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# Perceptions regarding Flipped Classroom teaching method among first year MBBS students in a Medical College in National Capital Region, India

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## Abstract

**Background:** Flipped classroom aims at exposing the students to teaching material outside of class first and utilizing the class time in deeper understanding of the topic with the discussion in the presence of the teacher. It is a method of teaching learning wherein the students take responsibility of their learning. The present study was conducted to introduce flipped classroom approach as teaching learning method and to obtain students feedback.

**Materials and method:** The study was descriptive study done in the Department of Anatomy after obtaining the IEC clearance. First year MBBS students who volunteered to participate (138 out of 150) were included in the study after obtaining informed consent. The students were given a pre-class reading material in form of PowerPoint Presentation with voice over for the topics selected for flipped class using Institutional Learning Management System (LMS) seven days before the class. Class time was utilized in discussion of the topic. A questionnaire was used which was validated by other faculty members. Responses were collected using a 5 point Likert scale. Analysis was done by Microsoft Excel 2010.

**Results:** The concept of flipped classroom was well accepted by the students. It was observed that 70% of the students found flipped classroom is more interesting method of learning anatomy compared to traditional lectures. 30% of the students believed flipped class required more time and more preparation. They were of the view that these classes were more interesting, interactive, and motivated them to learn compared to the didactic lectures.

**Conclusion:** Flipped classroom is not a new concept. However, in our country this concept of teaching learning is not very commonly used in medical colleges and can be used as an alternative to the traditional lectures for better understanding of the topic and can be used more often.

**Keywords:** Flipped classroom, Medical College, MBBS.

## Introduction

Didactic lectures are the most common teaching

learning method used in most of the medical colleges. This is one way method in which students are at the receiving end. Too much interaction with the students

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is not possible due to time constraints. It is difficult to meet the needs of all the students by the faculty members. Also, with the new CBME curriculum for MBBS number of didactic lectures is reduced to one third. Hence, introduction of some different teaching learning method is required wherein there is active involvement of the students. Flipped classes or inverted classes is the reversal of traditional didactic lectures wherein the students are given some learning materials, prepared videos or recorded lectures and are asked to come prepared with the topic so that class time can be utilised in more discussion and interaction for better understanding.<sup>1</sup> This concept was made famous by Eric Mazur. He said that the process is three times more useful to the students in understanding the topic and the approach is more interactive focusing on the students.<sup>2</sup> Flipping is an effort to engage students in active learning, in which learners need to be responsible about their learning.<sup>3</sup> The flipped classroom approach was used in different courses from many years now. It is recently introduced for medical teachings.<sup>4</sup> Flipped classroom is an effective teaching-learning method stated by Bergmann, Overmyer and Wilie<sup>5</sup>. There is more constructive learning in the class timing (Tucker)<sup>6</sup>. These classes help in creating students who can be self-directed learners (Minhas, Ghosh and Swanzey)<sup>7</sup>. Zappe et al<sup>8</sup> stated that the Flipped classes will help student utilize their time in a better way. Hamdan et al<sup>9</sup> stated that flipped classroom results in motivating the student to learn better. Cohen and Brugar<sup>10</sup> stated that learning becomes the responsibility of the students. Learning can be at their pace. There is also establishment of more communication between the teacher and the students. According to Schmidt and Ralph,<sup>11</sup> the students are better prepared for the classes. Among all the benefits there are some disadvantages also as stated by Collins<sup>12</sup>. He said that applying new teaching learning module is a challenge even if one is well prepared. Other problem can be that the teacher is over enthusiastic, but the students are not reciprocating i.e., they attend the classes without doing the pre class assignment as stated by Rath<sup>13</sup>.

Anatomy is a pre-clinical subject taught in the first year of MBBS curriculum. Better knowledge of this subject is very helpful to the doctors in pursuing their clinical practices. It is considered as one the difficult

subjects of this curriculum. So, the need arises to implement some better teaching methods to help learn anatomy in a better way and flipped class can be an alternative to the regular traditional lectures. Flipped classes were used in different fields of education. The use of this method is limited in medical sciences. It is already known that it proves to be a better alternative to didactic lectures. With this background study was undertaken to introduce flipped classroom teaching to first year MBBS students in learning Anatomy and to obtain students feedback and their perceptions on acceptability of flipped classroom.

### Materials and methods

The study was a descriptive cross-sectional study conducted in first year MBBS students. The project was conducted in the department of Anatomy after obtaining Institutional Ethical Committee (IEC) clearance. First year MBBS students of batch 2019-20 (138 out of 150 students) who volunteered to participate were included. Convenient sampling method was used for the study. Informed consent was taken. The students who did not give consent were excluded from the study. The volunteered students were sensitized to the concepts of flipped classroom. They were told about the way it was supposed to be carried out. It was expected from them to come prepared for the class. In class there will be discussion and small presentation on the topic. Any student can be asked to summarize the topic. The topics were selected from Gross Anatomy with clinical importance for flipped classroom. Few days before the scheduled class 4 one liner questions were given as an assignment as a reminder to read the topic before class.

**Pre-Class Activity:** The students were given a pre-class reading material (power-point presentation with voice over) prepared by the authors and validated by two senior faculty members of the department. The reading material was provided to the students by using institutional LMS (Learning Management System) one week prior to the class. The students need to read the given notes before attending the class.

**In Class Activity:** Class time was utilized in discussion of the topic. Students were asked to take a pre-test to see whether they have read the topic.

Topic discussed with the students on the principle of think pair and share. At the end of the class one of the students was asked to summarise the entire topic. Post-class test was taken. A questionnaire was used which was validated by other faculty members and MEU members. The feedback was obtained anonymously. The students were not asked to write their name and roll number. Feedback was obtained at the end of the session. The questionnaire was validated by senior faculty members in the Department and MEU members. Responses were collected using a 5-point Likert scale. Statistical analysis was done using Microsoft Excel 2010. The questionnaire was tested among a group of 10 students before administration.

There was a formative assessment taken a week after the flipped class. The result of this formative assessment was compared with the last batch who had traditional lectures on the same topic by the faculty members.

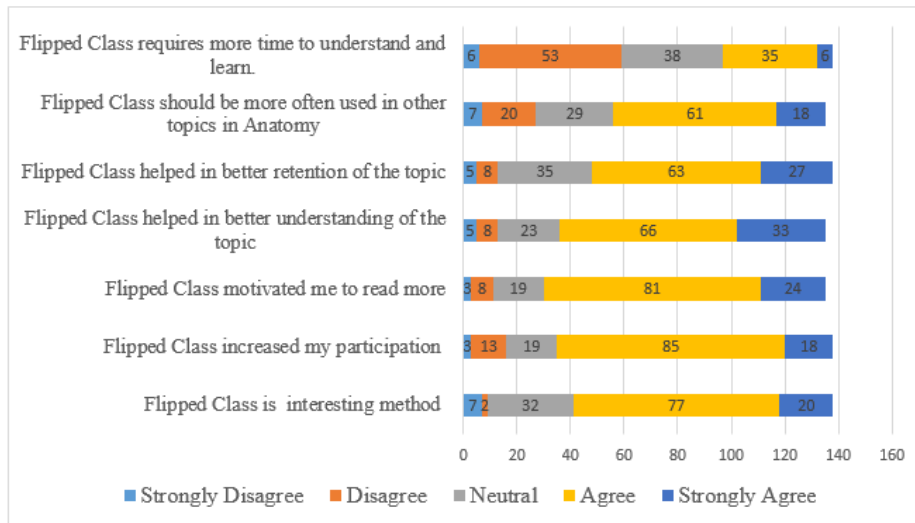
## Results

The study group comprised of 138 students.

**Table 1: Students opinion about Flipped Class Room Teaching Method**

S.No.	Questions	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
1	FC is more interesting method of learning Anatomy compared to traditional lecture	7	2	32	77	20
2	FC increased my participation in the class	3	13	19	85	18
3	FC motivated me to read more about the topic	3	8	19	81	24
4	FC helped in better understanding of the topic	5	8	23	66	33
5	FC helped in better retention of the topic	5	8	35	63	27
6	FC should be more often used in other topics in Anatomy	7	20	29	61	18
7	FC requires more time to understand and learn.	6	53	38	35	6

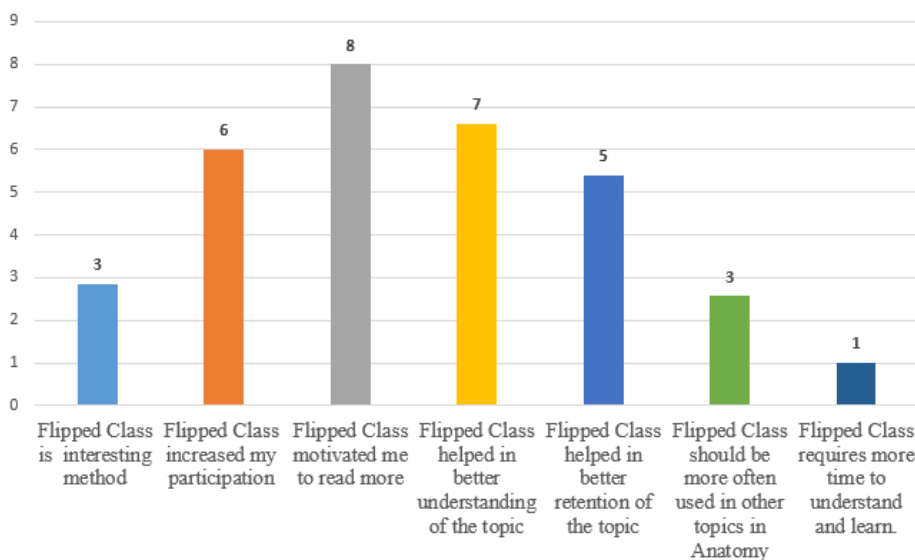
Results were expressed in percentage and frequency. For the open-ended questions, all the views were noted. It was observed that the newer method of teaching learning was well accepted by the students. 138 students out of 150 participated in the study. Feedback obtained after flipped classroom session showed that 70% of the students found flipped classroom is more interesting method of learning anatomy compared to traditional lectures. 71% of the students felt that their participation in the class was increased. 76% of the students were motivated to read more about the topic. 75% of the students felt that the topic was better understood. 64% of the students were of opinion that flipped classroom helped in better retention of the topic. 60% of the students recommended that more flipped class should be taken in Anatomy. However, 30% of the students believed flipped class required more time and more preparation. The results were summarised in the Table number 1 and Figure 1. The result of pre-test and post-test were analysed. There was improvement in the post-test score.



**Fig 1: Students opinion about Flipped Class Room Teaching Method**

There were open-ended questions as well in the questionnaire. The students were of the opinion that FC is a good way of learning a topic. The PowerPoint presentation provided was very useful. Initial reading and then attending the classes gave more idea regarding the topic. All the points were well covered in the discussion. Their doubts were cleared. The discussion helped them in retention of the topic. They liked the active participation and interaction during the class. They also believed reading the topic on their own increased their interest. After attending the FC, they were able to apply the knowledge gained in a better way in the dissection hall. They were able to

identify the structures with confidence. They wanted more topics to be covered in similar way. It should be done often. Few MCQ should be given at the end of the class. Clinical case scenario should be given and discussed in this way. Some students felt that some more time could have been given to read the materials given. It should be used for smaller topics and in small groups. Further difficult topics which requires deep understanding should be avoided to be taken as FC. Few students also suggested that individual doubt clearing session should be held after the classes.



**Fig 2: Ratio of Strongly agree/Strongly disagree about Flipped Class Teaching Method**

Fig 2 represent ratio of Strongly agree/Strongly disagree about Flipped Class Teaching Method Students strongly agree 8 times more than strongly disagree to the fact that Flipped classroom motivated them to read more.

### Discussion

In the present study, flipped classes were introduced to teach anatomy. Most of the students were of opinion that it is better than traditional lecture where there is one way delivery of the content. It is more interactive. This concept is becoming popular these days. Present day students are more tech savvy and prefer use of technology in teaching learning. Students believe that this method is more engaging and fun to learn a new topic. Also, with the introduction of new CBME based curriculum there is need to make our students self-directed life-long learner. Flipped class proves helpful in this. It is more learner centred. It helps the students in critical thinking<sup>14</sup>.

The result of the present study showed that it was accepted very well by first year MBBS students in learning Anatomy. This new concept of learning was appreciated by the students and the other faculty members. Their interaction and participation in the class was good. In the study conducted by Fatima et al<sup>15</sup> it was observed that students felt that FC was very interactive and helped in depth understanding of the topic. The difficulty was in clearing of their queries and misconceptions. In the present study the perceptions of the students were somewhat similar.

Flipped classroom was accepted well in study conducted at Ripah University, Pakistan.<sup>16</sup> Similar perception in the study by Sunita Sreegire et al (2018)<sup>17</sup>. Various other studies also had similar results. In the present study also, it was well accepted by our students. They wanted more classes to be taken as flipped class. Study by Nour<sup>18</sup>, S K Gubbiyapa et al<sup>19</sup>, Veeramani et al<sup>20</sup> found that student satisfaction was very high and flipped classroom was accepted as effective teaching learning tool. In their study 86% students felt that flipped classroom was a better approach to learning.

Maria Jose<sup>21</sup> used this method of teaching learning during the pandemic time and reported positive affect of the method both on the motivation

and perception of learning. In the present study also, the students were motivated to learn more about the topic. Latorre-Coscolluela<sup>22</sup> reported that the respondents liked the flipped classes because of their active involvement. The students who participated in the present study also liked the interactive session.

Agarwal and Kaushik<sup>23</sup> emphasised on use of videos, recorded lectures to start the discussion. Smith and Boscak<sup>24</sup> in their study observed that the students' satisfaction increased with the use of this module and the skills developed during the course is better.

### Conclusion

FC was well accepted among students giving us indication for its further use not only in gross anatomy but also to some topics in embryology and neuroanatomy. FC can be implemented to other first year subjects and to other subjects in medical curriculum.

**Declaration of Ethical clearance:** Taken from institutional Ethical Committee before commencement of study.

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**Conflict of interest:** None to declare.

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## Predictors of Social Isolation and Loneliness among Elderly Residing in a Slum in Eastern India

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### Abstract

**Background:** Geriatric population in India is expected to reach about 20% of total population by 2050.<sup>4,5</sup> This brings along newer challenges of not only physical morbidities, but psychosocial morbidities too for this group of population. Social withdrawal and isolation, loneliness are two of those mental morbidities of concern. Social isolation is an objective state defined as the absence of contact with other people and integration with other members of society.<sup>6</sup> In contrast, loneliness is a subjective feeling caused by 'being without some definite needed relationship or set of relationships'.<sup>7</sup> Social isolation & loneliness both have impact on physical and mental well being of a person.<sup>10-16</sup> So, present study was conducted with the objective of assessing the extent of loneliness and social isolation among elderly in an urban community, and determining the covariates of the same.

**Methods:** This cross-sectional community-based study was undertaken from December 2019 to February 2020 among 246 elderly men and women, 60 years & above residing in a slum in Chetla Kolkata. They were interviewed about their demographic, financial supports and social supports. Social Isolation was assessed with the help of six item Lubben Social network scale-6.<sup>17,18</sup> Loneliness was assessed with the help of the UCLA Loneliness Scale version 3.<sup>19,20</sup> **Statistical Analysis:** Descriptive and univariate analysis, multiple logistic regression was done to find out factors associated with loneliness & social isolation.

**Results:** Social isolation and loneliness were present in 120 (48.78%) and 125 (50.81%) subjects respectively. Multivariate logistic regression revealed that age>69 years, marital status other than married, inadequate income, and those living alone were at increased risk of social isolation. Inadequate income and male sex were at greater risk of loneliness.

**Conclusion:** Social isolation & loneliness are present in almost half of the elderly living in an urban slum of Kolkata, which is alarming.

**Key word:** geriatrics, urban slum, Social network, UCLA loneliness scale,

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## Introduction

The process of aging is a biological phenomenon, characterized by decline in intrinsic physiologic function. Aging in human beings encompasses three domains: chronology (usually the age of 60-65 years), change in social role and change in capabilities.<sup>1</sup> The last century experienced a significant increase in longevity, resulting in increase in geriatric population worldwide. Better prevention and control of communicable as well as non-communicable diseases, improvement in nutrition and sanitation, increased level of education and expansion of health facilities were significant contributors to mortality reduction and increase in longevity.<sup>2</sup> In the year 2000, number of persons aged 60 years or more was about 605 million. By 2050, the global geriatric population is expected to rise to two billion. Low to middle income countries are expected to experience the most dramatic change in demographics.<sup>3</sup> This will result in widening of the narrow apex of the population pyramid. In India, according to Sample Registration Survey (SRS) 2010, 7.5% of the total population were aged 60 years or more, which is expected to reach about 20% of total population by 2050.<sup>4,5</sup> However, the apparent achievement of increased life expectancy brings with it new challenges in the form of various geriatric morbidities. Apart from physical morbidities, like cardio-respiratory problems, joint problems, frailty, genito-urinary problems, falls, fractures, eye and ear problems and malignancies, psychosocial morbidities are being increasingly identified. These consist of memory impairment, social withdrawal and isolation, loneliness, self-neglect, anxiety, depression and suicidal tendencies.

Social isolation is an objective state defined as the absence of contact with other people and integration with other members of society.<sup>6</sup> In contrast, loneliness is a subjective feeling caused by 'being without some definite needed relationship or set of relationships'.<sup>7</sup> The emerging concept of nuclear family, industrialization and fast lifestyle has set the stage for increasing social isolation and loneliness. Researchers have found that 12 to 20% of elderly people might experience social isolation.<sup>8,9</sup> Social

isolation may be accompanied by feelings of boredom and marginality or exclusion.<sup>7</sup> Factors contributing to social isolation include different forms of loss, deterioration of physical health, mental illnesses, low morale, geographic location, communication and transportation difficulties.<sup>10,11,12</sup> Social isolation has been linked with not only increased mortality rates for elderly people, but also morbidities like elevated blood pressure, increased propensity to dementia, depression and suicidal tendency.<sup>13,14,15,16</sup>

Studies addressing isolation and loneliness among elderly in the developing countries is sparse. Thus, the present study was undertaken with the objective of assessing the extent of loneliness and social isolation among elderly in an urban community, and determining the covariates of the same.

## Materials & Methods

This cross-sectional community-based study was undertaken for period of three months, from December 2019 to February 2020. Elderly men and women aged 60 years and above, able to speak and comprehend English and/or Bengali, residing in a slum in Chetla, Kolkata, India were included. Those who were seriously ill, unable to respond, were not properly oriented with time, place or person, had some form of speech disorder, terminally ill and non-ambulatory were excluded. The protocol was approved by the Institutional Ethics Committee and informed consent from the participants was mandatory for inclusion. Participation was voluntary.

### *Schedule*

The 20-min structured interview included questions about the participant's demographic characteristics (like age, gender, marital status, education, occupation), financial supports and social supports, along with validated inventories for assessing social isolation and loneliness.. Social Isolation was assessed with the help of six item Lubben Social network scale-6.<sup>17,18</sup> On the Lubben scale, a score of zero to thirty measures the extent of social contact with family and friends, and being at risk of social isolation is defined as having a score of



less than twelve. Crohnbach's alpha in our population was 0.82, indicative of high internal consistency. Loneliness was assessed with the help of the UCLA Loneliness Scale version 3.<sup>19,20</sup> It is a 20-item scale designed to measure one's subjective feelings of loneliness. Participants rate each item on a scale from '1' (Never) to '4' (Often). Some items are reverse scored. Minimum and maximum possible scores are 20 and 80 respectively. Persons having scores greater than or equal to median score of the study population was taken as lonely. High internal consistency (Crohnbach's alpha of 0.87) was observed. In cases where a participant's answers raised a concern about co-existence of some psychiatric morbidity like depression, the participant was referred to health workers of UHC Chetla for evaluation, referral to psychiatric counseling and proper management. This notification practice was clearly explained to the participant as part of the informed consent process.

#### Sample size

All elderly subjects residing in the said slum were approached. At least three attempts were made to contact any individual found absent on the first day. Finally, 345 subjects were approached. Investigator interviewed all participants in a private setting. Twenty-nine subjects were excluded as they were terminally ill and/or not able to respond. Among the remaining 316 subjects, response rate was 77.8%. Principal causes of non response included length of the questionnaire (57), not willing to participate (10) and 3 subjects refused to participate in the study without giving any specific reason for

non-participation. Finally, 246 subjects completed the interview.

#### Statistical analysis

Data was analyzed using Microsoft excel and SPSS version 20.0. A bivariate analysis was done to ascertain the association between Social Isolation and Loneliness with some independent variables. Only those found to be significant were entered into a multiple logistic model LINK FUNCTION= LOGISTIC) by ENTER method. Diagnostic tests were done after modeling to assess goodness-of-fit and assumptions pertaining to logistic regression. A p-value less than 0.05 was considered as statistically significant.

### Results

Out of 246 subjects, majority were married, and lived with their spouse. Social isolation and loneliness were present in 120 (48.78%) and 125 (50.81%) subjects respectively. Most of them (61.79%) had inadequate income. Scores attained in the inventories by the study population are shown in (Table 1). There was strong correlation between the scores obtained in the two scales. (Pearson correlation coefficient - 0.72,  $p < 0.05$ ). 89 individuals reported both social isolation and loneliness. Multivariate logistic regression revealed that marital status other than married (like widowed, unmarried, divorcee), inadequate income, and those living alone were at increased risk of social isolation whereas age less than 69 years conferred a decreased risk. (Table 2) Inadequate income and male sex were at greater risk of loneliness. (Table 2).

**Table 1: Scores attained in the inventories by the study population.**

Inventory	Maximum attainable score	Minimum attainable score	Cut off	Maximum attained score	Minimum attained score	Mean score (SD)
Isolation	30	0	<12	18	3	12.6(3.7)
Loneliness	80	20	≥4	69	22	42.3(7.4)

Note: Pearson correlation coefficient between isolation score and loneliness score is - 0.72;  $p$  value < 0.05; both social isolation and loneliness was present in 89 individuals.

**Table 2: Covariates of social isolation and loneliness in the study population. (n=246)**

Variables	Social Isolation			Loneliness		
	No	OR(95%CI)	AOR(95%CI)	No	OR(95%CI)	AOR(95%CI)
<b>Age in completed years</b>						
60-69(158)	66	0.47(0.27-0.82)	0.59(0.34-0.76)	57	0.18(0.09-0.33)	0.26(0.07-1.08)
70-79(76)	46	1	1	58	1	
≥80(12)	8	1.30(0.36-4.72)	0.98(0.64-3.83)	10	1.55(0.311-7.745)	
<b>Sex</b>						
Male(104)	57	1.52(0.91-2.53)		59	1.51(0.91-2.51)	
Female(142)	63	1		66	1	
<b>Religion</b>						
Hindu(211)	102	0.88(0.43-1.81)		111	1.67(0.80-3.45)	
Muslim(35)	18	1		14	1	
<b>Education</b>						
≤Primary(77)	35	0.82(0.47-1.43)		39	0.96(0.55-1.66)	
Secondary(147)	74	1		76	1	
≥HS(22)	11	0.99(0.40-2.42)		10	0.78(0.32-1.91)	
<b>Income adequate</b>						
Yes (94)	14	1	1	23	1	1
No(152)	106	13.17(6.77-25.60)	4.78(3.49-12.01)	102	6.30(3.53-11.24)	2.49(1.88-7.32)
<b>Marital status</b>						
Married(109)	16	1	1	19	1	1
Others(137)	104	18.32(9.47-35.42)	6.62(2.02-14.66)	106	16.20(8.57-30.61)	4.58(2.06-9.74)
<b>Living status</b>						
Alone(34)	24	2.9(1.32-6.36)	2.15(1.04-5.63)	20	1.46(0.70-3.03)	
Lives with spouse and/or kin(212)	96	1	1	105	1	

Note: In the model for social isolation, Nagelkerke R square = 0.476; in the model for loneliness, Nagelkerke R square = 0.412

## Discussion

Our study showed very high percentage of geriatric loneliness and social isolation. Covariates of social isolation were increasing age, marital status other than married (like widowed, unmarried and divorcee), inadequate income, and those living alone. Covariates of loneliness were inadequacy of family income and male gender. Interestingly, living alone was not associated with loneliness. This might be due to adaptation to living alone over a long period. Only those persons who recently started to live alone due to death of spouse or close relative reported loneliness (20 out of 34). (vide Table 3)

Along with the gradual demographic aging of the population, social isolation and loneliness are also expected to rise. The socio-economic conditions of the elderly in the developing countries like India are complicated by inadequate health care facilities, rehabilitation, and recreation. Moreover, pension and social security are restricted to a lucky few.<sup>21</sup> Some surveys have shown that retired elderly people are confronted with the problems of financial insecurity and loneliness.<sup>22,23</sup> Our study also showed financial constraints and social isolation in alarming proportions. Studies from other countries have documented social isolation in the geriatric population. A study from Zambia documented loneliness in over half of their study population.<sup>24</sup> The prevalence of social isolation amongst older people was estimated to be 7 - 17% depending on the definition and outcome measure

used in various studies.<sup>25, 26</sup> Prevalence of loneliness was approximately 40% among elderly.<sup>27</sup> The higher percentage of both isolation and loneliness as observed in our study indicates the appalling condition of the aged persons in our community. There can be a positive correlation between loneliness and depression.<sup>28, 29</sup> Social isolation was associated with higher re-hospitalization rates in one study.<sup>30</sup> Loneliness may be risk factor for increased mortality in elderly, as shown in a longitudinal study.<sup>31</sup> Cacioppo JT et al have investigated the underlying mechanism of social isolation induced increased morbidity and mortality.<sup>32</sup>

There is immense scope of interventions towards minimizing social isolation and loneliness. In the modern era, both one to one interventions and group wise interventions have been applied with variable success.<sup>33</sup> It has to be found out whether such interventions can be feasible or effective in Indian scenario.

Our study has certain limitations. The high proportion of social isolation and loneliness observed may be due to some modification of the responses by the subjects, as they were not interviewed earlier regarding these or related topics. Further validation of the inventories in the Indian population may be required, involving larger number of respondents of different backgrounds. Longitudinal studies may be able to establish causal relationship of isolation or loneliness with morbidities, which could not be addressed in our study.

### Conclusion

Our study suggests that social isolation and loneliness is present in large proportions among urban elderly subjects. The authors also found out some possible predictors of isolation and loneliness. However, multi-centric, longitudinal studies with larger sample sizes are required to substantiate these observations.

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# Early Diagnosis of Typhoid Fever: Uses of Clinical Profile, Blood Culture and IGM Antibody: A Prospective Study from a Tertiary Care Centre in Western Uttar Pradesh

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## Abstract

### Objective:

- To study clinical profile of typhoid in children.
- To study Comparison of clinical profile and its correlation with blood culture and IgM antibody detection test for early diagnosis of fever.
- To study blood culture and widal at tertiary care centre in western UP.

**Methods:** The study was carried out in Department of Pediatrics, Saraswathi Institute of Medical Sciences, Hapur, UP. All the children presenting with fever, aged from 6 months to 18 years, visited in the pediatric OPD(outpatient department) and IPD(in patient department) of Saraswathi Institute of Medical Sciences from November 2020 to October 2022 were included in the study.

**Results:** IgM antibody test was found positive in total 167 cases and negative in 63 cases. Also, blood culture was reported positive in 157 cases and negative in 73 cases. Out of total positive IgM antibody, 138 showed positive for blood culture and 29 were reported negative in blood culture. Out of total negative IgM antibody, 19 showed positive for blood culture and 44 were reported negative in blood culture.

**Conclusion:** Present study shows that typhoid IgM procedure is more sensitive than the established Widal agglutination assay and results can be obtained within 15 minutes while widal agglutination test can be done after 1 week. Typhi IgM test can be done after 72 hours of illness as IgM antibody becomes positive after 3 days of infection with Salmonella typhi. It is cost effective and can be done bed side.

**Keywords:** OPD, IPD, IgM

## Introduction

Enteric fever is a global health problem. Its real impact is difficult to estimate because the clinical

picture is confused with other febrile infectious diseases. The incidence of typhoid fever has been estimated approximately 2.17 million cases with at

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least 217,000 deaths occurring worldwide annually [1]. The disease is endemic in the Indian subcontinent [2]. A delay in diagnosis and management may significantly increase the risk of adverse outcome and mortality [3]. Hence, an accurate diagnosis of enteric fever at an early stage is important not only for etiological diagnosis but also to identify the potential carriers and may be responsible for acute enteric fever outbreaks [4]. Although blood culture is the gold standard for the diagnosis of enteric fever, it is not routinely requested by physicians because it is expensive and there is delay in result of at least 2-3 days [5]. The Widal test has been used for almost 100 years and widely available in developing countries and is still regarded useful in endemic areas [6]. However, it becomes positive only in the second week of illness [7], and paired sera are required for confirmation of the diagnosis [8]. Hence, the limitation of the above traditional methods has prompted other novel tests to be developed. The typhoid immunoglobulin M (IgM)/immunoglobulin G (IgG) rapid test is also a new serologic test based on the lateral flow immunochromatographic principle. It detects the presence of specific IgM and IgG antibodies to *Salmonella typhi* lipopolysaccharide. The test becomes positive as early as in the first week of the fever; the results can be interpreted visually and available within 15 minutes. Hence, it provides an alternative for rapid and early diagnosis of typhoid fever. Two typhoid vaccines are licensed for use for the prevention of typhoid: the live, oral Ty21a vaccine (sold as Vivotif by Crucell Switzerland AG) and the injectable typhoid polysaccharide vaccine (Typbar TCV, Enteroshield vaccine).

### Objective

- To study clinical profile of typhoid in children.
- To study Comparison of clinical profile and its correlation with blood culture and IgM antibody detection test for early diagnosis of fever.
- To study blood culture and widal at tertiary care centre in western UP.

### Inclusion Criteria:

- All Febrile cases in the pediatric age group between 6 months to 18 years of age.
- Patients who have not taken any antibiotics prior to admission to this episode of fever.

### Exclusion Criteria:

- Any patient who has received antibiotics within 48 hours prior to evaluation will not be included in the study.
- All patients whose blood culture grew other species of *Salmonella* such as *S. paratyphi*.
- Fever with localization i.e tonsillitis, otitis media, abscess.

### Methodology

**Study Area:** The study was carried out in Department of Pediatrics, Saraswathi Institute of Medical Sciences, Hapur, UP

**Study Population:** All the children presenting with fever, aged from 6 months to 18 years, visited in the pediatric OPD and IPD of Saraswathi Institute of Medical Sciences from November 2020 to October 2022 were included in the study.

**Study Duration:** 2 years (November 2020 – October 2022)

**Study Type:** Observational Prospective Study

After taking clearance from Institutional Ethical committee, this prospective study was conducted in children from 6 months to 18 years of age attending Pediatric OPD and IPD in Saraswathi Institute of Medical Sciences from November 2020 to October 2022 consisting of 230 cases of suspected typhoid fever. In all the patients demographic data was noted. A detailed clinical history was taken in each case. The following investigations were carried out for all patients: Complete hemogram (CBC) was done in all patients, IgM antibody done in children of fever more than 3 days, Blood culture and sensitivity in all children on admission. & thereafter if the children's condition warrants it, Widal test (if child presented with fever of more than 7 days), Chest and Abdominal X-rays & USG abdomen-Machine: SIEMENS (ACCUSION X 300) and PHILIPS HD 15 (If Required).

The **Rapid test** for detection of IgM and IgG antibody in patient's serum was done in all groups. The test is based on lateral flow immune-chromatographic principle. The device contains two test strips: One for IgM detection and another for IgG detection. The IgM strip consisting of a dried conjugate pad containing antihuman IgM conjugated with colloidal gold, a nitrocellulose membrane immobilized with *S. Typhi* antigen lipopolysaccharide (LPS) at test line region "T" and a control line protein at control line "C." About 5 µl of specimen was added using micropipette into the S+B well or fill the provided disposable plastic dropper with the specimen up to the indicated mark on dropper and add into S+B well. Add 2 drops of buffer into Sample well and wait for appearance of pink/purple lines in result window. Results were read within 15 minutes. Positive result was observed as appearance of pink/purple lines at "T" and "C" region which indicates specimen has antibody to *S. typhi*. Negative result was observed as appearance of only one pink/purple line at "C" region which indicates that specimen has no antibody to *S. typhi*.

## Results

Out of total 230 cases, majority 94 (40.9%) patients were more than 15 years of age followed by 59 (25.6%) patients belong to 11-15 years age group and least 11 (4.8%) patients were less than 2 years age group.

**Table 1: Distribution of patients on the basis of their age**

Age in years	No. of cases (n=230)	Percentage
<2	11	4.8
2-5	24	10.4
6-10	42	18.3
11-15	59	25.6
>15	94	40.9

Widal test was found positive in total 63 cases and negative in 167 cases. Also, blood culture was reported positive in 157 cases and negative in 73 cases.

Out of total positive Widal test cases, 48 showed positive for blood culture and 15 were reported negative in blood culture.

Out of total negative Widal test cases, 109 showed positive for blood culture and 58 were reported negative in blood culture.

**Table 2: Comparison of WIDAL with blood culture**

		Blood Culture		Total
		Positive	Negative	
WIDAL test	Positive	48	15	63
	Negative	109	58	167
Total		157	73	230

Sensitivity, specificity and accuracy of the tests in studied patients was 30.57%, 79.45% and 46.1% respectively. Positive predictive value and Negative predictive value was 76.19% and 34.73% respectively.

**Table 3: Sensitivity, specificity and accuracy of the Widal test with respect to Blood culture**

Sensitivity	30.57%
Specificity	79.45%
Positive predictive value	76.19%
Negative predictive value	34.73%
Accuracy	46.1%

IgM antibody was found positive in total 167 cases and negative in 63 cases. Also, blood culture was reported positive in 157 cases and negative in 73 cases.

Out of total positive IgM antibody, 138 showed positive for blood culture and 29 were reported negative in blood culture.

Out of total negative IgM antibody, 19 showed positive for blood culture and 44 were reported negative in blood culture.

**Table 4: Comparison of IgM antibody with blood culture**

		Blood Culture		Total
		Positive	Negative	
IgM antibody	Positive	138	29	167
	Negative	19	44	63
Total		157	73	230

**Table 5: Sensitivity, specificity and accuracy of the IgM antibody with respect to Blood culture**

Sensitivity	87.90%
Specificity	60.27%
Positive predictive value	82.63%
Negative predictive value	69.84%
Accuracy	79.13%

## Discussion

In the present study the comparison of WIDAL test was performed with gold standard blood culture and it was found that the Sensitivity, specificity and accuracy of the Widal tests in studied patients was 30.57%, 79.45% and 46.1% respectively. Positive predictive value and Negative predictive value was 76.19% and 34.73% respectively. Our findings were supported by Sarma A et al<sup>84</sup> who reported that using blood culture as the standard and reference test for diagnosis of enteric fever, the sensitivity and specificity of the WIDAL and Typhidot tests were calculated from the samples having growth of Salmonella species as true positives and samples with no growth or growth of other organisms as true negatives. It was found that Typhidot has a high sensitivity of 75.0% and specificity of 81.0% while WIDAL test has a low sensitivity of 30.0% mobility, consumption of unhygienic food outside home and a high specificity of 78.0%. In this present study, out of 230 cases, Widal test was found positive in 63 cases (27.4%) which correlates with study done by Sharma J et al<sup>102</sup> who reports Widal test positivity of 26.2% with sensitivity 30.0%, specificity 78.0%, PPV 23.0% and NPV 83.0% of WIDAL w.r.t blood culture. Chaoudhury Z et al<sup>103</sup> reported that of 105 cases, blood culture was positive for *S. typhi* in 39.0% children, widal test was positive in 45.7% and Typhidot-M was positive in 74.3% cases. Sensitivity and specificity of Typhidot-M was 92.6% and 37.5% while sensitivity and specificity of Widal test was 34.1% and 42.8%, respectively. Anagha K et al<sup>82</sup> reported the Widal test showed 63.15% sensitivity and 62.5% specificity in the blood culture positive cases of typhoid fever. In the present study sensitivity of WIDAL test was 40.1% which was comparable to the findings of Enabulele O et al<sup>104</sup> who reported 35.0% sensitivity. Specificity of Widal test was found 79.0% in present study which was in accordance with Udayakumar S et al<sup>83</sup>(79.3%) and Andualem G et al<sup>105</sup>(68.4%). In a developing country like India, the Widal test has been used extensively in the serodiagnosis of typhoid fever. However, Lateef A et al<sup>106</sup> reviewed the significance of the Widal agglutination test and concluded that its use should not be encouraged in endemic areas. Ideally, in the Widal test, a fourfold rise of the antibody titer in paired sera is considered as diagnostic of typhoid

fever. However, paired sera are often difficult to obtain and as a specific chemotherapy, it has to be instituted on the basis of a single Widal test only. In the present study when IgM antibody tests were compared with blood culture then it was found that the IgM antibody has reported 144 positive cases with respect to blood culture with 157 positive cases and the sensitivity obtained was 91.72% and our findings were comparable with the previous findings given in the below table. Chaoudhury Z et al<sup>103</sup> reported that of 105 cases, blood culture was positive for *S. typhi* in 39.0% children, and Typhidot-M was positive in 74.3% cases and sensitivity and specificity of Typhidot-M was 92.6% and 37.5%. Sarma A et al<sup>84</sup> reported the sensitivity, specificity, PPV and NPV of Typhidot for IgM as 75.0%, 81.0%, 47.0% and 93.0% respectively.

## Conclusion

Present study shows that typhoid IgM procedure is more sensitive than the established Widal agglutination assay and results can be obtained within 15 minutes while widal agglutination test can be done after 1 week. Typhi IgM test can be done after 72 hours of illness as IgM antibody becomes positive after 3 days of infection with Salmonella typhi. It is cost effective and can be done bed side. So we suggest that typhoid IgM should be considered as a viable alternative for early diagnosis (after 72 hours) for typhoid fever to the long established Widal agglutination assay as IgM antibody becomes positive after 3 days of infection with Salmonella typhi. After analyzing the findings of the present study, it is suggested that though blood culture is gold standard for diagnosis of typhoid fever along with rising titer of Widal test, typhoid IgM with its higher sensitivity might actually be a practical alternative test for early diagnosis of enteric fever in which there is no localization of infection. Further multicentric intensive research on typhoid IgM test is recommended. IgM antibody is a highly sensitive quick diagnostic tool for early diagnosing enteric fever in children with sensitivity of 87.9% and PPV of 82.6%. IgM Antibody appears to be a practical alternative to Widal test in the early detection of typhoid fever in the resource-poor laboratories as it neither requires much laboratory equipment nor laboratory expertise to conduct the test.



Compliance with Ethical standard

**Conflict of interest:** None

**Source of funding:** None

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# Prescribing Pattern in Psychiatric OPD of a Tertiary Care Hospital

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## Abstract

**Background:** Psychiatric morbidity is on the rise in the developing economy India. Little data is available for policy makers to develop guidelines for rational and cost effective prescription of psychotropic drugs.

**Aims and Objectives:** The present study aims to analyze the prescription pattern of psychotropic drugs in a psychiatric Out Patient Department.

**Materials and Methods:** This was a Hospital based prospective analysis of 100 Psychiatric OPD prescriptions. Consent was obtained prior enrollment. Pharmacological data along with clinical and demographical profile was collected and analyzed. Data was collected in MS Excel and presented as numbers and percentages in the form of tables and figures.

**Results:** There was an equal gender distribution. Most of the patients belonged to the age group of 20-40 years(55%). Depression(38%) was the most common diagnosis among all the prescriptions evaluated. The most commonly prescribed drugs were antidepressants(38%) followed by anxiolytics, antipsychotics and mood stabilizers.

**Conclusion:** Prescribing pattern was in accordance with standard guidelines. This data gives a brief overview of the psychotropics prescription pattern in our demographic region.

**Keywords:** Psychiatry, Prescription Pattern, Psychotropic Drugs

## Introduction

Mental Illness are a growing concern especially among middle class socio-economic status in a developing country like India. Approximately 400 people in every 1000 are estimated to be suffering from psychotropic disorders in India.<sup>1</sup> Psychiatric morbidity are a major cause contributing to Disability Adjusted Life Years.<sup>2</sup>

Psychiatric OPDs differ from one another in receiving patients with different disorders. A lot

of factors affect the presentation of patients to OPDlike geographical factor, cultural factors, and environmental factors and prescribing pattern of practitioners.<sup>3</sup> Recently, a number of newer therapeutic modalities have evolved. It is necessary to evaluate the prescribing pattern in psychiatric OPDs to reduce overuse, misuse and to improve rationality and cost effectiveness of prescriptions.

This study was undertaken to analyze the prescription pattern of psychotropic drugs in a

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psychiatric Out Patient Department hoping to help by providing some data to policy makers for formulation or revision of guidelines.

### Materials and Methods

**Study Design:** The present study was a Prospective Hospital based Cross-sectional study.

**Study Setting:** This study was carried out at the Psychiatric Out Patient Department of Mahavir Institute of Medical Sciences, Vikarabad, Telanagana.

**Study Duration:** This research was conducted for a period of two months i.e; from September 2022 and October 2022.

**Inclusion Criteria:** 100 Random Prescriptions of patients attending the Psychiatric OPD irrespective of age and gender who gave consent for participation in the research study were included in the study.

**Exclusion Criteria:** The patients who did not consent, those who were agitated, restless and those were being treated in the In Patient Department were excluded from the study.

**Data Analysis:** Pharmacological data along with clinical and demographical profile was collected and analyzed. Data was collected in MS Excel and presented as numbers and percentages in the form of tables and figures.

### Results

**Table No. 1 Gender**

Gender	No. of Patients
Male	52(52%)
Female	48(48%)

As depicted in the above table, almost an equal gender distribution was observed.

**Table No. 2 Age**

Age Group	No. of Patients
<20 Years	4(4%)
20-40 Years	55(55%)
41-60 Years	36(36%)
>60 Years	5(5%)

As depicted in the above table, the most number of patients belonged to the age group of 20 to 40 years

followed by 41 to 60 years. Least number of patients belonged to the age group of below 20 years.

**Table No. 3 Disorder**

Psychiatric Diagnosis	No. of Patients
Depression	38(38%)
Panic Disorder	22(22%)
Schizophrenia	14(14%)
Adjustment Disorder	10(10%)
Obsessive Compulsive Disorder	10(10%)
Alcohol Dependence Syndrome	4(4%)

From the above table, Depression was diagnosed in 38% of patients, Panic disorder in 22%, Schizophrenia in 14%, Adjustment disorder in 10%, OCD in 10% and Alcohol dependence syndrome in 4%.

**Table No. 4 Drug Category**

Drug Category	No. of Patients
Antidepressants	38(38%)
Anxiolytic drugs	26(26%)
Antipsychotic Drugs	30(30%)
Mood Stabilizers	10(10%)

Antidepressants were prescribed to 38% of the study population, Anxiolytic drugs to 26%, Antipsychotic drugs to 30% and Mood stabilizers to 10% of the patients.

### Discussion

The present study was a hospital based observational study which aimed to study the prescription pattern in a psychiatric OPD of a tertiary care hospital. In our study, there was an equal gender distribution. Similar results were obtained by Rode<sup>4</sup>. The most number of patients attending the Out Patient Department belonged to the age group of 20-40 years. Least number of patients belonged to the age group of below 20 years followed by the group above 60 years. In a study done by Bagewadi<sup>5</sup>, also the most number of patients belonged to the age group of 20-40 years. Depression was diagnosed in 38% of patients, Panic disorder in 22%, Schizophrenia in 14%, Adjustment disorder in 10%, OCD in 10% and Alcohol dependence syndrome in 4%. Depression was the most common disorder in the studies done by Javedar<sup>6</sup> and Roopadevi<sup>7</sup>. Antidepressants were

the most commonly prescribed group of medications followed by anxiolytic drugs, antipsychotic drugs and mood stabilizers. Rodealso recorded similar results. This study analyzed the prescription pattern of psychotropic drugs in the hospital in our demographic region. We are hopeful that this data will add to the existing literature and will be helpful in formulating guidelines and developing policy.

### Conclusion

Prescribing pattern was in accordance with standard guidelines. This data gives a brief overview of the psychotropics prescription pattern in our demographic region.

**Ethical Clearance:** Ethical Clearance was obtained from the Institutional Ethical committee prior to commencement of the study.

**Conflict of Interest:** Nil

**Source of Funding:** This study was self-funded.

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# Assessment of Anxiety and Associated Risk Factors among General Public During COVID-19 Pandemic: A Community Based Study

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## Abstract

**Background:** Lockdown represents a remarkably effective strategy of social distancing to break the chain of transmission of COVID-19. This state of lockdown led to a significant influence on physical and mental well-being of people. The present study was conducted to assess the impact of COVID-19 pandemic on anxiety level of general public and find out the associated factors.

**Methods:** The present web based cross-sectional study was carried out among 450 participants in India in the month of May 2020. Data collection was done using online Google form. A semi-structured questionnaire was used. Generalized Anxiety Disorder Scale-7 (GAD-7) Scale was used to assess anxiety symptoms among the participants. Descriptive Statistics and Chi-square test were done using SPSS version 21.

**Results:** Age of the participants ranged between 18 to 71 years. Nearly one-third of the participants were health care professionals. Symptoms of mild anxiety was reported by 17.1% of participants, while 20.2% reported moderate anxiety. Anxiety was found to be significantly more among female gender, health care professional and among the study participants who were going to work daily.

**Conclusion:** Covid-19 pandemic has increased the anxiety level among general public.

**Keywords:** COVID-19, Generalized anxiety disorder scale, Health Personnel

## Introduction

COVID-19 disease caused by SARS-CoV2 is the third outbreak of human coronavirus. The other two epidemic due to human coronavirus

were SARS (Severe Acute Respiratory Syndrome) caused by SARS-CoV (SARS coronavirus) in 2003 and an outbreak of MERS (Middle East Respiratory Syndrome) caused by MERS-CoV (Middle East Respiratory Syndrome coronavirus) in 2014.<sup>(1,2)</sup> The

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SARS-CoV2 was first identified among traders of seafood market in Wuhan, China. By 30<sup>th</sup> January 2020 it was declared a Public Health Emergency of International Concern (PHEIC) by World Health Organisation.<sup>(3)</sup>

The first confirmed case of COVID-19 in India was reported from Thrissur district, Kerala on 30<sup>th</sup> January 2020.<sup>(4)</sup> A country wide lockdown was announced on 25<sup>th</sup> March 2020 to curb further spread of the virus.<sup>(5)</sup>

This lockdown has also given rise to a phenomenon of "Social isolation" which is known to increase the risk of adverse mental health outcomes.<sup>(6)</sup> People kept in isolation and quarantine experience significant distress in the form of anxiety, anger, confusion and the symptoms of post-traumatic stress.<sup>(7)</sup> A research paper which examined mental health during MERS outbreak reported that out of 1656 individuals who were isolated after coming in contact with MERS patients 7.6% suffered from anxiety while 16.6% had feelings of anger.<sup>(8)</sup> Another study conducted in Riyadh, Saudi Arabia to assess the psychological impact of MERS-CoV also reported elevated level of anxiety and stress among the participants due to the epidemic.<sup>(9)</sup>

The COVID-19 disease can have an unexpected physical outcome ranging from mild respiratory illness to being fatal. Government of India has issued health advisories to be followed regarding social distancing, wearing face masks, practice of hand washing, use of sanitizers and using Arogya Setu mobile application. Arogya Setu application is useful for contact tracing and timely alerting if someone comes in contact with a COVID positive person.

With this background, the present study was undertaken with the aim to assess the impact of COVID-19 pandemic on anxiety level of general public and the associated demographic factors and also to assess the practice of preventive measures and physical health among the general public.

## Material and Methods

A cross-sectional study was carried out in May 2020. Data collection was done via google form. Link to fill out the form was sent via email or WhatsApp and the snowball sampling technique was used. Sample was calculated assuming that 50% individuals

suffered anxiety due to COVID-19 pandemic. Considering an absolute error of 5%, Sample size was calculated by formula:  $N = \frac{Z^2 p q}{d^2}$

Where N = Sample size, Z = 1.96 at 95% Confidence level, p = 0.50, q = 1 - P = 0.50 and d = absolute error. Considering a 10% non-response rate the sample size was calculated to be 440. At the end of our study period, we got 450 completed forms.

Those who were 18 and above, having smart phones and could read and write in English were included in the study while those who did not give consent were excluded. A semi- structured questionnaire was devised and a pilot study was done among 20 participants. Necessary changes were made in the questionnaire after conducting the pilot study. Questionnaire consisted of following:

- Socio-demographic characteristics
- GAD-7 Scale
- Preventive measures against COVID-19

**Generalized Anxiety Scale (GAD-7):** A validated screening tool to assess generalized anxiety disorder. It is a self-rated questionnaire consisting of 7 questions. It assigns a score of 0,1,2 and 3 to the responses "Not difficult at all", "Somewhat difficult", "Very difficult" and "Extremely difficult" respectively. Score ranges between 0-21. Cut- off score of 5, 10 and 15 are taken for mild, moderate and severe anxiety respectively. A score of 10 or more warrants further evaluation. It has an 89% sensitivity and 82% specificity for a threshold score of 10. GAD-7 is an acceptable screening tool for panic disorder, social anxiety disorder and post-traumatic stress disorder.<sup>(10)</sup>

Ethical clearance (Ref.No. SU/SMS&R/76-A/2020/10) was taken from Institutional Ethical Committee. Personal information was kept confidential. Data was compiled in Microsoft Excel and analysed using SPSS version 21. Descriptive Statistics and chi-square test were done and the p-value less than 0.05 was considered as statistically significant.

## Results

A total of 450 participants were included in the study from all over the country. Maximum responses were recorded from Uttar Pradesh (37.1%). The

demographics show that the age of the participants ranged from 18 to 71 years and gender distribution was uniform in the study (males 52.9% and females 47.1%). Nearly one-third interviewed participants were graduates (37.1%) and postgraduates (31.1%). Nearly half of the participants were employed (45.3%) while the unemployed participants (54.7%) included students, home makers, retired persons and individuals who were out of work. Among the employed participants, more than half (53.4%) worked from home. Nearly one-third of the participants were health care professionals (36.4%).

**Table 1** depicts the practice of preventive measures to restrict the spread of corona virus infection. Most of the participants were following the government issued guidelines of sanitizing or washing hands regularly (91.1%) and wearing a mask while outside their homes (84.7%). Only one-third of the participants went outside their homes for about two to five times (32.4%) with purpose of procuring essential items during last 15 days. Most of the study population had downloaded Arogya Setu App (86.2%). Out of 388 individuals who downloaded Arogya setu, more

than half (52.8%) got to know about it from social media.

As shown in **Figure 1**, using cut-off score of GAD-7, 17.1% of participants reported mild anxiety, 20.2% reported moderate anxiety (cut-off score of 5 & 10 respectively) while none had symptoms of severe anxiety.

For finding out association between anxiety and study variables a cut off score of  $\geq 10$  was used. Anxiety was found more among female gender. ( $p = 0.031$ ) Anxiety was found to be significantly more among health care professional as compared to other participants. ( $p = 0.031$ ) Study participants who were going to work daily had significantly more anxiety of lockdown compared with participants who were going randomly or those who were working from home. ( $p = 0.0005$ ) Participants who could not avail health services in case of need faced more anxiety as compared to those who could utilize health services. The difference was found to be statistically significant. ( $p = 0.025$ ) There was also a significant association found between regular activities of the participants and anxiety. ( $p = 0.002$ ) (**Table 2**)

**Table 1: Distribution of study participants according to practice of preventive measures and physical health during Covid-19 pandemic lockdown (N=450)**

Study Variables	N (%)
Are you strictly following lockdown protocol?	
Yes	439(97.6)
No	11(2.4)
<b>Are you Sanitizing (for 20-30 seconds) or washing hands (for 40-60 seconds) regularly?</b>	
Yes	410(91.1)
No	40(8.9)
<b>Are you following guidelines of wearing a mask before leaving home?</b>	
Yes	381(84.7)
No	69(15.3)



Continue.....

Number of times you went out of home in last 15 days?	
Never	98(21.8)
Once	101(22.4)
Two to five times	146(32.4)
More than five times	105(23.3)
<b>Any illness experienced by respondent and/or family member in past 15 days</b>	
Yes	47(10.4)
No	403(89.6)
<b>Availability of health services in case of need in past 15 days (N=47)</b>	
Yes	30(63.8)
No	17(36.2)
<b>Have you downloaded Arogya Setu App?</b>	
Yes	388(86.2)
No	62(13.8)
Source of information of the Arogya Setu app (N=388)	
Family	54(13.9)
Friends	67(17.2)
Social Media	205(52.8)
Newspaper	36(9.4)
Television	26(6.7)
<b>Is the government of India handling the pandemic well?</b>	
Yes	229(50.9)
No	108(24)
Can't say	113(25.1)

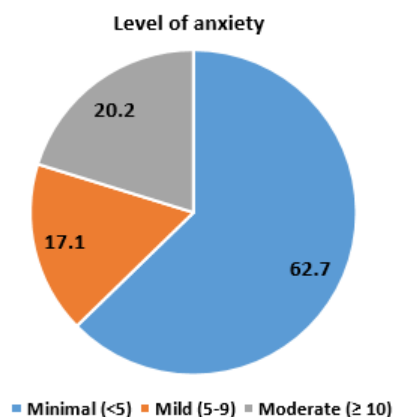


Figure 1: Anxiety level of study participants according to Generalized Anxiety Scale (GAD-7): (N=450)

**Table 2: Association of anxiety with baseline characteristics and physical health of the study participant**

Study Variables	Anxiety			$\chi^2$	P Value
	Present N (%) (N= 91)	Absent N (%) (N=359)	Total		
<b>Age</b>					
<30	53(19.6)	218(80.4)	271	0.187	0.666
≥ 30	38(21.2)	141(78.8)	179		
<b>Gender</b>					
Female	52(24.5)	160(75.5)	212	4.607	0.031
Male	39(16.4)	199(83.6)	238		
<b>Type of family</b>					
Nuclear	37(18.3)	165(81.7)	202	1.916	0.384
Joint	38(23.8)	122(76.2)	160		
Three generation	16(18.2)	72(81.8)	88		
<b>Literacy status</b>					
High school and below	4(40)	6(60)	10	3.72	0.293
Intermediate	25(18.8)	108(81.2)	133		
Graduate	30(18)	137(82)	167		
Post Graduate and above	32(22.9)	108(77.1)	140		
<b>Employment status</b>					
Employed	38(18.6)	166(81.4)	204	0.588	0.443
Unemployed	53(21.5)	193(78.5)	246		
<b>Health care professional</b>					
Yes	42(25.6)	122(74.4)	164	4.643	0.031
No	49(17.1)	237(82.9)	286		
<b>Working status during lockdown (N=204)</b>					
Daily going to work	20(35.7)	36(64.3)	56	14.994	0.0005
Going to work randomly	4(10.3)	35(89.7)	39		
Work from home	14(12.8)	95(87.2)	109		
<b>Illness experienced by respondents and/or family member in past 15 days</b>					
Yes	13(27.7)	34(72.3)	47	1.799	0.180
No	78(19.4)	325(80.6)	403		
<b>Availability of health services in case of need in past 15 days (N=47)</b>					
Yes	5(16.7)	25(83.3)	30	5.009	0.025
No	8(47.1)	9(52.9)	17		

\*Chi square test

## Discussion

Social isolation leads to lack of contact between individual and society. Various studies have reported a link between social isolation and stress, depression, anxiety and poor sleep quality.

In our study majority of the participants were 18 to 29-year-old (60.2%). Naser et al also reported a similar observation in their study, where more than half of the study population (55.4%) belonged to the age group of 18 to 29 years.<sup>(11)</sup> In the present study, half of the participants were working from home (53.4%) while the rest of the participants were either going to work daily or randomly (27.5% & 19.1% respectively). In contrast, Grover et al reported that in their study only 31.7% of the study subjects were working from home for variable number of hours.<sup>(12)</sup>

Prevalence of mild and moderate anxiety was observed to be 17.1% and 20.2% respectively in the present study. Majority of the participants had no anxiety (62.7%) while severe anxiety symptoms was not reported by any of the participants. Naser et al in a cross-sectional study conducted among population group consisting of general public, healthcare professionals, and university students observed a prevalence of 19% moderate anxiety although, occurrence of severe anxiety was found to be much higher than our study.<sup>(11)</sup> This may be due to difference in geographical area and gender composition of the study participants.

Grover et al in an online survey conducted to assess the psychological impact of COVID-19 Lockdown also reported a prevalence of 23.7% mild anxiety however, prevalence of moderate (8.7%) and severe (5.7%) anxiety was found to be lower than our study.<sup>(12)</sup> Gupta et al and Barzilay et al reported a prevalence of 9.9% and 22% of moderate anxiety respectively using a GAD 7 cut-off score of more than 10.<sup>(13,14)</sup>

In the present work, participants of age more than 30 years were having more anxiety as compared to those who were less than 30 years. Wang et al, in a study among Chinese population showed that people younger than 40 years had a higher level of anxiety during COVID 19 lockdown.<sup>(15)</sup> This can be due to the fact that older age group have more number of dependents on them. Also, they have more

family responsibility and job insecurity increased during pandemic. Huang and Zhao also reported significantly higher risk of anxiety among age group less than 35 years.<sup>(16)</sup>

Female gender had more anxiety as compared to males in the present study. Similar finding was reported in studies conducted in Jordan and Iran.<sup>(11,17)</sup> In contrast, a web based cross-sectional study conducted among Chinese population reported no association with gender.<sup>(16)</sup>

Unemployed people had more anxiety as compared to employed ones in the present study. Increased psychological distress was found to be associated with unemployment during COVID 19 pandemic in a study conducted among young people in Israel.<sup>(18)</sup> Naser et al also reported Anxiety score was differed significantly among employed and unemployed participants during COVID 19 pandemic.<sup>(11)</sup> This may be due to fear of future employment prospects as the country is facing financial and economic crisis and recession due to pandemic.

Anxiety was found significantly more in health professionals as compared to others in present paper. In a previous study conducted in Indore City, it was revealed that health professionals often have better awareness, positive attitudes towards pandemics and they often experience lower levels of anxiety compared to general population.<sup>(19)</sup> Whereas, a study from Ethiopia reported poor knowledge and erroneous beliefs of healthcare professionals during the Ebola virus outbreak in 2015 and it urged for an intense training of the healthcare professionals.<sup>(20)</sup> Naser et al in a study conducted among Jordanian population also reported higher level of anxiety among university students and health care workers.<sup>(11)</sup> Health care professionals have constant fear of getting infected after coming in contact of COVID positive patient. Also there was an uncertainty regarding availability of proper personal protective equipment (PPE) in the early days of the pandemic. All of these contributed to an increase in level of anxiety among health care professionals.

Most of people were sanitizing or washing hands and using masks before leaving home in the current study. This is in line with studies done by Taghrir

et al and Alzoubi and colleagues.<sup>(21,22)</sup> Azlan et al in a cross-sectional study conducted among general public in Malaysia also reported that almost half of the participants wore face masks.<sup>(23)</sup>

In our study, half of the subjects felt (50.9%) that India has been controlling this pandemic effectively so far. Our findings are similar to study done among people of Kashmir by Bhat et al which revealed that majority of the respondents (59.5%) found that the steps taken by the government to control COVID-19 are satisfactory. Most of the study participants had downloaded Arogya Setu application (86.2%) at the time of conducting this research. Downloading Arogya Setu application was made mandatory for all government employees. Timely identification helps to limit the spread of infection.<sup>(24)</sup>

### Conclusion

COVID -19 pandemic had affected the general well-being of the community. Restrictions of lockdown also increased the anxiety level among general public. Health care professionals were significantly affected by anxiety. This naturally prompts a more skill-based training of health professionals regarding following precautionary measures for effective prevention against possible spread of infection. Moreover, there is a need to promote awareness by conducting awareness sessions through various mediums to break the myths about pandemic which is being spread via social media platforms. Increase in number of affordable and accessible testing and health care facility can prove to be useful.

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# Clinico-epidemiological Profile of Paraquat Poisoning in Children at a Tertiary Care Centre: Case Series

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## Abstract

**Aims and objectives:** This case series is done to know the Clinico-epidemiological profile of paraquat poisoning in children and also the implication of available treatment guidelines in improving outcomes in the paediatric population as there are no standard treatment guidelines available.

**Materials and Methods:** Nine children were selected during the study period of October 2021 to February 2023, demographic data were collected, clinical parameters were assessed with details such as time of presentation, symptoms and first aid received, laboratory parameters such as LFT, RFT, chest radiographs obtained and serial values monitored. Treatment as per the available recommendation was initiated with immunosuppressive therapy and haemodialysis on a case-to-case basis.

**Results:** Among the 9 children, there were 6 females (67%) with an average age group of 15–18 years. eight (89%) of the 9 children developed acute renal failure. Seven children underwent haemodialysis. Five (55%) children developed hepatic dysfunction. Among the 9 children, 3 (67%) survived.

**Conclusion:** The study reveals that the mortality rate can be reduced, if the child presented to the hospital within 8 hours of ingestion of the compound, amount ingested is less than 20 ml, and early initiation of Haemodialysis within 8 hours and a trail of immunosuppressive therapy.

**Keywords:** Paraquat poisoning, haemodialysis, immunosuppressive therapy

## Introduction

Paraquat is a commonly used herbicide in India. Suicides due to paraquat (PQ) are an important cause of morbidity and mortality because there is no specific antidote available. The chemical structure of paraquat is 1,1'-dimethyl-4,4'-bipyridinium. It belongs to the group of dipyridyl herbicides<sup>[1]</sup>. Paraquat was first manufactured as a nonselective, quick-acting

pesticide by a British chemical company in 1962. It was rapidly absorbed by the plants and inactivated in contact with clay in the soil, leaving minimal residue. It is extremely toxic to humans, and even minimal ingestion of 10–20 mL of 20% paraquat is lethal<sup>[2]</sup> and can lead to renal failure, hepatotoxicity, and pulmonary fibrosis. The case fatality rate in paraquat is as high as 70%.

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Paraquat poisoning can be classified into 3 categories [2]

Mild/subacute poisoning - <20 mg/kg body weight

Moderate/severe acute poisoning - 20–40 mg/kg body weight

Fulminant/hyperacute poisoning >40 mg/kg body weight.

The use of immunosuppressive therapy (a combination of glucocorticoids and cyclophosphamide) may be beneficial in improving survival in these patients [3,4].

Paraquat poisoning in children is very rare, there are no case studies available for paraquat poisoning in children and no standard treatment guidelines for managing such cases are available. We report our experience of treating nine children of paraquat poisoning with immunosuppressive therapy and other supportive measures at Hassan institute of medical sciences, Karnataka.

### Methodology

All the children who presented with an alleged history of paraquat consumption were included in the study, a total of nine children over a period of 2 years (October 2021- February 2023) were taken into the study. The bio-data with age, sex, time of consumption, symptoms, first aid received, and treatment given were collected. Informed consent was taken. Laboratory parameters such as renal function test, liver function test, and chest radiographs were obtained. Serial values were monitored and assessed. Paraquat levels could not be assessed due to the non-availability of investigations required. The data was collected in a predetermined proforma sheet. Data were analysed in a descriptive pattern.

Following complications were monitored. Children were classified to have renal dysfunction according to the eGFR. Calculation of eGFR was done based on the Schwartz formula ( $eGFR = 0.55 \times \text{Height}/\text{Creatinine}$ ) [5]. Renal failure was classified based on acute kidney injury classification using

pRIFLE criteria (table 1) and serial creatinine values was monitored.

**Table 1: pRIFLE criteria.**

Staging	Serum creatinine criteria	Urine output criteria
Risk	eGFR decreased by $\geq 25\%$	0.5 mL/kg/hr for 8 hr
Injury	eGFR decreased by $\geq 50\%$	0.5 mL/kg/hr for 16 hr
Failure	eGFR decreased by $\geq 75\%$ or $< 35 \text{ mL}/\text{min}/1.73 \text{ m}^2$	0.3 mL/kg/hr for 24 hr or anuria for 12 hr
Loss	Persistent failure $> 4$ weeks	
ESRD	Persistent failure $> 3$ months	

eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease

Hepatic dysfunction was considered if serum bilirubin was  $> 2 \text{ mg}/\text{dL}$ . Children were monitored for signs of acute lung injury, acute respiratory failure, and circulatory failure.

Children were treated with the following medications, as per the available recommendations.

1. Airway, breathing and circulatory support
2. Gastric lavage and decontamination by activated charcoal
3. Skin and eye decontamination
4. Enhance elimination - haemodialysis
5. IV antibiotics - Amoxiclav 50mg/kg/day in 2 divided doses to prevent infection
6. Antioxidant therapy - Vitamin C (500mg/tab) once a day.

Vitamin E (400 IU/ tab) once a day.

Intravenous N-Acetyl cysteine 2g/day for 3 days.

7. Intravenous Methylprednisolone 30 mg/kg/day for three consecutive days.
8. Intravenous Cyclophosphamide 15 mg/kg/day for two consecutive days, followed by Intravenous Dexamethasone 8mg thrice a day until recovery or death.

## Results and Analysis

The nine children treated for paraquat poisoning are summarised in table 2.

**Table 2: Case summary of paraquat poisoning**

CASES	1	2	3	4	5	6	7	8	9
Age/Sex	13y/M	16y/F	15y/M	16y/F	16y/M	16y/F	17y/M	16y/F	17y/F
Time of presentation	2 hours	10 hrs	2 hrs	4 hours	5 hours	3 hours	3 hrs	3 hrs	3 hours
Amount	2-5 ml	50 ml	30-40 ml	5 ml	50-60 ml	40-50 ml	40-50 ml	~50 ml	10-20 ml
Complications	Nil	ARF, ALLI,	ARF, ALLI, PF	ARF	ARF, ALLI,	ARF, ALLI, with shock	ARF, ALLI,	ARF, ALLI, PF	ARF, PF
Peak Serum Creatinine (mg/dL)	0.75	5.07	4.98	4.2	6.09	2.3	3.21	2.96	2.99
Lowest eGFR (ml/kg/1.73m <sup>2</sup> )	102	15.9	17.4	20.9	14.4	40.6	24.5	26.7	29.9
Peak serum bilirubin (mg/dL)	0.6	3.3	26.3	2.3	4.3	0.8	0.7	8.1	0.7
Treatment	GL, AOT	GL, AOT	GL, HD, AOT	GL, HD, AOT	GL, HD, AOT	GL, HD, AOT	GL, HD, AOT, IST	GL, HD, AOT, IST	GL, HD, AOT, IST
Haemodialysis	Nil	Nil	7 cycles	1 cycle	3 cycles	2 cycles	2 cycles	5 cycles	7 cycles
Time of initiation of HD	NA	NA	22 hours	16 hours	20 hours	24 hours	12 hours	8 hours	8 hours
Ventilation	NA	MV	MV	NA	MV	MV	MV	MV	Oxygen
ICU stay	2 days	8 hours	11 days	2 days	2 days	3 days	2 days	8 days	7 days
Outcome	Survival	Death (8hrs)	Death (11 days)	Survival	Death (30hrs)	Death (48hrs)	Death (43hrs)	Death (8 days)	Survival

AOT: antioxidant therapies; ARF: acute renal failure; ALLI: acute liver injury; Cr: creatinine; F: female; GL: gastric lavage; HD: haemodialysis; M: male; MV: mechanical ventilation; NA: not applicable; NIV: non-invasive ventilation; PF: pulmonary fibrosis; IST: Immunosuppressive therapy.

The children were in the age group of 15-18 years, among the nine children, six were females (67%) and 3 males (33%), figure 1. Eight children presented to the hospital within 3 hours of ingestion, figure 2. On monitoring of the above children, eight (89%) of nine cases developed acute renal failure

with a peak serum creatinine of 6.09mg/dL, and eGFR 14.4ml/kg/1.73m<sup>2</sup>, figure 3. Seven children underwent haemodialysis, of which, two children (33%) underwent haemodialysis within 8 hours, one (16.6%) child within 12 hours, and four (67%) of them within 24 hours of ingestion of the compound.



Among the nine children, five (55.5%) developed hepatic dysfunction with peak serum total bilirubin of 26.3 mg/dL, of which serum indirect bilirubin was 15mg/dL.

Seven(78%) children developed respiratory distress, of which 6 received NIV and mechanical ventilation, and one child received oxygen therapy.

One child developed circulatory failure and shock.

Among the 9 children, 3 (33%) survived, figure 4,

Case No.1, the first case of survival, presented within 2 hours of consumption, had consumed a very small amount of the compound and did not develop any renal and liver dysfunction or respiratory compromise.

Case No. 4, the second case of survival presented within 3 hours of consumption, child was initiated with gastric lavage, and antioxidant therapy, had normal creatinine and eGFR on admission, underwent haemodialysis within 12 hours of consumption, started developing raising titres of serum creatinine, peak serum creatinine being 3.21mg/dL and reduction of eGFR, lowest being 24.5ml/kg/1.73m<sup>2</sup>. After 4 cycles of haemodialysis serum creatinine values gradually reduced and improvement in eGFR was noted. There was no hepatic dysfunction or respiratory compromise.

Case No. 9, the third case of survival, presented to the hospital within 3 hours of consumption, initiated with gastric lavage, antioxidant therapy, and immunosuppressive therapy, even though with initial LFT and RFT were normal, the child underwent haemodialysis within 8 hours of consumption. However, the Child developed renal dysfunction with raising creatinine on day 3, peak value being 2.9mg/dL, and the lowest eGFR of 29ml/kg/1.73m<sup>2</sup>. The child underwent 7 cycles of haemodialysis, following which creatinine values reached normal after 6 days. The child developed respiratory distress on day 10, chest x-ray suggestive of pulmonary fibrosis, figure 5, the child was continued with minimal oxygen support, antioxidants and immunosuppressants, which improved in a week. The child did not have hepatic dysfunction.

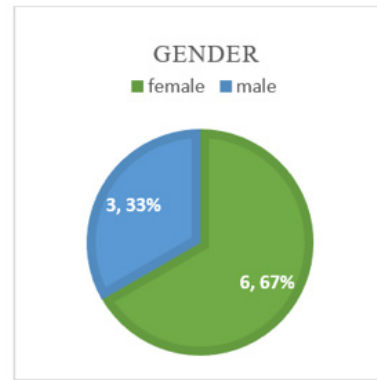


Figure 1: Gender distribution

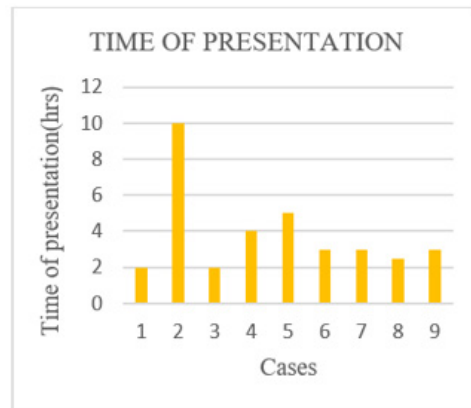


Figure 2: Time of presentation

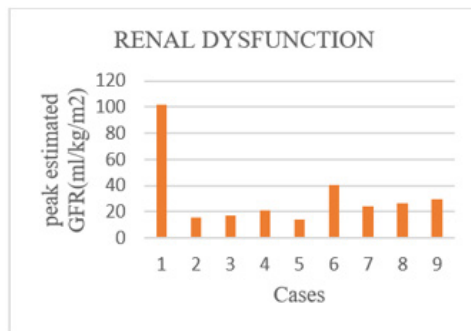


Figure 3: Lowest eGFR

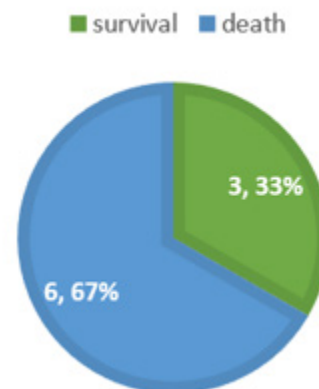


Figure 4: Mortality among the cases



**Figure 5: Pulmonary Fibrosis**

### Discussion

Paraquat was first manufactured and sold in early 1962 under the trade name Gramoxone, and commonly used herbicide. Paraquat is classified as a non-selective contact herbicide. It kills a wide range of annual grasses, broad-leaved weeds, and the tips of established perennial weeds. The principal target organ for paraquat poisoning is the lung and kidney, figure 5. Paraquat-induced toxicity is mainly due to generation of reactive oxygen species (ROS). Due to the uptake of paraquat against the concentration gradient in the lungs, the production of free radicals results in greater toxicity in the lungs as compared to other organs.

Due to the presence of free radicals and reactive oxygen species, lipid peroxidation occurs, leading to cell membrane damage and apoptosis.

Paraquat toxicity is most severe in the lungs and leads to acute alveolitis and diffuse alveolar collapse [6]. During the acute 'destructive phase' both type I and type II pneumocytes demonstrate swelling, vacuolation and disruption of mitochondria and the endoplasmic reticulum. Kidneys exposed to paraquat demonstrate the development of large vacuolation in proximal convoluted tubules which leads to necrosis[7].

Congestion and hepatocellular injury associated with rough and smooth endoplasmic reticulum degranulation and mitochondrial damage occur in the liver.

As of today, paraquat poisoning has no specific antidote, and supportive therapy is the mainstay of treatment for the prevention of lung injury from free radicals. The modalities include steroid pulse therapy (methylprednisolone, dexamethasone) along with cyclophosphamide for preventing the development of pulmonary fibrosis and haemodialysis to aid in eliminating paraquat from the circulation and gastric decontamination. It is important to note however that administering oxygen has been shown to increase paraquat toxicity through the provision of electron acceptors and thus should be used sparingly in those who are hypoxic. Even with aggressive treatment, the mortality in paraquat poisoning is alarmingly high, with the cause being multiorgan dysfunction and respiratory failure. There are a few exceptions with patient survival, but these can be attributed to ingestion of a smaller dose or early initiation of treatment and the outlook for a patient with ingestion of a higher dose or severe paraquat poisoning is still poor. Taking this into consideration, the crux of the management of paraquat poisoning comprises mainly preventive measures and early and aggressive decontamination to prevent any further absorption of the compound.

A case series by Pavan described to have a mortality of 35% to 50% in patients with paraquat poisoning, with all patients developing acute kidney injury, they described respiratory and multiorgan failure as the main causes of mortality.[8]

In a study by Lin et al., a therapeutic effect has been reported with a high dose of cyclophosphamide and glucocorticoid where survival is about 75%.<sup>[9]</sup> However, in our study, 3 children were initiated with immunosuppressive therapy, among which one child survived (33%).

An intensive care unit study and a meta-analysis conducted by Agarwal et al. concluded that immunosuppressive therapy with cyclophosphamide and glucocorticoids has a potential role in the management of paraquat poisoning in moderate to severe poisoning cases <sup>[10,11]</sup>

### Conclusion and Recommendation

The study reveals that the mortality rate can be reduced, if the child presented to the hospital within

8 hours of ingestion of the compound, the amount ingested is less than 20 ml and early initiation of Haemodialysis within 8 hours and a trial of immunosuppressive therapy.

Case reports on paediatric paraquat poisoning are not available, further studies are required for recommending treatment guidelines, as there is no specific antidote available and the compound is highly toxic, with high mortality rates, we should aim at preventing such exposures, and measures need to be taken to withdraw or limit the use of such compounds.

**Limitation of the study:**

- Paraquat levels were not measured.
- All children were not initiated with immunosuppressive therapy.

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**Conflict of interest:** None Declared

**Ethical approval:** the study was approved by the Institutional Ethics Committee

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## Safe Drinking Water Practices among the Households in Rural Field Practice Area of a Medical College: A Cross Sectional Study

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### Abstract

**Introduction:** Drinking water and sanitation are the door way to health which is the pre-requisite for progress, social equity and human dignity to improve the quality of life of people. Limited access to safe drinking water and poor sanitation can lead to under nutrition, water borne diseases, vector borne diseases and neglected tropical diseases.

**Methods:** A cross sectional study was conducted among 261 households of Singanodi Village which is the rural field practice area of Navodaya Medical College, Hospital & research centre, Raichur. The investigator had visited and interviewed each household and conducted face-to-face interview using a structured questionnaire which includes Socio- Demographic features and information on hygienic practices of water.

**Results:** In this study majority of the households(69%) did not practice any water purification methods. 77.4% of the participants practiced hand-washing with soap and water after defecation. 90.4% of the households clean the water storage vessels daily. Significant association was found between diarrheal diseases with distance to get water, water purification methods and hand washing with soap and water after defecation.

**Conclusions:** This study reinforces the importance of health education which plays an importance role in the prevention of water borne diseases.

**Keywords:** Drinking water, Rural area, Raichur

### Introduction

Drinking water and sanitation are the door way to health which are the pre-requisite for progress, social equity and human dignity to improve the quality of life of people. These are the most

important felt needs in public health in developing countries in this 21st century.<sup>[1]</sup> Water, sanitation and hygiene(WASH) strategy has been introduced as a part of sustainable development goal-6 to achieve the universal, affordable and sustainable access to safe drinking water, sanitation and hygiene by 2030.<sup>[2]</sup>

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Majority of population of India resides in rural area (68.85%).<sup>[3]</sup> Meeting the drinking water needs of such a large population can be a daunting task. The non-uniformity in level of awareness, socio-economic development education, poverty, practices and rituals and water availability add to the complexity of the task.<sup>[4]</sup> Limited access to safe drinking water and poor sanitation can lead to under nutrition, water borne diseases including diarrhoea and dysentery, vector borne diseases and neglected tropical diseases such as soil transmitted helminthiasis, schistosomiasis etc. Lack of access to suitable sanitation facilities is also a major cause of risks and anxiety, especially for women and girls. For all these reasons, sanitation that prevents disease and ensures privacy and dignity has been recognized as a basic human right.<sup>[5]</sup> This study was conducted with an objective to assess safety drinking water practices among the residents of rural field practice area of Navodaya Medical College, Hospital & research centre, Raichur.

### Materials and Methods

This cross sectional study was conducted among 261 households of Singanodi village which is the rural field practice area of Navodaya Medical College, Hospital & research centre, Raichur, during 1st December 2019 to February 29<sup>th</sup> 2020. People who resides for more than 6 months in that village and people aged > 18 were included in the study. Refugees, nomads, brick kiln workers, other temporary residents and those whose house remain closed on three repeated visits were excluded from the study. Ethical clearance was obtained from Institutional Ethical Review Board of Navodaya Medical College, Hospital and Research centre, Raichur. Informed consent was obtained from each respondent prior to the interview. A total of 261 houses were visited. The investigator had visited and interviewed each household and conducted face-to-face interview (preferably with the head of the family) using a structured questionnaire. The questionnaire containing demographic characteristics such as age, sex, religion, education, occupation, socio-economic status, type of family., Socioeconomic status was classified according to modified B. G. Prasad

classification.<sup>[6]</sup> Information on hygienic practices of water was collected which includes source and supply of water, distance to get water, sanitary practices.

Data were entered in MS EXCEL and analysis was done using SPSS vs 20 in the form of frequencies and percentages. Chi square test was applied to assess the association between sanitary practices and acute gastrointestinal diseases.

In this study the source of water supply to the village was underground water and bore well was linked to overhead tank to draw the water from source. The availability of the drinking water supply to the village is explained in the table 1.

In this study 261 households were studied. Majority of the study participants were <30 years of age groups, (64 %) of the participants were females and predominantly Hindus by religion (75.5%). Majority of the study participants were illiterate (71.6%) and belonged to class 3 socioeconomic status. Most of the study participants were residing in joint families (48.3% %) but no significant association was found between the socio-demographic features and acute diarrheal diseases. The association between socio-demographic features and acute diarrheal diseases of study participants are explained in the table 2.

In this study majority of the households had source of water supply within their premises(79.3%), majority of them did not use any methods for water purification(69%) and majority of the households practiced hand washing with soap and water after defecation (77.4%) which was significantly associated with acute diarrheal diseases. Majority of the households had covered the drinking water(92%), practiced hand washing with soap and water before drinking (81.2%) and clean the water storage vessels daily(90.4%), practiced dipping of glass into water before drinking(68.2%), Clean the glass or jug before drinking water (86.2%) which was not significantly associated with acute diarrheal diseases. The association of safe drinking water practices with acute diarrheal diseases are explained in Table 3.

**Table 1: Availability of the drinking water supply to the village**

Variable		Frequency	Percentage
Source of water	Underground water	261	100
Water drawing from source	Bore wells linked to Overhead tank	261	100.
Total		261	100

**Table 2. Association of Acute Diarrheal diseases with socio-demographic features.**

Variables		Diarrhea		Total(261)	$\chi^2$ Value	P value
		Present	Absent			
AGE	<30	18(19%)	78(81%)	96(100%)	4.43	0.109
	31-50	17(18.2%)	76(71.8%)	93(100%)		
	.>51	22(31%)	50(69%)	72(100%)		
Sex	Male	21(22.3%)	73(71.7%)	94(100%)	0.02	0.500
	Female	36(22%)	131(78%)	167(100%)		
Religion	Hindu	43(21.8%)	154(78.2%)	197(100%)	1.19	0.550
	Muslim	7(29.1%)	17(71.9%)	24(100%)		
	Christian	7(5.7%)	33(94.3%)	40(100%)		
Education	Illiterate	42(22.4%)	145(77.6%)	187(100%)	0.51	0.992
	Primary	2(25%)	6(75%)	8(100%)		
	Middle	2(20%)	8(80%)	10(100%)		
	High school	6(22.2%)	21(71.8%)	27(100%)		
	PUC/ diploma	4(20%)	16(80%)	20(100%)		
	Graduate / Postgraduate	2(4.5%)	7(5.5%)	9(100%)		
Socioeconomic status	Class II	3(21.4%)	11(71.6%)	14(100%)	4.43	0.109
	Class III	14(31.8%)	30(68.2%)	44(100%)		
	Class IV	21(20.1%)	83(79.9%)	104(100%)		
	Class V	19(19.3)	79(80.7%)	98(100%)		
Type of family	Nuclear	21(17.6%)	98(82.4%)	119(100%)	2.6	0.450
	Three generation	4(26.6%)	11(73.4%)	15(100%)		
	Joint family	32(25.1%)	95(74.9%)	127(100%)		
	Total	57(21.8%)	204(78.2%)	261(100%)		

**Table 3. Association of safe drinking water practices with acute diarrheal diseases.**

Variables		Diarrhea		Total(261)	$\chi^2$ Value	P value
		Present	Absent			
Distance to get water	Within the premises	50(24.1%)	157(75.9%)	207(100%)	5.71	0.017
	Outside the premises	7(13%)	47(87%)	54(100%)		
Covering of drinking water	Covered	53(21.9%)	189(78.1%)	242(100%)	0.1	0.597
	Not covered	4(21%)	15(79%)	19(100%)		

Continue....

Dipping glass into water before drinking	Practiced	39(27.6%)	141(72.4%)	180(100%)	0.01	0.520
	Not practiced	18(22.2%)	63(77.8%)	81(100%)		
Different methods of filtration	Boiling	13(26.5%)	36(74.5%)	49(100%)	22.1	0.000
	RO system	2(25%)	6(75%)	8(100%)		
	Cloth filtration	3(23%)	10(77%)	13(100%)		
	Do not purify	34(17.8%)	157(82.2%)	191(100%)		
Hand washing practices before drinking	Practiced	47(22.1%)	165(71.9%)	212(100%)	1.8	0.478
	Not practiced	10(20.4%)	39(79.6%)	49(100%)		
Hand washing with soap and water after defecation	Practiced	37(18.3%)	165(81.7%)	202(100%)	6.4	0.011
	Not practiced	20(33.6%)	39(66.4%)	59(100%)		
Cleans the water storage vessels daily	Clean the vessels	51(21.6%)	185(78.4%)	236(100%)	0.7	0.476
	Do not clean the vessels	6(24%)	19(76%)	25(100%)		
Clean the glass or jug before drinking water	Clean the jug	52(23%)	173(77%)	225(100%)	1.5	1.52
	Do not clean the jug	5(13.8%)	31(86.2%)	36(100%)		
	Total	57(21.8%)	204(78.2%)	261(100%)		

## Discussion

This study was conducted in order to assess the safe drinking water practices among the residents of Singanodi village which is the rural field practice area of Navodaya medical college, Hospital and Research centre Raichur. In this study the source of water supply to the Singanodi village was underground water. This is similar to a study done by Mishra S et al [12] and Venkatesh R [13] et al. In contrast to this a study done by Gaud N et al [7] and Chinamma D et al [10] showed that the main source of water in the villages was pipe water. A study done by Kaniambady S et al [9] showed that main source of water was protected dug wells. In this study majority of the households had source of water supply within their premises. This is similar to a study done by Shashikala SK et al [8] and Kuberan A et al [11]. In this study drinking water was covered by majority of the households. This is similar to study done by Pachori R et al [14]. In this study majority of the households(69%) did not use

any method for purification of drinking water. This is similar to study done by Goud N et al [7], Chinamma D et al et al [10] and Reshma et al [15]. In contrast to this a study done by Kaniambady S et al [9] showed that majority of the households were practicing boiling as a method of water purification. In this study majority of the households were practicing hand-washing with soap and water after defecation. This is similar to a study done by Kaniambady S et al [9], Pachori R et al [14] and Reshma et al [15]. In contrast to this a study done by Kuberan et al [11] showed that majority of the participants did not practice handwashing with soap and water after defecation. In this study 21.8% of households were reported diarrhoea from past 2 weeks. In this study majority of the households clean the water storage vessels daily. This is similar to a study done by Gaud N et al [7], Chinamma D et al [10], Kuberan A et al [11] and Reshma et al [15]. In this study majority of the households clean the jug or glass before drinking.

## Conclusion

In this study, groundwater was the major source of water to the village, availability of water, sanitation and hygiene was good in households. Majority of the households did not practiced any water purification methods and some households did not practice hand washing practice with soap and water after defecation. Health education is needed for better use of existing facilities and also to prevent the incidences of water and sanitation related diseases. Appropriate emphasis to be given for behaviour change communication to create awareness among villagers on the importance of water and sanitation practices by using various media to educate to them..

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### Declarations:

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**Conflict of interest:** None declared

**Ethical approval:** The study was approved by the Institutional Ethics Committee

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## Health Seeking Behaviour among Tribal Population of Shekharakund Colony, Wayanad, Kerala

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### Abstract

**Introduction:** Health is the major pathway to human development. The individual self, various diseases, and the availability and accessibility of health services all have an impact on how people behave seek health care.

**Objectives:** The present study is aimed to assess the health seeking behaviours in the tribes of Paniya and Kattumayakan in Shekarankundu colony, Wayanad.

**Methods:** Data to know the health seeking behaviour was collected using predesigned and pretested questionnaire in the native language. Questions were asked about adequate health check-ups in nearby health centres, utilisation of health benefits from nearby PHCs, detection of pregnancy, antenatal check-ups, mode of delivery, immunization of infants and prevalence of communicable and non-communicable disease (DM/HT) in the selected population, maternal and infant death in the community, knowledge about the antivenom for the snake envenomation, belief in black magic in causation and treatment of disease.

**Results:** Majority of the study population above 35yrs of age, did not seek health care benefits. 99% of the tribal population found it difficult to take leave from work, 92% complained about long waiting time, 48 % were not satisfied with the treatment, 95% of respondents said due to unavailability of doctors during the time they visited, 98% agreed the distance of health centre was long for them to visit every time. 52.9% of tribal population preferred allopathic treatment over traditional healers. Only 29.4% of the population were aware of snake anti-venom.

**Conclusions:** When treatment is sought, traditional medicines and healers play an important role in maintaining health and well-being among the ethnic groups. Traditional medicines and healers were preferred for treatment of both 'simple and complicated diseases' because of easy accessibility. They are aware of the superiority of modern health services but are hesitant to employ them due to the potential time loss.

**Key words:** Health seeking behaviour, Health services, Tribal health, tribal population, Wayanad.

### Introduction

WHO defines health as a comprehensive condition of physical, mental, and social well-being

rather than only the absence of sickness or disability.<sup>1</sup> Health is the major pathway to human development, which is the cornerstone for a healthy, wealthy and prosperous life. Perception of health, disease

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and health seeking behaviours are not same across culture. The individual self, various diseases, and the availability and accessibility of health services all have an impact on how people behave seek health care.

According to census, tribal population constitutes 8.1% of India's total population.<sup>2</sup> In Kerala, 1% of states population is formed by tribal. They belong to 35 communities. 22% still reside in the forest areas. The majority of them is concentrated in the districts of Wayanad (1,36,062 Tribal), Idukki (50,973), and Palakkad (39,665).<sup>3</sup>

The tribal population have their own concept of health and prefers to maintain a socio-cultural distance from others. Tribal Mobile Medical Units are operating throughout the state to provide primary healthcare services for the tribal population residing in the far-flung and difficult-to-reach tribal villages. Five of these units are operating in the Wayanad district, two each in Idukki and Palakkad districts and one each in Kasaragod, Malappuram, Kannur and Trivandrum districts. These units typically host 20 medical camps every month, offering the basic services including treating common ailments, providing prenatal and postpartum care, administering immunizations, preventing and controlling communicable diseases, etc. Through the medical camps, essential health education programmes particularly those on waterborne disease prevention are provided.<sup>3</sup> In spite of all these services available, very few of the tribal population utilise them as they rely on primitive traditional healing methods known and available to them. Also cultural factors, financial barriers, geographical remoteness and dwelling in reserve forest area are few other reasons for non-utilization of medical facilities.<sup>4</sup>

The present study is aimed to assess the health seeking behaviours in the tribes of Paniya and Kattumayakan in Shekarankundu colony, Wayanad.

### Materials and Methods

This was a cross-sectional study done in March 2019 at Shekarakund tribal colony, Wayanad, Kerala. After obtaining approval from the college administration, data was collected from members of Paniya & Kattunaykam tribes above 15 yrs of

age. Participation in the study was voluntary. Data to know the health seeking behaviour was collected using predesigned and pretested questionnaire in the native language (Malayalam). Questions were asked about adequate health check-ups in nearby health centres, utilisation of health benefits from nearby PHCs, detection of pregnancy, antenatal check-ups, mode of delivery, immunization of infants and prevalence of communicable and non-communicable disease (DM/HT) in the selected population, maternal and infant death in the community, knowledge about the antivenom for the snake envenomation, belief in black magic in causation and treatment of disease.

Study was conducted by home visits to each family. Question from questionnaire were asked in person after taking informed consent. Responses were obtained from total 20 families in Shekarakund colony. Total 50 subjects were included. Data analysis was done in MS excel. The data collected were expressed as percentage and proportions.

### Results

Total number of subject in the present study were 50 of which 24 (48%) were in the age group 19-36 years. 27 (54%) of the subjects were male and 23 (47.1%) were females. Majority of subjects in the study were illiterate (47.1%) and 29.4% had primary level education. Majority of the population went to nearby healthcare facility for moderate illness (52.9%), for delivery (8.5%), and for immunization of infants. (Table 1)

**Table 1: Distribution of healthcare seeking behaviour among tribal population.**

	Seek care	
	Yes	No
Moderate illness	52.9%	47.1%
Severe illness	12%	88%
Antenatal check up	25%	75%
Delivery	87.5%	12.5%
Postnatal care	36%	64%
Immunization of infants	76.5%	23.5%

Fig 1 shows that tribal population below 35yrs visited nearby health care centres for various illness whereas, whereas majority of those above 35yrs of age did not seek health care benefits. Fig 2 lists the reason given by tribal population for not attending

health care centres. 99% of the tribal population found it difficult to take leave from work, 92% complained about long waiting time, 48 % were not satisfied with the treatment, 95% of respondents said due to

unavailability of doctors during the time they visited, 98% agreed the distance of health centre was long for them to visit every time.

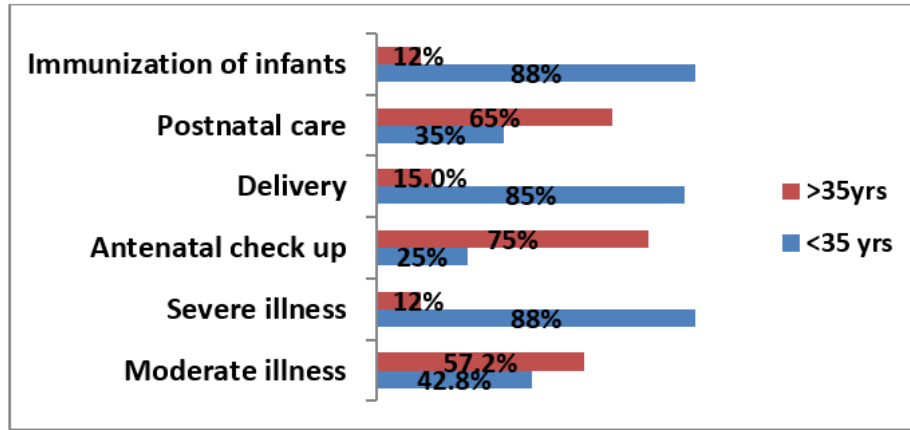


Fig 1: Health seeking behaviour among tribal population according to age.

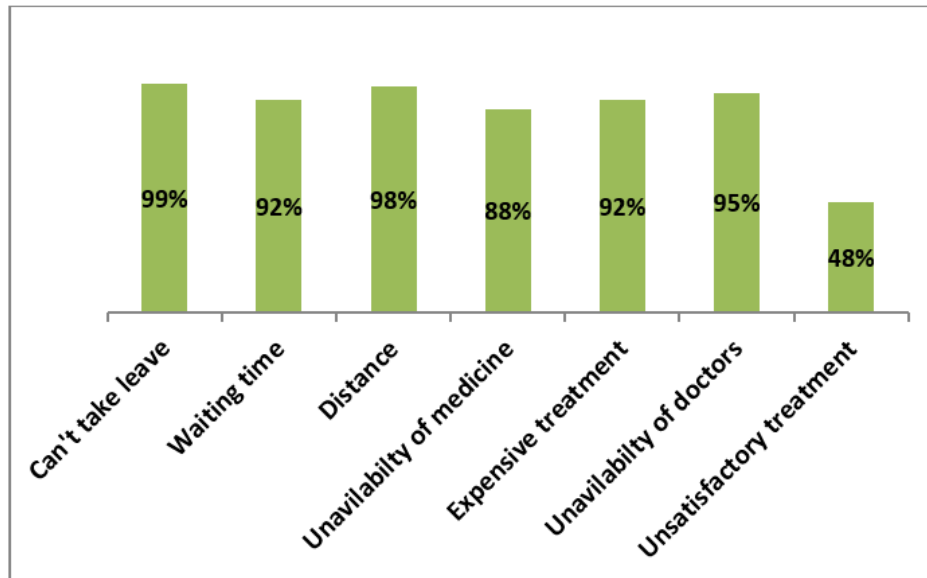


Fig 2: Reasons given by tribal population for not availing health services by health care centre

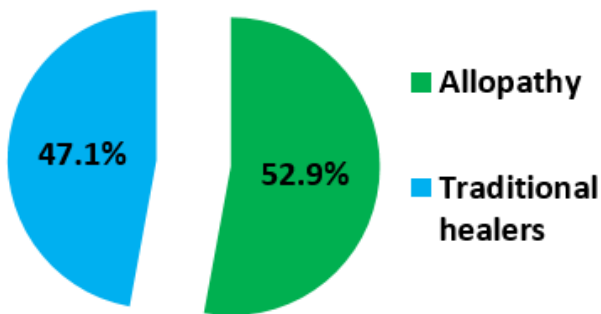


Fig 3: Preference of treatment by tribal population.

52.9% of tribal population preferred allopathic treatment over traditional healers. (Fig 2)

Table 2: Health benefits availed by tribal population.

Health benefits from ASHA/ Tribal promoter	Frequency	Percentage
Yes	43	86%
No	7	14%

86 % of tribal population availed health benefits provided by ASHA & other tribal promoters (Table 2). Only 29.4% of the population were aware of snake anti-venom (Fig 4).

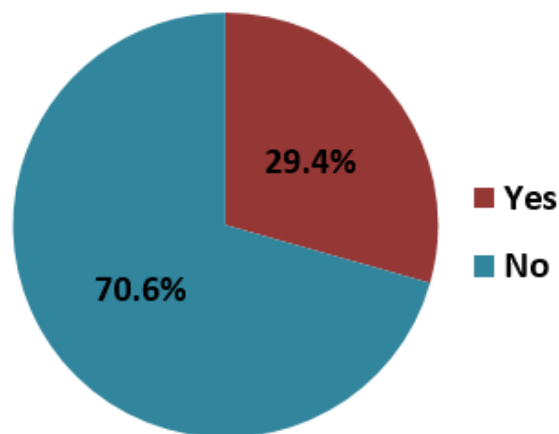


Fig 4: Awareness about snake anti-venom among tribal population.

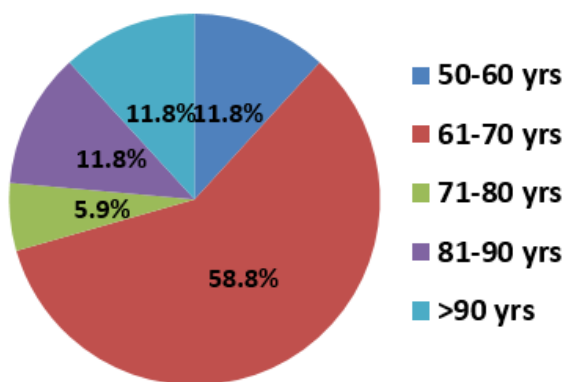


Fig 5: Average age of mortality in tribal population

### Discussion

This is a cross sectional study conducted in Paniya and Kattunaikan tribe in Shekharankundu colony, Wayanad. The nearby health centre is Vaduvanchal PHC at a distance of 4 km from the colony. Majority of tribal population below the age of 35 yrs utilised treatment services from nearby health centre for various illness such as, moderate illness, severe illness, antenatal check-ups, delivery, postnatal care, and immunization of infants. Similar findings were seen in a study by Sonowal et al which revealed that younger generation are more inclined than the older ones to turn towards modern system of medicine.<sup>5</sup> This is due to the increasing awareness, effectiveness, availability and affordability.

Due to advancement in health education and adequate knowledge, 87.5% deliveries in the study tribal population were conducted in health care institutes and only 12.5% at home. This could be due to the gradual change in health seeking behaviour

among tribal women related to parenthood. Also lots of efforts are made by government and health centres to provide quality reproductive health services-including institutional delivery, safe abortions, treatment of RTIs, and family-planning services, to meet unmet needs while ensuring full reproductive choice to women.<sup>6</sup>

As for antenatal and postnatal check-ups only very few (25% and 36%) seek help from health care institutions. This is because various quasi-medical options are available for general and maternal and reproductive healthcare. Reasons for pursuing any of these options varied from trust to perception of quality, treatment, availability of resources, cost, and regularity of services.<sup>7</sup> Other than that, lack of financial assistance, poor health education are few reasons for very few going for ANC and postnatal check-ups. Though ASHA workers and other tribal health promoters provide with essential drugs and nutritive food, etc, still, only 86% availed these services. Lack of knowledge about such services and also there is lack of health workers for home visit.

76.5% tribal population get their infants immunized. Lack of knowledge about vaccine preventable diseases, financial constraints were the few reasons given by 23.5% who did not get their infants immunized. This is similar to findings from other studies.<sup>4,8</sup>

When treatment is sought, traditional medicines and healers still play an important role in maintaining health and well-being among the ethnic groups.<sup>7</sup> Traditional medicines and healers were preferred for treatment of both 'simple and complicated diseases' like cold, cough, fever, headache, poison bites, skin diseases and tooth infections was accessible.<sup>9</sup> There are studies that have mentioned the beliefs of some tribal population that cause of disease is none other than hostile spirits, ghosts, breach of some taboos, and curse of gods. Therefore, they seek remedies through religious and magical practices to propitiate the supernatural powers. They do not come to avail modern system of medicines and on the other hand, herbal medicine or indigenous medicines are their next preference of treatment which is obtained through local people.<sup>4, 10</sup> Though in the present study 52.9% of tribal population prefers allopathic treatment, still, 47.1% prefer traditional healers and

medicines. Factors affecting health seeking behaviour among tribal population included taking leave from their work(99%), long distance of health centres placed (98%), unavailability of doctors 24hrs (95%), long waiting time (92%), expensive treatment (92%) and unavailability of medicines in health centres (88%). 48% of the respondents were even unsatisfied with the treatment provided. Similar findings were observed in other studies too.<sup>9,11,12</sup>

29.4% of respondents were aware about snake anti-venom available and 70.6% were unaware about it, in the present study. This shows proper health education is required to make tribal population aware of snake anti-venom and also about various diseases. Very few though aware of snake anti-venom, most of the tribal population still go for methods like sucking blood to treat snake bite. A study among tribal of Rajasthan, where over 80% of snakebite, scorpion sting, and other poisoning cases were cared by faith healers.<sup>13</sup>

### Conclusion

The perception of sickness and health is intimately tied to the behaviour of seeking health among tribal population. The choice that a tribal person must make between modern systems, that are frequently portrayed by the media and often unfamiliar professionals as superior to the traditional ones and traditional practises and beliefs, that are loaded with socio-religious values, is the greatest dilemma in health seeking behaviour that a tribal person frequently faces. They are aware of the superiority of modern health services but are hesitant to employ them due to the potential time loss.

**Conflict of interest:** None

**Funding:** self

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# Anthropometric Assessment of Nutritional Status among Under-five Children Attending Government Immunization Centres in Bankura Municipality, West Bengal

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## Abstract

**Background:** Malnutrition, a major public health problem in India, is one of the major reasons behind under-five morbidities and mortality. The NFHS-5 data (2019-21) shows a significant prevalence of underweight, stunting and wasting at national, state and district levels. Identifying the problem and the reasons behind it can help us planning necessary actions for reducing the burden of malnutrition in days to come.

**Objectives:** To assess the nutritional status and to explore the different risk factors among under-five children attending government immunization centres in Bankura municipality, West Bengal

**Materials and methods:** A total of 163 under-five children were included in the study. After receiving informed consent from the accompanying person, they were interviewed and anthropometric measurements of the children, like height, weight, MUAC, were taken.

**Results:** The prevalence of underweight, stunting and wasting, were 22.1%, 15.9% and 27.6% respectively. Different factors associated with undernutrition included socioeconomic status, mother's employment status, maternal age at childbirth, type of delivery, child-feeding practices like colostrum feeding, time of initiation of complementary feeding.

**Conclusions:** A significant proportion of under-five children were found to be underweight, stunted or wasted. The majority of the associated factors identified were modifiable, and hence awareness generation in common people may reduce the burden of undernutrition in under-five population.

**Key-words:** Under-five, Malnutrition, Undernutrition, Underweight, Stunting, Wasting.

## Introduction

Throughout the lifespan of an individual, nutrition plays a vital role in multiple dimensions of life and

directly or indirectly influences various aspects of health, like - growth and development, optimal functioning of different systems in body, mental and physical capabilities of individual and resistance and

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susceptibility to different disease as well as outcomes in those conditions. There are various nutritional assessment techniques, e.g. anthropometric measurements, biochemical evaluation, clinical examination, dietary intake assessment etc. Among these techniques, anthropometric measurements are used most frequently for assessment of nutritional status among under-five children. Anthropometric measurements include weight, length or height, mid upper arm circumference (MUAC), head circumference (HC), chest circumference (CC) measurements etc.<sup>1</sup>

Malnutrition, especially among under-five children, is one of the major public health problems in India. According to National Family Health Survey-5 (NFHS-5) data, 32.1% under-five children were underweight, 35.5% were stunted and 19.3% were wasted in India.<sup>2</sup> NFHS-5 data for Bankura District in West Bengal revealed 38.8% under-five children were underweight, 30.3% were stunted, 26% were wasted and 8.3% were severely wasted in Bankura.<sup>3</sup>

There has been very limited data available regarding the different factors associated with the nutritional status of the under-five children in this part of the country in recent time. To bridge this knowledge gap, this study was conducted with objectives to assess the nutritional status and to explore different associated factors among under-five children attending the government immunization centres in Bankura municipality, West Bengal.

## Materials and Methods

An observational, descriptive, cross-sectional study was conducted among under-five children attending government immunization centres of Bankura town, West Bengal, India, during the months of October - December, 2022. The two immunization centres selected for our study were - immunization centre in Bankura Sannilani Medical College (BSMC) and immunization centre in Urban Family Welfare Centre (UFWC), Patpur, which is situated in the urban field practice area of BSMC. Data were collected on consecutive fifteen days excluding the Sundays and government holidays.

All under-five children attending the immunization centres to receive vaccination and whose guardian/ accompanying person gave the informed consent to participate in the study, were included as participants. Any child with acute or chronic illness at the time of data collection, and children attending the immunization centres but not receiving vaccination, were excluded from the study.

Sample size for the study was calculated using formula,  $n = Z^2PQ/L^2$ , where  $Z = 1.96$  for 95% confidence interval;  $P = 38.8\%$ , the prevalence of underweight among under-five children in Bankura district, as per NFHS-5 data<sup>3</sup>;  $Q = 100 - P$ ;  $L =$  allowable error of 8%. Considering 10% nonresponse rate among subjects, the minimum number of sample size was 159. Consecutive under-five children attending the two immunization centres were approached till the last allotted day of data collection, and a total of 163 under-five children were included in our study as participants.

At first, the purpose and procedure of the study were explained to the person accompanying the under-five children. After receiving written informed consents from the accompanying person, they were first interviewed using a pre-tested, pre-designed, interviewer administered structured questionnaire. Following this, the relevant anthropometric measurements of the children were taken following standard operating procedures. The different tools used for the study were: Salter weighing scale, Bathroom type weighing scale, Infantometer, Stadiometer, Shakir's tape. The height and weight measurements were used to assess the nutritional status of the children with the help of WHO Z-score growth charts (weight-for-age, length/height-for-age, weight-for-length/height).

The anthropometric measurements were assessed as follows:

Weight-for-age measurements were classified as obese ( $> +3$  Z score), overweight ( $+3$  to  $+2$  Z score), normal ( $+2$  to  $-2$  Z score), underweight ( $-2$  to  $-3$  Z score) and severely underweight ( $< -3$  Z score). Length/height-for-weight measurements were classified as tall ( $> +3$  Z score), normal ( $+3$  to  $-2$  Z score), stunting ( $-2$  to  $-3$  Z score), severe stunting ( $< -3$  Z score). And the weight-for-length/height measurements were

classified as obese ( $> +3$  Z score), overweight ( $+3$  to  $+2$  Z score), normal ( $+2$  to  $-2$  Z score), wasting ( $-2$  to  $-3$  Z score) and severe wasting ( $< -3$  Z score).<sup>4</sup> Mid-upper-arm circumference or MUAC measurements were classified as normal ( $\geq 12.5$  cm), moderate acute malnutrition or MAM ( $11.5 - 12.5$  cm) and severe acute malnutrition or SAM ( $< 11.5$  cm).<sup>5</sup> For the purpose of analysis, we further categorized the weight-for-age, length/height-for-age and weight-for-length/height variables into dichotomous variables:  $- 2$  Z score or above (denoting normal and over-nutrition) and below  $- 2$  Z score (denoting undernutrition).

The variables considered for our study could be classified as independent variables (sociodemographic, childbirth related and child feeding related) and dependent variables (anthropometric measurements including - weight, length/height, mid-upper-arm-circumference).

Data were entered in Microsoft Excel Spreadsheet and were checked for completion, duplication or validity. Categorical data were expressed in frequency and percentage. Chi-square test was done to assess the association of sociodemographic, childbirth related and child-feeding related variables with nutritional status among the subjects.

## Results

The sociodemographic profile of the study subjects revealed that almost half (48.5%) of the under-five children belonged to age group of 0-6 months. About 51.5% were girl children. Majority (96.3%) of the children were Hindu by religion. Most of the children resided in urban areas (61.9%) and belonged to joint families (72.4%). Mothers of 93.3% and fathers of 95.1% under-five children were literate. Mothers of 83.4% children were homemakers. About 53.4% children belonged to families with Class III, IV and V, according to BG Prasad's socioeconomic status (SES) scale, May 2022.<sup>6,7</sup>

It was found that mothers of 9.2% under-five children were teenage and 4.9% were 36 years or above at the time of childbirth. Almost 60.1% children were of first birth order and about 73.6% were delivered by caesarean section [Table-1]. All the deliveries were institutional, conducted by medical professionals (doctors or nurses).

Child-feeding practices [Table-2] revealed that pre-lacteal feeding was given to 8.6% under-five children. About 15.3% children were deprived of colostrum. Age-appropriate exclusive breastfeeding was not practiced in about a quarter of the children (25.8%). Complementary feeding was initiated either earlier or delayed in 5.9% and 45.3% under-five children, respectively.

The nutritional status of the under-five children, based on anthropometric assessments, were presented in Table-3. It was found that, according to WHO weight-for-age Z-score classification, 1.2% were obese, 0.6% were overweight, 76.1% were normal, 15.3% were underweight and 6.8% were severely underweight. The WHO length/height-for-age Z-score classification revealed 12.9% were tall, 71.2% were normal, 8.5% were stunted and 7.4% were severely stunted. Almost 1.8% were obese, 1.8% were overweight, 68.7% were normal, 8.6% were wasted and 19.0% were severely wasted, according to WHO weight-for-length/height Z-score classification. Only one under-five child had moderate acute malnutrition (MAM) according to MUAC measurement (hence, not considered for statistical analysis).

The proportion of underweight or severely underweight was significantly higher among children whose mothers were homemakers ( $P = 0.044$ ), who belonged to Class III, IV and V according to Modified B G Prasad's SES scale May 2022 ( $P = 0.029$ ), whose mothers were 19 years or less at the time of childbirth ( $P = 0.035$ ), who were born by normal vaginal delivery ( $P = 0.005$ ), who were deprived of colostrum ( $P = 0.019$ ) and those who had earlier initiation of complementary feeding ( $P = 0.025$ ) [Table-4]. No statistically significant association was found between stunting or severely stunting with various sociodemographic, birth related and child-feeding related factors [Table-5]. The proportion of wasted and severely wasted under-five children were significantly higher among age group of 0-6 months ( $P = 0.015$ ), whose mothers were employed ( $P = 0.032$ ), who were born by normal vaginal delivery ( $P = 0.041$ ) and those who had earlier initiation of complementary feeding (0.039) [Table-6].



**Table 1. Distribution of study subjects according to childbirth related factors (N = 163)**

Variables	Frequency (%)
<b>Maternal age at childbirth</b>	
≤ 19 years	15 (9.2)
20 – 25 years	63 (38.7)
26 – 30 years	52 (1.9)
31 – 35 years	25 (15.3)
≥ 36 years	8 (4.9)
<b>Birth order of child</b>	
1	98 (60.1)
2	56 (34.4)
≥ 3	9 (5.5)
<b>Birth spacing (from previous childbirth)*</b>	
1 – 2 years	7 (10.8)
2 – 3 years	5 (7.7)
≥ 3 years	53 (81.5)
<b>Type of delivery</b>	
Normal vaginal	43 (26.4)
Caesarean section	120 (73.6)

\* For children with birth order of 2 or above

**Table 2. Distribution of study subjects according to child-feeding related factors (N = 163)**

Variable	Frequency (%)
<b>Pre-lacteal feeding</b>	
Not Given	149 (91.4)
Given	14 (8.6)
<b>Colostrum feeding practice</b>	
Given	138 (84.7)
Not given	25 (15.3)
<b>Age-appropriate exclusive breastfeeding practice*</b>	
Done	121 (74.2)
Not done	42 (25.8)
<b>Onset of complementary feeding**</b>	
On time	41 (48.8)
Earlier	5 (5.9)
Delayed	38 (45.3)

\* Exclusive breastfeeding till date in children aged less than six months and exclusive breastfeeding till six completed months in children aged six months or above were considered as 'age-appropriate exclusive breastfeeding practice'.

