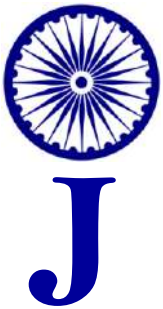




National Board of Examinations – Journal of Medical Sciences (NBEJMS)

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As per the directions of MoHFW & support, NBEMS has successfully implemented the Aadhaar Authentication in all NBEMS's examinations conducted since Dec 2025.



LIVE CCTV feed from all test centres shall be relayed to NEBMS Command Centre



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Volume 4 • Issue 7 • July 2026

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**EDITORIAL**

**NBEMS & NEET-PG: Successfully Meeting Operational Responsibilities, Conducting Examinations, and Augmenting Efficiency**

Minu Bajpai<sup>1,\*</sup> and Abhijat C. Sheth<sup>2</sup>

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**NBEMS has been conducting NEET-PG, reflecting the strengths of computer-based examination architecture and centralised digital security systems.** This distinction is often cited as a best-practice model for high-stakes medical examinations.

The National Board of Examinations in Medical Sciences (NBEMS) has been entrusted with the conduct of the National Eligibility-cum-Entrance Test for Postgraduate Medical Courses (NEET-PG) ever since the introduction of the examination as a single national entrance test for postgraduate medical admissions. Over the past decade, NBEMS has successfully conducted

NEET-PG annually across the country, facilitating merit-based admissions to MD, MS, PG Diploma, FNB, DNB, DrNB and other postgraduate medical training programmes.

NEET-PG has evolved into one of the largest computer-based medical entrance examinations globally, with participation by more than two lakh medical graduates annually. The examination is conducted through a secure digital platform across multiple cities and examination centres, ensuring uniform standards, transparency, and nationwide comparability of candidate performance (Figure 1).

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Figure 1. As per the directions of MoHFW & support, NBEMS has successfully implemented the Aadhaar Authentication in all NBEMS's examinations conducted since Dec 2025.

Since its inception, NBEMS has demonstrated substantial operational capability in managing large-scale, high-stakes examinations through:

- Computer-based testing with encrypted question delivery systems.
- Standardised examination processes across centres nationwide.
- Extensive use of biometric verification and digital candidate authentication.
- Multi-layer security protocols for question paper generation, storage and transmission.
- Centralised monitoring and audit mechanisms.
- Robust psychometric analysis and normalisation methodologies where required.
- Transparent publication of examination schedules, information bulletins and results.
- Structured grievance redressal mechanisms.

Importantly, unlike conventional paper-based examinations, NEET-PG has been conducted in a computer-based environment that substantially reduces the risks associated with the physical transportation, storage, and handling of question papers.

### Measures Undertaken concerning Examination Security in National Examinations

NBEMS has been proactively strengthening its examination governance

framework to further reinforce public confidence and examination integrity (Figure 2).



Figure 2. Banner on Website is displayed on NBEMS website regarding prevention of use of Unfair Means Practice. Dedicated email id: [reportumc@natboard.edu.in](mailto:reportumc@natboard.edu.in) is created to report UMC/Touts etc. to NBEMS. Advisory for Cheating/Impersonation to be sent to candidates by email and should be on NBEMS website

Key measures undertaken include:

### **Enhanced Cybersecurity Architecture**

- Strengthening of encrypted question paper delivery systems.
- End-to-end digital security protocols.
- Multi-factor authentication mechanisms.
- Continuous vulnerability assessment and penetration testing of examination infrastructure.
- Real-time cybersecurity monitoring during examination conduct.

### **Strengthened Candidate Verification**

- Enhanced biometric authentication.
- Multi-stage identity verification.
- Improved candidate photograph validation and matching systems.
- Prevention of impersonation through advanced verification technologies.

### **Improved Examination Centre Governance**

- More stringent empanelment criteria for examination centres.
- Enhanced audit and compliance requirements.

- Mandatory security certification and infrastructure verification.
- Increased deployment of surveillance systems and monitoring protocols.

### **Real-Time Monitoring and Incident Response**

- Centralized command-and-control monitoring systems.
- Rapid-response mechanisms for any reported irregularity.
- Escalation protocols involving examination administrators, technology partners and law-enforcement agencies when required.
- Detailed post-examination audit processes.

### **Governance and Accountability Measures**

- Periodic review of standard operating procedures.
- Enhanced documentation and audit trails.
- Strengthening of vendor management and contractual accountability.
- Greater coordination with the Ministry of Health and Family Welfare, law-enforcement agencies and cybersecurity experts (Figures 3 and 4).



Figure 3. LIVE CCTV feed from all test centres shall be relayed to NEBMS Command Centre. More than 300 dedicated officials will observe the conduct of examination from Central Command Centre



Figure 4. Regional Command Centers

Over more than a decade of conduct, NBEMS has successfully established NEET-PG as a credible, transparent and technologically robust national entrance examination. The Board's experience in conducting large-scale computer-based assessments, combined with constantly strengthened security and

governance measures, has further enhanced the resilience, integrity and reliability of the NEET-PG examination system. Continued investment in technology, cybersecurity, institutional accountability and independent oversight remain critical to maintaining public trust and safeguarding merit-based admissions in India.



REVIEW ARTICLE

**Global Regional Disparities, Journal Distribution, and Temporal Trends in Orthopaedics and Sports Medicine Research (1996–2025): A SCImago-Based Bibliometric Analysis**

Raju Vaishya,<sup>1,\*</sup> Sudhir Shekhawat,<sup>2</sup> Abhishek Vaish,<sup>3</sup> Karthik Vishwanathan<sup>4</sup> and Murali Poduval<sup>5</sup>

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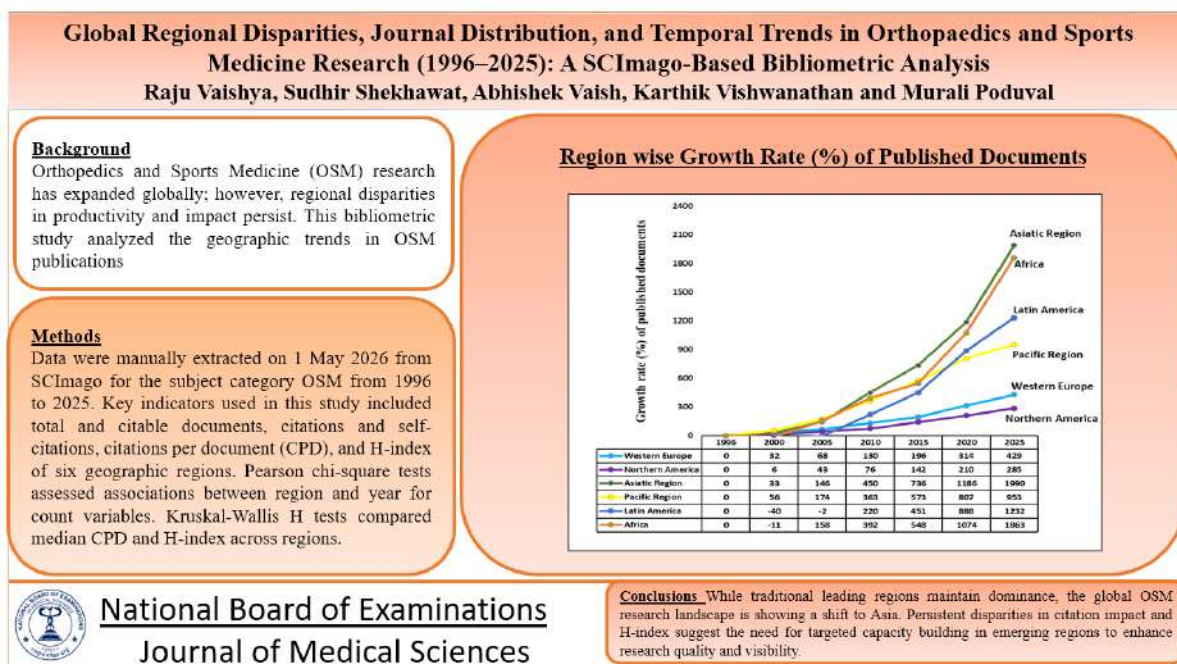
**Abstract**

