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# Exploring the Role of Emerging Pharmacotherapies in the Management of Alcohol Addiction: A Review

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## Abstract

Alcohol Use Disorder (AUD) poses a significant global public health challenge due to its widespread prevalence and substantial impact on individuals and society. Despite existing pharmacological and psychosocial interventions, treatment outcomes remain varied and often suboptimal.

The review includes an analysis of medications such as acamprosate, disulfiram, naltrexone, and newer agents like nalmefene, baclofen, ondansetron, and varenicline. Each drug's mechanism of action and clinical efficacy are discussed, highlighting their roles in reducing alcohol consumption, preventing relapse, and managing withdrawal symptoms. Additionally, the review examines the potential benefits of combining pharmacotherapies with psychosocial interventions to enhance treatment outcomes.

Methodologically, literature from PubMed, Google Scholar, and Embase was systematically reviewed to identify relevant studies published between 1990 and 2023. Quantitative and qualitative investigations focusing on pharmacotherapies for AUD were included, without exclusion criteria based on study design or geography.

Findings indicate varying degrees of effectiveness and safety profiles among different pharmacotherapies, underscoring the importance of personalized treatment approaches tailored to individual patient characteristics and comorbidities. The review concludes with implications for clinical practice and future research directions aimed at optimizing treatment strategies for AUD.

**Keywords:** alcohol use disorder, pharmacotherapy, acamprosate, disulfiram, naltrexone, review.

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## Introduction

Alcohol is a highly prevalent, chronic and relapsing medical condition among the people, with a very strong addiction factor. According to 2016 data suggests that 100.4 million people globally use alcohol, causing them addictive to alcohol and lead to condition called as alcohol usage disorder which makes it a significant public health concern.<sup>1</sup>

The alcohol consumption varies throughout decades and also country-wise, according to world health statistics 2023, the per capita of alcohol consumption (among 15+ years) are low i.e in 2005-10 there was increase and 2010-15 there was decrease in the alcohol consumption. The country wise trend of alcohol consumption; trend per capita covering WHO areas that include 17% and 18% (2000-2019) in Europe and Africa region. Similarly, stagnation in the region of America, high in South East Asia and Western Pacific region (112% and 40%) was seen.<sup>2</sup>

The alcohol disorders can be classified with many descriptions, with chronic and acute specifiers, such as episodic, excessive, habitual, intoxication abuse and dependence. It depends on the patterns and the amount of intake of the alcohol.<sup>3</sup>

Even with the increasing rates, the treatment for alcohol deaddiction remain quite low. Attributing it to stigma, social barriers regarding alcohol consumption, other reasons include that the mild cases tend to get recovered by naturalistic method, moderate cases too recover reasonable with some behavioural psychosocial changes. Hence the turnout and willingness to get treated remain low.<sup>4</sup>

For severe alcohol usage disorders, treatment is multidimensional with the pharmacological and psychosocial approaches. From moderate to severe alcohol usage disorder (AUD) treatment guidelines include acamprosate, disulfiram and naltrexone.

The above drugs have a high efficacy over the AUD outcomes.<sup>5</sup>

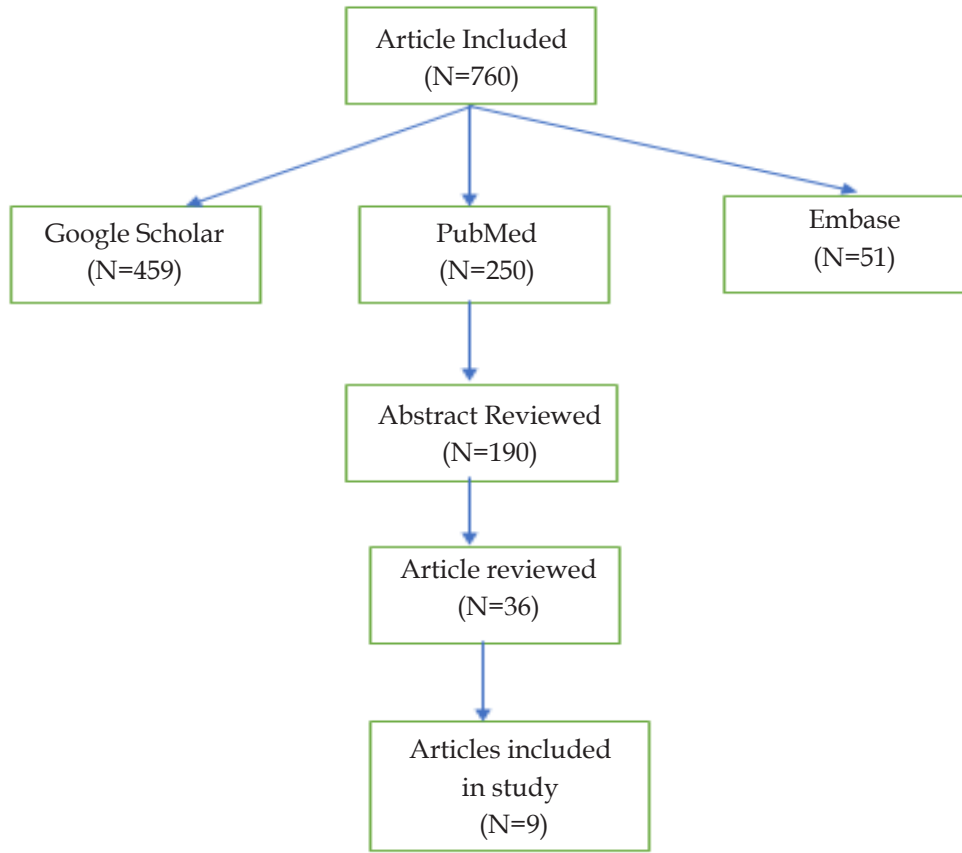
The pharmacological treatments include glucocorticoids, pentoxifylline and anti-tumour necrosis, they aim to decreasing the inflammation of the liver. Similarly, S-adenosylmethionine, N-acetyl cysteine, propylthiouracil, antioxidants decrease the oxidative stress to liver. Another drug Colchicine has anti-inflammatory and anti-fibrogenic effect. New medications development is particularly important for the treatment of co-morbidity disorders that commonly occur among individuals with alcohol use disorder, particularly affective disorders, anxiety disorders, suicidality, and other substance use disorders. This aspect of alcohol use disorder is relevant to the fact that addictive disorders often present with significantly more severe symptoms when they co-exist with other mental health disorders.<sup>6</sup>

The purpose of the study is to discuss the efficacy, mechanism of action, and tolerability of approved, repurposed, and novel pharmacotherapies for the treatment of AUD with a clinical perspective.

## Methodology

During August 2023 to December 2023, three of the authors, Akhila, Saurish and Jencil performed a systematic review of the literature to identify original articles reporting quantitative and qualitative investigations of newer pharmacotherapies, which were used in alcohol usage disorders. The search engine used in finding articles are PubMed, Google Scholar, EmBase electronic databases using the Medical Subject Heading (MeSH) terms *Alcohol usage disorder, pharmacotherapy* and *new*. We also conducted a manual search of reprint files, reference sections of review articles, and other publications.

**Table 1: Systematic representation of article selection**



**Table 2: Keywords used for article search in databases.**

Alcohol, alcoholic, alcohol disorder, alcohol usage disorder	Alcohol disorder
Pharmacotherapies, approved, repurposed, novel, precision medicine,	New pharmacotherapies
India	India

Eligible studies were those published from January 1990 through January 2010 in English. We did not have any exclusion criteria.

**Results**

Standard protocol followed in India:

**Disulfiram**

Disulfiram remains a viable option as a treatment for alcohol dependence and has been shown in recent studies to be successful in treating patients with alcohol dependence in a manner that is superior to both naltrexone and Acamprosate.

Usage

Mechanism of action: Disulfiram acts by inhibiting the enzyme acetaldehyde dehydrogenase (ALDH) via its metabolite S-methyl N, N-diethyl-dithio-carbamate-sulphoxide, leading to accumulation of acetaldehyde in blood. Since the inhibition of ALDH by disulfiram is irreversible, the DER will get terminated only after production of new ALDH once disulfiram is stopped. Hence patients should be advised to take alcohol only after 2 weeks of stopping disulfiram.<sup>12</sup>

Efficacy

One of three studies that compared unsupervised disulfiram with placebo reported significantly more abstinence. In a meta-analysis of two studies looking at abstinence at 12 months following unsupervised disulfiram compared to placebo, there was an effect which favoured disulfiram but the difference was not statistically significant.<sup>13</sup>

Side effects

A total of 32 (21%) neurological reactions to DSF were included in the Danish Data. The most frequent

diagnosis was polyneuropathy (18 cases). In our review, 11 (36%) reports were related to neurological side effects. Five of them were related to peripheral neuropathies. The earliest onset of neuropathy in the patients taking DSF was 10 days. Most reports placed the onset of symptoms at several months after commencing treatment<sup>1</sup>

### **Acamprostate**

The pharmacokinetics of acamprostate administered as an enteric-coated tablets are time- and dose-independent, and its accumulation ratio is about 2.4 at steady-state.<sup>15</sup>

#### **Usage**

It is thought to work as a weak antagonist of NMDA receptor and to inhibit the activity of the metabotropic glutamatergic receptor type 5 (mGluR5). Acamprostate was initially thought to modulate  $\gamma$ -aminobutyric acid type A (GABA-A) receptors but in-vitro evidence is consistent with an indirect effect.<sup>15-16</sup>

#### **Efficacy:**

In a still ongoing longitudinal study, it is shown that acamprostate helps significantly the recovery of some cognitive functions (independently of alcohol abstinence) in particular long-term visual-spatial memory and set-shifting ability, starting from the third month of abstinence from alcohol.

#### **Side effects:**

It is contraindicated in severe renal impairment and dose reduction in mild renal impairment, as renal impairment is related to increased plasma concentrations of acamprostate.

### **Naltraxone**

Oral and injectable forms of naltrexone are commercially available. It is used for managing of AUDs and it is effective to reduce alcohol use and craving. It is believed that Naltraxone (NTX) may lead to the antagonism of opioid pathways towards the nucleus accumbens, and thus reduces the amount of released dopamine.<sup>17</sup>

Naltrexone had provided effects in reducing risky drinking (percent high intensity drinking days only) among high reward/high relief drinkers,

inconsistent with prior findings among older adults. Among young adult heavy drinkers with this high reward/high relief profile, and relative to general adult treatment-seeking samples, may be more likely to be in the binge/intoxication stage (with emerging relief drinking tendencies), and therefore may still respond well to naltrexone.<sup>18</sup>

#### **Side effects:**

Impaired drug metabolism and hepatotoxicity in patients with underlying liver disease (LD) are likely barrier for use of this drug despite recent evidence demonstrating its safety among various patient populations without LD. We demonstrated that naltrexone is safe in patients with AUD and LD. Notably, no increase in adjusted means of AST and ALT supports a growing body of evidence supporting the safety of naltrexone in patients with LD prescribed naltrexone at dosages used for treating AUD<sup>19-20</sup>

#### **New drugs:**

### **Nalmefene**

Nalmefene is an antagonist at the mu- and delta-opioid receptor and a partial agonist at the kappa receptor and has been studied for substance use disorders, especially alcoholism, since the 1990s. The Nalmefene has a comparable chemical structure to naltrexone but was proposed to offer a number of potential advantages relative to naltrexone including a more effective binding to central opioid receptors. The relatively higher affinity of nalmefene at the kappa-receptor may be responsible for the increased hypothalamic-pituitary-adrenal axis activation via increased adrenocorticotrophic hormone<sup>21</sup>

#### **Side effects:**

Nalmefene, being a modulator of the opioid system, interacts with other opioids (methadone, buprenorphine, codeine) and may precipitate an opioid withdrawal syndrome. It has been reported in patients with opioid abuse (oxycodone or codeine) and in maintenance therapy with methadone and buprenorphine, Nalmefene has been studied in patients with stable psychiatric diseases showing that patients with AUD and psychiatric comorbidity (n=42) experienced adverse events after 6 months of nalmefene use with the same frequency as the general population (40%).<sup>22</sup>

## Baclofen

Baclofen is an agonist for gamma-aminobutyric acid (GABA)<sub>B</sub> receptors on pre- and postsynaptic neurons in the central nervous system (CNS) and peripheral nervous system.<sup>5</sup> The Agonism of GABA<sub>B</sub> receptors found on type Ia presynaptic neurons arising from extrafusal muscle spindles causes an influx of potassium (K<sup>+</sup>) leading to hyperpolarization of the neuronal membrane, as well as decreased calcium (Ca<sup>2+</sup>) influx at presynaptic nerve terminals.<sup>5,6</sup> The net result is a decrease in the rate of action potential threshold being reached by presynaptic type Ia neurons and decreased amplitude of excitatory postsynaptic potentials arising from gamma motor neurons that innervate the muscle spindles.<sup>23</sup>

### Side effects:

The severe adverse effect (SAEs) were the following: mental confusion (4 cases), behavioural disinhibition or mania (2), delusions and/or hallucinations (3), depression with ideas of suicide (1), voluntary self-intoxication (7), lowering epileptic threshold (5), withdrawal syndrome with confusion and delirium (1), baclofen abuse (1), liver function problems (4), hepatic encephalopathy (1), and cardiovascular problems (4). In a 2013 report (ANSM 2013), 263 cases of adverse events were notified.

## Ondansetron

Currently, ondansetron represents an exciting approach for AUD personalized treatment as it is effective in specific subtypes of individuals (i.e., early onset AUD - the initial onset of AUD at the age of 25 years or younger - and LL genotype) Ondansetron, by blocking the 5-HT<sub>3</sub> receptor, is known to affect dopaminergic signalling in the brain, and the scientific rationale for the use of a 5-HT<sub>3</sub> antagonist in the treatment of alcohol dependence is well established. Thus, by blocking the activation of the 5-HT<sub>3</sub> receptor, ondansetron may reduce the ethanol-stimulated release of dopamine, leading to reduced feelings of pleasure or reward and, consequently, reduced craving and consumption<sup>25</sup>

## Varenicline

Although not FDA-approved to treat AUD, it is prescribed off-label and clinical trials offer promising

results about its efficacy in reducing alcohol cravings and consumption. Varenicline is thought to reduce cravings and rewarding effects of cigarettes by partial binding to  $\alpha 4\beta 2$  nicotinic acetylcholine receptors to prevent full activation of these receptors and subsequent dopamine release by nicotine and may have a similar mechanism of action in alcohol reinforcement and craving.

It is found that varenicline did not reduce the number of heavy drinking days or sustain abstinence, but it did reduce the daily amount of alcohol consumed, alcohol craving and levels of the alcohol marker phosphatidyl ethanol in the blood. Although heavy drinking days were not reduced, other symptoms of AUD were decreased by varenicline and it may be a promising treatment option for AUD, especially in patients comorbid for smoking.<sup>26</sup>

## Discussion

It should be noted that, in some cases, combination drug therapies have been recommended. For example, a combination of ondansetron and naltrexone (4  $\mu$ g/kg ondansetron + 25 mg naltrexone twice a day) collectively improved drinking outcomes in early onset AUD, such as drinks per day, drinks per drinking day, and number of days abstinent.<sup>27</sup>

Alcohol consumption has major impact on public health due to their increasing burden and also concern toward severity for other co-morbidity condition. As World Health Statistics (2023) data reveal that countries in South East Asia and West Pacific Region have high alcohol consumption rate (112% and 40%). In our article we discussed about effective treatment for AUD by providing pharmacological and psychosocial agent and its mechanism which are approved by FDA and off label drugs.<sup>13</sup>

Naltraxone has well effectiveness in alcohol withdrawal treatment through its chemical activities to remain abstinence from consuming alcohol were this drug showed impaired drug metabolism and hepatotoxicity. Hence, it is not safer to use naltrexone among LD patients for AUD. Nalmefene has better reaction than Natraxone due to their interaction with opiod and withdrawal syndrome.<sup>18</sup>

New regime such as ondasetron has considered as personalized AUD treatment by directly reducing

dopamine for alcohol consumption, off label medicine varenicline has significant affect in treating AUD especially in smoking patient. Several drugs have effectiveness on treatment for AUD, the drug combination shows better effectiveness toward

treatment method. It's a matter of scientific evidence for physicians to prescribe the medication to the patients with high success rate. Therefore it is very important to consider a evidence based treatment method considering the pros and cons of medication.

Author	Country/City	Study objective	Study design	Sample size	Results
Kalra G et al		Role of disulfiram in the present day and long-term pharmacotherapy of alcohol dependence along with future research needs in this area.	Review		Supervised disulfiram therapy did not have any major impact on the treatment outcome in this disorder. One of the most cited disulfiram trials to date, the Veterans Affairs multisite cooperative study also showed that disulfiram and placebo treated patients had similar outcomes
Jorgensen CH et al		To review the effect of disulfiram in the treatment of patients with alcohol use disorders.	Review		significantly more abstinence with disulfiram; five of the six studies reported significantly more days until relapse following treatment with disulfiram
Alharbi et al	Saudi Arabia	DSF's safety-related research to be used in alcohol withdrawing treatment	Review	38	38 cases had side effect due to the treatment of DSF which affected various organs, diagnosis and drug interactions
Mason BJ		Overview of FDA approved treatment and off labelled drug for the treatment of AUD	Review		Study about neuro-circuitary and neuropharmacological mechanism involved in AUD treatment must be given by trained professional which help in evidence based behavioural therapy. Thus, continues need of pharmacological medication development needed for AUD

Continue.....

Farhadian N et al		Analyze the impact of pharmaceutical treatments on individuals with HIV and AUD's using injectable extended-release naltrexone (XR-NTX) or oral naltrexone (NTX).	Systematic review	7	The study helped in understanding the efficacy of NTX and effectiveness of XR-NTX in treating AUDs among persons living with HIV(PLH). Since the final conclusion assume that, NTX and XR-NTX administered to person living with HIV and AUDs led to reduced alcohol consumption, improved undetectable virus, no involvement in ART adherence, and no adverse events.
Kirchoff RW et al	Minnesota	To review the articles published on naltrexone either oral or injectable drug in the management of AUD at acute setting	Systematic review	2	This shows the current clinical practice and comfortability of practitioner. Thus, therapeutic options help in exploring further treatments
Roos CR et al	USA	1. Identifying the reward drinking adults 2. Identifying the predictors of naltrexone response from phenotype 3. Identifying naltrexone mechanism among reward drinkers	Secondary analysis of RCT	128	The three profiles were identified Low reward/ Low relief, Reward drinkers and High reward/High relief. Among High reward/ High relief naltrexone reduced percent high intensity drinking days (PHID), the positive affect and urge to drink within days were decreased.
Ayyala D et al	USA	Aimed to understand the affect of naltrexone among patients with liver diseases	Retrospective cohort	160	Naltrexone was safer to use among liver disease patients along with compensated cirrhosis. However more research studies must be needed to understand the decompensatory cirrhosis.

Continue.....

Michael Soyka et al	Meiringen	To understand the previous analysis on opioid antagonists in alcohol dependence by analysing first 2 studies on nalmefene and also to know the rationale of Europe medical agency (EMA) approved Selincro for the treatment of alcoholism.	Review	6	The opioid antagonist such as naltrexone found to be effective in alcohol treatment. The available literature have verified that Nalmefene found to be effective in alcohol dependence treatment.
López-Pelayo H et al	Amsterdam	To evaluate the nalmefene after 6 years of introduction in Europe by clinical, pre-clinical and pivotal registration study in the treatment of AUD	Opinion	8	Nalmefene is the treatment method in AUD among heavy user and abstinence. The further research is needed on limited use, pro's and con's of Nalmefene.
Romito JW et al	USA	The history of baclofen, their safe dose for both oral and intrathecal routes for administration and their diagnosis and management in toxicity and withdrawal	Narrative review		The use of baclofen due to its spasticity has been used as off label medication for renal or hepatic related medical conditions. Withdrawal syndrome, commonly seen with intrathecal baclofen administration, typically responds well to re-initiating or supplementing baclofen dosing. Additionally, various pharmacological adjuncts can help manage withdrawal symptoms.
De Beaurepaire R et al	France	To understand the dose dependent and potential toxicity due to their high dose in treatment of AUD	Narrative review	16	The use of Baclofen in RCT especially in meta-analysis was not completely demonstrative but observational studies have shown the positive treatment using baclofen. Therefore, the prescription of baclofen had severe adverse effects due to their inappropriate treatment monitoring.

Addolorato G et al	Italy	To assess the liver safety profile of Low -Dose ondansetron and placebo with AUD		303	There was no change in Biochemical markers of liver injury patient on low dose of AD04, whereas GGT was seen elevated among AUD due to excess alcohol consumption whereas no changes among patients with low dose of AD04.
Lohoff FW	USA	To comprehensively review the pharmaco genetic research on off label and US FDA approved treatment for AUD	Review	11 drugs	Limited studies and data are conducted in guiding clinicians for prescribing drugs. The FDA guidelines will help in reducing physical and psychosocial aggressive behaviour however long-term behaviour cannot be assessed with short RCT. The genetic variation among population will be treatment variation. Thus, due to less evidence the physicians have less evidence in ordering genotype testing in predicting naltrexone testing response, which could be addressed in future.
Ross H et al	Canada	To prioritise the effectiveness of treatment method in the treatment of AUD especially in emergency department	Opinion	NA	The importance of pharmacological methods, and any other desirable treatment methods in solving AUD. This will also help in reducing stress to healthcare system as well emergency department

### Conclusion

With the review , we can conclude that the newer drugs like nalmefene, baclofen, ondansetron and varenicline have potential for long term treatment of alcohol disorder. These drugs have to be given

attention and more clinical trial have to be done to promote and spread knowledge on these drugs. Moreover, adequate information and testing have to be done on the side effects and the remission of alcohol after the use of these drugs.

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# Chemical Occupational Hazards in Dentistry: A Comprehensive Review

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## Abstract

Dentists are exposed to various types of chemicals while providing care that may be potentially toxic and can pose a serious health hazard in the absence of appropriate precautionary measures. These include hazardous chemical agents used in clinical dentistry include Mercury, powdered natural rubber latex (NRL), disinfectants, methyl methacrylate, metal alloys, silica and nitrous oxide (N<sub>2</sub>O). Exposure to these chemicals can result in acute and chronic health effects. Acute effects include skin and eye irritation, respiratory distress, and allergic reactions, while chronic exposure can lead to more serious conditions such as asthma, neurological disorders, and even cancer. This review article aims to identify and categorize the common chemicals used in dental practices and their associated health hazards and to provide safety guidelines and best practices for minimizing exposure to hazardous chemicals in dental settings.

**Keywords:** Chemical hazard, dentistry, occupational risk

## Introduction

Dentists are exposed to various types of chemicals while providing care that may be potentially toxic and can pose a serious health hazard in the absence of appropriate precautionary measures. Most of the dental materials undergo an extensive range

of tests both before and after use.<sup>[1]</sup> Even so, some dental materials in direct contact can be harmful or sometimes they are aerosolized during high-speed cutting and finishing and may thereby be inhaled by dental staff. If the health effects of these chemicals are not known, they can result into health problems taking years to manifest.<sup>[2]</sup>

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These chemical substances usually act in three ways i.e. local action, inhalation and ingestion. The illness may occur depending on the duration of exposure, quantity of exposure and individual susceptibility.<sup>[3]</sup> Dental professionals, including dentists, dental hygienists, dental assistants, and laboratory technicians, are regularly exposed to a variety of chemicals that include mercury, powdered natural rubber latex (NRL), disinfectants, methyl methacrylate, metal alloys, silica and nitrous oxide (N<sub>2</sub>O).<sup>[4]</sup>

Exposure to these chemicals can result in acute and chronic health effects. Acute effects include skin and eye irritation, respiratory distress, and allergic reactions, while chronic exposure can lead to more serious conditions such as asthma, neurological disorders, and even cancer.<sup>[5]</sup> This review article aims to identify and categorize the common chemicals used in dental practices and their associated health hazards, to review the scientific literature on the health effects of these chemicals, and to provide safety guidelines for minimizing exposure to hazardous chemicals in dental settings. Thorough understanding of these hazards and implementing effective safety protocols can help to promote awareness and education among dental professionals, thereby promoting overall occupational health and well-being.

### Hazards from chemical used for treatment

#### Nitrous oxide

Exposure to nitrous oxide in dental offices is usually small, but the exposure is continuous and occurs over the long term.<sup>[6]</sup> Workers are exposed to N<sub>2</sub>O while administering the anaesthetics gas to patients. Several human studies have shown that occupational exposure to N<sub>2</sub>O, may cause reduced fertility, congenital malformations (anaesthetic gases slow the rate of cell division and increase the rate of abnormal cell formation and chromosomal aberrations), spontaneous abortions, and neurologic, renal, and liver disease as well as documented decreases in mental performance, audiovisual ability, and mental dexterity in susceptible individuals.<sup>[1]</sup>

### Hazards from chemical used for cleaning and disinfection

#### Formaldehyde

Liquid and vapour forms of formaldehyde may cause severe abdominal pain, nausea, vomiting and eye irritation and also it is a common cause of allergic contact dermatitis.<sup>[7]</sup> Formaldehyde is classified as a known human carcinogen by several health organizations, including the International Agency for Research on Cancer (IARC). The individuals allergic to formaldehyde are usually develop eczema on the hands or face as shown in Figure 1. The characteristic features of formaldehyde allergy are anaphylactic reaction or shock and generalized urticaria.<sup>[8]</sup>



**Figure 1. Eczema on hands due to formaldehyde allergy**

#### Alcohol based hand sanitizer (ABHS)

Commonly used sanitizer contains ethanol or isopropyl alcohol that may result in contact irritant dermatitis, which may vary in intensity from mild to concerning, can present as dryness, itching, irritation, pruritis, and skin cracking as shown in Figure 2. Similarly, allergic contact dermatitis can also vary from mild to severe symptoms and may sometimes be accompanied by respiratory distress. Even though less widely reported, contact urticaria syndrome has also been associated with alcohol sanitizer use. It presents as swelling, redness, burning sensation, tingling, and/or itching within minutes (up to an hour) after applying alcohol. This urticarial reaction is localized and is characterized by wheal-and-flare.<sup>[9,10]</sup> Ethanol-based hand sanitizers can cause alcohol poisoning on swallowing that can induce intoxication and hypoglycaemia. The use of alcohol-

based hand sanitizers is also associated with a small but measurable risk of fires and burns.<sup>[9,10]</sup>



**Figure 2. Contact dermatitis due to ABHS**

### Detergent

Detergents are also widely utilized in dentistry for cleaning a variety of surfaces but it may contain possible eye, skin, and respiratory irritants. Some products may cause allergic dermatitis or contain sensitizers such as nickel or limonene.<sup>[11]</sup>



**Figure 3. Contact dermatitis due to detergent**

### Low level disinfectant

This group of chemicals include chlorine compounds, quaternary ammonium salts, iodophors and phenolic compounds that are used widely for disinfection in dental clinics. Most of these also act as an eye, skin, and respiratory irritants, particularly when concentrated.<sup>[11]</sup>

### Glutaraldehyde

The most serious adverse health effect documented among employees exposed to glutaraldehyde

vapor is occupational asthma, a chronic condition characterized by bronchial hyperresponsiveness. Reactions can be either immediate or delayed, with a latent period ranging from a few weeks to several years from the onset of exposure. In addition, an increased prevalence of irritant symptoms, including itching of the eyes with increased lacrimation (tearing), rhinitis, sore throat, coughing and burning nose have also been reported. Glutaraldehyde also acts as a contact allergen, typically on contact with solutions containing more than 2% glutaraldehyde, giving rise to contact dermatitis, usually on the hands but occasionally on the face.<sup>[12]</sup>

### Orthophthalaldehyde

It is an alternative for glutaraldehyde although, it also comes with certain health hazards and act as respiratory and skin irritant. It may result in dyspnoea and dry cough with a subsequent diagnosis of bronchial asthma. It also results in immediate and late-phase skin reactions that are immunoglobulin (Ig) E-mediated and manifest as serous papules and urticaria of the skin.<sup>[13]</sup>



**Figure 4. Papular urticaria of hands due to Orthophthalaldehyde**

### Hydrogen peroxide

Hydrogen peroxide is designated as a hazardous substance when present at concentrations above 5%. Direct exposure of skin or eyes to hydrogen peroxide may cause severe irritation or burns (Figure 5) of skin, oral and ocular mucosae, respiratory tract with burning, erythema and oedema, while ingestion may be irritating to the oesophagus and stomach, causing bleeding and sudden distension. Nausea and vomiting were the most common symptoms secondary to ingestion. Hydrogen peroxide is

cytotoxic in nature, the end result of which can be cell death. While hydrogen peroxide may be injurious to tissue directly, secondarily derived oxidants such as hydroxyl radical as well as hypochlorous acid can also contribute to tissue injury.<sup>[14]</sup>



**Figure 5. Chemical burn due to hydrogen peroxide**

### Ethylene Oxide

Exposures to ethylene oxide may result in eye pain and blurred vision, sore throat, respiratory irritation and lung injury, headache, nausea, dizziness, vomiting, diarrhoea, shortness of breath, convulsions, skin irritation and cyanosis. Chronic exposures to ethylene oxide have mutagenic potential and are linked with neurotoxicity, peripheral paralysis, muscle weakness, cancer, reproductive disorders, etc.<sup>[15]</sup>

### Hazards from other chemicals

#### Latex

The population at risk for latex allergy includes healthcare workers due to sweating and multiple gloves changing or latex-fruit syndrome (allergy to various fruits).<sup>[16]</sup> Natural rubber latex (NRL) gloves dusted with cornstarch powder are the most often used but dental personnel should also note that latex is also present in other equipment like Adhesive bandages and tape, Air or water syringe tips, Amalgam carriers, Anaesthetic masks, Bite blocks, Impression materials, Irrigation tubing, IV tubing and bags, Mixing bowls, Operative masks with rubber ties, Orthodontic rubber bands, Oxygen

masks, Polishing discs, Prophylaxis cups, Rubber dams, Suction tips, suction tubing, Syringes, eyewear, clinical gowns and rubber dam.<sup>[17]</sup>

The gloves and the mask may be a source of allergies – primarily in those persons who use rubber products on a regular basis.<sup>[17]</sup> The etiology of latex sensitivity is based on a reaction to the plant containing allergenic proteins in natural rubber. Referred to as Type I allergy (Atopy) to natural rubber latex protein, allergic reactions can be severe sometimes fatal due to the repeated exposure to latex products.<sup>[17,18]</sup>

Turjanamaa et al.<sup>[19]</sup> established that 2.8-17% of the employees of health service are allergic to latex and 8.8% of dentists were found to be allergic. The American Dental Association (ADA) began investigating the prevalence of Type I latex hypersensitivity in dental personnel in 1994 and results showed that 6.2% of participants were positive for Type I latex hypersensitivity.<sup>[20]</sup>

Clinical signs of the immediate allergic reactions to latex can include rash, conjunctivitis accompanied by lacrimation and swelling of eyelids, mucous rhinitis, edema, bronchospasms, and allergic shock. In case of latex sensitization it presents as: contact urticaria and dermatitis or atopic dermatitis (Figure 6).<sup>[21]</sup> Corn-starch or the so-called absorbable dusting powder also plays an important role in latex allergies. The powder does not include detectable proteins but, as some studies demonstrated, the health service employees who had an anaphylactic reaction to the dusting powder were positive in skin tests.<sup>[21]</sup> Chemical agents involved in the production of gloves process such as benzothiazole, thiuram, and carbamate also have strong allergenic potential.<sup>[22]</sup>



**Figure 6. Contact dermatitis due to NRL gloves**

## Mercury

Although amalgam containing mercury is no longer as widely used as it once was, it is nevertheless frequently encountered in dental procedures and remains a hazard for the dental staff. Hypersensitivity to mercury or its salt causes an inflammatory and sometimes vesiculating reaction when it is in contact with skin.<sup>[23]</sup> According to decreasing toxicity of mercury it is classified as organomercury, mercury vapour, and inorganic mercury.<sup>[24]</sup> The mercury body burden of dental personnel has often shown higher levels than the general population posing a greater risk of exposure to mercury for dentist.<sup>[25]</sup> Urine mercury level is used for determining long time exposure to mercury. The level at which symptoms of subtle, non-specific chronic mercury intoxication are recognized at concentrations above 25–50 mg Hg/l urine. Because of the diffuse nature of symptoms diagnosis of chronic mercury intoxication is always based on history of exposure. Weakness, fatigue, loss of appetite, gastrointestinal disturbances, diarrhoea, desquamative dermatitis and renal disturbances (nephritis) are described as symptoms occurring after long time exposure to low level exposure.<sup>[26]</sup> The active component (methyl and ethyl mercury) has a particular affinity for brain tissue. Classical symptoms after high exposures are tremors of fingers, limbs and tongue, insomnia, headache, progressive, tremulous illegible handwriting with slurred speech and erethism.<sup>[24]</sup> Another method to evaluate occupational exposure is to measure the air mercury level at the workplace. WHO has decided an exposure limit of 50 mg Hg/m<sup>3</sup> air. Oral manifestation may include metallic taste, hypersalivation, gingivitis or stomatitis.<sup>[27]</sup>

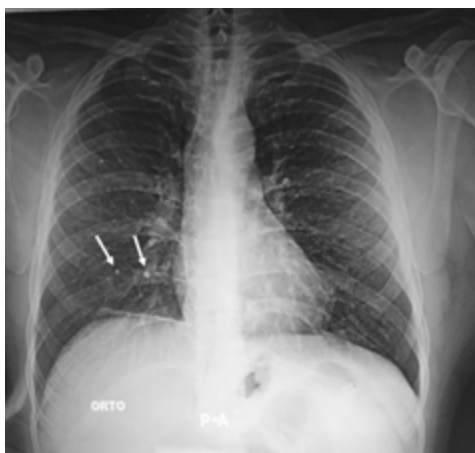
## Acrylic Resin

Dental polymer materials based on methyl methacrylate (MMA), seem to appear to affect several body systems, including the skin, the respiratory tract, and the neurological system in dental personnel. Monomers used in dentistry present severe cytotoxicity (monocytes, granulocytes and endothelial cells).<sup>[28]</sup> The free monomers during polymerization may cause a wide range of adverse health effects such as irritation to skin, eyes or mucous

membranes, allergic dermatitis, and paraesthesia in the fingers. Additionally, disturbances of the central nervous system such as headache, pain in the extremities, nausea, loss of appetite, fatigue, sleep disturbances, irritability, loss of memory, and changes in blood parameters may also be noted.<sup>[29]</sup> Allergic respiratory problem due to dental materials is also an important occupational hazard as it can lead to dyspnoea, wheezing, coughing, rhinorrhoea and it can trigger or aggravate occupational asthma.<sup>[30]</sup> It has been shown that MMA affects the integrity of latex examination gloves, which not only allows MMA to penetrate the skin, but also allows significant virus leakage.<sup>[31]</sup>

## Dental alloys

Metallic dusts or fumes of dental alloys that are generated during the casting and finishing of the metal are potentially toxic to the dentist and other dental laboratory workers. Both the International Agency for Research on Cancer (IARC) and the National Institute of Occupational Safety and Health (NIOSH) consider chromium (VI) compounds as carcinogens.<sup>[32]</sup> Hard-metal pneumoconiosis, caused by cobalt dust, is a severe and progressive type of pneumoconiosis that result in interstitial fibrosis with diffused reticulonodular infiltration of lungs (Figure 7). In addition, molybdenum exposure can cause biochemical changes.<sup>[33,34]</sup> Studies have reported that patients with pneumoconiosis had considerable amount of chromium-cobalt particle in the lung tissue and the patient subsequently developed adenocarcinoma of the lung.<sup>[35]</sup> Both NIOSH and the American Conference of Governmental Industrial Hygienists (ACGIH) classify beryllium as a potential carcinogen<sup>[36]</sup> and may lead to acute chemical pneumonitis, and chronic beryllium granulomatosis.<sup>[33,34]</sup> The major health risks of nickel and its compounds are related to the increased risk of respiratory cancers primarily in the lung and nasal sinuses, as well as chronic irritation of the upper respiratory tracts, pneumoconiosis, bronchial asthma, and allergic contact dermatitis.<sup>[33,34]</sup> IARC classifies metallic nickel as possibly carcinogenic to humans while NIOSH considers all compounds of nickel as potential human carcinogens.<sup>[32]</sup>



**Figure 7. Chest X-ray of patient with pneumoconiosis showing small rounded and irregular radio-opacities**

### Silica

Inhalation of dust containing free silica or silicon dioxide leads to silicosis. It is a devastating interstitial lung disease characterized by diffuse pulmonary fibrosis (Figure 8). Patients generally report with pulmonary and systemic symptoms, including dyspnoea, pleurisy, cough, fevers, fatigue, and weight loss. Physical examination frequently reveals hypoxia.<sup>[37]</sup>



**Figure 8. Chest X-ray of patient with silicosis showing large numbers of rounded, solitary nodules or bigger, confluent opacities**

### Hazard due to chemical used in radiology

Developing solutions and fixing solutions may cause health effects. Glutaraldehyde is primarily used as a hardening agent causes skin sensitization and allergic contact. Sulphur dioxide released during

the mixing process of chemical components causes bronchospasm.<sup>[32]</sup>

### Recommendations for Minimizing Exposure and Enhancing Safety:<sup>[38]</sup>

#### 1. Administrative controls:

- o Implement standard operating procedures (SOPs) and adhering to the established safety guidelines for the use and handling of hazardous chemicals.
- o Conduct regular training and education sessions on chemical safety and emergency response procedures and increasing awareness about the health risks associated with chemical exposure and the importance of following safety protocols.
- o Provision of appropriate emergency response equipment to reduce the impact of the exposure and medical follow-up for workers who have had a chemical exposure.
- o Implement regular health surveillance programs to monitor the health of dental professionals.
- o Conduct periodic assessments of workplace safety to identify and mitigate potential hazards.

#### 2. Use of Personal Protective Equipment (PPE):

- o Ensure the use of appropriate PPE (gloves, masks, protective eyewear, and gowns).

#### 3. Engineering Controls:

- o Elimination of a hazardous chemical and substitute with an alternative (using digital impression techniques to minimize the use of impression materials)
- o Maintain proper ventilation systems to reduce the concentration of airborne chemicals.
- o Use local exhaust ventilation (LEV) systems to remove hazardous fumes.

### Discussion

Chemical occupational hazards in dentistry are a global concern, affecting dental professionals' health

and safety. There are various health risks associated with the chemical exposure in dentistry that can be broadly categorized into two groups: Acute effects (Skin irritation, contact dermatitis, respiratory distress including asthma and bronchitis, eye irritation and conjunctivitis) and Chronic effects (Long-term respiratory issues such as chronic obstructive pulmonary disease (COPD), neurological disorders due to prolonged exposure to neurotoxic substances like mercury, increased risk of cancer, particularly with prolonged exposure to formaldehyde and other carcinogenic substances).<sup>[39]</sup> According to the World Health Organization (WHO), approximately 75% of dental professionals report experiencing some form of occupational health issue related to chemical exposure. In the United States, the Occupational Safety and Health Administration (OSHA) has highlighted that dental professionals are at a high risk of exposure to hazardous chemicals, with adverse health effects being commonly reported.<sup>[32]</sup> In Europe, a study conducted by the European Agency for Safety and Health at Work (EU-OSHA) revealed that nearly 70% of dental professionals experience skin and respiratory problems due to chemical exposure. Similar trends are observed in Australia and Canada, where occupational health and safety agencies emphasize the importance of minimizing exposure to hazardous chemicals in dental practices.<sup>[40]</sup> In India, the prevalence of chemical occupational hazards in dentistry is significant, though it is often underreported due to lack of awareness and regulatory oversight. A study conducted indicates that around 60% of dental professionals reported experiencing health issues related to chemical exposure.<sup>[41]</sup> The lack of stringent regulations and standardized safety protocols in many dental practices across India contributes to higher exposure risks.<sup>[42]</sup> Therefore, there is a pressing need for better awareness, training, and implementation of safety measures to protect dental professionals in India.

### Conclusion

Ensuring the safety of dental professionals from chemical occupational hazards is paramount for maintaining a healthy and productive workforce. The prevalence of these hazards is high, and their impact is particularly pronounced in countries like India, where regulatory oversight may be less stringent.

By implementing comprehensive safety guidelines, promoting the use of safer alternatives, and ensuring regular training and education, dental practices can significantly reduce the risks associated with chemical exposure. Through heightened awareness and adherence to safety protocols, the dental profession can create a safer working environment, ultimately leading to improved occupational health outcomes. A concerted effort is needed to enhance occupational safety in dentistry, ultimately protecting the health and well-being of dental professionals globally.

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# Navigating Biological Health Hazards in Dentistry: Understanding Risks and Ensuring Safety

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## Abstract

Occupational hazards can be defined as a risk to a person usually arising out of employment. It can also refer to a work, material, substance, process or situation that predispose or itself causes accidents or diseases at work place. The history of occupational hazard awareness can be traced back to the 18<sup>th</sup> century when “Bernadine Ramazzini”, who is referred to as the “Father of occupational medicine”, recognized the role of occupation in the dynamics of health and disease. Dental practice encompasses a diverse range of services to patients of all ages, aimed at preventing, diagnosing, and treating oral diseases and conditions. However, the practice of dentistry also entails exposure to various biological hazards that can pose risks to the health and safety of dental personnel. Therefore, the present review will be an attempt to provide an overview of the different categories of biological hazards faced by dental professionals by examining the various sources, potential health effects, and strategies for mitigation.

**Keywords:** Biological hazard, Cross-infection, Dentistry, Occupational hazard, Risk

## Introduction

Occupation is one of the major determinants of our income, livelihood, life-style, social-interactions and health, but with all kind of work comes certain amount of stress or illness.<sup>[1]</sup> Occupational health is an area of work in public health to promote and

maintain the highest degree of physical, mental and social well-being of the workers in all occupations, the prevention of deviation from health among workers caused by their working conditions, their protection from risks resulting from factors adverse to health.<sup>[2]</sup> Occupational hazards can be defined as a risk to a person usually arising out of employment. It

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can also refer to a work, material, substance, process or situation that predispose or itself causes accidents or diseases at work place.<sup>[3]</sup>

The history of occupational hazard awareness can be traced back to the 18<sup>th</sup> century when “Bernadine Ramazzini”, who is referred to as the “Father of occupational medicine”, recognized the role of occupation in the dynamics of health and disease. His most important contribution to occupational medicine was his book on occupational diseases, “De Morbis Artificum Diatriba” (Diseases of Workers). He proposed that the physicians should extend the list of questions for their patients by adding, “what is your occupation?”.<sup>[4]</sup>

The Occupational Health Research Institute (OHRI) at B. J. Medical college, Ahmedabad was rechristened as “National Institute of Occupational Health” (NIOH) in 1970, is a premier institute under the aegis of Indian Council of Medical Research (ICMR) under the Department of Health Research, Ministry of health and family welfare, Government of India. This institute function as a WHO collaborative and reference centre for occupational health with objectives of promotion of highest quality of occupational health through fundamental and applied research, promotion of intensive research to evaluate environmental stresses/factors at the workplaces and development of technologies and health programmes through basic and fundamental research along with generation of human resources in the field.<sup>[5]</sup>

Dental practice encompasses a diverse range of services to patients of all ages, aimed at preventing, diagnosing, and treating oral diseases and conditions. Occupational health and safety in dentistry are paramount to protecting the welfare of dental professionals and promoting a healthy work environment.<sup>[6]</sup> However, the practice of dentistry also entails exposure to various biological hazards that can pose risks to the health and safety of dental personnel. Biological hazards can arise from various sources, usually from exposure to infectious agents. Understanding and mitigating these hazards are essential for safeguarding the health and well-being of dental personnel and ensuring the delivery of safe and effective dental care.<sup>[7]</sup> This review aims to provide an overview of the different categories

of biological hazards faced by dental professionals by examining the various sources, potential health effects, and strategies for mitigation. The prime objective is to raise awareness about occupational health and safety issues in dentistry and promote best practices for protecting the well-being of dental personnel.

### Biohazards in Dentistry

Dentists belong to a professional group potentially exposed to harmful biological factors which most often are infectious microorganisms, less frequently - allergenic or toxic microorganisms contributing to the biological hazards in dentistry. The source of harmful factors is, in most cases, the patient, but it may also be the water used in a dental unit.<sup>[8]</sup> There are 4 basic routes of spreading harmful microorganisms in a dental surgery:<sup>[9]</sup>

- Blood and body fluid-borne route - through the blood and other body fluid of an infected patient
- Saliva-droplet route - through a droplet aerosol of saliva, gingival fluid, nasopharyngeal secretion or blood emitted by an infected patient, natural organic dust particles (dental caries tissue or filling material) mixed with air and water during the work of both high-speed and low-speed handpieces, scaler and air-water syringe. The aerosol is present not only in the operating field and the space between a patient and a doctor, but is dispersed almost evenly to different parts of a dental office, reaching as far as, 2 meters
- Direct contact with a patient and contaminated equipment
- Water-droplet route - through a water droplet aerosol emitted from a hand piece of a dental unit which may contain microorganisms present in a unit reservoir, or developing in biofilm inside a unit tubing.

Legnani et al<sup>[10]</sup> made an assessment of the aerosol contamination resulting from dental procedures. Air contamination was measured by means of the Surface Air System method and the “plate” method (Air Microbial Index). It was proved that during working hours the average air bacterial load increased over three times, and the air load levels were 1.5 times

(aerobic bacteria) and 2 times (anaerobes) greater as compared to the initial load.<sup>[10]</sup>

A vast range of microorganisms, from prions

through viruses and bacteria to fungi can spread via any of the above-mentioned routes and cause diseases that are mentioned in the Table 1.

**Table 1: Infectious agents causing health hazards**

Disease <sup>[11-23]</sup>	Agent	Transmission	General Symptom
Creutzfeldt-Jakob disease	Prion	Saliva-droplet route	Lack of co-ordination, Problems with walking and balance. Impaired thinking, management and judgement. Behavior change, mood swings, anxiety, depression and confusion. Insomnia or changes in sleeping pattern. Unusual sensation Slurred speech. Vision problems.
Hepatitis B	Hepatitis B virus (HBV)	Blood and body fluid-borne route	Initial symptoms are nonspecific-anorexia, nausea, vomiting, abdominal pain, and jaundice. In cases of severe liver damage -jaundice, hepatic encephalopathy, ascites, gastrointestinal bleeding secondary to esophageal varices, coagulopathy, or infections.
Hepatitis C	Hepatitis C virus (HCV)	Blood and body fluid-borne route	Initial symptoms are nonspecific-anorexia, nausea, vomiting, fatigue, malaise, abdominal pain, joint pain and jaundice, dark coloured urine. In cases of severe liver damage - hepatic encephalopathy, ascites, gastrointestinal bleeding secondary to oesophageal varices, coagulopathy, or secondary infections.
Hepatitis D	Hepatitis D virus (HDV)	Blood and body fluid-borne route	Majority of the patients are asymptomatic. Signs and symptoms- fever, abdominal pain, nausea, vomiting, jaundice, confusion, bruising, or bleeding.
Hepatitis G	Hepatitis G virus (HGV)	Blood and body fluid-borne route	Co-infection with HCV.

Continue.....

HIV/AIDS	Human Immunodeficiency Virus (HIV)	Blood and body fluid-borne	In the order of decreasing frequency: Fatigue, Muscle pain, Skin rash, Headache, Sore throat, Swollen lymph nodes, Joint pain, Night sweats, Diarrhoea
Herpes simplex virus-1 infection	Herpes simplex virus-1 (HSV-1)	Saliva-droplet route Direct contact	Most commonly asymptomatic. Symptomatic- "cold sore" or fever blister with pain, halitosis, and dysphagia, malaise, anorexia, fevers, tender lymphadenopathy, localized pain, tenderness, burning, or tingling prior to the onset of mucocutaneous lesions.
Herpes simplex virus-2 infection	Herpes simplex virus-2 (HSV-2)	Saliva-droplet route Direct contact	Genital ulcers, sores, crusts, tender lymphadenopathy, and dysuria, genital itching, irritation, and excoriations
Severe acute respiratory syndrome (SARS)	SARS-Corona Virus (SARS-CoV)	Saliva-droplet route Direct contact	Fever, myalgia, weakness, dry cough, shortness of breath, difficulty breathing.
Tuberculosis (TB)	Mycobacterium tuberculosis	Saliva-droplet route ("droplet nuclei")	Chronic cough, haemoptysis, weight loss, low-grade fever, and night sweats
Legionellosis	Legionella pneumophila Legionella bozemanii Legionella longbeache	Water-droplet route	Fever (high grade), weakness, anorexia, malaise, fatigue, and lethargy; mild and nonproductive cough, haemoptysis, Pleuritic chest pain, abdominal pain, nausea, vomiting, and watery diarrhoea, headache, delirium, confusion, stupor, agitation, and hallucinations.
Candidiasis	Candida albicans Candida tropicalis	Saliva-droplet route	Infection of skin, nails, oral cavity or an endogenous allergic reaction in people with decreased immunity.
Pneumonia	Pneumocystis carinii	Saliva-droplet route	Dry cough, fever with sweats, difficulty in taking a deep breath and haemoptysis

### Recommended safe practice guidelines for the prevention of Biohazard

**Administrative control** - Infection prevention must be made a priority in any dental health care setting. The next level of controls includes administrative controls. Because it is not always possible to eliminate or control the hazard at the

source, administrative controls are frequently used for biological hazards in healthcare. Administrative controls focus on ensuring that the appropriate prevention steps are taken, that all proper work procedures are documented, that dental personnel are trained to use the proper procedures, and that their use is enforced.<sup>[24]</sup>

The following key administrative recommendations for dental settings should be followed:[24]

- Develop and maintain infection prevention and occupational health programs.
- Provide supplies necessary for adherence to Standard Precautions (e.g., hand hygiene products, safer devices to reduce percutaneous injuries, personal protective equipment).
- Assign at least one individual trained in infection prevention responsibility for coordinating the program.
- Develop and maintain written infection prevention policies and procedures appropriate for the services provided by the facility and based on evidence-based guidelines, regulations, or standards.
- Facility should have system for early detection and management of potentially infectious persons at initial points of patient encounter.

**Infection prevention education and training to dental health care professionals**—To guarantee that infection prevention policies and procedures are comprehended and adhered to, education and training are essential. All dental practitioners should get education on the fundamental ideas and procedures for stopping the spread of infections. Dental staff safety (such as OSHA bloodborne pathogens training) and patient safety (such as highlighting job- or task-specific needs) should both be covered in training. At the very least, once a year, at the setting's orientation, and if new duties or processes are introduced, education and training should be given. Training records have to be kept up to date in compliance with federal and state regulations.[24,26]

**Dental health care personnel safety** - Additionally, infection prevention programs should address occupational health needs, such as vaccination against diseases common to dental professionals (e.g., varicella, chickenpox, tetanus, diphtheria, and pertussis), hepatitis B, MMR (measles, mumps, and rubella), and Tdap (tetanus, diphtheria, and pertussis). They should also manage exposures or infections in personnel requiring post-exposure

prophylaxis, screen for tuberculosis (TB) upon hiring, regardless of the setting's risk classification, and adhere to OSHA bloodborne pathogens standards. Medical service referral agreements can be established with licensed healthcare providers in a hospital's occupational health programme, with educational establishments, or with healthcare facilities that provide staff health services.[25,26]

**Standard precautions**— They are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered. These practices are designed to both protect dental professional and prevent them from spreading infections among patients. Standard Precautions include: hand hygiene, use of personal protective equipment, respiratory hygiene/cough etiquette, sharps safety (engineering and work practice controls), safe injection practices (i.e., aseptic technique for parenteral medications), use of sterile instruments and devices, and maintaining clean and disinfected environmental surfaces.[25]

Alcohol-based hand rub or water and plain soap (hand antisepsis) should be used for routine dental exams and nonsurgical treatments. Antimicrobial soap is designed specifically for use in healthcare facilities. Even though alcohol-based hand rubs work well for hand hygiene in medical settings, it's still best to wash your hands with soap and water if your hands are visibly dirty, after handling objects like instruments, materials, or equipment with your bare hands that could be contaminated with blood, saliva, or respiratory secretions, before and after treating each patient, and both before and after putting on and taking off gloves.[26]

Personal protective equipment (PPE) refers to wearable equipment that is designed to protect an individual from exposure to or contact with infectious agents. PPE that is appropriate for various types of patient interactions and effectively covers personal clothing and skin likely to be soiled with blood, saliva, or other potentially infectious materials (OPIM) should be available. These include gloves, face masks, protective eye wear, face shields, and protective clothing (e.g., reusable or disposable gown, jacket, laboratory coat). Examples of appropriate use of PPE for adherence to standard precautions

include – use of gloves in situations involving possible contact with blood or body fluids, mucous membranes, non-intact skin (e.g., exposed skin that is chapped, abraded, or with dermatitis) or OPIM, use of protective clothing to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated, and use of mouth, nose, and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids.<sup>[27]</sup> Dentists should be trained to select and put on appropriate PPE and remove PPE so that the chance for skin or clothing contamination is reduced. Hand hygiene is always the final step after removing and disposing of PPE. Training should also stress preventing further spread of contamination while wearing PPE by keeping hands away from face, limiting surfaces touched, and removing PPE when leaving work areas.<sup>[27]</sup>

Precautions to restrict respiratory secretions in patients and those accompanying who exhibit signs and symptoms of a respiratory illness are included under respiratory hygiene/cough etiquette. These precautions should be taken at the time of admission into the institution and continue during the stay. These include hanging signs at the entrances instructing patients with respiratory infection symptoms to cover their mouths and noses when coughing or sneezing, to use and discard tissues, and to wash their hands after coming into contact with respiratory secretions; providing tissues and no-touch containers for disposing of tissues; offering masks to coughing patients and other symptomatic individuals upon entering the dental setting; and providing space and encouraging individuals with respiratory infection symptoms to sit as far away from others as possible. These patients could be kept apart while they wait for care, if it is an option.<sup>[26]</sup>

Most percutaneous injuries (e.g., needlestick, cut with a sharp object) among dentists involve burs, needles, and other sharp instruments. Engineering and work-practice controls are the primary methods to reduce exposures to blood-borne pathogens from sharp instruments and needles. From an occupational health perspective, good engineering controls such as proper design and maintenance of facilities, room design, the use of Sharps with Engineered Sharp Injury Protection (SESIPs), decontamination

of materials and facilities, local and general exhaust system. Effective biological waste containment also contributes to minimize the transmission of infectious agents.<sup>[27]</sup>

Examples of safe needle devices that have built-in engineering features include:<sup>[27]</sup>

- Needle less connectors for IV delivery systems
- Protected needle IV connectors
- Needles that Retract into a Syringe or Vacuum Tube Holder
- Hinged or Sliding Shields Attached to Syringe
- Self-blunting phlebotomy and winged steel needles
- Blunt Tip Suture Needles
- Retractable finger/heel-stick lancets

Key Recommendations for safe injection practices are:<sup>[26,28]</sup>

- Prepare injections using aseptic technique in a clean area.
- Disinfect the rubber septum on a medication vial with alcohol before piercing.
- Do not use needles or syringes for more than one patient (this includes manufactured prefilled syringes and other devices such as insulin pens).
- Medication containers (single and multidose vials, ampules, and bags) are entered with a new needle and new syringe, even when obtaining additional doses for the same patient.
- Use single-dose vials for parenteral medications when possible.
- Do not use single-dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution for more than one patient.
- Do not combine the leftover contents of single-use vials for later use.
- If multidose vials are used dedicate multidose vials to a single patient whenever possible. If multidose vials will be used for more than one patient, they should be restricted to a centralized medication area and should not enter the immediate patient treatment

area (e.g., dental operatory) to prevent inadvertent contamination. If a multidose vial enters the immediate patient treatment area, it should be dedicated for single-patient use and discarded immediately after use. Date multidose vials when first opened and discard within 28 days, unless the manufacturer specifies a shorter or longer date for that opened vial. Do not use fluid infusion or administration sets (e.g., IV bags, tubings, connections) for more than one patient.

### Discussion

As dental professionals, we are constantly exposed to various biological hazards that can pose significant health risks. Therefore, it is imperative to understand these risks and implement effective safety measures to protect both ourselves and our patients. Biological health hazards in dentistry primarily include exposure to bloodborne pathogens, respiratory pathogens, and other infectious agents.<sup>[29]</sup>

These hazards arise from direct contact with patients' blood, saliva, and other bodily fluids during dental procedures. The most common pathogens include: Hepatitis B and C Viruses (HBV and HCV), Human Immunodeficiency Virus (HIV), Mycobacterium tuberculosis, Influenza and other respiratory viruses, Herpes Simplex Virus (HSV), Candida species.<sup>[29]</sup> The primary risks associated with biological hazards in dentistry include: Infection Transmission (Pathogens can be transmitted from patient to dental professional, from professional to patient, and between patients if proper infection control measures are not followed), Occupational Diseases (Dental professionals may develop occupational diseases due to repeated exposure to infectious agents) and Cross-Contamination (Improper sterilization and disinfection practices can lead to cross-contamination between instruments and surfaces).<sup>[29]</sup>

To mitigate these risks, a comprehensive approach to infection control and safety is necessary. Some key strategies that should be strictly followed include adherence to standard precautions, which include hand hygiene (use soap and water or alcohol-based hand sanitizers before and after each patient contact), use of personal protective equipment (PPE) such as

gloves, masks, protective eyewear, and gowns should be used appropriately to create a barrier against infectious agents, using EPA-registered disinfectants for surfaces, use of sterilized instruments, proper handling and disposal of sharps and waste, aerosol management using high-volume evacuation systems, good ventilation, and rubber dams, vaccination against common infectious diseases like hepatitis B and influenza, regular training and education programs for dental staff on the latest infection control practices and guidelines, establishing and following protocols for managing exposure to bloodborne pathogens, including immediate washing of the area, reporting the incident, and seeking medical evaluation, and conducting regular risk assessments to identify potential hazards and update safety protocols accordingly.<sup>[30]</sup>

### Conclusion

In conclusion, understanding and navigating biological health hazards in dentistry is crucial for ensuring the safety of both dental professionals and patients. By adhering to stringent infection control practices, using appropriate protective measures, and staying informed about the latest guidelines and recommendations, the risks associated with biological hazards in the dental setting can be effectively mitigated so that the highest standards of safety and care can be maintained in dental practice.

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**Conflict of Interest:** Nil

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# Effect of Family Focused Therapy among Caregivers and Patients on Prognosis of Bipolar Disorder Patients: A Systematic Review and Meta Analysis

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## Abstract

**Background:** Bipolar affective disorder is a chronic condition with high relapse rate, morbidity, and psychosocial impairment that often persist despite pharmacotherapy highlighting the need for psychosocial treatments. Non pharmacological intervention like family focused therapy (FFT) can improve the disease outcome i.e. depression and mania symptoms and reduces relapse rate.

**Objective:** To assess the effect of family Focused therapy on disease outcome of bipolar affective disorder patients.

**Materials and Method:** In this review Pub med, Medline, Google scholar, Cochrane database between 1999 to 2024 were searched by using RCT, reviews fulfilling inclusion criteria were included. Randomized controlled trials comparing family focused therapy with pharmacotherapy as usual, enhanced care, added in the study. Adolescents without any psychotic feature, any neurological disorders, and substance use disorders were included in this review. Two independent reviewers extracted data and assessed the quality of the trials. The results were presented in form of forest Plots.

**Results:** A total of 13 studies, including 1208 bipolar patients, were included in the review for qualitative analysis. Amongst them eight studies involving 584 bipolar patients receiving Family focused therapy included in meta analysis in depression and mania outcome. Overall, there was a reduction in depressive and manic symptoms among the bipolar patients receiving family focused therapy compared to treatment as usual and enhanced care. For depression {SMD:-0.38(-0.67,-0.08,95%CI)}. For Mania SMD:-0.45(-0.77,-0.12,95%CI). Significant reduction of relapse rate were found. No significant changes of medication adherence and quality of life were found.

**Conclusion:** Family focused therapy adjunct to pharmacotherapy in bipolar affective disorder is effective in reducing depressive and manic symptoms. Reducing number of mood episodes, and hospitalization and increased time between episodes.

**Keywords :** Family focused therapy, Bipolar Disorder, Depression, Mania, Hypo- mania.

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## Introduction

Bipolar Disorder (BPAD) is a chronic illness characterized by severe mood fluctuations and profound functional deficit. Bipolar disorder, with mood swings between depression and mania, may affect up to 1.5% of adults, and increases the risk of suicide and disability<sup>1</sup>. Most people improve over time, but two thirds may have residual dysfunction, and at least 40% may have recurrent episodes<sup>2,3</sup>. 50-65% of individuals with BPAD, have illness onset before the age of 18 years of age. 18% and 28% before 13 years of age.<sup>4,5</sup>

Family focused treatment is a semi-structured treatment that provides psycho education about the nature of mood episodes, individual and family Coping strategies to manage mood swings, and training for the Patient and family members in communication and problem Solving skills for management of Bipolar I & Bipolar II Disorder<sup>6,7</sup>. Family focused therapy carried with pharmacotherapy has been found effective than other supportive Care and Pharmacotherapy in treating episode recovery and reducing rates of re-occurrence over 1-2 yrs<sup>9,10</sup>. There is no systematic review and meta analysis to clarify which therapy is more effective, how its impact differs from general population, and what are the most utilized measures to assess, disease outcome, quality of life, in this population.

**Objective:** The present meta analysis assess the effect of Family focused therapy on depressive, manic or hypo manic symptoms, relapse rate and medication adherence among bipolar disorder patients. As per comments table is shifted to the appendix section

## Materials and Methods

The protocol was prepared according to Preferred reporting items of Systematic Review and Meta analysis. (PRISMA) guidelines and registered at International Prospective Register of Systematic Reviews (PROSPERO) Registration ID: CRD 42023438573

The review included Randomized control trials reporting the effect of family focused therapy on the disease outcome of bipolar affective disorder patients. The author searched Pub Med - Medline, Google Scholar, Cochrane, Control Register of controlled Trials (CENTRAL) and other Clinical Trial register for this review. Preclinical studies, Case report, care series, review Commentaries, observational Studies including Case Control, Cohorts, quasi experimental studies, Letter to editors, Conference abstracts, editorials, methodological papers, dissertation and studies were excluded from this review. This review

included studies published from 1999 to 2024. The last search for the study was April 2024<sup>11,12,13</sup>

The key terms and Mesh term for the PICO (Participants, Intervention, control and outcome) were used to search for the studies were 'Bipolar disorder', 'family focused therapy', 'psycho social intervention', 'Depression', 'Mania', 'Hypomania', 'quality of life'. 'Medication adherence'

The searched strategy for different databases is depicted in the [Appendix 1.]

## Participants:

## Inclusion Criteria:

This review included studies published from 1999 to 2024 on bipolar affective disorder patients Adolescent (9-17 years) adult (18-65 years) and their caregivers (age group 18-65 yrs) BPAD I and BPAD II with active mood symptoms at least 2 weeks to 1 months. At least 1 family member (parent/spouse) is willing to participate in family treatment.

**Exclusion criteria:** Those studies with Bipolar disorder patients having Severe psychosis, lasting 3 or more months, Evidence of MR, neurological illness or pervasive developmental disorder. Substance addictions last 3 months were excluded from this review.

**Interventions:** Investigator's or therapist's provided the family focused therapy to the patients of BPAD I & II and their caregiver, typically administered in 12 one hour session (8 weekly, 4 biweekly and then monthly) over 4 months and was comprised of three modules: psycho education about managing depression and mood swings, enhancing family communication, and problem solving skill training. In the first segment, families learn about the nature, symptoms, course, and treatment of bipolar disorder. In the 2nd segment patient and their family are helped to move and rebuilt effective relationship patterns by Communication Enhancement skills training. In the third segment 4 weeks problem solving skill training was given along with treatment as usual was provided. Enhanced care (three weekly family psycho -education sessions followed by three monthly individual sessions that focused on mood management) health education was Considered as the comparator intervention<sup>14,15</sup>

## Primary and Secondary outcomes

The Primary disease outcome was the intensity of the disease (the effect of family focused therapy. on prognosis of the disease outcome. i.e. depression, mania and hypomanic state of the disease of the patients.

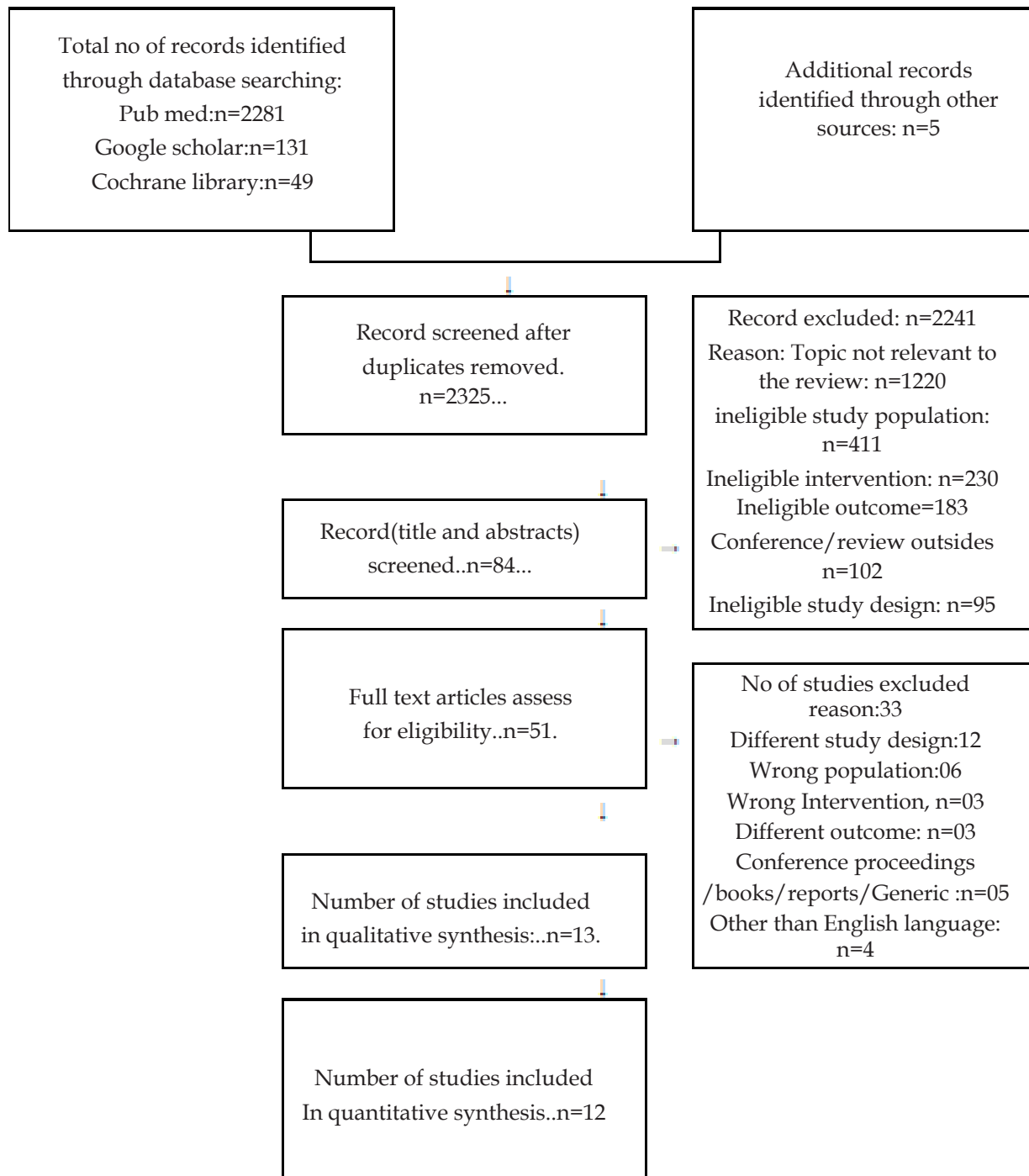
The secondary outcome is the effect of family focused therapy on medication adherence, and quality of life of the BPAD patients.

**Screening & reviewing of studies**

Following initial searching of the databases duplicates were removed Using Zotero software, then, two reviewers(MM, SD) independently screened the titles and abstract of studies selected from the database

search using the Rayan Web app for systematic review ( Ref). The articles eligible for full text review were identified and extracted. The authors independently reviewed the identified full text articles for their possible inclusion. Any disagreement arising in the process was resolved by discussion between the authors (MM & SD). The final list of the included studies that made the inclusion and exclusion criteria was prepared.

**Table 1: PRISMA flow diagram**



**Data collection extraction and management**

The Data extraction from (DEF) was prepared for the study and relevant information on Microsoft Excel (Version 2016) and relevant information including participants details and study details including study design, country of research, sample size, age, disease outcome (Mania, hypomania & depression status tool used, intervention given), Mean and SD and total participants pre, and post were independently extracted from included studies by the reviewers (MM& SD).

**Assessment of Risk of bias in included studies**

Two authors independently assessed the risk of bias for each trial using the criteria outlined in the risk of bias tool 2.0 of the Cochrane risk of bias tool for Randomised controlled trial (ROB2). Studies were described as low risk, some concerns of high risk depending on the criteria given in the Cochrane handbook. Any disagreement was resolved by discussion or by involving a third assessor.

**Statistical Analysis**

For continuous variables i.e. mood symptoms (depression, Mania, hypomania scores) the authors calculated the pooled standardized mean difference between FFT and depression score, FFT and Mania score. For quality of life, medication adherence hazard ratio and odds ratio was calculated between FFT and relapse rate, FFT and medication adherence.

The authors assessed the heterogeneity between the studies using visual inspection forest plots, the Cochrane Q test and I2 statistic. heterogeneity was considered if the I2 value was greater than 25% or Cochrane Q greater than 0.1. Heterogeneity was graded as moderate and high for I2 value of 25%, 50% and 75%. in case of heterogeneity random effect of model was used. The authors explored the sources of heterogeneity by sensitivity analysis according to the risk of bias of included studies. For the outcome, publication bias was investigated using funnel plots. Statistical analysis were performed and forest plots were prepared by Revman 5.4 software. To sided p value,<0.05 was considered statistically significant except for the subgroup analysis and heterogeneity test in which p value 0.10 was considered as significant.

**Results**

A total of 2466 articles were searched from different data bases and 51 articles were found eligible for full text selection. Out of 51 articles, 13 studies match the inclusion and exclusion criteria and were included in qualitative synthesis and 08 in quantitative synthesis of meta - analysis. (Figure I)

This review included 13 Randomized control trial with a total of 1208 Bipolar affective disorder patients. The characteristics of the included studies were described in Table 2.

**Table 2: Characteristics of the included studies**

Sl No	Year	Author	Country/Setting	Study Design (Period)	Sample Size(Rct/ Analytical)	Participanta (Age, Yrs, Mean (Eg/Cg) Inclusion And Exclusion Criteria)	Intervention (Eg/Cg)	Outcome (Measurement/ Timepoint)	Result (Outcome)
1	2022	DJM	UCLA	RCT(4 YRS)	n=114 EG:54, CG:-60)	High risk youths(9-17.8 yrs) MDD OSBD, current mood symptoms, F/H o BD	FFT 4 months (for IG, Enhanced care (for CG)	High risk yo(n=114,mean age 13.3+ _2.6yrs,72 female were followed104.3+ _65.8 weeks after randomization. youth with other specified BD vs MDD, younger age, earlier symptom onset, more severe mood symptoms, lower psychosocial functioning and more familial conflict over time had higher mood instability rating throughout the study period .mood instability mediated the association between baseline diagnosis and mother offspring conflict at follow up(Z=2.88,p=.004,alpha beta=0.19,95% CI=0.06-0.32. psychosocial associations did not moderate these associations	Interventions that are successful in reducing mood instability may enhance long term outcomes among high risk youths

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2	2022	Marc J. Weintraub	UCLA SEMEL INSTITUTE	RCT (2 YRS)	n=119 EG:61, CG:-66)	High risk youths(9-18 yrs) active mood symptoms and Family I/o BD)	4 months FFT or Enhanced care.	Youths in FFT reported greater improvements in family functioning over 24 months compared to EC group=(5,76.8)=3.1, p<0.05. Improvement in family functioning partially mediated participants improvements in depressive symptoms, B=-0.22. p<0.01,95%ci -0.55,-0.02. The effects of FFT vs EC on family functioning were stronger among youths with co morbid anxiety and externalizing disorder than among youth without these co morbid disorder	Temporal link between changes in youths perceptions of family functioning and improvement in depressive symptoms among high risk youths in FFT
3	2021	Amy SG,KDC, MKS	UCLA	RCT	N=40 (EG:20+ CG = 20)	Youths ages(9-17 yrs) high risk group	4 months FFTHR or Enhanced care.	Depression at pre treatment among FFTHR group46.6(11.8), among Enhanced care group 50.0(16.7, p=.41,Depression at post treatment among FFTHR group41.7, EC group is 37.3(15.2),p=.34  In Mania symptoms at pre treatment 9.4(7.4) among FFTHR group, whereas among EC group it was 13.6(6.2),p=.06Mania at post treatment FFTHR group=9.3(6.2),among EC group 10.4(6.2,p=.58	Improvement in mania or hypo manic symptoms and depressive symptoms among FFTHR group than Enhanced care group.
4	2020	DJM	UCLA, UCAM, SU, California	RCT	n=127(EG:61, CG=66)	9-17 yrs youths ,and their parents MDD, OSBD, Active mood symptoms, at least 1 first or second degree relatives with BDI or BDII.	FFT(12 session in 4 months PE,CEST,PSST). Enhanced Care(6 session in 4 months of family and individual PE)	64.6% female, mean(Sd)age, 13.2(2.6 yrs) were follow up for a median of 98 weeks (range0-255)weeks, no differences were detected between treatments in time to recovery from pre treatment symptoms. High risk youths in the FFT group had longer intervals from recovery to the emergence of the next mood episode( $f^2=5.44$ ,p=.02,H ratio=0.55,95% CI,0.48-0.92,and from randomization to the next mod episode( $f^2=4.44$ , p=.03,H ratio=0.59,95% CI,0.35-0.91) than youths in enhance care group. FFT was associated with longer intervals to depressive episodes but did not differ from enhanced care group in time to manic or hypo manic episode conversion to BD or symptoms trajectories youths in the FFT group.	Family skill training for youths at high risk for BD is associated with longer times between mood episode.

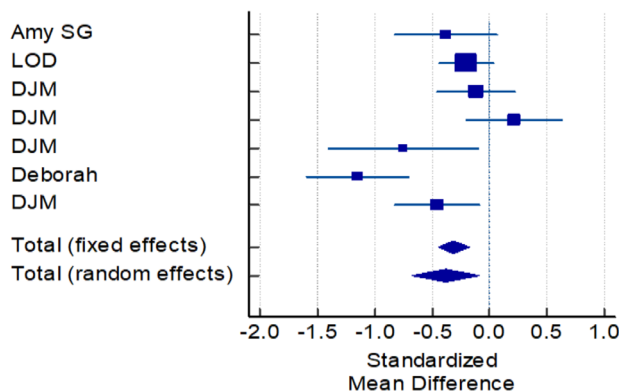
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5	2020	Lisa O Donnell	Unv of Colorado,boulderCO,unv. Of Pittsburgh school of medicine, unv of Cincinnati,USA	RCT	n=144 (EG:72, CG=72)	Adolescents (age range 12-18 yrs 1 month.)met DSM-IVTR criteria for diagnosis of BDI or BDII criteria, for a mood episode in the previous 3 months at least 2 weeks of syndromal depressive symptoms and 1 week of syndromal manic or hypomanic symptoms. and families	FFT A vs EC(enhanced care)	In FFT-A group low conflict families had grater adolescents rated family cohesion throughout the study compared to the high conflict families. High conflict families tended to shows larger reduction in conflict over 2 yrs than low conflict families in both treatment group. In the early stages of BD psycho education and skill training may improve family cohesion.	Greater reduction in conflict over the course of the study compared to low conflict families.
7.	2017	DJM	Unv. Of California, losangels. Unv of Colorado,boulder(Dept of psychology OPD),unv. Stanford Unv. school of medicine.	Singles blind parallel group RCT upto 4 yrs follow up.	n=133 (EG:68, CG=65)	9 to 17 yrs MDD, at least one first or 2 <sup>nd</sup> degree relatives with lifetime H/o Bipolar disorder I orII	FFTHR (12 session) vs Enhanced care(6 family and individual session)	Among 133 participants MDD v s unspecified BD was approximately y:2:1(mean age 13.1+-2.7.The mean CDRS depression scores at baseline is 46.6+_14.4.Score of 40 is usually indicator of MDD, YMRS score of 12 have been suggested as a cut off for defining hypomania in adolescents.	
8.	2017	Lisa a O Donneil	Unv of Colorado,boulder(Dept of psychology OPD),unv. Stanford Unv. school of medicine.	RCT	n=141 (EG:70,CG-71)	Adolescent mean age 15-17 yrs with BDI and BDII who had a mood episode in the previous 3 months.	FFT-A.(21 sesion in 9 months of PE,CET,PSST) vs EC (3 family psycho education session)	Among 141 adolescents (15.6+_1.4 yr) with BDI II who had a mood episode in the previous 3 months FFT 21 session in 9 months of PE, CEST, PSST and Enhanced care group was getting 3 PE session. Two treatment group did not differ in overall quality of life scores over 24 months. FFT-A had greater improvement in quality of family relationship and physical well-being than participants in EC group.	
9	2014	DJM	Unv of Colorado,boulderCO,unv. Of Pittsburgh school of medicine,unv of Cincinnati,USA	RCT	n=145 EG:72 CG:73	Adolescents (age range 12-18 yrs 1 month.)met DSM-IVTR criteria for diagnosis of BDI or BDII criteria, for a mood episode in the previous 3 months at least 2 weeks of syndrome depressive symptoms and 1 week of syndrome manic or hypo manic symptoms. and families	21 session FFT vs 3 weekly sessions of EC	Among 145 adolescents (mean age 15.6 yrs) with BDI and II disorder 15.2% withdraw shortly after randomization. Time to recovery or recurrence and proportion of weeks did not differ between two treatment group. There were no treatment group differences in the % of weeks free of mood symptoms across study year 1 and 2.There were also main effect of treatment groups by time (yr I and yr II) interaction on % of weeks with depressive symptoms.	

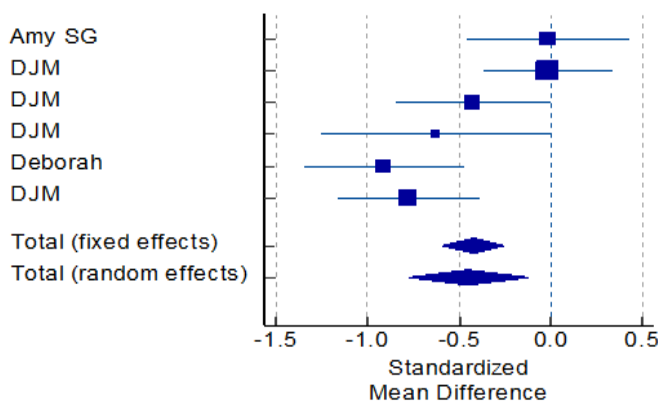
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10	2013	DJM	Unv of Colorado,boulder(Dept of psychology OPD),unv. Stanford Unv. school of medicine	RCT	n=40 EG:21,CG:19	9-17 yrs youths ,and their parents MDD, OSBD, Active mood symptoms, at least 1 first or second degree relatives with BDI or BDII	FFT-HR vs EC	<b>Among 40</b> youth (mean 12.3+ 2.8, range 9-17 yrs) with BD not otherwise specified. The effects of FFT-HR on time to recovery were robust [chi square (1)=3.96, p=0.47, HR=2.69] when baseline hypomania status[ chi square(1)=16.22, p<0.001, HR=5.88] and baseline depression status chi square(1)=7.52, p=0.006, HR=3.0 were included in a cox proportional hazard model. The treatment effects was marginally significant [chi square(1)=2.71, p=.099,HR=2.02].	FFT-HR may hasten and help sustain recovery from mood symptoms among youth at high risk for BD.
11	2011	Deborah A .per LICK	Mount Senai Outpatient Mental Health Clinic, New York.	RCT	n=46	Primary Caregivers(spouse or parent),had more frequent contact with pt than other caregivers, help to support the pt financially, is contacted by treatment staff for emergencies has been involved in the pts treatment. of the pt BPAD I or II,,age-18 yrs or older.	FFT-HPI (12-15 session) vs HE (8-12 session)	The primary family caregivers of 46 patients with BDI (n=40, BDII n=6) 2 HE participants1 FFTHR participants i.e prior to phase II and were not able to followed (average14.3+ 1.6 session over4.7+ 1.1 months in FFT-HPI and 8.1+ 2.4 sessions in randomization to FFT-HPI was associated with significant decreases in caregivers depressive symptoms and health risk behaviour Depressive symptoms reduction also observed in FFT-HPI group. Patient's depression was partially mediated by reduction in caregiver's depression level.	Families coping with bipolar disorder may benefit from family interventions as a results changes in the caregivers ability to manage stress and regulate their mood even hen pts are not available for treatment.
12	2009	DJM	Unv of Colorado, unv. Of Pittsburgh school of medicine,	2sites RCT 2 year follow up.	n=58 EG:30,CG:-28)	12-18 years, Diagnosed BPADI, II, or not otherwise specified,1 parent concurrent physician diagnosis of Bipolar, I,II, NOS, at least 1 week episode of manic, mixed, or hypo manic symptoms, or a 2 week episode of depressive symptoms past 3 months	FFT- A and protocol pharma co therapy s Enhanced care and protocol pharmacotherapy.	Analysis were by Intent to treat ,did not differ across the FFT-A(60 %) and EC condition(64.5%),no group differences were found rate of recovery from index episode. FFT-A group recovery of depressive symptoms than EC group (H ratio 1.85,95% CI,1.04-3.29, p=.04) FFT- A group shows more favourable trajectories of depression symptoms for 2 years.	FFT is effective with pharmacotherapy in stabilizing bipolar depressive symptoms among adolescents.
13	2003	DJM	Unv of Colorado, unv. Of Pittsburgh school of medicine	RCT,2 yr follow up	n=101 EG:31,CG:-70)	Adult18-65 yrs manic ,mixed, or depressed episode past 3 months, no alcohol or substance use disorder past 6 months, living with or in regular contact with a care giving family member.	FFT vs CM(21 session)	Rate of study completion did not differ across the FFT(22/31,71%) and crisis management group(43/70, 61%).Patients undergoing FFT had fewer relapses11/31,35% and longer survival intervals (mean+ _sd73.5+28.8 weeks) Hazard ratio=0.38, 95% CI.0.20-0.75, p=.003. FFT group shows greater reducing in mood disorder symptoms and better medication adherence during the 2 year than patients undergoing crisis management group.	Combining family psycho education with pharmacotherapy enhances the post episode symptomatic adjustment and drug adherence of bipolar patients.





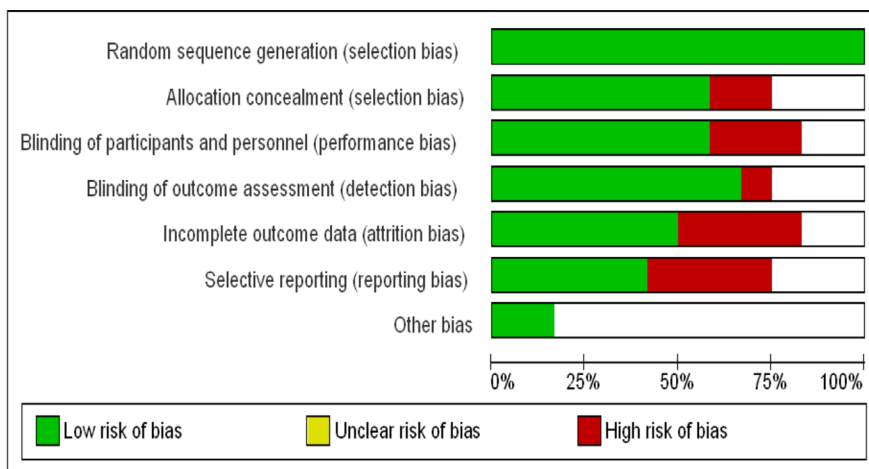
**Figure 1: Forest plot showing effect of Family focused therapy on depression among bipolar disorder patients.**



**Figure 2: Forest plot showing effect of Family focused therapy on mania symptoms among bipolar disorder patients.**

On sensitivity analysis, it was found that studies with low risk of bias [SMD -0.45 (95% CI, (-0.77, -0.12),  $I^2 = 0%$ ), and some concern SMD: -0.83 (95% CI, (-0.37, -0.12)  $I^2 = 0%$ ) had significant reduction of mania and depressive symptoms without any

presence of heterogeneity. However, the studies with high risk of bias showed no significant reduction of depressive and manic symptoms after family focused therapy {SMD -0.72 (95% CI -1.57, 0.12),  $I^2 = 92%$  with substantial heterogeneity.



**Figure 3: Risk of bias graph**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
AMYSG2021	+	+	+	+	-	-	
DEBORAH2011	+	+	+	+	+	-	
DJM2003	+	-			-	-	
DJM2009	+	+	+	+	+		
DJM2013	+	+	+	+	+	+	
DJM2014	+	+	+	+	+	+	
DJM2017	+		-		-	+	
DJM2020	+	-	-		+	+	
DJM2022	+	+	+	+	-		+
LOD2017	+	+	+	+	+		
LOD2020	+			-		+	+
MJW2022	+		-	+		-	

Figure.4: Summary of risk of bias of individual studies

**Risk of bias in included studies:** Four. (DJM 2013, DJM 2014, DJM 2009, LOD 2017 Studies were found of low risk of bias) DJM2017, DJM 2003, LOD 2020 studies of some concerns (DJM 2003, AMYSG 2021, DJM 2020...) studies were at high risk of bias (AMYSG2021, DEBORAH2011, DJM2003.) studies were shown missing data (DJM2013, DJM2014, DJM2009, DEBORAH2011, LOD2017, DJM2020, DJM2022, MJW2022, LOD2020, DJM2017, AMYSG2021. For Randomization domain, All studies were found low risk of bias (4) studies were found high risk of bias.<sup>21,22,23</sup> Medication adherence and quality of life of patients of bipolar affective disorder: one in each study reported medication adherence is improved after the intervention of family focused therapy,<sup>14</sup> one study has reported that quality of life of the patients of bipolar affective disorder is better than before<sup>33</sup> in comparison with control group.

**Discussion**

Various forms of psychosocial intervention have been found efficacious as adjunctive treatments for bipolar disorder, including family-focused therapy, interpersonal and social rhythm therapy, cognitive-behavioral therapy, and individual or group psycho education. When used in conjunction

with pharmacotherapy, these interventions may prolong time to relapse, reduce symptom severity, and increase medication adherence. This review included 13 randomized control trial Family focused therapy is effective in reduction of depressive and manic symptoms.

A systematic review conducted by David J Micklowitz on 2006 showed when FFT is used in conjunction with pharmacotherapy, these interventions may prolong time to relapse, reduce symptoms severity and increase medication adherence<sup>14,15,16</sup> Eduard Vieta done a systematic review they conclude that combining psychosocial intervention and pharmacotherapy which are tailored to patients individual needs, may decrease the risk of relapse, improve patients adherence and decreases the length of hospital stay.<sup>28</sup>

Christing Mirable-Sareen conducted a systematic review on 2006 showed CBT, FFT, and psycho education offer the most robust efficacy in Regard to relapse prevention. Family focused therapy is useful in reduce depressive symptoms rather than manic or hypo manic episode.

This findings supports the following systematic review:

David J M 2021 Feb Higher study retention was associated with family or conjoint therapy and brief psycho education compared with standard psycho education

A systematic review conducted by Sibel Chakir (yr.2010.)<sup>20</sup>study also support this findings.

**Limitation(s):** First, This review includes Family focused therapy as the intervention. However, there are other non pharmacological interventions that could be effective in reducing the disease outcome of bipolar affective disorder patients. This review could not explore those interventions. Secondly most of the studies included in the review had risk of biases. The researcher must consider the quality of the studies while interpreting the results. None of the studies in this review could blind the participants, and few studies could blind for intervention giver and outcome assessors. This might introduce the chances of outcome assessment being influenced by the outcome assessors.

### Conclusion

In this review we systematically searched and included randomized control trial that reported the effect of family focused therapy on relapse prevention, reducing depressive, manic or hypo manic symptoms, improving medication adherence

of the bipolar affective disorder patients. This is the strength of our review. This review found significant reduction of depressive symptoms than manic or hypo manic symptoms.

The studies included in the review were mostly have biases regarding blinding of outcomes assessors and reporting of the result. Therefore the findings need to be interpreted cautiously. Beneficial effect of FFT on relapse prevention, medication adherence and disease symptoms outcome .only one study found effect of FFT on quality of life of patients and caregivers depression and burden state. Future good quality RCT are needed to evaluate the effect of FFT on BPAD patients Quality of life, medication adherence, caregivers burden and caregivers depression status.

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**Conflict of interest:** The authors declare no conflicts of interest

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**Ethical Approval:** was taken from ethical Committee of Medical college Hospital, Kolkata. Ref. no-MC/Kol/IEC/NON-SPON/657/03/2020,Dated 12/03/2020.

### Appendix:Pubmed-MEDLINE

#1	'Bipolar Disorder'[Mesh]OR Bipolar Affective Disorder"[Mesh]OR Mood disorder[Mesh]' Bipolar Disorder[tw]OR[Bipolar Affective Disorder[tw]
#2	'Family focused therapy'[Mesh]OR Family Therapy'[Mesh]or' Psychosocial therapy'[Mesh]OR 'Family focused therapy'[tw] 'Family Therapy'[tw]
#3	'Depression'[Mesh]OR' Mania[Mesh],psychiatric status[Mesh]Depressive state"[Mesh]OR Manic state[Mesh]'Prognosis'[Mesh]'hypo mania'[Mesh] Depression'[tw] OR Mania[tw]OR 'psychiatric status[tw] 'hypo mania'[tw]
#4(#1AND#2AND#3)	Bipolar Disorder'[Mesh]OR Bipolar Affective Disorder"[Mesh]OR Mood disorder[Mesh]' Bipolar Disorder[tw]OR[Bipolar Affective Disorder[tw] 'Family focused therapy'[Mesh]OR Family Therapy'[Mesh]or' Psychosocial therapy'[Mesh]OR 'Family focused therapy'[tw] 'Family Therapy'[tw] Depression'[Mesh]OR' Mania[Mesh],psychiatric status[Mesh]Depressive state"[Mesh]OR Manic state[Mesh]'Prognosis'[Mesh]'hypo mania'[Mesh] Depression'[tw] OR Mania[tw]OR 'psychiatric status[tw] 'hypo mania'[tw]
#5	'Quality of Life'[Mesh]OR 'life quality[Mesh]
#6(#1AND#2AND#5)	'Bipolar Disorder'[Mesh]OR Bipolar Affective Disorder"[Mesh]OR Mood disorder[Mesh]' Bipolar Disorder[tw]OR[Bipolar Affective Disorder[tw] Family focused therapy'[Mesh]OR Family Therapy'[Mesh]or' Psychosocial therapy'[Mesh]OR 'Family focused therapy'[tw] 'Family Therapy'[tw] 'Quality of Life'[Mesh]OR' life quality[Mesh]

#7	'Medication Adherence'[Mesh]OR 'Medication compliance'[Mesh]OR 'Treatment compliance'[Mesh]
#8((#1AND#2AND#7)	Bipolar Disorder'[Mesh]OR Bipolar Affective Disorder'[Mesh]OR Mood disorder[Mesh]' Bipolar Disorder[tw]OR[Bipolar Affective Disorder[tw] Family focused therapy'[Mesh]OR Family Therapy'[Mesh]or' Psychosocial therapy'[Mesh]OR 'Family focused therapy'[tw] 'Family Therapy'[tw] 'Medication Adherence'[Mesh]OR 'Medication compliance'[Mesh]OR 'Treatment compliance'[Mesh]

Google Scholar:

#1	'Bipolar Disorder' OR 'Bipolar Affective Disorder' OR Mood disorder
#2	'Family focused therapy' OR Family Therapy' or 'Psychosocial therapy'
#3	Depression OR 'Depressive disorder' 'Mania' OR 'Manic disorder' 'Hypo-mania OR 'Hypo manic mood
#4(#1 AND#2 AND#3)	'Bipolar Disorder' OR 'Bipolar Affective Disorder' OR Mood disorder Family focused therapy' OR Family Therapy' or 'Psychosocial therapy' AND Depression OR 'Depressive disorder' 'Mania' OR 'Manic disorder' 'Hypo-mania' OR 'Hypo manic mood
#5	'Quality of life'
#6(#1 AND#2 AND#5)	Bipolar Disorder' OR 'Bipolar Affective Disorder' OR Mood disorder Family focused therapy' OR Family Therapy' or 'Psychosocial therapy' AND Quality of life'
#7	'Medication Adherence' OR 'Medication compliance' OR 'treatment adherence'
#8((#1 AND#2 AND#7)	Bipolar Disorder' OR 'Bipolar Affective Disorder' OR Mood disorder Family focused therapy' OR Family Therapy' or 'Psychosocial therapy' AND Quality of life' 'Medication Adherence' OR 'Medication compliance' OR 'treatment adherence'

### Cochrane central Library

#1	Bipolar Disorder'[Mesh]
#2	'Family focused therapy'[Mesh]
#3	Bipolar Disorder'[tiab]OR Family focused therapy'[tiab]
#4	'psychosocial therapy'[Mesh]
#5	'family therapy'
#6	#1Or #2OR#3OR#4
#7	Mania[Mesh]OR hypo mania[Mesh]
#8	Depression'[Mesh]
#9	#7OR#8
#10	'Medication Adherence' OR 'Treatment adherence'
#11	'Quality of life'
#12	#10 OR#11
#13	#1OR#2#10
#14	#1OR#2#11

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# Biofilm Production by Uropathogens Causing Catheter Associated Urinary Tract Infection among ICU Patients

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## Abstract

**Background:** Biofilm is slimy layer of an extracellular matrix made of polymeric substances, colony providing resistance not only against antibiotics but also against the human immune system. **AIM:** Biofilm production by uropathogens causing catheter associated urinary tract infection among ICU patients. **Objectives:** To identify & isolates the pathogen from urinary samples, determine Antibiotic Susceptibility Test of the isolated pathogens & detect the biofilm production of isolated pathogens.

**Material and Methods:** Uropathogens isolates from clinical samples received in the department of microbiology over a period of 1 year were included in the study. Isolates were identified and species determined by standard methods. Antibiotic susceptibility test was done by Kirby Bauer disc diffusion test and *Biofilm* detected by Congo red agar method.

**Result:** A total of 233 isolates were used to check biofilm formation out of which 104(46.63%) showed strong biofilm formation and 98 isolates were negative biofilm producers by Congo red test. The majority of strains that formed strong biofilms were *Escherichia coli*(49) and *Enterococcus spp.* (19). On the other hand, 12 *Escherichia coli* strains showed weak slime formation with 2 *Staphylococci* strains. Furthermore, out of all samples, 15(6.43%) were indeterminate for any biofilm formation. Out of those 233 isolated strains, the pattern of antibiotic resistance indicated that the greatest proportion of isolates were resistant to NX (norfloxacin) (97%), AMP Ampicillin (90%), and followed by GEN Gentamycin (69%).

**Conclusion:** In conclusion, the prevalence of biofilm-dependent CAUTI was high, with *E. coli* represented the highest biofilm producer. Therefore, minimizing the duration of catheterization as possible and the usage of silicone catheter instead of latex are recommended. Using carbapenems in treatment of biofilm-dependent CAUTI should be considered.

**Keywords:** Biofilm; Intensive Care Unit; Congo Red Agar; Urinary Tract Infection.

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## Introduction

Biofilm were structured as slimy layers of an extracellular matrix composed of polymeric substances that form colonies, offering resistance not only to antibiotics but also to the human immune system. <sup>(1)</sup> This structural complexity enables biofilms to protect bacteria from antimicrobial agents, leading to persistent and challenging-to-treat chronic infections, as well as facilitating the spread of antibiotic resistance. The establishment and spread of antibiotic resistance are greatly aided by biofilms, which are essential for the transmission of resistance genes between bacterial species. To break up biofilms and improve the efficacy of antibiotic treatments, it was crucial to comprehend the mechanisms underlying biofilm resistance. <sup>(2) (3)</sup>

Catheter-associated urinary tract infections (CAUTI) account for 80% of nosocomial urinary tract infections (UTIs) and up to 40% of all nosocomial infections. The organisms commonly contaminating these devices were *Escherichia coli*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Klebsiella pneumonia*, *Staphylococcus epidermidis*, and *Enterococcus faecalis*. These organisms have a higher propensity to cause urinary tract infections the longer the urine catheter is left in place. <sup>(4)</sup>

Biofilm was present in implanted foreign bodies, prostate stones, and the urothelium. Invasion of the renal tissue by bacteria adhering to the uroepithelium and creating biofilm can result in pyelonephritis and potentially chronic bacterial prostatitis. <sup>(5)</sup>

The prevalence of hospital-associated UTIs, which make up more than 40% of nosocomial infections, is particularly high among ICU patients. With 25% of hospitalized patients needing catheterization during treatment, urinary catheters are a popular equipment used in healthcare settings, making UTIs especially problematic in these patients. <sup>(6)</sup>

One important aspect of the pathophysiology

of catheter-associated UTIs was the development of biofilm by uropathogens, which can result in antibiotic resistance and difficulties with treatment. Research has shown that uropathogens like *Escherichia coli* (*E. coli*) developing biofilms were the reason for the high rates of recurrence and antibiotic resistance in UTIs. <sup>(7)</sup>

## Material and Methods

A cross-sectional study was conducted in the Microbiology Department at Teerthanker Mahaveer Medical College and Research Centre, Moradabad, Uttar Pradesh. The study was conducted for 1 year after the approval from college CRC and IEC.

**Inclusion Criteria:** Only adults above 18 age group, indwelling urinary catheters for at least 2 days, and had UTI symptoms among ICU patients.

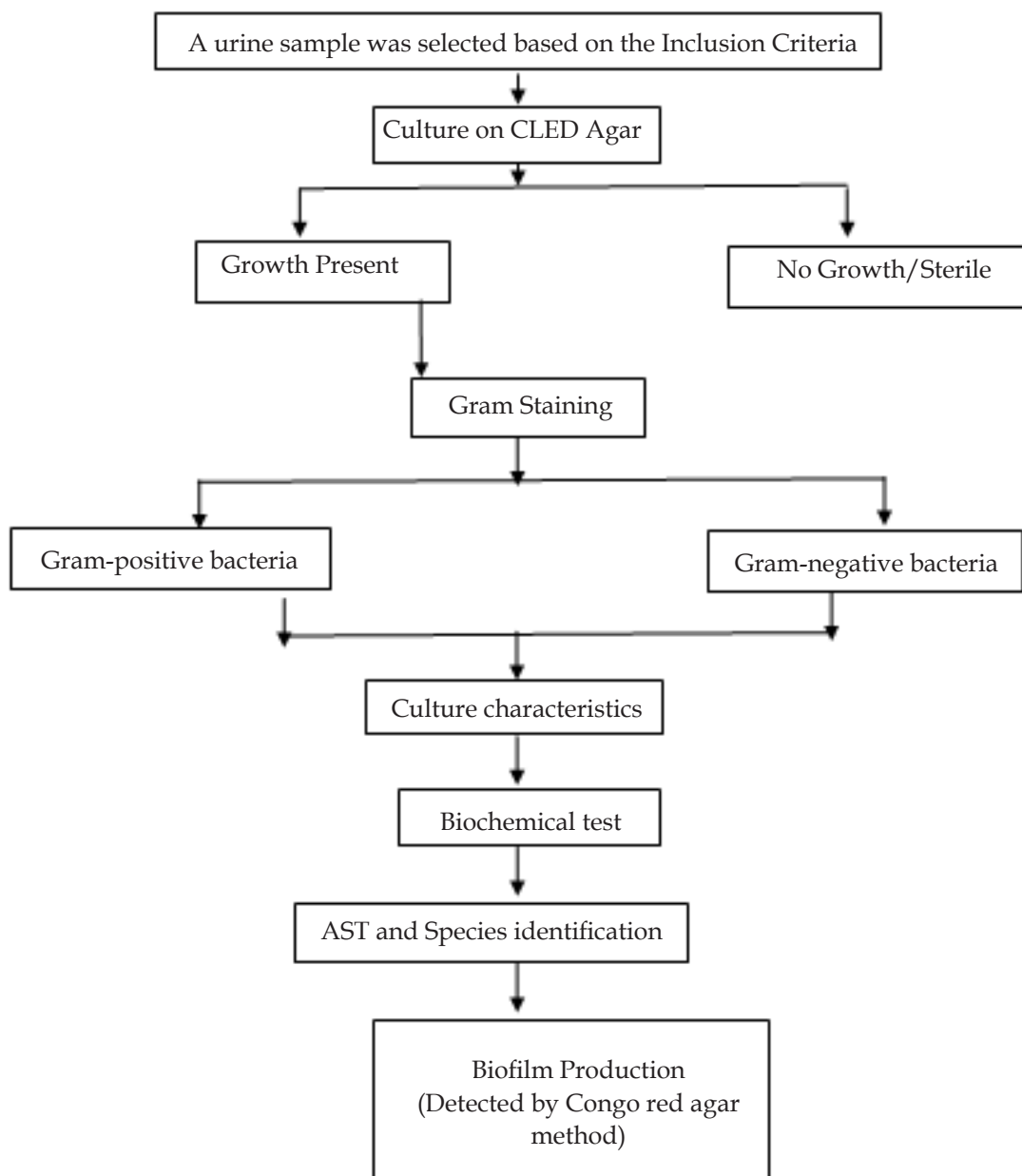
**Exclusion Criteria:** Patients denying consent, Individuals who had UTIs before getting catheters.

## Sample Size Calculation

The required sample size (N) was determined using the formula  $N = Z_{\alpha/2}^2 P(100-P) / E^2$ , Where  $Z_{\alpha/2}$ : Standard normal rate (1.96 for 95%), P: Prevalence rate (78%), E: Absolute error (5%), N: Minimum sample size. The calculated minimum sample size was 263.58, rounded up to 264. However, the authors included 264 isolates as we received more isolates during the study period.

## Study Procedure

The urine sample was first collected based on the inclusion criteria, The sample was processed on CLED agar, after 24-48 hours, growth was observed and then gram staining was carried out, Culture characteristics were done for gram-positive Bacteria (catalase and coagulase test), and gram-negative bacteria (biochemical test), AST was done based on CLSI guideline 2023 for species identification and the Congo Red Agar method was carried out for biofilm production. <sup>(8) (9) (10)</sup>



Catalase positive, Coagulase positive=*Staphylococcus aureus*

Catalase positive, Coagulase negative = Coagulase-negative *Staphylococcus aureus* (CONS)

Catalase negative = Bile esculin *Enterococcus*

## Results

During the study period, out of a total of 264 different clinical samples, 111 (42.06%) samples were from males, and 153 (57.94%) samples were from

females. The most commonly affected age group was 51- 60 years, with 58 cases (21.96%), followed by the 31-40 years age group with 47 cases (17.80%), as illustrated in [Table/Fig-1].

**Table 1: Distribution of different genders in the study population according to different age groups and sex wise.**

AGE GROUP	MALE	FEMALE	TOTAL
18-20	7	9	16
21-30	13	29	42

Continue.....

31-40	19	28	47
41-50	21	22	43
51-60	26	32	58
61-70	11	20	31
>71	14	13	27
TOTAL (264)	111	153	264

Out of 264 samples taken, 233 (88.25) were growth-positive isolates whereas 31 (11.75) were sterile. 93 (39.91) isolates were obtained from males and 140 (60.09) isolates were obtained from females respectively. The data was analyzed using statistical application software IBM SPSS version 20.

**Table 2: Distribution of bacterial growth according to gender of patients.**

BACTERIAL GROWTH	MALE No. (%)	FEMALE No. (%)	TOTAL
GROWTH	93 (39.91)	140 (60.09)	233
STERILE	18 (58.06)	13 (41.94)	31
TOTAL	111 (42.04)	153 (57.96)	264

Out of 264 clinical samples processed, bacterial growth was detected in 233 samples only. Among all bacterial isolates, *Escherichia coli* was isolated in 99(42.48) samples which was the highest in number. Followed by *Klebsiella pneumoniae* 28 (12.01%).

**Table 3: Distribution of isolates based on gender**

PATHOGEN ISOLATED	MALE	FEMALE	TOTAL
<i>Escherichia coli</i>	37	62	99
<i>Escherichia coli</i> (ESBL)	7	9	16
<i>Klebsiella pneumoniae</i>	11	17	28
<i>Pseudomonas</i> spp.	11	13	24
<i>Enterococcus</i> spp.	6	18	24
<i>S.aureus</i>	3	8	11
<i>S.aureus</i> (MRSA)	6	5	11
<i>Acinetobacter baumannii</i> complex	5	2	7
CONS	3	3	6
<i>Proteus</i>	3	2	5
<i>Citrobacter koseri</i>	1	0	1
<i>Serratia marcescens</i>	0	1	1
Total	93	140	233

**Table 4: Antibiogram of isolated Pathogen**

Pathogen isolated	AMP (R)	GEN (R)	AK (R)	AZM (R)	FOS (R)	NIT (R)	NX (R)	MRP (R)	PB (R)	CL (R)	LZ (R)	VA (R)	HLG (R)	CIP (R)	CX (R)
<i>Escherichia coli</i> (N=99)	97	69	12	46	2	5	98	47	0	0	-	-	-	-	-
<i>Escherichia coli</i> (ESBL) (N=16)	16	10	4	8	2	1	16	10	0	0	-	-	-	-	-
<i>Klebsiella</i> spp. (N=28)	26	20	3	12	0	2	27	15	0	0	-	-	-	-	-
<i>Pseudomonas</i> spp. (N=24)	23	22	12	17	1	5	24	18	0	0	-	-	-	-	-
<i>Acinetobacter</i> spp. (N=7)	7	4	1	2	0	0	7	6	0	0	-	-	-	-	-
<i>Proteus</i> spp.(N=5)	5	3	3	3	0	0	5	2	2	2	-	-	-	-	-
<i>Citrobacter koseri</i> (N=1)	1	0	0	0	0	0	1	0	0	0	-	-	-	-	-
<i>Serratia marcescens</i> (N=1)	1	0	0	0	0	0	1	1	0	0	-	-	-	-	-
<i>S. aureus</i> (N=11)	5	5	2	3	1	0	10	-	-	-	2	0	-	6	0

Continue.....

S. aureus (MRSA) (N=11)	9	9	1	4	1	2	11	-	-	-	1	0	-	4	11
Enterococcus spp. (N=24)	16	16	6	-	1	5	22	-	-	-	4	0	9	14	14
CoNS (N=6)	4	4	1	4	1	0	5	-	-	-	2	0	-	4	4
TOTAL (264)	210 (90%)	162 (69%)	45 (19%)	99 (47.36)	9 (3%)	20 (8%)	227 (97%)	99 (54%)	2 (1%)	2 (1%)	9 (17%)	0 (0%)	9 (17%)	28 (53%)	29 (55%)

NOTE- \*AMP (Ampicillin), GEN (Gentamicin), AK (Amikacin), FOS (Fosfomycin), NIT (Nitrofurantoin), NX (Norfloxacin), MRP, (Meropenem), PB (Polymyxin B), CL (Colistin), LZ (Linezolid), VA (Vancomycin), HLG (High level Gentamicin), CIP (Ciprofloxacin) and CX (Cefoxitin).

R\* (Resistance).

Table 4: summarizes the resistance of isolates to antimicrobial agents. Of those 233 isolated strains, the pattern of antibiotic resistance indicated that the greatest proportion of isolates were resistant to NX (Norfloxacin) (97%), AMP (Ampicillin) (90%), and followed by GEN (Gentamicin) (69%).

