these cultures because of this pandemic, as well as most participants reporting that they have not participated in social events and do not shake hands of relatives and friends. This study reveals that about 50% of participants were following the pandemic news, whereas more than one third of them did not follow the rumours related to pandemic, which may be broadcast more quickly than the SARS-CoV-2 infection spread.¹⁸ This indicates the awareness of community about the pandemic.

There are contradictions about society masking,^{19,20} and this study found that most of responders adhered to wearing face masks when they were going out of their home. This agrees with what was found in the literature: utilization of masks is most the necessary action for the public to reduce the spread of COVID-19 infection.²¹ In addition to this, literature shows that masks are more effective to reduce the possibility of COVID-19 contagion.²²

On the other hand, adherence to mask wearing will prevent the spread of COVID-19 transmission among community members, especially in crowd zones, because masking will reduce the possibility of face touching, particularly touching of the eyes, nose and mouth.²³ This study explored that most participants were keen to not touch their mouth, eyes and nose which reflected their good behavior regarding face touching.

The findings of the study show that the majority of participants were keen to initiate contact with health authorities when they felt clinical signs of COVID-19 infection. In Saudi Arabia, the Ministry of Health has launched an application on Android and Apple devices called “Tetamman” to receive suspected cases, contacts and returnees from travel. One of the main limitations of this study is sample size was not enough.

Conclusion

After regression of COVID-19 curve towards a

flat line, the level of Saudi commitment to preventive measures was still high. Moreover, most responders were keen to keep a distance from a person who has signs of SARS-CoV-2 infection.

Declaration:

Conflicts of Interest: There is no conflict of interest in this article.

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Ethical Clearance: Taken

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Development of Information System-Based Policy for COVID-19 affected Students in the Semi-Arid Area of Indonesia

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Abstract

This study aimed to provide an overview of the diet of students during the COVID-19 pandemic, socioeconomic status, the physical activities undertook the practiced COVID-19 prevention behavior, and student health. The sample size obtained was 253 participants, who were new students for the 2020/2021 academic year. Structural equation modeling was used for statistical analysis. Students could access nutritious food, but it was not followed by regular daily exercise. Students were also found to have good COVID-19 prevention behavior, for example using masks, washing hands, and coughing and sneezing etiquette, but only 41% of students had sufficient rest or sleep. Students have a good level of health, despite lacking physical activities. COVID-19 preventive behavior and socioeconomic status indirectly had an impact on student health. The right policies are necessary to improve student health.

Keywords: COVID-19, socioeconomic, student health, diet, exercise, structural equation modeling

Introduction

The first positive case of COVID-19 in Indonesia was found on Monday, March 2, 2010, which was transmitted through human-to-human. On 11 June 2020, the Government of Indonesia announced 35,295 confirmed cases of COVID-19, 2000 cases of death, and 12,636 cases of recovery from 424 districts/cities in all 34 provinces¹. The impact of COVID-19 has caused a public health emergency, thousands of deaths, a sluggish economy, increased unemployment, and quarantines around the world².

In response to the handling of the COVID-19 pandemic, Indonesia adopted a policy of restricting

access to anticipate an even greater risk of transmission by implementing Large-Scale Social Restrictions and prohibiting the implementation of mass activities. The types of mass activities referred to include educational and/or work activities, religious activities, weddings, and other social activities. There are many challenges faced in the application of online lecturing systems, both from within students and from the environment. Not all students have the ability to adapt quickly as many students are not familiar with the use of e-learning. Also, the limited availability of 4G and 3G broadband, low economic background, and other factors are challenges that can hinder the implementation of online learning policies.

The unique challenge in Semi-Arid Area of Indonesia, especially in East Nusa Tenggara is that students are scattered in various islands, which is one of the archipelago provinces of Indonesia with insufficient support for access to information. Improvement continues to be made for the development of better lectures. This system can also be developed as an information center

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for students related to health. Students need to get the latest information about COVID-19 and the university has to monitor the health development of students. The purpose of this study was to provide an overview of the student diet during the COVID-19 pandemic, the physical activities undertook, the practiced COVID-19 prevention behavior, and the student's health status. We believe that this research is important because the condition of students during this pandemic can be a source of information in planning and implementing University policies related to students especially in low income areas.

Method

Sample and Data collection

This type of research is quantitative with a Cross-Sectional Study design³. Power Analysis was chosen to determine the minimum sample size needed to obtain adequate statistical power to develop the model⁴, conducted by using *G*Power 3.1.9.4* software⁵. The sampling technique used a quota sampling⁶. The inclusion criteria were new students for the 2020/2021 academic year, coming from the arid regions of the East Nusa Tenggara archipelago and undergoing lectures entirely online. The data collection method used was an online survey that accessed through an e-learning system based on a *Modular Object-Oriented Dynamic Learning Environment (Moodle)*⁷, was carried out for 3 months from July to October 2020 and obtained 253 participants.

Variables

Student Health

Physical Health Questionnaire measuring somatic symptoms that have a potential link between psychological disorders and physical illnesses⁸, closely related to their mental health state⁹⁻¹¹. The construct validity was tested using Confirmatory Factor Analysis (CFA), using *Jeffreys's Amazing Statistics Program* (JASP 0.14)^{12,13}. After testing, 11 items were obtained (see Table 1). Modified PHQ has a good internal consistency (Cronbach's $\alpha = 0.832$). Cut-off point¹⁴ of model analysis shows that Physical Health Questionnaire (modified) had a Relative Noncentrality Index (RNI) of 0.951 and Comparative Fit Index (CFI) of 0.95,

Standardized Root Mean Square Residual (SRMR) of 0.048, The Root Mean Square Error of Approximation (RMSEA) of 0.063.

COVID-19 Preventive Behavior

COVID-19 Preventive Behavior is measured using the COVID-19 Preventive Behavior Scale¹⁵, based on health behaviors recommended by the World Health Organization¹⁶ and the Government of Indonesia in the COVID-19 pandemic. The scale consists of 6 items, responses using a semantic differential ranging from 1 (never) to 5 (always). To be categorized as having adequate preventive behavior, the respondent must get a score of >3 (a score of 3 or less is considered inadequate) on a minimum of 5 items out of 6 items. When any researchers choose to use the total score, high scores indicate that participants report a high frequency of preventive behavior.

Validity testing uses EFA and CFA. One factor solution extracted, with all item loaded adequately (>0.30 , $p < 0.05$; see Table 1). EFA, CFA and scale reliability analysis using JASP 0.14^{12,13}. Reliability Cronbach's $\alpha = 0.754$, the scale have a good fit; Chi-squared Test $p = 0.092$, SRMR = 0.036, RMSEA = 0.052, GFI = 0.98, RNI = 0.98, IFI = 0.981, and TLI = 0.967.

Socioeconomic Status

Socioeconomic status was measured using 3 questions: How much is your family's monthly income, what was your father's last education level, what was your mother's last education level. Responses of income are 1 ($< 1.000.000$ IDR); 2 (1.000.000 - 2.000.000 IDR); 3 (2.000.000 - 3.000.000 IDR); 4 (3.000.000 - 4.000.000 IDR); 5 (4.000.000 - 5.000.000 IDR); 6 ($> 5.000.000$ IDR). Response of education level are 1 (Not completing elementary school); 2 (Elementary School); 3 (Middle School); 4 (High School); 5 (Undergraduate); 6 (Master Degree); 7 (PhD).

Daily Exercise

Self-evaluation of daily physical exercise: do you exercise for at least 30 minutes regularly. Responses are 1 (never) to 5 (always).

Sleep Duration

Self-evaluation of daily sleep adequacy: how many

hours of sleep/rest do you have in a day. Responses are 1 (Less than 8 hours a day); 2 (8 hours or more a day)

Nutritious Diet

Self-evaluation regarding the adequacy of nutrients in daily food consumption: how often do you eat a balanced nutritious diet. Responses are 1 (never) to 5 (always).

Model Development

It is hypothesized that the COVID-19 preventive behavior, socioeconomic status, daily exercise, sleep duration, and nutritious diet have a direct and indirect effect on the student health conditions. Based on these hypotheses, Model 1 is developed in Amos^{17,18}.

Maximum likelihood and bootstrap estimates were used to adjust for the lack of multivariate normality. Model 1 shows fairly good fit statistics (see Figure 1). We use the modification indices to provide suggestions for further model modifications¹⁷. After Model 2 was developed, both models are included in a single analysis¹⁷. We found that Model 1 significantly worse than Model 2 ($p < 0.01$)¹⁷, it was decided to use model 2 to test the research hypothesis as the final model.

Result

Descriptive Statistics

The family income of 38.7% of the participants is less than 69 USD, below the poverty limit in East Nusa Tenggara (see Table 2). Participants tend to have a good level of health; however, headaches are the most common complaint (Mean = 14.1; SD = 4.36). Only 41% of participants had sufficient time to rest or sleep. Participants tend to be able to access nutritious food (often 29.2% and always 26.9%), but unfortunately, it is not followed by regular daily exercise (never 19.0%, rarely 23.7%, sometimes 29.6%). A total of 180 participants (71.15%) had an adequate level of COVID-19 prevention behavior, while 73 participants (28.85%) were still less aware of doing it.

Modeling Results

Conducting COVID-19 preventive behavior does not directly improve student health ($\beta = -0.095$, lower = -0.256, upper = 0.136, SE = 0.101, $p = 0.503$) (see

Table 3). Higher socioeconomic background does not directly predict lower health problems ($\beta = -0.079$, lower = -0.246, upper = 0.091, SE = 0.088, $p = 0.372$). Coming from a more prosperous family does not directly guarantee that students will be having lesser health problems. COVID-19 preventive behavior is positively related to rest and sleep duration ($\beta = 0.146$, lower = 0.01, upper = 0.258, SE = 0.064, $p = 0.04$). Doing social distancing, as well as stay at home provide greater opportunities for students to be able to rest longer.

Awareness of maintaining health encourages students to maintain their diet and nutritional intake. It was found that COVID-19 prevention behavior is positively related to a nutritional diet ($\beta = 0.484$, lower = 0.338, upper = 0.613, SE = 0.07, $p = 0.001$). One of the reasons that are often mentioned by students is to maintain the body's immune system. This reason also encourages students to be active in the daily exercises, explaining the positive relationship between COVID-19 preventive behavior and daily exercise ($\beta = 0.3$, lower = 0.126, upper = 0.445, SE = 0.082, $p = 0.001$).

The higher the level of COVID-19 preventive behavior, the more active students will be in exercising with the aim of keeping their bodies in fit condition. Meanwhile, socioeconomic status was positively related to sleep duration ($\beta = 0.185$, lower = 0.045, upper = 0.316, SE = 0.068, $p = 0.009$) and Nutritious Diet ($\beta = 0.21$, lower = 0.09, upper = 0.329, SE = 0.062, $p = 0.001$), but not related to daily exercises ($\beta = -0.002$, lower = -0.15, upper = 0.151, SE = 0.077, $p = 0.956$).

It was found that all mediating variables have a positive relationship with student health: sleep duration ($\beta = 0.158$, lower = 0.027, upper = 0.28, SE = 0.066, $p = 0.022$), nutritious diet ($\beta = 0.337$, lower = 0.18, upper = 0.49, SE = 0.081, $p = 0.001$) and daily exercise ($\beta = 0.159$, lower = 0.015, upper = 0.301, SE = 0.074, $p = 0.031$) contribute to improving student health (see Table 3).

Direct Effects

The result of direct effects indicate that daily exercise is directly depends on COVID-19 preventive behavior only ($\beta = 0.3$, $p = 0.001$). Sleep duration is directly depends on COVID-19 preventive behavior ($\beta = 0.146$, $p = 0.04$), and socioeconomic factors ($\beta =$

0.185, $p = 0.009$). Nutritious diet is directly depends on socioeconomic factors ($\beta = 0.21$, $p = 0.001$) and COVID-19 preventive behavior ($\beta = 0.484$, $p = 0.001$).

Student Health is directly depends on daily exercise ($\beta = 0.159$, $p = 0.031$), sleep duration ($\beta = 0.158$, $p = 0.022$) and nutritious diet ($\beta = 0.337$, $p = 0.001$). Socioeconomic factors ($\beta = -0.079$, $p = 0.372$) and COVID-19 preventive behavior ($\beta = -0.069$, $p = 0.503$) do not have a direct effect on student health (see Table 4). The null hypothesis that there is no direct effect of COVID-19 preventive behavior and socioeconomic factors on student health cannot be rejected.

Total Effects

The result of total effect indicates that daily exercise depends, directly or indirectly, on COVID-19 preventive behavior ($\beta = 0.3$, $p = 0.001$). Relatively high scores of COVID-19 preventive behavior are associated with high daily exercise scores. Sleep duration is depends, directly or indirectly, on COVID-19 preventive behavior ($\beta = 0.146$, $p = 0.04$), and socioeconomic factors ($\beta = 0.185$, $p = 0.009$) (see Table 4). High scores of COVID-19 preventive behavior and socioeconomic factors are associated with high sleep duration scores. Nutritious diet is depends, directly or indirectly, on socioeconomic factors ($\beta = 0.21$, $p = 0.001$) and COVID-19 preventive behavior ($\beta = 0.484$, $p = 0.001$). High scores of COVID-19 preventive behavior and high socioeconomic factors scores are associated with high nutritious diet scores.

Student Health is depends, directly or indirectly, on daily exercise ($\beta = 0.159$, $p = 0.031$), sleep duration ($\beta = 0.158$, $p = 0.022$) and nutritious diet ($\beta = 0.337$, $p = 0.001$). High scores on the daily exercise, sleep duration, and nutritious diet are associated with high scores on student health. Meanwhile, socioeconomic factors ($\beta =$

0.02 , $p = 0.826$) and COVID-19 preventive behavior ($\beta = 0.164$, $p = 0.069$) do not have a total effect on student health (see Table 4).

Indirect Effect

It was found that the socioeconomic status ($\beta = 0.1$, $p = 0.003$) and COVID-19 preventive behavior ($\beta = 0.234$, $p = 0.001$) had a significantly positive indirect effect on student health, thus the null hypothesis that has no indirect effect on COVID-19 preventive behavior and socioeconomic factors on student health can be rejected (Table 4). Several paths can explain these indirect effects.

There are 3 paths that can explain the indirect effect of COVID-19 preventive behavior on student health ($\beta = 0.234$, $p = 0.001$). COVID-19 preventive behavior effects daily exercise (direct $\beta = 0.3$, $p = 0.001$) and in turn has a positive effect on student health (direct $\beta = 0.159$, $p = 0.031$) (see Figure 1 for model path). Second, COVID-19 preventive behavior effects sleep duration (direct $\beta = 0.146$, $p = 0.04$), then the latter has an effect on student health (direct $\beta = 0.158$, $p = 0.022$). Third, COVID-19 preventive behavior effects nutritious diet (direct $\beta = 0.484$, $p = 0.001$), then effects the student health (direct $\beta = 0.337$, $p = 0.001$). Among these paths, the nutritious diet path is the most important for explaining student health, followed by daily exercise and sleep duration.

On the other hand, there are 2 paths that can explain the indirect effect of socioeconomic status ($\beta = 0.1$, $p = 0.003$) on student health. First, socioeconomic status effects nutritious diet (direct $\beta = 0.21$, $p = 0.001$), then effects the student health (direct $\beta = 0.337$, $p = 0.001$). Second, socioeconomic status effects sleep duration (direct $\beta = 0.185$, $p = 0.009$), then the latter has an effect on student health (direct $\beta = 0.158$, $p = 0.022$).

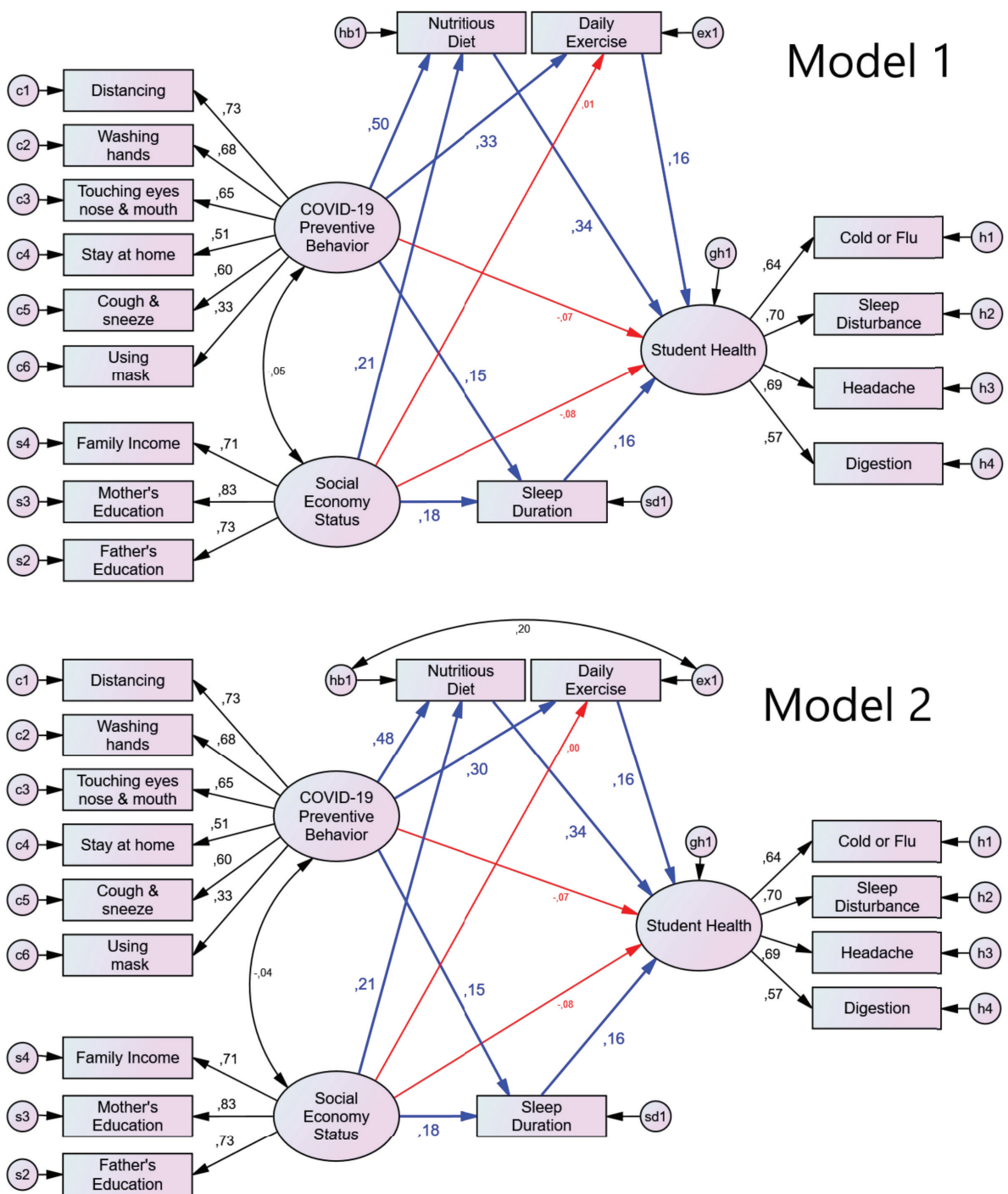


Fig. 1 Standardized path coefficients of the hypothesized model 1 and model 2. Blue solid arrows mean significant regression weight while red solid arrows indicate insignificant regression weight. *Model 1*: CMIN/DF = 1.258, p = 0.045, TLI = 0.965, CFI = 0.973, RMSEA = 0.32; *Model 2*: CMIN/DF = 1.178, p = 0.115, TLI = 0.976, CFI = 0.981, RMSEA = 0.22

Source: Amos Output ¹⁸

Table 1. Items and Factor loadings of Variables' Scales

Variable	Factor	Items	R2	Loading	p
Physical Health	Flu/Cold	Have you had any health problems (feeling unwell) since the beginning of college up to now?	0.454	0.762	< .001**
		In the past two months, how many times have you had mild flu (you feel uncomfortable but don't make it necessary to rest at home)?	0.342	0.490	< .001**
	Sleep Disturbance	How often do you have trouble sleeping at night?	0.317	1.024	< .001**
		How often do you wake up from sleep at night?	0.384	0.954	< .001**
		How often do you have nightmares or disturbing dreams?	0.402	0.835	< .001**
	Headaches	How often do you get headaches?	0.505	1.075	< .001**
		How often do you get headaches when there is a lot of pressure on things to get done?	0.738	1.541	< .001**
		How often do you get headaches because you are frustrated that something is not working properly or when you are upset with someone?	0.613	1.375	< .001**
	Digestion/ Gastrointestinal	How often do you experience stomach upset (indigestion)?	0.529	1.023	< .001**
		How often do you feel nauseous?	0.330	0.557	< .001**
		How often do you experience constipation or diarrhea?	0.392	0.678	< .001**
	COVID-19 Preventive Behavior	Prevention	Avoid touching eyes, nose and mouth	0.423	0.753
Wash your hands with soap and running water or alcohol (hand sanitizer) regularly			0.463	0.609	< .001**
Maintain a distance of at least 1 meter (3 feet) between you and those around you			0.577	0.799	< .001**
Stay away from outdoor crowds or stay at home			0.245	0.519	< .001**
Properly use a cloth mask when leaving the house			0.105	0.168	< .001**
Cover your mouth and nose with the inside of your bent elbow or tissue when you cough or sneeze			0.332	0.550	< .001**

**<0.01 Two Tailed Significance (bias-corrected)

Table 2. Descriptive Statistics

Variables		n	%
COVID-19 Preventive Behavior	Adequate	180	71.2%
	Lack	73	28.8%
Father's Education	< Elementary school	9	3.6%
	Elementary School	44	17.4%
	Middle School	21	8.3%
	High School	106	41.9%
	Undergraduate	65	25.7%
	Master Degree	7	2.8%
	PhD	1	0.4%
Mother's Education	< Elementary school	8	3.2%
	Elementary School	50	19.8%
	Middle School	39	15.4%
	High School	96	37.9%
	Undergraduate	56	22.1%
	Master Degree	3	1.2%
	PhD	1	0.4%
Family Income per Month	< 69 USD	98	38.7%
	70 – 139 USD	49	19.4%
	140 – 209 USD	36	14.2%
	210 – 279 USD	37	14.6%
	280 – 349 USD	22	8.7%
	> 350 USD	11	4.3%
Status of residence	Boarding House	98	38.7%
	Living with Relatives	46	18.2%
	Living with Parents	109	43.1%
Daily Exercise	Never	48	19.0%
	Rarely	60	23.7%
	Sometimes	75	29.6%
	Often	35	13.8%
	Always	35	13.8%
Sleep Duration	Less than 8 hours	149	58.9%
	8 hours or more	104	41.1%
Nutritious Diet	Never	4	1.6%
	Rarely	23	9.1%
	Sometimes	84	33.2%
	Often	74	29.2%
	Always	68	26.9%
		Mean	SD
COVID-19 Preventive Behavior	Avoid touching eyes nose mouth	3.37	1.16
	Washing hands	4.24	0.90
	Social Distance	3.84	1.05
	Stay home/avoid crowds	3.86	1.05
	Use mask	4.82	0.52
	Cough/sneeze etiquette	4.31	0.96
Student Health	No Flu/Cold	12.6	1.65
	No Sleep Disturbance	15.4	3.57
	No Headache	14.1	4.36
	No Digestion Problems	17.3	2.72

Table 3. Bias-Corrected Regression Weight and Standardized Regression Weight

Parameter			Estimate	Lower	Upper	SE	p(BC)
Regression Weights							
Sleep Duration	β	COVID19 Prevention	0.093	0.007	0.174	0.042	0.038*
Sleep Duration	β	Socioeconomic	0.083	0.02	0.145	0.032	0.01*
Nutritious Diet	β	COVID19 Prevention	0.637	0.424	0.907	0.124	0.001**
Nutritious Diet	β	Socioeconomic	0.194	0.082	0.318	0.061	0.001**
Daily Exercise	β	COVID19 Prevention	0.501	0.212	0.789	0.149	0.001**
Daily Exercise	β	Socioeconomic	-0.002	-0.183	0.177	0.092	0.956
Student Health	β	Socioeconomic	-0.076	-0.253	0.083	0.088	0.356
Student Health	β	COVID19 Prevention	-0.095	-0.411	0.169	0.145	0.47
Student Health	β	Sleep Duration	0.337	0.058	0.66	0.155	0.018*
Student Health	β	Nutritious Diet	0.351	0.164	0.621	0.115	0.001**
Student Health	β	Daily Exercise	0.13	0.016	0.268	0.065	0.026*
Washing Hands	β	COVID19 Prevention	0.796	0.647	0.961	0.078	0.001**
Stay Home	β	COVID19 Prevention	0.697	0.478	0.915	0.109	0.001**
Coughing Sneezing	β	COVID19 Prevention	0.741	0.537	0.962	0.108	0.001**
Sleep Disturbance	β	Student Health	2.367	1.714	3.289	0.415	0.001**
Headache	β	Student Health	2.865	2.164	4.055	0.468	0.001**
Avoid Touching	β	COVID19 Prevention	0.98	0.811	1.186	0.095	0.001**
Using Mask	β	COVID19 Prevention	0.224	0.102	0.432	0.08	0
Father Education	β	Socioeconomic	0.807	0.627	0.983	0.091	0.001**
Mother Education	β	Socioeconomic	0.898	0.747	1.104	0.091	0.001**
Family Income	β	Socioeconomic	1	1	1	0	...
Distancing	β	COVID19 Prevention	1	1	1	0	...
Flu/Cold	β	Student Health	1	1	1	0	...
Digestion	β	Student Health	1.471	1.064	2.003	0.237	0.001**
Standardized Regression Weights							
Sleep Duration	β	COVID19 Prevention	0.146	0.01	0.258	0.064	0.04*
Sleep Duration	β	Socioeconomic	0.185	0.045	0.316	0.068	0.009**
Nutritious Diet	β	COVID19 Prevention	0.484	0.338	0.613	0.07	0.001**
Nutritious Diet	β	Socioeconomic	0.21	0.09	0.329	0.062	0.001**
Daily Exercise	β	COVID19 Prevention	0.3	0.126	0.445	0.082	0.001**
Daily Exercise	β	Socioeconomic	-0.002	-0.15	0.151	0.077	0.956
Student Health	β	Socioeconomic	-0.079	-0.246	0.091	0.088	0.372
Student Health	β	COVID19 Prevention	-0.069	-0.256	0.136	0.101	0.503
Student Health	β	Sleep Duration	0.158	0.027	0.28	0.066	0.022*
Student Health	β	Nutritious Diet	0.337	0.18	0.49	0.081	0.001**
Student Health	β	Daily Exercise	0.159	0.015	0.301	0.074	0.031*
Washing Hands	β	COVID19 Prevention	0.684	0.583	0.768	0.047	0.001**
Stay Home	β	COVID19 Prevention	0.511	0.362	0.635	0.069	0.001**
Coughing Sneezing	β	COVID19 Prevention	0.596	0.458	0.702	0.062	0.001**
Sleep Disturbance	β	Student Health	0.7	0.582	0.803	0.056	0.001**
Headache	β	Student Health	0.694	0.581	0.791	0.054	0.001**
Avoid Touching	β	COVID19 Prevention	0.65	0.535	0.752	0.055	0.001**
Using Mask	β	COVID19 Prevention	0.333	0.182	0.493	0.08	0.001**
Father Education	β	Socioeconomic	0.73	0.625	0.814	0.049	0.001**
Mother Education	β	Socioeconomic	0.833	0.746	0.907	0.04	0.001**
Family Income	β	Socioeconomic	0.711	0.617	0.794	0.045	0.001**
Distancing	β	COVID19 Prevention	0.73	0.62	0.807	0.048	0.002**
Flu /Cold	β	Student Health	0.638	0.519	0.735	0.055	0.001**
Digestion	β	Student Health	0.571	0.445	0.683	0.059	0.001**

*<0.05; **<0.01; 95% confidence intervals (bias-corrected percentile method); Two Tailed Significance (bias-corrected)

Table 4. Total. Direct and Indirect Effects

Effects	Socioeconomic		COVID Preventive		Daily Exercise		Sleep Duration		Nutritious Diet	
	estimate	p(BC)	Estimate	p(BC)	estimate	p(BC)	estimate	p(BC)	estimate	p(BC)
Total Effects										
Daily Exercise	-0.002	0.956	0.501	0.001**	0	...	0	...	0	...
Sleep Duration	0.083	0.01*	0.093	0.038*	0	...	0	...	0	...
Nutritious Diet	0.194	0.001**	0.637	0.001**	0	...	0	...	0	...
Student Health	0.019	0.817	0.225	0.054	0.13	0.026*	0.337	0.018*	0.351	0.001**
Digestion	0.029	0.821	0.331	0.053	0.192	0.025*	0.496	0.015*	0.516	0.001**
Headache	0.056	0.819	0.645	0.066	0.374	0.029*	0.965	0.017*	1.005	0.001**
Sleep Disturbance	0.046	0.826	0.533	0.071	0.309	0.032*	0.798	0.021*	0.831	0.001**
Flu/Cold	0.019	0.817	0.225	0.054	0.13	0.026*	0.337	0.018*	0.351	0.001**
Standardized Total Effects										
Daily Exercise	-0.002	0.956	0.3	0.001**	0	...	0	...	0	...
Sleep Duration	0.185	0.009**	0.146	0.04*	0	...	0	...	0	...
Nutritious Diet	0.21	0.001**	0.484	0.001**	0	...	0	...	0	...
Student Health	0.02	0.826	0.164	0.069	0.159	0.031*	0.158	0.022*	0.337	0.001**
Digestion	0.012	0.821	0.094	0.06	0.091	0.028*	0.09	0.017*	0.192	0.001**
Headache	0.014	0.825	0.114	0.065	0.11	0.028*	0.109	0.017*	0.234	0.001**
Sleep Disturbance	0.014	0.825	0.115	0.072	0.111	0.033*	0.11	0.02*	0.236	0.001**
Flu/Cold	0.013	0.825	0.105	0.064	0.102	0.029*	0.101	0.021*	0.215	0.001**
Direct Effects										
Daily Exercise	-0.002	0.956	0.501	0.001**	0	...	0	...	0	...
Sleep Duration	0.083	0.01*	0.093	0.038*	0	...	0	...	0	...
Nutritious Diet	0.194	0.001**	0.637	0.001**	0	...	0	...	0	...
Student Health	-0.076	0.356	-0.095	0.47	0.13	0.026*	0.337	0.018*	0.351	0.001**
Standardized Direct Effects										
Daily Exercise	-0.002	0.956	0.3	0.001**	0	...	0	...	0	...
Sleep Duration	0.185	0.009**	0.146	0.04*	0	...	0	...	0	...
Nutritious Diet	0.21	0.001**	0.484	0.001**	0	...	0	...	0	...
Student Health	-0.079	0.372	-0.069	0.503	0.159	0.031*	0.158	0.022*	0.337	0.001**
Indirect Effects										
Student Health	0.096	0.002**	0.32	0.001**	0	...	0	...	0	...
Digestion	0.029	0.821	0.331	0.053	0.192	0.025*	0.496	0.015*	0.516	0.001**
Headache	0.056	0.819	0.645	0.066	0.374	0.029*	0.965	0.017*	1.005	0.001**
Sleep Disturbance	0.046	0.826	0.533	0.071	0.309	0.032*	0.798	0.021*	0.831	0.001**
Flu Cold	0.019	0.817	0.225	0.054	0.13	0.026*	0.337	0.018*	0.351	0.001**
Standardized Indirect Effects										
Student Health	0.1	0.003**	0.234	0.001**	0	...	0	...	0	...
Digestion	0.012	0.821	0.094	0.06	0.091	0.028*	0.09	0.017*	0.192	0.001**
Headache	0.014	0.825	0.114	0.065	0.11	0.028*	0.109	0.017*	0.234	0.001**
Sleep Disturbance	0.014	0.825	0.115	0.072	0.111	0.033*	0.11	0.02*	0.236	0.001**
Flu Cold	0.013	0.825	0.105	0.064	0.102	0.029*	0.101	0.021*	0.215	0.001**

* < 0.05; ** < 0.01; Two Tailed Significance (bias-corrected)

Discussion

We found that COVID-19 prevention behaviors are accepted as important and are closely related to other health behaviors. This closeness means that an increase in COVID-19 prevention behavior will also be followed by an increase in other health behaviors, especially eating nutritious food, exercising, maintaining diet, and sleeping patterns. Performing these behaviors will improve the health level, especially for students. Eating nutritious food is a very important factor for students to maintain their body health. On the other hand, besides COVID-19 preventive behavior, socioeconomic status also affects a nutritious diet. To counteract the negative impact of the low socio-economic status of the family, it is necessary to develop several policies by educational institutions to maintain the quality of student health.

Universities in low income areas can endorse the use of climatologically available balanced-nutrition sources. East Nusa Tenggara is an archipelago and is a semi-arid climate with vegetation that tends to be dominated by savanna and steppe. The dominant agricultural products are rice, maize, and beans. This can be seen from the type of food consumed, such as corn, peanuts, moringa, papaya leaves, or pumpkin shoots. Judging from the mixture of food ingredients, it is quite diverse and almost complete in nutrition, because the energy source is found in corn, protein sources come from nuts, and vitamins and minerals come from vegetables. This type of food is usually consumed by farming communities or from the middle to lower economic groups, who rely on farming in the garden. Although it is fairly simple, it contains almost complete nutrients.

Educational institutions need to issue a special policy regarding COVID-19 on campus, thus facilitating the educational process to comply with health protocols during the COVID-19 pandemic. Dissemination of health information using various media (including forums and classes in e-learning) needs to be encouraged.

The quality of sleep/rest for students needs to be considered well, especially when adapting to the online lecture system. College assignments should not be used as compensation for distance learning. Class management using Asynchronous Learning has to be encouraged to adapt with time schedules, furthermore it will enabling students that living on remote areas

to access learning material offline, thus, the effect of low socioeconomic status on the quality of rest can be reduced by providing opportunities for students directly to rest well and lowering the academic burden.

Conclusion

COVID-19 preventive behavior and socioeconomic status indirectly affect the health of students. Students tend to be able to access nutritious food, but it is not followed by regular daily exercise. Participants have adequate COVID-19 prevention behavior, for example using the mask, washing hands, and cough/sneeze etiquette but only half of participants had sufficient time to rest or sleep. Overall, students have a good level of health.

Conflict of Interest: There are no conflicts of interest.

Source of Funding: The study was self-funded project.

Ethical Clearance: This study was carried out after obtaining ethical approval from the Institutional Ethics Committee on the Nusa Cendana University in April 2020.

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Women Empowerment and their Role in Ensuring Household Food Security in Mymensingh Division of Bangladesh

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Abstract

The study was carried out to determine the women empowerment, their role in household food security of the districts of Mymensingh division in Bangladesh. The study also emphasized to explore the influence of women empowerment status on household food security, food consumption pattern. A total of 200 women from four selected districts (Mymensingh, Sherpur, Netrokona, Jamalpur) were interviewed for the study.

Most of the participants are of bangali (98%) ethnicity; and follower of Islam religion (95%). When the respondents were classified according to their occupation, most of them found to be housewives (77.3%). The study found an overall empowerment score of 42.61+13.31 (Mean+SD) in a range of 0-100. The study reveals that 41.8% of the households are severely food insecure, whereas 43.2% are moderately food insecure. It observed that, households with empowered women are more food secure than household with less empowered women ($p=0.02$). A positive relation was found for empowerment score with food consumption score ($r=0.190$).

The study reveals empowerment of vulnerable women group is significantly associated with the food security and dietary consumption of the corresponding households. The study suggest further research to determine the cause-effect relationship of these factors, confounding factors that may influence the relationship and specific aspects of empowerment of women that effectively influence the food security, dietary consumption and nutrition profile at larger community.

Keywords: Bangladesh Demographic Health Survey, Food and Agricultural Organization, Household Income and Expenditure Survey, Household Food Insecurity Access Scale, Nutrition health and demographic survey of Bangladesh (NHDSBD)

Introduction

Empowerment is a complex concept. It may vary in cultures, persons, sexes, occupations and position in life. Men and women may have a different view on empowerment in general and on women's empowerment in particular¹. As women constitute approximately 50% of total population in Bangladesh, sustainable development is not possible without incorporating them in mainstream of national development activities.

Economic empowerment of women upholds when they involve in any income generating activities other than household works. At divisional level, employed women of all divisions receive cash as a major form of earning (about 81% to 94%), but in case of Sylhet (68.8%) and Khulna (73.8%) the percentage is slightly lower.² There is significant difference between the proportion of women of Mymensingh division and women of other divisions with respect to their role played in decision making in health and household purchase. In Mymensingh, the percentage of women taking decision alone as against husband taking decision alone are 26.8% and 36.7% respectively in women's health, 7.3% and 54.7% respectively in major household purchase, 1.3% and 51.9% respectively in purchase of daily household

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needs and 48.2% and 14.8% in child health. This is the highest percentage in almost all categories among the division². The concept of food security is defined as including both physical and economic access to food that meets people’s dietary need as well as their food preferences.³ The profound influence of household food security on dietary intake and health and nutritional status of adults and children is supported by a substantial body of research. Food security has multi-dimensional effects, resulting in hunger and malnutrition. After effects of food security include reduced dietary intake, decreased household food supply, psychological dysfunction, and various health problems.⁴ The significance of determining vulnerability to food insecurity and malnutrition among the families of having less empowered women is paramount. Monitoring food security could be helpful to identify and understand this basic aspect of well-being of the women of Bangladesh.⁵

Methodology

Study design

The design for the present study is cross-sectional study design.

Sampling design

Sample size was calculated using standard statistical formula at the outset of the study. The appropriate sample size for a population based survey is determined largely by three factors:

- The estimated prevalence of the variable of interest (prevalence of employment status)
- The desired level of confidence
- The acceptable margin of error.
- Sample size was calculated for the key indicator.

The following formula was used to calculate the sample size.

$$n = \frac{z^2 p(1-p)}{d^2}$$

Where, n= required sample size for survey, expressed as number of units of analysis,

z= the standard normal deviate, set as 1.96 (95% CI)

p= the proportion of favorable value of major study variable

Here, prevalence of employment status in women .32(32%)

d= acceptable error of margin, here set as 0.065(6.5%)

According to recent report the prevalence of employment status among women in Bangladesh is 32%.² For this descriptive cross sectional study with 95% confidence interval, and 6.5% precision, A total of 200 women were selected finally for the study. Women of four district (Mymensingh, Sherpur, Jamalpur, Netrokona) were interviewed. The sampling was drawn from the NHDSBD-2011 under the framework of integrated Multipurpose sampling (IMPS) design developed on the basis of sampling frame on the population and housing census 2001.

Questionnaire Development:

Before the survey, a structured questionnaire was developed.

The questionnaire was categorized into major four sections:

- Section A: Household demographic questionnaire
- Section B: Women empowerment questionnaire
- Section C: Household food security questionnaire
- Section D: Morbidity questionnaire.

Data Collection and Quality Control:

The secondary data used for this survey collected from NHDSBD-2013. Due to missing of empowerment data field activities were employed at the same location of NHDSBD-2013. The field activities started on September 2017- January 2018. A team was responsible for regular observations at the household level and checks of data for validity and completeness. All of the data collection forms were checked either at the field or as soon as the team returns from the field on the same evening for completeness, accuracy and consistency.

Study indicators

Women empowerment

There are a number of studies available on empowerment measuring techniques. After a careful study of the available literature ⁶ five indicators of empowerment were selected for this study. These were: a woman’s decision making ability within the family

(Indicator 1), ownership of assets (Indicator 2), access to and decisions on credit and control over income (Indicator 3), leadership (Indicator 4) and workload and leisure (Indicator 5)

A number of items/questions were arranged under each of these five domains. A scoring procedure was adopted to measure the empowerment of women in each of the indicator (Table 1)

Table 1: Measuring women empowerment score

	Empowerment indicator	Item	Responses and scoring	Possible score range
1.	Role in decision making	8	Egalitarian/Jointly (2), feminine (1), others (0)	0-16
2.	Ownership of asset	16	A weighted score was given to each asset upon their monetary value ,ownership (sole or joint)	0-505
3.	Control over use of income	6	Yes(2), No(0)	0-12
4.	Leadership	10	Full influence(2), Moderate influence(1) No influence(0)	0-20
5.	Workload Leisure	6	Very satisfied(3), Neither satisfied nor dissatisfied(1), dissatisfied (0)	0-18

Formula used to calculate individual indicator score-

$$\text{Individual indicator score} = \frac{\text{Score obtained} \times 100}{\text{Maximum Possible score}}$$

Formula used calculate total empowerment score-

$$\text{Total empowerment score} = \frac{\text{Indicator 1} + \text{Indicator 2} + \text{indicator 3} + \text{Indicator 4} + \text{indicator 5}}{5}$$

The empowerment score of a respondent in a particular indicator of empowerment was computed by adding the scores obtained in all items I that class. Score of each indicator was converted to the scale of 100. Finally, an average score was computed by adding scores of all five dimensions and then divided with 5. The score was further ranked to classify respondents into three broad categories (highly empowered, moderately empowered and less empowered).

Food Security

Household food security was measured by Household Food Insecurity Access Scale HFIAS tool consists of nine questions which are aimed in extracting information required for defining the households’ food insecurity status.

Frequency of consumption of food items was measured using the food consumption score (FCS) established by WFP. FCS is a well defined indicator and its cut –offs are standardized and has been used

across regions and livelihood groups. It is a composite score based on dietary diversity, food frequency and relative nutritional importance of different food groups. Formula for calculating FCS-

$$FCS = a_{Staple} \times X_{Staple} + a_{pulse} \times X_{pulse} + a_{vegetable} \times X_{vegetable} + a_{fruit} \times X_{fruit} + a_{Meat \& fish} \times X_{Meat \& fish} + a_{Dairy} \times X_{dairy} + a_{Sugar} \times X_{Sugar} + a_{oil} \times X_{oil}$$

Table 2: Different scales of food security categorized into two groups

Tool (score)	Food secure household	Food insecure household
HFIAS (0-27)	Food secure	Mild, moderate, severe
Food consumption score	Low and high consumption score	Poor and borderline consumption score

Data Management and Analysis

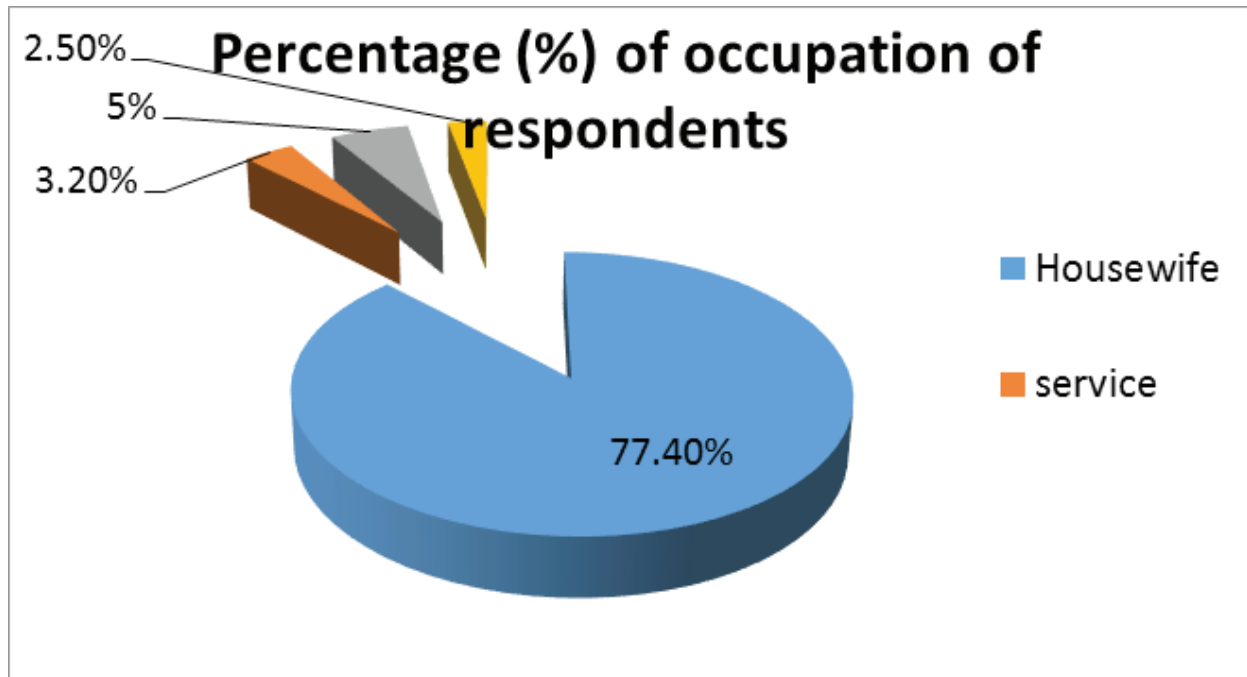
Data management for household survey included editing of questionnaires, computerization of data and preparation of tables. Frequencies, percentage, mean and standard deviation (SD) were calculated for the demographic characteristics and other indicators. Differences in categorical variables were tested using Chi-square tests. All tests was considered significant at $p < 0.05$ level. Degree of correlation between continuous variable was measured by Karl Pearson correlation coefficient. Data analysis was performed using the SPSS version 21.0 windows.

Result

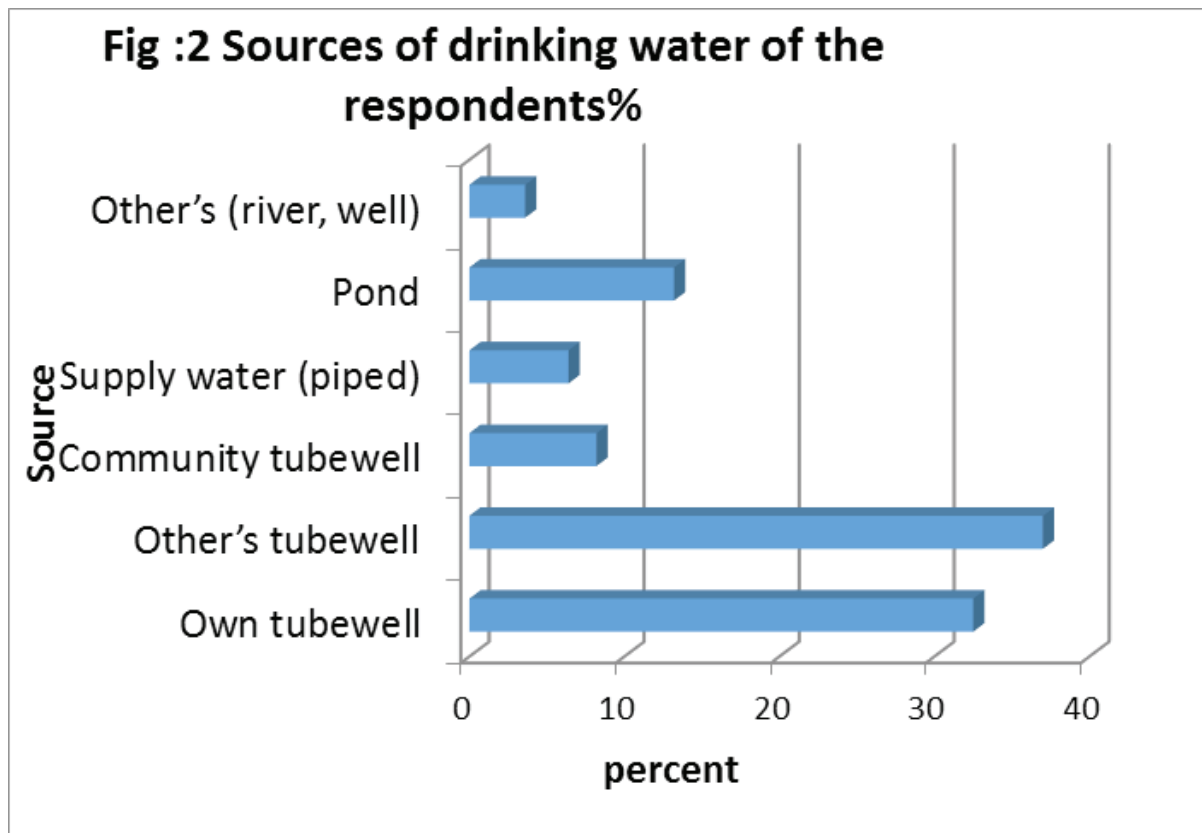
Chapter 1: socio economic profile of respondents

Table 3: Socio economic characteristics of the respondents (n=200)

Characteristics	Number	Percentage
Ethnicity		
Bangali	197	98
Garos	3	2
Religion		
Islam	198	99
Hindu	2	1
Education		
No education	57	28
Primary	64	32
Secondary	70	35
Secondary complete or higher	6	3.3



. Figure 1: Occupation distribution of the respondents



Chapter 2: Women empowerment

Table 4 summarizes the distribution of empowerment score obtained by the respondents in five different indicators. The study found an overall empowerment score of 41.74+21.312 (Mean+SD) in a range of 0-100. Women were found more empowered in the indicator of “workload and leisure” presenting a score of 65.48, whereas they were poorly empowered in “asset ownership” (10.48).

Table 4: women empowerment score distribution in different indicators

Indicators	Mean±SD	Minimum	Maximum
Role in decision making	40.19±12.66	4.55	72.73
Asset ownership	12.4±15.37	0	91.85
Control over use of income	40.64±23.5	8.33	100
Leadership	50±25.0	0	100
Workload and leisure	65.48±30.03	0	100
Overall empowerment	41.74±21.312	10.91	85.34

*all the scores were converted into a scale of 100

Chapter 3: Household food consumption and food security

Figure 3 portrays the food consumption profile of the households according to the methodology of WFP. Acceptable food consumption was found in 64% of the household, whereas 32% households reported of borderline food consumption.

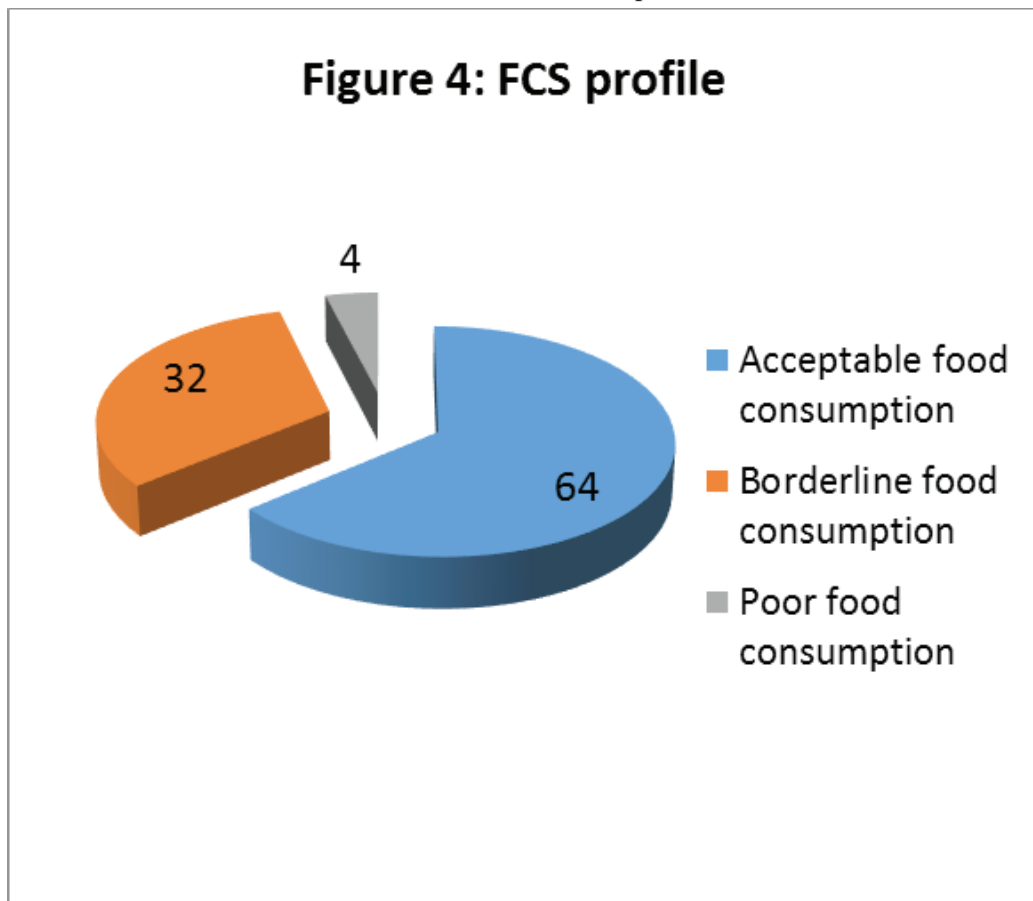
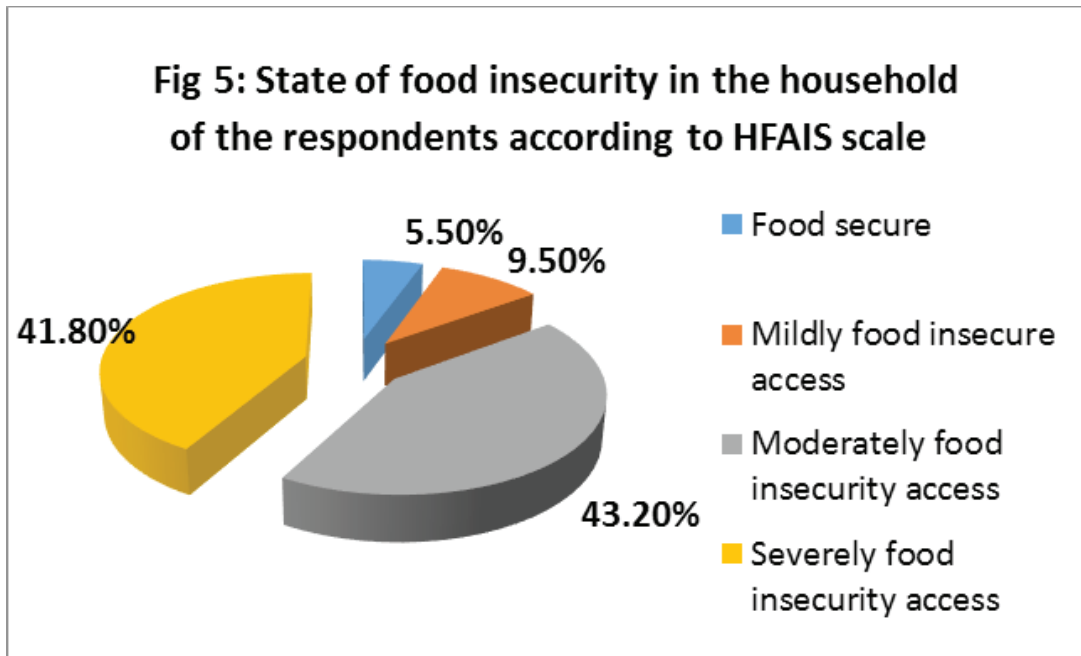


Figure 4 depicts that the state of food insecurity in the households of the respondents. Following the scoring protocol of HFAIS the study reveals that 41.8% of the households are severely foodinsecure, whereas 43.2% are moderately food insecure.



Chapter 5: Influence of women empowerment on food security

The study measured empowerment score, along with the calculation of household food insecurity access score (HFIAS) and Food consumption score in the respondents.

Table 5: Weekly dietary consumption pattern in the household of the respondents in last seven days by empowerment.

	Less Empowered (Mean)	Moderately Empowered (Mean)	Highly Empowered (Mean)
Food Groups			
Cereals	7.00	7.00	7.00
Roots and tubers	5.18	5.08	4.89
Pulse	1.26	0.70	1.45
Green leafy vegetables	5.33	5.84	5.89
Fruits	2.58	2.89	2.84
Meat and poultry	3.78	3.54	4.45
Dairy	0.97	1.34	1.40
Oil and fats	6.93	7.00	6.89
Sugar, molasses and honey	2.15	2.46	2.79

Table 6: State of food insecurity in the household of the respondents according to HFIAS scale by empowerment

	Less Empowered	Moderately Empowered	Highly Empowered	P Value*
State of food insecurity	n	n	n	n
Food secure	2	3	7	0.02
Mildly food insecure access	4	7	10	
Moderately food insecure access	28	30	37	
Severely food insecure access	39	34	19	
* Fisher's exact test was used in place of chi square test to see the statistical significance level because some cells contained less than 5 observations.				

Discussion

The objective of the study was to determine the empowerment, food security among the women group of Mymensingh divisions in Bangladesh. The study also attempted to see the influence of empowerment on the food security and dietary quality of the respondents. The mean empowerment score indicates that each women participated in the survey have an empowerment level of 42.61 (maximum possible score is 100), whereas BDHS 2014 reported that 42% of women in Bangladesh can make decision in key four indicators (own health care, major household purchases, child health care and visits to their family or relatives)⁷. However, there might be an apparent corroboration of findings of the survey with BDHS. Among five empowerment indicator, asset ownership showed a notable difference than the others (10.48 vs. 42.19, 43.64, 52.39 and 64.37). Although, a good number of respondents reported of having sole, or joint ownership, but in case of selling power. May be the reason behind this is our social structure, which disabled the vulnerable women's access to the assets. Participants of the study showed the best empowerment performance in the leisure and workload.

The study reveals that acceptable food consumption was found in 64% of the household, whereas 32% households reported of borderline food consumption.

A study in Bangladesh where 120 thalassemia patients were taken as a sample, 35.8% of patients consumed acceptable low food diet, 32.5% consumed borderline food diet and only 6.7% of patients consumed acceptable high food diet.⁸

Another study in Bangladesh 2% of the children belonged to families with poor food consumption score and 21.3% belonged to families with borderline food consumption score.⁹

According to the scoring protocol of HFAIS the study reveals that 41.8% of the households are severely food insecure, whereas 43.2% are moderately food insecure.

A study in Bangladesh where 100 households were taken as a sample, Among those about 19% households were food insecure. Of those households, 6% were mildly food insecure, 11% and 2% households were moderately and severely food insecure, respectively.¹⁰

The study found a significant relationship ($p=0.02$) between empowerment and food insecurity category. It observed that, households with empowered women are more food secure than household with less empowered women.

Limitation of the Study

However, it was not possible to take different confounding factors that may influence the relationship were not considered in the study. The study suggest further research to determine the cause-effect relationship of these factors, confounding factors that may influence the relationship and specific aspects of empowerment of women that effectively influence the food security, dietary consumption and nutrition profile at larger community.

Conclusion

Empowerment of women is considered important since it is believed that empowerment of women is vital to reduce poverty as well as achieving the Sustainable Development Goals (SDGs). Several studies already found empowerment has significant effect on child nutrition status. In this regards, this study seeks to investigate the current status of empowerment of vulnerable women group, along with their food security and iron deficiency status.

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Ethical Consideration: This study was approved by Ethical Review Board of University of Dhaka. The researchers clarified the objective of this research and obtained informed consent from the respondents.

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Competing Interest: Authors declare to have no conflict of interest.

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Multifocalelectroretinography Result before and after Peribulbar Injection of Allogeneic Umbilical Cord – Mesenchymal Stem Cell Secretome for Late-Stage Retinitis Pigmentosa

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Abstract

Background: Retinitis Pigmentosa (RP) is a rare retinal genetic disease without available treatment to date. Previous studies show growth factor and regenerative ability of secretome from cultured allogeneic umbilical chord mesenchymal stem cells (UC-MSC). This study aimed to report multifocal electroretinography of retinal photoreceptor response from RP patients, before and after injection of secretome from allogeneic UC-MSC.

Patients and Methods: Four subjects with severely damage retina (visual field defect of 25 %- 50% in initial Humphrey perimetry examination) were recruited and given peribulbar injection of secretome from allogeneic cultured UC-MSC. Visual acuity, visual field examination, multifocal electroretinogram of retinal photoreceptor examination were observed before and periodically after injection until six months period

Results: Overall, we observed subtle changes in N1 and P1 amplitude and implicit time only in ring 1 at 1, 3 and 6 month post secretome injection.

Conclusion: Peribulbar injection of allogeneic UC-MSC secretome had very minimal influence on photoreceptor activity in late-stage RP patients.

Keyword: Retinitis Pigmentosa, Secretome, Umbilical Chord, Allogeneic, Electroretinogram.

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Introduction

Retinitis Pigmentosa (RP) is a retinal disease characterized by progressive peripheral retinal photoreceptors damage causing blindness mostly in productive age. Mutation of genes, disruption of oxygen supply, and chronic inflammation of the Retinal Pigment Epithelium (RPE) are considered to be etiology of RP^{1,2}.

A study by Yoshida et al.³ found a significant level of inflammatory cytokines in vitreous humor and aqueous humor of RP patients. This inflammation was speculated to contribute to RPE damage and led to photoreceptor death³. However to date, despite extensive understanding about the pathophysiology of RP, there has been no definitive therapy for the disease^{1,3}

Mesenchymal stem cells (MSC) have an ability to modulate immune system and suppress inflammatory cytokine activity. Previous evidence suggested that stem cells are also able to control immune response and produce microRNA (miRNA), Nerve Growth Factor (NGF), Brain Derived Neurotrophic Factor (BDNF), Ciliary Body Neurotrophic Factor (CBNF) and other neurotrophic factors to revitalize the residual bipolar and photoreceptor cells in retina of RP patients. In support of this, more recent study using bone marrow autologous mesenchymal stem cell with intravitreal injection technique showed a temporary visual acuity improvement in a small group of RP patients^{2,4}, which opens a potential venue for RP therapy using stem cells.

Cultured umbilical cord-mesenchymal stem cells (UC-MSC) releases growth factors and genetic materials in its secretome which has a regenerative capability. Exosome found in the secretome, contains miRNA – a non-coding RNA, which contributes to epigenetic control. Several studies have suggested that miRNA may influences the epigenetic of cells to either silence or activate the genes⁵. Taken together, we speculated that secretome taken from UC-MSC contribute to influence mutated genes through modification of transcription, acetylation and methylation of histone which hopefully can improve metabolism as well as function of photoreceptors^{5,6}. Nevertheless, none of previous studies have used UC-MSC in patients with RP.

We performed a preliminary study to observe the effect of UC-MSC secretome on patients with RP. In this case series, we investigated the changes in electrophysiology, as a proxy of sub-clinical photoreceptor activity, of peribulbar injection of secretome from UC-MSC for patients with RP. The rationale of this study are two folds: first, peribulbar has extensive capillary blood vessels, therefore is a good entrance to ocular's blood circulation⁷. Second, secretome is rich of growth factors and genetic materials

which potentially incite regenerative process and epigenetic control to improve photoreceptor function in patients with RP and slow the progression of RP⁸⁻¹⁰.

Material and Methods

Study Design and Patient Selection

We performed an interventional case series of 4 patients with confirmed RP based on their clinical history, symptoms, dilated fundus examinations, Humphrey visual field analyzer (HFA) and electroretinography (ERG) examination. The Study conducted in June 2018 – June 2019 at Dr. Sardjito General Hospital, Yogyakarta, Indonesia. Patients were selected from our existing RP registry. We only included patients with visual acuity better than 20/100 or cone receptor ERG amplitude more than 0,68 μ V or with visual field wider than 10°. This condition is better than floor effect which is the final stage of RP. We speculated that there will be photoreceptors still functioning in the retina. Written consent was obtained from each participant. This study was conducted in accordance to Declaration of Helsinki (1964). This study was registered in www.clinicaltrials.gov with identifier NCT04315025 and ethical approval was obtained from Medical and Health Research Ethics Committee, Faculty of Medicine Public Health and Nursing, Universitas Gadjah Mada (KE/ FK/ 0616 / EC/2018).

The study was conducted at Public Hospital Dr. Sardjito, Yogyakarta. The stem cells isolation was performed at Prodia Stem Cell Indonesia (ProSTEM) Laboratory, Jakarta.

Stem Cell Isolation and Secretome Production

Isolation and Culture of Umbilical Cord Mesenchymal Stem Cell

Fresh Umbilical Cord (UC) tissue sample was obtained, minced into less than 5 cm pieces then stored into transport medium containing PBS with 1% antibiotic-antimycotic. To obtain a pellet of cells, initially the minced UC tissue was digested with sterile solution of 0.3% type I and/or II collagenase in 50 mL conical centrifuge tube. We subsequently added growth medium of approximately twice volume of collagenase solution and centrifuged at 500G for 5 mins. The tissue was then stored at 37°C for 1 hour. The supernatant

was removed, and remaining cells were resuspended in culture medium. The viability of cells can be assessed by using Trypan blue exclusion Culture cells T75 culture dishes in 10 ml of complete MSC medium at a density of 25×10^6 cells/ml. The plate of cells was incubated at 37 °C with 5% CO₂ mixture in a moistened chamber until 3 hours. After removing the non-adherent cells that accumulate on the surface of the dish, then we left the remaining cells for 8 additional hours incubation for culture. Next, we replaced the medium with 10 ml of fresh complete medium. This procedure was frequently performed for every 8 hours until 72 hours from initial culture. Afterwards Cells were frozen in MSC growth media plus 10% DMSO at a density of 2×10^6 cells/vial^{11,12}. (Figure 1)

Collection of Conditioned Medium

We collected MSC at 4–5th passages and they were seeded with a density of 3×10^3 cells/cm² in Corning® uncoated culture plastic. Cells were cultured to 70–80% density in 100 mm culture dishes. MSC bathed thoroughly 3 times using 10 mL of HBSS without Ca²⁺ and Mg²⁺, and recultured again with low glucose MSC DMEM (DMEM-LG, HyClone). Cells were cultured in a chamber moistened with 5% CO₂ at 37°C for different time periods. Conditioned media samples containing secretome were collected and continue with centrifugation at 3000 rpm for 10 min at 4 °C to remove debris, then frozen in aliquots at –70°C^{11,12}.

Marker Detection

MSCs population was successfully cultured with positive stained for CD 73, CD 90 and CD105. The secretome was then collected from the culture^{12,13}. (Figure 1)

Clinical Examinations and Secretome Injection

Clinical evaluations were performed at pre-injection, 1, 3, and 6 month post-injection. Each evaluation included general eye examination, dilated fundus examination by a retinal specialist, visual field examination using Zeiss Humphrey Field Analyzer 3 (Carl Zeiss Meditec AG, Jena, Germany), multifocal ERG (mf-ERG) examination using Metrovision MonPackOne (Metrovision, Perenchies, France), fundus photography and optical coherence tomography (OCT)

using Zeiss Cirrus HD-OCT (Carl Zeiss Meditec AG, Jena, Germany). Best corrected visual acuity (BCVA) was measured with Snellen chart and converted to LogMar visual acuity value.

Electroretinography Examination

Mf-ERG examination was performed by a single trained operator with Metrovision® device. The examination was done alternately on each eye. Non-examined eye was patched with black, non-transparent eyepatch. We followed a standardized mfERG examination protocol by the International Society for Clinical Electrophysiology of Vision¹⁴. Briefly, a centre forehead AgCl ground electrode, an outer canthus reference skin electrode and a Jett corneal electrode were placed. We used lubricant eye gel on the surface of Jett electrode that contact to the cornea. MfERG examination was performed on the fully dilated pupil and after adjustment of refractive error. All patients underwent a 20 minutes photopic and scotopic preadaptation. Sixty-one scaled hexagons were then displayed on a high resolution, black and white cathode ray tube (CRT) monitor with a frame rate of 75 Hz as the multifocal stimuli¹⁴. We recorded the amplitude (nV/deg²) and implicit times (ms) of the first order kernel responses (N1 and P1 waves). The result was grouped into five rings: ring 1 covers central to 2°; ring 2 between 2°–5°; ring 3: 5°–10°; ring 4, 10°–15°; ring 5 : wider than 15°.

Peribulbar secretome injection

All patients received 2 ml peribulbar secretome injection containing original growth factors, exosome, microRNA from cultured umbilical cord MSC extraction¹⁵. Only the worse eye was selected due to ethical consideration, determined from the visual acuity, fundus pathology, OCT and ERG examination before the injection. Peribulbar injection was done in a semi-sterile procedure room. Standard surgical septic-antiseptic and sterile eye draping procedures were carried out to ensure minimal risk of contamination, Peribulbar secretome injection was performed using a 26G injection needle under topical anesthesia. Patients evaluated for any infection, inflammation and increase of ocular pressure in the 1st and 7th day after injection.

Results

There were four patients recruited for this study. Table 1 showed the demographic data of the patients. Overall, we recorded subtle changes in N1 and P1 amplitude and implicit time in ring 1 for subject 1, 3 and 4 at 1, 3 and 6 month post secretome injection (Table 2). Subject 1 demonstrated decreased N1 amplitude within ring 1 at 1 month after injection, but subsequent increase after 3 months and 6 month. In addition to N1 amplitude. There was a slight decrease in P1 amplitude also within ring 1 at 1, 3 and 6 month after injection. Ring 2, 3, 4, 5 showed flat patterns at each follow-up. (Table 2)

Subject 2 showed a very limited ring 1 electric activity of N1 amplitude before injection and stayed on a decreasing pattern at 1, 3 and 6 months follow-up, then the mfERG trends ended as noise, similar to the implicit time. A different response was shown by P1 amplitude, where a decreased of amplitude on the 1st month after injection followed by noise on the 3rd month after injection. Ring 2, 3, 4, 5 showed a flat pattern. (Table 2)

Subject 3 ring 1 showed N1 wave detected noise before injection, until one month after injection. There was a slight electrical N1 activity seen at 3 month. P1 amplitude wave became noise at 1 month and then re-appeared at 3 month which remained until 6 month. There was a small increase in P1 activity at 6 month. Ring 2, 3, 4, 5 also showed flat pattern. (Table 2)

Subject 4 ring 1 showed a slight improvement of N1 and P1 amplitude at 1 month after injection which was relatively stable until 3 month. However at 6 month, both N1 and P1 amplitude was reduced. N1 and P1 implicit times after secretome injection were longer than before injection at all follow up examinations. Ring 2, 3, 4, 5 showed flat pattern. (Table 2)

All patients showed very little visual acuity fluctuations. Most patients demonstrated an improvement at 6th month after secretome injection. Patients 1, 3 and 4 showed a increase visual acuity 6th month post injection, while patient 2 showed the same value before and after injection. (Table 2)

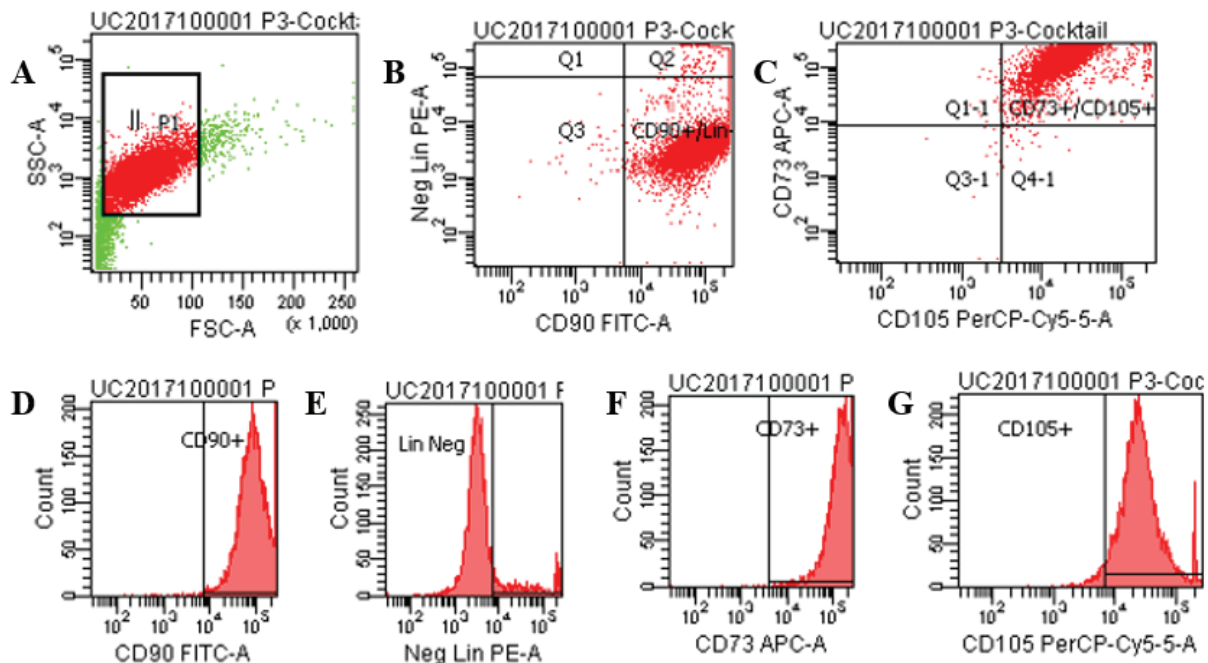


Figure 1. Mesenchymal stem cells staining

The cells were stained with specific antibody for MSC. (A) cells were initially displayed on SSC density plot (gate P1) which subgated onto identification (B) CD90 and Lin Neg (gate Q4) and (C) CD73 and CD105 (gate Q2-1). Cells positive for CD 90 FITC-A (D), Lin neg PE-A (E), CD 73 APC-A (F) and CD105 PerCP-Cy5-5-A (G)

Table 1. Patients' Demographic Data

Cases	Occupation	Injected eye	Age (y.o)	Visual Acuity in injected eye (logMAR)	IOP on Injected eye (mmHg)
Patient 1	Hospital staff	OD	31	0.5	8
Patient 2	Small village traders	OD	44	0.3	12
Patient 3	College students	OS	21	0.5	11
Patient 4	Retired	OS	51	0.7	13

IOP: Intra Ocular Pressure; y.o = years old; OD: oculus dexter; OS: oculus sinister.

Table 2. mfERG (N1, P1, and Implicit time) values on Ring 1.

Patient	Period	N1		P1		Visual Acuity
		Amplitude (nV)	Implicit time (ms)	Amplitude (nV)	Implicit time (ms)	LogMAR
1	Preinjection	-802	34.2	384	51.1	0.5
	Day 30	-162	17.6	379	50.6	0.5
	Day 90	-301	31.3	343	60.7	0.5
	Day 180	N	N	121	34.1	0.4
2	Preinjection	-176	17.2	195	57.2	0.3
	Day 30	-98.5	23.5	166	40.7	0.2
	Day 90	N	N	N	N	0.2
	Day 180	N	N	259	31.7	0.3
3	Preinjection	N	N	226	36	0.5
	Day 30	N	N	N	N	0.5
	Day 90	-28.1	50	143	63.5	0.5
	Day 180	N	N	273	43.2	0.4
4	Preinjection	-244	17.2	149	30.6	0.7
	Day 30	-341	25.1	410	48.9	0.3
	Day 90	-279	29.3	467	47.9	0.3
	Day 180	-61.1	33.3	214.0	50.4	0.2

N: noise, Normal visual acuity 6/6 = Logmar value 0

Discussion

In this study, we demonstrated subtle changes in N1 and P1 amplitude within ring 1 with prolonged implicit time, but these changes of retinal electrical activity shown by mfERG were only evident mostly within the first 3 months and did not show a specific pattern. Ring 2, 3, 4 and 5 remained flat in all follow-up period. These findings suggest that despite strong theoretical background of secretome as regenerative stimulator of photoreceptor cells, peribulbar secretome injection showed very little effect in patients with late-stage RP.

There is very little evidence in this area. A recently published study by Ozmerit and associates reported an improvement of P1 amplitudes and implicit time in all rings after sub-tenon Umbilical cord MSC injection in patient with RP¹⁶. Our findings with secretome only injection, however, did not show similar pattern of improvement. There are two things that may cause this difference. Secretome alone is not sufficient to generate supporting effect to photoreceptors and variation of retinal damage severity level in this 4 subjects may differ their response to secretome¹⁷.

Different stage of RP determines the amount of dying photoreceptor, thus require different amount of growth factor contained within secretome^{1,3,18,19}. Cultured UC-MSC produces secretome which contain growth factor and exosome²⁰. However, secretome alone only contain limited source of growth factor and exosome, when not combined with MSC. In our study, a mixture of secretome with nutrition rich conditioned media was injected to peribulbar space. Hypothetically, growth factor may activate dormant resident stem cell that lies beneath the RPE. This resident stem cell will start the regeneration process of the photoreceptor. Activated resident stem cell also send homing signal through the circulation for other stem cells from other reservoir marching in to target tissue^{20,21}. This is the paracrine effect that expected to happen in secretome injection²¹⁻²³. If stem cell was injected, the situation may be different. Stem cells will continuously produce growth factor and exosome required to repair the damage tissue^{22,23}. In genetic disease like RP, revitalization of tissue will be more likely to happen than regeneration. Mutated genes would likely initiate abnormal protein synthesis that leads to photoreceptor death but epigenetically

MSC will influence the protein synthesis and support an optimal life of photoreceptor²³⁻²⁵.

Strength of our study included meticulous preparation of UC-MSC and secretome, ensuring minimal contamination. However, there are few limitations noted in this study. First, RP is a rare genetic disease with no gold standard of treatment. Therefore, we were unable to provide comparison with other treatment group. Second, there were only very few patients recruited for this study because this is the first study to provide preliminary data on the effect of secretome treatment for patients with RP. Thus it is considered unethical to recruit a large number of patients when no prior beneficial or harmful effects are documented. Third, RP patients often come to visit ophthalmologist in the later stage of the disease when wide atrophy of photoreceptor already exist. It is hard to find group of patients with the same stage of photoreceptor damage because patients more likely unaware of peripheral visual field loss in early stage of the disease.

Conclusion

In this preliminary group of patients with late-stage RP, we demonstrated subtle changes and limited individual variation without any specific pattern of mfERG activity after peribulbar secretome injection, suggesting that peribulbar injection of allogeneic UC-MSC secretome may only have minimal influence on photoreceptor activity in late-stage RP patients. At the same time, our findings also suggested that there may be potential value of secretome injection in patients with RP, but the beneficial effects of secretome injection have not been well-concluded despite its strong theoretical foundation. Therefore, further studies with more subjects with less severe stage of RP are warranted.

Ethical Clearance: Ethical approval was obtained from Medical and Health Research Ethics Committee, Faculty of Medicine Public Health and Nursing, Universitas Gadjah Mada (KE/ FK/ 0616 /EC/2018).

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who involved in secretome production and stem cell isolation but has no involvement in the study design, data collection nor data analysis. None of other authors has any conflict of interest.

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Aerobic Fitness and the Risk of Metabolic Syndrome in Adolescents

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Abstract

In order to determine whether aerobic fitness is associated with individual features of metabolic syndrome (MS) and metabolic risk score (MRS), a sample of 206 adolescents (Girls=105; Boys=101) was assessed. Participants were divided into two (fit: n=114; unfit: n=92) groups based on their estimated aerobic fitness levels. Prevalence of MS in the total sample was 5.3% with majority of cases from the unfit group (3.4%). 47.6% of the participants had one or more metabolic risks, again majority from the unfit group (30.6%). When adolescents with one or more metabolic risks were compared with their non-risk peers, those without risk demonstrated significantly ($p<0.05$) more favorable profile in all features of MS, MRS and peak $\dot{V}O_2$. Aerobic fitness was significantly ($p<0.05$) correlated with all features of MS and MRS except for triglycerides. Fitness moderately predicted MRS ($R^2=19.7\%$), after controlling for percent fat (% fat). Unfit adolescents were 7.1 (95% CI=3.80-13.20) times likely to develop risk of MS compared to their fit peers. Low aerobic fitness was independently associated with MRS or any component of MS in Nigerian youth. These results further reinforce the need to include aerobic fitness among public health strategies aimed at preventing the risk of MS in youth.

Keywords: adolescents, aerobic fitness, health promotion, metabolic health, $\dot{V}O_2$ max

Introduction

The coexistence of three or more cardiovascular disease (CVD) risk factors in the same person is known as metabolic syndrome (MS). This includes abdominal obesity, hypertension, hyperglycemia, hypoalipolipoproteinemia and hypertriglyceridemia. The MS has become a major health challenge worldwide in recent times, increasing the risk of CVD, Type 2 diabetes and some form of cancer in adults.¹ However, CVD risk factors have been shown to originate in childhood and adolescence,² and progress to adulthood.³ From public health perspective, the ability to determine which youths are at risk for MS could be beneficial for

primordial prevention.

In adults, low aerobic fitness (cardiorespiratory fitness-CRF) and low physical activity (PA) levels are associated with adverse risk profiles and CVD manifestation, while higher fitness levels result in more favorable risk profile.⁴ Despite the strong evidence in adults suggesting that low CRF may predict the development of the MS,⁵ little is known about this relationship in youth. Moreover, findings from previous studies on the relationship between physical activity or fitness and the MS have been equivocal. While a few studies^{5,6} have reported that low aerobic fitness in youth was associated with MS, others have failed to demonstrate this relationship.^{7,8} Therefore, further investigation into this problem is warranted, particularly among African youth at the risk of developing MS as this could serve as a first step in the prevention of the

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disorder.

Viewed from another perspective, there is limited information on the relationship between CRF and metabolic risk in youth; therefore the association between fitness and the risk of MS remains nebulous. This study was primarily conducted to examine the association between CRF, indicators of MS and metabolic risk score (MRS) among the youth. A secondary purpose of the study was to evaluate the prevalence of MS among a cohort of adolescents in north central Nigeria. It was also of interest to determine the differences in health indicators between adolescents with or without metabolic risk factors. It was hypothesized that unfit adolescents will demonstrate unhealthy metabolic risk profile.

Materials and Methods

Participants

Participants comprised 218 apparently healthy secondary school children (115 girls and 110 boys), ranging in age from 11 to 19 years drawn from the sampled secondary schools in Kogi East Senatorial District, Kogi State of Nigeria. Details of the sampling procedure and criteria for including or excluding participants have been described elsewhere.⁹ Written informed consent of parents and assent of participants were obtained before data collection. All tests were conducted from 9-12 hours in accordance with the principles of Helsinki Declaration after prior approval was received from the Ethics Review Board of Kogi State University, Nigeria.

Anthropometric measurements

Participants' physical characteristics were measured using standard procedures.¹⁰ Body mass and stature were measured indoors with the aid of an electronic weighing scale (Seca digital floor scale, Sec-880; Seca, Birmingham, UK) and a wall-mounted stadiometer (Model Sec-206; Seca, UK). Participants' body mass index (BMI) was computed and expressed as weight in kilograms divided by stature in meters ($\text{kg}\cdot\text{m}^{-2}$).

Both the triceps and medial calf skinfold thickness was measured on the right side of participants' bodies with the aid of the Harpenden skinfold calipers (Creative Health Products, MI, USA). All measurements were taken thrice and the median of the three readings

recorded. The revised regression equations of Slaughter et al, as cited¹¹ for black children, were used to estimate percent fat. Participants were categorized into healthy weight (HW) and overweight (OW) based on their age- and sex-specific fatness levels according to the FITNESSGRAM revised data.¹² Waist circumference (WC), which estimates abdominal fat,¹³ was measured with a retractable metal tape (Creative Health Products, MI, USA) at the level of umbilicus and midway between the lower rib margin and the iliac crest. Readings were taken at the end of a quiet expiration to the nearest 0.1cm. Two measurements were taken and the average score recorded.

Fitness testing

Participants' CRF was assessed using the progressive aerobic cardiovascular endurance run (PACER) protocol. The PACER is a widely used, valid, and reliable test of aerobic fitness which has been shown to enhance fitness motivation among children and adolescents.¹⁴ The maximum speed at which a participant completed the test was used to predict peak $\dot{V}O_2$ ($\text{ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$) using the regression equation of Leger et al.¹⁵ Details of the administrative procedure of the test has been previously described.¹² To assess the influence of CRF on metabolic risk factors, the total sample was divided into two groups on the basis of each participant's peak $\dot{V}O_2$ value according to sex and age-specific FITNESSGRAM revised health-related cut-points.¹² Details of classification of participants into fitness categories (fit or unfit) has been previously described.¹⁶

Biochemical measurement

Fasting glucose (GLU), high density lipoprotein cholesterol (HDL), and triglycerides (TG) were obtained using finger stick blood samples, which were analyzed with a CardioCheck Plus Analyzer (CCPA) (PTS Diagnostics, Indianapolis, IN, USA). The CCPA is a valid and reliable instrument for analyzing blood lipids.¹⁷ Details of the protocol have been previously described.⁹

Blood pressure measurement

Blood pressure measurements were taken with an automated digital BP monitor (HEM-705 CP; Omron,

Tokyo, Japan) after participants were quietly seated for 10 minutes. The resting systolic blood pressure (SBP), diastolic blood pressure (DBP) and pulse rate were monitored on each participant's right arm using appropriate cuff sizes. This instrument has been shown to be accurate.¹⁸ Measurements were taken twice at 2-minute intervals, and the average of the two readings recorded. The mean arterial pressure (MAP) was computed using the formula: $DBP + 0.33 \times \text{pulse pressure}$.

Continuous metabolic risk score

A continuous MRS was computed from the following variables: GLU, SBP, WC, HDL, and TG. Each of these variables was standardized by subtracting the mean value for each sex group from the individual's value and then dividing the product by the value of standard deviation [$z = (\text{value} - \text{mean})/\text{SD}$]. The standardized HDL was multiplied by -1 because it is inversely related to the MS risk. The z-scores of the individual risk factor were summed to create a clustered MRS (continuous variable) for each participant with a lower score indicating a more favorable metabolic risk profile. This approach has been used in the pediatric populations previously.^{2,19} A dichotomous variable, metabolic risk profile (MRP) was created and this pertains to presence (risk) or absence (no risk) of MS risk.

Threshold for MS

Participants were classified as having MS if they had three out of the following: TG concentration of ≥ 1.7 mmol; HDL concentration of ≤ 1.04 mmol; GLU concentration of ≥ 5.6 mmol; SBP level ≥ 130 mmHg; and WC in the 90th percentile for age and sex as recommended by the International Diabetic Federation (IDF).²⁰ However, participants with one or two indicators were considered at risk of MS.

Data Analysis

Descriptive statistics (mean \pm SD) of measured and derived variables were used to summarize the sample's characteristics. The independent samples t-test was computed to test for differences in physical characteristics, performance, and features of metabolic syndrome between fit and unfit participants. Zero-order correlation coefficients were used to assess the relationship between CRF and participants' metabolic risk factors. Multiple regression analysis was conducted to determine the independent association between CRF and MRS. The independent association of CRF and MRP was examined using binary logistic regression model. Odd ratios of being at risk of metabolic syndrome were calculated between fitness categories. The model was adjusted for fatness as a confounding variable. All statistical analyses were performed using the Statistical Package for the Social Sciences (Windows Version 20; SPSS Inc, Chicago IL, USA) and statistical significance was set at an alpha level of 0.05 or less.

Results

Due to absenteeism and incomplete data, 206 (105 girls and 101 boys) completed the measurements, and their data included in the statistical analyses. This amounted to a participation rate of 94.5%. Participants' demographic, anthropometric and performance characteristics stratified by fitness status are presented in Table 1. With respect to the groups' general characteristic, unfit participants generally displayed significantly ($p < 0.05$) more unfavorable values in most variables than fit participants. However, there were no significant ($p > 0.05$) differences in %fat and TG between the groups.

Table 1: Characteristics of participants stratified by fitness status

	Combined	Fit (n = 114)	Unfit (n = 92)		
Variable	Mean SD	Mean SD	Mean SD	t-value	p
Age (y)	14.7 2.3	13.0 1.3	16.9 1.0	24.189	0.0005
Weight (kg)	53.0 12.4	48.5 12.0	58.7 10.6	6.431	0.0005
Stature (cm)	160.1 9.7	157.19.5	163.8 8.8	5.259	0.0005
Body fat (%)	15.5 7.0	15.3 6.6	15.7 7.6	0.459	0.647

Cont... Table 1: Characteristics of participants stratified by fitness status

BMI (kg.m ⁻²)	20.5 3.5	19.5 3.5	21.8 3.2	4.996	0.0005
WC (cm)	65.8 8.8	62.0 7.1	70.5 8.4	7.796	0.0005
SBP (mmHg)	105.5 16.6	99.2 16.6	113.3 13.1	6.785	0.0005
DBP (mmHg)	69.9 14.4	66.7 14.8	74.0 12.7	3.789	0.0005
MAP (mmHg)	81.7 13.8	77.5 13.9	87.1 4.7	5.27	0.0005
GLU (mmol)	5.1 0.7	4.9 0.6	5.3 0.8	3.417	0.001
HDL (mmol)	1.3 0.4	1.4 0.4	1.2 0.3	3.328	0.001
TG (mmol)	1.0 0.9	1.0 1.2	1.0 0.4	0.057	0.955
MRS	-7.7 2.2	-8.4 2.2	-6.9 1.9	5.260	0.0005
Peak $\dot{V}O_2$ (ml.kg ⁻¹ .min ⁻¹)	40.4 4.4	43.2 3.2	37.0 2.9	14.174	0.0005

Table 2: Characteristics of participants stratified by metabolic risk profile

Characteristic	Without Risk (n = 108)	With Risk (n = 98)	t-value	P
Age	13.7 ± 2.1	15.9 ± 1.9	7.877	0.0005
Weight	50.3 ± 11.9	56.0 ± 12.4	3.376	0.001
BMI	19.8 ± 3.4	21.3 ± 3.5	3.050	0.003
%fat	15.2 ± 5.9	15.8 ± 8.2	0.596	0.552
WC	61.9 ± 6.3	70.1 ± 9.1	7.484	0.0005
SBP	99.6 ± 15.7	112.0 ± 15.2	5.790	0.0005
GLU	4.8 ± 0.5	5.4 ± 0.8	6.425	0.0005
HDL	1.5 ± 0.4	1.1 ± 0.3	6.637	0.0005
TG	0.8 ± 0.3	1.2 ± 1.2	3.024	0.003
MRS	-9.0 ± 1.3	-6.4 ± 2.2	10.205	0.0005
Peak $\dot{V}O_2$	42.0 ± 4.3	38.6 ± 3.7	6.206	0.0005

The number and proportion of participants in each fitness category considered to be at risk of individual features of metabolic syndrome are presented in Figure 1. As expected, there were higher proportions of participants at risk of MS in the unfit group compared

to their fit peers. As indicated, the risk of HDL (23.8%) was highest with majority coming from the unfit group. Elevated blood GLU (21.4%) and abdominal obesity (15%) were the next highest respectively; again, with greater proportions from the unfit group.

Figure 2 displays the observed number of adolescents with number of metabolic risk factors by fitness status. Clustering or MS was found in 5.3% of the participants with majority of cases being from the unfit group. When participants with one or more risk factors were

compared with those without risk factors (MRP) the ‘no risk’ category had significantly ($p < 0.05$) more favorable peak $\dot{V}O_2$ and other metabolic risk factors compared to the ‘risk’ group. Only %fat had no significant ($p > 0.05$) difference between the two groups. Details of the results are presented in Table 2.

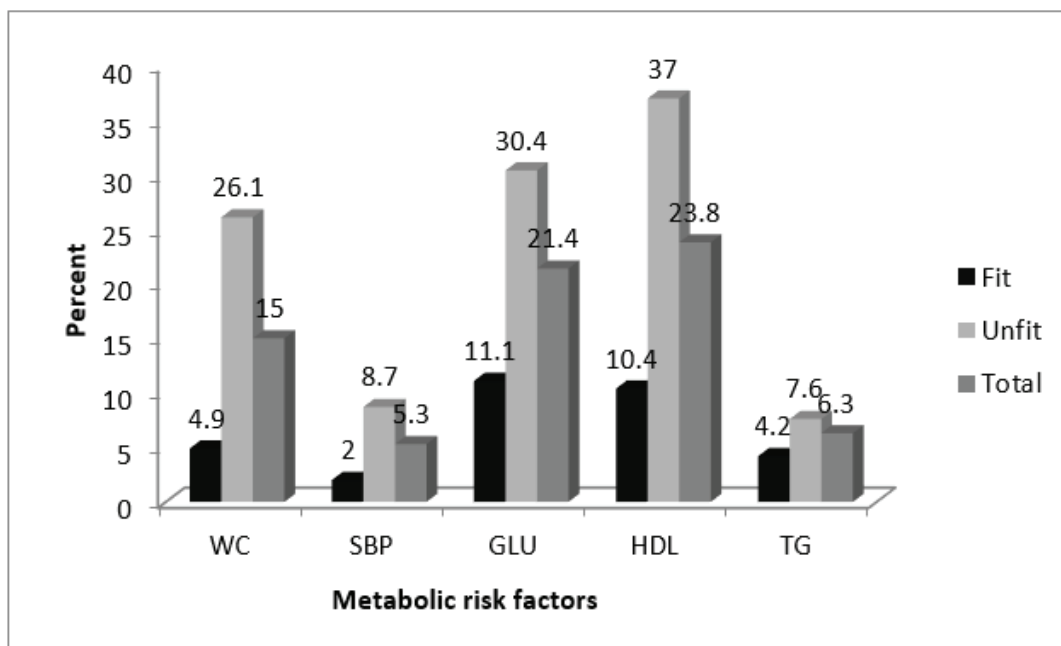


Figure 1: Prevalence of metabolic risk abnormalities by fitness status

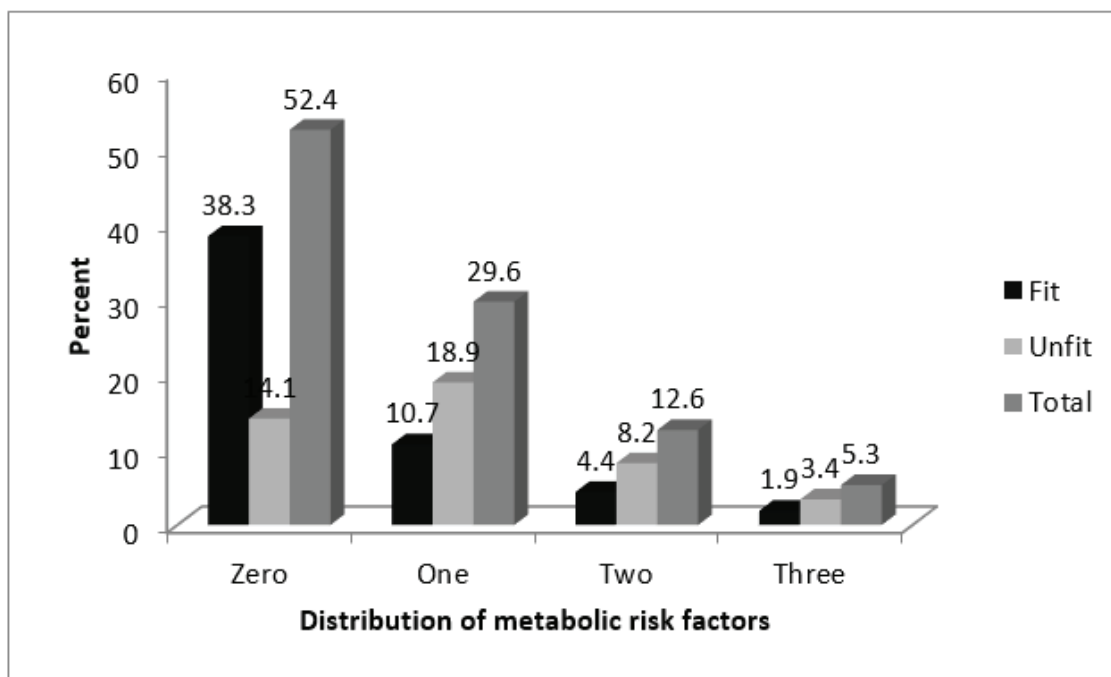


Figure 2: Distribution of metabolic disease risk by fitness status

Table 3 presents results of the zero-order correlation coefficients between CRF, components of metabolic syndrome and MRS. In general, the relationships can be described as weak to moderate. The strongest relationship was observed between CRF and WC. In this study, fatness correlated significantly ($p < 0.01$) with peak $\dot{V}O_2$. Consequently, a partial correlation analysis was computed controlling for %fat, and yet, the correlation between fitness and the metabolic risk indicators as well as MRS remained significant ($p < 0.05$].

Results of the hierarchical multiple regression model assessing the extent to which CRF could predict MRS after controlling for the confounding variable (body fat) are presented in Table 4. Fatness explained 2% of the variance in MRS in step 1. The addition of fitness in step 2 increased the total variance explained

by the model cumulatively to 19.7%, thus indicating that fitness explained additional variance of 17.7% ($\beta = .460, p < 0.0005$) after controlling for the covariate. Fitness was the only significant predictor in step 2.

Results of the logistic regression model assessing the effects of CRF and body fat on MRP showed that CRF displayed significant effect ($\chi^2_{(2, N = 206)} = 47.5, p < 0.0005$), indicating that the model was able to differentiate between adolescents without MR and those at risk. As a whole, the model explained between 20.6% and 27.5% of the variation in risk of MS and correctly classified 73.3% of the cases. Fitness was a strong predictor of MS risk with an odd ratio of 7.1 (95% CI=3.80-13.20), thereby suggesting that the likelihood of an unfit adolescent being at risk of MS is seven times that of a fit counterpart.