**Background:** Orthopedics and Sports Medicine (OSM) research has expanded globally; however, regional disparities in productivity and impact persist. This bibliometric study analyzed the geographic trends in OSM publications. **Methods:** Data were manually extracted on 1 May 2026 from SCImago for the subject category OSM from 1996 to 2025. Key indicators used in this study included total and citable documents, citations and self-citations, citations per document (CPD), and H-index of six geographic regions. Pearson chi-square tests assessed associations between region and year for count variables. Kruskal-Wallis H tests compared median CPD and H-index across regions. **Results:** Total publications differed significantly across regions ( $\chi^2(30)=6388.49$ ,  $p<0.001$ ), over time. Western Europe and Northern America consistently led in research output and citations. Asiatic Region showed the most rapid growth, particularly after 2010. Significant regional differences were observed in median CPD ( $H=12.90$ ,  $p=0.024$ ) and H-index ( $H=23.74$ ,  $p<0.001$ ), with North America maintaining the highest cumulative influence. Analysis of journal distribution in 2025 demonstrated marked regional disparities in journal representation and their quartile rankings ( $\chi^2(15)=42.07$ ,  $p<0.001$ ). Western Europe and Northern America contributed the majority of Q1 journals. Pacific, Latin American, and African regions showed steady but comparatively smaller growth. **Conclusions:** While traditional leading regions maintain dominance, the global OSM research landscape is showing a shift to Asia. Persistent disparities in citation impact and H-index suggest the need for targeted capacity building in emerging regions to enhance research quality and visibility.

**Keywords:** Bibliometric analysis, Orthopedics and Sports Medicine, SCImago, Regional disparities, Global research trends

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## Graphical Abstract



**National Board of Examinations**  
**Journal of Medical Sciences**

## Key Highlights

- Western Europe and Northern America are the leaders in OSM research output and impact from 1996 to 2025, while the Asiatic Region exhibits the most substantial growth trajectory.
- Significant regional differences exist in citation impact and H-index, with North America's consistent superior cumulative influence.
- Emerging regions (Asia, Latin America, Africa) are narrowing quantitative gaps.

## Introduction

Orthopedics and Sports Medicine (OSM) is a medical speciality focussing on musculoskeletal (MSK) disorders, trauma, and athletic injuries. With aging populations, increased sports participation, and rising trauma incidence, research output in this field has grown substantially. Bibliometric analyses are useful for quantifying scientific productivity,

mapping research trends, and assessing impact [1].

Research productivity in medicine shows notable global disparities, with high-income regions leading while emerging economies show rapid growth. Prior studies have documented the overall expansion of OSM publications, with marked increases, especially from Asia [2]. The region-specific investigations have highlighted the rise of Asian research [3], European contributions [4], Italian productivity [5], and output from Africa/Nigeria [6]. Additional analyses have examined journal rankings, top-cited articles, and authorship patterns such as gender diversity. However, comprehensive long-term evaluations comparing major geographic regions (Western Europe, Northern America, Asiatic Region, Pacific, Latin America, and Africa) remain limited, particularly those extending into 2025. Most published research has targeted individual countries, shorter timeframes, or narrow topics. A wider regional investigation is required to understand evolving patterns in

productivity, citation impact, and self-citation behaviors amid globalization and differing research capacities.

This bibliometric study fills these gaps by utilizing manually extracted SCImago Journal Rank data (as of 1 May 2026) for the OSM category across 1996–2025. It systematically investigates temporal and regional variations in total documents, citable documents, citations, self-citations, citations per document (CPD), and H-index. Statistical methods include Pearson chi-square tests for count variables and Kruskal-Wallis H tests for continuous indicators. The findings are intended to help researchers, institutions, and policymakers understand the global evolution of OSM research, recognize the contributions of emerging regions, and support targeted efforts to address knowledge and infrastructure disparities [7].

The aim of this study was to evaluate global regional disparities, journal distribution, and temporal trends in orthopaedics and sports medicine research from 1996 to 2025 using SCImago-based bibliometric indicators, with particular emphasis on publication output, citation impact, self-citation patterns, and journal quartile representation across six major geographic regions.

## Methods

### *Study design and data source*

This bibliometric study utilized data manually extracted on 1 May 2026 from the SCImago Journal Rank database for the subject category “Orthopedics and Sports Medicine.” Two parallel search pathways were used: (1) country rankings by region and year, and (2) journal rankings by region for the year 2025. The six geographic regions analysed were Africa, Asiatic

Region, Latin America, Northern America, Pacific Region, and Western Europe. To allow standardized longitudinal comparisons and improve interpretability of temporal trends, data were collected at 5-year intervals: 1996, 2000, 2005, 2010, 2015, 2020, and 2025. This bibliometric study utilized data manually extracted on 1 May 2026 from the SCImago Journal Rank database (<https://www.scimagojr.com/>), as per the following search strategy:

#### *A) For Country Rankings:*

SCImago website>>Country Ranking>>All subject areas>>Orthopedics and Sports medicine>>Region (Africa; Asiatic region; Latin America; Northern America; Pacific region; Western Europe)>>Year (2025)>>Download (Excel file)>>Data analysis.

#### *B) For Journal Rankings:*

SCImago website>>Journal Ranking>>All subject areas>>Orthopedics and Sports medicine>>Region (Africa; Asiatic region; Latin America; Northern America; Pacific region; Western Europe)>>Year (2025)>>Download (Excel file)>>Data analysis.

### *Variables assessed*

The extracted bibliometric indicators included total documents, citable documents, total citations, total self-citations, citations per document (CPD), and H-index. These variables were organized by geographic region and year to evaluate temporal trends in research productivity and scientific influence. In addition, the geographical distribution of OSM journals and their quartile

classifications (Q1–Q4) for 2025 were recorded to assess regional representation within indexed journals and journal quality strata. Post-hoc pairwise comparisons were not performed because the primary objective was to examine overall global regional disparities rather than individual inter-regional differences.

### Statistical analysis

Categorical count variables, including total documents, total citations, and total self-citations, were analysed using the Pearson chi-square test of independence to examine the association between geographic region and publication year. Continuous bibliometric indicators that were non-normally distributed, including median CPD and median H-index, were compared across regions using the Kruskal–Wallis H test. All statistical tests were two-tailed, and a p-value of less than 0.05 was considered statistically

significant. Statistical analyses were performed using IBM SPSS Statistics version 29.0 (IBM Corp., Armonk, NY, USA).

### Results

#### *Published Documents*

The distribution of total published documents differed significantly across geographical regions over the study period, from 1996 to 2025. There was a strong association between region and publication year ( $\chi^2(30) = 6388.49$ ,  $p < 0.001$ ). Western Europe and Northern America contributed the largest share of publications throughout all years, whereas the Asiatic region showed the most pronounced growth trajectory, particularly after 2010. Pacific, Latin American, and African regions contributed comparatively smaller but progressively increasing publication outputs (Table-1; Supplementary Figure-1).

