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ISSN 0019-5847

96 TH YEAR OF PUBLICATION

Volume 124 (JIMA)
Volume 70 (RNI)
Number 02
February 2026
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**Disclaimer:** Please note that the comparison is not based on head to head studies.

#EUFOREA. Allergic Rhinitis Pocket Guide - EUFOREA. EUFOREA. Published October 13, 2025. https://www.euforea.org/news/allergic-rhinitis-pocket-guide/. Last accessed on: 27 November, 2025.

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Special Article

# Haemovigilance Programme of India : Strengthening Blood Transfusion Safety

**Akanksha Bisht**[1]

The Haemovigilance Programme of India (HvPI), launched in December 2012, is implemented by the National Institute of Biologicals (NIB), NOIDA, under the Ministry of Health & Family Welfare. Serving as the National Coordinating Centre (NCC), HvPI aims to monitor, report, investigate, and analyze adverse reactions related to blood transfusion and donation across India.

To date, **1,728** blood centres have enrolled under HvPI, and over **80,000** adverse reaction reports have been submitted via the Haemovigilance software. Although reporting is currently voluntary, the data collected helps formulate expert-led guidelines and recommendations to improve transfusion safety nationwide which are freely available on NIB Website **nib.gov.in**

HvPI also focuses on capacity building. It has conducted 86 Continuing Medical Education (CME) Programmes, Workshops and Webinars, training over **16,400** healthcare professionals. The participants have predominantly been from blood centres, including medical officers, nurses, technical staff, as well as blood donors and motivators. Moving forward, we aim to enhance collaboration with our clinical colleagues, who play a critical role in recognizing bedside transfusion reactions and promptly reporting them to the blood centres. Strengthening this partnership is essential for improving patient safety and transfusion outcomes.

A **toll-free helpline (1800-180-2588)** is available to provide assistance and answer queries related to the programme.

Blood centres can enroll in HvPI free of cost by submitting the required enrolment form, available at https://nib.gov.in/media/Annexure7.pdf either by post to NIB, NOIDA or via email at haemovigilance@nib.gov.in.

HvPI has also developed a key reference document, **"Good Blood Transfusion Practices – Guidance for Rational Use of Blood",** available at https://nib.gov.in/media/Good%20Blood%20Transfusion%20Practices%20Guidance.pdf, to support rational and safe blood use.

Active clinician participation and increased reporting serves as a critical tool in ensuring patient safety and improving clinical outcomes in transfusion medicine. By actively reporting adverse transfusion reactions, clinicians contribute to a national database that enhances protocols, and reduces preventable risks. Participation in HvPI not only reinforces a culture of continuous learning but also empowers clinicians with data-driven insights to make safer, more informed decisions. Embracing this programme is a step toward advancing quality care and safeguarding the well-being of every patient receiving blood transfusion therapy.

**Haemovigilance Programme of India (HvPI)** looks forward to a collaborative partnership with the **prestigious Indian Medical Association (IMA)** to enhance the safety and quality of blood transfusion practices across the country.

## Acknowledgment

(1) Dr Neelam Marwaha, Former Professor & Head, Department of Transfusion Medicine, PGIME&R, Chandigarh.

(2) Prof Ravneet Kaur, Head, Department of Transfusion Medicine, GMCH, Chandigarh.

(3) Dr Debasish Gupta, Former Professor & Head, Department of Transfusion Medicine, SCTIMST, Trivandrum, Kerala.

(4) HvPI acknowledges all the blood centres for their active participation in HvPI and reporting of adverse transfusion/donor reactions to the central database.

[1]S-I & Head Haemovigilance Programme of India, NIB Noida , MoHFW, GoI.


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February 2026
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# Contents

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## (National & International)

Editorial

# Psychiatry as Compulsory Subject in Undergraduate Discipline in MBBS Curriculum

India has one-fifth of the world's population with approximately 140 crore people is living in our country. As per National Mental Health Survey (NMHS) 2015-16, approximately 10.6% of adults are suffering from a diagnosable mental disorder with a lifetime prevalence of 13.7%. One in every seventh citizen of our country is suffering from mental illnesses and our country has doubled the contribution of mental health burden in the Global burden of diseases since 1990. Among the one third patients attending general medical clinics are suffering from common mental disorders like Depression, Anxiety, Somatization disorder and at least half of them remain undiagnosed and undertreated. There are approximately 14 crore and 1 crore fellow citizens who are suffering from Common Mental Disorders (CMDs) and Severe Mental disorders (SMDs) respectively. It's not only the 15-crore population merely, the impact is much bigger, around 15 crore families are suffering from mental, emotional and behavioural disorders including substance use disorders. The treatment gap in mental health in our country ranges from 70-92% and we have fewer than one Psychiatrist per 1,00,000 population[1,2].

Unfortunately, Psychiatry as a subject in Undergraduate and Postgraduate curriculum has not received sufficient attention which was deserved in our country. The mental health is an integral part of overall health and well-being, still as a subject of course study in National Medical Commission (NMC) curriculum has not evolved accordingly. It's still being considered as an allied and peripheral discipline under the big umbrella of Medicine and not considered as a principal discipline of study. It was not studied as a compulsory subject in the UG curriculum which a MBBS student may easily skip during his career. Moreover, the journey from being a 'pseudo-science' to become a 'true science 'was ever challenging. The science and art of Psychiatry have not been integrated in the overall science and art of medicine. Psychiatry derives itself its origin from brain and marks its signature as function of brain with manifestations of behavioural and emotional symptoms. The brain is the master organ of the body which controls and regulates all body functions. The lack of emphasis on mind body interface and integration with the discipline with medical and allied disciplines has made Undergraduate students less competent to become an efficient Indian Medical Graduate (IMG). The limited number of teaching hours, not having a separate examination and minimal weightage given for assessments have led to the situation where medical students often consider Psychiatry not essential to learn as a subject in the mainstream discipline of Medicine[3].

This overall neglect has far-reaching implications. This is high time to reconsider and realign medical education in current scenario and emerging demand of day-to-day clinical practice. The introduction of Psychiatry as a compulsory subject with a separate

theory and practical subject has now become a reality demanding a curricular reform and essential for public health intervention strategy. In this scenario, the only sustainable approach is to ensure quality teaching focusing Psychiatry as a principal discipline in the UG curriculum. NMC has ensured compulsory Rural posting and District Residency Programme (DRP) for Indian Medical Graduate (IMG). The NMC curriculum has highlighted the importance of key competencies to become equipped to identify, manage and refer psychiatric conditions. More importantly, these competencies must be cultivated during the formative Undergraduate years, when this will be integrated at examination level, this will ensure the students to work on and engage themselves seriously in the field of Psychiatry. This will boost up the clinical confidence and will robustly help to bridge the learning gap and treatment gap.

Globally as a discipline Psychiatry occupies a core place in medical education, In the United States, the medical students have to undergo at least eight weeks of structured Psychiatry clerkship. In the United Kingdom, students receive around 80 hours of training in behavioural sciences followed by a three months rotation in Psychiatry, Denmark recognized Psychiatry as a major clinical discipline as early as the 1950s, dedicating about 7% of total curriculum time to the discipline. In Asian countries like Sri Lanka and Malaysia, Psychiatry is an examinable subject at the Undergraduate level. Several Indian Medical institutions have already demonstrated the feasibility and potential benefits of independent Psychiatry examinations. AIIMS Rishikesh and AIIMS Deogarh are ahead of other institutions and have introduced Psychiatry as an independent examined subject, The results are encouraging, outcome is inspiring; students here showed higher motivation, improved knowledge, attitude and skills[4].

At present the UG curriculum has been revised by NMC with greater emphasis to the discipline. As there are no theory and practical examinations in Psychiatry as the qualifying competency, the discipline has now been perceived by UG students as a non-essential subject. This neglect has direct consequences on clinical competency. Several Indian studies have shown that more than 50% of Medical Officers in primary health care setting lack the ability or confidence in identifying and treating Psychiatric Disorders. Learning is best achieved during formative years, Medical Educators often assert 'assessment drives learning'. Therefore, unless Psychiatry is meaningfully examined, it will continue to be marginalized in student's learning priorities.

In India, the status of **Psychiatry** as an Undergraduate subject has undergone a massive transformation recently. Historically, it was a minor "appendage" of General Medicine, but new regulations have elevated its importance significantly.

### The NMC Shift (CBME 2019) :

With the introduction of the **Competency-based Medical Education (CBME)** by the National Medical Commission (NMC) in 2019, Psychiatry is no longer just a few optional lectures. It is now a **mandatory clinical posting** with defined "certifiable competencies."

- **Clinical Postings :** MBBS students must now complete a mandatory **4-week** clinical posting in Psychiatry (increased from the previous 2-week requirement).
- **Theory :** Approximately **40–45 hours** are dedicated to theoretical teaching.
- **Assessment :** While still technically grouped under "General Medicine" for the final summative (University) University exams, it is now an **independent head of passing** in internal assessments, and questions from Psychiatry are mandatory in Medicine Paper II.

In the traditional University exam structure (Third Professional Part II), Psychiatry is not a standalone paper like Surgery or Pediatrics. However, some **Institutes of National Importance (INIs)** like **AIIMS Rishikesh** and **AIIMS Bhubaneswar** have pioneered making Psychiatry a **separate major subject** with its own independent professional examination.

### Key Components of the UG Psychiatry Curriculum :

The focus has shifted from rote memorization of rare disorders to managing common conditions that an Indian Medical Graduate (IMG) will face in primary care:

- **Core Topics :** Depression, Anxiety, Substance Use Disorders (Alcohol/Tobacco), and Psychiatric Emergencies (Suicide/Agitation).
- **AETCOM :** The "Attitude, Ethics, and Communication" module now integrates Psychiatric principles to help students develop empathy and better doctor-patient relationships.
- **Skills :** Students are now required to demonstrate skills in **Mental State Examination (MSE)** and history taking, rather than just "observing."

### Current Status Overview :

| Feature | Previous Status (Pre-2019) | Current Status (Post-2019 CBME) |
|---|---|---|
| **Duration** | 2 Weeks | 4 Weeks |
| **Status** | Minor part of Medicine | Independent Department/ Core Clinical Posting |
| **Examination** | Minimal questions in Medicine | Mandatory questions + Internal Assessment |
| **Focus** | Theoretical/ Observational | Skill-based/ Competency-oriented |

The Indian Psychiatric Society (IPS), the largest

professional body of Psychiatrists of Indian origin, has been at the forefront of advocating Psychiatry to be a compulsory UG examination subject. Visionary such as Dr Masani, Dube, Bagadia, Bhaskaran and Trivedi emphasized the necessity of formal teaching and examination in Psychiatry. In the presidential address at Annual National Conference of Indian Psychiatric Society (ANCIPS) 2012, Prof Roy Abraham Kallivayalil (former Vice President of IMA as well) argued that Psychiatry should be considered as a separate subject and absence of UG examination in this subject has remained as a critical gap.

India stands at a critical juncture. The burden of mental health is on rise, the treatment gap remains vast, the medical education must evolve to meet up these challenges. The Global models, national policy frameworks and empirical evidence all converge on one final conclusion that Psychiatry must be recognized as an essential subject in medical curriculum, seen a s a primary care specialty, accorded essential competency status, and made a separate examinable subject in the MBBS final examination. This is not merely an academic adjustment but a moral and public health imperative as we rise with the slogan, **'there is no health without mental health**'.

## Acknowledgement

Office bearers and Executive Council of Indian Psychiatric Society (IPS)

UG Education Subcommittee of IPS

1) Prof Priyaranjan Avinash, Chairperson
2) Dr Roy Abraham Kallivayalil, Advisor
3) Dr Kiran Kumar K & Dr Ranjan Bhattacharyya, Co-Chairpersons
4) Dr Snehil Gupta, Member
5) Dr Christiana George, Convenor
6) Dr Vipul Shah, EC Coordinator

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**Prof (Dr) Ranjan Bhattacharyya**
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*Hony Editor, JIMA*

Original Article

# Unveiling the Hidden Thyroid Burden : A Cross-sectional Study to Determine the Prevalence of Subclinical Hypothyroidism and Subclinical Hyperthyroidism at a Tertiary Care Center in Uttar Pradesh

**Rahul Garg[1], Anmol Thakre[2]**

**Abstract**

**Background :** Subclinical Thyroid Disorders are increasingly recognized as important health concerns, yet their prevalence in Uttar Pradesh remains understudied.

**Aims and Objective :** This study was carried out to determine the prevalence of Subclinical Hypothyroidism and Subclinical Hyperthyroidism among patients attending a Tertiary Care Center in Uttar Pradesh.

**Materials and Methods :** A cross-sectional study was conducted on 196 patients aged more than 18 years. Serum Thyroid-stimulating Hormone (TSH), Free Thyroxine (FT4) and Free Triiodothyronine (FT3) levels were measured.

**Results :** The prevalence of Subclinical Hypothyroidism was 12.76% and Subclinical Hyperthyroidism was 3.06%. A female predominance was observed in both groups. Prevalence was highest in 31-40 years age group. The total thyroid dysfunction prevalence was 23.4%.

**Conclusion :** This study reveals a significant prevalence of Subclinical Thyroid Disorders in Uttar Pradesh, emphasizing the need for routine thyroid function screening, especially among women and older adults.

**Key words :** Subclinical Hypothyroidism (SCH), Subclinical Hyperthyroidism (SCHyper), Thyroid Stimulating Hormone (TSH), Free Triodothyronine (FT3), Free Thyroxine (FT4).

Thyroid disorders represent a significant public health challenge Worldwide, with subclinical forms gaining increasing attention due to their subtle yet potentially impactful nature[1]. In India, the prevalence of thyroid disorders varies considerably across different regions, influenced by factors such as Iodine intake, environmental conditions, and genetic predisposition[1,2].

Subclinical Hypothyroidism (SCH), defined by elevated Thyroid Stimulating Hormone (TSH) levels with normal free Thyroxine (FT4) levels, has been associated with an increased risk of cardiovascular diseases, dyslipidemia, and adverse pregnancy outcomes[3,4]. Subclinical Hyperthyroidism, characterized by suppressed TSH levels with normal FT4 levels, has been linked to osteoporosis, atrial fibrillation and other cardiovascular complications[5-7].

The clinical significance of these subclinical disorders lies in their potential progression to overt thyroid dysfunction and the associated health risks. Early detection through screening can facilitate timely interventions, potentially preventing complications and improving overall health outcomes[8]. However, the absence of specific symptoms often leads to these conditions going undetected, highlighting the importance of routine screening, especially in high-risk populations.

***Editor's Comment :***

- Subclinical Thyroid Disorders are prevalent in our community. Women are at higher risk.
- Routine thyroid screening is crucial, especially for women and older adults.

Despite the growing recognition of Subclinical Thyroid Disorders' importance, there is a paucity of data on their prevalence in many parts of India, including Uttar Pradesh. Existing studies may not reflect the current demographic pattern relevant to specific regions within the state. This knowledge gap hampers the development of targeted screening strategies and management guidelines tailored to local needs.

The present study aims to address this research gap by estimating the prevalence of Subclinical Hypothyroidism and Subclinical Hyperthyroidism among patients attending a Tertiary Care Center in Agra, Uttar Pradesh. By elucidating the prevalence rates and associated demographic factors, this study seeks to contribute valuable data to inform clinical practice, guide public health initiatives, and serve as a foundation for future research in the region.

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***Received on : 29/08/2024***
***Accepted on : 12/11/2024***

***How to cite this article :*** Unveiling the Hidden Thyroid Burden : A Cross-Sectional Study to Determine the Prevalence of Subclinical Hypothyroidism and Subclinical Hyperthyroidism at a Tertiary Care Center in Uttar Pradesh. Garg R, Thakre A. *J Indian Med Assoc* 2026; **124(2):** 18-21.

## Materials and Methods

### Study Design and Setting :

We conducted a cross-sectional study at our Tertiary Care Center in Agra, Uttar Pradesh. The study protocol was approved by the Institutional Ethics Committee, and all procedures were performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

### Study Population :

The study was conducted on 196 patients. Patients aged more than 18 years attending both Outpatient and Inpatient Departments of our hospital were eligible for inclusion. We excluded pregnant women, patients with known thyroid disorders (Overt Hypothyroidism or Hyperthyroidism) and those unable to provide informed consent.

### Data Collection :

After obtaining written informed consent, a structured questionnaire was used to collect demographic data (age, gender) and relevant medical history. Blood samples were collected for Thyroid Function Tests, including serum TSH, FT4 and FT3 levels, using standardized assays.

### Diagnostic Criteria :

- Subclinical Hypothyroidism: TSH levels above 4.68 µIU/mL with normal FT4 levels.
- Subclinical Hyperthyroidism: TSH levels below 0.46 µIU/mL with normal FT4 levels.
- Normal thyroid function: TSH levels within the range of 0.46-4.68 µIU/mL with normal FT4 levels.

### Statistical Analysis :

Data were analyzed using MS Excel and R software. Prevalence rates were calculated with corresponding 95% confidence intervals. Continuous variables were described using means, medians, and Standard Deviations, while categorical variables were presented as frequencies and percentages. Chi-square test, Z-test and Cochran-Armitage test for trend were used to compare the proportion of thyroid dysfunction in different age groups, as appropriate. A p-value <0.05 was considered statistically significant.

## Results

### Demographic Characteristics :

A total of 196 patients were included in the study. The mean age of the study population was 45.8 ± 12.3 years, with 62.75% (123/196) being females and 37.25% (73/196) being males (Table 1).

### Prevalence of Thyroid Disorders :

Out of 196 patients screened, 25 (12.76%) were diagnosed with Subclinical Hypothyroidism, and 6 (3.06%) with Subclinical Hyperthyroidism. Additionally, 9 (4.59%) patients had Clinical Hypothyroidism, 4 (2.04%) had Clinical Hyperthyroidism and 2 (1.02%) were unclassified. The remaining 150 (76.53%) patients were euthyroid.

### Subclinical Hypothyroidism and Subclinical Hyperthyroidism :

All the results have been summarized in Table 2.

### Gender Distribution :

A statistically significant difference was observed in the gender distribution of Subclinical Thyroid Disorders ($p<0.01$). Women were more likely to have Subclinical Hypothyroidism (OR: 2.1) and Subclinical Hyperthyroidism (OR: 3.2) compared to men.

Table 1 — *Demographic characteristics of the study population*

| | |
|---|---|
| Number of patients | 196 |
| Males | 73 (37.25%) |
| Females | 123 (62.75%) |
| Mean Age (years) | 45.8±12.3 years |

Table 2 — *Characteristics of patients with Subclinical Hypothyroidism and Subclinical Hyperthyroidism*

| Characteristic | Subclinical Hypothyroidism (SCH) | Subclinical Hyperthyroidism (SCHyper) |
|---|---|---|
| Number of patients | 25 | 6 |
| Males | 6 (24%) | 1 (16.67%) |
| Females | 19 (76%) | 5 (83.33%) |
| Mean age (years) | 46.36±13.7 | 48.67±18.2 |
| Mean TSH (µIu/mL) | 7.17±2.8 | 0.27±0.16 |
| TSH range (µIu/mL) | 4.76-17.71 | 0.05-0.43 |
| Mean FT3 (pg/mL) | 3.78±0.6 | 4.04±0.8 |
| FT3 range (pg/mL) | 2.91-5.04 | 2.81-4.89 |
| Mean FT4 (pmol/L) | 16.25±2.7 | 18.77±3.1 |
| FT4 range (pmol/L) | 12.20-23.55 | 13.94-22.60 |

Table 3 — *Distribution of thyroid dysfunction in different age groups*

| Age | No of patients | Euthyroidism | Clinical Hypothyroidism | SCH | Clinical Hyperthyroidism | SCHyper | Unclass-ified | TTD | Percentage |
|---|---|---|---|---|---|---|---|---|---|
| 18-30 | 64 | 56 | 2 | 3 | 1 | 2 | 0 | 8 | 12.5% |
| 31-40 | 28 | 18 | 3 | 7 | 0 | 0 | 0 | 10 | 35.7% |
| 41-50 | 46 | 34 | 0 | 8 | 2 | 1 | 1 | 12 | 26.1% |
| 51-60 | 34 | 25 | 1 | 5 | 1 | 2 | 0 | 9 | 26.4% |
| >60 | 24 | 17 | 2 | 2 | 1 | 1 | 1 | 7 | 29.1% |
| Total | 196 | 150 | 8 | 25 | 5 | 6 | 2 | 46 | 23.4% |

SCH : Subclinical Hypothyroidism, SCHyper : Subclinical Hyperthyroidism, TTD : Total Thyroid Dysfunction

### Age Distribution :

Compared to the 18-30 age group, all other age groups show higher odds of thyroid dysfunction (Table 3). The 31-40 age group has a significantly higher odds ratio (3.89) with a p-value < 0.05. Other age groups show elevated odds ratios, but they are not statistically significant at the 0.05 level. Cochrane-Armitage test for trend showed a statistically significant (p=0.03) linear trend in the proportion of thyroid dysfunction as age increases.

## Discussion

This cross-sectional study provides valuable insights into the prevalence of subclinical thyroid disorders among patients attending a Tertiary Care Center in Agra, Uttar Pradesh. Our findings reveal a considerable prevalence of Subclinical Hypothyroidism (12.76%) and Subclinical Hyperthyroidism (3.06%) in this population.

The prevalence of SCH in our study falls within the range of 3-16.9% reported by various studies across India[9-13] and prevalence of SCHyper (3.06%) aligns with the Global prevalence range of 0.2-11.3% reported by Carlé, *et al*[14] but if Indian data is concerned, it is more than the prevalence (1.6%) reported in a study conducted in Cochin by Unnikrishnan, *et al*[1].

The female predominance observed in both SCH (76%) and SCHyper (83.33%) groups is consistent with previous studies, suggesting a higher susceptibility of women to thyroid disorders[15]. This gender disparity could be attributed to various factors, including hormonal influences, autoimmune predisposition, and pregnancy-related changes in thyroid function.

The mean age of patients with SCH (46.36 years) and SCHyper (48.67 years) in our study suggests that middle-aged and older adults may be at higher risk for these conditions. This finding is in line with other studies that have reported an increased prevalence of thyroid disorders with advancing age[15,16].

### Clinical Significance :

The clinical significance of our findings lies in the potential health implications of Subclinical Thyroid Disorders. SCH has been associated with an increased risk of progression to overt hypothyroidism, adverse cardiovascular outcomes[3], dyslipidemia[4], Non-alcoholic Fatty Liver Disease[17] and neuropsychological impairments[18]. Similarly, SCHyper may lead to osteoporosis, atrial fibrillation, other cardiovascular complications and progression to overt thyrotoxicosis, if left untreated[5,6].

Our study highlights the importance of routine thyroid function screening, especially in women and older adults. Early detection of Subclinical Thyroid Disorders can facilitate timely interventions, potentially preventing progression to overt disease and associated complications. This is particularly relevant in the context of India's ongoing nutrition transition and increasing life expectancy, which may influence the prevalence and impact of thyroid disorders.

### Strengths and Limitations :

The strengths of our study include its focus on a specific region (Agra, Uttar Pradesh) where data on Subclinical Thyroid Disorders is not available. No study has been conducted in North India to determine the prevalence of Subclinical Hyperthyroidism till date. However, our study has several limitations. First, the single-center design and relatively small sample size limit the generalizability of our findings to the broader population of Uttar Pradesh. Second, we did not assess factors such as Iodine intake, autoimmune status, or family history, which could provide further insights into the etiology of Subclinical Thyroid disorders in this population. Third, the cross-sectional nature of the study precludes any conclusions about causality or the natural history of subclinical thyroid disorders in this population.

## Conclusion

This study reveals a significant prevalence of Subclinical Hypothyroidism and Subclinical Hyperthyroidism among patients attending a Tertiary Care Center in Agra, Uttar Pradesh. The observed female predominance and age distribution patterns align with existing literature, highlighting the need for targeted screening strategies. These findings underscore the importance of routine thyroid function testing, especially in women and older adults, to enable early detection and management of Subclinical Thyroid Disorders.

**Funding :** None.

**Conflict of Interest :** None.

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Original Article

# Knowledge Assessment of Government Medical Officers Dealing with Cases of Sexual Violence Against Females in relation to Medical Examination of Survivor and Accused in Bhavnagar District of Gujarat : A Cross-sectional Study

**Sweta H Patel[1], Amit Kumar[2], Hemal Moga[3], Divyesh Vadgama[4], Devendra Panchal[4], Amit Parmar[5], Bhargav Purohit[6]**

## Abstract

**Background :** Healthcare professionals play a crucial role in the adjudication of sexual violence cases, which requires a sensitive and informed approach. Despite their importance, studies have shown that health services often lack a gender-sensitive approach in documenting testimony, conducting physical examinations and collecting evidence for medico-legal purposes.

**Materials and Methods :** A cross-sectional study was conducted among Medical Officers in the Bhavnagar district to assess their knowledge regarding the medical examination of survivors and accused individuals in cases of sexual violence against females. A pre-formed, pre-tested and validated questionnaire with a maximum score of 25 was administered via Google Forms. The study included 43 participants with varying levels of experience in handling such cases.

**Results :** The results showed that participants with different levels of experience scored between 13-20 out of 25. Specifically, 18 participants with 0-5 years of experience, 8 participants with 6-10 years of experience and 17 participants with over 11 years of experience demonstrated a need for improved knowledge and skills in this area.

**Conclusion :** The findings of this study highlight the need for regular training programs to enhance the practical efficacy of Medical Officers in conducting medical examinations of survivors and accused individuals in cases of sexual violence. The results can inform policy decisions and guide the development of targeted training initiatives to improve the response of healthcare professionals to sexual violence cases.

**Key words :** Government Medical Officers, Knowledge Assessment, Sexual Violence, Medical Examination, Survivor, Victim, Accused.

Women experiencing physical violence are more likely to seek medical attention at healthcare centers than any other institution, presenting an opportunity for healthcare providers to mitigate the effects of sexual violence[1]. The role of healthcare providers is crucial in responding to survivors of sexual violence with empathy and humanity while adhering to technical and legal procedures[2,3].

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***Received on : 14/05/2025***
***Accepted on : 02/06/2025***

***Editor's Comment :***

- Incorporating the new details on Gujarat's first study, knowledge gaps in legal documentation and consent, experience impacts, and calls for systemic reform.
- This pioneering Gujarat study reveals Medical Officers' strong clinical knowledge but critical gaps in legal documentation, consent, and sample collection.
- Experience alone doesn't guarantee knowledge — tertiary exposure and training do.

### Importance of Healthcare Provider Response :

The Criminal Law (Amendment) Act, 2013,[4] emphasizes the importance of prioritizing survivors' health and ensuring adequate care during judicial proceedings. Effective response to sexual violence requires training for all stakeholders, including Medical professionals, Law enforcement and the Judiciary[5].

### Medical Assessment in Sexual Assault Cases :

The collection and evaluation of forensic evidence, along with genital examination, are critical components of medical assessment in reported sexual assault cases. Healthcare providers require extensive knowledge to document history and conduct medico-legal examinations to verify the commission of a crime and identify factors that may mimic sexual assault[6].

***How to cite this article :*** Knowledge Assessment of Government Medical Officers Dealing with Cases of Sexual Violence Against Females in relation to Medical Examination of Survivor and Accused in Bhavnagar District of Gujarat : A Cross-sectional Study. Patel SH, Kumar A, Moga H, Vadgama D, Panchal D, Parmar A, Purohit B. *J Indian Med Assoc* 2026; **124(2):** 22-4.

### Objective of the Study :

This study aims to highlight the essential medico-legal aspects of sexual violence against females, equipping healthcare professionals with the knowledge and skills necessary to effectively manage cases of sexual offenses during their medical careers.

## Materials and Methods

### Study Design and Setting :

A cross-sectional study was conducted at the Department of Forensic Medicine and Toxicology, Government Medical College Bhavnagar, over a period of four consecutive months (ie, from 6th April, 2023 to 5th August, 2023).

### Study Participants and Ethics :

The study was conducted among Government Medical Officers dealing with medical examinations of survivors and accused individuals in cases of sexual violence against females in Government Hospitals of Bhavnagar district. The study received approval from the Institutional Ethics Committee. A pre-formed and pre-tested validated questionnaire was utilized as the study tool. The questionnaire consisted of 25 structured, validated "yes" or "no" items designed to assess knowledge regarding the medical examination of survivors and accused individuals in cases of sexual violence against females. The questionnaire covered various aspects, including history taking, consent, medical examination, sample collection and opinion formation. A pilot study was conducted on 15 Medical Officers who were not part of the original study to validate the questionnaire.

### Data Collection :

The final questionnaire was shared with participants via a WhatsApp group in the form of a Google Form. Medical Officers who did not submit completely filled questionnaires were excluded from the study. A cross sectional study was conducted by the Department of Forensic Medicine and Toxicology at Government Medical College Bhavnagar for a period of 4 consecutive months.

## Results

A total of 43 participants completed the test, with a maximum score of 25. The scoring system awarded 1 point for correct answers and 0 points for incorrect answers. The knowledge level was categorized based on the percentage of correct answers.

### Classification of Knowledge Level :

- Poor : 0-50%
- Intermediate/Adequate : 51-70%
- Good/High : 71-100%

### Participant Performance :

Participants with varying levels of experience scored between 13-20 out of 25.

### Specifically :

- 18 participants with 0-5 years of experience.
- 8 participants with 6-10 years of experience.
- 17 participants with over 11 years of experience.

### Knowledge Assessment :

**The questionnaire assessed knowledge in five areas:**

(1) History Taking (6 marks).

(2) Consent (4 marks).

(3) Medical Examination (8 marks).

(4) Sample Collection (5 marks).

(5) Opinion (2 marks).

### Performance Metrics :

The results of Table 1 indicate varying levels of knowledge among participants, with the highest correct response rate observed in Medical Examination (79.94%) and the lowest in Opinion (63.95%).

### Correlation between Years of Experience and Knowledge Level :

The Spearman Rank Correlation analysis showed a p-value of 0.4301, indicating no significant correlation between years of experience and knowledge level. The Spearman r-value was 0.1267, with a 95% confidence interval of -0.1975 to 0.4258, further supporting the lack of correlation.

## Discussion

This study is the first of its kind conducted in Gujarat, India. The findings indicate that participants demonstrated adequate knowledge in clinical aspects, particularly in

Table 1 — *Frequency distribution of knowledge among 43 participants*

| | *History Taking Marks* | *Consent* | *Medical Examination* | Sample Collection | Opinion |
|---|---|---|---|---|---|
| Total Marks in Each Section | 6 | 4 | 8 | 5 | 2 |
| Maximum Marks Obtained In Section | 6 | 4 | 8 | 5 | 2 |
| Minimum Marks Obtained In Section | 0 | 1 | 3 | 0 | 0 |
| No of Participants with Maximum Marks | 3 | 7 | 8 | 6 | 16 |
| No of Participants with Minimum Marks | 1 | 3 | 1 | 1 | 4 |
| Total Answers | 258 | 172 | 344 | 215 | 86 |
| Total Correct Answers | 186 | 118 | 275 | 141 | 55 |
| Correct Responses (%) | 72.09 | 68.60 | 79.94 | 65.58 | 63.95 |

medical examination and opinion formation, but showed gaps in legal documentation. Tables 2, 3 & 4 shows younger participants (25-30 years) excelled in theoretical aspects of opinion formation, while senior participants (51-55 years) performed better in practical aspects of medical examination.