Table 3: Zero-Order and partial correlations between CRF and features of Metabolic Syndrome

Group	N	%fat	WC	GLU	HDL	SBP	TG	MRS
Comb	206	-0.41**	-0.58**	-0.15*	0.28**	-0.49**	-0.12	-0.44**
Fit	114	-0.57**	-0.45**	0.11	0.31*	-0.35**	-0.23*	-0.35**
Unfit	92	-0.52**	-0.31**	-0.07	-0.06	-0.22*	0.02	-0.21*
Partial r								
Comb	206	-	-0.53**	-0.20**	0.31**	-0.44**	-0.12	-0.43**
Fit	114	-	0.30**	0.09	0.27**	-0.13	-0.24**	-0.26**
Unfit	92	-	-0.23*	-0.14	0.08	-0.23*	-0.06	-0.25*

* $p < 0.05$ ** $p < 0.01$

Table 4: Fitness as predictor of MRS in a generalized linear model (n = 206)

Group	Variable	Model1			Model2		
		R2	β	P	R2	β	P
Comb	%fat	0.020	0.141	0.043	-	-0.046	0.507
	CRF	-	-	-	0.197	-0.460	0.0005
Fit	%fat	0.063	0.251	0.007	-	0.076	0.482
	CRF	-	-	-	0.112	-0.309	0.005
Unfit	%fat	0.000	0.004	0.967	-	-0.144	0.233
	CRF	-	-	-	-0.060	-0.287	0.019

Discussion

The main findings of this study include: First, the prevalence of MS is relatively lower than those previously reported for youth in developed countries, and it is higher in the unfit than fit participants. Second, the youth in our study have relatively more favorable metabolic risk indicators. Third, there is a higher proportion of youth with metabolic risk in the unfit than fit category; and the risk of hypoalbuminemia, abdominal obesity, and hyperglycemia are most common. Fourth, low CRF is associated with higher metabolic risk.

The prevalence of MS of 5.3% found in this study is similar to the 5% observed in Iranian youth²¹ and 4.6% reported for American youth,²² but the prevalence rate of 11.9% reported for the Norwegian children² is strikingly higher than ours. A plausible reason for this high prevalence rate despite the relatively younger age (mean age difference = 5y) of the Scandinavian children may be due to the generally low physical activity levels.

With the exception of HDL in which the participants had unfavorable value, the mean values of the features of MS in our sample are generally lower than the cut-off values established by the IDF.²⁰ This is not surprising as majority of the Nigerian youth in our study live in rural areas where the people are predominantly peasant farmers and artisans; occupations which require considerable physical labor. Moreover, the staple food in the area includes grains, roots and stem tubers with lots of vegetables and little or no fast foods. The generally healthy lifestyle among the youth probably explains the low prevalence of overweight and obesity (precursors of MS) in the study area.

Our results also indicate that, to a reasonable extent, decreasing levels of aerobic fitness was associated with increasing levels of risk factors. For instance, 37% of adolescents from the unfit group had low HDL compared to 13.2% in the fit category. Similar trends were observed regarding the other metabolic risk indicators. These findings are supported by previous studies in American²³ and European²⁴ youth.

In the present study, the unfit youth demonstrated significantly more unhealthy metabolic profile (Table 1) than their fit peers. These results which clearly support the fact that fitness confers some health benefits on

youth are corroborated by research in both American²² and Portuguese²⁵ youth.

Our results showed that the mean scores for all indicators of MS and MRS (except for HDL) were significantly ($p < 0.05$) higher in participants with unhealthy MRP compared to those with healthy MRP (Table 2). In this regard, our findings are consistent with previous reports.⁸ In a study of 3843 Iranian youth, Heshmat and Co-workers²¹ reported that the MRS score was higher in participants with three or more metabolic risk factors compared to their counterparts with no risk factors.

We observed statistically significant ($p < 0.05$) correlations between fitness and features of MS (except for TG). Even after adjustment for fatness, the relationships remained significant. These results are consistent with those of Buchan and Colleagues²⁶ but are at variance with some previous reports.^{8,27} Potential reasons for these inconsistent results may relate to age differences, measurement protocols used and sampling variations. For instance, the sample in the cohort used by Shaibi and others⁸ was on the average, 3.5y younger than that of the present study (14.7y).

Our results indicated that fitness was independently associated with MRS after adjusting for body fat. The relationship between fitness and the dependent variable was stronger in the fit than the unfit group. In this regard, our findings agree with previous reports on studies in children and adolescents.^{16,24,26}

Our findings should be interpreted in the light of a number of limitations. First the cross-sectional design precludes determination of causality. Another limitation is the non-inclusion of sexual maturity because this variable is known to influence fitness test results in children and adolescents. The main strength of this study is the use of health-related cut-points for estimating CRF. This approach indicated that the participants who met the FITNESSGRAM CRF standards had better metabolic risk profile than those who did not meet these standards.

Conclusion

In conclusion, these data suggest that clustering of metabolic risk factors exists in adolescents living in Kogi

State of Nigeria. Furthermore, fitness is independently associated with MRS in the adolescents. The relationship between fitness and MS is stronger in the fit than unfit with the contribution of fitness in predicting MS being modest. From a public health perspective, findings from this study highlight the need to develop more effective strategies to prevent metabolic syndrome in youth in order to guarantee better health prospects during adult life. The FITNESSGRAM PACER test protocol is valid, reliable and simple to administer, and can be used in a field situation as part of epidemiological surveillance intervention to help detect youth at risk of MS as it has potentially great clinical and public health implications.

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Conflict of Interest: The authors have no conflict of interest

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Nutrition Interventions for Improving Nutritional Status of Toddlers in Cirebon Regency Indonesia

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Abstract

Background: One of the highest nutritional problems in Indonesia is stunting. Cirebon Regency has a stunting prevalence of 25.6%. The prevalence of stunting above 20% is considered high according to the WHO. This study aims to analyze the differences in nutrition knowledge, attitudes, and practices of mothers of children under five before and after nutrition education interventions as well as to analyze nutrient intakes and nutritional status of toddlers before and after being given eggs and milk supplementation.

Methods: Pre-experimental study, with one group pre and posttest design. Subjects were 58 toddlers. The intervention given to mothers of toddlers was nutrition education which was carried out in three meetings, and supplementary feeding in the form of eggs and milk for 90 days for toddlers. The data collected consisted of household socio-demographic, toddlers characteristics, nutritional knowledge, attitude and practice, nutrient intakes, nutritional status and hemoglobin levels.

Conclusion: Nutrition education interventions increased the nutritional knowledge and practice of mothers with children under five, while supplementary feeding for 90 days increased nutrients intake for toddlers but did not improve their nutritional status and did not increase the hemoglobin levels.

Keywords: children, nutrient intakes, nutrition education, stunting.

Introduction

One of the highest nutritional problems in Indonesia is stunting in children under five. About 30.8% of children under five are stunted in Indonesia. The prevalence of stunting above 20% is considered high according to the WHO 2010¹. West Java Province is a province with high stunting prevalence among children under five. Many regencies or cities in West Java have a stunting prevalence of children under five with the

number exceeds 20%. One of them is Cirebon Regency, which has a stunting prevalence of 25.6%².

The efforts to reduce the prevalence of nutritional problems include providing nutrition education to mothers of children under five and the Supplementary Feeding Program (SFP). The nutrition education may increase the mother's knowledge, where the increase in knowledge is expected to be able to change the nutritional attitudes and behaviors of the mothers³. The main target of supplementary feeding in Indonesia is severe underweight toddlers.

Research shows the nutrition education can increase the mother's self-efficacy, which in turn can improve the child feeding behaviors³. The nutrition education given to the intervention group reduces the stunting rates by 10% more than the control group⁴. Giving SFP in the form of eggs to stunting toddlers for one month shows

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the improvement in nutritional status (height for age Z-score/HAZ)⁵. Another study with one egg a day for six to nine months had a significant effect on increasing the linear growth and reducing stunting in the Andean population in Ecuador⁶. The provision of milk for toddler showed positive relationship between milk consumption and child growth⁷. A research that was conducted in Southern Ethiopia showed that giving chicken eggs to toddlers aged 6-12 months increased their hemoglobin levels and decreased the incidence of anemia⁸. The aim of this study was to analyze the differences in the mother of children under-five's nutritional knowledge, attitudes and practices before and after the nutrition education interventions as well as nutrient intakes and nutritional status of children under five before and after being given eggs and milk supplementation.

Material and Methods

This research was pre-experimental with one group pre and posttest design. The research was conducted in Cirebon Regency, West Java Province from March to November 2020. The research subjects were 58 mothers and children under five with inclusion criteria: 1) toddlers aged 6-59 months and living with their mothers; 2) mothers of toddlers aged 18-45 years; 3) mothers of toddlers are willing to sign an informed consent and participate in the intervention conducted by researchers.

The types of data collected included the household socio-demographic, nutrition knowledge, attitude, and practice of mothers, the toddler consumption, anthropometric data (HAZ), and hemoglobin levels. The interventions carried out for mothers under five were nutrition education which was given in 3 meetings for 3 months using digital media, brochures, leaflets and posters with the topics: 1) Stunting, 2) Nutrition of pregnant women, 3) Basic nutrition, 4) Sanitation and hygiene, 5) Children's eating habits, and 6) Exclusive breastfeeding and complementary feeding. Meanwhile the intervention for children under five is by providing them eggs and milk for 90 days. Data processing was performed by Paired t-test and Wilcoxon test using SPSS 21.0.

Results and Discussion

Socio Economy and Demography of Household:

Table 1 shows the socio-economic and demographic conditions of the respondents. Most of the respondents (44.8%) came from small families (≤ 4 people) with a maternal age range of 21-40 years (87.9%). Most of them (51.7%) had <elementary education. The majority (81.0%) of the respondents were housewives (did not work outside the home) and 74.1% of households had income below the Regional Minimum Wage.

Table 1: Socio economy demography of household (n=58)

Characteristic	n	%	Mean±SD
Number of family (persons)			4.2±1.0
Small (≤ 4)	22	44.8	
Medium (5-6)	16	27.6	
Big (≥ 7)	16	27.6	
Age of mother (years)			32.6 ±6.3
≤ 20	3	5.2	
21-40	51	87.9	
≥ 41	4	6.9	
Education of mother (years at school)			
No education	2	3.5	

Cont... Table 1: Socio economy demography of household (n=58)

Elementary school (≤ 6)	30	51.7	
Junior high school (7-9)	17	29.3	
Senior high school(10-12)	9	15.5	
Occupation of mother			
Farmer	2	3.5	
Trader	7	12.0	
Farm worker	2	3.5	
Housewife	47	81.0	
Household income per month			US\$200.6 \pm 243.1
Under Regional Minimum Wage:<US\$158	43	74.1	
Above Regional Minimum Wage: \geq US\$158	15	25.9	

Characteristics of Toddlers: Table 2 shows that most children under five (41.4%) aged 25-36 months, boys and girls are at the same number (50%). As many as 87.9% of children under five had normal birth weight. Majority of the children under five (65.5%) received early initiation of breastfeeding and 41.4% of them were breastfed exclusively for six months. More than 70% of the children had good eating patterns and health parenting.

Table 2: Characteristics of toddlers (n=58)

Characteristic	n	%	Mean \pm SD
Age (month)			34.2 \pm 11.1
6-12	2	3.5	
13-24	11	18.9	
25-36	24	41.4	
37-48	14	24.1	
49-60	7	12.1	
Sex			
Male	29	50	
Female	29	50	
Birth weight (kg)			2.9 \pm 0.5
Low birth weight:<2.5	7	12.1	
Normal: \geq 2.5	51	87.9	

Cont.... Table 2: Characteristics of toddlers (n=58)

Early initiation of breastfeeding			
Yes	38	65.5	
No	20	34.5	
Breastfeeding patterns			
Exclusive	24	41.4	
Predominant	10	17.2	
Partial	24	41.4	
Eating patterns score			88.0±7.0
High >80%	45	77.6	
Medium 60-80%	13	22.4	
Low <60%	0	0	
Health parenting score			85.0±8.0
High >80%	41	70.7	
Medium 60-80%	16	27.6	
Low <60%	1	1.7	

Nutrition Knowledge, Attitude, and Practice of Mothers: The nutrition education intervention given to mothers showed an increase in nutrition knowledge from 59.9 (±16.2) (pre-intervention) to 69.4 (±16.9) (post-intervention) (p=0.001). Nutrition practice also increased from 76 (±12.6) (pre-intervention) to 83 (±9.0) (post-intervention) (p=0.000).

Table 3: Knowledge, Attitude, and Practice of mothers

Variable	Pre-intervention		Post-intervention		p-value*
	n	%	n	%	
Knowledge					0.001
Low (<60%)	27	46.6	14	24.1	
Medium (60-80%)	20	34.5	24	41.4	
Good (>80%)	11	19	20	34.5	
Mean(±SD)	59.9±16.2		69.4±16.9		
Attitude					0.182
Negative (<60%)	2	3.4	1	1.7	
Neutral (60-80%)	34	58.6	31	53.4	
Positive (>80%)	22	37.9	26	44.8	
Mean(±SD)	77±10.3		79±9.9		
Practice					0.000
Low (<60%)	6	10.3	2	3.5	
Medium (60-80%)	32	55.2	18	31.0	
Good (>80%)	20	34.5	38	65.5	
Mean(±SD)	76±12.6		83±9.0		

*Paired sample t-test

Research in Uganda also showed the same results that nutrition education interventions improve the mother’s knowledge and feeding practices, as well as providing significantly different results ($p < 0.05$) between the intervention group and the control group⁹. Other studies showed that the nutrition education can improve the feeding behaviors³, and when the mother’s knowledge increased through nutrition education, this

knowledge will be internalized into behavioral change¹⁰.

Nutrient Intakes of Toddlers: Table 4 shows the energy adequacy level with the RDA reference at pre-intervention was 86% and then increased to 101% at post-intervention ($p = 0.000$). An increase also occurred in protein from 168.0% to 230.5% ($p = 0.000$), calcium from 56.7% to 82.2% ($p = 0.000$), zinc from 121.7% to 170.9% ($p = 0.000$), iron from 121.7% to 170.9%, and vitamin A from 102.0% to 143.1%.

Table 4: Energy and nutrient intakes of toddlers before and after intervention

Nutrient	pre-intervention	post-intervention	p-value
	Mean±SD	Mean±SD	
Energy			
Intake (kcal)	1148±393.5	1386±426.2	0.000 ¹⁾
Adequacy level (%RDA)	86±28.5	101±31.1	0.000 ¹⁾
Protein			
Intake (g)	35.6±17.5	49.7±15.6	0.000 ¹⁾
Adequacy level (%RDA)	168.0±80.0	230.5±73.5	0.000 ¹⁾
Calcium			
Intake (mg)	392.1±398.4	606.4±331.8	0.000 ¹⁾
Adequacy level (%RDA)	56.7±60.0	82.2±47.3	0.000 ¹⁾
Zinc			
Intake (mg)	4.1±5.1	6.0±3.6	0.000 ²⁾
Adequacy level (%RDA)	121.7±160.5	170.9±102.0	0.000 ²⁾
Iron			
Intake (mg)	7.0±7.4	10±4.4	0.000 ¹⁾
Adequacy level (%RDA)	89.7±103.1	125±57.6	0.000 ¹⁾
Vitamin A			
Intake (RE)	420.2±458.0	596.5±398.4	0.002 ²⁾
Adequacy level (%RDA)	102.0±110.9	143.1±92.4	0.001 ²⁾

1) Wilcoxon test

2) Paired t-test

The nutritional intake and adequacy level of children under five increased during post-intervention because supplementation of egg and milk increased daily food consumption. High-quality protein source foods (such as eggs and milk) showed to be effective for children’s growth¹¹. Zinc deficiency is a risk factor for stunting in children aged 2-5 years¹². Low calcium intake, presumably due to inadequate milk intake after weaning will contribute significantly to the high rates of stunting among children aged 2-5 years old in South Africa¹³. Vitamin A deficiency is associated with the high rates of stunting among children aged 6-59 months in Uganda¹⁴.

Nutritional Status and Hemoglobin Level of Toddlers: Table 5 shows a decrease in the prevalence of the severe stunted category from 25.9% (pre-intervention) to 22.4% (post-intervention), stunted children under five fell from 44.8% (pre-intervention) to 43.1% (post-intervention), and an increase for normal children under five from 29.3% (pre-intervention) to 34.5% (post-intervention). In addition, the height for age Z-score (HAZ) increased from -2.3 (pre-intervention) to -2.2 (post-intervention). However, this increase in HAZ was not significant (p=0.648). The prevalence of children under five with anemia decreased from 91.4% (pre-intervention) to 79.3% (post-intervention), but it was not statistically different (p=0.102).

Table 5: Nutritional status of children before and after intervention

Dependent variable	Pre-intervention		Post-intervention		p-value
	n	%	n	%	
Nutritional status					0.648
Severe stunted (z-score<- 3SD)	15	25.9	13	22.4	
Stunted (-3 SD ≤z-score<-2 SD)	26	44.8	25	43.1	
Normal (-2 SD ≤z-score≤ +2 SD)	17	29.3	20	34.5	
Mean(±SD)	-2.3±1.3		-2.2±1.2		
Hemoglobin level (mg/dL)					0.102
Anemia: (<11)	53	91.4	46	79.3	
Non-anemia:(≥11)	5	8.6	12	20.7	
Mean(±SD)	9.2±1.3		9.5±1.6		

*Wilcoxon Test

Height is an anthropometric measurement that describes the state of skeletal growth and is relatively insensitive to changing in a short time. Longer supplemental feeding interventions are needed to see their impact on HAZ. Research on giving eggs as additional food for children under five which has a positive impact on children’s growth was carried out for

6 months⁶. According to Mohammed et al. 2019 stunting and anemia are two related things¹⁵. Children with low hemoglobin levels also have low HAZ¹⁶. The research of Omer et al. 2019 shows a significant difference (p<0.05) in the average hemoglobin levels between the intervention group and the control group after the provision of eggs and eggshell powder for 6 months, this means that it takes a longer intervention time of around 6 months to see the impact of the intervention on anemia

status of children under five⁸.

Optimal protein consumption will increase the toddler's height. Sources of protein can be obtained from animals, which is commonly known as animal protein. One source of the animal protein is eggs. Chicken eggs are a source of animal protein which is relatively easy to obtain and cheap in price. Eggs are a source of high-quality animal protein because they have a complete amino acid composition. The results of research conducted on animals indicate that there will be growth disorders if one or more amino acids are not given to the food consumed by these animals¹⁷. Milk is very important to support the growth of a child. In one study, it was found that instant cow's milk is associated with linear growth in children¹⁸. Children who regularly consume milk does have higher HAZ than those who do not consume milk⁷. Meta-analysis studies show a positive relationship between milk consumption and children's growth¹⁹.

Consumption of cow's milk (not yet fortified) is not significantly associated with the incidence of anemia and stunting in children under five. This is because cow's milk is low in iron²⁰. However, other studies shows consumption of cow's milk is associated with the linear growth in toddlers, thereby reducing the risk of stunting, but predisposes to gastroenteritis and hidden bleeding, thus increasing the risk of anemia in children under five^{21,22}.

Conclusion

Nutrition education interventions improved the nutrition knowledge and practice of mothers. This will have a positive impact on their children's feeding patterns. Supplementary Feeding Intervention (SFI) in the form of eggs and milk for 90 days increased the energy and nutrients intake of children under five, but was not be able to improve the child's HAZ and did not increase the hemoglobin level. Longer SFI are needed to have a result in improved nutritional status of children.

Conflict of Interest: The authors hereby declare that they have no conflict of interest within this research.

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A Comparative Study on Factors Influencing Preventive Behavior of Dementia between Elders Attending Dementia Care Village Senior Centers and Elders Attending General Senior Centers in Korea

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Abstract

Background: We compared the dementia prevention behaviors between elders attending dementia care village senior citizen clubs and elders attending general senior citizen clubs. Also, this study indicated direction of the national responsibility system for dementia by identifying the factors influencing preventive behavior of dementia.

Methods: The subjects of this study were 125 elders attending dementia care village senior citizen clubs and elders attending general senior citizen clubs. Data were collected through personal interview using a questionnaire from October 8 to 22, 2019. Collected data were analyzed with SPSS/WIN 22.0

Results: As a result of analyzing the factors affecting dementia prevention behaviors of elderly people aged 65 years or older, drinking ($\beta = 0.21$, $p = 0.013$), health status ($\beta = 0.20$, $p = 0.025$), interest in dementia ($\beta = 0.18$, $p = 0.035$), and self-efficacy ($\beta = 0.22$, $p = 0.030$) were influential factors, and the explanatory power was 18%.

Conclusion: The findings support the further development of interventions tailored to increase self-efficacy and that can increase interest in dementia in people with dementia.

Keywords: Dementia, Senior centers, elderly, Primary prevention

Introduction

In Korea, the elderly population aged 65 or over was reported as 13.8% of the total population in 2017, and is expected to enter 20% by 2026. Among them, the elderly with dementia account for 9.9% of the elderly, and are expected to increase rapidly to 10.0% in 2030 and 15.1%

in 2050⁽¹⁾. In addition, Dementia causes a significant strain on national budgets; the worldwide economic burden of caring for patients with dementia was roughly US\$818 billion in 2015 and the cost of care is expected to double every 10 years⁽²⁾. Dementia is a representative disease with a high morbidity increase with age, and it is a disease that shows not only defective memory but also complex problems such as language, executive ability, judgment, behavioral problems, and difficulty of daily life⁽³⁾.

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As the dementia prevalence and care costs of the elderly increased, demands for national intervention increased, and in September 2017, the government announced a plan to promote the “National Responsibility System for Dementia”⁽⁴⁾. The government emphasized that this is the duty of the state in the future. World Health Organization(WHO) has identified dementia as a “major health threat to humanity,” and urged global efforts to solve it. As of 2019, Korea has established dementia care centers in 252 public health centers across the country to provide comprehensive support such as dementia customized consultation and early dementia screening. The dementia center, which was established before 2019, focused on early screening projects, but the effect was halved due to the increase in the number of simple medical examinations for the achievement of dementia related institutions⁽⁵⁾.

Therefore, in order to reduce the social burden on dementia in the future, it is necessary to develop and implement a dementia prevention program that can be helpful to the elderly and those at high risk of dementia. In addition to the national responsibility system for dementia in 2019, a pilot project for dementia care villages is implemented. The dementia care villages aims to reduce therapist-centered therapeutic intervention in dementia management and to create an environment where elderly people can live safely with dementia by reflecting a subject-centered approach. Even if elderly have dementia, they can live with their local infrastructure so that they can live comfortably in the village where they lived.

Also, dementia care center assigns the dementia care village, and the dementia care village provides information on dementia and prevention education related to dementia to elderly⁽⁶⁾. Dementia, once developed, focuses on maintaining symptoms or preventing exacerbations through a long-term process rather than curing the disease. Therefore, it is important to prevent dementia in order to control the risk factors of dementia in advance and to reduce the incidence. In previous studies on dementia prevention behavior, the higher the knowledge about dementia and the positive the attitude about dementia, the higher the dementia prevention behavior⁽⁷⁾. Self-efficacy also had a positive effect on dementia prevention behavior⁽⁸⁾. In addition, self-efficacy of caregivers of people with dementia was

significantly associated with health-related quality⁽⁹⁾, and self-efficacy affected the quality of life by reducing depression and anxiety⁽¹⁰⁾.

However, to our knowledge, few studies have examined the relationship between knowledge, attitudes, self-efficacy and dementia prevention behaviors in senior citizen clubs. The purpose of this study is to investigate the determinants of dementia prevention behaviors by applying and Knowledge, Attitude, Belief, and Practice model (KABP)⁽¹¹⁾. KABP is emphasizes that some desirable health behavior requires positive attitudes and beliefs by right knowledge. This study is to investigate the relationship between knowledge, attitudes, self-efficacy and dementia prevention behaviors and the elders attending dementia care village senior citizen clubs, and compare with elders attending general senior citizen clubs to see if the national dementia care system implemented by the state achieves value in the areas of health welfare and second-class citizen support. This is to find out whether the “national responsibility system for dementia in Korea” policy⁽⁴⁾ implemented in the country implies the value that can prevent and manage the actual dementia and contribute to the public benefit and the development of the community. The aim of this study is to compare the dementia prevention behaviors between elders attending dementia care village senior citizen clubs and elders attending general senior citizen clubs, and to identify the factors influencing preventive behavior of dementia.

Methods

Design

This study was a descriptive correlation study to assess the level of dementia prevention behavior of elders attending dementia care village senior citizen clubs and elders attending general senior citizen clubs, and to identify the influencing factors of dementia prevention behavior.

Sampling and Conceptual framework

The subjects of this study were the elderly aged 65 years or older who used 4 designated dementia care villages located in S1, N, and S2 city in Gyeonggi-do and 4 general senior citizen clubs. The 125 participants in this study, excluding the 5 questionnaires were rejected

because there were many missing items. This study applies conceptually framework by KABP model and previous studies to identify the relationship between dementia prevention behavior and variables of elders attending dementia care village senior citizen clubs and elders

attending general senior citizen clubs. Figure 1 shows the conceptually framework of this study, KABP model is composed of knowledge of dementia(knowledge), attitudes of dementia(attitude), self-efficacy(belief), and preventive behaviors of dementia(practice).



Figure 1. Conceptual framework of this study

Instruments

General characteristics of the elderly

The general characteristics of the subjects in this study were gender, age, marriage, education level, income, religion, housing environment and living arrangement, and level of interest in dementia. Also, alcohol, smoking, exercise, and health status were examined.

Knowledge of dementia

To investigate the level of dementia knowledge among the elderly, the tool developed by the Kim et al⁽¹²⁾ was used. Dementia knowledge refers to the level of knowledge about the causes, symptoms, treatment, and prevention of dementia, and the tool consists of 16 questions, and 1 point if correct, 0 points if incorrect or not answered. The score ranges from 0 to 16, with higher scores indicating higher knowledge of dementia.

Attitude for dementia

Attitudes toward dementia was measured by the tool developed by Lee YH⁽⁷⁾. The questionnaire consists of a total of 15 questions, with a 4-point Likert scale, with a range of 15 to 60 points, with higher scores indicating a positive attitude toward dementia. Cronbach's $\alpha = 0.75$ in Lee's study, and Cronbach's $\alpha = .72$ in this study.

Self-efficacy

Self-efficacy was measured by the tool developed by Lee KY⁽¹³⁾. It consists of a total of 8 questions and is on a 5-point Likert scale. The score ranges from 8 to 40 points. Higher scores indicate higher self-efficacy. In the study of Lee KY⁽¹³⁾, the tool's Cronbach's $\alpha = .87$, and in this study, Cronbach's $\alpha = .83$.

Dementia prevention behavior

The dementia prevention behavior was measured by the tool developed by Lee YH et al⁽⁷⁾. Dementia prevention behavior consisted of 12 questions. The score ranges from 12-36 points on a 3-point Likert scale. Higher scores mean better dementia prevention. In Lee's⁽⁷⁾ study, Cronbach's $\alpha = .75$ and Cronbach's $\alpha = .75$ in this study.

Data Collection

The general senior citizen clubs were selected with a recommendation from the social worker which the 3km neighborhood with similar geographical, environmental, and cultural characteristics to the dementia care village senior citizen clubs. The agreement to participate in the study stated the subject's anonymity and confidentiality, voluntary participation and withdrawal of consent, and personal information protection matters. This was orally explained to all study subjects and completed with a questionnaire with written consent. The questionnaire was completed with the help of researchers and

research assistants. The time required to complete the questionnaire for this study was about 10 minutes, and toothbrush sets or socks were rewarded to the participants who responded to the written consent and questionnaire.

Data Analysis

The data collected in this study were analyzed using the SPSS program 22.0 according to the purpose of the study. The general characteristics of the subjects were obtained from error, frequency, percentage, mean, and standard deviation. The differences between the elderly using the dementia care village senior citizen clubs and the elderly using the general senior citizen clubs were analyzed by independent t-test, χ^2 test, and one-way ANOVA. Post-test was analyzed by Scheffe test. The correlation between the measurement variables related to dementia prevention behavior of the elderly using the dementia care village senior citizen clubs and the elderly using the general senior citizen clubs was analyzed by Pearson’s Correlation coefficient. Finally, multiple regression analysis was used to determine the determinants of dementia prevention behavior.

Results

Differences in the General Characteristics of the Subjects

Table 1 compares the general characteristics of the study subjects. There was no significant difference between the two groups in age, education level, monthly income, religion, living arrangement, smoking, and exercise. Comparison of the general characteristics of the elderly using the dementia care village and the elderly in the general senior citizen clubs, there was a significant difference in drinking ($\chi^2 = 9.01, p = 0.003$), health status ($t = 2.39, p = 0.018$), and interest in dementia ($t = 3.32, p < 0.001$) [Table 1].

Differences in dementia knowledge, attitudes, self-efficacy, and dementia prevention behaviors between the of the Subjects

In this study, the dementia knowledge score of the elderly using the dementia care village senior citizen clubs was 11.30 out of 16 points, and 9.8 points for the elderly in the general senior citizen clubs. The dementia knowledge score was significantly higher among the elderly using the dementia care village senior citizen clubs ($t = 3.33, p < 0.001$). Attitudes toward dementia among the elderly using the dementia care village senior citizen clubs were 44.38 out of 60 points, and 41.33 for the elderly in the general senior citizen clubs. The attitude score for dementia was significantly higher in the elderly using the dementia care village senior citizen clubs. Self-efficacy ($t = 4.65, p < 0.001$) and dementia prevention behaviors ($t = 2.26, p = 0.026$) were also significantly higher in the elderly using the dementia care village senior citizen clubs than those in the general senior citizen clubs [Table 2].

Comparison of correlation between dementia knowledge, attitudes, self-efficacy, and dementia prevention behaviors between the of the Subjects

Table 3 compares the correlation between dementia knowledge, attitude, self-efficacy, and dementia prevention behaviors of the elderly using the dementia care village senior citizen clubs and the elderly using the general senior citizen clubs. Dementia knowledge ($r = 0.241, p = 0.038$) and self-efficacy ($r = 0.321, p = 0.008$) were statistically significant variables related to dementia prevention behavior in the elderly using the dementia care villages senior citizen clubs. The level of dementia prevention behavior was higher in high score of dementia knowledge and self-efficacy. Self-efficacy ($r = 0.209, p = 0.041$) was found to have a

Table 1: General characteristics of the subjects (N=125)

Variable		Elderly using dementia care village senior citizen clubs (n=55)	Elderly using general senior citizen clubs (n=70)	χ^2 or t	p
		n(%)	n(%)		
Age(years)	Mean±SD	81.13±6.13	82.09±6.34	-0.85	0.396

Cont... Table 1: General characteristics of the subjects (N=125)

Sex	Male	10(18.2)	10(14.3)	0.35	0.627
	Female	45(81.8)	60(85.7)		
Marriage	Married	16(29.1)	10(14.3)	4.09	0.059
	Bereavement	39(70.9)	60(85.7)		
Education level	Uneducated	24(44.4)	37(52.9)	1.26	0.534
	Elementary	23(42.6)	23(32.9)		
	≥ Middle	7(13.0)	10(14.3)		
Monthly income(₹10,000)	≤ 49	35(63.7)	32(47.8)	6.47	0.091
	50~99	17(30.9)	33(49.2)		
	≥100	3(4.4)	2(3.0)		
Religion	Yes	40(74.1)	41(58.6)	3.23	0.072
	No	14(25.9)	29(41.4)		
Living arrangement	Family	32(58.2)	36(51.4)	0.57	0.452
	Alone	23(41.8)	34(48.6)		
Alcohol	Yes	4(7.3)	20(28.6)	9.01	0.003
	No	51(92.7)	50(71.4)		
Smoking	Yes	1(1.8)	1(1.4)	0.03	0.863
	No	54(98.2)	69(98.6)		
Exercise	Yes	42(76.4)	51(73.9)	0.09	0.754
	No	13(23.6)	18(26.1)		
Health status	1-5(range)	3.33±0.88	2.91±1.04	2.39	0.018
Interest in dementia	1-5(range)	3.11±0.94	2.51±1.05	3.32	<.001

Statistically significant correlation with dementia prevention behavior in the elderly using general senior citizen clubs.

Factors influencing dementia prevention behaviors of the subjects

In this study, a hierarchical regression analysis was conducted to investigate the determinants of dementia prevention behavior [Table 4]. First, variables of alcohol, health status, and interest in dementia, which showed significant difference in general characteristics, were analyzed by using independent variables. alcohol variable was dummy. Next, the analysis was conducted with independent variables in order of knowledge of dementia, attitude of dementia, and self-efficacy. The possible presence of auto-correlation and multicollinearity for the regression model were assessed with the Durbin-Watson statistic (1.63), tolerance (.71~.99), and variance inflation factor (1.01~1.41), confirming

that the basic requirements of regression analysis were satisfied. Hierarchical regression analysis showed that in Model I, drinking ($\beta = 0.18$, $p = 0.035$), health status ($\beta = 0.28$, $p < .001$), and interest in dementia ($\beta = 0.27$, $p = 0.004$) were significant determinants of dementia prevention behavior. The hierarchical regression model I was statistically significant ($F = 8.80$, $p < .001$) and the explanatory power was 16%. In Model II, when dementia knowledge, attitudes, and self-efficacy were added, drinking ($\beta = 0.21$, $p = 0.013$), health status ($\beta = 0.20$, $p = 0.025$), and interest in dementia ($\beta = 0.18$, $p = 0.035$), and self-efficacy ($\beta = 0.22$, $p = 0.030$) were significant factors affecting dementia prevention behavior. The model II was statistically significant ($F = 5.53$, $p < .001$) and the explanatory power was 18%.

Table 2: Differences of measuring variable between the elderly attending the dementia care village senior citizen clubs and the elderly attending the general senior citizen clubs (N=125)

Variable	Range	Elderly attending dementia care village senior citizen clubs (n=55) M±SD	Elderly attending general senior citizen clubs (n=70) M±SD	t	p
Knowledge of dementia	0~16	11.30±2.52	9.81±2.44	3.33	<.001
Attitude of dementia	15~60	44.38±5.11	41.33±5.95	3.02	0.003
Self-efficacy	8~40	32.75±5.70	27.85±5.931	4.65	<.001
Preventive behavior of dementia	12~36	30.69±3.22	29.34±3.37	2.26	0.026

Table 3. Correlation among knowledge of dementia, attitude of dementia, self-efficacy, and preventive behavior of dementia (N=125)

Variable	Knowledge of dementia r(p)	Attitude of dementia r(p)	Self-efficacy r(p)	Preventive behavior of dementia r(p)
Elderly attending dementia care village senior citizen clubs (n=55)				
Knowledge of dementia	1			
Attitude of dementia	0.186(0.087)	1		
Self-efficacy	0.236(0.041)	-0.032(0.408)	1	
Preventive behavior of dementia	0.241(0.038)	0.030(0.415)	0.321(0.008)	1
Elderly attending general senior citizen clubs(n=70)				
Knowledge of dementia	1			
Attitude of dementia	0.235(0.025)	1		
Self-efficacy	0.040(0.372)	0.3450(0.002)	1	
Preventive behavior of dementia	0.010(0.497)	0.114(0.173)	0.209(0.041)	1

Table 4. Hierarchical regression analysis for preventive behavior of dementia (N=125)

Variables	Model I			Model II		
	B	S.E	β(p)	B	S.E	β(p)
(Constant)	22.06	1.66		20.65	2.71	
Alcohol	1.51	0.71	0.18 (0.035)	1.82	0.72	0.21 (0.013)
Health status	0.95	0.28	0.28(<.001)	0.67	0.30	0.20 (0.025)
Interest indementia	0.79	0.27	0.27 (0.004)	0.58	0.31	0.18 (0.035)
Knowledge of dementia				-0.10	0.11	-0.08 (0.323)
Attitude of dementia				0.01	0.06	0.01 (0.989)
Self-efficacy				0.12	0.05	0.22 (0.030)
R ²		0.18			0.22	
Adjusted R ²		0.16			0.18	
F (p)	8.80(<.001)			5.53(<.001)		

Discussion

This study compares the degree of dementia prevention behavior between the elderly attending dementia care village senior citizen clubs and the elderly attending general senior citizen clubs, and evaluates the effect of social value of dementia prevention program implemented as a national dementia prevention program. Attempts have been made to provide basic data for the development and activation of future dementia prevention programs.

In the study results, first, the elderly using dementia care village senior citizen clubs were less drink alcohol, better health status, and higher level of interest in dementia than the elderly using general senior citizen clubs. This suggests that the elderly using dementia care village senior citizen clubs each week have a customized preventive program for dementia and have been educated about the relationship between dementia and alcohol in dementia prevention. In addition, education on the importance of health care seems to have made efforts for health care on its own⁽¹³⁾. In addition, as they were regularly exposed to and participated in dementia prevention education, their interest in dementia increased more than the elderly who using general senior citizen clubs. However, most of the studies on dementia knowledge education programs were developed for health professionals⁽¹⁴⁾ and caregivers⁽¹⁵⁾. In the future, a strategy for developing and expanding knowledge education programs for dementia for the elderly living in the community is needed.

Second, the level of dementia knowledge, dementia attitude, self-efficacy, and dementia prevention behavior were more positive or higher in the elderly using dementia care village senior citizen clubs than in the elderly using general senior citizen clubs, significantly. The results of the training which is about symptom of dementia, difference between amnesia and dementia, and risk factors of dementia for 2 times a week for 3 weeks, total 6 times, can be interpreted in the same context that the experimental group who received dementia education increased the knowledge of dementia and positive attitude toward dementia compared to the control group⁽¹⁶⁾.

Third, the dementia prevention behaviors of the elderly using dementia care village senior citizen clubs

were significantly correlated between the knowledge of dementia, self-efficacy, and the dementia prevention behaviors. The results of this study are supported by the findings that suggest that more educational programs and campaigns are needed to improve knowledge about dementia⁽¹⁷⁾. Also, the elderly using general senior citizen clubs were significantly correlated between the self-efficacy and dementia prevention behavior. As a result of a study by Tonga et al⁽¹⁸⁾, an increase in self-efficacy can have a positive effect on the quality of life by reducing depression and anxiety in dementia patients. Therefore, in order to increase dementia prevention behaviors, it is necessary to provide programs that can give attention to health status and dementia, and to improve dementia knowledge.

Fourth, as a result of analyzing the determinants of dementia prevention behavior in the elderly, drinking ($\beta = 0.21$, $p = 0.013$), health status ($\beta = 0.20$, $p = 0.025$), interest in dementia ($\beta = 0.18$, $p = 0.035$), and self-efficacy ($\beta = 0.22$, $p = 0.030$) were found to have an effect. In this study, self-efficacy was found to have the greatest influence on dementia prevention behavior. Self-efficacy might be related to other constructs from positive psychology, such as hope, resilience, optimism, and self-esteem⁽¹⁰⁾. It is also a powerful factor in predicting changes in motivation and behavior for health promotion⁽¹⁸⁾. One study reported that self-efficacy, optimism, and self-esteem were positively related to quality of life and dementia prevention behavior in patients with mild dementia in a community group⁽¹⁹⁾. Similarly, another study reported that result with the previous study result which the significant effect of self-efficacy on dementia prevention behavior among middle-aged women⁽⁷⁾. In other words, the interest in dementia in this study may mean that the attitude toward dementia to understand dementia is changing positively, and the self-confidence of dementia prevention behavior influences on dementia prevention behavior. In the "National Responsibility System for Dementia" in Korea, the dementia care village is a project that "improves awareness of dementia through education and participation of local residents, and induces the elderly to help each other"⁽²⁰⁾. It is thought that the elderly's negative perception of dementia decreased and their sense of self-efficacy increased through periodic education in the Senior Citizens of the Dementia Safe Village.

Therefore, it is necessary to include linguistic persuasion, accomplishment, and surrogate experience, which are the elements that promote self-efficacy, which are shown in the theory of self-efficacy to consist of dementia prevention program. In Korea, although it has been less than a year since the start of dementia care village project, the dementia prevention behavior of the elderly who use dementia care village was higher than that of the elderly who use general senior citizen clubs. It explains the importance of the national responsibility system. In the future, it is necessary to make efforts to continue education and programs related to dementia prevention behaviors of the elderly, not one-time.

Conflict of Interest: Nil

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Ethical Consideration: The study was approved by the Institutional Review Board (IRB No EU19-09) of the researchers' university. Researchers explained researcher's information, research purpose, informed consent.

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Histology and Immunohistochemistry Localization of ESAT-6 Expression on Caseous and Non-caseous Granuloma of Extrapulmonary Tuberculosis

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Abstract

Background: TB diagnosis by histopathological examination is based on the presence of epithelioid granuloma with caseous necrosis. The absence of caseous necrosis will make it difficult to distinguish between TB and non-TB granulomas. The use of ESAT-6 as a confirmative examination of TB immunohistochemically has not been fully used nor are there sufficient data showing the features of ESAT-6 immunolocalization in a granuloma. The purpose of the study was to identify differences in ESAT-6 expression in caseous and non-caseous EPTB granulomas.

Methods: A cross sectional study using 66 samples of formalin fixed paraffin embedded tissues from several anatomical lesions. The samples previously diagnosed as tuberculous granuloma were evaluated histologically and immunohistochemically. Mann Whitney tests were used for statistical analysis.

Result: There were no significant differences in histological findings and immunohistochemical staining of ESAT-6 on macrophages of caseous and non-caseous granuloma of EPTB. ESAT-6 protein was expressed on cytoplasm of epithelioid macrophages, foamy macrophages, Langhans type giant cells and some necrosis areas in the granulomas.

Conclusions: This study showed that macrophages of caseous and non-caseous granuloma of EPTB expressed ESAT-6 protein in the same way. This finding supports the use of the anti ESAT-6 antibody as a complementary diagnostic test in diagnosing granuloma of EPTB.

Keywords: caseous and non-caseous granuloma, ESAT-6, extrapulmonary tuberculosis, histology, immunohistochemistry

Introduction

Extrapulmonary-tuberculosis (EPTB) adds an extra burden to the tuberculosis (TB) problem worldwide. Only about 11% of lymph nodes with TB are suspected to be tuberculous lesions before histopathological examination. Others have a very wide range of suspicious diagnoses¹. Frequently, the patients show symptoms of having a tumor that resembles cancer rather than having a concomitant pulmonary TB. It is not an impossible case to receive a request for examining a piece of tissue

for evaluating cancer, but the microscopic examination reveals only a dense pattern of inflammatory cells arranged in a special structure. This structure is commonly called as granuloma.

Tuberculous granulomas consist of aggregates of lymphocytes, macrophages in the form of epithelioid cells, Langhans type giant cells, and caseous necrosis². Other cellular composition found on granulomas include neutrophils, monocytes, dendritic cells, and fibroblasts³.

In the progression to active TB, disease pathogenesis is correlated with the increased areas of caseous necrosis in the center of granulomas⁴.

Diagnosis of EPTB by histopathological examination is based on the presence of the epithelioid granuloma with caseous necrosis. The absence of caseous necrosis will make it difficult to distinguish between TB and non-TB granulomas. Microbiological methods sometimes fail to demonstrate the presence of acid-fast bacilli on the tissue sample. Meanwhile, nucleic acid amplification is an expensive and complicated method for routine examination⁵.

It is reported that immunohistochemical staining of anti ESAT-6 antibodies was found to be highly sensitive compared to the antibodies for anti-PlcA, anti-Tb8.4 and anti-HspX on tuberculous lymphadenitis⁶. Another study reported higher positivity of ESAT-6 expression on caseous necrotizing granulomas than non-necrotizing granulomas without clearly emphasizing where the immunolocalization took place since immunohistochemistry is a specific way to demonstrate the localization of an antigen⁷. Here, we report the histological finding on EPTB and found that immunohistochemical staining of ESAT-6 on macrophages of caseous necrosis or non-caseous necrosis extrapulmonary granulomas is expressed equally on cytoplasm of epithelioid macrophages, foamy macrophages and Langhans type giant cells in the granulomas.

Our study provides the features of the localization of ESAT-6 expression on macrophages of EPTB granuloma with and without caseous necrosis. This study supports the use of ESAT-6 immunohistochemically as a complementary tool for diagnosing EPTB.

Methods

We used sixty-six samples of formalin fixed paraffin embedded tissues from several anatomical lesions obtained from a surgical procedure, previously diagnosed as tuberculous granuloma histologically. The tissues were obtained from the laboratory of Anatomic Pathology of RSUP Dr. Achmad Muchtar Bukittinggi, YRSI Ibnu Sinna Padang, RSUP Dr. M. Djamil Padang, Faculty of Medicine Andalas University, Padang, and the Laboratory of Anatomic Pathology of the Faculty of

Medicine, Public Health and Nursing (FKKMK) UGM Yogyakarta Indonesia. Histology and immunohistology processing were conducted at Anatomic Pathology Laboratory of Faculty of Medicine Andalas University Padang on January- March 2019. The Medical and Health Research Ethics Committee in FKKMK UGM Yogyakarta approved this study with certificate number: KE/FK/1021/EC/2018.

Based on histopathological review, the granulomas were divided into two categories: granuloma without caseous necrosis and granuloma with caseous necrosis. Histological findings were thoroughly observed. To investigate the expression of ESAT-6 protein, the avidin-biotin complex method was used. The following primary antibody was used: rabbit polyclonal anti-bacteria ESAT6, Bioss, bs-13107R with dilution 1:200. The goat anti-rabbit IgG from Vector laboratories was used with dilution 1:200 as the secondary antibody. We applied 3-3' diaminobenzidine (DAB), Dojindo Laboratories, as the chromogen. The immunohistochemistry method was performed according to the primary antibody datasheet. The cellular expression of the ESAT-6 protein was evaluated by a semi-quantitative system according to Immunoreactive score (IRS) which was modified⁸. The final IRS modification score is the multiplication of proportion score to intensity score, which ranges between 0 to 17. In this present study, the IRS modification score of 0 to 1 was considered as none or negative, 2 to 3 was weak, 4 to 8 was intermediate and above 8 was treated as strong.

The Shapiro-Wilk test was performed as a test of normality before using Mann Whitney tests to analyze the difference of ESAT-6 IRS between the two types of granulomas.

Results and Discussion

The mean age of the patients was 28.89 in the range of 12 - 58 years. As shown on the baseline features in Table 1, the majority of the patients are at the age range of 25-64 years old. Patients in caseous granuloma type had younger age than non-caseous granuloma. Other studies have reported younger age for EPTB with median age of 36 years⁹, and 25.1 years¹⁰.

Table 1. Baseline features of the study (n=66)

Characteristic	Number
Age group	
0 - 14 years	3 (4.5%)
15 - 24 years	26 (39.4%)
25 - 64 years	37 (56.1%)
≥ 65 years	0 (0%)
Gender	
Male	22 (33.3%)
Female	44 (66.7%)
Location of the specimen	
Neck	47 (71.2%)
Supraclavicular	4 (6.1%)
Submandibular	3 (4.5%)
Axilla	2 (3.0%)
Breast	4 (6.1%)
Omentum	1 (1.5%)
Peritoneum	3 (4.5%)
Caecum	1 (1.5%)
Ileum	1 (1.5%)
Type of Granuloma	
Granuloma with caseous necrosis	48 (72.7%)
Granuloma without caseous necrosis	18 (27.2%)

Female was the predominant gender. We found a male to female ratio of 1:2 in line with others who reported predominance in females such as in Addis Ababa Ethiopia ¹⁰ and China ¹¹. Meanwhile, in America and Australia, there were slightly more males than females ^{9,12}.

The majority of the samples were taken from lesions of the neck (71.2%) which most of them were lymph nodes specimens. Several studies reported lymph nodes

as the most frequent extrapulmonary site for TB ^{9,10,13}. Others reported the most frequent sites for EPTB are skeletal ¹¹ and pleural ¹⁴. EPTB granuloma with caseous necrosis was more common than granuloma without caseous necrosis with a ratio of almost 1:3. Others reported the presence of non-caseous granuloma at 21.5% ¹³ and 11.3% ¹ overall. Another study reported more than a third of histopathology positive cases did not have caseating granuloma in the histologic finding ⁹.

Table 2. Age difference of the subjects according to epithelioid granuloma type of extrapulmonary tuberculosis

	Epithelioid granuloma (n=66)		p
	Caseous (n=48)	Non-caseous (n=18)	
Age	23.00 (12- 58)	36.00 (12 - 56)	0.033

*data presented in median (minimum-maximum); ** Mann Whitney test

We identify the components that build the appearance of granuloma as the hallmark of tuberculous pathology in caseous granuloma and non-caseous granuloma according to previous in vitro and in vivo studies to compare the differences more explicitly^{15,16}. For both of the granulomas, there were no special features of histopathology to separately identify them distinctly. We found that all granulomas consisted of well-formed granuloma except for 1 sample from the

non-caseous granuloma. Poorly formed granulomas existed concomitantly in 35 samples from caseous granuloma and 10 samples in non-caseous granuloma. Poorly formed granulomas exist as clustering of few macrophages on the edge of the lesion. It becomes more compact and begins forming giant cells when epithelioid cells are displayed. Although poorly formed granuloma more often occurred in caseous granuloma than non-caseous granuloma, however, the result was not significant statistically.

Table 3. Histological findings on each sample

Granuloma epithelioid type					
Histological findings		Caseous		Non caseous	
		n=48	%	n=18	%
Granuloma's structure* ^a	Well-formed granuloma	48	100.0	17	94.4
	Poorly formed granuloma	35	72.9	10	55.6
Granuloma's size	Small * ^b	44	91.67	17	94.4
	large* ^c	47	97.9	6	33.3
The size of Langhans giant cells	Small (nuclei<7)	45	93.8	18	100.0
	Large (nuclei>15)	48	100.0	16	88.9
The present of another giant cells	Touton GC	0	0.0	0	0.0
	Foreign body GC	0	0.0	0	0.0
Macrophage morphology	Epithelioid	48	100.0	18	100.0
	Foamy	48	100.0	18	100.0
Lymphocyte cuff	Other than lymphoid * ^d	3	100.0	8	88.9
Neutrophil	scattered	29	60.4	4	22.2
	crowded	13	27.1	0	0.0
	minimal	6	12.5	14	77.8
Hyalinization	present	1	2.1	1	5.6
	none	47	97.9	17	94.4
Calcification	present	2	4.2	1	5.6
	none	46	95.8	17	94.4

*^a Granuloma's structure Well-formed granuloma

*^b multiple separated granulomas were seen on a medium power field/ 100x

*^c a large single separated or a confluent granuloma which seen on a medium power field/ 100x

*^d 3 samples in caseous granulomas and 9 samples in non-caseous granulomas

Touton GC: ring arranged nuclei

Foreign body GC: nuclei >200 and randomly arranged

There was no significant difference in size of granuloma, and both of the granulomas had small and large size granulomas. One slight difference was that the non-caseous granuloma had fewer large size granulomas than the counterpart, but the result was not significant statistically. Both types of granuloma had large and small size of Langhans type giant cells. Epithelioid and foamy macrophages could be found in both types of granulomas. None of them had Touton type or foreign body type giant cells. Mild neutrophil distribution could be found in both types of granuloma. Only several of the caseous necrotic type had crowded neutrophils. Neutrophils contribute to persistent inflammation and also have antimycobacterial activity.

We found hyalinization on 1 sample for each granuloma type and calcification on 2 samples on caseous granuloma and 1 sample on non-caseous granuloma. Finding of hyalinized granuloma in TB positive cases histopathologically can be indicative for possible TB when a limited small biopsy sample is obtained ¹⁷. Calcification findings on chest x-rays

or computed tomography might indicate past infection of TB ⁹. Here we found calcification on either caseous granuloma or non-caseous granuloma with prominent fibrous matrix in some part of granuloma. It was unclear whether it is a sign indicating that these lesions are in the final stage development of the disease, and the clinical follow-up may provide information on the patient's condition. Unfortunately, at this time, there is no follow-up information about it.

ESAT-6 expression on macrophages of granulomas

ESAT-6 was expressed in 60 samples. Each type of granuloma had 3 samples which had no reactivity with the anti ESAT-6 antibody. Five samples (4 samples in caseous granuloma and 1 sample in non-caseous granuloma) which showed mild reactivity on less than 10% area were considered as negative on the IRS. The total of ESAT-6 IRS positives was 83.33% out of all samples. There were 85.42% of caseous granuloma and 77.78% of non-caseous granuloma which had positive IRS (table not shown).

Table 4. ESAT-6 Immunoreactive score (IRS) category on epithelioid granuloma type of extrapulmonary tuberculosis

ESAT-6 Immunoreactive score	Epithelioid granuloma (n=66)		Total
	Caseous (n=48)	Non-caseous (n=18)	
Negative	7 (63.6%)	4 (36.4%)	11 (100.0%)
Mild	3 (75.0%)	1 (25.0%)	4 (100.0%)
Moderate	26 (78.8%)	7 (21.2%)	33 (100.0%)
Strongly positive	12 (66.7%)	6 (33.3%)	18 (100.0%)

Table 5. ESAT-6 Immunoreactive score on epithelioid granuloma type of extrapulmonary tuberculosis

	Epithelioid granuloma (n=66)		p
	Caseous (n=48)	Non-caseous (n=18)	
ESAT-6	4.00 (0 - 12)	7.00 (0 - 14)	0.478

*data presented in median (minimum-maximum); ** Mann Whitney test

The median of ESAT-6 IRS was slightly higher in non-caseous epithelioid granulomas however the difference was not significant statistically. Both types of granuloma expressed ESAT-6 on cytoplasm of epithelioid macrophages, foamy macrophages, Langhans giant cells and in the necrosis area of caseous granuloma type (Figure 1).

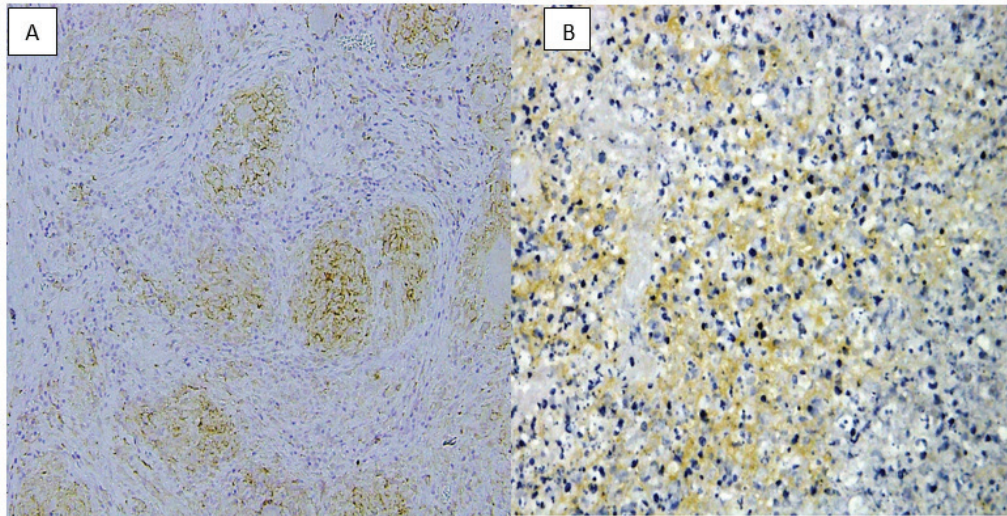


Figure 1. Immunohistochemistry ESAT-6 expression on granuloma of extrapulmonary tuberculosis A. expression on separated granuloma (original magnification x100), B. expression on necrosis area with cellular debris which shown brown patches around the shadow of the cell nucleus (original magnification x400)

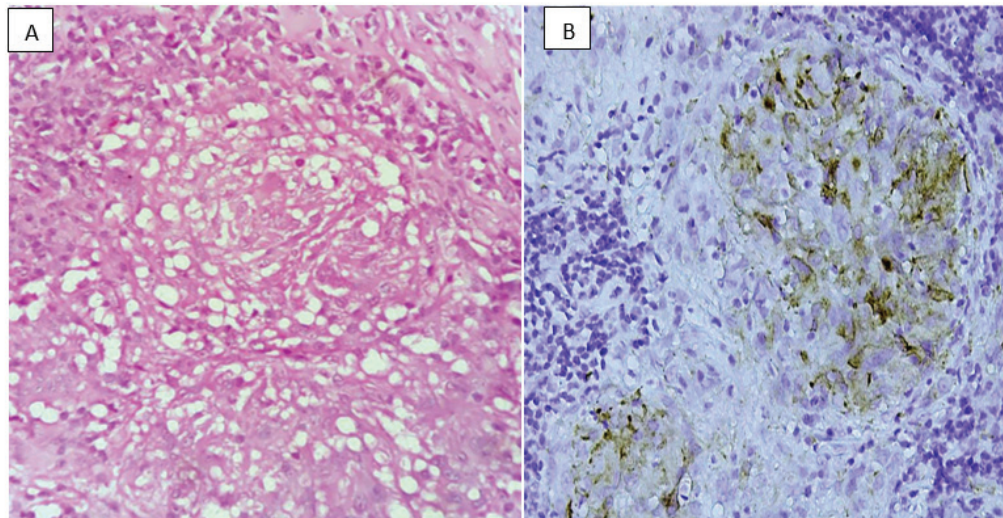


Figure 2. A. histology of granuloma (HE, original magnification x400) B. Immunohistochemistry localization of ESAT-6 expression. Strong ESAT-6 expression is seen on cytoplasm of epithelioid cells (original magnification x400)

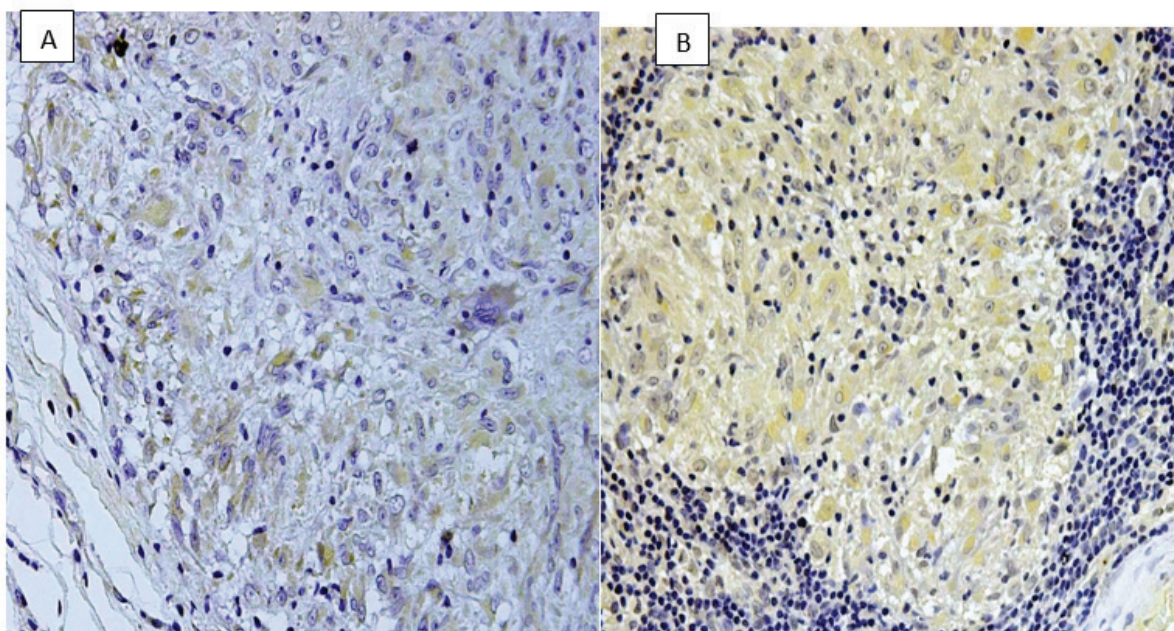


Figure 3. Immunohistochemistry localization of ESAT-6 expression. Moderate ESAT-6 expression is seen on cytoplasm of epithelioid cells and Langhans giant cells. A. granuloma with loosely arranged cells and few cells stained B. more compact granuloma cells (original magnification x400)

Being a host response to an unresolved chronic stimulus, granuloma pathogenesis is driven by the *M. tuberculosis* antigen. Even though several Mycobacterium's components can induce granuloma, ESAT-6 the virulent antigen of *M. tuberculosis*, is best known to induce granuloma response from the early infection¹⁸ along with the formation of epithelioid macrophages¹⁹, foamy macrophages²⁰, giant cells and the caseous necrosis^{21,22}. So far, the presence of caseous necrosis has become an evidence to differentiate tuberculous granuloma from another granuloma due to other causes such as sarcoidosis or leprosy²³. When it cannot be found, another histopathological examination such immunohistochemistry should be in consideration to support the diagnosis. As a virulent antigen, ESAT-6 protein considered as best candidate for this purpose.

Tuberculous granuloma model declared that at the beginning of granuloma formation, uninfected macrophages are recruited to the side where the first macrophage is infected by mycobacterium. This RD1 locus where ESAT-6 is encoded is responsible for the aggregation of macrophages. It only aggregates the macrophages before becoming a well-formed granuloma as the infection progresses. At later stages of infection,

granuloma become compact and consist of tightly pack cells resembling epithelioid cells. Meanwhile, as the infection progresses, the mycobacterium that lack the RD1 locus make loosely formed aggregates and display epithelioid cells only in the center of some aggregates²⁴.

Finding positive expression of ESAT-6 on cytoplasm of macrophages of hyalinized and calcification granuloma is somewhat different from previous study. It revealed that the tuberculous granuloma cytoplasm of macrophages and Langhan's giant cells were positive for mycobacterial antigens immunohistochemistry with anti-ESAT-6 antibody, but negative results were shown by granulomas with extensive fibrosis⁶. It is possible the negativity may be due to antitubercular drugs given to the patients prior to biopsy. Here, we did not have any information about the patients' antitubercular therapy. Whether granulomas with the extensive fibrosis did not have any epithelioid macrophages and Langhans giant cell at all, there are no further explanations. ESAT-6 expression in macrophages and Langhans cells remaining in hyalinized granulomas could still be observed in this study.

We performed immunohistochemical examinations using anti ESAT-6 antibodies and histopathological review to assess the differences between caseous granuloma and non-caseous TB. Expression of ESAT-6 in caseous and non-caseous granulomas helps in supporting the diagnosis of TB, however, advanced studies that compare other antigens are needed, in combination with other diagnostic methods such as radiology, microbiology, nucleic acid amplification and therapeutic response.

Conclusions

Histopathology is very helpful in making the diagnosis of a disease. However, sometimes the diagnosis still cannot be confirmed after a thorough histopathological examination. The similarity in histopathological features of several lesions with different causes is one of the obstacles to getting a definitive diagnosis. Better therapy can be given according to the pathological cause. The examination of antigens in histopathological specimens can help increase the chances of reaching a definitive diagnosis when other test results were very limited. The use of anti ESAT-6 antibody can be a complementary diagnostic test in diagnosing granuloma of EPTB.

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Cost Benefit Analysis of Implementation Occupational Health and Safety: Literature Review

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Abstract

Assessment of management commitments is required for investment in Occupational health and safety program. This systemic literature review evaluates 15 cases of Occupational health and safety (OHS) interventions to assess whether the implementation of OHS is beneficial. Search engines used in literature review are Medline, Embase, Web of Science, Cochrane Library, Pubmed. Studies related to benefit cost analysis included in the search include also looking at company productivity. The focus of this analysis includes samples, design, theoretical framework, implementation OHS, validity and results. Results show, in 15 cases, cross-sectional research design looked at pre-after comparisons in the absence of control groups. The positive return on investment from the implementation of OHS is shown in 13 studies. Two other studies concluded that their chosen implementation of OHS was not cost-effective. The main benefit is to reduce sick leave. In 3 cases the perceived benefit is an increase in productivity and quality. The conclusions in this study required a guideline for the evaluation of the implementation of OHS.

Keywords— *Cost Benefit Analysis, Occupational Health and Safety, Risk management, economic evaluation*

Introduction

Failure (risk of failures) in any process or work activity, and during a work accident however small, will result in a loss effect. According to ⁽¹⁾that failure can be caused by human error and or by organizational factors. One of the causes of organizational factors as the cause of work process failure is the absence of corporate commitment to the implementation of OHS, limitations of work rules and procedures, as well as limited budget of work programs implementation of OHS⁽²⁾. In a business industry, of course in the business process there must be risks. Therefore all aspects of OHS start from process safety, electrical work safety, occupational safety at altitude, job safety in areas that may burn or explode,

driving safety (due to remote and large areas), industrial hygiene, office and industrial ergonomics, chemical safety, construction or heavy equipment safety, working fitness (for heavy work), and even food safety for even workers (workers in remote areas) applied in the oil and gas industry, it is no wonder that OHS is a very crucial aspect.

Studies show that legal, financial and moral reasons are the main drivers for businesses to engage in the implementation of OHS⁽³⁾. Management considers that regulation as a real risk because it is related to the reputation of the company. Management supports the calculation of the benefits of OHS implementation for the company can increase management's commitment in complying with and implementing the OHS program ⁽⁴⁾. The economic aspects of the implementation of Occupational health and safety in companies have historically been used to estimate all the costs and benefits of a proposed program in monetary value,

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which is then combined into summary measures such as net present value (NPV) or cost-benefit ratio. Often used in business to compare various corporate interventions and investments, NPV is calculated by adding all benefits and reducing all costs – with discounts applied accordingly – to provide the current value of future net cash flow ⁽⁴⁾. The cost-benefit ratio represents the total benefit divided by the total cost. If NPV > 0 or cost benefit ratio > 1 then it can be said that a program will be financially profitable so that top management (decision makers) can implement the program. Thus, cost-benefit analysis can provide an estimate on the financial aspects of the project before it is implemented.

For OHS programs, it is important to measure the cost. Because for management this will affect their decision making more than the total social cost ⁽⁵⁾. Therefore, systematically literature review will help assess whether the implementation of OHS is an appropriate investment made by the company. Therefore, in this study will collect all business case studies that focus on implementing OHS and analyze the underlying

assumptions of each case and component considered.

Method

For this integrated review, search engines include Medline, Embase, Web of Science, Cochrane Library, Pubmed. Searches conducted include economy, Occupational health and safety, business case, cost-benefit analysis, ROI, Productivity. Inclusion criteria include working and active population studies, intervention results based on measurement of costs and benefits in monetary terms, research studies, and published in English. Exclusion criteria include populations under 18 years of age, as well as studies that only show the results of the implementation of OHS are not economic results. Searches 1306 in Medline, 1775 at Embase, 669 on the web of Science, 188 at the Cochrane Library, and 158 in Pubmed. After removal of duplicate reference 3535. The study was then filtered by title and abstract so that another 3125 references were eventually issued. So in the end, after setting the inclusion criteria, there were a total of 15 articles.

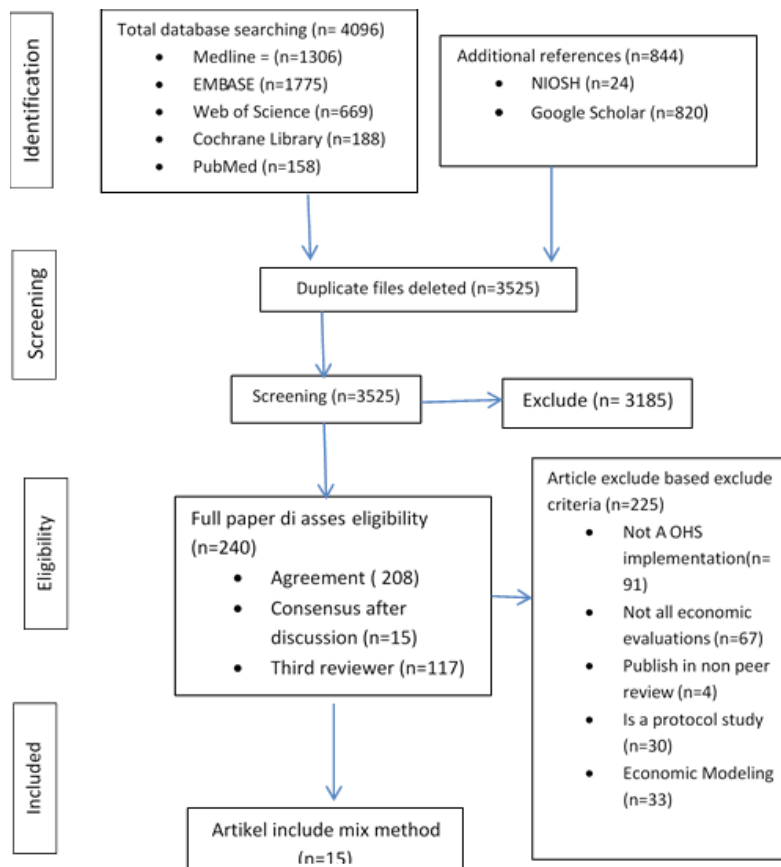


Figure 1 Literature Review Flow Chart

Theoretical Framework

The theoretical framework used for any study is not described in any article included in this Systematic literature review. The three main keywords used in this review literature are “cost effectiveness”, “cost and benefit”, and “return on investment”. Since the purpose of this study is to evaluate the economy, positive monetary returns are the main driver of research.

Result

Samples from all studies that work and work actively, Samples selected from various types of industries such as banks, forestry, construction, manufacturing, consulting services, government organizations Table 1. Samples were entered from six countries (United States, United Kingdom, Netherlands, Finland, Bangladesh). Sample sizes vary from 50 to 8000 samples. 85% of the studies used two tail analysis with $P < 0.05$. The characteristics of the sample are well explained among the studies.

Cost of Implementation OHS

The cost of implementing OHS is divided into several costs such as labor costs, equipment. In some cases⁽⁶⁾, “lost time due to sick leave” counts as a benefit but in some cases it is included in the total avoidable cost and cannot be presented separately⁽⁷⁾⁽⁸⁾. The company covers most of the medical costs that usually result in additional medical costs that can be avoided for such cases⁽⁹⁾. Other avoidable costs usually consist of costs related to personnel turnover which according to this case study is quite large.

Benefit of Implementation OHS

The benefits of OHS implementation in 15 cases mean that the return of profit from the implementation of OHS is paid back by the resulting benefit within one year. The median value was \$256.35 per worker in the first year. In just a few cases, the benefits of implementing OHS achieved extreme results of more than \$12000 due to a large increase in productivity due to engine changes. In most cases, the benefits of implementing OHS range from \$6–600 per worker in the first year⁽¹⁰⁾. The benefits of OHS implementation and the period of return on capital do not seem to be affected by the size of the company (i.e., there is no difference in findings for small or large companies)⁽¹⁰⁾. In other cases, there

are negative OHS implementation benefits but, due to investment depreciation, the benefits are much greater in fact. Management accepted the case as a profitable investment.

Economic Evaluation

There are four different methods used in calculating the economic benefits of Occupational health and safety implementation. The cost-benefit ratio was used in two studies. The CER ratio is calculated by dividing the cost of intervention by the unit of effectiveness. There are six studies using CBA analysis. CBA is a systematic process for calculating and comparing the benefits and costs of decisions. Return on investment is used to evaluate investment efficiency. A higher ROI means an investment return compared to the cost of investing⁽⁴⁾. Seven studies using only one economist evaluation method.

Discussion

The interaction of causal relationships with settings is noted as a threat to the external validity of the study. Most studies collect data from one or two settings, the result of financial and situational factors. The results of the study can be switched to similar settings but not every business setting. Selecting multiple settings increases the generalization of the study findings⁽¹¹⁾⁽¹²⁾. Selecting a study population from various units and settings and using a blinded test study design or double blinded test can reduce the threat to the validity of the study⁽¹³⁾.

Limited measurement reliability was recorded in six studies, raising questions about conclusions and statistical validity⁽¹³⁾. Certain results, and participants’ perspectives on the efficacy of interventions, were measured based on self-reports. Based on the results, it is difficult to conclude that the participant’s report is accurate, and the size of the results is reliable. The use of tools that measure objective results can reduce the threat of reliability. In the literature this review shows that OHS investments will be profitable. Other cases show an average benefit of \$256 per worker and a repayment period of less than a year⁽¹⁴⁾. The benefits of increased productivity are enormous in two cases. In 13 cases, the authors adjusted the influence of factors other than intervention⁽¹⁵⁾⁽¹⁶⁾⁽¹⁷⁾. Many cases provide incomplete cost and benefit estimates. Intangible benefits are not

assessed in any case.

The strength in this systematic literature review is that business cases are searched systematically using the Internet search engine⁽¹⁻¹³⁾. This literature review emphasizes CBA to ensure the commitment and approval of top management (decisionmakers) to implement Occupational health and safety (OHS)⁽¹⁸⁾. As shown above, the case provides meaningful information on how OHS can create a positive balance between cost and benefits⁽¹⁹⁾⁽²⁰⁾.

The limit in this study is result from the implementation of OHS is the total dollars saved each year or ROI. Most studies are longitudinal and the assumption that the benefits will continue at the same rate as the first year could be wrong. It's possible that this review missed a reported case study in such a business that showed unfavorable results were less likely to be published. As a result, the published studies included in this review may bias the interpretation of evidence regarding the implementation of OHS.

Conclusion

This systematic literature review shows the economic benefits of OHS Implementation. It is expected that the company's management will implement OHS based on data, evaluation of health and economic impacts, and their assessment of the importance of OHS for the company. The foundation of policies and regulations related to Occupational health and safety must be economically and ethically healthy. However, since economic value is an important factor driving top management decision making, conducting well-designed business case studies should be expanded. For subsequent research it is expected to include variable intangible benefits such as reputational damage and the risk of breaking regulations into CBA analysis.

Reliable and valid guidelines are required to report a business case. Case values can be underestimated when the structure and consensus among business management is lost. Theory-based study provides stronger evidence of a positive correlation between OHS implementation and economic effectiveness. In the selection of research samples for the next study is expected from different geographical regions and business settings, with racial and socioeconomic diversity of workers, can produce a

more representative sample.

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Implementation of Sharia Health Services in Medan Haji Hospitals and Jakarta Haji Hospitals

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Abstract

Sharia hospital is a hospital whose management is based on maqhashid sharia. The four main characters in Islamic services are rabbaniyah, akhlaqiyah, waqi'iyah and insaniyah. Therefore, this study aims to explore the understanding and perceptions of hospital health caregivers about Islamic services and to explore a picture of Islamic health practices in Islamic hospitals based on the patient's perspective. Methodology: The study was conducted using descriptive explorative quantitative methods. The method of collecting data using a questionnaire with 210 respondents in both hospitals, both RS Haji Jakarta and RS Haji Medan, using total sampling technique. Result: Medan Hajj Hospital and Jakarta Hajj Hospital in terms of leadership and policies are 100% in accordance with Sharia. Sharia health services by nurses 52% of the Medan Hajj Hospital and 56% of the Jakarta Hajj Hospital have implemented health services according to Sharia. The application of Sharia health services based on the patient's perspective in the Jakarta Hajj Hospital 54% and the Medan Hajj Hospital 56% of patients / families have experienced the application of health services according to Sharia. This research can be used as a reference in improving health services in accordance with sharia principles.

Keywords : *Sharia Health, Spiritual, Service, Sharia hospital, Jakarta hajj hospital*

Introduction

Health includes physical, emotional, social or cultural and spiritual dimensions. The physical dimension is the most tangible dimension because it can be examined directly. Physical health can be seen from the mechanistic abilities of a person's body. A person is said to be physically healthy if he does not feel or complain of pain and objectively does not appear sick. All body organs function normally or are not disturbed. The social dimension is a dimension that can be seen from human behavior in a social group, family and others, as well as acceptance of social norms and behavior control. Social health is seen from a person's

ability to make and maintain relationships with other people. Social health can be realized if a person is able to relate to other people or groups well, regardless of race, ethnicity, religion or belief, social status, economy, politics, etc., as well as mutual tolerance and respect. Meanwhile, the emotional dimension is a dimension that looks at how a person's emotional reactions are. Healthy in the emotional dimension can be seen from a person's ability to express their emotions, recognize emotions, control emotions, and how to deal with problems that arise in them.¹

The spiritual dimension can be seen from one's religious beliefs and practices. Spiritual health is seen from one's ability to achieve peace of mind. Spiritual health is reflected in the way a person expresses gratitude, praise, and trust in God, for example, seen from one's religious practices. Spiritual health is also defined as a condition in which a person performs worship and all the

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religious rules he adheres to.²

The spiritual dimension is a dimension that rarely gets special attention from some of these health dimensions. In fact, the spiritual dimension is known to be an important aspect of holistic patient care.³ Holistic health care must be concerned with the spiritual aspect because basically spiritual values are universal.⁴ Spiritual service must be done in relation to the patient's experience and care, wherever they are. Spirituality can assist individuals in interpreting crises in a more productive way. As a result, pain can also be used as a means of developing spirituality. Therefore, health workers are expected to be present in the spiritual needs of their patients.⁵ Although many have been informed that spiritual aspects are important to be included in health, spirituality has not been formally included in the health education curriculum. This is due to the absence of clear guidelines and definitions of spiritual concepts.¹

Methodology

This research uses descriptive explorative quantitative method. The method of collecting data using a questionnaire with 210 respondents which is divided into 2, namely the respondents of the Medan Hajj Hospital and the Jakarta Hajj Hospital, with each hospital taken by 5 leaders, 50 nurses, and 50 patients / patient families. Data analysis method using statistical computer software.

Result & Discussion

Following are the results of the calculation of the frequency distribution of the respondents.

Description of Respondent Characteristics

Based on the data in Table 1, it can be seen that most of the age ranges of nurses at the Medan and Jakarta Hajj Hospital are at the age of 25-45 years, namely 29 people (58%) and 28 people (56%). This research is in accordance with the theory where the age between 25 - 45 years is a productive age, so the distribution of nurses in the Medan and Jakarta Hajj Hospital is a productive age. This research is in line with research in Moewardi hospital which states that the age characteristics of nurses are in the range of 21-35 years.⁶ The majority of nurses at the Medan and Jakarta Hajj Hospital were female, as many as 37 people (74%) and 35 people (70%). This

study supports research which states that in the world of nursing it is very synonymous with the work of a woman, even though many men become nurses but the proportion of women in the world of nursing still dominates.⁷ Most of the nurses at Haji Medan Hospital were undergraduate with 34 people (68%). Most of the nurses at the Jakarta Hajj Hospital have D3 education, namely 36 people (52%). This is influenced by the policies of the hospital regarding the admission of new nurses who apply at the related hospital.

Based on the data in Table 2, it can be seen that most of the patients at the Medan Hajj Hospital are at the age <25 years, namely 26 people (52%) and at the Jakarta Hajj Hospital are at the age 25-45 years, as many as 29 people (58%). The majority of patients were both male, as many as 29 people (58%) and 28 people (56%).

Overview of the Implementation of Sharia Health Services

Table 3 shows that 100% of the leaders in the Medan Hajj Hospital and 80% of the leaders in the Jakarta Hajj Hospital implemented health services according to Sharia. The results showed that the leaders at the Medan Hajj Hospital and the Jakarta Hajj Hospital were already in accordance with Sharia in implementing the implementation of Sharia health services. This was shown by the implementation of Sharia Standards for Patient Services (SSPP). The SSPP includes psychospiritual services for a variety of health care needs.⁸

Several policies that have been implemented by the leadership at Medan Hajj Hospital and Jakarta Hajj Hospital among them carry out prayer together at the beginning and end of the shift, before and after nursing actions, before and after giving medication. Establish a policy that nurses recommend breastfeeding mothers to wear the hijab, nurses provide hijab for female patients to be operated on. There are regulations for nurses to treat patients according to gender, one of which is related to EKG and DC / catheter placement. There is a policy for nurses to remind patients of prayer times, guide how to pray for bedrest patients, teach how to purify according to the patient's condition, guide patients how to worship according to their abilities, guide prayers for patients with sakaratul maut. In addition, by providing Islamic education media in the room in the form of leaflets and spiritual books.⁹

Table 4 shows that the implementation of Islamic health services by nurses at the Medan and Jakarta Hajj Hospitals is not yet fully in accordance with Sharia. The results showed 26 nurses (52%) nurses at the Medan Hajj Hospital and 28 nurses (56%) nurses at the Jakarta Hajj Hospital implemented health services in accordance with Sharia.

The implementation of Islamic health services by nurses at the Medan Hajj Hospital is not yet fully in accordance with Sharia, as is the case at the Jakarta Hajj Hospital. One of the standard indicators of patient service sharia is treating patients according to gender.⁸ In this case, this point has been implemented but has not been fully implemented by nurses both at the Medan Hajj Hospital and at the Jakarta Hajj Hospital because the results of the study showed that the majority of nurses working were female, namely 37 people from Medan Haji Hospital (74%) of 50 nurse respondents, and in Jakarta Hajj Hospital as many as 35 people (70%) of 50 nurse respondents. On the other hand, the majority of patients were male, namely 29 people (58%) of the 50 patient respondents at the Medan Hajj Hospital.

The implementation and application of Islamic nursing clearly shows that there is a gender-appropriate service delivery policy. Service to female patients is performed by female health workers. However, male patients are still served by female officers in certain conditions. This is due to the limited number of male health workers. EKG placement in female patients will be served by female nurses as well so that comfort can be maintained. However, gender-appropriate services in both the Jakarta Hajj Hospital and Medan Hajj Hospital have not been carried out properly due to the limited number of nurses, the majority of whom are female nurses. As for the number of nurses according to gender where the Jakarta Hajj Hospital was male 15 (30%) and female 35 (70%) then at the H aji Hospital Medan Male 13 (26%) and female 37 (74%).

i. Patient / Patient Family

The results showed that most of the implementation of Sharia health services in the Jakarta Hajj Hospital, namely 27 people (54%) patients / patient families had experienced the implementation of health services according to Sharia, and 23 people (46%) patients felt that the implementation of health services was less than

Sharia. , the Medan Hajj Hospital shows 28 people (56%) patients / patient families feel that the implementation of health services is in accordance with Sharia, and 22 people (44%) patients feel that the implementation of health services is less Sharia. In both hospitals, the results showed that it was not too significant related to the implementation of sharia health services, most of the patients had experienced the implementation of sharia-based services, but there were also many patients who had not or did not feel the application of sharia health services. Some patients stated that the two Islamic hospitals were in line with their expectations, especially in terms of services. Thus, the patient's expectations when visiting the hospital can be fulfilled.

This is like the definition of nursing expressed by Sorensen and Luck Mann's that nursing care is a series of steps and planned actions directed to meet needs and solve problems. Patients also feel Islamic health services such as nurses being friendly, polite, giving a head scarf when they are about to operate, are advised to wear a hijab while breastfeeding and guide worship in hospitals.¹⁰ Here it can be seen that there is a correspondence between the results of current research and existing theories / research. Where the nursing action is carried out in an Islamic form in the form of Islamic akhlak which should be implemented in an Islamic hospital.

Perceptions of Health Workers About Sharia Health Services in Islamic Hospitals

Through an open-ended questionnaire, data on perceptions of health workers about Islamic services were obtained at Islamic hospitals. The majority of nurses reported that they received training in Islamic nursing when they started work. Most of the nurses said that nursing - health services in Islam are nursing services carried out in accordance with Islamic values by applying Islamic concepts.¹¹ The differences felt by nurses between ordinary hospitals and hospitals with Islamic writing include the hospital feeling more comfortable and more organized, upholding hospitality and courtesy, and facilitating religious activities such as holding regular recitation every week .¹² While the application of Islamic nursing services carried out by nurses is saying greetings, reading prayers before and after work and taking action, and always trying to take

actions according to gender. Ustad or clergy who provide spiritual guidance to health care providers and patients. The majority of nurses also said that there are already regulations and SOPs on Islamic Nursing.

Conclusion

1. Respondent characteristics

a. Nurse

The majority of nurses, namely 58% of the nurses at the Medan Hajj Hospital and 56% of the nurses at the Jakarta Hajj Hospital, were between 25 - 45 years old.

The majority of nurses, namely 74% of nurses at the Medan Hajj Hospital, and 70% of the nurses at the Jakarta Hajj Hospital are female.

The majority of nurses at the Medan Hajj Hospital, 68% have an undergraduate degree, and 52% at the Jakarta Hajj Hospital have a D3 education.

b. Patient

The majority of patients in Medan Hajj Hospital, 52% were <25 years old, and in Jakarta Hajj Hospital, 58% of patients were aged 25-45 years.

The majority of patients, namely 58% of patients at the Medan Hajj Hospital and 56% of the patients at the Jakarta Hajj Hospital were male.

2. The description of the implementation of Sharia health services in the Medan Hajj Hospital and the Jakarta Hajj Hospital from the leadership side and the 100% policy according to Sharia. Sharia health services by nurses 52% of Medan Hajj Hospital nurses and 56% of Jakarta Hajj Hospital nurses have implemented health services according to Sharia. The application of Sharia health services based on the patient’s perspective in the Jakarta Hajj Hospital 54% and the Medan Hajj Hospital 56% of patients / families have experienced the application of health services according to Sharia.

Table 1. Frequency Distribution of Nurse Respondents Demographic Data

Nurse Demographic Data		Medan Hajj Hospital (n = 50)		Hajj Hospital Jakarta (n = 50)	
		N	%	N	%
a.	Age				
	<25 years	6	12%	0	0
	25-45 years	29	58%	28	56%
	45-65 th	15	30%	22	44%
	Total	50	100%	50	100%
a.	Gender				
	Men	13	26%	15	30%
	Woman	37	74%	35	70%
	Total	50	100%	50	100%
a.	Education				
	High school	14	28%	0	0
	D3	0	0	36	52%
	S1	34	68%	24	48%
	S2	2	4%	0	0
	Total	50	100%	50	100%

Table 2. Frequency Distribution of Patient / Family Respondents for Demographic Data

Patient Demographic Data	Medan Hajj Hospital (n = 50)		Haji Hospital Jakarta (n = 50)	
	N	%	N	%
Age				
a. <25 years	26	52%	0	0
b. 25-45 years	15	30%	29	58%
c. 45-65 th	9	18%	21	42%
Total	50	100%	50	100%
Gender				
a. Men	29	58%	28	56%
b. Woman	21	42%	22	44%
Total	50	100%	50	100%

Table 3. Frequency Distribution Implementation of Sharia Health Services by Leaders

Implementation of Sharia Health Services	Medan Hajj Hospital (n = 5)		Haji Hospital Jakarta (n = 5)	
	N	%	N	%
In accordance with the Sharia	5	100%	4	80%
Less Sharia	0	0	1	20%
Total	5	100%	5	100%

Table 4. Frequency Distribution Implementation of Sharia Health Services by Nurses

Sharia Health Services	Medan Hajj Hospital (n = 50)		Haji Hospital Jakarta (n = 50)	
	N	%	N	%
Corresponding Sharia	26	52%	28	56%
Less Sharia	24	48%	22	44%
Total	50	100%	50	100%

Ethical Clearance- Taken from **Ethical clearance** committee of Faculty of Health Science, UIN Syarif Hidayatullah Jakarta

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Conflict of Interest –Nil

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Assess the Level of Practice on Usage of Personal Protective Equipment among Health Care Workers

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Abstract

Background: Personal protective equipment (PPE) provides a physical barrier between microorganism and wearer. It's important to assess the level of compliance with use of PPE by the various health care workers (HCWs) who make direct contact with patients.

Methods: Non-experimental descriptive design was used with quantitative survey approach. Setting of the study was in a tertiary hospital, Bengaluru. Samples were all HCWs those who were available during study period. Sample size was total 200. Non probability, purposive sampling technique was used for the study. The data was collected using an observational checklist.

Results: Out of 200 HCWs, majority (34%) was nursing students and remaining (33%) of each were doctors, and staff nurses. Percentage wise distribution of HCWs according to the level of practice on usage of PPE in wards showed that majority (60%) had average practice, whereas the lowest percentages (6%) had poor practice. Majority (72%) of HCWs in intensive care unit (ICU), operation theatre (OT) and labour room (LR) had good practice whereas the lowest percentage (1%) had poor practice. There was significant association found between the practice scores on usage of PPE with the selected demographic variables i.e. HCWs, age, educational qualification and years of work experience.

Conclusion: Findings of the present study concluded that there is a requisite to improve the practices of HCWs' on usage of PPE. Periodic reinforcement and training programs are needed for all level of HCWs in order to maintain adherence with appropriate use of PPE.

Keywords: Practice, Personal protective equipment, Health care workers

Introduction

Personal protective equipment (PPE) is designed to protect health care providers from serious workplace injuries or illnesses. PPE provides a physical barrier

between microorganism and wearer. It offers protection by preventing microorganism from contaminating hands, eyes, clothing, hair and shoes. A breach in infection control practices facilitates transmission of infection from patients to health care workers, other patients and attendants.

PPE includes gloves, protective eye wear (goggles), mask, apron, gown, boots/shoe cover, hair cover. PPE should be used by all health care providers, supporting staffs, laboratory staffs, and family members who provide care to patients in situations where they have contact with blood, body fluids, secretions or excretions.

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The emergence of life-threatening infections such as severe acute respiratory syndrome (SARS) and re-emerging infectious diseases like plague and tuberculosis had highlighted the need for efficient infection control programs in all health care settings and research into standard precautions has been carried out in many countries.

Nosocomial infections transmitted by direct-contact can be prevented by adapting standard precautions guidelines. Appropriate use of PPE is the easiest way to prevent contact from secretions and transfer of pathogens. It's important to assess the level of compliance with use of PPE by the various health care workers HCWs who make direct contact with patients.¹

A HCW is one who delivers care and services to the sick and ailing either directly as doctors and nurses or indirectly as aides, helpers, laboratory technicians, or even medical waste handlers. There are approximately 59 million healthcare workers worldwide. Recognizing the vital role played by health care workers as "the most valuable resource for health" the World Health Organization (WHO) had declared the years 2006 to 2015 as the "The decade of the human resources for health."

In a report published by the WHO, the disease burden caused by percutaneous sharps injuries among HCWs was found to be three million per year. Moreover, 40% of hepatitis B, 40% of hepatitis C, and 4.4% of HIV among HCWs were due to needle stick injuries. It is very unfortunate that approximately 1000 HCWs die annually from occupational HIV, which can and should have been prevented. Despite this, almost 80% of healthcare workers remain unimmunized (against Hepatitis B) in many parts of the world.

The need of the hour is to prioritize occupational health of HCWs and ensure that the workforce is adequately trained and healthy. As humanitarians, it is our duty to help the most vulnerable sections but we should not end up paying the price of our lives for it.²

Material and Methods

The study was conducted in a tertiary hospital at Bengaluru during July 2019. In present study, a quantitative survey approach and non-experimental

descriptive design was adopted. Non probability, purposive sampling technique was used to collect data from 200 HCWs (doctors, staff nurses & nursing students) who were available at the time of data collection. HCWs working in selected areas of hospital were taken as subjects. The investigators had collected the data after getting permission from administrator of hospital and principal of college of nursing. The data was collected through concealed observation method using an observational checklist to assess the practice on usage of PPE among HCWs (for wards) and a separate observational checklist to assess the practice on usage of PPE (for ICU, OT, & LR). Each sample was observed once to assess the practice. After the completion of data collection, subjects were informed regarding the study and demographic profile of HCWs were obtained. An observational checklist was also used to assess availability of PPE related resources in the hospital. Descriptive statistics includes frequency, percentage, range, mean, median and standard deviation was used to describe the result. Inferential statistic like Chi square test was used to find the association with selected demographic data.

Results

Study revealed that out of 200 HCWs majority (34%) was nursing students and remaining (33%) of each were doctors, and staff nurses. Majority (48.5%) of samples were of the age group of below 25 years, whereas the least percentages (5.5%) were of the age group of >50 years. (76.5%) of HCWs were females followed by (23.5%) were males. The highest percentage (45%) of respondents had work experience of > 2 years whereas the lowest percentages (3%) had work experience of < 1 year and (34%) were nursing students who were studying B.Sc. nursing. Majority (33.5%) of samples were working in the other wards (i.e. had both medical and surgical cases), whereas the least percentages (8%) were working in medical wards. Among 66 doctors, the highest percentage (64%) of doctors had MBBS and above education, whereas the lowest percentages (36%) were PG medical students. Out of 66 staff nurses' majority (74%) of staff nurses had B.Sc. nursing education whereas the least percentages (3%) had Post Basic B.Sc. nursing education. Among 68 nursing students majority (47%) of nursing students were studying 3rd year B.Sc., whereas the lowest percentages

(22%) were studying 2nd year B.Sc.

Table no. - 1 Frequency and percentage distribution of HCWs according to the level of practice on usage of PPE (wards

n=100

Sl no.	Variables	Frequency (f)	Percentage (%)
10.	Level of practice – Good practice	34	34
	Average practice	60	60
	Poor practice	6	6

Majority (60%) of HCWs had average practice, whereas the lowest percentages (6%) had poor practice.

Out of 33 doctors; who worked in wards, majority (67%) had good practice, (33%) had average practice whereas none of them had poor practice. Among 33 staff nurses, majority (58%) had average practice, (24%) had good practice whereas the lowest percentages (18%) had poor practice. Out of 34 nursing students, majority (88%) had average practice, (12%) had good practice whereas none had poor practice.

Table no.-2: Practice scores of HCWs according to the level of practice on usage of PPE (wards)

n= 100

Variables	No. of items	Maximum scores	Range	Mean	Median	Standard deviation
Level of practice on usage of PPE	23	23	13	16.58	17	3.03

Data in table-2 shows that the range of practice scores was 13, mean was 16.58, median was 17 and standard deviation was 3.03.

Table no.-3: Frequency and percentage distribution of HCWs according to the level of practice on usage of PPE (ICU, OT & LR)

n= 100

Sl no.	Variables	Frequency (f)	Percentage (%)
14.	Level of practice – Good practice	72	72
	Average practice	27	27
	Poor practice	1	1

Majority (72%) of HCWs had good practice whereas the lowest percentage (1%) had poor practice.

Out of 33 doctors, who worked in ICU, OT& LR; all (100%) had good practice, whereas none of them had average and poor practice. Among 33 staff nurses, majority (55%) had good practice, (42 %) had average practice whereas the lowest percentages (3%) had poor practice Out of 34 nursing students, majority (62%) had good practice, and (38%) had average practice whereas none of them had poor practice.

Tableno.-4: Practice scores of HCWs according to the level of practice on usage of PPE (ICU, OT & LR)

n=100

Variables	No. of items	Maximum scores	Range	Mean	Median	Standard deviation
Level of practice on usage of PPE	23	23	18	20.16	27	7.14

Data in the table-4 shows that the range of practice scores was 18, mean was 20.16, median was 27 and standard deviation was 7.14.

Tableno.-5: Association between the practice scores on usage of PPE among HCWs with demographic variables [Wards]

n=100

Sl no.	Variables	χ^2	Level of significance
1	HCW	38.15	Significant
2	Age	16.13	Significant
3	Educational qualification	38.15	Significant
4	Years of experience	24.72	Significant

For HCWs, age and educational qualification (df- 4, chi square value- 9.49, $p < 0.05$) and for years of experience (df- 6, chi square value- 12.59, $p < 0.05$)

Chi square value was calculated to find out the association between the practice scores on usage of PPE with socio - demographic variables. The finding reveals that there is significant association between the practice scores on usage of PPE with selected demographic variables i.e. HCWs, age, and educational qualification and years of work experience.

The finding of association between practice scores on usage of PPE among 100 HCWs with selected demographic variables in ICU, OT & LR reveals that there is significant association between the practice scores on usage of PPE with selected demographic variables i.e. for HCWs - χ^2 value of 16.36 (df- 4, chi square value- 9.49, $p < 0.05$) , age- χ^2 value of 38.36 (Df- 4, chi square value- 9.49, $p < 0.05$) , educational qualification- χ^2 value of 16.36 (df- 4, chi square value-

9.49, $p < 0.05$) and years of work experience - χ^2 value of 33.42 (df- 6, chi square value- 12.59, $p < 0.05$) .

All the wards (medical, surgical, other wards, ICU, OT and LR) of the hospital have 100% resources related to PPE availability.

Discussion

Healthcare workers are at great risk of blood borne infections. Most of them are because of occupational exposure. ³ According to the fact sheet given by WHO, there are several factors which can cause health care-associated infections. Among this prolonged and inappropriate use of devices and antibiotics, high-risk and sophisticated procedures, immunosuppression and other severe underlying patient conditions and insufficient application of standard precautions are some of factors

which present regardless of the resources available.⁴ To prevent disease transmission in healthcare settings, PPE must be used consistently and correctly by HCWs to prevent exposure and the transport of pathogens to their bodies.⁵ We found that (34%) samples were nursing students whereas (33%) of each were doctors and staff nurses. With regard to usage of PPE in wards, majority (60%) of HCWs had average practice, (34%) had good practice followed by (6%) had poor practice whereas in ICU, OT & LR (72%) HCWs had good practice, (27%) had average practice followed by (1%) had poor practice. So, practices of HCWs on usage of PPE were not adequate.

A cross sectional study was done by Archana Lakshmi P. A., Gladius Jennifer H., Meriton Stanly A. et al (2018)¹ on PPE use among health care providers (HCPs) of two tertiary health care institutions in Tamil Nadu. The HCPs included in the study was 1060. Among them, there were (38.9%) doctors, (51.9%) nurses and (9.2%) technicians. Among 862 HCPs who worked outside the operation theatre (OT) and ICU, appropriate use of PPE among the HCPs were only (18.1%). Appropriate use of PPE was high among the doctors (31.5%) followed by nurses (9.3%) and technicians (8.2%) which was statistically significant ($\chi^2=56.82$, $p=0.0001$). Among the HCPs working in OT, appropriate use of gloves, mask, apron, gown and hair cover was 100%. But the use of goggles and shoe cover was very low.