Table 1. Region wise and Year wise total published documents

Region	1996	2000	2005	2010	2015	2020	2025
Western Europe	3730	4909	6261	8575	11037	15438	19723
Northern America	4357	4613	6225	7674	10547	13509	16778
Asiatic Region	744	988	1830	4093	6222	9570	15551
Pacific Region	249	389	683	1153	1677	2259	2622
Latin America	225	136	221	721	1239	2224	2998
Africa	62	55	160	305	402	728	1217
Chi-square test, p-value	$\chi^2(30) = 6388.49$ , $p < 0.001$						

Figure 1 depicts substantial regional variation in the growth of published documents between 1996 and 2025. The Asiatic Region exhibited the most pronounced increase, rising from baseline levels in 1996 to an exceptional 1990% growth by 2025. The African Region also showed remarkable expansion, despite an initial decline in 2000 (-11%). Growth accelerated sharply after 2005, reaching 1863% by 2025. The Pacific Region demonstrated sustained and consistent growth throughout the study period,

achieving 953% growth by 2025. Latin America displayed early negative growth (-40% in 2000 and -2% in 2005), followed by a marked recovery after 2010. The region experienced rapid expansion thereafter, reaching 1232% growth by 2025. In contrast, traditionally dominant regions showed comparatively moderate increases. Western Europe recorded gradual yet stable growth, reaching 429% by 2025, while Northern America demonstrated the slowest relative increase (285%).

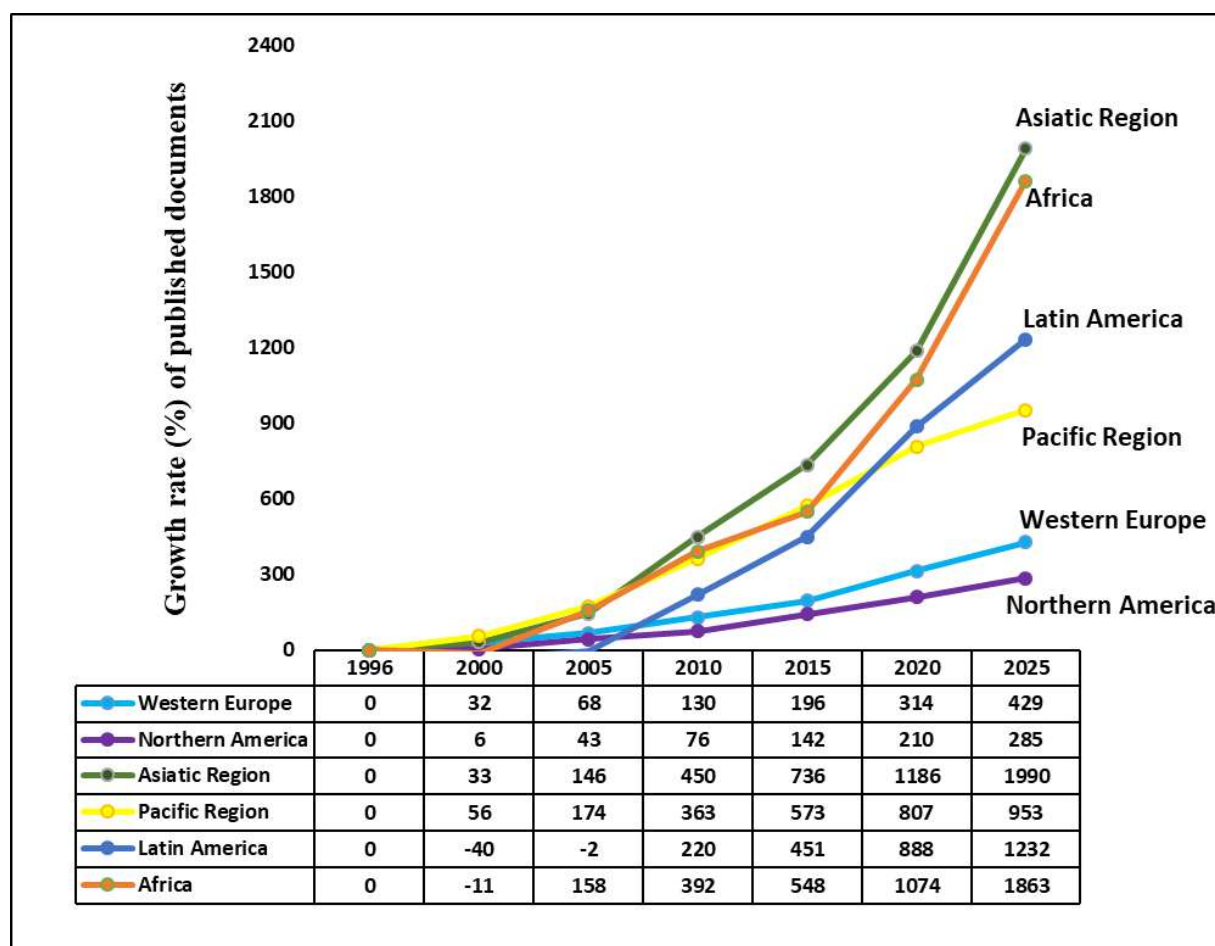


Figure 1. Region wise Growth Rate (%) of Published Documents (Baseline: 1996)

Growth rate (%) was calculated using 1996 as the baseline reference year. The value for 1996 is therefore presented as 0% for all regions because it represents the starting point of comparison. Subsequent percentages indicate the relative change in the number of published documents compared with the 1996 publication output, calculated as:

$$\text{Growth Rate (\%)} = (\text{Publications in Year X} - \text{Publications in 1996}) * 100 / \text{Publications in 1996}$$

There was a significant association between geographical region and publication year for total citable documents ( $\chi^2(30) = 6035.72$ ,  $p < 0.001$ ). Western Europe and Northern America dominate overall citation output throughout the study period, while the Asiatic region exhibited

the most rapid expansion in scientific productivity, particularly after 2010. Pacific, Latin American, and African regions showed steady but comparatively smaller increases (Table 2 and Supplementary Figure 2).

Table 2. Region wise and year wise total citable documents

Region	1996	2000	2005	2010	2015	2020	2025
Western Europe	3683	4626	5879	8154	10313	14314	18340
Northern America	4300	4371	5785	7180	9662	12473	15762
Asiatic Region	742	973	1793	3990	6001	9111	14716
Pacific Region	245	370	639	1099	1579	2113	2458
Latin America	224	136	212	699	1182	2119	2877
Africa	62	52	153	296	384	688	1171
Chi-square test, p-value	$\chi^2(30)=6035.72$ , $p < 0.001$						

### **Citations**

A significant association was found between geographical region and year for total citations ( $\chi^2(30) = 1.21 \times 10^7$ ,  $p < 0.001$ ). Western Europe and Northern America consistently accounted for the highest citation volumes throughout the study period, whereas the Asiatic Region showed a marked increase after 2005.

Pacific, Latin American, and African regions demonstrated progressive but comparatively lower citation accumulation. The decline in citation totals observed in 2025 most likely reflects incomplete citation accrual for recently indexed publications rather than a true reduction in scientific influence (Table 3 and Supplementary Figure 3).