In our study, Ampicillin, Norfloxacin and Gentamicin demonstrated reduced sensitivity against gram-negative organism and Ampicillin, Norfloxacin, Gentamicin, Ciprofloxacin were showed reduced sensitivity against gram positive organism.

A total of 233 isolates were used to check biofilm formation out of which 104(46.63%) showed strong biofilm formation and 98 isolates were negative biofilm producers by Congo red test. The majority of strains that formed strong biofilms were *Escherichia coli*(49)and *Enterococcus spp.* (19). On the other hand, 12 *Escherichia coli* strains showed weak slime formation with 2 *Staphylococci* strains. Furthermore, out of all samples, 15(6.43%) were indeterminate for any biofilm formation.

**Table 5: Distribution of biofilm producer pathogens**

PATHOGEN ISOLATED	BIOFILM							
	STRONG POSITIVE		WEAK SLIME PRODUCER		INDETERMI-NATE		NEGATIVE	
	No.	%	No.	%	No.	%	No.	%
<i>Escherichia coli</i> (115)	49	42.60	12	10.43	6	5.21	48	41.73
<i>Klebsiella spp</i> (28)	13	46.42	1	3.57	2	7.14	12	42.85
<i>Pseudomonas spp.</i> (24)	8	33.33	1	4.16	0	0	15	62.5
<i>Enterococcus spp.</i> (24)	19	79.16	0	0	2	8.33	3	12.5
<i>Staphylococci</i> (22)	8	36.36	2	9.09	3	13.63	9	40.90
<i>Acinetobacter Baumannii Complex</i> (7)	2	28.57	0	0	1	14.28	4	57.14
CONS (6)	2	33.33	0	0	1	16.66	3	50
<i>Proteus Spp.</i> (5)	3	60	0	0	0	0	2	40
<i>Citrobacter koseri</i> (1)	0	0	0	0	0	0	1	100
<i>Serratia marcescens</i> (1)	0	0	0	0	0	0	1	100
Total (233)	104	44.63	16	6.86	15	6.43	98	42.06

## Discussion

Among the most common bacterial diseases in humans was urinary tract infections or UTIs. Catheterization-associated urinary tract infections (CAUTIs) were diagnosed in patients who had fever

(temperature  $\geq 38^\circ\text{C}$ ) without any other apparent cause, urgency, or suprapubic discomfort.

The persistence of uropathogens associated with biofilms affects most facets of CAUTI diagnosis, treatment, and prevention. <sup>(11)</sup> Meanwhile, in patients

with underlying diseases or under intensive care, the relevant detection of biofilm producers is crucial since CAUTIs are a common nosocomial infection.

In most cases, urinary catheterization is recommended to treat urinary tract obstruction, allow patients with neurogenic bladder dysfunction and urine retention to drain their bladders, support urologic surgery, and collect accurate measurements of urine production in people with clinical illness.<sup>(12)</sup>

A cross-sectional observational study was conducted over 6 months among 264 catheterized CAUTI patients brought into the intensive care unit of TEERTHANKER MAHAVEER MEDICAL COLLEGE & RESEARCH CENTRE. Urine and foley tip samples were collected and cultured to identify the causative uropathogens. In the study, 233(88.25%) of the 264 patients studied exhibited notable bacteriuria, and 31(26%) samples were sterile. In the current study, overall CAUTI cases were higher among female patients 140(60.08%) compared to male patients 93(39.92%). Jayasukhbhai et al.,<sup>(13)</sup> and Almalki and Varghese<sup>(14)</sup> reported (56.46% and 75% respectively) of CAUTI in female patients which was similar to our study in this study, the prevalence of UTI was higher in females may be due to the high load of periurethral flora in females which was introduced during catheterization. We find out UTIs were more common in the age between 51-60. According to the study, *E. Coli* was the most often isolated pathogen out of these 233 strains 115(49.35%), followed by *Klebsiella spp* 28(12.01%), *Pseudomonas spp.*24(10.30%), *Enterococci* 24(10.30%) and *Staphylococci* 22(9.44%). Several other studies also revealed *E. coli* as the commonest pathogen ranging from 22 to 70%. In contrast to the current study, Ghanwate et al.,<sup>24</sup> isolated 50% *P. aeruginosa* as the commonest agent followed by *Enterococcus spp.* (31%), *E. coli* (25%).

In our study higher frequency of *E. Coli* was isolated from females than in males, 62 (62.62%) from females and 37(27.27%) from males. As the result shows females had a higher prevalence of *E. coli* than did males. Biofilm-producing bacteria showed comparatively better resistance against tested drugs in their antibiotic sensitivity patterns. Resistance trends among the isolates, both biofilm producers and nonproducers, are depicted in Table

4: Our study showed that imipenem, meropenem, nitrofurantoin, amikacin, and piperacillin-tazobactam were the most effective antibiotics against gram-negative isolates. Narmeen Mahmoud et al also found that imipenem and amikacin were the most effective antibiotics against gram-negative isolates. In our study, Cefotaxime, ceftriaxone, aminoglycosides, norfloxacin, ciprofloxacin, and ofloxacin demonstrated reduced sensitivity against gram-negative bacteria. Gram negative bacteria are more resistant than gram positive because of their outer membrane, which protect them from their environment and prolonged use of antibiotics. In our study Norfloxacin, Ciprofloxacin, Gentamicin show reduced sensitivity against gram positive bacteria and most effective antibacterial are Vancomycin and Linezolid for gram-positive bacteria. The present study showed more drug resistance in biofilm-forming isolates than in non-biofilm-forming isolates which is similar to S. Pramodhini et al.<sup>(15)</sup>

One element that contributed to the chronic, indolent infection in CAUTI was the development of biofilm along the catheter surface. In the current research, the detection of the biofilm was carried out by the Congo Red agar method. The detection of the biofilm Pfaller et al.'s research demonstrated the Congo Red method's advantages, including the colonies' ability to survive on the medium and its speed, sensitivity, and reproducibility.<sup>(16)</sup>

Microbial biofilms were associated with persistent infections that do not react to standard antibiotic treatment.<sup>(17)</sup>

The relationship between uropathogen biofilm development and antibiotic resistance has only been the subject of a small number of research. Since biofilm formation was a complicated process involving many different variables and components, more research is required to assess this correlation. However, prior research has indicated that the development of biofilms may be facilitated by early antibiotic usage.<sup>(18)</sup> To test this theory, however, more research on the consequences of exposure to sub-inhibitory antibiotic doses is required.

## Conclusion

The study emphasizes how crucial early detection of biofilm-forming uropathogens in CAUTI patients to guide appropriate antimicrobial therapy and prevent the development of antibiotic resistance. Strategies to prevent CAUTI, such as daily assessment of the need for catheter removal and adherence to standard care bundle approaches during catheter insertion and maintenance, are crucial.

The study on biofilm production by uropathogens causing catheter associated urinary tract infections (CAUTI) among ICU patients has provided insightful information about the frequency and significance of biofilm formation in this particular clinical context. The results of the study highlight the role that biofilms play in the persistence and recurrence of UTIs, particularly in patients who are catheterized.

**Ethical clearance:** Taken from institutional ethical committee TMU Moradabad Ref no. /MC/CRC/PR/2023/488 dated: 9.06.23

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# Burnout Syndrome among Doctors of a Tertiary Care Hospital in Southern Kerala

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## Abstract

**Background:** Burnout in health care professionals has gathered significant attention due to its impact on quality of care and medical personnel. As a result of the intense emotional demands of the work environment, clinicians are particularly susceptible to develop burnout above and beyond usual workplace stress. In order to cultivate occupational intervention programs there is a need to estimate the prevalence of burnout among physicians.

**Methods:** From a total of 108 participants, data was collected using a questionnaire primarily consisting of “personal burnout” domain of the Maslach Burnout Inventory, which is a validated instrument to assess the burnout using three dimensions which includes emotional exhaustion, depersonalization and low personal accomplishment. In addition to summary statistics, analysis was done to find out the factors significantly affecting burnout.

**Result and conclusion:** The findings of this study indicate that the burnout syndrome is present among doctors across all specialty categories. 3.7% showed high emotional exhaustion, 13.9 showed high depersonalization and 12% showed low personal accomplishment. Age, gender, working hours, years of experience were the some of the factors significantly affecting burnout. Burnout exists among healthcare professionals and measures should be taken to identify causes and take remedial actions.

**Keywords:** Burnout, Healthcare Professionals, Kerala, Maslach Burnout Inventory.

## Introduction

The medical profession has witnessed many changes due to the advancements in technology and improved hospital settings over the past few years which in turn have resulted in rising demands on

the quality of patient care. According to International Classification of Diseases-11<sup>th</sup> revision “Burn-out is a syndrome conceptualized as resulting from chronic workplace stress that has not been successfully managed. It is characterized by three dimensions: feelings of energy depletion; feelings of negativism

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or cynicism related to one's job; and reduced professional efficacy<sup>(1)</sup>. To provide the best possible service and also for a better working environment every institution has their own methods<sup>(2)</sup>. However, burnout still affects a large number of health professionals.<sup>(3)</sup> Physician burnout is a condition that is not well understood and discussed<sup>(4)</sup>. There is no doubt that physician burnout, if left undressed, can lead to severe personal and professional consequences<sup>(5)</sup>. Among the healthcare workers during the COVID-19 pandemic, burnout is significantly more common, especially among doctors and support personnel<sup>(6)</sup>. Burnout is concerning for healthcare workers because caregivers who are experiencing burnout may be more dangerous for their patients' health than patients themselves<sup>(7)</sup>. Among resident physicians in training, burnout is prevalent and potentially avoidable<sup>(8)</sup>. Working in emotionally taxing circumstances makes the residency program stressful<sup>(9)</sup>. The findings that medical students' mental health profiles at matriculation are comparable to or even better than those of age-matched college graduates pursuing other careers, and that once they enter medical school, their mental health deteriorates to a worse degree than that of the age-matched college graduates, point to the curriculum and learning environment as the primary causes of burnout<sup>(10,11)</sup>. Because the causes differ between nations and even within a single country, every institution should carry out a separate investigation to determine the causes of burnout and implement preventative measures<sup>(2)</sup>.

Studies to assess the prevalence of burnout among Indian health professionals are less. Indian health professionals vary from western professionals in terms of available facilities, infrastructure, patient load, working hours, emotional toil and working environment. In spite of these challenges there have been tremendous changes in the health sector of Kerala such as low infant mortality, increased life expectancy etc. To sustain the gains that are achieved and also for the further improvement it is very important to understand and take remedial measures for the burnout syndrome among doctors since they are the backbones of the healthcare system of a country. We wanted to assess the prevalence of burnout and its correlates among Indian health professionals in a tertiary medical college in Kerala, so that we can

introduce strategies even from medical education period to reduce the burnout among health professionals and its consequences.

## Materials and Methods

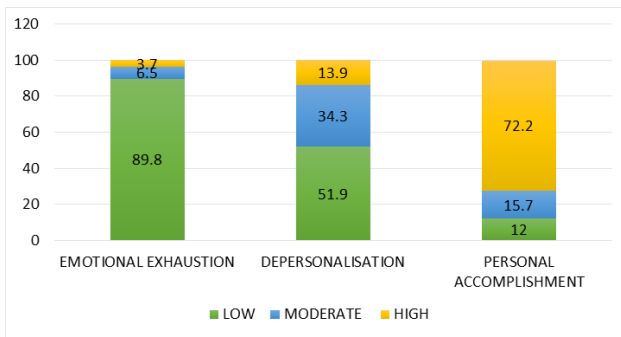
A cross sectional study was done among the doctors of clinical department of a medical college in Kerala. 108 doctors of the clinical departments were included. Those who were not available even after 2 consecutive visits and those who did not return the form were excluded. Data was collected through a semi structured Questionnaire. An appropriate rapport was established before administering the questionnaire. Proper instructions were given about the questions and informed consent was taken. Sociodemographic variables comprising of gender, marital status, type of family, educational status, designation was assessed. Burnout was measured by using the Maslach Burnout Inventory (MBI), which was first described by Maslach et al. (1996). The Maslach burnout model has three dimensions: emotional exhaustion, depersonalization and reduced personal accomplishment<sup>(12)</sup>. A key aspect of burnout syndrome is increased feelings of emotional exhaustion; as emotional resources are depleted; workers feel they are no longer able to give of themselves at a psychological level. Another aspect is the depersonalization (i.e., negative cynical attitudes and feelings about one's clients). A third aspect of burnout syndrome reduced personal accomplishment refers to the tendency to evaluate oneself negatively, particularly with regard to one's work with clients. MBI scale includes 22 seven-point questions on frequency of symptoms ranging from "0 = never" to "6 = every day". Among the 22 questions nine were for emotional exhaustion, five for depersonalization, and eight for personal accomplishment. All data collected were entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS)v 27. Mann Whitney U test and Spearman correlation test was used to find out the association between various factors and burnout. Informed consent was taken from the study participants and confidentiality of personal information was maintained throughout the study. Approval from Institutional ethical committee was obtained before the start of the study.

**Results and Discussion**

The mean age of the study participants was 39.35(11.7) years.

**Table 1. showing frequency and percentage of different sociodemographic variables.**

Serial number	Variables	Number	Percentage
1	Gender	Male	60 53.7
		Female	48 46.3
2	Marital status	Married	9 8.3
		Unmarried	99 91.7
3	Type of family	Nuclear	16 15
		Joint	23 85



**Figure 1: Distribution of burnout based on its domains.**

Out of the total 108 participants 3.7%, 13.9%, 12% reported high scores of emotional exhaustion, depersonalisation and low personal accomplishment

respectively. This was in contrast with a similar study conducted among 100 residents in South India where 15% respondents reported burnout in dimension of emotional exhaustion, 44% in the dimension of depersonalisation and 50% in the dimension of reduced personal accomplishment<sup>(9)</sup>. The Burnout in our study was very low compared to studies from Germany, Nigeria, Turkey and other Western countries with the level of emotional exhaustion (37.4%), high level of depersonalization (45.6%) and low perception of personal accomplishment (50.3%). This may be because most doctors in Kerala in Tertiary care setting do not have to deal with mundane issues like paperwork, insurance companies and regulatory bodies compared to other countries<sup>(13,14)</sup>.

**Table 2. showing factors significantly associated with burnout syndrome.**

Factors	Category	Mean score	*p value
Gender	Male	7.9	0.01 (depersonalization)
	Female	5.8	
Marital status	Married	8	0.011 (emotional exhaustion)
	Unmarried	14	
Type of family	Nuclear	41.2	0.006 (personal accomplishment)
	Joint	34.4	
Alcoholism	Yes	8.9	0.023 (depersonalization)
	No	6.5	
Skip meals	Yes	10.5	0.001 (emotional exhaustion)
	No	6	
Skip meals	Yes	8.53	0.001 (depersonalization)
	No	5.04	
Thought of leaving profession	Yes	12.6	0.001 (emotional exhaustion)
	No	5.8	

Continue.....

Thought of leaving profession	Yes	9.9	0.001 (depersonalization)
	No	5.02	
Speciality	Surgical	7.29	0.03 (emotional exhaustion)
	Medical	10.14	
Speciality	Clinical	9.26	0.002 (emotional exhaustion)
	Paraclinical	4.13	
Speciality	Clinical	7.4	0.019 (emotional exhaustion)
	Paraclinical	4.2	

\*(for the particular domain of burn out according to Maslach Burnout Inventory.)

Supporting our study another study from Maharashtra showed that males experienced more burnout than females<sup>(15)</sup>. It correlates significantly that depersonalisation burnout ( $p=0.01$ ) seen more in males (mean score 7.9) when compared to females (mean score 5.8). We concur with the discussion of Maslach and Jackson (1985), who suggest that significantly lower levels of depersonalization among female respondents may be a product of traditional gender-role socialization<sup>(16)</sup>. It is widely accepted that girls and boys are taught to relate with others differently. Boys are encouraged to be autonomous and emotionally disconnected, girls are encouraged to be dependent and emotionally connected (Gilligan, 1982; Walters, Carter, Papp, & Silverstein, 1988). More specifically in terms of professional therapeutic practice, if women are traditionally encouraged to be more empathic and sensitive to others, whereas men are traditionally encouraged to be less emotional and more independent, male therapists may be more

prone to deal with people in depersonalized ways (Maslach & Jackson, 1985). Although this rationale would also suggest that women may be more at risk for emotional exhaustion and involvement, this study did not reveal significant differences in this dimension.

A similar study conducted in a tertiary medical centre in Kerala also showed difference in prevalence of burnout across various specialties which could be because of the varied emotional and type of work demands of different specialties<sup>(17)</sup>. Medical residents have more interaction with patients that might be the cause for higher patient-related burnout when compared with surgical residents. In that study personal burnout was higher for surgical residents which did not yield significance in our study. A study on doctors working in the specialties of surgery and gynaecology in Germany was also able to find high personal burnout (48.7%)<sup>(18)</sup>.

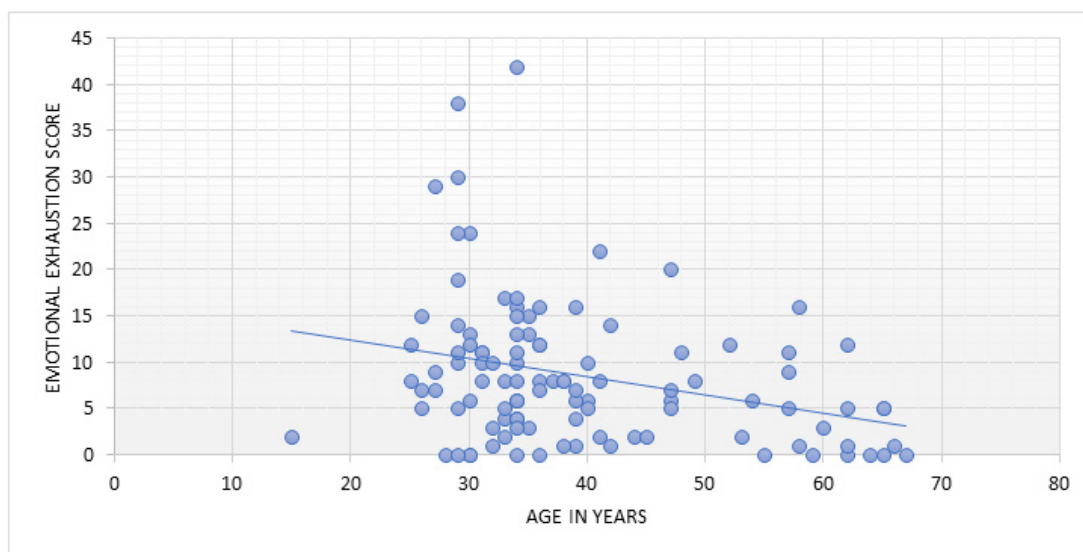
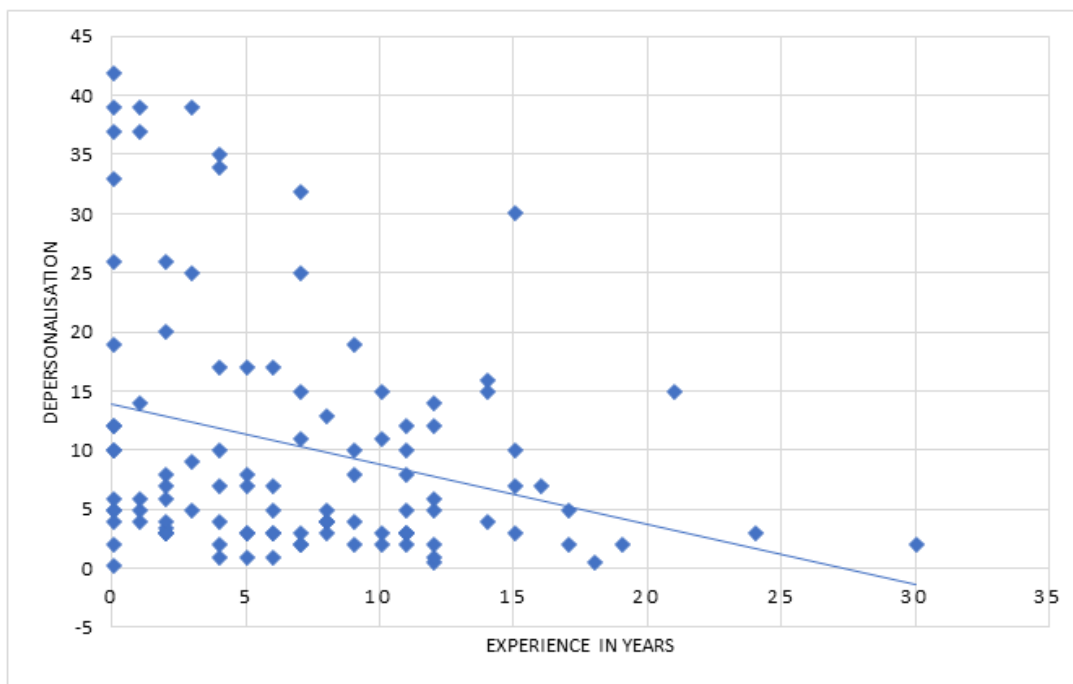


Figure 2 : Correlation of age with emotional exhaustion

This chart (Figure 2) shows as age increase burn out decreases. With Spearman correlation significance was obtained with all three domains i.e Emotional exhaustion (p value = 0.002), depersonalisation (p value= 0.036), low personal accomplishment (p value = 0.002).

In all studies doctors of younger age group and with low experience in practice experiencing more burnout than Doctors who are more experienced and aged.



**Figure 3: Correlation of Experience in years with Depersonalisation burnout**

The chart (Figure 3) shows as work experience increases burnout decreases. The chart (Figure 3) shows as experience increases burnout decreases. With Spearman correlation we got significance in all three domains i.e., Emotional exhaustion (p value= 0.005), depersonalisation (p value= 0.001), low personal accomplishment (p value = 0.016).

Similar to a study published in Ethiopian journal, in terms of experience and age, our findings indicate that as clinicians get older, levels of depersonalization and emotional exhaustion go down<sup>(19)</sup>. In agreement with previous studies (Cicone, 2003; Lippert, 2000; Vredenburgh et al., 1999) it may be stated that with life experience comes an emotional maturity that serves as a buffer against symptoms of burnout as therapists age. These therapists may have developed long-standing, reliable personal and professional support systems and coping strategies over time. Also, with age, a sense of personal accomplishment may be gained.

Working hours showed positive correlation with burnout. Using Spearman correlation test we obtained significance in Emotional exhaustion (p value= 0.001) and depersonalisation (p value= 0.0001). Similar positive correlation was obtained between night duties per month and burnout.

Aside from particular work settings, several job-related variables also affect the degree to which clinicians may experience burnout symptoms. As hours worked per week increased, personal accomplishment decreased, and emotional exhaustion and depersonalization increased. This finding is contrary to studies by Vredenburgh et al. (1999) and Lippert (2000), which report elevated feelings of personal accomplishment with increased client contact hours per week. The effect of hours worked per week transcends work setting and holds true for all clinicians, although it is unclear how the way in which those hours are spent may affect symptoms of burnout.

## Conclusion and Acknowledgement

Burnout in our study is less compared to other studies but it is more severe among young doctors. Our findings allowed to outline a risk profile for burnout syndrome., namely male, young doctors, who are unmarried and lives in a nuclear family with more number of working hours per week and night duties per month are prone for burnout syndrome. Clinicians new to the field and those at higher risk for experiencing symptoms of burnout should consider adopting self-care measures and collegial supports to prevent further deleterious effects. These may include but are not limited to increasing awareness of the signs and symptoms of burnout through education, self- awareness, and supervision.

We sincerely thank all the doctors who sincerely cooperated with us for the study. We sincerely thank each and every member of our group for their innovative ideas, support, time, and hard work without which the project would not have been a real success.

Institutional Ethical Committee issues expedited approval for all student research projects in this institution. IRC :P35/2024 Date:19/06/2024

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# Psychosocial Burden and Quality of Life of Primary Caregivers of Children with Cerebral Palsy

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## Abstract

**Background:** Caregiving for a child with Cerebral Palsy is time consuming and stressful, often leading to psychosocial burden and lowering the quality of life of the caregiver.

### Aims:

1. To assess caregiver burden and Quality of life of primary caregivers of children with Cerebral Palsy (CP)
2. To make a comparison of the Quality of life and burden among caregivers of children with different functional levels.

**Settings and Design:** A cross sectional study was done on primary caregivers of children with Cerebral Palsy (n=60) on regular follow up in Government Medical College, Thrissur to assess their psychosocial burden and quality of life and its association with child's level of functioning.

**Methods and Materials:** Functional levels were assessed by the GMFCS and MACS scores. The psychosocial burden was assessed using the Zarit Burden Interview and quality of life(QOL) was measured using the WHOQOL-BREF.

**Statistical Analysis:** Data analysis was done using Chi-square test and student t-test.

**Results:** All caregivers were mothers. Two third had moderate to severe psychosocial burden and QOL scores in all domains were low (<50). More than 60% of the mothers complained of moderate to severe chronic pain and almost half of them were on medications for chronic health conditions. Mothers of children with poorer GMFCS and MACS scores had more chance of having moderate to severe psychosocial burden (p value-0.001) and had poorer quality of life (QOL) (p value-0.009). Mothers with moderate to severe psychosocial burden had poorer QOL (p value-0.01).

**Conclusions:** Mothers of CP children have significant burden, and interventions to reduce burden and improve quality of life are imperative to reduce stress; which would affect both the child and the caregiver.

**Key-words:** Cerebral Palsy; GMFCS; MACS; Caregiver health Quality of life, Psychosocial burden

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## Introduction

Raising a child with intellectual or physical disability is a challenging task for any parent. This is especially so, when the child is suffering from a condition like Cerebral Palsy where physical as well as cognitive abilities of the child are affected to varying levels<sup>1</sup>. This creates extensive social and economic burden on the caregivers<sup>2,3</sup>. The mother is still expected to fulfill all her usual roles at home, and the stress leads to psychological as well as physical health issues. Studies have identified factors influencing the psychosocial burden to be the disability level of the CP patient as well as the age, marital status and education of the caregiver.<sup>4-6</sup>

Countries like USA, UK and Australia have government schemes for financial support for children with CP and their caregivers, with special schemes for respite care, additional caregiver and caregiver pension.<sup>7-9</sup>

In contrast to the developed countries, in a country like ours, where there is a significant proportion of the population below the poverty line, the resources available for parents of children with disabilities are few. Estimating the nature of caregiver's problems will lead to better focus on caregiver interventions in the long-term care of disabled children.

Kerala has among the highest literacy rates as well as a well-established public health system<sup>10</sup>. No studies have been conducted so far in this set up to assess the burden among mothers of children with CP. This study measured the psychosocial burden of these caregivers; as well as their quality of life. It also looked at the influencing factors with special emphasis on the functional level of the child.

## Materials and Methods

This cross-sectional descriptive study was conducted between January 2014 to May 2015 in the Department of Pediatrics, in Government Medical College, Thrissur, a tertiary care institution in Kerala. The study was approved by the Institutional Ethics Committee, Government Medical College, Thrissur on 24/01/2014. Primary caregivers of children with Cerebral Palsy attending the Pediatric Neurology Clinic were recruited after obtaining informed consent. Caregivers of children less than two years

of age and caregivers with chronic illnesses were excluded. Sample size was calculated based on a study by Pruthi<sup>11</sup>, assuming a non responder rate of 10%. A total of 60 primary caregivers were included in the study. The details of affected children including age, gender, Socio economic status, type of CP and disability pension status was collected. The health care needs of the children were assessed in terms of number of hospital visits, need for hospital admissions and chronic medication in the three months prior to interview. The functional status of the children was evaluated using the Gross Motor Function Classification System (GMFCS) and Manual Ability Classification System (MACS).<sup>12-15</sup>

Caregiver details including age, gender, education, occupation as well as family support was collected. The caregiver burden of subjects was assessed using the Zarit Burden Interview<sup>16</sup> developed by Zarit, Reever and Bach (1980), containing 22 items, and for each item, caregivers were asked to respond about the impact of the patient's illness on their life, by indicating how often they felt in a particular way, ("never", "rarely", "sometimes", "quite frequently", "nearly always").

The caregiver quality of life was assessed by the WHOQOL-BREF - World Health Organization Quality of Life BREF - Assessment Instrument: short version which contains 26 questions divided into four domains:

- A. *Physical health.*
- B. *Mental health/Psychological*
- C. *Social relationships.*
- D. *Environment*

Each question was assigned an appropriate number of points from 1 to 5 with 1 point denoting very dissatisfied and 5 very satisfied. The mean scores of the questions pertaining to each domain was computed, which gave the raw domain score. The transformed domain score was used for analysis.<sup>17,18</sup>

The socioeconomic status of the caregiver was assessed using the modified Kuppaswamy scale, meant for use in urban Indian population.<sup>19</sup>

**Data analysis:** Data was analyzed using SPSS version 18. Student t test was used for analysis of

continuous variables and Chi square test was used for categorical variables.

## Results

A total of 60 caregivers were enrolled. Of the sixty affected children, there was an almost equal male-female distribution. The study included children with ages from two to eighteen. Majority belonged to the upper lowersocio economic class (60 percent) followed by upper middle class (37 percent). Among the different types of Cerebral Palsy, Spastic quadriplegia (32 percent) and spastic hemiplegia (28 percent) followed by spastic diplegia (20 percent) were the most common while choreoathetoid CP was the least common (3 percent). Under the GMFCS, 27 out of the sixty children belonged to Level 5, and 25 of these children had a level five MACS as well (Table 1), meaning these children were completely dependent on the caregiver. Only 50% of the children were receiving state provided disability pension.

**Table 1: GMFCS and MACS levels of CP children**

Levels	GMFCS		MACS
	Frequency	Percentage	Frequency
1	10	16.67	13
2	15	25	12
3	2	33	5
4	6	10	5
5	27	45	25
Total	60	100	60

17 percent of the children required frequent medical attention; with average of one OPD/month. Around 40 percent of children required hospital admissions in the last 3 months (Length of stay - average 5.6 days, average expenditure Rs. 2900/stay). 75 percent of children were on regular medication; costing an average of Rs300/month.

All the sixty primary caregivers in this study were mothers; and 60% of them were above 30 years of age. 77 percent caregivers had completed secondary education. Ten of these mothers had done graduation level studies and one had completed her post graduation. There were no illiterate mothers. Only around 17 percent of the mothers were employed; and more than half of them had only part time jobs, with a mean income of Rs.2000/month. Seven of the mothers had given up their jobs and six

of them had to cut down on working hours in order to look after the disabled child. The state government aided caregiver pension (Aswasakiranam) <sup>19</sup> which provided Rs.600 monthly, paid into the caregiver's bank account was being procured by only 18 mothers. Parents reported that the application process was tedious, and they were kept waiting for more than a year before the amount got sanctioned. The payment was also reported to be irregular.

Two thirds of the mothers noted that they had moderate to severe physical pain almost every day; mostly lower backpain. In addition, almost half the mothers had chronic health concerns .

Most of the caregivers were living in their own homes (90 percent) and there was overcrowding in more than half of the households. In our study, 70 percent of mothers had support from other family members in caring for their child, commonly the husband or mother-in-law. However, the help was available only for an average of two hours per day and the bulk of the caregiving was still being handled by the mother alone. None of the caregivers had paid help- night or day.

## Caregiver Burden

In the study group, 58 percent of mothers had moderate caregiver burden and 6 percent had severe burden i.e almost two third of mothers had moderate to severe burden (Table 2).

**Table 2: Caregiver Burden (Zarit Burden Interview)**

Severity of burden	Frequency	Percentage
No burden	2	3.3
Mild burden	19	31.7
Moderate burden	35	58.3
Severe burden	4	6.7
Total	60	100

A positive and significant association was seen between higher level of GMFCS and severity of caregiver burden with a p value of 0.001.( Table 3). Mothers of children with poorer MACS(3,4,5) had more probability of having moderate or severe burden. (p value of 0.001). In our study, no significant association was found between the primary caregiver's educational or occupational status and caregiver burden.

**Table 3 : Caregiver Burden vs GMFCS and MACS**

GMFCS	Caregiver Burden			
	No burden	Mild burden	Moderate burden	Severe burden
Level 1& 2	2	15 (79%)	9 (20%)	1 (25%)
Level 3,4,5	0	4 (21%)	26(80%)	3(75%)
Total	2	19	35	4
Chi Square - 17.198		p value: 0.001		
MACS	No burden	Mild burden	Moderate burden	Severe burden
Level 1& 2	2 (100%)	14 (74%)	8 (22%)	1 (25%)
Level 3,4,5	0	5 (26%)	27 (78%)	3 (75%)
Total	2	19	35	4
Chi square-16.365		p value :0.001		

### Quality of Life

The transformed mean score in all domains were less than 50. The worst affected was the psychological domain (Table 4). It was found that mothers with moderate to severe burden had lower domain scores indicating poorer quality of life. The Quality of life of the caregiver was better in all four domains when the child had good gross motor functioning (GMFCS 1&2) and fine motor functioning (MACS 1&2); highly significant in the physical and psychological domains. (Table 5). Caregiver Quality of life had no correlation

with caregiver's education or occupational status.

**Table 4: Mean domain scores and Standard deviation**

Domains	Mean ± SD	Max - Min scores
Physical health	.03 ± 10.9	78.5 - 25
Psychological	39.79 ± 11.02	70.8 - 16.6
Social Relationships	42.77 ± 12.9	66.6 - 16.6
Environmental	41.9 ± 11.6	59.4 - 21.8

**Table 5: Quality of life and functional classification**

Domains	GMFCS 1&2 mean score (n = 25)	GMFCS 3,4,5 mean score (n = 35)	df	t test value	p value
Physical	52.43	44.89	47	2.01	0.009
Psychological	45.83	35.47	48	2.01	0.0002
Social	46.67	40	43	2.02	0.06
Environmental	44.63	41.69	45	2.03	0.39
Domains	MACS 1&2 Mean(n=25)	MACS 3,4,5 mean(n=35)	Df	t test value	p value
Physical	53.43	44.18	47	2.01	0.001
Psychological	46.33	35.12	47	2.01	0.00007
Social	47.67	39.28	43	2.02	0.01
Environmental	46.5	0.36	33	2.03	0.06

### Discussion

The most common types of CP in the study population were spastic quadriplegia and spastic

hemiplegia. In a study done in 2002, Singhi PD had reported that spastic quadriplegia was the most common, suggesting no major changes over the past 15 years.<sup>20</sup>

Majority of the study group had significant psychosocial burden and this indicates the need for effective interventions to reduce the burden, as this has been proven to have a negative impact on both the caregiver as well as the child<sup>3,5</sup>. This could be done by forming peer groups where problems could be discussed and issues addressed, which were not available at the time of our study.

There was a significant positive association between the caregiver's burden and level of the child's disability as measured by MACS and GMFCS. Previous investigators have found conflicting results in this regard. Glenn<sup>21</sup>, Marx<sup>22</sup> and Wallander<sup>23</sup> had reported no significant difference in caregiver stress based on the child's GMFCS levels while Basaran<sup>24</sup> found a significant difference in caregiver depression with poorer functioning abilities of the child. Chavez also described a worsening of burden with severe disability<sup>3</sup>. Most of the studies which could find no significant difference are from Western literature where there is an efficient state run support system in contrast to our setting.

The caregivers in our study had a poor quality of life with psychological domain being the worst affected. Adenuga<sup>26</sup> had reported poorer QOL in CP caregivers and had found physical health, social relationships and environmental health to be more affected. Similar findings have been reported by Basaran<sup>24</sup>, Ones<sup>27</sup> and Pandit<sup>28</sup>. Pruthi<sup>11</sup> had published similar results in a comparison study of caregivers of children with Cerebral Palsy, Thalassemia and no major illnesses. However, a few studies reported a good Health Related QOL in caregivers of CP children<sup>29</sup>.

The caregivers of children with better GMFCS and MACS scores had a better quality of life in all domains. With respect to GMFCS, the difference was significant in the physical and psychological domains which appear to be more affected due to the caregiving role. Similar findings were reported by Sonune et al<sup>30</sup>. Physical, psychological and social domains were significantly affected when the child had poor MACS scores. Previous investigators had looked into this relationship with respect to GMFCS. Adenuga<sup>26</sup> had found that physical health, social relationships and environmental health were more affected.

The educational qualifications of the mothers reflected Kerala's high literacy rates, but most of the mothers were not working. Mbugua<sup>31</sup> had identified unemployment as a risk factor for maternal depression. In this study, most of the mothers with moderate or severe burden were unemployed but the difference was not found to be significant.

The state government provides a monthly pension to caregivers of the chronically ill<sup>32</sup>, but only 30 percent of mothers were receiving this pension. The process of application and its approval is a long drawn process and very often the mother is unable to follow it up due to the other demands on her time, leading to delay in availability of pension. Making this process an easier and transparent one could go a long way in helping these mothers.

Cerebral Palsy is a chronic condition requiring medications and therapy which leads to a heavy burden on the caregiver, both physical and economic with hospital admissions being an additional burden. Khanna<sup>33</sup> and Vadivelan<sup>2</sup> have described similar findings.

To summarize, caregivers of children with CP have significant psychosocial burden and poor Quality of life. The medical community has to recognize the need to take care of not only the child, but also the mother.

## Conclusion

Primary caregivers of children with Cerebral Palsy, who are almost always the mothers, have significant psychosocial burden and poorer quality of life. Support from the State as well as family and community has to be improved to help these mothers.

**Conflict of interest** None

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**Ethical Clearance:** Obtained from the Institutional Ethical Committee, Government Medical College Thrissur on 24/01/2014

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# Dietary patterns among students and their socio demographic variables in Dakshina Kannada: A Cross Sectional study

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## Abstract

**Introduction:** The Indian subcontinent seems to be at a particular risk for NCDs due to the regularisation of unhealthy habits and sedentary lifestyle which is exposed quite early in life and becomes exaggerated and fixed with the adolescence period. Dietary habits are also useful in the sustainability of the ecosystem, with the human-food environment very much linked. Hence a good analysis of dietary patterns has become of consideration now.

**Methodology:** It is a cross sectional study, conducted between a three month period, January to March 2024. It is a self-administered questionnaire based study. A total of 214 students participated. Data was collected and analysed in Excel through SPSS.

**Results:** The mean age of the participants was 20.35 years. 65.38% of the population had meals 3 times a day. 30.8% of the population never ate fruits in their diet. 44% of the students had vegetables every day and 36% had veggies 3-6 times a day. 56% had dairy products every day. 33.6% of them consumed fast/ processed food 1-2 times a week. 40.6% of the students consume sugary beverages once a week.

**Discussion:** 34% consume fruits only 1-2 times a week, another study by Cunningham SA et al shows that there is an average consumption of 15 times per week among the participants. Items like chocolate, packaged food, bakery food, fried food, Italian food, Chinese food and carbonated drinks are the most preferred food among adolescents.

**Conclusion:** Dietary patterns has always been volatile and mores in the adolescent age group. Like our study has shown, adolescents have uncertain behaviour and erratic eating patterns. It is also seen that they have fast food or processed food a few times a week, though they also eat vegetables and protein rich food regularly.

**Keywords:** Dietary patterns, adolescents, students, nutrition, India

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## Introduction

We all know that adolescence is the mark of an age which is in between childhood and adulthood. It is a transition period, both mentally and physically. It is usually considered to be between 10-19 years of age. This phase categorises problems as academic, physical development and nutrition.<sup>[1]</sup> Physical and sexual development, social and economic autonomy, identity formation, the learning of life skills necessary for adult interactions and duties and the ability to reason abstractly are all characteristics of adolescence. Second only to that of infancy, adolescence is distinctive of a rapid growth phase. Nutrition and the transition in adolescence are closely interconnected. This is since dietary patterns, mannerisms and habits are influenced by many elements. These factors include influencing by peers, accessibility of food, dietary preferences, imitation of parental patterns, cultural traditions, personal and societal beliefs, body image and influence by mass media. Inadequate nutrition can result in slowed and hindered linear growth as well as poor organ remodelling.<sup>[2-4]</sup> Early childhood health promotion, which includes encouraging a balanced diet and frequent exercise, may have a significant influence on children's health and wellbeing as they grow older. The availability of appropriate time and intensity for the intervention, family engagement, especially for younger children, and the inclusion of self-assessment and feedback in therapies for older children are other elements that enhance efficacy.<sup>[5]</sup>

The Indian subcontinent seems to be at a particularly high risk for NCDs, with the regularisation of unhealthy habits and sedentary lifestyle, which is exposed quite early in life and becomes exaggerated and fixed with the adolescence period. Obesity in specific seems to be on the rise, with the prevalence rising among the youth. Influenced by television advertisements and peer pressure, they seem to prefer junk food with less nutritional values. This has become like a slow poisoning in terms of public health and is leading to physical abnormalities. Obesity in turns becomes a risk for diabetes, hypertension and stroke. Adolescents are at a higher risk of these disorders.<sup>[6-8]</sup>

In another tangent, dietary habits also are useful in the sustainability of the ecosystem, with the human-food environment very much linked. Hence a good analysis of dietary patterns has become of consideration now. The logistics, in food wastage, health and malnutrition all of them require the data of dietary patterns and recommendations for sustainability.<sup>[9-10]</sup>

Over the years, there has been a decline in the adoption of these sustainable eating practices on a global scale. A nutritious dietary pattern is one that follows the requirements of dietary guidelines for the consumption of different food groups. Following a healthy diet plan indicates meeting all of your needs for energy and nutrients. Because eating habits and behaviours developed in childhood and adolescence tend to track into adulthood and can predict adults' diet-related diseases, it is crucial to assess children and adolescents' healthy dietary patterns and to recognise the main modifiable determinants of these patterns.<sup>[11]</sup>

Hence with this study we are trying to determine the dietary patterns among the students in dakshina kannada.

## Methodology

Study design: Cross-sectional study.

Study duration: 3 months: January- March 2024

Sample Size: 214 students

Sampling technique: Convenient sampling

Study instruments: Questionnaire method

Study setting and method of collection of data: The study was done amongst The study was started after obtaining the necessary permission from the ethics committee. After obtaining permission, consent from students was obtained regarding age, dietary patterns and other socio-demographic data. Information regarding their employment and health was obtained through a structured questionnaire validated by experts. A total of two visits or phone contact was done for collecting the information. The medical students were asked to fill the questionnaire by themselves.

Study population: Students studying various postgraduates courses across medical, dental, engineering, physiotherapy, nursing, management, law and commerce.

Inclusion criteria: Students willing to participate.

No exclusion criteria as such

Topography: The study was done with the online forms sent to every colleges.

Statistical analysis: Data obtained was entered in an MS Excel spreadsheet followed by analysis using SPSS version 22 (licensed to JSS Medical College). The demographic characteristics such as age, gender, occupation etc. were represented using the arithmetic mean, standard deviation and percentages. The possible associations between the selected demographic variables (age, gender, education) were found using t-test/ chi-square.

## Results

**Table 1: Demographic details of study population**

Particulars	Total (N=214)(%)
Male	96 (44.85981)
Female	117 (54.6729)
trans	1 (0.46729)
<b>Age</b>	
15-18	32(14.95327)
19-22	158(73.83178)
23-26	24(11.21495)

**Table 5: Dietary patterns of the students.**

Dietary patterns	Every day N (%)	1-2 times a week	3-6 times a week	Rarely (once a week)	Never
How often do you eat fruits?	24 (11.21495)	74 (34.57944)	43 (20.09346)	7 (3.271028)	66 (30.84112)
How often do you eat vegetables?	95(44.39252)	29(13.5514)	77(35.98131)	11(5.140187)	2(0.934579)
How often do you eat dairy products (milk, yogurt, cheese)?	120 (56.07477)	37 (17.28972)	42 (19.62617)	5 (2.336449)	10 (4.67289)
How often do you eat protein-rich foods (meat, poultry, fish, legumes)?	43 (20.09346)	58 (27.1028)	85 (39.71963)	19 (8.878505)	9 (4.205607)

Mean age .	20.35047 years .
Median age .	20 years .

Majority of the participants belonged to age group 19-22, with the mean age being 20.35 years.

**Table 2: Frequency of meals per day**

On average, how many meals do you have in a day?	
1 time	1 (0.4629%)
2 times	45 (21.02804%)
3 times	141 (65.88785%)
4 times	26 (12.14953%)
5 times	1 (0.46729%)

65.88% of the population have 3 meals per day.

**Table 3: Frequency of water per day.**

How much water do you drink in a day?	
A little (1-3 glasses)	17 (7.9439)
Moderately (4-8 glasses)	143 (66.8224)
A lot (more than 8 glasses)	54 (25.2336)

66.8% of the population drank 4-8 glasses per day.

**Table 4: Effect of Culture on eating habits.**

Do your cultural or traditional practices affect your eating habits?	
Yes	55 (25.70093)
No	159 (74.29907)

<b>How often do you eat fast food or processed snacks?</b>	27 (12.61682)	72 (33.64486)	58 (27.1028)	57 (26.63551)	0
How often do you drink sugary beverages (sodas, energy drinks, sweetened juices)?	12 (5.60745)	60 (28.03738)	41 (19.15888)	87 (40.65421)	14 (6.54206)
How often do you eat meals outside (restaurants, street food, etc.) in a week?	12 (5.60477)	73 (34.11215)	29 (13.5514)	87 (40.65421)	13 (6.07477)

When it comes to the dietary patterns of the students, 30.8% of the population never ate fruits in their diet. 44% of the students had vegetables every day and 36% had veggies 3-6 times a day. 56% had dairy products every day. When it came to protein rich foods, 39.7% of the students consumed it 3-6 times a week. 33.6% of them consumed fast/ processed food 1-2 times a week, and 27% 3-6 times a week. 40.6% of the students consume sugary beverages once a week.

### Discussion

Our study shows that 30% of the participants never consume fruits, while 34% consume fruits only 1-2 times a week, another study by Cunningham SA et al shows that there is an average consumption of 15 times per week among the participants and with the lowest at 5 times a week. This is a study on a rural district and it contradicts the hypothesis that urban people consume more fruits.<sup>[12]</sup>

Our study showed that a majority of the participants consumed vegetables and dairy every day, while another study by Sharma S et al shows that low mixed diet had a daily consumption of green vegetables, this had a prevalence of 76.5%. while the high mixed diet had more consumption of chicken, meat, egg and milk/curd which had a 23.5% prevalence. Here also adolescent boys had a 3.6 times higher odd of consuming low mixed diet than the girls<sup>[13-14]</sup>.

Our study also shows that a significant number of participants (34.1%) had habits of consuming meals outside their homes 1-2 times a week and 13.5% consuming meals outside 3-6 times a week. Several studies have linked food away from home to poor nutrition and dietary quality. <sup>[15]</sup> Another study by Watts AW et al shows that a large number of the teenagers seeking treatment for obesity reported

buying snacks and consuming meals cooked outside the home.<sup>[16]</sup> The food that is typically consumed while dining out has a high energy level, which can lead to an excessive calorie intake and possibly eventually obesity.<sup>[17]</sup>

It was seen in our study that only around a quarter (25.2%) of the study population was drinking the recommended amount of water in a day. For adolescent girls and boys, the European Food Safety Authority (EFSA) recommends a water consumption of 2.0 L and 2.5 L per day, respectively. Since 60-70% of the body is made up of water, consuming enough of it can be beneficial to one's health, wellbeing, and ability to function both mentally and physically. Water is a vital nutrient for both life and wellness. Reduced body temperature physical activity capacity, weariness, focus, alertness and cognitive function can all be negatively impacted by even slight losses of it in the body.<sup>[18]</sup>

The most attractive food choices for adolescents which the majority consume 2 times or more per week, which is in line with a study by Jena S et al are items like chocolate, packaged food, bakery food, fried food, Italian food, Chinese food and carbonated drinks. These are the most preferred foods among adolescents. IT was also seen that skipping meals was very common according to the studies referred above, though our study showed that a majority number (65%) of students consumed 3 meals per day. Culture also does not seem to play an important role in the dietary habits of the students in the district, this may be due to the fact that in college there is an amalgamation of many cultures and this leads to changing of dietary patterns along the way.<sup>[19-20]</sup>

## Conclusion

Dietary patterns have always been volatile especially with the adolescent age group. Like our study has shown, adolescents have uncertain behaviour and erratic eating patterns and therefore consume fast food or processed food a few times a week. Though it was seen that they also eat vegetables and protein rich food regularly. Adolescents have an increased appetite and this also might be a factor to include more diet patterns in their routine. College means an amalgamation of cultures and traditions, so in this environment there could be a break and change in their regular food patterns along with trying new foods and patterns due to the influence of their friends. In terms of public health, adolescents represent a vital population for economic and health prosperity, therefore interventions could be more focused to this age group. Educational campaigns through social media regarding the locally available farm fresh foods along with a regulation on the pesticide sales would be the next step forward to better health.

**Recommendation:** Regular and periodic awareness and education should be provided for students regarding the importance of a healthy diet and its implications in daily life as well as in the future. This will help them to make the right choices as well as build a more sustainable economy. Future studies should include a larger sample population, from different states and more different backgrounds. Dietary patterns do change as we get older, with a shift to vegetables and lighter meals as we grow older, though there are no concrete studies on this. On the interventions, digital awareness campaigns with influential people at the helm, who the adolescents regularly consume through social media need to participate to educate the public<sup>(21)</sup>. Government programmes like mid-day meals have been highly effective and beneficial in this regard. Further more, they could provide more awareness about the food grown in the locality by their own farmers and market them effectively for consumption purposes. This would decrease the processing ingredients which are added and help in better nutrition for the public.

**Limitation:** Sample size is not adequate to represent the whole district. A more qualitative approach might be helpful.

## Conflict of Interest: Nil

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## A Point Prevalence Survey Study of Anti-Microbial Consumption in a Tertiary Care Hospital

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### Abstract

**Background:** As per WHO (2019), Antimicrobial resistance (AMR) is one of the top ten global public health threats facing humanity. Surveillance systems (Point Prevalence Study) are the cornerstones of successful implementation of sustainable antimicrobial stewardship programs and thus reduce AMR. This study was conducted to observe the antimicrobial consumption practices .

**Objectives:** The objectives of the PPS study were to estimate the prevalence of antibiotic use, most commonly prescribed antimicrobials, assess antibiotic usage as per AWaRe classification

**Methods:** A cross sectional PPS (on a single day in December 2021) was conducted in a tertiary care hospital with prior ethical approval. All admitted patients in the ICU/wards receiving at least one antimicrobial admitted before 9.00 am on the day of data collection were included. Data was collected using two structured case record forms: ward level and patient level data. The outcome measures were analyzed & represented in percentages.

**Results:** 278 patients with antibiotic prescriptions were surveyed & total antimicrobials prescribed were 429. Prescriptions with a single antibiotic are 55.1% (145), two antibiotics are 32.8% (118), ≥ 3 antibiotics are 12.1% (15). As per WHO AWaRe classification, 43.5% (187) were of Access, 55.4% (238) of Watch & 0.1% (4) of Reserve category. Community acquired infection (38.5%) followed by Surgical prophylaxis (28.4%) was the most common diagnosis. 8.6% (24) & 16.5% (46) patients were receiving double anaerobic cover & double gram negative cover respectively. Most commonly used antimicrobials was Metranidazole (21.44%) followed by Ceftriaxone (19.11%).

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**Conclusion:** To preserve the future effectiveness of antibiotics, it is imperative to rationally scrutinize and improve prescribing practices. This PPS survey would be helpful in generating baseline data for identifying strategies directed at reducing antimicrobial use & to develop evidence based antimicrobial prescribing guidelines.

**Keywords:** AMR (Antimicrobial resistance), PPS (Point Prevalence Study), Antibiotic consumption, AMSP (Antimicrobial Stewardship Programme), AWaRe classification

## Introduction

Health crises such as viral pandemics arise suddenly and require immediate actions, others emerge more slowly and are more unnoticeable and intractable. An example of the latter is antimicrobial resistance (AMR), which has been declared as one of the top ten global public health threats facing humanity by WHO in 2019<sup>[1]</sup>.

This threat is aggravated by the drying pipeline of new antimicrobials<sup>[2]</sup>. In the dearth of newer antibiotics, the best possible approach is to efficiently handle the existing antimicrobials. A safe and effective approach for antibiotic use involves prescribing an antibiotic with the narrowest spectrum of antimicrobial activity, fewest adverse effects and lowest cost<sup>[3]</sup>.

WHO has declared that misuse and overuse of antimicrobials are the main drivers in the development of drug-resistant pathogens<sup>[4]</sup>. Other factors include over prescribing and improper dispensing of antimicrobial, poor infection prevention and control practices in hospitals and clinics, and lack of hygiene and poor sanitation<sup>[5]</sup>.

Approximately 0.7 million people die every year worldwide from drug-resistant strains of microbes. The number is estimated to increase to 10 million by 2050, surpassing cancer (8.2 million deaths per year)<sup>[6]</sup>. A report from 2010 shows that India is the largest consumer of antibiotics recording  $12.9 \times 10^9$  units (10.7 units per person)<sup>[7]</sup>.

In 2015, World Health Organization (WHO) developed a global action plan, as mandated by the World Health Assembly (WHA) 2015 resolution on antimicrobial resistance (GAP AMR) wherein the member states are to produce national strategic plans for AMR<sup>[9]</sup>. India as a responsible signatory to GAPAMR rolled on the National Action Plan on AMR (NAP AMR) on 19th April 2017<sup>[10]</sup>.

WAAW (world antimicrobial awareness week) is a global campaign that aims to raise awareness

of antimicrobial resistance worldwide<sup>[11]</sup>. India launched the National programme on AMR containment in the year 2013 and the National Action Plan on Antimicrobial Resistance in 2017. Identifying the growing AMR and gross deficiency in practice of AMSP, NCDC (NARS-Net, NAC-NET) & ICMR (AMRSN) stepped up to establish country wide antimicrobial resistance surveillance and research network<sup>[12]</sup>. Globally, AMSP have resulted in a reduction of 22%-36% antibiotic usage with a significant cost savings in many countries.

To achieve this objective, National Centre for Disease Control (NCDC) co-ordinates antibiotic surveillance through National Antimicrobial Consumption Network (NAC-NET) comprising of 35 tertiary health care institutions. Through a comprehensive analysis of consumption patterns, they aim to highlight the amount and trends of antimicrobial usage, identify potential areas where interventions can be implemented and protect the health of future generations<sup>[13]</sup>.

AWaRe classification (ACCESS, WATCH, RESERVE) - a stewardship framework (to measure and improve appropriate antibiotic use) - that categorizes antibiotics into Access, Watch, and Reserve groups. Access includes narrow-spectrum antibiotics recommended as first-line or second-line antibiotics; Watch includes broad-spectrum antibiotics with a high chance of resistance to be used only for specific indications; and Reserve includes antibiotics to be used only as a last resort<sup>[14]</sup>.

A point prevalence survey can be defined as the prevalence calculated at a particular point in time and offers cross-sectional quantitative information about patterns of drug utilisation<sup>[15]</sup>. Surveillance systems (PPS) are the cornerstones of successful implementation of sustainable antimicrobial stewardship programs and thus reduce AMR<sup>[16]</sup>. The targets for interventions were- improving surgical prophylaxis, decreasing double anaerobic cover, initiating culture of sending cultures and de-escalation

therapy. So this PPS study was conducted to observe the antimicrobial consumption practices in this tertiary care hospital.

### Objectives:

#### The main objective of the study

1. To estimate the prevalence of antibiotic use, commonly used antibiotics, patient variables associated with increased antibiotic use in the hospitals
2. To assess the proportion of patients on antimicrobials in a health care facility, to know the Clinical (therapeutic/prophylactic) indications where antibiotics are prescribed and to identify the most commonly prescribed antimicrobial

### Methodology

Infectious diseases constitute an important cause of hospital admissions in Indian hospitals for which antimicrobial regimens are prescribed and consumed.

A cross sectional Point prevalence survey was conducted in the tertiary care hospital in the month of December 2021 after obtaining prior approval from institutional ethics committee. This hospital is a multispeciality (broad & superspeciality) tertiary care, teaching hospital with 1267 bedded capacity /

#### Inclusion Criteria

All admitted patients in the ICU/wards receiving at least one antimicrobial admitted before 9.00 am on the day of data collection were included in the study.

#### Exclusion Criteria

Outpatients and patients admitted after 9 am, those scheduled to be discharged on the day of data collection were excluded from the study.

The survey was conducted on a single day (1<sup>st</sup> December 2021) in the month of December. The data was collected from all the clinical departments in the tertiary care hospital {departments included are : Departments of General Medicine, Paediatrics, Surgery, Gynaecology and Obstetrics, Orthopaedics, Intensive care units and others (Neurology, Cardiology )}.

The study was conducted by a team of members under supervision of NCDC and Pharmacology

HOD. A survey skill exercise was organized before the study to train all the survey members regarding the methodology of survey (collection of data). The survey was conducted at one point of time commencing at 9.30 a.m on that day (1<sup>st</sup> December 2021). The data was collected using two well structured case record forms: ward level data and patient level data. Data collected from the ward-level included the date of the survey, ward name, ward type and total number of available beds and admitted patients by healthcare facility. Patient-level data included age, sex, antimicrobials received, diagnoses, and indication for treatment. The survey was coordinated and monitored by the team leader (i.e Head of the Department of Pharmacology) to maintain the quality of the data collection process.

### Statistical Analysis

The data collected was expressed as descriptive statistics. The data was exported to Microsoft Excel for further analysis.

The following parameters were analyzed -

Number (% of patients on antimicrobials), Number (%) of antimicrobials used for Community Acquired Infections (CAI), Hospital Acquired Infections (HAI), Medical Prophylaxis (MP), Surgical Prophylaxis (SP), Unknown and others, Number of patients receiving double anaerobic cover (DAC) and Double cover for Gram Negative Infections (DGNI), antibiotic usage as per AWaRe classification.

The study followed the standard PPS methodology (from WHO version) by global point prevalence survey of antimicrobial consumption and resistance

### Results

Guntur Medical College is affiliated with the Dr. NTR University of Health Sciences and works in conjunction with Government General Hospital, a tertiary care hospital with 1267 beds, of which ICU beds are 145 and Acute Beds are 1122. It caters to the needs of the people of Coastal districts of Andhra Pradesh. It was included in the National Antibiotic Consumption Network (NAC - NET) under National Antimicrobial Resistance Containment Programme in phase 3 under the aegis of NCDC

In this tertiary care hospital, Annual Hospital admissions accounted to 73283 in the year 2021. The total number of beds in the hospital are 1267. Round the year the total number of beds occupied in different wards is 100%.

In the surveyed departments, the number of patients admitted at the time of our survey were 533, out of which 450 (84.42%) patients are eligible. Of these eligible patients, patients receiving antimicrobial agents in various wards are 278 (61.7%). of which 46.7

%(130) are males and 53.3 % (148) are females.

Of 278 patients with antibiotic prescriptions on the day of PPS survey, the total number of antimicrobials prescribed were 429. Number of patients/prescriptions with a single antibiotic are 55.1% (145), two antibiotics are 32.8 % (118), three or more than three antibiotics are 12.1% (15). Average antibiotics per eligible patient is 0.95 and Average antibiotics per patient on antibiotics is 1.54.

**Table 1: Demographic characteristics of study participants**

CHARACTERSTICS	Frequency (%)
No. of patients admitted	533
No. of eligible patients	450 ( 84.4%)
No. of patients receiving antimicrobials	278 ( 61.7%)
Age	49.5 ± 1.2 years
Gender	
Male	130 (46.7 %)
Female	148 (53.3%)
Average Days of stay	5.9 days
No. of antimicrobials per prescription	
1	145 (55.1%)
2	118 (32.8%)
≥3	15 (12.1%)
No. of antimicrobials prescribed	429
Route of administration	
Oral	126 (29.3%)
Parenteral	303 (70.6%)
Average antibiotics per patient on antibiotics	1.54
Prescriptions are with stop review date mentioned	10 (2.3 % )
Antibiotics based on WHO AWARE classification of antimicrobial consumption	Access: 187 (43.5 %) Watch: 238 (55.4 %) Reserve: 4 (0.1%)

Out of these, 70.6 % (303) & 29.3% (126) antibiotics are administered with parenteral and oral route respectively. Only 2.3 % (10) prescriptions are with stop review date mentioned.

According to WHO AWARE classification

of antimicrobial consumption, the antimicrobials prescribed belong to category (Access: 187 – 43.5%, Watch: 238 – 55.4 %; Reserve: 4 – 0.1%). Out of the total prescriptions 10 antibiotic prescriptions were of the 'Not Recommended' category.

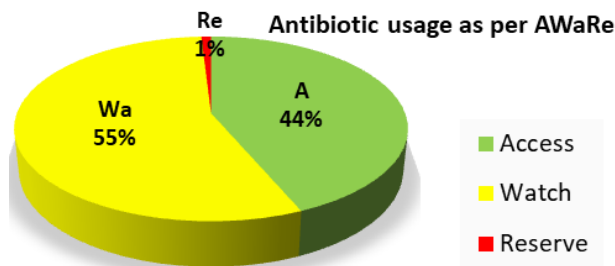


Figure 1: Overall Antibiotic usage as per AWaRe

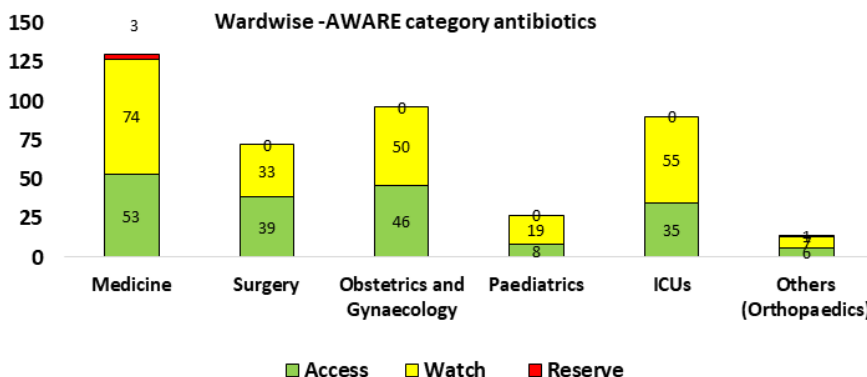


Figure 2: Ward wise break up of AWaRe category antibiotics

Only 0.7% (2) patients are on definitive therapy. 8.6 % (24) & 16.5 % (46) patients are receiving double anaerobic cover & double cover for gram negative organisms respectively.

Most commonly used antibiotic/antimicrobial in the institution/hospital is Metranidazole. Most commonly prescribed antibiotics as per AWaRe classification (METRONIDAZOLE - A, CEFTRIAXONE - W, PIPERACILLIN AND TAZOBACTAM - W, CEFIXIME - W, AMOXICILLIN AND POTASSIUM CLAVULANATE - A).

Table 2 : Clinical Conditions of common Antibiotics

Antibiotic	Clinical Condition
Metranidazole	Pleural Effusion, Acute Febrile Illness (AFI), Stroke, Pseudocyst
Ceftriaxone	Cellulitis, Appendicitis, Bronchiolitis, Hydronephrosis
Piperacillin and Tazobactam	Dengue, Sepsis, Diabetic Foot, Cholelithiasis
Cefixime	Acute Gastroenteritis, AFI, Pyelonephritis
Amoxicillin and Clavulanic Acid	AFI, Meningoencephalitis, polytrauma

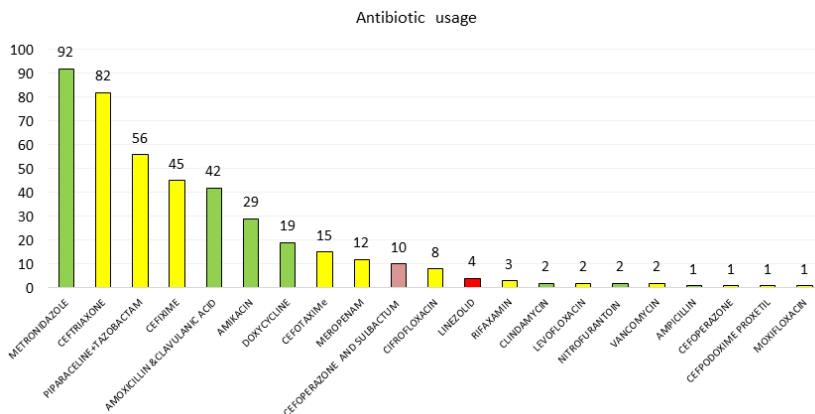


Figure 3: Overall Antibiotic usage

Piperacillin & tazobactam, ceftriaxone, metronidazole are the most common antibiotics used in Intensive care units.

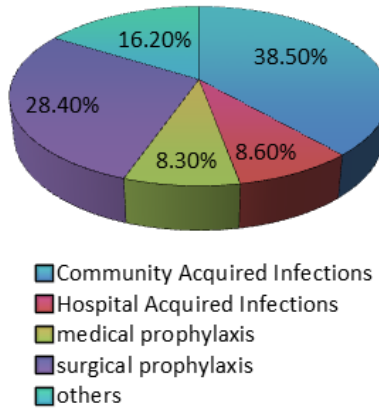


Fig 4: Antibiotic use by Diagnosis

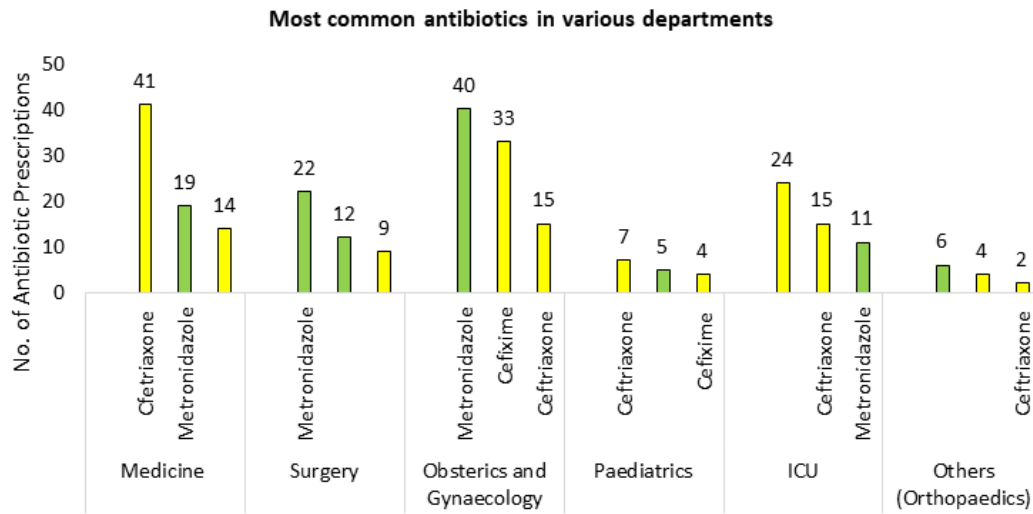


Figure 5: Most common antibiotics in various departments

**Discussion**

National Centre for Disease Control (NCDC- (NARS-Net , NAC- NET)) is the nodal agency for the National Programme on AMR containment in India. The network sites compile the data on the antibiotics consumed in their respective health facilities and send it to NCDC. This was a comprehensive antimicrobial PPS that involved most of the clinical departments of this tertiary care hospital. Data collection was carried out on a single day and all patients case sheets on at least one antimicrobial agent were assessed.

The prevalence of antimicrobial utilization at our hospital was recorded as 61.7 % (patients receiving AMA) with 278 antimicrobial prescriptions. The prevalence rate is comparable to other studies by

Sumanth Gandra et al<sup>[17]</sup>, N.shanmuga Vadivoo<sup>[18]</sup> et al and Nirula et al<sup>[19]</sup> where the rates are 61.52 %, 70.11 % & 46.54 %. respectively.

In the present study, the percentage of male to female ratio treated in our survey are 46.7 %(130) and 53.3 % (148) . In contrast, other studies by Nirula et al<sup>[19]</sup> and Sumanth Gandra<sup>[17]</sup> et al has male to female ratio (58.4 % : 41.5%) and (59.1 % : 40.8%) respectively.

Out of 278 patients with antibiotic prescriptions, 55.1% (145) of prescriptions are with single antibiotic, 32.8 % (118) are with two antibiotics, 12.1 % (15) are with three or more than three antibiotics. This is in correspondence to a study by Nirula et al<sup>[19]</sup> & Sumanth Gandra et al<sup>[17]</sup> where 54.4%, 69.45%

of prescriptions are with single antibiotic, 33.6 % & 20.28% are with two antibiotics, 11.8 % & 10.26% are with three or more than three antibiotics respectively.

In the present study, 70.6 % (303) & 29.3 % (126) antimicrobials were prescribed parenterally & orally. In a study by Aditi M Panditrao et al<sup>[20]</sup>, Nirula et al<sup>[19]</sup> and Najmi A et al<sup>[16]</sup>, 77.9%, 76.25% and 30.55% of overall antimicrobial prescriptions were administered parenterally respectively. In the present study, Only 2.3 % (10) prescriptions are with stop review date mentioned compared to a study by Najmi et al<sup>[16]</sup> where 19.48% were with stop review date mentioned. This indicator was very low and an area of concern which has to be improved.

In the present study, based on WHO AWARE classification of antimicrobial consumption, the antimicrobials prescribed belong to category (Access: 187 – 43.5 %; Watch: 238 – 55.4 %; Reserve: 4 – 0.1%). Out of the total prescriptions 10 antibiotic prescriptions were of the 'Not Recommended' category. In a study by Aditi M Panditrao, et al<sup>[20]</sup>, where 57.9%, 38.0% & 4.07% of use was from the 'Watch', 'Access' and 'Reserve' categories which is comparable to the present study.

In the present study, 38.5% & 8.6% of antibiotic use seen with Community (CAI) & hospital acquired infections and 8.3 % & 28.4 % with Medical & surgical prophylaxis respectively. & Others causes (16.2%). In a study by SK Singh et al<sup>[21]</sup>, 26.87% & 19.20% were prescribed for community & hospital-acquired infections; 17.24% & 28.70% for medical & surgical prophylaxis respectively; and 7.99% for other or undetermined reasons. In a study by Aditi M Panditrao et al<sup>[20]</sup>, the most common indications for antimicrobial use were CAIs (40.2%) requiring hospitalization, similar to present study.

In the present study, number of patients receiving double anaerobic cover are 24 (8.6%) & double cover for gram negative organisms are 46 (16.5 %). In a study by Aditi M Panditrao, et al<sup>[20]</sup>, nearly 2.7% & 7.1% of antimicrobial prescriptions were prescribed as double anaerobic cover and double cover for Gram-negative organisms respectively.

In the present study the most common antimicrobial prescribed is metronidazole (21.44 %) followed by ceftriaxone (19.11%). In contrast, a study

by Nirula et al<sup>[19]</sup> reported ceftriaxone (28.12%) as the most common antimicrobial prescribed, & in other studies by Sumanth Gandra et al<sup>[17]</sup> and Singh SK et al<sup>[21]</sup> was betalactams (53.2 % & 47.6 %) followed by aminoglycosides (10.4 % & 10 %) respectively. In another study by Najmi et al<sup>[16]</sup>, the most common antimicrobial class was betalactams followed by fluoroquinolones.

## Conclusion

To preserve the future effectiveness of antibiotics and reduce patient harm due to antimicrobial resistance, it is imperative to rationally scrutinize and improve the prescribing practices. A point prevalence survey can be used as a tool for measuring the quality of antimicrobial prescribing and the effect of interventions to improve prescribing.

The findings of this PPS survey were helpful in generating baseline data for identifying strategies for interventions directed at reducing antimicrobial use and for evaluating the impact of future interventions. The targets for interventions were: curtailing antibiotic prescriptions of not recommended category, decreasing double anaerobic cover, initiating culture of sending cultures (i.e., increasing the use of microbiology testing) and adopting stop/review date mentioning on the prescription, application of WHO AWaRe classification for selection of antibiotics, initiating a hospital specific local antibiotic policy, practising Antimicrobial Stewardship Programme interventions along with improving the infection control practices in the hospital. This will be of helpful to develop evidence based antimicrobial prescribing guidelines.

Ethical approval: Approval by NERC (NCDC ethics review committee dated 21 Jan 2020) = already attached the certificate to the concerned mail

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# Characterizing the Outbreak of Hand, Foot, and Mouth Disease in Western India

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## Abstract

**Introduction:** Hand, foot, and mouth disease (HFMD), also known as “Tomato Flu,” is a viral illness predominantly affecting children under 10 years old. It is caused by enterovirus. This study focuses on the first outbreak of HFMD reported in the western region of India. The objective of the study was to explore the outbreak’s scope and characteristics, including the distribution of age and gender, symptoms experienced, and the duration of illness.

**Methods:** Epidemiological data, including age, sex, symptoms, and duration of illness, were collected from suspected cases, and samples were collected for laboratory diagnosis. Data analysis was performed to understand the extent, trends, and characteristics of the outbreak.

**Results:** A total of 30 suspected cases of HFMD were reported, with the majority of cases (76.37%) occurring in children aged 5-6 years. Male cases outnumbered female cases. Most cases exhibited mild symptoms, with lesions observed on the hands, feet, and mouth. The average duration of illness was short, with all cases recovering within a week. The laboratory testing conducted in this study confirmed the outbreak of HFMD.

**Conclusion:** This outbreak of HFMD in a private school highlights the need for vigilance and preventive measures to control the spread of the disease. The findings emphasize the importance of age and gender considerations in epidemiological investigations. The generally mild nature of the disease observed in this study supports the favorable prognosis of HFMD, but the occurrence of severe cases requiring hospitalization underscores the potential for complications. Continued monitoring and appropriate management are necessary to prevent severe cases and potential complications associated with HFMD outbreaks.

**Key words:** HFMD, Tomato Flu, Clinico-epidemiology, Enteroviruses

## Introduction

Coxsackievirus (CV) A16, enterovirus (EV)-A71

Hand, Foot, and Mouth Disease (HFMD) is a viral illness primarily affecting infants and children, caused by enteroviruses such as Coxsackievirus

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A16, Enterovirus 71, and more recently, CVA6. The disease spreads mainly through the oral-fecal route or by contact with contaminated materials, including saliva, nasal secretions, or surfaces touched by an infected person<sup>1,2</sup>. It is characterized by fever, a rash, and oral ulcers, typically appearing on the palms, soles, and other areas like the buttocks, knees, and elbows. The virus enters through the mouth, replicates in the throat and intestines, and then spreads through the bloodstream to target the skin and mucous membranes, resulting in blisters and sores due to viral damage to epithelial cells<sup>2,3</sup>. The symptoms are usually mild, but severe cases, particularly those from Enterovirus 71 (EV71), can cause serious complications like viral meningitis or encephalitis. While most recover fully, severe infections can lead to long-term neurological issues or temporary conditions like nail loss or skin peeling<sup>3</sup>. Recent years have seen an increase in HFMD cases in Southeast Asian countries such as Bangladesh<sup>4</sup>, Malaysia<sup>5</sup>, Pakistan<sup>6</sup>, Taiwan<sup>7</sup>, China<sup>2,8</sup>, Japan<sup>9</sup>, and Singapore<sup>10</sup>. In India, states like West Bengal<sup>11</sup>, Maharashtra<sup>12, 13, 14</sup>, Kerala<sup>15</sup>, Ladakh<sup>16</sup>, Rajasthan<sup>17</sup>, Himachal Pradesh<sup>18</sup>, Uttarakhand<sup>19</sup> and multi state study<sup>2</sup> have reported HFMD outbreaks, though the frequency remains lower compared to other diseases. This study focuses on a localized HFMD outbreak among school children in Daman District, part of the Union Territory of Dadra & Nagar Haveli and Daman & Diu (UT of DNH&DD). By investigating the clinico-epidemiological aspects of this outbreak, the study aims to provide a comprehensive understanding of HFMD's impact, identify specific local patterns and risk factors, and inform targeted public health interventions to better manage and prevent future outbreaks in this region.

## Methods

The study was conducted in the Daman District, located in the UT of DNH&DD, India, specifically at latitude 20.3974° N and longitude 72.8328° E in the Western Ghats region. (Fig -1) On 01/09/2022, in response to a notification from a school about students exhibiting rash symptoms, the District Surveillance Unit of Daman District mobilized a Rapid Response Team. This team, consisting of a District Surveillance Officer, Epidemiologist, Pediatrician, and Laboratory Technician, was assembled to carry out a comprehensive investigation. The team assessed the situation at the affected school and, based on the clinical presentation, suspected HFMD

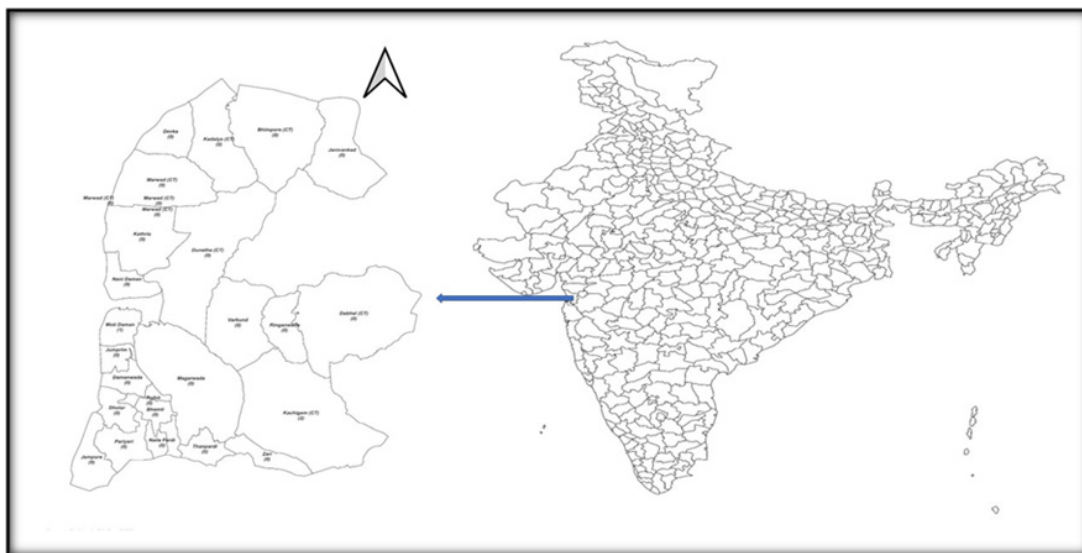
as the underlying cause. A line list was created to record suspected cases, and active surveillance was implemented in the affected area, including nearby schools and Anganwadi Centers. Epidemiological data, including age, sex, symptoms, and duration of illness, were collected from suspected cases, and samples were collected for laboratory diagnosis and sent to the referral laboratory for the confirmation. Data analysis was performed to understand the outbreak's extent, trends, and characteristics, guiding the implementation of preventive measures and control strategies. Active surveillance continued for 28 days from the last reported case. The following case definition was adopted in the present outbreak investigation and active surveillance "presence of characteristic macular/papular/vesicular rash on the hands, limbs or buttocks, with or without oral ulcers, fever, coryza (runny nose), malaise, or irritability" [15, 20, 21].

## Results

During the investigation, a total of 30 suspected cases of Hand, Foot, and Mouth Disease (HFMD) were reported. Among these cases, 28 were identified in a private school, while 2 cases were detected through active surveillance in the affected area. The index cases were two six-year-old male students who had shown symptoms 15 days prior and had attended school during that time. The majority of cases (93.33%) exhibited mild symptoms and did not require hospitalization, while only 2 cases necessitated hospital care. In terms of the geographical distribution, 80.00% of the cases were reported from urban areas, with the remaining 20.00% originating from rural areas. The age range of the affected children was 2 to 8 years, with the highest proportion (40.00%) in the 5-year-old age group, followed by 4-year-olds (36.37%), 6-year-olds (13.33%), and individual cases from the 2-year-old, 7-year-old, and 8-year-old age groups. Among the reported cases, 80.00% were male, while only 6 cases were female. Regarding the symptoms observed, it was found that 73.33% of cases (22 cases) exhibited a macular/papular/vesicular rash without fever, while 26.67% (8 cases) presented with both fever and rash. The average duration of fever in the study was 4 days. The rash primarily appeared on the hands (in 30 cases) and feet (in 28 cases), followed by the knees (in 10 cases) and mouth (in 5 cases) Fig 2-4. Out of the 30 children, throat swab samples were taken from 8 patients, while stool samples were collected from

6 patients. Among the throat samples, 75.00% tested positive for pan enteroviruses, and among the stool samples, 66.67% tested positive for pan enteroviruses. The calculated attack rate for the outbreak was

determined to be 6.44 per 100 populations. The affected children received symptomatic treatment, and all cases eventually recovered without major complications.



**Fig 1: Showing the geographic location of the District Daman, UT of Dadra Nagar & Haveli And Daman & Diu**



**Fig 2:**



**Fig 3:**



**Fig 4:**

**Fig 2-4: Showing the small multiple round/oval macules with a red areola over (2-3) palms front and dorsal side (4) dorsal of feet.**

## Discussion

The occurrence of an outbreak of Hand, Foot, and Mouth Disease (HFMD) in a school located in the Daman district of western India is a noteworthy event, considering that HFMD outbreaks are relatively infrequent in India. Prior research has documented HFMD outbreaks in various regions of India, including schools,<sup>13, 22</sup> emphasizing the importance of ongoing surveillance and the implementation of preventive measures. The observation that children between the ages of 5 and 6 years were the most affected by the HFMD outbreak is consistent with previous studies.<sup>22</sup> This age group is known to be at higher risk for HFMD due to several factors. Firstly, children in this age range often have close contact and engage in activities that facilitate the spread of the virus, such as attending school or daycare centers. They also have developing immune systems that may be less able to effectively combat the infection. Additionally, at this age, children are more likely to put objects in their mouths, increasing their susceptibility to the oral-fecal route of transmission, which is one of the main modes of HFMD spread. The higher proportion of male cases in the present outbreak can be attributed to the demographic composition of the

affected population within the school. If there were a higher number of male students in the school, it is expected to see a higher proportion of male cases. This finding aligns with similar gender distribution patterns observed in other regions, such as Bangladesh, West Bengal, and Ladakh.<sup>4,11,16</sup> However, it is important to note that the higher proportion of male cases may also be influenced by other factors such as differences in behavior, hygiene practices, or individual susceptibility to the virus, which would require further investigation for a comprehensive understanding.

The present study found that the majority of HFMD cases exhibited mild symptoms, primarily presenting with lesions on the hands, feet, and mouth. These findings are consistent with previous studies that have described HFMD as a generally mild disease.<sup>13</sup> The short recovery period observed in this study, with all cases recovering within a week, further supports the favorable prognosis of HFMD in most cases. However, it is important to acknowledge that despite the predominantly mild nature of the disease, the occurrence of severe cases requiring hospitalization underscores the potential for complications associated with HFMD. These findings emphasize the need for continued vigilance and appropriate management to prevent and address severe cases and potential complications. The urban area where the school was located showed a higher number of reported cases compared to rural areas. This observation is consistent with studies conducted in various regions, indicating that the incidence of HFMD tends to be higher in urban areas, transportation hub cities, and economically developed regions with higher population density and mobility.<sup>23, 24</sup> The urban setting and the influx of students from nearby locations may have contributed to the increased transmission and spread of the disease within the school.

### Conclusion

The study emphasizes the need for continuous HFMD surveillance in educational settings and effective preventive measures. Key strategies include early detection and reporting, stringent hygiene practices, and proper infection control. Rigorous handwashing, frequent disinfection of surfaces,

and isolating infected individuals are essential for preventing outbreaks. Educating parents, caregivers, and staff about symptoms and hygiene, along with proper disposal of contaminated materials and active monitoring, helps reduce transmission and manage the disease effectively, ensuring the safety of children in school environments.

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### Ethics approval and consent to participate

The data collected and analyzed in this study were obtained as part of routine surveillance efforts, adhering to the established guidelines and protocols of the Integrated Disease Surveillance Programme. Therefore not applicable' to that section.

### Competing interests

The authors declare that they have no competing interests

### Availability of data and materials

The dataset supporting the conclusions of this article is included within the Article.

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# Self-Care Practices and Role of Family Support in Control of Blood Pressure Among Hypertensive Patients Visiting a Tertiary Care Centre

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## Abstract

**Background:** Blood pressure (BP) control depends on adherence to self-care practices and family support is important to achieve this self-care. But the research in this area are limited.

**Aims:** To study self-care practices and role of family support in control of blood pressure among hypertensive patients and to study factors associated with control of blood pressure.

**Methods and Material:** A cross-sectional study was conducted among 300 hypertensive patients selected by systematic random sampling method who attended the outpatient department by structured questionnaire using an adapted Hypertension Self-Care Activity Level Effect(H-SCALE) scale. Chi-square test, Logistic regression test was used.

**Results:** Mean age of study participants was 58.6±11.1years. Medication adherence, DASH diet adherence and adherence to physical activity was among 71.7%, 6.3%and 48.7% respectively. 16.3%, 90.7%and 85.7% were adherent to weight management practices, adherent to nonsmoking and alcohol abstinent, BP control was among 61.7% and strong family support was among 7.9%. Adherence to weight management practices and not living alone were associated with BP control, which was found statistically significant using multivariate logistic regression.

**Conclusions:** Weight management practices and DASH diet adherence were poor.

**Keywords:** blood pressure control, self-care practices, family support, India.

## Introduction

Today we live in a rapidly changing environment-demographic aging, rapid urbanization

and globalization of unhealthy lifestyles. Due to this non-communicable diseases such as cardiovascular diseases, cancer and chronic lung disease have

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overtaken infectious diseases as the world's leading cause of mortality.

Worldwide estimated 1.28 billion adults living in low and middle-income countries aged 30-79 years have hypertension. About 46% of adults with hypertension are unaware about this and 42% of adults are diagnosed and treated. Approximately 1 in 5 adults (21%) with hypertension is under control.<sup>1</sup> An estimated 17.9 million (32% of all global deaths) people died from CVDs (2019). Among them 85% deaths were due to heart attack and stroke. Among 17 million premature deaths (<70 years) due to NCDs 38% were caused by CVDs (2019).<sup>2</sup> NCD burden Reduction is crucial for global development. Target 3.4 in SDG3 includes reduction of premature NCD mortality by third by 2030.<sup>3</sup> It is estimated that 1 in 4 adults in India has hypertension and set a target of 25% relative reduction in the prevalence of hypertension by 2025. Uncontrolled blood pressure is risk factors for CVDs. Of the estimated 220 million people in India living with hypertension, only 12% have their BP under control.<sup>4</sup> The prevalence of hypertension in urban India will be 29-45% in men and 25-38% in women by 2025.<sup>5</sup>

In India, NCDs are associated with estimated to 60% deaths. To tackle this problem the govt. of India has started the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases since 2010 with aim to control the modifiable risk factor for NCDs.

Promotion of healthy lifestyle by behaviour changes, screening, early diagnosis of persons for risk factors and prompt referral for disease management. Total 1.3 crore population were screened for hypertension under NPCDCS (2019).<sup>6</sup> The early diagnosis by opportunistic screening at health care facility level, NCD clinics, Health and Wellness Centres and population based screening by ASHAs at community level. Follow up screening done yearly for hypertension

Comprehensive management of hypertension requires both pharmacological and lifestyle modification. According to the World Health Organization, self-care is defined as "the ability of individuals, families and communities to promote health, prevent disease, maintain health and to cope

with illness and disability with or without the support of a healthcare provider".<sup>7</sup> According to European society of hypertension (ESH), patients with high-normal BP and low-moderate CV risk lifestyle advice offered to reduces risk of hypertension. Also advice given on self-care activities and lifestyle modification strategies to achieve optimal BP control.<sup>8</sup> But the research in areas of role of family support, self-care practices and BP control are limited in studies done at hospital settings. Hence we planned this study with the aim to study self-care practices and family support to achieve BP control in the hypertensive patients visiting to tertiary care centre located at Pune metropolitan city and the Knowledge, awareness level about hypertension among the patients are different. Hence the results of our study can be useful to encourage the patients and their family members to maintain blood pressure level under control state and prevention of further complications.

**Aim:** To study self-care practices and role of family support in control of blood pressure among hypertensive patients.

#### **Objectives:**

- i. To study self-care practices in hypertensive patients for control of blood pressure level.
- ii. To study the role of family support in hypertensive patients for control of blood pressure level.
- iii. To study the association between self-care practices, role of family support and control of blood pressure.

#### **Material and Methods**

The Cross-sectional study was conducted at hypertension OPD of Medicine department of tertiary care centre of government medical college from Pune. Data was collected after obtaining clearance from the institutional ethics committee.

Study population and Selection of cases: Hypertensive patients >18 years visiting to OPD were selected by systematic random sampling method. Average monthly OPD was 600. Every 5<sup>th</sup> patient coming to hypertension OPD was taken as sample between March 2023 to June 2023.

**Subject Eligibility:****Inclusion Criteria:**

1. Hypertensive patients >18 years and taking anti-hypertensive medication for >6 months duration.
2. Those who were willing to participate in the study.

**Exclusion Criteria:**

1. Patients with Cognitive impairment.

**Sample Size:**

Sample size was calculated to be 293 using the following formula:

Estimated prevalence of medication adherence (P)<sup>7</sup> = 54.8%

Confidence level: 95%,

Power: 80%,

Absolute precision: 5.7%

Total sample round off to 300 was taken.

**Data Collection:**

Epidemiological information was taken using structured questionnaire. The patient's interviews was taken by the principal investigator of the Department of Community Medicine after taking their written informed consent.

**Data collection tools:**

Data was collected using a structured questionnaire using an adapted Hypertension Self-Care Activity Level Effect (H-SCALE) scale. All socio-demographic characteristics, Health-seeking behaviour, comorbidities details, family support and self-care practices, BP measurement was taken.

**Operational Definitions:**

**Medication adherence:** 3-item scale was used to measure how many days the person took the medication in a week at the recommended dosage and at the recommended time. The scores for each item were summed (range 0-21). Good adherence-score of 21.<sup>7</sup>

**DASH diet Adherence:** 11-item scale used to assess the intake of healthy foods associated with

the nutritional composition of the DASH diet. The sum of the scores on all items ranged from 0 to 77 and total score of DASH-Q scale was 0-77. A score of  $\leq 32$ -low diet quality, score between 33 to 51- medium quality, and scores of  $\geq 52$  were considered as good adherence.<sup>7</sup>

**Physical activity engagement:** 2-item scale measured the number of days of physical activity of at least 30 minutes for each participant. The scores on both items were summed (range 0-14). Score of  $\geq 8$  was considered as good adherence to physical activity.<sup>7</sup>

**Smoking:** The scores of 2-item scale were summed (range 0-14). Score  $\geq 1$  were considered as non-adherent to non-smoking.<sup>7</sup>

**Alcohol use:** Individuals who did not drink alcohol at all were considered as alcohol abstinent.<sup>7</sup>

**Weight management:** 10-item scale measured weight management activities in last month. The sum of the scores on all items ranged from 10-50. Individuals who scored  $>40$  were considered as adherent to weight management practices.<sup>7</sup>

**Family support:** 16-item scale measured the influence of family members on diet and other health behaviour. For addiction 16 item scale was used. 16 score for no support, 16-32 for mild, 33-48 for moderate, 49-64 for strong support. For those who don't have addiction 14 item scale was used. 14 score for no support, 15-28 for mild, 29-42 for moderate, 43-56 for strong support. Those have either of alcohol/smoking addiction are scored as 15-no support, 16-30 for mild, 31-45 for moderate, 46-60 for strong support.

**BP control** - Mean BP  $<140/90$  mmHg in all individuals based on the average of 2 readings.<sup>7</sup>

**BP measurement:** Blood pressure was measured using mercury sphygmomanometer, first by palpatory method followed by auscultatory method. 2 such readings were recorded with 5 minutes interval and average value taken as Blood Pressure.<sup>9</sup>

**Data analysis:**

Data was entered into MS-Excel and analysed

by statistical package for social sciences (SPSS) Version 20. For Descriptive Statistics-frequency and percentage, continuous variables mean and standard deviation were used. Chi-square test, Univariate and multivariate logistic regression were used to find association. Statistical significance of tests was decided at  $p$ -value $<0.05$ .

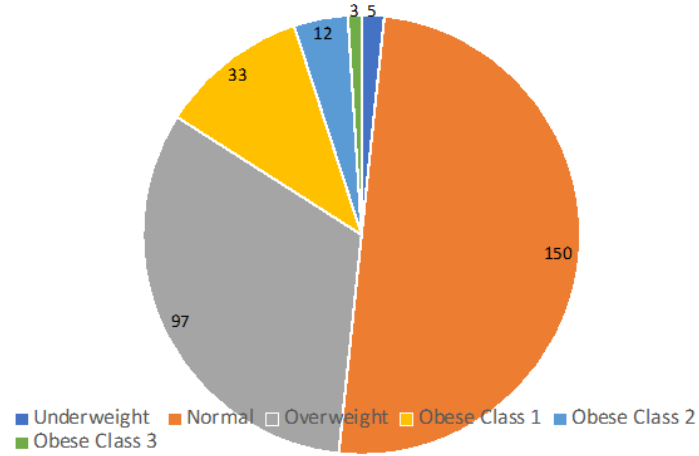
## Results

Among 300 study participants, there were 154 males and 146 females, 226 were having orange ration card, only 44 were below poverty line and 30 study participants were living alone. Mean age of study participants was  $58.6 \pm 11.1$  years.

**Table 1: Gender wise distribution of Sociodemographic factors among study participants**

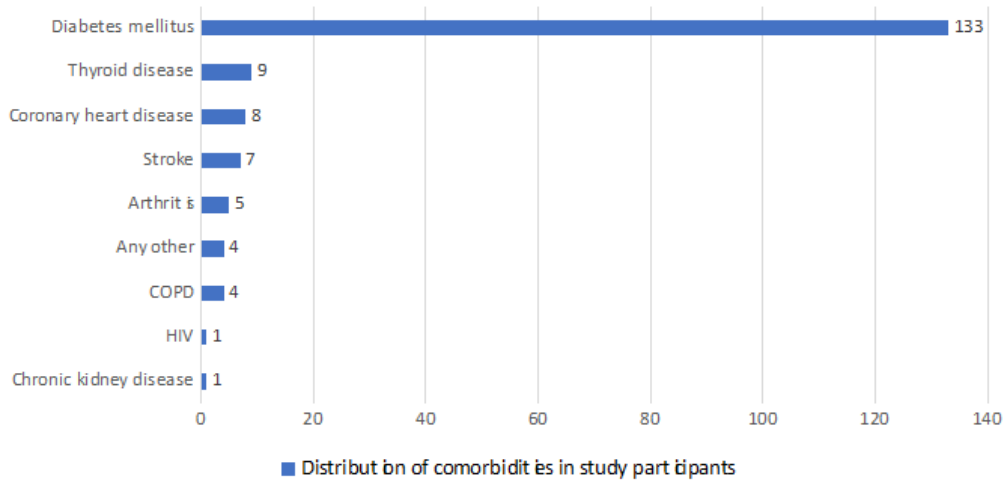
Characteristics	Male (n=154)	Female (n=146)	Total (n=300)
<b>Age group</b>			
<40 years	7(4.54)	9(6.16)	16(5.33)
40-59 years	52(33.77)	68(46.58)	120(40)
$\geq 60$ years	95(61.69)	69(47.26)	164(54.67)
<b>Marital status</b>			
Married	142(96)	132(90.41)	274(91.33)
Unmarried	6(3.89)	3(2.05)	9(3)
Divorcee	2(1.29)	0(0)	2(0.67)
Widow/er	4(2.59)	11(7.53)	15(5)
<b>Education</b>			
Illiterate	13(8.44)	40(27.39)	53(17.67)
Primary	45(29.22)	63(43.15)	108(36)
Secondary	55(35.71)	23(15.75)	78(26)
Higher-secondary	21(13.67)	13(8.9)	34(11.33)
Graduated	14(9.09)	6(4.1)	20(6.67)
Post-graduated	6(3.89)	1(0.68)	7(2.33)
<b>Religion</b>			
Hindu	134(87.01)	119(81.50)	253(84.33)
Muslim	16(10.39)	27(18.49)	43(14.33)
Buddhism	1(0.64)	0(0)	1(0.33)
Christian	2(1.29)	0(0)	2(0.66)
Jain	1(0.64)	0(0)	1(0.33)
<b>Occupation</b>			
Retired, unemployed	50(32.5)	5(3.4)	55(18.3)
Homemaker	0(0)	113(77.4)	113(37.7)
Elementary occupation	48(31.7)	18(12.3)	66(22)
Plant, machine operators and assembles	1(0.6)	0(0)	1(0.3)
Craft related trade workers	12(7.8)	2(1.4)	14(4.7)
Skilled, agricultural and fishery workers	30(19.5)	5(3.4)	35(11.7)
Skilled worker, shop, market sales workers	5(3.2)	3(2.1)	8(2.7)
Technicians/associate professionals	4(2.6)	0(0)	4(1.3)
Professionals	4(2.6)	0(0)	4(1.3)

No significant association was found between control. socio-demographic factors and blood pressure



**Fig 1: Distribution of study participants according to BMI**

Half of study participants were having normal BMI, while 1/3<sup>rd</sup> were overweight.(fig. 1)



**Fig 2: Comorbidities among study participants**

Diabetes is most common comorbidity found in study participants followed by thyroid disease and coronary heart disease. (fig. 2)

**Table 2: Distribution of self-care practices and family support among study participants**

	Frequency, n=300	Percentage (%)
<b>Self-care practices</b>		
<b>Medication adherence</b>		
Adherent	215	71.7
Non-adherent	85	28.3
<b>DASH diet adherence</b>		
Adherent	19	6.3
Medium quality diet	151	50.3
Low quality diet	130	43.3

Continue.....

<b>Physical activity adherence</b>		
Adherent	146	48.7
Non-adherent	154	51.3
<b>Non smoking</b>		
Adherent	272	90.7
Non-adherent	28	9.3
<b>Alcohol abstinence</b>		
Adherent	257	85.7
Non-adherent	43	14.3
<b>Weight management adherence</b>		
Adherent	49	16.3
Non-adherent	251	83.7
<b>Family support in self-care*</b>		
No support	07	2.3
Mild	66	22
Moderate	204	68
Strong	23	7.7

\*There are 7 out of 300 participants who don't have family hence categorized as having no family support. Among remaining 293 participants, there was no study participant with no family support in

self-care practices.

Among 300 study participants, 185 were having blood pressure under control.

**Table 3: Association of self-care practices and blood pressure control.**

Variable	Unadjusted OR(95% CI)	P-value	Adjusted OR (95% CI)	P-value
<b>Medication adherence</b>				
Non-adherence	2.18(1.31-3.63)	0.003	1.58(0.91-2.75)	0.10
Adherence	Reference		Reference	
<b>DASH diet adherence</b>				
Non-adherence	1119155169(0.000- 0.0)	0.99	3631707(0.000-0.0)	0.99
Adherence	Reference		Reference	
<b>Physical activity adherence</b>				
Non-adherence	1.4(0.88-2.24)	0.16	0.72(0.42-1.42)	0.22
Adherence	Reference		Reference	
<b>Non Smoking</b>				
Non-adherence	1.69(0.78-3.69)	0.19	1.11(0.47-2.67)	0.81
Adherence	Reference		Reference	
<b>Alcohol abstinence</b>				
Non-adherence	1.85(0.97-3.54)	0.06	1.39(0.67-2.87)	0.37
Adherence	Reference		Reference	
<b>Weight management adherence</b>				
Non-adherence	12.36(3.74-40.78)	0.000	9.13(2.49-33.38)	0.001
Adherence	Reference		Reference	
<b>Living alone</b>				
Yes	1.97 (0.92-4.22)	0.08	4.2 (1.29-12.63)	0.01
No	Reference		Reference	

**Table 4: Association of family support and blood pressure control**

Variable	Unadjusted OR(95% CI)	P-value	Adjusted OR(95% CI)	P-value
No support	1.9(0.27-13.52)	0.52	0.19(0.02-2.13)	0.18
Mild	5.36(1.65-17.48)	0.005	2.1(0.58-7.66)	0.26
Moderate	2.7(0.89-8.25)	0.08	1.55(0.46-5.22)	0.48
Strong	Reference		Reference	

Binary logistic regression enter model was used which is model fit. (61.7 to 66% improvement). Hosmer and Lemeshow test was non-significant and omnibus test was significant with value as 0.000. Independent variables taken were family support, medication adherence, DASH diet adherence, weight management adherence, physical activity adherence, alcohol abstinence, non-smoking and living alone. Dependent variable was Blood pressure (BP) control.

In univariate analysis, unadjusted odds of having uncontrolled BP is 5.36 times (CI 1.65-17.48) ( $P$  0.005) in mild family support than having strong family support. Similarly, unadjusted odds of having uncontrolled BP is 2.18 times (CI 1.31-3.63) ( $P$  0.003) in those who are not adherent to medication. Unadjusted Odds of having uncontrolled BP is 12.36 times (CI 3.74-40.78) ( $P$  0.000) in those who are non-adherent to weight management practices (Table 3).

The odds of having uncontrolled BP is 9.13 times (CI 2.49-33.38) ( $P$  0.001) in study participants with non-adherence to weight management than those adherent to weight management as reference group. Similarly, odds of having uncontrolled BP is 4.2 times (CI 1.29-12.63) ( $P$  0.01) in study participants living alone than those not living alone. (Table3)

### Discussion:

Today's world experiencing change in a disease pattern from acute to chronic diseases and this makes self-care as an appropriate strategy for promotion, prevention, maintenance of health of individuals. Health in one hand highly personal responsibility and other hand a major public concern. BP control is an important treatment goal for prevention of CVDs and related complications.<sup>7</sup> Self-care practices like behaviour relating to diet, sleep, exercise, weight, alcohol, smoking, drugs and cultivation of healthful habits is important strategy to improve long-term adherence of recommended lifestyle changes.<sup>10</sup>

The study shows medication adherence in 71.7%, Adherence to DASH diet was very poor 6.3%, Physical activity adherence was 48.7%, 9.3% subjects were smoker, Alcohol abstinence was 85.7%, Adherence to weight management practices was seen among 16.3%. Similar findings about medication adherence was noted in study by Khairulnissa Ajani et al, (2021) which was 72%,<sup>11</sup> and study done by Sivakumar, Krithiga et al, (2023) which was 79.2%.<sup>12</sup> which is low comparable to study done by Khairulnissa Ajani et al, (2021) which was 27.11%.<sup>11</sup> It might be due to unhealthy dietary practices like eating more salty and fast food containing white flour, preservatives, saturated fat and less amount of fibres. PREMIER trial showed DASH diet and other lifestyle practices together reduced BP and cardiovascular events.<sup>13</sup>, the result is almost similar to various studies.<sup>12,14,15</sup>

In present study 9.3% subjects were smoking, the results are higher than study conducted by Sivakumar, Krithiga et al, (2023)<sup>12</sup> and Gelaw.S et al (2020)<sup>14</sup> this may be due to difference in socio-demographic profile and awareness about the disease among participant. Alcohol abstinence was 85.7% which is lower than study by Sivakumar, Krithiga et al, (2023) which was 94.1%,<sup>12</sup> and higher than study by Gelaw S et al, (2020) which was 65.6%,<sup>14</sup>

As Obesity is risk factor of hypertension and maintenance of healthy weight is crucial. Study revealed Adherence to weight management practices was 16.3% which is poor comparable to study done by Gelaw. S et al, (2020) which was 55.1%.<sup>14</sup> this shows the need of strengthening of yoga and physical activity related component of NP-NCD program.

The study shows significant association between family support and BP control. As family support increases from mild to strong, BP control also increases, these finding was similar to study done by Chacko S et al (2020).<sup>7</sup> So, the involvement of family members to achieve the BP control is crucial because

they can help hypertensive patient to change their behaviour, promotion and maintenance of healthy lifestyle. They can encourage them for going regular follow-ups and monitoring of BP levels regularly.

Study revealed 71.3% study participants monitor BP once/month, which is lesser than study conducted by Sivakumar, Krithiga et al, (2023)<sup>12</sup> might be due to less awareness regarding self-care. Health workers at hospital and community health worker can encourage and do counselling for regular BP checks and its importance.

Study shows, 61.7% achieved BP control which is less than study done by Joseph N et al, (2016) which was 72.4%.<sup>15</sup> Study found no significant association between BP control and socio-demographic factors, similar results found in study by Sivakumar Krithiga et al, (2023)<sup>12</sup> however study by Joseph N et al (2016) had found significant association between adherence to self-care practices and socio-demographic factors-age, sex, education and occupation.<sup>15</sup> This may be due to difference in study population and study setting between these studies.

This study shows that those who have medication adherence achieved better BP control than non-adherent group. Similar findings was reported in other studies.<sup>16,17,18</sup>

Self-care practices are very important and they are strongly associated with BP Control in individuals with hypertension. Additionally, family support enhances adherence to self-care practices related to BP management.<sup>7</sup> BP control in individuals with hypertension often requires adherence to self-care activities beyond medications.<sup>18</sup>

Self-care practices among DM were assessed frequently but there was paucity of literature about self-care practices in hypertension. This study highlights importance to adherence to self-care practices in blood pressure control. Results may not be generalized to entire population as hospital based study. Data given by study participants was self-reported and no objective measurement was done.

### Conclusion

Overall, BP control was achieved in 3 out of 5 study participants with diagnosed hypertension and on treatment. Adherence to self-care practices is less

in present study population. Medication Adherence was almost in three-fourth study participants. DASH diet adherence and weight management adherence were poor. Almost half of study participants were adherent to physical activity. Adherence to alcohol abstinence and no smoking was followed by maximum study participants. Family support and adherence to weight management practices have positive effect on blood pressure control. Counselling by hospital staff like Drs and staff nurses regarding importance of lifestyle modification done at time of diagnosis itself and at each follow up may prove beneficial for BP control.

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**Ethical Clearance:** Name of the ethics committee: Institutional Ethics Committee, B.J. Govt. Medical College & Sassoon General Hospitals, Pune Dated: 29/03/2023, Number: BJGMC/IEC/Pharmac/ND-Dept. 0323061-061

**Conflict of interest** Nil

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# Unveiling the Hidden Struggles of Hemophilia: A Comprehensive Cross-Sectional Study in South-India

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## Abstract

**Background:** Hemophilia is a rare genetic bleeding disorder characterized by delayed blood clotting due to deficiencies in clotting factors. Despite advancements in treatment, hemophilia poses significant health and social challenges for patients.

**Objective:** This study aims to investigate the profile and consequences of hemophilia among patients in Mangalore, India, focusing on their awareness, treatment, and quality of life.

**Methods:** A cross-sectional study was conducted among hemophilic patients attending Government Wenlock District Hospital, KMC Hospital Attavar, and members of the Hemophilia Federation (India). Data was collected using a semi-structured questionnaire and analyzed using SPSS version 25.0.

**Results:** The study included 69 male participants aged 20-58 years. Most participants (81.2%) were diagnosed within the first year of life. Hemophilia A was more prevalent (81.2%) than Hemophilia B (18.8%). Bleeding episodes occurred once or twice a month for most participants (84%). Regular exercise was reported by 76.8% of participants, and 10.1% reported physical impairment due to hemophilia. Blood transfusions were common (26.1%), with 5.8% affected by Hepatitis C due to transfusions. Preventive prophylaxis was used by 60.9% of participants when required. Satisfaction with welfare centers was neutral to fairly satisfied for most participants.

**Conclusion:** Hemophilia significantly impacts the lives of patients, highlighting the need for improved awareness, treatment accessibility, and support systems to enhance their quality of life.

**Keyword:** Hemophilia, clotting factors, bleeding episodes

## Introduction

Hemophilia is a rare, X-linked recessive genetic

disorder resulting in delayed blood clotting due to deficiencies in clotting factors VIII (Hemophilia A)

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or IX (Hemophilia B)<sup>1</sup>. Hemophilia C, caused by a deficiency of factor XI, and parahemophilia, due to factor V deficiency, are less common variants<sup>2</sup>. This notoriety has brought hemophilia into public awareness, but it remains a misunderstood condition with significant health and social implications.