\*\*For children aged six month or above

**Table 3. Distribution of study subjects according to nutritional status (N = 163)**

Nutritional status	Frequency (%)
<b>Weight-for-age classification:</b>	
Obese	2 (1.2)
Overweight	1 (0.6)
Normal	124 (76.1)
Underweight	25 (15.3)
Severely underweight	11 (6.8)
<b>Length/height-for-age classification:</b>	
Tall	21 (12.9)
Normal	116 (71.2)
Stunted	14 (8.5)
Severely stunted	12 (7.4)
<b>Weight-for-length/height classification:</b>	
Obese	3 (1.8)
Overweight	3 (1.8)
Normal	112 (68.8)
Wasted	14 (8.6)
Severely wasted	31 (19.0)
<b>Mid-upper-arm-circumference*:</b>	
Normal	83 (98.8)
Moderate Acute Malnutrition	1 (1.2)

\* for children aged six months or above

**Table 4. Association of different factors with nutritional status based on weight-for-age classification (N = 163)**

Variables	Weight-for-age		Test result	P value
	≥ - 2 Z score	< - 2 Z score		
<b>Gender</b>			$\chi^2 = 0.344$	0.558
Male	60 (75.9%)	19 (24.1%)	df = 1	
Female	67 (79.8%)	17 (20.2%)		
<b>Mother's occupation</b>			$\chi^2 = 4.052$	0.044
Homemaker	102 (75.0%)	34 (25.0%)	df = 1	
Employed	25 (92.6%)	2 (7.4%)		
<b>Socioeconomic status (BG Prasad's SES scale, May 2022)</b>			$\chi^2 = 4.795$	0.029
Class I and II	65 (85.5%)	11 (14.5%)	df = 1	
Class III, IV and V	62 (71.3%)	25 (28.7%)		
<b>Maternal age at childbirth</b>			$\chi^2 = 10.359$	0.035
≤ 19 years	7 (46.7%)	8 (53.3%)	df = 4	
20 - 25 years	49 (77.8%)	14 (22.2%)		
26 - 30 years	44 (84.6%)	8 (15.4%)		
31 - 35 years	20 (80.0%)	5 (20.0%)		
≥ 36 years	7 (87.5%)	1 (12.5%)		
<b>Birth order of child</b>			$\chi^2 = 1.880$	0.391
1	73 (74.5%)	25 (25.5%)	df = 2	
2	46 (82.1%)	10 (17.9%)		
≥ 3	8 (88.9%)	1 (11.1%)		
<b>Birth spacing (from previous childbirth)*</b>			$\chi^2 = 0.068$	0.966
1 - 2 years	6 (85.7%)	1 (14.3%)	df = 2	
2 - 3 years	4 (80.0)	1 (20.0%)		
≥ 3 years	44 (83.0)	9 (17.0%)		
<b>Type of delivery</b>			$\chi^2 = 7.763$	0.005
Normal vaginal	27 (62.8%)	16 (37.2%)	df = 1	
Caesarean section	100 (83.3%)	20 (16.7%)		
<b>Pre-lacteal feeding</b>			$\chi^2 = 0.542$	0.462
Done	12 (85.7%)	2 (14.3%)	df = 1	
Not done	115 (77.2%)	34 (22.8%)		

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<b>Colostrum feeding</b>			$\chi^2 = 5.507$	0.019
Done	112 (81.2%)	26 (18.8%)	df = 1	
Not done	15 (60.0%)	10 (40.0%)		
<b>Age-appropriate exclusive breastfeeding practice</b>			$\chi^2 = 0.098$	0.755
Done	95 (78.5%)	26 (21.5%)	df = 1	
Not done	32 (76.2%)	10 (23.8%)		
<b>Onset of complementary feeding**</b>			$\chi^2 = 7.371$	0.025
On time	36 (87.8%)	5 (12.2%)	df = 2	
Earlier	2 (40.0%)	3 (60.0%)		
Delayed	32 (84.2%)	6 (15.8%)		

\* For children with birth order of 2 or more. \*\* For children aged six months or above

**Table 5. Association of different factors with nutritional status based on length/height-for-age classification (N = 163)**

Variables	Length/height-for-age		Test result	P value
	≥ - 2 Z score	< - 2 Z score		
<b>Gender</b>			$\chi^2 = 1.054$	0.305
Male	64 (81.0%)	15 (19.0%)	df = 1	
Female	73 (86.9%)	11 (13.1%)		
<b>Mother's occupation</b>			$\chi^2 = 0.565$	0.452
Homemaker	113 (83.1%)	23 (16.9%)	df = 1	
Employed	24 (88.9%)	3 (11.1%)		
<b>Socioeconomic status (BG Prasad's SES scale, May 2022)</b>			$\chi^2 = 1.793$	0.181
Class I and II	67 (88.2%)	9 (11.8%)	df = 1	
Class III, IV and V	70 (80.5%)	17 (19.5%)		
<b>Maternal age at childbirth</b>			$\chi^2 = 8.100$	0.088
≤ 19 years	9 (60.0%)	6 (40.0%)	df = 4	
20 - 25 years	55 (87.3%)	8 (12.7%)		
26 - 30 years	46 (88.5%)	6 (11.5%)		
31 - 35 years	20 (80.0%)	5 (20.0%)		
≥ 36 years	7 (87.5%)	1 (12.5%)		

Continue.....

<b>Birth order of child</b>			$\chi^2 = 5.591$	0.061
1	77 (78.6%)	21 (21.4%)	df = 2	
2	52 (92.9%)	4 (7.1%)		
≥ 3	8 (88.9%)	1 (11.1%)		
<b>Birth spacing (from previous childbirth)*</b>			$\chi^2 = 0.847$	0.655
1 - 2 years	6 (85.7%)	1 (14.3%)	df = 2	
2 - 3 years	5 (100.0%)	0 (0.0%)		
≥ 3 years	49 (92.5%)	4 (7.5%)		
<b>Type of delivery</b>			$\chi^2 = 307$	0.580
Normal vaginal	35 (81.4%)	8 (18.6%)	df = 1	
Caesarean section	102 (85.0%)	18 (15.0%)		
<b>Pre-lacteal feeding</b>			$\chi^2 = 0.886$	0.346
Not Done	124 (83.2%)	25 (16.8%)	df = 1	
Done	13 (92.9%)	1 (7.1%)		
<b>Colostrum feeding</b>			$\chi^2 = 1.427$	0.232
Done	118 (85.5%)	20 (14.5%)	df = 1	
Not done	19 (76.0%)	6 (24.0%)		
<b>Age-appropriate exclusive breastfeeding practice</b>			$\chi^2 = 0.117$	0.732
Done	101 (83.5%)	20 (16.5%)	df = 1	
Not done	36 (85.7%)	6 (14.3%)		
<b>Onset of complementary feeding*</b>			$\chi^2 = 1.510$	0.470
On time	36 (87.8%)	5 (12.2%)	df = 2	
Earlier	5 (100.0%)	0 (0.0%)		
Delayed	31 (81.6%)	7 (18.4%)		

\* For children with birth order of 2 or more. \*\* For children aged six months or above

**Table 6. Association of different factors with nutritional status based on weight-for-length/height classification (N = 163)**

Variables	Weight-for-length/height		Test result	P value
	≥ - 2 Z score	< - 2 Z score		
<b>Age group</b>			$\chi^2 = 8.354$	0.015
0 - 6 months	49 (62.0%)	30 (38.0%)	df = 2	
6 - 12 months	33 (80.5%)	8 (19.5%)		
12 - 60 months	36 (83.7%)	7 (16.3%)		

Continue.....

<b>Gender</b>			$\chi^2 = 0.174$	0.676
Male	56 (70.9%)	23 (29.1%)	df = 1	
Female	62 (73.8%)	22 (26.2%)		
<b>Mother's occupation</b>			$\chi^2 = 4.590$	0.032
Homemaker	103 (75.7%)	33 (24.3%)	df = 1	
Employed	15 (55.6%)	12 (44.4%)		
<b>Socioeconomic status (BG Prasad's SES scale, May 2022)</b>			$\chi^2 = 0.128$	0.721
Class I and II	54 (71.1%)	22 (28.9%)	df = 1	
Class III, IV and V	64 (73.6%)	23 (26.4%)		
<b>Maternal age at childbirth</b>			$\chi^2 = 3.590$	0.464
≤ 19 years	10 (66.7%)	5 (33.3%)	df = 4	
20 - 25 years	46 (73.0%)	17 (27.0%)		
26 - 30 years	41 (78.8%)	11 (21.2%)		
31 - 35 years	17 (68.0%)	8 (32.0%)		
≥ 36 years	4 (50.0%)	4 (50.0%)		
<b>Birth order of child</b>			$\chi^2 = 0.575$	0.750
1	73 (74.5%)	25 (25.5%)	df = 2	
2	39 (69.6%)	17 (30.4%)		
≥ 3	6 (66.7%)	3 (33.3%)		
<b>Birth spacing (from previous childbirth)*</b>			$\chi^2 = 1.135$	0.567
1 - 2 years	6 (85.7%)	1 (14.3%)	df = 2	
2 - 3 years	3 (60.0%)	2 (40.0%)		
≥ 3 years	36 (67.9%)	17 (32.1%)		
<b>Type of delivery</b>			$\chi^2 = 4.158$	0.041
Normal vaginal	26 (60.5%)	17 (39.5%)	df = 1	
Caesarean section	92 (76.7%)	28 (23.3%)		
<b>Pre-lacteal feeding</b>			$\chi^2 = 0.293$	0.589
Not Done	107 (71.8%)	42 (28.2%)	df = 1	
Done	11 (78.6%)	3 (21.4%)		
<b>Colostrum feeding</b>			$\chi^2 = 0.285$	0.593
Done	101 (73.2%)	37 (26.8%)	df = 1	
Not done	17 (68.0%)	8 (32.0%)		

Continue.....

<b>Age-appropriate exclusive breastfeeding practice</b>			$\chi^2 = 0.928$	0.335
Done	90 (74.4%)	31 (25.6%)	df = 1	
Not done	28 (66.7%)	14 (33.3%)		
<b>Onset of complementary feeding*</b>			$\chi^2 = 6.455$	0.039
On time	35 (85.4%)	6 (14.6%)	df = 2	
Earlier	2 (40.0%)	3 (60.0%)		
Delayed	32 (84.2%)	6 (15.8%)		

\* For children with birth order of 2 or more. \*\* For children aged six months or above

## Discussion

**Under-five nutritional status:** the prevalence of underweight, stunting and wasting, as found in our study, were 22.1%, 15.9% and 27.6% respectively. These findings were similar to another study, conducted in Assam, India, where the prevalence of under-five underweight, stunting and wasting were 25.1%, 18.3% and 24.8% respectively.<sup>8</sup> In another study in West Bengal, the prevalence of stunting was 14.1%, which was close to the finding of our study.<sup>9</sup> The prevalence of wasting in our study was also close to the prevalence of 26.4% that was observed in a study conducted in Tamil Nadu, India.<sup>10</sup> Many other studies have reported varying degree underweight (9.7% – 35.4%), stunting (31.5% – 62%) and wasting (6.4% – 31%).<sup>11-15</sup>

**Underweight and risk factors:** studies by Khobragade AW and Kumar LD also observed significant association between underweight and low SES.<sup>11,13</sup> These findings have similar resemblance to our study. Studies by Das M in India, Wemakor in Ghana concluded higher proportion of underweight among mothers aged 18 years or less at the time of childbirth. Low maternal age at childbirth was also found to be associated in our study.<sup>16,17</sup> Child-feeding practices are known to influence the nutritional status of under-five children. Our study found that underweight was more common among children who were deprived of colostrum and those who had earlier initiation of complementary feeding. Proportion of underweight was significantly higher among children not receiving colostrum, as found in studies by Kumar D in India, Liben ML in Ethiopia.<sup>18,19</sup> Early

initiation of complementary feeding was also found to have association with underweight, as found in studies by Kumar D, Masuke et al.<sup>18,20</sup>

**Stunting and risk factors:** different studies all over the world had observed association of stunting with different factors like religion, maternal education, mother's age, maternal at childbirth, EBF and colostrum feeding practices etc.<sup>9,10,11,14,16,18,19</sup> In our study, proportion of stunting was higher among children who were Hindu, having mothers 19 years or less at the time of childbirth, 1-2 years of birth spacing, colostrum feeding not being done, although these findings were not statistically significant.

**Wasting and risk factors:** lower age of the child was found to have association with wasting, as revealed in studies by Das M, Pradhan MR.<sup>16, 21</sup> Our study also showed similar finding where the proportion of wasting was higher in age children less than 6 months. The study by Kumar D showed 1.5 times higher chance of wasting in children who did not have proper complementary feeding.<sup>18</sup> Another study by Masuke R revealed higher wasting among children with earlier initiation of complementary feeding.<sup>20</sup> This finding was similar to ours, where children having earlier initiation of complementary feeding had higher proportion of wasting. A study in Ethiopia revealed 0.99 times more risk of wasting in children born by caesarean section, although the finding was not statistically significant.<sup>22</sup> Wasting was higher in proportion among children born by normal delivery, as we found in this study, and the result was similar to that of the Ethiopian study. Certain studies concluded that children born of unemployed mothers

had higher risk of wasting, owing to the economic advantage due to employment.<sup>23</sup> On the contrary, our study revealed higher proportion of wasting among children, born of employed mothers. This can possibly be explained by the fact, that unemployed mothers, especially the homemakers, can devote a major portion of their time in caring for and ensuring adequate nutrition of the under-five children.

### Conclusion

A significant proportion of underweight, stunting and wasting were observed in our study, reaffirming the problem of undernutrition among the under-five children in our country. Many factors like socioeconomic status, maternal age at childbirth, child-feeding practices (colostrum feeding, EBF practice, timing of complementary feeding initiation) were identified, which are mostly modifiable. Hence, there is always scope for awareness generation in the community regarding optimum timing for marriage and childbirth, child-feeding practices etc.

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# Development and Application of Critical-Thinking and Decision-Making Skills' Enhancement Module among School-Going Adolescents in Manipur: A Quasi-Experimental Study

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## Abstract

**Background:** Life skills aid as a principal catalyst to promote healthy adolescent development by preventing key causes of death. Building critical-thinking and decision-making skills lays the foundation stone for unfolding all other essential life skills.

**Objectives:** To evaluate effectiveness of an educational intervention module on critical-thinking and decision-making skills of school-going adolescents in Imphal West district, Manipur.

**Methods:** Quasi-experimental study was conducted in co-educational state board schools of Imphal West district of Manipur among classes IX and XI from December,2020 to October,2022 with 210 students in intervention and 206 in control school. Structured questionnaire was self-administered at three time points. Health education module devised by researchers, comprised of four sessions given at three weeks interval to intervention school. Chi-square test, Independent sample-t-test and ANOVA were applied for analysis.

**Results:** Critical-thinking skills {Wilks's Lambda=0.061,F(2,208)=1602.82,p<0.001,  $\eta^2=0.94$ } and decision-making skills {Wilk's Lambda=0.11,F(2,208)=831.84,p<0.001,  $\eta^2=0.89$ } of the experimental group improved significantly across the three time points but not for the control group. Between the group comparison indicated that mean change in scores for both the skills was significantly greater for experimental group (p<0.001) when compared to control. Life skills intervention module had a large effect size for both the skills at both the post-tests

**Conclusion:** This study affirmed the effectiveness of the educational intervention with significant improvement in both skills for experimental school immediately after the intervention which was sustained till the third month.

**Keywords:** Critical-thinking skills, Decision-making skills, Life skills education

## Introduction

WHO describes adolescence as phase

transitioning amidst childhood and adulthood, aged 10-19 years, a critical stage for laying the foundations of good health throughout the life course.<sup>[1]</sup>

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Globally, ~1.5 million, aged 10-24 years died in 2019.<sup>[2]</sup> Probability of dying among youths in India was 6 per 1000 in 2020.<sup>[3]</sup> Being equivalent to 17.74% of the world population, India has world's highest number of 10-24-year-olds. In 2011, Manipur accounted for 0.24% of total adolescent population of India. India is experiencing demographic window of opportunity, a "youth-bulge" that will last till 2025.<sup>[4]</sup> Early and accelerated investment is needed to capitalize this advantage.

Admiration for greater autonomy, burden to conform with peers, expanded avenues of technology, socio-economic characteristics, engagement in experimental activities, psychological frailty in tackling conflicts and apprehension about future are host of factors making them susceptible to preventable risk-taking behaviours.

Life skills education based on participatory learning methods, is an indispensable vehicle in gearing up young people to mediate above risks. WHO defines life skills as the ability for adaptive and positive behavior that enable individuals to deal effectively with demands and challenges of everyday life.<sup>[5]</sup> Interventional studies conducted across India and globally have presented significance of varied life skill educational programs in overall enrichment of life skills,<sup>[6-15]</sup> improved academic achievement at schools,<sup>[16-18]</sup> and reductions in high-risk health behaviors like substance abuse, violence, insecure sexual behaviour, conduct problems, peer problems, suicidal expressions and improvements in prosocial behaviors, mental health and general self-efficacy.<sup>[19,20]</sup>

WHO enlists ten life skills. Critical-thinking skill is an ability to analyze information and experiences in an objective manner, helping them to appraise the factors that influence behavior. Decision-making skill is the potentiality to define a problem, think of the alternatives, identify consequences for each alternative, select one, and finally evaluate the decisions made.<sup>[5]</sup> Life skills education module encompassing these two skills as the prime ingredients will serve as a value-added primordial prevention program for the youth, moulding their way for development of supplementary life skills.

Role of schools in identity establishment, access to adolescents on a large scale, feasibility of encouraging environment, experienced teachers already in place, high credibility with parents, possibilities for long-term evaluation are some of the reasons why schools are deserved place for the commencement of life skills education.

Life skills enhancement module focussing on critical-thinking and decision-making skills will enable the acquisition of critical reflection on health-related issues, giving reflective access to the other two areas: communication-interpersonal skills and coping-self management skills. Hardly any known studies have been conducted in schools of Manipur in this regard. It is thus a need of the hour to determine their baseline skills and further appraise the impact of an interactive and engaging educational intervention module.

## Materials and Methods

**Objective:** To evaluate the effectiveness of an educational intervention module on critical-thinking and decision-making skills of school going adolescents in Imphal West district, Manipur. Quasi-experimental study was conducted from December,2020 to October,2022. Students of co-educational, state board schools having both classes IX and XI were included and those who were absent on the day of data collection were excluded.

**Sample size:** Taking mean change score for decision-making skills as  $0.05 \pm 0.35$  for experimental and  $-0.09 \pm 0.35$  for control group from study by Shukla et al, significance of 0.05, power of 85%, design-effect of 1.5 and non-response rate of 20%, minimum sample size was calculated as 202 for each group.<sup>[13]</sup>

**Sampling:** Of 617 schools of Imphal West district, 336 schools are co-educational, of which 28 have both IX and XI. Of these, twenty schools were under Manipur board. One school each was allocated to intervention and control group using purposive sampling such that the distance between them was  $\geq 5$  km. Grades IX and XI had two sections each in both the schools with average student strength of 55. Total eligible participants were 220. To reach the sample size of 202 in each group, both sections of both grades were included.

**Study tool:** Structured and pre-tested questionnaire was used to collect data. Critical-thinking and decision-making skills were assessed using the study tool developed by Claudia Mincemoyer and Daniel Perkins (2001) after taking due permission over email. Critical-thinking scale with reliability of 0.72 had 20 items based on five-point Likert scale (minimum: 20, maximum:100). Decision-making scale with reliability of 0.63-0.89 had five items based on four-point Likert scale (minimum:0, maximum:15). Higher scores indicated greater skills.

**Intervention:** Health education plan comprised of four sessions starting from the acquaintance with topic using slides, further elaboration of "how to think critically and decide" using pamphlets, case scenarios and role-plays followed by "importance of choices made in life" using short videos and group discussions, ending with quiz program on "adolescent risk-taking behaviours" and pledge singing in last session. Sessions were conducted in class rooms, 45 mins per session. Face and content validity of the intervention module was scrutinized by the experts.

**Data collection:** In Session I, questionnaire was self-administered to the students in both groups for pre-testing followed by life skills education initiation in intervention school. There was a gap of three weeks between subsequent sessions. Entire intervention was completed in nine weeks. There was no intervention or continuous reinforcement given to control group. Post-test I was held nine weeks after pre-test in the last session (Session IV) itself and post-test II was done three months after the post-test I for both the schools. After second post-test, the intervention materials were distributed in control school followed by briefing.

**Data analysis:** After checking for completeness and consistency, data were entered in IBM SPSS-26 and summarized using descriptive statistics. Distribution of data was assessed using Kolmogorov-Smirnov test. Chi-square for categorical and Independent sample-t-test for continuous variables were used to assess comparability between two groups. Repeated-measure ANOVA with post-hoc Bonferroni correction was used to assess mean change within the group across three timepoints. Effect size of the intervention

was assessed using Cohen's d. P value of <0.05 was considered as statistically significant.

**Ethical issues:** Ethical approval was obtained from the Research Ethics Board, (No.A/206/REB-Comm(SP)/RIMS/2015/538/16/2019). Study was registered prospectively in Clinical Trial Registry of India (CTRI/2021/01/030274). Informed written consent from school principal, informed verbal consent from parents and assent from the students were obtained. Their roll numbers were taken as the unique code to ensure confidentiality.

## Results

In the intervention and control school, six and eight students were respectively absent on the days of data collection. Study participants included in the analysis in intervention and control school were 210 and 206 respectively. The intended sample size was retained. Both the groups were comparable in terms of variables of interest ( $p>0.05$ ) as highlighted in Table 1.

**Critical-thinking skills** of the experimental group differed significantly across the three time points {Wilks's  $\Lambda=0.061, F(2,208)=1602.82, p<0.001, \eta^2=0.94$ }. Post-hoc, scores at post-test I ( $73.48\pm 6.34$ ) and post-test II ( $74.30\pm 6.16$ ) were significantly higher when compared with pre-test score ( $44.92\pm 5.19$ ) as shown in Table 2. Control group did not differ significantly across the three time points {Wilks's  $\Lambda=0.976, F(2,204)=2.53, p=0.082, \eta^2=0.024$ }.

**Decision-making skills** of experimental group differed significantly across the three time points {Wilks's  $\Lambda=0.11, F(2,208)=831.84, p<0.001, \eta^2=0.89$ }. Post hoc, scores at post-test I ( $4.22\pm 1.93$ ) and post-test II ( $11.16\pm 1.73$ ) were significantly higher when compared with pre-test score ( $11.24\pm 1.72$ ) as is shown in Table 2. Control group did not differ significantly across the three time points (Wilks's  $\Lambda=0.961, F(2,204)=4.187, p=0.077, \eta^2=0.039$ ).

There was no significant difference between the two groups at baseline for critical-thinking ( $p=0.453$ ) or for decision-making skills ( $p=0.278$ ). Table 3 indicates that mean change in scores of critical-thinking ( $28.56\pm 7.48, p<0.001$ ) and decision-making skills ( $6.94\pm 2.48, p<0.001$ ) was significantly higher for experimental group at Post-test I when compared

to control group. The influence of intervention on the experimental group was maintained uptill Post-Test II as compared to control group.

There was significant difference between the two groups in terms of self-perceived class performance assessment in latest test/ exam at Post-Test II ( $p < 0.001$ ). Greater proportion of students in the experimental group assessed their performance in

class test as 'good' (43.3%), 'very good' (26.7%) or 'excellent' (11.4%) when compared to control group (37.9%, 13.6% and 2.9% respectively).

Intervention module had a large effect size of 4.74 at post-test I and 4.89 at post-test II for critical-thinking skills and 3.69 at post-test I and 3.72 at post-test II for decision-making skills.

**Table 1: Comparison of background characteristics between groups (N=416)**

Characteristics	Experimental Group (N=210)	Control Group (N=206)	p-value
	n (%)	n (%)	
Age (years)(Mean±SD)	15.52 ± 1.73	15.59 ± 1.80	0.693*
<b>Gender</b>			
Male	106 (50.5)	98 (47.6)	0.554†
Female	104 (49.5)	108 (52.4)	
<b>Grade</b>			
IX	103 (49.0)	97 (47.1)	0.689†
XI	107 (51.0)	109 (52.9)	
<b>Address</b>			
Urban	127 (60.5)	126 (61.2)	0.886†
Rural	83 (39.5)	80 (38.8)	
<b>Family Type</b>			
Nuclear	117 (55.7)	124 (60.2)	0.355†
Joint	93 (44.3)	82 (39.8)	
<b>No. of Siblings</b>			
<2	57 (27.2)	64 (31.1)	0.352†
2	61 (29.0)	66 (32.0)	
>2	92 (43.8)	76 (36.9)	
<b>Birth Order</b>			
1	66 (31.4)	65(31.6)	0.912†
2	69 (32.9)	64 (31.0)	
>2	75 (35.7)	77 (37.4)	
<b>Father's Educational Status</b>			
Illiterate	15 (7.1)	18 (8.7)	0.745†
Primary school	21 (10.0)	28 (13.6)	
High School	94 (44.8)	88 (42.7)	
Higher Secondary School	42 (20.0)	36 (17.5)	
≥Graduate	38 (18.1)	36 (17.5)	
<b>Mother's Educational Status</b>			
Illiterate	22 (10.5)	28 (13.6)	0.698†
Primary school	29 (13.8)	35 (17.0)	
High School	86 (41.0)	80 (38.8)	
Higher Secondary School	40 (19.0)	34 (16.5)	
≥Graduate	33 (15.7)	29 (14.1)	

<b>Father's Occupation</b>			
Employed	153 (72.9)	151 (73.3)	0.919 <sup>†</sup>
Unemployed	57 (27.1)	55 (26.7)	
<b>Mother's Occupation</b>			
Employed	92 (43.8)	109 (52.9)	0.063 <sup>†</sup>
Unemployed	118 (56.2)	97 (47.1)	
<b>Self-perceived grading of class performance in latest test</b>			
Excellent	8 (3.8)	7 (3.4)	0.523 <sup>†</sup>
Very Good	30 (14.3)	27 (13.1)	
Good	81 (38.6)	72 (35.0)	
Fair	63 (30.0)	57 (27.7)	
Bad	20 (9.5)	31 (15.0)	
Very Bad	8 (3.8)	12 (5.8)	

\*Independent sample-t-test

†Chi-square test

**Table 2. Comparison of skills at three time points for experimental group (N=210)**

Timepoint		Mean Difference (A-B)	P-value*
A	B		
Critical-thinking			
Pre-Test	Post-Test I	-28.56	<0.001
	Post-Test II	-29.38	<0.001
Post-Test I	Pre-Test	28.56	<0.001
	Post-Test II	-0.81	<0.001
Post-Test II	Pre-Test	29.38	<0.001
	Post-Test I	0.81	<0.001
Decision-making			
Pre-Test	Post-Test I	-6.94	<0.001
	Post-Test II	-7.02	<0.001
Post-Test I	Pre-Test	6.94	<0.001
	Post-Test II	-0.08	0.004
Post-Test II	Pre-Test	7.02	<0.001
	Post-Test I	0.08	0.004

\* Repeated-measure ANOVA using Bonferroni correction

**Table 3. Between group comparison of mean change in scores (N=416)**

Timepoint	Experimental Group (n=210) (mean±sd)	Control Group (n=206) (mean±sd)	P-value*
Critical-thinking			
Post-test I-Baseline	28.56±7.48	0.40±3.82	<0.001
Post-test II-Baseline	29.38±7.50	0.30±3.78	<0.001
Decision-making			
Post-test I-Baseline	6.94±2.48	0.11±0.84	<0.001
Post-test II-Baseline	7.02±2.49	0.07±0.89	<0.001

\*Independent sample-t-test

## Discussion

In this study, both skills of experimental group improved significantly after the intervention. Pathania et al and Joseph et al perceived significant improvement in scores after intervention.<sup>[10,11]</sup> In 2020, Kannada district displayed significant betterment in critical-thinking by 5.3 and decision-making skills by 1.1.<sup>[7]</sup> Other studies explored coinciding outcomes.<sup>[8,14,15,19,21,22]</sup> Contrarily, Sangma et al in Meghalaya, found improvement ( $p=0.015$ ) in critical-thinking but not in decision-making skills ( $p=0.598$ ).<sup>[6]</sup> Variation in study population, intervention program, study tools and the time context might explain this dissemblance.

Experimental group of this study had significantly higher skills in post-test I compared to control group. Mansuri in her study at South Mumbai ( $p<0.001$ ), Vashishtha et al in Agra city and Parvathy V et al in Kerala ( $p<0.05$ ) examined coinciding results.<sup>[13,15,23]</sup> Further, both skills were still significantly higher three months after the post-test I in intervention school in this study. This can be backed by findings of Joseph et al and Daisy et al, where both the skills were significantly higher one month after the intervention.<sup>[12,17]</sup> Follow-up at six months after post-test I still showed significant improvement in the study by Ahuja et al.<sup>[16]</sup> This suggests combination of participatory and experiential learning techniques like brain-storming, skit, case scenarios, video presentations, quiz, debates, group discussions etc helps in enhancement, inculcation and retention of life skills.

After intervention, self-perceived class performance significantly differed between the two groups in this study ( $p<0.001$ ) implying affirmative impact of the module on academic achievements. Daisy et al recognized that life skills intervention had developed the study skills thereby impacting positively on the academic performance.<sup>[17]</sup> Likewise, Srikala et al found that students receiving life-skills education in Bangalore were significantly better adjusted to schools and teachers ( $p<0.001$ ) even at the end of one year.<sup>[22]</sup> This emphasizes the need to institutionalize school mental health program using life skills approach.

Strengths and limitations: Amalgamation of innovative learning techniques, use of validated

questionnaire and large effect size of the intervention were some of the strengths. COVID-19 pandemic during the timeframe ensuing in school closure served as hindrance. Out-of-school or drop-out children were not addressed. Self-administering the questionnaire might have given rise to social desirability bias.

Conclusion: Study affirmed the effectiveness of the self-designed educational intervention module. Orientation programs sensitizing parents and teachers who are responsible to equip adolescents with permissive circumstances at homes and schools is a prerequisite at this moment.

**Conflict of interest:** Nil

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## Assessment of Water, Sanitation and Hygiene (WASH) in Schools of Jammu District- A Cross Sectional Study

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### Abstract

**Background:** Provision of safe sanitation services reduces transmission of feccoral diseases, school drop outs, under-nutrition which in turn are important for overall development of children. The study was conducted to evaluate the adequacy of water, sanitation and hygiene (WASH) facilities in schools of rural Jammu.

**Methodology:** A Cross Sectional survey was conducted in 54 (public and private) schools in rural Jammu using the questionnaire approved by the Global Task Team for Monitoring WASH in Schools.

**Results:** Piped water was the main source of water supply. Facilities for drinking water were available in all schools. 94.3% schools had 1-9 drinking water points. All schools were doing filtration/chlorination of water. 51% schools reported water and soap availability in girl's toilets and group hand washing activities were conducted once a week in 31.5% schools. Toilets were cleaned once per day in 80% of the schools. 88% schools had toilets within school premises. Menstrual hygiene materials were available in 42 schools.

**Conclusions:** Environment and sanitation facilities at most of the surveyed schools were reasonably good but not fully satisfactory.

**Key-words:** WASH, Sanitation, Indicators, School, Assessment

### Introduction

Sanitation is not only about hygiene and illness, but also about individual and social dignity. Of the 6 Health related MDGs, Goal 7 is related to environmental sustainability focusing on sustainable access to improved water sources and improved sanitation.<sup>1</sup> In light of the strong interaction between sanitation and health, and of insufficient progress towards improving sanitation, 2008 was declared the International Year of Sanitation.<sup>2</sup> The impact

of deficient sanitation on health, education and economic development is profound. In 2015, United Nations General Assembly agreed to adopt the 2030 memorandum for sustainable development. However, even after seven years into SDG there is no remarkable achievement into SDG targets 6.1 and 6.2 (Access to safely managed drinking water source and Access to safely managed sanitation).<sup>3</sup>

The centrality of sanitation to development though widely acknowledged appears to be a distant

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reality given the fact that in 2020, 3.6 billion people lacked access to basic sanitation services. Two third of Population resides in rural areas and half in sub-Saharan Africa still lack even basic services.<sup>4</sup> Other challenge is urbanization, it is estimated that 57% of urban dwellers lack access to toilets that provide full sanitation, 16% lack access to basic sanitation services, and almost 100 million urban residents practice open defecation.<sup>5</sup>

India being the second most populous country in the world is faced with the challenge to provide safe water and sanitation facilities to its countrymen. It is encouraging to note that as per National Family Health Survey - 4, in India 91% of urban households and 89% of rural households have access to an improved source of drinking water. Half of Indian households (48%) use improved toilet facilities. Although the number of households practicing open defecation was 55 percent during NHFS-3 survey, it reduced to 39 percent during NFHS-4. The percentage of households with improved sanitation facilities has increased in almost all the states and union territories over the last four years from 2015-2016 (NFHS-4) to 2019-2020 (NFHS-5).<sup>6</sup>

The Government of India is committed to provide sanitation facilities to each and every child of the country and to achieve this many Total Sanitation Campaign (TSC) introduced in 1999 to expand sanitation coverage throughout the country with more focus on rural areas. School Sanitation Hygiene Education (SSHE) has been given due importance in TSC with toilet coverage in every school for two main reasons one is increase in school attendance by reducing security concerns for girls and other one is to improve health outcomes through reduction in diseases.<sup>7</sup> Similarly Swachh Bharat Swachh Vidyalaya is again an effort of the government to guarantee that all Indian schools have fully functional and well maintained water, sanitation and hygiene facilities.<sup>8</sup>

Parsing through the published literature revealed that very few researchers have studied WASH in rural schools both in India and globally. Against this background, the present study was conceptualized to comprehend the ground realities as far as school environment and sanitation is concerned by

evaluating the adequacy of WASH facilities at school level.

## Methodology

The present descriptive, cross-sectional study was carried in the rural field practice area of the Department of Community Medicine, Government Medical College Jammu after obtaining ethical clearance from Institutional Ethical Committee of Government Medical College, Jammu vide letter no. IEC/GMC/Cat C/ 2020/195 Dated 31-08-2020. A list of all government and private schools in R. S Pura area in Jammu district was obtained. Fifty -four schools were selected from the list by systematic random sampling. Heads of the chosen schools were contacted and were informed about the purpose of the study. They were guaranteed that a total confidentiality of data shall be maintained. Their informed consent was taken. A group of students undergoing training for sanitary health inspectors in the department of Community Medicine were guided to collect data for the study. They collected data during school working hours. A pre tested close ended questionnaire was used to for monitoring WASH in the selected schools.<sup>9</sup> The questionnaire used in the present study was approved by the Global Task Team for Monitoring WASH in Schools in the SDGs, convened by the Joint Monitoring Programme for Water and Sanitation (JMP). The questionnaire consists of core questions which are the minimum needed to monitor WASH in schools as part of the SDGs and a set of expanded questions to support harmonised monitoring of WASH in schools as part of the SDGs. Information on parameters was collected from Head of the school/ Deputy/ or in their absence, any senior teacher, teacher on duty or any other teacher who was deputed for the purpose by the Head. Direct observation of the water, sanitation and hygiene facilities was also carried out by the investigators using a defined checklist.

## Results:

Out of the 54 schools that were surveyed, majority were co-educational and a little less than half of the surveyed schools were higher secondary and one third of the surveyed schools were Government schools.

**Table1: Core Drinking Water, Sanitation and Hygiene (WASH) questions in surveyed schools:**

QUESTIONS	Number (n=54)	Percentage (%)
<b>Water:</b>		
1. What is the main source of drinking water provided by the school?	54	100
Piped water Supply		
Well/ spring, Rainwater, Bottled water, Tanker-truck, Lake/River/Stream or No water source	0	0
2. Is drinking water from the main source currently available at the school		
Yes	54	100
<b>Sanitation:</b>		
1. What type of student toilets/latrines are at the school?		
Flush / Pour-flush toilets	54	100
Pit latrines with slab, Composting toilets, Pit latrines without slab, Hanging latrines, Bucket latrines, No toilets or latrines	0	0
2. How many students Toilet/ Latrines are currently usable		
1-3	14	26.0
3-5	10	18.5
>5	20	37.0
3 (a) Are the toilets/latrines separate for girls and boys?		
(b) How many Toilet/ Latrines are at the School		
Girls only	30	55.6
Boys only	22	40.7
Common use	2	3.7
<b>Hygiene Questions</b>		
1. Are there hand washing facilities at the school?		
Yes	54	100
2. Are both soap and water currently available at the hand washing facilities?		
Yes Water and Soap	28	51.8
Water only	26	48.2

Piped water was the main source of water supply in all the schools. Half of the facilities had both soap and water for hand washing. None of the school was

without availability of water for hand washing (Table 1).

**Table 2 a: Expanded Drinking Water questions:**

QUESTIONS	Number (n=54)	Percentage (%)
<b>AVAILABILITY</b>		
1. In the previous two weeks was drinking water from the main source available at the school throughout each school day		
Yes	54	100
2. Is drinking water from the main source typically available throughout the school year		
Yes (always)	54	100
Mostly (Unavailable < 30 days total)	0	0
No (Unavailable)	0	0
<b>ACCESSIBILITY</b>		
3. Is drinking water accessible to those with limited mobility or vision		
Yes	53	98.1
No	1	1.9
4. Is drinking water accessible to the smallest children at the school		
Yes	50	92.6
No	4	7.4
5. How many drinking water points (e.g. taps) are at the school		
1 -9	51	94.3
10-19	3	5.7
<b>QUALITY</b>		
6.(a) Does the school do anything to the water from the main source to make it safe to drink		
Yes	54	100
6.(b) if yes, what treatment method is used		
Filtration	39	72.2
Chlorination	15	27.8
Boiling, Solar water Disinfection, Ultraviolet disinfection, Others	0	0

Drinking water facilities were adequate in most of the schools (Table 2a)

**Table 2b: Expanded Sanitation Questions:**

Questions	Number (n)	Percentage (%)
<b>ACCEPTABILITY</b>		
1. Are water and soap available in a private space for girls to manage menstrual hygiene		
Yes, water and soap	28	51.8
Water, but not soap	26	48.2

Continue.....

2. Are there covered bins for disposal of menstrual hygiene material in girl's toilets		
Yes	45	83.3
No	9	16.7
3. Are there disposal mechanisms for menstrual hygiene waste at the school		
Yes	39	72.2
No	15	27.3
4. How many times per week are the student toilets cleaned		
at least once per day	44	81.5
2-4 days /week	10	18.5
once per week, less than once per week	0	0
5. In general, how clean are the student toilets		
Clean	44	81.5
Somewhat clean	10	18.5
<b>ACCESSIBILITY</b>		
6. Is there at least one usable toilet / latrine that is accessible to the smallest children at the school		
Yes	51	94.4
No	3	5.6
7. Is there at least one usable toilet/latrine that is accessible to those with limited mobility or vision		
Yes	51	94.4
No	3	5.6
8. Where are the student's toilets located		
Within school building	48	88.9
Outside building, but on premises	6	11.1
Off premises	0	0
<b>AVAILABILITY</b>		
9. When are students permitted to use the school toilets / latrines		
At all times during the school day	54	100
During specific times during the school days,	0	0
There are no toilets available for use at the school	0	0
<b>QUALITY</b>		
10. Are culturally appropriate anal cleansing material currently available to all students and latrines or septic tanks emptied (or latrines safety covered) when they fill up		
Yes	54	100
11. Is there currently functional lighting in the student toilets on the day of the survey /questionnaire		
Yes	53	98.1
No	1	1.9

Covered bins for disposal of menstrual hygiene materials in girls' toilets were present in 4/5ths of the schools and less than 3/4<sup>th</sup> of the surveyed schools

had disposal mechanisms for menstrual hygiene waste. Toilets were cleaned at least once /day in at least 80% of the schools. (Table 2b)

**Table 2C: Expanded Hygiene Questions:**

Questions	Number (n)	Percentage (%)
<b>ACCESSIBILITY</b>		
1. Are there hand washing facilities accessible to those with limited mobility or vision		
Yes	48	88.9
No	6	11.1
2. Are there hand washing facilities accessible to the smallest children at the school		
Yes	49	90.7
No	5	9.3
<b>AVAILABILITY</b>		
3. Where are hand washing facilities with water and soap located at the school		
Toilets	44	81.5
Food preparation area	1	1.9
School Yards	9	16.6
Class rooms, Food consumption area, Other	0	0
4. How many hand washing facilities are located at the school		
(a) Total no of taps		
1 - 3	24	44.0
4-6	22	41.0
≥7	8	15.0
<b>QUALITY</b>		
5. How many times per week are group hand washing activities conducted for all students		
At least once per school day	3	5.6
2-4 days/week	34	62.9
Once per week	17	31.5
Less than once per week	0	0
6. Which of the following provisions for Menstrual Hygiene Management (MHM) are available at the school		
MHM (e.g. pads)		
Yes	42	77.8
No	12	22.2
Bathing areas and MHM education	0	0
7. How is solid waste (garbage) from the school disposed of?		
Collected by municipal waste system	35	64.9
Burned on premises	18	33.2
Openly dumped on premises	1	1.9
Buried and covered on premises	0	0

MHM materials were available in 42 schools and solid waste was disposed of by municipality in 2/3<sup>rd</sup> of the surveyed schools and was burned in premises in the rest. (Table 2c)

### Discussion

Water, sanitation and hygiene (WASH) facilities are the basic requirements of an individual and there is a high political commitment for provision of these services both in homes as well as in schools. The findings of the present study reiterate that we need to have inter- sectoral coordination and the four important components of sanitation which are safety; accessibility; affordability and cultural sensitivity should be addressed together.<sup>10</sup> Our results regarding drinking water facilities in school are in concordance with a study conducted in Kerala and another survey conducted by Water Aid India.<sup>11,12</sup>

As per Global base line report 2018, approximately 50 per cent of Indian schools were deficient in basic sanitation facilities due to various reasons like lack of resources, lack of infrastructure and lack of attitude.<sup>13</sup> Very few studies have assessed the effect of WinS interventions on pupil health and school attendance. Lack of school toilets affect academic achievement due to high adolescent dropout rates especially among girls.<sup>14,15</sup> Anjali Adukia observed that school-toilet provision noticeably improved enrollment of adolescent girls, especially when offering separate latrines for girls and boys.<sup>16</sup> All surveyed schools in a Vietnam study had student latrines but activities promoting toilet use among children were not performed in schools whereas in our study, group hand washing activities were conducted at least once a week in 31.5% schools.<sup>17</sup> Assessment of sanitation in schools of rural Karnataka, revealed that 90% of the schools were having drinking water points which is in line with our findings while only 10% of the schools had adequate hand washing points with soap which is much lesser than our reported finding of 50%.<sup>18</sup> A similar study conducted in public primary schools in Kenya revealed that piper water supply was available in only 30% schools and only 55% of the schools had hand washing points as opposed to 100% in our study.<sup>19</sup> In another multi-national cross-sectional WASH study, 2270 schools were surveyed in rural regions of six Sub-Saharan African countries

and only 1%-23% of rural schools reported improved water sources on premises, improved sanitation, and water and soap for hand washing.<sup>20</sup>

### Conclusion and Acknowledgement:

School children are the most compelling advocates of hygiene practices in the community, so we need to endow them with a healthy school environment. However, more research in this domain is the need of the hour.

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**Conflict of interest:** Nil

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**Ethical Clearance:** IEC GMC, Jammu

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## Study of Eye Problems among Long Term Computer users in Ahmedabad City

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### Abstract

**Background:** India being the forerunner in the cyber world the occupational health problem is slowly awakening to this group of modern occupational diseases, which are slowly taking its roots among the information technology (IT) professionals. Studies have also shown that computer users are at greater risk of developing eye problems and visual fatigue.

**Methodology:** Cross sectional study was carried out over a period of one year time among 800 participants to study the eye problems among computer users.

**Results:** Out of 800 participants; 70.25% participants had any computer related eye problem. If participants work more than four hours in a single spell prevalence of eye problems was 84.49%. Prevalence of visual problem was maximum (76.67%) who use computer for seven to nine hours per day.

**Conclusion:** It is observed that occurrence of visual problems are related more to number of hours spent gazing at the screen than number of years of work.

**Keywords:** Eye Problems, Long term computer use, Visual fatigue,

### Introduction

Contemporary technology revolution has made our life with so much convenience that people would hardly imagine life without computer, internet, cable TV, cellular phones, various tools and gadgets. Computers are one of the main tools in businesses, educational institutes, offices, homes and even in cars. The increasing use of personal computer in homes has become an integral part of life. Together with all above factor and dwindling prices, India stands 5<sup>th</sup> among highest computer user in the world with 57 million users which is 3.56% of world computer users.<sup>1</sup> According to census 2011 data 9.4% households in India had a computer. In Gujarat

8.8 % households owned a computer out of which 3.1% had internet access.<sup>2</sup> Ahmedabad is not out of this development and its proof is in survey done by TCS on students of higher secondary school which indicates that students of Ahmedabad use home PCs (72.56%) and laptops (72.87%).<sup>3</sup> The application of computer technology and the accompanying use of Video display terminals are revolutionizing the work places in India and their use will continue to grow in the future.<sup>4</sup> On one hand, these technologies including computers have made lives so much easy but on the other hand have created many risks for human health. The negative risks associated with the usage of these technologies are increasing with their growing demand day by day.

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India being the forerunner in the cyber world the occupational health problem is slowly awakening to this group of modern occupational diseases, which are slowly taking its roots among the information technology (IT) professionals. These problems if ignored can prove debilitating and can cause crippling injuries forcing one to change one's profession.<sup>5,6</sup> The work environment constitutes an important part of man's total environment, so health to a large extent is affected by work conditions.<sup>7</sup> Physical environment plays an important bearing on health. Occupational environment too plays a major role on the health of the exposed. The health hazards get more severe when the duration of the exposure increases. The more time spent on this type of activity, the higher the risk of developing visual, musculoskeletal and psychological problems.<sup>8-9</sup> Studies have also shown that computer users are at greater risk of developing eye problems and visual fatigue.<sup>10</sup>

### Material and Methods

The present study titled "Study of Eye problems among computer users in Ahmedabad City" was conducted at government and private offices of Ahmedabad city.

**Study Design:** Cross sectional study.

**Study Period:** The study was carried out over one year time duration.

**Sample Size:** In the pilot study the prevalence of eye related problems among computer users was found to be 67%. Considering this prevalence sample size was calculated with allowable error of 5%. Calculated sample size was 788 but for the convenience of study, the sample size was decided to

be 800. The study subjects were drawn from software development workers, call center workers and data entry workers to have an adequate representation from all sectors of Information Technology industry.

### Inclusion Criteria

- Duration of computer use is more than 1 year.
- Uses computer for more than 3 hours/day or 21 hours/week.

### Exclusion Criteria

- Any disease of eye
- Any acute injury related to eye

**Data Collection:** List of offices was procured from internet. Offices from this list were randomly selected and prior permission of the proprietor of selected offices was taken. All the selected offices were visited with prior appointment convenient to proprietor and study participants. Verbal consent from each employee, who were using computer as per inclusion criteria was taken and he/she was given predesigned, pretested questionnaire to fill up the questions regarding their, Demographic profile, Job profile; Work duration, Work distribution, Work environment, eye problems and its severity with its duration.

Each part of questionnaire was explained to participants in detail. Filled up questionnaire was collected and checked for completeness of information.

**Statistics:** Data entry and data analysis was done in Epi-Info software version 7.1. Odds ratio and Chi-Square tests were used to test the significance.

## Results

**Table 1: Sex wise distribution of visual problems among the study participants**

	Male n=569 (%)	Female n=231 (%)	Total n=800 (%)	Odds Ratio (95% CI)
Visual problems	392 (68.89)	170 (73.59)	562 (70.25)	0.73 (0.56-1.11)
Eye pain	201 (35.33)	105 (45.45)	306 (38.25)	0.6 (0.4-0.6)
Eye strain	170 (29.88)	92 (39.83)	262 (32.75)	0.6 (0.46-0.88)

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Eye redness	75 (13.18)	24 (10.39)	99 (12.38)	1.3 (0.82-2.13)
Blurring of vision	115 (20.21)	45 (19.48)	160 (20.00)	1.04 (0.7-1.5)
Watery eyes	100 (17.57)	50 (21.65)	150 (18.75)	0.77 (0.52-1.12)
Dry eye	81 (14.24)	38 (16.45)	119 (14.88)	0.84 (0.55-1.28)
Difficulty in focusing	101 (17.25)	37 (16.22)	138 (17.25)	1.13 0.74-1.7
Double vision	16 (2.81)	9 (3.90)	25 (3.13)	0.71 0.31-1.63
Headache	291 (51.14)	137 (59.31)	428 (53.50)	0.71 (0.52-0.92)

Among study participants 71.12% were males and 28.88% were females. Prevalence of visual problems in the study participants was 70.25% (562/800). Prevalence of eye problems varies from

38.25% (eye pain) to 3.13% (double vision). All eye problems were more among females as compared to males except for eye redness, blurring of vision and difficulty in focusing. (Table No. 1)

**Table 2: Prevalence of headache according to duration of single spell of computer work**

Work duration in single spell (hrs)	Visual problem*		Headache†		Total n=800
	Yes (%)	No (%)	Yes (%)	No (%)	
<2	26 (29.54%)	62 (70.46%)	33 (37.50%)	55 (62.50%)	88 (11%)
2-3	124 (55.85%)	98 (44.15%)	84 (37.84%)	138 (62.1%)	222 (27.7%)
3-4	194 (83.62%)	38 (16.38%)	138 (59.48%)	94 (40.52%)	232 (29.0%)
>4	218 (84.49%)	40 (15.51%)	173 (67.05%)	85 (32.95%)	258 (32.2%)

\*, Chi square value = 136.67, df=3, P<0.001

†, Chi square value = 35.47, df=3, P<0.001

Table 2 shows that prevalence of visual problems and headache were more or less same in all the groups. Prevalence of visual problems among participants

with less than 3 years of job was 67.78% while 75.44% in those with 3 to 5 years of job. These difference were statistically not significant.

**Table 3: Prevalence of visual problems by duration of computerwork/day**

Computer work (hrs/day)	Visual problem*		Headache†		Total n=800
	Yes (%)	No (%)	Yes (%)	No (%)	
3-5	33 (39.7)	50 (60.24)	14 (16.87)	69 (83.13)	83 (10.38)
5-7	108 (70.59)	45 (29.41)	52 (33.99)	101 (66.01)	153 (19.13)
7-9	230 (76.67)	70 (23.33)	176 (58.67)	124 (41.33)	300 (37.50)
>9	191 (72.35)	73 (27.65)	186 (70.45)	78 (29.55)	264 (33.00)

\*, Chi square value = 43.39,df=3, P<0.001

†, Chi square value = 101.91,df=3, P<0.0001

Prevalence of visual problems was highest (76.67%) in those participants who use computer for 7 to 9 hours/day and lowest (39.76%) in those who use computer for less than 5 hours/day. This difference was statistically highly significant. Prevalence of headache among study participants

was proportional to computer work/day. Highest prevalence (70.45%) was among the participants who were working for more than 9 hours/day. This difference was statistically highly significant. (Table No. 3)

**Table 4: Prevalence of visual problems according to completed years ofcomputer related job**

Work duration in single spell (hrs)	Visual problem*		Headache†		Total n=800
	Yes (%)	No (%)	Yes (%)	No (%)	
1-3	223 (67.78)	106 (32.22)	170 (51.67)	159 (48.33)	329 (41.13)
3-5	172 (75.44)	56 (24.56)	125 (54.82)	103 (45.18)	228 (28.50)
> 5 years	167 (68.72)	76 (31.28)	133 (54.73)	110 (45.27)	243 (30.38)

\*, Chi square value = 4.16,df=2, P>0.05

†, Chi square value = 0.75,df=2, P>0.05

Prevalence of visual problems among participants with 3 to 5 years of job is 75.44% (x2 4.16, df =2, P > 0.05), statistically insignificant. Prevalence

of headache among participants who worked more than 5 years is 54.73% . (x2 0.75, df =2, P > 0.05), statistically insignificant.

**Table 5: Prevalence of computer related health problems by refractiveerror status of participants**

Type of health problem	Refractive error		Total	Odds ratio(95% CI)	χ <sup>2</sup> df=1	P value
	Yes n=143 (%)	No n=653 (%)				
Visual problems						
Yes	123	439	562	2.28 (1.45-3.59)	13.25	< 0.001
	(82.55)	(67.43)	(70.25)			
No	26	212	238	(1.45-3.59)	13.25	< 0.001
	(17.45)	(32.57)	(29.75)			

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Headache						
Yes	89	339	428	1.36 (0.95-1.96)	2.85	> 0.05
	(59.73)	(52.07)	(53.50)			
No	60	312	372			
	(40.27)	(47.93)	(46.50)			

Prevalence of computer related visual problems were 2.28 times higher who had refractive error, odds ratio 2.28, 95% CI (1.45-3.59),  $P < 0.001$ , statistically significant. Prevalence of headache was 1.36 times higher who had refractive error, odds ratio 1.36, 95% CI (0.95-1.96),  $P > 0.05$ , statistically insignificant (Table 5)

### Discussion

In the present study 70.25% of participants had visual problems (Table No. 1). Similar results were found in study by Suparna K. et al (76%) and Talwar R. et al (76.5%).<sup>11-12</sup> However it was lower (59.5%) in study by Bhanderi et al.<sup>13</sup> Also the prevalence of visual problems was higher in females (73.59%) as compared to males (68.89%). Similar results were observed in other studies.<sup>11,13-14</sup>

In the current study statistically significant association was found between the duration in single spell of work without break and visual problems and headache (Table No. 2). Similarly WHO and Chakarpani et al also found a significant association between duration of work without break and any computer related health problem.<sup>5,15</sup>

In the present study total hours of computer usage per day was significantly associated with visual problems and headache. (Table 3) Similar significant association was found by other studies.<sup>12,14,16</sup> However no significant difference was found between visual problems and job duration (Table No. 4). These results were in agreement with study findings of Sharma A. K. et al.<sup>14</sup>

In the present study 143 (18.63%) of participants had refractive errors which is lower than the findings of Bhanderi et al<sup>13</sup> (35.8%). A significantly higher proportion of participants with refractive error reported occurrence of visual problems. Study on visual problems by Bhanderi et al, Bergqvist et al and Nakaishi et al had shown similar relationship between

computer related visual problems and presence of refractive error in the participants.<sup>13,17-18</sup> Potential explanation of increased risk of visual problems is that computer tasks is a type of near work that looks at letters on the screen which are formed by tiny dots called pixels, rather than a solid image. This causes the eyes which already have some corrective problem to work a bit harder to keep the images in focus.

### Conclusion

From the findings of present study it was evident that very high morbidity attributed to computer work has already taken roots in information technology professionals and it is a matter of great concern. It is observed that occurrence of visual problems are related more to number of hours spent gazing at the screen than number of years of work.

**Ethical clearance:** Ethical clearance was taken from institutional ethical committee of GMERS Medical College, Himmatnagar

**Sources of funding:** Self

**Conflict of interest:** Nil

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## Role of Magnetic Resonance Imaging in the Evaluation of Sellar, Parasellar and Suprasellar Lesions

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### Abstract

**Introduction:** Magnetic resonance imaging (MRI) is now widely available, and considerable body of experience has been accumulated in using it to evaluate this region. MRI is now accepted as the imaging procedure of choice in the evaluation of sellar and parasellar pathology. The aims and objectives are to know the characteristic MRI features of the sellar, parasellar and suprasellar lesions and to describe the incidence of the various lesions and their age and sex distribution in the study population.

**Methodology:** Prospective study of 30 patients referred for imaging having clinical features raising suspicion of sellar, parasellar and suprasellar lesions. They underwent magnetic resonance imaging of the brain-sella using 1.5 TESLA PHILIPS ACHIEVA MRI MACHINE in the Department of Radiodiagnosis, KIMS & RF, Amalapuram.

**Results:** Out of 30 cases 4 cases were pituitary macroadenoma, 3 cases each of pituitary microadenoma, craniopharyngioma, meningioma and aneurysm. 2 cases of each hypothalamic hamartoma, Pituitary colloid cyst, Rathke's cleft cyst, Arachnoid cyst and primary empty sella were found. And 1 case of each Suprasellar tuberculoma, Trigeminal schwannoma, Suprasellar retinoblastoma and PNS rhabdomyosarcoma were found.

**Conclusion:** MR imaging characteristics of the most common lesions like pituitary macroadenoma, microadenoma, craniopharyngioma, meningioma and aneurysm were sufficiently distinct to allow them to be differentiated from each other and from most other entities. Other characteristics such as extrasellar versus intrasellar location, nature of contrast material enhancement, the presence of cystic components, and clinical findings permit further differentiation among the various other abnormalities. The superior resolution and multiplanar capacity of MR imaging best depicts the extent of sellar, parasellar and suprasellar lesions.

**Keywords:** Magnetic resonance imaging, Pituitary tumours, Brain imaging, Sellar and parasellar lesions, Sella turcica

### Introduction

The sellar and parasellar region is an anatomically complex area that represents a crucial crossroad of

important adjacent structures, e.g. orbits, cavernous sinus and its content, suprasellar cistern and its contents, polygon of Willis, hypothalamus through

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the pituitary stalk and dural reflections forming the diaphragm sellae and the walls of the cavernous sinuses. Although the cavernous sinus represents the most relevant parasellar structure, from the practical and clinical point of view all the structures that surround the sella turcica can be included in the parasellar region. The anatomy of the sellar and parasellar region is intricate, and the pathology diverse.<sup>(1)</sup> Various types of tumours, cysts, vascular lesions, inflammatory processes, infections and congenital lesions are found in and around the sella. The clinical presentation of the sellar and parasellar lesions is also very variable. Pituitary axis dysfunction, visual field defects, hydrocephalus, intracranial mass effect and other neurologic deficits are some of the most common features.<sup>(2,3)</sup> Many different imaging modalities have been used for assessment of this area, but for the most part the introduction and widespread use of high resolution computed tomography (CT) relegated its imaging predecessors, such as plain skull roentgenograms, pleuridirectional tomography and pneumoencephalography to obsolescence.<sup>(4)</sup>

Magnetic resonance imaging (MRI) is now widely available, and considerable body of experience has been accumulated in using it to evaluate this region. MRI is now accepted as the imaging procedure of choice in the evaluation of sellar and parasellar pathology. Its major advantages are its superior soft tissue contrast and its capacity for multiplanar imaging. Also there is no artefact from bone, and the patient is not exposed to ionizing radiation. Use of I.V. gadolinium is very helpful in defining sellar and parasellar pathologies. The advent of dynamic contrast study has proved very useful in detection of pituitary microadenoma. Involvement of the optic chiasm, cavernous sinus, sphenoid sinus, orbit, temporal lobes and carotid arteries can all be best seen with MRI. CT is preferred for evaluating calcification and bone detail. The CT has its own drawbacks of high doses of ionizing radiation, artifacts due to presence of bony structures and inherent limitation of soft tissue resolution. But CT still remains important screening modality. Regardless of which imaging modality is used, it is useful to review the normal radiological anatomy and to survey the more common types of pathologic entities that occur in it. It is important to make an attempt to characterize

the histological etiology of masses involving sellar, juxtaseellar region. This is of profound clinical importance as this determines the use of surgical versus nonsurgical techniques, a transsphenoidal versus intracranial surgical approach and the degree of resection. In present study, we have evaluated 100 patients, having referred with strong clinical suspicion or preliminary CT showing abnormality in the sellar, parasellar region. The MRI findings are correlated with histopathological findings.

## Methodology

30 patients referred for imaging having clinical features raising suspicion of sellar, parasellar and suprasellar lesions were prospectively studied in 2021. They underwent magnetic resonance imaging of the brain-sella. MR imaging was performed using 1.5 TESLA PHILIPS ACHIEVA MRI MACHINE, in the Department of Radiodiagnosis, KIMS & RF, Amalapuram. A standard head coil was used for the examination.

**Patient population:** Study included 30 patients from inpatient and outpatient department having clinical features raising suspicion of sellar, parasellar and suprasellar lesions. Also the patients who have been diagnosed as having sellar and parasellar lesions on CT scan and needs further evaluation with MRI. Certain patients having hormonal alterations pointing towards pituitary pathology were included in the study additionally.

### Inclusion criteria:

1. All patients clinically suspected to have sellar, parasellar and suprasellar lesions.
2. All patients who shows sellar lesions on CT imaging.
3. All patients who show enlargement of sella with or without destruction on plain film.
4. All patients in whom the conditions are incidental.
5. Cases of all age groups.

### Exclusion criteria:

1. Patients who are not co-operative and morbidly sick.
2. Patients who are not giving consent for scanning.

3. Patients in whom MRI is contraindicated.
4. Patients with no relevant clinical data.
5. Patients who are allergic to contrast medium.

**Precontrast** First the brain screening sequence was performed with T2W and FLAIR axial sequences. After this, high resolution T1SE and T2SE sequences focused on the sellar region are performed in all cases.

**Post contrast study:** Routine T1FS postcontrast axial sequence is also performed in required cases using Gadolinium (gadobenate dimeglumine).

### Results

Out of 30 cases were 11 males and 19 were females. The youngest patient was 3.5yr male child while the eldest was a 78 year old female. Maximum no. of patients was in 21 to 30 years age group (26.66%).

Headache and nausea & vomiting were the common presenting features in the majority of cases,

accounting for 22 (73.33%) and 14 (46.66%) cases respectively.

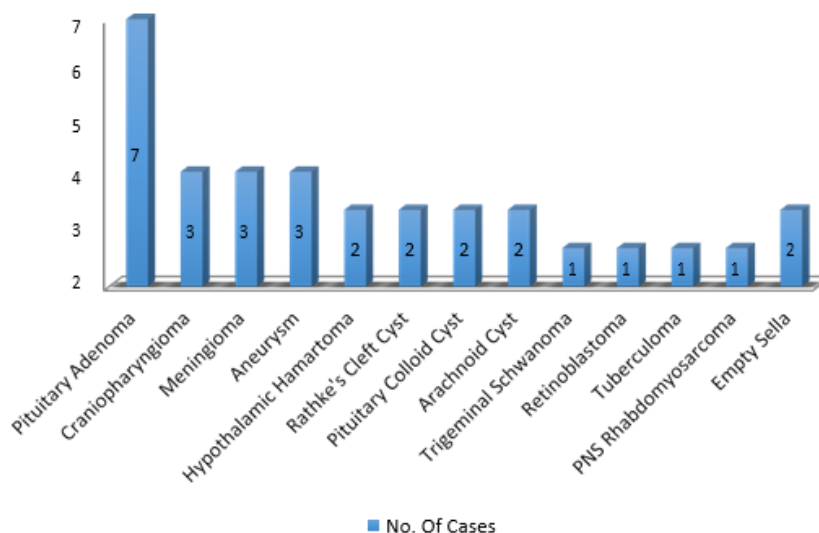
Visual disturbances were next common symptom accounting 30% cases followed by convulsions in 26.66% of cases. Amenorrhea presented in 10% cases. Loss of libido was present in 6.66% cases. Loss of consciousness in 3.33% cases

Most common lesion in adults were pituitary adenomas accounting for 6 cases (20%).

Second most common lesion in adults were meningiomas and carotid artery aneurysms accounting for 3 cases each (10%).

Most common lesion in children were craniopharyngiomas accounting for 3 cases (10%).

Second most common lesion in children were hypothalamic hamartoma accounting for 2 cases (6.66%).



**Graph 1: Distribution of lesions in sellar, parasellar and suprasellar regions**

**Table 1. Distribution of types of lesions in sellar, parasellar and infrasellar regions**

Type of Lesions	Sellar	Parasellar Extension	Suprasellar Extension	Infrasellar Extension
Macroadenomas (n=4)	4(100%)	2(50%)	4(100%)	1(25%)
Microadenomas(n=3)	3(100%)	0	0	0
Craniopharyngioma(n=3)	3(100%)	3(100%)	3(100%)	0
Meningioma (n=3)	1(33.33%)	3(100%)	1(33.33%)	0
Aneurysm (n=3)	0	3(100%)	1((33.33%)	0
Hypothalamic Hamartoma (n=2)	0	2(100%)	1(50%)	0

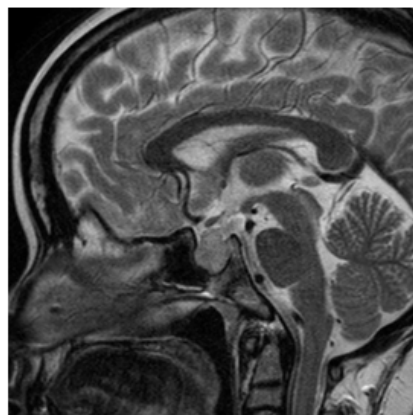


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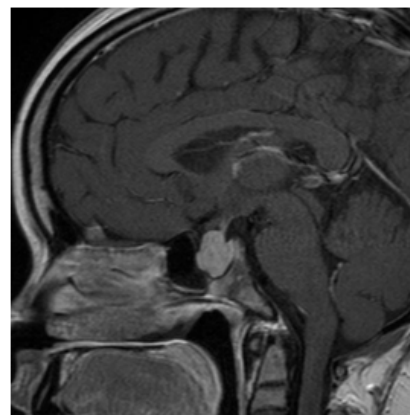
Rathke's Cleft Cyst (n=2)	2(100%)	0	2(100%)	0
Pituitary Colloid Cyst(n=2)	2(100%)	0	0	0
Arachnoid Cyst (n=2)	0	0	2(100%)	0
Trigeminal Schwannoma(n=1)	0	1(100%)	0	0
Retinoblastoma (n=1)	0	1(100%)	1(100%)	0
Tuberculoma (n=1)	0	0	1(100%)	0
PNS Rhabdomyosarcoma(n=1)	1(100%)	1(100%)	0	1(100%)

**Table No. 2: Distribution of different types of lesions according to their MRI enhancement**

Type of Lesions	None	Homogenous Enhancement	Heterogenous Enhancement	Peripheral Enhancement
Macroadenomas (n=4)	0	3(75%)	1(25%)	0
Craniopharyngioma(n=3)	0	0	3(100%)	0
Meningioma (n=3)	0	2(66.66%)	1(33.33%)	0
Aneurysm (n=3)	0	0	3(100%)	0
Hypothalamic Hamartoma (n=2)	2(100%)	0	0	0
Rathke's Cleft Cyst(n=2)	2(100%)	0	0	0
Pituitary Colloid Cyst(n=2)	2(100%)	0	0	0
Arachnoid Cyst (n=2)	2(100%)	0	0	0
Trigeminal Schwannoma (n=1)	0	1(100%)	0	0
Retinoblastoma (n=1)	0	1(100%)	0	0
Tuberculoma (n=1)	0	0	0	1(100%)
PNS Rhabdomyosarcoma(n=1)	0	0	1(100%)	0

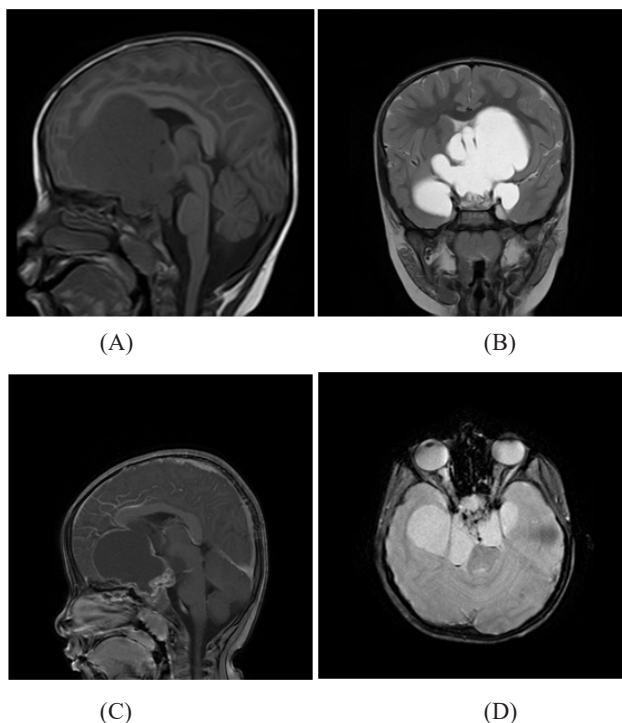
**PHOTOGRAPHS****MRI IMAGES OF VARIOUS CASES**

(A)



(B)

**Case No.1: PITUITARY MACROADENOMA:** A) T2W and B) Post Contrast T1W sagittal images showing a lesion in sellar and suprasellar region, hyperintense on T2 and showing homogenous enhancement on post contrast.



**Case No.2: CRANIOPHARYNGIOMA:** A)T1W sagittal image, B)T2W coronal image and C)T1W post contrast sagittal images showing a large solid cystic lesion in suprasellar region with cystic component iso-hypointense on T1W, hyperintense on T2W and show peripheral enhancement on post contrast images. Solid component show mixed signal on T1W and T2W images and heterogenous enhancement on contrast study. D) Axila Gradient image (T2FFE) shows areas of blooming suggestive of calcification.

### Discussion

The present study was undertaken with the aim of evaluating MRI findings in sellar, parasellar and suprasellar lesions and to describe the incidence of the various lesions and their age and sex distribution in the study population.

Study included 30 patients from inpatient and outpatient department having clinical features raising suspicion of sellar, parasellar and suprasellar lesions.

The patients belonged to all age groups ranging from 3.5 to 78 years. However, the majority of the patients (about 26.66%) belonged to the third decade of life. This was similar to Banna et al<sup>(5)</sup> (1980) in their retrospective study of 230 sellar and parasellar lesions, encountered maximum number of patients with their third and fourth decades. Abdullah

et al<sup>(6)</sup> also reported incidence of pituitary lesions with mean age of 32+/- 12 years in retrospective study of 160 cases. Reich et al<sup>(7)</sup> reported a high incidence of patients (15 out of 20), above the range of 40 years. This was probably related to fact that most of their patients had aneurysm, meningiomas and metastases, where as only five patients had pituitary adenoma and craniopharyngiomas.

There was a female preponderance in our study which was similar to; Banna et al<sup>(5)</sup> experience in contrast of Reich et al<sup>(7)</sup> reported a male preponderance.

Symptoms of the raised intracranial tensions like headache, nausea & vomiting were the most common clinical presentations followed by ophthalmological symptoms in our series of patients with sellar, parasellar and suprasellar lesions.

The most common lesion detected in our study was pituitary adenoma (7 out of 30) which was similar to experience of Benjamin et al<sup>(8)</sup> and Johnsen et al<sup>(9)</sup>.

Out of 7 adenomas 4 were macroadenomas and 3 were microadenomas by size criterion. So the macroadenoma to microadenoma ratio was about 1.3:1. Johnsen et al<sup>(9)</sup> found the total proportion of macro to microadenomas 2.5:1.

Patients with macroadenomas typically presented with symptoms of mass effect rather than endocrinological disturbances. In present study all 4(100%) patients presented with symptoms of visual disturbances, 3(75%) patients presented with headache nausea & vomiting, while 1(25%) patient of macroadenoma presented with endocrinological disturbances. Pittmann HH et al<sup>(10)</sup> in his study of pituitary adenomas found headache, visual symptoms and amenorrhea as most common symptoms.

On T1W images 3 cases (75%) of macroadenomas were isointense to grey matter and 1 (25%) was hyperintense.

The hyperintensity on T1WI in 1 case was found to be due to presence of pituitary apoplexy. Out of 51 cases studied by Johnsen et al<sup>(9)</sup>, he found about 82% lesions were isointense to grey matter.

On T2W images the macroadenomas showed variable signal intensity depending upon their composition.

After the contrast administration, 3 cases (75%) showed homogenous enhancement on postcontrast study while 1 case (25%) showed heterogeneous enhancement. Johnsen et al<sup>(9)</sup> found homogenous enhancement in 46% cases.

Intrasellar extension with sellar enlargement was found in all cases. This finding was consistent with various other studies.<sup>(9,11)</sup>

Suprasellar extension is seen in all 4 patients (100% cases). Benjamin et al<sup>(8)</sup> and Johnsen et al<sup>(9)</sup> also have got similar findings.

Pituitary apoplexy was seen in 1 (25%) case showed iso-hyperintense signal on T1W and iso-hypointense on T2W. Blooming signal was seen on gradient images. Patient presented with loss of consciousness. Johnsen et al<sup>(9)</sup> found incidence of hemorrhage about 14% in 71 cases. In other large surgical series the incidence of the haemorrhage was 17% in 560 patients<sup>(12)</sup>.

In a study by Pusey et al<sup>(13)</sup> which compared the CT and MRI in assessment of craniopharyngiomas, they found that, CT was superior to MR in demonstrating calcifications within the tumors. MR failed to demonstrate areas of calcification in three of 14 cases in which calcification was demonstrated by CT.

Taylor et al<sup>(14)</sup> found that 91% of meningiomas were isointense on T1 and 55% were isointense on T2W. In contrast, 79% of macroadenomas were isointense on T1W, while only 32% of macroadenomas showed isointensity on T2W. This led to finding that T2W signal intensity may be an important point to distinguish between the adenoma and meningioma.

On MRI all 3 cases of aneurysm were heterogeneous in appearance and were showing variable amount of flow void (hypointensity) on both T1W and T2W images. All three cases showed some degree of intramural thrombosis. 2 cases showed peripheral crescent of hyperintensity on T1W images, which is due to methemoglobin.

### Conclusion

MR imaging characteristics of the most common lesions like pituitary macroadenoma,

microadenoma, craniopharyngioma, meningioma and aneurysm were sufficiently distinct to allow them to be differentiated from each other and from most other entities. Other characteristics such as extrasellar versus intrasellar location, nature of contrast material enhancement, the presence of cystic components, and clinical findings permit further differentiation among the various other abnormalities. The superior resolution and multiplanar capacity of MR imaging best depicts the extent of sellar, parasellar and suprasellar lesions.

**Ethical clearance:** Taken from institutional ethics committee

**Source of funding:** Self

**Conflict of Interest:** Nil

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# Study of Stroke Due to Intra Cranial Atherosclerosis in Bihar Population

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## Abstract

**Background:** Ischemic stroke is quite heterogeneous in its patho-physiological mechanism associated with atherosclerosis. Little is known about measures for prevention of the disease apart from latest technologies and medications.

**Method:** 100 patients of different age groups were studied with MRA, to rule out occlusion or lesion; tropical distribution of infarction, clinical manifestations, recurrence after treatment was also noted.

**Results:** Clinical manifestations included 33% alcoholic, 21% homocystine, 80% HTN, 54% DM, 30% Hyper-lipidemia, 35% smoking, 48% HTN + DM, 17% HTN + DM +Hyper-lipidemia, 7% HTN + DM + Hyper-lipidemia, + smoking + Alcohol. Highest occlusion was observed 51 (39.9%) in MCA followed by 20 (14.4%) ICA, 23 (16.6%) BA, 18 (13.04%) VA and least was 2 (1.4%) in VA+BA. Highest tropical distribution of infarction was 28% cortical followed by 24% sub cortical and cortical, 23% cortical, 11% cerebellum, 8% Brainstem and recurrence was observed in 19% patients.

**Conclusion:** The present pragmatic study will help for efficient management and risk control for Neuro-physician and neurosurgeon because risk factor control remains the best strategy for preventing recurrence because recurrence of the stroke worsen the physical and mental conditions of the patients.

**Keywords:** MRA, HTN, DM, Homocystine, recurrence

## Introduction

Intracranial atherosclerosis of major arteries is most common proximate mechanism of ischemic stroke worldwide. Intracranial atherosclerosis (IATH) has been recognised as a serious cause of stroke. It is reported that IATH is present in 7-10% of patients with cerebra vascular disease <sup>(1)</sup>. In general the risk factors are thought to be the same as for non-intra cranial vascular disease and include HTN hyper-cholestremia, tobacco chewing and smoking and

DM, in addition, possibly to genetic factor and race-ethnicity <sup>(2)</sup>. It is also noted that, metabolic syndrome, cluster of risk factors that are linked to insulin resistance and increased risk of coronary heart disease are involved in stroke with atherosclerosis <sup>(3)(4)</sup>.

Hence to evaluate the various aetiologies of the stroke associated with atherosclerosis of major arteries of the brain in different age groups and both sexes was studied with help of MRA.

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## Observation and Results

**Table-1:** Clinical manifestations of stroke patients - 33% alcoholic, 21% homocysteine, 80% HTN, 54% DM, 30% hyper-lipidemia, 35% smoking, 48% HTN + DM, 17% HTN + DM + Hyper-lipidemia, 7 (7%) HTN + DM + Hyper-lipidemia + Alcohol

**Table-2:** Distribution of atherosclerotic lesions (occlusion) in variables arterial 15 (36.9%) MCA, 20 (14.4%) ICA, 6 (4.3%) ACA, 18% (13.04%) VA, 6 (4.3%) BA, 23 (16.6%) PCA, 4 (2.89%) MCA + ICA, 4 (2.89%) ICA + MCA + ACA, 4 (2.89%) BA + PCA, 2 (1.4%) VA + BA

**Table-3:** Tropical distribution of Infarction - 28% cortical, 23% Sub cortical, 24 cortical and sub cortical, 8 % Brain stem, 11% cerebellum, 6% others.

**Table-4:** Study of recurrence in un-controlled risk factors - 6% Drug compliance to anti-platelets, 3% Drug (anti-platelets), 2% single anti-plate, 3% statins, 2% HTN controlled, 2% DM controlled, 1% Hyper-lipidemia controlled.

## Material and Method

100 patients aged between 25 to 60 years admitted at Neuro-Surgery department of Sri Krishna medical college and hospital Muzaffarpur-842003, Bihar was studied.

**Inclusive Criteria:** Diagnosis of ischemic stroke due to large intracranial atherosclerosis was selected for study.

**Exclusion Criteria:** Patients with organic mental disorders, arterial fibrillation, acute anterior wall ST elevation myocardial infarction < 30 days, mitral stenosis, intra cardiac thrombus or vegetations, intra cranial tumours, arterio-venous malformations, Moyamoya disease, arteritis were excluded from study.

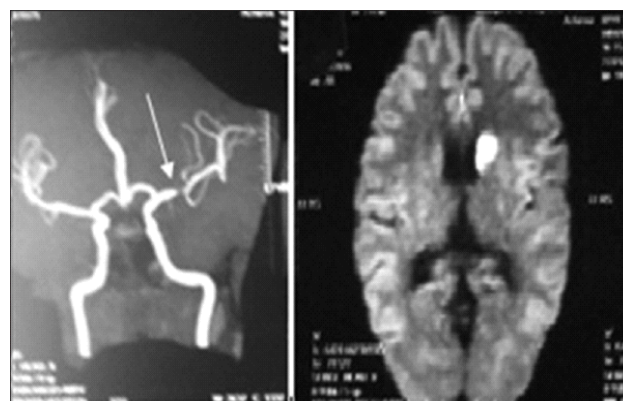
**Method:** The diagnosis of ischemic stroke due to large artery intra cranial atherosclerosis was made as per the TOAST (trial of ORG 10172 in acute stroke treatment) classification. Physical and neurological examination was done disease duration laboratory findings, any complications and treatment received was noted. The data was noted in pre-designed case record forms.

MRA (Magnetic Resonance angiography) (GE systems 1.5 T) was done in all patients. stenosis (segmental flow gap or luminal stenosis or occlusion) was assessed in proximal middle cerebral arteries, internal carotid arteries VAS, and BA. The distribution of stenosis and occlusive lesions was noted. Patients were put on treatment with anti-platelet, drugs in addition to other required medications.

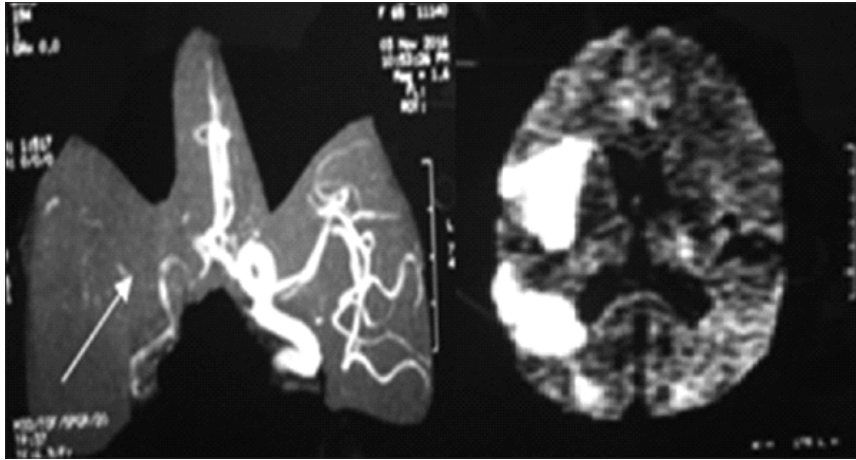
HTN (Hyper tension) history of HTN in the post, systolic Blood pressure (SBP)  $\leq$  140 mm/Hg and or diastolic blood pressure  $\leq$  90 mm/Hg, Diabetes Mellitus (DM) - History or DM Fasting blood glucose > 126 mg/dl or 2-h post parandial blood glucose > 200 mg/dl. HbA1C > 6.5 Hyper homocysteinemia - elevated levels of serum homocysteine more than 20  $\mu$  moles/L. Hyper-lipidemia - History of dyslipidemia cholesterol, cholesterol > 200 mg/dL, LDL (Low density lipoprotein) > 100 mg/dl or triglyceride > 150 mg/dl. Smoking history, history of alcoholism was also noted.

The duration of study was June 2019 to July 2021.

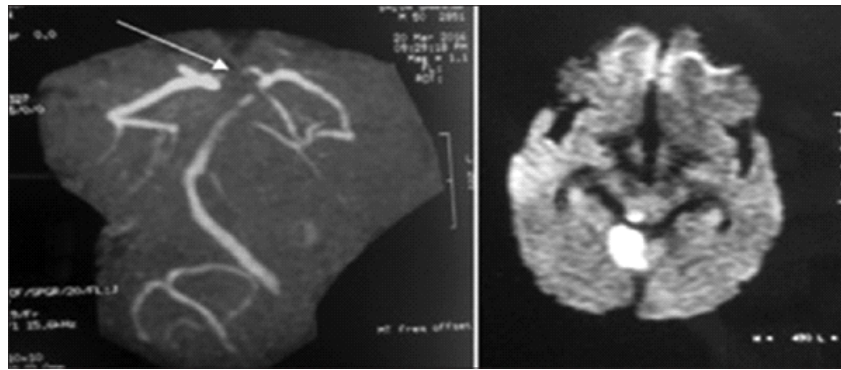
**Statistical analysis:** Various findings of clinical manifestations, distributions of atherosclerotic lesions, tropical distributions recurrence of strokes were classified with percentage. The statistical analysis was performed in SPSS software. The ratio of Male and female was 3:1.



**Figure 1:** Left middle cerebral artery stenosis with diffusion weighted imaging showing subcortical infarct



**Figure 2: Right middle cerebral artery/internal carotid artery occlusion with diffusion weighted imaging showing corresponding infarct**



**Figure 3: Basilar artery stenosis, right superior cerebellar, and right posterior cerebral artery not visualized with diffusion weighted imaging showing infarct in the midbrain and occipital cortex**

**Table 1: Clinical Manifestations of stroke patients due to atherosclerosis**

SI No	Clinical Manifestations	No. of patients (100) %
1	Alcoholic	33 (33%)
2	Homocystine	21(21%)
3	HTN	80 (80%)
4	DM	54 (54%)
5	hyper-lipidemia,	30 (30%)
6	Smoking	35 (35%)
7	HTN + DM	48 (48%)
8	HTN + DM + hyper-lipidemia,	17 (17%)
9	HTN + DM + hyper-lipidemia, + Smoking + Alcohol	7 (7%)

**Table 2: Distribution of atherosclerotic lesions (occlusion) in various arteries**

Name of the Artery	Frequency of lesion	Percentage of distribution of lesions
MCA	51	36.9
ICA	20	14.4
ACA	6	4.3
VA	18	13.04
BA	6	4.3
PCA	23	16.6
MCA + ICA	4	2.89
TCA + MCA + ACA	4	2.89
BA + PCA	4	2.89
VA + A	2	1.4

(MCA = Middle cerebral artery, ICA = Internal carotid artery, ACA = Anterior Cerebral artery, VA = Vertebral

artery, BA = Basilar artery, PCA = Post cerebral artery)

**Table 3: Tropical distribution of Infarction**

Cortical	28
Sub cortical	23
Cortical and sub cortical	24
Brain stem	8
Cerebellum	11
Others	6

**Table 4: Study of recurrence in un-controlled risk factors (No. of patients: 19)**

Parameters	Recurrence Number
Drug compliance to anti-platelets	6
Drug anti-platelets	3
Single anti-platelet	2
Statins	3
HTN Controlled	2
DM Controlled	2
Hyper-lipidemia controlled	1

### Discussion

Present study of stroke due to intra cranial atherosclerosis in Bihar population. The clinical manifestations were 33% alcoholic, 21% homocysteine, 80% HTN, 54% DM, 30% hyper-lipidemia, 35% smoking, 48% HON+DM, 17% HTN+DM+ hyper-lipidemia,, 7% HTN + DM + hyper-lipidemia, + smoking + alcohol (Table-1). In the distribution atherosclerosis lesions (occlusions) in various arteries, 5 (36.9%) MCA was highly involved followed by 23 (16.6%) BA, 20 (14.4%) ICA, 18 (13.04%) ACA and least was 2 (1.4%) in VA + A (Table-2). In tropical distribution of infarction highest was 28% cortical followed by 24% cortical and sub-cortical, 23% sub-cortical, 11% cerebellum, 8% brainstem and 6% others (Table-3). Total recurrence in the study was 19%, Drug compliance to anti-platelet was 6%, anti-platelet drugs - 3%, single anti-plate lets - 2%, statins - 3%, HTN controlled 2%, DM controlled 2%, hyper-lipidemia, controlled 1% (Table-4) (Figures -1, 2 and 3). These findings are more or less in agreement with previous studies <sup>(5)(6)(7)</sup>.

Concurrent atherosclerosis extra cranial and intracranial arteries was also studied HTN emerged as the strongest risk factor for concurrent lesion or

occlusion followed by DM, coronary artery and smoking. Occlusion of large branches of the circle Willis can lead to stroke by hypo-perfusion or by artery to artery embolism <sup>(8)</sup>. It is also noted that stroke is one of the leading causes of death in India. Stroke was the cause of the death in 13% which was similar to death due to coronary artery disease 14% in Andhra Pradesh <sup>(9)</sup>.

Apart from atherosclerosis gene disorders do leads to stroke in young individual without known risk factors and they include CADASIL (cerebral autosomal dominant arteriopathy with sub cortical infarcts and leukoencephalopathy), Fabry's disease, sickle cell disease <sup>(10)</sup>. Hence genetic contribution to stroke is polygenic. It was also observed that apolipoprotein E gene (gene involved with lipid metabolism) was evaluated in stroke patients.

It is accepted globally that as tea is the commonest beverage after water. It is shown beneficial effect that, tea consumption of 450 ml or more than or equal to three cups per day was associated with reduction of incidence of recurrent ischemic stroke, significant decrement of systolic blood pressure, better control of fasting hyperglycaemia and lowering down of the level of total cholesterol and LDL level in the subject with hypercholesterolemia <sup>(11)</sup>.

### Summary and Conclusion

Present study of strokes due to atherosclerosis has multiple aetiologies like HTN, DM, smoking and dyslipidemia as they are not being adequately controlled hence there are challenge of high stroke incidence. Apart from public awareness, it needs more inventional studies to find out the efficacy of preventive agents such as antihypertensive and anti-platelets because exact pathogenesis of stroke is still unclear.

**Limitation of study:** Owing to tertiary location of research centre, small number of patients and lack of latest technologies, we have limited findings and results.

This research paper is approved by Ethical Committee of Srikrishna Medical College and hospital Muzaffarpur-842003, Bihar.

**Conflict of Interest:** No

**Funding:** Self



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# Study of the Characteristics of Positive Contacts and Hospitalized Cases in Multiple Waves of the Covid -19 Pandemic in Pali District of Western Rajasthan: A Secondary Data Analysis

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## Abstract

**Background:** Coronavirus disease 2019 (COVID-19), the pandemic that invaded the world in 2020, caused more than 70 million cases and exceeded a million and a half deaths worldwide by the end of the year. Age and sex have been identified as two of the prominent risk factors in COVID-19 deaths. Early epidemiological studies conducted in China, India, and Iran revealed that fewer females were infected by SARS-CoV2(4-9).

It is imperative for national governments to identify which population members are at high risk of becoming ill or more likely to die. This analysis emphasizes the early epidemiological features of COVID-19 cases in the OPD in order to guide to policy decisions on the health, commercial, social, and economic fronts in case of any future surge in Covid cases.

**Methods:** The data collected during contact tracing (urban and rural ) and hospital admissions during the periods: February 2020 to October 2020 (first wave) and April 2021 to June 2021 (second wave) and December 2021 to February 2022 (Third wave) were analyzed for demographics and other characteristics.

Present study shows that frequency of positive case is more in rural people in age group II (15-50 years) than urban people. Male case is higher in rural areas and female cases are higher in urban areas, hospital admission and ICU admission were higher in rural people while death was reported higher in urban areas.

Better targeting of interventions may help to limit expensive interventions such as intensive care admissions and avoid deaths. To create an efficient, equitable response to the pandemic, especially in countries where resources are limited awareness of the roles of gender, age and geography in the outbreak are imperative.

**Key words:** Covid-19, pandemic, demographics, role of gender, age, ICU, deaths

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## Introduction

Coronavirus disease 2019 (COVID-19), the pandemic that invaded the world in 2020, caused more than 70 million cases and exceeded a million and a half deaths worldwide by the end of the year<sup>1</sup>. The World Health Organization declared COVID-19 a pandemic on March 11, 2020, as unprecedented numbers of positive cases spread across the globe<sup>2</sup>.

Age and sex have been identified as two prominent risk factors in COVID-19 death epidemiological studies conducted in China, India, and Iran revealed that fewer females were infected by SARS-CoV2<sup>3,4</sup>.

Public health response to COVID-19 required behavior changes— isolation at home, wearing masks, hand hygiene, avoiding and limiting social gatherings and their effectiveness depends on generalized compliance. Original data from two waves of a survey conducted in March–April 2020 in eight Organizations for Economic Co-operation and Development countries showed large gender differences in COVID-19–related beliefs and behaviors. Women were found more likely to perceive the pandemic as a serious health problem and to agree and comply with restraining measures. More conscious adherence to Covid appropriate behavior among women contributed to substantial gender differences in mortality and women-led countries responded effectively to the pandemic. Hence gender-based public health policies and communication were important in this pandemic as also stated by Klein et al in 2020<sup>5</sup>.

A complex interplay among biological, behavioral, environmental, and socioeconomic factors led to gender -specific COVID-19 outcomes. Sex differences in the immune response to infectious diseases and the role of sex steroids regulating immunity have been reported. It has been proposed that estrogens may exert protective effects against COVID-19 and a clinical trial is underway to determine if estradiol can reduce the severity of COVID-19 infection<sup>6,7,8</sup>. Pandemic related micro-level studies have focused on comorbidities but few studied sociodemographic factors

Knowledge on the association between demographic factors and different severity stages of

COVID-19 such as duration and severity of infection, intensive care unit (ICU) admissions and death was needed to provide differences in underlying pathophysiological mechanisms like immunity, coagulopathy and comorbidities. This knowledge guides clinical decision-making, non pharmaceutical interventions and screening especially when there is a shortage in healthcare resources such as ICU beds as also felt by Brien et al in their study<sup>9</sup>.

These demographic factors may also be important for studying their confounding effect on the design and interpretation of clinical trials and treatment protocols. The aim of this secondary data analysis was to describe the association between demographic factors and COVID-19 in different waves of the pandemic to guide to policy decisions on the health, commercial, social, and financial aspects in case of any future surge in Covid-19 cases.

### Objectives:

1. To describe demographic characteristics and compare all three waves in Pali district.
2. To compare characteristics of District hospital admissions in all three waves.
3. To recommend caution in future epidemics on lessons learnt in all three waves based on key analysis outcomes of this study.

### Methods

- Study Period – 6 months
- Study design: Secondary data analysis of the Hospital admissions and contact tracing data generated between 1<sup>st</sup> March 2020 and February 28<sup>th</sup> 2022 covering all three waves.
- Study area: Department of Community Medicine and Anatomy, GMC Pali
- Data collection and analysis: The data collected during contact tracing (urban and rural) and data of hospital admissions from the hospital medical record during the periods: February 2020 to October 2020 (first wave) and April 2021 to June 2021 (second wave) and December 2021 to February 2022 (Third wave) were analyzed. It was analyzed using excel and SPSS software (Version 22) in terms of proportions, percentage and Chi-Square test was used to compare and contrast the data between the multiple waves.

- Ethical considerations: The study was approved by the Institutional Ethics Committee of Government Medical College, Pali, Rajasthan.

On comparison of the three waves, the second wave in the district had higher ICU admissions and deaths with rural admissions being more and worst affected age was between 15-50 years as seen in Table 1.

## Results

**Table 1: Demographic difference between the three waves in Pali District, 2021**

Variables	Total (n=60357)	First Wave (n <sub>1</sub> =16676)	Second Wave (n <sub>2</sub> =26443)	Third Wave (n <sub>3</sub> =17238)
Male	38060 (63.1%)	10966 (65.8%)	16540 (62.5%)	10554 (61.2%)
Female	22297 (36.9%)	5710 (34.2%)	9903 (37.5%)	6684 (38.8%)
Below 15 years	4663 (7.7%)	1042 (6.2%)	1542 (5.8%)	2079 (12.1%)
15 to 50 years	41871 (69.4%)	10972 (65.8%)	19174 (72.5%)	11725 (68.0%)
Above 50 years	13823 (22.9%)	4662 (28.0%)	5727 (21.7%)	3434 (19.9%)
Urban	16598 (27.5%)	2852 (17.1%)	5198 (19.7%)	8548 (49.6%)
Rural	43759 (72.5%)	13824 (82.9%)	21245 (80.3%)	8690 (50.4%)

**Table 2. Differences seen among rural and urban areas in all three waves of Covid -19 pandemic in Pali District Rajasthan 2021**

Variables	Total (n=60357)	Rural (n <sub>1</sub> =43759)	Urban (n <sub>2</sub> =16598)	P-Value
Gender				
Male	38060 (63.1%)	27767 (63.5%)	10293 (62.0%)	0.001057
Female	22297 (36.9%)	15992 (36.5%)	6305 (38.0%)	
Age				
Below 15 years	4663 (7.7%)	3441 (7.9%)	1222 (7.4%)	0.047106
15 to 50 years	41871 (69.4%)	30249 (69.1%)	11622 (70.0%)	
Above 50 years	13823 (22.9%)	10069 (23.0%)	3754 (22.6%)	

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Hospital					
	Yes	9781 (16.2%)	9171 (21.0%)	610 (3.7%)	<0.00001
	No	50576 (83.8%)	34588 (79.0%)	15988 (96.3%)	
ICU Admitted					
	Yes	665 (1.1%)	622 (1.4%)	43 (0.3%)	<0.00001
	No	59692 (98.9%)	43137 (98.6%)	16555 (99.7%)	
Death					
	Yes	845 (1.4%)	343 (0.8%)	502 (3.0%)	<0.00001
	No	59512 (98.6%)	43416 (99.2%)	16096 (97.0%)	
p-value<0.05 considered significant					

**Table 3. Differences seen among male and female population in all three waves of Covid -19 pandemic in Pali District Rajasthan 2021.**

Variables	Total (n=60357)	Male (n <sub>1</sub> =38060)	Female (n <sub>2</sub> =22297)	P-Value	
Hospital					
	Yes	9781 (16.2%)	6076 (16.0%)	3705 (16.6%)	0.0358
	No	50576 (83.8%)	31984 (84.0%)	18592 (83.4%)	
ICU Admitted					
	Yes	665 (1.1%)	408 (1.1%)	257 (1.2%)	0.8389
	No	59692 (98.9%)	37652 (98.9%)	22040 (98.8%)	
Death					
	Yes	845 (1.4%)	496 (1.3%)	349 (1.6%)	0.00818
	No	59512 (98.6%)	37564 (98.7%)	21948 (98.4%)	
p-value<0.05 considered significant					

## Discussion

Present study conducted is a secondary data analysis of all test screenings and cases of the COVID-19 pandemic in Pali, Rajasthan, India, from January 2020 to May 2021 results showed over 60,357 confirmed cases of COVID-19 and 845 deaths during that 17-month period. Gender showed significant differences- morbidity, hospital admission, ICU admission and death was higher among males. High testing rates led to the identification of more cases in subsequent waves thus, differences in the identified number of cases and the actual number of cases largely depends on the extent of testing and diagnosis as suggested by Baig et al<sup>10</sup>. However, some studies suggest that increase in confirmed cases and deaths due to the corona virus was associated with significantly disturbed market situations, depressed sentiment, implementation of restrictions and lockdowns which contributed to the financial instability and increased illness<sup>10,11</sup>.

In this study comparison of all three waves showed reported cases were higher among males, age group 15 to 50 years, and rural areas. Hospital admission and deaths were highest in second wave while ICU admissions was highest in first wave. However, other global studies have shown more equal distributions between the genders for case frequency, but males surpassed females in intensive care admission and death<sup>12</sup>.

Our study showed the age distribution of COVID-19 cases was similar to worldwide data in which patients were from all age groups. Although in later waves COVID-19 transmission had increased in all age groups, the increase was most significant among the young in Europe and the United States unlike our study where the young continued to be the least affected<sup>13,14</sup>. A significant feature of an infectious disease is its severity, including its ability to cause death. Our overall case-fatality was 0.93 (95%CI 0.83–1.04), which was consistent with worldwide figures. Global figures also showed higher death rates for men compared to women. Male to female fatality rates in countries with available data ranged from 3.5 to 1<sup>13</sup>.

Deaths from COVID-19 have occurred more in the elderly as per our data. The high prevalence of COVID-19 infections and deaths in Spain and Italy

were probably due to older populations. Median population ages for Italy and Spain were 46.5 and 43.5 years respectively, and the percentage over age 65 years were 25% and 20% respectively<sup>13,14</sup>.

In comparing case rates, the potential effect of false negatives and unconfirmed cases between both sexes should be taken into consideration. However, the impact of sex on susceptibility to CoV2 infection cannot be entirely excluded in our studies. Our findings regarding increased mortality in CoV2+ males are consistent with prior reports, suggesting that sex may modify CoV2 infection or susceptibility to experiencing disease caused by this infectious agent<sup>14,15</sup>. Indeed, intrinsic biological differences may be contributing to higher susceptibility to infection and poorer outcomes in males compared to females. Literature suggests that an inherent difference in the activation of an adaptive immune responses in females, including elevated cytotoxic T cell activation and up regulated expression of antiviral and pro-inflammatory genes such as interferon-gamma (IFNG) that have estrogen response elements<sup>16,17,18,19</sup>. Thus, female sex hormones may play a role in the risk reduction for worse outcomes in the setting of COVID-19. Better designed prospective studies are required to confirm the impact of sex on COVID-19 morbidity and mortality.

Origin of the second wave (December 2020–March 2021) has been traced to a wholesale shrimp market of Wuhan, China. There was an increase in new cases during this period attributed to the strain B.1.36.16, which would replace the A.6 strain of the first wave<sup>20</sup>. Dense living conditions in community and the lack of personal precautions to prevent infection spread contributed to spread in clusters and families who were in contact with a confirmed case<sup>21</sup>. During the third wave (April 2021 to September 2021), super spreading events were identified at entertainment establishments. Number of cases increased to more than the first and second waves combined but very few required hospital admissions. Additionally, strain Alpha-B.1.1.7 was presented; which spread much faster than other variants, both strains Beta-B.1.351 and Delta-B.1.617.2 were found during third wave.

Our results indicate that the Second wave was most serious among all the waves but this finding

differs from other studies like from Thailand by Kunno J et al (2020) showing that the first wave of COVID-19 pandemic had the most negative impact on public health<sup>22</sup>. In contrast, the second wave showed unstable evolutionary dynamics. Also, sufficient epidemiologic investigations and contact tracing could not be performed during the third wave, as there was a marked increase in the proportion of unknown routes of transmission<sup>23</sup>

Reason for the clear differences across phases and waves is not yet known, although it has been suggested that the new delta variant of COVID-19 emerged in Pali the middle of 2021, and transmission to the general population was replicated across the country.

This finding was also observed by Matsunaga N et al in a study conducted in Japan where the second wave had a smaller proportion of severe cases (12.0% vs 33.1%) as compared to first wave and Mortality (1.2% vs 7.3%) in hospitalized or discharged patients was also lower in the second wave<sup>24</sup>. A different finding was observed in a study by Fan G et al 2021 and Sigler et al 2021, based on data collected from 53 countries where the second wave had a smaller proportion of fatal cases as compared to first wave<sup>25,26</sup>. Similar finding was observed by Simone I et al (2021) in Spain where the second wave had lower case fatality rate (13.2% vs 24%) as compared to first wave<sup>27</sup>.

## Conclusions

The second wave was the worst in Pali district of Western Rajasthan. In all three waves the males, ages 15-60 years, hospital admissions, ICU admissions and deaths amongst rural population remained higher.

**Recommendations:** Demographic and sex aggregated data analysis ensures better targeting of interventions and limits expensive interventions such as intensive care admissions and avoidable deaths for future waves. Such data is also important for planning vaccination campaigns as the more vulnerable populations are identified as high risk to create an efficient, equitable response to the pandemic, especially in countries where resources are limited. Continuous scrutiny of the roles of gender, age and geography in the outbreak are much needed.

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# Prevalence and Predictors of Psychiatric Disorders in Patients with Epilepsy in a Tertiary Level Care Hospital

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## Abstract

**Background:** Common mental disorders are severe and frequent co-morbid psychiatric illnesses with epilepsy. Different study findings across the world showed that patients with epilepsy have a higher burden of mental disorders than the general population. However, these issues in patients with epilepsy have been consistently undiagnosed.

**Objectives:** The study aimed to screen common mental disorders and the determinants among patients with epilepsy.

**Methods:** An institutional-based cross-sectional study was conducted among patients with Epilepsy from March 10 to May 15, 2021. Patients were assessed for the risk of common mental disorders using a pretested, structured, self-reporting questionnaire (SRQ-20). The collected data were entered into Epi-data version 3.1 software and analyzed using R version 4.0 software. Descriptive statistics were computed using frequency, percent, mean, and standard deviations. A simple logistic regression model was fit to identify the association and strength of exploratory variables and common mental disorders at a 95% confidence interval and p-value < 0.05.

**Results:** The study included 202 patients diagnosed with epilepsy and yielded a response of 91.4%. About 53% of the patients were males. The magnitude of common mental disorders among patients with epilepsy was 57.9% (95% CI: 44.56, 71.24). Being more than one substance user (AOR=5.7; 95%CI: 1.6, 20.7) and Not having social support (AOR=4.3; 95%CI: 1.5, 11.9) were the identified determinants of common mental disorders.

**Conclusion:** The magnitude of common mental disorders among patients with epilepsy were high. Not having social support and khat chewing were the identified risk factors significantly associated with common mental disorders. Early screening and treatments are the key interventions to prevent complications and deaths from common mental disorders.

**Keywords:** epilepsy, mental disorders, psychiatric illness

## Introduction

Mental health is the crucial aspect of health closely allied with the physical and physiological

changing aspects of the human body [1]. A clinically important impairment in a person's cognition, emotion control, or behavior caused by a failure

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in the biological, psychological or developmental processes underpinning mental functioning is known as a mental disorder [2]. As well as insomnia, fatigue, irritability, forgetfulness, difficulty concentrating, substantial distress, impairment of social, or occupational activities, and somatic complaints, mental disorders encompass a wide range of mental disorders that do not fit into standard diagnostic criteria [3].

The World Health Organization reported that mental disorder is the direct risk factor for mortality and morbidity. Psychiatric comorbidities occur in about one-third of patients with epilepsy during the lifespan, and the risk of these comorbidities are much higher in patients with treatment-resistant seizures [4].

Mental disorders have a vital negative impact on the quality of life and living standards of patients with epilepsy. Risk factors for common mental disorders among epileptic patients were being female, young age, marital status, lower-income, unemployment, low educational status, worse QOLIE-89 scores, lack of social support, frequent seizures attacks, side effects of antiepileptic drugs, medication non-adherence, nicotine dependence, alcohol misuse, family history of psychiatric illness, comorbidity of medical condition, duration of illness, and poly-pharmacy [5].

Despite the high burden of common mental disorders among patients with epilepsy, they remain under-investigated and inappropriately treated [6]. Better understanding and treatment of common mental disorders can assist early complication management and better health outcomes for people living with epilepsy. However, the magnitude and determinants of common mental disorders in patients with epilepsy are not determined well in low income countries, including Ethiopia in general and the study area in particular. Therefore, this study aimed to assess the magnitude of common mental disorders and the determinants among patients with epilepsy.

## Methods

This institutional-based cross-sectional study was conducted from March 10 to May 15, 2021.

## Population

The source population for this study was all patients with epilepsy (N=521) attending at the hospital for epilepsy treatment, while the study population was those patients 18 years and older. Those patients who dropped out the treatment, missed the appointment, or transferred out to other health institutions during the data collection period were excluded.

## Sample size determination and sampling procedure

The sample size was determined using the single population proportion formula by considering a 95% confidence level, a 5% margin of error, and a 50% proportion of common mental disorders. Taking the 10% non-response rate and the correction formula ( $N < 10,000$ ), the final sample size was 202. A simple random sampling technique was applied using their medical record numbers. The patients were interviewed and their medical records reviewed.

The patient was screened for common mental disorder using the SRQ-20 dichotomous items (Yes=1, No=0). The likelihood of a common mental disorder was considered when he/she responded to nine or more positive (yes) answers out of the total. Otherwise, the patient was considered not at risk of common mental disorder.

Patients with Epilepsy who scored mean or above of the social support assessing questions (got counseling, financial aid, and or physical support from family, friends) correctly were considered as getting social support. Otherwise didn't get social support.

## Data management and analysis

Data entry, cleaning, and coding were performed using Epi-data version 3.1 software, and the analysis was done using R version 4.0 software. Descriptive statistics were computed using frequency, percent, mean, and standard deviation. Bivariate and multivariate logistic regression analyses were employed to assess the association between the exploratory variables and mental disorders. The strength of the association was measured using the adjusted odds ratio (AOR) and 95% confidence interval (CI). A p-value < 0.05 was considered a statistically significant predictor of common mental disorders.

## Results

### Socio-demographic characteristics of the study participants

A total of 202 patients with epilepsy participated in the study, with a response rate of 91.4%. About 52% and 54% of the patients were males and single. About 20% of the patients were unable to read and write. About one-third of the patients were students. Almost 40% of them were living in rural areas and had a monthly income of fewer than 700 Birrs.

### Seizure characteristics of patients with epilepsy

About 52% of the current and ever substance-using patients were at risk of common mental disorders. Of 35.3% of multi-substance users, 72% were at risk of common mental disorders. Of 20.3% of phenytoin drug users, 76% were at risk of common mental disorders. Similarly, out of 20.3% of patients who had a seizure during treatment, 76% were at risk of having a common mental disorders.

### The magnitude of common mental disorders among patients with epilepsy

The magnitude of common mental disorders among patients with epilepsy was 57.9% (95% CI: 44.56, 71.24).

### Factors associated with a diagnosable mental disorder

On bivariate analysis, occupational status, social support, types of substances used, types of anti-epileptic drugs used, and seizures during treatment were factors associated with common mental disorders at 20% of level of significance. Whereas in the multivariable analysis, only social support and types of substances used showed a significant association with common mental disorders.

For those patients who hadn't received social support, the odds of developing common mental disorders were about four (AOR=4. 3; 95%CI: 1.5, 11.9) times higher compared to those who had. Similarly, for those patients abused by more than one substance, the odds of common mental disorders were about six (AOR=5. 7; 95%CI: 1.6, 20.7) times higher compared to those khat chewers.

## Discussion

This study identified the magnitude of common mental disorders and the determinants among patients with epilepsy attending hospital. The study revealed that 57.9% (95% CI: 44.56, 71.24) of the patients had common mental disorders. This finding was higher than the studies done in northwest Ethiopia (45.2%), Addis Ababa, Ethiopia (27.1%), Mexico (36.6%), Sudan (45.5%), the systematic review (32.71%), Hawassa, Ethiopia (34.2%), and Nigeria (31-37%), respectively. However, it was lower compared to the studies from Burkina Faso (67.3%) and Nigeria (37%)<sup>[6]</sup>. The possible reasons for the difference might be due to differences in the study period, study area, and socio-cultural practice.

The present study showed that patients who had no social support were about fourfold more likely to have common mental disorders (AOR=4. 3; 95%CI: 1.5, 11.9) compared to those who had social support. This finding was consistent with a study done in Ethiopia. This could be explained by the fact that lack of social support might deteriorate the patient's health and quality of life due to fear of lacking support in the future when he/she gets sick.

The study also identified the use of addiction-inducing substances while on anti-epilepsy treatment was significantly associated with common mental disorders. For patients who used more than one substance, the odds of common mental disorders (AOR=5. 7; 95%CI: 1.6, 20.7) were 6 times higher compared to those who used chat. This was supported by a study done in central Ethiopia <sup>[7]</sup>. The possible justification for this typical finding might be that the content of chemicals in more substance users might bring a higher risk of common mental disorders than only chat users when taken along with anti-epileptic drugs.

The findings of this study indicate that common mental disorders are common co-morbidities in patients with epilepsy. Healthcare professionals should assess and treat psychiatric and physical co-morbidities among patients with a history of seizures to improve patient health outcomes. The families of patients with epilepsy should be made aware of the disorders and their related psychological co-morbidities so that the patients can receive sufficient support from their families.

### Conclusion

The risk of common mental disorders among patients with epilepsy was high. Social support and the type of substances used were the identified factors significantly associated with the risk of common mental disorders.

**Declaration of Ethical clearance** Taken from ethical committee of institute

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## A Socio-demographic and Clinical Study on Surgical Cases in a Tertiary Care Teaching Hospital, Suraram, Hyderabad

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### Abstract

A descriptive study on surgical case profile related to socio demographic and clinical aspects was conducted in a tertiary care teaching hospital Hyderabad, Telangana. This was a retrospective and record based study. A total of 885 case sheets were collected from Medical record department among which 488 were males and 397 were females. In-patient surgical case sheets were collected from 1<sup>st</sup> July 2021 to 30<sup>th</sup> June 2022 for a period of one year after obtaining permission from the Institutional Ethics Committee. Absolute professional secrecy was maintained. All inpatient case sheets from department of Surgery were collected from the medical records and considered for this study. The study results were evaluated and analyzed by SPSS software.

We found that highest number of patients admitted was in the age group of 31 to 50 years. Co-morbid conditions like hypertension and diabetes (23.9%) was associated with surgical conditions. Majority of patients were from urban locality (62.7%). Pain abdomen (36.3%) followed by swelling both inflammatory and tumor (35.5%) were the common clinical presentations at the time of admission. Highest cases of surgical conditions in our study were inflammatory swellings (17.9%), followed by benign tumors (17%), hernias(12.4%), appendicitis 9.2%, cholecystitis and cholelithiasis (9%), acid peptic diseases (7.2%) and renal calculi contributing 6.3%. Of the malignant conditions (3.16%) noticed, carcinoma of breast was common in females and oral cancers were commonest in males. Inguinal hernias were common in males and incisional hernias were common in females. Highest number of cholecystitis and cholelithiasis were observed in female population. Mean hospital stay was 6 days in our study. Most of the cases were reported in rainy season and treated conservatively (50.7%), very least genetic predisposition (0.4%) was observed in the study population. Study results were similar when compared with other studies conducted in India and abroad.

**Key words:** Socio demographic profile, clinical profile, surgical cases.

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## Introduction

The role of surgery in the public health agenda has increased in prominence since a decade and attempts to quantify surgical capacity suggest that it is a significant public health issue. Surgery has become an integral part of global health care, with an estimated 234 million operations performed yearly. The Lancet Commission for Global Surgery (LCoGS) estimated that 5000 surgeries are required to meet the surgical burden of disease for 100,000 people<sup>1</sup>. Indian population has compared to the global estimate of 5000 surgeries per 100,000 people. One-third of these surgeries would be needed for the age group 30-49 years, in the Indian population.

The WHO in 2002 reported that 11% of the entire disease burden was attributable to surgically treatable conditions<sup>2</sup>. The surgical disease burden of India is increasing day by day, a total of 4642 surgeries were performed per year for a population of 88,273. Cataract (22.8%), Caesareans (3.8%), surgeries for fractures (3.27%) and hernia (2.86%) were the commonest surgeries. 44.2% of surgeries belonged to the essential surgeries<sup>3</sup>.

Studies conducted on socio economical status in relation to the disease burden revealed a great disparity between developed and under-developed countries. The mortality among low socio economic individuals in relation to surgical conditions is very high compared to higher economic individuals. Socio demographic studies are useful to explain the incidence and prevalence of diseases in the community, can also explain the prevalence of disease and its mortality in the geographic area.

The aim of the study is to describe the socio-demographic and clinical pattern of surgery inpatient cases admitted in a tertiary care teaching hospital with the following objectives.

- To study the most common cases admitted in the General surgery department.
- To explain the socio-demographic details in relation to the diseases of surgery.
- To study various clinical presentation in relation to the surgical diseases.
- To identify postoperative complications and the mortality.

This study is helpful to identify the most common surgical cases reporting to the institution and to establish a better diagnostic and management protocol, which will be useful to reduce the morbidity and mortality.

## Material and Methods

A Descriptive cross sectional and retrospective study on socio-demographics and clinical pattern on surgical cases was conducted in a tertiary care teaching hospital, Hyderabad Telangana. In patient surgical case sheets were collected from 1<sup>st</sup> July 2021 to 30<sup>th</sup> June 2022, for a period of one year from the Medical record department of the hospital, 885 in patient case details were collected after obtaining permission from the Institutional Ethics Committee. The name of the patient was not revealed and absolute professional secrecy was maintained. All inpatient case sheets from department of Surgery collected from medical records was considered for this study.

The following data was collected from the case sheets.

- IP Number, Age, Sex, Marital status, Locality and Religion. Educational qualification.
- Nutritional habits, any seasonal distribution.
- Smoking, alcohol and other addictions.
- Any genetic pre disposition of the disease and associated co-morbid conditions if present.
- Clinical presentations of each case reporting to the hospital.
- Diagnostic methods used to evaluate the disease.
- Number of cases treated conservatively, number of cases treated with surgery.
- Any postoperative complications developed. Any specific treatment protocol followed.
- Duration of stay in hospital. Any cases referred to higher centers and reasons.
- Cases advised rehabilitation. Cases discharged with full recovery
- Cause of death if any during first 24 hrs of surgery.
- Cause of death if any during postoperative period.

All the above data was taken in to excel sheet in a pre-structured pro-forma and was statistically analyzed by using SPSS (version 21).