### Impact of Experience :

The study reveals that knowledge levels do not necessarily correlate with years of experience. Doctors working in Tertiary Care Centers affiliated with Medical Colleges scored higher, likely due to increased exposure to sexual offense cases and regular training.

### Areas for Improvement :

The study highlights significant gaps in knowledge related to consent and sample collection. Regular Training Programs should focus on these areas to improve the quality of care provided to survivors of sexual violence.

Table 2 — *Distribution of Participants by Age and Score*

| Age group (in years) | Score | |
|---|---|---|
| | 11 to 15 | 16 to 20 |
| 25-30 | 4 | 8 |
| 31-35 | 5 | 5 |
| 36-40 | 0 | 2 |
| 41-45 | 1 | 4 |
| 46-50 | 0 | 5 |
| 51-55 | 2 | 6 |
| 56-60 | 0 | 1 |

Table 3 — *Maximum and Minimum Scores by Age Group*

| Age group (in years) | Maximum | Minimum |
|---|---|---|
| 25-30 | Opinion | Consent |
| 31-35 | Opinion | Sample Collection |
| 36-40 | Medical Examination | Sample Collection |
| 41-45 | History Taking | Consent |
| 46-50 | History Taking | Consent |
| 51-55 | Medical Examination | Consent |
| 56-60 | Medical Examination | Sample Collection |

Table 4 — *Distribution of Participants by Years of Experience and Score*

| Experience in dealing with sexual offence cases (in years) | SCORE | |
|---|---|---|
| | 11 to 15 | 16 to 20 |
| < 5 | 7 | 11 |
| 06 – 10 | 3 | 5 |
| 11 - 15 | 0 | 6 |
| 16 - 20 | 0 | 4 |
| 21 - 25 | 0 | 7 |

### Need for Systemic Change :

The persistence of outdated practices, such as the two-finger test, despite being banned, underscores the need for systemic reforms. Guidelines and protocols for medico-legal care, such as those issued by the Ministry of Health & Family Welfare in 2014, emphasize the importance of prioritizing counseling and respecting survivors' privacy and physical integrity.

## Conclusion

The study's findings emphasize the need for targeted training programs and systemic reforms to ensure that medical professionals provide high-quality care to survivors of sexual violence. The study's questionnaire can serve as a valuable tool for Medical Officers to focus on critical medico-legal aspects of sexual violence against females, enhancing their competence in managing such cases and contributing to the administration of justice. The findings can inform policy decisions, supporting the implementation of regular training programs to improve the practical skills of medical professionals in conducting medical examinations of survivors and accused individuals in cases of sexual violence.

**Source of funding :** None.

**Conflict of Interest :** No conflicts of interest to declare.

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Original Article

# Epidemio-clinical Profile and the Effect of Intensity of Clotting Factor Administration on Haemophilia A Patients in a Resource Limited Peripheral Medical College

**Abhilash Chatterjee[1], Tapan Kumar Kundu[2], Aditi Chowdhury[3], Mitali Bera[4], Imran Khan[3]**

**Abstract**

**Background :** Epidemio-clinical data of the Haemophilia children in the Eastern India are scarce. Supply of clotting factor is also a major issue for a resource limited Haemophilia Treatment Centre. So, our aim was to study the epidemio-clinical profile of the Haemophilia children attending a Peripheral Medical College and the impact of intensity of clotting factor administration on the Annualised Bleeding Rate (ABR) of Haemophilia A patients to find a suitable prophylactic regimen.

**Materials and Methods :** This was a cross sectional retrospective hospital based single centre study on the Haemophilia patients under the age of 18 years diagnosed with clotting factor estimation and attending a resource limited Haemophilia Treatment Centre of a Peripheral Medical College between July, 2019 to December, 2019. Epidemio-clinical data were obtained. The mean ABR was compared between different groups of intensity of clotting factor administration.

**Results :** Haemophilia A comprised of 46 (88.46%) and Haemophilia B 6 (11.54%) patients. Family history was present in 34 (65.38%). Hemophilia was severe in 46 (88.46%). The most common first clinical presentation was bruise. Knee joint was most common joint involved. Occurrence of target joint was seen in 28 patients (53.85%). No patient could receive the full annualised dose of the prescribed prophylactic factor therapy. Episodic treatment were received by 22, prophylactic therapy by 30 patients. Comparison of ABR between the three groups of intensity of clotting factor administration was statistically significant (p value 0.002065) and comparison between intermediate level prophylactic group and low level prophylactic group was statistically not significant (p value 0.68947).

**Conclusion :** Given the limited supply of clotting factor, one has to settle with the intermediate or low level prophylaxis regimen and with strict compliance to regular infusions and required intervals between the infusions.

**Key words :** Haemophilia, On Demand Therapy, Prophylactic Therapy, Low Level Prophylaxis, Intermediate Level Prophylaxis, Target Joint.

Haemophilia A and B are congenital bleeding disorders caused by an X-chromosome linked deficiency in coagulation factors VIII or IX respectively. Severe deficiency is associated with bleeding into the joints and recurrent bleeding results in haemophilic arthropathy, disability and reduced Quality of Life. As per the recent population statistics by World Federation of Haemophilia (WFH) about 1,97,183 people are suffering from Haemophilia Globally and India contributes to 9.2% of the Haemophilia burden. Data on epidemiological and clinical profile of the Haemophilia children in the peripheral parts of West Bengal and Eastern India are scarce[1].

The bleeding is treated with intravenous Factor VIII/IX concentrate either on demand or prophylactically. In Haemophilia, prophylaxis can be defined as the administration of clotting factor concentrate in anticipation of or to prevent bleeding. On demand or episodic treatment refers to administration of replacement factor only in response to clinically evident bleeding. Now-a-days prophylactic therapy is becoming more common[1].

***Editor's Comment :***

- Haemophilia though rare do occur in rural community occasionally. There is little to choose between intermediate and low level prophylaxis regimen. But what is must is strict compliance to the schedule of clotting factor administration.

Haemophilias are divided into three different degrees of severity with clotting factor activity as Severe (<1%), Moderate (1-5%) and Mild (5-40%)[2].

Our aim was to study the Clinico-epidemiological profile of the Haemophilia children attending the resource limited Haemophilia Treatment Centre of a Peripheral Medical College and the impact of intensity of clotting factor administration on the Annualised Bleeding Rate of Haemophilia A Patients.

## Material and Method

A cross sectional retrospective hospital based single centre study was conducted in the Paediatric Haemophilia treatment centre in a resource limited Peripheral Medical College from July, 2019 to December, 2019. Institutional Ethics Committee (IEC) approval was taken. Informed written consent was taken from the parents or legal guardian if applicable.

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***Accepted on : 13/12/2024***

***How to cite this article :*** Epidemio-clinical Profile and the Effect of Intensity of Clotting Factor Administration on Haemophilia A Patients in a Resource Limited Peripheral Medical College. Chatterjee A, Kundu TK, Chowdhury A, Bera M, Khan I. *J Indian Med Assoc* 2026; **124(2):** 25-8.

All children of Haemophilia who attended Paediatrics Haemophilia Treatment Centre were study population. In 52 Haemophilia patients were included in the study.

### Inclusion Criteria :

- Haemophilia patients diagnosed with clotting factor assessment.
- Age below 18 years.
- Haemophilia patients attending for prophylactic clotting factor administration and admitted for on demand factor concentrate therapy.

### Exclusion Criteria :

- Patients with platelet and vascular disorders.
- Patients with clinically relevant coagulation disorders other than Haemophilia A or B.
- Patients with Hepatitis B virus, Hepatitis C virus or Human Immune Deficiency Virus infections.
- Subjects with hepatic or renal impairment.
- Patient having chronic illness or taking chronic medication.

The study was neither sponsored nor funded.

Retrospective data were obtained and recorded in a predesigned proforma by interviewing the Haemophilia children or their parents and from the Haemophilia Treatment Centre records. For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc, Chicago, IL, USA) and GraphPad Prism version 5.

Standard half life clotting factors were used in our study. Prophylactic therapy was initiated with 20 IU/kg/dose three times weekly ie, 3120 IU/kg/year. Their mean annualized clotting factor administration were calculated and the relationship with their mean Annualized Bleeding Rate was analysed.

Annualised clotting factor administration was calculated by the clotting factor administered per kg body weight during 6 months period multiplied by two.

The Annualized Bleeding Rate (ABR) was calculated as the number of reported bleeding events during six months and multiplied by two.

Determination of intensity of prophylactic clotting factor administration was on the basis of those between 3120 – 2341 IU/kg/year (More than 75% of the prescribed dose) as intermediate level prophylactic group and between 2340 – 1561 IU/kg/year (ie, between 75-50% of the prescribed dose) as low level prophylactic group.

The Annualized Bleeding Rate between the intermediate level prophylactic group, low level prophylactic group and on demand group in Haemophilia A patients were compared. One way ANOVA test was applied between them. The Annualized Bleeding Rate between the intermediate level prophylactic group and low level prophylactic group was compared by applying 't' test.

## Results

Determination of intensity of prophylactic clotting factor administration was on the basis of —

*Intermediate level prophylactic group - those between 3120 – 2341 IU/kg/year (More than 75% of the prescribed dose)

Table 1 — *Epidemio-clinical profile of Haemophilia children (N=52)*

| | | |
|---|---|---|
| Age in years | 1-5 years | 13 (25%) |
| | 6-10 years | 25 (48.08%) |
| | 11-15 years | 14 (26.92%) |
| | Total | 52 |
| Residence | Rural | 45 (86.54%) |
| | Urban | 7 (13.46%) |
| | Total | 52 |
| Socio-economic status | Lower | 31 (59.62%) |
| | Lower middle | 5 (9.62%) |
| | Upper lower | 11 (21.16%) |
| | Upper middle | 5 (9.62%) |
| | Total | 52 |
| Type of Haemophilia | Haemophilia A | 46 (88.46%) |
| | Haemophilia B | 6 (11.54%) |
| | Total | 52 |
| Haemophilia severity | Mild | 0 (0%) |
| | Moderate | 6 (11.54%) |
| | Severe | 46 (88.46%) |
| | Total | 52 |
| Family history | Absent | 18 (34.62%) |
| | Present | 34 (65.38%) |
| | Total | 52 |
| First clinical presentation | Bruise | 30 (57.69%) |
| | Gum bleed | 3 (5.77%) |
| | Joint bleed | 11 (21.15%) |
| | Muscle bleed | 4 (7.69%) |
| | Prolonged bleeding from wound | 3 (5.77%) |
| | Scalp haematoma | 1 (1.92%) |
| | Total | 52 |
| Modality of Treatment | On demand | 22 (42.31%) |
| | Prophylactic | 30 (57.69%) |

Table 2 — *Epidemio-clinical profile of Haemophilia children (N=52)*

| | Mean | SD | Min | Max |
|---|---|---|---|---|
| Age in years | 8.3743 | 2.6583 | 3 | 14 |
| Weight (in kg) | 25.6743 | 9.3687 | 11 | 50 |
| Height (in cm) | 122.9061 | 18.4366 | 82 | 164 |
| BMI | 16.3592 | 1.8224 | 11.57 | 21.97 |
| Age at presentation (in months) | 19.7728 | 16.8940 | 8 | 72 |

Table 3 — *Clinical profile of joint involvement (N=52)*

| | | Total (N=52) |
|---|---|---|
| Knee joint bleeds | | 38 (73.08%) |
| Ankle joint bleeds | | 16 (30.77%) |
| Wrist joint bleeds | | 14 (26.92%) |
| Elbow joint bleeds | | 12 (23.1%) |
| Target joint | | 28 (53.85%) |
| Target joint type : | Knee | 21/28 (75%) |
| | Ankle | 5/28 (17.86%) |
| | Wrist | 1/28 (3.57%) |
| | Elbow | 1/28 (3.57%) |
| | Total | 28 (100%) |

Table 4 — *Effect of level of clotting factor administration on the Annualized Bleeding Rate (ABR) of Haemophilia A patients (N=46)*

| Intensity of clotting factor administration | No of patients | Annualized Bleeding Rate | | | | p-value |
|---|---|---|---|---|---|---|
| | | Mean | SD | Min | Max | |
| Intermediate level prophylactic group* | 13 | 4.77 | 1.30 | 4 | 8 | 0.002065 |
| Low level prophylactic group** | 13 | 6 | 2.58 | 4 | 12 | |
| On demand group*** | 20 | 7.8 | 2.59 | 4 | 12 | |

**Corresponds to the intermediate level prophylactic group description (3120-2341 IU/kg/year).*
***Corresponds to the low level prophylactic group description (2340-1561 IU/kg/year).*
****Corresponds to the on demand group description (those Haemophilia A patients who were administered clotting factor based on clinically evident bleeding not on prophylaxis.*

**Low level prophylactic group – those between 2340-1561 IU/kg/year (ie, between 75-50% of the prescribed dose)

***On demand group included those Haemphilia A patients who were administered clotting factor based on clinically evident bleeding not on prophylaxis.

## Discussion

Out of total 52 Haemophilia patients, 25 (48.08%) patients were of 6-10 years age, 14 (26.92%) patients of 11-15 years age and 13 (25%) patients of 1-5 years age. In a study by Manco Johnson, patients were of less than 30 months age[3]. In a study in Bangladesh[4] 22 (44%) patients were of 6-15 years and 19 (38%) patients were of 16-30 years age.

In 45 (86.54%) patients were staying at Rural area. In 31 (59.62%) patients belonged to Lower Socio-economic class, 11 (21.16%) in Upper Lower Socio-economic class, 5(9.62%) in Lower Middle Socio-economic class and 5 (9.62%) in Upper Middle Socio-economic class according to Modified Kuppuswamy's scale[5].

Haemophilia A was observed in 46 patients (88.46%) while Haemophilia B was observed in 6 patients (11.54%). In most of the earlier studies, Haemophilia A constituted around 80% of total Haemophilias[4,6,7]. In a Pakistani study, proportion of Haemophilia A was found to be low (65%) [8].

In 46 Haemophilia patients (88.46%) had Severe and 6 Haemophilia patients (11.54%) had Moderate factor deficiency. In a study in Jodhpur, 44% cases had Severe, 36% had Moderate, and 20% had Mild disease[6]. Other studies from India showed similarly high percentages of severe Haemophilia[9-11]. Striking contrast was seen in a study in Bangladesh where only 10 % of Haemophilia B had Severe disease[7]. Data from the high-income countries showed prevalence of 39%, 14% and 45% of Mild, moderate and Severe cases, respectively[1].

Family history of Haemophilia was present in 34 patients (65.38%). Similar results were obtained in a study in India where family history was present in 53% of Haemophilia A and 45% of Haemophilia B patients[9]. In a study in Bangladesh, 40% cases had family history of bleeding[7].

In 30 (57.69%) patients had bruise as the first clinical presentation,11 patients (21.15%) had joint bleed, 4 patients (7.69%) had muscle bleed, 3 patients (5.77%) had gum bleed, 3 patients (5.77%) had prolonged bleeding from wound and scalp Haematoma was present in 1 patient (1.92%). In one study, postcircumcision bleed has been found to be the most common initial bleed (51.4-62% of the case)[12]. In a study at Jodhpur, Post-traumatic bleed was the most common first clinical presentation in 36% cases[6]. In a study at Bangladesh, bruises and echymoses were the most common initial presentation in 40% of cases[7].

Knee joint bleeds were observed in 38 (73.08%) patients, Ankle joint bleeds in 16 (30.77%), Wrist joint bleeds in 14 (26.92%) and Elbow joint bleeds in 12 (23.1%). Similar findings were seen in a study at Jodhpur, where Knee joint was predominantly affected (68%) followed by Ankle joint (52%) then Elbow joint (36%)[6]. In a study at Korea, joints more frequently affected were the knee (89.0%), the Elbow (22.5%) and Ankles (21.5%)[12].

When bleeding occurs repetitively into the same joint, it is called a Target joint[13]. Target joints were present in 28 (53.85%) patients. In a study at Jodhpur, 37.5 % patients of haemophilia had developed Target joint[14]. In our study, the Target joint involved was knee joint in 21 (40.38%), Ankle joint in 5 (9.62%), Wrist joint in 1 (1.92%) and Elbow joint in 1 (1.92%) patient. In a study at Jodhpur, knee joint was the predominant Target joint in 28.57% cases[14].

22 (42.31%) Haemophilia patients received on demand and 30 (57.69%) patients received prophylactic coagulation factor therapy. In a study in Indonesia, 50% patients received on demand factor therapy and 50% patients received prophylactic factor therapy[15]. In a study in Italy, 51% patients received prophylaxis and 49% patients received on demand therapy[16].

Prophylactic therapy administered to 26 of the Haemophilia A patients were 20 IU/kg/dose thrice weekly that is equivalent to 3120 IU of clotting factor per kg per year. But none of the patients could receive the full quota of the clotting factor. These patients were divided into two subgroups. Intermediate level prophylactic group comprising of 13 patients, received more than 75% of the prescribed dose (3120-2341 IU of clotting factor per kg per year). Low level prophylactic group comprising of 13 patients, received 75-50% of the prescribed dose (2340-1561 IU of clotting factor per kg per year). On demand therapy administered to 20 of the Haemophilia A patients received 1538 IU of clotting factor per kg per year.

The Annualized Bleeding Rate (ABR) was calculated as the number of reported bleeding events in 6 months and multiplied by 2. The mean ABR in the intermediate level prophylactic group was 4.77 (SD 1.30), that in the

low level prophylactic group was 6 (SD 2.58), that in the on demand group was 7.8 (SD 2.59). The three groups were compared by applying one way ANOVA test and the result was statistically significant (p value 0.002065). Similar results were obtained by a systematic review and meta-analysis done by Carolina J Delgado-Flores, *et al*[17].

When the annualised bleeding rate was compared between intermediate level prophylactic group with that of low level prophylactic group by applying t test, the result was statistically not significant (p value 0.68947).

A study done by jiu-Mu-Zhuang, *et al* concluded that low intermediate treatment dose of prophylaxis with FVIII can significantly improve the bleeding phenotype and delay the joint injury progression, when compared with on demand treatment[18].

An article highlighted more than 90% cost of hemophilic treatment is due to clotting factor. 80% of World Haemophilia patients live in resource limited conditions. 10-20% of these are identified. Advocacy are necessary to engage the Government along with other measures[19].

Low dose FVIII prophylaxis was cost effective, efficacious and safe for the treatment of joint bleeds and consequent joint changes were observed by Verma SP, *et al*[20].

Supply of clotting factor is a major issue for a resource limited Haemophilia Treatment Centre. Issue may be with the quantity and its regularity of supply and also its cost-effectiveness. Infusions of the clotting factor should be tailored according to requirements at the level of the Haemophilia Treatment Centre and at the individual level of the patient for optimal utility in terms of affordability, feasibility and accessibility keeping in mind the interest of the children who are bleeding and crippling and becoming burden to themselves and the society.

## Conclusions

Given the limited supply of clotting factor, one has to settle with the intermediate or low level prophylaxis regimen and with strict compliance to regular infusions and required intervals between the infusions. The effectiveness of these regimens should be determined through different studies in the future.

**Funding :** None.

**Conflict of Interest :** None.

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Original Article

# The Unspoken Realism of Hurdles among School Teachers — The Aftermath of COVID Lockdown in Western Maharashtra

**Akhila B S[1], Kajal Srivastava[2], Chaitali Borgaonkar[3], Hetal Rathod[2], Sudhir L Jadhav[2], Priyanka Borkar[4]**

**Abstract**

**Background :** The COVID-19 epidemic has profoundly impacted the educational system not just in India but also across the World. The outbreak has placed teachers in an unanticipated predicament where the lockdown situation led to the closure of educational institutions and expedited the transition from conventional to online learning strategies, which could have had implications on the school teachers' physical, social, and mental well-being.

**Aims and Objectives :** • To explore the various health related, psychosocial, and financial challenges faced by school teachers during the COVID lockdown. • To provide recommendations based on the study findings.

**Materials and Methods :** A cross sectional study on teachers working in schools of Western Maharashtra was carried out and evaluated using pretested self-developed questionnaire. Data was entered in Microsoft Excel and analysed using MedCalc software version 3.1. Frequency, percentage was also calculated.

**Results :** Out of the total study population of 100 teachers, main findings showed that exacerbation of health problems (14.0%), stress from Authorities (35.0%), Episodes of feeling low (24.0%), Domestic violence (11.0%) and Financial difficulties (37.0%) were faced by school teachers during lockdown period.

**Key words :** Challenges, School Teachers, Stress, Lockdown, COVID-19.

The COVID-19 pandemic began with the breakout of SARS-CoV-2 in Wuhan at the end of 2019, and its fast Worldwide spread[11]. Governments all throughout the world have imposed stringent isolation measures in order to reduce the number of illnesses and fatalities caused by a lack of suitable treatments. Schools were closed under this unprecedented scenario and millions of students were denied access to education, exacerbating social disparities[1].

The COVID-19 epidemic had serious repercussions for the working environment of frontline personnel[8]. Frontline personnel are job groups that interact with consumers, clients, patients, students, and so on, and they frequently perform critical duties that cannot be performed from home (The Lancet Editorial 2020)[2]. It had a significant effect on teachers as well.

Due to the everyday stress of managing work overload, emotions, and resolving conflicts in the classroom, teaching is an incredibly challenging profession[1]. Firstly, the teaching-learning process is complicated by detours in learning and other negative implications including lack of access to facilities, improper infrastructure, inadequate nutrition, absenteeism, social issues especially when parents are also insufficiently prepared for homeschooling or distance learning or are otherwise unavailable to take care of their children[3]. Secondly, educators are frequently perplexed and stressed because they are unaware of their responsibilities and how to establish connections with students to assist learning[3]. Even in the most ideal of circumstances, transitions to remote learning systems are messy and frustrating. In many instances, school closures culminate in teacher sequestration or disruptions. Thirdly, establishing, sustaining and strengthening online education, as well as assessing and validating learning, are substantial technological and human challenges that must be overcome in order to efficiently and widely deliver learning from classrooms to homes[4].

Because of the extra responsibility entailed with home teaching, recent research had found that teachers experience stress during lockdown, which is frequently accompanied by symptoms of Anxiety, Depression and Sleep Disturbance[5]. Another point to consider is that the COVID-19 pandemic has not only caused a health

***Editor's Comment :***

- The study underlines the necessity of protecting the wellbeing of teachers to boost teaching quality and indirectly the health of students.
- There is a need to consider various issues that impact educators' ability to work effectively and adopt measures to solve these problems, with the aid of Government, parents, institutions, and educationists.

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***Received on : 22/02/2024***
***Accepted on : 25/10/2024***
***Received on : 22/02/2024***
***Accepted on : 25/10/2024***

***How to cite this article :*** The Unspoken Realism of Hurdles among School Teachers — The Aftermath of COVID Lockdown in Western Maharashtra. Akhila BS, Srivastava K, Borgaonkar C, Rathod H, Jadhav SL, Borkar P. *J Indian Med Assoc* 2026; **124(2):** 29-32.

catastrophe, but also a huge Worldwide economic slump, the impacts of which have been especially hard because teacher job insecurity was already a concern before to the pandemic and COVID-19 has only contributed to intensify this problem with increased redundancies and instability causing a significant adverse psychological impact on them as well[2,9,10].

The majority of previous study has been on the effects of school closures on children's mental health and learning, as well as the necessity of preparing teachers for upcoming changes in online teaching practises. Few studies have examined teachers' psychological challenges in the backdrop of COVID-19 confinement, despite the likelihood that their mental health may have a direct bearing on the emotional wellbeing of their children[1].

In the current scenario, when health is seen holistically, relatively few research has taken that component into consideration in benefit of the educators. Therefore, the purpose of our study is to assess the various challenges experienced by school teachers during COVID lockdown period including physical, mental, social, and financial aspects, since comprehending about the pandemic's consequences is vital not just for teachers, but also for children, parents, and educational administrators, who are directly or indirectly influenced by the welfare of educators[1].

## Material and Methods

This was a cross-sectional study conducted in selected schools of Western Maharashtra for a study period of 6 months (July, 2022- December, 2022). A total of 100 school teachers from classes 1 to 12 in the selected Private and Government schools were included in the study. Besides attaining prior approval from the Institutional Ethical Committee before the start of the study, informed written consent from the teachers were also taken along with permission from the respective school authorities as a part of the study. Exclusion criteria included teachers who were suffering from illnesses, non-cooperative students, and absentees.

The Sample size was calculated using WinPepi VI 1.65 software in reference to the article " Teachers' Response to Stress, Anxiety and Depression During COVID-19 Lockdown: What Have We Learned from the Pandemic?", with prevalence of stress being 46.6% and acceptable difference of 10% within 95% CI. Though the minimum sample calculated was 96, 100 teachers were enrolled for the study.

Stratified random sampling was carried out - initially the field area was divided into a list of equal number of government and private schools followed by random selection of equal proportion of school teachers from each group. The sample selection process was as described in flow chart (Fig 1).

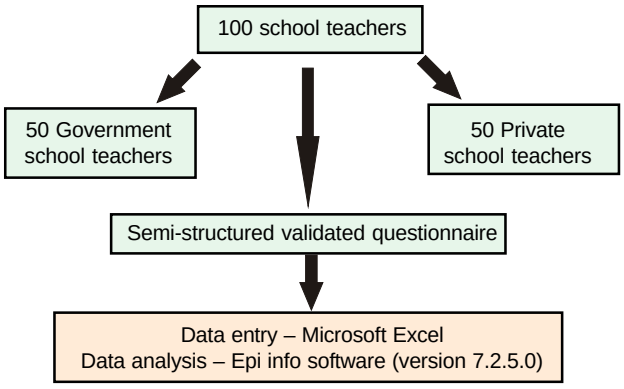


Fig 1 — Showing Flow Chart

A semi- structured validated questionnaire was used for data collection. A total of thirty-nine questions encompassing various sections namely Socio-demographic details, health problems, mental issues, social and financial difficulties was developed to gain insight into the way teachers perceived the pandemic and the challenges they encountered. All data was presented in the form of numbers and percentages. Data was entered in Microsoft Excel and analysed using MedCalc software (version 3. l). Frequency, percentage was calculated for the nominal variables and descriptive statistics was calculated for the quantitative variables.

## Observations

### Socio-demographic Variables :

In 100 School teachers (84% female and 16 male) participated in the study with majority of them belonging to age group 40-50(41%, 95%CI: 31.26%- 51.29%), nuclear family (58%, 95%CI: 47.71%- 67.80%) and having children (84%, 95%CI: 75.32% -90.57%).

Under the physical aspect, 40% (95%CI:30.33% -50.28%) of the population experienced new health issues, with Hypertension (20.5%), hair and skin issues (20.5%) and Diabetes Mellitus (15.9%), making up the majority in addition to 14.0% (95%CI: 7.87%- 22.37%) showing exacerbation of existing health problems during the lockdown period. Besides, 9.52% (95% CI: 3.52% - 15.56%) also reported new menstrual problems including polymenorrhoea followed by oligomenorrhoea.

The psychological aspect revealed that 76% (95% CI: 16.02% - 33.57%) teachers had new episodes of feeling low out of which only 20.83% (95% CI: 7.13% - 42.15%) sought treatment. Besides household activities and daily gatherings was perceived as depressing by 53% and 7% of the population respectively.

When social aspect was considered, it was found that teachers had experienced increased stress from an array of sources including School Authorities (35%, 95% CI: 25.73% -45.18%), Parents (21%, 95% CI: 13.49% -

30.29%), Students (19%, 95% CI: 11.84% - 28.07%) and Own Children (25%, 95% CI: 16.19% -35.64%). Eleven percentage (95% CI: 5.62% - 18.83%) of them additionally mentioned increase in physical abuse as well. Few positive findings were also noted which included 61% using their time for innovative ideas like new hobbies (83.61%), extra income source (8.20%), knowledge gain (4.92%) and others (3.28%).

Financial aspect showed a substantial financial strain being experienced by 37% teachers (95% CI: 27.56% - 47.24%) mostly due to loss of job (24.32%), reduced family income (8.11%). This had an effect mainly on daily needs (54.05%), recreational activities (32.43%) and fee payment (13.51%).

## Discussion

Globally, the schooling system has been seriously impacted by the COVID-19 pandemic. In 210 economies, there have been complete or partial school closures, with 84 economies experiencing more than 40 weeks of closure (a full school year), according to UNESCO (2021b)[15].

### Physical Aspect :

The current study identified a considerable rise in new health conditions, including Diabetes Mellitus, Hypertension, Hair and Skin Disorders, and others, as well as an aggravation of already existing illnesses. These results are in line with those of previous research that have noted similar findings. This includes the studies carried out by Idris F, *et al* (2021) and Kozubal A, *et al* (2022), who stated, among other findings, back discomfort, eyesight loss, sleep disturbance, gastrointestinal issues, and the worsening of existing conditions as major health problems faced during lockdown[12,13]. Research conducted in India by Kumari A (2020) additionally evaluates the prevalence of physical illness on a scale of increasing severity underlying related issues[6]. Even if the major health concerns were somewhat distinct from those in other studies, it's crucial to remain cognizant that they all point to an upsurge in health issues during the same period.

### Psychosocial Aspect :

Despite the fact that the assessing methodologies used were not precisely comparable, various studies conducted all over the World corroborated our results of elevated stress and poor mental health among teachers during the COVID lockdown period. While a few studies (Nielsen K, *et al* 2021; Lacomba-Trejo L, *et al* 2021; Jakubowski TD, *et al* 2021) highlighted a spike in Stress, Anxiety and Depression during the pandemic, other studies (Idris F, *et al* 2021; Ozamiz-Etxebarria N, *et al* 2021; Aperribai L, *et al* 2020) identified a number of elements that may have played a role, including increased workloads, impending deadlines, concerns about one's own well-being and those of family members, job instability, and parenthood[1-5,12,14]. In line with our presumption that Stress was a key factor in the present situation, we observed that the teachers endured a substantial level of stress from not just the school authorities but also from parents, students, their own children, and family. Furthermore, we investigated into the domestic violence component and observed that 11.0% of them had been subjected to it which is extremely concerning given that it may merely be the tip of the iceberg given the taboo tied to it.

### Economic Aspect :

According to UNESCO (2021c), closing schools has a detrimental effect on people's economic and social stability all over the World[4]. In 2020, according to a UNICEF estimate, approximately 8 million children were not enrolled in school and the unemployment rate had dramatically grown (UNICEF, 2020). Very few studies have been done specifically emphasising on the teachers, especially the financial aspect, in spite of the fact that numerous researchers contributed to the study of the Socio-economic impact of COVID-19 and its influence on the education sector as a whole during this pandemic. Therefore, in order to shed some light on the financial situation of teachers in schools during the COVID-19, we conducted further research and observed that, in accordance with the UNICEF report, more than one-third of the teachers faced financial hardship, primarily in the form of job loss and pay reduction[10]. Our findings were backed up by research conducted in Nepal by Devkota N that assessed the economic situation of school teachers and found a significant decline in employment as well as a significant decrease in monthly income and savings[7].

## Conclusion

The study underlines the necessity of protecting the wellbeing of teachers to boost teaching quality and indirectly the health of students and to consider various issues that impact educators' ability to work effectively and adopt measures to solve these problems, with the aid of Government, Parents, Institutions and Educationists.