The incidence of hemophilia varies worldwide, with estimates suggesting that approximately 1 in 5,000 male births are affected by Hemophilia A, and 1 in 30,000 by Hemophilia B<sup>3</sup>. These figures underscore the rarity of the condition and the challenges in achieving widespread awareness and understanding. In India, the prevalence is believed to be lower, possibly due to underdiagnosis and lack of comprehensive data collection systems<sup>4</sup>.

Hemophilia's clinical manifestations are characterized by spontaneous or prolonged bleeding, particularly into joints and muscles, leading to pain, swelling, and, if untreated, chronic joint disease and disability. The historical risk of blood-borne infections, such as HIV and Hepatitis C, from contaminated blood products has been a significant concern<sup>5</sup>. While modern treatments and stringent blood screening have mitigated these risks, they have not eliminated them entirely, especially in resource-limited settings.

Hemophilia's recognition as a disability under the 'Rights of Persons with Disabilities Act 2016' in India<sup>6</sup> marked a significant step toward improving the lives of affected individuals. This legislation provides legal protections and entitlements, including reservation in government jobs and access to disability benefits. However, challenges remain in ensuring that all patients benefit from these provisions, given the variability in healthcare access and quality across the country.

This study aims to examine the demographic profile, awareness, treatment practices, and social implications of hemophilia among patients in Mangalore, India. By understanding these factors, we hope to highlight areas for improvement in patient care and support, contributing to better health outcomes and quality of life for individuals with hemophilia.

## Methods

A cross-sectional study was conducted among known hemophilic patients attending Government Wenlock District Hospital, KMC Hospital Attavar, and members of the Hemophilia Federation (India). The study included all patients who met the inclusion criteria: patients with hemophilia attending the specified hospitals and federation, aged 18 years or older, irrespective of their treatment status. Patients who were unwilling to participate were excluded from the study. A convenience sampling technique was used to select participants for this time-bound study.

After obtaining institutional ethics committee approval (IEC KMC MLR 04-19/202) and necessary hospital permissions, data collection commenced. A pretested semi-structured questionnaire, administered via Google Forms for federation members, was used to gather data. The questionnaire comprised of two parts: demographic details (Part A) and haemophilia-related questions (Part B). The data collected from the questionnaires were entered and analysed using SPSS version 25.0.

The questionnaire was designed to capture a comprehensive range of information, including demographic details (age, education, occupation), hemophilia diagnosis and type, frequency and severity of bleeding episodes, physical activity levels, complications arising from hemophilia (such as infections from blood transfusions), and awareness of treatment options and preventive measures. Participants were also asked about their satisfaction with the healthcare services they received and the impact of hemophilia on their social and economic lives.

## Results

The results of this study are presented in a series of tables that summarize the demographic details, frequency of bleeding episodes, exercise habits, complications, awareness of hemophilia-related issues, and satisfaction with healthcare services among the participants.

The table no 1 shows that the majority of participants (76.8%) were aged between 20-40 years, with a significant proportion having attained higher education, primarily graduates (82.6%). This suggests a relatively young and educated hemophilic population in the study area.

The table no: 2 depicts, Hemophilia A is more in proportion (81.2%) than Hemophilia B (18.8%). Most participants (81.2%) were diagnosed within the first year of life, indicating early detection and diagnosis of the condition. The majority of participants (84%) experience bleeding episodes 1-2 times per month, highlighting the chronic and recurring nature of the condition. Most participants (91.3%) reported no immobilization days due to bleeding episodes, with a median of 0 days and an Inter quartile range (IQR) of 0 to 0 days, indicating effective management of the condition for the majority. A small percentage (8.6%) experienced immobilization for 2-7 days. More than half of the participants (55.1%) engaged in regular exercise for 2-5 hours per week, indicating a positive trend towards maintaining physical fitness despite their condition. Joint swelling is a common issue, with nearly half of the participants (49.3%) experiencing it 1-2 times per month, and a significant portion (44.9%) not experiencing any swelling.

The table no: 3 depicts that the high levels of awareness about carrier detection (91.3%) and prenatal diagnosis (91.3%) were observed. Prophylaxis utilization was noted in 60.9% of participants.

As shown in the table no 4, that the satisfaction with welfare centers had a median score of 3 (neutral) with an IQR of 3 to 4 (neutral to fairly satisfied), indicating general contentment but also room for improvement.

The table no 5 portrays that median impact on education and financial status was 0, with no significant financial impact reported. Social acceptance issues and employment denial had a notable presence, highlighting ongoing social challenges.

**Table 1: Demographic Characteristics of Participants (n=69)**

Characteristics	Frequency	Percentage (%)
<b>Age (years)</b>		
20-30	26	37.7
31-40	27	39.1
41-50	10	14.5
51-60	6	8.7
<b>Education level</b>		
Higher secondary	6	8.7
Graduate	57	82.6
Post graduate	6	8.7
<b>Residence</b>		
Urban	47	68.1
Rural	22	31.9

**Table 2: Profile of hemophilia Type and diagnosis (n=69)**

Items	Frequency	Percentage (%)
<b>Haemophilia Type</b>		
A	56	81.2
B	13	18.8
<b>Diagnosing age</b>		
Median (IQR)	0.5 (0.3-1.0)	
Within 1 year	56	81.2
After 1 year	13	18.8
<b>Frequency of bleeding episodes per month</b>		
1-2 times	58	84.0
3-4 times	10	14.5
≥5 times	1	1.4
<b>Days of Immobilization</b>		
None	63	91.3
2 to 3 days	3	4.3
4-7 days	3	4.3
<b>Frequency of Joint Swelling per Month</b>		
None	31	44.9
1-2 times	34	49.3
3-4 times	04	5.8

**Table 3: Awareness of Hemophilia Management\***

Awareness type	Frequency
Carrier detection	63
Pre natal diagnosis	63
Home remedies (RICE#)	59
Prophylaxis awareness	67
Prophylaxis utilization	42

\*more than one option was selected

# Rest, Ice, Compression and Elevation (RICE)

**Table 4: Satisfaction with Welfare Centers (n=69)**

Satisfaction level	Frequency	Percentage	Median (IQR)
Not satisfied	1	1.4	3 (3-4)
Insufficiently satisfied	6	8.7	
Neutral	39	56.5	
Fairly satisfied	20	29.0	
Strongly satisfied	3	4.3	

**Table 5: Social and Educational Impact of Hemophilia**

Impact type	Yes (n=69)	No (n=69)	Sometimes (n=69)
Physical impact	7	62	--
Social acceptance issues	7	44	18
Educational impact	2	67	--
Financial status impact	0	69	--
Employment denial	11	58	--

**Discussion**

The findings of this study provide a comprehensive understanding of the profile and consequences of hemophilia among patients in Mangalore, India, and highlight several key aspects when compared to previous studies.

**Demographic Characteristics**

The mean age of participants in this study was 34.2 years with a standard deviation of 9.1 years, indicating a relatively young population. This is

consistent with global studies, such as the one by Stonebraker et al. (2010), which also reported a young demographic profile for hemophilia patients<sup>7</sup>even among the wealthiest of countries. The prevalence (per 100 000 males. The high level of education, with 82.6% of participants being graduates, is noteworthy and contrasts with some studies that suggest lower educational attainment due to chronic health conditions. This suggests that despite the challenges posed by hemophilia, many patients in this study area have managed to achieve significant educational milestones.

**Hemophilia Type and Diagnosis**

Hemophilia A was more prevalent (81.2%) than Hemophilia B (18.8%), aligning with global data, including the World Federation of Hemophilia’s annual survey, which consistently shows a higher prevalence of Hemophilia A. The median age at diagnosis in this study was 0.5 years (IQR 0.3-1.0), indicating early diagnosis, which is crucial for effective management and aligns with the findings of Soucie et al.<sup>8</sup> in the United States, who also reported early diagnosis in most cases.

**Frequency of Bleeding Episodes**

Participants in this study reported a median of 2 bleeding episodes per month (IQR 1-2). This is comparable to the findings of Srivastava et al.<sup>9</sup>, who reported similar frequencies, highlighting the chronic and recurring nature of the condition. The consistency in the frequency of bleeding episodes across different studies underscores the importance of regular and effective management strategies for hemophilia.

**Physical Impairment Due to Bleeding Episodes**

Most participants (91.3%) reported no immobilization days due to bleeding episodes, with a median of 0 days (IQR 0-0). This suggests effective management and contrasts with older studies(3), which reported higher rates of physical impairment. The improvement may be attributed to better prophylactic treatments and healthcare practices that have been implemented over the past few decades.

**Exercise Habits**

Regular exercise was reported by more than half of the participants, with a median of 5 hours per week

(IQR 3-6). This aligns with the recommendations by the World Federation of Hemophilia<sup>10</sup>, which emphasize the benefits of physical activity in maintaining joint health and overall well-being. The fact that a significant portion of participants engage in regular exercise is a positive indicator of adherence to recommended health practices.

### Awareness of Hemophilia Management

High levels of awareness were observed in this study, with 91.3% aware of carrier detection and prenatal diagnosis, and 97.1% aware of prophylaxis. This is in line with the findings of Padke<sup>11</sup> who reported high levels of awareness and knowledge about hemophilia management in urban settings. However, the actual utilization of prophylaxis at 60.9% indicates a gap between awareness and practice, similar to findings by Fischer et al. (2013), who noted that while awareness is high, consistent utilization of prophylactic treatment remains a challenge.

### Satisfaction with Welfare Centers

The level of satisfaction with welfare centers was generally positive, with a median satisfaction score of 3 (neutral) and an IQR of 3 to 4 (neutral to fairly satisfied). This aligns with the findings of Brenda Riske<sup>12</sup> associated with adherence and better outcomes. However, satisfaction with US Hemophilia Treatment Centers (HTC, who reported varying levels of satisfaction with hemophilia care services, suggesting that while basic needs are met, there is room for improvement in service delivery and patient support.

### Social and Educational Impact

The study found minimal impact on education and no significant financial status impact, with only 2.9% reporting educational impairment and none reporting financial impact. However, 10.1% faced social acceptance issues and 15.9% reported employment denial, indicating ongoing social challenges. These findings highlighted the social stigmas and employment challenges faced by individuals with hemophilia, despite advancements in medical care.

### Conclusion

This study provides valuable insights into the current status of hemophilia patients in Mangalore, India. The findings highlight improvements in

early diagnosis, education levels, and effective management of bleeding episodes. However, there are still gaps in the utilization of prophylactic treatments and social acceptance. Continued efforts are necessary to address these challenges and ensure comprehensive care and support for individuals with hemophilia. Further research with larger, more diverse populations is recommended to validate these findings and guide future healthcare policies and practices.

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# Prevalence of Dyslipidemia and Associated Factors in a Rural Population in North Kerala

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## Abstract

**Background:** An imbalance in blood lipids called dyslipidaemia leads to arterial inflammation and plaque development. Changes in lipid levels can be brought on by a number of conditions, including obesity, liver and chronic renal disease, smoking, steroids, alcoholism, diabetes mellitus, and alcohol misuse.

**Methods:** This cross-sectional study was conducted from December 2023 to June 2024 in Puzhakkattiri panchayat with a sample size of 599 selected using purposive sampling. Factors affecting the outcome variables was assessed using chi-square test and Fisher Exact test. Correlation between the continuous variables was calculated using Pearson correlation.

**Results:** Prevalence of dyslipidaemia was found to be 60.1%. Age group is statistically significant with altered total cholesterol, triglycerides and HDL levels. In this study, the levels of total cholesterol and triglyceride were higher among females as compared to men. Higher blood lipid levels are seen in patients having higher BMI and high waist to hip ratio. Triglycerides and HDL levels were found to be significantly associated with Hypertension and diabetic status of the patient.

**Conclusion:** The study reveals that hypercholesterolemia is prevalent in rural Kerala, with age group, gender, obesity, hypertension, diabetes significantly affecting total cholesterol, triglycerides, and HDL levels. Reducing modifiable risk factors and promoting diet and physical exercise can help to control diabetes and hypertension.

**Keywords:** Prevalence of dyslipidaemia, associated factors, North Kerala.

## Introduction

Dyslipidemia is a broad term which refers to an imbalance of blood lipids. It may be either

high level of low-density lipoprotein cholesterol (LDL - C) or triglycerides (TG) which causes the plaque formation and arterial inflammation or low level of high-density lipoprotein cholesterol

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(HDL C)<sup>(1)</sup>. Dyslipidaemia usually does not cause any symptoms, but often co-exist with HOD syndrome (Hypertension, Obesity and Dyslipidaemia) and increases the risk of cardiovascular disease and stroke. Hypercholesterolemia is a modifiable risk factor causing 18% of global cerebrovascular diseases, 56% of ischemic heart diseases resulting in 4.4 million deaths annually. One third of ischaemic heart disease in the world is attributable to high cholesterol. Overall, raised cholesterol is estimated to cause 2.6 million (4.5% of total) deaths and 29.7 million Disability Adjusted Life Years (2% of total DALYS).<sup>(2)</sup>

The risk of coronary heart disease increases with increase in plasma cholesterol concentration. A diet containing more energy than needed may lead to prolonged post prandial hyperlipidemia and to deposition of triglycerides in adipose tissue resulting in obesity.<sup>(3)</sup> In 2008, the global prevalence of raised total cholesterol among adults was 39% (37% for males and 40% for females).<sup>(4)</sup>

Among other non-communicable diseases, prevalence of dyslipidaemias was found to be 81.2% in India<sup>(5)</sup>. Recent studies report that hypercholesterolemia is present in 25-30% of urban and 15-20% of rural population. The most common dyslipidemia in India are borderline high LDL cholesterol and low HDL cholesterol and high triglycerides.<sup>(6)</sup> Keralites have the highest cholesterol level in India that ranges from 197 to 229mg/dl compared to 157 to 180mg/dl nationally which is attributable to the high intake of saturated fat from coconut, meat, milk, and oil.<sup>(7)</sup>

Regional disparity was observed with higher prevalence of hypercholesterolemia in northern states and hypertriglyceridemia in southern states. Low HDL-C was the most common lipid abnormality (72.3%).<sup>(7)</sup>

MN Krishnan et al found that most risk factors of CAD were highly prevalent in the state and included overweight or obesity in 59 %, abdominal obesity in 57 %, hypertension in 28.4 %, diabetes in 15.2 %, high total cholesterol in 52.3 % and low level of high-density lipoprotein (HDL cholesterol in 39 %).<sup>(8)</sup> The Tamilnadu based study by Ajay S also observed a similar burden of dyslipidemia among rural and

urban areas. Study also highlighted the linear association of Age and BMI with dyslipidemia<sup>(9)</sup>.

There are no studies done in Malappuram district assessing the risk factors for dyslipidaemia and the factors affecting it. Knowledge on prevalence of dyslipidaemia in the field practice area of MES Medical College will help to plan an appropriate intervention here.

The aim of the study was to determine the prevalence of dyslipidemia and the factors associated with dyslipidemia among the adult population more than 18 years of age residing in Puzhakkattiri Panchayat.

## Methodology

This cross-sectional study was conducted in Puzhakkattiri panchayat from December 2023 to June 2024 among all the adult population who were residing here for at least 6 months and consented to participate in the study. Those who were not able to apprehend the questions were excluded from the study. Sample size was calculated by the formula  $Z^2 PQ / d^2$ . In a previous study, the prevalence of dyslipidemia was found to be 63.8%.<sup>(1)</sup> The sample size calculated was 580. We have included 591 participants in this study. Purposive sampling method was used to collect the data. Hypercholesterolemia is diagnosed if fasting cholesterol value  $\geq 240$ . Patient is diagnosed to have hypertriglyceridemia if the fasting triglyceride level  $\geq 200$ . LDL levels is high if the fasting LDL level  $\geq 190$ . HDL level is considered to be low if the level  $\leq 40$ . Asian classification was used to categorise the BMI. Patient is said to be overweight if the BMI  $\geq 23.5 \text{ kg/m}^2$ . Normal waist to hip ratio is less than 0.9 for males and less than 0.85 for females. Hypertension was classified according to JNC 8 criteria. Puzhakkattiri Panchayat is the field practice area of MES Medical College, Perinthalmanna. Houses were selected by conducting a health checkup camp. General physical examination of the participants was conducted including, measurements of Blood pressure, weight, height, waist, hip. Fasting Blood samples were collected to examine their lipid profile. Demographic details also were collected using a questionnaire.

## Data Analysis

Microsoft Excel was used for data entry. A statistical analysis software package (SPSS version 26) was used to analyse the data. Normality of data was checked using Kolmogorov Smirnov test and appropriate parametric or non-parametric test was applied. For qualitative data chi-square test or Fisher exact test was used to find out the significant difference in groups. Pearson correlation test was used to find the correlation between the quantitative variables.

## Results

**Table no.1 Showing the baseline characteristics of study participants.**

Sl No	Variables	Frequency	Percentage
<b>1</b>	<b>Age group</b>		
	19-29	82	13.9
	30-39	119	20.1
	40-49	138	23.4
	50-59	104	17.6
	60-69	87	14.7
	>70	61	10.3
<b>2</b>	<b>Gender</b>		
	Male	223	37.7
	Female	368	62.3
<b>3</b>	<b>Marital Status</b>		
	Unmarried	43	7.3
	Married	474	80.2
	Legally divorced	2	.3
	Separated	9	1.5
	Widow/widower	63	10.7
<b>4</b>	<b>Religion</b>		
	Hindu	144	24.4
	Islam	447	75.6
<b>5</b>	<b>Educational Status</b>		
	Illiterate	49	8.3
	Primary school	95	16.1
	Middle school	115	19.5
	High school	214	36.2
	Degree	105	17.8
<b>6</b>	<b>Occupational Status</b>		
	Clerical/Shop/ Farm	32	5.4

	Semi-professional	21	3.6
	Semiskilled worker	40	6.8
	Skilled worker	28	4.7
	Student	37	6.3
	Unemployed	345	58.4
	Unskilled worker	88	14.9
<b>7</b>	<b>Hypercholesterolemia</b>		
	No	236	39.9
	Yes	355	60.1
<b>8</b>	<b>Hypertriglyceridemia</b>		
	No	377	63.8
	Yes	214	36.2
<b>9</b>	<b>HDL category</b>		
	0-40	181	30.6
	41-50	207	35.0
	>50	203	34.3
<b>10</b>	<b>LDL category</b>		
	Normal	252	42.6
	High	339	57.4
<b>11</b>	<b>Hypertension</b>		
	Normal	280	47.4
	Hypertensive	311	52.6
<b>12</b>	<b>Waist hip ratio male</b>		
	Normal	19	8.5
	High	204	91.5
<b>13</b>	<b>Waist hip ratio female</b>		
	Normal	39	10.6
	High	329	89.4
<b>14</b>	<b>Waist hip ratio</b>		
	Normal	58	9.8
	High	533	90.2
<b>15</b>	<b>Body mass index (BMI)</b>		
	Overweight and above	339	61.2
	Normal and below	215	38.8

Prevalence of dyslipidaemia/hypercholesterolemia was found to be 60.1 % among the study participants. Hypertriglyceridemia present in 36.2 % of the people. 35% of the people had HDL levels between 41-50, while 34.5 % had HDL level more than 50 mg/dL. Among the study participants 52.6 % had hypertension. The overall normal Waist to hip ratio (WHR) among the study participants was

9.8% (8.5% in males, 10.6% in females). BMI among the study participants was seen normal in 38.8% where the remaining 61.22% were either overweight or obese.

**Table no 6. showing association between age group and the Lipid profile of the study participants**

SI No	Lipid profile	Age group		P Value
<b>1</b>	<b>Hypercholesterolemia</b>	<b>≥40</b>	<b>&lt;40</b>	<b>0.001</b>
	No	135	255	
	Yes	101	100	
<b>2</b>	<b>Hypertriglyceridemia</b>			<b>0.008</b>
	No	234	143	
	Yes	156	58	
<b>3</b>	<b>HDL category</b>			0.08
	0-40	131	50	
	41-50	129	78	
	>50	130	73	
<b>4</b>	<b>LDL levels</b>			0.008
	Normal	151	239	
	High	101	100	

There was a Statistical association between hypercholesterolemia, triglycerides, LDL levels and the age group of the study participants with P value  $\leq 0.05$ .

**Table no. 2 showing the association between Gender of the study participants and Lipid profile.**

SI No	Lipid profile	Gender		P Value
<b>1</b>	<b>Hypercholesterolemia</b>	<b>Male</b>	<b>Female</b>	0.08
	No	99	137	
	Yes	124	231	
<b>2</b>	<b>Hypertriglyceridemia</b>			0.14
	No	134	243	
	Yes	89	125	
<b>3</b>	<b>HDL category</b>			<b>0.001</b>
	0-40 mg/dL	91	90	
	41-50 mg/dL	78	129	
	>50 mg/dL	54	149	
<b>4</b>	<b>LDL Levels</b>			0.61
	Normal	98	154	
	High	125	214	

Significant association was found between gender and HDL category. Levels of HDL was more seen in females comparing to males (P value= 0.001)

**Table no. 3 showing the association between BMI and Lipid profile of the study participants**

SI No	Lipid profile	BMI		P Value
<b>1</b>	<b>Hypercholesterolemia</b>	<b>Overweight and above</b>	<b>Normal and below</b>	0.2
	No	130	94	
	Yes	209	121	

Continue.....

<b>2</b>	<b>Hypertriglyceridemia</b>			0.001
	No	199	160	
	Yes	140	55	
<b>3</b>	<b>HDL category</b>			0.001
	0-40	112	53	
	41-50	131	68	
	>50	96	94	
<b>4</b>	<b>LDL category</b>			0.47
	High	198	131	
	Low	146	106	

Level of triglycerides, HDL and LDL were also found to be significantly associated with BMI. Levels of Triglycerides and LDL were more in groups

having higher BMI when compared to normal or low BMI, whereas HDL decreases with increase in BMI. (P value ≤ 0.05).

**Table no. 4 Association between Waist Hip ratio (WHR) and Lipid profile of the study participants.**

Sl No	Lipid profile	WHR		P Value
<b>1</b>	<b>Hypercholesterolemia</b>	<b>Normal</b>	<b>High</b>	0.81
	No	24	212	
	Yes	34	321	
<b>2</b>	<b>Hypertriglyceridemia</b>			0.04
	No	44	333	
	Yes	14	200	
<b>3</b>	<b>HDL category</b>			0.17
	0-40	12	169	
	41-50	21	186	
	>50	25	178	
<b>4</b>	<b>LDL category</b>			0.72
	Normal	26	226	
	High	32	307	

Hypertriglyceridemia was seen more in people with higher WHR (P value=0.04).

**Table no. 5 showing association between hypertensive status and lipid profile**

Sl No	Lipid profile	Hypertensive status		P Value
<b>1</b>	<b>Hypercholesterolemia</b>	<b>Normal</b>	<b>Hypertensive</b>	0.001
	No	131	105	
	Yes	149	206	
<b>2</b>	<b>Hypertriglyceridemia</b>			0.002
	No	Normal	180	
	Yes	High	131	
<b>3</b>	<b>HDL category</b>			0.07
	0-40	73	108	
	41-50	103	104	
	>50	104	99	
<b>4</b>	<b>LDL category</b>			0.1
	Normal	129	123	
	High	151	188	

There is significant association between hypercholesterolemia and hypertriglyceridemia.

**Table no.6 showing association between Diabetes and Lipid profile of the study participants.**

Sl No	Lipid profile	Diabetic status		P Value
		Normal	Diabetes	
1	<b>Hypercholesterolemia</b>			0.64
	No	164	72	
	Yes	253	102	
2	<b>Hypertriglyceridemia</b>			0.001
	No	290	87	
	Yes	127	87	
3	<b>HDL category</b>			0.002
	0-40	110	71	
	41-50	154	53	
	>50	153	50	
4	<b>LDL category</b>			0.74
	Normal	76	176	
	High	98	241	

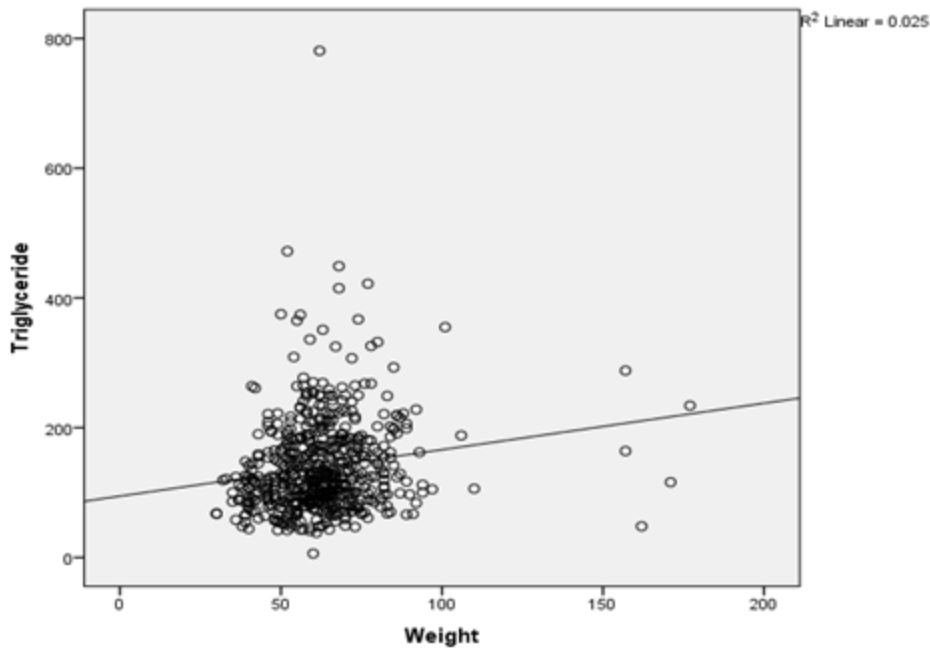
Hypertriglyceridemia and HDL levels were found to be significantly associated with Diabetes.

**Table no. 7 showing correlation matrix between the continuous variable and the Triglyceride levels.**

		Weight	SBP	DBP	FBS
Triglyceride	Pearson Correlation coefficient r	0.158	0.165	0.182	0.255
	P Value	0.0001	0.0001	0.0001	0.0001

Pearson Correlation test was used to find the correlation between the continuous variables and various parameters of lipid profile.

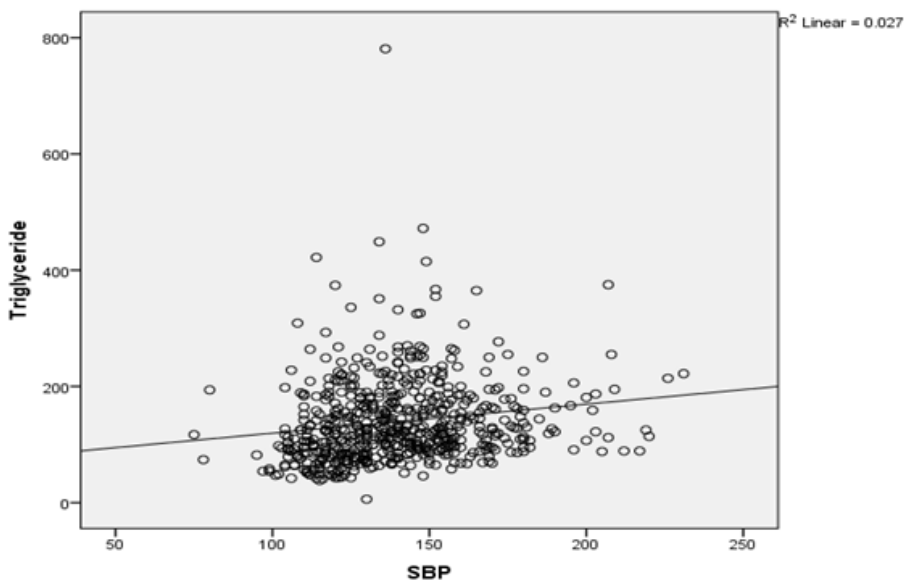
There is a weak positive correlation obtained between body weight, blood pressure, fasting blood sugar levels with the Triglyceride ( $P < 0.01$ )



**Figure no. 1 showing scatter plot diagram of triglyceride levels and weight of the participants**

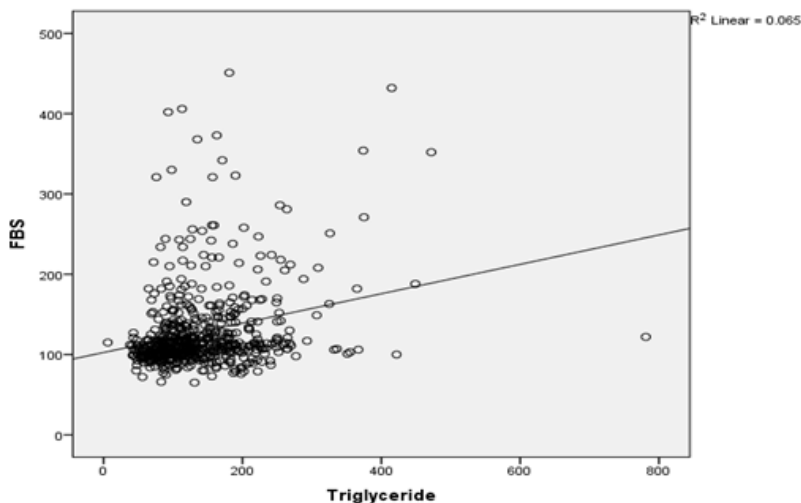
A weak positive correlation was identified between the triglyceride value and body weight. The

triglyceride level increases with increase in weight ( $r=0.158$ ,  $p$  value  $=0.0001$ )



**Figure no. 2 showing scatter plot diagram of triglyceride levels and systolic blood pressure of the participants**

Weak positive correlation was seen between triglyceride level and systolic BP. ( $r=0.165$ ,  $p$  value  $=0.0001$ ).



**Figure no. 3 showing scatter plot diagram of triglyceride levels and fasting blood sugar of the participants**

Fasting blood glucose level and triglyceride levels were found to have weak positive correlation. (Pearson correlation coefficient  $r= 0.255$ ,  $p$  value  $= 0.0001$ )

**Discussion**

In our study, the Prevalence of dyslipidaemia/hypercholesterolemia was found to be 60.1%. Similar

results were found in another study conducted by Ashlesh et al in northern Kerala, where the prevalence of dyslipidaemia was found to be 63.8%<sup>1</sup>. However, another study conducted by Joshi et al showed that only 13.9 % of the rural population had dyslipidaemia<sup>11</sup>. Study conducted by Ajay et al showed a prevalence of dyslipidaemia among urban

and rural population was found to be 74.5% and 68.8% respectively<sup>9</sup>. Study conducted by Nirwan et al showed the overall prevalence of dyslipidaemia was 80%<sup>10</sup>. Study conducted by Vijaykumaret al showed that 37 % of the rural population had dyslipidaemia.<sup>12</sup>. Our result was much higher than the global prevalence published by the World Health Organization<sup>13</sup>. In our study, the total cholesterol levels, triglycerides, LDL levels were found to be high in older age groups when compared to the younger people. Another study showed that there is a declining trend in lipid levels after 40 years of age<sup>14</sup>. In our study higher lipid levels are found in participants having higher BMI or overweight. Similar results were seen in a study conducted by Vijayakumar et al in rural population of Kerala<sup>12</sup>. Dyslipidaemia is closely related to insulin resistance. Obese people have higher risk of insulin resistance and lead to decreased clearance of VLDL, increased triglycerides and decreased HDL levels in blood<sup>16</sup>.

In our study, lipids levels (except HDL levels) were found to be high in those who are more than 40 years of age ( $p < 0.05$ ). In our study, the levels of total cholesterol and triglyceride were higher among females as compared to men. Similar results were found in the study conducted by Joshi et al<sup>11</sup>. However, another study showed that men have higher altered lipid levels as compared to females<sup>14</sup>. Higher lipid levels are seen in patients having higher BMI or overweight. Similar results were seen in a study conducted by Vijayakumar et al in rural population of Kerala.<sup>12</sup> The waist to hip ratio was also related to increased levels of triglycerides in blood. These findings were consistent with the results obtained from previous studies<sup>16,17</sup>. Triglycerides and HDL levels were found to be significantly associated with Hypertension and diabetic status of the patient similar to the previous studies <sup>11,12</sup>. In the study population, dietary consumption of excessive fat and calorie intake, together with inactivity, could be the main causes of dyslipidaemia. Deep-frying of foods and re-frying in the used oil can produce trans-fatty acid, which can also alter the lipid levels.

### **Strength and weakness**

Our study was able to identify certain risk factors that may leading todyslipidaemia. Study estimated lipid profile of the study participants

(triglyceride levels, HDL and LDL levels) other than just measuring total cholesterol. Demographic details like education, occupation, socioeconomic status was not determined. Also, the study did not assess the behavioural risk factors like lack of physical activity, dietary pattern and substance use. This study conducted over a short period of time, may not have captured long-term trends or changes in the lipid profile.

### **Conclusion and Recommendations**

According to the findings in the study, hypercholesterolemia is highly prevalent in the rural Kerala. Altered total cholesterol and triglyceride levels were found to be significantly associated with age  $\geq$  40). The levels of total cholesterol and triglycerides were higher among females when compared to men. Higher lipid levels are seen in persons having higher BMI or overweight. High Waist-Hip ratio was also related to increased levels of triglycerides in blood. High Triglycerides and low HDL levels were found to be significantly associated with Hypertension and diabetic status of the participants. This study found that hypertension is associated with obesity. Obesity was significantly associated with hypercholesterolemia hence reduction in obesity can help to control lipid levels thereby reducing the hypertension. Dietary modifications, physical exercise also should be promoted to control serum lipid levels. Hypercholesterolemia was also seen in younger age groups. Early screening and preventive measure must be taken for lessening the disease burden.

**Conflict of interest:** None

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**Ethical Clearance/Statement of Ethics:** Ethical clearance was obtained from MES Ethics committee No.IEC/MES/13/2023

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sincerely express our: gratitude to Mr Robin and other Medico social workers from the Department of Community Medicine for the assistance they have provided to us for completing this study.

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# Status and Factors Affecting E-Health Literacy among Users of Smart Devices: A Community Based Cross Sectional Study

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## Abstract

**Background:** e-health literacy can be a powerful tool to engage communities in their own health care management

**Materials and method:** Sample size was calculated to be 384 rounded to 400 using Cochran's formula. Simple random sampling technique was used to select the participants. eHEALS tool was used to measure electronic health literacy. Frequencies, proportions, chi squared values as measures of association and Phi( $\Phi$ ) and Cramer's V for strength of association were calculated.

**Results:** There were 118 (29.5%) males and 282 (70.5%) females with a mean age of 45.1 (11.8) years. Median eHEALS score was 19 with IQR (13.5- 21.7). Age (= 38.95, df=1, p=<.001), education (= 15.51, df=4, p=.003), presence of comorbid condition (= 13.01, df=1, p=.003), practice of self-medication (= 10.76, df=2, p=.004) and trust on online information (= 9.9, df=2, p=.007) emerged as factors significantly associated with adequate e-health literacy.

**Conclusion:** Digitally literate communities can participate more fully in taking care of their own health.

**Keywords:** e-health literacy, management of health problems, online health resources, online health information

## Introduction

The illiterate of 21<sup>st</sup> century will not be the ones who cannot read and write but those who cannot learn, unlearn and relearn. Alvin Toffler.<sup>1</sup>

Rapid strides in scope and reach of health-related information and communication technologies have been largely made possible by the extensive network and ease of use of the internet.<sup>2</sup>

Digital health literacy is defined as the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem.<sup>3</sup> Digital health literacy has emerged as one of the major influencing factors impacting the health outcomes of a community in an increasingly digitized healthcare ecosystem.<sup>4</sup>

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Digital health literacy is vital in digital health ecosystem.<sup>5</sup> The Organisation for Economic Co-operation and Development has defined the digital divide as the gap between individuals, households, businesses, and geographic areas at different socio-economic levels in both their opportunities to access information and communication technologies (ICTs) and to their use of the internet for a wide variety of activities.<sup>6</sup>

Due to rapid digital transformation with ever-increasing importance of the Internet of Things, the digital divide has the potential to be the new face of inequality.<sup>7</sup>

The disparity in the rural-urban healthcare system in the country is also reflected in the digital divide. Data from NFHS-5 reveals that 72.5% urban and 48.7% rural males and 51.8% urban and 24.6% rural females have ever used the internet.<sup>8</sup>

**Need of the study:** The present study is undertaken to find status of digital health literacy of an urban community and attempts to find association between e-health literacy and various sociodemographic variables.

### Objectives-of the study

1. Assess the digital health literacy of among 15 to 65 year old residents of an urban community using eHEAL scale.
2. Find association between e-health literacy and various sociodemographic variables.

### Materials and method

**Study design:** This community based cross sectional study was conducted after obtaining ethical clearance from the Institutional Ethical Committee vide letter number SGRD/IEC/2023-169.

**Sample size calculation:** Cochran's formula  $N = z^2 p(1-p)/e^2$  was used. With assumed prevalence (p) of electronic health literacy in the community as 50% (no studies available on prevalence of electronic health literacy in Punjab) could be found, an absolute margin of error (e) as 5%,  $z=1.96$  for confidence level of 95%, the sample was calculated to be 384. The sample size was rounded to 400 for more intuitive understanding of the interpreted results.

**Study participants-** One participant who owned or had access to an internet enabled smart device- smart phone, laptop etc was chosen from each of 400 randomly selected households in the urban field practice area after taking their informed consent and assuring confidentiality of the information shared.

**Data collection-** Information was gathered through a predesigned and pretested. An 8-item electronic Health Literacy Scale (eHEALS) was used to assess the electronic health literacy of the participants. A pilot study was conducted on 20 participants. The Cronbach alpha was calculated to find the internal consistency of the eHEALS tool. It was found to be .694. Principal Component Analysis (with varimax rotation) was performed for dimensionality reduction. It yielded one principal component with items loadings ranging from .46 to .81.

**Statistical analysis-** Frequencies and proportions were calculated in descriptive analysis while chi squared test with appropriate Yates correction was used in inferential statistics.  $\Phi$  coefficient and Cramer's V were calculated to find the strength of association between the categorical variables. Microsoft excel and SPSS version 24.0 were used for data analysis.

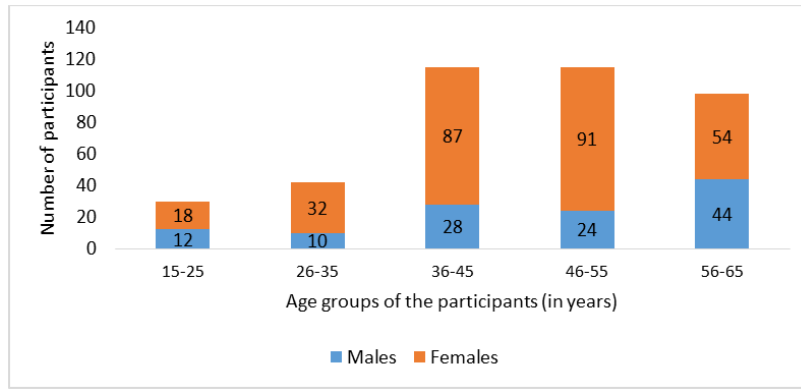
### Results

There were 115 participants each in the age group of 36-45 years, 98 in the age group of 56-65 and just 30 in the age group of 15-25.

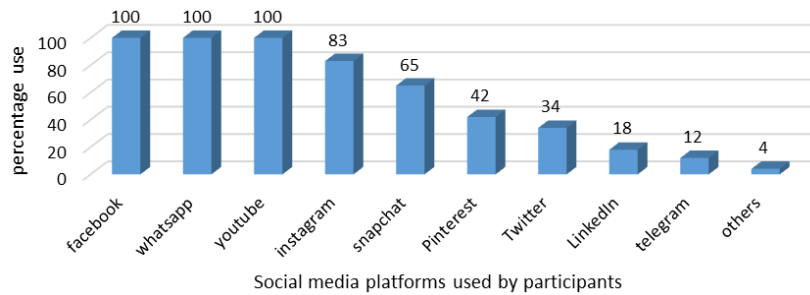
There were 118 (29.5%) males and 282 (70.5%) females among the 400 participants. Fig.1

Socioeconomic status was assessed by using modified Kuppaswami scale. Most of the respondents 112 (28%) belonged to the lower middle class followed by upper lower class 98 (24.5%). Most of the participants 155 (38.7%) were graduates while 121 (30.2%) had studied up to intermediate level.

The social media platforms with universal usage were Facebook, WhatsApp and YouTube i.e 100% each while government run portals and websites were routinely used by 16 (4%) of the participants. Fig 2.

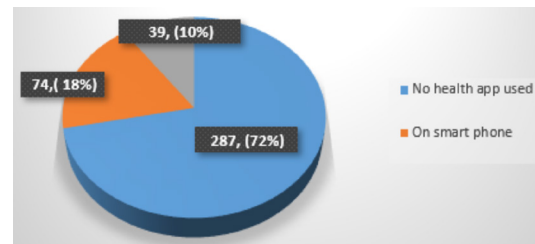


**Fig 1. Distribution of participants according to age and sex**



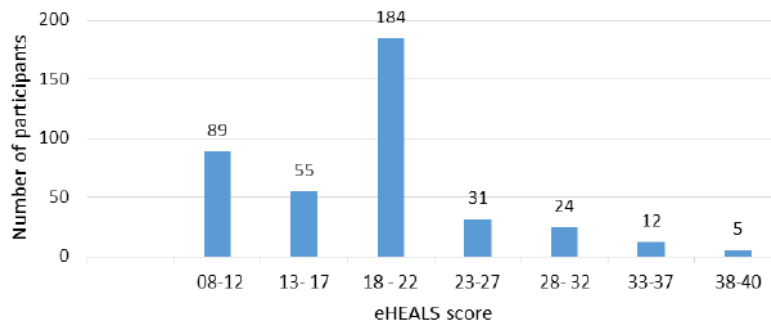
**Fig 2. Percentage distribution of social media platforms used by participants**

Health related applications were found in 74 (18%) users of smart mobile phones and wearable technology was used by 39 (10%) of the participants. Most of the participants 287 (72%) did not use any health apps. Fig 3. The most frequently used health applications were for monitoring distance walked (n=58), nutrition related (n= 41), water in take (n=40), heart rate, respiration rate and oxygen saturation levels (n=36 each).



**Fig 3: Platform for use of health applications**

The electronic health literacy of the participants was assessed by using an 8-item eHEALS tool.<sup>9</sup> The 8 statements are rated on a 5-point Likert scale from strongly disagree to strongly agree. The total score ranges from 8 to 40. The higher the score, the higher the electronic health literacy is considered. Fig-4



**Fig 4: Distribution of participants according to eHEALS score**

The median score was 19 (IQR=13.5- 21.7 The study participants were divided into two groups based on the median score. 271(67.7%) of the participants, who had score of  $\leq 19$  were categorised

as having inadequate e- health literacy while 129 (32.3%) who had score more than 19 were categorized as having adequate e health literacy.

**Table 1: Factors associated with e-health literacy among users of smart device**

Factor	Subsets of factor	Adequate e-health literacy (n=129)	In adequate e-health literacy (n=271)	Degrees of freedom (df)	Chi sq. value ( $\chi^2$ )	P-value	Effect size ( $\Phi$ and Cramer's V)
Age (in years)	<45(136)	72 (52.9%)	64 (47.0%)	1	38.95	0.00001	$\Phi=0.317$ Medium
	>45(264)	57 (21.5%)	207 (78.4%)				
Sex	Males(118)	31 (26.2%)	87 (78.3%)	1	2.36	0.124	
	Females (282)	98 (34.7%)	184 (34.6%)				
SES	Upper(45)	14 (31.1%)	31 (68.8%)	4	8.57	0.0725	
	Upper middle(87)	20 (22.9%)	67 (77.0%)				
	Lower middle(112)	35 (31.2%)	77 (68.7%)				
	Upper lower(98)	42 (42.8%)	56 (57.1%)				
	Lower lower(58)	18 (31.0%)	40 (68.9%)				
Education	Middle(67)	16 (23.8%)	51 (76.1%)	4	15.51	0.003	CV=0.196 Large
	Secondary(145)	34 (23.4%)	111 (76.5%)				
	Higher Sec(117)	49 (41.8%)	68 (58.1%)				
	Graduates(40)	17 (42.5%)	23 (57.5%)				
	Post graduates(31)	13 ((41.9%)	18 (58.0%)				
Co morbid condition	Yes(176)	74 (42.0%)	102 (57.9%)	1	13.01	0.003	$\Phi=0.185$ Small
	No (224)	55 (24.5%)	169 (75.4%)				
Practice self-medication	Yes (148)	46 (31.0%)	102(68.9%)	2	10.76	0.004	CV=0.164 Small
	No (24)	15 (62.5%)	9 (37.5%)				
	Sometimes(228)	68 (29.8%)	160 (70.1%)				
Self-rated health status	Good (109)	30 (27.5%)	79 (72.4%)	2	3.79	0.150	
	Okay (147)	56 (38.0%)	91 (61.9%)				
	Bad (144)	43(29.8%)	101 (70.1%)				
Trust online information	Mostly (56)	08 (14.2%)	48 (85.7%)	2	9.9	0.007	CV=0.157 Medium
	Never (102)	38 (37.2%)	64 (62.7%)				
	Sometimes (242)	83 (34.2%)	159 (65.7%)				
Electronic device possession	Personal (251)	57 (22.7%)	271 (77.3%)	1	3.15	0.075	
	Shared (149)	72 (48.3%)	147 (51.6%)				
Screentime	Unrestricted (233)	70 (30.0%)	163 (69.9%)	1	1.01	0.314	
	Restricted (167)	59 (35,3%)	108 (64.6%)				

## Discussion

### Age and e-health literacy

The mean age of the participants was 45.1 (11.8)

years. Of the 136 participants less than 45 years of age, 72 (52.9 %) possessed adequate e-health literacy while only 57 (21.5%) of 264 participants aged more than 45 years possessed adequate e-health literacy.

This association between age of the participants and e-health literacy was found to be highly statistically significant ( $= 38.95$ ,  $df=1$ ,  $p<.001$ ) with medium strength ( $\Phi=.317$ ) of association.

A meta-analysis done in Hongkong also found that the younger age group is associated with better eHEALS score.<sup>10</sup>

Another study done among adults in China also found a significant association between younger adults and better e-health literacy scores. ( $F = 3.18$ ,  $p < 0.05$ ) and male gender ( $t = 2.00$ ,  $p < 0.05$ ).<sup>11</sup>

The negative relationship between older age and poorer digital health literacy was also found in a review study conducted by Wang.<sup>12</sup>

#### Sex and e-health literacy

31 (26.2%) of 118 male participants and 98 (34.7%) of 282 female participants had adequate e-health literacy. No statistically significant association of sex with e-health literacy was found. The above findings are in consonance with the meta-analysis done by Estrela M which found that sex of the adult participants did not have any influence over the digital health literacy. ( $B = - 0.17$ , 95%CI [-0.64; 0.30]).<sup>13</sup>

However, another online cross-sectional study conducted among internet users across five regions in Ghana, found that males scored significantly more than females on electronic health literacy scale.<sup>14</sup>

Hagen *et al* found male adolescents to be more digitally literate than female adolescents in a research conducted among university students.<sup>15</sup>

#### SES and e-health literacy

No statistically significant association was found between socioeconomic class of the participants and e-health literacy ( $= 8.5,7$   $df=4$ ,  $p<.07$ ). However, a study found a positive association of income with higher eHEALS scores. (SII 13.27 vs 7.30).<sup>16</sup> Similar associations of limited ehealth literacy with poorer standards of living were found in a study in Ghana.<sup>17</sup>

#### Education and e-health literacy

145 (36.2%) were educated up-to secondary school ie matriculation, 117 (29.5%) had completed higher secondary, 67 (16.6 %) had studied till middle

school while only 31(7.7%) were postgraduates. This association between educational level of the participants and e-health literacy was found to be highly statistically significant ( $= 15.51$ ,  $df=4$ ,  $p=.003$ ) with a large effect size (Cramer's  $V=.196$ ).

The positive association of level of education and digital literacy was observed by Adil et al among university students. This study concludes that educational level is the major factor for unequal response towards digital health literacy.<sup>18</sup>

Another study observed that inpatient portal use registration and use was positively associated with higher educational attainment of the inpatient and better digital literacy score.<sup>19</sup>

Reduced odds of having internet use in respondents with lower education level (none: 0.09 (0.06, 0.15), GCSE's or equivalent: 0.40 (0.24, 0.69)) compared to being educated beyond A-level was seen in another study.<sup>20</sup>

#### Comorbid condition and e-health literacy

74 (42.04%) of the 176 participants with a chronic comorbid condition and only 55 (24.5%) of the 224 participants without a comorbid condition had good e-health literacy. Presence of a comorbid condition of chronic nature was found to be highly statistically significantly associated with adequate e-health literacy ( $= 13.01$ ,  $df=1$ ,  $p=.003$ ) with a small effect size ( $\Phi=.185$ )

A study conducted in China revealed that chronic non communicable disease management was significantly better in digitally literate participants ( $\beta=0.42$ ,  $P<0.01$ ).<sup>21</sup>

The association between frequency of self-medication and e-health literacy was found to be highly statistically significant ( $= 10.76$ ,  $df=2$ ,  $p=.004$ ) with a small effect size (Cramer's  $V=.164$ ).

In a Saudi Arabia study, significant positive correlation exists between the health literacy screening scale (BRIEF) and the self-medication scale (SMS) scores ( $r = 421$ ,  $p < 0.001$ ).<sup>22</sup>

A study in Taiwan found a positive correlation between perceived wellbeing and digital health literacy ( $B 0.29$ , 95% CI 0.10-0.49,  $p < 0.001$ )<sup>23</sup>

The association between levels of trust on online information and e-health literacy was found to be highly statistically significant ( $= 9.9$ ,  $df=2$ ,  $p=.007$ ) with a small effect size (Cramer's  $V=.157$ ).

Similar observation was made in a study conducted in Slovenia, where participants with a sufficient level of DHL were more likely to seek information through search engines and websites of official institutions.<sup>24</sup>

A study conducted in China on patients in outpatient department found that face-to-face inquiry for obtaining health information was important in the low eHealth literacy group while Internet-based technologies crucially affected decision-making skills in the high eHealth literacy group.<sup>25</sup>

This difference could be due to difference in research settings.

### Conclusion

The internet is increasing being recognized as an important determinant of health by the health care systems worldwide. The spectrum and reach of health information and services can be vastly improved through the interactivity via the Internet of Things, particularly for those who are able to engage critically and productively with the online health resources as compared to those who rely solely on the traditional health care. e-health literacy is a key to unlock the access to the online health resources and empower communities to become more involved in their own health care management in the spirit of self-reliance and self-sufficiency as envisaged in the primary health care.

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# Study of Different Spirometric Parameters in Patients of Neurotic Disorder with Dyspnoea

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## Abstract

**Background:** The number of neurotic disorder patient, who have respiratory distress is very high, that can be due to obstructive or restrictive lung disease. Spirometry is a good tool for the diagnosis of obstructive and restrictive lung disease. Depending on spirometric parameters, different lung diseases can be diagnosed.

**Method:** 139 patients of age group 18 years - 60 years, of any gender, are included in our study. Diagnosed patients of neurotic disorder with dyspnoea are treated as case and Patients of dyspnoea who are referred to our pulmonary lab for spirometry, from departments other than psychiatry are treated as control. Spirometry is done by a portable spirometer and appropriate statistical methods are applied for the analysis.

**Results:** We find that the overall abnormal spirometric patterns are more in control group. It is 40.7% in control and it is 32.1% in case. The results, when compared, it is seen that the number of reversible obstructive pattern is more in control group than case. It is 7.8% in control and 3.5% in case. Irreversible obstructive pattern is also more common in control group. It is 22.14% in control and 4.28% in case. But the restrictive pattern is more in case than control. It is 24.285 in case and 10.71% in control. It is significantly high in case than control.

**Conclusion:** The results of this study concluded that lung functions were significantly depressed in neurotic disorder patients with dyspnoea. All types of pulmonary disorders may affect neurotic disorder patients but restrictive type of disorder was more pronounced in neurotic disorder patients with dyspnoea

**Keywords:** Respiratory Distress, Neurotic disorder, Spirometric parameters, Lung diseases, Depression.

## Introduction

Prevalence of neurotic disorder in India is

very high (around 20.7 per thousand population)<sup>1</sup>.

Depression is the most common chronic condition

next to hypertension experienced in general medical

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practice. Incident of dyspnoea among the patients of neurotic disorder is very common. Many times these patients are misdiagnosed and treated inappropriately. One study showed that about 50.1% of psychiatric patients have significant physical illness and among them 58.2% was previously undiagnosed<sup>2</sup>.

In this background we undertake our study 'study of different spirometric parameters in patients of neurotic disorder with dyspnoea' to measure the prevalence of lung disease in patients of neurotic disorder with dyspnoea.

We measure different spirometric parameters of patients from both the study group and control group. Depending on the results of spirometry parameters we plan to estimate the prevalence of different lung diseases in both the groups. And then we plan to compare the result to see the differences of prevalence of lung diseases in these two groups. We plan to divide both the group into different subgroups based on age and sex. Then we plan to compare the results of subgroups to see whether there is any difference in the subgroups or not.

If FEV1/FVC is less than 70% then it is considered as obstructive pattern. If there is an improvement of more than 12% or more than 200ml in post bronchodilator inhalation state then it is considered as reversible obstructive pattern and if it is less than this then it is considered as irreversible obstructive pattern<sup>3</sup>.

If FVC/Predicted FVC is less than 75% then it is considered as restrictive pattern<sup>4</sup>.

Through all this we wanted to measure the prevalence of undiagnosed lung disease in patients of neurotic disorder with dyspnoea and the magnitude of lung disease in different subgroups.

## Materials and Methods

**Study Area:** Department of Physiology, R.G.Kar medical college and hospital, Kolkata and Department of Psychiatry, R.G.Kar medical college and hospital, Kolkata

**Study Population:** Patients of dyspnoea who are referred to our pulmonary lab for pulmonary function test from other departments of our hospital are my

study population. Those who are referred from Dept. of psychiatry with diagnosis of any neurotic disorder are taken as "Case" & from other departments apart from Psychiatry are taken as "Control".

**Study Period:** Duration of our study is 1 year, from 2016 to 2017.

### Inclusion criteria:

#### A) For case:

- a) Diagnosed patients of neurotic disorder with dyspnoea.
- b) Patients from age group 18years - 60years.
- c) Those patients who gives consent for the study.

#### B) For control:

- a) Patients of dyspnoea who are referred to our pulmonary lab for spirometry, from departments other than psychiatry.
- b) Patients from age group 18years-60 years.
- c) Those patients who gives consent for the study.

### Exclusion Criteria:

#### A) For case:

- a) History of any previously diagnosed organic disorder which can cause dyspnoea (like- obstructive lung disease, restrictive lung disease, congestive heart disease, pneumonia, anaemia, myocardial ischemia, hypothyroidism, upper airway obstruction, obesity etc.)
- b) Patients from age group younger than 18 years and older than 60 years.
- c) Too ill or unable to participate.

#### B) For control:

- a) Patients who have neurotic disorder.
- b) Patients from age group younger than 18years and older than 60 years.
- c) Patients from age group younger than 18years and older than 60 years.
- d) Too ill or unable to participate.

**SAMPLING METHOD:** All patients referred from psychiatry department, who satisfy inclusion criteria, will be included in our study.

**SAMPLE DESIGN:** Total enumeration.

**STUDY TYPE:** Case control study.

**STUDY DESIGN:** Cross sectional study.

**PARAMETERS MEASURED:** Forced vital capacity (FVC), Forced expiratory volume of 1st second (premedication and post medication), FEV1/ FVC% and predicted FVC/FVC%.

**STUDY TECHNIQUE:** Patients of neurotic disorder, diagnosed by psychiatry department, who have dyspnoea, who attend our pulmonary lab, and who satisfy our inclusion criteria for the study are properly explained about the study protocol and informed consent is taken from them. Then spirometric parameters are measured in these patients. Patients of dyspnoea, who are referred to

our pulmonary lab for pulmonary function test from departments other than psychiatry, are taken as control group. They are properly informed about our study protocol and informed consent is taken from them.

**STUDY TOOLS:** Spirometry is done by a portable spirometer (HELIOS 702)

**DATA ANALYSIS:** Data is recorded in MS excel sheet and appropriate statistical methods are applied for the analysis.

**Results and Analysis**

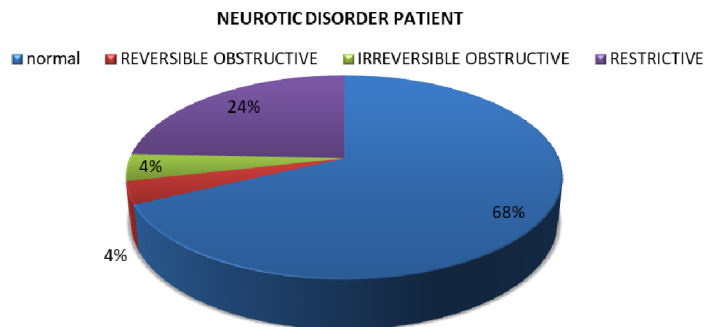
Spirometry is done in patients of case & control groups. Then the results are divided into normal, reversible obstruction, irreversible obstruction and restrictive pattern. Then we compare the results to determine the difference in prevalence of different patterns in both the groups.

**Table 1: Shows the comparison of spirometric parameters between cases and control**

	SL. NO.	N	Mean	Std. Deviation	Std. Error Mean	p-value
FVC(L)	control	140	2.20	.737	.062	.984
	case	140	2.20	.650	.055	
% of PREDICTED FVC	control	140	84.20	21.75	1.83	.208
	case	140	87.25	18.5	1.56	
FEV1 (L)	control	140	1.71	.68	.06	.270
	case	140	1.79	.55	.05	
% of FEV1/FVC	control	140	76.53	12.8	1.08	.000
	case	140	82.08	9.755	.82	

Here we can see that there is no significant difference in the measured spirometric parameters of

both the groups except FEV1/FVC%.



**Figure 1: Shows the distribution of cases according to the spirometric pattern.**

Normal- 95(67.85%)  
 Reversible obstruction- 5(3.57%)  
 Irreversible obstruction-6(4.28%)  
 Restrictive- 34(24.28%)

32.14% of patients with neurotic disorder have either obstructive or restrictive lung disease. Among this restrictive lung disease is 75.55%.

Result of patients from departments other than psychiatry

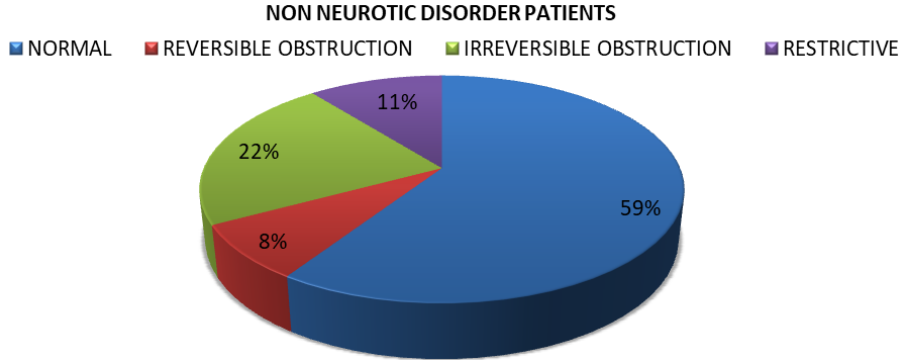


Figure 2: Shows the distribution of control according to the spirometric pattern.

Normal-83(%)  
 Reversible obstruction -11  
 Irreversible obstruction -31

Restrictive-15  
 40.71% of patients have either obstructive or restrictive lung disease. Among them restrictive lung disease is 26.31%.

Table 2: Shows the comparison of presence of reversible obstructive spirometric pattern between cases and control.

			control	case	p-value
REVERSIBLE OBSTRUCTIVE	absent	Count	129	135	>0.05
		% within subjects	92.1%	96.4%	
	present	Count	11	5	>0.05
		% within Subjects.	7.9%	3.6%	

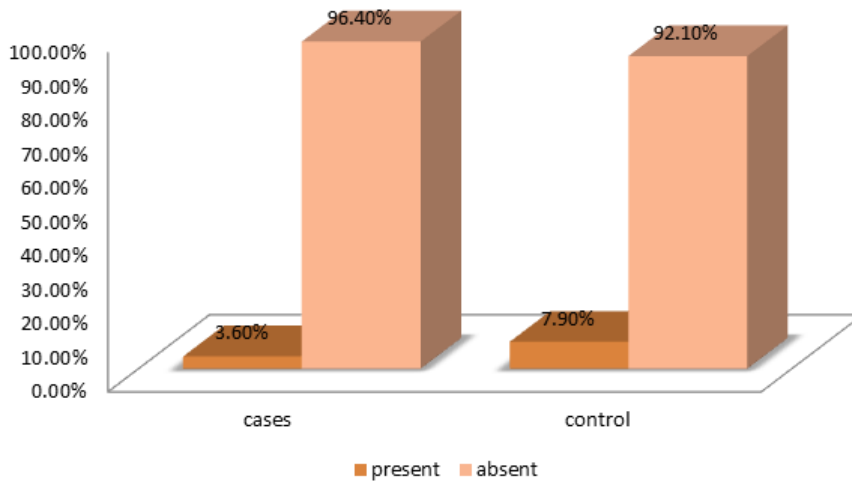
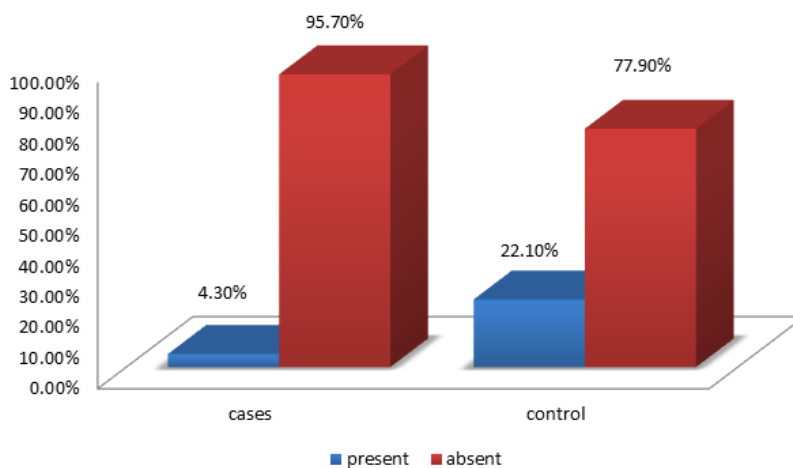


Figure 3: Shows the distribution of presence and absence of reversible obstructive spirometric pattern in cases and control

Table-2 and figure-3 shows that presence of reversible spirometric pattern is less in cases than that of the control but that change is not significant (p>0.05)

**Table 3: Shows the comparison of presence of irreversible obstructive spirometric pattern between cases and control.**

			SL. NO.		p-value
			Control	case	
IRREVERSIBLE OBSTRUCTIVE	absent	Count	109	134	0.001
		% within subjects	77.9%	95.7%	
	present	Count	31	6	0.001
		% within SL. NO.	22.1%	4.3%	

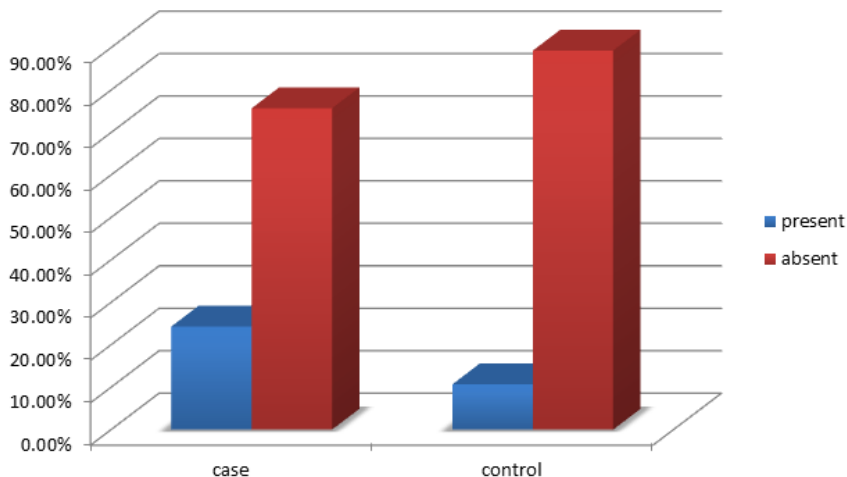


**Figure 4: Shows the distribution of presence and absence of irreversible obstructive spirometric pattern in cases and control**

Table 3 and and figure 4 shows that among irreversible obstructive pattern than that of the cases. the control there is significantly ( $p < 0.001$ ) more

**Table 4: Shows the comparison of presence of restrictive spirometric pattern between cases and control**

			control	case	p-value
RESTRICTIVE	absent	Count	125	106	<0.05
		% within subjects	89.3%	75.7%	
	present	Count	15	34	0.003
		% within Subjects	10.7%	24.3%	



**Figure 5: Shows the distribution of presence and absence of restrictive spirometric pattern in cases and control**

Table-4 and figure-5 shows that among the cases restrictive spirometric pattern is significantly ( $p < 0.03$ ) more than that of the control.

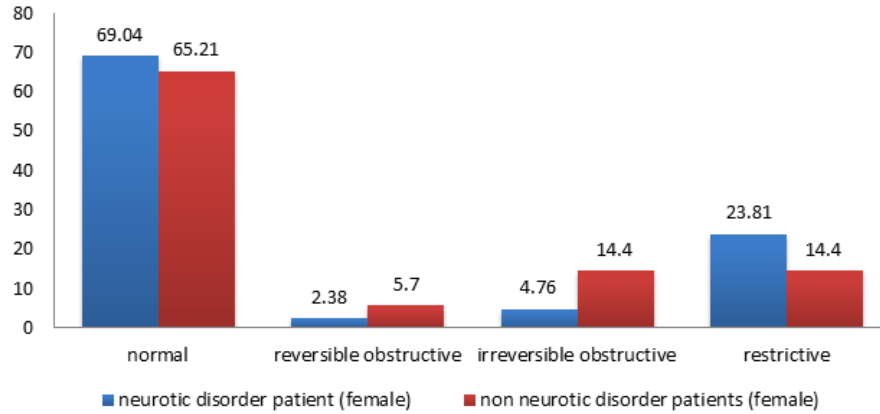


Figure 6: Distribution of spirometric pattern results in female patients from both case and control group

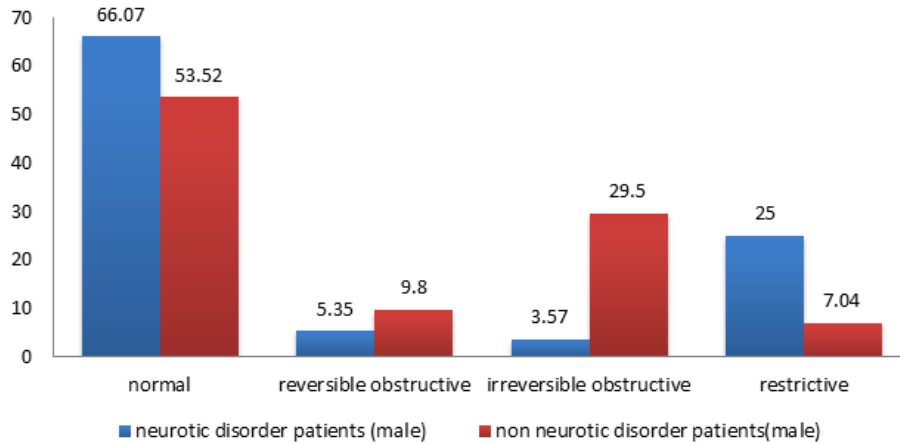


Figure 7: Shows the distribution of spirometric pattern in male patients from both groups

Figure-6 and figure-7 shows that both among the cases and control in both sexes normal spirometric pattern is more than the other spirometric pattern {**Female neurotic disorder** [Normal-69.04%, Reversible obstruction- 2.38%, Irreversible obstruction- 4.76%, Restrictive- 23.81%] **Female non neurotic disorder** [Normal-65.21%, Reversible obstruction- 5.7%,

Irreversible obstruction-14.4%, Restrictive- 14.4%] **Male neurotic disorder** [Normal-66.07%, Reversible obstruction- 5.35%, Irreversible obstruction-3.57%, Restrictive- 25%] **Male non neurotic disorder**- [Normal-53.52%, Reversible obstruction- 9.8%, Irreversible obstruction-29.5%, Restrictive- 7.04%]}

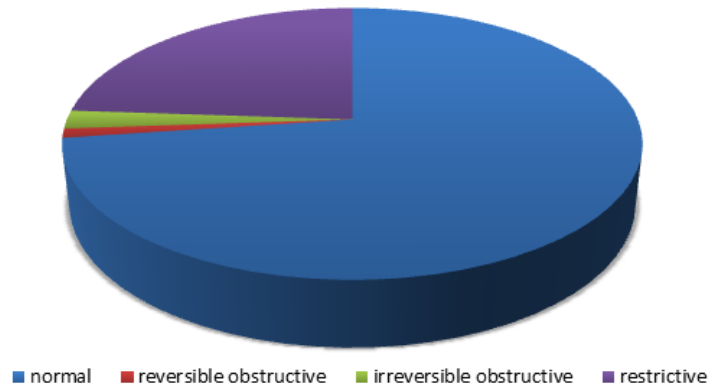


Figure 8: Distribution of spirometric pattern in patients below 40 years (neurotic disorder)

Figure -8 shows that normal spirometric pattern is more [Normal-67 (72.8%) Reversible obstruction- 1 (1.08%), Irreversible obstruction-2 (2.17%), Restrictive- 22 (23.9%)] in cases below 40 years.

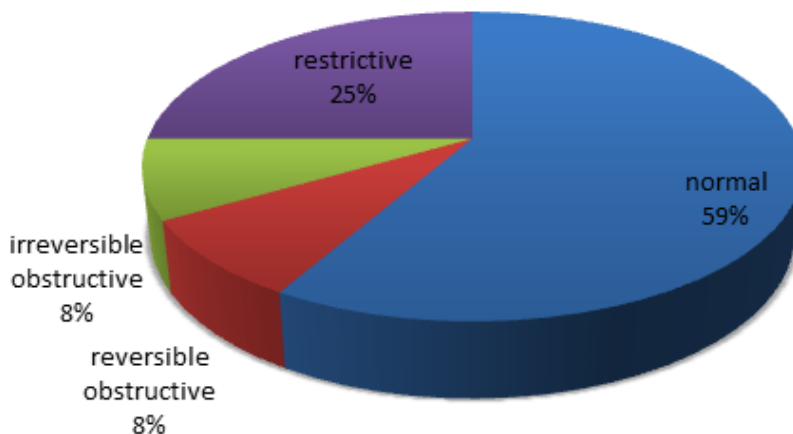


Figure 9: Shows the distribution of spirometric pattern in cases aged above 40 years

Figure 9 shows the following distribution of spirometric pattern in cases above 40 years Normal-28 (58.3%), Reversible obstruction- 4 (8.3%), Irreversible obstruction-4 (8.3%) Restrictive- 12 (25%)

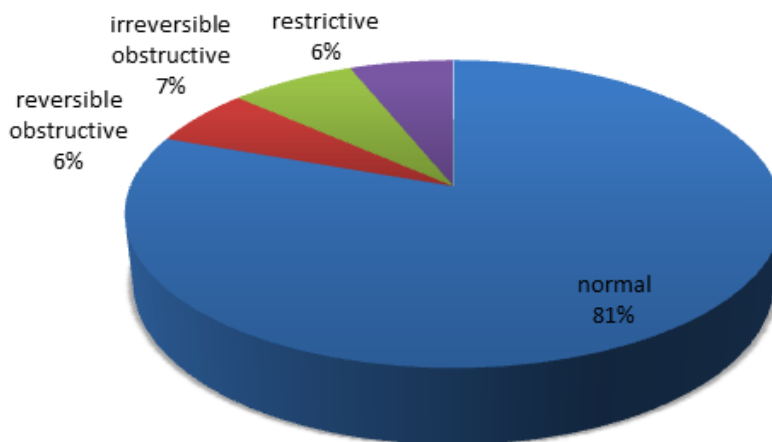


Figure 10: Distribution of results in non neurotic disorder patients aged below 40 years

Normal-66 (80.48%), Reversible obstruction- 5 (6.09%), Irreversible obstruction-6 (7.3%), Restrictive- 5 (6.09%)

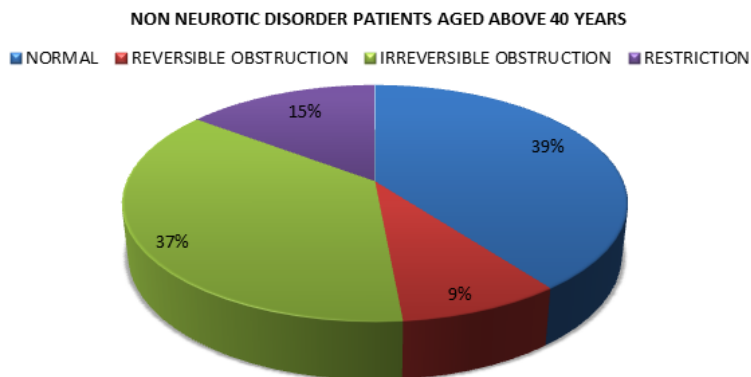


Figure 11: Distribution of results in non neurotic disorder patients aged above 40 years

Normal-27 (39.7%), Reversible obstruction- Restrictive- 10 (14.7%)  
 6(8.8%), Irreversible obstruction- 25(36.7%),

**Table 5: Shows the comparison of spirometric parameters in different age groups of females between cases and controls**

SEX	age group		SL. NO.	N	Mean	Std. Deviation	Std. Error Mean	P-value
female	≤40 yrs	FVC(L)	Control	41	2.10	.483	.075	.161
			Case	60	1.97	.417	.054	
		% of PREDICTED FVC	Control	41	91.61	19.92	3.1	.622
			Case	60	89.60	20.10	2.5	
		FEV1 (L)	Control	41	1.69	.47	.07	.727
			Case	60	1.67	.34	.04	
	% of FEV1/FVC	Control	41	80.68	10.76	1.67	.028	
		Case	60	84.96	8.4	1.09		
	>40 yrs	FVC(L)	Control	28	1.57	.515	.097	.319
			Case	24	1.70	.388	.079	
		% of PREDICTED FVC	Control	28	77.57	23.3	4.4	.174
			Case	24	85.50	17.01	3.5	
		FEV1 (L)	Control	28	1.26	.46	.09	.382
			Case	24	1.36	.37	.08	
% of FEV1/FVC	Control	28	80.06	10.96	2.07	.744		
	Case	24	79.13	9.42	1.92			

**Table 6: Shows the comparison of spirometric parameters in different age groups of male between cases and controls**

SEX	age group		SL. NO.	N	Mean	Std. Deviation	Std. Error Mean	p-value
male	≤40 yrs	FVC(L)	control	29	2.91	.722	.134	.344
			case	32	2.74	.680	.120	
		% of PREDICTED FVC	control	29	89.69	20.02	3.7	.508
			case	32	86.53	17.02	3.0	
		FEV1 (L)	control	29	2.3	.69	.12	.862
			case	32	2.35	.61	.10	
	% of FEV1/FVC	control	29	79.5	11.94	2.19	.040	
		case	32	84.7	5.7	.91		
	>40 yrs	FVC(L)	control	42	2.22	.66	.1	.077
			case	24	2.52	.63	.13	
		% of PREDICTED FVC	control	42	77.60	20.8	3.2	.208
			case	24	84.08	18.2	3.7	
		FEV1 (L)	control	42	1.56	.658	.11	.142
			case	24	1.77	.48	.09	
% of FEV1/FVC	control	42	67.8	12.86	1.98	.047		
	case	24	74.17	12.8	2.63			

## Discussion

The present study showed that there is a significant difference in percentage of predicted value of FEV1/FVC% between cases and control. In case the mean value of percentage of predicted of FVC were 87.25 and mean observed value of FVC and FEV1 were 2.2 L and 1.79 L respectively. In control population the mean value of percentage of predicted of FVC were 84.20 and mean observed value of FVC and FEV1 were 2.2 L and 1.71 L respectively.

Another study by Islam et al also investigated other varieties of depressive illness including small number of MDD patients and found significant decreased lung function compared to control<sup>5</sup>.

The present result correlates with the study Khandaker Nadia Afreen et al<sup>6</sup>, who found very high abnormal lung function in MDD patients. In their study, among 60 newly diagnosed MDD patients, only 6(10%) patients had normal and 54 (90%) patients had abnormal lung function. It is noteworthy that majority of the patients suffered from restricted type of disorder and small percentage of patients were presented with irreversible obstructive disorder and in some patients there were coexistence of both abnormalities. These results corroborate with the other study<sup>6,7</sup>.

We found that the overall abnormal spirometric patterns were more in control group. It was 40.7% in control and 32.1% in case. The results, when compared, it was seen that the number of both reversible and Irreversible obstructive pattern is more in control group than case. But the restrictive pattern was more in case than control. It was 24.28% in case and 10.71% in control which was significantly high. All these patients with obstructive disorder had small airway obstruction according to spirometer.

Kupfer Et al<sup>8</sup> shows, apparent impact of neurotic disorder on poor lung functioning may be explained by the reduced psychomotor activity along with poor respiratory muscle strength in depressive illness.

Our study also showed the spirometry in different age groups of the study subjects which was not explored by the other previous study. Distribution of results of both patients group aged 40 years or below and above 40 years shows that restrictive pattern is

more common than control population of the same age group, and reversible and irreversible obstructive patterns are more common in control population of this age group.

In case of female patients aged 40years or below from both groups shows that the control population have more reversible and irreversible obstructive pattern. Restrictive pattern is more common in case population.

In female patients aged above 40years from both case and control groups shows that the control population have more irreversible obstructive pattern than case. Reversible obstructive patterns are more common in case population. Restrictive pattern is same in both the groups.

In male patients, both age group of below and above 40years shows that the control population have more reversible and irreversible obstructive pattern and restrictive pattern is more common in case population.

To our knowledge, five large epidemiologic studies to date have attempted to examine associations between lung function and depressive symptoms. The first two studies focused on risk and prevalence of depression in the presence of chronic lung disease. Findings from Bisschop et al suggest that chronic lung disease is associated with increased risk of depression over 3 years of followup; however they reported no association of incident lung disease and CES-D<sup>9</sup>. These findings may suggest that the association of chronic lung disease and depression is more important over a longer time period, which is in agreement with our evidence for an association in "healthy" adults of depression and pulmonary function measures earlier in the CLD disease process.

NIH-PA Author Manuscript studies have assessed lung function and mental health<sup>10,11</sup> [26, 27 p3] but only one was performed in a sample representative of the general population<sup>10</sup> [27p3]; this study reported that asthma and chronic bronchitis were associated with mental health problems but objective lung function assessed by spirometry was only associated with anxiety<sup>10</sup> [27p3]. The final study was conducted in a population of adults who had served in Vietnam<sup>7</sup> [26]; generalized anxiety disorder and major depressive disorder was associated with

poor lung function; however, only generalized anxiety disorder remained significant after adjustment for covariates.

Our study shows that the prevalence of restrictive spirometric pattern is high in patients of neurotic disorder. This restrictive spirometric pattern may be due to decreased psychomotor activity.

Limitation of the study:

1. The sample size is less.
2. It is an observational cross-sectional study not a follow up study.
3. Different categories of neurotic disorder patients were included in this study but as our sample size is less the comparison of lung function between the different categories of neurotic disorder were not done.

### Conclusion

Overall, our results suggest that neurotic disorder may play a role in the chronic lung disease process, and that sex and age play a role. If this association is replicated in other studies, it would be very interesting to evaluate whether improvement in mental status would translate into improvement in pulmonary function. That is why each neurotic disorder patient with dyspnoea should undergo spirometry screening.

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# Relationship between Cellphone Screen Time (Including Social Media apps like Whatsapp, Instagram, Facebook) and its Effect on Sleep Quality in Medical UG Students

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## Abstract

**Background:** Over half of the population in most nations uses mobile phones, and the mobile phone market is expanding rapidly. The amount of time spent using a screen-enabled device like a smartphone, computer, television, or video game console is known as screen time. In addition, increased screen time has also been quite prevalent amongst medical students due to the recent trend of screen-based readings and various other reasons.

**Aims & Objectives:** To demonstrate that medical undergraduate students suffer from poor-quality sleep as a result of excessive screen time.

**Methodology:** A cross sectional study was conducted among 279 medical UG (Undergraduate) students of BJ Medical College from August 2021 to September 2022.

**Results:** There was a positive correlation between MRSRF (Mobile Related Sleep Risk Factors Questionnaire) factors like "screen usage time", "time spent on social media", "duration of mobile use after lights have been turned off", "keeping mobile phone near pillow/bed while sleeping" and sleep parameters (PSQI components) like daytime dysfunction, sleep disturbance, sleep latency and worsening of subjective sleep quality and this correlation was statistically significant.

**Conclusion:** Total screen time, time spent on social media, duration of mobile use after lights have been turned off, and keeping a mobile phone on the bed and near the pillow while sleeping worsens the quality of sleep and also leads to daytime dysfunction, sleep disturbance, sleep latency, and worsening of subjective sleep quality.

**Keywords:** Screen time, Sleep Quality, Social media, Mobile use.

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## Introduction

Nowadays, mobile phones also known as cell phones are essential to modern communication and widely used by more than half of the population globally. The amount of time spent using a screen-enabled device like a smartphone, computer, television, or video game console is known as screentime<sup>[1]</sup>. Studies indicate screen time has a direct impact on mental and physical health.<sup>[2]</sup>

While using electronic devices before bed is common, research shows that these devices can disrupt sleep by suppressing melatonin production (natural hormone facilitating sleep) and causing neurophysiological arousal, which keeps individuals alert when they should be relaxing.<sup>[3]</sup>

Adults in good health have a 24-hour sleep-wake cycle in their bodies. Melatonin, a natural hormone secreted by pineal gland that causes feelings of drowsiness, is released into the body after sunset. Short-wavelength enriched light, also known as blue light, is produced by electronic back-lit devices like computers, tablets, readers, and phones. Blue light from fluorescent and LED lights has also been shown to reduce or delay the natural production of melatonin at night. Blue light can also shorten the amount of time you spend in slow-wave and rapid-eye-movement (REM) sleep, which is critical for cognitive function. In addition, increased screen time has also been quite prevalent amongst medical students due to the recent trend of screen-based readings and various other reasons.

**Aims & Objectives:** To demonstrate that medical undergraduate students suffer from poor-quality sleep as a result of excessive screen time.

While many studies have investigated the general population's screen time and sleep quality, there is a specific need to focus on medical students due to their unique lifestyle, stress levels, and academic pressures. These factors can amplify the effects of screen time on sleep quality. This study aims to provide a detailed analysis of various screen-related behaviours and their specific impacts on different aspects of sleep quality among medical students.

**Methodology:** A cross sectional study was conducted among 279 UG (Undergraduate) students of Medical College at Ahmedabad, Gujarat from September 2021 to March 2022. Subjects who had been

diagnosed with sleep disorder, any chronic physical or mental illness affecting sleep, using psychotropic drugs/sedatives, consuming caffeine, alcohol/any other substance on regular basis were excluded from study. While, we included UG medical students of > 18 years, studying in Medical College at Ahmedabad, Gujarat, using mobile phones for educational, social & entertainment purposes, who are generally healthy and devoid of any chronic medical/ psychological conditions that affect sleep.

After a consent form, the participants filled a semi-structured proforma, followed by PSQI (Pittsburgh Sleep Quality Index), MRSRF (Mobile related sleep risk factors questionnaire).

The PSQI includes a scoring key for calculating a patient's seven subscores, each of which ranges from 0 to 3.<sup>[4]</sup> 0 score indicates no difficulty and 3 indicates severe difficulty.

The 7 component scores are then added to make a global score with a range of 0– 21.

- 0 means no difficulty.
- 5 or more indicates poor sleep quality.
- 21 means severe difficulties in all areas. (The higher the score, the worse the quality).

### MOBILE-RELATED SLEEP RISK FACTOR QUESTIONNAIRE (MRSRF)<sup>[5]</sup>:

MRSRF Questionnaire includes seven items that focus on the following areas: Total duration of mobile use/day, hours spent on social media apps/day, using mobile while in bed after the lights have been turned off, using blue light filters on mobile, keeping the mobile on the bed and near pillow while sleeping, keeping the mobile 2 meters away from the bed while sleeping and putting the mobile on airplane mode while sleeping.

Data analysis:

Data analysis were performed using SPSS version 22. Categorical data was represented in the form of Frequencies and proportions. The chi-square test was used as a test of significance for qualitative data. P value (Probability that the result is true) of <0.05 was considered statistically significant after assuming all the rules of statistical tests. As data were not normally distributed, Non-Parametric tests in form of the Wilcoxon-Mann-Whitney Test were used

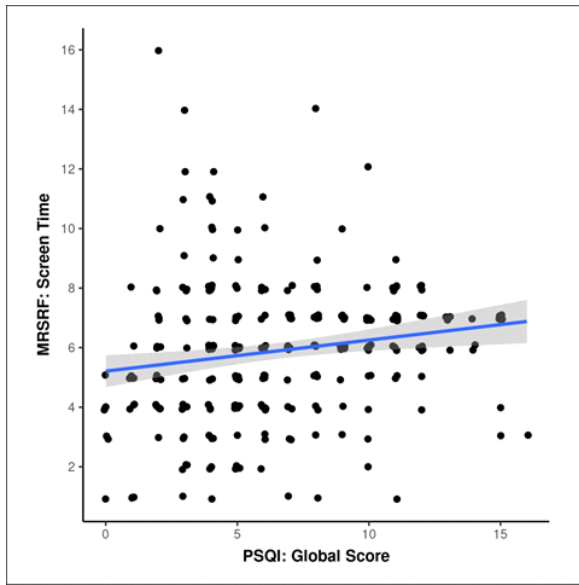
to compare the two groups for statistical inference and Non-parametric tests like Spearman Correlation was used to explore the correlation between the two variables.

## Results

**Table 1: Association between PSQI Global Score Category and Parameters**

Parameters	PSQI Global Score Category		p value
	<5(Normal sleep quality) (n = 100)	≥5(Poor Sleep Quality) (n = 179)	
Age (Years)	21.06 ± 1.83	21.22 ± 1.72	0.454 <sup>1</sup>
Gender			0.304 <sup>2</sup>
Male	60 (60.0%)	96 (53.6%)	
Female	40 (40.0%)	83 (46.4%)	
Year of MBBS			<0.111 <sup>2</sup>
First Year	26 (26.0%)	41 (22.9%)	
Second Year	9 (9.0%)	46 (25.7%)	
Third Year	10 (10.0%)	37 (20.7%)	
Final Year	55(55.0%)	55(30.7%)	
PSQI: 1*** (Subjective sleep quality)	0.49 ± 0.50	1.50 ± 0.71	<0.001 <sup>1</sup>
PSQI: 2*** (Sleep Latency)	0.64 ± 0.66	1.97 ± 0.94	<0.001 <sup>1</sup>
PSQI: 3*** (Sleep Duration)	0.68 ± 0.60	1.50 ± 0.90	<0.001 <sup>1</sup>
PSQI: 4*** (Habitual Sleep Efficiency)	0.12 ± 0.48	0.47 ± 0.80	<0.001 <sup>1</sup>
PSQI: 5*** (Sleep Disturbances)	0.46 ± 0.52	0.98 ± 0.37	<0.001 <sup>1</sup>
PSQI: 6 (Use of sleep medications)	0.00 ± 0.00	0.00 ± 0.00	—
PSQI: 7*** (Daytime Dysfunction)	0.31 ± 0.61	2.15 ± 1.36	<0.001 <sup>1</sup>
PSQI: Global Score***	2.68 ± 1.29	8.70 ± 2.86	<0.001 <sup>1</sup>
MRSRF: Screen Time***	5.62 ± 2.88	6.04 ± 1.94	0.015 <sup>1</sup>
MRSRF: Time on Social Media***	1.94 ± 1.25	2.39 ± 1.58	0.002 <sup>1</sup>
MRSRF: Mobile Phone Useage After Light-Out (Yes)	77 (77.0%)	153 (85.5%)	0.074 <sup>2</sup>
MRSRF: Duration of Mobile Phone Useage After Light-Out***	46.36 ± 32.07	74.97 ± 44.66	<0.001 <sup>1</sup>
MRSRF: Mobile Near Bed While Sleeping (Yes)***	69 (69.0%)	150 (83.8%)	0.004 <sup>2</sup>
MRSRF: Mobile 2 Metres Away While Sleeping (Yes)***	29 (29.0%)	31 (17.3%)	0.023 <sup>2</sup>
MRSRF: Airplane Mode While Sleeping (Yes)	16 (16.0%)	22 (12.3%)	0.386 <sup>2</sup>
MRSRF: Blue Light Filters Used (Yes)***	58 (58.0%)	77 (43.0%)	0.016 <sup>2</sup>

**\*\*Significant at  $p < 0.05$ , 1: Wilcoxon-Mann-Whitney U Test, 2: Chi-Squared Test, 3: Fisher's Exact Test.** The following variables were significantly associated ( $p < 0.05$ ) with the variable 'PSQI Global Score Category': PSQI: 1(Subjective Sleep Quality), PSQI: 2(Sleep Latency), PSQI: 3(Sleep Duration), PSQI: 4 (Habitual Sleep Efficiency), PSQI: 5(Sleep Disturbances), PSQI: 7(Daytime Dysfunction), PSQI: Global Score, MRSRF: Screen Time, MRSRF: Time on Social Media, MRSRF: Duration of Mobile Phone Usage After Light-Out, MRSRF: Mobile Near Bed While Sleeping, MRSRF: Mobile 2 Metres Away While Sleeping, MRSRF: Blue Light Filters Used. [Table 1]



**Figure 1: Correlation between “PSQI: Global Score” and “MRSRF: ScreenTime” (n = 279)**

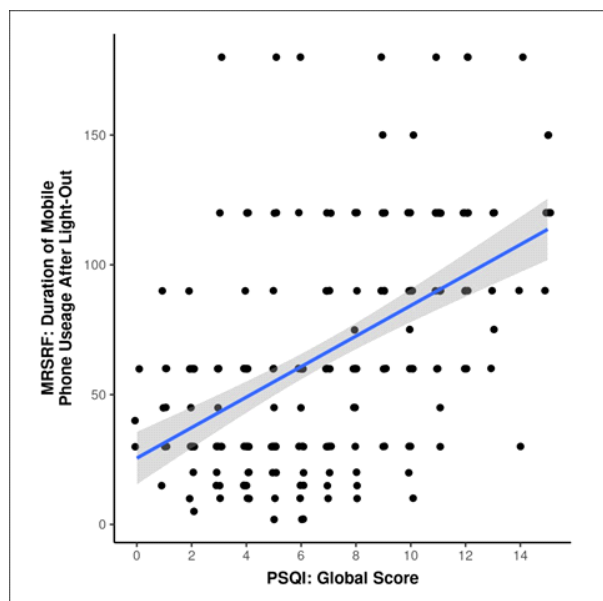
The above scatterplot depicts the correlation between “PSQI: Global Score” and “MRSRF: Screen Time”. Individual points represent individual cases. The blue trendline represents the general trend of correlation between the two variables. The shaded grey area represents the 95% confidence interval of this trendline.

Non-parametric tests (Spearman Correlation) were used to explore the correlation between the two variables, as at least one of the variables was not normally distributed. There was a weak positive correlation between “PSQI: Global Score” and “MRSRF: Screen Time” and this correlation was statistically significant ( $\rho = 0.25, p = < 0.001$ ). For every 1 unit increase in MRSRF: Screen Time, the PSQI: Global Score increases by 0.27 units. [Figure 1]

**Table 2: Odds Ratios and Relative Risk**

Predictor/Risk Factor	Outcome	Odds Ratio (95% CI)	Relative Risk (95% CI)
MRSRF: Mobile Phone Usage After Light-Out: Yes	PSQI Global Score Category: <5	0.57 (0.3-1.06)	0.71 (0.52-1.04)
MRSRF: Mobile Phone Usage After Light-Out: Yes*	PSQI Global Score Category: ≥5	1.76 (0.94-3.28)	1.25 (0.98-1.71)
MRSRF: Mobile Phone Usage After Light-Out: No	PSQI Global Score Category: <5	1.76 (0.94-3.28)	1.4 (0.97-1.94)
MRSRF: Mobile Phone Usage After Light-Out: No	PSQI Global Score Category: ≥5	0.57 (0.3-1.06)	0.8 (0.58-1.02)

\*As shown above, there is significant association between the two variables, with increased odds of poor sleep quality on using a cellphone after lights have been turned out. [Table 2]



**Figure 2: Correlation between “PSQI: Global Score” and “MRSRF:Duration of Mobile Phone Usage After Light-Out” (n = 230)**

The above scatterplot depicts the correlation

between “PSQI: Global Score” and “MRSRF: Duration of Mobile Phone Usage After Light-Out”. Individual points represent individual cases. The blue trendline represents the general trend of correlation between the two variables. The shaded grey area represents the 95% confidence interval of this trendline. Non-parametric tests (Spearman Correlation) were used to explore the correlation between the two variables, as at least one of the variables was not normally distributed. There was a moderate positive correlation between “PSQI: Global Score and MRSRF: Duration of Mobile Phone Usage After Light-Out”, and this correlation was statistically significant ( $\rho = 0.5, p = <0.001$ ).

For every 1 unit increase in “MRSRF: Duration of Mobile Phone Usage After Light-Out”, the “PSQI: Global Score” increases by 0.04 units. Hence, as the duration of mobile phone usage (screentime) after lights have been turned off increased, the quality of sleep worsened. [Figure 2]

**Table 3: Correlation of various sleep parameters with “Mobile related sleep risk factors”**

		Daytime Dysfunction (PSQI 7)	Sleep disturbance (PSQI 5)	Sleep Latency (PSQI 2)	Worsening of subjective sleep quality (PSQI 1)
Screen Usage time	Spearman Correlation Coefficient=	0.1	0.2	0.3	0.3
	P Value=	0.019	0.002	<0.001	<0.001
Time on social media	Spearman Correlation Coefficient=	0.2	0.2	0.4	0.3
	P Value=	0.009	0.001	<0.001	<0.001
Duration of mobile use after lights have been turned off	Spearman Correlation Coefficient=	0.2	0.3	0.5	0.5
	P Value=	<0.001	<0.001	<0.001	<0.001
Mobile phone on bed and near pillow while sleeping	Point- Biserial Correlation Coefficient=	0.13	0.14	0.32	0.23
(Yes, No)	P Value=	0.007	0.017	<0.001	<0.001

There was a positive correlation between mobile related risk factors and sleep parameters as above

mentioned and this correlation was statistically significant. As mobile related risk factors like (1)

screen usage time, (2) time spent on social media, (3) duration of mobile use after lights have been turned off, (4) keeping a mobile phone on the bed and near the pillow while sleeping : got increased, there was an increase in sleep parameters like (1)daytime sleepiness, (2)sleep disturbance, (3)sleep latency, and (4)worsening of subjective sleep quality. [Table 3]

There was a positive correlation between mobile related risk factors and sleep parameters as above mentioned and this correlation was statistically significant. Also, as mentioned in “figure 1” for every 1 hour (1 unit) increase in screen-time , the quality of sleep declined by 27% (0.27 units).

### Discussion

Over the past few decades, there has been an increase in sleep issues among adults and adolescents. This is concerning since sound physical, cognitive, and psychological growth depends on getting enough sleep. Research has focused more and more on the function of electronic media usage in identifying risk factors for sleep issues and has discovered shorter sleep durations with more amounts of screen time spent.<sup>[6]</sup> In this study, the median screen time(hours) was 6 hours, while in a study conducted by Yeluri et al the median screen time averaged 5.13 hours<sup>[7]</sup>. In a study done by Baby et al, the same was 5.25 hours.<sup>[8]</sup>

There are many longitudinal studies which shows the long term impact of screen usage on sleep quality. Such as longitudinal study by Twenge et al (2018) found that increased screen time over several years is associated with a gradual decline in sleep duration and quality among adolescents.<sup>[12]</sup> Another research done by King et al (2019) followed adults over five years and found that those with higher screen time had more significant sleep disturbances and reduced sleep efficiency over time.<sup>[13]</sup> These studies indicate that the long-term impact of screen time on sleep quality can be substantial, reinforcing the importance of managing screen usage to maintain good sleep health.

In present study, about 82.4% of participants reported of using cellphone, after lights have been turned off, while an almost consistent finding was found in a similar study by Rafique et al, where about 88.7% of participants reported the same use.<sup>[5]</sup> In this

study, 35.8% of the participants had PSQI Global Score Category: <5(Normal sleep quality) while, 64.2% of the participants had PSQI Global Score Category: ≥5(Poor sleep quality). The findings were close to a study done by Akcay et al, where 66.6% of adolescent participants had poor sleep quality<sup>[9]</sup>. A study by Baby et al, where 66% of engineering students had poor sleep quality.<sup>[8]</sup>

With respect to sleep quality (PSQI Global Score-Category), there was a significant difference between the 2 groups in terms of “screen time” ( $W = 7389.500$ ,  $p = 0.015$ ), with the median screen time being highest in the group with poor sleep quality(  $\geq 5$ ), but there was only weak positive correlation between the two. An almost similar finding was present in study conducted by Rafique et al, where screen usage time of >8 hours was positively but weakly correlated with sleep disturbances and a decrease in the length of actual sleeping time (P value 0.023 and 0.022, respectively).<sup>[5]</sup>

There was a significant difference between the 2 groups in terms of “Duration of Mobile Phone Usage After lights have been turned out” ( $W = 3632.500$ ,  $p = <0.001$ ), with the median “Duration of Mobile Phone Usage After Light-Out” being highest in the group with poor sleep quality ( $\geq 5$ ). There were increased odds of poor sleep quality on using a cell phone after lights have been turned out. Also, there was a moderate positive correlation between, the “Duration Of Mobile Phone Usage After Lights have been turned out” and poor sleep quality and this correlation was statistically significant ( $\rho = 0.5$ ,  $p = <0.001$ ). This finding has been consistent with many similar studies like, a Study by Yeluri et al, bedtime gadget use had a significant adverse relationship with sleep quality, quantity, and time taken to fall asleep (sleep latency).<sup>[7]</sup>

As per a study conducted by Rafique et al, using a mobile after the lights have been turned off for at least 30 minutes (without a blue light filter in the mobile) showed a positive but weak correlation with daytime sleepiness, sleep disturbances and increased sleep latency ( $p = 0.003$ ,  $0.004$  and  $0.001$ ).<sup>[5]</sup> As per a study conducted by Alshobaili et al, as the time of smartphone usage at bedtime increased, the quality of sleep worsened.<sup>[10]</sup>

There was a significant difference between the various groups in terms of distribution of “MRSRF: Mobile On The Bed And Near The Pillow, While Sleeping” ( $\chi^2 = 8.324$ ,  $p = 0.004$ ). There were increased odds of poor sleep quality on keeping cell phones on the bed and near the pillow while sleeping. This finding was consistent with another quite resembling study conducted by Rafique et al, where keeping the mobile near the pillow while sleeping was positively but weakly correlated with daytime sleepiness, sleep disturbances, and increased sleep latency ( $p = 0.003$ ,  $0.004$  and  $0.001$ ) and hence poor sleep quality.<sup>[5]</sup>

Mobile use and sleep-related parameters- In the present study, there was a positive correlation between MRSRF (Mobile Related Sleep Risk Factors Questionnaire) factors like “screen usage time”, “time spent on social media”, “duration of mobile use after lights have been turned off”, “keeping the mobile phone on the bed and near the pillow, while sleeping” and sleep parameters (PSQI components) like daytime sleepiness, sleep disturbance, sleep latency and worsening of subjective sleep quality and this correlation was statistically significant. Also in research done by Demirci et al, quite close results were obtained where, the smartphone use severity was positively correlated with PSQI global scores ( $r = 0.156$ ,  $p = 0.014$ ), and PSQI components like subjective sleep quality ( $r = 0.138$ ,  $p = 0.030$ ), sleep disturbance ( $r = 0.153$ ,  $p = 0.016$ ), and the daytime dysfunction ( $r = 0.244$ ,  $p < 0.001$ ).<sup>[11]</sup>

### Conclusion

Total screen time, time spent on social media, duration of mobile use after lights have been turned off, and keeping a mobile phone on the bed and near the pillow while sleeping worsens the quality of sleep and also leads to daytime dysfunction, sleep disturbance, sleep latency, and worsening of subjective sleep quality. Using a blue light filter while sleeping seemed to have some protective effect as a larger proportion of participants in the group with normal sleep quality reported of using the blue light filter, while those in the group with poor sleep quality denied using it. Interventions to reduce screen time, particularly before bed, and to educate students about the importance of sleep hygiene are essential to improve their overall health and academic performance.

**Ethical Clearance:** Above study had been given Ethical Clearance by below mentioned Ethical Committee.

Name: The Institutional Ethics Committee, B.J. Medical College & Civil Hospital, Ahmedabad. Date: 28-08-2021, Number :185/2021

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# A Study of Pituitary Macroadenoma Transnasal Endoscopic Excision

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## Abstract

**Background:** Pituitary macroadenomas are typically benign tumors over 10mm in size, originating from glandular tissue in the pituitary gland. Understanding tumor consistency is crucial for determining the surgical approach. Imaging, especially MRI, helps assess tumor size, extent, and consistency, which influence the ease of resection, success, and complication risks.

**Aim:** To study the presentation, radiological evaluation, surgical technique, complication and management of pituitary macroadenoma.

**Materials and Methods:** This observational study was conducted at a tertiary care hospital in Chennai from March to September 2016, involving 28 patients with pituitary macroadenomas. Data on demographics, tumor type, presentation, consistency (from MRI T2-weighted images), intraoperative findings and complications, along with their management were collected and analyzed using descriptive statistics.

**Results:** Of the 28 cases, 17(60.7%) were nonsecretory, and 11(39.3%) were secretory. Common symptoms included headaches (71.4%) and visual defects (42.8%). MRI revealed 46.4% of tumors were solid, 35.7% semisolid, and 17.9% cystic, with 50% extending to the suprasellar region. Surgical findings indicated that most solid tumors (92.3%) were firm, 60% of semisolid tumors were soft and 40% were firm, while cystic consistency matched MRI predictions. The most common postoperative complication was diabetes insipidus in 3 cases (10.7%).

**Conclusion:** Pituitary macroadenomas were most common in the 5th decade. Nonsecretory tumors were more common, particularly in females, while secretory tumors were more prevalent in males. MRI was useful tool in predicting tumor consistency, and the transsphenoidal endoscopic approach was effective for removing cystic and soft macroadenomas.

**Key Words:** Pituitary Macroadenoma, Magnetic Resonance Imaging, Transnasal endoscopic excision

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## Introduction

Pituitary adenomas (PA) are tumors from hormone-secreting cells of the pituitary gland. Most are benign, with 35% being invasive and only 0.1%-0.2% classified as carcinomas.<sup>1</sup> They account for 10%-25% of intracranial tumors<sup>2</sup>, with a prevalence of 16.7%<sup>3</sup> based on meta-analysis. In Istanbul, 32% of pituitary adenomas were microadenomas, while 68% were macroadenomas.<sup>4</sup> Gruppetta M reported macroadenoma prevalence of 32.8 per 100,000.<sup>5</sup> A study in northeastern India found pituitary adenomas mainly in young adults (mean age 38.12 years), with a female preponderance and 40.6% of PA were non-functioning.<sup>6</sup> In Rajasthan, India, the prevalence of pituitary adenoma was 10%.<sup>7</sup> Microadenomas are tumors <1 cm, confined to the sella turcica, while macroadenomas are ≥1 cm and often extend beyond it.<sup>3,8</sup> Pituitary neoplasms are classified as functional (causing hormone-related symptoms) or nonfunctional (presenting with mass effects like headaches or visual defects, or found incidentally).<sup>6,9,10</sup> MRI is crucial in pituitary adenoma surgery, assessing tumor size, extent, and consistency, which impact resection ease and complication risks. It provides detailed visualization of the mass, optic chiasm, vessels, and cavernous sinuses. Variations in signal characteristics can indicate hemorrhage, cysts, or necrosis.<sup>11</sup> Clinical knowledge of macroadenoma consistency aids in surgical planning.<sup>12</sup> The transsphenoidal approach is the preferred surgical technique for macroadenomas due to its low morbidity and mortality.<sup>13-15</sup> Complete excision depends on factors such as cavernous sinus invasion, tumor size, and consistency. The surgical goals are tumor removal, vision restoration, and preservation of pituitary function. Key challenges in treating pituitary adenomas in developing countries include low awareness, limited brain imaging facility in rural areas, poor follow-up, and financial constraints.<sup>16</sup> Patient education is essential for early detection and understanding treatment risks.<sup>17</sup> Genetic screening in sporadic cases and family members will lead to improved outcomes.<sup>18</sup>

The present study was carried out to study the presentation, radiological evaluation, surgical technique, complication and management of pituitary macroadenoma in the given setting.

## Methods and Material

This observational study was conducted at a tertiary care medical college and hospital in Chennai and data was collected from March to September 2016. Institutional ethical clearance (IEC NO-19022016) was obtained. Informed consent was obtained from the study participants. It included patients diagnosed with pituitary macroadenoma from neurology and surgical endocrinology OPDs, referred to otorhinolaryngology. Participants included those fit for surgery, newly diagnosed, and recurrent cases. Exclusion criteria were patients in poor general condition or with comorbidities unfit for surgery.

The study included 28 patients, who were recruited using a convenient sampling method. Data collected involved patient age, sex, tumor type, presentation, consistency, intensity, extension based on MRI T2 images, intraoperative findings, tumor excision, and both perioperative and postoperative complications, along with their management.

Statistical analysis: Data was coded in Excel and analyzed using EPI INFO version-7. Descriptive statistics, including mean, standard deviation, frequency, and proportion, were used to describe the study characteristics.

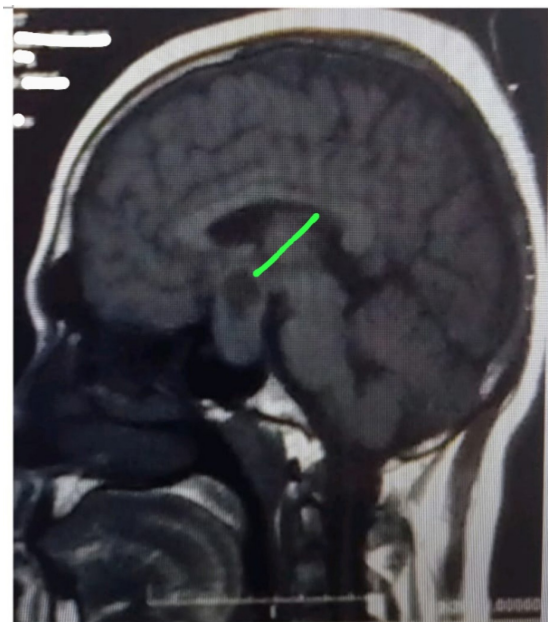
## Results

A total of 28 pituitary macroadenoma cases were studied, with participants aged 24 to 58 years (mean age 40.39 ± 10.76). Most pituitary macroadenomas were found in the 41-50 age group, accounting for 9 cases (32.14%). The study included 15 females (53.6%) and 13 males (46.4%). Of the 28 cases, 17(60.7%) were nonsecretory, while 11(39.3%) were secretory. Secretory tumors were more common in males, accounting for 7 cases (53.8%), while nonsecretory tumors were predominant in females, comprising 11 cases (73.3%) [Table-1].