Conclusion

Findings of the present study concluded that there is a requisite to improve the practices of HCWs' on usage of PPE. The demand of the hour is to observe cyclically practices of HCWs, prioritize their occupational health and to ensure that the workforce is adequately trained and fiercely motivated and encouraged. Periodic reinforcement and training programs are needed for all level of health care workers in order to maintain adherence with appropriate use of PPE. Authorities should monitor and supervise health care workers towards infection prevention practices and control measures with the routine services through preparing and introducing health care workers infection prevention guidelines, protocol, rules, regulations and opportunities

to promote the desired team spirit at all health facility levels.

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Study on Relationship between Serum Iron, Transferrin and Ferritin With Proteinuria in Adult Nephrotic Syndrome Patients in Vietnam

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Abstract

Background: the loss of proteinuria in nephrotic syndrome (NS) patients reduces serum albumin and leads to many other changes such as dyslipidemia, disorders of blood clotting, disorders of hematopoietic components. The more and longer the loss of proteinuria occurs, the more pronounced these disorders are iron, transferrin and ferritin in serum. **The objectives:** Study the relationship between serum iron, transferrin and ferritin levels and proteinuria in NS patients. **Subjects and Research Methods:** randomized and controlled selection of 68 patients with NS in adults and without kidney failure; research according to the cross-descriptive method. **Results:** serum iron and transferrin levels in patients with NS are inversely correlated with proteinuria, with the following equations: $y = -0.0633x + 9.531$, $R^2 = 0.0105$ and $y = -0.0041x + 0.725$, $R^2 = 0.0182$; serum ferritin concentration positively correlated with proteinuria, with the equation $y = 2.7432x + 583.65$, $R^2 = 0.0017$.

Conclusion: in NS serum iron and transferrin concentrations are inversely correlated with proteinuria, while serum ferritin is positively correlated with proteinuria.

Keywords: iron, transferrin, ferritin, proteinuria, nephrotic syndrome

Introduction

Nephrotic syndrome (NS) is a common clinical glomerulonephritis disease that often recurs repeatedly and can lead to kidney failure if not treated and cared for well. Currently, the diagnosis and determination of NS are no longer difficult, however, the pathogenesis mechanism and the disorders caused by nephrotic disease still have many concerns. In NS, the loss of protein in urine is much and prolonged reduces serum albumin and leads to many other changes such as dyslipidemia, clotting disorders, disorders of hematopoietic components. If the excretion of proteinuria in NS is more and more persistent, these disorders are more pronounced including disorders of

iron, serum transferrin and ferritin ^{(2),(3),(5),(8)}. In normal people, the daily requirement of iron is about 0.5-1mg and the source of iron is mainly from foods of animal and plant origin. All iron in the body is about 4g, of which 65% is in Hb, 15-30% is stored in the retinal system of the endothelium and liver parenchyma cells in the form of ferritin. Iron is an important component in the synthesis of hemoglobine and myoglobine, for ferritin has been identified as a predictor of the development and progression of atherosclerosis. Iron deficiency and ferritin stagnation in the body will cause iron deficiency anemia, affect the metabolic activity of the cells, as well as cause glomerular fibrosis leading to impaired kidney function, worsen the course of treatment and prognosis of patients with NS ^{(1),(3),(4),(6)}. However, research on the components of serum iron and its association in NS has not been given adequate attention, while this disorder may contribute to worsening of kidney disease and worse prognosis.

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To find out this problem, we performed the topic “Study on relationship between serum iron, transferrin and ferritin with proteinuria in patients with nephrotic syndrome”.

Objectives of the thesis: to find out the relationship between serum iron, transferrin and ferritin with proteinuria in nephrotic syndrome patients.

Research subjects and methodology

We selected a convenient sample of 68 NS patients without kidney failure from May 2019 to May 2020, aged 16 years and over, hospitalized for treatment at Internal Department of Hue University of Medicine and Pharmacy Hospital, Vietnam. Criteria for diagnosis of NS include: proteinuria ≥ 3.5 grams/24 hours; blood protein < 60 grams/L and blood albumin < 30 grams/L, increased blood cholesterol and total edema⁽⁷⁾.

Criteria for the exclusion of NS patients not included in the study are patients with one of the following diseases:

- Endocrine disorders, hypertension, hepatitis, liver failure, kidney failure, rheumatoid arthritis.
- Blood diseases.
- Acute and chronic infections.

- Pregnant women.
- Cases of alcoholism.
- The cases are being treated for NS.
- Patient has been transfusion or lipid-rich products.
- Patients are taking vitamin B12, taking iron-containing drugs, oral contraceptives and some drugs that alter serum iron levels.

Research Methods

Research method according to cross-sectional descriptive method. Patients are carried out clinical examination and tests to diagnose NS, eligible for inclusion in the research group.

Tests are conducted on Cobas analyzers, at Labo of Hue University of Medicine and Pharmacy Hospital, a reputable and reliable hospital. Before the test, instruct patients to eat normally, not to eat or drink foods containing high amounts of iron. All tests are done when the patient first arrives in the hospital, has blood drawn in the morning and has not eaten.

Quantification of serum iron, ferritin and transferrin concentrations by immunoturbidity measurement.

Normal values of serum iron, transferrin and ferritin concentrations

Type	Normal value
Serum iron	5,83-34,5 $\mu\text{mol/L}$
Serum transferrin	2-3,6 mmol/L
Serum ferritin in men	30-400 pmol/L
Serum ferritin in women	15-150 pmol/L

Proteinuria test at the same time as serum iron, ferritin and transferrin test. Proteinuria is tested by turbidity measurement. Normal value of proteinuria in 24-hour urine samples < 140 mg/24 hours and in

randomized samples < 150 mg/L.

Processing data according to the method of medical statistics, Excel 2007.

Research Results

Table 1. General characteristics of the subject of the study group

Rate Characteristics		Male		Female		Total	
		n	%	n	%	n	%
Age	<30	32	47.0	6	8.8	38	55.8
	30-50	8	11.8	7	10.3	15	22.1
	>50	11	16.2	4	5.9	15	22.1
	\bar{X} CI 95%	24 (27.7-37.6)		42 (28.5-46.1)		33.4 (29.1-37.6)	
Occupation	Officer	21	30.9	5	7.3	26	38.2
	Farmer	19	27.9	8	11.7	27	39.7
	Homemaker	11	16.2	4	5.9	15	22.1
Area	Urban	24	35.3	9	13.2	33	48.5
	Rural	27	39.7	8	11.8	35	51.5
Total		51	75	17	25	68	100

Male accounted for 51 patients (75%), female 17 patients (25%), the difference is statistically significant with $p < 0.05$. The average age of the study team is 33.4. Occupation in agriculture accounts for 39.7% and in rural areas 51.5%.

Table 2. Results of biochemical tests of the study group

Test results		Rate		Overall average CI 95%
		n	%	
Serum protein (gram/L)	<40	7	10.3	44.4 CI 95%: 43.2-45.6
	40-60	61	89.7	
Serum albumin (gram/L)	<20	62	91.2	16.4 CI 95%: 15.7-17.1
	20-40	6	8.8	
Proteinuria (gram/24 hours)	3.5-5	12	17.6	9.7 CI 95%: 8.4-11.5
	5-10	30	44.1	
	>10	26	38.2	
Serum iron ($\mu\text{mol/L}$)	Low	21	30.9	8.9 CI 95%: 8.1-9.7
	Normal	47	69.1	
	High	0	0.0	
Serum transferrin (mmol/L)	Low	68	100	0.68 CI 95%: 0.64-0.72
	Normal	0	0.0	
	High	0	0.0	
Serum ferritin (pmol/L)	Low	0	0.0	610.3 CI 95%: 521.9-699.2
	Normal	22	32.4	
	High	46	67.6	

The Serum albumin < 20 grams/L accounts for 91.2% (62 cases), the average concentration was 16.4 grams/L. Proteinuria concentration was mainly over 5 grams/day, accounting for 82.3% (56 cases), the average concentration was 9.7 grams/day. The serum iron concentration at a low level < 5.83 μmol/L, accounting

for 30.9%, the average concentration was 8.9 μmol/L. In 100% of cases, the serum transferrin concentration was lower than normal, the average concentration was 0.68 mmol/L. Serum ferritin at high levels accounted for 67.6% (46 patients), average concentrations were 610.3 pmol/L.

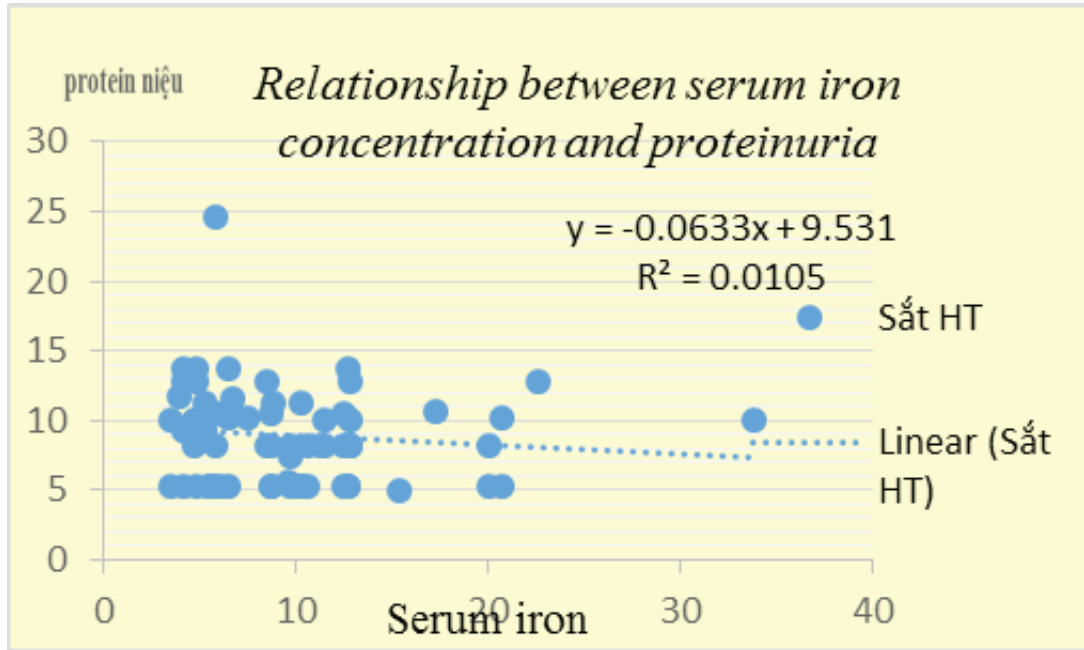


Figure 1. Relationship between serum iron concentration and proteinuria

The relationship between the serum iron concentration and proteinuria is inversely correlated, with the equation $y = -0.0633x + 9.531$, $R^2 = 0.0105$.

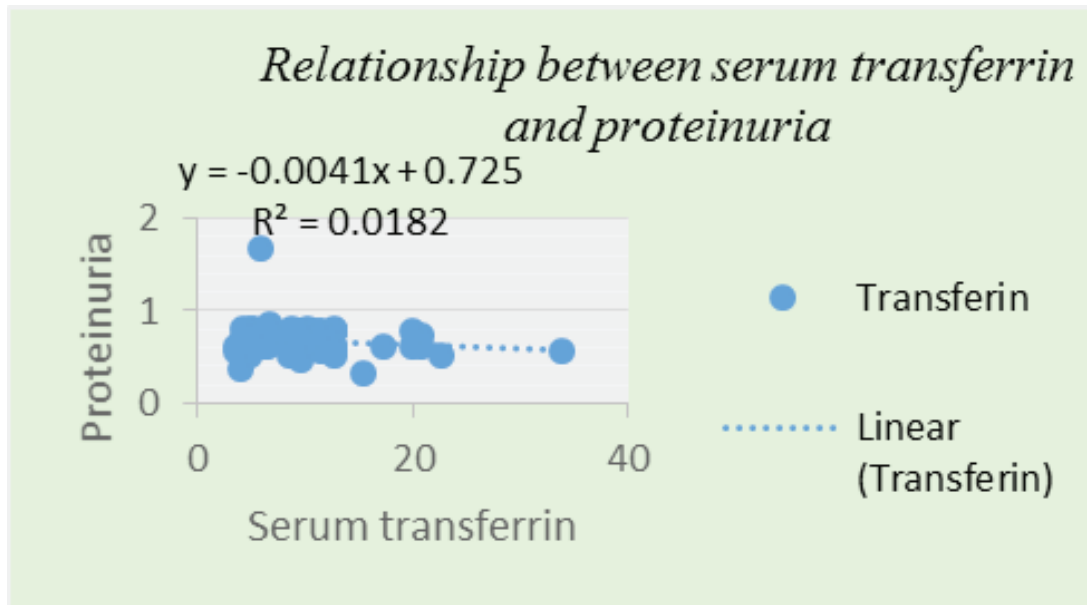


Figure 2. Relationship between serum transferrin concentration and proteinuria

The relationship between the serum transferrin concentration and proteinuria is inversely correlated, with the equation $y = -0.0041x + 0.725$, $R^2 = 0.0182$.

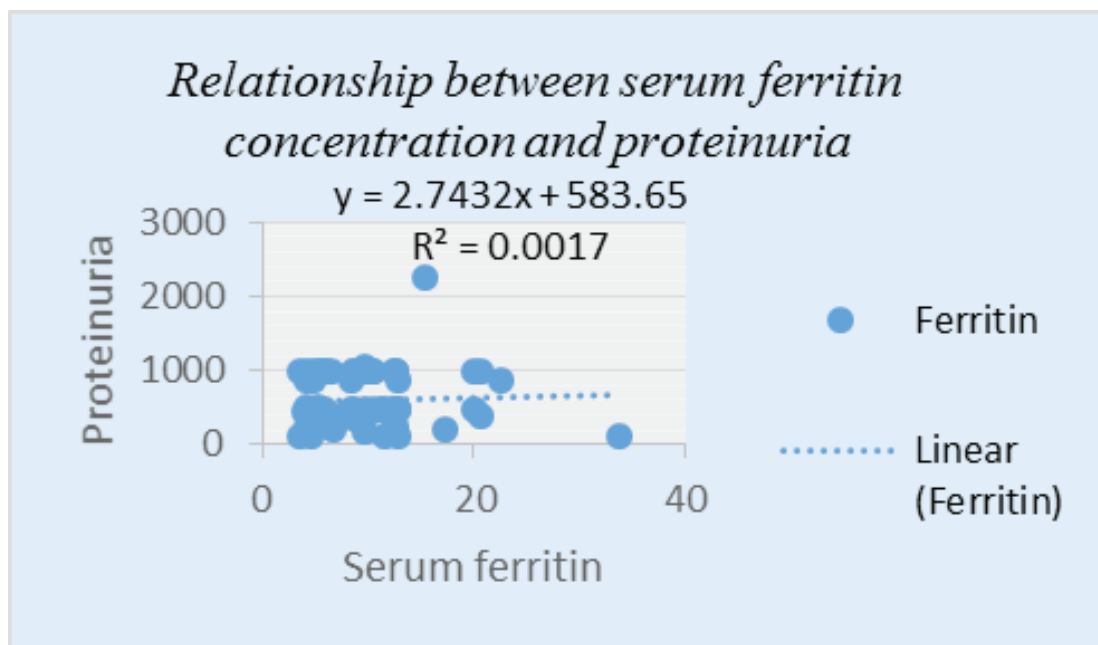


Figure 3. Relationship between serum ferritin concentration and proteinuria

Relationship between serum ferritin concentration and proteinuria is positively correlated, with the equation $y = 2.7432x + 583.65$, $R^2 = 0.0017$.

Discussion

The loss of protein to urine in NS leads to many changes in humors, including decrease in serum albumin, changes in iron, transferrin and ferritin in serum. Prolonged reduction in serum iron and transferrin levels may cause iron deficiency anemia, for increased ferritin has been shown to be an independent risk of atherosclerosis. Thus, in NS if the loss of proteinuria is more and more prolonged, these disorders will be more severe, making treatment and prognosis of NS worse (3),(4),(5)

The results in Figure 1 show that the correlation between serum iron concentration and proteinuria is inversely correlated, with the equation $y = -0.0633x + 9.531$, $R^2 = 0.0105$, thus the higher the proteinuria, the lower the serum iron. In this study, data in Table 2 showed that up to 21 patients had lower than normal iron serum concentrations ($<5.83 \mu\text{mol/L}$), accounting for 30.9%, average serum iron concentration the serum was $8.9 \mu\text{mol/L}$, in no case of serum iron increased, this indicates that in NS serum iron has been lost in the urine along with protein. The more proteinuria

is lost, the decrease in serum iron and the lack of iron in NS is the risk of further damage to the kidneys. It was found that the iron-releasing macrophages cycle during the day with the highest iron release in the morning and lowest in the afternoon, so the serum iron concentration is also seen highest in the morning and low most in the afternoon⁽⁸⁾. Our study is that all cases are blood drawn for testing in the morning, which also indicates that the serum iron concentration in the study group is the highest in the day.

Relationship between serum transferrin concentration and proteinuria, through data in Figure 2, it shows that the serum transferrin concentration with proteinuria is inversely correlated with the equation $y = -0.0041x + 0.725$, $R^2 = 0.0182$. Transferrin is synthesized mainly in the liver, with the loss of transferrin in the urine sufficient to decrease the serum transferrin concentration in NS. A decrease in transferrin can lead to iron deficiency anemia. In NS, transferrin synthesis is positively correlated with albumin synthesis, but this synthesis is not sufficient to compensate for urinary protein loss. Therefore, the treatment of maximizing the serum transferrin concentration in nephrotic patients

is primarily based on reduced proteinuria⁽⁶⁾. Data in Table 2 show that in 100% of cases NS had lower serum transferrin concentrations than normal, the highest serum transferrin concentration was 1.68 mmol/L, the lowest 0.32 mmol/L and the average concentration mean is 0.68 mmol/L (95% CI: 0.64-0.72). This suggests that in NS, the more protein a patient loses to the urine, the lower the transferrin and the higher the risk of anemia.

The results in Figure 3 show that the serum ferritin concentration is positively correlated with proteinuria with the equation $y = 2.7432x + 583.65$, $R^2 = 0.0017$. Studies have shown that ferritin is a high molecular weight protein that reflects iron stores in the body, but can also increase responsiveness in some acute diseases, so in our study we excluded NS patients with comorbid conditions can alter ferritin levels. The increase in ferritin synthesis in NS patients compensates for the decrease in serum albumin due to loss of protein in the urine^{(1),(2)}. Also through the research data in Table 2 showed that the serum ferritin concentration tended to increase, accounting for 67.6% (46 patients) and the average concentration was 610.3 pmol/L, so in NS patients. Serum ferritin levels are much higher than normal. Compared with the study of Nguyen Tran Kien and et al⁽⁹⁾, the increase rate of serum ferritin in NS is 58%, this rate is lower than our study, which can be explained by the patient group of the study. We have too low blood albumin level (mainly about 20 gams/L) as shown in Table 2. This result shows that in NS serum ferritin concentration often increases and correlates positively with urinary protein loss.

Conclusion

By studying the relationship between serum iron, transferrin, and ferritin with proteinuria in non-renal impaired adult NS patients, we conclude that serum iron and transferrin concentrations are inversely correlated with proteinuria. Serum ferritin is positively correlated with proteinuria ($p < 0.01$).

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Duration of Father Out-Migration and Its Impact on Nutritional Status of Left-Behind Children: A Cross-Sectional Study in Rural EAG States in India

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Abstract

Millions of children are left behind due to parental migration. Most out-migrants are unskilled male labour from Empowered Action Group (EAG) states in India. Therefore, the present study tried to compare nutritional outcomes (mainly stunting, wasting, and underweight) of left behind under five (Under-5) children based on the duration of the father migration in India's EAG states. The study used the National Family Health Survey 2015-16 (NFHS 4) data. The multivariate logistic regression models were used to measure the unadjusted and adjusted effects of the duration of father's migration on child malnutrition in the study area. The present study also suggested no significant effect duration of father's migration on under-5 children nutrition except underweight. The underweight prevalence was 14% less likely (OR: 0.86 95% CI 0.76-0.97) among the left-behind children with the duration of father migration more than 12 months compared to their counterpart. The nutritional status was low among all under-five children irrespective of father migration duration in the study area. Still, the under-5 children's malnutrition prevailed noticeably among socio-economically disadvantaged groups. There is a need to implement unique programs and policies related to children's nutrition to eliminate child malnutrition's burning issues among left-behind households.

Keyword: Duration of migration, Nutritional status, EAG states, Rural, India

Introduction

Malnutrition in children is a significant public health challenge in India and one of the leading countries among the South-Asian countries [1]. National Family and Health Survey 2015-16 (NFHS 4) report exhibits about 38%, 21%, and 36% under-five children are stunted, wasted, and underweighted, indicating chronic malnutrition privileged in India [2]. Existing literature has suggested that the level of urbanization, community socio-economic status, and living condition significantly affects early childhood malnutrition [3,4]. Maternal education and empowerment, breastfeeding practice, mother's health, and dietary practice are significant factors of child nutrition [5].

Migrants' remittances also play a significant role in improving children's nutritional status suggested by many previous researchers [6,7,8]. Pieces of evidence from existing literatures presented conflicted results regarding the effects of parental migration on children's nutritional status. Démurger and Xu (2015) found that nutritional negligence was higher among left-behind than non-left-behind [9]. On the other hand, few studies suggested no association between parental migration and the nutritional status of left-behind children [7,8]. However, most of the previous research on impact of paternal migration on nutritional outcomes of left behind children was mainly conducted in China, Philippines and Vietnam [10].

In contrast, few studies focused on India [8]. Therefore, present study has tried to assess the impact of duration of father's migration on the nutritional status of left behind children (aged between 6 to 59 months) in the rural Empowered Action Group (EAG) states in India. This paper examined the effect of duration of father's migration instead of parental migration because of data availability, i.e., NFHS only gives indirect information about husband migration [2]. The selection of rural EAG states mainly due to co-existence of outmigration^[11] and child malnutrition^[2].

Data and Methods

The study used National Family Health Survey 2015-16 (NFHS 4), nationally representative data. A multi-stage, systematic and stratified sampling design was adopted for each state, where the primary sampling units were select with PPS. The details of the sampling techniques and survey objectives are available in the NFHS-4 report [2].

The outcome variable in this study is child nutritional status, mainly stunting, wasting, and underweight. The present paper followed World Health Organisation (WHO) standard estimation to define outcome variables, i.e., stunting, wasting, and underweight^[12]. The three malnutrition-related outcome variable are binary outcomes- Stunting (stunted "1", non-stunted "0"), wasting (wasted '1', non-wasted '0'), and underweight (underweighted '1', non-underweighted '0').

The primary predictor variable in the study is left-behind children due to father migration. In this study, left-behind children refer to the children whose fathers were away from home for one or more months during the survey. The NFHS-4 survey asked a question to the woman- Is your husband is away from home? And another question was the duration of away from home? Based on above two questions the period of husband migration has been categorized into two categories- (a) less than 12 months or short-term out-migrants and (b) more than 12 months or long-term out-migrants. Therefore, the under-five left behind children categories into two sub-groups-

(a) left-behind children of short term out-migrated father
(b) left-behind children of long term out-migrated father.
Other independent variables are children's age, mother's age, child's gender, mother's education, religion, caste, and wealth status.

The present study employs bivariate and multivariate techniques to accomplish the study objectives. The bivariate analysis was applied to examine the levels of nutrition of under-five left-behind children. The multivariate binary logistic regression models were used to examine the association between the duration of the father's migration and child malnutrition. The study included the left-behind children aged between 6-59 months. The final sample size is 4138 left-behind children (age 6-59 months) in this study. The present paper excluded samples of non-EAG states, urban, the husband with more than one wife, visitors, children aged less than 6 months and more than 59 months, and a missing sample of migration duration to determine the study sample^[13]. The analysis was done by used STATA version-14

Result

Sample Characteristics:

Table 1 shows the outcome variable's descriptive statistics and the predictors in the study sample from NFHS-4 (2015-16). About 60.2 % of children were left behind those whose fathers were long term out-migrated during the survey. And nearly 50%, 44%, and 20% of total left-behind children were stunted, underweight, and wasted, respectively, in India's rural EAG states. Most of the children were 18 to 35 months old (32.8%), whereas most mothers were 25 to 29 years old (40.5%). About 50.6% of mothers were not literate. The sex distribution of children shows an almost similar pattern. Hindus had the highest share of the sample (83.0%) and Muslims (16.0%). The percentage of sample was highest in other backward classes (52.0%), followed by scheduled caste (22.8 %) and other (16%). The largest proportion of the respondent belongs from poorest wealth status (52.0%).

Table 1: Descriptive statistics of the outcomes variables and the predictors of the study samples from NFHS-4, 2015-16 (n=4,138)

Outcome variables and predictors	%	95% CI
Stunting		
No	50	48-51
Yes	50	49-52
Wasting		
No	79.8	79.1-81.5
Yes	20.2	19.2-21.2
Underweight		
No	56.1	55.1-58.3
Yes	43.9	42.2-44.9
Left Behind Children		
Left-behind of short term out-migrated father	39.8	38.0-41.0
Left-behind of long term out-migrated father	60.2	58.8-62.2
Child's age(in months)		
06-17	23.1	21.8-24.4
18-35	32.8	31.4-34.2
36-43	15.9	14.8-17
44-60	28.3	26.9-29.7
Mother's age		
15-19	2.4	2-2.9
20-24	30.1	28.7-31.5
25-29	40.5	39-42
30-49	27.1	25.7-28.4
Sex of the children		
Male	51.2	49.7-52.7
Female	48.8	47.3-50.3
Mother's education		
No education	50.6	49.1-52.1
Primary	13.2	12.2-14.2
Secondary	32	30.6-33.5
Higher	4.2	3.6-4.8
Religion		
Hindu	83	81.9-84.2
Muslim	16	14.9-17.1
Other	1	0.7-1.3
Caste		
Scheduled Caste	22.8	21.6-24.1
Scheduled Tribe	9.6	8.7-10.5
Other Backward Class	51.6	50.1-53.1
Other	16	14.9-17.1
wealth status		
Poorest	52	50.4-53.5
Poorer	26.9	25.6-28.3
Middle	12.3	11.3-13.3
Richer	6.4	5.7-7.2
Richest	2.5	2.1-3

Nutritional status of left-behind children by the duration of father's out-migration:

There were no significant differences in stunting based on the duration of the father's out-migration (Table 2). The wasted level was slightly higher (21.4%) among

the left-behind children of short-term out-migrants father compared to children of the long-term out-migrant father (19.4%). Similarly, the under weight was higher among left-behind children of short-term out-migrated fathers (46.2%) than their counterparts (42.4%).

Table 2: Bivariate estimates of stunted, wasted, and underweighted by the left-behind status of children in Rural EAG states in India, 2015-16

Nutritional status	%	Chi2 test
Stunted		
Left-behind of short term out-migrated father	50.3	0.0021
Left-behind of long term out-migrated father	49.9	
Wasted		
Left-behind of short term out-migrated father	21.4	4.1896*
Left-behind of long term out-migrated father	19.4	
Underweighted		
Left-behind of short term out-migrated father	46.2	6.9346***
Left-behind of long term out-migrated father	42.4	

Association between children's nutritional status and duration of father out-migration:

The long term migrated father's left-behind were 14% (OR: 0.86 95% CI 0.76-0.97) less likely underweighted than their counterparts confirmed by unadjusted odds ratio (Table 3). There was no significant association between stunting/wasting and duration of father's out-migration.

Table 3: Unadjusted odds ratio of children nutritional status by left-behind status in rural EAG states, India, 2015-16

Left Behind Status	Stunted	Wasted	Underweighted
Unadjusted OR with 95% CI			
Left-behind of short term out-migrated father [Ref]	1.00	1.00	1.00
Left-behind of long term out-migrated father	0.98 [0.87-1.11]	0.88 [0.76-1.03]	0.86** [0.76-0.97]

Note: OR stands for odds ratio; Ref. denotes reference category; CI stands Confidence Interval * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Socio-economic correlates of children’s nutritional status:

The adjusted odds of stunting, wasting, and underweight increased with increasing age (Table 4). The likelihood of stunting, wasting, and underweight decreased with increasing mothers’ education and wealth quintile. Our result found no significant association between under-five children’s nutrition and sex of the children, religion, and mother’s age. The children age group 18-35 months were more likely stunted (AOR: 2.34 95% CI 1.96-2.79) and underweighted (AOR: 1.35 95% CI 1.31-1.61) compared to reference category

children in the age group 06-17 months. The likelihood of wasting status was declined with the increasing age of the children. The children in the most prosperous family were less likely stunted (AOR: 0.48 95% CI 0.30-0.76), wasted (AOR: 0.42 95% CI 0.22-0.82), and underweighted (AOR: 0.26 95% CI 0.15-0.46) compared to poorest. The children belong from Scheduled tribe family 74% (AOR: 1.74 95% CI 1.32-2.29) more likely wasted compared Scheduled caste. Under-5 children of higher educated mothers are probably less stunted (AOR: 0.54 95% CI 0.37-0.79) and underweighted (AOR: 0.47 95% CI 0.31-0.71) compared to illiterate mothers.

Table 4: Adjusted odds ratio of stunting, wasting, underweight by left-behind children’s socio-economic background in rural EAG states in India, 2015-16

Background characteristics	Stunted		Wasted		Underweighted	
	AOR	95% CI	AOR	AOR	95% CI	95% CI
Duration of father migration						
Less than 12 months [Ref.]	1.00		1.00		1.00	
More than 12 months	1.00	0.88-1.14	0.93	0.79-1.09	0.87**	0.76-0.99
Sex of the Children						
Male [Ref.]	1.00		1.00		1.00	
Female	0.94	0.83-1.07	0.95	0.82-1.11	1.04	0.91-1.18
Child’s age(in months)						
06-17 [Ref.]	1.00		1.00		1.00	
18-35	2.34***	1.96-2.79	0.59***	0.49-0.72	1.35***	1.13-1.61
36-43	2.06***	1.67-2.54	0.47***	0.37-0.61	1.3**	1.06-1.61
44-60	2.09***	1.74-2.52	0.48***	0.39-0.6	1.27**	1.06-1.53
Wealth Status						
Poorest [Ref.]	1.00		1.00		1.00	
Poorer	0.81**	0.7-0.94	0.67***	0.55-0.81	0.67***	0.57-0.78
Middle	0.56***	0.45-0.69	0.58***	0.44-0.78	0.46***	0.37-0.58
Richer	0.45***	0.34-0.61	0.65**	0.44-0.95	0.43***	0.32-0.59
Richest	0.48**	0.30-0.76	0.42**	0.22-0.82	0.26***	0.15-0.45
Caste						
Scheduled Caste [Ref.]	1.00		1.00		1.00	
Scheduled Tribe	0.82	0.64-1.05	1.74***	1.32-2.29	0.94	0.74-1.2
Other Backward Class	0.78**	0.66-0.92	1.07	0.88-1.31	1.00	0.86-1.18
Other	0.69***	0.55-0.86	0.98	0.74-1.31	0.75	0.59-0.94
Mother’s Education						
No education [Ref.]	1.00		1.00		1.00	
Primary	0.87	0.71-1.06	0.92	0.73-1.18	0.81*	0.67-0.99

Cont... Table 4: Adjusted odds ratio of stunting, wasting, underweight by left-behind children's socio-economic background in rural EAG states in India, 2015-16

Secondary	0.72***	0.62-0.85	0.93	0.76-1.13	0.72***	0.61-0.85
Higher	0.54***	0.37-0.79	0.62	0.37-1.05	0.47***	0.31-0.71
Religion						
Hindu [Ref.]	1.00		1.00		1.00	
Muslim	1.09	0.91-1.31	0.82	0.65-1.04	0.96	0.8-1.16
Other	0.79	0.41-1.53	1.38	0.69-2.74	1.49	0.78-2.88
Mother's age						
15-19 [Ref.]	1.00		1.00		1.00	
20-24	0.84	0.55-1.3	1.35	0.81-2.24	1.05	0.69-1.62
25-29	0.73	0.48-1.12	1.11	0.67-1.85	0.98	0.64-1.5
30-49	0.71	0.46-1.09	1.14	0.68-1.93	0.92	0.6-1.43

Note: AOR stands for adjusted odds ratio; Ref. denotes reference category; CI stands Confidence Interval * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Discussion

This study has contextualized the impact of the duration of the father's migration on left-behind children's nutritional status in rural India. This study has found no significant effect of father migration duration on the left-behind child's stunting and wasting nutritional status except underweight; similar results also found in China^[7]. The present study suggested that the left-behind children of long term out-migrants were less likely underweighted than short-term out-migrants' children. A cross-country study including India by Nguyen^[8] also reported similar findings. The lower likelihood of underweighted among the above children may be the positive impact of migrant remittance. Migrants remittances maybe help to buy nutritional food for children. The prior studies found a significant association between the migrants' remittance socio-economic development of the migrant family^[14], and it's substantially influenced the children's nutrition and health condition^[15].

The present study has demonstrated that the children aged 18-35 months are at the highest odds of being stunted and underweight, a similar result also suggested by Mishra et al.^[16]. The children who belonged to the poorest household were the most vulnerable to being under nutrient children in Rural India, a similar

result found by Khan and Mohanty^[17]. This study also suggested that maternal education's improvement was positively affected the reduction of under-five (under-5) children's malnutrition, a similar result postulated by Lin and Mishra et al.^[18,16]. The higher educated women are more careful and aware of their children's diet pattern, which may improve their children's nutritional^[20]. The prevalence of wasted under-5 children was noticeably high in Scheduled tribe was found in this study.

Conclusion

This study concluded that under-5 children's nutritional status was significantly worse, far from goal 2 of SDGs in the study area. Present study also suggested no significant effect of duration of father's migration on under-5 children nutrition except underweight. The under-5 children's malnutrition prevailed noticeably among socio-economically disadvantaged groups (poor, scheduled caste, illiterate). This study also suggested that wealth and educational status is high influential socio-economic factors to eradicate child malnutrition. However, there is need to address new policies and evaluate existing policies related under-5 children nutrition to eliminate burning issues of malnutrition in rural EAG states irrespective of the father's migration duration.

Ethical Clearance: Not Applicable

Source of Funding: Self

Conflict of Interest: Nil

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Pregnancy Induced Hypertension among Pregnant Women in Dhaka City, Bangladesh

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Abstract

This cross-sectional study has been conducted in the Bangabandhu Sheikh Mujib Medical University Gynaecology and Obstetrics Division on 72 patients who have been admitted from December 2018 to March 2019, in order to find out the percentage of pregnancy-induced high blood pressure among pregnant mothers. Of the 72 patients, 25(34.7%) have been diagnosed with pre-eclampsictoxaemia 27(37.1%) induced pregnancy and 20(27.8%) with eclampsia. Most people were 21-25 years old and their average age was 25.3 years old. Of the 72 patients, 38 were primipara (52.8 percent). 20 (27.8%) of newborns were delivered before 37 weeks, while 52 (72.2%) were delivered before 37 weeks. A cesarean section was available in 37 of all patients (51 percent). The cesarean portion in PIH & PET was higher. Of the 72 newborn patients 16(22.2%) were low in birth weight, and patients with eclampsia were more likely to experience low birth weight. 35 of 72 patients had poor fetal results, including 1.4 percent perinatal and 33.3 percent asphyxiated infants. Only 5 (6.5 percent) had complications in maternal outcomes such as strokes, renal eclampsia. All participants in this study are women who are pregnant and receive prenatal care. WHO normally recommends patients with an antecedent of antenatal treatment less than 4 times eclampsia. In patients with eclampsia it is more common to see low birth weight, pre-term delivery and the complication for prenatal mortality.

Keywords: Primipara, eclampsia, asphyxiated infants, hypertension, blood pressure, Dhaka, Bangladesh

Introduction

One of the most common complications of birth and one of the most common causes for fetal and maternal morbidity and death worldwide, hypertensive pregnancy disorder⁽¹⁾. Almost 10 per cent of all births are complicated by elevated blood pressure and the frequency is greater if women are nulliparous or have several fetuses⁽¹⁾. The pattern to complicate multigrain loss is if proper management is not achieved in good time⁽²⁾.

One of the main causes of maternal death and morbidity is hypertensive pregnancy disorders in Bangladesh. Details on the occurrence of this condition would be documented on a prescribed schedule, including blood pressure, albuminuria, edema, immunization and antenatal treatment. Even though the effects of these conditions have been minimized in developed countries by adequate prenatal care on the mothers and fetuses, it endangers the result of pregnancies in most developing countries such as Bangladesh. Lack of education, a lack of sufficient antenatal care and nutrition has caused births more likely to suffer the symptoms of hypertensive disorders. Bangladesh, which also has an exceptionally high rate of maternal mortality due to preventable reasons, is a country with a high population density. In Bangladesh, death from mothers is a significant issue of public health⁽³⁾.

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Hypertensive maternity disease involves gestational high blood pressure, gestational uric hypertension protein, and chronic high blood pressure. The risk of high blood sugar disorders, including preterm birth, restrained intrauterine development, perinatal mortality, acidic renal and hepatic dysfunction, anteriorpartum hemorrhage, postpartums hemorrhage (Postpartum hemorrhage) including epilepsy, stroke, premature delivery, and maternal death, is complicated by 5-10 percent across all pregnancies⁽³⁾.

Maternal or fetal outcomes of hypertensive pregnancy disorders rely on various factors particularly if the early pregnancy is high in hypertension. Hypertension caused by pregnancy, which involves both hypertension and preeclampsia in infancy, a common and morbid complication of pregnancy. Emerging data indicates that insulin resistance associated with critical hypertension may play a role in hypertension triggered by pregnancy. Conditions associated with increasing insulin resistance may be predisposed to hypertensive pregnancy, including gestational diabetes, ovary syndrome, and obesity.

The group of symptoms concerned with elevated blood pressure, proteinuria and convulsion during breastfeeding are the hypertensive pregnancy disorders. Preeclampsia and eclampsia have the most severe effects on mother and infant. Eclampsia is typically the product of the preeclampsia of a central nervous system and is often unconscious and can lead to death if untreated. Both preeclampsia and eclampsia are not well evaluated in their long term sequelae and mortality is the cause of hypertensive diseases in the pregnancy. Hypertension (Sbp > 140 mmHg or DBP 11 > 90 mmHg) and proteinuria (0.3 g protein in 24-hour or 1+ on a dipstick) after 20 weeks of gestation for the previously normotenseness women lead to new onset of hypertension (SBPs > 140 mmHg or DBPs 11 > 90 mmHG). It is a life-threatening, multi-organ illness that appears to be the main cause of maternal mortality. Its clinical manifestations are due to widespread vasospasm, coagulation system triggering and changes in the volume-related and blood pressure-control humoral and autoregulatory systems⁽⁴⁾.

High perinatal death and morbidity rates are blamed for pre-ecampsia, largely due to the early end of pregnancy. The symptoms of chronic placental hypo-perfusion⁽⁴⁾

are fetus growth limitation, oligohydramniotics, and no comforting fetal status.

Preeclampsia is significant in the developed as well as in the developing world. It also remains a leading cause of death and morbidity of pregnancy and perinatal conditions. With a prior history of preeclampsia, pre-existing diabetes, multiple births, family history of preeclampsia⁽³⁾, the likelihood of preeclampsia is enhanced.

Pregnancy with high maternal and perinatal mortality is highly dangerous and relatively normal. Antenatal appointments should be screened in order to guard from the hazards of preeclampsia pregnant. Bangladesh is one of the developed countries that lack functional antenatal care services and is also the leading cause of maternal and perinatal mortality in developing countries. Although eclampsy has become increasingly avoidable and uncommon in developing countries, in Bangladesh it remains a major problem in obstetrics.

In Bangladesh, Eclampsia accounts for 16% of maternal death. It remains the leading cause in many other areas of the world of maternal and perinatal mortality, including Bangladesh. In developing countries this is a common problem, where analphabets, lack of knowledge, health education, poverty and superstition preclude women from seeking healthcare during pregnancy. There is a lack of sufficient maternal treatment in developed countries such as Bangladesh. The coverage of prenatal care (minimum 1 visit) in Bangladesh is 48.7% .

While exact etiology is still unknown, the incidence of complications with proper antenatal care can be avoided. There are many disorders in our country because of poor prenatal care, early marriage and more pregnancy. This can reduce the complication by early detection and treatment. With this backdrop, this study was designed to determine the hypertensive disorders of pregnant women in Bangladesh.

Justification of the study

Hypertension is one of the common complications of pregnancy, contributing significantly to maternal and perinatal mortality and morbidity.

Hypertension is a symptom of chronic condition pre-existing or arising during birth for the first time. The recognition and successful control of this therapeutic organization play a decisive role in the result of both mother and baby pregnancy. Many births exist unrestricted in developed countries such as Bangladesh, where there are many prospects unnoticed before significant complications arise.

Early marriage in this country is more commonly seen in the underprivileged sector and hypertensive condition & associated complication is also popular. It may cause severe maternal and fetal problems or losses if it is untreated and neglected. This study shows the maternal and fetal results of a patient with high blood pressure. This study findings can be used to increase awareness among hypertensive moms, public health professionals, clinicians and health officials who can use an intervention program to minimize mortality and morbidity in mothers and fetuses due to the effects of hypertension.

The research is intended to provide useful knowledge on hypertension during pregnancy and the pregnancy of the high-volume mother to medical staff, public health professionals, average citizens and hypertensive mothers. In order to produce a better result, the individual involved would have a preventive action at a reasonable moment, effectively mitigating the unfortunate fate, reducing maternal and fetal mortality and morbidity.

Materials and Methods

Study Objectives

General Objective: To estimate the proportion of pregnancy induced hypertension among pregnant women.

Specific objective

- 1) To find out the complication of hypertension among respondents.
- 2) To find out the factors responsible for hypertension.
- 3) To find out the type of hypertension disorder in pregnancy.

Study design: It was a descriptive type of cross-sectional study.

Study population: Pregnant woman with hypertension (either pre-existing or pregnancy-induced) delivered baby at the obstetric department of Bangabandhu Sheikh Mujib Medical University irrespective of age.

Sample population:

The sample population was those who were available at the time of data collection.

Study site: Bangabandhu Sheikh Mujib Medical University which is a tertiary level hospital in Dhaka.

Study Area: Bangabandhu Sheikh Mujib Medical University which is a tertiary hospital in Dhaka. The hospital established in 1965 which situated at Shahbag, Dhaka. This study is done in the Obstetrics and Gynecology Department, This department situated in building Block-C (8th Floor). The emergency unit of the obstetric department is situated in building Block-D (ground floor).

Study Period: Total Study lasted for a period of four months commencing from December 2018 to March 2019.

Sample size: Statistical calculation of sample size was followed by using a sound statistical formula, indicated below:

$$n = \frac{Z^2 pq}{d^2}$$

Where, n = Desired sample size, Z = Standard normal deviate, usually set at 1.96

which corresponds to 95% confidence level.

$$p = 30.2\% = 0.312$$

$$q = 1 - p = (1 - 0.312) = 0.688$$

d = Degree of absolute precision, usually at 0.5%

Therefore, the desired number of participants is

$$n = \frac{(1.965)^2 * 0.312 * 0.688}{(0.025)^2}$$

$$= 329.84$$

The sample size was taken to be 72 after discussion with the supervisor of the study.

Inclusion & Exclusion Criteria

Inclusion criteria - Having the ability to understand interview questions. – Having the ability to give information.

Exclusion criteria - Those who are seriously ill or unwilling to talk to the interviewer would be excluded from the study.

Sampling technique:

A purposive sampling technique was used

Data collection tools:

A questionnaire was prepared and printed. The final questionnaire was used for data collection. Hospital -records were also reviewed.

Data collection technique:

Face to face interview, observation and record review. A brief introduction was given verbally to each respondent by the interviewer at the beginning of the interview to explain the purpose and importance of the study. The questionnaire was filled up by the interviewer during the interview. Socio-demographic, previous reproductive information was collected by the interviewer.

Data management & analysis:

All the data were checked, cleaned and edited after collection. Then those cleaned data were entered into the SPSS program of computer were done by the SPSS-20 program on the computer. Analyses were done according to the objectives and variables of the study. Simple techniques of data analysis, as for example-frequency, percentage, average etc were done by the SPSS program in the computer and results were presented in the form of tables and graphs.

Limitations of the study:

1. As it is a hospital record-based study of BSMMU, the findings of the study about antenatal checkup may not reflect the actual picture of the entire Bangladesh

2. The patients who did not bring their antenatal care visit card or who had no obstetric checkup records were not included in the study population.

3. Many of the respondents did not give their previous history of pregnancy-induced hypertension.

4. As I have used some administrative record-based data which may include women with incorrect information.

5. Shortage of time for data collection was the main limitation.

6. Small sample size was one of the weaknesses of this study.

7. The sampling technique was used in this study was purposive sampling which had chances of bias.

Result & Discussion

Hypertension can be graded as chronic if recognized before 20 weeks of gestation, or if it happens only in the second half of pregnancy. This distinction is clinically beneficial since almost all hypertension arising in the first half of pregnancy results from underlying chronic hypertension. The progression of hypertension in the second half of pregnancy is more complicated, arising from either a pregnancy-specific phase or a complex interplay of pregnancy with renal failure or chronic hypertension leading to exacerbation of hypertension. The research sought to see the result of women with hypertensive disorder during pregnancy and to figure out the respondents' obstetric background and socio-demographic characteristics. This is a cross-sectional descriptive style of research and was performed at Bangabandhu Sheikh Mujib Medical University among pregnant women who were admitted to the eclampsia and labour ward for delivery for antenatal checkups in the antenatal treatment outpatient unit. Pregnant women aged 20 weeks or older who had medical tests during this pregnancy were included. Bangladesh's maternal mortality rate is 3.2 per thousand live births. Eclampsia is the third-largest source of maternal mortality. Many preeclamptic and gestational pregnant women eventually experience eclampsia and complications and even death.

WHO reports that 15 percent of women have a degree of hypertension during pregnancy. Fortunately,

most of these cases are benign, not requiring medication or complication. However in some cases women have a hypertensive pregnancy condition like pre-eclampsia, which can lead to severe complications or death. Hypertensive pregnancy results in 12% global maternal mortality and up to 40% maternal death in some countries.

72 pregnant women with hypertensive conditions were studied. Much research population is from low-income communities. Of 72 patients, 32% had monthly income ranging from 8,000 to 10,000; 16.7% had monthly family income > 10,000; 15.3% had s 6,000; and only 6.9% had < 4,000 taka. [Table: 1]

Much of the sample population refers to the age group 25 years and are more likely to experience hypertension than the other age group. To compare this study with another previous study, a Relationship with Parity study like this shows that the majority (52 percent) was primiparous; simulating with other studies at home and abroad. Regarding the level of education, 26 percent are in high school, 44.41 percent are in elementary school, 25 percent are illiterate. Buchbinder et al 19 observed 25.4 ±5.3 in patients with moderate preeclampsia and 25.9 ±6 years with extreme preeclampsia. Relationship with parity indicates that 71.5 percent of the majority are primipara, with 26.4 percent in high school being 44 percent in elementary school, 25 percent analphabet. [Table: 1]

Table 1: Distribution of respondents by Demographic information

Variables	Frequency	Percentages
Age		
≤ 20 years	9	12.5
21-25 years	26	36.1
26-30 years	20	27.8
>30 years	17	23.6
Religion		
Muslim	62	86.1
Hindu	10	13.9
Education		
Illiterate	18	25
Primary	32	44.4
Secondary	19	26.4
Degree and Above	3	4.2
Occupation		
House Wife	27	34.7
Agriculture	23	31.7
Service	22	30.6
Husbands Occupation		
Agriculture	24	33.3
Service	22	30.6
Business	16	22.2
Rickshaw puller	9	12.5
Others	1	1.4
Family Income		
≤4000	21	29.2
4001-6000	5	6.9

Cont... Table 1: Distribution of respondents by Demographic information

6001-8000	11	15.3
8001-10000	23	31.9
>10000	12	16.7
Family Member		
<4	32	44.4
4-6	34	47.2
7-8	6	8.3

The number of family members ranges from 4-6 in most patients. According to national statistics, the family member is 2.3 and the goal is 3.5. People of specified occupations were found, most of them housewives. [Table: 1]

Among the sample group, P.E.T. suffered mostly. (37.1%), followed by PIH (34.3%), and Eclampsia (27.8%). [Figure: 1]

Most participants in this sample received prenatal treatment, this care has an increasingly important role to play in reducing maternal and perinatal morbidity and mortality because pregnancy hypertension cannot be prevented, but usually maternal death can. Considering antenatal treatment, 80.6 percent of the overall population obtained antenatal care independent of maternity forms of hypertensive disorders. 73% of patients received antenatal treatment, so it is clear that there could be a link between less antenatal care and eclampsia. Factors identifying between low-risk and high-risk women experiencing hypertensive symptoms and recognizing the condition as early as possible to schedule rational antenatal treatment and maternal-fetal monitoring .

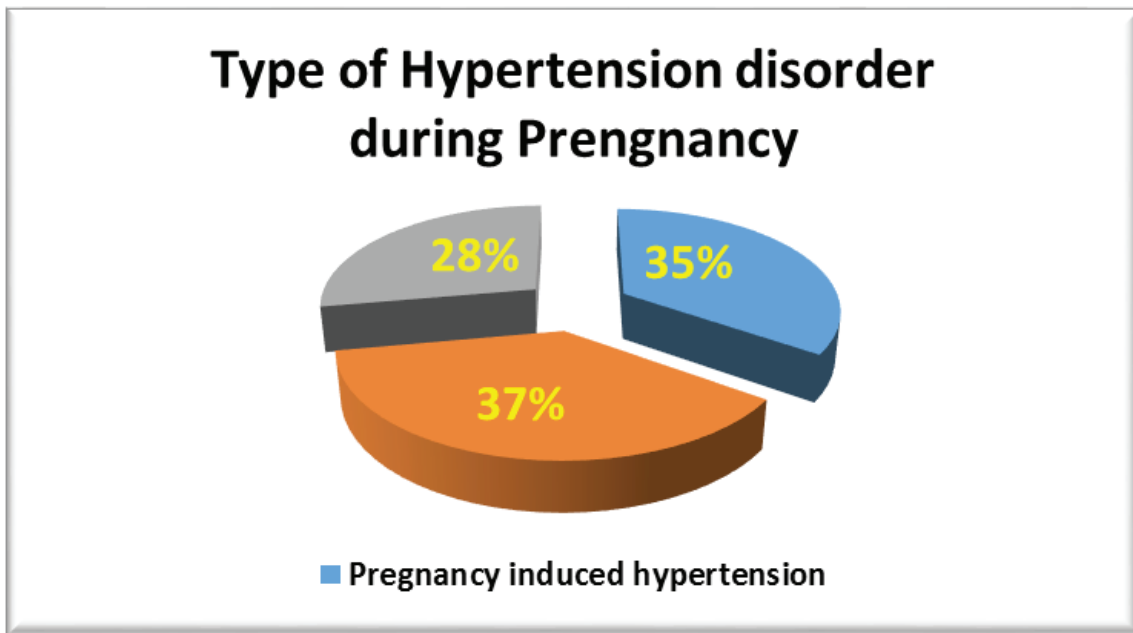


Figure 1: Distribution of respondents by type of hypertension disorder during pregnancy

Table 2: Distribution of respondents by complication during pregnancy period

Variables	Frequency	Percentages
Edema Present		
Yes	43	59.7
No	29	40.3
Proteinurea Present		
Yes	5	6.9
No	29	40.3
Don't Know	38	52.8
Experience convulsion		
Yes	20	27.8
No	52	72.2
Unconscious		
Yes	1	1.4
No	71	98.6
Family History of hypertension		
Yes	20	27.8
No	52	72.2

Table 3: problems during pregnancy

Variables	Frequency	Percentages
Abortion		
Yes	27	37.5
No	45	62.5
Stillbirth		
Yes	6	8.3
No	66	91.7
Neonatal Death		
Yes	6	8.3
No	66	91.7

A typical complication of hypertensive disease is prematurity, either due to spontaneous labour or obstetric activity of interrupting pregnancy due to impaired maternal-fetal. A research in our area showed a higher relative risk of prematurity in pregnant women with chronic hypertension compared to a pregnancy-induced population. Prematurity raises perinatal morbidity and mortality rates of potential imminent or late sequels, requiring public policy to protect these neonates.

Analyzing fetal result, it was clear that 31(51.9%) were alive and well, 24 births. (33.1%) were birth-asphyxiated, 13% were stillborn, 1(1.4%) died after birth.

In the present study, fetal outcome in eclampsia patients was comparatively poor than the other 2 classes. Considering low birth weight was 16. On the other birth weight, 28%. Hand-cumulative evidence from another retrospective analysis revealed a birth-weight incidence of 28%(2).

The present research found that 32.3% of babies were born before 37 completed weeks; the remainder was delivered after 37 weeks. There is no substantial correlation in pregnant women between prior experience of hypertension and hypertensive disorder. There is no clear link between pregnant women's family history of hypertension and hypertensive disorder.

A recent study found that both gestational and chronic hypertension increased the relative risk of premature SAG, limited intrauterine growth, and low birth weight were the results of premature delivery among women with severe pre-eclampsia.

In this report, 50% of babies were born via cesarean section; most of them had PET and PIH. In eclampsia patients, cesarean section was comparatively fewer than the other 2 categories.

Of 72 patients, 46.5 percent) had different complications and all were eclampsia patients. This group of patients had no maternal mortality. Of 72 patients, 20 experienced convulsion. Of 20 patients experiencing seizures, 75% of seizures occur at home and 25% of seizures occur in hospital.

Of the 72 patients, only 20 patients took hypertension medication, and 52 patients took no hypertension medication.

Since the study was limited to a few patients admitted to Bangabandhu Sheik Mujib Medical's gynecology and obstetrics department. University over a brief period of time, the research might have little epidemiological significance, yet it definitely provides an aggregate picture of hypertensive condition patients in our nation.

Conclusion

The births all come from all social backgrounds and were aged 18 - 39 years. In this study, the age of the pregnant woman was linked with hypertension, which was higher than the respondent's age and higher. All pregnant women should be appropriately trained, appropriate technologies should be used to recognize risk factors, and appropriate antenatal treatment and care should be given for them during childbirth. Sensitizing and emphasizing the risk factors within the population on health issues is an important step in controlling hypertensive disease during pregnancy. This can be achieved in multiple mainstream media

The family history of elevated blood pressure and the hypertension of the respondents during this pregnancy are not closely related.

Ethical Consideration: This study was approved by Ethical Review Board of Northern University. The researchers clarified the objective of this research and obtained informed consent from the respondents.

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Knowledge of Diabetes in Geriatric Patients attending Hospitals in Dhaka City, Bangladesh

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Abstract

Diabetes mellitus is a persistent disease in Bangladesh, which reportedly has a strong proportion of 7.1 million diabetics over 60 years old. Limited knowledge is a significant variable which affects and mainly prevents the development and progression of diabetes. In order to determine the awareness of Type 2 diabetes among Geriatric patients in selected Dhaka hospitals, this cross-sectional clinical study was performed between May and August 2018. The research was carried out among 450 diabetic type 2 patients >60 years of age from three urban and suburban Dhaka hospitals. Data is obtained by standardized questionnaires face-to-face interviews. The average age was 64.86 ± 4.65 years for the respondents. 56 percent of the research participants were guys. With 34.2% of respondents who did not attend school and just 13.8% of graduates, education was low. Much of the respondents (63.56 percent) referred to diabetes. The awareness level of respondents with signs (80.7%), risk factors (84.4%), avoidance (84%), and management (71.6%) was low. Just 8.7 percent heard the risks of diabetes. The overall awareness score for the participants was recorded as fair (18.9%), decent (30.7%) and bad (50.4%). The awareness score was closely linked to schooling and diabetes period ($p < 0.01$). The research indicated a lack of information among respondents. Geriatric diabetes patients with more diabetes treatment needs. It may also be argued that repeated enhancement and inspiration in combination with diabetes health education will contribute to a positive awareness improvement.

Keywords: Diabetes Knowledge, Geriatric patients, Knowledge, Diabetes Mellitus, Hospitals, Dhaka, Bangladesh

Introduction

Diabetes is a mainly hyperglycaemic condition leading to risk of vascular damage (retinopathy, nephropathy and neuropathy). The disease is defined by its level. The risk of macro-vascular complication (ischemic cardiovascular disease, stroke, and peripheral vascular disease) is reduced, with a significant deterioration in life, and a decrease in the quality of lives⁽¹⁾ due to specific diabetic micro-vascular complications.

Diabetes is a silent epidemic and 246 million people live with diabetes in the world according to WHO, nearly 6% of the adult population worldwide. The figure for diabetes is estimated to be at 438 million by 2030. Nearly 90-95% of diabetes is type 2 or early maturity; this affects medieval people. Type 1 or diabetes in

young children affects 70,000 children under 15 years of age annually. A sedentary lifestyle is the main cause of the increase in diabetes incidence. Exercise and diet can either decrease or delay diabetes incidence by more than 50%. Type 2 diabetes accounted in high-income countries for 85%-95% of all diabetes and may represent an even higher proportion of all diabetes in low and middle-income. Because of their migration in large numbers before and after colonization Asians from the Bangladesh subcontinent were given greater attention in diabetes studies. Initially, the prevalence of diabetes in Bangladeshi immigrants was found to be higher than in the Bangladeshi subcontinent population and was usually also greater than in the host country's predominant racial or other racial groups. In other migrant groups, like the Japanese in Hawaii, the prevalence of diabetes is also

higher. Consequently, the differences in the prevalence rates in these migrant Bangladeshis could well be due to differences between different communities in various countries and regions of Bangladesh (2).

Older people with diabetes are increasingly aware of their need for the management and complication of metabolism, in addition to targeted exercise programs and extensive geriatric evaluation and intervention. Education interventions for ethnic minority groups in Glasgow show that there is strong clinical evidence supporting the role of targeted exercise programmes. The findings indicated an improvement in diabetes awareness and improved behaviors in the intervention population, in particular with respect to the gravity of type 2 diabetes(3).

The diabetic issues are on the rise. There are still effective prevention measures, but they are not rationally or commonly used. A diabetes person makes the bulk of his or her choices about the condition, be it at home, in the office or in his or her current society. Bangladesh has a severe lack of knowledge about proper diagnosis and care of diabetes mellitus and its related high morbidity and mortality. This loss of consciousness may be the fundamental cause which has an effect on perceptions and behaviors. Further analysis on knowledge, experience and conditions conducive to action, etc is required to define targets for researching health inequalities with type 2 diabetes. Both elderly people with diabetes would potentially benefit from the initiative in this direction. This research would also lead to investigating the current state of type 2 diagnosis in geriatric patients. Based on the results it appears appropriate to advise robust prevention and rehabilitation services for geriatric healthcare in the future, taking into account multifactorial issues affecting older patients.

Operational definitions:

Geriatrics - Person who are of the age 60 years and above.

Type 2 Diabetes Mellitus-Previously diagnosed persons with diabetes according to WHO criteria [1].

- Fasting plasma glucose : >7.0mmol/l (126mg/dl)

OR

- 2-h plasma glucose (after ingestion of 75g oral glucose load): >11.1mmol/l(200mg/dl)

Knowledge

In this study, it refers to respondents' level of knowledge about concept of diabetes, symptoms, risk factors, prevention and control, relation with hypertension, complications and prognosis.

Diabetic complications

Diabetes related complications as diagnosed by a physician and revealed by medical documents

Methodology

Study objectives:

General objective:

- To assess the level of knowledge related to type 2 diabetes in elderly patients visiting hospital outpatient departments.

Specific objectives:

- To assess the socio-demographic characteristics of the respondents;
- To assess the clinical characteristics of the study subjects;
- To assess the knowledge among geriatric patients regarding diabetes, symptoms, risk factors, prevention, control, complication, relation with hypertension and prognosis;
- To find out the association between knowledge with socio-demographic factors and clinical variables.

Study design:

This was a descriptive cross-sectional study.

Study population:

Geriatric diabetic patients of Dhaka city were the study population of this study.

Sample population:

The patients were chosen from Geriatric clinics, Diabetic clinics and different OPD's the hospitals who

came for regular health checkups and consultation.

Study site and area:

The study was carried out in three hospitals of Dhaka city. The hospitals were selected purposively; selected hospitals were Probin Hospital Agargaon, Bangladesh Community General Hospital and Supreme General Hospital, Jatrabari.

Study period:

The study period was four months started from September to December 2019.

Sample Size:

Sample size was determined by the following formula:

$$n = \frac{z^2 pq}{d^2}$$

Where, n= Expected sample size

Z=1.96, the standard normal deviation set as 1.96 with 95% confidence interval.

P= 0.5 (as there is no reasonable estimate of any prevalence rate, we use 50%).

q=1-p

=1-0.5

=0.5 or 50%

d=degree of error(absolute precision of the study assumed 0.05.

z=the reliability be reliability coefficient at the 95% C.I=1.97.

$$n = \frac{(1.96)^2 * 0.5 * 0.5}{(0.05)^2}$$

n=384.16

With turn over 10%, the sample size was 422, and finally, the sample size was taken 450.

Inclusion and exclusion criteria:

Inclusion criteria: Person who are aged sixty years and above with history of diabetes and those who were willing to participate was included.

Exclusion criteria: Person who was apparently mentally and physically disabled and was not willing to participate was excluded.

Sampling technique:

Purposive sampling technique was used.

Data collection instruments: A structured questionnaire was compiled adapting questions from published studies and adding questions that were considered of value based on local beliefs and clinical importance and was pre-tested for data collection. The questionnaire covered three sections.

Section 1 Provided socio demographic information, this included name, age, sex, level of education, what they do and marital status.

Section 2 Contained questions related to diabetes namely duration of diabetes, age of detection of diabetes, way of diagnosis, family history, level of blood glucose at the of diagnosis and testing of glucose in urine was done or not at the time of diagnosis.

Section 3 Included questions regarding knowledge on diabetes and its risk factors, symptoms, prevention, control, complication, relation with hypertension, and prognosis.

Data collection technique:

Selection and listings of the hospitals were done according to convenience. Formal written requests were submitted to the respective Hospital Superintendent/ Hospital Authority of the selected hospitals. Interviewers recruited were final year medical students. Training and overall idea about the study was given to the interviewers before data collection. Before starting the interview willingness to participate was sought and verbal consent was taken from the subjects. Face to face interview was conducted according to convenience. After the procedure was over it was checked and corrected by the investigator.

Data management and analysis:

The data obtained by questionnaire were first checked for the completeness by the principal investigator. All the interview procedures were reviewed by the researcher and supervisor then the data was entered in the computer after coding, cleaning and editing in SPSS version 16. One way ANOVA, Multiple Regression Analysis and Linear Regression was done to compare the groups and analyzed after that presented in tables and graphs.

Defining knowledge score

A scoring system was developed for each component: each correct answer was given a score of 1. And for multiple answers score of 1 was divided by total no of answers which was present. Three categories were defined on the basis of the score obtained by each participant: poor (< 40% of the total score); average (41%-60% of the total score); and good (> 60% of the total score)

Quality Control and Quality Assurance

As researcher, collected all the data and make analysis for result so there is least chance of quality

deviation and bias.

Limitation of the study:

The three hospitals were chosen purposively, hence it may not be generalizable and representing the whole population is limited. Since the respondents were elderly there was difficulty getting information from them and sometime they were impatient. Therefore, there was chance of some information bias.

Results

All 450 respondents were included among the analysis. Where majority of the participants belonged to the 60-65 age group (63.78%) with mean age ± SD was 64.86 ± 4.650. One third (1/3) participants 154 (34.2%) had Informal education, where Graduated only 62 (13.8%) participants. Maximum respondent was married 325 (72.22%) compare to 13 (2.89%) respondent was still unmarried and 98 (21.78%) widower/widow. Female respondent were mostly housewives 162 (36%). On the other hand 125 (27.78%) males were having retired life compared to 17 (3.78%) females. 127 (27.78%) were still engaged in some form of work in comparison with 18 (4%) females for earning. (Table 1)

Table 1: Socio-demographic Characteristics of respondents (n=450) Variable

Variable	Frequency	Percentage
Sex		
Male	259	57.55
Female	191	42.45
Age		
60 to 65 Years	287	63.78
66 to 70 years	123	27.33
Above 70 years	40	8.89
Education		
Informal Education	154	34.2
Primary Education	87	19.3
Secondary Education	83	18.4
Higher Secondary	64	14.2
Graduation	62	13.8
Marital Status		
Married	325	72.22

Cont... Table 1: Socio-demographic Characteristics of respondents (n=450)Variable

Unmarried	13	2.89
Widower/widow	98	21.78
Divorcee	14	3.11
Occupation		
Retired	142	32
Services	24	5
Business	75	17
Labor	36	8
Housewife	162	36

Knowledge regarding concept of Diabetes among Geriatrics people

The most interesting thing is out of 450 respondents 164 (36.44%) didn't have any knowledge regarding diabetes mellitus. The respondents were asked to on they understand by diabetes, most of them 286 (63.56%) answered increase in blood glucose level (Figure1).

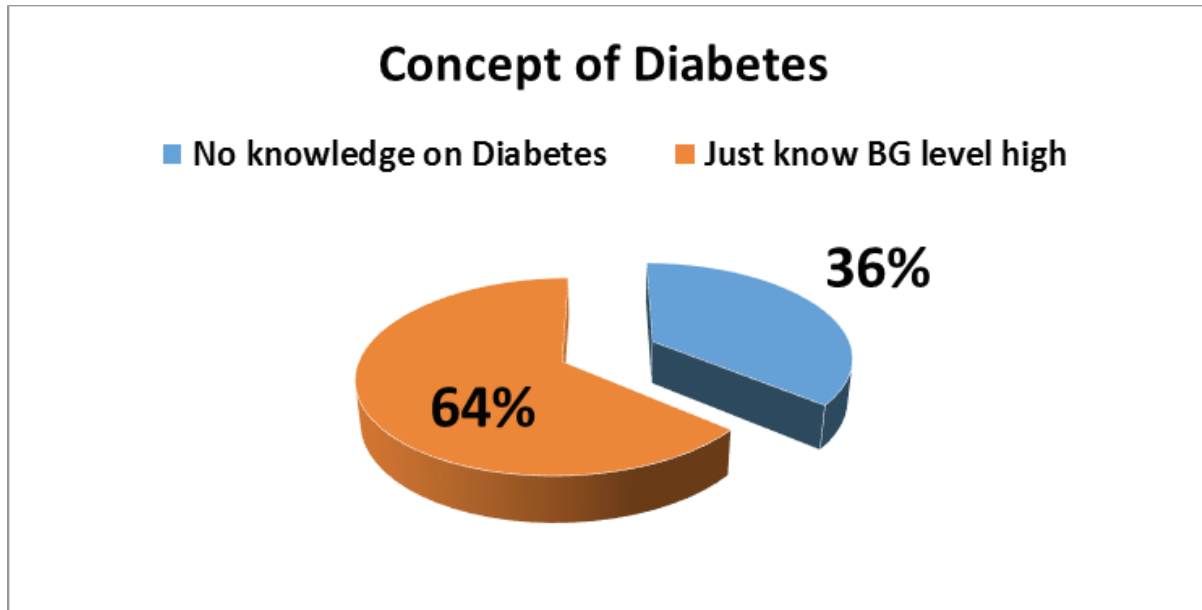


Figure 1: Knowledge regarding concept of Diabetes

Almost 184 respondents had knowledge that excessive urination as symptoms of diabetes. But only 12 respondents had knowledge of loss of body weight being symptoms of diabetes. Around half of respondents 224 person had knowledge that intake of sweets as a risk factors of diabetes. But only 2 persons had knowledge of alcohol/smocking being a risk factor of diabetes. 158 maintaining diet as a preventive measure but only 5 knew that avoiding alcohol/smocking is also a preventive measure. Similarly 255 people had known

that drug therapy is a control measure but only 2 people knew quitting alcohol/smocking also a control measure. Unbelievably only 10 respondent had knowledge of infections being a complication of uncontrolled diabetes. From this study we see 286(63.56%) had good knowledge on concept, 104(23.1%) had good knowledge that diabetes can complicate hypertension and 271 (60.2%)had good knowledge that diabetes is incurable. (Table 2)

Table 2: Distribution of respondent according to different concept of knowledge (n=450)

Level of Knowledge	Frequency	Percentage
Concept of Diabetes		
Good	286	63.56
Poor	164	36.44
Symptoms of Diabetes		
Good	35	7.8
Average	52	11.6
Poor	363	80.7
Risk factors of Diabetes		
Good	23	5.1
Average	27	10.4
Poor	380	84.4
Prevention of Diabetes		
Good	26	5.8
Average	46	10.2
Poor	378	84.0
Control Measures of Diabetes		
Good	48	10.7
Average	80	17.8
Poor	322	71.6
Complication due to uncontrolled diabetes		
Good	39	8.7
Average	87	19.3
Poor	324	72.0
Diabetes worsen hypertension		
Good	104	23.1
Poor	346	76.9
Curability of Diabetes		
Good	271	60.2
Poor	179	39.8

Concept of curability of diabetes

Almost Two third 271 people knows that Diabetes is Incurable disease, whereas only 27(6%) knows it can be cured but a big portion one third 152(33.8%) had no knowledge on curability. (Figure 2)

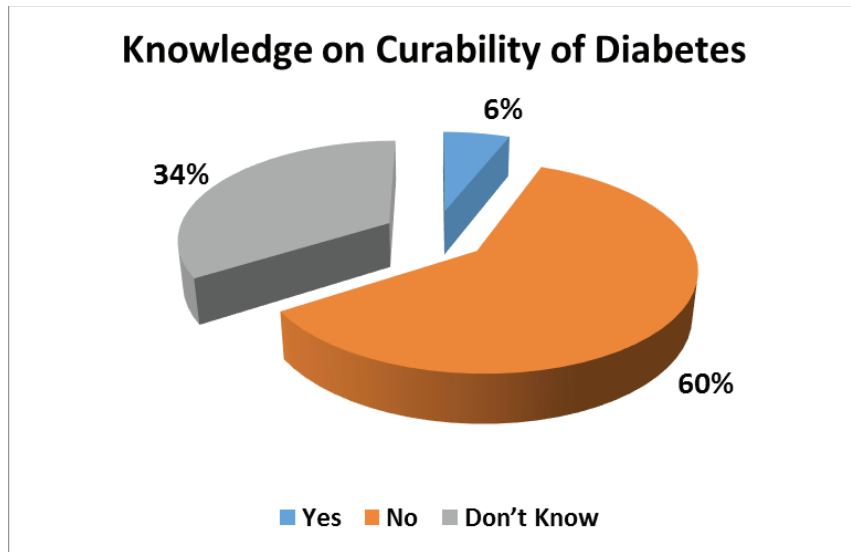


Figure 2: Respondent Knowledge regarding curability of Diabetes.

Distribution of total knowledge score which was found to be 18.9% good, 30.7% average and 50.4% poor. Study shows that diabetic knowledge have significant ($p < 0.001$) difference with education ($F = 207.78$) and occupation ($F = 39.72$) (Table 3)

Table 3: Association of diabetes knowledge with socio-demographic characteristics

Variable	Categories	Knowledge Score		
		Mean \pm SD	F-value	P-value
Sex	Male	0.41 \pm 0.25	28.51*	<0.001
	Female	0.27 \pm 0.26		
Education	Informal Education	0.11 \pm 0.16	207.78*	<0.001
	Primary Education	0.25 \pm 0.19		
	Secondary Education	0.50 \pm 0.14		
	Higher Secondary	0.58 \pm 0.11		
	Graduation	0.68 \pm 0.16		
Occupation	Retired	0.47 \pm 0.26	39.72*	<0.001
	Services	0.51 \pm 0.18		
	Business	0.43 \pm 0.20		
	Labour	0.05 \pm 0.12		
	Housewife	0.26 \pm 0.24		
Duration	3 years and Less	0.31 \pm 0.25	13.09*	<0.001
	More than 3 years	0.41 \pm 0.29		
Complication	None	0.25 \pm 0.02	6.024*	<0.001
	1 complication	0.26 \pm 0.02		
	2 complications	0.26 \pm 0.02		
	3 complications	0.30 \pm 0.04		
	4 complications	0.27 \pm 0.09		
	5 complications	0.00 \pm 0.00		

*Significance at level of 0.001

Discussion

In all non-industrialized populations, the prevalence of type 2 diabetes has increased exponentially. Data suggests that societal, economic and accelerated urbanization epidemics are caused and are correlated with longevity change. A cross-sectional research was conducted among 400 adults in Bangladesh's Dhaka, Mymensing, Sylhet and Khulna district where Diabetes Mellitus prevailed at 9.75%⁽⁴⁾. The number of elderly people is growing by the improved health care services for everyone by 2000 and is now a strong share of the general public. More than half (53 percent) of diabetics are over 60 years old and over 85% over 45 years of age⁽⁵⁾. In the developed world, obesity and diabetes can be believed to be a major problem where there is a high prevalence of malnutrition among people in low socio-economic strata⁽⁶⁾. The rise in diabetes prevalence is more a universal phenomenon, not a Bangladeshi manifestation⁽²⁾. Although the present risk for poor Bangladeshis is less high than that of rich Bangladeshis, the rapid expansion of fast food exposes urban slum-residents in Indiana to the risk of diabetes⁽⁷⁾. In fact, very few studies on diabetes sensitization among people with the condition, as well as virtually no data on the entire population, were carried out in the literature on knowledge's of diabetes in developed countries. In other countries where experiments have concentrated predominantly on diabetic patients and are mostly clinical⁽⁸⁾, reference bias is added in developed countries.

Older people with diabetes are increasingly regarded as having demands beyond those of metabolic disturbance treatment and its complications on its own⁽⁹⁾. Elderly treatment is a costly training. Therefore in Bangladesh, where services are limited, the idea of vulnerable groups is more important even for the older population. The groups in question are elderly widows, children less seniors, parents without a son, mentally challenged people, the seniors of migration from other countries and the aged in an alien environment. These categories are disadvantaged groups⁽¹⁰⁾.

A first step in formulating a prevention policy for diabetes is an awareness of diabetes in a community. This research reflects a step forward in which awareness and practice of type 2 diabetes is measured in a hospital-based study among 450 geriatric patients in urban

and suburban Kolkata, eastern India. In developed countries like Bangladesh, there is very little proof of awareness and experience on diabetes. This statistics are particularly relevant for planning public health strategies with a special relation to national diabetes management programs. No related research was undertaken in Bangladesh with an emphasis on geriatric people.

In contrast to the various studies where respondents belonged to all age group the average age \pm SD for participants in this sample was 64.86 ± 4.650 [12]. India 49.2 percent of people surveyed were ≥ 60 years of age in a Karnataka report⁽¹¹⁾ More than 35.72 percent of respondents — 60 years of age⁽¹²⁾ have engaged in another survey.

This research indicates that only 13.8% of students were graduates and 34.2% had no form of schooling in this study. This is equivalent to studies in Gujarat, India, where analphabets were 37% and just 10% graduates⁽¹³⁾. This is close. Similarly, 18.3 percent women and 10.5 percent men were illiterate⁽¹⁴⁾ were recorded in a study in Pakistan. In comparison, two surveys performed in Karnataka, India and Nigeria have found that the literacy of interviewees has been 87.4% and 83% respectively⁽¹¹⁾. The majority of men who have been retired 125 (27.78%) and 162 (23.1%) of women are domestic women, provided that this research was conducted by elderly people 60 years.

Concepts and information of diabetes have been tested for respondents. Just 64 percent of 450 respondents would correctly reply that diabetes is an elevated blood glucose level (Fig. 4.2.1). On the other hand, 63 percent did not know about diabetes from the Gujarat study⁽¹³⁾. A rudimentary description of the study of diabetes among Omani population could not be provided by 53.5 percent⁽¹⁵⁾. The Nigerian research reveals, however that 80.2 per cent knew diabetes as a type of sugar disorder in their study. Furthermore, surprisingly, 78.1% of those polled said that diabetes is due to poisoning and only 14.6% could say this due to insulin shortages⁽¹⁶⁾.

The lack of awareness of respondents was disturbing. With regards to signs, risk factors, prevention measurements, diabetes management measures; 247 (54.9 percent), 189 (42 percent), 272 (60.4 percent), and 173 (38.4 percent) have no knowledge of diabetes (tables 4.2.1 - 4.2.4), or 300 (66.7%). However, 60.2% said that

diabetes cannot be treated, and only 6% considered it curable. The other Gujarat study showed that 60% knew there was no diabetes complication and that 38.23% also assumed that diabetes could be cured⁽¹³⁾. Complication awareness among respondents was very low since 211 interviewees were unaware of the risk for complications related to untreated diabetes (Table 4.2.5). Many of you who knew 206 of these complications referred to cardiopathy as the most prevalent complication, followed by 191 interviewees and 186 interviewees.

An information score of 19 percent, 31 and 50% was considered to be fine, mediocre, mediocre (Figure 4.5.1). It was observed that more women were also on the lower portion of this sample. The score of information differed with respondents' academic status. These results were more or less identical with the Pakistani analysis, where there was 13.6%, 38.2%, 48.2% respectively as fine, average and poor⁽¹⁴⁾. However, in another analysis, the situation was significantly different: the knowledge score was 15.35% low, 59.9% on average and 24.8% good⁽¹¹⁾. The average knowledge score compared with these was much higher.

Findings have showed a substantial ($p < 0.001$) disparity in knowledges with educational history ($F=207.78$), profession ($F=39.72$), and increased period of diabetes ($F=13.09$). This may be attributed to the schooling of the respondents of which graduates have greater awareness than those who do not go to school.

The big hypothesis of the analysis was that the respondents lacked knowledge of diabetes. This illustrates the critical need to develop diabetes awareness. Co naissance of diabetes, including diabetes complications, was low suggests that most patients did not obtain diabetes instruction from their doctors. This is because of numerous reasons such as insufficient information provision and often lack of time as a result of the large patient pressures and the lack of well trained support personnel such as teachers. Older people with diabetes are gradually recognized as having requirements above and above those connected alone to metabolic disturbance treatment. In the later years of life, diabetes raises challenges that are more focused on the secondary prevention and the maintenance of psychosocial health than on purely metabolic objectives. To date, no research in India has explicitly discussed the health needs of the

diabetic age group. Prevention of diabetes, community and elderly treatment remains an important problem. The findings of the study probably only depict the 'spit of the iceberg' and in fact probably indicate the 'best case' in Bangladesh.

Several studies have shown that an education program can enhance glycemic control, especially in the older population⁽¹⁷⁾. Patients with an emphasis on diet and exercise may appeal to a conventional physician focused on risk factor control or drug treatment, comorbid disease functional limitations and dietary and exercises challenges. Patients need to prescribe food plans and workout plans that are culturally appropriate and tailored to the particular patient to make them understand how necessary it is to stick to those behaviors⁽⁶⁾.

If effective and prompt steps are taken, diabetes and its symptoms will generally be avoided. Health education is of significant importance in diabetes and its risks prevention and management. Must bring about a positive shift in self-care practice in the area of diabetes prevention, is importantly the frequent health education/reinforcement and inspiration. Since there is a disparity between diabetics' awareness, attitudes and behaviors, it is important to establish methods to turn positive attitudes into effective practices. In order to refresh their awareness on diabetes so that improved diabetes diagnosis and information can be imparted to patients, ongoing medical instruction for medical and paramedical staff can take place annually. Evidence suggests that clinical trials have been breaking off to very slowly in the population and increased measures are needed to convey critical messages of public health through mainstream media and media. The need to take the time to raise awareness of diabetes in Bangladesh's urban, rural and large public lectures and door-to-door campaigns.

Conclusion

This study attempts to assess the general knowledge of diabetes in geriatric patients attending hospitals as it influences the management of type 2 diabetes at individual as well as community level. This hospital-based study, confined to three hospitals in Dhaka City, showed that participants lack knowledge of BASE diabetes and was significantly influenced by sex, education, occupation,

and diabetes duration.

Diabetes education is critical as awareness changes and expertise contribute to improved disease prevention. It is important to remember, to be successful, campaigns aimed at raising awareness of diabetes must be adapted to local community and people's beliefs. Bangladesh currently lacks formal diabetes education and information services for both people at risk of the condition and people with it. So far, nothing has been done to determine the extent of current awareness and attitudes of people with diabetes or their educational needs.

This research on a small sample that does not constitute the entire population indicates low awareness of type 2 diabetes among geriatric patients in Dhaka City. This highlights the need for expanded diabetes education in the form of social media advertisements, public seminars, and large door-to-door campaigns in urban and rural Bangladesh.

Ethical Consideration: This study was approved by Ethical Review Board of Northern University. The researchers clarified the objective of this research and obtained informed consent from the respondents.

Funding: No funding to be mentioned.

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Assessment of the Survival and Sensibility of Mature Anterior Teeth with Periapical Lesion after One Step Regenerative Approach Using Different Disinfection Maneuvers : A Randomized Clinical Trial

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Abstract

Aim: evaluate outcomes of single visit regenerative endodontic procedures using conventional irrigation protocol in comparison to LASER disinfection in comparison to 0.2% Nano Chitosan irrigating solution for treatment of necrotic mature anterior teeth with periapical lesions.

Methodology: 45 patients were recruited in this trial. Preoperative standardized cone beam computed tomography (CBCT) was performed for the patients after fulfillment of inclusion criteria.

After complete diagnostic steps and signing of consent forms and performance of access cavity preparation, patients were randomly distributed into three groups with three disinfection maneuvers:

1. **Group A (Intervention 1)** final disinfection using Low Power Diode LASER disinfection.
2. **Group B (Intervention 2)** final rinse using 0.2% Nano Chitosan irrigation disinfection in a side perforated needle.
3. **Group C (Control)** conventional irrigation protocol using 1.25% sodium hypochlorite irrigating solution and 17% EDTA only.

Platelet rich fibrin was packed inside the root canals followed by collagen plug and Biodentin. Teeth were restored using resin modified glass ionomer.

Patients were recalled for regular follow ups at 6 and 12 months. Patients were examined for survival of treated teeth and any inflammatory signs or symptoms. All samples were tested for sensibility. All data were statistically analyzed.

Results: Single visit regenerative endodontics possessed an overall percentage of success 95.5% in all groups in terms of survival of treated teeth. Regarding sensibility nano chitosan also possessed the highest percentage of cases regaining sensitivity by 73.3% followed by laser group 67.7% followed by the control group with 46.7% also with no statistical significant difference between all groups.

Conclusion: Within limitations of this study single visit regenerative endodontics can be applied to cases with necrotic pulps and periapical lesions where thorough disinfection is recommended in cases of single visit approach to ensure maximum elimination of bacterial cells from root canal hindering successful

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regenerative process.

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disinfection.

Introduction

Preservation of the natural dentition had always been a primary objective in endodontic practice. The most important drawback of conventional root canal treatment is that the survival of affected pulp is hindered¹. Thus a new treatment approach was introduced utilizing the body ability to regenerate, called Pulp Regeneration. Regeneration was first introduced in the dental field as a solution for immature apex treatment, due to difficulties encountered during its conventional root canal treatment.²

American Dental Association adopted the tissue engineering concept and pulp regeneration in 2009³. Regeneration was focused on improving both the functionality and durability of the affected tooth. Based on the success of pulp regeneration in treating immature teeth, ambitious dentists started to look forward on regenerating the pulp of mature teeth⁴. Doubts about treating mature teeth with the same protocol, as the small apical foramen might not provide a good portal for the entry of stem cells and growth factors, which in turn is very important for the success of pulp regeneration⁵.

The majority of articles present in literature concerning regenerative endodontics is concerned about treatment of affected teeth with immature apex, after proper systematic search online, insufficient evidence and randomized controlled trials were found supporting the methodological steps for regenerative approach for mature teeth. Most available studies are case reports. Very few randomized controlled trials which are the gold standard of interventional trials resulting in the highest level of evidence that contributes effectively in the clinical decision-making process. Since the main challenge in single visit regenerative process is the canal disinfection as a fundamental for success of the regenerative process. The aim of this study was to evaluate the outcomes of single visit regenerative endodontic procedures using conventional irrigation protocol of sodium hypochlorite combined with EDTA in comparison to LASER disinfection, or 0.2% Nano Chitosan irrigating solution for treatment of necrotic mature anterior teeth with periapical lesions.

Methodology

This trial design was Prospective, parallel, randomized, double blinded clinical trial as the participants and outcome assessors will be blinded. The Allocation ratio was 1:1 and the framework was superiority to prove that intervention and added disinfection maneuvers resulted in better results than control and conventional disinfection maneuver.

The Inclusion criteria were 18- 50 years old patients free from any physical or mental handicapping condition with no underlying systemic diseases, Single canalled anterior teeth having non-vital, mature, radiographic evidence of periapical lesion.

The exclusion criteria were any known sensitivity or adverse reactions to pharmaceuticals necessary to complete the trial⁶, Non-restorable coronal portion of teeth⁷ and radiographic evidence of external or internal root resorption.⁷

A total of 45 Samples from outpatient clinic of Cairo university were recruited and referred for preoperative CBCT for accurate assessment and standardization of follow up records.

After access cavity and chemo-mechanical preparation, 45 participants were randomly and equally assigned using paper folded numbers arranged according to a random sequence generator (random.org) into either of three groups:

1. **Group A** final disinfection using Low Power Diode LASER disinfection.
2. **Group B** final flush was performed using 0.2% Nano Chitosan irrigation disinfection in a side perforated needle inserted 1 mm shorter than the working length.
3. **Group C (Control)** disinfection was performed only by conventional irrigation protocol using 1.25% sodium hypochlorite irrigating solution and 17% EDTA only as disinfection means.

All Participants were anaesthetized using Articaine 4% solution. Preoperative isolation, Access cavity preparation was done. Working length was determined using an electronic apex locator. Conventional mechanical instrumentation was performed by controlled memory Ni Ti instruments that were used as a single use.

Irrigation using 1.25% NaOCl by side perforated needle was done in between each file with 20 mlas final flush and 17% EDTA solution.

First Interventional group samples were disinfected with diode LASER 940 nm wavelength using Siro Laser Blue Device to augment the canal disinfection prior to regenerative process⁸⁻¹¹. The LASER fiber was inserted 1mm shorter than the W.L, created a circumferential disinfecting beam along the root canal for 2 seconds.

Interrupted 10 cycles of laser application were done to ensure preservation of stem cells viability as well as canal disinfection with a 5 seconds gap inbetween with total contact time of 20 seconds^{9,12,13}.

Second interventional group final rinse using 20 ml of 0.2% Nano Chitosan irrigation¹⁴⁻¹⁸ delivered over 4 interrupted injections at time interval of 3 minutes each using side perforated needle^{16,18,19}. For the control group only conventional irrigation protocol was used.

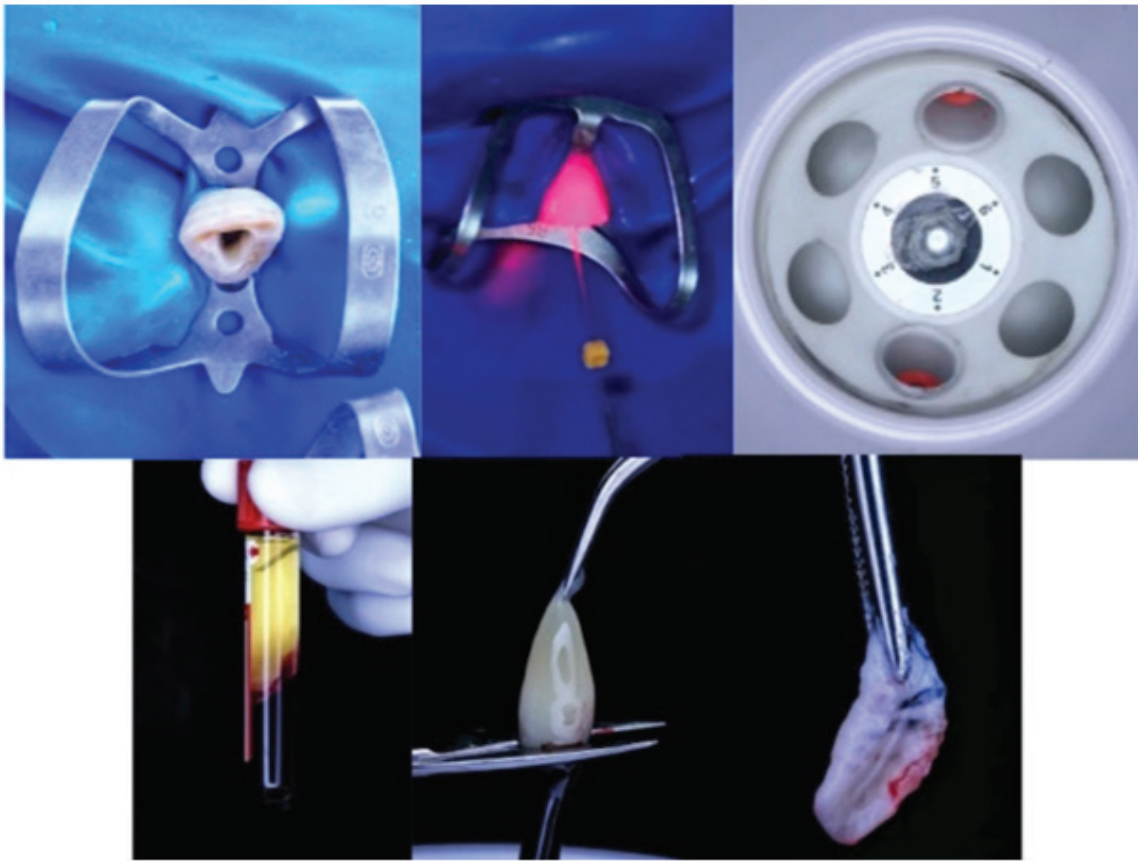


Figure 1 : Procedural steps for LASER disinfection followed by PRF preparation

All participants undergone single visit regenerative endodontic procedures using autologous platelet-rich fibrin according to Narang et al protocol²⁰. A blood sample was collected in 10-mL glass tubes without anticoagulant. The blood sample was immediately centrifuged in an electric powered centrifuge at 4500 rpm for 12 mins. The resultant product consisted of

PRF was put in a sterile cup for 10 minutes to allow the release of the proper serum contained within. PRF was packed inside the dry canals to the apical canal end using different sized pluggers. A collagen plug and Biodentin was placed at the level of the cervical line. Pulp chamber was restored using resin modified glass ionomer or resin composite.

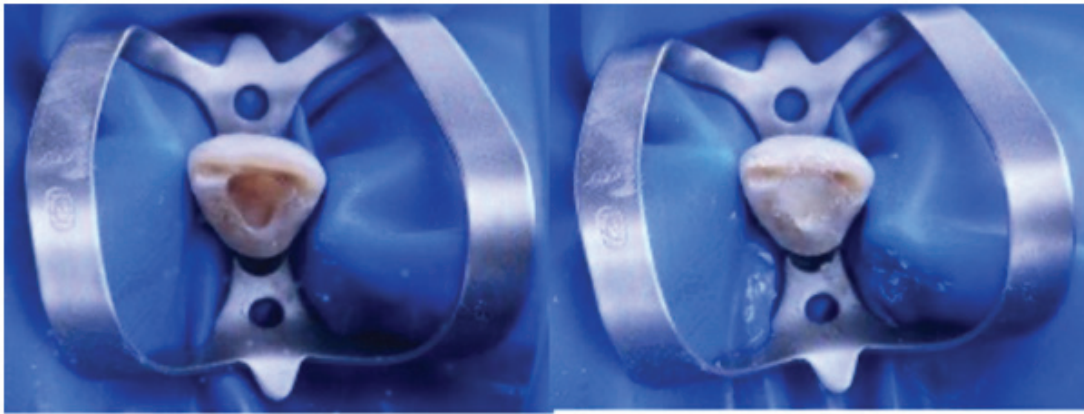


Figure 2: Packing of PRF inside canal followed by Biodentin

Assessment of **primary** [survival] and **secondary** outcomes were done for each participant after 6 and 12 months. Survival was assessed by evaluating integrity of the remaining tooth structure and restoration, Absence of cracks and fractures in tooth structure and restoration, Absence of tenderness to biting, Absence of swelling and absence of spontaneous pain.

Sensibility testing was done by placement of electric rod of the pulp tester on the labial surface of the tooth after tooth isolation and application of a spot of conducting material. A reference of contra lateral tooth was also been assessed²⁰. According to the manufacturer's instructions, the readings between 0-80 were interpreted as sensibility regain. Above 80 result interpreted as non regain of sensibility²¹.

Sample size calculation was done to test the null hypothesis. Computation of power is based on a hazard ratio of 3.32. It assumes instantaneous hazard rates of 0.180 for the control group versus 0.598 for the laser group. Since the hazard rate is constant across intervals this is equivalent to median survival times of 3.85 intervals for the control group versus 1.16 intervals for the laser group. It is also equivalent to a cumulative survival at 4 intervals of 0.49 for the control group versus 0.09 for the laser group. The computation assumes an attrition rate of 0.10 per interval. The study had power of 71.7% to yield a statistically significant result.

Study discontinued in case of severe persistent immediate post operative swelling, severe persistent immediate postoperative pain that didn't decrease by analgesic. Regarding implementation the participant enrollment was performed by the principal investigator, the participants assignment was done by drawing folded papers.

Results

Regarding the age distribution there was no statistically significant difference between the three groups. ($p = 0.594$); In group A the mean and standard deviation values of age were (28.07 ± 7.48), while in group B they were (30.87 ± 7.27) and in group C they were (30.73 ± 10.22).

Regarding gender distribution; In group A the gender distribution showed 7 males (46.7%) and 8 females (53.3%) and in group B it showed 5 males (33.3%) and 10 females (66.7%) While in group C it showed 8 males (53.3%) and 7 females (46.7%). Using Chi square test here was no statistically significant difference between the three groups. ($p = 0.533$).

Regarding survival in group A 15 patients (100%) showed survival and no patients showed no survival (0%) while in group B 14 patients (93.3%) showed survival and 1 patient (6.7%) showed no survival, And in group C 14 patients (93.3%) showed survival and 1 patient (6.7%) showed no survival. Using chi square test results showed that there was no statistically significant difference between the three groups. ($p = 0.434$).

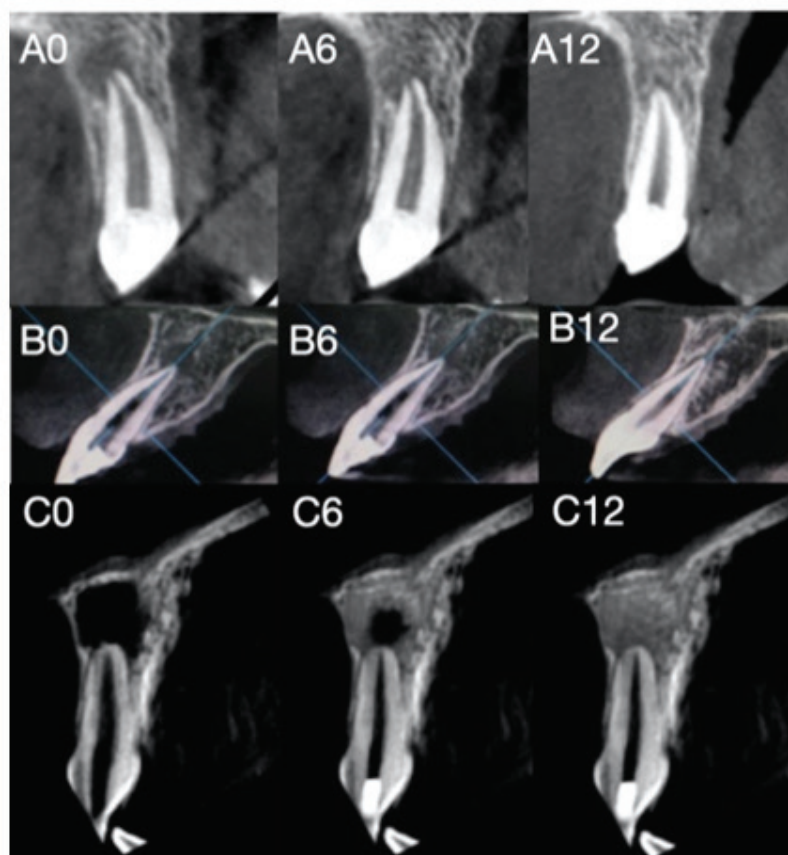


Figure (3) Samples of Healing from groups; A0 LASER group preoperatively, A6 at 6 month and A12 at 12 months interval. B0 nano chitosan group group preoperatively, B6 at 6 month and B12 at 12 months interval. C0 control group preoperatively, C6 at 6 month and C12 at 12 months interval

Regarding Sensibility In group A 10 patients (66.7%) showed sensibility and 5 patients (33.3%) showed no sensibility while in group B 11 patients (73.3%) showed sensibility and 4 patients (26.7%) showed no sensibility. In group C 7 patients (46.7%) showed sensibility and 8 patients (53.3%) showed no sensibility Using chi square test analysis showed that there was no statistically significant difference between the three groups. ($p = 0.293$).