**Following are the recommendations : -**

- Workshops for new teaching techniques and coping skills
- Health check ups
- Counselling sessions
- Interdisciplinary approach involving teachers, school authorities, parents and students

- An improvement in the legislative process and policy making aimed at enhancing the working conditions for teachers.

### Limitations of the study :

- This is a short-term study with a small sample size; so future research should be done on long term basis.
- Research on the long-term circumstances of educators during and after the pandemic is required, employing qualitative techniques like in-depth interviews, focus group discussion

**Financial Support and Sponsorship :** Nil

**Conflicts of Interest :** There are no conflicts of interest.

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**DISCLAIMER**

**Journal of the Indian Medical Association (JIMA)**

The Journal of the Indian Medical Association (JIMA) (ISSN 0019-5847) is published monthly in English language from Editorial Offices at Sir Nil Ratan Sircar IMA House, 53, Sir Nilratan Sarkar Sarani, Kolkata-700014. Telephone No. : +91-33-22378092, (+919477493027); websites: https://onlinejima.com & www.ejima.in ; Emails: jima1930@rediffmail.com ; jimaeditorial@gmail.com.

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***— Hony Editor***

Original Article

# Study on NAFLD and Liver Stiffness in Type 2 Diabetes Patients with Normal BMI

**Nilpadhini Debbarma[1], Avik Chakraborty[2], Dipankar Prakas Bhaumik[3], Sonali Bhaumik[4]**


## Abstract

**Background :** With increasing incidences of NAFLD in both obese and non obese individuals it is very important to correlate the incidence of NAFLD in Type 2 Diabetes mellitus with normal weight. Although there are multiple studies where liver stiffness has been studied using conventional elastographic techniques studies correlating liver stiffness with non invasive markers of fibrosis are lacking.

**Aims and Objective :** To assess the prevalence of Non-alcoholic Fatty Liver Disease (NAFLD) and liver stiffness in Type 2 Diabetes Mellitus (T2DM) patients with normal Body Mass Index (BMI) and explore the relationship between liver stiffness and non-invasive markers of liver fibrosis.

**Materials and Methods :** A cross-sectional study was conducted from January, 2023 to July, 2024 at Tripura Medical College and Dr BRAM Teaching Hospital, including 100 T2DM patients with normal BMI. Liver stiffness and fat content were measured using Fibroscan. Non-invasive markers APRI and FIB-4 scores were used to predict fibrosis severity. Data were analysed using SPSS 26.0.

**Results :** Among the 100 patients, 63% were diagnosed with NAFLD, with a slightly higher prevalence in females. The prevalence of liver fibrosis was 65%, with higher rates in females. Positive correlations were found between liver stiffness and non-invasive markers: APRI (r=0.507, p<0.0001) and FIB-4 (r=0.443, p<0.0001).

**Conclusion :** There is a significant prevalence of NAFLD and liver fibrosis among T2DM patients with normal BMI. Regular screening and early intervention are crucial for preventing progression to severe liver conditions.


**Key words :** Type 2 DM, NAFLD, Liver Stiffness.

Non-alcoholic Fatty Liver Disease (NAFLD) may be defined as excessive fat accumulation in the liver with ≥5% of hepatocytes containing visible intracellular triglycerides or steatosis affecting at least 5% of the liver volume or weight in patients without any history of significant alcohol consumption (20 gm in women and 30g in men daily)[1]. NAFLD encompasses a spectrum of liver conditions ranging from simple steatosis (known as Non-alcoholic Fatty Liver or NAFL), to Non-alcoholic Steatohepatitis (NASH) characterized by histologically evident ballooning degeneration of hepatocytes and hepatocellular injury, which can then progress to fibrosis, cirrhosis, and hepatocellular carcinoma[2,3]. While NAFLD is commonly associated with obesity, emerging evidence suggests that it can also occur in individuals with normal Body Mass Index (BMI), especially those with metabolic conditions like T2DM in whom, it is increasingly now recognized as a significant public health issue. In fact, epidemiological studies suggest that, in general up to 10-20% of individuals diagnosed with NAFLD could be lean.[4] Infact, individuals with lean NAFLD have been found to have an increased risk of developing Type 2 Diabetes mellitus (T2DM) and exhibit higher all-cause mortality compared to their obese counterparts with NAFLD[2,5,6].

***Editor's Comment :***

- In Type 2 Diabetes Mellitus patients with normal BMI ie, those without obesity, NAFLD (63%) and liver fibrosis (65%) are common.
- Non-invasive markers like APRI & FIB 4 show strong positive correlation with liver stiffness measured by Fibroscan. Hence it supports the utility of these markers. Therefore, regular screening & early intervention are essential in Type 2 Diabetes Mellitus population to prevent progression to advanced liver disease irrespective of body weight.

The prevalence of NAFLD among T2DM patients with normal BMI is not well-documented, particularly in the Indian population. Understanding the burden of NAFLD in this subgroup is crucial for developing targeted screening and management strategies. Additionally, liver stiffness, a key indicator of liver fibrosis, can be non-invasively measured using transient elastography (Fibroscan). Non-invasive markers such as the Aspartate Aminotransferase-to-Platelet-Ratio Index (APRI) and the FIB-4 score are valuable tools for assessing liver fibrosis risk and severity[7-11].

This study was conducted to assess the prevalence of Non-alcoholic Fatty Liver Disease (NAFLD) and liver stiffness in patients with Type 2 Diabetes Mellitus (T2DM) who have a normal Body Mass Index (BMI) and attend Tripura Medical College and Dr BRAM Teaching Hospital. The objectives were to determine the prevalence of NAFLD among T2DM patients with normal BMI, evaluate liver stiffness using

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***Accepted on : 30/06/2025***

***How to cite this article :*** Study on NAFLD and Liver Stiffness in Type 2 Diabetes Patients with Normal BMI. Debbarma N, Chakraborty A, Bhaumik DP, Bhaumik S. *J Indian Med Assoc* 2026; **124(2):** 33-5.

Fibroscan technology, and explore the relationship between liver stiffness and non-invasive markers of liver fibrosis, such as the APRI (Aspartate Aminotransferase-to-Platelet-Ratio Index) and the FIB-4 score (a fibrosis index based on age, AST, ALT, and Platelet count).

This hospital-based cross-sectional study was conducted in the Department of Medicine at Tripura Medical College and Dr BRAM Teaching Hospital, Hapania, West Tripura, over one and a half years from January, 2023 to July, 2024. The study population included T2DM patients with a normal BMI attending the Department of Medicine. Inclusion criteria were adults aged 18 years and older with T2DM for more than five years and a normal BMI (18.5-24.9) as per WHO guidelines. Exclusion criteria included patients with pre-existing Acute or Chronic Liver Disease, heart failure or other causes of congestive hepatomegaly, rib cage deformities preventing the use of Fibroscan, pregnant women, unwilling participants, and those with an implantable defibrillator or Pacemaker.

The sample size was calculated to be 100 using a non-probability (convenient) sampling method. Data was collected using a semi-structured proforma to gather detailed medical history, anthropometric measurements, and biochemical investigations. Liver fat and stiffness measurements were performed using Fibroscan, with APRI and FIB-4 scores derived from observed values. Transient elastography (Fibroscan) was used to measure liver stiffness and fat content, with liver stiffness results categorized as F0 to F4 based on kilopascals (kPa), and liver fat content assessed using the Controlled Attenuation Parameter (CAP).

Operational details included calculating BMI by dividing weight in kilograms by height in meters squared. Liver stiffness was measured using Fibroscan, with normal results between 2 and 7 kPa. Results were categorized from F0 (1-6 kPa) to F4 (≥10.4 kPa). CAP was measured in decibels per meter (dB/m) to assess liver fat content, with categories from S0 (no steatosis) to S3 (severe steatosis). APRI was calculated using AST level and platelet count to predict fibrosis severity, and FIB-4 was an index using age, AST, ALT and Platelet count to assess liver fibrosis risk.

Data was entered into MS Excel and analyzed using SPSS 26.0, with statistical tests such as the chi-square test, t-test and Pearson correlation applied at a significance level of $p<0.05$. Ethical approval was obtained from the Institutional Ethical Committee, and informed consent was obtained from all participants, ensuring confidentiality and adherence to ethical guidelines.

## Results

The study included 100 diabetic patients with normal BMI, with an average age of 55.6 years (±9.9years). The age range was between 32 and 84 years. The majority of participants (68%) were between 51-75 years, and the gender distribution was 61% male and 39% female.

Among the 100 participants, 63% were diagnosed with NAFLD using Fibroscan.

The prevalence of NAFLD was slightly higher in females (64.1%) than in males (62.3%), but this difference was not statistically significant (p-value >0.05).

The highest prevalence of NAFLD was observed in the 51-75 years age group

The grades of fatty liver showed that a significant number of patients are in the advanced stages of the disease, with Grade III being the most prevalent (36.5%), followed by Grade II (33.3%) and Grade I (30.2%).

The prevalence of liver fibrosis in the study population was 65%. Similar to NAFLD, liver fibrosis was more common in females (71.8%) than in males (60.7%), although this difference was not statistically significant (p-value=0.265). The majority of fibrosis cases were found in the 51-75 years age group, with no fibrosis observed in patients younger than 35 years.

The most common stage of fibrosis was Stage 2 (33.8%), followed by Stage 1 (29.2%) and Stage 4 (26.2%). The presence of significant fibrosis in a large proportion of patients highlights the importance of early detection and intervention to prevent progression to cirrhosis or liver failure.

The APRI and FIB-4 scores were used to assess fibrosis severity and risk. Most participants had moderate to significant fibrosis based on APRI and FIB-4 scores,with a substantial proportion at moderate risk according to the FIB-4 score. Specifically, the APRI score indicated that 66% of participants had moderate or significant fibrosis, while the FIB-4 score showed that 56% were at moderate risk.

There was a positive correlation between liver stiffness and non-invasive markers of liver fibrosis:

- **APRI and Liver Stiffness :** Pearson correlation coefficient (r) = 0.507, p-value <0.0001, indicating a strong positive correlation.
- **FIB-4 and Liver Stiffness :** Pearson correlation coefficient (r)=0.443, p-value<0.0001, also indicating a significant positive correlation.

## Discussion

The study indicates a significant burden of liver disease among diabetic patients with normal BMI. Dash, *et al* reported the overall NAFLD prevalence of 54% in Type 2 Diabetes Mellitus patients by random effects models with variations across different populations[12]. Although it did not specifically involve those with normal BMI.

The study highlights the need for targeted screening and

management strategies for middle-aged and older adults with Diabetes.

A significant number of patients are in the advanced stages of the disease. Tsai, *et al* in their study found that patients with T2DM are more likely to have advanced liver disease, with more than 50% (83/163) of the subjects having moderate to severe NAFLD13.

It was seen that age is a significant factor in the development of fibrosis among diabetic patients.

The presence of significant fibrosis in a large proportion of patients highlights the importance of early detection and intervention to prevent progression to cirrhosis or liver failure.

There was a positive correlation between liver stiffness and non-invasive markers of liver fibrosis: however, APRI picked up significant fibrosis with higher sensitivity than FIB 4.

The score relations suggest that non-invasive markers like APRI and FIB-4 scores can be effective in assessing liver stiffness and fibrosis risk in diabetic patients (Figs 1&2).

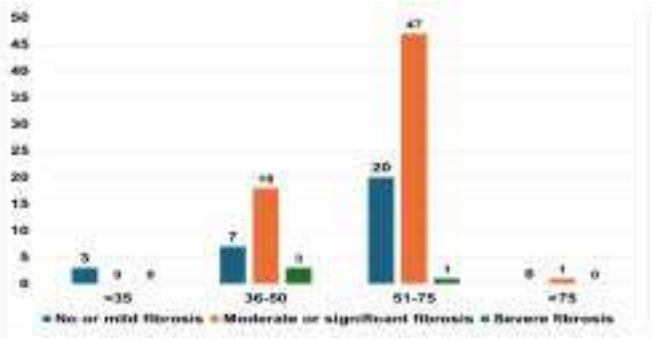


Fig 1 — Fibrosis by APRI across age groups

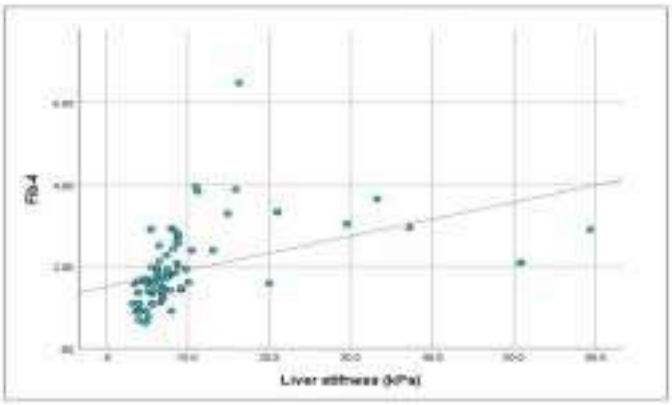


Fig 2 — Correlation between Fib-4 and Liver Stiffness

## Conclusion

The study concludes that there is a significant prevalence of NAFLD and liver fibrosis among diabetic patients with normal BMI. Despite gender differences being statistically insignificant, there was a slightly higher prevalence in females. The findings emphasize the importance of regular screening and early intervention to prevent progression to severe liver conditions. This study, being the first of its kind in northeast India, particularly in Tripura, suggests the need for further research with larger and more diverse samples to validate these findings.

The study underscores the need for comprehensive management strategies focusing on liver health in diabetic patients, regardless of their BMI. Regular screening, early detection and appropriate interventions are crucial to prevent the progression of NAFLD and liver fibrosis to more severe liver conditions such as cirrhosis and liver failure. Overall, this study highlights the importance of addressing liver health in diabetic patients and provides valuable insights for clinical practice and future research.

**Funding :** None.

**Conflict of Interest :** None.

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Original Article

# Evaluation of Accuracy on Waist to Height Ratio as A Screening Tool for Obesity in Children Aged 5-12 Years

**Kotana Siva Prasad[1], A Thumjaa[2], M Mathivanan[3]**

**Abstract**

**Background :** Obesity and its related disorders have turned out to be a Global health issue and it is the fifth most common cause of death Worldwide. Waist to Height Ratio (WHtR) is a better screening tool than BMI to identify central obesity. WHtR is superior than BMI and it is more accurate in identifying co-morbidities like cardiovascular risks in children with obesity. Hence, this study was done to screen WHtR in determining obesity in children aged from 5-12 years.

**Materials and Methods :** A cross-sectional observational study was done in 940 children aged 5 to 12 years who came to OPD. Demographic data and anthropometric measurements like Weight, Height and Waist circumference and BMI were recorded. Data was analysed by SPSS.V.28.

**Result :** Among 940 children, 509(54.1%) were Boys and 431(45.8%) were Girls, in which 118 children were Obese, out of which 62(52.5%) were boys and 56 (47.5%) were girls. Mean WHtR was 0.44±0.08. There was significant correlation between WHtR and BMI (p value<0.00001). Our study showed higher AUC range of 0.089 and 0.090 with higher specificity levels which shows that WHtR can be used to determine obesity in children.

**Conclusion :** WHtR is a simple, easy, inexpensive, less age dependent and accurate index for identifying overweight and obesity in children.

**Key words :** Obesity, Waist to Height Ratio, BMI.

Obesity and its related disorders have turned out to be a Global health issue and it is the fifth most common cause of death Worldwide. WHO further clarifies that the fundamental cause of obesity and overweight is an energy imbalance between calories consumed and calories expended[1]. During the past years, there is seen to be increased consumption of high calorie foods, less physical activity leading to increased prevalence of obesity and its risks such as Type 2 DM , cardiovascular diseases and metabolic syndromes in children[2]. According to WHO, the prevalence of childhood obesity was 8.4% and overweight was 12.4%. In the year 2022, over 390 million children and adolescents were overweight and 160 million were living with obesity, In which 19% of girls and 21% of boys were overweight. If this trend persist, India will contribute approximately 11% of the Global burden of childhood obesity by 2030[3]. According to World Obesity Federation (WOF) 2024, over 30 million Indian children and adolescents of age 5-19 years were Obese, with a prevalence of 9%. If similar trends persist, over 80 million children will be Obese, with a prevalence rate of 24% by the year 2035[4]. WHtR is an anthropometric parameter used as an efficient and easy tool for quick, mass screening and to detect obesity in early childhood[5]. WHtR does not need age and gender-specific charts for interpretation. WHtR is better screening tool than BMI to identify central obesity[6]. Hence, the study was done to screen WHtR in determining obesity in children aged from 5-12 years.

***Editor's Comment :***

- This cross-sectional observational study evaluated the accuracy of Waist-to-height Ratio (WHtR) as a screening tool for obesity in 940 children aged 5-12 years.
- WHtR showed a significant correlation with BMI (p<0.00001) and demonstrated high specificity in identifying overweight and Obese children.
- The study concludes that WHtR is a simple, cost-effective, age-independent, and reliable tool for screening childhood obesity.

## Materials and Methods

A cross sectional observational study was conducted in Children aged 5 to 12 years attending OPD, Department of Paediatrics, Aarupadai Veedu Medical College and Hospital. All children aged 5-12 years attending Paediatric OPD were included in this study where as children with congenital anomalies and chronic systemic illness were excluded. Informed consent was obtained from all the patients by giving a detailed explanation of the study protocol. Demographic information such as name, gender, age, and anthropometric measurements like Weight, Height, Waist, circumference and Body Mass Index (BMI) was recorded. Height was measured by standing upright and recorded to the nearest 0.1cm by using a stadiometer, and Waist circumference was measured by a nonelastic tape midway between the lower border of the rib cage

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***Received on : 29/10/2024***
***Accepted on : 03/05/2025***

***How to cite this article :*** Evaluation of Accuracy on Waist to Height Ratio as A Screening Tool for Obesity in Children Aged 5-12 Years. Prasad KS, Thumjaa A, Mathivanan M. *J Indian Med Assoc* 2026; **124(2):** 36-8.

and the upper iliac crest to the nearest 0.1 cm. Weight was measured to the nearest 0.1 kg using a calibrated weighing mission. Weight to Height Ratio was determined using the formula Waist circumference (cm) divided by Height (cm) and Body Mass Index was determined using the formula, Weight(Kg)/Height($m^2$). Data was collected and compared by Pearson's correlation co-efficient to correlate WHtR and BMI. Area under curve was used to determine the best cut off value of WHtR to predict obesity.

## Results

In our study 940 children were enrolled in the age group of 5-12 years, 509(54.1%) children were Boys and 431(45.8%) children were Girls. The mean WHtR in Boys and Girls were 0.445±0.07 and 0.442±0.09 respectively and overall mean WHtR was 0.44±0.08.

In this study, WHtR were calculated for 940 children, out of which 633(67.3%) children were normal where as 189(20.1%) and 118(12.5%) children were over weight and Obese respectively. p value is 0.404 (p>0.05) which suggests that there is no significant difference between boys and girls in WHtR as shown in Table 1.

Based on the BMI, 214(22.7%) were Underweight, 513(54.5%) were Normal, 142(15.1%) were Overweight and 71(7.5%) were Obese respectively. p value is 0.0039 (p<0.05) which suggests that there is a significant difference between Boys and Girls in BMI as shown in Table 2.

Pearson correlation was performed to find the correlation between WHtR and BMI in the study population. The results show statistically significant correlation (p value<0.05) between WHtR and BMI in detecting overweight and obesity among children belong to the age groups of 5 to 12 years as shown in Table 3.

Table 1 — *Distribution of children based on WHtR*

| | Normal | | Overweight | | Obesity | | p value |
|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | |
| Boys | 352 | 55.6 | 95 | 50.2 | 62 | 52.5 | 0.404 |
| Girls | 281 | 44.4 | 94 | 49.8 | 56 | 47.5 | |
| Total | 633 | 100 | 189 | 100 | 118 | 100 | |

Table 2 — *Distribution of children based on BMI*

| | Underweight | | Normal | | Overweight | | Obesity | | P Value |
|---|---|---|---|---|---|---|---|---|---|
| | N | % | N | % | N | % | N | % | |
| Boys | 129 | 60.2 | 253 | 49.3 | 79 | 55.6 | 48 | 67.6 | 0.0039 |
| Girls | 85 | 39.7 | 260 | 50.6 | 63 | 44.3 | 23 | 32.3 | |
| Total | 214 | 100 | 513 | 100 | 142 | 100 | 71 | 100 | |

Table 3 — *Correlation between Waist Height ratio and BMI*

| | Waist-to-height Ratio | | BMI | | r value | p value |
|---|---|---|---|---|---|---|
| | N | % | N | % | | |
| Overweight | 189 | 20.1 | 142 | 15.1 | 0.63 | <0.00001 |
| Obesity | 118 | 12.5 | 71 | 9.5 | | |

The best cut off value of WHtR by ROC to identify Over weight in boys was >0.445 (AUC-0.086) with sensitivity of 74% and specificity of 95%. Where as the cut off value to identify obesity in Boys was >0.485 (AUC-0.089) with sensitivity of 76% and specificity of 98%. In Girls, the best cut off value of WHtR by ROC to identify Over weight was >0.445 (AUC-0.086) with sensitivity of 75% and specificity of 97%. To identify obesity in Girls, best cut off value of WHtR by ROC was >0.475 (AUC-0.090) with sensitivity of 80% and specificity of 99% as shown in Table 4, which concludes that WHtR can be used as a screening tool in predicting obesity in children.

## Discussion

Obesity is excessive accumulation of body fat, which can lead to chronic diseases like Hypertension, Diabetes and Cardiovascular disorders. Obesity is commonly measured using Body Mass Index (BMI), but this metric alone does not capture the full scope of adiposity or its distribution. Although Body Mass Index (BMI) is widely used for assessing obesity, studies have highlighted its limitations in preventive practice, particularly its lack of precision in evaluating cardiovascular risk and body fat distribution[7-9].

In this study, 940 children were enrolled, out of which 509(54.1%) were Boys and 431(45.8%) were Girls. The mean WHtR was 0.44±0.08 , which was similar to the study done by Gabriela Ricardo, *et al*[10] with 4964 children aged 6-10 years in Brazil with the mean WHtR of 0.44±0.04. In a population based study done in India by Avina Sarna, *et al*[11], the WHtR obtained in children aged 5-19 years showed a mean value of 0.43±0.04 which is more comparable due to similar ethnicity and cultural backgrounds. The mean BMI was 15.8±2.5, whereas the mean BMI from the study done by Avina Sarna, *et al*[11] was 16.2±3.1 which shows a slight increase in mean BMI which was contradictory to our study.

In our study, overweight and Obese using WHtR was 20.1%(189) and 12.5%(118) respectively. The optimal cut off values of WHtR >0.445 in both Boys and Girls were taken to predict overweight and WHtR>0.485 and >0.475 in Boys and Girls were taken respectively to predict obesity and proved that these cut off values were appropriate and effective in predicting overweight and obesity which was similar to a study done by Weili Yan, *et al*[12] in 2055 school going children in China aged 8-18 years in which WHtR was used for diagnosing overweight and obesity and the cut off values of WHtR for overweight in both Boys and

Table 4 — *AUC including the optimal Waist-to-height Ratio cut-off*

| Waist to Height ratio | | Cut-off | AUC | Sensitivity | Specificity |
|---|---|---|---|---|---|
| Boys | Overweight | 0.445 | 0.086 | 74 | 95 |
| | Obesity | 0.485 | 0.089 | 76 | 98 |
| Girls | Overweight | 0.445 | 0.086 | 75 | 97 |
| | Obesity | 0.475 | 0.090 | 80 | 99 |

girls was >0.445 and cut off values for obesity in Boys and Girls were >0.485 and >0.475 respectively. These WHtR cut off values were statistically significant and can be used to evaluate obesity in children. The proportion of the children who were overweight and Obese in the quoted study was 18% and 7.3% respectively. But Marrodan, *et al*[13] conducted a study in 2319 children aged 6-14 years, in which WHtR >0.47 and >0.48 in Boys and Girls to diagnose overweight and >0.51 and >0.5 in boys and girls to diagnose obesity were taken as the cut off and proved that these cut off values were effective in predicting overweight and obesity which was contradictory to our study.

The correlation between WHtR and BMI in detecting overweight and obesity showed statistically significant correlation (p value<0.00001) between WHtR and BMI. Similar results showing significant correlation between WHtR and BMI in detecting overweight and obesity were obtained by the study done by Valesca Mansur Kuba, *et al*,[14] in which 175 school going children aged 6-10 years from Brazil were enrolled. Another study done by Gabriela ricardo, *et al*[10] in 4964 children aged 6-10 years in Brazil also showed results similar to our study.

In our study, the AUC was 0.086 in both Boys and Girls to predict overweight using a WHtR cut off >0.445 and AUC-0.089 in Boys and 0.090 in Girls to predict obesity which showed higher specificity values proving that these WHtR can be used as a screening tool in predicting obesity in children which was similar to a study conduted by Yalan Dou, *et al*[15] on 8130 children and adolescents aged 7-18 years which showed higher AUC range of 0.84 and satisfactory sensitivity and specificity levels with an optimal WHtR cut off value of 0.487 in Boys and 0.456 in Girls.

In our study, WHtR is significantly useful in predicting overweight and obesity in children.

**Recommendation :** Additional large-scale prospective studies are needed to confirm the usefulness of WHtR for predicting comorbidities of obesity in children and adolescents.

## Conclusion

WHtR is a simple, easy, inexpensive , less age dependent and accurate index for identifying overweight and obesity in children and adolescents. The cut-off points of WHtR >0.445 for both boys and girls were used to detect overweight and >0.485 for Boys and >0.475 for Girls were used to predict obesity.

**Funding and Competing Interests :** No external funding for conduction of this research was received. None of the authors have any competing interests.

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Original Article

# Evaluation of Pro-inflammatory and Coagulation Biomarkers among PLHIV on Highly Active Antiretroviral Therapy with Effect of Viral Suppression on them

**Neha Yadav[1], Kunal Bansal[2], Ritu Aggarwal[3], Deepak Jain[4], Aparna Yadav[5]**

**Abstract**

**Background :** HIV infection considered Chronic Inflammatory Disease carries risk of Cardiovascular Disease (CVD) events and cancer not related to AIDS, even after initiation of Antiretroviral Therapy (ART) due to increased levels of highly sensitive C-reactive Protein (hs-CRP), Interleukin-6 (IL-6) and D-dimers persisting due to various causes.

**Aims and Objectives:** Present study aimed at evaluating these biomarkers, both baseline and after ART initiation, with effect of viral suppression and immunological status upon them.

**Materials and Methods :** Prospective observational study was conducted on newly diagnosed HIV positive patients started on ART. Measurement of IL-6, hs-CRP and D-dimer by immuno-enzymatic assay was carried out both at start of therapy and after six months of ART. CD4+ cell count was measured by Fluorescent Activated Cell Sorter (FACS) method. Frequency distribution, paired T-test and cross tabulation was used to create summary tables and compare items.

**Results :** Mean value of hs-CRP and D-dimer was 19.06 mg/ l and 728.03 ng/ ml before ART which decreased to 16.09 mg/ l and 554.09 ng/ ml after ART initiation respectively. Mean value of biomarkers in patients on ART with HIV viral load as Target Not Detected (TND) and higher CD4+ cell count was less, compared with those having higher viral load count of <150 copies/ ml and it was statistically significant. Majority (69.14%) of the study participants had HIV -1 viral load as TND after six months of ART initiation.

**Interpretation and Conclusion :** Timely and proper ART initiation is instrumental in decreasing overall mortality and morbidity. Development of risk stratification system involving these biomarkers will further help predict beforehand and quantify any undetected clinical risk in PLHIV.

**Key words :** ART, CD4+, CVD, D-dimer, hs-CRP, IL-6, PLHIV.

HIV is now considered a Chronic Inflammatory Disease, rather than a fatal one, in countries where ART is available. It results in chronic immune activation causing rise of pro-inflammatory cytokines such as Interleukin-6 (IL-6) and high sensitivity C-reactive Protein (hs-CRP). Coagulation biomarkers like Tumor Necrosis Factor (TNF) may also be elevated leading to development of a hypercoagulable state due to rise in levels of factor VIII and decreased levels of protein S. These cytokines also down regulate the expression of several proteins which are required for fibrinolysis. HIV replication has been shown to be a major factor causing up-regulation of coagulation pathways along with inflammatory and thrombotic activity for Cardiovascular Disease (CVD) risk[1]. Chronic inflammation among PLHIV may be as a result of activation of dendritic cells and lymphocytes, injury to endothelial lining and mucosal barrier, along with other factors related to HIV replication[1,2].

***Editor's Comment :***

- HIV infection has a tendency to increase various inflammatory bio-markers.
- Timely ART initiation with its proper compliance leads to lower levels of these bio-markers and drastically reduces HIV viral load causing overall reduction in mortality and morbidity among PLHIV.

Currently available ART drugs cannot eradicate HIV virus from the human body because a pool of latently infected CD4+ (cluster of differentiation 4) cells is established during the earliest stages of acute HIV infection. It persists within the organs/ cells and fluids (eg, Brain, Liver and Lymphoid Tissues) despite prolonged suppression of plasma viraemia by ART to <50 copies/ml. The primary goal of ART is maximal and sustained reduction of plasma viral levels and restoration of immunological functions. This reduction in viral load also leads to an overall reduced transmissibility thereby reducing number of new infections[3].

ART has been found to be associated with lower levels of these biomarkers, so interrupting or delaying ART because of unpleasant side effects or they becoming ineffective over time, further increases the risk of non-AIDS related illnesses like neurocognitive disorders, CVD, Metabolic

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***Received on : 29/01/2025***
***Accepted on : 11/04/2025***

***How to cite this article :*** Evaluation of Pro-inflammatory and Coagulation Biomarkers among PLHIV on Highly Active Antiretroviral Therapy with Effect of Viral Suppression on them. Yadav N, Bansal K, Aggarwal R, Jain D, Yadav A. *J Indian Med Assoc* 2026; **124(2):** 39-43.

Syndrome, Bone abnormalities and non-HIV associated cancers (in particular, Kaposi sarcoma) in the long term[3-5].

Enormous literature is available Worldwide regarding evaluation of various biomarkers among PLHIV but currently there is lack of sufficient Indian literature, emphasizing the importance of various inflammatory and coagulation biomarkers like D- dimer, hs-CRP and IL-6 in assessing progress of HIV infection to chronic inflammatory stage and various other accompanying diverse clinical associations. Present study conducted in PGIMS Rohtak was aimed at evaluating these biomarkers among PLHIV and their response to ART initiation, along with effect of viral suppression and immuno-logical status upon these biomarkers.

## Material and Methods

**Study Setting and Ethical Approval :** With prior permission from Institutional Biomedical Research Ethics Committee (BREC) vide their letter no. BREC/19/TH/Micro-02 dated 26.12.2019, present study was carried out in Department of Microbiology, over a period of one year from January, 2020 to February, 2021.

**Study Design :** Prospective observational study was conducted on newly diagnosed HIV patients started on ART.

**Study Population :** Total of 35 pre-diagnosed HIV patients enlisted from ART Center of Medicine Department were enrolled for this study after obtaining written informed consent from them prior to sample collection.

**Inclusion Criteria :** Patients of either sex and above 18 years of age with pre- diagnosed HIV infection.

**Exclusion Criteria :**

(i) Refusal to participate / not providing consent.

(ii) Pregnant and lactating females.