MRI showed tumor intensity as hyperintense in 14 cases (50%), isointense in 8(28.6%), and hypointense in 6(21.4%). Of the 28 cases, 25(89.3%) were new and 3(10.7%) were recurrent. The most common symptom was headache (71.4%), followed by visual defects (42.8%) [Table-2].

In the MRI-weighted images, 13 tumors (46.4%) were classified as solid, 10(35.7%) as semisolid, and 5(17.9%) as cystic. Most tumor extensions occurred in the suprasellar region, with 14 cases (50%), while 7 cases (25%) showed extensions into both the suprasellar and parasellar regions. In 3 cases (10.7%), the tumors were confined to the sellar region [Table-3].

MRI image shows suprasellar extension of pituitary macroadenoma in Figure 1.



**Figure 1: MRI –Suprasellar extension of pituitary macroadenoma**

MRI revealed 10 tumors as semisolid; intraoperatively, 6(60%) were soft and 4(40%) were firm. Of the 13 solid tumors, 12(92.3%) were firm and 1(7.6%) was soft during surgery. Cystic consistency on MRI matched intraoperative findings [Table-4]. Cystic tumours were removed by suction.

Suprasellar extension on MRI matched intraoperative findings in 12 cases, while 2 cases showed lateral (parasellar) extension without carotid encasement or cavernous sinus invasion. Suprasellar and parasellar extensions were consistent in only 5 cases, with 2 cases showing discrepancies between MRI and intraoperative findings [Table-5].

Intraoperative cerebrospinal fluid (CSF) leaks were detected in six cases (21.4%) [Table-6].

Complete excision was achieved in 21 cases (75%), while 7 cases (25%) had incomplete excision. The most common postoperative complication was diabetes insipidus, occurring in 3 cases (10.7%). Additionally, one case experienced pneumoencephalocele with CSF leak, and another had a cerebrovascular accident (CVA) alongside diabetes insipidus [Table-7].

Intraoperative CSF leak repairs were performed in 6 cases, with 1 additional repair done postoperatively; a lumbar drain was placed in 1 case. Postoperative diabetes insipidus was treated with intranasal desmopressin in 3 cases, while 2 cases of CVA were managed conservatively [Table-8].

**Table 1: Age and Sex wise Distribution of Types of Pituitary Macroadenoma [n=28]**

Age Groups In Years	Type of Pituitary Macroadenoma		Total(%)
	Secretory-n(%)	Non Secretory-n(%)	
20-30	5(71.4)	2(28.6)	7(100)
31-40	2(28.5)	5(71.4)	7(100)
41-50	3(33.3)	6(66.7)	9(100)
51-60	1(20.0)	4(80.0)	5(100)
Total(%)	11(39.3)	17(60.7)	28(100)
<b>Sex</b>			
Male	7(53.8)	6(46.1)	13(100)
Female	4(26.7)	11(73.3)	15(100)
Total(%)	11(39.3)	17(60.7)	28(100)

**Table 2: Modes of Presentation of Pituitary Macroadenoma [n=28]**

Modes of Presentation*	Number of Individual-n	Percentage
Head Ache	20	71.4
Prolactinoma	05	17.8
Apoplexy	01	3.5
Visual Defects	12	42.8
Acromegaly	05	17.8
Cushings Syndrome	01	3.5

\*Multiple responses

**Table 3: Tumour Consistency and Tumour Extension Based on MRI Weighted Images[n=28]**

Tumour Consistency	Number of Individual-n	Percentage
Cystic	5	17.9
Semisolid	10	35.7
Solid	13	46.4
Total	28	100
Tumour Extension		
Sellar	03	10.7
Suprasellar	14	50.0
Sellar And Parasellar	04	14.3
Suprasellar And Parasellar	07	25
Total	28	100

**Table 4: Surgical Implication of Consistency Based On MRI WI [n=28]**

Consistency Based On MRI	Tumour Consistency Per Operative			Total (%)
	Cystic-n(%)	Firm-n(%)	Soft-n(%)	
Semisolid	0(0.0)	4(40.0)	6(60.0)	10(100.0)
Solid	0(0.0)	12(92.3)	1(7.69)	13(100.0)
Cystic	5(100.0)	0(0.0)	0(0.0)	5(100.0)
Total(%)	5(17.8)	16(57.1)	7(25.0)	28(100.0)

**Table 5: Surgical Implication of Tumour Extension Based on MRI WI [n=28]**

Tumour Extension On MRI	Tumour Extension-Per Operative		Total(%)
	Matching-n(%)	Not Matching-n(%)	
Sellar	3(100)	0(0.0)	3(100.0)
Suprasellar	12(85.7)	2(14.2)	14(100.0)
Sellar And Parasellar	4(100.0)	0(0.0)	4(100.0)
Suprasellar And Parasellar	5(71.4)	2(28.5)	7(100.0)
Total (%)	24(85.7)	4(14.2)	28(100.0)

**Table 6: Peroperative Complication [n=28]**

Peroperative Complication	Number of Individual-n	Percentage
CSF Leak	6	21.43
Nil	22	78.5
Total	28	100

**Table-7: Post Operative Complication [n=28]**

Post Operative Complication*	Number of Individual-n	Percentage
Diabetes Insipidus	3	10.7
Pneumoencephalocoel	1	3.5
CVA	2	7.1
CSF Leak	1	3.5
Nil	23	82.1

\*multiple response.

**Table 8: Management of Complications [n=28]**

Management Of Complications*	Number of Individual -n	Percentage
CSF Leak Repair	7	25.0
Desmopressin	3	10.7
CVA Conservative Management	2	7.1
Lumbar Drain	1	3.5

\*multiple response.

## Discussion

This study included 28 pituitary adenoma patients with a mean age of  $40.39 \pm 10.76$  years. Non-secretory macroadenomas were more common (60.7%) than secretory types (39.3%). Similarly, Cawich S et al<sup>19</sup> found a mean age of  $45.4 \pm 14.8$  years, with 55% non-secretory and 44.4% secretory

macroadenomas. Castro MC<sup>20</sup> reported 74.42% non-secretory and 22.58% secretory adenomas.

The predominant symptoms were headache (71.4%) and visual defects (42.8%) in the present study. Table-9 shows the comparative studies on modes of presentation of pituitary macroadenoma.

**Table 9: Comparative Studies On Modes Of Presentation**

Modes Of Presentation	Castro MC <sup>20</sup>	Cawich S et al <sup>19</sup>	Junko et al <sup>21</sup>	Present Study
Head Ache	-	72.3%	12.8%	71.4%
Galactorrhoea	6.9%	19.3%	18.0%	10.7%
Apoplexy	-	05%	-	3.5%
Visual Defects	-	80.7%	71.7%	42.8%
Acromegaly	7.6%	-	5.1%	3.5%
Cranial Nerve Palsy	-	16%	-	-
Amenorrhoea	-	26%	-	-

In this study, MRI showed tumor intensity as hyperintense in 50%, isointense in 28.6%, and hypointense in 21.4% of cases. According to Heck A et al<sup>22</sup>, T2-weighted MRI revealed 40% hyperintense, 33% isointense, and 27% hypointense tumors.

In the present study, MRI showed 46.4% of tumors were solid, 35.7% semisolid, and 17.9% cystic. Among 10 semisolid tumors, 60% were soft and 40% firm during surgery. Of 13 solid tumors, 92.3% were firm and 7.6% soft. Cystic tumors had consistent MRI and surgical findings.

Yamato et al<sup>23</sup> reported that 62.06% of pituitary macroadenomas were solid and 37.93% semisolid. Of 15 semisolid tumors on MRI T2WI, 13 were soft and 2 were hard during surgery, while 3 of 14 solid tumors were hard and 11 were soft. They found no significant correlation between tumor consistency on MRI T2WI and during surgery.

In the present study, 50% of tumors extended to the suprasellar region, while 25% extended to both the suprasellar and parasellar regions. MRI showed suprasellar extension consistent with surgery in 85.7% of cases, while 14.2% showed lateral extension. Suprasellar and parasellar MRI findings matched surgical findings in 71.4% of cases, with 28.5% showing discrepancies. Ramakrishnan VR<sup>24</sup> reported that 67% of the 106 patients had suprasellar tumor extension. Ahmadi et al studied 198 pituitary adenomas using preoperative high-resolution CT. Direct cavernous sinus invasion was noted in 19 cases<sup>25</sup>. Evaluating parasellar extension is crucial, as clinical signs appear late and tumor markers show inconsistent correlations.<sup>26</sup> Hardys' classification indicates grade A and B tumors are easier to remove, while grade C and D tumors (with a superior margin over 20 mm) are more challenging, with 40% showing residual tumor post-surgery.<sup>27</sup> Knosp et al<sup>28</sup> proposed

a grading system for cavernous sinus invasion, where greater lateral growth around the Internal Carotid Artery (ICA) indicates higher grades, allowing en masse dissection only for tumors with minimal suprasellar extension.

In this study, complete excision was achieved in 21 cases (75%), while 7 cases (25%) had incomplete excision. Of the incompletely removed tumors, 5 underwent subtotal removal and 2 partial removal. Complete resection was possible when there was a clear dissection plane and minimal suprasellar extension. Intraoperative carotid Doppler monitoring was used to avoid carotid artery injury. Among the 5 subtotal resections, 3 involved suprasellar and parasellar extension affecting the right cavernous sinus and sphenoid sinus, while the other 2 had suprasellar extension with lateral carotid encasement. One of these patients, who had galactorrhea and developed pituitary apoplexy, required urgent surgery, but the blood-clotted sellar tissue was difficult to identify. These 5 tumors were very hard and had to be removed in pieces. Arbolay Omar<sup>29</sup> found that endonasal endoscopic transsphenoidal surgery achieved gross tumor removal in 92.4% of cases and subtotal resection in 7.8%. Fan YP et al<sup>30</sup> reported that out of 28 patients, total resection was performed in 16, subtotal resection in 8, partial resection in 3, and biopsy in 1 due to excessive bleeding and hardness.

In this study, CSF leak was the only perioperative complication, occurring in 6 cases (21.4%). The most common postoperative complication was diabetes insipidus, noted in 3 cases (10.7%). One case also had pneumoencephalocele with a CSF leak, while another had a CVA with diabetes insipidus. Castro MC et al<sup>20</sup> found that complications in patients included CSF fistulas in 8.5%, meningitis in 3.1%, and one death from major intracerebral hemorrhage postoperatively. Junko et al<sup>21</sup> reported transient diabetes insipidus in 13 cases (33.3%), cerebrospinal fluid leakage in 3 cases (7.7%), and subarachnoid hemorrhage in 1 case (2.6%). The low complication rate is influenced by factors such as tumor resection extent, tumor type, and preservation of surrounding structures. Junko et al<sup>21</sup> noted that 11 patients with CSF fistulas were treated conservatively in 7 cases (5.53%), while 4 (3.1%) required reoperation.

Recent pooled data suggest that patients with endoscopically treated non-functioning pituitary adenomas experience lower rates of postoperative pituitary dysfunction, higher total resection rates, and improved visual acuity<sup>31</sup>. Vaibhav et al<sup>32</sup> also reported reduced morbidity and complications with the endoscopic transnasal transsphenoidal approach for pituitary adenomas.

In this study, perioperative CSF leak repair was performed in 6 cases using a multilayer closure method involving fat, cartilage, nasoseptal flap, Surgicel, and tissue glue, followed by nasal packing with Meurocell for one week. The postoperative period was uneventful, with no leaks observed during diagnostic nasal endoscopy. Three patients developed postoperative diabetes insipidus within 24-48 hours, presenting with polyuria, nocturia, and polydipsia. Biochemical tests confirmed hypernatremia, increased osmolarity, and hyposmolar urine. After fluid management, all patients improved within 7-10 days. Two hypertensive patients developed a postoperative CVA due to elevated blood pressure, resulting in anterior cerebral artery infarction. The CVA was managed conservatively and not attributed to surgery, as carotid artery monitoring was done preoperatively. Postoperative care requires a multidisciplinary approach involving neurosurgeons, endocrinologists, and intensive care teams. Preoperative hormonal assessments guide perioperative management. Prompt diagnosis and treatment of complications improve outcomes, though some may require lifelong surveillance and treatment.<sup>33</sup>

**Limitations:** This was an observational study conducted only in one medical college which may limit the generalizability of the findings.

## Conclusion

In this study, pituitary macroadenomas were most common in the 5th decade of life, with non-secretory tumors being more prevalent, especially in females, while secretory tumors were more common in males. Headaches and visual defects were common symptoms, particularly with suprasellar extension. Acromegaly was the most frequent secretory tumor, followed by prolactinoma. MRI, especially T2-weighted imaging, was effective in

predicting tumor consistency. The transsphenoidal endoscopic approach was suitable for removing cystic and soft macroadenomas but less for solid tumors with extensive suprasellar extension and parasellar carotid encasement. Complications, such as CSF leaks and hemorrhage, were minimal with meticulous dissection techniques.

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**Conflicts of interest:** Nil

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# A Retrospective Study on Adverse Events Following COVID-19 - Vaccines (AEFI) Reported to ADR Monitoring Centre in a Tertiary Care Health Centre, Andhra Pradesh

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## Abstract

**Background:** Vaccination against COVID-19 is going around globally to prevent the incidence of COVID-19 disease and its complications. As there have been no large-scale research studies about AEFI following COVID-19 vaccines, our plan of action was to examine and assess the clinical patterns that occur after COVID-19 immunization and determine which COVID-19 vaccine has a lower frequency of side effects. AEFI

**Methods:** This is a retrospective study of the AEFIs reported with COVID-19 vaccines (1<sup>st</sup> or 2<sup>nd</sup> dose or both) at the Government General Hospital, Guntur, AP, from Jan 16<sup>th</sup> 2021 – October 31<sup>st</sup> 2021 after obtaining prior approval of the Institutional Ethics Committee (IEC) and PvPI, Ghaziabad. The ADR monitoring facility in Guntur collected and evaluated the adverse incidents reported using descriptive statistics in MS Excel. The results were presented in bar and pie charts.

**Results:** AMC received a total of 575 Adverse Events Following Immunization (AEFIs) after COVID-19 vaccinations were given. The most frequently detected adverse events following immunization (AEFIs) were fever, recorded in 21.9% (136 cases), headache in 20.9% (120 cases), nausea and vomiting in 4.3% (25 cases), and rashes in 2.1% (12 cases). The bulk of the Adverse Events Following Immunization (AEFIs) were moderate and occurred in individuals aged between 28 and 37 years. Adverse local responses were noted following the administration of the initial dosage of Covishield.

**Conclusion:** In this study, most of the negative events reported were non-serious. The incidence of adverse events following Covaxin was few compared to Covishield. The mean occurrence of symptoms was 0 to 4 days.

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Additionally, it is necessary to continue conducting longitudinal surveys in the field of pharmacovigilance to thoroughly examine any potential long-term negative effects of vaccines.

**Keywords:** AEFI, COVID-19 vaccines, Pharmacovigilance, COVISHIELD, COVAXIN.

## Introduction

The SARS-CoV-2 virus, which caused the COVID-19 pandemic, continues to be highly prevalent. The development of and its worldwide health consequences prompted the creation of a secure vaccination. This pandemic is an ongoing crisis that necessitates the immediate implementation of immunization in the country. <sup>(1)</sup>

There have been 35 million confirmed cases of COVID-19 globally as of 24 January 2022, with 5 million fatalities, according to the World Health Organization (WHO). A total of around 200,000 new cases of the coronavirus were recorded in April and May of 2021, prompting the acceleration of the vaccination program (Covishield, Covaxin) among the public of our country. The COVID-19 pandemic, caused by the SARS-CoV-2 virus, continues to be prevalent. The development of a safe vaccine was prompted by the appearance of and its worldwide health consequences. This pandemic is an ongoing crisis that has necessitated the swift implementation of immunization across the country <sup>(9)</sup>.

Various types of vaccines are available based on viral components; mRNA (Pfizer, Moderna), viral vector (Johnson and Johnson, Covishield), and inactivated vaccines (Covaxin). In India, only Covaxin and Covishield were available <sup>(2)</sup>. As of June 2024, 220 crores of vaccine doses had been administered as per Ministry of Health and Family Welfare ([covid19dashboard.mohfw.gov.in/](https://covid19dashboard.mohfw.gov.in/)), Gov of India.

On January 16, 2021, a vaccination program against COVID-19 was launched in India, with a focus on healthcare professionals. Vaccines were given to healthcare staff in the first phase and the senior population in the following phase according to protocol. Covishield (Serum Institute of Pune) and Covaxin (Bharath Biotech) were the vaccines used. The necessity to closely observe trends in adverse events in the general population has taken precedence over the previously mentioned acceptable safety profile of randomized control trials. Although the database did

capture a small number of significant adverse events, the vast majority of reported adverse events were mild reactions (after COVID-19 vaccination).

Vaccine-related adverse effects can be categorized as mild, moderate, or severe reactions, depending on the seriousness of the symptoms and the level of intervention needed. Among the minor side effects, fever and injection site pain were the most prevalent adverse effects following immunization. Other side effects reported were nausea, vomiting, headache, muscle aches or myalgia and diarrhoea are among the minor side effects that have been recorded <sup>(3)</sup>. The database includes reports of serious adverse outcomes such as stroke, seizures, thromboembolic events, and cardiac problems. <sup>(2)</sup>

The remarkable and swift progress in the creation of COVID-19 vaccines using an innovative platform, coupled with their quick production on a large scale, presents a distinct difficulty in monitoring the safety of these vaccines. Vaccine pharmacovigilance is crucial for closely monitoring any adverse events that may occur after COVID-19 vaccination, as well as detecting any changes in the patterns or trends of adverse drug reactions (ADRs). This surveillance is essential for ensuring safety and upholding confidence within the community. The data and information obtained from vaccine pharmacovigilance can be valuable for identifying and reducing avoidable adverse events following immunization (AEFI) and enhancing the prescribers' understanding of how to manage them efficiently. All Adverse Events Following Immunization (AEFI) are sent to the Adverse Drug Reaction (ADR) Monitoring Centre (AMC) for further transmission to the Pharmacovigilance Programme of India (PvPI), located at the Indian Pharmacopoeia Commission (IPC) in Ghaziabad, using the vigiflow software.

The ADR Monitoring Centre was created in 2013 at Guntur Medical College (GMC)/ Government General Hospital (GGH), a Tertiary Care facility, that reported approximately over 5000 Adverse Drug Reactions (ADRs) up until now. In 2021, it was acknowledged as one of the top 10 pharmacovigilance

centres in India and the system gathers ADR and AEFI data from Guntur General Hospital (GGH) and other facilities in the area and then captures these reports in ADR reporting forms and uploads them to PvPI, IPC, Ghaziabad using Vigiflow software.

The purpose of this study is to gather, examine, and assess the clinical patterns of adverse events following immunization (AEFI) that occur after the administration of COVID-19 vaccines. These AEFI cases have been reported to our Adverse Drug Reaction (ADR) monitoring centre, which is located at a Tertiary Care Teaching Hospital.

### Methods

A retrospective and observational study was undertaken at the ADR Government General Hospital, Guntur, following the acquisition of ethics approval and PvPI, Ghaziabad. The ADR monitoring center gathered and analysed the adverse events reported after COVID-19 vaccinations. The study population included individuals who received doses of COVID-19 vaccinations (Covishield, Covaxin: 1st dose, 2nd dose, or both) and experienced adverse events. These events were reported to the ADR monitoring center at Government General Hospital, Guntur. The study spanned 10 months, commencing on January 16, 2021, and concluding on October 31, 2021.

The Adverse Events Following Immunization (AEFI) that occurred after administering COVID-19 vaccinations were recorded and documented in the AEFI forms at the ADR monitoring centre (AMC) of the Tertiary care teaching hospital in Guntur, Andhra Pradesh. These records were then uploaded to PvPI Vigiflow.

### Statistical analysis

The acquired data was evaluated utilizing descriptive statistics and presented in the form of frequencies and percentages. Data are shown employing bar and pie charts as necessary, utilizing the M.S. Excel program.

### Results

From January 16, 2021, to October 31, 2021, a total of 306 people who received the vaccine reported 575 adverse events to the ADR Monitoring Centre.

The study included and analysed 306 individuals who reported AEFI to the ADR monitoring centre. Out of the total, 169 individuals (55%) were female, while 137 individuals (45%) were male. The AEFI described in this study pertains to individuals aged 18 to 80 years. The current study documented Adverse Events Following Immunization (AEFIs) associated with COVID-19 vaccination (Covishield, Covaxin), encompassing individuals who have received either the first dose, second dose, or both. Most of the negative incidents occurred among those aged 28-37 years, with a total of 200 adverse events. A minimal number of Adverse Events Following Immunization (AEFIs) were documented within the older population with no specific comorbidities.

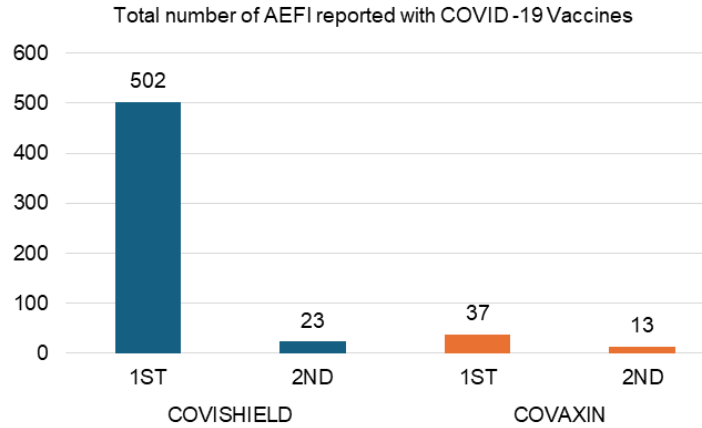
**Table no: 1 Demographic details of reported AEFI**

Age/Gender	Total no of recipients who reported AEFI	Total no of AEFI reported
<b>18-27</b>	<b>71</b>	<b>139</b>
Female	33	65
Male	38	74
<b>28-37</b>	<b>104</b>	<b>200</b>
Female	53	104
Male	51	96
<b>38-47</b>	<b>59</b>	<b>111</b>
Female	39	72
Male	20	39
<b>48-57</b>	<b>51</b>	<b>86</b>
Female	35	56
Male	16	30
<b>58-67</b>	<b>16</b>	<b>31</b>
Female	7	15
Male	9	16
<b>68-77</b>	<b>4</b>	<b>5</b>
Female	1	1
Male	3	4
<b>78-87</b>	<b>1</b>	<b>3</b>
Female	1	3
Grand Total	306	575

Out of the 306 individuals who received the COVID-19 vaccine, 279 of them experienced more than one negative event. A total of 502 adverse events following immunization (AEFI) were recorded after

the first administration of Covishield vaccination, accounting for 87.3% of the cases. Additionally, 23 cases (4%) were reported after the second administration of Covishield vaccination. Similarly,

37 cases (6.4%) were reported after the first dose of Covaxin, and 13 cases (2.3%) were reported after the second dose of Covaxin vaccination.



**Figure no 1: Total number of AEFI reported in both doses of COVID-19 vaccines**

The most frequently reported systemic adverse events following immunization (AEFI) were fever (21.9%), headache (20.9%), nausea and vomiting (4.3%), rashes (2.1%), palpitations (1.6%), chest pain (1.4%), diarrhoea (1.6%), generalized weakness (1.6%), and other non-specific events (including dry mouth (0.2%), back pain (0.9%), sweating, and one episode of hypoglycaemia (0.2%) where Random Blood

sugars (RBS) was 40mg/ml was noted). Following the first dosage of Covishield, 7.5% (43 patients) reported local injection-site symptoms, including pain and discomfort. Our study did not experience the warning symptoms of sleepiness, drowsiness, or fainting, which were like the adverse effects of the Covishield vaccine listed in their monograph<sup>22</sup>.

**Table no 2: Reported AEFI with 1<sup>st</sup> and 2<sup>nd</sup> doses of COVID-19 Vaccines**

Symptoms	COVISHIELD		COVAXIN	
	1 <sup>ST</sup>	2 <sup>ND</sup>	1 <sup>ST</sup>	2 <sup>ND</sup>
Local reactions	43			
Head ache	104	4	7	5
Fever	117	10	6	5
Myalgia	95	7	6	2
generalized weakness	9			
Fatigue/tiredness	12			
Chills	8	1	3	
Rash	11			1
facial oedema	1			
Itching	2			
Nausea	5			
Vomiting	19		2	
Diarrhoea	9			
abdominal pain	2		1	
Constipation	1			
Palpitations	8		1	

Continue.....

chest pain	6		2	
SOB	14			
Tachycardia	1			
weakness of limbs	3			
Vertigo	1			
dizziness/giddiness	7		7	
tingling/paraesthesia	2			
Drowsiness	1		1	
Fainting			1	
slurred speech	1			
deviation of mouth	1			
Cough	4	1		
dry mouth	1			
Sweating	1			
hypoglycaemia	1			
low back pain	5			
throat ulcers/throat pain	3			
burning micturition	1			
Dysphagia	1			

## Systemic AEFI

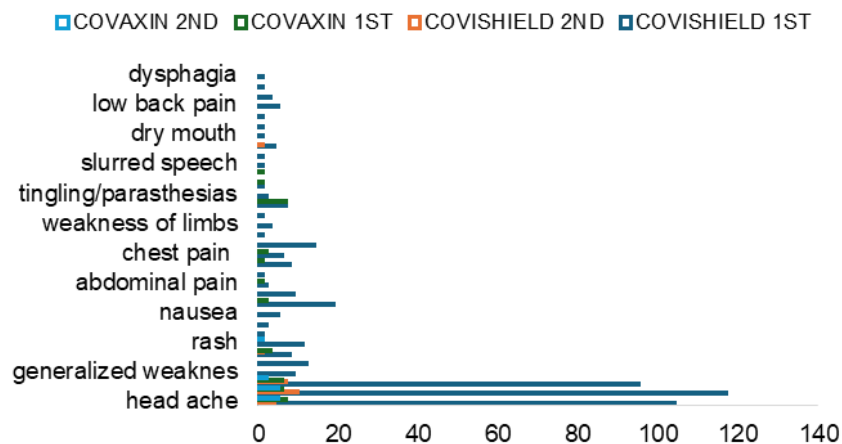
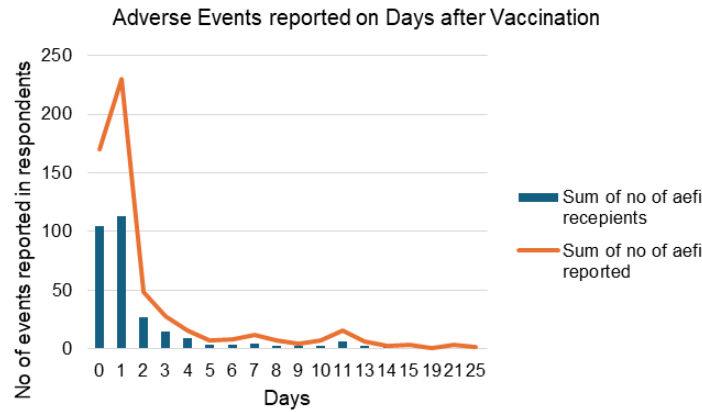


Figure no 2: Systemic AEFI following COVID-19 Vaccines

The large number of Adverse Events Following Immunization (AEFI) reported occurred within 0 to 4 days following vaccination and resolved spontaneously, which was depicted in Figure 3. The symptoms were classified as mild, moderate, severe, and serious. One serious life-threatening adverse

event (death) was reported following the initial dose of the Covishield vaccine, and one serious adverse event (unconsciousness) which led to hospitalization was also reported. The remaining AEFI (573) were mild to moderate which resolved with or without symptomatic treatment.



**Figure no 3: Adverse Events reported on Days after Vaccination**

Following COVID-19 vaccinations, the adverse event patterns were primarily widespread and included headache, myalgia, fever, and gastrointestinal symptoms such as constipation, diarrhoea, nausea, and vomiting. The documented neurological effects include weakness in the upper and lower limbs, dizziness or vertigo, and one instance of slurred speech after the administration of the first dose of Covishield.

**Discussion**

As of currently, a total of 10,080,000,000 individuals worldwide have received the COVID-19 vaccine. Out of this, 406 crores (52.1%) of the population have been fully vaccinated with both doses. Approximately half of the population in India has received complete vaccination. (3)

502 (87.3%) AEFI were reported following the initial dose of Covishield vaccination, 23 (4%) following dose of Covishield vaccination, 37 (6.4%) following 1st dose of Covaxin, and 13 (2.3%) following subsequent dose of Covaxin vaccination. 502 Adverse Events Following Immunization (AEFI) were reported. Among them, two adverse events were observed: one resulting in death and one causing unconsciousness. the incidents occurred after the administration of the first dose of the Covishield vaccine.

In line with our research, a study done by Deep Kamal et.al. revealed that most of the adverse events recorded after administering the ChAdOx1 nCoV-19 vaccine (Covishield) were non-serious. In all, 57% of individuals experienced a non-severe adverse event following their initial immunization dose, while the

reported rate of major adverse events was only 0.2%. The overall incidence of non-serious adverse events was around 14.1% following the administration of the subsequent dose of the vaccine. There were no significant adverse effects reported following the administration of the subsequent dose of the vaccine. (8)

The current investigation observed that the majority of negative occurrences occurred within the initial week (0 to 4 days) after immunization and were resolved without intervention. A minimal number of negative incidents were recorded following the administration of the first dose of Covishield on the 15th, 21st, and 25th days, the second dose of Covishield on the 11th day, and the second dose of Covaxin on the 9th day. This finding aligns with a study conducted by Deep Kamal et.al., which observed that the majority of negative incidents occurred within the initial 48 hours following the administration of both the first and second vaccine doses. The investigation saw a reduction in the occurrence of negative events after 48 hours of vaccination, and no adverse events were reported after two weeks (post-day 15) of vaccination. (8)

The study found that the most frequently reported adverse events following COVID-19 vaccination were fever, headache, malaise, and tenderness or discomfort at the injection site. The majority of Adverse Events Following Immunization (AEFI) were of mild to moderate severity. The incidence and intensity of Adverse Events Following Immunization (AEFI) were lower in the senior population (aged > 60 years). One patient experienced a change in mental state and subsequently died after receiving the first

dose of Covishield, resulting in hospitalization. This incident was classified as a serious adverse event. The residual Adverse Event Following Immunization (AEFI) was resolved promptly within a few days.

The most commonly reported side effects, according to an interim review of four clinical studies on the ChAdOx1 nCoV-19 vaccine, were injection site discomfort (63.7%), injection site pain (54.2%), headache (52.6%), and weariness (53.1%). Most adverse responses were a mild-to-moderate intensity and disappeared a few days after the immunization. The findings of our investigation were comparable to these results. <sup>(17)</sup>

A majority of the reported adverse reactions were generic. There were reports of local adverse events following immunization (AEFI) after the first dose of Covishield. Additional unfavourable occurrences observed after receiving COVID-19 vaccines included angina, irregular heartbeats, xerostomia, impaired speech, diminished strength in both the upper and lower extremities, paresthesia, and dizziness (Covishield). <sup>(13)</sup>

In the current study, the occurrence of adverse effects after the first and second administration of Covaxin was less frequent compared to Covishield. The reported adverse effects are as follows: headache (7 cases, 1.2%), fever (6 cases, 1%), myalgia (6 cases, 1%), chills (3 cases, 0.5%), vomiting (2 cases, 0.3%), dizziness (8 cases, 1.4%), sleepiness (1 case, 0.2%), palpitations (2 cases, 0.3%), and chest discomfort (8 cases, 1.4%). In a separate research conducted by Raches Ella, et al., the Covaxin (BBV152) group experienced several adverse events. These included injection site pain (17 [5%] out of 375 participants), headache (13 [3%]), fatigue (11 [3%]), fever (9 [2%]), and nausea or vomiting (7 [2%]). The requested adverse events reported were predominantly mild (69%) or severe (31%) in severity, with a higher frequency observed after the initial dose. <sup>(7)</sup>

#### Limitations:

Our study has a few limitations,

1. The investigation was conducted in a singular facility, limiting the generalizability of the data.
2. The possibility of bias due to unobserved variables cannot be excluded.

3. Only adverse events reported to our centre are taken into consideration.
4. The study does not take comorbidities into account.

#### Conclusion

This study aimed to investigate and identify the clinical patterns and degree of adverse events that occurred after receiving either of the doses of the COVID-19 vaccines Covishield or Covaxin. The documented Adverse Events Following Immunization (AEFI) primarily include mild adverse events such as headache, muscle pain, fever, and chills. A higher incidence of adverse events was seen following administration of the first dosage of the vaccine as compared to the second dose. The incidence of adverse events following administration of Covaxin was lower in comparison to Covishield. In this study, the average duration of symptoms ranged from 0 to 4 days.

To create an innovative approach to vaccinating against new infectious illnesses, it is crucial to have access to precise and ample data regarding the effectiveness of vaccine pharmacovigilance. Comprehensive investigations are necessary to evaluate the delayed (long-term sequelae) symptoms of immunization on a large scale. A crucial component of vaccination regulation is vaccine pharmacovigilance, which should be implemented properly for the benefit of the public.

No funding sources are present.

Ethical Clearance/Statement of Ethics-Institutional Ethics Committee Guntur Medical College, & Government General Hospital, Guntur application no: GMC/IEC/132/2021, date-08-10-2021

No conflicts of interest

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# A Study on Clinical Profile of Euvolemic Hyponatremia in Elderly Hospitalized patient

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## Abstract

**Background and Aim:** The study aims to delineate the clinical characteristics and management challenges of euvolemic hyponatremia in the elderly hospitalized population, with a focus on improving patient outcomes through better understanding and treatment of this condition.

**Materials and Methods:** This study was done on patients, who were admitted to Chalmeda Anand Rao Institute of Medical Sciences Hospital, Karimnagar during a period of 2 years. A total of 50 patients with Euvolemic Hyponatremia (29 male, 21 female) were studied.

**Results:** Among 50 patients, 29 are male, accounting for 58% of the cases, while 21 are female, making up the remaining 42%. This indicates that euvolemic hyponatremia is more prevalent in males compared to females. Euvolemic hyponatremia in elderly hospitalized patients reveals that the highest incidence occurs in the 71-80 years age group, which accounts for 50% of the cases, the prevalence decreases with age, with the 61-70 years group comprising 44% of the patients, and > 80 years groups each representing 6% of the total. Syndrome of inappropriate antidiuretic hormone secretion (SIADH) is a cause in 18% of patients, with drug-induced hyponatremia and hypothyroidism affecting 16% and 14%, respectively.

**Conclusion:** This study offers a comprehensive examination of the clinical profile of euvolemic hyponatremia in elderly hospitalized patients. The most common symptoms of lethargy, dizziness, underscore the need for vigilant monitoring, particularly given that asymptomatic cases are frequent. The identification of SIADH, drug-induced hyponatremia, and hypothyroidism as common underlying causes emphasizes the necessity of thorough diagnostic evaluation.

**Keywords:** Euvolemia, Hyponatremia, SIADH, elderly hospitalized patients

## Introduction

Hyponatremia, characterized by a plasma sodium

content of less than 135 mEq/L, is the most common electrolyte observed in hospitalized patients, with a particularly high prevalence among the elderly

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due to their impaired ability to maintain water and electrolyte homeostasis.<sup>[1]</sup> Euvolemic hyponatremia, where patients do not exhibit signs of dehydration or over hydration, is frequently encountered in clinical practice and is often associated with the syndrome of inappropriate antidiuretic hormone secretion (SIADH), hypothyroidism, or adrenalin sufficiency.<sup>[2]</sup>

Epidemiology, Hyponatremia is most common electrolyte problem in patients who are admitted to hospital with a frequency ranging from 20-35%. This phenomenon is especially prevalence among older population because they have limited access to food and drink, use many medicines and have multiple coexisting medical conditions. This study focuses on immediate outcomes and does not provide data on long term prognosis.

The clinical manifestations of hyponatremia are diverse and can range from asymptomatic to severe neurological symptoms, which can lead to increased morbidity and mortality if not managed appropriately.<sup>[3]</sup> Interestingly, while euvolemic hyponatremia is the most common type of hyponatremia in hospitalized patients, its diagnosis and management remain challenging due to the variety of underlying etiologies and the potential for non specific clinical presentations.<sup>[4]</sup> Appropriate management and close monitoring to improve outcomes and reduce mortality. The study found that lower GCS scores were assess with higher mortality rates. Moreover, the condition has been linked to an increased risk of fall in the elderly, highlighting the need for targeted prevention strategies.<sup>[5]</sup> The introduction of new drugs such as lixivaptan, a selective vasopressin V2-receptor antagonist, has shown promise in safely correcting serum sodium concentrations, indicating advancements in treatment options.<sup>[6]</sup>

The study aim was to assess the clinical profile of euvolemic hyponatremia in elderly hospitalized patients.

## Materials and Methods

### Study Design

The Study design was a Prospective observational study.

### Study Centre:

The study was conducted at Department of General Medicine, Chalmeda Anand Rao Institute of Medical Sciences, Karimnagar.

### Study Duration:

The study duration was 2 years.

### Inclusion Criteria:

- Subjects age > 60 years
- Gender
- Patients admitted to MICU
- Hypertension
- Diabetes mellitus

### Exclusion Criteria:

- Patients aged <60 years
- Patients with hypovolemic hyponatremia (vomiting, diarrhoea)
- Patients with hypervolemic hyponatremia (CCF,CKD,CLD)

### Ethical Approval

This study protocol was approved by the Institute Ethical Committee, Chalmeda Anand Rao Institute of Medical Sciences, Karimnagar (Ref.No.CAIMS/IEC/PH/049/dated: 3.9.2022).

### Statistical Analysis

SPSS (version 29.0) program was used to input and analyse data. The qualitative data were described in terms of numbers and percentages. Descriptive statistics will be used to summarize will be analysed using appropriate statistical methods. Sub group analyses may be performed based on demographic or clinical characteristics. The obtained results were considered significant at the 95% level.

## Results

In elderly hospitalized patients reveals that the highest incidence occurs in the 71-80 years age group, which accounts for 50% of the cases. The prevalence decreases with age, with the 61-70 years group comprising 44% of the patients, and > 80 years groups each representing 6% of the total.

**Table 1: Distribution of study subjects based on age**

Age (Years)	Number of patients (N)	Percentage (%)
61-70 years	22	44%
71-80 years	25	50%
>80	3	6%
Total	50	100%

**Table 2: Distribution of study subjects based on gender**

Gender	Number of Patients (N)	Percentage (%)
Male	29	58%
Female	21	42%

Out of the total 50 patients, 29 are male, accounting for 58% of the cases, while 21 are female, making up the remaining 42%, more prevalent in males compared to females in the studied population.

**Table 3: Distribution of study subjects based on GCS score Vs Hyponatremia Severity**

Hyponatremia Severity	GCS Score	Number of Patients	Percentage
Mild	>13	23	46%
Moderate	08-12	18	36%
Severe	<8	9	18%

Among the 50 patients evaluated, 46% had mild hyponatremia with a GCS score >13, Moderate hyponatremia with GCS scores between 8 and 12 was observed in 36% of the patients. Mean while, severe hyponatremia, characterized by a GCS score of < 8 was seen in 18% of the patients.

**Table 6: Distribution of study subjects based osmolarity and sodium levels**

Severity	Mean Serum Osmolarity	Mean Urinary Osmolarity	Mean Urinary Sodium
Mild	280mOsm/kg	500mOsm/kg	40mmol/L
Moderate	260mOsm/kg	450mOsm/kg	35mmol/L
Severe	240mOsm/kg	400mOsm/kg	30mmol/L

This trend indicates that as hyponatremia severity increases, serum and urinary osmolarity and sodium levels decrease, reflecting the worsening electrolyte imbalance and impaired

**Table 4: Distribution of Subjects based on Symptoms**

Symptom	Count	Percentage
Asymptomatic	20	20%
Lethargy	11	22%
Dizziness	10	20%
Abnormal behaviour	5	10%
Seizures	3	6%
Coma	1	2%

This data emphasizes that most common symptoms is lethargy (22%), followed by asymptomatic cases (20%), dizziness (20%). Abnormal behavior (10%), Seizures (6%) and coma (2%) are less common.

**Table 5: Distribution of study subjects based on Diagnosis**

Diagnosis	Number of Patients	Percentage
Hypothyroidism	13	26%
SIADH	18	36%
Drug-induced	15	30%
Adrenal insufficiency	1	2%
Meningitis	1	2%
Malignancy	2	4%
Total	50	100%

This break down emphasizes the diverse etiological factors contributing to hyponatremia in the studied population, with SIADH, hypothyroidism, and drug-induced causes being the most prevalent. Drugs used are fluoxetine, amitriptyline, Antipsychotics and antiepileptics.

water excretion as associated with more severe forms of hyponatremia. Daily fluid restriction < 1 liter, use of vasopressin 2 receptor selective antagonists for non-responders.

**Table 7: Distribution of study subjects based on severity**

Severity(n=9)	Drug Use	SIADH	Liver Failure	Recovered	Died
Severe	1	1	1	3	3

This data underscores the critical nature of severe hyponatremia, as it is associated with significant mortality despite some patients recovering.

**Table 8: Distribution of study subjects based on outcome**

Outcome	Number of Patients	Percentage
Recovered	43	86%
Death	7	14%

Among patients with hyponatremia, the majority, constituting 86%, experienced recovery, while 14% unfortunately succumbed to the condition. These findings underscore the importance of timely diagnosis, appropriate management, and close monitoring to improve outcomes and reduce mortality in patients with hyponatremia. Recovered patients were discharged; follow up was not done in our study.

## Discussion

The clinical profile of euvolemic hyponatremia in elderly hospitalized patients is multifaceted, with various studies highlighting its prevalence, aetiology, and associated risks. Euvolemic hyponatremia, characterized by a normal fluid balance with low serum sodium levels, is the most common type of hyponatremia in hospitalized patients. The condition is particularly prevalent among the elderly due to their impaired ability to maintain water and electrolyte homeostasis, which contributes to significant morbidity and mortality. Contradictions and interesting facts emerge when considering the causes and implications of euvolemic hyponatremia. While the syndrome of inappropriate antidiuretic hormone secretion (SIADH) is a common cause, other factors such as medication use, particularly diuretics, and underlying endocrine disorders also play a role.

Notably, the study of euvolemic hyponatremia's association with falls in the elderly highlights its impact on patient safety, with mild hyponatremia being an independent risk factor for falls (Hyohdoh et al., (2023).<sup>[7]</sup> Furthermore, the introduction of new

therapeutic agents like lixivaptan has shown promise in safely correcting serum sodium concentrations in euvolemic hyponatremia.

In summary, euvolemic hyponatremia in elderly hospitalized patients is a common and complex condition with diverse etiologies and significant clinical implications. The condition's association with increased morbidity and mortality underscores the importance of accurate diagnosis and appropriate management. The advent of new treatments offers hope for more effective management, but the need for careful evaluation of underlying causes remains paramount. Future research should continue to explore the mechanisms and treatment strategies for euvolemic hyponatremia to improve patient outcomes. The study on the clinical profile of euvolemic hyponatremia in elderly hospitalized patients categorized participants based on the severity of their hyponatremia in to mild, moderate, and severe. In the mild category (ages 61-70), there were 10 males and 12 females, with 3 asymptomatic patients.

The study also provides a gender-based distribution of the condition, with 29 males accounting for 58% of the cases, while 21 females make up the remaining 42%. This indicates that euvolemic hyponatremia is more prevalent in males compared to females in the studied population. It is because more males in the sample of study. The most common symptom is lethargy (22%), followed by asymptomatic cases, dizziness.

Abnormal behaviour (10%), seizures (6%), and coma (2%) are less common. Syndrome of inappropriate antidiuretic hormone secretion (SIADH) is a cause in 18% of patients, with drug-induced hyponatremia and hypothyroid is affecting 16% and 14%, respectively. The GCS scores show that 68% of patients have a GCS > 13, indicating mild impairment, while 22% have a GCS between 8-12, and 10% have a GCS < 8, indicating severe impairment. Hyponatremia severity is mild in 46% of cases, moderate in 36%, and severe in 18%. Regarding volume status, 52% of patients are euvolemic, 30% are hypovolemic, and 18% are hypervolemic.

The study's outcomes for severe hyponatremia highlight the critical nature of the condition, as it is associated with significant mortality despite some patients recovering. The presence of underlying conditions such as drug use, SIADH, and may complicate the prognosis and outcomes for these patients.

The study provides data on the mean serum osmolarity, mean urinary osmolarity, and mean urinary sodium levels across different severities of hyponatremia. For mild hyponatremia, the mean serum osmolarity is 280 mOsm/kg, the mean urinary osmolarity is 500 mOsm/kg, and the mean urinary sodium is 40 mmol/L. In moderate hyponatremia, these values decrease to 260 mOsm/kg for mean serum osmolarity, 450 mOsm/kg for mean urinary osmolarity, and 35 mmol/L for mean urinary sodium. Severe hyponatremia shows the lowest values, with a mean serum osmolarity of 240 mOsm/kg, mean urinary osmolarity of 400 mOsm/kg, and mean urinary sodium of 30 mmol/L.

A study by Yuki Hyohdoh et al [7] explores the impact of mild hyponatremia on the incidence of in-hospital falls among elderly patients. The findings highlight the significant risks associated with even mild hyponatremia, such as increased fall rates, which underscores the importance of monitoring and managing sodium levels to prevent such adverse outcomes.

Compared to the current study, Hyohdoh et al [7] research emphasizes the broader implications of mild hyponatremia on patient safety, whereas the current study provides a detailed breakdown of demographic and clinical characteristics across different severities of hyponatremia. Lixivaptan safely and effectively corrects serum sodium concentrations in hospitalized patients with euvolemic hyponatremia by William T. Abraham et al.[8] Kidney International which investigates the efficacy of Lixivaptan in correcting serum sodium levels in patients with euvolemic hyponatremia.

The results demonstrate the drug's effectiveness in normalizing sodium concentrations without significant adverse effects. The current study, by contrast, focuses more on the clinical profile and outcomes of hyponatremia rather than treatment

options. Abraham et al.'s work is treatment-centric, while the current study is descriptive and diagnostic parameters.

A study of the clinical profile of hyponatremia in elderly patients admitted to medical wards by Chandregowda et al.[9] provides a comprehensive overview of hyponatremia's clinical profile in elderly patients, similar to the current study. Both studies highlight common symptoms, causes, and demographic distributions, with a focus on the elderly population. However, Chandregowda et al. [9] study may offer a broader range of patient conditions and outcomes, while the current study provides a specific focus on euvolemic hyponatremia and its severity-related characteristics.

A study by Shaik Mahezabeen et al (2023) [8] descriptive study on hyponatremia in elderly patients aligns closely with the current study in terms of objectives and scope. Both studies categorize hyponatremia by severity and analyze associated symptoms and outcomes. However, Shaik Mahezabeen et al. [8] may place more emphasis on hospital-based management practices and patient care strategies, while the current study details the statistical and clinical profile distribution.

A study by Mahim Mittal et al[11] Insights into the profile of hyponatremia in a tertiary care setting, which may include diverse patient demographics and etiologies. The current study's focus on euvolemic hyponatremia provides a narrower scope, detailing specific clinical parameters and outcomes. Mittal et al.' [11] broader approach can complement the specific findings of the current study by providing a wider context for hyponatremia management. A study by Talia Diker-Cohen (2018) et al [12] showed that euvolemic hyponatremia induced by endocrine disorders, provided a detailed exploration of specific causes and their clinical management.

The current study complements this by offering a broader look at the clinical profile and outcomes of euvolemic hyponatremia in elderly patients, including but not limited to endocrine causes also Diker-Cohen et al.'s focus on endocrinopathy offers a more targeted analysis of one cause, enriching the current study's findings. Usmanetal [13] provide a clinicopathological profile of hyponatremia in

medical wards, which aligns with the current study's objectives. Both studies discuss symptoms, causes, and outcomes, but Usman et al. may offer a broader etiological spectrum.

The current study's detailed analysis of euvolemic hyponatremia by severity and related clinical parameters provides a focused contribution to understanding specific patient profiles and outcomes. Summary Overall, the current study complements existing literature by providing detailed demographic, clinical, and outcome data specific to euvolemic hyponatremia in elderly patients, enriching the broader context of hyponatremia research through its focus on severity-related characteristics and outcomes.

### Conclusion

In conclusion, this study offers a comprehensive examination of the clinical profile of euvolemic hyponatremia in elderly hospitalized patients, contributing significantly to the existing body of knowledge on this prevalent and complex condition. The research highlights the condition's highest incidence. The most common symptoms of lethargy, dizziness, and nausea/vomiting underscore the need for vigilant monitoring, particularly given that asymptomatic cases are frequent. The identification of SIADH, drug-induced hyponatremia, and hypothyroidism as common underlying causes emphasizes the necessity of thorough diagnostic evaluation.

The study's detailed analysis of hyponatremia severity and its correlation with serum osmolality, urinary osmolality, and urinary sodium levels provides valuable clinical parameters for patient assessment. The findings underscore the critical nature of severe hyponatremia, given its association with significant mortality, despite some patients achieving recovery. The research suggests that the advent of new treatments like lixivaptan may revolutionize the management of euvolemic hyponatremia. Future studies can build upon these findings to advance the field further. Overall, this study underscores the complexities of euvolemic hyponatremia in elderly patients, emphasizing the need for accurate diagnosis, careful evaluation

of underlying causes, and effective management strategies to improve patient outcomes.

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# Comparative Trial of Furosemide-Spironolactone Combination and Furosemide-Metolazone Combination in Treating Refractory Edema in Nephrotic Syndrome Patients

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## Abstract

**Introduction:** Nephrotic syndrome is defined as the presence of nephrotic range proteinuria, hypercholesterolemia, and generalized edema. Proteinuria that is more than 85% albumin is selective proteinuria. Albumin has (-ve) charge, and it is loss of glomerular membrane (-ve) charges could be significant in causing albuminuria.

**Objective:** Comparison of Furosemide-Spironolactone Combination and Furosemide-Metolazone Combination in Treating Refractory Edema in Nephrotic Syndrome Patients.

**Materials and methods:** This was a cross-sectional study design of six month from December 2023 to May 2024.

**Results:** The mean Age of the patients enrolled for the study with the minimum age being 1 year and maximum age being 14 years and the mean age was 5.6 years. It shows that weight loss at day 4 and 5 was significantly higher in group B as compared to group A.

**Conclusions:** Group B patients having lower mean abdominal girth as compared to group A. Mean Serum electrolyte values like S.Na<sup>+</sup>, S.K<sup>+</sup>, S.Ca<sup>+</sup> of both the groups were compared and found to be similar thus highlighting that both the combinations had similar effects in the patients with respect to electrolyte abnormalities.

**Key words:** Nephrotic syndrome, Edema, Furosemide, Spironolactone, Metolazone

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## Introduction

Nephrotic syndrome (NS) is a common renal disorder with an annual incidence of 1.2 to 16.9 per 100,000 children.<sup>1</sup> It is 15 times more common in children than adults.<sup>2</sup> Among children more common male were female with a male to female ratio of 2.6:1.<sup>3</sup> but once adolescence is reached, there is no significant difference between genders.<sup>4</sup>

Nephrotic syndrome is defined as the presence of nephrotic range proteinuria, hypercholesterolemia, and generalized edema. Proteinuria that is more than eighty five percent (85%) albumin is selective proteinuria. Albumin has (-ve) charge, and it is loss of glomerular membrane (-ve) charges could be significant in causing albuminuria. This construct do not permit clear separation of causes of proteinuria, except in minimal change nephropathy, in which proteinuria is selective.<sup>5</sup>

From a therapeutic perspective, nephrotic syndrome may be classified as steroid sensitive, steroid resistant, steroid dependent.<sup>6</sup> Edema, the most important clinical manifestation of nephrotic syndrome. Its pathogenesis is not fully understood and various theories are Underfill theory and Overfill theory.<sup>7,8</sup>

Infusion of 5% albumin (10-15 ml/kg) or 20% albumin (0.5-1 g/kg) may be used in subjects who does not respond despite two boluses of saline.<sup>9</sup> Very few has been written about the combination of diuretic agents in truly diuretic refractory patients.<sup>10</sup> The prognosis for patients with minimal-change nephropathy is good. Approximately 3% of cases who initially respond to steroids become steroid-resistant.<sup>11</sup>

Both metolazone and spironolactone can be used as add on drugs with loop diuretics like furosemide thus preventing the metabolic complications like hypokalemia. And preventing the development of resistance in cases of refractory edema. There is limited data regarding the comparison of furosemide-spironolactone and furosemide-metolazone combination for treating refractory edema states like nephrotic syndrome in pediatric population. Thus our study aims to compare the efficacy of both the combinations.

**Objective:** Comparison of Furosemide-Spironolactone Combination and Furosemide-Metolazone Combination in Treating Refractory Edema in Nephrotic Syndrome Patients.

**Null hypothesis:** There is no difference in between Furosemide-Spironolactone Combination and Furosemide-Metolazone Combination.

**Alternative hypothesis:** There is difference in between Furosemide-Spironolactone Combination and Furosemide-Metolazone Combination.

## Materials and Methods

**Study design:** We conducted a cross-sectional study to compare the efficacy of oral furosemide-metolazone versus oral furosemide-spironolactone combination therapy in management of edema in nephrotic syndrome. Very few researches mainly on individual drug therapy, has been done.

**Place of study:** Pediatric ward of Rama Medical College Hospital & Research centre, Kanpur, Uttar Pradesh.

**Study Duration:** The study period was six month from December 2023 to May 2024.

**Subject selection:** Children of age group 6 months to 14 years attending the OPD and IPD in pediatric department with complaint of generalized swelling and decreased urine output were admitted and diagnosed as case of nephrotic syndrome by the following parameter:

1. Bedside urine protein 3+/4+ (significant nephrotic range proteinuria 40mg/m<sup>2</sup>/24 hour)
2. Hypoalbuminemia (serum albumin <2.5 g/dl)
3. Hyperlipidemia (serum cholesterol >200 mg/dl),

### Inclusion criteria:

1. Children diagnosed with nephrotic syndrome according to above mentioned
2. Criteria and not achieving weight loss or diuresis after 2 days of treatment with oral furosemide therapy.
3. Age more than 6 month and less than 14 years.

### Exclusion criteria

1. Nephritic syndrome
2. Nephrotic syndrome patient caretakers who refuse to give consent
3. The patients who achieved weight loss or diuresis within 2 days of treatment with oral furosemide therapy.

**Sample size:** Children admitted in pediatric ward with inclusion criterion during the period of six month (according to the previous six month hospital data of nephrotic syndrome children admission in pediatrics ward data the sample size was 60. During this period maximum numbers of patients are included in the study.

**Data Collection:** Data including age, gender, residence, height, weight, and blood pressure abdominal girth was recorded. Regular weight recording was done to monitor the decrease or

increase of edema. Physical examination was done to detect infections and underlying systemic disorder. This study adds to the current available evidence on comparison of these drugs.

### Statistical Analysis

Initially data were entered in MS-excel then transferred it into SPSS 26.0. Descriptive statistics was calculated. T-test was used to compare the mean values and proportions respectively with significance level at  $p < 0.05$ .

### Results

The mean Age of the patients enrolled for the study with the minimum age being 1 year and maximum age being 14 years and the mean age was 5.6 years.

**Table 1: Descriptive statistics and distribution of study participants**

Characteristics	N	Min.	Max.	Mean	S.D.	
Age (in years)	60	1.00	14.00	5.61	3.09	
	Group A		Group B		Total	
Gender	Male	Female	Male	Female	Male	Female
N	20	10	16	14	36	24
%	66.7 %	33.3 %	53.3 %	46.7 %	60.0%	40.0%
Age (in years)	5.57	2.81	5.65	3.40	5.61	3.09
Cases	Number	Percentage	Number	Percentage	Number	Percentage
New case	7	23.3%	9	30.0%	16	26.7%
Relapse	23	76.7%	21	70.0%	44	73.3%

The patients were divided into 2 groups with 30 patients in each group. The number of males in Group A and B were 20 and 16 while the number of females being 10 and 14 respectively. The mean Age of group

A and B being 5.57 years and 5.65 years respectively. Both the groups had almost equal number of new cases and relapse cases.

**Table 2: Comparison between the two groups of study participants**

Characteristics	Group						p-value
	Group A		Group B		Total		
	Mean	SD	Mean	SD	Mean	SD	
Age (in years)	5.57	2.81	5.65	3.40	5.61	3.09	0.918
Weight in kgs. at day 1	20.18	6.02	20.03	7.11	19.61	6.54	0.619
Weight in kgs. at day 2	19.71	5.88	19.13	7.21	18.92	6.53	0.806
Weight in kgs. at day 3	19.30	5.90	18.35	6.81	18.32	6.32	0.976
Weight in kgs. at day 4	17.77	5.77	16.08	6.60	17.42	6.15	0.171

Continue.....

Weight in kgs. at day 5	17.42	5.58	15.64	6.49	17.03	6.01	0.051
SBP in mm hg at day 1	107.67	9.03	104.93	9.82	106.30	9.45	0.266
SBP in mm hg at day 2	100.07	6.49	99.55	6.19	62.32	6.33	0.363
SBP in mm hg at day 3	107.17	8.07	104.33	9.44	105.75	8.82	0.216
SBP in mm hg at day 4	62.67	6.03	60.33	5.98	61.50	6.07	0.138
SBP in mm hg at day 5	105.73	8.10	103.57	8.06	104.65	8.08	0.303
DBP in mm hg at day 1	61.77	6.25	60.07	5.53	60.92	5.91	0.269
DBP in mm hg at day 2	103.87	7.10	102.30	8.04	103.08	7.56	0.427
DBP in mm hg at day 3	60.93	5.53	59.90	5.23	60.42	5.36	0.460
DBP in mm hg at day 4	103.27	6.44	101.87	7.48	102.57	6.96	0.440
DBP in mm hg at day 5	60.77	5.32	59.33	4.44	60.05	4.91	0.262
Abdominal girth in cm at day 1	49.92	4.83	46.10	5.38	48.01	5.42	0.322
Abdominal girth in cm at day 2	49.55	4.91	45.27	5.11	47.41	5.41	0.211
Abdominal girth in cm at day 3	49.07	5.00	45.00	5.03	47.03	5.38	0.237
Abdominal girth in cm at day 4	48.67	4.97	44.70	4.83	46.68	5.25	0.180
Abdominal girth in cm at day 5	48.25	5.00	44.27	4.75	46.26	5.23	0.042

The table 2 describes about the weight loss following the diuretic therapy for 5 days in both the groups. It shows that weight loss at day 4 and 5 was significantly higher in group B as compared to group A (the p-values being 0.17 and 0.05 for day 4 and 5 respectively). Thus it showed that efficacy of frusemide metolazone combination (group B) was more than frusemide spironolactone combination (group A).

The mean systolic and diastolic BP was lower in group B as compared to group A but the results were statistically insignificant. This showed that

patients receiving Frusemide-spironolactone(group A) and those receiving frusemide-metolazone combination had almost same SBP and DBP and both the combinations had similar effects in reducing the blood pressure. Mean abdominal girth in both the group A and B the values being lower in group B as compared to group A with the values being statistically significant for day 5, showing that patients in Group B had lower abdominal girth as compared to group A thus indicating better diuretic action of frusemide-metolazone combination as compared to frusemide-spironolactone combination.

**Table 3: Distribution of clinical parameters of study subjects**

Parameters	Group						p-value
	Group A		Group B		Total		
	Mean	SD	Mean	SD	Mean	SD	
TLC in /cumm.	308.53	1641.56	8.40	4.07	158.47	1160.79	0.321
LYMPHOCYTES	32.46	4.98	36.15	4.32	34.30	4.99	0.093
POLYMORPHS	53.78	6.12	56.40	6.28	55.09	6.29	0.108
EOSINOPHILS	.75	.34	.66	.25	.71	.30	0.291
S. Cholesterol in mg/dl	300.03	73.07	295.90	52.43	297.97	63.08	0.802
S. Na+ (meq/lit)	139.63	5.18	139.27	4.86	139.45	4.99	0.779
S.K+ (meq/lit)	4.05	.58	4.19	.70	4.12	.64	0.403
S.Ca2+ (meq/lit)	8.51	.89	8.07	.95	8.29	.94	0.073
S. Albumin (g/dl)	2.64	.27	2.69	.30	2.67	.29	0.451
s.urea (mg/dl)	43.82	6.81	44.85	6.21	44.34	6.49	0.544
S. Creatinine (mg/dl)	.75	.25	.83	.23	.79	.24	0.167
pus cells /hpf	4.73	2.75	4.97	2.16	4.85	2.46	0.716

Parameters TLC, DLC, S. cholesterol, S. Electrolytes, S. Albumin, S. Urea, S. Creatinine, Urine Pus cells for both the groups A and B and compares between them for both the Groups. Both the groups were similar in above parameters and the p value was statistically insignificant.

### Discussion

The mean Age of group A and B were 5.57 and 5.65 years respectively. The number of new cases and Relapse Cases were almost the same in both the groups. Similar results were seen in other study.<sup>12</sup>

Weight loss following diuretic therapy in both the groups. It showed that group B had higher mean weight loss as compared to group A, especially on days 4 and 5 of the diuretic therapy. Thus, showing that frusemide metolazone combination had better diuretic action than frusemide spironolactone. Similarly Ghose et al. showed frusemide-metolazone combination better, Paton et al. also showed that metolazone higher efficacy than other thiazide diuretics.<sup>13,14</sup>

Group B had more urine output as compared to Group A particularly in days 4 and 5 of therapy. Marone et al. showed that addition of metolazone to frusemide increased the urine output in patients with refractory edema states.<sup>15</sup> Oimomi et al. also showed that combination diuretic therapy has better diuretic action as compared to single diuretic. The systolic and diastolic blood pressure was reduced in both the groups following diuretic therapy but there was no significant difference in blood pressure in both groups.<sup>16</sup> Paton et al. also showed that metolazone reduces blood pressure in patients receiving it apart from diuretic action.<sup>13</sup> Sica et al. also showed that metolazone, frusemide and spironolactone all have similar effects in reducing blood pressure in patients receiving them.<sup>17</sup>

The Abdominal Girth of both the 2 groups i.e. frusemide-spironolactone group (group A) and frusemide-metolazone group (group B) with group B having lower mean abdominal girth as compared to group A. Similarly Salahuddin M et al. also showed that metolazone-frusemide combination was slightly better than frusemide-spironolactone combination.<sup>18</sup> Cachero SD et al. also stated that addition of

metolazone to frusemide increases diuresis in cases with refractory edema.<sup>19</sup> The mean duration of hospital stay was similar in both the groups and frusemide-metolazone combination didn't reduce the duration of hospital stay when compared with the frusemide-spironolactone group.

### Conclusion

This study helps in developing protocols for treatment of refractory edema cases in nephrotic syndrome for clinicians improving patient care, prognosis and outcome. Group B patients having lower mean abdominal girth as compared to group A. Mean Serum electrolyte values like S.Na<sup>+</sup>, S.K<sup>+</sup>, S.Ca<sup>+</sup> of both the groups were compared and found to be similar thus highlighting that both the combinations had similar effects in the patients with respect to electrolyte abnormalities. This study paves way for clinical trials of other combinations for treatment of refractory edema cases in nephrotic syndrome.

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# Breast Cancer Awareness: Perceived Barriers Andscope of Peer Advisor to its Early Detection among Women, In an Urban Slum of Kolkata

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## Abstract

**Background:** Breast cancer is the second-leading cause of death worldwide, reportedly responsible for 9.6 million deaths in 2018<sup>1</sup>. Delay in approaching health care causes late treatment while screening promotes early treatment. An assessment of the feasibility of the role of peer advisor, a member of the community to navigate breast related awareness among women at risk for breast related disease was done.

**Method:** Cross-sectional study of sample size of 100 in selected borough under Kolkata municipal ward. Pretested structured questionnaire was used on consenting eligible women in enlisted household. Data was entered and analysed in microsoft excel.

**Result:** Of the total study population 50% had heard about breast cancer, 24% had heard about breast related disease from friend and family Four percent had heard about SBE, while 10% knew about mammography. Fifty seven percent felt shy to touch breast, 36% were embarrassed to speak a doctor and 19% were shy to speak to a family member. Considering all the information willing and capable women attending health care sector from a community may be taken up for a one to one training to disseminate information to the peer women in the community.

**Conclusion:** Women are more open to discuss breast related problem / examination from similar aged peer within the comfort of their own homes. Thus, the concept of peer advisor may be explored in the next step of research to find out its feasibility and acceptability along with efficacy.

**Keywords:** Self-breast examination SBE, breast cancer awareness, community participation.

## Introduction

Breast cancer is the second-leading cause of death worldwide, reportedly responsible for 9.6

million deaths in 2018<sup>1</sup>. It is the most common form of cancer among women<sup>2</sup> World Health Organization established the Global Breast Cancer Initiative (GBCI) in 2021 which aims to reduce the global breast

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cancer mortality by: early detection; timely diagnosis and comprehensive breast cancer management. Epidemiological profile of breast cancer in India shows disease is more commonly affecting younger women in the age group of 25-50.<sup>2</sup>

Cancer survival becomes more difficult in higher stages and more than 50% of Indian women present with stage III or IV of this cancer. This causes significantly lower five-year survival rate of breast cancer patients in India (66%) as compared to the United States of America (90%)<sup>3</sup>. Awareness about symptoms and screening like BSE, mammography is important for early detection.<sup>4</sup> Teaching BSE helps in creating awareness as well as early diagnosis leading to better survival rates. India being a resource poor country any process which is affordable acceptable with community participation, principles which form the pillars of primary health care can be explored towards early detection of breast cancer. The role of frontline health worker has been seen in studies by Khapre<sup>5</sup> where training ASHA as the person to advise on breast related disease to women in the village was hugely successful. With the large number of responsibilities already on the ASHA the study was done to scope the suitability of recruitment of any member of community based on age availability and receptivity. Such a selected and trained member of community shall for navigate breast related awareness among women vulnerable to breast cancer.

### Materials and Methods

A cross-sectional observational study conducted in the urban field practice area of tertiary level medical college, between August 2023 and December 2023. The study area is located in a borough under Kolkata Municipality ward area. A qualitative interview method was used. At a prevalence of 48.8%<sup>6</sup> at 95% CI and power 80%, with error 20%, sample size was calculated to be 100.

A pre-designed, structured interview schedule was used for data collection. From the enlisted

households of the field practice area, every household was visited and if present, eligible candidate was recruited for the study. Consenting women above the age of 18 years residing study area were included. Severely ill/moribund women and women who had already been diagnosed with breast cancer were excluded from the study.

### Results

Half of the subjects had heard of breast cancer. Adequate percentage of women do attend the primary health care centre for maternal and child health related causes and other ailments. This affords scope to identify and recruit women among health centre frequenters to be trained as peer advisor. Fig 1 A shows the median age women who did have a mammography were at a higher than those who did not. Awareness of BSE as a method of screening was low being 4% only. The necessity for behavioural change communication at this level is definitely required. Fig 1B and shows the difference in median age of women who practised BSE from those who do not do so is not significantly different. Suitable trained woman can approach all age brackets for dissemination of information on breast related morbidities. The sources of breast cancer information included a highest of 24% from friend and relatives of near age.

Table 2 shows that there was significant association between source of information about breast cancer and age ( $p=0.002$ ), the highest being information from friend/family. Significant association was also observed with respect to median age and embarrassment felt in discussing about breast related problems with a doctor, with older age bracket feeling more embarrassment. No significant association was seen with age of those having or not having knowledge about breast cancer, mammography or feeling any embarrassment discussing breast related issue with family members.

**Table 1: Showing distribution of variables pertinent to knowledge and practise about breast cancer awareness among study population**

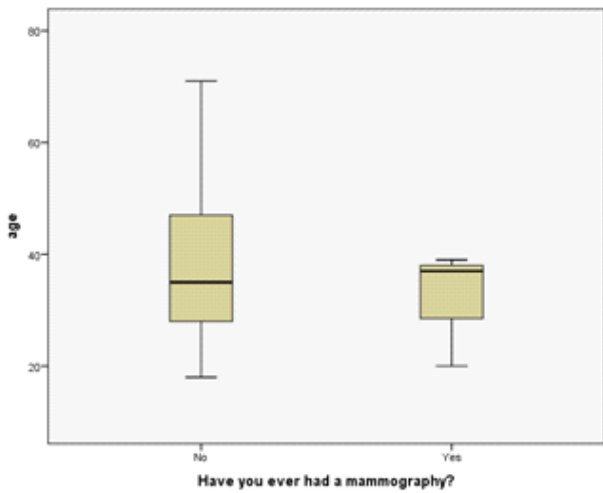
N=100		Percent	Inference
Ever heard of breast Cancer50			
Women accessing health care facility	Visited health care facility for MCH in last 2 years	73	Despite women visiting health care facilities information regarding breast screening is not shared  Scope of identifying PEER advisor for training
	Visited health care facility otherwise	48	
	Advised on breast Ca	2	
Aware of any screening method		12	
Self-breast examination	Aware and considers useful	4	Awareness about simple and effective method of screening not adequate
	Practices	1	
	Aware but does not practise	3	
	Feels shy to touch breast	57	
	Lack of privacy at home	1	
	Ever had breast examination clinically	6	
Information on mammography	Knows about it	10	BCC required Scope of Peer advisor available
	Ever had one	3	
	Considers expensive	66	
	Afraid to have one	4	
Source information of breast cancer	Doctor / health care worker	5	Health education strategies may involve peer representatives to address stigma fear and develop awareness as population is more comfortable with peer members
	Friends' relatives	24	
	Television, internet	16	
	Others	5	
	Embarrassed to speak to a doctor	36	
	Embarrassed to speak to a family member	19	
	Worried about people's opinion in case of diagnosis with breast Ca	49	
Information			
Common cause for Breast Ca as stated	• Genetic	10	Acceptable trained Peer Advisor from community providing IEC
	• Advanced age	11	
	• Obesity	4	
	• Alcohol consumption	3	
	• Having no children	3	
	• Lump	25	
Common symptoms as stated	• Pain	17	
	• Redness	6	
	• Thickening of skin	6	
	• Discharge or bleeding from nipple	6	
		4	
		4	

**Table 2 showing relation of variables with respect to age knowledge and practise pattern among study population**

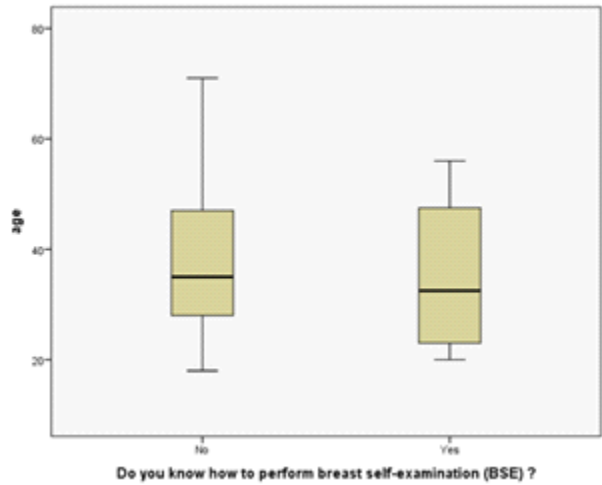
Heard about Breast Cancer	No (n=50)	Yes (n=50)				p-value
Mean age ± SD (years)	39.86± 13.09	35.54± 12.62				0.096
Source of information	NA (n=50)	Friends (n=24)	TV/media (n=16)	Doctor (n=5)	Others (n=5)	
Mean age ± SD (years)	39.86± 13.09	37.96±10.59	26.44 ± 7.29	45.6± 11.5	43± 20.26	0.002*
Knows about mammography	N (n=90)	Y(n=10)				
Mean age ± SD (years)	38.39± 13.16	31.5± 9.55				0.112
Embarrassment felt with family members	No (n=72)	Yes (n=19)	DK (n=9)			
Mean age ± SD (years)	36.06± 11.57	43.63± 13.88	38.33± 18.76			0.075
Embarrassment felt in speaking with doctor	No(n=58)	Yes(n=36)	DK(n=6)			
Mean age ± SD (years)	34.67± 11.88	42.47± 14.12	38.33± 7.5			0.016*

Significant association ( $p < 0.05$ )<sup>\*</sup> between source of information about breast cancer and age ( $p = 0.002$ ). Significant association was also observed with respect to age and embarrassment felt in discussing about breast related problems with a doctor.

Fig 1A and 1B showing age wise knowledge and practise patterns regarding modes of cancer screening among study population



**Fig 1 A Inference: The median age of having a mammography is higher than those not have had one**



**Fig 1B Inference: The median age of knowledge of SBE do not vary greatly among those practising and those not.**

**Discussion**

Awareness about breast cancer and about its screening methods were low with 50% of the women participating in the study had heard of breast cancer while only 12% of them were aware of any screening methods. Somdatta et al.,<sup>7</sup>, in a study Delhi urban colony found 56% women were aware of breast cancer while only 11% knew about breast self-examination,

Sideeq et al.,<sup>8</sup> in Kashmir found 26% women had heard of breast cancer and 6.87% had knowledge of BSE.

It was seen that 73% of women who heard about breast cancer did visit a health care centre for maternal and child health causes in the last year while 48% visited for other health concerns. This seems a vast opportunity missed on imparting health education on breast examination. This opportunity may be capitalized not only as a point of start for breast related awareness but may help to develop a cadre of Peer advisor from attendees. Such a peer advisor may be trained over her repeated visits to health care centre to act as a bridge between breast related information from health care worker to community at large

Findings of Subhojit Dey et al.,<sup>9</sup> where less than half of the women were aware of breast cancer detection methods or clinical breast examination (CBE)/ mammography was as low as 7% parallels findings of present study where 4% were aware of BSE, 1% practising and 10% aware of mammography. The median age of those knowledgeable about BSE did not vary greatly from those who did not know about it and did not practice it. This data suggests that training peer advisor from the aware group may be a useful strategy. Both peer and near peer groups can be targeted for benefit.

This study noted the most common source of information on breast cancer was friends and relatives (24%) while study done in Delhi (Subhojit Dey et al.,<sup>9</sup> shows media as found the most important source of breast cancer information (25%). This variation may be due to the difference in median age group of the study population and other demographic differences. Madhukumar et al.,<sup>10</sup> found, most women (57%) came to know about breast cancer from media, other sources being hospital staff (19%) and neighbours/relatives (11%). Thus, there is a requirement to present breast cancer related information through an engaging platform to boost propagation of knowledge. A study done by Sadler et al.<sup>11</sup> reported that direct mail interventions presented a more promising population based strategy for spreading awareness compared to mass media. Direct mailing was found to be an efficient and inexpensive way to reach females not exposed to mass media. On the other hand, in a country like ours mailing may

not be as efficient, however, a one-on-one message delivered by peer advisor in place of individual mail may be beneficial.

The common barriers to early detection of breast cancer as perceived by the subjects were feeling shyness about breasts (57%), embarrassment to speak to a doctor (36%), Rabbani et al.<sup>12</sup> recognised that focused Community based educational interventions successfully improved the government efforts of breast cancer control. In their study the educational interventions significantly reduced the women's fears about talking to their doctors about symptoms and made them less embarrassed. Fung et al.<sup>13</sup> reported that context specific and culturally appropriate breast cancer educational interventions addressed these prevalent barriers by the involvement of community partners. This further supports the idea that development of trained peer advisors will help overcome the common barriers, open discussion about breast cancer and promote early diagnosis.

Knowledge about risk factors were inadequate which concurs with known evidence of low knowledge of risk factors. Somdatta et al., (2008), concludes only 35% women knew about risk factors, while Paunikar et al.<sup>15</sup>, found 65% aware of one risk factor. Relation to menarche and menopause was identified as risk factor by 58%<sup>10</sup>

Present study shows, the common symptoms stated were lump (25%), pain (17%), redness (6%), Similarly, Sideeq et al.,<sup>8</sup> stated in their study only 21.37% women knew common presenting symptoms. Other studies<sup>14,15</sup> found 51% and 78.57% women respectively, were aware of at least one sign/symptom. Overall, the awareness level regarding signs and symptoms of breast cancer was higher than awareness of the risk factors. Information material in vernacular or pictorial format if supplied by appropriately trained peer advisor from the community can be a direct source of reaching women at home, not easily approachable otherwise.

The common discernible thread for operational issue is 24% of women gathered information about breast ailment from peer group. , the median age of those practising SBE is not vastly different from those not doing so. Only 19% are shy about opening up to breast related problems to family peer as compared

to doctors which figures to 36%. Considering all the information a system of "Peer Advisor trainer" where willing and capable women from a community may be taken up for a one to one training who can disseminate information to the community. This exercise ensures acceptance of sensitive information from an acceptable peer withing similar age bracket ultimately enhancing BSE as effective screening. The practise of annual or 5 yearly mammography being expensive may reserved for older women .The current WHO recommendations promote awareness in the community and encourage early diagnosis of breast cancer especially for women (40 – 69 years) who are attending PHC or hospitals <sup>15</sup> may be improvised by recruiting peer advisor from them.

Barriers to breast cancer awareness and practise of BSE were fear shyness and missed opportunities. However, the very factors which are barriers to adequate KAP about breast cancer can be used to develop a cadre of Peer advisor. She would be members of the community who frequents health care facility within 1 year trained and motivated to act as a medium to develop breast related awareness among females within her community. Considering women to be more comfortable with a member of their community, within their home premises this effort may be fruitful. The study further highlights that age wise older women are more shy and may open up on a one on one basis to a peer .

### Conclusion

The study was an initial scoping to assess the state of affairs with respect to breast related disease information and examination. The women are more open to discuss breast related problem / examination from similar aged peer within the comfort of their own homes. Thus, the concept of peer advisor may be explored in the next step of research to find out its feasibility and acceptability along with efficacy. The findings from the present study do indicate peer informer of relevant age bracket if trained may help bridge the gap between service provider and intended subject Considering India to be still resource poor, emphasis on Peer advisor may be a cheaper, acceptable, accessible primary health care approach.

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Ethical Clearance/Statement of Ethics (Institutional ethical committee of Calcutta National Medical College NO EC/CNMC /2022/8 dated 13/4/22

**Conflicts of interest:** nil

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# To Understand the Challenges Faced by Female Sex Workers in Seeking Health Care in Miraj town (Maharashtra)

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## Abstract

**Background:** Sex workers face challenges in terms of health, emotion, financial, and social because of their profession. Great majority of female sex workers tend to self-diagnose and seek over-the-counter medication from pharmacies or use traditional home remedies for sexually transmitted infections treatment rather than to visit health institution. Present study is conducted to understand the challenges faced by female sex workers in seeking health care.

**Methods:** 138 female sex workers aged 18-45 years in urban area of Miraj city and registered with NGO were purposively selected from the reference population. Information was collected on characters like age, education, duration of sex work, place of work, and monthly income, any illness in last one year, treatment taken for the same, place of treatment, and problems encountered in taking treatment etc. by using pre-tested and structured questionnaire and in-depth interview guide.

**Results:** Mean age of the participants was  $34.82 \pm 6.83$  years. Mean duration of sex work was 11.18 years. 68.11% respondents had no formal education. 43.48% participants experienced one or other illness during last one year

Challenges faced by the participants in seeking health care at government facilities included-unaware of health care facilities (10.86%), facilities far away from their place of work (15.94%), inconvenient OPD timings (26.08%) and inconvenient location of hospitals (9.42%).

Fear of revealing occupation secret (20.28%), fear of result (6.52%) and negative attitude of health worker towards the participants (34.05%) were the obstacles for not seeking health care from government health facilities.

**Key Words:** Female sex worker, sex work, sex trade, peer educator, STDs, HIV

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## Introduction

The Joint United Nations Programme on HIV/AIDS has defined sex work as the receipt of money or goods in exchange for sexual services, either regularly or occasionally<sup>1</sup> Sex work in India operates discreetly due to unfavourable legal environment.<sup>2</sup> Literature suggests that women who are involved in sex work are often forced, to engage in sex work against their will, due to economic reasons.<sup>3,4</sup>

As per recent figures, 8,68,000 women in India are currently engaged in sex work.<sup>5</sup> In India, there exist an intricate correlation between sex work and prevalent issues such as caste discrimination, poverty and gender inequality. Furthermore, practices like underage marriage and the dedication of young girls to sex work as part of religious traditions contribute to this complex scenario.<sup>6</sup>

Female Sex workers (FSWs) encounter challenges distinct from those faced by women in the general population while availing various social schemes.<sup>7</sup> The secret nature of sex work and stigma has restricted FSWs' access to various government services, including health and social services.<sup>8</sup>

Health interventions has often focused FSWs primarily as the recipients of prevention interventions for HIV and other sexually transmitted infections.<sup>9,10</sup>

In India, FSWs encounter severe stigma, exposing them to an elevated risk of communicable diseases and physical violence.<sup>11</sup> Factors such as HIV-related stigma, stigma associated with sex work, and the prevalence of STIs pose significant barriers for FSWs while accessing healthcare services.<sup>12</sup> Past negative experiences within the government healthcare system and knowledge of other FSWs unfavourable experiences serve as deterrents, discouraging them from seeking services at Anti-Retroviral Treatment centres.<sup>13</sup>

Studies have shown that service providers' judgmental and negative attitudes, coupled with a lack of confidence and the fear of being identified as sex workers, serve as obstacles hindering the access and utilization of health services for FSWs.<sup>14,15</sup> FSWs residing with family members or relatives are less inclined to visit or access healthcare, possibly influenced by the secretive nature of their sex work.

Additionally, FSWs in rural and semi-urban areas are less prone to seek STI treatment at NGO clinics, potentially attributed to the perceived inadequacy of services in those regions.<sup>16</sup>

With the above background, present study was carried out to understand the challenges faced by female sex workers in urban area of Miraj town registered with Sampada GraminMahila Sanstha (SANGRAM) NGO while seeking health care at Government health care facilities. The primary focus of this NGO is working with marginalised groups like sex workers to prevent HIV and gender-based violence, and to provide care and support for group members in need.

## Material and Methods

This was a quantitative research study conducted in Miraj Town, Maharashtra. Data collection was done from January to June 2023. Female sex workers aged 18 to 45 years who were involved in the sex trade for at least six months prior to the survey were the part of the study. The study employed the convenient sampling method, followed by a snowball-sampling technique. Thus during study period 138 FSWs were interviewed. A pre-tested and structured questionnaire and in-depth interview guide was used to collect data. A pilot study was conducted with 5 FSWs to test the questionnaire. Minor modifications of the questionnaire were made after the pilot to ensure that the words used were understandable and acceptable. The results from this pilot study are not included in the analysis. During study, information was collected on demographic characters like age, education, duration of sex work, place of work, and monthly income, any illness in last one year, treatment taken for the same and place of treatment. Their knowledge about clinical signs or symptoms of HIV, RTI/STI and Information about problems encountered in taking treatment was also obtained. Face to face interviews were performed in a place where respondents felt relaxed and confident to openly discuss the interview questions.

The study was approved by Institutional Ethics Committee of Government Medical College Miraj.

## Results

**Table 1: Age wise distribution of participants**

Age (years)	Frequency	Percentage
20-25	19	13.77
26-30	37	26.82
31-35	42	30.42
36-40	25	18.12
41-45	15	10.87
Total	138	100.0

Age wise distribution of the study participants is shown in table 1. Mean age of the participants was  $34.82 \pm 6.83$  years. No participant was below 20 years of age group.

25 (18.13%) participants were engaged in sex work since 1 to 5 years, while 101 (73.18 %) participants were engaged in sex work since 5 to 20 years. Only 12 (08.69%) were in the occupation for 20 years and more. Mean duration of sex work was 11.18 years

In the present study, 57 (41.30%) participants were married while 17 (12.33%) were never married. 41 (29.71 %) participants were either separated, divorcee or widow. 23 (16.66%) were devadasi (that means they were married to God) They were the victims of old traditions which pushed them into the profession as sex worker.

94(68.11%) respondents had no formal education. Only few i.e., 17 and 6 attended secondary school and higher secondary school respectively. Only two were graduated. The various reasons for not attending the schooling were - offering themselves to God, early marriage, parent's poverty, apathy as female child etc.

**Table 2: distribution of the participants suffering from common illness in last one year (n=60)**

Diseases	Frequency	Percentage
Skin infection	05	3.62
Pain /burning while urination/warts	03	2.17
HIV positive	02	1.44
Diabetes mellitus	02	1.44
Persistent cough	06	4.34
Common cold (URI)	21	15.21
Fever	34	24.63
Body ache	42	30.43

In the present study, out of 138 participants, 60 (43.48%) participants experienced one or other illness during last one year. Three (2.17%) participants suffered with reproductive health problems like pain in lower abdomen /burning urination and warts of which two participants were HIV Positive (table 2). Both these HIV positive participants were on ART (antiretroviral treatment) since 5 years. No problem identified in lockdown period for getting ART treatment. Two participants were diagnosed of having diabetes mellitus six months before and both were taking treatment from private practitioner. Out of these 60 participants, 44 consulted private practitioner identified by the NGO for medical care, 12 took self-medication and only 4 participants attended the government facilities for medical care

**Table 3: Challenges in visiting Government Health facilities for seeking health care(n=138)**

Challenges	Frequency	Percentage
Not knowing about health center	15	10.86
Health facility is far away	22	15.94
OPD timings inconvenient	36	26.08
Inconvenient location of hospitals	13	09.42
Fear of result	09	06.52
Fear of occupation secret disclosure	28	20.28
Negative attitude of health worker	47	34.05
Reluctant to attend health center	20	14.94
Don't care for symptoms	05	04.17

When asked about the challenges faced by the participants in seeking health care at government facilities, 22(15.94%) said that the government facilities are far away from their place of work. According to 36(26.08%) participants, OPD timings are inconvenient while according to 13(9.42%) participants the location of hospitals is inconvenient.15 (10.86%) participants said that they did not know about such health care facilities as these FSW are brought here for sex trade from other places like Nepal, Bihar, Karnataka etc. (Table 3)

According to 28 (20.28%) participants, fear of revealing occupation secret was one of the major obstacles for not seeking health care from government health facilities. Fear of result (after examination or laboratory testing) and negative attitude of health worker at government facilities towards the participants were another obstacles reported by 9 (6.52%) and 47 (34.05%) participants respectively in seeking health care at government facilities were. 20 (14.94%) participants were still reluctant to attend health center while 5 (4.17%) participants did not care about the illness they suffered.

When asked about the attitude towards action taking during illness, 18 (13.04%) participants felt that there was no need of treatment during illness as these illness subsides as its own, 21 (15.21%) felt that home remedies were sufficient and 22 (15.94%) relied on self-medication. 34 (24.63%) participants felt that they should go to government health facilities. 95 (68.84%) felt that they should consult private health services from nearby practitioner for the common illnesses as these private practitioners provide low cost treatment and the friendly reception.

Knowledge about route of transmission of HIV through blood transfusion, through sex without use of condom, from mother to child, from use of infected syringes and needles and wet kissing was known to 39.13%, 64.49%, 12.31%, 18.84% and 5.79% respondents respectively.

Lower abdominal pain, ulcer on the genital area, vaginal discharge, pain during intercourse and genital itching were the most common symptoms of STD according to 85%, 72.5%, 70.84%, 51.67% and 50% participants respectively.

When asked about the experience on the health facility 90% informed about their dissatisfaction about the health care services received from government health care provider. 10% participants informed that they felt discrimination in treatment after disclosing even their address. Hence most of them attend private practitioner identified by their NGO.

82% participants received health service information from peer educators, 12% received information from fellow friends, 5% from others sources (TV, customers,) and 1% had received information from healthcare provider during the visit.

All the participants regularly use condoms for sex. These condoms are distributed to them regularly by the NGO. The NGO working for these FSW provides health services and distributes condom to these FSW in collaboration with NACO.

90 percent participants were aware of treatment (ART) for HIV positive patients and its availability at government health center free of cost. But all participants get tested for hepatitis, STI etc every six monthly at private clinics.

60% participants said that separate health services should be made available near to their work area for 24 x 7 hours so that they could attend it as per their need and without any fear.

## Discussion

Several factors may contribute to individuals entering into sex work including economic circumstances, lack of alternative employment opportunities and social inequalities.<sup>17</sup>

Majority of our study participants are deserted / separated wives with or without family support. Even they did not reveal their profession to their family members. Such women may be brought to the city by procurers for the sex trade, or may fall into their hands after arrival if they have no connections in city to assist them in finding food and accommodation.<sup>18</sup>

82% participants in present study received information about health facilities and availabilities of health services from peer educators. Positive peer influence and community support can encourage individuals to seek healthcare. Ketkesone Phrasisombath et al. also mentioned that 44% received health information from peer educators, 34% from fellow friends, 26% from a pimp, and 26% from healthcare provider.<sup>16</sup> Peer workers and other outreach workers help FSWs to get benefits of the program e.g. free HIV testing, consulting for STI treatment, linking them with other social benefit schemes, providing free condoms to promote safer sexual practices etc.<sup>16,19,20</sup>

Most of the participants use condom during sex for protection against STDs and HIV infection and also for prevention of pregnancy hence no one had infected with STDs or pregnant during last one

year. The NGO with the help of NACO provides good quality condoms regularly that offer protection during sex to these FSW.

Almost all the participants take treatment in the private hospital nearby and a private physician visiting to peer educators' office fortnightly. Abel G also pointed out the same observation in his study that most sex workers have regular sexual health check-ups and most access their General Practitioner for both general health needs (91.8%) and sexual health needs (41.3%).<sup>21</sup>

People differ in their willingness to seek help from health care services. Some go readily for treatment others only when in great pain and in advanced state of ill health.<sup>22</sup>In our study 43.48% respondents reported general medical ailments such as fever, body ache, UTI, skin infection, diabetes etc followed by 2.17 % who reported to have a sexually transmitted infection including HIV. Similar findings are also stated by Bala Ritu et al in their study.<sup>23</sup>

In the present study no participant had revealed their identity at government health facilities as they were afraid of discrimination in treatment. The fear of judgment on the part of health professionals is a decisive factor for sex workers not to seek medical care or, when they do, not to reveal their profession.<sup>24</sup>

The study by Bungay et al. pointed out that sex workers do not reveal what they do in clinics for fear of judgments, discrimination due to their social position or for fear of the consultation being limited to STIs, reducing the focus on health problems not related to the sexuality.<sup>25</sup>

Challenges faced by the participants in seeking health care at government facilities included-unaware of health care facilities (10.86%), government facilities far away from their place of work (15.94%), inconvenient OPD timings (26.08%) and inconvenient location of hospitals (9.42%).

According to 28 (20.28%) participants, fear of revealing occupation secret was one of the major obstacles for not seeking health care from government health facilities. Fear of result (after examination or laboratory testing) and negative attitude of health worker towards the participants were other obstacles in seeking health care at government facilities by 9 (6.52%) and 47 (34.05%) participants respectively. Similar findings were also mentioned by various authors.<sup>14,15</sup>

The study participants were affiliated with local NGO. This NGO provides a range of services to support the well-being and empowerment of FSWs. It works to eliminate the stigma and discrimination associated to sex work. In addition to its central activity of condom distribution, it also plays a role in creation of awareness about HIV/AIDS and providing need based health services in the locality of participants. Due to this and to keep the occupational secret confidential, most of the participants avail health services from the private practitioner made available by NGO. They provide low cost treatment with friendly reception. This is one of the reason that very few participants avail health services from Government Hospital.

### Conclusion

To improve the health seeking behaviour of FSW, it is essential to implement strategies that reduce stigma, provide non-judgemental healthcare services, address economic vulnerabilities and create supportive environments. Health care service providers at Government health facilities should be trained to provide non-discriminatory, non-judgmental, and trauma-informed care to the FSWs. Creating safe and welcoming spaces where sex workers can access healthcare without fear of discrimination or exposure can encourage them to seek essential services. In the present study, data was collected from female sex workers who were available on the days of interview. The results may not be generalised to other FSWs because we have no assurance that our small purposive sample was an accurate representation of the total population of sex workers in the city. This study provided impetus for further research and valuable information that can be used when designing services and information campaigns for FSWs in this particular setting.

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**Conflicts of interest:** Nil

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# Financial Literacy Among Postgraduate Residents of Government Medical College in A District of Western Maharashtra

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## Abstract

**Background:** Financial literacy is the ability of managing financial matters. It involves application of various financial skills like budgeting and investing etc. The doctors throughout the medical education have to focus on acquiring medical knowledge & skills. The vulnerability to financial problems remains largely due to lack of proper knowledge of finance. So, the present study to assess the financial literacy among postgraduate residents is undertaken.

**Materials and Methods:** It was an observational descriptive study. We included all 212 postgraduate residents of government medical college, out of which 180 postgraduate residents participated in the study. Questionnaire based on the OECD financial literacy survey was used as study tool.

**Results:** Among the study participants, 40% were found to be financially literate. 46.7% percent of the participants were literate by financial knowledge .88.33% of the participants were literate by financial behaviour .70% of the participants were literate by financial attitude. Financial literacy was significantly associated with age, gender. It was significantly more in in-service postgraduate residents (p value<0.05). Financial literacy was highly significant in postgraduates working in pre-para clinical departments (p value<0.01). No significant association was found between financial literacy and marital status.

**Conclusion:** The postgraduate residents have shown significant deficits in overall financial literacy as well as in financial knowledge, investment practices. Financial training workshop sessions should be conducted during residency period. Future studies to evaluate the changes in knowledge and behaviour before, during and after the training is the need of hour.

**Keywords:** Financial literacy, Financial knowledge, Financial behaviour, Budgeting, Investment practices

## Introduction

Financial literacy is defined as “A combination of awareness knowledge, skill attitude and

behaviour necessary to make sound financial decisions and ultimately achieve individual financial wellbeing.”<sup>[1,2,3]</sup> Financial literacy has three aspects

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namely financial knowledge, attitude and behaviour. [3,4] Financial Knowledge involves understanding of key financial concepts and ability to evaluate benefit in real life financial situations. [2] Financial knowledge is a prerequisite for making sound financial decisions. [5] Financial Behaviour involves study of day-to-day money management, financial planning, savings, spending, bill payments, gathering information before purchase of financial products, reliance on credit. [2] Financial attitude aims at prioritization of short-term wants over long-term security, personal inclination towards financial matters. [5] Several studies suggest that the negative financial attitude weaken the financial decision making. [5,6,7]

Financially literate individuals can take informed decision contributing to long-term financial stability and security. The doctors are vulnerable to financial problems because of their unsatisfactory levels of financial knowledge and lack of awareness in terms of investments. [5] This leads to inefficient financial decisions, avoidable losses and agony. [8] The academic and work performance is negatively impacted by financial stress. The financial health of residents correlates with their mental health, resilience and academic or clinical performance. [9] The study done by Ross et al in undergraduate medical students had found that 66.2% of the students reporting money as source of stress and 78.1% students reporting coursework as source of stress. [10] Thus, money came in as second most common cause of stress after coursework. [10,11]

Most doctors begin their careers without proper financial knowledge. [5] The residents are overworked and having no scope for getting financial knowledge in traditional education system. That leaves the vacuum presently for acquiring the financial skills. The cost of medical education is rising with the looming of private medical institutions and so is the uptrend of educational debt. Prior studies have indicated a correlation between financial stress and burnout among medical professionals. This underscores the need for postgraduate residents to have the financial skills.

The Prevailing literature suggests that only about 25% to 60% of the Healthcare professionals are financially literate [12]. The study done by Cawyer CR et al. involving obstetrician/gynaecologist

residents demonstrated that participants who completed a financial literacy curriculum reported significant improvements in their sense of well-being, as measured by the Expanded Well-Being Index (E-WBI). [13] Many studies in North America have addressed the issue of financial literacy among residents. [9] In India, there are a very few studies done to assess the financial literacy among postgraduate residents.

The present study was designed to evaluate financial literacy among postgraduate residents and to determine association between demographic factors, background characteristics and financial literacy.

## Methodology

### Study design and setting

It was an observational descriptive study. It was conducted at a Government Medical College in Solapur district of Western Maharashtra, in month of August 2023.

### Study Participants and Sample size

The postgraduate residents from Government Medical College in Solapur district of western Maharashtra were the study participants. The medical college consisted of total 212 postgraduate residents.

**Inclusion Criteria:** All postgraduate residents of the medical college willing to give consent to participate in the study were included in the study.

**Exclusion Criteria:** Those postgraduate residents, not willing to give consent to participate in this study were excluded from the study.

### Study tool and technique

The semi-structured questionnaire based on Organization for Economic Cooperation and Development financial literacy questionnaire was developed as study tool. [1,2] The OECD is an international organisation promoting policies aimed at sustainable economic growth. India as a key partner participates in policy discussions in OECD bodies. It was pretested in pilot study. The study tool composed of demographic characteristics (age, gender, marital status), background characteristics such as quota of admission of postgraduates (in- service / regular

quota), working as postgraduate resident in pre-para clinical or clinical department, questions on financial knowledge, financial behaviour and financial attitude.

**Financial knowledge score:** It consisted of 8 questions on division, time value of money, interest on loan, simple interest, compound interest, inflation, risk-return relationship and diversification. (Minimum score 0 and maximum score 1.) The score for qualifying as 'literate by financial knowledge' is  $\geq 6$  out of 8.

**Financial behaviour score:** It consisted of 14 questions on household budget, ability towards meeting monthly expenses, evaluation of options prior to selection of financial products/ services, gathering information before purchase of financial products/ services, saving money, bill payments, affordability, personal financial affairs and setting long term goal. The score was calculated after merging information of the results of related questions. The score for qualifying as literate by 'financial behaviour' is  $\geq 6$  out of 9.

**Financial attitude score:** It consisted of 3 questions on attitude towards spending money, saving money and planning money. Total Score is obtained by adding together the scores for each of the three questions and then dividing by 3. (Minimum score 1 and maximum score being 5). The Score for qualifying as literate by 'financial attitude' is  $\geq 3$  out of 5.

**Financial literacy score:** The score for qualifying as a financial literate is if the combined score of at least 15 out of 22 with minimum of 6 in financial knowledge, 6 in financial behaviour and 3 in financial attitude.<sup>[2]</sup>

**Statistical analysis:** The data was analysed in Microsoft Excel. The mean and standard deviation of scores of financial knowledge, financial behaviour and financial attitude were calculated. The variables of demographic factors and background characteristics as well as variables in different domains of financial literacy were mentioned in percentages. The

chi-square test was used to determine the association.

**Ethical Considerations:** The Institutional Ethical Committee approval was taken with reference No. IEC/VMGMC/SCSMGH, Solapur 165/03-06-2023. Informed written consent of each of the study participant was taken before the questionnaire administration. The anonymity and confidentiality of the data was maintained.

## Results

**Table No. 1 Demographic and Background profile of study participants (n=180)**

Variables	Number (n)	Percentage (n%)
<b>1. Age</b>		
<30	117	65%
$\geq 30$	63	35%
<b>2. Gender</b>		
Male	84	46.7%
Female	96	53.3%
<b>3. Marital status</b>		
Married	69	38.33%
Unmarried	111	61.67%
<b>4. Admission Quota</b>		
In Service	12	6.67%
Regular	168	93.33%
<b>5. Department</b>		
Clinical	135	75%
Pre-Para clinical	45	25%

A total of 180 postgraduate residents finally participated in the study. 53.3% were female and 46.7% were male participants, 65% of the participants belonged to less than 30 years of age group and 35% belonged to greater than or equal to 30 years of age group, 61.67% of participants were unmarried and 38.33% participants were married. Among background characteristics, 6.67% of the study participants were in-service postgraduate residents and 93.33% postgraduate residents were admitted in regular admission quota.

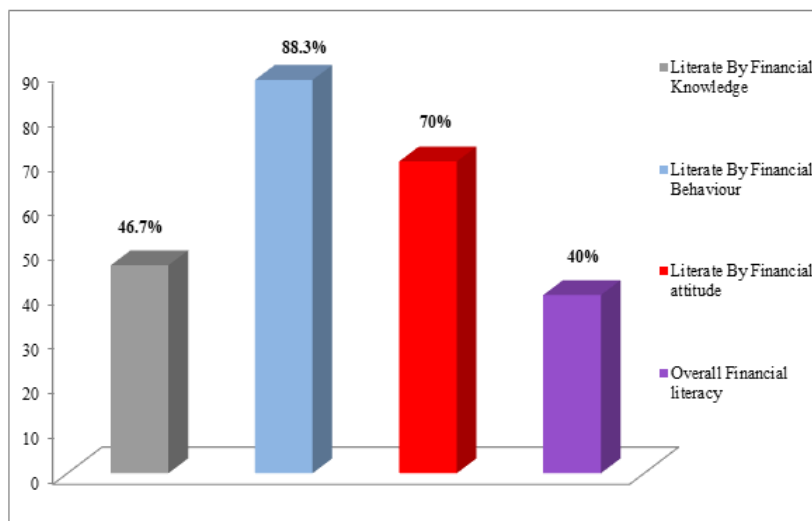


Figure No. 1 Showing Financial Literacy among study subjects

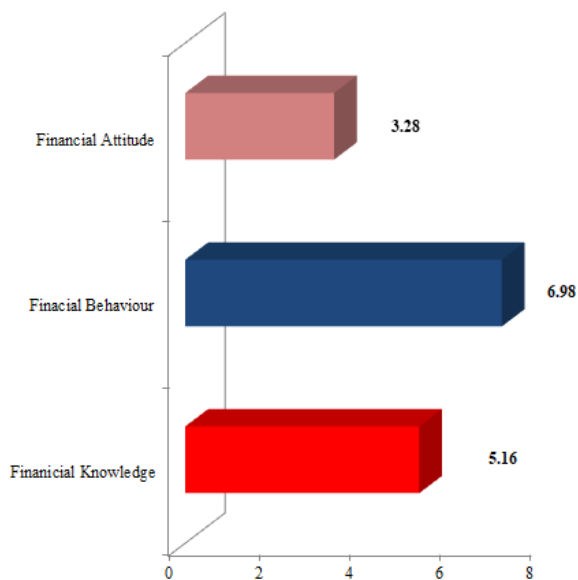


Figure No. 2 Showing mean score of Financial Attitude, behaviour & Knowledge

Among the study participants, 40% were found to be financially literate. 46.7% percent of the participants were literate by financial knowledge. 88.33% of the participants were literate by financial behaviour. 70% of the participants were literate by financial attitude. Mean financial attitude score was  $3.28 \pm 0.89$ , Mean financial behaviour score was  $6.98 \pm 1.26$  and mean financial knowledge score was  $5.16 \pm 1.53$ .

Considering various domains of financial literacy only 31.7% had investments, 41.7% had savings, 53.3% participants do make monthly budget, and 100% participants responded positively on paying bills in time, only 23.3% participants responded positively to the ability of meeting living cost without borrowing. 90% participants responded positively to set long term financial goals and strive to achieve them.

61.7% participants had knowledge about simple interest. Only 10% of participants had knowledge about compound interest. 53.3% had knowledge about diversification and 53.3% had knowledge about inflation. 40% participants have shown positive financial attitude towards spending money. 53.35% have shown positive financial attitude towards saving money. 37% have shown positive attitude towards planning money.

Financial literacy was significantly associated with age and gender. It was also found that the financial literacy was significantly more in in-service postgraduates, than those who were not from in-service (i.e. regular) ( $p < 0.05$ ). Financial literacy was also significantly more in the post graduate residents working in pre-para clinical departments than those in clinical departments. ( $p < 0.01$ ). No significant association was found between financial literacy and marital status.

**Table No. 2 Association of demographic and background characteristics with financial literacy of study participants(n=180)**

Particulars	Financial Literate (n%)	Not literate (n%)	Chi square Statistics
<b>1. Age (Years)</b>			
<30	39 (33.33%)	78 (66.67%)	$\chi^2= 6.19$ p<0.05
≥ 30	33 (52.30%)	30 (47.62%)	
<b>2. Gender</b>			
Male	41 (48.81%)	43 (51.19%)	$\chi^2=5.09$ p<0.05
Female	31 (32.29%)	65 (67.71%)	
<b>3. Marital status</b>			
Married	27 (39.13%)	42(60.86%)	$\chi^2=0.03$ p>0.05
Unmarried	45 (40.54%)	66 (59.46%)	
<b>4. PG Admission Quota</b>			
In service	9 (75%)	3 (25 %)	$\chi^2=6.56$ p<0.05
Regular	63 (37.5%)	105 (62.5%)	
<b>5. Department</b>			
Clinical	42 (31.11%)	93 (68.89%)	$\chi^2=17.78$ p<0.01
Pre-Paraclinical	30 (66.7%)	15 (33.33%)	

## Discussion

Financial literacy is recognized as important, but remains an overlooked area<sup>[14]</sup>. This study evaluates the financial literacy among postgraduate residents.

We, in the present study, found 40% of the participants to be overall financially literate. The study done by Neeraj Agarwal et al.<sup>[12]</sup> among health care professionals (HCPs) had found 68.3% to be financially literate. The financial literacy in present study was more when compared with the findings of study done by Mulligan et al.<sup>[15]</sup> (25%). But it was less when compared to the studies done by Altan et.al<sup>[16]</sup> (60%) and Ahmed et al.<sup>[17]</sup> (52%) and This may be due to different financial literacy assessment tools and due to difference in social, cultural and economic differences of sample population.

In our study we had found 46.7% percent of the participants were literate by financial knowledge. 88.33% of the participants were literate by financial behaviour. 70% of the participants were literate by financial attitude. NCFE-FLIS 2019<sup>[2]</sup> conducted among respondents in age group of 18 to 80 years, have reported 49% respondents to be literate by financial knowledge which was similar to our study findings. NCFE-FLIS 2019<sup>[2]</sup> have reported 53% respondents to be literate by financial behaviour and 89% to be literate by financial attitude.

The financial literacy was more in males (48.1%) compared to female participants (32.9%). The similar findings have been reported in study done among HCPs by Neeraj Agarwal et al.<sup>[12]</sup>, also in a study done by Jaykumar et al.<sup>[18]</sup> In the study done by Anness S. Tambolkaret al.<sup>[5]</sup>, it was found that financial knowledge of male doctors is significantly higher than that of female doctors.

Prior studies suggested age, sex, marital status, ethnicity, educational level, cadre title, income, financial attitude, and so on, as significant determinants of one's financial literacy status.<sup>[12,19,20]</sup> In our study significant association was seen between financial literacy with age and gender. Study done by Jaykumar et al.<sup>[18]</sup> have also shown association between age and financial literacy and gender and financial literacy. The study done by Anness S. Tambolkar et al.<sup>[5]</sup>, have also shown increase in financial knowledge in seen with increasing age with the highest level of financial knowledge is seen in respondents of age 50 years and above.

This study has shown no significant association between financial literacy and marital status. This is similar with the findings of study done by Ryan J. Cone et al.<sup>[14]</sup> This is in contradiction with the study done among HCPs by Neeraj Agarwal et al.<sup>[12]</sup> This may be due to difference in work experience of HCPs and residents. The residents may delegate financial decision-making to their partners due to overwork

or it may be due to different socio-cultural patterns. Married residents might face financial stress related to familial responsibilities, coupled with long hours of work and irregular schedules. Some researchers have noted that those who are married are more financially literate although another researcher has found that the marital status does not matter and the result came to be almost the same and there is no significant gap at all.<sup>[21]</sup> The result is quite inconclusive as different researchers have different results.<sup>[21]</sup>

Moreover our study considered background characteristics such as quota of admission of postgraduates (In- service / regular quota), working as postgraduate resident in pre-para clinical or clinical department, for the first time in this study ever done in India. We found, financial literacy was significantly more in in-service postgraduates, than those who were not from in-service (i.e. regular). This may be due to in-service candidates might be acquiring financial skills during the service period as a part of administrative trainings and the administrative role in nature of such jobs. It also may be due to experience over time as they continuously manage the finances.

We also found that the financial literacy was significantly more in the post graduate residents working in pre-para clinical departments than those in clinical departments. This may be due to facts that postgraduates working in clinical departments are always burdened due to high working hours and irregular schedules. The study done by Neeraj Agarwal et al. <sup>[12]</sup> have mentioned the branch as significant influencers of financial literacy.