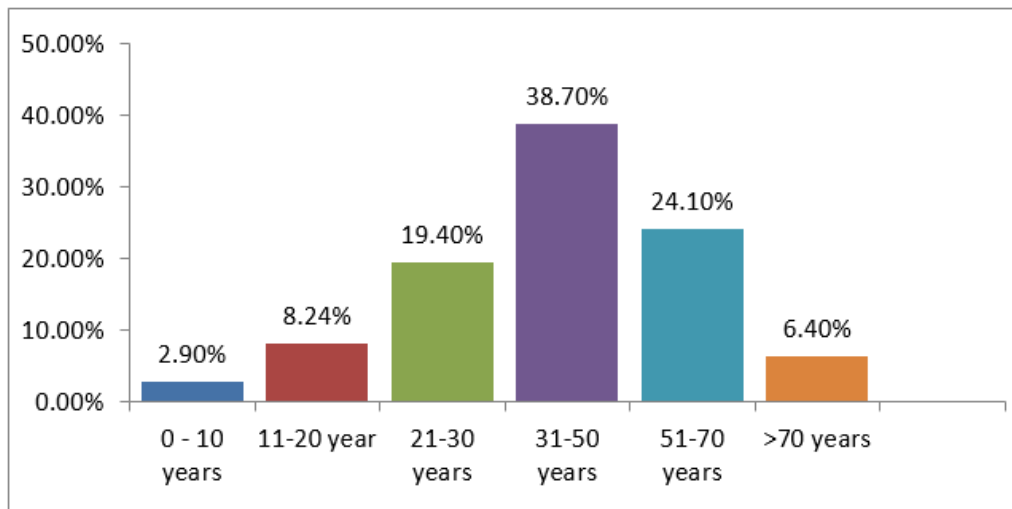
## Results

A descriptive and retrospective study on socio

demographic and clinical profile of surgical cases was conducted in a tertiary care teaching hospital in Hyderabad Telangana. 885 case records were collected from Medical record department among them 488 were males and 397 were females and the following results were found.

**Table 1: Socio demographic details of study population.**

Socio-demographic details	Findings	Socio-demographic details	Findings
Study population	Male - 488, Female - 397	Seasonal distribution of cases	Rainy - 64.10% Winter - 30% Summer - 5.90%
Religion	Hindu - 86.75% Muslim - 12.7% Christian - 0.45%	Personal habits	No habits - 81.4% Smoking & Alcoholism - 18.6%. Drugs - 0.3%
Genetic predisposition	No - 99.6% Yes - 0.4%	Reporting cases	New - 97.1% Recurrence - 2.9%
Locality	Urban - 62.7% Rural - 37.3%	Nutritional habits	Mixed diet - 97% Vegetarians - 3%
Choice of treatment	Conservative- 50.7% Surgery - 49.3%	Outcome	Discharge with full recovery - 97%, Referral - 2.7%



**Figure-1: Age wise distribution of study population.**

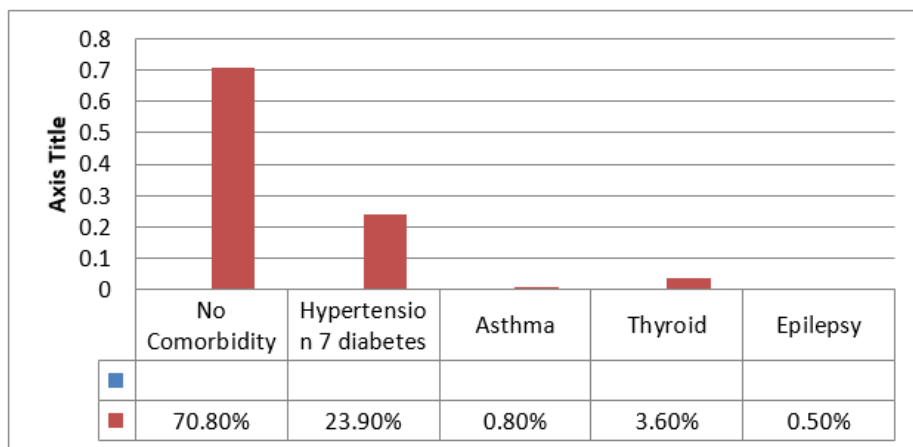


Figure 2: Showing Co-morbidity associated with study population.

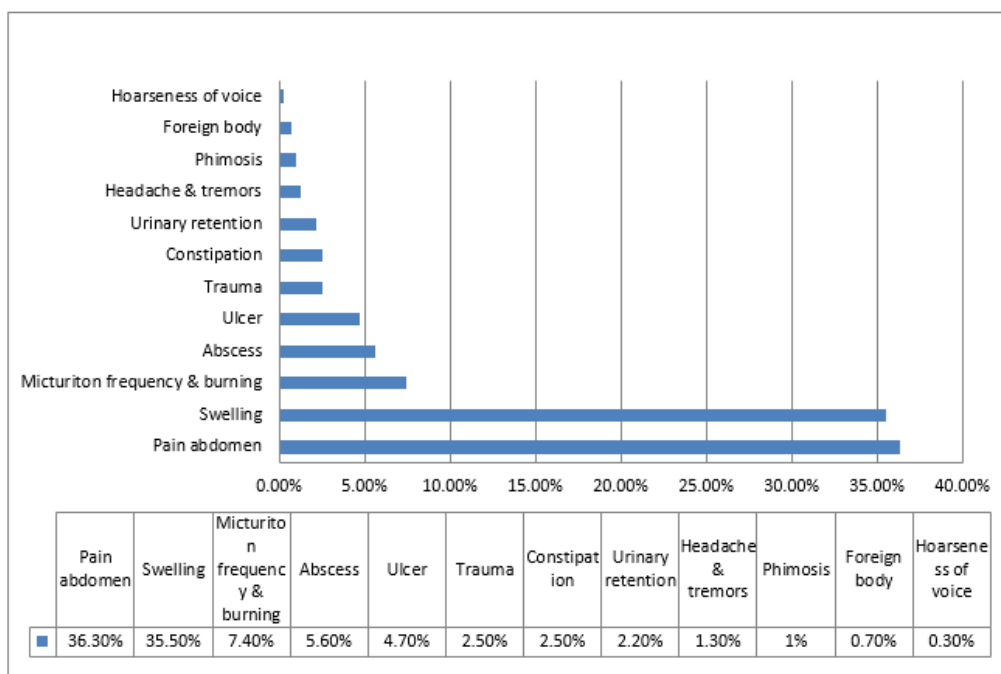


Figure-3: Clinical presentation in a study population.

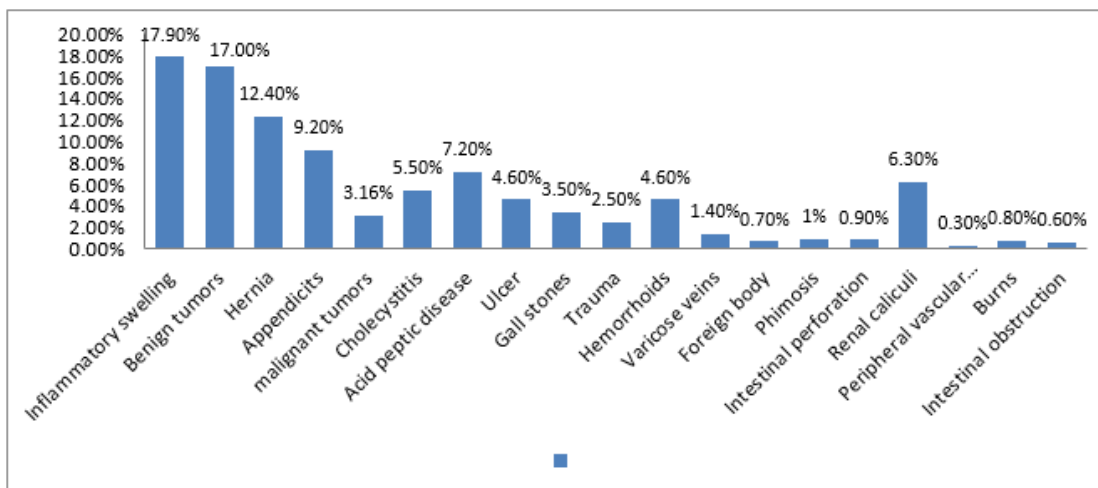


Figure-4: Surgical case diagnosis details in study population.



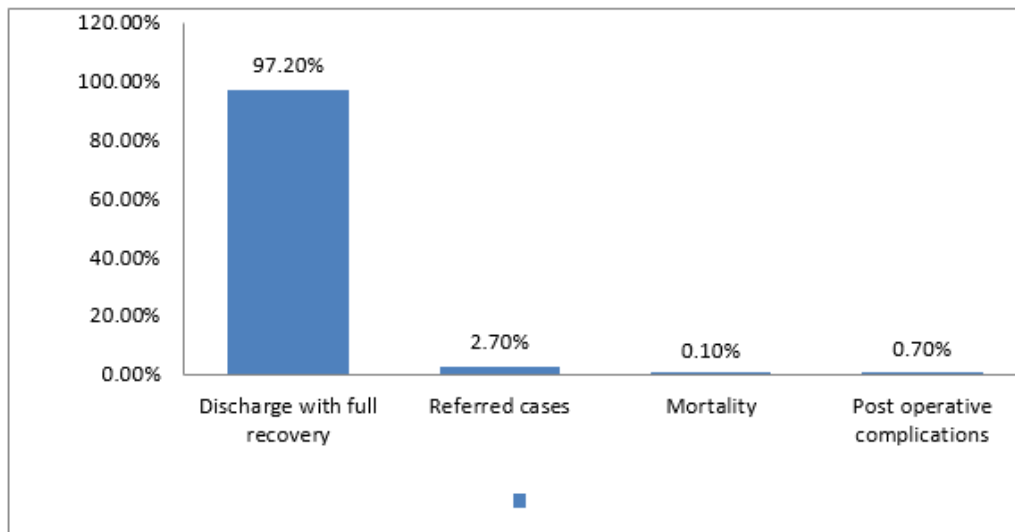


Figure -5: Showing surgery outcome in study population.

### Discussion

A descriptive and retrospective study on socio demographic and clinical profile of surgical cases was conducted in a tertiary care teaching hospital in Hyderabad Telangana. A total of 885 case sheets were collected from Medical record department among which 488 were males and 397 were females. The study results revealed that the age wise distribution of study population showed the highest number of cases (38.8%) were in the age group of 31 to 40 years and lowest number of cases reported was in the age group of 1 to 10 years.

Highest number of population 86.75% belonged to Hindu religion whereas Muslims were 12.7% and Christians were 0.45%. Majority of the patients 62.7% belonged to urban area and 37.3% were from rural area. Regarding nutritional habits, 97% were consuming mixed diet and 3% were vegetarians.

Among seasonal distribution of cases, majority of the cases, 64.10% reported during rainy season, winter contributes 30% and less number of cases 5.90% were reported in summer. Statistics relating to personal habits showed 81.4% as not having any habits, 18.6% were known smokers and alcoholics whereas 0.3% was addicted to drugs. 99.6% of study population did not have any genetic predisposition, only 0.4% cases showed genetic predisposition.

Most of the patients attended the hospital with a clinical presentation of pain abdomen, 36.3% of study population presented with this complaint at the time of admission, swelling was the second highest 35.5% and burning micturition with frequency reported

third highest 7.4%. Other clinical presentations were abscess 5.6%, ulcer 4.7%, constipation and injuries 2.5% each, urinary retention 2.2%, trauma with headache 1.3%, Phimosis 1% and hoarseness of voice 0.3%. Majority of the cases around 97.1% reported were new cases whereas recurrent cases reported were 2.9% only.

In regard to clinical diagnosis, inflammatory swellings were predominant in our study population, 17.9% of cases were reported, among which cellulitis and abscess were predominant. Benign tumours were second highest (17%), in which lipomas were highest followed by fibro adenomas and thyroid nodule. Hernia placed in third row 12.4%, among which, inguinal hernia was the most common hernia observed in males, whereas incisional hernia was observed as commonest in the female population. Appendicitis was the 4<sup>th</sup> most common condition (9.2%) observed in our study, highest number was observed in male population. Acid peptic diseases ranked 5<sup>th</sup> commonest in our study, highest number observed in male population. Renal calculi were reported as the 6<sup>th</sup> commonest clinical condition; slight male preponderance was noticed in our study. Cholecystitis was the 7<sup>th</sup> common disease and more common in female population in our study. Ulcers and Haemorrhoids were 4.6% each in 8<sup>th</sup> position and Gallstones 3.5% in ninth position was noticed. Other clinical conditions reported were malignant tumours (3.16%), varicose veins (1.4%), Phimosis (1%), intestinal perforation (0.9%), burns (0.8%), foreign bodies (0.7%), intestinal obstruction (0.6%) and peripheral vascular diseases (0.3%) in our study. Among malignant tumours, carcinoma of breast was

highest in female population and oral cancers were highest in male population.

Regarding treatment of cases, 50.7% of cases were treated conservatively whereas 49.3% of cases were treated with surgery, proper treatment protocol was followed in every case. 38.8% of patients had hospital stay for more than one week, 31.1% stayed for 3 days to 1 week, 21.1% stayed for 2 to 3 days and 8.4% stayed for less than 24 hours.

0.7% of surgically treated patients developed post operative complications, 2.7% were referred to higher centres and only one case 0.1% died in the hospital during the first post operative day. 97.2% patients were discharged with full recovery. Lowest mortality may be due to referrals of high risk cases.

A study conducted by Adefemi Oladiran and Afolabi<sup>4</sup> at department of surgery, University college hospital Ibadan, Nigeria. The most commonly performed surgical procedures observed in their study were laparotomies (30.06%), biopsies (29.70%) and herniorrhaphies (11.40%). Hernia was noticed as the 3<sup>rd</sup> most common condition reported in their study, similar results were found in our study.

A study conducted by Prashant D Pawar, Aniruddha A. Malgaonkar<sup>5</sup> at Department of Surgery, Rajiv Gandhi Medical College, Thane, India shows abdominal pain was the most common presenting symptom with 11.82%. Similar results were observed in our study.

A study title Abdominal wall hernias epidemiological profile was conducted by Bharati Pandya and Tanweerul Huda<sup>6</sup> et al at Mahatma Gandhi Institute of Medical Sciences Sevagram revealed that inguinal hernias was the most common surgical condition (80%) followed by incisional hernias, whereas in our study among hernias, inguinal hernia was the most common surgical condition followed by incisional hernia was observed.

A study on age of patients undergoing surgery was conducted by A J Fowler<sup>7</sup> and T E F Abbott at England from 1999 to 2015 shows highest number of surgeries were observed in the age group of above 75 years but in our study we found 31 to 50 years age group are highest. Mean duration of hospital stay in their study was 5 days whereas in our study it was 6 days.

### Conclusion

Abdominal pain was the most common presenting complaint followed by swelling as observed in the

present study, inflammatory swellings were the predominant surgical conditions followed by tumors and hernias. Cellulitis and abscess reported highest in inflammatory swellings, among hernias inguinal hernias reported highest in males and incisional hernias were highest in females. Appendicitis was the fourth common condition and highest number was observed in male population. Acid peptic diseases ended up being the fifth common condition, renal calculi was sixth common condition and cholecystitis was seventh common surgical condition observed in our study. Female preponderance was observed in cholecystitis. Several studies conducted in India and abroad also showed similar results.

**Conflict of interest:** Nil

**Ethical clearance:** Yes, obtained permission from Institutional Ethics Committee.

**Source of fund:** Self

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# Demographic, Clinical and Etiological Profile of Children Admitted with Febrile Seizures in a Tertiary Care Hospital of North India

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## Abstract

This retrospective hospital-based study was conducted in Paediatric emergency from 1<sup>st</sup> June 2022 to 30<sup>th</sup> November 2022 to study the clinical demographic and etiological profile of paediatric patients admitted with febrile seizures.

Out of total enrolled 243 children, 153(63%) were male and 100(37%) were females. Mean age of the patients was 23.5 months. Mean time interval between onset of fever and occurrence of seizures was 18 hours. Overall, 170(70%) patients had simple seizures. Only 85(35%) patients had positive family history and 73(30%) had recurrence of seizures during the same episode of illness. Acute respiratory infection was the commonest cause for febrile seizure in 190(78%) children.

**Keywords:** Febrile seizure, Children, Age

## Introduction

Febrile seizures are seizures that occur between the age of 6 and 60 months with a temperature of 38°C (100.4°F) or higher, that are not the result of central nervous system infection or any metabolic imbalance, and that occur in the absence of a history of prior afebrile seizures. Febrile seizures are among the leading causes of paediatric emergency hospital admissions and affect 2- 5% of neurologically healthy infants and children<sup>[1]</sup>. The peak incidence in children is between 12 months and 18 months of age<sup>[2]</sup>. This study was planned to evaluate the febrile seizure epidemiology and risk factors, clinical presentations, as well as triggers commonly implicated in febrile seizures.

## Methods

The prospective hospital-based study was conducted in the Paediatrics Department of Government Medical College Jammu, Jammu and Kashmir. Children reporting in paediatric emergency with fever provoked seizures were screened for Febrile Seizure as per definition. Those included in the study were children aged 06-60 months admitted with Febrile Seizure diagnosis. Those with age < 6 months or > 60 months, afebrile seizures, CNS infections, developmental delay, electrolyte imbalance, known cases of inborn error of metabolism and known cases of chronic diseases were excluded from study.

A total of 243 patients were included in the study over a period of 6 months from 1<sup>st</sup> June 2022 to 30<sup>th</sup> November 2022. The sample was irrespective

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of gender, race, ethnicity, geographical distribution and socioeconomic status. Informed written consent of parents and approval of institutional ethical committee were obtained. Data was collected using a predesigned proforma. Simple Febrile Seizure was defined as a generalised seizure with no focal seizure activity or focal manifestations during the postictal period, lasting less than 15 minutes and not recurring within the next 24 hours or during the same febrile illness. A Complex Febrile Seizure was defined as a seizure with features suggestive of focal activity at the onset, during or in the postictal period or a seizure lasting more than 15 minutes or a seizure that recurred within 24 hours or within the same febrile illness. Frequency and percentage were calculated for qualitative variables like age, gender, family history, type of Febrile Seizure.

### Results

Of the 243 cases, 153(63%) were male and 100 (37%) were female with male-to-female ratio being 1.5:1. In terms of age, 146 (60%) patients were in the 19-24-month group, and the mean age of the patients was 23.5 months. Only 85 (35%) patients had positive family history of Febrile seizure and 73(30%) had recurrence of seizures during the same episode of illness. Besides, 158(65%) patients had only one episode of seizure during the illness. Single-episode category patients had increased frequency of simple seizures. ARI was the commonest cause in 190(78%) patients, acute gastroenteritis in 30 (12%) patients, enteric fever in 12 (5%) , urinary tract infection in 4 (1.65%) and dengue in 5 (2%) patients.

### Discussion

Our documented mean age of onset of seizures is consistent with various studies<sup>[3,4,5,6]</sup>. Febrile Seizure usually occurs within first 24 hours of onset of fever and our study results are consistent with results of earlier studies<sup>[7,8]</sup>

Majority of our patients had first episode of seizure and it is in line with results reported earlier<sup>[9]</sup>

### Conclusion

Majority of patients were male and presented within the first 24 hours of fever, with first episode

and simple FS. Anaemia, malnutrition, raised TLC were found to be FS risk factors. Further studies are needed to assess the association of FS with malnutrition and bacterial infections.

**Funding:** Nil

**Conflict of Interest:** Nil

**Ethical clearance:** Ethics committee of Gmc Jammu

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# A Study of Maternal Outcomes in Post Dated Pregnancy

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## Abstract

**Background:** Post-dated pregnancy may be associated with perinatal complications like fetal distress, meconium aspiration syndrome and fetal asphyxia. This study was designed to study maternal outcomes in post dated pregnancy (or beyond 40 weeks gestation).

**Materials & Methods:** Real time ultrasound scanning was performed using (Philips EPIQ 5G, Philips EPIQ 7G and Philips affinity 50 G model) 1-5 MHz biconvex probe and general survey of foetus was done. Total 114 pregnant women beyond 40 weeks of gestation were studied. A detailed clinical history like menstrual history, marital, family history of the pregnant women included in the study was taken. For induction, cervical ripening agents like dinoprostone gel or misoprostol tablets were used. Then the patients were observed for uterine contractions and strict foetal heart rate monitoring was done.

**Results:** In this study total 114 cases beyond 40 weeks of gestation were analyzed to know the maternal and foetal outcome in post-dated pregnancies. Majority of the postdated pregnancies 102 (89.5%) were in between 40 weeks -40 weeks 6 days. Primigravida were 55.3% while only 44.7% were multigravida. Out of total 114 patients having pregnancies beyond 40 weeks of gestation, 67.6% were delivered vaginally while 32.4% underwent lower segment caesarean section. Majority (65.8%) of patients had Bishops score  $\leq 4$ , Bishops score  $> 6$  (20.2%), Bisops score in between 5-6 (14%). Incidence of meconium stained liquor was 6.1%.

**Conclusion:** Post-dated pregnancy is a high risk pregnancy, so correct dating is done by early first trimester USG or by second trimester USG so that induction can be done at 40 weeks and timely detection of foetal distress and management can be safely introduced.

**Keywords:** Term pregnancy, post dated pregnancy, induction, maternal complications, maternal outcomes

## Introduction

A post dated pregnancy is the one which extends to or beyond 40 weeks or 280 days from the first day of the last menstrual period (LMP) and has an incidence of 4% to 14%.<sup>1</sup> A Post term or prolonged pregnancy (PTP) is the one which extends to or beyond 42 weeks

or 294 days from the first day of the last menstrual period.<sup>2</sup> Post-dated pregnancies may be the result of error of last menstrual period (most common), previous history of prolonged pregnancy, maternal obesity, more common in primigravida, male fetus, older maternal age, maternal race/ethnicity (non-Hispanic White women are at higher risk than

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African American, Hispanic, and Asian women), placental sulfatase deficiency (X-linked recessive disorder) which result in reduced placental estrogen synthesis. This leads to poor expression of oxytocin and prostaglandins receptors in myometrium.<sup>3,4</sup>

The criteria for diagnosing post-dated pregnancy are correlation of menstrual history, clinical findings and ultrasonography (USG). Ultrasonographic dating in early pregnancy can improve reliability of expected date of delivery (EDD). Sonography is most useful when performed before the 20<sup>th</sup> week of gestation, with measurement of the crown-rump length in the first trimester as the most accurate parameter. Menstrual recall, early palpation of uterine size and Doppler auscultation of foetal heart sound are less accurate but helpful methods used to determine the estimated date of delivery.<sup>5,6</sup>

In post dated pregnancy, there are chances of foetal hypoxia, asphyxia, intracranial damage, meconium aspiration syndrome (MAS), macrosomia, atelectasis, septicaemia, hypoglycaemia, stillbirths, birth injuries, jaundice, respiratory distress syndrome. These perinatal risks increase with increase in the gestational age beyond 40 weeks.<sup>7</sup> The maternal risks include an increase in labour dystocia, maternal trauma such as severe perineal injury related to macrosomia and operative vaginal delivery and an increase in the rate of caesarean delivery, instrumental delivery, maternal mortality and postpartum haemorrhage.<sup>8</sup> Proper management is a prerequisite to reduce the rate of perinatal mortality and morbidity in this group of patient. This study was designed to study maternal outcomes in post dated pregnancy (or beyond 40 weeks gestation).

### Materials & Methods

The observational study was conducted in the Department of Obstetrics and Gynaecology, Himalayan Institute of Medical Sciences (HIMS), Swami Ram Nagar, Dehradun, over a period of one year. Subjects were recruited from patients presenting in Obstetrics and Gynaecology OPD, IPD and Emergency at HIMS, Dehradun with post dated pregnancy after obtaining written informed consent and ethical clearance from the institute of ethics committee.

### Inclusion Criteria

Pregnant women more than 40 weeks of gestation, singleton pregnancy, and cephalic presentation

### Exclusion Criteria

Congenital anomalies of foetus, chronic hypertension, pre-eclampsia and eclampsia, pre existing or gestational diabetes, heart diseases, antepartum haemorrhage, multiple gestation, non-vertex presentation and previous LSCS.

Real time ultrasound scanning was performed using (Philips EPIQ 5G, Philips EPIQ 7G and Philips affinity 50 G model) 1-5 MHz biconvex probe and general survey of foetus was done. Total 114 pregnant women beyond 40 weeks of gestation were studied. A detailed clinical history like menstrual history, marital, family history of the pregnant women included in the study was taken. The patients were evaluated by calculating the exact gestational age which was calculated by using Naegele's formula (add seven days to the first day of the last menstrual period and count forward by nine months or count back three months) in women with regular menstrual cycles.<sup>9</sup> Initially labour was assessed for spontaneous delivery. If it failed Bishop's score was used to assess the induction of labour.

For induction, cervical ripening agents like dinoprostone gel or misoprostol tablets were used. Then the patients were observed for uterine contractions and strict foetal heart rate monitoring was done. After 6 hrs of dinoprostone gel instillation or 4 hrs of misoprostol tablet induction, per vaginal examination was done. If cervix was favourable, oxytocin augmentation was done after assessing the uterine contraction. On admission Non-stress test was done of each patient. Bishop score  $\geq 6$  was regarded as favourable and score of  $< 6$  was regarded as unfavourable.<sup>10</sup> Decision for caesarean section or instrumental delivery was taken according to the foetal heart rate and the progress of labour. Record was kept about the mode of delivery and if any post partum maternal complication occurred they were labelled under maternal morbidity.

The data were collected and entered in MS excel 2010. Different statistical analysis were performed using SPSS software version 22. The one

sample Kolmogorov –Smirnov Test was employed to determine whether the data sets differed from a normal distribution or not. Normally distributed data were analyzed using parametric tests and non-normally distributed data were analyzed using non-parametric tests.

## Results

All 114 patients were studied and maternal outcome in the form of complications were identified.

**Table 1: Distribution of cases according to gestational age and type of vaginal delivery (N=77)**

Gestational age (weeks)	Total no. of vaginal delivery (n=77)	Induced labour (n=35) (%)	Spontaneous labour (n=42) (%)
40 w-40w 6d	67	32 (47.8%)	35 (52.2%)
41 w-41w 6d	7	2 (28.6%)	5 (71.4%)
>42 w	3	1 (33.3%)	2 (66.7%)

In the present study, out of total 77 vaginal delivery, 42 patients went into spontaneous labour

Foetal outcome in the form of complications and duration of NICU stay were observed. In our study majority of cases were between 20 to 35 yrs of age (98.2%), 1 (0.9%) was less than 20 yrs of age, 1 (0.9%) was more than 35 yrs of age. Majority of the cases 102(89.5%) with post-dated pregnancies were between 40 weeks to 40 weeks 6 days gestational age, only 9 (7.9%) were between 41 weeks to 41 weeks 6 days and 3 (2.6%) were more than 42 weeks.

and delivered vaginally while 35 patients delivered vaginally through induced labour [Table 1].

**Table 2: Distribution of cases according to mode of delivery (N=114)**

Mode of Delivery	Number of cases	Percentage (%)
Vaginal Delivery	77	67.6
Caesarean Section	37	32.4

Out of total 114 cases who were postdated, 77 (67.6%) had vaginal delivery, while 37 (32.4%)

underwent caesarean section [Table 2].

**Table 3: Distribution of cases according to spontaneous onset of labor and vaginal delivery (N=51)**

Gestational Age (weeks)	Parity	Spontaneous Labour	Delivered Vaginally %	%
40w - 40w 6d	Primi	17	13	76.5
	Multi	24	22	91.7
41w - 41w6d	Primi	7	4	57.1
	Multi	1	1	100
≥42w	Primi	0	0	0
	Multi	2	2	100
Total		51	42	82.4

In this study 51 cases went into spontaneous labour, out of which 42 (82.4%) delivered vaginally.

Multigravida had higher incidence of vaginal delivery following spontaneous onset of labour [Table 3]

**Table 4: Distribution of cases according to vaginal delivery after induction (N=50)**

Gestational Age (weeks)	Parity	Labour Induced	Delivered Vaginally	%
40w - 40w 6d	Primi	30	18	60
	Multi	17	14	82.4
41w - 41w6d	Primi	1	1	100
	Multi	1	1	100
≥42w	Primi	0	0	0
	Multi	1	1	100
Total		50	35	70

In the present study, Labour was induced in 50 patients out of which 35 (70%) delivered vaginally. Multigravida had higher incidence of vaginal delivery

following induction of labour. Overall (N=114), 35 patients (30.7%) patients were delivered vaginally after successful induction [Table 4].

**Table 5: Distribution of cases according to BISHOPS Scoring (N=114)**

Gravida Gestational	Age (weeks)	BISHOP Score		
		≤4 (%)	5-6%	>6%
PRIMI n=63	40 WK - 40 WK 6D n=56	44 (78.6%)	6 (10.7%)	6(10.7%)
	41WK - 41W 6D n=7	4 (57.1%)	1(14.3%)	2(28.6%)
	> 42WK n=0	0	0	0
MULTI n=51	40 WK - 40 WK 6D n=46	25(54.3%)	7(15.2%)	14(30.5%)
	41 WK-41WK 6D n=2	1(50%)	1(50%)	0
	> 42W n=3	1(33.3%)	1(33.3%)	1(33.3%)
Total = 114		75 (65.8%)	16 (14%)	23 (20.2%)

In the present study, both in primigravida and multigravida Bishop score was ≤ 4 in 75 patients (65.8%) which was maximum, Bishop Score of >6 in 23 patients (20.2%) and Bishop Score of 5-6 in 16 patients (14%) [Table 5].

**Table 6: Distribution of patients according to maternal complications (N=114)**

Maternal Complications	No. of cases
Cervical/Lateral injury	6 (5.26%)
PPH	7(6.14%)
Wound Infection	1(0.87%)
Mortality	0
Total (n=14)	12.28%

In the present study, maternal complications like cervical injuries, Lateral vaginal wall injuries were found in 6 patients (5.26%), PPH was seen in 7 patients (6.14%), wound infection in 1 patient (0.87%). No maternal mortality was reported [Table 6].

## Discussion

In the present study majority of the women 98.2% were included in the age group of 20-35 years, 1 (0.9%) patient was < 20 yrs of age and 1 (0.9%) was > 35 yrs of age. A study was conducted by Sonali, Rai A et al<sup>11</sup> in 2020 where maximum number of patients belonged to the age group of 25-30 years (54.17%). A similar study conducted by Dobariya PV et al<sup>12</sup> in 2017, in which there were 58 (69.05%) patients in age group 20 to 30 years. Another study by Akhtar P et al<sup>13</sup> was conducted in 2014, on pregnancy beyond 41 weeks of gestation where they found that 82% of patients were in the age group of 18 to 29 years. So various studies shows that majority of the postdated pregnancy occurs between 20-35 years of age which is similar to our study. This may be because mostly reproduction occurs in this age group in our country.

It was observed in the present study that majority of the patients 102 (89.5%) with postdated



pregnancies were seen in gestation between 40 weeks -40 weeks 6 days, only 9 (7.9%) were between 41 weeks-41 weeks 6 days and 3 (2.6%) were more than 42 weeks. A study conducted by Sonali, Rai A et al<sup>11</sup> in 2020 found that the maximum number of patients (77.5%) belonged to the gestational age of 40-41 weeks of gestation. A similar study conducted by Francis S<sup>14</sup> in 2015 showed that 89.5% of pregnancies were between 40-40 weeks 6 days, 7.5% between 41-41 weeks 6 days and 3% were beyond 42 weeks period of gestation. A study similar to our study by Patel N, Modi P<sup>15</sup> in 2015 showed that 76% were between 40-41 weeks of gestation, followed by 16 % between 41-42 weeks of gestation and 8% were in >42 weeks of gestation. Thus results of various studies are similar to our study. Present study revealed majority 55.3% were primigravida while 44.7% were multigravida which is similar to the study conducted by Sonali, Rai A<sup>11</sup> in 2020 in which they found that 62.5% of the patients were primigravida. A similar study was conducted by Agrawal S et al<sup>16</sup> in 2020 in which they found that 63.3% were primigravida however 14.9% were multigravida. Another similar study by Mahapatro et al<sup>17</sup> in 2015 showed that maximum 72% of patients were primigravida. This study is similar to various studies and this can be explained by the fact that nulli-parity increases the risk of prolonged pregnancy.

In the present study, 67.6% post-dated females were delivered vaginally, while 32.4% were delivered by Lower segment caesarean section. A study was conducted by Lata, et al<sup>18</sup> in 2019 and they observed that vaginal delivery occurred in 68 % patients and 32% were delivered by LSCS. In another study conducted by Kandalgaonkar VP et al<sup>19</sup> (2019) it was found that 78.12% had vaginal delivery and 16.7% patient had LSCS. Another study which supported our study was conducted by Shinge N et al<sup>20</sup> in 2013 which showed that 53.7% underwent spontaneous vaginal delivery and 37% patients required caesarean section as mode of delivery. So results of our study are similar to various other studies.

In the present study, 77(67.6%) post-dated females were delivered vaginally and 51 patients went into spontaneous labour, out of which 42 spontaneously delivered vaginally (36.8%). Multigravida had higher incidence of vaginal delivery following spontaneous

onset of labour and labour was induced in 50 patients out of which 35 delivered vaginally (30.7%). Multigravida had higher incidence of vaginal delivery following induction of labour. In a study by Kandalgaonkar VP et al<sup>19</sup> maximum patients 80 (78.12%) underwent vaginal delivery, of which 45 (46.9%) delivered spontaneously and 35 (36.5%) delivered vaginally after successful induction. In a similar study in 2018 on 'maternal and perinatal outcome in pregnancy beyond 40 weeks' by Begum MM et al<sup>21</sup> it was observed that out of 56 vaginal delivery 48 patients delivered between 40.1 weeks and 41 weeks of gestational age, out of 48 cases 22 (45.8%) progressed and delivered spontaneously, and 26 cases (54.2%) delivered after induction of labour. In a similar study in 2017 by Ritika et al<sup>22</sup> found that 28% had successful spontaneous vaginal delivery and 72% had induced deliveries respectively. In a similar study in 2013 by Shinge N et al<sup>22</sup> found that maximum patients (53.7%) underwent spontaneous vaginal delivery. In another study in 2006 by Caughey AB et al<sup>23</sup> found that maximum patients (68%) underwent spontaneous vaginal delivery. So results of our study have correlated with various other studies.

Poor Bishop's score is associated with failure of induction and lesser chances of vaginal delivery. In the present study Bishop Score was  $\leq 4$  was seen in maximum patient (65.8% overall) followed by Bishop Score of  $>6$  in 20.2% and Bishop Score of 5-6 (14%) including both primigravida and multigravida. In a study by Kandalgaonkar VP et al<sup>19</sup> maximum patients had Bishop's score less than 4 and they needed further intervention by induction of labour by either tablet misoprostol or dinoprostone gel or augmentation of labour by oxytocin infusion.

## Conclusion

Post-dated pregnancy is a high risk pregnancy, so correct dating is done by early first trimester USG or by second trimester USG so that induction can be done at 40 weeks and timely detection of foetal distress and management can be safely introduced. Most common maternal complication noted was PPH followed by cervical injuries. Vaginal delivery rate was the maximum in patients who went into spontaneous labour as compared to those who were induced. Failure of induction followed by fetal

distress is the most common indication of caesarean section in post dated pregnancy.

**Conflict of interest:** None

**Funding source:** Self financed

**Ethical Clearance:** Approved by the IEC, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun

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# Clinical Based Feedback

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## Abstract

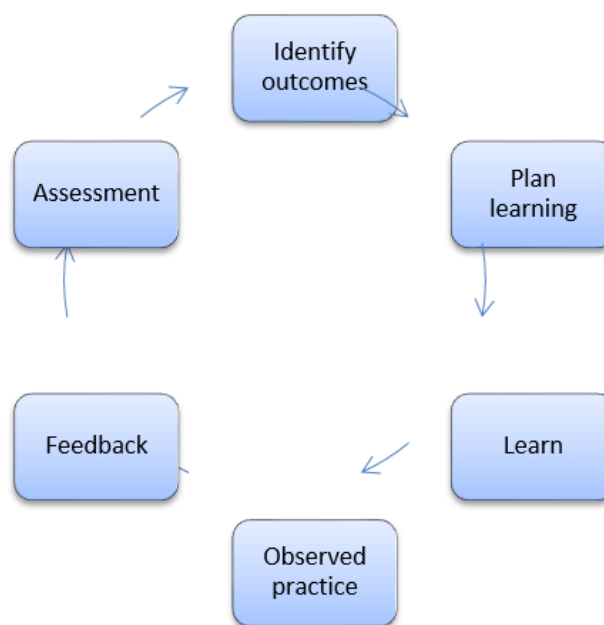
According to the Merriam-Webster dictionary, feedback is the transmission of evaluative or corrective information about an action, event, or process to the original or controlling source, or the return to a portion of a machine, system, or process's output. Feedback is an essential component of the learning and development process for students. Among the most important forms of teacher-learner interaction is feedback. Medical educators have identified feedback as one of the primary catalysts needed to improve performance. Feedback on effectiveness should be provided immediately after students have observed performance behavior. Feedback is at the heart of medical education in the promotion of learning and the achievement of objectives. This paper investigates the significance of feedback in the learning experience, as well as feedback obstacles and practical feedback guidelines.

**Key words** Feedback, Document, Assessment, Learning

## Purpose of Feedback

Feedback is a continuous component of the educational process that aids and improves learning. It is not a distinct pedagogical unit, but rather a continuing component of teaching and assessment. It is a critical component of formative assessment<sup>1</sup>.

1. This needs to update the student on his or her progress.
2. Informs the participant learning and academic deficiencies.
3. Encourages the learner to participate in suitable learning activities<sup>2&3</sup>



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### Challenges in the Way Input Is Given

Feedback is a collaborative and directive process that should be seen as crucial to clinical education. In the lack of mention of feedback, a learner’s uncertainty about just a new medical setting grows. The very next factors play a significant role in determining the feedback process:

1. Lack of direct task observation. When feedback is given based on close scrutiny of a particular assignment, it has the biggest effect on students’ behavior. Direct observation is frequently absent in the hectic clinical setting<sup>2</sup>.
2. The desire to refrain from giving students constructive criticism and honest feedback. When a learner’s performance is poor, it can be more difficult and upsetting to provide feedback. Such feedback is required, which necessitates talent as well as process knowledge. While it may be tempting to avoid upsetting a student, doing so may result in “vanishing feedback,” or withholding valuable feedback <sup>4</sup>.
3. Absence of outside feedback. Without external feedback, pupils may create their own, although self-evaluation is frequently inaccurate. Higher performers frequently underrate their own abilities, whereas lesser performers frequently overrate theirs.<sup>8,9</sup>

### Student-To-Student Comments

Students view the practice of giving feedback to peers as advantageous to the development of knowledge, abilities, and professional traits<sup>8</sup>. Peer feedback can encourage students to take on high amounts of responsibility, and some students even claim to have improved their meta-cognition<sup>8,9</sup>. Unsurprisingly, there are legitimate worries about the objectivity and veracity of peer review. Insufficient instruction and social discomfort have both been identified as contributing factors to students’ incapacity to offer constructive criticism to classmates<sup>8-12</sup>. Students are obviously worried about providing bad feedback to their peers, the performance of their comments, and the effects of this negative feedback on their peers’ progress. Fortunately, students find it helpful to utilize a structured technique when giving feedback to peers<sup>7,8</sup>.

### Self-Evaluation and Performance Analysis

Feedback is intended to help students perform better, but it also serves as a tool for encouraging critical self-evaluation and performance reflection. Self-evaluation appears to be erroneous; high achievers tend to underrate themselves while poor performers tend to over-estimate. However, receiving outside criticism enables students to compare their own self evaluation to relevant standards<sup>6</sup>.

### Effective Response

The learning process cannot be successful without effective feedback. Effective and consistent feedback encourages excellent behavior, encourages self-reflection, and inspires the learner to strive for their intended objective. The manner in which feedback is given to students might affect how they respond. Feedback can motivate a student to think on their performance and make improvements, or it can be unfavorable and demoralizing. For giving feedback, we’ve discovered that utilizing an organized manner is helpful<sup>8,13&15</sup>. One example is Pendleton’s model (1984), which is shown in

**Table 1.** This feedback methodology gives students the chance to assess their own performance and find areas for development. Additionally, it enables immediate observational feedback.

The activity in **Table 2.** Allows for practice and reflection on applying Pendleton’s concept of

**Table 1**

Sl. no	Feedback model
1	Ask the learner what went well
2	Tell the learner what went well
3	Ask the learner what could be improved
4	Tell the learner what could be improved

**Table 2**

Sl. no	An activity
1	What were the advantages of the feedback-giving process?
2	What could be done better?

### Providing Effective Feedback

Direct observation and clear goals are required to provide effective feedback, with good performance reinforced and poor performance

corrected<sup>16</sup>. Although offering constructive criticism those points out both the learner's strengths and weaknesses might take time and be challenging, the consequences of not doing so can be quite detrimental. Feedback can cause performance to decline if not delivered appropriately. Feedback can make a learner defensive and self-conscious if it is handled improperly<sup>17</sup>. Feedback must be constructive, descriptive, and without judgment. There are a few things to keep in mind when providing effective feedback.

Specific feedback should include:

1. Planned in advance, taking into account location, time, and environment
2. Descriptive
3. Specific
4. Placement of emphasis on behavior rather than personality
5. Particular
6. Brief
7. Verification by the recipient
8. Genuine

### Conclusion

Receiving feedback is essential for learning and is covered in most curricula. Despite the growing body of research on feedback, there is little agreement on the most effective strategy. There is no single feedback model that will work in all clinical settings. Each clinical educator should participate in the feedback process and seize the opportunity to develop their own best practices. Frequent and effective feedback encourages learning and drives learners towards desired outcomes. Clinicians frequently lack these skills because health professions students are rarely taught how to give and receive feedback. Direct observation and feedback is an effective method for informing the learner of their progress at a specific stage.

### Take-home message

The setting for learning should encourage feedback.

1. Effective feedback has the power to influence behaviors and enhance skills.

2. Using a structured feedback format (like Pendleton's) to deliver feedback on a learner's behavior.
3. The curriculum should be designed to encourage students to provide feedback because it aids in self-reflection and the provision of clear, constructive suggestions.

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## Assessment of the Nutritional Disorders among School Going Adolescents in Rural Bankura District of West Bengal: A Cross-Sessional Study

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### Abstract

**Background:** Adolescent is very crucial period of life for growth and development of body and mind. Nutrition influences growth and development throughout infancy, childhood and adolescents.

**Aims:** To find out the prevalence of nutritional deficiency disorders and dietary assessment among adolescent age group.

**Materials and Methods:** Community based descriptive cross-sectional study was conducted among 6 rural schools of Bankura-I community development block in Bankura district from February to May 2014. With the help of pre-designed, pre-tested, semi-structured schedule total 600 adolescent students were interviewed and clinical examinations were done.

**Results:** Mean age of study population was  $13.2 \pm 2.19$  years. 7.0% of pupils were vegetarian and 93.0% was non-vegetarian. More than one fourth students consumed fast food /junk foods  $\geq 3$  serving/ week in this study. Total 442 students were eligible for mid-day meal. Out of that 5.7% student did not take mid-day meal from their school. Iron folic acid (IFA) tablet was given only to girl students. 55.6% girls consumed IFA tab but rest did not consume IFA tablets. Pallor was detected clinically in 33.5% of adolescents.

**Conclusions:** School based as well as Community-based adolescent-friendly health and nutrition education and services and economic development may improve the overall health and nutritional knowledge and status of adolescents.

**Keywords:** Adolescents, Nutritional disorders, Dietary assessment, Rural community

### Introduction

Adolescent period is very crucial for growth and development of life. Adolescent is considered to be

no longer a child nor an adult, as per definition by WHO includes persons aged 10-19 years<sup>1</sup>. It is very crucial period of life for growth and development

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of body and mind. Nutrition influences growth and development throughout infancy, childhood and adolescents. So, during the period of adolescence, nutrient needs are the greatest. Inadequate diet and unfavorable environmental condition may adversely affect the growth and developed some nutritional problems of them. The adolescent girls are more commonly affected in this situation in our society. In developing countries like India inadequate food intake, improper feeding practices, mal-distribution of food within family, improper cooking habit, excess intake of fast food / junk food, underlying diseases and low socio-economic condition affect the different nutritional disorders of adolescents. In prospective analyses, socioeconomic status, family meal frequency, and home availability of healthy food were positively associated with the vegetable and fruit and starchy food patterns and inversely associated with the fast-food pattern. Dietary enquiry for the nutritional examination for instance to detect specific nutrient deficiencies; iron, vitamin A, Vit-B complex and iodine in particular. In the same study on clinical examination; angular stomatitis, glossitis, pallor, dental caries, enlarged thyroid and eye change of vitamin A deficiency were also found<sup>2</sup>. Physical signs of specific micronutrient deficiencies are important to keep in mind, with emphasis on those that are likely of common occurrence in the area.

### Objectives

1. To conduct dietary assessment among the adolescents.
2. To find out the prevalence of different nutritional deficiency disorders among study subjects

### Methodology

Community based descriptive cross-sectional study was conducted in rural schools of Bankura-I community development block in Bankura district. Total study duration was 4 months from February to May 2014. The study population was students enrolled in class V-XII, belonging to age group 10-19 years. Total population of Bankura-I, Community Development Block were 1,12,335. Out of that 22.0% was adolescent. School going adolescents were 14,700 in this block. Study subject was selected by using inclusion / exclusion criteria (differently

abled, teenage pregnant, seriously ill were excluded). Dey et al.<sup>3</sup> reported that on clinical examination, pallor (40%) of the population (30% female; 46% male) So taking prevalence of pallor of school going adolescents as 40%, sample size was calculated by using the formula:

$$N = \frac{Z\alpha^2 X_p X_q}{d^2}$$

Assuming non respondents as 4%, i.e., (577\*0.04=23) was taken. So, the final sample was reached 577+23= 600 school going adolescents. 15% of schools i.e. (39 X0.15=6) were taken purposively for this study. Then the six schools were selected from the list of schools in the Block through simple random sampling (SRS) method. Equal number of students (i.e.,100 in numbers) was taken from each selected school. Then students of each standard were taken proportionately to the number of attendances in particular class. Finally, students in each standard were picked up for the study from their attendance register by used Simple random sampling technique. Socio-demographic variables and dietary history were taken. Outcome variable was prevalence of different nutritional deficiency signs. Ethical clearance from Institutional Ethics Committee was obtained. Then permission from the Head master/ Head mistress of the selected schools was taken and school governing body was also informed about these activities. Informed consent from Students' age more than 18 years was obtained or those who are less than 18 years their legal guardian was informed for their consent. If guardian was unavailable then assent was taken for <18 yrs. old students from head of the institution or respective class teachers. Pre-designed, pre-tested, Semi-structured schedule was used. Pretesting of schedule was done in a co-education school of nearby block. The study was done by two ways: (A) Interview of the study subjects for their socio-demographic characteristics and dietary habits, (B) Clinical examination for different nutrients deficiency signs. Clinical examinations were done to assess the different nutrients deficiency disorders like pallor; goiter; bitot's spot; vit B complex deficiency signs (Glossitis, Angular stomatitis); dental caries and skin condition. Same tools and procedures were applied for all participants to collect the data.



After collection; the data were entered in MS Excel spread sheet calculate with the help of software SPSS 22.0 version. Percentage was used to express different types of nutritional deficiency disorders that was depicted as diagram. Descriptive statistics were expressed by mean and  $\pm$ SD.

**Ethical approval:** The study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. It was carried out with patients verbal and analytical approval before sample was taken. The study protocol and the subject information and consent form were reviewed and approved by a local ethics committee according to the document number [No: PR-HC/06/115(28) Dated: 10.01.2013] to get this approval.

### Results

600 school going adolescents participated in this study in the stipulated time-period. Mean age of study population was  $13.2 \pm 2.19$  years (range 10 years - 19 years). Mean age of boys were  $12.95 \pm 2.24$  years and girls were  $13.47 \pm 2.11$  years in this study. Majority of adolescents i.e., 71.5% belonged to early adolescent group (aged between 10 years-14 years) (Table 1). According to sex, boys were majority i.e. 51.2% but girls were 48.8%. Maximum of study population was Hindu by religion (64.5 %) and Muslim was 35.5%. 63.0% of students belonged to nuclear family and rest to joint family (37.0%) in this study. 42.8% of study population was in low socio-economic condition

(BPL category). About 87.5% of study population belonged to large families those family members were more than 4 in the present study. Birth order was found to be  $> 2$  in 49.2 % of students. In this study 6.0% of study population's parent was not alive (either father or mother). Average number of family members of study subjects was  $6.5 \pm 2.22$  ranges from 3 to 17 members. Average no. of brother and sister of study subjects was  $3.5 \pm 1.31$ . Only 7.0% of pupils were vegetarian and 93.0% was non-vegetarian in this study (Fig. 1). Milk /milk products, fruits and sugar/jaggery consumption were less than 60% among study population (Fig. 2). Students consumed less numbers of serving of milk & milk products (ghee and butter), fruits, sugar / jaggery and fleshy food but cereal intake was sufficient that was  $3.19 \pm 0.44$  servings per day in this study (Table 2). Study shows more than one fourth students consumed fast food / junk foods  $\geq 3$  serving/ week in this study. Total 442 students were eligible for mid-day meal. Out of that 5.7% student did not take mid-day meal from their school. IFA tab. was given only to girl students. 55.6% girls consumed IFA tab but rest did not consume IFA tab. in this study. Pallor was detected clinically in 33.5% of adolescents. Glossitis and dental problems were found in around 11.0%. Angular stomatitis (7%), Goitre only 2.0% & Bitot's spot was very less in this study (Fig. 3). 21.2 % boy and 46.4% girl students were having pallor in this study (Table 3).

**Table 1: Distribution of study subjects according to Socio-demographic characteristics (n=600).**

Socio-demographic characteristics	Variables	No.	Percentage
Age	Early adolescent (10 - 14 years)	429	71.5
	Late adolescent (15 - 19 years)	171	28.5
Sex	Boys	307	51.2
	Girls	293	48.8
Religion	Hindu	387	64.5
	Muslim	213	35.5
Family type	Nuclear	378	63.0
	Joint	222	37.0
SES	BPL card holder	257	42.8
	APL card holder	343	57.2

Continue.....

Type of family according to no. of family members	Small family ( $\leq 4$ )	75	12.5
	Large family ( $>4$ )	525	87.5
Birth order	$\leq 2$	305	50.8
	$>2$	295	49.2
Parents' living status	Yes	564	94.0
	No	36	6.0

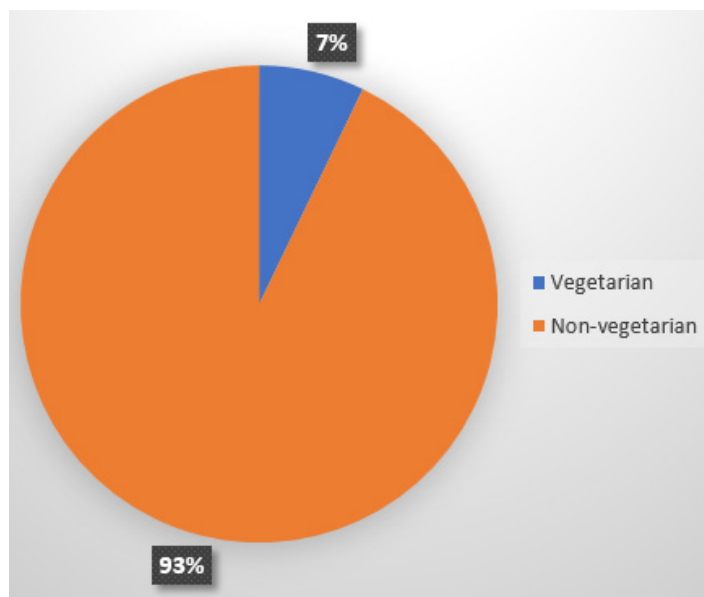


Fig 1. Study subjects according to dietary habit (n=600).

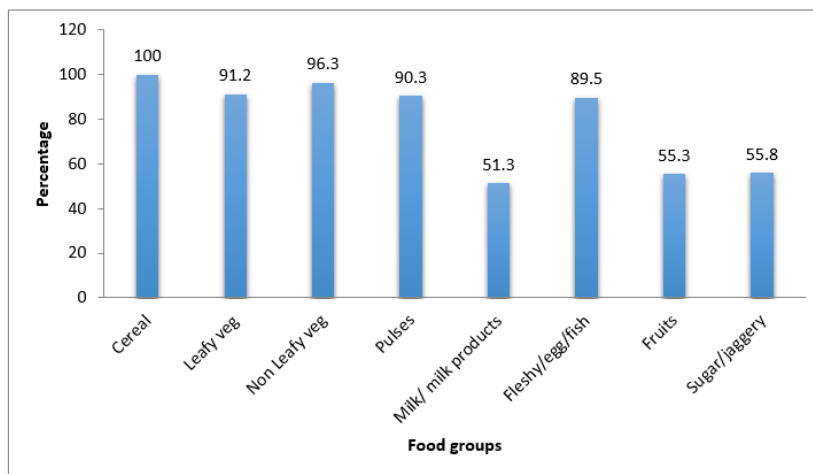


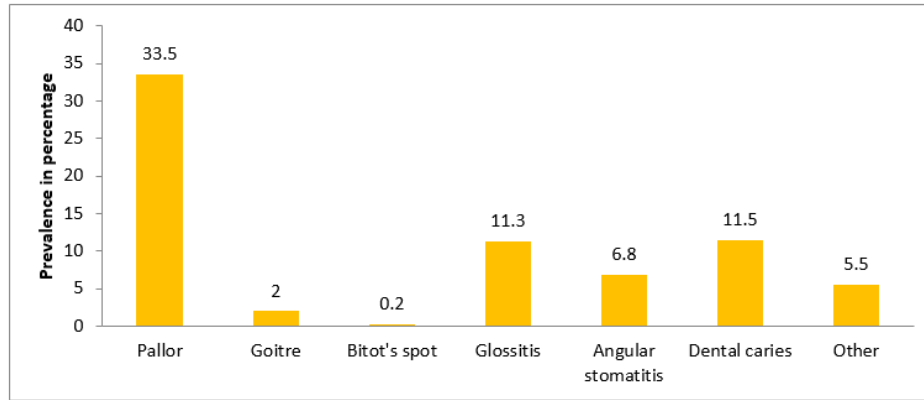
Fig. 2. Bar diagram of distribution of study subjects according to consumption of different food items (n=600).

Table 2: Distribution of average number of serving per day and per week of different food items

Food items	Average no. of serving/day	Average no. of serving/week
Cereal	3.19± 0.44	22.32± 3.07
Green leafy vegetable	0.50± 0.69	5.06± 4.00
Other vegetables	1.75± 1.06	12.82 ± 6.53

Continue.....

Pulses	0.77 ± 0.87	6.66 ± 5.19
Milk & milk products (ghee and butter)	0.30 ± 0.52	2.83 ± 3.55
Fleshy food/egg/fish	0.29 ± 0.59	3.94 ± 3.50
Fruits	.05 ± 0.24	1.44 ± 1.89
Sugar & jaggery	0.03 ± 0.17	1.29 ± 1.63



**Fig. 3. Bar diagram of different nutritional problems clinically detected among the study subjects.**

**Table 3: Sex wise distribution of study subjects according to pallor (n=600).**

Sex	Pallor		Total
	Present No. (%)	Absent No. (%)	
Boys	65(21.2)	242(78.8)	307(100.0)
Girls	136(46.4)	157(53.6)	293(100.0)
Total	201(33.5)	399(66.5)	600(100.0)

**Discussion**

In the present study 600 school going adolescents participated. The number of boys and girls included in the study were found 51.2% and 48.8% respectively. These findings were similar to the study conducted by B.Das & S.Bisai<sup>4</sup>. Mean age of students was 13.2± 2.19 years (range 10 years - 19 years). The finding was more or less similar to the findings of Dambhare DG et al. In their study they have divided adolescence period in to two groups, early and late adolescence<sup>5</sup>. Mean age of boys and girls were 12.95±2.24 years and 13.47±2.11 years respectively in this study. Present study, showed that majority of adolescents i.e. more than 70.0% belonged to early adolescent group aged between 10 years-14 years because students of were less in numbers. Maximum of study population was Hindu by religion about two third (64.5%). More than 60.0% of students belonged to nuclear family

and 42.8% of students were from low socio-economic condition (BPL category). 87.5% of students belonged to large families. Near about half of students' birth order were more than 2.

In this study, 6.0% of the study population was found having no parent alive at the time of data collection (either father or mother). Average number of family members of study subjects was 6.5± 2.22 (ranging from 3 to 17). In present study only 7.2% of pupils were of vegetarian and 92.8% students having non-vegetarian were found but remarkable number of adolescent girls (21.25%) having vegetarian diet was found in a study conducted by Baliga, *et al*<sup>6</sup>.

Using a seven-day food-frequency questionnaire of different food items, it was revealed that milk / milk products, fruits and sugar/jaggery consumption were less than 60% among the students and it was also found that the number of serving/wk of milk & milk products (ghee and butter), fruits, sugar / jaggery and fleshy food were less but numbers of serving / day of cereal was adequate. More than one fourth students consumed fast food /junk foods (≥ 3 serving/ wk) in this study.

Alam N et.al. found their study that consumption of staple food (rice or wheat) in the last seven days was universal with no difference between the asset

quintiles. Consumptions of non-staple food items, such as meat, eggs, *dal* (lentils), fruits, and leafy vegetables, were not frequent in rural areas. Half of them did not eat meat and milk each, and 40% did not eat eggs at all<sup>7</sup>. About 6% students did not eat mid-day meal though they were eligible for mid-day meal from their school. IFA tablets were given to girl students but 55.6% girls consumed it in this study but all adolescents were included under NIPI.

Pallor was detected clinically 33.5% of adolescents while 21.2% boy and 46.4% girl students were having pallor in this study. On clinical examination, pallor was present in 40% of the population (30% female; 46% male) that was found in a study in Darjeeling<sup>8</sup>. Similar prevalence was reported by CMS Rawat *et al.* at Meerut<sup>9</sup>. Overall, 28.45% of the school going adolescents had anaemia with girls suffering significantly more 38.89% ( $p < 0.05$ ) as compared to boys 23.75%<sup>5</sup>. Panda *et al.*<sup>10</sup> also observed the similar results for anaemia among adolescents. Several studies had reported anaemia almost similar to the present study. A higher prevalence was noted by J Rajaratnam *et al.* in Tamil Nadu<sup>11</sup>. Toteja GS *et al.* found 90.1% prevalence of anemia among adolescent girls from 16 districts of India, with 7.1% having severe anemia<sup>12</sup>. Bulliyy *et al.* found 96.5% prevalence among non-school going adolescent girls in three districts of Orissa, of which, 45.2%, 46.9%, and 4.4% had mild, moderate, and severe anemia<sup>13</sup>.

Vitamin B complex deficiency manifested in the form of glossitis (11.0%) angular stomatitis (7%), was found in this study. More or less similar finding of angular stomatitis and glossitis (6%) was found in a study in Darjeeling<sup>8</sup>. Goitre (2.0%) was found in the present study

Prevalence of dental caries was found in more than 10.0% in the present study. In a study of Vaishnav, *et al.* reported that 287(25%) adolescents have dental caries.<sup>14</sup> While Paul *et al.* and Chaudhary S *et al.* were found 22.6% and 13.3% of dental caries among adolescents respectively in their study<sup>15,16</sup>.

Bitot's spot was observed only in 0.2% of adolescents in this study but a study by Chaudhary S *et al.*, 3.3% adolescents have bitot's spots while Pathak P *et al.*, found more (15.9%) adolescents with bitot's spots<sup>16,17</sup>.

## Conclusions

Recently adolescent health including adolescent nutrition is an issue of discussion. Their nutrition is very essential for growth and development. A community based descriptive cross-sectional study was done among adolescent students. Most of the students were non-vegetarian. They consume cereals adequate amount but fruits, vegetables, fleshy food milk and milk products were less. One third of students suffered from pallor followed by Vitamin B complex deficiency manifestation in the form of glossitis, angular stomatitis etc. Measures which can be implemented in order to improve the nutritional disorders of school going adolescents are to reduce micronutrient deficiency disorders, it is essential to educate and create awareness among adolescent students through their school health programmer as well as at the community levels. Healthy eating practices are to be promoted among the students like to consume of adequate amount of locally available and seasonal food and fruits, to increase consumption of protective foods and to reduce intake of fast food / junk food.

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**Institutional Review Board Statement:** Ethical review and approval was taken from Institutional Ethics Committee.

**Conflicts of Interest:** All authors have no conflicts of interest.

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# Clinico-epidemiological Profile of Acute Pancreatitis Secondary to Organophosphate Poisoning in Children at a Tertiary Care Centre: Case Series

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## Abstract

Organophosphate poisoning is common poisoning seen in developing countries. Accidental poisoning is rare in children but adolescents consume it with suicidal intention. Complications following op compound poisonings are well known but children developing acute pancreatitis is a rare complication.<sup>[1-2]</sup> Hence we present a case series of children developing acute pancreatitis in op compound poisoning. All five cases were treated conservatively and successfully discharged.

**Keywords:** organophosphate poisoning, Acute pancreatitis.

## Introduction

Organophosphate poisoning is common poisoning seen in developing countries<sup>[3]</sup>, as they are extensively used as pesticides for protection of vegetable and fruit crops. children and women are being the usual victims. Accidental poisoning is rare in children but adolescents consume it with suicidal intention.

Common organophosphate compounds are

Chloroethion, Diazinon, DEP (di-isopropyl fluorophosphate), Malathion, Methyl parathion, OMPA (Octa Methyl pyrophosphoramidate), Parathion, TEPP (Tetraethyl pyrophosphate), THIO-TEPP, HETP (Hexaethyl tetraphosphate)<sup>[4]</sup>

Op compounds irreversibly inhibits cholinesterase causing accumulation of acetylcholine at NM junction resulting in stimulation of autonomic nervous system, central nervous system and skeletal muscle leading to symptoms of organophosphorus compound poisoning. Complications following op compounds are well known however children developing acute pancreatitis due to OP compound is one of the rare complications. Following op compound poisoning there is increase in exocrine secretions of pancreatic fluid in pancreatic duct resulting in increase in pressure causing pancreatitis which usually disappears in a week. Acute pancreatitis as a complication of OP compound poisoning has been infrequently addressed. Early recognition and appropriate therapy for acute pancreatitis may lead to improved outcome<sup>[5]</sup>. Here we report five rare

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cases of acute pancreatitis in children induced by op compound poisoning.

### Methodology

Five children presenting as acute pancreatitis following organophosphate consumption were included in the study over a period of 2 years (October 2021- February 2023). The data related to age, sex, time of consumption, signs and symptoms were collected. Informed consent was taken. Laboratory parameters such as S.Cholinesterase, S.lipases, S.amylases, blood sugars and imaging such as USG/CT abdomen were obtained. Serial values were monitored and assessed. The data was collected in a predetermined proforma sheet. Data were analysed in a descriptive pattern. Cases were treated as per the standard protocol. Children were treated with the following medications as per the available recommendations.

1. Airway, breathing and circulatory support.
2. gastric lavage
3. Intravenous Atropine at 0.05mg/kg/hr.
4. Intravenous Pralidoxime 50mg/kg/dose

Case 1: A fifteen-year-old female child with history of consumption of op compound (HAMLA – cypermethrin & chlorpyrifos) brought to emergency room presented within 6 hours of consumption. On arrival patient had fasciculations, salivation and bilateral pin point pupils. Stomach wash was given, treated as per the standard protocol. S. cholinesterase level was <455 U/L, blood sugar was 151mg/dl. Serial monitoring of S. cholinesterases and blood sugars were done. Blood sugars were within normal limits. On day eight of consumption, patient developed pain abdomen and vomiting. USG abdomen done was normal, S. lipase (specific for pancreatitis) was raised 112 U/L on day eight, S. amylase was 181 U/L both reached peak level to 960 U/L and 210 U/L respectively on day eighteen. Patient was treated symptomatically, keeping the child nil orally and iv fluids until there was no gastric aspirate. S. lipase levels were reduced to 116 U/L and S. amylase levels to 56 U/L, patient symptomatically improved and was discharged on day 22.

Case no: 2 A seventeen-year-old female child presented with history of consumption of combination of Chlorpyrifos & cypermethrin, presented within 4hrs of consumption. On admission, child was disoriented (GCS – E3V2M6), with pin point pupils, excessive salivation and lacrimation. Child was hemodynamically stable. Treatment started as per standard operational Protocol. Lab investigations showed Serum cholinesterase levels < 455U/L and blood sugar of 143mg/dl. Serial monitoring of Cholinesterase and blood sugars were done. Blood sugars were within normal limits. On day 11 of illness, child developed pain abdomen with persistent vomiting, lab investigations revealed raised Lipase level of 102 U/L and amylase level of 134 U/L which peaked to 310 U/L and 180 U/L respectively on day 15. CT abdomen done revealed bulky pancreas without necrotizing lesions. child was kept nil per orally, treated symptomatically. On day 25 of illness both serum Lipase and Amylase levels were reduced to 80 U/L and 113 U/L respectively. child was clinically improved and discharged on day 29.

Case 3: A seventeen-year-old female child presented with history of consumption of QUINLOPHOS 25% within 4 hours of consumption, on admission vitals were stable with pin point pupils. stomach wash was given and treated as per the protocol. Serum Cholinesterase was <455U/L and blood sugar was 132 mg/dl. Serial monitoring of cholinesterase and blood sugars were done. Blood sugars were within normal limits. On day 5 of illness patient developed nausea, pain abdomen. Serum Lipase and amylase levels were raised to 215 U/L and 130U/L, which peaked to 330 U/L and 150 U/L respectively on day 8. CT abdomen done revealed bulky pancreatitis. child was kept nil oral, treated symptomatically until there was nil nasogastric aspirate. Serum Lipase and Amylase levels started declining by day 9 to 113 UL and 94 U/L respectively and patient condition got improved and discharged on day 11.

Case 4: A sixteen-year-old male child presented with history of op compound consumption a combination of chlorpyrifos 50% and cypermethrin

5% within 2 hrs. of consumption. On admission, vitals were stable with excessive salivation, fasciculation and pin point pupils. Stomach wash was given, treated as per the protocol. S. cholinesterase was 1080 U/L and blood sugar was 120 mg/dl. Serial monitoring of S. cholinesterase and blood sugars were done. blood sugars were within normal limits. As patient developed vomiting, abdominal pain on day 9, investigations done, Serum Lipase and amylase was raised to 205 U/L and 139 U/L respectively, which reached to peak levels of 340 U/L and 210 U/L respectively by day 14. CECT abdomen revealed minimal ascites. Patient was kept nil per oral treated symptomatically. Serum lipases and Amylases were reduced to 113U/L and 93 U/L. Child was improved clinically and discharged on day 19.

Case 5: A fifteen-year-old male child presented

with history of op compound consumption, chlorpyrifos 20% within 3hrs of consumption. On admission, vitals were stable with fasciculations. stomach wash was given, treated as per the standard protocol. S. cholinesterase level was 2120 U/L and blood sugar was 112mg/dl. Serial monitoring of S. cholinesterase and blood sugars were done. Patient developed excessive vomiting with bilious aspirate on day 6, S. lipase and Amylase were raised to 280 U/L and 140 U/L respectively and reached peak levels of 330 U/L and 160U/L by day 9. CT abdomen done revealed bulky pancreas with minimal ascites. child was kept nil oral, treated symptomatically until nil nasogastric aspirate. S. lipase and amylase levels were reduced to 112 U/L and 120 U/L on respectively. Child was improved clinically and was discharged on day 14.

Case summary of organophosphate poisoning developing acute pancreatitis, Table 1

Cases	1	2	3	4	5
Age/sex	15yr/F	17yr/F	17yr/F	16yr/M	15yr/M
Time of presentation following consumption	6 hrs.	4 hrs.	4 hrs.	2hrs	3 hrs.
Compound	HAMLA	Chlorpyrifos and cypermethrin	Quinalphos 25%	IP-L 505	Chlorpyrifos 20%
Symptoms	Pain abdomen, vomiting	Pain abdomen and vomiting	Nausea, pain abdomen	Pain abdomen, vomiting	Excessive vomiting with bilious aspirate
Onset of pancreatitis	Day8	Day 11	Day 5	Day 9	Day 6
S. lipase					
Initial	181 U/L	102U/L	215U/L	205U/L	280U/L
Peak	960 U/L	310U/L	330U/L	340U/L	360U/L
Final	116U/L	80U/L	113U/L	113U/L	112U/L
S. amylase					
Initial	181U/L	134U/L	130U/L	139U/L	140U/L
Peak	210U/L	180U/L	150U/L	210U/L	160U/L
Final	56U/L	113U/L	94U/L	93U/L	120U/L
Blood sugars at admission	151mg/dl	143mg/dl	132mg/dl	120mg/dl	112mg/dl
Peak S. lipase and S. Amylase levels	Day 18	Day 15	Day 8	Day 14	Day 9



Continue.....

Imaging	USG Abdomen - normal	CT Abdomen- bulky pancreas without necrotic lesion	CT Abdomen - bulky pancreas	CECT Abdomen- minimal ascites	CT Abdomen - Bulky pancreas with minimal ascites
Treatment	GL, PPI	GL, PPI	GL, PPI	GL, PPI	GL, PPI
Outcome	Discharged (Day22)	Discharged (Day 29)	Discharged (Day 11)	Discharged (Day 19)	Discharged (Day 14)

GL-gastric lavage; F- female; M-male; PPI - proton pump inhibitors

USG - ultrasonogram; CT - computed tomography; CECT - contrast enhanced computed tomography

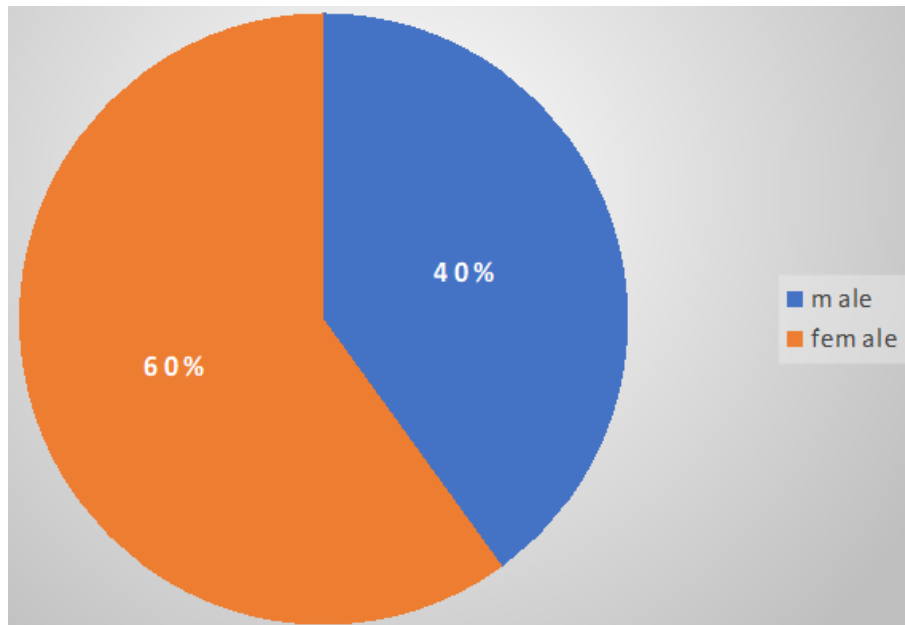


Figure 1: Gender distribution

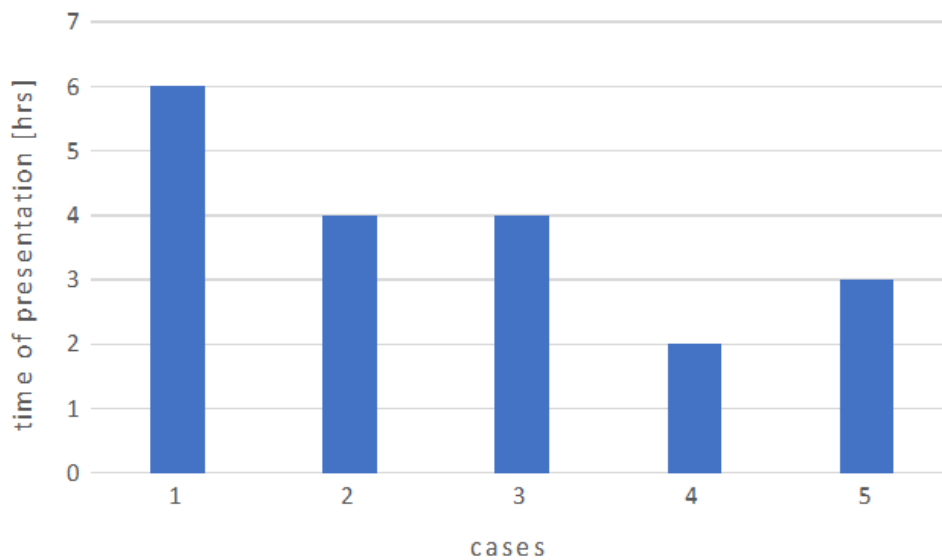
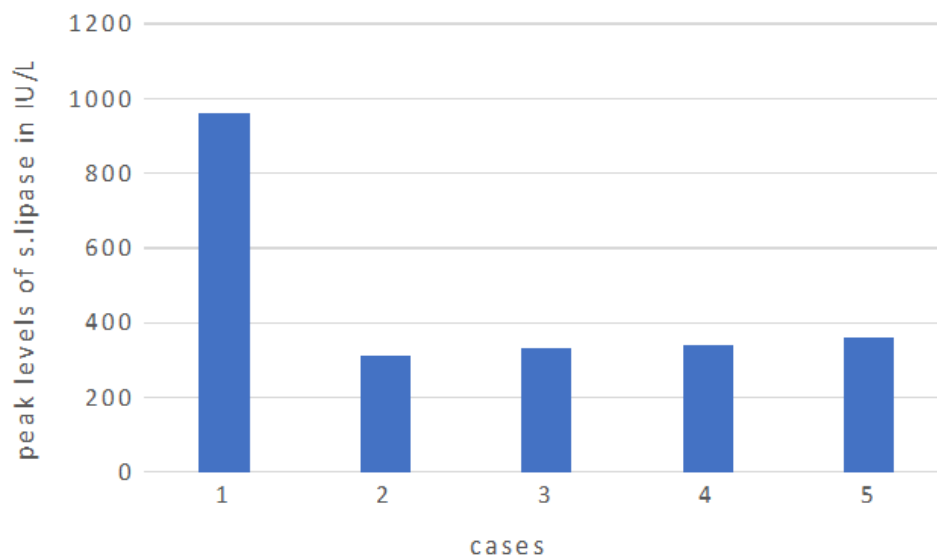
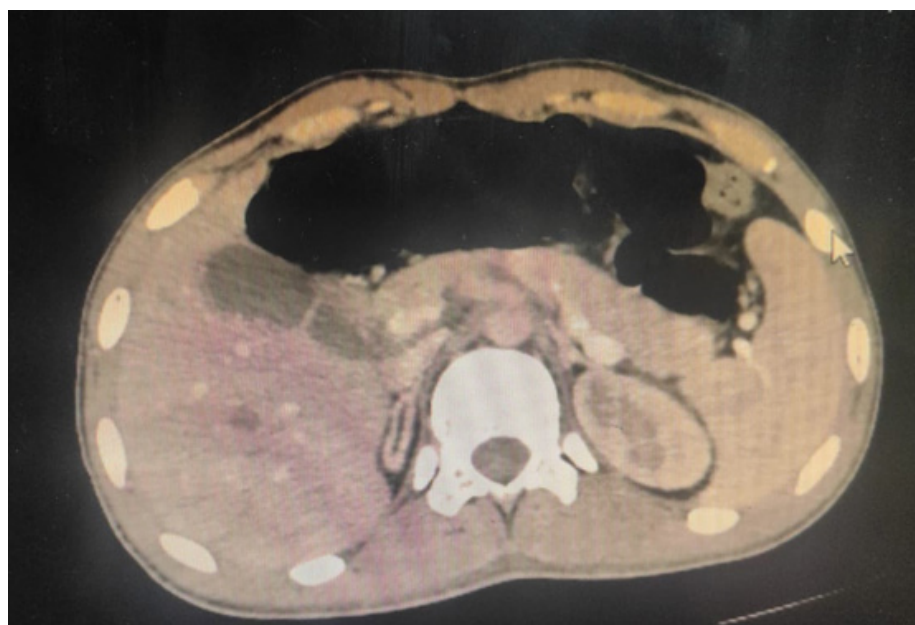


Figure 2: Time of presentation following op compound consumption



**Figure 3: peak levels of s. lipase in IU/L**



**Figure 4: CT abdomen showing bulky pancreas with minimal ascites**

### Discussion

Organophosphate poisoning is a common poisoning seen in developing countries. Children developing acute pancreatitis following op compound poisoning is a rare complication<sup>[6-7]</sup>. case reports on children with organophosphate poisoning developing acute pancreatitis are not available. Hence, we are reporting these five cases who developed acute pancreatitis. Literature suggests that possible pathological mechanism for pancreatic insult is due to excessive cholinergic stimulation of the pancreas and ductal hypertension<sup>[8]</sup>

In our study common age of organophosphate consumption presenting as acute pancreatitis are between the age of 15-17 years, 40% were male and 60% were female child [figure 1]. Mean time of onset of presentation as pancreatitis following op compound consumption was on eighth day [figure 2]. All five children developed severe pain abdomen, vomiting and nausea as a common presentation which is similar to study done by Manjunath goud, Bhavna Nayal et al<sup>[9]</sup>. serial monitoring of S. cholinesterase, S. amylases, S. lipase were done. Mean peak levels of S. lipase and Amylase reached on thirteenth day, peak

levels of S. lipases were 960IU/L,310IU/L,330IU/L,340IU/L,360IU/L in our cases 1,2,3,4,5 respectively [figure 3]

All children underwent imaging, CT abdomen of three children showed features of pancreatitis with bulky pancreas, one had minimal ascites [ figure 4] and another child had normal USG reports.

Three out of five children discharged within 20 days and two children after 20 days. All five children survived and discharged successfully.

### Conclusion

Acute pancreatitis following organophosphate poisoning is rare complication in children. Diagnosis of acute pancreatitis should be given more importance and timely appropriate management can reduce the hospital stay and can be lifesaving in children.

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**Ethical approval:** the study was approved by the Institutional Ethics Committee

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## Factors Influencing Institutional Delivery and Its Associates among Antenatal Women in Surat city: A Cross Sectional Study

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### Abstract

**Background:** India has focused to incentivize institutional delivery. Skilled care is key for reducing maternal and neonatal mortality. We examined the determinants influencing institutional delivery, its associates among antenatal women and birth preparedness among 310 pregnant women attending an urban health centre.

**Methods:** A facility based cross-sectional study conducted among 310 antenatal women at Urban Health Training Centre attached to Government Medical College, Surat, Gujarat. Predesigned, semi- structured, pretested questionnaire was used for data collection after informed written consent.

**Results:** This study was conducted among 310 pregnant women attending an urban health centre. Mean age of participants was 22.9±3.6 years. Highest educational level for most of participants (38.4%) was higher secondary. Around three-fourth 238 (76.7%) of participants were satisfied with institutional delivery whereas one-tenth (9.7%) participants were not ready for institutional delivery out of 72 (23.2%) unsatisfied participants. Majority 196 (63.2%) participants were aware about Janani Suraksha Yojana. Time required to reach health facility was significantly associated with birth preparedness.

**Conclusion:** Study results shows that 23.2% participants were unsatisfied with institutional delivery and some 9.7% were opting for home delivery. Institutional delivery can be increased by promoting awareness about government schemes and fulfilling the need of participants.

**Keywords:** Antenatal women, Birth preparedness, Institutional delivery

### Introduction

Maternal death related to obstetric complications remains great challenge in developing countries. [1] Majority of maternal deaths occur during labor, delivery, and within 24 hour spost-partum. There are several interconnected socio cultural factors which delay care-seeking and contribute to maternal deaths,

apart from medical causes. Care-seeking is delayed because of delay in (a) Identifying the complication (b) Deciding to seek care (c) Identifying and reaching health facility and (d) Receiving adequate and appropriate treatment at health facility. [2] Preparing for childbirth and its probable complications can reduce delays in seeking care. [3] Maternal Mortality Ratio (MMR) of India has declined over the years to

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103 in 2017-19 from 113 in 2016-18, 122 in 2015-17 and 130 in 2014-2016 and MMR of Gujarat in 2017-19 was 70 (per one lakh live birth).<sup>[4]</sup>

Institutional delivery is a delivery that takes place at any medical facility staffed by skilled delivery assistance. It is estimated that using institutional delivery could reduce 16 to 33% of maternal deaths.<sup>[5]</sup> According to NFHS-5 institutional delivery in public facility in Gujarat is 43.3%<sup>[6]</sup> which needs to be increased for safe delivery. One of the effective strategies for reducing number of maternal deaths is delivery by skilled birth attendant.<sup>[7]</sup> Maternal education is broadly positioned to positively affect the mother's and her children's health.<sup>[8]</sup>

Birth preparedness like higher number of antenatal care visits, having good knowledge on the danger signs of labor, primary and above educational level of the husband, and less than 30-min travel time to the nearby health institutions had significantly increased the rate of institutional delivery service utilization.<sup>[5]</sup> Government of India has launched Universal Immunization Programme in 1985, Child Survival and Safe Motherhood (CSSM) in 1992, Reproductive and Child Health (RCH-I) in 1997, (RCH-II) in 2005 and Janani Suraksha Yojana (JSY) in 2005.<sup>[9]</sup> JSY is safe motherhood intervention under the National Rural Health Mission (NRHM) being implemented with the objective of reducing maternal and neonatal mortality by promoting institutional delivery among the poor pregnant women. The Yojana, launched on 12th April 2005, by the Hon'ble Prime Minister, is being implemented in all states and UTs with special focus on low performing states. JSY is a 100 % centrally sponsored scheme and it integrates cash assistance with delivery and post-delivery care.<sup>[10]</sup> Knowledge about financial assistance and transportation provided in JSY was 37.2% and 32.9% respectively.<sup>[2]</sup> Institutional delivery was found higher due to linkage of monetary incentives like JSY and referral transport schemes.<sup>[11]</sup>

Ministry of Health and Family Welfare launched an innovative scheme to provide free health check-ups to pregnant women at government health centres and hospitals by private doctors under the Pradhan Mantri Surakshit Matritva Abhiyan (PMSMA) referred to as 'I pledge for 9' on June 9, 2016, invited the private sector to provide free Ante-Natal Care services on the 9th of every month on voluntary

basis to pregnant women, especially those living in underserved, semi-urban, poor and rural areas.<sup>[12]</sup>

At UHTC Althan monthly around 5 deliveries are conducted. India's maternal mortality ratio (MMR) – maternal deaths per 100,000 live births – dropped 10 points to 103 for 2017-19, according to the special bulletin released by the Registrar General of India, bringing it closer to the global sustainable development goal of bringing down MMR to 70<sup>[13]</sup> but still not achieved completely so there is a need for better dissemination of knowledge and application of that knowledge.

## Materials and Methods

A facility based cross-sectional study among antenatal women attendees from November 2020 to April 2021 at urban health training centre (UHTC) Althan attached to Government Medical College, Surat Gujarat. Althan is the field practice area of Department of Community Medicine in Surat, Gujarat. Due permission was obtained from health service provider. This UHC provides primary healthcare services like immunization, antenatal care, family planning, and treatment of minor ailments to the community.

A predesigned, semi- structured, pre tested questionnaire was used for data collection. Proper explanation of the study to the participants was done in a local language they can understand and consent form was signed.

### Sample size

Desk review was done before conducting this study which revealed that around 5 ANC women attend UHTC OPD per day. Assuming three interviews per day and 20 working days per month; in 6 months of study duration, approximately 300 to 350 ANC were feasible to study after considering a drop out of 15%. A total of 310 antenatal women who attended antenatal clinic of UHTC were consecutively included in the study.

### Study setting

This study was conducted at field practice area of Community Medicine Department, Surat at Urban Health Training Centre; which was chosen purposively.

### Inclusion criteria

Antenatal women of more than twenty weeks of pregnancy from Community Medicine Department attached field practice area.

### Exclusion criteria

Participants who did not give the consent

### Study tool

The questionnaire was divided into three domains assessing "Socio demographic details"; "Perception about health care delivery centre" and "Knowledge about governmental schemes and birth preparedness". Exit interview was present at the end of questionnaire for assessment of reasons for home delivery, if applicable.

BPACR index was calculated from the following indicators<sup>[2]</sup>:

Percentage of the women who knew about > 8 danger signs of pregnancy.

Percentage of the women who knew about financial assistance provided by government in Janani Suraksha Yojana (JSY).

Percentage of the women who knew about transportation provided by government in JSY.

Percentage of the women who availed Antenatal Care (ANC) in 1st trimester by skilled provider.

Percentage of the women who identified skilled birth attendant for delivery.

Percentage of the women who identified mode of transportation.

Percentage of the women who saved money to pay for expenses.

BPACR index was calculated as  $\sum \text{Indicator}/7$

### Data collection and analysis

Informed written consent was taken from the participants and they were allowed to not give the interview midway if they felt uncomfortable or they have any other work. Data collection was done by face to face interview using data collection tool. Data entry was done in Microsoft excel and analysis was done in SPSS trial version 23. Univariate analysis was done including descriptive statistics of mean, standard deviation, frequency and percentage.

The variables with association of  $p\text{-value} < 0.2$  were further analysed by Logistic regression to assess independent predictors of Birth preparedness.  $P < 0.05$  was considered to be statistically significant. Privacy was maintained by interviewing in a secluded place and confidentiality was ensured by giving ID number to the participants.

## Results and Discussion

According to NFHS-5 institutional delivery in Gujarat is 94.3% and of Kerala is 99.8% while institutional delivery of Gujarat in public facility is 43.3%.<sup>[6]</sup> In our study Majority (90.3%) of the participants opted for institutional delivery but still few participants (9.7%) were willing to remain at home for delivery. Similarly, in study done by Olowokere et al. majority (97.0%) participants opted for institutional delivery.<sup>[14]</sup>

This study was conducted about satisfactory factors towards institutional delivery and birth preparedness among 310 pregnant women attending an urban health centre. Mean age of participants was 22.9 years (standard deviation, SD 3.6 years). Highest educational level for most of participants (38.4%) was higher secondary. Ninety seven (31.3%) participants were graduates or professionals as compared to two-fifth (42.9%) of their husbands. Almost six-tenth (61.9%) participants were involved in unskilled or semi-skilled work and two-fifth (38.1%) participants were homemakers. Around one-third (35.5%) of participants belonged to upper middle class followed by 33.5% participants who belonged to middle class. BPACR index was calculated as  $\sum \text{Indicator}/7$  which was observed to be 62.3%.

**Table 1 Distribution of participants on the basis of their factors of satisfaction towards institutional delivery (n=238)**

Satisfactory factor	Number	Percentage (%)
Doctor always there	170	71.4
Always open	50	21
Staff responds well	98	41.2
Always has necessary medicines	127	53.4
Not a long wait	146	61.3
Staff treat women respectfully	163	68.5

Table 1 depicts that about three-fourth (71.4%) women stated that their satisfaction towards institutional delivery is mainly due to availability of doctor. Around three-fourth 238 (76.7%) of the participants were satisfied with institutional delivery whereas one-tenth (9.7%) participants were not ready for institutional delivery out of 72 (23.2%)

unsatisfied participants. Qualitative assessment was done for women who choose home as planned place for delivery. Their reasons were; no privacy in the hospital (30.0%), comfortable environment at home (23.3%), can keep eye on other children (16.7%), no clean wards (16.7%), relatives not ready to stay with me in hospital (13.3%).

**Table 2 Distribution of participants according to awareness about Government initiatives related to pregnancy (n=310)**

Yojana	Number	Enrolment process through		Place to get benefits	
Janani Suraksha Yojana	196 (63.2%)	Health Centre	69 (35.2%)	Govt.	196 (100%)
		ASHA	127 (64.8%)	Private	00
Chiranjeevi yojana	62 (20.0%)	Healthcentre	41 (66.1%)	Govt.	50 (80.6%)
		ASHA	21 (33.9%)	Private	12 (19.4%)
Kasturba Poshan Sahay Yojana	119 (38.4%)	Health Centre	37 (31.1%)	Govt.	119 (100%)
		ASHA	82 (68.9%)	Private	00

Table 2 depicts that 63.2% participants were aware about Janani Suraksha Yojana. Majority of participants (56.4%) were aware about nutritional benefit during pregnancy followed by cash incentive (34.1%). Almost similar results were found in a study conducted by Anikwe et al. that two-thirds and one-third of women, respectively, especially those from

backward and below poverty line (BPL) families knew about cash incentive and referral transport schemes.<sup>[15]</sup> Awareness about JSY scheme was higher in our study than a conducted by Acharya A. et al, in which they observed that 32.7% were aware about transportation and 37.2% about financial assistance provided by government in JSY scheme.<sup>[2]</sup>

**Table 3: Factors affecting the level of birth preparedness**

Factors	Categories	Adjusted Odds Ratio (CI)	p-Value
Education of women	Illiterate	1	
	Class 12 or below	0.89 (0.45-1.79)	0.76
	Higher than class 12	0.96 (0.44-2.11)	0.92
Type of family	Nuclear	1	
	Joint	0.97 (0.48-1.95)	0.92
	Three generation	0.63 (0.29-1.34)	0.23
Awareness about danger signs during pregnancy	No	1	
	Yes	1.39 (0.67-2.87)	0.37
Awareness about exclusive breastfeeding	No	1	
	Yes	1.22 (0.61-2.42)	0.56
Time required to reach health facility	<30 minutes	1	<0.01
	30-60 minutes	0.26 (0.14-0.48)	
	60-90 minutes	0.05 (0.02-0.11)	
	90-120 minutes	0.04 (0.01-0.12)	
Parity	Nulliparous	1	
	Multiparous	1.19 (0.57-2.47)	0.65

Table 3 shows factors affecting the level of birth preparedness. Participants who made any two out of four arrangements were counted as less prepared and who made three or more arrangements were counted as well prepared. Time required to reach health facility was significantly associated with birth preparedness. Participants who were residing within 30 minutes distance had highest odds of being well prepared. Distance is important for reaching to the health facility timely and getting assistance from skilled birth attendant during delivery. It will be helpful for safe delivery and healthy baby. In current study, most of the participants belonged to urban area and an urban health centre being present in that area, almost half (47.7%) participants were within less than 30 minutes distance. Similarly, in a study by Ekabua J et al, they observed that 49.5% were within 2 km distance while 42.5% were resided in 2-5 km area and 8% resided in more than 5 km area from health facility. [16] Debelew et al. found that being in urban residence and having health centre within two hours distance were among the higher level factors increasing birth preparedness and complication readiness. [17] Similarly, our study also found that time required to reach health facility was the significant factor with birth preparedness. Participants who were residing within 30 minutes distance had highest odds of being well prepared. However, Klobodu et al. study found that travel time to nearest health facility is not significantly associated with birth preparedness. [18]

This study depicted that education, type of family, awareness about danger signs and parity were not significant factor for birth preparedness. On the contrary parity, education and joint family system were associated with having a birth plan in study by Acharya et al. [2] In multiparous chance of being well prepared was higher in our study which differs from study by Smeele et al. where parity is significant predictor for birth preparedness and nulliparous women were well prepared. [19] In India, nulliparous women generally are not aware of pregnancy related complications and preparedness to avoid it. Multiparous women have higher preparedness due to their past experience.

### Conclusion

Around three-fourth (76.8%) of the participants were satisfied with RCH services of the health

facility. Awareness about government schemes was low with highest being in JSY of (63.2%). Majority of participants had chosen healthcare system as a place of delivery but one-tenth (9.7%) participants were not ready for institutional delivery and qualitative assessment was done for them in which main factor found was no privacy at UHTC.

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# Study of Role of Parenting in Children with Low Academic Performance

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## Abstract

Parental involvement in school has been demonstrated to be a key factor for children's academic outcomes. However, there is a lack of research in Chile, as well as in Latin American countries in general, leaving a gap in the literature about the generalization of findings outside developed and industrialized countries, where most of the research has been done. The present study aims to analyse the associations between parental involvement in school and children's academic achievement. Cluster analysis results from a sample of 498 parents or guardians whose children attended second and third grades in 16 public elementary schools suggested the existence of three different profiles of parental involvement (high, medium, and low) considering different forms of parental involvement (at home, at school and through the invitations made by the children, the teachers, and the school). Results show that there are differences in children's academic achievement between the parental involvement profiles, indicating children whose parents have a low involvement have lower academic achievement. Findings are in line with international research evidence, suggesting the need to focus on this variable too in Latin American contexts.

**Keywords:** parental involvement profiles, children's academic achievement, elementary education, family and school relations, child development

## Introduction

On an international scale, parental involvement in school has long been heralded as an important and positive variable on children's academic and socio-emotional development. From an ecological framework, reciprocal positive interactions between these two key socializing spheres - families and schools - contribute positively to a child's socio-emotional and cognitive development (Bronfenbrenner, 1987).<sup>1</sup> Empirical findings have demonstrated a positive association between parental involvement in education and academic achievement (Pérez Sánchez et al., 2013; Tárraga et al., 2017), improving children's self-esteem and

their academic performance (Garbacz et al., 2017) as well as school retention and attendance (Ross, 2016).<sup>2</sup> Family involvement has also been found to be associated with positive school attachment on the part of children (Alcalay et al., 2005) as well as positive school climates (Cowan et al., 2012).<sup>3</sup> Research has also evidenced that programs focused on increasing parental involvement in education have positive impacts on children, families, and school communities (Jeynes, 2012; Catalano and Catalano, 2014).<sup>4</sup>

Parent-school partnership allows for the conceptualization of roles and relationships and the impact on the development of children in a

broader way (Christenson and Reschly, 2010).<sup>5</sup> From this approach, families and schools are the main actors in the construction of their roles and forms of involvement, generating new and varied actions to relate to each other according to the specific educational context. The main findings in the family-school field show a positive influence of this partnership, contributing to academic achievement and performance, among other positive consequences (Epstein and Sander, 2000; Hotz and Pantano, 2015; Sebastian et al., 2017).<sup>6</sup>

There is also strong support from international research showing the positive influence of parental involvement over academic achievement, as has been demonstrated in a variety of meta-analyses across different populations and educational levels (Castro et al., 2015; Jeynes, 2016; Ma et al., 2016).<sup>7</sup> Moreover, although there is a wide range of parental involvement definitions, some more general and others more specific, there is a consensus among research results about the positive influence of parental involvement over child academic achievement. For example, in the meta-synthesis of Wilder (2014)<sup>8</sup>, where nine meta-analyses are analyzed, this influence was consistent throughout the studies, regardless the different definitions and measures used.

However, most of the studies on parental involvement in education hail from Anglophone countries and are based on cross-sectional and correlation designs (Garbacz et al., 2017)<sup>9</sup> while in Latin America research remains scarce. In a recent systematic review of the literature on parental involvement in education in Latin America, only one Mexican study from 1998 was found which was also heavily influenced by interventions from the United States (Roth Eichin and Volante Beach, 2018)<sup>10</sup>. Chile has acknowledged the importance of collaborative relationships between families and schools developing a National Policy for Fathers, Mothers and Legal Guardians Participation in the Educational System (Política de Participación de Padres, Madres y Apoderados/as en el Sistema Educativo) in 2002 which was recently updated in 2017 (Ministerio de Educación, Gobierno de Chile, 2017). Since the publication of this policy various local initiatives have sprouted in the country seeking to strengthen

school family relations (Saracostti-Schwartzman, 2013). Nevertheless, the majority of research in the country has thus far been of a qualitative nature with a focus on describing relations between family members and their schools, and identifying tensions between these two spheres (Gubbins, 2011).

Thus, this study seeks to advance the analysis of the effects of parental involvement in school on the academic achievement of Chilean students. The study aims to analyse how different parental involvement profiles (based on the main forms of parental involvement identified in literature) influence children's academic achieved. Parental involvement can take a wide variety of forms, among them, communication between family and school, supporting learning activities at home and involvement in school activities have been highlighted (Schueler et al., 2017), these are included in this study using the scales proposed by Hoover-Dempsey and Sandler (2005).

## Materials and Methods

The study included 498 parents or guardians whose children attended second and third grade in 16 public schools with high levels of socio-economical vulnerability (over 85% according to official records of the schools) within three different regions in Meerut. Parents and guardians were aged between 20 and 89 years old ( $M = 35.02$ ,  $SD = 7.02$  for parents,  $M = 59.27$ ,  $SD = 11.74$  for grandparents and  $M = 43.14$ ,  $SD = 15.41$  for other guardians) and students between 7 and 12 ( $M = 8.30$ ,  $SD = 0.93$ ). The majority of them were mothers (83.9%). The majority of fathers and mothers had completed high school (33.1 and 40.6%, respectively), followed by elementary education (28.1 and 23.3%, respectively), no education completed (17.3% for both), professional title (7.2 and 6.8%, respectively) and university title (4.4 and 4.6%, respectively).

This study is part of a wider project focusing on the effectiveness of interventions aimed at strengthening the link between families and schools. Prior to data collection, after obtaining permission from the schools, informed consent forms were signed by the students' legal guardians to authorize their participation. The data referring to the students (evaluation of learning outcomes) was compiled

through official school records. The data referring to the families (parental involvement) was collected in paper format during parent teacher meetings at the end of the school year considering their behavior during the preceding year. Two research assistants trained for this purpose were present for the applications.

#### Instruments

Parental involvement was assessed using the five scales proposed by Hoover-Dempsey and Sandler (2005) that aim to measure the level of family involvement in children's education in elementary school from the point of view of the fathers, mothers and/or guardians. Scales have been adapted and validated by a panel of experts (Reininger, 2014).

Scales included in this study are: (1) Parental involvement activities at home [five items, such as "someone in this family (father, mother and/or guardian) helps the child study for test" or "someone in this family (father, mother and/or guardian) practices spelling, math or other skills with the child"]; (2) Parental involvement activities at school (five items, such as "someone in this family attends parent-teacher association meetings" or "someone in this family attends special events at school"), (3) Child invitations for involvement (five items, such as "my child asks me to talk with his or her teacher" or "my child asks me to supervise his or her homework");

(4) Teacher invitations for involvement (six items, such as "my child's teacher asks me to help out at school" or "my child's teacher asks me to talk with my child about the school day"); and (5) General school invitations for involvement (six items, such as "this school staff contact me promptly about any problem involving my child" or "parents' activities are scheduled at this school so that we can attend"). The first four scales have a four-point Likert response scale, that indicate the frequency of the items, from 0 (*never*) to 3 (*always*). The last scale has a 5-point Likert scale response, indicating the grade of agreement with the items, from 1 (*strongly disagree*) to 5 (*strongly agree*). Internal consistency of all scales was adequate ( $\alpha = 0.79$ ,  $\alpha = 0.72$ ,  $\alpha = 0.72$ ,  $\alpha = 0.85$ , and  $\alpha = 0.87$ , respectively).

Students' academic achievement was evaluated through the final average grade obtained at the end of

the school year, recorded in a scale from 1 (*minimum achievement*) to 7 (*maximum achievement*).

## Results

Hierarchical cluster analysis was used to identify parental involvement profiles based on the five subscales of parental involvement scale (typified to avoid the influence of the different scale responses), applying the standardized Euclidian Distance method and using Ward's algorithm. Cluster analyses results showed that the optimal solution was the grouping of the participants into three groups.

To label the groups, we examined the family involvement profiles by computing a one-way ANOVA on the standardized scores of the five parental involvement scales with the clusters serving as the factors. The result revealed that the clustering variables significantly differed between the involvement scales [Parental involvement at home:  $F(2,497) = 147.83$ ,  $p < 0.001$ ,  $\eta^2 = 0.37$ ; Parental involvement at school:  $F(2,497) = 148.82$ ,  $p < 0.001$ ,  $\eta^2 = 0.38$ ; Child invitation for involvement:  $F(2,497) = 225.34$ ,  $p < 0.001$ ,  $\eta^2 = 0.48$ ; Teacher invitation for involvement:  $F(2,497) = 84.77$ ,  $p < 0.001$ ,  $\eta^2 = 0.26$ ; General school Invitation for involvement:  $F(2,497) = 53.38$ ,  $p < 0.001$ ,  $\eta^2 = 0.18$ ]. Scheffe *post hoc* multiple comparisons showed the differences were statistically significant between all the parental involvement profiles in all variables, with the first cluster scoring higher than the second and the third in all the scales, and the second higher than the third. Based on these differences and the scores, the first cluster was labeled as *High involved parents*, representing 144 parents (28.9%) that scored above the mean in all the involvement scales (from 0.54 to 0.91 standards deviations). The second cluster was named *Medium involved parents*, including 228 parents (45.8%) that have scores close to the media in all the involvement scales (from 0.14 to 0.16 standards deviations). Finally, the third cluster was classified as *Low involved parents*, including 126 parents (25.3%) that scored below the mean in all the involvement scales (from 0.61 to 0.91 standards deviations).

Finally, ANOVA results showed that there were significant differences in academic achievement scores between the three clusters of parent involvement profiles,

$F(2,430) = 5.37, p = 0.003, \eta^2 = 0.03$ . Scheffe *post hoc* multiple comparisons showed that high ( $M = 5.97, SD = 0.49$ ) and medium ( $M = 6.00, SD = 0.50$ ) involved parents had children with higher academic achievement than low involved parents ( $M = 5.8, SD = 0.47$ ). Complementarily, results from correlations between parental involvement and academic achievement scores support these results, showing a significant and positive correlation ( $r = 0.14, p = 0.003$ ).

### Discussion

From the results presented, we can conclude the existence of three different profiles of parental involvement (high, medium and low) considering different scales of parental involvement (at home, at school and through the invitations made by the children, the teachers and the school). Secondly, results showed that there were differences in academic achievement scores between the parent involvement profiles, where high and medium involved parents had children with higher academic achievement than low involved parents.<sup>10</sup>

As shown, international literature reveals that the degree of parental involvement is a critical element in the academic achievements of children, especially during their first school years highlighting the need to generate scientific evidence from the Chilean context. Most of the studies in this area come from Anglophone countries (Garbacz et al., 2017) while in the Latin American context research is still scarce. Results from our study corroborate that parental involvement can contribute alike in other cultural contexts, pointing to the need to also implement policies to promote it.

In this context, Chile has acknowledged the importance of collaborative relationships between parents and schools leading to the development a National Policy for Father, Mother and Legal Guardian Participation. Nevertheless, most of the research in the country has thus far been of a qualitative nature with a focus on describing family-school relations and identifying tensions between these two spheres (Gubbins, 2011). Thus, this study seeks to make progress in the analysis of the effect

of parental involvement and children's and academic achievements of students.

**Declaration of Ethical clearance:** Taken from ethical committee of institute

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# A Prospective Comparative Observational Study on Maternal and Fetal Outcome in Oligohydramnios

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## Abstract

**Background:** The health of the mother and foetus is threatened by oligohydramnios. It is a clinical condition identified by a sonographically measured amniotic fluid index (AFI) of less than 5 cm.

**Method & Materials:** Hospital-based based prospective comparative Observational Study. This study was conducted to observe the outcome of pregnancy in oligohydramnios. Study group- 100 cases with AFI < 5 cm. Control group- 100 cases with AFI 5cm to 24 cm, admitted to Dept. of Obstetrics and Gynaecology in TMCH from 1st August 2021 to 31 July 2022. For all selected women, USG was done and AFI was calculated. These women were followed till day 7 of puerperium. Data were analyzed using IBM SPSS version 23. The variable was analyzed using a chi-square test p-<0.05 was considered statistically significant.

**Results:** The results of the present study revealed that, the rate of the Caesarian section was significantly higher in the oligohydramnios group compared to the control group (70% vs. 39% respectively). There was a significantly increased in Fetal distress, meconium-stained liquor, low Apgar score at 1 and 5 min, low birth weight, admission to NICU, and early neonatal death.

**Conclusion:** In conclusion, oligohydramnios is a high-risk pregnancy, and patients with oligohydramnios should expect proper antepartum, rigorous foetal surveillance, and intrapartum care for a better feto-maternal outcome.

**Keywords:** Oligohydramnios; amniotic fluid index; Maternal outcome; Fetal outcome; Prospective study.

## Introduction

For the developing foetus, nature has created a floating bed in the form of an amniotic fluid cavity filled with liquor amnii. The quantity of liquor amnii at any time during gestation is the product of water exchange between the mother, fetus, and placenta and is maintained within a relatively narrow range.<sup>(1)</sup>

The amniotic fluid serves several roles during pregnancy. It creates a physical space for

fetal movement, which is necessary for normal musculoskeletal development. It permits fetal swallowing essential for the development of GIT, and fetal breathing necessary for lung development. Amniotic fluid guards against umbilical cord compression and protects the fetus from trauma<sup>(2)</sup>.

Amniotic fluid is derived from the ultrafiltrate of maternal plasma<sup>(3)</sup>. By the start of the second trimester, the amniotic fluid volume expands into the foetal extracellular space, which is comparable to

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foetal plasma, and diffuses through the skin of the foetus<sup>(4)</sup>. In the second half of pregnancy, foetal urine is the primary source of amniotic fluid. Fetal lungs are another significant source since they generate fluid that enters the amniotic compartment through the respiratory tract. The primary method of amniotic fluid removal by foetal swallowing<sup>(5)</sup>.

Reduced amniotic fluid volume is known as oligohydramnios<sup>(6)</sup>. It is defined sonographically when the AFI is less than 5cm or the single greatest vertical pocket of liquor is less than 2cm. We use the amniotic fluid index (AFI) to measure the volume of amniotic fluid because the majority of publications support this method<sup>(7)</sup>.

Oligohydramnios in the third trimester is very often associated with placental abnormality, or with a maternal complication such as preeclampsia or vascular disease<sup>(8)</sup>. The underlying cause in such cases is frequent uteroplacental insufficiency, which can impair fetal growth and reduce fetal urine output. Exposure to selected medications like ACE inhibitors, Angiotensin receptor blockers, and NSAIDs has also been linked with oligohydramnios.

Numerous studies demonstrate that oligohydramnios is linked to a number of unfavourable pregnancy outcomes. Because oligohydramnios frequently causes umbilical cord compression during labour, leads to foetal distress, meconium aspiration syndrome, severe birth asphyxia, and low APGAR scores<sup>(9)</sup>. Oligohydramnios is also associated with maternal morbidity in form of increased rates of induction or operative interference<sup>(10)</sup>.

The goal of the current study is to determine how oligohydramnios in third-trimester pregnancy affects maternal and fetal outcomes.

## Materials and Methods

**Place of study:** The present study was conducted in the Department of OBSTETRICS AND GYNAECOLOGY, Tezpur Medical College and Hospital, Tezpur Assam

**Study design:** Hospital-based based prospective comparative Observational Study.

**Study population:** Antenatal patients attending the outpatient department and ELR in the Department

of obstetrics and gynaecology, Tezpur medical college and hospital, Tezpur, Assam

**Duration of study:** One year from 1<sup>st</sup> AUGUST 2021 to 31<sup>st</sup> JULY 2022. Patients with AFI less than 5cm were taken as study groups and AFI 5cm to 24cm taken as control.

### Inclusion criteria

- All cases attending ANOPD and ELR in 3rd trimester with oligohydramnios.
- The Same number of matching cases with normal AFI has been selected for the control group

### Exclusion criteria

- Pregnancy with PROM and PPROM.
- Multiple pregnancies.
- Pregnant women not willing to give consent.

**Study group** – 100 cases with AFI < 5 cm.

**Control group-** 100 control with AFI 5cm to 24cm, admitted to the Department of Obstetrics and Gynaecology in TMCH during the study period. These women were followed till day 7 of puerperium.

### Method of Collection of Data

A previously set questionnaire was filled after thorough history taking, general examination, obstetrical examination, and baseline investigation, and AFI was calculated sonographically with informed consent from the patient/ next of kin.

### Data Analysis

Different outcomes, mode of delivery, need for a cesarean section, amniotic fluid colour APGAR score at 1 and 5 minutes, birth weight, and admission to the NICU. The findings were noted, summarized, and statistically evaluated. Data were analyzed using IBM SPSS version 23. The variable was analyzed using a chi-square test  $p < 0.05$  was considered statistically significant.

## Results

This study compares 100 pregnant women with AFIs less than 5 cm and 100 pregnant women with AFI between 5-24cm in the third trimester.

**Table 1: Mode of Delivery**

Mode of Delivery	Study Group	Control Group
	%	%
Vaginal Delivery	30	61
LSCS	70	39

The Chi-square test is done. P value is 0.000011 which is statistically significant. The majority were delivered by LSCS (70%) whereas 30% were delivered vaginally in the study group. In the control group, 39% underwent LSCS, and 61% delivered vaginally.

**Table 2: Indication For Lscs**

Indication For LSCS	Study Group		Control Group	
	Number	%	Number	%
Breech	3	4.28	2	5.12
CPD	4	5.71	10	25.64
FD	51	72.85	16	41.04
IF	4	5.71	10	25.64
IUGR	8	11.42	1	2.56

Chi-square test was done. P value is 0.000197 which is statistically significant. In the study group, the most common indication for LSCS was fetal distress (51%). In the control group, only 16% underwent LSCS for fetal distress. This difference found to be statistically significant indicating majority of LSCS is done in oligohydramnios due to fetal distress in comparison with control group

**Table 3. Colour of Liquor**

Colour	Study Group	Control Group
	%	%
Clear	51	80
Thick	28	5
Thin	21	15

Chi-square test has done. P value is 0.00001 which is statistically significant. Liquor was thin meconium stained in 21% of the study group whereas 15% in the control group, thickly meconium stained in 28% of the study group while it was 5% in the control group. This difference was found to be statistically significant indicating oligohydramnios is associated with more meconium-stained liquor in comparison with the control group.

**Table 4. APGAR SCORE At 1 and 5 Min**

Score	Study Group		Control Group	
	1 min, in%	5 min, in%	1 min, in%	5 min, in%
<4	10	0	1	0
4-7	20	21	7	6
>7	70	79	92	94

Chi-square test is done. The P value is 0.000247 which is statistically significant. APGAR score at 1 min was >7 in 70% of patients in the study group and 92% of patients in the control group and for 5 min

P value is 0.00191 which is statistically significant.

79% of the study group had APGAR Score  $\geq$  7 at 5 min.

94% in the control group had APGAR Score >7 at 5 min.

**Table 5. Birth Weight**

Birth Weight in Kg	Study Group	Control Group
	%	%
<2	25	8
2-2.5	15	17
2.5-3	52	55
>3	8	20

Chi-square test is done. The P value is 0.00276 which is statistically significant. The occurrence of low birth weight (<2.5kg) in the study group is 40% and 25% in the control group. This difference was found to be statistically significant which indicates that in oligohydramnios, the incidence of low birth weight is more compared with the control group.

**Table 6. Admission To Nicu**

	Study group	Control group
	%	%
Yes	53	19
No	47	81

Chi-square test was done. P value is 0.00001 which is statistically significant. 53% of babies in the study group were admitted to NICU, but only 19% of babies in the control group were admitted to NICU.



## Discussion

The present study is a hospital-based prospective comparative observational study comparing 100 women admitted to the department of obstetrics and gynaecology at Tezpur Medical College and Hospital with AFI of less than or equal to 5 cm to women with AFI of between 5 and 24cm.

According to the present study findings, the rate of vaginal delivery was greater in the control group (61%) than in the study group (30%). Contrarily, the study group had greater rates of CS than the control group (70% vs. 30% respectively). This is consistent with what Hanafy et al<sup>(11)</sup> reported that the rate of C.S. in the study group is significantly higher than that in the control group (40.0% vs. 20.0%, respectively).

Moreover, in the study group, the rate of caesarean sections due to foetal distress was more compared to the control group. The result of our study is comparable with the study by Sreelakshmi et al<sup>(12)</sup>.

Meconium-stained liquor was more common in the study group in comparison with the control group. Sebastian et al<sup>(13)</sup> also found similar results to our findings.

In terms of foetal outcomes, the current study revealed that babies with a normal amniotic fluid index had considerably higher Apgar scores than babies with oligohydramnios. This is comparable to the observation of Biradar kd et al<sup>(14)</sup> that the APGAR Score of the study group was less than 7 in 25% at the first minute and 18.2% at the fifth minute.

The current study also showed that there was a statistically significant difference found in LBW baby in the two groups under study (40% vs.25%). Comparable results were obtained by Sowmya K et al et al<sup>(15)</sup>.

The results of the present study showed that there was a statistically significant difference between the two groups in relation to the admission of the new born to NICU. As opposed to 19% in the control group, and 53% of neonates in the study group. Similar results were also found by Chandra p et al<sup>(16)</sup>.

## Conclusion

Oligohydramnios increases the risk of foetal distress, caesarean section, NICU admission, and low Apgar score. The severity of oligohydramnios and foetal well-being determined the mode of delivery. In conclusion, oligohydramnios is a high-risk pregnancy, and patients with oligohydramnios should expect proper antepartum, rigorous foetal surveillance, and intrapartum care for a better foeto-maternal outcome.

**Conflict of Interest:** None Declared

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**Ethical Approval:** This study was approved by the institutional Ethics Committee.

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# A Comparative Study of Serum Lipid Profile in Normal Pregnancy and Pregnancy Induced Hypertension

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## Abstract

**Background:** Pregnancy induced hypertension is a significant contributor to maternal and foetal morbidity and mortality worldwide. Studying the lipid profile and risk variables is crucial for illness prevention, management, and a better prognosis.