(iii) Patients with pre-diagnosed malignancy, history of Tuberculosis, previous history of CVD, Myocardial Infarction, Coronary Artery Disease, Stroke, Peripheral Vascular Disease, or Congestive Heart Failure.

(iv) History of previous ART or refusal to start ART

**Sample size :** Required for study was calculated as:

$$N = (Z_{1-\alpha/2} + Z_{1-\beta})^2 / \Delta^2$$

where n= sample size required. $Z_{1-\alpha/2}$ is level of significance at 95% confidence interval = 1.96. $Z_{1-\beta}$ is assuming 80% power of the study = 0.84. $\Delta^2 = 0.5$.

Now, $N = (1.96+0.84)^2 / (0.5)^2 = 8/0.25 = 32$.

Considering loss to follow-up and dropout rate of 10%, the required sample size came out to be 32. Hence, minimum of 35 subjects were registered for this study.

**Sampling Technique :**

(i) Blood was collected by venipuncture using all aseptic precautions and serum/ plasma separation was done.

(ii) Specimens were stored at -20°C. Repeated freezing and thawing of samples was avoided[6].

**Test Methodology :** Demographic profile of the enrolled cases was assessed and subjected to detailed physical and clinical examination along with routine investigations. CD4+ cell count, D-dimer, IL-6 and hs-CRP were measured both at start of therapy and after six months of ART. HIV-RNA was measured only after six months of ART according to the National AIDS Control Organization (NACO) guidelines[7].

**Measurement of Proinflammatory and Coagulation Biomarkers :** All serum samples were processed for measurement of D-dimer, IL-6, and hs-CRP. IL-6 levels were measured by immuno-enzymatic assay following manufacturer's instructions of DIAsource® IL-6 ELISA kit (DIAsource® Louvain-la-Neuve, Belgium) based on monoclonal antibodies directed against distinct epitopes of IL-6. Testing for hs-CRP was done by DIAsource® hs-CRP ELISA kit (DIAsource® Louvain-la-Neuve, Belgium) based on monoclonal antibodies directed specific for different regions of CRP following a typical two-step capture or sandwich type ELISA. D-dimer was detected by using kit based on sandwich ELISA for the quantitative determination of D-dimer in plasma based on monoclonal antibodies. (Kit- Technozym® D-dimer ELISA, Technoclone Herstellung von Diagnostica, Vienna, Austria).

**Measurement of CD4+ Count :** One ml of blood was collected in EDTA vacutainer and was processed by Fluorescent Activated Cell Sorter method as per kit instructions (Kit- Sysmex CD4% easycount, Equipment – Sysmex Partec GmbH CyFlow Counter, Kobe, Japan).

**Measurement of HIV RNA Levels :** Five ml of blood sample has to be collected in EDTA vacutainers and plasma was separated. HIV RNA levels were measured by quantitative Polymerase Chain Reaction (PCR) (Kit - Abbott Real Time HIV-1 reagents, Equipment's- Automated m2000sp system and Abbott m2000rt, Libertyville Township, IL, USA). The amplification cycle at which a specific fluorescent signal was detected was proportional to the amount of HIV-1 RNA present in the original sample. The assay had a lower limit of detection of around 80- 150 HIV-1 RNA copies/ ml as being reported as <150 copies/ml for 0.2 ml volume of plasma sample. Specificity of test was 99.28 to 100 %.

**Statistical Analysis :** Data was entered into Microsoft Excel and further statistical analysis was done using Statistical Package for Social Sciences (SPSS), version 20. Frequency distribution, paired T-test and cross tabulation was used to create summary tables and

compare items within and across categories. The quantitative variables in patients were expressed as mean ± SD and compared using paired t-test. The association was tested using categorical data and analyzed using chi-square test. p value of <0.05 was considered statistical significant.

**Disposal of Waste :** All biomedical waste generated in the laboratory in this study was discarded as per the Biomedical Waste Management and Handling Rules, 2016 guidelines.

## Results

**Demographic Details of Cases :** Total of 35 pre-diagnosed HIV patients were enrolled, who were willing to be part of study and start ART. Out of these 35 participants, 27 (77.1%) were male and rest 8 (22.9%) were female. Their age range was 18-59 years of age with mean age of 36 years. The youngest among study population was 22 years of age while oldest was of 53 years of age. Majority of the patients were married (62.9 %) with literacy level of secondary schooling and above (51.4%) (Table 1).

Mean value of hs-CRP and IL-6 was higher in male participants as compared to females. However, the mean difference before and six months after ART initiation decreased in both genders. Mean value of D-dimer post ART initiation was higher in males as compared to females. In contrast, the mean value of CD4+ before and after six months of ART was higher among female patients as compared to males. The mean difference pre and post ART initiation also increased after six months implying that CD4+ cell count increased more in females as compared to males (Table 2).

The mean difference between hs- CRP value, D- dimer and CD4+ levels before and after six months of ART initiation was statistically significant (Table 3). Mean value of hs-CRP, IL-6, D-dimer in patients having higher HIV viral load of <150 copies/ ml was significantly higher than in those with HIV-1 viral load as TND. However, the CD4+ count in patients with viral load followed opposite pattern, in which patients with HIV viral load as TND had more CD4+ cells/ ml as compared to the group having higher viral load. The mean difference for all the parameters was statistically significant (Table 4).

Table 1 — *Demographic details of study Participants (n=35)*

| Demographic factors | Frequency | Percentage |
|---|---|---|
| **Gender :** | | |
| Male | 27 | 77.10 |
| Female | 8 | 22.9 |
| **Age Group (in years) :** | | |
| 18-29 | 12 | 34.3 |
| 30-39 | 7 | 20 |
| 40-49 | 12 | 34.3 |
| 50-59 | 4 | 11.4 |
| **Marital Status :** | | |
| Married | 22 | 62.9 |
| Unmarried | 9 | 25.7 |
| Divorced | 1 | 2.9 |
| Separated | 2 | 5.7 |
| Widow | 1 | 2.8 |
| **Highest Education :** | | |
| Illiterate | 5 | 14.3 |
| Primary school | 12 | 34.3 |
| Secondary school | 10 | 28.5 |
| College and above | 8 | 22.9 |
| **Risk Factors :** | | |
| Heterosexual | 8 | 22.9 |
| MSM | 2 | 5.7 |
| Injectable drug users/ unsafe injections | 8 | 22.9 |
| Blood Transfusions history | 2 | 5.7 |
| Unknown | 7 | 20 |
| Sex worker | 2 | 5.7 |
| Migrant labor | 2 | 5.7 |
| Trucker | 4 | 11.4 |

MSM - men having sex with men

## Discussion

In present study, value of inflammatory markers (hs-CRP and IL-6) was found above the normal range before the initiation of ART. Mean value of hs-CRP in participants being 19.06 mg/l before ART, which was above the normal

Table 2 — *Comparison of mean of pro-inflammatory biomarkers, coagulation biomarker and CD4+ cell count, before and after six months of ART between Male and Female participants*

| Parameter | Gender | Mean |
|---|---|---|
| Hs-CRP (mg/l) Pre- ART | Male | 19.59 |
| | Female | 17.25 |
| Hs-CRP Post- ART | Male | 16.28 |
| | Female | 15.44 |
| IL-6 (pg/ml) Pre- ART | Male | 95.11 |
| | Female | 63.38 |
| IL-6 Post- ART | Male | 93.67 |
| | Female | 69.25 |
| D-dimer (ng/ml) Pre-ART | Male | 724.81 |
| | Female | 738.88 |
| D-dimer Post-ART | Male | 558.19 |
| | Female | 540.25 |
| CD4+ (cells/ ml) Pre- ART | Male | 356.89 |
| | Female | 383.88 |
| CD4+ Post- ART | Male | 375.22 |
| | Female | 428.25 |

Hs-CRP, high sensitivity C-reactive protein; ART, antiretroviral therapy; IL-6, interleukin-6; CD4+, cluster of differentiation 4

Table 3 — *Association between mean value of pro-inflammatory biomarkers, coagulation biomarker and CD4+ cell count, before and after six months of ART in study participants as paired differences (Paired sample 't' test)*

| Paired differences | Mean | P- value |
|---|---|---|
| Hs CRP (mg/l)Pre- ART - hs CRP Post ART | 2.97 | 0.001* |
| IL-6 (pg/ml)Pre-ART - IL-6 Post ART | -0.23 | 0.946 |
| D- dimer (ng/ml) Pre-ART - D- dimer Post ART | 173.94 | 0.002* |
| CD4+ (cells/ml) Post ART- CD4+ Pre-ART. | 24.29 | 0.043* |

P≤0.05; Hs-CRP : High sensitivity C-reactive Protein; ART : Antiretroviral Therapy; IL-6 : Interleukin-6; CD4+ : Cluster of Differentiation 4

Table 4 — *Association between mean value of pro-inflammatory biomarkers, coagulation biomarker and CD4+ cell count Post ART with HIV-1 Viral Load in study participants (Independent sample t-test)*

| Biomarker | Mean difference | p-value |
|---|---|---|
| hs-CRP (mg/l) | -15.51 | 0.001* |
| IL-6 (pg/ml) | -133.82 | 0.001* |
| D-dimer (ng/ml) | -841.78 | 0.001* |
| CD4+ (cells/ml) | 212.70 | 0.007* |

P≤0.05; Hs-CRP, high sensitivity C-reactive protein; ART, antiretroviral therapy; IL-6, interleukin-6; CD4+, cluster of differentiation 4

range of 0-3 mg/l as per laboratory range of expected normal values. The mean value came down to 16.09 mg/l after ART. The mean of hs-CRP among males (19.59 mg/l) was higher than females (17.25 mg/l) before ART initiation and after six months of treatment, mean value of hs-CRP among males (16.28 mg/l) was still higher than in females (15.4 mg/l). Overall there was reduction in hs-CRP after 6 months of ART. In our study, hs-CRP of four patients increased, six patients had constant values, while in 21 patients the value decreased after six months of ART. The mean value of IL-6 in all 35 participants was 87.86 pg/ ml at baseline which was above normal range of 0-45 pg/ml set by laboratory, as derived from serum samples of 30 apparently healthy persons.

The baseline mean value of D-dimer was 728.03 ng/ ml which decreased significantly to 554.09 ng/ ml after six months of ART, considering normal laboratory reference range of less than 250 ng/ml and this decrease was statistically significant (<0.005). Several studies have indicated that ART reduces the level of D-dimer in HIV patients[5,8-11]. Still potential benefits of ART in relation to decreasing inflammatory and coagulation biomarkers differ by specific class or drug, emphasizing the need for anti-inflammatory treatment apart from ART to achieve a greater success rate[12-14].

In present study, mean value of CD4+ count in 35 patients before ART was 363.06 cells/ml, which increased to 387.34 cells/ ml after ART. Similar findings were observed in various other studies[5,9,15]. In contrast late ART initiation, late diagnosis, poor body response to ART are among few factors causing poor CD4+ recovery as seen in some other studies[16-18].

Majority (69.14%) of the study participants had HIV-1 viral load as Target not Detected (TND) after six months of ART initiation, indicating that viral load suppression was appropriate in these patients. It shows importance of timely starting ART and properly adhering to it, along with monitoring of inflammatory bio-markers so as to get good results and that ultimate goal of HIV target not getting detected can be persistently achieved. Mogosetsi, *et al*[19], conducted a study on South African population and included 98 HIV infected patients. Viral load levels were measured after six months of ART. Total of 90 out of 98 patients achieved viral load suppression. The reason for high prevalence of viral suppression, could be due to high adherence to medication, age of the PLHIV patients, better healthcare delivery system and ART regimen followed.

The mean value of findings from some studies suggest that despite patients being on ART, some of them still have raised inflammatory biomarkers. The reason can be attributed to residual immune activation which can be due to prevailing low levels of HIV replication[14-18,20]. Factors like ART regimen used, ethnical variability, duration of treatment and underlying inflammatory changes could be another reason for this variability.

## Conclusion

Overall the present study, suggests that timely and proper ART initiation is instrumental in decreasing both pro-inflammatory and coagulation biomarkers values in both genders. It shall help in building a risk stratification system or screening tool for PLHIV, thereby decreasing the overall morbidity and mortality among them. Also these bio markers can be utilized to monitor disease prognosis during ART particularly in resource poor setting where regular HIV-1 viral load monitoring facility is still unavailable.

### Recommendation :

Since this study involved comparatively less number of subjects, it is also recommended that a cohort study using larger population with longer follow up be designed to help quantify any clinical event risk associated with fluctuations in these pro-inflammatory biomarkers overtime in PLHIV. Also, a risk stratification system should be developed for HIV patients, involving all these biomarkers, to reduce overall mortality and morbidity among PLHIV.

### Limitations :

Present study had few limitations. Firstly, it was single centered study that included PLHIV who visited the hospital during study period. Secondly, patients were followed for maximum six months for the outcomes, limiting the scope to know more about changes in these biomarkers with accompanying quantification of clinical risk associated during the course of life in PLHIV. Also since this study was conducted the same time COVID-19 pandemic was reported, possibility of some baseline increase in inflammatory and coagulation biomarkers among study participants cannot be ruled out.

### Acknowledgment

Authors acknowledge National AIDS Control Organization (NACO), Haryana State AIDS Control Society (HSACS) for assistance in providing regular supply of logistics and consumables. Authors also thank patients who chose to take part in this study.

**Funding :** None.

**Conflicts of Interest :** None.

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Original Article

# From Plate to Planet : Analyzing the Dietary Water Footprint — A Cross-sectional Study

**Shimona N Nadar**[1], **Rekha Udgiri**[2]


## Abstract

**Background :** The Water Footprint (WF) is an environmental indicator that measures the volume of freshwater (*l* or cu. mm) used throughout the entire production chain of a consumer item or service. India is the World's largest user of freshwater due to its rapid development and massive population; the major contributor to this is the food system. The per capita Water Footprint (WF) of India is approximately 1,089 cubic meters per year, agriculture being the major contributor accounts for approximately 90% of the resource.

**Aims and Objectives :** To analyze the dietary pattern of the participants and to quantify the Water Footprints associated with the production of different food groups.

**Materials and Methods :** A cross-sectional study, was done among 130 employees of a Tertiary Care Center in Vijayapura district from May, 2024 to July, 2024. Data was collected by 116-item semi-quantitative FFQ to assess the food intake, which was later segregated into 31 food groups based on similarity in nutritional content. The Water Footprint for each food group was calculated using India-specific WF data. Data was analyzed using SPSS Software version 26.0.

**Results** : The mean ± SD of total dietary energy was 2368 ± 827 kcal/capita/day. The mean ± SD blue WF of diets in the study population was 1008 ± 342 l/capita/day, and the mean ± SD green WF of diets was 3236 ± 1216 l/capita/day. Rice and wheat being the main staple cereals contributed to about 380 l/capita/day of dietary green WF and 133 l/capita/day of dietary blue WF.

**Conclusion :** Substituting wheat and rice with lower water demanding crops like sorghum and millet, consuming more fruits and less meat can lower the Water Footprint. The shift to such diets could be a key step in mitigating the environmental impacts of current consumption patterns in India.


**Key words :** Water Footprint, Green WF, Blue WF, Food Frequency Questionnaire (FFQ), Dietary pattern.

The Water Footprint (WF) is an environmental indicator that measures the volume of freshwater (*l* or cu. m) used throughout the entire production chain of a consumer item or service. It is estimated by adding the water consumed to the water present in imported goods and deducting it from the water exported. Arjen Hoekstra first put forward the idea of a "Water Footprint" in 2002 during the International Expert Meeting on Virtual Water Trade in Delft, Netherlands. The recent National Water Policy (2012) of India placed a strong emphasis on evolving Water Footprints and water audit benchmarks on the use of water resources to encourage efficient use of water. The Water Footprint may be viewed as a complete indication of freshwater resource appropriation[1].

### Water Footprint (WF) consists of three components :

- Blue WF refers to the volume of surface and groundwater utilized for irrigation, industrial usage, and residential use during the manufacturing process (groundwater and surface water),
- Green WF refers to the amount of rainwater utilized during production, especially in agriculture (soil moisture and rainfall),
- Grey WF refers to the volume of freshwater required to dilute the pollutants produced during manufacturing (waste, polluted, and recycled water)[2].

**Editor's Comment :**

- This study highlights that Indian diets have a high-water footprint, largely driven by poultry and staple cereals such as rice and wheat. Promoting less water-intensive grains and more plant-based foods can help reduce pressure on freshwater resources and support sustainable nutrition. Such sustainable dietary transitions are essential to protect freshwater resources while supporting long-term food and nutrition security in India.

With a total WF of 1047 Billion Cubic Meters (BCM) annually, India has the highest WF among all nations, followed by China (967 BCM/year) and the United States (826 BCM/year). India has a per capita Water Footprint of 1089 cubic meters, which is less than the Global average of 1,243 cubic meters per capita. India's 1.2 billion population accounts for a substantial 12% of the World's total Water Footprint[3].

Almost 90% of India's annual freshwater usage is by the agricultural sector. These are likely to increase in the future as agriculture attempts to keep pace with India's growing population and changing dietary preferences. In the last few decades, the World has seen a significant shift in

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***Received on : 13/11/2024***
***Accepted on : 20/02/2025***

***How to cite this article :*** From Plate to Planet : Analyzing the Dietary Water Footprint — A Cross-sectional Study. Nadar SN, Udgiri R. *J Indian Med Assoc* 2026; **124(2):** 44-8.

food consumption patterns towards more animal products such as meat, milk, and eggs, mainly due to growing economies and rising individual incomes.

Considering India's present water productivity and its anticipated food demand for 2050, it is inevitable that the country will have to import virtual water. This is because in the near future, India's average (utilizable) water availability per capita will fall below the minimal quantity required to sustain a person's diet. This indicates that India's water shortage is a national as well as a local problem[4].

"The water-use impacts of food production should be a key consideration of sustainable diets. But until now, little has been known about the water scarcity demands of diets - especially the diets of individuals," Diego Rose[5].

A sustainable diet is defined by the Food and Agriculture Organization of the United Nations as "diets with low environmental impacts that contribute to food and nutrition security and the healthy life for present and future generations"[6]. Thus, the study of regional dietary Water Footprint will help in better understanding and suggestion of sustainable diet choices.

## Aims and Objectives

(1) To analyze the dietary patterns of the participants.

(2) To quantify the Water Footprints associated with the production of different food groups based on the dietary patterns of the participants.

## Material and Methods

This is a cross-sectional study conducted among 130 employees of a Tertiary Care Center in Vijayapura district. After obtaining Institutional Ethical Clearance, the study was conducted in May, 2024 to July, 2024. The participants were selected using the Convenient Sampling Technique. The participants were selected among Consultants, Residents, and Non-teaching staff. Data was collected after obtaining informed consent, using a 116-item semi-quantitative FFQ[7] and Socio-demographic profile by interview technique to assess the food intake, which was later segregated into 31 food groups based on similarity in nutritional content[8]. Blue and Green Water Footprint for each food group was calculated using India-specific WF data quantified by The Water Footprint Network. The following formulae was used to calculate the Water Footprint (WF) for each food group:

BWF/GWF of a food group (L/kcal/day) = BWF/GWF of that particular food group (L/kcal) X Energy obtained from the food group (kcal/day)[9]

The data thus obtained was entered into Microsoft Excel.

## Statistical Analysis

To statistically analyze the collected data a Statistical package for the Social Sciences (Version 26) was used. The findings were displayed as Mean, Standard Deviation, and percentages through charts and tables. To compare the variables a One-way ANOVA with the Kruskal-Wallis test was implemented. The correlation between Socio-demographic variables and the mean Blue and Green Water Footprint was studied using the Chi-square test. A p-value of <0.05 was considered statistically significant.

## Result

Table 1 displays the descriptive characteristics of the study population. A total of 130 individuals, between the age of 25 to 64 years were included in the study (the majority ie, 44.6% being from the 25-34 age group). The majority of participants (83.1%) were Hindu, and there were more Females (56.9%) in the sample. 57.7% of participants lived in Urban areas, and a majority (54.6%) of them belonged to the Upper Class according to Modified BG Prasad classification.

### Dietary Characteristics :

The mean ± SD of total dietary energy was 2368 ± 827 kcal/capita/day. The main staple cereals were rice and wheat with a mean consumption of 634 Kcal/capita/day and 563 Kcal/capita/day respectively.

### Diet and Water Footprints :

Fig 1 shows the mean ± SD dietary blue and green Water Footprints. The mean ± SD blue WF of diets in the study

Table 1 — *Socio-demographic Profile*

| Variables | | N (%) |
|---|---|---|
| Gender | Male | 56 (43.1%) |
| | Female | 74 (56.9%) |
| Age (in years) | 25 - 34 | 58 (44.6%) |
| | 35 - 44 | 48 (36.9%) |
| | 45 - 54 | 18 (13.8%) |
| | 55 - 64 | 6 (4.6%) |
| Residency | Rural | 55 (42.3%) |
| | Urban | 75 (57.7%) |
| Religion | Hindu | 108 (83.1%) |
| | Muslim | 12 (9.2%) |
| | Christian | 10 (7.7%) |
| Education | Illiterate | 2 (1.5%) |
| | Primary School | 14 (10.8%) |
| | High School | 17 (13.1%) |
| | Pre-university | 20 (15.4%) |
| | Graduation | 32 (24.6%) |
| | Post-graduation | 45 (34.6%) |
| Occupation | Teaching staff | 77 (58.8%) |
| | Non-teaching staff | 53 (40.5%) |
| Marital status | Married | 98 (75.4%) |
| | Unmarried | 32 (24.6%) |
| Socio-economic status (Acc to Modified B G Prasad classification) | Lower middle class | 31 (23.8%) |
| | Middle class | 23 (17.7%) |
| | Upper middle class | 5 (3.8%) |
| | Upper class | 71 (54.6%) |

population was 1008 ± 342 l/capita/day, and the mean ± SD green WF of diets was 3236 ± 1216 l/capita/day. Rice and wheat being the main staple cereals contributed to about 380 l/capita/day of dietary green WF and 133 l/capita/day of dietary blue WF. Fig 2 shows the top 5 contributors of energy among the study participants. Fig 3 shows the top 5 food groups contributing to the blue and green Water Footprint.

### Water Footprints of Food Groups :

The highest contributor to dietary Water Footprint was found to be Poultry, which was about 40% and 35% of total Dietary green WF and Dietary blue WF respectively. This was followed by the food group 'Other Vegetables' which contributed to 12% and 10 % of total Dietary GWF and BWF respectively. Fruits like Orange and Guava contributed the least in contrast to Mango which contributed to 6% of Dietary GWF and BWF. This was in line with the fact that Mango was the seasonal fruit during the study period. Fig 3 shows the top 5 food groups contributing to the blue and green Water Footprint.

Figs 4 & 5 show the Dietary Blue and Green water footprints of all the 31 food groups respectively.

Associations between dietary blue & green water Footprint and Socio-demographic characteristics:

Except for age, the study revealed that Blue and Green WFs had a significant association with all variables analyzed. Gender and Dietary WF were significantly associated, with males having higher Water Footprints than females (p=0.05). Furthermore, the Water Footprints and Socio-economic level were found to be statistically related, with WF being greater among participants from the upper class (p<0.05). Blue and Green WFs strongly correlated with education, with illiterates, graduates, and post-graduates having larger footprints. Residence was a highly reliable indicator of dietary WFs. Dietary Blue and Green WF were higher in the urbanized region.

Table 2 — *Association Between the BWF and GWF with Socio-demographic Profile*

| WF | | N | Mean (SD) | Median | 95% CI | p |
|---|---|---|---|---|---|---|
| **GENDER** | | | | | | |
| BWF | Male | 56 | 2382 (832) | 1038 | 580-2177 | 0.05* |
| | Female | 74 | 1800 (345) | 897 | 514-2177 | |
| GWF | Male | 56 | 3466 (1196) | 3300 | 1450-7156 | |
| | Female | 74 | 3000 (1219) | 2952 | 1368-7156 | |
| **SOCIO-ECONOMIC STATUS** | | | | | | |
| BWF | Lower middle class | 31 | 878 (402) | 741 | 514-2128 | 0.004* |
| | Middle class | 23 | 850 (244) | 768 | 547-1499 | |
| | Upper middle class | 5 | 1094 (313) | 1038 | 707-2177 | |
| | Upper class | 71 | 1321 (112) | 1329 | 1139-1434 | |
| GWF | Lower middle class | 31 | 2498 (1015) | 2020 | 1368-5321 | 0.001* |
| | Middle class | 23 | 2630 (976) | 2727 | 1368-4950 | |
| | Upper middle class | 5 | 3320 (831) | 3195 | 2048-4858 | |
| | Upper class | 71 | 3678 (1150) | 3380 | 2132-7156 | |
| **EDUCATION** | | | | | | |
| BWF | Illiterate | 2 | 1117 (0) | 1117 | 1117-1117 | 0.024* |
| | Primary school | 14 | 895 (355) | 677 | 547-1499 | |
| | High School | 17 | 915 (478) | 741 | 514-2128 | |
| | Pre-university | 20 | 769 (158) | 746 | 608-991 | |
| | Graduation | 32 | 1053 (226) | 1065 | 707-1434 | |
| | Post-graduation | 45 | 1148 (349) | 1038 | 853-2177 | |
| GWF | Illiterate | 2 | 3676 (0) | 3677 | 3677-3677 | 0.05* |
| | Primary school | 14 | 2606 (1083) | 2438 | 1368-4950 | |
| | High School | 17 | 2666 (1166) | 1972 | 1760-5321 | |
| | Pre-university | 20 | 2198 (500) | 2020 | 1519-2952 | |
| | Graduation | 32 | 3894 (694) | 3658 | 3090-4858 | |
| | Post-graduation | 45 | 3620 (1366) | 3260 | 2131-7156 | |
| BWF | Urban | 75 | 1080 (254) | 1065 | 707-2177 | 0.0 |
| | Rural | 55 | 910 (419) | 743 | 514-2177 | |
| GWF | Urban | 75 | 3643 (1003) | 3380 | 2132-7156 | |
| | Rural | 55 | 2681 (1280) | 2020 | 1368-7156 | |

## Discussion

This study provides an individual-level estimate of the Blue and Green Water Footprints of various Indian food groups. It was found that there was a vast difference in the Water Footprints across various Socio-demographic groups due to differences in consumption patterns. This factor should be considered while recommending a sustainable diet. According to the United Nations Food and Agriculture Organization (FAO), the average minimum daily energy requirement is approximately 2533 Kcal. The average energy intake in this study was 2368 ± 827 Kcal/day, which could probably be due to the underestimation of energy

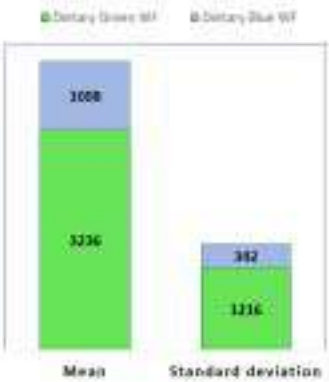


Fig 1 — Mean ± SD of Dietary Green and Blue WF (N=130)

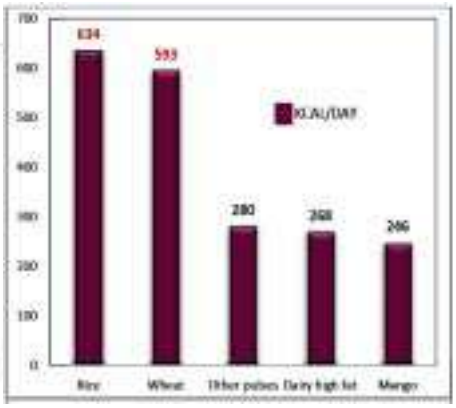


Fig 2 — Top 5 Energy Contributors

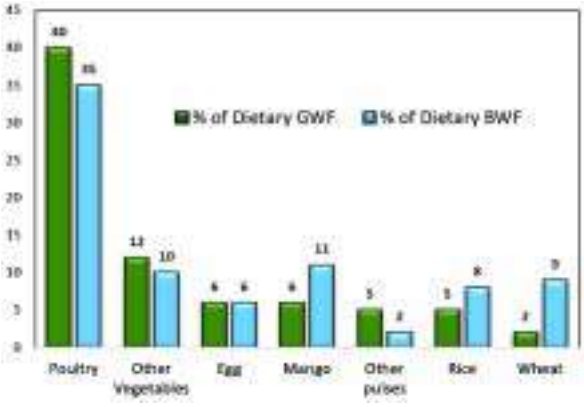


Fig 3 — Top 5 Contributors to Dietary WF

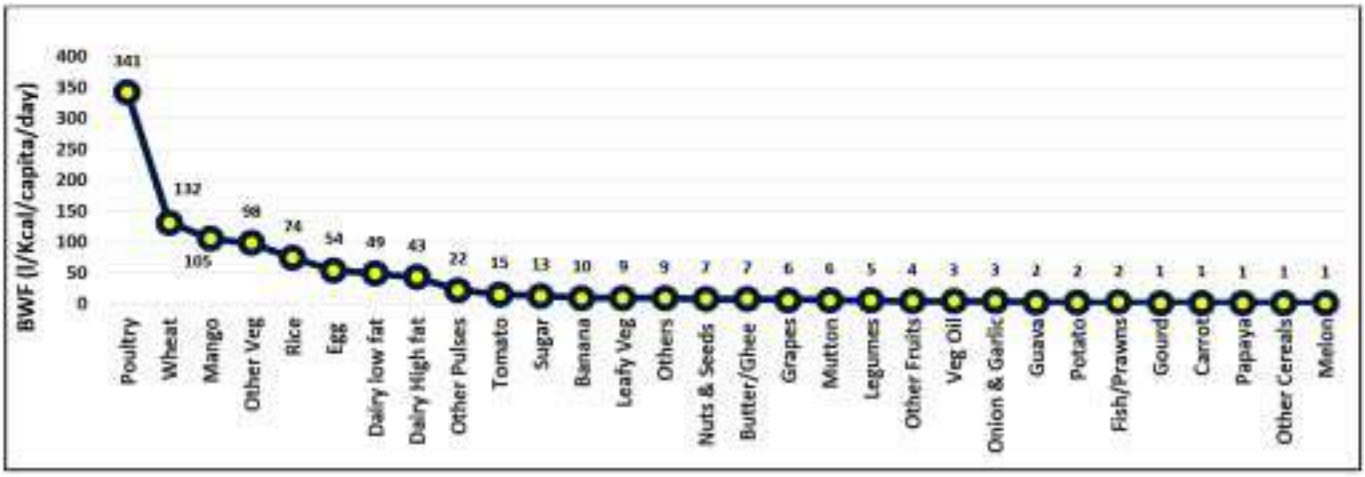


Fig 4 — Blue Water Footprint of 31 Food Groups (Lkcalday)

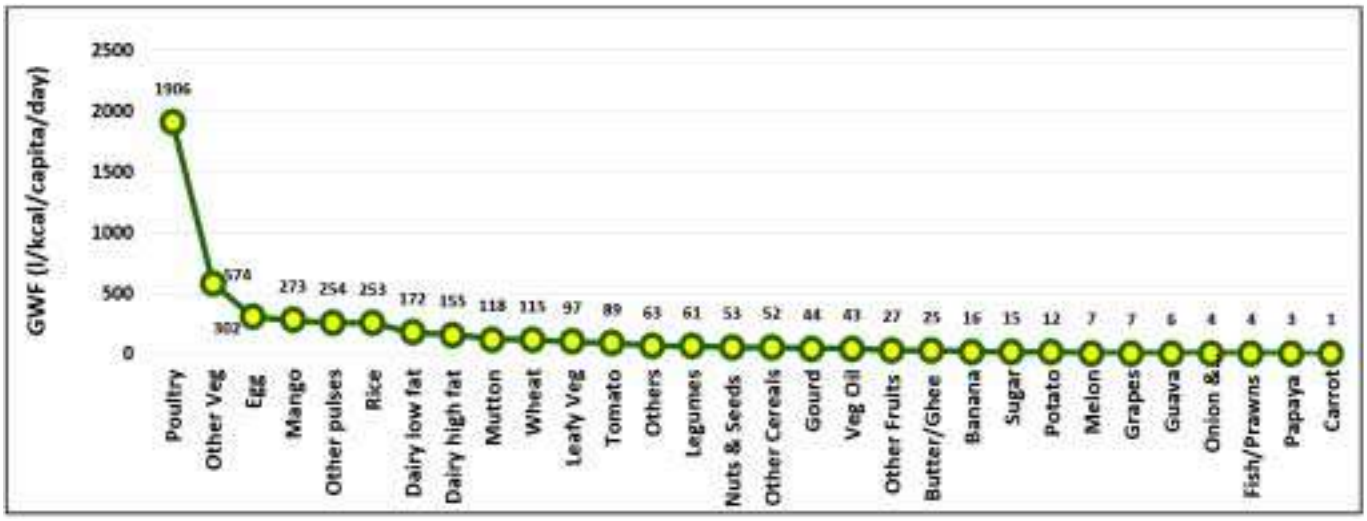


Fig 5 — Green Water Footprint of 31 Food Groups (Lkcalday)

intake using FFQ. There are currently no comparable middle-income country data available, however, the combined Green and Blue Water Footprint (4244 l/capita/day) was higher than the South European vegetarian diet (3176 l/capita/day), and lower than the average South European diet (5364 l/capita/day) according to a study done by Vanham *et.al*[10]. The mean blue WF of this study (1008 l/capita/day) was found to be considerably higher than that found for the European diet (299 l/capita/day) and the UK diet (160 l/capita/day) in a study by Vanham *et al*, and Hess *et al*[11]. These differences in dietary WFs are attributed to the difference in dietary patterns and also to the variation in WFs of various food groups due to climate and yield at the location of production. High dietary blue WF indicates that the Indian diet depends on ground and surface water resources. The groundwater tables are being depleted rapidly hence farmers face greater costs to extract irrigation water (Ahmed *et al*)[12]. Therefore, the high dependency of Indian diets on blue water has a tremendous impact on economic, social and environmental sustainability. In this study, the foods with the highest Blue and Green WF were poultry which is consistent with global averages as per study done by Mekonnen and Hoekstra *et al*[8]. Socio-demographic groups were significantly associated with dietary blue and green WF, due to the amount and type of food consumed. The strongest predictor of dietary blue WF was place of residence, which is significant given India's present water crisis. The blue WF of Urban diets was about 1.4 times higher than that of Rural diets, ie, 1080 l/capita/day compared to 910 l/capita/day while the green WF of Urban diets was approximately 1.2 times higher than that of Rural diets, or ie, 2681 l/capita/day compared to 3643 l/capita/day. Dietary modifications, such as replacing rice and wheat with alternative cereal crops that require less water (sorghum and millet), might be a significant adaptation to the restricted availability of groundwater resources. Dietary blue WF was lower in female participants, mostly as a result of reduced overall energy consumption. According to research by Bowen *et al*[13], urbanization and rising Socio-economic levels may be connected to the nutritional shift in India. Dietary WF rose with a higher quality of living

and was higher in Urban diets than in more traditional, Rural diets. This is linked to a decrease in the intake of grains and pulses and an increase in the consumption of processed foods, vegetable oils, and animal products (particularly dairy and poultry) (Misra, *et al*)[14]. According to this study, dietary modifications that result in higher overall calorie intake and animal product consumption; as they do in many Western nations, may raise dietary WFs and have an impact on water stress.