Table (1): Showing results of primary and secondary outcomes

Outcome		LASER Group	Nano Chitosan Group	Control Group
Survival	Yes	15 (100%)	14 (93.3%)	14 (93.3%)
	No	0 (0%)	1 (6.7%)	1 (6.7)
Sensibility Regain	Yes	10 (66.7 %)	11 (73.3%)	7 (46.7%)
	No	5 (33.3%)	4 (26.7%)	8 (53.3%)

Discussion

This is an innovative study assessing the different methods of disinfection along regenerative endodontic process and the applicability of SRPs. The most important objective of root canal therapy is to minimize the number of microorganisms in root canal systems to prevent or treat apical periodontitis. In mature teeth, disinfection is carried out with a combination of mechanical instrumentation, irrigation, and the placement of an intracanal medicament.²²

Regenerative endodontic therapy in mature teeth likely encounter more challenges than in immature teeth; less stem/progenitor cells in mature teeth, less probability of blood clot formation and narrower apical pathways for stem/progenitor cell migration will be major limitations²³.

SRP has been reported in immature teeth in several successful case reports and case series. Irrigation is crucial for the management of intra-canal infection, especially in the presence of apical periodontitis. Successful single-visit REP incorporated effective irrigation protocols, including the use of the high concentrations of NaOCl and EDTA together with suitable agitation techniques.

The irrigation protocols used for all groups involved the use of sodium hypochlorite and EDTA 17%. Sodium hypochlorite (NaOCl) was the main irrigant in the current study. Its germicidal ability is related to the formation of hypochlorous acid when in contact with organic debris. Copious irrigation with a total volume of 20 ml of 1.5% NaOCl for 5 minutes with a closed end side-vented needle, to minimize the possibility of extrusion of irrigant into the periapical space. The reduction of intracanal microbiota is not greater when 5.25% NaOCl is used as an irrigant as compared to 1.5%^{24,25}.

Concerning REP, 5.25% NaOCl concentration was found to be cytotoxic to stem cells in the apical tissues and decrease odontoblastic differentiation²⁶. This indirect effect is likely related to various deleterious effects of NaOCl on the dentin matrix leading to decrease in release of dentin matrix-derived growth factors such as TGF- β 1, consequently reducing cell attachment. NaOCl was then flushed away from the root canal with saline in an attempt to reduce any lingering toxicity that can reduce the regeneration responses as recommended

by Garcia et al^{27,28}. Sufficient disinfection protocols for REP can be successful without use of antibiotic pastes²⁹.

LASER has the potential to kill microorganisms and to remove debris and smear layer from root canals. Diode laser is considered the most common type of laser used for root canal disinfection. It is associated with least heat generation which is in favor of stem cells in root canals. In this trial 940nm wavelength diode laser had the ability of bacterial elimination from root canal as well as bacterial cells penetrated inside the root canal dentinal tubules^{30,31}.

Nano chitosan was selected as the second variable for disinfection due to the wide antibacterial effect as well as its potentiating role in regenerative endodontics. Impregnation of chitosan along the regenerative skeleton resulted in rendering the scaffolds composition more impressive for cell adhesion which can enhance initial cell attachment and proliferation of the DPSCs. Regarding the cytotoxic effect of nano chitosan particles 0.2mg/ml showed the least cytotoxic effect on cells.^{32,33}

For all groups, a solution of 17% EDTA was used as its chelating effect promotes the release of dentin-derived growth factors that were previously embedded into dentin during the process of dentinogenesis³⁴. These growth factors such as transforming growth factor- β 1 (TGF- β), dentin sialoprotein (DSP), platelet derived growth factors (PDGF), vascular endothelial growth factor (VEGF), placenta growth factor (PIGF) and fibroblast growth factor (FGF2), have been shown to stimulate proliferation, survival, and differentiation of dental stem cells³⁵⁻³⁷. Smear layer removal by EDTA greatly enhanced the attachment of Mesenchymal stem cells (MSCs) to the dentinal matrix³⁸, because these cells express several integrin and attachment molecules in their plasma membrane^{39,40}.

Platelet rich fibrin (PRF) is a highly resistant and elastic membrane which does not dissolve quickly after application⁴¹; allowing cellular migration, cytokine entrapment, and slow continuous release of cytokines such as platelet derived growth factor (PDGF), transforming growth factor β 1 (TGF β 1), Fibroblast growth factor (FGF), and vascular endothelial growth factor (VEGF) from 7 to 28 days⁴². These growth factors achieve peak level at 14th day coinciding with cell in growth; so it directs more efficiently stem cell

migration, proliferation, differentiation and supplements the angiogenesis⁴³.

Biodentine, a tricalcium silicate bioactive cement with mechanical properties similar to those of healthy dentin was used in the present study. Its microhardness as well as flexural and compressive strength allow us to name this material a 'dentin substitute'⁴⁴. Observations made in several studies suggesting that Biodentine demonstrates better mechanical properties, easier application and a shorter setting time than previously used mineral trioxide aggregate (MTA)^{45,46}. Biodentine also has a broad spectrum antibacterial effect and low cytotoxic activity.⁴⁷

Out of the recruited 45 samples only 2 teeth didn't survive. The first unsurvived tooth was in the control group and showed recurrent swelling and was marked as failure and shifted to conventional root canal treatment. The second case was in the nanochitosan group and a fracture resulted from a trauma for the patient rendered the tooth non restorable. A hypothesis for this result could be that if the intracanal bacterial load is effectively reduced, the inflammatory periapical lesions may heal even without root canal fillings as mentioned in previous trials^{48,49}

Results are in disagreement with the results reported by the study performed by Botero et al⁷ who reported only 33% of success with single visit regenerative process. The results cannot be compared as the selected cases were immature and blood column was selected as scaffold, this might be the reason for such low percentage of success. In referral to the systematic review analyzing the reasons of failure of regenerative endodontic cases by Almutairi et al²² who attributed 91% of failed reported regenerative cases to the use of blood column as scaffold and recommended the use of platelet concentrates.

Sensibility assessment revealed that 28 cases out of the 45 cases of all groups have regained tooth sensibility at the end of the 12 months follow up. Previous studies reported immature teeth with necrotic pulp treated with PRF revascularization responded positively to sensibility testing at 12-month follow-up^{50,51}. The results of sensibility for interventional groups may be attributed to higher level of disinfection and more favorable environment for regeneration process and thus faster development of neural component of regenerated

tissues which is last to form. More time is needed for sensibility regain which sometimes may reach two years as previously reported^{52,23}.

Conclusion

Within the limitations of this study the following can be concluded; Single visit regenerative endodontics can be applied to cases with necrotic pulps and periapical lesions where thorough disinfection is recommended in cases of single visit approach to ensure maximum elimination of bacterial cells from root canal hindering successful regenerative process., Single visit regenerative endodontics coupled with adequate disinfection maneuvers presented an overall percentage of success 95.5% in all groups in terms of survival of treated teeth. Finally samples regained sensibility with varying degrees. Nano Chitosan and laser groups were able to regain sensibility faster than the conventional irrigation protocol group.

Ethical Clearance: Approved from ethical committee of faculty of dentistry, Cairo University.

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Does the Covid-19 Effect on Kidney Functions? Question Need an Answers, Observational Study, Aljouf Region, Saudi Arabia

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Abstract

Background: Many of the published studies on COVID-19 have highlighted lungs as the main organ affected in this disease. Some studies suggest that it can leads to Acute Kidney Injury . Our goal in this study to evaluate the effect of covid-19 on kidney function.

A frequent monitoring of kidney functions in patients with COVID-19 can lead to early diagnosis of kidney disorders, and help in achieving the optimal therapeutic concentrations of drugs and reducing the risk of drug reactions.

Methods: the study was carried among the consecutive 82 COVID - 19 patients. These patients were symptomatic and diagnosed to be positive for corona virus. The data was extracted from the patient medical record files. Those patients were followed after discharge from hospital to repeat their investigations after three weeks

Results: Of the 82 patients, 68 patients (82.9%) had high leukocytes, 18 (21.9%) patients had hematuria, 34 (41.4%) had proteinuria and 10 patients (12.1%) had serum creatinine levels of more than 1.3 mg/dl.

The follow-up three weeks after discharged Investigations revealed that 12 (14.6%) patients had moderately high leukocytosis, 6 (7.3%) patients with hematuria and 8 (9.1%) patients with proteinuria and one patient with high creatinine (2.4%).

Conclusion: The Corona virus is affect mainly the respiratory system but can affect other system related to it too. It has a little effect directly on kidney either because there is no real effect on it or the immunity of patients prevent effectiveness of virus.

Keywords: Covid-19, Corona, Kidney function

Introduction

The coronavirus cases were eventually reported to the World Health Organization country office in China on the 31st of December 2019. Many of the cases were reported and searches for the source have shown that one of the seafood markets, a wet market as the origin , the market was where a large variety of vertebrates and invertebrate animals wild court and farm raised are sold. On January 1st, markets were closed (1). Furthermore,

on January 12th 2020, shares the genetic sequence of the novel coronavirus , which will be very important for the other countries as they developed specific diagnostic tests (2).

SARS CoV-2 (COVID -19) is a virus is a new type of coronaviruses that appeared suddenly in late 2019 in the city of Wuhan, China (3). Coronaviruses are common, you have likely had a coronavirus lots of times, it is one of the kinds of viruses that cause the common cold, but

they can also cause Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), two diseases that have very high case mortality rates. They are highly contagious, and the disease that SARS CoV-2 causes has been named as COVID-19(4).

The COVID-19 pandemic began in China , but new cases in china are very low, and now the majority of new cases are reported outside china. This raises the question; do we have a pandemic on our hands? And the answer is Yes.

Researchers have said they need to see evidence of sustained, domestic transmission in at least one more region outside of the pacific region that includes china, Japan, and south Korea before using the word “Pandemic” (5). COVID-19 pandemic affects patients of all ages with multiple comorbidities, including chronic kidney disease. However, it had been reported that acute kidney injury or failing of the kidneys were seen in those patients with and without chronic kidney disease (6).

There is a wide range of the percentages of patients might be affected with acute kidney injury, ultimately requiring dialysis or kidney replacement therapies, and it has been quoted from several studies that have been published thus so far that 22 even 40% of patients that are admitted to critical care units may require the use of dialysis therapies under the care of a nephrologist. The patients without the need for dialysis may develop acute kidney injury that may be their past the infection during the hospital course and these patients may even have chronic kidney disease after they have recovered from the virus (7). Several hospitals around the world, especially from cities of epicenters of COVID 19 pandemic such as hospitals from New York city have run into a shortage of both dialysis machines and dialysis staffing, which has made it difficult to provide these life-prolonging and life-sustaining therapies to patients that need them (8).

Despite several precautionary decisions made by the Saudi government to prevent the spread of infection, there are many cases are reported in most part of the kingdom. According the global health reports, the virus primarily affects the respiratory system and which may lead to several outcomes including death. Many of the published studies on COVID-19 have highlighted lungs as the main organ affected in this disease.

In Italy, patients who tested positive for COVID-19, roughly 47% were hospitalized and 6% required Intensive care admissions (Ministero della Salute. Covid-19. Situazione in Italia. Ministero della Salute. Salute.gov http://www.salute.gov.it/imgs/C_17_pagineAree_5351_30_file.pdf (2020)). Data on the impact of covid19 on kidney is scarce.

The data from a Chinese cohort of 1,099 patients with COVID-19, suggest that only 0.5% had Acute Kidney Injury (9). The potential mechanisms of kidney injury can be due to cytokine damage, organ crosstalk and systemic effects.

A frequent monitoring of kidney functions in patients with COVID-19 can lead to early diagnosis of kidney disorders, and help in achieving the optimal therapeutic concentrations of drugs and reducing the risk of drug reactions.

Methodology

This observational analytical study was carried among the consecutive 82 COVID - 19 patients. These patients were symptomatic and positive for polymerase chain reaction (PCR). The study was conducted from 26th April to June 2nd , 2020 from the hospitals of north region of the Kingdom of Saudi Arabia. Both male and female patients positive for coronavirus were eligible to be included in the study. The patients’ age ranged between 20-60 years. The data was extracted from the patient medical record files. The data that was extracted included demographic details like age and gender, biochemical parameters such as serum creatinine, complete blood count, and urine analysis from patient files. Those patients were followed after discharge from hospital to repeat their investigations after three weeks. The patients were tracked by their mobile numbers and WhatsApp reminder was sent for the follow-up.

The study protocol was approved by the Research Ethics Committee, Qurayat health affairs (approval no: 0043, dated , M.O.H, order no (0043) dated 23th April 2020. Informed consent was taken by the attending nurse in the presence of a relative as witness before specimen and data collection.

Results

All the patients that tested coronavirus positive were

males in the age range of 20- 60 years

Of the 82 positive symptomatic coronavirus patients, 68 patients (82.9%) had high leukocytes, 18 (21.9%) patients had hematuria, 34 (41.4%) had proteinuria and 10 patients (12.1%) had serum creatinine levels of more than 1.3 mg/dl.

Table 1: Age, gender, hematology and renal parameters of patients at the time of diagnosis

Characteristics	Patients (no)	Percentage
Age	20-60	---
Gender	Males	100%
Test of coronavirus	Positive	100%
Leukocytes	68 high	82.9%
Hematuria	18	21.9%
Proteinuria	34	41.4%
Creatinine	10 above 1.3 mg/dl	12.1%

Patients were followed three weeks after discharged from hospital. The new investigations were carried out at the primary health care center where they were registered. The follow-up

Investigations revealed that 6 (14.6%) patients had moderately high leukocytosis, 3 (7.3%) patients with hematuria and 4 (9.1%) patients with proteinuria and one patient with high creatinine (2.4%).

Table 2 : Age, gender, hematology and renal parameters of patients after 3 weeks of discharge

Characteristics	Patients (no)	Percentage
Age	20-60	----
Gender	Males	-----
Test of coronavirus	Negative	
Leukocytes	12 patients high	14.6%
Hematuria	6 patients	7.3%
Proteinuria	8 patients	10%
Creatinine	2 patient above 1.2 mg/dl	2.4%

Discussion

We report here a cohort of 82 patients with lab.-confirmed Covid -19 infection. Patients had upper respiratory tract infections symptoms. They were admitted to the hospitals in northern area, KSA, by March 2, 2020.

All of the patients are males, Perhaps because the men are more likely to go out and communicate with

others outside the home, which puts them at risk of contracting this virus and thus transmitting it to others. While women are less likely to leave their homes and also during their exit they follow the instructions in addition to wearing the Hijab, which makes them less likely to be infected with this virus.

The new 2019 novel coronavirus is very unusual , since it was discovered in Wuhan, the capital city of China's Hubei Province late last year, the virus has

killed thousands of people and infected millions(10). For every single person who is effected, it seems as if there is going to be up to three or four other persons who could also be affected.(11,12). The first confirmed case of what was then an unknown coronavirus was traced back to November 2019 in Hubei.

We found there is an effect on the kidneys like acute kidney injury in Dawei Wang, MD1; Bo Hu, MD1; Chang Hu, MD1; et al, "Patients' clinical manifestations included fever, nonproductive cough, dyspnea, myalgia, fatigue, normal or decreased leukocyte counts, and radiographic evidence of pneumonia. Organ dysfunction (e.g., shock, acute respiratory distress syndrome (ARDS), acute cardiac injury, and acute kidney injury) and death can occur in severe cases".(13). But in our study, we find a negligible effect on kidneys which may be related to the situations of patients their self . Also sever Acute respiratory distress syndrome can lead to other organ dysfunction .

Acute kidney injury (AKI) was detected in different MERS cases, with possible influence on disease severity (14,15, 16). AKI has neither been a typical feature of SARS, nor has it been a common observation in infected cases as a result of any other corona virus, including human HCoV-NL63, -229E, -OC43, and -HKU1. It is noteworthy that a high percentage (76%) of MERS-CoV cases were reported as having underlying chronic diseases such as DM, chronic CVD and chronic renal disorders.

The present study found most of clinical manifestations are in respiratory system which extended from mild to severe symptoms depend on the immune system of patients who are infected with coronavirus. Common symptoms at onset of illness were fever, myalgia, fatigability, and anorexia. Some of patients presented with diarrhea which is atypical symptoms.

Recently, it had been reported by various studies that the incidence of liver injury were ranging between 14.8% to 53%, which was a major indication by abnormal ALT/AST levels accompanied by slight elevation of bilirubin levels.40-51 The albumin was reported to be decreasing in severely reported cases and the level of albumin was reported to be between 26.3-30.9 g/L.46 The likelihood to develop liver injury in severe COVID-19 cases was remarkably higher compared to mild cases.40-42 In fatal

cases of COVID-19, the incidence of liver injury could be reaching up to 58.06% and 78%.(17)

Acute kidney injury are commonly seen in patients with MERS-CoV and SARS-CoV infections, and electron microscopic examination showed viral particles in the renal tubular epithelial cells in SARS patients (15) and in the patient with MERS.(18) These findings may explain the deterioration in renal function in a substantial number of patients with SARS and MERS. The effect of SARS-CoV-2 on kidneys is yet to be explored, but emerging data suggest that the kidney may be an important target organ for SARS-CoV-2 (19)

But as their interpretation , The 2019-nCoV infection caused clusters of severe respiratory illness similar to severe acute respiratory syndrome coronavirus and was associated with high mortality and ICU admission. we believe that there are alternative explanations. In First, the effect of kidney function is clearly mild. Secondly, when kidney function for patients with different durations of symptoms are tested, there is no evidence that later presentation is associated with greater kidney function impairment.

There are some effect of infection for the organ other than respiratory, Hepatic dysfunctions in severe COVID-19 was observed to be along with activated coagulation and fibrinolytic pathways, relatively depressed platelet count, increased neutrophil counts and higher neutrophil to lymphocyte ratios, and elevated level of ferritin (14). Despite that those biomarkers are considered as non-specific biomarkers of inflammation, it is believed that they are fitting the paradigm of the medical condition severity that coincide with a failure of innate immunity (15).Such imbalance in the immunity favours NETosis and activating of coagulation and might as well changes systemic iron metabolism secondary to activate the macrophage. (20). Notably, this changing of immunity balancing happens with increasing of age, and old patients could consequently be predicted to fare worse, with a higher dependence on such pathways.(20)

Most significantly, other respiratory viruses yield the same increase of liver functional biological markers, which are reported to be in relation to hepatic damaging due to immunity interaction(s) that involve "intrahepatic cytotoxic T cells and Kupffer cells.(21) This phenomenon waxes and wanes in line with respiratory viral infection

and in the non-existence of hepatic viral amplification that could be explaining the reason of worsening outcome not observed in forty-two cases with chronic liver disease and COVID-19 who had outcome data”.

Conclusion

COVID-19, a new and aggressive sometimes deadly respiratory illness that is believed to have started in a live animal market in China, has spread rapidly throughout that country and the world. This virus is affect mainly the respiratory system but can affect other system related to respiratory system. It has a little effect directly on kidney either because there is no real effect on it or the immunity of patients prevent effectiveness of virus.

Conflicts of Interest: No conflicts.

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Chronic Complication Profiles of T2DM in Endocrine Outpatient Clinic, Dr Soetomo General Hospital, Surabaya

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Abstract

Background: Nowadays, the number of diabetic complications is still increasing each year. There are some factors that affect the early appearance of diabetic complications. By knowing these factors, doctors and patients will pay attention and prevent the early appearance. Therefore, diabetic patients will reduce the risk of death. **Objectives:** The study aimed to determine the most frequently occurring profile of diabetic macroangiopathy and microangiopathy in people with type 2 diabetes mellitus. **Method:** Descriptive qualitative with a cross-sectional design. **Results:** Patients who are most commonly diagnosed type 2 diabetes mellitus with diabetic complications are in the age group 46 – 55 year (32%), male (50.6%), high school educated (59.9%), private employees (36.6%), average of HbA1c level is 8.68%, controlled HbA1c (54.5%), and duration of type 2 diabetes mellitus with no data on duration (56.9%). The shown complications are single microangiopathy (30.6%), single macroangiopathy (22%), microangiopathy and macroangiopathy combination (9.4%), multiple microangiopathies (2.7%) and multiple macroangiopathies (2.7%). The microangiopathy complications are retinopathy (22.6%), nephropathy (22.1%), and neuropathic diabetic (10.3%) while the most macroangiopathy complications are coronary heart disease (19.2%), peripheral circulatory complication (14.8%), and stroke (11%).

Keywords: Macroangiopathy and microangiopathy, common diabetic complication's profile, Diabetes Mellitus Type 2

Introduction

The number of people with diabetes in the world is 463 million, with 10,681,400 of them from Indonesia. This places Indonesia is the 7th position of

countries with the most diabetic people in the world.² Hyperglycemia is associated with abnormalities in endothelial dysfunction and also becomes an

indication of microangiopathies and macroangiopathies.

If hyperglycemia is properly controlled by maintaining a normal HbA1c level, the incidence of diabetes mellitus complications can be reduced.³

Diabetic chronic complications can be grouped as either macroangiopathy or microangiopathy. In macroangiopathy, coronary heart disease, peripheral artery disease, and ischemic stroke. Meanwhile, in microangiopathy, there are 3 kinds of complications: diabetic retinopathy, diabetic nephropathy, and diabetic neuropathy.

There are 4 pillars in treating diabetes mellitus type 2: education, nutritional therapy, physical activity, and pharmacology using HbA1c level for blood glucose control.⁵ These numbers are still rising. This study aims

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to identify the most common macroangiopathy and microangiopathy cases at Dr. Soetomo Hospital. This study aims to analyzing diabetic factors such as age, sex, last education, occupation, duration of type 2 diabetes mellitus (T2DM), and the most types of chronic complications that occur. This is the first research that analyzing diabetic factors in Dr. Soetomo Hospital to improve the diabetes treatment.

Materials and methods

This descriptive, qualitative, and cross-sectional design has a population of all patients diagnosed with T2DM with or without chronic diabetic complications. A non-probability sampling method with a consecutive sampling technique is used by taking several quota samples from the population until the quota is met.⁶

The minimum sample size that suggested for the descriptive study is equal to or more than 100 samples.⁷ Samples were taken at the Endocrine outpatient clinic in Dr. Soetomo from 255 patients who received treatments from July 2018 until July 2019, selected based on the inclusion and exclusion criteria.

The variables studied are age, gender, last education, occupation, average HbA1c level, duration of T2DM, and chronic diabetic complications such as coronary heart disease, stroke, diabetic foot, retinopathy, neuropathy, and nephropathy diabetic. The research used medical records as instruments. The data was subsequently analysed using the 23 version of SPSS and Microsoft excel. The collected data will be presented descriptively in the form of frequencies and percentages.

Results & Discussion

Table 1. Additional Data of Age and Gender

Variables	Category	Total of People with Complications		
		Macroangiopathy	Microangiopathy	Macroangiopathy and Microangiopathy
Age	17–25 Years	-	1	-
	26 – 35 Years	1	4	-
	36 – 45 Years	9	15	3
	46 – 55 Years	18	32	5
	56 – 65 Years	21	20	12
	≥66 Years	11	13	7
Gender	Male	36	39	12
	Female	24	46	15

Table 2. Data frequency of research variable

Variables	Category		Total	%
Age	17-25 years		1	0.6
	26-35 years		5	2.9
	36-45 years		27	15.7
	46-55 years		55	32.0
	56-65 years		53	30.8
	≥ 66 years		31	18.0
Sex	Man		87	50.6
	Woman		85	49.4
Last Education	Primary School		24	14.0
	Junior High School		16	9.3
	High School		103	59.9
	Higher Education		20	11.6
	Uneducated		5	2.9
	Others		4	2.3
Profession	Housewife		56	32.6
	Others		2	1.2
	Civil Servant		19	11.0
	Private Employees		63	36.6
	Unemployed		11	6.4
	Entrepreneur		21	12.2
HbA1c level	Controlled	HbA1c level <7% at <60 years	43	16.9
		HbA1c level <8% at ≥60 years	96	37.6
	Uncontrolled	HbA1c level >7% at <60 years	81	31.8
		HbA1c level >8% at ≥60 years	29	11.4
Duration of T2DM	≤5 years		48	18.8
	≤6 years		62	24.3
	No data		145	56.9
Type of complications	Complications profile	Single Macroangiopathy	56	22.0
		Single Microangiopathy	78	30.7
		Macroangiopathy and Microangiopathy	24	9.4
		Multiple Macroangiopathy	7	2.7
		Multiple Microangiopathy	7	2.7
		Without Complications	83	32.5
	Microangiopathy	Retinopathy diabetic	46	22.6
		Nephropathy diabetic	45	22.1
		Neuropathy diabetic	21	10.3
		Macroangiopathy	Coronary heart disease	39
		Peripheral circulatory complication	30	14.8
		Stroke	22	11.0

Based on Table 1, it was found that there are 55 people of mostly around 46 to 55 years old who had been diagnosed with chronic complications. Age is an important factor that affect the prevalence of diabetes and impaired glucose tolerance. According to WHO, if someone's age has reached 30 years old, the fasting blood glucose concentrations will be increase by 1-2mg%/year, and the blood sugar level 2 hours after eating will increase to 5-6-13 mg%⁸. This shows that age is related to diabetes prevalence. Furthermore, it's easier for this age group to become obese because their physical activity is decreasing. The number of insulin receptors that are ready to bind with insulin decrease, therefore affecting the decrease of GLUT-4 translocation rate.⁹ According to previous research, patients with macroangiopathy and microangiopathy mostly occur in patients aged 46-65 years old.¹⁰ The decrease of body functions, especially the pancreas, also occurs in this age group.¹¹

In terms of gender, there are almost the same numbers of man and woman respondents with chronic complications, 26 and 24 respectively. A previous research by Lathifa, also found such similarity while a research by Yuhelma found that diabetes mellitus mostly occurred in women. The later is due to women having a higher level of LDL or bad cholesterol and triglyceride than men. In women, the increasing higher lipid levels can be increase the risk of diabetes mellitus 3-7 times higher.¹³ In this research, men have slightly higher number of complications of diabetes than women. These conditions can be caused by several factors such as lifestyle, culture, smoking habits, exercise, stressors, and socio-economic conditions, much like those found in Dr. Soetomo's patients.

Our recent education data in patients who experience chronic complications showed that most respondents were educated up to Senior High School level while a research by Yuhelma showed that patient's last education was dominated by Junior High School level.¹³ Another research showed that respondents with higher education might be more knowledgeable about health, giving them higher awareness on how to maintaining their health.¹⁴ Therefore, it's concluded that recent educations is related to the appearance of chronic complications due to how patients pay attention to their health and how they maintain necessary treatment.

The collected data shows that chronic complications mostly occur in respondents who work as a private employees. Busy work life can affect people's dietary needs and reduce their physical exercise time, giving them a higher risk for diabetes. According to a previous study by Sitohang, people with chronic complications are mostly found in working groups¹⁶, This shows that physical activity is one of the most important pillars in the management of T2DM as it's related to improving insulin sensitivity for glucose to enter cells without insulin.¹⁸

HbA1c levels is a long-term glycemic control index for 2-3 months. In this study, there are 139 respondents (54%) with a controlled HbA1c level. At Dr. Soetomo Hospital, there are several conditions correlating to respondents with high HbA1c levels. The first is patients with severe conditions or patients after first hospitalization and later died. The second is patients with tumor and cancer at the time of their high HbA1c level but then after surgery the next HbA1c examination was done in the other health facilities. Lastly, other conditions such as patients who only did 1-time HbA1c examination because they didn't routinely come for the follow-ups. Diabetes treatment is a long-term treatment that requires patients to be obedient in coming for the next follow-ups. Patients' disobedience in following the course of the treatment and lack of lifestyle changes are some of the reasons why the HbA1c control target wasn't achieved.¹⁹

In this research, the collected data shows that the duration of type 2 diabetes mellitus was challenging to assess as shown by patient's inability to present this data. It's very difficult to detect when T2DM can occur due to the progressive nature of the disease meaning that new symptoms appear when the condition starts to worsen.

The next dominant data is 39 patients (15.3%) who were diagnosed with T2DM for 1 to 5 years. With the lack of public attention and the habit of underestimating this disease, most people are unaware of the typical symptoms of diabetes and they will start to treat it when the condition is already mild. In addition, when people are diagnosed with T2DM, the function of their pancreas will decrease $\pm\pm 50\%$. A few years before being diagnosed with T2DM or while in prediabetes condition, there might abnormalities in laboratory and

clinical findings that can contribute to a cardiovascular risk factor.¹⁸ People who had been suffering for 1 to 5 years from T2DM are susceptible to the quickening of this disease because some are not compliant with the treatment. Meanwhile, research by Lathif showed that the level of pathogenicity of the disease can be seen from the disease's duration, especially diabetes mellitus.¹² However, if the long-suffering condition is balanced with a healthy lifestyle and compliance to the treatment, the early appearance of chronic complications can be prevented and delayed.²¹

The collected data of complications profile is mostly dominated with single microangiopathy. Similarly, another previous research found the most common microangiopathy complication that occurs in patients is diabetic nephropathy.²²

The dominating type of complications in this research is diabetic retinopathy as found in 46 respondents (22.6%). Similar to a research by Suryathi, among 123 respondents, 74 patients (60.16%) were diagnosed with diabetic retinopathy.²³ This complication occurs due to a long hyperglycemic condition that can cause the increase of aldose reductase enzyme activities so that the production of polyols like sugar and alcohol in eye tissues, lens, blood vessels, and optic nerve increases. The characteristic of polyol is that it cannot pass through the basal membrane, making it accumulate in large quantities in the cell. In this condition, the accumulation of polyol can increase the osmotic pressure, which can cause several disorders such as morphological and functional disorders of cells. Several patients are unaware of this complication and only assume that this is a common eye disease symptom so that the onset of the complications process is often detected.^{24,25}

In addition to retinopathy, the next most complications is diabetic nephropathy with 45 respondents.

Similarly, a research by Edwina, it was found that the most dominant complications was diabetic nephropathy found in 42.6% of respondents.²² Nephropathy can be seen in microalbuminuria examination accompanied by glomerular filtration rate examination to assess patient's kidney function. Patients with a fast decreasing glomerular filtration rate may experience glomerulopathy and poor metabolic control. Retinopathy is also a clue to diagnosing nephropathy diabetic. Some people with

chronic complications are diagnosed with more than 1 complications.^{26,27}

According to table 1, there are 39 respondents diagnosed with coronary heart disease. The epidemiology of coronary heart disease shows that hyperinsulinemia or excessive insulin contributes to a higher cardiovascular risk. Based on Permana, 50 to 70 percent of people with diabetes mellitus have coronary atherosclerosis.³ People with diabetes have 4-8 times higher risk of congestive heart disease.²⁸

Another microangiopathy found is diabetic foot. According to previous research at Haji Adam Malik General Hospital in Medan, diabetic foot was common as it was found in 38% of respondents.²⁹

Table 1 shows that 22 respondents (11%) were diagnosed with stroke. According to the American Diabetic Association, patients with diabetes mellitus have a 1.5 times higher chance of having a stroke.³¹ The pathophysiology of this disease includes several conditions such as hypertension, dyslipidemia, heart disease, and hyperlipidemic conditions.³²

Based on the research data, the last complication is diabetic neuropathy with a total of 21 respondents. According to a previous study in Ciptomangunkusumo Hospital, diabetic neuropathy is the most commonly occurring in 54% of respondents.⁴ Similarly according to the International Diabetes Federation, the most commonly occurring complication in Indonesia is diabetic neuropathy with 17.6% respondents.² This is due to persistent hyperglycemia that can stimulate the production of oxidative free radicals which will damage the vascular endothelium and Nitrite Oxide and block the vasodilation process so that the blood flow to the nerves will decrease. Along with low myoinositol conditions in cells, this condition will lead to neuropathy. If the metabolic damage continues, the disease will trigger worse conditions such as irreparable ischemic and axons structural damage.^{35,36}

Conclusion & Acknowledgment

This research concluded that T2DM with diabetic complications is most commonly diagnosed in patients within

1. The age group of 46-55 year (55 respondents or 32%)
2. Similar prevalence of chronic complications in man and woman respondents, 87 (50.6%) and 85 (49.4%) respectively
3. Most common level of recent education is Senior High school with 103 respondents (59,9%)
4. Controlled HbA1c level is found in 139 respondents (54.5%) with the compositions of HbA1c levels <7% in 43 respondents aged < 60 years (16.9%) and HbA1c level <8% in 96 respondents (37.6%) aged >60 years with severe conditions. While the average of HbA1c level is 8.68%.
5. Most T2DM patients were unable to present data on illness duration (145 respondents or 56.9%).
6. With regards to complications, there are 78 respondents with single microangiopathy (30.6%), 56 respondents with single macroangiopathy (22%), 24 respondents with microangiopathy and macroangiopathy (9.4%), 7 respondents with multiple microangiopathies (2.7%) and 7 respondents with multiple macroangiopathies (2.7%).
7. The Most commonly occurring complications are retinopathy with 46 respondents (22.6%), nephropathy with 45 respondents (22.1%), and neuropathic diabetic (21 respondents or 10.3%). The occurrence of macroangiopathy complications are dominated by coronary heart disease with 39 respondents (19.2%), the peripheral circulatory complication with 30 respondents (14.8%), and stroke with 22 respondents (11%).

Conflict of Interest: There was no conflict of interest in this study

Ethical Clearance: The Ethical Clearance is taken from health research ethics committee at Dr. Soetomo General Hospital Surabaya, Indonesia

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Evaluation of Implant Stability after Conventional Versus Piezoelectric Alveolar Ridge Splitting with Immediate Implantation in Mandibular Posterior Region “A Randomized Controlled Trial”

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Abstract

Aim of the Study: The purpose of this study is to answer a clinical question whether the use of piezoelectric alveolar ridge splitting (ARS) with simultaneous implant placement will enhance implant stability in comparison with conventional motorized surgical disc and bur or not.

Materials and Methods: twenty four dental implants were placed in fourteen edentulous ridges and were divided into 2 equal groups (Group I & Group II). Patients in both groups underwent ARS for narrow edentulous posterior mandibular ridge with simultaneous implant placement. In Group I, 12 implants were placed in 8 edentulous ridges after ARS performed using piezoelectric saws. In Group II, 12 implants were placed in 6 edentulous ridges after ARS performed using conventional motor driven surgical disc and bur. Implant stability was measured by means of Osstell™ device, first intraoperatively, then at 6 months and 9 months postoperatively. Moreover, radiographic assessment of marginal bone loss (MBL) was done at 6 months postoperatively. Bone width gain was calculated from pre and post-operative cone beam CT.

Results: Regarding implant stability, there was a statistically significant difference between the two groups at all time intervals. Regarding MBL, and width gain, there was no statistically significant difference between both groups. **Conclusion:** Piezosurgery enhanced implant stability but didn't mitigate the bone loss associated with ARS or increase amount of ridge width gain.

Keywords: Piezosurgery, alveolar ridge splitting, dental implants, implant stability.

Introduction

Alveolar ridge splitting (ARS) is a technique used to treat small to moderate alveolar ridge with deficiency. It was described by Simion as a longitudinal splitting of the

ridge in two parts, provoking a greenstick fracture using small chisels. The created 4 walled defect provides the surface from which the osteogenic cells can be recruited⁽¹⁾. But ARS has complications; like risk of buccal wall fracture, and more pronounced MBL around implants compared with those placed in pristine bone without ARS.⁽²⁾

Conventional ARS utilizes rotating instruments, such as bur, disc and saw. These motorized devices have certain drawbacks that include: overheating of bone and risk of soft tissue injury to important anatomical structures⁽³⁾. Moreover, the cutting action is the result

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of macro or micromechanical shocks at different speeds. which may cause bone trauma and damage that may interfere with healing response ⁽⁴⁾.

Piezosurgery (PS) is performed by means of a device that uses microvibration at a frequency capable of cutting bone. PS has many benefits; due to its selective cutting property, it is safe to use near important soft tissue. Also, due to the cavitation effect, the operative field in PS remains almost free of blood during the cutting procedure. PS also possesses the advantage of micrometric cutting which is achieved by the microvibrations with limited amplitude. This offers highly precise cutting ⁽⁵⁾.

Some authors have reported its positive effects on the rate of bone repair and remodeling ⁽⁶⁾, and its contribution to better osseointegration outcome when drilling prior to implant placement ⁽⁷⁾⁽⁸⁾⁽⁹⁾.

The present study is to compare between PS and conventional ARS with simultaneous implant placement in enhancement of implant stability and mitigation of MBL by time.

Materials and Methods

This study was conducted on 10 patients with 14 thin edentulous mandibular posterior ridges attending the outpatient clinic in academic hospital of Faculty of dentistry - Cairo University department of oral and maxillofacial surgery.

Study group: 8 edentulous ridges received 12 implants simultaneously after ARS was performed using piezoelectric saws.

Control group: 6 edentulous ridges received 12 implants simultaneously after ARS was performed using motor driven disc and bur.

Eligibility criteria: Adult patients with thin edentulous ridges who had sufficient alveolar bone height and were free from any systemic diseases that may affect bone healing.

Preoperative patient assessment: Preoperative CT was performed to determine the suitable implant size. Study casts with wax-up were prepared for planning for future implants placement and surgical guides' fabrication.

Surgical phase:

- At the edentulous site, a full thickness crestal incision was performed followed by two buccal vertical releasing incisions at the mesial and distal ends of the site located 2 mm away from the papillae of the neighbouring teeth.

- Split thickness flap elevation using a mucoperiosteal elevator was performed to expose the bone buccally.

- A mid-crestal bony incision was done at least 1-2 mm from neighbouring teeth using a piezoelectric US1 saw insert (US-II LED Guilin Woodpecker Medical Instrument Co.,Ltd.) for the study group and motorized disc for the control group. Fig (1)

- Two vertical cuts were made with the piezoelectric saw in the study group and conventional fissure bur for the control group at both ends of the midcrestal bony cut on the buccal surface of the alveolar ridge, ending 2-3 mm short of the preplanned implant length.

- Ridge splitting osteotomes were introduced inside the crestal cut and gradually malleted to expand the ridge in a lateral direction. Implants were inserted.

- Xenograft (OneXeno Graft®, Germany) was used to fill the gap and PRF was used as a membrane to promote healing.

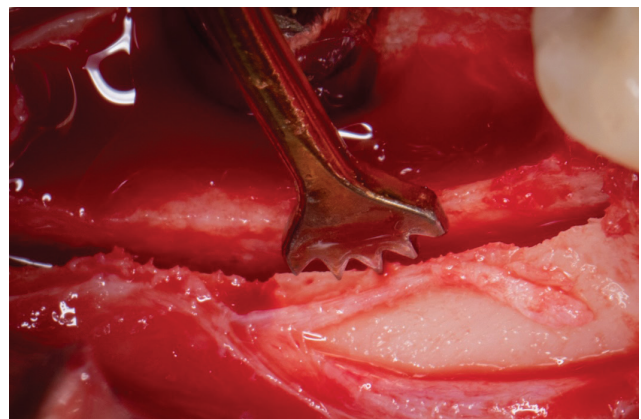


Figure (1): Photograph showing mid crestal osteotomy using piezoelectric saw in case no 10 in the study group

Outcomes:

- 1- Implant stability was estimated by Osstell™

(Integration Diagnostics, Göteborg, Sweden), first intraoperative, 6months and 9 months postoperatively. The values were expressed as numbers between 1-100 ISQ. Fig (2)



Figure (2): Photograph showing implant stability measuring using Osstell device in case no 10 in the study group

2- Cone Beam assessment was done immediately, and 6 months postoperatively to evaluate the MBL and the ridge width gain.

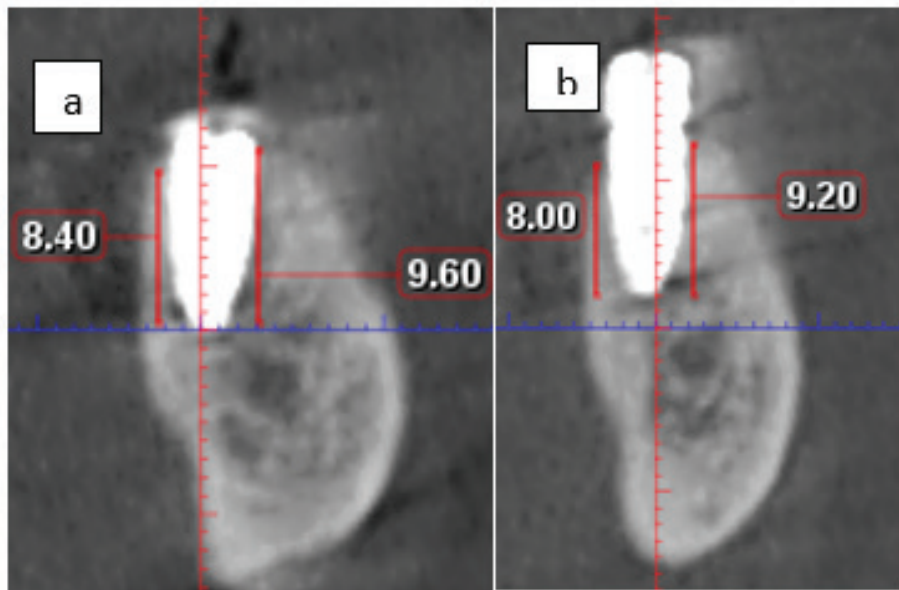


Figure (3): CBCT showing alveolar bone height measurements buccally and lingually in lower first molar region in study group case no 8 immediately (a), and after 6 months postoperatively(b)

Statistical Methods

Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, data showed parametric (normal) distribution. Independent sample t-test was used to compare between two groups in non-related samples. Paired sample t-test was used to compare between two groups in related samples. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

Results

Table (1) Shows comparison between the mean, standard deviation (SD) values of implant stability values (ISQ) in both groups at different follow up times:

Group	Point of comparison	0 Mon	6 Mon	9 Mon
Control group	Mean	65.00	70.33	69.63
	SD	8.283	5.29	5.88
Study group	Mean	68.69	75.79	74.98
	SD	6.12	4.26	5.06
t-test	Standard error of differences	2.97	1.96	2.241
	Mean difference	3.68	5.45	-5.35
	95% Confidence interval of diff.	From -9.9673 to 2.6007	From -9.5534 to -1.3633	From -9.99793552471 to -0.70206447529
	t-value	-1.23832	-2.77916	2.3871
	p-value	0.114325	0.00547	0.0260

The result is significant at $p < 0.05$.

Table (2) shows comparison between mean, standard deviation of MBL between the 2 groups:

Group	Point of comparison	0-6 m
Control group	Mean	-0.44 a
	SD	0.53
Study group	Mean	-0.25 a
	SD	0.58
p-value	0.495ns	

Means with different small letters in the same column indicate significant differences; non-significant ($p > 0.05$)

Discussion

Piezosurgery (PS) was selected in the present study to test the possible mitigation of bone loss and enhancement of osseointegration; PS had showed

very promising results in studies on bone healing after surgical drilling and on osseointegration after dental implants⁽¹⁰⁾. evaluated the level of alveolar bone crest after osteotomy with piezosurgery and burs using a model of dog alveolar ridges: histological analysis

showed a bone level gain in the group treated with piezosurgery, and bone loss in the diamond and carbide bur groups. Also, in their study, Anesi et al, found out that on making osteotomies in rabbits skulls, the cutting of the piezosurgical tips produced double the amount of bone inside the created gaps when compared with rotary burs⁽¹¹⁾. As for implants, *Garcia-Moreno et al* conducted a systematic review to assess the primary and secondary stability of dental implants placed at sites prepared with PS and conventional drilling (CD), they deduced that PS preparation improves secondary stability after 2 and 3 months in comparison to CD, with similar implant survival rates⁽¹²⁾.

RFA analysis was used as a reliable method to test and monitor the quality of bone-implant interface and consequently, provided clinical evidence of implant stability. This agrees with Turkyilmaz et al, who found statistically significant correlations between bone density and ISQ values in a human cadaver study. A significant influence of the peri-implant bone loss on ISQ values was also observed⁽¹³⁾.

All cases in the current study were successfully split except one case in the control group that showed buccal plate fracture and was excluded from the study. This agrees with results of Sohn who reported malfracture of the buccal segment in 5 out of 23 cases in immediate splitting of the mandible. They recommended the delayed technique in the mandible in patients with high bone quality and a thick cortex and narrower ridge in the mandible to avoid complete fracture of the buccal segments⁽¹⁴⁾. However, Chauhan et al used conventional drills for ARS in the mandible and reported 100% success with immediate implant placement⁽¹⁵⁾.

At 6 months postoperatively, the mean ISQ value in the control group was 70.3, while in the study group was 75. This was similar to results obtained by El-Halawany et al (68.7 for control group, 73.3 for study group) who performed conventional cutting in their study⁽¹⁶⁾. Also, close results were obtained by *Kamel et al* who used PS⁽¹⁷⁾. The results were slightly higher than those reported by *Altaweel et al*⁽¹⁸⁾. These results are not very different from ISQ values of implants placed in unsplit alveolar ridges at 6 months postoperatively (mean 70); like those reported by *Nguyen et al*⁽¹⁹⁾. These ISQ scores indicate that the implants placed after ARS are clinically stable

and are near to implants placed in pristine bone.

The study group showed statistically significant higher ISQ values than the control group at 6 months. This could be explained by the positive effect of piezosurgery on bone healing as proved by many studies. This effect ranged at the molecular level from superior osteoblastic activity and more osteoclasts indicating faster remodeling, to increased expression of BMP-4 and TGF- β 2 as well as reduction of proinflammatory cytokines⁽⁷⁾. On the macro level, PS leaves thinner bone gaps after osteotomy, which leads to easier and faster recovery because the osteoblasts are closer to the blood capillaries, increasing the supply of growth factors. Also, the less heat generation achieved by the better cooling system contributes to the better healing in piezosurgery cases⁽¹¹⁾⁽⁹⁾. Our results are also in accordance with Da Silva Neto et al., who used resonance frequency analysis to evaluate the implant stability quotient (ISQ) of dental implants that were installed in sites prepared by either conventional drilling or piezoelectric tips. The results showed significant increases in the ISQ values for the piezosurgery group immediately postoperatively, at 9 days, and 150 days postoperatively⁽⁸⁾.

However, Esteves et al, who evaluated bone healing in rats' tibiae after osteotomies with piezosurgery and traditional bone drilling, analyzed the collected samples histomorphometrically, immunohistochemically, and on molecular basis at different time intervals. Histologically and histomorphometrically, bone healing was similar in both groups. Immunohistochemical analysis didn't detect significant differences in expression of all the proteins and most of the genes tested⁽²⁰⁾.

The mean alveolar bone loss from time of insertion till 6 months is (0.44mm) in the control group and (0.25mm) in the study group. These results are similar to those of kamel et al who reported bone loss of 0.3mm-0.4mm over a period of 6 months from time of insertion. Bassetti reported higher MBL of 1.19mm. This may be explained by the less initial bone width in their study (2.9) than that in our study⁽²¹⁾, As Ella et al reported more bone loss in the narrow ridges, but was more obvious in the non-grafted ridges than the grafted one⁽²²⁾.

There was no statistically significant difference between both groups regarding MBL. The use of bone

graft and PRF may have interfered with evaluation of the true effect of the piezosurgery in the initial healing period considering that they can both affect bone healing and remodeling.

The mean amount of gain in the study group was (2.96 mm) which is higher than that of the control group (2.54 mm), the difference of which was found statistically non-significant. Our results were similar to Shahakbari et al, who reported a mean gain in ridge width in the conventional group of 2.72 mm and in the piezosurgery group of 3.37mm⁽²³⁾. Nonetheless, PS facilitated the splitting greatly. The micrometric precise cutting of the tips allowed the cutting into very narrow alveolar ridges with ease and without their fracturing. Therefore, it's preferred in the mandible where the splitting is harder.

Conclusion

Piezosurgery improves implant stability, but doesn't reduce amount of MBL around dental implants after ARS.

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Competing Interests: No conflict of interest

Ethical approval: The Ethics and research committee, Faculty of Dentistry, Cairo University approved the study and patients' consent was obtained.

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Osteoblast Migration Effect of the Freeze-Dried Homologous Platelet Rich Plasma

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Abstract

Background: Platelet-rich plasma (PRP) which is made by blood donors (homologous) from the blood bank (Palang Merah Indonesia), is named homologous PRP (HPRP) that can be used for periodontal tissue regeneration therapy. The freeze-drying and a terminal sterilization processes have to be done so that h-PRP has lengthen store time, maintained the level of growth factors comparable to fresh PRP and also to stop retroviruses activity. The both procedures can influence the cells and stimulates growth factor release from the platelets and granulocytes. The effectiveness of growth factors in FD HPRP can enhance the migration of osteoblasts, which are involved in the healing of periodontal tissues. The research aim was to investigate the effect of FD HPRP into the migration of osteoblast.

Methods: The HPRP was freeze-dried and done γ -irradiation by 20 and 25 KGy for the sterilization and compared with Injectable Platelet-Rich Fibrin (iPRF) (positive control group) and one group non treated as negative control so that there were 4 group experiments. The migration of osteoblasts were measured after 24 hours and the data were analyzed by one way ANOVA test.

Result: There were not significant differences among FD HPRP 20, FD HPRP 25 and iPRF ($p > 0.05$) but significant differences with negative control ($p < 0.05$).

Conclusion: There was effect among of FD HPRP 20 and 25 on osteoblast migration.

Keywords: Freeze-dried homologous platelet-rich plasma, Injectable platelet-rich fibrin, Osteoblast migration

Introduction

Periodontitis is an inflammatory disease that leads to destruction of periodontal tissues, causing tooth movement and eventually tooth loss¹. Currently, clinical treatments for periodontitis focus on plaque removal and local inflammation control, such as scaling and

root planing². Those therapies to minimize symptoms and prevent disease progression, but cannot improve the attachment of periodontal tissues^{3,4}. The main goal of periodontal therapy is regeneration⁵. The tissue engineering approach involves in the combination of scaffold, cells and bioactive molecules (growth factors) to induce tissue regeneration^{6,7}. Among them, bioactive molecules (growth factors) control diseased conditions, stimulate innate regenerative, and provide signals for tissue formation⁸. Growth factors promote wound healing by promoting proliferation of cells (mitogenesis), migration of cells (chemotaxis), and stimulation of new blood vessel formation (angiogenesis)⁹. Many materials capable of stimulating tissue regeneration have been proposed to achieve the best healing results⁶.

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Platelet plays a key role during wound healing process in promoting regeneration by providing growth factors, various cells, cytokines, and coagulation factors¹⁰. Platelets are very important in wound healing because promote the initial coagulation at wounds and also release many growth factors¹¹. Platelet-rich plasma (PRP) is a first-generation platelet concentrate, consisting of a high platelet count, as well as various growth factors in a small plasma volume¹². Platelet-rich plasma has received attention in musculoskeletal regenerative therapy because it clinically enhances neoangiogenesis, tissue repair, and regeneration¹³. Some researches have shown that using PRP during the placement of dental implants promotes osseointegration and bone regeneration¹¹.

Platelet-rich plasma (PRP) can be prepared from patient's own blood (autologous PRP) and multiple donor (homologous PRP)¹⁴. However, autologous PRP have problem when patients with poor general health, multidrug therapy or hematologic disorders and the volume blood absence required could often cause adverse effects, in particular in repeated treatments¹⁵. Homologous PRP (HPRP) taken from healthy, screened and habitual blood donors has several advantages including easy preparation, more platelet count, almost unlimited availability and limited costs^{14,15,16}. Recent clinical studies have tested HPRP as a treatment for hand and finger wounds¹⁴, aggressive periodontitis¹⁶, and long bone defects¹⁷.

One of the major problems that do not allow for long-term PRP storage is the relatively short of growth factors in PRP¹³. Therefore, patients are required to donate a large amount of blood just before surgery for fresh PRP preparation¹⁵. Platelet storage method at room temperature in the long term was introduced by lyophilization or freeze-drying techniques¹⁸. The ability to store PRP for a long time and keep the growth factors therein contained will eventually expand its clinical use¹³. According Nakatani et al.¹⁸PRP can be preserved by freeze-drying technique without loss of wound healing properties. Kinoshita et al.¹³ showed PDGF in FD PRP stored for 4 weeks after freeze-dried can demonstrate pharmacological activity. Freeze-dried PRP (FD PRP) could maintained baseline levels of GFs for the entire 8-week duration¹⁹.

Benefit of freeze-dried PRP is easy storage, as its powder form enables storage in a refrigerator or even at room temperature and also facilitate the controlled release of active growth factors¹⁹. Procedure of the FD PRP requires a freeze dryer, and the risk of contamination increases with the freeze-drying process. During PRP preparation, technicians should take care to avoid contamination¹⁸. Shiga et al.²⁰ suggested that FD PRP should be prepared in a clean room using good sterilization procedures to avoid infection. Sterilization is needed to support the bioactivity and storage of FD PRP for a long time¹⁹. In the study of Muraglia et al.²¹ FD PRP sterilized with gamma radiation at dose 25 KGy showed no colonies were detected. Based on this result, this study uses gamma ray radiation of 20 and 25 KGy.

Another platelet concentrates recently introduced besides PRF, that is Injectable Platelet-Rich Fibrin (iPRF)²². Injectable platelet-rich fibrin (i-PRF) was developed by modifying spin centrifugation forces in nonglass tubes without anticoagulants²³. Some researches compared iPRF with PRP against fibroblast²⁴, osteoblast behavior²², cartilage regeneration²⁵, antimicrobial efficacy²⁶ and iPRF showed better results. But not yet compared FD HPRP with i-PRF, so in this study i-PRF used as positive control.

Methods

This research is a laboratory experimental research, the sample using MG63 cell line was divided into 4 groups (FD HPRP 20, FD HPRP 25, iPRF as positive control and one group non treated group as negative control).

Freeze-Dried Homologous Platelet-Rich Plasma (FD HPRP)

Donor blood bags were taken from a blood bank (Palang Merah Indonesia) with double blood bags. The blood bag and centrifugation bowl were balanced in balance. The centrifugation bowl that had been balanced was placed into the centrifugation side facing away and the blood bag aligned with the lobe of the cup. Rotate 32XG, temperature 4 ° C for 30 minutes. The centrifugation cup was removed slowly so that the blood does not mix again, the blood was placed in the main bag of the extractor's diploma slowly. Then it was clamped and the connecting hose between the main

and the satellite bags were opened. Plasma was flowed into the satellite bag, plasma was left in the main bag approximately three centimeters from the surface of the red blood cells concentrated. The connecting hose between the main and the satellite bags were sealed using an electric scaler. Then cut the connecting hose. Blood bags containing plasma from PMI were frozen at -40°C for 12 hours, then freeze-dried for 48 hours using a freeze-drier machine (Freeze Dryer Modulyo, Edwards). After that, the sterilization process with radiation 20 and 25 KGy.

Injectable Platelet Rich Fibrin (iPRF)

10 ml of blood was taken, placed in a plastic tube (Gibco) without anticoagulant, then centrifuged at 700 rpm for 3 minutes at room temperature. After centrifugation, the top of the iPRF which was colored yellow was taken²².

Cell Culture

Human osteoblast cell line MG-63 (ATCC Bethesda, USA) was culture in a T75 Flask (TPP Switzerland) with DMEM (Gibco), FBS (Sigma), Penicillin Streptomycin (Gibco), Fungizone (Gibco) media incubated at 37°C and 5% CO_2 . Osteoblast cells that are 80-90% confluent, the cell medium is removed, then DMEM (Gibco) is inserted into a flask containing osteoblasts. The cells were washed using trypsin-EDTA 0.25% (Gibco) so that the cells attached to the flask would be released. The cells were put in a 15 ml conical (Biologix) containing DMEM, then centrifuged at 1500 rpm for 5 minutes. The cells will settle at the conical base then DMEM is added and aspirated. The cells were seeded into a 96-well plate as much as 100 μL . The cells were incubated overnight and then treated.

Cell Migration

Osteoblast cells were seeded in 24 plate wells with a density of 2.5×10^3 cells / well. Cells were incubated for 24 hours at 37°C and 5% CO_2 until they reached confluent. Then a sterile 20–200 μL pipette tip was held

vertically to scratch a cross in each well. The detached cells were removed by washing with 500 μL PBS, one group was not given any treatment as negative control, and the other group was given FD HPRP 20, FD HPRP 25, and iPRF as much as 100 μl in each well. Incubate the plate in the incubator. Observe the condition of the cells after 24 hours incubation under a microscope with five the field of view. Then look at the scratch area that is still open using TScratch software 1.0.

Statistical Analysis

The analysis of the scratch images was performed using the TScratch Version 1.0 software which calculates the scratch area (= open wound area) for each image. The data were analyzed using SPSS 24. Comparison of open wound area from FD HPRP 25, FD HPRP 20, iPRF and negative control was carried out using one-way ANOVA and LSD post hoc test. $p < 0.05$ were considered significant.

Results

The data in this study is the open wound area using TScratch Version 1.0 software in the treatment of FD HPRP 20, FD HPRP 25, iPRF and negative control (Figure 1). The smallest open wound area in iPRF than other group, then the open wound area FD HPRP 25 was smaller than FD HPRP 20 and negative control (Table 1). The smaller the open wound area value indicates increased cell migration.

A normality and homogeneity test was performed using Levene's test which showed normal and homogen ($p > 0.05$). Then statistical analysis was continued using one-way ANOVA to find out if there is a difference from 4 groups. Table 2 shows significant differences between the groups ($p < 0.05$). Then followed by Post Hoc LSD test to find out the difference in the open wound area among the groups. Post Hoc LSD test shows that was no significant difference ($p > 0.05$) among FD HPRP 20, FD HPRP 25 and iPRF, but significant difference with negative control ($p < 0.05$) (Table 3).

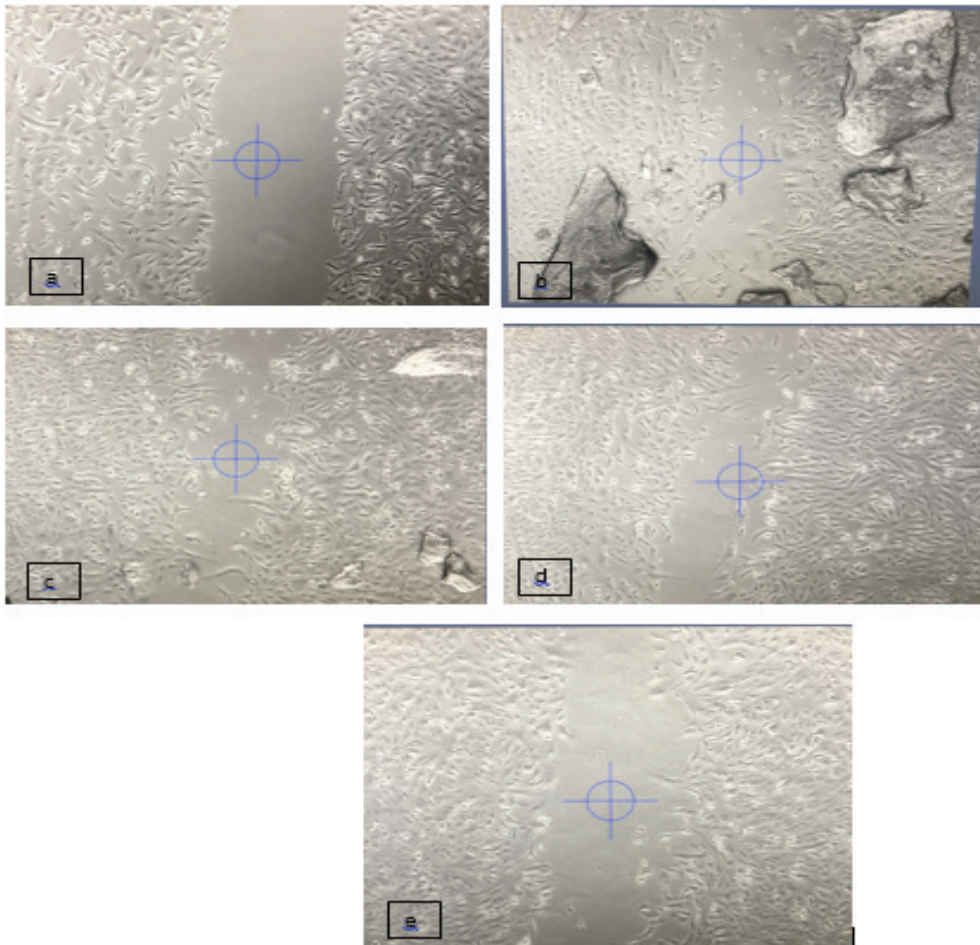


Figure 1. Open wound area using Tscratch software. A) Before treatment. 24 hours after treatment B) FD HPRP 20, C) FD HPRP 25, D) iPRF, E) Negative control

Table 1. The mean and standard deviation of FD HPRP 20, FD HPRP 25, iPRF and negative control group

Groups	n	Mean	Std. deviation
Negative Control	6	7.676	1.114
iPRF	6	3.593	.566
FD HPRP 20	6	4.310	.519
FD HPRP 25	6	4.020	.923

Table 2. The result of one-way ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	63.239	3	21.080	31.407	.000
Within Groups	13.423	20	.671		
Total	76.662	23			

Table 3. The result of the Least Significant Differences (LSD) test among the groups

Groups	Groups	Mean Difference	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Negative Control	i PRF	4.083	.473	.000	3.096	5.070
	FD HPRP 20	3.366	.473	.000	2.380	4.353
	PRP 25	3.656	.473	.000	2.670	4.643
i PRF	Negative Control	-4.083	.473	.000	-5.070	-3.096
	FD HPRP 20	-.716	.473	.145	-1.703	.270
	FD HPRP 25	-.426	.473	.378	-1.413	.560
FD HPRP 20	Negative Control	-3.366	.473	.000	-4.353	-2.380
	i PRF	.716	.473	.145	-.270	1.703
	PRP 25	.290	.473	.547	-.696	1.276
FD HPRP 25	Negative Control	-3.656	.473	.000	-4.643	-2.670
	i PRF	.426	.473	.378	-.560	1.413
	FD HPRP 20	-.290	.473	.547	-1.276	.696

Discussion

Periodontal regeneration is a complicated process that involves multiple aspects including the control of infection and inflammation, recruitment of stem/progenitor cells, promotion of cell migration, proliferation and differentiation, as well as new tissue formation^{5,6}. Migration in osteoblast cells is an a very important process in tissue repair. Osteoblast develop and migrate to the injured area, synthesize new extracellular matrix, and a role in wound healing²⁷. Cell migration requires spatial and temporal processes that detect and transfer extracellular stimuli into intracellular signals²⁸. Growth factors promote wound healing by promoting proliferation and migration cells⁹.

PRP is widely use and believed to serve growth factors for wounds, thereby accelerating the wound healing process¹⁰. Many studies have been carried out to reinforce the authenticity of PRP application and achieve satisfied results¹¹.Growth factors such as PDGF-BB, TGF-,1, IGF-I, PDEGF, PDAF and PF-4, released from PRP and involved in wound healing, are considered to be promoters of tissue regeneration¹². Growth factors released by activated platelets promotes

the proliferation, migration and differentiation of several cell types including endothelial cells, osteoblasts, fibroblasts, chondrocytes, and MSCs⁹.

The results showed that open wound areas FD HPRP 20, FD HPRP 25 and iPRF decreased significantly after 24 hours compared to the negative control group. Decrease of the open wound area indicates that the treatment could effect migration osteoblast cell. This result according with Nakatani's research¹⁸ that FD PRP can increase in vivo bone regeneration similiarly to fresh PRP, this show that biology activity of growth factors in FD PRP can maintained. Pietramaggiore et al.²⁹ reported that growth factor bioactivity and its healing effect in FD PRP can be used in chronic wound healing. In accordance with the research Kinoshita et al.¹³ that FD PRP can maintain platelet derived growth factor (PDGF) pharmacological activity during 4 weeks of storage. PDGF is growth factors that promote cell proliferation and migration³⁰.

In current study, as well as in previous studies FD PRP can promote osteoblast migration compared with non treated group. Another experiment from Pietramaggiore et al.²⁹ comparing single and multiple

injection applications in the wound area of diabetic mice with FD PRP containing trehalose, fresh PRP, multiple doses of recombinant VEGF or no treatment demonstrated multiple doses of VEGF and use of FD PRP promote faster wound closure when compared with the nontreated group. Horimizu et al.³¹ reported that storage of FD PRP-coated collagen sponges at 4°C did not cause a significant loss in bioactivity. Shiga et al.²⁰ reported that FD-PRP could accelerated bone union in a rat PLF model even after 8-week storage.

In this result, open wound area in FD HPRP 25 smaller than FD HPRP 20, this is indicated that osteoblast migration in FD HPRP 25 more faster than FD HPRP 20. This is due to the gamma ray dose given in the sterilization process. According to Muraglia et al.²¹ FD PRP sterilized with gamma radiation at dose 25 KGy showed no colonies were detected, thus affecting the effectiveness of FD HPRP 25. So, FD HPRP can be stored for a long time with the sterilization process in advance to maintain its content and avoid infection. According Andia et al.³² FD PRP is significant for promoting alveolar bone regeneration either when used alone or when added to fresh PRP to augment growth factor concentrations. The freeze-drying process represents an option for patients who need multiple applications, maintaining the properties of fresh PRP and showing positive results.

Conclusion

Freeze-dried homologous palatetelet rich plasma could affect the speed of osteoblast migration. These results highlight the potential value of freeze-dried PRP for used in dental treatment and others.

Conflict of Interest The authors declare no conflicts of interest in preparing this article

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Ethical Clearance Taken from Ethics Commission, Faculty of Dentistry, Universitas Gadjah Mada, Indonesia with registration number No.00520 / KKEP / FKG / -UGM / EC / 2020

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National Survey of Risk Behavior and Past Historied with Helminthiasis in Thailand

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Abstract

Background: Helminthiasis are health problems worldwide including Thailand. People with helminth infections can develop gastrointestinal symptoms, general malaise and weakness, malnutrition, and impaired growth and physical development. Early detection of behaviors are necessary to prevent helminthiasis and the improve the quality of life further. This study aimed to investigate the risk behaviors and its association with their history regards helminthiasis.

Methodology: A cross sectional study was conducted among 15,253 people in 76 provinces, Thailand during January and July 2019. A cluster random sampling was used to select the participants. Constructive questionnaire was used to measure demographic data, risk behavior, past medical history of helminthiasis. Multiple logistic regression was used to analyze associations.

Results: The risk behaviors regard helminthiasis in Thai people were agriculture working with barefoot (19.44%), unsanitary defecation (15.61%), outside walking barefoot (8.96%), consumption of papaya salad mixed with raw fermented fish (11.99%), raw pickled cyprinoid fish (1.67%), and raw minced cyprinoid fish (1.53%), respectively. Raw cyprinoid fish consumption was significantly associated with increased risk of liver fluke infection. Barefoot during works or contact soils was significantly associated with hookworm infection. Unwashed hand and unsanitary defecation were significantly associated with *A. lumbricoides* infection.

Conclusion: The rate of some risk behaviors was relatively high in Thailand. National survey for all risk factors are important to improve in access to service, optimization of public health management, reduction in risk factors, and increased quality of life in Thai people.

Keywords: National survey, Risk behavior, Helminthiasis, Thailand

Introduction

Helminthiasis are health problems worldwide, and more than 1.7 billion people have helminth infections,

particularly in at least one of the five neglected tropical diseases. Statistics indicate that more than 1.5 billion people, or 24% of the world's population, are infected with soil-transmitted helminths¹. In ASEAN countries, it is estimated that 300 million people are infected with helminth infections caused by soil transmitted helminths; specifically, 126.7 million people are infected with *Ascaris lumbricoides*, 115.3 million are infected with *Trichuris trichiura*, and 77.0 million are infected with hookworm. More than 10 million people in

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ASEAN countries (particularly Thailand, Lao's People Democratic Republic, Cambodia, and Vietnam) suffer from either liver or intestinal fluke infections caused by foodborne helminths². In Thailand, the national prevalence rate of helminth infections was 18.1%, with a high prevalence rate of liver fluke, *Opisthorchis viverrini* infections³. In addition, data collected on the incidence of liver fluke infections in Thailand by the Ministry of Public Health showed that the percentage of Thai people infected with liver flukes was 8.7%⁴. One type of liver fluke, *O. viverrini*, is associated with hepatobiliary tract diseases, including cholangiocarcinoma, which is a serious health problem in Thailand^{5,6}. People with helminth infection can develop gastrointestinal symptoms, general malaise and weakness, malnutrition, and impaired growth and physical development¹. Therefore, the current behavior and past medical histories of helminthiases among residents at the national-wide scales need to be determined. These data may be useful for further prevention and control campaigns in Thailand.

Methodology

Study design and area: A cross-sectional survey was conducted from January to July 2019 and included people living in 76 provinces, Thailand. Participants were randomly selected from the villages in each province using a cluster random sampling method. A total of 15,253 participants were calculated according to Francis et al⁷, were recruited. Data on demographic characteristics, behavior, past medical histories with helminthiases were collected using a questionnaire. All participants provided written consent before submitting questionnaires.

Questionnaire and collection: Questionnaires were designed and constructed to ask the participants included demographic characteristics, consumption

behavior (17 items), prevention behavior of soil transmitted helminths (3 items), cooking behavior (5 items), defecation behavior (4 items), past histories with stool examination and treatment from government services, and past medical histories with helminthiases and protozoa. The questionnaires has reliability value according to practice with Cronbach's Alpha Coefficient = 0.75. Each questionnaire was analyzed and interpreted for their parts. Practice level were calculated and analyzed according to Best [8]. Evaluation of practical level with 17 questions; 4 choices (frequently, sometimes, ever, never) and 14 questions; 3 choices (frequently, sometimes, never). Participants were completed questionnaire by themselves or their parents/ care takers for children or dependency.

Statistical analysis: Statistical analyses were performed using the computer program STATA for Windows, version 13 (StataCorp LLC, Lakeway Drive, College Station, Texas, USA). The demographic characteristics of the participants were presented as frequencies and percentages for categorical variables. Multivariable logistic regression analysis was performed to estimate the odds ratios (ORs) and 95% confidence intervals (95% CIs) to assess the associations between potential risk factors and past medical histories with helminthiases. A P-value <0.05 was considered statistically significant.

Results

Demographic characteristics: The majorities of participants were female (57.32%), in age 25-59 years old (46.85%), in primary school (56.13%), in Buddhist (92.41%), and agricultures (53.79%). In family member, this study indicates that majority of Thai people habitat 3 person (44.71%) and followed by 5 persons (30.83%) and 2 persons (10.08%), respectively (Table 1).

Table 1. Demographic characteristics of participants who have completed questionnaires (n=15,253)

Demographic characteristics	No. participants	%
Gender		
Male	6,510	42.68
Female	8,743	57.32
Age (years)		

Cont... Table 1. Demographic characteristics of participants who have completed questionnaires (n=15,253)

0-5	923	6.05
6-24	3,180	20.85
25-59	7,146	46.85
60+	4,004	26.25
Education		
Uneducate	1,501	9.84
Primary school	8,561	56.13
Junior secondary school	2,483	16.28
Hihg secondary school	1,863	12.21
Bachelor and above	845	5.54
Religion		
Bhuddhist	14,096	92.41
Islam	983	6.44
Christ	145	0.95
Others	29	0.19
Occupation		
Agriculture	8,205	53.79
Workers	1,085	7.11
Employed	2,230	14.62
Fisherman	85	0.56
Government officer	342	2.24
others	3,306	21.67
Family members		
1	718	4.71
2	1,538	10.08
3	6,819	44.71
5	4,703	30.83
7	1,414	9.27
>10	60	0.39

Behavior regards helminthiases infection: Consumption of raw or under cooked found frequently in papaya salad mixed with raw fermented fish (11.99%) and followed by fermented fish (8.84%), papaya salad mixed with raw crab, shrimp (3.28%), and raw minced beef (3.67%). Other raw dishes related to infect helminth are shown in Table 2

Table 2. Raw Thai dishes and consumption behavior regard helminths (n=15,253)

Dishes	Consumption							
	Frequently		Sometimes		Ever		Never	
	No.	%	No.	%	No.	%	No.	%
Raw chopped fish	212	1.39	2779	18.22	1065	6.98	10582	69.02
Raw miched fish	233	1.53	2781	18.23	963	6.31	10876	71.3
Raw pickled fish	254	1.67	3817	25.02	924	6.06	9881	64.78
Raw fermented small fish	329	2.16	4966	32.56	991	6.5	8356	54.78
Raw fermented fish	1348	8.84	5428	35.59	767	5.03	7241	47.47
Papaya salad mixed with raw fermentd fish	1829	11.99	6994	45.85	826	5.42	5429	35.59
Raw shrimp dish	362	2.37	5047	33.09	1013	6.64	8554	56.08
Raw snail dish	98	0.64	2282	14.96	778	5.1	11621	76.19
Raw minced frog, snake, bird	52	0.34	589	3.86	323	2.12	13706	89.86
Raw beetle	71	0.47	1263	8.28	404	2.65	12945	84.87
Raw freshwater vegetables	284	1.86	2196	14.4	496	3.25	11678	76.56
Raw minced prok	380	2.49	3783	24.8	739	4.84	10081	66.09
Raw minced beef	560	3.67	3772	24.73	605	3.97	10027	65.74
Raw minced sheep and goat	141	0.92	1675	10.98	411	2.69	11327	74.26
Raw wild pork	49	0.32	361	2.37	195	1.28	13885	91.03
Papaya salad mixed with raw crab/ shrimp	500	3.28	5185	33.95	734	4.81	8540	55.99
Papaya salad mixed with raw sanils	210	1.38	2895	18.98	816	5.35	10719	70.27

Health behaviors regard helminth infection were analyzed and found that the majorities of prevention of helminth were hygenic and sanitation of toilet at house (95.1%) and followed by cooked food (86.89%) and cleaned fruit and vegetables (85.26%). Meanwhile, the majorities of risk behaviors were natural freshwater

drinking (46.08%) and followed by unhygenic and sanitation at farm (15.61%), and barefoot during working and contact soil (8.96%). Health behaviors regard helminth infection are shown in Table 3.

Table 3. Health behaviors regard risk and prevention of helminth (n=15,253)

Behaviors	Practices					
	Frequently		Sometimes		Never	
	no	%	no	%	no	%
Handwashing	10,465	68.61	4,377	28.7	411	2.69
Sanitary place for cooking	12,567	82.39	2,110	13.83	576	3.78
Cleaned fruit and vegetables	13,004	85.26	1,881	12.33	368	2.41
Freshwater drinking	5,438	35.65	2,787	18.27	7,028	46.08
Cooked food	13,253	86.89	1,674	10.97	326	2.14
Shoes/boot wearing						
Casual shoes	12,431	81.5	2,519	16.51	303	1.99
Working shoes	7,879	51.66	6,008	39.39	1,366	8.96
Boot	7,825	51.3	4,463	29.26	2,965	19.44
Defecation						
Hygienic and sanitation at house	14,506	95.1	596	3.91	151	0.99
Hygienic and sanitation at farm	7,490	49.11	4,865	31.9	2,898	19
Unhygienic and sanitation at farm	2,381	15.61	6,522	42.76	6,350	41.63
Handwashing after toilet usage	10,223	67.02	4,372	28.66	658	4.31

Past medical histories with helminthiases and protozoa: Participants were asked about their past medical histories with stool examination, helminth and protozoa infection and related treatment by previous health government mobile service and in hospitals. The results reveal that liver fluke, *O. viverrini* is the highest of infection (0.94%), and followed by *Taenia* spp.

(0.39%), hookworm (0.37%), *A. lumbricoides* (0.23%), *S. stercoralis* (0.07%), minute intestinal fluke (0.06%), and *T. trichiura* (0.03%), respectively. Meanwhile, two intestinal protozoa were recorded and identified to *C. ceyatanensis* and *E. histolytica*. Past medical histories of helminthiases and protozoa infection are shown in Table 4.

Table 4. Past medical histories with helminthiases and protozoa among Thai people (n=15,253)

Histories with Helminth and Protozoa	No. of intection	% of infection
Opisthorchis viverrini	143	0.94
Taenia spp	59	0.39
Hookworm	56	0.37
Ascaris lumbricoides	35	0.23
Strongyloide stercoralis	10	0.07
Minute intestinal fluke	9	0.06
Trichuris trichiura	4	0.03
Cyclospora ceyatanensis	2	0.01
Entamoeba histolytica	1	0.01

Factor associated to helminthiases: The associations of behaviors with past medical histories of each helminthiases were analyzed using multivariable logistic regression analysis are shown in Table 5. The final model showed that being people who raw cyprinoid fish consumption (adjusted odds ratio [aOR] 8.015 [95% CI: 4.918-13.061], $P > 0.05$) was significantly associated with *O. viverrini* infection. Unprotected by

barefoot during working/outside building/contacted soil was significantly associated with hookworm infection (adjusted odds ratio [aOR] 1.362 [95% CI: 0.809-2.291], $P > 0.05$). In addition, unhygienic behavior particularly unwashed hand and unsanitary defecation, was significantly associated with *A. lumbricoides* infection (adjusted odds ratio [aOR] 2.652 [95% CI: 0.936-7.517], $P > 0.05$).

Table 5. Factor associated to helminthiases among Thai people (n=15,253)

Behaviors	Histories with helminthiases		Odds ratio	95%CI	P-value
	Infection	Uninfection			
	(No. of infected/%)	(No. of uninfected/%)			
Raw cyprinoid fish consumption and liver fluke infection					
consumed	339/2.91	11,293/97.09	8.015	4.918-13.061	<0.05

Cont... Table 5. Factor associated to helminthiases among Thai people (n=15,253)

no consumed	17/0.37	4,539/99.63	1	-	
Prevention of hookworm infection					
Shoes	15/3.34	433/96.66	1	-	
Barefoot	709/4.50	15,030/95.50	1.362	0.809-2.291	<0.05
Prevention of Ascaris lumbricoides infection					
Hygeine	4/0.10	4,118/99.90	1	-	
Unhygeine	31/0.26	12,035/99.74	2.652	0.936-7.517	<0.05

Discussion

Helminthiases are health problems worldwide, including Thailand especially in rural communities. In Thailand, the national survey indicates that liver fluke; *O. viverrini*, hookworm, *A. lumbricoides* and *Taenia* spp. were the main problem among helminth infection³. Presently, the past medical histories with helminthiases have been found that *O. viverrini* is still found the highest in this national survey. This result indicates that national-wide is still needed to conduct the prevention and control campaign in the high prevalence. Foodborne helminth: *Taenia* spp., and soil transmitted helminths including hookworm and *A. lumbricoides* were found in these participants. This current data indicates that national survey to screen regards helminth are needed. Recent study reveals that the most of participants had frequently consumed raw fermented fish which was mixed in papaya salad, fermented fish (8.84%), papaya salad mixed with raw crab, shrimp, and raw minced beef. This result is similar to previous studies that report about Thai people particularly in northeast and north region favor consumed papaya salad mixed with raw fermented fish, raw fermented fish, raw pickled fish⁹⁻¹¹. In raw cyprinoid fish dishes including minced, fermented fish, and pickled fish has been reported that found the infective stages of *O. viverrini*^{12,13}. Therefore, health intervention and modification may

benefit to improve behavior regards helminth that is similar to other study areas where have successful intervention^{14,15}. The associations of behaviors with past medical histories of each helminthiases were analyzed and the final model showed that being people who raw cyprinoid fish consumption was significantly associated with *O. viverrini* infection. Current data is showed the fact of risk factor especially in the high prevalence of infection and transmission where have people are still consumed raw cyprinoid fish. Previous study reported that cyprinoid fish in natural freshwater around Thailand is still found the infective stage of *O. viverrini*^{16,17}. In addition, raw beef dish has been found frequently in some parts of Thailand which are the traditional food mainly in northeastern and northern part. This dish is a foodborne cestode; Taeniasis that is common found in patients who favor consumed raw beef dish. Therefore, health literacy is needed to consider in the favor people for preventing related cestodes and virulence bacteria.

Health behaviors regard helminth infection were analyzed and found that the majorities of prevention of helminth were hygienic and sanitation of toilet at house and followed by cooked food and cleaned fruit and vegetables. These results indicate that most of Thai people have a high quality to prevent helminth infection. However, natural freshwater drinking, unhygienic and sanitation at farm, and barefoot during working and

contact soil were found in some people of Thailand. These behaviors are at risk to infect many parasites mainly hookworm, *S. stercoralis*, *A. lumbricoides* that found endemic in Thailand where have the appropriate conditions of environment. Unprotected by barefoot during working/outside building/contacted soil was significantly associated with hookworm infection. In addition, unhygienic behavior particularly unwashed hand and unsanitary defecation, was significantly associated with *A. lumbricoides* infection. This is showed that soil transmitted helminths are still found in many parts of Thailand. Direct skin contact with soil that results from walking around barefoot and poor sanitary standards are both risk factors for contracting these infections [18]. Hookworm and *S. stercoralis* infections are more common in tropical and subtropical countries with hot and humid climates^{19,20}. Improvement of sanitary in the high risk areas and health literacy for high risk group are extensively considered.

Conclusion

The rate of some risk behaviors was relatively high in Thailand. Past medical histories indicate the population at risk of helminthiasis. National survey for all risk factors are important to improve in access to service, optimization of public health management, reduction in risk factors, and increased quality of life in Thai people.

Ethical Clearance: This study was approved by the Ethics Committee for Research Involving Human Subjects of the Ministry of Public health, Thailand.

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Effect of Propolis and Pomegranate Extract Mouthwashes on Taste Alteration, Salivary pH and Antibacterial Activity in High Caries Risk Patients: A Randomized Control Trial

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Abstract

Dental caries prevention is the key to control dental caries worldwide problem nowadays. Chlorhexidine is the gold standard antibacterial agent but it has many side effects so natural products have been proposed as a safer alternative; Propolis and pomegranate are known with their great antibacterial properties.

Aim: This study assessed taste alteration, salivary pH and antibacterial activity of propolis and pomegranate mouthwashes compared to chlorhexidine mouthwash in high caries risk patients.

Materials and Methods: A total of 80 participants were divided randomly into four groups, in a parallel group design. Group 1: propolis mouthwash, group 2: pomegranate mouthwash, group 3: chlorhexidine mouthwash and group 4: saline. Salivary sample was collected at baseline, immediately after mouthwash usage and after seven days. The pH of the collected saliva and streptococcus mutans bacterial count were assessed. Participants received a questionnaire to assess taste alteration on the seventh day. Statistical analysis took place using ANOVA/ Kruskal-Wallis and Wilcoxon tests.

Results: Chlorhexidine has a significantly higher incidence of taste alteration compared to the other mouthwashes which showed statistically similar incidence. The highest salivary pH value was recorded after immediate usage of mouthwashes in all groups, after seven days there was no significant change in chlorhexidine and saline groups. There was no statistically significant difference between the total percentage reduction of bacterial count in all groups but with highest percentage of reduction after immediate usage.

Conclusion: Propolis and pomegranate mouthwashes could be considered as an alternative to chlorhexidine mouthwash.

Key-words: bacterial count, propolis, pomegranate, salivary pH, taste alteration.

Introduction

Dental caries has been one of the most demanding problems facing the world ⁽¹⁾. During the initial phase

of caries disease, *Streptococcus mutans* are the most frequently associated microorganisms⁽²⁾. The most efficient way of mechanical plaque removal is tooth brushing, but patients usually brush their teeth the wrong way, in a time that's less than the time required for plaque removal or their compliance decreases with time⁽³⁾.

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A mouthwash is a chemotherapeutic agent used to enhance oral hygiene and prevent dental caries. Chlorhexidine (CHX), is the gold standard antibacterial

mouthwash⁽⁴⁾. However, studies of chlorhexidine as a mouth rinse had reported many adverse effects, including taste alteration and staining, which make it a problem about using it for a long period⁽⁵⁾. Therefore, the WHO suggested that researchers should investigate natural products⁽⁶⁾.

Propolis is a natural substance made by bees for building and preservation of their hives. It consists of flavones, flavanones, and flavanols with which we link its biological activity. It is known for its antimicrobial activity⁽⁷⁾. In spite of the prominence of propolis worldwide, only a limited number of studies has been carried out to determine the inhibitory effect of propolis against cariogenic bacteria.

Nowadays pomegranate fruit is widely used in many aspects in dentistry due to its biological activity without adverse effects or toxicity. It contains different bioactive compounds like phenolics, flavonoids and proanthocyanidine compounds⁽⁸⁾. There are many in vitro studies that determined the antibacterial action of Pomegranate extract against *S. mutans* but very limited number of in vivo studies studied its efficacy against dental caries.

Materials and Methods

This randomized controlled clinical study was conducted in the Faculty of Dentistry, Cairo University, Egypt.

Sample size calculation

Based on a previous study by Balappanavar et al. 2013⁽⁹⁾, it was required to study 17 in each group. This number was to be increased to a sample size of 20 to compensate for losses during follow up.

Eligibility criteria:

Participants included in this study were high caries risk patients according to the ADA caries risk assessment form, doesn't suffer from systemic health problem, not taking any drug that can intervene with salivary secretion with age range from 17-50 years.

Allocation, sequence generation, and blinding

Allocation of mouthwash through opaque bottles to ensure complete concealment. As patients entered

the study sequentially, they were assigned their study numbers. Sequence generation was accomplished using (www.random.org). It was a triple blinded study.

Grouping of participants

A total of 80 participants were randomly divided into 4 groups (n=20) according to the tested mouthwash.

Preparation of ethanolic extracts:

In general, there are several methods to obtain extracts from natural products. Ethanol extraction was used as it produces low wax propolis extracts rich in biologically active compounds, also the most important active components of the propolis show high solubility in 70% aqueous ethanol. While in pomegranate more bioactive compounds were present in the ethanolic extract such as camphor which has an antibacterial effect.

Propolis extract was prepared in the form of finely grinded powder. Propolis was extracted by adding ethanol and propolis to the automatic shaker for seven days⁽¹⁰⁾. Then, the mixture was cooled, to precipitate all insoluble residues. Afterwards it was filtered to remove the wax⁽¹¹⁾. The filtrate obtained was evaporated till dryness, obtaining a powder.

Pomegranate extract was prepared using all the fruit parts including the two edible (seeds and arils) and the non-edible parts (exocarp and mesocarp). Pomegranate fruits were cut into small parts by a blender then added to a mixture of distilled water and ethanol. The solution was left for maximum dissolution in the solvent, filtered and then evaporated. Volume was regained using distilled water, and the oven was used for evaporation, in order to get the residues of the ethanolic extract of pomegranate⁽¹²⁾. Then total polyphenolic and flavonoid content in the propolis and pomegranate extracts were determined using Folin-Ciocalteu method. Disk diffusion method was used to measure the minimal inhibitory concentration for *S. mutans* to the experimental mouthwashes. It was found that the MIC for propolis mouthwash was 1.172 mg/ml and for pomegranate it was 3.9 mg/ml.

Preparation of mouthwashes:

Using a mixer, propolis and 100 ml of distilled water were mixed together, centrifuged and purified,

pomegranate extract was filtered through many gauze layers, and then, then dilution took place for both mouthwashes by adding the same volume of distilled water containing 0.4% methylparaben as preservative and 0.04% sodium saccharine, also, essential oil of saffron and flavor were added. pH of both mouthwashes was adjusted using 0.1 mg/ml sodium bicarbonate to be 6.5 for propolis mouthwash and 6.8 for pomegranate mouthwash.

Saliva sample collection

Baseline unstimulated saliva was obtained; subjects were asked to sit on a normal chair. The subjects sat with their head leaning forward and saliva was allowed to dribble over a period of two minutes and was collected in a tube.

Participants were instructed to use the mouthwash for 60 seconds and then the second unstimulated salivary sample was obtained, then the patients were instructed to use the mouthwash 3 times/day then present to the clinic for the final salivary sample after seven days. pH and bacterial count were assessed at baseline, immediately after using the mouthwash and after seven days. While taste alteration was assessed after seven days of usage of the mouthwash.

Outcomes assessment:

In the taste alteration questionnaire; participants were asked to rank the mouthwash according to alteration of taste. They ranked every item from very bad, bad, neutral good and very good. Regarding salivary pH, the

collected saliva was measured immediately by digital pH meter. And regarding *S. Mutans* count, 0.5 ml of saliva were diluted using a tenfold solution of phosphate buffered saline and then it was plated on Mitis-Salivarius agar along with bacitracin and 10% sucrose. The plates were incubated in an incubator at 37⁰C for 48 hours.

After incubation, morphological characteristics of the bacteria identified the colonies ⁽¹³⁾ The number of the colonies was determined, and expressed as colony forming unit (C.F.U.).

Statistical Analysis

Statistical analysis took place with significance level set at P≤0.005 using ANOVA/ Kruskal-Wallis and Wilcoxon tests.

Results and Discussion

Regarding taste alteration; statistical analysis took place using Chi square test and results are shown in table (1). While in ‘negative change’ response, Chlorhexidine has the highest mean value of taste alteration which is statistically significant to that of Propolis mouthwash, Pomegranate mouthwash and saline; which showed no statistical significance between them. As for ‘neutral’ response, Chlorhexidine has the least mean value which is statistically significant to that of propolis mouthwash. While, the response frequencies in Pomegranate mouthwash group and saline showed the highest neutral responses with no statistically significant different between them.

Table (1): Taste alteration

	Alteration of the taste		
	Negative change	Neutral	Positive change
Propolis mouthwash (n=17)	2 ^{ab}	15 ^{ab}	0
Pomegranate mouthwash (n=18)	1 ^b	17 ^a	0
Chlorhexidine (n=17)	8 ^a	9 ^b	0
Saline (n=18)	0 ^b	18 ^a	0
P-value	0.001*		

*: significant at P≤0.05. Means with different superscript letters within each column are statistically significantly different at P≤0.05

The special effect of chlorhexidine on taste alteration may be because of its nature, and the mechanism can be attributed to decreased movement of paracellular ion and blockage of ion channels in taste receptor cell membranes⁽¹⁴⁾. On the other hand, propolis and pomegranate mouthwashes have no significant effect due to their natural ingredients which don't cause any adverse effects and can be considered as a good alternative to patients who want to avoid chemical agents⁽¹⁵⁾. Regarding the absence of any negative changes with the saline mouthwash, this could be attributed to the low salt concentration in saline. These results are in agreement with Graziani et al. 2015⁽¹⁶⁾ in which participants reported taste alteration after using chlorhexidine mouthwash, On the other hand Gupta and Purohit. 2018⁽¹⁷⁾ reported that there was no significant taste alteration due to short term use of chlorhexidine

mouthwash.

Regarding salivary pH, results are presented in table (2); in intragroup comparison, repeated measures ANOVA showed that there were statistically significant differences in salivary pH between different evaluation times within Propolis mouthwash ($P=0.021$), Pomegranate mouthwash ($P=0.036$) and Chlorhexidine ($P=0.045$) groups. While, there was no statistically significant differences in salivary pH within saline group ($P=0.835$). The highest salivary pH value was recorded after immediate usage of tested mouthwashes in all groups. However, after seven days of usage there was statistically significant decrease in pH values in both propolis and pomegranate groups. While in chlorhexidine and saline mouthwash groups there was no statistically significant changes.

Table (2): Salivary pH

	Baseline	Immediate	7 days	P-value
Propolis mouthwash	7.02±0.41aB	7.16±0.37aA	6.93±0.45bB	0.021*
Pomegranate mouthwash	7.27±0.53aA	7.33±0.39aA	7.01±0.48abB	0.036*
Chlorhexidine	7.0±0.52aB	7.19±0.59aA	7.42±0.31aA	0.045*
Saline	7.17±0.37aA	7.28±0.33aA	7.28±0.54abA	0.835NS
P-value	0.249NS	0.609NS	0.007*	

Regarding intergroup comparison, one-way ANOVA followed by Tukey's post-hoc test showed that there was no statistically significant difference in baseline and immediate pH readings between different mouthwashes ($P=0.249$ and $P=0.609$). While after seven days, there was a statistically significant difference in salivary pH between different mouthwashes ($P=0.007$). Chlorhexidine has the highest mean salivary pH ($7.42±0.45$), while Propolis mouthwash showed significantly the lowest salivary pH ($6.93±0.45$). However, there was no statistical significance difference between salivary pH of Pomegranate mouthwash and saline groups with mean values of ($7.01±0.48$) and

($7.28±0.54$) respectively.

*: significant at $P≤0.05$; NS: non-significant at $P>0.05$. Means with different superscript lowercase letters within each column and uppercase letters within each row are statistically significantly different at $P≤0.05$

The possible explanation of the immediate increase in pH after mouthwashes usage depends mainly on the salivary flow rate. The higher the salivary flow rate, the higher the salivary buffering capacity due to the increase in the concentration of bicarbonate which increases the pH of the saliva, and raises its buffering

capacity⁽¹⁸⁾. Increase in salivary pH after usage of propolis mouthwash is in accordance with Porto et al. 2019⁽¹⁹⁾ who found that there was significantly increase in salivary pH after usage of propolis based products due to the effect of active ingredients. While the increase in salivary pH after pomegranate mouthwash usage was in agreement with Kadam et al. 2019⁽²⁰⁾ who found that pomegranate mouthwash caused an immediate increase in salivary pH after usage due to polyphenolic and flavonoids.

Regarding chlorhexidine also a group of studies showed immediate increase in salivary pH after rinsing as Gupta et al. 2014⁽²¹⁾ found that chlorhexidine mouthwash caused immediate rise in pH due to increase in salivary flow rate which provides a rise in calcium and phosphate levels. On the other hand, a study by Bescos et al. 2020⁽²²⁾ showed that a significant decrease in salivary pH after seven days of using chlorhexidine mouthwash by changing the ratio of certain types of bacteria which is very important to maintain balance in the oral cavity of healthy individuals.

Both natural products exhibited a gradual decreasing salivary pH until seven days while chlorhexidine manifested a gradual increase in pH in comparison to other groups because of its unique feature; substantivity. While changes within natural extracts were faster and more potent at immediate pH measurement, there was a gradual decrease in salivary pH as time increases due to

lack of substantivity.

Regarding S. Mutans bacterial count, results are shown in table (3); in intragroup comparison percentage change of bacterial count using Wilcoxon signed-rank test showed that there was a statistically significant difference in mean bacterial reduction within the different mouthwashes at different time intervals (P=0.025 in Propolis mouthwash group, P<0.0001 in Pomegranate mouthwash, P=0.008 in Chlorhexidine group and P<0.012 in saline group). The percentage reduction values after immediate usage were statistically significantly higher than that after immediate- seven days of usage in all groups. There was no statistically significant difference between total percentage reduction and base-line immediate percentage reduction. While in saline group total percentage reduction was significantly higher than baseline- immediate percentage reduction. While in intergroup comparison of percentage change of salivary *streptococcus mutans* using Kruskal-Wallis test followed by Mann-Whitney showed that there was a statistically significant difference between different mouthwashes in immediate – seven days percentage change (P=0.034). Saline group yielded significantly higher percentage change compared to Propolis, Pomegranate mouthwash and Chlorhexidine groups. While, there was no statistically significant difference between different mouthwashes in baseline – immediate percentage reduction (P=0.332) and in percentage total reduction (P=0.118).

Table (3): Percentage difference of bacterial count

	Baseline – Immediate	Immediate – 7 days	Baseline – 7 days	P-value
Propolis mouthwash	86.55%aA	16.80%bB	89.40%aA	0.025*
Pomegranate mouthwash	79.19%aA	2.68%bB	80.88%aA	<0.0001*
Chlorhexidine	80.98%aA	17.51%bB	84.31%aA	0.008*
Saline	78.04%aB	51.07%aC	89.25%aA	0.012*
P-value	0.332NS	0.034*	0.118NS	

*: significant at $P \leq 0.05$; NS: non-significant at $P > 0.05$. Means with different superscript lowercase letters within each column and uppercase letters within each row are statistically significantly different at $P \leq 0.05$

Salt content of saline has powerful antibacterial properties, by sucking water out of bacteria through osmosis, which leads to cell collapse and cell death. This effect is long term on bacteria and that's obvious in the baseline- seven days results that the antibacterial effect of saline is much higher.

Chlorhexidine is a molecule carrying positive charge that binds to the sites that are negatively charged on the cell wall; cell wall becomes unstable and this interferes with the bacterial functions. The uptake of the chlorhexidine by bacteria is very fast, usually its action takes place within 20 seconds. So, the effect of chlorhexidine is immediate and fast.

Regarding the antibacterial action of propolis, the mechanism is controversial and not completely understood. The strong antibacterial activity is usually referred to the high content of biologically active ingredients, which causes either direct action on the microorganism, or through stimulation of the immune system that leads to the activation of the natural defense mechanism.

This is in agreement with Nagappan et al. 2016⁽²³⁾ showed that chlorhexidine has a more long-lasting effect than propolis mouthwash, this could be explained by the different structure and effects of the propolis used in the study, which may be due to difference in the season, place of collection, bee's species and contamination of wax. On the contrary Nazeri et al. 2019⁽²⁴⁾ found long lasting effect of propolis compared to chlorhexidine mouthwash resulting from the suggested mechanism of action of propolis which renders RNA polymerase of bacteria inactive and leads to direct damage of the cell membrane.

Regarding the antibacterial action of pomegranate, it plays a role in decreasing salivary actions of alpha-glucosidase, on the other hand, it increased the activities of ceruloplasmin, an enzyme that has an antioxidant effect⁽²⁰⁾. Pomegranate has the ability to prevent the production of chemicals from bacteria that has the ability to adhere to the teeth⁽²⁵⁾.

These results are in agreement with various studies that have been carried out to evaluate the antibacterial efficacy of pomegranate extract; Hajjattahi et al. 2016⁽²⁵⁾ stated that pomegranate had a significant antibacterial

effect on *streptococcus mutans* count due to its high content of several antibacterial compounds.