Table 3. Region wise and year wise total citations

Region	1996	2000	2005	2010	2015	2020	2025
Western Europe	142387	230691	308529	385834	373514	377049	18768
Northern America	228354	316221	368504	370944	347744	244217	12009
Asiatic Region	29785	43003	71893	91403	112200	124580	9567
Pacific Region	17692	34891	48050	75284	75043	71457	2718
Latin America	1393	13239	8348	21191	27466	32548	2042
Africa	2234	3362	7173	9809	10496	27267	1088
Chi-square test, p-value	$\chi^2(30) = 1.21 \times 10^7, p < 0.001$						

A highly significant association was found between geographical region and year for total self-citations ( $\chi^2(30) = 2.84 \times 10^6, p < 0.001$ ). Northern America contributed the largest proportion of self-citations throughout the study period, followed by Western Europe, while the

Asiatic Region exhibited a marked increase after 2005. The reduction observed in 2025 likely reflects incomplete citation accumulation for recently indexed publications rather than a true decline in self-citation activity (Table-4; Supplementary Figure-4).

Table 4. Region wise and Year wise total self-citations

Region	1996	2000	2005	2010	2015	2020	2025
Western Europe	22572	33640	45081	63807	64705	61335	4802
Northern America	95237	120837	145745	145152	142668	92122	4800
Asiatic Region	5326	6872	11429	19406	26518	36539	3685
Pacific Region	2476	4393	6954	13488	13995	11568	707
Latin America	255	1606	2036	5686	6257	6351	365
Africa	144	284	632	774	916	1810	166
Chi-square test, p-value	$\chi^2(30) = 2.84 \times 10^6, p < 0.001$						

A statistically significant difference was found in median CPD among geographical regions ( $H = 12.90$ ,  $df = 5$ ,  $p = 0.024$ ). Regions such as Northern America, Western Europe, and the Pacific

exhibited higher citation impact during earlier years, whereas Asiatic, Latin American, and African regions showed comparatively lower citation density (Figure 2 and Supplementary Table 1).

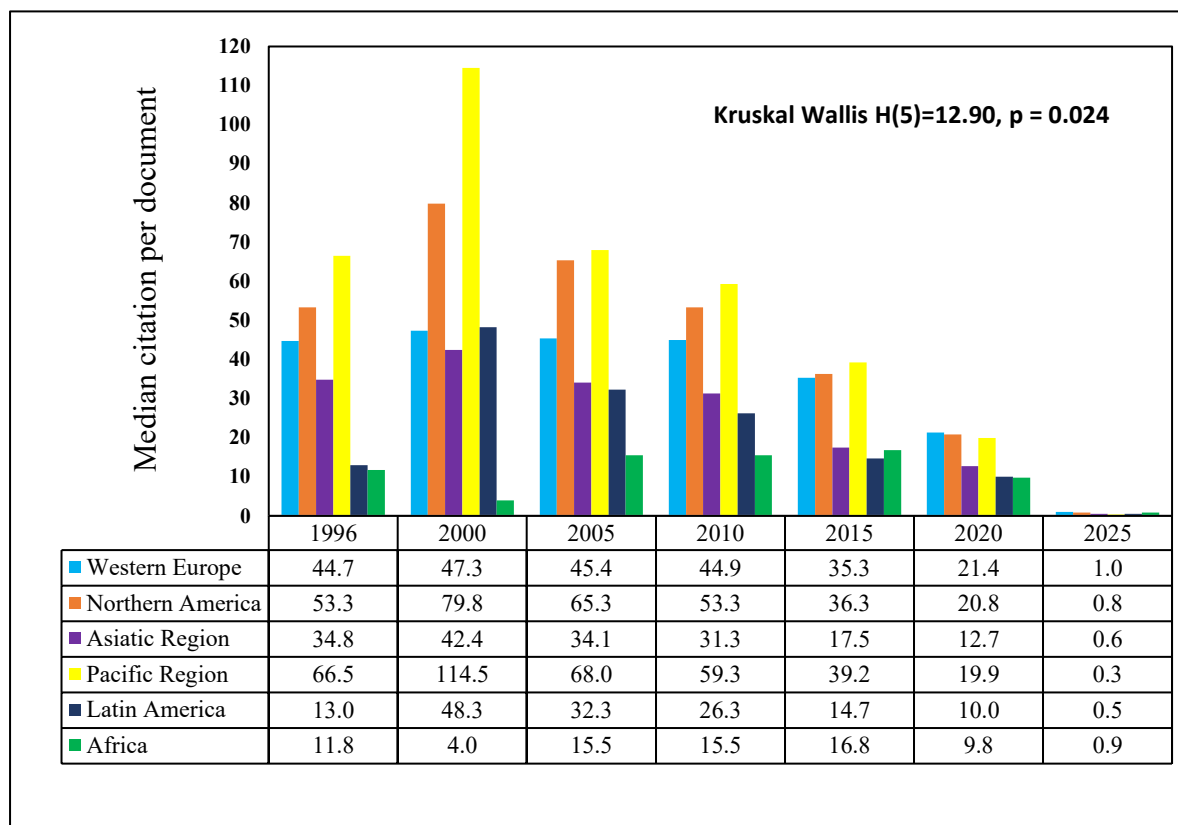


Figure 2. Region wise and Year wise Median Citations Per Document

**H-index**

The distribution of median H-index values differed significantly across regions (Kruskal–Wallis  $H = 23.74$ ,  $df = 5$ ,  $p < 0.001$ ). Northern America demonstrated the highest H-index throughout the study period. Western Europe and the Pacific

region showed intermediate performance, whereas the Asiatic region exhibited a progressive decline over time. Latin America and Africa maintained comparatively lower H-index values across all years (Figure 3 and Supplementary Table 2).

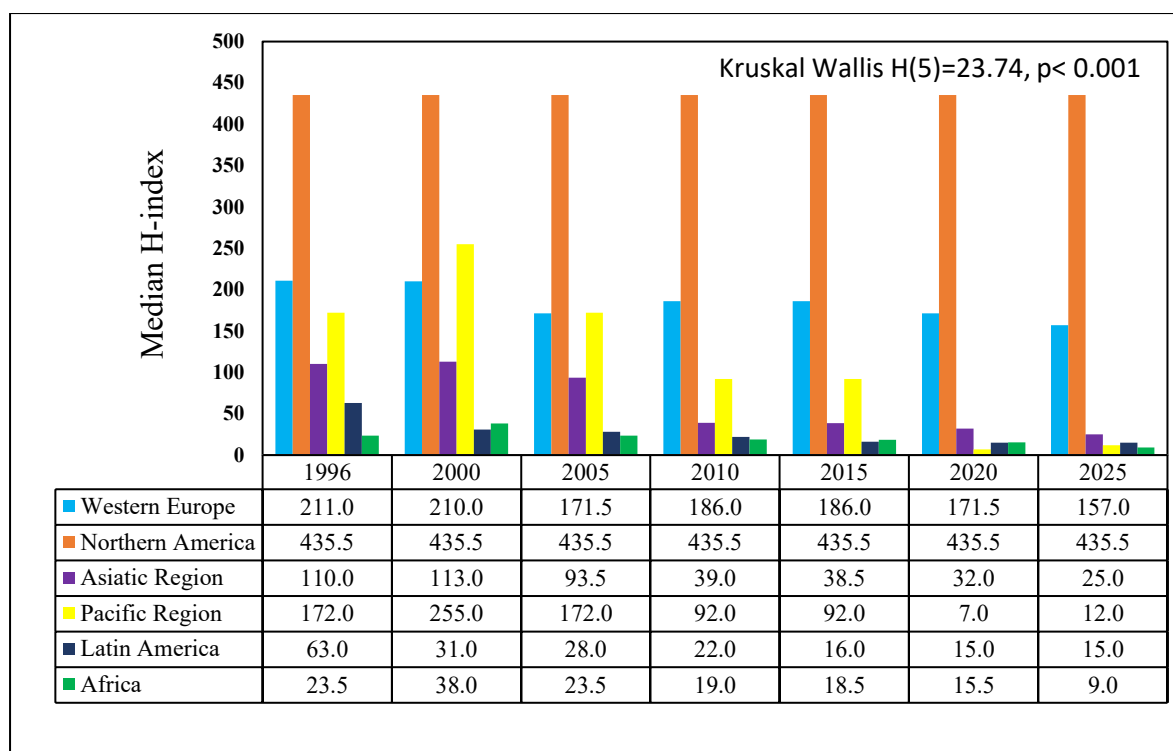


Figure 3. Region wise and Year wise Median H-index

Table 5. Region wise Distribution of in Orthopedics and Sports Medicine Journals in 2025 (N = 341)