**Method and Materials:** This study was a case control study conducted in the Department of Obstetrics and Gynaecology, Tezpur Medical College and Hospital, Tezpur. A total of 100 (one hundred) were selected, out of which 50 (fifty) normotensive pregnant women served as a control and 50 (fifty) hypertensive women constituted the study group. Besides baseline routine investigations, estimation of Serum lipid profile was done by collecting blood samples from antecubital vein of every case and control and were analysed at department of Biochemistry, Tezpur Medical College and Hospital, Tezpur.

**Results:** The hypertensive group had a significant rise in Triglyceride (TG), total cholesterol, LDL-C levels and decreased HDL-C levels as compared to the control group.

**Conclusion:** Abnormal lipid profile during pregnancy plays an important role in development of pre-eclampsia.

**Keywords:** Pregnancy Induced Hypertension (PIH); Lipid Profile; Pre-eclampsia (PE); Triglycerides (TG), High Density Lipoproteins (HDL-C).

## Introduction

Pregnancy Induced Hypertension is defined as a blood pressure greater than 140/90 mm Hg on two separate occasions at least 6 hours apart. Pre-eclampsia is a pregnancy-related condition that affects multiple systems<sup>(1)</sup>. Pre-eclampsia (PE) is one of the most common pregnancy complications and a major cause of maternal and neonatal mortality and morbidity worldwide<sup>(2,3)</sup>. It is identified by elevated blood pressure and proteinuria after 20 weeks of gestation in a previously normotensive patient. Pre-eclampsia affects 3-5% of women worldwide<sup>(4)</sup>. As per

the report of India's third National Family Health Survey (NFHS-3, 2005-06), which was based on self-reported symptoms suggestive of preeclampsia and eclampsia by women who had a live birth in the five years preceding the survey, the incidence of preeclampsia and eclampsia in India might be higher (~28% and 7.4–11.3% respectively) as compared to its incidence worldwide<sup>(5)</sup>.

Pre-eclampsia appears in the second and third trimesters of pregnancy<sup>(6)</sup>. Hypertension is the most common symptom of PE, which is caused by vasospasm in the kidneys, uterus, placenta, and

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brain. Endothelial prostacyclin levels in pregnant women are typically 8-10 times higher than in non-pregnant women. However, this increase is only 1-2 times greater in women with pre-eclampsia. Pre-eclampsia patients have higher thromboxane levels than normal pregnant women (7). Vasospasm is ensured by endothelial cell destruction because prostacyclin is a vasodilator and thromboxane is a vasoconstrictor(8). Increased lipid synthesis increases the rate of thromboxane prostacyclin, which aids in the pathogenesis of pregnancy-induced hypertension (9). Injury and dysfunction of endothelial cells are important in the pathogenesis of PE. Women with a history of PIH have significantly different lipid parameters and increased susceptibility to lipoprotein peroxidation when compared to women with normal pregnancy-the most common factor associated with PE is placental vasculopathy. If PE is caused by a combination of factors, triglyceride-related vasculopathy could be one of them(10). Triglycerides are likely to be deposited in predisposed vessels such as the uterine spiral arteries and contribute to endothelial dysfunction both directly and indirectly through the generation of small dense LDL cholesterol, resulting in endothelial dysfunction and thus fetoplacental insufficiency and proteinuria in pre-eclampsia patients. The present study was conducted to look into the differences in lipid profiles between normal and hypertensive women.

## Material and Methods

**Study Design:** Case control study.

**Study Site:** Department of Obstetrics and Gynaecology, Tezpur Medical College and Hospital, Tezpur, Assam which is a tertiary care hospital.

**Study Duration:** July 2021- June 2022.

**Sample Size:** The sample size calculated via online sample calculator came out to be 50 in each group. A total of 100 study participants were recruited among which 50 were women with Pregnancy Induced Hypertension who were taken as cases while 50 women who were normotensive were taken as controls.

**Inclusion Criteria:** Women with singleton pregnancy, age between 18-37 years, gestational age between 20-42 weeks and who were known cases of Pregnancy Induced Hypertension.

**Exclusion Criteria:** Women with eclampsia, multiple pregnancies, severe anaemia, and history of smoking or any chronic medical illness were excluded.

**Consent:** An informed written consent was obtained before recruiting any participants for the study and participants were explained about the objectives of the study.

**Procedure:** A thorough general physical examination was done along with ultrasonography for confirmation of gestation age. Routine laboratory investigation was done viz., CBC, KFT, LFT, HIV, HBsAg, VDRL. Blood pressure was measured by the sphygmomanometer from the right arm while the patient was in semi recumbent position with the arm roughly at the level of heart.

**Estimation of serum lipid profile:** Peripheral blood sample (5ml) was collected from antecubital vein of every case and control and collected in vacutainer and sent to the Department of Biochemistry for analysis. The sample were analysed for serum triglyceride, total cholesterol and HDL-Cholesterol by enzymatic methods with the help of ROCHE diagnostic kit. Serum LDL-C was calculated by using Friedewald equation :  $LDL-C = TC - (TG/5 + HDL-C)$

**Statistical Analysis:** Data was expressed as mean and percentage. Statistical analysis was done using Chi-square, Student T test. Statistical package for social sciences (SPSS-23) and Microsoft Excel software were used for analysis.  $P < 0.05$  was considered as significant at 95% CI.

**Ethical Issues:** The study was conducted as per already established guidelines and protocols and had no ethical issue related to animal or human experimentation.

## Results

**Table 1:** 50 Pregnancy Induced Hypertension cases are taken in this study. It is seen most commonly the patients belong to the age group of 20-24 years 26 (52%), followed by 25-29 years 15 (30%). 4 cases are found in the age group of >30 years. The youngest patient is 18 years old, while the oldest is 34 years old in the study.

**Table 2:** Out of 50 cases selected for the study, 25 (50%) cases present with SBP between 141-160 mmHg. 13 (26%) of them have SBP between 161-180 mmHg, 9 (18%) have SBP of 181-200 mmHg and 3 (6%) cases present with SBP of >200 mmHg at the time of admission.

**Table 3:** Out of 50 cases selected for the study, 10 (20%) are in 91-100 mmHg group, 15 (30%) in 101-110 mmHg group, 20 (40%) in 111-120 mmHg group and 5(10%) cases have DBP >120 mmHg.

**Table 4:** It was found that Mean  $\pm$  SD of triglycerides, total cholesterol, and LDL cholesterol among the women in the study group was higher than the Mean  $\pm$  SD of triglycerides, total cholesterol, and LDL cholesterol among women in the control group. Further, Mean  $\pm$  SD of HDL-cholesterol among the study group was lower than the Mean  $\pm$  SD of HDL-Cholesterol among the control group. Statistically, there is a significant difference in case of triglycerides, total cholesterol, HDL- cholesterol and LDL-cholesterol.

**Table 1: Table with Age Wise Distribution of Patients**

AGE (YEARS)	NO. OF PATIENTS	PERCENTAGE
< 20 YEARS	5	10%
20-24 YEARS	26	52%

25-29 YEARS	15	30%
>30 YEARS	4	8%
TOTAL	50	100%
MEAN AGE	23.5	
SD	$\pm$ 4.24	

**Table 2: Table Showing Distribution of Cases According to Systolic Blood Pressure**

SBP ON ADMISSION	NO. OF CASES	PERCENTAGE
141-160 mm Hg	25	50%
161-180 mm Hg	13	26%
181-200 mm Hg	9	18%
>200 mm Hg	3	6%
TOTAL	50	100%

**Table 3: Table Showing Distribution of Cases According to Diastolic Blood Pressure**

DBP ON ADMISSION	NO. OF CASES	PERCENTAGE
91-100 mm Hg	10	20%
101-110 mm Hg	15	30%
111-120 mm Hg	20	40%
>120 mm Hg	5	10%
TOTAL	50	100%

**Table 4: Table with Serum Lipid Profile of Controls And Cases**

PARAMETERS	STUDY GROUP (MEAN $\pm$ SD)	CONTROL GROUP (MEAN $\pm$ SD)	P- VALUE
Triglyceride	224.30 $\pm$ 38.41	178.06 $\pm$ 21.02	< 0.001
Total Cholesterol	206.82 $\pm$ 29.89	166.64 $\pm$ 18.80	< 0.001
HDL-Cholesterol	38.92 $\pm$ 6.09	45.64 $\pm$ 4.69	< 0.001
LDL-Cholesterol	119.94 $\pm$ 20.24	90.22 $\pm$ 15.41	<0.001

## Discussion

Recently, there has been much debate about the role of lipid metabolism in the development of Pregnancy Induced Hypertension and Pre-eclampsia. Previous research found that plasma lipid levels in women with pre-eclampsia were higher than in healthy pregnant women <sup>(11,12)</sup>. The lipid changes are thought to contribute to the endothelial

cell damage associated with PE. Lipid peroxidation is low in all cells and tissues. Free radical oxidation and antioxidant neutralisation are balanced in good health <sup>(13)</sup>. Antioxidant nutrients are abundantly used in PE to combat the cellular changes caused by free radicals such as lipid peroxides. Abnormal lipid metabolism is not only a symptom of PE; it also plays a role in its pathogenesis <sup>(14)</sup>.

Based on these findings, the current study was designed to compare serum lipid levels in pregnancy-induced hypertension and normal pregnancy. The mean SD serum triglyceride level in the hypertensive group was 224.30 38.41. The mean SD of serum triglyceride level in the control group was 178.06 21.02; the difference is statistically significant. Jayanta De et al<sup>(15)</sup> and Torun Clausen et al<sup>(16)</sup> found that hypertensive women had higher triglyceride levels than normotensive women. The mean serum concentration of total cholesterol in the current study is 166.64 + 18.80 in controls and 206.82 + 29.89 in cases; the difference is statistically significant. Md. Zakir H et al. <sup>(17)</sup>, S. WareJauregui et al. <sup>(18)</sup>, and Shruthi Mohanty et al. <sup>(19)</sup> found a significant increase in total cholesterol levels in hypertensive women compared to normotensive women. The mean serum concentration of LDL cholesterol in the current study is 90.22 + 15.41 in controls and 119.94 + 20.24 in cases; the difference is statistically significant. Torun Clausen et al<sup>(16)</sup> and Carlos A. Negrato et al<sup>(20)</sup> also found a significant increase in LDL-cholesterol levels in hypertensive women compared to normotensive women. In the current study, the mean serum concentration of HDL cholesterol in controls is 45.64 + 4.69 and in cases is 38.92 + 6.09, a statistically significant difference.. Carlos A. Negrato et al<sup>(20)</sup> and S. WareJauregui et al<sup>(18)</sup> also observed a significant decrease in HDL-Cholesterol levels in hypertensive women compared to normal pregnant women.

### Conclusion

An atherogenic lipid profile with elevated triglycerides, LDL-C, and decreased HDL-C contributes to the development of Pre-eclampsia by causing oxidative stress and endothelial dysfunction, and it plays a significant role in the development of Pre-eclampsia. This research contributes to a better understanding of the role of a changed lipid profile in the pathophysiology of Pregnancy Induced Hypertension and Pre-eclampsia. Detecting lipid profile changes in early pregnancy may aid in early diagnosis and the prevention and slowing of disease progression through medication or lifestyle changes.

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# Addressing the Socio-demographic Determinants of COVID-19 Vaccine Hesitancy among the General Population in a Rural Block of Andhra Pradesh, India: A Community Based Cross-sectional Study

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## Abstract

**Background:** Vaccine hesitancy continues to impede the attempts made globally in combating the COVID-19 pandemic. Hence, this study aims to determine the socio-demographic factors associated with COVID-19 vaccine hesitancy among the general population in a rural block of Andhra Pradesh.

**Methods:** A community based cross-sectional study was conducted among the general population of a rural block in Andhra Pradesh. A total of 210 participants were recruited through multi-stage random sampling technique. Data was collected through semi-structured schedule method. Descriptive statistics was computed to describe the socio-demographic characteristics, and Chi-square test was applied to assess the association between vaccine hesitancy and socio-demographic characteristics of the study participants.

**Results:** COVID-19 vaccine hesitancy rate among rural population was 45.5%. Statistically significant association was observed between vaccine hesitancy and socio-demographic characteristics like: age between 40-49 years, females, Hindus, illiterates, unemployed, marginal workers, lower middle class and those with two children in their family.

**Conclusion:** High prevalence of vaccine hesitancy was noted among rural population. Mass media strategies, evidence-based communication, and policy measures will have to be implemented across rural areas with special focus on groups identified with vaccine hesitancy.

**Keywords:** COVID-19 vaccine, Vaccine hesitancy, Vaccine acceptance

## Introduction

The first human cases of COVID-19 were reported by officials in Wuhan city, China, in

December 2019.<sup>[1]</sup> Since then the world is witnessing a major global humanitarian disaster, which has affected all aspects of life across the planet.<sup>[2]</sup> India

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was one of the world's worst-affected countries due to the COVID-19 pandemic. The pandemic has resulted in a huge impact across societies, with governments worldwide imposing restrictions to prevent the spread of the virus.<sup>[3]</sup> However, it is recognized that such preventive measures may not be sufficient to halt the spread of COVID-19.<sup>[2]</sup> In this situation a vaccine is considered to be the most awaiting, cost effective intervention. Currently vaccination prevents 2-3 million deaths a year, and a further 1.5 million could be avoided if global coverage of vaccinations is improved.<sup>[4]</sup> Hundreds of global Research and Development institutions were engaged in unparalleled speed to develop the vaccine.<sup>[5]</sup> Every nation is combating the outbreak with vaccination; and the success or failure of any vaccination programme is largely dependent on public behaviour.<sup>[6]</sup> Antivax groups' statements, conspiracy theories, myths and misperceptions, questions about the speed of vaccine development and long-term side effects, and expert opinion on challenges with the COVID-19 vaccine were proliferating in the national media.<sup>[7]</sup> In this situation of public health emergency, where vaccines are released in crisis, building vaccine confidence is the main challenge; without such confidence, vaccine hesitancy is natural. In fact WHO had mentioned vaccine hesitancy as one of the top global health threats.<sup>[4]</sup> Available literature suggests that vaccine hesitancy for COVID-19 varies significantly across the countries from 28 to 76%.<sup>[8]</sup> WHO defined vaccine hesitancy as a "delay in acceptance or refusal of vaccination despite availability of vaccination services".<sup>[4]</sup> It is a complex and context specific phenomenon varying across the time, place, and vaccines. It is influenced by factors such as complacency, convenience, and confidence;<sup>[9]</sup> however, high vaccine coverage is needed to flatten the epidemic curve.<sup>[10]</sup> Vaccine hesitancy affects not only the individual who is hesitant to take the vaccine, but the whole community, making it tough to reach the level of herd immunity. Understanding the magnitude of vaccine hesitancy, and identifying the key determinants that are responsible for vaccine hesitancy among rural community, may help to address these determinants. It will also contribute to help the policy makers and vaccination programme planners to develop strategies, to improve the uptake of COVID-19 vaccine. Majority (68.84 %) of Indian

population resides in rural areas;<sup>[11]</sup> Among rural population, very few studies have been conducted to understand hesitancy for COVID-19 vaccine at micro level. There are lacuna in research with regard to socio-demographic factors responsible for COVID-19 vaccine hesitancy. Thus, this study was carried out to conduct a comprehensive and systematic appraisal of COVID-19 vaccine hesitancy, in a community based sample of general population, living in a rural block of Andhra Pradesh.

### Research Questions

1. What is the extent of vaccine hesitancy for COVID-19 vaccine among general population of a rural block?
2. Is there any association between socio-demographic factors and COVID-19 vaccine hesitancy among rural population?

### Research Hypothesis

Among rural population, COVID-19 vaccine hesitancy will be associated with their socio-demographic factors.

### Objectives

1. To estimate the prevalence of COVID-19 vaccine hesitancy among the general population of a rural block.
2. To determine the socio-demographic factors associated with COVID-19 vaccine hesitancy.

### Materials and Methods

**Study design:** Community based cross-sectional study

**Study setting:** Housing unit of study participants living in the selected villages of rural Rajahmundry Block

**Study population:** All men and women above 18 years of age

**Inclusion criteria:** Study participants residing in the village at least for a period of 1 year were included in the study.

**Exclusion criteria:** Seriously ill patients, mentally disabled, those with history of allergic reactions were excluded from the study.

**Sample size:** By applying the formula,  $4pq/L^2$ , the sample size obtained was 189 ( $p = 13.7\%$ , the prevalence of COVID-19 vaccine hesitancy,<sup>[12]</sup> and  $L$  is allowable error of 5%). Accounting for 10% non-response rate, the final sample size was arrived at 207.

**Sampling technique:** The participants were recruited in the study through multi-stage random sampling technique; Rajahmundry rural block consists of 9 villages; 5 villages were selected by simple random sampling technique (Lottery method). Each village has 1500 to 4200 households. From each village 42 households were selected again by simple random sampling. Each household has an average size of 5 members; From each household one participant was selected randomly. A total of 210 participants were recruited for the study.

**Study period:** 3 months (January 2021 to March 2021)

**Study tools:** Semi-structured schedule with a set of questions

**Data collection:** The study participants were explained about the purpose of the study, and were assured of the anonymity and confidentiality; Informed consent was taken prior to the interview.

**Data analysis:** Descriptive statistics was computed to describe the socio-demographic characteristics of the study participants. Chi-square test was applied to assess the association between vaccine hesitancy and socio-demographic factors.

## Results

A total of 210 participants were enrolled in the study. Around 10 participants were non-responsive; hence, complete data was collected from 200 participants. An aggregate of 91 (45.5 %) participants showed vaccine hesitancy.

**Table 1: Comparison of socio-demographic characteristics between vaccine acceptance and vaccine hesitancy groups**

Socio-demographic variables	Vaccine acceptance n=109 (54.5%)	Vaccine hesitancy n=91 (45.5%)	Total n=200	p-Value
<b>Age (years)</b>				
18-29	25 (22.94%)	18 (19.78%)	43 (21.5%)	0.00001
30-39	48 (44.04%)	9 (9.89%)	57 (28.5%)	
40-49	24 (22.01%)	27 (29.67%)	51 (25.5%)	
50-59	7(6.42%)	16 (17.58%)	23 (11.5%)	
>/=60	5 (4.59%)	21 (23.08%)	26 (13%)	
<b>Sex</b>				
Male	77 (70.64%)	19 (20.88%)	96 (48%)	0.00001
Female	32 (29.36%)	72 (79.12%)	104 (52%)	
<b>Religion</b>				
Hindu	106(97.24%)	78 (85.71%)	184 (92%)	0.028
Muslim	1 (0.92 %)	6 (6.59 %)	7 (3.5%)	
Christian	1 (0.92 %)	4 (4.40% )	5 (2.5%)	
Others	1 (0.92 %)	3 (3.30 %)	4 (2%)	
<b>Caste</b>				
OC	35 (32.11%)	34 (37.36%)	69 (34.5%)	0.661
BC	51 (46.79%)	35 (38.46%)	86 (43%)	
SC	18 (16.51%)	16 (17.58%)	34 (17%)	
ST	5 (4.59%)	6 (6.59%)	11 (5.5%)	
<b>Literacy status</b>				
Literate	98 (89.91%)	39 (42.86%)	137 (68.5%)	0.00001
Illiterate	11 (10.09%)	52 (57.14%)	63 (31.5%)	

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<b>Employment status</b>				
Employed	102 (93.58%)	66 (72.53%)	168 (84%)	0.00005
Unemployed	7 (6.42%)	25 (27.47%)	32 (16%)	
<b>Socioeconomic status</b>				
Upper	4 (3.67%)	2 (2.20%)	6 (3%)	0.00001
Upper middle	24 (22.02%)	2 (2.20%)	26 (13%)	
Middle	23 (21.10%)	8 (8.79%)	31 (15.5%)	
Lower middle	38 (34.86%)	44 (48.35%)	82 (41%)	
Lower	20 (18.35%)	35 (38.46%)	55 (27.5%)	
<b>Marital status</b>				
Married	106 (97.25%)	80 (87.91%)	186 (93%)	0.009
Unmarried	3 (2.75%)	11 (12.09%)	14 (7%)	
<b>Head of the family</b>				
Yes	61 (55.96%)	62 (68.13%)	123 (61.5%)	0.078
No	48 (44.04%)	29 (31.87%)	77 (38.5%)	
<b>Type of family</b>				
Nuclear	58 (53.21%)	59 (64.84%)	117 (58.5%)	0.095
Joint	16 (14.68%)	15 (16.48%)	31 (15.5%)	
3-generation	35 (32.11%)	17 (18.68%)	52 (26%)	
<b>Number of children in the family</b>				
No children	1 (0.92%)	4 (4.40%)	5 (2.5%)	0.00001
1 child	8 (7.34%)	7 (7.69%)	15 (7.5%)	
2 children	63 (57.80%)	76 (83.51%)	139 (69.5%)	
3 or more	37 (33.94%)	4 (4.40%)	41 (20.5%)	

Table 1 explains that Chi-square test revealed significant association between vaccine hesitancy and socio-demographic factors of the study participants like: age between 40-49 years, females, Hindus,

illiterates, unemployed, lower middle class and those with two children in their family. p-value < 0.05 was considered as statistically significant.

**Table 2: Distribution of employed participants according to duration of work**

Variables	Frequency	Percentage %
Employed (n=168)		
Main workers (>6 months)	149	88.7 %
Marginal workers (<6 months)	19	11.3 %

Table 2 depicts that out of the total working participants, majority (88.7%) were main workers

(engaged in economically productive work for more than 6 months).

**Table 3: Comparison of vaccine hesitancy between main workers and marginal workers**

Variables	Vaccine acceptance n=102	Vaccine hesitancy n=66	Total n=168	p-Value
Main workers	98(96.08%)	51 (77.27%)	149 (88.7%)	0.0001
Marginal workers	4 (3.92%)	15 (22.73%)	19 (11.3 %)	

Table 3 demonstrates that Chi-square test showed significant association between marginal workers (engaged in economically productive work for less than 6 months) and vaccine hesitancy.

### Discussion

The prevalence rate of COVID-19 vaccine hesitancy among rural population was 45.5%. As predicted in research hypothesis, among rural population, there are socio-demographic factors associated with COVID-19 vaccine hesitancy.

In the present study, most (28.5%) of the participants were between 30 to 39 years of age; whereas 13% were above 60 years. In contrast to this finding, Qattan et al., [2] reported that 45.32% of the participants were between 30 to 39 years, and 3.57% were more than 60 years of age. The difference observed was, it was an online cross-sectional survey, conducted to determine the acceptability of a COVID-19 vaccine among healthcare workers, in the Kingdom of Saudi Arabia. Among the vaccine hesitancy group (n=91), most of the participants were between 40-49 years. Interestingly, Al-Mohaithef and Padhi found that majority (79.2%) of the respondents who were aged 45 years and above, showed interest to uptake the vaccine if it is available.[5] Malik Sallam reported that age is also an important predictor, as younger adults are less enthusiastic about taking COVID-19 vaccines.[8]

Majority (52%) of the participants were females. This finding is consistent with Khubchandani et al, [7] who reported a majority of 52%. Our results confirmed a higher vaccine hesitancy rate among women than men, which is consistent with previous studies. [8], [13], [14] In general, Indian women are more likely to practice preventive behaviours and avoid risk behaviours; with regard to health, they give high priority to the family members, and low priority to themselves; these might be the possible reasons for their vaccine hesitancy behaviour. In contrast to this finding, Mohamad Ali and Hossain found that vaccine hesitancy was high among males. [15]

In the present study, 92% of the participants were Hindus, as it was the predominant population in the study area. Dissimilar to this finding, a study carried out in Bangladesh, reported that majority (93.2%) were Muslims.[15]

Masthi and Sowmyashree found that 18.6% were illiterates. [16] This finding is in contrast with the present study, where 31.5 % illiteracy was observed. In addition, our study showed significant association between illiteracy and vaccine hesitancy, which is similar to previous research by Khubchandani et al. [7]

Majority (84%) of the study participants were employed. This finding is contradictory to a previous study conducted in United States (47%). [14] Unemployed and marginal workers exhibited vaccine hesitancy, with significant association. Impressively, Dror et al., [17] found unemployment as a positive predictor for vaccination. Short work duration, low economic status, and fear of losing the daily wages might be the possible reasons for vaccine hesitancy among marginal workers.

Most (41%) of the participants belonged to lower middle class and were likely to hesitate vaccine uptake; this finding is in line with previous studies. [7], [18]

Majority (93%) of the participants were married; Previous research by Al-Hanawi et al., [6] revealed that 63.43% were married, which was less compared to the present study. Additionally, it was found that unmarried participants were significantly associated with COVID-19 vaccine hesitancy. In contrary to this finding, Qattan et al., [2] found that unmarried individuals are more willing to accept COVID-19 vaccine rather than married individuals. The reason could be that their study participants were health care workers, and they have more chances of exposure to infection rather than general population.

A study in Tamil Nadu revealed that majority (82.1%) of the participants were from nuclear families. [19] In contrary to this finding, the present study reported that 58% were from nuclear families. The difference could be due to the fact that in previous study, the sample included rural as well as urban communities; and urban communities mostly prefer to be in a nuclear family, rather than joint or three-generation family.

Nearly 70% of the participants responded that they have 2 children in their family. In contrast to this finding, Khubchandani et al., [7] found that majority (53 %) of the respondents have no children at home. The possible reason for the difference could be that

their study investigated a community-based sample of the American adult population, whose children prefer to be independent at an early age, and they stay away from parents. The present study revealed that participants with 2 children were more likely to show vaccine hesitancy. Similar to this finding, previous research also concluded that vaccine hesitancy was higher among those who had children at home. [7] Belief on rumours in social media; and fear of death and family disruption following vaccination, could be the reasons for vaccine hesitancy among adults, who had children at home.

**Limitations:** First, the study is limited to a particular rural geographical location in Andhra Pradesh; it is not a state-wide representative survey. Second, there is possibility of social desirability bias, as the interviewer was affiliated to the health system.

### Conclusion

There is high level of COVID-19 vaccine hesitancy among general population, in a rural block of Andhra Pradesh; and the vaccine hesitancy was associated with socio-demographic characteristics of the participants. Understanding the subgroups of the population, which have high levels of vaccine hesitancy will guide to develop specific targeted interventions, and to design social vaccine, to overcome the vaccine hesitancy.

**Recommendations:** Effective Behaviour Change Communication campaigns. Mass media strategies, Evidence-based communication, and policy measures will have to be implemented across rural areas, with special attention towards the groups identified with vaccine hesitancy.

**Conflicts of interest:** Nil

**Source of funding:** Self

**Ethical Clearance:** Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study.

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# A Study on Self Medication Practices During Covid-19 Pandemic

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## Abstract

Self Medication(SM) “involves the use of medicinal products by the consumer to treat self recognized disorders or symptoms, or the intermittent or continued use of a medication prescribed by a physician for chronic or recurring diseases or symptoms”. The objective of this study was to determine practices of Self Medication. The present study was conducted in the field practice areas of the Department of Community Medicine, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, from August 2021 to July 2022. It was a community based cross-sectional study. A total of 424 people was included. Simple Random Sampling was done. Individuals  $\geq 18$  years of age from families of RHTC and UHTC, those who experienced an episode of illness after start of Covid-19 pandemic and those who gave consent were included in the study. Patients who were bed-ridden and/or suffering from mental illness and those who did not give consent were excluded from the study. Data entry and analysis was done in IBM SPSS v 26.0. Relevant statistical tests were applied wherever required. Nearly half of the study population practised Self Medication as a form of treatment at least once in the preceding 12 months. The major source of information for the choice, dosage and duration of the medicines consumed for Self Medication in our study was found to be the pharmacist (69.0%). It was followed by prior experience (31.0%) and previous prescription (15.2%). In our study analgesics and antipyretics were found to be consumed by the highest percentage of study participants. People should be made aware of the risks of Self Medication and should be guided on responsible Self Medication. Awareness campaigns may be organised in this regard.

**Key Words:** Self medication, Covid 19, types of medicine

## Introduction

According to WHO, Self Medication(SM) “involves the use of medicinal products by the consumer to treat self recognized disorders or symptoms, or the intermittent or continued use of a medication prescribed by a physician for chronic or recurring diseases or symptoms”. SM practises have the potential to cause antimicrobial resistance, undesirable side effects, and in certain circumstances, even death. The prevalence of SM use is estimated

to be high in India, with one metaanalysis showing the mean prevalence to be 53%<sup>(1)</sup>. There are many advantages and disadvantages of Self Medication. The common advantages are that Self Medication is a faster and cheaper form of treatment solution<sup>(2)</sup>. The consultation cost is bypassed and consultation time is saved. In hilly, tribal and other hard to reach areas, where there might be a shortage of health work force, patients might depend upon Self Medication<sup>(3)</sup>. Self Medication reduces the work absenteeism due to

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minor symptoms<sup>(4)</sup>. There are many disadvantages of Self Medication. Resorting to Self Medication might mask the symptoms of chronic diseases. Thus, it might delay the diagnosis of such conditions. Some drugs may interact with other drugs. These drug interactions can lead to harmful effects on human body and have unpredictable effects on the disease. Inadequate dose of a medicine might be used. This might lead to the patient not getting relief from the ailment. For antimicrobials, it might lead to AMR. Antimicrobial Resistance (AMR) is a major challenge faced by humanity. Self Medication can cause irrational use of antimicrobials and thus can lead to AMR.

The objective of this study was to determine practices of Self Medication.

### Material and Methods

The present study was conducted in the field practice areas of the Department of Community Medicine, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, from August 2021 to July 2022. It was a community based cross-sectional study. A total of 424 people was included. Simple Random Sampling was done.

**Inclusion Criteria** Individuals  $\geq 18$  years of age from families of RHTC and UHTC. Individuals

who experienced an episode of illness after start of Covid-19 pandemic. Individuals who gave consent to be a part of study.

**Exclusion Criteria** Individuals  $< 18$  years of age. Individuals who do not give consent to be a part of the study. Patients who were bed-ridden and/or suffering from mental illness. Ethical clearance was obtained from Institutional Ethics Committee. Confidentiality was maintained and the participants were adequately assured of the same. Data entry and analysis was done in IBM SPSS v 26.0. Relevant statistical tests were applied wherever required.

### Results

**Table 1: Consumption of any medicine in last one year by the study participants (N=424)**

Consumed any medicine	n (%)
Yes	400 (94.3%)
No	24 (5.7%)

**Table 2: Consumption of Self Medication in last one year by the study participants (N=400)**

Self Medication	n (%)
Yes	210 (52.5%)
No	190 (47.5%)

**Table 3: Source of Information regarding Self Medication**

Source of Information	Rural (N=117) n (%)	Urban (N=93) n (%)	Total (N=210) n (%)
Pharmacist	83 (70.9%)	62 (66.7%)	145 (69.0%)
Family, Friends and Neighbours	4 (3.4%)	6 (6.5%)	10 (4.8%)
Previous prescription	21 (17.9%)	11 (11.8%)	32 (15.2%)
Prior experience	35 (29.9%)	30 (32.3%)	65 (31.0%)
Advertisement	1 (0.9%)	0	1 (0.5%)
Others	0	1 (1.1%)	1 (0.5%)

**Table 4: Type of Medicines consumed by users of Self Medication**

Type of Medicine	Rural (N=117) n (%)	Urban (N=93) n (%)	Total (N=210)
Analgesic	80 (68.4%)	60 (64.5%)	140 (66.7%)
Antipyretic	70 (59.8%)	51 (54.8%)	121 (57.6%)
Antibiotic	33 (28.2%)	6 (6.5%)	39 (18.6%)
Antacid	13 (11.1%)	5 (5.4%)	18 (8.6%)



Continue.....

Antiemetic	6 (5.1%)	2 (2.2%)	8 (3.8%)
Antihistamine	34 (29.1%)	30 (32.3%)	64 (30.5%)
Antidiarrhoeal	3 (2.6%)	5 (5.4%)	8 (3.8%)
Antihypertensive	5 (4.3%)	4 (4.3%)	9 (4.3%)
Antidiabetic	6 (5.1%)	5 (5.4%)	11 (5.2%)
Others	7 (6.0%)	4 (4.3%)	11 (5.2%)

### Discussion

As shown in **table 1**, from a total of 424 study participants taken, 400 had suffered from an episode of illness in the past 12 months for which they required medication. Out of these 400 study participants, 210 (52.5%) used Self Medication as a form of treatment at least once in the preceding 12 months.

As shown in **table 3**, the major source of information for the choice, dosage and duration of the medicines consumed for Self Medication in our study was found to be the pharmacist (145, 69.0%). It was followed by prior experience (65, 31.0%) and previous prescription (32, 15.2%). Pharmacist was the major source of information in most of the studies (5,6,7,8,9). Another study<sup>(10)</sup> found that the major source of information was previous prescription, while family members and friends were the major source of information in rural Meghalaya and rural Sahaswan<sup>(11)</sup> and<sup>(12)</sup> respectively. A higher proportion of people from rural areas (17.9%) used previous prescription as a source of information for Self Medication, as compared to their urban counterparts (11.8%). This may be because of difficulties in repeated follow-ups in rural areas, due to accessibility or transportation issues.

Similar to our study (**table 4**), analgesics and antipyretics were found to be consumed by the highest percentage of study participants in other studies also<sup>(10,7,13,14)</sup>. Similar finding was reported in other study<sup>(15)</sup>. Another study<sup>(16)</sup> found that analgesics were the medicine most commonly used for Self Medication. Another studies<sup>(5,17)</sup> found the use of antibiotics to be 43.9% and 34.95% respectively. This was higher than that found in our study (18.6%). These studies were undertaken at predominantly urban places like urban areas of Kolkata and Puducherry.

### Conclusion

People should be made aware of the risks of Self Medication and should be guided on responsible Self Medication. Awareness campaigns may be organised in this regard. The pharmacists should be sensitised to the risks and benefits of using non-prescription medicines in the treatment of common illnesses without the advice of a doctor. Necessary information regarding use of non-prescription medicines should be printed on the label. This may be done in the local language to ensure maximum reach.

**Conflict of interest:** nil

**Source of Funding:** self

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# Prognostic Biochemical Markers Predicting Severity Caused by COVID 19: A Retrospective Observational Study Conducted in a Small Health-care Set UP in Western U.P.

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## Abstract

**Background:** For assessment of mild to severe outcome points of SARS COV-2 we need to observe patients with comorbidities along with basic laboratory markers like NLR, PLR, CRP, D-dimer, serum Ferritin etc. For the prediction of SARS COV-2 severity our study aims at basic available laboratory prognostic biomarkers.

**Methods and Result:** Our study included 46 patients with mild, moderate and severe outcomes which were categorised according to CRP, Serum Ferritin and D- dimer with p-Value < 0.001 for both outcomes which are significant as compared to outcome patients with p-Value = 0.01 which is slightly less significant.

**Conclusion:** A raised value of CRP, ferritin, D-dimer and involvement of male gender and old age patients were associated with severity of the disease.

Among these parameters, D-dimer was known to be the best predictor of the outcome.

**Keywords:** COVID-19, comorbidities, severe outcomes, CRP, D-dimer, Serum Ferritin

## Introduction

A novel Coronavirus(SARS- COV-2) causing a cluster of respiratory infections was identified on 7th Jan 2020 in Wuhan, China<sup>1</sup>. An explosive increase in number of cases led WHO to declare this outbreak as a public health emergency of intestinal concern on 30th Jan 2020<sup>2</sup>. Since, being declared as a pandemic by WHO on March 2020, Covid 19 infection posed great threat to human health<sup>3</sup>.

On 29th September 2022, there have been 61,39,42,561 confirmed cases of Covid 19 including

65,20,263 deaths globally reported to WHO. India recorded 528611 Coronavirus deaths since the epidemic began, according to WHO. In addition, India reported 4,45,79,088 Coronavirus cases<sup>4</sup>. In India, first confirmed case was reported on 27th Jan 2020 in Thrissur, Kerala in a female presented with a symptoms of sore throat and dry cough<sup>5</sup>.

It was noticed that SARS-COV-2 infection, especially in older patients and those with pre-existing illness, can progress to severe disease with critical respiratory symptoms and significant

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pulmonary changes visible by imaging techniques<sup>6</sup>. It is well documented that inflammatory mechanisms and markers play a vital role in Covid-19 cases related outcomes of the disease<sup>7</sup>.

Several studies showed low lymphocyte count, NLR with quick index of inflammation detection convenient in laboratory examination<sup>1</sup>. Clinicians should consider serum levels of CRP, D-dimer and Ferritin, which may be used in risk stratification to predict severe and fatal Covid-19 in hospitalised patients<sup>6</sup>. Our study used simple available laboratory markers of good predictive value for Covid-19 prognostic which summarises these markers that might be useful in indicating progression from mild to severe disease.

### Material and Methods

We conducted a retrospective study in Western UP in a tertiary care hospital on 46 patients positive with COVID 19 antigen test. The study was conducted between the period April 2021 to June 2021.

**Inclusion criteria-** The study incorporated all the adult (>18 years) COVID 19 patients of both genders which are hospitalised with all disease severity levels.

**Data Collection-** Laboratory data and clinical records were considered in each study and then data will be collected on the basis of demographic and clinical data which includes age, gender, presenting symptoms, outcomes and comorbidities.

Various laboratory investigations were done like CRP, Neutrophil to Lymphocyte ratio, D-Dimer and Serum ferritin.

**Clinical Outcome-** Primary outcome of this study was placed on admission in ICU, if the patient had one or more of the following symptoms:

1. Respiratory rate >30 cycles / min.
2. SPO<sub>2</sub> < 90% on room air or respiratory failure require mechanical ventilation.
3. Presence of shock or other organ failure requires monitoring or treatment in ICU.
4. Different prognostic biomarkers will be compared and the patients were divided into Mild, Moderate and Severe.

Furthermore, patients symptoms, such as shortness of breath, cough, sore throat, rhinorrhea, loss of smell etc were documented.

### Statistical analysis:

The collected data was entered in Ms excel and was imported in IBM SPSS vs. 25.0. The collected data was analysed by appropriate statistical tools and techniques. A  $p < 0.05$  was taken as statistically significant.

### Result

Screening of 46 patients record were conducted. Out of 46 patients, 7 were less than 30 years. The mean age of patients included in the study was 48, besides 54.35% were males (Table-1).

**Table-1: Overall distribution of patients group according to age and gender (n=46)**

Gender	No	Percent (%)
Male	25	54.35
Female	21	45.65

The patients with severe outcome complaint with the symptoms of fever, shortness of breath, cough, rhinorrhea, loss of smell and lower respiratory tract symptoms like dry cough predominantly. The comorbid conditions were observed more in poor prognostic patients whose age were >30 years.

The moderate and severe outcome patients showed highly significant p-value as 0.045 and 0.03 respectively as compared to mild outcome patients with p- value 0.669 which is not significant.

(Table 2 and 3).

**Table-2: Distribution of age according to comorbidity (n=29)**

S. No	Age group	Number
1	< 30 years	2
2	30 years	0
3	> 30 years	27

**Table-3: Comparison of comorbidity p-Value in different outcomes (n=29)**

S. No	Outcomes	No.	%	p- value
1	Mild	22	47.83	0.04
2	Moderate	16	34.78	-
3	Severe	8	17.39	-

In our study, Neutrophil Lymphocyte Ratio(NLR) was significantly higher in severe outcome patients. Patients with poor prognosis showed significant lymphopenia. There was not much difference between all the outcomes in the case of platelets. The moderate and severe outcome

patients had raised levels of CRP, serum ferritin and D-dimer with p-values <0.001 for both outcomes which are significant as compared to mild outcome patients with p-value 0.01 which is slightly less significant (Table-4).

**Table-4: Comparison of prognostic markers of COVID-19 patients in three outcomes alongwith their p-Values (n=46)**

	Severity			p-Value
	Mild	Moderate	Severe	
NLR	2.22±1.49	4.35±4.34	8.95±3.88	0.10
CRP	7.69±6.03	44.10±20.66	62.26±7.04	<0.001
D-Dimer	162.70±174.77	238.95±202.80	512.62±245.89	<0.001
Ferritin	175.73±99.26	319.85±116.61	302.90±105.33	<0.001
p-Value	<0.001	<0.001	<0.001	

The comparison of various biochemical parameters of COVID-19 patients have been tabulated (Table-5).

	Age	NLR	CRP	D-dimer	Ferritin
No	46	46	46	46	46
Mean	48.00	4.1387	29.8513	250.0817	247.976
Std. Error of mean	2.350	.58231	3.80493	34.07182	18.5226
Median	46.50	2.2000	19.1200	186.0500	245.050
Std Deviation	15.936	3.94943	25.80630	231.08635	125.6262
Variance	253.956	15.598	665.965	53400.900	15781.935
Range	56	18.00	70.28	959.92	504.4
Minimum	22	.60	.40	.08	11.3
Maximum	78	18.60	70.68	960.00	515.7

## Discussion

It has been shown that Covid-19 infection is associated with severe systemic immune response and extensive tissue damage by a cytokine release syndrome "Cytokine storm" resulting in capillary leak, thrombus formation and organ dysfunction<sup>8</sup>.

Sustained cytokine production and hyper inflammation with severe Covid-19 cases is in association with distinctive form of immune dysregulation<sup>9,10</sup>. Several studies reminisce us that the prognostic markers does not play the sole role in severity of the disease but also we need to be in focus of cytokines and immune functions<sup>1</sup>. In Covid-19 patients, progression from mild to severe cases in dependable on inflammatory response<sup>11</sup>.

In our study, we have focused an association between different prognostic parameters with

outcome of the disease. Involvement of male gender was observed significantly higher as comparison to female gender which is in concordance with result of Sagar S Maddani et.al.<sup>12</sup>.

In our study, old patients with COVID-19 were more prone to severe infection(Liu et al, 2020 a)<sup>13</sup>. One of the main reason for severe disease was observed in cases with underlying age related comorbidities. This was similar to Wang et al, Yang et al)<sup>14,15 16</sup>.

CRP is an acute phase reacting inflammatory marker that is highly related with many severe complications and even death<sup>17</sup>.

A useful relationship between severity of disease and values of CRP has been seen in many studies which is of clinical importance. It has been observed, that CRP was denoted as an early prognostic marker of disease severity in several studies.<sup>18</sup>

Several metaanalysis studies observed correlation between increased CRP with severe COVID 19 infection which is in concordance with our study.<sup>3</sup>

An essential inflammatory marker i.e. ferritin is used to prognosticate the severity & mortality of the disease.<sup>11</sup> At the transcriptional and translational level ferritin expression is regulated by cytokines.<sup>19</sup>

In our study, we observed a significant level of ferritin. The raised levels may be due to cytokine storm which is released from lung parenchymal macrophages.<sup>2</sup>

It is also known as the inflammatory condition and the levels of inflammatory markers are directly proportional to one another helping in forecasting the outcome of the disease.<sup>12</sup> One of the main prognostic biomarker in our study is D-dimer which is a fibrin degradation product resulting from fibrin hydrolysis. D-dimer detects coagulation, clotting disorder, pulmonary embolism and myocardial infection in infectious disease alongwith severity of disease in long stay patients.<sup>1</sup>

In current study, few limitations were noticed, the study was based on laboratory reports obtained from outdoor patients due to limited medical resources. Limited number of patients were involved in our study. We investigated easy, effortless and economical biomarkers leaving behind IL-6, Lactate dehydrogenase, troponin etc in our study.

### Conclusion

A raised value of CRP, ferritin, D-dimer and involvement of male gender and old age patients were associated with severity of the disease.

Among these parameters, D-dimer was known to be the best predictor of the outcome. For healthier outcome, we can use these parameters with limited medical resource so that high risk patients can be referred to higher centers.

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**Conflict of Interest:** None

**Ethical Clearance:** Taken

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## Study of Lipid Parameters in Subclinical Hypothyroidism

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### Abstract

**Introduction:** The Diagnosis of subclinical hypothyroidism is mostly biochemical as most of the patients have a serum TSH above the normal and serum free and total T4 and T3 are normal. Due to recent increasing prevalence of sub-clinical hypothyroidism and metabolic risk factors such as adverse cardiac function and hyperlipidemia, it recommended the importance of screening by assessment of serum TSH.

**Aims:** To assess the lipid profile in patients diagnosed with sub-clinical hypothyroidism

**Methods and Materials:** This study is a hospital based cross sectional study and comprised a total of 96 subjects performed in Chalmeda Anandrao Institute of Medical Sciences. Patients presenting to OPD with vague complaints of hypothyroidism are selected. They are screened for subclinical hypothyroidism by doing fasting TFT comprising freeT4, freeT3 and TSH and fasting lipid profile is also done for the patient. Laboratory analysis of blood urea, serum creatinine done.

**Results:** A Total number of 96 patients were studied, majority of them were between age group of 46 to 55 years.

The BMI distribution among SCH has no correlation to serum TSH levels.

Prevalence of subclinical hypothyroidism is more common among women.

TSH values range from minimum of 5.8 mIU/l to maximum of 25mIU/l.

Hypercholesterolemia was found in 40.6% of patients. LDL was elevated in 42.7% of cases. Triglyceride was elevated in only 27.1%. HDL values were found to be normal in 66.7% of cases.

**Conclusion:** Our study concludes that there are significant elevations in total cholesterol and serum LDL in subclinical hypothyroidism. There is no much significant changes in triglycerides and HDL levels.

**Keywords :** SCH- Sub-clinical hypothyroidism, TSH- Thyroid stimulating hormone, LDL- Low density lipoprotein, HDL- High density lipoprotein.

### Introduction

The diagnosis of subclinical hypothyroidism is mostly biochemical as most of the patients have

a serum thyroid stimulating hormone above the normal reference range and serum free and total thyroxine T4 and T3 are normal<sup>1</sup>.

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The prevalence is 7 to 26% in studies conducted in elderly. Since the hormone levels are normal there comes a confusion between compensated hypothyroidism and euthyroid state<sup>2</sup>.

It is also associated with dyslipidemia and adverse cardiovascular risk profile. Now the recent practical approach of treatment of subclinical hypothyroidism is levothyroxine therapy for persons with serum TSH of more than 10mIU/L and the therapy is individualised for patients with a TSH value of less than 10mIU/L<sup>3</sup>.

Subclinical hypothyroidism is a common endocrine problem with 3 to 8% prevalence among general population. Antithyroid antibodies are positive in 80% of patients with Sub clinical hypothyroidism. Prior radioiodine therapy, external neck and head irradiation may cause mild form of thyroid dysfunction<sup>3</sup>. Transient elevation of TSH values may occur after episodes of postpartum thyroiditis. Due to recent increasing prevalence of Subclinical hypothyroidism and metabolic risk factors such as adverse cardiac function and hyperlipidemia, the American Thyroid association has recommended the importance of screening by assessment of serum TSH values above the age of 35 years and followed up every 5 years later. Because of high likelihood of SCH to cause complications during pregnancy and brain development of fetus, screening of pregnant women for subclinical hypothyroidism is suggested<sup>3</sup>.

"In the conclusions of Whickham survey<sup>4</sup>, the risk of acquiring hypothyroidism was 4.3% per year in women in a year, if both the levels serum TSH and anti-thyroid antibodies were found to be elevated, 2.6% chance in patients with elevated TSH alone, and 2.1% chance per year with positive anti-thyroid antibodies alone." On follow up of the course of patients with subclinical hypothyroidism, a recent prospective study by Gerold Huber and team<sup>5</sup> concluded that high risk factors for progression to overt hypothyroidism were base line TSH >12uIU/mL, reduced thyroid reserve and positive for thyroid peroxidase antibody. So treatment of subclinical hypothyroidism holds good in various situations and in prevention of conversion to overt hypothyroidism<sup>2</sup>.

## AIMS

To assess the lipid profile in patients diagnosed with sub-clinical hypothyroidism

## Materials and Methods

### Study design and duration

A cross sectional study was undertaken from January 2022 to December 2022

### Sample size:

A Total of 96 patients presenting to the OPD with vague complaints of hypothyroidism are selected.

### Study centre:

The Study was Conducted in the Department of General Medicine, Chalmeda Anand Rao Institute of Medical Sciences, Karimnagar.

### Inclusion Criteria

- All newly detected cases of subclinical hypothyroidism [normal t3, t4, free t4 and TSH > 5.5 mU/L]

### Exclusion Criteria

- Patients aged twelve or less.
- Patients on thyroxine
- Known case of diabetes and hypertension
- Chronic renal failure
- Chronic liver disease
- Primary adrenal failure
- On drugs like beta blockers ,diuretics, steroids, OCP,
- Patients already on hypolipidemic drug

### Procedure

Cases were selected from patients presenting to general medicine op, general surgery op, endocrinology op and obstetrics and gynaecology op. Patients presenting to these op with vague complaints of obesity, recent gain of weight, tiredness, coarse facial features, hair loss, dry skin, infertility, voice changes, memory disturbance, cognitive dysfunction, mood disorders, swelling of neck, menstrual irregularities are selected. They are screened for SCH by doing fasting TFT comprising freeT4, freeT3 and TSH and fasting lipid profile is

also done for the patient. Among the 620 patients screened for subclinical hypothyroidism, 96 turned out to have the disease. All pregnant females are screened with TFT. Patients are selected after they fit into the inclusion and exclusion criteria. Clinical data comprises of thorough symptomatic analysis and physical examination and detailed history regarding past illness and drug intake. Laboratory analysis of blood urea, serum creatinine, TFT comprising of free T3, free T4, and TSH. And fasting lipid profile. Thyroid function test was done using ELISA and lipid profile using enzymatic kit method.

### Ethics Approval

This is to certify the ethical committee of Chalmeda Anand Rao Institute Of Medical sciences, Karimnagar, has unanimously approved Dr. K. Ramyasree, Post Graduate student in the subject of M.D. General Medicine at Chalmeda Anand Rao Institute of Medical Sciences, Karimnagar to take up the work entitled "Study of lipid parameters in subclinical hypothyroidism".

### Result

The collected data was analysed with SPSS 16.0 version. To describe about the data descriptive statistics, frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To assess the relationship between the variables Pearson's Correlation was used. To find the significance in categorical data Chi-Square test was used. In both the above statistical tools the probability value .05 is considered as significant level. Using this computer software, multiple variables like mean range percentages, standard deviation, chi square and p value etc are used to test for the statistical significance of the study. A p value of less than 0.05 denotes significant relationship.

**Table 1: TSH Distribution**

TSH	Frequency	Percent
<10	47	49.0
10-20	33	34.4
>20	16	16.7
TOTAL	96	100

**Table 2: Total Cholesterol Distribution**

Total cholesterol	Frequency	Percentage
Normal	39	40.6
Borderline	18	18.8
High	39	40.6
Total	96	100.0

**Table-3: LDL Distribution**

LDL	Frequency	Percent
Normal	41	42.7
Borderline	14	14.6
High	41	42.7
Total	96	100.0

**Table-4: Triglyceride Distribution**

Triglyceride	Frequency	Percent
Normal	70	72.9
Borderline	16	16.7
High	10	10.4
Total	96	100.0

**Table-5: HDL Distribution**

HDL	Frequency	Percentage
Abnormal	32	33.3
Normal	64	66.7
Total	96	100.0

### Discussion

In this study I screened patients for subclinical hypothyroidism and evaluation of dyslipidemia in these patients. Among 96 cases of subclinical hypothyroidism, 33% of them were found to be between age group of 46 to 55 years." The mean age of presentation was found to be 41.3 years, ranging from minimum of 11 years to maximum of 60 years. This prevalence rate increases as age increases. The BMI distribution among subclinical hypothyroidism has no correlation to serum TSH levels. Among 96 patients with subclinical hypothyroidism, 61.5% of patients had a normal BMI between 20 and 25 kg/m<sup>2</sup> and 13.5% of patients had BMI beyond 25 kg/m<sup>2</sup>. In regard to the sex distribution of patients, it was clearly evident that the prevalence of subclinical hypothyroidism is more common among women. Among 96 cases of subclinical hypothyroidism, only 8 cases were men.

On analyzing TSH distribution, it was found that among 96 cases, the mean TSH value was 12.3 mIU/l. The TSH values range from minimum of 5.8 mIU/l to maximum of 25mIU/l. 34% of the cases had TSH values between 10 and 20 mIU/l. On analysing the lipid profile abnormalities, patients were subjected to fasting lipid profile comprising serum total cholesterol, serum triglyceride, serum HDL and serum LDL. The reference range of serum lipid profile. Total cholesterol:

Normal:	200mg/dl
Borderline:	201 to 239
High:	> 240mg/dl
Normal:	< 200 mg/dl

Hypercholesterolemia was found in 40.6% of patients. Among 96% patients, 39 cases had high total cholesterol values. Borderline high values were found in 18.8% of patients. Mean cholesterol value of 213 mg/dl ranging from minimum of 119 to 310 mg/dl. LDL was elevated in 42.7% of cases. Among 96 cases, 41 patients had elevated LDL levels more than 160 mg/dl. Borderline high LDL values were found in 14.6%. The mean LDL value was 139 mg/dl ranging from minimum of 76 to 290 mg/dl.

Triglyceride was elevated in only 27.1%. Among 96 cases, only 26cases had high triglyceride values. Mean triglyceride value of 121.3 mg/dl ranging from minimum of 76 to 222 mg/dl.

HDL values were found to be normal in 66.7% of cases. The mean HDL was 51.9 mg/dl ranging from minimum of 33 to 70 mg/dl.

Similarly among the 96 cases, 41 patients had high serum LDL levels and 14 had borderline high LDL levels. among those 41 patients 17 of them were having TSH between 10 to 20 mIU/l and 15 of them were having TSH > 20 mIU/l. So TSH levels has significant correlation with total cholesterol and LDL levels. As the TSH level increases, the serum total cholesterol and LDL also increases.

Statistical analysis of Colorado thyroid prevalence study<sup>6</sup> showed significant elevation of total cholesterol and LDL in subclinical hypothyroidism compared to euthyroid controls. A meta-analysis conducted to evaluate the effect of thyroxine treatment<sup>7</sup> on

the lipid profile in subclinical hypothyroidism has shown significant reduction in total cholesterol level and LDL levels.

“In a randomised control trial, patients with subclinical hypothyroidism treated with thyroxine showed significant lowering of total cholesterol and serum LDL levels<sup>8,9</sup>”.

A metaanalysis in patients treated with thyroxine for subclinical hypothyroidism showed significant reduction in total cholesterol levels, without much significant change in serum HDL and triglyceride levels. The lowering of serum cholesterol was noticed in patients with levels more than 240mg/dl<sup>10</sup>.

Analysis of reports has showed increased prevalence of depression and bipolar affective disorder in patients with subclinical hypothyroidism<sup>11</sup>. Improvements in neuropsychiatric manifestations are seen with appropriate treatment with thyroxine<sup>10,11</sup>. These analysis concluded impairment of working memory in subclinical hypothyroidism. Also treatment with l-thyroxine showed improvement in memory performance and frontal executive functions<sup>12,13</sup>. “Subclinical hypothyroidism undetected during pregnancy adversely affect the survival and neuropsychological development of fetus. So this suggest the importance of screening of pregnant women for hypothyroidism and treatment of subclinical hypothyroidism<sup>13</sup>.”

The major practical benefit of initiation of treatment in subclinical hypothyroidism is improvement of symptoms, cognitive function like memory, lowering of levels of serum total cholesterol and serum LDL levels. Also treatment significantly improves cardiac function like myocardial contractility.<sup>14</sup>

## Conclusion

Lipid parameters in sub-clinical hypothyroidism has Increased prevalence among females.

And Increased prevalence of subclinical hypothyroidism beyond the age group of 50 years of which 34% of patients has TSH levels between 10 to 20 mIU/l. Significant elevations in total cholesterol and serum LDL in subclinical hypothyroidism.

Association of TSH with total cholesterol and LDL elevations. No much significant changes in triglycerides and HDL Levels.

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# Legal Solutions to Health Misinformation and Disinformation During the Covid-19 Pandemic Outbreak

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## Abstract

The spread of false information online has increased dramatically in recent years. Around the COVID-19 pandemic, a digital epidemic of misinformation, or “infodemic,” has arisen. Since the beginning of 2020, digital platforms have served as both a source of and a remedy for Disinformation. After a few months of the epidemic, it is clear that ensuring health professionals access to necessary medical equipment and supplies is less crucial than fighting falsehoods online. Actions such as (a) urging social media firms to delete material about the epidemic that is contentious, (b) putting up special forces to counteract propaganda and false information (e.g., E.U., U.K.), and (c) incarcerating suspicious coronavirus false claims, including in connection to the public health interventions, were high priorities for many government agencies around the world in response to COVID-19. State of emergency measures used early on shaped future debates on how to strike a fair balance between free speech and censorship on the internet by, among other things, restricting access to news and encouraging journalists to hold back on their reporting.

**Keywords:** Online trust, information access, health misinformation, online conviction, COVID-19.

## Introduction

To control the COVID-19 pandemic, it will be necessary to confront epidemics with a deluge of false information. Yet, very few studies have tried to identify the traits shared by those who accept false information. We are not simply combating a disease outbreak but also an informational pandemic. The problem with fake news is that it spreads even more quickly and readily than a virus. Similar worries were raised by the WHO secretary director on February 15, reinforcing the danger that the COVID-19 pandemic poses from widespread online Disinformation. International law does not forbid states from

disseminating false information, with a handful of exceptions. False cures and ineffective preventative strategies have spread online simultaneously with the new coronavirus 2 strain of SARS, putting even more people in danger. Since January 2020, we’ve learned that guaranteeing much-needed medical tools and resources for health professionals is just as critical as combating falsehoods online.

Restricting access to information during emergencies would have far-reaching effects on our digital relationships, which are crucial to the smooth operation of our political, economic, scientific, and other institutions. The purpose of this study is to

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provide a synopsis of the influence of the news media and other sources of information on the epidemic. The purpose of this piece is to draw attention to the detrimental effect of false information on the epidemic. Moreover, the study discusses a few suggestions that might help reduce this load since avoiding the creation and spread of false information is crucial.

### **The impact of and legal response(s) to health disparities brought on and exacerbated by misinformation and disinformation about health-related issues.**

Several initiatives were launched to stem the spread of COVID-19 misinformation. There has never been such a tremendous plague and loss of human life, based on the disintegration of law and order. Among these measures is promoting social isolation by suggesting that people work from home, use authorised face-masks, and practice good hand hygiene. However, several difficulties have been encountered in putting these techniques into action. False information played a significant role in spreading the coronavirus. Misinformation concerning COVID-19 was also widely disseminated through social media. According to a poll of American opinions and perspectives on the virus, those who acquire information from social network platforms are more likely to believe myths about the causes, transmission pathways, and preventative measures for COVID-19.

The general public may dismiss scientifically verified knowledge and recommendations because of widespread exposure to erroneous information. The credibility of recent scientific discoveries on COVID-19 therapies and vaccine candidates has been doubted, even though these treatments and candidates are effective.

Myths and misconceptions have hampered the vaccine's uptake regarding the drug. Vaccination has the potential to be a crucial strategy in controlling the virus's spread. Unfortunately, it has been challenging to employ vaccination as a preventative tool because of the unfavourable attitude of society due to misinformation. This is significant since the rule of law serves as the cornerstone for guaranteeing that both public and private entities are held accountable,

that just laws uphold essential freedoms, that government is transparent, and that justice is easily available. A flood of false information was broadcast to the public after the outbreak, making it difficult for people to act sensibly. When rumours of a probable lockdown spread, it devastated food and paper goods availability. After an influential person spread false information, the price of medications thought to treat COVID-19 skyrocketed within minutes. It is evident from the conversations that false information about the epidemic significantly contributed to its rapid spread. As a result, society has to reflect on what went wrong and make amends, so that false information regarding similar incidents isn't allowed to propagate in the future.

### **The development of legal and policy structures and strategies to address misinformation and Disinformation about health-related issues**

The spread of false information in the digital realm is worldwide, much like the epidemic itself. Local remedies are just part of the answer, as seen by the legislative reactions and interim measures proposed thus far. Without international strategies, domestic initiatives risk trampling on decades of progress toward greater individual freedom. The COVID-19 reaction was addressed by lawful Convention WHA73.1 approved by WHO Participating Nations. The Resolution urges Member Countries to offer trustworthy COVID-19 information, take action to combat misinformation and disinformation, and make use of digital media throughout the response in recognition that regulating the infodemic is a crucial component of managing the COVID-19 outbreak. Accurate reporting and well-informed public conversations are the best defence against the spread of misinformation online. Digital interactions are now vital to our political, fiscal, scientific, and educational institutions, restricting admittance to information in moments of predicament should have long-term ramifications for all these spheres. With more and more people turning to digital resources like search engines and social media channels for their health data, issues like inaccurate information about non-communicable diseases and health disinformation are becoming more pressing. To begin with, governments are aggressively combating the transmission of misleading information by imposing new obligations

on the numerous players via various measures such as law, partnerships, literacy, and administrative agencies. Second, as vehicles of communication, both social and conventional media have tacitly or openly recognised their responsibilities in aiding the spread of false information. Various forms of self-regulation have been used, including technological tools, to identify and remove false or misleading content and promote trustworthy sources. In addition, they've established internal mechanisms for evaluating disinformation operations and are fully dedicated to halting the spread of harmful words. Lastly, civic society has raised public awareness about health-related deception and misinformation risks. Fact-checking, discrediting, and counter-disinformation operations have helped the general public recognise and stop distributing false or misleading information.

### **The responsibility of healthcare systems to respond to and address misinformation and Disinformation**

Several strategies with solid scientific backing exist for addressing health misconceptions. Providing evidence-based options is one strategy that might be used in healthcare systems. Individuals often respond positively when a single false belief is corrected by introducing a new, accurate belief. Concerning COVID-19, a reasonable alternative to Disinformation has yet to be discovered. International bodies are also urged by the law act (WHA73.1) to combat false and misleading information within the digital arena, seek to stop harmful cyber actions that undermine the health reaction, and encourage the dissemination of scientific data to the general public. As executives with an assertive bent amass additional powers via emergency measures and tribunals, legislative bodies and other organisations are hindered in exercising their constitutional obligations and respective roles, the COVID-19 pandemic poses a potential threat risk of further eroding restrictions on governmental power. Similarly, social media sites depend on the contributions of civil society groups and fact-verification initiatives, whose work incentivises the platforms to take additional action on this issue. The World Health Organisation (WHO) relies on the cooperation of its member nations to implement and disseminate accurate medical information, which can be gathered only with the cooperation of global organisations of scientists. Because of insufficient

coordination between various tiers of government, the present paradigm is one in which even commendable attempts to combat disinformation and deception fail to yield ideal outcomes.

### **Distinct privacy and technology concerns**

Fake news and its effort to establish a post-truth culture have spread at an alarming rate because of the proliferation of digital media and investigative journalism. Increased misinformation about the COVID-19 outbreak has sparked anti-mask, anti-5G, and anti-vaccine rallies worldwide. To better combat misinformation, legal tech-based acts makes it helpful to reevaluate the function of algorithms. Users are more likely to be led astray by harmful Disinformation while using this technology. Sites for sharing and distributing information online should be more forthcoming about the metrics they employ to determine the relative prominence of various pieces of content, with particular attention paid to the suppression of potentially hazardous materials in favour of more trustworthy ones. While all parties acknowledge that industry players should not serve as arbiters of truth, they are the ones most equipped to solve the underlying technological issues. Defining the law acts of free speech is becoming more complicated as new technology makes it more powerful. Repressing false information, whether by deleting it, drowning it in a sea of silence, rendering it unavailable, or censoring the source, is the most prompt and efficient response to the spread of disinformation. However, legislative safeguards the freedom of free expression, established to avoid repression, which has historically still been built on narrative regarding higher aims, may conflict with these techniques. Through the lawful dissemination of incorrect information and hate discourse on public health, digitalisation has aided in growing social divides and extremism. Disputes and tensions that begin in cyberspace often lead to real-world violence, assaults on vulnerable groups, and even civil war. The concept of "infodemic" brought the issue of content regulation to the forefront by referring to the spread of misinformation concerning a pandemic. Social media and search engine titans Google and Facebook have joined the fight against false news. Google has activated an "SOS warning" for searches related to the Coronavirus epidemic, directing users to recent tweets, WHO advisories, and other helpful resources.

## The availability of tort remedies for misinformation

When handling the information epidemic, the United Kingdom and the WHO-based law acts work together. Misinformation has deadly consequences. According to recent studies, there were roughly 6,000 individuals hospitalised throughout the world in the first three months of 2020 due to false information about the coronavirus. A minimum of 800 persons, according to the study's authors, may have lost their lives over this period owing to erroneous information about COVID-19. When seen in this way, it's hard to see the world and not feel worried. Companies in the social media industry have recently developed legal-based applications with the explicit goal of hooking us. They figured out how to make money from the vast amounts of people's time they had seized. Due to the lack of oversight, they grew into massive, international conglomerates. The World Health Organisation (WHO) and the U.K. government have joined forces to attempt to contain the COVID-19 infodemic by collaborating on several communication activities designed to counter the distribution of misinformation. Since the beginning of the COVID-19 epidemic, which has taken several measures on their own and in collaboration with partners to prevent Disinformation. BBC World's mid-2020 programming slate included "Stop the Spread." It hoped to get the word out about how much inaccurate information there is about COVID-19 and for people to start doing their own fact-checking to reduce the harm and spread of Disinformation. WHO has coined the word "infodemic" to describe the rapid dissemination of information, some of which is true and some not that often coincides with the development of an infectious illness.

## Conclusion

The successful prevention of the COVID-19 outbreak may be hampered by the spread of erroneous data, leading to people making incorrect decisions and skewed beliefs in global health recommendations. Misinformation may be successfully combated via population-specific communication tactics and messages. The influence of healthcare disinformation on public behavioural change has always been strong, but its significance during the COVID-19 epidemic became strikingly

obvious. Some people died due to trusting erroneous information about the cause of the outbreak, the nature of the virus, and possible treatments. The public's apathy about the pandemic may be traced mainly to the widespread dissemination of false information about the virus's prevalence rate, predominance, and pace of propagation. Vaccine apprehension emerged as a concurrent pandemic after the emergency use authorisation of several COVID vaccines revived popular distrust in scientific knowledge and the widespread dissemination of false information. That's why it's more crucial than ever to have trustworthy healthcare news sources and constantly check in on social platforms to ensure that only correct data is being shared with the public. Dispelling such falsehoods needs a concerted effort from several groups, including local municipalities, law protection agencies, social media firms, community groups, and others. This article discusses the difficulties of combating Disinformation in the age of social media, the devastating effects of misinformation on efforts to address public health problems, and the many methods used by governments all over the globe to address this problem.

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## Menstrual Practices among Medical Students in a Tertiary Care Teaching Hospital in Central Kerala

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### Abstract

**Introduction:** Menstruation is a part of women's healthy well-being. The objective of this study was to assess the menstrual hygiene practises among female medical students in a tertiary care teaching hospital in Central Kerala.

**Methods:** An institution-based cross-sectional study was conducted in 2021 among 225 female undergraduate MBBS students aged 18–25 years in a tertiary health care facility in Kerala. The data was collected using an expert validated semi-structured questionnaire after obtaining informed consent from the participants via Google Forms. The universal sampling technique was used, and the data was analysed with SPSS version 20.0.

**Results:** The mean age of the study participants was  $21.65 \pm 1.34$  years and 91.1% were from the APL socioeconomic category. 95.5% of participants were using disposable sanitary pads. The frequency of washing external genitalia and changing sanitary products were adequate in 69.4% and 33.8% respectively. The common mode of disposal of menstrual products were burning(50.2%), incineration(34.7%) and discarded into general waste(8.9%). 66.7% were not allowed to do religious activities during menstruation.

**Conclusion:** Most of participants used disposable sanitary pads. The frequency of changing sanitary products and their disposal was found to be inadequate. Menstruation related myths were common among participants.

**Keywords:** Sanitary pads, Menstrual hygiene, Menstrual cup, medical students, myths

### Introduction

Menstruation is a part of women's healthy well-being. Women's health has a big impact on the community in addition to themselves. Individuals' attitudes on menstruation and how it should be addressed can differ based on their experiences, how they assess their health. In addition social and

cultural influences also have an impact. Menstruation poses social, psychological, and health challenges for young girls and women living in middle income countries.<sup>[1]</sup>

Menstruation-related issues are considered taboo and not to be discussed publicly, so related research was insufficient. But it is extremely important to

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ensure the safety and quality of menstrual hygiene products as they are in repeated, direct contact for a longer duration in women's lives.<sup>[2]</sup>

Sanitary protection material that is preferred by an individual is based on personal choice, cultural acceptance, economic status, and availability in the local market. Clothes were commonly used as menstrual absorbents in the past.<sup>[3]</sup> However, recently there has been a rise in awareness regarding menstrual hygiene and the usage of various sanitary products, and among them, the usage of sanitary pads is more prevalent. Also, due to the easy accessibility of social media, people are able to learn about various new sanitary products.<sup>[4,5]</sup>

Most of them were using disposable sanitary products, which pose a major threat to the environment. So it is advisable to use sustainable, reusable, and eco-friendly products like menstrual cups. It is not advisable to flush the used sanitary products or throw them away with general waste. Burning is also not advisable; instead, incineration can be used as a method of disposal.<sup>[6,7,8]</sup>

If adequate menstrual hygiene is not maintained, women may contract genito-urinary tract infections, which can lead to pelvic inflammatory diseases.<sup>[4]</sup> This study gives an understanding of the practices female medical students adopt for maintaining proper menstrual hygiene. This study aims to assess the menstrual hygiene practices among female medical students within the age group of 18–25 years in Central Kerala.

## Materials and Methods

**Study design:** Institution-based cross-sectional study.

**Study area:** The study was conducted at a private medical college in Central Kerala.

**Study population:** MBBS undergraduate students from the selected medical college in Central Kerala.

**Inclusion criteria:** Female medical students aged between 18 and 25 who were willing to participate in the study. Informed consent was obtained via Google form from all the participants.

**Sample size:** Sample size was calculated using the formula,  $n = Z\alpha^2pq/d^2$  at 5% significance level with an allowable error of 6.2% and was found to be 218.<sup>[9]</sup>

**Sampling method:** Universal sampling

**Study duration:** November 2021 to December 2021

### Study tools and data collection:

The study tool used for data collection was a semi-structured questionnaire containing personal details and questions on the menstrual practices of female medical undergraduate students between 18-25 years of age. The purpose of the study was well explained to all the participants. An online questionnaire via Google Forms was kept active for four days and then closed. Data from online Google forms were entered into MS Excel spreadsheets. Throughout the procedure, anonymity was maintained.

**Statistical analysis:** The information gathered was entered into a Microsoft Excel spreadsheet, and a master chart was created. The data was analyzed using the software SPSS version 20. Frequency distribution tables and graphs were generated. Descriptive statistics were expressed in percentage and frequency.

**Ethical concern:** Informed consent was obtained from medical students prior to data collection through Google forms. Confidentiality was maintained through the anonymity of the collected data. The study adhered to the terms of the Declaration of Helsinki for research in humans.

## Results

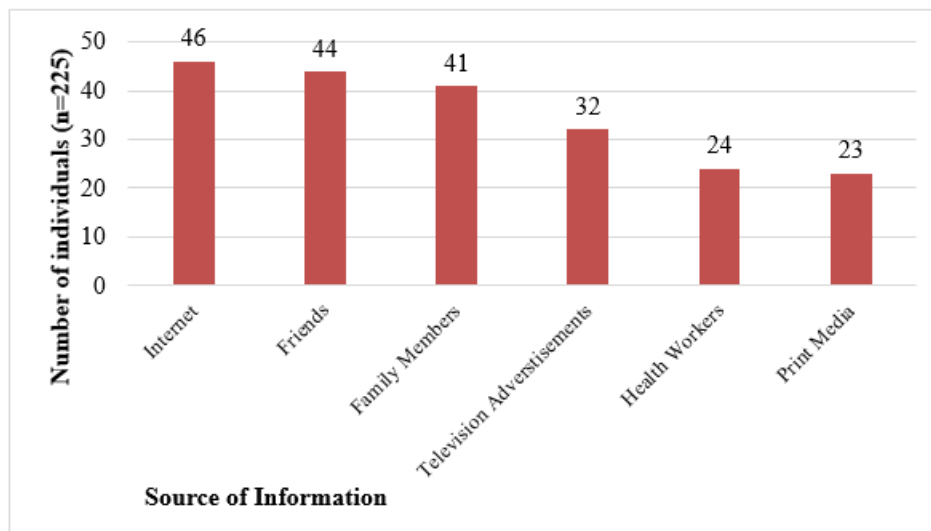
Among the 237 participants, 12 of them found it difficult to give information about their personal menstrual hygiene practices, so the study was conducted among 225 participants (response rate: 94.9%). The mean age of the study participants was  $21.65 \pm 1.34$  years. The majority of them were from the APL socio-economic category (Table 1).

**Table 1: Distribution of study participants based on socio-demographic characteristics (n=225)**

Variables	Category	Frequency (%)
Age (in years)	18 - 21	103 (45.8%)
	22 - 25	122(54.2%)
Marital status	Married	10 (4.4%)
	Unmarried	215 (95.6%)
Highest Educational status	Higher Secondary or equivalent	211 (93.8%)
	Degree or equivalent	14 (6.2%)
Socio economic status	APL	205 (91.1%)
	BPL	20 (8.9%)
Year of admission	Final year	54 (24%)
	Third year	53 (23.6%)
	Second year	62 (27.6%)
	First year	56 (24.9%)

The majority of participants [214 (95%)] were aware of sanitary pads, but only one participant (0.4%) was aware of period underwear. Tampons [148 (65.8%)], menstrual cups [178 (79%)], the use of fresh

cloths [125 (55.6%)], and old rag cloths [61 (27.1%)] were also known to many participants. Common sources of information among participants were the internet, friends, and family members (Figure 1).



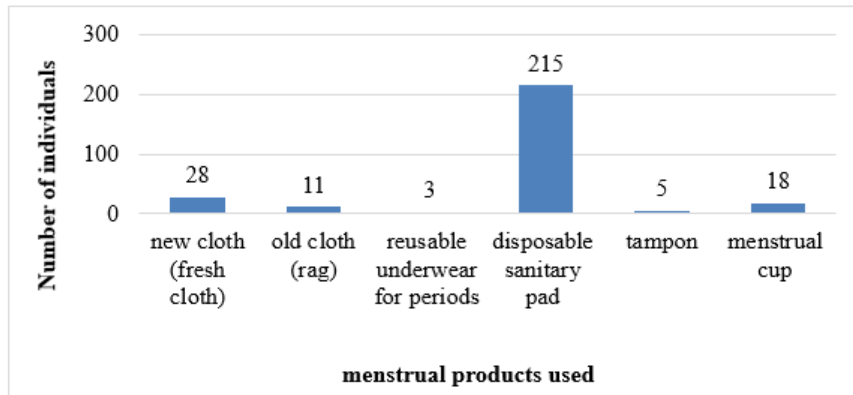
**Figure 1: Distribution of study participants based on source of information about menstrual hygiene products (multiple responses)**

**Table 2: Distribution of study participants based on activities forbidden during menstruation (multiple responses)**

Activities forbidden during menstruation	Number of individuals (n=225)	Percentage (%)
Not allowed to do religious activities	150	66.7
Not go to certain places.	52	23.1
Not to touch certain things	47	20.9
Not to eat certain food	10	4.4
Not allowed to cook	5	2.2
Not allowed to go out	1	0.4

Two-thirds of the participants were not allowed to participate in religious activities (Table 2). About

70 participants had no restrictions, and a few of them were not allowed to eat certain foods or cook food.



**Figure 2: Distribution of study participants based on the products used during menstruation (multiple responses) n=225**

Out of the 225, the majority (95%) had used disposable sanitary pads, and only a few of them used tampons, cloths, or menstrual cups during menstruation (Figure 2). The expense of sanitary

products had no financial impact on 109 (49%) of the participants. It had a moderate and significant financial impact among the 91 (40%) and 25 (11%) study participants.

**Table 3: Menstrual practices among study participants**

Menstrual Hygiene	Category	Number of participants	Percentage (%)
Reuse of sanitary products (n=225)	No	192	85.3%
	Yes	33	14.7%
Method of drying re-used sanitary products (n=33)	Dry it outside in bright sunlight	23	69.7%
	Dry it inside house	7	21.2%
	Dry it in a hidden area indoors	2	6.1%
	Others	1	3%
Method of cleaning re-used sanitary products (n=33)	With water only	1	3%
	With soap and water	12	36.4%
	With soap, savlon/dettol and water	18	54.6%
	Doesn't clean	1	3%
	Cleaning solution	1	3%
Frequency of changing menstrual products (n=225)	Once	4	1.8%
	Twice	48	21.3%
	Thrice	97	43.1%
	Four or more times	76	33.8%
Frequency of cleaning external genitalia (n=225)	Once	4	1.8%
	Twice	19	8.4%
	Thrice	46	20.4%
	Four or more times	156	69.4%
Mode of disposal at place of stay (n=225)	Burning	113	50.2%
	Incineration	78	34.7%
	Throw the pads/clothes in general waste	20	8.9%
	Flush them in toilet	5	2.2%
	Others	9	4%

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Convenience in changing sanitary material at the institution (n=225)	Convenient	182	80.9%
	Inconvenient	43	19.1%
Facilities towards menstrual hygiene at the institution (n=225)	Appropriate for managing menstrual hygiene	169	75.1%
	Inappropriate for managing menstrual hygiene	56	24.9%
Modes of disposal at the institution (n=225)	Throw into separate bin in toilet	186	82.7%
	Flush them in toilet	5	2.2%
	Throw into biomedical waste	22	9.8%
	Throw into general waste bin	12	5.3%

The majority of participants [193 (85%)] do not reuse their sanitary products. Details regarding menstrual practices among study participants are given in table 3. The majority (182, 80.9%) could change their menstrual hygiene products whenever they wanted, while the remaining (43, 19.1%) found it inconvenient. Table 4 shows the difficulties faced by participants in practicing menstrual hygiene practices in the institution.

**Table 4: Distribution of study participants based on difficult in practicing menstrual hygiene practices in institution (multiple response, n=43)**

Reasons	Number of participants
No separate waste bins in washroom for disposing sanitary materials	32
No incineration facilities for disposable sanitary pads/cloths	23
No tissue paper or soap	6
No emergency accessibility of sanitary products	6

## Discussion

This study assessed the menstrual hygiene practices among medical students in central Kerala. In the present study, the majority were using disposable menstrual pads, and very few used new clothes. A similar result was found in the study conducted in Korea by Hansol Choi et al on women of reproductive age (18–45 years). They found that disposable menstrual pads (64.6%) and cloth menstrual pads (4.5%) were used in their study population. [7] But in

a study conducted among the adolescent schoolgirls of Nagpur, it was found that the majority of the girls were using old clothes, and very few were using sanitary pads that were available in the market. [8] The use of sanitary pads in the present study was much higher than in the above study; this may be due to the higher socioeconomic status, greater availability of the pads, or greater awareness about menstrual hygiene among medical students.

In the present study, only 15% of the participants reused their sanitary products. As per the study conducted by Subhash et al in Nagpur, the practice of reusing old clothes was reported by 45.74% of participants. [8] This may be due to the higher socioeconomic status of the present study population. In the present study, among those who reused the sanitary products, it was revealed that 70% of them dried their reusable sanitary products outside under bright sunlight, which is comparable to a study conducted in Nagpur, where 63.1% of them dried their reusable sanitary products outside under bright sunlight.[8]

The frequency of washing external genitalia among the present study population was satisfactory in 70% of participants when compared to a study conducted in Nagpur, where it was unsatisfactory in 66% of participants. [8] This difference may be due to the higher literacy rate and a better standard of sanitary hygiene practices. In the current study, about 34% of individuals changed their sanitary products four or more times per day, which was much more than the studies conducted by Prajapati et al (5.5%) in Gujarat. [8] The population in the present study had better knowledge regarding the change in sanitary products.

Half of the study participants in the present study were financially affected (significantly or moderately) by the practice of safe menstrual hygiene. In a study done by Dhara et al in rural areas of Gujarat, it was found that 9.7% of women couldn't use sanitary pads because of the cost. [9] Another study done in Maharashtra found that non-usage of sanitary pads was reported in 40% of the individuals from rural areas, owing to their socio-economic status. [8] This result is in congruence with the study conducted by us.

According to the present study, most of the participants preferred burning as the main mode of disposal. While others prefer incineration, and very few opt for other methods such as disposal into general waste, flushing down the toilet, etc. Very few used reusable menstrual cups. Similar results were found in a previous study conducted among adolescents from rural high schools in the Thrissur district, Kerala. They found that the majority of girls preferred burning as the major mode of disposal (75.6%), followed by throwing them into general waste, while the rest flushed it down the toilet. [10]

With reference to the present study, a large proportion of the participants involved in the study found it convenient enough to change their sanitary materials at work (81%), and therefore look after their sanitary hygiene. Only a few found it inconvenient. Now, according to the community-based cross-sectional study conducted on schoolgirls in Maharashtra, they observed that the majority of the girls find it inconvenient to change their sanitary material at school and do not do so. [8] Only a small number of participants change the products at school. Thus, we come to the conclusion that the standard of sanitary hygiene is better in institutions in Kerala than in other states as it has a higher literacy rate and standard of hygiene. Our state also takes a huge step towards raising awareness about the importance of hygiene for girls of menstrual age.

In the current study, the majority (192) disposed of the sanitary materials into separate bins kept in the toilet at work. A similar study done by Karthika et al in Thrissur district, Kerala, found that, among the rural high school students, 75.6% resorted to burning. [10] This could be associated with a lack of awareness or the stigma associated with the topic in question.

In research conducted based on whether there are appropriate facilities at their workplace for managing menstrual hygiene, 22% of females disagreed. The most common reason for their disagreement is the lack of separate waste bins in the washroom for disposing of sanitary pads and materials, followed by the lack of incinerating facilities for disposable sanitary pads/clothes. In a review article compiled by Rajanbir et al, the frequency of women reporting a lack of waste bins for disposing of sanitary pads was lower than in the present study. [11] In the present study, females complained of a lack of incineration facilities for the disposal of pads. However, in the study by Rajanbir et al., they did not dispose of pads despite the availability of incinerators due to their shyness.

The study was limited to medical students due to the ongoing COVID pandemic and the omicron variant. Due to the social stigma, the population had to be limited to students, as the topic is considered sensitive.

## Conclusion

Menstrual hygiene is important in the empowerment and well-being of girls and women worldwide. Most of the participants used disposable sanitary pads. The frequency of changing sanitary products and their disposal was found to be inadequate among most of the participants. Menstruation-related myths were common among participants. The majority are able to change the menstrual hygiene products at the institution when they want to, while the remaining finds it inconvenient. The institution can provide better hygienic conditions, such as a separate bin to dispose of used sanitary items, facilities for proper hand hygiene, and health awareness programmes for students.

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**Conflict of Interest:** Nil

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# Prevalence of Risk Factors for NCDs and its Associated Factors in Rural Field Practice Area of RDJMMCH, Turki, Muzaffarpur

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## Abstract

**Introduction:** Non-communicable diseases (NCDs) are diseases that are not transmissible directly from one person to another. NCDs mainly consists of cardio vascular diseases, diabetes, stroke etc. It accounts for 68% of global deaths. The prevalence rates in India is 1.6% to 7.4% and 1% to 13.2% in rural and urban population respectively.

**Objective:** To determine the prevalence and associated risk factors for NCDs in rural field practice areas of RDJMMCH, Turki, Muzaffarpur.

**Methods:** A cross-sectional study done among people above 30 years of age residing in study area from March to April, 2023. Data was collected using CBRA (community based risk assessment) checklist for NCDs. Sample size of 157 was calculated assuming the prevalence of risk factor for NCDs being 30% with 95% confidence interval and absolute precision of 7.5%. Systematic random and simple random sampling was applied.

**Results:** Mean age of participants was 47.9 years. Majority of them were females (56%) belonging to Hindu religion (98%). 41% were illiterate and major occupation practiced was farming (74%). Prevalence of risk factor for NCDs was 17.2%. On performing Chi-Square test smoking, alcohol, physical inactivity and family history of NCD's were found to be significantly associated.

**Conclusion:** As prevalence of risk factor for NCDs is 17.2%. Thus, it is the need of hour to have timely update about the disease and motivate them for healthy lifestyle.

**Keywords:** NCDs, Riskfactors, Rural field practice area

## Introduction

Non-communicable diseases (NCDs) are diseases that are not transmissible directly from one person to another. NCDs mainly consists of cardio vascular diseases, diabetes, stroke etc

Non-communicable diseases (NCD) accounts for 68% of global deaths with cardiovascular diseases

being the leading cause (46% of all NCD deaths).

Asian Region (SEAR) accounts for 20.8% of total CVD deaths. Compared with all other countries, India suffers the highest loss in potentially productive years of life, due to deaths from CVD in people aged 35-64 years.

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India is currently experiencing a rapid epidemiologic transition. The escalating epidemic of NCDs is a public health challenge in our country. WHO estimates that these diseases (with mostly preventable risk factors) account for 60% of all deaths and significant morbidity in India.<sup>(1)</sup>

The globe is witnessing a rapid epidemiological transition. Infectious and nutritional diseases are receding among adults, Whereas non-communicable diseases are becoming increasingly common as the cause of morbidity and mortality. In recent years, most of the developing countries including India are facing this challenge.

The CAD has assumed the “epidemic” proportion in India and many other developing countries. The prevalence rates can be estimated from several studies over the past several decades which have ranged from 1.6% to 7.4% in rural population and 1% to 13.2% in urban population. Though the disease is more prevalent in urban population, it is progressively increasing in rural population in terms of absolute numbers.<sup>(2)</sup>

Besides increasing the life expectancy of the Indian population, greater connectivity to urban areas allows rural populations to adopt urban lifestyles without migration to urban areas. Prevalence of risk factors for NCDs and its associated factors in rural population has gained public health importance, as two thirds of India’s population live in rural areas. It is well known that rural populations have limited access to health care and limited ability to bear the high cost of treatment.<sup>(3)</sup>

The most important behavioral risk factors of heart disease and stroke are unhealthy diet, physical inactivity, tobacco use, and harmful consumption of alcohol. Effects of the behavioral risk factors may show up in individuals as raised blood pressure, raised blood glucose, raised blood lipids, and overweight and obesity. These “intermediate risks factors” can be measured in primary care facilities and indicate an increased risk of heart attack, stroke, heart failure, and other complications.<sup>(4)</sup>

The NFHS surveys provide valuable insights into the health of rural India but there is a growing recognition that they may not be representative of the changing demographic profile of the country

and therefore are not capturing the true patterns of disease burden. NFHS-5 Survey sampled women aged 15–49 and men aged 15–54 years, and therefore, cannot provide information about the prevalence of NCDs in older adults, who represent a growing proportion of the Indian population and in whom the incidence of NCDs and their associated risk factors is known to be higher.<sup>(5)</sup>

Hence, this cross sectional study was planned in a rural area which is near to the town area with the objective of determining the prevalence for risk factor for NCDs and its associated factors.

### Objective

1. To Determine the prevalence for NCDs In Rural Field Practice Areas Of RDJMMMCH, Turki, Muzaffarpur
2. Associated Factors for NCDs In study population.

### Material and Methods

Cross sectional study was carried out in Kurahhahi village, (with population of around 10000) the rural field practice area of department of Community Medicine, RDJMMCH, Turki. The study period was from March to April 2023. Simple random sampling and systematic random sampling was applied for the study population above 30 years and not severely ill.

### Sampling method and procedure:

Sample size was calculated using formulae- $z^2 \frac{PQ}{d^2}$

Where Z= relative deviate (1.96)

P= 30%<sup>(1)</sup> Q= 100-p

D=7.5% calculated sample size is 143

10% non response =14

Total sample size=143+14=157

Total population above 30 years =2669

Sampling interval=2669/157=17

The entire village was divided in terms of lane with respect to center of village. 1<sup>st</sup> lane was selected using simple random sampling (bottle method). from the chosen lane 1<sup>st</sup> house was selected using lottery

method. systematic random sampling for further houses(every 17<sup>th</sup> house). Each lane was covered in this way. Those houses with more than one eligible person for study, again lottery method was used and one person was selected from one house.

Data was collected by interns posted in the rural health center after taking verbal informed consent from the participants. The Questionnaire consisted of two parts, first part had basic socio demographic data of the study participants such as age, sex, address, education, and socio economic status. The second part included community based risk assessment checklist (CBRA)for NCDs<sup>(6)</sup>.

#### Inclusion and exclusion criteria:

Those who were above 30 were included and those below 30 years, severely ill and did not wish to participate were excluded from the study.

**Statistical analysis:** Data entry was done using Microsoft excel 2010 and analysis was done using SPSS v23.0. Descriptive statistics like percentages, frequencies, mean were calculated and chi-square was used to find out the association,  $p < 0.05$  was considered significant.

### Results

Total 157 patients participated in the study.

**Table 1: Distribution of study participants of RHTC according to socio-demographic characteristics**

Parameters	RURAL Health centre (n=157)
<b>AGE</b>	
30-39	43(27.45%)
40-49	46(29.36%)
>50	68(43.33%)
<b>GENDER</b>	
Males	69(43.92%)
Females	88(56.1%)
<b>RELIGION</b>	
Hindu	155(98%)
Muslim	02(2%)
Others	00
<b>EDUCATION</b>	
Illiterate	64(40.8%)
Primary	39(24.8%)
High school	48(30.6%)
Secondary	01(0.6%)
Graduate	05(3.2%)
Post graduate	00
<b>OCCUPATION</b>	
Unskilled	04(2.5%)
Semiskilled	116(74%)
Skilled	13(8.3%)
Semi professional	2(1.3%)
Professional	0
Unemployed	22(14%)

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TYPE OF FAMILY	
Nuclear	63(40.1%)
Three generation	42(26.8%)
Joint	52(33.3%)
SOCIO-ECONOMIC STATUS	
*B.G. Prasad classification. <sup>(7)</sup>	
Upper Class I	5(3.25%)
Upper Middle Class II	20(12.7%)
Middle Class III	35(22.3%)
Lower Middle Class IV	46(29.3%)
Lower Class V	51(32.5%)

**Table 2: Prevalence of risk factors for NCDs**

VARIABLES	CATEGORIES	SCORE<4	SCORE >4	P value
Age	30-39	38(88.4%)	5(11.6%)	.333
	40-49	39(84.8%)	7(15.2%)	
	>50	53(77.9%)	15(22.1%)	
Gender	Male	59(85.5%)	10(14.5%)	.426
	Female	71(80.7%)	17(19.35%)	
Religion	Hindu	113(71.9%)	42(26.7%)	Test couldn't be applied
	Muslim	0	2(1.2%)	
Education	Illiterate	49(76.6%)	15(23.4%)	Test couldn't be applied
	Primary	34(87.2%)	5(12.8%)	
	Secondary	41(85.4%)	7(14.6%)	
	Higher secondary	1(100%)	0	
	Graduate	5(100)	0	
	Post graduate	0	27(17.2%)	
Occupation	unemployed	16(72.7%)	6(27%)	Test couldn't be applied
	Unskilled	3(75.0%)	1(25.0%)	
	Semi-skilled	99(85.3%)	17(14.7%)	
	Skilled	10(76.9%)	3(23.1%)	
	Semiprofessional professional	2(100%)	0	
	Type of family	Nuclear	49(77.8%)	
3 generation	33(78.6%)	9(21.45%)		
joint	47(92.3%)	5(7.7%)		

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Socio-economic status	Class I	5(100%)	0	Test couldn't be applied
	Class II	17(85.0%)	3(15.0%)	
	Class III	24(68.6%)	11(31.4%)	
	Class IV	39(84.8%)	7(15.2%)	
	Class V	45(88.2%)	6(11.8%)	
Smoke/smokeless products	Yes	83(95.45%)	4(4.6%)	0.000*
	No	47(67.1%)	23(32.9%)	
Alcohol	Yes	2(22.2%)	7(77.8%)	0.000*
	No	128(86.5%)	20(13.55)	
Physical activity	<150 min a week	99(95.2%)	5(4.8%)	0.000
	>150 min a week	31(58.5%)	22(41.5%)	
Family history	Yes	16(44.4%)	20(17.2%)	0.000
	No	114(94.2%)	7(5.8%)	

Table 1 shows –Majority population were Hindu (98%) and females were around (56.1%) ,participants above the age of 50 years were (43.33%). Around (40.8%) were illiterate and belonged to lower strata-CLASS V (32.5%) according to B G Prasad scale. The above data of the study shows that 74% of the population were semi skilled.

Table 2 - In our study, the variables like age, gender, religion, occupation, socio economic status and lifestyle habits were categorized into two score , one < 4 and the other one > 4 for which test of association (chi-sqaure and fisher's test ).was applied

Variables like alcohol consumption, physical activity and family history for NCD was found to be significant with P value < 0.0001. Other than this, Age ,Gender and type of family p value was >0.05 and in rest of the variables data was insufficient for any test application.

## Discussion

Present study showed mean age of the study participants were 47.96 years and around (98.75%) were Hindus. In around (44.6%) participants tobacco consumption was positive but only (5.8%) had history of alcohol consumption. This may be because of easy availability of tobacco and tobacco products in smokeless form un rural india.physical activity was present among 33% of participants. Around (22.9%)

had family history of some or the other NCDs. Around (17.%)females and (10.8%) males were found to be obese.

Study done by Kadiyala P et al on Prevalence of risk factors and 10 year risk estimation of cardiovascular diseases among rural population of Mysuru, Karnataka showed mean age of the participants 56.76 years and around 86% of them were Hindus.physical activity was seen in 20.1% of the participants .11% showed positive family history of NCDs.here also females(40%) were found to be more obese than males(12%)(1).

Another study done by Kavi A, Walvekar PR, Patil RS on Biological risk factors for coronary artery disease among adults residing in rural area of North Karnataka in which mean age of the participants were 38.2 years family history for NCDs was present among 6.3% of the participants and here also 52% females and 23% males were found to be obese.(2)

A study done in Uttar Pradesh by Srivastav S, Mahajan H, Goel S, Mukherjee S. on Prevalence of risk factors of non communicable diseases in a rural population of district Gautam-Budh Nagar showed mean age of the participants 37 years and 97% of them were Hindus. Tobacco consumption was found positive in 35% participants and alcohol consumption was little higher (16.9%) ,this may be because of place

where it was conducted was urban setting and easy availability of alcohol. and in this study also females were more obese than males.<sup>(8)</sup>

Dr. Anand N et al conducted a study on NCD risk factors and Socioeconomic inequalities in field practice of Madhubani Medical College, Bihar. Which showed around 86.1% of the participants were above 40 years and 77.65% of participants were Hindus tobacco consumption was positive among 27.3% and alcohol consumption among 11.4% of participants even though Bihar being a non-alcoholic state around 35.4% of study participants were found to be overweight.<sup>(9)</sup>

A study done on Bihar origin residing in Bangladesh by Ahmed S et al on Association between behavioural, metabolic risk factors of non-communicable diseases and socio-demographic factors. Which showed mean age of the participants 47.2 years 74.6% of the participants gave positive history for tobacco consumption alcohol consumption was found to be positive among 3.3% of the participants. Around 54.6% participants were found to be over weight.

### Conclusion

The present study finding suggested prevalence of risk factor for NCDs is 17% in rural filed practicing area of RDJMMCH, Turki. Factors responsible were intake of tobacco ,alcohol, family history and physical inactivity.

### Recommendations

- Health education activities to be conducted in rural and urban areas to create appropriate awareness about risk factors associated with NCDs.
- Activities should be conducted to encourage people for no use of smokeless tobacco/ smoking, alcohol and physical activity and healthy life.

### Limitations

- Many other risk factors like BMI, fast food intake and laboratory investigations were not done in this study

**Conflict of interest:** None,

**Source of Funding:** Self

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# To Study the Clinical and Etiological Profile of Patients with Hepatic Encephalopathy

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## Abstract

Hepatic encephalopathy (HE) is a term used to describe a reversible syndrome of impaired brain function involving a complex spectrum of nonspecific neurological and psychiatric manifestations occurring in patients of severe acute or chronic liver insufficiency. Hepatic encephalopathy (HE) is one of the most devastating complication of cirrhosis having high morbidity and mortality. There is very limited data regarding the incidence and risk factors of hepatic encephalopathy so this study is to find the clinical and etiological profile of hepatic encephalopathy.

**Methodology:** The study was conducted in patients visited in OPD/IPD of medicine department, SGRDIMSR, Amritsar (Punjab) in the time period from 1 April 2021 to 31 July 2022. A total of 150 patients were taken up for this study. All the diagnosed patients of liver cirrhosis of any etiology (Recently detected or old patients) were included in the study.

## Findings

In this study most of patients were males (81%) in the age group of 31 to 60 yrs (65%). Most common etiology found to be alcoholic (53%) with presenting symptoms of altered talks(51%).

**Conclusion:** Education of the society about the precipitating factors can lead to early detection of hepatic encephalopathy and thus decrease the morbidity and mortality related to it. So there is need for Screening programs and education.

**Key Words:** Hepatic encephalopathy, complication of cirrhosis, alcoholic cirrhosis

## Introduction

Hepatic encephalopathy (HE) is a term used to describe a reversible syndrome of impaired brain function involving a complex spectrum of nonspecific neurological and psychiatric manifestations occurring in patients of severe acute or chronic liver insufficiency.<sup>1</sup>

There are three types of hepatic encephalopathy based on etiology. Type A is a component of acute liver failure. Type B occurs due to Porto-systemic shunting in the absence of liver dysfunction and Type C is associated with liver cirrhosis<sup>2</sup>

The first step to diagnose hepatic encephalopathy is to establish that patient has neuropsychiatric

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dysfunction and carefully exclude other conditions which may mimic the features.<sup>3</sup> There is change in personality include increased irritability, lack of restraint with poor risk assessment. Subtle but apparent intellectual decline. Inability to draw/construct and difficulty in writing are common. Reduced spontaneous movement, slowness, a fixed stare, loss of enthusiasm /interest and altered sleep pattern with increased day time sleepiness are early evidences of disturbed consciousness.<sup>4</sup>

Hepatic encephalopathy (HE) is one of the most devastating complication of cirrhosis having high morbidity and mortality. There is very limited data regarding the incidence and risk factors of hepatic encephalopathy so this study is to find the clinical and etiological profile of hepatic encephalopathy.

### Methodology

The study was conducted in patients visited in OPD/IPD of medicine department, SGRDIMSR, Amritsar (Punjab) in the time period from 1 April 2021 to 31 July 2022. A total of 150 patients were taken up for this study. All the diagnosed patients of liver cirrhosis of any etiology (Recently detected or old patients) were included in the study.

Exclusion criteria for the study was setup which included the patients who presented with High grade of encephalopathy (Grade 4 of West Haven criteria), Severe malnutrition, Neurological diseases/ Any Psychiatric illness, Presence of renal failure, Respiratory failure, Cardiac failure diseases, Sepsis, History of Substance abuse /Alcohol in past 2 weeks.

After screening the patients of cirrhosis on the basis of the above exclusion criteria, they were subjected to a battery of 5 pen and paper tests which constitute the Psychometric testing and calculate the PHES Score

After informed consent, a detailed history of patients about symptoms of jaundice, upper gastrointestinal bleed, altered senses and other relevant complaints were asked. All patients were examined for fever, jaundice, anemia, pedal edema, tremors, and ascites. Past history of alcohol intake, any drug intake, blood transfusions and prior hospitalization were taken. The relevant investigations such as complete blood count, liver

function tests, random blood sugar, renal function tests, serum electrolytes, BT, CT, PT, Urine -routine, microscopy, ascitic fluid studies, viral markers (HBsAg, HCV), HIV, Ultrasound (abdomen + pelvis), Chest radiograph and ECG were done.

### Statistical analysis

All distribution values among the study population were tested for significance and P values were calculated. The distribution of parameters among the various groups of the study population, were subjected to One-Way Analysis of Variance -ANNOVA Score for calculation of mean, Standard deviation, P value. The Significance of correlation among various parameters, the r value was calculated by Pearson Coefficient of correlation. The Receiver Operating Characteristic curve ROC analysis was done to obtain the sensitivity and specificity of tests used to establish the encephalopathy.

### Findings

**Table 1**

Age (Years)	No.	%age	Mean	SD
1-30	7	4.67	26 ± 5.164	5.164
31-60	98	65.33	48.82 ± 7.122	7.122
61-90	45	30	67.311± 6.138	6.138

Table 1 shows the distribution of age of the study population. Age group (1-30y) made 4.67%(n=7) of the population; Age group (31-60y) made 65.33% (n=98) of the population and Age group (61-90y) made 30% (n=45) of the population.

**Table 2**

	Males	Females
Study population	122(81.33%)	28(18.67%)

Table 2 shows distribution as per Sex. 81.33%(n=122) of the study population were males and 18.67% (n=28) of the population were females.

**Table 3**

Years of Education	Cases
5 years	24(16%)
8 years	67(44.67%)
10 years	24(16%)
≥12 years	35(23.33%)



Table 3 shows distribution as per number of years of education in the study population. The maximum education years were taken to be 12, for there was no significant improvement in psychometric scoring seen in higher number of years of education. 16% (n=24) of the population was educated up to 5 years of age, 44.67% (n=67) of the population was educated upto 8 years and 16% (n=24) of the population was educated upto 10 years and 23.33% (n=35) had  $\geq 12$  years of education.

**Table 4**

Etiology	No. of Cases	Percentage (%)
Alcoholic	80	53.33
NASH	21	14
HBV	5	3.33
HBV $\pm$ Alcoholic	4	2.67
HCV	16	10.67
HCV $\pm$ Alcoholic	8	5.33
Others	16	10.67

Table no 4 shows the distribution of cases as per the etiology of the disease. 53.33% (n=80) patients were chronic alcohol consumers, 14% (n=21) were diabetics and classified as NASH. 10.67% (n=16) patients were HCV reactive and 3.33% (n=5) patients were hepatitis B positive.

**Table 5**

Chief Complaint	No.	Percentage (%)
Yellow Discolouration of Eyes	54	36
Fatigue	40	26.67
Altered Talks	77	51.33
Abdominal Distention	65	43.33
Hematemesis	14	9.33

Table no 5 shows distribution of various complaints in the study population. 51.33% (n=77) patients presented with altered talks, abdominal distention in 43.3% (n=65), fatigue in 26.67% (n=40) and yellow discoloration of eyes in 26.67%. (n=40)

**Table 6**

Chief Complaint	No.	%Age
Liver Cirrhosis	150	100.00
Splenomegaly	58	38.67
Ascites	92	61.33
Portal Vein Thrombosis	4	2.67

Table 6 shows the distribution of features of ultrasound abdomen in the study population. All (n=150) patients had liver cirrhosis, 61.33 % (n=92) patients had ascites and 38.67% (n=58) had splenomegaly. 2.67% (n=4) of patients had portal vein thrombosis.

**Table 7**

GROUPS	No. of Patients	PHES Score	
		Mean (Range)	Mean (Range)
Group A	46	-2.39(-1 to -4) $\pm 1.22$	1.22
Group B	41	-6.41(-5 to -8) $\pm 0.97$	0.97
Group C	63	-8.69(-6 to -13) $\pm 2.69$	2.69

Table 7 shows progressive deterioration of the PHES score with worsening of degree of encephalopathy. Group A has a mean of  $2.39 \pm 1.22$ , Group B has a mean of  $6.41 \pm 0.97$  and Group C has a mean PHES score of  $8.69 \pm 2.69$ . The Analysis of variance calculator showed P value  $< 0.001$  and was statistically significant.

## Discussion

This study was an observational study consisting of 150 patients of cirrhosis of liver. The study population had a mean of age of 40 years, with the majority of the population in the age group of (31-60) years. Similar observations were seen in the PREDICT study<sup>5</sup>, which was a nationwide clinic epidemiological study in India, conducted to study the prevalence of MHE in patients of cirrhosis, in which the mean age was 49.5 years. Also, in a study by Awad MM et al<sup>6</sup>, the mean age was  $52.0 \pm 7.47$  in MHE patients, by Das A et al<sup>7</sup>, mean age was 51.5 years and the mean age was 52.2 years in a study by Saleh A et al<sup>8</sup>.

The males constitute 81.33% of the population and females were 18.67%. The demographic profile matched the PREDICT study, in which the mean age of study population (n=1114) was 49.5 years and majority of them were males (n=901) (81%).<sup>5</sup> Similarly in Studies by Duarte-Rojo A et al<sup>9</sup>, MM et al<sup>6</sup> and Das et al<sup>7</sup>, males were in majority.

Almost in all the patients with hepatic encephalopathy, there is a well defined underlying

etiological factor. Most common etiology found to be alcohol related liver disease, present in 50.33% (n=80) of the population followed by viral infection which was present in 21.45% (n=32). This distribution matched the PREDICT study which also showed alcohol-related liver disease as the most common etiology (482 [43.27%]) followed by viral infection (Hepatitis C and B) (239 [21.45%]).<sup>5</sup> In a study by Mishra D et al<sup>10</sup>, out of 4,331 patients of cirrhosis of liver; 2,742 (63.3%) had alcohol as etiology, 858 (19.8%) had viral hepatitis-related cirrhosis and in a study by Goyal P et al<sup>11</sup>, the etiological distribution of cirrhosis of liver in North India was alcohol (49.2%; n = 352), hepatitis C virusinfection (29.4%; ), and non-alcoholic fatty liver disease (NAFLD) (13.6%).

### Conclusion

This study concluded that in patients presenting with hepatic encephalopathy, there are various factors which plays in precipitating it, and cirrhosis of liver is the most common among them. In later stages of hepatic encephalopathy, mortality rate was high. Early detection of the precipitating factors of liver failure leads to early diagnosis of hepatic encephalopathy and thus decreasing the mortality. So education of the society about the precipitating factors can lead to early detection of hepatic encephalopathy.

**Conflict of interest:** No

**Source of funding:** Self

**Ethical Clearance:** Ethical Clearance was given by committee.

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## A Link between Anxiety and Sattvik Food as a Potential Pathway

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### Abstract

One of the main causes that has put a person's social and physical health under stress but also significantly impacted their mental health is epidemic. The most prevalent and well observed mental condition is anxiety. It can cause a paradigm shift in the eating habits of an individual. The 5000-year-old Indian medical system Ayurveda, which educates about hostile care for the mind, body, and spirit relates major psychological stress like anxiety with improper diet. Following a sattvik diet helps a person lead a stress-free life and reduces a person's risk of illness to mental disorders like depression, anxiety, mood disorders, and hyperacidity; Sattvik diet/ aahar is considered as one of the safe, organic and energetic food. People who eat a diet high in whole food such as fruits, nuts, whole grains, legumes and unsaturated fats are up to 35% less likely to develop depression than those who eat less of these. A healthy digestion of meal with proper engagement of gastric juices, its digestion and absorption are directly related to hormonal balance and production of serotonin level.

**Key Words:** sattvikahar, health, ayurveda, psychologicalstress, mentaldisorders, anxiety

### Introduction

Stress can be defined as "the generalized, non-specific response of the body to any factor that overwhelms, or threatens to overwhelm, the body's compensatory abilities to maintain homeostasis" (Sherwood, 2015). Stress can be more related to acute stress i.e., short term stress and chronic stress i.e., long term stress. People suffering with acute or chronic stress often experience certain physiological changes like slowed gastric emptying, elevation of blood pressure, increase in heart rate, mobilization of energy stores, and decrease in blood flow to non-essential organs, e.g., the digestive system, kidneys,

and skin. Many unfavorable consequences, including chronic degenerative and noncommunicable illnesses including diabetes, cancer, and hypertension, have long been related to stress.

Epidemic became one of the major reasons which not only stressed out an individual's social and physical health but also affected mental health in major aspects. Out of all mental disorders, anxiety is the most common which can be seen day in and out. The symptoms of pathological anxiety are persistent, severe, or disruptive to day-to-day activities (Gale, C.K. *et al.*, 2011). To top this situation people's shift to unhealthy eating to find some comfort to overcome

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their anxiety. The world of today has adjusted to a way of eating that has several harmful impacts on health. Anxiety is so common that it is often linked to cooccurring disorders and can cause a paradigm shift in the eating habits of an individual (Bhasarkar *et al.*, 2021). The appetite and food intake can be increased by eating foods with pleasing flavors, aromas, and textures. Additionally, it has been demonstrated that emotions other than hunger, such as stress, anxiety, despair, and boredom, impact feeding behavior (Sherwood, 2015). Some people tend to overeat and therefore consume a lot of unhealthy food. People having persistent anxiety, or an anxiety disorder are more likely to have long-term heightened levels of corticotrophin-releasing factor (CRF) hormones in their system. One such hormone; Serotonin is agreeably said to be a happy hormone and is also involved in brain functions. One of the major roles of this hormone is to inhibit gastric secretions. Reduced levels of serotonin in the brain may lead to memory problems, mood disorders and may drop a person into anxiety and depression (Bhasarkar *et al.*, 2021).

Ayurveda which is first Indian medicine system is 5000-year-old teaches about holistic care addressing the mind, body and spirit. It inevitably explains that food is medicine and focuses on eating right to bring balance in life, exercising, breathing fully, reducing stress, sleeping well, and following all the basics concepts to keep whole body well balanced and healthy. Conventional nutrition science not just focuses on the type, quality and quantity of food but also talks about the ambience within which a particular food is consumed by a person. It is always recommended by well-known dietitians and nutritionists that an individual should sit down and eat a particular meal with a perfect mental attitude and in sound and healthy surroundings. Now a days, people are least concerned about this basic setting and to make this situation worse they are not even alert to the context of hygiene while consuming a meal.

### Effects of Unhealthy eating

#### Eating in inappropriate quantity

Unhealthy eating does not always mean eating foods which are not good for the body, but unhealthy eating also means not eating in appropriate quantity. An inappropriate quantity of food sometimes leads

to under or over nutrition. In ayurveda, there can be a cascade of consequences related to excessive *ahara matra* (food quantity) identified as *Ama* (unripe) and related pathogenesis. *Ama* can be understood as undigested metabolic waste, a byproduct of inefficient digestion. This results in blockade and interruption in normal physiology. Problems like eczema (chronic skin condition), chronic fatigue syndrome, connective and joint tissue disorders are some very common examples associated with *ama* (Rastogi, 2014).

#### Effects of fried foods

Potatoes are mostly consumed in fried form like French fries hence little is known about acrylamide which is a type of toxin released by deep frying potatoes. Acrylamide is produced during natural chemical reaction when sugars and asparagine (an amino acid in plant-based food) which is carcinogenic in nature. Carcinogenic acrylamide is produced when potatoes are deep-fried (Tareke *et al.*, 2000). Deep-fried meals contain high levels of the toxin 4-hydroxy-trans-2-nonenal (HNE). Food becomes toxic once it reaches room temperature. Numerous cytotoxic and genotoxic consequences are brought on by HNE (Esterbauer *et al.*, 1991). It results in thiol oxidation, metabolic inhibition, and proarrhythmic alterations in cellular excitability. Free radicals are also produced because of fast meals. Almost all biomolecules can interact with free radicals in a variety of ways, changing their inherent characteristics and increasing their susceptibility to harm. All parts of the cellular machinery, including carbohydrates, lipids, proteins, and nucleic acids, are affected by this oxidative damage. Reactive oxygen species (ROS) can also damage DNA by changing its nitrogenous bases, as can the byproducts of their reactions with diverse biomolecules (Valko *et al.*, 2007).

Studies show unpredictable patterns in these sets of genes as cellular mechanism gets majorly affected hence body is prone to diseases. Psychological stress shoots down the body's defense system by suppressing its immunity. Thus, the body becomes vulnerable to innumerable diseases. Some of the evidence of low immunity results in reduced leukocyte count. A person frequently experiencing stress is more prone to cancer also ATF3, which is also known as stress gene, is a crucial link between stress and cancer.

Activated ATF3 gene shows metastatic spread of breast cancer. Although activation and responses of ATF3 gene occurs under stressful conditions. In the presence of activated ATF3 gene normal as well as benign cells often fall into apoptotic condition. But somehow immune system cells show blind response towards cancer cells which travel towards the tumor site and ATF3 gene is expressed. In due course, ATF3 influences immune cells to work in unpredictable patterns which makes cancer cells undetectable and move to different areas of body.

### Effects of eating cold foods

Cold or raw food (*sheeta veerya*) or foods which have cold potency reduces enzyme production in stomach. Modern foods like ice cold food and beverages ayurveda explain it that consuming these hinders with digestive gastric juices which ultimately perform poor in the digestion of food and produce a huge amount of *ama*. So, a huge amount of *ama* leads to disease. Due to too much sugar content which causes obesity and CO<sub>2</sub> gas in it which causes acid reflux resulting in GERD later disturbs the environment of Gastrointestinal tract.

### Effects of eating reheated or microwaved foods

Another research suggests that when food is reheated again and again after getting cold it not only destroys its nutritional properties but also bacteria start to grow within the food. When this food is consumed it ferments in the stomach and hence it produces air and acidity. This also leads to indigestion of food i.e., production of *ama*. Acidity and excessive salt imbalance the body; in fact, salt has a direct impact on heart rate. Over salination raises body temperature and causes the heartbeat to quicken.

Microwave cooking or heating is also never appreciated by ayurveda as its use's electromagnetic waves to heat food which can potentially change the molecular structure of food resulting in dangerous health outcomes. Consumption of red meat heavily associated with colorectal and prostate cancer and cardiovascular disease also heterocyclic amines combined with a high fat diet can enhance colon carcinogenesis and TMAO produced by gut bacteria from L-carnitine in meat is associated with atherosclerosis and cardiovascular disease (Gerhardsson *et al.*, 1991).