In our study, taking into account various domains of financial literacy, only 31.7% of participants had investments. only 10 % of them had correctly answered the question about compound interest as against 97.7% in the study done in US by Jaykumar et al. <sup>[11]</sup> This difference may be due to economic differences of sample population. It was interesting to note that only 23.3% had responded positively to the ability of meeting living cost without borrowing. This may be due to familial obligations, prior debts during under graduation, irregular disbursement of stipends. The findings highlight need for financial education training to increase the financial literacy as well as financial growth prospects of postgraduate residents.

## Conclusion

The postgraduate residents in the study have shown significant deficits in overall financial literacy as well as in financial knowledge, investment practices. This indicates the need for financial awareness among the postgraduate residents. Financial literacy has shown to be associated with age and gender, as well as the type of in-service or regular admission quota and the clinical or pre-paraclinical department of residency. These results underscore the importance of considering these variables while assessing financial literacy among medical professionals. The residents from Pre-Para clinical department have shown higher overall financial literacy than their clinical counterparts. This may be due to high working hours and so high burnout for the residents working in clinical departments.

Medical institutions often traditionally focus on clinical skills and knowledge. The financial acumen required for managing personal and professional finances gets neglected. There many studies recommending to include financial knowledge in the medical curriculum. To make postgraduate residents able to take financial decisions based on the facts, the integration of financial literacy into medical training is must. There should be a structured curriculum having modules on personal finance, finance planning, debt management, investment strategies. Focus should also be given on conducting regular workshops and seminars by financial experts for postgraduate residents.

To have adequate financial knowledge at start of career, financial training programs can be thought out to begin at undergraduate level itself. Mentorship programmes connecting postgraduate residents with financially savvy professionals is also a need. This holistic approach to medical education can help to curate the long term well- being of residents. "National Medical Commission (NMC) in its "Post-Graduate Medical Education Regulations, 2023" have mentioned that Institutions may arrange training in any other courses like finance and accounts etc., which are beneficial to the post-graduate students.<sup>[22]</sup> Future studies to evaluate the changes in financial knowledge, behaviour, practices before, during and after training should be done.

Limitations: The present study was conducted in a Government Medical College. Multi- centric study all over the state or all over India needs to be done to assess the financial literacy among post graduate residents. It can also be further expanded to medical

officers, medical faculties working in medical education and as well as to the medical professionals.

**Ethical Clearance:** Institutional Ethics Committee Dr. V. M. Govt. Medical College and Shri. C. S. M. General Hospital, Solapur Approval No.165 /Date: 03-06-2023

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# A Cross-Sectional Survey to Assess the Response of the Soft Tissues in Patients Rehabilitated with Complete Dentures

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## Abstract

Lesion of the oral mucosa associated with wearing of removable dentures may represent with acute or chronic reactions. Few oral carcinomatous lesions have possible association with the wearing of the denture. The purpose of the study is to elicit the response of the oral soft tissues in patients rehabilitated with complete removable prosthesis. This study aims to evaluate the soft tissue response in patients aged 50-70 years rehabilitated with complete denture, with post insertion check-up period of 1-3 weeks.

**Keywords:** Geriatric patients, Removable complete denture, Soft tissue response, Survey.

## Introduction

Placement of a removable prosthesis in the oral cavity may produce profound change of the oral soft tissues that likely to have an adverse effect on the integrity of the tissues. Soft tissues reactions could result from a mechanical irritation by the dentures, an accumulation of microbial plaque on the dentures or occasionally a toxic or allergic reaction to constituents of the denture materials<sup>1</sup>. Mucosal inflammation in denture wearer occurs in various forms like local and generalized. Acute and chronic inflammatory condition of the oral mucosa can be classified on

the basis of their respective etiological factors. The consequence and conditions that can be associated with mucosal inflammation can be a direct sequelae of denture wearers such as, denture stomatitis also called as inflammatory papillary hyperplasia or chronic atrophic candidiasis, traumatic ulcers, epulis fissuratum also called as inflammatory fibrous hyperplasia, denture injury tumour or denture epulis and oral cancers etc. The purpose of the study is to elicit the response of the oral soft tissues in patients rehabilitated with complete removable prosthesis.

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**Aim of the Survey**

The aim of this study were to evaluate the soft tissue response in patients aged 50-70 years rehabilitated with complete denture, with post insertion check-up period of 1-3 weeks.

**Objectives**

1. Test to find out if gender is independent with respect to duration of the lesion
2. Test to find out if gender is independent with respect to effect of the lesion
3. Test to find out if gender is independent with respect to nature of the lesion

Several lesions are found to be more frequent in females than in males .This high frequency of lesions among females is not well understood. It has been suggested that it may be due to the fact that female patients wear their dentures more often and perhaps for longer duration of time for aesthetic purpose. The objective of this research was to study the prevalence of denture induced lesion. Almost 80 percent of the cases reported in this study were males. This does not reflect the true percentage of male patients with denture; it may be due to either cultural or personal reasons as female patients prefer to be treated by consulting their female doctors rather than out of turn doctors posted in outpatient department for post insertion problems. More over female patients turning up for post insertion appointments are less due overburden of issues in taking care of their families.

**Methodology**

The study population comprised of a random sample of total of 30 elderly male and female patients with age group between 50-70 years from semi urban area who had visited the hospital for first time to rehabilitate their edentulous mouth with complete denture prosthesis and post insertion check-up done for period of 1-3 weeks. Systemic and medical conditions were similar, these patients were seen to

have lifestyle associated medical conditions such as diabetes and hypertension which were under control and no other significant medical issues were seen. Informed consents were taken from the patients prior to the treatment. Statistical analysis was done on lesion affect which was divided in to reversible and irreversible reaction. Analysis was also done on the nature of the lesion which was divided into localized, localized with pain and generalized form. Dental examinations were performed in the clinics in well illuminated set up and following WHO methodology. Instruments for oral examination: plane mouth mirrors; metallic periodontal probes (Community Periodontal Index (CPI) probe) that conform to WHO specification, i.e., 0.5 mm ball tip; a black band between 3.5 and 5.5 mm and rings at 8.5 and 11.5 mm from the ball tip; and several pairs of tweezers; containers one for used instruments and one for disinfecting or sterilizing instruments and concentrated disinfecting solution in sufficient quantity; rubber gloves; wash basin for either water and soap or disinfectant solution; cloth or paper hand towels; and gauze. Generally, a minimum of 30 mouth mirrors and 30 periodontal probes per examiner should be provided, as this will permit some instruments to be sterilized while the others are being used. Used instruments should be placed in disinfectant solution, then washed and drained well before sterilization.

**Statistical Analysis**

Gender representation in the sample (Fig 1):

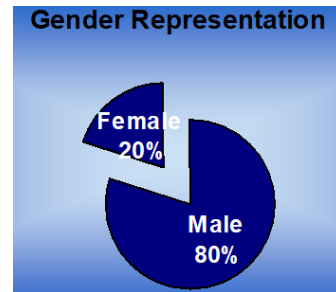
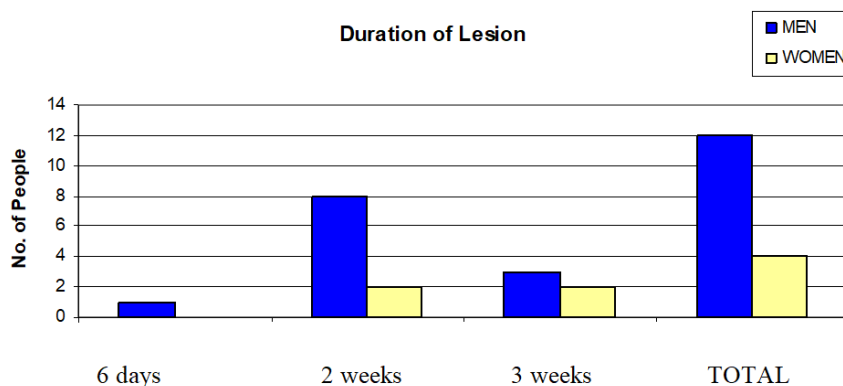


Fig 1: Gender representation in the sample

**Duration of Lesion:**

**Table 1: Distribution of the duration of lesion**

	Duration of Lesion			
	6 days	2 weeks	3 weeks	Total
MEN	1	8	3	12
WOMEN	0	2	2	4
Total	1	10	5	16



**Fig 2: Graphical representation of the duration of lesion**

Total number of patients observed clinically for the response of soft tissue rehabilitated with complete dentures - 30

Number of patients affected by the pathological changes in the denture bearing areas - 16

Percentage of patients affected by pathological changes - 53.3%

Test to find out if gender is independent with respect to duration of lesion:

Test Procedure:

Null Hypothesis:  $H_0$  -The two groups i.e. males and females are independent of each other in duration of lesion.

Alternative Hypothesis:  $H_1$  - The two groups i.e. males and females are not independent of each other

in duration of lesion.

Level of Significance:  $\alpha = 0.05$

**Test Statistic:**  $\chi^2 = \sum (O-E)^2/E$

Where O = Observed frequency and E = Expected frequency.

Critical region: We find the degrees of freedom (d.f) which is computed using the formula  $(r-1) \times (c-1)$  where r = no. of rows and c = no. of columns. Here d.f=2. The  $\chi^2$  value and the 'p value' are computed using the formula stated above. The decision criterion is to reject  $H_0$  in favour of  $H_1$  if  $p < 0.01$ . Otherwise we accept  $H_0$ .

Computation: The expected frequencies are as follows

**Table 2: statistical computation of the duration of lesion**

	Duration of Lesion			
	6 days	2 weeks	3 weeks	Total
MEN	0.750	7.500	3.750	12
WOMEN	0.250	2.500	1.250	4
Total	1	10	5	16

The  $\chi^2$  value with 2 d.f = 1.0067

The p value = 0.5866

Inference: Clearly  $p > 0.05$ .

Therefore we accept the null hypothesis and conclude that the two groups viz. male and female are independent of each other with respect to the duration of lesion.

Percentage of number of patents where duration of lesion for 6 days - 6.25%

Percentage of number of patients where duration of lesion for 2 week - 62.25%

Percentage of number of patients where duration of lesion for 3 weeks -31.25%

**Lesion effect:**

**Table 3: Distribution of gender independent effect of the lesion**

	Lesion Effect			
	Reversible	Irreversible	No Change	Total
MEN	13	0	11	24
WOMEN	3	0	3	6
Total	16	0	14	30

Test to find out if gender is independent with respect to lesion effect:

Test Procedure:

Null Hypothesis:  $H_0$  -The two groups i.e. males and females are independent of each other in lesion effect.

Alternative Hypothesis:  $H_1$  - The two groups i.e. males and females are not independent of each other in lesion effect.

Level of Significance:  $\alpha = 0.05$

$$\text{Test Statistic: } \chi^2 = \sum (O-E)^2/E$$

Where O = Observed frequency and E = Expected frequency. Critical region: We find the degrees of freedom (d.f) which is computed using the formula  $(r-1) \times (c-1)$  where r = no. of rows and c = no. of columns. Here d.f=1. The  $\chi^2$  value and the 'p value' are computed using the formula stated above. The decision criterion is to reject  $H_0$  in favour of  $H_1$  if  $p < 0.01$ . Otherwise we accept  $H_0$ .

Computation: The expected frequencies are as follows

**Table 4: statistical computation of the effect of the lesion**

	Lesion Effect			
	Reversible	Irreversible	No Change	Total
MEN	12.8	0	11.2	24
WOMEN	3.2	0	2.8	6
Total	16	0	14	30

The  $\chi^2$  value with 1 d.f = 0.0335

The p value = 0.8548

Inference: Clearly  $p > 0.05$ .

Therefore we accept the null hypothesis and

conclude that the two groups viz. male and female are independent of each other with respect to the lesion effect.

Percentage of number of patients affected by reversible changes - 53.3%

**Nature of Lesion:**

**Table 5: Distribution of the nature of the lesion**

	Nature of Lesion					
	Localized	Localized + Pain	Generalized	Nil	Normal	Total
MEN	9	1	3	10	1	24
WOMEN	2	1	0	3	0	6
Total	11	2	3	13	1	30

Test to find out if gender is independent with respect to nature of lesion:

Test Procedure:

Null Hypothesis:  $H_0$  -The two groups i.e. males and females are independent of each other with

respect to the nature of lesion.

Alternative Hypothesis:  $H_1$  - The two groups i.e. males and females are not independent of each other with respect to the nature of lesion.

Level of Significance:  $\alpha = 0.05$

Test Statistic:

$$\chi^2 = \sum (O-E)^2/E$$

Where O = Observed frequency and E = Expected frequency.

Critical region: We find the degrees of freedom (d.f) which is computed using the formula  $(r-1) \times (c-1)$

where r = no. of rows and c = no. of columns. Here d.f=4. The  $\chi^2$  value and the 'p value' are computed using the formula stated above. The decision criterion is to reject  $H_0$  in favor of  $H_1$  if  $p < 0.01$ . Otherwise we accept  $H_0$ .

Computation: The expected frequencies are as follows

**Table 6: statistical computation of the nature of the lesion**

	Nature of Lesion					
	Localized	Localized+Pain	Generalized	Nil	Normal	Total
MEN	8.8	1.6	2.4	10.4	0.8	24
WOMEN	2.2	0.4	0.6	2.6	0.2	6
Total	11	2	3	13	1	30

The  $\chi^2$  value with 4 d.f = 0.3939

The p value = 0.8212

Inference: Clearly  $p > 0.05$ .

Therefore we accept the null hypothesis and conclude that the two groups viz. male and female are independent of each other with respect to the nature of lesion.

Percentage of patients affected by nature of lesion (localized) - 36.6%

Percentage of patients affected by nature of lesion (localized+pain) - 6.6%

Percentage of patients affected by nature of lesion (generalized) --- 10%

## Discussion

In randomized populations of denture wearers the prevalence of denture stomatitis has been shown to vary from 25% to 65%. Lesions were more frequently seen in women than in men and the prevalence increased with age<sup>2</sup>. In a study on the prevalence of denture stomatitis, a population of 465 older adults denture wearers chosen at random were examined in their homes, of these 65% were affected by denture stomatitis. The prevalence of angular cheilitis is about 20% in patients with denture stomatitis and less than 10% in denture wearers with clinically healthy oral mucosa. Angular cheilitis is seen more frequently in women than in men and the conditions seems to

associated with wearing of the denture but not with edentulous state. Denture irritation hyperplasia is a chronic inflammatory tissue reaction to ill-fitting dentures; this condition has been reported 5% to 10% of elderly denture wearers. This condition is seen more frequently in women than in men. Traumatic ulcer most commonly develops within 1 to 2 days after insertion of new dentures. In randomized study, traumatic ulcers were observed in 5% of older adults<sup>3</sup>. Katzetal found there is no evidence that oral cancer may develop due to chronic mechanical or chemical irritation by dentures, however the studies underline the necessity of regular management of the geriatric patient's oral mucosa. Asif alishahhas found in his study that oral lesion due denture wearing was common in female than in male<sup>4</sup>. No significant differences were detected between male and female patient in the number of mucosal injuries in anatomical areas evaluated in maxilla and mandible<sup>5</sup>. Kivoviks reported greater frequency of ulceration due denture wearing among men compared to female patient<sup>6</sup>. He believes dietary factors play a role in development of mucosal injury

Limitation of the study is that almost 80 percent of the cases reported in this study were males, this does not reflect the true and equal distribution of cases based on gender. The implication of this research article on public health professionals is that, an attempt should be made to educate complete denture wearers about the importance of periodic examination due to the changing soft tissues for detection of early mucosal

reaction, in order to maintain their oral and denture hygiene at an optimum level. Moreover, to prevent or minimize the extent of the lesion, denture wearers should be recalled regularly for an examination of the edentulous mouth and the dentures. It is important that examination is carried out by a person who has adequate Prosthodontic knowledge. The prevalence of denture induced oral lesion was found to differ significantly from that reported in other studies. However, further studies need to be carried out on a bigger sample size for conclusive results.

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**Ethical clearance statement - copy of the certificate has been attached as a separate file.**  
Name: Dr U Krishna kumar - Principle investigator, with reference no: RRDCH/IEC/2023/114 dated 17/08/2023

### Conclusion

Within the limitation of this study, it is found that gender is independent with respect to 1) duration of the lesion 2), effect of the lesion 3), nature of the lesion in the patients rehabilitated with complete removable denture. In order to prevent or minimize the extent of the lesion, denture wearers should be recalled for an examination of the oral cavity and the dentures. It is important that the examination is carried out by a person who has adequate knowledge on geriatric Prosthodontics. Various studies also confirm the fact that soft tissues change in contour and thickness following tissue recovery. The success or failure of dentures is dependent on the health and condition of the supporting structures.

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# Assessment of Pattern of Using Personal Audio Devices among Adults in Karnataka: A Cross-Sectional Study

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## Abstract

**Introduction:** Exposure to personal audio devices for longer and loud noise contributes to hearing loss. Recent advances in technology have led to evolution of PAD and changes of usage pattern. This study highlights advancement in technology impact the choices, habits, behavioural trends of adults on the pattern of usage. This study is undertaken to determine the prevalence and pattern of using of personal audio devices (PAD) in Karnataka as the research is scarce.

**Methods and materials:** This cross-sectional study was conducted during July 2022-December 2022 using Google forms in an online platform in adults. A convenience method was used and 200 participants who gave consent were recruited. Socio-demographic profile, the pattern of using personal audio devices were included in the proforma. Data analysis was done in SPSS 26. Descriptive statistics and inferential statistics was computed.

**Results:** The most commonly used PAD was Bluetooth 55%, majority used for a duration of 1-5yrs 54.5%, most of them used routinely 33.5%, in a medium volume 76.5%. Around 83.5% used during travelling, 54% while walking. Pearsons Correlation between no. of days of usage of PAD and hours showed significant results with moderate positive correlation with  $r=0.5$  and  $p=.000$ .

**Conclusion:** Highly risky behaviour in the pattern of using PAD is found in adults. Hence there is need to create awareness to practice healthy using patterns of PAD.

Keywords: Pattern, Personal Audio Device, Karnataka

## Introduction

WHO estimates that over a billion young people worldwide are at risk of hearing loss due to unsafe

listening practices<sup>1</sup>. Over the years, advancement and access to technology has been increasing and number of people using such technology to communicate has risen. Increased exposure to loud sounds through

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personal audio systems and entertainment venues puts people at high risk of hearing damage. Globally, 466 million people have disabling hearing loss. Of this total, 432 million (93%) are adults and 34 million (7%) are children<sup>2</sup>.

Without action, there may be 630 million people with disabling hearing loss by 2030 and over 900 million by 2050, with a corresponding increase in the global annual cost of more than US\$750 billion<sup>1,3</sup>. Risk factors for hearing loss include preventable factors like noise exposure, which is on the rise due to modern lifestyles. Exposure to loud sounds in social settings can triple the likelihood of hearing loss, with 40% of individuals at events like clubs or concerts being exposed to potentially damaging levels<sup>4,5</sup>.

The widespread use of personal audio devices (PAD) like smartphones has increased the risk of hearing loss, with an estimated 50% of users listening at risky levels. Hearing loss can affect communication, cognition, education, and employment, and those with hearing loss have a higher unemployment rate and may experience social isolation and stigma<sup>5-8</sup>.

Young people's noise exposure can contribute to age-related hearing loss, which can cause communication difficulties and emotional and cognitive effects. Seniors with hearing loss are twice as likely to experience depression, isolation, frustration, cognitive decline, and decreased personal safety compared to those without hearing loss, according to recent evidence<sup>9-13</sup>.

Although noise-induced hearing loss is permanent, it can be prevented by adopting safe listening practices. Individuals can limit volume and exposure to noisy activities to protect their hearing. Governments, healthcare providers, manufacturers, and civil society can also create an environment that promotes safe listening<sup>9-13</sup>.

Recent advances in technology have led to evolution of PAD and changes of usage pattern. This study highlights advancement in technology impacts the choices, habits, behavioural trends of adults on the pattern of usage. It determines the duration, hours of usage and the activity of usage of the PAD which is essential for designing the educational campaigns. By identifying the common pattern, habits of usage authorities can develop targeted interventions to the

public and encourage safe listening. During and post pandemic the use of PAD has increased because of increased availability of smartphone due to various reasons, hence this study was undertaken with the objectives to determine the pattern of using personal audio devices in adults and to find out the association of pattern of using PAD with the volume levels.

## Methods & Materials

A cross sectional study was conducted by Google forms between July 2022- December 2022 in adults 18 years and above. Sample Size was calculated using formula  $n = Z^2 [P (1-P)] / d^2$ , d absolute precision was determined to be 7%,  $Z = 1.96$  (Confident interval at 95%),  $P$  (Prevalence) = 50%. The sample size was 196. It was rounded off to 200. Convenience sampling method was used. Study participants who gave written consent for the participation were included.

A pretested self-designed, self-administered questionnaire was used for collecting data by google forms from the study participants. The items in the questionnaire were prepared based on a comprehensive review of the literature. Validation of questionnaire was ensured by consultation with subject experts and pilot study was conducted before sharing the google forms. The questions consisted of consent form, socio-demographic profile, Pattern of usage included type of personal audio device, duration of usage, no. of days of usage weekly, hours of usage per day, volume level, type of music preferred, sharing of PAD and usage of PAD during routine activities like Sleeping, driving, studying, travelling and walking were included.

### Operational definition:

**Bluetooth Device:** Any device that uses Bluetooth technology for wireless communication.

**Headphones:** Audio devices worn over the ears, typically consisting of two ear cups connected by a headband, used for listening to audio.

**Earphones:** Small audio devices that fit directly into the ear canal, providing a portable and compact listening experience.

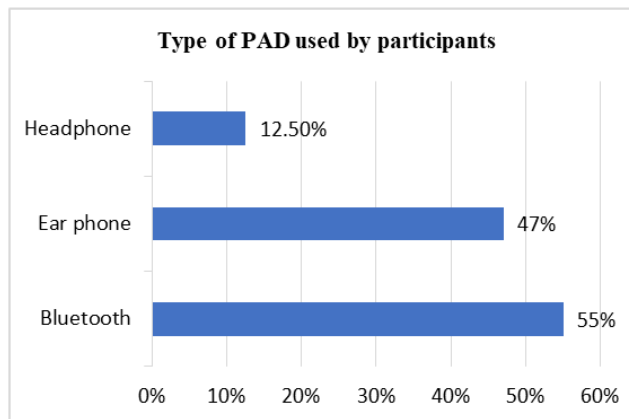
Data was entered in Microsoft excel and analysis was accomplished in SPSS vs 26. Descriptive statistics was used to determine prevalence of PAD. Inferential Statistics.

**Results**

**Table 1: Socio-demographic profile of Participants n=200**

Study Variables	n	Percentage (%)
<b>Age in years</b>		
<30	129	64.5
>30	71	35.5
<b>Gender</b>		
Male	120	60
Female	80	40
<b>Marital Status</b>		
Married	78	39
Unmarried	122	61
<b>Education</b>		
Profession or Honours	20	12.0
Graduate or Postgraduate	161	78.5
Intermediate or post high school diploma	16	8.0
High School Certificate	03	1.5
<b>Employment</b>		
Employed	100	49.0
Unemployed	16	7.0
Student	88	44.0
<b>Area of Residence</b>		
Urban	52	74.0
Rural	148	26.0
<b>Type of device</b>		
In ear	137	68.5
Out ear	23	11.5
Both	40	20.0
<b>Duration of usage</b>		
< 1 year	58	29.0
1-5 year	109	54.5
6-10 years	24	12.0
>10 years	9	4.5

<b>No of days of using personal audio devices per week</b>		
1 day	29	14.5
2days	26	13.0
3 days	23	11.5
4 days	20	10.0
5 days	20	10.0
6 days	15	7.5
7 days	67	33.5
<b>Hours of usage per day</b>		
< 1 hour	62	31
1-2 hours	66	33
3-4 hours	46	23
5-6 hours	13	6.5
hours	7	3.5
>8 hours	6	3
<b>Volume level</b>		
High	27	13.5
Medium	153	76.5
Low	20	10.0
<b>Type of music preferred</b>		
Soft	143	71.5
Metal	9	4.5
Pop	16	8.0
Rock	32	16.0



**Figure 1: Type of personal audio devices used by the participants**

**Table 2: Pattern of using personal audio devices during activities by participants n=200**

Questions	Frequency n	Percentage
<b>Sharing of PAD with others</b>		
Yes	56	28.0
No	144	72.0
<b>During Exercise</b>		
Yes	66	33.0
No	134	67.0
<b>Sleeping with PAD plugged</b>		
Yes	39	19.5
No	161	80.5
<b>Driving</b>		
Yes	58	29.0
No	142	71.0
<b>Studying</b>		
Yes	57	28.5
No	143	71.5
<b>Travelling</b>		
Yes	167	83.5
No	33	16.5
<b>Walking</b>		
Yes	108	54.0
No	92	46.0

**Table 3: Type of music preferred according to the age, type,, volume, pattern of usage of PAD**

Variable	Metal	Pop	Rock	Soft	Total (%)
<b>Age of participant</b>					
<30 years	6(4.66)	13(10.08)	26(20.15)	84(65.11)	129(100)
>30 years	3(4.22)	3(4.22)	6(8.45)	59(83.09)	71(100)
<b>Type of PAD</b>					
In ear	5(3.65)	12(8.76)	25(18.25)	95(69.34)	137(100)
Out ear	2(8.69)	0(0)	3(13.04)	18(78.27)	23(100)
Both	2(5.0)	4(10.0)	4(10.0)	30(75.0)	40(100)
<b>Volume level</b>					
High	3(11.11)	2(7.4)	14(51.85)	8(29.64)	27(100)
Low	0(0)	1(5)	0	19(95)	20(100)
Medium	6(3.92)	13(8.5)	18(11.76)	116(75.82)	153(100)

Continue.....

<b>Duration of usage of PAD</b>					
<1 year	0(0)	5(8.62)	9(15.51)	44(75.87)	58(100)
1-5 years	8(7.33)	9(8.25)	18(16.52)	74(67.9)	109(100)
6-10 years	0(0)	2(8.3)	4(16.67)	18(75)	24(100)
>10 years	1(11.11)	0	1(11.11)	7(77.78)	9(100)
<b>No. of days of usage of PAD</b>					
<3 days	0	10(12.82)	10((12.8)	58(74.36)	78(100)
>3 days	9(7.38)	6(4.92)	22(18.03)	85(69.67)	122(100)
<b>Hours of usage</b>					
< 2 hours	4(3.13)	11(8.6)	20(15.63)	93(72.64)	128(100)
>2 hours	5(6.95)	5(6.95)	12(16.66)	50(69.44)	72(100)

Most participants <30 years and >30 years preferred soft music 65.11% and 83.09% respectively. Most of them preferred rock 51.85% in high volume.

**Table 4: Pearsons Correlation between no. of days of usage of PAD and hours.**

Variable	Pearsons correlation	p value
No. of days of usage of PAD vs hours	r=0.5	.000

Pearsons Correlation between no. of days of usage of PAD and hours showed significant results with moderate positive correlation with r=0.5 and p=.000

## Discussion

This study determined the pattern and usage of personal audio devices among adults. In the present study regular use of earphone was seen in 67(33.5%) of the adults, which was similar to study conducted by A. A Alarfai et al<sup>14</sup> 32.5% in teenagers and adults whereas Pandey et al<sup>15</sup> 15.2% in medical students. It was also observed that these studies were observational cross-sectional studies.

Majority of the study participants were using PAD for >1 hr i.e., 69% similar to the study by Rekha et al<sup>16</sup>, however study conducted in Korea<sup>17</sup> (47.6%), the proportion of students using personal listening

devices for more than 1 h is lower compared to our study. This can be due to different socio demographic characteristics and cultural differences.

In our study we have included all the types of PAD used by the participants. Increase use of PAD > 1hr has an impact on hearing. The inappropriate use of PAD among these groups can be due to the lack of awareness regarding harmful effects. Since there is upward trend in usage of PAD, its important to address the situation and improve the awareness in the young population. Around 27(13.5%) listened at high volume. The prevalence of listening to loud or very loud music was estimated to be 37.4% and 35% in studies in Brazil and USA, respectively<sup>18,19</sup> The observed differences could be explained by the different geographical location. Majority of our participants listened to their PADs at a medium volume 153(76.5%) similar to Rekha et al<sup>16</sup> 63.3% and contrary to Hoover et al<sup>20</sup> 53%.

Most of participants preferred soft music 143(71.5%). Around 58(29%) were using PAD for < 1 year similar to Kim et al<sup>17</sup> and majority of study participants were using PAD for >1 year. However post COVID 19 ear infections has been increased due to long hours of usage of headphone/ earphone with the pandemic forcing adults to work from home and students attending online classes using headphones/ earphones<sup>18</sup>.

Prevalence of usage of PAD while driving is 58(29%), similar to Pandey et al<sup>15</sup> 20.8%. This behaviour leads to increased accidents and injuries to adults. Sleeping with PAD plugged is found in 39(19.5%) similar to Pandey et al 18.1<sup>15</sup>%. In contrast by S Harshitha et al<sup>22</sup> it was found to be 33%. In our study nearly three fourth of the participants did not share the PAD while only 56(28.0) shared the PAD which was similar to A Alarfai et al<sup>14</sup>, Sachdeva S<sup>23</sup>. Sharing of PAD leads to increased ear infections.

Around 57(28.5%) used PAD during studying contrast to the study conducted by S Harshitha<sup>22</sup> et al which was 8%. Present study revealed around 167(83.5%) used during travelling similar to the study by S Harshitha et al<sup>22</sup> which was 84%.

There is a statistically significant moderate positive correlation ( $r = 0.5$ ,  $p=0.000$ ) between the number of days of usage of the PAD and the hours of usage. This study revealed as the number of days of using the PAD increases, the total hours of usage also increased.

This study was conducted in a smaller sample size hence it cannot be generalised. Further studies involving larger sample and hearing difficulties has to be conducted. The level of volume measured in this study is by recall method and it is unlikely that the volume setting measured in this way is comparable across devices.

### Conclusions & Recommendation

This study concludes that there is risky pattern of usage of PAD among adults. Hence its important to develop strategies for improving adults' awareness and attitude towards the use of PAD.

**Ethical clearance:** The study followed Declaration of Helsinki guidelines. Informed consent was obtained by the participants. No intervention was conducted and was a cross-sectional study.

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# Outcome of Newborns Born to Anaemic Mother in a Rural Tertiary Care Hospital, Comparative Study

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## Abstract

**Background:** Anaemia is one of the most common nutritional deficiency issues in pregnant women. Maternal anaemia has been linked to Intrauterine growth restriction (IUGR), low birth weight (LBW) and persistent pulmonary hypertension of newborn (PPHN). Prematurity, poor Apgar scores, and intrauterine foetal mortality are more likely in anaemic pregnant women than in nonanaemic pregnant women. Maternal anaemia increases the odds of preterm delivery and low birth weight of the newborns, which increases foetal morbidity and death. According to the World Health Organization (WHO), anaemia affects over 40% of non-pregnant and more than 50% of pregnant women in developing countries. Globally, 14% of pregnant women in developed countries are anaemic, while the prevalence is significantly higher in developing nations, at 56%. Alarming, in India, 65-75% of pregnant women suffer from anaemia, indicating the scale and severity of the problem. More than 40% of the non-pregnant women and more than 50% of the pregnant women in developing countries are affected. Hence, this study was aimed to assess neonatal outcomes among babies born to anaemic mothers in comparison to Non-anaemic and to find the correlation between maternal and neonatal haemoglobin and serum ferritin levels.

**Methods:** This was a cross sectional analytic study conducted in the Department of Paediatrics in collaboration with the Department of Obstetrics, A records of 100 anaemic and 30 non anaemic mothers, and newborns over a period of one year (October 2020 to April 2021) were reviewed. Maternal Haemoglobin levels were assessed using Automated Haematology Analyzers. Based on WHO criteria, anaemia was classified as mild (9-10.9g/dl); moderate (7-8.9g/dl) and severe (<7g/dl). Newborn parameters assessed were birth weight measured using a calibrated infant weighing scale and APGAR (Appearance, Pulse, Grimace, Activity and Respiration) score was assessed at 1 and 5 minutes after birth too evaluate newborn health. Statistical analysis was done using SPSS software. Statistical tests applied were Chi-square tests for comparing categorical variables and T-test/ANOVA for comparing continuous variables. Regression analysis was used for assess the strength of association between maternal anaemia and neonatal outcome.

**Results:** Pre-term birth was significantly more among severe anaemia compared to mild and moderate anaemia. Low birth weight was significantly more among subjects with severe anaemia (81.8%) compared to moderate anaemia (59.2%) which was significantly more than mild anaemia (37.5%). Appearance, Pulse, Grimace, Activity,

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Respiration (APGAR) score at 1 minute < 7 was significantly more among severe anaemia (100.0%) compared to moderate anaemia (61.2%) which was significantly more than mild anaemia (82.5%).

APGAR score at 5 minutes < 7 was significantly more among severe anaemia (100.0%) compared to moderate and mild anaemia (2.5% and 6.1% respectively). There was a significantly positive association of maternal and newborn haemoglobin levels. There was a significantly positive association of maternal and newborn Ferritin levels. Antenatal visits >3 were significantly more among Non-Anaemic mothers compared to Anaemic mothers. The mean Maternal Hb, Maternal Ferritin, Hb of newborn and Serum Ferritin of Newborn was significantly more among Non-Anaemic group compared to Anaemic group.

**Conclusion:** Low maternal haemoglobin levels are associated with increased risk of preterm delivery, LBW babies. The APGAR score <7 at 1min and 5min was significantly more with increase in severity of anaemia.

**Keyword:** Low birth weight, neonatal outcome, maternal anaemia.

## Introduction

Anaemia is one of the most common nutritional deficiency issues in pregnant women. WHO defines it as haemoglobin (Hb) levels less than 11 g/dl and haematocrit of 0-332. A haemoglobin level of 9.0-10.9 g/dL is considered mild anaemia, 7.0-8.9 g/dL is considered moderate anaemia, and less than 7 g/dL is considered severe anaemia. Taking into consideration the physiological changes that occur during pregnancy, the Centers for Disease control and Prevention (CDC) advises that haemoglobin levels in pregnant women not go below 10.5 gm/dl during the second trimester<sup>1</sup>. The World Health Organization (WHO) defined anaemia as public health significance based on the prevalence calculated from haemoglobin levels in the blood (normal, 4.9 percent; mild, 5.0-19.9 percent; moderate, 20.0-39.9 percent; and severe, 40.0 percent).<sup>2,3</sup> Iron Deficiency Anaemia (IDA) is the most common cause of anaemia during pregnancy. Apart from Iron Deficiency Anaemia, there are several other risk factors connected with maternal anaemia that led to poor foetal outcomes. These risk factors include malnutrition, an unhealthy lifestyle, hemoglobinopathies, age (<20 or >35 years old), twin or multiple pregnancies, smoking or alcohol use, a history of menstruation abnormalities, or previous infections.<sup>4</sup> It can have catastrophic consequences for both the mother and the foetus, with a high chance of maternal death. Maternal anaemia has been linked (IUGR), LBW, and (PPH). Prematurity, poor Apgar scores, and intrauterine foetal mortality are more likely in anaemic pregnant women than in nonanaemic pregnant women.<sup>5</sup> Maternal anaemia increases the odds of preterm delivery and low birth weight of the newborns, which increases foetal morbidity and death. Infants are so compromised that they are born

with a low APGAR scores at both 1 and 5 minutes after delivery<sup>6</sup>. Mild anaemia normally has no effect on pregnancy, severe anaemia, on the other hand, is linked with poor outcomes such as tachycardia, dyspnoea, and high cardiac output failure, which can be deadly<sup>7</sup>. The objective of this study was to assess neonatal outcomes among babies born to anaemic mothers in comparison to Non-anaemic and to find the correlation between maternal and neonatal haemoglobin and serum ferritin levels.

According to the National health Survey (NFHS-5) conducted in 2019-21, 52.2% of pregnant women in India were anaemic<sup>22</sup>. This prevalence has shown minimal improvement over the years. Data from the earlier NFHS rounds indicated that about 50% of the pregnant women were anaemic, with no substantial or consistent decline observed between NFHS-2, NFHS-3 and NFHS-4<sup>23</sup>

## Methods

This was a cross-sectional analytic study conducted in the Department of Paediatrics in collaboration with the Department of Obstetrics, of rural tertiary care hospital of North India after approval by the institutional ethics committee between October 2020 to April 2021. After approval of Institutional ethical committee and after obtaining written informed consent from parents, study population included all women in labour and having haemoglobin <11 g/dl was considered as case and above 11g/dl as control. 100 anaemic mothers were enrolled in study and 30 non-anaemic mothers were taken as control. Anaemic mothers were further categorized as mild (9-10.9 g/dl), moderate (7-8.9 g/dl) and severe (<7 g/dl). The Sample size was 100 anaemic mothers aged

18-35 years and 30 non-anaemic mothers. Inclusion criteria were Age of pregnant ladies between 18-35 years and Singleton pregnancy. Exclusion criteria included women age <18 years, height less than 145 cm, history of smoking, tobacco use, alcoholics, or narcotic drug intake, medical illnesses like Diabetes mellitus, heart disease etc, blood transfusion in antenatal period/malaria, pregnancy-induced hypertension, eclampsia and recurrent abortions (Bad obstetric history). Maternal data was collected based on Questionnaire which include a number of antenatal visits, socio-demographic details (using the Modified BG Prasad Scale<sup>24</sup>), obstetrics details, anthropometry & diet preferences of the mother. The Neonatal outcomes were recorded on Performa as live birth/Stillbirth/IUD, type of delivery (vaginal/caesarean /instrumental). Gestational age of baby was assessed by Dates of the mother (EDD) & New Ballard Score. Term neonate is a neonate born between 37 and 42 weeks of gestation while a preterm neonate is a neonate born before 37 completed weeks of gestation. APGAR scores<sup>25</sup> of babies at 1 & 5 min was recorded. Babies were weighed immediately after birth without any clothing on an electronic weighing machine. Neonate with weight <2.5 kg was further classified into LBW, VLBW(<1.5 kg), ELBW(<1 kg). Based on weight and gestational age baby was categorized as AGA/SGA/LGA. Neonatal Hb& ferritin was assessed using cord blood. The results were compared in terms of neonatal outcomes in both groups of anaemic& non anaemic mothers. All women who came for delivery in the labour room at rural tertiary care hospital of North India and fulfilled inclusion criteria were included in the study. All blood samples of the mother and neonate were investigated for: Maternal Hb, Maternal Serum ferritin, and Neonatal Hb, and Neonatal Serum ferritin. Haematological tests included haemoglobin, total leucocyte count (TLC), and platelets. All these parameters were measured by automated haematology analysers using Coulter's concept of Electronic Impedance<sup>26</sup>.

### Statistical Analysis

Descriptive statistics were performed by calculating the mean and standard deviation for the continuous variables. Categorical variables were presented as absolute numbers and percentage.

The software used for the statistical analysis was SPSS (statistical package for social sciences) version 25.0 and MedCalc software. The statistical tests used

were: Unpaired or Independent t-test is used for comparison of mean value between 2 groups when the data follows the normal distribution, chi-square test is used to investigate whether distributions of categorical variables differ from one another. The p-value was taken significantly when less than 0.05 ( $p < 0.05$ ) and a Confidence interval of 95% was taken.

### Results

The mean Gestational Age (weeks), Age and Weight was compared between Anaemic and Non-Anaemic groups using the unpaired t-test. There was no significant difference in mean Gestational Age (weeks), Age and Weight between Anaemic and Non-Anaemic groups. As per the severity of maternal Anaemia, mild anaemia was reported among 40.0%, moderate among 49.0% and severe anaemia among 11.0% subjects. Antenatal visits >3 were significantly ( $p$ -value=0.004\*) more among Non-Anaemic mothers compared to Anaemic mothers. LSCS was significantly ( $p$ -value=0.001\*) more among Non-Anaemic mothers compared to Anaemic mothers. There was no significant difference in distribution of AGA and SGA between Non-Anaemic and Anaemic mothers. In both groups there was no baby large for gestational age. APGAR score at 1 minute < 7 was significantly ( $p$ -value=0.001\*) more among Anaemic mothers compared to Non-Anaemic mothers (Chi-square value = 16.109,  $p$ -value = 0.001\*) (fig 1). The mean Maternal Hb, Maternal Ferritin, Hb of newborn and Serum Ferritin of Newborn was compared between Anaemic and Non-Anaemic groups using the unpaired t-test (table 4). The mean Maternal Hb, Maternal Ferritin, Hb of newborn and Serum Ferritin of Newborn was significantly ( $p$ -value=0.001\*) more among Non-Anaemic group compared to Anaemic group. There was a significantly ( $p$ -value=0.001) positive association of maternal and newborn haemoglobin levels (fig 3). Pearson correlation=0.743,  $p$ -value=0.001\* There was a significantly ( $p$ -value 0.001) positive association of maternal and newborn Ferritin levels (fig 4). Pearson correlation=0.640,  $p$ -value=0.001\*. Low birth weight was significantly more among subjects with severe anaemia (81.8%) compared to moderate anaemia (59.2%) which was significantly ( $p$  value<0.5) more than mild anaemia (37.5%) (fig 5). APGAR score at 1 minute < 7 was significantly ( $p$ -value < 0.001) more among severe anaemia (100.0%) compared to moderate anaemia (61.2%) which was significantly more than mild anaemia (82.5%) (table 1). APGAR score at 5 minutes < 7 was significantly ( $p$ -value=0.044) more among

severe anaemia (100.0%) compared to moderate and mild anaemia (2.5% and 6.1% respectively). APGAR score at 5 minutes < 7 was significantly

(p-value=0.049\*) more among Anaemic mothers compared to Non-Anaemic mothers (Chi-square value = 3.901, p-value = 0.049\*) (table 2).

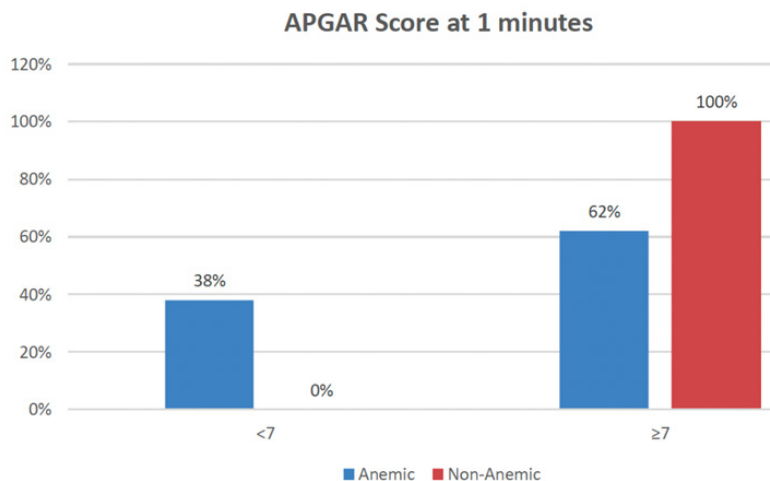


Fig 1: Bar graph showing data of APGAR Score at 1 minutes of Non-Anaemic and Anaemic mothers

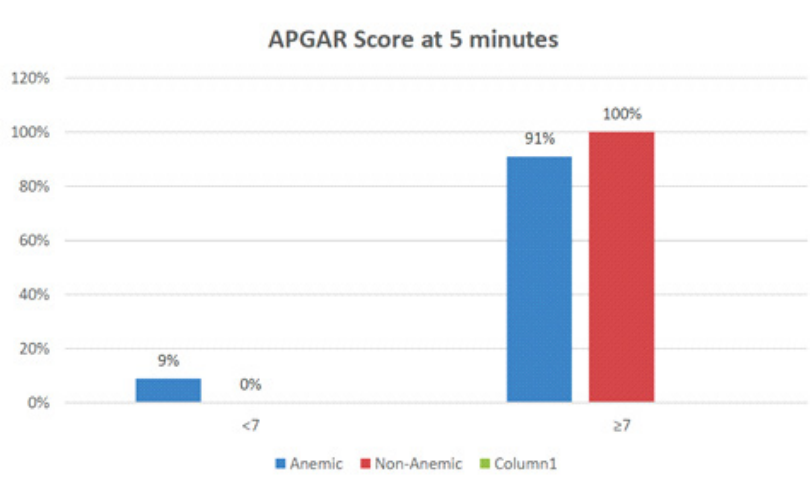


Fig 2: Bar graph showing data of APGAR Score at 5 minutes of Non-Anaemic and Anaemic mothers

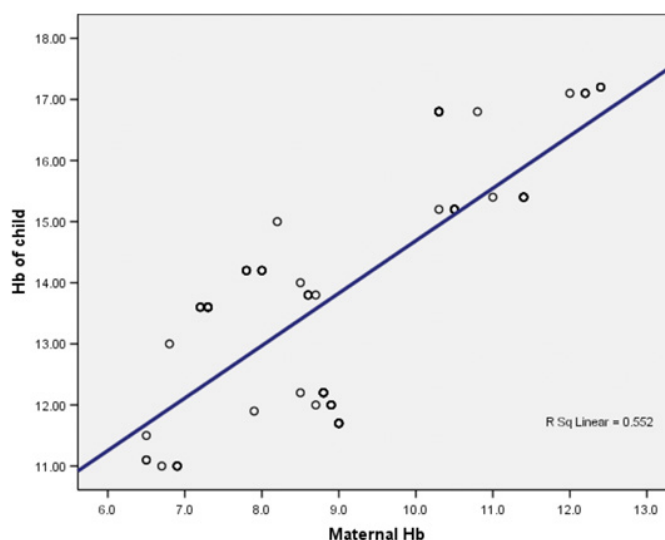


Fig 3: Correlation of maternal Hb & Neonatal Hb among Anaemic group

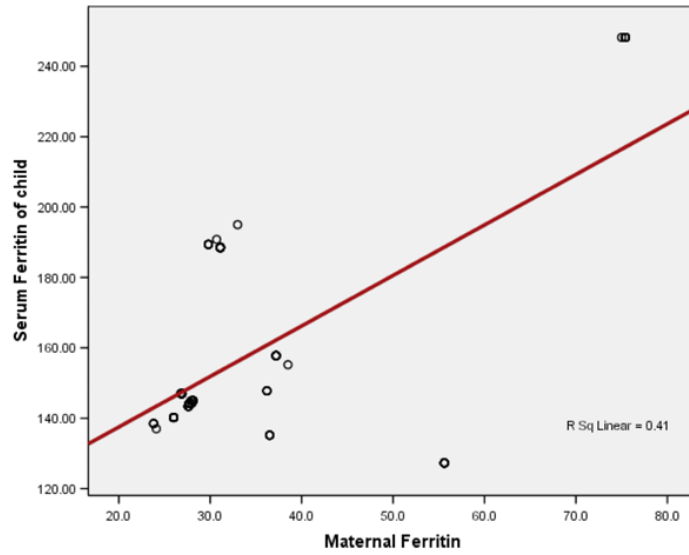


Fig 4: Correlation of Maternal & Neonatal ferritin among anaemic mothers.

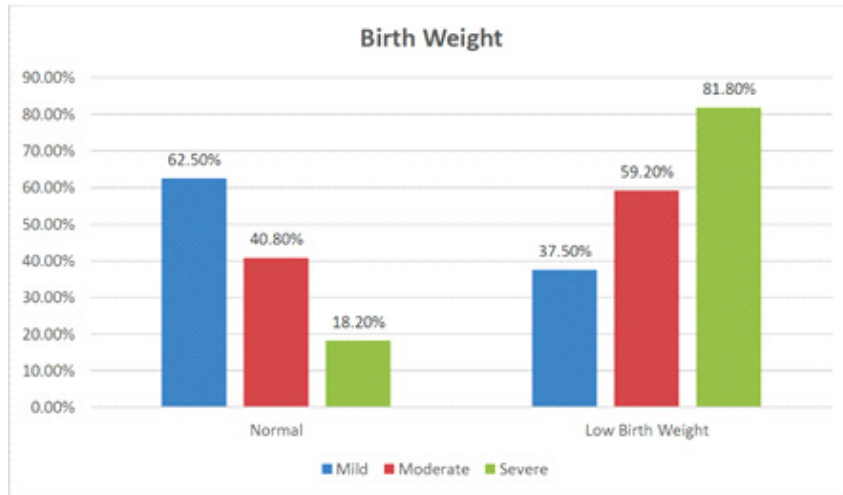


Fig 5: Bar graph showing data of anaemic mothers according to birth weight of newborn and severity of anaemia in mothers

Table 1: Neonatal outcomes among anaemic mothers according to severity of anaemia and APGAR score of newborn at 1 minute.

APGAR score at 1 Minute	Severity of anemia		
	Mild	Moderate	Severe
< 7	7 17.5%	19 38.8%	11 100.0%
≥ 7	33 82.5%	30 61.2%	0 0.0%

$\chi^2$  value = 52.789, p-value < 0.001\*

**Table 2: Neonatal outcomes among anaemic mothers according to severity of anaemia and APGAR score of a newborn at 5 minutes**

APGAR score at 5 minutes	Severity of anemia		
	Mild	Moderate	Severe
< 7	1	3	3
	2.5%	6.1%	27.3%
≥ 7	39	46	8
	97.5%	93.9%	72.7%
$\chi^2$ value = 13.098, p-value = 0.044*			

### Discussion

In our study, mild anaemia was reported among 40.0%, moderate among 49.0% and severe anaemia among 11.0% subjects. Similar to our study, Figueiredo et al.[8] stated that 20.1% pregnant women were diagnosed with mild anaemia, and 4.8% were diagnosed with moderate anaemia.

Shah N et al.[9] found that 29.5% cases were mild, 53% moderate and 17.5% were severely anaemic. Adhikari et al.[10] found that majority of mothers had mild and moderate anaemia 90.0% and severe anaemia was seen in 10%. Similar result was seen in a study conducted in India which documented 6.9% of anaemic mothers had severe anemia<sup>11</sup>. Various studies have documented less than 5% anaemic mothers had severe anaemia<sup>12,13</sup>. In current study, pre-term birth was found among 43.0% subjects. Preterm birth was significantly more among Anaemic mothers compared to Non-Anaemic mothers. Pre-term birth was significantly more among severe anaemia compared to mild and moderate anaemia. Shah T et al.[9] reported that children born < 37 weeks is 17.4% in anaemic group, in comparison to 10 (5.15%) pre-term births in non-anaemic group. study by Srouf et al.<sup>15</sup> also documented close association of low serum ferritin with low birth weight, and preterm birth. In present study, the occurrence of low birth weight among anaemic mothers was 53.0%. There was no significant difference in distribution of AGA and SGA between Non-Anaemic and Anaemic mothers. Adhikari et al.[10] found that 25.0%

newborns were LBW in the case and 8.0% were LBW in the control group. The risk of LBW was 3.9 times higher in anaemic mothers compared to the controls. Similar observations were reported in various studies<sup>[16,17]</sup> In study of Nadia et al.<sup>[18]</sup> the newborn birth weight was affected by maternal anaemia, out of 50 newborns 35 babies born to mothers with mild anaemia had mean birth weight of 3.1 Kg, 11 babies born to mothers with moderate anaemia had mean birth weight of 2.7 kg and 4 babies born to mother with severe anaemia the mean birth weight was 2.2 kg. There was a significant correlation of Haemoglobin and ferritin level among mothers with the Haemoglobin and ferritin level of the newborns showing a higher chance of anaemia among mothers with severe and moderate anaemia. The mean Maternal Hb, Maternal Ferritin, Hb of newborn and Serum Ferritin of Newborn was significantly more among Non-Anaemic group compared to Anaemic group. Terefe et al.<sup>[19]</sup> found that the significantly lower ferritin level and haemoglobin concentration in newborns delivered from IDA mothers compared to NA mothers may make them prone to iron deficiency and anaemia in early infancy. This may have serious consequences on cognitive development and cellular immunity. In current study, APGAR score at 1 minute < 7 was significantly more among severe anaemia (100.0%) compared to moderate anaemia (61.2%) which was significantly more than mild anaemia (82.5%). APGAR score at 5 minutes < 7 was significantly more among severe anaemia (100.0%) compared to moderate and mild anaemia

(2.5% and 6.1% respectively). We found that APGAR score < 7 at 1 minute and 5 minutes was significantly more among Anaemic mothers compared to Non-Anaemic mothers. In similarity to our study, Ahmad et al.<sup>[20]</sup> stated that the majority of newborns of the anaemic mothers group had an APGAR score of <5 at one minute, with a highly significant difference from the non-anaemic group. Our study results are consistent with the findings of Lone et al.<sup>21</sup> who found that maternal anaemia is associated with a 2.1 times increased risk of APGAR score of <5 at one minute, in a univariate analysis of their study population. In our study, NICU admission of the newborns was significantly more among mothers with moderate and severe anaemia. Shah N et al.<sup>[9]</sup> found high incidence of adverse foetal outcome in the form of preterm (20%), IUGR (28%), NICU admission (25.5%) and IUD (3%) seen in present study. Although the sample is representative of the urban population of the municipality investigated, caution should be exercised when interpreting the results by extrapolating them to other locations that do not have a population group that is similar to the one in this study.

### Conclusion

Low maternal haemoglobin levels are associated with increased risk of preterm delivery, LBW babies. The APGAR score <7 at 1min and 5min was significantly more with increase in severity of anaemia. APGAR score at 1 minute and 5 minutes < 7 was significantly more among Anaemic mothers compared to Non-Anaemicmothers. The mean Maternal Hb, Maternal Ferritin, Hb of newborn and Serum Ferritin of Newborn was significantly more among Non-Anaemic group compared to Anaemic group. The children born to the anaemic mothers have higher chances of having anaemic children. The study shows the effects of maternal anaemia on the neonatal outcome. Cord blood haemoglobin decreases significantly with decreasing maternal haemoglobin. There is a linear relationship between maternal and cord blood haemoglobin.

Government has introduced multiple programmes/schemes for the control and prevention of maternal anaemia. But still the prevalence is high among rural population. Anaemia in pregnancy

definitely has a very poor outcome on the newborn with increase in severity of anaemia in terms of low birth weight, poor APGAR score.

### Limitations:

Small sample size, single center study, unable to randomize the samples is some of the limitations of the study

**Ethics clearance:** Institutional Ethical Committee, approval letter no-SHKM/IEC/2020/138 GMC; dated November 21,2020.

**Contributors:** AD, SD, MY: conceptualized the study, collected and interpreted the data and prepared the initial manuscript; SD, DM supervised the study, revived literature and revised the initial manuscript. All authors approved the final version of the manuscript and are accountable for all.

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**Conflict of interests:** None

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# A Study among Health Care Workers for Handhygiene Safety in Tertiary Care Hospital, Bundelkhand Region

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## Abstract

**Background:** Hand hygiene is crucial for preventing healthcare-associated infections and ensuring patient safety. Developed countries and developing countries have 5-10% and 40% respectively acquired infection, according to WHO. This study evaluates hand hygiene practices among healthcare workers in a tertiary care hospital in the Bundelkh and region of India.

**Aim & Objective:** To observe and evaluate the hand hygiene practices among doctors, nurses, and other healthcare staff in various departments of the hospital.

**Settings and Design:** Cross sectional study.

**Methods and Material:** A cross-sectional study was conducted over seven months, involving doctors, nurses, and ward boys across clinical departments. The World Health Organization (WHO) Hand Hygiene Observation Form was used for data collection. The study focused on hand hygiene practices before and after specific patient interactions.

**Statistical analysis used:** MS words excel sheet

**Results:** Of 521 healthcare workers observed, hand hygiene practices varied by department and professional category. The Medicine department exhibited the highest hand hygiene practices at 91%, while the TB and Chest department showed the lowest at 68.8%. Among professionals, nurses had a 74.8% hand hygiene actions, compared to 88.1% for consultants, 91.3% for senior residents, and 90.5% for junior residents. Non-PG junior residents and emergency medical officers achieved 100% hand hygiene practices. Hand hygiene was performed 82.6% of the time before touching patients and 92.1% before aseptic procedures. Hand hygiene was highest after body fluid exposure (95.1%) but lower after touching patients (82.8%) and their surroundings (81.3%).

**Conclusions:** Ensuring consistent hand hygiene practices across all departments and professional categories is essential for enhancing patient safety and infection control. Regular training according to WHO guidelines are important for improving hand hygiene practices.

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**Key-words:** Hand Hygiene, Health care worker, WHO observation form

**Key Messages:** Habits that alleviate the people from activity and prog them towards a slothful norm can cause lots of health issues causing chronic non-communicable diseases that afterward changes to near incurable outcomes.

## Introduction

Healthcare settings and organizations that are dedicated to improving patient safety must prioritize the surveillance and prevention of health care-associated infections, as they pose a significant threat to patient safety.<sup>1</sup>In healthcare, patient safety refers to the security of both patients, or clients, and healthcare professionals (HCPs). In the healthcare system, it is an organizational, management, financial, and clinical concern. A major factor influencing the quality of healthcare is patient safety culture. Patient safety places a strong emphasis on the reporting, examination, and avoidance of medical mistakes that frequently result in unfavorable health outcomes.<sup>2</sup> Rubbing the hands with Alcohol Based Hand Rubs internationally recommended as the preferred method for hand hygiene in the usual encounters with patients, except in case of handwashing with soap and water is advised.<sup>3</sup> Developed countries and developing countries have 5-10% and 40% respectively acquired infection, according to WHO.<sup>4</sup>For making hand hygiene safety effectively possible, it is essential to make familiar with many types of hand washing technique as well as the timing in which a particular type of hand washing technique is accomplish. In all type of health care settings, hand washing procedure is mainly responsible for prevention of infection and control procedure. That why poor hand hygiene increases the risk of hospital acquired infection causing a negative impact on treatment which causes several health complications and also prolong the length of hospital stay for patients.<sup>5</sup> Hand hygiene is a cost-effective procedure that plays an important role in infection control and patient safety at all level of health care.<sup>6</sup>Many Studies which have done before shown that patient safety culture is influenced by several factors, including organizational culture, leadership commitment to patient safety, staff education, knowledge and training, communication among health-care professionals, patient involvement, and reporting and learning from adverse events.<sup>7</sup> There are some factors which have an effect on patient safety culture, mainly due to workload, staffing pattern and the

available resources.<sup>8</sup> The assessment of patient safety culture is not only essential for improving patient safety outcomes but also for enhancing the quality of care delivered to patients. It is a fundamental responsibility of health-care organizations to provide safe and effective care to patients, and the assessment of patient safety culture is a critical step towards achieving this goal.<sup>9</sup>

In this context, the current research aims to examine the current hand hygiene practices among healthcare workers in a tertiary care hospital located in the Bundelkhand region.

**Aim & Objective:** To observe and evaluate the hand hygiene practices among doctors, nurses, and other healthcare staff in various departments of the hospital.

(This study is needed because antibiotic resistance is a serious public health issue, especially in tertiary healthcare settings and also helped reduce in patient load. Poor hand hygiene practices can help to spread drug-resistant infections, which complicate treatment and increase health risks. In the Bundelkhand region, this is the first tertiary care hospital, where healthcare resources are limited, it's crucial to understand how hand hygiene can prevent the spread of these infectious agents. By examining hand hygiene practices among healthcare workers, this study aims to highlight their importance in reducing infections and promote safer healthcare environments.)

## Materials and Methods

The study utilized a cross-sectional methodology. All medical professionals (doctor, nurse, and ward boy) from clinical departments of tertiary health care centres were included in this study, which lasted seven months. The study was approved by the institute ethics committee (Ref No. IEC/RDMC/Cert/12). The hospital was located in the Bundelkhand region of India. Data collection was conducted using the World Health Organization (WHO) Hand Hygiene Observation Form, a recognized tool worldwide<sup>1</sup>. Observers were strategically positioned to closely

monitor how healthcare workers practiced hand hygiene during routine patient care activities. The data collected in the research was analyzed using MS Excel. We used it to describe the data and draw conclusions from it. We examined the data more closely to identify any variations in hand hygiene practices across different healthcare departments and among various professional categories.

**Results**

**Table 1:** Healthcare staff’ hand hygiene habits fluctuate between hospital departments, which is indicative of variations in how hand hygiene practices are followed. Of the observed actions, 76.7% involve proper hand hygiene, indicating that the Emergency department has the highest level of hand hygiene practices. By contrast, the department of TB and Chest has the least amount of hand hygiene practices, with only 68.8% of acts observed following hand hygiene guidelines. Curiously, the department of medicine has a high overall hand hygiene action of 91.0%; a noteworthy fraction of recorded activities (9.0%) still does not follow adequate hand hygiene.

**Table-2:** The data from table 2 reveals varying levels of hand hygiene practices across different professional categories within the healthcare setting. Nurses/staff exhibit hand hygiene action of 74.8%, while consultants, senior residents, and junior residents demonstrate higher rates of 88.1%, 91.3%, and 90.5% respectively. Nurse practitioners, junior and emergency medical officers display perfect hand hygiene action of 100%, indicating exemplary commitment to hand hygiene. However, interns show a slightly lower hand hygiene practice at 81%.

**Table-3:** The percentage of instances where healthcare workers performed hand hygiene actions before and after specific tasks. Before touching the patient, hand hygiene was observed 82.6% of the time, while it was not performed in 17.4% of cases. Prior to aseptic procedures, hand hygiene practices were higher at 92.1%, with only 7.9% of instances lacking hand hygiene. After exposure to body fluids, hand hygiene was practiced in 95.1% of occurrences and missed in 4.9%. After touching the patient, hand hygiene was seen 82.8% of the time, with 17.2% Hand hygiene. Similarly, after touching patient surroundings, hand hygiene was performed 81.3% of the time, and not done in 18.8% of instances.

**Table 1: Department wise**

Percentage of Hand Hygiene Action		
	No	Yes
Emergency	7(23.3%)	23(76.7%)
Medicine	7(9.0%)	71(91.0%)
Surgery	15(10.1%)	133(89.9%)
Paediatrics	15(15.3%)	83(84.7%)
Obstetrics/Gynaecology	15(15.5%)	82(85.5%)
Orthopaedics	8(14.8%)	46(85.2%)
TB & chest	5(31.3%)	11(68.8%)

**Table 2: Professional Category**

Percentage within hand Hygiene Action			
		Hand Hygiene Action	
		No	Yes
Professional Category	Nurse/Staff	31(25.2%)	92(74.8%)
	Consultant	15(11.9%)	111(88.1%)
	Senior Resident	10(8.7%)	105(91.3%)
	Junior Resident	12(9.5%)	114(90.5%)
	Non-PG Junior Resident	0(0%)	7(100%)
	INTERN	4(19%)	17(81%)
	EMO	0(0%)	3(100%)

**Table 3: Before/After**

Percentage of Hand Hygiene Action			
		HH Action	
		No	Yes
Before/After	Before touching the patient	30(17.4%)	142(82.6%)
	Before aseptic procedure	8(7.9%)	93(92.1%)
	After Body fluid Exposure	4(4.9%)	77(95.1%)
	After touching the Patient	15(17.2%)	72(82.8%)
	After touching patient surrounding	15(18.8%)	65(81.3%)

### Discussion

During the seven months data collection in tertiary care hospital, total 521 healthcare workers were observed for hand hygiene opportunities. In this study according to departmental category, medicine department exhibits highest level of hand hygiene practices (91%) but Krishnamoorthy Yuvaraj et al found in his study that medicine department exhibit 40% hand hygiene practices<sup>10</sup>. According to study which was done by Krishnamoorthy Yuvraj et al in Tamil Nadu found that 36%,42% and 34% hand hygiene actions performed in general surgery, paediatrics & obstetrics and gynaecology department respectively whereas in this study department like surgery (89.9%), pediatrics, obstetrics & gynecology (in range from 84.7% to 85.5%) exhibits relatively good hand hygiene practices. The TB and chest department exhibits low level of hand hygiene practices as compared to other departments.

The study done by Patil Vaibhav B. et al found that 68.7% consultants, 49% senior and junior residents doctors performed Hand hygiene practices<sup>11,13,15</sup>. Similar in another study which is done by Prabhu Deepthi j. et al found that 61% doctors performed better hand hygiene practices which is highest among all other professional categories<sup>12</sup>. But in current study according to professional category, Consultants, senior residents, and junior residents did hand hygiene practices about 88.1%, 91.3%, and 90.5%. Nursing staff, junior residents and emergency medical officers did even better, following hand hygiene practices perfectly. But interns didn't do as well, with only 81% followed the hand hygiene practices. Nurses and staff did pretty well too, with about 74.8% followed the hand hygiene practices.

The study done by Krishnamoorthy Yuvraj et al found that five moments of hand hygiene was 39% (Before touching a patient), 46.1% (before aseptic procedure), 51% (after body fluid exposure), 34% and 35% after touching the patients and their surroundings respectively<sup>10</sup>. But in this study five moments of hand hygiene found that, before touching the patient, 82.6% of hand hygiene actions were observed, indicating relatively good hand hygiene action in this aspect. However, the hand hygiene actions were lower before aseptic procedures (92.1%) and after body fluid exposure (95.1%). After touching the patient or their surroundings, hand hygiene actions were observed in 82.8% and 81.3% of instances, respectively.

In another study which is done by Anguraj Symphonia et al found that WHO moments 3 (after body fluid exposure risk) was 93.1% but in our study 95.1% health care workers performed better hand hygiene after patient's body fluid exposure<sup>14</sup>.

### Conclusion

Based on this study, hand hygiene practices among healthcare staff vary across departments and professional category. While some departments like the Emergency department show good hand hygiene practices, other department especially TB and Chest, demonstrate low level of hand hygiene practices. Nurses generally follow hand hygiene practices less as compared to consultants and residents. Overall, hand hygiene is better before aseptic procedures and after exposure to body fluids, but there are gaps before and after patient contact and touching patient surroundings. Improving consistency in hand hygiene across all the five moments by WHO is crucial to enhance patient safety and infection control in healthcare settings.

**Recommendation:** To make sure healthcare workers follow hand hygiene in better way, for that it is necessary to conduct regular training on half yearly basis. This training should teach the health care workers about the latest handwashing methods and recent guidelines (Educational workshops should be held on hand hygiene practices at all medical colleges in India. These workshops helps students and faculty learn important skills to follow hand hygiene rules, which will keep patients safer and reduce the chances of infections. Participants should take part in engaging demonstrations, discussions, and hands-on activities to practice the best techniques and build a culture of safety in healthcare settings. Using interactive training and practice sessions can really help them remember and use these practices correctly.

For better hand hygiene practices make the rules same for all departments, put up hand washing posters everywhere to remind the health care workers about handwashing, and all the experienced staff should demonstrate hand hygiene to others, make hand hygiene practices is a part of everyday tasks, and always look for ways to do it even better to keep patients safe.

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**Conflict of interest:** None

**Ethical Clearance:** The study was approved by the institute ethics committee with (Ref No. IEC/RDMC/Cert/12) dated 24-08-2024.

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# Understanding the Role of Maternal Mental Health in Pregnancy and Postpartum Depression

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## Abstract

**Objective:** This study aimed to investigate the dynamics of maternal mental health during pregnancy and the postpartum period, examining the prevalence of mental health disorders, changes over time, and the role of social support.

**Methods:** A longitudinal study design was employed, with a sample of 80 pregnant women recruited from obstetrics and gynaecology clinics. Participants completed standardized measures assessing depressive symptoms, anxiety levels, stress, and perceived social support at multiple time points from the second trimester to twelve months postpartum. Qualitative interviews were also conducted to explore participants' subjective experiences.

**Results:** The study found high prevalence of depressive symptoms, anxiety, and stress during pregnancy and the postpartum period. Depressive symptoms decreased over time, while anxiety and stress remained stable. Perceived social support was associated with better mental health outcomes. Qualitative analysis revealed diverse emotional experiences of pregnancy and coping strategies employed by participants.

**Conclusion:** Addressing maternal mental health is crucial for comprehensive perinatal care. Routine screening, early intervention, and fostering social support networks are essential for promoting maternal well-being.

**Keywords:** Maternal mental health, pregnancy, postpartum period, social support.

## Introduction

Maternal mental health is a critical aspect of overall well-being during pregnancy and the postpartum period, significantly impacting both the

mother and her child. Pregnancy and the postpartum period are characterized by profound physiological, hormonal, and psychological changes, making women particularly vulnerable to mental health challenges.<sup>(1,2,3)</sup> Among these challenges, postpartum

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depression (PPD) stands out as a prevalent and debilitating condition that can profoundly affect maternal functioning and the parent-child relationship.<sup>(4)</sup>

Understanding the complexities of maternal mental health during this transformative period is essential for ensuring the well-being of both mothers and infants. Research has highlighted various risk factors for PPD, including a history of mental health disorders, lack of social support, and hormonal fluctuations. Moreover, cultural, socioeconomic, and environmental factors can also influence maternal mental health outcomes.<sup>(4,5)</sup>

By exploring the multifaceted dimensions of maternal mental health, healthcare providers can develop effective interventions and support systems tailored to the needs of pregnant and postpartum women. Through a comprehensive understanding of these issues, healthcare professionals can implement proactive strategies to promote maternal well-being and mitigate the adverse effects of perinatal mental health disorders.<sup>(6)</sup>

Worldwide about 10% of pregnant women and 13% of women who have just given birth experience a mental disorder, primarily depression. In developing countries this is even higher, i.e. 15.6% during pregnancy and 19.8% after child birth.<sup>(7)</sup>

A recent meta-analysis showed that about 20 % of mothers in developing countries experience clinical depression after childbirth.

In India, recent studies estimated the prevalence of perinatal depression to be between 14 and 24%. Researchers estimated in 2020 the magnitude of other pregnancy-related disorders such as pregnancy-related stress and anxiety to be 30.9% and 23%, respectively.<sup>(8)</sup>

## Methodology

Our study methodology involved a longitudinal study design, spanning duration of one year to investigate the dynamics of maternal mental health during pregnancy and the postpartum period. To understand the Role of Maternal Mental Health in Pregnancy and Postpartum Depression, we collected data from rural as well as urban area.

A sample size of 80 pregnant women was recruited from obstetrics and gynecology clinics in urban and suburban areas, ensuring diverse demographic representation. The study was conducted after clearance from the Institutional Ethical Committee. Written consent was obtained from beneficiaries before interviewing. A pretested structured interview schedule was used to collect required information and data.

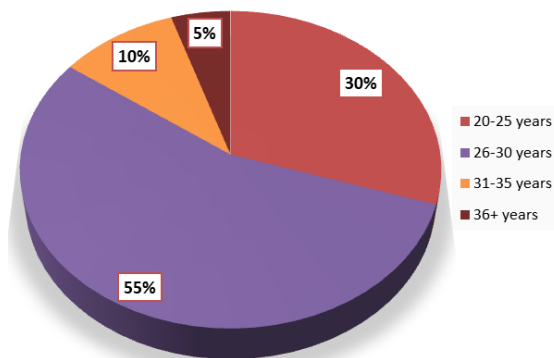
Participants were enrolled during their second trimester of pregnancy and followed up at regular intervals until twelve months postpartum.

Baseline assessments were conducted during the second trimester visit, where participants completed standardized measures to assess various aspects of maternal mental health, including depressive symptoms, anxiety levels, stress levels, and perceived social support. Additionally, demographic information such as age, education level, socioeconomic status, and previous mental health history was collected through structured interviews and self-report questionnaires.

Throughout the study period, participants received regular follow-up assessments at specific time points: during the third trimester of pregnancy, at six weeks postpartum, six months postpartum, and twelve months postpartum. These assessments involved repeated administration of the same standardized measures to track changes in maternal mental health over time. Additionally, qualitative interviews were conducted at select time points to gain deeper insights into participants' subjective experiences of pregnancy and the postpartum period.

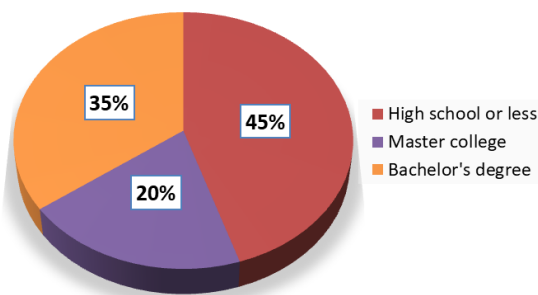
Data analysis employed both quantitative and qualitative methods. Quantitative data were analyzed using descriptive statistics to summarize demographic characteristics and mental health outcomes. Longitudinal changes in mental health measures were analyzed using repeated measures analysis of variance (ANOVA) to assess trends over time. Qualitative data from interviews were transcribed and analyzed thematically to identify recurring themes and patterns related to maternal mental health experiences during pregnancy and the postpartum period.

**Results**



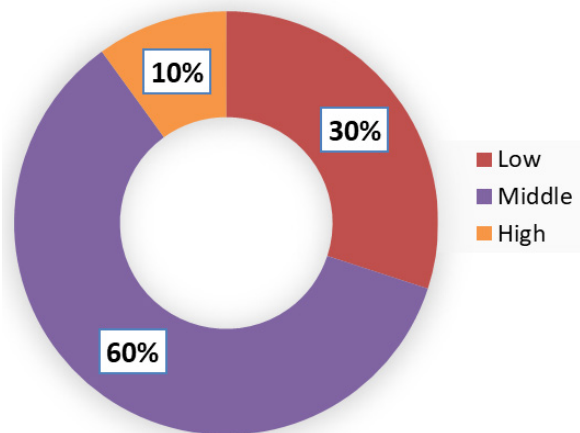
**Fig 1: Age Distribution of Participants**

From the above figure we find that from all the participant 55% were belong to 26-30 years age group, 30% were belong to 20-25 years age group, 10% were belong to 31-35 years age group and 5% were belong to more than 36 years age group.



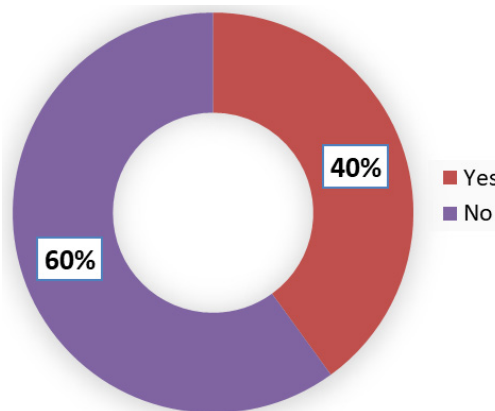
**Fig 2: Education Level of Participants**

From the above figure we find that from all the respondents 45% were belong to High school or less education, 35% were belong to Bachelor's degree and 20% were belong to Master college.



**Fig 3: Socioeconomic Status of Participants**

From the above figure we find that from all the participant 60% were belong to middle class, 30% were belong to low class and 10% were belong to high class.



**Fig 4: Previous Mental Health History of Participants**

From the above figure we find that from all the participant 60% said they had Previous Mental Health History and 40% were said they had not Previous Mental Health History

**Table 5: Prevalence of Maternal Mental Health Disorders at Baseline (Second Trimester)**

Mental Health Measure	Mean (SD)
Depressive Symptoms	12.4 (3.2)
Anxiety Levels	15.7 (4.1)
Stress Levels	18.9 (5.6)
Perceived Social Support	25.6 (6.3)

From the above table we find that from all the participant about Mental Health Measure mean (SD) of Perceived Social Support is 25.6 (6.3), Stress Levels is 18.9 (5.6), Anxiety Levels is 15.7 (4.1) and Depressive Symptoms is 12.4 (3.2).

**Table 6: Changes in Maternal Mental Health Measures Across Time Points**

Time Point	Depressive Symptoms (Mean $\pm$ SD)	Anxiety Levels (Mean $\pm$ SD)	Stress Levels (Mean $\pm$ SD)	Perceived Social Support (Mean $\pm$ SD)
Third Trimester	13.2 (3.5)	16.5 (4.2)	20.1 (5.2)	24.8 (6.1)
Six Weeks Postpartum	15.6 (3.8)	18.9 (4.7)	22.5 (5.8)	23.2 (5.9)
Six Months Postpartum	14.8 (3.6)	17.2 (4.5)	21.3 (5.4)	25.4 (6.2)
Twelve Months Postpartum	12.7 (3.3)	15.9 (4.1)	19.8 (5.0)	27.0 (6.5)

**Table 7: Qualitative Themes Emerging from Interviews**

Theme	Description
Emotional Experience of Pregnancy	Participants reported a range of emotions during pregnancy, including excitement, anxiety, and uncertainty.
Transition to Motherhood	Mothers described the process of adapting to their new role, facing challenges but also experiencing personal growth and fulfillment.
Social Support	The presence of supportive relationships was highlighted as crucial for maternal well-being, with partners, family, and friends playing significant roles.
Coping Strategies	Various coping strategies were employed by participants, including seeking professional support, engaging in self-care activities, and relying on social networks for emotional support.

## Discussion

The present study provides valuable insights into the dynamics of maternal mental health during pregnancy and the postpartum period, shedding light on the prevalence of mental health disorders, changes over time, and the role of demographic and psychosocial factors. The findings underscore the significance of addressing maternal mental health as a critical component of comprehensive perinatal care, with implications for both maternal and child well-being.<sup>(9)</sup>

The prevalence of maternal mental health disorders observed in this study aligns with previous research indicating that pregnancy and the postpartum period are periods of heightened vulnerability to mental health challenges. The high prevalence of depressive symptoms, anxiety, and stress underscores the importance of routine screening and early intervention to support maternal mental health. These findings highlight the need for healthcare providers to adopt a proactive approach to identifying and addressing maternal mental health concerns throughout the perinatal period.<sup>(10)</sup>

The longitudinal analysis of maternal mental health measures revealed intriguing patterns of change over time. While depressive symptoms tended to decrease from the third trimester to twelve months postpartum, anxiety levels and perceived stress remained relatively stable or showed slight fluctuations. This pattern suggests that the transition to motherhood is characterized by dynamic changes in mental health, with depressive symptoms potentially ameliorating as women adapt to their new role. However, the persistence of anxiety and stress underscores the ongoing challenges faced by mothers during the postpartum period, highlighting the need for sustained support and intervention beyond the immediate postpartum period.<sup>(11,12,13)</sup>

The stability of anxiety levels and stress across time points raises important questions about the factors contributing to maternal mental health during pregnancy and the postpartum period. While demographic factors such as age, education, and socioeconomic status were not directly examined in this study, previous research has highlighted their potential influence on maternal mental health outcomes.<sup>(14)</sup>

The significant role of social support in maternal mental health emerged as a prominent theme in both quantitative and qualitative analyses. Perceived social support was associated with lower levels of depressive symptoms and higher levels of well-being across time points, highlighting the protective effect of social networks on maternal mental health. These findings underscore the importance of fostering supportive relationships and community resources to enhance maternal resilience and mitigate the risk of mental health disorders during pregnancy and the postpartum period.

The qualitative themes elucidate the multifaceted experiences of pregnancy and motherhood, emphasizing the emotional complexity and adaptive processes involved in transitioning to parenthood. Mothers described a range of emotions, including excitement, anxiety, and uncertainty, underscoring the need for comprehensive psychosocial support to address the diverse needs of pregnant and postpartum women. The findings also highlight the importance of coping strategies in navigating the challenges of motherhood, with participants employing various adaptive mechanisms to manage stress and promote well-being.

Implications for clinical practice and policy arise from the study findings, emphasizing the importance of integrating mental health screening and support into routine perinatal care. Healthcare providers play a crucial role in identifying at-risk mothers, providing psychoeducation, and connecting women with appropriate resources and interventions. Additionally, healthcare systems should prioritize the development of multidisciplinary approaches to maternal mental health, involving collaboration between obstetricians, mental health professionals, and community organizations to provide comprehensive support throughout the perinatal period.

Limitations of the study warrant consideration when interpreting the findings. The sample size was relatively small, limiting the generalizability of the results to broader populations of pregnant and postpartum women.

## Conclusion

In conclusion, this study contributes to our understanding of the complexities of maternal mental health during pregnancy and the postpartum period, highlighting the prevalence of mental health disorders, changes over time, and the influence of social support.

In this study on maternal mental health introduces a novel approach by focusing on the intersection of socioeconomic status and cultural influences on depressive symptoms among new mothers. By employing a mixed-methods design, I not only quantitatively assessed the prevalence of depressive symptoms but also qualitatively explored how cultural norms impact help-seeking behaviours. This dual approach provides a comprehensive understanding of the complexities surrounding maternal mental health within diverse cultural contexts, offering new insights that could inform tailored interventions and support strategies.

**Conflict of interest:** nil

**Source of funding:** nil

**Ethical Clearance:** Taken from Institutional Ethics committee. **Date:** 16/05/2022 IEC No - 02/2022

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## Fetal biometry at the Time of Diagnosis of Gestational Diabetes in Undernourished (low BMI) Mothers from Rural KONKAN Region of Maharashtra, India (BKLWHANC-4)

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### Abstract

**Background:** To measure fetal biometric parameters and perform oral glucose tolerance test at first antenatal visit in rural undernourished pregnant mothers in a cross sectional study. Compare fetal biometry between mothers diagnosed with gestational diabetes and those with normal glucose tolerance.

**Methods:** Every undernourished pregnant woman at the time of registration in the antenatal clinic underwent oral glucose tolerance test using the protocol set by Ministry of Health and Family Welfare, Government of India. In addition, anthropometric assessment and an ultrasound scan were offered to every woman. Fetal biometric parameters (biparietal diameter, abdominal circumference, femur length and head circumference) were measured. Fetal weight was estimated. All the measures were converted to gestation specific standard deviation scores. Comparison of parameters between mothers with and without gestational diabetes (GDM) was done using t-test. Association between gestational diabetes and fetal biometry was analysed using odds ratios.

**Conclusion:** Our unexpected results of small fetal size along with AC of undernourished pregnant women with gestational diabetes will have clinical implications on treatment of gestational diabetes and fetal outcome in rural India.

**Key words:** Fetal Growth, KONKAN, Gestational Diabetes, Under nutrition

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## Introduction

India is witnessing the escalation in diabetic patients<sup>[1-2]</sup>. This is mainly attributed to rapid nutrition transition happening over last two decades which has laid to unhealthy diet (over nutrition), increase in obesity. This has also laid to the increase in incidence of gestational diabetes (GDM)<sup>[2]</sup>. These changes are very much evident in urban India. Though nutrition transition has also intruded into rural parts, yet India is still predominantly a rural country where there is substantial burden of under nutrition, maternal and neonatal mortality<sup>[3]</sup>. Prevalence of major risk factors (obesity, overweight, physical inactivity) which play crucial role in the development of GDM is still very low in rural settings. There are very few studies exploring the effect of maternal under nutrition in a GDM pregnancy on fetal growth. Prevalence of Low Birth Weight (LBW), early, late childhood and adolescent under nutrition is very high in KONKAN region of the state of Maharashtra, India<sup>[4]</sup>. According to Developmental origins of Health and Disease (DOHaD) hypothesis these factors increase the risk of adult Non-Communicable Diseases (NCD)<sup>[5]</sup>. KONKAN area is also witnessing rise in NCD's<sup>[3]</sup>. BKL Walawalkar Hospital was set up in DERVAN area of rural KONKAN region in 1996. It is a tertiary care referral centre in the region. Recently we concluded a study in our hospital on estimating the prevalence of GDM in rural KONKAN region<sup>[6]</sup>. In the same study, fetal ultrasound measurements were recorded as a part of antenatal investigations. Fetal overgrowth in abdominal circumference and increase in fetal weight is observed in mothers with GDM which is driven by obesity. But this has never been investigated in undernourished mothers. Its impact on pregnancy outcomes needs to be investigated. We now report the association between GDM in undernourished mothers and fetal ultrasound measurements.

## Materials and Methods

The details of our earlier study to estimate the prevalence of GDM in our region are already reported<sup>[6]</sup>. The study took place between March 2020 and November 2020. In addition to oral glucose tolerance test (OGTT), the subjects also underwent ultrasound scan and anthropometry measurements. The data on fetal biometric parameters measured was stored in

the Microsoft Access database. The study took place during March 2020 to November 2020.

We followed GDM diagnosis protocol laid down by Maternal Health Division, Ministry of Health and Family Welfare, Government of India where pregnant woman undergoes OGTT at her first antenatal visit irrespective of gestation<sup>[7]</sup>. This enabled us to diagnose GDM in wide range of gestation and record fetal biometry at the time of diagnosis.

## Fetal measurements

Fetal size was measured using ultrasound. Scans were performed by trained radiologists using Philips HD 11 ultrasound scanner. Biparietal diameter (BPD) was measured from the outer table of the proximal calvarium to the inner table of the distal calvarium. Abdominal circumference (AC) was calculated using transverse diameter and anteroposterior diameter. Occipito-frontal diameter (OFD) was measured, and head circumference (HC) was calculated using the formula  $(BPD+OFD) \times 1.62$ . Femur length (FL) was measured along the long axis of the ossified femoral diaphysis. Sonographic gestation was an average of the predicted ages based on biparietal diameter, head circumference, femur length and abdominal circumference measurements<sup>[8]</sup>. Ultrasound scans were performed by 2 sonologists. The variation attributable to observers ranged from 0.05% - 0.09% for these measurements. Fetal weight (EFW) was estimated using BPD, HC, AC and FL<sup>[9]</sup>.

## Statistical methods:

Total 506 pregnant women underwent OGTT. Out of these 312 women had fetal ultrasound measurements. None of the women was diagnosed with any fetal anomaly.

Comparison of basic characteristics between those with and without ultrasound scan was done using t-test. Due to wide spread of gestation of OGTT at registration, we created five groups (0-16 weeks, 16-20 weeks, 20-24 weeks, 24-28 weeks and >28 weeks) of gestation at registration. In each group every fetal biometric measurement was converted to gestation specific standard deviation (SD) score. Independent sample t-test was used to compare fetal biometric parameters between those with and without GDM. In order to see the association of above normal or below

normal fetal biometric parameters with GDM, we created gestation of OGTT specific tertile ( $1/3^{\text{rd}}$ ) of the SD score of each fetal biometric parameter. Thus lowest tertile or lowest  $1/3^{\text{rd}}$  of gestation specific SD score of that parameter and similarly highest tertile or uppermost  $1/3^{\text{rd}}$  of gestation specific SD score of that parameter represented undernourished/poorly grown and overnourished/over grown foetuses for that parameters respectively. We used middle tertile as a reference and tested the associations with GDM using odds ratios (OR) and 95% confidence intervals (CI). The SPSS version 25.0 for windows (SPSS Inc, Chicago) and STATA 13.0 (STATA Corp, Texas) was used for statistical analysis.

There was no exclusion criteria. It was a sample of convenience. We performed OGTT in every woman who consented. Our subjects come from remote areas and many of them did not wait for ultrasound scans. This has created a selection bias. But our main aim was to generate some cross sectional information on gdm and fetal growth in the region where no prior information is available.

#### Ethics:

At the time of registration, informed and written consent was obtained from all the pregnant women to use the data. Additional permission to analyse the data was granted by Institute Ethics Committee of BKL Walawalkar Rural Medical College and

Hospital. Institute ethics committee is registered with the Government of India. Registration code is EC/755/INST/MH/2015/RR-18.

## Results

Overall, 312 subjects had ultrasound scan measurements at the time of registration. Table 1 compares the basic characteristics of the subjects between those with ultrasound scan at the time of OGTT. Those without ultrasound scan had lower gestation at the time of registration. Table 2 compares Z scores of fetal biometric parameters of pregnant women between those without and with GDM. Foetuses of women diagnosed with GDM in early gestation (0-16 weeks) had significantly lower AC ( $p=0.016$ ), lower FL ( $p=0.039$ ) and lower fetal weight ( $p=0.028$ ). Foetuses of mothers diagnosed with GDM at gestation of 16-20 week had significantly lower AC ( $p=0.028$ ) and lower femur length ( $p=0.016$ ). Table 2 also shows the association of GDM with fetal biometric parameters. Foetuses of mothers with GDM diagnosed at 0-16 weeks of gestation had higher likelihood of lower AC [OR 7.5, 95% CI 1.46-22.7], lower FL [OR 14.0, 95% CI 1.3-24.5] and lower EFW [OR 4.0, 95% CI: 1.73-21.84]. Association with lower AC [OR 1.61, 95% CI: 1.08-4.37], lower FL [OR 7.6, 95% CI: 1.8-70.1] was also observed in those with diagnosis of GDM at 16-20 weeks of gestation.

**Table 1: Comparison of the basic characteristics of the subjects between those with ultrasound scan and those without at the time of OGTT at registration**

	USG done (n=312)	USG not done (n=194)	P value
Age (years)	26.2	26.7	0.770
Gravida			
Primi	148 (49.3%)	96 (54.2%)	0.301
Multi	152 (50.7%)	81 (45.8%)	
Gestation at registration (weeks)	24.8	20.2	0.000*
Height (cm)	153.3	154.3	0.092
Weight (kg)at registration	48.6	47.8	0.482
BMI (kg/m <sup>2</sup> )at registration	20.7	20.3	0.339

**Table 2: Fetal biometry between normoglycemic and GDM mothers**

Gestation at diagnosis	Parameters	Normal	GDM	P	OR (95 % CI) for GDM in Q <sub>1</sub> (Q <sub>3</sub> as reference)	P	OR (95 % CI) for GDM in Q <sub>2</sub> (Q <sub>3</sub> as reference)	P
0-16 weeks (n=40)	BPD	-0.080	0.166	0.466	0.32 (0.06-1.70)	0.173	0.52 (0.10-2.58)	0.420
	AC	0.318	-0.358	0.016	7.5 (1.46-22.7)	0.039	10.0 (0.65-154.39)	0.079
Normal n=30	HC	0.054	-0.113	0.620	1.40 (0.28-7.13)	0.680	0.9 (0.17-4.70)	0.901
GDM n=10	FL	0.157	-0.352	0.039	14.0 (1.3-24.5)	0.011	5.33 (0.50-56.2)	0.135
	EFW	0.574	-0.574	0.028	4.0 (1.73-21.84)	0.028	1.00 (0.04-24.55)	1.000
16-20 weeks (n=61)	BPD	0.005	-0.034	0.918	0.22 (0.02-2.20)	0.169	0.75 (0.14-3.87)	0.731
	AC	0.473	-0.064	0.028	1.61 (1.08-4.37)	0.022	-	-
Normal n=52	HC	-0.071	0.472	0.542	1.06 (0.19-5.98)	0.948	0.67 (0.09-4.48)	0.675
GDM n=9	FL	0.117	-0.774	0.016	7.6 (1.8-70.1)	0.045	1.00 (0.06-17.18)	1.000
	EFW	0.039	-0.274	0.684	0.8 (0.5-1.2)	0.292	0.8 (0.58-1.19)	0.338
20-24 weeks (n=56)	BPD	0.002	-0.011	0.967	1.07 (0.22-5.13)	0.931	0.70 (0.13-3.68)	0.676
	AC	-0.056	0.229	0.398	0.67 (0.09-4.54)	0.677	2.46 (0.51-11.79)	0.252
Normal n=48	HC	0.037	-0.152	0.573	1.5 (0.29-8.01)	0.618	1.42 (0.27-7.44)	0.676
GDM n=8	FL	-0.015	0.064	0.811	1.07 (0.22-5.13)	0.931	0.70 (0.13-3.68)	0.676
	EFW	-0.062	0.186	0.716	1.00 (0.04-24.54)	1.00	1.00 (0.04-25.54)	1.000
24-28 weeks (n=48)	BPD	-0.0569	0.191	0.471	0.69 (0.13-3.75)	0.669	1.00 (0.20-4.95)	1.000
	AC	-0.081	0.274	0.300	0.38 (0.08-1.93)	0.238	0.24 (0.04-1.43)	0.102
Normal n=41	HC	0.003	-0.128	0.962	3.46 (0.32-37.47)	0.285	11.7 (1.23-110.95)	0.014
GDM n=7	FL	0.038	-0.129	0.627	0.67 (0.14-3.17)	0.609	0.27 (0.04-1.65)	0.141
	EFW	-0.020	0.768	0.834	1.14 (0.12-10.38)	0.906	1.00 (0.11-8.94)	1.000
>28 weeks (n=107)	BPD	-0.000	0.002	0.990	1.25 (0.37-4.17)	0.717	2.2 (0.71-6.79)	0.165
	AC	-0.006	0.023	0.895	0.43 (0.13-1.43)	0.164	0.87 (0.30-2.47)	0.789
Normal n=73	HC	-0.012	0.041	0.818	0.54 (0.17-1.69)	0.284	0.74 (0.25-2.17)	0.586
GDM n=34	FL	0.006	-0.022	0.899	1.4 (0.49-4.10)	0.539	0.7 (0.21-2.27)	0.551
	EFW	-0.010	0.036	0.842	0.69 (0.21-2.27)	0.550	1.12 (0.38-3.35)	0.832

BPD= Biparietal diameter (mm);

AC = Abdominal circumference (mm);

HC= Head Circumference (mm);

FL= Femur Length (mm);

EFW= estimated fetal weight (gm); figures in the normal and GDM columns are means of gestation specific SD scores of respective fetal parameters; Q<sub>1</sub>, Q<sub>2</sub>, Q<sub>3</sub> are tertiles of SD scores of respective parameters; OR: odds ratio; CI: Confidence interval.

## Discussion

We have reported fetal biometry by ultrasound measurements at wide range of gestation on undernourished pregnant women diagnosed with GDM from rural KOKAN region. In almost all the Indian studies on pregnancies with GDM, fetal growth refers to neonatal anthropometric parameters

at delivery or outcomes like macrosomia. We have not calculated fetal growth velocity at diagnosis as this was first ultrasound investigation at the time of registration in the antenatal clinic. Most of the reports comparing fetal biometry and growth in GDM and non-GDM pregnancies come from North America and Europe. A recent report from US<sup>[10]</sup> found larger AC at 24-30 weeks of gestation in mothers with GDM.

A study in UK<sup>[11]</sup> found higher HC at 12 weeks, higher AC and higher EFW at 16 weeks in GDM mothers. But within ethnicity, fetal measurements were smaller in south Asian mothers with GDM than white European mothers with or without GDM. In another report from UK<sup>[12]</sup> diagnosis of GDM was preceded by rapid growth in AC between 20 and 28 weeks of gestation. A study in Africa<sup>[13]</sup> found increased abdominal circumference at 16-18 weeks of gestation. In a report from China<sup>[14]</sup> BPD, HC and AC were higher at 37-40 weeks in mothers diagnosed with GDM. Larger AC at 29-32 weeks and 37-40 weeks of gestation was also reported in Chinese mothers with GDM<sup>[15]</sup>. Our data is limited only to fetal biometry at her first antenatal registration visit coupled with OGTT as well as ultrasound scan. Women in our region come to our hospital from far away villages. In our sample of 506, only 60% had ultrasound scan on the day of OGTT as remaining staying in the remote regions rushed back home. Very rarely they came back to the hospital for subsequent investigations or ultrasound scans. This puts constraints on analysis of fetal growth trajectory. Despite these limitations we would like to highlight the fact that it comes from region with substantial undernutrition (low BMI)<sup>[4]</sup>. There is little published data from India on fetal ultrasound measurements in mothers diagnosed with GDM. There are some reports about GDM in populations with low BMI<sup>[16,17]</sup>. Ours is probably first report on fetal biometry in Indian mothers with low BMI diagnosed with GDM. We expected increased fetal abdominal circumference in women with GDM. However, to our surprise all fetal parameters were smaller including abdominal circumference in pregnant women diagnosed with GDM at 0-16 weeks and 16-20 weeks when compared with mothers with normal glucose tolerance in our study. Estimated fetal weight was also lower at diagnosis windows of 0-16 weeks and 16-20 weeks respectively. We were able to find just one study from south Indian city of Chennai where all fetal ultrasound measurements at 20 weeks of gestation except anterior abdominal wall thickness were smaller in pregnant women with GDM<sup>[18]</sup>. Our findings also resonated with another report from China<sup>[19]</sup> where Fetal parameters in the lowermost decile had a high risk of GDM at 22-24 weeks of gestation. A review by Newbern et al attributes smallness of fetal parameters to deficiency

of placental growth hormone<sup>[20]</sup>, however we do not have any placental measurements in our study. Fetal biometry is affected by fetal nutrition which depends on nutrition of mother. Low fetal parameters can also be ascribed to the intrauterine growth restriction as an effect of GDM<sup>[21]</sup>.

## Conclusion

To summarize we have reported data on fetal biometry at the time of diagnosis of GDM in undernourished Indian mothers across wide range of gestation. Fetal weight, femur length including abdominal circumference were lower in mothers with GDM. This findings are completely opposite from those found in obese mothers with GDM, were fetal parameters are large. This smallness of fetal parameters in undernourished mothers with GDM needs further systematic investigation.

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# Bias, Stigma and Empowerment among Girl Childhood Cancer Patients and Survivors: A Survivor-led Study

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## Abstract

**Background:** Childhood cancers cause significant morbidity and mortality, with notable gender disparities in access to healthcare. The Girl Child Project Initiative by CanKids addresses these inequities by offering holistic care and empowerment for young female cancer survivors. The study focuses on challenges, worries and stigma experienced by girl child survivors.

**Methods:** The study included 82 female childhood cancer survivors registered with Cankids from six major Indian cities- Delhi, Mumbai, Ahmedabad, Lucknow, Kolkata, and Chennai. A five-point Likert scale questionnaire was used for eliciting information on challenges before start of treatment, worries during treatment and stigma as well as other problems experienced as cancer survivors and facilitators of survivorship.

**Conclusion:** Social support and counselling from fellow survivors were highly valued by the participants. The findings of the study suggest that developing countries can leverage survivors to manage and mitigate cancer-related stigma.

**Keywords:** girl child cancer survivors, social support, childhood cancer, gender disparities, peer support, stigma, survivorship

## Background

Cancers in the 0–14 age group account for 4.0% of

all cancers in India.<sup>1</sup> It remains unclear whether girls with cancer in India have a higher likelihood of being “missed” (i.e., not diagnosed or treated) compared

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to boys. This potential issue raises concern about the barriers faced by female childhood cancer survivors in accessing adequate healthcare, adhering to medical advice, and seamlessly reintegrating into society.<sup>2</sup>

CanKids KidsCan, a National Society for Change for Childhood Cancer in India was established in 2004 with a vision of achieving global standards of survival and holistic quality of life for childhood cancer patients. The organization works to support children and their families affected with cancer, operating through a network of 141 Hospital Support Units, 20 Care Centres, 1 Paediatric Palliative Care Centre, and 2 Canshalas (a special school for children with cancer).

A study conducted by Cankids through PGIMS Rohtak revealed significant gender disparities in childhood cancer care as only one in every three children diagnosed with cancer were females, boys were twice as likely to complete treatment, and treatment abandonment rates were higher among girls (14% vs. 6% for boys).<sup>3</sup>

In response to these findings, Cankids initiated the Girl Child Project in 2013 to understand the reasons for gender inequality and cancer stigma, and to empower girl child survivors and their peers. This project employs "girl brigades," comprised of cancer-surviving girls, who work with newly diagnosed peers to enhance treatment adherence, reduce abandonment rates, and support a smooth return to society after completing treatment.

Present study aims at understanding the challenges/ Worries / Concerns experienced by girl child survivors before, during and after treatment through a scientifically planned study.

## Material & Methods

### Study Design and Participants

This cross-sectional study was conducted in six cities (Delhi, Mumbai, Ahmedabad, Lucknow, Kolkata, Chennai) included 210 registered female childhood cancer survivors, with 100 recruited and 82 responding.

### Study tool and data collection

A structured questionnaire with Likert scale options was used, covering four domains:

pre-treatment challenges, worries during treatment, survivor concerns, and opinions on improving treatment adherence and reintegration. Interviewers administered the questionnaire after obtaining informed consent.

### Ethics Approval

The study received ethical approval from the Genbandhu Ethics Committee (ECG002/2019). Informed consent was obtained from all participants prior to their enrolment in the study.

### Data management and Statistical analysis

Data was entered into Excel and analyzed using SPSS version 24.0. The analysis profiled girl child cancer survivors by socio-demographic parameters. Likert scale responses were analyzed for four domains, expressed in frequencies with scores presented as mean and standard deviation.

## Results

### Profile of pediatric girl cancer survivors

The study included 82 pediatric girl cancer survivors aged 11-34, with an average age of 19 years. The median survival time was 8 years. Importantly though, a large proportion of girl child cancer survivors missed education however, with CanShala's assistance, 25% completed graduation, 17% senior secondary education, and 18% secondary education. The socioeconomic background of parents reflects poor financial situations and moderate education levels. The findings on challenges, problems and concerns experienced by girl child cancer survivors as elicited through 5 point likert scale are presented in subsequent sections.

### Challenges faced even before starting treatment

On pre-treatment challenges, a Likert scale questionnaire with 12 questions was used, rating each from "Not at all" =0, "A little" = 1, "Moderate" =2, and "A lot" =3. Average scores were calculated for each of the 12 questions. The questions with scores of 2 or more indicated major challenges while scores between 1.5 to 2 as moderate challenges and below 1.5 indicating minor challenges. Of the 12, five concerns were seen as major one namely, disruption in education (Mean: 2.1), coping with symptoms

(Mean: 2.0), financial constraints (Mean: 2.0), travel difficulties (Mean: 2.0), and getting diagnosed (Mean: 1.8).

**Table 1: Major challenges faced before starting treatment: Response to likert scale and mean scores**

List of challenges	LIKERT SCALE					SCORE	
	Not at all	A little	Moderate	A lot	Don't Know	Mean	Standard Deviation
Disruption in education	12 (14.6%)	9 (11%)	18 (22%)	37 (45.1%)	6 (7.3%)	2.1	1.1
Coping up with initial disease symptoms	12 (14.6%)	13 (15.9%)	8 (9.8%)	38 (46.3%)	11 (13.4%)	2.0	1.2
Lack of Finances for treatment	13 (15.9%)	8 (9.8%)	14 (17.1%)	37 (45.1%)	10 (12.2%)	2.0	1.2
Travelling to hospital and back	12 (14.6%)	12 (14.6%)	15 (18.3%)	38 (46.3%)	5 (6.1%)	2.0	1.1
Getting diagnosed	17 (20.7%)	10 (12.2%)	15 (18.3%)	29 (35.4%)	11 (13.4%)	1.8	1.2

**Worries experienced during treatment**

On experiences of the paediatric girl cancer survivors during treatment likert scale questionnaire included 18 questions. Here also responses were measured on a Likert scale as **Never = 0, Sometimes = 1, Often = 2 and All the time = 3.**

The major concerns during treatment as reported by girl child cancer survivors were only two: that is *“painful treatment and procedures and the*

*pain”*(Mean Score: 2.3), *“Will I lose my hair and have other side effects”* (Mean Score: 2.0). Moderate concerns included *“financial worry”* (Mean Score: 1.7), *“Will I miss years of school/college”* (Mean Score: 1.7), *“Comments on appearance”* (Mean Score:1.6) and *“fear of the future”* (Mean Score: 1.6), *“Depression and anxiety”*(Mean score: 1.5). Importantly, fear of death, integration into society were noted as minor worries.

**Table 2: Major and moderate worries experienced during treatment: Response on likert scale and average scores**

List of worries during treatment	LIKERT SCALE					SCORE	
	Never	Sometimes	Often	All the time	Don't Know	Mean	SD
Painful treatment and procedures and the pain	6 (7.3%)	14 (17.1%)	9 (11%)	46 (56.1%)	7 (8.5%)	2.3	1
Will I lose my hair and have other side effects	11 (13.4%)	15 (18.3%)	13 (15.9%)	34 (41.5%)	9 (11%)	2	1.1
Financial worry - where will the funds come from for treatment	16 (19.5%)	19 (23.2%)	8 (9.8%)	29 (35.4%)	10 (12.2%)	1.7	1.2
Will I miss years of school/college	14 (17.1%)	25 (30.5%)	12 (14.6%)	25 (30.5%)	6 (7.3%)	1.6	1.1
Comments on appearance	16 (19.5%)	23 (28%)	8 (9.8%)	27 (32.9%)	8 (9.8%)	1.6	1.2
Fear of the future	22 (26.8%)	10 (12.2%)	14 (17.1%)	27 (32.9%)	9 (11%)	1.6	1.3
Depression/ sadness/anxiety	18 (22%)	24 (29.3%)	13 (15.9%)	20 (24.4%)	7 (8.5%)	1.5	1.1

**Problems/challenges and issues of concern for survivors after treatment**

In order to understand the problems & challenges of survivors after treatment, Likert scale questionnaire contained 23 questions.

The major challenges and concerns reported by survivors were **to be self sufficient and to take care of myself without depending on others** (Mean: 2.1) and **to selflook after and manage side effects** (Mean: 2). Importantly, the survivors expressed their

desire to help other diagnosed girl child cancer patients (Mean: 2.5). However, concerns such as relapse, pursuing education, getting job, getting

married, keeping cancer as secret, self-image were seen as minor concerns.

**Table 3: Major problems/challenges and issues of concern for survivors: Response to likert scale and average scores**

List of problems/challenges and issues that most concern you as a survivor	LIKERT SCALE					SCORE	
	Not at all	A little	Moderate	A Lot	Don't Know	Mean	Standard Deviation
I want to help other girls diagnosed with cancer and during their treatment	8 (9.8%)	5 (6.1%)	11 (13.4%)	58 (70.7%)	0 (0%)	2.5	1
I want to take care of all difficulties I face without depending on others	15 (18.3%)	8 (9.8%)	8 (9.8%)	50 (61%)	1 (1.2%)	2.1	1.2
I want to be responsible for looking after my own late side effects and my health	16 (19.5%)	9 (11%)	16 (19.5%)	39 (47.6%)	2 (2.4%)	2	1.2

**Opinion about what can help more girls to initiate treatment, stay with treatment, complete treatment, reintegrate into society, and become survivor advocates**

Paediatric girl cancer patients, as members of the KidsCan Konnect group, were asked to give their opinion on measures that could help more girls seek, continue, and complete cancer treatment, seamlessly reintegrate into society, and become survivor advocates. This was done using a Likert scale questionnaire with 7 points. Average scores were calculated for each concern related to these opinions where Not at all = 0, A little = 1, Moderate = 2 and A lot = 3. Concerns with a mean score of 2 or more were categorized as major, while those scoring less than 1.5

were categorized as minor.

Almost all paediatric cancer survivors emphasized the importance of having events for girl cancer patients/ survivors with public participation and encouragement (Mean Score: 2.9), more girl child cancer survivor role models to motivate and inspire (Mean Score: 2.8), KCK girl brigade to help fight stigma and gender bias (Mean Score: 2.8), a girl survivor support group to provide counseling throughout the treatment journey (Mean Score: 2.7), Counselling for parents to attend the forum (Mean Score: 2.7), a dedicated helpline/communication platform (girl child cancer helpline/whatsapp group) (Mean Score: 2.7), and regular support group meetings of the forum (Mean Score: 2.6).

**Table 4: Opinion about what can help more girls to come for treatment, stay with treatment, complete treatment, reintegrate into society and become survivor advocates: Response on likert scale and average scores**

List of opinion about what can help more girls come for treatment, stay with treatment, complete treatment, reintegrate into society and become survivor advocates	LIKERT SCALE					SCORE	
	Not at all	A little	Moderate	A Lot	Don't Know	Mean	Standard Deviation
There should be events for girl cancer patients/survivors with public participation and encouragement.	0 (0%)	4 (4.9%)	13 (15.9%)	64 (78%)	1 (1.2%)	2.9	0.4

Continue.....