Global Region	No. of Journals	Global Contribution (%)	Journals' Quartile Distribution			
			Q1	Q2	Q3	Q4
Western Europe	146	42.8%	43	42	37	24
Northern America	96	28.2%	34	28	23	11
Asiatic Region	39	11.4%	5	9	5	20
Latin America	9	2.6%	1	1	2	5
Pacific Region	2	0.6%	0	1	1	0
Africa	2	0.6%	0	0	1	1
Chi-square test, p-value			$\chi^2(15) = 42.07, p < 0.001$			

**Regional Distribution and Quartile Analysis of Journals**

Significant regional differences were observed in the distribution and quartile ranking of journals in 2025 ( $\chi^2(15)=42.07, p<0.001$ ) (Table 5). Western Europe contributed the highest number of journals, followed by Northern America,

and these two regions accounted for most Q1 journals. In contrast, the Asiatic Region contributed a greater proportion of Q3 and Q4 journals, whereas Latin America and Africa showed limited representation in indexed journals overall. These findings highlight persistent structural inequalities in journal visibility and high-impact

publication opportunities across global regions.

The journal distribution analysis highlighted structural inequalities in scientific publishing. Western Europe and Northern America accounted for the majority of indexed journals and Q1 journals in OSM. In contrast, the Asiatic Region, despite substantial publication growth, remained low in higher-quartile journals. Similar limitations were observed in Latin America and Africa, where relatively few journals were represented in SCImago rankings.

## Discussion

This bibliometric analysis of orthopaedics and sports medicine (OSM) research from 1996 to 2025 demonstrates persistent yet evolving regional disparities in scientific productivity and impact. Western Europe and Northern America maintained dominance across most bibliometric indicators throughout the study period, whereas the Asiatic Region exhibited the most rapid growth in publication output, particularly after 2010. Although emerging regions are narrowing the quantitative gap, citation impact, H-index, and high-quartile journal representation remain concentrated in historically dominant scientific regions.

Western Europe and Northern America maintained dominance throughout the study period, but the Asiatic Region demonstrated the most dynamic expansion, particularly after 2010, consistent with earlier observations of rising Asian contributions [2,3]. By 2025, the Asiatic Region had substantially narrowed the gap with traditional leaders, with total documents reaching 15,551 compared to 19,723 in Western Europe and 16,778 in Northern America. This trajectory aligns

with broader economic and research infrastructure development in Asia, including increased funding, international collaborations, and a growing number of researchers [2,4]. Pacific, Latin American, and African regions showed steady but more modest increases, highlighting ongoing challenges related to resources, training, and publication opportunities in lower-resource settings [6,8].

Citation patterns broadly paralleled publication output, but notable differences in impact persisted across regions. Northern America, Western Europe, and the Pacific Region showed stronger citation density in earlier years, whereas the Asiatic, Latin American, and African regions generally had lower CPD values. The lower citation values recorded in 2025 are most plausibly explained by inadequate citation accrual time for recently indexed documents. Self-citation should also be interpreted cautiously: although elevated self-citation may inflate bibliometric indicators, it may also reflect continuity of scholarly work, expanding intra-regional collaboration, and the maturation of emerging research ecosystems. Accordingly, self-citation patterns are best interpreted alongside overall citation volume and other indicators of external scientific influence.

Self-citation analysis demonstrated significant regional variation ( $\chi^2(30) = 2.84 \times 10^6$ ,  $p < 0.001$ ), with Northern America recording the highest self-citation counts, followed by Western Europe, largely reflecting their greater publication output and mature research ecosystems. The Asiatic Region showed the most pronounced increase in self-citations after 2005, paralleling its rapid growth in research productivity and expanding intra-regional collaboration networks. Although elevated self-citation rates may inflate

bibliometric indicators and perceived scientific influence, they can also represent legitimate continuity of scientific inquiry and the maturation of emerging scholarly communities [1]. Importantly, self-citation patterns should be interpreted alongside overall citation volume, as established regions continued to demonstrate stronger externally validated citation impact despite high self-citation totals. These findings suggest that rising self-citation in emerging regions may reflect evolving research ecosystems rather than solely strategic citation practices, emphasizing the need for normalized self-citation and collaboration-adjusted metrics in future bibliometric analyses.

H-index findings also demonstrate global disparities (Kruskal-Wallis  $H = 23.74$ ,  $p < 0.001$ ). Northern America consistently achieved the highest median H-index (435.5 across years), followed by Western Europe and the Pacific which showed intermediate performance, whereas the Asiatic Region experienced a progressive decline in median H-index despite volume growth. This pattern suggests that while quantity has increased rapidly in Asia, building highly influential bodies of work comparable to North American standards would require time, international visibility, and high-impact dissemination [5]. Latin American [9] and African [6] regions maintained lower H-index values, consistent with smaller overall output and resource constraints.

These results extend previous bibliometric work in OSM. Vaishya and Vaish (2024) previously reported global growth up to 2021 [2]; the current study confirms continuation of these trends through 2025 and provides detailed regional comparisons. Country-level studies on Europe, Italy, and Asia similarly

document rising productivity but varying impact [3,4,5,6]. The findings also align with earlier studies indicating the shift toward multipolar scientific production while highlighting persistent quality and visibility gaps [7].

Our findings align with and extend several recent bibliometric investigations in the field. For instance, the sustained leadership of Northern America and Western Europe in citation impact and H-index echoes patterns observed in journal-specific analyses, such as the 15-year review of sports medicine studies in *The Journal of Bone and Joint Surgery* [10] and earlier broad assessments of the orthopedic literature [11]. The rapid quantitative growth from the Asiatic Region complements studies documenting evolving journal rankings and rising Asian contributions [12]. At the same time, persistent disparities in citation density and cumulative influence are consistent with analyses of top-cited articles [13], subspecialty variation in citations [14], and factors driving high citability in Orthopedic papers [15]. Additionally, while our regional focus highlights macro-level productivity shifts, complementary work underscores important equity dimensions within the OSM literature. Gender disparities in authorship remain evident despite increasing numbers of women surgeons [16], with systematic reviews confirming ongoing challenges to gender diversity and equality in Orthopedic surgery authorship and leadership [17,18]. These patterns are particularly relevant in sports medicine, where diversity trends continue to evolve [19]. Integrating such insights signifies the need for multifaceted strategies that address not only geographic but also demographic equity to fully realize the global potential of OSM research.