## Conclusion

According to the United Nations Food and Agriculture Organization (FAO), Sustainable diets are those with low environmental impacts, contributing to food and nutrition security and a healthy life for current and future generations. In the context of this study, the high dietary blue Water Footprint (WF) highlights the heavy reliance of Indian diets on ground and surface water resources. This presents a sustainability challenge, as these resources are under increasing stress. A shift towards less water-intensive food items is essential for ensuring the sustainability of water resources for future generations. Specifically, by substituting wheat and rice with other cereal crops with lower water demand like sorghum and millet. Incorporating more fruits and less meat into the diet can also lower the water footprint as meat production is water-intensive as compared to plant-based foods. This approach can help safeguard water resources for future generations, supporting both environmental sustainability and long-term food security. The shift to such diets could be a key step in mitigating the environmental impacts of current consumption patterns in India.

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Original Article

# Diagnostic Accuracy of Maternal Renal Interlobar Vein Impedance Index in the Prediction of Pre-eclampsia at 20-24 Weeks

**Suchita Sureshkumar Bahurupe[1], Kajal Mitra[2], Prashant Onkar[3], Suresh Phatak[3]**

**Abstract**

**Background :** Pre-eclampsia (PE) is a major hypertensive disorder of pregnancy and a leading cause of maternal and perinatal morbidity and mortality. Early prediction remains a clinical challenge. This study aimed to assess the diagnostic value of the maternal Renal Interlobar Vein Impedance index (RIVI) measured during the mid-trimester as a predictor of preeclampsia.

**Materials and Methods :** This prospective cohort study included 50 pregnant women who underwent renal Doppler ultrasound between 20 and 24 weeks of gestation. Doppler parameters assessed included the renal interlobar artery Resistance Index (RI) and Renal Interlobar Vein Impedance index (RIVI) on both sides. Participants were followed until delivery, and preeclampsia was diagnosed based on the presence of hypertension with proteinuria. Statistical analysis was performed using SPSS to calculate sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and diagnostic accuracy.

**Results :** Preeclampsia developed in 13 women (26%). The diagnostic accuracy of RIVI was 54.0% on the right side and 46.0% on the left. Right-sided RIVI showed a sensitivity of 76.92% and specificity of 45.95%, while left-sided RIVI demonstrated higher sensitivity (92.31%) with lower specificity (29.73%). The highest negative predictive value (91.67%) was observed with left RIVI. Renal interlobar artery RI demonstrated lower predictive performance, with a maximum diagnostic accuracy of 64.0%.

**Conclusion :** Maternal renal interlobar vein impedance index, particularly on the left side, shows higher sensitivity than arterial RI for predicting preeclampsia and may serve as a useful adjunct in mid-trimester screening.

**Key words :** RIVI, Renal Interlobar Vein, Pre-eclampsia, Hypertension, RI.

Pre-eclampsia (PE) is a significant hypertensive disorder of pregnancy, affecting 2-8% of pregnancies Worldwide, with rates as high as 5-15% in India[1]. This condition contributes substantially to both maternal and perinatal morbidity and mortality[2]. It is characterized by the new onset of hypertension and proteinuria after 20 weeks of gestation and can lead to severe complications for both the mother and the fetus[3]. These complications include eclampsia, HELLP syndrome (hemolysis, elevated liver enzymes, and low platelet count), preterm birth, Intrauterine Growth Restriction (IUGR) and placental abruption[2,3]. Despite extensive research efforts, the precise cause of Pre-eclampsia remains elusive[4]. Researchers believe it involves a complex interaction of genetic, immunological, and environmental factors[4]. Early prediction and timely management of the condition are critical in reducing the risk of severe outcomes for both the mother and the fetus[5].

To predict the development of Pre-eclampsia, several clinical parameters and biomarkers are currently in use[6]. These include maternal characteristics such as age, parity, and a history of Pre-eclampsia[6]. Biochemical markers like placental growth factor and soluble fms-like tyrosine kinase-1, as well as biophysical markers such as uterine artery Doppler, are also commonly used[7]. Among these, uterine artery Doppler Ultrasonography, performed between 20-24 weeks of gestation, has become a valuable tool for assessing the risk of Pre-eclampsia[8]. This method evaluates the uteroplacental blood flow, and increased resistance or abnormal waveforms in the uterine artery are often associated with impaired placentation, which is a hallmark of Pre-eclampsia[9]. However, while the uterine artery Doppler can offer insights into the risk of developing the condition, its predictive accuracy is limited[10]. This limitation has prompted the search for additional markers to enhance the early detection of Pre-eclampsia[10].

One promising new marker that has emerged is the maternal Renal Interlobar Vein Impedance (RIVI) index[11]. Recent studies suggest that this index, measured using

***Editor's Comment :***

- Renal Interlobar Vein Impedance index (RIVI), particularly of the left kidney, demonstrates high sensitivity and negative predictive value for the early prediction of Pre-eclampsia at 20-24 weeks of gestation.
- Compared to the traditional renal interlobar artery Resistive Index (RI), RIVI shows superior diagnostic accuracy, reflecting early renal and systemic microvascular changes associated with Pre-eclampsia.
- Color Doppler assessment of RIVI is a simple, non-invasive and reproducible technique that can be easily incorporated into routine obstetric ultrasound.
- Early identification of high-risk pregnancies using RIVI may allow timely intervention and improved maternal and fetal outcomes.
- Larger multicentric studies are warranted to validate its routine clinical application.

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***Accepted on : 30/06/2025***

***How to cite this article :*** Diagnostic Accuracy of Maternal Renal Interlobar Vein Impedance Index in the Prediction of Pre-eclampsia at 20-24 Weeks. Bahurupe SS, Mitra K, Onkar P, Phatak S. *J Indian Med Assoc* 2026; **124(2):** 49-53.

Ultrasonographic Color Doppler, may be a novel and reliable tool for predicting Pre-eclampsia[11,12]. The kidneys play a crucial role in maintaining Blood Pressure and fluid balance during pregnancy and changes in renal hemodynamics are thought to contribute to the pathophysiology of Pre-eclampsia[13]. RIVI measures the resistance to blood flow within the renal interlobar veins, with higher values indicating increased renal vascular resistance[12]. This increased resistance is hypothesized to be associated with the early stages of Pre-eclampsia, reflecting both systemic endothelial dysfunction and altered renal perfusion[13]. As such, RIVI may provide a useful early marker for detecting Pre-eclampsia before clinical symptoms become evident[11,12].

Ultrasonographic color Doppler is a non-invasive imaging technique that provides real-time information about blood flow dynamics in various organs, including the kidneys[14]. It is already an important tool in obstetric care, used to monitor fetal well-being, placental function, and maternal hemodynamics[14]. The use of color Doppler to assess RIVI is relatively new, but initial findings suggest that combining this method with existing predictive markers could improve the accuracy of early detection[15]. By identifying women at risk of Pre-eclampsia earlier in their pregnancy, healthcare providers can intervene in a timely manner, potentially preventing the progression of the disorder and reducing its adverse effects[5].

Given the high incidence of Pre-eclampsia and the limitations of current screening methods, particularly in countries like India, there is a pressing need to identify novel and reliable markers for early detection[1,16]. Preliminary studies have shown that RIVI may correlate with the development of Pre-eclampsia, but larger cohort studies are needed to validate these findings[11,12]. This study aims to assess the diagnostic accuracy of RIVI at 20-24 weeks of gestation, contributing to the refinement of screening protocols and improving outcomes for both mothers and their babies[11]. If successful, the integration of RIVI into current screening strategies could significantly enhance the early identification and management of Pre-eclampsia, ultimately improving maternal and fetal health[12,15].

## Material and Methods

The study population consisted of 50 pregnant women who were referred to the Radiology Department for routine Ultrasound evaluations of fetal health. Participants were recruited through convenience sampling. Inclusion criteria required that participants be in their first pregnancy, with a gestational age between 20 to 24 weeks, determined by their Last Menstrual Period (LMP). Women were excluded if they had a known history of Diabetes Mellitus (DM), Hypertension (HTN) or Renal disease prior to pregnancy, or if parenchymal kidney disease was detected on gray-scale Ultrasound before the Doppler examination.

Pre-eclampsia was diagnosed by an Obstetrician who monitored the participants throughout the study. Diagnostic criteria for Pre-eclampsia included elevated Blood Pressure readings (greater than 140/90 mmHg) and Proteinuria (protein levels of +1 or higher in urine tests).

The Doppler Ultrasound examination involved a detailed review of the renal parenchyma, excluding any major disturbances and a Doppler study of the interlobar arteries and veins in both kidneys. To ensure accurate results, the Doppler angle was minimized by selecting the mid-point of the medullary vessel, where the most consistent readings could be obtained. The impedance index, an important measurement in the study, was also recorded. To standardize the procedure, all Ultrasounds were performed by a single Radiologist, ensuring consistency in the technique and interpretation of results. Before the Ultrasound, all patients underwent a thorough physical and clinical examination.

The Doppler Ultrasound examinations were performed using a SAMSUNG RS 80A and SAMSUNG HS70 machine with convex probe frequency of 1-7MHz. Key study variables included the participant's age, gestational age, Body Mass Index (BMI) and Doppler Ultrasound indices. Measurements included the renal interlobar artery Resistance Index (RI) and the Renal Interlobar Vein Impedance (RIVI) index, which were obtained from both kidneys and documented for further analysis.

### Statistical Analysis :

Data were entered into Microsoft Excel and analyzed using SPSS version 24.0. Quantitative variables were expressed as mean and Standard Deviation, while qualitative variables were shown as proportions. The Student's t-test was used to compare variables between normal and Pre-eclampsia groups. Receiver Operating Characteristic (ROC) curve analysis was applied to determine the optimal cut-off points for RI and RIVI, along with their sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV). A p-value of less than 0.05 was considered significant. Interobserver variability was assessed using Cohen's Kappa statistic.

## Results

Of 50 pregnant women included, 13 developed Pre-eclampsia (26%) and 37 had a normal pregnancy.

Diagnostic accuracy of Renal Interlobar Vein Impedance index for Pre-eclampsia prediction

Table 1 presents the diagnostic accuracy for the Renal Interlobar Vein Impedance Index (RIVI) was found to be 54.0% for the right renal interlobar vein and 46.0% for the

Table 1 — *Presents the diagnostic accuracy for the Renal Interlobar Vein Impedance Index (RIVI) for both right and left interlobar renal veins.*

| Right Renal Interlobar Vein Impedance (RIVI) | | | Sensitivity Analysis | Left Renal Interlobar Vein Impedance (RIVI) | | | Sensitivity Analysis |
|---|---|---|---|---|---|---|---|
| | PE+ (n=13) | PE- (n=37) | Sensitivity=76.92%<br>Specificity=45.95% | | PE+ (n=13) | PE- (n=37) | Sensitivity=92.31%<br>Specificity=29.73% |
| RIVI (<0.4) | 3 | 20 | PPV=33.33% | RIVI (<0.4) | 1 | 26 | PPV=31.58% |
| RIVI (>0.4) | 10 | 17 | NPV=85.0% | RIVI (>0.4) | 12 | 11 | NPV=91.67% |
| P value (Fisher Exact) - 0.0002 | | | | P value (Fisher Exact) - <0.0001 | | | |

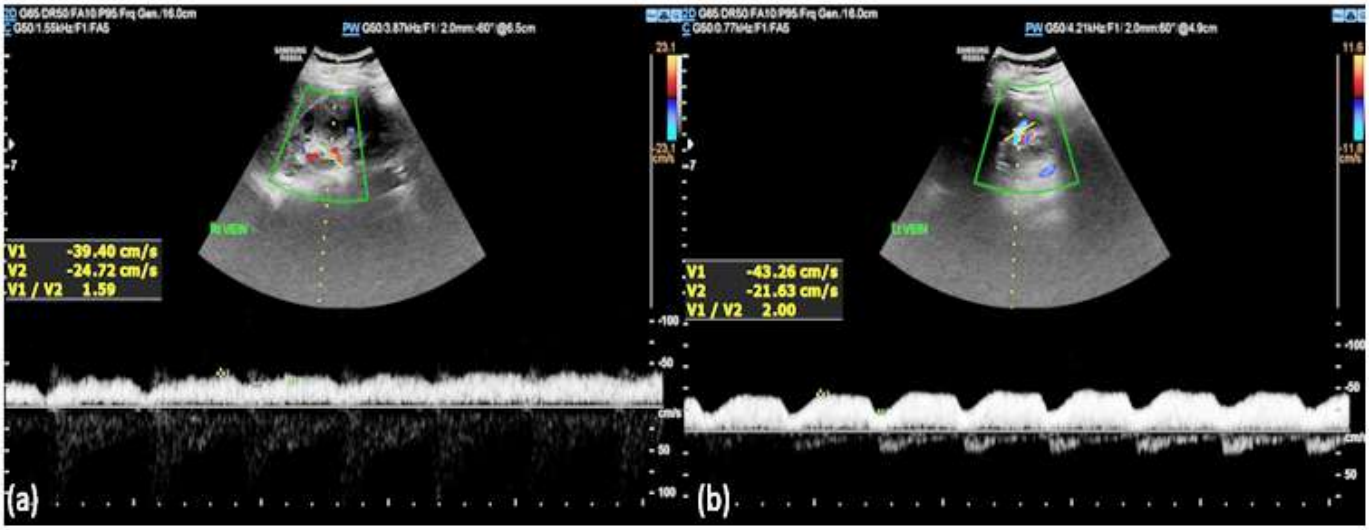


Fig 1(a) & (b) — Showing Bilateral Maternal Renal Interlobar Vein Doppler Flow Indices

left. When comparing RIVI to clinical diagnosis as the gold standard, the Right renal interlobar vein showed a sensitivity of 76.92%, specificity of 45.95%, a positive predictive value of 33.33%, and a negative predictive value of 85.0%. In contrast, the Left renal interlobar vein demonstrated higher sensitivity at 92.31%, but with lower specificity at 29.73%. Its positive predictive value was 31.58%, and the negative predictive value was 91.67%. Overall, the Left RIVI proved to be more useful in predicting the development of Pre-eclampsia compared to the Right side.

Fig 2 shows the ROC curve analysis for the Left Renal Interlobar Vein Impedance Index (RIVI) against Pre-eclampsia (PE) shows an excellent AUC of 0.964 with a statistically significant asymptotic significance of 0.000. The 95% confidence interval for the AUC ranges from 0.885 to 1.000, confirming the reliability of Left RIVI in differentiating between PE and non-PE cases

Fig 3 shows the ROC curve analysis for Right Renal Interlobar Vein Impedance Index (RIVI) shows an AUC of 0.929, indicating high diagnostic accuracy with significant statistical reliability in differentiating between Right RIVI and Pre-eclampsia (PE).

## Diagnostic Accuracy of Interlobar Artery RI for Pre-eclampsia Prediction :

Table 2 shows the diagnostic accuracy for the Resistivity Index (RI) of the renal interlobar artery was 19.61% for the Right side and 64.0% for the Left side. In sensitivity analysis comparing RI to clinical diagnosis as the gold standard, the Right renal interlobar artery demonstrated a sensitivity of 23.08%, specificity of 18.42%, a positive predictive value of 8.82%, and a negative predictive value of 41.18%, resulting in a diagnostic accuracy of 19.61%. Conversely, the Left renal interlobar artery showed a

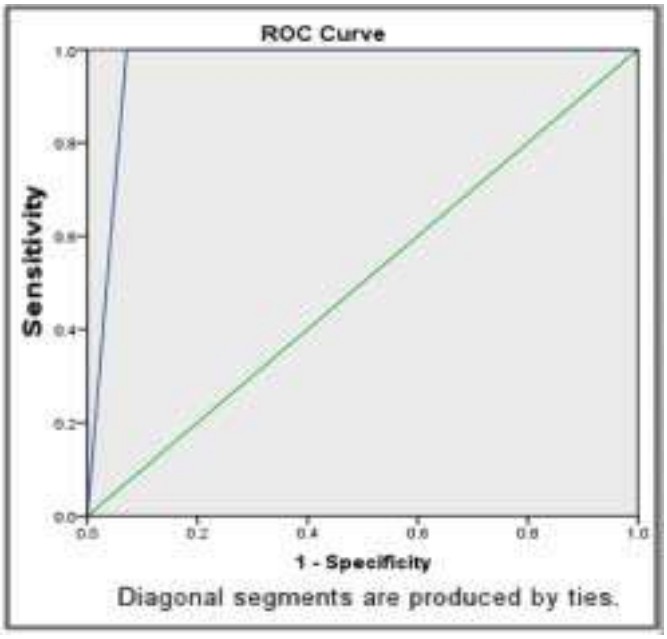


Fig 2 — Shows the ROC curve analysis for the Left Renal Interlobar Vein Impedance Index (RIVI) agai

Table 2 — *Showing the diagnostic accuracy for the Resistivity Index (RI) of the right and left renal interlobar arteries.*

| Right Renal Interlobar artery RI | | | Sensitivity Analysis | Left Renal Interlobar artery RI | | | Sensitivity Analysis |
|---|---|---|---|---|---|---|---|
| | PE+ (n=13) | PE- (n=37) | Sensitivity=23.08%<br>Specificity=18.42% | | PE+ (n=13) | PE- (n=37) | Sensitivity=15.38%<br>Specificity=81.08% |
| RI (>0.7) | 10 | 31 | PPV=8.82% | RI (>0.7) | 11 | 7 | PPV=22.22% |
| RI (<0.7) | 3 | 7 | NPV=41.18% | RI (<0.7) | 2 | 30 | NPV=73.17% |
| P value (Fisher Exact) - 0.54 | | | | P value (Fisher Exact) - <0.0001 | | | |

sensitivity of 15.38%, a much higher specificity of 81.08%, a positive predictive value of 22.22% and a negative predictive value of 73.17%, yielding a diagnostic accuracy of 64.0%. While RI was not as effective a predictor of imminent Pre-eclampsia (PE), it can still be used alongside RIVI for predicting the condition. Notably, the Left RI was more predictive of PE compared to the Right, similar to the findings for RIVI.

Fig 4 shows the ROC curve for the Right Renal Interlobar Artery Resistive Index (RI) indicates good diagnostic accuracy with an AUC of 0.893, demonstrating its effectiveness in distinguishing between Right renal interlobar artery RI and Pre-eclampsia (PE).

Fig 5 shows the ROC curve for the Left Renal Interlobar Artery Resistive Index (RI) shows high diagnostic accuracy, with an AUC of 0.929 and a standard error of 0.056, indicating statistical significance (p<0.001), and a 95% confidence interval of 0.819 to 1.000, confirming its reliability in distinguishing between Left renal interlobar artery RI and Pre-eclampsia (PE).

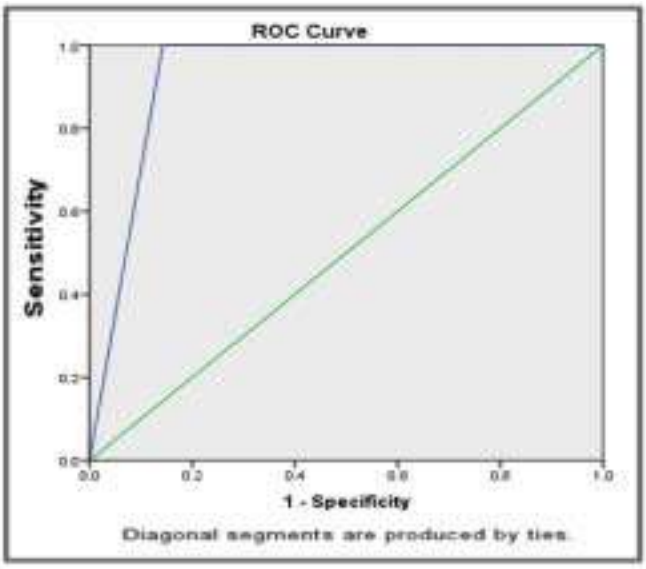


Fig 4 — Shows the ROC curve for the Right Renal Interlobar Artery Resistive Index (RI)

## Discussion

Doppler Ultrasound measurements showed that the mean maximum velocity of the Left renal interlobar vein (16.46 cm/s) was lower than that of the Right (24.36 cm/s), consistent with studies by Patel, *et al* (2017) and Ahmed, *et al* (2019)[17,18] who also observed asymmetry in renal vein velocities. This asymmetry may result from anatomical or physiological differences, with the right kidney's proximity to the liver influencing venous return

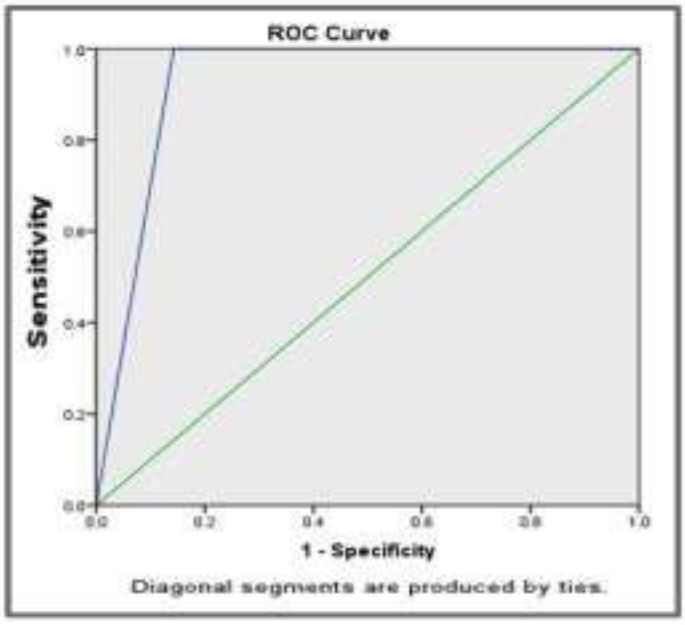


Fig 3 — Shows the ROC curve analysis for Right Renal Interlobar Vein Impedance Index (RIVI)

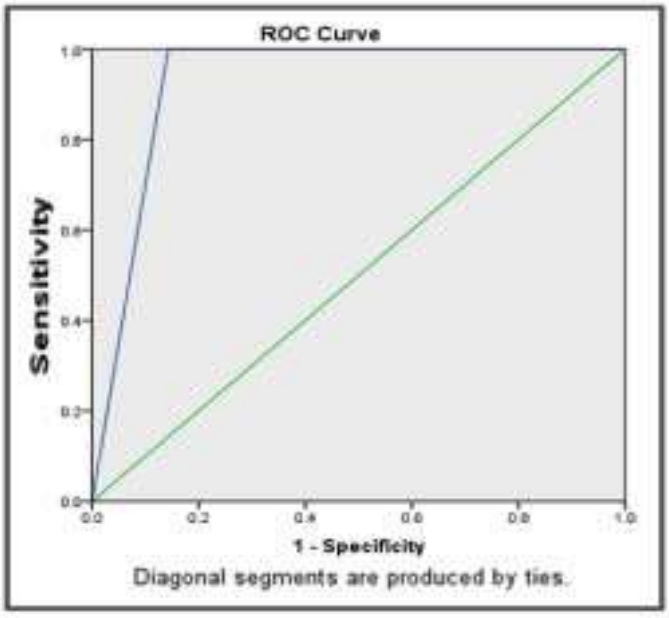


Fig 5 — Shows the ROC curve for the Left Renal Interlobar Artery Resistive Index (RI)

and flow dynamics[19]. Additionally, the difference in mean velocity (delta V) and Renal Interlobar Vein Impedance (RIVI) underscores the importance of evaluating each kidney independently during Doppler assessments.

The Resistivity Index (RI) of the renal interlobar arteries also showed asymmetry, with the Left side having a higher mean RI (0.56) than the Right side (0.43). This finding aligns with Gupta, *et al* (2020)[20] who suggested the Left kidney's longer renal artery and different hemodynamic forces could explain the difference. Sensitivity analysis revealed that RIVI, particularly on the left side, was a more reliable predictor of Pre-eclampsia (PE) than RI. The Left RIVI demonstrated a sensitivity of 92.31% and a Negative Predictive Value (NPV) of 91.67%, higher than those of the right RIVI and both sides' RI. These results are consistent with studies by Davis and Thompson (2021) and Li, *et al* (2022)[21,22], which highlighted the higher diagnostic accuracy of renal impedance measurements for detecting systemic vascular resistance changes linked to PE, improving maternal and fetal outcomes through timely intervention.

Several studies have explored the predictive value of the maternal Renal Interlobar Vein Impedance Index (RIVI) for Pre-eclampsia (PE). Balci, *et al* (2016)[11] found that women who developed PE had significantly higher RIVI, suggesting it as a reliable early marker for the condition. Gyselaers (2012)[12,23] confirmed that RIVI was elevated in both early-onset and late-onset PE, linking it to lower birth weight and higher Proteinuria in early-onset cases. Another study by Gyselaers (2012) established reference values for RIVI, noting a gestation-dependent increase, especially in the Left kidney for PE cases[23]. Salehi, *et al* (2012)[24] found that the Left kidney's RIVI was a significant predictor of PE, while Moura, *et al* (2017)[25] observed that RIVI was not a reliable first-trimester predictor of hypertensive disorders. Ma'yesh (2018)[26] reported that PE affected fetal renal blood flow, suggesting potential long-term health impacts. Overall, RIVI is a useful tool for predicting and managing PE, though its early-pregnancy predictive value is limited.

RIVI demonstrated superior diagnostic accuracy, particularly on the left side, with higher sensitivity and negative predictive value than RI, indicating its reliability for early PE detection[21,22]. This aligns with existing research suggesting that venous impedance indices like RIVI are better indicators of microvascular changes associated with PE than arterial indices. While RI has been a standard in prenatal care, the study advocates for RIVI's inclusion as a more precise measure[21].

## Conclusion

Based on the study's findings, it is recommended that the Renal Interlobar Vein Impedance Index (RIVI) be integrated into routine prenatal screening for Pre-eclampsia (PE), particularly in Urban Tertiary Care settings where the population resembles the study demographic (well-educated, mainly housewives, urban dwellers). Given RIVI's superior diagnostic accuracy and sensitivity—especially on the left side—it should be utilized as a primary screening tool for early PE detection, potentially replacing or complementing the traditional Resistivity Index (RI).

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Review Article

# Recurrent Implantation Failure : Etiology, Treatment Strategies and Contemporary Clinical Perspectives

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**Abstract**

**Background :** Recurrent Implantation Failure (RIF) is a challenging clinical phenomenon characterized by the failure to achieve a clinical pregnancy after multiple embryo transfers as per good practice recommendations from the European Society of Human Reproduction and Embryology (ESHRE). The body further noted a cumulative predicted implantation probability of at least 60% in the failed cases. This review delineates the etiology of RIF, encompassing immunological, anatomical, embryonic, and microbiome factors, and outlines current approaches to treatment, including lifestyle modifications, immunotherapy, endometrial receptivity enhancement, and Assisted Reproductive Technology (ART) strategies. We covered recent evidence, including systematic reviews, umbrella reviews, and cohort studies, to provide an updated overview of RIF etiology and management. Recent advances emphasize the use of individualized diagnosis through endometrial receptivity assays and pre-implantation genetic testing. Current treatments range from evidence-based interventions, such as blastocyst transfer, pre-implantation Genetic Testing for Aneuploidy (PGT-A), to hysteroscopic evaluation with major findings suggesting that therapy should be tailored according to underlying etiology with immuno-modulatory treatments such as granulocyte colony-stimulating factor, intravenous immunoglobulin (IVIG), platelet-rich plasma (PRP) and peripheral blood mononuclear cells (PBMC). Contemporary perspectives increasingly emphasize the dynamic “biosensor” role of the endometrium, highlighting the integrated contribution of embryo competence and endometrial function. Standardizing the definition and management of RIF remains crucial for improving reproductive outcomes.