There should be more girl child cancer role models to motivate and inspire	0 (0%)	3 (3.7%)	11 (13.4%)	67 (81.7%)	1 (1.2%)	2.8	0.5
The KCK girl brigades will help fight stigma and gender bias	(0%)	2 (2.4%)	9 (11%)	68 (82.9%)	3 (3.7%)	2.8	0.4
If girl survivor group/parents had been there to talk to at the beginning and during treatment	2 (2.4%)	2 (2.4%)	15 (18.3%)	60 (73.2%)	3 (3.7%)	2.7	0.7
Parents should also be counselled and attend the forums	2 (2.4%)	4 (4.9%)	14 (17.1%)	61 (74.4%)	1 (1.2%)	2.7	0.7
There should be a girl child cancer helpline/WhatsApp group/Communication Platform	0 (0%)	4 (4.9%)	13 (15.9%)	64 (78%)	1 (1.2%)	2.7	0.5
There should be regular girl child forums and support group meetings	0 (0%)	2 (2.4%)	24 (29.3%)	53 (64.6%)	3 (3.7%)	2.6	0.5

## Discussion

The characterization of the study, girl paediatric cancer survivors' in terms of age at diagnosis aligns with the other studies which revealed a similar trend of adolescent diagnoses<sup>4,5</sup>.

Educational attainment is a key measure of the quality of long-term survivorship. The support provided by CanShalas helped cancer survivors in completing their education. Highlights CanShala's impact on childhood cancer survivors' educational success.

Childhood cancers are often curable, but barriers prevent treatment. Sneha and colleagues found that financial burdens of childhood cancer, including nonmedical costs like transportation and accommodation, significantly impact families' financial stability, second only to the disease itself.<sup>6</sup> Consistent with these previous reports it was notably evident in our study that lack of finances for treatment and travelling to hospital and back were significant challenges for survivors.

The findings of the other studies indicated that childhood cancer survivors face a myriad of challenges during and after treatment, impacting their lives. Our study also revealed coping with symptoms as major concerns for survivors. In addition to transportation, education disruption, financial constraints, and Social pressure, treatment perception, and family

issues were minor concerns, with diet-related issues being least challenging.

Several investigations have documented that paediatric cancer patients endure demanding healthcare treatment modalities<sup>7</sup>, painful medical procedures<sup>8-9</sup>, unpleasant treatment side effects<sup>11,12</sup>, and the fear of death<sup>7</sup>. In our study childhood cancer survivors reported that during the course of cancer treatment, they often tussle with a multitude of worries. At the forefront of these apprehensions is the fear of painful treatment procedures and the associated discomfort. Additionally, the uncertainty surrounding potential hair loss and other treatment side effects weighs heavily on the minds of patients. Children and their families frequently report psychosocial cancer-related stressors, such as distressing emotional reactions<sup>13</sup>, disruption in routines and in social, occupational, and family roles<sup>15</sup>, and issues with peers including bullying and restricted participation in peer activities<sup>13</sup>. Specifically, a significant subset of children undergoing cancer treatment experience persistent cancer-related distress, including increased symptoms of anxiety, irritability, depression<sup>16-18</sup>, and posttraumatic stress<sup>19</sup>. Due to the unanimous counselling and support to the survivors provided by the CanKids during the entire treatment journey, the emotional toll of depression, guilt, anxiety and fear of death were considered as minor worries.

Most populations commonly exhibit a behaviour of not revealing the diagnosis of cancer, especially to close friends and relatives<sup>20</sup>. A study conducted by Ray et al. found that 11.6% of the participants cited social stigmas, such as concerns about their daughter's marriage, as the primary reason for not revealing their illness<sup>21</sup>. A study conducted by Krishnan and his colleagues found that 75% of the volunteers believed it is more advantageous to withhold the diagnosis within the community. Additionally, 30% of the participants expressed concerns that disclosing the diagnosis could negatively impact the child's future and have enduring consequences for the family<sup>20</sup>. Contrary to expectations, the findings of the current study suggest that young female cancer survivors who received treatment and counselling in our specialist paediatric research advocacy group had rather high levels of empowerment. They expressed the view that revealing the cancer diagnosis, adapting to it, and forming new friendships were not perceived as difficult, but rather seen as minor issues.

The seamless reintegration of children after completing their treatment was not a major concern in our study, due to the robust social and psychological support provided by CanKids. The comprehensive support system offered by CanKids alleviated many of these worries. Cankids unique approach offers uninterrupted psychosocial resources, combating stigma and bias. Our study highlights unanimous support for this indispensable model.

### Conclusion

Five major barriers identified were disruption in education, travelling time to access treatment, lack of finances, diagnostic delays and initial ability to deal with the disease. These were particularly challenging for families with low socio-economic conditions.

Stigmatizing factors were primarily to do with body self-image, fear of the future and lack of finances, for which good psycho-social and peer support could make a real difference.

The measures undertaken to empower girl survivors, like the girl brigades, girl forum, communication platforms and awareness events and their participation in these have a very real impact.

This important survivor-led research study, was able to evaluate the Cankids Girl Child project and its interventions over the last decades to

demonstrate that it has achieved desired results in some measure to overcome bias and stigma, and that empowerment of the girl survivor members and through the girl brigades, girl child forums by improving and maintaining their health leads to better health outcomes.

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**Ethical Clearance**: The study was approved by (ECG002/2019) Genbandhu Ethics Committee.( The meeting was held on 19th May 2019)

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# Relationship between Post Covid 19 Duration and Biomarkers: A Retrospective Study in Hospitalised Patients

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## Abstract

**Background:** The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), now known as coronavirus disease 2019 (COVID-19) were initially reported in Wuhan, China and rapidly spread throughout world in December 2019. The present retrospective study was postulated to assess the relationship between the post COVID 19 duration and biomarkers.

**Methods:** About 369 subjects diagnosed as COVID-19 infection confirmed by "Nasopharyngeal Reverse Transcription Polymerase Chain Reaction (RT-PCR) positive for SARS-CoV2" of all disease severity and admitted to Viveka Hospitals, Nagpur, Maharashtra, INDIA were included in the study. The laboratory investigations viz., D-Dimer, ferritin and C-reactive protein (CRP) and Lactate dehydrogenase (LDH) recorded at the time of admission, after 15<sup>th</sup> day and 30<sup>th</sup> day of discharged were retrieved from the hospital records. The relationship was computed using Paired t-test and the confidence interval was set at 95%. The study was initiated after approval from the Institutional Ethics Committee of Viveka Hospitals, Nagpur.

**Results:** The mean D Dimer and ferritin values showed significant ( $p = 0.000$ ) decrease after 15 days of discharge and CRP and LDH showed insignificant ( $p > 0.05$ ) increase and decrease respectively as compared to day of admission. After 30<sup>th</sup> days of discharge D Dimer increased significantly ( $p = 0.000$ ) and ferritin and CRP decreased insignificantly ( $p > 0.05$ ).

**Conclusion:** It can be concluded from the study that COVID-19 biomarkers responds differently after 15<sup>th</sup> and 30<sup>th</sup> days of discharge. The suitable changes in medical protocols after 15<sup>th</sup> day and 30<sup>th</sup> days of discharge can reduce morbidity amongst the COVID 19 patients.

**Keywords:** COVID-19, biomarkers, D-Dimer, Ferritin, C-Reactive Protein (CRP), Lactate dehydrogenase (LDH)

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## Introduction

Coronaviruses are a large family of viruses that may cause respiratory illnesses in humans ranging from common colds to more severe conditions such as Severe Acute Respiratory Syndrome (SARS) and Middle Eastern Respiratory Syndrome (MERS). 'Novel coronavirus' is a new, previously unidentified strain of coronavirus. The novel coronavirus involved in the 2019 outbreak has been named SARS-CoV-2 by the World Health Organization (WHO). The first known case of COVID-19 originated from the city of Wuhan in Hubei Province, China. From there, it has spread to every inhabited continent worldwide. As of 30 April 2023, the COVID-19 pandemic has resulted in over 6.9 million deaths worldwide. [1]

For severe COVID-19 disease, major risk factors include age, male sex, obesity, smoking, and comorbid chronic conditions such as hypertension, type 2 diabetes mellitus, and others like chronic obstructive pulmonary disease (COPD), immunodeficiency, and malignancies. [2,3,4,5,6,7,8]

The accurate and reliable estimation of Oxidant/Antioxidant levels in COVID-19 patients, utilizing biomarkers such as LYM, ferritin, D-dimer, WBC, and CRP, can facilitate the diagnosis and prognosis. [9] Comorbidities are medical conditions that coexist alongside a primary diagnosis and affect health, including treatment and outlook. Common comorbidities among hospitalized people include hypertension, diabetes and chronic lung disease. [10]

The review of literature shows that no studies have been undertaken on duration of COVID 19 and biomarkers hence, it was postulated to study the relationship between duration of COVID 19 and biomarkers amongst patients admitted in hospitals.

## Material and Methods

It was a retrospective study conducted by retrieving data of 369 subjects[11] diagnosed as

COVID-19 infection and were admitted to Viveka Hospitals, Nagpur, Maharashtra, INDIA designated for COVID-19 patients' isolation in the period from 1st of April 2020 to 31st of July 2021. All patients were given Standard Medical protocol as given by Ministry of Health and Family Welfare for Covid-19.[12]

**Inclusion Criteria:** The study included all adults (> 18 years old) hospitalized in Non-ICU isolated patients with COVID-19 infection confirmed by "Nasopharyngeal Reverse Transcription Polymerase Chain Reaction (RT-PCR) positive for SARS-CoV2" of all disease severity.

**Exclusion Criteria:** The study excluded all adults (> 18 years old) hospitalized in ICU isolated patients with COVID-19 infection confirmed by "Nasopharyngeal Reverse Transcription Polymerase Chain Reaction (RT-PCR) positive for SARS-CoV2" of all disease severity.

The laboratory investigations viz., D-Dimer, Ferritin, C-reactive protein(CRP) and Lactose dehydrogenase (LDH) recorded at the time of admission, after 15 day and 30<sup>th</sup> day of discharge were retrieved from the hospital records.

**Statistical Analysis:** Data was analysed using Paired t test and the confidence interval was set at 95%. The study was initiated after approval from the Institutional Ethics Committee of Viveka Hospitals, Nagpur, with Reg. No. ECR/1639/INST/MH/2021, Dated 20<sup>th</sup> Feb 2024.

## Observation and Results

### D-Dimer and Duration of COVID 19

An elevated D-dimer in COVID-19 patients has been reported by several scientists. [13,14,15] The statistical analysis of the mean D dimer values of patients according to the duration of COVID19 has been presented in Table 1.

**Table 1: D Dimer levels of COVID-19 Patients**

SN	COVID 19 Biomarkers	Mean	Std. Deviation	Paired t test Value	P value
1.	D-DIMER ng/ml	785.50	980.43	9.154	0.000
	D DIMER After 15 <sup>th</sup> Day ng/ml	293.00	316.53		
2.	D-DIMER ng/ml	785.50	980.43	8.684	0.000
	D DIMER After 30 <sup>th</sup> Day ng/ml	335.66	275.90		
3.	D DIMER After 15 <sup>th</sup> Day ng/ml	293.00	316.53	-2.083	0.038
	D DIMER After 30 <sup>th</sup> Day ng/ml	335.66	275.90		

The data presented in Table 1 shows that the D-Dimer values after 15<sup>th</sup> day of discharge ( $t=9.154$ ,  $p=0.000$ ) and 30<sup>th</sup> day after discharge ( $t=8.684$ ,  $p=0.000$ ) were significantly lower than the mean D-Dimer values on admission. However, the comparison between the D-Dimer values of 15<sup>th</sup> and 30<sup>th</sup> days, showed significant increase ( $t=2.083$ ,  $p=0.038$ ).

An elevated D-dimer in patients of COVID-19 infection and the patients with serum D-dimer  $\geq 400$  ng/ml predicted fatal outcome in COVID-19 patients.<sup>[15]</sup> The elevated D-dimer values ( $\geq 0.5$  mg/L) were associated with nearly three fold higher risk of poor outcomes in COVID-19 patients (pooled-OR: 3.39; 95% CI: 2.66–4.33;  $p<0.00001$ ).<sup>[16]</sup> In a retrospective, multicentre cohort study reported the d-dimer levels greater than  $1.0 \mu\text{g/mL}$  (18.42, 2.64–128.55;  $p=0.0033$ ) on admission in COVID-19 patients.<sup>[3]</sup> Old patients with SARS-CoV-2 tend to show increased levels of D-Dimer compared with younger patients.<sup>[17,18]</sup>

In the present study the D Dimer values were observed between 1.27 to 7500 ng/dl whereas several scientists reported serum d Dimeras  $> 400$  ng/ml,  $1.0 \mu\text{g/mL}$  and ( $\geq 0.5$  mg/L) respectively as risk of poor outcomes in COVID 19 patients.<sup>[16,3,15]</sup> This indicates that the D-Dimer values of the present study were considerably high as compared to the reported studies. However, no mortality was observed amongst them.

### Ferritin and Duration of COVID 19

Ferritin has a very crucial role in COVID-19 pneumonia in predicting the severity of illness and assessing response to treatment during hospitalization.<sup>[19]</sup> Serum ferritin levels were closely related to the severity of COVID-19 and serum ferritin  $\geq 200$  ng/ml predicted fatal outcome in COVID-19 patients.<sup>[20,3,15,17,21,13]</sup> The statistical analysis of the mean ferritin values of patients according to the duration of COVID 19 has been presented in Table 2.

**Table 2: Ferritin levels of COVID-19 Patients**

SN	COVID 19 Biomarkers	Mean	Std. Deviation	Paired t test Value	P value
1	Ferritin (ng/ml)	371.82	458.23	3.713	0.000
	Ferritin After 15 days(ng/ml)	255.26	475.81		
2	Ferritin (ng/ml))	371.82	458.23	5.959	0.000
	Ferritin After 30 Days(ng/ml)	215.89	221.70		
3	Ferritin After 15 days(ng/ml)	255.26	475.81	1.605	0.109
	Ferritin After 30 Days(ng/ml)	215.89	221.70		

The data presented in Table 2 shows that the mean Ferritin value of patients on admission was  $371.82 \pm 458.23$  ng/ml which significantly decreased on 15<sup>th</sup> ( $t=3.713$ ,  $p=0.00$ ) and 30<sup>th</sup> days of discharge ( $t=5.959$ ,  $p=0.00$ ). However, the comparison between the Ferritin values of 15<sup>th</sup> and 30<sup>th</sup> days, showed an insignificant decrease ( $t=1.605$ ,  $p=0.109$ ).

A ferritin cut-off value at 272.5 ng/ml. COVID-19 patients with elevated ferritin levels had a higher incidence of severity illness (50.0 vs 2.9%) and liver injury (52.3 vs 20.0%) when compared with patients with normal ferritin levels ( $p<0.05$ ).<sup>[21]</sup> The elevated ferritin group showed longer viral clearance time (median 16 vs 6 days,  $p<0.001$ ) and in-hospital length (median 18 vs 10 days,  $p<0.001$ ).<sup>[22]</sup> In ROC analysis, the level of ferritin  $\geq 264.5$  ng/ml predicted

severe COVID-19 with 73.9% sensitivity and 94.2% specificity.<sup>[23]</sup>

In the present study the ferritin levels of patients ranged between 54.819ng/ml to 178.282 ng/ml during admission and were above the cut-off value<sup>[21]</sup> however, none of COVID 19 patients were critical. There after, the ferritin levels decreased considerably after 15 and 30 days and ranged between -8.946ng/ml to 88.535ng/ml. Studies comparing ferritin level on admission between COVID-19 patients between survivors and non-survivors demonstrated that non-survivors showed ferritin levels on admission around 1400 ng/mL, which is between 3 and 4 times higher than that observed in survivors.<sup>[24]</sup> The higher levels of serum ferritin in very severe COVID-19 as compared to severe COVID-19 might be correlated

to secondary bacterial infection, protection from which could be of vital importance for reducing the mortality rate in very severe COVID-19.<sup>[3]</sup>

### C-Reactive Protein (CRP) and Duration of COVID 19

C-Reactive Protein(CRP) was found to be an independent determinant factor for severe COVID-19 patients. <sup>[3,20,16,15]</sup> The mean CRP values of patients on admission, 15<sup>th</sup> day and 30<sup>th</sup> days of discharge have been presented in Table 3.

**Table 3: CRP levels of COVID-19 Patients**

SN	COVID 19 Biomarkers	Mean	Std. Deviation	Paired t test Value	P value
1	CRP (mg/l)	59.52	143.13	0.902	0.368
	CRP After 15 days	67.35	196.20		
2	CRP (mg/l)	59.52	143.13	1.574	0.116
	CRP After 30 Days	46.49	64.82		
3	CRP After 15 days	67.35	196.20	1.933	0.054
	CRP After 30 Days	46.49	64.82		

The data presented in Table 3 shows that the mean CRP value of patients on admission was  $59.52 \pm 143.13$  mg/l which on 15<sup>th</sup> day of discharge increased to  $67.35 \pm 196.20$  mg/l and decreased to  $46.49 \pm 64.82$  mg/l on 30<sup>th</sup> day. The CRP values after 15<sup>th</sup> day of discharge ( $t=0.902$ ,  $p=0.368$ ) and 30<sup>th</sup> day after discharge ( $t=1.574$ ,  $p=0.116$ ) were insignificantly lower than the mean CRP values on admission. However, the comparison between the CRP values of 15<sup>th</sup> and 30<sup>th</sup> days, showed a significant decrease ( $t=1.933$ ,  $p=0.054$ ).

The average CRP level of deceased patients reported was 137.79 mg/l, while the average CRP level of survivors was 14.37 mg/l.<sup>[25]</sup> The CRP levels above 30 mg/L were significantly associated with an increased risk of developing severe COVID-19 for those who have higher ages and comorbidities (ARR 3.99, 95% CI: 1.35– 11.82;  $p=0.013$ ).<sup>[26]</sup> A study also predicted fatal outcome in COVID-19 patients with

Serum CRP  $\geq 30$  ng/ml.<sup>[15]</sup>

In the present study the CRP levels on admission ranged between 5 to 100 mg/l and were very high as compared to the reported values. According to a study, COVID-19 patients exhibited higher median CRP levels at baseline [58 (IQR: 2.0–127.8) mg/L] that decreased significantly to 2.4 (IQR: 1.4–3.9) mg/L after 40 days after symptom onset ( $p<0.0001$ ).<sup>[26]</sup> Similarly, in the present study, the CRP values were found to be decreased on 30<sup>th</sup> day of discharge, but at a slower pace.

### Lactate dehydrogenase (LDH) and Duration of COVID 19

Several scientists have reported the increased LDH levels to the development of COVID-19 disease. <sup>[27,28,3,29,30,17,18,16]</sup> The mean LDH values of patients on admission, 15<sup>th</sup> day of discharge have been presented in Table 4.

**Table 4: LDH levels of COVID-19 Patients**

SN	COVID 19 Biomarkers	Mean	Std. Deviation	Paired t test Value	P value
1	LDH (U/Liter)	309.71	638.23	0.635	0.526
	LDH After 15 days	307.58	638.37		

In the present study, the initial LDH value was  $309.71 + 638.23$  u/l, which decreased after 15<sup>th</sup> day of discharge but the statistical analysis did not show any significant difference between them ( $t=0.63$ ,  $p=0.526$ ). Fatal outcome in COVID-19 patients

with Serum LDH  $\geq 400$  U/L had been predicted.<sup>[15]</sup> LDH  $> 731$  U/L significantly predicted mortality in an adjusted multivariate analysis while LDH  $< 425$  U/L was associated with lower rates of ICU admission.<sup>[17]</sup> However, in the present study, the LDH levels were

less than the critical values reported, which shows the less severity of COVID 19 patients.

### Conclusion

The mean D Dimer and ferritin values showed significant ( $p=0.000$ ) decrease after 15 days of discharge and CRP and LDH showed insignificant ( $p>0.05$ ) increase and decrease respectively as compared to day of admission. After 30<sup>th</sup> days of discharge D Dimer increased significantly ( $p=0.000$ ) and ferritin and CRP decreased insignificantly ( $p>0.05$ ). The biomarkers showed different trends when compared between 15<sup>th</sup> day and 30<sup>th</sup> day of discharge, the D-Dimer increased significantly ( $p=0.000$ ) and CRP decreased significantly ( $p=0.000$ ) whereas ferritin decreased insignificantly ( $p>0.05$ ). It can be concluded from the study that COVID19 biomarkers responds differently after 15<sup>th</sup> and 30<sup>th</sup> days of discharge. The suitable changes in medical protocols after 15<sup>th</sup> day and 30<sup>th</sup> days of discharge can reduce morbidity amongst the COVID 19 patients.

**Study Limitations:** The study was limited to the COVID-19 Non-ICU patients of all disease severity.

**Future Research Recommendations:** Future studies can be carried out on effects of supplementations on biomarkers and nutritional status of patients. In depth studies can be carried out on the biomarkers.

**Conflict of interest:** Nil

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# Assess the Knowledge, Attitude and Perception of Patients who Suffered from Myocardial Infarction Towards the Disease and their Associated Life Style Behaviour

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## Abstract

**Introduction:** Cardiovascular diseases (CVDs) are the leading cause of death worldwide, accounting for 17.9 million deaths annually. In India, CVDs account approximately 25% of all mortality, with ischemic heart disease and stroke being the most predominant causes. The study aims to assess knowledge, attitude, and perception of Myocardial Infarction patients' towards Myocardial Infarction (MI) and their associated life style behaviour.

**Material and Methods:** A cross-sectional non-experimental study was to assess the knowledge, attitude, and perception of Myocardial Infarction (MI) patients and their associated lifestyle behaviours. The study was focused exclusively on patients diagnosed with MI, excluding those with acute illness, limited comprehension, or psychiatric illness. A validated questionnaire was used to assess the level of knowledge, and standardized scales were used to measure to assess the attitude and perception. The study received ethical and administrative approval from institution and data analysis was performed using SPSS version 20.

**Results:** The mean knowledge score was 12.9 out of 25, with a significant association between age groups and knowledge scores. The study found that a majority of myocardial patients have a positive attitude and 65% having moderate positive perception towards lifestyle behaviour modification related to myocardial infarction (66.7%), with male showing a higher association compared to female.

**Conclusion:** This research has highlighted the importance of health literacy in determining cardiovascular outcomes, which will guide the development of targeted interventions for secondary prevention of MI that specifically address health literacy gaps.

**Keywords:** Myocardial Infarction, lifestyle behaviour , knowledge, attitude, perception

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## Introduction

Cardiovascular diseases (CVDs) account for 17.9 million deaths worldwide each year, making them the primary cause of death. These illnesses include rheumatic heart disease, coronary heart disease, and cerebrovascular disease, among other medical conditions. Heart attacks and strokes account for more than four out of five deaths from CVD, with one-third of these deaths occurring prematurely among those under the age of 70. Tobacco, alcohol, poor diet, and physical inactivity are behavioral risk factors for heart disease and stroke. An increased chance of heart attack, stroke, heart failure, and other consequences can result from these risk factors<sup>1</sup>

The South Asian region accounted for the biggest portion of the estimated 422 million prevalent cases of cardiovascular disease (CVD) worldwide in 2015, according to the findings of the Global Burden of Disease (GBD) study group.<sup>2</sup> In 2022 alone, CVD caused an estimated 19.8 million deaths worldwide, corresponding to 396 million years of life lost and another 44.9 million years lived with disability (YLD)<sup>3</sup>. Between 2025 and 2050, a 90.0% increase in cardiovascular prevalence, 73.4% increase in crude mortality, and 54.7% increase in crude DALYs are projected, with an expected 35.6 million cardiovascular deaths in 2050 (from 20.5 million in 2025).<sup>4</sup>

CVDs have become the leading cause of mortality in India, accounting for a quarter of all mortality. In 2017, CVD accounted for 26.6% (25.3%-27.4%) of overall fatalities and 13.6% (12.5%-14.6%) of total DALYs in India, up from 15.2% (13.7-16.2) and 6.9% (6.3-7.4) in 1990.<sup>5</sup> Ischemic heart disease and stroke are the predominant causes, responsible for over 80% of CVD deaths. The epidemic is characterized by socioeconomic gradients, with tobacco use and low fruit and vegetable intake becoming more prevalent among those from lower socioeconomic backgrounds.

MI has a major prevalence among heart patients in India, with the main incidence occurring in men aged 29-69 years. Many studies suggest that lack of knowledge about lifestyle changes before and after MI increases morbidity and mortality rates. A study by Ångerud, K. et al (2013) found that only 16% had adequate knowledge about heart diseases and

factors associated with them. A study on patients' attitudes and knowledge about MI revealed that 65% had inadequate knowledge and negative attitudes towards the disease, leading to increased morbidity and mortality rates.<sup>6,7</sup> Cardiac rehabilitation in terms of medication compliance, regular follow up, life style modifications and exercises are very important to prevent future cardiac events. This is only possible with adequate knowledge, attitude, and perception to change behaviour. Moreover, there are limited studies conducted among patients with myocardial infarction to understand their perception. Hence the current study was planned to assess the knowledge, attitude and perception regarding Myocardial Infarction (MI) and associated life style behavior of the patients with MI which will be a potential determinant in maintaining the subsequent health behaviour of the patients.

## Title

A descriptive study to assess the knowledge, attitude and perception of patients who suffered from myocardial Infarction towards the disease and their associated life style behaviour

## Objectives

### The objectives of this study are to

1. Assess the level of knowledge, attitude and perception regarding MI and associated lifestyle behavior among patients with myocardial infarction.
2. Associate the score of knowledge, attitude and perception of MI and associated life style behavior of patient with selected socio-demographic variables.
3. Correlate the score of knowledge with attitude, knowledge with perception and perception with attitude of MI and associated life style behavior of patient with MI.

## Hypotheses

H<sub>0</sub>-There is no significant difference between knowledge, attitude and perception regarding MI and associated life style behavior of the patients with myocardial infarction.

H<sub>1</sub>- There is a significant difference between knowledge, attitude and perception regarding MI and associated life style behavior of the patients with myocardial infarction.

H<sub>2</sub>- There is a significant association between knowledge, attitude and perception regarding MI and associated life style behavior with selected demographic variables among myocardial infarction patients.

H<sub>3</sub>- there is no significant correlation of the score of knowledge with attitude, knowledge with perception and perception with attitude of MI and associated life style behavior of patient with MI.

### Materials and Methods

- **Research design:** A Non-Experimental descriptive design was used to assess the knowledge, attitude, perception regarding Myocardial Infarction (MI) and their associated life style behaviour of patients with MI.
- **Setting:** The study was conducted in the outpatient department of Cardiology department at Bhopal Memorial Hospital and Research Centre. The study was limited to the OPD of a single health care facility and to the patients diagnosed with Myocardial Infarction(MI).
- **Sampling & sample size:** A convenient sampling technique is used in this study. As the time duration for data collection was limited ,the probability sampling techniques were not utilized. The sample size was 150, calculated using Epi-info. The sample size was adequate enough to account for the generalizability. Further, the sample was not assessed for any comorbidities. Epi-info was used to calculate the sample size and a sample of 150 was derived. Moreover, those patients with acute illness, limited comprehension and having a confirmed diagnosis of psychiatric illness were excluded

- **Data collection:** data was collected from July to September 2022 over a period of three months, with each patient's data collection taking 20-30 minutes.

Tools used in this study:

- **TOOL I:** Demographic Variables which included age, gender, income per month, education, family history, marital status, religion, residential area, occupation, diet
- **TOOL II:** A validated questionnaire comprising 25 questions was used to assess the knowledge regarding MI. The validation was done by six experts in the field of medicine and nursing.
- **Tool III and IV:** Standardised scales- Control Attitude Scale-Revised and Brief Illness perception questionnaire were used to measure attitude and illness perception. Both the scales had 8 items measured on a likert format with 5 points ranging from "5 = strongly agree" to "1 = strongly disagree" and a rating scale with 10 points ranging from "0-10".<sup>8,9</sup> Permissions were obtained from the respective authors to use the tools in the study.

**Ethical approval:** The permission obtained to conduct of the research study has been approved by the Ethical Committee (IEC/30/Nursing College/22) and Scientific Committee (BMHRC/ISC/ Desp/2022/50) of the institution, Bhopal Memorial Hospital & Research Centre, Bhopal (BMHRC).

**Validity and reliability of the tool:** The validation was done by six experts in the field of medicine and nursing for self-structured knowledge questionnaire. A robust score of 0.8 for reliability was obtained for the tool. Standardized tools were used for measuring the attitude and perception. The permission was obtained from consent author.

Tools	Reliability Method	Reliability coefficient	Remarks
Knowledge - Structured Knowledge Questionnaire	Split Half Method	r=0.811	Self-structured tool
Attitude Scale	Cronbach's alpha internal consistency coefficient	r= 0.8	Standardized tool
Brief Illness Perception Questionnaire (B-IPQ) - likert scale	Cronbach's alpha internal consistency coefficient	r=0.85	Standardized tool

**Data analysis:** Descriptive and inferential statistics was used to analyse the data using SPSS version 20. Karl Pearson correlation was used to

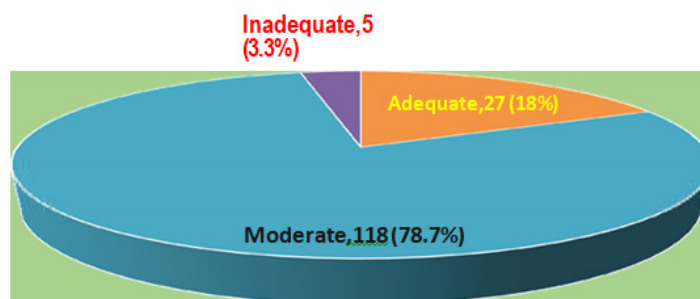
correlate the different outcome variables of the study as the outcome variables were continuous data and may influence each other.

## Results and Interpretation

**Table 1: Assess demographic variables of among patients with myocardial infarction. (n=150)**

S.no	Socio-demographic variables of patients	Frequency (%)	
1.	Age in years	<30-40 year	24(16%)
		41-50 year	45(30%)
		51-60 year	51(34%)
		Above 60	30(20%)
2.	Gender	Male	90(60%)
		Female	60(40%)
3.	Family income (Monthly)	Rs<10,000	69(46%)
		Rs.10,001-20,000	49(32.7%)
		Rs.20,001-30,000	17(11.3%)
		Rs.>31,000	15(10%)
4.	Educational status	Illiterate	40(26.7%)
		Primary	34(22.7%)
		Secondary	49(32.7%)
		Graduate and above	27(18%)
5.	Marital status	Married	111(74%)
		Unmarried	13 (8.7%)
6.	Religion	Divorced	1(.7%)
		Widow	25(16.7%)
		Hindu	87(58%)
		Muslim	63(42%)
7.	Residential area of patient	Rural	10 (6.7%)
		Urban	140(93.3%)
8.	Occupational status	Service	61(40.7%)
		Non-service	89(59.3%)
9.	Diet	Vegetarian	78(52%)
		Nonvegetarian	72(48%)
10.	Family history of myocardial infarction	Yes	53(35.33%)
		No	97(64.67%)

2. Assess the level of knowledge regarding MI with myocardial infarction (n=150) and associated lifestyle behavior among patients



**Fig 1: Frequency and percentage distribution of knowledge score among Myocardial Infarction patients**

The figure above illustrates that the mean knowledge score was  $12.9 \pm 2.7$ ; it was shown that 3.3% (5) of participants had inadequate knowledge,

18% (27) had adequate knowledge, and 78.7% (118) had moderate knowledge.

**Table 2: Assess the level of attitude regarding MI and associated lifestyle behavior among patients with myocardial infarction** n=150

Level of Attitude	Frequency(f)	Percentage(%)	Mean	SD
Moderate	50	33.3	30.33	7.10
High	100	66.7	30.49	7.14

The table 2 shows that the majority of participants have high level of attitude (66.7%), compared to a moderate level (33.3%). This indicates that majority of the participants has a more positive or favorable

attitude. The mean score of moderate (30.33) and high (30.49) levels and the standard deviations are similar (7.10 for moderate and 7.14 for high).

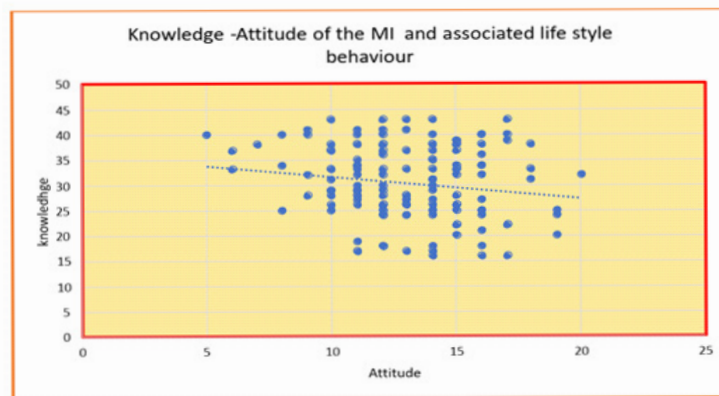
**Table 3: Assess the level of attitude regarding MI and associated lifestyle behavior among patients with myocardial infarction**

Level of Perception	Frequency(f)	%	Mean	SD
Very low	4	2.7	52.93	14.02
Low positive	12	8.0	52.82	12.80
Moderate	98	65.3	52.79	11.17
High positive	36	24.0	54.24	9.86

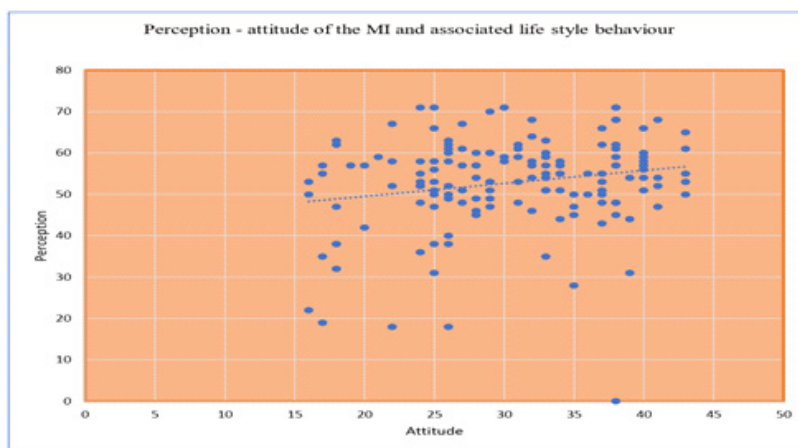
The data presented in table 2 shows the level of perception among patients with myocardial Infarction. In the perception assessment, majority of the subjects have moderate level of perception (65.3%) with mean score of 52.79, SD = 11.17 and high positive perception (24.0%) mean score of 54.24, SD = 9.86.

Figure 3 and figure 4 depicts the relationship between knowledge and attitude of the patients, attitude and perception score of the patients respectively. The Karl Pearson’s correlation coefficient,  $r = .163$  with the  $p = .05$  shows a significant moderate positive correlation between the knowledge score and attitude of the patients. Similarly there was a significant moderate positive correlation between attitude and perception score ( $r=0.20, p=0.01$ ) while there was no relationship between the knowledge and perception score of the patients.

**Correlate the score of knowledge, attitude and perception of MI and associated life style behavior of patient with selected socio- demographic variables.**



**Figure 3: Scatter diagram showing the relationship between knowledge and attitude of the patients related to MI**



**Figure 4: Scatter diagram showing the relationship between attitude and perception of the patients related to MI**

### Discussion

The study findings reflect that amongst 150 participants most are middle-aged to older 51-60 year age group (34%), while fewer patients were in the 30-40 age with a higher representation of males (60%). In a similar way, the INTERHEART study, which found that South Asians had a lower mean (SD) age of first myocardial infarction (53.0 [11.4] years) than people from other countries (58.8 [12.2] years;  $p < 0.001$ )<sup>10</sup>. This was probably explained by the higher level of risk factors in younger individuals. In addition, several conditioning factors such as education, socio-economic status, fetal programming and early life contribute to the increased risk of cardiovascular risk among South Asians<sup>11</sup>. The study also observed that 60% of MI patients were male, reported by Kundu et al. (2017-18) study, which found that men experience a greater burden of premature cardiovascular mortality compared to women<sup>12</sup>.

In this study majority of the participants were reported as vegetarian as compared to nonvegetarians. Furthermore, most (64.7%) of the patients reported no family history of MI. contrasting with a systematic review which found vegetarians had a 15% lower risk of cardiovascular disease and a 21% lower risk of ischemic heart disease compared to non-vegetarians<sup>13</sup>. Clinical guidelines suggest that after a MI, patients should be assisted in changing their lifestyle and using medicine to lower their risk of recurrence and its related complications<sup>14-15</sup>. However, maintaining these preventive behaviours

can be challenging, if they do not follow regular life style modification it may lead to higher mortality or hospital readmissions. The ability to get and comprehend basic health information and services and, as a result, take part in decisions pertaining to one's health is known as health literacy. Health literacy crucial for secondary prevention in patients with MI<sup>(16-18)</sup>.

The current study found majority of the participants have secondary education 49(32.7%) indicating a need for enhanced health literacy strategies. This is consistent with findings by<sup>19</sup>Diederichs et al (2018), which reported A significantly higher proportion of individuals with CVD had inadequate health literacy as compared to those without CVD(men 41.8% vs. 33.6%, women 46.7% vs. 33.4%). The socio-demographic variables had no association with the health literacy score of the individuals except the various categories of age groups.

In contrast, Garcia-Codina O reported younger age, high socio-economic status and employed status as significant determinants of health literacy<sup>20</sup>. Despite relatively low health literacy scores, 66.7% of participants demonstrated a positive attitude and 65.3% had a positive perception towards MI-related lifestyle changes. Males exhibited a stronger association with attitude towards lifestyle modification than females. Other socio-demographic factors did not significantly influence attitudes or perceptions related to MI.

The study findings focus on the need to incorporate health literacy in the management of the post MI patients. Health literacy includes the skills and resources that people need to appraise health information, and to access and engage with health services and providers.<sup>21,22</sup> Even though, patients had a positive attitude and perception towards their lifestyle changes, sustained motivation from the healthcare providers are essential to keep up the momentum.

### Conclusion

In conclusion, this study highlights that while patients with MI generally possess moderate knowledge and have a positive attitude and perception towards their condition and lifestyle changes, and also highlighted the importance of health literacy as a determinant of cardiovascular outcomes. Enhanced educational programs tailored to patients' specific needs and socio-demographic backgrounds could further improve their knowledge and management of MI. Additionally, healthcare providers' especially nursing officers, nurse educators, nurse practitioners and policy makers should consider these factors when developing and implementing lifestyle modification programs to ensure better patient outcomes and adherence.

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**Conflict of Interest:** The authors declare no conflict of interest.

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# Clinicopathological Study of Hashimoto Thyroiditis: Retrospective Study in a Tertiary Care Hospital

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## Abstract

**Background:** Hashimoto thyroiditis is an autoimmune disease in which thyroid cells are destroyed by both cell mediated and antibody mediated processes. It is the most common cause of hypothyroidism in iodine sufficient areas with an incidence of 0.3-1.5 /1000 per year. During the histopathological evaluation of HT, thyroid neoplasms including papillary thyroid carcinoma (PTC) are detected incidentally which is currently one of the primary area of research in thyroid pathology. This study aimed to explore the role of histopathological study along with its correlation with clinical presentation, biochemical and radiological parameters in the diagnosis of HT.

**Methods:** This was a retrospective study conducted in a tertiary care hospital over a period of 5 years from June 2019 to June 2024. A total of 45 cases of thyroidectomy specimens were included in the study. All the thyroidectomy specimens which showed only features of Hashimoto thyroiditis on histopathological as the only pathology were included in the study. All the relevant clinical information, radiological findings of thyroid gland, thyroid hormone assay and thyroid autoantibody studies were collected from the clinical records of the patients and analysed statistically.

**Result:** In our study, most of the cases belonged to the 31-40 years age group. Females were more affected than males. Majority of the patients presented with midline neck swelling and diffuse thyroid enlargement without nodularity. Autoantibody titre showed presence of antithyroglobulin antibodies anti-TPO antibodies in almost all cases. On microscopic examination of the thyroidectomy specimens, the most common finding were hurthle cell change and lymphoid follicles which were present in all cases.

**Conclusion:** majority of Hashimoto thyroiditis patients run a benign clinical course but in minor percentage of cases there is increased risk of development of malignancies particularly papillary thyroid carcinoma. Close follow up of these patients can lead to early diagnosis and prompt treatment for better management of the patients.

**Keywords:** Autoantibodies, goitre, Hashimoto thyroiditis, hypothyroidism

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## Introduction

The term thyroiditis reflects various group of disorders characterised by thyroid inflammation. Thyroiditis can be classified into acute, subacute and chronic thyroiditis. Chronic thyroiditis include autoimmune thyroiditis (Hashimoto thyroiditis), postpartum thyroiditis, drug induced and iatrogenic thyroiditis. The most common cause of thyroiditis is autoimmune disease. In United states Hashimoto thyroiditis (HT) is the most common cause of hypothyroidism.<sup>1</sup>

Hashimoto thyroiditis also known as chronic autoimmune thyroiditis and chronic lymphocytic thyroiditis is an autoimmune disease in which thyroid cells are destroyed by both cell mediated and antibody mediated processes.<sup>2</sup> HT is the most common cause of hypothyroidism in iodine sufficient areas. It has an incidence of 0.3 -1.5 /1000 per year.<sup>3</sup> Both genetic susceptibility (HLA gene polymorphism and familial aggregation) and environmental factors are responsible for the development of HT.<sup>4,5</sup> Iodine supplementation in iodine deficient areas increases the lymphocytic infiltration of thyroid gland by three fold along with an increase in serum antithyroid antibodies.<sup>6</sup> Clinically these patients present as diffuse or nodular thyroid swelling with or without symptoms. The combined findings of clinical presentation, radiological finding, biochemical assay for autoantibodies, hormonal assay lead the way towards the diagnosis of HT. However the diagnosis of HT is confirmed by histopathological examination of thyroidectomy (partial/total) specimen. During the histopathological evaluation of HT, thyroid neoplasms including papillary thyroid carcinoma (PTC) are detected incidentally. PTC coexisting with HT currently is one of the primary area of research in thyroid pathology. Various studies demonstrated significant association of HT with the prevalence of PTC.<sup>7,8,9</sup> A number of studies also demonstrated that patients with PTC with co-existent HT had better prognosis.<sup>10,11</sup> This study aimed to explore the role of histopathological study along with its correlation with clinical presentation, biochemical and radiological parameters in the diagnosis of HT.

## Materials and Methods

This was a retrospective study conducted in a tertiary care hospital over a period of 5 years

from June 2019 to June 2024. A total of 45 cases of thyroidectomy specimens were included in the study. All the thyroidectomy specimens which showed only features of Hashimoto thyroiditis on histopathological as the only pathology were included in the study. Patients with coexistent pathology such as thyroid neoplasm along with HT were excluded from this study. All the thyroidectomy specimens after receiving were fixed in 10% formalin solution. After fixation, grossing was done in each case according to the standard protocol and then the grossed tissues were subjected to routine tissue processing method and Haematoxylin and eosin stained slides were prepared and examined under the microscope. All the relevant clinical information, radiological findings of thyroid gland, thyroid hormone assay and thyroid autoantibody studies were collected from the clinical records of the patients. Radiological examination of the thyroid gland included ultrasonography and were represented as TIRADS (Thyroid Imaging Reporting and Data System) score. Thyroid hormone assay i.e. measurement of FT3, FT4 and TSH hormones were done by Electro chemiluminescence immunoassay (ECLIA) method. Anti Thyroglobulin antibody and Anti TPO- antibody were also measured by ECLIA method. Anti TPO value > 34IU/ml and anti Tg > 115IU/ml were considered as positive.

Statistical analysis: All the data were expressed in numbers and percentage. The software version IBM SPSS 2.0 was used for statistical analysis.

## Results

A total of 45 cases of HT diagnosed histopathologically were included in the study. In our study, most of the cases belonged to the 31-40 years age group (n=15, 33.3%) (Table 1). Females were more affected (n=39, 86.6%) than males (06, 13.3%) (Table 1). Majority of the patients presented with midline neck swelling and diffuse thyroid enlargement without nodularity accounted to 41 (91%) and 37 (82.2%) respectively (Table 1). Thyroid ultrasonography showed TIRADS (Thyroid Imaging Reporting and Data Systems) score of 2, 3, 4 in 29 (64%), 15 (33.4%) and 01 (2.2%) cases respectively (Table 2). On biochemical study of thyroid hormone assay 13 (28.9%) were euthyroid, 27 (60%) showed subclinical hypothyroidism and 05 (11.1%) cases showed overt

hypothyroidism (Table 2). Autoantibody titre showed presence of antithyroglobulin antibodies and anti-TPO antibodies in 45 (100%) and 34 (75.5%) cases respectively (Table 2). On microscopic examination of the thyroidectomy specimens, the most common finding were hurthle cell change and lymphoid

follicles which were present in all cases (45, 100%) (Table 3). The other less common findings were thyroid follicular atrophy (n=24, 53.4%), squamous metaplasia (n=2, 4.5%) and stromal fibrosis (n=9, 20%) (Table 3)

**Table 1: Clinical findings of patients with Hashimoto Thyroiditis n = 45**

	Parameters	Number	Percentage(%)
A	Age(years)		
	21-30	6	13.3
	31-40	15	33.3
	41-50	14	31.1
	51-60	7	15.48
	>60	3	6.6
B	Sex		
	Female	39	86.6
	Male	06	13.3
C	Clinical Parameters		
	Midline neck swelling only	41	91.1
	Both pain and swelling	04	08.8
D	Thyroid enlargement		
	Diffuse thyroid enlargement without nodularity	37	82.2
	Diffuse thyroid enlargement with nodularity	08	17.68

**Table 2: Radiological, Biochemical and immunological findings in patients of Hashimoto thyroiditis n= 45**

	Parameters	Number	Percentage (%)
A	Radiological Findings (Thyroid USG)		
	TIRADS Score 2	29	64.4
	TIRADS Score 3	15	33.4
	TIRADS Score 4	01	2.2
B	Biochemical findings (Thyroid hormone assay)		
	Euthyroidism (Normal FT4 & TSH)	13	28.8
	Subclinical hypothyroidism FT4-Normal, TSH (4.5 to 10 mu/L)	27	60
	Overt hypothyroidism (FT4-low, TSH>10Mu/L)	05	11.1
C	Immunological findings (Autoantibody study)		
	Antithyroglobulin antibodies	45	100
	Anti-TPO antibodies	34	75.5

**Table 3: Microscopic findings of the thyroidectomy specimens in case of HT Patients n = 45**

	Microscopic findings	Number	Percentage(%)
1	Thyroid follicular atrophy	24	53.4
2	Hurthle cell change	45	100
3	Squamous metaplasia	02	4.5
4	Lymphoid follicles	45	100
5	Stromal fibrosis	09	20

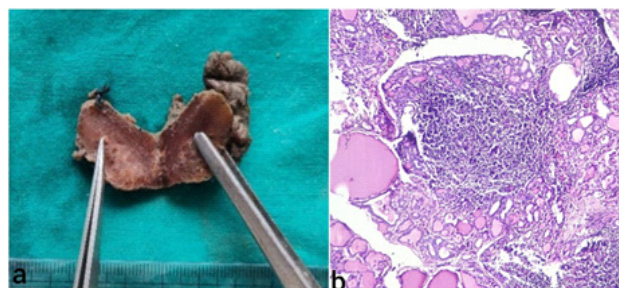
### Discussion

Hashimoto thyroiditis (HT) ID 10:E06 is defined as a prototype of autoimmune disease presenting with goitre, elevated circulating antithyroid antibodies and often with hypothyroidism.<sup>12</sup> HT was first described in 1912 by Dr. Hakaru Hashimoto, who called it struma lymphomatosa.<sup>13</sup> HT alternatively also known as Hashimoto disease, struma lymphomatosa, chronic lymphocytic thyroiditis, goitrous thyroiditis and lymphadenoid goitre.<sup>12</sup> HT is the most common cause of hypothyroidism in iodine sufficient areas.<sup>14</sup> Histologically it is characterised by infiltration of thyroid parenchyma by mononuclear cells, lymphoid follicles with germinal centres, hurthle cells or oncocytic cells lining residual thyroid follicles and stromal fibrosis.<sup>12</sup>

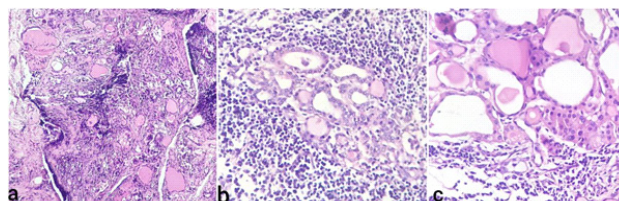
Various factors are responsible for the development of HT<sup>15</sup> which included genetic susceptibility [Human leucocyte antigen (HLA), gene polymorphism], environmental factors and production of autoantibodies against thyroglobulin, thyroid peroxidase (TPO) and antithyroid stimulating hormone (TSH) receptor due to breakdown of immune tolerance.<sup>3</sup>

Majority of the patients of HT belongs to the age group of 30-50 years. In our study, 29 cases out of 45 (64.5%) were in the age group of 31-50 years (Table 1) which was similar to previous studies.<sup>16-19</sup> In our study there was a female predominance 39/45 (86.6%) similar to various other studies in the past.<sup>11,17,18,20</sup> In the present study, the most common clinical presentation was diffuse painless swelling of the thyroid gland similar to other studies by Pooja et al, Lekha DBS et al<sup>17,20</sup>. (Table 1) In our study 29 cases out of 45 (64.4%) (Table 2) showed TIRADS score 2 on thyroid USG indicating a benign nodule

with 1.5% risk of malignancy. Biochemical studies showed subclinical hypothyroidism in 27 (60%) and overt hypothyroidism 05 (11.1%) case (Table 2) which was contrast to the study by P Caturegli et al<sup>5</sup> which showed majority of the patients (75%) were euthyroid. In the present study anti T4 antibody was found in 100% of the cases similar to the study by Pooja Jain et al.<sup>17</sup> In our study, histopathologic examination of the thyroidectomy specimen (Figure 1a) showed presence of thyroid atrophy (Figure 2b) in 24 (53.4%) cases. Lymphoid follicles (Figure 1b) and hurthle cell changes (Figure 2c) were seen in all the cases i.e. 45/45 (100%). Stromal fibrosis was seen in 9 (20%) cases (Figure 2a).



**Figure 1 showing gross specimen of thyroid after thyroidectomy (1a) and (1b) showing presence of lymphoid follicles and lymphoplasmacytic infiltrate in the stroma along with thyroid follicles in case of HT (H&E 100X)**



**Figure 2 showing stromal fibrosis (2a), atrophied thyroid follicles (2b) and hurthle cells (2c) in case of HT (H&E, 400X)**

**Limitations of the study:** Limited sample size is prone to biases of the retrospective analysis. Since the study was conducted in a tertiary care hospital, the cases may not be representative of the general population study.

**Future Perspective:** Recent advances in molecular technology will likely provide better understanding of the reliability between genetic factors and environmental factors in HT and new therapeutic approaches to HT. Future studies also include areas such as the challenge of differentiating HT and graves disease, the complex link between gut microbacteria and HT onset, and the management of HT alongside complications like papillary thyroid carcinoma or type 1 diabetes.<sup>21</sup>

### Conclusion

Hashimoto thyroiditis is the most common cause of hypothyroidism in iodine sufficient areas. Though majority of the patients run a benign clinical course, in minor percentage of cases there is increased risk of development of malignancies particularly papillary thyroid carcinoma. Close follow up of these patients can lead to early diagnosis and prompt treatment for better management of the patients.

**Ethical consideration:** Since it is a retrospective study, there were no interaction between researchers and patients. Identity of patients were concealed and confidentiality was maintained. Permission was taken from the department to analysis the data.

**Conflicts of interest:** None declared

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# A Study on Correlation of Depression among Diabetic Population in a Tertiary Care Hospital in Eastern India

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## Abstract

**Background of the study:** Diabetes Mellitus is a chronic disease which affects almost every organ in the human system. Depression is found to be quiet common among diabetic population, and it can be associated with bad prognosis. This study was taken up to find out the correlation of different components of depression with diabetes.

**Methodology:** 200 diagnosed cases of diabetes were selected according to the inclusion criteria attending the OPD, Department of Medicine of a tertiary care hospital in eastern India.. Then, they were assessed for any risk of depression in the Department of Psychiatry and relevant investigations were done.

**Results & Conclusion:** The analysis showed that certain factors related to diabetes can subsequently cause depression. More studies are required to establish the findings with a larger group of study and time frame.

**Keywords:** diabetes, depression, mental health, anxiety, mood disorders, insomnia, insulin.

## Introduction

Type 2 Diabetes Mellitus (T2DM) and depression are the major public health problems across the globe. Worldwide, more than 365 million peoples have been estimated to have T2DM and almost 300 million people have major depression. Both these disorders are projected to be among the five leading

causes of disease burden by 2030<sup>(1)</sup>. Depression is common among the people with diabetes and it is associated with poor outcomes. Depression can be viewed as a modifiable independent risk factor for the development of T2DM and for the progression of complications from type1 and type 2 diabetes <sup>(2)</sup>. The recognition and addressal of this association can

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have profound implication for the prevention and treatment of this disorder <sup>(1)</sup>.

Eighty percentage of the people with T2DM reside in developing countries. But much of the research around depression among the people with diabetes has been conducted in developed countries <sup>(3)</sup>.

This study was carried out to investigate the correlations of different components of depression among the diabetic population attending our hospital during the month of August to December, 2017. In developing countries like India the study can add some more relevant information. <sup>(3, 4)</sup>

**Materials & Methods**

This observational study was carried out at College of Medicine and Sagore Dutta Hospital (COMSDH), Kamarhati, Kolkata, a tertiary care hospital. The patients, diagnosed of diabetes were recruited on voluntarily basis for the study. Hamilton scale and Becks depression inventory (self questionnaires) were used for the diagnosis of the depression. Baseline investigations (Fasting Blood Sugar [FBS], Post Prandial Blood Sugar [PPBS], HbA1C and Lipid profile, Liver function Tests, FT3,FT4 and TSH) along with anthropometric measurements like height, weight, Basal metabolic index (BMI) were taken into account. The cases were not receiving any psychiatric treatment.

Inclusion Criteria- A case of Diabetes (Type 1 & 2) in specified age group of 25 yrs to 60 yrs of both genders.

Exclusion criteria- Patients suffering from other co-morbid illnesses like Hypothyroidism, Ischemic Heart diseases, Hypertension, Depression under treatment and Chronic Kidney diseases were excluded from the study.

After data collection, analysis was done using SPSS version 18.

Informed consent was taken from each patient participating in the study.

**Results**

Factor Analysis Showing Various Factors that Led to Depression

**Table 1: KMO and Bartlett’s Test**

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.859
Bartlett’s Test of Sphericity	Approx. Chi-Square	615.170
	df	21
	Sig.	.000

**Table 2: Rotated Component Matrix<sup>a</sup>**

	Component						
	1	2	3	4	5	6	7
INSOMNIA NO DIFFICULTY SLEEPING	-.232	-.096	.036	-.250	.086	.702	.000
INSOMNIA LATE UNABLE TOSLEEP IF OUT OF BED	.017	.142	.082	-.078	.054	-.216	.827
INCAPACITY	.139	.020	.043	.311	-.006	.619	-.227
SLIGHT RETARDATION	.014	-.050	.760	.177	.274	.002	-.247
AGITATION PLAYING WITH HAND	.102	.017	.000	-.022	.766	.000	.018
ANXIETY PSHYCO WORRYING MINOR MATTERS	.442	.864	.014	.223	.071	.298	.609
ANXIETY SOMATIC	.791	.220	.515	.230	-.200	-.013	.274
SOMATIC GASTRO	-.004	-.028	.239	.776	-.264	.159	.049
SOMATIC GENERAL HEAVINESS IN LIMB, BACK	-.040	.043	.107	.727	.360	-.078	-.035
GENETIAL SYMPTOM MILD CONTROLLED	-.358	.462	.293	.434	.041	.140	.112
GENETIAL SYMPTOM MILD UNCONTROLLED	-.075	.455	.250	.209	.878	.538	.188
LOSS OF WEIGHT DUE TO ILLNESS	.603	.276	.017	.131	.427	.140	.214
INSIGHT CAUSED DUE TO BAD FOOD, CLIMATE	.033	.777	-.021	-.087	.000	.707	.176
Extraction Method: Principal Component Analysis.							
Rotation Method: Varimax with Kaiser Normalization.							
Rotation converged in 17 iterations.							

A factor analysis was conducted to identify the major factors of diabetes that may lead to depression.

KMO and Bartlett’s test declares a significant result and shows adequacy of samples to perform the tests (table 1 & 2). After a Varimax rotation, various major factors identified are as follows-

1. Anxiety Somatic
2. Anxiety psycho
3. Slight retardation
4. Somatic gastro
5. Genital symptoms

6. Insomnia late

All these factors explain around 73% of the variation. These factors have a great impact on the psychology of the patients, which in turn might have led to depression among the patients. Out of these factors Anxiety psycho, Genital and Insomnia late have the maximum effect as they have a very high factor loading of more than .8.

**Table 3: CORRELATION BETWEEN DEPRESSION & VARIED SYMPTOMS OF DIABETES**

Correlations					
		DEPRESSED MOOD	INSOMNIA LATE	ANXIETY PSYCHOLOGICAL	GENITAL SYMPTOMS
Pearson Correlation	DEPRESSED MOOD	1.000	.729	.652	.851
	INSOMNIA LATE	.729	1.000	.585	.592
	ANXIETY PSYCHOLOGICAL	.652	.585	1.000	.661
	GENITAL SYMPTOMS	.851	.592	.661	1.000
Sig. (1-tailed)	DEPRESSED MOOD	.	.000	.000	.000
	INSOMNIA LATE	.000		.000	.000
	ANXIETY PSYCHOLOGICAL	.000	.000	.	.000
	GENITAL SYMPTOMS	.000	.000	.000	.
N	DEPRESSED MOOD	200	200	200	200
	INSOMNIA LATE	200	200	200	200
	ANXIETY PSYCHOLOGICAL	200	200	200	200
	GENITAL SYMPTOMS	200	200	200	200

The above table 3 shows that there exists positive correlation between depressions and its symptoms or factors. There is maximum correlation between depression and genital symptoms. The lack of sexual urge leads to depression largely. The result of the statistical analysis conveys that after genital, there is maximum correlation with the late night sleep disorder i.e. late insomnia. This symptom induces

a sense of depression among the patients. The third correlation certifies that the anxiety problem, which is a psychological disorder, which frequently lead to high level of depression. The result shows that these three factors have very nominal correlation among each other, which is been diagnosed in only a few patients, and it can be ignored as majority of patients are lacking in these symptoms.

Model	NPAR	CMIN	DF	P	CMIN/DF
Default model	19	6.398	8	.603	.813
Saturated model	27	.000	0		
Independence model	6	306.680	21	.000	14.604

Model	NFI Delta1	RFI rho1	IFI Delta 2	TLI rho2	CFI
Default model	.979	.945	1.005	1.015	1.000
Saturated model	1.000		1.000		1.000
Independence model	.000	.000	.000	.000	.000

Model	RMSEA	LO 90	HI 90	PCLOSE
Default model	.000	.000	.054	.932
Independence model	.197	.177	.216	.000

A model is developed from the relevant factors after varimax rotation to show the effects of the factors on physical and mental state which led to depression. CFA requires a lot of tests so that the model fits the data well.

The  $\chi^2$  (chi square) test yields a value of 2.398 which, evaluated with degree of freedom of 8, has a corresponding p-value of .503. By observing the p-value, which is very high, we cannot reject the null hypothesis for goodness of fit. More over the RMSEA is .000 which represents an excellent fit of data.

By observing the Model Fit, displays several fit indexes produced by IBM SPSS AMOS. The CMIN presents the minimum discrepancy value in the default model row is (6.505/8=.813).The values less than 2 is acceptable.

The NFI is .979

CFI topped out at 1.000

RMSEA bottomed out at .000. This model represents a good fit to the data.

Therefore, this can be concluded that this represents a superb fit of the model.

## Discussion

The prevalence of major depression in patients with diabetes is mostly estimated around 12% (ranging from 8-22%),while milder type of depression or elevated depressive symptoms in general are reported to be present in 15-35%.<sup>(5)</sup>

Compared to the non diabetic controls, patients with diabetes are reported to be about 1.4-3 times as likely to suffer from co morbid depression.<sup>(6,7,8)</sup> Although there have been some studies also which failed to show any significance difference in the

prevalence of depression (or affected disorder in general)between diabetic and non diabetic individual.

The relative risk for developing T2DM in depressed patient (Depression-diabetes) is reported to be 1.6.<sup>(9)</sup>Conversely concerning the relative risk for developing depression in patient with diabetes (DM-DEPRESSION), two recent Meta analysis of prospective studies have yielded a relative risk around 1.2<sup>(9)</sup>.

Depressive symptoms seem to be slightly more prevalent in type2DM than type 1DM, although this difference is not regarded to be statistically significant<sup>(8)</sup>.

Diabetes Mellitus is a heterogeneous disease in which hyperglycemia is the central factor. Insufficient insulin action on peripheral target tissues of the body gives rise to abnormalities of carbohydrate, protein and fat metabolism. This insufficient insulin action in peripheral tissues occurs as a result of insufficient insulin secretion (type1), diminished tissue response to insulin (Type2), or as a combination of both<sup>(10, 11)</sup>. While depression may contribute to poor prognosis related to diabetes, diabetes and its complications may also lead to depression<sup>(12,13)</sup>.

## Conclusion

This study states that several symptoms of diabetes, can lead to depression. There are mainly three factors out of seven, which affect the depression level. The genital symptoms mainly induce a feeling incapability, which mainly led to depression. Late night insomnia and excessive anxiety may also cause depression. From the study, it can be concluded that prolonged diabetes slowly give rise to depression. Now a days more and more people are falling prey to diabetes. Therefore, everybody should be careful

and maintain the normal sugar level, specially if there is risk of diabetes & depression. This study will be helpful for the patients not only for self-analysis but also for awareness of the society.

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# Knowledge, Perception and Attitudinal Assessment of Drug Promotional Literature Among Medical Undergraduate Students: A Questionnaire-Based Study

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## Abstract

**Background:** Understanding drug promotional literature (DPL) equips medical students with the ability to navigate the pharmaceutical industry ethically and responsibly. Medical students should be trained to critically evaluate DPL for accuracy, bias, and completeness. The present study aimed to assess the knowledge, attitudes, and perceptions regarding DPL among medical undergraduates.

**Methods:** A cross-sectional questionnaire-based survey was conducted on second and third year undergraduate medical students where a prevalidated questionnaire structured on the principal concept of DPL and items assessing the attitude and perception regarding DPL, was administered. Knowledge regarding DPL assessment was adjudged using WHO criteria. The individual item response was tabulated and analysed accordingly.

**Results:** Drug reference guide, followed by textbooks and DPLs were regarded as most common source of drug information. Respondents' knowledge regarding DPL was assessed against the standard WHO criteria. 43.04% respondents believe that the promotional claims in DPLs are largely biased, 47.83% respondents believed that DPLs do not adequately highlight the safety concerns of the products, while 33.91% believed that DPLs only focus on the effectiveness of medications. 46.08% opined that they would cross-verify the information highlighted in DPLs before prescribing them. 93.47% passionately believe that medical undergraduates should be trained to critically assess DPLs as a part of their curriculum.

**Conclusion:** Medical professionals should critically evaluate DPLs, seek additional sources of information, and prioritize patient safety by considering the full risk-benefit profile of any medication. Educators should ensure that medical undergraduates are equipped to assess DPL critically and ethically, fostering responsible use of promotional information in their future careers.

**Key Words:** Drug Promotional Literature, Medical Undergraduates, Questionnaire-based study, Ethical Promotion, Assessment

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## Introduction

Drug promotional literature (DPL) refers to materials created by pharmaceutical companies or their representatives to promote specific medications or therapeutic products. These materials are usually targeted at healthcare professionals (HCPs) such as doctors, pharmacists, and nurses, but they can also be directed at patients and the general public. The content aims to increase awareness, sales, and usage of the promoted drug. DPL contains product information comprising of details about the drug, including its brand and generic names, composition, dosage forms, and indications. [1] Summaries of clinical studies supporting the drug's efficacy, safety, and benefits over competing products, illustrated using charts, graphs, and images highlighting key points like clinical trial results, patient outcomes, or the drug's mechanism of action makes DPL a comprehensive product information source. It also contains testimonials or endorsements from medical professionals or patients highlighting positive experiences. [1]

Drug promotional materials must also comply with local regulatory guidelines, such as those established by the FDA in the U.S., the EMA in Europe, or similar authorities in other countries. These regulations ensure that the information is accurate, not misleading, striking a fair balance and discussing both the potential benefits and the possible side effects or risks of the medication. [2] DPL has various formats. It can be in form of brochures and flyers distributed during conferences, seminars, or by sales representatives, or in form of digital media and advertisements aimed at HCPs and general public. [2]

However, DPL is also constrained with some ethical challenges, like bias, conflict of interest and ethical compliance issues. DPL may emphasize the positives of a drug while downplaying its risks or alternative treatments. [3] HCPs may be influenced by promotional materials, which could lead to prescribing behaviours that are not entirely evidence based. Ensuring that promotional literature adheres to strict ethical guidelines is crucial to prevent misleading claims and ensure patient safety. [3]

Understanding DPL equips medical students with the ability to navigate the pharmaceutical industry ethically and responsibly. Medical students should be trained to critically evaluate DPL for accuracy, bias, and completeness. This includes questioning the data presented, understanding study design

limitations, and considering alternative therapies. By critically appraising promotional content and prioritizing patient welfare, they can avoid being unduly influenced by marketing and make informed, evidence-based prescribing decisions. [3] The present study aimed to assess the knowledge, attitudes, and perceptions regarding DPL among medical undergraduates.

## Methods

A cross-sectional questionnaire-based survey was conducted for a period of 1 month which included second and third year undergraduate medical students of a tertiary care teaching hospital in Eastern India. Permission for the conduct of the study was obtained from the Institutional Ethics Committee vide approval no IEC-SAKS/2024 - 34 dated 05.04.2024 and informed consent was obtained from all the students prior their participation.

As a part of the study tool, a questionnaire was structured focussing on the principal concept of DPL, with items assessing the attitude and perception regarding DPL. The questionnaire was pilot tested in a group of 30 students, who were not included as the study sample otherwise. The reliability coefficient of the questionnaire was assessed to be 0.76 (Cronbach alpha). The final questionnaire was distributed among the enrolled participants and filled questionnaires were retrieved. The individual item response was tabulated and analysed accordingly.

For assessing the knowledge of the students regarding DPL, each student was given a DPL and were asked to evaluate the same according to the WHO criteria on prescribed proforma [4] under following subheads:

1. The names of the active ingredients using either international non-proprietary names or the approved generic name of the drug.
2. The brand name.
3. Content of active ingredient(s) per dosage form or regimen.
4. Name of other ingredients known to cause problems.
5. Approved therapeutic uses.
6. Dosage form or regimen.
7. Side-effects and major adverse drug reactions.
8. Precautions, contraindications, and warnings.

9. Major interactions.
10. Name and address of manufacturer or distributor.
11. Reference to scientific literature as appropriate.

Data was collected, tabulated, and analysed using descriptive statistics involving frequency and percentages. All statistical analysis was performed using Microsoft Excel and GraphPad Prism.

### Results

The study included 230 undergraduate medical students for the final analysis. While the questionnaire was administered to 280 undergraduate medical students, a total of 230 filled questionnaires were returned, conferring an aggregate response rate of 82.14%.

There were 56.08% (n=129) female respondents and 43.91% (n=101) male respondents, with the age range varying from 19 to 22 years.

Respondents' knowledge regarding DPL was assessed against the standard WHO criteria. All respondents identified generic and brand name as a critical component of DPL. 95.22% (n=219), 86.95% (n=200) and 86.08% (n=198) respondents identified approved therapeutic uses, side effects and drug interactions as critical components of DPL, respectively. Only 8.69% (n=11) respondents

identified references of scientific literature as a component of DPL. (Table 1)

28.69% (n=66) of respondents regarded drug reference guides like CIMS, MIMS etc as the most common source of drug information followed by 21.3% (n=49) respondents believing in textbooks and 15.21% (n=35) respondents believing in DPL. 14.78% (n=34) of respondents regarded journals and conference proceedings as an information hub, 14.34% (n=33) of respondents believed in internet sources followed by 5.65% (n=13) in pharmacopoeia.

Assessing the perception regarding DPLs, it was observed that 43.04% (n=99) respondents believe that the promotional claims in DPLs are largely biased, 47.83% (n=110) respondents believed that DPLs do not adequately highlight the safety concerns of the products, while 33.91% (n=78) believed that DPLs only focus on the effectiveness of medications. (Table 2)

Probing the attitude regarding the DPLs, it was noted that 46.08% (n=106) of respondents opined that they would cross-verify the information highlighted in DPLs before prescribing them. 75.22% (n=173) of respondents opined that they consider DPLs as a measure to update their drug knowledge. 93.47% (n=215) of respondents firmly believe that medical undergraduates should be trained to critically assess DPLs as a part of their curriculum. (Table 2)

**Table 1: Knowledge of DPL Assessment using WHO Criteria**

Criteria	Correct Responses
Generic name	230 (100%)
Brand Name	230 (100%)
Active Drug	176 (76.52%)
Approved therapeutic uses	219 (95.22%)
Other ingredients known to cause problems	149 (64.78%)
Dosage Forms	80 (34.78%)
Regimen	92 (40%)
Side effects/ adverse effects	200 (86.95%)
Precautions	72 (31.30%)
Contraindications	79 (34.34%)
Warning	78 (33.91%)
Major drug interactions	198 (86.08%)
Manufacturers/ distributors name and address	96 (41.74%)
References	20 (8.69%)

**Table 2: Perception and Attitude Assessment of the Respondents regarding DPL**

	Agree	Disagree	Neutral
<b>Perception</b>			
DPLs are reliable sources of drug information	78 (33.91%)	87 (37.82%)	65 (28.26%)
Promotional claims in DPLs are largely biased	99 (43.04%)	131 (56.95%)	0 (0%)
DPLs only focus on the effectiveness of the medicine	78 (33.91%)	152 (66.08%)	0 (0%)
DPLs adequately highlight the safety concerns of the product	101 (43.91%)	110 (47.83%)	19 (8.26%)
<b>Attitude</b>			
DPLs help to update my drug knowledge	173 (75.22%)	55 (23.91%)	2 (0.87%)
I would cross-verify the information highlighted in DPLs before prescribing them	106 (46.08%)	124 (53.91%)	0 (0%)
I think medical undergraduates should be trained to critically assess DPLs as a part of their curriculum	215 (93.47%)	12 (5.22%)	3 (1.30%)

## Discussion

Drug advertisement through promotional literature remains a cornerstone of pharmaceutical marketing strategies. According to the World Health Organization (WHO), 'promotion' encompasses all informational and persuasive activities conducted by manufacturers and distributors to encourage the prescription, supply, purchase, and/or use of medicinal products.<sup>[5]</sup> DPL typically features details on product characteristics, side effects, dosage regimens, contraindications, and various marketing claims. These references should be accurate, dependable, informative, up-to-date, and substantiated. The limited time available to access medical literature and keep up with the constantly evolving scientific knowledge of medicines has made DPL a convenient and readily available source of drug information for physicians. This accessibility can significantly influence physicians' prescribing behaviour.<sup>[6]</sup> Finding its relevance in medical undergraduates, DPL introduces medical students to how drugs are marketed in the real world. Understanding these marketing strategies is important as they transition into clinical practice where they will encounter pharmaceutical representatives regularly. DPL can provide insights into the focus areas of the pharmaceutical industry, such as emerging therapeutic areas, trends in drug development, and innovations in treatment options.<sup>[7]</sup> Exposure to DPL during medical training may

influence future prescribing behaviours. Studies have shown that drug promotion can have a lasting impact on how HCPs choose to prescribe medications. By analysing DPL critically, medical students can learn to recognize potential biases in the information presented by pharmaceutical companies and be more cautious about letting marketing influence their clinical decisions.<sup>[8]</sup>

The present study critically evaluated the perception, attitude, and knowledge of second and third-year medical undergraduates regarding DPL. In an attempt to assess the knowledge regarding DPL using standard WHO criteria, it was observed that all respondents identified generic and brand name as a critical component of DPL, while 95.22%, 86.95% and 86.08% respondents identified approved therapeutic uses, side effects and drug interactions as critical components of DPL, respectively. Only 8.69% respondents identified references of scientific literature as a component of DPL. Our findings were quite similar to the previous studies by Jaiswal et al<sup>[9]</sup> and Deolekar et al<sup>[10]</sup>.

46.08% of respondents opined that they would cross-verify the information highlighted in DPLs before prescribing them. This is critically important as it ensures that the details provided are accurate, dependable, and based on up-to-date scientific evidence, helping to safeguard patient safety and effective treatment. Jaiswal et al<sup>[9]</sup> highlighted that 87.15% of respondents believed that the accuracy of

information provided in DPL should be verified.

75.22% of respondents opined that they consider DPLs as a measure to update their drug knowledge. 93.47% of respondents firmly believe that medical undergraduates should be trained to critically assess DPLs as a part of their curriculum. This training would equip them with the skills to evaluate the accuracy, reliability, and relevance of the information presented, fostering responsible prescribing practices in their future careers. In the Competency-Based Medical Education (CBME) framework, the critical assessment of DPL using the STEP criteria (Safety, Tolerability, Efficacy, Price) is incorporated into the pharmacology curriculum of the MBBS program. This approach aids in fostering rational prescribing practices among medical students.

In assessing perceptions regarding DPL, it was found that 43.04% of respondents believe that promotional claims in DPLs are largely biased. Additionally, 47.83% respondents felt that DPLs do not sufficiently emphasize the safety concerns of the products, while 33.91% believed that DPLs primarily focus on the effectiveness of medications. DPLs often highlight the benefits and positive attributes of a medication, such as its effectiveness, unique features, and advantages over competitors. However, these materials may downplay or omit detailed information about potential safety concerns. The information might be presented in a way that minimizes their severity or frequency, with a focus on rare or mild adverse effects, while serious or common side effects might be less emphasized. DPL may not adequately address the risks associated with long-term use, especially for newer drugs where long-term data may be limited. DPL might not provide comprehensive information on all possible drug interactions, which are crucial for comprehensive prescribing knowledge.<sup>[11]</sup> Pharmaceutical companies produce DPL to promote their products and increase sales. As a result, the content is often biased towards presenting the drug in the best possible light. This promotional bias can lead to selective reporting of data from clinical trials that support the drug's efficacy while downplaying or omitting data that highlight safety concerns or adverse effects. Regulations often mandate that DPL includes information on side effects and contraindications, but the specifics of how this information is presented can

be influenced by the company's marketing strategies. Proper regulations and mandated conformance to these regulations should be ensured to encourage ethical drug promotion through DPLs.

The strength of this study remains in its inclusion of second- and third-year medical undergraduates as respondents, since they are at the threshold of clinical journey, thus infusing sound perception regarding DPL can promote ethical prescribing in upcoming medical graduates. Our study is constrained by its single-center approach, which remains as a limitation of this research work.

## Conclusion

DPL plays a significant role in informing HCPs about new medications, but its focus on the positive attributes of a drug often comes at the expense of thoroughly addressing safety concerns. To mitigate this issue, it is important for medical professionals to critically evaluate promotional materials, seek additional sources of information, and prioritize patient safety by considering the full risk-benefit profile of any medication. Educators should ensure that students are equipped to assess DPL critically and ethically, fostering responsible use of promotional information in their future careers.

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# Comparative Analysis of the Cost of Thalassemia Screening VS Treatment in Different Healthcare Sectors in Delhi National Capital Region

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## Abstract

**Background:** Thalassemia is a single gene disorder that is passed on from parents to children. According to the World Health Organization, the carrier rate of thalassemia is between 3-7%. Treatment and management of a thalassemia major patient costs the family around USD 5389-13474 per year (INR 100,000–250,000) depending on the age and presence of complications. Screening of antenatal women have the potential to reduce the burden of thalassemia and could offer a much effective strategy.

**Methods:** A hospital based cross-sectional study was conducted to assess the cost of treatment and screening. Patients visiting thalassemia treatment centres in the National Capital Region were asked questions to assess the annual cost of treatment incurred.

**Results:** The annual treatment of thalassemia patients in government, non-governmental/charitable and private sector hospitals is being reported here. When analyzing the cost for the population at large, screening costs only 0.01% of the treatment cost.

**Conclusion:** Therefore, we can infer that screening in whole population is much more efficacious as compared to treatment in 10,000 people. Thus, screening and prevention not only reduces the morbidity and mortality associated with the disease, but also is a better public health model for countries with high prevalence of thalassemia.

**Key Words:** Thalassemia screening, cost analysis, single gene disorder

## Introduction

Thalassemia is a single gene disorder which is inherited in an autosomal recessive pattern<sup>1,2</sup>. Thalassemia major usually presents early; within

the first 2 years of the life of the child and is fatal unless started on a regular transfusion regimen<sup>3</sup>. Based on the clinical severity, thalassemia is divided into transfusion dependent and non-transfusion dependent states<sup>4</sup>. As it is inherited in autosomal

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recessive manner, the parents of the affected child are carriers who pass on the defective gene to the child<sup>4</sup>.

Among inherited conditions, thalassemia is one of the most prevalent disorders, affecting nearly 200 million people globally<sup>5,6</sup>. The carrier frequency of beta thalassemia in India is estimated to be 3% to 7%, thus posing a major public health concern<sup>7</sup>. In India, approximately 8000-10,000 children every year are born with beta-thalassemia major, which represents 10% of the thalassemia-major burden around the world<sup>8</sup>. Across India, as the thalassemia prevalence vary between 0.6% and 15% in different populations, it is estimated that there are approximately 42 million beta thalassemia carriers<sup>9,10</sup>. There are multiple strategies that have been suggested for reducing the burden of thalassemia in the country. Detection of carriers through population-based screening (e.g. in schools, colleges etc), focused group screening (antenatal women in first trimester) and cascade screening of extended family members of an affected child are strategies that have been suggested. Of these, mandatory antenatal screening is probably the most cost-effective method of detecting carrier state, as antenatal period offers a captive period where the pregnant lady is expected to return to the healthcare facility desirous of healthcare.

## Methods

A hospital based cross-sectional survey was conducted after receiving Institutional Ethics Committee approval (reference no IIPHD\_IIEC\_S\_33\_2019 dated 10 December 2019) among the parents of thalassemia patients to assess the annual treatment cost at a government institute (Post Graduate Institute of Child Health, Noida), a non-governmental organization (Red Cross Society) and patients visiting a private hospital in Delhi. The study was conducted over a period time of three months starting from December 2019 to March 2020. The study participants were thalassaemic patients and their families. After taking written consent from the parents of patients aged  $\leq 25$  years and patients aged  $>25$  years, interviewer administered questionnaire was administered. Participants were approached through the respective hospitals and the Red Cross Society helped in contacting patients who were under their support. Based on the objective of the study,

purposive sampling was done to select participants from the hospitals from where permission was granted. To assess the cost of treatment, using 7% prevalence and 5% precision, the sample size of 100 was calculated. Considering 10% non-response rate, the final sample size estimated was 110 and were balanced between the 3 groups. Anonymous, interviewer administered questionnaire was prepared to assess treatment cost. A similar questionnaire by Thalassaemia International Federation has been used as a guidance document<sup>10</sup>. The questionnaire was pretested and piloted before finalization to ensure appropriateness and completeness.

The study participants were asked about their annual cost of treatment. Costs were collected by components and presented separately as well as in aggregate. User costs were collected and presented separately from treatment costs. Non-medical user costs included cost of transportation and cost of wage loss. The study has not included cost of complications beyond treatment of primary condition of thalassemia.

For screening, costs associated with prenatal screening of thalassemia among antenatal women during their first trimester using hemoglobin electrophoresis was examined. Screening in thalassemia patients is done by (antenatal women in their first trimester) by HPLC test (high performance liquid chromatography) followed by confirmatory test in the spouses of thalassaemic females to see whether the couple is "at risk" or not. After detection of "at risk" couples, couples are referred to genetic counseling. Finally, those who agree for genetic counseling are advised to have prenatal genetic diagnosis of the fetus by chorionic villus sampling (CVS) at around 12 weeks of gestation. After prenatal genetic diagnosis, most couples with thalassemia major affected fetus opt for termination of pregnancy. Screening costs assessed in this study is an aggregate of all the above tests. Cost of prenatal screening was assessed from various private laboratories in Delhi NCR (Lal Path labs, House of Diagnostics, SRL, Prognosis lab, Niramaya, BLK Hospital, GangaRam Hospital, Apollo Hospital) and government hospitals (All India Institute of Medical Sciences, Kalawati Children's Hospital and Safdarjung Hospital) in Delhi and laboratories where screening of thalassemia and genetic counselling is

being done. Purposive sampling was done for cost of prenatal screening tests as all labs and hospitals do not provide genetic counselling and pre-natal diagnosis tests. Cost of prenatal screening tests was asked from private hospitals and laboratories based on convenience and mean costs were calculated. The costs were presented separately by individual tests as well as in aggregate, separately for each type of provider. It is to be noted that only cost of treatment incurred by the patient's family is calculated and not that was incurred by the hospital since they receive free treatment through government schemes. The out of pocket expenses incurred by family such as caretaker salary loss also has not been calculated. Ethical approval for conducting the research was taken from Institutional Ethics Committee of Indian Institute of Public Health, Delhi.

## Results

Background characteristics of the respondents (parents of thalassemia patients) are displayed in Table 1. 50 patients attending government hospital, 20 attending NGO and 30 attending private hospital were enrolled. 10 families who underwent prenatal were interviewed for the costs. The overall response rate was 88% (97/110). The age of patients included in the study ranged from 1 to 39 years (mean 13 years and SD 6.5). Around 56% of the patients were females. The majority of parents of the patients (40%) were salaried followed by unemployed (29%). Homemakers constituted about 17% of the total participants while only 12% accounted for daily wage workers. Forty-three percent completed their education up to school or equivalent, 34% studied up to the fifth standard while 15% had not attended school at all. The monthly household income of the respondents ranged from USD 36 (INR 3,000) to USD 4,268 (INR 3,50,000). The mean and median monthly income of the respondent was around USD 900 (INR 73947) and USD 304 (INR 25000) respectively with interquartile range USD 121- 1433 (INR 10000-117500).

### Components of cost of screening/couple

Screening cost included the cost of HPLC test which was considered as the first test to check the carrier status of the parents. The test was found to cost an average of USD 4.27 (INR 350) in government

institutes and about USD 14 (INR 1153) in private institutes. If both the parents were tested positive, they are advised to go for genetic counseling which costs USD 16.6 (INR 1360) on an average in private hospitals and labs. There was no fee for genetic counseling in government hospitals. If the parents agree then they undergo prenatal diagnosis to know whether the baby is thalassemic or not. This test costs about USD 24.3 (INR 2000) in government and USD 233 (INR 19116) in private institutes. If the baby turns out to be thalassemic major, then most couples would opt for termination of the pregnancy which costs USD 298 (INR 24500) in private and USD 6 (INR 500) in government hospitals. Overall, the average cost of screening in government hospitals amounts to USD 34.7 (INR 2850) per couple; in private hospitals, the average cost for screening is USD 563 (INR 46170) per couple. Difference in private and government screening cost was USD 132 (INR 10830) but is not statistically significant.

### Components of annual government and private treatment cost

Current recommendation states that transfusion therapy should be started as soon as the patient is diagnosed with haemoglobin level less than 7gm/dl at least on two consecutive tests (12) varying methods of obtaining blood, different practices in screening for blood pathogens and different costs of drugs and equipment. It is evident that all countries would benefit from the sharing of experience and expertise in order to harmonize and optimize the quality of treatment as much as possible. The need for management guidelines for Transfusion Dependent Thalassaemias (TDT). After the thalassemia patient has been diagnosed with thalassemia major, pre transfusion haemoglobin level test needs to be done to maintain the haemoglobin level above 9.5-10gm/dl (13) including Germany, due to immigration. \n\nMethod\n\nSelective review of the literature with consideration of national guidelines.\n\nResults\n\nThe hemoglobinopathies encompass all genetic diseases of hemoglobin. They fall into two main groups: thalassemia syndromes and structural hemoglobin variants (abnormal hemoglobins. Chelation therapy (removal of excess iron from the body with drugs) needs to be initiated along with the transfusion of blood to maintain serum ferritin level below 1000 ng/ml (12) varying methods of obtaining blood, different practices in screening for

blood pathogens and different costs of drugs and equipment. It is evident that all countries would benefit from the sharing of experience and expertise in order to harmonize and optimize the quality of treatment as much as possible. The need for management guidelines for Transfusion Dependent Thalassaemias (TDT).

Treatment for thalassemia includes the cost of regular transfusion of leukodepleted blood, medical treatment such as chelation therapy and investigations at each hospital visit and annually to monitor for complications. In government hospitals such as PGICH, Noida which is supported by National Health Mission, Blood Cell, Uttar Pradesh, all patients are provided free of cost NAT tested and leukoreduced blood and chelation therapy. All routine investigations are also provided free of cost to the patient through the NHM budget. At such centres, the cost incurred by the patient would only be for their travel to the hospital and additional investigations. The cost incurred by the hospital is borne by the budget for hemoglobinopathies under the National Health Mission, Ministry of Health and Family Welfare.

In the case of non-governmental organizations and government institutions, maximum proportion is spent by the patients on laboratory tests followed by

cost of referral at NGOs. Cardiology, endocrinology and hepatology evaluation is done once annually and on sos basis and referral to specialist involves multiple visits to different specialists. In government setup, physician fee is usually free and it constitutes USD 12 (Rs. 1000) to patients visiting NGOs.

Chelation and leukodepleted blood were given free of cost to patients at the government hospital and NGOs. In the case of private hospitals, chelation constitutes the highest cost component (75%) although it also includes physician cost, and drug cost. It accounts for USD 3,016 (INR 2, 47,323) annually. After this, 10% is accounted for by specialist cost, 7% is spent on hospitalisation while 6% on transfusion. Cardiac evaluation and ferritin test accounts for only 1% of the components of the treatment cost.

Overall, the average annual cost per thalassemia patient was USD 32 (INR 2681) and USD3840(INR 3,14,906) in government vs private sector respectively for transfusion and chelation as shown in table 3. It is again highlighted that in government centres, this cost is borne by the state government either directly or through National Health Mission as the case may be whereas in NGO and private hospitals, the cost is borne by the family.

**Table 1: Background characteristics of participants (N=97)**

Background characteristics	N=97
Age of Patients (years), Mean(SD)	13(6.55)
Sex of Patients, n(%)	
• Male	55(56.70)
• Female	42 (43.30)
Employment status of parents, n(%)	
• Unemployed	28(29.17)
• Daily wage worker	12(12.50)
• Salaried	39(40.63)
• Homemaker	17(17.71)*
Education level of parents, n(%)	
• No schooling	15(15.46)
• Upto class 5	34(35.05)
• High school	42(43.30)
• Graduate and above	6(6.18)
Monthly family income in rupees, Median(IQR)	25000(10000-117500)

\*One respondent did not disclose her/his employment status

**Table 2: Difference in treatment cost between government, NGO and private sector**

	Difference in means	P-value	Confidence Interval	T-Statistics
Cost difference between government and NGO vs. private treatment	-314906	<0.001	(-347479.1,-282332.9)	-19.50
Cost difference between government and NGO vs. private screening	-10830	0.17	(-29950.63-8290.63)	-1.79

**Table 3: Estimated cost of treatment of thalassemia (INR)**

	Government and NGO		Private	
	Monthly Range (Average cost)	Annual	Monthly Range (Average cost)	Annual
Cost of Transfusion	300-1650 (771)	3305	500-4400(1584)	19010
Cost of Chelation	250-6000 (1861)	3190	9000-35000(20600)	247323
Cost of Physician	100-200 (106)	342	Included in chelation therapy cost	
Cost of Referrals	100-2000 (942)	2885	1200-7500(2875)	32093
Cost of Laboratory tests				
1.Ferritin	150-500(254)	1020	300-550(460)	1843
2.Cardiac	1500-6500(4046)	4046	1900-6000(4677)	4677
Total average cost of treatment per year		14161		314906
Mean percentage of annual income spent on treatment	7.19%		18.11%	

In government center, all services were provided free to the patient and the cost incurred was borne by the government whereas in NGO and Private, the cost was borne by the patient's family.

### Discussions

The annual cost of treatment per patient, amounts to USD 32 (INR 2681) in government hospitals and USD 3840 (INR 3,14,906) in private hospitals (Table 2). This expenditure will increase year after year as treatment is required for lifetime and can reach up to USD 292(INR 24006) in government and USD 34,391(INR 28,19,764) in private over 24 years (mean life expectancy of thalassemia patients)<sup>14</sup>by only considering a 10% annual inflation rate. It may be noted that the study does not calculate the rate of development of complications and additional investigations and treatment costs for these complications. The highest cost component in private settings is chelation therapy. As it acquires the highest cost component and is required very frequently, every

effort has been made by the government to make it free for the patient. NGOs and private hospitals also have been providing this at subsidised rates to the patients who cannot afford.

As compared to these costs, the screening cost were only USD 4.2 (INR 350) in government facilities and USD 14.5 (INR 1,193) in private facilities. Hence, screening during the first trimester should be encouraged irrespective of the fact that parents are thalassemic or not. Parents are usually willing to undergo tests during this period for the well-being of the baby(15).

We also report that 18% of the annual family income was spent by families belonging to the upper class households. Poorer patients have to spend a significant fraction of their earnings on travel, cost of medicines and investigations when not supported in government centers. Even 11-22% of their annual income can have a huge impact as many families already had less resources.

“Prevention is indeed better than cure. A majority of studies done in this genre have reported screening of antenatal women to be cost-effective as compared to the treatment done in thalassemia patients<sup>16</sup>. We can conclude that screening for all pregnant women of India will cost around USD 67,24,57 (INR 55,135,150) considering USD 4.2 (INR 350) as primary screening test cost and that India would have around 1,57,529 pregnant women annually (according to NFHS 4)<sup>17</sup>. The treatment costs on the other hand for a year in 10,000 individuals<sup>18</sup> will cost around USD 39.6 million (INR 3250 million). Screening cost is thus only 0.01% of the treatment costs in the country. Therefore, from a public health perspective, we conclude that the investment for screening in antenatal period is an investment that should be mandated as a compulsory activity. Although there are government initiatives encouraging antenatal screening for thalassemia, currently they are not mandatory and hence the antenatal testing is currently purely voluntary which makes the acceptance poor. There is an urgent need to increase awareness and also to promote such activities through the government so as to improve the acceptance for this activity.

The studies reviewed also confirm the same findings. Kantharaj et al, 2014 reported that the cost of preventing the birth of 10,000 patients every year by screening of antenatal women is estimated to be USD 395 million (INR 6175 million). In contrast, the cost of treating these 10,000 patients over an estimated life span of 40 years is USD 4274 million (INR 66,800 million) thus highlighting that prevention is only one-tenth of the treatment costs<sup>4</sup>. Koren et al reported in a study done in Northern Israel in the year 2014 that the cost of preventing one affected newborn was USD 63,660 compared to USD 1,971,380 for treatment of a patient during 50 years (mean annual cost: USD 39,427)<sup>19</sup>. Ahmadzadeh et al from Iran also reported that the total cost of preventing one case of Thalassemia (100 USD) is less than a single year of optimum treatment for a case with major Thalassemia (6500 USD)<sup>16</sup>. Our study is unique we did this costing exercise for India which has the largest burden of thalassemia and that considering the healthcare delivery heterogeneity, we evaluated each economic strata separately and still showed benefit of prevention.

## Conclusions

This study provides a practical and convenient approach to evaluate policies, laws and other factors such as family income, education level and employment status influencing access to health facilities. This study provides evidence regarding the impact of prenatal screening. There is an urgent need for the mandatory inclusion of antenatal screening and prenatal diagnosis in at-risk couples after proper genetic counseling as part of the thalassemia control program in India. The role of civil societies is paramount in this regard. It is noteworthy that a significant fraction of annual income is spent on treatment by families from any economic strata. India thus is in dire need for a dedicated centrally co-ordinated thalassemia screening and treatment program which engages all stakeholders for sustainability.

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**Conflicts of interest:** None

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# Prevalence of Depression and Associated Risk Factors among the Elderly Population attending Government Medical College Hospital of North Karnataka: A Cross-Sectional Study

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## Abstract

**Background:** Depression among the elderly is a critical public health issue that significantly impairs physical health, cognitive functioning, daily activities, and social interactions. However, it often remains underdiagnosed and inadequately treated in this age group, exacerbating its impact on their overall quality of life. Recognizing the growing concern, this study aims to estimate the prevalence of depression and identify associated risk factors among individuals aged above 60 years attending a Government Medical College Hospital in North Karnataka.

**Methods:** This cross-sectional study was conducted at tertiary care hospital, BIMS, Belagavi. A total of 400 study participants were randomly selected and interviewed using a structured questionnaire which consisted of socio-demographic profile and The Geriatric Depression Scale (GDS) scale. GDS, a validated self-report assessment tool was used to assess depression. Statistical analysis, including chi-square test was used to determine association between depression and socio-demographic risk factors.

**Results:** A total of 400 geriatric subjects participated in our study. Majority of them were females (54.5%) and from rural area (64.5%). The overall prevalence of depression was found to be 21.25%. Depression was more prevalent among females, rural residents, and individuals staying alone or widowed. Illiteracy and presence of chronic disease were associated with higher rates of depression. Significant associations were found between depression and socio-demographic variables like gender, residence, marital status, literacy and presence of chronic illness.

**Conclusion:** This study highlights high prevalence of depression among geriatric population with various socio-demographic factors playing a role in its occurrence. Early recognition and appropriate interventions for depression in the elderly are crucial to prevent adverse consequences and improve overall quality of life.

**Keywords:** Depression, Geriatric, prevalence, elderly healthcare.

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## Introduction

Depression is not a natural part of aging.<sup>1</sup> Depression is often reversible with prompt recognition and appropriate treatment. However, if left untreated, depression may result in the onset of physical, cognitive, functional, and social impairment, as well as decreased quality of life, delayed recovery from medical illness and surgery, increased health care utilization, and suicide.

The GBD 2019 study found that the global burden of mental disorders, including depression, has increased significantly from 1990 to 2019. Specifically, mental disorders were among the top ten leading causes of DALYs worldwide, with no significant reduction in burden observed since 1990. The study also highlighted that depressive disorders remain a major contributor to global health challenges, with incidence rates remaining high, especially among women.<sup>2</sup> Depression is the most common psychiatric disorder among the elderly and although India is the most populous country in the world in terms of elderly population >60 years of age, depression in the elderly is not yet perceived as an important health problem in the country.<sup>3</sup> Significant predictors for depression found among the elderly in the studies conducted previously were urban residence, female sex, increasing age, nuclear family, illiteracy, and poverty. A meta-analysis of the risk factors of depression in the elderly found bereavement, sleep disturbance, disability, prior depression, and female gender to be significant risk factors for depression.<sup>4-8</sup> However, a study on community-dwelling elderly in Tamil Nadu found that age, female gender, cognitive impairment, and disability status were not significantly associated with geriatric depression.<sup>8</sup> Hence, there is need to enquire into the prevalence of depression in the geriatric population. It was against this backdrop of importance of depression coupled with lack of community-based studies in these subjects i.e. geriatric population, in this part of India that prompted us to take up the present study.

## OBJECTIVE

To estimate the prevalence of depression and identify the associated risk factors in the elderly population.

## Methods

A cross sectional study was carried out at Government Medical College Hospital which is a government tertiary care hospital attached to medical college, BIMS, Belagavi. The study was conducted during two months. The estimated sample size was 400 with prevalence assumed to be 50% and 10% relative error of prevalence. All the patients above 60 years of age attending our hospital were included in the study after taking informed consent. Individuals who were living with hearing impairments, diagnosed psychiatric conditions (such as schizophrenia or intellectual disabilities), or neurological disorders (including Parkinson's disease, severe head injuries, or brain tumors) at the time of the study were not included. All 400 randomly selected geriatric study participants were interviewed using a pre-tested, pre-designed, structured questionnaire containing various socio-demographic parameters. Depression was assessed using the 15-item Geriatric Depression Scale (GDS), which is a 15-item self-report assessment used as a basic screening measure of depression in the elderly.<sup>9</sup>

Accuracy of the GDS-15 is not influenced by the severity of medical burden, age, or other sociodemographic characteristics and even the "very old" and ill can be screened appropriately.<sup>10</sup> Moreover, the presence of a major depressive episode among elderly home-bound adults can be reliably detected. Hence, this scale is better suited in identifying depression in the elderly.<sup>11</sup> Those with a GDS score 5 or more were categorized as depressed. Using this cut-off, a high sensitivity and specificity of the 15-item GDS has been reported.<sup>12</sup>

Approval of the Institutional Ethics Committee has been obtained prior to commencement of the study.

## Statistical analysis

Data was entered and tabulated using SPSS version 22.0. Summary figures like rates, ratios, and percentages were used for statistical analysis. The Chi-square test was used to find the association between depression and socio-demographic risk factors.

**Results**

A total of 400 geriatric subjects were included in the study. The majority 218 (54.5%) of participants were females, 258 (64.5%) of them were from rural area, 186 (46.55%) of them belonged to 66-70 years of age, 224 (56%) and 236 (59%) of them were married and illiterate respectively, 285 (71.25%) were from nuclear family. (Table 1)

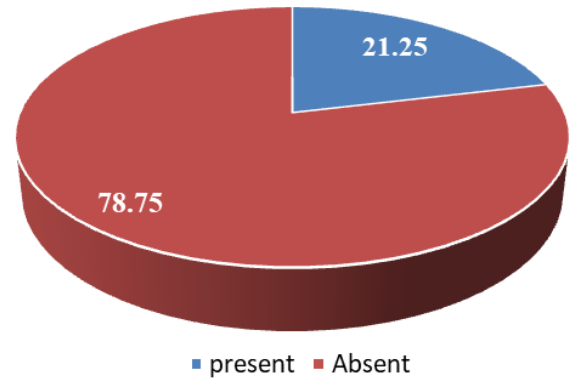
The prevalence of depression was found to be 21.25% among the study participants as shown in Figure 1. Depression was more among females (25.68%), rural population (24.08%) and those staying alone or widow (35.22%). The prevalence of depression was found to increase with age. We found that depression was more among illiterate (35.36%) and those with presence of chronic illness (27.6%). We found significant association between depression and various socio-demographic variables likeresidence, gender, marital status, literacy, and presence of chronic illness. (Table 2)

**Table 1: Distribution of socio-demographic profile**

Variable		Frequency (%)
Age	60-65	148 (37)
	66-70	186 (46.55)
	71-75	46 (11.5)
	76-80	20 (5)
Gender	Male	182 (45.5)
	Female	218 (54.5)

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Residence	Urban	142 (35.5)
	Rural	258 (64.5)
Marital status	Married	224 (56)
	Unmarried/ widow	176 (44)
Type of family	Nuclear	285 (71.25)
	Joint	115 (28.75)
Education	Literate	164 (41)
	Illiterate	236 (59)
Working status	Working	184 (46)
	Not working	216 (54)
Monthly Per capita Income	<= 1000rs	358 (89.5)
	>1000rs	42 (10.5)
Chronic Illness	Present	224 (56)
	Absent	176 (44)



**Figure 1: Prevalence of depression. (n=400)**

**Table 2: Association between Depression and socio-demographic variables. (n=400)**

Variable		Depression		Chi square value	p value
		Present	Absent		
Age	60-65	23	125	5.08	0.166
	66-70	44	142		
	71-75	12	34		
	76-80	06	14		
Gender	Male	29	153	5.63	0.018
	Female	56	162		
Residence	Urban	21	121	5.49	0.019
	Rural	64	194		
Marital status	Married	23	201	36.68	<0.001
	Unmarried/ widow	62	114		

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Type of family	Nuclear	63	222	0.432	0.51
	Joint	22	93		
Education	Literate	58	106	33.095	<0.001
	Illiterate	27	209		
Working status	Working	36	148	0.576	0.447
	Not working	49	167		
Monthly Per capita Income	<= 1000rs	79	279	1.358	0.244
	>1000rs	06	36		
Chronic Illness	Present	62	162	12.571	<0.001
	Absent	23	153		

### Discussion

In the present study, the prevalence of depression was found to be 21.25%. The prevalence was significantly higher in the rural residents, females, older elderly (in the age group of 76-80 years), those living alone without a spouse i.e. unmarried or widowed, nuclear families, illiterates, those not working, in the poor with monthly per capita income of <Rs.1000 and those with some chronic disease like hypertension, diabetes mellitus, asthma, cardiac and renal diseases. In the present study, the association between depression and residence, sex, marital status, educational status and chronic illness was found to be statistically significant.

Studies have revealed that the prevalence rates for depression in community samples of elderly in India vary from 6 to 50%.<sup>13</sup> The prevalence has been reported to be 45.9% in the urban slums of Mumbai,<sup>14</sup> 29.36% in the urban slums of Dharwad district, Karnataka,<sup>15</sup> 31.4% in a rural population of Ahmednagar, Maharashtra,<sup>16</sup> and 12.7% in a cross-sectional study of 1000 elderly in Vellore, Tamil Nadu.<sup>17</sup>

In the present study, the prevalence of depression was found to be significantly more in elderly females (25.68%) than in the male subjects (15.93%). Ramachandran et al., study observed that depression was significantly more frequent in females than in males, which was similar to the findings of the present study.<sup>18</sup>

In the present study, the prevalence of depression was found to increase with increasing age. Some of

the reasons for increase in the prevalence after the age of 60 years may be an increased economical and physical dependency, loss of the spouse, negligence by the family members and loss of self-esteem. Similar findings were found in Jariwala Vishal et al's and Raj Kumar et al's studies.<sup>19,20</sup> The subjects who were living alone i.e. unmarried or widowed had a significantly high prevalence of depression (35.22%) as compared to the other subjects. A low prevalence was found among the subjects who lived with their spouses and children. This reflected 'the loss of spouse' as one of the most important factors which were responsible for the increased prevalence of depression. The negligence by children, feeling of loneliness, a poor status in the family and a sense of insecurity may be the reasons for the increased prevalence of depression in these subjects as compared to those in those who were living with their spouses and children. Several studies also found that the prevalence of depression was significantly high among the elderly who lived alone.<sup>21,22</sup>

In the present study, there was an increase in the prevalence of depression from the higher to the lower socio-economic status. The prevalence was high among the subjects who were having a monthly per capita income of Rs. 1000. The increase in the prevalence among the subjects of the lower socio economic status reflect the role of economic dependency and thereby, negligence by the family members. The associated high prevalence of illiteracy in this group might be an additional factor for the increased economical dependency. Similar findings were also observed in Raj kumar et al., Ramachandran et al., and Jain RK's studies.<sup>23-25</sup>

## Conclusion

The prevalence of depression among the study participants was found to be 21.25%, with significant associations observed between depression and socio-demographic factors such as rural residence, female sex, increasing age, loss of spouse, nuclear family, illiteracy, dependency on others, and the presence of chronic illnesses. With the increasing longevity and a rising proportion of the elderly population in India, coupled with the trend towards urbanization and nuclear family setups, depression among the elderly is poised to become a prominent public health concern.

### Implications for Public Health and Community Medicine Professionals:

This study underscores the urgent need for community medicine professionals to prioritize mental health screening in elderly care, integrate mental health interventions into primary healthcare, and raise awareness about geriatric depression among healthcare providers and caregivers. Public health initiatives targeting early detection and management of depression in elderly populations, especially in rural and underserved communities, could significantly improve their quality of life and reduce the burden on healthcare systems.

### Limitations of the Study:

The study's cross-sectional design limits the ability to establish causality between identified risk factors and depression. Additionally, the use of a single hospital-based sample may not fully represent the broader elderly population, particularly those not seeking medical care. The reliance on self-reported data could also introduce bias, as participants may underreport or inaccurately recall their symptoms and socio-demographic details.

### Recommendations

The National Programme for Health Care of the Elderly (NPHCE) and its efforts to address elderly healthcare, including depression exists. However, our study highlights gaps at the community level, especially in rural and underserved areas where mental health services are often limited.

To enhance the NPHCE, we propose:

1. **Community-Level Screening:** Train health workers to screen for depression and integrate this into existing outreach services.
2. **Accessible Mental Health Services:** Implement telemedicine, mobile clinics, and mental health camps to reach underserved areas.
3. **Support for High-Risk Groups:** Develop support groups, psychoeducation, and caregiver training for vulnerable elderly populations.
4. **Monitoring and Evaluation:** Regularly assess the NPHCE's reach and impact to identify barriers and refine strategies.

These enhancements would complement NPHCE efforts, making it more effective in addressing elderly depression at the grassroots level.

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# To Assess the Validity of Preoperative Scoring System in Difficult Laparoscopic Cholecystectomy

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## Abstract

**Background:** Laparoscopic cholecystectomy (LC) is the gold standard treatment for cholelithiasis. Furthermore, in comparison to traditional open cholecystectomy, laparoscopic cholecystectomy offers minimal invasive technique, reduced postoperative pain, quicker recovery, an earlier return of bowel function, and a shorter hospital stay. However a surgeon may encounter difficult cases which can increase the risk of complications, Various Scoring system are used to determine the pre operative predictability of difficult laparoscopic cholecystectomy. In our study we studied Randhawa and Pujahari scoring system and assessed its sensitivity and specificity, whether this scoring system is valid or not.

**Conclusion:** In our study done at Sri Guru Ramdas University of health sciences and research we took 100 cases and predicted whether the laparoscopic cholecystectomy will be easy or difficult on the basis of Randhawa and Pujahari scoring system and compared the scores with the surgical outcome whether it was easy or difficult laparoscopic surgery. In our study while assessing the validity of Randhawa and Pujahari scoring system positive predictive value came 90% and negative predictive value of 86.6% with sensitivity and specificity of 81.82% and 92.86%

**Keywords:** Difficult Laparoscopic Cholecystectomy (DLC), Scoring Systems, Validity, Risk Factors.

## Introduction

Laparoscopic cholecystectomy (LC) is the gold standard treatment for cholelithiasis. Furthermore, in comparison to traditional open cholecystectomy,

laparoscopic cholecystectomy offers minimal invasive technique, reduced postoperative pain, quicker recovery, an earlier return of bowel function, and a shorter hospital stay.<sup>1</sup>

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Laparoscopic cholecystectomy has many benefits, but it is not without risks. Numerous complications can arise during laparoscopic surgery; some are specific to this particular technique, while others are typical of laparoscopic surgery in general. For a variety of reasons, between 2% and 10% of patients require conversion to open surgery.<sup>2</sup> Common bile duct injury, bile leakage, gallbladder perforation, damage to the vascular and visceral structure during the use of a trocar and Veress needle, and additional complications like external biliary fistula, perihepatic collection, wound sepsis, hematoma, adhesions, foreign body inclusions, metastatic port-site deposits, and cholelithoptysis are among the complications that can arise.<sup>3</sup> Risk factors that increase the complexity of laparoscopic cholecystectomy include preoperative and intraoperative variables like age, body mass index (BMI), male gender, history of abdominal surgery, acute cholecystitis with fever, leucocytosis, presence of gallbladder stones, and specific ultrasonography findings like gallbladder distention and wall thickness  $\geq 4$  mm, impacted gallstones, and pericholecystic fluid collection.