### Sattvik Aahar

In the three texts of Bhagwat Gita (verses) it states the following: "Foods in the mode of goodness increase the duration of life, purify one's existence and give strength, health, happiness and satisfaction. Such nourishing foods are sweet, juicy, fattening and palatable. Foods that are too bitter, too sour, salty, pungent, dry and hot, are liked by people in the modes of passion. Such foods cause pain, distress, and disease. Food cooked more than three hours before being eaten, which is tasteless, stale, putrid, decomposed and unclean, is food liked by people in the mode of ignorance."

A sattvik diet is an arrangement that places significance on seasonal food commodities, milk and its products, fresh seasonal fruits, nuts, seeds, fats and oils, seasonal vegetables, lentils and whole grains. Sattvik dishes are vibrant, juicy, light, appetizing, and nourishing. Sattvik meals provide the body with the right quantity of energy. The Sattvik diet is beneficial for spiritual development since it fosters mental clarity and peace. A sattvik diet reduces stress and lowers a person's risk of developing mental illnesses like anxiety, mood disorders, depression, and hyperacidity.

Every food affects physical and mental health differently. Certain food nourishes our body with nutrients and positivity and calmness in mind. As it is rightly said what we eat reflects our mind so supporting the statement the best diet for physical strength, a good mind, good health and longevity is sattvic diet. *Sattvik Aahar* or sattvic diet is purest of all diets as *sattvic* itself means pure. Sattvik Aahar includes sprouted whole grains, fresh fruits, land and sea vegetables, pure fruit juices, nut and seed milk and cheese, legumes, nuts, seeds, sprouted seeds, honey and herbal teas. (Bhasarkar *et al.*, 2021).

Food needs to be prepared and consumed with the right procedure. Although digestion of food starts within the mouth itself but there are different modes of intake of different foods. Complex and heavy food needs to be chewed well and properly mixed with enzymes in the mouth. Enzymes like ptyalin and salivary amylase help in breaking down food into small particles which further easily get mixed with digestive enzymes. Insufficiency

of enzyme causes indigestion of food which is the major cause for undigested metabolic waste. To avoid such complications heavy and complex foods are requested to be consumed in the early hours of the day then consuming them later. Simple foods do not require much time for digestion so they can be consumed in the later hours of the day.

Foods that do not upset the stomach are referred to as sattvik. Our bodies will absorb more nutrients and remain healthy if food is correctly digested in our GI tract. Fresh fruit, pure fruit juices, milk, honey, entire grains that have been sown, land and sea veggies, cheese, nuts, seeds, legumes, sown seeds, and herbal teas are examples of sattvik foods. Sattvik diets help people live stress-free lives and lower their chance of developing mental health problems like depression, anxiety, mood disorders, and hyperacidity. Up to 35% less people who consume a diet rich in whole foods, such as fruits, nuts, whole grains, legumes, and unsaturated fats, are likely to experience sadness. (Sharma, U *et al.*,2019).

#### **Sattvik foods function as body and mind healer**

Diets that follow “good” eating habits, the Mediterranean diet, conventional diets, the anti-inflammatory diet, and diets with more variety are all linked to reduced anxiety. Chronic disease risk is minimized by therapeutic diets with clinical use, such as the DASH diet. All these eating regimens have something in common, such a focus on fruits and vegetables, a restriction on refined carbohydrates and sugar, and a higher intake of minimally processed foods. Ayurveda spices such as ginger, turmeric, cinnamon, black pepper, garlic, and other condiments have therapeutic potential. Spices and herbs not just add flavor to a variety of dishes, but they also heal a person inside out. They are excellent sources of bio actives such as curcumin in turmeric, piperine in black pepper, and gingerol in ginger. These bio actives are not just working as anti-inflammatory, antibacterial, and antithrombotic which could protect against oxidative damage by inhibiting and addressing free radical damage but cell signaling, production and regulation of growth factors, cytokines, and eicosanoids are critical factors modulated by bio actives in foods we choose to consume. Thus, this influences our genetic predispositions and lifestyle such as exercise, sleep

and toxic or stressful environment. As discussed, earlier sattvik diet maintains our GI system which is very important for proper digestion and absorption. Recent studies implicate that 90% (Gershon, 2012) of all serotonin in the body is in the GI tract. Commonly known serotonin is known as a happy hormone and body needs a proper balance of this to maintain good mood of an individual.

#### **Conclusion**

Ayurveda emphasizes these aspects of life and teaches us to follow basic principles so that our body and mind have a strong connection between them. Ayurveda confirms that a person eating *sattvik ahar* i.e., pure diet will not just have a healthy body with immense physical strength but a stable and calm mind too which will improve decision making skills, maintain healthy social relations, reduce mental fatigue and build strong body and mind connection. Smooth functioning of stomach is very important because if digestion is healthy then most nutrients are being absorbed by the body, building healthy muscles. Also, production of hormones will be optimum, especially serotonin which will help in reducing psychological stress, more specifically anxiety issues. Disease caused by foods which are over cooked, microwaved, processed foods, fast foods, fried and frozen foods etc. are inevitable. So, food should be consumed in its natural state and cooked on fire only once. Sattvik diet functions all in one with eating a healthy and balanced diet i.e., easily digestible helps to build immunity, rapid healthy response and brings harmony between physical and mental health. Sattvik ahar does not agitate the stomach at all. By maintaining a peaceful state of mind and preventing it from any kind of agitation, Sattvik Ahar thus helps in dealing with anxiety.

**Ethical clearance:** Not applicable

**Source of funding:** Self

**Conflict of Interest**

Miss. Mansi, Miss. Parul Sharma, and Miss Khyati Jain as author of this research article declare that we have no competing interests regarding this work. We confirm that the manuscript has been read and approved by all named authors and there are no other persons who satisfied the criteria for authorship but are

not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us. We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

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# Prevalence of Middle Cerebral Artery Stenosis in Bihar Population (A Trans-cranial Doppler Study)

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## Abstract

**Background:** The prevalence and causes of intra cranial arterial stenosis in adults' stroke patients is largely unknown. Hence it has become a great clinical challenge for Neuro-physician, neurosurgeon and radiologist to find out the aetiologies of intra cranial arterial stenosis.

**Method:** 100 patients of aged between 25 to 60 years were selected for study. Their past history and clinical manifestations were noted TCD examination was performed with portable machine (multi-drop (R) + DWL), which is a 2MHz power motion single channel TCD, MCA was approached through temporal windows by use of standard protocol. stenosis of arteries were defined by the peak systolic flow velocity more than 140 cm/sec for MCA.

**Results:** The highest clinical manifestation was HTN 75%, followed by DM 58%, obesity 52% and hyper cholestremia 48%, smoker 38%, CAD 32% and least was PVD 2%. In odds ratio study HTN was highest 8.5, followed by CAD ratio was 6 and least ratio was alcoholics 1.6.

**Conclusion:** The present study revealed the aggravating factor like HTN, DM, and CAD. Atherosclerosis causes stenosis of MCA and peak systolic velocity more than 140 mc/sec for MCA. Hence the patients having such clinical manifestations will be more prone for stenosis of MCA.

**Keywords:** Temporal Acoustic window, TCD, Peak systolic Flow, Multi-drop B+ DWL, Stenosis

## Introduction

Prevalence of cerebral artery stenosis varies by their locations. Risk of intracranial arteries stenosis is much higher than that in extra cranial arteries in Indian population<sup>(1)</sup>. It has been estimated that intra cranial arteries stenosis may contribute to 30 to 50% if ischemia strokes and middle cerebral artery (MCA) is the most commonly affected<sup>(2)</sup>. Moreover symptomatic intracranial artery stenosis seems to be relatively unstable because of high frequency

of progression<sup>(3)</sup>. The prevalence and causes of intracranial artery stenosis in adult stroke patients are also largely unknown<sup>(4)</sup>. Relationship between intracranial artery stenosis and clinical manifestations in different age group of patients are still uncertain.

Hence attempt was made to correlate the various manifestation related MCA stenosis in different age groups and both sexes so that aetiologies of the intracranial arterial stenosis can be evaluated and present study will be valuable guidance for

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treating the stenosis of intracranial arterial stenosis especially MCA.

### Material and Method

100 (one hundred) adult patients admitted in Department of Neurosurgery Sri Krishna Medical College hospital Muzaffarpur - 842003, Bihar were studied.

**Inclusive Criteria:** Patients aged between 25 to 60 years having high risk but asymptomatic for stroke were selected for study.

**Exclusion Criteria:** Previous history of stroke or transient stroke attack (TIA) poor or incomplete echo window for Trans cranial Doppler were excluded from studies.

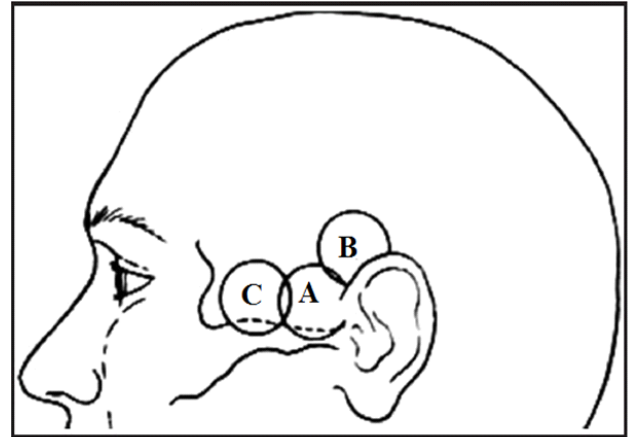
**Method:** Past Medical history of HTN, Diabetes Mellitus (DM), Hypercholesterolemia coronary artery disease (CAD) and smoking BMI BP, Fasting serum lipids, fasting blood glucose were noted.

High risk asymptomatic for stroke population was defined as per the modified Framingham clinical assessment criteria. According to this HTN, DM, history of smoking excessive consumption of alcohol CAD, peripheral vascular disease (PVD), high cholesterol and obesity were taken as vascular risk factors and recorded cardiovascular disease included history of myocardial infarction or angina, Fasting Cholesterol > 200 mg/dl was considered as hypercholesterolemia and obesity was BMI > 30 kg/m<sup>2</sup>.

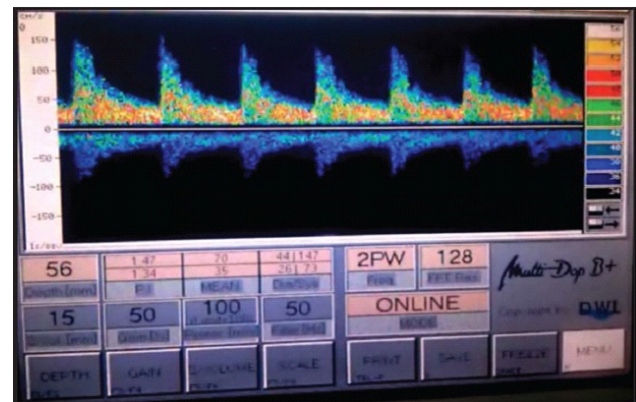
TCD examination was performed with portable Medline (Multi-drop (R) B + DWL) which is a 2 MHz power motion single channel TCH. Bilateral middle cerebral arteries were studied through the temporal windows by use of a standardized protocol. Insonation depth, peak systolic velocity, end diastolic velocity, Mean flow velocity for all vessels were recorded, cerebral arteries that could not be insonated because of poor acoustic windows were excluded from the study. Presence of intra cranial arterial stenosis was diagnosed according to peak flow velocity based on published criteria which was validated against MR angiography and clinical outcomes. The criteria for stenosis of arteries were defined by the peak systolic flow velocity more than 140 cm/sec for middle cerebral artery (MCA).

The duration of study was June 2019 to July 2021.

**Statistical analysis:** Various findings in MCA stenosis were recorded. The statistical analysis was carried out SPSS software. Ratio of male and female was 2:1



**Figure 1: Temporal acoustic windows to identify MCA: A, pre auricular position; B, posterior window; C, anterior window. The probe should be placed in pre auricular region to identify MCA. If not successful, position B should be tried before position C**



**Figure 2: TCD of right MCA on a patient showing peak systolic flow velocity**

### Observation and Results

**Table-1:** Study of clinical Manifestations in MCA stenosis patients 75 (75%) HIM, 58 (58%) DM, 38 (38%) Smoking, 26 (26%) alcoholise, 32 (32%) CAD, 48 (48%) Hyper-cholestremia, 52 (52%) obesity, 2 (2%) PVD

**Table-2:** Study of adds ratio of various risk factors

**Table 1: Study of clinical manifestation MCA stenosis patients**

(No of patients: 100)

Sl No	Manifestations	No of patients	Percentage (%)
1	HTN	75	75
2	DM	58	58
3	Smokers	38	38
4	Alcoholics	26	26
5	CASD	32	32
6	Hypercholestremia	48	48
7	Obesity	52	52
8	PVD	2	2

HTN = Hyper tension, DM = Diabetes Mellitus, PVD = Peripheral Vascular Disease

**Table 2: Study of odds ratio of various risk factors in MCA stenotic patients**

Variables	Odds ratio	95% CI
HTN	8.5	1.1-63
DM	2.0	0.7-5
Smokers	2.2	1-5.3
Alcoholic	1.6	0.6-3.8
Hypercholesterolemia	2.2	1-4
CAD	6	2.7-16.2
PVD	2.6	0.1-16.4
Obesity	2.1	0.8-5.1

CAD = Coronary Artery Disease

PVD= Peripheral Vascular disease

DM = Diabetes Mellitus

HTN = Hyper tension

- 8.5 odds ratio and CI 1.1-5 in HTN
- 2.0 odds ratio and CI 0.7-5 in DM
- 2.2 odds ratio and CI 1-5.3 in Smokers
- 1.6 odds ratio and CI 0.6-3.8 in Alcoholic
- 2.2 odds ratio and CI 1-4 in hypercholestremia
- 6 odds ratio and CI 2.7-16.2 in CAD
- 2.6 odds ratio and CI 0.1-16.4 in PVD
- 2.1 odds ratio and CI 0.8-5.1 in obesity

## Discussion

Trans Cranial Doppler (TCD) study in stenosis of MCA in Bihar Population. The clinical manifestations were 75% of HTN, 58% DM, 38% smokers, 26% alcoholics, 32% CAD, 48% hypercholestremia, 52% obesity, 2% PVD (Table-1). In the study of odds ratio also HTN had 8.5, CAD had 6, DM 2.0, smokers 2.2, PVD 2.6, obesity 2.1, odd ratios (Table-2). TCD technique was approached temporal acoustic window to identify MCA (Fig-1) and TCD of right MCA patient showing peak systolic velocity (Fig-2). These findings are more or less in agreement with previous studies <sup>(5)(6)(7)</sup>.

Identification of underlying causal aetiology during the treatment and prevention in adult / young stroke patients, The most common aetiologies are Large Artery atherosclerosis (LAA) and small vessel diseases (SVD). The causes of LAA and SVD are hypercholestremia could be due to obesity, DM, smoking, alcoholism and rarely PVD. These factors aggravate the stenosis in MAC and results into stroke <sup>(8)</sup>. It is also reported that moyamoya, disease plays vital role in stenosis of intracranial arteries. This disease is more prevalent in Asian countries including India <sup>(9)</sup>.

Identification of exact mechanism of intracranial stenosis especially MCA is challenging. High resolution magnetic resonance imaging (CH-MRI) may be helpful in distinguishing characters if stenosis by offering arterial wall imaging. It is also reported during TCSS (Trans cranial colour code duplex sonography) study that stenosis of intracranial arteries patients were quite variable, i.e. from 83 to 94% and 67 to 72% suggesting that patients with ischemic cerebro - vascular disease were prone to intra-cranial artery stenosis and ischemic stroke <sup>(10)</sup>. Hence SVD aetiologies are not clearly understand

## Summary and Conclusion

The trans cranial Doppler study of intra cranial stenosis in different age groups and both sexes and its clinical manifestations are universally accepted and secondary treatment is to avoid lipid or fatty diet, smoking, alcohol which enables obesity DM and HTN. But this study demands further genetic, cardio vascular, nutritional, patho-physiological,

pharmacological study because exact pathogenesis of stenosis, IHD and stroke is still unclear.

**Limitation of study:** Owing to tertiary location of research centre, small number of patients and lack of latest technologies, we have limited findings and results.

This research paper was approved by Ethical committee of Sri Krishna Medical College and hospital Muzaffarpur-842003, Bihar.

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# Comparison of Lipid Profile of Sedentary Workers with the Athletes Undertaking Aerobic Exercises Regularly

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## Abstract

**Background:** Incidence of cardiovascular disease has increased rapidly in India. Serum lipid levels are among the most important causative factors which in turn related to lifestyle of an individual.

**Aim:** This study was aimed to compare the lipid profile of sedentary workers with the athletes undertaking exercises regularly.

**Materials and Methods:** It was a cross sectional analytical study. It was undertaken among 150 adult males of age 20-50 years. Participants were selected on the basis history of regular exercise and apparently healthy adult males with no athletic or exercise activity for comparison. Known sufferers of hypertension, dyslipidemia or on anti-hyperlipidemic drugs were excluded. All five athletic clubs in district town of Birbhum were selected for data collection. Estimation of serum lipids was done at the biochemistry laboratory of the district hospitals.

**Results:** Mean total Cholesterol level (mg/dl) of the non-athletes ( $208.7 \pm 30.7$ ) was found to be more than athletes ( $197.3 \pm 71.1$ ) and the finding was statistically not significant ( $p = 0.21$ ). Mean LDL level (mg/dl) non-athletes ( $131.5 \pm 24.3$ ) was found to be more than athletes ( $107.5 \pm 15.5$ ) and the finding was statistically significant ( $p=0.000$ ).

**Conclusion:** Regular physical activity improves the HDL cholesterol which is known cardio-protective. Though the total cholesterol was lower in athletes compared to those with sedentary life style but the finding was not statistically significant. This study did include the diet history of the participants.

**Key words:** Lipid profile, Sedentary, Exercise

## Introduction

Over the years the incidence of cardiovascular disease has increased manifold in India as well as the rest of the world. It has become a significant cause of morbidity and premature deaths worldwide.<sup>[1]</sup> Several risk factors are responsible for this increase

including hyperlipidemia, aging, hypertension, smoking and diabetes. Hyperlipidaemia is described as an increase in the levels of lipids circulating in the blood, leading to the deposition of the same in blood vessels of the body particularly the coronary arteries. This contributes to the formation and atherosclerosis which is forerunner of cardiovascular disease.

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The American College of Sports Medicine (ACSM), 2013, defines exercise as a “planned, structured and repetitive bodily movement done to maintain or improve one or more components of physical fitness.”<sup>[2]</sup> Exercise has been reported to decrease the incidence of cardiovascular disease primarily through a decrease in atherogenesis by favourably altering the lipid profile.<sup>[3]</sup> However; this effect varies considerably among exercise intervention studies.<sup>[4]</sup>

Several mechanisms, occurring simultaneously are responsible for the decrease in atherogenesis and cardiovascular disease in humans. The most consistent finding is an increase in the levels of HDL. HDL exerts its anti-atherogenic effect through the transport of cholesterol from the peripheral tissues (including arteries) directly to liver by a reverse cholesterol transport processes.<sup>[5,6]</sup>

The response of LDL to exercise is somewhat more complex and studies have reported inconsistent findings. While some studies have reported a decrease in the levels of LDL following exercise, others have failed to demonstrate the same. Exercise has also been shown to decrease the total cholesterol, triglyceride and ratio of total cholesterol to HDL-cholesterol. Body weight losses decrease cholesterol and triglyceride level and also lead to a decrease in cardiovascular risk.<sup>[7]</sup>

With this background the present study was carried out to compare the lipid profile of sedentary workers with the athletes undertaking aerobic exercises regularly.

## Materials and Methods

It was an analytical study with cross sectional design. The study was undertaken in the Birbhum district of West Bengal. The study duration was 1 year (January 2016 to December 2016). Participants were 150 adult males aged 20-50 years. No female participants were available at those athletic clubs. Among them, 75 were athletes and involved in regular athletic or sports activity. Another comparison group of same number of apparently healthy adult males of sedentary workers (office workers) without any regular exercise and sports activities. Known suffers of hypertension, dyslipidemia or on

anti-hyperlipidemic drugs for any reason and any diagnosed cardiovascular disease was excluded from the study.

The sample size is calculated based on the difference between two means, using the LDL levels of 125.30 in the sedentary group and 105.75 in the exercising group based on the study by Gandarpur ASK.<sup>7</sup> Considering a 95% confidence interval and a 80% power of the study the minimum calculated sample size was 74 in each group. The final sample contained 75 participants in each group.

All five athletic clubs in and around the district town of Birbhum were selected for data collection. Line listings were done for athletes and non-athletes of each club and 15 athletes were selected in athlete group and 15 non-athlete office staffs were randomly selected in non-athlete group for comparison from each of the clubs from those who gave consent for participation. Total 391 persons gave consent for participation in this study. Club-1 had 47 athletes and 30 non-athlete staffs who gave consent. Club-2 had 40 athletes and 31 non-athlete staffs who gave consent. Club-3 had 51 athletes and 34 non-athlete staffs who gave consent. Club-4 had 43 athletes and 30 non-athlete staffs who gave consent. Club-5 had 52 athletes and 33 non-athlete staffs who gave consent. Total 75 athletes and 75 non-athlete staffs were selected as study participants from 5 clubs. Total study participants for study were 150 comprising 75 athletes and 75 non-athletes.

Participants were intimated about the details of the study and their support and cooperation were sought. They were assured that their participation in the study is voluntary and confidentiality and anonymity of data were ensured. Data on exercising were collected by interviewing the respondents with the help of a predesigned and pretested schedule.

5 ml venous blood was collected from the ante-cubital vein of each subject after an overnight fast of 12-14 hours between 8am and 9 am in the laboratory. Serum was separated within one hour of the blood collection and stored at -20°C until analyzed for lipid profile. Estimation of serum lipids by quantitative

EIA method using ERBA-XL-600 (Full auto Analyser) and ERBACHEM-5-B2 (Semi auto analyser) at the biochemistry laboratory of the Birbhum district hospitals using the same algorithm. Dietary history of the participants was not taken and may be considered as the limitation of the study.

Informed consent was taken from each and every participant after describing all the details of the study and they were assured about the confidentiality and anonymity.

Collected data were checked for consistency and completeness and were entered in Microsoft Excel data sheet. Data were organized and presented using the principles of descriptive statistics. Analysis was done using SPSS version 22 software. Independent sample T test was done to compare means of different values of serum lipid profiles between the two groups. These comparisons were also checked for statistical significance taking Confidence Interval (CI) of 95%.

The study was approved by the Institution Ethics Committee of Budwan Medical College and Hospital with the letter number BMC/PG/1216. Study subjects were also assured about the confidentiality and anonymity of the information and their consent was taken before examination.

## Results

The Mean weight (in kg) of the non-athletes ( $74.4 \pm 9.3$ ) was found to be more than athletes ( $68.8 \pm 7.2$ ) and the finding was statistically significant ( $p = 0.000$ ). Mean height (in meters) of athletes ( $2 \pm 2.1$ ) was found to be more than non-athletes ( $1.6 \pm 0.1$ ) though this finding was not statistically significant ( $P = 0.16$ ). Mean BMI non-athletes ( $27.2 \pm 4$ ) was found to be more than athletes ( $25.2 \pm 3$ ) and the finding was statistically significant ( $p = 0.001$ ). Mean Waist-Hip ratio (WHR) non-athletes ( $0.9 \pm 0.04$ ) was found to be more than athletes ( $0.8 \pm 0.08$ ) and the finding was statistically significant ( $p = 0.009$ ). Mean Abdominal skin-fold thickness (in millimetres) non-athletes ( $26.3 \pm 2$ ) was found to be more than athletes ( $24.3 \pm 1.2$ ) and the finding was statistically significant ( $p = 0.000$ ). (**Table 1**)

Mean total Cholesterol level (mg/dl) of the non-athletes ( $208.7 \pm 30.7$ ) was found to be more than athletes ( $197.3 \pm 71.1$ ) and the finding was statistically not significant ( $p = 0.21$ ). Mean Triglyceride level (mg/dl) of non-athletes ( $158.3 \pm 32.2$ ) was found to be more than athletes ( $139.1 \pm 11.9$ ) and this finding was statistically significant ( $P = 0.000$ ). Mean LDL level (mg/dl) non-athletes ( $131.5 \pm 24.3$ ) was found to be more than athletes ( $107.5 \pm 15.5$ ) and the finding was statistically significant ( $p = 0.000$ ). (**Table 2**)

**Table 1: Comparison of physical characteristics and addiction among athletes and non-athletes (n=150)**

Variables of physical characteristics	Mean $\pm$ SD			t value	p value
	Population	Athlete	Non-athlete		
Mean age	$31.8 \pm 8$	$32 \pm 8.3$	$31.7 \pm 7.8$	.22	0.824
Weight	$71.6 \pm 8.8$	$68.8 \pm 7.2$	$74.4 \pm 9.3$	-4.15	0.000*
Height	$1.7 \pm .1$	$1.7 \pm .09$	$1.7 \pm 0.1$	0.16	0.78
BMI	$26.2 \pm 3.7$	$25.2 \pm 3$	$27.2 \pm 4$	-3.6	0.001*
WHR	$0.8 \pm 0.08$	$0.8 \pm 0.1$	$0.9 \pm 0.04$	-2.7	0.009*
Abdominal skin-fold thickness	$25.3 \pm 1.9$	$24.3 \pm 1.2$	$26.3 \pm 2$	-7.4	0.000*
Smokers <sup>#</sup>	74 (49.3%)	19 (25.3%)	55(73.3%)	34.57 <sup>##</sup>	0.000*
Alcohol <sup>#</sup>	81 (54%)	43 (57.3%)	38 (50.7%)	.67 <sup>##</sup>	0.413

# Proportions

## Chi square test

\*Statistically significant

**Table 2: Comparison of Lipid profile among athletes and non-athletes****(n=150)**

Lipid profile (mg/dl)	Mean $\pm$ SD			t value	p value
	Population	Athlete	Non-athlete		
Total Cholesterol	202.9 $\pm$ 54.9	197.3 $\pm$ 71.1	208.7 $\pm$ 30.7	-1.28	0.21
Triglyceride	202.9 $\pm$ 54.9	139.1 $\pm$ 11.9	158.3 $\pm$ 32.2	-4.9	0.000*
LDL	119.5 $\pm$ 23.6	107.5 $\pm$ 15.5	131.5 $\pm$ 24.3	-7.2	0.000*
HDL	50.5 $\pm$ 7.9	53.8 $\pm$ 7.9	47.1 $\pm$ 6.5	-5.6	0.000*

### Discussion

The aim of the present study was to examine the blood lipid levels of people engaged in regular physical activity with a cohort of age matched males with a sedentary lifestyle. Several changes that have been reported with exercise on the post-prandial lipid levels could not be elicited in the present study. The present study could not control for many confounders like weight, BMI, WHR, Abdominal skin fold thickness and smoking, these may have influenced the final results. Since all blood was collected in the empty stomach, only the relation between the fasting lipid levels and exercise could be elicited.

The mean HDL level (mg/dl) athletes were significantly more than non-athletes. HDL-C has been described as the most sensitive fraction of the total cholesterol levels that has been to be consistently affected by exercise.<sup>[8]</sup> Increases in HDL levels of 1.8 mg/dl and 7.2 mg/dl has been reported in males and females respectively, following 12 and 16 weeks of exercise training.<sup>[9,10]</sup> Among 111 people and with a 24 weeks training exercise program, Kraus et al. reported an increased serum LDL-C by 4.3mg/dl.<sup>[11]</sup> O'Donovan et al. also showed a similar increase in the serum HDL-C by 1.4mg/dl among 64 men result with a 24 weeks exercise program.

However, the results may have been influenced by other factors like life style modifications, diet or medications. A meta-analysis based on electronic database searches of MEDLINE (1966-2005) for randomized controlled trials, that examined the effect of exercise training on HDL-C level, among patients not on medications or dietary therapy, showed that the effect of aerobic training resulted in a 2.53-mg/dL elevation of net HDL-C change.<sup>[4]</sup> Durstine et al. suggested that a minimum exercise volume may exist above which an HDL-C elevation occurs.<sup>[12]</sup> Verification of the same was beyond the scope of the present study.

In addition to quantitative changes, qualitative changes in HDL have also been linked to improvements in cardiovascular risks. However, the mechanisms of the improved HDL function are unclear. Improvement in cholesterol efflux capacity and the antioxidative and anti-inflammatory properties of HDL have been proposed to explain the same.<sup>[13]</sup>

In the present study, the mean Triglyceride level of people with regular exercise was found to be significantly lower than people with a sedentary lifestyle. LeMura et al. reported a decrease in serum fasting triglyceride by 1.6 mg/dl following a 16 weeks of exercise training among 12 women.<sup>[14]</sup> Another study by Kraus et al reported a significant decrease of 28.4mg/dl in triglyceride levels in their study among 111 people and with a 24 weeks training exercise program.<sup>[11]</sup> In the same study that reported an increase in LDL-C levels following a 24 week exercise programme, O'Donovan et al. also showed an increase in TG levels by 2.2 mg/dl at the end of the study period.<sup>[15]</sup>

People with a sedentary lifestyle had a significantly lower mean LDL level (131.5  $\pm$  24.3 mg/dl) the exercising group (107.5  $\pm$  15.5 mg/dl) Unlike HDL-C, LDL-C levels following exercise has shown inconsistent and conflicting results after only low- and moderate-intensity exercise.<sup>[3]</sup> While some studies have shown a decrease in the mean LDL-C level among both men and women over a 12 - 24 week period of exercise,<sup>[10,11,14]</sup> other studies have shown a completely opposite result with 24 weeks exercise program which increased the serum LDL-C by 3.1mg/dl among 64 men.<sup>[15]</sup> It has been proposed that the decrease in LDL-C levels were due to many factors including changes in the body weight, or a reduction in the total body fat,<sup>[16]</sup> rather than a direct decrease in the LDL-C levels. A decrease of 0.8 mg/dL

per kilogram of body weight loss has been proposed. [17] Like in HDL-C, in addition to quantitative changes in HDL levels, qualitative changes in particle size of the LDL has been proposed with conflicting results. [18,19]

### Conclusions

Regular physical activity improves the HDL cholesterol which is a known cardio-protective factor of lifestyle. Though the total cholesterol was lower in athletes compared to those with sedentary lifestyle in comparison group but the finding was not statistically significant.

### Limitation:

This study was entirely based on the findings of serum lipid levels of athlete group and non-athlete comparison group and did not include the dietary history of the study participants as a limitation to be considered.

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# Prevalence of Haemoglobinopathy among Young College Students in Anand-Gujarat: A Premarital Screening Program for Carrier Detection of Hemoglobin Disorders

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## Abstract

**Background:** Hemoglobin disorders are the leading health concern in the World including India. Effective screening programs, awareness campaign and proper prenatal diagnosis are the only ways to eradicate the disease. Very sparse data are available on the spectrum of haemoglobinopathies in the central part of Gujarat state. Hence, this study was undertaken to find out the prevalence of haemoglobinopathies among the students of Anand People's Medicare Society, Anand District, Gujarat, India.

**Methods:** In this prospective study, total 2195 students were screened for haemoglobinopathies after taking clinical and familial history. A complete hemogram report was obtained by an automated hematology counter and hemoglobin variants were quantitated by performing HPLC on Bio-Rad Variant II. The prevalence of hemoglobinopathies was 7.06%, which includes  $\beta$ -thalassemia trait (2.73 %), sickle cell trait (3.82%), homozygous sickle cell disease (0.09%), Hb D trait (0.22%), Hb E (0.09%) trait and other haemoglobinopathies (0.08%).

**Conclusion:** Population groups with high gene frequency of haemoglobinopathies requires a routine premarital screening program, awareness and education for identification, prevention of high-risk marriages and birth of thalassaemic homozygotes.

**Keywords:** Haemoglobinopathies, Sickle cell anemia, Thalassemia, Premarital Screening

## Introduction

Haemoglobinopathies are severe, autosomal recessive haemoglobin disorders, if right time

identification and treatment is not provided, can be associated with high mortality and morbidity. [1] Haemoglobinopathies can be classified into three groups: hereditary persistence of fetal haemoglobin,

reduce in the number of amino acids in globin chain synthesis-Thalassemia, abnormal synthesis of haemoglobin with deletion, substitution of one or more amino acid in globin chain.<sup>[2]</sup>

The clinical spectrum of the disorders varies from asymptomatic conditions to serious disorders like thalassemia major that requires regular blood transfusions and extensive medical care. Most of children have a severe clinical presentation but are managed sub-optimally due to lack of financial resources in majority of the families. Thus, preventing the birth of affected children is the best option for India. A prerequisite for this is the knowledge of the prevalence of  $\beta$ -thalassemia and other haemoglobinopathies in different regions of the country and in particular in different ethnic groups. The best course of action for India is to understand the incidence of  $\beta$ -thalassemia and other haemoglobinopathies in various parts of the nation, particularly in various ethnic groups to prevent the birth of impacted children.<sup>[3]</sup>

The World Health Organization (WHO) estimated that 7% of people are carriers of a haemoglobin abnormality.<sup>[4]</sup>Prevalence of  $\beta$ -thalassemia carrier by community examining found as high as 17% in certain population in India because of consanguinity, caste and area endogamy.<sup>[4,5]</sup>According to Modell and Petrou et al., 12% of actual haemoglobinopathies features attributes in Gujarat whereas 4% of haemoglobinopathies are prevalent in Maharashtra and 37.18% are prevalent in Odisha.<sup>[6,7]</sup> The prevalence of HbE is 7.5% in Uttar Pradesh, while in the upper Assam region of north-eastern India has prevalence as high as 47.94% and is very less in Gujarat (0.23%).<sup>[8-10]</sup>

Screening programs should aim to identify asymptomatic carriers of haemoglobin disorders in young population to assess the risk of having children with severe form of disease. In countries with high prevalence of haemoglobinopathies, premarital screening programs are essential for the identification and prevention of high-risk marriages.<sup>[11]</sup>

The main objective of our study was to find the prevalence of haemoglobinopathies among the students of Anand People's Medicare Society (APMS) located in Anand District, Gujarat, India

and estimating the number of students who would benefit from such program.

## Material and Methods

The present study was cross-sectional voluntary screening program. This study included total 2,195 students of Anand People's Medicare Society (APMS), Anand for screening of haemoglobin disorders from August, 2019 to April, 2021 at Indian red cross society, Gujarat State branch, Ahmedabad. Indian Red Cross Society has charged 150/-per student as screening token charge from all students participated in study. Awareness about haemoglobinopathies was provided to all students by pre counselling.

### • Inclusion Criteria:

1. All undergraduate and postgraduate students of Anand people's Medicare Society, Anand. 2] Age group involved ranged from 18 to 30 years.

### • Exclusion Criteria:

1. Already screened and referred to instance of haemoglobinopathies as screening test costs will be paid by understudies.

The study populations included an undifferentiated mixture of urban and rural undergraduate and postgraduate students of the age group of 18 years to 30 years. Students who already have undergone for hemoglobinopathy screening program were excluded from the study (should we include it above in exclusion criteria?). Educational talks, audiovisual presentations were provided and posters displayed for awareness generation before taking an informed consent for testing. A well-designed proforma was used to get information on the caste/ethnic group, linguistic group and religion, consanguinity in the family, any family history of blood disorders as well as to record all the laboratory findings.

**Sample Collection:** A 2-ml intravenous blood sample was collected in EDTA according to practical manual of Dacie.<sup>[12]</sup> RBC indices was measured on a haematology counter (Sysmex K4500), HbA<sub>2</sub>, HbF and other haemoglobin variants were quantitated by HPLC using the Variant Haemoglobin Testing System (Biorad Variant II) as described in the instruction manual. HbA<sub>2</sub> level of >4.0 % was used as a cut off for diagnosis of  $\beta$ -thalassemia carriers.

### Statistical analysis:

The 95 % confidence interval was calculated. The chi-square test was used to compare the distribution of various alleles causing haemoglobinopathies in Anand.

### Results

Total 2,195 students were screened for hemoglobinopathies, among them 1066 (48.5%) were male and 1129 (51.4%) were female students. No student has positive history of blood transfusion or any major illness in the past.

Of the 2,195 individuals, 155 (7.06%) students were found to be carriers of various haemoglobinopathies and 2040 (92.9%) students had normal haemoglobin pattern on HPLC. The prevalence of different haemoglobinopathies among the students shows that sickle cell trait (with co-existence / co-inheritance of one or more Alpha thalassemia gene) was the commonest haemoglobinopathy followed by typical thalassemia, sickle cell trait, Hb D Punjab trait, atypical thalassemia, Haemoglobin E trait, Double heterozygous for sickle cell anemia, Delta Beta Thalassemia trait and Hereditary persistence of fetal haemoglobin. Thus, the overall prevalence of haemoglobinopathies was 7.06% in the present study.

Table 1 shows the haematological parameters in different group of haemoglobinopathies that can differentiate the anemia in to mild, moderate and severe form. The value of haemoglobin in different haemoglobinopathies varied among the different

categories of subjects. This difference was statistically significant ( $P = 0.002$ ). Table 1 shows interpretation of haemoglobinopathies with respect to haemoglobin (g/dl) level. Out of total 155 carrier cases, maximum diagnosed cases except double heterozygous for sickle cell anemia and Hb E trait had hemoglobin level above 12 g/dl, followed by double heterozygous for sickle cell anemia and Hb E trait had hemoglobin level in between 8-12 g/dl. (Hb significantly falls in these cases).

MCV and MCH were decreased in Hb E, Double Heterozygous anemia, Hb sickle c/o and in typical thalassemia whereas it was normal in sickle cell trait, atypical beta thalassemia and Hb D Punjab. In Hb S, Hb D and in atypical thalassemia showed normal MCH values while in others it was decreased. RBC count value in all haemoglobinopathies was within the normal range. (Table 2)

HbS ranged between 36 to 38% (on chromatogram) in the Sickle cell trait, which is less than HbA value. In the cases of Sickle cell trait (with co-existence / co-inheritance of one or more alpha thalassemia gene), Hb S was >24% with HbA2 level 3.5-7% and Hb F <1%. In typical Beta thalassemia and atypical Beta thalassemia, HbA2 level was >3.5% with Hb F <1%. In cases of double heterozygous for sickle cell anemia, HbS was >84.6%, HbA2 was ranging from 3.9 % and HbF 8.10%. Students with HbD Punjab heterozygous stated had unknown peak at D window and HbD was ranged between 32.50%. Students with HbE showed raised peak in A2 region i.e.28.30%. (Table: 3).

**Table: 1 Haemoglobin value in different group of haemoglobinopathies**

Haemoglobin value (gm/dl)	Sickle cell trait (with co-existence / co-inheritance of one or more Alpha thalassemia gene),N	Sickle cell trait, N	Double heterozygous for sickle cell anemia, N	Typical Beta Thalassemia minor, N	Atypical Beta Thalassemia minor, N	Hb D Punjab trait, N	Hb E trait, N	Hereditary persistence of fetal haemoglobin, N	Delta Beta Thalassemia trait, N	Grand Total, N(%)
> 12 gm/dl	48	10	0	28	4	5	0	1	1	97(62.5%)
Mild (12-10) gm/dl	21	0	0	21	0	0	1	0	0	43(27.7%)
Moderate (10-8) gm/dl	3	0	2	7	0	0	1	0	0	13(8.4%)
< 8 gm/dl	2	0	0	0	0	0	0	0	0	2(1.4%)
Grand Total	74	10	02	56	04	05	02	01	01	155(100%)

$\chi^2 = 48.48$ , d.f. = 24,  $P = 0.002$

**Table: 2 Haematological parameters in different group of haemoglobinopathies**

Haemoglobinopathies	Hb (g/dl) mean±S D	RBC count (million/ cmm) mean ±SD	MCV (fl) mean ± SD	MCH (pg) mean ± SD
Sickle cell trait (with co-existence / co-inheritance of one or more Alpha thalassemia gene) (74)	13.2±2.1	5.0±0.9	71.8±8.7	23.1±3.5
Sickle cell trait (10)	13.7±0.9	4.1±0.9	88.5±6.4	29±3.2
Double heterozygous for sickle cell anemia (02)	9±0.9	4.2±0.3	67.5±2.5	21.4±0.2
Typical Beta Thalassemia minor (56)	11.9±1.6	5.7±0.9	65.5±5.9	21.2±2.7
Atypical Beta Thalassemia minor (04)	14.8±0.8	4.9±0.3	88±4.3	29.9±1.1
Hb D Punjab trait (05)	14.3±0.8	4.9±0.2	86.6±3.2	29.2±1.2
Hb E trait (02)	10.7±0.8	4.6±0.1	70±5	23.1±2.5

**Table 3: shows HPLC results in different haemoglobinopathies.**

Haemoglobinopathies (N)	HbA2			Hb F			HbS			Hb D
	<3.5%	3.5-7%	>7%	<1%	1-5%	>8%	21-30%	31-40%	>80%	31-40%
Sickle cell trait (with co-existence / co-inheritance of one or more Alpha thalassemia gene) (74)	30	44	00	56	18	00	60	14	00	-
Sickle cell trait (10)	09	01	00	07	03	00	00	10	00	-
Double heterozygous for sickle cell anemia (02)	00	02	00	00	00	02	00	00	02	-
Typical Beta Thalassemia minor (56)	00	56	00	39	17	00	-	-	-	-
Atypical Beta Thalassemia minor (04)	00	04	00	04	00	00	-	-	-	-
Hb D Punjab trait (05)	05	00	00	04	01	00	-	-	-	05
Hb E trait (02)	00	00	02	01	01	00	-	-	-	-
Hereditary persistence of fetal haemoglobin (01)	01	00	00	00	00	01	-	-	-	-
Delta Beta Thalassemia trait (01)	01	00	00	00	00	01	-	-	-	-

## Discussion

India is an ethnically diverse country with marked regional variation. Anand People's Medicare Society campus has different people of varied ethnic groups of different cities and district. Due to migration, there is constant mixing of people from different regions. Hence, this study was attempted to find out the difference in the prevalence of various haemoglobinopathies among the students studying in APMS campus. Appropriate laboratory tests are required for the diagnosis and confirmation of these disorders.

Haemoglobinopathies are common around the world; in any case, it is progressively common in some geological territories. In India, according to medical clinic-based study, normal recurrence of sickle cell quality is around 5%.<sup>[13]</sup> The most noteworthy recurrence of sickle cell quality in India is accounted for in Orissa (9%), pursued by Assam (8.3%), Madhya Pradesh (7.4%), Uttar Pradesh (7.1%), Tamil Nadu (7.1%) furthermore, Gujarat (6.4%).<sup>[13]</sup> The appropriation of beta thalassemia isn't uniform in the Indian subcontinent. In spite of the fact that certain networks are recognized to have

high predominance, it has been identified in pretty much every Indian populace. The predominance of beta thalassemia characteristic changes from 1-17% in various populaces of India.<sup>[11]</sup> Earlier studies show prevalence of beta thalassemia in different district of Maharashtra 1-6% and in Gujarat 0-9.5%.<sup>[14]</sup>

In our study, most common haemoglobinopathies observed were Sick cell trait (with co-existence / co-inheritance of one or more Alpha thalassemia gene (3.37%), followed by typical beta thalassemia minor (2.55 %), sickle cell trait (0.45 %), Hemoglobin D trait (0.22%), atypical beta thalassemia minor (0.18%), Sick cell disease (0.09%) and haemoglobin E trait (0.09%). Frequency of haemoglobin E in Gujarat was very less.<sup>[15]</sup> This is comparable to the frequency reported by Shah et al. (2018), Patel et al. (2012) and Bhukhanwala et al. (2013).<sup>[16-18]</sup>

In the present study, increased value of HbF between 1-3% was observed in 30% cases of beta thalassemia trait and increased value of HbF>5% was not observed in any cases which is less compare to Greer et al. (50%) and Shukla et al. (42%).<sup>[19,20]</sup>

In our study HbS was ranged between 35 to 39% in cases of sickle cell trait and HbS value was less than HbA value. Hb value was above 12 gm% in all haemoglobinopathies. HbS was ranged between 21-34% with HbA2 <3.5% and HbF <1% with low blood indices in sickle cell trait (with co-existence / co-inheritance of one or more Alpha thalassemia gene) patients. The similar finding was reported previously in sickle cell trait cases.<sup>[21]</sup> Elevated level of HbA2 >3.5% is signet for identification of  $\beta$ -thalassemia carriers and marginal HbA2 level may be due to co-existence / co-inheritance of one or more Alpha thalassemia gene identified by HPLC and further confirmation can be achieved by molecular methods like AMRS-PCR, whole genome sequencing.<sup>[22]</sup>

In this study HbS was >84.6%, HbA2 was 3.9 % and HbF was 8.10% in cases of double heterozygous for sickle cell anemia. In the study of Bhukhanwala et al. reported that level of HbF is up to 20%<sup>[18]</sup>. In present study students with HbD Punjab heterozygous state had unknown peak at D window. HbD was ranged between 32.50% and HbE showed raised peak in A2 region about 28.30%. Incidence of Hb D & Hb E is very less in Gujarat.<sup>[16]</sup>

The present study shows the prevalence of  $\delta\beta$ -thalassemia and HPFH in Gujarat with low incidence of 0.04%. This finding is important as an earlier large multicenter study covering cities from different regions also reported few subjects with  $\delta\beta$ -thalassemia and HPFH <1% in Indian population. Carrier detection of  $\delta\beta$ -thalassemia and HPFH is necessary as combination with  $\beta$ -thalassemia can result in major complications.<sup>[14]</sup>

#### **Limitation:**

The limitation of present study is voluntary participation of the subjects. So, it may not be able to represent population of interest and whole community level prevalence. Further large-scale population-based screening should be carried out to find out the real status of hemoglobinopathies in different community and geographical area.

#### **Conclusion**

Our study was an effort to find out the carrier status for sickle cell anemia, thalassemia and other haemoglobinopathies among the participants. Identification of these individual is very important as they may be transmitting abnormal gene and can give rise to various combination of haemoglobinopathies and thalassemia in their progeny which may lead to high morbidity and mortality. As hemoglobinopathies are not curable, the possible ways for reducing the incidence in India are by generating knowledge, mass campaign, population screening, genetic counseling and prenatal diagnosis. Thus, it can reduce the possibility of hemoglobin disorders of offspring, mental and physical disturbance of affected patients and socio-economic burden of the family. Hence suitable control measures need to be undertaken in India.

**Ethical considerations:** The research protocol was approved by the Institutional Ethical Committee of H M Patel center for medical care & education, Karamsad under the faculty of medicine.

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## Enforcement of Section 5 of COTPA in a District in South India: Hits and Misses

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### Abstract

The Cigarettes and Other Tobacco Products Act (COTPA) has been enacted in the year 2003 and came into force in the following year. Section 5 of COTPA prohibits advertisement of cigarette and other tobacco products. Despite being in force for more than 15 years COTPA has not been enforced to its fullest extent.

**Objectives:** The study's goal was to assess the current level of compliance to Section 5 of COTPA in Kolar.

**Methodology:** A sample size of 423 Points of Sale (PoS) shops was calculated based on 95% confidence level, by using Open Epi software 3.01, a 50% anticipated compliance rate and a 5% error margin with a design effect of 1.1. Data analysis was done using SPSS Version 22.

**Results:** Among the 423 PoS surveyed very few were found displaying advertisements in the form of boards (6 Nos, 1.4%), Posters (6 Nos, 1.4%), banners (2 Nos, 0.5%), or stickers (2 Nos, 0.5%). In fact, no shop was found to have displayed any dangle, LCD, product show case, illuminated boards, black lit or offering promotional gifts and inserts.

**Conclusion:** The study revealed a fair amount of compliance to Section 5 of COTPA in Kolar. In fact the very absence of any shop displaying danglers, LCDs, illuminated or black lit advertisement boards or offering promotional gifts and inserts were encouraging findings.

**Key Words:** Tobacco, Section 5, Compliance, Point of Sale

### Introduction

The use of tobacco has grown in epidemic proportions and is considered as posing one of the greatest risks to global public health that has ever existed and killing more than 8 million people every

world year around the world. More than 7 million deaths are caused by tobacco use directly, while the remaining fatalities are brought on by exposure to secondhand smoke. Around 80% of the 1.1 billion smokers globally reside in low and middle-income

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countries (LMIC), where the burden of tobacco-related illness and deaths are the highest.<sup>1</sup> According to Global Adult Tobacco Survey (GATS) 2016-17, India's current tobacco usage prevalence is 32 %. While 11 % of tobacco consumption in India is in the form of smoking tobacco, smokeless tobacco constitutes 21 % of tobacco users.<sup>2</sup>

Even though several studies point to the growing burden of tobacco use, the extent, pattern and factors associated with tobacco use is not clearly known. According to NFHS-4 Report (2015-16), In the age group of 15 to 49, about 45% of males and 7% of women use some form of tobacco. The most popular method of tobacco use among men is chewing paan-masala or gutkha (15%), closely followed by cigarette smoking (14%) and using bidis (13%).<sup>3</sup>

In 2019 WHO reported the GATS study of India that 38% of adult smokers and 33 % of adult smokeless tobacco users witnessed to quit tobacco through mobile phone cessation messages and also emphasized to ban tobacco marketing by direct advertisements in National, International, radio and local magazines. At least 90% of the population covered by sub national legislation has been completely banned the tobacco advertisement, promotion and sponsorship.<sup>4</sup>

Majority (98%) of the shops in many zones of Delhi were not advertised any tobacco products have followed the implementation of Section 5 of the COTPA Act effectively.<sup>5</sup>

The COTPA (Cigarettes and Other Tobacco Products Act) has been in force since its introduction in 2004 and contains provisions that restrict advertising and control trade, commerce, manufacturing, supply, and distribution of tobacco products. The Prohibition of Smoking in Public Places went into effect on October 2, 2008 (Rules) which was officially made into a law to deal with the gaps existing in the present COTPA and also act as a ban on public smoking.<sup>6</sup>

Though Anti-Tobacco laws have been formulated and implemented in almost all the states of India, compliance to these laws have been limited. Keeping in view the lack of strictness in the enforcement of such laws, the aim of COTPA has not been realized as contemplated. Due to the perfunctory enforcement of law, the full potential of COTPA is yet to be realized to its fullest extent.

The legal measures to implement is a big challenge. The current study was expected to bring out compliance abidance at the points of sale of cigarette and other tobacco products in accordance with the COTPA. It was also envisaged that the study would generate actionable evidence for proper enforcement of COTPA.

## Methodology

A community based cross-sectional study was conducted out during the months of March - April 2020 to assess compliance to the provisions mandated under COTPA for tobacco control with specific reference to Section 5 related to advertisement of tobacco at the point of sale (PoS). For the study Talukas were assumed as clusters and three clusters (viz. Kolar, Mulbagal and Bangarpet Talukas) of Kolar District were selected randomly where all the PoS of tobacco products were observed to assess the compliance to the Section 5 of COTPA.

Three field teams were formed comprising at least two members to covertly observe and record their findings regarding the compliance to the Section 5 of COTPA pertaining to the PoS. Each team was given the responsibility to collect information from a particular cluster allotted to it.

Four core indicators namely, profile, type of the PoS, display of advertisement and display of health warning at the PoS were captured using this tool.

The teams made observations on the PoS during the busiest period of business hours for 20 minutes and filled the observational checklist at the field level itself. No interactions were made with anyone. Surveys were conducted in all the clusters simultaneously by different teams until the required total sample size was achieved.

To ensure quality and reliability of data all team members were trained to comprehend health problems related to tobacco, the provisions for tobacco control under COTPA, identifying PoS of tobacco and conducting the required survey with Observation checklist. Additionally, 10% of the observations were visited by a team of investigators to validate the observations made by the field investigators. Photographs of observed violations were also taken as supportive proof.

Before beginning the main survey, a practice run was conducted at select field sites to improve recording skills. Errors made was discussed and process of entering information in the Observation Checklist was revised.

A sample size of 423 Points of Sale (PoS) shops was calculated based on 95% confidence level, by using Open Epi software 3.01, with 50% anticipated compliance rate and a 5% error margin with a design effect of 1.1., as three clusters (Kolar, Mulbagal and Bangarpet Talukas) were randomly selected out of five. Data analysis was done using Microsoft Office Excel 2010.

This study was conducted as part of evaluation of the status of implementation of COTPA in collaboration with the Tobacco Control Board (TOCB), Kolar, Karnataka.

Prior to the start of the study, the Institutional Ethical Clearance has been obtained.

## Results

**Table 1: Type of Point of Sale/Tobacco shops based on business**

Sr. No.	Type of Shop (Business)	Units in No.	Units in (%)
1.	Total number of PoS (Tobacco shops) observed	423	100
2.	No. of temporary shops	19	4.5
3.	No. of permanent shops	404	95.5
4.	No. of exclusive tobacco shop	13	3
5.	No. of tobacco shop selling mainly tobacco products but also sells other things	392	93
6.	No. of shops for whom tobacco sale is not a major business	17	4

Three clusters with a total of 423 PoS were visited (141 PoS in Kolar, Mulbagal and Bangarpet Talukas respectively). More than 95% of PoS were permanent ones and 93% of PoS sold mainly tobacco products

but also sold other items besides tobacco. Only 3% of the shops were selling tobacco products exclusively. (Table 1)

**Table 2: Profile of Point of Sale/Tobacco vendors in district Kolar of Karnataka**

S. N	Variables	No.	%
1.	Total number of PoS observed for Section 5	423	
2.	No. and % of PoS displaying advertisements	16	3.8%
3.	No. and % of PoS displaying advertisement boards	6	1.4%
4.	No. and % of PoS displaying advertisement posters	6	1.4%
5.	No. and % of PoS displaying advertisement banners	2	0.5%
6.	No. and % of PoS displaying advertisement stickers	2	0.5%
7.	No. and % of PoS carrying out advertisement through LCD	Nil	Nil
8.	No. and % of PoS displaying advertisement dangles	Nil	Nil
9.	No. and % of PoS giving promotional gifts/ offer	Nil	Nil
10.	No. and % of PoS having product showcases	50	11.80%

(Table 2) Majority 50 (12%) of the shops were showcasing tobacco products like, cigarettes, bidis and other tobacco containing items for easy visibility. Only 16(3.8%) shops had display of advertisements of which 6 (1.4%) shops were found displaying such advertisement in the form of boards and 6 (1.4%) were found having posters of tobacco products while only 2(0.5%) PoS had banners and stickers for advertisement of tobacco products. None of the PoS had any digital display i.e. LCD and the dangles for advertisements. No shop was found to offer any promotional gifts along with the tobacco products.

**Table 3: Compliance of advertisement boards displayed at each point of sale in District Kolar of Karnataka**

Sr. No	Number of Point of sale violating the provision of Section 5 for display of advertisement boards	No.	(%)
1.	Size of boards exceeded 60x45 cm	6	1.4
2.	Boards were illuminated or back lit	Nil	Nil
3.	Boards displayed brand name/ pack shot	5	1.2
4.	Board displayed promotional message	Nil	Nil
5.	Advertisements extended to full body	5	1.2

As regards to the advertisement of tobacco products at the PoS were concerned only 6(1.4%) shops had exceeded the board size of more than 60cm x 45cms. Only 5 (1.2%) shops displayed brand name which the investigator noticed only for local bidi brands. At Bangarpet PoS (2%) Honey comb poster displayed without mentioning the brand name. There were full body advertisements over the walls at 5 (1.2%) PoS. Illuminated or black lit boards were not found at any PoS. None of the shops visited displayed any promotional messages. (Table 3)

**Table 4: Compliance related to health warnings on the advertisement boards in district Kolar of Karnataka**

Sr. No	Point of Sale (PoS) violating the provision of Section 5 for display of advertisement boards	No.	(%)
1.	Boards displayed health warning	54	13
2.	Boards haven't displayed health warning	369	87
3.	Health warning not written in white background with black letters	Nil	Nil
4.	Size of health warning was more than 20 x 15 cm	50	12
5.	Health warning written on uppermost portion of a board	50	12
6.	Health warning written in local language	50	12

(Table 4) Indicates the state of compliance of the

PoS to health warnings on the advertisement boards. Out of the total shops selling tobacco, 369 (87%) of the sellers did not display any health warnings on the advertisement boards. Out of those displayed health warnings, (5.8%) the same was not written on white background with black letters and in 50 (12%) of them the size of health warning was more than 20 cm x 15 cm. Further, among 50(12%) of the shops the health warnings were displayed at the top portion of the boards and were written in local language.

## Discussion

The current compliance monitoring Survey was conducted by visiting 423 shops (PoS) in Kolar District, Karnataka. The overall compliance according to Section 5 of COTPA which deals with prohibition of direct or indirect advertisement, promotion and sponsorship of cigarettes and other tobacco products in Kolar District was 84% (357). However, Jain ML et.al found a higher compliance rate of 94%, 91%, 93% and 94% to the same section of COTPA at Alwar City, Thanagaji block, Ramgarh block and Alwar rural respectively in Rajasthan.<sup>7</sup>

Lower rates of compliance were reported in a study conducted in Delhi during the year 2017 (55%). A further lower compliance rate of compliance (53%) was also reported by Khargekar et. as compared to our findings. This difference could be due to a differential in the initiatives of the law enforcing authorities to implement COTPA and also could be due to the awareness drive launched recently by the District Tobacco control Task Force on tobacco.<sup>8,9</sup> A study conducted at Shimoga, Karnataka in 2018 reported 8.4% of the PoS had displayed advertisement related to tobacco products, where as in our study it was only 3.8%.<sup>10</sup>

Though the investigators noticed only 5(1.2%) shops displaying brand names of the tobacco products confined to local bidi brands, at some places honey comb posters were found without any brand name. Though at 5(1.2%) places full body advertisement over the walls of the PoS areas were noticed in a study which was reported by Govil S et. al and reported that most of the advertisement boards were supplied by tobacco companies to the vendors (PoS) and were found to be clearly advertising the company's product in Ahmedabad City.<sup>11</sup> Compliance

assessment conducted by Divyambika Catakapatri Venugopal et al at Chennai<sup>12</sup> found that 85.6% of PoS advertised tobacco, and while 83.1% of them had illuminated and attractive boards, 89.8% had open attractive display of the products. In contrast to this open showcasing of cigarettes and other tobacco products were only 11.8% was found in the current study carried out in Kolar.

In yet another study conducted by Sonu Goel et.al<sup>13</sup> among the three jurisdictions (Chennai city, and the districts of Vadodara and Mohali) the non-compliance rates related to health warnings on advertisement boards (boards did not display health warnings) was recorded as 16.3% and the size of the health warnings less than 20 cm x 15 cm among the health warning display boards was present at 99% of the PoS but in this study 87% of PoS did not display any advertisement boards related to health warnings. Close to a similar observation was made in a study conducted by Pimple S et. al in Mumbai, where 75% of the PoS had not displayed health warnings.<sup>14</sup>

### Conclusion

The study revealed a fair amount of compliance to Section 5 of COTPA in Kolar district. In fact the very absence of any shop displaying danglers, LCDs, illuminated or black lit advertisement boards or offering promotional gifts and inserts were encouraging findings. However, the practice of showcasing tobacco products like, cigarettes, displaying oversized advertisement boards than permissible, display tobacco brands and honey combed advertisements of tobacco products, need to be curbed. These indicates a fair degree of enforcement of the act and probably a good degree of awareness regarding the act.

### Ethical approval

For conducting study was obtained from the Institutional Ethics Committee, Sri Devaraj Urs Medical College, Tamaka, Kolar (IEC Ref No, SDUMC/KLR/IEC/309/2019-20. The study doesn't require patient information sheet or informed consent.)

### Availability of data and materials:

The data used to support the findings of this study are available in the Department Research Locker. If required the data will be shared.

**Patient consent for publication:** Not required for this study.

**Source of Funding:** Tobacco Control Board, Kolar, Karnataka

**Conflict of Interest:** Nil

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# Bacteriological Analysis of Bronchoalveolar Lavage Fluid in Patients with Respiratory Tract Infections

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## Abstract

**Background and Aim:** Bacterial respiratory infections are most commonly causes of illness for all age group patients in ICU. Most of the patients suffer from urosepsis, postoperative disease and lower respiratory infection when admitted in ICU's. Broncho alveolar lavage (BAL) is an ideal sample that allows the recovery of pathogens cellular and noncellular components from the epithelial surface of lower respiratory tract. This study was performed to detect pathogenic organisms by microscopy of BAL fluid and isolate and identify various bacteria and fungi from BAL fluid in culture and analyze their antibiogram.

**Material and Methods:** The cross-sectional prospective study was conducted in the Department of Microbiology, tertiary care teaching hospital, India. The study included 200 BAL samples taken from all consecutive patients referred with suspicion of pneumonia. Bronchial wash was done with the help of fiberoptic bronchoscope under local anaesthesia. All BAL samples were cultured on three bacteriological media agar plates using a sterile 4mm nichrome loop (0.01ml), and incubated at 37 C for 72 hours for quantitative bacterial culture using standard laboratory techniques. Bacterial isolates were identified by performing standard microbiological procedures such as study of colony morphology, Gram staining and standard biochemical tests.

**Results:** Out of the total 200 samples, 120 (60%) were from males, and 80 (40%) were female patients. The predominant GNB was *Klebsiella pneumoniae* 45 (61%), followed by *Pseudomonas aeruginosa* 22(30%), *Esch. coli* 6(8%) and the fungal isolate was *Aspergillus niger* 5(1%). *Klebsiella* & *Pseudomonas* were highly sensitive to amikacin, piperacillin-tazobactam, imipenem, gentamycin, followed by tobramycin.

**Conclusion:** Results of the present study demonstrate the high incidence of gram-negative isolates. The study also suggests that regular antimicrobial sensitivity monitoring should be done as most isolates are highly resistant to cephalosporin and other commonly used antimicrobials.

**Key Words:** Amikacin, Broncho alveolar lavage, Gram-Negative Bacteria, *Klebsiella Pneumoniae*,

## Introduction

Bacterial respiratory infections are most commonly causes of illness for all age group patients, which cured with invasive mechanical ventilation

in ICU.<sup>1</sup> It is systemic pathway via which body acquired fresh oxygen and remove carbon dioxide. The respiratory tract systems are classified in the following parts upper and lower respiratory tracts.<sup>2</sup>

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Upper respiratory tract structure consist of nose, nasal passages, paranasal sinuses, the pharynx and the part of larynx above the vocal folds. The commonly occurring URTI are common cold, tonsillitis, pharyngitis, laryngitis, rhino sinusitis and otitis media.<sup>3</sup> Lower respiratory tract structure includes larynx, vocal folds, trachea, bronchi, bronchioles and alveoli. The most commonly occurring respiratory tract infection are tracheitis, bronchiolitis and pneumonia. It can have severe effects which may lead to hospitalization and loss of life.<sup>4</sup>

Pulmonary infections may be defined as those infections presenting with symptoms such as cough with expectoration, dyspnea, wheeze, chest pain/discomfort to potentially life-threatening infections usually for period ranging from 1-3 weeks.<sup>5,6</sup> Most common causes of infections in these patients are viruses and bacteria. Most frequent bacteria involved in exacerbations include Haemophilus influenzae, Streptococcus pneumoniae, Moraxella catarrhalis.<sup>7</sup> The bacteriological profile of pulmonary infections varies within the same country due to differences in the frequency of use of antibiotics, environmental factors, and ventilation in the critically ill patients. Also, increasing variety of emerging pathogens provide challenges for the microbiology laboratory.<sup>8</sup> In these patients the high mortality rate of these infections is attributed, in most part, to bacterial etiological agents as well as to the lack of prompt and appropriate access to treatment. Effective antimicrobial therapy depends on the identification of the etiologic agent. It is therefore necessary to obtain the appropriate material for bacteriological diagnosis. The advent of bronchoscopy and quantitative invasive techniques like Bronchoalveolar lavage has improved sensitivity and specificity of diagnostic techniques in diagnosis of pulmonary infections.<sup>9</sup>

Broncho alveolar lavage (BAL) is an ideal sample that allows the recovery of pathogens cellular and noncellular components from the epithelial surface of lower respiratory tract.<sup>10</sup> It is increasingly utilized as diagnostic tool though in the past it remained as investigative and research tool. Early diagnosis and proper choice of antimicrobials is crucial for management of these patients and as the sputum culture yields diagnosis in fewer than 50% of patients with pulmonary infections. Further if the sputum

culture report is inconclusive or the patient shows little response to the antibiotics reported as sensitive the situation gets complicated.

This study was performed to detect pathogenic organisms by microscopy of BAL fluid and isolate and identify various bacteria and fungi from BAL fluid in culture and analyze their antibiogram.

## Material and Methods

The cross-sectional prospective study was conducted in the Department of Microbiology, tertiary care teaching hospital, India. The study was carried out for the duration of 1 year. The study included 200 BAL samples taken from all consecutive patients referred with suspicion of pneumonia. **Ethical Approval was taken from ethical committee of the Medical College, Hospital and Research centre, Ahmedabad, Gujarat.**

### Inclusion criteria

Patients with progressive infiltrates on chest roentgenogram 48 hours or more after ICU admission with or without ventilatory support along with fever, purulent secretions, patients in whom clinical examination and routine laboratory findings could not clinch the diagnosis and patients not responding to empirical treatment were included in the study.

### Exclusion criteria

Patients with Pulmonary Tuberculosis, Chronic Kidney Disease, Pulmonary oedema, recent cardiac manifestations were excluded from the study.

Bronchial wash was done with the help of fibreoptic bronchoscope under local anaesthesia (transtracheal). Around 10-30 mL of sterile normal saline was instilled into the infected lung lobe/ bronchopulmonary segments. Instilled saline was suctioned back and collected into sterile containers. Initial microscopic examination consisted of wet mount and Gram staining to observe the presence of pus cells and epithelial cells, bacteria. Bronchial secretions with less than  $10^3$  CFU/ml were regarded as commensals or contaminants and were excluded from the study. Collected samples of 200 patients were sent to microbiology laboratory immediately for further processing.

All BAL samples were cultured on three bacteriological media (Nutrient, Chocolate and MacConkey's) agar plates using a sterile 4mm nichrome loop (0.01ml), and incubated at 37 C for 72 hours for quantitative bacterial culture using standard laboratory techniques. Sample was also inoculated in brain heart infusion broth. For growth positive plates, the colony forming units was calculated.<sup>11</sup>

Bacterial isolates were identified by performing standard microbiological procedures such as study of colony morphology, Gram staining and standard biochemical tests.<sup>12</sup> Antibiotic susceptibility testing was performed by Kirby-Bauer disc diffusion method on Mueller-Hinton agar and on Blood agar for fastidious organisms. After incubation at 37°C for 18-24 hours, the results were read and interpreted as per CLSI guidelines.<sup>13</sup>

#### Statistical analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). For all tests, confidence level and level of significance were set at 95% and 5% respectively.

### Results

Out of the total 200 samples, 120 (60%) were from males, and 80 (40%) were female patients. The majority of cases were in the age group 51-60 years, followed by the age group 61-70 yrs. The least number of patients belonged to the age group between 18-30 yrs. Out of 200 samples processed, 78 were positive for growth on culture. Most of the isolates were Gramnegative bacteria (GNB). Among 78 isolates, 73 were GNB, and 5 were fungal isolates. The predominant GNB was *Klebsiella pneumoniae* 45 (61%), followed by *Pseudomonas aeruginosa* 22(30%), *Esch. coli* 6(8%) and the fungal isolate was *Aspergillus niger* 5(1%). The highest numbers of isolates were in the age group of 51-60yrs followed by 61-70yrs, and the least number of isolates was in the age group of 18-30yrs.

*Klebsiella* & *Pseudomonas* were highly sensitive to amikacin, piperacillin-tazobactam, imipenem, gentamycin, followed by tobramycin. They showed resistance to cephalosporins and slightly resistant to ciprofloxacin also.

**Table 1: Age and Gender wise distribution of subjects**

Age Group	Male	Female	Total
15-30	11	8	19
31-40	2	24	26
41-50	23	9	32
51-60	56	21	77
61-70	28	18	46
Total	120	80	200

**Table 2: Spectrum of bacterial isolates from BAL fluid**

Isolates	Number	Percentage
<i>Klebsiella</i>	45	57.69
<i>Pseudomonas</i>	22	28.20
<i>Esch.coli</i>	6	7.69
<i>Aspergillus niger</i>	5	6.4
Total	78	100

### Discussion

Chronic respiratory diseases represent an important health challenge, both in developing and developed countries because of their frequency and economic impact. Respiratory tract infections are the second most common cause of hospital acquired infections. The etiological agents of Lower respiratory tract infections and their susceptibility patterns vary from area to area and these are a major cause of mortality and morbidity across the globe. Also, clinical findings alone may not be sufficient for definitive diagnosis. A variety of invasive and non-invasive tests have been proposed as guides for diagnosis and treatment. Bronchoalveolar lavage provides a very useful tool for diagnosing lower respiratory tract infections.

The present study was conducted to determine the bacterial etiology in patients with respiratory infections with the perspective of evaluating BAL fluid, which provides a handy diagnostic tool. The present study showed positive BAL cultures in 78 samples out of 200 samples collected. Of these, GNB were the predominant organisms, being 73 and 5 were fungal growths. These results are similar to the studies done by Goel et al<sup>14</sup>, Barsanth et al<sup>15</sup>. The maximum numbers of positive cases were between the age group 51-60yrs followed by 61-70yrs. This may be due to more respiratory cases observed with



increasing age which lowers host defense.<sup>16</sup> The rate of isolation was higher in males than in females shown in Table 1, which was on par with the findings of Shah et al.<sup>17</sup> Birasen Behera et al.<sup>18</sup>

In this study, among culture-positive GNB cases, *Klebsiella pneumoniae* was the commonest bacterial isolate followed by *Pseudomonas* and *E. coli*. A resembling study was done by Khatun Mst and Shamsuzzaman S.M. et al.<sup>19</sup> percentage of *Acinetobacter baumannii* were 34.21%, *Pseudomonas aeruginosa* 15.79%, *Klebsiella* spp. 23.68%, *Citrobacter* spp. 2.63%, *Enterobacter* spp. 2.63%, *Staphylococcus aureus* 7.89%, *Staphylococcus epidermidis* 2.63%, *Moraxella catarrhalis* 5.26%, *Proteus* spp. 5.26%.

In our study, all GNB isolates were susceptible to amikacin followed by piperacillin-tazobactam, gentamycin, tobramycin, and imipenem while resistant to cephalosporins. High degree of resistance against all the generations of cephalosporins was seen among the gram-negative isolates. The reason for such high a percentage of beta lactam-resistant organisms could be the frequent use of cephalosporins in the empirical antibiotic regimens. Similar findings were observed by Regha IR et al.<sup>20</sup> Goel et al.,<sup>14</sup> Barsanti et al.<sup>15</sup> Olugbue V. Onouha et al.<sup>21</sup>

In our study, most gram-negative isolates were sensitive to amikacin, piperacillin, tazobactam, followed by imipenem. Therefore it can be one of the best combinations for treating infections induced by gram-negative bacilli, which are similar to the study reported by Olugbue V. Onouha et al.<sup>21</sup> In such cases of highly resistant strains to most of the frequently used broad spectrum antibiotics, Colistin/ Polymyxin B remains the last option for treatment. As such all health care personnel should be trained in proper hygiene techniques and aseptic precautions for all therapeutic and diagnostic procedures done, which can go a long way in preventing nosocomial infections to an extent.

The increasing antibiotic resistance problem, mainly due to wide spread and irrational use of antimicrobial agents in hospitals and community is of great concern, especially in developing countries. Hence it is very necessary that robust measures be adopted. A combined clinical, microbiological and infection control approach which include

proper diagnosis, appropriate specimen collection, strict antimicrobial stewardship and hospital infection control should be adopted and stringently implemented.

## Conclusion

Results of the present study demonstrate the high incidence of gram-negative isolates. The study also suggests that regular antimicrobial sensitivity monitoring should be done as most isolates are highly resistant to cephalosporin and other commonly used antimicrobials. Proper identification of the probable pathogens and their antibiotic susceptibility pattern can help our health professionals to choose the right antibiotic therapy and improve the outcome.

Ethical approval was taken from the institutional ethical committee and written

Informed Consent was taken from all the participants.

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## Selection of Community Medicine as a subject for Post-Graduation: Students' Perspective

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### Abstract

**Background:** It has been a common observation that medical graduates are often not enthusiastic to choose community medicine as a career. Majority of students who enter in community medicine is not by their genuine interest in the subject but by default.

**Aims & Objectives:** (1) To explore the views of medical students regarding their career choice.(2) To assess possible reasons for medical students opting for or shying away from community medicine as a career option.

**Material and Methods:** A cross-sectional study was carried out among 3<sup>rd</sup>& 4<sup>th</sup> year students and Interns at C.U.SHAH Medical College and Hospital situated in Surendranagar, Gujarat. Self-structured pretested questionnaire was used for collection of data. Out of 250 students 200 students participated for study.

**Results:** A small number of students opted for preventive and social medicine (15%), selection of Community medicine as a career option was significantly low among males (8%) and students having a doctor in their family (6%).The popular choice among male and female were medical and surgical specialties (50%). Choice of Public health was least among 3<sup>rd</sup> year students. "Lack of personal satisfaction" ranked topmost in rejection criteria.

**Conclusion:** The study reveals that there were a lot of misconceptions about the subject; its future prospects, opportunities etc. The peer review about the subject was also not very encouraging. This needs to be changed by making the subject interesting during undergraduate training and making them aware about the opportunities the subject offers.

**Keywords:** Community medicine; Career option; Medical students

### Introduction

Community Medicine is synonymous with Public Health, Preventive Medicine and Social Medicine. It is that field of medicine which is concerned with

the study of health and disease in population of a defined community or group.<sup>1</sup> It helps to identify health problems and needs of the population through community diagnosis and by systemic application of planning, implementation and evaluation of

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health programmes, it seeks to meet the identified needs of a given community.<sup>2</sup> It has been a common observation that medical graduates are often not enthusiastic to choose public health discipline as a career.<sup>3</sup> Public Health had not been attracting the best candidates from the health professions.<sup>4</sup> Anywhere in India Toppers from PG Medical entrance exam always prefer clinical subjects. Among those who choose Community medicine as their PG subject, higher number them either with low ranks or they left with no other option. As per current data of Indian Association of Preventive and Social Medicine (IAPSM) number of MD PSM Doctors in India is 4193, which is significantly low in comparison with the need of MD PSM Doctors in India.<sup>5</sup>

Hence this present study carried out to find the possible reasons why medical students are opting for or shying away from Community Medicine as their carrier choice and to find out the possible reasons for their decision.

### Materials and Methods

A Cross sectional study was performed at C. U. Shah Medical College and Hospital (CUSMC), Surendranagar. The study subjects consist of Medical students of Third First year, Third Second year (4<sup>th</sup> year) and Interns of CUSMC. Out of 250 students 200 participated for the study. Those who were absent on study day and who did not want to take part were excluded from the study. Self-structured pre tested questionnaire was used for the collection of data. Ethical approval from the research committee has been taken. There was not any source of funding because none needed. Each data collection form was analyzed twice to run over all errors.

### Statistical analysis

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA). For all tests, confidence level and level of significance were set at 95% and 5% respectively.

### Results

The study was performed amongst the 3<sup>rd</sup> year part I, final year students and interns at C.U.Shah

Medical College and Hospital. Out of 250 students 200 were included in the study. Amongst them 106 were boys (53%) and 94 were girls (47%). Figure 1 shows the gender wise selection of Community Medicine for Post-Graduation. Girls (22%) were more attracted towards community medicine as their career choice compared to boys (8%) and it was statistically significant with 'P-value' less than 0.05.

Number of students from 3<sup>rd</sup> first, final year and internship was 70, 40 and 66. Table 2 shows the year wise response for choosing CM for PG, from which it is clearly seen that final year and internship students' view regarding choosing CM for PG was significantly higher than 3<sup>rd</sup> year students.

Majority of students (93%) responded that community medicine is an important field (Figure 2a) and most of students (78%) gave positive response regarding Cm as a good subject in Under-graduation (Figure 2b). Although they knew the importance of subject still for very less number of students (15%) community medicine was first career choice (Table 2). Selection of Medicine (27%) and Surgery (24%) stands highest for career choice by students followed by community medicine (15%) and Obs & Gyn (11%).

Figure 4 shows the students' response for choosing CM as a career choice according to their performance in final exam. It seems that attraction towards choosing CM was higher in students who got Second class (28%) in their final exam in compared to First class (6%). Similar difference was shown for choosing CM by students whose family member is doctor (Table 3). Those who belonged to Doctor Family were less likely to choose CM as career choice (6%) in comparison with those who does not belong to Doctor Family (19%). Both results were statistically significant. Figure 5 shows various reasons for choosing CM as a career choice. Among them interest in public health (44%) was the main reason followed by interest in research (33%) and social service (23%).

Table 4 shows various reasons for rejecting CM as a career choice by students, in which "Career in CM/ Public Health will not be satisfying for me" (42%) was the top most reason, followed by "Cannot earn name/ fame equivalent to counterparts in Medicine/ Surgery" (18%) and "I might not be able to earn as much as my counterparts in other clinical subjects" (18%) respectively.

**Table 1: Response regarding choosing CM for PG among 3<sup>rd</sup> first, final year students and interns**

Year	Yes (%)	No (%)	Total (%)
3 <sup>rd</sup> year part I	2 (2.85)	68 (97.14)	70 (100)
Final year	18 (28.12)	46 (71.87)	64 (100)
Intern	10 (15.15)	56 (84.84)	66 (100)
Total	30 (15)	170 (85)	200 (100)

Chi-square: 14.838    df: 2    P value: 0.000599

**Table 2: Response regarding preferred career choice**

Career choice	Response (%)
Community Medicine	30 (15)
General Practice	12 (6)
Medicine	53 (26.5)
Surgery	47 (23.5)
Obs & Gyn	21 (10.5)
Radiology	9 (4.5)
IAS	10 (5)
Ophthalmology	7 (3.5)
Pediatrics	7 (3.5)
Dermatologist	4 (2)
Total	200 (100)

**Table 3: Selection of CM as a career choice among student's whose family member is doctor**

Family member Doctor	Yes (%)	No (%)	Total (%)
Yes	4 (6.45)	58 (93.55)	62 (100)
No	26 (18.84)	112 (81.16)	138 (100)
Total	30 (15)	170 (85)	200 (100)

Chi-square: 5.15    df: 1    P value: 0.023

**Table 4: Response regarding possible reasons for rejecting CM as a career choice**

Reasons	Response (%)
Cannot earn name/fame equivalent to counterparts in medicine/ surgery	31 (18.24)
Career in CM/ Public Health will not be satisfying for me	71 (41.76)
Career in CM/ Public Health will not bring me any recognition in society	9 (5.29)
Lack of info regarding future career prospects after choosing CM	17 (10)
I am not impressed with anyone In this field	3 (1.76)
The subject is looked down by my peers & seniors	3 (1.73)
I have not seen anyone doing well in this field	2 (1.18)
I might not be able to earn as much as my counterparts in other clinical subjects	30 (17.65)
The subject is not projected well by faculty/ postgraduates	1 (0.59)
I have heard of postgraduates/ faculty feeling frustrated after choosing CM	3 (1.76)
Total	170 (100)

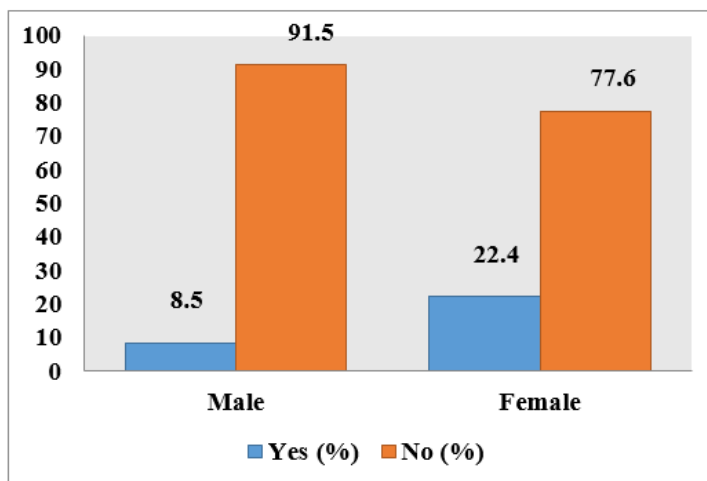


Figure 1: Gender wise selection of Community medicine for PG

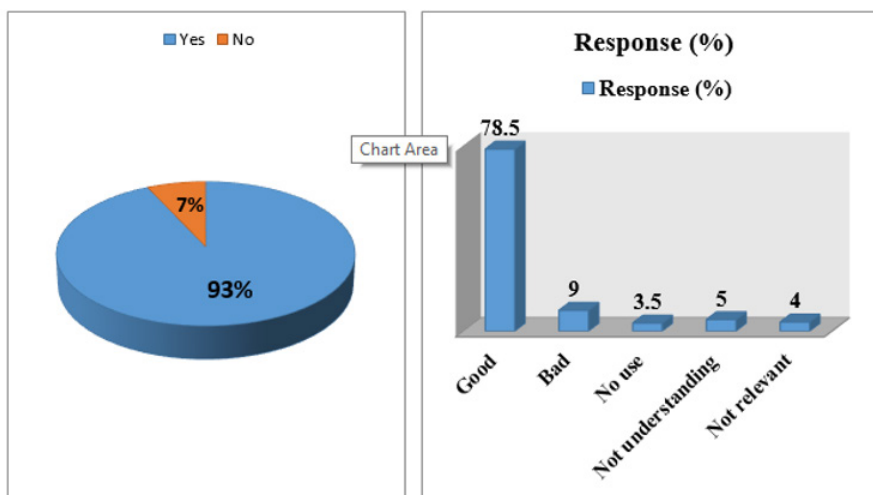


Figure 2a: Response regarding CM as an important field

Figure 2b: Response regarding CM in UG

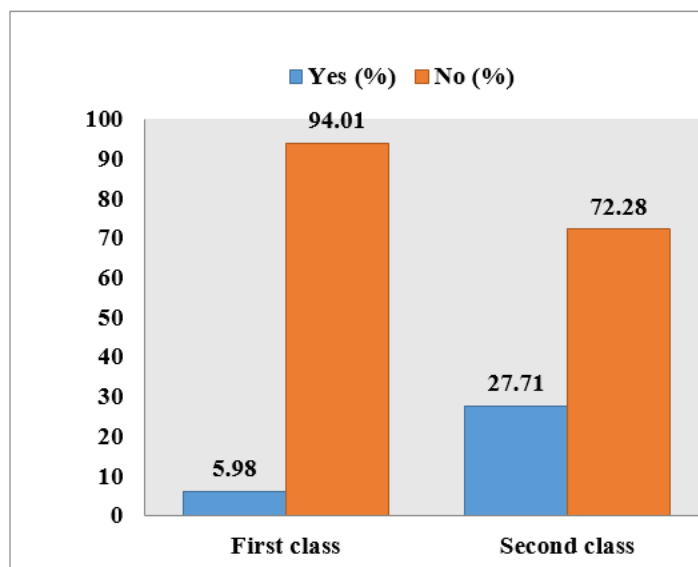
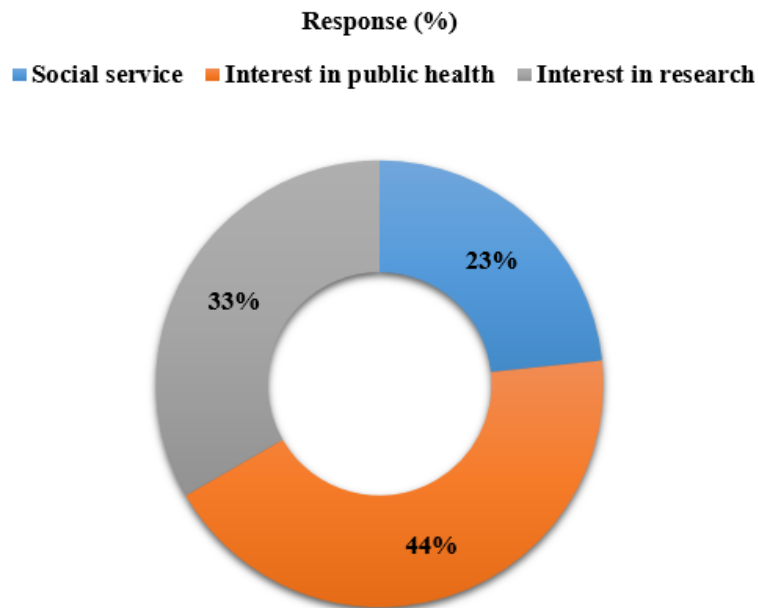


Figure 3: Response regarding students' Performance in final exam for choosing CM as a career choice



**Figure 4: Reasons for choosing CM as a career choice**

### Discussion

Both type of responses positive and negative seen for choosing community medicine as a career choice among the students of the study. In the current study about 15% students gave positive response for choosing career in community medicine, similar results were found in the study done by Manish kumar singh et al.<sup>6</sup> Another study done in Bangladesh by Ahmed et al shows that only 3% of medical students opted for community medicine specialties<sup>7</sup>, so clearly there were more positive response compared to study of Ahmed et al. In this study significantly higher number of female students were attracted towards choosing community medicine as a career option in compared to male students. Similar results reported in the Dutch study by Soethout MB.<sup>8</sup> Medicine and Surgery were the most preferred subjects by the students for their Post-Graduation which was similar to study done by Egenti et al<sup>9</sup> and Ahmed et al.<sup>7</sup>

The main reason for not choosing PSM as a future choice was "Career in CM/ Public Health will not be satisfying for me" followed by "Career in CM/ Public Health will not be satisfying for me" and "I might not be able to earn as much as my counterparts in other clinical subjects" respectively. Similar findings were seen in the study by Manish and Arvind kumar Singh<sup>6</sup> and study of Schafer S et al.<sup>10</sup>

In current study, statistically significant seen in

those who not having doctor in their family were more likely to choose community medicine in compared to those who belonged to doctor family. Similar results were found in the study done by Manish Kumar et al<sup>6</sup> and study done in Nepal by Roy B et al.<sup>11</sup> There was inverse association seen between getting first class in exam and choosing community medicine and it was statistically significant. Those who got second class in exam were more likely to choose community medicine while those who got first class were less likely to choose it. Study done by Nath Anita, Ingle Gopal and Manish Kumar et al shown the similar result in their study.<sup>12</sup>

### Conclusion

Community medicine is the branch which deals with the birth of the medicine to recent advances. It includes every department in some or other manner. So it is necessary to spread the right knowledge about the subject to everyone. It's a wide-spread sea with unlimited opportunities. Although, almost every students in our study consider community medicine as an important field but they are not that much enthusiastic to choose it as a career choice. Even students who came from doctor family they also don't want to choose it, because this subject has been looked down by their parents and peers for future choice. Due to that and also by believing that unsatisfactory career and less name/ fame and money leads to neglect this

subject. Also it has been like a ritual that students who perform well during their under graduation are most probably going to choose clinical side rather than non-clinical. The study reveals that there were a lot of misconceptions about the subject; its future prospects, opportunities etc. The peer review about the subject was also not very encouraging. This needs to be changed by making the subject interesting during undergraduate training and making them aware about the opportunities the subject offers.

Ethical approval was taken from the institutional ethical committee and written

Informed Consent was taken from all the participants.

**Source of funding:** Nil

**Conflict of Interest:** None declared

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# To Assess the Knowledge & Practice about Diabetes Mellitus among Diabetic Patients of Rural Field Practice Area, North Karnataka: A Cross-Sectional Survey

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## Abstract

**Introduction:** Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use its insulin. According to the World Health Organization report, India today heads the world with over 32 million diabetic patients, and this number is projected to increase to 79.4 million by the year 2030. Recent surveys indicate that diabetes now affects a staggering 16% of the urban population and 5-8% of the rural population in India.

**Objectives:** To study the diabetic profile & to assess knowledge about Diabetes mellitus among diabetic patients of Rural field practice areas.

**Methodology:** A cross-sectional survey was conducted at the Rural health Training Centre, Ukkali, under the department of Community Medicine, among the diabetic patients attending the Diabetic clinic for a period of six months. A Pre-designed, pre-tested questionnaire was used to assess the socio-demographic profile of patients, profile of diabetes & knowledge about diabetes mellitus.

**Results:** A total of 110 diabetic patients with a mean age of 66yrs  $\pm$  6 (M 52%, F 48%) showed irregularity in treatment due to the cost of treatment & frequent changing of treatment providers (40%). The majority of patients think that eating excess sugar causes diabetes (72%), it runs in the family (48%) & around 60% are not having any idea about hypoglycemia. Overall knowledge found was poor.

**Conclusion:** There is a need to increase awareness about chronic diseases like diabetes mellitus among people by strengthening the IEC activities in PHCs, RHTCs & Private hospitals because this will reduce the suffering of people not only physically but also economically.

**Keyword:** Diabetes, Knowledge, Practice, self-care

## Introduction

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough

insulin or when the body cannot effectively use the insulin it produces.<sup>1</sup> According to the World Health Organization (WHO) report, India today heads the world with over 32 million diabetic patients and this

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number is projected to increase to 79.4 million by the year 2030. Recent surveys indicate that diabetes now affects a staggering 16% of urban population and 5-8% of rural population in India.<sup>2</sup>

Complications associated with diabetes can be reduced by the early diagnosis of the disease and proper treatment. Patient education has been termed as the corner stone for patients with Type II Diabetes Mellitus. Patients need to make informed decisions about diet, exercise, weight control, blood glucose monitoring, use of medications, foot care, eye care and control of macro vascular risk factor.<sup>2</sup>

The use of a knowledge, attitudes, and practices (KAP) based survey is considered a good resource model to access the qualitative and quantitative information held by the individual & will help to assess the effectiveness of health education interventions. There is strong evidence that educated diabetic patients with good knowledge and health literacy achieve better disease control and management involving non-pharmacological treatment and pharmacological drug therapy.<sup>3-5</sup> Hence a survey was planned to assess the awareness and practice towards the diabetes and self-care among the rural population.

### Material and Method

A cross-sectional survey was conducted at Rural health Training Centre, Ukkali under department of Community Medicine among the diabetic patients attending the Diabetic clinic at for the period of six months. Those people with diagnosed diabetes were enrolled into the study after explaining them the purpose of the survey (Informed consent was taken). Institutional Ethics Committee clearance was obtained before the start of the study. With 95% confidence level and margin of error of  $\pm 10\%$ , and anticipated the percentage of adequate knowledge regarding diabetes among diabetic peoples, a sample size of minimum 100 diabetic patients by using the formula:  $n = \frac{z^2 p(1-p)}{d^2}$  where  $Z = z$  statistic at 5% level of significance,  $d$  is margin of error 10%,  $p$  is the percentage of adequate knowledge regarding diabetes (50%).

A Pre-designed, pre-tested questionnaire were used to assess the socio-demographic profile of patients, profile of diabetes like duration, treatment taken, type of treatment, complication experienced. The proforma also contains the questionnaires related to knowledge regarding diabetes like causes of diabetes, treatment options, side-effects associated with treatment, complications due to diabetes, foot care. The information collected was entered in excel sheet and Data analysis was done for frequency distribution & tests of significance.

### Observations

Total 110 diabetic patients with mean age of 66 years  $\pm 6$  (range = 51 to 76 years with nearly equal sex distribution (M 52%, F 48%) were interviewed during the study period.

**Table 1 - Socio-demographic profile of Diabetic patients**

Variables		Frequency	%
Age (years)	51 - 60	71	64
	61 - 70	24	22
	71 onwards	15	14
Gender	Male	52	47
	Female	58	53
Occupation	Agriculture	57	52
	Housemaker	37	33
	Business	05	05
	Not working	11	10
SE status	Class V	66	60
	Class IV	31	28
	Class III	11	10
	Class II	02	02
Education	Illiterate	77	70
	Literate	33	30

According to the table I, majority of the diabetic participants were in the age group of 51 to 60 years, females more than males, involved in agriculture by occupation, belonging to class-IV socio-economic status and illiterate by education.

**Table 2-distribution of participants according to the profile of diabetes**

Variables	Groups	Frequency (n=110)	%
Diabetic since (years)	<1 yr	13	12
	1 - 3 yrs	12	11
	4 - 5 yrs	61	55
	>5 yrs	24	22
Treatment	OHG	98	89
	Insulin	12	11
Regularity of treatment	Regular	80	73
	Irregular	30	27
Hypertension	Yes	53	48
	No	57	52
h/o stroke	Yes	06	05
	No	104	95

Eye sight	Normal	74	67
	Reduced	36	33
Treatment from	Private	56	51
	Government	52	47
	Others (AYUSH)	02	02

According to table II, mean years of being diabetic was 5 years & SD  $\pm$  4 with minimum 6 months to maximum 10 years duration. Majority (89%) were on oral hypoglycemic treatment, majority (73%) were taking treatment regularly, 48% were also having hypertension, 5% had history of stroke, eye sight reduced in 33% participants and 51% were taking treatment from private doctors followed by Government (47%) health centers.

**Table 3: Patient's Diabetes Knowledge Questionnaire (n=110)**

Q. No.	Questions	Yes	No	Don't know
1.	Eating excess sugar causes diabetes	72%	18%	10%
2.	Diabetes is caused by lack of Insulin	15%	10%	75%
3.	Insulin is necessary to control the blood sugar	12%	06%	82%
4.	If diabetes is not treated, the blood sugar will be high	52%	13%	35%
5.	Diabetes runs in the family	48%	16%	36%
6.	Diabetes cannot be cured	49%	26%	25%
7.	High Fasting blood glucose level is indicative of DM	11%	41%	48%
8.	Diabetes can be monitored regularly by urine sugar test	22%	23%	55%
9.	Diet modification is necessary to control diabetes	24%	16%	60%
10.	Wounds heal slowly among diabetics	51%	12%	37%
11.	Diabetics should take self-care about feet	45%	30%	25%
12.	Diabetes can affect Eye sight	30%	18%	52%
13.	Diabetes can affect Kidneys	25%	15%	60%
14.	Diabetes can affect sense like touch	10%	12%	78%
15.	Low sugar is commonly seen among diabetics on treatment	30%	25%	45%

According to the table III, overall knowledge regarding diabetes and its care among diabetic

patients was (average 30%) below average. Most of the diabetics know that wounds on feet will heal

slowly (51%), so they should take self-care of feet or wounds (45%) but do not practice any foot care to prevent occurrence of wounds. Majority of patients think that eating excess sugar causes diabetes (72%), it runs in family (48%). Majority were unaware about the role Insulin in diabetes (82%), importance

of diet modification in treating diabetes (76%), and other systems affected like eyes (70%) & Kidney (75%). Around 70% are not having an idea about the hypoglycaemia, a very common side effects of diabetes treatment & its prevention.

**Table 4: Distribution of participants according to the Practice of diabetic care (n=110)**

Variables		Frequency	%
DM was diagnosed	Routine check-up	22	20
	Community screening	63	57
	Symptoms	14	13
	Complications	11	10
Treatment initiated after diagnosis	within 24hrs	27	05
	One week	18	16
	One month	87	79
Reasons for irregularity in treatment	Financial	64	58
	Consulting another doctor	24	22
	wait & see attitude	12	11
	AYUSH treatment	10	09
Expenditure for DM treatment monthly	Rs. < 1000	73	66
	Rs. > 1000	37	34
Frequency of blood sugar check	Once in month	23	21
	One to three months	55	50
	Three to six months	32	29
Self-care of foots	Yes	18	16
	No	92	84

According to the table IV, expenditure for the management of the diabetes was found around Rs.1,000 per month including consultation, travelling, wound care & or hospitalization among 66% of the participants. About 21% participants get their sugar tested in nearby PHC/RHTC/private Labs monthly where as 50% once in 3 to 6 months and 29% once in 3 to 6 months. Most common reason for irregularity in taking treatment found was increasing cost of tablets (58%) & consulting change of doctor for treatment (22%).

### Discussion

Among 110 diabetic patients with mean age of 66years  $\pm$  6 (M 52%, F 48%) showed irregularity in treatment due to the cost of treatment & frequent changing of treatment providers (40%). Overall knowledge found was poor. Majority of patients think that eating excess sugar causes diabetes (72%), it runs in family (48%) & around 60% are not having an idea about the hypoglycemia. Most of the diabetics were having adequate knowledge regarding slow wound healing on feet (51%), need of self-care of feet

or wounds (45%) but do not practice any foot care to prevent occurrence of wounds (16%).

Al-Yahya A et al showed in their study that the most common barrier to comply with regular follow-up was inadequate knowledge about the importance of periodic eye exam 47.1%. Patients with low socio-economic status had a significantly poor knowledge regarding diabetes ( $P < 0.0001$ ) and diabetic retinopathy ( $P < 0.015$ ), respectively. However, patients with low educational level had a significantly poor knowledge ( $p < 0.0001$ ) and poor practice regarding diabetes ( $P < 0.013$ ), respectively.<sup>6</sup>

HyderMKetal the impact of Prediabetes Education Program (PEP) was assessed by administration of questionnaire before and after PEP with an interval period of 30 days. Baseline assessment of knowledge among prediabetics shown that 90% had poor knowledge but after PEP program 43% had average knowledge and 44% could score good knowledge. Baseline assessment of attitude exhibited 30% with negative attitude but after counseling 68% shown positive attitude. Regarding practice assessment 35%

had very poor and 52% shown poor practice but after PEP 71% shown good practice and 15% shown very good practice. Prediabetes education program could bring significant improvement in knowledge attitude and practice.<sup>7</sup>

Chakravarty R et al, the mean (SD) age of the respondents was 35.2 ( $\pm$ 12.61) years and 62% had a graduate or higher level of education. The median KAP scores were 10 (8-12), 5 (3-5) and 2 (2-3) out of a maximum of 18, 5 and 6, respectively. Higher educational and socioeconomic levels were associated with better attitude scores, but knowledge levels were comparable. Correlations between KAP scores were poor. This study reveals that lay people have appropriate knowledge and attitude regarding diabetes mellitus to some degree but there are important lacunae and practices are often found wanting.<sup>8</sup>

Jaiswal K et al, conducted a cross-sectional, questionnaire-based survey in patients (n=100) of a tertiary care teaching hospital in central India. Among them, 46% participants were in the age group of 41-60 yrs. About 94% patients were aware about high blood sugar level & 90% monitoring it. About 85% were aware of hypoglycemic symptoms and its treatment and 80% knew about development of other complications. Regular checkup was done by 70%, while 73% were adhered to treatment.<sup>9</sup>

Muhammad FY et al, conducted hospital based cross-sectional study and level of KAP was found to be directly related to glycemic control ( $P < 0.01$ ). The level of education (odds ratio [OR]: 5.0 and 95% confidence interval [CI]: 0.196-0.452) and monthly income (OR: 4.4 and 95% CI: 0.123-0.326) were found to be independent predictors of diabetes-related KAP.<sup>10</sup>

### Conclusion

There is a need to increase the awareness about the chronic diseases like diabetes mellitus among the people by strengthening the IEC activities in Primary health care levels, because this will not only reduce the suffering of people physically but also economically. This is addressed by regular public sensitization and motivational health educational campaigns to improve the treatment outcomes of Diabetes mellitus in India.

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## Importance of Serosal Fluid Cytology as an Aid to Primary Diagnosis: A Descriptive Cross-sectional Study

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### Abstract

Cytological study of fluids is an inexpensive, simple procedure and has significant utility in diagnosing neoplastic and non neoplastic lesions. The cytological examination of fluids in combination with physical examination helps identify aetiologic agents, follow the natural process of the disease and monitor the response to the treatment.

**Aim:** To determine the diagnostic utility of serosal fluid cytology and analyse the incidence of neoplastic and non neoplastic lesions using serous fluid cytology.

**Materials and Methods:** This was a descriptive cross-sectional study comprising 311 cases conducted in a tertiary care hospital. Purposive sampling was used to recruit the participants. All the patients with pleural effusions, ascites or in whom Cerebral Spinal Fluid (CSF), pericardial and synovial fluids examination was indicated were included. The provisional diagnosis was obtained from case sheets, including relevant clinical information. Smears were prepared from freshly tapped specimens without adding anticoagulants and were processed by routine, conventional smear technique. The data were analysed using the SPSS version 22.0 for Windows. Numerical variables were reported as frequency and percentage. The chi-square test was used wherever necessary, and the p-value less than 0.05 were considered significant.

**Results:** The peritoneal fluid was the most common fluid collected in the present study, followed by pleural fluid and CSF. The malignancy rate in the present study was 19 (10.4%) of peritoneal fluid, 6 (5.9%) for pleural fluid, and 2 (4.1%) for CSF.

**Conclusion:** Adenocarcinoma was the most common malignancy found in this study, which was in concordance with the research conducted earlier, where gold standard investigations confirmed the findings. In the peritoneal fluid, most of the patients had cirrhosis and tuberculosis. In pleural fluid and cerebrospinal fluid, most of them had tuberculosis and chronic inflammatory conditions, respectively. Previous researchers confirmed similar findings in their studies. It is seen that malignant and benign conditions like tuberculosis can be diagnosed well with effusion cytology.

**Keywords:** serosal cytology, CSF, pleural, automated.

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## Introduction

The pleura, pericardium, and pelvis are all covered in serous body cavities, which are mesothelium-lined potential spaces (peritoneum). A tiny amount of fluid, called an ultrafiltrate of plasma, normally aids in the movement of the organs. Fluid may build up and cause an effusion if the generation and resorption of this plasma ultrafiltrate are not correctly balanced<sup>1</sup>.

Effusion is the accumulation of fluid in the body cavity. This fluid during disease process undergoes abnormal and disproportionate qualitative and quantitative changes<sup>2</sup>. Pathological conditions like congestive heart failure, hepatic cirrhosis, hypoproteinemia, infections like bacterial pneumonia and tuberculosis, neoplastic conditions like mesothelioma, metastatic carcinoma, and other conditions like trauma, pancreatitis, and peritonitis are the common cause of pleural and peritoneal effusion. Exudative and transudative kinds of effusion exist. Transudative cells have lower levels of protein than exudative cells and a higher overall cell count, low number of total cells<sup>2</sup>. This study was done to compare the results of cytological analysis of body fluids by manual and automated method.

## Materials and Methods

The present study was a hospital based prospective cross-sectional study conducted in the Department of Pathology at Subharti Medical College and associated Chhatrapati Shivaji Subharti Hospital from August 2020-Nov 2022.

Sample size: 311 cases

Study Design- Hospital Based Cross-sectional Study

### Inclusion criteria:

- All body fluid sample

### Exclusion criteria

- Insufficient quantity <1ml.
- Fluids with coagulum, purulent and flocculent samples, turbid samples
- Pediatric age group.
- Sputum and seminal fluid

## Procedure

- Fluids were collected in a sterile wide-mouth universal container with proper labelling and identification number.
- Processing was done immediately after receiving.
- If there was any delay in transport it was refrigerated at 4 degree Celsius.
- Essential clinical details were recorded.

After centrifugation for (1500 rpm for 5 min/ cytospin) is stained with May Grunwald Giemsa (MGG) for dry smear and Haematoxylin and Eosin (H&E) and Papanicolaou (Pap) for wet smear. Smears are examined and cytological findings were noted. Biochemical Analysis of the fluid was recorded.

## Results

The present cross-sectional study was conducted in the Department of Pathology at Subharti Medical College and associated Chhatrapati Shivaji Hospital. A total of 311 body fluids samples were evaluated from Dec. 2020 to May 2022. Cytological analysis was done in all cases and clinicopathological correlation was done, and comparative analysis of body fluid was done by automated and manual method in 232 cases. Age of the patients in the present study ranged from 21-89 years. Out of 311 samples, maximum were in the age group of 18-30 years (24.76%) followed by 41-50 years (23.47%).

Males (57.23%) were comparatively more as compared to females (42.77%) in present study.

Based upon the biochemical analysis and cell count, body fluids were divided into transudate and exudate. Exudative fluid was found in 58.52% of the cases while transudative fluid in 41.48% of the cases.

Transudative nature was found maximum in CSF fluid (30.55%) while exudative nature was revealed mostly in ascitic fluid (47.59%). When transudate/exudate distribution was compared according to fluid type using chi square test, statistically significant difference was found as  $p < 0.05$ .

### Correlation of clinical diagnosis with different type of body fluids.

Clinical Diagnosis	Frequency(n)	Percentage(%)
Peritoneal Fluid (n=148)		
Chronic Liver Disease	103	69.59
SBP (Subacute Bacterial Peritonitis)	15	10.13
Abdominal Tuberculosis	20	13.51
Pancreatitis	10	6.75
Pleural Fluid (n=66)		
TB	38	57.57
Pneumonia	26	39.39
CHF	2	3.03
CSF (n=93)		
Meningitis	92	98.92
VP Shunt	1	1.07
Other Inflammatory Condition	1	1.07
Pericardial Fluid (n=2)		
Myocardial Infraction	2	100%

Ascitic (47.59%) was the most common type of fluid obtained in this study followed by CSF (30.55%) and pleural fluid (21.22%). Pericardial fluid (21.22%) was the least common type of fluid received.

Total cell counts of body fluid (cells/cubic mm) was found more in automated method as compared to manual method. When total cell count was compared between automated and manual method using t test, statistically significant difference was found as  $p < 0.05$ .

### Discussion

Effusion cytology dates back to the 19<sup>th</sup> century. Since then, effusion cytology has gained tremendous importance in the medical literature. The cytological interpretation of individual cells that are exfoliated into these fluids is of paramount importance since they provide an insight into the diagnostic, prognostic and therapeutic aspect of various

pathological process in the body. A better knowledge of spectrum of clinical history and clinical signs of pleural, peritoneal, pericardial analysis, along with radiological, biochemical and cytological evaluation of the fluids helps in narrowing the diagnostic dilemma faced by physicians and helps in better management of patients. Body fluids are segregated into transudates and exudates. Cytological analysis comprises of microscopic examination, wherein the total and differential cell counts are performed using a hemocytometer. In our study automated hematology analyzers (Horiba H2500) with a Body Fluid Mode (BFM) are provided for the extension of its function in the analysis of cells in BFs.<sup>3</sup>

Due to dearth of literature in automated vs manual microscopy studies, the present cross-sectional study was conducted in the Department of Pathology at Subharti Medical College and associated Chhatrapati Shivaji Hospital among 311 body fluids samples received in In the present study majority of cases were peritoneal, (47.59%) was the most common type of fluid obtained in this study followed by CSF (30.55%) and pleural fluid (21.22%). Pericardial fluid (21.22%) was the least common type. It is comparable to the studies<sup>4</sup>. In contrast study<sup>5</sup> showed pleural fluid is predominant. This difference could be because of nature of cases received in health care facilities and selection of cases based on inclusion and exclusion criteria. The aim of the study was to compare cytological analysis of body fluids by manual vs automated method with reference to a) Total cell count b) Differential cell count and clinicopathological correlation of the fluid.<sup>6</sup>

The present study showed slightly male predominance over female, male (57.23%) and female (42.77%).

Based on biochemical analysis fluids were divided into exudative and transudative type of effusion. Transudative has less protein content, low total cell count while exudative have high protein content and raised total cell count.<sup>7</sup> Out of 311 cases, 129(41.48%) were transudative fluid and 182(58.52%) were exudative fluid. Transudative nature was found maximum in CSF fluid while exudative nature was revealed mostly in ascitic fluid. When transudate/



exudate distribution was compared among the study subjects according to fluid type using chi square test, statistically significant difference was found as  $p < 0.05$ .<sup>8</sup>

*Sheetal et al*<sup>35</sup> assessed 375 samples comprising of peritoneal fluid 183(48.8%), followed by pleural fluid 102(27.2%), cerebrospinal fluid 49(13.1%), pericardial fluid 24(6.4%) and synovial fluid 17(4.5%)<sup>9</sup>. He distributed cases on the basis of effusion with majority of patient had cirrhosis 95(51.9%) followed by tuberculosis 24(13.1%) and cancer 19(10.4%). Similarly *Anita et al* conducted a study on 70 patients comprising of pleural fluid (31), pericardial fluid(5) and peritoneal fluid(34). He did clinic cytological correlation with cirrhosis of liver(70.6%) followed by abdominal tuberculosis(23.6%). Both the studies are similar to our study where clinocytological correlation was done of 311 body fluid samples with chronic liver disease 65.5% followed by tuberculosis(57.7%).<sup>10</sup>

### Conclusion

Evaluation of body fluid is simple, quick safe and cost-effective process which helps the treating clinicians to reach a diagnosis and to understand the disease progression. The automated approach performed the bodily fluid analysis with great, fundamental accuracy. For the assessment of cerebral fluid, pleural fluids, and the ascitic fluids cell counts, an automated approach is a helpful extra tool, particularly in an emergency situation. It provides the reproducibility, precision, accuracy, rapid and reliable data on RBC and WBC count, and is easier for quality control and standardization than manual method. Fully automated analysis meets time and quality requirements and are objective in material handling. Moreover, automated method would bring homogeneity between different laboratories. Further studies with large number of samples are required to draw a definite conclusion.

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# Obstacles and Challenges in Gaining Access to Family Planning Services in Covid Era: A Cross-Sectional Descriptive Study

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## Abstract

**Introduction:** Although WHO recommended continuing sexual and reproductive health services during COVID-19 pandemic, the services were either stopped completely or limited. Hence our study aims to determine the challenges in the accessibility to family planning services as well as the impact on contraception and safe abortion services during COVID-19 era.

**Methods:** This is a cross-sectional descriptive study conducted in the department of Obstetrics & Gynaecology, SRM hospital, Chennai from September 2021 to November 2021. Random sampling method was used to enroll participants after considering the inclusion and exclusion criteria.

**Results:** Almost half of the study population (49.24%) faced difficulty in following any form of contraceptive measure amid pandemic. Non-availability of contraceptive supply (14.72%) was the major hurdle during the pandemic. Among the respondents who had terminated the pregnancy, the majority had done by general medical practitioner (66.67%) while only thirty-three percent terminated under specialist care. While comparing the complications during pregnancy termination, general medical practitioner approach led to more complications than specialist care.

**Conclusion:** Non-availability of contraceptive supplies, FP services amid COVID-19 pandemic has exerted detrimental impact on the women reproductive health. Continuing FP and safe abortion services are essential during pandemic to sustain the success of high-quality reproductive services.

**Keywords:** Abortion, Contraception, COVID-19 pandemic, Family planning, Unwanted pregnancy

## Introduction

The Coronavirus disease first started as an epidemic in China became the fastest growing public

health pandemic of the century in due short course of time.<sup>[1]</sup> Since its onset, the debilitating impacts of coronavirus on health infrastructure have been

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documented globally which have exerted unequal health burdens among various populaces. As a preventive strategy, social distancing was adopted worldwide in order to control COVID-19 transmission which ultimately led to the implementation of partial or complete lockdown. This has hindered the accessibility to the contraceptive and safe abortion services along with contraceptive usages resulting in 2.7 million unintended pregnancies in the first year.<sup>[2]</sup> The upsurge in unwanted pregnancies, unsafe abortions and associated complications<sup>[3]</sup> thereby threatened the onerous progress on the contraceptive coverage targets defined by the Sustainable Development Goals (SDGs).<sup>[2]</sup>

Although World Health Organizations (WHO) has recommended the continuation of sexual and reproductive health services including family planning amid COVID-19 pandemic,<sup>[4]</sup> the routine reproductive health services were hindered due to the shift in the point of health care services towards COVID-19 patient management. Also non-compliance of patients due to COVID-19 fear, lack of clinical resources allocation, transportation as well as economical issues led to the decline in the uptake of reproductive health services contributing in the rise of unintended pregnancies and unsafe abortions. This forms the rationale for the healthcare professionals to actively implement reproductive healthcare services for women. Providing access to the reproductive health services via clinical resource allocation at the community level including contraception provision is the key to mitigate COVID-19 comprehensively along with high-quality family planning services. This will not only reduce the maternal morbidity and mortality, it will also improve newborn and child health.<sup>[5]</sup> Continuing safe abortion and family planning services during pandemic has been evidently challenging. Also, there are dearth of studies which specifically investigated the COVID-19 impact as a stress on reproductive health care services. Hence our study aims to determine the challenges in the accessibility to family planning services as well as the impact on contraception and safe abortion services during COVID-19 era.

### Methods

This was a cross-sectional descriptive study conducted in the outpatient clinic of Obstetrics &

Gynaecology, SRM medical hospital, Chennai for duration of 3 months (September 2021 to November 2021). Random sampling method was used to enroll participants. Every consecutive participant in the reproductive age group (18-45 years), willing to participate and are sexually active visiting outpatient clinic for various medical conditions were included after obtaining written informed consent. Women with psychiatric disorders or who are mentally challenged, those who already underwent permanent sterilization and who are not willing to participate were excluded. The ethical approval has been received from the institutional scientific committee. (Reference number- 2996/IEC/2021)

A semi-structured questionnaire containing questions regarding sociodemographic characteristics, awareness on contraception use, difficulties in gaining family planning and contraception access, reasons for avoiding contraception during COVID-19 pandemic and its outcome was formed after extensive review of literature.<sup>[4, 6, 7]</sup> The questionnaire was validated by the Gynecologists and pilot study was conducted prior to the commencement of the study to improve the clarity of the questionnaire.

The data was entered in the Microsoft excel sheet and the statistical analysis was performed by using SPSS version 20 statistical software. Mean as well as standard deviation was used for continuous data. For categorical data percentage was calculated. Chi square test was used to analyze the association of complications during pregnancy termination with age group, parity, method of termination and difficulty in accessing medical facility during covid time for pregnancy termination. The p value less than 0.05 was considered statistically significant.

### Result and Discussion

A total of 197 women participated in the study within the reproductive age group of 18-45 years. The mean age of the respondents was 26.27 years with predominant age group of 21-30 years (81.7%) (Table 1).