The substantial percentage growth observed in the Asiatic Region should be interpreted in the context of the denominator effect, whereby percentage increases appear disproportionately large when baseline values are low [20-26]. Thus, the very high relative growth in publication output from Asia reflects both genuine expansion in academic productivity and the mathematical effect of lower starting values in 1996. This distinction is important to avoid overinterpretation of relative growth without parallel consideration of absolute output and citation influence.

The journal distribution analysis further supports the existence of structural inequalities in scientific publishing. Western Europe and Northern America accounted for most indexed journals and the majority of Q1 journals, whereas the Asiatic Region, despite substantial growth in research output, remained underrepresented in higher-quartile journals. The limited representation of Latin America and Africa may reflect disparities in research infrastructure, editorial access, mentorship, indexing exposure, and publication support systems. These findings support the need for stronger international collaboration, targeted capacity building, equitable research funding, and editorial initiatives that enhance visibility for underrepresented regions.

The *implications of these findings* are multifaceted:

- For policymakers and funding bodies in emerging regions, the data support investments in research capacity building, international collaborations, and open-access publishing to enhance visibility and citation potential.

- Established regions can leverage their strengths in high-impact research while fostering equitable partnerships.
- Journal editors and societies should consider initiatives to support authors from lesser represented regions, such as mentorship programs and special issues, to promote global equity in OSM knowledge generation.

The regional trends in academic productivity observed in this study appear to parallel patterns seen in the orthopedic healthcare market and clinical utilization landscape. North America continues to dominate both scientific output and orthopedic product consumption, whereas the Asia-Pacific region represents the fastest-growing sector globally, driven by expanding healthcare infrastructure, increasing surgical volumes, aging populations, and greater access to musculoskeletal care [27]. Recent bibliometric analyses have similarly documented the rapid rise of Asian orthopaedic research output and its growing global influence [3,27]. This parallel evolution suggests that bibliometric productivity may potentially correlate with clinical productivity and market growth, reflecting not only strengthening academic ecosystems but also broader healthcare development and rising utilization of orthopedic services. Such integration of scientometric trends with healthcare-market expansion may provide a unique framework for understanding the global evolution of orthopedic practice, innovation, and research.

Future bibliometric research in OSM should incorporate country-level analyses, field-weighted citation metrics, collaboration network mapping, and qualitative assessment of thematic research

priorities. Longitudinal follow-up beyond 2025 will help determine whether rapid growth in the Asiatic Region translates into sustained gains in citation impact and journal quality representation. Integration of altmetrics and clinical translation indicators may also provide a more comprehensive understanding of research value.

Strengths of this study include the 30-year study period, the use of standardized SCImago methodology, the broad regional comparison, and the inclusion of multiple bibliometric indicators together with journal quartile analysis. However, several limitations should be acknowledged. First, reliance on the SCImago database may underrepresent certain journals, particularly those that are regional, newly indexed, or non-English. Second, the analysis was conducted at an aggregate regional level and therefore does not capture country-level variation, subspecialty-specific patterns, or collaboration networks. Third, self-citation patterns were analysed quantitatively but not normalized in relation to collaboration structure or disciplinary citation behaviour.

### **Conclusion**

The global orthopaedics and sports medicine research landscape is evolving, with rapid growth from the Asiatic Region occurring alongside the continuing dominance of Western Europe and Northern America. Despite major gains in publication volume, substantial disparities persist in citation impact, H-index, and representation in higher-quartile journals. Strengthening research infrastructure, international collaboration, editorial support, and access to high-visibility publication platforms will be essential to

reduce these disparities and promote a more equitable global research environment.

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### **Conflict of Interest**

The authors declare that they do not have conflict of interest.

### **Ethical Approval**

No ethical approval was needed for this bibliometric review article.

### **Data availability**

The raw data is available with the corresponding author.

### **Author's Contributions**

RV, AV: Conceptualization, Methodology, Literature review, Manuscript writing, editing and final approval. SS: Methodology, Statistical analysis, Literature review, Manuscript writing, editing and final approval. RV, AV, KV, MP: Methodology, Literature review, Manuscript writing, editing and final approval.

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*Use of AI tool:* Author's declare that they have used ChatGPT 4.0 to edit the manuscript for grammar corrections and improving the readability. However, the final manuscript by the authors and take the full responsibility of its contents.