Since it was initially described in 1985, laparoscopic cholecystectomy has been the accepted procedure for treating benign biliary diseases. These days, cholecystectomies are among the most common surgical procedures worldwide. Due to the learning curve, there was an increased risk of bile duct injuries and complications during the early stages of the laparoscopic technique's development. However, over time, the percentage of serious lesions dropped from 0.08 to 0.12% and 1.5% of all lesions. The complexity of cholecystectomy has been linked to subsequent events.<sup>4</sup>

Even though LC is the most frequently performed operation these days, conversion is necessary for some intended LC for a variety of reasons. It often takes longer than expected and necessitates conversion to an open cholecystectomy because of intraoperative complications that must be addressed for the procedure to end safely. Nonetheless, a conversion rate of roughly between (2% and 10%) has been reported in recent literature.<sup>5</sup>

Between 2 and 15% of cases of laparoscopic cholecystectomy were converted to open procedures in the early years of the procedure. The conversion

rate fell to roughly 1–6% following years of studying and mastering the laparoscopic technique and increasing surgeons' experience. This conversion was an attempt to steer clear of issues brought on by a number of procedural challenges. Cases of dense adhesions at Calot's triangle, upper abdominal surgery history, acutely inflamed and gangrenous gallbladder, gallbladder empyema, Mirizzi's syndrome, prior cholecystostomy, and cholecystogastric or cholecystoduodenal fistula are taken into consideration when determining difficulty.<sup>6</sup>

The majority of the time, it's difficult to gauge the degrees of difficulty. However, forecasting is required in order to inform the patient about the likelihood of conversion. Similarly, the surgeon can mentally prepare for the challenging cholecystectomy in order to improve postoperative outcomes. This preparation can include having a strong surgical team, planning the procedure appropriately, performing an intraoperative cholangiogram, and being ready overall. Knowing the predictors for completing such difficult surgeries is always preferable. The likelihood of potential complications and conversion to open surgery can be estimated based on risk factors such as patient demographics (age, gender, body weight, comorbidity, and ASA score), clinical findings (acute versus chronic cholecystitis), and the surgeon's experience.<sup>7</sup>

A study using six parameters—old age, male gender, upper abdominal tenderness at the time of surgery, thickened gallbladder wall detected sonographically, and preoperative diagnosis of acute cholecystitis—was reported by Kama et al. and was found to be significantly associated with the risk of open cholecystectomy.<sup>8</sup>

There are a number of factors that have been identified that could affect how difficult a cholecystectomy is. These include factors related to the patient, like age, sex, anatomical variations, prior surgeries, obesity, or pathologies like severe inflammation or impacted stones. External factors, like malfunctioning equipment, could also have an impact.<sup>9</sup>

There are multiple studies done to predict the pre operative difficulty in laparoscopic Cholecystectomy as our study was done in indian framework Jaskiran S. Randhawa. Aswini K. Pujahari predictive score study is more preferable, As a result, the objective of this study is to access the validity of the Jaskiran S. Randhawa. Aswini K. Pujahari predictive scoring system. This study will define the precision of the scoring system that predicts the pre operative difficulty of laparoscopic cholecystectomy. By calculating the precision of this scoring system, we will find out about the rationality of this scoring system, as this scoring system allow us to define difficulty in LC pre operatively which makes outcome predictable.

**Materials and Methods:**

**Study Period:** 01<sup>st</sup> January 2023 to 31<sup>st</sup> March 2024.

**Study Design:** Prospective observational study.

**Number of cases:** 100

Informed Consent was taken from all the patients for this study.

**Methodology**

All the patients above 18 years, for symptomatic gallbladder disease were included in the study. All the cases were given scores on the basis of Randhawa and Pujahari scoring system, on the basis of this scoring system cases were assigned as easy, difficult and very difficult pre operatively. The following parameteres were used to measure the outcome of surgery:

1. Time taken for surgery
2. Bile/stone spillage
3. Injury to cystic duct or cystic artery
4. Conversion to open cholecystectomy

**ETHICAL APPROVAL STATEMENT**

The study was ethically approved by Sri Guru Ram Das Institute of Medical Sciences and Research, Sri Amritsar Date - 10-10-2022 and Ref no SGRD/IEC/22-93

**RANDHAWA AND PUJAHARI SCORING SYSTEM FOR DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY**

Scoring factors	Minimum	Maximum	Total
History	<50 years(0)	>50 years (1)	1
Age Sex	Female (0)	Male(1)	1
History of hospitalization for acute cholecystitis/pancreatitis Clinical	No (0)	Yes(4)	4
BMI weight(kg/height(m <sup>2</sup> ))	<25(0)	25-0-27.5(1) >27.5(2)	2
Abdominal Scar	No (0)	Infa- umbilical(1)	1
		Supra- umbilical(2)	2
Palpable GB Sonography	No (0)	Yes(1)	1
Wall thickness	Thin (0)	Thick> 4mm (2)	2
Pericholecystic collection	No (0)	Yes(1)	2
Impacted stone	No (0)	Yes(1)	1

Preoperative risk based on the scoring system

Risk	Score
No Risk	0-5
Moderate	6-10
High Risk	11-5

**PARAMETERS OF DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY:**

Parameters	Easy	Difficult	Very Difficult
Times taken for surgery	<60 min	60-120 min	>120min
Bile/stone spillage	No	Yes	Yes
Injury to duct or artery	No	Yes	Yes
Conversion to open cholecystectomy	No	No	Yes

**Inclusion Criteria**

Patients above 18 years with symptomatic gallbladder disease

**Exclusion Criteria.**

1. Patients with gallbladder carcinoma
2. Peritonitis
3. History of upper quadrant surgeries in the past
4. Coagulopathies
5. Portal hypertension
6. Pregnancy (excluding second trimester)

there surgical outcome on the basis of Randhawa and Pujahari scoring system and compared the outcome of the surgery with prediction score. Surgical outcome was measured on the basis of following parameters:

1. Time taken for surgery
2. Bile/stone spillage
3. Injury to cystic duct or cystic artery
4. Conversion to open cholecystectomy

On the basis of Randhawa and Pujahari scoring system out of 100 cases 60 were predicted easy and 40 were predicted difficult and in our result out of these 60 easy predicted cases 52 were easy and 8 were difficult, out of 40 predicted difficult cases 34 cases came out to be difficult, 4 cases came out to be easy 2 very difficult and

**Results**

In our study we took 100 cases and predicted

**Table No 1: Co-relation of predictive outcome with the final outcome**

Co-relation of predictive outcome with the final outcome	Pre-operative prediction	Easy outcome	Difficult outcome	Very Difficult Outcome	R value
Easy	60	52	8	0	0.758
Difficult	40	4	34	2	
Total	100	56	42	2	

Spearman’s rho correlation; R value = 0.758; p <0.001; Highly significant

**Table No 2: Surgical outcome in study**

Risk factor	Level	Easy	Difficult	Very Difficult	P Value
Sex	Female 71	39(54.9%)	32 (45.0%)	0 (.0%)	.00005
	Male 29	5(17.2%)	22 (75.8%)	2 (6.9%)	
Age	<50 (68)	28(41.17%)	40(58.8%)	0.00%	0.062
	>50 (32)	16(50.0%)	14(43.7%)	2(6.03%)	
BMI	100	44(44%)	54 (54%)	2 (2%)	.0002

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History of previous Pancreatitis/Cholecystitis	No (57)	43(75.00%)	14(25.00%)	0.00%	.0001
	Yes (43)	1(2.32%)	40(93.02)	2(4.50%)	
Palpable Gall Bladder	No (92)	44(47.82%)	48(52.1%)	0.00%	0.003
	Yes (8)	0.00%	8(100%)	0.00%	
History of Previous Abdominal Surgeries	Supra Umbilical (19)	6(31.5%)	13(68.4%)	.0%	.486
	Infra Umbilical (26)	12(46.1%)	14(53.8%)	.0%	
Gallbladder wall thickness	No	43(57.3%)	30(40.0%)	2(2.7%)	0.0001
	Yes	1(4.0%)	24(96.0%)	0%	
Impacted Stone	No (75)	41(50.0%)	41(50.0%)	.0%	0.0008
	Yes (25)	3(16.6%)	13(72.2%)	2(11.1%)	
Pericholecystic fluid collection	No (94)	43(45.7%)	49(52.1%)	2(2.1%)	0.328

Chi square test;  $p < 0.05$  is significant;  $p < 0.001$ ; Highly significant

Table no 2 shows comparison of preoperative risk factors and surgical outcome in the present study. The relationship between sex and surgical outcome is significant. The relationship of BMI with surgical outcome is significant. The relationship between history of pancreatitis, palpable gall bladder and surgical outcome is significant. The relationship between history of previous abdominal surgeries is not significant as. The relationship between gall bladder wall thickness, impacted stone is significant. The relationship between pericholecystic fluid collection and surgical outcome is non-significant.

### Discussion

Laparoscopic cholecystectomy (LC) has become the gold standard for treating symptomatic gallstones and other gallbladder disorders due to its minimum invasiveness, reduced postoperative discomfort, shorter hospital stays, and faster recovery time compared to open surgery. Certain instances, known as “difficult laparoscopic cholecystectomy” (DLC), pose major technical obstacles. Preoperative grading methods have been created to estimate the complexity of LC, which helps with surgical planning and patient counselling.<sup>50</sup> To help surgeons make decisions and manage patients, these scoring systems take into account a variety of preoperative criteria.

These scoring methods assist with risk stratification of patients and surgery planning by assessing characteristics such as the degree of inflammation, adhesion presence, anatomical abnormalities, and comorbidities.

These scoring systems have various benefits when used in challenging laparoscopic cholecystectomy procedures. It lowers the subjectivity in surgical decision-making by enabling a consistent and objective assessment of patient factors. Surgeons can potentially lower the risk of intraoperative complications, optimize resource allocation, and customize their strategy by identifying high-risk patients. Preoperative risk classification also makes it possible to have discussions with patients about informed consent and to set reasonable expectations for the surgical process and its results.

These methods are helpful in complex laparoscopic cholecystectomy procedures, but it's important to recognize their limitations. These grading methods rely on preoperative evaluations, which might not always precisely represent the results of the intraoperative procedures.

There are many preoperative scoring methods, in our study we studied the validity of Randhawa and Pujahari scoring system.<sup>10</sup>

In our study, 100 patients had laparoscopic cholecystectomy, and we took Randhawa and

Pujahari study's prognostic risk factors for difficult laparoscopic cholecystectomy. Sex, BMI, history of hospitalization, abdomen pain, previous abdominal surgery, palpable gall bladder, and ultrasonographic findings like gall bladder wall thickness, pericholecystic fluid collection, impacted stone were included as risk factors in this study.

Randhawa and Pujahari<sup>10</sup> scoring system included age more than 50 as a risk factor but results were non significant. However in our study age more than 50 was considered as a difficult predictor for Difficult LC. 32 patients had age more than 50 who were predicted of DLC, Out of which 14 turned out to be difficult and 2 turned out to be very difficult LC, rest of the 16 cases had easy outcome. Statistically there is a significant association between age > 50 and outcome of surgery. (p value <0.05).

According to Randhawa and Pujahari<sup>10</sup> scoring System, male sex was considered as a risk factor for DLC. Laparoscopic cholecystectomy can be more challenging in older patients because of lower physiological reserve, altered anatomical features, and an increased risk of comorbidities. IN our Study 29 were male and 71 were females. out of 29 male cases 22 cases had Difficult LC and 2 had very Difficult LC. In our study there was a significant association of male sex with difficult laparoscopic cholecystectomy with p value <0.05 however there was no significant relation between age and surgery outcome according to Randhawa and Pujahari score.

According to Randhawa and Pujahari's<sup>10</sup> scoring system patients with HIGH BMI are considered under DLC. In our study 42 patients had BMI > 25 which is considered as a risk factor for DLC, out of which 28 patients had DLC and 2 patients had Very DLC and had to underwent open cholecystectomy. There was significant association seen between high BMI and difficult laparoscopic cholecystectomy. (P value <0.05).

Pujahari and Randhawa's<sup>10</sup> model have mentioned previous history of abdominal surgery as a risk factor but did not find any significant correlation, same came in our result. The p value came >0.05 (p value = 0.483) which is non significant.

Pujahari and Randhawa's studies found that a clinically palpable gallbladder was linked to

a challenging laparoscopic cholecystectomy. In our study out of 100 cases 8 cases had clinically palpable gallbladder, out of which all the 8 cases had difficult laparoscopic cholecystectomy but out of 92 patients with no palpable gall bladder 44 had easy LC AND 48 had DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY. The p value came out to be <0.05 showing significant correlation between palpable gall bladder and difficult surgical outcome.

Both cholecystitis and pancreatitis are considered as a risk factor in Pujahari and Randhawa's studies and both came out to be significant factors for outcome of surgery. Dissection may be more difficult in patients with a history of pancreatitis due to inflammatory alterations in the periportal area and surrounding tissues. In our study previous history of cholecystitis and pancreatitis showed significant association with difficult laparoscopic cholecystectomy with p value <0.05.

Agrawal and Randhawa's study considered thickness of more than 4mm as a preoperative predictor of difficult laparoscopic cholecystectomy and results showed significant association between gall bladder thickness >4mm and difficult laparoscopic cholecystectomy. In our study ultrasound proven gall bladder thickness >4mm was seen in 25 patients out of 100, out of these 25 patients 24 had difficult laparoscopic cholecystectomy. There was a significant association of gallbladder thickness with difficult laparoscopic cholecystectomy with p value <0.05.

In our study Impacted stones showed a significant association with a p value <0.05 whereas Pujahari and Randhawa scoring system gave no significant correlation between impacted stone and outcome of surgery.

In both Pujahari and Randhawa's<sup>10</sup> study and our study accumulation of pericholecystic collection did not showed any significant association with difficult laparoscopic cholecystectomy (p value >0.05).

Two patients required conversion to open cholecystectomy because of difficult anatomy, the factors associated with conversions were male sex, past history of cholecystitis/pancreatitis, Gall bladder thickness >4mm, Impacted stones and BMI >27.5. This variation can be attributed to the surgeon-to-surgeon variations, the underlying prognostic determinants of the individual, lack of uniform

evaluating system, and difference in sample size. The experience of the surgeons and time spent in perfecting the surgical techniques help in achieving a low rate of complications.

It is crucial to recognize the limits of the Randhawa scoring system even though it provides insightful information about the anticipated complexity of a laparoscopic cholecystectomy. The preoperative evaluations and imaging investigations that the scoring system depends on do not always fully reflect the scope of intraoperative difficulties. Because unforeseen complications may develop during surgery that were not fully anticipated in the preoperative scoring system, surgeons should be adaptable and ready to modify their technique depending on real-time discoveries.

### Conclusion

In our study done at Sri Guru Ramdass University of health sciences and research we took 100 cases and predicted the difficulty score on the basis of Randhawa and Pujahari scoring system and compared the scores with the surgical outcome whether it was easy or difficult laparoscopic surgery. Out of 100 cases 60 cases were predicted for easy laparoscopic cholecystectomy and 40 were predicted for difficult laparoscopic cholecystectomy. However, in final outcome out of 40 difficult predicted cases 36(90.0%) came out to be difficult laparoscopic cholecystectomy and out of 60 easy predicted cases 52(86.6%) came out to be easy. Hence in our study while assessing the validity of Randhawa and Pujahari scoring system positive predictive value came 90% and negative predictive value of 86.6% with sensitivity and specificity of 81.82% and 92.86%.

In conclusion, the Randhawa and Pujahari<sup>10</sup> scoring system is a useful tool for risk assessment and surgical planning in complicated laparoscopic cholecystectomy situations. Surgeons can forecast the complexity of a surgical treatment and adjust their approach accordingly by using the Randhawa scoring system, which integrates several clinical and radiological criteria into a comprehensive scoring system. The grading system's ability to direct clinical practice and improve outcomes for patients having laparoscopic cholecystectomy can be further enhanced by ongoing validation and optimization.

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# Preventive Dietary Knowledge to Combat Non-Communicable Diseases: A Descriptive Study Contextualized Bangladeshi Female University Students

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## Abstract

Non-communicable diseases (NCDs) represent one of the most pressing and intricate public health issues. This study aimed to verify the dietary knowledge of female university students regarding NCDs. This was a descriptive type of cross-sectional study with 385 female university students of Dhaka, Bangladesh. Data were gathered by pre-tested and semi-structured questionnaires. Analysis was performed by using multivariate techniques followed by regression modeling. This study reflected that the majority of the female students belonged to the age group <22 years. The study found that 77% of the respondents had poor knowledge of preventive diets to combat NCDs. It was observed that the highest level of poor knowledge was about the dietary policies that cause NCDs (85.7%) and benefits of fruits & vegetables intake to combat NCDs (83.4%) among female university students. Also, the highest level of poor knowledge is significantly ( $p<0.05$ ) related to the students who did not have any family history of NCDs (AOR=2.57) and also 3<sup>rd</sup> year group (AOR=2.34). This study showed that few female university students had overall good knowledge, and the state of information regarding preventative diet to combat NCDs was unsatisfactory. This study discovered that several relevant predictors under socio-demographic repercussions were highly significant in relation to inadequate knowledge.

**Keywords:** Non-communicable diseases, NCDs, Preventive Dietary Knowledge

## Introduction

Non-communicable diseases (NCDs) represent Bangladesh's critical and multifaceted public health dilemma. These conditions are chronic, enduring for prolonged durations, and typically progressing

slowly<sup>1</sup>. In 2019, NCDs were responsible for 1.62 billion Disability Adjusted Life Years (DALYs), constituting 63.8% of the overall DALYs, indicating a global rise in their prevalence<sup>2</sup>. Globally, NCDs constituted 74% of total mortality, emerging as the

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predominant contributor to premature death<sup>3</sup>. In 2012, the World Health Organization (WHO) issued a cautionary report highlighting that NCDs account for 68% of global mortality. Within this context, approximately 75% of all NCD-related fatalities were concentrated in low-and middle-income countries (LMICs)<sup>4</sup>.

Bangladesh and many other LMICs are undergoing an epidemiological transition marked by a shift from infectious diseases to NCDs<sup>5</sup>. NCDs impose significant health and economic burdens, particularly affecting the productivity of younger populations. By 2030, these diseases will result in a global economic loss of \$47 trillion. Failure to mitigate NCDs could lead LMICs to incur an economic deficit exceeding \$7 trillion from 2011 to 2025, averaging around \$500 billion annually<sup>6</sup>.

Numerous elements shape consumers' eating habits, genetic predispositions, personal factors<sup>1</sup> like culture, expertise, preferences, and time for meal preparation, and economic and political aspects such as food cost and accessibility. Additionally, the dissemination of food-related information, whether through education or marketing, plays a significant role in influencing dietary choices<sup>7</sup>. Furthermore, people in Bangladesh lack awareness about integrating healthy habits into their daily lives, primarily due to insufficient knowledge, infrastructure, and resources, and a failure to acknowledge its significance<sup>8</sup>. Research indicates that understanding nutrition can empower individuals to promote good health and decrease the chances of developing chronic diseases by impacting dietary habits<sup>9</sup>. Younger adults, including college students, face unique challenges as they navigate independent dietary choices for the first time, often constrained by limited knowledge, experience, time, and financial resources, potentially resulting in unhealthy dietary patterns and adverse health consequences<sup>10</sup>. Insufficient nutrition knowledge among some young people contributes to poor mental and physical health. In the past, parents, usually mothers, were the primary source of nutritional education at home, shaping their children's eating habits<sup>11</sup>. Studies have consistently found a significant connection between maternal education and children's health. Educated mothers tend to have children with lower rates of

malnutrition, including underweight, wasting, and stunting<sup>12</sup>.

This study examines dietary knowledge among female university students in Bangladesh to prevent NCDs. Focusing on women is strategic as they often manage household nutrition, impacting broader societal health. The research aimed to identify knowledge gaps on dietary awareness related to NCDs. Findings will inform future interventions and policies to enhance dietary practices among young Bangladeshi women, reducing the NCD burden.

## Methods

### Study design

A quantitative cross-sectional study was carried out using analytical approach from June to December 2023. Semi-structured data were collected in this study to obtain information on socio-demographic characteristics, clinical characteristics and knowledge on preventive diets to combat NCDs among female university students of Bangladesh.

### Study participants, sample size, and sampling technique

This study considered a total of 385 undergrad female students studying in the Akij College of Home Economics of Dhaka, Bangladesh. Quantitative information for this study was collected from the respondents identified as students of the Akij College of Home Economics, and provided their consent to participate in this study.

Initially a potential standard sample size was assumed as 367 calculated by using the formula " $n = \frac{Z^2pq}{d^2}$ " where Z (standard normal deviate) considered as 1.96; p (reasonable estimate of prevalence rate 60.5%) was considered as 0.60<sup>13</sup> and margin of error was considered as 0.05. With a minimum calculated sample 367, an additional 5% was added as cushion to take into account non-response and the final samples were 385.

A total number of 500 students of Akij College of Home Economics of Dhaka district were considered as study. Akij College of Home Economics was selected through random sampling as study place. A total of 385 students were selected followed systematic random sampling from the pool of 500

students listed by the college and were considered as the participants of this study.

### Data collection

Quantitative data was collected by using a pre-tested and semi-structured questionnaire through the interviewer-administered method. Respondents were interviewed according to their convenience on August 2023 and onwards. All authors had access to the collection and preserving participants' information during or after data collection.

### Ethical considerations

This study was approved by the Ethical Review Committee of the Department of Public Health of Northern University Bangladesh (NUB/ DPH/ EC/ 2022/ 20) and conformed to the Declaration of Helsinki.

### Questionnaire design

The questionnaire was pre-validated by two independent reviewers and pre-tested among 10 respondents. The quality of the questionnaire addressed the responses of the pre-test. The pivotal components of the questionnaire were: (i) Socio-demographic characteristics: age, education, religion, marital status, number of children, residence type, Parental education, parental occupation, monthly family income, family size, and family type; (ii) Clinical characteristics: nutritional status measurement through calculating body mass index (BMI), had any of NCDs, family history of NCDs; (iii) Knowledge on preventive diets to combat NCDs: dietary policies to cause NCDs, selected ideal dietary guidelines

to combat NCDs, food causes of NCDs, benefits of food & vegetables intake to combat NCDs, patterns of obesogenic food consumption, adverse effects of tobacco use and risk factors of passive smoking.

### Data analysis

Collected data was checked and analyzed employing the Statistical Package for the Social Sciences (SPSS) software. Study characteristics were subjected to descriptive statistics (frequency and proportions) to summarize the obtained data.

Relevant continuous data were categorized followed by mid-values of the percentage scores as cut points<sup>14</sup>. A multinomial logistic regression analysis was performed followed by a modeling procedure considering a backward elimination process, including pre-specified confounders i.e., age, education, religion, marital status, number of children, residence type, Parental education, parental occupation, monthly family income, family size, family type, nutritional status, had any of NCDs, Family history of NCDs. Odds Ratios with 95% confidence intervals concerning Knowledge on preventive diets to combat NCDs (poor and good) were calculated for the specified exposures.

## Results

### Participant's characteristics

A total of 385 female college students were enrolled in this study. The majority of the respondents belonged to the age group <22 years (68.8%) and had a positive family history of NCDs (55.3%), as depicted in (Table-1).

**Table 1: Demographic characteristics of the respondents according to the total knowledge on preventive diets to combat NCDs (n=385)**

Characteristics	Number of participants, n (%)	Knowledge on preventive diets to combat NCDs		p-value
		Good n (%)	Poor n (%)	
<b>Age (in years)</b>				
<22	265(68.8%)	60(15.6%)	205(53.2%)	0.35
>22	120(31.2%)	30(7.8%)	90(23.4%)	
<b>Education</b>				
1 <sup>st</sup> Year	55(14.3%)	10(2.6%)	45(11.7%)	0.05*
2 <sup>nd</sup> Year	143(37.1%)	32(8.3%)	111(28.8%)	
3 <sup>rd</sup> Year	117(30.4%)	23(6.0%)	94(11.7%)	
4 <sup>th</sup> Year	70(18.2%)	25(6.5%)	45(11.7%)	

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<b>Number of children</b>				
No children	381(99.0%)	90(23.4%)	291(75.6%)	0.34
≥1	4(1.0%)	0(0.0%)	4(1.0%)	
<b>Residence type</b>				
Hostel	63(16.4%)	18(4.7%)	45(11.7%)	0.53
Mess	23(6.0%)	4(1.0%)	19(4.9%)	
Sublet	9(2.3%)	1(.3%)	8(2.1%)	
Home	290(75.3%)	67(17.4%)	223(57.9%)	
<b>Father's education</b>				
<HSC	167(43.4%)	34(8.8%)	133(34.5%)	0.13
>HSC	218(56.6%)	56(14.5%)	162(42.1%)	
<b>Mother's education</b>				
<HSC	259(67.3%)	60(15.6%)	199(51.7%)	0.49
>HSC	126(32.7%)	30(7.8%)	96(24.9%)	
<b>Father's occupation</b>				
Service	119(30.9%)	24(6.2%)	95(24.7%)	0.45
Day laborer	1(0.3%)	1(0.3%)	0(0.0%)	
Self-employed/Business	179(46.5%)	43(11.2%)	136(35.3%)	
Farmer	6(1.6%)	2(0.5%)	4(1.0%)	
Unemployed / Retired person	61(15.8%)	16(4.2%)	45(11.7%)	
Other's	19(4.9%)	4(1.0%)	15(3.9%)	
<b>Mother's occupation</b>				
Service	49(12.7%)	8(2.1%)	41(10.6%)	0.27
Housewife	308(80.0%)	73(19.0%)	235(61.0%)	
Other's	28(7.3%)	9(2.3%)	19(4.9%)	
<b>Monthly family income (in USD)</b>				
<273	139(36.1%)	34(8.8%)	105(27.3%)	0.39
>273	246(63.9%)	56(14.5%)	190(49.4%)	
<b>Family size (in numbers)</b>				
<4	178(46.2%)	39(10.1%)	139(36.1%)	0.30
>4	207(53.8%)	51(13.2%)	156(40.5%)	
<b>Family type</b>				
Living alone	92(23.9%)	23(6.0%)	69(17.9%)	0.63
Nuclear	268(69.6%)	63(16.4%)	205(53.2%)	
Combined	25(6.5%)	4(1.0%)	21(5.5%)	
<b>Nutritional status (measured by BMI)</b>				
Under weight (<18.5)	40(10.4%)	9(2.3%)	31(8.1%)	0.92
Normal weight (18.5-23.5)	271(70.4%)	65(16.9%)	206(53.5%)	
Over weight (25.0-30.0)	59(15.3%)	12(3.1%)	47(12.2%)	
Obese (<30)	15(3.9%)	4(1.0%)	11(2.9%)	
<b>Had any of NCDs</b>				
Yes	8(2.1%)	2(0.5%)	6(1.6%)	0.59
No	377(97.9%)	88(22.9%)	289(75.1%)	
<b>Family history of NCDs</b>				
Yes	213(55.3%)	65(16.9%)	148(38.4%)	0.01*
No	172(44.7%)	25(6.5%)	147(38.2%)	

Along with that, approximately two-third (63.9%) of study respondents belonged to families having monthly income >273 USD. Moving towards parents' educational and occupational background majority of the respondent's mothers had not completed their education up to higher secondary (HSC) level and were housewives (67.3% and 80.0% respectively) and the majority of respondent's fathers (56.6%) had educational qualification from higher secondary and above, and were businessman (46.5%).

### Respondent's characteristics associated with knowledge on preventive diets to combat NCDs

Table 1, also showed multivariate (cross-table) analysis, which reveals that respondent's age group

<22 years (53.2%) and 2<sup>nd</sup> year students (28.8%) were significantly associated with poor knowledge on preventive diets to combat NCDs. It also showed that the rate of poor knowledge is highest among unmarried students (67.3%) and among Muslim students (70.6%). On the other hand, monthly family income of >273 USD (49.4%) and nuclear family (53.2%) were significantly associated with poor knowledge. Among the respondents, those who had normal weight (53.5%) and those who had no NCD experience (75.1%) were significantly associated with poor knowledge. But interestingly, respondents who had and who didn't have a family history of NCDs, had poor knowledge on preventive diets (38.4% and 38.2% respectively).

**Table 2: Insights of preventive dietary knowledge to combat NCDs (multiple responses)**

Preventive dietary knowledge on individual components	Total knowledge on preventive diets			
	Good		Poor	
	n	%	n	%
1. Dietary policies to cause NCDs	55	14.3	330	85.7
2. Ideal dietary guidelines to combat NCDs	132	34.3	253	65.7
3. Food causes of NCDs	81	21	304	79
4. Benefits of fruits & vegetables intake to combat NCDs	64	16.6	321	83.4
5. Patterns of obesogenic food consumption	98	25.5	287	74.5
6. Adverse effects of tobacco use	153	39.7	232	60.3
7. Risk factors of passive smoking	116	30.1	269	69.9

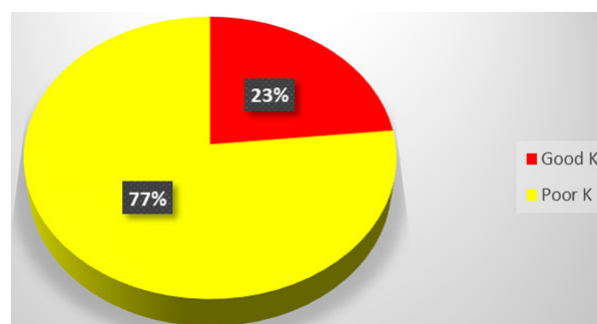
### Insights of preventive dietary knowledge to combats NCDs

Table 2 reflected that, the majority of respondents (85.7%) had poor knowledge about the dietary policies that cause NCDs. Moreover, 83.4% of the respondents had poor knowledge about the benefits of fruit and vegetable intake to combat NCDs.

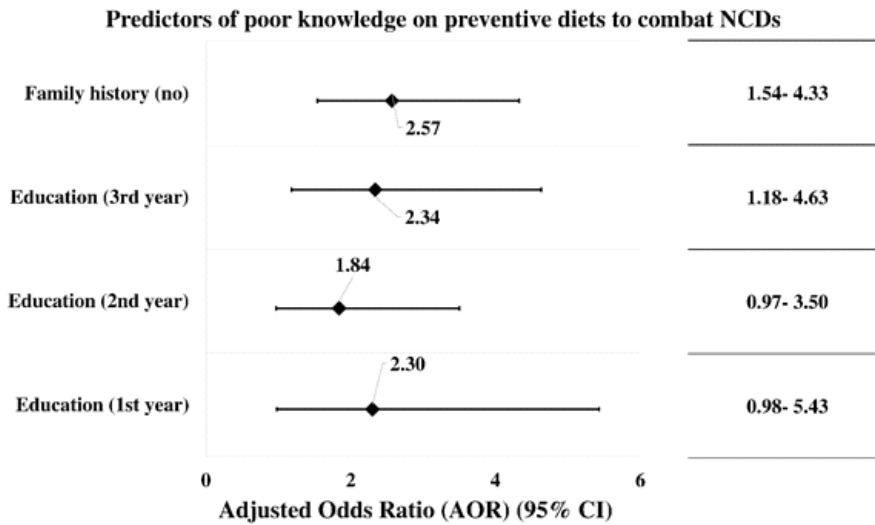
Several individual components that had an impact on poor knowledge by more than 50% of total knowledge. These were ideal dietary guidelines to combat NCDs (65.7%), patterns of obesogenic food consumption (74.5%), adverse effects of tobacco use (60.3%), and risk factors of passive smoking (69.9%).

### Total knowledge on preventive diets to combat NCDs

Total knowledge on preventive diets to combat NCDs was observed as poor knowledge (77%) among more than three-fourth of female university students and very few had overall good knowledge (33%) (Figure 1).



**Figure 1: Total knowledge on preventive diets to combat NCDs (n=385)**



**Figure 2: Predictors associated with the poor knowledge on preventive diets to combat NCDs (n= 385)**

Figure 2 footnote: Regression Analysis was performed to analyze. Statistically significant predictor was considered at  $p \leq 0.05$ . The reference category for education was '4<sup>th</sup> year', for family history of NCDs was 'Yes', and knowledge on preventive diets to combat NCDs was 'Good'.

**Predictors associated with the poor knowledge on preventive diets to combat NCDs**

This study revealed significant predictors associated with poor knowledge of preventive diets to combat NCDs among the respondents. Significant variables from cross-tabulation were enrolled in the regression analysis procedure. The outcome of the initial regression analysis and the adjusted modeling were similar. For this reason, the result of adjusted modeling is mentioned in this study.

The study significantly revealed that respondents with no family history of NCDs had 2.57 times more (AOR/ $p=2.57/0.01$ ; 95% CI: 1.54-4.33) poor knowledge about the preventive diet of NCDs compared to the other group. In addition, the study also reflected that the odds of poor knowledge were 2.34 times higher (AOR/ $p=2.34/0.02$ ; 95% CI: 1.18-4.63) among the 3rd year group of the respondents compared to another groups.

**Discussion**

This study aimed to determine the preventive dietary knowledge on NCDs among the undergrad female students of Dhaka city. It was revealed

that more than three-fourths of female university students (77%) have poor knowledge on preventive diets. Similarly, in the northeast part of Bangladesh, 61% of university students have no adequate healthy dietary habits<sup>15</sup>. More participants (85.7%) did not know about the nutritional policies that cause NCDs. Respondent’s parents, especially mothers are not well educated (67.3% of mother’s education is under HSC, and most of them are housewives (80%). The lack of adequate planning, implementation, and monitoring could be attributed to the discouraging output observed<sup>16</sup>. Following selected nutritional guideline was found poor (65.7%) among the students. Research in China, shows that university students also do not abide by Chinese Dietary Guidelines as well<sup>17</sup>.

Highlighting the status of preventive dietary knowledge on NCD, it was found that the knowledge about the benefits of fruit and vegetable intake was severely low (83.45%). In another study of Bangladesh, for the age of 26 years that means post-graduate students, this percentage was nearly similar (89.7%)<sup>18</sup>. On the other hand, the Tanta University survey in Egypt found that as regards the consumption of fast food, chips, spicy food, and soft drinks, the highest proportion of the studied subjects reported that they took them once or less than 82 once / day<sup>19</sup>.

Knowledge on fatty food consumption was intensely poor (74.5%). The National Youth and Adolescent Survey in Iraq reported that 47% of

Iraqis consumed fast food, which was lower than our study's percentage<sup>20</sup>. 69.9% of female students were unaware of risk factors of passive smoking in this study. Low prevalence had also been observed in other studies conducted on female college students of different universities in Saudi Arabia<sup>21</sup>.

Comparatively, 4th year university students (6.5%) had a better understanding of preventive dietary knowledge than others. The study significantly found that the odds of poor knowledge were 2.34 times higher among the 3rd year respondents compared to another group. A robust outcome revealed in other intellectual outcomes focused on young adults who usually have poor knowledge on dietary choices to combat NCDs<sup>8-10</sup>. The study indicates that respondents without any family history of NCDs were likely to have limited knowledge about preventive diets for NCDs, serving as a significant predictor. As a unique outcome, this portion was not similarly portrayed in other studies where they mentioned the education and occupation of mothers triggered the nutrition of their child, which is significantly associated with the status of NCDs among them<sup>11, 12</sup>.

The study highlights a critical situation concerning dietary knowledge and practices for preventing NCDs. Research on preventive dietary knowledge in Bangladesh is currently insufficient and still in its early stages. Therefore, additional surveys are necessary to draw efficient conclusions in this issue. Despite several limitations, the study's outcomes provide robust support for policy makers in establishing effective intervention models. Besides, the findings of this study could aid in addressing knowledge gap, particularly among female population.

### Conclusions and Recommendations

This study disclosed several significant predictors of poor preventive dietary knowledge to combat NCDs. Among them, dietary policies to cause NCDs; benefits of fruit & vegetable intake in combating NCDs, and patterns of obesogenic food consumption found as significant predictors for poor preventive dietary knowledge to combat NCDs among female university students. It was also found that the highest level of poor knowledge is strongly

related to the respondents who did not have any family history of NCDs and also the 3<sup>rd</sup> year group. Knowledge regarding preventive strategies need to be improved from both the personal and the family level through several effective educational and behavioral interventions. Effectively utilizing the identified barriers will enhance existing policies for preventing NCDs and improving preventive dietary knowledge among Bangladeshis.

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## Prevalence of Gestational Auto-immune Thyroid Dysfunction and its Association with Anaemia in a Rural District of West Bengal

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### Abstract

**Background:** Maternal thyroid dysfunction is associated with risk of obstetric complications and also heralding the risk of abnormal fetal neuro-development. The prevalence and type of thyroid dysfunction in pregnancy varies widely according to ethnicity, demographic and geographical location. Thyroid dysfunction in pregnancy may be associated with autoimmune component too. Anaemia in pregnancy may aggravate with thyroid dysfunction in comparison to euthyroid pregnant subjects. Some epidemiological studies suggested that Iron deficiency anemia may be related to autoimmune thyroid dysfunction in pregnancy. This study aimed to estimate the prevalence of thyroid dysfunction in different trimesters of pregnancy, the association with anemia in pregnancy and whether autoimmunity plays a role in development of thyroid disorder.

**Methodology:** A cross-sectional study was conducted over a period of 1 year in the department of Biochemistry of Bankura Sammilani Medical College. Antenatal mothers attending the antenatal OPD in different trimester were selected depending on predefined inclusion and exclusion criteria. Blood samples were collected for estimation of serum TSH, Free T4, haemoglobin, haematocrit, RBC indices. Serum anti-TPO antibody was estimated only in patients with altered thyroid hormone concentration. Results of the study was compiled, tabulated and analysed using SPSS version 21.

**Results:** 326 pregnant mothers were included as study participants among which 164 were in first trimester and 162 were in second trimester. The prevalence of hypothyroidism among pregnant women was found to be 46.3 % whereas only 1.8% were hyperthyroid. 93.3% of the hypothyroid pregnant women had sub-clinical hypothyroidism and the remaining had overt hypothyroidism. 8 subjects out of the total 157 patients with deranged thyroid function were found to be anti-TPO positive. The prevalence of iron deficiency anaemia among hypothyroid mothers were 36.4% in comparison to 33.1 % in non-hypothyroid mothers.

**Conclusion:** Screening of thyroid function status in various stages of gestation is essential because of the high prevalence of hypothyroidism among pregnant women. Estimation of serum anti TPO antibody should be done

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in all thyroid dysfunctions. Thyroid disorders in pregnancy may be associated with increased severity of iron deficiency anaemia.

**Key words:** Thyroid disorders, anti TPO antibody, Iron deficiency anaemia, Gestation

## Introduction

Thyroid dysfunction, one of the most common variant of gestational endocrine disorder results from inappropriate adaptation of thyroid hormone to physiological changes of pregnancy. These variations in results from an interplay of factors like raised thyroglobulin concentration due to physiological hyper-estrogenemia and increased iodine loss due to increment in glomerular filtration rate, alteration of metabolism of maternal thyroid hormones and changes in placental iodine transport. Gestational thyroid hormone synthesis and iodine requirement increases 50% above the baseline non-pregnant level(1)

Thyroid disorders during first trimester have been associated with adverse obstetric and fetal outcome. The maternal complications are miscarriages, pregnancy induced hypertension, placental abruption, preterm labour. Thyroid dysfunction may also result in fetal complications like prematurity, intrauterine growth restriction, fetal demise and perinatal mortality. Children born to untreated mothers have profound effect on cognitive and neurological development.

Prevalence of thyroid disorders during pregnancy has a wide geographic, ethnic and environmental variation. Western literature shows a prevalence of hypothyroidism in pregnancy of 2.5% and hyperthyroidism in pregnancy has prevalence of 0.1 to 0.4%. The prevalence of thyroid dysfunction in Indian pregnant women was found to be 4.8% to 11% according to other studies (2,3). Thyroid hormones increases the synthesis of erythropoietin and thereby stimulates erythropoiesis in the bone-marrow(4). Autoimmune thyroid dysfunctions is a leading pathology of thyroid dysfunction in pregnancy. Autoimmune thyroid disease (AITD) may also cause anaemia due to pernicious anaemia, autoimmune haemolytic syndrome or rheumatic disorders. Deranged iron metabolism, and oxidative stress may causes anaemia in thyrotoxicosis.(5) Moreover, iron-deficient states itself reduces thyroid hormone production as iron is crucial for the catalytic property

of thyroid peroxidase. (6). So, presence of thyroid dysfunction may aggravate the chances of anaemia in pregnancy, an iron-starved metabolic phase and a vicious cycle may initiate. In this instance the study is designed to estimate prevalence of thyroid disorders among pregnant women of different trimesters in the Bankura district of West Bengal and to find out the association of anaemia with thyroid dysfunction in pregnancy .

## Materials and Method

This cross-sectional observational study was conducted in the Department of Biochemistry of Bankura Sammilani Medical College and Hospital after getting institutional ethical clearance (Vidememo no:BSMC/IEC/2488 dated 26/07/2022). The report of this study is prepared using The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (7). The study participants were apparently healthy pregnant women with uncomplicated singleton pregnancy irrespective of parity attending antenatal OPD. Pregnant Women with multiple pregnancies, previous history of thyroid disorder, hypertension, gestational diabetes, urinary tract infection, renal disease, cardiac, pulmonary disorders, autoimmune disease, repeated miscarriage or any history of obstetric or medical complications and having antithyroid medications were excluded from the study. Considering the prevalence of thyroid disorder in pregnancy 11% and 10% dropout rate respectively, the calculated sample size for each trimester was 165 pregnant patient in each trimester (8). The pregnant women who fulfilled the predefined inclusion and exclusion criteria and voluntarily agreed to participate in the study were included as study subjects after receiving duly written consent. Venous blood was collected using standard aseptic guideline in appropriate vials. Serum TSH, free T4 was estimated by CLIA (Chemiluminescence immunoassay technique) using Centaur CP analyser. Serum anti-TPO (Thyroid peroxidase) antibodies was estimated using ELISA (Enzyme Linked Immunosorbent assay). The trimester specific reference interval of thyroid hormones

as per European thyroid association was used as Cut-off. (9) Anti-TPO was estimated in Patients with altered thyroid hormones. The anti-TPO antibody titre >40IU/ml will be taken as positive for thyroid autoimmunity (10) Hematological parameters like Red blood cell (RBC) count, hematocrit (HCT), hemoglobin (Hb), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular concentration (MCHC) were estimated from EDTA blood using 5 part cell counter of Sysmex.

**Statistical Analysis:** Data has been collected, compiled and tabulated in Microsoft excel. Data analysis was done using proper descriptive and inferential statistics by SPSS version 21. Prevalence of thyroid dysfunction in different trimesters has been calculated. Association of thyroid dysfunction with anti-TPO positivity and Hematological parameters has been done and considered statistically significant if  $P < 0.05$ .

## Results

In this study, about 326 pregnant mothers were included as study participants according to predefined inclusion and exclusion criteria. Among the 326 pregnant mothers, 164 were in first trimester and 162 were in second trimester. The Cut-off for the hypothyroidism was used as TSH concentration > 2.50  $\mu$ U/ml and > 3.00  $\mu$ U/ml in second trimester

was used as per The European Thyroid Association 2014 guidelines. With this criteria, there were 84 and 67 hypothyroid cases among the enrolled 164 and 162 pregnant mothers of first and second trimester respectively. However, the number of hyperthyroid cases were very low in this study, like 4 and 2 cases in first and second trimester respectively as evident from Table 1. The hypothyroid cases were categorised as Overt hypothyroidism (TSH > 10  $\mu$ U/ml) and Sub-Clinical Hypothyroidism respectively as shown in Table 2. The total prevalence of overt hypothyroidism is almost 3%. The haematological parameters of the study population according to trimester has been illustrated in Table-3. The anti-TPO antibody screening was done for all the pregnant mothers having thyroid dysfunction and it was found that 8 subjects out of the total 157 patients with deranged thyroid function were anti-TPO positive. This is shown in Figure-1. A Chi-Square test was done to estimate whether there was a significant difference among the IDA prevalence among the pregnant mothers. The cut-off for Hemoglobin was taken as 11 g/dl and 10.5 g/dl. [11] There was no statistically significant difference in the propensity to IDA among the hypothyroid mothers (as shown in Table-4). But, the prevalence of IDA among hypothyroid mothers were 36.4% in Comparison to 33.1 % in non-hypothyroid mothers.

**Table 1: Table showing trimester Specific distribution of cases in Pregnant Mothers. (Figure in parenthesis indicate Percentage).**

Sl.no	Trimester	No. of Pregnant mothers	Hypothyroidism	Hyperthyroidism
1.	1 <sup>st</sup> Trimester	164	84 (51.2%)	4 (2.4%)
2.	2 <sup>nd</sup> Trimester	162	67 (41.3%)	2 (1.2%)
3.	Total	326	151 (46.3%)	6 (1.8%)

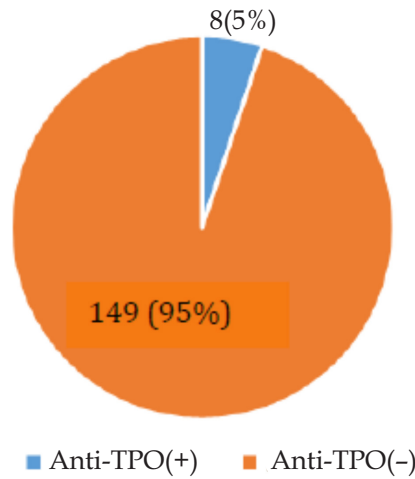
**Table 2: Table showing distribution of Hypothyroidism as overt and Sub-clinical hypothyroidism.**

Sl.no	Trimester	Overt Hypothyroidism Cases	Sub-Clinical Hypothyroidism Case
1.	1 <sup>st</sup> Trimester (n=84)	5	79
2.	2 <sup>nd</sup> Trimester (n=67)	5	62
3.	Total (n=151)	10	141

**Table 3: Table showing distribution of Hematological parameters as Mean± SD.**

Sl	Trimester	Hemoglobin (g/dl)	RBC (cell/cmm)	PCV/HCT (%)	MCV (fl)	MCH (pg)	MCHC (g/dl)
1.	1 <sup>st</sup> Trimester (n=164)	11.4±1.22	4.19±0.5	35.78±3.33	85.3±6.9	27.5±2.7	32.1±1.2
2.	2 <sup>nd</sup> Trimester (n=162)	11.16±1.1	4.11±0.43	35.2±3.18	86.4±7.5	27.2±2.77	31.3±1.0

Pie-Diagram showing distribution of Cases on Anti-TPO antibody Positivity



**Figure-1: Showing Distribution of Thyroid Dysfunction cases (n=157) on the basis of Anti-TPO positivity**

**Table: 4 Table Showing distribution of IDA cases among the pregnant mothers with or without hypothyroidism**

Sl.no	Thyroid Status	Developed IDA	Did not Develop IDA	P-value
1.	Hypothyroid	55	96	P=0.53 <sup>#</sup>
2.	Non-Hypothyroid	58	117	

<sup>#</sup> [p>0.05 is statistically insignificant]

**Discussion**

The prevalence of hypothyroidism among pregnant women in the present study was 46.3 % whereas only 1.8% were hyperthyroid. As compared to a cross-sectional multicenter study in India done by Dhanwal et al (12), the results of our study showed a higher prevalence of hypothyroidism among pregnant women. Various prevalence were found in studies done in various parts of India indicating inter-assay, dietary and geographical differences.(13,14)

Further when we categorised the hypothyroid cases, about 93.3% of the hypothyroid pregnant women had sub-clinical hypothyroidism and the remaining had overt hypothyroidism. Both overt

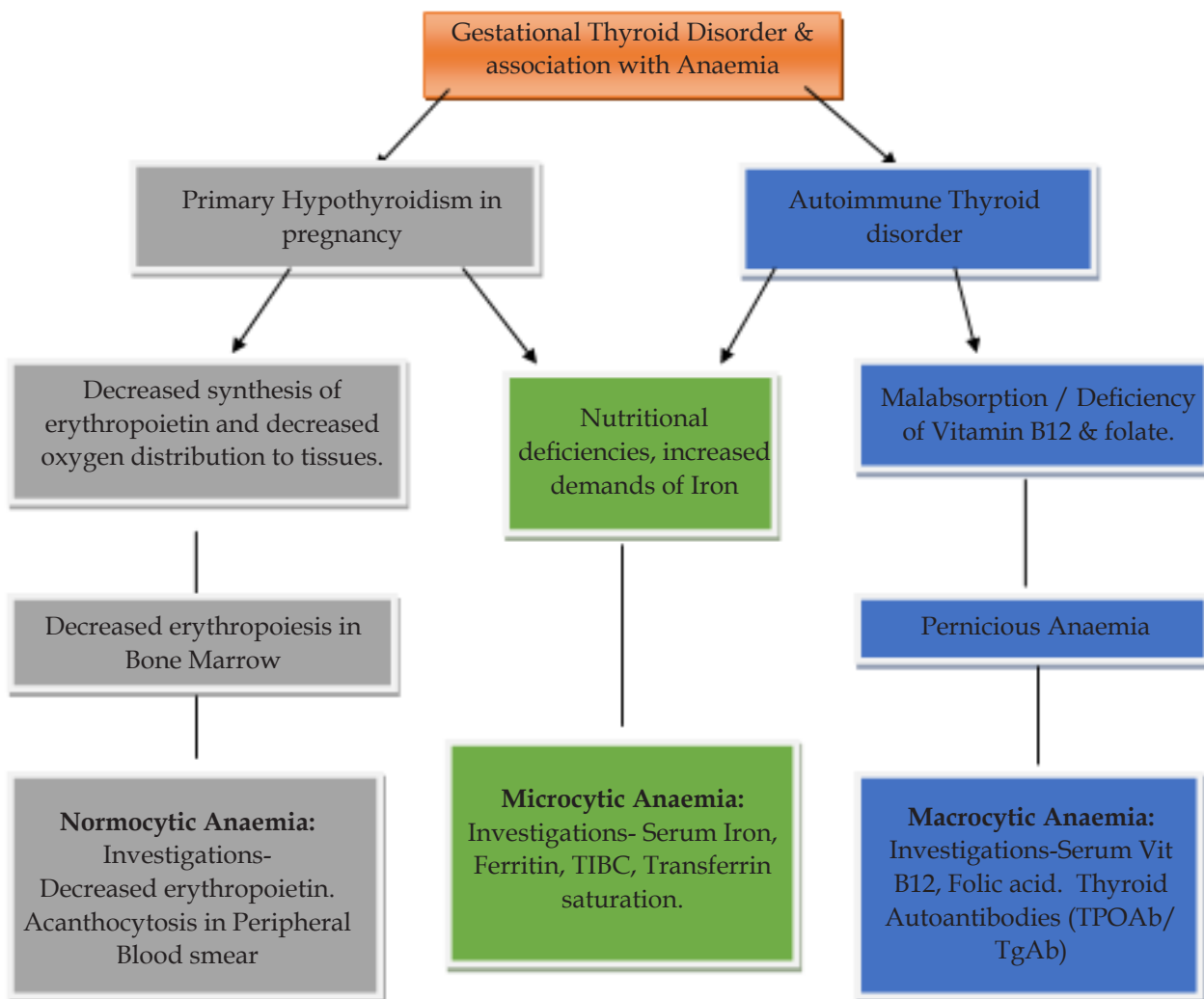
and subclinical hypothyroidism have unfavourable outcomes in pregnancy and development of foetus. (15) While guidelines of diagnosis and treatment of overt hypothyroidism is well established, the diagnosis and treatment for subclinical hypothyroidism remains controversial as TSH and fT4 level estimations exhibit inter-assay differences and can be influenced by ethnicity, maternal age, weight and smoking habits. (16)

The anti-TPO antibody screening was done for all the pregnant mothers having thyroid dysfunction and it was found that 8 subjects out of the total 157 patients with deranged thyroid function were anti-TPO positive. Many studies have been done to reveal relation of thyroid autoimmunity with dietary iodine uptake.(17) It has been postulated that more

than adequate iodine uptake may lead to higher prevalence of thyroid autoimmunity(18)

In our study, prevalence of IDA among hypothyroid mothers were 36.4% in comparison to 33.1 % in non-hypothyroid mothers. Apart from nutritional deficiencies, normocytic anaemia

may develop in hypothyroid states due to lack of erythropoiesis. Normochromic anaemia has been found to be the most common anaemia in hypothyroidism.(19) Anemia in hypothyroidism can be normochromic normocytic, hypochromic microcytic, and macrocytic.(14)



**Figure 2: Shows the pathophysiology and different anaemia associated with gestational thyroid disorders.**

A study done by Singh et al, concluded that the prevalence of anemia in hypothyroid pregnant patients was 69.95%, highlighting need for appropriate strategies to prevent and treat anaemia. In their study, dimorphic anaemia was most common among hypothyroid pregnant women.(20) Autoimmune thyroid disorders during pregnancy have been associated with various maternal as well as fetal complications.(21) In a meta-analysis done in 2020, indicated that TPOAb-

positive pregnant women have increased risk of anemia.(22) Association have been found between autoimmune thyroid disorders and pernicious anaemia.(4) Pregnancy is a physiological state with increased metabolic demands. Most of Indian women already carry the burden of nutritional deficiencies most importantly Iron deficiency. The demand of iron, folic acid, vitamin B12, iodine further increases during pregnancy. Thyroid dysfunction being the most common gestational endocrinal disorder may

affect the severity of anaemia. Autoimmune thyroid dysfunctions is an important pathology of thyroid dysfunction in pregnancy

### Conclusion

In present study, the high prevalence of hypothyroidism among pregnant women highlights the importance of screening thyroid disorders in gestation in various stages. Screening of thyroid auto-antibodies should be done in all thyroid dysfunctions. Since thyroid disorders can increase the severity of anaemia in pregnancy, early detection and correction of anaemia should be done. Guidelines to treat anaemia in both hypothyroid and euthyroid states should be followed.

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**Ethical Clearance/Statement of Ethics:** Institutional ethical clearance from Bankura Sammilani Medical College (Vide memo no:BSMC/IEC/2488 dated 26/07/2022)

**Conflict of interest:** There is no conflict of interest.

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# An Epidemiological Study on Knowledge, Attitude and Practices of Breast-Feeding and Newborn Care among Mothers in Pali District of Western Rajasthan, 2024

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## Abstract

**Introduction:** Breastfeeding is one of the most important determinants of child survival, birth spacing, and prevention of childhood infections. As per NFHS- 5, in Rajasthan, the current Infant mortality Rate (IMR) and Neonatal Mortality Rate (NMR) are at 35.2 and 24.9 per 1000 live births respectively. Safe delivery, early breastfeeding, newborn care within first few days and correct weaning practices are very crucial for the health of mothers and their baby. The study findings aim to orient the breastfeeding promotional activities and channelize efforts where gaps still exist in correct breast-feeding and newborn care practices.

**Objectives:** 1. To study knowledge and attitude about breastfeeding and newborn care in rural areas of Pali district of Western Rajasthan.

2. To study factors affecting breastfeeding and newborn care practices including weaning patterns in the selected rural area.

**Methods:** An analytical cross sectional study among mothers of less than one year old infants was conducted using a pretested questionnaire in villages of catchment area of RHTC of GMC Pali using convenient sampling until the sample size of 384 was reached.

**Results:** Colostrum was fed by 80% of the mothers interviewed. Exclusive breastfeeding was just 12% in our study. There was statistically significance between parity, and type of delivery with the good practices. Among participants 77% had good knowledge but only 47% followed correct practices.

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**Conclusion:** Pre lacteal feeds, non-exclusive breast feeding, unhealthy weaning foods were points of concern. Existing gaps between knowledge and action can be filled by repeated emphasis on desired good practices.

**Key words:** Breast feeding, newborn , care, Western Rajasthan, prelacteals

## Introduction

Breastfeeding is one of the most important determinants of child survival, birth spacing, and prevention of childhood infection<sup>1</sup>. In India and in Rajasthan undernutrition and IMR are still high and need to be reduced to targets set as per Sustainable Development Goals (SDGs). In India, the infant mortality has declined during the last decade. As per NFHS 5 the IMR and NMR were 32 and 22 per 1000 live births respectively. In Rajasthan itself, the current IMR and NMR are at 35.2 and 24.9 per 1000 live births respectively<sup>2</sup>. Breastfeeding cultural practices in India, mainly revolve around the concept of ritual purity and 'hot and cold' foods, restricted diet after childbirth and remaining in seclusion because of misconceptions related to childbirth<sup>3</sup>.

Health of a mother and her newborn child depend on care she received during pregnancy and the first few weeks after delivery. Existing practices for breastfeeding, weaning, immunization, prevailing beliefs, practices and sociodemographic factors influence the infants growth and development<sup>3</sup>.

In India, breastfeeding after birth was considerably delayed and in most cases, the valuable colostrum was discarded<sup>4</sup>. Nevertheless, with the consistent improvement in Health education under the National Rural Health Mission and efforts of local ASHAs and Anganwadis these practices have improved. The study of local beliefs, socio-cultural factors helps in channelizing the breastfeeding promotional activities to fill the gaps in knowledge<sup>5,6</sup>.

In order to make the community based maternal and child health education interventions more effective there was a need to have a baseline study on the current practices associated with new born care, breast feeding, weaning, immunization practices among people living in the arid areas of Western Rajasthan

### Objectives

1. To study knowledge and attitude about breastfeeding and newborn care in rural areas.

2. To study factors affecting breastfeeding and newborn care practices including weaning patterns in the selected rural areas.

## Materials and Methods

**Study Setting:** Catchment villages of RHTC of GMC Pali

**Study Design:** Analytical cross sectional study

**Study Participants:** Mothers with children less than one year old.

**Sample Size Selection:** Considering the prevalence rate of adequate knowledge of breastfeeding to be 50% in Western Rajasthan rural areas (as no previous study was available), the sample size was determined using allowable error of 5% of prevalence after the substitution of values,  $n = 4pq/d^2$ ,  $p = 50$  (participants with Adequate knowledge),  $q = (100-p) = 50$ ,  $d =$  relative permissible error = 5% of  $p$ ,  $n =$  sample size, ( $n = 384$ ). Three hundred and eighty four mothers that had a live baby of an age below one year in villages in a radius of 20 km around the RHTC made the estimated sample size.

**Inclusion Criteria:** All the mothers who gave birth within the last one year to a live baby

Mothers willing to participate in the study.

**Exclusion Criteria:** Mothers who delivered and stayed outside of the study area.

Mothers who were seriously ill and hospitalized.

**Study Period - 3 months**

**Data Collection and analysis:**

A pretested questionnaire was used and consecutive mothers of villages under RHTC were interviewed. The questionnaire (adapted from the questionnaires by the Division of Nutrition, Physical Activity, and Obesity, National Center for Chronic Disease Prevention and Health Promotion of CDC, Atlanta, USA) included socio-economic and demographic data, initiation and duration of breastfeeding, prelacteal feeds, supplementary

and complementary feeding /weaning practices and newborn care practices (cord care, eye care, immunization, growth monitoring )<sup>7</sup>. Three trained field volunteers after taking informed consent obtained information using questionnaire in vernacular language (translated and back translated). Twelve points on safe delivery, colostrum, initiation and duration of breastfeeding, time of first bath of newborn, cord care, eye care, weaning time and weaning foods, cord care, immunization and growth monitoring were asked for both knowledge assessment and actual practices from the participants and a score of less than six was taken as ‘inadequate knowledge’ and more than six incorrect breastfeeding and newborn and infant care practices were taken as ‘poor practice’.

**Statistical Analysis:**

Data entered in Microsoft Excel was analyzed using Epi info Version 7.1. Qualitative variables were expressed by frequency and proportion and Quantitative variables were expressed using Mean and Standard deviation. Chi square and Fischer exact test were used to find the significant association between groups. A p- value less than 0.05 has been considered to be statistically significant.

**Ethical Considerations**

The study was approved by the Institutional Ethical committee approval of Government Medical College, Pali vide Letter No.EC/New/Inst/2022/0066/003 dated 5/2/2023.Written Informed Consent was obtained after explaining the objectives of the study and the participants were assured about confidentiality of data.

**Observations and Results**

In our study, 384 participants were enrolled for the study.

**Table 1: Frequency Distribution of study participants demographic characteristics (n=384)**

Variables	Frequency (%)
<b>Age (in years)</b>	
≤20	11 (03)
21-25	184 (48)
26-30	173 (45)

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>30	16 (04)
<b>Age at marriage (in years)</b>	
≤20	64 (17)
21-25	208 (54)
26-30	97 (25)
>30	15 (04)
<b>Education</b>	
Illiterate	58 (15)
Primary	85 (22)
Secondary	65 (17)
High school	58 (15)
Higher secondary	54 (14)
Graduate and above	64 (17)
<b>Socio- Economic status</b>	
Upper (I)	34 (09)
Upper Middle (II)	73 (19)
Middle (III)	106 (28)
Lower Middle (IV)	112 (29)
Lower (V)	59 (15)
<b>Parity</b>	
1	114 (30)
2	158 (41)
>2	112 (29)
<b>Place of Delivery</b>	
Government hospital	289 (75)
Private hospital	87 (23)
Home	08 (02)
<b>Type of Delivery</b>	
Spontaneous Vaginal Deliveries (SVD)	295 (77)
Caesarean	89 (23)

Table 1, shows the frequency distribution of study participants baseline characteristics. The maximum of 184 (48%) of participants are aged between 21-25 years. Most participants 208 (54%) were married between the ages of 21-25 years. Majority 85 (22%) of participants have primary education. Most participants fall into the middle 106 (28%) and lower middle 112 (29%) socio-economic classes. The maximum 158 (41%) of participants have two children and most deliveries were carried out in government hospitals 289 (75%).

**Table 2: Frequency Distribution of study participants practices on Breast feeding, weaning and new born care (n=384)**

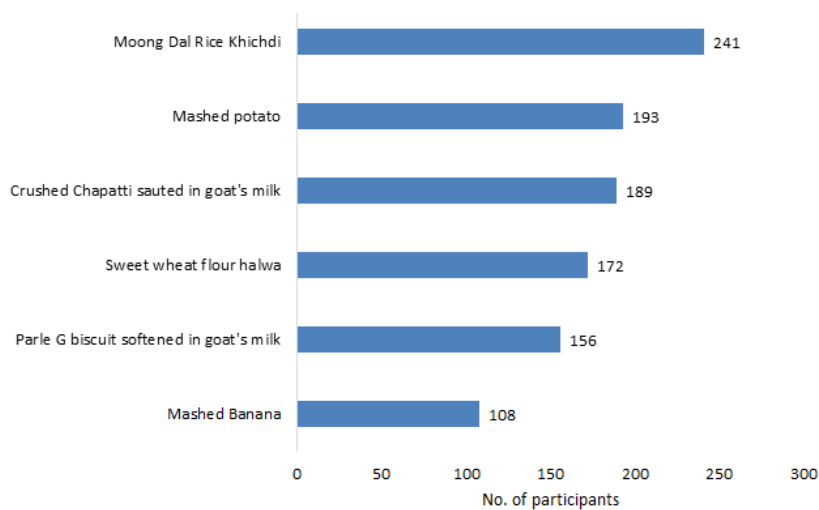
Variables	Frequency (%)
<b>Cord Practices</b>	
Knife	89 (23)
Scissors	269 (70)
Surgical Blade	26 (07)
<b>Cord Dressing</b>	
Spirit Swab	06 (02)
Talcum Powder	11 (03)
Cow Dung	08 (02)
Turmeric	16 (04)
None	343 (89)
<b>Time of initiation of BF</b>	
Within 1 hr	215 (56)
Within 4 hrs	89 (23)
Within 8 hrs	36 (09)
More than 8 hrs	44 (11)
<b>Breast Feeding Practices#</b>	
Colostrum Given	308 (80)
Prelacteal feed given	300 (86)
Exclusive breast feeding	46 (12)

Continue.....

<b>Usage of Kajal</b>	
Yes	250 (65)
No	134 (35)
<b>Bathing</b>	
Early Bathing	236 (61)
Delayed Bathing	148 (39)
<b>Immunization as per age</b>	
Yes	372(97)
No	12(3)
<b>Growth Monitoring records in Mamta card (for recording immunization, weight &amp; height of infants in Rajasthan)</b>	
Yes	315(82)
No	69(18)

#Multiple response

Table 2, shows the frequency distribution of study participants practice on Breast feeding, weaning and newborn care. Majority of participants 343 (89%) did not apply anything on the umbilical cord. About 215 (56%) of participants initiated breastfeeding within one hour of delivery. About 80% of participants gave colostrum, while only 12% practiced exclusive breastfeeding.

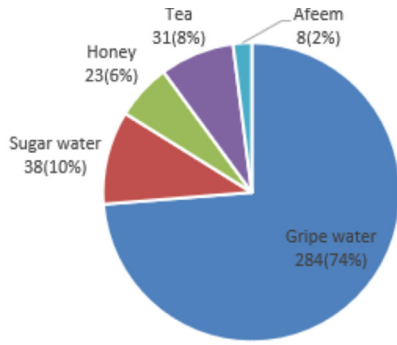


#Multiple response

**Figure 1: Frequency distribution of complementary weaning foods among study participants**

Figure 1, shows maximum combination of complementary foods given to babies were Moong Dal Rice khichdi followed by mashed potatoes.

Further age of weaning initiation was 3-5 months and mothers had knowledge of prolonged breastfeeding upto 24-27 months.



**Figure 2: Frequency distribution of study participants pre lacteal/inaugural feeding**

Figure 2, shows asprelacteal/inaugural feeds, three fourth of the participants gave gripe water (janam ghutti) followed by sugar water 10% respectively.

**Table 3: Frequency distribution of study participants with adequate knowledge and following correct practices of Breast feeding and newborn care (n=384)**

Knowledge	Frequency (%)
Adequate knowledge	296 (77)
Inadequate knowledge	88 (23)
<b>Practices</b>	
Good Practice	180 (47)
Poor Practice	204 (53)

Table 3, shows 77% of the study participants had adequate knowledge and 47% followed correct practices on breast-feeding and new born care respectively.

**Table 4: Association of study participants knowledge with demographic variables (n=384)**

Variables	Adequate knowledge (%)	Inadequate knowledge (%)	p- value
<b>Age (in years)</b>			
≤20	08 (73)	03 (27)	0.35
21-25	145 (79)	39 (21)	
26-30	126 (73)	47 (27)	
>30	10 (63)	06 (37)	
<b>Age at marriage (in years)</b>			
≤20	45 (70)	19 (30)	0.01*
21-25	170 (82)	38 (18)	
26-30	65 (67)	32 (33)	
>30	09 (60)	06 (40)	
<b>Education</b>			
Illiterate	45 (78)	13 (22)	<0.01*
Primary	49 (58)	36 (42)	
Secondary	45 (69)	20 (31)	
High school	48 (83)	10 (17)	
Higher secondary	49 (91)	05 (09)	
Graduate and above	53 (83)	11 (17)	
<b>Socio- Economic status</b>			
Upper (I)	28 (82)	06 (18)	0.03*
Upper Middle (II)	63 (86)	10 (14)	
Middle (III)	74 (70)	32 (30)	
Lower Middle (IV)	85 (76)	27 (24)	
Lower (V)	39 (66)	20 (34)	
<b>Parity</b>			
1	104 (91)	10 (09)	<0.01*
2	89 (56)	69 (44)	
>2	96 (86)	16 (14)	

Place of Delivery			
Government hospital	229 (79)	60 (21)	<0.01*
Private hospital	54 (62)	33 (38)	
Home	06 (75)	02 (25)	
Type of Delivery			
SVD	224 (76)	71 (24)	0.57
Caesarean	65 (73)	24 (27)	

\*p<0.05, statistically significant

Table 4: There was a significant association between age at marriage, education and knowledge; those who married younger had more inadequate knowledge. There was a strong association between education level and knowledge (p<0.01), with higher education correlating with better knowledge. A significant association was found (p<0.01) among those with one child and adequate knowledge.

**Table 5: Association of study participants Practice on new born care with demographic variables (n=384)**

Variables	Good Practice (%)	Poor Practice (%)	P-value
<b>Age (in years)</b>			
≤20	04 (36)	07 (64)	0.90
21-25	86 (47)	98 (53)	
26-30	82 (47)	91 (53)	
>30	08 (50)	08 (50)	
<b>Age at marriage (in years)</b>			
≤20	17 (27)	47 (73)	<0.01*
21-25	96 (46)	112 (54)	
26-30	58 (60)	39 (40)	
>30	09 (60)	06 (40)	
<b>Education</b>			
Illiterate	14 (24)	44 (76)	<0.01*
Primary	22 (26)	63 (74)	
Secondary	30 (46)	35 (54)	
High school	35 (60)	23 (40)	
Higher secondary	39 (72)	15 (28)	
Graduate and above	40 (63)	24 (37)	

Socio- Economic status			
Upper (I)	14 (41)	20 (59)	<0.01*
Upper Middle (II)	50 (68)	23 (32)	
Middle (III)	36 (34)	70 (66)	
Lower Middle (IV)	50 (45)	62 (55)	
Lower (V)	30 (51)	29 (49)	
Parity			
1	36 (32)	78 (68)	<0.01*
2	78 (49)	80 (51)	
>2	66 (59)	46 (41)	
Place of Delivery			
Government hospital	132 (46)	157 (54)	0.52
Private hospital	45 (52)	42 (48)	
Home	03 (38)	05 (63)	
Type of Delivery			
SVD	128 (43)	167 (57)	0.01*
Caesarean	52 (58)	37 (42)	

Table 5, shows that the distribution of good and poor practices is relatively consistent across all age groups. There was a statistically significant association between age at marriage and practices with p<0.05. Higher levels of education are associated with better practices, with p-value < 0.01. Participants from the Upper Middle (II) of socio-economic status group exhibit the highest percentage of good practices (68%). There was statistical significance between parity, and type of delivery with the good practices with (p-value<0.05) respectively.

## Discussion

In our study majority of the mothers were between 21-25 years (48%) and age at marriage for most was 21-25 years (54%). About 15% of mothers were illiterate and majority of the mothers were para 2(41%) or primigravidae(30%). Our findings

are somewhat similar to the study by MB Singh et al done in Western Rajasthan<sup>4</sup>.

Our study showed that 56% of the mothers initiated breastfeeding within one hour, 19% used pre lacteal feeds. As per the study done in by Haladiya et al (1997), the 77% of rural women in Western Rajasthan discarded colostrum<sup>3</sup>. In our study, 80% mothers fed colostrum and 86% gave prelacteal feed of gripe water /janam ghutti. Other studies have also found similar practices in the community<sup>8,9,10</sup>. A study by K Madhu et al (2009) revealed that most of the mothers initiated breastfeeding (97%) within first two hours<sup>10</sup>.

Exclusive Breastfeeding was just 12% in our study. In arid regions with frequent droughts and extremes of temperature, family members give water to the infant fearing dehydration. In studies done in Ethiopia, Uganda exclusive breastfeeding was found to be also very low and comparable to our study<sup>11,12,13</sup>.

In our study, most mothers had initiated early breastfeeding and continued to breastfeed upto two years. Other studies conducted in rural areas show that almost all the mothers initiate breastfeeding and continue till beyond two years like in Puducherry by Vijay Lakshmi et al (2014) and in Chandigarh slums by Puri et al (2008)<sup>14,15</sup>.

Weaning foods mainly consisted of moog dal khichdi, goat's milk with wheat rotis or biscuits. No tinned powder milk formulas or tetra packs were used. These findings are similar to the study by MB Singh et al<sup>16</sup> in the Thar desert where similar weaning foods were seen. Even in studies done by Arifeen et al and Dewey et al in countries like Bangladesh and Honduras respectively the use of powder milk and tetra packs was seldom seen due to poor economic conditions and ban on these products<sup>17,18</sup>.

The mean age at food supplementation initiation was 3-5 months. Mean age for prolonged breast feeding was 27.1 months which was comparable to the study in Uttar Pradesh and Northern India done by Islam et al and Baqui et al respectively<sup>19,20</sup>.

K Madhu et al (2009) found 90% of the deliveries were hospital deliveries and 10% were home deliveries. An untrained birth attendant (40%) mainly gave the care provided during the home deliveries.

In both in-hospital and home deliveries, nothing was applied for umbilical cord dressing (67%). Talcum powder (10%) and turmeric was used by some mothers for cord dressing<sup>10</sup>. In our study, 98% of the deliveries were hospital deliveries and only 2% were home deliveries. The care provided during the home deliveries was mainly given by trained dais (100%). In both hospital and home deliveries, nothing was applied for umbilical cord dressing (89%).

It was found that most of the newborns, 61%, were bathed within one hour after birth with luke warm water, which is lower than that reported by Manju Rahi et al.[6] which noted that a large percentage, 82.6%, of home delivered babies were bathed immediately after birth. The early bathing of newborns significantly increases risk of hypothermia as stated by Semanew Y et al, Deshpande et al in Meghalat area of Maharashtra and by Abbad et al in Madhya Pradesh irrespective of the ambient temperature<sup>11,21,22</sup>. Other positive findings of our study were the high rates of immunization (97%) and growth monitoring (82%) were seen which are figures similar to the observations made by Yonzen et al in 6 districts of Rajasthan<sup>23</sup>.

**Limitations:** This study is limited to one district only with a minimum study sample and needs prospective and qualitative studies to better understand the underlying causes behind incorrect practices.

## Conclusions

Among the participants 77% mothers had good knowledge but only 47% had all correct practices of breastfeeding and newborn care. Community based health education intervention programmes involving ASHAS, AWWs, Local NGOs should aim at correcting the local incorrect practices like feeding pre lacteals, premature weaning, early bathing, applying kajal and prolonged breastfeeding.

The existing gap between knowledge and action can be filled by repeated emphasis on correct practices, which would help in achieving the desired proportion of ideal newborn care.

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# Understanding Drowning Fatalities in Odisha, India: A Data-Driven Approach

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## Abstract

**Background:** Death, morbidity, or mortality are the three possible consequences of drowning, which is defined as the process of experiencing respiratory impairment from submersion or immersion in liquid. Drowning is the third most common unintentional injury-related death cause worldwide, accounting for around 320,000 deaths annually, or 7% of all injury-related deaths. Children 1-4 years old have the highest rate of drowning, followed by those 5-9 years old. Males are particularly at risk, with a drowning mortality rate twice that of females.

**Methods:** Case information was extracted from secondary data collected from the Revenue & Disaster Management Department for the period from January 1, 2016, to December 30, 2022, in Odisha, with projections extended to 2044. Statistical analyses were conducted using SPSS between 2016 and 2023.

**Conclusion:** There were 7,721 identified drowning deaths in Odisha. Death rates due to drowning have risen each year. The number of deaths in 2017-18 nearly doubled compared to the previous year and then slowed until 2020-21, with an average annual increase of 172 deaths. In 2021-22, the number decreased to 1,209, before jumping to 1,738 in 2022-23. The findings highlight the urgent need for comprehensive public health interventions to address this critical issue. The results suggest a need for effective drowning prevention strategies.

**Key words:** Drowning, Burden of disease, Mortality, Disability adjusted life year

## Introduction

Millions of lives are lost to drowning every year, making it a major global public health concern.

Approximately 500,000 drowning deaths are reported each year, though actual numbers may be higher due to underreporting of many cases

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(1). In India, drowning accounts for a considerable proportion of unintentional injury and deaths, particularly in states with extensive river systems and coastal areas (2). However, drowning may be made intentionally and might be a case of suicide. According to WHO estimates, there were 449,000 drowning deaths globally in 2000 (7.4 per 100,000 persons), with low- and middle-income countries accounting for 97.0 percent of these deaths (3). 3,442,895 disability-adjusted life years (DALYs) were lost in India in 2016 as a result of both fatal and non-fatal drowning, according to data from the Global Burden of Disease (GBD) research. This represents 0.7% of the DALYs lost that year from all causes (4). According to a nationally representative study, the ratio of male drowning deaths to female drowning deaths was 2:1(5). A further study using the same data set discovered that males drowned at a rate of 97/100,000 compared to 69/100,000 for girls between the ages of 0 and 5 years(6). Retrospective assessments of medical records revealed that men accounted for 85% and 78% of drowning deaths (7)(8). According to data from the national police, men were involved in 77% of fatal drowning occurrences.

Global drowning mortality is estimated to have declined by 44.5% between 1990 (531,956 deaths) and 2020 (295,210 deaths) (9), though the precision of health surveillance in capturing drowning mortality and morbidity is debated (10)(11). Studies using verbal autopsy in Bangladesh and India have highlighted a previously hidden burden among children in low- and middle-income countries, prompting increased interest from governments, multilateral organizations such as the World Health Organization (WHO) and United Nations Children's Fund (UNICEF), non-governmental organizations, and donors (12)(13). Significant advances include the development of a new drowning definition in 2005 (Van et al. 2005), followed by increased interest in the drowning burden in low- and middle-income countries, particularly in Asia, as evidenced in the WHO World Report on Child Injury Prevention (14).

By employing rigorous statistical techniques, including analysis of variance (ANOVA) and regression analyses, this research aims to identify significant trends and patterns in drowning fatalities. Furthermore, this study forecasts drowning deaths

for the years 2023 to 2044 using a third-degree time-series model, providing crucial insights for policymakers and public health officials. Previous studies have highlighted the importance of temporal analysis in understanding drowning trends and implementing effective prevention strategies. For instance, Rahman et al. (2009) emphasized the need for region-specific drowning prevention measures based on local epidemiological data (15). Similarly, a study by Franklin et al. (2010) demonstrated the effectiveness of predictive models in informing targeted interventions for drowning prevention (16). In Odisha, various factors contribute to the high incidence of drowning, including geographical features, socio-economic conditions, and seasonal variations. The state's extensive network of rivers and proximity to the sea increase the risk of drowning, particularly during the monsoon season when water levels rise significantly (17). Additionally, socio-economic factors such as limited access to swimming lessons and life-saving equipment further exacerbate the risk. This study employs a comprehensive statistical approach to analyze drowning data, incorporating both descriptive and inferential statistics. The analysis of variance (ANOVA) is used to determine the significance of trends in drowning cases across different years, while regression analyses provide insights into the relationship between time and drowning incidents. The goodness of fit of these models is evaluated to ensure the reliability of the predictions.

The findings of this research have important implications for public health planning and policy formulation in Odisha. By identifying high-risk districts and time periods, targeted interventions can be designed to reduce drowning fatalities. Furthermore, the predictive models developed in this study can aid in resource allocation and emergency preparedness, ultimately contributing to the prevention of drowning deaths in the state. By providing a detailed statistical analysis of drowning cases and projecting future trends, this study aims to contribute to the understanding and prevention of drowning fatalities in Odisha.

## Material and Method

This study adopts a comprehensive statistical approach to analyze and forecast drowning fatalities

in Odisha, India, from 2016 to 2022-23, with predictions extending to 2044. The methodology is divided into several key stages:

### Data Collection

Data on drowning deaths were collected for all 30 districts of Odisha for the period 2016-2022 from various official sources, including the National Crime Records Bureau (NCRB) and state government reports<sup>20</sup>. The data were compiled into a comprehensive dataset for further analysis.

### Descriptive Analysis

Initial descriptive statistics were calculated to understand the basic characteristics of the drowning data.

### Trend analysis and regression models

To understand the temporal trends in drowning fatalities, various regression models were fitted to the data:

1. **First-Degree (Linear) Regression:**  $y = \beta_0 + \beta_1x$
2. **Second-Degree (Quadratic) Regression:**  $y = \beta_0 + \beta_1x + \beta_2x^2$
3. **Third-Degree (Cubic) Regression:**  $y = \beta_0 + \beta_1x + \beta_2x^2 + \beta_3x^3$
4. **Fourth-Degree Regression:**  $y = \beta_0 + \beta_1x + \beta_2x^2 + \beta_3x^3 + \beta_4x^4$

The coefficients ( $\beta$  \beta) were estimated using the least squares method, and the goodness of fit for each model was evaluated using the coefficient of determination ( $R^2$ ). Analysis of Variance (ANOVA) was performed to test the significance of the trend lines at each degree of regression and increase of the degree of the equation. The F-test was used to compare the explained variance by the model to the unexplained variance, determining the statistical significance of each model. Critical values for the F-test were obtained from statistical tables to evaluate the significance levels. Based on the regression analysis, the third-degree cubic model was selected as the best fit due to its higher goodness of fit ( $R^2$ ) and statistical significance. This model was used to predict future drowning fatalities from 2023 to 2044. The prediction intervals were calculated to provide a range within which the actual future values are expected to fall. The statistical analyses were conducted using SPSS.

## Result and Discussion

The number of drowning deaths in Odisha is steadily increasing from 2016 onwards (Table 1 and Fig.1) with a total number of 7738 deaths till 2023 with an annual average of 1103. Attempt has been made to analyze the death numbers statistically and to predict the numbers likely to occur in future. The figure in 2017-18 almost doubled that of the preceding year and then slowed down till 2020-21 with an average increasing rate of 172 per year till 2020-21. In 2021-22 the figure decreased to 1209 and then jumped to 1738 in the year 2022-23. First- to fourth-degree time series lines were fitted to the data set. The equations with their goodness of fit ( $R^2$  in percent) are presented in Table 2. The increase of goodness of fit from first- to second-degree is nominal (1.33%), but increase from second- to third-degree is substantial (5.98%) followed by 1.64% increase in case of fourth-degree line. This suggests possible best fit of the third-degree line, for which analysis of variance was performed. The results are given in Table 3. In case of first-, second- and third-degree lines, the calculated values of F are greater than the corresponding critical values suggesting the statistical significance of these three lines. The increases of the degrees of lines, however, are not significant as the computed values are less than the critical values. The fourth-degree line, which has goodness of fit of 97.45% is also statistically insignificant. Thus, it is concluded that the third-degree time-series line ( $y = 399.1 + 584.1x - 160.4x^2 + 16.47x^3$  (Fig.2) is the most befitting line, in which y is the number of drowning death and x is the year number from 2016-17, which is the starting point of computation ( $x = 0$ ). Substituting the value of years, prediction has been made for drowning deaths till 2043-44 (Table 4). It is a matter of grave concern that drowning fatalities in Odisha are projected to exceed 200,000 by 2044 if no significant interventions are made. This alarming trend highlights the urgent need for comprehensive preventive measures, including public awareness, safety regulations, and targeted intervention strategies. Without immediate and effective action, the current trajectory could lead to a substantial rise in preventable deaths.

CAGR (Compound Annual Growth Rate) of drowning death is calculated from the data provided in the Table 4.

$$CAGR = \left[ \frac{EV}{BV} \right]^{\frac{1}{n}} - 1$$

Where EV (End Value) = the drowning death value in the final year (2043-44); BV (Beginning Value)= the drowning death value in the starting year (2023-24); n = number of years between the start and end year.

The drowning death rate in Odisha is projected to grow at a CAGR of 25.77% from 2023-24 to 2043-44, which represents a dramatic rise in fatalities over the next two decades. This exponential growth highlights a critical need for the local administration to be prepared for the upcoming surge in drowning-related emergencies. Given this trend, the current

infrastructure, including rescue services, healthcare systems, and public safety measures, may be insufficient to manage the expected load. Urgent steps are required to bolster community-based drowning prevention programs, improve emergency response readiness, and allocate resources effectively. Authorities should also consider investing in predictive analytics to anticipate high-risk periods and locations, and implement strategic interventions to mitigate the rising fatality rates.

**Table 1. Number of drowning death in Odisha from 2016 – 2023**

Year	Drowning death	Year	Drowning death
2016 – 17	418	2020 – 21	1337
2017 – 18	820	2021 – 22	1209
2018 – 19	999	2022 – 23	1738
2019 – 20	1200	Average	1103

**Table 2. Regression equations and goodness of fit of year verses drowning cases in Odisha**

Degree of equation	Trend line equation	Goodness of fit (%)
First	$y = 559.1 + 181.2x (\pm 256.003)^{\S}$	88.50
Second	$y = 497.9 + 254.7x - 12.23x^2 (\pm 240.778)^{\S}$	89.83
Third	$y = 399.1 + 584.1x - 160.4x^2 + 16.47x^3 (\pm 154.524)^{\S}$	95.81
Fourth	$y = 434.2 + 239.1x + 142.6x^2 - 65.39x^3 + 6.822x^4 (120.668)^{\S}$	97.45

<sup>§</sup>95% confidential intervals are given in brackets

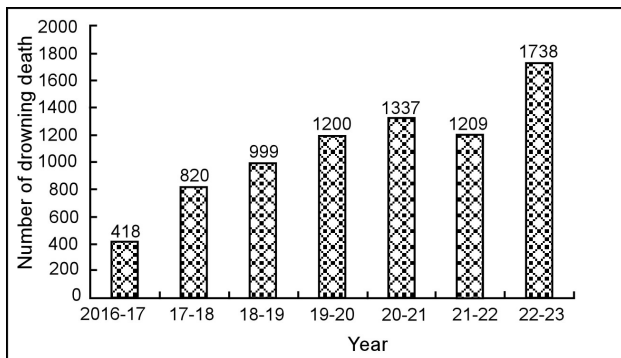
**Table 3. Completed analysis of variance (ANOVA) for significance of trend lines of drowning cases in Odisha**

Source of Variation	Sum of squares	Degrees of freedom	Mean Squares	F-test result
First-degree regression (CSS <sub>R1</sub> )	919336.320	1	919336.320	F <sub>1</sub> = 38.49*
First-degree deviation (CSS <sub>D1</sub> )	119419.680	5	23883.936	(F <sub>v1=1, v2=5, α=0.05</sub> = 6.61) <sup>†</sup>
Second-degree regression (CSS <sub>R2</sub> )	933118.511	2	466559.256	F <sub>2</sub> = 17.67*
Second-degree deviation (CSS <sub>D2</sub> )	105637.489	4	26409.372	(F <sub>v1=2, v2=4, α=0.05</sub> = 6.94) <sup>†</sup>
Added by second-degree (CSS <sub>R2-1</sub> )	13782.191	1	13782.191	F <sub>2-1</sub> = 0.52 (F <sub>v1=1, v2=4, α=0.05</sub> = 7.71) <sup>†</sup>
Third-degree regression (CSS <sub>R3</sub> )	995246.929	3	331748.976	F <sub>3</sub> = 22.87*
Third-degree deviation (CSS <sub>D3</sub> )	43509.071	3	14503.024	(F <sub>v1=3, v2=3, α=0.05</sub> = 9.28) <sup>†</sup>
Added by third-degree (CSS <sub>R3-2</sub> )	62128.418	1	62128.418	F <sub>3-2</sub> = 4.28 (F <sub>v1=1, v2=3, α=0.05</sub> = 10.13) <sup>†</sup>
Fourth-degree regression (CSS <sub>R3</sub> )	1012224.524	4	253056.131	F <sub>4</sub> = 19.08
Fourth-degree deviation (CSS <sub>D4</sub> )	26531.476	2	13265.738	(F <sub>v1=4, v2=2, α=0.05</sub> = 19.25) <sup>†</sup>
Added by fourth-degree (CSS <sub>R4-3</sub> )	16977.595	1	16977.595	F <sub>4-3</sub> = 1.28 (F <sub>v1=1, v2=2, α=0.05</sub> = 18.51) <sup>†</sup>
Total variation (CSS <sub>T</sub> )	1038756.000	6		

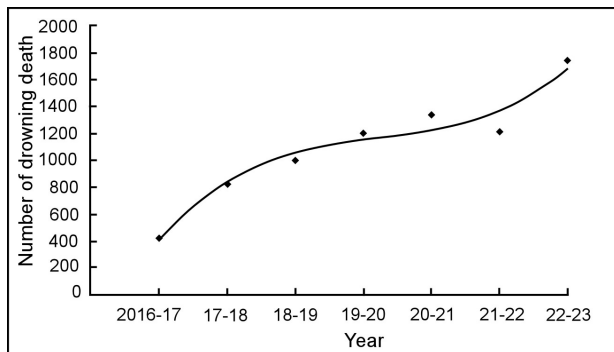
\*Significant F value, <sup>†</sup>Critical values of F are given within brackets

**Table 4. Prediction of drowning deaths on the basis of third-degree time-series line**

Year	Drowning death	Year	Drowning death	Year	Drowning death
2023-24	2277	2030-31	22332	37-38	94457
24-25	3239	31-32	28657	38-39	110988
25-26	4670	32-33	36143	39-40	129372
26-27	6670	33-34	44890	40-41	149708
27-28	9337	34-35	54996	41-42	172095
28-29	12771	35-36	66560	42-43	196632
29-30	17069	36-37	79681	43-44	223417



**Figure 1. Third-degree trend line fitted to drowning deaths in Odisha**



**Figure 2. Third-degree trend line fitted to drowning deaths in Odisha**

The analysis revealed that drowning deaths nearly doubled from 2016 to 2018, then slowed down till 2021 before a notable increase in 2022. These fluctuations could be attributed to several factors, including seasonal variations, socio-economic conditions, and possible changes in reporting accuracy. The marked increase in drowning deaths during 2022 could be related to extreme weather events or other environmental changes that warrant further investigation. The study shows a clear gender disparity in drowning fatalities, consistent with both national and international trends. In Australia, from

2002 to 2012, there were 303 drowning cases among boys and 165 among girls<sup>(9)</sup>. Similarly, in Mangalore, India from 1994 to 2005, there were 767 drowning cases among males and 217 among females<sup>(8)</sup>. This data highlights a male-to-female drowning mortality ratio of approximately 2:1<sup>(6)(8)</sup>. The higher mortality rate among males may be attributed to greater exposure to water-related activities and a propensity for risk-taking behaviors<sup>(6)(9)</sup>.

Both high- and low-income environments have different drowning risk variables. Participation in water-based recreational activities, like swimming, boating, and fishing, is linked to an increased risk of drowning among people in high-income countries (HICs)<sup>(16)</sup>. In contrast, in low-income countries (LMICs), children under five often drown in nearby natural bodies of water, despite not usually participating in recreational activities<sup>(17)</sup>. Risk factors for drowning in children in LMICs include lack of adult supervision, unsafe water access near homes, and limited swimming skills. Environmental factors such as open water bodies, floods, and inadequate barriers around water sources also increase the risk. No discernible gender variations in drowning rates were seen in the 5 to 9 age group, which is in contrast to other research conducted in LMIC rural situations<sup>(14)(18)</sup>. The high incidence of drowning in Odisha is influenced by a combination of geographical, socio-economic, and seasonal factors<sup>(15)</sup>. Additionally, retrospective reviews and police data corroborate the predominance of male victims, underscoring the need for gender-specific prevention strategies<sup>(6)(9)</sup>. The state’s extensive network of rivers, lakes, and proximity to the Bay of Bengal increases the risk of drowning, particularly during the monsoon season when water levels rise significantly<sup>(20)(21)(22)(23)(24)</sup>.

Socio-economic constraints, such as limited access to swimming lessons and life-saving equipment, further exacerbate the risk, especially for children and marginalized communities.

### Conclusion

This study provides a comprehensive analysis of drowning fatalities in Odisha, India, over the period 2016-2023, with predictions extending to 2044. The key findings and implications of this research are as follows:

The number of drowning deaths in Odisha has shown a steady increase from 2016 onwards, with significant variations across different years. The application of various regression models revealed that the third-degree cubic model provides the best fit for the data, with a high coefficient of determination (95.81%). ANOVA results indicate that the first-, second-, and third-degree models are statistically significant, while the fourth-degree model, despite its higher goodness of fit ( $R^2$ ), is not statistically significant. Predictions based on the third-degree model suggest a concerning upward trend in drowning fatalities, with the number of deaths likely to exceed 2,00,000 by 2044.

### Implications for Public Health and Policy

The identification of high-risk districts and time periods can inform targeted interventions to prevent drowning deaths. The identification of high-risk districts and time periods can inform targeted interventions to prevent drowning deaths. Public health strategies should focus on improving water safety education, increasing access to life-saving equipment, and implementing community-based drowning prevention programs. Examples of evidence-based interventions include supervised daycare for children under five, swimming lessons with water survival skills, installation of barriers such as fencing around water bodies, and training in resuscitation techniques for community members. Additionally, providing life jackets and creating designated safe swimming zones have been shown to reduce drowning incidents. The predictive models developed in this study can aid in resource allocation and emergency preparedness, enabling authorities to take proactive measures to reduce drowning fatalities.

### Future Research Directions

Further research is needed to explore the socio-economic and environmental factors contributing to the high incidence of drowning in Odisha. Longitudinal studies and real-time data collection can enhance the accuracy of future predictions and inform dynamic intervention strategies. Collaboration with local communities and stakeholders is essential to develop culturally appropriate and effective drowning prevention programs.

By providing a detailed statistical analysis and forecasting of drowning fatalities, this study aims to contribute to the understanding and prevention of drowning deaths in Odisha. The findings highlight the urgent need for comprehensive public health interventions to address this critical issue.

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**Ethical Approval:** There is no human or animal subject involved in this study

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# The Role of Neck Circumference in Predicting Body Fat Distribution: A Cross-Sectional Study Among Healthy Female Medical Students

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## Abstract

**Background:** Obesity, characterized by excessive fat accumulation, poses significant health risks. Traditional anthropometric measures like BMI, waist circumference (WC), and waist-to-hip ratio (WHR) are commonly used to assess obesity, but they have limitations. This study investigates neck circumference (NC) as an alternative measure for assessing body fat distribution, particularly in the context of the “thin-fat Indian” phenotype, which exhibits central obesity despite a generally lean physique.

**Methods:** This cross-sectional study, conducted at AIIMS Mangalagiri, Andhra Pradesh in 2023, included 63 healthy female medical students aged 18-25 years. After obtaining ethical approval and informed consent, participants underwent anthropometric measurements including NC and body fat percentage, the latter determined via bioelectrical impedance analysis (BIA). NC was measured following ISAK guidelines. Statistical analysis was performed using IBM SPSS Statistics (version 25), with Pearson’s correlation coefficient and simple linear regression analysis used to explore the relationship between NC and body fat parameters.

**Results:** The mean age of participants was 20.8±8.2 years. Mean NC was 30.03 ± 4.74 cm. The analysis revealed a strong positive correlation between NC and body fat percentage across various body sections (all  $r > 0.74$ , all  $p < 0.001$ ), with the highest correlation observed for arm fat percentage ( $r = 0.960$ ). Simple linear regression analysis indicated that NC significantly predicts several body fat measures, accounting for 57.9% of the variability in BMI, 68.7% in total body fat percentage, 79.3% in subcutaneous fat percentage, 55.7% in visceral fat percentage, 92.2% in arm fat percentage, 88.9% in trunk fat percentage, and 87.1% in leg fat percentage.

**Conclusion:** The findings suggest that NC is a robust predictor of body fat distribution, particularly for arm and trunk fat percentages. This aligns with previous research highlighting NC as a valuable tool for identifying

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obesity-related health risks. The strong correlations and high coefficients of determination underscore the potential of NC as a simple, non-invasive, and cost-effective method for assessing body fat composition, especially in community settings.

**Keywords:** Anthropometric assessment, Body fat percentage, Community health, neck circumference, Medical students

## Introduction

Obesity is a health condition characterized by an excessive accumulation of fat tissue due to an imbalance between energy intake and energy expenditure<sup>(1)</sup>. The World Health Organization (WHO) defines obesity as the abnormal or excessive build-up of fat in the body that adversely impacts health<sup>(2)</sup>. Anthropometric measures are commonly used to determine overweight and obesity due to their usefulness. The most often utilized anthropometric indices include body mass index (BMI), waist circumference (WC), and waist-to-hip ratio (WHR)<sup>(3-6)</sup>.

While various techniques like Dual Energy X-ray Absorption (DEXA), Bioelectrical impedance analysis (BIA), Computed tomography (CT), and Magnetic resonance are available for assessing body composition and distinguishing between muscle and fat accumulations, these methods are not commonly used in community settings due to concerns about radiation exposure, cost-effectiveness, and the need for trained experts<sup>(7)</sup>.

Research indicates that the way fat is distributed throughout the body is more closely linked to cardiovascular risk than overall obesity. Furthermore, the characteristic Asian Indian phenotype is commonly referred to as the "thin-fat Indian," indicating that Asian Indians tend to have higher levels of body fat and lower levels of muscular mass in comparison to other ethnic groups, such as Caucasians. Asian Indians exhibit a characteristic of having thin limbs, indicating a lower amount of muscle mass. Although they have a thin physique, they exhibit central obesity, characterized by a larger waist/hip ratio and a higher subscapular/triceps skinfold ratio<sup>(8)</sup>.

Utilizing BMI as a means of identifying obesity in community settings is insufficient and can present various practical challenges such as lack of properly calibrated weighing scales<sup>(7)</sup>. Alternative approaches,

such as measuring waist circumference (WC) and calculating waist-to-hip ratios, are employed to detect central obesity. Multiple studies have demonstrated that waist circumference (WC) is a more accurate predictor of mortality risk compared to body mass index (BMI). In addition, WC is highly responsive to the distribution of adipose tissue and body dimensions, and it is strongly associated with BMI<sup>(9)</sup>. However, measuring waist circumference may not be accurate as it involves measuring variations in breathing and after eating and cannot be performed during pregnancy. Waist hip ratio is one more parameter that is strongly correlated with body fat percentages. However, implementing these procedures can be difficult among conservative groups, particularly among females in a community context, due to cultural sensitivities<sup>(10,11)</sup>.

In order to combat obesity and its associated problems, it is crucial to develop a more readily available and efficient method for identifying obesity in community environments. Neck circumference, without the drawbacks described before, is considered to be a measure of how fat is distributed in the upper body. It can be a new and alternative method for assessing and categorizing individuals as obese, overweight, or normal weight based on their body composition<sup>(12,13)</sup>. So, in the present study we aimed to measure the neck circumference and its association with body fat percentage in female medical students.

## Materials and Methods

This is a cross-sectional study conducted in the year 2023 at AIIMS, MG. The study commenced after obtaining approval from the institute ethics committee (AIIMS/MG/IEC/2022-23/245). This included a cohort of apparently healthy female students from medical disciplines, enrolled at AIIMS, Mangalagiri, in the age group of 18 to 25 years. Exclusions comprised individuals under steroid therapy or with known systemic ailments. Study protocol was explained to all the participants

before enrolling them to the study. We obtained informed written consent from all subjects (n=63). Subsequently, they were directed to a designated secluded area for the acquisition of anthropometric measurements, following a stipulated interval post-prandial, and refraining from strenuous physical exertion, excessive fluid intake, alcohol consumption, or bathing. The anthropometric assessments were measured by an ISAK-certified practitioner, ensuring adherence to standardized protocols.

The parameters assessed included the determination of body fat percentage via bioelectrical impedance analysis, facilitated by a digital body composition monitor (Omron HBF 702T Digital Body Composition Monitor, Omron, Japan). Additionally, neck circumference (NC) was measured following ISAK guidelines<sup>(14)</sup>. Subjects were positioned in a relaxed seated stance, with arms resting alongside the body and head aligned with the Frankfort plane. NC measurements were taken immediately superior to the thyroid cartilage and perpendicular to the neck's longitudinal axis, utilizing an anthropometric tape with 1 mm precision (cescrof, Brazil)

**Statistical analysis:** Statistical analysis was

performed using IBM SPSS Statistics (version 25, IBM Corp., USA). Data normality for both neck circumference (NC) and body fat percentage was assessed and confirmed. Descriptive statistics are presented as mean  $\pm$  standard deviation (SD). The relationship between NC and body fat percentages was investigated using Pearson's correlation coefficient. The coefficient of determination ( $R^2$ ) was calculated to quantify the proportion of variance in body fat percentage explained by NC. Additionally, simple linear regression analysis was conducted to determine if NC significantly predicts body fat percentage.

To account for potential bias, a bias-corrected and accelerated bootstrap analysis (BCa) with 1000 bootstrap samples was employed. This analysis generated 95% confidence intervals (CI) for both the Pearson's correlation coefficient and the regression coefficients.

## Results

The study participants were a group of female medical students with a mean age of [20.8 $\pm$ 8.2] years. The mean height of the participants was 159.02  $\pm$  6.43. The mean weight was 56.74  $\pm$  10.63 and, the mean neck circumference was 30.03  $\pm$  4.74

**Table 1: Correlation between neck circumference and body fat percentage at various sections**

Parameters	Mean $\pm$ SD	r	p value	Bca 95% confidence interval	
				Lower	Upper
Body mass index	22.38 $\pm$ 3.49	.761**	< .001	0.633	0.858
Total Body fat%	40.31 $\pm$ 6.42	.829**	< .001	0.731	0.897
Subcutaneous fat %	25.59 $\pm$ 4.85	.890**	< .001	0.806	0.947
Visceral fat%	3.69 $\pm$ 2.39	.746**	< .001	0.649	0.834
arms fat %	42.83 $\pm$ 6.05	.960**	< .001	0.894	0.998
trunk fat%	21.68 $\pm$ 4.83	.943**	< .001	0.883	0.979
Leg fat%	38.91 $\pm$ 6.32	.933**	< .001	0.875	0.975

Pearson's correlation was done. Bias corrected and accelerated bootstrap analysis (BCa) was done to find 95% confidence interval using 1000 bootstrap samples. r- Pearson's correlation coefficient.

Table 1 shows that there is a strong positive correlation between neck circumference and body

fat percentage in all sections of the body (all r values > 0.74, all p values < 0.001). We observed strong correlation is between neck circumference and arm fat percentage (r = 0.960). There was a weak correlation is between neck circumference and visceral fat percentage (r = 0.746)

**Table 2: Simple linear regression analysis**

Parameters	R <sup>2</sup>	Adjusted R <sup>2</sup>	Constant	β coefficient	P value	95% confidence interval of coefficient	
						Lower bound	Higher bound
Body mass index	.579	.572	5.562	.560	< .001	.440	.680
Total Body fat%	.687	.682	6.596	1.123	< .001	.932	1.134
Subcutaneous fat %	.793	.789	-1.767	.911	< .001	.794	1.029
Visceral fat%	.557	.550	-7.606	.376	< .001	.292	.461
arms fat %	.922	.920	6.024	1.226	< .001	1.136	1.316
trunk fat%	.889	.887	-7.165	.961	< .001	.875	1.046
Leg fat%	.871	.869	1.584	1.243	< .001	1.123	1.364

R<sup>2</sup> - Coefficient of determination. With neck circumference as independent factor and other parameters as dependent factors.

Table 2 presents the results of a simple linear regression analysis examining the relationship between neck circumference and various body fat parameters. The analysis reveals that neck circumference significantly predicts several body fat measures. Specifically, neck circumference accounts for 57.9% of the variability in BMI, 68.7% in total body fat percentage, 79.3% in subcutaneous fat percentage, 55.7% in visceral fat percentage, 92.2% in arm fat percentage, 88.9% in trunk fat percentage, and 87.1% in leg fat percentage. These results indicate strong positive correlations, particularly for arm and trunk fat percentages, suggesting that neck circumference is a robust predictor of body fat distribution in the studied population. The high coefficients of determination (R<sup>2</sup>) across all parameters underscore the potential of using neck circumference as a reliable measure for estimating body fat composition.

### Discussion

The present study investigated the association between neck circumference (NC) and body fat percentage in a cohort of female medical students. Our findings suggest that NC may be a promising and practical method for assessing body fat composition within this population group.

The study demonstrates a statistically significant positive correlation between NC and total body fat percentage, as well as with other fat distribution measurements obtained through bioelectrical

impedance analysis (BIA). This indicates that individuals with larger neck circumferences tend to have higher body fat percentages. This finding aligns with the previous study which suggests that NC can be a valuable tool for identifying individuals who may be at increased health risk due to specific fat distribution patterns<sup>(15)</sup>.

Our results are consistent with previous research that has highlighted the potential of NC as a surrogate marker for overall adiposity and central obesity<sup>(16-18)</sup>. This is particularly relevant in community settings where access to sophisticated body composition analysis techniques, such as DEXA or CT scans, may be limited due to cost considerations or practical constraints<sup>(19-21)</sup>. Other techniques which do not require costly equipment such as BMI, WHR, and waist circumference each have specific drawbacks. BMI does not differentiate between fat and muscle and fails to indicate fat distribution. WHR requires precise measurements of both waist and hip circumferences, can be influenced by posture and food intake, and may complicate longitudinal assessments due to changes in both measurements. Waist circumference, while useful for measuring abdominal fat, does not distinguish between subcutaneous and visceral fat, can be affected by body build and height, and varies by gender and ethnicity. Measuring WHR and waist circumference measurement can be cumbersome and may require a private setting, which can be impractical in some clinical or community settings. These limitations highlight the need for using these measures in combination with other tools for a comprehensive evaluation of body composition and health risks.

Compared to these techniques, NC measurement offers a simpler, less expensive, and less training-intensive alternative. Also, the NC can be measured regardless of the individual attire<sup>(22, 23)</sup>. Furthermore, NC is insensitive to variables such as food intake, breathing, or physical well-being. NC is a more effective metric than waist circumference and body mass index in assessing obesity levels in pregnant women<sup>(24)</sup>.

In our previous research study suggests that NC demonstrated a stronger correlation with truncal fat compared to arm or leg fat in male medical students<sup>(25)</sup>. This aligns with established knowledge regarding sex hormones and fat distribution. Androgens, the dominant sex hormones in males, promote visceral and subcutaneous fat storage in the abdominal region<sup>(26)</sup>. This central fat accumulation, characterized by a higher proportion stored in the trunk, explains the stronger correlation between NC and truncal fat observed in boys. However, the pattern in females differed, with NC correlating well with arm fat, total body fat, and leg fat. This finding reflects the influence of estrogen, the primary sex hormone in females. Estrogen is known to promote a more peripheral fat distribution pattern, with fat accumulating in the limbs, buttocks, and breasts<sup>(27)</sup>. This peripheral fat distribution likely explains the broader association of NC with various fat depots, including arm and leg fat, observed in females. We also observed that the correlation between neck circumference and various fat percentages (total, visceral, limb) is more in females compared to males (from our previous study).

**Strength and limitations:** The study employed a standardized approach to NC measurement, ensuring data accuracy and consistency. The inclusion of a relatively homogenous population group (female medical students) strengthens the study's internal validity. However, the cross-sectional design limits the ability to establish causal relationships between NC and health outcomes. Additionally, the generalizability of these findings to broader populations beyond female medical students may require further investigation in more diverse samples.

**Future directions:** Longitudinal studies exploring the long-term health outcomes associated

with NC measurements can provide valuable insights. Furthermore, research investigating the effectiveness of NC as a screening tool for obesity in larger and more diverse community settings would be beneficial.

## Conclusion

Our study reveals strong relationship between body fat percentage and neck circumference. Further, this study contributes to the growing body of evidence supporting the utility of NC as a simple, non-invasive, and cost-effective method for assessing body fat composition, particularly in community settings. While further research is warranted to explore the generalizability of these findings and their long-term health implications, NC presents itself as a promising tool for promoting public health initiatives aimed at combating obesity and its associated health risks.

**Ethical Clearance:** The study commenced after obtaining approval from the institute ethics committee (AIIMS/MG/IEC/2022-23/245).

**Conflict of interest:** None

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# Physical, Mental and Social Health of the People who Practice Yoga and Meditation: A Comparative Study

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## Abstract

**Background:** Yoga and meditation is a new way of life. Yoga is derived from the Sanskrit word (yolk) which means to unite. Yoga is now being portrayed as a remedy for several illnesses including the physical, mental and spiritual practices or disciplines which originated in ancient India.

**Material and Methods:** A descriptive cross-sectional online comparative study was conducted across yoga centres and other societies in urban Bengaluru. Data was collected by convenient sampling technique from 98 study subjects who practiced yoga and meditation and 98 subjects who do not practice yoga and meditation using predesigned structured proforma by sharing online google forms via various platforms like whatsapp, mail. The data analyzed using SPSS version 23. Data was expressed in frequency, percentages, mean, Standard deviation and logistic regression. Mann Whitney U test was used to compare mean difference between two study groups.

**Results:** Out of 176 participants surveyed, majority participants were in age group of 41-60 years. Among 98 study subjects who practice yoga and meditation majority were females 48%. It was observed in present study that by using WHOQOL BREF questionnaire, regular yoga and meditation practice was associated with a positive impact on all 4 domains of HRQOL (Mann-Whitney  $P < .05$ ).

**Conclusions:** There was significant difference in means scores in all domains of WHO HRQOL among study subjects who practice yoga and meditation and study subjects who do not practice yoga and meditation. The odds of comorbidities were lower among those who practice yoga and meditation. Overall, a yoga and meditation practice was found to be an effective tool for promoting HRQOL.