**Key words :** Recurrent Implantation Failure, Embryo Transfer, Endometrial Receptivity, PGT-A, Immunotherapy.

Implantation is a highly coordinated process that depends on the synchronized development of a competent blastocyst and a receptive endometrium[1]. Despite significant advancements in Assisted Reproductive Technology (ART), implantation remains a major limiting step, and the inability of embryos to implant continues to account for the majority of ART failures. Recurrent Implantation Failure (RIF) has long been defined by a fixed number of unsuccessful embryo transfers, typically three or more[2], but such a criterion does not reflect variations in maternal age, embryo viability, or center-specific success rates. The lack of a standardized definition complicates clinical diagnosis and management, as multiple factors, including maternal age, embryo quality, number of embryos transferred, and cycle characteristics, contribute to RIF. In response to these limitations, the 2023 ESHRE good practice recommendations introduced a probabilistic definition that considers RIF to be present when the cumulative predicted chance of implantation, based on embryo quality and patient characteristics, exceeds 60% without achieving pregnancy[3]. This patient-centered definition better reflects the multifactorial nature of implantation and encourages individualized evaluation.

RIF affects approximately 10-15% of couples who undergo IVF and often leads to emotional exhaustion, financial distress, and decreased confidence in treatment[2,3]. Although most implantation failures document a random nature, especially in the context of untested embryos, a proportion of patients consistently fail to achieve pregnancy despite the transfer of morphologically high-quality or genetically screened embryos. This pattern suggests that underlying biological dysfunction, whether embryonic, endometrial, immunological, or vascular, may be present[1,3,4]. Therefore, an understanding of the interplay between embryonic competence and endometrial receptivity is essential for optimizing outcomes.

***Editor's Comment :***

- Recurrent implantation failure is a multifactorial condition for which contemporary guidelines favour a probability-based, patient-centered definition over fixed cycle-count criteria.
- Successful management depends on individualized evaluation of embryo competence, endometrial receptivity, uterine factors, immune–vascular status, and microbiome.
- Evidence-based strategies (blastocyst transfer, PGT-A in selected cases, hysteroscopic correction, treatment of chronic endometritis, lifestyle optimization) should be prioritized over empirical add-ons.
- The embryo–endometrium “biosensor” concept highlights implantation as a dynamic dialogue, underscoring the need for dual-focus, personalized care.

## Etiology of Recurrent Implantation Failure (Tables 1&2):

### Embryonic Factors :

Embryo quality is arguably the primary determinant of implantation success[5,6]. A substantial proportion of embryos, even those appearing morphologically normal,

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***Received on : 11/12/2025***
***Accepted on : 02/02/2026***

***How to cite this article :*** Recurrent Implantation Failure : Etiology, Treatment Strategies and Contemporary Clinical Perspectives. Rahman SM, Chakraborty P. *J Indian Med Assoc* 2026; **124(2):** 54-8.

Table 1 — *Definition/s of recurrent implantation failure from different perspective*

| Definition Approach | Key Elements Considered | Key Years | Typical Threshold | Strengths | Limitations |
|---|---|---|---|---|---|
| Cycle-count based | Number of failed ET cycles | 2004- 2021 | ≥2-3 failed ET cycles | Simple, easy to apply clinically | Ignores embryo quality, maternal age |
| Embryo-number based | Total good-quality embryos transferred | 2011- 2021 | ≥4-6 high-grade embryos | Accounts for cumulative exposure | Arbitrary quality cutoffs, no ploidy data |
| Euploid-ET based | Failed euploid blastocyst transfers | 2021- 2023 | ≥2-3 failed euploid SETs | Focuses on "true" RIF | Requires PGT-A access, expensive |
| Probability-based (ESHRE) | Cumulative predicted implantation chance | 2023 | >60% predicted success without achievement | Age/embryo stage adjusted | Complex calculation needed |

Table 2 — *Optimized embryo transfer strategy in recurrent implantation failure*

| ET Parameter | RIF-Optimized Approach | Rationale/Evidence | Practical Implementation |
|---|---|---|---|
| Embryo Stage | Single/double blastocyst >cleavage | Higher IR/LBR | Day 5/6 euploid where possible |
| Fresh *versus* Frozen | Frozen-thawed preferred | Better synchrony, higher CPR (19-24%) | HRT-FET cycles |
| Embryo Transfer | Single euploid blastocyst (good prognosis) | Minimize multiples, maximize per-transfer success | Double blastocyst if indicated |
| Luteal Support | Individualized duration | ERA-guided if indicated | Progesterone optimization |
| Adjuncts | ERA/PGT-A in selected | Addresses specific defects | After 2+ unexplained failures |

are chromosomally abnormal. Aneuploidy increases significantly with maternal age and is a major contributor to implantation failure[5]. Evidence from recent meta-analyses indicates that euploid embryo transfer significantly increases implantation and live birth rates, particularly in women aged 35 years and above[4-6]. From the paternal side, contributions, including sperm DNA fragmentation, epigenetic abnormalities, and mitochondrial dysfunction, may further compromise embryo development[7]. Although techniques such as Intracytoplasmic Sperm Injection (ICSI) circumvent fertilization barriers, do not fix intrinsic sperm defects that affect early embryogenesis[2,5,6]. However, preimplantation genetic testing for aneuploidy (PGT-A) improves implantation rates by selecting euploid embryos, offering potential benefit in RIF cases[6]. In summary, optimization of both oocyte and sperm quality remains foundational in the evaluation of RIF.

## Uterine and Anatomical Factors :

Structural abnormalities of the uterine cavity constitute a well-recognized cause of implantation failure[7-9]. The septate uterus remains one of the most strongly implicated congenital anomalies with recent evidences consistently shows improvement in reproductive outcomes following septum resection[8]. Similarly, acquired pathologies such as intrauterine adhesions, submucosal fibroids, and endometrial polyps have been associated with reduced implantation rates[8,9]. Hysteroscopy used to be considered the gold standard for diagnosing and correcting cavity abnormalities and is recommended in women with RIF, particularly if prior imaging was inconclusive[7,9]. Even minor irregularities of the cavity may adversely affect endometrial receptivity by disrupting vascular supply, altering cytokine expression, or interfering mechanically with embryo apposition.

## Endometrial Receptivity and the Biosensor Concept :

Beyond anatomical considerations, the functional state of the endometrium plays a pivotal role in determining implantation success. Emerging evidence suggests that the endometrium functions as a "biosensor," capable of assessing embryo competence and modulating its receptivity accordingly[4]. In healthy cycles, endometrial stromal cells undergo a process of decidualization that facilitates embryo invasion, immune tolerance, and placental development. When decidualization is impaired due to hormonal imbalance, inflammation, or genetic predisposition the embryo–endometrium dialogue becomes disrupted[1].

Conditions such as chronic endometritis have gained renewed attention herein, with studies demonstrating improved reproductive outcomes following targeted antibiotic therapy[9,10]. Similarly, thin endometrium, typically defined as endometrial thickness below 7 mm, may indicate inadequate proliferation or vascularization, although its causal role in RIF remains debated. Molecular receptivity tests such as Endometrial Receptivity Array (ERA) evaluate gene expression profiles to facilitate personalized embryo transfer timed to optimal WOI. However, current evidence does not support routine use of these assays in RIF, as discrepancies in study design and outcome reporting limit their clinical applicability[11].

## Immunological Factors :

Maternal-fetal immune tolerance to the semi-allogenic embryo is necessary for embryo implantation[1]. Dysregulation of uterine Natural Killer (uNK) cells, macrophages, regulatory T cells and altered dendritic cell and macrophage activity has been implicated in implantation failure[6]. Recent studies suggest polymorphisms in Killer cell Immunoglobulin-like Receptors (KIR) and Human Leukocyte Antigen (HLA) interactions may affect uNK cell activity and vascular remodeling at the implantation site[12]. However, the interpretation of immunologic findings is challenging due to methodological variability across studies. Excessive activation of NK cells, imbalanced Th1/Th2 responses, or aberrant HLA/KIR interactions have been proposed as possible mechanisms[1,2,12], yet their predictive value

remains inconsistent. Consequently, immunologic testing is not universally recommended[3]; nevertheless, targeted immunomodulatory therapies may benefit selected individuals whose clinical presentation and laboratory findings suggest immune-mediated implantation failure.

### Thrombophilic and Vascular Influences :

Vascular dysfunction and impaired endometrial perfusion have also been proposed as contributors to RIF. Inherited thrombophilias, including hyperhomocysteinemia, Factor V Leiden and prothrombin gene mutations, and acquired disorders such as antiphospholipid syndrome can increase microthrombotic events within the endometrium[7,9], potentially impairing implantation. However, current evidence does not support routine thrombophilia screening in RIF patients unless clinically indicated[3]. The vascular hypothesis also encompasses impaired spiral artery remodeling or endothelial dysfunction[1], which may influence decidualization and early placentation.

### Microbiome and Infectious Contributors :

The uterine microbiome has recently emerged as an additional determinant of reproductive success[4,6]. A microbiota dominated by Lactobacillus species is generally considered favorable, whereas dysbiosis characterized by increased Gardnerella, Atopobium, or anaerobic species has been associated with lower implantation rates. Altered vaginal and endometrial microbiota, including decreased Lactobacillus species and chronic endometritis, have been linked to RIF[13,14]. Hysteroscopic evidence of micropolyps, stromal edema, or abnormal vascular patterns prompts biopsies that can identify plasma cell infiltration, thereby guiding antibiotic therapy[14]. Although microbiome profiling is promising, its role in routine RIF evaluation remains exploratory.

### Lifestyle and Psychosocial Influences :

Lifestyle factors exert significant effects on implantation and ART success. Obesity alters endocrine function, reduces endometrial receptivity, and increases inflammatory markers[15]. Cigarette smoking impairs oocyte competence and increases sperm DNA fragmentation[2,4]. Alcohol consumption and exposure to environmental toxins have also been implicated[8]. Additionally, the psychological stress associated with repeated ART attempts may adversely influence endocrine and immune function[3]. Therefore, lifestyle modification forms an essential component of comprehensive RIF management.

### Diagnostic Evaluation in RIF :

A structured evaluation is essential to identify reversible contributors and avoid unnecessary interventions. Current consensus emphasizes embryo quality assessment, review of laboratory parameters, and reconsideration of ovarian stimulation strategies[3]. Uterine evaluation through Transvaginal Ultrasound and hysteroscopy is recommended to identify structural abnormalities or signs of chronic endometritis. Basic endocrine tests, including thyroid function and prolactin levels, should be considered, as should semen analysis with optional sperm DNA fragmentation assessment. More advanced tests, such as receptivity assays, immune profiling, or thrombophilia screening, should be reserved for select cases where clinical suspicion is high. A stepwise, evidence-based approach helps balance diagnostic yield with avoidance of over-testing.

### Therapeutic Strategies in Recurrent Implantation Failure (Figs 1-3) :

### Lifestyle Modifications :

Optimizing Body Mass Index (BMI), discontinuing smoking and alcohol intake, and implementing effective stress-management strategies are recommended to enhance IVF outcomes, with even stronger emphasis in women with RIF.

### Improving Implantation Potential : Selection, Transfer, and Adjuvant Measures in RIF

Optimizing embryo selection and refining transfer strategies are central to improving outcomes in women with RIF[4]. Blastocyst-stage transfer enhances physiologic selection by allowing only embryos with higher developmental competence to progress to transfer, while PGT-A further improves selection by identifying euploid embryos[5]. Numerous studies report higher implantation and live birth rates following euploid transfer, particularly in women of advanced maternal age or those with previous failed cycles, though considerations such as cost, accessibility, and potential biopsy-related risks remain important[2,6,8]. Alongside embryo selection, adjustments in ovarian stimulation protocols, luteal phase support, and prioritizing blastocyst over cleavage-stage transfer can enhance implantation efficiency. Assisted hatching may provide benefit in selected patient cohort, especially those with prior failures or older maternal age though evidence remains mixed. Frozen–thawed blastocyst transfer may also offer advantages over fresh cycles in RIF[3]. However, the benefits must be weighed against procedural costs, accessibility, and potential biopsy risks. Low-molecular-weight Heparin (LMWH) can improve live birth rates in RIF patients with confirmed thrombophilia[7,9], but its routine use for all RIF cases is not universally recommended[3].

### Correcting Uterine Factors :

Hysteroscopic treatment of uterine abnormalities such as septa, fibroids, adhesions, and polyps is supported by moderate- to high-quality evidence demonstrating improved clinical pregnancy rates[2,4,16]. Even subtle intrauterine lesions may disrupt implantation and warrant correction. Endometrial injury or “scratch”, prior to embryo transfer historically proposed to improve receptivity[16] by inducing local inflammation thereby provoking decidualization and increasing cytokine release, has

shown inconsistent results in unselected IVF populations but may offer benefit in strictly defined RIF cases[3], thus requires further standardization.

### Immunomodulatory Therapies :

A growing number of RIF patients are being offered immuno-modulatory therapies, although evidence supporting their use remains heterogeneous. Granulocyte colony-stimulating factor (G-CSF) has gained interest following studies reporting improved implantation rates (2, 4), including a recent 5-year cohort where intrauterine G-CSF was associated with significantly higher implantation compared with controls[12]. However, effects on clinical and chemical pregnancy rates were less conclusive. Intralipid infusion, believed to modulate NK-cell function, has shown favorable results in several meta-analyses, although the quality of evidence varies[17]. Similarly, glucocorticoids, intravenous immunoglobulins (IVIG) may reduce uNK cells cytotoxicity and improve Treg cell function in selected patients but require cautious use due to limited definitive evidence[18]. Platelet-rich Plasma (PRP) and Peripheral Blood Mononuclear Cell (PBMC) infusions have demonstrated improvements in implantation and clinical pregnancy in multiple small trials and systematic reviews[19], but standardization of preparation and administration protocols remains lacking. LMWH may be considered in patients with documented thrombophilia or antiphospholipid syndrome, though routine use in RIF is not supported[3].

### Microbiome Management and Infection Treatment :

Treatment of chronic endometritis with targeted antibiotics has consistently improved reproductive outcomes and is now considered a critical component of RIF management when diagnosed. Restoration of normal microbiota through probiotics, antibiotics; in single or in combination or other microbiome-modulating interventions[20] is under investigation and may become a future therapeutic avenue.

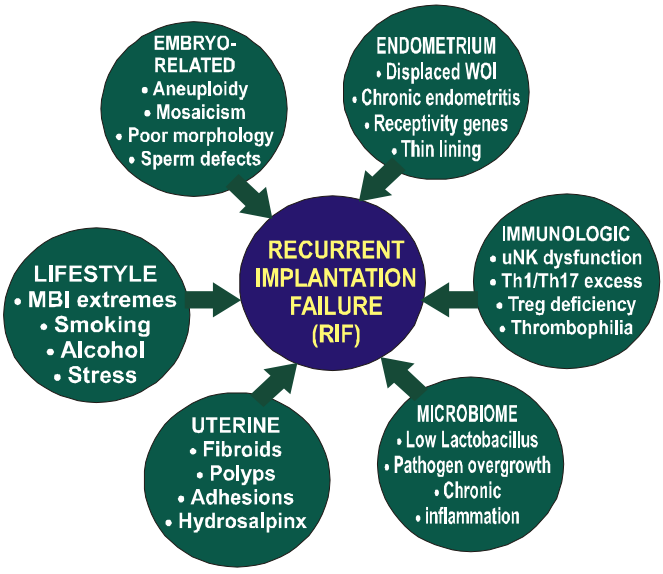


Fig 1 — Conceptual Map of RIF Etiologies. Conceptual framework showing major etiologic domains contributing to recurrent implantation failure and their interactions

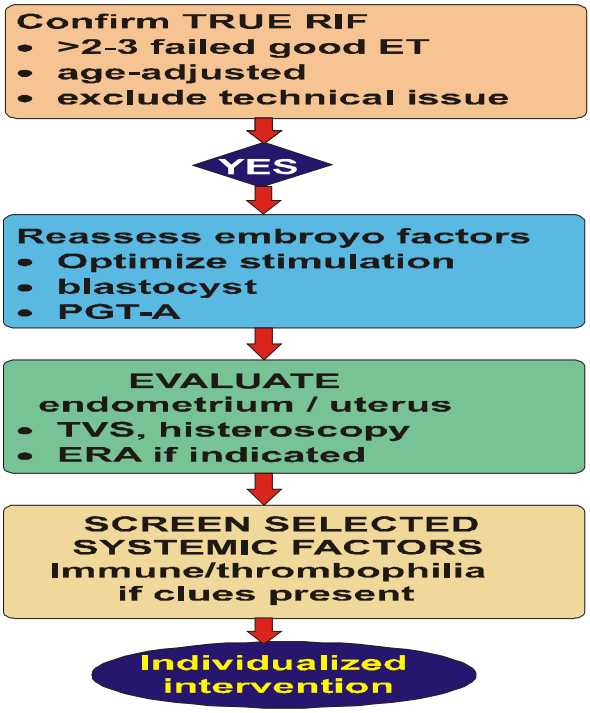


Fig 2 — Stepwise RIF Management Pathway. Clinical algorithm for evaluation and management of recurrent implantation failure

### Male Factor Interventions :

Management of male factor infertility includes optimization of lifestyle habits, antioxidant supplementation, correction of varicocele when indicated, and refinement of sperm selection techniques[3]. Although these interventions may improve sperm DNA integrity and embryo development, their specific impact on RIF requires further study.

### Psychosocial Support :

Recognition of the psychological burden of RIF is important, as stress can influence endocrine signaling, immune function, and treatment adherence. Counselling, stress-reduction techniques, and structured support programs contribute significantly to patient well-being and may indirectly improve cycle outcomes[2,3].

### Contemporary Perspectives :

Recent literature challenges the notion of RIF as a distinct clinical entity[21]. With the increasing use of euploid single embryo transfer, many cases previously labeled as RIF now appear to reflect random biological variation. In present times, individualized assessment including maternal age, embryo quality, endometrial status, and immunological profile is essential for effective management. Immunomodulatory approaches and endometrial receptivity optimization represent the forefront of therapeutic strategies[22]. Nonetheless, persistent implantation failure

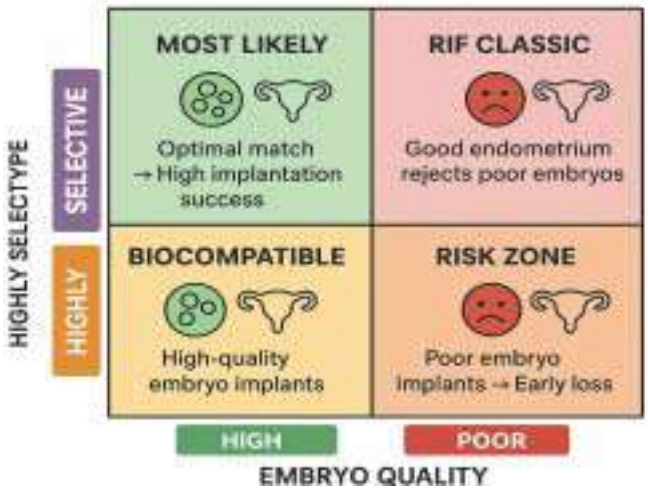


Fig 3 — Schematic of the embryo–endometrium "biosensor" concept
X-axis: embryo genomic/functional quality from "high" to "poor".
Y-axis: endometrial phenotype ranging from "highly selective/low receptivity" to "highly receptive/low selectivity"

after transfer of high-quality or genetically normal embryos suggests that underlying pathological mechanisms do exist for a subset of patients. The emerging biosensor model reframes implantation not as a one-sided failure of the embryo or endometrium but as a dynamic interplay between both. This conceptual shift encourages dual-focus reproductive management, emphasizing both embryonic competence and endometrial health.

## Conclusion

RIF remains one of the most challenging conditions in reproductive medicine. Its multifactorial etiology necessitates a comprehensive, individualized approach that balances evidence-based diagnostics with judicious therapeutic selection. High-quality embryos, a receptive uterine environment, optimal maternal health, and well-regulated immune function form the cornerstones of successful implantation. Although several adjuvant treatments such as G-CSF, intralipids, PRP, and PBMC infusions show promising results, the current evidence is insufficient for universal recommendation. As the field moves toward a more precise understanding of embryo–endometrium interactions, future research must focus on improving prognostic models, validating targeted therapies, and minimizing empirical use of interventions. Ultimately, careful patient-centered evaluation and evidence-driven management offer the best opportunity to improve outcomes and reduce the burden of RIF on affected couples.

**Funding :** None.

**Conflicts of Interest :** None.

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Review Article

# Consent in Indian Law : Analyzing Provisions in the Bharatiya Nyaya Sanhita 2023

**Padmakumar Krishnankutty Nair**[1]

**Abstract**

**Background :** Consent is a cornerstone of legal and ethical frameworks, safeguarding individual autonomy and ensuring accountability. In 2023, the Bharatiya Nyaya Sanhita (BNS) introduced significant reforms to Indian criminal law, including provisions that redefine and strengthen the concept of consent in various legal contexts. This review article examines various sections related to consent in Indian Law, with a particular focus on its codification in the BNS. It explores key changes brought about by the BNS, comparing them to the provisions under the Indian Penal Code (IPC), and evaluates their implications for medico-legal practices, criminal justice, and individual rights. The article also explains various ethical considerations surrounding consent, including its role in protecting vulnerable populations. By analyzing these reforms, this article aims to provide a comprehensive understanding of the intersection of consent and Indian Laws in the context of evolving societal norms and legal standards.

**Key words :** Consent, Bharatiya Nyaya Sanhita (BNS) 2023, Medico Legal Practise, Age of Consent.

Consent is a fundamental principle in law and one of the critical issues in the area of medical treatment[1]. In India, the concept of consent has been extensively addressed with significant updates in the recently enacted *Bharatiya Nyaya Sanhita (BNS) 2023*, which replaces the Indian Penal Code (IPC). The BNS introduces changes that redefine the legal interpretation of consent, particularly in cases related to sexual offenses, medical procedures and other criminal matters. This review article critically examines the various provisions on consent (section 25, 26,27, 28 and 30) under the *Bharatiya Nyaya Sanhita 2023*[2] analyzing their implications, challenges, and the extent to which they align with contemporary legal and ethical standards.

## Section 25 :

This section of BNS essentially explains legal principle of consent and age of consent for an act that might cause some risk or harm.

When a person does an act (a) without an intention to cause death or serious injury and (b) Does not know whether it is likely to cause death or serious injury, the act will not be a crime if done to another person who is above the age of eighteen years and has given consent for that act. Consent given can be implied or explicit.

Implied consent means it is understood from conduct or circumstances while explicit consent is consent which is clearly expressed in words or writing[3].

Even if the person doing the act knows, it might cause some harm, the act is not considered an offence. This applies when both parties understand and agrees to the harm or risks involved. Here, the autonomy of an adult person is recognized to decide their own safety and well being provided the harm is not sure.

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***Received on : 25/05/2025***
***Accepted on : 10/06/2025***

***Editor's Comment :***

- Understanding any updates -here consent and BNS- related to medico legal practise is essential for ensuring ethical and legal compliance.

In medical practise patient gives consent to risky procedures including surgery knowing that complications may arise. The medical practitioner here lacks intent to harm and he is not criminally responsible if the procedure leads to injury or death.

## Section 26 :

This section explains that an act that causes harm is not an offence if it is done with good intention and with the consent of the person.

An act done to a person in good faith for the benefit of that person with the consent is not an offence even if the act causes harm or intended to cause harm or likely to cause harm. The main requirement of this section is that there must be no intention to cause death. Consent given can be implied or explicit. Good faith here is assessed by considering whether reasonable precautions and care were taken. The act must be for the benefit of the person which means the intention is to protect the life and health of the person. Even if harm is the result from the act, it will not become an offence, if it meets all criteria of good faith, benefit and consent.

A doctor performing a medical procedure on a patient even if the procedure is risky or likely to cause death, the doctor is protected if it is done with the consent. But the person performing the procedure should not have an intention to cause death. In such cases consent given must be after understanding the risk and harm of the act.

## Section 27 of BNS :

This section provides protection to perform actions for the benefit of minors or persons of unsound mind. Act done for the benefit of person below the age of twelve years or person of unsound mind is not a crime or offence

***How to cite this article :*** Consent in Indian Law : Analyzing Provisions in the Bharatiya Nyaya Sanhita 2023. Nair PK. *J Indian Med Assoc* 2026; **124(2):** 59-60.

if it results harm if done (a) in good faith and (b) with the consent of legal guardian or person who is having lawful charge of the person.

Under the armpit of this section a medical practitioner can perform a procedure on a child with the consent of parents or legal guardians even if there are risks for the procedure. It has to be proved that, act is done in good faith for the benefit of the child. Same way a procedure can be done on a person having mental illness too with the consent of parents or legal guardians.

This section will not give protection: If (i) the act done has an intention to cause death or attempting to cause death. (ii) The person doing the act is aware that act is likely to cause death and the purpose of act is (a) not to prevent death or serious injury and (b) not cure any serious disease or injury. Section will not give protection to any act which voluntarily causes serious injury or attempt to cause serious injury for a purpose other than preventing death or hurt.

Section 89 refers to the former equivalent section of the Indian Penal Code. The word “insane person” appears in section 89 of the IPC, while “person of unsound mind” appears in BNS section 27[4].

### Section 28 of BNS :

Section 28 of BNS describes what are the situations where consent is invalid. (i) Consent is not valid if it is given under fear of injury or misunderstanding. (ii) If the person doing the act is aware that consent was given due to fear or misunderstanding, then that consent is also not valid. (iii) Consent is invalid if the person who gives consent is unable to understand the nature and consequence of act for which he gives consent because of unsoundness of mind or intoxication. (iv)Consent provided by children below twelve years is not valid.

Purpose of this section is to ensure protection for vulnerable section of society such as children and persons with mental incapacity.

### Section 30 of BNS :

Act done in good faith, even without consent is not an offence (a) If it is impossible for that person to give consent (b) If the person is incapable of giving consent and (c) No guardian or no person lawfully in charge is available to give consent. The act done must be for the benefit of that person.

This section will not give protection: If (i) the act done has an intention to cause death or attempting to cause death. (ii) the person doing the act is aware that act is likely to cause death and the purpose of act is (a) not to prevent death or serious injury and (b) not cure any serious disease or injury. Section will not give protection to any act which voluntarily causes serious injury or attempt to cause serious injury for a purpose other than preventing death or hurt.

When a patient is unconscious after a road accident and doctor performs an Emergency Surgery to save the life, the doctor is protected under this section. Here it is impossible for that person to give consent. If a doctor administers a life saving treatment, the doctor will be legally protected, when the patient is having severe intellectual disability and is incapable of giving consent. A child is found alone and severely injured, emergency medical team can provide treatment legally without waiting for consent from guardian or person lawfully in charge of child.

### Section 25 and 27 of BNS :

According to Indian majority act 1875 section 3, every person domiciled in India will attain the age of majority on completion of eighteen years[5].From this it is understood that a person attains full legal capacity to give contract or consent for any medical procedures when attaining eighteen years of age. Section 25 of BNS essentially explains this legal age of consent as eighteen years for an act that might cause some risk or harm. At the same time section 27 BNS states that Act done for the benefit of person below the age of twelve years is not a crime or offence if it results harm if done (a) in good faith and (b) with the consent of legal guardian or person who is having lawful charge of the person. Thus gap between 12 years and 18 years remains a grey area and clarity is required especially when they seek medical procedures without the support of parents or guardians.

## Conclusion

Consent plays a fundamental role in Indian Law, shaping legal provisions across various domains, including medical practice. The Bharatiya Nyaya Sanhita (BNS) 2023, replacing the Indian Penal Code, retains and refines several consent-related provisions to align with contemporary legal and societal needs. BNS upholds the essential principles of voluntary, informed, and legally valid consent. The legal framework surrounding consent in India strikes a balance between individual autonomy and the state’s responsibility to protect vulnerable individuals from coercion, fraud, and exploitation.

However, evolving societal norms and technological advancements such as telemedicine, digital consent, and data privacy necessitate continuous legal adaptation.

**Funding :** None.

**Conflict of Interest :** None.

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Review Article

# Osteoarthritis of Knee Treated with Intra-articular Injections (Hyaluronic Acid, Platelet Rich Plasma, Corticosteroids) — A Systematic Review

**Midun Kumar V[1], Nanthivarman S[2], Soundararajan K[3], Vijaya Kumar C S[4]**

**Abstract**

**Background :** Osteoarthritis (OA) of the knee is a degenerative, progressive, long-term disease of the articular cartilage that causes pain and physical impairment in elderly people. Thirteen percent of senior citizens report having knee OA. The following categories could be used to group knee OA treatment options: surgical, pharmaceutical, procedural and conservative. Due to its higher risk of problems and joint revision, joint replacement is the gold standard and should only be used for severe grades of Osteoarthritis in the knee. The initial option for adults with knee OA and cartilage degradation is a nonsurgical strategy.Every year, about 10% of the individuals with Osteoarthritis (OA) in their knees receive intra-articular injections of various medications, particularly in the three months following OA diagnosis. Patients with knee OA can have their symptoms lessened by administering injections of corticosteroids, Hyaluronic Acid (HA) and Platelet-rich Plasma (PRP), among other substances. This review's objectives were to provide a summary of intra-articular injections used to treat OA and to list the traditional pharmaceuticals that were employed.

**Key words :** Knee Osteoarthritis, Intra-articular Injections, Corticosteroids, Hyaluronic Acid, Platelet Rich Plasma.

Degenerative Joint Disease, commonly referred to as Osteoarthritis (OA) of the knee, is usually caused by gradual loss of articular cartilage due to wear and stress. Seniors are most likely to experience it. Primary and secondary Osteoarthritis are the two categories of the condition. Articular degeneration in primary Osteoarthritis has no discernible underlying cause[1]. Either aberrant articular cartilage, as in Rheumatoid Arthritis (RA), or an aberrant concentration of force across the joint, as in post-traumatic reasons, can result in Secondary Osteoarthritis[2,3].

Because, radiographic results may not often match with symptoms, the diagnosis is primarily clinical. The primary symptoms, which frequently manifest as impairments in patients, include pain, soreness, restrictions in range of motion, joint effusion, and inflammation[4]. Three symptoms-decreased function, stiffness, and persistent knee pain-as well as three signs-limited movement, crepitus, and bony enlargement-are commonly used to diagnose knee OA. Activity and pain are typically associated; weight-bearing activities make the pain worse, while resting helps it get better. Joint failure is ultimately the final stage[5,6]. The "gold standard" for confirming a diagnosis and ruling out other conditions is frequently a radiograph. Anteroposterior and lateral knee x-rays reveal subchondral degenerative disease, osteophyte formation, and joint space narrowing.

***Editor's Comment :***

- Intra-articular injections are effective non-operative options for knee osteoarthritis, with PRP providing superior and longer-lasting pain relief and functional improvement, hyaluronic acid offering moderate, time-limited benefit, and corticosteroids giving rapid but short-term symptomatic relief; hence, treatment should be individualized based on disease severity, patient expectations, and cost-effectiveness.