Conclusion

Propolis and pomegranate mouthwashes have the least effect on taste alteration compared to chlorhexidine mouthwash and saline, chlorhexidine mouthwash and saline cause long lasting increase in salivary pH compared to propolis and pomegranate mouthwash and propolis and pomegranate mouthwashes have similar antibacterial effect as chlorhexidine mouthwash on short and long terms of usage.

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The Effectiveness of Nutrition Education and Egg and Milk Supplementation during Pregnancy in Cirebon Regency Indonesia

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Abstract

Background: Chronic energy malnutrition and anemia are nutritional problems in pregnant women that often occur in developing countries. Nutritional intervention in pregnant women is needed to prevent any nutritional problems in both the mother and the fetus. This study aims to determine the effectiveness of nutrition education along with egg and milk supplementation on the knowledge and nutritional attitudes and nutritional status of a pregnant women.

Methods: The study design was pre-experimental with one group pretest posttest. Subjects were 45 pregnant women in the 2nd and 3rd trimesters. Nutritional interventions were given in the form of nutrition education along with egg and milk supplementation for pregnant women (90 days). The data collected consisted of pregnancy history, food consumption, household food security, nutritional knowledge and attitudes, mid-upper arm circumference, and hemoglobin levels. Data were analyzed using the paired t-test and Wilcoxon tests.

Conclusions: Nutrition education intervention had an effect on increasing nutritional knowledge of pregnant women, and supplementation of egg and milk for three months increased the mid-upper arm circumference. Nutritional intervention is needed as an effort to prevent chronic energy malnutrition in pregnant women.

Key words: nutrition intervention, nutritional status, pregnancy, supplementation.

Introduction

Nutritional problems in developing countries that are commonly experienced by pregnant women are chronic energy malnutrition (CEM) and anemia¹. Pregnant women who experience CEM and anemia have a greater risk of morbidity, especially in the third trimester of pregnancy compared to normal pregnant women. In addition, chronic energy malnutrition in pregnant women increases the risk of giving birth to infants with low birth weight, death during childbirth, and bleeding².

The prevalence of chronic energy malnutrition in pregnant women in Indonesia based on the 2018 Basic Health Research (Riskesdas) was 17.3%. Based on the WHO threshold, the prevalence is still in the moderate

category (10-19%)³. The CEM condition in mothers during pregnancy contributes to 20% of the incidence of maternal mortality⁴. Apart from CEM, iron deficiency anemia prevalence in Indonesia was 48.9% in pregnant women aged 15-49 years⁵. Cirebon Regency Health Profile showed an increase in anemia in pregnant women from 6.12% (2017) to 10.74% (2018)⁶.

One of the efforts to overcome malnutrition can be done by providing supplemental food to pregnant women to increase energy intake⁷. Based on the Indonesia Recommended Dietary Allowances pregnant women in the second and third trimesters are recommended to increase their energy intake by 300 kcal/day, while protein intake in the second trimester needs to be added by 10 g/day and 30 g/day in the third trimester. Eggs and milk are sources of protein that have high biological

value, which are necessary for fetal growth and muscle formation².

The supplementary feeding program that was carried out for 90 days for pregnant women was able to increase the total energy intake, mother's weight, and nutritional status of the pregnant women⁸. The purpose of this study was to analyze the effectiveness of nutrition education on nutrition knowledge and attitudes and the impact of egg and milk supplementation on the nutritional status of the pregnant women.

Material and Methods

This study used a pre-experimental study design (one group pretest posttest). The research was conducted from August to November 2020 in Cirebon Regency, Indonesia. Cirebon Regency is one of the 160 stunting locus districts established by the Indonesian government.

This study involved 45 pregnant women who were selected by non-probability sampling. The inclusion criteria set were the 2nd and 3rd trimester of pregnancy, 18-40 years old and willing to participate in the research project. Pregnant women who meet the requirements received an explanation of the purpose of the study and are willing to sign the informed consent.

The types of data collected consisted of the characteristics of pregnant women, household food security, food consumption, and nutritional status of pregnant women. Data was collected through interviews with pregnant women using a set of questionnaires. Anthropometric data was obtained through direct measurements. Body weight was measured using a digital scale with a capacity of 150 kg and an accuracy of 0.1 kg, height was measured using a stature meter with a capacity of 200 cm and an accuracy of 0.1 cm, while the upper arm circumference was measured using MUAC tape. Measurement of Hb levels were using the SLS-Hemoglobin method.

Food consumption data was collected using a 2x24-hour food recall. Food consumed is grouped into cereals and tubers, protein foods, added sugar, added oil and fruits and vegetables.

Measurement of nutritional knowledge and attitudes was carried out using a tested and validated questionnaire (Cronbach's alpha = 0.678). For nutritional knowledge,

correct answers are given a score of 1 and incorrect answers are given a score of 0. For nutritional attitudes, the answers to agree are given a score of 3, doubt 2, and disagree with 0 for statements that are positive. The reverse scoring applies to negative statements.

Measurement of household food security was carried out by interview using the Household Food Insecurity Access Scale (HFIAS) questionnaire which consisted of 9 questions. Each question is graded with a score of 0-3. A score of 0 means never, 1 means rarely (1-2 times in 4 weeks), 2 means sometimes (3-10 times in 4 weeks) and 3 means often (>10 times in 4 weeks). The HFIAS method categorizes food security into four levels, namely food secure if the total score is 0-1, mildly food insecure if the total score is 2-7, moderately food insecure if the total score is 8-14, and severely food insecure if the total score is 15-27⁹.

Nutrition education intervention was carried out by nutrition cadres in three meetings with the pregnant women. Nutrition education was provided in the form of lectures and discussions with the help of leaflets. Egg and milk supplementation for pregnant women is given every day for 90 days. Ethical clearance Number 295/IT3.KEPMSM-IPB/SK/2020 was obtained from the Research Ethics Commission of the IPB University.

Evaluation of changes in nutrition knowledge and attitudes of the pregnant women, nutritional status, and hemoglobin levels was carried out by comparing the data measured at baseline and endline. Descriptive analysis was performed for all variables. Paired t-test and Wilcoxon test were performed to test differences in variables. Data was analyzed using SPSS for Windows 26.0.

Results and Discussion

Subject Characteristics: Table 1 shows that the majority of the research subjects were pregnant women aged 20-35 years (64.4%). This age is less likely to experience pregnancy complications than younger or older age group¹⁰. It was found that 11.1% of the pregnant women had MUAC <23.5 cm which indicates they suffered from chronic energy malnutrition, and 28.9% of them suffered from anemia. During pregnancy, the need for nutrients increases. In the second and third trimesters, if the pregnant woman experience malnutrition, then the

fetus will be stunted and will not develop according to the mother’s gestational age¹¹.

Table 1: Summary characteristics of pregnant women (n=45)

Variable	n	%
Age (year)		
<20	1	2.2
20-35	29	64.4
>35	15	33.3
Gestational age		
Trimester 1	3	6.7
Trimester 2	37	82.2
Trimester 3	5	11.1
Parity		
Primiparous	15	33.3
Multiparous	30	66.7
Pregnancy interval		
First pregnancy	17	37.8
<2 years	2	4.4
≥2 years	26	57.8
BMI at pre-pregnancy (kg/m²)		
Underweight (<18.5)	7	15.6
Normal (≥ 18.5 - <25.0)	20	44.4
Overweight (≥ 25.0 - <27.0)	11	24.4
Obese (≥ 27.0)	7	15.6
MUAC (cm)		
Normal (≥23.5)	40	88.9
Chronic energy malnutrition (<23.5)	5	11.1
Anemia		
Not Anaemia (≥11 g/dl)	32	71.1
Anaemia (<11 g/dl)	13	28.9
Mild (10-10.9 g/dl)	11	84.6
Moderate (7.0-9.9 g/dl)	2	15.4

Number of pregnant women classified as multiparous (2-4 times pregnant) was 66.7%. The women who have ≥3 times the number of pregnancies are at risk of developing anemia¹². Pregnant women with pregnancy interval ≥2 years amounted to 57.8%. If the mother has a gestation interval <2 years, there is a 2.513 times greater risk of giving birth to a baby with low birth weight than a mother who has a pregnancy interval of ≥2 years¹³.

The nutritional status before and during pregnancy can affect the growth of the fetus that is conceived and

affects the new born baby². In this study, it is known that 11.1% of the pregnant women had MUAC <23.5 cm which indicates chronic energy malnutrition and there were 28.9% of them had anemia. Pregnant women with chronic energy malnutrition status have a risk of anemia 1,975 times compared to pregnant women with normal nutritional status¹⁴.

Table 2 shows the average household HFIAS score was 3.1 ± 3.6. Most of them (46.7%) experienced mildly food insecure. Number of households that had achieved

food secure was 44.4%. Food insecurity can affect nutritional status of pregnant woman and her unborn child¹⁵.

Table 2: Household food security based on HFIAS measurement

Food security	Total	
	n	%
Food Secure (0-1)	20	44.4
Mildly Food Insecure (2-7)	21	46.7
Moderately Food Insecure (8-14)	3	6.7
Severely Food Insecure (15-27)	1	2.2
Total	45	100
HFIAS score (Mean ± SD)	3.1±3.6	

Food Consumption: The average consumption of cereals and tubers before the intervention was 174.7 g/day and after the intervention was 220.8 g/day ($p=0.082$) (Table 3), and it is still below the recommended daily intake of 300-400 g. Consumption of protein source foods before intervention was 128.2 g/day and after intervention was 233.1 g/day ($p=0.004$). The paired t-test showed no significant difference in the consumption of added sugar ($p=0.080$) and added oil ($p=0.260$) between before and after the intervention.

Table 3: Food groups and consumption

Food groups	Food intake (g)		Recommended daily intake (g)	p
	Baseline	Endline		
Cereals and tubers	174.7 + 103.8	220.8 + 119.5	300-400	0.0822)
Protein foods	128.2 + 102.0	226.1 + 130.9	70-140	0.0042)
Added Sugar	5.4 + 14.0	1.4 + 4.8	40	0.0801)
Added oil	4.5 + 12.1	18.0 + 66.9	25-200	0.2601)
Fruits and vegetables	263.3 + 198.8	381.4 + 304.9	400	0.0281)

1) Paired t-test

2) Wilcoxon test

Food consumption during pregnancy is one of the major determinants of pregnancy outcome. The results of the interviews with the respondents explained that the mother's food portion during pregnancy was relatively the same as before pregnancy, resulting in low consumption of several types of food groups. The source of protein in the form of tofu or tempeh is quite

dominant as a source of vegetable protein, and fish is quite dominant as a source of animal protein. Animal protein source foods such as chicken and beef were rarely consumed because the prices are not cheap.

The average consumption of protein source foods by the endline has exceeded the daily recommendation. One of the factors that cause the increase in protein is the egg and milk supplementation given to pregnant women. Increasing the protein intake of pregnant women is one

of the factors that increase the upper arm circumference.

The average consumption of vegetables and fruit before the intervention was 263.3 g/day and after the intervention increased to 381.4 g/day (p=0.028). Consumption of vegetables and fruit during the second and third trimesters needs to be increased or maintained to control the fasting glucose levels and insulin resistance¹⁶.

Nutritional knowledge and nutritional status:

Providing nutrition education for pregnant women through nutrition cadres has the potential to increase maternal nutritional knowledge¹⁷. Table 4 shows that the score of nutrition knowledge after nutrition education was increased. The mean score of nutrition knowledge

before nutrition education was 66.4+15.1, increasing to 72.0+18.7 after nutrition education (p=0.043). However, the nutritional attitude score did not increase significantly (p> 0.05). When nutritional knowledge is not good enough, it will affect the nutrition intake and nutritional status during pregnancy¹⁸. Nutrition education is an important strategy in preventing anemia. Nutrition education have an effect on the success of increasing hemoglobin levels in pregnant women¹⁹.

Eggs are one of the protein sources with the most complete and highest amounts of essential amino acids²⁰. Milk protein has high biological value so that it is a good source of amino acids for those who consume it²¹. The effect of providing egg and milk supplementation to MUAC of pregnant women can also be seen in Table 4.

Table 4: Effect of nutrition intervention on nutrition knowledge, attitude, and nutritional status of pregnant women

Variable	Mean±SD		P
	Baseline	Endline	
Knowledge	66.4(15.1)	72.0(18.7)	0.0431)
Attitude	56.5(10.8)	57.8(9.8)	0.6052)
MUAC (cm)	27.7(4.0)	30.5(3.7)	0.0472)
Haemoglobin (g/dL)	11.9(1.3)	10.9(1.1)	<0.0012)

- 1) Paired t-test
- 2) Wilcoxon test

The size of the mid-upper arm circumference of the pregnant women increased from 27.7+4.0 cm (baseline) to 30.5+3.7 cm (endline) (p=0.047). This study proved that giving additional food in the form of egg and milk for 90 days was effective in increasing the mid-upper arm circumference of the pregnant women. Supplementary feeding can be given to them with normal nutritional status to prevent for chronic energy malnutrition⁷.

The hemoglobin level of pregnant women decreased from 11.9+1.3 g/dL (baseline) to 10.9+1.1 g/dL (endline). As the gestational age increases, the

iron reserve requirement for pregnant women is getting higher. Those in third trimester pregnancies have a higher potential for anemia than those in the first and second trimesters²². In the second and third trimesters, the need for iron in pregnant women increases due to an increase in blood and plasma volume, which causes blood cell dilution and a decrease in hemoglobin levels. Iron needs in the third trimester of pregnancy cannot be met only from food alone, it is recommended that iron adequacy be supplemented through supplementation²³.

Conclusion

Nutrition education interventions had an effect on increasing the nutritional knowledge of pregnant women, and supplementation of egg and milk for three

months increased the mid-upper arm circumference. However, the intervention had not shown an impact on nutritional attitudes and the improvement of Hb levels. Nutritional intervention is needed as an effort to prevent chronic energy malnutrition in pregnant women. Longer intervention in giving egg and milk (180 days) is needed to improve the nutritional status of pregnant women so that later they can give birth to healthy babies and avoid stunting.

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The Effectiveness of Telemedicine as a Supplementary Antenatal Care in Increasing Knowledge of Pregnant Women

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Abstract

Background: Limited access to health services can occur because an area is difficult to reach, lack of health personnel and facilities, and due to social changes such as during a pandemic. This systematic review aims to study the effectiveness of telemedicine as an antenatal care supplement in increasing the knowledge of pregnant women.

Methods: Perform a search for PubMed, ProQuest, and Scopus data sources with population-based keywords, intervention, comparison, and predefined results. The assessment of article quality used the Joanna Briggs Institute (JBI) critical assessment tool.

Results: Four studies were synthesized in this systematic review, 2 were experimental studies and the other 2 were descriptive studies. The intervention that was given was the use of telemedicine as a tool to deliver health education or a tool to monitor the physical condition of the mother from a distance. The message given can be in the form of a written message, voice message, or video. Interactive communication between mothers and health care providers can be done with this technology.

Conclusion: The application of telemedicine as an effort to increase the knowledge of pregnant women in settings with difficult access to health facilities and pandemic conditions is quite developing, but still requires further study regarding pregnancy outcomes. Further research is needed on the use of telemedicine concerning health costs and costs incurred by both parties. In Indonesia, there are still opportunities to develop telemedicine conceptually and the technology that will be used.

Keywords: Antenatal care (ANC), mother's knowledge, mHealth, telemedicine

Introduction

The seventeenth SDGs agenda has been announced in 2015, and one of them is to improve health status for various ages, and one of the indicators is to reduce the global maternal mortality ratio to 70 / 100,000 live births. Everyday throughout 2017, approximately 810 women died from preventable causes associated with pregnancy and childbirth. In the sub-Saharan Africa, the maternal mortality ratio is 154 / 100,000 live births (254,000 mothers), while in South Asia it is around 58,000 women die due to pregnancy and childbirth.⁽¹⁾ Good care before, during, and after childbirth can save a mother's life and newborn baby.⁽¹⁾ The important cause of maternal death is delayed in recognizing danger signs in pregnancy,

which results in delays in seeking assistance, and delays in reaching health facilities.⁽²⁾

Limited access to services due to remote and inaccessible locations, lack of resources and health facilities, as well as poverty, can cause delays in early detection of danger signs in pregnancy. ⁽¹⁾ Detection of risks and danger signs in pregnancy as early as possible is a strategy to prevent delays in reaching health facilities so it is necessary to improve the level of knowledge of mothers about danger signs in pregnancy. However, social restriction policies during a pandemic due to prevent the transmission of viral transmission among health workers and pregnant women, potentially resulting in a lack of knowledge of mothers about problems in pregnancy^(3,4)

Policies related to health care in response to new social life have an impact on antenatal care limit attendance and appointments to meet. The clinic may face staff shortages and a lack of personal protective equipment. Finally, changes in prenatal care, themselves, can be a barrier to ANC. On the other hand, women may avoid prenatal care because infectious symptoms, isolation, or treatment are suspected.⁽³⁾

The rapid development of informatics and communication technology made telemedicine or telehealth an alternative to deal with that conditions.^(5,6) The use of telemedicine was one of the solutions to overcome the problem of shortages of health workers and difficulties in accessing health facilities, in overcoming geographic constraints, time spent, and costs incurred by patients with positive outcomes across health disciplines.⁽⁷⁾ In the Covid-19 pandemic situation, telemonitoring was very useful for maintaining continued contact with pregnant women by health workers, but by minimizing exposure to each other.⁽⁸⁾

The use of information and communication technology in antenatal care (ANC) has been developed in various countries around the world and has been considered quite promising.⁽⁵⁾ This systematic review aims to study the effectiveness of telemedicine as supplementary antenatal care in increasing the knowledge of pregnant women.

Methods

Study Design

The research question is: how much is the effectiveness of telemedicine as a supplementary ANC in increasing the knowledge of pregnant women? An article search was carried out with the PICO (population, intervention, comparison, and outcome) approach.⁽⁹⁾ The preparation of this systematic review was carried out regarding PRISMA (Preferred Reporting Items for Systematic Review and Meta-analysis statements) as a guide for preparing a systematic review.^(9,10)

Search Strategy

The search for articles in this systematic review was conducted electronically, using 3 databases: PubMed or MEDLINE, Scopus, and ProQuest. The search was conducted in December 2020. The terms used were

predefined using keywords based on PICO, with the following description: Women, a mother as the target population. Intervention factors were searched using the keywords telemedicine, telehealth, telemonitoring, mHealth, remote consultation, and remote monitoring, while the comparison was searched using the keywords usual monitoring, face to face antenatal care (ANC), and usual ANC. The expected outcome was the mother's knowledge. Boolean operators were used to combining these keywords in the title and/or abstract. Only articles with open access that present abstracts and full text were used.

Eligibility Criteria

This study focused on pregnant women of all ages from various countries, both in rural and urban settings, or limited health workers, or geographic conditions that made access to health care facilities difficult or in socially restricted conditions such as during a pandemic. Articles related to comorbidities in pregnancy such as hypertension in pregnancy, gestational diabetes, and mental health disorders were exclusion criteria. Studies that were included were those published in the last 5 years and the English language. The duration of intervention was from the beginning of pregnancy to 36 weeks of gestation. Types of intervention could be in the form of short text messages, instructional videos, interactive videos, telephone or video containing educational material for pregnant women such as danger signs in pregnancy and health messages. The tools used by cell phones use either the internet or the cellular line.

Study Selection

The study designs which included the inclusion criteria were randomized controlled trial, quasi-experimental, cross-sectional, and case-control. Studies that involved cohort studies, qualitative, and systematic review, and gray literature were excluded.

Data Extraction

Data extraction was based on study design, target population, and type of intervention. The focus of the article was the level of the mother's knowledge.

Quality Assessment

The final study result was reviewed by two

independent reviewers. The disagreement was resolved through discussion. The assessment was carried out on the possibility of bias in the validity of the study, the population and sample of the study, the analysis of causal inference, and recommendations, and the final results of the study.⁽¹¹⁾ Journal’s impact factor and journal rank were taken into consideration. The quality of the selected articles was assessed using the Joanna Briggs Institute (JBI) critical appraisal instrument, which was

consists of questions to assess the quality of the articles based on the type of study design, by RSA and SH.

Result Synthesis

The base data search was carried out by RSA in December 2020. The level of scientific evidence and risk of bias, grouped in Levels of Evidence from Sackett, consists of 5 levels^(12,13)

Table 1. Levels of Evidence from Sackett

Level	Level Type of evidence
Ia	The evidence comes from systematic reviews or metaanalysis
Ib	The evidence comes from at least 1 randomized controlled trial
IIa	The evidence comes from at least 1 non-randomized controlled trial
IIb	The evidence comes from at least 1 quasi-experimental
III	The evidence comes from non-experimental studies, such as comparative studies, correlational studies, cohort, and case-control study
IV	The evidence comes from expert committee reports, or clinical opinions and/or experiences of competent individuals

A narrative synthesis was depicted in tabular form which includes the author’s name, year of publication, study design, location or setting, target population, forms of intervention and comparison, the results obtained, and their implications (Table 1) A pie diagrams were used to describe the percentage of the type of intervention given and the level of evidence. The results of the Odds ratio (OR) in analysis bivariate statistical or Exponent B (Exp B) on logistic regression were synthesized in the narrative.

Results

Overall Study Overview

The final results of the search for articles on the data source PubMed (MEDLINE), Scopus, and ProQuest

resulted in 40 articles published in the last 5 years (2016-2020), open access, and available in full text; includes 20 articles from PubMed, 19 from Scopus, and 1 from ProQuest. Four articles were the same, and articles in which discuss comorbidities in pregnancy were excluded because they did not match the population criteria so that there were only 9 articles left. Inappropriate study design, i.e. cohort, qualitative, and systematic review, were left aside for the next stage. Some articles contained more than one exclusion criteria, so the final result resulted in 5 articles selected for critical appraisal using the Joanna Briggs Institute’s (JBI) critical appraisal instrument. One article was excluded from the list of articles reviewed, because the quality did not meet the requirements, so there was only 4 article left.

The use of telemedicine can be for providing information or monitoring the mother’s conditions. The contents of the information provided to increase the mother’s knowledge can be in the form of written messages, voice messages, videos, and SMS (short message service) interactive. This telemedicine technology can also be a device that measures the mother’s blood pressure and temperature so that it can be monitored by a doctor at a referral hospital (Figure 1) The message conveyed was knowledge about dangerous signs in pregnancy such as vaginal bleeding, fever, seizures, swelling, discharge of smell amniotic fluid from the vagina until loss of consciousness. The danger signs for a newborn include a blue baby, a baby with difficulty breathing, the baby is unable to drink, the baby is very small, the baby’s skin is erupting, and the baby’s temperature is too cold or too hot. Practice-related educational messages include breastfeeding and immunization for mothers and babies.

Based on these search above, we found 2 articles with experimental design and 2 articles with a cross-sectional design (Figure 2). The experimental design used was quasi or pseudo-experimental where the researcher in the field could not control confounding variables that might affect the final results of the study, so regression to the average was carried out regression to the mean. ⁽¹⁴⁾ While the other 2 articles were cross-sectional studies, in which the researcher observes the study subjects for a certain period without observing the course of the disease. For public health planning purposes, this is generally done by calculating the occurrence of the effect of interest for a given population. Data also collected based on individual characteristics, such as exposure to determinant factors, as well as information about the results. In this way, the cross-sectional study provides a ‘snapshot’ of the results and the characteristics associated with them, at a particular point in time. ⁽¹⁵⁾

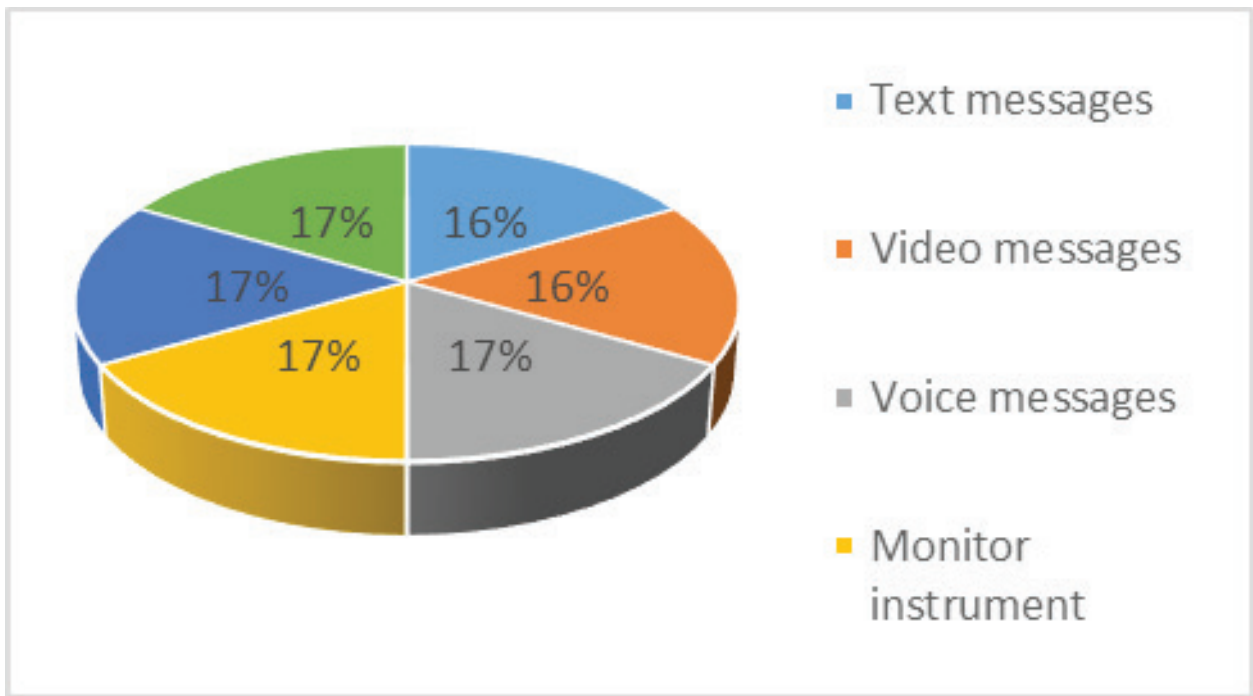


Figure 1. Types of intervention using telemedicine

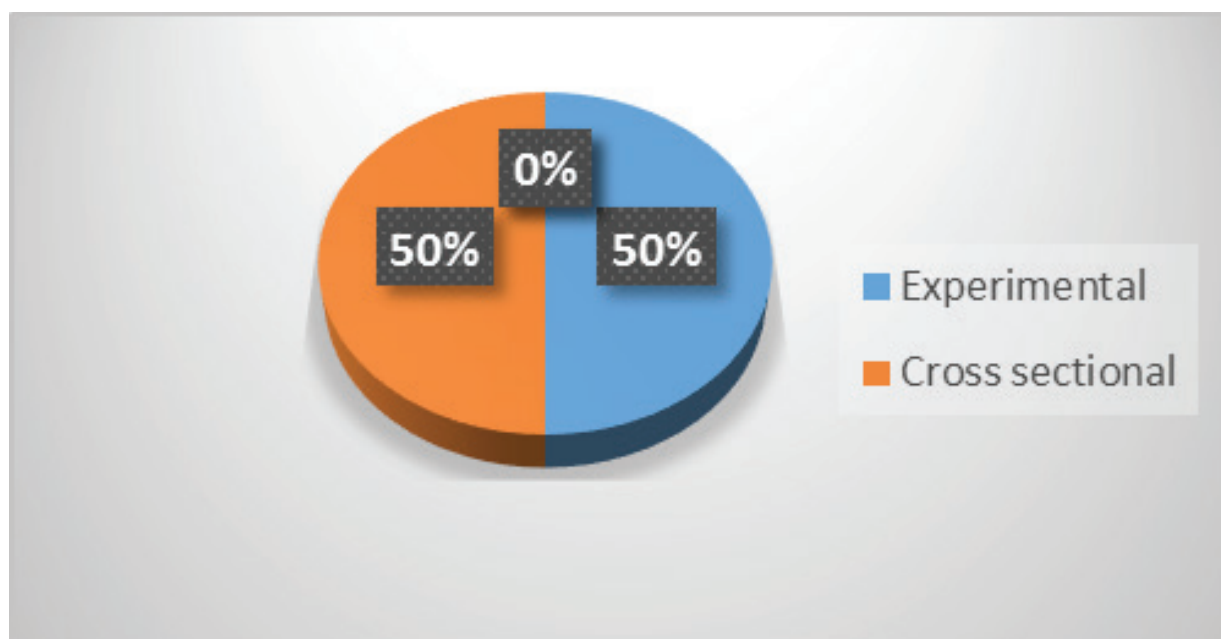


Figure 2. Study designs of articles

Narrative Synthesis of the Study

A quasi-experiment in the city of Dodoma, Tanzania, showed a significant increase in maternal knowledge of danger signs in pregnancy and newborns. The same effect was shown on the readiness of the mother in facing childbirth. The interventions had provided in the form of text messages (SMS) that were sent regarding danger signs of pregnancy, danger signs in newborns, and preparation for childbirth. This research was conducted in an urban setting where the welfare and education levels of mothers were higher than in rural areas; likewise, ownership of a cellular telephone was almost certainly owned by every mother; so that the effect of using interactive SMS cannot be applied in rural areas.⁽¹⁶⁾ This finding was very different from a study conducted in Chamwino District, Tanzania, in a rural setting where only 25.2% of women had extensive knowledge of obstetric danger signs at delivery.⁽¹⁷⁾ The effect of the intervention was indicated by Cohen's d 85% which means intervention has a profound effect on the level of knowledge of mothers about danger signs in pregnancy and newborns.⁽¹⁶⁾

Murthy et al.(2020) Intervened in the form of a quasi-experimental study in Mumbai, India, a slum area with a population that was very dense and had a large area. The intervention was in the form of voice messages

containing health education for pregnant women and babies, which were given from 6 weeks of gestation to 1-year-old babies. The expected result was increased knowledge and practice in the health sector. This was indicated by the willingness of the mother to receive the tetanus toxoid vaccine, and the very important result was the mother immediately consults a doctor when vaginal bleeding occurred⁽¹⁸⁾ This method can prevent “3 being late”, namely delays in recognizing danger signs in pregnancy, making decisions, and being late in getting services at health facilities.⁽¹⁹⁾ Interventions containing voice messages were also carried out in Bangladesh, with settings in rural areas (Matlab), slums areas (Bhasantek), and urban areas (Bhramanbaria). The intervention, called ‘Aponjon’, was a voice message containing knowledge and behaviors related to maternal and neonatal health that was given for 3 months. Aponjon not only had an impact on improving knowledge and behavior related to maternal and neonatal health but also increased maternal compliance to visit postnatal care to health facilities.⁽²⁰⁾

Behavioral practices were observed in mothers of infants aged less than 6 months that receive education via voice messages for at least 3 months, during pregnancy. Telemedicine was not only used to provide education to pregnant women but can also remotely monitor the health of pregnant women. for example for

the mother's blood pressure and temperature. This was done in Madagascar, where pregnant women receive a 'PANDA monitor point of care', which was connected to a 'PANDA medical unit' that allows doctors at the referral hospital to monitor.⁽²¹⁾ The same thing was done in Japan, where pregnant women were monitored with a device called *iCTG*. This tool could remotely monitor the mother's cardiocograph and blood pressure. During the examination, the device was connected to a smartphone or laptop at a Hokkaido Hospital. The doctor could visually examine the mother and make notes on the results of the examination in the medical record.⁽²²⁾

Discussion

Main Findings

Telemedicine is promising for use in situations where access to health facilities is difficult, such as limited health facilities, long distances to health facilities, and limited face-to-face opportunities due to pandemic conditions. This is supported by the increasing use of cellular phones globally and the increasing science of technology in the field of medical instruments. Not only benefiting pregnant women, but telemedicine also makes it easier for health workers to monitor pregnancy remotely.^(21,22) All require the development of information communication technology and health technology. The use of telemedicine has also been shown to increase maternal adherence to postpartum checkups.⁽¹⁸⁾

Researchers in selected articles made adjustments to maternal age, gestational age, education level, parity, and economic and occupational conditions of mothers. The factor of maternal education level might have had a strong influence on the level of maternal knowledge so that the intervention was not merely the cause of increasing maternal knowledge.⁽¹⁶⁾ Another factor associated with participation in the mHealth program could be influenced by the factor of well-being in wealthier women were more likely to participate in the program than those who were not well-off (OR = 2.0, 95% CI: 1.0-4.1), as shown in Vander Vliet's study thesis with pregnant women participants in Timor Leste in 2016. However, ownership of a private cell phone was not associated with maternal participation.⁽²³⁾

Some interventions did not impose additional costs on mothers, because they were a national program of a country, but some were paid. It was necessary to consider the cost-effectiveness and the burden that must be borne by users of this technology. The opportunity of telemedicine in Indonesia in the current situation is quite large. Based on data from the Indonesian Ministry of Communication and Information, internet usage in urban areas was 61.83% while in rural areas it is 32.5%; so that telemedicine can get a place, especially in big cities.⁽²⁴⁾ The smartphone user in Indonesia is 86.2% and among women, the user is 65.09%.⁽²⁴⁾ As many as Indonesian 86.2% use smartphones, and among women the users were 65.09%. The most commonly used instant messaging was *WhatsApp* 31.7% and most users are housewives.⁽²⁵⁾ Thus, the development of telemedicine using the *WhatsApp* platform is very likely to be developed. Considering that the Indonesian government has sent mobile sub-district internet service centers to all sub-districts in Indonesia, it is hoped that one-day telemedicine can be developed throughout Indonesia, to deal with the geographical conditions of the Indonesian archipelago.⁽²⁶⁾

Limitations

Limitation in this study included the risk of observation bias. Based on the study design, the level evidence-based of the selected articles is level IIb for studies quasi experimental and III for descriptive studies such as cross-sectional.⁽¹³⁾ Recall bias can occur when the mother forgets about the data needed, such as blood Hb levels. This can be overcome by matching the data with the cards for pregnant women or with existing data at health facilities. However, this is not easy, because not all mothers can show their pregnant mother's card. Difficulty in requesting data to health facilities can occur because officers are busy serving patients. Mothers who could not be contacted because they returned to their hometown before delivery resulted in a reduction in the amount of data analyzed. However, this was anticipated from the start based on the amount of data retrieved. From the articles discussed, no information shows the great influence of telemedicine on reducing maternal mortality.

Conclusion and Recommendations

Telemedicine provides an opportunity to overcome

problems antenatal care in areas where access to health services is far away and there are limited health facilities and personnel. In conditions of social distancing such as during a pandemic, telemedicine is promising to maintain contact between health workers and mothers. Further research is needed on the use of telemedicine related to health insurance and the number of costs incurred by both parties (pregnant women and health service providers), as well as investments made by the government if this is a government program. In Indonesia, the use of telemedicine as a complement routine ANC still needs to be developed in terms of the concept and technology used. Pregnancy outcomes the method telemedicine need to be further investigated to ensure both the success and safety of this method.

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Ethical Clearance: Not Applicable

Conflict of Interest : Nil.

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Scoping Review to Identify Potential Solutions to Challenges Faced by Village Health Workers in Bhutan

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Abstract

Community health workers (CHWs) have been readily utilized in a variety of economic and institutional settings over the last six decades. However, due to the diverse responsibilities, implementation styles, and sociocultural factors among different regions, the influence and benefits of CHWs differs widely among various nations. We present potential approaches to addressing the current challenges faced by VHWs in Bhutan, which are categorized into four overarching categories. These include improving management and community expectations, improving societal factors for VHWs, providing monetary support for VHWs and improving and expanding training. Like many CHW programs in developing regions, Bhutan's VHW program is able to offer a cost-effective source of health resources to communities in need. However, significant time and resources need to be invested to ensure that the dramatic reduction in VHWs becomes abated, as there is a clear increased cost onto the Bhutanese healthcare system and a decrease of necessary health services provided to communities. Although our study uses the Kingdom of Bhutan as a model, these recommendations can and should be implemented by other countries facing similar challenges with their community health worker programs.

Keywords: *Bhutan, Challenges, Issues, Literature Potential, Solutions, "Village Health Workers"*

Introduction

In 1979, the Kingdom of Bhutan developed its CHWs program, named the village health workers (VHWs) program. The nation differed from other developing regions in that it created the program as a country-wide initiative and central point of support for the Bhutanese healthcare system.¹ Similarly, to other developing nations, Bhutan is a resource constrained country with a shortage of healthcare providers.² Within Bhutan, VHWs are trained briefly for a two-week period and then given yearly refreshers.³ with their training focusing on: first-aid, public health, and treatment of minor illnesses.⁴ Unlike many other country's CHWs, Bhutanese VHWs are not financially compensated for their services. This is an essential point to note, as there has been a ~20% decrease in VHWs since 1992.² Both

the economic and health benefits of CHWs have been extensively studied in developing nations,² but there has been limited research conducted within Bhutan relating to VHWs. Using prior research from our team, we reveal that there is a clear economic argument for investing in the VHWs program as well as expanding training and programing based on the urban-rural divide.⁵

The role of CHWs in developing nations can be as straightforward as dispensing basic medications or as involved as providing mental health counseling for vulnerable communities.⁶ It is essential to note, that the level of participation of CHWs within their communities is entirely based on the institutions and governments which back them. Within Bhutan, VHWs could be trained to provide a more central role in neonatal care, maternal education, and childbearing support.⁷⁻¹⁰ Additionally,

Bhutan’s VHWs can expand access to drugs by providing a variety of medications and treatments, ranging from antimalarial and antiretroviral drugs to micronutrient supplements and vitamin A tablets.¹¹⁻¹² Many nations also employ CHWs to serve as counselors for sex education and family planning, alcohol and substance use disorders, and for individuals with depression/anxiety.¹³⁻¹⁵ Notably, ample evidence has positively regarded the integration of VHWs for administrative and clerical support to local health officials as well as for data collection initiatives.¹⁶⁻¹⁷ CHWs in a variety of developing nations have performed diverse tasks with improvements to health outcomes in a cost-effective manner. As such, substantial consideration should be undertaken to better utilize and invest in this vital health resource as a method of strengthening the Bhutanese healthcare system. More specifically, improving management and community expectations, improving societal

factors for VHWs, providing monetary support for VHWs, and improving and expanding training could not only promote health outcomes, but also do it cost-effectively.

Lastly, in previous research, data from over 95% of all reported disease admissions within Bhutan were used to model the cost-savings associated with VHWs.⁵ These findings demonstrated that for every VHW that was added to Bhutan not only were their costs saved for the healthcare system, but also hospital admissions were averted, and money was saved in the form of lost wages and transportation. Furthermore, for every VHW that exited the program costs were incurred. These results revealed that recent losses in VHWs have led to a significant decrease in healthcare and community savings.

Methods

Articles related to VHWs from within and other countries using the different electronic databases and search engines were used to find out the most appropriate articles for the review.

Title of the articles	Author’s name	Publication year
The Kingdom of Bhutan health system review	Thinley, S., et.al	2017
Women’s groups practicing participatory learning and action to improve maternal and newborn health in low-resource settings	Prost, A., et.al	2013
Community based newborn care	Gogia, S., et.al	2011
Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases	Lewin, S., et.al	2010
Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes.	Lassi, Z. S., et.al	2015
Task-shifting from doctors to non-doctors for initiation and maintenance of antiretroviral therapy	Kredo, T., et.al	2015
Traditional birth attendant training for improving health behaviors and pregnancy outcomes	Sibley, L. M., et.al	2012
Roles and effectiveness of lay community health workers in the prevention of mental, neurological and substance use disorders in low and middle-income countries	Mutamba, B. B., et.al	2013
Allied health assistants and what they do: a systematic review of the literature.	Lizarondo, L.,	2010
Evidence on feasibility and effective use of mHealth strategies by frontline health workers in developing countries: Systematic review. Tropical Medicine and International Health	Agarwal, S., et.al	2015

Cont...

Motivational Factors Influencing Retention of Village Health Workers in Rural Communities of Bhutan	Tshering, D., et.al	2019
Leadership and governance of community health worker programs at scale	Schneider, H., et.al	2017
Retention of female volunteer community health workers in Dhaka urban slums	Alam, K., Tasneem, S., et.al	2012
Retention and sustainability of community-based health volunteers' activities	Chatio, S., et.al	2017
Community health worker incentives and disincentives	Bhattacharyya, K., et.al	2001
Global experience of community health workers for delivery of health-related millennium development goals	Bhutta, Z. A., et.al	2010
A Pilot School Meal Program Using Local Foods with Soybean in Rural Bangladesh: Effects on the Nutritional Status of Children	Murayama, N., et.al	2018
Principles for a framework for alternative payment models	Nussbaum, S., et.al	2018

Meta-synthesis was used to co-relate, gauge and interpret the findings from the studies to build a probable potential solution to address the issues and challenges that the VHWs has been facing. The concept of Preview, Question, Read and Summarize (PQRS) concept was applied to synthesize the main categories of issues and challenges faced by the village Health Workers.

Results and Recommendations

This review revealed the range of issues and challenges faced by the Village Health Workers which are conceptualized and categorized into four broad topics.

Improving Management and Community Expectations:

Village Health Workers identified a lack of oversight and support from all sectors of government with regards to their roles within.¹⁸ A high level of reporting VHWs indicated a lack of consistent communication from government and health officials served as a demotivating factor for VHWs.¹⁹ Evidently, it is important to ensure that VHWs feel supported within their roles as health workers so as to ensure retention of VHWs and overall motivation towards their duties. While Bhutanese

communities clearly know that VHWs can provide basic medications, first aid, and serve as point of contact for health resources/education, it is less clear to communities whether VHWs can provide a range of other services.¹⁸ It is critical that community expectations of what services VHWs can and cannot provide be managed in order to reduce confusion and foster greater clarity onto the VHWs program.

To our knowledge, annual VHWs awards are delivered to the best VHWs within a district. These particularly dedicated VHWs, and others of similar commitment, could be given the opportunity to serve as a guide for other VHWs by serving as team leaders. The role of team leader would entail regular monitoring of VHWs within a certain region, providing guidance and answers to queries, serving as a liaison between the Ministry of Health and other VHWs, and disseminating training refreshers and updated health-related information to VHWs, to name a few. Studies have indicated a more local approach to the management of CHWs can prove to be more effective and efficient in overseeing CHWs.²⁰ Furthermore, small-scale campaigns which aim to promote awareness of the services VHWs provide can be instituted as a method of clarifying expectations and the role of VHWs. These

initiatives can be as simple as placing flyers near schools, health centers, and government buildings or more robust in the form of road billboards/signs. Additionally, it is important for community level meetings to be called to highlight the specific roles and services that VHWs have within their communities. These action plans will serve to rectify misconceptions on VHWs and provide a clear notion on the role of VHWs within their communities.

Improving Societal Factors for VHWs:

Perhaps non-intuitively, societal factors were found to be the primary demotivating factor among Bhutanese VHWs who left the program.¹⁹ More specifically, a lack of appreciation and respect for VHWs was seen to be a central issue. VHWs often reported that their services were not valued and that their role within communities were often overlooked.¹⁸ Similar challenges have also been extensively reported relating to CHWs in Africa.²¹⁻²² Simple forms of identification, such as VHW badges or vests/uniforms, which identify CHWs as extensions of the government sector or even as appointed workers of the Bhutanese government can significantly increase moral among VHWs and respect among community members.²³ Many CHWs in developing countries report feeling an increased sense of responsibility as well as increased facility of interacting with their community's due to these ID badges and uniforms.²³⁻²⁴

Due to the unique spiritual and cultural paradigm of the Bhutanese people, a specific day of appreciation can be created as one which celebrates the health workers of the country –including VHWs. Additionally, existing holiday can be utilized to also take moments of gratitude for VHWs and other health workers.²³⁻²⁴ Along with the informational campaigns previously mentioned, attention should be placed on highlighting the role of health workers within Bhutan. The purpose of these campaigns should aim to promote a sense of respect and appreciation for VHWs and other similar health workers. These campaigns would target both the social demotivating factors of VHWs as well as encourage individuals to further utilize their VHWs for health-related matters.

Providing Monetary Support for VHWs:

The World Health Organization (WHO) has stated

that the standard of compensation for CHWs is providing some form of monetary support.²⁵ These standards may prove difficult for Bhutan as there are significant resource constraints. However, among Bhutanese VHWs who exited the program, lack of monetary support was reported as a significant driver for leaving the program, with 35% of workers stating that any sort of monetary allowance would significantly increase retention.¹⁸ Additionally, VHWs reported lost wages in the form of having to finance work-related transportation and phone calls. These health workers also noted lost income in the form of losing working days due to government and community support efforts. Providing a monthly salary of Nu. 4,5000 (\$64.29), which reflects ~40 hours of work a month for a Bhutanese health assistant, would not only increase VHW retention but will also further motivate these health workers to become more involved with their work. The salaried model has been employed extensively in a variety of economic and regional settings with consistent benefits to health outcomes and cost-effectiveness.²⁶ This method of compensation is particularly beneficial as it establishes a reliant source of income for VHWs and solidifies their role within communities as an extension of the health force. A salaried model also allows for a greater request of time and attention to be given to the role of VHW. This latter facet is essential as a formal form of compensation is needed if VHWs are asked to expand their duties within their communities.

A Kick Back System would aim to reimburse VHWs for any work-related expenses they are made to pay out of pocket. VHWs spend a significant portion of their time utilizing their phone plans to connect individuals to healthcare providers, to aggregate communities for government/health officials, and to disperse medications within their neighborhoods. As such, they would be provided with a monthly phone plan by the Bhutanese government to cover these expenses. Additionally, transportation and any other work-related costs would be reimbursed to VHWs. Establishing a system of placing claims to reimburse these costs could significantly increase retention within the program.

Lastly, a fee-for-service form of payment would allow VHWs to log the number of hours they worked per month in order to gain compensation. A description of the services provided by VHWs can be noted as form

of monitoring and a monthly cap of 30 hours per month could also be established. While fee-for-service models hold inherent flaws with regards to the propensity to file billing claims with no effect on health outcomes, this may still prove a cheaper option for financially compensating VHWs.

Improving and Expanding Training:

Research has indicated that a quarter of sampled groups do not feel that VHWs are sufficiently trained.¹⁹ This is evidently problematic as communities should be confident in the health workers who serve them. This same point has been expressed by VHWs who have also reported a lack of training as a central demotivating factor. It is essential to ensure that VHWs are receiving comprehensive training and refresher workshops to both establish their morale and that of their communities as well as to provide the best quality of service possible. Additionally, CHWs in many developing nations are able to serve an expanded role by offering a variety of services. Some of these expanded roles may serve as a beneficial addition to the training repertoire of Bhutanese VHWs, both with regards to cost-savings and health outcomes.

Expanding VHWs training sessions to a bi-yearly plan where they receive comprehensive training every six months would also be a valuable approach. The training would focus on ensuring that VHWs feel confident and supported in their role as CHWs. Evidently, it would also aim to certify that VHWs are prepared and well-versed in all their responsibilities. The current practice of delivering compensation to VHWs for their training time would continue.

Furthermore, for many Bhutanese communities' access to substance use disorder services is not a feasible reality. Currently, alcohol-related liver disease is the leading cause of death in Bhutan and 47.9% of the population reports using some form of smokeless tobacco product.² However, CHWs in many developing nations have served a supportive role for combating these issues within their communities.¹⁴⁻¹⁵ Through providing additional training to VHWs on how they could support their communities, both through individual counseling and general public health initiatives, VHWs can play a grass-root level role in abating this disease.

The prevalence of contraceptive usage within Bhutan is 65.6% with the adolescent birth rate at 28.4 per 1000 people.² Additionally, the 2015 STI rate was at its highest at 92 cases per 10,000 individuals. These figures indicate a greater need to expand these essential services. As such, VHWs could be provided with a variety of contraceptives and trained in family planning practices to further support their communities through this needed health service. Ample research has revealed that family planning services and increasing access to contraceptives are highly cost-effective strategies and can significantly improve the livelihood of impoverished communities.

The Bhutan Annual Health Bulletin cites malnutrition as a key concern of the Bhutanese Government. Additionally, nutritional anemia cases in 2019 exceeded 11,000 health center admissions.² Due to the intimate role that VHWs have with their communities, the creation of a micronutrient package (MNP) program for at risk communities can be implemented through these health workers. Studies have clearly delineated the role that MNP have played in reducing anemia and vitamin A deficiency rates as well as overall increasing the nutritional value in low-resource settings.²⁶ While many Bhutanese BHUs have MNP available for their communities, the implementation of this program in a more localized manner with greater oversight is likely to yield better usage rates than currently observed.

Many urban VHWs are already functioning as community organizers and overall facilitators for government efforts.¹⁸ Allowing for greater involvement in these sorts of roles could significantly increase clerical and organizational efficiency. Additional research has also shown that lack of career opportunities within the VHWs program was also identified as a demotivating factor.¹⁹ As such, creating opportunities for VHWs to serve as assistants to local government officials would allow VHWs to continue their role more officially. The potential for urban VHWs to play a greater role in community organization and governmental affairs could abate the growing decrease in VHWs.

Discussion

Our analysis highlights several of the challenges that the Bhutanese VHWs program faces as well as various methods which could be utilized to improve and

upscale the program. In order to better manage VHWs, it is fundamental that a local approach to management via VHW team leaders be utilized. These leaders will not only serve as a point of contact to disseminate health resources but can also act as source of motivation and encouragement for VHWs. The creation of a team leader's proponent would incur a limited cost, both in terms of financial resources and time, and would very likely only serve to bolster the current VHWs program. With regards to managing community expectations and confusion, the usage of community level meetings is a vital tool to clearly delineate the role that VHWs hold. While the implementation of informational campaigns would be an additional asset to the VHWs program the financial investment is a notable barrier. As such, we find that the creation of VHWs team leaders and community meetings are easily implementable pillars to improving management and community expectations.

An extensive amount of research has been conducted on identifying the demotivating factors relating to Bhutan's VHWs,¹⁹ one of the key findings was the importance of improving the societal factors surrounding VHWs. Past research in developing nations has clearly shown that symbols of moral, such as badges/uniforms and honoree titles, have a significant effect in improving CHWs motivation and overall role as health workers.²³⁻²⁴ Due to these findings, and the limited costs associated with such intervention, we highly recommend that appropriate efforts are undertaken to use these symbols in order to improve community's perceptions of VHWs and foster a greater sense of appreciation for VHWs. We also recommend for the implementation of appreciation campaigns for health workers and the use of existing ceremonial events to promote a sense of gratitude for VHWs. It is important to note, that the primary focus of these interventions should be a multifaceted approach which aims to highlight the efforts and work that VHWs and other health workers undergo within Bhutan. These sorts of interventions are ones which require limited financial capital and can be easily instituted to increase VHW retention and motivation.

As previously mentioned, the WHO has clearly delineated the importance of financially incentivizing community health.²⁵ Not only have studies been overwhelming in their support for proper financial investment into these health workers, but our own

research has displayed a clear economic argument for the cost-saving nature of VHWs. As such, we strongly advocate for the creation of a monthly salary which reflects a 40 hour a month stipend. This marginal investment will serve as a pillar for ensuring that VHWs remain motivated in their work as well as allow for future upscaling and expansion of the program to be possible. While our team finds a monthly salary to be clearly cost-effective, if financial aspects prove too notable a barrier, it is possible to utilize the Kick Back System or Fee-for-Service model of payment. To a lesser extent, either of these two payment models would serve to progress the goal of VHW retainment.²⁷ The important point to note is that through a regular source of income, VHWs can properly invest the time needed to not only continue their current duties but also expand their skill repertoire to other health services. This would allow for not only a better quality of services but also a more diverse set of amenities which communities may utilize at a more cost-effective manner (i.e. utilizing a VHW as a mental health resource rather than a more costly physician or a health assistant).

Lastly, the improvement and expansion of current training efforts are a central facet of retaining and upscaling the VHWs program. Prior to any new health skills being taught to VHWs, it is vital for an increase in refresher trainings to ensure that VHWs feel secure in their current role. Once this is achieved, we recommend prioritizing VHWs to be properly trained for mental health counseling, in particular for counseling surrounding alcohol and substance use disorder. Despite having no formal training in mental health therapy, past research models have elucidated that Bhutanese VHWs are already serving as a source of mental and emotional support for their communities. Due to this we find that this initiative would allow for a significant expansion of mental health resources for underserved communities as well as create a localized approach to combat the rising prevalence of alcohol use disorder in Bhutan. Additionally, the implementation of local MNP disbursement and education program by VHWs is a facile and effective manner of combating childhood anemia and malnourishment. Likewise, training VHWs to serve as an outlet for sex education and family planning can lead to less unplanned and teen pregnancies as well as less sexually transmitted illnesses. As such, these sorts of programs should swiftly be undertaken as there a

relatively few barriers to its implementation.

Conclusion

While the current VHWs program provides very basic health services to communities, expanding training to these health workers can allow them to deliver more complex and specialized services in a cost-effective manner, facets which are already utilized in many CHW programs globally. In order to do this, however, there is a need to properly invest in improving the societal factors surrounding VHWs as well as financially compensate these health workers for their work. Together these interventions, amongst others, can prove useful to increasing VHW retention, expanding vital services to communities, and reducing overall costs onto the Bhutanese healthcare system.

Declarations

Ethical approval and consent to participate: Not applicable

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Knowledge and Perceived Stigma Towards Tuberculosis among Tuberculosis Suspect by Gender in Community in Indonesia

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Abstract

Objective: This study aims to description knowledge and perceived stigma towards tuberculosis among tuberculosis suspect.

Background: Knowledge and TB-related stigma constitutes ones of the major social factors causing delayed diagnosis and treatment.

Methods: This study is a further analysis of the Indonesia 2013-2014 national TB prevalence survey. Eligible population age ≥ 15 was interviewed to find TB symptoms and was screened with thorax x-ray for suspects to be tested MTB with microscopy, LJ culture and X-pert MTB/RIF. All positively screened participants also were interviewed about knowledge, attitude and stigma. Descriptive analysis was done using STATA.

Results: Total sample: 8.466. The proportion of TB suspect participants reported the way of TB transmission namely black magic, genetic and through food/drink were 18%, 47% and 59% respectively and high for males who living in rural and Sumatera. The proportion of the TB suspect participants mention hiding family member who has TB was 13% and high for males living in rural. Only 20% of participants mentioned that TB treatment was free. However, the participant reported they knew TB can be cured was 75%.

Conclusion: TB-related stigma was still high among TB suspects especially in rural Indonesia. Interventions concentrating on reducing TB patients' stigma should focus on improving patients' knowledge about TB.

Keywords: Tuberculosis, stigma, knowledge, gender, knowledge

Introduction

Tuberculosis remains the leading cause of death from an infectious disease among adults worldwide. The World Health Organization (WHO) reported Globally,

the best estimate is that about 10 million people (range, 9.0–11.1 million) developed TB disease in 2018. Among the three countries with the highest estimated TB incidence rates were contributed from India (27%), China (9%) and Indonesia (8%)¹.

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Indonesia, in 2017, the national inventory study found that about 80% of new cases were detected, 41% of these cases were not reported and the rest almost 20% were undetected or under-diagnosis². The Directly Observed Treatment Short course (DOTS), the internationally recommended strategy for TB control, was adopted in 1995. DOTS comprises five components of which case detection by sputum smear microscopy

and some by molecular rapid test and standardized treatment with supervision and patient support are the major ones (Ministry of Health, 2011).

TB stigma and knowledge can be a barrier to early diagnosis and a deterrent to treatment adherence. Some studies found that no knowledge of TB and TB-related stigma constitutes one of the major social factors causing delayed diagnosis (Ali et al., 2017)⁵ and factors accounted for treatment non-adherence⁶ among TB patients. TB stigma and low knowledge of TB can lead people to feel discriminated and stigmatized for instant rejection and emotional problems because of misconceptions⁷. These fears lead many TB patients to hide their symptoms and it may contribute to delayed healthcare seeking, poor treatment adherence, and poor prognosis⁸.

Stigma defines as existing 'when a person is identified by a label that sets the person apart and links the person to undesirable stereotypes that result in unfair treatment and discrimination'⁶. Different propositions have been propounded concerning the etiology of stigma and fear of being infected is an obvious cause of discrimination⁹. While scientifically unfounded beliefs about the transmission of the disease have been found to be significant predictors of stigma¹⁰. Stigma and discrimination may affect the extent to which the patient is able to obtain, maintain and complete treatment¹¹.

One pulmonary TB patient with smear positive is estimated to transmit an average of 10 other people per year¹². From these infected individuals, 10-12% will develop TB after a few weeks or decades¹³. Without treatment, about 70% of patients with positive smear and 20% of patients with negative smear will experience death over a 3-year period¹⁴. Thus, stigma toward TB is a complex and multifaceted behavioral issue that needs to be understood better. However, few studies have examined TB-related stigma and its associated factors among TB patients in Indonesia. Therefore, we conducted further analysis to know magnitude of the problem on knowledge and stigma toward TB among pulmonary tuberculosis suspects in the community in Indonesia based on the Indonesia 2013-2014 national TB prevalence survey. Our goal was to provide policy-makers with recommendation for more organized TB control program to improve TB knowledge

Material and Methods

This cross-sectional survey with national coverage carried out from 2013-2014 with stratified multi-stage cluster sampling. Stratification was done by regions and urban/rural status. Indonesia was divided into three regions: Sumatera (46 clusters), Java-Bali (64), and other regions (outside Java-Bali and Sumatera) (46). The 156 clusters were distributed in 136 districts/cities throughout 33 provinces. The inclusion criteria were that residents who should have lived in the selected cluster for a minimum of one month and be aged 15 years and above.

All participants were interviewed about TB symptoms and received direct digital chest radiography (CXR). Participants were considered presumptive TB cases if they reported a cough for two weeks or more and/or hemoptysis and/or had abnormality in lungs or pleura based on the CXR. The presumptive TB cases were asked to submit spot and morning sputum specimens for direct microscopy examination with Ziehl-Neelsen staining and Lowenstein Jensen culture. X-pert MTB/RIF was carried out if the smear was positive or decisive culture results were not available. For knowledge, attitude and stigma information, all positively screened participants were interviewed for KAP and TB related stigma

In this study, analyzed is using STATA 14.0 (College Station, TX, USA). Suspect TB participants. Participant were asked about how can TB be transmitted including variables: because of black magic, inherited genetically, through food/drink, after eating and drinking together with TB a patient, using the same eating utensil of a TB patient, through common use of public facilities and through hand shaking with a Tb patient. Some questions were asked the main TB symptoms, whether TB treatment curable and free TB treatment. Attitude toward TB related stigma were also available on hide a family member who has TB

Ethic Statement

The National TB prevalence survey 2013-2014 was approved by ethic committee of National Institute of Health Research and Development. Participant was voluntary and all participants gave written informed consent before being involved in the study. All identity details of the survey participants were kept confidential.

Result

A total of 8.466 participants completed the survey questionnaire. The number of suspected TB is the most male than female and most live in rural areas. Most of the suspects aged 15-54 years were 5.633 (66.53%)

and had a high school education up to university level of 6.666 (78.73%). The number of suspects originating from the Sumatra region is almost the same as in Java Bali ranging from 38-40%. Most of the suspects came from other provinces such as the provinces of Sulawesi, Kalimantan, Papua, Ambon and others (43%).(table 1)

Table 1. Number and Percentage of Samples by Age, Education in Residence and Region

No	Indicator	Male		Female		Male+ Female	
		n	%	n	%	n	%
	Age group						
1	15-54	3353	59.52	2280	40.48	5633	100
2	55 +	1670	58.95	1165	41.05	2833	100
	Level of education						
3	<= Junior High school	1176	65.48	620	34.52	1796	100
4	Senior High School+	3843	57.68	2823	42.32	6666	100
	Residence						
5	urban	1893	60.34	1244	39.66	3137	100
6	rural	3130	58.34	2199	41.26	5329	100
	Region						
7	Sumatera	1575	61,98	966	38.02	2541	100
8	Java-Bali	1654	59.93	1106	40.07	2760	100
9	Other	1794	56.68	1371	43.32	3165	100

Majority 65% of suspects of men and women already know that TB transmission through sputum splashes from coughing TB sufferers. However, there are still 18.5% of suspects who still believe that TB is caused by magic blows and 28.44% believe that TB is caused by blows / obstacles and this believe is more common in men than women. Approximately 60-65% of suspected men and women know that TB transmission can be

through eating and drinking together with sick people and using the same eating utensils with sick people and this is more common in men than women. Only 20% suspect know that TB treatment is free and the majority of men know that treatment is free compared to women. There are still around 13% of the suspect kept a secret if a family member is exposed to TB and this is also done more by men (62%) than women (38%)(Table 2).

Table 2. Overview of Knowledge about the Mode of Transmission and Causes of TB and the Respondents' Attitudes to TB by Gender

No	Knowledge of how transmission and causes of TB	Male				Female				Male + female			
		yes		no		yes		no		yes		no	
		n	%	n	%	n	%	n	%	n	%	n	%
1	Because of the blow / blow to the chest	1497	62.17	3526	58.2	911	37.83	2532	41.8	2408	28.44	6058	71.56
2	Black magic	1005	64.18	4018	58.23	561	35.82	2882	41.77	1566	18.5	6900	81.50
3	Inherited genetically	2442	61.37	2581	57.52	1537	58.63	1096	42.48	3979	47.00	4487	53.00
4	Through food/drink	3090	61.39	1933	56.31	1943	38.61	1500	43.69	5033	59.45	3433	40.55
5	Through sputum sparks from coughs of TB sufferers	3385	61.00	1638	56.15	2164	39.00	1279	43.85	5549	65.54	2917	34.46
6	Using the same eating / drinking utensil	3480	60.8	1975	57.52	1965	39.02	1478	42.08	5013	59.21	3453	40.79
7	Through the same food	3352	60.9	1671	56.41	2152	39.1	1291	49.59	5504	65.01	2962	34.99
8	Through communions of public facilities	1949	63.67	3074	56.87	1112	36.33	2331	43.13	3061	36.16	5405	63.84
9	Trough Hand shaking	1415	63.71	3608	57.77	806	36.29	2637	42.23	2221	26.23	6245	73.77
11	know main TB Symptom	3897	60.63	1126	55.00	2530	39.37	913	45.00	6427	75.92	2039	24.08
12	TB can be cured	3894	60.73	1129	54.97	2518	39.27	925	45.03	6412	75.74	2054	24.26
13	TB drug free	931	54.16	4092	60.65	788	45.84	2655	39.35	1719	20.03	6747	79.7
14	Would hide family member who has TB	703	62.32	4320	85.87	425	37.68	3018	41.13	1128	13.32	7338	86.68

The men in rural areas more than 50% still know the cause of TB is due to blunt magic. In addition, they also know that TB can be transmitted through food and drink and hereditary diseases. Men are more likely to know the cause of TB due to magical blah, and how TB is transmitted through food and drink and eating together with TB sufferers in Sumatra and Java Bali compared to other regions. Men who answered yes, kept it a secret that there were more TB family members compared to women in both urban and rural areas in

Sumatra and Java, while in other areas there were more women. Presentation male who answered yes, free TB treatment was almost the same as women in urban and rural areas in Sumatra and Java, while in other areas it was more on women. As many as 60% of men in rural areas say yes, knowing the main symptoms of TB and can be cured. In other areas the presentation said yes, knowing the main symptoms of TB and can be cured only at most women (43%) compared to men, while in Sumatra, Java Bali more in men at 30%. Table 3

Table 3: Overview of TB Suspect Stigma in Urban and Rural Areas and in the Three Regions According to Gender and Region

No	TB transmission Stigma	District								Region										
		Urban				Rural				Sumatera				Jawa Bali			Other			
		male		female		male		female		male		female		male	Female		male		female	
		n	%	n	%	n	%	n	%	n	%	n	%	%	n	%	n	%	n	%
1	Yes, blackmagic	319	31.71	179	31.91	686	68.26	382	68.9	392	39.00	212	37.79	28.26	140	24.96	329	32.74	209	37.25
2	Yes, trough food/drink	1273	41.2	800	41.17	1817	58.8	1143	58.83	1067	34.53	619	31.86	29.71	568	29.23	1105	35.76	756	38.91
3	yes, Trough inherited genetically	1011	41.4	632	41.12	1431	58.6	905	58.88	850	34.81	467	30.38	29.65	436	28.37	868	35.54	634	41.25
4	yes, know main TB Simtom	1549	39.75	1025	40.51	2348	60.25	1505	59.49	1313	33.69	779	30.79	30.23	747	29.53	1406	36.08	1004	39.68
5	yes, woud hide family member who has TB	268	38.12	134	31.53	435	61.88	207	29.45	207	29.45	117	27.53	32.29	112	26.35	269	38.26	196	46.12
6	yes, Tb can be cured	1557	39.98	1016	40.35	2337	60.02	1502	59.65	1219	31.30	717	28.47	33.56	842	33.44	1368	35.13	959	38.09
7	yes, tb drug free	406	43.61	350	44.42	525	56.39	438	55.58	290	31.15	209	26.52	30.40	239	30.33	358	38.45	340	43.15

(see below the reference)

Discussion

Findings from this study demonstrate the community’s knowledge and attitudes towards TB etiology in Indonesia. Although most participants were aware of TB and knew its symptoms, the belief that TB is witchcraft, hereditary and trough food transmission still dominantly. Basic knowledge about the cause and mode of transmission is needed to reduce the stigma caused by traditional beliefs and negative attitudes towards TB¹⁵.

Various studies have highlighted the importance of knowledge and misconceptions about TB transmission. Misconceptions may include notions such as transmission through food/drink or sharing utensils etc. that it will be a tendency to discrimination and stigmatization¹⁶. In Pakistan, contaminated food was considered the source of infection by considered emotional trauma/ stress the causative agent of TB¹⁷. While in Malaysia only of the respondents knew that genetic, sexual intercourse, sharing clothes, using the same toilet, using the same tooth-brush and shaking hands do not spread

TB infection¹⁸. Misconceptions and false beliefs or myths among TB patients have turned TB into a social stigma. This stigmatization can play an important role in reluctance of patients in seeking treatment. Such stigmatization of TB patients in the society can lead to reluctance in seeking treatment¹⁹

This current study shows that some participants admitted still believe that black magic and genetic can cause TB particularly males living in rural. The belief that TB is black magic and hereditary may be caused by witchcraft is similar to findings in other studies. In rural Uganda, many TB patients mentioned that causes of TB were through included sharing utensils, heavy labor, smoking, witchcraft or black magic and hereditary transmission. This perceived may effect TB patients were to seek care late or to avoid care^{20 21}.

The level of knowledge and stigma is to some extent a barometer indicating the success of programs and the effective TB control to help patients and communities rethink the nature of TB and use clinical services more effectively²². Some studied identified features of TB-related stigma that respondents isolated themselves from friends was to hid their TB from other members of the community. It can cause of self-discrimination identified included fear of transmitting TB, and avoiding gossip and potential discrimination⁹. Stigma and consequent discrimination have an impact on TB control, concerns about being identified as a person with TB make them delaying seeking care and continuing with care²³. This can lead to drugs resistant TB and increase transmission.

Conclusion

Our findings suggest that public health interventions designed to improve knowledge on TB should include consideration of the individual patient's cultural and social context and the role that stigmatization may have in health-seeking behaviors. The study of TB stigma needs to be conducted in a socio-cultural context, and associations with knowledge, attitudes and health responses need to be further explored. A successful stigma intervention may need to be sensitive to the cultural context of TB patients and their families and communities.

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Discrimination Against People Infected with Hepatitis B Virus

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Abstract

Hepatitis B virus (HBV) infection continues to be a significant public health problem, affecting more than 2 billion people globally. Around 40 million people in India are HBV carriers, constituting a large proportion of the worldwide HBV burden. Unfortunately, millions of people with chronic hepatitis B around the world face compelling discrimination that limits their education, careers, income and personal relationships. Many factors are associated with stigma against HBV. Amongst them, lack of knowledge and awareness levels of HBV infection appears to be a significant factor for HBV stigma. Many studies have found that fear of HBV infection is the most common cause of HBV stigma. HBV related stigma affected admission to certain schools or parental rejection at schools, denial of treatment at hospitals/clinics and also acts as an impediment to marriage and having children, so affecting both personal and family life. Female gender, older age, individuals with lower education level tended to have more HBV related discrimination. Public officers like civil servants, or teachers were less likely to exhibit HBV-related discrimination as compared to farmers. Receiving HBV vaccination was related to decreased HBV-related discrimination scores, indicating a protective effect of that HBV vaccination not only from HBV infection, also reduces their levels of HBV-related discrimination

Key words: Hepatitis B virus, infections, AIDS, treatments

Introduction

Hepatitis B virus (HBV) infection continues to be significant health problem, affecting more than 2 billion people globally.¹ India accounts for a large proportion of the worldwide HBV burden, almost 10–15% of the entire pool of HBV carriers of the world.² It is estimated that 40 million people in India are HBV carriers. About 15–25% of these HBsAg carriers are likely to die prematurely due to cirrhosis and liver cancer. Infections occurring during infancy and childhood have the greatest risk of becoming chronic.³ HBV carriers and hepatitis B patients suffer experience significant discrimination and stigmas well as suffer physical injury. Perceived discrimination negatively impacts individuals' self-

identity and quality of life.⁴

There is a long history of social discrimination against while applying for jobs or educational opportunities. Many companies and schools still require HBV test results at the time of recruitment.⁵ HBV-related discrimination in everyday life has not decreased over the years. Hepatitis B patients still experience hardship and feelings of isolation in various places. Most of the people in India have lack of education about hepatitis B infection; HBV patients endure even greater hardship. And to prevent spread of the disease, most important would be the role of health education not only of the population in general and the high-risk population in particular but also the Health Care Workers.⁶

There is a remarkable progress in the pharmacological prevention and treatment of HBV and liver cancer,⁷ However, various studies shown that the health related stigma associated with these diseases has a direct negative impact on quality of life as well as healthcare delivery

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system . Social discrimination against patients with leprosy, tuberculosis, and HIV is present for the years. People living with infectious diseases are frequently criticized and experience significant stigmatization.^{8,9} individuals infected with HBV as well as their family members felt ashamed about having HBV. Hence, Hepatitis B carriers have been described as modern day “lepers” or “AIDS,”^{10,11}

Discrimination against HBV-Definition & Types

Discrimination against hepatitis B patients is defined as (1) negatively judging and unfairly treating hepatitis B patients or HBV carriers and (2) such judgment and treatment being a result of the patients’ or carriers’ HBV infection status. HBV-related discriminations divided into 2 general types: discrimination in an employment or school enrollment situation and discrimination in everyday life by strangers, neighbors, co-workers, friends or family, and more distant relatives.¹²

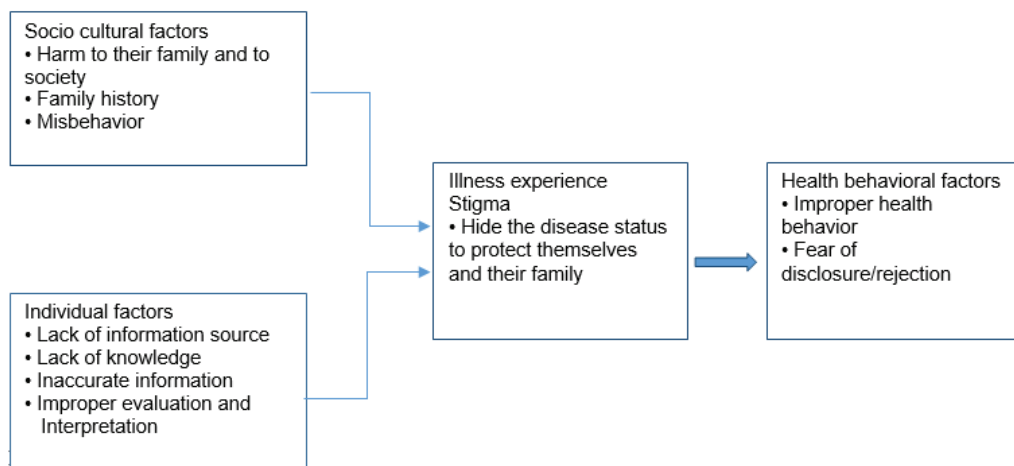
The causes of stigma

Various studies have accredited the individual and socio cultural factors as causes of stigmata. Maxwell et al. found that lack of knowledge and awareness levels of HBV infection resulting in misunderstanding of diseases were associated with stigma.¹³ Lack of knowledge about false transmission routes may greatly increase the probability of severe HBV-related discrimination. Many studies have found that fear of HBV infection is

the most common cause of HBV stigma.^{14,15} Most Asian or Asian Americans stated that sharing of contaminated food and eating utensils was the most common route of HBV transmission, as revealed in both qualitative and quantitative studies.^{16,17,18} Similarly, HBV-infected patients also expressed their fear of transmitting the virus to dear ones through casual contact.¹⁹ HBV infected patients is often viewed as harmful to society or to the family, and HBV-positive status wrongly stigmatizes family members and increases the fear of “loss of face.”²⁰, so he or she can no longer function well in his or her social network.²¹

Risk factors for HBV related Stigma

There are few studies correlating different risk factors with HBV stigma. One study had shown female gender associated with HBV related discrimination. Older age is associated with increased prejudice towards HBV as reported by a Chinese study.¹² Individuals with higher education tended to have less severe discrimination compared with those with less. Occupation of an individual also affected the level of HBV related discrimination. Public officers like civil servants, or teachers were less likely to exhibit HBV-related discrimination as compared to farmers. Receiving HBV vaccination was related to decreased HBV-related discrimination scores, indicating a protective effect of that HBV vaccination not only from HBV infection,²² also reduces their levels of HBV-related discrimination.



Conceptual framework for HBV-Related stigma²³

Figure 1: Conceptual model of

Conceptual framework for HBV-Related stigma²³

Outcome of stigma

Participants in both qualitative and quantitative studies have experienced HBV-related stigma both personally and socioeconomically. The stigma affected admission to certain schools or parental rejection at schools and also resulted in loss of employment.²⁴ Another outcome is that HBV-related stigma acts as an impediment to marriage and having children, affecting

both personal and family life.²⁰ Studies have indicated that HBV-related stigma is a hindrance to accessing services.²³ HBV-positive individuals were reluctant to disclose their status to friends and coworkers.²⁵ ,and these individuals reported higher perception of stigma patients living with HBV have been denied employment, refused entry to foreign countries. The stigmata also prevalent in certain hospitals and clinics, among doctors and staff, a patient with HBV infection denied treatment, specifically surgical care.

Table-1:Few quantitative & qualitative studies on HBV related stigmatization

Authors/Year/ Geographic region	Study design	Sample	Stigma definition	Stigma-related variables	Stigma-related consequences/Findings
Maglalang et al., 2015 CA, USA ²⁶	Evaluation of San Francisco Hep B Free (SFHBV) intervention	Cantonese or English-speaking community dwellers (Asian) 40 in 2013	“Saving face”	A cultural norm of maintaining a positive reputation that is required for social acceptance	To increase awareness and to motivate people to seek treatment or screening for HBV Participants’ awareness of HBV was impacted by SFHBV campaign.
Yu et al., 2016 China ²⁷	Survey design	Community dwellers 6,538 from 42 villages	Yes: negatively judging and unfairly treating. A part of attitude toward HBV patients and carriers	Fear of infection Knowledge about transmission HBV vaccination status	Tried to avoid: accepting gift hugging/shaking hands having dinner together children playing together children marrying with HBV infected person
Carabez et al., 2014 CA, USA ²⁸	Descriptive survey design	HBV infected patients 60 Chinese 27 Japanese 17 Korean 11 Vietnamese 9 Filipino 10 mixed Asian	No	Knowledge Fears of liver cancer	Stigma is not a main purpose. Fears of transmission to loved ones and social stigma

Cont... Table-1: Few quantitative & qualitative studies on HBV related stigmatization

Eguchi & Wada, 2013 Japan 29	Cross-sectional design	3,129 workers	No A part of attitude 2 items to measure	Attitudes toward HBV- and HCVinfected colleagues	Had prejudiced opinions Avoided contact with infected colleagues Knowledge was associated attitudes.
Maxwell et al., 2012 CA, WA, DC, USA 13	Correlational Design	653 Vietnamese 260 Hmong 493 Korean 329 Cambodian	No	Knowledge Awareness Susceptibility Severity	38% Vietnamese, 55% Hmong, 47% Korean, and 70% Cambodian believed that people avoid people with HBV (stigma). Respondents with higher knowledge scores were more likely to agree that people avoid people with HBV
Lee et al., 2014 CO, Northeast, & MA, USA (Qualitative study)	Individual interview/Focus group interview	Community health leaders: 9 Koreans 14 Khmers	To explore factors influencing HBV and liver cancer prevention health behavior within the sociocultural contexts	Sociocultural Socio-medical Socio-linguistic Socio-resource Individual Health-related behavioral	Individual factor: perceived transmission of HBV as a “contagious” or “contaminant.” KAs tend to emphasize sanguinity and family history, whereas CAs blame the unhealthy environment during Khmer rouge era and in refuges campus

Reducing Stigma and Discrimination against HBV

Each workplace has unique needs and an organizational culture, thus hepatitis B employment policies also varies from company to company. Employers should routinely offer education for all employees from entry level through senior leadership to reduce the stigma. We need to address the fear of health care workers about getting infected with HBV by protecting themselves through standard precautions while dealing with patients with HBV. Proper HBV education, resources to perform HBV testing and vaccination against HBV could reduce HBV stigma among the health care providers and family members of HBV infected patients.

Conclusion

Available research suggests that, stigma and discrimination with hepatitis B is predominantly associated with poor understandings of transmission rather than linked to concepts of moral deficit in the ways that have characterized other infectious diseases like HIV and hepatitis C related stigma and discrimination. Hence, proper hepatitis B education among health care providers and affected communities, development of culturally appropriate resources, and enhancement of the communication skills of health care providers can effectively provide accurate and accessible information about hepatitis B, which can significantly reduce stigma and discrimination related to hepatitis B.

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Molecular Detection of *Aggregatibacter actinomycetemcomitans* and *Porphyromonas gingivalis* in Children with Periodontal Disease

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Abstract

Objective: The aim of the present study was to evaluate the presence of *Aggregatibacter actinomycetemcomitans* (*A. actinomycetemcomitans*) and *Porphyromonas gingivalis* (*P. gingivalis*) in healthy and different stage of gingivitis for children aged between 9 and 12 years using Polymerase Chain Reaction (PCR) and to compare their presence in children in their healthy, mild and severe gingivitis. **Method:** Subgingival plaque samples were collected from 94 children and were grouped as Group A-control (healthy), Group B- mild gingivitis, Group C moderate gingivitis, and Group D severe gingivitis and were subjected to PCR assay. **Results:** All data were analyzed by using SPSS program (version 21 for windows 7) chi-square test at $p \leq 0.05$. *A. actinomycetemcomitans* was detected in 0 (0%), 4 (13.4%), 37 (92.5%) and 12 (100%) whereas *P. gingivalis* was detected in 0 (0%), 0 (0%), 6 (15%) and 0 (0%) samples in group A, B, C and D respectively. **Conclusion:** There is nor *A. actinomycetemcomitans* or *Porphyromonas gingivalis* found in group A (healthy moth children). Both the microorganisms were present in group C. In group B and D only *A. actinomycetemcomitans* was present.

Keywords: gingivitis, *Aggregatibacter actinomycetemcomitans*, *Porphyromonas gingivalis*, Polymerase Chain Reaction.

Introduction

Periodontitis is a critical worldwide wellbeing concern and is presumably the most well-known interminable irresistible infection of people. Incessant periodontitis is viewed as a site-explicit ailment. The clinical indications of ceaseless periodontitis—aggravation, pocket development, connection misfortune, and bone misfortune—are accepted to be brought about by the immediate, site-explicit impacts of subgingival plaque amassing. Because of this neighborhood impact, taking, connection misfortune, and bone misfortune may happen on one surface of a tooth, while different surfaces keep up ordinary connection levels. ¹.

Periodontitis is described by locality contamination and aggravation of tooth-supporting tissues, prompting different degrees of periodontal connection misfortune in influenced teeth. Various types of periodontitis are multifactorial sicknesses where microorganisms present in dental biofilms are included. Etiologic microorganisms of periodontal illnesses ordinarily incorporate gram-negative anaerobic microscopic organisms; among those, *Porphyromonas gingivalis*, *Prevotella intermedia*, *Tannerella forsythensis* (some time ago *Bacteroides forsythus*), and *Treponema denticola* are carefully anaerobic and *Aggregatibacter* (earlier *Actinobacillus*) *actinomycetemcomitans* and *Campylobacter rectus* are facultative/microaerobic. A few statistics and conduct attributes, for example, race, age, sexual orientation, and smoking, just as financial status, seem, by all accounts, to be identified with the pervasiveness of periodontitis ².

Periodontitis is a dynamic pathologic condition that has its root in adolescence. Epidemiologically, there is a transmission from youth gum disease to grown-

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up periodontitis³. It is exceptionally compelling to explore the early colonization of kids with periodontal pathogens since their essence could distinguish a patient as a bearer or being at danger of creating periodontitis in youthfulness. The advancement of strategies in subatomic science went for the identification of bacterial pathogens, has permitted not just the obtaining of learning in microbial hereditary qualities however has likewise set the bases for the advancement of improved symptomatic procedures. Polymerase chain reaction (PCR) has risen as the most useful asset for the enhancement of qualities and their RNA transcripts. It is currently broadly acknowledged that the PCR strategies give a progressively touchy method for the discovery of putative bacterial species when contrasted with ordinary culture procedures. It is fast, moderately basic, and ready to distinguish low quantities of bacterial species with discovery breaking points of as few as 25–100 cells. A PCR test is likewise suit-capable for the recognition of periodontal pathogens, particularly in subgingival plaque in kids where there are a set number of pathogens present³.

Materials and Methods

Study subjects

The subjects (45 boys and 49 girls) were enrolled in the study at the pedodontics clinic in the college of dentistry, Al-muthanna University. The study was conducted over a period of 6 months, from January 2019 to June 2019. These children were aged 9-12 years. Subjects receiving or those that have received antimicrobial therapy in the last 3 months prior to our visit were excluded from the study. Informed consent from the parents of the children was obtained after a thorough explanation of the aims and objectives of the study and the project was approved by the Faculty's Ethics Committee.

Sample collection

The subjects were 94 children (45 boys and 49 girls) mean age was (9-12) years who were referred to

the pediatric dental clinic in POP department of college of dentistry, Al-muthanna university, also the samples were collected from the specialized center for dentistry in Al-muthanna government. All the subjects with no antibiotic consumption for the last 6 months. For each patients plaque and saliva samples were taken from the deepest sites of one front tooth and one molar with sterile swab, sterile curette and combined into a single tube per patient for study group and stored in anaerobic broth and was immediately transported to the Laboratory, Department of Microbiology, Faculty of Medicine, Al-Muthanna University. The specimens were processed within 10 min of arrival in the laboratory.

Ethics statement

The approval has been taken from all the parents of children, informing them that the samples would be for the study purpose only and no more samples will be needed.

Bacterial DNA extraction

Bacterial DNA was extracted from the plaque and saliva samples, (gSYNC™ DNA Mini Kit Blood / cultured cell/ Protocol/ Geneaid/ Korea) was used according to the manufacturer's instructions

Bacterial detection by PCR

The eluted supernatant containing bacterial DNA served as a template for the PCR amplification using the method previously described by⁴ and². Each amplification reaction was performed in a total volume of 50. *A. actinomycetemcomitans*, and *P. gingivalis* were done as above except that the appropriate primers were added. Table 1 lists the primer sequences and PCR conditions with their amplicon size used in this study. The amplification products were visualized and photographed under UV light after 1 h of ethidium bromide staining. Typical bands of the *A. actinomycetemcomitans*, and *P. gingivalis* are shown in Fig. 1 and Fig. 2 respectively.

Table (1): The primer sequences and PCR conditions with their amplicon size (Base pair (BP)).

Bacteria (Gene's Name)	Primer Sequence (5' - 3')	Size (BP)	Conditions	Reference
Identification Genes				
hbpA gene of <i>A. actinomycetemcomitans</i>	F5' AGACCCAATGCAAAAAGTAACG 3' R-5' GCAGTTCTGGGCTGAATTG 3'	160	95°c 5min 1x	4
			95°c 1min 60.8°c 45s 35x 72°c 45s	
			72°c 5min 1x	
16 SrRNA gene of <i>P. gingivalis</i>	F-5' AGGCAGCTTGCCATACTGCG 3' R-5' ACTGTTAGCAACTACCGATGT 3'	404	95°c 1min 1x	2
			95°c 30s 65°c 1min 40x 72°c 1min	
			72°c 2min 1x	

Gel preparation & Electrophoresis

Electrophoresis is carried out using TBE (Tris-Borate-EDTA buffer) Good quality agarose gel was prepared 2% TBE (1X), added (0.5µg/ml) ethidium bromide. After PCR step was finished test tubes were moved from thermocycler(UK) , 8µl from each amplicon specimen to new empty test tube , 2µl of dye was added to each test tube ,mix and added the content of each tube to the lane carry the same name of the test tube, added 10 µl of marker to the first lane of agarose gel, run the gel for 35 min. at 120 Volt. ,400 Amp, view the gel under

UV transilluminator 360 bp band of amplicon appear in +ve and -ve samples *A. actinomycetemcomitans* and *Porphyromonas gingivalis* no band in control negative or negative samples.

Results

In this study, the overall recovery of *A. actinomycetemcomitans* and *Porphyromonas gingivalis* by using PCR is (42.5 % & 2.1 %) respectively, based on specific primers hbpA & 16SrRNA with molecular length about 160 and 404 bp respectively as in figure (1) and (2) respectively.

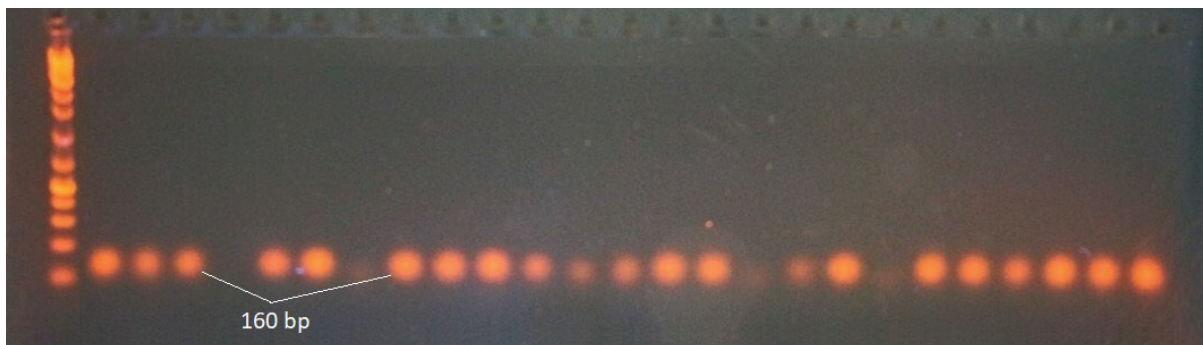


Figure (1): Agarose gel electrophoresis 1.5% for hbpA PCR products, gel was electrophoresed for 1 hours at 70 Volt. The size of PCR product is 160 bp. most lanes show positive result.



Figure (2): Agarose gel electrophoresis 1.5% for 16SrRNA PCR products, the gel was electrophoresed for 1 hours at 70 Volt. The size of the PCR product is 404 bp. 1 and 3 lanes show a positive result.

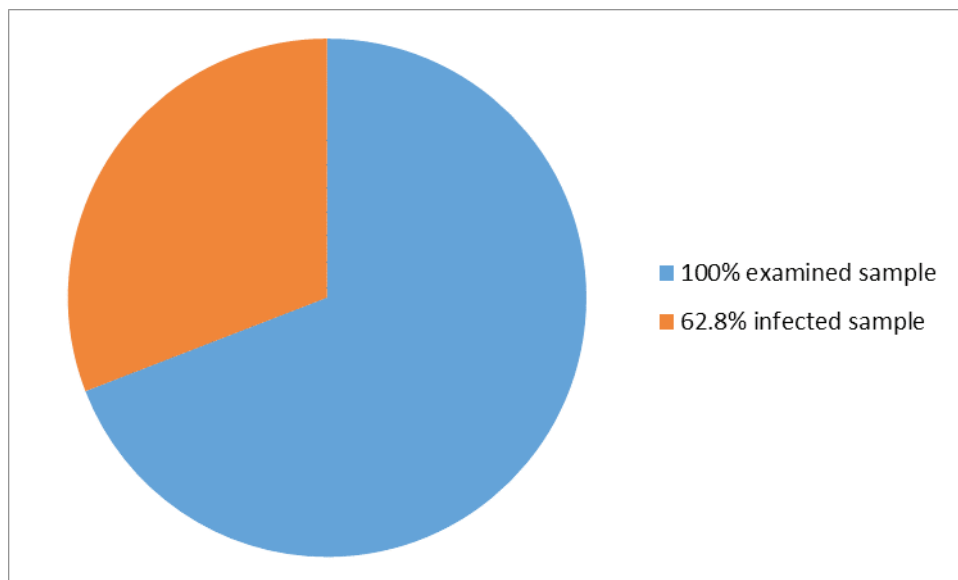


Figure (3) percentage of infected samples comparative with examined samples

The statistical analysis shows a significant correlation between the infection and age at $p \leq 0.05$, where results showed that the high infection rate among age group ranging from 11-12 years in both *A. actinomycetemcomitans* and *P. gingivalis* at 96% and, 100% and the least affected group was 9-10 years 4% and 0% respectively.

Also, in this study we found a significant correlation between the infection and gender at $p \leq 0.05$, the male was more effective with infection than female in both *A. actinomycetemcomitans* and *P. gingivalis*

Table (1) Number of examined and infected samples with *A. actinomycetemcomitans* depend on Oral health

Oral health	No of examined samples	No of infected samples (percentage)
healthy mouth	13	0 (0%)
mild gingivitis	29	4 (13.4%)
moderate gingivitis	40	37 (92.5%)
severe gingivitis	12	12 (100%)
Total	94	53* (56.4%)

*significant correlation between infected with *A. actinomycetemcomitans* and oral health, *A. actinomycetemcomitans* detected in all stages of gingivitis.

Table (2) Number of examined and infected samples with *P. gingivalis* depend on Oral health

Oral health	No of examined samples	No of infected samples (percentage)
healthy mouth	13	0 (0%)
mild gingivitis	29	0 (0%)
moderate gingivitis	40	6 (15%)
sever gingivitis	12	0 (0%)
Total	94	6 *(6.4%)

*low significant correlation between infected with *P. gingivalis* and oral health, *P. gingivalis* detected in moderate infection only.

Out of 94 children studied, 59 (62.8%) were positive for the targeted periodontal pathogens as shown in figure (3). In descending order, the overall occurrence rates of these pathogens were as follows: 53 (56.4%) for *A. actinomycetemcomitans*, and 6 (6.4%) for *P. gingivalis*, as shown in table 1 and 2. By stage of infection group, there are no periodontal pathogens were carried in plaque and saliva by healthy children (group A), 4 (13.4%) from 29 children have mild infection (group B); 37 (92.5%) of the 40 moderate infection (group C); and 12 (100%) of the 12 children suffering from severe infection (group D), of the 94 children investigated in all groups, the predominant isolate was *A. actinomycetemcomitans* (56.4 %); followed by *P.*

gingivalis (6.4 %) which is isolated from children have moderate infection (group C) only.

one periodontal pathogen in the plaque and saliva of 55 children and 4 children have moderate infection carried two pathogens per child.

Discussion

Microbiological studies have shown that the arrangement of subgingival plaque is exceptionally unpredictable and variable. Up until this point, around 500 bacterial species have been distinguished in sound or unhealthy periodontal tissues⁵.

Up until now, there is just a couple of planned longitudinal information on the pervasiveness of periodontal pathogens in the oral hole of solid youngsters. As appeared in the present examination, Iraqi youngsters harbored a large portion of these periodontal pathogens before the age of 18 years. Additionally, except for *P. gingivalis*, the carriage of periodontal pathogens is regular in youth after the age of 6 years, achieving grown-up carriage rate by the age of 9—12 years⁷. Some of the different investigations reports predominance of *A. actinomycetemcomitans* is low in small kids and increments with age, yet unexpectedly, our outcomes demonstrated that its commonness was most elevated in age somewhere in the range of 9 and 12 years. Our finding is upheld by a previous investigation directed by⁶ mong younger children in Taiwan where they found the predominance of *A. actinomycetemcomitans* was most noteworthy in age bunch 7—multi-year olds and from there on declined in grown-up control gathering. In this present Yuan's examination, it was contemplated that following young person, *A. actinomycetemcomitans* maybe step by step overwhelmed by immunological variables. *A. actinomycetemcomitans* among school children in Taiwan where they found the prevalence of *A. actinomycetemcomitans* was highest in age group 7—12 year olds and thereafter declined in the adult control group. In this Yuan's study, it was reasoned that following adolescents, *A. actinomycetemcomitans* might be gradually overcome by immunological factors.⁶

P. gingivalis was found in a lot of lower extents of the youngsters in our examination. The pervasiveness of *P. gingivalis*, might be transient and their colonization in periodontally sound youngsters may be an uncommon occasion. Despite the fact that colonization doesn't really initiate a disease that causes the demolition of the periodontium, ceaseless nearness is likely essential for these microscopic organisms. Conversely, the degree of *A. actinomycetemcomitans* present in the subgingival site might be a key factor for the forecast of periodontitis in kids. Studies have demonstrated that their essence in the spit is an impression of their colonization of the subgingival and supragingival destinations⁷. The demonstration of incitement by biting a bit of paraffin wax permits the still-joined microscopic organisms or bunches of microorganisms to relax from the oral biofilms into spit. Truth be told, a few investigations have shown the predominance of salivation over

pooled subgingival tests for the identification of some periodontal pathogens⁸.

Commonness investigation of this nature utilizing subjective sub-atomic enhancement (PCR) philosophies isn't without its confinements, particularly when contrasting the predominance results and some distributed information dependent on less delicate customary social strategies with their bewildering scientific categorization and uncertainty of phenotype database. What's more, the thickness of every one of the pathogens which might be applicable to the level of carriage of these microscopic organisms in the mouth of sound kids couldn't be dictated by the subjective nucleic corrosive testing utilized in our investigation.

The isolation rate of *P. gingivalis* depends on several factors like virulence of isolates, the health status of patients and the effect of environmental conditions⁷.

Although this study has indicated that *P. gingivalis* represent only 6.4% of total isolates, but⁸ found that the rate of *P. gingivalis* in subgingival plaques reach to 60% of cases. This may depend on *P. gingivalis* structure, its metabolism, and its ability to colonize the oral epithelial cells in the oral cavity so it involved in the pathogenesis of periodontitis by destroying the tissues supporting the tooth which eventually may lead to tooth loss.

Because *P. gingivalis* is a potent periodontal pathogen, it would be expected to be detected in most patents with disease and rarely detected in subjects who are periodontal healthy⁹.

Many studies concentrated and focused on these genetic primers and found that *P. gingivalis* detection could be achieved with varying degrees of success with primers specific for 16s rRNA -encoding genes, yet, the rRNA sequences of *P. gingivalis* show approximately 95% homology. So, these genes are ideal targets for the unique identification of *P. gingivalis*¹⁰.

Previous studies showed that 16S rRNA had homology at a rate 100% among human saliva isolates from adults and children¹¹.

All in all, the perfect skill for precise identification of pathogens in subgingival plaque tests presently can't seem to be created. The high affectability and particularity of PCR legitimize its utilization in epidemiological

investigations of periodontal sicknesses¹².

Conflict of Interest: None

Funding: Self

Ethical Clearance: Not required

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A Very Rare Case of anomalous Right Coronary Artery

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Abstract

Congenital coronary anomaly is rare occurrence, and is found in very meagre population undergoing coronary angiography. The individual may not show any specific symptoms during electrocardiography and finding of anomaly is usually incidental during coronary angiography. No specific evidence based management or guideline is available for patients with coronary anomaly. We present one such case of a 65-year-old male patient presented with chest pain and had anomalous right coronary artery arising from Left coronary system.

Key words: anomalous; congenital; percutaneous coronary intervention; right coronary artery,

Introduction

The evolution in imaging technologies like coronary angiography and computed tomography has helped immensely in understanding the anatomy of coronary circulation system. With the availability of imaging techniques, the number of literatures have also grown exponentially. Of the total population undergoing coronary angiography, congenital coronary anomalies are observed in only 0.024 – 0.066% of the population^{1,2}

The coronary arteries start developing in the third week of embryogenesis. Presence of only one coronary artery is a very rare occurrence. There are no specific symptoms observed in patient at the time of diagnosis and the findings are incidental during angiography. Seldom cases are reported where blood supply to whole heart is done from a single origin³⁻⁵. Here, we present a case of a 65-year-old male, who had anomalous right coronary artery, presented with chest pain and no other complaints.

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Case Report

A 65-year-old male presented to our facility with complaints of on and off chest pain since three days. A week before presentation, his electrocardiography (ECG) done at other facility showed symptoms of inferior wall myocardial infarction. He was thrombolysed with reteplase. Post stabilization, he was referred to our centre for coronary angiography and further treatment. His ECG done at our centre showed inferolateral ischemia. His blood pressure was normal, pulse was 81/min and SPO2 was 98% on presentation. His coronary angiography done through right radial route. The angiogram revealed following details: dominant LCX vessel showed 40% stenosis in ostial, 80% stenosis in mid segment post obtuse marginal (OM), and 95% stenosis in distal segment (Figure 1); left main showed ectasia in mid segment; proximal left anterior descending artery showed 50% stenosis and TIMI III flow was visible in distal part; the diagonal branch was <2 mm in diameter and had 60% stenosis in ostial region; right coronary artery was arising from the left circumflex artery. (Figure 2).