**Keywords:** Yoga, Meditation, WHOQOL-BREF, Domain.

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## Introduction

World Health Organization defined health as being not only the absence of disease and infirmity but also the presence of physical, mental and social well-being, quality-of-life issues have become steadily more important in health care practice and research.<sup>1</sup> Quality of life integrates aspects of physical, psychological and social health.<sup>1</sup> Yoga influences physical, mental, social and spiritual aspects of people's lives.<sup>2</sup>

The well being of an individual has both subjective and objective components. QOL is the subjective component of well being.<sup>3</sup> The World Health Organization (WHO) has defined "QOL" as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns."<sup>4</sup>

Yoga is an ancient Indian system of philosophy designed to build balance & health to the physical, mental & emotional dimensions of the individual.<sup>5</sup> Yoga also increases proprioception and improves balance.<sup>6</sup> Yoga decreases the risk of heart attack and stroke.<sup>7</sup> Overweight and obesity are strong risk factors for diabetes, hypertension and ischemic heart disease.<sup>8</sup>

Meditation is an age old self-regulatory strategy and is used to reduced stress and anxiety.<sup>9</sup> A considerable body of findings has amassed supporting the capacity of MBIs (Mindfulness Based Interventions) to reduce substance use and attenuate factors promoting substance use, such as craving and stress.<sup>10</sup> Patients with chronic diseases often suffer from physical and psychologic distress, lowering their quality of life.<sup>11</sup> It is a philosophy that good medicine should be based on good science.<sup>12</sup> Yoga and meditation has been effectively used in the management of stress.<sup>13</sup>

HRQOL is an important measure used to assess the impact of diseases or disabilities on the physical, mental and social domains of population health.<sup>14</sup>

There is limited research in the area exploring the differences in health-related quality of life (HRQOL) among those who practice yoga and meditation and those who do not practice yoga and meditation. The aim of Preventive and Social Medicine is health promotion and disease prevention, hence there is strong reason to include yoga in the teaching curriculum of Community Medicine in Medical

students so that our future health care workers adopt, maintain and practice positive health. In this background present study was undertaken to determine the impact of yoga and meditation on physical, mental and social health of study subjects.

## Objectives

1. To describe the Socio-demographic characteristics of study subjects.
2. To assess and compare the physical, mental and social health in the study subjects who practice yoga and meditation (Group A) and study subjects who don't practice yoga and meditation (Group B).

## Material and Methods

A total of 176 study subjects were accessed, 98 Group A subjects (study subjects who practice yoga and meditation) were accessed from various yoga centres situated in Bengaluru Urban and 98 subjects of Group B (Study subjects who do not practice yoga and meditation) were accessed from various other societies located in Bengaluru Urban by convenient sampling technique obtaining a sample size of 98 per group for a comparative study.

### Sample size calculation:

$$n = \frac{2 [Z_{1-\alpha/2} + Z_{1-\beta}]^2}{(d/\sigma)^2}$$

$$Z_{1-\alpha/2} = 1.96 \text{ at } 95\% \text{ Confidence Interval}$$

$$Z_{1-\beta} = 0.84 \text{ at } 80\% \text{ Power}$$

$$d/\sigma = \text{Effect Size}(0.4)$$

$$n = \frac{2[1.96+0.84]^2}{(0.4)^2}$$

$$= 98 \text{ per group}$$

Group A: 98 Study Subjects who practice yoga and meditation

Group B: 98 Study Subjects who do not practice yoga and meditation

The common eligibility criterion in the study for both Group A and Group B men and non pregnant women between 18 and 80 years old who were willing to give a informed consent for being enrolled in the study, those who have access to internet and aware about entering details in the google forms.

Data was collected using pre-designed, pre-structured self administered proforma by sharing online google forms via various platforms like whatsapp and mail. The study was conducted from September 2021 to March 2022. The google form included questions on sociodemographic variables, self reported height, weight, co morbid conditions and WHOQOLBREF questionnaire. In the present study, based on the height and weight entered by the study participant BMI was calculated. In this study, BMI classification proposed by the WHO Western Pacific Regional Office in collaboration with IOTF (International Obesity Task Force) steering committee (2000) for Asian people was used.

The study protocol was reviewed and approved by the ethics committee of the teaching Institute and informed consent was obtained from all the study subjects ensuring them that all the information will be kept strictly confidential and will be used only for research purposes.

Submitting the forms confirmed the participation of study subjects.

### Evaluation of Quality of life using WHOQOL-BREF Scale

The evaluation instrument used in the present study to assess quality of life among the study subjects (Group A and Group B) was WORLD HEALTH ORGANIZATION QUESTIONNAIRE FOR QUALITY OF LIFE (WHOQOL-BREF). The WHOQOLBREF is a 26-item questionnaire evaluating quality of life from four domains which includes physical health, psychologic health, social relationships and environment/surroundings.

### Scoring Procedure

The WHOQOL-BREF (Field Trial Version) produces a quality of life profile. It is possible to derive four domain scores. The four domain scores denote an individual's perception of quality of life in each particular domain.

In the present study brief version of the WHO's QOL scale (WHOQOL-BREF) was used. This instrument is derived from the WHOQOL-100. The WHOQOL-BREF questionnaire contains two items from the Overall QOL and General Health and 24 items of satisfaction that divided into four domains: Physical health with 7 items (DOM1), psychological health with 6 items (DOM2), social relationships with 3 items (DOM3) and environmental health with 8 items (DOM4).

Each item is rated on a 5-point Likert scale. Each item of the WHOQOL-BREF is scored from 1 to 5 on a response scale. Raw domain scores for the WHOQOL were transformed to a 4-20 score according to guidelines. Domain scores are scaled in a positive direction (i.e., higher scores denote higher QOL). The mean score of items within each domain is used to calculate the domain score. After computing the scores, they are transformed linearly to a 0-100-scale.

### Statistical analyses

The information collected was analysed with the SPSS software, version 23. Descriptive analysis performed included frequencies, percentages, mean, standard deviation and Logistic regression. Mann Whitney U test was used to compare difference between means cores of different domains of WHOQOL-BREF among Study subjects (Group A and Group B). The level of significance was set at 0.05 and p-value <0.01 was considered as statistically highly significant.

## Results

**Table 1: Distribution of study subjects according to sociodemographic characteristics.**

Age(Years)	Group A(Study subjects who practice yoga and meditation)			Group B(Study subjects who do not practice yoga and meditation)		
	Males	Females	Total	Males	Females	Total
18-20	02(04.2)	05(10.0)	07(07.1)	02(03.6)	01(02.3)	03(03.1)
21-40	17(35.4)	21(42.0)	38(38.8)	37(67.3)	31(72.1)	68(69.4)
41-60	28(58.3)	24(48.0)	52(53.1)	16.0(29.1)	11(25.6)	27(27.6)
>60	01(02.1)	-	01(1.0)	-	-	-
Total	48(48.9)	50(51.1)	98(100.00)	55(56.1)	43(43.9)	98(100.00)

**Note:** Figures in parenthesis indicates percentages.

In the present study among study subjects who practiced yoga and meditation (Group A), majority were females 50(51.1%) and 48 (48.9%) were males. Among study subjects who did not practice yoga and

meditation (Group B), majority were males 55(56.1%) and 43(43.9%) were females. Among both groups study subjects were highest in 41-60 years age group.

**Table 2: Association between study subjects(Group A and Group B) and WHO Quality of Life-BREF Domains**

QOL Domain	Group A (Study subjects who practice yoga and meditation)		Group B (Study subjects who do not practice yoga and meditation)		Mann Whitney U Test value	P value
	Mean	Standard Deviation	Mean	Standard Deviation		
Physical Health(Domain1)	66.4	9.0	54.8	14.4	2525.5	<.0000001
Psychological Health (Domain2)	80.9	13.8	60.5	24.0	2290.5	<.0000001
Social Relationship (Domain3)	78.8	16.6	62.2	26.8	3103.0	<.0000001
Environmental Health(Domain4)	83.2	11.9	65.1	25.2	2692.5	<.0000001

**Note:** Figures in parenthesis indicates percentages.

Physical health Domain among Group A (Study subjects who practice yoga and meditation) study subjects was (Mean=66.4, Standard deviation=9.0) as compared to Group B (Study subjects who do not practice yoga and meditation) study subjects (Mean=54.8, Standard Deviation=14.4). This mean difference was found to be statistically significant. (P<0.0000001)

Social relationship Domain among group A (Study subjects who practice yoga and meditation) study subjects was (Mean=78.8,Standard deviation=16.6) as compared to Group B (Study subjects who do not practice yoga and meditation) study subjects(Mean=62.2, Standard Deviation=26.8). This mean difference was found to be statistically significant.(P<0.0000001)

Psychological health Domain among group A (Study subjects who practice yoga and meditation) study subjects was (Mean=80.9, Standard deviation=13.8) as compared to Group B (Study subjects who do not practice yoga and meditation) study subjects(Mean=60.5, Standard Deviation 24.0). This mean difference was found to be statistically significant. (P<0.0000001)

Environmental health Domain among group A (Study subjects who do not practice yoga and meditation) study subjects was (Mean=83.2,Standard deviation=11.9) as compared to Group B (Study subjects who do not practice yoga and meditation) study subjects (Mean=54.8, Standard Deviation=14.4). This mean difference was found to be statistically significant. (P<0.0000001)

**Table 3: Results of logistic regression on association between practice of yoga and meditation and chronic co-morbid conditions.**

Variable	B	S.E	P Value	Odds Ratio/ Exp(B)	95% Confidence Interval	
					Upper	Lower
Practice of yoga and meditation	-0.473	0.427	0.042	0.623	0.270	1.439

$P=0.042$  ( $P<0.05$  is significant), indicating that practicing yoga has a statistically significant effect on the likelihood of having chronic co morbid conditions. The odds of chronic co morbid conditions are 0.623 times lower among those who practice yoga and meditation (Group A) study subjects as compared to study subjects who do not practice yoga and meditation (Group B).

The BMI of Group A study subjects [(Mean=23.75), (S.D=3.59)] as compared to Group B study subjects [(Mean=23.82), (S.D=4.06)] and weight (kgs) was Group A study subjects [(Mean=60.83), (S.D=11.29)] as compared to Group B study subjects [(Mean=70.43), (S.D=15.21)]

### Discussion

In the present study, it was observed that among study subjects who practiced yoga and meditation, most of them 51.1% were females, while in a study done at Madhya Pradesh by Anuj M et al showed maximum study participants who practiced yoga and meditation were males (80%).<sup>5</sup>

In the present study, study subjects who practiced yoga and meditation were highest 52(53.1%) in the age group of 41-60 years while in study done in Madhya Pradesh by Anuj M et al showed maximum people who practiced yoga and meditation were in age group of 26-33 years(53%).<sup>5</sup>

In the present study, mean difference in physical health domain scores among subjects who practice yoga and meditation and subjects who do not practice yoga and meditation was highly significant ( $P<0.0000001$ ) which is similar to study conducted by Meenakshi Verma et al on impact of yoga on quality of life ( $P<0.01$ ).<sup>15</sup>

In the present study, mean difference in psychological, social and environmental health domain scores among subjects who practice yoga and meditation and subjects who do not practice yoga and meditation was highly significant ( $P<0.0000001$ ) while in study conducted by Meenakshi Verma et al on impact of yoga on quality of life the mean difference was found to be insignificant [Psychological domain ( $P=0.68$ ), Social domain ( $P=0.69$ ), Environmental domain ( $P=0.16$ )], the difference could be because the present study was done in general

population while study done by Meenakshi Verma et al was on health care professionals.<sup>15</sup> While according to the study done by Woolery A et al that there is positive association with respect to psychological domain and practice of yoga.<sup>16</sup>

The study done by Catherine woodyard et al also shows that there is positive association with respect to physical, psychological domain and practice of yoga which is similar to the findings of present study.<sup>17</sup>

Yoga has been found to be helpful in the management of obesity which are consistent with findings of present study. Training of yoga resulted in decrease in body weight, BMI and waist hip ratio.<sup>8</sup> A study conducted by Guarracino JL, et al. showed that yoga had a statistically significant role in controlling weight, hypertension which are similar to findings of present study.<sup>18</sup>

### Conclusion

- Majority of females practiced yoga and meditation. The majority of the study subjects who practice yoga and meditation are between 41-60 years.
- There was significant difference in the mean scores by Mann Whitney U test in physical, psychological, social and Environmental domain among Group A (study subjects who practice yoga and meditation) and Group B (Study subjects those who do not practice yoga and meditation). Regular yoga and meditation practice was associated with a positive impact on all 4 domains of WHO HRQOL.
- The odds of chronic co morbid condition was lower among those who practice yoga and meditation compared to those who do not practice yoga and meditation.
- School yoga program should be initiated and strengthened under the school health program, as children are quick learners and high adapters. Educating children about meditation and self-control will help them to improve their academic performance and call for effective peer relationships. It should also be promoted among teenagers who are more prone to juvenile delinquency like substance abuse, depression and aggression and self-harm.

- The benefits of using meditation at the workplace are multifactorious hence, companies must offer these courses to their employees.
- Grass-root level workers like ASHA should also be involved in creating awareness about the importance of yoga. Concerted efforts from the community local leaders, NGO's with adequate financing, capacity building, political commitment and intersectoral coordination are the prerequisites to strengthen the awareness and practice of yoga in the community.
- Yoga and meditation is beneficial for attaining complete physical, mental and social wellbeing so practicing yoga will help in attaining the health as defined by WHO.

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# Impact of Chronic Pain on Sleep Quality and its Association with Depression: A Multicentric Prospective Observational Study

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## Abstract

**Background:** Chronic pain patients have been reported to complain about poor sleep quality and associated depression. Depressive mood and pain severity are the most frequently encountered predictors. The study was done to examine the impacts of chronic pain on depression and poor sleep quality dimensions.

**Materials & Methods:** The study was a prospective, comparative, observational outcomes research study. The study was conducted at two dedicated pain clinics - one government and one private Pain Clinic in Kolkata; and one public routine health care facility. In the present study chronic pain related quality of life in health (patient's mental status and pain disability) was assessed at baseline, during follow-up visit and end of the study. Association of depression, anxiety and sleep disturbances among chronic pain patients were also assessed. **Results:** Moderately severe depression was more prevalent in group 2 (15%), whereas moderate depression was more common in group 3 (40%) as compared to other groups. Severe depression was mainly absent in the majority of our study population except group 2 where 5% participants were assessed having severe depression. Sleep disturbances were more prevalent in group 3 patients ( $7.475 \pm 2.0247$ ) initially as compared to other groups. There was significant improvement in quality of sleep among all three groups ( $p < 0.0001$ ) after 6 months of treatment with most prominent improvement in group 3 patients ( $3.5 \pm 1.7319$ ).

**Conclusion:** Chronic pain patients suffer from poor sleep quality – a function of depressed mood rather than pain intensity, duration, or anxiety. Future longitudinal studies with larger sample sizes are needed to confirm the mediating effect of poor sleep quality.

**Keywords:** Chronic pain, pain clinics, depression, sleep disturbance, quality of life, association

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## Introduction

Chronic pain is persistent pain that lasts more than 3 months and more than the expected healing period. [1-2] It has deleterious effects on patients' health, daily activities, and workplace productivity.<sup>3</sup> Its tenacious nature contributes to the co-occurrence of depression and poor sleep quality. Of all patients with chronic pain, 22.9%-60.8% meet the criteria for depression. Chronic pain explains the variance in depression; which might occur as a result of the shared neuroplasticity alterations and underlying processes between chronic pain and depression.<sup>5</sup>

Chronic pain negatively influences quality of life (QoL) of the patients specifically with respect to psychological and environmental aspects. Effective pain management results in improved QoL and reduces disability.<sup>6-8</sup> Optimal treatment of patients experiencing chronic pain can be achieved by assessing pain characteristics such as location, intensity, quality, duration, effect on QoL, and clearly defining the goal of therapy.<sup>9,10</sup>

Untreated chronic pain can lead to increased disability, increased depression and anxiety, sleep deprivation, reduced quality of life and social isolation among chronic pain patients and increased treatment burden in families and decreased quality of life among partner/caregivers.<sup>11</sup>

In the present study chronic pain related quality of life in health (patient's mental status and pain disability) was assessed at baseline, during follow-up visit and end of the study. Association of depression, anxiety and sleep disturbances among chronic pain patients were assessed.

## Materials and Methods

The study was a prospective, comparative, observational outcomes research study. The study was conducted at two dedicated pain clinics - one government (ESI Institute of Pain Management, ESI Hospital Sealadah, Kolkata) and one private Pain Clinic in Kolkata; and one public routine health care facility (Department of Orthopedics, Medical College & Hospital, Kolkata). Structured questionnaire delivery, history taking and physical clinical examination was conducted at the Pain Clinics and also at Clinical Pharmacology OPD, Calcutta School of Tropical Medicine, Kolkata.

## Inclusion criteria

- Subjects with confirmed diagnosis of chronic pain - pain persisting for more than 3 months (i.e. two clinic visits separated by at least 3 months).
- Subjects receiving outpatient care at one of the participating facilities / pain clinics
- Subjects 18 years of age and older - both sexes
- Subjects willing to give written informed consent

## Exclusion criteria

- Pregnant
- Suffering from any serious disease such as unstable coronary heart disease, heart failure, advanced kidney or liver failure
- Any condition resulting in severe learning disability (e.g. brain injury) or
- Those unable to comprehend for other reasons will be excluded from the study.

Considering margin of error at 5% and a 95% confidence interval, with an estimated population size of 240, (approximately 240 chronic pain patients fitting all inclusion and exclusion criteria are expected to attend the pain clinics one day every week for one year) with 50% response distribution, the calculated recommended sample size comes to around 148 (using standard Raosoft software). Considering 20% dropout, estimated sample size was 118. However, for the purpose of logistic reasons and considering constraints in time, it was planned to restrict the total sample size to 120 i.e. 40 in each group.

This was a prospective, non-randomized, observational outcomes research study. All screen-eligible subjects who gave informed consent were included on an average of 4-6 patients per OPD days for the study. Clinical presentation, history of chronic pain and other socio-demographic baseline data were assessed by using pre-structured questionnaire and validated pain scales. Chronic pain related quality of life in health (patient's mental status and pain disability) was assessed at baseline, during follow-up visit and end of the study. Association of depression, anxiety and sleep disturbances among chronic pain patients were also assessed.

## Study Tools

- Initial Pain Assessment Tool
- NRS [Numeric Pain Rating Scale]
- Brief Pain Inventory<sup>12</sup>
- Pain Detect Pain Questionnaire<sup>13</sup>
- Mental Status among chronic pain patients (PHQ-9 Patient Depression Questionnaire score)<sup>14</sup>
- Sleep Problems Questionnaire (SPQ)<sup>15</sup>

Initial pain assessment scale and questionnaires was used as a screening interview for the selection of eligible participants. Brief pain inventory included a total of 9 questions and survey required approximately 8-10 minutes. This questionnaire assessed worst, least and average pain intensity of last 24 hrs and how pain has interfered basic functions of their life. *Pain Detect* Pain screening Questionnaire<sup>13</sup> helped to identify neuropathic components in patients with chronic pain. Patient health questionnaire- 9 (PHQ-9)<sup>14</sup> helped to assess present mental status of the chronic pain patients. The 4-item Sleep Problems Questionnaire (SPQ)<sup>15</sup> helped to assess quality of sleep in patients with chronic pain problems.

Descriptive statistics has been analyzed. Where possible, demographic and categorical data were analyzed with parametric or non-parametric tests whichever found applicable. Quantitative data are presented as mean  $\pm$  standard deviation, while qualitative data are demonstrated as frequency and percent. The statistical tests for comparison were independent sample t-test, F- test, one-way analysis of variance test (ANOVA) etc. Different levels

have been expressed at 95% Confidence Interval. A P-value of less than 0.05 was considered statistically significant.

## Results

A total of 143 patients suffering from chronic pain attending two dedicated pain clinics - one public (ESI Institute of Pain Management, ESI Hospital Sealdah, Kolkata) and one private Pain Clinic in Kolkata; and one public routine health care facility (Department of Orthopedics & Physical Medicine & Rehabilitation, Medical College & Hospital, Kolkata), were initially recruited in the study after they fulfilled the study selection criteria and gave written informed consent. Out of these, 124 patients completed the study. Final analysis was done for 120 chronic pain patients, including 40 patients in each center for uniformity in the analysis. Nineteen (19) study subjects in total were unavailable for follow-up, of which 9 patients belonged to group 2 (Medical College & Hospital, Kolkata), 3 patients belonged to group 3 (Private Pain Clinic, Kolkata) and 7 patients belonged to group 1 (ESI Institute of Pain Management, ESI Hospital Sealdah, Kolkata)

## Baseline Profile and Clinical Data of Study Subjects

All the study subjects were recruited on an ambulatory (out-patient) basis. As seen in (Table 1) all the study groups were comparable in respect to age, height, weight, religion and marital status. The male and female gender distribution was almost equivalent in group 2 and group 3 but different in group 1 (80% male and 20% female).

**Table 1: Baseline demographic profile in chronic pain patients in three groups**

Characteristics	GROUP 1 [Public Pain Clinic] (n=40) [Mean $\pm$ SD]	GROUP 2 [Public Routine Health Care Facility] (n=40) [Mean $\pm$ SD]	GROUP 3 [Private Pain Clinic] (n=40) [Mean $\pm$ SD]
Mean Age (in years)	47.41 $\pm$ 11.19	44.85 $\pm$ 13.80	45.67 $\pm$ 14.42
Mean Height (in cm)	164.8 $\pm$ 6.55	164.17 $\pm$ 5.38	169.2 $\pm$ 4.80
Mean Weight (in kg)	61.6 $\pm$ 9.32	54.64 $\pm$ 6.80	65.87 $\pm$ 13.05

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<b>Sex</b>			
Male	32 (80)	13 (32.5)	17 (42.5)
Female	8 (20)	27 (67.5)	23 (57.5)
<b>Religion</b>			
Hindu	29 (72.50)	30 (75)	31 (77.5)
Muslim	11 (27.50)	10 (25)	8 (20)
Others	0 (0)	0 (0)	1 (2.5)
<b>Marital Status</b>			
Unmarried	9 (22.5)	9 (22.5)	6 (15)
Married	30 (75)	26 (65)	29 (72.50)
Separated	1 (2.5)	1 (2.5)	2 (5)
Others	0 (0)	4(10)	3 (7.5)
<b>Age Groups</b>			
19-39 years	9 (22.5)	13 (32.5)	17 (42.5)
40-59 years	27 (67.5)	18 (45)	15 (37.5)
>60 years	4 (10)	9 (22.5)	8 (20)

**Causes of pain**

Most of participants mentioned that low back pain [group 1 (50%), group 2 (42.5%) and group 3 (55%)], arthritis [group 1 (7.5%), group 2 (15%) and

group 3 (5%)] and neuropathy [group 1 (10%), group 2 (2.5%) and group 3 (12.5%)] were the main causes of chronic pain among all categories (Table 2).

**Table 2: Common Diagnosis in Different Groups of Chronic Pain Patients**

<b>Diagnosis</b>	<b>Group 1 (Pub. Pain Clin.) [N (%)]</b>	<b>Group 2 (Priv. Pain Clin.) [N (%)]</b>	<b>Group 3 (Pub. Routine Healthcare Facility) [N (%)]</b>
Low Back Pain	20 (50)	17 (42.5)	22 (55)
Fibromyalgia	2 (5)	0 (0)	3 (7.5)
Plantar Fasciitis (Heel Pain)	2 (5)	3 (7.5)	2 (5)
Post Traumatic Adhesive Capsulitis (Frozen Shoulder)	3 (7.5)	4 (10)	1 (2.5)
Arthritis	3 (7.5)	6 (15)	2 (5)
Neuropathy	4 (10)	1 (2.5)	5 (12.5)
Facial pains	1(2.5)	0	1(2.5)
Spondylitis/ Spondylolisthesis	1 (2.5)	5 (12.5)	1 (2.5)
Ankle pain	2 (5)	3 (7.5)	1(2.5)
Others (CRPS, Phantom Limb Pain, SacroiliatisEtc)	2 (5)	1 (2.5)	2 (5)

As seen in Table 2 associated chronic diseases or / disorders like diabetes, hypertension, thyroid problems etc were more common in group 3 (40%) and group 2 (32.5%) as compared to group 1 (22.5%).

Diabetes as associated disease was more common in group 3 (25%) as compared to group 2 (12.5%) and group 1(10%).

### Depression status among chronic pain patients

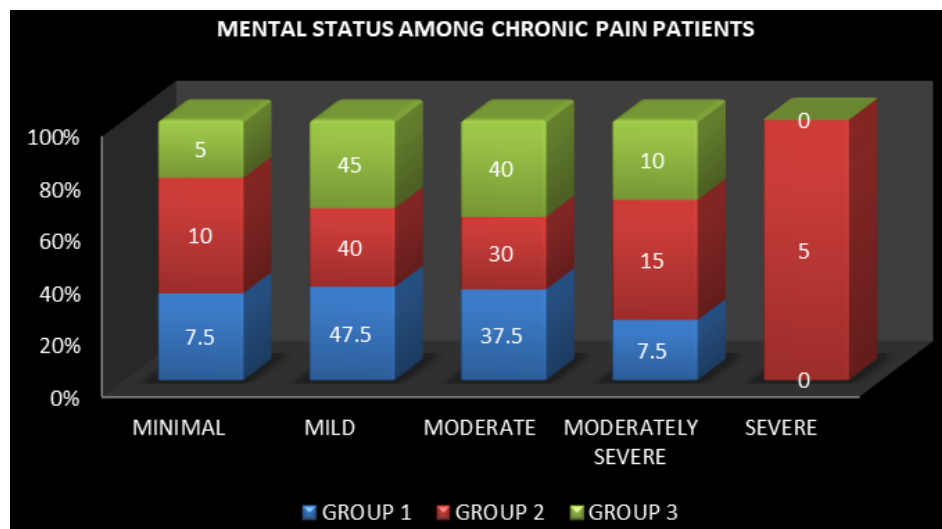
Depression was evaluated by a self-administered and validated measure known as 'Patient Health Questionnaire-9 (PHQ-9)' depression scale, a self-administered version of mental disorder assessing tool PRIME-MD.<sup>14</sup> PHQ-9 is a preformed questionnaire consisting of nine questions. The response to each of the nine questions is evaluated by frequency of the symptoms over the last 2 weeks and is categorized as 'Not at all', 'several days', 'more than half the days' and 'nearly every day'. The above response categories are scored as 0, 1, 2 and 3 respectively, giving a total score of 0-27. The severity of depression was assessed by PHQ-9 depression severity score: 0-no depression,

(1-4) - minimal depression, (5-9) - mild depression, (10-14) - moderate depression, (15-19) - moderately severe depression and (20-27) - severe depression.<sup>14</sup>

Depression severity assessment according to PHQ-9 DSS revealed that all the chronic pain patients under present study were having more or less depressive components. Moderately severe depression was more prevalent in group 2 (15%), whereas moderate depression was more common in group 3 (40%) as compared to other groups. Severe depression was mainly absent in the majority of our study population except group 2 where 5% participants were assessed having severe depression (Table 3/Figure 1).

**Table 3: Level of depression among chronic pain patients**

	Group 1 [N (%)]	Group 2 [N (%)]	Group 3 [N (%)]
Minimal	3 (7.5)	4 (10)	2 (5)
Mild	19 (47.5)	16 (40)	18 (45)
Moderate	15 (37.5)	12 (30)	16 (40)
Moderately Severe	3 (7.5)	6 (15)	4 (10)
Severe	0	2 (5)	0



**Fig. 1: Level of depression among chronic pain patients**

Depression was found to be more prevalent among female patients suffering from chronic pain in group 2 and 3 as compared to group 1. It was observed that 'mild' and 'moderate' depression was more prevalent

in female participants in all those groups, whereas 'moderately severe' depression was slightly higher in male participants. (Table 4)

**Table 4: Patient Characteristics among different depression severity groups**

Severity of Depression	Sex	Group 1 (Mean)			Group 2 (Mean)			Group 3 (Mean)		
		No. of Cases	Avg. PHQ-9 Score	Avg. NRS Score	No. of Cases	Avg. PHQ-9 Score	Avg. NRS Score	No. of Cases	Avg. PHQ-9 Score	Avg. NRS Score
Minimal	Male	3	4	2	3	4	3.35	1	4	2
	Female	0	0	0	1	4	3.32	1	4	2.7
Mild	Male	4	7.47	2.73	4	7.5	3.45	8	7.6	2.45
	Female	15	8	3.25	12	7.75	3.97	10	7.7	2.11
Moderate	Male	11	11.36	3	3	14	3.33	5	12.2	2.6
	Female	4	11.75	3	9	13	4.7	11	11.45	2.445
Moderately Severe	Male	3	15.67	3.67	3	17	3.8	3	16.3	2.54
	Female	0	0	0	3	16.33	4.5	1	16	2.75
Severe	Male	0	0	0	1	20	3	0	0	0
	Female	0	0	0	1	20	4.3	0	0	0

**Sleep disturbances among chronic pain patients**

Sleep disturbances among chronic pain participants were assessed with the help of Sleep Problems Questionnaire (SPQ),<sup>15</sup> a four item questionnaire. It measures the most common symptoms of poor sleep in both healthy and distressed populations. Symptoms of insomnia were assessed at both time points with the 4-item, self-administered SPQ, characterized by scores ranging from 0 to 20 with higher scores indicating greater sleep disturbance. The items enquired about trouble falling asleep, trouble staying asleep, waking too early, and

awakening in the morning feeling tired and worn out. Patients rated each item on a scale of 0 to 5, based on the number of days a symptom was experienced, with 4 representing 15–21 days and 5 representing 22–31 days in the past month, respectively. Sleep disturbances were more prevalent in group 3 patients (7.475 ± 2.0247) initially as compared to other groups. There was significant improvement in quality of sleep among all three groups (p<0.0001) after 6 months of treatment with most prominent improvement in group 3 patients (3.5 ± 1.7319) [Table 5].

**Table 5: The Sleep Problems Questionnaire (SPQ) Score among chronic pain study participants**

	Day 0	After 6 Months	95% CI	T Value	P Value
Group 1	6.875 ± 1.8192	4.41 ± 1.6231	1.6975-3.2324	6.3945	<0.0001
Group 2	6.675 ± 2.7239	5.13 ± 2.4474	0.3923 -2.6976	2.6684	0.0093
Group 3	7.475 ± 2.0247	3.5 ± 1.7319	3.1363 -4.8136	9.4357	<0.0001

**Discussion**

The NRS [Numeric Pain Rating Scale] is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of their pain. Higher scores indicate greater pain intensity. Chronic pain patients prefer the NRS over other measures of pain intensity, including the pain VAS, due to comprehensibility and ease of completion.<sup>16,17</sup>

The overall mean intensity of pain on NRS scale which was found to be lower [(4.92), NRS scale; 0 to 10] in group 1 as compared to group 2 (5.32) and group 3 (5.47) initially. There was a significant decrease in mean pain intensity (p<0.01) in each group after 2 & 6 months of treatment follow-up from the baseline. Improvement of pain intensity on presentation was significantly higher in group 3 as compared to group 1 & 2 (p<0.01).

The impact of chronic pain on function can be subdivided into patients' physical capacities, the ability of patients to perform activities of daily living and their ability to function in adult roles such as employment. Focus groups of people with persistent pain indicate that their overall physical functioning was degraded because of their pain, supporting the recommendation that assessment of functioning should be an integral part of pain assessment.<sup>18</sup> The ability (or inability) to perform necessary and desired functions, in turn, can significantly impact quality of life. Pain affected the daily general activities ( $4.25 \pm 1.13$ ); walking ability ( $2.92 \pm 1.47$ ); and enjoyment of life ( $6.37 \pm 1.11$ ) of the respondents at baseline more in case of group 3 patients.

The severity of depression was assessed by PHQ-9 depression severity score: 0-no depression, (1-4) - minimal depression, (5-9) - mild depression, (10-14) - moderate depression, (15-19) - moderately severe depression and (20-27) - severe depression. Depression severity assessment according to PHQ-9 DSS revealed that all the chronic pain patients under present study having more or less depressive components.<sup>14</sup> Moderately severe depression was more prevalent in group 2 (15%), whereas moderate depression was more common in group 3 (40%) as compared to other groups. Depression was found to be more prevalent among female patients suffering from chronic pain in group 2 and 3 as compared to group 1. It was observed that 'mild' and 'moderate' depression was more prevalent in female participants in all those groups, whereas 'moderately severe' depression was slightly higher in male participants.

Pain nearly always disrupts sleep in chronic pain patients, and insomnia increases pain intensity and frequency and reduces pain threshold—even in people without reported pain complaints.<sup>19</sup> Assessment and management of sleep disturbances is an important first-line approach to care of the patient with chronic pain conditions. A variety of tools are available, including the STOP-BANG<sup>20</sup>, developed to assess risk of obstructive sleep apnea in perioperative patients. Proceeding with a sleep assessment for any patient on opioids plus sedatives or hypnotics is also a reasonable approach, to more specifically determine the need for treatment and, perhaps more importantly, to balance the risks of continuing with

either or both of these sedating prescriptions. Sleep disturbances were more prevalent in group 3 patients ( $7.475 \pm 2.0247$ ) initially as compared to other groups. There was significant improvement in quality of sleep among all three groups ( $p < 0.0001$ ) after 6 months of treatment with most prominent improvement in group 3 patients ( $3.5 \pm 1.7319$ ).

## Conclusion

In conclusions, among chronic pain patients in Eastern India, poor sleep quality and depression are prevalent issues, and this requires the assessment and treatment of both conditions. Considering poor sleep quality in the context of chronic pain is highly necessary for managing depression, including its occurrence and progress. This finding can be utilized to tailor evidence-based interventions for patients in chronic pain clinics. Chronic pain patients suffer from poor sleep quality—a function of depressed mood rather than pain intensity, duration, or anxiety. However, it is difficult to draw a causal relation in this relatively small sample size. Future longitudinal studies with larger sample sizes are needed to confirm the mediating effect of poor sleep quality.

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**Conflict of interest:** The author has no conflict of interest to declare.

**Ethical Clearance:** Ethics approval has been taken from the IEC-CSTM, Kolkata [Ref. No CREC-STM 20-2013 dated 09-02-2013].

**Consent:** Informed consent was obtained from all participants before collecting the data.

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# Health-Seeking Behavior and its Determinants among Attendees of a Tertiary Care Hospital in Visakhapatnam

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## Abstract

**Background:** Health-seeking behavior is an important factor in health management, but this is often ignored while providing health facilities to people. The main aim of the study was to understand health-seeking behavior and to find out their perceptions of better healthcare delivery.

**Methods:** This descriptive cross-sectional study was conducted among 400 attendees of a tertiary care hospital in Visakhapatnam by systematic random sampling from August to September 2021. The predesigned; pretested questionnaire was administered among them after obtaining their valid informed consent.

**Results:** More than half of them were between 20-30 years age group and females, >3/4th were married, Hindus were dominating and belonged to socio-economic class IV and V. 83.25% of participants living in nuclear families. 62% thought that they are having better health currently. 47.5% preferred government health facilities for their illness. Only 14.8% of the attendees visited the health facility immediately on the day of onset. Half of them used their personal funds/savings for treatment. More than 1/4th had health insurance to cover their health expenditure and their income was affected by sickness.

**Conclusion:** It is essential to carry out health awareness measures to reduce disease burden and to reduce the time gap between the onset of symptoms and utilizing health care services.

**Keywords:** Health Seeking Behaviour, Determinants, Tertiary care hospital

## Introduction

According to WHO, health is a state of complete physical, mental, and social well-being and not merely

the absence of disease or infirmity.<sup>1</sup> It is not a static condition, constant change and adaptation to stress result in homeostasis. When an individual decides about health, he/she weighs up the potential risks or

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benefits of a particular behavior. But they do so in a way that is mediated by their immediate practical environment, their social rootedness, socioeconomic status, and their whole outlook on life more generally which may or may not be relevant to an act of health-seeking behaviour.<sup>2</sup>

Health-care-seeking behavior was defined as: formal, when professional help was sought from health care services and/or health care providers (physicians, psychologists); informal relational when help was sought from members of his / her social network (parents, friends, teachers, trusted persons.<sup>5</sup> There is urgent need to address the reasons behind their perceptions regarding their current health status being average and poor health.<sup>3</sup> Health-seeking behavior is drawing out the factors that enable or prevent people from making 'healthy choices', in either their lifestyle behaviors or their use of medical care and treatment. Thus, health care-seeking behavior is conceptualized as a 'sequence of remedial actions' taken to correct 'perceived ill-health'.<sup>4</sup>

Health-seeking behavior is an important factor in health management, but this is often ignored while providing health facilities to people. As a result, facilities for providing health care do not get the desired acceptance of the community and are therefore rendered unsuccessful. Not only the decision-makers, but health care provider should also understand the health-seeking behavior of the community along with their health-seeking practices and their perception regarding the service delivery. This becomes especially relevant among underprivileged populations like urban slums, and tribal populations.<sup>7</sup> In this view, this study was conducted among attendees of a tertiary care hospital which is one of the centers working for the urban slum population and rural population in Visakhapatnam offering OPD, IP, and emergency services, with the following objectives.

1. To understand the health seeking behavior among attendees at the tertiary care hospital.
2. To assess the healthcare utilization and financing of the attendees in the last year.
3. To know the perception of the participants about their health currently and in the last year.

## Methodology

**Study design:** It was a descriptive cross-sectional study.

**Study setting:** A tertiary care hospital in Visakhapatnam.

**Study population:** Attendees of a tertiary care hospital in Visakhapatnam who were more than 18 years of age.

**Sample size calculation:** By using the below formula sample size was calculated.

$$\frac{\frac{z^2 \times p(1-p)}{e^2}}{1 + \left( \frac{z^2 \times p(1-p)}{e^2 N} \right)}$$

n= 384 is the minimum sample required for the study, we included 400 participants.

**Sampling method** Individuals visiting to tertiary care hospital were selected by systematic random sampling method.

**Data collection:** Daily nearly 400 patients visit the respective OPD. Every 5th person visiting to adult OPD was selected. A predesigned and pretested questionnaire was used to collect the required data from the participants. The questionnaire consisted of 4 sections which included Socio-demographic data, perception about their health currently and for the last 1 year, Health seeking related questions, and Healthcare utilization and financing in the last year.

**Duration of the study:** From August 2021 to September 2021(2 months).

### Inclusion criteria:

Adults (more than 18 years of age) attending and residing near tertiary care hospital in Visakhapatnam.

### Exclusion criteria

Individuals not willing to take part in the study and very sick individuals.

**Data Analysis:** Data entry was done by using MS excel and data analysis was done by using Statistical Package for Social Sciences (SPSS) version 21. Frequencies and percentages were used to convey descriptive statistics.95% confidence intervals were calculated.

## Results

The Socio-demographic profile of the study population was shown in Table 1. Majority (57.25%) of the participants were females. The most common age group visited to tertiary care hospital was between 20-30 years age group (55.75%). 78.5% of participants were Hindus and 79.25% were married. 83.25% of participants living in nuclear family. According to modified kuppuswamy classification 35.8% belonged to Class IV and 20.5% to Class V.

Health-seeking behavior of the participants is shown in Table 2. 64.25% did not suffer from any serious diseases in the last 1 year and the main reason behind the serious disease was believed to be heredity (65.74%). Out of diseased persons, 93.71% took the treatment, while 6.29% haven't taken any treatment for the disease. The main reasons for not taking the treatment were lack of knowledge (28.3%) and lack of nearby health facilities (20.7%).

Health care utilization of the participants is shown in Table 3. 47.5% of participants availed Government health facilities for their illness and the reason for choosing a particular health facility was affordability (31%) and less distance from home (23.8%). Only 14.8% of the attendees visited the health facility immediately on the day of onset. 56.5% of participants took 15-30 minutes to reach the nearest health facility.

Health care financing of the participants is shown in Table 4. 51.8% of the attendees used their funds/savings for treatment. Only 39.5% of the participants had health insurance. 21.2% availed of health services free of cost. More than 3/4th of their income is insufficient to meet the health expenditure.

Perception about their health currently and for the last 1 year based on Likert scale was shown in Table 5. 62% of them thought that they are having better health currently while 44.5% had good health in the past year.

**Table no.1: Socio-demographic profile of the study population (n=400)**

Variables		Frequency	Percentage (%)
Gender	Male	171	42.8
	Female	229	57.3
Age (in years)	<20	29	7.3
	21-30	223	55.8
	31-40	66	16.5
	41-50	42	10.5
	51-60	21	5.3
	>60	19	4.8
Religion	Muslim	40	10
	Hindu	313	78.3
	Christian	47	11.8
Marital status	Married	319	79.8
	Unmarried	61	15.3
	Divorcee	4	1
	Widow/Widower	16	4
Education	Illiterates	47	11.8
	Primary school	14	3.5
	Middle school	10	2.5
	High school	33	8.3
	Intermediate	214	53.5
	Degree	82	20.5
Socioeconomic class	Class I	27	6.8
	Class II	34	8.5
	Class III	114	28.5
	Class IV	143	35.8
	Class V	82	20.5
Type of family	Nuclear	333	83.3
	Joint	14	3.5
	3-Generation family	53	13.3

**Table no 2: Distribution of participants according to their health seeking behavior.**

Variables	Frequency	Percentage [ 95% CI]
<b>Suffering from serious diseases in last 1year (n=400)</b>		
Yes	143	35.8[31.1-40.4]
<b>Reason for disease (n=143)</b>		
Man Made	40	28.0 [20.6-35.3]
Seasonal	9	6.3 [2.3-10.3]
Hereditary	94	65.7 [58-73.5]
<b>Treatment seeking behavior (n=143)</b>		
Yes	90	93.7 [55-70.9]
<b>Reason for not taking treatment (n=53)</b>		
Lack of knowledge	15	28.3 [16.2-40.4]
Lack of money	18	34 [21.2-46.7]
Lack of nearby health facility	11	20.7[9.8-31.7]
Self-Limiting	9	17 [6.9-27.1]

**Table no 3: Distribution of participants according to their health care utilization(n=400).**

Variables	Frequency	Percentage [ 95% CI]
<b>Time gap between visit to the health facility and onset of symptoms</b>		
Immediately	59	14.8 [11.3-18.2]
<3 days	215	53.8 [48.9-58.6]
>3 days	126	31.5 [26.9-36.1]
<b>Source of availing health facility</b>		
Government	190	47.5 [42.6-52.4]
Private	177	44.3 [39.4-49.1]
Quack	33	8.3 [5.6-10.9]
<b>Reason to choose particular health facility</b>		
Trust over the provider of the facility	28	7.0 [4.5-9.5]
Near to home	95	23.8 [19.6-27.9]
Affordable	124	31.0 [26.5-35.5]
Staff availability & Co-operation	23	5.8 [3.5-8]
Good quality treatment	56	14.0 [10.6-17.4]
Less time consuming	41	10.3 [7.3-13.2]
Health Centre far away	33	8.3 [5.6-10.9]
<b>Time taken to reach the nearest health facility</b>		
<15min	106	26.5 [22.2-30.8]
15min-30min	226	56.5 [51.6-61.4]
30min-60min	45	11.3 [8.2-14.3]
>60min	23	5.8 [3.5-8]
<b>Way to reach health facility</b>		
Walking	47	11.8 [8.6-14.9]
Public transport services (Bus, taxi, train)	215	53.8 [48.9-58.6]
Own vehicle	85	21.3 [17.2-25.3]
Bicycle	33	8.3 [5.6-10.9]
Rented vehicle	20	5 [2.9-7.1]

**Table no 4: Distribution of participants according to their health care financing (n=400)**

Variables	Frequency	Percentage [95% CI]
<b>Source of health care finance</b>		
Income of other house hold member	150	51.8 [46.9-56.6]
Money lender	34	37.5 [32.8-42.2]
Pawned assets or property	9	8.5 [5.8-11.2]
<b>Having health Insurance</b>		
Yes	158	39.5 [34.7-44.3]
<b>Money spent on health facilities for treatment (in rupees)</b>		
Free of cost	85	21.23 [17.2-25.3]
<1000	291	72.8 [68.4-77.1]
1001-2000	70	17.5 [13.8-21.2]
2001-3000	8	2 [0.6-3.4]
>3000	16	4 [2.1-5.9]
<b>Sickness affecting the income of house hold</b>		
Yes	293	73.25 [68.9-77.6]

**Table No. 5 Perception about their own health currently and for last 1 year (n=400)**

Perception	Likert's Scale				
	Poor	Average	Good	Better	Excellent
Current year	21(5.25%)	40(10%)	83(20.75%)	248(62%)	8(2%)
Past 1 year	16(4%)	61(15.25%)	178(44.5%)	107(26.75%)	38(9.5%)

### Discussion

According to Saswatkumar Pradhan, 34.20% of sample households visit government hospitals/ doctors during any illness, 29.5 % rely on quack, 18.5% visit gunia (priest), 13.7% visit village medicine men, only 4.1% visit private clinic due to low socio-economic status.<sup>2</sup> In a study by Parvin N. Yerpude et al.,<sup>18</sup> among those who received treatment, 48.30% got treatment in the public sector while 30.61% got treatment in the private sector and Somen Kumar Pradhan<sup>22</sup> study 41.72% sought care in private hospitals while 33.11% sought for government health care facilities. Shwetha studied health health-seeking behaviour of migrant workers in Bangalore city found that 59% of them preferred home remedies as a priority for their illness & 41% preferred private hospitals for major illnesses. Around 52.9% of study subjects waited for more than 3 days before seeking health care<sup>11</sup> whereas in this study only 14.8% visited the hospital immediately on the day of onset may be due to fear of getting an infection during the Covid-19 pandemic.

In this study, 47.5% of attendees attended Government health facilities for treatment because it was free of cost and near to home whereas a study by Lakhwinder P Singh and Shiv D Gupta<sup>7</sup> found that the problems being faced by the people while utilizing government health care services were inaccessibility due to lack of transportation, the unsympathetic attitude of the staff dispensing the health services, and shortage or nonavailability of medicines. In this study, 8.3 % were approached quacks for their illness as they are easily available and quick healing as in Syed Azizur Rahman's study where traditional healers who are still very popular.<sup>17</sup>

In this study, 47.5% of attendees attended Government health facilities for treatment because it was free of cost and Savitha S et al., studied the impact of Sampoorna Suraksha Programme, a micro health insurance scheme on the health seeking behavior of households during illness in Karnata. In this study, due to reduction in financial barrier, the insured individuals opted to seek care at private hospitals

than public hospitals due. Equity in health seeking behaviour was observed among the individuals who had insurance<sup>23</sup>. While in this study 51.8% of the attendees were used their personal funds/savings for treatment. Only 39.5% of the participants had health insurance and more than 3/4th of their income is insufficient to meet the health expenditure.

### Conclusion

Nearly half of the attendees preferred government health facilities for their illness but only a few of them visited health facilities immediately on the day of onset. Half of them used their savings for their treatment expenses but it burdened their income. There is a need to address their perception about their health. Awareness programs should be conducted to improve their knowledge regarding good health-seeking behavior. The community should build trust in health facilities for good healthcare utilization.

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**Conflict of interest** None declared.

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# Assessment of Cognitive, Attitudinal and Behavioural Competence of Anganwadi Workers Regarding Integrated Child Development Services (ICDS) Services in District Dehradun, Uttarakhand

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## Abstract

**Background:** The dietary and health condition of ICDS recipients has been the focus of the majority of research. Given that AWW are the primary resource persons, there has been less emphasis placed on assessing their knowledge and understanding of the suggested ICDS programs.

**Objective:** Assessment of cognitive, attitudinal and behavioral competence of Anganwadi workers regarding ICDS services in district Dehradun, Uttarakhand

**Methods:** Using the convenience sample method, this cross-sectional study was carried out over the course of one month at AWC's situated within the Himalayan Institute of Medical Sciences (HIMS), Dehradun's field practice region.

**Conclusion:** Out of 24 AWWs, 79.2% had adequate knowledge, 83.4% had positive attitude and 75% had good practices regarding ICDS services.

**Key words:** Integrated Child Development Services (ICDS), Cognitive, Attitudinal, behavioral competence, Anganwadi Workers (AWW)

## Introduction

India, marked by significant regional disparities, deep-rooted social hierarchy, and a rich multicultural

tapestry, grapples with substantial health and nutrition challenges.<sup>[1]</sup> Malnutrition, particularly under-nutrition, has been identified as a 'silent emergency' by United Nations Children's fund

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(UNICEF), highlighting the critical issue as it reflects the state of maternal health services. [2] Globally, nearly half of the deaths among children under five years of age in 2022 were linked to undernutrition, underscoring the severe impact of poor nutrition on child mortality. In India, the National Family Health Survey (NFHS-5) reports a mortality rate of 41.9 per thousand live births for children under five, stressing the urgent need for effective nutritional and health interventions.[3]

The Integrated Child Development Services (ICDS) scheme, launched on October 2, 1975, stands as one of the world's largest programs aimed at the holistic development of children. [4] Over the past 25 years, the scheme has expanded significantly, now reaching a population of roughly 7 percent of India's one billion people. [5] In Uttarakhand, child development projects were launched in 1978-79 in the three development blocks of Chakrata, Kirtinagar, and Dharchula. Today, the state has expanded to 105 child development projects, including 97 rural and 8 urban projects, across 95 development blocks in all 13 districts. [6]

The Integrated Child Development Services (ICDS) focuses on vulnerable demographics including children under six years of age, pregnant and lactating mothers, and women between fifteen and forty-five years old. These groups are at high risk for malnutrition and associated health complications. ICDS's mission is to disrupt the cycle of malnutrition, illness, impaired learning capabilities, and mortality by offering pre-school education and primary healthcare. [7] These initiatives are now integrated into the Saksham Anganwadi and Poshan 2.0 programs, part of the Integrated Nutrition Support Programme during the 15th Finance Commission cycle from 2021-22 to 2025-26. [8] However, according to the National Family Health Survey-5 (NFHS-5), services from an Anganwadi reach just over half (50.3%) of children under six, highlighting the need for expanded coverage and effectiveness. This could involve improving infrastructure, increasing the number of centers, training Anganwadi workers, and ensuring better implementation of existing programs to address the needs of all eligible children. [9]

In Uttarakhand, where child and maternal health indicators are notably poor, studying the cognitive, attitudinal, and behavioral competence of AWWs is

essential to enhance service quality, identify specific training needs, and ensure effective implementation of child health and nutrition programs. This assessment helps improve outcomes for children and optimize the overall impact of Anganwadi services in the region.

**Aim:** Assessment of cognitive, attitudinal and behavioural competence of anganwadi workers regarding ICDS services in district Dehradun, Uttarakhand

### Objectives:

#### Primary objective:

1. To assess the cognitive, attitudinal and behavioural competence of anganwadi workers regarding ICDS services.

#### Secondary Objectives:

1. To delineate sociodemographic profile of AWWs
2. To assess the infrastructure and general environmental conditions of Anganwadi Centers (AWCs).

### Material and Methods

**Study Place:** This study was conducted at Anganwadi centers located within the field practice area of Himalayan Institute of Medical Sciences (HIMS), Dehradun.

**Study Design:** Cross sectional study

**Study Period:** Onemonth, from May, 2023 to June, 2023.

**Inclusion Criteria:** The study focused on Anganwadi centers (AWCs) that were easily accessible for approach.

**Exclusion Criteria:** The study excluded Anganwadi centers that were closed after two consecutive visits and Anganwadi workers (AWWs) who did not provide consent to participate.

**Sampling Method:** convenience sampling method

**Sampling Procedure:** Two centers fall under the Department of Community Medicine at the Himalayan Institute of Medical Sciences: The Rural Health Training Center (RHTC) and the Urban Health Training Center (UHTC), covering the population of

46,000 and 54,000 respectively. RHTC comprises six villages with 26 Anganwadi centers, while UHTC covers 18 wards with 43 Anganwadi centers.

For the study, 19 Anganwadi centers were selected from UHTC and 5 from RHTC due to their proximity to our center. Repeated attempts were made for Anganwadi centers that were closed during the initial visit. If a center remained closed after two consecutive attempts, it was excluded from the study. In such cases, the next nearest Anganwadi center was selected for inclusion.

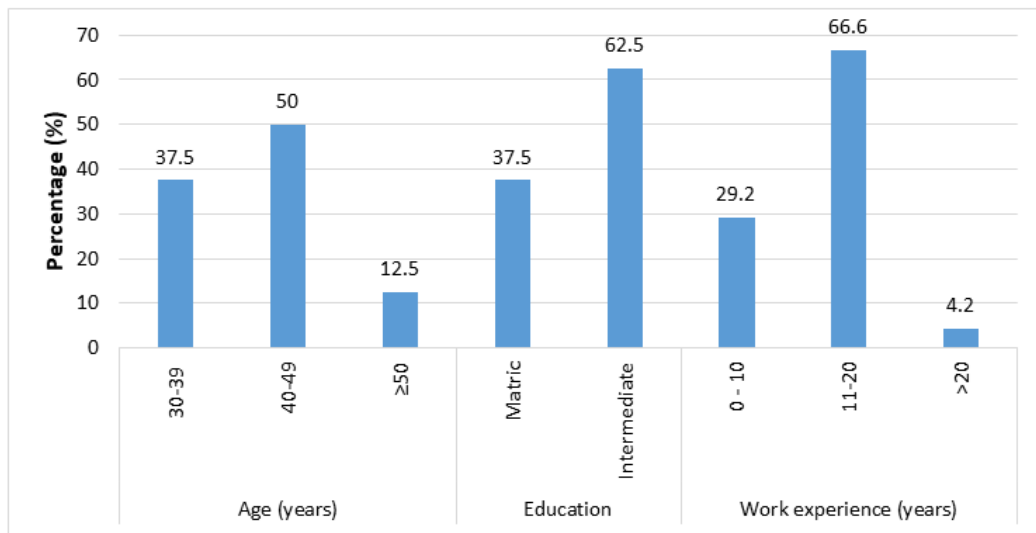
**Data Collection Tool:** The study involved administering a pre-designed, semi-structured, and validated questionnaire following written informed

consent. For the knowledge section, participants received one point for each correct answer and zero points for incorrect ones. A score of more than 50% was considered indicative of adequate knowledge. The same scoring method was applied to assess the attitudes and practices of AWWs regarding the services provided by ICDS.

**Ethical Clearance:** Ethical approval was secured from the Institute Ethical Committee prior to the commencement of the study.

**Data Analysis:** The collected data was entered into an MS Excel spreadsheet and analyzed using SPSS version 20.

**Results**



**Figure 1: Socio-demographic profile of AWW's:**

Figure 1 illustrates that the largest proportion (50%) of Anganwadi workers (AWWs) belong to the age group of 40-49 years. Additionally, 62.5% of AWWs had completed their education up to the 12th grade, while 66.6% reported having work experience as an AWW for a duration ranging from 11 to 20 years.

**Table no. 1: Knowledge of AWWs regarding ICDS**

S.N	Questions asked	*Correct Responses (N=24)	Percentage (%)
1.	What are the services being under the ICDS?	22	91.7

2.	How many beneficiaries come under the ICDS?	24	100
3.	Growth monitoring should start from at what age and its purpose?	24	100
4.	Flattened growth line on the growth chart means?	17	70.8
5.	What kind of services pregnant women receives under ICDS?	16	66.6

Continue.....

6.	What are the services for adolescent's girls?	7	29.2
7.	What are the materials available for PSE?	24	100
8.	What is the average weight of 1 year child?	15	62.2
9.	Exclusive breastfeeding should be continued till?	19	79.2
10.	What are the daily activities you performed at AWC?	13	54.2
11.	What are the medicine available in AWCs?	14	58.3
12.	What kind of diet should be given during diarrhea?	19	79.2
13.	ORS should be discarded if not used completely after?	16	66.7
14.	What is the gap between 2 successive doses of DPT vaccine?	19	79.2
15.	Measles vaccine given at what age?	22	91.7
16.	First dose of vitamin A given at?	23	95.8
17.	Minimum number of Tab. Of Iron & folic acid that a pregnant women should consume	21	87.5

\*Multiple response

Table 1 demonstrates that, among AWWs, 91.7% correctly identified the services offered, 100% of beneficiaries enrolled in ICDS, the appropriate age to begin growth monitoring (100%), its goal, and the significance of the flattened growth line on the growth chart. The percentage of AWWs who were aware of the services available for pregnant women was roughly 66.6%; however, only 29.2% of them were aware of the programs offered for adolescent girls. The availability of PSE materials was known to nearly 100% of people. Regarding the everyday tasks carried out in the Anganwadi Centers, 54.2% of AWW are correctly informed, and 58.3% are aware of the availability of medications in AWCs. A little over 79.2% of AWWs knew what kind of food should be consumed during diarrhea and how long (66.7%) ORS should be kept in storage. Out of 24 AWWs, around 62.2% were correctly informed on the typical weight of an infant, and 79.2% had a great understanding of exclusive breastfeeding. Nearly all AWWs were aware of the proper measles vaccination age (100%), vitamin A dosage (95.8%), and interval between two DPT vaccination doses (79.2%). About 87.5% of AWWs were correctly informed about the recommended daily allowance of iron folic acid (IFA) for expectant mothers. The range of correct knowledge scores is 7 to 17, with an average of  $14.25 \pm 3.74$  SD.

**Table 2: Attitude of AWWs regarding ICDS**

Variables	Correct responses (N=24)	Percentage (%)
In PIH, can we advise only rocksalt?	17	70.84%
Is it absolutely necessary to give vitamin A supplements to under 5 children?	24	100%
Is it absolutely necessary to give ORS after each loose stool?	22	91.6%
Is adolescent marriage justifiable?	21	87.5%
Is it absolutely necessary to maintain the growth chart of a child?	24	100%

Table 2 reveals that, of the 24 AWWs, 17 (70.84%) had a positive attitude regarding the following: the need to maintain a child's growth chart (100%), the importance of giving ORS in cases of diarrhea (91.6%), the effect of rocksalt intake in pregnancy-induced hypertension (PIH), and the marriage age of adolescents (87.5%).

**Table 3: Practices of AWWs regarding ICDS**

Variables	Correct responses (N=24)	Percentage (%)
Do you maintain a record of immunization? (check)	23	95.8%
Do you provide prophylaxis against blindness and anemia? (check)	23	95.8%
Do you maintain the Anganwadi survey register? (check)	20	83.3%
Do you maintain a register of services for pregnant women and lactating mothers? (check)	15	62.5%
Do you maintain a register of supplementary nutrition and PSE for children? (check)	16	66.7%
Do you maintain a birth and death register? (check)	12	50%
Do you maintain a medicine distribution register? (check)	11	45.8%
Do you maintain mahila mandal register? (check)	15	62.5%
Do you maintain growth chart register? (check)	17	70.8%

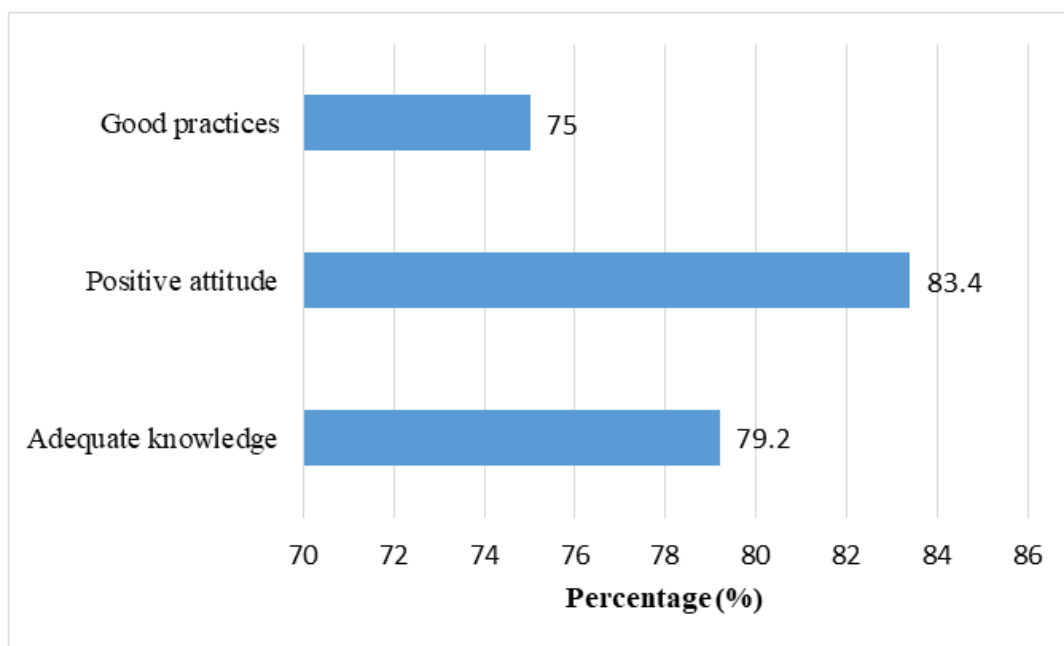
Table 3 demonstrates that 23 AWWs (95.8%) kept immunization records, survey registers (83.3%),

registrations for services for expectant mothers and breastfeeding women (62.5%), and prophylactic measures against anemia and blindness (95.6%). A growth record was kept by 70.8% of AWWs, a mahila mandal registration by 62.5%, a medicine distribution register by 45.8%, a birth and death register by 66.66%, and a supplemental nutrition and pre-school education (PSE) register by roughly 66.7% of the AWWs.

**Table no. 4: Infrastructural facilities of AWCs**

Variables	Yes (%)
Adequate ventilation	18 (75)
Toilet	24(100)
Ownership -rented	24(100)
Type of building -pucca	24(100)
Electricity supply	24 (100)
Available drinking water?	22 (91)
Open space area	19 (79.6)
Separate cooking room	0
Separate storage area	0
Different types of charts and posters	23 (95.8)
Almirah	1(4.2)
Weighing machine	18 (75)
Chairs	8 (33.3)
Table	8 (33.3)

According to Table No. 4, AWCs with sufficient ventilation comprised 75% of the total. About 91 per cent of the 24 AWCs had access to drinking water, while the remaining 24 had rented pucca buildings with electricity supplies. While open space is present in about 79.6% of AWCs, none of them feature separate kitchens or storage areas. The proportion of charts and posters in the AWCs was about 95.8%. Out of all the AWCs, only 4.2% had an almirah, 75% had a weighing machine, and 33.3% had tables and chairs.



**Figure 2: Knowledge, attitude and practices level of AWWs regarding ICDS services**

Figure 2 shows that out of 24 AWWs, 79.2% had adequate knowledge, 83.4% had positive attitude and 75% had good practices regarding ICDS services.

### Discussion

According to this survey, 50% of AWWs are between the ages of 40 and 49. These results are in line with research by Thakur et al. [10], Khobragade A W et al [11], Bhattarai P et al [12]. Regarding schooling, the majority of AWWs (62.5%) had completed their 12th grade. These results are in line with research by Kumar et al. [13], who also found that a larger number of AWWs (92%) passed their 12th grade.

In terms of job experience, the majority of AWWs (66.6%) had between 11 and 20 years of experience, which was consistent with the findings of Khobragade A W et al [11] study. In terms of knowledge, 79.2 percent of AWWs were sufficiently informed on ICDS services. Every AWW was accurately aware of the beneficiaries under ICDS, demonstrating their understanding of the people they assist. This result is consistent with the research by Thakur et al. [10], which also discovered that AWW had satisfactory scheme knowledge (98.67%).

In our study, 100% of AWWs acknowledged the significance of beginning growth monitoring to track a child's progress, demonstrating AWWs' strong

commitment to the practice. The discrepancy between our study's findings and those reported by Thakur et al. [10], where only 56.67% of AWWs had satisfactory knowledge about growth monitoring, suggests considerable variation in training effectiveness or knowledge retention among AWWs in different regions or at different times. This gap indicates potential challenges in standardizing training across all regions where ICDS is implemented.

The vast majority of AWWs (79.2%) were correctly informed on the need of exclusive breastfeeding for a child's growth and well-being, approximately similar to study conducted by Mahajan et al [14] (81%). Critical areas such as knowing when to start the measles vaccination (91.7%) and how many Iron Folic Acid (IFA) tablets a pregnant woman should take (87.5%) were demonstrated by AWWs, whose proficiency in these areas was comparable to that of Jena et al [15] study (73.3%). While Jena P et al. discovered a relatively wide deviation in the results (23.3%), the majority of AWWs (70.8%) properly comprehended the meaning of the flattened line on the growth chart, which is important for spotting future growth concerns. [17] This variation might be attributed to differences in training quality, regional education programs, or methodologies used in the studies.

In a study conducted by Thakur et al. [10], all AWWs had satisfactory knowledge about the services

available for adolescent girls under the Kishori Shakti Yojna (under BPL), but only a low percentage (29.2%) of AWWs possessed accurate knowledge about services provided to adolescent girls, indicating a need for further education and training in addressing the unique needs and challenges faced by adolescent girls.

It appears that more work has to be done to raise awareness among the remaining AWWs, as only almost two-thirds (66.6%) of them showed knowledge regarding services for pregnant women. A sizable percentage of AWWs may benefit from extra training or support in these areas, as seen by the correct knowledge reported at 54.2% and 58.3%, respectively, about the daily tasks carried out at Anganwadi Centers and the availability of medicines.

In this study, 83.4% of participants had a positive view about ICDS services, with regards to vitamin A supplements to children under five being 100% and rocksalt consumption in pregnancy-induced hypertension at 70.84%. upholding the growth chart at 100%, providing ORS after every stool at 91.6%, and 87.5% for teenage marriage. Similar research was done and nearly identical results were reported by Thakur et al.<sup>[10]</sup>

In terms of practices, 75% of AWWs had ICDS services that met good practices standards. According to the research, 95.8% of AWWs keep immunization records; 83.3%) register anganwadi surveys; 62.5%) register services for expectant mothers and lactating women; 66.7%) registers for supplemental nutrition and Pre-School Education (PSE); 50% register births and deaths; and 45.8% registers for the distribution of medications. The results are in line with the Joshi et al.<sup>[16]</sup> study. In our study, while the majority of AWWs demonstrate good practices in delivering ICDS services, there are still areas for enhancement, particularly in record-keeping and register maintenance.

In 95.8% of the AWCs, there were charts and posters, and 75% of the AWCs had enough ventilation. AWCs had electricity and toilets in 100% of cases, drinking water in 91%, and open spaces in 79.6% of cases. Of the AWCs, only 4.2% had an almirah, and 75% had a weighing machine. One third had tables and chairs. Not a single AWC has a separate

kitchen or storage space. All of the AWCs were Pucca-type and rented. Our study's infrastructural and environmental findings are remarkably similar to those of studies conducted by Thakur et al.<sup>[10]</sup>, Baseer et al.<sup>[17]</sup> and Balinga et al.<sup>[18]</sup>. In our study, while AWCs generally have basic infrastructure and facilities, there are areas for improvement to create more conducive environments for delivering ICDS services.

## Conclusion

AWWs in India access training through ICDS, NIPCCD, state programs, and online modules. Strengthening these programs requires enhanced, practical curricula, continuous training, interactive methods, increased tech use, mentorship, robust feedback, and better funding to improve effectiveness and support for child health and development.

**Conflict of interest:** Nil.

**Ethical Clearance:** Ref No .HIMNS/MC/CM2023/142 Dated:24 June 2023 from Swami Himalyan University.

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## Recommendations:

1. Infrastructure and Supplies Strengthening
2. Incentives and Motivation
3. Continuous Training and Orientation
4. Community Participation and Public Awareness
5. Empowerment of Anganwadi Workers
6. Targeted Training and Support Programs

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# Preferred Learning Styles and Perception Regarding Present Curriculum among MBBS Students of a Peripheral Medical College in West Bengal, India

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## Abstract

**Background:** Learning style of an individual refers to the method through which one learns the best. There has been a paradigm shift in medical education in recent years.

**Objectives:** To identify preferred learning styles among MBBS students of a tertiary Medical College in West Bengal, India and to assess their perception regarding present curriculum.

**Methodology:** An observational, analytical, cross-sectional study was conducted among the undergraduate medical students of Bankura Sammilani Medical College using VARK questionnaire (version 8.01) to identify preferred learning styles of the students. The questionnaire also included a set of 11 items to assess the perception of students about the present curriculum system using a 5-point Likert scale.

**Results:** Majority (83.5%) of the students preferred a single mode of learning (unimodal) style. The most preferred unimodal style of learning was Kinesthetic (44.7%). Most of the students agreed that the current method of teaching was satisfactory.

**Conclusions:** Exploring different learning styles could potentially be used in the curriculum so that instructors could plan appropriate teaching learning method according to their learning needs. New medical curriculum was reported as satisfactory by the students.

**Key-words:** Learning Styles; Unimodal; Kinaesthetic VARK; Medical students

## Introduction

Medical education is a dynamic process where both students and facilitators should always update

themselves. There are several challenges the medical students face such as acquiring a large amount of knowledge within a limited time period in a manner so that it is effectively retained, interpreted and

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remembered by the students. This has resulted in important changes in the field of medical education, with a shift from conventional teaching to the use of problem-based, student-centered learning and interactive. Most medical curricula have implemented creative methods of teaching and learning to changeable degrees.<sup>1</sup> It has been argued that facts of learning styles can be helpful for both facilitators and students, in that the facilitators can choose a proper teaching-learning style to associate with the learning styles of students alike, students with knowledge of their learning styles could be empowered to identify and use the techniques of learning best right to their individual styles, resulting in better educational satisfaction.<sup>2,3</sup>

VARK (Visual, Aural, Reading and Kinaesthetic) questionnaire has been specifically designed to identify the learning styles as it can identify whether a student has a strong learning preference or whether the student is a "flexible" learner who can take in information from multiple methods. Students have different learning style preferences in the ways they take in and process the information, so the students who have a combination of learning preferences are multimodal, whereas those who prefer only one learning method have a single-mode preference. Students with a visual learning preference prefer to take in and give information holistically and often draw pictures and diagrams to explain concepts. Students with an aural learning preference prefer to listen and talk when learning. Students with a read-write learning preference prefer lists, handouts, and textbooks to understand new material while students with a kinesthetic learning prefer hands-on approach, including trial and error, real-life examples, and application of new material.<sup>4</sup>

Since there are few published data on learning styles among undergraduates in medical colleges in eastern part of India, we decided to undertake this project to identify the learning styles of Phase II & Phase III MBBS students in one of the peripheral medical colleges in eastern India along with their perception about the present curriculum system.

#### **Objectives:**

This study was conducted with the following objectives: (i) To identify preferred learning styles among MBBS students of a peripheral Medical

College in West Bengal, and (ii) to assess their perception regarding present curriculum

### **Methodology**

An observational, analytical, cross-sectional study was conducted among the undergraduate medical students of Bankura Sammilani Medical College, West Bengal during the months of Mar-June of 2023 to assess the preference of learning styles and their perception about the present curriculum system. Students under new curriculum, as proposed by National Medical Commission (NMC) and completing at least one year of MBBS course were included in our study as study participants. All students fulfilling the inclusion criteria, and approachable on the days of data collection were included in the study. The final sample size was 188. First, the students were explained the purpose and procedure of the study. After receiving informed written consent from each of them, data were collected using a pre-designed, pre-tested, structured, self-administered questionnaire. The questionnaire included different socio-demographic variables (age, gender, religion, caste, parents' education and occupation, socioeconomic status, residence etc.), VARK questionnaire (version 8.01) to identify preferred learning styles of the students.<sup>5</sup> The questionnaire also included a set of 11 items to assess the perception of students about the present curriculum system using a 5-point Likert scale (responses ranging from strongly disagree to strongly agree).<sup>6</sup> Data entry and analysis were done on IBM Statistical Package for Social Sciences trial version.

### **Results**

Majority of the students (73.4%) participating in this study were from 5<sup>th</sup> semester, while the rest were 3<sup>rd</sup> semester students. The mean and median age of the students were  $21.9 \pm 0.082$  years and 22 (IQR = 2) years respectively. The age of the students ranged between 19 and 25 years, but did not follow normal distribution. About 60.4% students were male. Most of the students (86.2%) followed Hinduism, while the rest followed Islam (10.6%), Christian (0.5%) and other religions (2.7%). Based on caste, 63.8% belonged to general caste, 16% SC, 4.8% ST and 15.4% OBC. Most of these students (85.1%) were from nuclear families. Mothers of 55.9% students and

fathers of 80.9% students completed education up to graduation or above. The mothers of 80.3% students were homemaker. Based on BG Prasad’s SES scale, updated for August 2023, 68.1% were class I, 16% class II, 8% class III, 6.9% class IV and 1.1% were class V. More than half (52.1%) students had their schooling in English medium, while 41% had Bengali medium. The permanent residency of 61.2% students were in urban areas. More than two-third (67.6%) students stayed in hostel, while 22.3% stayed as paying guest, 8.5% stayed in their own home, during the time of their undergraduate course.

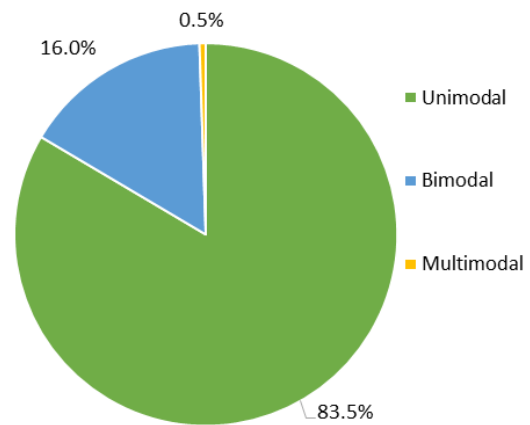
Based on VARK Questionnaire responses it was found that majority (83.5%) of the students preferred a single mode of learning (unimodal) style, while 16% students preferred bimodal and 0.5% students preferred multimodal style of learning [Figure 1]. The most preferred unimodal style of learning was Kinesthetic (44.7%), followed by Aural (29.3%), Visual (6.9%) and Read/write (2.6%). Aural and Kinesthetic were the most preferred bimodal style of learning (6.4%), followed by Visual and Kinesthetic (4.8%), Visual and Aural (2.6%), Visual and Read/write (1.1%) and Aural and Read/write (1.1%). The only multimodal style of learning preferred by the students included Aural and Read/write and Kinesthetic altogether [Table 1].

When the perception of the students about the present curriculum was explored, it was found that majority of the students *agreed* that the current method of teaching was satisfactory, there was good interaction between the students and teacher during the class, the multiple mode of assessment would help the students to excel, the laboratories in different departments give the students sufficient materials for learning and experimenting, the self-directed leaning (SDL) is a very effective approach for learning, the

viva voce system is an effective method for evaluation and the semester system is satisfactory. Majority of students also *strongly agreed* that the lectures should be accompanied by multimedia tool such as animation and videos, problem based learning (PBL) should be incorporated in the learning process, small group discussions (SGD) give better understanding regarding the subjects and that there is huge academic workload faced by the students [Table 3].

**Table 1. Preferred mode of learning (N=188)**

Mode of learning	Frequency (%)
Visual (V)	13 (6.9)
Aural (A)	55 (29.3)
Read/write (R)	5 (2.6)
Kinesthetic (K)	84 (44.7)
Visual and Aural (VA)	5 (2.6)
Visual and Read/write (VR)	2 (1.1)
Visual and Kinesthetic (VK)	9 (4.8)
Aural and Read/write (AR)	2 (1.1)
Aural and Kinesthetic (AK)	12 (6.4)
Aural and Read/write and Kinesthetic (ARK)	1 (0.5)
Total	188 (100.0)



**Figure 1. Pie chart showing preferred mode of learning.**

**Table 2. Relationship between preferred learning style and different variables (N=188)**

Particulars	Variables	Unimodal style	Multimodal style
		Frequency (%)	Frequency (%)
Semester	5 <sup>th</sup> semester	114 (82.6)	24 (17.4)
	7 <sup>th</sup> semester	43 (86.0)	7 (14.0)
Age group	21 years and below	50 (78.1)	14 (21.9%)
	22 years and above	107 (86.3)	17 (13.7)

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Sex	Male	97(85.1)	17(14.9)
	Female	60(81.1)	14(18.9)
Religion	Hindu	136 (84)	26 (16)
	Muslim	17 (85)	3 (15)
	Christian	0(0.00)	1(100%)
	Others	4(80)	1(20)
Caste	General	94 (78.3)	26 (21.7)
	Scheduled Caste	28 (93.3)	2 (6.7)
	Scheduled Tribe	8 (88.9)	1 (11.1)
	Other Backward Class	27 (93.1)	2 (6.9)
Family Type	Nuclear	132 (82.5)	28(17.5)
	Joint	25(89.3)	3 (10.7)
Medium of school	Bengali	69 (89.6)	8 (10.4)
	English	77 (78.6)	21 (21.4)
	Hindi	9(81.8)	2(18.2)
	Others	2(100.0)	0(0.0)
Permanent Residence	Urban	94 (81.7)	21 (18.3)
	Rural	63 (86.3)	10 (13.7)
Current Residence	Hostel	108 (85.0)	19 (15.0)
	Paying guest	34 (81.0)	8 (19.0)
	Own house	15(78.95)	4 (21.05)

Table 3. Perception of students about curriculum system (N=188)

Questions	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
	Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)
1. Current method of teaching is satisfactory	13 (6.9)	31 (16.5)	8 (4.3)	111 (59.0)	25 (13.3)
2. There is good interaction between students and teachers during the classes	8 (4.3)	26 (13.8)	8 (4.3)	118 (62.8)	28 (14.9)
3. The multiple mode of assessment helps the students to excel	4 (2.1)	8 (4.3)	5 (2.7)	117 (62.23)	54 (28.7)
4. Lectures should be accompanied with multimedia tool such as animation and video	1 (0.5)	2 (1.1)	2 (1.1)	50 (26.6)	133 (73.7)
5. The laboratory gives sufficient lab materials for experiments	21 (11.2)	45 (23.9)	7 (3.7)	86 (45.7)	29 (15.4)
6. Problem based learning should be applied in the learning process	0 (0.0)	0 (0.0)	2 (1.1)	68 (36.2)	118 (62.8)
7. Small group discussion gives better understanding regarding the subject	3 (1.6)	4 (2.1)	7 (3.7)	83 (44.1)	91 (48.4)
8. Self-directed learning is a very effective method of learning	4 (2.1)	21 (11.2)	10 (5.3)	93 (49.5)	60 (31.9)
9. The viva voce system is effective	4 (2.1)	4 (2.1)	9 (4.8)	104 (55.3)	67 (35.6)
10. There is huge academic workload	3 (1.6)	18 (9.6)	3 (1.6)	67 (35.6)	97 (51.6)
11. Satisfied with the semester system	16 (8.5)	19 (10.1)	11 (5.9)	117 (62.2)	25 (13.3)

## Discussion

This study was conducted among 188 MBBS students of Bankura Sammilani Medical College to assess their preferred learning style and to assess the perception of students about the present curriculum system.

In this study majority (83.5%) of the students preferred unimodal style of learning. The most preferred unimodal style of learning was Kinesthetic (44.7%) where as Aural and Kinesthetic were the most preferred bimodal style of learning (6.4%). The only multimodal style of learning preferred by the students included Aural and Read/write and Kinesthetical together (0.5%). A survey from Iran, by Peyman H et. al. found that about 58.2% of the study participants preferred to use multiple mode of learning styles and 41.8% preferred only one learning style. Around 27.6%, 13.4% and 17.0% preferred quad-modal, tri-modal and bi-modal learning styles respectively.<sup>[7]</sup> A study done by Liu and Ginther on students of America found that around 40% percent preferred visual style, 20-30% preferred aural style and 30-40% preferred either reading/writing and kinesthetic or their combination.<sup>[8]</sup> In a study by Husmann PR et. al. on anatomy students (2018) in the USA found that most common mode of learning style was kinesthetic.<sup>[9]</sup> A study by Habibpour et al (2016), on medical students in Iran found that reading-writing was most common learning style<sup>[10]</sup>.

In this study 49.5% students agreed that self-directed leaning (SDL) is a very effective approach for learning. A study done by Premkumar et al. evaluated the self-directed learning readiness of medical students across the training years and found the importance of SDL in medicine, the current curriculum may require an increase in learning activities that promote SDL.<sup>[11]</sup> In a study by Dayananda R et al. the majority of the students agreed that in small-group teaching they learned and retained information better.<sup>[12]</sup> In our study 48.4% students strongly agreed that small group discussions (SGD) give better understanding regarding the subjects.

## Conclusion

The preferred learning styles among medical students in this study were kinaesthetic followed by aural. Exploring different learning styles

could potentially be used in the curriculum so that instructors could plan appropriate teaching learning method according to their learning needs. Self-directed learning, small group discussion, problem-based learning were reported as satisfactory by the students as per the new curriculum.

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**Conflicts of Interest:** None

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# Delays in Diagnosis and Initiation of Treatment among Adult Tuberculosis Patients Registered Under NTEP in Urban Visa Khapatnam: A Mixed Method Study

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## Abstract

**Introduction:** Our understanding of the health system and patient factors responsible for the time delay in diagnosis and treatment is limited. Further research is needed to analyze the health system factors responsible for delay in diagnosis of TB and to identify key factors related to delay in initiation of treatment, in particular the pathways involving health care providers and patients contributing to the complexity and long delays. Hence the current study was done to identify the magnitude of the problem and reasons for delays in diagnosis and treatment using a mixed-method approach.

**Materials & Methods:** A Mixed -method study was conducted in 8 selected Tuberculosis units (TUs) of Urban Visakhapatnam district among 102 people with tuberculosis followed by a series of Focus group discussions (FGD), In-depth interviews (IDI) & Key informant interviews (KII) with patients & health care workers associated with T.B service delivery.

**Results:** Majority (59.8%) were males. The median patient care seeking delay was found to be 30 days. The mean diagnostic delay duration of  $1\pm 1.1$  days with no treatment delay. The mean total patient pathway duration was  $44.3\pm 50.2$  days. Lack of awareness, fear and stigma derived qualitatively further explained the quantitative findings.

**Conclusion:** There were minimal delays in diagnosis and treatment initiation, but a significant proportion of delays were seen in seeking medical care.

**Key Words:** Tuberculosis, Diagnostic delay, NTEP, Patient pathway, Stigma.

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## Introduction

Tuberculosis (TB) is a Chronic Communicable bacterial disease. In 2022, an estimated 10.6 million people fell ill with tuberculosis (TB) worldwide, including 5.8 million men, 3.5 million women and 1.3 million children. TB is present in all countries and age groups. TB is curable and preventable. Multidrug-resistant TB (MDR-TB) remains a public health crisis and a health security threat. Only about 2 in 5 people with drug resistant TB accessed treatment in 2022.<sup>1</sup>

National Tuberculosis Elimination Program (NTEP) emphasizes on achieving the sustainable development goal of ending TB by 2025.<sup>2</sup> Prolonged delays have been associated with further transmission of the infection in the community and thus posed a great challenge to TB elimination efforts globally.<sup>3</sup> A recent analysis of TB transmission dynamics and delay has stressed that time delays to diagnosis are the most important obstacles to the control of the TB epidemic.<sup>4</sup> This could be due to several factors, principally found within the categories: patients delaying seeking healthcare or failure of the health care systems to diagnose and treat patient's promptly.<sup>5,6</sup> Our understanding of the health system and patient factors responsible for the time delay in diagnosis and treatment is limited. Hence this study, aimed to identify the magnitude of the problem and reasons for delays in diagnosis and treatment.

### Objectives:

1. To assess the proportion of patients who had delays in diagnosis and treatment.
2. To identify the reasons for delays in diagnosis and treatment of adult tuberculosis patients under NTEP.
3. To know perceptions of Health care workers and patients on delays in diagnosis and treatment.

## Materials and Methods

**Study design:** Mixed method study.<sup>7</sup>

**Quantitative Component:** A Cross-sectional observational study.

**Qualitative Component** Focused group discussions (FGD), In-depth interviews (IDI), Key informant interview (KII).

**Study period:** November 2019 to December 2021.

### Study participants:

**Inclusion Criteria:** Out of 26 TUs in Visakhapatnam, adult tuberculosis Patients registered in 8 TUs during January 2021 to June 2021 and health care providers. Senior Treatment Supervisors (STO), Senior Tuberculosis Laboratory Supervisor (STLS), Medical officers, Accredited social health activist (ASHA), Auxiliary nurse midwife (ANM), TB Health Volunteer (TBHV) associated with tuberculosis service delivery who gave consent.

### Exclusion Criteria:

- Seriously and terminally ill patients.
- Patients who were not available at home on three different days of home visit were declared not available

**Sample size:** Taking a mean total delay of  $41.2 \pm 27.9$  days in a study conducted by Patki et al<sup>8</sup> the sample size arrived at 132. (Due to ongoing COVID 19 Pandemic we could collect only 102 samples out of desired 132.)

**n-** Sample size,  $Z_{1-\alpha/2}$  - value of Z at 95% CI=1.96;  
**d-** Margin of error (or) absolute precision.

$$n \geq \left( \frac{Z_{1-\alpha/2} \sigma}{d} \right)^2$$

**Sampling technique:** Line listing of all TB cases registered in urban Visakhapatnam was obtained through the Nikshay portal, the required sample was taken from all 8 TUs using a simple random sampling method.

For 3 FGD's 24 Health care workers, 12 participants for KII and 22 patients for In-depth interviews were included in the study.

**For quantitative data,** line listing of all TB patients registered in urban Visakhapatnam (January 2021 to June 2021) was obtained through the Nikshay portal, the required sample was taken from all 8 TUs using a simple random sampling method.

**For qualitative data:** Specifically Knowledgeable, Vocal, Experienced, and willing individuals were

chosen. Homogenous purposive sampling for participants in FGD's, Random purposeful sampling for patients and health care workers participating in IDI & KII.

Quantitative data was collected using a pretested semi-structured questionnaire while qualitative data was obtained through in-depth interviews, Key informant interviews and focused group discussions with the aid of Field guide for FGD and interview guides for KII and IDI.

#### Data Collection Method:

**Quantitative data:** All patients identified from the Nikshay portal were contacted within 30 days of their treatment initiation to minimize the recall bias. Quantitative data was obtained using questionnaire.

**Qualitative Data:** Focused Group Discussions were conducted with Medical Officers (MO's), Senior TB Laboratory Supervisor (STLS), Lab technicians (LT'S), ASHA, ANM, TBHV's. A prescheduled field visit was made to T. Us for conduction of FGDs based on the feasibility of study population and field staff. FGD were done in neutral venues like T.B. units or nearby PHC'S. The audio recording was done with the help of a health worker after taking consent. An observer was given the task of recording body language and group dynamics by drawing a sociogram to depict the interpersonal lines of communications to analyze preferences within a group. A total of 3 FGD'S were conducted till data saturation achievement, each FGD lasted for 35 to 50 minutes on an average.

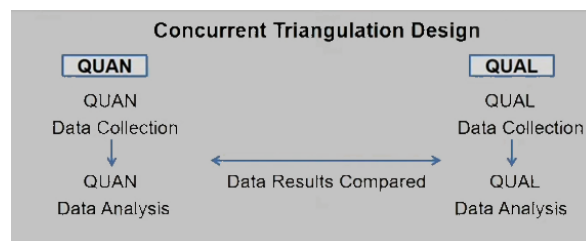
In depth interviews were carried out with patients at their house who were initiated on treatment in the using semi-structured format to collect personal lived -in experiences. A total of 22 IDI's were conducted till data saturation was achieved. Each IDI lasted for 10 to 15 minutes.

Key Informant Interviews (KII) were conducted with the aid of an interview guide to key personnel associated with T.B service delivery. A total of 12 KII were conducted till data saturation achievement, each KII lasted for 10 to 15 minutes on average. A comprehensive data sheet was developed for entering all the data collected. Field notes and Audio recordings of interviews were saved digitally.

The study was conducted after approval by the institutional ethics committee (Regd No: REG NO; EC/NEW/INST/2019/397). Confidentiality of the subjects was maintained. All permissions required from District Tuberculosis Control Officer (DTCO), District Medical and Health Officer (DMHO) were taken.

**Ethical Considerations:** The study was conducted after approval by the institutional ethics committee (Regd No: REG NO; EC/NEW/INST/2019/397). Confidentiality of the subjects was maintained. All permissions required from District Tuberculosis Control Officer (DTCO), District Medical and Health Officer (DMHO) were taken.

#### Data Analysis:



**Quantitative component:** Quantitative Data was analyzed using Microsoft Excel and SPSS VER 17. Continuous variables are expressed as median and standard deviation, categorical variables are expressed as proportions.

**Qualitative component analysis:** Thematic analysis was done for FGD, Key informant interviews and in-depth interviews. Qualitative data transcripts were refined and grouped through Atlas.ti software to derive a conceptual framework of expression.

## Results

Table 1: shows the mean age of study population was found to be  $39.40 \pm 14.68$  years.

Table 2 shows that-A median delay of 30 days (IQR - 43) was observed in Seeking Medical Care.

Table: 3 shows that Lowest proportion of delay (5.4%) and highest proportion of delay (64.9%) in seeking medical care was observed in the age category more than 60years and 18-45 years respectively. The findings were not found to be statistically significant. ( $p=0.906$ )

Males (58%) were found to have more delay in seeking medical care than females.

medical care was found in upper middle class. and lowest (8%) being lower middle class.

Highest proportion (52%) delay in seeking

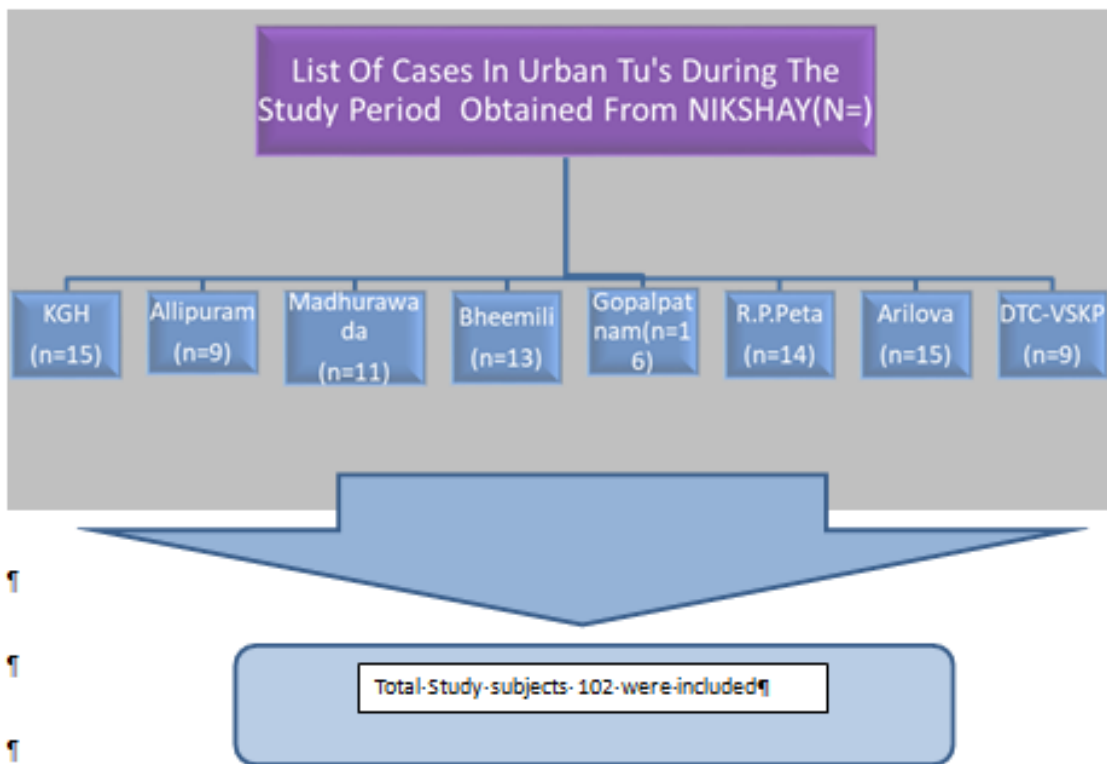


Fig 1 Nikshay portal, the required sample was taken from all 8 TU's using a simple random sampling method.

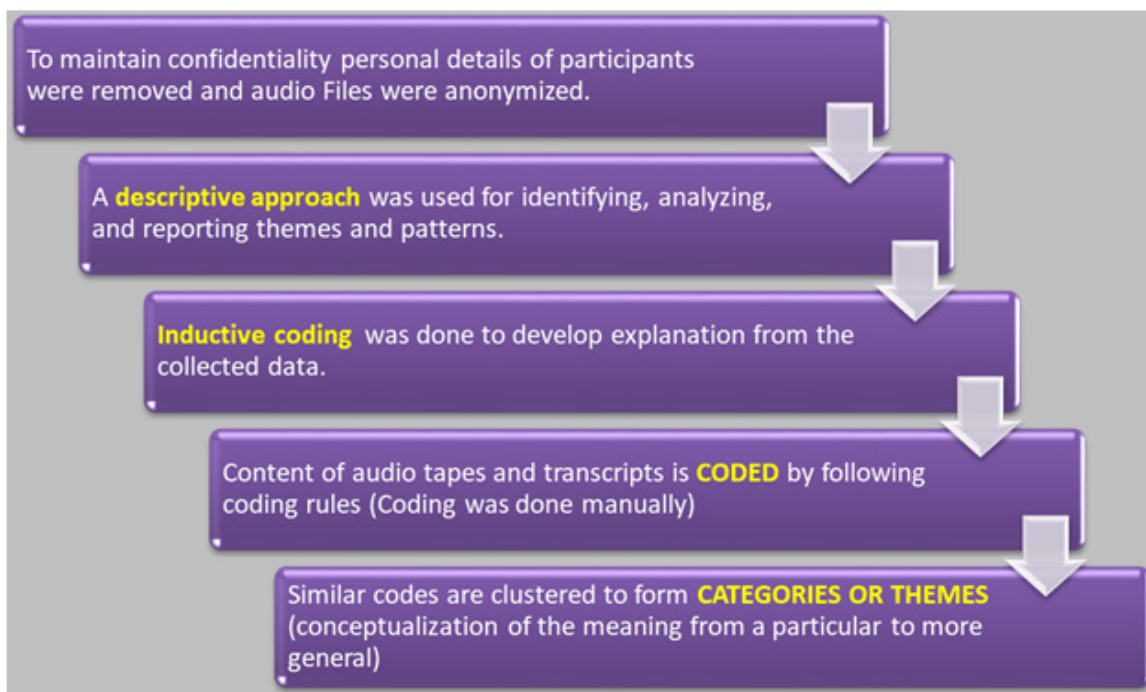


Fig 2: FLOWCHART OF THEMATIC ANALYSIS FOR QUALITATIVE DATA

**Quantitative (Cross Sectional Study)****Table 1. Demographic Profile Of Study Population**

Variables		Frequency (N)	Percentage (%)
<b>Age (in years)</b>			
18-45		65	63.7
46-60		31	30.4
>60		6	5.9
<b>Gender</b>			
Female		41	40.2
Male		61	59.8
<b>Education</b>			
Literate		71	69.6
Illiterate		31	30.4
<b>Occupation</b>			
Employed		65	63.7
Unemployed		37	36.3
<b>Socio-economic status</b>			
Upper class		26	25.5
Upper Middle		52	51.0
Middle class		17	16.7
Lower Middle		7	6.9
<b>Based on availing Direct benefit transfer</b>			
YES		66	64.7
NO		36	35.3
<b>Patient contribution to family income before and after treatment initiation</b>			
Before	No	37	36.3
	Yes	65	63.7
If yes how many continued after treatment initiation	No	25	38.4
	Yes	40	61.6

**TABLE 2. DISTRIBUTION OF DIFFERENT DELAYS IN STUDY POPULATION**

DELAY	MEDIAN (DAYS)	MEAN (DAYS)	SD
SEEKING MEDICAL CARE	30	43.01	50.133
DIAGNOSTIC DELAY	1	1.00	1.117
DELAY IN TREATMENT INITIATION	0	0.38	0.868
TOTAL PATIENT PATHWAY DURATION	30	44.3922	50.23039

TABLE 3: DISTRIBUTION OF DELAYS IN RELATION TO VARIOUS STUDY VARIABLES

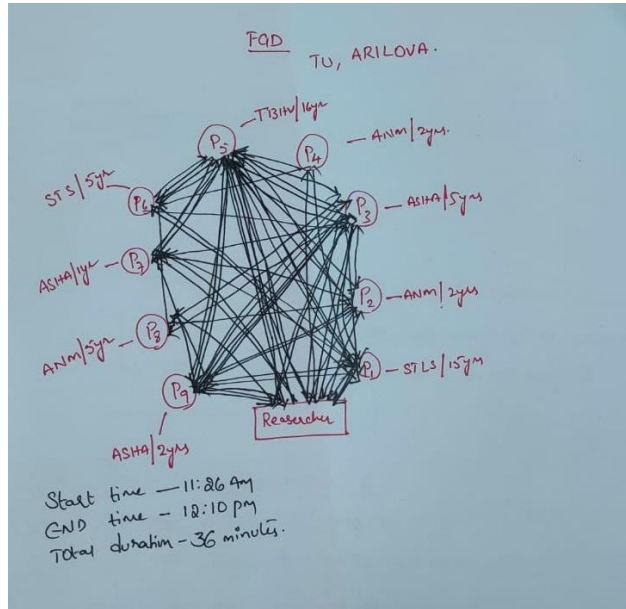
Variable	Delay in seeking medical care				Total Patient Pathway delay			
	Delay (%) 74	No delay N(%) 28	Total 102	P- value	Delay N(%) 38	No delay N(%) 64	Total 102	P- value
Age				0.906				
18-45	48(64.9%)	17(60.7%)	65(63.7%)		27(71.1%)	38(59.4%)	65(63.7%)	0.38
46-60	22(29.7%)	9(32.1%)	31(30.4%)		10(26.3%)	21(32.8%)	31(30.4%)	
>60	4(5.4%)	2(7.1%)	6(5.9%)		1(2.6%)	5(7.8%)	6(5.9%)	
Gender				0.57				0.12
Females	31(41.9%)	10(35.7%)	41(40.2%)		19(50.0%)	22(34.4%)	41(40.2%)	
Males	43(58.1%)	18(64.3%)	61(59.8%)		19(50.0%)	42(65.6%)	61(59.8%)	
Education				0.472				
Literate	53(71.6%)	18(64.3%)			29(76.3%)	42(65.6%)		0.256
Illiterate	21(28.4%)	10(35.7%)			9(23.7%)	22(34.4%)		
Occupation				0.32				0.605
Employed	45(60.8%)	20(71.4%)			23(60.5%)	42(65.6%)		
Unemployed	29(39.2%)	8(28.6%)			15(39.5%)	22(34.4%)		
SES				0.68				0.79
Upper class	17(23.0%)	9(32.1%)	26(25.5%)		8(21.1%)	18(28.1%)	26(25.5%)	
Upper Middle	39(52.7%)	13(46.4%)	52(51.0%)		21(55.3%)	31(48.4%)	52(51.0%)	
Middle	12(16.2%)	5(17.9%)	17(16.7%)		7(18.4%)	10(15.6%)	17(16.7%)	
Lower Middle	6(8.1%)	1(3.6%)	7(6.9%)		2(5.3%)	5(7.8%)	7(6.9%)	

TABLE 4: COMPARISON OF THEMES EMERGED FROM QUALITATIVE INTERVIEWS

Themes	Category	Sub-category	Codes
<b>Reasons for delays</b>	Health Care Workers' perspective	Patient issues	Awareness, stigma, non-acceptance, lack of family support, rejection, fear, superstitions, lack of education, refusal to do tests, habits, poverty, doctor shopping, Vulnerability, non-formal providers, long treatment duration.
		Field issues	Migrants, over burdened staff, bad experiences.
		Delay	Report delays, stigma, non-acceptance
		Screening	Family, denial, lying, fear, blaming
		Man-power	Less staff, other surveys, target pressure, over burden, online uploading, frequent reviews
		Monetary issues	not aware, others account, funding issues, technical constraints
	Key informant perspective	Reasons for patient pathway delay	lack of awareness, fear, social stigma, poor technique, non-response, working population.
		Reasons for interruption in treatment	side-effects, fear, migration, provider switching, poor counselling, habits
		Reasons for health system delay	Work load, COVID, less staff, no transport, more population
	patients perspective	Knowledge	Awareness, stigma, fear, provider switching, Side-effects fear, lost reports, perceptions, misinterpretation
		Practices	self-medication, non-formal providers, provider switching, OTC, superstitions, poor response, knowledge, mental stress, lack of time, negligence, lost records
		Social issues	Migration, burden, poverty, lack of family support
<b>Proposed solutions</b>	Health Care Workers Perspective	For patients	Drug pack, motivation, education, camps, active screening
		For staff	Target free approach, logistics, frequent trainings, air-purifiers, prophylaxis, human resources
	Patients' Perspective	Programme	Short treatment period, supplementary medications, monetary support

A total of two themes were derived through thematic analysis. 1.Reasons for delays. 2.Proposed solutions

**QUALITATIVE (FGD, KII, IDI)**



**Figure 3: Sociogram of FGD done at ARILOVA T.U.**

**Focused Group Discussions**

From the summary of 3 FGD'S conducted the codes derived were categorized into 6 Sub- categories, which include 1. Patient level issues, 2. Field level issues, 3. Delays, 4. Screening, 5. Man-power issues, 6. Monetary issues. (\*Only Few reflections are given here)

**1. Patient Issues:**

**Patient awareness:**

“Due to lack of awareness, they will not consider cough>2wks as TB, instead they will say that it may be due to seasonal change or just anormal cough which will subside on its own”. (ASHA/Experience 17 years)

**2. Field issues:**

**Proposed Solutions:**

“Conducting more awareness meetings may help, recovered patients should come forward to participate in activities like TB champ” TBHV/6years)

**3. Delay:**

When they were asked about delays in reporting and treating the cases, they responded

**Sputum report delay:**

“Generally, report will come in 24 hours but if there is more workload sometimes it may be delayed during COVID time. (STLS /18 years)

**4. Screening:**

When the respondents were asked about family screening, they responded as follows:

**Family screening:**

“We don't have symptoms, why should we give sputum for testing? “(STLS/8years)

**5. Manpower:**

When participants were asked about any other issues, they responded saying,

“We have more population to cover and many other works like fever survey etc., so, a dedicated staff like TBHV will give better results.” (STLS/8years)

**KEY INFORMANT INTERVIEWS:**

A total of 12 Key informant interviews (KII) were conducted. From the summary of KII's we developed codes, from codes arrived to 3 subcategories.

1. Reasons for patient pathway delay. 2.Reasons for interruption in treatment. 3.Reasons for Health system Delay.

**1. REASONS FOR PATIENT PATHWAY DELAY:**

“Lack of awareness could be the reason. Few are giving fake address or wrong mobile numbershence we are facing difficulties for follow up.” (STLS/5years)

**2. REASONS FOR INTERRUPTIONS IN TREATMENT:**

“Initially they begin treatment at one place and shift to another place for work or some otherreasons, usually they live in slums and it's very difficult for us to trace them”(STLS/5years)

**3. REASONS FOR HEALTH SYSTEM DELAY:**

When participants were asked what could be the reasons for delays on health system they said,

“There is only one lab technician for both KGH and Allipuram. So, dispatching reports at earlier point is not possible. (STLS/4years)

## IN-DEPTH INTERVIEWS:

22 IDI were conducted. After Summarizing the codes from transcripts and audio tapes 3 subcategories were generated.

1. Knowledge 2. Patient practices 3. Social issues

### KNOWLEDGE

When patients were asked about their awareness and knowledge about T.B in order to explore the reasons for patient pathway delays, they responded

#### Fear:

*"I feared that my family won't accept me if I tested for T.B, so I hide it from them for quite along time"*

(Male/38years)

### PATIENT PRACTICES:

#### Self-medication:

*"I used to have cough like severe cough with yellow colored sputum since three weeks. Since it's not controlled, I used antibiotics.,"*

(Female/23years)

### SOCIAL ISSUES:

#### Burden on families:

*"Our income is not meeting our needs, for taking food during this treatment so we are borrowing money"*

(Female /32)

#### Migration:

*"Initially, I got tested for T.B in Kadapa district I was given medication for a month then we came here"* (Female/38 years)

## Discussion

A total of 102 patients were assessed for delays in diagnosis and treatment initiation and qualitative inputs were considered to understand perceptions pertaining to delays at different levels.

In present study, the Mean age & Median age were 39.4± 14.68 years & 39 years. Similar findings were seen in a study done by **Lestari et al**<sup>5</sup> where median age was found to be 35 years. In another study by **Belay et al**<sup>9</sup> the mean age of the study population was 32.7 ±12.3. In India distribution of TB diagnosed incident cases showed a predominance in age groups between 15 to 30 years of age.<sup>10</sup>

In the present study males (59.8%) are more than females (40.2%), similar gender distributions were seen in **Mistry et al**<sup>11</sup> where males were 61% and females were 39%. The male predominance may be because of their greater exposure to the disease mostly due to workplace environment.

In the present study 69.6% of the study subjects were literates and 30.4% were illiterates, similarly in a study by **Mistry et al**<sup>12</sup> had 34% of the illiterate patient's, although, tuberculosis frequently attributed to illiteracy and poor knowledge in our study majority (69.6%) of the participants were literate, this may be due to urban study setting.

In the present study, Males had 58.1% of delay in seeking medical care. Similar findings were seen in **Lestari et al**<sup>5</sup> in which men had longer delays.

The present study demonstrated median patient care seeking delay of 30 days(IQR 60-1) which was similar to a study by **Goel et al**<sup>6</sup> with median patient delay of 30 days (IQR 6.5-58.5) and similar findings were seen in a study by **Roberts et al**<sup>13</sup> where Median delay was found to be 30 days (IQR :11-72 days), whereas in a study by **Belkina et al**<sup>14</sup> it was 27 days (IQR: 6-62 day). Present study findings are synonymous with a study by **Paynter et al**<sup>15</sup> which had median patient delay of 34.5 days. In a systemic review of literature by **Sreeramareddy et al**<sup>16</sup> average patient delay was 31.7 days.

Present study demonstrated a mean delay of 43 days in Seeking medical care which are contrary to the results by **Mistry et al**<sup>12</sup> where mean duration was 15 days in new treatment TB patients, from the same study it was found that patient-related factors responsible for delay are provider shopping, delay in approaching provider after leaving the previous provider, refusal to get tests done, symptomatic treatment for a long duration, delay in advising TB-relevant tests, wrong diagnosis which were similar to codes generated through qualitative approach in current study.

In present study the reasons for patients delays found to be Lack of awareness, lack of perceived risk, Self-medication, over the counters drugs, fear of wages loss which were like qualitative study results by **Goel et al**<sup>6</sup>.

The mean diagnostic delay duration in current study was 1±1.1 days. Whereas higher mean was seen in study by **Patki et al**<sup>8</sup> showed 32.7± 19.8 days.

No treatment delay was observed in present study population, because majority of the patients were kept on treatment on the day of diagnosis itself. Similar findings were seen in study by **Patki et al**<sup>8</sup>.

In present study the mean total patient pathway duration was 44.3±50.2 days and a median total delay of 30(IQR 17-60) which were consistent with findings from a study by **Patki et al**<sup>8</sup> where mean total delay of 41.2 ± 27.9 days and median total delay 35.5 (interquartile range [IQR]: 13–44) days was seen.

In the Present study total pathway delay is attributed to patient delay the reasons were stigma, fear, over the counter drugs and visit to non-formal providers which are similar to findings in a study by **Belkina et al**<sup>14</sup> Contrary to this finding, in a study by **Rajeswari et al**<sup>17</sup> mean total delay was 60 days (range 0-425) which was due to health system delay.

### Conclusion

Overall, the study population experienced minimal delays in diagnosis and treatment initiation. However, a significant proportion of delays occurred when seeking medical care in the patients' pathway to the healthcare system. The NTEP program was performing excellently in most aspects in urban Visakhapatnam. Emphasizing contact screening and increasing patient awareness will help the NTEP achieve its vision of "END TB 2025."

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**Conflict of interest:** Nil

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