The analgesics and anti-inflammatory drugs used in pharmacological therapy are given gradually. As per the guidelines, the first course of treatment for symptomatic OA should begin with acetaminophen (up to 4 g/day)[7]. This is because studies have shown that acetaminophen is as effective as Non-steroidal Anti-inflammatory Drugs (NSAIDs) but has fewer gastrointestinal side effects and a stronger correlation with warfarin maintenance[8]. In cases when acetaminophen is ineffective or symptoms are moderate to severe, NSAID medication (ibuprofen, naproxen, diclofenac) is advised.

The most widely used pharmacological compounds are NSAIDs, however their use is restricted due to a high frequency of gastrointestinal adverse effects, including peptic ulcer and gastrointestinal bleeding, as well as renal failure and elevated Blood Pressure[9]. Although Cyclooxygenase-2 inhibitors (COX-2) are known to lessen gastrointestinal side effects and enhance safety, they are also linked to increased costs and cardiovascular problems such Myocardial infarction and Stroke.

The main benefits of intra-articular injection are improvements in pain and function as well as temporary symptom alleviation. Hyaluronic Acid (HA), Platelet-rich Plasma (PRP) and corticosteroid injection are a few of

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***Received on : 27/04/2024***
***Accepted on : 21/06/2024***

***How to cite this article :*** Osteoarthritis of Knee Treated with Intra-articular Injections (Hyaluronic Acid, Platelet Rich Plasma, Corticosteroids) — A Systematic Review. Midun Kumar V, Nanthivarman S, Soundararajan K, Vijaya Kumar CS. *J Indian Med Assoc* 2026; **124(2):** 61-5.

the substances utilized to treat knee OA symptoms[10,11].

This review's objectives were to provide a summary of the traditional pharmaceuticals utilized and to give an overview of the intra-articular injections used to treat OA.

## Intra Articular Injection of Knee :

When medication is no longer helpful, for patients who prefer to postpone or avoid surgery, or for those who do not tolerate pharmacological oral therapy, intra-articular injection of the knee may be a good option[12]. The shots ought to be as painless as feasible. Selecting the injection location correctly is essential; in fact, studies have shown that suprapatellar and medial infrapatellar injections hurt more than lateral infrapatellar injections[13,14]. The vastus medialis obliquus must be crossed in the medial subpatellar approach because the soft tissues are thinner there. With a mildly flexed joint, the patient lies supine during the lateral patellofemoral approach. When the needle reaches the middle of the patellar equator, it should be placed between the patella and the femoral condyle[15] (Table 1).

## Technique :

The knee joint is the most often treated joint in the body because it has the biggest synovial space. It is the most accessible joint to enter and provide medication into because it frequently develops visible or palpable effusions[16]. Puncturing a balloon allows for easy access when there is a lot of fluid present.

The patient is typically supine during aspiration of the knee, with the knee supported and stretched to the greatest extent feasible. The typical site of entry is medial, roughly at the patella's midway, or just below the place where a line parallel to the medial border is crossed by a horizontal line tangential to the patella's superior pole[17,18]. A 1.5 to 2 inch long, 20-gauge needle is aimed either upward or downward and slides into the joint area below the patella's undersurface.

Firm pressure applied with the hand cephalad on the patella above the suprapatellar bursa site can aid in aspiration of the knee (Fig 1). The fluid is aspirated and the needle is retracted gently if any cartilage is contacted.

On the lateral side, a comparable method may be applied, particularly in cases when the peak fluid bulge is lateral[19]. When there is a significant amount of fluid in the suprapatellar bursa, the lateral approach is very useful. The entry site is superior to the patella and lateral.

Even though it is less frequently done, the infrapatellar approach can be helpful when there is little to no fluid present and the knee cannot be fully extended[20]. The needle is inserted cephalad to the infrapatellar fat pad and medially or laterally to the inferior patellar tendon while the knee is bent. Using this method to acquire fluid is challenging[21,22].

Table 1 — *Showing Some Cortico-steroid Suspensions for Intra-articular Injection*

| Preparations | Concentration (mg/ML) | Usual Dose (mg)* |
|---|---|---|
| Hydrocortisone tabutate (Hydrocortone-TBA) | 50 | 25-100 |
| Betamathasone acetate and betamethasone sodium phosphate (celestone Soluspan) | 6** | 1.5-6 |
| Methylprednisolone acetate (Depo-Medrol***) | 20 | 4-40 |
| Triamcinolone acetonide (Kenalog-40) | 40 | 5-40 |
| Triamcinolone diacetate (Aristocort Forte) | 40 | 5-40 |
| Triamcinolone hexacetonide (Aristospan) | 20 | 5-40 |

*Amount injected varies depending on the size of the joint
**Available as 3 mg acetate and 3 mg phosphate
***Available in 20 mg/mL, 40 mg/mL, and 80 mg/mL preparations

## Corticosteroids :

Joint discomfort can be effectively treated for short to medium periods of time by Intra-articular Steroid Injection (IASI) of the knee. Corticosteroids lessen the synovial inflammatory phase by downregulating aggrecans and collagenases, agents/modulators of proinflammatory mediators, and mononuclear cells. The intricate method

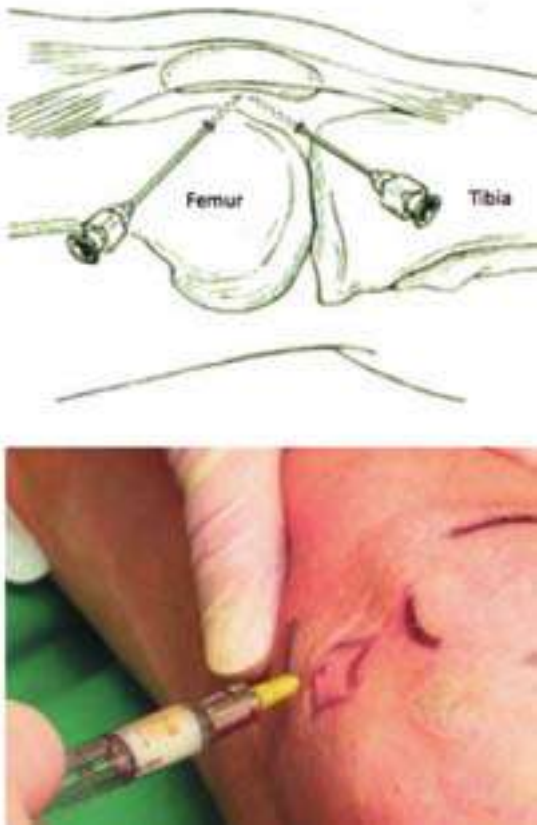


Fig 1 — Top, arthrocentesis of the knee joint via the usual medial entry. Bottom, actual injection of corticosteriod suspension into knee via medial approach.

of action results in a reduction of leukocyte counts and synovial blood flow, along with the release of inflammatory mediators[23-25]. Since the advancement of cartilage destruction in knee OA is linked to joint inflammation, IASI may slow the disease's progression.

Numerous corticosteroids are available for purchase, including betamethasone (Celestone), dexamethasone (Decadron) LA, triamcinolone acetonide (Kenalog), and methylprednisolone acetate (Depo-Medrol)[26]. Triamcinolone acetonide (Kenalog) and methyl-prednisolone acetate (Depo-Medrol) are the most commonly utilized. As indicated in Table, their usual dosage is 40 mg, with a minimum three-month gap between injections.

### Hyaluronic Acid :

Synovial fluid and extracellular matrix naturally include high-molecular-weight glycosaminoglycan, or HA, which is made of chains of repeating disaccharide units. Its purpose is to increase the viscosity of synovial fluid by lubricating the joint and absorbing shocks during motions[27]. Moreover, HA helps to prevent nociceptors and the enzymatic breakdown of cartilage. Moreover, exogenous HA may function as a free-radical scavenger and promote the production of endogenous HA. Decreases in HA content and molecular weight can be attributed to aberrant generation of synoviocytes, molecular fragmentation, and dilution of synovial fluid due to effusion[28]. Experimental studies have indicated that the mechanical impact of exogenous HA cannot explain the sustained effects. Rather, the HA clearance is influenced within a few days by the Intra-articular Hyaluronic Acid (IAHA) preparation[29,30].

Three forms of HA are distinguished by their varying molecular weights and the range of possible varieties: There are three different kDa ranges: Low (500–730 kDa), Moderate (800–2000 kDa) and High (2000–6000 kDa), which includes crosslinked HA formulations (Table 2).

After receiving acetaminophen, NSAIDs, and symptomatic slow-acting medications continuously or intermittently, IAHA is recommended for patients who are not responding to treatment. For knee OA, IAHA has been acknowledged as a dependable and safe therapeutic method. According to earlier research, the side effects of IAHA, such pain or swelling, almost invariably happen at the injection site or inside the joint and are equally likely to happen in patients receiving a placebo as they are in those receiving active treatment. Rarely do serious adverse outcomes occur. Nothing about unanticipated adverse occurrences was reported after the product was launched, according to the Food and Drug Administration's premarket approval database.

Table 2 — *Showing Approved Hyaluronon Preparations*

| | Sodium Hyaluronate (Hyalgan) | Sodium Hyaluronate (Supartz) | High-Molecular-Weight Hyaluronan (ORT Hovisc) | Hylin G-F 20 (synvisc) |
|---|---|---|---|---|
| Type of Product | Natural | Natural | Natural | Chemically cross-linked |
| Moleculat weight (X 106 deltons) | 0.5-0.73 | 0.6-1.2 | 1.0-2.9 | 6.0 |
| Concentration (mg/mL) | 10 | 10 | 15 | 8 |
| Dose volume (mL) | 2 | 2.5 | 2 | 2 |
| Dose interval | 1 week | 1 week | 1 week | 1 week |
| Number of doses | 3 to 5 | 5 | 3 or 4 | 3 |

### Platelet Rich Plasma :

Autologous plasma that has been enhanced with a concentration of platelets is what produces Platelet-rich plasma (PRP). PRP provides and releases growth factors, α-granules and cytokines, which can stimulate healing and facilitate tissue repair[31]. Fibrinogen, Tissue Growth Factors (TGFs), Platelet-derived Growth Factors (PDGFs), interleukin-1 receptor antagonist (IL-1RA) and Vascular Endothelial Growth Factors (VEGFs) can all be released in response to a PRP injection. These growth factors function both locally and systemically, promoting the inhibition of cytokines and catabolic enzymes, regulating inflammation and local angiogenesis, attracting local fibroblasts and stem cells to damaged areas and stimulating the production of more growth factors by healthy neighboring cells.

A wide range of PRP preparation methods, platelet counts, injection volumes, anticoagulant and activating agent usage, patient sex, physical attributes and OA severity have all been documented in the literature. Current research suggests that PRP injections can improve pain relief and functional improvement in patients with symptomatic knee OA for at least 12 months, though some authors have reported good score values up to 24 months after the start of treatment[32]. The duration of the beneficial effects of PRP injections is unknown. PRP therapy was found to be clinically superior to other injectable therapies (HA, IASI and Saline) in terms of lowering the symptomatology of pain related to Osteoarthritis (OA) and improving functional results with comparable or lower risks of adverse events[33].

The biggest barriers to therapy at the moment are the absence of standardization and the need for more investigation into how leukocytes, activation and platelet concentration affect therapeutic efficacy beyond PRP's cost-effectiveness.

### Stem Cell Therapy :

Stem cell injections have been suggested as a new regenerative therapy for knee OA because of their ability for multilineage differentiation[34,35]. But according to a recent systematic review, there are very few RCTs in this

field, the studies that are available have a significant risk of bias, and there are no long-term findings[36]. We locate two studies comparing stem cell treatments for Osteoarthritis (OA) to PRP or HA[37].

### Prolotherapy :

Small doses of an irritant solution, such as hyperosmolar dextrose (d-glucose), with concentrations ranging from 12.5 to 25%, are injected into painful joints during prolotherapy in an effort to promote the tensile strength of the ligaments, tendons, and joint capsules that stabilize the joint and restore joint stability[38,39]. Even though the current studies' results were statistically significant, the lack of a control group, short follow-up periods, limited sample sizes, and structural evaluations make it difficult to determine the therapeutic relevance or significance[40,41].

### Conclusion :

IA corticosteroid has dubious long-term efficacy when compared head-to-head with alternative comparators such IA PRP, ketorolac, or normal saline, despite the fact that pain and function improve quickly. IA corticosteroid plus HA combination therapy may be more beneficial than IA corticosteroid therapy alone, however more research with a bigger sample size is required to prove this. While IA HA did not show any symptomatic improvement when compared to normal saline, small studies comparing HA with PRP or diclofenac showed a significant improvement in pain and function at least over 6 months when compared to HA therapy alone. These studies also need more investigation.

Using a range of comparators, including HA, ozone, and normal saline, conflicting outcomes were reported over IA PRP; some studies had follow-up periods of 36 or 60 months. Likewise, varying outcomes are documented in relation to stem cell treatments. Standardization of PRP and stem cell products is therefore desperately needed. Small studies have shown that prolotherapy can be useful in either a single or combo regimen. Not a single one of the IA treatments in the review showed evidence of septic arthritis or significant side effects.

With imaging guidance, joint injection accuracy and clinical results are improved. Future research should focus on topics including placebo effects, drug delivery technologies, cost-effectiveness of various IA therapies, potential negative effects of IA NSAIDs or local anesthetics on cartilage and product standardization.

**Funding :** None.

**Conflict of Interest :** None.

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Case Series

# Extrapulmonary Tuberculosis in Adults with Varied Radiological Presentations — A Case Series

**Jijo Joseph[1], Krishnapriya Vijayalekshmi[2], Varun Narayan[3], Robert P Ambooken[4]**

**Abstract**

**Background :** Tuberculosis (TB) remains a serious Global public health concern and is responsible for the highest number of deaths from any infectious disease worldwide. Extrapulmonary Tuberculosis (EPTB) shows various clinical and radiological features depending on the organ it affects, which can often mimic other diseases. Here, we are reporting five cases of Extrapulmonary Tuberculosis with multisystem involvement as diagnosed in our institute over a period of three years. This case series includes patients with Extrapulmonary Tuberculosis affecting the brain, spine, and abdomen. Three individuals presented solely with extrapulmonary symptoms, while two exhibited both pulmonary and extrapulmonary manifestations. Certain radiological patterns of EPTB are characteristic and can help in early diagnosis, preventing unnecessary biopsies or surgeries. While definitive diagnosis relies on positive culture or histological analysis, recognizing specific imaging findings can greatly assist in timely detection and management.

**Key words :** Extrapulmonary Tuberculosis, Tuberculoma, Gastric Fistula, Tuberculosis.

Tuberculosis (TB) remains a serious global public health concern and is responsible for the highest number of deaths from any infectious disease Worldwide[1]. In 2024, Globally, 10.8 million people were diagnosed and reported to have a new episode of TB. Of these cases, 81% had pulmonary TB, and 19% had extrapulmonary TB. While TB predominantly affects the lung parenchyma in more than 80% of people, extrapulmonary TB is also commonly encountered. Extrapulmonary Tuberculosis (EPTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB affecting organs other than the lungs[2]. EPTB shows various clinical and radiological features depending on the organ it affects, which can often mimic other diseases[3]. Therefore, early diagnosis and treatment are essential. This case series aims to explore the diverse radiological presentations of Extrapulmonary Tuberculosis in adults, emphasizing the role of imaging modalities in the diagnosis and management of this elusive form of TB. Here, we are reporting 5 cases of Extrapulmonary Tuberculosis with multisystem involvement as diagnosed in our institute over a period of 3 years.

***Editor's Comment :***

- Extrapulmonary tuberculosis can present with highly diverse and often deceptive clinical and radiological features, frequently mimicking malignancy or other inflammatory conditions.
- Recognising characteristic imaging patterns across different organ systems is crucial for timely diagnosis, particularly when routine investigations are inconclusive.
- Early identification and prompt initiation of antitubercular therapy can significantly improve patient outcomes, even in cases with complex multisystem involvement.

## Case Presentation

### Case 1 :

A 39-year-old female patient without any comorbidities with presenting complaints of fever, generalized tiredness for 2 weeks, with malena and anemia was evaluated. Contrast Enhanced Computed Tomography (CECT) of abdomen was done which showed defect with wall thickening in the lesser curvature of stomach in the posterior aspect with a tract extending to anteroinferior aspect of the body- tail region of the Pancreas with air pockets in the inferior aspect of pancreas with a small adjacent collection. Multiple prominent lymph nodes in the periportal, peri gastric and paraaortic region with thrombosis of portal vein and splenic vein (Fig 1). Features suggestive of gastric fistula with omental nodularity & thickening and we raised a possibility of Tuberculosis as etiology. Oesophago-gastro-duodenoscopy was performed which showed fistulous opening in the lesser curvature. Ultrasound guided omental biopsy was performed which showed no malignancy or granulation tissue. In view of development of bicytopenia with ongoing high grade fever episodes and lymphadenopathy in CECT, a diagnosis of lymphoma was suspected and Bone marrow biopsy was performed, which showed inconclusive reports. A diagnostic laparoscopy was performed on which showed findings suggestive of Tuberculosis and omental biopsy was taken whose results confirmed the diagnosis of abdominal Tuberculosis. Biopsy from omentum and falciform ligament showed

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***Received on : 08/06/2025***
***Accepted on : 10/07/2025***

***How to cite this article :*** Extrapulmonary Tuberculosis in Adults with Varied Radiological Presentations — A Case Series. Joseph J, Vijayalekshmi K, Narayan V, Ambooken RP. *J Indian Med Assoc* 2026; **124(2):** 66-9.

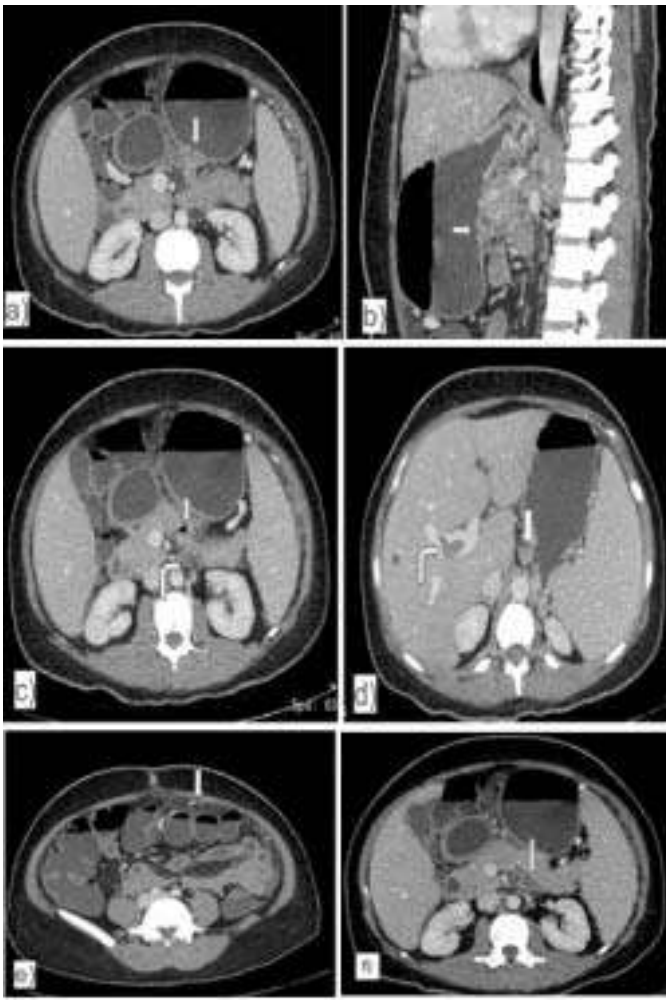

Fig 1 — (a) Defect with wall thickening in the stomach, (b) Air pockets in the inferior aspect of pancreas(straight arrow), (c) with a small adjacent collection (bent arrow), (d) Thrombosis of portal vein (bent arrow) and prominent perigastric lymph node (straight arrow), (e) Omental thickening with stranding and nodularity and (f) non-visulization of splenic vein (straight arrow).

caseating granulomatous inflammation, Patient was started on ATT and symptomatically improved over time.

### Case 2 :

A 29-year-old female, with complaints of fever, which was high grade with chills since one month and non-projectile vomiting for 2 weeks, myalgia and generalized tiredness. Patient had a history of travel outside the country. Due to persisting headache the clinician advised for an MRI brain with contrast which revealed numerous small discrete nodular and ring enhancing lesions scattered in brain parenchyma on both sides with enhancing leptomeningeal thickening in left sylvian fissure with areas of restricted diffusion, adjacent insular and temporal lobe showing focal oedema and enhancement (Fig 2). We raised a possibility of multiple Tuberculomas with Meningitis and Cerebritis. CSF analysis picture favouring tuberculous picture. Bone marrow aspirate, culture & sensitivity and biopsy taken

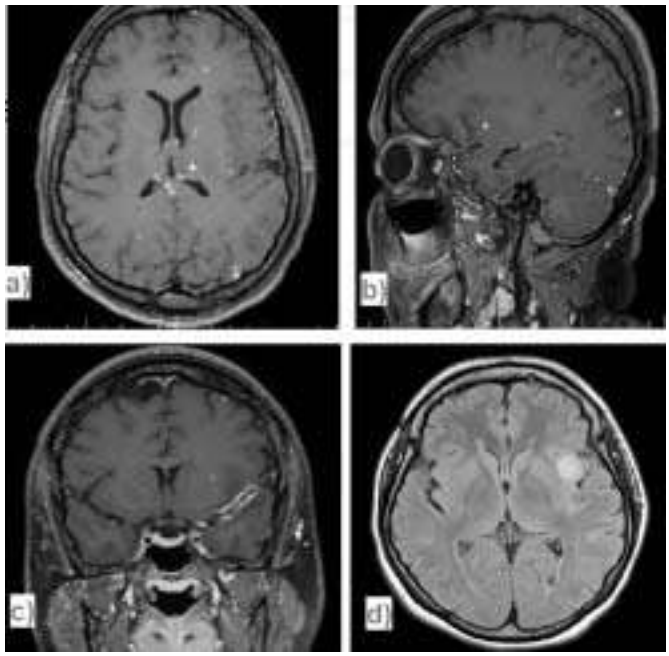

Fig 2 — Contrast enhanced MRI Brain (a) axial and (b) sagittal images showing multiple nodular enhancing lesions in both cerebral hemispheres. (c) Enhancing leptomeningeal thickening in left sylvian fissure. (d) T2 FLAIR hyperintensity in left insular region and temporal lobe.

which showed caseating granuloma with necrosis confirming Tuberculosis. She was started on anti-tubercular therapy & intravenous steroids and symptomatically better.

### Case 3 :

A 59-year-old male patient presented with complaints of urinary incontinence for 5 days, gradual onset of weakness of both upper and lower limbs and generalised tiredness since 3 days. Contrast enhanced Magnetic Resonance Imaging (MRI) of Spine was done. Evidence of reduced disc height with heterogenous signal intensity noted involving the C5-C6 intervertebral disc and vertebral body, with partial destruction of the C6 vertebral body. Anterior epidural, pre and para vertebral collection noted extending along the intervertebral disc region which is compressing the cervical spinal cord at C5 -6 level causing cord oedema (Fig 3). We raised the possibility of Tuberculous Spondylitis. On further work up patient had pulmonary findings favouring Tuberculosis and confirmed with sputum samples and diagnosed as pulmonary and extra Pulmonary Tuberculosis. Patient started antituberculosis therapy. Patient was also advised to started on IV steroids and symptomatic improvement noted. Patient was improved and symptomatically better after antituberculosis therapy.

### Case 4 :

A 27-year-old male patient with no other comorbidities, came with history of vomiting and abdominal pain. Ultrasonography abdomen was done which revealed

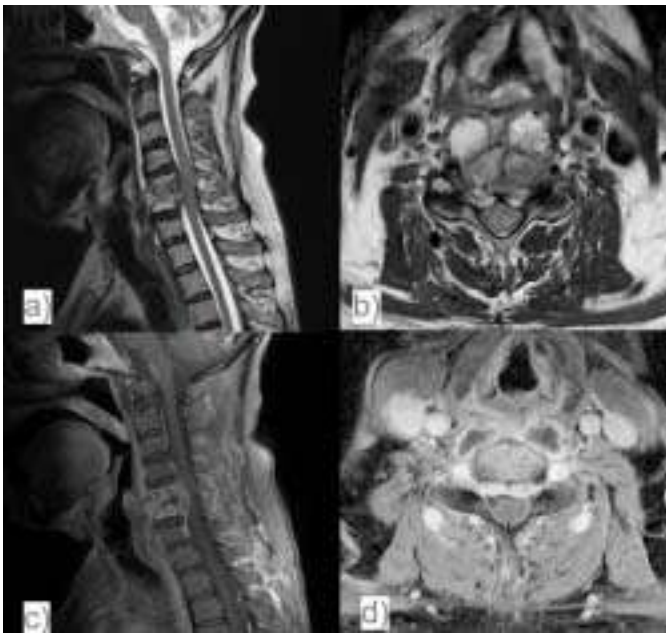

Fig 3 — (a,b) Evidence of reduced disc height with T2/STIR hyperintense area noted at the C5 – C6 intervertebral disc, similar areas with edema involving the C5 and C6 vertebral body with partial destruction of the C6 vertebral body in the superior aspect. (a) Spinal cord edema noted extending from C5 to C6 level. (c,d) Anterior epidural soft tissue with heterogenous peripherally enhancing collection noted from C5 to C6 level causing spinal canal narrowing and spinal cord compression at the same level.

moderate ascites, omental thickening and dilated bowel loops. CECT Abdomen was done which revealed grossly dilated small bowel loops with transition point in mid ileal loop suggestive of intestinal obstruction. Free fluid in peritoneal cavity with peritoneal thickening and enhancement along with extensive mesenteric and omental fat stranding. Covered part of the thorax shows necrotic nodal mass also noted in subcarinal region (Fig 4). The patient underwent surgery, obstruction was revealed and omental sampling shows caseating granulomas and confirmed with the diagnosis of Tuberculosis. Patient started ATT and symptomatically improved over time.

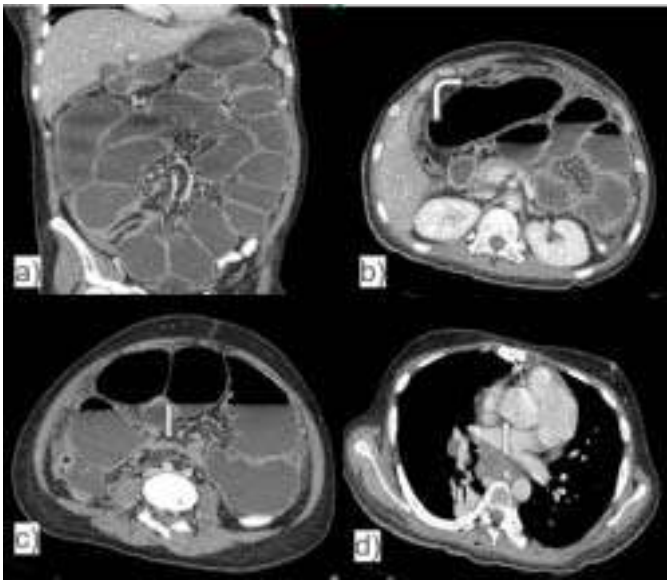

Fig 4 — (a) CECT Abdomen showing dilated small bowel loops, (b) Peritoneal thickening and enhancement with mesenteric and omental fat stranding (curved arrow), (c) Narrowing suggestive of transition point in mid ileum (arrow), (d) Necrotic nodal mass also in subcarinal region (arrow).

### Case 5 :

A 58-year-old female patient, who is a known case of Ankylosing Spondylitis on biologicals presented with complaints of abdominal distension for 2 weeks and loss of appetite and weight loss. No h/o cough or fever were present. Ascitic fluid analysis-showed low Serum-ascites Albumin Gradient (SAAG) high protein. CECT abdomen was taken which revealed diffuse omental and mesenteric fat stranding and nodularity with moderate ascites. Peritoneum showed diffuse thickening (Fig 5). The possible differential diagnosis is Tuberculosis and peritoneal Carcinomatosis. Omental biopsy was performed, and biopsy reports were suggestive of granulomatous inflammation (Tuberculosis) and antitubercular therapy was initiated. Patient become symptomatically better after completion of ATT and follow up imaging shows significant reduction in the abdominal imaging findings.

## Discussion

This case series includes patients with Extrapulmonary Tuberculosis affecting the brain, spine and abdomen. Three individuals presented solely with extrapulmonary symptoms, while two exhibited both pulmonary and extrapulmonary manifestations.

Extrapulmonary Tuberculosis (EPTB) can affect various organs, most commonly the Lymph nodes (50%), Pleura (18%), Genitourinary system (13%), Bones and Joints

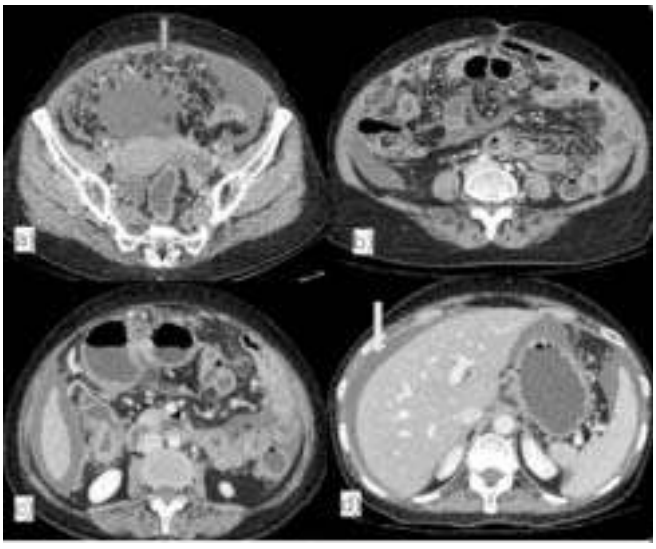

Fig 5 — (a,b,c) Diffuse omental & mesenteric fat stranding and nodularity, (a,b,d) Peritoneum shows diffuse thickening and ascites.

(6%), Gastrointestinal system (6%), Central Nervous System (CNS) (3%) and Spine (3%)[4]. Approximately half of all skeletal TB cases involve the spine, with spondylodiscitis — also known as Pott's disease — being the most prevalent form[5].

Central Nervous System (CNS) Tuberculosis is a severe manifestation, presenting in different forms such as parenchymal, meningeal, calvarial, spinal or combinations thereof. MRI is generally more effective than Computed Tomography in detecting CNS Tuberculosis. Parenchymal involvement most often appears as a tuberculoma, which may be solitary or multiple[6].

Abdominal Tuberculosis is the most frequent extrapulmonary form, accounting for about 5% of all TB cases Worldwide[7]. Tuberculous lymphadenitis, affecting 55-66% of abdominal TB cases, is the most common presentation[8]. Gastric involvement is rare, occurring in 0.4%-2% of cases, typically in the antrum and distal body. Symptoms range from vague epigastric discomfort to upper gastro intestinal bleeding, with antral narrowing potentially causing gastric outlet obstruction. The presence of sinus tract and fistula is rare but strongly suggestive of Tuberculosis. The most involved parts are the gastric antrum and distal body[9,10].

Certain radiological patterns of EPTB are characteristic and can help in early diagnosis, preventing unnecessary biopsies or surgeries. While definitive diagnosis relies on positive culture or histological analysis, recognizing specific imaging findings can greatly assist in timely detection and management.