He was advised for percutaneous coronary intervention to LCX and RCA. A 6 Fr guiding catheter was advanced through right femoral route to cannulate left coronary system. A 0.14" fielder FC guidewire was

used to cross the distal RCA lesion and parked there. A 4.0 x 15 mm everolimus eluting stent coated with biostable polymer was negotiated and deployed in mid LCX lesion at 12 atm (Figure 3A). The mid-distal lesion was predilated with 2.0 x 12 mm balloon at 14 atm. Thereafter, another 2.25 x 28 mm everolimus eluting stent coated with biostable polymer was negotiated and

deployed mid to distal left circumflex at 11 atm (Figure 3B). The final post dilatation was done two times with 2.5 x 12 mm NC balloon at 16 atm.

Adequate expansion of stent was confirmed by views from different angles. Final TIMI III flow was observed post procedure and no dissection was observed (Figure 4).

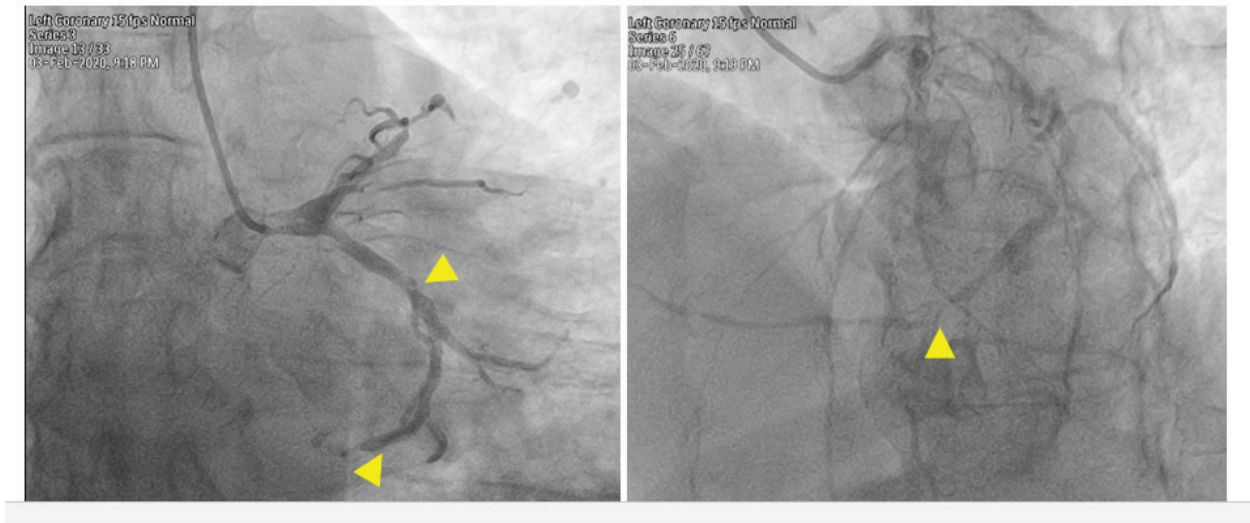


Figure 1: Left circumflex artery showed 40% stenosis in ostial, 80% stenosis in mid segment post obtuse marginal

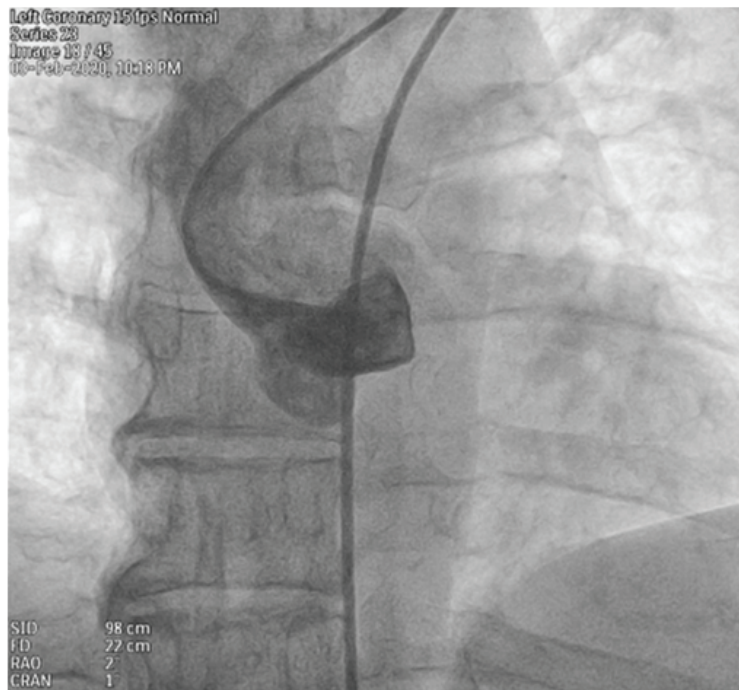


Figure 2: Angiogram of Aorta shows there is no visual of right coronary artery

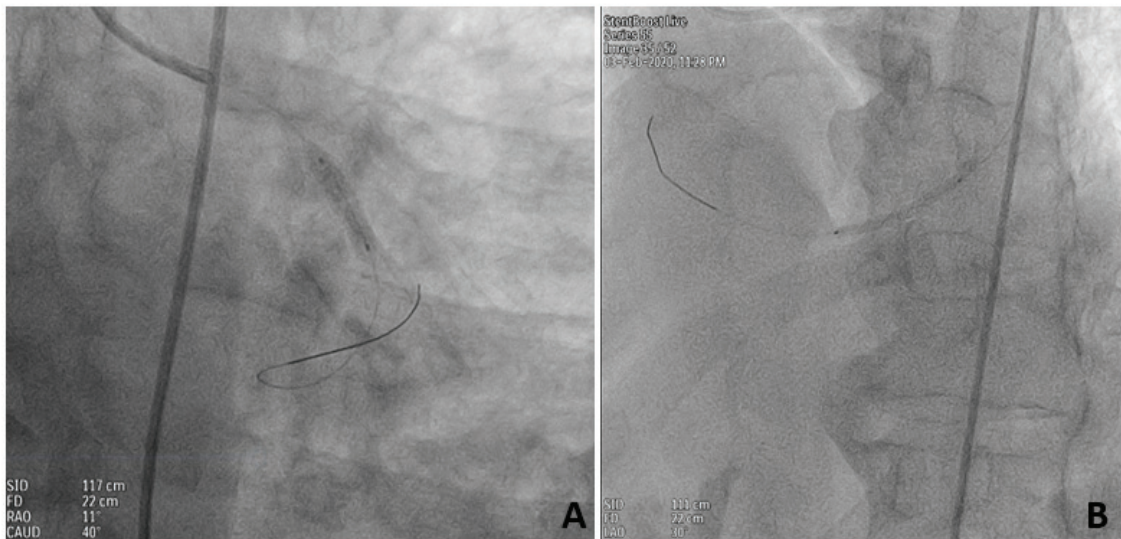


Figure 3: (A) A 4.0 x 15 mm everolimus eluting stent was negotiated and deployed in mid left circumflex lesion at 12 atm (B) 2.25 x 28 mm everolimus eluting stent polymer was negotiated and deployed in mid to distal left circumflex at 11 atm



Figure 4: Final TIMI III flow after postdilatation with 2.5 x 12 mm NC balloon at 16 atm

Discussion

There is no standardized treatment or evidence based guidelines available for the treatment of anomalous right coronary artery. Patient is treated conservatively with anti-platelets, anti-hypertensive and lipid-lowering treatment or with revascularization therapy may be used percutaneous coronary intervention therapy. Patients with congenital anomaly of RCA does not have any specific symptoms and diagnosis with electrocardiogram may be misdiagnosed with coronary artery disease or may stay undiagnosed. If undiagnosed, the patient may not be further evaluated with other imaging techniques. This may explain the low prevalence of patients with anomalous right coronary artery.

In the present case, there was no visual of right coronary artery during coronary angiogram. The blood supply was done through collaterals evolved from the left circumflex artery. Right coronary artery arising from left sinus of Valsalva should not be confused with congenital absence of RCA. This is due to the fact that in congenital absence of RCA, circulation of right side is completely relying on left coronary artery patency. While in the present case, retrograde filling of the RCA from distal left circumflex was observed. As per classification by Lipton et al⁶, 9 types of single coronary artery anomaly are mentioned considering the site of origin and their anatomical course. Other imaging techniques like computed tomography, magnetic resonance imaging could not be employed due to financial constricts. Such cases where origin of RCA from left circumflex are rarest of rare and have reported incidence of 0-0.035% of cases⁷.

Conclusion

Identification of anomalous right coronary artery is challenging and suspicion should arise when one cannot appreciate RCA even after taking multiple shoots in the right coronary sinus. Doing percutaneous angioplasty of anomalous right coronary artery can be challenging and should be undertaken with precision and expertise.

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Conflicts of Interest: There are no conflicts of interest.

Ethical Clearance: Ethical clearance was obtained from 'Dr Rane's Ethics Committee'.

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Cuff Leak Test for Predicting Post Extubation Stridor in Intubated Adult Patients- A Prospective Observational Study

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Abstract

Aim: This study aimed to evaluate whether the Cuff Leak Test (CLT) helps to predict post-extubation stridor (PES) in intubated patients.

Materials and Method: A prospective observational study was conducted in the adult ICUs of a tertiary care hospital. Patients who were intubated and ventilated for more than 3 days were enrolled in the study if inclusion and exclusion criteria were met. Standard cuff pressure was maintained throughout the course of intubation of the patients. CLT was conducted before the extubation and cuff leak volume was noted for all patients. A cuff leak volume of ≤ 140 ml was considered a positive cuff leak test.

Results: A total of 53 patients were enrolled in the study with a mean age of 62 ± 16 years. The overall incidence of PES was found to be 13.2%. A total of 19 (34.85%) patients had a positive CLT of which, 4 patients developed PES and of the 34 patients with negative cuff leak test, 3 patients developed PES. Overall, the cuff leak volume in PES group was comparatively lower than non-PES group. Age, gender, duration of intubation, chronic morbidities and even cuff leak volume were not statistically significant in predicting PES.

Conclusion: Positive CLT or the absolute leak volume does not accurately predict the PES in intubated patients

Key words: cuff leak test, post-extubation stridor, cuff leak volume, laryngeal edema

Introduction

Endotracheal (ET) intubation is required to protect the airway and to provide respiratory support in respiratory distress. But this procedure can subject the patients to a lot of pulmonary and airway related complications^[1]. Laryngeal edema is one of the common life-threatening complications of ET intubation which can lead to post-

extubation stridor (PES)^[1]. Other causes and risk factors for PES can be tube-related, airway-related, and patient- and disease-related factors^[2,3]. Usually, the duration of intubation and size of the ET tube exerts pressure on the larynx which may be one of the reasons for laryngeal edema^[4,5].

Incidence of PES varies widely among published studies, between 1.5-26%^[2,6-9,14]. Laryngeal edema is seen commonly in most of the patients intubated for more than 4 days^[4]. Early recognition is the key factors that will help to understand the successful extubation. CLT is a non-invasive test and is thought to give a clue for patency of airway in intubated patients^[4]. The principle is based on the fact that more the cuff leak volume around ET tube lesser the chances of airway

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edema^[4,8-9]. CLT was initially introduced in 1988 by Adderley and Mullins in children with croup, where they proposed that coughing on a deflated ET tube cuff predicts successful extubation^[10]. By measuring the volume of air leak around the deflated cuff, Miller and Cole in 1996 makes CLT more quantitative^[7]. The cut-off value for predicting positive results varied in different studies with the reported maximum value of 140ml^[2,11].

Literature has shown different cuff volumes and techniques to identify PES. Thus, the validity and efficacy of the CLT are controversial or inconclusive^[12,13,15]. Thus, we aimed to evaluate whether CLT is an appropriate clinical test in predicting post extubation stridor.

Material and Methods

A prospective, observational study was conducted in the Intensive Care Units (Medical, Cardiac, Neurology, and Surgical ICUs) of a tertiary care hospital between Dec 2018 and Feb 2019. Before the commencement of the study, ethical clearance was obtained from the Institutional ethics committee (RECH/ EC/ 18-19/ 493).

All the intubated patients with age above 18 years, who were intubated for more than three days and were ready for extubation according to their primary consultant and intensivist were included for the study. The patients who were intubated primarily due to upper airway obstruction who presented with stridor were excluded. Each patient was intubated with the ET tube of a low-pressure, high-volume cuff and the cuff pressure was maintained at 25-30 cm H₂O. CLT was performed immediately before the extubation, once oral, subglottic, and endotracheal suctioning were performed.

Prior to the CLT, patient was placed in a semi fowler's position and ventilated with VC- assist control mode and tidal volume (TV) was targeted based on the ideal body weight during the cuff leak test. The initial inspiratory and expiratory tidal volumes were monitored and recorded with the cuff inflated. The cuff was then deflated, and the expiratory TV was recorded for six subsequent breath cycles and the average value was

calculated. The cough expired volumes were excluded during the CLT. The cuff leak volume was measured by calculating the difference between the expiratory TV with the cuff inflated and deflated.

After the CLT was performed, the patient was extubated as per the physician's order and was monitored continuously for 24 hours for signs of PES^[14]. A cuff leak volume of ≤ 140 ml was considered a positive cuff leak test. All the other data collected, such as date of intubation, date of extubation, ET tube size, diagnosis, previous medical and intubation history, history of the laryngeal disease, and the cause for intubation were recorded in a structured proforma.

The analysis was carried out using SPSS v10.0 software, South Asia, India. Descriptive statistics were used for representing the demographic details. After assessing normality using the Shapiro-Wilk test, the data was compared between stridor and non-stridor group. Normally distributed data were analyzed using Student's t-test; and Mann-Whitney U test was used if the samples were not normally distributed. A Chi-square test was used for analyzing the categorical variables.

Results/ Findings

A total of 53 patients with a mean age of 62±16 years and who were ready for extubation were enrolled in the study. Of the 53, 24 were male and 29 were female patients. The overall incidence of PES in our study was 13.2%. Among 53 patients, 19 had a positive cuff leak test (cuff leak volume ≤ 140 ml). Remaining 34 patients had cuff leak volume greater than 140ml. Three patients with a normal CLT developed PES and was managed conservatively with steroids. Among the 19 with a positive CLT, four patients develop PES. The patients who developed stridor from the positive CLT group had a cuff leak volume of less than 100mL. The remaining 15 patients did not develop stridor, even though CLT was positive. (Figure-1) Among the 4 patients who showed PES from positive cuff leak test group, three of them were managed by steroids and one patient had to be reintubated due to severe respiratory distress.

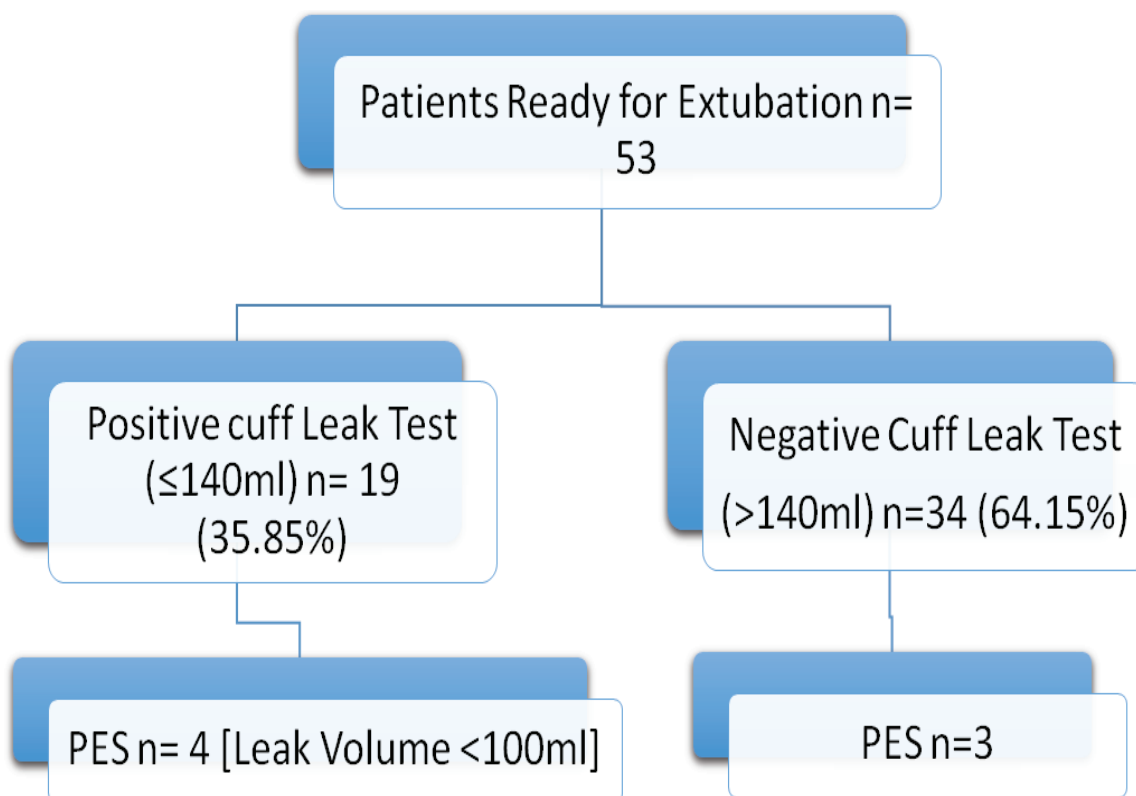


Figure- 1. Flow chart of patients with outcomes of CLT and occurrence of stridor

The demographics, duration of intubation, and leak volume between patients who develop stridor and who did not develop stridor was compared and presented in table-1. The analysis showed that the occurrence of PES was more among women than men but was not statistically significant (17.2% vs 8.3%, p=0.057). Two patients had pre-existing laryngeal pathology amongst whom, one patient with laryngopharyngeal reflux pathology developed stridor. No significant difference in co-morbidities between the groups was observed. Patients with stridor had a lesser leak volume than those without stridor (leak volume=128±69 vs 255±139) but was not statistically significant (p=0.084).

Table-1 Comparison of demographics, duration of intubation and cuff leak volume between stridor and non-stridor group

Characteristic		Overall (N=53)	Stridor (n=7)	No stridor (n=46)	P-value
Age (Years)		62±16	61±13	59±18	0.174
Gender n (%)	Males	24 (45.28)	2 (28.57)	22 (47.83)	
	Females	29 (54.72)	5 (71.43)	24 (52.17)	
History of laryngeal disease n (%)		2 (3.77)	1 (14.29)	1 (2.17)	
Duration of intubation median(IQR), Days		8(5, 14)	8 (4, 16)	7(5, 15)	
Leak Volume (ml)		231±153	128±69	255±139	0.084

Discussion

Post Extubation Stridor is a life-threatening complication which occurs immediately after extubation. It may require treatment ranging from nebulization with racemic epinephrine to reintubation based on the severity. Many studies have been conducted to estimate the incidence of PES and showed a wide range of results ranging from 2-30%.^[2,6-9] We found that the incidence of PES in our study was 13.2%. Study done by Wang C et al. showed a slightly higher incidence of PES (18.2%)^[13]. Whereas lower incidences were found by Gros A et al^[16], Schnell D et al^[17] and Kriner EJ et al^[11], i.e., 6.7%, 9.4% and 4.3% respectively. The high variance observed among the published studies may be because of different underlying medical conditions, the number of days on ET tube and mechanical ventilation, degree of airway edema, use of pre-extubation steroids, etc.

CLT was introduced to predict upper airway obstruction post extubation and can thereby reduce the chances of extubation failure. Lesser the cuff leak volume, higher is the risk for PES. The overall cuff leak volume in this study was 231±153 ml. Cuff leak volume was almost similar in the study by Wang C et al^[13] but slightly higher leak volume was found in the study by Miler R et al^[7]. Endotracheal tube size and the diameter of the trachea can also affect the cuff leak volume during the test.

The cuff leak volume was comparatively lesser in the stridor group as compared to the non-stridor group, even though no statistically significant difference was observed. Similar results were found in Sahbal MA et al^[18] and Wang C et al^[13]. This may suggest that there may be a requirement of better predictive value for the cough leak test. But certain studies have shown a predictive value of 140 mL is effective in predicting post extubation stridor^[19,20].

Even though the cuff leak volume for positive cuff leak test was considered to be ≤140 ml in this study, it did not successfully rule out all the PES cases. But, when we compare with the total number of patients in positive and negative CLT groups, positive CLT provided positive results in more patients than negative CLT for PES (21.05% vs 8.82%).

All the patients who developed PES were successfully managed with oxygen therapy and steroids and only one patient required reintubation in whom the leak volume was 98ml.

Overall, this study does not support the use of CLT as a solid predictive tool to rule out PES in intubated patients.

Limitations and Future Directives

The major limitation of this study was a small sample size. We could not document the dosage of steroids used to manage PES. The diameter of the ET tube and events during intubation was not documented which could have given us a better understanding of the cuff leak volume in the stridor group.

A good sample size with the use of CLT along with laryngeal ultrasound in predicting stridor can give a better idea of predicting PES. Future studies can explore the effect of lung mechanics on the development of laryngeal edema. Also, the impact of airway properties with respect to abnormal airflow and their impact on the CLT should also be investigated.

Conclusion

Positive CLT or the absolute leak volume does not accurately predict the PES in intubated patients.

Conflicts of Interest: There are no conflict of interest related to this manuscript.

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Control of Blood Pressure in District Dehradun, India: is Rule of Halves Still Valid?

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Abstract

Background: Hypertension is one of the most important causes for cardiovascular disease (CVD) which poses a major public health challenge. Rule of Halves in hypertension has long been used as a standard referral point for level of awareness, treatment & control of blood pressure in general population considering it to be 50 percent at each level.

Aim and Objectives: To validate “Rule of Halves”, for updated teaching to medical and nursing students and formulation of appropriate strategies for prevention and control of Hypertension at community level.

Methodology: A cross section survey was conducted covering all households in the randomly selected 30 villages of district Dehradun, Uttarakhand by house-to-house visit. A pre-validated, structured questionnaire was used for capturing data. Hypertension was defined as Systolic Blood pressure -140mmHg or greater &/ or Diastolic Blood pressure of 90mm Hg or greater or both or treatment with antihypertensives.

Result: Out of 1946 screened, 39 percent (749) were found hypertensive. Out of them, less than half (43.5%) were aware, more than 2/3rd (87.1%) were under treatment and approximately one third were well controlled (36.2%) with given treatment. Age more than 40 years, female gender and self-employment were found significant factors after adjusting the confounding factors for hypertension in binary logistic regression analysis.

Conclusion: Hypertension was more among younger age group and females had better control of Hypertension. Awareness regarding hypertensive status is still less than fifty percent, but those who are aware, majority of them are on treatment, but control on given treatment is far from optimal.

Keywords: Hypertension, Rule of Halves, Awareness, Treatment, Controlled

Introduction

It is well established that non-communicable diseases especially cardiovascular diseases (CVD) are major causes of death and disability in low-income countries including India¹. High Blood pressure has been ranked as third most important risk factor attributing burden of diseases in south Asia (2010)² and hypertension per se

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poses substantial public health burden on cardio vascular health status and health care system in India^{3,4} High Blood Pressure (BP) is a silent invisible killer that rarely causes symptoms per se but its complication accounts for 57% of all stroke deaths and 24% of all coronary heart disease (CHD) deaths in India⁵. It is one of the most important risk factors for CVD and a reduction of high or moderately elevated BP levels results in a decrease in stroke and myocardial infarction rates^{6, 7}. Despite the high prevalence, prevention, detection, awareness, treatment, and control of hypertension is still suboptimal and unsatisfactory even in well-developed countries⁵ & the state of developing countries like India is even worse⁶. With a growing epidemic of non-communicable diseases in developing countries, particularly India, data on prevalence, awareness and control of these diseases are of great importance. In 1972 Wilber and Barrow¹⁰, while studying the diagnosis and treatment of hypertension in the southern United States of America, described the 'Rule of Halves': half of the cases were not known, half of those known were not treated and half of those treated were not controlled. The utility of this rule has often been questioned by various authors. As the rule is being taught to medical and nursing students religiously for so many years without updating, hence present study was planned to validate the "Rule of Half", so that updated information can be delivered to students and appropriate strategies can be implemented for prevention and control of Hypertension at community level.

Materials & Methods

Setting and study population

Uttarakhand is one of the hilly states of the India with more than 70% rural population. Multistage sampling was used for arriving at desired sample. State has 13 districts; out of which district Dehradun was selected. Dehradun has six blocks; present study was conducted in Doiwala block of district Dehradun. There are 44 villages in block Doiwala, as per census 2011. Out of which 30 villages were randomly selected for the study. A cross sectional survey was conducted covering all the households in the randomly selected villages by house-to-house visit. Persons who were above 19 years of age and willing to participate were included in the study after obtaining informed consent excluding pregnant women.

Study was conducted from April 2018-November 2019.

Sample size was calculated based on estimate of prevalence of controlled hypertension for rural Indians as 10.7% based on meta-analysis of prevalence, awareness and control of Hypertension⁽¹¹⁾. Considering absolute precision of 2 percent at 5 percent level of significance and 2 design effect, Sample size came out to be 1900.

Study tool and its administration-

A pre-validated, structured questionnaire was used for capturing data. Questionnaire included information on Bio- demographic profile (age, sex, education etc.), awareness about hypertension and its associated risk factors. Participants were asked about their status of Hypertension if it is already known to them. Questionnaire was administered to participants in Hindi language by 10 field research investigators. Each of them was briefed and trained in the methodology of asking questions. A training manual was developed and provided to each field research Investigator as ready reckoner. To help reduce inter-observer variability, three supervisors (medical and nursing faculty) of Institute, assisted in data collection. Furthermore, every 10th questionnaire was checked by supervisors.

Blood Pressure Measurement

Blood pressure was recorded in sitting position in right arm to nearest of 1 mm Hg with an Omron digital Blood pressure instrument. Participants were asked to sit quietly and rest for 5 minutes with uncrossed legs prior to measurement. Two blood pressure measurements were taken. Participants were asked to rest for three minutes between each of the reading. During data analysis mean of two readings were calculated. In case if there was discrepancy of more than 20 mm of Hg in first and second reading then third reading was taken and mean of second and third reading was calculated to assess blood pressure of participant. A trained observer, who was unaware of clinical status of study participants has recorded blood pressure.¹²

JNC VII guidelines¹² were followed for defining awareness, treatment and control of hypertension

Hypertensive: having SBP of 140mmHg or greater &/or DBP of 90mm Hg or greater or both or treatment with antihypertensives

- **Aware hypertensive** - subjects with prior diagnosis of hypertension/high BP will be considered as 'aware'.

- **Treated hypertensive:** those with current antihypertensive drug therapy as 'treated'; only pharmacological treatment will be considered as treatment including allopathic or any alternative medication

- **Regular treatment:** Patients taking their prescribed medication at least 6 days per week.

- **Controlled hypertensive:** subjects showing SBP<140, DBP<90, and taking antihypertensive medication

All the patients were provided reports of Blood pressure and were appropriately referred to medicine OPD of AIIMS, Rishikesh, if needing consultation.

Ethical approval for the study was obtained from Research and Ethics committee of Institute.

Results

Total 1946 participants were included in the study with 56.2 percent women and 43.8 percent men. 72.4 percent of the study participants were above 40 years of age and majority of them were living in nuclear families (58.5%). 30 percent of them were illiterate or educated upto primary level, while 14 percent of them were postgraduates. About one third of them were employed in formal sector and approximately half of them were student, homemaker and retired. Approximately 10% were self-employed.

Out of total 1946 screened, 39.1 percent (749) were found hypertensive. Out of those who were found hypertensive (749), less than half of them (326/749=43.5%) were aware of their status. Those who were aware of their status 87.1% (284/326) of them were under treatment. Those who were under treatment, 36.2 percent (103/284) were well controlled with given treatment (**Figure-1**). In this study it was also revealed that 75.3 percent (214/284) of those who were on treatment were taking it regularly (Rule of halves does not include this variable hence it is not included in the tables, but separately analysed).

Table 1 shows that men were 14 percent more hypertensive than women, while awareness of disease status was 18% higher in them. It was observed that more women (20%) were controlled on the given treatment than men. It is observed that gender is significantly associated with prevalence of hypertension, its awareness, treatment and control. Prevalence of hypertension increases with increasing age. Those who were in 20–40-year age group were least aware of their hypertensive condition. Here the age was significantly associated with only prevalence and awareness of hypertension.

Table 2 shows that hypertension is more prevalent among three generation families and all of them were receiving antihypertensive treatment, however controlled with given treatment was better in people living in nuclear and joint families. It is revealed that type of family is significantly associated with only awareness, not with treatment or control of blood pressure.

Table 3 shows that those who are illiterate or educated upto primary level have highest prevalence of hypertension. It is seen that educational status was significantly associated with awareness of hypertensive status with significant p value <0.05.

Table 4 shows that those who are retired have highest prevalence of hypertension. It is seen that employment status was highly significantly associated with hypertensive cases and its awareness in accordance with rule of halves with significant p value <0.05.

Table 5 shows important findings of Binary logistic regression analysis, which was applied to determine the independent role played by significantly associated independent variables with awareness of being hypertensive, treatment among those who are aware and control of hypertension in those taking treatment with antihypertensive. Model for prediction of awareness and those who are controlled on treatment was not statistically significant and could explain only 65% variability. Model could explain 83% of the variability in aware hypertensives on treatment after controlling the effect of confounders and model was statistically significant. It was revealed that gender is negative and significant (b=-0.84; p=0.04; OR 0.43 [CI 0.19-0.96]) predictor of controlled blood pressure in those who are on treatment and is less likely to be controlled than

the other category and the difference is statistically significant (0.04). For every one unit increase in the predictor the odds of being controlled in those taking antihypertensive changes by a factor of 0.432 with male

gender is less likely to be controlled than female gender. Other factors in the table were not important in predicting the awareness, treatment status and control of high blood pressure of the hypertensive participants in the absence of confounding factors.

Table- 1 Gender & age wise distribution of hypertensive cases in accordance with Rule of Half					
Gender	Total No. (%)	Hypertensive No. (%)	Hypertensive cases who were Aware No. (%) *	Aware cases being Treated No. (%) *	Cases on treatment having BP under control No. (%) *
Men	852 (43.8)	395(46.4)	142(35.9)	119(83.8)	30 (25.2)
Women	1094 (56.2)	354(32.4)	184(52.0)	165(89.7)	73(44.2)
Total	1946 (100.0)	749 (38.5)	326 (43.5)	284 (87.1)	103 (36.2)
Chi -square value p Value		39.4 0.001	19.5 0.001	2.5 >0.05	10.8 0.001
Age (in Years)	Total No. (%)	Hypertensive No. (%) *	Hypertensive cases who were Aware No. (%) *	Aware cases being Treated No. (%) *	Cases on treatment having BP under control No. (%) *
<20	18 (0.9)	0	0	0	0
20-40	823 (42.3)	181 (21.9)	38 (20.9)	27 (71.0)	13 (48.1)
40-60	708 (36.1)	323 (45.6)	147 (45.5)	128 (87.1)	45 (35.1)
>60	397 (20.4)	245 (61.7)	153 (62.4)	129 (84.3)	45 (34.8)
Total	1946 (100.0)	749 (38.5)	326 (43.5)	284 (87.1)	103 (36.2)
Chi -square value p Value		199.5 <0.0001	89.8 <.0001	5.8 0.06	1.84 0.4
*Percentages are calculate considering value in previous cell as denominator for depicting validity of rule of half.					

Table- 2: Type of family wise distribution of hypertensive cases in accordance with Rule of Half

Type of Family	Total number No.(%)	Hypertensive No.(%) *	Hypertensives whowere Aware No. (%) *	Awarebeing Treated No. (%) *	Cases on treatment having BP under control No. (%) *
Nuclear	1139 (58.5)	422 (37.0)	167 (39.6)	145 (86.8)	52 (35.8)
Joint	657 (33.8)	258 (39.3)	125 (48.4)	105 (84.0)	41 (39.0)
Three generation	150 (7.7)	69 (46.0)	34 (49.2)	34 (100.0)	10 (29.4)
Total	1946 (100.0)	749 (38.5)	326 (43.5)	284 (87.1)	103 (36.2)
Chi -square value		4.74	6.1	0.03**	1.05
p Value		0.09	0.046	0.872	0.6

*Percentages are calculate considering value in previous cell frequency as denominator for depicting validity of rule of half.
 † Joint and three generation families clubbed for calculating statistical significance

Table- 3: Educational status wise distribution of hypertensive cases in accordance with Rule of Half

Educational Status	Total number No.(%) *	Hypertensive No.(%) *	Hypertensive cases who were Aware No. (%) *	Aware cases being Treated No. (%) *	Cases on treatment having BP under control No. (%) *
Postgraduate& professional	268 (13.8)	102 (38.0)	32 (31.4)	26 (81.2)	6 (23.0)
Above primary to Graduate	1092 (56.1)	399 (36.5)	156 (30.1)	132 (84.6)	46 (34.8)
Primary or illiterate	586 (30.1)	248 (42.3)	138 (55.6)	126 (91.3)	50 (39.6)
Total	1946 (100.0)	749 (38.5)	326 (43.5)	284 (87.1)	103 (36.2)
Chi -square value		5.4	24.1	4.0	2.7
p Value		0.07	<0.0001	0.13	0.25

*Percentages are calculate considering value in previous cell frequency as denominator for depicting validity of rule of half.

Table- 4 Occupational status wise distribution of hypertensive cases in accordance with Rule of Half

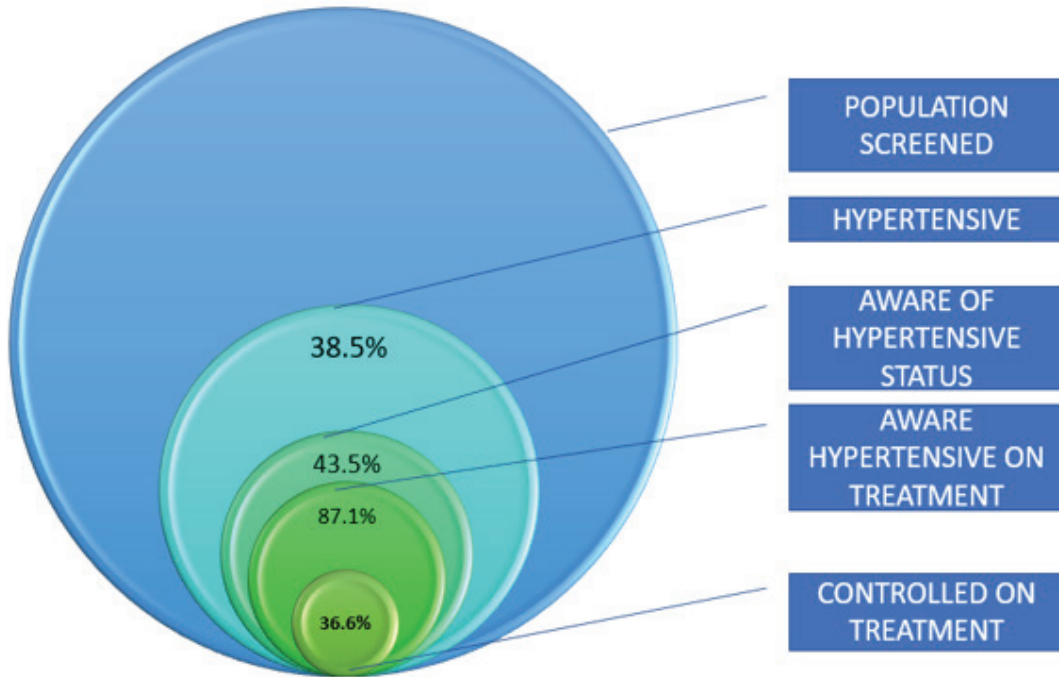
Occupation	Total No. (%)	Hypertensive No. (%)	Hypertensives who were Aware No. (%)	Aware cases being Treated No. (%)	Cases on treatment having BP under control No. (%)
Employed in formal sector	551 (28.3)	201 (36.5)	59 (29.3)	51 (86.4)	15 (29.4)
Unemployed	127 (6.5)	50 (39.7)	20 (40.0)	16 (80.0)	6 (37.5)
Student	69 (3.5)	8 (11.6)	0	0	0
Retired	110 (5.7)	76 (69.0)	39 (51.3)	34 (87.1)	8 (23.5)
Housemaker	765 (39.3)	275 (35.9)	150 (54.5)	131 (87.3)	57 (43.5)
Self employed	190 (9.8)	85 (44.7)	40 (47.1)	35 (87.5)	10 (28.5)
Laborer(Daily wages)	134 (6.9)	54 (40.3)	18 (33.3)	17 (94.4)	7 (41.1)
Total	1946 (100.0)	749 (38.5)	326 (43.5)	284 (87.1)	103 (36.2)
Chi -square value		48.6	34.7	1.8	7.5
p Value		<0.0001	<0.0001	0.87	0.18

*Percentages are calculate considering value in cell of previous row as denominator for depicting validity of rule of half.

Table- 5 Binary Logistic regression of independent variables as predictors for awareness, treatment, and controlled hypertensives in accordance with Rule of Half

	Awareness 65% prediction by Model 1 NS			Treatment 86.2% prediction by Model 1 significant			Controlled 65.9% prediction by Model 1 NS		
	β	OR (Confidence Interval)	p	β	OR (Confidence Interval)	p	β	OR (Confidence Interval)	p
Age group > 40 years	1.42	4.1 (2.4-7.0)	0.001	1.69	5.42 (1.7-16.4)	0.003	NS		
Gender	NS			NS			-0.84	0.43 (0.19-0.96)	0.04
Family type	NS			NS			NS		
Education	NS			NS			NS		
Occupation Self employed	0.80	0.44 (0.20-0.95)	0.03	NS			NS		

Fig 1. Diagram Representing Application Of Rule Of Half In Rural Adult Community At Dehradun [n=1952]



Discussion

Early detection and treatment for hypertension is a key strategy for cardiovascular diseases worldwide. The first step to early detection will always begin with the level of awareness about hypertension among the general population. Despite increasing effort by national and international health organizations for past several decades, awareness and management of high blood pressure still remains far from optimal^{10,13}.

The rule of halves in hypertension¹⁴ has long been used as a standard referral point for level of awareness and treatment in general population. Time and again the famous rule of halves has been challenged for its existence and relevance to prove its validity in view of the rapid development and improvement in the health care and health delivery systems. Its validation works on the surrogate assessment of awareness and management of high blood pressure. In context to increasing prevalence of hypertension in this mountain state of India our study focuses on establishing the validity of rule of half among rural population of Uttarakhand.

In our study of 1946 community dwellers of more than 19 years, hypertension was observed in 38.5% of screened population with higher preponderance in males than females (46.4% vs 32.4%). 21.9% of hypertensives were of the age group of less than 40 years suggesting rise in the risk factors for high blood pressure hypertension and vulnerability of this age group to hypertension.

The high prevalence reported in the present study reflecting the increase in trend of hypertension with increasing age group. A sharp increase in hypertension prevalence was observed from the fourth decade. Several studies have consistently demonstrated a positive relation between age and blood pressure¹⁵⁻¹⁹.

The observed prevalence of hypertension in rural Dehradun was higher than the national average of 27.6%¹¹ and Prospective Urban Rural Epidemiology (PURE) study in India which reported the prevalence of hypertension to be 30.7% and another large nationwide study (ICMR-INDIAB study) by Bhansali et al. revealed the prevalence to be 26.3% of the population.²⁰⁻²¹ Like our results, the study conducted by Agarwal AK

et al in Aligarh, Dwivedi S et al in Nanjagund taluk, Olatunbosun ST et al in urban Nigeria., Parekh et al in Vadodara district., Mahmood et al in Bareilly, Kokiwar et al in central India reported the rates of hypertension were higher in females than in males as opposed to the recent studies from other parts of India and other developing countries.²²⁻²⁷

Level of awareness of hypertension in our study was 43.5% and was proportionately low (20.9%) in younger age group of <40 years than in more than 40 years. Similar proportion of awareness was observed by study from Aligarh²⁸ in rural community of more than 40 years of age.

Validating the rule of half in community, our study on 1942 community dwellers observed the awareness among hypertensives was 43.5% out of which 87.1% were on treatment (76.1% on regular treatment) and only 48.1% were controlled at the time of screening (Fig 1). Almost similar pattern of rule of half was observed by study done by Deepa et al⁹ in southern India where a lower prevalence of hypertension was reported (21.1%) with 37% of hypertensive being aware. Less proportion of those who are aware were taking treatment (50%) and 40% of them were effectively controlled with the treatment. Similar to our finding a study in rural population of 160 screened participants in northern India observed a nearly similar prevalence of hypertension (41.9%) but in population of more than 40 years²⁸ with 40.3% of them aware of their high blood pressure. A much higher prevalence of hypertension (52%) was reported in urban study from Shimla²⁹ in 400 participants of ≥ 20 years with a high proportion of awareness among them (67%), although the proportion of them taking treatment (88%) and those who were controlled (35%) on the treatment was similar to our study finding. Study conducted in urban Mumbai which shows about 37.48% of total population is hypertensive, and 95.2% of the diagnosed were taking treatment. However, only 31.1% of those taking treatment were adequately controlled.³⁰

Going with the rule of half the proportion of awareness among hypertensives in our study was similar to that observed in study done by Deepa et al⁹ (40.3%) and Nafis Faizi et al²⁸ (40.3%) but lower than the study from urban community of Shimla (67%)²⁹. Similar to our finding of proportion of treatment (87%) in several

community studies in India^{28,29,30} the proportion of treatment among the population who are aware of hypertension was more than 50% with the rural community ~95% and urban 88%, which was observed to be defying the rule of half. Interestingly our study and that done in other part of India reports a higher level of awareness and treatment among hypertensives than a study conducted in the Northern China (29%) with only 20% on antihypertensive drugs of which 0.9% achieved control on blood pressure but in age group of >35 years¹⁹.

While our study finding observed a higher level of awareness across gender, several studies in northern and south India did not observe the finding^{28,29,9}. In our study occupation was significantly associated with the level of awareness and treatment among the hypertensives with homemakers being more aware followed by retired and self-employed. Such association was also observed by study from Shimla²⁹ and from southern India⁹. Education status was observed to be significantly associated with level of awareness with the primary and illiterate hypertensives being more aware and 39.6 percent controlled in those taking treatment as compared to 31.4 percent post graduate professionals who were aware of hypertension and only 23% of those taking treatment were controlled. These findings are contrary to most of the studies done in rural areas across Northern and southern India. Our study observed that Joint family and third generation family had better level of awareness of being hypertensive and better proportion having control of blood pressure in those taking treatment. Similar observation was made by the study done by Kanika Kaushal et al²⁹ in Himachal Pradesh where joint family was significantly associated with higher proportion of awareness, treatment, and control of blood pressure in treatment group. (χ^2 12.8; 0.002). The meta-analysis study shows the overall estimates for the prevalence of awareness, treatment, and control of BP were 25.3% (21.4–29.3), 25.1% (17.0–33.1), and 10.7% (6.5–15.0) for rural Indians¹¹. These studies had concluded that rule of halves is still prevalent in Indian scenario; however, our study findings are similar as far as the awareness regarding hypertension goes, but only 13.7% of total hypertensives present with control BP in our study.

Our study is unique as an important link of treatment to control of high blood pressure in population was studied which is the key to prevention of

hypertension. 76.1% of hypertensives who were aware were on regular treatment (Taking medicine at least six days per week). This suggests an increasing awareness of importance of regularity of treatment for this disease in the population of this region.

Predicting the independent role played by significantly associated independent variables with awareness of being hypertensive, age group of >40 years were more likely to be aware with odds of being aware to be 4.1 with a minor though significant contribution by the self-employed (OR=0.44). Female on treatment were able to predict the odds of controlled hypertensives more than males. None of the other predictors were able to explain the dependent on awareness, treatment and control outcome in absence of confounding factors.

Conclusion

In comparison to established rule of halves (50% are aware of hypertensive status, 50% are on treatment & 50% are controlled with treatment, Study revealed 40% are aware of their status, much more people (87%) were on treatment but lesser people (36.6%) were controlled. Age, gender, education, employment status was factors significantly associated with hypertension, but only age group of >40 years was found significant predictor for being aware and those on treatment and female gender for controlled on antihypertensive after adjusting the confounding factors.

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Evaluation of Survival of Mature Second Premolar with Periapical Lesion Following Different Regenerative Treatment Protocols: A Randomized Controlled Trial

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Abstract

Introduction: The aim of the present study was to compare the survival, periapical healing and regaining sensibility of necrotic mature second premolars with periapical lesion following treatment with two different regenerative protocols, Platelet Rich Plasma (PRP) versus Platelet Rich Fibrin (PRF) pulp regeneration. Both regenerative endodontic procedures were used for regeneration of pulp tissue in the root canal.

Methods: Twenty eight patients with mature, single canalled, necrotic, and asymptomatic second premolar with radiographic evidence of periapical lesion were included. At the first visit, the tooth was anesthetized, isolated and an access cavity was performed. Mechanical preparation of root canals was performed using the standardized technique reaching apical canal preparation to K-file size #40-60. Antibiotic paste was injected in canal, and the cavity was temporarily sealed. Two weeks later, regenerative procedures were performed by applying PRP (group 1) and PRF (group 2) in root canal and pulp chamber space. Collagen plug was placed directly over platelet concentrates followed by biodentin. Survival was defined as retention of the tooth in the arch at 12 months recall. Cone beam computed tomography assessments were done through recording of bone healing of periapical lesion and density of pulp chamber space at 12 months recall. The electric pulp test was used to record at 3,6,9 and 12 months follow-up.

Results: There was no statistically significant difference in survival of teeth and healing of periapical lesions between the two groups at 12 months recall. Readings of sensibility revealed statistically significant difference ($P < .0001$) between baseline and the 12-months follow-up, with no statistically significant difference between the two groups.

Conclusions: PRP and PRF combined with revascularization protocol were successful treatment modalities for survival of mature necrotic teeth and healing of periapical lesion. Platelet concentrates protocol is successful in regaining sensibility of necrotic teeth.

Keywords: Pulp Regeneration, pulp revascularization, mature teeth, pulp chamber.

Introduction

Regenerative endodontics has many confusing unanswered questions when it comes to treatment modalities and outcomes; therefore, it has attracted enormous attention and interest of researchers in the field of endodontics in recent years. Since the first attempts by Nygard Ostby¹, passing by the position statement released by the European Society of Endodontology² and

the American Association for Endodontists³, and till date pulp regeneration has been considered as the paradigm shift treatment in endodontics. Several case reports have documented revascularization of necrotic root canal systems by disinfection followed by establishing bleeding into the root canal system via over instrumentation. Although many case reports are largely from teeth with immature apices, it has been noted that reimplantation of avulsed teeth with an apical opening of

approximately 1.1 mm demonstrate a greater likelihood of revascularization.^{4,5}

Utilizing the microenvironment of the periradicular region for regeneration is dependent upon the spatial orientation of stem cells and signaling molecule on the suitable scaffold to achieve pulp regeneration. Recently platelet concentrates have shown their success in regeneration as they comprise increased concentration of growth factors and increase the cell proliferation over time when compared to the blood clot. The use of platelet concentrates aids in breaking down the robust assumption that pulp regeneration is only a treatment protocol for immature permanent tooth as mature roots lack proper connection with the periapical tissues due to narrow apical foramen.^{6,7}

Clinical regenerative endodontic treatment has focused on immature necrotic teeth, but it should be extended to mature teeth as an alternative to conventional endodontic treatment. There have been very few clinical reports attempting to revascularize pulp in the entire root canals of mature necrotic teeth.⁸⁻¹²

The use of bovine thrombin for the activation of Platelet Rich Plasma (PRP) has been an issue of controversy, as it requires non-autologous anticoagulant known to hinder the process of pulp regeneration. This led to the development of the second generation, Platelet concentrate known as Choukroun Platelet Rich Fibrin (PRF) which is totally autologous in nature¹³ Platelet rich fibrin was obtained by collecting a blood sample from patient then transferred into a test tube without anticoagulant and centrifuged immediately using a tabletop centrifuge at 2500 rpm for 10 minutes. Three distinct layers were formed in the tube: platelet-poor plasma at the top, a PRF clot in the middle, and red blood cells at the bottom.¹⁴⁻¹⁷

PRF is a natural fibrin-based biomaterial prepared from an anticoagulant-free blood harvest without any artificial biochemical modification that allows obtaining fibrin membranes enriched with platelets and growth factors. PRF by Choukroun's technique is derived from an autogenous preparation of concentrated platelets without any manipulation. When delicately pressed between two gauzes, the PRF clot becomes a strong membrane with high potential in clinical application¹⁸⁻²⁰.

Materials and Methods

This single-blind, randomized, controlled clinical trial was registered in the ClinicalTrials.gov database (NCT03635515). Based on the previous study by Narang et al. in 2015 the probability of positive pulp test among PRF is 0.2.

At the first visit, after the administration of the local anesthesia and rubber dam isolation, removal of carious enamel and dentin and access cavity was opened using round bur (size 3) and tapered stone with round end. Cleaning and shaping process started with confirmation of apical patency using K-file #15, and working length was determined using an apex locator and reconfirmed using radiograph.

Mechanical instrumentation was done using rotary M-pro system according to manufacturer's instruction; Orifice opener of tip #17 and taper of 8% was introduced to the coronal 2/3 of the canal, followed by files #20, #25, #35 with 6% taper to the full working length. Further apical preparation was done if needed using manual K-files #40-60, until clean dentin chips were obtained from the canal. Irrigation was done with total volume of 20 mL of 2% sodium hypochlorite, and 17% EDTA as a final flush.²¹⁻²⁴

The canal was dried with paper points, and an inter-appointment medication of bimix antibiotic paste, which was prepared by grinding one tablet of metronidazole (500 mg) and one tablet of ciprofloxacin (500mg), which were then mixed with saline to form a homogenous paste of reasonable creamy consistency. This mix is then injected into the canal to a level just below the cemento-enamel junction. Glass ionomer filling was used as a temporary restoration between visits, for proper coronal seal. The dressing remained for 14-21 days. In cases of flare up cases, another disinfection appointment was scheduled until the tooth is symptom free and the canal was dry.

In the second visit, complete removal of glass ionomer restoration was done, as well as the intracanal medication by the same irrigation protocol previously mentioned. Biodentin was used to replace the glass ionomer and build up the tooth, then access cavity was re-opened followed by preparation of a circumferential step at the level of pulp horns using a tapered stone with

flat end, this step acted as a support for collagen plug, which acts as a barrier between platelet concentrates and biodentin restoration as to restore pulp chamber space.

After access preparation and chemo-mechanical preparation, Randomization software was used to generate a list for random participant assignment as they were recruited. This randomization was performed by an operator not involved in the study into either of two groups:

- PRP Group, in which regeneration procedures was performed to regenerate both the root canal and pulp chamber space using platelet-rich plasma.

- PRF Group, in which regeneration procedures was performed to regenerate both the root canal and pulp chamber space using platelet-rich fibrin.

Regenerative endodontic procedures using Autologous platelet-rich plasma (Group 1, n=14)

This was performed by obtaining venous blood by venipuncture of the antecubital vein to be collected in sterile glass tubes with anticoagulant. After collecting venous blood, it has been centrifuged at 3200 rpm for 15 min to obtain the three layers: RBCs, 'buffy coat' and acellular plasma. The upper part of the acellular plasma is called platelet poor plasma (PPP) which was discarded. The remaining plasma is termed platelet rich plasma and was collected with a pipette. Then, fibrin polymerization was induced by adding 10% calcium chloride solution for 10-20 minutes to the PRP in order to form the PRP that was used immediately.²²

Regenerative endodontic procedures using Autologous platelet-rich fibrin (group 2, n=14):

A blood sample was taken as previously explained but without anticoagulant in 10-mL glass tubes, then immediately centrifuged for 10 mins at speed of 3000 rpm. The resultant product consists of the following three layers: top-most layer consisting of acellular plasma, platelet rich fibrin clot in the middle, and Red corpuscle base at the bottom.

In both groups, K-file #15 was introduced beyond the apex as to allow for bleeding then the platelet concentrates were introduced inside the canal. Platelet concentrates were placed till the level of the pulp horns

(i.e. the level of the circumferential step), upon which the collagen plug (Fig 1 A and B) and biodentin was placed, so as to allow for closure of access cavity. (Fig 1 C)

Clinical examination was done in follow up visits after 12 months to determine any defect in tooth structure, restoration and to check for signs of infection as sinus tract or swelling. Electric pulp tester was used to evaluate the sensibility of the teeth at 3,6,9 and 12 months follow up periods. Cone beam computed tomography was used to evaluate the healing of periapical lesion after 12 months follow up period.

Assessment of primary (survival) and secondary (clinical and radiographic) outcomes was done for each participant. Survival was defined as retention of the tooth in the arch at the time of the postoperative recall.²³⁻²⁶

Cone beam computed tomography assessments were done through the recording of the relevance of bone healing of periapical lesion and density of pulp chamber.

For restored pulp chamber space, post-operative CBCT images were acquired in DICOM format and assessed using a third party software: OnDemand3D App, cybermed, Seoul, Korea (version 1.0.10.5385). Region of interest module (ROI) was used to measure the average density of internal structure of pulp chamber.²⁷

For standardization of the ROI measurements two lines were drawn tangential to the buccal and lingual/palatal inner dentin surfaces on each selected cut. On these 2 tangents 2 lines were measured respectively each is 2.5 mm in length, then the borders of these 2 lines were joined to represent the ROI where the average radiographic density was measured using the OnDemand software.

Electric pulp tester was used to record if the intervention and comparator group teeth included in the study regained sensibility or not. Preoperative reading for the included teeth in the study was recorded to ensure pulp necrosis of the involved tooth. Readings were recorded preoperative and after 3,6,9 and 12 months.

Results

A total of 28 patients were recruited for this study between February and October 2017. All patients who

were recruited received their designated treatment. There was no significant difference in age of both groups (p=0.352). PRP group consisted of 6 females (42.9%) and 8 males (57.1%). PRF group consisted of 7 females (50%) and 7 males (50%). Chi square test revealed that the difference between groups was not statistically significant (p=0.71). PRP group consisted of 9 upper teeth (64.3%) and 5 posterior teeth (35.7%). PRF group consisted of 10 anterior teeth (71.4%) and 4 posterior teeth (28.6%). Chi square test revealed that the difference between groups was not statistically significant (p=0.69),

In PRP group, survival was observed in 13 cases (92.9%), with only one lower non-survived tooth. In PRF group, survival was observed in 13 cases (92.9%) with only one upper non-survived tooth. Chi square test revealed that the difference between groups was not statistically significant (p=1). (Table 1). In PRP group, healing was observed in 13 cases (92.9%), while one upper tooth showed no healing. In PRF group, Healing was observed in 13 cases (92.9%), while one upper tooth showed no healing. Chi square test revealed that the difference between groups was not statistically significant (p=1). (Table 2, Fig 2)

Regeneration of pulp tissue into Pulp chamber (Average density) was measured by hounsfield unit, the average density of ROI in PRP group was 200.6±27.38 and 198.0±20.6 in PRF group. Independent t test

revealed that the difference between both groups was not statistically significant (p=0.79). (Table 3, Fig 3)

According to the manufacturer’s electric pulp test instructions, diagnosis of a vital pulp is when the patient feels ache, tingling, or anesthesia with readings between 0 and 39. Diagnosis of a nonvital pulp is when the patient feels ache, tingling, or anesthesia with readings between 40 and 79. Finally, if the readings are 80 without ache, tingling, or anesthesia, the result is a tooth with necrotic nonvital pulp.

Comparison of sensibility results between groups at 3 and 6 months, reveled that there was no statistically significant difference between groups, as both recorded a median value of 80. At 9 months, a higher median value was recorded in PRP group. However, Mann Whitney U test revealed that the difference between groups was not statistically significant (p=0.46). At 12 months, a slightly higher median value was recorded in PRP group. However, Mann Whitney U test revealed that the difference between groups was not statistically significant (p=0.86). Comparison of sensibility results between groups at 3 and 6 months, In both PRP and PRF groups, the median value remained constant at 3 and 6 months, then gradually significantly decreased at 9 and 12 months, as revealed by Friedman and Wilcoxon signed Rank tests (p=0.00).(Table 4)

Table 1: Descriptive statistics and test of significance showing comparison of survival of both groups (Chi square test)

Group	SURVIVED		NOT SURVIVED		Total		
	Count	%	Count	%	Count	%	
PRP	13	92.9%	1	7.1%	14	100%	
PRF	13	92.9%	1	92.9%	14	100%	
P	1ns						

Significance level: p≤0.05, ns=non-significant

Table 2: Descriptive statistics and test of significance showing comparison of healing of both groups (Chi square test)

Group	HEALED		NOT HEALED		Total	
	Count	%	Count	%	Count	%
PRP	13	92.9%	1	7.1%	14	100%
PRF	13	92.9%	1	92.9%	14	100%
P	1ns					

Significance level: $p \leq 0.05$, ns=non-significant

Table 3: Descriptive statistics of average density results and test of significance showing comparison between groups (independent t test)

	PRP	PRF	Difference				t	P
			Mean	SD	C.I. lower	C.I. upper		
Mean	200.61	198.00	2.62	9.5	-17.1	22.3	0.28	0.79ns
Median	190.98	191.35						
Std. Deviation	27.38	20.61						
Range	92.65	69.65						
Minimum	175.68	160.70						
Maximum	268.33	230.35						

C.I.=95% confidence interval

Significance level: $p \leq 0.05$, ns=non-significant

Table 4: Descriptive statistics of sensibility results and test of significance showing comparison between groups and within the same group

Groups	3months	6months	9months		12months	P within the same group (Friedman test)
PRP	Mean	80.0a	80.0a	41.93b	33.50c	0.00*
	Median	80.00	80.00	35.00	29.00	
	Range	.00	.00	60.00	63.00	
	Minimum	80.00	80.00	20.00	17.00	
	Maximum	80.00	80.00	80.00	80.00	
PRF	Mean	80.0b	80.0a	36.71b	32.29b	0.00*
	Median	80.00	80.00	30.00	26.50	
	Range	.00	.00	59.00	60.00	
	Minimum	80.00	80.00	21.00	20.00	
	Maximum	80.00	80.00	80.00	80.00	
P Between groups (Mann Whitney U test)	1ns	1ns	0.46ns		0.86ns	-----

Significance level: $p \leq 0.05$, *significant, ns=non-significant

Wilcoxon signed rank test: Within the same group (row), means sharing the same superscript letter are not significantly different

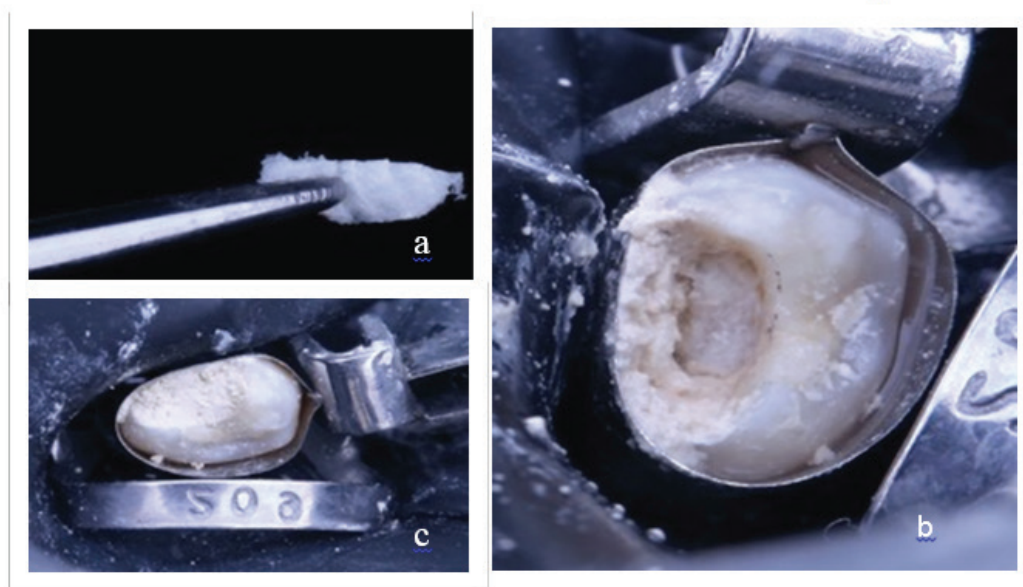


Figure 1: (a) photograph showing collagen plug that was cut to fit in access cavity. (b) photograph showing collagen plug placed over circumferential step. (c) intraoral photograph showing placement of Biodentin to seal access cavity preparatio

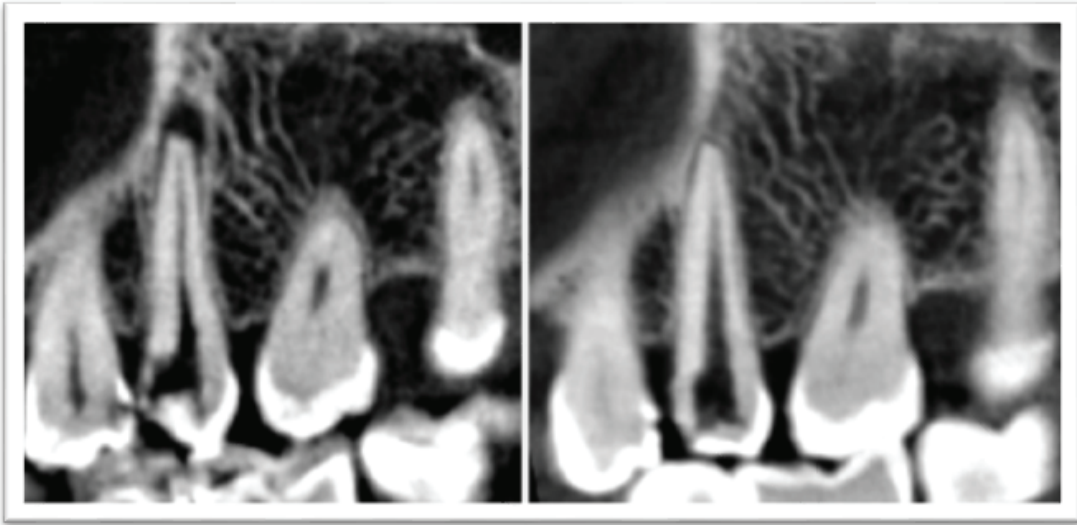


Figure 2: Pre-operative and Post-operative (1 year follow up) CBCT showing healing of periapical lesion related to upper left second premolar in sagittal plane.

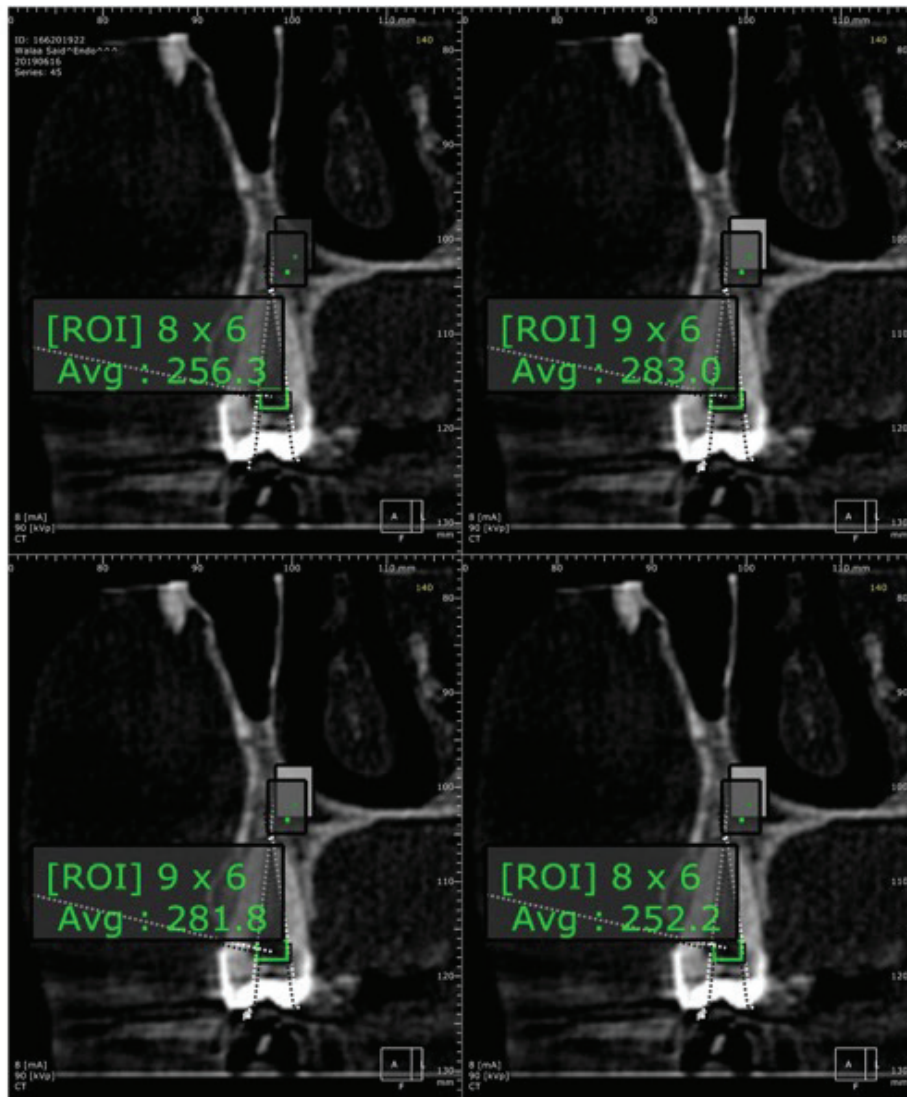


Figure 3: CBCT (coronal plane) showing average density of restored pulp chamber space (ROI)

Discussion

Maxillary or mandibular single canaled mature second premolars were selected as the teeth of choice in the present study. Each tooth is unique in; length, canal diameter and shape. Since apical constriction diameter of maxillary single canaled second premolars is variable from 0.40 mm to 0.80 mm, and mandibular single canaled second premolars is variable from 0.19 mm to 0.80 mm, therefore there is no standardized apical canal size.²⁸ Dentin removal appears to be the primary method for decreasing microorganism numbers. However, it may not be possible to remove bacteria that are deep in the tubules regardless of the technique. Irrigants are unable to reach the apical portion of the root if the canal is not enlarged to a size #35 or #40 file.²⁹ The larger preparation sizes have been shown to provide adequate irrigation and debris removal as well as significantly decreasing the number of microorganisms. There is a relationship between increasing the size of the apical preparation, canal cleanliness and bacterial reduction. Instrumentation techniques that advocate minimal apical preparation may be ineffective at achieving the goal of cleaning and disinfecting the root canal space.^{30,31}

Based on animal and human studies, it could be concluded that the size of the apical foramen does not have to be 1 mm in diameter for new tissue to grow into the canals after regenerative endodontic procedures. It was suggested that the width of apical foramen should be at least 1.1 mm to allow revascularization of a reimplanted human permanent central incisor.³²

Sodium hypochlorite (NaOCl) was the main irrigant in the current study. Its germicidal ability is related to the formation of hypochlorous acid when in contact with organic debris. Copious irrigation with a total volume of 20 ml of 2% NaOCl for 5 minutes with a closed end side-vented needle, to minimize the possibility of extrusion of irrigant into the periapical space. Although Concentration of 5.25 % NaOCl is a tissue solvent and antimicrobial agent, but it has a proteolytic action on the dentin collagen matrix; decreasing the elastic modulus and flexural strength of human dentin, while a 0.5% solution does not.^{33,34} Moreover, The reduction of intracanal microbiota is not any greater when 5.25% NaOCl is used as an irrigant as compared to 0.5%. Concerning REP, 5.25% NaOCl concentration was

found to be cytotoxic to stem cells in the apical tissues and decrease odontoblastic differentiation.³⁵ This indirect effect is likely related to various deleterious effects of NaOCl on the dentin matrix leading to decrease in release of dentin matrix-derived growth factors such as TGF- β 1, consequently reducing cell attachment. (Zhao *et al.* 2000) NaOCl was then flushed away from the root canal with saline in an attempt to reduce any lingering toxicity that can reduce the regeneration responses.³⁶

Inter-appointment medication of bimix antibiotic paste was used for disinfection, which was prepared by grinding one tablet of metronidazole (500 mg) and one tablet of ciprofloxacin (500 mg), which were then mixed with saline to form a homogenous paste of reasonable creamy consistency. This mix is then injected into the canal to a level just below the cemento-enamel junction.²¹ Triple antibiotic paste was not used in our study because several case reports and studies have shown that minocycline causes visible crown discoloration³⁷ and significant reduction in tooth fracture resistance^{38,39} as it causes demineralization of intertubular dentin by binding to calcium ions via chelation to form an insoluble complex and become incorporated into the tooth matrix causing the discoloration⁴⁰ and reduction in phosphate/amide ratio and microhardness of dentin. Also the acidity of TAP (PH = 2.9) is more than that of DAP (pH = 3.4) having more demineralization effect on the intertubular dentin, causing significant reduction in phosphate/amide ratio and decrease in the dentin microhardness and fracture resistance.⁴¹

Furthermore, a highly resistant and elastic membrane of fibrin is obtained, which does not dissolve quickly after application allowing cellular migration, cytokine entrapment, and slow continuous release of cytokines such as platelet derived growth factor (PDGF), transforming growth factor b1 (TGFb1), Fibroblast growth factor (FGF), and vascular endothelial growth factor (VEGF) from 7 to 28 days.⁴² These growth factors achieve peak level at 14th day coinciding with cell in growth so it directs more efficiently stem cell migration, proliferation, differentiation and supplements the angiogenesis.⁴³

In our study, electric pulp tester readings were obtained at 3,6,9,12 months follow up periods.⁴⁴⁻⁴⁵ There was no statistical difference between the two groups

in sensibility testing throughout the follow up period. Moreover our results showed early positive sensibility testing at 9,12 months recall, these results could be due to restoring of the pulp chamber space which was filled with revascularized tissue.

There was no statistical difference between PRP and PRF groups, with 92.9% successful periapical healing coinciding with that of Shivashankar and Keswani and Pandeywhom reported complete radiographic periapical healing following revascularization of immature teeth after 12 months.^{18,46}In addition, our results support the successful outcome of revascularization of mature teeth in the studies of Saoud where there was resolution of periapical lesion after 13-14 months, and 8-26 months respectively.^{10,11}

Cone beam computed topography was used to determine the average density of tissues in pulp chamber space (Region of interest) after 1 year follow up period. Our results coincide with and lies within the range of Nakashima in his studywho concluded that low-density area ranging from 0 to 425 was considered as the dental pulp.

Conclusion

Platelet rich plasma and platelet rich fibrin combined with revascularization protocol were successful treatment modalities for survival of mature necrotic teeth with periapical lesion. Platelet concentrates protocol is successful in regaining sensibility of necrotic teeth. PRP and PRF combined with revascularization protocol showed satisfactory healing of periapical lesions after 1 year follow up period.Both regenerative endodontic protocols (PRP and PRF) were successfulin regeneration of pulp tissue in pulp chamber of the treated tooth.

Ethical Clearance- Taken from ethics committee, Faculty of dentistry, Cairo University.

Source of Funding- Self funded research.

Conflict of Interest –Authors deny conflict of intrest.

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Pain, New Caries and Failure of Carious Primary Teeth after Application of Silver Diamine Fluoride Versus Sodium Fluoride Varnish: A Randomized Clinical Trial

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Abstract

Background: The aim of this study was assessment of the pain, new caries and failure of carious primary teeth after application of silver diamine fluoride versus sodium fluoride varnish immediately after application and after 3,6,9,12, months.

Methods: This study was performed on 62 children with 255 carious primary teeth. After proper selection according to eligibility criteria and proper diagnosis. They were randomly allocated (1:1) into two groups. Group I (SDF): 38% Silver Diamine Fluoride and group II (NAF): 5% Sodium Fluoride Varnish. Assessment of postoperative pain, new caries, and failure at baseline, after 3,6,9,12, months.

Results: Independent t-test was performed to compare between both groups and revealed that group II was significantly higher than group I after 9 and 12 months regarding postoperative pain, new caries, and failure. Also, strong positive significant correlation between failure and pain, and between failure and new caries was found using Spearman's correlation coefficient test.

Conclusions: SDF application is a successful alternative conservative treatment which eliminates the need to general anesthesia. Also, it is inexpensive, fast, and pain-free procedure but it causes discoloration. Its successful results regarding stopping progression of new caries compensate its drawbacks such as discoloration.

Keywords: *New caries, Early Childhood Caries, Conservative, Abscess, Pain*

Introduction

Dental caries is a dynamic, multifactorial, non-communicable disease. Although many children complain from untreated ECC as reported by FDI Oral Health Atlas, the present dental care delivery system

cannot manage the significant prevalence of ECC worldwide⁽¹⁾. Beside pain and infection caused by ECC, More importantly, poor dentition significantly affects children's nutrition and consequently their growth, development^(2,3).

Minimal invasive dentistry is a concept of patient care that prevents dental disease causes not only dealing with symptoms. Accordingly, health-promotion strategies demonstrated that FDI encourages the use of fluoride to prevent ECC in children^(4,5).

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Even though sodium fluoride (NaF) varnish is the most common material used in ECC prevention, Cochrane Collaboration revealed in his systematic review that 5% NaF varnish (22,600 ppm fluoride) application can reduce ECC development with 37% only which is insufficient percentage of reduction⁽⁶⁾.

For thousands of years, silver had been valued for its antimicrobial properties. Combination between the silver powerful antimicrobial activity and the benefits of a high dose of fluoride resulted in new formula that precipitate and obstruct dentinal tubules. thus, it is considered a drug, paving the way for expedited approval of SDF^(9,10).

Silver diamine fluoride (SDF) is a brush-on liquid that stops dental caries lesions. SDF gained clearance from the U.S. Food and Drug Administration (FDA) as a Class II medical device in August 2014. SDF stops caries development by forming, on the tooth surface, a hard, black, impermeable layer which is resistant to decay and it is considered a sign of caries arrest. The success rate is similar for restorations placed under GA. (11,12).

In children with problems in communication and behaviors that can't be managed in a conventional procedure, the SDF treatment option will be helpful to avoid sedation and general anesthesia and the associated risks. Despite its esthetic hazards which considered as the main drawback of SDF^(13,14).

The AAPD (2020), urges researchers to conduct well-designed randomized clinical trials comparing the outcomes of SDF Silver diamine fluoride to know its ability to prevent new caries and pain. Although several systematic reviews support the effectiveness of SDF, they all show that further clinical trials are required to create protocols for ideal case selection and its use. Accordingly, this study was performed to evaluate its effect to prevent new caries progress and correlate it with post-operative pain and failure compared to NAF^(15,16).

Materials and Methods

Study design & Sample size calculation:

This randomized clinical trial (number NCT03557996) was conducted after approval of Research Ethics Committee was obtained from Faculty

of Dentistry– Cairo University (No. 18 -7-3). The sample size of 62 patients was calculated by using online power calculator [<https://www.sealedenvelope.com/power>].

Eligibility criteria

Children were recruited from outpatient clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University. Children were carefully assessed for eligibility to participate in our study. Accordingly, all selected children were with carious primary teeth high caries risk patients, uncooperative children and whom with financial barrier in accessing dental care. On the other hand, all children with spontaneous pain from caries, tooth mobility, pulpal infection, were excluded.

Randomization, allocation and grouping:

Patients included in current trial were randomly distributed in one of two groups (simple randomization 1:1 allocation ratio through:

- **Sequence generation:** by using Rndom.org. online software.

- **Allocation concealment:** 1:1 allocation ratio done using opaque envelop⁽²⁹⁾.

- **Patients grouping:**

Group I: (38%) Silver Diamine Fluoride applied every 6 months.

Group II: (5%) Sodium Fluoride Varnish applied every 3 months.

- **Blinding:** Assessors and statistical analysts were blinded.

Clinical procedure:

- **Diagnosis:**

Tactile examination at baseline and each recall visit, treated lesions were assessed for dentin color and hardness of treated lesions using gentle pressure with a probe⁽³⁰⁾.

Preparation of Children:

Patient assessment chart was filled with all outcomes. Informed consent with photos was obtained from parents

before SDF treatment. It described all the benefits and side-effects of SDF.

Clinical application:

In group I, to protect surrounding gingival tissues, cotton rolls were used to minimized potential pigmentation. SDF was applied directly to the affected tooth surface only, a gentle flow of compressed air was used for 1 minute at least and excess SDF was removed with gauze, finally the site was isolated for up to three minutes.

In group II, teeth were wiped with gauze, NaF was applied by painting a thin film on all teeth surfaces directly with a micro brush supplied with the varnish. Then child was instructed to close their mouth to set the varnish. Rinsing or suctioning immediately after application was not recommended.

Post-operative instructions:

In group I, no eating or drinking for 30 min. to 1 hour to improve arrest results, Also, parents were instructed to avoid rinsing after treatment, to brush their teeth with fluoridated toothpaste at night not immediately after

SDF application.

In group II, the child was advised not to brush or floss teeth for at least four hours after the treatment, to eat soft food for the remaining time of the same day, to brush his teeth with fluoride toothpaste from the next morning.

- Follow up:
 - o Reapplication of material:

In group I, reapplication was performed every 6 months, while in group II it was performed every 3 months. Also, SDF was applied to any new lesion appeared during follow up periods.

- o Data collection methods:

All the children were recalled after 3, 6, 9 and 12 months to assess progress of new caries, (tactile examination) and photographs, postoperative pain (detailed questionnaire) and related failure (abscess, pain, infection, swelling) in both groups.

Results

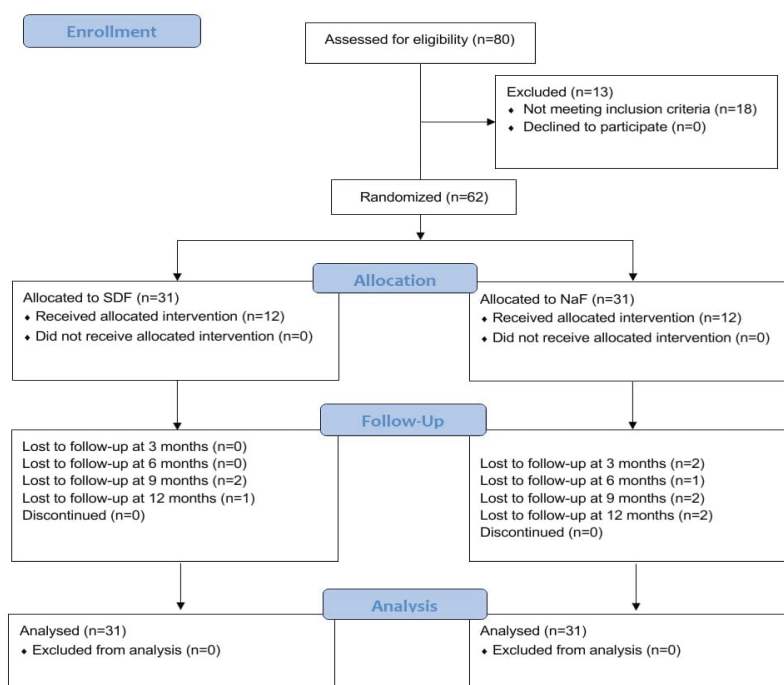


Figure (1): CONSORT flow diagram, showing patient flow during the trial

Patients flow during this clinical trial presented in figure (1). Data were collected, tabulated, statistical analysis performed using Statistical Package for Social Science (SPSS)® Ver. 24

All demographic of patients in both groups were compared and revealed insignificant difference as presented in table (1).

In post-operative pain, group I increased to 2.7% after 12 months. while in group II increased to 8.6% after 12 months as presented in table (2) and figure (2,3). Also, comparison between group I & II regarding pain existence among teeth was performed using chi square test which revealed statistical significant difference between them after 9 and after 12 months with a *p* value (*P*= 0.01*,0.03*) respectively as presented in table (2).

In New caries, in group I the highest new caries percentage was after 6 months 1.3%, then decreased to 0.6% after 12 months. While in group II, the highest percentage was after 12 months 8.5 % as presented in

table (3) and figure (2,3). Also, comparison between both groups regarding new caries at each follow up was performed by using chi square test which revealed significant difference after 9 months and after 12 months (*P*<0.5) as presented in table (3),

In failure, in group I the highest failure percentage was after 12 months 2.6%, while in group II, the highest percentage was after 12 months 8.5 % as presented in table (4) and figure (2,3). Also, comparison between both groups regarding failure at each follow up was performed by using chi square test which revealed significant difference after 9 months and after 12 months (*P* < 0.05) as presented in table (4),

Correlation between failure and pain was performed using Spearman’s correlation coefficient which revealed strong significant positive correlation in both groups in all follow up visits. Also, it was performed between failure and new caries and revealed strong significant positive correlation in both groups in all follow up visits as presented in table (5).

Table (1): Demographic data (ages, gender chief complains and dental history) of group I & II:

		Group I		Group II		P value
		N (31)	%	N (31)	%	
Age	<4 years	6	19.4	7	22.6	0.4
	4-5 years	23	74.2	22	71.0	
	>5 years	2	6.5	2	6.5	
Gender	Male	20	64.5	14	45.2	0.3
	Female	11	35.5	17	54.8	
Chief complaint	Esthetics	10	32.2	12	38.7	0.5
	Discomfort	12	38.7	14	45.2	
	Others	9	29	5	16.1	
Dental history		13	41.9	7	22.6	0.6

Group I: 38% Silver Diamine Fluoride SDF.

Group II: 5% Sodium Fluoride Varnish NaF.

N; count

%; Percentag

Table (2): Pain existence among teeth in both groups

Pain / tooth	Group I		Group II		P value
	N	%	N	%	
Baseline	0	0	0	0	1
3 months	0	0.0	2	1.9	0.09
6 months	3	2.0	0	0	0.9
9 months	0	0.0	6	5.6	0.01*
12 months	4	2.7	9	8.6	0.03*

*N; count**%: percentage***significant ($p \leq 0.05$)***Table (3): Comparison between both groups regarding new caries:**

New caries	Group I		Group II		P value
	N	%	N	%	
Baseline	0	0	0	0	1
After 3 months	0	0	2	1.9	0.3
After 6 months	2	1.3	0	0	0.2
After 9 months	0	0	6	5.7	0.006*
After 12 months	1	0.6	9	8.5	0.003*

*N; count**%: percentage***significant ($p \leq 0.05$)***Table (4): Comparison between group I & II regarding failure:**

Failure	Group I		Group II		P value
	N	%	N	%	
Baseline	0	0	0	0	1
After 3 months	0	0	2	0.9	0.2
After 6 months	3	2.0	0	0	0.14
After 9 months	0	0	6	5.7	0.03*
After 12 months	4	2.6	9	8.5	0.03*

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

Table (5): Correlation between failure & pain and between failure & new caries in both group during follow up:

Failure	Pain		New caries	
	Group I r (P)	Group II r (P)	Group I r (P)	Group II r (P)
After 3 months	0.98 (0.00*)	0.89(0.00*)	0.82(0.00*)	0.71(0.00*)
After 6 months.	0.91 (0.00*)	0.87 (0.00*)	0.72(0.00*)	0.66(0.00*)
After 9 months.	0.99 (0.00*)	0.79 (0.00*)	0.78(0.00*)	0.76(0.00*)
After 12 months	0.90 (0.00*)	0.84 (0.00*)	0.85(0.00*)	0.79(0.00*)

Group I: 38% Silver Diamine Fluoride SDF. Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference.

r: spearman`s correlation.

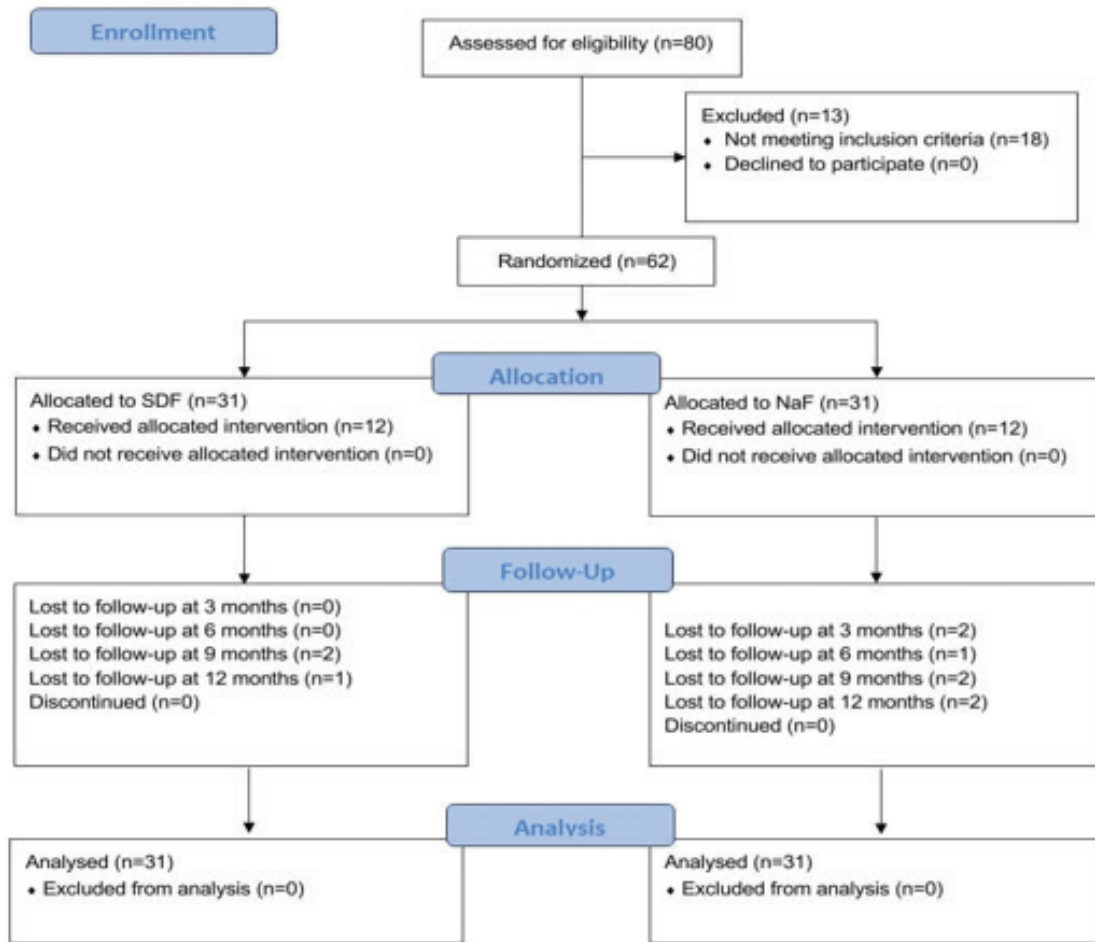


Figure (1): CONSORT flow diagram, showing patient flow during the trial

Patients flow during this clinical trial presented in figure (1). Data were collected, tabulated, statistical analysis performed using Statistical Package for Social Science (SPSS)® Ver. 24

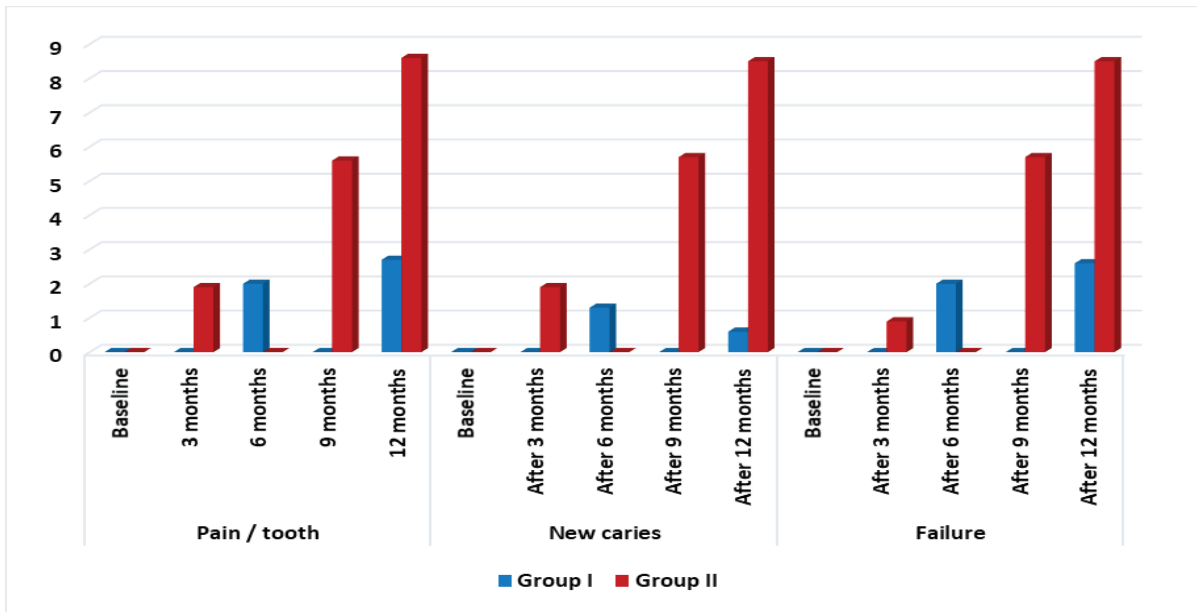


Fig (2): Pain existence among teeth, new caries, and failure in both groups during follow up

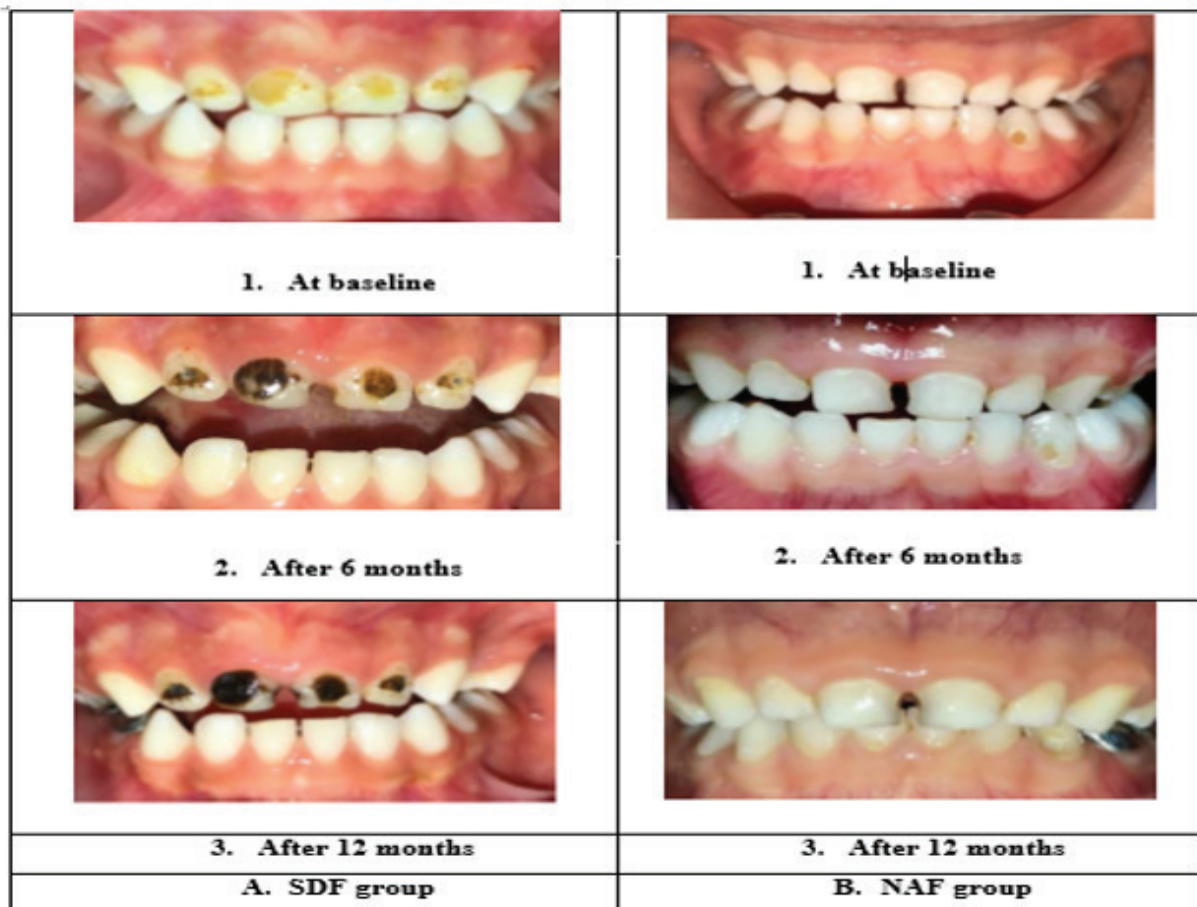


Figure (3): Group I (SDF) and group 2(NAF) at baseline and after 6 and 12 months

Discussion

Treatment of ECC in very young children is great challenge, as very young children can't cooperate during procedures of conventional dental treatment⁽¹²⁾. Therefore, researchers should develop evidence-based approaches to look for a less invasive effective management technique like SDF varnish as conservative approach controlling caries to avoid general anesthesia⁽¹³⁾.

Some researchers have also encouraged for SDF therapy as an important prevention-centered caries-management approach in very young children. Nevertheless, a literature search in PubMed and ClinicalTrials.gov databases revealed that no well-designed clinical trials have assessed postoperative pain over than three months and related between failure and new caries⁽¹¹⁾.

Biannual application of 38% SDF revealed more successful than application once per year in caries control. Other studies confirmed that for children with bad oral hygiene, caries arrest rate can be increased by increasing the frequency of application from annually to semiannually^(14,16).

Because 5% NaF varnish is considered a standard of care for preventing ECC, 5% NaF was used as a positive control group because every enrolled child should have the right to receive an effective preventative strategy. Application every 3 months was adopted for NaF varnish, because this study is recommended for children with high caries risk, meanwhile it has less toxic dose than SDF⁽¹⁷⁾.

Application was done without removal of carious tissues because there is no evidence proved that excavation prior to application affects their ability to arrest caries.^(18,19,20) A protective coating of vaseline was used to avoid the possible transitory henna-appearing tattoo that may occur if SDF contacted tissues^(23,24).

Pain existence in this study was due to failure of caries arrest of the lesion, extension of decay leading to abscess leading to tooth failure, it may be attributed to that some children missed their follow up and their re-application, others did have not followed oral hygiene measures properly. There were few available

studies measuring pain, eligible teeth were selected with no radiographs due to young age and severely uncooperative children, this might lead to accurately assess the proximity of caries to the pulp in some cases.

Only two studies assess the adverse effect of SDF. The first one concluded that the incidence of pain either in teeth or gum as apparent by patients and reported by parents. The second one is reported at three months follow up period the prevalence of tooth pain as perceived by patients and reported by parents, there was insignificant statistical difference in oral pain among groups in all follow up periods⁽²³⁾.

In new caries, group I was significantly better than group I after 9,12 months^(26,27). Our findings also are consistent with the other study which reported that a 38% SDF solution was significantly more effective for caries prevention in primary teeth than the other group⁽³⁴⁾.

Even though the progress of new caries may be decreased after SDF application, but there are no studies have confirmed an absolute reduction. A recent systematic review reported that there is inadequate prove that SDF prevents caries in primary dentition especially in coronal part⁽³⁰⁾. Therefore, it is prudent to highlight the great effect of preserving good oral hygiene with SDF for ECC treatment⁽²³⁾.

Regarding failure, group II, comparison revealed statistical significant difference at 9 months and at 12 months. The following outcomes were considered to indicate treatment failure a yellow and, soft lesion, pain, or infection. On the other hand, it found that high failure rate was in SDF group. The only explanation for this is the younger age group, higher caries experience, compromised oral-health related behaviours⁽³¹⁾.

Conclusion

- SDF is a simple & economical alternative curing method for uncooperative children.

- Biannual application of 38% SDF is more effective than that of 5% NaF varnish.

- Staining of teeth can be accepted if eliminated pain, general anesthesia or hospitalization.

Funding

The study was **self-funded**.

Competing Interests: No Conflict of Interest

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Estimating the Proportion of Bone Mineral Density Loss in Patients with Normal Kidney Function among South Indian Population

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Abstract

Background: Bone Mineral density (BMD) is considered as one of the golden tool to measure the bone quality in which two measurements namely T- Score and Z –score are used to report the BMD test results. Whenever there is deterioration of BMD it is associated with low skeletal mass. Creatinine is a chemical waste molecule that is generated from this muscle metabolism. Creatinine is a good marker for muscle mass. However, limited studies have been done which tell us the association between BMD loss and serum creatinine (SCr) levels.

Methodology: 200 participants who were referred for CECT abdomen and pelvis were scanned using 128 slice Philips Brilliance CT. Using BMD software, four different vertebral bodies from L1-L4 were taken and ROI was placed at the central portion of the trabecular bone, two reference ROI's, one in retro spinal muscle and one in fat tissue were also placed. To measure CT attenuation value, a ROI graphic tool was drawn at the trabecular bone. Average HU of BMD, T score and Z score values were taken from L1-L4.