**Table 1. Age of the respondents (years)**

Age groups (Mean- 26.27, standard deviation- 4.190, Median- 26.00, Standard error of mean- 0.299)	No. (%) of respondents
< 20 years	11 (5.6)
21-30 years	161 (81.7)
> 30 years	25 (12.6)

Among the respondents, twenty-five percent were primi parity and seventy-five percent were multi-parity (Table 2). Majority of the respondents were reported to have contraception knowledge (96.95%) and seventy-five percent respondents were using various contraception methods. Among the contraceptive users, barrier method was the majorly used contraception measure (36.04%). During COVID-19 era, almost half of the study population (49.24%) faced difficulty in following any

form of contraceptive measure. Non-availability of contraceptive supply was the major hurdle in following contraception during COVID-19 era (16.75%). Among the respondents with unplanned pregnancy, thirty-six percent continued the pregnancy and fourteen percent terminated the pregnancy. Non-availability of family planning (FP) services was the predominant reason for continuing pregnancy (70%). Among the respondents who had terminated the pregnancy, majority had done by approaching general medical practitioner (66.67%) while only thirty-three percent terminated under specialist care. The respondents who had approached general medical practitioner, difficulty in consultation with the specialist was the major reason (94.44%). However, only six percent of the respondents reported COVID-19 fear as the most probable reason. Respondents who had terminated their pregnancy, majority faced medical complications during pregnancy termination (55.56%) due to difficulty in accessing medical facility regarding pregnancy termination (55.56%).

**Table 2. Contraceptive and family planning services implementation challenges reported by the respondents**

Challenges	Sub-group	No. (%) of respondents
Parity	Primi	49 (24.87)
	Multi	148 (75.13)
Contraception knowledge	Yes	191 (96.95)
	No	6 (3.05)
Current contraception	Yes	148 (75.13)
	No	49 (24.87)
Methods used	Natural	34 (17.26)
	Barrier	71 (36.04)
	Hormonal Injection	8 (4.06)
	Hormonal pills	30 (15.23)
	IUCD*	5 (2.54)
	Not applicable	49 (24.87)
Difficulty in contraception	Yes	97 (49.24)
	No	42 (21.32)
	Not applicable	58 (29.44)
Type of difficulty	Consulting specialist	25 (12.69)
	COVID fear	15 (7.61)
	Non availability	33 (16.75)
	Transport	29 (14.72)
	Not applicable	95 (48.22)

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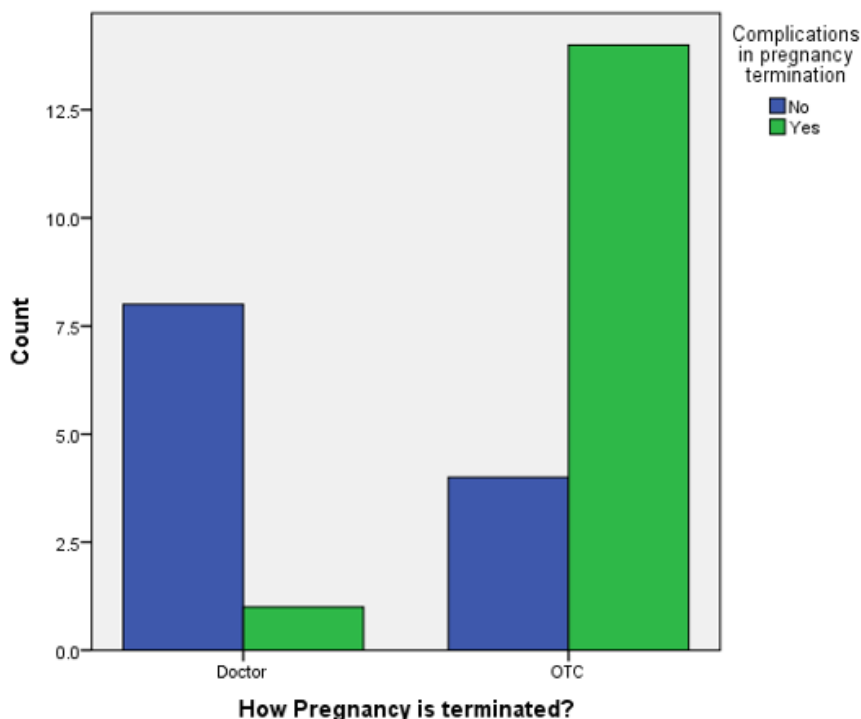
Unplanned pregnancy	Yes	97 (49.24)
	No	100 (50.76)
Pregnancy continuation and termination (n=97)	Continued	70 (35.53)
	Terminated	27 (13.71)
	No pregnancy	100 (50.76)
Reason for continuing pregnancy (n=70)	Diagnostic delay	16 (22.86)
	Family pressure	5 (7.14)
	Non-availability of FP* services	49 (70.00)
Pregnancy termination method (n=27)	Gynecologist	9 (33.33)
	General medical practitioner	18 (66.67)
Reason for General Medical Practitioner (n=18)	Consulting specialist	17 (94.44)
	COVID fear	1 (5.56)
Complication in pregnancy termination (n=27)	Yes	15 (55.56)
	No	12 (44.44)
Difficulty in accessing medical facility for pregnancy termination (n=27)	Yes	15 (55.56)
	No	12 (44.44)

FP- Family planning, IUCD- Intrauterine Contraceptive Device

**Table 3: Comparison between pregnancy termination method approached and associated medical complications with Chi-Square test**

How pregnancy terminated	Complications in pregnancy termination		Total
	No	Yes	
Gynecologist	8	1	9
General medical practitioner	4	14	18
Total	12	15	27

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	10.800 <sup>a</sup>	1	.001		
Continuity Correction <sup>b</sup>	8.269	1	.004		
Likelihood Ratio	11.748	1	.001		
Fisher's Exact Test				.003	.002
N of Valid Cases	27				



**Figure 1. Relationship between pregnancy termination methods used with associated complications**

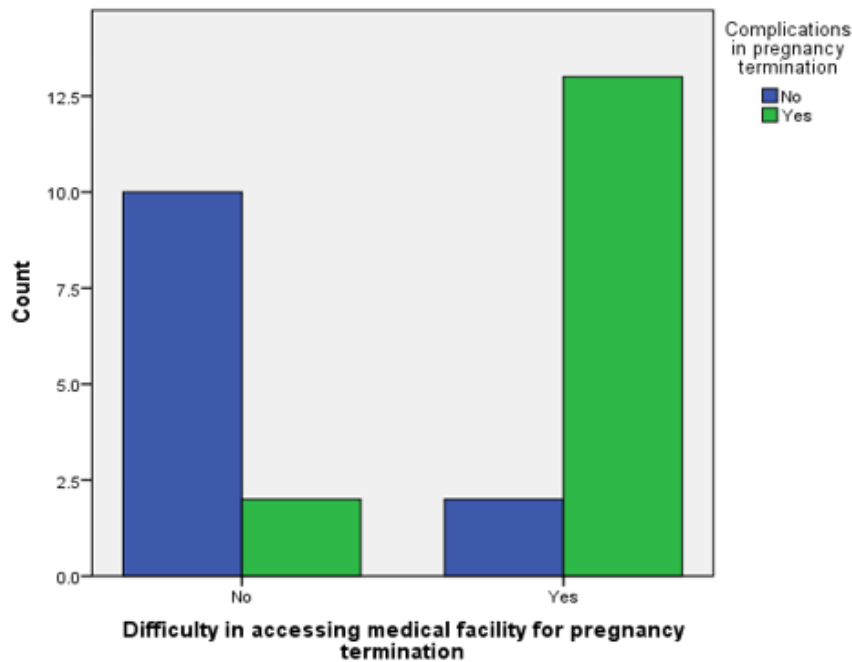
This bar chart illustrates the relationship between pregnancy termination methods approached with the complications faced during pregnancy termination. Out of eighteen respondents who had approached general medical practitioner, fourteen respondents

faced medical complications in pregnancy termination. However, out of nine respondents who had adopted the specialist care, only one faced medical complication during pregnancy termination.

**Table 4: Comparison between difficulty in accessing medical facility and medical complications in pregnancy termination**

Difficulty in accessing specialist medical facility for pregnancy termination	Complications in pregnancy termination		Total
	No	Yes	
No	10	2	12
Yes	2	13	15
Total	12	15	27

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	13.230 <sup>a</sup>	1	.000		
Continuity Correction <sup>b</sup>	10.547	1	.001		
Likelihood Ratio	14.502	1	.000		
Fisher's Exact Test				.000	.000
N of Valid Cases	27				



**Figure 2. Relationship between difficulties in accessing specialist medical facility for pregnancy termination with complications in pregnancy termination**

The bar chart depicts the relationship between difficulties in accessing medical facility for pregnancy termination with the associated medical complications. Among the fifteen respondents who faced difficulties in accessing specialist medical facility for pregnancy termination, thirteen respondents faced complications in pregnancy termination. On the other hand, only two respondents faced complications in pregnancy termination that have accessed specialist medical support for pregnancy termination.

While comparing the medical complication during pregnancy termination, general medical practitioner approach of medical termination led to more complication as compared to the specialist care which was found statistically significant ( $p < 0.001$ ) (Table 3) (Figure 1). Also, difficulty in accessing specialist medical facility for pregnancy termination was significantly associated with complication faced during pregnancy termination ( $p < 0.001$ ) (Table 4) (Figure 2). Our study reported that the majority of women had knowledge regarding contraception (96.95%) which was higher than the studies conducted in Nigeria (82%) and Pakistan (68.5%).<sup>[8,9]</sup> However, a study conducted among women in rural area of Nagpur (India) had comparable knowledge regarding contraception (100%).<sup>[10]</sup> These variations might be due to the differences in the sample size as

well as socio-demographic profile of the respondents based on the geographical location with varied socio-cultural norms and customs.

Majority of the respondents in our study faced difficulty in following contraceptive method (49%) among which non-availability of the contraceptive supplies amid pandemic was the most probable reason (16.75%). According to the WHO survey done across 105 countries, 90% of the respondents have experienced health services disruptions during pandemic among which FP services were hindered the most (68%).<sup>[11]</sup> A study conducted in Uttar-Pradesh (India) reported the decline in the use of contraception up to sixty percent and also there was reduction in safe abortion care.<sup>[6]</sup> Almost half of the respondents in our study had unplanned or unintended pregnancy (49.24%) with the major reason being non-availability of family planning services (70%). Guttmacher Institute in its recent analysis reported a 10% decline in the Sexual and Reproductive Health (SRH) services in low and middle income countries (LMICs) owing to COVID-19 would led to an additional 15.4 million unintended pregnancies, unsafe abortions over 3.3 million and 28000 maternal mortalities. This will also result in the spike of 3,325,000 more unsafe abortions and 1,000 additional maternal mortalities.<sup>[12,13]</sup>

COVID-19 has impacted women's ability to use contraceptive measure in numerous ways. Supply chain of contraceptive commodities got disrupted which limited its production, distribution as well as availability resulting in market stock-outs.<sup>[14]</sup> Some health care facilities reduced the services and health care providers have been redirected from providing family planning service to COVID-19 management.<sup>[15-17]</sup> Also, lockdown and fear of getting exposed to COVID-19 prevented women from visiting health care facilities.<sup>[18]</sup> This is supported by the findings of our study where only 33% of the women underwent pregnancy termination under specialist care. Our study also showed a significant association between pregnancy termination methods used as well as difficulty in accessing specialist medical facility for pregnancy termination with the pregnancy termination related complications. This clearly highlights the difficulties faced by the women in accessing medical facilities for pregnancy termination during pandemic.

The COVID-19 pandemic has made the goal of achieving universal access to SRH services by 2030 more challenging. Most importantly for women who have experienced unintended pregnancies owing to lack of access to contraceptive measures amid COVID-19 pandemic, the impacts are chronic. This necessitates the countries to incorporate FP services as well as reproductive health services in the package of fundamental health services as well as to strategize the data collection process via health management information systems in order to understand the COVID-19 impact on contraceptive services and its usage. Our study has certain limitations. The small sample size might not be able to infer the gravity of challenges faced by the women in accessing FP services during COVID-era in the country. The reason might be the decreased patient flow in the outpatient clinic of the tertiary health care centre amid lockdown imposed by the governmental law due to upsurge in COVID-19 cases. Also, more longitudinal studies are required to analyze the patterns of challenges over time in accessing FP services during COVID-19 era.

### Conclusion

The non-availability of contraceptive supplies, FP services amid COVID-19 pandemic have exerted

detrimental impact on the women reproductive health as a whole. Health care professionals should proactively engage to ensure the continuation of reproductive health care services to women via clinical resource allocation at the community level. Continuing medical health services including contraception and safe abortion services are essential during pandemic to sustain the success of high-quality reproductive services which will significantly decrease maternal morbidity as well as mortality thereby improving newborn and child health.

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## Role of Montelukast on Vitamin D Levels in Asthma and Seasonal Allergic Rhinitis in Eastern India

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### Abstract

**Background:** Allergic rhinitis and asthma are both chronic heterogeneous disorders, with an overlapping epidemiology of prevalence, health care and social costs in quality of life. Both are inflammatory disorders with a similar pathophysiology and vitamin D has a significant role in the pathogenesis of the disease.

**Aims and Objective:** The objective of this study was to evaluate the role of serum vitamin D in patients with symptomatic allergic rhinitis and active asthma during the allergy season and observe the effect of montelukast 10 mg daily as treatment.

**Materials and methods:** This study included 130 asthmatic and seasonal allergic rhinitis patients following a single-blind, placebo run-in period of 3 days–5 days, patients were randomized to oral montelukast 10 mg ( $n = 68$ ) or placebo ( $n = 62$ ) daily during the 2-week, double-blind, active-treatment period. The serum vitamin D was also evaluated in both the groups.

**Results:** The serum vitamin D levels were found to be higher in patients taking monteleukast compared to placebo after 2 weeks ( $p < 0.001$ ). Montelukast reduced the Total Nasal symptoms score which includes Daytime nasal symptoms and Nighttime symptoms compared to placebo after 2 weeks ( $p < 0.001$ ). **Conclusion:** Montelukast provides significant relief from symptoms of seasonal allergic rhinitis, while also conferring a benefit for asthma, in patients with both allergic rhinitis and asthma. Further, it has a beneficial role in improving vitamin D levels.

**Keywords:** Vitamin D, Asthma, Allergic Rhinitis, Montelukast, Leukotriene receptor antagonist

### Introduction

Allergic rhinitis and asthma are both chronic heterogeneous disorders, with an overlapping

epidemiology of prevalence, health care and social costs in quality of life. Allergic rhinitis (AR) is the most common type of chronic rhinitis, affecting 10–20% of the population, and evidence suggests that

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the prevalence of the disorder is increasing. Severe AR has been associated with significant impairments in quality of life, sleep and work performance.<sup>1</sup> On the other hand, Asthma is one of the most common chronic diseases worldwide and has been increasing in prevalence over the last few decades.<sup>2,3</sup> Its exact cause remains unknown and likely has its origins in complex interactions among multiple genetic and environmental factors. Asthma and AR may both be clinical manifestations of a systemic inflammatory process within the respiratory tract. The link between these two airway disorders has been called the "integrated airway hypothesis."<sup>4</sup> Fewer epidemiological studies have shown an association between rhinitis and asthma where about 19-38% of patients with allergic rhinitis have coexistent asthma.<sup>4,5</sup> The indications where data from clinical studies in patients with rhinitis and coexistent asthma have shown an improved control of nasal symptoms also frequently results in improved asthma symptom scores.<sup>5</sup>

Vitamin D has been shown to play a role in immunomodulation by interacting with T lymphocytes, dendritic cells, mast cells, monocytes and macrophages and some epidemiological studies have reported decreased vitamin D level in the blood of Asthma and allergic rhinitis patients.<sup>6,7</sup> Montelukast is a leukotriene receptor antagonist used for the maintenance treatment of asthma and seasonal allergic rhinitis. It acts by inhibiting physiological actions of LTC<sub>4</sub>, LTD<sub>4</sub> and LTE<sub>4</sub> at the Cystiene Leukotriene levels (Cys LT<sub>1</sub> receptor).<sup>8</sup>

The role of montelukast on vitamin D in asthma and seasonal allergic rhinitis is still controversial. In India, vitamin D insufficiency/deficiency has been emerging in recent years. The treatment of montelukast on vitamin D deficiency could prevent asthma and seasonal AR upto some extent. None of the study has shown the effect of montelukast on vitamin D levels in AR as well as in asthma in eastern India. Thus the aim of our study was to study the role of serum vitamin D levels on asthma and allergic rhinitis subjects in Eastern India and observe if Montelukast treatment can lead to altered vitamin D levels in allergic rhinitis and asthma patients and develop its role in the diagnosis of disease.

## Materials and Methods

The preliminary study included 130 asthmatic and seasonal allergic rhinitis patients following a single-blind, placebo run-in period of 3 days–5 days over a period of 6 months attending the Respiratory Medicine and ENT outpatient departments of ICARE Institute of Medical Sciences, Haldia, West Bengal which is a tertiary care hospital in the eastern part of India. Patients were randomized to oral montelukast 10 mg OD/ day ( $n = 70$ ) or placebo ( $n = 60$ ) daily during the 2-week, double-blind, active-treatment period. Informed consent was obtained from allergic rhinitis and bronchial asthma patients for the study. The inclusion criteria having a history of asthma or allergic rhinitis with eosinophilia on blood smear present. The study was approved by the Institutional Human Ethics Committee according to Helsinki guidelines. The exclusion criteria for the study were type 1 diabetes mellitus, protein energy malnutrition (PEM), taking drugs which interferes with vitamin-D metabolism like anti epileptic drugs or received vitamin D either oral / injection in last 6 months and subjects having any chronic liver, kidney or lung or neurological diseases. Total Nasal Symptoms score (TNSS) [out of 15] which includes daytime and nighttime symptoms were assessed between montelukast and placebo. Daily Rhinitis Symptoms score were also evaluated. 5ml venous blood samples were obtained from the AR and/ or asthma patients in placebo and after 2 weeks followup taking oral montelukast. Non-fasting serum samples of asthma and AR subjects were analyzed for routine biochemical parameters immediately after collection while aliquots of the samples were also stored at  $-20^{\circ}\text{C}$  for the assay of 25-hydroxyvitamin D. Serum vitamin D was measured as 25-hydroxyvitamin D is considered as the indicator of vitamin D. 25-hydroxyvitamin D was estimated by using commercially available ELISA kits (Calbiotech, USA). Anti-25-hydroxyvitamin D antibody (capture antibody) coated wells were incubated with standards (25-hydroxyvitamin D), samples and vitamin D-biotin conjugate at room temperature for 90 minutes. The binding of vitamin D-biotin conjugate to the wells by the capture antibody decreased by competition with 25-hydroxyvitamin D present in the standards or samples. Following a wash step, bound vitamin D-biotin was detected with streptavidin-horse radish

peroxidase (SA-HRP) using tetramethylbenzidine (TMB) as the substrate. For drawing the calibration curve from the measured absorbance readings, a 4-parametric logistic (4-PL) curve was used.

Statistical analysis of different biochemical parameters was performed by Students' *t*-test. All variables were expressed as mean  $\pm$  SD (standard deviation). Means obtained from two normally distributed sample groups were compared by Student's unpaired two-tailed "*t*"-test and for nonparametric Mann-Whitney *U*"-test. All statistical analyses were performed by using Graph Pad prism software (version 5, 2007, San Diego, California, USA). Statistical analysis for sex distributions was evaluated by chi-square test by using statistical software STATA (version 8, Copyright 1984–2003, Stata Corporation, Texas, USA).

## Results

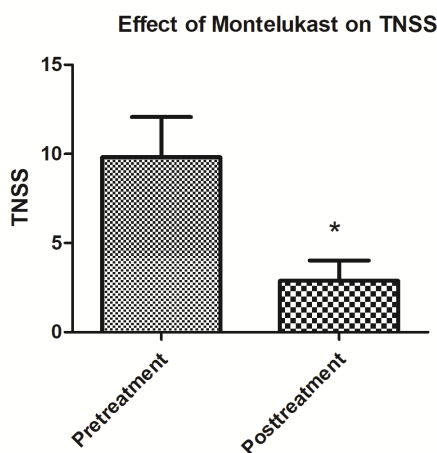
The demographic profile as well as biochemical profile of the bronchial asthma and/or allergic rhinitis subjects is depicted in Table 1. There was no significant difference in age, sex distribution or BMI in either of the two groups between placebo and oral montelukast subjects (Table 1). Moreover, TNSS were lower in subjects taking oral montelukast as compared to placebo and were statistically significant ( $2.92 \pm 1.20$  versus  $9.78 \pm 2.39$ ;  $P < 0.001$ ) (Figure 1). However, serum 25 OH vitamin D levels were higher in oral montelukast taking cases as compared to placebo and were statistically significant ( $22.10 \pm 4.84$  versus  $16.34 \pm 3.29$  ng/ml;  $P < 0.001$ ) (Figure 2).

**Table 1 Demographic and biochemical profile of subjects.**

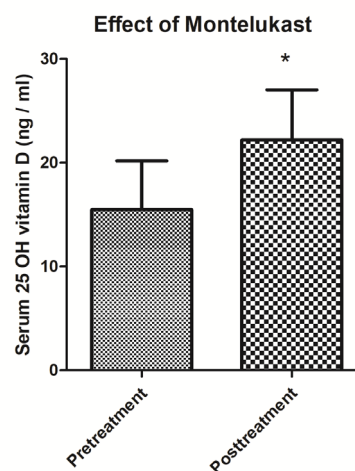
Demographic and Biochemical profile of AR and/or Asthma patients		
	Placebo (n=62)	Oral Montelukast (n=68)
Age (in years)	31.75 $\pm$ 15.71	32.42 $\pm$ 23.05
Sex (M/F)	31/29	38/32
BMI (kg/m <sup>2</sup> )	24.20 $\pm$ 1.39	25.69 $\pm$ 1.98
TNSS	9.78 $\pm$ 2.39	2.92 $\pm$ 1.20 *
FPG (mg/dl)	87.62 $\pm$ 11.29	89.18 $\pm$ 10.90
Total Chol. (mg/dl)	175.40 $\pm$ 17.38	189.20 $\pm$ 23.41

TNSS, Total Nasal Symptoms Score; FPG, fasting plasma glucose. Age, BMI, and serum levels of biochemical parameters were expressed as the means  $\pm$  SD. Statistically significant, \*  $p < 0.001$  vs Placebo.

TNSS were determined as described in methods for placebo and AR and/or asthma subjects. Values expressed as the means  $\pm$  SD. Statistically significant, \*  $p < 0.0001$ , vs Bronchial asthma.



**Fig. 1** TNSS score in placebo and oral montelukast intake in AR and asthma subjects.



**Fig. 2** Serum levels of vitamin D in placebo and oral montelukast intake in AR and asthma subjects.

Serum levels of 25 OH vitamin D were determined as described in methods for placebo and AR and/or asthma subjects. Values expressed as the means  $\pm$  SD. Statistically significant, \*  $p < 0.0001$ , vs Bronchial asthma.

### Discussion

The deficiency of vitamin D tends to increase in all the age groups which is promising to be a global health problem worldwide due to sedentary lifestyle, poor dietary intake, limited exposure to sunshine, sunscreen use, increased time spent indoors and intrinsic factors such as the skin melanin content and increased cutaneous destruction of vitamin D<sub>3</sub>. Vitamin D plays an important role in the regulation of immune system, lymphocyte function, T cell antigen receptor signalling or activation, cytokine production and acts as an immuno-modulator in allergic rhinitis as well as in asthma.<sup>[9, 10, 11]</sup>

On the otherhand, Montelukast sodium (Singulair<sup>®</sup>, Merck) is a selective and orally-active leukotriene-receptor antagonist (LTRA) that inhibits the cysteinyl leukotriene 1 (CysLT1) receptor. Montelukast mediates the bronchoconstrictor and proinflammatory actions of the CysLTs and acts as an effective and well-tolerated preventative treatment for asthma and allergic rhinitis in adults and children. In addition, montelukast has anti-inflammatory, mainly anti-eosinophil, properties.<sup>[8, 12]</sup>

Several studies have concluded randomly the lower levels of vitamin D which is associated with an increased incidence of asthma and other allergic symptoms.<sup>13</sup> Some studies have also established vitamin D deficiency as the strongest predictor of asthma or serum IgE levels and familial history of vitamin D deficiency also being a predictor of asthma.<sup>14</sup> One of the study by Li *et al.* in 435 asthma patients older than 18 years reported lower concentration of 25(OH) vitamin D which is similar to our study in the pretreatment group or placebo.<sup>15</sup>

Moreover, another study from Shaaban and Hashem also estimated serum vitamin D level in 75 adults with asthma and 75 healthy controls older than 18 years and reported that vitamin D level is lowered in the subjects which is in verification with our study in the pretreatment group.<sup>16</sup> This may

be due to reduced serum vitamin D levels may be related with increased expression of tumor necrosis factor- $\alpha$  which is mediated by enhanced expression of this proinflammatory cytokine through which lower vitamin D levels could exert a proinflammatory effect in asthma.<sup>17</sup> Another study performed by Moradzadeh *et al.* in which the vitamin D level was analysed in 5,329 normal Iranian individuals showed that 27.2% suffered mild vitamin D deficiency, 42.8% moderate and 5.1% had a severe deficiency.<sup>18</sup> A study by Arshi *et al.* reported the prevalence of severe vitamin D deficiency was significantly greater in patients with allergic rhinitis than the normal population (30% vs. 5.1%;  $p = 0.03$ ) demonstrating that there is an association between serum vitamin D levels and allergic rhinitis subjects.<sup>19</sup> Our previous study also observed the severity of serum vitamin D levels which upon supplementation of vitamin D led to increase in serum vitamin D levels in asthmatic and allergic rhinitis subjects.<sup>20</sup>

A study from Philip G *et al.*, observed a marked improvement in nasal and ocular symptoms after the two weeks treatment with montelukast 10 mg and reported that this significant reduction in the symptoms of allergic rhinitis has a positive impact on asthma-related problems in association with both the disorders.<sup>21</sup> Further, montelukast plays a pivotal role and has a beneficial impact on cough and associated disorders.<sup>22</sup> Our study also established this which is similar to this study and further it also indicates that the serum vitamin D level is improved in the posttreatment subjects taking montelukast. Moreover, TNSS is also lowered in patients taking montelukast suggestive of its beneficial role in asthmatic and allergic rhinitis subjects. This may be due to the fact that montelukast inhibits physiologic actions of LTD<sub>4</sub> at the CysLT1 receptor without any agonist activity due to which bronchoconstriction is inhibited with decreased airway and blood eosinophils leading to improved control over asthma and allergic rhinitis.<sup>23</sup> Moreover, leukotrienes are inflammatory mediators which mediates the slow-reacting substance of anaphylaxis produced by a number of cell types including eosinophils, mast cells, basophils, macrophages and monocytes. The cleavage of arachidonic acid in cell membranes which exert biological effects by binding and activating specific receptors results in the synthesis of these

mediators. These series of events occurring leads to contraction of the human airway smooth muscle, chemotaxis and increased vascular permeability.<sup>24</sup> These effects have led to their significant role in the pathogenesis of asthma and allergic rhinitis.

Our study have revealed that serum vitamin D has been significantly improved as well as TNSS have also enhanced in patients taking montelukast in AR and asthma subjects but nevertheless few limitations were there in our study which needs to be mentioned. The sample size of the study was less. Secondly, all of the patients included in this study were adults and no paediatric children were involved. Moreover, few of the patients were taking some other drugs such as antihistamines, topical corticosteroids which might interfere with serum vitamin D levels. Despite these limitations it has been observed that serum vitamin D levels were significantly improved in patients suffering from AR and asthma. However, supplementation of monteukast may be beneficial in the prevention of the pathogenesis of AR and asthma. Moreover, a large longitudinal study needs to be done to conclude the fact. Montelukast has been found to offer defence against severe asthma attacks and AR in adults and also in the improvement of serum vitamin D levels. Further trials focusing on children and adults who experience frequent severe asthma attacks and AR are needed before definitive clinical recommendations can be made.

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# A Study on Waist Circumference as a Screening Tool for Obesity and its Effectiveness in Comparison with BMI among 5-15 Years Urban School going Children at Karimnagar

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## Abstract

**Introduction:** World-wide obesity trends are causing serious public health concern and in many countries threatening the viability of basic health care delivery. Waist circumference as a screening measure of central obesity in children where obesity is a global phenomenon affecting all socio-economic groups, irrespective of age, sex or ethnicity.

**Aims and Objectives:** Waist circumference Reference values are in percentiles for children with 5-15 years of age in Karimnagar city. To screen over weight and obese children using waist circumference and in comparison with that of BMI (reference values)

**Material and Methods:** The study was prospective case control observational study included for 5-15 years of 1000 school going children in Karimnagar city from January 2021 to October 2022 For each group children - Height, weight, waist circumference and BP were recorded and BMI was calculated according to their (formula)  $wt/(ht)^2$ .

**Results:** There was good correlation with waist circumference and BMI in each age group.

1. The reference values for each age group were constructed for WC, BMI, SBP and DBP.
2. The study population was observed over weight (OW) and obesity with their reference values i.e. OW between 85th and 95th percentile and obese over 95th percentile for both WC and BMI. There was good correlation between BMI and waist circumference for age groups and both the sexes and screening results of OW and obese raising WC and BMI were almost similar. This indirect WC alone can be used to screen over weight and obesity.

**Conclusion:** Reference values for both waist circumference and BMI, age wise and gender wise were constructed. Reference values for BMI and Waist Circumference with cutoff points of 75th, 85th and 95th percentiles were constructed. The reference values were developed both in percentiles and mean with standard deviation. Using these reference values, children were screened for overweight, obesity using both BMI and WC. Children at risk ("action point" >75th percentile of WC) for metabolic syndrome were identified. There is good correlation between BMI and Waist Circumference. WC measurement alone on regular basis during school health checkup can help to screen, intervene and monitor Overweight and obese children.

**Key words:** Body Mass Index; Basal Metabolic Rate; Diabetes mellitus; Magnetic Resonance Imaging; Obstructive Sleep Apnea

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## Introduction

World-wide childhood obesity trends are causing serious public health concern and in many countries threatening the viability of basic health care delivery. Waist circumference as a screening measure of central obesity in children where obesity is a global phenomenon affecting all socio-economic groups, irrespective of age, sex or ethnicity<sup>1</sup>. Etiopathogenesis of childhood obesity is multifactorial and includes genetic, neuroendocrine, metabolic, Psychological, environmental and social- cultural factors. The treatment of overweight and obesity in children and adolescents requires a multi-disciplinary, multiphase approach, which includes dietary management, physical activity enhancement, and reduction of sedentary behaviour, pharmacotherapy and bariatric surgery<sup>2</sup>. In children and adolescents, overweight and obesity are defined using age and sex specific monograms for BMI. Children with BMI equal to or exceeding the age, gender specific 95th percentile are defined obese. Those with BMI equal to or exceeding 85<sup>th</sup> but are below 95th percentile are defined overweight and are at risk for obesity related comorbidities<sup>3</sup>. Obesity index that predicts metabolic syndrome Includes BMI, Waist circumference, waist hip ratio, and waist height ratio and so on<sup>4</sup>. The true measure of obesity/overweight is a total body fat content but can be measured as on today using dual energy X-ray absorptiometer (DEXA). This method is available in a few research centres and not accessible and not affordable to many<sup>4</sup>. Many studies have been conducted using indices like BMI, waist circumference, hip ratio, waist height ratio alone or in combination for screening and evaluating children with obesity and overweight<sup>6</sup>. There are very few studies which have used waist circumference alone to identify obesity and overweight and also they have formulated waist circumference percentiles for their children and they have found this tool useful not only to identify obesity and overweight but also central obesity better predictor of metabolic syndrome<sup>7</sup>. Waist circumference is found to be more useful than BMI in screening for obesity and overweight<sup>8</sup>. In this context, a clinical study to have waist circumference as percentiles was taken up to screen obesity and overweight in school going children age 5-15 years of Karimnagar city and thereby using percentile chart and also to compare its usefulness with that of BMI.

## Material and Methods

**Study Design:** Prospective cross sectional study

**Study Place:** Schools in Karimnagar city after obtaining the ethical clearance. Pre tested questionnaire method of primary source of information technique was used on school children in the age group of 5-15 years in Karimnagar.

**Period of study:** January 2021 to October 2022

**Sample size:** 1000 healthy school going children using the purposive sampling technique who met the predefined criteria.

### Inclusion Criteria:

School going healthy children between age group of 5-15 years

### Exclusion Criteria:

1. Children suffering from chronic illness
2. Children on long term medications
3. Children with congenital anomalies

## Methodology and Sampling

In this study data regarding the list of schools in Karimnagar city was collected from Deputy Director of public instruction office and the schools were selected by purposive samplings.

1. The following information was collected
  - Age
  - Sex
  - Height
  - Weight
  - BMI
  - Waist circumference
  - Blood pressure
2. Waist circumference was measured in centimetres without compression of soft tissue at mid way level between lower rib margin and iliac crest using non stretchable measuring tape.
3. All measurements were taken while subject was standing with feet together, arms at the side, body weight evenly distributed and wearing little clothing.

4. Regarding comparison to Body mass index, height and weight will be measured by using stadiometer with child bare foot upright on ground with heels buttock touching well and hand in Frankfurt plane.
5. A calibrated and standardized mechanical scale was used to measure weight; body mass index was calculated (weight in kgs and height in meters).
6. Childhood central obesity was a serious public health problem where 90th and 95th percentile of body mass index were taken as a reference.
7. The data that was collected was transferred to a excel sheet as the master chart and was analysed.

and ‘p’ values were calculated. Chi-square test was used to test the significance of difference between quantitative variables and Fischer exact test for qualitative variables. A ‘p’ value less than 0.05 and 0.01 taken to denote significant relationship.

**Results**

A total of 1000 subjects were employed in the present study, of which 408 were males and 592 were female subjects. The age group wise distribution from 5 to 15 years indicated that there were 28,117,92,75,81,78,117,101,116,112, and 83 subjects in the age group of 5 to 15 respectively. Further, Cramer’s V revealed a significant association between age and gender (CV=.201; p<.0001), where we find that more male subjects in 7 and 8 years age groups and both males and females equal in 5 year age group and in remaining age groups we find more of female subjects.

**Statistical Analysis:**

Data analysis was done with the help of computer using the SPSS 25Version software range, frequencies, percentages, means, standard deviations chi-square, regression analysis, correlation, ANOVA

**Table -1: ANOVA**

		Sum of Squares	Df	Mean Square	F	Sig.
Waist Circumference	Between Groups	15145.287	10	1514.529	28.629	0.0001**
	Within Groups	52320.635	989	52.903		
	Total	67465.922	999			
BMI	Between Groups	876.531	10	87.653	7.326	0.0001**
	Within Groups	11832.798	989	11.964		
	Total	12709.329	999			

In BMI, we find a significant mean difference across different age groups, as one way revealed significant difference between mean BMI scores of subjects in the age groups of 5 to 15 years. F value of 7.326 with 8 and 989 degrees of freedoms found to be significant at .0001 level. Two seventy four (274) out of 1000 children had WC above 75th percentile representing those at “Action Point”, who needed intervention to prevent from becoming obese

and at risk for metabolic syndrome. Taking into consideration between 85th and 95th percentile of WC as overweight 14.02% (83/592) female children and 9.06% (37/408) male children and overall 12% (120/1000) children in study group were overweight. Taking into consideration between 85th and 95th percentile as BMI 10.7% (44/408) males and 10.9% (65/592) females and overall 10.9% (109/1000) of study population showing overweight.

**Table 2: Distribution of Children with >95th Percentile of WC, BMI, SBP and DBP**

Age	SBP			DBP			WC			BMI		
	M	F	T	M	F	T	M	F	T	M	F	T
5-7	4	2	6	3	2	5	0	0	0	2	0	2
8-10	12	16	28	9	12	21	2	2	4	7	8	15
11-13	25	48	73	15	37	52	14	13	27	9	13	22
14-15	15	33	48	4	19	23	3	14	17	2	8	10
Total	56	99	155	31	70	101	19	29	48	20	29	49
Percent	13.73	16.72	15.5	7.6	11.82	10.1	4.7	4.9	4.8	4.90	4.90	4.9

This table shows WC, BMI, SBP and DBP 4.7% (19/408) males, 4.9% (29/592) females and an overall 4.8% (48/1000) of children in the study group were obese taking into consideration of >95th percentile of

WC. 4.9% (20/408) of male children and 4.9% (29/592) female children and an overall of 4.9% (49/1000) children in the study group were obese taking into consideration >95th percentile of BMI.

**Table-3: Comparison between WC and BMI in identifying overweight and obese children**

	WC			BMI		
	Male	Female	Total	Male	Female	Total
Overweight (>85th and <95th Percentile)	37 9.06%	83 14.02%	120 12.00%	44 10.7%	65 10.9%	109 10.9%
Obese (>95th percentile)	19 4.6%	29 4.9%	48 4.8%	20 4.9%	29 4.9%	49 4.9%
Total	408	592	1000	408	592	1000

This observation indicates WC is as good as BMI in identifying overweight and obesity.

### Discussion

Waist circumference provides a simple yet effective measure of truncal adiposity in children and adolescents. WC is recommended as an index for central fat distribution, but there is no global standard for it. 53.2% of children who were obese using WC were either OW or Normal using BMI. The relationship between an increasing WC in obese children 12 to 14 years old with an adverse lipid profile has been observed<sup>1</sup>. Bogulosa heart study showed that an abdominal fat distribution indicated

by WC in children between 5 and 17years. Old children were associated with adverse concentration of tri-glycerol LDL, cholesterol, HDL, cholesterol and Insulin. WC as it correlates well with BMI and metabolic abnormalities and is a straight forward methodology for predicting risk for cardiovascular disease and could be adopted as an alternative or additional measurement to BMI in children. Various international organizations and expert groups such as WHO, have attempted to define metabolic syndrome<sup>3</sup>. Out of all definitions, modified NCEPATPIII (2003) AND IDF definitions (2007) have a universal appeal and can be easily adopted in developing countries like ours.

**Table 4: IDF and NCEP definition of metabolic syndrome for children and adolescents**

CVD risk factors	International Diabetic Federation(IDF)	NCEP ATP III modified as per age
Waist Circumference	≥90 <sup>th</sup>	>90 <sup>th</sup> percentile
Blood Pressure	SBP≥130 OR DBP ≥85MM Hg or taking Antihypertensive drug	>90 <sup>th</sup> percentile
HDL-C(mg/dl)	≤40	≤40
Triglyceride(mg/dl)	≥150	≥110
Glucose	≥100	≥110
Diagnosis	Central obesity +2 or more criteria	3 or more among 5 criteria

NCEP ATP III: National Cholesterol Education Program Adult Treatment Panel III; HDL-C High Density Lipoprotein Cholesterol; CVD: Cardio Vascular Disease

In our study screening for overweight and obese using waist circumference alone, using 75th

percentile as cut off value for action point to identify those at risk, 274/1000 were at risk 24.51% being boys

and 29.39% being girls<sup>4</sup>. This 75th percentile as cut off value was as per recommendation of **Hirrschler et al.** who conducted a study with 5103 children aged 4 to 13 years and findings were summarized as WC value could be the right and practical tool to identify young children at risk for future type-2 diabetes and cardiovascular disease. **Anuradha Khadilkar et al** developed age and sex specific waist circumference percentiles in age 2 to 18 years old children. WC values increased with the age in both boys and girls. The median waist circumference at age >15 years was greater in boys than in girls. ROC (Receiver Operating Characteristic) analysis suggested that the 70th percentile as a cut off for metabolic risk<sup>8</sup>. Metabolic syndrome is no more an adult problem. Recent estimation for economic impact of Non-Communicable Disease (NCD) on India for the year 2012-13 has shown total losses associated with five NCD (Diabetes, CVS, Respiratory Diseases, Cancer and Mental Health) was USD 2.6 trillion, cardiovascular diseases alone estimated to maximum loss that is USD 1.21 trillion. Thus the need to identify the risk factor for metabolic syndrome early in life. Waist circumference in screening protocol to estimate the prevalence of central adiposity in school age children should be a prime priority and provides an indicator of the future health of children and aids in instituting appropriate remedial strategies for those at risk factors of central obesity<sup>9</sup>. Percentiles between 85 and 95 and/or above 95th percentile are significantly higher metabolic risk parameters as compared with those with less than 85th percentile for both WC and BMI. A study of central fatness using waist to height ratio in UK children and adolescence over two decades supports the simple message **“Keep your waist circumference to less than half of your height”**.

### Conclusion

Childhood obesity is one of the serious problems encountered nowadays.

1. Reference values for both waist circumference and BMI, age wise and gender wise were constructed.
2. Reference values for BMI and Waist Circumference with cut off points of 75th, 85th and 95th percentiles were constructed.
3. The reference values were developed both in percentiles and mean with standard deviation.
4. Using these reference values, children were screened for overweight, obesity using both BMI and WC.
5. Children at risk (“action point” >75th percentile of WC) for metabolic syndrome were identified.
6. There is good correlation between BMI and Waist Circumference.
7. WC measurement alone on regular basis during school health checkup can help to screen, intervene and monitor overweight and obese children.

### What this Study Adds?

WC shows good correlation with BMI. WC alone can be used to screen OW and obese children. Recording WC alone or along with other anthropometric measurements during routine school health checkup is of great help in screening for and monitoring early intervention in case of overweight and obese children. It also helps to identify the secular trends in WC.

**Conflict of Interest:** NIL

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# Relation of Hepatitis B Viral Load with Hepatitis B Envelope Antigen in Hepatitis B Positive Cases

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## Abstract

**Background:** Despite of effective vaccine and impressive treatment, number of cases of hepatitis b virus rising day by day. The reasons include low antibody titre in blood after vaccination, needle stick injury in medical personnel, lack of awareness in general public about the mode of transmissions and prevention. Also the treatment part is expensive and monitored by repeated viral load and envelope antigen estimation. We are conducted a study to decrease the cost of diagnosis and monitoring of treatment by analyse if any relationship between viral load and envelope antigen.

**Method:** Total number of 54 blood samples of hepatitis b positive patients who were known to be infected the time of withdrawn of blood, collected in a period of one year. The serums separated by centrifugation and preserved. All samples were tested for viral load by Thermo Fisher PCR kit and also for estimation of hepatitis b envelope antigen by indirect ELISA. Results were analysed.

**Conclusion:** On the basis of this study we can conclude that there is a relationship between hepatitis b envelope antigen and viral load. When viral load reached in a patient up to a particular level antigen start rising and then both proportionally increasing. In our study that particular level of viral load is  $>10^6$  copies/ml. It shows if envelope antigen of hepatitis b virus present in blood, the value of viral load should be more than  $10^6$  copies/ml. In the scarcity of PCR only Elisa for envelope antigen can draw an approximate estimation of viral load.

**Key words:** Hepatitis b virus, viral load, envelope antigen

## Introduction

Hepatitis B is well known burden to health. Hepatitis B virus is a DNA virus, member of *Hepadnaviridae* family<sup>(1)</sup>, causes acute and chronic hepatitis followed by cirrhosis, even hepatocellular carcinoma.<sup>(2)</sup> A very low dose of blood and blood products can transmit the infection. Other routes of transmission are sexual and

perinatal.<sup>(3)</sup> Risk groups are medical and paramedical personal. Even in the presence of effective vaccine we are facing a huge number of cases day by day. Due to low antibody response ( $< 10$  IU/ml)<sup>(4)</sup> or non responders for vaccine exposure can built disease. High viral load in positive patients associated with high infectivity and vaccine ineffectiveness in preventing

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hepatocellular carcinoma. It is important to lower the viral load and infectivity markers in infected patients. The common markers in serum of high infectivity<sup>(5)</sup> and treatment response are HBV DNA and Hbeag. Here we are going to develop relation between HBVDNA load and Hbeag to measure the effect of treatment and lower the infectivity in patients. by reducing the need of both tests simultaneously. it will turn into low cost of treatment also.

### Material and Methods

Up to one year from October 2021 to September 2022, 54 blood samples of known hepatitis B positive patients drawn, serum separated and preserved. Indirect Elisa was used to detect Hbeag. Viral load measured by DNA PCR with the help of Thermo Fisher PCR kit. To maintain the quality of tests negative and positive controls with standards was run with sample. Results were analysed.

### Results and Discussion

HBV DNA detected in 22 patients out of 54. Hbeag detected in 13 patients in 22 HBV positive patients while not detected in HCV negative patients. All 13 hbe antigen positive samples has viral load more than  $10^6$  Copies/ml. It is also observed that as the viral load increased the hepatitis b envelope antigen titre also increased in the serum of hepatitis-B positive patients.<sup>(6)(7)(8)(9)</sup> T. Jake Liang and M Kraiden et al. found the same result in their research, they accepted that DNA viral load of hepatitis b and envelope antigen increased simultaneously.

**Table 1: Shows the results of tests:**

Tests	Viral load	Envelope antigen
Detected	22	13
Not detected	32	41
Total samples	54	54

**Table 2: Shows the relationship between envelope antigen and viral load**

Viral load in copies/ml	Envelope antigen coi
$10^1-10^2$	0.0
$10^3-10^4$	0.0
$10^5-10^6$	1.5-1.7
$10^7-10^8$	2.12- 2.51
$10^9->10^9$	2.82- 2.97

**Table 3: shows distribution of value of viral load in samples.**

Viral load in copies/ml	No. of samples for viral load	Envelope antigen samples
Not detected	32	41
$10^1-10^2$	4	0
$10^3-10^4$	3	0
$10^5-10^6$	5	3
$10^7-10^8$	7	7
$10^9->10^9$	3	3
Total	54	54

### Conclusion

As per the experience of this analysis Hbeag can be judged by the value of viral load of HBV DNA. There is a relation seen between HBeag and HBV DNA. Both are increasing simultaneously after a particular value of viral load. If viral load is more than  $10^6$  copies per ml there is not any urge of HBeag testing or if Hbeag positive value is available and PCR facility is not available nearby it can be infer that the viral load is more than  $10^6$  copies per ml approximately.

**Informed Consent:** written informed consent was taken from patients.

**Ethical Approval:** ethical committee approval was taken from the Institutional Committee Of Ethics, VIMS ( VIMSE/2022/11-89).

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**Conflict of Interest:** there was no conflict of interest

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## Urate Nephropathy: A Rare Case Report

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### Abstract

Acute hyperuricemia most commonly occurs in patients who experience tumor-lysis syndrome. Hyperuricemia along with other electrolyte abnormalities like hyperkalemia, hypocalcemia, and hyperphosphatemia leads to acute kidney injury (AKI) due to acute uric acid nephropathy which is associated with significant morbidity. High risk patients are thus closely monitored for signs of these laboratory abnormalities. Extreme exercise, rhabdomyolysis, and seizures are rare causes of acute hyperuricemia. Serum uric acid level is not routinely monitored as a part of postictal labs. We report an unusual case of AKI in a young male and no associated rhabdomyolysis who was found to have acute uric acid nephropathy. Timely administration of Rasburicase prevented the need for dialysis in this patient and led to complete renal recovery. This case illustrates the importance of doing a urine microscopy and checking uric acid level in patients who develop unexplainable AKI, as timely management helps improve outcome.

**Keywords:** hyperuricemia, acute kidney injury, rhabdomyolysis, hyperkalemia.

### Introduction

Uric acid is the final end product of purine metabolism. Acute hyperuricemia is caused by the increase of purine metabolism, which is the result of the increased cellular turnover or the aggressive cancer chemotherapy regimens which cause cell lysis and release of purine metabolites<sup>[1]</sup>. The deposition and accumulation of uric acid in renal tubules leads to acute uric acid nephropathy typically characterized by oliguric AKI, elevated serum uric acid concentration (usually more than 10-15 mg/dL), presence of uric acid crystals in the urinary sediment, and an elevated urine uric acid to creatinine ratio of greater than 1<sup>[2]</sup>. Acute uric acid nephropathy is

readily recognized when acute kidney injury (AKI) develops in cancer patients either due to spontaneous tumorlysis or following chemotherapy. With timely recognition and management, the pathologic features of acute uric acid nephropathy are reversible. We report a patient who developed AKI due to acute uric acid nephropathy. Timely therapy with Rasburicase prevented the need for renal replacement therapy in our patient and resulted in complete renal recovery.

### Case Presentation

A 33-year-old white male presented to Department Of General Medicine, SGT Medical College Hospital And Research Institute, Gurgaon with chief complaint of multiple joint pain, vomiting,

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fever since 3 years. Patient also became apneic and cyanotic and was subsequently sedated and intubated for airway protection. Brain CT done was unremarkable. Vitals signs showed elevated blood pressure of 170/90 and heart rate in 120s. Initial labs showed mild leukocytosis and a normal renal function with serum creatinine (scr) of 1.3 mg/dL. Urine drug screen was negative. He was then transferred for neurology consultation and ICU admission. Repeat labs showed mild elevation in scr of 1.7mg/dL. Initial serum electrolytes and lactic acid were within normal limits. Serum creatine kinase (CK) level was mildly elevated at 297 U/L. Pt was started on iv hydration with ringers lactate (LR) at 100 ml/hr along with antiseizure medications, namely, iv Midazolam, Levetiracetam, and Lacosamide. He remained seizure free. Labs on day 2 showed worsening AKI with scr of 4.9 mg/dL and bicarbonate of 18 mEq/L with CK level of 663 U/L. Repeat scr was noted to be 5.2mg/dL with lactic acid of 3.6 mmol/L and phosphorus of 5.4 mg/dL. Patient had remained nonoliguric with urine output of about 40-60 ml/hr. Urgent urine microscopy was performed which showed numerous uric acid crystals and occasional granular casts. A stat serum uric acid level was noted to be significantly elevated at 15 mg/dL. Urinalysis showed clear urine with ph 5.5, specific gravity of 1.005, 0-5 RBCs, 0-5 WBCs, no proteins, and 1+ blood. A spot urine uric acid to creatinine ratio was found to be elevated at 1.2. Based on the above findings a diagnosis of acute uric acid nephropathy was made. IV fluids were changed from LR to iv sodium bicarbonate at 150ml/hr. Patient was given a dose of iv Rasburicase 0.2 mg/ kg. Repeat labs done about 4 hrs after Rasburicase administration showed that serum uric acid level had dropped to 4 mg/dL. Scr however continued to rise to 6.1mg/dL with CK level of 464 U/L. A significant increase in urine output of about 100-150 ml/hr was however noted soon after Rasburicase administration. Day 3 scr started trending down to 6 mg/dL and serum uric acid had further dropped to 0.8. There was continued renal recovery with scr of 5.5 and CK level of 792 U/L on day 4. Patient remained seizure free throughout his hospital stay and his renal function completely recovered to normal by day 7.

### Discussion

Uric acid is the final oxidation product of dietary and endogenous purine metabolism. Uric acid

must be continuously excreted to prevent its toxic accumulation in human tissues in which it is poorly soluble, especially in the acidic environment of the distal nephron. Approximately 75% of daily uric acid is excreted by the kidney [2]. Hyperuricemia is caused by states of enhanced purine catabolism which increases the urate load on the kidney leading to their intrarenal precipitation. Tumor lysis syndrome (TLS) is one such potentially life-threatening complication that occurs in high risk cancer patients with highly proliferative malignancies and large tumor burdens receiving cytotoxic chemotherapy. Lysed cancer cells release phosphorus, potassium, and nucleic acids which are metabolized to xanthine and then oxidized to uric acid. Patients at the highest risk of TLS are thus closely monitored for these laboratory abnormalities and started on appropriate preventive measures to reduce risk of acute uric acid nephropathy.

Acute hyperuricemia plays a major role in the pathogenesis of uric acid nephropathy. Supersaturation of urine and precipitation of uric acid crystals cause intraluminal obstruction of the distal nephron. This in turn leads to dilatation, inflammation, and obstruction of the proximal tubules [3]. Ejaz et al. have also described at least five crystal independent mechanisms by which uric acid contributes to AKI [4]. It induces renal vasoconstriction through direct inhibition of the endothelial nitric oxide synthase causing reduction in nitric oxide through stimulation of the renin-angiotensin system. Inflammatory pathways by which uric acid causes AKI include activation of proinflammatory mediators like monocyte chemoattractant protein-1, C reactive protein, and mitogen-activated protein kinase. In addition, uric acid also stimulates the production of oxidants via an increase in nicotinamide adenine dinucleotide phosphatase oxidase in both adipocytes and endothelial cells. Uric acid also has been found to have antiangiogenic properties by causing inhibition of endothelial migration and proliferation and inducing endothelial cell apoptosis. Finally, hyperuricemia leads to development of preglomerular arteriolar disease which impairs the renal autoregulatory response. Uric acid has also been reported to have antioxidant properties and it is possible that, in conditions of severe oxidative stress, a rise in uric acid might provide some antioxidant benefit[4,5]. Ejaz el al. proposed that although

the antioxidant properties of uric acid may be beneficial under certain conditions, the net effect of hyperuricemia, particularly if marked and persistent, will affect the renal outcome adversely.

Acute uric acid nephropathy should be suspected in high risk patients who develop oliguric AKI with significantly elevated serum uric acid concentration of more than 10-15 mg/dL and presence of copious uric acid crystals in the urinary sediment [3]. The urinalysis however may be normal if there is no output from the obstructed nephrons [4]. As renal failure is also associated with a rise in serum uric acid as a result of decreased excretion, it may be difficult to determine if hyperuricemia or AKI developed first. Kelton J et al. have proposed that, in adults, a urine uric acid to creatinine ratio of more than 1 is highly suggestive of acute uric acid nephropathy [6]. Some researchers also report that the calculation of uric acid excretion corrected for creatinine greater than 0.57 mg/dL GFR is suggestive of uric acid nephropathy since other forms of AKI would have reduced uric acid excretion [3].

Seizures lead to distinctive metabolic changes depending on the type, length, and intensity of the seizures as well as the patients preexisting condition. Whole body muscle contractions and the activation of the neuroendocrine system to secrete catecholamines increase the cerebral, muscular, and cardiac oxygen demands, while impaired breathing impedes the compensatory mechanisms to satisfy this demand. This causes the irritated muscles to release CK and myoglobin and hypoxic tissues to leak lactate, ammonia, and urea. Afterwards, an inflammatory reaction with cytokine release and leukocytosis occurs [7]. Seizure induced rhabdomyolysis and AKI have been reported [7, 8]. However, seizures have rarely been reported as cause of hyperuricemia and acute uric acid nephropathy.

Acute severe hyperuricemia following recurrent episodes of grand mal seizures or status epilepticus was first reported by Warren et al. in 1975 [9]. None of the patients had significant myoglobinuria nor pigmented granular casts in the urine. All the seven patients reported in the study developed reversible renal failure with two requiring hemodialysis. In 1978, Luhdorf et al. found a significant increase in serum uric acid level in seventeen patients, within

24 hours of two or more grand mal seizures [10]. Of the six patients with severe hyperuricemia only two had developed impaired renal function. A case of seizure induced acute urate nephropathy has been reported in a young male following status epilepticus. This patient developed rhabdomyolysis and anuric renal failure requiring renal replacement therapy despite allopurinol and Rasburicase administration. A case of rhabdomyolysis following status epilepticus with hyperuricemia was also recently reported in young male who developed oliguric renal failure requiring hemodialysis.

Hypoxia and seizure induced lactic acidosis also impairs the renal tubular secretion of uric acid. Warren et al. postulate that seizure induced hyperuricemia could be due to a combination of overproduction and impaired tubular secretion of uric acid. Saugstad has also proposed that excessive release of hypoxanthine by hypoxic tissues after seizures could be transformed to uric acid by xanthine oxidase thus causing hyperuricemia. As uric acid is also considered an effective antioxidant, it is possible that an elevation in uric acid would be to counteract the oxidative stress during epileptic seizure. Metabolic acidosis which accompanies seizures creates an acidic urine in which uric acid is less soluble causing precipitation of uric acid in the tubular lumen. Dehydration due to profuse sweating and hyperthermia during seizures causes increased tubular water resorption and increased urine uric acid concentration. Renal ischemia due to shunting of blood flow from visceral organs to muscles during seizures may also contribute to the kidney injury [10]. Urine microscopy in our patient also showed occasional granular casts suggesting that uric acid also caused mild tubular injury. Early markers of renal tubular injury like urinary  $\beta_2$  microglobulin and N-acetyl-beta-D-glucosaminidase (NAG) were however not measured in our patient.

The pathologic features of acute uric acid nephropathy are reversible. The most efficient therapy for dramatically lowering uric acid is Rasburicase, a recombinant form of urate oxidase, a nonhuman proteolytic enzyme that oxidizes uric acid to allantoin, and a metabolite that is far more soluble than uric acid. Rasburicase is contraindicated in patients with G6PD deficiency (G6PDD) due to

risk of drug induced hemolytic anemia. G6PD level was however not checked before administering Rasburicase in our patient. He had a low risk for developing hemolytic anemia due to him being from an ethnicity with low prevalence of G6PDD and absence of any prior history of anemia. He was however closely monitored after Rasburicase administration and tolerated it well. Rasburicase therapy is efficacious in reducing serum uric acid levels with associated diuresis much faster and more effectively than allopurinol, a xanthine oxidase inhibitor. Allopurinol prevents the formation of new uric acid; however, it does not remove the existing uric acid. Moreover, allopurinol also increases the urinary excretion of xanthine which can crystallize and cause kidney injury. Urinary alkalization to pH>6 helps uric acid solubility; however it has not been proven to be an effective therapy in TLS with acute uric acid nephropathy, due to increased calcium phosphate precipitation. Hemodialysis is also quite effective in rapidly reducing uric acid concentrations. Kjellstrand et al. found that oliguria due to acute uric acid nephropathy responds quickly to hemodialysis with initiation of diuresis when serum uric acid concentration falls below 10 mg/dL. Peritoneal dialysis is much less efficient in reducing uric acid concentration.

In our patient urine microscopic findings of uric acid crystals lead to early diagnosis of uric acid nephropathy. Timely administration of Rasburicase prevented the need for hemodialysis in this patient and led to complete renal recovery. Our case illustrates the importance of urine microscopy and of monitoring uric acid levels in patients with prolonged seizures and AKI without rhabdomyolysis, as uric acid could be the likely culprit.

**Informed Consent:** written informed consent was taken from patients.

**Ethical Approval:** ethical committee approval was taken from the institutional committee of ethics.

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# Assessment of Exposure to Factors Favoring Covid 19 Transmission among Medical Students in South Kerala during the First Wave of the Pandemic

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## Abstract

Transmission of SARS -Cov occurs primarily between people through direct, indirect, or close contact with infected people through infected secretions such as saliva and respiratory secretions. To prevent transmission there are several measures implanted by health authorities all over the world like social distancing, use of face masks, hand washing or use of sanitizer, contact tracing and quarantine, isolation, etc. This study was intended to determine medical students' exposure (while at home due to lockdown) to environmental factors favoring the transmission of Covid 19. After getting institutional ethical clearance a cross-sectional study was done among 82 medical students. The mode of data collection was through google forms. The students were asked to report the factors (already practicing) that favor covid 19 transmission to which they were exposed during the last 2 weeks. All the study subjects were tested for Covid 19 during the next 2-week period. Data were analyzed descriptively to find out the number and percentage. The median age of the sample was 22 years ( Q<sub>1</sub> 21, Q<sub>3</sub> 23). Comorbidities that could favor covid 19 transmission were present in 12.2% of students. The percentage of students who visited crowded places in the last 2 weeks which could increase the risk of transmission ranged from 6 % to 29%. Social distancing was practiced by 51%, Wearing a mask was practiced by 62%, and using soap/sanitizer by 73% of medical students. Out of the total 82 medical students 4 tested positive for Covid 19. The study concluded that exposure to risk factors of covid 19 transmission was optimum among medical students during the pandemic phase.

**Keywords:** Covid 19, transmission, Pandemic

## Introduction

Coronaviruses are a large family of viruses that are known to cause illnesses ranging from the common cold to more severe diseases such as Middle

East Respiratory Syndrome (MERS) and severe acute respiratory syndrome (SARS). A novel coronavirus (SARS -CoV 2) was identified in 2019 in Wuhan, China. This is a new coronavirus that has not been previously identified in humans. On 11 March

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2020, WHO declared Novel Coronavirus Disease (COVID-19) outbreak as a pandemic<sup>(1)</sup>. So far there are 4.4 cores confirmed cases in India and 5.3 lakhs deaths<sup>(2)</sup>.

The first case of COVID-19 reported in India is from Kerala state on 30 January 2020 and within three days cases increased to three on February 3, 2020. These cases were related to students who had returned from Wuhan, China. COVID-19 was reported in various states of India during March. Most cases are imported as infected people with a travel history to affected countries. The state of Kerala so far reported 67.67 lakhs of cases and 70,913 deaths<sup>(3)(4)</sup>.

Current evidence suggests that transmission of SARS-CoV-2 occurs primarily between people through direct, indirect, or close contact with infected people through infected secretions such as saliva and respiratory secretions, or through their respiratory droplets, which are expelled when an infected person coughs, sneezes, talks or sings. As environmental contamination has been documented by many reports, likely that people can also be infected by touching these surfaces and touching their eyes, nose, or mouth before cleaning their hands. Airborne transmission of the virus can occur in healthcare settings where specific medical procedures, called aerosol-generating procedures, generate very small droplets called aerosols<sup>(5)(6)</sup>.

Based on what we currently know, the transmission of COVID-19 is primarily occurring from people when they have symptoms, and can also occur just before they develop symptoms when they are close to others for prolonged periods. While someone who never develops symptoms can also pass the virus to others, it is still not clear to what extent this occurs. A recent study from China that clearly and appropriately defined asymptomatic infections suggests that the proportion of infected people who never developed symptoms was 23%.<sup>(7)(5)</sup>. To prevent transmission there are several measures implemented by the Government of India and its States like Social distancing, The use of face masks, Hand washing or use of sanitizer, contact tracing, the practicing quarantine, and testing those who develop symptoms so that they can be isolated if they are infected and require care.

Young adults represent 20% of the population of the state of Kerala. Non-compliance to covid 19 regulations were high among young adults with higher education and high Socioeconomic status<sup>(8)</sup>. As far as medical students are concerned it is their responsibility to play a supportive role in practicing the regulations insisted by Covid 19 and thereby reduce the risk of spreading. This study was intended to find out the exposure of medical students (while at home due to lockdown) to environmental factors favoring the transmission of Covid 19.

### Objective

1. To assess the self-reported exposure to factors favoring Covid 19 transmission among medical students in a medical college in South Kerala during the first wave pandemic.

### Methodology

A Cross-sectional study was conducted among the medical students of Government Medical College Kollam in Kerala during the period of lockdown in the pandemic phase of Covid 19 in the year 2021. The medical college was closed during the lockdown period as instructed by the government. For attending university examinations, the students were called back to medical college. The students on arrival were quarantined for 14 days and Covid 19 test was done at the end of 14 days. The medical students were interviewed regarding their adherence to Covid 19 regulations imparted by the government for the last 2 weeks of their arrival at the medical college to assess the risk of transmission.

The sample size was found using the prevalence of covid 19 from (a previously published study<sup>(9)</sup>) as 19% and Z at 95% Confidence interval, and a relative precision of 20%, using the equation for sample size  $Z^2_{\alpha/2} PQ/L^2, n$  is found as 390 and adjusted the same for the finite population of 100 using the equation  $n/1+(n/N \text{ population})$  final sample size arrived was 80. Data was collected through google forms containing semi-structured questionnaire using social media platforms. Covid positivity status was determined after 14 days. Covid 19 tests were done at Virology Research Institute Government Medical College Kollam according to the revised Indian Council of Medical Research guidelines<sup>(10)</sup>. Sociodemographic variables, pre-existing medical

illness, and Compliance to covid 19 regulations like adherence to SMS (Social distancing, face mask, soap/sanitizer) strategy were recorded. The use /practice of SMS guidelines always was taken as adherence in this study.

Data analysis was done using the Statistical Package of Social Sciences software version 20 (trial version). Quantitative variables were summarised using mean and standard deviations and Median with Q1 and Q3 for nonnormal distributions, whereas qualitative variables were expressed as percentages and proportions.

### Ethical Considerations

Consent was obtained from medical students electronically before the administration of the questionnaire. Permission from the concerned departments was obtained. Institutional ethical clearance was obtained before starting the study. (IEC NO 4/EC-4/2021/GMCKLM)

### Results

The study was conducted among 82 medical students to find out the self-reported adherence to covid 19 regulations. Females and males constituted 59.8% (49/82) and 40.2% (33/82) of study participants respectively. The median age of study participants was 22 (21,23) years. Out of the 82 students 2 students had come from neighboring states outside the Kerala state to report back to the medical college. The other 80 students were from different districts of Kerala. Analysis was done to know the housing conditions of the students and revealed that only two students had overcrowding at their houses. Comorbidities that could be a risk factor for Covid 19 infection like diabetes mellitus, hypertension, use of systemic steroids, bronchial asthma, and neurological diseases were asked and 10 students out of 82 (12.2%) had given comorbidities.

The practice of SMS (Social distancing, Mask use, and Hand washing with soap/sanitizer) was assessed among medical students during the lockdown period and the results are given in table 1. The results showed that overall adherence to the practice of Social distancing was 51% and to wearing a mask it was 62% and 73% for the habit of using soap/sanitizer

**Table 1: Table showing adherence to SMS among medical students during the lockdown period.**

Practice	Social distancing	Mask	Soap/Sanitizer
Always	42(51.2%)	51(62.2%)	60(73.2%)
Sometimes	29(35.41%)	18(22%)	22(26.8%)
Never	11(3.4%)	13(15.9%)	0

During the lockdown period, the motto from the government was to 'stay home stay safe'. The history of going out of home in the last two weeks before the interview was obtained. 16 students reported staying at home in the last two weeks, 52 reported going out once or twice, 11 got out more than three times and 3 of them reported going out on almost all days.

Out of the 82 students, 10 were coming from 'Containment Zones' (According to the Union Ministry for Health and Family Welfare, containment zones are specific geographic areas where Covid-19 positive cases are found in large numbers). There were 4 students (4.9%) who gave a history of known close contact with Covid 19 positive case in the last 14 days, 7 students were not sure about the contact, and 71 students out of the total 82 didn't have a history of known contact with any Covid positive case. One student responded that there was a positive case of home isolation. One student gave a history of air travel outside India. Exposure to crowded places like bus station/bus, railway station/train, Hotel, crowded shops, and market were assessed for the last 2 weeks and the result is given in Table 2

**Table 2: Exposure to crowded places during the last 2 weeks**

Crowded place	No of subjects	Percentage
Open Market	19	23.2
Bus/ railway station	12	14.6
Hospital	16	19.5
Restaurant	12	14.6
Public transportation	9	11
Social Gathering	6	7.3
Shopping centres	29	35.5

All 82 students were tested for Covid 19 using the True Nat test/ RT- PCR test accredited by the Indian Council of Medical Research. Out of the total 82 medical students test positivity rate in total was

4/82 i.e. 4.8%. The positivity rate among contacts of Confirmed Covid 19 cases was 2% and the positive rate among symptomatic was 25%. There were

2 males and 2 females out of the 4 students diagnosed positive for Covid 19. The details are given below in Table 3.

**Table 3: Table showing Covid 19 test done among medical students n=82**

Day of testing for Covid since Quarantine started	Reason for testing	Type of test done	Number of students tested	Covid 19 Positive	Covid 19 negative
3 <sup>rd</sup>	Symptomatic	RT- PCR	3	1	2
6 <sup>th</sup>	Contact with Positive case	RT - PCR	5	1	4
7 <sup>th</sup>	Contact with positive case	RT- PCR	3	0	3
10 <sup>th</sup>	Symptomatic	RT-PCR	1	0	1
12 <sup>th</sup>	Contact with Positive case	RT- PCR	4	1	3
13 <sup>th</sup>	Screening	True NAT	49	1	48
14 <sup>th</sup>	Screening	True NAT	17	0	17
Total			82	4	78

### Discussion

The number of SARS - Cov 2 cases was rising all over the world. To prevent the transmission there were widespread practices at individual, familial, and community levels. Nevertheless, people were exposed to certain risk factors due to the nature of their health conditions, profession, role, or due to ignorance. This study was done to find out the exposure to factors (self-reported) favoring Covid 19 transmission in the pandemic phase among medical students when they were at home due to regulations imparted by the lockdown. Exposure to risk factors of covid 19 transmission like comorbidities, travel history, visits to high-risk places, and adherence to SMS (Social distancing of 1to 2-meter, face mask, soap/sanitizer) strategy was studied.

The study population consisted of males and females in a ratio of 41:49, and Covid 19 positivity among males and females was found in the ratio of 1:1 in our study. The risk factor of Covid 19 being more in males since Covid 19 is community-acquired and men are out of houses than females. But an equal ratio was found here due to the reason that during lockdown everyone could remain home and also due to the lesser sample size. The transmission mechanisms of SARS-CoV-2 include droplet transmission, close contact transmission, and airborne transmission<sup>(6)</sup>. The presence of unprotected people in public places increases the risk of Covid 19 transmission and our study described the distribution of subjects who were

exposed to crowded places with or without practicing SMS strategy suggesting a higher number were going to crowded places<sup>(11)</sup>. The Government had advised many regulations during the Covid 19 pandemic phase like Stay home stay safe, containment zones, the practice of SMS, lockdown, and restriction of office hours during the peak pandemic time. Compliance with Covid 19 regulations was studied in the same age group was studied by Nivette et all with a view that young adults are identified internationally as a group with low compliance rates. The level of adherence to social distancing was 51.2%, for mask usage 51%, and hand washing it was 73.2% in our study which is much lower than the compliance reported by Nivette et all in young adults (Social distancing 97% and handwashing 95%)<sup>(8)</sup>. The prevalence of Covid 19 was 4.8% in the study which is much higher than the national studies (0.73%) owing to the lower sample size <sup>(12)</sup>.

### Conclusions

The study was done to find out self-reported exposure to factors favoring transmission of Covid 19 among medical undergraduates. There was greater exposure to crowded places and the practice of Covid 19 regulations was optimum among the medical students.

### Limitations

1. Data were collected from records and through google form since there were restrictions for direct interviews.



2. The sample size was restricted to 82 (the maximum number of medical students who were quarantined)
3. Bivariable analysis was not done to find out any association since the numbers in each cell were not adequate for analysis.

### Recommendations

Strengthening awareness among medical students regarding the importance of practicing infection control practices in the community.

**Conflict of interest:** None to declare.

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# Study of Interleukin-10 Gene Expression in Breast carcinoma in Telangana Population

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## Abstract

**Background:** Carcinoma breast is the second most common malignancy next to carcinoma cervix in India and abroad. Hence, the expression of IL-10 m-RNA gene in tumour can be a novel prognostic indicator.

**Method:** 30 mastectomy specimens of carcinoma Breast patients aged between 30 to 70 years were studied. 2 to 5 gram of tumour tissue and equivalent sample from normal peri-tumoral breast were taken from resected breast immediately after surgery and preserved in RNA-later solution. IL-10 m-RNA expression was detected and quantified by RT-PCR analysis through TaqMan chemistry, on 30 samples and 30 controls. After fixation with formalin 2 micro sections of 4-5micron thickness were taken from tumor area and corresponding paraffin blocks were prepared, mounted, on albumin coated slide for H & E staining and results were observed and recorded.

**Results:** Histologically, 08 specimens were diagnosed as grade-I (26.5%), 16 were grade-II (53.5%) and 06 were grade-III (20%). 10 specimens (33.5%) had reactive lymph node, and the remaining 20 (66.5%) had metastatic lymph node. Mean RQ values for IL-10 were calculated by the formula for comparative ct (cycle threshold) method. 26 neoplastic tissue specimens (86.5%) showed strong expression of IL-10 mRNA, while only 2 (6.5%) normal peritumoral surrounding tissue showed IL-10 expression. 4 (13.5%) neoplastic tissue and 28 (93.5%) peritumoral tissue showed weak expression of IL-10. All grade 3 tumours showed strong expression of IL-10.

**Conclusion:** Present pragmatic study had evidence that, IL-10 m-RNA gene expression was significant in neoplastic breast tissue and may have potential prognostic significance.

**Keywords:** Interleukin-10, m-RNA, RT-PCR, Taqman-chemistry, mastectomy

## Introduction

Prevalence of breast carcinoma is quite common disease next to cervical cancer of uterus in India and abroad associated with morbidity and mortality

in majority of cases. As it is idiopathic, several parameters of investigation to predict the prognosis in the breast carcinoma of female are available in every medical institutions and research centres.

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It is presumed that aetiology of cancer is multifactorial with various epidemiological attributes in combination with genetic factors <sup>(1)</sup>. The roles of high penetrate genes like BRCA1, BRCA2, PTEN etc are observed in breast cancer <sup>(2)</sup>. These were high penetrating genes observed only in final or third stage breast cancer patients who had poor prognosis with high mortality rates, whereas, Interleukin 10 (IL-10) gene can be traced in primary stages of breast cancer and can predict the prognosis of breast cancer as it has influence on tumour genesis <sup>(3)</sup>.

The role of IL-10 in cancer is well accepted but poorly understood as it exhibits both pro and anti-tumour activities. Destruction and suppression of immune system is one of the hall marks of cancer and Interleukin 10 is well documented for its immune suppression<sup>(4)</sup>. T-cells, B-cells, dendrite cells and monocytes/ macrophages are present during inflammation and IL-10 is abundantly produced by tumour associated macrophages (TAMS) which form a major component of tumour tissue <sup>(5)</sup>. Hence attempt was made to evaluate the role of IL-10 gene expression in tumour tissue so that we can predict the prognosis of breast cancer.

### Material and Method

A prospective study of Interlukin-10 m-RNA expression in Breast carcinoma was conducted in pathology department of Gandhi Medical College, Secunderabad.

**Inclusive Criteria:** Properly labelled mastectomy specimens, fresh unfixed tissue samples, tumour tissue and adjacent normal tissue for analysis, patients having complete clinico-pathological data were selected for study.

**Exclusion Criteria:** HIV positive patients, patients already under treatment for breast cancer were excluded from study.

**Method:** 30 patients of carcinoma breast aged between 30-70 years were chosen. Out of 30 cases, 4 cases (14%) were pre-menopausal and 26 (86%) were post-menopausal.

2 to 5 grams of tumour tissue and equivalent tissue from normal peritumoral breast were taken from the resected breast immediately after surgery

and preserved in RNA-later solution. IL-10 m-RNA expression was detected and quantified by RT-PCR analysis through TaqMan chemistry on these 30 samples and 30 controls.

After fixation with formalin, two micro sections of 4-5 micron thickness were taken from the tumour area and corresponding paraffin blocks were prepared, mounted on albumin coated slide for H & E staining.

Duration of study was from January-2016 to August-2017

**Statistical analysis:** Histological grading of tumours, distribution of lymph-nodes, Mean RQ values for IL-10 was evaluated in every patient's specimen. The statistical analysis was carried out in SPSS software.

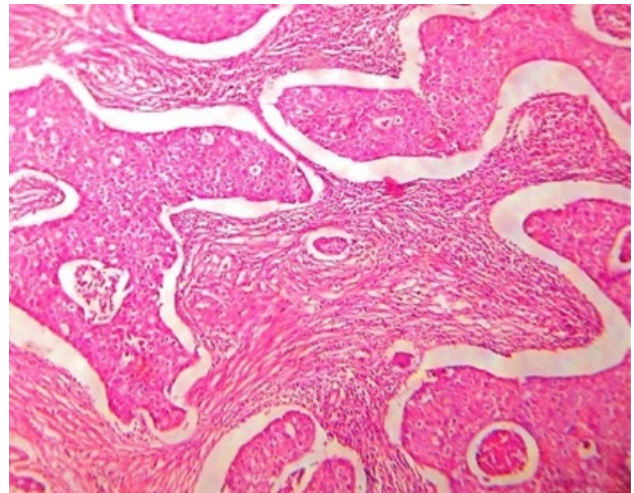


Figure-1 invasive ductal carcinoma- H&E 10x

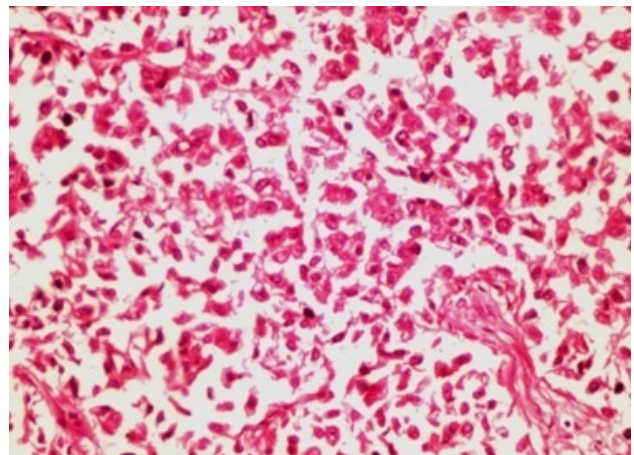
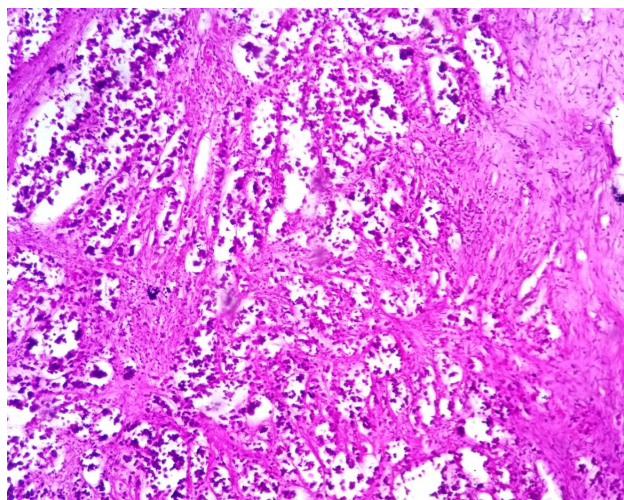


Figure-2 FIG.NO.16&17 IDCC-MODERATELY DIFFERENTIATED (GRADE- 2) H&E 40x



**Figure-3: NO IDC-POORLY DIFFERENTIATED (GRADE-3) H&E 10x**

**Observation and Results**

**Table-1:** Bloom Richardson Scaling system of histological grading – Grade-I 8 (26.5%), grade-II 16 (53.5%), grade-III 6 (20%)

**Table-2:** Distribution of lymph node metastasis in subjects – 10 specimens (33.5%) reactive lymph node, 20 specimens (66.5%) metastatic lymph node.

**Table-3:** Mean RQ values for Interleukin-10 – 26 (86.5%) Neoplastic tissue and 2 (6.5%) surrounding or peri-tumoral tissue showing strong IL-10 expression. 4 (13.5%) Neoplastic tissue and 28 peri-tumoral tissue (93.5%) showing weak expression of IL-10 m-RNA.

**Table-4:** Present study results were compared with previous studies.

**Table 1: Bloom Richardson scoring system**

Histological grade	Number of cases	Percentage (%)
Grade-I	08	26.5
Grade-II	16	53.5
Grade-III	06	20
Total cases	30	100

Majority of patients categorized as grade-II (53.5%) of cases and least were in grade-III (20%) followed by grade-I (26.3%). Positive lymph nodes were present in 66.5% of cases and Negative in 33.5% of cases.

**Table 2: Distribution of lymph nodes metastasis of study subjects**

Lymph node spread	Number of cases	Percentage (%)
Reactive lymph node	10	33.5
Metastatic lymph node	20	66.5

**Table 3: Mean RQ values for Interleukin-10**

Details	Neo plastic tissue	Surrounding or peritumoral tissue
No. of cases showing strong expression of IL m-RNA	26 (86.5%)	02 (6.5%)
No. of cases showing weak expression of IL m-RNA	04 (13.5%)	28 (93.5%)

All grade-3 tumours expressed strong expression of IL-10 indicating that IL-10 expression is more in high grade tumours.

**Table 4: Present results were compared with previous studies**

Name of Author	Size	Results
Venet sonokos etal. 1997	26 Breast tumour cases	IL 10 m RNA detected in 16 tumour tissues breast tissue
Llanes-Fernandez L etal. 2006	27 breast tumour cases	23 samples exhibited strong expression of IL-10
Chavey C etal. 2007	108 breast tumour cases	All expressed IL-10 m RNA  IL-10 expressed more in ER/PR negative cases correlating with higher grades
Hemang Kumar Bhatacherya 2016	60 breast tumour cases	60% (n=36) expressed IL-10 as compared to no IL-10 expression observed in any peritumoral tissue.
Present study 2022	30 breast tumour cases	26 (86.5%) cases showed strong IL-10 expression in tumour tissue

## Discussion

Present study follows IL-10 mRNA expression in tissues of carcinoma breast patients in Telangana population. Microscopically, as per the Bloom-Richardson scoring system – 8 patients (26.5%) had Grade-I breast carcinoma, 16 had Grade-II (53.5%) and 6 had Grade-III (20%) (Table-1). The distribution of lymph nodes in the present study showed that 10 patients (33.5%) had reactive lymph nodes, while remaining 20 patients (66.5%) showed lymph nodes metastasis. (Table-2). The mean RQ values for IL-10 showed that 26 cases (86.5%) of neoplastic tissue and 2 cases (6.5%) of peri-tumoral tissue had strong expression of IL-10, whereas 4 cases (13.5%) of neoplastic tissue, and 28 cases (93.5%) of peri-tumoral tissue had weak expression of IL-10 (Table-3) (figure-1, 2 and 3). These findings are more or less in agreement with the previous studies <sup>(6)(7)(8)</sup>.

Inter leikin-10 (IL-10), also known as human cytokine synthesis inhibitory factor (CSIF), is an anti-inflammatory cytokine produced by Th2 cells and inhibits cytokine production by Th1 cells. IL-10 is a multifunctional cytokine with both immunosuppressive and anti-angiogenic functions. In consequence, it can have both tumour promoting and tumour inhibiting properties <sup>(9)</sup>.

It is reported that, the presence of peritumoral inflammatory infiltrate in Breast carcinoma may reflect an anti-tumour immune response. Angiogenesis is necessary for the development of breast cancer and the extent of angiogenesis correlates with tumour development and patient survival <sup>(10)</sup>.

It is suggested that modulation of the innate and adaptive response through B-cells, T-cells, macrophages, dendritic cells, natural killer cells and other mediators by the immune system is critical in initiation and progression of breast cancer. Immune regulatory cytokines are important components of biological milieu associated with breast cancer <sup>(11)</sup>.

It was revealed that IL-10 suppresses the multiple immune responses through T-cells, B-cells and antigen presenting cells and might promote tumour

development by acting to suppress the anti-tumour immune responses <sup>(12)</sup>. Hence IL-10 has strong expression in tissues of breast carcinoma. Increased IL-10 concentration levels are also noted in serum of breast cancer patients. It is proposed that IL-10 is secreted at a higher rate by metastatic cancer cells for down-regulating the host inflammatory response of cell mediated immunity facilitating spread of tumour<sup>(13)</sup>.

## Summary and Conclusion

Present study of IL-10 gene expression in Breast carcinoma in Telangana population revealed that IL-10 may serve as a useful biomarker with potential prognostic value in breast carcinoma tumour tissue when compared with peri-tumoral tissue.

The present study demands that such clinical trials must be carried out in large number of patients in hi-tech research centres where latest technologies of oncology are available to confirm the significant results of present study.

**Limitation of study:** Owing to tertiary location of research centre, small number of patients and lack of latest technologies, we have limited findings and results

**Ethical Clearance:** This research work was approved by Ethical committee of Gandhi Medical College, Secunderabad, Telangana.

**Conflict of Interest:** No

**Source of Funding:** No

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# Study of Lipid Profile in Chronic Kidney Disease in Pre-dialysis Patients

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## Abstract

**Background:** Chronic Kidney Disease (CKD) causes irreversible damage to renal tissue resulting in decreased kidney function. It will affect the cardio-vascular system and leads to morbidity and mortality. Study of lipid profile in chronic kidney disease in pre-dialysis patients

**Method:** 150 CKD adult patients were studied and compared with 150 controlled group. Lipid profile was studied after a minimum 12 hour fasting. About 10 ml blood was collected from median cubital vein and centrifuged at 5000 rpm for ten minutes then lipid profile was done by VITROS slidemethod. The obtained results in both groups were noted and compared.

**Result:** Biochemical parameters had significant p values ( $p < 0.001$ ) except serum sodium. Overall dyslipidemia was present in 27 (18%) CKD and absent in 123 (82%) CKD patients out 150, 9 (6%) patients were in 3<sup>rd</sup> stage, 45 (30%) were at stage-IV, 96 (64%) were at V<sup>th</sup> stage. In correlation of lipid profile with GFR, TG, HDL and VLDL had significant p value ( $p < 0.001$ ).

**Conclusion:** Present pragmatic study proved that, dyslipidemia progress with CKD. Early monitoring of lipid profile may help to control the progression of CKD and avoid morbidity and mortality of CKD patients.

**Keywords:** Dyslipidemia, cardiovascular, disease, chronic kidney disease, Viro slide method.

## Introduction

Chronic kidney disease (CKD) is associated with premature atherosclerosis and increased incidence of cardio vascular morbidity and mortality<sup>(1)</sup>. Several factors contribute to atherogenesis and cardio vascular disease in patients with CKD. The main risk factors are lipid disorders oxidative stress inflammation, physical inactivity, anaemia, hypertension, vascular calcification, endothelial dysfunction and depressed nitric oxide availability<sup>(2)</sup>.

Numerous studies have been conducted to compare the features and mechanism of CKD

- induced dyslipidemia. In the plasma, lipid are carried by water soluble particles known as lipoproteins, which consists of nonpolar lipid core (triglycerides, cholesterol esters) surrounded by an envelope composed of specific apolipoproteins (apo) phospholipids and other polar lipids. The plasma lipoproteins are commonly classified as either high density (HDL), low density (LDL), intermediate or very low density (VLDL), lipoproteins according to their ultra-centrifugation characteristics. Chylomicrons and VLDL serve as vehicles to transport triglycerides and cholesterol from the sites of absorption from intestine, liver. In contrast HDL serves as a vehicle to

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transport excess cholesterol from peripheral tissues to the liver for disposal. Hence attempt is made to evaluate the lipid profile to know the severity of CKD.

### Material and Method

150 adult patients admitted at Bharati Vidyapeeth Medical College hospital, Pune-411043 Maharashtra were studied.

**Inclusive Criteria:** The patients confirmed having CKD (chronic kidney disease) and above the age of 18 years.

**Exclusion Criteria:** Patients of HIV, hepatitis, terminal stage of cancer patient, below 18 years patients and stage of renal disease (CKD-stage V) on haemodialysis patients having Diabetes mellitus patients already on lipid lowering drug therapy.

**Methods:** 150 chronic kidney disease patients were compared with 150 normal healthy volunteers (controlled group). Blood samples were drawn cubital fossa after a maximum of 12 hour fasting. About 10ml of blood was drawn and transfused to dried glass plain vials serum was separated within 2 hours after collection and centrifuged at 5000 rpm for 10 minutes. The supernatant clear serum was then pipetted out and stored in dry thin walled vials at 40°C. The samples were analysed on the same day. Study of lipid profile was done by VITROS slide method.

The duration of study was January-2019 to January-2023.

**Statistical analysis:** Various parameters were compared in Chronic Kidney Disease and controlled group (normal group) with t test and GFR was correlated with Pearson co-efficient regression method. The statistical analysis was carried out in SPSS method. The ratio of male and female was 2:1.

### Observation and Results

**Table-1:** Comparison of Biochemical parameters in CKD patients and controlled groups

- Blood Urea - 206.73 ( $\pm 82.10$ ) in CKD group, 14.10 ( $\pm 4.30$ ) in controlled group, t test 28.06 and  $p < 0.001$
- S. creatinine - 8.60 ( $\pm 4.30$ ) in CKD group, 0.75 ( $\pm 0.23$ ) in controlled group, t test 22.2 and  $p < 0.001$

- S. total protein - 6.06 ( $\pm 0.60$ ) in CKD group, 6.82 ( $\pm 0.44$ ) in controlled group, t test 11.42 and  $p < 0.001$
- S. Albumin - 3.36 ( $\pm 0.52$ ) in CKD group, 4.22 ( $\pm 0.32$ ) in controlled group, t test 10.1 and  $p < 0.001$
- S. Sodium - 139.60 ( $\pm 6.11$ ) in CKD group, 140.45 ( $\pm 5.18$ ) in controlled group, t test 1.18 and  $p < 0.23$  (p value is insignificant)
- S. Potassium - 5.62 ( $\pm 2.10$ ) in CKD group, 14.10 ( $\pm 4.30$ ) in controlled group, t test 28.06 and  $p < 0.001$
- S. Calcium - 8.38 ( $\pm 1.26$ ) in CKD group, 8.95 ( $\pm 0.75$ ) in controlled group, t test 4.47 and  $p < 0.001$
- S. Phosphorous - 7.32 ( $\pm 2.14$ ) in CKD group, 3.65 ( $\pm 0.82$ ) in controlled group, t test 19.01 and  $p < 0.001$
- Haemoglobin - 7.60 ( $\pm 1.50$ ) in CKD group, 12.05 ( $\pm 1.60$ ) in controlled group, t test 22.08 and  $p < 0.001$

Note: (sr. sodium) all parameters have significant p value ( $p < 0.001$ )

**Table-2:** Prevalence of individual and overall study of Dyslipidemia in both CKD and controlled group.

Lipid profile parameter

- TC - CKD  $< 260$  - 76 (50.6%), 74 in controlled, CDD  $> 200$  74 (49.3%), 26 in controlled group
- TG  $< 150$  - 48 (32%) in CKD, 68 in controlled group,  $> 150$  102 (68%) in CKD, 32 in controlled group
- HDL  $< 40$  - 110 (73%) in CKD group, 22 in controlled group, 40-60 40 (26.6%) in CKD group, 78 in controlled group
- LDL  $< 130$  - 87 (58%) in CKD group, 69 in controlled group,  $> 130$  - 63 (42%) in CKD group, 31 in controlled group
- VLDL  $< 30$  - 48 (32%) in CKD group, 89 in controlled group,  $> 30$  102 (68%) in CKD group, 11 in controlled group

Overall N (present) 27 (18%) in CKD Dyslipidemia, 6 in controlled group, absent in 123 (82%) in CKD and 45 in controlled group.

**Table-3:** Study of profile in CKD patients at various stage



Stage-I - NIL, Stage-II - NIL

Stage-III - Number of patients 9 194.6 ( $\pm$  55.6) TG, 40.30 ( $\pm$  5.40) HDL, 115.2 ( $\pm$ 17.4) LDL, 26.4 ( $\pm$ 10.62) VLDL

Stage-IV - Number of patients 45 - 198.4 ( $\pm$  42.2) TC, 152.4 ( $\pm$ 66.4)TG, 39.16 ( $\pm$  6.80) HDL, 119 ( $\pm$ 36.12) LDL, 32.46 ( $\pm$  14.8) VLDL

Stage-V - 96 patients - 208 v42.15) TC, 192.8 ( $\pm$  56.68) TG, 35.63 ( $\pm$  4.82) HDL, 126.8 ( $\pm$ 36.29) LDL, 39.22 ( $\pm$  12.15) VLDL

**Table-4:** Correlation of lipid profile parameters with GFR

0.100 TC, 0.306 TG, 0.325 HDL, 0.108 LDL, 0.275 VLDL

P value was significant in TG, HDL and VLDL

Mean GFR 1175 ( $\pm$  7.93) ml/min/1.73 m<sup>2</sup>

**Table 1: Comparison of Biochemical parameters in CKD patients and controlled group**

No. of CKD patients: 150

Sl. No	Biochemical parameters	CKD group 150	Controlled group 100	t test	p value
1	Blood Urea	206.73 ( $\pm$ 82.10)	14.10 ( $\pm$ 4.30)	28.6	P<0.001
2	Serum creatinine	8.60 ( $\pm$ 4.30)	0.75 ( $\pm$ 0.28)	22.2	P<0.001
3	Serum total protein	6.06 ( $\pm$ 0.60)	6.82 ( $\pm$ 0.44)	11.42	P<0.001
4	Serum Albumin	3.36 ( $\pm$ 0.52)	4.22 ( $\pm$ 0.32)	16.1	P<0.001
5	Serum sodium	139.60 ( $\pm$ 6.11)	140.45 ( $\pm$ 5.18)	1.18	p>0.23
6	Serum potassium	5.62 ( $\pm$ 1.28)	4.26 ( $\pm$ 0.70)	10.8	P<0.001
7	Serum Calcium	8.38 ( $\pm$ 1.26)	8.95 ( $\pm$ 0.75)	4.47	P<0.001
8	Serum phosphorous	7.32 ( $\pm$ 2.14)	3.65 ( $\pm$ 0.82)	19.01	P<0.001
9	Haemoglobin	7.60 ( $\pm$ 1.50)	12.05 ( $\pm$ 1.60)	22.08	P<0.001

Except serum sodium all value have significant p value (p<0.001)

**Table 2: Prevalence of Individual and overall study of Dyslipidemia in both controlled and CKD group**

Lipid profile parameter	CKD group with % 150			Controlled group with 100%
	<200	76	506	
TC	<200	76	506	74
	>200	74	49.3	26
TG	<150	48	32	68
	>150	102	68	32
HDL	<40	110	73	22
	40-60	40	266	78
LDL	<130	87	58	69
	>130	63	42	31
VLDL	<30	48	32	89
	>30	102	68	11
Overall prevalence	N	27	18	55
	Ab	123	82	45

**Table 3: Study of lipid profile in CKD patients at various stages**

CKD stage	No. of cases	TC	TG	HDL	LDL	VLDL
1	0	--	--	--	--	--
2	0	--	--	--	--	--
3	9 (6%)	194.6 (±22.20)	146.2 (±55.60)	40.30 (±5.40)	115.2 (±17.48)	26.40 (±10.62)
4	45 (30%)	198.4 (±42.25)	152.4 (±66.49)	39.16 (±6.80)	119.6 (±36.12)	32.46 (±14.80)
5	96(±64%)	208 (±42.15)	192.8 (±56.68)	35.63 (±4.82)	126.8 (±36.29)	39.22 (±12.15)

**Table 4: Correlation of lipid profile parameter with GFR**

		GFR	TC	TG	HDK	LDL	VLDL
GFR	Pearson correlation	1	0.100	0.306	0.325	0.108	0.275
	P value		0.26	0.001	0.001	0.242	0.002

TG, HDL and VLDL have significant correlation with GFR but TC, LDL have insignificant correlation

Note: Mean GFR = 11.75±7.93 ml/min/1.73 m<sup>2</sup>

### Discussion

Present study of lipid profile in CKD patients of Maharashtra population. In the comparison of biochemical parameters in CKD patients and controlled groups except serum sedum all values were highly significant (p<0.001) (Table-1). Study of prevalence of Individual and overall study of dyslipidemia in both controlled group and CKD patients 27 (18%) had presences dyslipidemia and 23 (82%) had absence of dyslipidemia (Table-2). The study of lipid profile in CKD patients at various stage.

3<sup>rd</sup> stage had 9 (6%), 4<sup>th</sup> stage had 45 (30%), V<sup>th</sup> stage had 96 (64%) CKD patients with elevated

lipid profile (Table-3). In correlation of lipid profile parameters with GFR - TR, HDL and VLDL have significant correlation with GFR mean GFR = 11.75 (± 7.93) ml/min/1.73 m<sup>2</sup> (Table-4). These findings are more or less agreement with previous studies<sup>(5)(6)(7)</sup>.

Hyperlipidemic can potentially accelerate progression of renal disease by several mechanisms. First resorption of fatty acids phospholipids, and cholesterol contained in the filtered proteins (albumin and lipoproteins) by tubular epithelial cells can stimulate tubule-interstitial inflammation, foam cell formation and tissue injury<sup>(8)</sup>. Second factor is accumulation of lipoproteins in glomerular

mesangium can promote matrix production and glomerulo-sclerosis<sup>(9)</sup>. In addition to this impaired HDL mediated reverse cholesterol transport can further contribute to tissue injury by limiting the unloading of the excess cellular cholesterol and phospho lipid burden. In fact low plasma HDL had been identified as an independent risk factor for progression of renal disease<sup>(10)</sup>. Moreover of hereditary Lecithin cholesterol acyltransferase (LCAT) deficiency, this is associated with marked reduction in HDL: cholesterol and impaired HDL mediated reverse cholesterol transport results in progressive renal disease (11).

It is reported that, consumption of high fat diet exacerbates hyper lipidemia whereas correction of hyperlipidemia attenuates the severity of glomerulo sclerosis and tubulo intestinal fibrosis in animal studies<sup>(12)</sup>. Moreover pharmacological intervention aimed at normalization of HDL metabolism per se with no change in serum total cholesterol has been shown to retard the progression of renal disease in 5/6 nephrectomised rats<sup>(15)</sup>. Numerous factors contribute to atherogenic diathesis and high risk of cardio vascular disease in CKD. These include oxidative stress inflammation, hypertension and altered metabolism of lipids carbohydrate Nitric oxide calcium and phosphate in CKD patients.

### Summary and Conclusion

Dyslipidemia is a common cardio vascular risk factor CKD in adult patients. Some lipid abnormalities such as reduced HDL elevated TG and atherogenic risk tends to increase with worsening renal function. Statin exert positive effects in CKD and renal transplanted patients, where no advantage have been revealed in end stage renal disease patients in terms of survival or cardio vascular morbidities. New hypolipidemic therapies lead to an additional lowering cholesterol levels but further studies are necessary to evaluate their potential application to CKD patients in order to improve clinical outcomes because exact pathogenesis of dyslipidemia is still un-clear.

**Limitation of study:** Owing to tertiary location of research centre, small number of patients and lack of latest technologies, we have limited findings and results.

This research paper is approved by Ethical committee of Bharati Vidyapeeth (deemed to be university) medical college pune-411043 (Maharashtra)

**Conflict of Interest:** No

**Funding:** Self

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# Study to Assess the Knowledge of Hospital Waste Management among Healthcare Personnel at Medical College in Haryana

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## Abstract

**Background:** Hospital Waste collection and proper disposal has become a significant concern for both the medical and general community. It is estimated that 10-25% of healthcare waste is hazardous, with the potential to create a variety of health problems. Handling, segregation, mutilation, disinfection, storage, transportation and final disposal are vital steps for safe and scientific management of Hospital waste in any establishment.

**Objectives:** To assess the knowledge of hospital Waste management among healthcare personnel working in a tertiary care centre.

**Methods:** To assess the knowledge of hospital Waste management among healthcare personnel working in a tertiary care hospital. A hospital based cross sectional study was conducted. The Study participants included nursing staff, ward boys and cleaning staff working in the institute who deal with Medical waste and were selected randomly to make the sample size of 250 with equal representation in both categories. A pretested semi-structured questionnaire was used.

**Results:** The study showed gaps in the knowledge of categories of respondents. The knowledge of the existence of Medical waste management in nurses was (79%), as well as in cleaning staff was (37%). The knowledge in practical aspects of Medical waste management was better in nurses, as compare to cleaning staff.

**Keywords:** Hospital waste, Knowledge, Management

## Introduction

General waste is the waste that does not pose an immediate hazard or to the environment pollution or threat to health. Waste management activities include collection, transportation, treatment and disposal of wastes. Academic institutions produce wastes, which are not disposed of effectively or economically, which cause pollution. According to the Basel convention, "Wastes are substances or objects which are disposed

or are intended to be disposed or are required to be disposed of by the provisions of national laws". Hospital Waste divided into two classes based on the risk it poses - General waste and Hazardous waste. "General waste" means waste that does not pose an immediate hazard or threat to health or to the environment, and includes non-hazardous substances, materials or objects. "Hazardous waste" means any waste that contains organic or

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inorganic elements or compounds that may, owing to the inherent physical, chemical or toxicological characteristics of that waste, have a detrimental impact on health and the environment and includes hazardous substances or materials. The knowledge of the existence of biomedical waste management was better among doctors (96%) as compared to nurses (88%), paramedical staff (70.9%) or the cleaning staff (16.9%). The knowledge of practical aspects of BMW management was better in nurses, paramedical staff and cleaning staff.<sup>[1]</sup> The total amount of waste generated by health-care activities, about 85% is general, non-hazardous waste. The remaining 15% is considered hazardous material that may be infectious, toxic or radioactive.<sup>[3]</sup> There are a number of legislations to enforce proper disposal of BMW in India, for example Biomedical Waste (Management & Handling) Rules 1998, and Solid Waste (Management & Handling) Rules 2000, Hazardous Wastes (Management & Handling) Rules 1989.<sup>[2,3]</sup> Studies

carried out in India showed that the awareness and practices on biomedical waste management among health care personnel is far below than the acceptable level.<sup>[8,9]</sup>

## Methodology

A hospital based cross sectional study was conducted. The Study participants included nursing staff, ward boys and cleaning staff working in the institute who deal with Medical waste and were selected randomly to make the total sample size of 250 with equal representation in both category i.e 125 in each. A pretested semi-structured questionnaire was used. Only those healthcare workers were included in the study who had been working in the institution for >6 months. A pretested semi-structured questionnaire was used for collected the data from the tertiary care hospital, Microsoft excel & SPSS(ver. 20) was used for data analysis.

**Table 1: Distribution of health care personnel on the basis of knowledge regarding Medical waste**

Sr. No.	Knowledge regarding Medical waste management	Nursing Staff n=125 (%)	Ward boys and Cleaning staff n=125 (%)
1.	waste is hazardous	98(78)	80(64)
2.	Medical waste is segregated at source	90(72)	86(69)
3.	Storage time for BMW as per BMW rules (48 hours)	80(64)	28(22)
4.	Awareness of separate colour coding containers	104(83)	80(64)
5.	Diseases transmitted through Medical waste	96 (77)	52 (42)
6.	Understanding of colour coding		
	Yellow Bag	100(80)	26 (21)
	Red Bag	98(78)	32 (26)
	Black Bag	107(86)	28 (22)
	Blue Bag (Sealed pack container)	108(86.4)	32 (26)
7.	Awareness about discarding objects causing punctures or cuts	96 (77)	64 (51)
8	Awareness about discarding of needles	109 (87)	24 (19)
9	Identification of bio-hazard symbol	92 (74)	30 (24)
10	Awareness about universal precautions	90 (72)	80 (64)
11	There is incinerator facility in our hospital	116 (92)	44 (35)

## Results

The study showed gaps in the knowledge of categories of respondents. The knowledge of the existence of Medical waste management in nurses

was (79%), as well as in cleaning staff was (37%). The knowledge in practical aspects of Medical waste management was better in nurses, as compare to cleaning staff.

## Conclusion

The present study highlighted the lack of knowledge at every level. Waste management is everybody's concern. The need of a comprehensive training for all the categories of hospital staff is highly recommended

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# A Hospital Based Prospective Observational Study on the Maternal and Fetal Outcome in Premature Rupture of Membranes in low-risk Pregnancies at a Tertiary Care Hospital

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## Abstract

**Background:** Amniotic fluid plays multiple important roles in pregnancy like homeostasis, protection from trauma, infection, and also facilitates cervical dilation in labour. Therefore, if the fetal membranes are ruptured before time, the consequences that follow can be detrimental to the fetus as well as the mother. The etiology of premature rupture of membranes (PROM) is still largely unclear and the complications are manifold. However prompt diagnosis and early management can help limit the adverse consequences and ensure a safe delivery.

**Methods:** This prospective observational study was conducted in the Department of Obstetrics and Gynecology, in a tertiary care hospital in Tezpur, Assam, over a period of 1 year (2021-2022). Out of all the patients who attended the OPD or emergency labour room, 94 cases were included in the study as per the inclusion and exclusion criteria. The data of these women was entered into a proforma and the study was done after due ethical clearance.

**Results:** Hospital incidence was 1.3%, with more women being primigravidae. Majority of cases had unknown etiology but women from lower socioeconomic class showed more chances of PROM. Caesarean section was the mode of delivery in 68% cases. Most common maternal morbidity factor was fever at 7.4%. Most babies had a good APGAR score. 20.2% of babies required admission to NICU. No maternal or perinatal mortality was seen.

**Conclusion:** PROM is an enigmatic condition associated with high risk of maternal and perinatal morbidity and mortality, even in the absence of other obstetric complications. Timely management and appropriate intervention can greatly improve both outcomes.

**Keywords:** Premature rupture of membranes, maternal outcome, fetal outcome

## Introduction

Ideally, the rupture of membranes occurs during active phase of normal labour. However, if such rupture of membranes, occurs at or after 37

completed weeks of gestation, spontaneously before the onset of uterine contractions is the phenomenon called "Premature Rupture of Membranes" (PROM).<sup>1</sup> PROM is seen to occur in about 8%<sup>2</sup> of pregnancies and labour usually sets in 12-24 hours after the rupture

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of membranes<sup>3</sup>. The etiology is often unclear but there are a few risk factors that have been associated with women presenting with PROM such as local infection, incompetent cervix, fetal malpresentation, hydramnios, multiple gestation, fetal anomalies, smoking, inherent weakness of the membranes and accidental trauma, etc. However, the majority of these patients do not present with any clear cause of PROM. Diagnosis is usually made from the history by patient, usually of vaginal passage or leakage of fluid similar to water or urine. PROM significantly affects both the fetal and maternal outcome. It is also one of the most frequent instances in which a typical uncomplicated pregnancy can become a high-risk situation for both the mother and the fetus. The hazards to maternal health in these patients are concerns of infection<sup>4</sup> i.e., development of antepartum or postpartum infection in the form of fever, urinary tract infections, chorioamnionitis, endometritis, septicaemia, and wound dehiscence. There is also an increased rate of dysfunctional labour and need for caesarean section especially in unfavourable cervix and more chance of postpartum haemorrhage. For the newborns, main concern is sepsis as PROM exposes the fetus to ascending infections<sup>5</sup> without the protective barrier that the membranes pose. There may be oligohydramnios and associated complications, respiratory distress<sup>6</sup>, malpresentation and more babies requiring admission to the neonatal intensive care unit. Studies demonstrate that the longer the interval between ROM and delivery, the higher the risk of maternal and perinatal morbidity and mortality. This result served as the primary justification for the policy of rapid induction of labour<sup>7</sup> at least 12-18 hours following PROM if spontaneous labour does not set in. An accurate diagnosis of ROM and management of the delivery that results in a high rate of successful vaginal deliveries without an increase in newborn and maternal infections are the key goals for the obstetrician and the patient with suspected PROM. Therefore, the pregnancy should be carefully managed to prevent adverse outcomes. The goal of the obstetrician is obviously to deliver a healthy baby and mother.

### Methods

This prospective study was conducted after obtaining due ethical clearance, in the Department

of Obstetrics and Gynecology, in a tertiary care hospital in Tezpur, Assam, over a period of 1 year (1<sup>st</sup> August 2021- 31<sup>st</sup> July 2022). Out of all the patients who attended the OPD or emergency labour room, 94 cases were included in the study as per the following inclusion and exclusion criteria and statistically analysed for the maternal and fetal outcomes.

### Inclusion Criteria

1. Pregnant women at 37 - 42 weeks of gestation with history of leaking from cervix for <24 hours, confirmed by clinical examination.
2. Pregnant women with ultrasonographic evidence of oligohydramnios with history of PROM.

### Exclusion Criteria

1. Patients with high-risk pregnancies like
  - Multiple gestations
  - Elderly primigravida
  - Precious pregnancy
  - History of previous caesarean section
  - Congenital anomalies
  - Malpresentation
  - Severe anemia (Hemoglobin <7 gram%)
  - Antepartum haemorrhage
2. Maternal complications like heart disease, hypertensive disorders, diabetes.
3. Cases with fetal distress, fetal growth restriction.

### Results

A total of 7229 patients delivered at the study hospital during the study period, out of which 94 patients were fit to be included in the study as low risk PROM cases. This brought the hospital incidence to be 1.3%.

The number of primigravidae (61.8%) was higher in this study than multigravidae (38.2%).

Most of the women did not show any direct causative factor for PROM, i.e. most cases were idiopathic in nature, however, the majority of patients were from lower socioeconomic background.

A history of PROM in previous pregnancies was seen in 10.6% cases, poor general health contributed



to 7.4% cases while history of UTI complicated 0.9% cases.

The most common mode of delivery was lower segment caesarean section (in 68%) while in 30 patients, vaginal delivery was possible, with 27 (28.7%) normal vaginal deliveries and 3 (3.19%) being instrumental deliveries.

The interval between rupture of membranes to delivery being an important aspect, was studied and found to be 12-24 hours for most cases (52 out of 94, i.e. 55%). 32% cases delivered within 12 hours (30 out of 94), while about 13 % (12 of 94) took longer than 24 hours to deliver.

The maternal morbidities studied showed that puerperal fever was the most common event (7.4% cases), followed by diagnosed UTI (in 6.3% cases) and clinical chorioamnionitis (in 4.2% cases). Wound infection and postpartum haemorrhage was noted in 3.1% cases each. Puerperal sepsis developed in about 2% cases.

No maternal death was recorded during this study.

Neonatal parameters showed that 80% of the delivered babies did not require admission to NICU, with 82 (87%) of them having good APGAR scores at the first minute after birth which improved to 89 (94.6%) good APGAR scores at the fifth minute after birth.

No perinatal death was recorded in this study.

**Table 1: Predisposing Factors**

Factor	Frequency	Percentage
Idiopathic	67	71.2
History of coitus	13	13.8
Lower socioeconomic status	58	61.7
Poor general health	7	7.4
History of PROM in previous pregnancy	10	10.6
History of UTI	1	0.9

**Table 2: Modes Of Delivery**

MODE OF DELIVERY	FREQUENCY	PERCENTAGE
Normal Vaginal Delivery	27	28.72
Instrumental (Forceps/ Ventouse) Delivery	3	3.19
Caesarean section	64	68.08

**Table 3: Rom-Delivery Interval**

ROM -DELIVERY INTERVAL	NUMBER	PERCENTAGE
Within 12 hours	30	31.91
12-24 hours	52	55.31
>24 hours	12	12.76

**TABLE 4: MATERNAL OUTCOME**

OUTCOME	NUMBER	PERCENTAGE
Fever	7	7.4
Urinary Tract Infection	6	6.3
Clinical Chorioamnionitis (CAM)	4	4.2
Postpartum Hemorrhage (PPH)	3	3.1
Wound infection	3	3.1
Puerperal sepsis	2	2.1
Death	0	0

**TABLE 5: APGAR SCORE**

APGAR SCORE	%	%
	AT 1 MINUTE	AT 5 MINUTES
<7	12.76	5.31
≥7	87.23	94.69

**TABLE 6: ADMISSION TO NICU**

ADMITTED TO NICU	NUMBER	PERCENTAGE
Yes	19	20.21%
No	75	79.79%

## Discussion

There are many studies that focussed on different aspects of PROM in all pregnancies. In this study, the sole focus was on the problems posed by PROM isolated from other complications of pregnancy. As such, the results obtained can compare with the existing similar studies as well as shed light on the outcomes exclusive to PROM.

This study supports early detection, management and action to improve the fetomaternal outcomes.

Incidence in low risk pregnancies is 1.3% which is quite lower than other studies like Shahela N. et al<sup>8</sup> (3.6%) and Jigyasa S. et al<sup>9</sup> (6.7%), which did not have such strict exclusion criteria. Idrisa A. et al<sup>10</sup>, however, recorded similar incidence (1.3%).

### *Maternal parameters and outcome*

In this study we saw that the majority (61.8%) of women were primigravidae, which is similar to studies by Jigyasa S. et al (57% vs 43% multigravidae) and Loveleen S. et al<sup>11</sup> (62.7% vs 37.3% multigravidae).

The lower socioeconomic background played a factorial role in PROM with 61.7% cases belonging to this strata, in concurrence with studies by Tigist E. et al<sup>12</sup> (70.3% cases) and Idrisa A. et al (79.5% cases).

The predisposing factors found possible were studied and it was found that in this study most cases were idiopathic (71.2%), 13.8% had history of recent coitus, 10.6% cases had a history of PROM in previous pregnancies and 0.9% presented with history of UTI. Comparably, Loveleen S. et al in their study had 47.3% cases with no definite cause, 9.09% with recent history of coitus, 16.3% had history of PROM in previous pregnancies, while 26.4% came with history of UTI.

Maternal morbidity increased with the delay in seeking medical care.

The most common maternal morbidity parameter was puerperal pyrexia seen in 7.4% patients in this study. Rauf Abdul et al<sup>13</sup> found puerperal pyrexia in 7% cases, similar to this study. While Arpita A. et al<sup>14</sup> in 10.5% cases and Loveleen S. et al recorded 11.8% cases in their studies, which are higher than in this study.

Next commonest maternal morbidity was urinary tract infections, in 6.3% cases while Arpita A. et al

recorded only 0.5% cases. Much higher incidence in studies by Shahela N. et al in 53% patients, by Jigyasa S. et al in 51% as they included subclinical infection as well.

Clinical chorioamnionitis was seen by Lars Ladfors et al<sup>15</sup> in 25.7% patients, by Shahela N. et al in 13.5%, by Arpita A. et al in 11.9% and by Loveleen S. et al in 3.6% cases. This study has similar rates to Loveleen S. i.e, 4.2%, which is much lower than the other studies.

Wound infection rates are seen to be 6.5% in the study by Rauf Abdul et al, 6% in the study by Tigist E. et al and 4.5% by Loveleen S. et al. This study had lower rates than the others with 3.1% cases.

The rate of puerperal sepsis in this study was 2.1% which is similar to Arpita A. et al having 1.4% cases. Tigist E. et al had a higher rate of 11.4%.