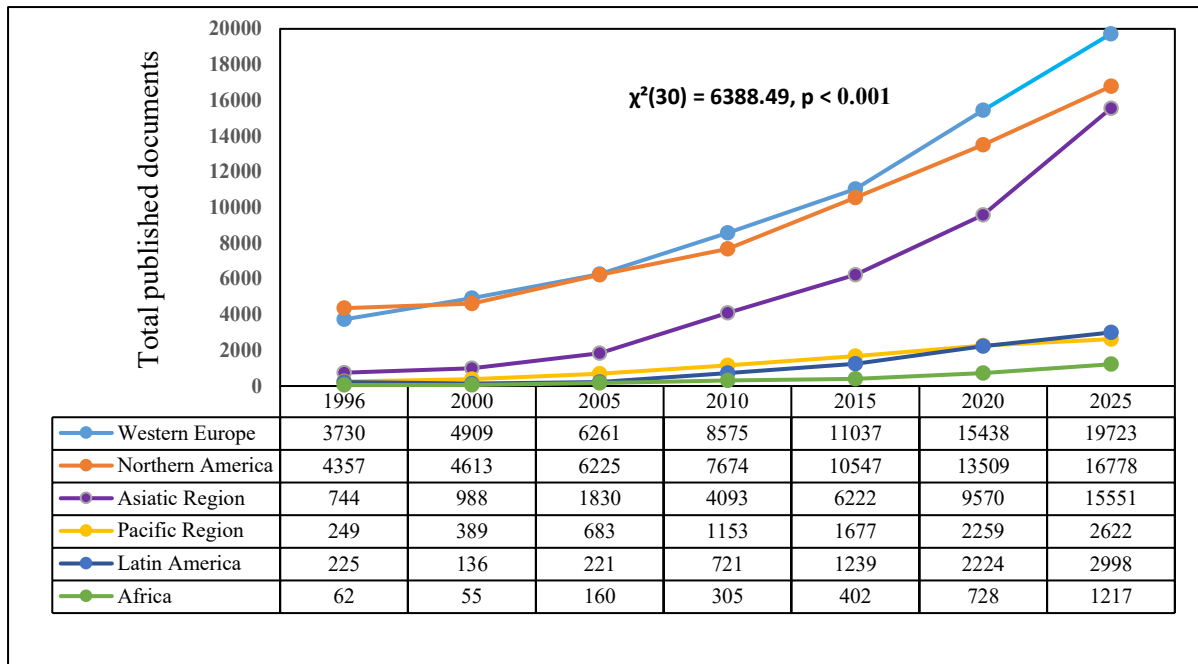
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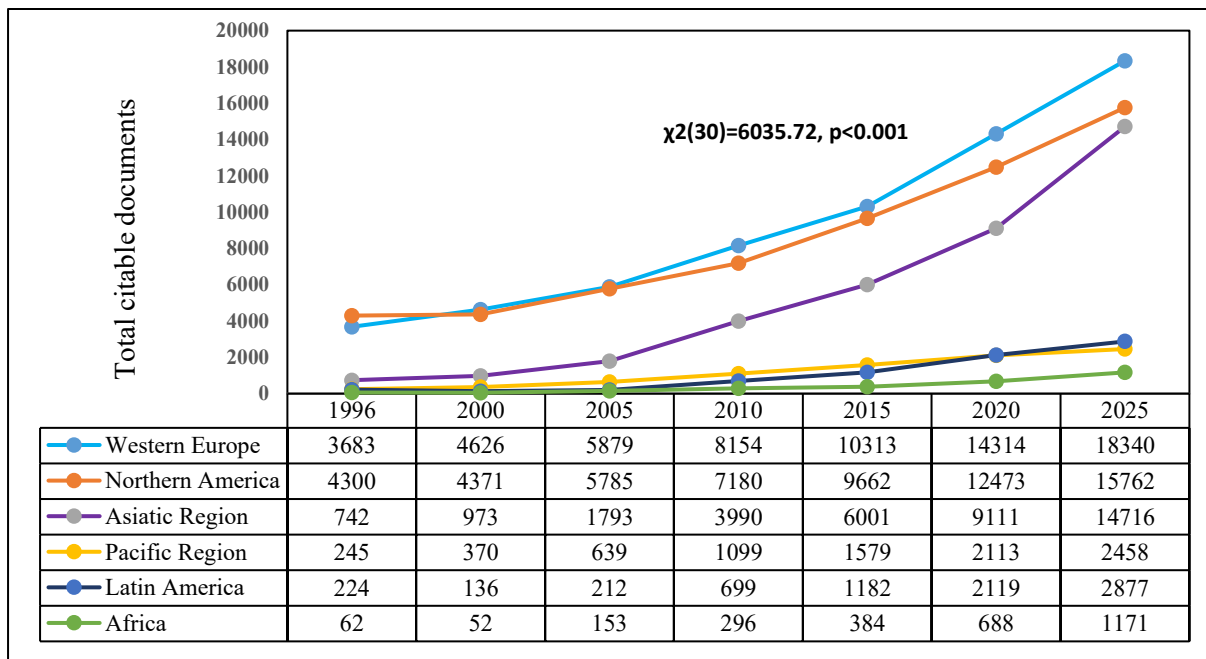
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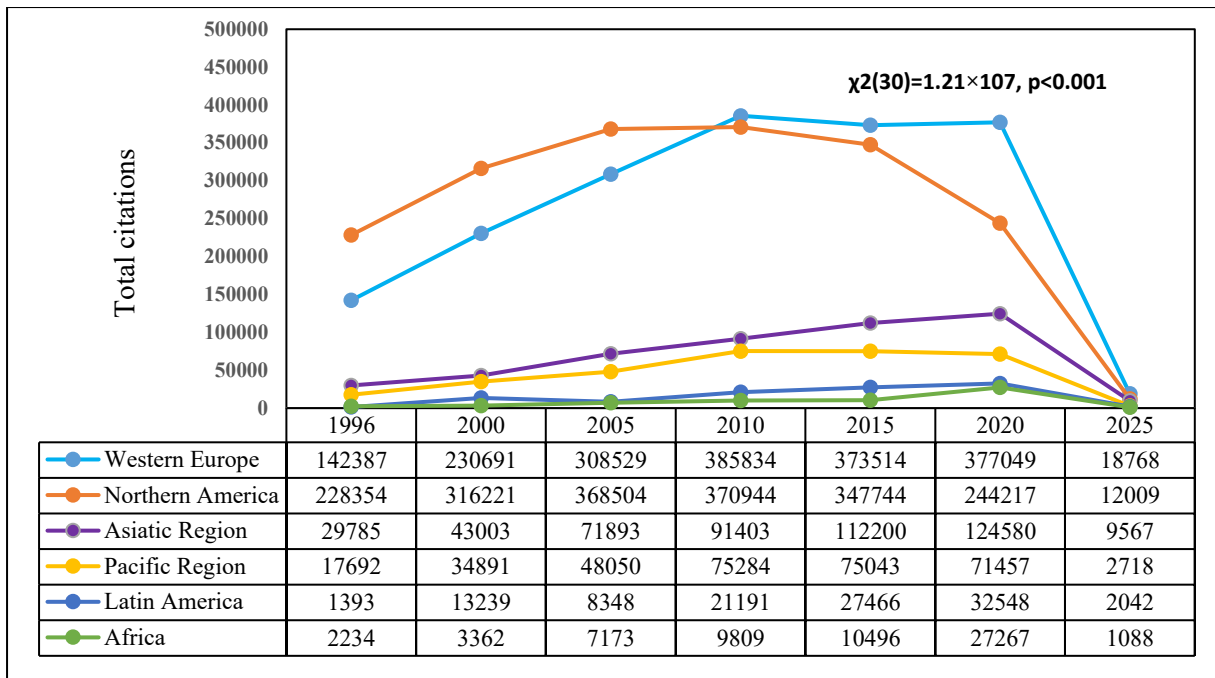
**SUPPLEMENTS**



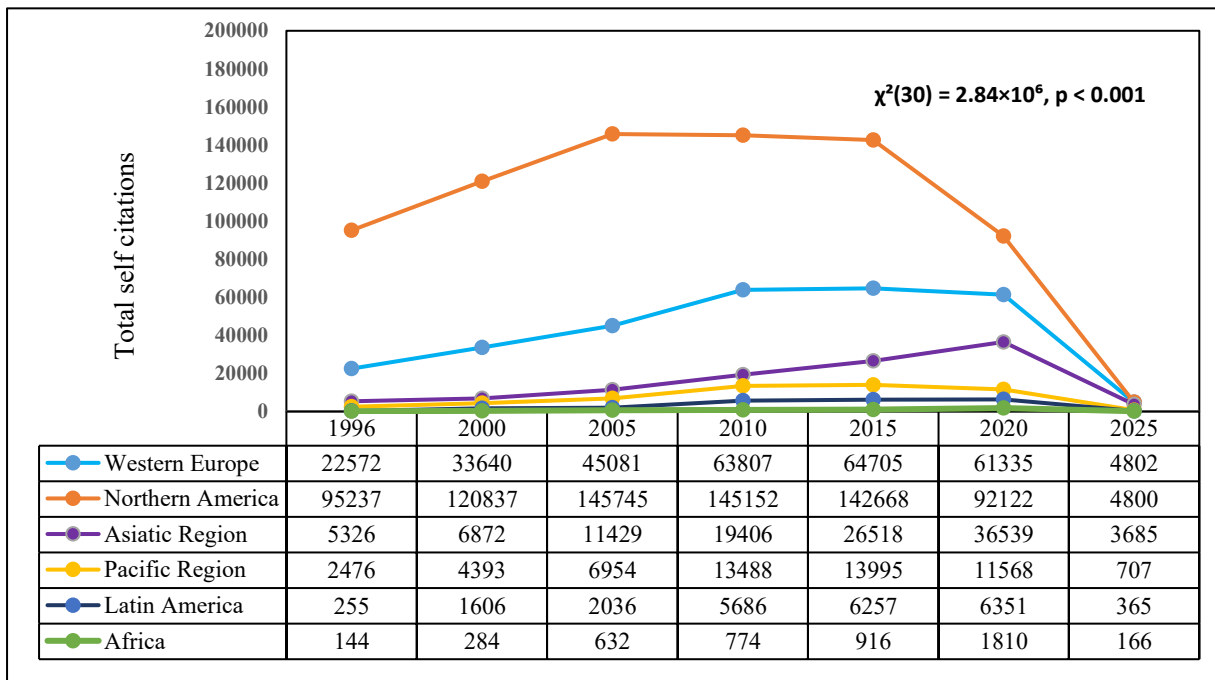
**Supplementary Figure-1: Region wise and year wise total published documents**