Statistical Analysis: The data was analysed using SPSS version 16.0. For assessment of normal BMD values, the results of measurements were averaged for age, creatinine level, T score and Z score and descriptive statistics was calculated. Spearman's correlation coefficient was used to estimate the correlation between serum creatinine with T score and Z score.

Results: T Score and SCr correlated negatively at -0.25. The correlation between Z Score and SCr was also negatively correlated at -0.187.

Conclusion: It was evident from the study findings, that there is a non-association between SCr and T Score levels which showed that BMD of a person was not associated with normal kidney function. Thus, SCr levels cannot be used as a biomarker for osteoporosis or osteopenia.

Keywords: Bone mineral density, T score, serum creatinine, Quantitative computed tomography, Hounsfield unit

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Introduction

BMD reflects the bone rigidity which is a result of the calcium and phosphorus deposits. It is considered as one of the golden tool to measure the bone quality and density⁽¹⁾. Measuring the BMD from axial and appendicular skeleton helps to assess the reason for the shrinkage of bone with age⁽²⁾. Quantitative computed

tomography (QCT) is a reputed technique used to measure the BMD in the axial skeleton which can be further used for the evaluation of risk with fractures in the vertebra, degree of bone loss, follow-up of osteoporosis and other bone related metabolic ailments⁽³⁾. The measurements named, T Score and Z Score are being used to report BMD test results. Deterioration of BMD is associated with low skeletal mass⁽⁴⁾. SCr levels can be used as a marker to assess muscle mass in subjects with normal renal function⁽⁵⁾. Therefore, SCr levels could be directly proportional to BMD⁽⁶⁾. Subjects with poor renal function have significantly lower BMD, than those with mild-to-moderate CKD who don't have a very significant loss⁽⁷⁾.

The relationship between SCr levels and BMD remains unexplored and its findings might help to test the efficiency of the QCT machine and its BMD software.

Methods

The study protocol followed was reviewed and approved by the Research Committee, and ethical clearance was also obtained. All the subjects provided written informed consent to participate after a detailed

explanation about the study was given by the principal investigator.

Subjects

This was a cross sectional study. A total of 200 patients who were referred for CECT of abdomen and pelvis scans, were recruited. Patients above 20 and below 60 years of age with a creatinine level in the range of 0.7 - <1.2 mg/dl were included in the study. Patients below 20 years and above 60, with fractures in spinal vertebra (L1-L5), implants in the spine, osteoporosis, osteopenia or anydiseases which causes low BMD , consumption of calcium supplementation andCKD and renal insufficiency were excluded from the study.

Image Acquisition/SCr reading

Images were acquired using Phillips Incisive 128 slice MDCT. CT images were acquired using a standard CECT protocol using the following image parameters as depicted in table 1. The serum creatinine values of each patient was collected from their blood reports available in the patient's file obtained 4 days prior to CECT.

Table 1. BMD image acquisition protocol

Resolution	Standard
Scan type	Abdomen
Scan mode	Helical
Scan angle	180
Collimation	64x0.625
FOV	350
Thickness	5 mm
Increment	5 mm
Rotation time	0.75
KV	120
Mas	250
Matrix	512
Filter	Standard B
Window centre /width	60x360

BMD and corresponding HU values were analysed using the BMD software and stored in the Philips intellectual space portal workstation. BMD of lumbar spine using ROI's at (L1-L4) was measured and averaged from the reconstructed plain scan images, using phantom less BMD application as shown in figure

1. ROI's were drawn on the vertebra avoiding any bony pathologies and two reference ROI's were used: one in retro spinal muscle (+40 HU to +120 HU) and one in fat (0 - to -100HU). The complete T score and Z score was then taken into consideration as shown in figure 2.



Figure 1- BMD analysis at the lumbar vertebra with subcutaneous fat and Para spinal muscle as calibration references

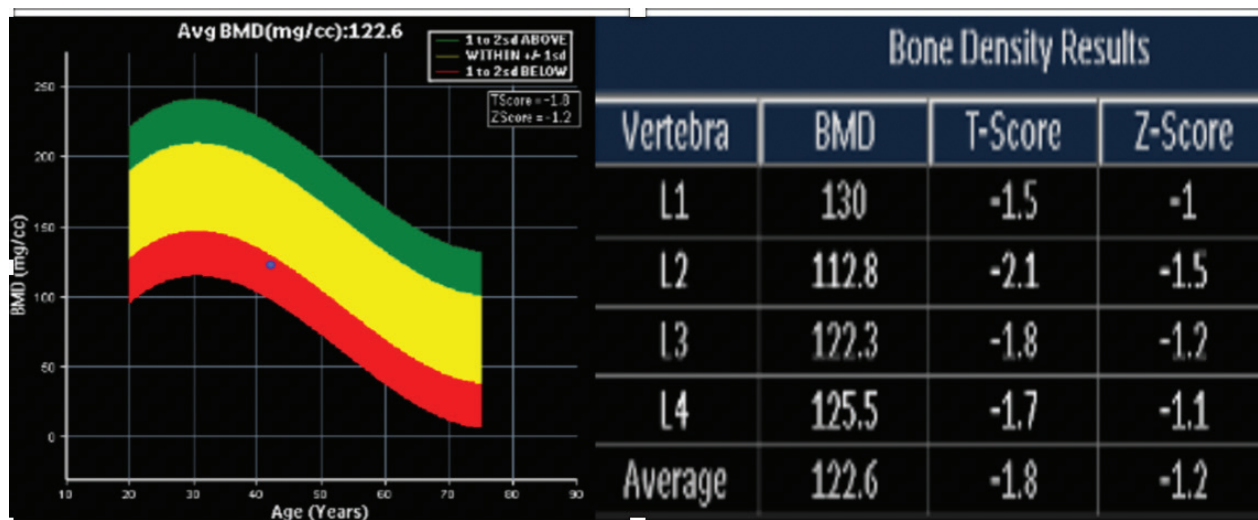


Figure 2- L1-L4 averaged BMD and their averaged Z score and T score

Statistical Analysis

All analyses were performed using the SPSS software package (version 16.0). The mean, standard deviation was calculated for Serum Creatinine, age,

Z score and T score. Median, Q1 and Q3 of T Score and Z Score was also analysed. Spearman's correlation coefficient was used to find the correlation between SCr with T Score and Z Score respectively.

Results

Demographic characteristics of the participants

Out of the 200 participants aged between 20-60 years, mean age was 39 + 11.6 and creatinine levels between 0.7-1.2 mg/dl with a mean of 0.87 + 0.16. 125 patients were males (62.5%) and 75 were females (37.5%).

Estimating the proportion of bone loss

105 patients had no bone loss (52.5%) and 95 had

bone loss (47.5%). Out of the 95 patients with bone loss 74 (77.8%) patients had osteopenia and 21 (22.2%) patients had osteoporosis. All these values were recorded prospectively. The evaluation of normal vs bone loss was done according to world health organization (WHO) set guidelines, which states that a T score between -1 and +1 is reflected as a standard, a T score of -1 to -2.5 is considered osteopenic and if the T score is -2.5 or lower is considered to be osteoporotic. The frequency and percentage of bone loss where “positive” indicates the presence of bone loss and “negative” indicates no bone loss as depicted in table 2.

Table 2. Proportion of bone loss

Loss	Frequency	Percentage
Negative	105	52.5
Positive	95	47.5
Total	200	100.0

SCr in relation to T Score and Z score

A mean T Score of -0.84+1.46 was found after analysing the BMD data. T Score and SCr showed negatively correlation at -0.25. SCr in relation to Z Score was also analysed with a mean of -0.08+1.3. The correlation between Z Score and SCr was negatively correlated at -0.187 as depicted in table 3.

Table 3. SCr correlation with T score and Z score

Age-Mean ±SD	SCr-Mean ±SD	T score-Mean ±SD	Z score-Mean ±SD	Median T score	Median Z score	Q1 T score	Q3 T score	Q1 Z score	Q3 Z score
39+11.6	0.87+0.16	-0.84+1.46	-0.08+1.32	-1	-0.25	-1.9	-1	-0.2	-0.7

Discussion

Osteoporosis being the one of the most common bone ailment, it has been affecting our societies from a very long time and is mainly described as the disruption of the equilibrium between bone formation and resorption⁽⁸⁾. Subsequently this loss of bony constituent creates changes in bone microarchitecture which markedly favours the incidence of fractures, all of

which makes it closely related with high morbidity and mortality rates⁽⁹⁾.

Reduction in skeletal muscle mass can be linked to decline BMD⁽¹⁰⁾. Since SCr can serve as an indicator for muscle mass, Huh et al assessed the association between SCr and BMD in an elderly population whose kidney function was normal and came to a conclusion that SCr imitated muscle mass, and low levels of SCr was related

to low levels of BMD independently⁽¹¹⁾. Greater muscle mass is said to be related to better results and long life in people with CKD states⁽¹²⁾. Proper lifestyle choices, facilitated by choosing a balanced diet and regular exercise can help improve an individual's maximum bone potential at an early age⁽¹³⁾. If there is a vitamin D receptor genotype variant such patients are susceptible to low bone density⁽¹⁴⁾.

Robert H et al., evaluated the linkage between BMD and fractures in partakers with or without CKD by taking health, age and body composition into consideration. They came to a conclusion that BMD values provided information pertaining to fracture risk in the elderly with or without moderate CKD⁽¹⁵⁾. Therefore, by looking at the values we can predict the risk of future fractures in such individuals irrespective of their renal health. Simerjot K Jassal et al., conducted a study to determine the relationship between kidney function and BMD and related it to bone loss, and osteoporotic fracture. They found that measured renal function had declined with age. They concluded that there is an associations between kidney function and BMD which is the strongest when CKD is high, which shows that if a patient has declining renal function the BMD values may be low⁽¹⁶⁾.

Myong Jun-Pyo Myong et al., conducted a study in Korea to find the relationship between BMD and CKD among general population in Korea and concluded that there was a link between eGFR and BMD in men and women. This study shows that if GFR decreases, there can be a decline in BMD. Therefore, there's higher risk of osteoporosis or osteopenia in people with reduced renal function⁽¹⁷⁾. Using modern therapy for osteoporosis, it is important to use newer pathogenetic approaches which aim towards the elimination of any imbalances between the relationship of osteoclast – osteoblast while using anabolic support of all bone cells. "Osteomed Forte" is a drug that complies these requirements⁽¹⁸⁾.

In this cross sectional study, 95 participants out of 200 were detected with bone loss (47.5%) and it was observed that most of the participants with bone loss were from the age range from (41-60) about 62.1%. Therefore, as age increases bone density decreases even with good renal health. We also evaluated the average of normal creatinine levels (0.87+0.16) with BMD and independently associated it with the average values of

T Score (-0.84+1.46) and Z Score (-0.08+1.32), and the principle finding was that T Score (-0.25) and Z Score (-0.187) were not associated with normal creatinine levels. A negative correlation between BMD and normal kidney function done by evaluating serum creatinine levels cannot give an explanation about the bone health of an individual.

QCT permits measurement of volumetric bone density without any superimposition of cortical bone and other surrounding soft tissue⁽¹⁹⁾. The site most commonly used to measure BMD using QCT is the lumbar spine. The trabecular bone is the main site for osteoporotic bone loss, therefore the density loss in that region is higher than that other sites like in cortical bone⁽²⁰⁾. Phantom-less CT scans can be used to estimate lumbar BMD with accuracy similar to that of dual energy x-ray absorptiometry (DEXA) scans which is considered a gold standard in detecting BMD. QCT is largely applied to both prospective and retrospective studies which can assess patient bone density and therefore can be helpful for research and clinical practice⁽²¹⁾. The QCT machine used for this study was Philips Incisive 128 slice CT. The Philips BMD software can therefore be used as an effective tool to diagnose osteoporosis/osteopenia. In this study we found that out of the 95 patients with bone loss 74 (77.8%) patients had osteopenia and 21 (22.2%) patients had osteoporosis. Moreover, we tested the efficiency of our MDCT system in evaluating BMD without any extra radiation, time and cost to the patient.

Conclusion

The present study has provided information about the relationship between Serum creatinine and T Score levels. It was evident from this study that there is a non-association between SCr and T Score levels which showed that BMD of a person was not associated with normal kidney function thus SCr levels cannot be used as a biomarker for osteoporosis or osteopenia. The results showed a loss in bone health in patients with good kidney function, this loss may be associated with other pathophysiological conditions other than normal SCr which weren't taken into account in this study.

'Declarations'

Ethics approval and consent to participate- The study protocol followed was reviewed and approved by

the Research Committee of Manipal College of Health Profession and Manipal Academy of Higher Education, and ethical clearance was also obtained by Kasturba Medical College and Hospital, MAHE, Manipal. A detailed explanation about the study was given by the principal investigator after which they provided consent for publication. All the patients included in this research gave written informed consent to publish the data contained within this study.

· Availability of data and material- The data has been uploaded as supplementary files in the upload section.

Competing Interests- The authors declare that they have no competing interests in this study.

Funding- Not applicable

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

Abbreviations:

BMD- bone mineral density

SCr- serum creatinine

ROI- region of interest

CECT- contrast enhanced computed tomography

HU- Hounsfield unit

QCT- Quantitative computed tomography

CKD- Chronic kidney disease

eGFR- estimated glomerular filtration rate

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Social Inequalities in Child Nutrition in Uttar Pradesh, India

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Abstract

Background: The various maternal and childhood well-being programs have been designed to address childhood malnutrition in India. The levels and the inequality in child nutrition are higher among economically poor and socially backward communities within the state.

Objective: To estimate and compare the inequality in child nutrition status across socio-demographic characteristics in the Uttar Pradesh state of India.

Methods: Data from the National Family Health Surveys (NFHS-4 & NFHS-3) was used for Uttar Pradesh – the most populous state of India. The nutrition status was assessed in terms of undernutrition (weight-for-age), stunted (height-for-age), wasted (weight-for-height) and anaemia level. Health inequalities indices, the absolute difference, Ratio, Population Attributed Risk, and Population Associated Fraction were calculated using WHO HEAT 2.0 software.

Results: The nutrition and anaemia levels vary according to background characteristics; however, the levels of undernutrition and anaemia among children were high in all groups. The wasting and anaemia levels were higher among younger children, whereas the proportion of underweight and stunted was higher in older children. The inequality indices showed a substantially higher burden of undernutrition among socially backward scheduled castes and tribes, and those residing in rural areas.

Conclusion: The study illustrated that despite the declining trend of childhood malnutrition in Uttar Pradesh, the socially backwards have a disproportionately higher burden of malnutrition. There is a need to reassess the ongoing nutritional programs concerning pervasive social inequality in child nutrition and anaemia level.

Key Words: Undernutrition, Stunting, Wasting, Anaemia, Uttar Pradesh, India

Introduction

Malnutrition among children has been a major public health problem globally, and especially in developing countries. It continues to exert a heavy toll and affect tens of millions of children¹ (UNICEF, 2019). Globally, the prevalence of child stunting and wasting in 2019 was 21.3 % (144 million) and 6.9 % (47 million) among under-

five children respectively². The 2019 edition of *The State of the World's Children* (SOWC) reported that despite progress in the last two decades, at least one-third of children are not getting the nutrition they need to grow well (stunted, wasted or overweight), and two-thirds are at risk of malnutrition and hidden hunger because of the poor quality of their diets¹. Asia is home to more than half of the total undernourished children in the world – it accounts for 54 % of all stunted children in the world³. Asia has shown progress in reducing the numbers of undernourished children. But in recent years, in South Asia, 58.7 million children under 5 years were stunted and 25.9 million were wasted in 2018, and contributed to 39.4 and 59.6 per cent of global stunted and wasted

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under five children⁴ In India, about 54% were not getting the nutrition they need to grow well (stunted, wasted or overweight) compared to 50 % in South Asia. India accounts for the highest proportion of stunting (38 %) and wasting (21 %) in the region⁴.

The prevalence of malnutrition among children in India has reduced, stunting to 38.4% from 48.0%, underweight 35.7% from 42.5% and wasting 22.9% from 34.2% during NFHS-3 (2005-06)⁵ and NFHS-4 (2015-16)⁶. However, India topped the list of the countries with the most number of stunted and wasted among under-five children. India is among 88 countries that are identified to miss global nutrition targets by 2025⁷. The evidence suggested that the country's progress is not on track to achieve the World Health Assembly (WHA) nutrition target for 2025 and the SDG Zero Hunger target by 2030^{1,2}. Malnutrition was the primary reason behind about 68 % of deaths of under-five children in India^{4,8,9}. However, the national patterns can cover up inequalities in nutrition indicators within the country and by socio-demographic characteristics. India has also been identified as one with the highest rates of domestic inequalities in malnutrition⁷ and child survival¹⁰. The malnutrition Disability-adjusted life years (DALY) rate was much higher in states with lower social development indicators and was recorded highest in the states of Uttar Pradesh^{8,10,12}. The stunting level in Uttar Pradesh is over 40% and their rate among individuals in the lowest income group is more than double those in the highest income group at 22.0% and 50.7%, respectively⁶. Also, stunting prevalence is 10.1% higher in rural areas compared to urban areas⁶. Elucidating social inequalities in nutritional indicators is pivotal for informed priority-setting, guiding the equitable distribution of resources and targeting interventions according to need. This paper examines social inequality in nutrition indicators by age and sex of child, religion and caste of the head of household and place of residence.

Material and Methods

Study site and population: The analysis was restricted only to under-five children to identify the inequality in the nutrition status in Uttar Pradesh state in the view of existing relatively very high malnutrition.

Data: The data for the present analysis is taken from published reports of NFHS-4 (2015-16)⁶ and NFHS-

3 (2005-06)⁵. The National Family Health Surveys provide information on population, health, and nutrition for India and each state and union territory.

Outcome variable:

Anthropometric measurement – Three anthropometric indices viz. underweight (weight-for-age), stunted (height-for-age), and wasted (weight-for-height) were used to classify the malnourished among under-five children. In the NFHS survey Z-scores for weight-for-age (WAZ), height-for-age (HAZ), and weight-for-height (WHZ) were calculated using 2006 WHO standards or reference¹³. Children whose weight-for-age is below -2 SD from the reference population median were classified as underweight; Stunting was calculated based on height-for-age. Z-score (HAZ) below -2 SD from the median of the WHO reference population. The wasting was calculated using weight-for-height and children below -2 SD from the reference median^{6,13}.

Anaemia - Anaemia was classified into four categories - mild, moderate, severe or not anaemic with respective cut-off values of anaemia were 10.0–10.9 g/dl (mild), 9.0–9.9 g/dl (moderate), < 9.0 g/dl (severe) and ≥ 11 g/dl (not anaemic). Further, for the analysis, it was grouped dichotomously as < 11 g/dl (anaemic) and ≥ 11 g/dl (not anaemic).

Statistical Analysis: The analysis was performed using SPSS.20 statistical software and MS Excel. Further, health inequality indices were computed using WHO HEAT software 2.0^{14,15}. Four inequality indices, the absolute difference (D), Ratio (R), Population Attributable Risk (PAR), and Population Attribution Fraction (PAF) were computed with a 95% confidence interval. i). **Absolute Difference (D)** - The absolute difference is a simple, unweighted measure of inequality that shows the absolute inequality between highest and lowest subgroups values, $D = Y_{high} - Y_{low}$ ii). **Ratio (R)** – The ratio is a simple, unweighted relative measure of inequality that shows the relative inequality between highest and lowest subgroups values, $D = Y_{high} - Y_{low}$. ii). **Population Attributable Risk (PAR)** – PAR is a complex, weighted measure of inequality. This explains the potential of improvement in a health indicator if all subgroups reached the same level of health as a reference subgroup. PAR is calculated as the difference between

the estimate for the reference subgroup Y_{ref} and the average μ , $= Y_{ref} - \mu$. iv). **Population Attributable Fraction (PAF)** – The PAF is a complex, weighted relative measure of inequality. It shows the relative potential of improvement in a nutrition indicator that could be achieved if all subgroups reached the same level of health as a reference subgroup. The PAF is calculated by dividing the population attributable risk (PAR) by the average value μ and multiplying the fraction by 100, . $PAF = PAR / \mu * 100$.

The higher value of D and R indicates higher absolute inequality, and the zero value of absolute difference and one of the ratio indicates the existence of no inequality. Similarly, the larger values of PAR and PAF indicate a larger degree of inequality. The zero value of PAR and one of PAF indicates that all subgroups have reached the same level of health as the reference subgroup.

Results

Malnutrition among children

In the NFHS-4 survey, 40% and 12% of children under five years of age were underweight and severely underweight respectively. Forty-six per cent and 21% of children under five years of age were stunted and severely stunted respectively. Eighteen per cent were wasted or too thin for their height, and six per cent of children were severely wasted. The children’s nutritional status in Uttar Pradesh had improved since NFHS-3 by some measures, but not by all measures.

Stunting decreased from 57% to 46% in the 10 years between NFHS-3 and NFHS-4, and the percentage of underweight children decreased marginally from 42% to 40%. However, in the same period, wasting increased from 15% to 18%. Thus, despite recording gains in stunting and underweight during the last decade, child malnutrition is still a major problem in Uttar Pradesh state (Figure 1). There were only small differences in the level of undernutrition by the age and gender of the child. The proportion of underweight and stunted was lowest for youngest children (<12 months), but they were having the highest wasting (weight for height). Male children (19%) recorded more wasting compared to female children (16.6%). Children born in Schedule Caste (SC) and Scheduled Tribe (ST) households were relatively more malnourished compared to children belonging to other castes households (Table 1). No differences in child nutrition were observed by the religion of the head of household. But children from rural areas were relatively more underweighted (41%) compared to urban (33.7%) areas, however, there was no difference in severely underweighted children by place of residence. In the case of stunting, more rural children were stunted (48.5% vs 37.9%) and severely stunted (22.7% vs 15.4%) compared to their urban counterparts, however, and no such difference was observed in the case of wasting.

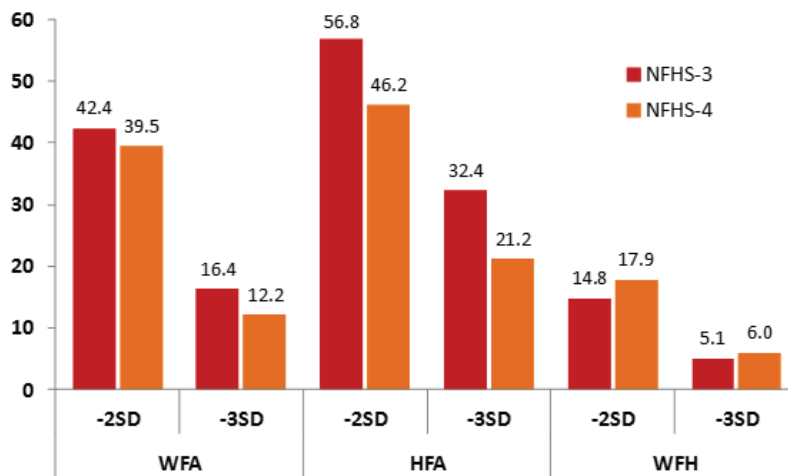


Figure 1: Level of malnutrition among children (0-59 months) in NFHS-3 and NFHS-4

Anaemia among Children

Anaemia is a condition that is marked by low levels of haemoglobin in the blood. Iron deficiency is estimated to be responsible for about half of all anaemia globally, but anaemia can also be caused by malaria, hookworm and other helminths, other nutritional deficiencies, chronic infections, and genetic conditions (NFHS-4).

Among children aged 6 and 59 months, more than three-fifth (62.2%) of children were anaemic, including 26.4% mildly anaemic, 34% moderately anaemic, and 2.4% suffering from severe anaemia. The level of anaemia had declined from 73.9% in NFHS-3 to 62.2% in NFHS-4 and severe anaemia level declined from 3.6% in NFHS-3 to 2.4% in NFHS-4 (Figure 2).

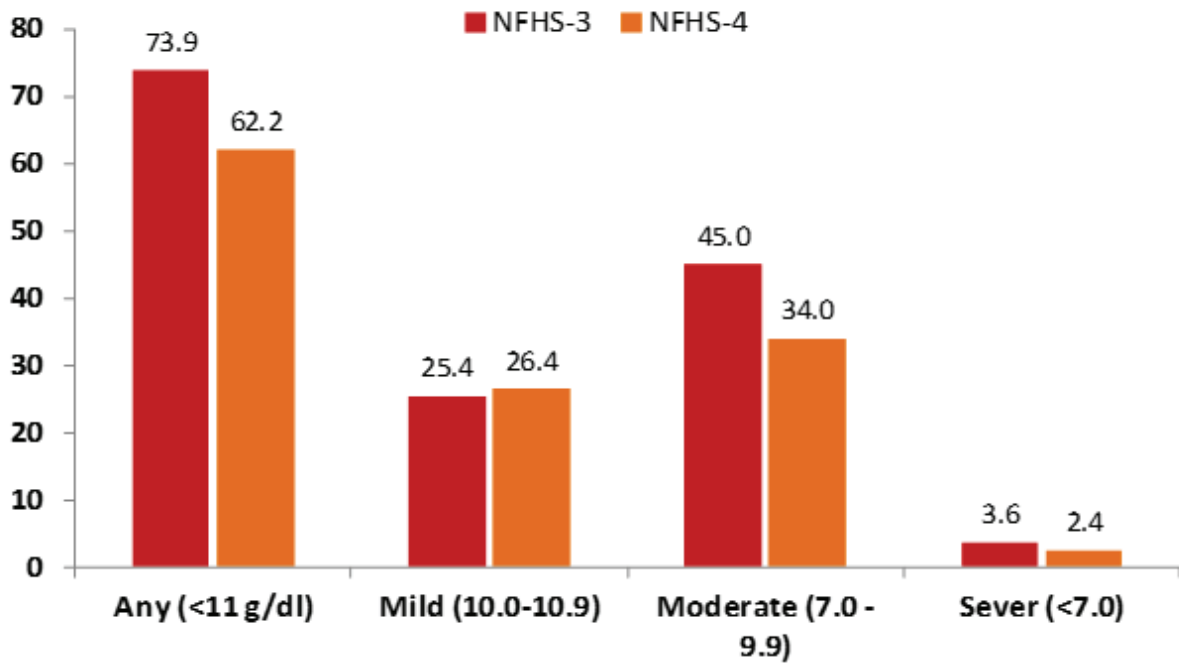


Figure 2: Level of anaemia among children (6-59 months) in NFHS-3 and NFHS-4

The level of anaemia (<11 g/dl) declined by age of children, more than three-fourths of children of age group 12-23 months were anaemic compared to about half of children aged 36-59 months. There was no difference in the prevalence of anaemia among girls and

boys. Similarly, caste wise no difference was observed in the anaemia level, except Scheduled tribe children who had a slightly higher prevalence of anaemia (65.7%). Children belonging to Muslim households and residing in urban areas were relatively more anaemic.

Table 1: Prevalence of underweight (weight-for-age), stunted (height-for-age), wasted (weight-for-height) and anaemia among under-five children by background characteristics, NFHS-4

Background characteristics	Underweight (Weight-for-Age)		Stunted (Height-for-Age)		Wasted (Weight-for-Height)		Anaemia (<11.0 gm/dl)	Sample
	-3SD	-2SD	-3SD	-2SD	-3SD	-2SD		
Child Age								
<12	11.1	31.7	10.6	21.7	12.5	29.5	71.4	7047
12-23	12.9	40.1	23.9	50.4	6.2	20.2	77.1	7396
24-35	13.5	42.0	25.1	54.1	4.8	15.1	69.4	7319
36-59	11.8	41.5	22.9	50.9	3.5	12.8	51.4	15398
Gender								
Male	12.3	39.4	21.6	46.3	6.6	19.1	63.2	19505
Female	12.1	39.6	20.8	46.2	5.4	16.6	63.1	17655
Caste								
SC	14.1	44.4	25.0	52.3	6.6	18.6	63.4	9413
ST	14.6	46.0	26.2	50.9	7.6	22.3	65.7	580
OBC	12.4	40.2	21.1	46.5	5.8	18.0	62.9	20226
Others	8.7	30.0	15.7	36.7	5.4	16.2	63.3	6848
Religion								
Hindu	12.1	39.4	21.2	46.1	6.1	18.0	61.8	29243
Muslim	12.5	39.7	21.2	46.5	5.6	17.5	68.4	7917
Place of Residence								
Urban	10.2	33.7	15.4	37.9	6.6	18.0	65.0	7768
Rural	10.7	41.0	22.7	48.5	5.8	17.8	62.7	29392
Total	12.2	39.5	21.1	46.2	6.0	17.9	63.2	34357

Inequality in child nutrition and anaemia level

The inequality in child nutrition level is studied using four outcome indicators viz. underweight (< -2SD), stunting (< -2SD), wasting (< -2SD) and any anaemia (<11 g/dl). Although nutrition and anaemia levels vary somewhat according to background characteristics, these remain widespread in all groups. In the case of underweight (weight for age), there was an absolute difference of about 10% point and the ratio of 1.3 between the highest and the lowest prevalence of underweight among age-groups. The value of PAR and PAF were 7.8 and 19.7 respectively, indicating a significant decline of 7.8 % points, and 19.7% decline in underweight level if the level of malnutrition in all age groups brought down to the level of the reference group (<12 months). There was no significant difference in underweight level by gender of child and religion of the head of household. But the level of underweight varied

by caste and place of residence, and there would be a decline of 9.5 and 5.8 % points if the level of underweight brought down to the respective level of underweight among 'other castes' and urban. In the case of stunting (height for age), the absolute difference was even much larger (32.4 % or a ratio of 2.5) between the level of stunting among children in the age group <12 months and 24-35 months. The PAR and PAF values were 24.2 and 52.8 respectively, indicating that if the percentage of stunting could be brought down to a level of that in <12 months for all age groups, a decline of 24.2% points or 52.8% decline in stunting could be achieved. But there was no significant difference in stunting by gender and religion. However, stunting varied considerably by caste and place of residence, and a decline of 9.5 and 8.4 % in overall stunting could be achieved if the level of stunting could be brought down to the level of that among 'other castes' and urban respectively.

Table 2: Inequality indices for underweight (< -2SD), stunted (< -2SD), wasted (< -2SD) and anaemic (<11 gm/dl) among under-five children by background characteristics in Uttar Pradesh, NFHS-4

Characteristics	Index	Underweight (Weight-for-Age)	Stunting (Height-for-Age)	Wasting (Weight-for-Height)	Anaemia
Child age	D	10.3 (8.8 – 11.9)	32.4 (30.9 – 33.9)	16.7 (15.5 – 17.9)	25.7 (24.5 – 26.9)
	R	1.3 (1.3 – 1.4)	2.5 (2.4 – 2.6)	2.3 (2.2 – 2.4)	1.5 (1.5 – 1.5)
	PAR	7.8 (6.8 – 8.8)	24.2 (23.3 – 25.1)	5.1 (4.6 – 5.5)	12.5 (11.9 – 13.1)
	PAF	19.7 (17.2 – 22.2)	52.8 (50.8 – 54.7)	28.4(26.0 – 30.9)	19.5 (18.6 – 20.4)
Sex	D	0.2 (0.8 – 1.2)	0.1 (-0.9 – 1.1)	2.5 (1.7 – 3.3)	0.1 (-0.9 – 1.1)
	R	1.0 (1.0 – 1.0)	1.0 (1.0 – 1.0)	1.2 (1.1 – 1.2)	1.0 (1.0 – 1.0)
	PAR	0.1 (-0.4 – 0.6)	0.1 (-0.5 – 0.6)	1.3 (0.9 – 1.7)	0.1 (-0.5 – 0.6)
	PAF	0.2 (-1 – 1.4)	0.1 (1.0 – 1.3)	7.3 (5.0 – 9.6)	0.1 (-0.7 – 0.9)
Caste	D	16.0 (11.8 – 20.2)	15.6 (14.1 – 17.1)	6.1 (2.6 – 9.6)	2.8 (-1.1 – 6.7)
	R	1.5 (1.4 – 1.7)	1.4 (1.4 – 1.5)	1.4 (1.2 – 1.6)	1.0 (1.0 – 1.1)
	PAR	9.5 (8.5–10.5)	9.5 (8.5 – 10.6)	1.7 (0.9 – 2.5)	0.2 (-0.2 – 0.7)
	PAF	24.0 (21.5 –26.5)	20.6 (18.4 – 22.9)	9.4 (5.0 – 13.9)	0.4 (-0.3 – 1.1)
Religion	D	0.3 (-0.9 – 1.5)	0.4 (-0.9 – 1.6)	0.5 (-0.5 – 1.4)	6.6 (5.5–7.8)
	R	1.0 (1.0 – 1.0)	1.0 (1.0 – 1.0)	1.0 (1.0 – 1.1)	1.1 (1.1 – 1.1)
	PAR	0.1 (-0.2 – 0.3)	0.1 (-0.2 – 0.3)	0.4 (-0.4 – 1.1)	1.4 (1.2 – 1.7)
	PAF	0.2 (-0.5 – 0.8)	0.2 (-0.4 – 0.7)	2.1 (2.0 – 6.3)	2.2 (1.8 – 2.6)
Place of residence	D	7.3 (6.1 – 8.5)	10.6 (9.4 – 11.8)	0.2 (-0.8 – 1.2)	2.3 (1.1 – 3.5)
	R	1.2 (1.2 – 1.3)	1.3 (1.2 – 1.3)	1.0 (1.0 – 1.1)	1.0 (1.0 – 1.1)
	PAR	5.8 (4.8 – 6.7)	8.4(7.4 – 9.4)	0.0 (-0.2 – 0.2)	0.5 (0.2 – 0.7)
	PAF	14.6 (12.2 – 17.0)	18.1(16.0 – 20.2)	0.2 (-0.9 – 1.4)	0.8 (0.4 – 1.2)

Note: D = Absolute Difference; R = Ratio; PAR = Population Attributable Risk; PAF= Population Attributable Fraction.

There was a significant difference of 16.7% (15.5–17.9%) and a ratio of 2.3 (2.2–2.4) between the level of wasting among children <12 months and 36-59 months. Overall, a decline of 5.1 % points (PAR) or 18.5% (PAF) decline in overall wasting could be achieved if wasting in all age group brought down to a level of 36-59 months. There was an absolute difference of 2.5% and 6.1% in wasting by sex of child and caste of the head of household. However, a 7% and 9% decline in overall wasting level could be achieved if all respective groups could arrive at a level of the lowest category, i.e. females and 'others' castes. However, there was no significant difference was observed by the religion of the head of household and place of residence. In the case of anaemia, only child age showed major variation, all inequality indexes illustrated significant variation. An absolute difference of 25.7% (24.5–26.9%) points

and a ratio of 1.5 was observed in the level of anaemia between the age group <12 months and 36-59 months. The overall level of anaemia could be brought down by 12.5% points or a 19.5% decline in anaemia level if all age groups had anaemia level equal to that in 36-59 months. No inequality by sex of the child and caste of the head of the household was observed. However, the religion of the head of household and place of residence showed minor variation in anaemia level.

Discussion

Malnutrition among children has been a major problem in Uttar Pradesh - the most populous state of India⁶. This paper contributes to growing empirical literature on inequalities in child malnutrition that are predominantly unnecessary, avoidable and unjust. The findings suggest that Uttar Pradesh have a very high

burden of underweight, stunting, wasting, and anaemia among under-five children. Inequality was more predominant in underweight and stunting compared to wasting and anaemia. Similar results were also reported by some other studied^{16,17}. The higher prevalence of child malnutrition in the state may be attributed to poverty and maternal undernutrition¹⁸. Undernutrition during pregnancy has been reported as one of the major causes of low birth weight because underweight women are likely to give birth to low birthweight babies^{18,19}. Other than poverty, the factors associated with maternal undernutrition in India, such as the early marriage of women, adolescent pregnancy, shorter birth intervals, beliefs and taboos associated with pregnancy, and breastfeeding practices, rearing and caring of children are also responsible for child malnutrition²⁰⁻²⁷. The studies revealed that though the anaemia levels varied somewhat according to background characteristics, anaemia among under-five children is widespread in all socio-demographic groups. Anaemia among children impaired cognitive performance, motor development, and scholastic achievement. Anaemia is a major health problem in Uttar Pradesh, especially among under-five children⁶.

The underweight and stunting were lower in younger children (< 12 months), whereas wasting and anaemia was higher among children less than two years. Malnutrition during the first two years of a child's life is quite important because if the foundation for good nutrition is not properly established during this period a child may not be able to grow to its full potential in the future^{21,30-32}. The proportion of children who were underweight or stunted increased rapidly with age, till months 24-25 months, whereas wasting among children decreases with increasing child's age. The study showed no significant gender differences in underweight, stunting and anaemia level in Uttar Pradesh, however, wasting was significantly higher among male children compared to female children. But similar to the present study, Jose (2017)³¹ reported no gender gap in malnutrition at the all India level according to NFHS-III (2005–2006) data. However, the state-level analysis showed gender differential in malnutrition level in many states and reported higher wasting among male children compared to female children in many states of India. Some studies reported a significant difference in

stunting between male and female children³²⁻³⁵, while others did not find any such difference²³. Zere et al. (2003)³⁵ reported significantly higher stunting among male children but no gender difference was reported in underweight and wasting in south-Africa.

The key findings of the study suggest that Uttar Pradesh have vast social disparities on several indicators of malnutrition including underweight, stunting, and wasting. It showed that the socially backward castes have a higher burden of child malnutrition and the resultant inequalities were higher for all malnutrition indicators except for anaemia. These findings are consistent with the results of previous studies that socioeconomic backward groups have a disproportionately higher burden of malnourishment^{16,20-22,28,36-38}. The contribution of social castes to the inequalities in childhood malnutrition could be due to differences in their economic status, availability of food and other resources, utilization of maternal and childhood health services. However, no such difference was observed by the religion of the head of household. But some studies reported that Hindu children were malnourished compared to Muslim children in India^{34,39}. The rural-urban difference was significant in underweight and stunting, but no such difference was observed in wasting and anaemia level. Several earlier studies have also reported a higher prevalence of underweight and stunting among children from rural areas³⁵⁻³⁷.

The use of simple and complex measurement of absolute and relative inequalities in childhood malnutrition makes this paper very unique. Furthermore, inequalities in indicators of malnutrition by social castes are notable finding in this study. The PAR and PAF measurement revealed that a considerable improvement can be achieved in the average underweight, stunting if malnutrition indicator reached to the level of 'other castes' children. However, the study has some limitations, it analysed select socio-demographic indicators, and several important maternal and household level indicators are not considered in the present study.

Conclusion

The recent Lancet series on maternal and child undernutrition progress 2021 reiterated the importance of delivering nutrition interventions within the first

1,000 days of life to curtail child malnutrition and mortality⁴⁰. The present study also added that apart from these international experiences and guidelines, and the ongoing national nutrition programmes and interventions in the state, more specific efforts are required to design and implement these programmes on a priority basis, keeping in view the nature of social inequality in childhood malnutrition in the Uttar Pradesh state. The study revealed that the sorry state of malnutrition continued in the state despite ongoing national programme. Programme like integrated child development scheme (ICDS), Mid-day meal schemes, Special Nutrition Programs (SNP), Balwadi Nutrition Programs (BNP) has not brought the desired results. The social gradient of long-term malnutritional status among children needs special focus. More intensive and community focused nutrition programmes involving all stakeholders need to improve child nutrition across all social group within the state. The constant monitoring of social inequalities in child nutrition will help in lining up the targets of interventions for improving child health and survival and assessing the progress towards the SDGs goals.

Conflict of Interest – All co-authors have seen and agree to the contents of the manuscript and authors have no conflicts of interest to declare.

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Ethical Clearance – The study is based on secondary data and reports freely available in the public domain.

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The Correlation between Pandemic Covid-19 Stress Level and Frequency of Relapse in Coronary Heart Disease Patients

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Abstract

Background: Severe acute respiratory syndrome of coronavirus 2 (SARS-CoV-2) as the cause of coronavirus disease (COVID-19) has caused global pandemic around the world. Patients who have coronary heart disease have been identified as highly vulnerable with increased morbidity and mortality while suffering from COVID-19. In addition, patients with coronary heart disease are also suffering with clinically significant stress. Stress can cause the body to release hormones that will make heart to beat faster.

Aim: This study aims to determine the relationship between the stress level of COVID-19 pandemic and frequency of relapse in patients with coronary heart disease.

Methodology: The design of this study was cross-sectional which involved accidental sampling technique with descriptive analytic method, using Perceived Stress Scale (PSS-10) instrument as independent variable and one-question questionnaire as dependent variable. The study was conducted at Indonesian Red Cross Hospital in Bogor City with a total sample of 33 coronary heart disease patients. The data analysis techniques used were univariate and bivariate with Kendall's Tau statistical test.

Result: Out of 33 participants, 28 (84.8.8%) had moderate COVID-19 pandemic stress levels and 17 (51.5%) experienced moderate relapse frequency.

Conclusion: There was a relationship between the COVID-19 pandemic stress level and the frequency of relapse in coronary heart disease patients.

Keywords: Coronary heart disease, COVID-19, Relapse, Stress

Introduction

In 2015, The World Health Organization (WHO) has estimated that non-communicable disease (NCDs) account for about 70% of all global deaths, which approximately 39.5 million out of 56.4 million deaths. 45% (17.7 million) of the morbidity cases were caused by heart and blood vessel disease. Data taken from Ministries of Regional Health Research (2018) showed

that the prevalence of heart disease based on doctor's diagnosis in Indonesia was 1.5%, with the highest prevalence rank was found in West Java (1.6%).¹³

In 2014, The Indonesian Sample Registration System recorded that coronary heart disease was 12.9% of all the highest causes of death in Indonesia. Based on the data from Indonesian Health Care and Security Agency, there was an increase in health costs for coronary heart disease cases from year to year. In 2016, the fund spent for coronary heart disease treatment reached to 7.4 trillion Rupiah and up to 9.3 trillion Rupiah in 2018. This imposed heavy burden on the government in limiting coronary heart disease cases by reviewing the risk factors.¹ Carney and Freedland (2016) stated that major depression is a common comorbid condition in patients with coronary heart disease (CHD). Major

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depression is a debilitating comorbid disorder that can seriously complicate recovery and increase the risks of further cardiac morbidity and mortality.

COVID-19 is a respiratory disease, but many patients show manifestations of cardiovascular disease. In a study done by Shi, et al. (2020), out of 416 COVID-19 patients, 57 patients died from COVID-19 and 19.7% had cardiovascular injuries. It involved 4.1% having heart failure, 5.3% experiencing cerebrovascular disorders such as stroke, and 10.6% experiencing coronary heart disease.⁵

The rapid infection spread and the high number of confirmed deaths have been responsible for the symptoms of anxiety, depression and stress reported by the public and the medical team.²² During the COVID-19 pandemic outbreak, quarantine and physical distancing are mandatory to contain the spread of the disease. The main consequence of quarantine is a change in lifestyle and nutritional habits.⁸ A recent review on the psychological impact of quarantine reported negative psychological effects including post-traumatic stress symptoms, confusion, and anger.⁸

In the prevention and control of non-communicable diseases including coronary heart disease, the government initially focuses on preventive actions which include health check-ups, stop cigarette smoking, improve physical activities, healthy and balanced diet, adequate rest, and stress management.¹⁵ Current evidence shows that depression is associated with about a doubling in risk of cardiac events in patients with coronary heart disease.⁷ This condition is associated with the treatment the patients have to undergo and the occurrence of serious complications. The stress experienced by the CHD patients is related to the treatments that must be followed such as diet or eating arrangements, drug consumption and also exercise⁵. Meanwhile, the variables that are commonly regarded as components of stress includes depression, anxiety, lack of social support, acute and chronic life events.⁴ In short, stress become a negative predictor for improvement of coronary heart disease. The risk of this disorder increases when there is physical fatigue or organic.⁹

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 109 patients diagnosed with coronary heart diseases from January to December 2019. It has recently been reported that out of 5 patients diagnosed with coronary heart diseases, 4 of them experienced stress, and 3 of them had relapse two times in the last one month.

This type of research uses descriptive analytic method with cross sectional design. The population in this study were patients with coronary heart disease with a sample of 33 participants. The study inclusion criteria were coronary heart disease patients, in conscious state, willing to fill in the Google Form. Meanwhile, the exclusion criteria were patients who had decreased consciousness or unwilling to fill in Google Form. The sampling technique used was accidental sampling.⁸ After the number of samples was identified, then steps were taken for the first participant who was given code 1, the next sample number was coded 2, and so on until all the samples were fulfilled by 33 participants.

Researchers submitted a research permit issued by STIKes Wijaya Husada Bogor to the head of the PMI Bogor 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 internal medicine inpatient room to ask for permission and explained the instruments to be used for the research and asked for help to collect the cellphone numbers of coronary heart disease patients / families for filling out the questionnaire form for stress levels and the frequency of coronary heart disease recurrence. Types of data collected in this study are primary data through Google Form and secondary data through medical records to determine the number of coronary heart disease population.

The Google Form questionnaire contained personal identity, the Perceived Stress Scale (PSS-10) questionnaire and one question to assess the frequency of patient relapse.

The ordinal dispatch scales for the COVID-19 pandemic stress levels were categorized as follows:

1. Mild stress (total score 1-14)
2. Moderate stress (total score 15-26)
3. Severe stress (total score > 26)

The frequency of recurrence in patients with coronary heart disease was categorized into 3 groups:

1. ≤ 1 : Low
2. 2: Moderate
3. ≥ 3 : High

The magnitude of the relationship determined by the Kendall Tau test.

Results

This research was conducted in August 2020 for 5 days via Google Form. The average participants were 45-72 years old, 22 (66.7%) of participants were female, the average background education was high school, 25 participants (75.8%) did not have a history of being active smokers, and 22 participants had no coronary heart disease history in the family.

Table 1. Results of the COVID-19 pandemic stress level

COVID-19 Pandemic Stress Level	Total	Percentage (%)
Mild stress	5	15,2
Moderate stress	28	84,8
Total	33	100

Based on Table 1, it can be seen that most of the participants experienced moderate COVID-19 pandemic stress level with 28 (84.8 percent) people.

Table 2. Frequency distribution of Coronary Heart Disease (CHD) Relapse

Frequency of coronary heart disease relapse	Total	Percentage (%)
Low	1	3
Moderate	17	51,5
High	15	45,5
Total	33	100

From the Table 2 above, it can be seen that most of the participants with coronary heart disease relapse was in the moderate category, namely 17 (51.5 percent) people.

Table 3. Correlation between COVID-19 Pandemic Stress Level and Relapse Frequency in Coronary Heart Disease Patients at Indonesian Red Cross Hospital in Bogor City

No.	COVID-19 Pandemic Stress Level	Frequency of coronary heart disease Recurrence						Total		P- Value
		Low		Moderate		High		F	%	
		F	%	F	%	F	%			
1.	Mild stress	0	0	0	0	5	15,2	5	15,2	0,006
2.	Moderate stress	1	3	17	51,5	10	30,3	28	82,8	
	Total	1	3	17	51,5	15	45,5	33	100,0	

The table above shows that, around 33 participants, which 17 (51.5%) of participants with the COVID-19 pandemic stress level were in the moderate category and the frequency of coronary heart disease recurrence was in the moderate category (1 time in 1 month).

Discussion

A. Stress level during COVID-19 pandemic

Based on the frequency distribution of the COVID 19 pandemic stress level in coronary heart disease patients at PMI Bogor Hospital, the majority of participants had moderate stress levels with a total of 28 patients (84.8%).

The results of the study are in line with Hamzah Shatria's (2018) study entitled "The effect of stress on acute myocardial infarction during intensive care". Whereas from 160 participants, 68 participants (42.5%) mostly experienced stress.¹⁹

According to Soeharto, I. (2014), factors related to risk factors for coronary heart disease (CHD) are determined through the interaction of two or more risk factors, including: non-modifiable and controllable risk factors. The non-modifiable factors include heredity, age, gender, and controllable factors. While modifiable risk factors involve dyslipidemia, high blood pressure, smoking, diabetes mellitus, overweight, obesity, and stress.¹⁸

People with coronary heart disease have high levels of stress. This condition is related to higher risk of COVID-19 complications. Stress can cause the body to release stress hormones that can make your heart to beat faster.¹⁹ There is strong epidemiological evidence to suggest that psychological stress plays a significant role in the development of heart disease. Stress both physically and mentally is a risk factor for CHD (Coronary Heart Disease) since it has an influence on the onset of CHD which hinders the normal blood flow.¹⁸ On the other hand, our bodies always respond to stressful situations that can help us survive.¹⁸

The results showed that all participants with coronary heart disease (33 participants) experienced stress within different levels. This can be seen in PSS10 questionnaire question via Google Form that the participants previously answered.

B. Relapse Frequency

Based on Table 2, it can be shown that most of the participants with the most frequency of coronary heart disease relapse was in moderate category, with 17 (51.5 percent) of participants.

Coronary heart disease is defined as heart disease caused by blockages in the coronary arteries. Acute blockage that occurs due to atherosclerotics in the walls of the coronary arteries, thus blocking blood flow to the heart muscle tissue. Not all attacks start suddenly with severe pain. The signs and symptoms of a heart attack vary from person to person. Many heart attacks go on as mild pain or discomfort. Even some people have no symptoms (it's called a silent heart attack). However, there are several signs that might refer to coronary heart disease relapse, such as: chest pain, shortness of breath, gastrointestinal symptoms, other symptoms including palpitations, pale face, rapid pulse.¹⁴

In accordance with Table 2, most of the 17 (51.5 percent) participants suffered relapse with as many as 2 relapses in a month. This can be related to the age factor, where participants are > 45 years old and age is one of the coronary heart disease factors that cannot be changed.

C. The Relationship between the COVID-19 Pandemic Stress Level and the Frequency of Relapse in Coronary Heart Disease Patients

Based on Table 3 from the results of the bivariate analysis, 17 participants (51.5%) suffered moderate COVID-19 pandemic stress level and relapse frequency in medium category. The results of the Kendall Tau test obtained p-value of 0.006 which indicated that there was a relationship between the stress level of the COVID-19 pandemic and the frequency of relapse in coronary heart disease patients at Indonesian Red Cross Hospital in Bogor City.

This study is in line with research conducted by Hamzah (2018) entitled "The effect of stress on Julius' myocardial infarction during intensive care". The results of this study suggested that stress was an independent predictor of complications in patients with acute myocardial infarction during intensive care with a value of 0.03. Therefore, there was a relationship between the effect of stress on complications of acute disease

infection complications during intensive care.¹⁴

Stress both physically and mentally is a risk factor for CHD (Coronary Heart Disease), because it has an influence on the onset of CHD. Our bodies always respond to stressful situations that can help us survive.⁹

Carney and Freedland (2016) stated that there was a relationship between stress and the frequency of acute myocardial infarction, where stress can activate bone marrow stem cells which in turn will produce excess white blood cells (leukocytes). These white blood cells can collect on the inside of the arteries, causing thickening of the artery walls.²³ Leukocytes rise is one of the factors that also contribute to the risk of heart attack.¹⁷

According to the theoretical analysis proposed by Hidayatullah (2014), there is a relationship between stress and the frequency of acute myocardial infarction, where stress can activate bone marrow stem cells which in turn produce excess white blood cells called leukocytes. These white blood cells can collect on the inside of the arteries, causing thickening of the artery walls caused by plaque buildup. Here the cells release enzymes that soften the connective tissue and result in disruption of plaque so this is a typical cause of coronary heart disease recurrence. Leukocytes are one of the causes besides factors such as high cholesterol, smoking, and genetic traits that also contribute to the risk of heart attack. Stress can encourage this if it is at a critical stage.¹³

From the results of this study, the p-value = 0.006 is smaller than α (≤ 0.05), which means that there was significant relationship between the independent variable and the dependent variable. The results of the stress level of the COVID-19 pandemic in 19 patients were obtained, namely from the frequency of relapse as many as 2 times a month consisting of ages ≥ 45 years. This is one of the risk factors for coronary heart disease, namely age. In addition, there are also other risk factors for coronary heart disease relapse including smoking, obesity and a family history of coronary heart disease.

Conclusion

There was a significant relationship between the COVID-19 pandemic stress level and the frequency of

relapse in coronary heart disease patients at Indonesian Red Cross Hospital in Bogor City, West Java, Indonesia.

Ethical Clearance: Ethical clearance was not required hence was not obtained.

Conflict of Interest: There was no conflict of interest in the research.

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Metallothionein and Malondialdehyde Correlation in Prostate Cancer Patients

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Abstract

Prostate cancer can be caused by heavy metals exposure that can be identified from increasing levels of metallothionein. Exposure to heavy metals is carcinogenic through the formation of ROS in the oxidative stress process. One of the markers of oxidative stress in prostate cancer is malondialdehyde. Purpose of study to determine the relationship between levels of metallothionein and malondialdehyde in prostate cancer. Research design was cross sectional with subjects were 30 patients with prostate cancer at district hospital at Purwokerto, Indonesia. Measurement levels of metallothionein and malondialdehyde used ELISA sandwich method. Data analysis used Spearman correlation test. There was a correlation between levels of metallothionein and malondialdehyde ($p < 0.05$, $r = 0.36$). The increase of metallothionein level cause enhancement malondialdehyde level. As a conclusion, study report that there was corelation between metallothionein and malondialdehyde levels illustrates the process of oxidative stress on prostate cancer due to heavy metals exposure.

Keywords: metallothionein, malondialdehyde, prostate cancer

Introduction

Prostate cancer is the most common visceral cancer in men. Prostate cancer ranks second as the most common cause of cancer-related deaths in men over 50 years of age. Risk factors for prostate cancer include age, endocrine status, genetic susceptibility, occupation, ethnicity, race and environmental factors. One of the environmental factors that are a risk factor for prostate cancer is exposure to heavy metals. Compared with non occupational exposure, high occupational Cd exposure may be associated with the increased risk of prostate cancer. Several studies find a positive correlation between cadmium and prostate cancer biomarker, prostate specific antigen (PSA)¹⁻³.

Exposure to cadmium induces metallothionein (MT) in some tissues, including the liver and kidneys. In acute toxicity, liver is the primary target, whereas in chronic toxicity, kidneys are major targets of Cd⁴. MT plays roles in the gastrointestinal absorption of Cd, Cd retention in tissues and decreases biliary excretion

of Cd⁵. Reactive oxygen species (ROS) are often implicated in Cd toxicology. Cd generated superoxide anion, hydrogen peroxide, and hydroxyl radicals, which are often accompanied by activation of redox sensitive transcription factors (e.g., NF- κ B, AP-1 and Nrf2) and alteration of ROS-related gene expression. It is agreed that oxidative stress plays important roles in acute Cd poisoning⁶.

Oxidative stress is associated with several pathological conditions including inflammation and infection. Chronic increases in ROS are known to induce somatic mutations and neoplastic transformation, including prostate cancer⁷. The review by Oh and colleagues. suggested that oxidative stress biomarkers MDA may be potentially predictive biomarkers of prostate cancer⁸. The study aimed to determine correlation between metallothionein and malondialdehyde in prostate cancer.

Methods

The research was analytic observational with cross sectional design. Forty samples were patients with prostate cancer through biopsy. The number of samples was calculated based on the correlation formula with $r = 0.5$, $\alpha = 0.05$ and $\beta = 0.20$. Measurement of metallothionein and malondialdehyde levels was carried out using the sandwich ELISA method. Data analysis

was performed using the Spearman correlation test.

Result

According to table, the average of metallothionein levels was 32.35 ± 26.50 ng/dL and malondialdehyde was 3.10 ± 0.42 ($\mu\text{mol/L}$). There was correlation between levels of metallothionein and malondialdehyde ($p < 0.05$, $r = 0.36$).

Table 1. The Characteristics of Metallothionein (MT) and Malondialdehyde (MDA) from Patients

Subject characteristics	Value
Age (yr)	68.25 ± 8.30
Metallothionein (ng/dL)	32.35 ± 26.50
Malondialdehyde ($\mu\text{mol/L}$)	3.10 ± 0.42

Table 2. Correlation between Metallothionein (MT) and Malondialdehyde (MDA)

Variable	p	r
MT – MDA	0.026	0.36

Discussion

Metallothionein levels increase in some tumors include breast, colon, kidney, prostate, ovarian, nasopharyngeal, bladder, salivary gland, testicular and thyroid tumors. Expression of metallothionein cannot be universally ascertained for all types of tumors, but the expression of metallothionein correlates closely with the proliferative capacity of tumor cells and also depends on differentiation status, growth factors and gene mutations. Study found the levels of metallothionein was higher than normal levels. These unique proteins are involved in diverse intracellular functions, but their role in the detoxification of heavy metals and in the maintaining of essential metal ion homeostasis, which is due to their high affinity for these metals, is mostly investigated⁹.

Results of study observed MT in prostate cancer were contradictory. While one study showed significantly lower MT in the tumorous tissue, the other identified a significantly increased MT level. In addition, a study based on radioimmunoanalysis revealed a non-significantly decreased MT level in the

tumorous tissue. Although prostate cancer is unique regarding the MT metabolism, no conclusive findings were provided by this meta-analysis and more studies are therefore needed¹⁰.

Metallothionein expression can be stimulated by heavy metals, cytokines and growth factors. Increased concentrations of heavy metals in the body trigger the formation of free radicals and ROS that cause oxidative damage. Oxidative damage is responded by cells by synthesizing proteins and antioxidants. One of the synthesized proteins is metallothionein. Metallothionein functions as an antioxidant in non-enzymatic oxidant defense systems to overcome oxidative damage. Oxidative damage induces Mt genes in many cell types. In metallothionein expression the intracellular level acts as an essential metal store, the take of ROS and the transcription activity regulator. Meanwhile, the emergence of metallothionein at the extracellular level, gives a very important role, namely as a sign of danger to damage that can be inflicted at the cellular level. In the process of controlling stress conditions, metallothionein is found in the blood with increased concentration⁹.

Oxidative stress is known to be one of the mechanisms that trigger the prostate development and progression of prostate hyperplasia. Oxidative stress is a cellular level condition that occurs when there is an imbalance between ROS production and the ability of a biological system to repair oxidative damage or neutralize the effects of reactive intermediates including peroxide and free radicals. High ROS production leads to a significant reduction of antioxidants, protein defense mechanisms, lipids and DNA damage and other cellular functional disorders. Oxidative damage can be exacerbated by a decrease in antioxidant efficiency. Oxidative stress has been linked to the development of Benign Prostate Hyperplasia and prostate cancer progression. ROS can indirectly cause random DNA formation by triggering autocatalytic lipid peroxidation, which produces a variety of genotoxic potential substances for breakdown products, including alkoxy radicals, peroxy radicals, and aldehydes, such as malondialdehyde¹¹.

Lipid peroxidation or reaction of oxygen with unsaturated lipids produces a wide variety of oxidation products. The main primary products of lipid peroxidation are lipid hydroperoxides (LOOH). Among the many different aldehydes which can be formed as secondary products during lipid peroxidation, malondialdehyde (MDA), propanal, hexanal, and 4-hydroxynonenal (4-HNE). MDA appears to be the most mutagenic product of lipid peroxidation, whereas 4-HNE is the most toxic (11). In this study MDA levels was higher than normal. several studies have found an increase of malondialdehyde in prostate cancer patients^{7,12,13}.

Increased levels of malondialdehyde and metallothionein in prostate cancer patients may be caused by exposure to heavy metals, especially cadmium. Study by Pizzino et al revealed that adolescents with elevated Cd levels had a significant increase in MDA and MT-1A compared to the control group¹⁴.

Conclusion

The correlation between malondialdehyde and metallothionein levels illustrates the process of oxidative stress on prostate cancer due to heavy metals exposure. Metallothionein can be considered as a biomarker of cadmium or other heavy metal exposure in prostate cancer screening, especially for cadmium exposed worker.

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Conflict of Interest : Authors declare that there are no conflict of interest in submitting this manuscript. All authors are responsible for developing and completing this manuscript submission.

Ethical Clearance: The research has been reviewed by Ethical Committee of Health Research, Faculty of Medicine, Universitas Jenderal Soedirman.

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“Treat All with All” – A Multidisciplinary Approach for an Unusual Case Scenario

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Abstract

Impaction of teeth is more common and widespread. Multiple impacted permanent teeth are usually related to syndromes, metabolic and hormonal disorders. However, in non-syndromic cases impaction of multiple teeth is rare. In this report, a case of A 23-years-old male patient with missing upper front teeth and irregularly placed lower front teeth, difficulty in speech and mastication. physical examination was not suggestive of any syndromes. On Extraoral examination the patient presented with a concave profile, competent lips, shallow Mento-labial sulcus. On clinical and radiographic examination revealed Angle's class III malocclusion on class III skeletal base, with impacted 13,12,11 and 24, anterior cross bite, rotation of 32,33,35,42,44, and horizontal growth pattern. Extraction of supernumerary teeth was carried out in all the quadrants and PEA 0.22 ROTH appliance was used to align the arches. Bi-jaw surgery with mandibular set back with bilateral split sagittal osteotomy and maxillary advancement with Le Fort I was done to attain ideal overjet and overbite.

The objective of this report is to increase awareness of such cases especially in the absence of hereditary/genetic/metabolic factors usually inherent in such scenarios. The patient management in such cases needs to be planned all with all multidisciplinary approach.

Key words - multidisciplinary approach, unusual case, multiple impacted teeth, supernumerary teeth, class III skeletal, bi-jaw surgery.

Introduction or Back Ground

An impacted tooth is a condition in which a tooth is embedded in the alveolus so that its eruption is prevented, or the tooth is locked in position by bone or by adjacent teeth. Studies have reported that the incidence of tooth impaction varies from 5.6-18.8% of population ¹. In our esthetic -conscious society, it is increasingly important to preserve the natural dentition. this certainly includes keeping or “saving” the impacted

teeth. Impaction involving a single tooth is a commonly observable finding. However, impaction of multiple teeth is an uncommon finding unless associated with some syndromes or systemic disorders.^{2,3} We report a case of multiple impacted permanent teeth in a non-syndromic unusual case scenario.

Pre-treatment assessment - A male patient of age 23 years on extra-oral examination presented with Dolichocephalic, Dolichofacial, concave profile, competent lips (figure-1A, 1B)

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Figure -1A EXTRAORAL SMILE



Figure- 1B EXTRAORAL LATERAL

Clinical examination intra-oral examination

1. Maxilla – U shaped, asymmetrical, 22-palataly placed. 21,22- clinically missing. supernumerary teeth present between 16, 15 and 24,25
2. Mandible - U shaped, symmetrical. 32,42,44 mesiolingually rotated and 33,35 mesiolabially rotated.
3. Occlusal features – class III incisor relationship with negative overjet of 3 mm and overbite of 4 mm with anterior and posterior crossbite. (figure -2 A, 2 B, 2 C)



Figure 2 A INTRAORAL RIGHT



Figure 2 B INTRAORAL LEFT



Figure 2 C INTRAORAL FRONTAL



Figure 2 D INTRAORAL OCCLUSAL

Radiographic examination –

1. Dental panoramic radiograph (Fig 3) – unerupted teeth – 18,13,12,11,27,28,38,48.
2. Cephalometric analysis (Table1)-

VARIABLE	PRETREATMENT	NORMAL
SNA	78°	82° ± 3
SNB	86°	79° ± 3
ANB	-8°	3° ± 1
Wits appraisal	BO ahead by 7mm.	0 mm
N ⊥ Pt A	-7mm	0±2 mm
N ⊥ Pog	7mm	0 to -4mm
Angle of inclination	88°	85
Go-Gn to SN	27°	32
Eff. Max. Length	87mm	89.6 ± 2.5
Eff. Mandi. Length	130mm	113.1 ± 3.6
Y- Axis	59°	66
Facial axis	0°	0
Upper incisor – NA(mm)	1mm	4mm
Upper incisor – NA(degrees)	15°	22
Upper incisor – SN	105°	102 ± 2
Upper incisor to maxillary plane angle	68°	70° ± 5
Lower incisor to mandibular plane angle	78°	92° ± 5
Lower incisor to NB	5mm	4mm
Lower incisor to NB	14°	25
Interincisal angle	147°	133° ± 10
Maxillary mandibular planes angle	19°	27° ± 5
Upper anterior face height	35%	45%
Lower anterior face height	65%	55%
Face height ratio	70%	62-65%
Lower incisor to APo line	5mm	1 -2 mm
Lower lip to Ricketts E Plane	4mm	-2 mm

Interpretation

- Retrognathic maxilla
- Prognathic mandible
- Skeletal class III
- Retroclined maxillary and mandibular incisors
- Horizontal growth pattern



Figure -3 – PRETREATMENT OPG

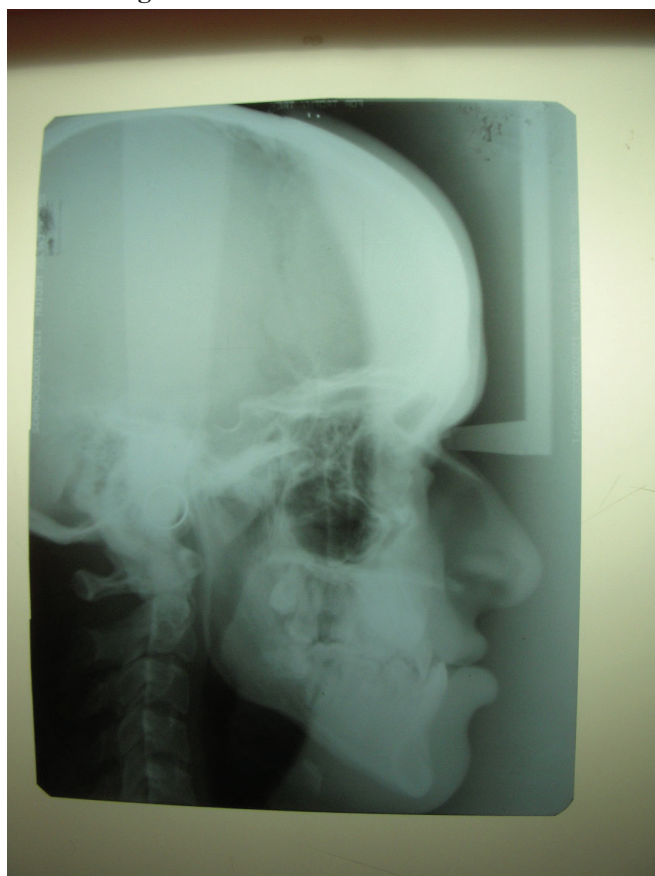


Figure – 4 PRETREATMENT LATERAL CEPHALOGRAM

DIAGNOSTIC SUMMARY

Angles class III malocclusion on class III skeletal base with impacted 11,12,13,24, anterior cross bite, rotation of 32,33,35,42,44 increased curve of spee and presence of supernumerary teeth

PROBLEM LIST

1. Impacted of 13,12,11, 24.
2. Speech problem
3. Masticatory dysfunction
4. Concave profile
5. Reverse overjet and overbite
6. Class III molar relation
7. Anterior and posterior crossbite.

Aims and Objectives of Treatment

1. Disimpaction of 13,12,11,24 and orthodontic eruption
2. To achieve an aesthetically pleasing profile
3. To correct skeletal Class III relationship

4. To achieve optimal overjet and overbite
6. To correct class III molar relationship
7. To relieve high frenum attachment
8. To achieve functionally stable occlusion

TREATMENT PLAN

Extractions:

Extraction of supernumerary teeth.

Appliances:

PEA roth-0.22 slot mechanotherapy

Special anchorage requirements:

None

Minor adjunctive surgery:

Frenectomy

Major adjunctive surgery:

BSSO mandibular set back

Maxillary advancement with LeFort I

Key Stages in Treatment Progress

	Date	Stage
1.	1 month	Banding and bonding in the upper arch on clinically erupted Surgical exposure of impacted 13,12,11 24 done in dept. of oral maxillo-facial surgery.
2.	2 months	Upper 0.16NiTi inserted soldered TPA given for reinforcing anchorage.
3.	3 month	Upper overlay wire made of 1mm S.S wire fabricated and inserted, and monkey hook were attached to 13,12,11,24 attachment overlay wire.
5.	6 month	Checkup done teeth responding favorably
6.	8 month	24 engaged to arch wire ,11-extruded mesially moved, 13 extruded.
7.	10 month	Overlay wire discontinued removable TPA given for 16 rotation correction. Upper 0.16 NiTi arch wire inserted and loosely engaged to 13,12,24. checkup done.
8.	11 month	11,24,25 0.22 ROTH bracket bonded, 0.16 NiTi arch wire engaged.

Cont... Table

9.	12 month	Checkup done advised extraction of 34 and supernumerary tooth present palated to 11.
10.	13 month	Lower anterior bonding and 36,46 banding done, lace back given canine to molar.0.16 NiTi arch wire inserted.
11.	16 month	Upper 0.016 NiTi and lower 0.014NiTi given
12.	20 month	Upper 16x22 NiTi and Lower-0.016NiTi given
13.	22 month	0.017 X 0.0 25 stainless steel arch wire was placed in the upper and lower arches.
14.	24 month	0.021 X 0.025 TMA wire placed in both upper and lower arches.0.021 X 0.025 stainless steel placed in the upper and lower arches. Surgical preparation done. Surgery and IMF done
15.	25 month	
16.	29 month	Post-surgical orthodontics in progress



Figure 5A- Mid Treatment Surgical exposure made of 1mm of impacted 13,12,11 24. PEA 022 ROTH bracket bonded.

Figure5B- Upper overlay wire S.S wire fabricated and 13,12,11,24 attachment inserted, and monkey hook was attached to overlay wire



Figure -5C- orthodontic surgical
Extrusion



Figure-5D- maxillary occlusal view



Figure -5E- Mid treatment 0.20 S. S Continuous wire



Figure -5F- maxillary occlusal view



Figure -6 – Mid treatment hanau face bow transfer



Figure -7- presurgical decompensation lateral cephalogram

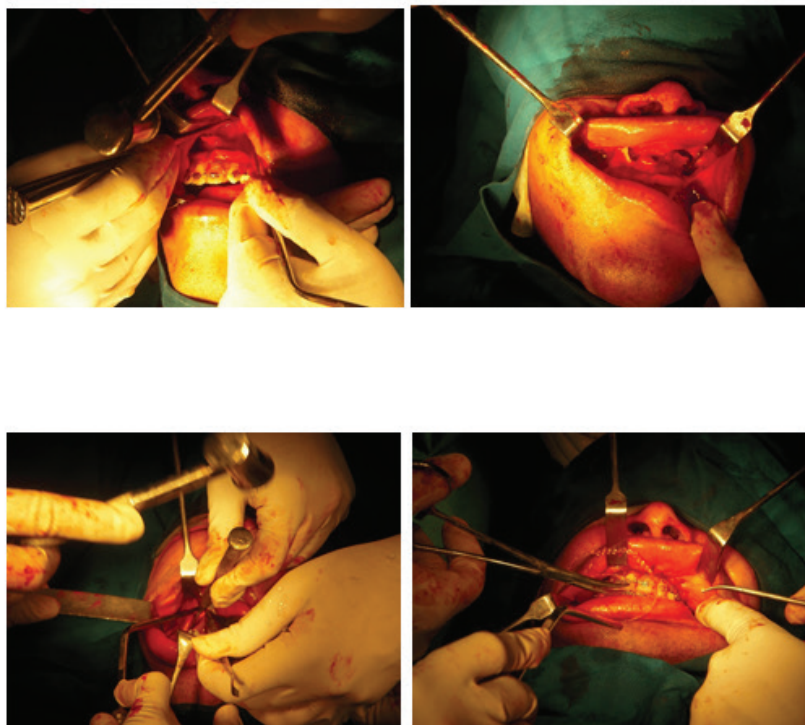


Figure 8- Surgical Procedure Down's Fracture / Lefort- I Osteotomy Maxillary Advancement & B.S.S.O Setback



FIGURE -9 POST SURGICAL TREATMENT – LATERAL CEPHLOMGRAM

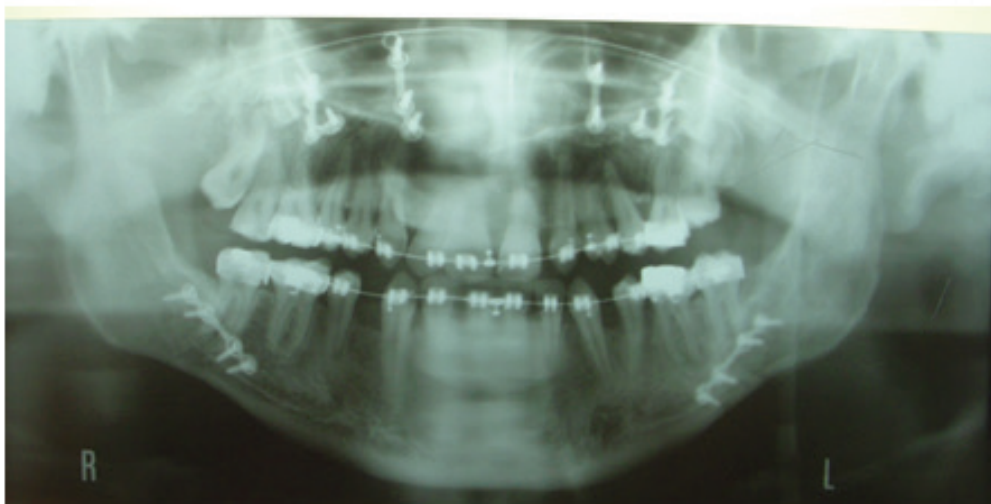


FIGURE -10-POST SURGICAL TREATMENT – OPG



FIGURE -11- POST SUGICAL EXTRA ORAL & INTRA ORAL PHOTOGRAPH

CEPHALOMETRIC ASSESSMENT- POST TREATMENT (Table – 3)

VARIABLE	MID TREATMENT	NORMAL
SNA		82° ± 3
SNB		79° ± 3
ANB		3° ± 1
Wits appraisal		0 mm
N ⊥ Pt A		0±2 mm
N ⊥ Pog		0 to -4mm
Angle of inclination		85
Go-Gn to SN		32
Eff. Max. Length		89.6 ± 2.5
Eff. Mandi. Length		113.1 ± 3.6
Y- Axis		66
Facial axis		0
Upper incisor – NA		4mm
Upper incisor – NA		22
Upper incisor – SN		102 ± 2
Upper incisor to maxillary plane angle		108° ± 5
Lower incisor to mandibular plane angle		92° ± 5
Lower incisor to NB		4mm
Lower incisor to NB		25
Interincisal angle		133° ± 10
Maxillary mandibular planes angle		27° ± 5
Upper anterior face height		45%
Lower anterior face height		55%
Face height ratio		62-65%
Lower incisor to APo line		0-2 mm
Lower lip to Ricketts E Plane		-2 mm

Discussion

Keeping above problem list, aims and objective in mind, a decision to treat is made, treatment should be as minimal as needed to facilitate natural eruption. "The majority of impacted teeth erupt if hard – or soft -tissue obstructions are removed from their eruption paths". Di Biase conducted a survey, which found that after the removal of supernumerary teeth, 75 % of the impacted maxillary incisors spontaneously erupted.⁴ so, first line of treatment planned was to remove supernumerary teeth followed by orthodontic relocation /surgical expose of impacted 13,12,11 24 done in dept. of oral maxillo-facial surgery at J.S.S DENTAL COLLEGE (figure 5A). Kokich and Mathews recommended surgical exposure and orthodontic eruption of an impacted tooth. when its apex is completely formed.⁵ presurgical orthodontic is started after forced orthodontic eruption of impacted teeth. (Figure 5E and Figure 7).

Jaw relation registration of any positional relationship of the mandible relative to the maxilla is made by Hanau's face bow ear piece type used to record the spatial relationship of the maxillary arch to some anatomic reference points and then transfer this relationship to an articulator.⁶(Figure-6). In the articulator the Lefort I maxillary advancement of 3 mm and hinge axis determines the arc of closure in every contacting position of the teeth. the path of closure is different from each open position of the mandible to tooth contact. This path results from the closing rotation combined with a gliding path of the axis.⁷ and then mandible bilateral sagittal split osteotomy 6mm setback was made of the articulator, intermediate and final splint fabricated by using cold cure acrylic resin.

Presurgical orthodontic phase we eliminated the dental compensation that has occurred with respect to the skeletal base (Figure -7).

Surgical phase- Down's Fracture / Lefort- I Osteotomy Maxillary Advancement of 3mm & B.S.S.O 4mm Setback had done on mandible. (Figure-8). Post-surgical changes were appreciated by lateral cephalogram (Table-3) and OPG (Fig -10). Intraoral patients showed

well settled occlusion with normal overjet and overbite (Fig-11).

Conclusion

Multiple impacted permanent teeth are rare condition and it is very difficult to find its association with syndromes, metabolic and hormonal disorders. HOWEVER, with this case report, a non-syndromic impaction of multiple teeth was managed orthodontically to improve the patient's masticatory and speech function which helped in a definite improvement in the profile of patient and in the occlusion. Mandibular prognathism and maxillary retrusion has been surgically corrected by BSSO mandibular set back and LE FORT I maxillary advancement. This Unusual Case Scenarios was managed with the concept of multidisciplinary approach I.e. "treat all with all".

Conflict of Interest – NIL

Source of Funding - Self

Ethical Clearance – patient consent was taken at the start of treatment. ethical approval is not taken form university because we treat lot of patient.

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Effect of Benson's Relaxation Therapy (BRT) on Post Caesarean Section Pain and Stress

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Abstract

Background: Pregnancy is exciting and unique period in a woman's life. During this period women's body undergo different anatomical and physiological changes. When there are some risk associated with normal vaginal delivery to mother and baby than caesarean section is required. Many mother encounter with various discomfort after caesarean delivery such as pain, stress, mood changes, postpartum depression. This study was conducted to evaluate the effect of Benson's relaxation therapy on level of pain and stress among post caesarean section mothers.

Method: A quasi experimental study was done with total 60 participant: 30 in each experimental and control group were enlisted with the help of convenient sampling method. Samples are randomly allocated to both group. The tool for data collection includes, socio demographic and maternal variables, Numerical pain rating scale for pain assessment and Modified Hung's postpartum scale to assess stress level. Pre-interventional assessment done for both group. Post interventional pain and stress was assessed on third day by using same tool.

Conclusion: This study concluded that there is constructive outcome of BRT in lessening pain and stress level among post caesarean section mothers. So to reliving such symptoms, this procedure can be implemented in hospital setting as it is simple and easy to use and practice, non expensive.

Keywords : *Benson's relaxation therapy, pain, stress, post caesarean section women*

Introduction

Pregnancy is exciting and joyful period in women's life. During pregnancy the body experience distinctive anatomical and physiological changes.¹ There are various ways of conveyance like ordinary vaginal delivery, assisted delivery or operative delivery which incorporates caesarean section. Caesarean Section is one sort of operational practice in which fetus after finish of seventh month are conveyed by opening of the maternal abdominal and uterine walls.²

WHO endorses that caesarean segment rates ought not go above 15% in any nation. Anyway the rate between 5% to 10% is generally worthy.³

Mothers faces a few kind of discomfort after caesarean delivery that differs from one woman to another. Pain and stress are one of the significant

inconveniencies which drive the post caesarean section mothers to create negative emotions towards childbirth. It might influence the mother-infant interaction.⁴ Studies propose a number of techniques which have been used to relieve this pain and stress among post Caesarean Section mothers.⁵

Several methods can be utilised to diminish post caesarean section discomfort. There are many non-pharmacological strategies which ease post LSCS discomfort but are not commonly used. These are deep breathing, accupressure, distraction, foot massage, relaxation exercises, guided imagery, therapeutic touch, music and repositioning.⁶

BRT is one kind of a non pharmacological technique which can relax the body through breathing awareness. Dr. Benson, professor has defined the term, 'Benson's

relaxation therapy. It characterized individual capacity to secrete synthetic substances and brain signal that makes organs and muscles relax and increment blood stream to the brain. It can lessen the pain, increase appetite, reduce stress, promote sleep, boost energy, feel relax and in a roundabout way increase attachment with child.⁷

This method is a blend of relaxation response procedures with person conviction framework/trust factor (concentrated on a specific type of articulation of the God name or a word that has a calming effect to the patient) more than once spoken with a standard beat with resignation.⁶

Some studies have indicated that the Benson’s relaxation technique is viable in improving physical activity, lessen uneasiness and decreases the stress and postoperative pain. So this treatment may likewise be valuable in lessening the post caesarean section pain and stress.⁸

Materials and Methods

A Quasi experimental : pre test post test control group design was adopted for present study. The study was carried out in selected hospital of Central Gujarat. Ethical clearance and formal permission were acquired before conduction of study. 60 post caesarean section mothers were choosen with aid of non probability conveniently sampling technique. Samples were randomly allocated in experimental and control group. Researcher developed perfoma was utilized to gather baseline information of participants, Numerical pain rating scale and Modified Hung’s Postpartum stress scale was used to evaluate pain and stress level respectively.

Pre-treatment assessment of pain and stress level was accomplished for both group. For interventional group, intervention administered twice a day with span of 10 minutes for 3 consecutive days. BRT was not administered in control group. Post test led on third day for both group.

Results and Discussion

Findings related to demographic and maternal variables of post caesarean section mothers of both group : showed that 36.7% of participants in experimental group belongs to 28-32 years while in control group 43.3% from 18 to 22 years of age. 46.7% in experimental and 50% in control group has completed their primary education and 83.4% were housewives in both group. 63.3% in experimental group and 40% in control group had height between 141 cm to 150 cm. Most participant, 56.7% experimental group and 70% in control group had weight between 51kg-60kg. Majority participants, 50% in experimental group and 43.3% in control group were primipara. In experimental group, indication of present caesarean section were fetal mal presentation (23.3%), previous caesarean section (20%) and oligohydramnios(3.3%) and in control group it was previous caesarean section (30%) and prolonged labour (3.3%). In both experimental and control group, 86.7% participants had emergency caesarean section. 76.7% in experimental group and 56.7% in control group had their 1st postnatal day

Findings related to effect of Benson’s relaxation therapy on level of pain and stress among post caesarean section mothers of both group

Table 1 Comparison of Benson’s relaxation therapy on level of pain in experimental and control group

Group		Mean	N	Std. Deviation	Wilcoxon test	p Value
Experimental	Pre Pain	7.50	30.00	0.82	465	<0.001
	Post Pain	2.56	30.00	1.22		
Control	Pre Pain	7.50	30.00	0.82	56	0.1591
	Post Pain	7.26	30.00	0.90		

Table 2 : Comparison of Benson’s relaxation therapy on level of stress in experimental and control group

Group		Mean	N	Std. Deviation	t	p Value
Experimental	Pre Hung’s Postpartum Scale	98.93	30.00	7.70	18.958	<0.001
	Post Hung’s Postpartum Scale	71.13	30.00	5.64		
Control	Pre Hung’s Postpartum Scale	99.90	30.00	9.45	0.844	0.4053
	Post Hung’s Postpartum Scale	99.70	30.00	9.67		

The data presented in table 1 and 2 depicts that there was statistically significant difference found in experimental group with p value of <0.001 and to compare of effect of BRT on pain and stress level Wilcoxon test and “t”- test were utilized respectively. So it is interpreted that the research hypothesis which state there is significant effect of BRT on level of pain and stress stands accepted at the 0.05 level of significance.

Findings related to association between pre-intervention level of pain and stress among post caesarean section mothers of both experimental and control group with selected demographic and maternal variables: Fisher chi square test was employed to established the association. For experimental group, monthly income of family($\chi^2=8.76$) was found to be associated with pre interventional level of pain with p value <0.05 and age ($\chi^2=12.2$), monthly income of family ($\chi^2=9.3$), type of caesarean section($\chi^2=4.69$) and postnatal day($\chi^2=5.59$) for interventional group and No. of deliveries including present delivery ($\chi^2=8.35$) for control group were found to be associated with pre interventional stress level as p value was led than 0.05. Remaining all variable were found statistically independent for both group (p value>0.05). So it is interpreted that the research hypothesis which state there is statistic significant association between pre interventional level of pain and stress with the selected socio demographic and maternal variable stands accepted at 0.05 level of significance.

Conclusion

The current study was led on 60 post caesarean

section women and presumed that BRT was effectual in decreasing pain and stress level. So BRT is non pharmacological approach which is simple, viable and non costly method to diminish pain and stress level. So this similar investigation should be conceivable on larger scale to know its efficacy on pain and stress and make it generalize.

Conflict of Interest: None

Source of funding: Self

Ethical Clearance: Permission was obtained from CHARUSAT Institutional Ethical Committee, Charotar University of Science and Technology, Gujarat, India

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Quality of Life in Obese Patients- Gender Differences

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Abstract

Objective: To assess the gender differences in Quality of Life (QoL) in patients with obesity.

Methods: A descriptive survey was conducted among 220 patients (110 males and 110 females) attending OPDs of a tertiary care hospital, Kerala using a standardized questionnaire SF 36 (version 1.0). Convenience sampling technique was used

Findings: The major co morbidity found among the subjects was diabetes mellitus ie.72 (65.5%) in males and 56 (50.9 %) in females .The percentage of males as per the obesity category i.e. Class I, II, III were 40, 36.5 and 23.5, where as that of the females were 60.9, 31.8 and 7.3 respectively. The mean QoL was found to be slightly above average for males (51.19+/- 12.54) than the females (48.79 +/- 12.86.). Of the 8 domains, the QoL in males were found to be poor in two domains where as in females it was poor in four domains. The physical component scores (PCS) were found to be better in both sexes i.e. 55.89 +/- 19.07 and 52.68 +/-21.04 compared to the mental component scores (MCS) i.e. 50.03+/-13.35 and 48.84+/-14.01.

Conclusion: The study has highlighted a poor QoL in obese women especially in the mental component scores in spite of a higher proportion of morbid obesity and DM in men.

Keywords: Obesity, Quality of life, Gender differences

Introduction

Obesity is reflected as a chronic and multifactorial disease that is concomitant with several co- morbidities, leading to poor quality of life (QoL) ¹People who are obese experience health-related quality-of-life (HRQOL) impairments. Impairment in an obese individual's capacity to live fully and actively may be as serious a consequence of obesity as its adverse effects on morbidity and mortality². Both physical and psychosocial functioning has been shown to be negatively affected by excess weight; greater impairments have been associated

with greater degrees of obesity³.

Impacts of health/ disease on physical and social wellbeing are becoming more important measures of wellness. The very nature of obesity to influence many other health care domains is the reason for its impact on QoL. Therefore it is essential to understand the ways in which obesity impacts the physical and mental components of QoL⁴.

The relationship between obesity and QoL has been investigated in a variety of settings. Most reports show that, there is a high risk for poor QoL in overweight and obese subjects¹. However, only a few studies have reported an association between overall obesity and HRQOL in Asian populations⁵.

HRQOL is increasingly regarded as an important measure of the impact of disease and treatment. Although

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there is evidence that overweight and obesity are related to decrements in physical domains of HRQOL such as physical functioning and pain, findings are mixed regarding association with mental domains of HRQOL. Some studies have suggested that obesity is associated with impaired mental HRQOL. However, other studies do not support this association, and a few have even reported better mental health among people with excess body weight⁶.

The impact of obesity may vary by gender. Significantly a higher number of women considered themselves as overweight than did men, and also reported experiencing discomfort due to excessive weight, than did men⁷. Gender has shown to be a factor influencing QoL⁸. Studies examining gender differences associated with subjective well-being and body weight are scarce.

The existing literature indicates that QoL of women and men is differentially impaired with more impairment in women than in men^{6,7} and also displayed a higher psychosocial impairment in women⁶. The present paper

adds to the existing body of research by systematically analyzing gender differences in obesity related QoL

Materials and Methods

The study was conducted among 220 obese patients (110 males and 110 females) in a tertiary care hospital, Kochi. Subjects were selected from various OPDs using non-probability convenient sampling. A descriptive survey design was used in this study. Ethical clearance was taken from the Institutional Ethical committee and informed consent obtained from each subject. A standardized QoL questionnaire SF – 36 (version 1.0) was used to assess the QoL of subjects. The QoL was assessed in eight dimensions ie. General health, Physical functioning, Role limitations due to physical health, Role limitations due to emotional problems, Energy/fatigue, Emotional well-being, social functioning, and Pain. Norm based scoring was used to equate all scores. Scores above 50 are considered better for all scales and summary measures while scores below 50 are considered worse. Data was analyzed with SPSS 17.0 using descriptive and inferential statistics.

Findings

Section I: Gender wise sample characteristics

Table 1: Gender wise distribution of the sample based on the demographic characteristics

N= 220

Variables	Male (n= 110) f (%)	Female (n= 110) f (%)
Age (years)		
18-32	10 (9.1)	4 (3.6)
33-47	33 (30.0)	33 (30.0)
48-62	38 (34.5)	42 (38.2)
63-77	29 (26.4)	31 (28.2)
Marital status		
Single	11 (10.0)	4 (3.6)
Married	99 (90.0)	104 (94.6)
Widower/widow	0 (0.0)	2 (1.8)
Occupation		

Cont... Table 1: Gender wise distribution of the sample based on the demographic characteristics

N= 220

Professional	19 (17.3)	18 (16.4)
Unskilled	24 (21.8)	22 (20.0)
Skilled	30 (27.3)	10 (9.1)
Unemployed	32 (29.1)	58 (52.7)
Retired	5 (4.5)	2 (1.8)
Mode of work		
Sedentary	26 (23.6)	39 (35.5)
Moderate	37 (33.6)	51 (46.3)
Heavy	47 (42.7)	20 (18.2)

Majority of the sample studied were between the age group 33 to 62 years (males 64.5% and females 68.2%). The percentage of unemployed was high in female gender (52.7%) than the male (29.1%).

Section II: Gender wise clinical characteristics of the sample

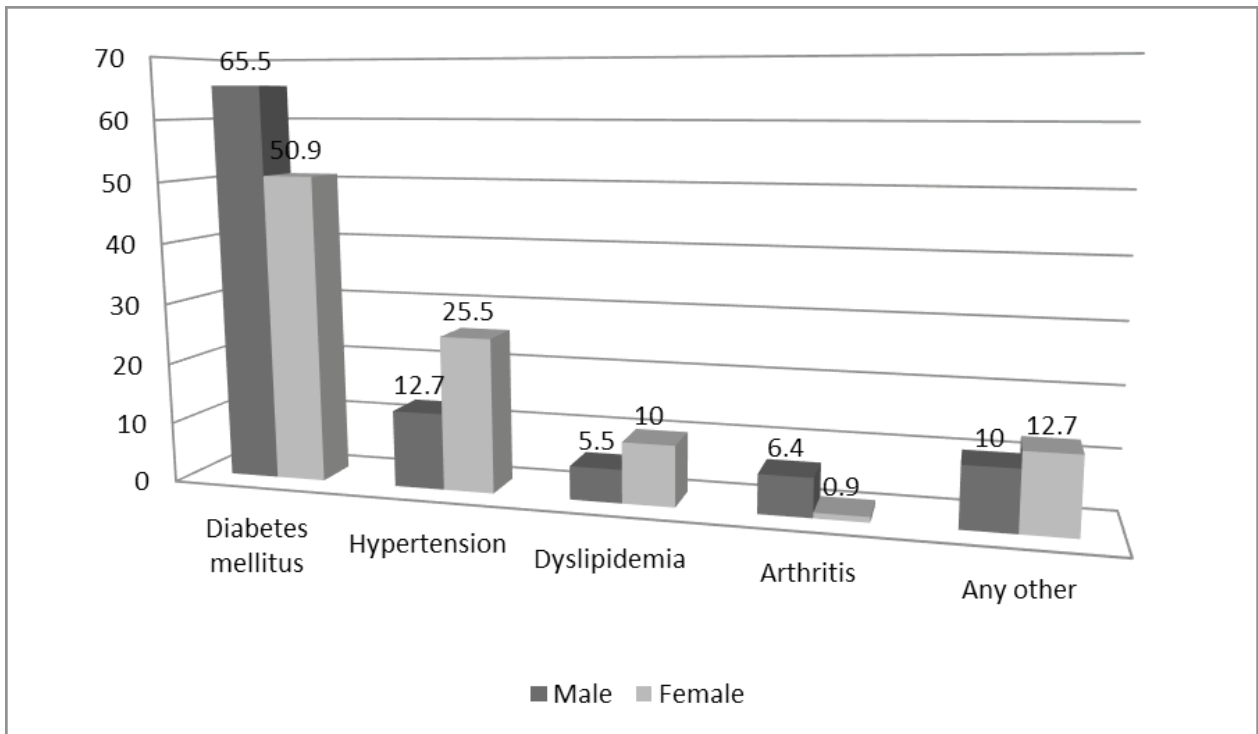


Fig. 1: Gender wise distribution of subjects based on their co-morbidities

Diabetes mellitus was the major co morbidity in both genders (65.5% in males and 50.9 % in females) followed by hypertension (12.7% in males and 25.5% in females).

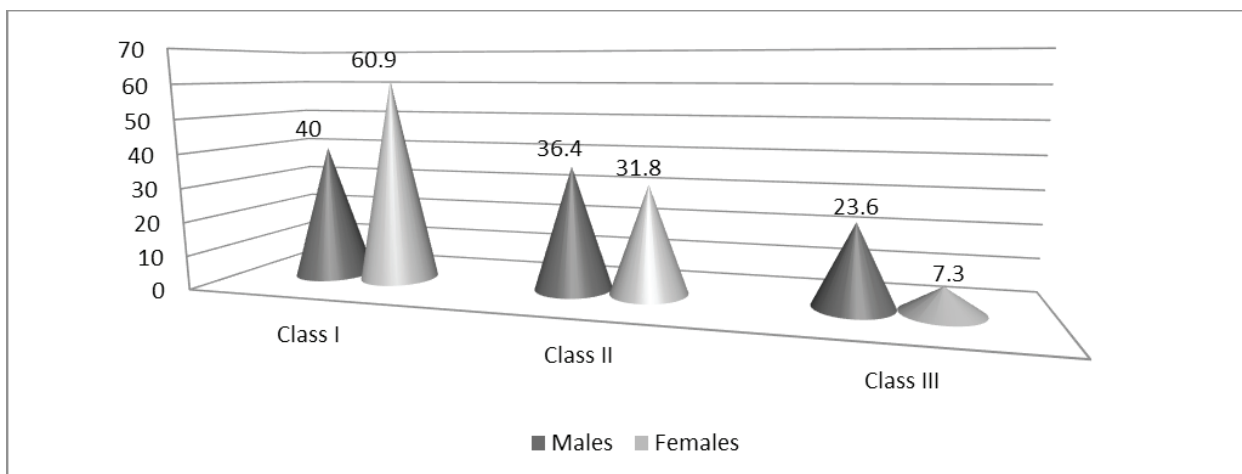


Fig. 2: Gender wise distribution of subjects based on the category of obesity

Majority of the female subjects belong to class I obesity category (60.9%). Only 7.3% of females were in class III while 23.6% of males belong to this class.

Section III: Gender wise QoL among obese patients.

Table 2: Gender wise distribution of subjects based on QoL

N= 220

QoL	Male (n=110) Frequency (%)	Female(n=110) Frequency (%)
Good QoL (>50)	56 (50.9)	54 (49.1)
Poor QoL (<50)	48 (43.6)	62 (56.4)

Majority of the females (56.4%) had a relatively poor score in QoL compared to the males (43.6%).

Table 3: Gender wise distribution of subjects based on the mean scores in eight domains of QoL

N=220

Domain of QoL	Male (n=110)	Female (n=110)
General health (GH)	40.05 +/- 11.85	32.78 +/-14.39
Physical functioning (PF)	54.37 +/- 23.16	52.59 +/- 24.51
Role limitations due to physical health (RPF)	51.70 +/- 26.96	47.61 +/- 28.15
Energy/ fatigue (E)	53.95 +/- 11.01	49.54 +/- 14.89
Emotional wellbeing (EW)	52.22 +/- 12.47	52.98 +/- 14.96
Social functioning (SF)	54.55 +/- 17.89	58.41 +/- 17.77
Pain (P)	61.61 +/- 25.15	57.86 +/- 27.01
Role limitations due to emotional problems (REP)	43.94 +/- 30.93	44.00 +/- 33.72

Of the 8 domains, the QoL in males were found to be poor in two domains (GH, REP) where as in females it was poor in four domains (GH, RPF, E, REP).

Table 4. Gender wise distribution of subjects based on the mean QoL, PCS and MCS scores

N= 220

Gender	QoL Mean +/-SD	PCS Mean+/-SD	MCS+/-SD
Male (n=110)	51.19 +/- 12.24	55.90+/- 19.08	50.03+/-13.36
Female (n=110)	48.79+/- 12.86	52.69+/-21.04	48.79+/-12.86

The mean QoL scores were better in males (51.19 +/- 12.24) .Though the PCS mean score were found equally good in both sexes, the MCS mean scores were poor in females (48.79 +/- 12.86).

Table 5: Gender wise Correlation between BMI and QoL in obese.

Gender	r value	P value
Male	-0.035	0.715ns
Female	-0.133	0.166ns

A negative correlation exists between BMI and QoL in both males (r = -0.035, p = 0.715) and females (r= -0.133, p= 0.166), which was not statistically significant.