PPH was noted by Rauf Abdul et al in 8% cases, which is higher than this study (3.1%), while Tigist E. et al had similar rates with 3.7%, and Arpita A. et al and Loveleen S. et al had slightly lower rates of 1% and 1.8% respectively. It was seen that PPH was higher with increasing parity and longer interval between rupture of membranes to delivery.

No maternal death was recorded in this study.

### *Delivery and PROM*

The mode of delivery in this study was found to be predominantly via caesarean section (68%). Higher incidence of caesarean section was also seen in studies by Shahela N. et al (77%), Jigyasa S. et al (54.3%), Arpita A. Jaiswal (77%) and Loveleen S. et al (71%).

Most cases (or 55%) in this study delivered within the window of 12-24 hours from rupture of membranes. Jigyasa S et al had most cases deliver after 24 hours of rupture of membranes (75%), and Rauf Abdul et al had very little difference in the proportion of patients delivering within 12 hours, 12-24 hours or after 24 hours, however, slightly higher number of cases managed to deliver in the 12-24 hour period (36%). This included the delay in the patients attending the hospital even after PROM.

### *Neonatal outcome*

Since this study includes low risk term pregnancies, the risks were less but still led to a

NICU admission rate of 20%, demonstrating that PROM poses significant risk to the fetus. Compared to this Tigist E. et al recorded a NICU admission rate of 25.4%.

The APGAR scores at first minute after birth for this study were good for 87% of babies (score of 7 or more). Similarly, Shahela N. et al recorded a good score in 78% babies, Jigyasa S. et al saw a favorable score in 75% and 94% babies had a good score in the study by Arpita A. et al.

The APGAR score at fifth minute after birth in this study was good in 94.6% babies and comparably, majority of the babies (76.2%) had a good score in the study by Tigist E. et al.

### Conclusion

PROM without other obstetric complications is not without its risks and may endanger a pregnancy.

The prognosis of the mother and baby can be drastically different pertaining to the interval between rupture of membranes to delivery, therefore prompt intervention and action is the mainstay of treatment and can significantly improve the maternal and fetal outcomes.

This study showed that the premature escape of liquor due to PROM leads to higher caesarean delivery rates which in itself increases the maternal morbidity, possibly even for future pregnancies. It is important to expedite the process of labour or delivery in these patients such that the infective exposure may be reduced as well as effectively treat any corresponding signs or symptoms in the mother and the baby, that may arise as a consequence of PROM. This study recorded a low rate of admission to neonatal intensive care unit, which is attributable to the timely management and prompt treatment. This in turn, also led to a low sepsis rate and decreased morbidity. This also reflects in the nil mortality recorded by this study.

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# Prediction of Fetal Growth Restriction using Transcerebellar Diameter and Abdominal Circumference Ratio

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## Abstract

**Objective:** To predict fetal growth restriction using transcerebellar diameter and abdominal circumference ratio (TCD/AC) in women with clinically diagnosed FGR.

**Materials and Methods:** A prospective observational cohort study was conducted on women >28 weeks of gestation with clinically diagnosed fetal growth restriction, at the Tertiary care centre. Total 120 women were enrolled, over a period of 18 months, from December 2020 to July 2022. Biometry was performed using ultrasonography and transcerebellar diameter and abdominal circumference ratio (TCD/AC) and head circumference and abdominal circumference ratio (HC/AC) were calculated. All women were followed up till delivery and fetomaternal outcome was recorded. After birth height, weight and ponderal index of the newborn were also noted. TCD/AC ratio was correlated with birth weight and ponderal index, for predicting FGR. TCD/AC ratio was also compared with routinely used HC/AC ratio for predicting FGR.

**Statistical Analysis:** The final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0®.

**Results:** A cut off value of TCD/AC >0.14 was found to have a sensitivity, specificity, PPV and NPV of 87.36%, 75.76%, 90.5% and 69.4% respectively with a diagnostic accuracy of 84.17%, in diagnosing FGR. There was a significant negative correlation between TCD/AC ratio with birth weight and ponderal index, with a correlation coefficient of 0.463 and 0.501 respectively. (p value < 0.001) TCD/AC was better predictor of fetal growth restriction with a diagnostic accuracy of 84.17% versus 40.83% with HC/AC. Significant positive correlation was observed between period of gestation (weeks) with transcerebellar diameter (mm), with correlation coefficient of 0.497 (p<0.001).

**Conclusions:** TCD/AC ratio is an effective gestational age independent parameter to predict FGR on ultrasonography, with better diagnostic accuracy than routinely used HC/AC. Hence it should be performed for all antenatal women clinically suspected to have FGR.

**Keywords:** Transcerebellar diameter, Abdominal Circumference, Fetal Growth Restriction, Head circumference, birth weight, Ponderal index.

## Introduction

The term “fetal growth restriction” (FGR) implies failure of a fetus to meet its genetically determined

growth potential due to fetal, placental or maternal factors.<sup>1</sup> The estimated incidence of fetal growth restriction is high (10%) but its recognition is low, as

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only 40% of these cases are identified during antenatal period.<sup>2</sup> A different set of clinical problem develops in infants of same weight but different gestational age, therefore identification of high risk newborns based on gestational age and weight is important.<sup>3</sup> Growth restricted fetus need to be identified antenatally because they have a high likelihood of intrapartum hypoxia, intrauterine death, low APGAR scores, meconium-stained liquor and neonatal mortality.<sup>4</sup> Besides these, growth restricted fetus have also reported long-term health problems, like risk of neurodevelopment disorders, endocrine and cardiovascular diseases.<sup>5</sup> Early detection of FGR is useful in deciding frequency of antenatal surveillance and timing of delivery.<sup>6,7</sup> Timely delivery of such infants leads to improved outcomes by fourfold reduction in morbidity and mortality.<sup>8</sup> It is also an important factor in stillbirth prevention strategies, as up to 30% of stillbirths are associated with FGR.<sup>9</sup>

Third trimester growth scan with dopplers is used for fetal weight determination and to classify fetuses that are small for gestational age (SGA), which is defined as an estimated fetal weight (EFW) <10<sup>th</sup> percentile.<sup>10</sup>

The cerebellum due to brain sparing effect is relatively resistant to hypoxia.<sup>5</sup> So transcerebellar diameter (TCD) is least affected by growth restriction. The abdominal circumference (AC) on the other hand correlates directly with liver size which is maximally affected by fetal malnutrition. Therefore TCD/AC ratio which utilizes the least and most affected fetal biometric parameter, is a very sensitive method of detecting fetal growth restriction.<sup>2,11</sup>

Several nomograms for the transcerebellar diameter to abdominal circumference ratio indicate that, from around 21-22 weeks of gestation, in normal fetuses, the TCD/AC ratio is gestation-age independent and remains constant (median value 0.13). A study in growth restricted fetus reported that an asymmetric pattern defined as transcerebellar diameter to abdominal circumference ratio (TCD/AC) ratio >95<sup>th</sup> percentile with median value 0.15 in second trimester and 0.16 in the third trimester, is predictive of birthweight < 10<sup>th</sup> centile.

In India, many women present to the hospital in third trimester with unknown gestational age and

it is difficult to ascertain whether they are preterm or growth restricted. Hence this study was carried out to ascertain whether transcerebellar diameter to abdominal circumference ratio (TCD/AC) can be used to diagnose fetal growth restriction, with unknown period of gestation.

## Methods

This prospective observational cohort study was conducted in Department of Obstetrics and Gynaecology, Department of Radiodiagnosis and Department of Pediatrics of a Tertiary care hospital over a period of 18 months from December 2020 to July 2022, after obtaining institutional ethics committee approval. A total of 120 women with singleton pregnancy in cephalic presentation and clinically diagnosed FGR at >28 weeks period of gestation with known LMP were recruited after informed consent. Women having BMI>35 kg/m<sup>2</sup>, polyhydramnios, Type 2 diabetes mellitus or a fetus with gross congenital anomaly were excluded.

After history, examination and antenatal investigations, ultrasonography was performed for biometry and EFW using Toshiba's model SSA640 and various ratio like TCD/AC and HC/AC were also calculated.

The women were followed up until delivery, and neonates with birth weight <10<sup>th</sup> centile were grouped as Small for gestational Age (SGA), using international standards for size at birth. The babies were grouped as symmetric or asymmetric FGR based on Ponderal index which was calculated by multiplying weight (in gram) with 100 and dividing by the cube of length (in centimetres). Cut-off of Ponderal index for babies with asymmetrical FGR was taken as < 2. Maternal outcomes like emergency LSCS and preterm delivery and fetal outcomes like MSL, APGAR score at birth, NICU admission and mortality rates were recorded in the two groups which had TCD/AC ratio of >0.14 and ≤0.14 to see if this ratio can predict adverse perinatal outcomes in babies with FGR.

The data entry was done in the Microsoft EXCEL spreadsheet. The data normality was checked by using Kolmogorov-Smirnov test. The final analysis was done with the use of Statistical Package for

Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, version 21.0®.

## Results

The present study conducted in the Department of Obstetrics and Gynecology, Radio diagnosis and Pediatrics over a period of 18 months, recruited a total of 120 women with clinically diagnosed FGR.

The mean age of study population was 24.37 years but there was no difference in the distribution of FGR between different age groups. The mean gestational age at diagnosis and at delivery was 35.79 weeks and 37.37 weeks, respectively. Majority (51.67%) of women in present study population were primigravida whereas only 31.67% were second gravida. On comparing the incidence of FGR babies in women with different BMI, women with lower BMI (<18.5 kg/m<sup>2</sup>) had a higher incidence of FGR babies (82.53%) relative to those with BMI >30 kg/m<sup>2</sup> which had only 23.53% of FGR babies.(p value <0.001) TCD/AC at cut off point of >0.14 with AUC of 0.832 had sensitivity of 87.36% and specificity of 75.8% for predicting FGR. HC /AC at cut off point of >0.311 with AUC of 0.832 had sensitivity of 21.8% and specificity of 90.9% for predicting FGR. [Figure 1].

TCD/AC ratio also had a PPV and NPV of 90.50% and 69.4% respectively which was higher as compared to PPV and NPV of HC/AC ratio of 86.4% and 30.6% respectively. TCD/AC was better predictor of fetal growth restriction with a diagnostic accuracy of 84.17% versus 40.83% with HC/AC[Table 1].

There was a significant negative correlation between TCD/AC and birth weight with a correlation coefficient of 0.463.(p value <0.0001) A significant negative correlation was observed between TCD/AC ratio with ponderal index with correlation coefficient of 0.501(p value <0.0001) which helped in diagnosis of asymmetrical FGR [Table No.2] [Figure no. 2a,2b]. On comparing TCD and gestational age, there was a significant positive correlation between period of gestation (weeks) with transcerebellar diameter (mm) [Figure 1] with correlation coefficient of 0.497 (p value <0.001).

In terms of neonatal outcome, NICU admission rates in FGR and AGA were 34.94% and 16.67% respectively, which were significantly higher in FGR(p value=0.044) group. There was no significant difference in the two groups in terms of MSL, APGAR score, prematurity and Caesarean section rates[Table no.3]. One Intrauterine death and one neonatal death occurred and both had TCD/AC>0.14.

**Table 1: Comparison of TCD/AC ratio and HC/AC ratio for predicting fetal growth restriction**

Variables	TCD/AC	HC/AC
Area under the ROC curve (AUC)	0.832	0.543
Standard Error	0.0409	0.0572
95% Confidence interval	0.753 to 0.894	0.450 to 0.634
P value	<0.0001	0.4521
Cut off	>0.14	>0.311
Sensitivity(95% CI)	87.36%(78.5-93.5%)	21.84%(13.7-32.0%)
Specificity(95% CI)	75.76%(57.7-88.9%)	90.91%(75.7-98.1%)
PPV(95% CI)	90.5%(82.1-95.8%)	86.4%(65.1-97.1%)
NPV(95% CI)	69.4%(51.9-83.7%)	30.6% (21.7-40.7%)
Diagnostic accuracy	84.17%	40.83%

**Table 2: Correlation between TCD/AC ratio with birth weight and Ponderal index**

Parameter	TCD/AC≤0.14 (AGA) (N=36) n(%)	TCD/AC>0.14 (FGR) (N=84) n(%)	P value	Correlational coefficient
Birth weight				
<10 <sup>th</sup> centile	11(30.56)	76(90.48)	<0.0001	-0.463
>10 <sup>th</sup> centile	25(69.44)	8(9.52)		
Ponderal Index				
<2 (asymmetrical FGR)	9(25)	71(84.52)	<0.0001	-0.501
≥2 (non FGR)	27(75)	13(15.48)		

**Table 3: Correlation between TCD/AC ratio and Fetomaternal outcome**

Parameter	TCD/AC≤0.14 (AGA) (N=36) n(%)	TCD/AC>0.14 (FGR) (N=84) n(%)	P value
Mode of delivery			0.157
Emergency LSCS	7(19.4)	27 (32.14)	
Vaginal delivery	29(80.5)	57(67.86)	
Preterm delivery			0.258
Yes	6(16.67)	22(26.19)	
No	30(83.33)	62(73.81)	
APGAR score at 1 min			0.075
<7	14(38.89)	47(56.63)	
≥7	22(61.11)	36(43.37)	
APGAR score at 5min			0.096
<7	9(25)	34 (40.96)	
≥7	27(75)	49 (59.04)	
NICU admission			0.044
Yes	6(16.67)	29 (39.94)	
No	30(83.33)	54 (65.06)	
MSL at birth			0.830
Yes	8(22.22)	17(20.48)	
No	28(77.78)	66(79.52)	

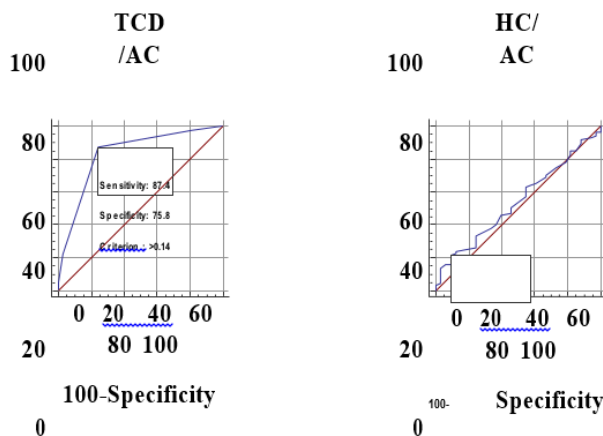


Figure 1: Receiver operating characteristic curve of TCD/AC and HC/AC ratio for predicting fetal growth restriction.

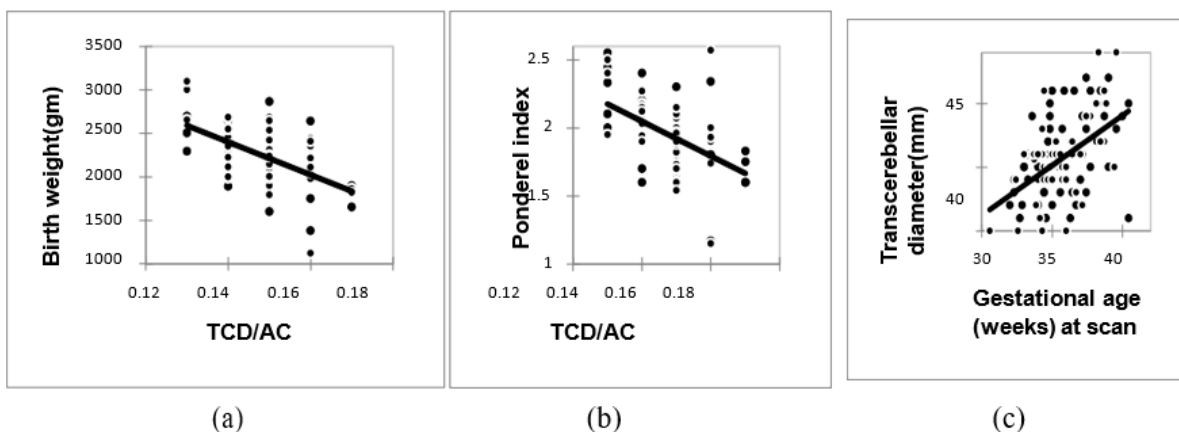


Figure 2(a,b): Correlation of TCD/AC ratio with birth weight and Ponderal index  
(c): Correlation of Transcerebellar diameter (mm) with gestational age

**Discussion**

The biometric parameters routinely used for estimation of gestational age - BPD, HC, AC and FL are influenced by fetal growth and external compressive forces.<sup>13</sup> For TCD cerebellum is measured which lies in the posterior cranial fossa, surrounded by the dense petrous ridges and occipital bone so it can withstand deformation by extrinsic pressure better than the parietal bones and hence is lesser affected than head circumference.<sup>14</sup>

In the present study, there was a positive correlation between transcerebellar diameter (in mm) and gestational age (weeks) with a correlation coefficient of 0.497. Similar earlier study also found a positive correlation between TCD and gestational age with correlation coefficient of 0.972.<sup>15</sup> Another cross sectional study on 500 women concluded that

TCD had significant correlation with GA in normal ( $R^2 = 0.979$ ) and FGR pregnancies ( $R^2 = 0.942$ ).<sup>16</sup>

Previous study on 100 women between 15-28 weeks was in concordance to the present study and showed TCD to have highest correlation with gestational age compared to other biometric parameters with r-value of 0.982 at 29-40 weeks.<sup>17</sup> A prospective study on 100 pregnant women in concordance demonstrated strong correlation between gestational age and TCD with correlational coefficient 0.862 at 20-22 weeks and 0.803 at 32-34 weeks.<sup>18</sup>

In the present study, the mean TCD/AC ratio was 0.15 and a value  $>0.14$  was found to have a sensitivity of 87.36%, specificity of 75.76%, PPV of 90.5% and NPV of 69.4% with a diagnostic accuracy of 84.17% in diagnosing FGR. Previous group of authors also found similar cut off for TCD/AC ratio where among



15 neonates with FGR, the mean TCD/AC ratio was  $14.17 \pm 0.89$  at early gestation and  $15.61 \pm 1.18$  at late gestation.<sup>19</sup> A study on 473 women in concordance with present study showed TCD/AC ratio  $>14.73$  was associated with small for gestational age due to maternal placental syndromes.<sup>20</sup>

A recent study of 2022 also concluded that TCD/AC is an age independent parameter that remains constant at any gestational age with a mean TCD/AC ratio of 0.13 with sensitivity, specificity, PPV, NPV and diagnostic accuracy for diagnosing FGR of 88%, 93.5%, 77.1%, 96.3% and 92.4% respectively.<sup>12</sup> Another study on a group of 285 women found TCD/AC ratio to have a sensitivity, specificity, PPV and NPV of 77.1%, 97.2%, 79.4% and 96.8% respectively in predicting FGR with overall diagnostic accuracy of 95% which was in concordance with the present study.<sup>15</sup> Another study on a group of 500 women showed that TCD/AC ratio had 99.03% sensitivity and 83.45% specificity, in predicting FGR.<sup>21</sup>

When the babies diagnosed as FGR by TCD/AC ratio were correlated with birth weight, 90.48% of them had low birth weight (0.14 was worse than with TCD/AC ratio  $< 0.14$ , but difference was not significant (p value  $>0.05$ ).

However, limitation of the present study was large interobserver variability in calculating transcerebellar diameter and abdominal circumference and difficulty in measurement of transcerebellar diameter due to calvarial shadow. Also, the study had a small study population for comparing maternal and fetal outcomes.

### Conclusion

TCD is reliable for determining gestational age in third trimester of gestation. At a cut off value of  $>0.14$ , TCD/AC had overall better diagnostic accuracy (84.17% vs 40.83%) than HC/AC ratio in predicting FGR. Hence, we recommend that the TCD/AC ratio should be routinely used while performing USG as it is a good predictor of fetal growth restriction and can also be used in women with unknown period of gestation as it is gestational age independent.

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**Conflict of Interest:** No

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## A Comparative Study of Coronary Stent Utilization Pattern with respect to Coronary Stent Price Regulation: A hospital-based study from Mumbai, India

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### Abstract

**Introduction:** India's National Pharmaceutical and Pricing Authority (NPPA) fixed a ceiling price for coronary stents on 13th February 2017. In this study we compare the coronary stent usage patterns in a hospital in India before and after the coronary stent price regulation was implemented.

**Methodology:** retrospective cohort study at a private-sector tertiary care hospital among patients that underwent PCI from 13th February 2015 to 12th February 2019, i.e., two years before and after the price regulation of coronary stents. Sampling was done by complete enumeration of the study population & those fulfilling eligibility criteria. Data were collected from the hospital's electronic health records and Cath-lab registry following the inclusion & exclusion criteria. Data on coronary stent utilization patterns were analyzed under different subgroups using descriptive statistics. The Chi-square test was applied to assess statistical significance. The results were considered significant when p value <0.05.

**Results:** 1135 patients were included in the study of which 604 of them underwent PCI before the price regulation of coronary stents, and 531 after. 1154 and 1092 stents at an average of 1.91 and 2.05 stents were used per case before and after the price regulation respectively.

**Conclusion:** The use of DES has increased after the coronary price regulation. Also, more third-generation DES which is the gold standard in coronary revascularization is being used compared to before. The use of superior imported stents also saw an increase after the coronary price regulation. There was only a marginal increase in stents used per case.

**Keywords:** Coronary stents, price regulation, medical devices

### Introduction

Percutaneous transluminal coronary angioplasty (PTCA) also called percutaneous

coronary intervention (PCI) is a minimally invasive procedure to open blocked coronary arteries allowing unobstructed blood flow to the myocardium.<sup>(1)</sup> Coronary stents (CS) are expandable

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tubular metallic devices that are introduced into the coronary arteries that show stenosis due to an underlying atherosclerosis disease. Various types of stents are available including traditional bare-metal stents (BMS) and drug-eluting stents (DES) and bioabsorbable vascular scaffolds (BVS). The most common metal used in coronary stents is stainless steel or cobalt-chromium which gives long-term mechanical stability to counteract vascular recoil. DES consists of three components: a metallic stent platform, an active pharmacological drug agent, and a carrier vehicle in form of a polymer coating that enables sufficient drug loading and release for a long time. The first-generation DES contains sirolimus or paclitaxel coating on a stainless steel base. In contrast, the second-generation DES has zotarolimus or everolimus coating on top of a biocompatible cobalt-chromium or platinum-chromium platform. Newer third-generation DES have ultrathin strut (defined as strut thickness  $<70 \mu\text{m}$ ) & biodegradable polymer coating which further reduce vascular injury and accelerate reendothelialization as well as reduce polymer-associated inflammation.<sup>(2,3)</sup> BVS are devoid of metallic structure and are entirely resorbed in a few months after serving their purpose. These are also referred to as fourth-generation DES.<sup>(4)</sup>

Cardiovascular disease (CVD) continues to be the leading cause of morbidity and mortality worldwide and in sync with global trends, India is not far behind. Ischemic heart disease (IHD) is a leading cause of mortality and disability-adjusted life years (DALYs) in India contributing to 17.8% of total deaths and 8.7% of total DALYs. The proportion of deaths and DALYs from IHD is significantly higher in men than women. With the progressive increase in the number of patients suffering from CVD, the field of interventional cardiology has rapidly expanded throughout the country.<sup>(5)</sup> In the year 2020 the coronary interventional registry in India included 751 centers which together performed 355326 PCIs implanting 482778 stents. In the pre-pandemic year of 2019, 493684 PCIs were performed implanting 631915 stents.<sup>(6,7)</sup>

In developing countries, growing populations and efforts by governments to expand universal health coverage have posed a challenge to meeting healthcare expenditures. As a result, countries have

implemented increased regulation for healthcare technologies, including price regulation for medical devices. Price regulation is the practice of restricting the minimum or maximum prices in the market by imposing legal requirements. The regulation of prices typically involves establishing a price cap for a predefined category of devices. India's National Pharmaceutical and Pricing Authority (NPPA) fixed a ceiling price for coronary stents at INR 7260 ( $\approx$ USD 88) for bare metal stents and INR 29600 ( $\approx$ USD 358) for drug-eluting stents on 13<sup>th</sup> February 2017.<sup>(8)</sup> Before this average retail price of bare metal stents was INR 45000 ( $\approx$ USD 544) and drug-eluting stents INR 120000 ( $\approx$ USD 1450). In issuing its order, the NPPA stressed that margins had become exorbitant and irrational and profiteering was rampant at various levels in the supply chain.<sup>(9)</sup> Multiple yearly revisions followed and the current price stands at INR 9373 for bare metal stents and INR 34128 for drug-eluting stents.<sup>(10)</sup>

In line with the increasing focus on price regulation, there is a mounting need for local and international literature outlining arguments for and against regulating the prices of medical devices. However, to date, there has been limited research undertaken on the application of price regulation to medical devices and the impact this has on the healthcare system, patients, and market dynamics. In this study we compare the coronary stent usage patterns in a hospital in India before and after the coronary stent price regulation was implemented.

## Methodology

A retrospective cohort study was conducted at Dr. L.H. Hiranandani Hospital, Mumbai, a private-sector tertiary care hospital. The study population was all patients that underwent PCI from 13<sup>th</sup> February 2015 to 12<sup>th</sup> February 2019 at the study center. The study population was divided into two cohorts. One, of those that underwent PCI before the price regulation of coronary stents, i.e., during the period 13<sup>th</sup> February 2015 to 12<sup>th</sup> February 2017, and the other of those that underwent PCI after the price regulation, i.e., during the period 13<sup>th</sup> February 2017 to 12<sup>th</sup> February 2019. Sampling was done by complete enumeration of the study population & those fulfilling eligibility criteria. Patients that underwent PCI with BMS, DES, or BVS were included in the study, and

those that underwent PCI with balloon angioplasty were excluded. Requisite permissions were taken from the concerned authorities of the institute. Data were collected from the hospital's electronic health records (EHR) and Cath-lab registry following the inclusion & exclusion criteria. A predesigned data gathering form comprising items developed according to the objective of the study was used &

data was entered into Microsoft Excel 2019. Data on coronary stent utilization patterns were analyzed under different subgroups using descriptive statistics. The Chi-square test was applied to assess statistical significance. The results were considered significant when  $p$  value  $<0.05$ . All ethical principles as per Helsinki Declaration were followed during the study.

### Results

A total of 1137 patients underwent PCI during the study period at the study center. 2 of them underwent PCI each using a drug-eluting balloon (DEB) and plain old balloon angioplasty (POBA) respectively, and did not meet eligibility criteria. The other 1135 of them underwent PCI using coronary stents and were included in the study. Among the 1135 patients included in the study, 604 of them underwent PCI

before the price regulation of stents, i.e., during the period 13<sup>th</sup> February 2015 to 12<sup>th</sup> February 2017. 531 of them underwent PCI after the price regulation of stents, i.e., during the period 13<sup>th</sup> February 2017 to 12<sup>th</sup> February 2019. Study participant general characteristics and the coronary stent usage pattern is given in Table 1.

**Table 1. General characteristics of study participants**

Variables	Pre-stent price capping (%)	Post-stent price capping (%)
No. of patients	604	531
Age in years	61.6 ± 11.7	60.2 ± 11.6
Male	446 (74)	408 (77)
Female	158 (26)	123 (23)
Total no. of stents used	1154	1092
Average no. of stents used per PCI	1.91	2.05
LMCA PCI	12 (1.9)	43 (8.1)
PAMI	73 (12.1)	119 (22.4)
SVD	268 (44.4)	234 (44.1)
DVD	238 (39.4)	183 (34.5)
TVD	98 (16.2)	114 (21.5)
Average cost of undergoing PCI	INR 496831 ± 88219	INR 437066 ± 68719

LMCA - Left Main Coronary Artery, PAMI - Primary Angioplasty in Myocardial Infarction, SVD - Single vessel disease, DVD - Double vessel disease, TVD - Triple vessel disease

**Table 2. Coronary stent usage pattern among study participants**

Variables	Pre-stent price capping (%)	Post-stent price capping (%)	Statistical significance
<b>Stent(s) used in each PCI</b>			
1 stent	266 (44)	223 (42)	$\chi^2 = 6.419$ df = 3 p-value = 0.0939*
2 stents	199 (33)	159 (30)	
3 stents	91 (15)	84 (16)	
4 or more stents	48 (8)	65 (12)	

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Types of stents			
Bare metal stents (BMS)	2 (0.2)	0	$\chi^2 = 94.333$ df = 2 p-value = 0.0001*
Drug-eluting stents (DES)	1053 (91.2)	1090 (99.8)	
Bioabsorbable vascular scaffolds (BVS)	99 (8.6)	2 (0.2)	
Types of DES			
1 <sup>st</sup> generation DES	651 (62)	235 (21)	$\chi^2 = 464.779$ df = 2 p-value = 0.0001*
2 <sup>nd</sup> generation DES	402 (38)	639 (59)	
3 <sup>rd</sup> generation DES	0	216 (20)	
Country of origin			
Indian	256 (22)	31 (3)	$\chi^2 = 188.288$ df = 1 p-value = 0.0001*
Other (Imported)	898 (78)	1061 (97)	

\*p-value <0.05 is considered statistically significant.

### Discussion

An average of 1.91 and 2.05 stents were used per case before and after the price regulation respectively. There was no statistically significant change in stent usage pattern in terms of the number of stents used per case. Although a decrease in single stent PCI & two stents PCI by 2% & 3% respectively the change was not statistically significant. Three stents PCI remained the same in both groups while 4 stents PCI increased by 5%. This could be attributed to increased complex LMCA PCI and PCI for TVD.

DES were the most commonly used coronary stent both before and after the price regulation of coronary stents, making up 91.2% & 99.8% respectively. Bare metal stent usage completely stopped after the price regulation so did the usage of BVS stents which fell to a mere 0.2%. At the same time, the market share of DES increased from 95.3% to 97.5% and that of BMS dropped from 4.7% to 2.5% in India.<sup>(6)</sup> Globally the drug-eluting stents (DES) segment dominated more than 85.4% of the coronary stents market share in 2020 led by the advantages associated with drug-eluting stents. BMS & BVS had 6.3 and 8.3% market shares respectively.<sup>(11)</sup> Permanent metallic drug-eluting stents (DES) are the current gold standard in percutaneous myocardial revascularization, as they have demonstrated to warrant easy deliverability, good scaffolding, low neointimal hyperplasia, low restenosis rate, and low incidence of major cardiac adverse events (MACE)

at long term follow up.<sup>(12)</sup> BMS were mostly used in government hospitals as various government health schemes did not cover DES in the past. They were also used in cases of financial constraints due to their lower cost.<sup>(13)</sup>

Use of 1<sup>st</sup> generation DES decreased by 41% from 62% to 21% while 2<sup>nd</sup> generation stent usage rose by 21% from 38% to 59%. 3<sup>rd</sup> generation stent usage rose by 20% from 0% prior to the regulation. The first-generation DESs were another leap forward compared with BMS, but still had concerns about late stent thrombosis and reduced deliverability with the 140µm strut/polymer thickness. The second-generation DESs were designed to overcome these flaws using for example thinner cobalt-chromium alloys, new cell-cycle inhibitors (everolimus/zotarolimus), and more biocompatible polymers. While the first-generation DES released the drug for a prolonged duration, the release kinetics of the second-generation DES was generally shorter. Various studies have consistently exhibited low MACE rates, target vessel failure, and definite or probable stent thrombosis with the 2<sup>nd</sup> generation DES as compared with first-generation DES. The 3<sup>rd</sup> generation stents further improved the clinical outcomes with even less late stent thrombosis.<sup>(14)</sup>

Usage of stents made in India fell by 19% while imported stents increased by 19% making up 97% of all stents used. This is contrary to the notion that the price regulations may allow Indian stent

makers to claim a larger portion of the market and further cultivate domestic production.<sup>(15)</sup> Two major companies have withdrawn their third-generation high-value DES and a first-generation bio-resorbable stent (BVS). Medtronic filed to remove its Resolute Onyx (DES) stent from the market, while Abbott filed to remove both its Absorb (a first-generation BVS) and Alpine (DES) stents due to financial sustainability concerns. Abbott's Absorb was priced at Rs 190,000 before the cap, whereas Xience Alpine (DES) was priced at Rs 150,000. Boston Scientific has also considered withdrawing its higher-end offerings from the region, due to an expected loss of \$7 million in 2017 as a result of the price capping in India. The implication for patients is decreased overall access to the most innovative and effective types of stents. Multiple RCTs show the safety and efficacy data of different imported DES. Indigenously manufactured Indian DES are mostly first-generation DES and lack such supportive data.<sup>(16)</sup> Although BVS are exempt from price regulation, the newer generation BVS has not made it to the Indian market.

### Conclusion

The use of DES has increased after the coronary price regulation. Also, more third-generation DES which is the gold standard in coronary revascularization is being used compared to before. The use of superior imported stents also saw an increase after the coronary price regulation. There was only a marginal increase in stents used per case. The use of PCI for complex coronary artery disease also increased after the price regulation. Price regulation of medical devices has led to overall benefits for the patient.

**Ethical clearance:** Taken from Institutional Ethics Committee.

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# Study of Coagulation Profile in Iron Deficiency Anaemia in Antenatal Patients and Effect of oral Iron Therapy

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## Abstract

**Background:** Iron deficiency anaemia (IDA) is a quite common factor during pregnancy in under developed countries. It impairs the coagulation factors of the blood and leads to frequency of pre-term labour and low birth weight infants

**Method:** 150 pregnant women having Hb% (gm/dl) less than 10% were compared with 100 normal (controlled) groups. The haematological and coagulation profile in both patients were studied and compared.

**Results:** The haematological parameters Hb%, TLC, DLC, MCV,(fl)MCH (pg) MCHC had significant p value ( $p < 0.001$ ) in both groups comparison. In the study of coagulation profile of both groups comparison except BT (bleeding time) all values were highly significant.

**Conclusion:** The present study will be a tool for physician, gynaecologist to treat such patient efficiently to present morbidity and mortality of mother and infant as well.

**Keywords:** Haematological, Coagulation profile, Hb%, ferritin, antenatal

## Introduction

AS per WHO (world health organisation) anaemia affects approximately 1.5 billion people in the world. The prevalence is very high in Africa, Asia, India, China, Bangladesh however it is also high in developed countries <sup>(1)(2)</sup>.

Anaemia caused by blood loss is because of excessive bleeding in ante partum and in the postpartum period or a problem with blood clotting mechanism. Anaemia can also results from heavy menstrual disorders in adolescent girls and women. Any of these factors will also increase the body's need

for iron because it is needed to make a new RBCs, It takes at least three months to replenish the RBCs, supply back to normal levels, the length of this time is extended with pre-existing iron and other nutrient deficiencies.

During pregnancy Iron balance must be adequate for the production of haemoglobin and myoglobin<sup>(3)</sup>. IDA during pregnancy associated with increased frequency of pre-term labour and low birth weight infants.

Coagulation results from interaction of blood vessel, platelets, coagulation factors, coagulation system

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undergo significant changes in pregnancy. Decline in platelet count may result in pre-eclampsia which may lead to morbidity and mortality to both mother and infant by damaging vital organs like liver and kidney. IDA leads to thrombocytopenia in pregnancy associated with decrease in APTT values, which may cause risk of blood clot<sup>(4)</sup>. Hence coagulation profile and haematological parameters were evaluated and compared in both groups. These variations will help the clinician to treat such patients efficiently to avoid morbidity and mortality.

### Material and Method

150 pregnant women aged between 19 to 35 years regularly visited to ACPM Medical college hospital Dhule, Maharashtra-424001 were studied.

**Inclusive Criteria:** Hb% (gm/dl) less than 10 gm% for iron deficiency in second trimester pregnancy were selected for study.

**Exclusion Criteria:** Third trimester pregnancy, patients already on iron supplementation therapy, immune compromised patients were excluded from study.

**Method:** 150 Iron deficiency patients were compared with 100 normal (controlled) pregnant women.

Every antenatal pregnant patients having less than 10 (gm/dl) were studied and compared in both groups. CBC, Hb%, PT, INR, APTT, BT, CT, serum ferritin, test were conducted in every patients.

Duration of study was January-2021 to June-2022

**Statistical analysis:** Haematological parameters and coagulation profile of both groups were compared by t test and significant results were noted. The statistical analysis was carried out by SPSS software.

### Observation and Results

**Table-1:** Comparison of haematological parameters in both groups

- Hb% (gm/dl) 9.062(±1.26) in Iron deficiency group, (ID group), 12.14 (± 0.96) in controlled group, t test was 21.8 and p<0.001
- TLC - 9358.20 (± 1.26) in ID group, 8678.20 (± 24.4) in controlled group, t test was 208.1 and p<0.001
- DLC - 1766916.5 (± 578) in ID group, 708626.2 (± 147) in controlled group, t test was 150.4 and p<0.001
- MCV (fl)- 79.30 (± 10.55) in ID group, 87.12 (±12.42) in controlled group, t test was 5.17 and p<0.001
- MCH (pg) - 22.12 (± 4.50) in ID group, 29.18 (± 2.96) in controlled group, t test was 14.9 and p<0.001
- MCHC (g/dl)- 28.10 (± 1.90) in ID group, 32.72 (± 2.20) in controlled group, t test was 17.1 and p<0.001

**Table-2:** Comparison of coagulation profile in both groups

- PT - 10.6(± 2.46) in ID group, 13.50 (± 2.10) in controlled group, t test was 9.98 and p<0.001
- INR -0.68(± 0.15) in ID group, 0.98 (± 0.16) in controlled group, t test was 14.8 and p<0.001
- APTT - 29.08(± 3.05) in ID group, 33.35 (± 4.05) in controlled group, t test was 9.42 and p<0.001
- BT - 3.26 (± 1.84) in ID group, 3.38 (± 1.72) in controlled group, t test was 0.52 and p>0.61 (Insignificant p value)
- CT - 7.82 (± 1.92) in ID group, 10.05 (± 3.18) in controlled group, t test was 6.29 and p<0.001
- Ferritin - 7.68 (± 11.7) in ID group, 98.12 (± 52.8) in controlled group, t test was 16.8 and p<0.001

**Table 1: Comparison of haematological parameters in both groups**

Parameters	Mean value (with ±SD) in Iron deficiency (150)	Mean value (with ±SD) controlled group (100)	t test	p value
Hb% (gm/dl)	9.062 (± 1.26)	12.140 (±0.96)	21.8	P<0.001
Total leukocyte count (TLC)	9358.20 (± 26.62)	8678.12 (± 24.40)	208.1	P<0.001

Continue.....

Differential leukocyte count (DLC)	1766916.5 (± 578)	708626.2 (±147)	150.4	P<0.001
MCV (fl) (Mean Capsular volume)	79.30 (± 10.55)	87.12 (± 12.42)	5.17	P<0.001
MCH (pg) (Mean Capsular Haemoglobin)	22.12 (± 4.50)	29.18 (± 2.96)	14.9	P<0.001
MCHC (g/dl) (Mean Cell Haemoglobin Concentration)	28.10 (± 1.90)	32.72 (± 2.20)	17.1	P<0.001

P&lt;0.001 = p value is highly significant

**Table 2: Comparison of coagulation profile both groups**

Parameters	Mean value with SD in Iron deficiency (150)	Mean value controlled group (100)	t test	p value
PT (Prothrombin time)	10.6 (± 2.46)	13.50 (± 2.10)	9.98	p<0.001
INR (International Normalized Ratio)	0.68 (± 0.15)	0.98 (± 0.16)	14.8	p<0.001
APTT (Activated partial Pro-thromboPlastintime)	29.08 (± 4.05)	33.56 (± 4.05)	9.42	P<0.001
BT (Bleeding time)	3.26 (± 1.84)	3.38 (± 1.72)	0.50	p>0.60 Insignificant
CT (Clotting time)	7.82 (± 1.92)	10.05 (± 3.18)	6.24	P<0.001
Ferritin	7.68 (± 11.76)	98.12 (± 52.84)	16.8	P<0.001

Except (Bleeding time) study all parameters have highly significant p value (p&lt;0.001)

### Discussion

Present study of coagulation profile in Iron deficiency anaemia in antenatal patients and effect of oral Iron therapy in Maharashtra population. The Iron deficiency patients were compared with controlled group with haematological parameters viz Hb%, TLC, DLC, MCV (fl), MCH (pg), MCHC (g/dl) and p value was highly significant (p<0.001) (Table-1). The comparative studies of coagulation profile in both groups. The parameters were PT, INR, APTT, BT, CT, Ferritin. Except BT parameters all studies were highly significant (p<0.001) (Table-2). These findings

are more or less in agreement with previous studies (5)(6)(7).

The major signs and symptoms of Iron deficiency anaemia (IDA) in pregnancy can be summarized as fatigue, low physical and mental capacity, headache, vertigo, leg cramps, pagophasia, cold intolerance, koilonychias, mucosal paleness and angular stomatatis. IDA during pregnancy poses number of maternal and foetal problems, including premature birth, Intra-uterine developmental retardation, placental problems, and decrease in new born iron storage, the risk of decrease in maternal blood reserves

during birth and need for transfusion in cases heavy blood loss, cardiac stress. Sick cell crisis, ruptured uterus, trophoblastic disease (chorio-carcinoma), hypovolemic shock, blood transfusion, amniotic fluid embolism, intra uterine death, prolonged hospital stay, decreased maternal breast milk production and maternal depletion of Iron stores during and after the post partum period <sup>(8)(9)</sup>.

IDA may cause injury to endothelial cells exposing the underlying collagen to the plasma and coagulation factors. This may be initiate factor which lead to eclampsia or preeclampsia and sepsis <sup>(10)</sup>.

Anaemia occurs for different reasons these include increased destruction (break down) of RBCS, excess blood loss, (i.e., haemorrhage), inadequate production of RBCS by bone marrow<sup>(11)</sup>. In some case anaemia results from inherited disorder and other causes may include environment such as nutritional problem, malaria infection or exposure to drug or toxin. It frequently occurs during pregnancy. Delivery will have significant risk of further blood loss <sup>(12)</sup>.

It is established fact that 80% pregnant women in developing countries have IDA; severe IDA is dangerous for mother and her baby. IDA could be due to poverty and illiteracy also.

### Summary and Conclusion

The present study illustrates many haematological problems develop during pregnancy due to IDA, can lead to multiple emergencies, which ultimately lead to morbidity and mortality of both mother and foetus. But this study demands further embryological, genetic, nutritional, patho-physiological studies because exact mechanism of coagulation in IDA is still unclear.

**Limitation of study:** Owing to tertiary location of research hospital, less number of patients, lack of latest technique we have limited research results.

This research paper was approved by Ethical committee of ACPM Medical College, Dhule Maharashtra-424001

**Conflict of Interest:** No

**Funding:** Self

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# The Potential Impact of Herbal Galactagogue in India: A Review from Medical Perspective

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## Abstract

The herbal galactagogues is well-known and acknowledged as substitute approach to boost breast milk production by the general population and medical professionals under insufficient milk lactation case in postpartum women. In order to improve breastfeeding performance, this study examines breastfeeding women's viewpoints and attitudes on using herbal galactagogues while nursing and methods of decision-making. Herbs have been used as galactagogues for a very long time, and many commercial formulations have been created employing herbs. The herbal formulations contain a number of active ingredients, including polyphenols, flavonoids, isoflavones, and terpenes, which give the items a disagreeable taste and reduce consumption. Additionally, a few of these active chemicals become unstable in the presence of the environment. In this regard, many strategies can be used to cover the flavour and improve the stability. Both mother and child benefit physiologically and healthily from breastfeeding. However, issues like insufficient milk ejection can interfere with a mother's ability to breastfeed and may lead her to think about opting for galactagogues.

**Keywords:** Herbal, Galactagogues, Lactation, Postpartum, Pharmacological, Endangered Species

## Introduction

Prolactin (PRL) is well known pituitary hormone. It is of 23-kDa. Its requires for beginning and continuation of lactation. It is important in reproduction, growth, osmoregulation, metabolism, immunological processes, brain behaviour. Drug consumption during pregnancy has side effects which affects mother and foetus, results in congenital malformations. As they can trigger uterine contractions that result in miscarriage, an early birth, or harm to the foetus<sup>[1]</sup>. Herbal medicines are put

through various regulations than prescribed drugs under the Dietary Supplement Health and Education Act of 1994. Exclusive nursing requires a minimum of 480 kcal of energy per day, placing metabolic stress on the mother's physiology. The production of breastfeeding to be increased in order for moms to fulfill their responsibility to breastfeed <sup>[2]</sup>. The galactagogues + as examples include increased breastfeeding rates include fennel, papaya, green bean juice, and katuk leaf. One of the galactagogues is papaya leaf contain quercetin, which can stimulate prolactin <sup>[3]</sup>. A group of researchers from Indonesia

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and Malaysia has investigated the administration of papaya leaf to increment the volume of breast milk [4].

Previous evidences says consumption of plants helps infants and mothers beyond milk quality. More than 35,000 plant species and in rural population of our nation uses more than 8,000 herbs, mostly for medicinal purposes. The innate understanding that nature and man are partners in an unbreakable alliance and coexist in the foundation of ancient wisdom [5].

### **The importance of lactation and its general physiology**

Infant and early child nutrition is a key element in improving child survival and development. Lactation promotes development in the first two years of life, lowers mortality and chronic disease. In reality, effective nursing and supplemental feeding could prevent the loss of 220,000 lives each year. The human breast is developed in maturity, to allow milk release to occur after just a short period of hormone stimulation. Oestrogen and progesterone both influence the growth of the tubes and secretory alveoli during pregnancy [6].

### **Rare medicinal plants as potential galactagogue**

#### ***Euphorbia fusiformis* Buch.-Ham.Ex.D.Don**

*Euphorbia fusiformis* Buch.-Ham. Ex. D. Don- a endangered species found in India. Its available in the areas of Uttar Pradesh, Maharashtra, Karnataka, Tamil Nadu, Telangana, Nagar Haveli, Andhra Pradesh and West Bengal. In Karnataka state, Ramanagara district region's Vaidyas use aqueous solution of tuberous root of *E. fusiformis* can help lactating moms produce more milk. The pups' body weight (or growth) was measured and compared to pups who weren't treated, it was discovered that this plant's ethanolic extract had substantial galactagogue activity. Protein and glycogen concentrations in the tissues of the mammary gland was found to be increased as compared to control. Study by Manna et al., observed treatment with ethanolic extract of root showed a significant enhancement of milk secretion. The abundance of phytochemicals like steroids, terpenoids, glycosides and alkaloids are found in plants [7].

#### ***Leptadenis reticulata* (Retz) Wight & Arn**

*L. reticulata* is distributed in the areas of Gujrat, Punjab, the Himalayan ranges, Rajasthan. In India, it grows in Rajasthan, Gujarat, Punjab, the Himalayan ranges, Deccan Plateau, Karnataka, Kerala, Sikkim in India. Figure 1 illustrates its distinctive characteristics, which include revitalising, rejuvenating, and lactogenic effects [8].

Due to excessive exploitation of this herb, it came to brink of extinction. The presence of bioactive compounds like  $\alpha$ -amyryn, ferric acid, luteolin, diosmetin, rutin,  $\beta$ -sitasterol, sigmasterol, hetricontanol, simiarenol, apigenin, reticulum, deniculatin and leptaculin are responsible for therapeutic properties. Increased prostaglandin levels increase the likelihood of miscarriage, but taking this herbal medicine, leptaden, prevents the disease. The amalgamate treatment with progesterone shows lesser benefits as compared to leptaden therapy. It can also be administered if uterine symptoms lead to abortion [8].

#### ***Alstoniascholaris* Linn.**

*Alstoniascholaris* Linn R. Br., (Apocynaceae) is native tropical tree of Indian subcontinent, Australasia and Malay Peninsula [9]. The bark of this plant is employed as bitter astringent and lactogenic component shown in figure 1. The secondary metabolites found are alkaloids, steroids and triterpenoids. Isolated alkaloids includes nareline methyl ether, nareline ethyl ether, 5-epi-nareline ethyl ether, picrinine, scholaricine and scholarine-N(4)oxide, 12- methoxyechitamidine, 19-hydroxytubotaiwine, 19-epischolarine, and 6,7-seco-angustilobine [10]. *A. scholaris* seeds contains hallucinogenic properties, are induced by the presence of alkaloid like alstovenine, venenatine, chlorogenine, reserpine, ditamine and echitamine [10].

#### ***Euphorbia hirta* Linn.**

In Western, Mid-Western, and Eastern parts of Nigeria; Ghana in West Africa, and India, reported the use of *E. hirta* to treat jaundice, hypertension, anaemia and malaria, cough, asthma, and anti-fertility. The plant has been reported to be used in aphrodisiac, to facilitate childbirth by traditional birth attendants, and induce lactation as a galactagogue [11]. Studies

done by Koko et al., 2019 found that dosage of 200 mg/kg in animal model produced  $39.38 \pm 1.5$ g of milk as compared to control which was  $28.05 \pm 0.57$  g.

Enhancement of the lobuloalveolar system is another way to see the galactagogue activity. These rats received different doses of *E.hirta* aqueous extract (EHae). The rat's lobuloalveolar system developed as a result of the administration of 200 mg/kg of EHae<sup>[12]</sup>.

### *Fritillaria cirrhosa* D. Don

*F. cirrhosa* D. Don is a perennial herb belongs to the group Astavarga<sup>[13]</sup>. Astavarga is a collection of 8 therapeutic plants that are used in Himalayan traditional medicine (TMK). It belongs from the family of Liliaceae and critically endangered species<sup>[14]</sup>. It has ability to cure haematemesis, tuberculosis and rheumatism and to decrease pain in pregnant woman. It also has unique properties like refrigerant, diuretic, galactagogue, and aphrodisiac shown in figure 1<sup>[15]</sup>.

### Some medicinal plants as potential galactagogue

#### *Trigonella foenum graecum* Linn.

Fenugreek is a typical leguminous herb cultivated in India (*Trigonella foenum-graecum*). Fenugreek seeds are a great supply of galactamannan. The following bioactive substances are present: diosgenin, trigonellin, and galactomannan<sup>[16]</sup>. Pharmacological characteristics include galactagogic, antidiabetic, hypolipidemic, carminative, and gastric stimulant action<sup>[17]</sup>.

In previous studies, observed that production of breast milk within first two weeks of postpartum<sup>[18]</sup>. An experimentation done by El Sakka et al., provided tea with fenugreek to 66 women, apple tea or no supplement to placebo or control. In result they found mean volume of milk got doubled (73 ml) in fenugreek group than placebo (39 ml) and control (31 ml)<sup>[19]</sup>.

#### *Gossypium haebaceum* Linn.

*Gossypium* is one of the significant member of Malveaceae family. It is used to make food and medication. As effective painkillers and cotton are both used. The feeding of cotton seeds to buffaloes increases milk output compared to commercial mixtures (significance  $P < 0.01$ )<sup>[20]</sup>.

#### *Moringa oleifera* Lam.

*M. oleifera* Lam. is a deciduous tree with sparse foliage<sup>[21]</sup>. In the experimentation of Raguindinet

al., found significant increment in milk production in 6 randomised controlled trials induced by *M. oleifera*. This study inferences two things 1) increase in prolactin levels 2) improvement in infant's weights. Various studies found that *M.oleifera* has no toxicity or side effects over mother or infants. In previous studies it was noted that patients induced with *Moringa* has eminent level of prolactin  $19.5 \cdot 10^2$  mIU/L. This experimentation hypothesised that *Moringa* induces production of prolactin in the anterior pituitary gland<sup>[22]</sup>.

#### *Carica papaya* leaf

Quercetin present is one of the bioactive compound in papaya leaves and results in increment of breast milk shown in figure 1. This characteristic makes its natural galactagogue<sup>[23]</sup>. According to Herawati et al., leaves have a significant impact on the expression of the prlr gene, which increases the number of breast alveoli. The ethanol extract of *C. papaya* leaves in this research affected 81.5% of the breast alveoli in mice, increasing milk production<sup>[24]</sup>. Other plants employed as natural galactagogue are shown in Table 2.

Table 1: Some common herbal galactagogue

Plants	Reference
<i>Nigella sativa</i> L.	[25]
<i>Asparagus racemosus</i> Willd.	[26]
<i>Ipomoea digilata</i> Linn	[27]
<i>Lipidium sativum</i> L.	[28]
<i>Foeniculum vulgare</i> Mill	[29]
<i>Silybum marianum</i> (L.) Gaertn.	[30]
<i>Rubus idaeus</i> L.	[31]
<i>Cnicus benedictus</i> L.	[31]

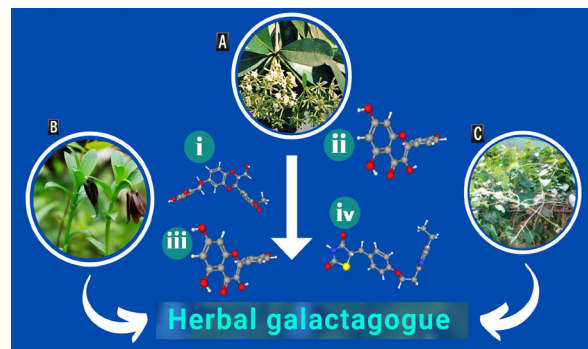


Figure 1: Herbal galactagogues (A) Flower of *Alstoniaschloasis* (L.) (Bhandary et al., 2020) (B) *Fritillaria cirrhosa* D. Don (<https://>

eol.org/pages/1088491 national museum of natural history (Smithsonian) (C) Creepers of *Leptadenisreticulata*(Retz) Wight & Arn (Mohanty et al., 2017) Secondary metabolites as galactagogues (i) Silibinin (ii) Kaempferol (iii) Quercetin (iv) Taxifolin (PubMed)

### Pharmacological galactagogues

In previous studies, during evaluation of galactagogue two major factors are highlighted. Firstly, principles of evidence-based medicine, which consist of blinding, randomisation and placebo control. Terms for selection of patients includes, mothers were feeding through breasts or pumps, infant's age, experience of feeding, etc<sup>[32]</sup>. Secondly, lactation management regulations should be followed.

**Table 2: Commercial galactagogue and its side effects**

Drug	Side Effects	References
Metoclopramide	anxiety, tiredness, nausea, vertigo, headache, hair loss	[33]
Domperidone	cardiac arrhythmia, cardiac arrest	[33]
Sulpiride	sedation, insomnia, restlessness, impaired concentration, weight gain, depression, xerostomia.	[34]

### Things to ponder

Due to numerous side effects and low capability of synthetic drugs, people start seeking alternatives in nature. But many questions come up in people's minds throughout this procedure. These are: 1) the ability of phytochemicals and secondary metabolites, which are recognised as nutritional supplements in breast milk production, to close the knowledge gap. 2) Clinical trials should replace in vitro model testings as the next step in the study. 3) In addition to giving

breastfed infants our undivided attention, immune and anti-inflammatory factors should be considered in study. 4) The study of these galactagogues' toxicity and safety should be given top precedence. 5) Traditional knowledge and oral history should not be disregarded, despite current advances in scientific study.. This helps us to understand the plant usage to improve health especially mothers and our future generations.

### Conclusion

The micro and macronutrients found in plant-based supplements can help lactating women and their babies' wellbeing. Future research should focus on the isolation and discovery of active metabolites to better understand the mechanism of these natural galactagogues. To ensure the administration of these bioactive compounds, the toxicity test of these galactagogues should be treated very seriously.

**Ethical Clearance:** No human or animal samples were taken for this research studies.

**Conflict of Interest:** There is no conflict of interest from the authors.

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## Screening for Autism Spectrum Disorders among 16 Months to 30 Months Old Children in a Tertiary Care Hospital, South India

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### Abstract

**Introduction:** Autism Spectrum Disorders (ASDs) are neuro-developmental disorders characterised by persistent impairment in reciprocal social communication and repetitive patterns of behaviour.

**Objectives:** To screen for ASDs in children aged 16 to 30 months using M-CHAT-F (Modified Checklist for Autism in Toddlers- Follow up) to estimate the prevalence of ASDs and to evaluate the factors associated with ASDs.

**Method:** Children aged 16 to 30 months were randomly screened for ASDs with MCHAT-F. Children who met the DSM-5 diagnostic criteria were labelled autistic and rest was followed up. Two controls for each case were selected randomly among the subjects who were screen negative.

**Results:** Nine hundred and twenty children were screened. Among them, 508(55.2%) children were boys and 412(44.8%) children were girls. Out of the 920 screened, 38(4.1%) children failed M-CHAT. Out of the 38, 12 (1.3%) children continued to fail in M-CHAT/F and were "M-CHAT screen positive". The mean age at diagnosis of ASD was 24±4.6 months. Prevalence of ASD in our setting was 1 in 102 and the male: female ratio was 8:1. The positive predictive value of M-CHAT-F was 75%. The average score on M-CHAT was 6.33 among ASD and 0.5 among control. Males, lack of exclusive breast feeding and excessive screen time were found to be factors associated with ASDs.

**Conclusion:** The prevalence of ASDs is high. The M-CHAT/F is an effective screening instrument for ASDs.

**Keywords:** Autism, MCHAT-F, Screening, Prevalence, Risk factors.

### Introduction

Autism Spectrum Disorders (ASDs) are neuro-developmental disorders characterised by persistent impairment in reciprocal social communication and repetitive patterns of behaviour. These children

have an impaired ability to use and interpret non-verbal behaviors such as eye-to-eye gaze, facial expressions and hence fail to develop peer relationships appropriate to their developmental level that permanently burdens the child and the

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family. These are not rare disorders, instead are more prevalent in the Pediatric population than cancer, diabetes and Down syndrome<sup>1</sup>. The prevalence has risen dramatically over the past few years and is 1 in 88 births presently<sup>2</sup>. Though information about autism is pervasive in the media, children with autism often remain inaccurately diagnosed. Symptoms of autism start appearing in the first year of life but the median age of diagnosis is still past the third birthday<sup>3</sup>. The American Academy of Pediatrics (AAP) recommends autism-specific screening at 18- and 24-month well-child care visits<sup>4</sup>. The purpose of screening children for ASDs comes from evidence gathered over the past 10 years that intensive early intervention results in improved outcomes in most young children with autism, including speech in 75% or more and significant increases in rates of developmental progress and intellectual performance<sup>1,5</sup>. But screening for ASD is not routinely happening in India. The AAP recommends the Modified Checklist for Autism in Toddlers (M-CHAT), a validated 2-stage autism screening tool for routine screening of children aged 16 to 30 months. It contains 23 items with yes or no answers. The child is considered to have failed the initial screening if he/she fails any three of the twenty three items or two of the six critical items. The M-CHAT Follow up (M-CHAT/F)<sup>6</sup> is the second step that gathers additional details about failed responses and reduces the M-CHAT's false-positive rate.

Prenatal and perinatal risk factors for ASDs like parental age, consanguinity, previous abortion, assisted reproductive techniques, prematurity, low birth weight, respiratory distress and formula feeding have been evaluated in developed countries<sup>7-11</sup>. Only one study in India by Madhu P, et al has demonstrated consanguinity as a significant risk factor for ASD<sup>12</sup>.

Hence, this study was designed with the primary objective of screening for ASD in children aged 16 to 30 months and estimating the prevalence of ASD. These objectives were (1) to measure the usefulness of M-CHAT in our setting (2) to evaluate the factors associated with ASDs by a nested case-control study.

### Materials and Methods

This was a prospective observational study done in KAPV Govt. Medical College, Trichy from June 1<sup>st</sup> 2021 to May 31<sup>st</sup> 2022. Children of age 16 months to

30 months attending the Pediatric OPD were randomly enrolled after parental consent. Children with known global developmental delay, neurodegenerative disorders, mental retardation and children whose parents refused consent were excluded. Recent data from the Centre for Disease Control and Prevention (CDC) estimate that an average of 1 in 88 children is affected by an ASD<sup>2</sup>. Based on this prevalence, the sample size was calculated to be 920 for 95% confidence limits, 80 power by Epi-stat calculator considering 10% of attrition.

### Method

Parents were explained briefly about the importance of screening for ASD and M-CHAT forms in English or Tamil (vernacular language) were distributed. Those who did not know to read or write or those who had doubts while filling the MCHAT form were helped by trained staff or doctor. The filled M-CHAT forms were scored by the doctor. Children who failed the M-CHAT were reviewed by the primary investigator with M-CHAT/F by personal interview on the same day and those items which the child failed in the questionnaire were clarified by putting forth specific examples of the child's typical behavior. If the child failed the M-CHAT/F, child was termed as screen positive. Screen positive children were formally assessed by the developmental paediatrician. Children who met the DSM-V diagnostic criteria for ASD were labelled autistic and started on early intervention. Children who were screen positive but did not meet the DSM-V diagnostic criteria were followed up by the developmental paediatrician.

Two controls for each case were selected randomly on the same day among the study subjects who were M-CHAT screen negative. Detailed history was taken from parents of cases and controls by the principal investigator. Male gender of the child, father employed in professional fields, employed mother, consanguinity, advanced maternal age at conception, previous abortions, assisted methods of reproduction, antenatal illnesses, caesarean section, preterm delivery, birth asphyxia, neonatal illnesses, non-exclusive breast feeding and excessive screen time were analysed as probable factors associated with ASD, based on the existing literature.

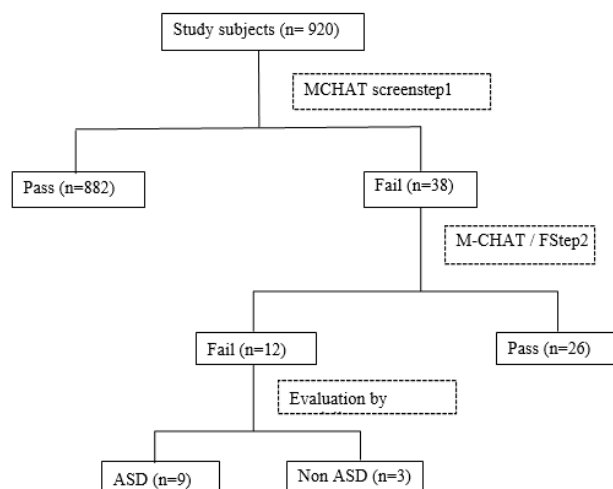
**Excessive screen time:** As per the latest AAP guidelines, presence of any exposure to media (including cell phones, tablets and television) in less than 2 years of age and exposure to such media more than 2 hours in a day, in more than 2 years of age was taken as excessive exposure to screen time<sup>13</sup>.

**Ethical consideration:** Ethical clearance was obtained from the hospital ethics committee and written informed consent was obtained from parents of the children.

**Statistical analysis:** The data was entered in Microsoft excel. The usefulness of M-CHAT in detecting ASDs in our setting was found by arriving at the positive predictive value. The average score of the case group and the control group on M-CHAT questionnaire and the average number of critical items failed was calculated. The probable risk factors among the cases and controls were analyzed with Chi square test. Odds ratio with 95% confidence interval [OR (95% CI)] was arrived at by univariate analysis. The normality of distribution of mother's age at conception of the case group and the control group was evaluated by Shapiro-Wilk test and found to be non- Gaussian. Comparison of median of mother's age between the two groups was done by Mann-Whitney U test. P value of < 0.05 was considered for statistical significance.

## Results

Nine hundred and twenty children of age 16 to 30 months selected randomly from those who attended the Pediatric OPD were enrolled in the study. Among them, 508 (55.2%) children were boys and 412 (44.8%) children were girls. Out of the 920 children screened, 38 (4.1%) children failed M-CHAT and 882 (95.9%) children passed M-CHAT. Out of the 38 children who failed M-CHAT, 12 (1.3%) children continued to fail in M-CHAT/F and were "M-CHAT screen positive", hence referred to the developmental paediatrician. The rest 26 (2.8%) children passed M-CHAT/F and were screen negative. Among the 12 children who were screen positive, 9 (1%) children met the DSM-V diagnostic criteria. They were diagnosed as ASD and referred for early intervention. The rest of the 3 (0.3%) children did not meet the DSM-V diagnostic criteria and were followed up by the developmental paediatrician (fig.1). There was no loss to follow up.

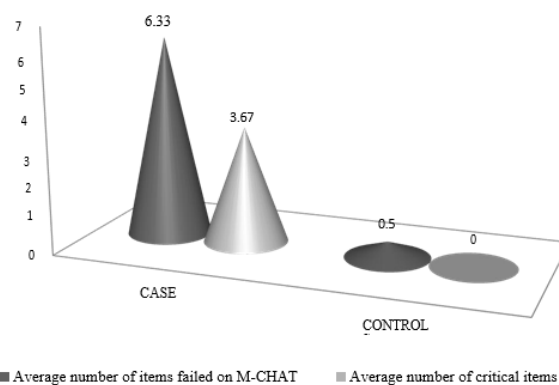


**Fig 1: Flow chart of screen results**

The mean age at diagnosis of ASD was 24±4.6 months. Prevalence of ASD in our setting was 9 in 920 children or 1 in 102. Male: female ratio was 8:1.

**Predictive power of M-CHAT:** Calculation of absolute sensitivity and specificity of M-CHAT cannot be determined until follow-up of the entire initial sample, which has begun, is complete. Follow up of the 908 children who were screen negative was practically not feasible and hence positive predictive value (PPV) of M-CHAT was determined among the screen positives. Among the screen positive, 9 children were diagnosed with ASD, which brings the PPV to 0.75 for M-CHAT with follow up.

**Score on M-CHAT:** The average score on M-CHAT was 6.3±2.6 among the children diagnosed with ASD and 0.5±0.5 among the control group. The average score on the 6 critical items of M-CHAT was 3.67±1.6 among the children diagnosed with ASD, while no child among the control group failed any critical item (Fig.2).



**Fig 2: Average number of items failed in M-CHAT among the cases and controls**

**Factors associated with ASDs:** The distribution of the probable risk factors of ASDs among the cases and the controls is as shown in Table 1.

Sex of the child: The odds of being male sex was 10 times in children with ASDs compared to normal children ( $p=0.02$ ).

**Table 1. Results of comparison of categorical variables between the cases and controls**

Variables		ASD	Non-ASD	ODDS ratio	95%CI		P
					Lower	Upper	
Sex	Male	8	8	10	1.026	97.50	0.02
	Female	1	10				
Consanguinity	Present	2	1	4.86	0.38	62.63	0.19
	Absent	7	17				
Conception	Assisted	2	1	4.87	0.38	62.63	0.19
	Spontaneous	7	17				
Previous abortions	Present	4	2	6.4	0.89	45.99	0.05
	Absent	5	16				
Antenatal risk factors	Present	2	1	4.86	0.38	62.63	0.19
	Absent	7	17				
Delivery	Caesarean	7	7	5.5	0.88	34.46	0.05
	Vaginal	2	11				
Neonatal risk factors	Present	4	4	2.8	0.50	15.66	0.23
	Absent	5	14				
Breast feeding	Non-	6	4	7	1.19	41.36	0.02
	Exclusive	3	14				
Mother's employment	Employed	3	9	0.5	0.10	0.26	0.41
	Home	6	9				
Father's employment	Professional	5	9	1.25	0.25	6.23	0.79
	Non	4	9				
Excessive screen time	Present	8	4	28	2.65	295.71	0.01
	Absent	1	14				

**Maternal age at conception:** The normality of distribution of mother's age at conception of both groups were found to be non-Gaussian. The median maternal age of the cases and the controls was 32 and 28 respectively, the difference was significant ( $p=0.04$ ).

**Breast feeding and ASDs:** The odds of children being not exclusively breastfed was 7 times in children with ASDs compared to normal children ( $p=0.02$ ).

**Screen time and ASDs:** The odds of children having excessive screen time exposure was 28 times in children with ASDs compared to normal children ( $p=0.01$ ).

Comparison of consanguinity ( $p=0.19$ ), previous abortions ( $p=0.05$ ), artificial methods of conception

( $p=0.19$ ), antenatal illnesses ( $p=0.19$ ), caesarean mode of delivery ( $p=0.05$ ), neonatal illnesses ( $p=0.23$ ), mother's employment ( $p=0.41$ ) and father's employment in professional fields ( $p=0.79$ ) were not different between the cases and controls.

## Discussion

Parents fail to recognise the early symptoms of autism and even when there is any developmental concern, it is less often brought to the notice of primary paediatrician which emphasises the need for implementation of regular screening of toddlers for ASDs. A survey completed in 2004 revealed that 44% of pediatricians care for at least 10 children with ASDs; however, only 8% routinely screened for ASDs<sup>14</sup>.

**Early diagnosis:** Colby Chlebowski, et al showed that children screened with the M-CHAT in their study were diagnosed 1 year earlier (mean age at diagnosis of 25 months) than the current median age at diagnosis in the United States<sup>15</sup>. These results are comparable to the mean age at diagnosis of ASD in our study which is 24 months. This is an important finding of the study suggesting that implementing standardized screening for ASD will give them the benefit of early intervention.

**Prevalence of ASDs:** Prevalence of ASD in our setting was 1 in 102. The most recent data from the CDC estimate that an average of 1 in 88 children is affected by an ASD<sup>2</sup>. However, the CDC's prevalence data were ascertained on the basis of review of health records for 8-year-old children, and it is not expected that all ASD cases will be detectable in toddlers.

**Predictive power of M-CHAT:** The positive predictive value (PPV) of M-CHAT when used as a single step process was 0.24. The follow up interview raises the PPV to 0.75. Colby Chlebowski, et al study yielded a PPV of 0.06 for M-CHAT as a one step process and completing the M-CHAT/F yielded a PPV for identifying ASD of 0.54<sup>15</sup>. It would not be feasible to develop a screening instrument with a high sensitivity for ASD due to symptom overlap between diagnoses and heterogeneity of symptoms in ASD. Therefore, administering a checklist with acceptable PPV, as standard practice in screening toddlers will improve the early detection of ASD.

**Score on M-CHAT:** The average score on M-CHAT was 6.33 among the children diagnosed with ASD and 0.5 among the control group and no child in the control group failed any critical item. Robins DL, et al in their study screened 1293 children for ASDs and children who were diagnosed with ASD in their study failed an average of 10.3 items, which is higher than our study while the screen negative children's average score was 0.5 similar to our study.

**Factors associated with ASDs:** Despite the fact that the number of ASD cases in our study is less ( $n = 9$ ), a nested case-control study with 1:2 ratio of cases and controls was performed and the probable factors associated with ASDs were analysed.

**Sex of the child:** The prevalence of ASDs in previous studies was always found to be higher

in boys than girls with a male: female ratio of 4:12. Correspondingly male sex was a significant factor associated with ASD in our study

**Maternal age at conception:** Systematic review by Alexander Kolevzon, et al showed that advanced maternal age was associated with risk of autism 7 before controlling for potential confounders. Maternal age an independent risk factor after adjusting for other variables. Our study also shows maternal age as an associated factor.

**Breast feeding and ASDs:** Lack of breastfeeding in the first 6 months of life was an associated factor in our study, which is similar to the existing literature. Schultz, et al showed that children who were never breastfed were more likely to develop ASDs (OR=2.48,  $P < .001$ ) and children who used formula without DHA/ARA were more likely to have ASDs (OR=4.41,  $P = .022$ ) (11).

**Screen time and ASDs:** Philips et al., have reported that radiofrequency radiations emitted from electronic gadgets can induce significant changes in the molecular repair mechanisms. Some of the observed effects of exposure to radiofrequency waves include cognitive impairment and memory deficit, both of which are seen in autism. There is not much of literature on the association between excessive exposure to electronic gadgets and ASDs. It is interesting that in our study, there was significant association between excessive screen time exposure and ASDs ( $p = 0.01$ ). This warrants future research in this area with the fact that exposure to these media is alarmingly rising in young children.

In our study there was no significant association for ASD with other prenatal factors. This is in contrast to the existing literature. Madhu P, et al showed a risk factor of 3.22 ( $p < 0.0001$ ) for ASD when parents are consanguineous<sup>12</sup>.

## Conclusion

This study has shown the importance of screening toddlers for ASDs facilitating early diagnosis and intervention which is crucial for good outcome. The M-CHAT is an effective screening instrument for ASDs. The PPV for M-CHAT is higher when the two step screening process is used. Hence, M-CHAT should be used along with the M-CHAT/F. Male

sex, elderly maternal age at conception, absence of exclusive breast feeding in the first 6 months of life and excessive screen time have shown association with ASDs and warrant further studies in a larger sample.

**Source of funding:** Nil

**Conflict of Interests:** Nil

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# An Uncommon Cause of Upper Gastrointestinal Bleeding: A Case Report of Mallory: Weiss Tear

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## Abstract

Mallory-Weiss tear refers to a condition in which the lining of the esophagus tears due to excessive strain, resulting in bleeding. This condition is commonly caused by vomiting or retching and can lead to significant complications if not promptly treated. Early identification and management of Mallory-Weiss tear are critical for the prevention of further damage and the promotion of optimal patient outcomes. Clinicians should maintain a high index of suspicion for this condition in patients with a history of retching or vomiting and prioritize appropriate diagnostic and therapeutic interventions to minimize the risk of adverse outcomes.

**Keywords:** Mallory - Weiss Tear, Esophagus tears, Gastroesophageal reflux disease.

## Introduction

Mallory-Weiss tear is a medical condition that refers to a tear or rupture in the lining of the esophagus or stomach. It usually occurs as a result of excessive vomiting, coughing, or straining, and can cause symptoms such as severe abdominal pain, vomiting blood, and black, tarry stools. The condition is named after two doctors, Kenneth Mallory and Soma Weiss, who first described the tear in 1929. While Mallory-Weiss tears can often heal on their own, in severe cases, medical intervention may be necessary to prevent complications such as bleeding, infection, or perforation of the esophagus or stomach.<sup>1</sup>

Excessive alcohol use is regarded as one of the most major risk factors, with around 50% to 70% of people diagnosed with Mallory-Weiss syndrome having a history of the condition. The severity of

upper GI bleeding in Mallory-Weiss syndrome is also known to be greater when portal hypertension and esophageal varices are present.<sup>2</sup>

Additional risk factors are bulimia nervosa, hyperemesis gravidarum, and gastroesophageal reflux disease (GERD). All of these disorders entail reflux of stomach contents into the oesophagus. Nevertheless, none of the above-mentioned risk factors were found in a significant proportion of patients (approximately 25% of cases).<sup>3</sup>

The syndrome is caused by recurrent actions of a rapid increase in intraabdominal pressure, which including retching, vomiting, straining, coughing, cardiopulmonary resuscitation (CPR), or abrupt abdominal injuries.<sup>2</sup> A Mallory-Weiss tear refers to a tear in the mucous membrane lining of the lower esophagus or upper stomach. The tear is usually

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caused by forceful or prolonged vomiting, coughing, or straining, which increases the pressure in the abdominal cavity and can result in a partial or full-thickness tear.<sup>4</sup>

The pathophysiology of a Mallory-Weiss tear involves the following sequence of events:

**Increased intragastric pressure:** An increase in the pressure inside the stomach due to forceful vomiting, coughing, or straining can lead to a sudden increase in the pressure within the lower esophagus and upper stomach.

**Shearing force on the mucosa:** The sudden increase in pressure causes a shearing force on the mucous membrane lining the lower esophagus and upper stomach, leading to a tear or laceration.<sup>5</sup>

**Blood vessel rupture:** The tear or laceration may involve blood vessels in the submucosal layer, leading to bleeding.

**Contraction of muscles:** The bleeding can stimulate the contraction of the muscles in the area, which can cause further tearing and exacerbate the bleeding.

**Activation of coagulation cascade:** The exposure of submucosal blood vessels to the bloodstream can trigger the coagulation cascade, leading to the formation of a clot and the cessation of bleeding in some cases.<sup>6</sup>

The severity of a Mallory-Weiss tear can range from mild bleeding to life-threatening hemorrhage, depending on the depth and extent of the tear and the presence of underlying conditions that may impair blood clotting or increase the risk of bleeding. Treatment typically involves supportive measures, such as fluid resuscitation, blood transfusion, and endoscopic therapy to control bleeding and promote healing.<sup>7</sup>

**Prevalence:** A study published in the American Journal of Gastroenterology in 2020 found that the prevalence of Mallory-Weiss tear in the United States was 2.2 cases per 100,000 persons per year.<sup>8</sup>

**Diagnosis:** The diagnosis of Mallory-Weiss tear is usually made using upper endoscopy, a procedure in which a flexible tube with a camera is inserted through the mouth and into the esophagus and

stomach. However, a study published in the Journal of Gastrointestinal and Liver Diseases in 2021 found that endoscopy may not always be necessary for the diagnosis, and that other tests such as esophageal manometry and pH monitoring can also be useful.

**Treatment:** The treatment of Mallory-Weiss tear typically involves supportive care such as intravenous fluids and blood transfusions if necessary. In some cases, endoscopic therapy such as injection of epinephrine or placement of clips may be necessary to stop bleeding. A study published in Gastrointestinal Endoscopy in 2021 found that endoscopic therapy was effective in treating Mallory-Weiss tear, with a success rate of 88%.<sup>9</sup>

**Prognosis:** The prognosis of Mallory-Weiss tear is generally good, with most patients recovering within a few days to a week. However, in rare cases, complications such as aspiration pneumonia or esophageal stricture may occur. A study published in the World Journal of Gastroenterology in 2020 found that the mortality rate from Mallory-Weiss tear was 0.04%.<sup>10</sup>

## Case Report

A 77 years old female patient came with complaint of coffee colored vomiting in the last one day, also she had a past medical history of Mallory Weiss Tear, Parkinson's Disease with Dementia and was also bed ridden from last 3 years. While admitting to the emergency department patient was hemodynamically stable and was managed with IV fluids, Pantop infusion and other supportive therapy. All the reports (i.e., blood, coagulation profile, serology, LFT, KFT) were normal. X-ray of chest was also normal. Ultrasonography of whole abdomen was done and suggested for hepatic cyst. Patient denied for melena and hematemesis.

Patients' vitals were normal and on ultrasound whole abdomen report, observations found were: poor acoustic window due to excessive bowel gas and also compromised study as patient was unable to hold the breath. A cystic SOL (space occupying lesions) were found at the right lobe in the liver of size 2.7 x 2.9 cm. Upper gastro-intestinal endoscopy report showed Mallory Weiss Tear in the Gastro-oesophageal junction with no visible vessel or active bleeding.

Patient was treated with medications Tab Pantoprazole 40 OD, Syp. Sucralfate 2 tsp BD, Tab Rasagiline 1 mg OD was prescribed to treat Parkinson's disease, Tab Levodopa (100mg) + Carbidopa(25mg) TDS, Tab Donepezil + Memantine 5mg OD HS. Syrup Lactulose was prescribed for constipation.

Patient was advised to continue with liquid oral diet and also monitor the vitals continuously. Later on, patient was also diagnosed with Syrup Potklor 15ml TDS. Antibiotic i.e., Inj. Ofloxacin 200mg was also prescribed to the patient during her hospital stay.

During discharge, patient was hemodynamically stable with no episodes of melena, and hematemesis with stable stool episodes. Patient was prescribed with antibiotics like tablet ofloxacin 200mg 1 tablet twice in a day for 5 days, tablet metronidazole 400mg 1 tablet twice in a day for 5 days, proton pump inhibitor like tablet pantoprazole 40mg 1 tablet twice in a day before meals to continue, syp sucral-o suspension (combination of sucralfate + oxetacaine) 2 tsf twice daily to continue, tab syndopa plus (combination of levodopa (100mg) and carbidopa (25mg)) 1 tablet OD daily, tab amantadine 100mg- 1 tablet OD daily for parkinson's disease, tab Donep-M (combination of Donepezil(5 mg)+ Memantine (5mg)) 1 tablet HS, tab Thyroxine 100mcg 1 tablet OD before breakfast, tab Verapamil 40mg 1 tab three times daily, tab rabeprazole 20mg 1 tablet once daily, tab Ursodeoxycholic acid 150mg 1 tablet three times a day, tab tramadol 50 mg 1 tab thrice daily, tab alprazolam 0.25mg OD at bedtime.

Patient was also advised for Foley's catheter in situ (from hospital) and to get it change after every 1 week. Follow-up to be done after 2 weeks.

### Discussion

This patient is 77 years old female having Parkinson's disease and Dementia and also bed ridden. Since one day patient was having coffee colored vomiting. And then admitted to the emergency department of the hospital. On the first day patient's vitals were monitored and was given antacid, Syrup sucralfate suspension, Levodopa and carbidopa, Rasagiline (drugs for Parkinson's Disease), injection cefotaxime 1gm twice in a

day, later on second day antibiotic changed to ceftizoxime and also vomiting was stopped. Patient was on the oral liquid diet and syrup Duphalac oral solution was started. On the third day syrup Potklor was added in the therapy and also all the vitals were stable. On the fourth day patient was advised for the USG and in that Hepatic cyst was observed and was continued with the liquid diet; also injection ofloxacin 200 mg was added. On the sixth day patient was discharged with medications including antacids, antibiotics, sucralfate suspension, anti-parkinsonian drugs, anti-anginal, tab thyroxine, analgesic, tab Ursodeoxycholic acid, benzodiazepines. Patient was hemodynamically stable during the discharge and also advised to review in the OPD after 10 days.

### Conclusion

Patient was diagnosed with Mallory Weiss Tear due to Erosive Antral gastritis. Admitted to the emergency department with complaint of coffee colored vomiting and Parkinson's Disease and Dementia. On USG it showed a cystic SOL. Patients vitals were hemodynamically stable during admission. Patient was further treated with antacids, medications for Parkinson's Disease and Dementia, antibiotics, suspension. Mallory Weiss Tear mostly caused by continuous vomiting with coughing, hematemesis. In some cases, this leads to severe internal bleeding. If this is not treated, it may lead to shock and then death.

**Conflict of Interest:** None.

**Source of Funding:** Self Funding.

**Ethical Clearance:** Not required as no intervention done in patient treatment.

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# The Relationships of Paranormal Beliefs and Locus of Control among Students of Medical College, Delhi

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## Abstract

**Background:** The phenomenon of Paranormal beliefs has puzzled scientific community. Studies on this subject have been hindered by conceptual and methodological issues. There is little evidences found between locus of control and paranormal. This constituted rationale of current study. We studied relationships between paranormal beliefs, as measured by Paranormal Belief Scale (Tobacyk& Milford, 1983) and locus of control as measured by ROT-IE scale among medical students of Delhi.

**Methodology:** The study population consists of medical undergraduate students in Delhi who were enrolled at college during the time of the study. All undergraduate students who gave consent were included in study. A pre-tested and predesigned questionnaire asking their socio-demographic information and relationship between their sense of personal control(locus of control measured by the ROT-IE scale) and paranormal beliefs(using revised form of the Paranormal Belief Scale) was administered. Chi-square test and Pearson's correlation test were used to test significance

**Results:** Means and standard deviations for the PBS-R and the IELOC Scales were reported separately for socio-demographic parameters. Females scored higher than males on all subscale except extraordinary life forms and precognition but it was statistically significant. Bi-variate correlation between locus of control and revised paranormal belief scale revealed that as persons tend towards internal locus of control, their paranormal belief become low.

**Conclusion:** In our study it was shown that there was significant relationships among paranormal beliefs and locus of control.

**Key words:** Locus of control, paranormal beliefs, medical students, India

## Introduction

The term paranormal is used to describe phenomena, which violate basic limiting principles

of science. Paranormal belief can be defined as, "a proposition that has not been empirically attested to the satisfaction of the scientific establishment but

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is generated within the non-scientific community and extensively endorsed by people who might normally be expected by their society to be capable of rational thought and reality testing<sup>1</sup>. Tobacyk and Milford (1983) identified seven relatively independent dimensions of paranormal belief (traditional religious beliefs, psi beliefs, witchcraft, superstition, spiritualism, extraordinary life forms, and precognition) and constructed a Paranormal Belief Scale which provides a separate score for degree of belief in each of these seven dimensions<sup>2</sup>. Early studies into paranormal beliefs rendered most negative view on believers, emphasising deficiencies in intelligence, education and personality. However, these early studies tended to focus on simple superstitions compared with the recent research focus on more complex and sophisticated phenomena such as psychokinesis and precognition<sup>3</sup>.

Two areas that have received a lot of attention in relation to paranormal beliefs have been locus of control and psychopathology<sup>4,5</sup>. The connection between paranormal beliefs and feelings of control were proposed as far back as the 1940's by Malinowski (1948), with these beliefs serving as a kind of illusion of control. (Langer, 1975)<sup>6</sup>.

Early research had shown that there was a relationship between more external locus of control and greater belief in paranormal phenomena. On one hand in uninvolved and uncommitted college students greater belief in the paranormal was related to external locus of control whereas in actively involved students such as readers of psychic books greater belief in the paranormal was related to internal locus of control<sup>1</sup>.

Paranormal beliefs are fascinating phenomena. As this phenomenon has puzzled the scientific community, investigation of individual differences in the belief in the paranormal has been a prominent avenue to inquire. Studies on this subject have been hindered by conceptual and methodological issues, making the available findings for most part uninterpretable and inconclusive. Also little evidences are found about the possible relationships between locus of control and paranormal beliefs in medical college students and this constituted the rationale of the current study.

We studied relationships between paranormal beliefs, as measured by Paranormal Belief Scale (Tobacyk & Milford, 1983) and locus of control as measured by the ROT-IE scale (7,8). The goal of this study was to assess relationship between locus of control and the belief in paranormal of students of a medical college.

## Material and Methods

**Participants:** The study population consists of all medical undergraduate students in Delhi who were enrolled at college during time of study August to September 2020 from first to final year.

## Methodology

The study was conducted in classroom settings. Subjects were approached at beginning of class and asked to participate in study. Participation was voluntary, and subjects willing to participate were given enough time to fill the forms. They were instructed to read directions of each scale carefully and respond to all items anonymously and to seek assistance if necessary.

## Study tool

After obtaining ethical committee approval, study recruited students who were willing to participate. After obtaining written informed consent from all participants a pre-tested and predesigned questionnaire consisting of socio-demographic information, their astrological and paranormal beliefs was administered. The participants were administered revised form of Paranormal Belief Scale and Internal- External Locus of Control Scale.

**Revised Paranormal Belief Scale (RPBS)** by Tobacyk (1988) was used to study their paranormal beliefs. It is a 26-item scale which provides a result on seven dimensions of paranormal beliefs: Traditional religious belief, Psi, Witchcraft, Superstition, Spiritualism, Extraordinary life forms and Precognition. The responses are scored on a seven-point Likert scale. Higher rating indicates stronger endorsement on all but one item from the Psi subscale (question 23) which in turn needs to be negatively scored. The sum of all items is indicative of a general tendency to adopt paranormal belief, while subscales can be used to measure specific dimensions of paranormal belief<sup>7</sup>.

The locus of control scale consists of degree to which people report a sense of personal control in daily experiences. It is a 20 item questionnaire to measure extent to which individuals believe they have ability to control what happens to them (internal) or how much they think that forces beyond their control affect their situation (external). Thus, individuals with an internal locus of control believed that events are product of their own behaviors, while individuals with an external locus of control believed that events are product of chance, luck, or influence of other people<sup>8</sup>.

## Results

A cross-sectional study was conducted among 179 students in a Government Medical College, located in New Delhi to assess relationship between locus of control and their belief in paranormal events.

Of total 179 students, there were 57(31.8%) females and 122(68.2%) males in the study with mean age of 20.23(+/- 1.65).Majority of participants belong to Hindu religion 169(94%) and general category(61.6%),133(74.4%) fathers of respondent have at least college education while 112(62.7%) mothers of participants had college education. Majority were from nuclear family 132 (73.3%).

When asked about their belief in science of astrology,77 % of students didn't believe in astrology and 77.8% didn't think that it has scientific basis. About 84% of student thought that education of a person has nothing to do their belief in astrology and 90.2% believed that financial status also has no impact on their astrology belief.

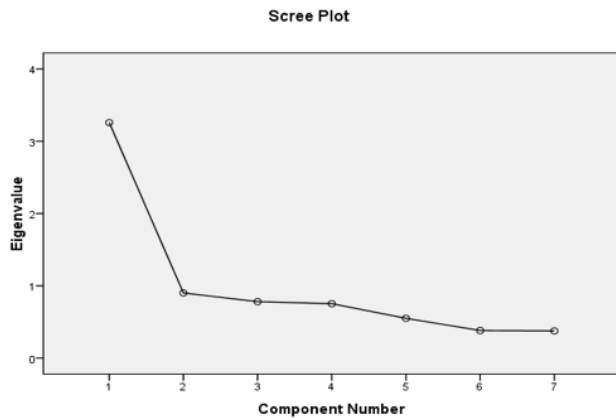
Means and standard deviations for PBS-R and IELOC Scales were reported separately for gender, caste, religion, nativity (urban, rural), education of parents and family type. Females scored higher than males on all subscale except extraordinary life forms and precognition but it was statistically significant. Education of father was significantly associated with Traditional religious beliefs, Psi and Precognition. Education of mother was significantly associated with Psi and Precognition. Religion was significantly associated with Extra ordinary life forms and caste of participants as significantly associated with witch craft.

On showing relation between locus of control scoring with respect to socio demographic characters like gender, caste, religion, parents education, family type (nuclear or joint) and nativity (Urban or rural)it was reported that no participant showed very strong and any external locus of control with any socio demographic variables. There were 53 participants who showed both external and internal locus of control with variables while there were 104 and 27 participants that reported internal locus and very strong internal locus with socio demographic characters respectively .Females were having higher scores than males .Participants of general category were having lower score than other categories participants .Hindu religion subjects were having higher scores than subjects of other religion. Subjects with father having school education have higher score and mother with no education have higher locus score. Participants belonging to joint family and those living in urban area were having higher scores,

**Table 1: Intercor relations of revised paranormal belief scale \scores**

	Traditional Religious Belief	Psi	Witch-Craft	Superstition	Spiritualism	Extra Ordinary Life forms	Precognition
Traditional Religious Belief	1	0.22(0.003)	0.49 (0.000)	0.24 (0.001)	0.45 (0.000)	0.27 (0.000)	0.38 (0.000)
Psi		1	0.52 (0.000)	0.18 (0.016)	0.47 (0.000)	0.28 (0.000)	0.41 (0.000)
Witch-Craft			1	0.29 (0.000)	0.59 (0.000)	0.36 (0.000)	0.54 (0.000)
Superstition				1	0.22 (0.003)	0.59 (0.036)	0.25 (0.001)
Spiritualism					1	0.47 (0.000)	0.55 (0.000)
Extra Ordinary Life forms							0.26 (0.000)
Precognition							1

To examine the relationships among paranormal beliefs scores intercorrelations among global and subscale scores of related devices were computed by Pearson correlation technique. As seen in table 1 there is significant correlation between all variables to each other.



**Fig1: Figure showing component correlation of PBS-R**

We have tested component correlation of PBS-R by Bartlett’s of sphericity which comes out to be 348.8(0.000) which indicated that correlation is highly significant among the components. So we can apply factor analysis. After applying factor analysis i.e. principal component analysis to PBS-R item extracted 1 factor at default which is explaining total 47% of variance .Since there is only 1 component extracted we can’t apply rotation rotation method.

**Reliabilities and factorial validities**

Internal consistencies “Cronbach a” of the PBS-R and IELOC Scales were 0.811 and 0.376 respectively and the split-half “Spearman-Brown reliabilities were 0.780 and 0.717 respectively.

**Table 2: Table showing bivariate correlation between locus of control and revised paranormal belief scale**

PBS-R	Traditional Religious Belief	Psi	Witch-Craft	Superstition	Spiritualism	Extra Ordinary Life forms	Precognition
Locus of control	-0.007 (0.92)	0.003 (0.96)	-0.127 (0.09)	-0.183* (0.01)	-0.191* (0.01)	0.123 (0.10)	-0.144 (0.05)

Table 2 shows bi variate correlation between locus of control and revised paranormal belief scale revealed that as persons tend towards internal locus of control, their paranormal belief become low. Superstition and spiritualism were significantly correlated with internal locus of control.

**Discussion**

The study was conducted among medical students to find the relationship between their paranormal beliefs and locus of control. Education of father was significantly associated with Traditional religious beliefs, Psi and Precognition. Education of mother was significantly associated with Psi and Precognition. Religion was significantly associated with Extra-ordinary life forms and caste of participants as significantly associated with witch craft.

The internal consistencies and other reliability indices of PBS-R and IELOC Scales were sufficiently high for specific sample as we get “Cronbach alpha” of the PBS-R and IELOC Scales were 0.811 and 0.376

respectively and the split-half “Spearman-Brown reliabilities were 0.780 and 0.717.

In our study females scored higher than males on all subscale except extraordinary life forms and precognition but it was statistically significant. In similar study conducted in Turkish females scored significantly higher than males on the Superstition subscale, and males scored significantly higher than females on the Extraordinary Life Forms subscale<sup>1</sup>. They are higher among women than men and it was supposed that the difference is due to women’s richer fantasy life .Tobacyk and Milford reported higher scores of females on Traditional Religious Belief and Precognition in a USA sample which were dissimilar to the present results but reported more beliefs in Extraordinary Life Forms among males, which was similar to the present results<sup>2</sup>. Moreover Wolfradt reported higher scores of females subscale scores except Traditional Religious Belief and Extraordinary Life Forms in a German sample<sup>9</sup>.

The major point of our study was to find out relationship between paranormal beliefs and locus of control. Related to this aim, inter correlations among scales and subscales were computed. Bivariate correlation between locus of control and revised paranormal belief scale revealed that as persons tend towards internal locus of control, their paranormal belief become low. Superstition and spiritualism were significantly correlated with locus of control. As seen in Table 4, small but significant correlations between the global scores of the PBS-R and the IELOC Scales were found as expected. These findings supported previous research reporting correlations between paranormal beliefs and locus of control (Tobacyk & Milford, 1983; Scheidt, 1973)<sup>2,10</sup>. Upon suggestions of previous researchers (Davies & Kirkby, 1985; Tobacyk et al., 1988) about utility of multidimensional conceptualization, inter correlations among the subscales of the PBS-R and IELOC Scales were examined<sup>5,10</sup>. All paranormal subscales were significantly correlated with global locus of control. Tobacyk and Milford (1983) reported a significant correlation only between Extraordinary Life Forms and locus of control. There were significant positive inter correlations among subscales of the two scales<sup>2</sup>. Traditional Religious Belief and Witchcraft with Unjust World, Personal Control, Chance and Fate; Precognition and Psi and Superstition with all subscales except Interpersonal Control; Spiritualism with Chance and fate; Extraordinary Life Forms with Chance and fate, and Control in Achievement Situations (Table 2) These findings were not comparable with Davies & Kirkby (1985) and Tobacyk et al's (1988) studies because they used Sphere of Control Scale to measure locus of control<sup>5,11</sup>.

**Limitation:** Our study was done among medical students of a metro city of a lower middle income country. But there is a need for further research that can focus on finding relation between paranormal beliefs and personality of non-medical as well as medical students of second and third tier cities.

### Conclusion

In the present study it was shown that there were significant relationships among paranormal beliefs and locus of control in an Indian medical students. It was also shown that there were differential

relationships among the various dimensions depending on factor analyses of paranormal beliefs and locus of control scales and between those dimensions.

However, there is a need for further researches following on these preliminary results that focus on those multidimensional relationships more closely with more improved measurement devices with balanced samples of genders and other than college students. Moreover if there is a relationship between having paranormal beliefs and an external locus of control in real life behind those low level correlations or in other words if there is real significance behind those statistical significances this should be reconsidered in light of the preliminary impressions held by Snyder stated in special issue of Journal of Social and Clinical Psychology<sup>12</sup>.

Bizarre behavior often reflects the inability of people to meet their needs such as to be protected attended listened to and being in connection with others. Finally an early and perhaps immature speculation might be such that persons who have an external locus of control based on their history of reinforcement or have a less perceived control may attempt to gain some kind of control over their lives by having bizarre behavior and/or complementary paranormal beliefs in absence of normal or adaptive means of control but with a cost that makes them appear psychopathological.

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# A Prospective Study on Surgical Management of Closed Distal End Femoral Fracture in Adults Using Distal Femur Locking Compression Plate

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## Abstract

**Background:** Distal Femur fractures are a highly incident complex case and pose a challenge to the treating orthopedician.

**Aims and Objectives:** The aims and objectives of this study were to To assess radiological union of distal femoral fractures by open reduction and internal fixation with locking compression plate, To study the functional outcome for internal fixation of fractures of the distal end femur by Locking Compression Plate and To evaluate the effectiveness and complications of distal end femur fractures treated with Locking Compression Plate based on, time till union, rate of infection, and fixation failures, functional outcome using NEER'S SCORE.

**Materials and Methods:** The Present study was done from April 2017 to April 2018 which comprised of fifteen patients with closed Distal end Femoral Fractures who were treated by Locking Compression plate. Overall final outcome was assessed in terms of radiological union, clinical assessment and regaining the lost knee function using NEER'S Score.

**Results:** Out of 15 patients, 12 patients were males and 3 patients were females. Out of 15 patients, 14 were due to RTA. Maximum number of cases was of Muller type C2-60%. Internal fixation was considered after patients general and medical condition was stabilized. The average operative time was 90 minutes. The size of plate was selected based on the type of fracture. 6 to 10 hole plate were used most commonly. Of 15 patients, 10(66.66%) showed radiological union within 16 weeks. 9 (60%) of the patients achieved weight bearing at the end of 14 weeks. Average flexion in this study was 100 degree with more than 3 (20%) patients having knee range of motion more than 110 degree. 1 Patient had stiff knee. More than 80% patients were extensor lag less than 5 degree. 2 patients had **VARUS MALALIGNMENT** out of 15 patients. Results according to NEER'S SCORE were Excellent in 20% patients, Good in 60%, Satisfactory in 6.6% and unsatisfactory in 13.3% patients. 2 patients had superficial infection and 1 patient had delayed union.

**Conclusion:** Locking compression plate is an optimal tool for Distal end femoral fractures. It provides rigid fixation in the region of femur, where a wide canal, thin cortices and frequently poor bone stock make fixation difficult.

**Keywords:** Distal Femur Fracture, Locking Compression Plate, Distal Femur, RTA.

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## Introduction

The incidence of distal femur fractures is approximately 37 per 1,00,000 person-years.<sup>1</sup> About 4% to 6% of all femoral fractures occur in the distal femur. Distal femur fractures shows bimodal distribution age of patients with younger patient being male compared to female. Distal femoral fractures mainly occur from two different injury mechanisms. They are often caused by high energy trauma mainly sustained in road traffic accidents. Open injuries with considerable comminution of condyles and metaphysis are frequently seen, as is low energy trauma, relating to elderly patients with severe osteoporosis. In high-energy trauma, the problem of restoring the function in a destroyed knee joint persists. Complex knee ligament injuries frequently occur additionally to extensive cartilage injuries. In elderly patients, extreme osteoporosis represents a particular problem for anchoring the implant.<sup>2</sup> Treatment options include conservative and surgical management. Conservative management may result in serious complications such as knee stiffness, inadequate alignment, delayed union or non-union, prolonged hospitalization and related morbidity<sup>3</sup>. To achieve functional rehabilitation of the limb, surgical treatment should be performed to achieve complete anatomic restoration of the joint surface, adequate anatomical alignment, stable and rigid fixation without external immobilization to allow early mobilisation<sup>4,5,6,7</sup>. Most surgeons agree that distal femur fractures need to be treated operatively to achieve optimal patient outcomes. Although good internal fixation results have already been reported with these fractures, over 30 years ago the number of revisions for non union, loss of reduction and implant failure has been high. The options for operative treatment are traditional plating techniques that require compression of the implant to the femoral shaft (blade plate, Dynamic Condylar Screw, non-locking condylar buttress plate), antegrade nailing fixation, retro grade nailing, sub muscular locked internal fixation and external fixation. However, as the complexity of fractures needing treatment has changed from simple extra-articular supra-condylar types to inter-condylar and metaphyseal comminuted types, these implants may not be ideal. Double plating, and more recently, locked plating techniques have been advocated. However, with double plating

there is often extensive soft tissue stripping on both sides of the femur, resulting in reduced blood supply and potential non-union and failure of the implants. Earlier most commonly used implant for the fixation of distal femur fractures are Fixed angle devices, usually in the form of Dynamic Condylar Screw (DCS) system, which is a supracondylar plate combined with a lag screw. This two piece device is more forgiving and allows correction in the sagittal plane after the lag screw is inserted.<sup>7, 8</sup> The locking compression plate (LCP) is being used in this study is a combi hole plate which is a single beam construct where the strength of its fixation is equal to the sum of all screw-bone interfaces rather than a single screw's axial stiffness or pullout resistance as seen in unlocked plates. Its unique biomechanical function is based on splinting rather than compression resulting in flexible stabilization, avoidance of stress shielding and induction of callus formation. Further when it is applied via a minimally invasive technique, it allows for prompt healing, lower rates of infection and reduced bone resorption as blood supply is preserved.<sup>9</sup> Internal fixation with locking plates creates a toggle free, fixed angle construct. The introduction of plates with the option of locked screws has provided the means to increase the rigidity of fixation in osteoporotic bone or in the presence of periarticular or juxta-articular fractures with a small epiphyseal segment. The implant offers multiple points of fixed-angle contact between the plate and screws in the distal part of femur, theoretically reducing the tendency for varus collapse that is seen with traditional lateral plates.<sup>10</sup>

Since there have been no published studies focusing specifically on the LCP condylar plate, this study will help us in defining the role of locking compression plate in the treatment of distal femur fractures. The study is justified for the fact that it will be one of the solutions for the age old complications associated with the treatment of supracondylar fractures with traditional fixed angle plates and nails of, postoperative loss of reduction (varus collapse) and malalignment due to their inherent lack of rigidity and in some cases, eventual implant failure. The locking compression plate is based on the firm principles of locked plating, which has really yielded a lot of success in the treatment of fractures over the years.

## Materials and Methods

**Study Site:** Department of Orthopaedics, Deccan College of Medical Sciences, Hyderabad.

**Study Population:** All patients who are above the age of 20-50 years and managed surgically were included in the study admitted from emergency department and Orthopaedic OPD into Department of Orthopaedics, Deccan College of Medical Sciences, Hyderabad.

**Study Design:** This was a Hospital Based Prospective Study.

**Sample Size:** Considering the proportion of subjects with any particular category of functional outcome as %, with 80% power of study and 95% precision, the required sample size would be 15. To account for non-participation, it was decided to include 20 subjects into study.

## Methodology

The following protocol was observed for patients with fracture lower end of femur on arrival.

1. General and systemic examination as well as local examination of the patient.
2. Thorough assessment of patient to rule out head/ chest/ abdominal/ spinal or pelvic injury.
3. Evaluation of patients in terms of:
  - a) age
  - b) Sex
  - c) Mode of trauma
  - d) Period between injury and arrival.
4. Musculo-skeletal examination of patient to rule out associated injuries or fractures.
5. Stabilization of patient with intravenous fluids, oxygen and blood transfusion as and when required.
6. Careful assessment of injured limb as regards to neurovascular status.
7. Primary immobilization of involved limb in skin traction/above knee plaster of paris slab and transport of patient to the Department of Radiodiagnosis in the same.
8. Radiological assessment: Anteroposterior and true lateral views of injured limb

including complete knee joint and distal femur/proximal leg.

### Inclusion Criteria

1. Those patients who are above the age of 20 years to 50 years and managed surgically were included in the study.

### Exclusion Criteria

1. Patients with open distal femoral fractures
2. Patient less than 20 years and more than 50 years with distal femoral fractures were excluded from study.
3. Patients lost in follow - up
4. Patients managed conservatively for other medical reasons.
5. Distal femoral fractures with neurovascular compromise
6. Patients with supracondylar fractures and associated multiple fractures were excluded from the study
7. Polytrauma patients and bilateral fractures who needed the expertise of other super specialities were excluded from the study.
8. Patients who didn't consent for surgery.

### Implant Used:

- The plate and screws were Indian manufactured from 316L stainless alloy with gun drilling technique.
- **LCP combi-holes** in the plate shaft - Intraoperative choice between angular stability and/or compression.

### Statistical Methods:

Data was collected in MS EXCEL and presented as numbers and percentages in the form of tables and figures.

## Results

**TBALE 1: AGE DISTRIBUTION**

AGE IN YEARS	DISTAL END OF FEMUR	%
21-30	3	20%
31-40	6	40%
41-50	6	40%
TOTAL	15	100%

**TABLE 2: GENDER DISTRIBUTIONS**

SEX	DISTAL END FEMUR	%
MALE	12	80%
FEMALE	3	20%
TOTAL	15	100%

**TABLE NO. 3 STUDY RESULTS**

Cases	Complications	Radiological Union	Knee Flexion	Knee Extension Lag	Work capacity	Total Period of follow up	Functional Outcome (NEER'S)
1	Nil	< 16 Weeks	110 Degrees	<5 Degrees	Normal	8 Months	Excellent
2	Nil	< 16 Weeks	110 Degree	<5 Degrees	Normal	8 Months	Excellent
3	Nil	30 Weeks	30 Degrees	10 Degrees	Light work	9 Months	Satisfactory
4	Nil	< 16 Weeks	110 Degrees	< 5 Degrees	Normal	6 Months	Excellent
5	Nil	< 16 Weeks	100 Degrees	< 5 Degrees	Alter Work	8 Months	Good
6	Nil	< 16 Weeks	100 Degrees	5 Degrees	Normal	6 Months	Good
7	Superficial Infection	< 16 Weeks	100 Degrees	5 Degrees	Alter Work	6 Months	Good
8	Delayed Union	34 Weeks	< 90 Degrees	10 Degrees	No Work	10 Months	Unsatisfactory
9	Superficial Infection	24 Weeks	Stiff Knee	No Extension	No work	8 Months	Unsatisfactory
10	Nil	< 16 Weeks	100 Degrees	5 Degrees	Regular	6 Months	Good
11	Nil	24 Weeks	100 Degrees	< 5 Degrees	Regular	6 Months	Good
12	Nil	< 16 Weeks	100 Degrees	5 Degrees	Regular	6 Months	Good
13	Nil	<16 weeks	100 Degree	<5 Degree	Regular	6 Months	Good
14	Nil	24 weeks	100 Degree	5 Degree	Regular	6 Months	Good
15	Nil	<16weeks	100 Degree	5 Degree	Regular	6 Months	Good

## Discussion

Present study was done at Deccan College of Medical Sciences, Hyderabad which comprised of fifteen patients with closed Distal end Femoral Fractures which were treated by Locking Compression plate. Overall final outcome was assessed in terms of radiological union, clinical assessment and regaining the lost knee function using NEER'S Score.

Out of 15 patients, 12 patients were males and 3 patients were females. This may suggest that RTA were most commonly seen in males when compared to females. Out of 15 patients, 14 were due to RTA which is attributable to the fact that fracture distal end of femur are associated with high velocity trauma. When seeing the relationship between age and mechanism of injury it was found that most of the vehicular accidents were seen in patients below the age of 50 years, and that of fall was not contributory. On seeing the relationship between sex and cause of fracture it was found that most of the vehicular accidents were seen in males rather than females, whereas it was not contributory in terms of fall from height. Maximum number of cases was of Muller type C2-60%. Internal fixation was considered after patients general and medical condition was stabilized. As we performed open reduction and internal fixation, the average operative time was 90 minutes. The size of plate was selected based on the type of fracture. 6 to 10 hole plate were used most commonly. Radiological union was defined as presence of bridging callus across three cortices. Of 15 patients, 10(66.66%) showed radiological union within 16 weeks. 9 (60%) of the patients achieved weight bearing at the end of 14 weeks. Average flexion in this study was 100 degree with more than 3 (20%) patients having knee range of motion more than 110 degree. 1 Patient had stiff knee. More than 80% patients were extensor lag less than 5 degree. 2 patients had **VARUS MALALIGNMENT** out of 15 patients. Results according to NEER'S SCORE were Excellent in 20% patients, Good in 60%, Satisfactory in 6.6% and unsatisfactory in 13.3% patients. 2 patients had superficial infection and 1 patient had delayed union.

In the study of Distal Femoral Locking Compression Plate Fixation in Distal Femoral Fractures: Early Results by EJ Yeap et al<sup>11</sup>, there were

four excellent results, four good, two fair and one failure out of 11 cases. These results are comparable to our study and can be attributed to the learning curve involved with usage of LOCKING COMPRESSION PLATES.

## Conclusion

Locking compression plate is an optimal tool for Distal end femoral fractures. It provides rigid fixation in the region of femur, where a wide canal, thin cortices and frequently poor bone stock make fixation difficult. Surgical exposure for plate placement requires significantly less periosteal stripping and soft tissue exposure than that of normal plates. Orthopaedic surgeons experience with locking compression plating technique will find it a useful technique. However careful understanding of its basic principles, identification of appropriate fracture patterns for use of LCP is essential to avoid complications like *generation of non union*.

**Locking Compression Plate** is an important armamentarium in treatment of fractures of distal end femur, especially when fracture is severely comminuted and in situations of osteoporosis. However a more comprehensive study with longer follow up periods is essential to throw more light into the advantages, complications and possible disadvantages of the use of Locking Compression Plate with special attention to the long term outcome.

**Ethical Clearance:** Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study.

**Conflict of Interest:** We declare no conflict of interest.

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# Traditional Dietary Practices and Related Taboos during Menstruation among Women of Rural Households in Haryana: A Qualitative Study

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## Abstract

**Background:** Women imbibe many myths, taboos, and practices about food during menstruation. The socio-cultural milieu of Indian society can explain the notions of menstrual restrictions. Aim: To know the traditional dietary practices and related taboos during menstruation among women of rural households in Sonapat, Haryana.

**Material and Methods:** This community-based cross-sectional study was conducted among 90 households in village Juan, Haryana selected by systematic random sampling from July 2021 to June 2022. Data regarding traditional dietary practices and related taboos during menstruation among women at the household level were collected using an open-ended questionnaire from a woman from each selected household after written informed consent. Data were analyzed using SPSS version 20.

**Results:** Mean age (SD) of the study participants was 44.1 (14) years with a range from 18-85 years. Two-thirds (66.7%) of study households reported avoidance of buttermilk/curd and pickles due to the belief of an increase in pain and cramps on consumption. One-third of study households preferred hot beverages such as tea (37.8%) and tea with clarified butter (31.1%) believing that pain and cramps get relieved, and clarified butter provides strength to the body.

**Conclusion:** There are a number of dietary practices and related taboos prevalent among study households that may affect mental health.

**Keywords:** Taboo, Menstruation, Haryana

## Introduction

Menstruation is a physiological process that holds great importance in a woman's life which involves dramatic changes linked to sexual development and maturation.<sup>1</sup> It is influenced by practices moulded by the immediate social environment, culture, and religious norms in which women live; stigmatizing

the menstruating woman.<sup>1-3</sup> The pain caused due to menstruation may not be as disturbing as it is for them to survive in a restrictive manner affecting their emotional and mental state.<sup>2,4,5</sup>

In many cultures, because of prevailing myths, misconceptions, and taboos around menstruation, menstruating women are handled in an exceptionally

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demeaning way, their touch, and even their vicinity at the sacred places in the house are viewed as ominous. The woman who cooks, cleans, and manages all the family errands suddenly gets to be sullied and, in this way, unfit to do anything including household chores, and are excluded from many educational, social, and cultural life during their menstrual period.<sup>1,2,4,6,7</sup>

United Nations International Children Fund (UNICEF) advised that good menstrual hygiene practices are essential during menstruation including maintenance of a balanced diet with plenty of fruits and vegetables rich in iron and calcium.<sup>8</sup> In some parts of India, some strict dietary restrictions are followed during menstruation such as avoidance of sour food like curd/ buttermilk, tamarind, and pickles; rice, milk, potato, onion, and sugarcane as it is believed that such foods will disturb or stop the menstrual flow or aggravate the dysmenorrhea.<sup>9,10</sup>

Many of these restrictions have no scientific support and are followed as a symbol of respect for elders which is more common among women in Indian rural settings. These practices may sometimes lead to negative health outcomes such as lack of nutrition and menstruation anxiety among girls and women.<sup>4,10-13</sup> Socio-demographic characteristics play an essential role in women's beliefs, behaviors, knowledge levels, and understanding of menstruation issues.<sup>6</sup> Every household member shares food taboos and beliefs. The women in the household transfer the practices related to menstruation to the next generation which varies from area to area. There is a dearth of data regarding traditional practices and food taboos during menstruation in rural Sonapat, Haryana. Thus, this study was planned to know the traditional dietary practices and related taboos during menstruation among women of rural households in Sonapat, Haryana.

### Material and Methods

A community-based cross-sectional study was conducted from July 2021 to June 2022 among households of the village Juan which is the field practice area of the Department of Community Medicine, Bhagat Phool Singh Government Medical College for Women, Khanpur Kalan Sonapat. It is habituated by around 920 households as per the record maintained by the department of Community Medicine.

**Study population:** All the households of Village Juan constituted the sampling frame. A list of all the households who were residing at least for 6 months or more was obtained from the Department of Community Medicine. The households that didn't give written informed consent were excluded.

**Sample size:** 10% of households in the study area i.e., 90 households.

**Sampling Technique:** The study households were selected through Systematic random sampling. As there were around 920 households and 90 households were chosen, the sampling interval calculated was 9. The first house was chosen randomly through a lottery method. After that, every 9<sup>th</sup> household was selected for data collection. A woman from each selected study household was interviewed. If a household had more than one woman, the eldest woman was interviewed.

**Study Tool:** An open-ended study schedule was used to collect data regarding socio-demographic characteristics, practices, and taboos regarding food during menstruation among women in the study household.

**Statistical analysis:** The data were collected and entered in the Microsoft Excel spreadsheet 2019. After cleaning of data, it was analyzed using Statistical Package for Social Sciences for Windows, Version 16.0. Chicago, SPSS Inc. The data were expressed in terms of frequency, and Proportion.