## Conclusion

Extrapulmonary Tuberculosis continues to pose a significant diagnostic challenge owing to its heterogeneous and often nonspecific clinical and radiological manifestations. This case series illustrates the wide spectrum of imaging appearances involving the central nervous system, spine, and abdomen, highlighting its potential to mimic malignancy and other inflammatory conditions. Awareness of characteristic radiological patterns, combined with appropriate clinical correlation, is essential for timely diagnosis and early initiation of antitubercular therapy, particularly in patients with multisystem disease. Radiological imaging remains central to guiding further evaluation, minimising diagnostic delays, and ultimately improving patient outcomes.

**Funding :** None.

**Conflict of Interest :** None.

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Case Report

# Uncovering the Uncommon : An Extremely Rare Adrenal Epithelial Cyst in a Young Female

**Madhuri Singh[1], Shirish S Chandanwale[2], Akshi Raj[1], Nimisha Choudhary[3], Archana Buch[4]**

**Abstract**

**Background :** Adrenal cysts account for less than 0.06% of adrenal lesions and are classified into endothelial cysts, pseudocysts, parasitic cysts and epithelial cyst. The endothelial and pseudocyst variants of adrenal cysts are most common with epithelial subtype contributing to only 9% of all adrenal cysts. Epithelial cysts are defined by the presence of a lining composed of cuboidal to columnar epithelial cells. Although most adrenal cysts are asymptomatic and discovered incidentally, larger lesions may cause flank pain or lead to complications such as hemorrhage or rupture. Due to the overlapping imaging characteristics with other cystic lesions, a definitive diagnosis typically relies on histopathological confirmation.

**Key words :** Epithelial, Cyst, Adrenal, Female.

Adrenal cysts are uncommon retroperitoneal lesions, first documented by Greselius during an autopsy in 1670[1]. They are typically incidental findings, accounting for only 1%-2% of adrenal incidentalomas[2]. Most adrenal cysts are nonfunctional and asymptomatic; however, larger lesions can present with diverse clinical manifestations, ranging from a palpable mass and abdominal discomfort to gastrointestinal symptoms. Histopathologically, adrenal cysts are classified into four subtypes based on their origin: endothelial cysts, pseudocysts, epithelial cysts, and parasitic cysts[3].

Epithelial cysts, also known as true cysts, are extremely rare and constitute only 9% of all adrenal cysts[4]. Due to the overlapping imaging characteristics among different cystic adrenal lesions, definitive diagnosis relies on histopathological confirmation. Here, we report an exceedingly rare case of an epithelial cyst in the right adrenal gland of a 28-year-old unmarried female, which was initially misdiagnosed radiologically as a pseudocyst.

## Case Presentation

A 28-year-old unmarried female presented to the surgical Outpatient Department with complaints of persistent pain in the left side of her abdomen. She also reported a six-month history of decreased appetite. The pain remained unresolved despite medication.On physical examination, her abdomen was soft and non-tender with no signs of distention. She had no dysuria, haematuria, fever, weight loss, or bowel irregularities. Her medical and surgical history was unremarkable. She had normal puberty, a regular menstrual cycle and no signs of hirsutism. Routine blood investigations and renal and hepatic function panels were within normal limits. Computed Tomography (CT) scan of the abdomen and pelvis revealed a large, well-defined, thin-walled, hypodense, non-enhancing cystic lesion measuring 6 cm, located in the left suprarenal region, initially suspected to be a pseudocyst (Fig 1a).

***Editor's Comment :***

- Adrenal epithelial cysts are rare entities that often mimic other cystic lesions on imaging, especially in young patients.
- Histopathological identification of an epithelial lining is essential for definitive diagnosis and surgical excision offers both diagnostic certainty and excellent clinical outcomes.

The patient subsequently underwent surgical excision, during which an adrenal cyst was identified and removed along with the left adrenal gland. The excised specimen was subjected to histopathological examination.

Gross examination of the specimen revealed an intact unilocular cystic tissue piece measuring 6 × 5.5 cm. The external surface appeared congested, and the cut surface displayed greyish-white areas with mucinous material in some regions (Fig 1b). Microscopic examination demonstrated a cyst lined by flattened to cuboidal to columnar epithelium, with a fibrocollagenous cyst wall devoid of inflammatory reactions or haemorrhage (Figs 1c & 1d). No evidence of endothelial lining, acellular laminated membrane, protoscolices, or malignancy was found in any of the sections examined. These histopathological findings ruled out a pseudocyst, parasitic, and endothelial cyst, confirming the final diagnosis of an epithelial cyst in the adrenal gland.

## Discussion

Adrenal cysts are rare retroperitoneal lesions, comprising approximately 4% of all adrenal masses[5]. Their underrecognition is attributed to their nonspecific clinical and radiological presentations. Although typically benign, adrenal cysts possess malignant potential in 7% of cases[6]. Smaller adrenal cysts are frequently asymptomatic and nonfunctional, while larger cysts especially those exceeding 10 cm may cause complications such as infection, haemorrhage, or rupture[7].

In this case, the patient's adrenal cyst measured only 6 cm, yet she experienced recurrent left flank pain for one year, which is uncommon for cysts of this size to be symptomatic.

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***Received on : 26/05/2025***
***Accepted on : 02/06/2025***

***How to cite this article :*** Uncovering the Uncommon : An Extremely Rare Adrenal Epithelial Cyst in a Young Female. Singh M, Chandanwale SS, Raj A, Choudhary N, Buch A. *J Indian Med Assoc* 2026; **124(2):** 70-1.

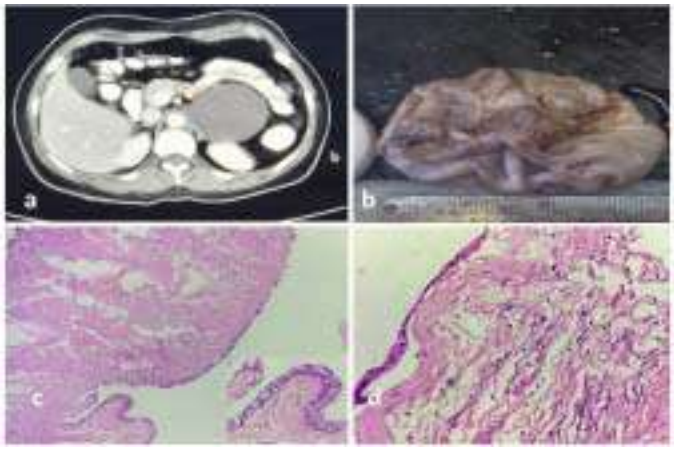

Fig 1 — (a) CT Abdomen and Pelvis: Well-defined thin walled hypodense, non-enhancing cystic lesion, (b) Gross: Unilocular cyst wall, (c) & (d) Microscopy: Cyst lined by flattened to cuboidal to columnar epithelium with fibrocollagenous wall (Hematoxylin and Eosin x400).

Adrenal cysts can develop at any age; however, they are most frequently diagnosed in individuals between their third and sixth decades of life, with a slight female predominance[8]. Reports of adrenal cysts in younger individuals are rare, making this early presentation in a 28-year-old particularly noteworthy and contributing to the initial misdiagnosis[9].

Histopathologically, adrenal cysts are categorized into four types : Endothelial cysts (45%) – Derived from lymphatic or vascular origins; usually small (0.1–1.5 cm in diameter). Pseudocysts (39%) – Lined by fibrous tissue and lacking epithelial or endothelial lining. Epithelial cysts (9%) – True cysts lined by cuboidal to flattened epithelium; includes congenital glandular (retention) cysts, cystic adenomas, and mesothelial cysts. Parasitic cysts (7%) – Rarely isolated to the adrenal gland, often associated with Echinococcus infection.

Ultrasound and CT imaging are effective in detecting adrenal cystic lesions but may not accurately differentiate among the subtypes (endothelial, pseudocyst, epithelial, and parasitic). In this case, the imaging suggested a benign cyst, yet it lacked specificity for definitive classification.

Given the rarity of adrenal cysts and the uncertainty of pre-operative diagnosis, no universal management protocol exists. However, surgical resection is recommended in the following scenarios:

- Symptomatic cysts, irrespective of size.
- Cysts larger than 5 cm.
- Cases with suspected malignancy.

Laparoscopic resection is the preferred approach for adrenal cyst excision, offering minimally invasive, effective removal while preserving adrenal function. In contrast, asymptomatic and benign cysts can often be managed conservatively with imaging follow-up.

Histopathological examination remains the gold standard for diagnosis, particularly when imaging findings are inconclusive.

## Conclusion

This case underscores the diagnostic challenges associated with epithelial cysts of the adrenal gland. While imaging modalities effectively detect adrenal cysts, they often lack specificity for definitive classification. Histopathological confirmation, characterized by an epithelial lining, remains essential for an accurate diagnosis.

Surgical resection, particularly laparoscopic adrenal cyst excision, is a safe and effective treatment strategy that facilitates complete cyst removal while preserving adrenal gland function. Given the rarity of adrenal epithelial cysts, increased awareness and multidisciplinary evaluation are vital to managing such cases effectively, preventing complications and ensuring optimal patient outcomes.

**Acknowledgement :** None.

**Statement of Ethics :** This study protocol was reviewed and the need for approval was waived by Dr DY Patil Vidyapeeth Institutional Ethics Committee.

**Declaration of Conflicting Interests :** The author(s) declared no potential conflicts of interest with respect to research, authorship and/or publication of this article.

**Funding :** The author(s) received no financial support for the research, authorship and/or publication of this article.

**Author Contributions :** Dr Madhuri Singh: conceptualization, data curation, formal analysis, investigation, writing - original draft; Dr Akshi Raj: validation and review; Dr Shirish Chandanwale: data curation,; Dr Nimisha: formal analysis, methodology Dr Archana Buch: methodology, validation.

**Data Availability Statement :** All data generated or analyzed during this study are included in this article and its supplementary material files. Further enquiries can be directed to the corresponding author.

**Consent :** A written informed consent was obtained from the patient for publication of the details of their medical case and any accompanying images.

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Short Communication

# Reduction in Life Expectancy among Telangana Doctors

**Sudeepta Rao Danapuneni[1], Tejasvi Kantam[2], Vishnupriya Rao Paturi[3], Suresh Gutta[4], Surendranath Chaparala[5], Dwarakanatha Reddy Duvvuru[6]**

**Abstract**

**Background :** Doctors are generally expected to have lower morbidity and mortality rates than the general population due to their medical expertise on living a healthy lifestyle. However, research suggested otherwise. The current study data included 4,481 Health Care Professionals, out of which 395 were deceased doctors and 4,086 were living doctors during the same period. While most doctor-deaths occurred after the age of 60, a few were recorded in younger age groups. Male doctors exhibited significantly higher mortality rates than their female counterparts, although the reduction in life expectancy was comparable across genders. When compared to the general population using Telangana census data, doctors were found to have a notably shorter lifespan. These findings highlight the urgent need for targeted health interventions and wellness programs for medical professionals.

**Key words :** Telangana, Life expectancy, Doctors, Mortality, Early Deaths.

It is assumed that Health Care Professionals (HCPs), particularly doctors, are often expected to live longer in comparison to the general population due to their extensive medical knowledge and adherence to healthier lifestyles[1]. However, recent research studies have suggested otherwise, with doctors in some Indian states dying notably younger than the general population[2,3]. In India, where the doctor-to-population ratio stands at 1:1800, the loss of even a single doctor adds significant strain to an already burdened system[4]. This study involves the mortality of doctors in Telangana, analyzing deaths by age and gender and comparing them with the general population to assess the reduction in their life expectancy.

## Methodology :

The Indian Medical Association (IMA) in Telangana has registered 4,481 life members, between March 2019 and March 2025 under IMA Family Security Scheme (FSS). Present study compiled relevant data of 395 deceased doctors and 4,086 living members from IMA FSS register (Table 1). The general population data for age at death in 5-year intervals and life expectancy in men and women, was taken from the life tables of 2016-20 years of Telangana[5], published by the Government of India. Descriptive statistics were used, Chi-square tests of difference between frequencies and Student's t-test for differences in means, with a p-value <0.001 considered as statistically significant.

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***Received on : 24/04/2025***
***Accepted on : 17/05/2025***

***Editor's Comment :***

- Behind the white coat lies a silent health crisis. Telangana doctors are losing valuable years of life, likely driven by stress, delayed self-care, and demanding work environments.
- Protecting those who heal others must become a public health priority - through proactive wellness programs, routine screenings, and a culture that encourages doctors to care for themselves too.

## Results and Discussion :

Among the 395 deceased doctors (aged 35-85 years), 351 were men and 44 were women (Table 2). The highest number of deaths occurred among male doctors aged 65-70 years (n=74). A few deaths were also noted in younger age groups: 3 doctors died between 35-40 and 2 between 40-45 years. The greatest reduction in life expectancy of 38.80 years was seen in the 35-40 age group (Fig 1). The average reduction across all doctors was 14.39 years (±6.60). Among men, life expectancy was reduced by an average of 13.66 years (±6.21), with a maximum of 38 years. For women, the average reduction was higher at 17.14 years (±8.28), with a maximum of 40 years in two individuals.

Doctors often prioritize patient care over their own health, leading to chronic stress, poor self-care, and missed health screenings[6]. While most deaths occurred among older HCPs, significant losses were also recorded in younger age groups[7]. Many doctors delay or skip routine check-ups, leading to undiagnosed conditions like diabetes, hypertension and hyperlipidemia. A study by the Indian Medical Association (IMA) in Kerala found that 27% of its members died from heart disease, while 25% died from cancer. Suicide also ranked high particularly among those who self-diagnose or use unhealthy coping strategies. This study found higher mortality may be linked to stress-related behaviors such as smoking, alcohol use, or excessive consumption of stimulants[6]. Compared with the general population in Telangana, doctors showed a significant reduction in their life expectancy.

## Conclusion :

Doctors in Telangana experience significantly shorter life

***How to cite this article :*** Reduction in Life Expectancy among Telangana Doctors. Danapuneni SR, Kantam T, Paturi VR, Gutta S, Chaparala S, Duvvuru DR. *J Indian Med Assoc* 2026; **124(2):** 72-3.

Table1 — *Study Population, Telangana Doctors*

| Age years at study / death | Living, N=4086 | | | | Demised, N=395 | | | |
|---|---|---|---|---|---|---|---|---|
| | Men | % | Women | % | Men | % | Women | % |
| 25-30 | 4 | 0.13 | 3 | 0.33 | 0 | - | 0 | - |
| 30-35 | 29 | 0.91 | 14 | 1.54 | 0 | - | 0 | - |
| 35-40 | 88 | 2.77 | 55 | 6.04 | 1 | 0.28 | 2 | 4.55 |
| 40-45 | 170 | 5.35 | 79 | 8.67 | 2 | 0.57 | 0 | - |
| 45-50 | 223 | 7.02 | 83 | 9.11 | 10 | 2.85 | 1 | 2.27 |
| 50-55 | 294 | 9.26 | 141 | 15.48 | 18 | 5.13 | 6 | 13.64 |
| 55-60 | 326 | 10.27 | 156 | 17.12 | 35 | 9.97 | 3 | 6.82 |
| 60-65 | 464 | 14.61 | 113 | 12.40 | 43 | 12.25 | 8 | 18.18 |
| 65-70 | 530 | 16.69 | 115 | 12.62 | 66 | 18.80 | 8 | 18.18 |
| 70-75 | 492 | 15.50 | 72 | 7.90 | 58 | 16.52 | 3 | 6.82 |
| 75-80 | 303 | 9.54 | 54 | 5.93 | 60 | 17.09 | 9 | 20.45 |
| 80-85 | 173 | 5.45 | 23 | 2.52 | 42 | 11.97 | 3 | 6.82 |
| 85+ | 79 | 2.49 | 3 | 0.33 | 16 | 4.56 | 1 | 2.27 |
| All | 3175 | 100 | 911 | 100 | 351 | 100 | 44 | 100 |

Table 2 — *Reduction in life expectancy*

| Age at death, years | Reduction in life expectation, years | | |
|---|---|---|---|
| | All | Men | Women |
| 35-40 | 38.80 | 37.50 | 40.10 |
| 40-45 | 34.20 | 33.10 | - |
| 45-50 | 29.90 | 28.90 | 31.00 |
| 50-55 | 25.80 | 24.90 | 26.70 |
| 55-60 | 21.70 | 21.10 | 22.40 |
| 60-65 | 17.90 | 17.40 | 18.40 |
| 65-70 | 14.50 | 14.20 | 14.90 |
| 70-75 | 11.30 | 11.10 | 11.70 |
| 75-80 | 9.00 | 8.60 | 9.40 |
| 80-85 | 7.20 | 6.80 | 7.70 |
| 85+ | 5.70 | 5.20 | 6.20 |
| All | 395 | 351 | 44 |
| Mean | 14.39 | 13.66 | 17.14 |
| SD | 6.60 | 6.21 | 8.28 |

SD = Standard Deviation
Chi-2, p<0.001 (men *versus* women, 50-85 years age)

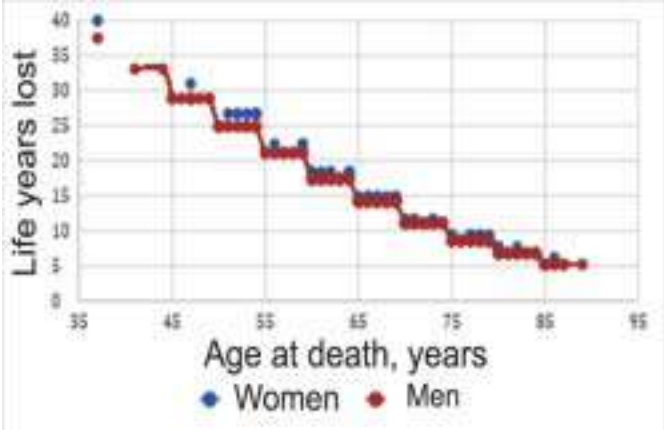


Fig 1 — Reduction in life expectancy

expectancy than the general population, presumably due to work-related stress, delayed medical care and unhealthy coping mechanisms. These findings highlight the urgent need for doctor-wellness initiatives, regular health screenings, and systemic support to reduce occupational burnout and improve health outcomes among HCPs.

**Funding :** No funding sources.

**Conflict of interest :** None declared.

**Ethical approval :** Not required.

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# Letter to the Editor

*[The Editor is not responsible for the views expressed by the correspondents]*

## Imperative Mandate for Thalassemia Screening in Pregnancy

Sir, — We write to emphasise the compelling need for mandatory and indispensable Thalassemia screening during pregnancy, with a specific emphasis on perinatal diagnosis. Current standards for thalassemia screening in pregnancy involve prenatal screening using various methods such as full blood count, hemoglobin electrophoresis, and thalassemia mutation tests[1]. These screening methods aim to identify pregnant women who are carriers of thalassemia genes, which can help in reducing the incidence of thalassemia[2]. Haematological parameters, such as the Mentzer formula (MCV/RBC) and HbA2 levels, have shown promise in differentiating between different types of thalassemia genotypes in pregnant women[3]. Additionally, raising awareness among pregnant women and their families about thalassemia is crucial to encourage early screening and detection[4]. Laboratories performing antenatal screening should utilize methods capable of detecting significant variants and quantitating haemoglobins A2 and F at the required cut-off points [5]. Overall, the current standards for thalassemia screening in pregnancy involve a combination of different screening methods and raising awareness among pregnant women. Thalassemia, a hereditary blood disorder, requires heightened scrutiny, particularly within distinct communities such as Lohana, Khoja, Agarwal, Bhanushalli, Bania, Neobuddhist, Sindhi, and Jain.

Individuals with chronic microcytosis and normal serum ferritin levels should undergo thorough evaluation for Thalassemia diagnosis. Hemoglobin electrophoresis is crucial for confirming the presence of Thalassemia, while computed parameters such as MCV/RBC ratio and RDW can indicate Beta-Thalassemia Minor[6]. Borderline HbA2 values should be reevaluated after correcting anemia to avoid false diagnoses, as elevated HbA2 levels can be observed in Megaloblastic anemia[7]. Microcytic hypochromic anemia can be caused by various conditions, including IDA and Thalassemia[8]. Thalassemia screening and Level-Three ultrasound during pregnancy are essential for ruling out congenital and hereditary diagnoses[9]. Thalassemia screening should be mandatory for every pregnancy[10].

Individuals manifesting chronic microcytosis and maintaining normal serum ferritin levels within these communities necessitate particular vigilance. An unequivocal Thalassemia diagnosis becomes imperative, making the conduct of hemoglobin electrophoresis paramount. Additionally, a meticulous examination of the Red Blood Cell (RBC) count assumes critical importance; an RBC count surpassing 5 x 10^9/L indicates a predisposition to Thalassemia minor. Various computed parameters, including the MCV/RBC ratio and Red Cell Distribution Width (RDW), serve as valuable indicators for suspecting Beta-Thalassemia Minor.

The gold standard for confirming a Thalassemia diagnosis remains hemoglobin electrophoresis. While normal results are anticipated in cases of Alfa Thalassemia trait, abnormalities signify the presence of Beta-Thalassemia trait or other Thalassemic syndromes. It is imperative to acknowledge that concurrent conditions, such as Iron Deficiency Anemia (IDA) or Megaloblastic anemia, may obscure the typical abnormalities associated with the Beta-Thalassemia trait.

To mitigate the risk of false diagnoses, it is crucial to reevaluate borderline Hemoglobin A2 (HbA2) values after correcting anemia. This is particularly relevant, given that elevated HbA2 levels may be observed in cases of Megaloblastic anemia, potentially leading to an erroneous diagnosis of Beta-Thalassemia minor. Microcytic hypochromic anemia, a frequently encountered clinical scenario, primarily originates from IDA, followed by Thalassemia, anemia of chronic origin, lead poisoning, sideroblastic anemia, and the ingestion of copper or zinc.

In light of these considerations, we underscore the absolute necessity of Thalassemia screening and Level-Three ultrasound during pregnancy as intrinsic components for ruling out congenital and hereditary diagnoses. The unequivocal stance is that every pregnancy should undergo mandatory Thalassemia screening as an indispensable and non-negotiable measure.

Disseminating this information through this esteemed platform will undoubtedly contribute significantly to the collective understanding of this crucial facet of maternal and child healthcare.

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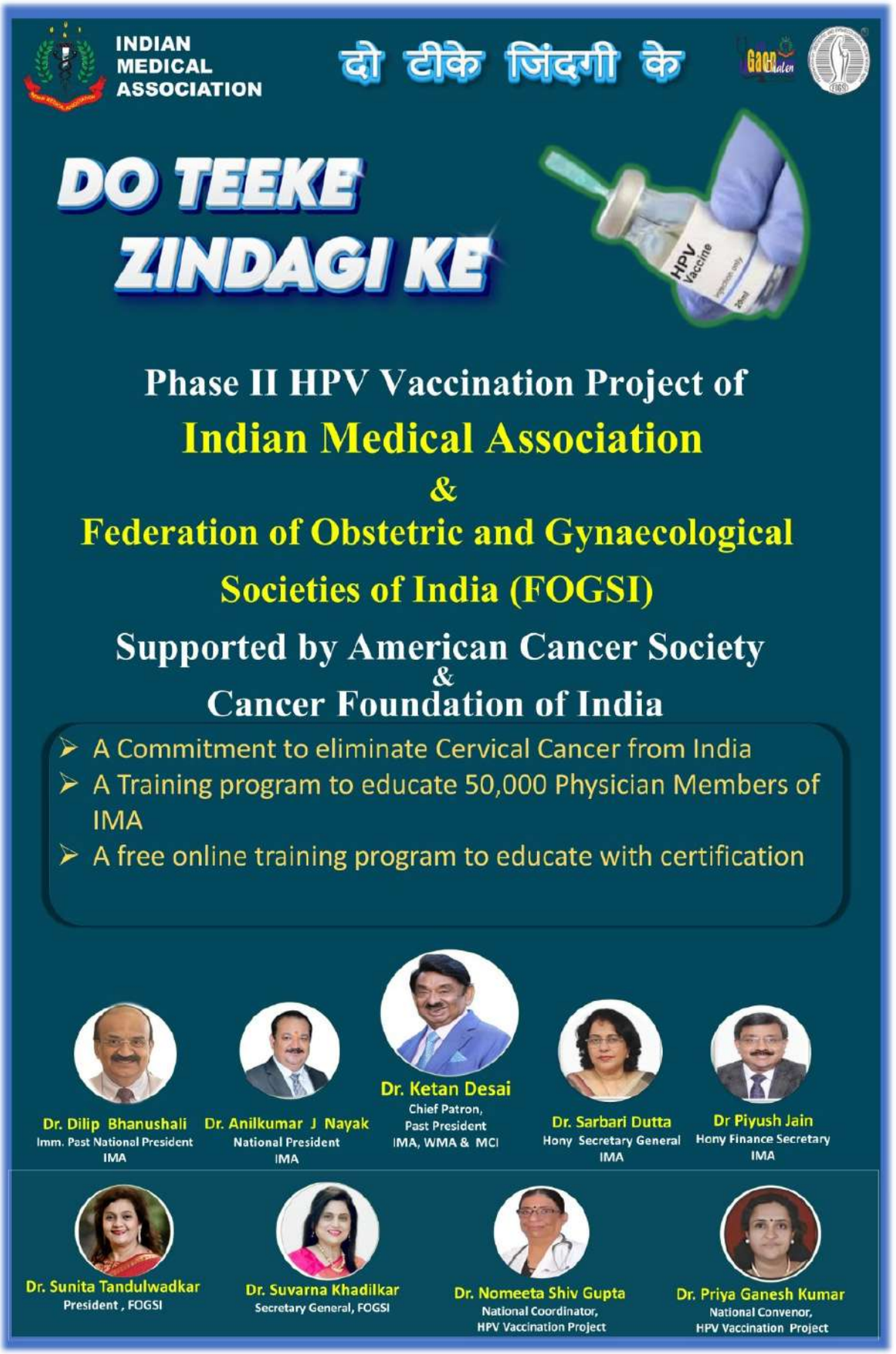
***How to cite this article :*** Imperative Mandate for Thalassemia Screening in Pregnancy. Singh S, Srivastava MK, Kunwar V. *J Indian Med Assoc* 2026; **124(2):** 74.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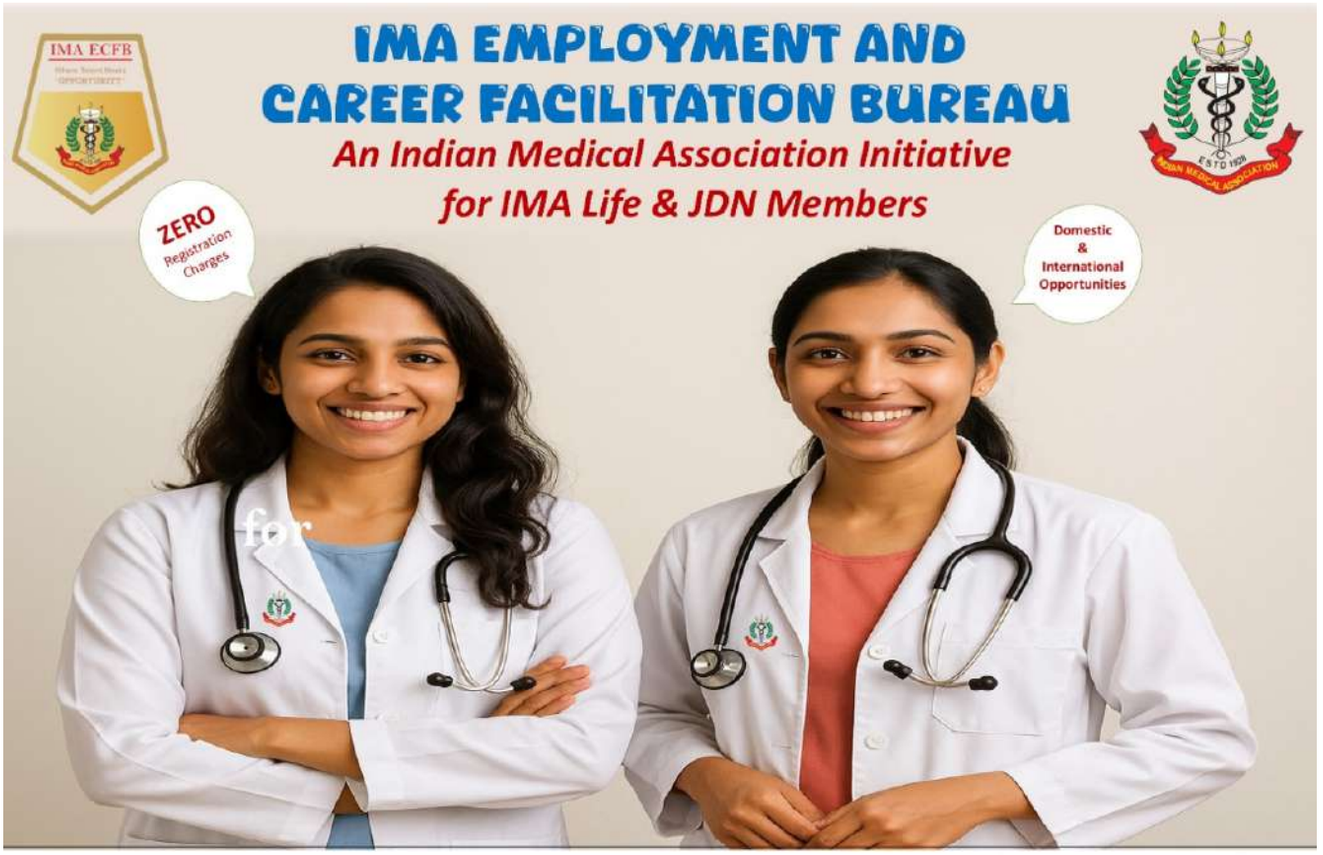


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# In Memoriam

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Indian Medical Association expresses profound grief on the sad demise of **Dr. Bharat C. Chhaparwal**, Past National Vice President and National President, IMA HQs (1994–1995).

**Dr. Bharat C. Chhaparwal** was a grassroot member of IMA Indore Branch (Madhya Pradesh). His visionary leadership, lifelong dedication to the medical profession, and selfless service to the Indian Medical Association have left an indelible mark on the fraternity.

The entire IMA family mourns this irreparable loss and extends heartfelt condolences to the bereaved family.

**May his noble soul rest in eternal peace**

**Indian Medical Association** expresses profound grief on the sad demise of Dr. S. N. Misra, Past Secretary General, IMA HQs.

Dr. Misra's visionary leadership, lifelong dedication to the medical profession, and selfless service to the Indian Medical Association have left an indelible mark on the fraternity.

The entire IMA family mourns this irreparable loss and extends heartfelt condolences to the bereaved family.

**May his noble soul rest in eternal peace**

**DR. KETAN DESAI**
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**RNI Regd. No. 2557**
**Vol. 70, No. 2, February 2026, Kolkata**

**Date of Publication : 20th February, 2026**

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Printed and Published by **Dr Prasanta Kumar Bhattacharyya** on behalf of Indian Medical Association and printed at Prabaha, 45, Raja Rammohan Sarani, Kolkata - 700009 and Published from Sir Nilratan Sircar IMA House, 53, Sir Nilratan Sarkar Sarani (Creek Row), Kolkata - 700014, Editor : **Dr Kakali Sen**