Discussion

The present study has shown that the QoL in obese women were more impaired than the obese men i.e. majority of the females (56.4%) had a poor score in QoL compared to the males (43.6%). This is in congruent with the study findings reported by Maria et al. that obese women (40%) had poor QoL as compared to obese men (13%)⁹ .

It was also found in this study that the mean mental component scores (MCS) were poor in females (48.79 +/- 12.86), although the mean physical component scores (PCS) were equally good in both sexes. This is line with other studies^{5,6,9}. It is believed that psychosocial and cultural pressures imposed mainly to women, make them suffer more with the subjective effects of being overweight having greater interference in self-esteem⁵. Another possible explanation of gender differences

in QoL is that women may exaggerate their health conditions than men even or women may have a higher rate of self-perceived health on general health.

Of the 8 domains, the QoL in males were found to be poor in two domains (GH, REP) where as in females it was poor in four domains (GH, RPF, E, REP). This is exactly similar to the finding of a study by Fulden Sarac et al. in Turkey¹⁰.

The negative correlation found between BMI and QoL in both males (r= -0.035) and females (r= -0.133) in the sample was not statistically significant (p> 0.05). A similar negative correlation was found between BMI and QoL among obese females in a study by Bookwala, J., & Boyar, J. (2008), which was statistically significant¹¹. But, this is in contrary to the study findings of Ogbeide 2010 where a negative correlation was found between BMI and QoL only in males (r= -0.37, p = 0.05)⁹.

Conclusion

This gender based study, where the sample had both sexes in equal number has shown that the QoL in obese women are poorer than the obese men, especially in mental component scores, although the morbidly obese were high among males. The findings highlight not only the need for professional support to women to improve their QoL but also suggest the need to analyze thoroughly the relevant psychosocial mediators.

Conflicts of Interest: Nil

Source of Funding: Nil

Ethical Consideration: Ethical clearance was taken from the Institutional scientific and Ethical committee and written informed consent was obtained from each subject.

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Comparison of Disability Score and Chronic Pain Grading with Different Treatment Modalities in a Sample of Temporomandibular Joint Disc Displacement with Reduction Patients

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Abstract

Background: The purpose of this study was to evaluate the effect of splint, laser and placebo laser therapies on the improvement of disability score and chronic pain grading in a sample of temporomandibular joint disorders disc displacement with reduction patients.

Methods: A sample of 30 Temporomandibular disorders patients (8 males and 22 females, mean age 25± 6.3 years) having disc displacement with reduction diagnosed by clinical examination (according to the research diagnostic criteria of temporomandibular disorders, and confirmed by magnetic resonance imaging were randomly divided into 3 treatment groups: group 1 received an anterior repositioning splint for 3 months, group 2 received low-level laser therapy, while group 3 received placebo laser therapy. Both laser groups received 12 laser sessions over 3 months. Assessments were performed before treatment (T1) and repeated after three months (T2) using the research diagnostic criteria Axis II questionnaire.

Between groups, there was no significant improvement in neither disability scores (Kruskal-Wallis test ($p < 0.05$) nor chronic pain grading after treatment (Fisher's exact test ($P \leq 0.05$)).

Conclusions: Conservative treatment modalities applied in this study had non-significant effects on the improvement of temporomandibular joint disorder related disability and chronic pain grading in patients with disc displacement with reduction.

Keywords: Chronic pain, Disability, Laser, Splint, Temporomandibular joint disorders.

Introduction

Temporomandibular joint (TMJ) disorders (TMDs) are a wide-ranging group of clinical problems involving any combinations of the masticatory musculature, the TMJ, and neighboring hard and soft tissue components.

Symptoms of TMDs include limitation of mandibular range of motion, masticatory muscles pain, joint pain, associated joint noise during function, and/or deviation of jaw opening⁽¹⁾. Such symptoms may have significant debilitating effects on the patient's quality of life⁽²⁾. Amongst internal derangement (ID) disorders of the TMJ, the most common is disc displacement with reduction (DDWR) that is frequently correlated with the onset of joint sounds⁽⁴⁾.

TMDs Symptoms occur in about 6 to 12 % of the adult population^(5,6). Around 17,800,000 workdays are lost yearly for every 100,000,000 working adults in the

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United States due to disabling TMDs.⁽¹⁾

Research Diagnostic Criteria for TMDs (RDC/TMD)⁽⁷⁾ provide guidelines for a dual-axis assessment, with both a physical and a psychosocial appraisal. Moreover, the RDC/TMD Axis II measures were found to demonstrate psychometric properties suitable for comprehensive assessment and management of TMD patients⁽⁸⁾.

Since Anterior repositioning splint (ARS) has been considered for years the gold standard for treatment and relief of DDWR symptoms^(4,9,10), it was of importance to evaluate the efficacy of a novel physiotherapy treatment modality on the chronic pain grading and disability. Low-level Laser Therapy (LLLT) was found to have a bio-stimulating and analgesic effects through direct irradiation without producing thermal response⁽¹¹⁾. The advantages of this treatment tool comprise partial or total pain reduction, excluded or reduced use of analgesic drugs with no adverse effects (anesthesia dolorosa)⁽¹²⁾.

Regarding the use of Laser for management of TMD, its promising effects have been documented in several studies⁽¹³⁻¹⁶⁾. Therefore the goal of this study is to evaluate the different effects of splint therapy and laser therapy on the disability score and chronic pain grading and compare these effects to a placebo laser Group.

Materials and Methods

Participants

This Randomized controlled clinical trial with parallel groups was conducted at the Department of Orthodontics and Dentofacial orthopedics, Faculty of Dentistry, Cairo University, Egypt, from September 2015 to September 2017. The study was approved by the Ethics Committee of Dental Research at the Faculty of Dentistry, Cairo University. This study was registered at ClinicalTrials.gov (NCT03576079). Written consent forms were signed by the participants. The patients were recruited from outpatient clinic of the Orthodontic Department, Faculty of Dentistry, Cairo University. 41 patients with a chief complaint of TMD clicking were screened clinically.

The inclusion criteria of the patients were: age \geq 18 years, with a clinical diagnosis of disc displacement with reduction as verified from signs and symptoms during clinical examination according to the RDC/TMD⁽⁷⁾ and confirmed by MRI. The patients were medically free from any systemic disease and did not previously undergo any orthodontic treatment, TMJ treatment or surgery. The exclusion criteria of the patients were: patients with multiple missing posterior teeth, presence of muscle pain due to systemic disease, dental-related pain, presence of a congenital abnormality, neoplasia of the TMJ.

MRI Acquisition

MRI acquisition was performed using GE MRI machine 1.5 tesla (General Electric Medical Systems, Milwaukee, WI, USA) with a TMJ coil. Four main sequences were obtained for both right and left sides with a total of 24 cuts (12 right and 12 left) in both open and closed mouth positions. Disc was considered as displaced if any forward position exceeding 10-11 degrees from the 12 o'clock position from the condylar head was noted⁽¹⁷⁾. To differentially diagnose between DDWR and DDWOR the open mouth images were observed. If the disc recaptures over the condylar head then DDWR is confirmed.

After confirming the diagnosis of DD with reduction using MRI, 30 patients were found eligible to participate. Thorough patient history and psychological assessment were performed according to RDC/TMD Axis II that comprises behavioral questionnaires, guidelines for scoring and assessments. This part of the examination was conveyed in the form of a questionnaire that was officially translated by the RDC/TMD research group into the Arabic language. This questionnaire was divided into chronic pain grading (CPG) and jaw disability checklist using VAS scales. In addition, this form contained depression and non-specific physical symptoms evaluation and demographics. This gave an idea on the pain level, the amount of disability caused by patients' TMD and how patients' psychological status is affecting their clinical condition.

Clinical Examination, Randomization and blinding: on MRI images were veiled by someone who was not involved in the study. These measurements were repeated by another examiner who was not involved in the study.

Clinical examination steps were done following the RDC/TMD booklet examination questionnaire. Sequence generation was carried out by another person that was not involved in the research using Microsoft Excel (2013). Patients were randomly assigned to three groups: laser or Splint or Placebo laser with a 1:1:1 allocation. Blinding was preformed using numbered opaque sealed envelopes.

Treatment Protocol:

For the splint group, an anterior repositioning splint (ARS) was constructed to position the mandible slightly forward in order to help establish normal condyle/disc relationship. The appliance was fabricated according to Okeson⁽¹⁸⁾. The appliance consisted of a maxillary vacuum splint with an anterior occlusal ramp which helped to guide the mandible in a forward position (Figure 1).

Blinding to the patient was done for placebo and laser interventions. Due to the nature of the intervention the operator and patients could not be blinded. Measurements



Figure 1: The ARS inside the patient’s mouth during opening and closing. During closing, the maxillary guiding ramp places the mandible in a forward position.

The laser group: Epic 10, 940 nm wavelength (Biolase technology 2010, Inc. USA) was set to pain therapy mode with an output of 4W, and an energy density of 1800 J (1.8 KJ) with a continuous laser mode CW (Figure 2). Before the laser application, the handpiece was covered with a protective cover supplied by the manufacturer. For safety, eye protection goggles were worn by the patients. The laser beam was applied covering 3 points: anterior and posterior to the neck

of the condyle and the center of the articular disc with massaging motion directly contacting soft tissue skin using the fan-shaped bleaching handpiece by moving the handpiece back and forth. The exposure time was 450 seconds applied bilaterally. Each patient received 12 treatment sessions: 6 treatment sessions twice per week for 3 weeks followed 6 maintenance sessions: 1 session per week for 4 weeks then 2 sessions every 2 weeks.



Figure 2: The Biolase laser device with the adjusted treatment settings.

For the placebo laser group: Laser was applied in the same manner as the laser group without foot-switch activation. Only one patient dropped out of the placebo group during the study.

Treatment Outcome Measures:

Clinical examination to assess the outcomes was repeated and recorded using the same pre-treatment method and the same questionnaire was filled by the patient. Scoring measurements collected from the RDC/TMD from axis II as disability points and disability scores were extracted and compared pre and post-treatment. Regarding the CPG it is classified and scored according to Von Korff and co-authors⁽¹⁹⁾.

Statistical Analysis

Numerical data were explored for normality by checking the data distribution and using Kolmogorov-Smirnov and Shapiro-Wilk tests. Wilcoxon signed-rank

test ($p < 0.05$) was used to study the changes in disability score and CPG by time within each group. Kruskal-wallis test ($p < 0.05$) was used to compare the change in disability scores between the 3 groups. Fisher’s exact test ($P \leq 0.05$) was used to compare chronic pain grading between the groups after treatment.

Results and Discussion

In all groups; there was no statistically significant change in CPG after treatment. There was a statistically insignificant improvement in the two intervention groups and an insignificant pain progression in the placebo group. On comparing the three treatment groups there was no statistically significant difference between CPG in the three groups (Figure 3). After treatment the number of patients with Grade I increased while those with Grade II decreased.

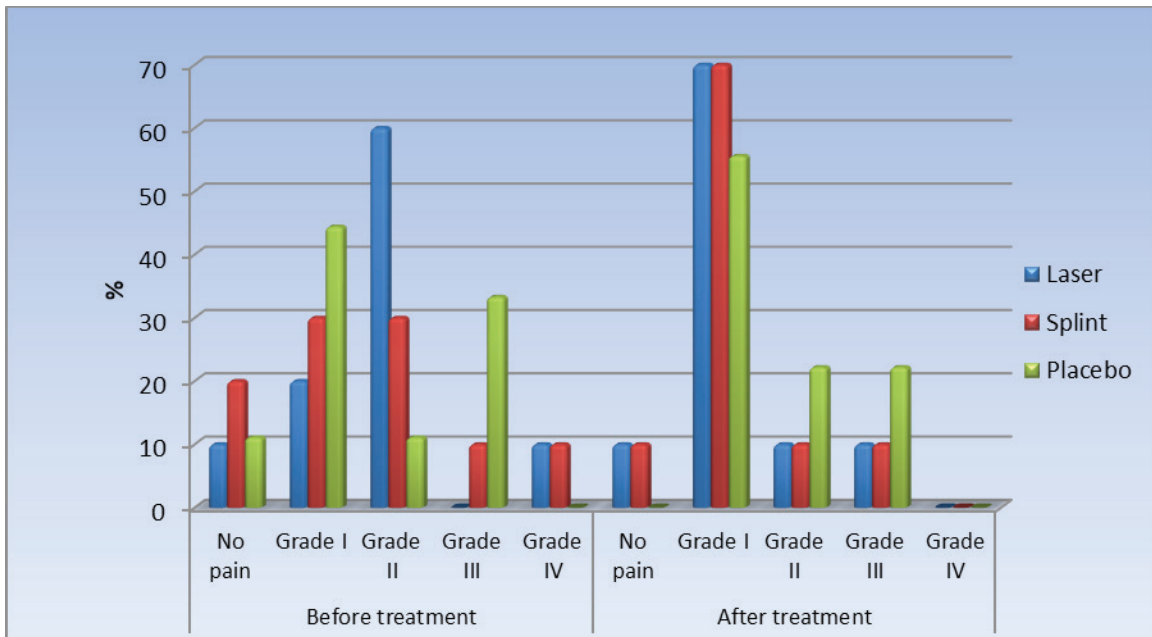


Figure 3: Bar chart representing chronic pain grade in the three groups.

In all groups; there was no statistically significant change in Disability score after treatment. There was a statistically insignificant decrease in splint (mean= -12.3±23.5) and laser (mean=-1.5±23.9) groups and a statistically insignificant increase (mean=4.1±41.4) in the placebo group. However, there was no statistically significant difference between mean Disability score in the three groups (Figure 4).

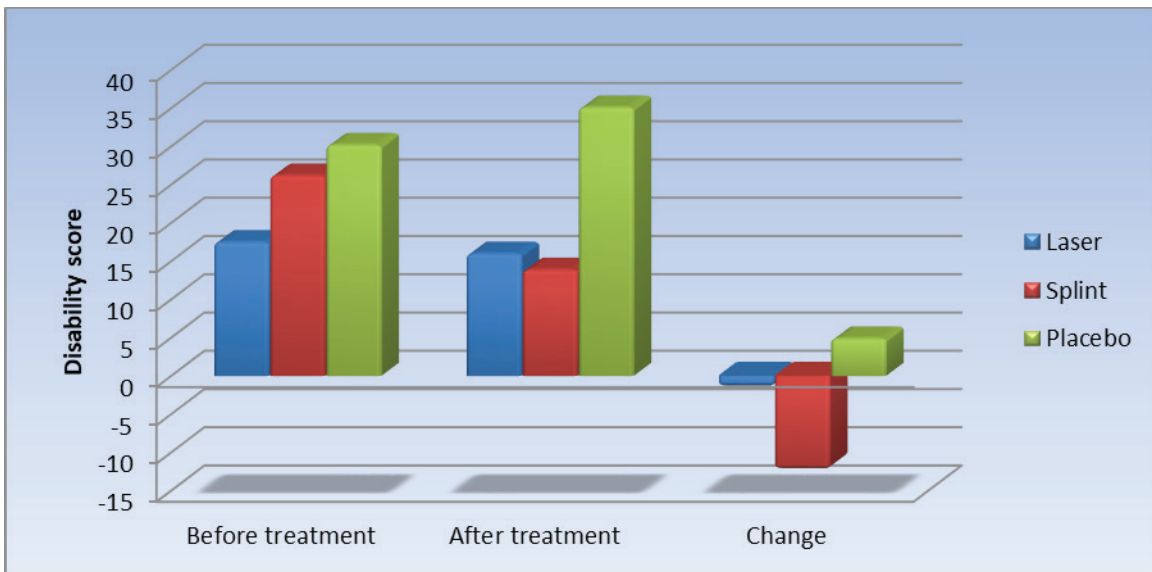


Figure 4: Bar chart representing changes in mean Disability score after treatment.

The judgment on the need for treatment intervention in TMD patients should be measured with three parameters: symptom intensity, disability, and progression, rather than the simple manifestation of a symptom. Such a measure would give an appropriate estimation of the problem of TMDs in the general

population⁽²⁰⁾.

Scientific data regarding different conservative treatment effects on disability and CPG are limited. Most of the previous studies were epidemiological^(6,7,19,21,22), others evaluated the effectiveness of conservative treatment on the psychosocial profiles of painful TMDs

but failed to address the assessment of their effects on disability^(23–25). Therefore it was difficult to compare the results of different conservative treatment options implemented in the current research with those of other studies.

Research indicates that 28% of TMD patients report disability and limitations, as well as unemployment⁽¹⁹⁾. Projections from research put the total cost of TMD in excess of \$4 billion per year in the U.S. Thus, TMD is clearly an economic burden to both patients and society,⁽²⁶⁾ although this condition is not really of much social importance in more developing countries and not covered by medical insurance and probably disregarded as a reason for disability. In addition, the socioeconomic level of our patients and the current work laws could have been a cofounder in affecting the disability score in our study sample. In our 3 months observation period, we found that although disability scores decreased within the laser and more in the splint groups and increased in the placebo group, these changes were statistically insignificant. Between groups, similar results were found yet again statistically insignificant. This was also probably be attributed to the short observation period, and the chronicity of DDWR, as Gatchel and colleagues⁽²⁶⁾ reported that early treatment of TMJ disorders may prevent chronic pain and disability.

There is a vast range of potential usages of a graded classification of chronic pain severity. In population surveys, the majority of persons report recurrent pain symptoms, many report intense and persistent pain, but fewer are severely disabled by pain. Graded classification could enable a more complete and reproducible differentiation of global pain severity among clinical cases⁽²¹⁾. Von Korff and co-authors⁽¹⁹⁾ showed that the principal advantages of the CPG methods as the simplicity of the measures and classification criteria; the provision of a categorical approach to grading the global severity of chronic pain. Changes that occurred in the patients of the current study regarding CGP showed no statistically significant results. A study by Chantaracherd and co-authors⁽³⁾ showed no association between TMJ intra-articular status and TMD impact represented by pain, jaw function, and disability.

This suggests that TMJ intra-articular disorders have minimal impact on patients' reported pain, function, and disability. Therefore our insignificant change in chronic pain grading could have been attributed to the short observation period and the chronicity of the TMD in the current sample.

Conclusions

No significant effects were found regarding the improvement of the patient's disability and chronic pain grading when applying a splint, laser or placebo laser therapies. The effect of TMD on patient's disability and the effect of different treatment modalities on improving patients' disability and daily activities and thus their quality of life may warrant further investigation.

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The main author was the principal investigator responsible for the recruitment, diagnosis, treatment of the patients, results interpretation and writing the manuscript. The second author was responsible for case supervision, RDC/TMD training, calibration of the principal investigator, and MRI interpretation. The third and fourth authors were involved in interpretation of the results, manuscript writing, and revision.

This study was self-funded by the main author and the laser device was provided by the Orthodontic Department, Faculty of Dentistry, Cairo University. Therefore there was no conflict of interest.

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Lower Extremities Fractures in Alnajaf/ Iraq

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Abstract

Purpose: To take an idea about the size of an important socioeconomically public health problem and to put solutions.

Material and Methods: All the patients who sustained lower extremities fractures in one year (between 1st Jan. till 31st Dec. 2018) included in this study. Data collected from the documents of Alsader medical city in Alnajaf, it included the types of fractures, ages, gender, side of fracture, and causes. Analysis of these data was done and the results were demonstrated in tables.

Results: The total number of the patients was (2466), males (1655) and females (811). The types of the fractures include: hip fracture 350, fracture femure 738, patellar fracture 49, leg fracture 831, ankle fracture 220 and foot fracture 278. People in the 1st decade were the most 697 followed by the 3rd decade 446, 2nd decade 440, 4th decade 287, 7th decade 193, 5th decade 155, 6th decade 142, and above 70 (106) patient. The most common cause of the fractures was RTA in 800 patient followed by fall 727, fall from height 594, and fall of heavy object 123 patients.

Conclusion: Children and adolescent are mostly affected. People below thirty represent more than 50% of the cases. Planes from all the government administrations showed be more effective to decrease the occurrence of such injuries by learning programs to avoid fractures in all ages, in order to decrease the socioeconomically burden on the community.

Key words: Lower Extremity, Fractures, Lower Limb, Alnajaf

Introduction

Lower limb fractures are common injuries. It account for about one third of all fractures. It may result in high rate of morbidity and mortality which can be reduced by early appropriate management.^(1,2) Fractures, mostly arising from injury, are a big public health problem.

In china injuries is the 5th most common cause of death, and resulting in more fatalities than DM and infectious diseases.^(3,4)

In general males had significantly higher fracture prevalence than females in every age group except in

old people where the prevalence is more in women.^(4,5,6)

The high incidence of lower limb fractures in women is related to hip fracture, due to osteoporosis which affects women more frequently. In US the number of osteoporosis –related fractures was estimated to exceed 2 million in 2005. With time it causes increasing economic burden on the health care system.^(5,6,7,8)

For our knowledge there are no updated papers which discuss this important issue in Iraq.

This paper is to discuss this problem from all sides regarding types of fractures, age groups and the causes. Hoping that the administrations will start putting planes

to decrease the rate of occurrence of these fractures and to put solutions and improve the methods of early management to decrease morbidity among population.

Material and method

This paper was conducted on patients attended the main hospital in Alnajaf (Alsader teaching hospital) in the period between the 1st of January 2018 to the 31st of December 2018. The data was collected from the documents of the outpatient clinic and from the emergency ward. The data include the age, gender, type of fracture, and the cause. For the age the patients were grouped according to the decades from one year old up to above 70 years old.

Regarding the types of fractures we started proximally from hip fracture, fracture femure, fracture patella, leg fracture, ankle fracture and foot fractures. Hip (proximal femure) fracture includes intra and extracapsular fractures. Fracture femure include all types of femoral shaft fractures including distal fractures. Leg fractures include isolated fractures of tibia or fibula or both of them. Ankle fractures include all fractures of

distal tibia and fibula. Foot fractures include the tarsals, metatarsals, and fracture phalanges.

The causes of fractures include fall during walking or playing, fall from height (FFH), road traffic accidents (RTA), fall of heavy object (FHO), direct hit, sport mainly foot ball (FB), bullet injury, injury due to explosions, and machine injuries.

Statistical Analysis

Statistical analysis was done by using SPSS (statistical package for social sciences) version 20, in which we use frequency and percentage, mean and standard deviation as descriptive statistics. Chi square test used for analytic statistics. P value ≤ 0.05 regarded significant.

Results

The total number of the patients was 2466 in one year. The number of the males was 1655(67.11%) and the number of females was 811(32.88%).

Table one shows details of gender, age range, mean age, and the side of the fractures.

Table (1): types of fractures, gender, age, side

Fracture Type	Male No.&%	Female No.&%	Age: rang	Mean age	Right side	Left side	Total
Hip	149 42.57%	201 57.42%	3-90	55.90	174 49.71%	176 50.28%	350 14.19%
Femure	516 69.91%	222 29.94%	1-88	17.40	379 51.35%	359 48.64%	738 29.92%
Patella	29 59.18%	20 40.81%	6-70	37.56	25 51.02%	24 48.97%	49 1.98%
Leg fractures	649 78.09%	182 21.90%	1-85	21.70	420 50.54%	411 49.45%	831 33.69%
Ankle	135 61.36%	85 38.64%	6-70	31.01	112 50.90%	108 49.09%	220 8.92%
Foot	177 63.66%	101 36.33%	3-75	30.67	136 48.92%	142 51.07%	278 11.27%
Total	1655 67.11%	811 32.88%	1-90	27.86	1246 50.52%	1220 49.47%	2466

The table show that the most common fracture was leg fractures (33.69%), followed by fracture femure (29.92%). It also shows that males affected more than females (67.11%) and (32.88%) respectively, ratio of (2.04:1). The mean age of the patients was (27.86) years. The right sides affected almost equally as the left sides in all fractures .

The table show that there was significant association (P<0.05) between hip fracture and female gender while all other fractures occur more in males.

Foot fractures include hind foot, mid foot and forefoot fractures. The hind foot fractures are those of calcaneum which constitute about 16% of all foot fractures , and the other 84% are those of mid and forefoot fractures. All affect males more than females.

Table (2) lower limb fractures/age groups

Fracture Type	Age group/No. &%								Total NO.
	1-10	11-20	21-30	31-40	41-50	51-60	61-70	>70	
Hip	18 5.14%	7 2%	14 45%	17 4.85%	18 5.14%	67 19.14%	138 39.42%	71 20.28%	350 14.19%
Femure	375 38.23%	122 16.53%	102 13.82%	60 8.13%	14 1.89%	27 3.65%	14 1.89%	24 3.25%	738 29.92%
Patella	---	3 6.12%	21 42.85%	5 10.20%	11 22.44%	3 6.12%	6 12.24%	---	49 1.98%
Leg fracture	278 33.45%	177 21.29%	178 21.41%	98 11.79%	51 6.13%	24 2.88%	14 1.68%	11 1.32%	831 33.69%
Ankle	5 2.27%	75 34.09%	42 19.09%	40 18.18%	28 12.72%	12 5.45%	18 8.18%	---	220 8.92%
Foot	21 7.55%	56 20.14%	89 32.01%	67 24.10%	33 11.87%	9 3.23%	3 1.08%	---	278 11.27%
Total	697 28.26%	440 17.84%	446 18.08%	287 11.63%	155 6.28%	142 5.75%	193 7.82%	106 4.29%	2466

Table (2) shows the type of the fracture in relation to age groups in decades. It is obvious that children up to ten years are mostly affected (28.26%) , and patient up to 30 years of age constitute about (64.18%) of the whole group It show significant association (P<0.05) between type of fracture and the age where fracture hip occur in old ages while all other fractures are more common in young people.

Table (3):causes of lower limb fractures

Fracture type	Cause of fracture/No.& %									Total
	Fall	Fall from height	Road Traffic Accident	Fall of heavy object	Direct hit	Foot ball	Bullet	Explosion	Machine	
Hip	246 70.28%	65 18.57%	35 10%	----	1 0.29%	----	3 0.85%	---	---	350 14.19%
Femure	161 21.18%	175 23.71%	324 43.90%	25 3.38%	1 0.13%	7 0.94%	25 3.38%	11 1.49%	9 1.21%	738 29.92%
Patella	17 34.69%	5 10.20%	27 55.10%	---	---	---	---	---	---	49 1.98%
Leg fractures	164 19.75%	200 24.09%	317 38.19%	38 4.57%	35 4.21%	32 3.85%	18 2.16%	27 3.25%	---	830 33.69%
Ankle	59 26.81%	71 32.27%	52 23.63%	---	18 8.18%	17 7.72%	3 1.36%	---	---	220 8.92%
Foot	80 28.77%	78 28.05%	45 16.18%	60 21.58%	5 1.79%	2 0.71%	7 2.51%	1 0.35%	---	278 %
Total	727 29.48%	594 24.08%	800 32.44%	123 4.98%	60 2.43%	58 2.35%	56 2.27%	39 1.58%	9 0.36%	2466

Table (3) show that the most common cause of neck femure fractures were fall(70.28%) ,while RTA was the most common cause of fracture femure(43.9%) , fracture patella (55.1%) and fracture leg (38.19%). Regarding ankle fractures the most common cause of fractures was fall from height(32.27%). For foot fractures the most common causes were fall(28.77%) and fall from height (28.05).

Discussion

Hip fracture(proximal femur)

The number of hip fracture expected to reach to 6.2 million by the year 2050 ,while it was 1.66 million in 1990. (8,9) It is more common in elderly people especially femals.The most common cause is fall.

Osteoporosis is the main risk factor, it represents a major health problem because of its association with low energy trauma or fragility fractures

Hip fracture has been recognized as the most serious consequences of osteoporosis because of its complications . (10)

In our series hip fracture represent 14.2% of lower limb fracture, while JA Kaye et al found that it represent 16.7%.⁽²⁾

A. Moayyer et al. found that the most common cause of hip fracture was fall. Female affected more than male and the percentage was 56.4% and 43.6% respectively.⁽¹¹⁾

These figures are comparable to our figures where more than 70% of hip fractures were due to fall, and females represent 57.4% while males were 42.6%. with mean age of more than (55) year.

Fracture femure

Worldwide RTA injuries cause over 1.3 million deaths and many more disabilities annually. Approximately one in ten RTA injuries involve a femoral shaft fracture.⁽¹²⁾

The annual rate in children up to 18 years was 19.15 per 100,000. The primary cause include fall in children less than 6 years old, pedestrian RT in 6-9 years old, and motor vehicle for teenager.⁽¹³⁾ JA Kaye et al. found that it represent 8.1% of lower limb fracture, while we found that it represent (29.92%) of lower limb fracture. In our study the mean age of patients was 17.4 years and about 38% were in the 1st decade and 16% in the 2nd decade which indicate that this fracture is more common in children. Also the most common cause was RTA (43.9%) followed by fall from height (23.7%) and fall in about (21.2%).

Fracture patella

Peter Larson et al founded that the mean age was 54 years for all patients, it was 46 year for males and 61 year for females. Females affected more than males; 56% for females and 44% for males.

They found that males have higher incidence than females in the 2nd decade of life, while females have higher incidence during the 6th and 7th decades.⁽¹⁴⁾

These results are not comparable with our study where the mean age in our study was 37 years and males affected more than females, 59% and 41%

respectively. People in the 3rd and 5th decades affected more commonly, 43% and 22% respectively.

Leg fracture (tibia and fibula)

Diaphyseal tibial fractures are the most common long bone fracture.⁽¹⁵⁾

Mario Serotorio et al found that the age range between 14 and 83 years with average (32) years. Males affected more than females, 73.74% and 26.26% respectively. The most common cause was RTA (80%). Right side affected more than left.⁽¹⁶⁾

The mean age in our study was 21.7 years ranging from 1-85 years. Males represent 78% and females 22% which is comparable to other studies. People in the 1st decade affected more (33%), followed by people in the 3rd decade (21.4%) and 2nd decade (21.3%). Leg fracture was the most common fracture of lower limb in this study represents 33.69% of the whole group. The most common cause of this fracture was RTA (38%) followed by fall from height (24%) and fall (19%).

Ankle fracture

Ankle fracture is one of the most common fractures increasing in aging population.⁽¹⁷⁾

Rasmus Elsoe et al found that the mean age of patients was 41.4 years, males represent 53% and females 47%. The peak incidence was among adolescent with male predominance. The cause of fracture was fall in 61% and sports in 22%.⁽¹⁸⁾

In our study the patients were younger with mean age of 31 years, males represent 61.36% and females 38.64%. Peak incidence was among people in the 2nd decade (34%). The main cause of the fracture was fall from height 32.3% followed by fall 26.8% and RTA 23.6%.

Foot fracture

Christian G. et al found that the mean age of patients was 36.1 year (females 41.3 years and males 31.3 years). Males represent 54.3% and females 45.7%. The peak incidence of the fracture was in the 2nd decade. People

under age of 30 years represent 43.9%.

The main cause of the fractures was low energy trauma (98.7%). Hind foot fracture occur in 8.3% of patient while mid and fore foot fractures occur in 91.7%.
(19)

In our study patients with foot fracture were younger with mean age of 31 years. Males represent 63.7% while females represent 36.3%. The peak incidence was among people in the 3rd decade of life. The cause of the fractures is low energy trauma in more than 78% of the cases. RTA was the cause in 16% of the cases. Hind foot fractures occur in 16% while mid and fore foot fractures occur in 84% of the cases.

Conclusion

Lower extremity fractures in general are more common in young people below 30 years except for hip fracture which is more common in old people. The most common cause is RTA. The most common type is leg fracture. Respect ion of regulation regarding road traffic is very important to decrease accidents. Also protection of children by family and school are most important. Regarding old people application of (fall prevention program) may be effective to decrease osteoporotic related fractures.

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Association between Effects of Sleep Pattern Behaviour of Children During Dental Treatment

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Abstract

Introduction : Young children have sleep alterations due to various social and cultural reasons which result in behavioural changes. Providing dental care for such children becomes a tedious task for practitioners. The children tend to be indifferent towards treatment thus hampering the prognosis of the best provided treatment.

Materials and Methods : 100 children between the age of 5 and 14 were included in the study. Demographic data and family status was recorded. They were then assessed on the basis of their behavior in the dental clinic using Frankl's behaviour scale.

Results : The results showed that sleep was a major factor that influenced the child's behavior. Mothers' occupation, type of family and number of siblings were also closely associated with the altered behavior of the child.

Conclusion : Sleep must be given equal importance as food and water. It is a very important factor that is required for growing children.

Key words - paediatric care, sleep pattern, behaviour management, child cooperation, pedodontic procedures, child control methods

Introduction

Children have highly altered sleep patterns and habits. When such type of children visit a clinic for dental treatment, it becomes tedious for the dentist to

perform treatment. Establishing a standard relation between child's sleep pattern and their behaviour at the clinic gives a better insight to the dentist while handling such children.

Managing a child is very different from the clinical and technical aspects of the established procedures due to psychological state of the child [1,2]. Verbal or non verbal communication modes of communication are used in paediatric dental care for establishment of a rapport with the young children coming for treatment. There are many factors which can hamper the communication between the dentist and child patient including but not limited to psychic, emotional, family or social character. Thus it is essential for the patient to understand the dentist's instructions. [3,4]

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It is most often noticed that children do not cooperate during dental procedures. The difficulties are not associated with the treatment but with the child's emotional status. Fear and anxiety are two most common features of emotion exhibited by a child at the Dental operator.^[5]

Pediatric dental practitioners strive hard to treat their child patients, their uncooperative nature in the clinics act as a barrier in effective delivery of the treatment. Approximately 20-30% of young children have bedtime issue or sleeping habits like sleep walking.^[6-8] These sleep habits vary or differ with age. Mostly toddlers have issues falling asleep and preschoolers on the other hand show traits of bruxism, enuresis, somnambulism. Adolescents present with problems associated with insomnia and daytime sleepiness.^[9] It is reported that children who have less total sleep duration are at a higher risk for developing behavioral problems such as anger, anxiety, overactivity, tantrums, and aggression.^[10] Shorter duration of sleep may be due to missing afternoon naps, late night sleeping etc.^[11]

The hours of sleep needed by children vary based on their age. Newborn 0-3 months 14-17 hours, Infant 4-12 months, 12-16 hours per 24 hours (including naps) Toddler 1-2 years 11-14 hours per 24 hours (including naps) Preschool 3-5 years 10-13 hours per 24 hours (including naps) School Age 6-12 years 9-12 hours per 24 hours Teen 13-18 years 8-10 hours per 24 hours^[12] Researchers have proved that sleep being insufficient does not only have a toll on the behaviour but may also influence the skills of the child.^[12-13]

Sleep which alters behavior, has been widely influenced by external factors such as cultural and environmental factors, family disputes, attention provided by the mother, and socioeconomic status.^[14-16]

Materials and Methods

In this study, children between 5 years to 14 years of age were chosen. A sample size of 100 children were selected. Special Children and children with other health problems comprising mental state were excluded from this study. A questionnaire was provided to obtain

information pertaining to sleep habits. It also included a set of questions which help gather information about the family of child, socioeconomic status using Kupusamy scale, as sleep alone cannot alter the behavior of a child. The children were then assessed in the dental operator unit on the basis of cooperation, acceptance and patience for any procedure. The child was shown a pictorial representation of the state of emotion as fearful and fearless. He/she was asked to choose their state of emotion from the chart. They were also shown a visual analogue scale, and were asked to rate their anxiety level. In the dental operator, child's behavior and cooperativeness during his/her preliminary examination and treatment was rated according to Frankl's behavior rating scale into definitely negative, negative, positive, and definitely positive.^[17]

The following traits were included:

- 1 = Definitely negative (—): Cries forcefully, refuses treatment, extreme negativism, fearful
- 2 = Negative (-): Reluctant to accept treatment, uncooperative, negative attitude but not very pronounced, i.e., sullen, withdrawn
- 3 = Positive (+): Acceptance of treatment, at times cautious, willing to comply but at times with reservations, usually follows dentist's directions
- 4 = Definitely positive (++) : Develops good rapport, takes interest, enjoys the treatment.

Using Pearson's Chi square test, the statistical analysis was done.

Results

From the statistical data collected, each of the questions put forth to the child was carefully analysed. The pediatric patients were subdivided into two categories based on age and the results were determined. The age groups chosen ranged from 5 to 9 years and 10 to 14 years, with 50 children in each category.

Based on their dentist visit to the clinic, it was determined that both groups had majority of the children visiting the clinic for the second time. This indicates

that the child patients had already been exposed to their fear or behavior pattern previously and have a sense of what would be done on the clinical set up. On an average nearly 30% of the children had visited the Dental clinic for the first time. The remaining 70% of the children had a first time experience.

Most children taken into consideration in this study were all single children with an average of 72% . The rest had younger or older siblings.

The occupation of the mother plays a key factor on the behaviour of a child. The more quality time spent between the child and mother, the child tends to be more well behaved .74% of the mothers accompanying these children were home makers. This indicates that children have more attention at home and tend to be more well behaved. In certain cases, the excess attention they get can take a toll on behavior and the child may be highly adamant .

Another factor altering behavior of child may be the type of family. Children growing in a secure family atmosphere makes them stronger and brave. Children coming from broken families tend to be very scared and frightened. The children included in this study come mostly from nuclear families 89% and the remaining 11% come from joint families. None of the children came from a broken family.

Based on the Kuppusamy scale, the socioeconomic status of the child’s family was assessed. Children between 5 to 9 years of age module belonged to the lower middle class with the next highest percentage pertaining to 10% of lower class and 7% of upper middle class. On the other hand children aged 10 to 15 years, belonged to lower middle class with 18% and the upper lower class with 17%. The socio economic status has an indirect impact on the children. At times, children coming from a lower background, tend to value money and be more understanding . These children show some traits of good behavior. Also the same children, can turn out to be very stubborn. This happens when they want materialistic things and are not able to acquire them.

When media usage by children was analysed ,it was seen that children between 10 and 14 years have nearly 62% of them who watch tv for less than one hour . And children between 5- 9 years watch tv for more time with nearly 44% watching tv regularly for 1- 2 hours . Only 5% of both age groups have the habit of watching tv for 3 to 5 hours.

Only 28% of the children were afternoon sleepers with 18% of them having night talking habits and 50% waking up in the middle of the night. There were no habits like bruxism and sleep walking. Only 23% of the children, were habit free and had the ability to have a sound sleep.

Table 1 Association of sleep with behaviour of child in the dental office for children between 5 to 9 years of age

	Less than 5 hours	6 to 8 hours	9 to 11 hours
Definitely negative	53.8	14.8	20
Negative	15.4	22.2	10
Positive	30.8	55.6	20
Definitely positive	0	7.4	50

From the table 1 its is clear that children between 5 to 9 years of age have shown definitely negative behavior when they had less than 5 hours of sleep. There was only 30.8 % of children who showed positive behavior. Whereas when these children had about 6 to 8 hours of sleep, 55.6% showed positive behavior in the dental

office. However there was a slight incline to negative behavior too. But children who had 9 to 11 hours of sleep in this category were considered well behaved due to their result.50% of the children fell in frankls behavior scale of definitely positive.

Table 2 Association of sleep with behaviour of child in the dental office for children between 10 to 15 years of age

	Less than 5 hours	6 to 8 hours	9 to 11 hours
Definitely negative	6.5	0	0
Negative	22.6	37.5	33.3
Positive	54.8	43.8	66.7
Definitely positive	16.1	18.8	0

10 to 15 years of children tend to be more matured. These children have the ability to control their behavior to an extent . From the table 2 we see that children irrespective of sleep exhibit positive behaviour. Definitely negative behavior is not seen at all for children getting more than 6 hours of sleep. However 6.5% of children with decreased sleep had definitely negative behavior. It is observed that a paid tube and negative behaviour is equally seen in the children under this category.

It is thus inferred from the results that sleep influences behavior of the child. Having sufficient amount of sleep is important for the child well being . This was indirectly beneficial to the dentist while treating children.

Discussion

Child anxiety has always been present when treatment is performed on the child. To avoid parental anxiety , the dental practitioner must educate the parents about the treatment and provide assurance to them. A pre visit appointment is essential . This will greatly influence the child’s behavior .^[18]

It is evident from the study that children who had more number of hours of sleep were well behaved

when compared to those with less sleep. This also hinders their process of learning and can also result in inappropriate neurobehavioral function.^[11]

When information is provided that child has had decreased number of hours of sleep and there is difficulty in assessing the behavior of child, projection methods can be adopted . It’s a method in which the child is allowed to draw any picture form his mind. Images drawn with negative features depicts fear in children.

According to a study done by Scharf et al.,^[19] a group of preschoolers with decreased amount of sleep appeared highly irritable and disturbed. This was misinterpreted by their parents as bad behavior like arrogance, obstinate nature and throwing tantrums. Dahl^[11] who was a part of this study, discovered that, these children with reduced hour of sleep may have poor cognitive development which directly affects the behavior of the child.

In a recent study, researchers at Tel Aviv University (TAU) identified that heightened activation of the amygdala is responsible for presenting a disturbing emotion regulation and increasing anxiety due to lack of sleep. The researchers found that even a single night

of sleeplessness changes the ability to regulate emotions and allocate brain resources necessary for objective cognitive processing.^[24]

Alfano in his study says studying the link between sleep disruption and maladaptive emotional processing in childhood is vital because that's when sleep and emotion regulatory systems develop. The increased need for sleep and greater brain plasticity in childhood suggests this period for early intervention as if let untreated these behavioral changes can elevate risk for depression and an overall poorer quality of life.^[25]

Visiting the dentist creates a great deal of stress and anxiety in patients. The common triggering factors for this fear and anxiety are the use of needles and syringes. In some children, the buzzing noise of the hand piece may also provoke a high level of anxiety.^[21] For such type of patients, behavior management techniques must be adopted.

Using Norman Corah's scale, a study showed that female children between 12 to 15 years of Age are more anxious than males in a Dental operator. The study showed that a significant percentage (34%) of middle school children suffered from high and severe dental anxiety.^[25] The fear and anxiety levels calculated in this study had no association with sleep pattern to assess behavior.

In a similar study conducted abroad, linear regression analysis was carried out to determine the relationship between behavior of children in dental operator and duration of sleep. According to Spearman's correlation, duration of sleep was positively correlated with cooperative behavior of child in dental operator, and gave a statistically significant value in the above study.^[23]

Conclusion

From this study we can conclude that sleep and behavior of child are associated with one and another. The more sleep a child has, the better behavior the child possesses. An emphasis and awareness should be made among parents the negative effect even a single day's loss of sleep can do to a child to help in guiding the child to

have a healthy sleeping practice.

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Effect of Structured Physical Therapy Exercise Protocol on Obesity Secondary to Hypothyroidism

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Abstract

Objectives: The objectives of the study were as follows : (1)To find effect of aerobic exercises along with medications on obesity secondary to hypothyroidism. (2) To find effect of resistance exercises along with medications on obesity secondary to hypothyroidism.(3) To find effect of aerobic and resistance exercises along with medications on obesity secondary to hypothyroidism.

Methods: Ethical clearance was obtained from the institutional ethical committee. A total of 30 hypothyroid and obese subjects were assessed and 24 were included in this study based on inclusion criteria, the individuals were allocated in two groups : Group A (n = 12) received only prescribed medications and group B (n= 12) received aerobic and resistance exercises along with prescribed medications. Pre - and post – test were done for assessing obesity by BMI and physical performance by Physical Performance Test Scoring form and the outcome measures were analysed after 8 weeks.

Results : Intergroup statistical analysis for BMI ($p < 0.05$) and Physical Performance Test Scoring form ($p < 0.05$) revealed extremely significant difference post-intervention. Analysis of BMI for Group A ($p = 1.613$) was not significant and for Group B ($p < 0.05$) was extremely significant.

Conclusion : The study results concluded that aerobic and resistance exercises was significantly effective in reducing BMI and improving Physical Performance compared to controlled group (Group A).

Keywords : *Aerobic and resistance exercises, Hypothyroidism, Obesity, Physical Performance.*

Introduction

Hypothyroidism is an underactive thyroid when Thyroid Stimulating Hormone (TSH) levels are elevated and Thyroxine (T4) levels are low. Prevalence of obesity secondary to hypothyroidism is 46%. ¹ Pathophysiology of obesity : Obesity is exaggeration of normal adiposity which secretes excessive adipokines. It leads to metabolic and immune dysfunction which worsens metabolic syndrome which later leads to obesity. ² Pathophysiology of obesity secondary to hypothyroidism : Thyroid hormone is essential to utilise energy from food (metabolism). This metabolism affects body temperature, heartbeat and lipid and glucose metabolism. When the thyroid levels are low, body process slows down. It leads to decreased energy expenditure, which leads

to obesity. Another cause is accumulation of water in interstitial spaces of the tissues which leads to puffiness. ³ Functions of thyroid hormone : Thyroid hormone regulates food intake and fat oxidation, thermogenesis, lipid and glucose metabolism and body metabolism. In hypothyroidism, thermogenesis, metabolic rate and resting expenditure rate declines.

Signs and symptoms : Fatigue, poor concentration, dry skin , constipation, feeling cold, fluid retention, muscle and joint aches, depression, prolonged menstrual bleeding, weight gain, poor memory and hoarse voice.

Role of physiotherapy in reducing obesity : Obesity is exaggeration of normal adiposity and is due to excessive secretion of adipokines. It leads to

metabolic and immune dysfunction which leads to worsening of metabolic syndrome. ²Aerobic training (bicycle ergometer) improves metabolism, decreases body weight, weight circumference and fat mass. Resistance training increases lean body mass, strength and metabolic rate which also causes significant decline in fat mass. The Aerobic and Resistance training is more effective in reducing total body mass and fat mass than Resistance training. Aerobic training is the optimal mode which reduces body and fat mass while resistance training increases lean body mass.⁴

It is found in earlier studies that aerobic and resistance exercises have significant effect on thyroid hormones. A review of literature shows significant effect of aerobic and resistance exercises on obesity. However, there is limited research available to show significant effect of aerobic and resistance exercises on obesity secondary to hypothyroidism.

Aerobic exercises included treadmill, static cycle and step up and resistance exercises included leg press, hamstring curls, quadriceps curls, triceps curls and trapezius strengthening. In the long term, it helped in reducing weight and preventing its complications.

Physicians assessed the individual. Necessary investigations were done. Then, they prescribed medications. Exercise therapist assessed the individual and structured an exercise plan and observed the individual to make sure the individual is performing with proper technique.

And if any complications were noted, medical help was sought immediately.

Methods

Ethical clearance was obtained from the Institutional Ethical Committee, KIMS DTU, Karad. The study included 30 individuals with hypothyroidism and obesity and were divided in two groups. Exclusion criteria

included individuals having cardiovascular disorders, other systemic problems, pregnant women, obesity in other than hypothyroid patients and individuals undergoing any other exercise programs. 30 individuals with hypothyroidism and obesity were assessed of which 3 were not meeting inclusion and exclusion criteria and 3 were not willing to participate in the study. 24 individuals were included in the study. After baseline assessment, which included BMI and Physical Performance Test Scoring form , they were allocated to respective groups using consecutive sampling method. The first group (Group A n = 12) received only medications. The second group (Group B = 12) received aerobic and resistance exercises with medications.

Sampling Method : Consecutive Sampling Method.

Group A received only medications.

Structured exercise program for Group B

- a. Aerobic exercises : Treadmill, Step up and static cycle exercises.
- b. Resistance exercises : Leg press, hamstring curls, quadriceps curls, triceps curls and trapezius strengthening.

Each exercise was performed for 3 minutes for 3 days/ week for 8 weeks with progression.

Group A enrolled 16 individuals, of which 4 individuals dropped out of the study due to irregular follow-up. Group B included 14 individuals, of which 2 individuals dropped out due to irregular follow-up and 1 individual due to transport issues. At the end of the study, a total of 24 individuals were taken for analysis.

Results

Primary outcomes used for the result were BMI and Physical Performance Test Scoring Form.

Table No.1: Age distribution

Age in Years	Group A		Group B	
	Frequency	%	Frequency	%
< 40	4	33	8	67
≥ 40	8	67	4	33
Total	12	100	12	100

Table No.2 Gender distribution

Sex	Group A		Group B	
	Frequency	%	Frequency	%
Male	3	25	0	0
Female	9	75	12	100
Total	12	100	12	100

Table No.3 BMI

BMI	Mean	SD
Post BMI Group A	28.099	3.839
Post BMI Group B	31.065	4.148

Table No.4: Physical Performance Test Scoring Form

PPT	Mean	SD
Post PPT Group A	30.92	2.968
Post PPT Group B	31.5	2.646

Discussion

This study “Effect of Structured Physical Therapy Exercise Protocol on Obesity Secondary To Hypothyroidism” was conducted to compare the difference of weight changes and physical performance in non exercising and exercising individuals. Progressively increasing weight affects physical performance and acts as a precursor to many diseases. The objectives of this study were to find effect of aerobic exercises on obesity secondary to hypothyroidism. To find the effect of resistance exercises on obesity secondary to hypothyroidism. To find effect of combined aerobic and resistance exercises on obesity secondary to hypothyroidism. In previous studies, Effect of bicycle ergometer on thyroid hormones after a treatment duration of 9 minutes with gradually increasing intensity every 3 minutes for a duration of 3 weeks was significant⁴. Effect of resistance training on thyroid hormones after a treatment duration of 8 weeks for 3 days / week was

significant and it caused significant changes in thyroid hormones⁸. But previous studies did not signify any changes in weight along with thyroid hormones and no improvement in physical performance was noted. Thus, it made indeed to study changes in weight as per BMI and physical performance. The study was conducted amongst clinically diagnosed hypothyroid subjects with of age group 18-70 years. 24 subjects were included in the study. The subjects were divided into two groups; Prior consent was taken. They were enrolled in two groups : Group A was Controlled Group which was only given medications and was observed for 8 weeks and Group B was Experimental Group which was given physiotherapy treatment along with medications. The Group B (treatment group) was given the following exercises : Aerobic Exercises – Treadmill, Step up and Static Cycle; Resistance Exercises – Multiple Exerciser. Each exercise was given for 3 minutes for a duration of 3 days /week for 8 weeks. Pre and post treatment BMI and

Physical Performance test scores were recorded for both groups and were used for statistical analysis. In intergroup comparison, p value of BMI in Group A was 0.135 and in Group B was 0.035. Post training there was significant improvement noted in BMI with aerobic and resistance training than with controlled group. Also, p value of PPT in Group A was 0.377 and in Group B was 0.035. Post training there was significant improvement noted in PPT with aerobic and resistance training than with the controlled group. Post training there is improvement in metabolism, lean body mass and strength and decrease in body weight and weight circumference. Thus, there is significant decrease in body weight which ultimately decreased BMI and increased metabolism which in turn improved physical performance of the patient.

Conclusion

We found that aerobic and resistance training was significantly effective in decreasing weight. This training was effective by reducing BMI and improving Physical Performance which improved quality of life of patients.

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Conflicts of Interest: The author declares that there are no conflicts of interest concerning the content of the present study.

Source of Funding : Self

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Role of Short Term Open Eye OrthoK Lens Wear in Inducing Myopia Control Changes in Eyes With Moderate Myopia

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Abstract

Purpose: To assess peripheral refraction, corneal, and visual acuity changes after open eye use of orthokeratology (OrthoK) contact lenses.

Methodology: OrthoK contact lenses were worn on separate occasions for half an hour and 2 hours in open eye condition. The peripheral refraction (PR) changes were assessed monocularly up to 30° nasally and temporally in the horizontal visual field using the open field autorefractometer. Average corneal power (ACP), central corneal thickness (CCT), and visual acuity (VA) was recorded using corneal topographer, specular microscope, and LogMAR chart respectively.

Results: Mean baseline PR at 25° and beyond both nasally and temporally was $-0.54 \pm 1.68D$ (mean \pm SD) which increased to mean $-1.29 \pm 1.43D$ ($p < 0.01$) post half an hour of lens wear and further increased to mean $-1.62 \pm 1.53D$ ($p < 0.01$) after 2 hours lens wear. The mean baseline ACP was $43.45 \pm 1.34D$ that reduced to mean $43.11 \pm 1.37D$ ($p < 0.01$) after half an hour of lens wear and a further reduction to mean $42.73 \pm 1.34D$ ($p < 0.01$) 2 hours post lens wear. Mean CCT changes after half an hour lens wear were not significant but it reduced by mean $14.92 \pm 4.68 \mu m$ ($p < 0.01$) 2 hours post lens wear as compared to baseline. The unaided VA improved from mean $0.85 + 0.37 \log$ at baseline to mean $0.49 + 0.35 \log$ ($p < 0.01$) after half an hour of lens wear and mean $0.39 + 0.35 \log$ ($p < 0.01$) after 2 hours of OrthoK lens wear.

Conclusion: Rapid corneal and peripheral refraction shifts are seen after half an hour of open-eye wear of the OrthoK lens with a gradual rise in impact for 2 hours of lens wear.

Keywords: Orthokeratology, peripheral refraction, myopia.

Introduction

Overnight orthokeratology (OrthoK) wear using reverse geometry lenses has proven to be an effective procedure for vision correction option since past few decades.^{1,2} Researchers have also proven its efficacy in myopia control by inducing peripheral myopic defocus

in children and teens.³⁻⁷ Reduction in central corneal thickness (CCT), flattening of corneal curvature, and improvement of visual acuity (VA) have also been reported post first overnight wear of OrthoK lenses.⁶ Peripheral myopic refraction changes post-OrthoK lens wear have a strong correlation with corneal flattening and daily usage of these lenses ensures myopia control in the young population.⁷ Although overnight OrthoK wear is mostly safe, a few studies^{8,9} have reported an increased incidence of corneal infection and lens binding post overnight OrthoK wear. Reducing the risk of overnight wear would increase its acceptance among practitioners as well as patients. A short term day time use may be the right solution to utilize the advantages of changes in

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peripheral refraction without the risk of development of ocular infection. Daytime OrthoK lens wear could be a potential method for reducing myopia progression.

This study aims to record changes post short term, day-time, open eyewear of OrthoK lenses on average corneal power (ACP), CCT, VA along with changes in peripheral refraction (PR). Based on the above ocular response to short term OrthoK lens wear it will be of interest if routine short term daytime wear of OrthoK lenses leads to myopia control.

Material and Method

This study recruited subjects from the student population of Lotus College of Optometry, Mumbai, India. After the explanation of study procedures in detail, written informed consent was taken from all subjects. No subjects reported a history of any ocular diseases or corneal ectasia and none were previous RGP lens wearers or extended soft lens wearers. Only subjects with a refractive error between -1.00DS to -4.00DS and with the rule astigmatism less than 1.50DC were included in the study.

This study used reverse geometry RGP contact lenses manufactured by Fargo (GP Specialist, USA). The lenses were made of Paragon HDS material with a Dk value of 100. The lenses were fitted as per the guidelines of the manufacturer that takes into account the subject's corneal curvature and refraction. Slit-lamp

fluorescein fitting evaluation was performed for good lens centration and movement with every blink.

The open field auto-refractometer WAM-5500 (Grand Seiko Co. Ltd, Japan) was used to record PR monocularly at baseline and post lens wear. In order to dilate the pupil for ease in the measurement of PR, the illumination of the room was dimmed. To record peripheral refraction a curved rail was designed and mounted at a distance of 2.50m from the subject's corneal apex (Figure 1). The curve mount was specifically designed to ensure all measurement LED points are equidistant from the subject's corneal apex. A total of five readings were taken at each point and averaged for the best accuracy. The instrument's conventional refraction values were converted to vector form of spherical equivalent 'M' and peripheral astigmatism form J180/J45 by the computer software for analysis. ACP was recorded using the TMS-4 corneal topographer (Tomey Corporation, USA). The topographer software records the ACP by averaging all the corneal data points on the reflected mires ahead of the entrance pupil. Accurate ACP values were recorded by capturing three corneal image maps with good centration and later averaging their values. CCT values were recorded using a non-contact specular microscope SP-3000P (Topcon Corporation, Japan) and a total of three readings were recorded and averaged. Monocular VA was recorded using a LogMAR chart under standard room illumination of 120 cd/m^2 .

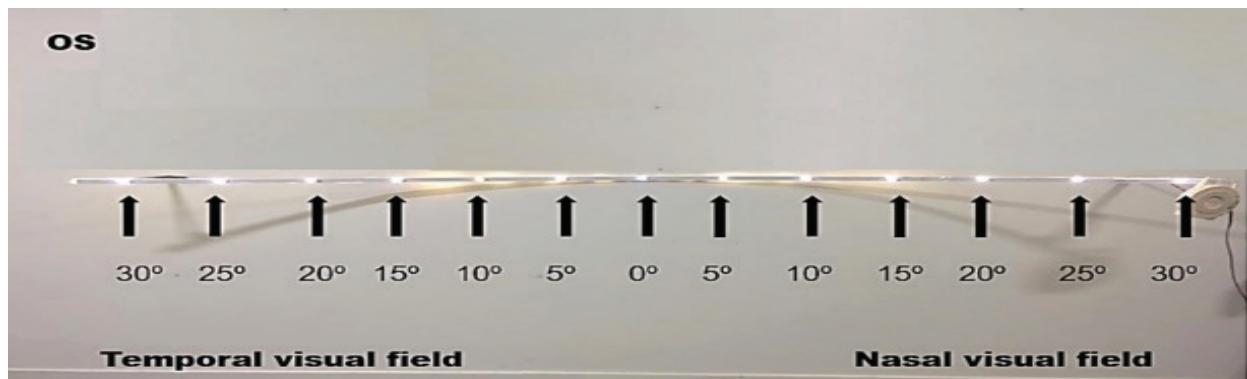


Figure 1: Fixation LED points located at 2.5m from the subject at 5° interval representing visual field eccentricities for measuring peripheral refraction. Prefix 'OS' denotes the left eye.

Study protocol: Detailed slit-lamp examination and non-cycloplegic refraction were performed to observe overall ocular health and to ensure subjects met the selection criteria. This study was divided into three visits; one baseline and 2 test visits. The baseline measurements during the first visit included VA, ACP, CCT, and PR. Subjects then wore best-fit OrthoK lenses in both eyes for half an hour in open eye condition on the second visit. A single examiner inserted and removed the OrthoK lenses during the same time of the day to avoid diurnal variations. Post half an hour wear lenses were removed and refraction; VA, ACP, CCT, and PR were recorded monocularly in the same sequence for all subjects. The subjects were then recalled after a week for the third visit that included OrthoK lens wear for 2 hours in open eye condition and again all values were recorded monocularly and compared to baseline. This was performed to ascertain if there were any further changes in ocular measurements with longer duration of lens wear.

Data analysis: Data were analyzed using SPSS software (version 20). Kolmogorov-Smirnov test was done to evaluate the normality of the data distribution. Repeated measures ANOVA with posthoc test (Bonferroni correction) was used when the data passed the normality test. The study chose a critical p -value of 0.05 or less for statistical significance.

Results

This study included 25 eyes of 15 subjects with a mean age of 20.45 ± 1.45 years (mean \pm SD) were recruited for the study. The mean objective baseline central refraction of the subjects was -2.52 ± 1.15 D (mean \pm SD).

Compared to the baseline mean refraction in central 10° of visual field reduced by -0.36 ± 0.26 D (mean \pm SD) post 30 min lens wear and -0.63 ± 0.32 D (mean \pm SD) post 2 hours lens wear and was statistically significant ($p < 0.01$) for both lens wear duration as observed in figure 2.

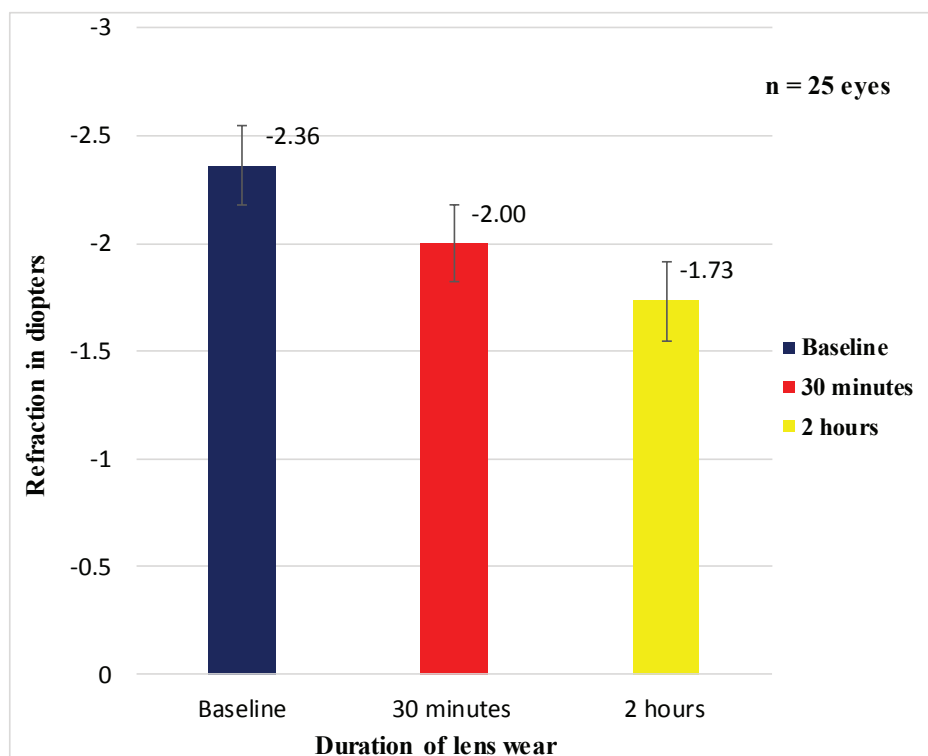


Figure 2: Comparison of changes in central 10° refraction after OrthoK lens wear in open eye condition post half an hour and post 2 hours to the baseline measurement. Error bars represent standard error of the mean.

Mean baseline PR at 25° and beyond both nasally and temporally was found to be -0.54 ± 1.68 D (mean \pm SD) which increased to -1.29 ± 1.43 D (mean \pm SD) post half an hour of lens wear and further increased to -1.62 ± 1.53 D (mean \pm SD) post 2 hours lens wear. Statistical significance ($p < 0.01$) was seen for both duration of lens wear as compared to baseline (figure 3). Compared to baseline no significant changes were seen in peripheral astigmatism J180/J45 for both lens wear duration ($p > 0.05$).

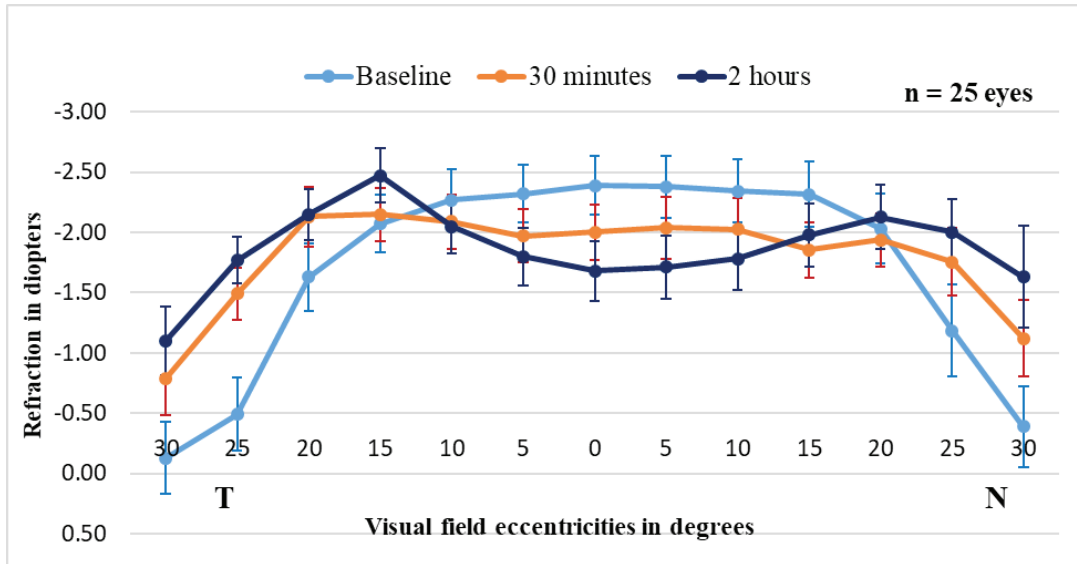


Figure 3: Comparison of peripheral refraction (M) changes after OrthoK lens wear in open eye condition post half an hour (indicated with orange line) and 2 hours (indicated with dark blue line) to the baseline measurement (indicated with a sky blue line). The letter ‘T’ denotes the temporal visual field and ‘N’ denotes the nasal visual field. Error bars represent standard error of the mean.

The unaided VA improved from mean $0.85 + 0.37$ log (mean \pm SD) at baseline to mean $0.49 + 0.35$ log (mean \pm SD) ($p < 0.01$) post half an hour of lens wear and mean $0.39 + 0.35$ log (mean \pm SD) ($p < 0.01$) after 2 hours of OrthoK lens wear. The VA post OrthoK lens wear displays better improvement with longer duration of lens wear as seen in figure 4.

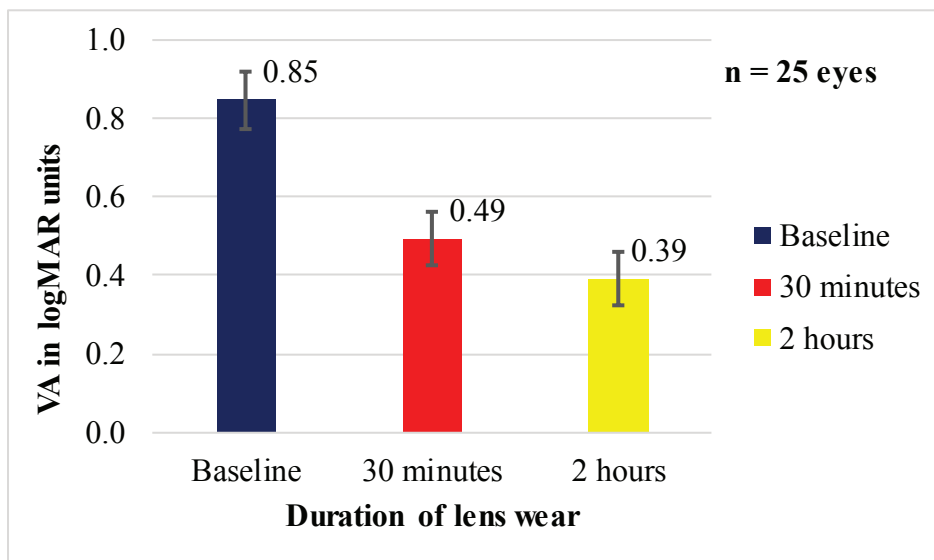


Figure 4: Comparison of changes in visual acuity after OrthoK lens wear in open eye condition post half an hour and post 2 hours to the baseline measurement. Error bars represent standard error of the mean.

Mean baseline ACP was 43.45 ± 1.34 D (mean \pm SD) that reduced to mean 43.11 ± 1.37 D (mean \pm SD) ($p < 0.01$) post half an hour of lens wear and a further reduction to mean 42.73 ± 1.34 D (mean \pm SD) ($p < 0.01$) after 2 hours lens wear. A gradual decrease in ACP with longer duration in lens wear is displayed in figure 5.

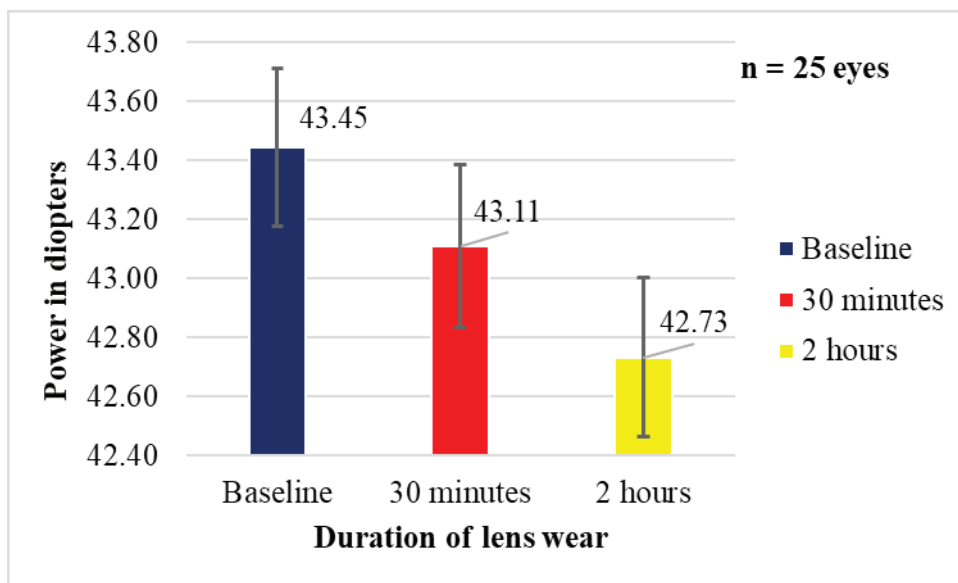


Figure 5: Comparison of changes in ACP after OrthoK lens wear in open eye condition post half an hour and post 2 hours to the baseline measurement. Error bars represent standard error of the mean.

Mean CCT recorded at baseline was 499.96 ± 35.93 μ m (mean \pm SD). Post half an hour of OrthoK lens wear a mean reduction of 1.72 ± 5.50 μ m (mean \pm SD) in CCT was seen as compared to baseline but was found to be not significant ($p > 0.05$). After 2 hours lens wear CCT further reduced by mean 14.92 ± 4.68 μ m (mean \pm SD) and was found to be statistically significant as compared to baseline ($p < 0.01$). Figure 6 displays a reduction in CCT with increased duration of lens wear.

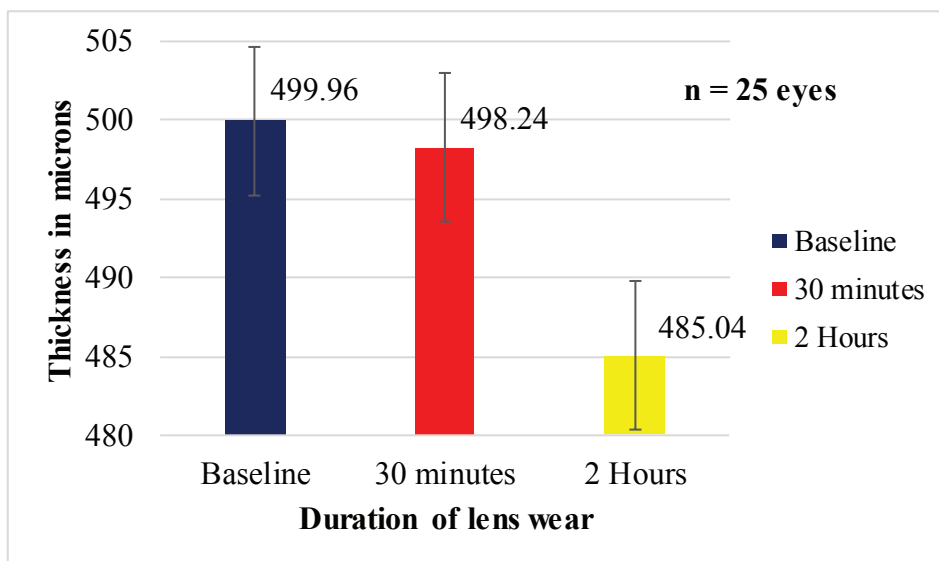


Figure 6: Comparison of changes in CCT after OrthoK lens wear in open eye condition post half an hour and post 2 hours to the baseline measurement. Error bars represent standard error of the mean.

Discussion

Ramkumar and Swarbrick¹⁰ in 2003 studied corneal topography and VA changes post usage of OrthoK lenses worn in open eye condition. Their findings reported significant change in apical corneal flattening of -1.21 ± 0.52 D (mean \pm SD) and improvement in uncorrected VA of -0.51 ± 0.25 log (mean \pm SD) post 1 hour of lens wear as compared to baseline values. This study reported a similar flattening of the cornea with the difference between baseline ACP and post 2 hours lens wear values were -0.71 ± 0.23 D (mean \pm SD). An improvement of 0.46 ± 0.28 log (mean \pm SD) in uncorrected VA was also recorded post 2 hours lens wear which is again in agreement with the above-mentioned study. The possible mechanism of corneal flattening was attributed by the authors to the tear film forces acting below the contact lens surface thereby compressing the cornea.

Jayakumar and Swarbrick¹¹ in 2005 evaluated changes in apical corneal curvature, central corneal thickness, and uncorrected VA post 1 hour of open eye OrthoK lens wear in young adults. Their findings reported similar changes in apical corneal flattening of 0.15 ± 0.01 mm (mean \pm SD) and improvement in uncorrected VA of 0.60 ± 0.28 log (mean \pm SD) post 1 hour of lens wear as compared to baseline values. Statistical changes in CCT as compared to baseline values were reported to be 5.2 ± 2.0 μ m (mean \pm SD) post 1 hour of lens wear as compared to baseline values and were mostly at the epithelial level. This study reported a more substantial reduction of 14.92 ± 4.68 μ m (mean \pm SD) μ m post 2 hours of open eye OrthoK lens wear. The reason can be attributed to the longer duration of 2 hours lens wear in this study versus 1-hour wear in the above-mentioned study.

Changes in PR post short term wear of OrthoK lenses has till date not been studied. The most relevant study was done by Kang and Swarbrick⁶ in 2013 who monitored PR after 1, 4, 7, and 14 nights of overnight OrthoK lens wear. They concluded that the highest shift in central refraction and PR occurred after wearing lens for 1 night with the least changes observed between

7 and 14 nights of lens wear. This study reported that compared to the baseline mean refraction in central 10° of visual field reduced by -0.36 ± 0.26 D (mean \pm SD) post 30 min lens wear and -0.63 ± 0.32 D (mean \pm SD) post 2 hours lens wear and was statistically significant ($p < 0.01$) for both lens wear duration. Mean baseline PR at 25° and beyond both nasally and temporally was found to be -0.54 ± 1.68 D (mean \pm SD) which increased to -1.29 ± 1.43 D (mean \pm SD) post half an hour of lens wear and further increased to -1.62 ± 1.53 D (mean \pm SD) post 2 hours lens wear. Statistical significance ($p < 0.01$) was seen for both duration of lens wear as compared to baseline. This study thus confirms rapid changes in corneal flattening and an increase in peripheral myopia after 2 hours of lens wear. Previous studies¹⁻⁷ have also concluded that peripheral increase in myopia refraction is an effective strategy to control myopia progression among children. The present study results will thus form the basis for a future longitudinal study where routine short term wear of OrthoK can be used as an alternative to overnight lens wear for myopia control.

Conclusion

Rapid changes in the cornea, peripheral refraction, and visual acuity are observed after half an hour of OrthoK lens wear with a steady increase in impact post 2 hours of lens wear. Further, a longitudinal study will be required to assess the role of short term OrthoK lens wear on myopia control.

Conflict of Interest: Nil

Source of Funding: Nil

Ethical Clearance: Approved

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Gender Stratified Physical and Psychological Health Status and Its' Correlation among Community-Dwelling Older Adults

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Abstract

Background: Maintenance of physical and psychological health is crucial to prevent general health problems in older persons. There is inadequate information on gender based physical and psychological health status in older adults attending primary care clinics in Malaysia.

Study Design: Cross-sectional study

Methods: 106 participants were required to perform physical performance tests consisting of 30secs chair stand (30sCS), chair sit and reach (CSR), back scratch (BS), timed up and go (TUG), single leg stance (SLS) and 2minutes walk (2MWT) tests. Psychological health measures consisted of Satisfaction with Life Scale (SWLS) and General Health Questionnaire-28 (GHQ-28).

Results: Only CSR was found to be significantly higher in men (M= 1.27, SD= 3.1) compared to women (M= -0.88, SD= 3.67). A significant correlation ($p < 0.05$) was found only in men between GHQ-28 and 30 seconds sit to stand test ($r = -0.424$), TUG ($r = 0.361$) and 2 Minute walk test ($r = -0.436$).

Conclusion: Older males and females had similar physical and psychological measures except for lower limb flexibility which was greater in females. Lower physical performance (lower body strength, mobility and endurance) correlated with higher psychological issues in older males. There may be a need to consider distinct physical and psychological needs between genders in order to provide optimum health prevention and management strategies among older adults.

Keywords: older adults, community-dwelling, physical health, psychological health, primary care, Malaysia

Introduction

The world's population is ageing and is expected to reach 2 trillion globally by year 2050, with about

50% living in Asian countries¹. It is estimated that by year 2030, 15% of Malaysian population will be older persons². Ageing is related to deterioration in physical and psychological health status³.

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Health status is a multifaceted concept determined by the presence or absence of both physical or psychological conditions⁴. Physical function is referred to the ability to perform movements which assist in performing activities of daily living (ADL)⁵. While, psychological health status is defined as emotional, mental and behavioural

wellbeing⁶. It may include attributes such as sleep quality, emotional health, cognitive functioning, health promotion behaviours and satisfaction of life⁷.

It has been shown that ageing process results in increase in body fat, decline in muscle strength, flexibility, agility, endurance and cognitive function³. As a result, decline in physical activity levels and functional fitness⁸. Changes in the neuro-musculoskeletal systems⁹ and loss of molecular and brain functions¹⁰ leads to simultaneous decline in physical and cognitive function with ageing¹¹.

Physical and psychological function are associated and appears as predictors of increased morbidity and mortality in older persons¹². For example, impairment in activities of daily living, slower walking speed, poor self-rated health, declined cognitive status and two or more clinic visits in the past month were identified as risk factors for depression¹³.

Information pertaining to physical and psychological status in older adults in Malaysia is scarce. The objective of this study was to examine gender specific physical and psychological health status and its correlation in older adults visiting a primary healthcare facility at Malaysia.

Methodology

Participants

106 community-dwelling older adults were recruited from a Primary Care Clinic at Cheras, Malaysia. Participants aged 60 years above and able to walk with or without assistive devices. Exclusion criteria were unable to comprehend and follow instructions in English or Malay language, known neurological and musculoskeletal impairments and on antipsychotic medications. Participants were provided with study information and consent was obtained. Sociodemographic data was obtained. Physical and psychological function were assessed.

Procedure

Physical health status was measured using Functional

Fitness MOT (FFMOT)¹⁴. The physical test included 30secs chair stand (30sCS), chair sit and reach (CSR), back scratch (BS), timed up and go (TUG), single leg stance (SLS) and 2minutes walk (2MWT) tests. It has good reliability and moderate-to-good correlation with intraclass reliability values(R) for all tests (0.80 to 0.98)¹⁵. Procedure for these tests are reported previously^{12,25}.

Psychological health status was measured using The Satisfaction with Life Scale (SWLS) and General Health Questionnaire-28 (GHQ-28). The SWLS indicates global cognition of satisfaction with one's life¹⁶. It consists of a short 5-items questionnainne. Malay version of SWLS has high internal consistency (Cronbach's $\alpha=0.83$)¹⁷. Higher scores denotes higher satisfaction.

GHQ-28 is a self-report questionnaire with 28-items and 4 subscales (somatic symptoms: items 1–7; anxiety/insomnia :items 8–14; social dysfunction: items 15–21, severe depression : items 22–28). Total score of ≤ 23 is normal, ≥ 24 as psychiatric issues and 23-24 as presence of distress¹⁸. The inter and intra-rater reliability is excellent (Cronbach's alpha: 0.90)¹⁹.

Data Analysis

Data analyses were conducted using the SPSS version 23 (Statistical Products and Services Solution). Independent t-test was used to examine gender differences for physical and psychological health status. Correlation analysis was conducted between SWLS, GHQ-28 and physical function parameters. Statistical significance of $p < 0.05$ was used.

Results

A total of 106 participants participated [54 males,(mean age (SD):68.5 \pm 6.5) ; and 52 females, (mean age (SD): 67.5 \pm 6.0). Only CSR was found to be significantly higher in men (M=1.27, SD=3.1) compared to women (M=-0.88, SD=3.67). Although not significant ($p > 0.05$), men scored higher in 30sCS (lower limb muscle strength; M=13.0, SD=3.8), BS (M=-2.4, SD=4.1), SWLS (M=26.7, SD=5.06) and GHQ-28 (M=15.6, SD=7.0) than women [30sCS: 12.8 \pm SD3.0, BS:-3.7 \pm SD 5.0, SWLS:24.9 \pm SD5.23,

GHQ-28:14.8±SD 5.8]

Table 1 shows means (standard deviation) of physical and psychological related measures respectively, stratified based on gender. Shapiro-Wilks analysis

showed that data was normally distributed. Only CSR test was found to be significantly higher in men ($p < 0.05$) than women. Significant correlation ($p < 0.05$) was found only in men between GHQ-28 and 30sSTS, TUG and 2MWT tests (Table 2).

Table 1: Gender specific Mean (Standard Deviation) of Physical and Psychological Measurements

	Mean (SD)			p-value for mean gender differences	d
	Men (n=54)	Women (n= 52)	Total (n= 106)		
Physical related Parameters					
30sCS (reps)	12.96 (3.74)	12.77 (3.20)	12.87 (3.47)	0.776	0.05
CSR (cm)	1.27 (3.14)	-0.88 (3.67)	0.21 (3.56)	0.002*	0.63
BS (cm)	-2.37 (4.17)	-3.73 (4.95)	-3.04 (4.60)	0.130	0.29
TUG (s)	8.90 (1.65)	9.04 (1.83)	8.97 (1.73)	0.664	0.08
SLS (s)	16.39 (9.09)	17.44 (9.01)	16.91 (9.02)	0.550	0.12
2MWT (m)	125.94 (29.03)	126.62 (39.92)	126.27 (34.64)	0.922#	0.01
Psychological related Parameters					
SWLS	26.72 (5.06)	24.90 (5.28)	25.83 (5.23)	0.073	0.35
GHQ-28	15.59 (6.96)	14.75 (5.75)	15.18 (6.38)	0.499	0.13

*Significance level at $p < 0.05$, 95% CI, Independent t-test

Equality of variance not assumed, $p < 0.05$ on Levene’s test

Table 2: Partial correlation between psychological health status and physical function parameters in men and women controlling for age and ethnicity

Variable	SWLS						GHQ-28					
	Men			Women			Men			Women		
	r	p-value	d	r	p-value	d	r	p-value	d	r	p-value	d
30sCS	0.106	0.455	0.01	0.242	0.091	0.06	-0.424	0.002*	0.18	-0.192	0.181	0.04
CSR	0.133	0.346	0.02	0.146	0.313	0.02	-0.261	0.062	0.07	-0.042	0.770	0.002
BS	0.030	0.835	0.01	0.025	0.863	0.01	-0.197	0.161	0.04	-0.026	0.856	0.0007
TUG	-0.132	0.351	0.02	-0.103	0.478	0.01	0.361	0.008*	0.13	0.069	0.636	0.005
SLS	0.169	0.232	0.02	0.147	0.309	0.02	-0.187	0.184	0.03	-0.144	0.320	0.02
2MWT	0.193	0.170	0.04	0.169	0.242	0.03	-0.436	0.001*	0.19	-0.068	0.641	0.005

*Significant difference at $p < 0.05$, 95% CI

Discussion

The aim of the study was to examine physical and psychological health status and its correlation among older adults visiting a primary care clinic. A significant correlation between greater physical performance (lower body strength, mobility and endurance) and lower psychological health status (GHQ-28) in male older adults was demonstrated.

Older men had higher mean scores in mobility (1.5%) and muscle strength of lower limbs (1.5%) compared to women but it was not significant. Previous studies have shown that both genders demonstrated similar lower body strength when stratified by age groups³. Nevertheless, rate of decline of lower body strength were higher in men (-4.4% per year) compared to in women (-4.0% per year)²⁰.

As for lower body flexibility, older men had significantly higher (0.6 times), reflecting higher

flexibility in men compared to women. This is supported by the report showing greater decline of lower body flexibility in women (0.7% per year) as compared to men (0.5%)²¹. In contrast, flexibility was higher (21%) in women compared to men²². A plausible reasoning for higher flexibility in men in this study maybe linked to higher levels of outdoor physical activities. Studies have shown greater outdoor participation in men than women by 19.2%²³.

TUG scores of men in this study (8.9 seconds) is in accordance to TUG normative values reported in Malaysia (8-11 seconds), but it was not the case in women (9.04 seconds) (normative: 10-12 seconds)²⁴. This indicates women in this study had higher functional mobility. This is supported by the characteristics of the participants in the present study with higher percentage of men having history of falls (27.8%) than women (23.1%).

In a recent meta-analysis²⁵, endurance measured using 2MWT displayed an average of 170.05 and 157 metres distance covered by men and women respectively. In comparison, the present study showed lower aerobic endurance (27%: men, 19.4%:women). Note that older adults in our study had comorbidities and were clients at a clinic compared to healthy older adults in previous study²⁵. Correspondingly, significant difference in aerobic endurance between different cognitive groups²⁶ and body mass index²⁷ were reported in Malaysian older adults.

Regarding psychological health, mean GHQ and SWLS scores were categorised as normal and satisfied respectively. A significant positive correlation existed between GHQ-28 and functional mobility, showing increased TUG performance time was related to increased GHQ-28 scores; indicating lower mobility (longer time to complete TUG) correlated with greater psychological issues or vice-versa in older men. Similarly, in older men, there was a significant negative correlation between GHQ-28 with lower limb muscle strength and endurance, suggesting greater muscle strength and endurance (30sCS:higher number and 2MWT:longer walking distance) correlated with lower psychological issues (GHQ-28:lower scores). These findings are supported by another study, showing greater physical function associated with improved psychological health in community-dwelling older adults⁷.

Our study highlighted that these association is gender specific but the reason is unclear. It could be because older women in our study having generally better physical and psychological health compared to older men. Contrary to other studies, more older men compared to women in the present study had history of falls. Fear of falling is a factor for physical activity participation limitation²⁸.

It should be highlighted that only physical function, requiring repetitive movements (e.g walking and getting out of a chair) were linked with psychological status, instead of static based (flexibility and static balance). Evidence have demonstrated that active, mobile and

ambulating older adults are more socially involved²⁹. Moreover, older men in the present study reported 9.4% lesser participation in exercise compared to women. Even a low intensity exercise regime performed twice a week for 2 months have significantly lower GHQ-28 scores, indicating better psychological health status among older adults without taking gender into consideration³⁰.

This study was limited to one urban primary health care clinic and the results cannot be generalised. Future studies should include multiple urban and rural primary health care settings.

Conclusion

In our study, physical and psychological health status were similar in gender, except for lower limb flexibility which was greater in female older adults. Lower physical performance (lower body strength, mobility and endurance) was correlated with higher psychological issues or vice-versa in older males. There may be a need to consider distinct physical and psychological needs between genders for optimum health prevention and management strategies.

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Patients Expectation of Orthodontic Treatment in Chennai, India

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Abstract

Objective: To measure the patients expectations towards orthodontic treatment.

Materials and Methods: A questionnaire was designed, developed and distributed to 175 subjects aged between 12-25 years which they completed before their initial appointment. Interaction with the patient's belief, fulfillment of their wishes with the appearance of face, age group, sex were examined. A re-test was again conducted to interviewed and then distributed to 22 subjects who completed the questionnaire before their initial appointment for which a valid and mean analysis was done. The variable of age and gender were explored.

Result: The questionnaire gave a clear idea of the patients mainly expect from their orthodontic treatment, which is very useful in improving the quality of the treatment and treatment planning and also their expectations.

Conclusion: The study lay out with a reasonable and well determined to know the belief of the patients.

Key words: patient's expectation, orthodontic treatment, questionnaire, estimation.

Introduction

Gratification of life has become progressively important in day to day life. Now-a-days the quality of treatment is very important and at the same time should satisfy the patient. Now Orthodontic treatment has been considered as a way for patients to attain a good and acceptable facial appearance within the social environment. Health related gratified condition of life has become progressively predominant researchers have recognized that established sequel to estimate are minimal attention to the actual individual are involved in the present well being condition¹. There are more ways

to evaluate the management of oral health management and the outcome in the following situations².

- Clinical study
- Patient care should be monitored regularly.
- Make a better interaction with doctor-patient.
- Between ill health differentiation
- Assessment of disparate procedure of organizing and capitalize system for health care management. Carr et al suggested a prototype, clinician are believed to be request for the efficacy of management and systematic funds use of resource³ and Nature of life which is related to health can be estimated by three problems, firstly the patients have individual expectations, secondly, patients will be at dissimilar levels in their ailment and thirdly, patients beliefs will make extra time⁴.

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It is generally accepted that focuses on the impact of health on a person's ability to live a fulfilling life included a number of domains for example

- Physical status
- Psychological
- Social interactions
- Economic
- Religion

Research paper revealed that numerous dental orthopedics cases are young one and youngster there may be some drawback to employ the satisfaction of life related to health. More difficulties are faced by youngster patient due experienced important changes and it is complicated to ascertain those changes due to orthodontic management⁴. Further researches have mostly concentrated on the utility and not the observation with dental orthopedics management⁵. Rarely interviewed and the dental orthopedics management. Several other researches are not too involved a valid along with reliable to analyses their rate these consideration are major to rigor in addition to lessen the discrimination⁶. When the patient gets treated there may be some positive experience and some negative experience. When there are negative experiences, we should settle down their belief make them from negative to positive .some of the studies have concentrated on determinants which will encourage the patient go through or The questionnaires used to measure patients expectations required further psychometric evaluations. Rarely interviewed and the dental orthopedics appliances, make uneasy or assumed the time period for dental orthopedics management⁷. A sound and definitive plan for patients extend with irrational impossible belief is thoughtful in successful orthodontic management, setting an agreement standard of service assigned an Orthodontic treatment has been a most sought after treatment now-a-days since patients come to get a better facial appearance and in other cases to improve their ability in speech and eating habits.

The general appearance of patients during their treatment is also discussed here. Many patients during their treatment found it difficult to interact in public, due to wearing braces of different types. Some of the types of braces are head braces, train track braces etc. Now-

a-days many other methods have been found for the patients to have an acceptable appearance like lingual braces, or wearing braces which are tooth colored.

The main aim of this study is to measure the patient's satisfaction with orthodontic treatment and to preliminarily assess its validity. It is done in questionnaire study in order to get a clear idea of the patientsexpectations who come for orthodontic treatment. It is done to investigate and correlate between the satisfaction with the patient's facial and dental appearance and its expectations. The effects of age and gender are explored along with various other important factors. The correlation were variant over gender and age group. The result was come to an end that fulfilment with dental aspect is significant predictor of orthodontic patient's belief of their management⁸.

Material and Methods

A sample size of 175subjects was taken and the questionnaire was distributed to the patients from various dental clinics in Chennai. The research was done on age and gender as well. But they are distributed to a certain criteria.

Criteria:

- New patients conferring to the dental orthopedics health center.
- Case age group into 12-25 years.
- Patient did not give a past history of orthodontic management.

QUESTIONNAIRE CONSTRUCTION

First a questionnaire was prepared based on the research done and what the patients expect by doing a few interviews with the patient's who come to the clinic for orthodontic treatment. The qualitative evaluation was planned and complete succeeding the requirement for qualitative analysis. These administered question were planned to enquire the patients about their belief of orthodontic management, concerning their aids and sustained. The main factor upon which the questions were asked is the 'general' and 'dental' appearance of the patient after the treatment is over. The questionnaire was constructed in the Yes / No format regarding their beliefs of the first consultation, sort of management,

predicted issues are correlation with the management of time period ,duration for complete the treatment, the number of dental visits during that and most importantly the benefits. The questionnaire also deals with other people’s reaction to the patients wearing braces as it is one of the most important factor now-a-days. The questionnaire was constructed in the Yes / No format as it is very easy for the patient to fill and get their opinion. It is then evaluated using kappa to know the value of this study. The mean analysis is also done for the same. After the questionnaire is filled it is recorded. The use of Yes / No format, Likert scale and Visual Analogue Scale have been used in a number of studies.

Questionnaire Distribution

The questionnaire was administered to 175 subjects with an age range of 12-25 years old. The standard schedule was drawn to finishing the questionnaire was nearly 5-10minutes. The data was later analyzed using an experimental study and represented. The first time the questionnaire was distributed to them before their initial appointment and later a re-test was conducted for about 22 subjects after their treatment to compare the patient’s response between the two studies and to reduce operator bias. The Research varies according to the patient’s age and gender correlation between the patient’s expectations

and their facial appearance.

Although only a few studies were made to evaluate the patient’s expectation of orthodontic treatment, we present data from the questionnaire that illustrates how many patients react positive to the treatment and the duration. Data were analyzed using mean and value analysis. The patient were asked to fill the questionnaire before their initial appointment and then the questionnaire was again distributed to 22 subjects who have completed their treatment for reliability.

Results

An overall of 175 people take part in their research throughout the time period of September 2011 to January 2012. The findings from the questionnaire was analyzed. The association was ascertained the female are considering more to undergo orthodontic treatment than males. Around 15 subjects participated in the construction of the questionnaire. The content of the analysis are such as their first consultation, sort of management, problems associated with the treatment, the response of the individuals to the patients issues with the treatment, the duration, the number of dental visits and most importantly the benefits from the treatment. The regularity of everyone topic along with sub topic is

Table 1.REACTION OF WEARING BRACES

Reactions of wearing Braces				
	Frequency	Percent	Valid Percent	Cumulative Percent
Negative reaction	69	39.4	39.4	39.4
No reaction	79	44	44	83.4
Positive reaction	27	14.3	14.3	97.7
Total	175	100	100	

From the above table (Table 1) it is said that about 39.4% of the people would give a negative reaction to the patients wearing braces, while about 44% of the people have said they would give no reaction and while about 14.3% of the patients said that they would give positive reaction.

Table 2.TENURE OF ORTHODONTIC TREATMENT

Tenure of Orthodontic Treatment				
	Frequency	Percent	Valid Percent	Cumulative Percent
4 years	9	5.1	5.1	5.1
3.5 years	17	9.7	9.7	14.9
3 years	22	12.6	12.6	27.4
2.5 years	8	4.6	4.6	32
2 years	24	13.7	13.7	45.7
1.5 years	31	17.7	17.7	63.4
1 year	49	28	28	91.4
6 months	4	2.3	2.3	93.7
Don't know	11	6.3	6.3	100
Total	175	100	100	

From the above, we see that according to the level of illness the duration of the treatment might be varied. In which most of them suggest that it will be around 6 months at the least. Table 2)

Table 3.FREQUENCY OF DENTAL CHECK-UP NEEDS

Frequency of Dental Check-up needs				
	Frequency	Percent	Valid Percent	Cumulative Percent
once every month-1	91	52	52	52
once every 2 months-2	42	24	24	76
once every 3months-3	29	16.6	16.6	92.6
once every 6 months-4	13	7.4	7.4	100
Total	175	100	100	

From the above, we see that frequency of Dental Check-up needs at different level of month. It was found that they have to visit the clinic every month. (Table 3)

Discussion

Questionnaire can be utilized in a comprehensive surrounding to collect the details about the attitude and performance of the consumer. The questionnaire was written from the attitude of the contributor. However the details that was gathered tends to be arguable and deceptive⁹ Patient based questionnaire are progressively utilized in Randomized Controlled Trial to assess new management and also take part of an audit. As supplemental branch of science the strength and effective of the measurement tool i.e. questionnaire need to be exactly try out that the data collected is meaningful. Previous study have manifested that the individuals are more distinctly to reacted to questionnaire that cover the problems that are relevant to them.¹⁰ During the analysis it is found that most of the patients in their early stages who took the questionnaire didn't think that they would get braces fitted in their initial appointment. There was a slight level of agreement of patient's getting their teeth extracted, having x-rays taken, diagnosis and impression taken while only few people say that they would get a surgery done. Most of the patient say that they think that wearing braces would be painful and restrict their intake in food and drinks. The reaction of other people to them wearing braces is also measured. From the given research done it is found that around 44% have said that they would not give any reaction to the patient's in wearing brace, while only 14.3% have said that they would give a positive reaction. Hence in order to eliminate those factors a number of ways have been introduced, like tooth colored braces or lingual braces, although lingual braces are still under research.

But the result which the patients expect after their treatment is very high. The main goal after finishing the treatment is that the patients to have their teeth aligned and straight which gives a better smile and make communication in the social environment easier as well as to eat and drink. Some people say that that also can also improve their chances for a better career. And for the frequency o visiting the dental clinic is that most patients took that they had to visit it once every month. The duration of the treatment they thought it would take was around a year.

An interviewed was organized to assure its quality of being dependable utilizing a numerical analysis

are suggested recently^{6, 10}. Validity was tested using kappa to assess the value of the questionnaire. Its main assessment was measuring device estimates what it focus to estimates.

Weakness of the study was found that mean and value are threatened by bias and errors. They are measures using kappa and hence measure the accurate significance could not be given. The robustness could not be given, since little size tryout –inspection. This study requires a questionnaire which measures the expectations of the patients before their management and also factors like the time period of management duration of the treatment, frequency of orthodontic appointment.

The questionnaire has recorded the patients high and low belief of their orthodontic management and their early beliefs. The statistical analysis used to confirm can be questioned even though it is supported by literature. Application of the questionnaire is that it is used to assess the expectation and requirement of the patient. It is also useful for permission and management planning. All these factors help to improve the quality of the treatment and give the required expectation of the patient.

Conclusion

This study layout the following:

- A definitive quantify of the patients expectation when they undergo orthodontic treatment
- It gives a clear idea of what the patient expects before the treatment like what they will do, sort of management, predicted involvements during the management, time period, appearance of visits and the utilizing from their management.

Ethical Clearance- Obtained from department of public health dentistry

Conflict of Interest- Nil

Funding- Nil

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