### Ethics approval

Ethics approval was taken from the Institutional Ethics Committee of BPS GMC (W), Khanpur Kalan, Sonapat. The study was done according to the guidelines laid under the Helsinki declaration 1975 which was later modified in 2013. The household members were explained the study's purpose and procedures, and their right to leave the study at any point in time. No biological sample was taken from the participants. A well-informed written consent was taken. Strict confidentiality and anonymity of the households were maintained. Access to data was restricted only to the investigators of the study. After the completion of data collection from each study household, health education in form of lectures or health talks was given to all the women of the study area. They were explained the scientific reasons regarding the practices and taboos related to food.

## Results

**Table 1: Sociodemographic characteristics of female respondents of the study households**

Sociodemographic characteristics		n (%)
Age group	18-29 years	14 (14.6)
	30-39 years	22 (24.7)
	40-49 years	23 (25.8)
	50-59 years	18 (20.2)
	60 and above	13 (14.6)
Occupation	Homemaker	78 (86.7)
	Self-employed	10 (11.1)
	Student	2 (2.2)
Education	Illiterate	30 (33.3)
	Up to Primary	19 (21.1)
	Middle	15 (16.7)
	High	12 (13.3)
	Secondary	7 (7.8)
	Graduate and above	7 (7.8)
Caste	Scheduled Caste	23 (25.6)
	Other Backward Class	23 (25.6)
	General	44 (48.9)
Socio-economic status (Modified B G Prasad 2020)	Class I, II	29 (32.2)
	Class III, IV, V	61 (67.8)

Table 1 shows that the mean age (SD) of the study participants was 44.1 (14) years with a range from 18-85 years. One-fourth of participants were in the age group 30-39 years (24.7%) as well as in the 40-49 years (25.8%) age group. Most of the study

participants were homemakers (87%) and illiterate (33.3%). Nearly half (48.9%) of the study participants were belonging to the others caste category and two-thirds (67.8%) to social classes III, IV, and V.

**Table 2: Distribution of the study households by their self-reported food choices during menstruation (n=90 for each food item)**

Foods	n (%)	Reasons
Avoid cold foods (buttermilk/ curd)	60 (66.7)	Increases the pain and cramps, white discharge per vagina
Avoid sour foods (pickles, tamarind)	59 (65.6)	Increases the pain and cramps, touch - may spoil the pickle
Avoid spicy foods	24 (26.7)	Increases stomach ache
Avoid non-vegetarian foods	8 (8.9)	Heavy bleeding or foul-smell bleeding
Not entering the kitchen to cook food	6 (6.6)	Food may get contaminated and spoiled
Didn't alter the quantity of food	83 (91.9)	More food is required for strength
Intake of Tea	34 (37.8)	Relives the pain and cramps
Intake of Tea with clarified butter	28 (31.1)	Relives the pain and cramps, butter provides strength to the body
Intake of Plenty of water	9 (10)	Relives the pain and cramps,

Table 2 shows that two-thirds of study households reported avoidance of buttermilk/curd and pickles due to the belief of an increase in pain and cramps on consumption. Ninety-one percent of study households didn't change the quantity of food consumed by females during menstruation as most of the study households considered more food is required for strength during menstrual bleeding. One-third of study households recommended hot beverages such as tea (37.8%) and tea with clarified butter (31.1%) due to the belief that pain and cramps get relieved, and clarified butter provides strength to the body.

### Discussion

Though menstruation is a physiological phenomenon, various traditional practices and related food taboos are observed all across the world during this time. We conducted a study to learn more about them at the household level in our study area and found more prevalence among our study participants. Most were related to avoidance of food items that increase the pain and cramps; fear of heavy or foul bleeding. The findings are consistent with the other studies done elsewhere in India and the world.<sup>3,10,11,14-18</sup> Our study also reported consumption of buttermilk/ curd foods during menstruation increases the likelihood of white discharge per vagina.

The current study reported that there are a few food items that are preferred during menstruation such as hot drinks (tea with or without clarified butter), and plenty of water as these are believed to relieve the menstrual pain and help in blood flow. The findings are supported by the study done by Bhatia D et al. but contradict Rana G et al.<sup>24</sup>

### Conclusion and Recommendations

This study concludes that there are a number of practices and related taboos regarding food among the households of rural Haryana. These misconceptions impact their practices to manage menstruation affecting the mental health of women. There is a need to address and ameliorate the ill practices which were in most of them away from scientific facts but mainly cultural in nature. To break the continuum of transference of these practices

to the next generation, it is imperative to intervene among girls and women at different levels. Strategies may include health education given at the household level, at religious centers, or in health care facilities, or to the mothers in the communities who could later transfer the information to the next generation.

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# Prevalence of Iron Deficiency in Chronic Heart Failure Patients in a Tertiary Care Hospital: An Observational Study

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## Abstract

**Introduction:** This is an observational study to explore the prevalence of iron deficiency (ID) and the relationship between the severity of chronic heart failure (CHF) and the degree of ID in CHF patients.

**Objective:** The objective of the study was to assess the extent of ID and its adverse effects on patients with CHF. This study was intended to assess the prevalence and effect of ID in anaemic as well as, non-anaemic subjects.

**Methodology:** Study subjects were from OPDs and IPD patients with the diagnosis of CHF, based on clinical and 2D echo findings. ID was diagnosed by basing on iron profile along with transferrin saturation (TSAT). The study period was from January 2017 to March 2018; from which 109 patients were included. In those cases, trans-thoracic echocardiography, chest X-Ray, necessary blood biochemistry and CBC were done. Data collected on 109 cases of CHF were analyzed using IBM SPSS 24.0 software.

**Results:** Iron deficiency was present in 86.2% of patients, 40.3% had functional ID (ferritin 100-300 and TSAT less than 20%) and 45.9% had absolute ID (ferritin less than 100). Interestingly, out of those who had no anaemia clinically or laboratory report wise approximately one-fourth of the patients had iron deficiency.

**Conclusion:** This study reveals that ID in HF is a hugely ignored area in India. This study brings out the need for large-scale studies in India so that this easily treatable condition can be well characterized and routine testing for ID could be introduced in the guidelines of our country.

**Keywords:** Chronic heart failure, Iron deficiency, Ejection fraction, New York Heart Association

## Introduction

Heart failure (HF) is not a commonplace problem and is increasing rapidly due to the prevalence

of coronary artery diseases stemming from the sedentary population. In cases of HF, the frequency of reduced exercise and reduced quality of life (QoL), in the form of frequent intake of carbohydrate/trans-

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fat rich food; indeed, lead to frequent hospitalization and mortality significantly, if anaemia co-exists. Moreover, anaemia is a common comorbidity among HF patients; which worsens the outcome of HF patients in terms of recovery, from frequent hospital admissions.<sup>1,2</sup> Iron Deficiency can exist without anaemia in chronic HF.<sup>3,4</sup> With anaemia or non-anaemia, the aerobic performance capability does reduce the frequency of heart attacks.<sup>3,5</sup> Particularly, this had been demonstrated recently in chronic HF.<sup>6</sup>

Indeed, during exercise patients develop some degree of severity in heart attacks; in the last few years, studies have revealed that corrections of iron level by parenteral iron in patients with chronic HF improved exercise tolerance with abnormal QoL.<sup>7-12</sup> It was observed in both anaemic and non-anaemic subjects of chronic HF that when shifted the focus from anaemia in HF to ID, there was a drastic moratorium in heart failure.<sup>12</sup> These studies had conflicting conclusions as to the prognostic importance of ID in Chronic HF, irrespective of the presence or absence of anaemia. To carry out a study to evaluate iron deficiency in HF and then compare the HF severity in iron deficient and non-iron deficient was the intention of the study.

### Materials and Methods

The sample size was calculated as per Danial Sample Size Formula, according to which, the number obtained was 96.04. However, there were 109 cases included in the study. Patients detected to have CHF according to clinical criteria were included. Then, Iron Profile and transferin saturation (TSAT) were done to establish ID statuses. Serum ferritin < 100 mg/L was taken as the absolute and serum ferritin (100–300 mg/L) with low TSAT (<20%) was functional ID. Patients presenting from January 2017 to March 2018 with Chronic Heart Failure (CHF) to OPD and IPD units of the Department of Cardiology and OPD of Health checkup units constituted the study population. In all the cases and transthoracic echocardiography, Chest X-Ray, necessary blood biochemistry including nPRO BNP and CBC were done.

The data obtained were analyzed; the study subjects were divided into two groups e.g., Iron Deficient and Non-Iron Deficient. Thus, two separate sets of data were created for analysis using IBM SPSS 24.0 statistics.

### Inclusion criteria

Patients of either gender aged > 18 years

Diagnosis of chronic heart failure in NYHA functional class II-IV

The echocardiographic finding of LVEF value,  $\leq 45\%$

At least 3 months' history of HF.

HF is on treatment for a minimum of 1 month

Patients who understood the study procedure and gave informed consent.

### Exclusion criteria

Those who had MI in the last 3 months according to history

CHF secondary to severe valvular diseases

Known cases of systemic inflammatory and collagen tissue disease

Clinically significant renal dysfunction (EGFR < 30 mL/min per 1.73 m<sup>2</sup>)

Severe anaemia (haemoglobin < 7 g/dL)

Patients on iron replacement therapy

Pregnancy or active breast-feeding

All data collected were analyzed using IBM SPSS 24.0 statistics.

### Observations

In this study, it was established that ID can exist without anaemia. This study came across 30.9% of non-anaemic subjects having ID.

**Table 1. Relation of iron deficiency with anaemia**

Iron deficiency	No.	%
ID without Anemia	29	30.9
ID with Anemia	65	69.1
Total	94	100.0

The prevalence of iron deficiency was 90.3% among anaemic CHF patients; which was 78.4% among non-anaemic CHF patients. This result revealed that iron deficiency state increasingly prevalent among CHF patients; nevertheless, clinical and laboratory investigations did not show anaemia (Table 2).

**Table 2. Iron deficiency among anaemic and non-anaemic CHF patients**

Anaemia	Iron deficiency						X <sup>2</sup> , p
	Present		Absent		Total		
	No.	%	No.	%	No.	%	
No	29	78.4	8	21.6	37	100	X <sup>2</sup> =2.916 P=0.888
Yes	65	90.3	7	9.7	72	100	
Total	94	86.2	15	13.8	109	100	

Since the X<sup>2</sup> values are below 0.95 (i.e., 0.888), the statistical test indicated that there is no effect of ID in chronic heart failures. Association of ejection fraction (EF) with ID This study revealed a trend

that the lesser the ID is, the better would be the EF (Table 3). However, this was not statistically significant ( $p=0.465$ ). Hence, there could be a chance factor.

**Table 3. Association of ejection fraction with iron deficiency.**

Ejection fraction percentage	Iron deficiency						X <sup>2</sup> ,p
	Present		Absent		Total		
	No.	%	No.	%	No.	%	
20-25	24	92.3	2	7.7	26	100	X <sup>2</sup> =1.532 P=0.465
26-39	59	85.5	10	14.5	69	100	
>=40	11	78.6	3	21.4	14	100	
Total	94	86.2	15	13.8	109	100	

Relationship of New York Heart Association (NYHA) functional class with LVEF among CHF with ID patients. With NYHA functional classes and LVEF among CHF with iron deficiency patients, of

94 cases 12.8% presented with NYHA II, 74.5% with NYHA III and 12.8% with NYHA functional class IV present (Table 4).

**Table 4. Classification and its details**

New York Heart Association Classification	Male		Female		Total		X <sup>2</sup> , p
	No.	%	No.	%	No.	%	
II	8	11.6	4	16	12	12.8	X <sup>2</sup> =0.323 p=0.851
III	52	75.4	18	72	70	74.5	
IV	9	13	3	12	12	12.8	
Total	69	100	25	100	94	100	

There were some other observations concerning iron deficiency HF; which were not clinically/statistically not significant, hence not included here.

### Discussion

Progression of CHF symptoms and outcomes depend to quite an extent on co-morbidities (1,2). Important comorbidity in CHF is an iron deficiency

that affects about 50% of patients (3). The present study aims at profiling the serum iron profile among CHF patients in Odisha's population in a tertiary care corporate hospital. Besides, the association of serum iron profile with LVEF and NT proBNP, with different parameters and grades had been studied. Based on the observations from our study, a comparison with the findings of the related research along with a critical review has been attempted in this chapter (Table 5).

**Table 5. Iron deficiency and anaemia among CHF patients in other studies**

Study	Prevalence of ID		
	The whole group (%)	Non-anaemic patients (%)	Anaemic patients (%)
Rangel et al 2013 <sup>13</sup>	36	26	10
Klip et al 2013 <sup>14</sup>	50	15	35
Sohankumar Sharma et al 2016 <sup>2</sup>	76	24.7	51.3
Von Haeling et al 2017 <sup>12</sup>	42.5	32.7	9.8
Present study	86.2	26.6	59.6

In this study, it is found that the presence of ID in HF was quite high. ID was present in 26.6% of HF patients even without anaemia. Recently, awareness of ID being important in the management of HF has been increasing worldwide. In the USA one prospective study in the community was done where HF was self-reported. This study detected 61.3% of HF patients had ID (9). In Europe, prevalence rates of ID in 37% to 50% of cases of HF indifferent studies.<sup>3,6,10</sup> Our study revealed ID prevalence to be 86.2% and anaemia prevalence to be 59.6%. Thus, 26.6% were having ID but no anaemia. That the ID burden in HF patients in Odisha is higher than in other studies cited was seen in our study. The reason could be that Odisha, India, is characterized by a high prevalence of malnutrition, anaemia and poverty.

A higher rate of ID in HF patients of Indian origin as compared to patients of other ethnicity was reported.<sup>4</sup> It is observed that only Hb levels should not be taken into account in the workup of anaemia if a patient is having HF. By doing so, we can miss the number of cases of ID in cases of HF. Functional ID being 42.3%, is a significant portion of the disease burden. These cases can remain undetected if care is not taken to do TSAT and serum ferritin at the very beginning of the management of Chronic Heart Failure.

### Conclusion

In conclusion, our study brings out the underestimated and ignored burden of ID in HF patients in India. The iron deficiency prevalence of 86.2% is extremely high among CHF in our study populations in comparison to the studies in other places outside India. Iron deficiency prevalence is higher in CHF patients even without anaemia. Hence iron profile should be taken as a routine investigation

along with haemoglobin in all the suspected CHF patients. This is also the present ESC-2016-guidelines.

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# Cross-sectional Study on Pattern of Ear, Nose and Throat Disorders among School Children in a Rural Area of West Bengal

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## Abstract

**Background:** Ear, Nose and Throat diseases are common in school going children who often miss school due to these illnesses. ENT diseases have not been given due importance by majority of the school authorities. The importance of ENT diseases screening is to identify the children at-risk, which may hamper their scholastic performance, and to refer them for detailed investigation and intervention.

**Objectives:** 1. To find out the pattern of common Ear, Nose and Throat Disorders among School children. 2. To find out the association if any regarding ENT morbidities and socio-demographic variables of the parents.

**Materials and Methods:** The study was a descriptive observational type of cross-sectional design. The school was chosen by random sampling method. Data were collected by interviewing the school children with a pre-designed and pretested schedule. Clinical examinations were done with the help of a check list containing the standard answer and definition of ENT morbidities. Collected data were analysed and proportions and Chi-square test were done.

**Results:** Among study population 52.6% were female and most of the children (63.5%) were < 14 years of age group. 61.6% having some form of ENT morbidities. Literacy status of parents and economic condition of the family were significantly associated with ENT morbidities.

**Conclusion:** Urgent need for health education and regular Ear, Nose and Throat check-up among the school children to increase their level of awareness and knowledge regarding ENT diseases and also decrease morbidities.

**Keywords:** Ear, Nose and Throat Disorders, School children, Rural Area

## Introduction

India being the second most populous country of the world. More than 400 million children, forming about 35% of its total population. Respiratory

tract symptoms such as cough, sore throat, and earache are frequent in children [1]. Among the ENT disorders, upper respiratory tract infection is very common showing recurrence of illnesses

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with seasonal variations. These upper respiratory infections may lead to otitis media, sinusitis and tonsillitis with higher morbidity [2]. When compared with otorhinolaryngological disorders of adults, the diseases are more common among children and are due to many factors like anatomical structure of Eustachian tube, immunological status, malnutrition, over-crowding, and ill ventilated dwellings with poor sanitation [3]. Ear, Nose & Throat diseases are common in school going children and frequently children miss school due to ENT diseases [4]. The practice of screening among school - age children has been in existence for more than 75 years in the west. In India, school screening programmes have been conducted since 1965 as per reports available. However, hearing health and other ENT diseases have not been given due importance by a majority of the school authorities. The importance of hearing screening is to identify the children at-risk. With this background, and fortified by the fact that no such study has been carried out specially in this part of the country, this cross-sectional study was conducted among the school children with the following objectives: 1. To find out the pattern of common Ear, Nose and Throat Disorders among School children. 2. To find out the association if any regarding ENT morbidities and socio-demographic variables of the parents.

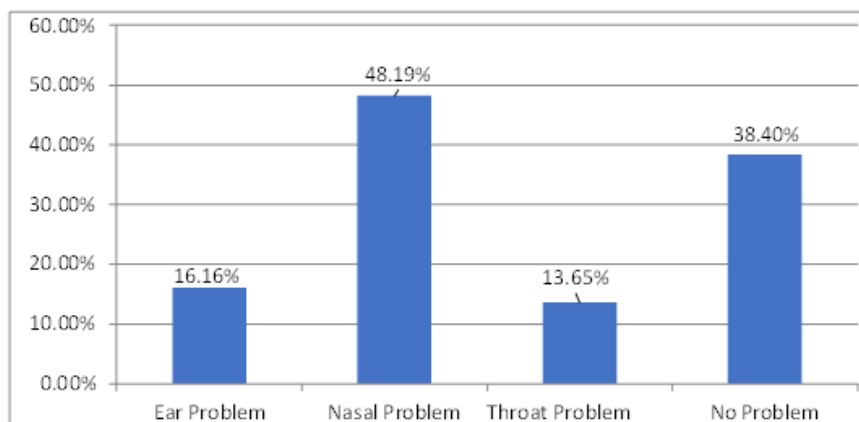
### Materials and Methods

The descriptive observational type of cross-sectional design study was carried out in a rural area of Singur Block, Hooghly District, West Bengal. This is a rural field practice area of All India Institute of Hygiene & Public Health, Kolkata. The area is inhabited by people of poor socioeconomic status. Study was conducted in three months. In the Singur Block all High schools were registered first and from them Paltagarh High school was selected by SRS method as a study school which is situated in Paltagarh village. Students of class VII & class VIII were the target population for the study. Students who were present on the day of visits were registered as a study population. Data were collected by interviewing the school children with a pre-designed and pretested schedule. For auditory canal, nasal septum & throat examinations Otoscope, Tuning fork, Nasal speculum, Tongue depressor were used. From

these population data were collected and clinical examination were done with the help of a check list containing the standard answer and definition of ENT morbidities. After consecutive 4-day visit out of 372 students 359 students were examined. Rest was absent on those days. Collected data were then analysed and statistical test were done with the help of Microsoft Excel & Epi-info (3.5.1) software. Test for the statistical significance was applied by using chi-square ( $\chi^2$ ) test for analysing the difference between the two proportions ( $P < 0.05$  was considered significant).

### Results

The present study was carried out to determine the pattern of Ear, Nose & Throat morbidities among rural school children of West Bengal. Study was conducted in Paltagarh village of Singur Block and 359 students were participated in the study. Out of them, 170 (47.4%) male and rest (52.6%) were female. Participated students were divided into two age groups, less than 14 years and more than 14 years. Among them 63.5% were less than 14 years of age and rest (36.5%) were more than 14 years. Fig. 1 shows 38.4% children have not any ENT problems whereas rest (61.6%) students have some form of ENT morbidities. Most of the students have nasal problems (48.19%) compare to Ear problems (16.16%) and Throat problems (13.65%). Among the total study population 61.6% were suffering some form of ENT disorders (Table - I). Ear discharge (CSOM), ear wax, otitis media and hearing deficit [air conduction (AC) less than bone conduction (BC)] were common ear problems among the study population and they were 24.8%, 17.5%, 4.2%, & 2.5% respectively. DNS (deviated nasal septum), rhinitis, hypertrophy turbinate and epistaxis were found as nasal problems and they were 27.0%, 18.1%, 6.7% & 1.1% respectively. Throat problems were found as caries tooth, enlarged tonsil & congested pharynx and they were 24.0%, 10.0% & 6.1% respectively (Table - I). Table II shows relationship between socio-demographic variables and any form of ENT morbidities. Study shows parents who were literate and per capita monthly family income were more, chances of developing ENT morbidities were less and these differences were statistically significant ( $p < 0.05$ ).



**Fig. 1: Bar diagram showing distribution of study population according to reported ENT symptoms in last 6 months (n=359)**

**Table I: ENT morbidities among study population (n=359) (multiple response)**

Clinical Problems		Total	Percentage (%)
Without any clinical problem		138	38.4
Ear problem	Otitis Media	15	4.2
	Wax	63	17.5
	CSOM	89	24.8
	Hearing deficit (AC<BC)	9	2.5
Nasal problem	DNS	97	27.0
	Rhinitis	65	18.1
	Epistaxis	4	1.1
	Hypertrophy Turbinate	24	6.7
Throat problem	Enlarge Tonsil	36	10.0
	Congested Pharynx	22	6.1
	Carries Tooth	86	24.0

**Table II: Relationship between Socio-demographic Variables and ENT Morbidities (n=359)**

Socio-demographic Variable		ENT Morbidities		Statistical Test
		Present	Absent	
Father's Literacy	Illiterate & Just literate (n=99)	70 (70.7)	29 (29.3)	$\chi^2 = 4.83, p=0.028, df=1, OR= 1.74, RR= 1.22, Significant$
	Literate (n=260)	151 (58.1)	109 (41.9)	
Mother's Literacy	Illiterate & Just literate (n=93)	83 (89.2)	10 (10.8)	$\chi^2 = 40.66, p=0.000.., df=1, OR= 7.7, RR= 1.72, Significant$
	Literate (n=266)	138 (51.9)	128 (48.1)	
Per Capita Family Income/Month (Rs)	<1000 (n=148)	104 (70.3)	44 (29.7)	$\chi^2 = 13.07, p= 0.0014, df=2, Significant$
	1000-2000 (n=173)	102 (59.0)	71(41.0)	
	>2000 (n=38)	15 (39.5)	23 (60.5)	

## Discussion

Ear, nose and throat diseases in children are major public health problems not only in India but

also in developing country. WHO suggests that, in developing countries, children should be screened regularly for early identification of ENT morbidities<sup>[4]</sup>. Present study was conducted in Paltagarh village of

Hooghly district of West Bengal for finding the ENT morbidities among school children. ENT disease one of the major public health problems in this region and 61.6% of study population having some form of ENT disease where most of the students have nasal problems (48.19%) compare to Ear problems (16.16%) and Throat problems (13.65%). Study conducted by Sen Gupta A. et al<sup>[4]</sup> shows out of 639 patients, 298 (46.64%) were suffering from only ear diseases, 117 (18.30%) were suffering from only nose diseases, 77 (12.05%) of them had only throat problems, whereas 95 (14.87%) had ear and nose problems, 32 (5.01%) had both throat and nose problem and 11 (1.72) of them had ear & throat diseases. Rest 9 (1.41%) patients had other problems like foreign body (F.B.) in the airway or oesophagus and TB lymph nodes. Study conducted by Sanjay Kumar et al<sup>[5]</sup> hearing loss was 15.96%. The study revealed that CSOM was 24.8% whereas study conducted by Sen Gupta Arup et al<sup>[4]</sup> it was slightly higher (37.6%). Other common ear morbidities in present study were ear wax (17.5%), otitis media (4.2%) whereas study conducted by Sen Gupta Arup et al<sup>[4]</sup> it was 9.9% and 19.6% respectively.

In present study common nasal problems were DNS (27.0%), Rhinitis (18.1%), Epistaxis (1.1%) but the study conducted by Sen Gupta Arup et al<sup>[4]</sup> these were 15.6%, 24.2%, 28.7% respectively. Present study shows enlarged tonsil, congested pharynxes were common throat problems and they were 10.0% and 6.1% respectively but Sen Gupta Arup et al<sup>[4]</sup> study they were 57.5% and 35.8%. Present study shows parents who were literate and per capita monthly family income were more chances of developing ENT morbidities were less and these differences were statistically significant. Similar finding was seen by study conducted by Sen Gupta Arup et al<sup>[4]</sup>. Study conducted by Shah V. et al<sup>[6]</sup> shows Prevalence of Ear Nose and Throat morbidity was 46.66%. Prevalence of symptoms related to ear was 14.33%, symptoms related to nose were 28.66% and symptoms related to throat were 10%. Common Ear Nose and Throat problems were common cold (23%), cough (9.67%), sore throat (8.34%) and ear ache (8.67%). Shah V. et al<sup>[6]</sup> also shows that Ear Nose and Throat morbidity was higher in 10-14 years age group (52.24%) as compared to 5-9 years age group (35.35%) and it was found statistically significant. No association was found between mother's education

and Ear Nose and Throat morbidity. Ear Nose and Throat morbidity was higher in Muslim (88.89%) as compared to Hindu (45.36%) and found statistically significant. Ear Nose and Throat morbidity was almost similar in male (46.25%) and female (47.14%). There was higher Ear Nose and Throat morbidity in lower (50.56%) socio-economic class as compared to upper (43.56%) class. So Accurate diagnosis at early phase of the disease and appropriate treatment as per required will promote to a greater extent to prevent the so many long-term complications<sup>[7-8]</sup>.

## Conclusions

In conclusion, data suggest that there is an urgent need for health education in the study population in order to increase their level of awareness and knowledge about common ENT diseases. This is particularly important in a developing country such as India. Increasing the awareness and knowledge of common ENT diseases could lead to an increase in understanding and acceptance of the importance of routine ENT examination for early detection and treatment of such conditions, thereby reducing hearing impairment or other unwanted morbidities. Hearing impairment and preventable ear, nose & throat diseases were found to be important health problems among School children specially <15 years age group in this region. It is the child's right not to be disabled at birth, or later. Prevention of impairment and disability are of primary importance. Regular screening of School children, giving education about common knowledge & practices of hygiene related to ENT will ensure that children continue their school-life and also future life without these disabilities.

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**Conflicts of Interest:** All authors have no conflicts of interest.

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## Study on Knowledge and Attitude about Menstrual Cup and its usage among Medical Students: A Cross Sectional Study

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### Abstract

**Introduction:** Millions of women globally experience menstruation every month. It is a normal biological process. Inadequate menstrual management has long been a major health issue in low- and middle-income nations, but it has only recently become a major public health concern. Females may manage menstruation with non-absorbent, unhygienic, and uncomfortable materials due to a lack of awareness, an unfavorable sociocultural environment, logistical and financial barriers, and a lack of a proper support system. Hence this study was undertaken to assess the knowledge and attitude among medical students.

**Methodology:** This study was conducted among 200 undergraduate female medical students, who were willing to participate in the study. Informed consent was taken and the oral questionnaire which consisted of socio-demographic data and questions regarding knowledge, attitude and practice was distributed. Descriptive analysis was done by calculating the percentage.

**Results:** 91% of the students were aware of the menstrual cup. A total of 168(84%) students said menstrual cup to be a safe device. A total of 171 (85.5%) students knew that the menstrual cup could be used among virgins. whereas 29 (14.5%) students were of the opinion that it cannot be used by virgins. 84(42%) of students had no idea about its association with TSS (Toxic shock syndrome). 73(36.5%) of students knew that it is not associated with TSS. 143(71.5%) said it can't be used during postpartum and 112(56%) knew that it is used during bathing and swimming. 134(67%) students knew that it can't be used as contraceptives and 88(44%) told it won't cause rupture of hymen. Finally in this study we came to know that none of them are using menstrual cup because majority of them said that they had fear of using 92(46%) and 51(25.5%) of them said they don't have adequate knowledge.

**Conclusion:** In this study all the students used sanitary pads, owing to its popularity and promotion. There was lack of awareness about the cup and there exists a huge gap between the knowledge and willingness of the students to accept the menstrual cup. So, we conclude that menstrual cup needs promotion in India because it is cost effective, eco-friendly and reusable. So, we boost the adoption rate of menstrual cups, youth should be targeted, who are more open to the idea of environment-friendly products.

**Key words:** Menstruation, Menstrual cups, sanitary pads

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## Introduction

Millions of women globally experience menstruation every month. It is a normal biological process. The start of menstruation indicates the start of the reproductive years in female life. It often marks the transition of a child to the full-grown adult woman in society. Though it is the most common biological process, in lower and middle-income countries, because of social issues and lack of guidance maximum of the girl's experience fear, confusion, shame, and discomfort while they try to be accustomed to their monthly period.<sup>1</sup>

Inadequate menstrual management has long been a major health issue in low- and middle-income nations, but it has only recently become a major public health concern<sup>2</sup>. Females may manage menstruation with non-absorbent, unhygienic, and uncomfortable materials due to a lack of awareness, an unfavourable sociocultural environment, logistical and financial barriers, and a lack of a proper support system.<sup>3</sup> These are linked to an increased risk of reproductive tract infections. Another issue is a lack of wash facilities, which leads to disempowerment, limited possibilities, and bad health.<sup>4</sup>

One of the most important aspects of proper menstruation management is having access to a safe, comfortable, and long-lasting period hygiene product. Sanitary pads and garments are the most commonly used solutions among women<sup>5</sup>. They have a number of drawbacks, including allergy, itching, pain, fear of leakage, storage, disposal, and environmental concerns, as well as the financial burden of monthly purchases.<sup>6</sup>

The menstrual cup has been explored as a means of menstrual hygiene management in developing countries like India. It is manufactured using health-grade non-toxic non-allergic medical-grade silicone. Menstrual cups are more economical than disposable ones and can be sterilized easily at home. It has very few side effects compared to sanitary pads and help to overcome financial burden of monthly purchase as menstrual cups are reusable for 5-10 years.<sup>7</sup>

Menstrual cups have been available for a long time, but their use is still uncommon. It is being embraced by more and more women as a sensible and secure option. Many studies have shown that most

users become comfortable using the cup within 2 to 3 consecutive cycles, and since it is not an absorbent like tampons, the risk of infection such as TSS and other serious health issues is rare or non-existent.<sup>4</sup>

## Methodology

This study is a cross sectional study and was conducted among 200 undergraduate female medical students belonging to 2<sup>nd</sup>, 3<sup>rd</sup>, and final MBBS, who were willing to participate in the study. Informed consent was taken and the oral questionnaire which consisted of socio demographic data and questions regarding knowledge, attitude and practice was distributed.

Pretested and pre validated oral questionnaire was used to collect data. The questionnaire included socio demographic details and details regarding usage of menstrual cups and awareness about the same. Barriers for the non-usage of it was also included. After the data was obtained, they were entered in M S excel and descriptive analysis was done by calculating the percentage.

## Results

In this study total 200 participants were included. Among them, 91% of the students were aware of the menstrual cup. A total of 168(84%) students said menstrual cup to be a safe device. A total of 171 (85.5%) students knew that the menstrual cup could be used among virgins. whereas 29 (14.5%) students were of the opinion that it cannot be used by virgins.

When asked about mechanism of action of menstrual cup majority of them, 170 (85%) knew that it acts by collecting menstrual blood. we wanted to know if students knew anything about the material used in cup manufacturing. We were surprised to know that 56(28%) of them had no idea about the material used in cup manufactured. About 105(52.5%) said cup were made of silicone, TPE, natural gum rubber and latex. About 39(19.5%) said that it is made of all the above material and 123 (61.5%) of them knew that the cup should be emptied within 6 -12 hours. Sterilization of the cup is the most important aspect in its usage because if not done properly could lead to the development of infection.30(15%) Of them told it could be done by washing under running water. 102(51%) said boiling is required. 4(2%) of them



voted for sterilization with microwave. Surprisingly 42(21%) of them had no idea about method of sterilization.

84(42%) of students had no idea about its associated with TSS (Toxic shock syndrome). 73(36.5%) of students knew that it is not associated with TSS.143(71.5%) said it can't be used during postpartum and 112(56%) knew that it is used during bathing and swimming.134(67%) students knew that

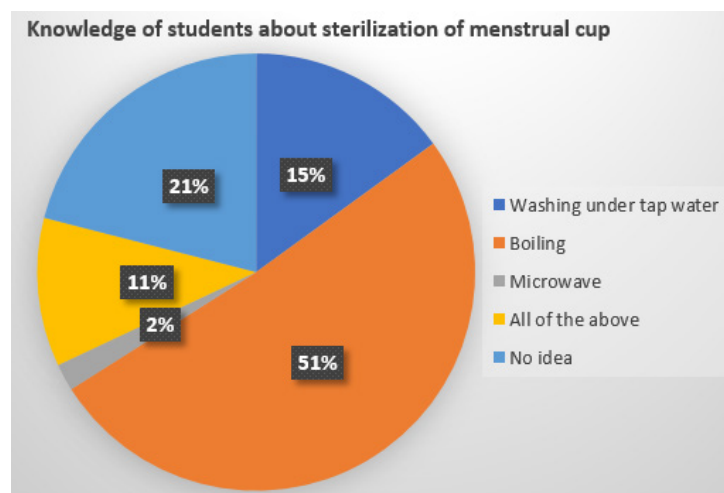
it can't be used as contraceptives and 88(44%) told it won't cause rupture of hymen. We asked about associated with infection, 81(40.5%) said it do not cause any infection. Finally in this study we know that none of them are using menstrual cup because majority of them said that they had fear of using 92(46%) and 51(25.5%) of them said they don't have adequate knowledge.

**Table 1: Knowledge of students about menstrual cup and its usage**

QUESTIONS	YES	NO	NO IDEA
Is menstrual cup a safe device	168(84%)	32(16%)	–
Can it be used by virgins?	171(85%)	29(14.5%)	–
Menstrual cup & association with TSS	43(21.5%)	73(36.5%)	84(42%)
Usage during postpartum period	57(28.5%)	143(71.5%)	–
Usage during swimming and bathing	112(56%)	47(23.5%)	41(20.5%)
Usage of cup as a contraceptive	17(8.5%)	134(67%)	49(24.5%)
Usage of cup leading to rupture of hymen	42(21%)	88(44%)	70(35%)
Usage of cup leading to vaginal infection	75(37.5%)	81(40.5%)	44(22%)
Will you use menstrual cup in future	27(13.5%)	173(86.5%)	–

**Table 2: Knowledge of students about mechanism of action of cup**

Mechanism of action of menstrual cup	Collection	Absorption
N=200	170(85%)	30(15%)



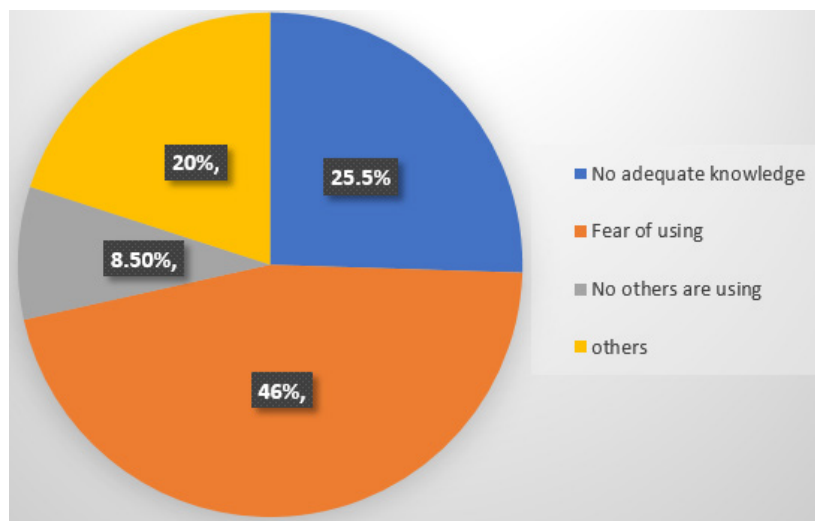
**Fig 1 Knowledge of students about sterilization of menstrual cup**

**Table 3: knowledge of students about the material used in manufacturing of the cup**

Material used in manufacturing cup	Silicone and TPE	Natural gum rubber	Latex	All of the above	No idea
N= 200	70(35%)	4(2%)	31(15.5%)	39(19.5%)	56(28%)

**Table 4: Knowledge of students about emptying of cup**

Emptying time of cup	1-2 hrs	6-12 hrs	12-24hrs	no idea
N=200	10(5%)	123(61.5%)	26(13%)	41(20.5%)

**Figure 2: Reason for not using menstrual cup**

### Discussion

In the present study out of 200 students 91% of students are aware of menstrual cup and 86.5% students know about menstrual cup. 168(84%) said that menstrual cup to be a safe device. A total 171 (85.5%) students were for usage of menstrual cup among virgins. Whereas 29(14.5%) students were of the opinion that it cannot be used by virgins (Table 1). In a study done by Manorama Eti, Shreya M.S wherein safety of menstrual cup was evaluated among medical student's girls, also found that cups are safe with no health issues and it can be used in virgins.<sup>8</sup>

Coming to menstrual cup and toxic shock syndrome (TSS), 84(42%) of students had no idea about its association. 73(36.5%) of students knew that it is not associated with TSS (Table 1). In an article published in the year 2019 by Anna Maria van Eijk et al, says that five case confirmed TSS was found in association with usage of cup. A total 143(71%) student said it can't use during postpartum period. its usage is usually not recommended until 6week postpartum because it can introduce infection as the tissue as not fully healed especially in case of normal delivery.<sup>9</sup>

Among the study participants, 70(35%) of the participants knew that menstrual cup is made up of

silicon and TPE, 2% said natural gum rubber, 15.5% said latex, 19.5% said it is made of all the material mentioned above and 56(28%) had no idea about the material used in cup manufactured (Table 3). In a previous study Meghana S and Gomathy E says that 36.7% of the participants knew that the menstrual cup is made up of silicone and 21.7% said it is made up of all the material mentioned above. We understand that 368(99%) students know the mechanism of action menstrual cup and it act by collecting the blood flow while 30(15%) had said that its mechanism is absorption.<sup>1</sup>

Sterilization of cup is the most important aspect in its usage because if not done properly could lead to development of infection. 15% of them told it could be done by washing under running water, 51% told it could be for boiling and 21% had no idea about the method of sterilization (Fig 2). Besides that, only 123 (61.5%) of them know that the emptying time of the menstrual cup is 6 - 12 hrs. Rest 77(38.5%) had no idea regarding this aspect (Table 4).

In the present study 56% says that it can be used during swimming and bathing. when asked about usage of cup leading to rupture of hymen 44% students told it won't cause rupture of hymen and 21% had misconception that it led to rupture of hymen. In another study conducted by Eti, Shreya M.S says that

Regarding usage of cup during swimming, majority of them 304 (81.7%) knew it could be used, and had an advantage over sanitary pads. 20 (5.3%) students were having a wrong notion about cup usage as a contraceptive device. They thought it could be used as a contraceptive device.<sup>8</sup>

we asked about why they are not using menstrual cup, majority 46% of them said they had fear of using and 25.5% of them says that they don't have adequate knowledge (Table 5). Finally, among 200 students who completed the questionnaire, none of them used menstrual cup.

It demonstrates that students are unaware of the advantages of using a menstrual cup versus sanitary pads. Menstrual cups are not widely used in India, and this is due to a variety of factors. As a result, students lack a thorough understanding of the material used in cup manufacturing, its sterilising procedure, its association with TSS, and its use during the postpartum period.<sup>8</sup>

Women in developing countries, such as India, want effective, safe, and economical menstrual products that are also eco-friendly. Menstrual cups are one such option! Adoption of the cup required familiarisation over several menstrual cycles, and peer support boosted acceptance in underdeveloped nations. Menstrual cups are safe and widely used around the world. They must be pushed in India since they have the potential to be an environmentally friendly and cost-effective solution to menstruation management.<sup>8</sup>

### Conclusion

In this study all the students used sanitary pads, owing to its popularity and promotion. There was lack of awareness about the cup and there exists a huge gap between the knowledge and willingness of the students to accept the menstrual cup. So, we conclude that menstrual cup needs promotion in India because it is cost effective, eco- friendly and reusable. So, we boost the adoption rate of menstrual cups, youth should be targeted, who are more open to the idea of environment-friendly products.

Moreover, this study targets the importance of the awareness campaign about the use of the menstrual cup as they can help to build good menstrual hygiene among reproductive women.

**Conflict of interest:** none

**Source of funding:** none

**Ethical clearance:** taken

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# An Emerging Infection “Scrub Typhus”- A Detailed Clinical Profile and Complications among Children in a Tertiary Hospital

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## Abstract

**Objectives:** To study the clinical profile and complications of **Scrub typhus** in children.

**Methods:** This descriptive study conducted in Siddhartha Medical college, Vijayawada, among children less than 12 years for a period of one year(December 2020-November 2021).A total of 49 children who are serologically/ clinically diagnosed cases of Scrub typhus.

**Results:** Scrub typhus mainly occurred in school going children with male predominance. Fever being the single most clinical presentation in most of the cases(95.9%) associated with pallor, hepatosplenomegaly. Co infection was documented in 14.2% cases with 85.7% cases showing increased morbidity and mortality. Mortality rate is more in infants.

**Conclusions:** Among cases of Acute febrile illness, Scrub typhus accounts for 9.8% of cases. Main clinical features were persistent fever, hepatosplenomegaly, thrombocytopenia, anemia along with capillary leak signs like edema with or without eschar.

**Infants** are at high risk for complications and mortality.

**Keywords:** Scrub typhus, anemia, thrombocytopenia, hypotension.

## Introduction

Scrub typhus is an **Emerging infectious** disease that is caused by *Orientia tsutsugamushi* from chigger bite. It is common in Asia-Pacific countries especially in India<sup>[1]</sup>. The disease is characterized by diverse clinical manifestations ranging from a mild, self-limiting state to variable severity like acute respiratory distress syndrome(ARDS), meningoencephalitis<sup>[2]</sup>.

Scrub typhus and other rickettsial infections are **grossly under-diagnosed** in India because of their non-specific clinical presentation, low index of suspicion among clinicians, limited awareness about the disease and lack of diagnostic facilities.<sup>[3]</sup>

Hence a high degree of suspicion and knowledge on clinical features is needed for early diagnosis and treatment<sup>[4]</sup>. So that significant morbidity and

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mortality can be avoided in Children. Use of empirical antibiotics have been recommended, pending serology to prevent life threatening complications.<sup>[5]</sup>

A cross sectional observational study was conducted, to study the clinical features and complications of pediatric scrub typhus. The aim of the study is to determine the clinical profile and risk factors in children presenting with scrub typhus and various clinical and laboratory clues to diagnose clinically, for the early diagnosis and treatment to prevent complications and mortality

### Aims and Objectives

#### Primary Objective:

1. To study the clinical profile of scrub typhus in children.
2. To study the complications of scrub typhus.

#### Secondary Objective:

1. To find out the laboratory clues for early diagnosis.
2. To identify the risk factors for complications in scrub typhus infection.

### Methods and Methodology

Study type: cross -sectional / observational/ institutional study.

- Place of study: department of pediatrics/old government general hospital, vijayawada affiliated to siddhartha medical college.
- Duration of the study: 1 year (December 2020 to November 2021)
- Sample unit: all children aged less than 12 years either positive scrub typhus
- Serology or clinically diagnosed scrub typhus cases(response to treatment).
- Sample size: 49 children meeting inclusion and exclusion criteria.
- Sampling technique: purposive sampling technique.

#### Inclusion Criteria:

All Children of Age Group From Birth to 12 years With

1. Positive scrub typhus serology
2. Clinically diagnosed cases where serology was not feasible(based on treatment response-

Standard therapy of Doxycycline(oral or IV) 4-5mg/kg/day or Azithromycin(oral or IV) 5mg/kg/day.

#### Exclusion Criteria:

Isolated other proven causes of acute febrile illnesses.

Serologically negative cases.

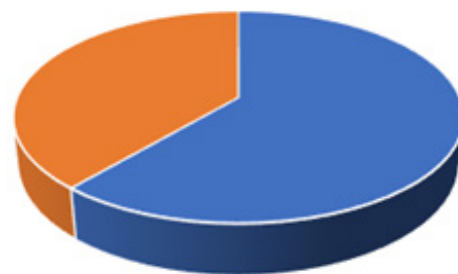
### Results

Totally **49 children** were diagnosed with Scrub typhus either serologically(**35**) or clinically(**14**). It comprised of about **9.8%** of cases with acute febrile illnesses. Scrub typhus affects mainly of **school going age group** (27(55%)) followed by preschool age group(9(18.4%)), toddlers (8(16.4%)) and infants (5(10.2%)) **Fig 1**. Affecting mainly boys(30(61.2%)) than girls(19(38.7%))**Fig 2**.



■ Infants      ■ toddlers  
■ pre schooler   ■ school going

**Fig 1: Age Distribution**



■ male

**Fig 2: Gender Distribution**

#### Clinical Presentation:

All 49 cases had a history of fever for a duration of <7days in 20(40%) cases, 7-14days in 22(45.8%) cases,>14 days in 6(12.2%) cases. So most cases are presented with history of fever for 1 to 2 weeks without diagnoses. Gastrointestinal symptoms were present in 25(51%) cases which includes vomiting(14(28.5%)), abdominal pain(10(20.4%)), loose stools 1(2%), abdominal distension(2(4%)) and jaundice(2(4%)).

**Clinical Features (Table 1):** Respiratory symptoms in 20(40.8%) cases which includes cough(11(22.4%)) and breathing difficulty (9(18.3%)). Central nervous system involvement in 15(30.6%) cases. Vascular leak symptoms like facial puffiness, hypotension in 4(8%) cases. Clinical signs includes altered sensorium in 5(10.2%) cases, tachypnea in 11(22.4%), tachycardia

in 9(18.3%), hypotension and rash noted in 2(4%) cases, pallor in 35(71.4%) cases, icterus in 2(4%) cases, lymphadenopathy in 11(22.4%) cases, edema in 4(8%) cases. The most pathognomonic finding of scrub typhus, eschar is seen in 13(26.5%) cases. Hepatosplenomegaly was documented in 35(71.4%) cases.

**Table 1: Clinical Profile: Symptoms and signs of Scrub typhus**

SYMPTOMS	FREQUENCY (n)	PERCENTAGE (%)	SIGNS	FREQUENCY	PERCENTAGE (%)
FEVER	49	100	FEBRILE STATE	45	91.8
<7 DAYS	20	40	ALTERED SENSORIUM	5	10.2
7-14 DAYS	24	45.8	PALLOR	35	71.4
>14 DAYS	6	12.2	ICTERUS	2	4
GASTRO INTESTINAL SYMPTOMS	25	51	LYMPH ADENOPATHY	11	22.4
VOMITING	14	28.5	EDEMA	4	8
ABDOMINAL PAIN	10	20.4	ESCHAR	13	26.5
LOOSE STOOLS	1	2	ISOLATED HEPATO MEGALY	7	14.3
ABDOMINAL DISTENSION	2	4	ISOLATED SPLENO MEGALY	2	4
JAUNDICE	2	4	HEPATO SPLENOMEGALY	35	71.4
RESPIRATORY SYMPTOMS	20	40.8	TACHYPNEA	11	22.4
COUGH	11	22.4	TACHYCARDIA	9	18.3
BREATHING DIFFICULTY	9	18.3	ASCITES	3	6
CNS SYMPTOMS	15	30.6	HYPOTENSION	2	4
HEADACHE	10	20.4	RASH	2	4
CONVULSION	5	10.2			
VASCULAR LEAK SYMPTOMS					
FACIAL PUFFINESS	4	8			

**Co infection;** was noted in 7(14.2%) cases which includes malaria in 4 cases, dengue positive in 2 cases and leptospirosis in 1 case. Acute rheumatic fever criteria positive in one case of scrub typhus serology positive case. 6 out of 7 cases with co infection showed significant morbidity(85.7%) with one mortality.

**Complications;** like moderate to severe Anemia noted in 5(10%) cases, thrombocytopenia in 40(81.6%), which is another important clue in diagnoses of scrub typhus. Hypotension noted in 3(6.1%) cases, transient hypertension in 1 case.

Pneumonia in 8(16.3%) cases, meningoencephalitis in 7(14.2%) cases, myocarditis, hepatitis and shock in 2 cases each. Other complications includes seizure, bradyarrhythmias, CCF, pleural effusion, ARDS, Acute Kidney injury & DIC.

**Mortality** is seen in 3 cases(6.1%). Causes of death being ARDS, Cardiogenic shock, encephalopathy.

## Discussion

Out of 49 children, 35 cases were diagnosed serologically and 14 cases were diagnosed clinically

based on criteria formulated by Rathi et al<sup>[6]</sup>.Scrub typhus constitutes about 9.8% of cases with acute febrile illnesses.

**Distribution**

Mean age of infection in my study is 6 years which is school going age group and most commonly affects boys of rural population. All these findings are similar to studies like Bhat NK et al, Kalal BS et al<sup>[8]</sup>, Kumar M,et al, Thomas R et al<sup>[1]</sup>, Rathi N,Rathi A et al<sup>[6]</sup>. The seasonal period in which scrub typhus infection occurred in my study is between August to January similar to studies like Thomas R et al<sup>[1]</sup> and Rathi N et al<sup>[6]</sup>.

Fever is present in 91.8% of patients at the time of admission whereas history of fever is present in all the patients. Lymphadenopathy documented in 22.4% cases which is lower than the cases reported in studies like Rathi N et al(41%)<sup>[6]</sup>,Bhat NK et al(38%)<sup>[7]</sup>,Kalal BS et al<sup>[8]</sup> (49%), and similar to the study done by Thomas R et al<sup>[1]</sup>.

Eschar is documented in 26.5% of cases similar to studies like Bhat Nk et al<sup>[7]</sup>,Kalal BS et al<sup>[8]</sup>.Rash is uncommonly present in my study(4%) which is in contradiction with the studies done by Thomas R et al<sup>[1]</sup> where rash is reported in 50% of cases and Rathi N et al<sup>[6]</sup> which reported 59% of cases with rash.

**Symptomatology**<sup>(TABLE 2)</sup>

**Table 2: Comparison Of Various Studies For Symptomatology**

STUDY	Rathi N, Rathi A (2009) <sup>[6]</sup>	Bhat NK, Dhar M, et al (2011-2012) <sup>[7]</sup>	Kalal BS et al., (2011-2012) <sup>[8]</sup>	Kumar M, Krishnamurthy S, Delhikumar CG, et al (2011) <sup>[9]</sup>	Thomas R, Puranik P,, et al (2008-2012) <sup>[1]</sup>	MY STUDY
Fever	100%	100%	100%	100%	100%	95.9%
Lymph adenopathy	41%	38%	49%	37%	21.8%	22.4%
Eschar	7%	20%	36%	11%	5.7%	26.5%
Rash	59%	20%	26.4%	20%	50%	4%

**CLINICAL PRESENTATION**<sup>(TABLE 3)</sup>

My study ,similar to other studies showed commonly hepatomegaly(82.7%),but it is associated with or isolated splenomegaly is present in 75.5% cases which is higher than other studies like Bhat NK et al<sup>[7]</sup>, Vivekanandan M et al<sup>[3]</sup> studies.Anemia(85.5%)

and or thrombocytopenia(81.6%) is documented in my study which is higher than other studies like Rathi N et al<sup>[6]</sup>, Bhat NK et al<sup>[7]</sup>,Vivekanandhan M et al<sup>[3]</sup>. Hyponatremia is noted in my study,similar to other studies.

**TABLE 3: COMPARISON OF VARIOUS STUDIES FOR CLINICAL PRESENTATION**

STUDY	Bhat NK, Dhar M, et al (2011-2012) <sup>[7]</sup>	Vivekanandan M, Mani A, Priya YS, et al (2011-2012) <sup>[3]</sup>	Kumar M, Krishnamurthy S, Delhikumar CG, et al (2011) <sup>[9]</sup>	Thomas R, Puranik P, et al (2008-2012) <sup>[1]</sup>	Rathi N, Rathi A (2009) <sup>[6]</sup>	MY STUDY
Hepatomegaly	82%	67.9%	91%	87%	99%	82.7%
splenomegaly	59%	32.1%	60%	50%	Not included	75.5%
Anemia	62%	69.8%	Not mentioned	68.7%	71%	85.5%
Thrombocytopenia	53%	66.7%	31%	Not included	68%	81.6%
Electrolyte imbalance	Not documented	Hyponatremia (<125meq/dl) 5.6%	Hyponatremia 17%	Hyponatremia 11.5%	64% hyponatremia	36.7% Hyponatremia (20.4%) Hypocalcemia (24.4%)
Average no of hospital day	7 days	7 days	6 days	7 days	7 days	7 days

**COMPLICATIONS**<sup>(TABLE 4)</sup>

61.2% (n=30) cases showed complications. Severe anemia (<6gm/dl) is seen in 4% cases which is less when compared to studies like Thomas et al<sup>[1]</sup>. Bhat NK et al<sup>[7]</sup>. Severe thrombocytopenia (<50,000) is seen in 42.7% which is less than the study done by Kalal BS et al<sup>[8]</sup>, more than the studies like Bhat NK et al<sup>[7]</sup>, Kumar M et al<sup>[9]</sup>. Meningoencephalitis is documented in 14.2% cases which is similar to the study by Rathi N<sup>[6]</sup> et al, Kala BS et al, Kumar M et al<sup>[9]</sup>. Pneumonia is seen in 16.3% which is higher than studies done by Kumar M et al<sup>[9]</sup>, Thomas R et al<sup>[1]</sup>. Hypotension is seen in 6.1% cases in my study which is higher than studies like Thomas M et al<sup>[1]</sup>, Rathi N et al<sup>[6]</sup> but lower than the studies like Kalal BS et al<sup>[8]</sup> and Kumar M et al<sup>[9]</sup>. Other rare complications are transient hypertension (2%), simple febrile seizures (2%), Diffuse cerebral atrophy (2%), myocarditis (4%), transient bradyarrhythmias (2%), Congestive cardiac failure (2%), pleural effusion (2%), ARDS (2%), Renal impairment (2%), Hepatitis (4%), DIC (2%), shock (4%). Mortality is seen in 3 cases (6.1%) due to ARDS, Cardiogenic shock and encephalopathy respectively which is similar to studies like Rathi N et al<sup>[6]</sup>, Bhat

NK et al<sup>[7]</sup> and higher than the studies done by Kumar M et al<sup>[9]</sup> and Thomas R et al<sup>[1]</sup>.

In addition to these findings, my study documented co infection of scrub typhus with other infections in total of 7 cases (14.2%). Co infection with malaria in 4 cases, dengue in 2 cases and leptospirosis in 1 case. One peculiar finding is that one of the serologically positive case showed features of Acute rheumatic fever which was diagnosed based on Modified Jones criteria and the case died due to cardiogenic shock despite the necessary cardiac support. 6 out of 7 cases with co infections showed severe morbidity and mortality.

One more important finding includes even the infants (n=5) can acquire scrub typhus, despite less outdoor activities and they are prone to develop severe complication which is 80% (n=4) and mortality in 40% (n=2) mainly due to endothelial damage and vascular leaking. Combination of all these features with capillary leak signs especially in endemic areas, diagnosis of Scrub typhus must be considered and treatment to be initiated early<sup>[10]</sup>.

**TABLE 4: COMPARISON OF VARIOUS STUDIES FOR COMPLICATIONS:**

COMPLICATIONS	Bhat NK, Dhar M, et al (2011-2012) <sup>[7]</sup>	Kalal BS et al, (2011-2012) <sup>[8]</sup>	Kumar M, Krishnamurthy S, Delhikumar CG, et al (2011) <sup>[9]</sup>	Thomas R, Puranik P., et al (2008-2012) <sup>[1]</sup>	Rathi N, Rathi A (2009) <sup>[6]</sup>	MY STUDY
SEVERE ANEMIA (<6g/dl)	6.1%	(<11g/dl) 69.8%	Not included	68.7%	71% (<9g/dl)	4%
SEVERE THROMBOCYTOPENIA (<50000)	27.2%	66.7%	31% (<1,00000)	Not included	Not included	42.7%
HYPOTENSION	Not mentioned	10%	34%	1%	3%	6.1%
HYPERTENSION (TRANSIENT)	Not mentioned	0	0	Not included	0	2%
MENINGO ENCEPHALITIS	30.3%	17%	17%	28%	15%	14.2%
SIMPLE FEBRILE SEIZURE	Not mentioned	15%	0	Not included	0	2%
DIFFUSE CEREBRAL ATROPHY	Not mentioned	0	0	Not included	0	2%
MYOCARDITIS	9.1%	0	34%	Not included	5%	4%
TRANSIENT BRADYARRHYTHMIA	Not mentioned	0	0	0	0	2%



Continue.....

CONGESTIVE CARDIAC FAILURE	Not mentioned	0	0	0	0	2%
PNEUMONIA	10.6%	0	3%	6.1%	21%	16.3%
PLEURAL EFFUSION	9.1%	0	14%	Not included	0	2%
ARDS	12.1%	0	9%	1%	5%	2%
HEPATITIS	13.6%	81.1%	31%	0	Not included	4%
RENAL IMPAIRMENT	16.7%	0	20%	0.4%	5%	2%
SHOCK	25.8%	10%	34%	1.9%	5%	4%
DIC	1.5%	0	9%	Not included	5%	2%
MORTALITY	7.5%	0%	2.8%	1.9%	8%	6.1%

### Conclusions

1. In cases of Acute febrile illness especially after monsoon season ,consider the diagnosis of Scrub typhus,
2. Consider empirical treatment with Doxycycline as delay in the treatment after complications may lead to serious morbidity and mortality.
3. Main clinical clues includes persistent fever, hepatosplenomegaly, thrombocytopenia, anemia along with leak signs like edema with or without Escher ,in endemic area consider the first differential diagnosis as Scrub typhus.
4. In resource limited settings,consider starting Doxycycline if the clinical clues points towards Scrub typhus as drastic response will be seen.
5. Although duration of fever doesn't correlate with the complications, delay in treatment may lead to serious complications.
6. Like other hemorrhagic fever, **Infants** are high risk group for complication and mortality as 80% of them showed complications and 66% mortality. Other risk factor includes **co infections** (14.2%).Consider doing investigations for other infections also for better outcome.

**Conflict of Interest:** None

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## Diabetes Mellitus and its Association with Body Mass Index in Sputum Positive Tuberculosis Patients in a Tertiary Health Care Centre

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### Abstract

**Background:** Tuberculosis is a chronic infectious disease that causes pulmonary tuberculosis and also affects other tissues of the body. People with diabetes mellitus and those who are underweight have an increased risk of getting active tuberculosis. The objectives of the study were to estimate the prevalence of diabetes mellitus and to determine its association with Body Mass Index in tuberculosis patients.

**Methods:** In the present record-based cross-sectional study, 100 sputum smear positive tuberculosis patients 18 years and older who attended the out-patient department of Pulmonary Medicine from 1/6/2020 to 31/12/2022 were included and sputum smear negative patients were excluded. Data entry and analysis was done in Microsoft Excel. Percentages were calculated and association between diabetes mellitus and Body Mass Index of the study population was assessed by chi square test.

**Conclusion:** The prevalence of diabetes mellitus in tuberculosis patients was almost double than that of the general population of India and its association with underweight was found to be statistically significant. So proper screening of all patients of tuberculosis for diabetes mellitus is necessary for early diagnosis and treatment. Health education and counselling are equally important.

**Keywords:** Body Mass Index, diabetes mellitus, prevalence, tuberculosis.

### Introduction

Tuberculosis is a chronic infectious disease caused by Mycobacterium Tuberculosis. It affects the lungs causing pulmonary tuberculosis, and can also affect intestine, meninges, skin, lymph glands, bones and joints and other tissues of the body.<sup>1</sup> As of today, about one-third of the population all over the world is infected asymptotically with tuberculosis, out of which 5 to 10 percent will develop signs

and symptoms of the disease in their lifetime.<sup>2</sup> The infection is usually acquired during childhood in the developing countries from where many new cases and deaths are reported. The annual risk of tuberculosis infection is about 0.5 to 2 percent in high burden countries.<sup>3</sup>

India has the highest number of incident cases of tuberculosis that occur each year. About 26 percent of the global incident tuberculosis cases in India in

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the year 2019.<sup>4,5</sup> In addition to the disease burden caused by tuberculosis, it also causes an enormous socioeconomic burden to India. Tuberculosis usually affects individuals in their most productive years of life. About two-thirds of all tuberculosis cases in India are male, but more than 50 percent of female cases occur before the age of 34 years.<sup>6</sup> In India, tuberculosis affects the poor people that include slum dwellers, migrant labourers and people residing in backward areas and tribal areas. Malnutrition, overcrowding, poor housing conditions are the reasons for the spread of the disease.<sup>7</sup>

There are over 347 million people all over the world suffering from diabetes mellitus, as reported by the World Health Organization.<sup>8</sup> The low and middle income countries have about 95 percent of tuberculosis patients and 70 percent of diabetes mellitus patients.<sup>9,10</sup> The prevalence of diabetes mellitus in India is 7.3% with urban regions in the country having a prevalence of 11.2%.<sup>11</sup> It is indicated that by the year 2030, diabetes mellitus will become the seventh leading cause of death all over the world and 90 percent of the diabetes mellitus cases will be of type 2 diabetes mellitus.<sup>12</sup> People with diabetes mellitus have two to three times increased risk of getting active tuberculosis compared to people without diabetes mellitus.<sup>13</sup>

In most of the underdeveloped regions of the world, malnutrition and tuberculosis are both serious problems, mainly in South Asian countries.<sup>14</sup> It is necessary to study the interaction of these two problems with each other. Malnutrition is associated with increased severity of infections including tuberculosis while infections in turn lead to malnutrition. In India, malnutrition is the most prevalent risk factor for tuberculosis. In immune compromised individuals and those with certain diseases, the risk of acquiring tuberculosis is significantly increased.<sup>15</sup> People with a weakened immune system such as people living with HIV (Human Immunodeficiency Virus) infection, malnutrition, diabetes mellitus or smokers have an increased risk of getting infected with tuberculosis. There are five risk factors that cause an increase in the number of new cases of tuberculosis. They are undernutrition, HIV infection, alcohol use, smoking and diabetes mellitus.<sup>16</sup>

The present study was carried out with the following objectives:

- i). To estimate the prevalence of diabetes mellitus in study population.
- ii). To estimate the prevalence of underweight in study population.
- iii). To determine the association of diabetes, addictions and HIV with BMI (Body Mass Index) in study population.

### Materials and Methods

The present record based cross-sectional study was carried out in a tertiary health care centre. The laboratory investigations of all the patients suspected of having tuberculosis that attended the OPD (Out-Patient Department) of Pulmonary Medicine from June 2020 to December 2022 with the complaints of cough more than 2 weeks duration that was not resolved by medication, were carried out. There were 2,224 such patients that attended the OPD during the study period. Out of these, 100 patients tested positive for sputum smear. These 100 patients were included in the present study.

**Inclusion criteria:** All the patients aged 18 years and above that were sputum smear positive.

**Exclusion criteria:** Patients who had symptoms suspected of tuberculosis but who tested sputum smear negative.

Demographic information of the study participants such as age, gender and place of residence was noted down. History of addictions was also noted. Anthropometric data such as height in centimetres and weight in kilograms was noted. The Body Mass Index (BMI) of each patient was calculated accordingly using the formula = weight in kilograms/square of the height in metres.

Laboratory investigations like blood sugar level, HIV (Human Immunodeficiency Virus) infection status was also noted down.

Before including the study participants in the present study, during their OPD visit they were explained about the nature and purpose of the study, they were informed that their names won't be revealed and verbal consent was obtained from them.

Data entry and analysis was done in Microsoft Excel. The mean age, mean height and mean weight of the study participants was calculated. The percentage of study participants who were underweight, those who had diabetes mellitus, those who had addictions was calculated. The association of diabetes mellitus, addictions and reactive HIV infection with underweight study participants was

tested for significance with the help of chi square test by constructing 2 x 2 tables. The degree of freedom was 1, meaning that at 5% level of significance, the chi square values more than 3.84 were considered statistically significant and those with a value below 3.84 were not statistically significant. The results were analysed and are given as follows.

## Results

**Table 1: Age and gender wise distribution of study population (n=100).**

Age group in years	Males		Females		Total	
	Number	Percent	Number	Percent	Number	Percent
15 to 24	3	3	7	7	10	10
25 to 34	11	11	4	4	15	15
35 to 44	19	19	5	5	24	24
45 to 54	15	15	5	5	20	20
55 to 64	12	12	6	6	18	18
65 and above	10	10	3	3	13	13
Total	70	70	30	30	100	100

Out of the total 100 study participants, 70 were males and 30 were females. The mean age of all the participants was 45.29 15.64 years. The mean age of males was 47.01 14.40 years while that of the females was 41.27 17.84 years. There were 38 participants that were residing in an urban area while 62 participants were residing in a rural area. The prevalence of

tuberculosis was highest (24%) in the age group of 35 to 44 years and lowest (10%) in the age group of 15 to 24 years.

Out of the total study participants, 38 (26 males and 12 females) were staying in an urban area while 62 (44 males and 18 females) were staying in a rural area.

**Table 2: Distribution of study population according to addictions (n=100).**

Addictions	Males		Females		Total	
	Number	Percent	Number	Percent	Number	Percent
Tobacco	10	10	1	1	11	11
Alcohol	1	1	0	0	1	1
Tobacco and alcohol	7	7	0	0	7	7
Smoking	1	1	0	0	1	1
Total	19	19	1	1	20	20

There were 20 percent study participants who had addictions with a majority of them (11%) having

the addiction of tobacco chewing.

**Table 3: Distribution of study population according to their Body Mass Index (n=100).**

Body Mass Index	Males		Females		Total	
	Number	Percent	Number	Percent	Number	Percent
Underweight	38	38	14	14	52	52
Normal	27	27	12	12	39	39
Pre-obese	5	5	3	3	8	8
Obese class I	0	0	1	1	1	1
Obese class II	0	0	0	0	0	0
Obese class III	0	0	0	0	0	0
Total	70	70	30	30	100	100

The mean height of all study participants was 158.22 7.40 cm. The mean height of the males was 160.60 6.41 cm while that of the females was 152.7 6.61 cm. The mean weight of all the study participants was 47.01 10.55 kg. The mean weight of the males was 47.2 10.21 kg while that of the females was 46.57 11.48 kg.

A majority of the study participants (52 percent) were underweight followed by normal BMI participants (39 percent), pre-obese participants (8 percent) and class I obesity participants (1 percent).

The mean BSL (Blood Sugar Level) of all the study participants was 133.8 71.54 mg/dl. The mean BSL of the males was 135.31 74.16 mg/dl while that of the females was 130.27 66.08 mg/dl. There were 16 study participants who had diabetes mellitus out of which 12 were males and 4 were females.

Out of the total 100 study participants, there were 6 study participants (3 males and 3 females) that had a reactive HIV test.

**Table 4: Association of diabetes with underweight in study population.**

Diabetes mellitus	Underweight (BMI<18.50)	
	Yes	No
Present	3	13
Absent	49	35

CHI SQUARE VALUE = 8.44 p value = 0.03677  
p < 0.05

The association of diabetes mellitus in the sputum positive tuberculosis study participants was statistically significant with their underweight status as shown by the chi square value of 8.44 and a p value less than 0.05.

**Table 5: Association of addictions with underweight in study population.**

Addictions	Underweight (BMI<18.50)	
	Yes	No
Yes	14	6
No	38	42

CHI SQUARE VALUE = 3.24 p value = 0.072  
p > 0.05

As it is evident from the table 8, the association of addictions of the study participants with their underweight status is not statistically significant as

the chi square value is less than 3.84 and p value is more than 0.05.

**Table 6: Association of HIV infection with underweight in study population.**

HIV status	Underweight (BMI<18.50)	
	Yes	No
Reactive	2	4
Non-reactive	50	44

CHI SQUARE VALUE = 0.90 p value = 0.34  
p > 0.05

The association of the HIV status of the study participants is not significant with their underweight status.

## Discussion

The mortality due to tuberculosis can be due to many risk factors that include diabetes mellitus, smoking, malnutrition and HIV infection.<sup>17</sup> The prevalence of diabetes mellitus in the study participants found by the present study was 16 percent which is higher than that of the general population of India (7.3%).

Similar findings were found by a study done by Kottarath MD et al.<sup>18</sup> in Kerala that showed a prevalence of diabetes mellitus to be 19.6% in the patients of tuberculosis. Studies done by Kumpatla S et al.<sup>19</sup> in Tamil Nadu and by Raghuraman S et al.<sup>20</sup> in Puducherry reported a prevalence of diabetes mellitus in tuberculosis patients to be 25 percent and 29 percent respectively. This was more than that found by the present study.

All the studies are showing a similar finding that the prevalence of diabetes in the tuberculosis patients is greater than that found in the general population. This tells us about the fact that diabetes mellitus and uncontrolled blood sugar level can reduce the immunity of an individual and make him or her more susceptible to acquiring tuberculosis.

Screening of the patients of tuberculosis for diabetes mellitus with tests for blood sugar level, glycated haemoglobin, etc. is necessary for its early diagnosis and treatment in order to keep a controlled blood sugar level and maintain the health and quality of life of the patients.

In the present study, the prevalence of underweight study participants was 52 percent and the association of diabetes mellitus with underweight was statistically significant. Similar findings were reported by a study conducted by A. Z. Soh et al.<sup>21</sup> which showed that diabetes mellitus and underweight were associated with approximately 2 to 3 times increased risk of acquiring tuberculosis. Low BMI increases the risk of tuberculosis and tuberculosis can cause loss of weight.<sup>22</sup> Low BMI indicates poor nutritional status and impaired cell-mediated immunity caused due to malnutrition increases the risk of acquiring tuberculosis.<sup>23</sup>

### Conclusion

In the present study, the prevalence of diabetes mellitus in the tuberculosis patients was found to be almost double than that of the general population of India with the prevalence being more in the males than the females. The association of diabetes mellitus with underweight of the study participants was statistically significant. So proper screening of all the patients of tuberculosis for diabetes mellitus is necessary for early diagnosis and treatment.

Though the association of addictions with the underweight status of study population was not statistically significant, it is known that addictions, especially smoking in case of tuberculosis aggravate the health status of a person and smoking damages the respiratory as well as cardiovascular system. So, the patients must be advised to completely stop the addiction that they are having.

Health education and counselling of the patients of tuberculosis about the things that they can do to maintain a normal blood sugar level in diabetic as well as non-diabetic study participants such as moderate exercise like walking every day for at least one hour, eating frequent meals without starving oneself, self-care in diabetes mellitus, importance of continuing the ongoing treatment and follow up, the harmful effects of addictions, consuming a healthy and balanced diet in order to maintain normal weight and to increase the weight to normal range in case of underweight patients, and proper nutrition is necessary.

**Ethical clearance:** Taken from Institutional Ethics Committee of the Institution.

**Source of funding:** Self.

**Conflict of Interest:** Nil.

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# An Online Knowledge-Attitude-Practice Survey in the Community about Adult Hypertension from Eastern India

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## Abstract

**Background:** To address the reasons for hypertension disease burden it is important to understand the knowledge, attitude, and practices (KAP) of all pertinent stakeholders including the community. This study explored the perception in the community regarding the burden of hypertension in India as this is lacking in Indian studies.

**Methods:** A cross-sectional survey was conducted through online mode in India using a validated, field-tested questionnaire incorporating KAP domain questions regarding hypertension. Scores to questions were appropriately assigned.

**Results:** The mean (SD) age of the respondents was 28.49 (7.508) years (n=225). The median (IQR) KAP scores were measured out of a maximum of 18, 5 and 4, respectively. Higher educational and socioeconomic levels were associated with better attitude scores, but knowledge levels were comparable. Correlations between KAP scores were poor.

**Conclusions:** This study reveals that laypersons in the community have appropriate knowledge and attitude regarding hypertension to some extent but there are important lacunae and practices are often found wanting. These issues need to be addressed through sustained public sensitization and motivational campaigns to improve the future and treatment outcomes of hypertension in India.

**Keywords:** KAP (knowledge-attitude-practices); Hypertension; Community; survey, India.

## Introduction

HTN presents a major area of intervention because it is a frequently occurring condition that is amenable to control through both nonpharmacological lifestyle factors and pharmacological treatment. While antihypertensive medications have been used for blood pressure control, there has been increasing

emphasis on the prevention and treatment of HTN by nonpharmacological means termed lifestyle modifications. The recommended lifestyle measures that have been shown to be capable of reducing blood pressure include (i) salt restriction, (ii) moderation of alcohol consumption, (iii) high consumption of vegetables and fruits and low-fat and other

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types of diet, weight reduction and maintenance, and (v) regular physical exercise. Hypertensive patients irrespective of their stage or grade should be motivated to adopt these measures. Motivating patients to implement lifestyle changes is probably one of the most difficult aspects of managing HTN.<sup>[1-3]</sup>

KAP questions tend to reveal not only characteristic traits in knowledge, attitude, and behaviors about health but also the idea that each person has of the disease. These factors are often the source of misunderstandings. The obstacle to change may be lack of knowledge. Recent reports have suggested that HTN knowledge is related to blood pressure control. The importance of HTN awareness and knowledge and the potential impact of BP education programs have been reported recently. Although the outcome of a KAP study seems simple, the results of the study can have a huge impact on the local community.<sup>[2]</sup>

As the KAP study explores what is known and what is done in relation to a health care-related objective which is about hypertension in this study, the results will reveal the baseline information of the community and may reveal the misconceptions in relation to practice of hypertension.<sup>[4,5]</sup>

## Methods

In this analytical cross-sectional study, a simple survey method was done in 225 people through online mode using Google survey platform and in this case the Google form was circulated through electronic media. The knowledge, attitude and practice (KAP) survey questionnaire was prepared in English construct validity check through peer review. Forward translation was done by (English and Bengali). The questionnaire was then back translated to English to ensure the original meaning was unchanged. The final questionnaire comprised of responder details and 31 questions (knowledge domain 15, attitude 8, practice 8).<sup>[6,7]</sup>

Inclusion criteria were both diabetic and non-diabetic individuals aged above 18 years. Exclusion criteria were patients with gestational hypertension, patients younger than 18 years. After approving the validity and reliability of the questionnaire, 125 participants were enrolled. They filled out the

questionnaire and their level of knowledge, attitude, and practice as well as the affecting factors were evaluated. Permission for conducting the study was accorded from the Institutional Ethics Committee (IEC) at Deben Mahata Government Medical College & Hospital, Purulia, West Bengal. The ethics committee had granted waiver of informed consent after due deliberation and upon satisfying that the study involved less than minimal risk to the participants in the community.

The study was designed as a eight-week-long questionnaire-based cross-sectional survey in the online mode across India and coordinated by the authors. The participating institution caters to patients of diverse socio-cultural and economic backgrounds. Respondents were visitors to the hospitals without any doctor or healthcare provider in their immediate family. Sampling was purposive and involved visitors to (a) various departments and administrative office (b) out-patients and indoor patients of the hospitals.<sup>[8,9]</sup>

The knowledge, attitude and practice (KAP) survey questionnaire was designed primarily by the author (RC) and approved by other two authors SS and RS. The master version was prepared in English and underwent face and construct validity check through peer review. The questionnaire was then back translated to English by the original translators to ensure the original meaning was unchanged. The final questionnaire comprised responder details and 27 items (knowledge domain 18, attitude 5, practice 4) related to hypertension. The questionnaire was administered to each respondent in an online mode (through Google forms) and scores were assigned for each question – one point for each correct answer and 0 for incorrect or uncertain response. Consolidated scores were obtained after summing across each of the three domains – knowledge, attitude and practice – individually. The scores on each domain were compared between centres, educational and socioeconomic subgroups. The study questionnaire (English version) is provided as supplementary material.

Sample size calculation assumed that the population of eligible respondents over a 4-week period was found to be 377. In the absence of supporting data, we also assumed that roughly

50% of the surveyed population is likely to have satisfactory knowledge-attitude-practice regarding antibiotic use. Thus, we estimated that the survey required 377 respondents to be interviewed so as to refine this 50% estimate with 4% margin of error and at 95% confidence level. Based on feasibility and by rounding off, we have kept a sample size of 125, RAOSOFT (Seattle, USA) sample size calculator, which is available online (<http://www.raosoft.com/samplesize.html>), was used for sample size estimation<sup>[8-11]</sup>.

Data were analysed using SPSS version 20.0 (Illinois; Chicago: IBM) and Medcalc version 15.8 (Mariakerke, Belgium: MedCalc Software bvba; 2015) software. Descriptive summary has been reported as frequency, mean (standard deviation [SD]) or median (interquartile range [IQR]). Mann Whitney U or Kruskal Wallis with Dunnet post hoc tests (for non-parametric data) or unpaired *t* test (for parametric data, Chi square test (for categorical data) were employed for comparing subgroups. Analyses were two-tailed and the cut-off for statistical significance was set at  $p < 0.05$ . Association between scores in different domains were quantified by Spearman's correlation coefficient rho on the presumption of linear associations on corresponding scatterplots.

### Results and Discussions <sup>[12,13, 15]</sup>

A large proportion of respondents (64.8%) stated not suffering from HTN. For the 225 study participants, the mean (SD) age was  $28.49 \pm 7.508$  years. Among the respondents a male preponderance 62.4% was observed. A higher proportion of the respondents 58.4% reported to be living in urban areas. 47.2 % of the respondents stated not having hypertension patients in family. About 86.4% of the study respondents had monthly family income of more than Rs 10,000 per month. 68.8 % respondents stated not drinking alcohol while 75.8 % patients reported not smoking.

Previous K-A-P studies from India have not focused particularly on Eastern Indian context with respect to community perception and practice in relation to hypertension. Therefore, various issues need to be addressed in order to close the gaps between KAP responses and actual practice. Although education is considered as an integral part

of hypertension management, it remains low in the practical priorities of clinicians. The results of this study encourage a positive outlook: all that is required is trained hypertension educator in hypertension management to counsel patients during their every visit. As a result, it is expected that counselling may have an impact in improving the perception about the disease, diet, and lifestyle changes and thereby addressing risk factors to prevent the complications of hypertension.

However, all participants had similar more or less access to information and to readily accessible education. Therefore, considering the average illiteracy rate and the demographic spread of the study participants from rural to urban, the findings of this study may be considered to represent those of the general population.<sup>[14, 16,17]</sup>

### Conclusions

The study shows an average level of hypertension awareness and good level of positive attitudes towards the importance of hypertension care. Yet at the same time the study found high levels of hypertension negligent behaviour among the study respondents. This paradoxical response was noted from the study and hence we propose on the need to carry out large-scale awareness programs specifically pertaining to the knowledge- gaps about hypertension in the community, after identifying the appropriate means to spread the message to the general population. There is also a need to develop of innovative tools and educational models that improve patient compliance and practices to hypertension management in Eastern India. Education and counselling on all aspects of hypertension is much needed. Planning for group as well as individual education programs will deliver preventative and management techniques for HTN. Limitations of study include the chance of respondents giving false information which is also possible for any KAP study survey. There is room for community practice to be improved by the provision of adequate information, increasing the availability of educational materials and proper guidance towards hypertension management. The study reinforces the view that the main approach to managing this problem is towards integrating all stakeholders' for understanding, compliance and management of the

disease by means of suitable health specialists and through widespread mass awareness campaigns by NGO's and Governmental agencies looking after public health.

**Conflict of interest:** None

**Source of Funding:** Self

**Ethical Clearance:** Taken from IEC, Deben Mahata Government Medical College & Hospital, Purulia, West Bengal.

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# A Case-Control Study on Low birth weight and Associated Epidemiological Determinants among Tribal Population of Dahod, Gujarat

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## Abstract

**Background:** The healthy future of society depends on the today's children and their mother's health. Low birth weight (LBW) is a valuable public health indicator of maternal health, nutrition, healthcare delivery. So, a case-control study was planned to assess the local scenario of district.

**Objectives:** To study the epidemiological determinants like socio-demographic, maternal, socioeconomic, environmental factors and Antenatal care (ANC) package utilization related to low birth weight.

**Methodology:** A Case-control study was carried out at tertiary care hospital, Dahod. We had selected 150 cases and equal number of controls for present study.

**Results:** The results showed that factors like kachha house (OR=1.82), chulha as kitchen fuel (OR=1.76), illiteracy (OR=2.85), labourer (OR=3.57), age above 30 years (OR=2.81), short stature (OR=12.95), less prepregnancy weight (OR=3.04), less body mass index (OR=1.84), less weight gain during pregnancy (OR=2.11)(OR=4.82), less interpregnancy interval (OR=0.41), less maternal age at time of marriage (OR=2.67), later registration of pregnancy (OR=0.001), less than 4 Antenatal care (ANC) visits (OR=2.29), less Iron folic acid (OR=2.70) and calcium supplementation (OR=2.18) than recommended and no utilization of take-home ration from anganwadi center (OR=2.18) were significantly associated with the risk of low birth weight babies.

**Conclusion:** Study provides local scenario of district as various epidemiological determinants are more prone for LBW. The best way is to act at grass root level, firstly from health care side by strengthening the available services and engaging every beneficiary and secondly from pregnant women and family side by educating and motivating them.

**Keywords:** Low birth weight, Epidemiological determinants, Case control study, Antenatal care

## Introduction

The healthy future of society depends on the

today's children and their mother's health.<sup>[1]</sup> To grow a healthy baby, mothers need good nutrition and rest, adequate antenatal care and a clean environment.<sup>[2]</sup>

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Low birth weight (LBW) has been defined by the World Health Organization (WHO) as weight at birth of less than 2,500 grams.<sup>[3]</sup> It is a valuable public health indicator of maternal health, nutrition, healthcare delivery and poverty.<sup>[4]</sup> Low birth weight is the single most important factor determining the survival chances of the child. Many of them die during their first year. Others become victims of protein- energy malnutrition and infection. The infant mortality rate is about 20 times greater among all LBW babies.<sup>[3]</sup>

The prevalence of low birth weight in Southern Asia was 26.4% in 2015.<sup>[5]</sup> As per National family health survey - 4 (NFHS) report, 18% of births had LBW in India.<sup>[6]</sup> As per Sustainable development goals (SDG), goal 3 is to end preventable deaths of newborns and children under five years of age by 2030, with all countries aiming to reduce neonatal mortality to 12 per 1000 live births, and under-five mortality to 25 per 1000 live births.<sup>[7]</sup>

In developing countries, including India, the majority of LBW infants because of intrauterine growth retardation (IUGR) with only 6.7% born prematurely.<sup>[8]</sup>

Low birth weight can affect the future health of the child. Our district is a tribal district of eastern Gujarat. As per NFHS- 4 in Dahod, 44.4 % of children categorized as stunted, 24.9% as wasted and 50.9 % as underweight. Etiology of Low birth weight is very complex varied from region to region<sup>[9]</sup> and therefore, to assess the local scenario of district, a case-control study was planned with the objectives of determining the epidemiological determinants more prone for low birth weight.

## Methodology

A Case- control study was carried out at tertiary care hospital named Zydus medical college and hospital, Dahod in the year 2021.

### Sample size:

Sample size was estimated by using formula  $n = \frac{(r+1)}{r} [ p(1-p) (Z_{\beta} + Z_{\alpha/2})^2 ] / (p_1 - p_2)^2$

Where, n is Required number of samples, r is the ration of control to cases (We are using 1:1), p is average proportion exposed,  $Z_{\alpha/2}$  is standard normal variate for 5% level of significance is 1.96,  $Z_{\beta}$  is

standard normal variate for power of study for 80% is 0.84,  $p_1$  and  $p_2$  are proportion in cases and controls respectively.<sup>[10]</sup>

On the basis of one of the important variables of LBW was maternal undernutrition (Body mass index < 18.5 kg/m<sup>2</sup>) from the previous study.<sup>[11]</sup> According to that sample size of 119 each was estimated for cases and controls. For better implications, we had selected 150 cases and equal number of controls for present study.

### Inclusion criteria:

All the mothers who gave birth (Normal or caesarean section) to singleton babies at term (37 to 42 weeks of gestation), newborns weighing less than 2,500 gm. were included as cases and weighing more than 2,500 gm. were included as controls.

### Exclusion criteria:

Mothers with preterm deliveries (< 37 weeks of gestation)<sup>[12]</sup>, multiple pregnancy, any medical condition and those who are not willing to participate

### Selection criteria:

After each case was selected, the next available newborn baby born in same environment with birth weight more than 2500 grams was selected and included in the control group.

### Study tool:

A pretested structured questionnaire included information like socio-demographic profile, maternal, environmental and local cultural factors, anthropometric measurements, utilization of ANC package and government services.

The study data was collected from abstraction of Mamta cards, medical records of mothers and new born babies (Birth weight was the first weight of the newborns measured within 15 min after birth<sup>[11]</sup>), anthropometric assessments and interview of mothers. Eligible mothers were interviewed face to face within 48 hours after delivery.

### Statistical analysis:

Data was collected, compiled and analyzed by using Microsoft Excel and SPSS (v-16). Summary statistics such as mean and standard deviation was

computed for cases and controls. Logistic regression analysis was applied.

#### Ethical Considerations:

Study was approved by the Institutional Ethical Committee of Zydus medical college and hospital, Dahod. Interview was started after informed individual consent for participation and when mother felt comfortable to give answers. All data will be stored

securely ensuring the participant's confidentiality.

#### Results

A total of 300 mothers with their respective newborns (150 cases and 150 controls) were included in the study. The mean birth weight was 2249 gm with SD of 218.5 gm for cases and 3034 gm with SD of 303.6 gm for controls.

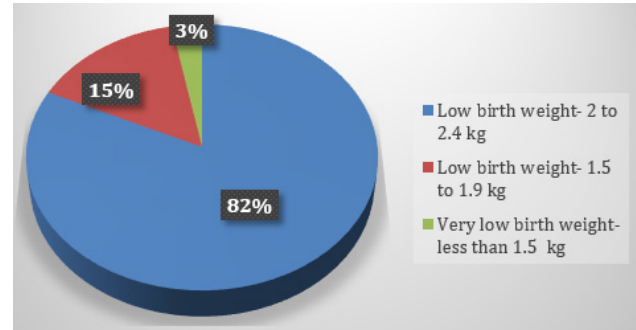
**Table 1: Sociodemographic and environmental factors**

Parameters		Cases	Percentage (%)	Controls	Percentage (%)	Odds ratio (95% CI)	P value
Socioeconomic class	I	2	1.33	1	0.67	1	
	II	41	27.33	42	28.00	0.49 (0.04 - 5.59)	0.564
	III	59	39.33	58	38.67	0.50 (0.04 - 5.76)	0.585
	IV	41	27.33	40	26.67	0.51 (0.04 - 5.87)	0.591
	V	7	4.67	9	6.00	0.39 (0.03 - 5.21)	0.475
House type	Kachha	95	63.33	73	48.67	1.82 (1.15 - 2.89)	0.01
	Pakka	55	36.67	77	51.33	1	
Kitchen fuel	Chulha	92	61.33	71	47.33	1.76 (1.15- 2.79)	0.015
	Gas	58	38.67	79	52.67	1	
Mother's education	Illiterate	45	30.00	21	14.00	2.85 (1.04- 7.82)	0.04
	Primary	48	32.00	40	26.66	1.6 (0.61- 4.18)	0.34
	Secondary	35	23.33	59	39.33	0.79 (0.30- 2.06)	0.63
	Higher secondary	13	8.67	18	12.00	0.96 (0.31 - 2.95)	0.94
	Graduate	9	6.00	12	8.00	1	
Father's education	Illiterate	28	18.67	22	14.67	1.45 (0.58-3.61)	0.41
	Primary	44	29.33	43	28.67	1.17 (0.51-2.68)	0.71
	Secondary	37	24.67	42	28.00	1.00 (0.43-2.33)	0.98
	Higher secondary	27	18.00	27	18.00	1.14 (0.47-2.79)	0.76
	Graduate	14	9.33	16	10.67	1	

Continue.....

Mother's occupation	Housewife	83	55.33	85	56.66	2.92 (0.90-9.45)	0.07
	Labourer	73	48.66	53	35.33	3.57 (1.08-11.71)	0.03
	Service	4	2.67	12	8.00	1	

Majority of the participants in both cases and controls belongs to joint and three generation family and Hindu religion. Table 1 shows about bivariate logistic regression analysis was performed between sociodemographic factors of mothers and LBW. It revealed that house type ( $p<0.01$ ), kitchen fuel ( $p<0.015$ ), mother's education ( $p<0.04$ ) and occupation ( $p<0.03$ ) were statistically significant. The results showed that mothers living in kachha house ( $OR=1.82$ ,  $CI=1.15-2.89$ ) and using chulha as a kitchen fuel ( $OR=1.76$ ,  $CI=1.15-2.79$ ) were having almost double the risk of having low birth weight babies. Illiterate ( $OR=2.85$ ,  $CI=1.04-7.82$ ) and labourer mothers ( $OR=3.57$ ,  $CI=1.08-11.71$ ) were having three times higher the risk.



**Figure 1: Distribution of Low birth weight categories**

Above pie chart shows that 82% of babies had birth weight of 2 to 2.4 kg and 15% had 1.5 to 1.9 kg. Around 3% babies were having very low birth weight (less than 1.5 kg).

**Table 2: Maternal factors**

Parameters	Cases	Percentage (%)	Controls	Percentage (%)	Odds ratio (95% CI)	P value	
Maternal age	< 19 years	4	2.67	1	0.67	4.33 (0.48-39.24)	0.19
	19-30 years	133	88.67	144	96.00	1	
	>30 years	13	8.67	5	3.33	2.81 (0.98-8.10)	0.05
Maternal height	$\leq 140$ cm	12	8.00	1	0.67	12.95 (1.66-100.9)	0.01
	> 140 cm	138	92.00	149	99.33	1	
Maternal pre-pregnancy weight	$\leq 40$ kg	46	30.67	19	12.67	3.04 (1.68-5.51)	0.0002
	> 40 kg	104	69.33	131	87.33	1	
Maternal BMI	<18.5 Kg/m <sup>2</sup>	88	58.67	65	43.33	1.84 (1.14-2.97)	0.01
	18.5-22.9 kg/m <sup>2</sup>	53	35.33	72	48.00	1	
	$\geq 23$ kg/m <sup>2</sup>	9	6.00	13	8.67	0.94 (0.37-2.36)	0.89

Continue.....

Weight gain during pregnancy	>11 kg	5	3.33	12	8.00	0.97 (0.29-3.24)	0.96
	Ideal - 9 to 11 kg	15	10.00	35	23.33	1	
	5 to 8 kg	66	44.00	73	48.67	2.11 (1.05-4.20)	0.03
	1 -4 kg	64	42.66	30	20.00	4.82 (2.29-10.63)	0.0001
Parity	1	60	40.00	48	32.00	1	
	2	55	36.67	65	43.33	0.68 (0.40-1.14)	0.14
	3 or more	35	23.33	37	24.67	0.76 (0.41-1.37)	0.36
Interpregnancy interval	Primigravida	60	40.00	48	32.00	1	
	>= 36 months	32	21.33	62	41.33	0.41 (0.23-0.73)	0.002
	<36 months	58	38.67	40	26.66	1.16 (0.67-2.01)	0.59
Age at marriage	< 19 years	24	16.00	10	6.67	2.67 (1.23-5.79)	0.01
	>=19 years	126	84.00	140	93.33	1	
History of abortion	Yes	4	2.67	1	0.67	4.08 (0.45-36.96)	0.21
	No	146	97.33	149	99.33	1	
Tobacco addiction	Yes	6	4.00	2	1.33	3.62 (0.74-17.73)	0.11
	No	144	96.00	148	98.67	1	

Table 2 explains about the maternal risk factors associated with low-birth-weight babies.

The mean+<sub>-</sub> SD of maternal age among the cases was 23 +<sub>-</sub> 3 years and 24 +<sub>-</sub> 3 years among controls. The mean+<sub>-</sub> SD of maternal height for cases and controls was 157 +<sub>-</sub> 7.6 cm and 159.1+<sub>-</sub> 6.1 cm, respectively.

Table showed that maternal age ( $p<0.05$ ), maternal height ( $p<0.01$ ), pre-pregnancy weight ( $p<0.0002$ ), maternal undernutrition ( $p<0.01$ ), weight gain during pregnancy ( $p<0.03$ ), Interpregnancy interval ( $p<0.002$ ) and age at marriage ( $p<0.01$ ) were statistically significant with LBW. It revealed that mothers aged above 30 years

had almost triple the risk (OR=2.81, CI=0.98-8.10). Maternal height of 140 cm or less were having almost 13 times higher risk (OR=12.95, CI=1.66-100.9). Maternal prepregnancy weight 40 kg or less had three times (OR=3.04, CI=1.68-5.51) and BMI less than 18.5 (OR=1.84, CI=1.14-2.97) had two times higher the risk. During pregnancy, Mothers who gained 5 to 8 kg weight and 1 to 4 kg weight had two times (OR=2.11, CI=1.05-4.20) and five times (OR=4.82, CI=2.29-10.63) higher the risk respectively. Interpregnancy interval (OR=1.16, CI=0.67-2.01) and maternal age at time of marriage (OR=2.67, CI=1.23-5.79) were risk factors. There was no difference in bad obstetric history and tobacco addiction in both the groups.



**Table 3: Antenatal care (ANC) package utilization history**

Parameters		Cases	Percentage (%)	Controls	Percentage (%)	Odds ratio (95% CI)	P value
Registration of pregnancy (Time during pregnancy)	No	4	2.67	1	0.67	6.54 (0.71-60.10)	0.09
	1 <sup>st</sup> trimester	52	34.67	85	56.67	1	
	2 <sup>nd</sup> trimester	75	50.00	58	38.67	2.11 (1.30-3.43)	0.002
	3 <sup>rd</sup> trimester	19	12.67	6	4.00	5.17 (1.94-13.79)	0.001
Antenatal care (ANC) visits attended	No	4	2.67	1	0.67	4.96 (0.54-45.07)	0.15
	< 4	42	28.00	20	13.33	2.60 (1.44-4.70)	0.0015
	>=4	104	69.33	129	86	1	
Iron folic acid (IFA) tablets consumption	No	8	5.33	7	4.67	1.80 (0.62-5.24)	0.27
	<100	82	54.67	48	32.00	2.70 (1.67-4.37)	0.0001
	>=100	60	40.00	95	63.33	1	
Calcium tablets consumption	No	9	6.00	7	4.67	2.14 (0.74-6.21)	0.16
	<100	102	68.00	78	52.00	2.18 (1.32-3.57)	0.002
	>=100	39	26.00	65	43.33	1	
Utilization of take-home ration from anganwadi center	Yes	106	70.67	126	84.00	1	
	No	44	29.33	24	16.00	2.18 (1.24-3.81)	0.006

Above table showed, registration of pregnancy ( $p<0.002$ ), number of ANC visits ( $p<0.001$ ), status of IFA ( $p<0.0001$ ) and calcium tablets consumption ( $p<0.002$ ) and utilization of take-home ration from anganwadi center ( $p<0.006$ ) were found to be statistically significant with LBW. The odds of LBW were two to five times higher among mothers who didn't register pregnancy in 1<sup>st</sup> trimester and had less than 4 ANC visits. The mothers who had taken IFA for less than 100 days were two times more prone. Similarly, less than 100 days calcium supplementation and no utilization of take-home ration from anganwadi center had two times higher risk.

## Discussion

In our study, maternal education was found to be significantly associated with LBW babies. Similar finding was observed by M M Nagargoje et al in Nagpur, Maharashtra [13], Arohi Dalal et al in Ahmedabad [9] and Ravi Kumar Bhaskar et al in Eastern Nepal.[14]

There was association between LBW and kachha houses in our study. Ravi Kumar Bhaskar et al [14] suggests the same finding. The likelihood of delivering LBW babies were significantly higher among mothers using Chulha (firewood) as a cooking

fuel. This finding supports the study done in India [15] and in Ethiopia. [11]

Our study revealed association between maternal occupation as a labourer and LBW. This finding is similar to study in Nagpur [13] and different from study in Ethiopia in 2015.[11] Our findings suggest socioeconomic class (S.E) had no association. Similar finding was observed by Ravi Kumar Bhaskar et al. [14]It was contrast to Habtamu Demelash et al, where S.E class negatively affect weight of new born.[11]

In our study, maternal age had significant association, which is consistent with other studies[11] [16]and Contrast to study in Nepal.[14] We found that maternal undernutrition and short stature were risk factors. These findings were consistent with other studies.[11][13] Study by Semira Ahmed et al in Ethiopia found that maternal undernutrition is significant.[17]

In present study, less than ideal (9 -11 kg) weight gain during pregnancy was highly significant. It was similar to study by Anil K C et al. [18] In our study, Maternal Pre-pregnancy weight 40 kg or less is higher risk which was consistent with study in Ahmedabad. [9]

As per our finding, mothers with birth spacing less than 3 years were prone for LBW. This finding is similar to study in Nagpur, India [13], Nepal [14] and Ethiopia.[11] Our results showed, Parity was not significant. Study by Ravi Kumar Bhaskar et al [15] observed similar finding but study by Anil K.C et al observed contrast finding.[18]

We observed that late registration of pregnancy and less than 4 ANC visits had significant association. Similar findings were found by Ravi Kumar Bhaskar et al [14]. Timing of the first ANC visit was associated with study by D.K Yadav et al.[19] S.D Singh et al support the finding of number of ANC visits.[20] We found that intake of recommended Iron supplements during pregnancy had protective effect. Similar result was observed by other studies.[14][17][18]

### Conclusion

In present study, findings showed that various epidemiological determinants were identified as significant determinants of low birth weight. As our district is tribal district, all these factors reflect about

Lack of education, Lack of knowledge about essential aspects of pregnancy, nutrition, and supplementation, Various cultural beliefs, Poor health seeking behavior, Decision making on importance of ANC checkup and utilization of health care services.

### Recommendations

In consideration with local scenario of our district, best way is to act at grass root level. Firstly, from health care side by strengthening the available services and engaging every beneficiary through different local platforms with involvement of village sarpanch or local leaders and secondly from pregnant women and family side by educating and motivating them.

Largely, MAMTA DAY services should be strengthened. Role of Female health worker should be strengthened to identify high risk mothers, timely intervention, nutritional and family planning counselling. Role of Accredited social health activist (ASHA) worker should best strengthened to aware and motivate women for early registration of pregnancy, recommended antenatal visits and maternal schemes utilization. Strengthening the adolescent girl services in district will plan the future healthy mothers and their babies.

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# To Study the Prevalence and Sources of Stress among Medical Students of Sangareddy District

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## Abstract

**Background:** This study aimed to investigate the stress levels experienced by medical undergraduates in order to comprehensively evaluate stressors, their sources and contributing factors.

**Method:** This cross-sectional study conducted at a private medical college in Sangareddy district, used the Kessler 10 Psychological Distress Inventory to evaluate the mental well-being of medical undergraduates. Additional data points were collected for analysis and Cronbach's alpha coefficient was used to scrutinize the questionnaire's reliability.

**Results:** This study conducted with a sample size of 320 participants, the prevalence of stress among medical students was explored. The sample group consisted of 36.25% males and 63.75% females, aged between 18 and 24 years with a mean age of 20.8 years (standard deviation of 1.3). The findings revealed that 72.5% of the medical students experienced mild to severe stress, with prevalence rates of 22.5% for mild stress, 21.3% for moderate stress and 28.7% for severe stress. Notably, female students had a slightly higher likelihood of experiencing stress compared to males.

**Conclusion:** We discovered that stress is significantly related with various factors such as procrastination, perceived physical ailments and multiple sources of stress. The most common sources of stress are demanding academic workloads, exam-related pressures, financial difficulties and personal problems.

**Keywords:** stress, medical students, Kessler, medical college, Sangareddy

## Introduction

Stress is a normal physiological and psychological response to demands and challenges. It can be triggered by various factors, including academic demands, time pressure, interpersonal relationships and personal problems etc<sup>1</sup>.

Medical college is a challenging and demanding environment that can expose students to high levels

of stress. Medical students face a heavy workload, intense competition and high stakes in their academic and clinical training. They also encounter various stressors related to their future career, such as the uncertainty of the job market, the demands of the profession and the ethical and moral dilemmas of medical practice<sup>2,3</sup>

Studies have consistently shown that medical students experience high levels of stress compared

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to their non-medical counterparts and the general population. A review of the literature found that medical students had higher rates of stress, anxiety and depression than the general population with rates ranging from 20% to 70% depending on the study and the measures utilized<sup>4,5</sup>.

Several factors contribute to the high levels of stress experienced by medical students. One of the main stressors is the academic demands of medical college, which include a heavy workload, challenging course material and high expectations for grades. Medical students also face the added pressure of clinical rotations, where they are expected to perform under the supervision of attending physicians and residents. Other stressors include time management challenges, financial concerns and personal relationships<sup>6,7</sup>.

One intriguing aspect of stress management in medical school is the use of adaptive coping strategies by students to tackle both external and internal stressors. Medical students often harbour the belief that their lives would significantly improve if the challenges they face were somehow lifted. Nevertheless, the transition from student to intern only adds to the burden of stress, as the responsibility for the well-being of patients now rests squarely on their shoulders<sup>8,9</sup>.

Stress can have negative consequences on the physical and mental health of medical students. It can lead to sleep disturbances, fatigue and decreased immune function, which can affect their performance and well-being. Stress can also increase the risk of developing mental health problems, such as anxiety, depression and burnout. Burnout, in particular, is a syndrome characterized by emotional exhaustion, depersonalization and a lack of accomplishment and it has been found to be prevalent among medical students<sup>10,11</sup>.

In addition to its impact on health, stress can also affect academic performance and retention. Studies have shown that high levels of stress are associated with lower grades and a higher risk of dropping out of medical college. Stress can also impact the quality

of care provided by medical students, as it can lead to poor communication and decision-making skills<sup>12-14</sup>.

In this background the present study was done with the following objectives.

#### **Objectives:**

To estimate the prevalence of stress among undergraduate medical students.

To identify the sources of stress.

To determine the association of stress with socio-demographic factors.

To examine the association between stress levels and academic performance.

### **Methodology**

#### **Study Subjects:**

It was a cross-sectional study conducted in all the male and female medical students in the four academic years of a private Medical College from Sangareddy district. The students were invited to participate in the study by sending invitation through Whatsapp. The data was collected from the students who accepted the invitation using a questionnaire prepared in google forms. The google forms link was sent through whatsapp. The study period was from October 2022 to February 2023.

#### **Inclusion Criteria:**

Students from all the semesters who had completed at least 6 months in medical college and all selected individuals who have accepted the invitation and gave consent were included in the study.

#### **Exclusion Criteria:**

Students who did not accept the invitation and who have not given consent.

#### **Study Tool:**

There were various methods that was used to address psychological distress scales among medical students, including the Perceived Stress

Scale (PSS), Stress Symptoms Inventory (SSI), Cohen Perceived Stress Scale (CPSS) and other commonly and less commonly used instruments. For this study, we employed the Kessler10 Psychological Distress instrument (K10), developed by Kessler and colleagues, which was widely utilized in population-based epidemiological studies to measure current (1-month) distress<sup>15,16</sup>.

The K10 was translated into several languages and was been utilized in the World Mental Health Survey of the World Health Organization as a clinical outcome measure. It consists of 10 questions regarding specific symptoms of distress, such as feeling tired or sad and offers responses on a scale from “none of the time” to “all of the time”. The responses are scored from 1 to 5 and all of the questions are combined to obtain a total score. A score below 20 is considered to indicate no stress, while scores between 20 and 24 indicate mild stress, scores between 25 and 29 indicate moderate stress and scores between 30 and 50 indicate severe stress. In addition to the K10 questions, the questionnaire also included additional questions related to academic achievement, sources of stress and perceived physical symptoms. The K10 has demonstrated good psychometric properties, with a Cronbach’s alpha co-efficient of 0.913 in this study.

#### **Collection of Data:**

To ensure the authenticity of the responses, google forms questionnaires were administered to the students two months prior to the examination period. The students were given ample time and privacy to answer additional questions on their academic achievements, sources of stress and number of days missed to college. It’s important to note that participation in the study was voluntary and the main aim was to obtain unbiased and accurate data.

#### **Analysis of Data:**

The study data was inputted into Microsoft Excel and analysed using SPSS software (version

26.0). The outcome variable, which was categorized dichotomously as either no stress or presence of stress, was created by combining the three levels of stress (mild, moderate and severe) into one category. Descriptive statistics, including mean, standard deviation and percentages, were used to summarize the study and outcome variables. The association between the categorical outcome variable (i.e., stress level) and the different study variables was observed and quantified using Pearson’s chi-square test for trend and odds ratios. Logistic regression was used to identify independent risk factors for stress. Odds ratios (adjusted) with 95% confidence intervals were calculated and a p-value of less than 0.05 was considered significant.

### **Results**

This research examined the stress levels of 320 medical students from 1st to 4th year. The participants had a mean age of 20.8 years, with a standard deviation of  $\pm 1.3$  and their characteristics are presented in Table 1.

The findings revealed that female students were slightly more likely to experience stress (73.5%) compared to their male counterparts ( $\chi^2=0.29$ ;  $p=0.58$ ) and third-year students had slightly higher stress levels (75.4%) than students in other years ( $\chi^2=0.42$ ;  $p=0.93$ ) (Table 1)

Moreover, the analysis indicated that there was no significant association between regular attendance in academic coursework and stress levels among the students. The distribution of stress did not significantly differ between regular and irregular attendees ( $\chi^2=1.2$ ;  $p=0.25$ ).

In this study, procrastination and the presence of stress showed statistically significant relation ( $\chi^2=3.8$ ;  $p=0.049$ ) (Table 1).

Students who reported physical symptoms were more likely to be stressed than those who did not perceive physical symptoms (Table 1).

**Table 1: The study characteristics**

Study characteristics		STRESS			
		Yes	No	Total	P Value
Gender	Male	82	34	116	0.584
	Female	150	54	204	
I am student of	1st Year MBBS	72	28	100	0.936
	2nd Year MBBS	68	28	96	
	3rd Year MBBS	49	16	65	
	4th Year MBBS	43	16	59	
Did you perceive any physical problems like headache, anxiety etc. due to stress?	Yes	184	46	230	0.000*
	No	48	42	90	
Procrastination (Postponement of work)	Yes	196	66	262	0.049*
	No	36	22	58	

\*The Chi-square is significant at less than 0.05 level

The distribution of stress levels among the study subjects, revealing a prevalence of approximately 72.5% for stress of all levels. The prevalence of severe stress was identified to be 28.7%, while moderate stress accounted for 21.3% and mild, no stress is 22.5%, 27.5% respectively.

different sources like “Demanding daily academic work”, “Pressure to perform well in exams”, “Financial problems”, “Personal problems” and “Other problems”, all these sources of stress have been shown statistically significant with p value less than 0.05 as shown in Table 2.

Students who are presented with stress have

**Table 2: Sources of Stress**

Sources of Stress		STRESS					
		Yes		No		Total	P Value
		Count	Row N %	Count	Row N %		
Demanding daily academic work	Yes	154	77.8%	44	22.2%	198	0.007*
	No	78	63.9%	44	36.1%		
Pressure to perform well in exams	Yes	192	75.0%	64	25.0%	256	0.045*
	No	40	62.5%	24	37.5%		
Financial Problems	Yes	116	86.6%	18	13.4%	134	0.000*
	No	116	62.4%	70	37.6%		
Personal Problems	Yes	166	78.3%	46	21.7%	212	0.001*
	No	66	61.1%	42	38.9%		
Other Problems	Yes	126	80.8%	30	19.2%	156	0.001*
	No	106	64.6%	58	35.4%		

\*The Chi-square is significant at less than 0.05 level

Table 3 shows the association between student's academic performance, year of study and procrastination with the presence of stress was examined through binary logistic regression.

The study revealed that there was no significant association between academic performance, year of study and procrastination with the stress experienced by the students.

**Table 3: Binary Logistic Regression Analysis**

Variables	AOR (95% C.I)	P-Value
<b>Year of Study</b>		
1 <sup>st</sup> year (ref)	-	-
2 <sup>nd</sup> year	1.0 (0.5-1.9)	0.88
3 <sup>rd</sup> year	0.8 (0.3-1.7)	0.57
4 <sup>th</sup> year	0.8 (0.4-1.9)	0.77
<b>Procrastination (Postponement of work)</b>		
Present (ref)	-	-
Absent	1.8 (0.9-3.3)	0.05
<b>Academic Performance in last 30 days</b>		
Very Poor (ref)	-	-
Poor	0.8 (0.2-3.1)	0.79
Good	0.8 (0.2-3.0)	0.81
Very Good	1.8 (0.3-11.1)	0.50

\*Significance at p < 0.05; AOR: Adjusted Odds Ratios; CI: Confidence Interval

Table 4 shows the proportion of male students with severe stress perceiving physical problems like headache, anxiety (38.9%) is slightly higher than that of female students ( $\chi^2=11.02$ ,  $p=0.012$ )

**Table 4: Relation between levels of stress and perceived physical problems due to stress**

Physical Problems			Kessler K10 Stress Levels					P Value
			No Stress	Mild Stress	Moderate Stress	Severe Stress	Total	
Did you perceive any physical problems like headache, anxiety etc. due to stress?	Yes	Male	18	20	10	28	72	0.012*
		Female	28	30	42	58	158	
	No	Male	16	16	10	2	44	0.056
		Female	26	6	10	4	46	

Note: \*Significance at p < 0.05

Table 5 shows the proportion of students with severe stress and very poor academic performance (50%) is substantially larger than those with other levels of stress ( $\chi^2=11.7$ ,  $p=0.22$ )

**Table 5: Academic Performance**

Academic performance		Kessler K10 Stress Levels				
		No Stress	Mild Stress	Moderate Stress	Severe Stress	Total
How is your academic performance during your past 30 days?	Very Poor	4	2	2	8	16
	Poor	20	18	16	30	84
	Good	60	48	48	54	210
	Very Good	4	4	2	0	10
	Excellent	0	0	0	0	0



Our findings demonstrated a Cronbach's alpha co-efficient of 0.913, which indicates a high degree of internal consistency among the survey questions used in the study.

### Discussion

Stress can sometimes serve as a motivating factor, helping people to focus and work harder towards achieving a goal. However, when stress is prolonged or chronic, it can have negative impacts on a person's performance and efficiency. Chronic stress can lead to physical and mental exhaustion, difficulty concentrating and a reduced ability to think and make decisions. It is important to find healthy ways to manage stress and to take breaks to recharge and reduce the risk of burnout.

Several studies have shown that medical students experience a higher prevalence of emotional distress compared to the general population<sup>17,18</sup>.

This research aimed to investigate the perceived levels of stress and their primary sources among health profession students and explore the possible association between stress levels and academic performance. The findings indicated that 28.7% of the participants reported high stress levels, which is consistent with previous studies conducted in Saudi Arabia. This may be due to the higher academic demands and time constraints placed upon the students<sup>19</sup>.

The study further revealed that the primary sources of stress were related to demanding daily academic work, pressure to perform well in exams, financial problems, personal problems. Similar results were reported in a study by Al-Dubai et al in medical students of Malaysia, which ranked academic stress, residence and other stressors encountered by students<sup>20</sup>.

In our study the procrastination or postponement of college work like exam preparations, record-work, assignments etc. to the last moment had ill effects on stress levels and you can see the similar procrastination effect on stress in the study conducted by Kufiyak, Elena from Moscow institute of Psychoanalysis<sup>21</sup>.

Stress is manifested in different forms and one of it is perceived in physical problems like headache,

anxiety, insomnia etc. and in this study, it showed a significance and is similar to the study conducted by Regab et al from Middle East and also Bergmann C from Germany<sup>22,7</sup>.

In a study conducted by Tyssen et al, it was discovered that mental distress and depression were significant predictors of suicidal ideation among medical students in Norway<sup>23</sup>.

This study employed the Kessler K-10 psychological stress assessment tool, which has been widely used in similar research studies. For instance, a related investigation conducted by Qamar K from Pakistan also utilized this tool and discovered that female medical students experienced higher levels of stress and Kessler k10 was also used in medical students by Sat pal et al from India<sup>24,25</sup>.

According to research conducted by a medical college in New Delhi, it was found that depression, anxiety, emotional distress is prevalent among medical students, highlighting the pressing need for personalized counselling, support and attention<sup>26</sup>.

### Conclusion

While conducting our study, we discovered that a large percentage of students (72.5%) were experiencing stress, with 28.7% of them being severely affected. Our research revealed that stress was significantly associated with various factors such as procrastination, perceived physical problems and multiple sources of stress such as demanding academic work, exam pressure, financial problems and personal problems.

### Recommendations:

Given that the majority of students are experiencing stress due to academic & other factors, it is imperative that they are equipped with better life skills such as time management, study planning and relaxation techniques such as meditation, yoga and extracurricular activities. Furthermore, it is necessary to review and make changes to the medical curriculum to address the mental health of students. Future studies should also be conducted to gain a deeper understanding of the various medical college environments in order to enhance the mental well-being of students throughout the country.

**Limitations:**

Student's family background, economic status and marital status, have not been taken into account which might have an impact on stress levels in medical students.

Since this cross-sectional study relied on self-reported data provided by the participating students, there is a possibility of reporting bias that may have resulted from a variety of factors. Respondent's personal interpretation of the questions, their desire to report their emotions in a certain way and the potential for inaccuracies in their responses could all contribute to this bias. Due to the limited scope of the study, it may not fully capture the negative impact of stress on medical students in its entirety. Therefore, the study results should be interpreted with caution and additional research may be necessary to corroborate the findings.

**Ethics Approval:**

Approval from the Institutional Ethics Committee was obtained for the study.

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