**Supplementary Figure-2: Region wise and year wise total citable documents**



Supplementary Figure-3: Region wise and year wise total citations



Supplementary Figure-4: Region wise and year wise total self-citations

**Supplementary Table-1: Region wise and Year wise Median Citations Per Document**

Region	1996	2000	2005	2010	2015	2020	2025
Western Europe	44.7	47.3	45.4	44.9	35.3	21.4	1.0
Northern America	53.3	79.8	65.3	53.3	36.3	20.8	0.8
Asiatic Region	34.8	42.4	34.1	31.3	17.5	12.7	0.6
Pacific Region	66.5	114.5	68.0	59.3	39.2	19.9	0.3
Latin America	13.0	48.3	32.3	26.3	14.7	10.0	0.5
Africa	11.8	4.0	15.5	15.5	16.8	9.8	0.9
Kruskal–Wallis H test, p-value	$H(5) = 12.90, p = 0.024$						

**Supplementary Table-2: Region wise and Year wise Median H-index**

Region	1996	2000	2005	2010	2015	2020	2025
Western Europe	211.0	210.0	171.5	186.0	186.0	171.5	157.0
Northern America	435.5	435.5	435.5	435.5	435.5	435.5	435.5
Asiatic Region	110.0	113.0	93.5	39.0	38.5	32.0	25.0
Pacific Region	172.0	255.0	172.0	92.0	92.0	7.0	12.0
Latin America	63.0	31.0	28.0	22.0	16.0	15.0	15.0
Africa	23.5	38.0	23.5	19.0	18.5	15.5	9.0
Kruskal–Wallis H test, p-value	$H(5) = 23.74, p < 0.001$						



ORIGINAL ARTICLE

**Correlation between NIHSS Score and Serum Ferritin levels among Acute Ischemic Stroke Patients**

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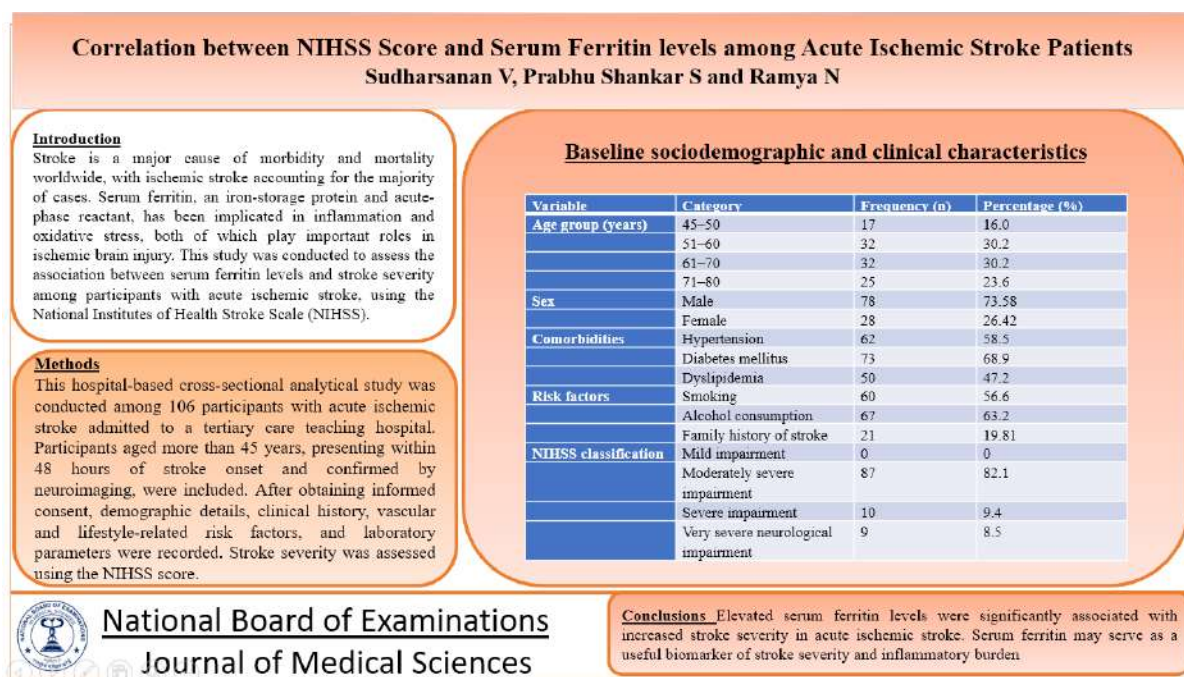
**Abstract**

**Introduction:** Stroke is a major cause of morbidity and mortality worldwide, with ischemic stroke accounting for the majority of cases. Serum ferritin, an iron-storage protein and acute-phase reactant, has been implicated in inflammation and oxidative stress, both of which play important roles in ischemic brain injury. This study was conducted to assess the association between serum ferritin levels and stroke severity among participants with acute ischemic stroke, using the National Institutes of Health Stroke Scale (NIHSS). **Materials and Methods:** This hospital-based cross-sectional analytical study was conducted among 106 participants with acute ischemic stroke admitted to a tertiary care teaching hospital. Participants aged more than 45 years, presenting within 48 hours of stroke onset and confirmed by neuroimaging, were included. After obtaining informed consent, demographic details, clinical history, vascular and lifestyle-related risk factors, and laboratory parameters were recorded. Stroke severity was assessed using the NIHSS score. Serum ferritin levels were measured and correlated with stroke severity and lipid profile parameters. Data were analysed using descriptive statistics, one-way ANOVA, independent samples t-test, and Pearson's correlation coefficient. **Results:** The majority of participants were males and belonged to the 51–70 years age group. Diabetes mellitus, hypertension, dyslipidemia, smoking, and alcohol consumption were common risk factors. Most participants had moderately severe neurological impairment based on NIHSS classification. Serum ferritin levels increased significantly with increasing stroke severity ( $p < 0.001$ ). Higher serum ferritin levels and NIHSS scores were significantly associated with smoking, alcohol consumption, hypertension, diabetes mellitus, and dyslipidemia. Serum ferritin showed positive correlations with total cholesterol, triglycerides, and LDL cholesterol, and a negative correlation with HDL cholesterol. **Conclusion:** Elevated serum ferritin levels were significantly associated with increased stroke severity in acute ischemic stroke. Serum ferritin may serve as a useful biomarker of stroke severity and inflammatory burden.

**Keywords:** Acute ischemic stroke, Serum ferritin, NIHSS score, Stroke severity, Oxidative stress

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## Graphical Abstract



## Introduction

Stroke remains one of the leading causes of morbidity and mortality worldwide, with ischemic stroke accounting for nearly 85% of all stroke cases [1]. The clinical course and outcome of ischemic stroke vary widely among participants, depending on the extent of cerebral injury, associated comorbidities, inflammatory response, and the timeliness of clinical intervention. Therefore, identifying reliable and easily measurable biomarkers that can reflect stroke severity is important for early risk stratification, prognostication, and appropriate clinical management [2].

Serum ferritin is an intracellular iron-storage protein which has gained attention as a potential biomarker in acute ischemic stroke due to its dual role as an indicator of body iron stores and also as an acute-phase reactant [3]. Elevated levels of ferritin are frequently associated with an inflammation and oxidative stress, both are

central mechanisms in the ischemic brain injury pathophysiology [4]. During an acute ischemic event, the reduced cerebral blood flow initiates a cascade of events - cellular injury, blood-brain barrier dysfunction, inflammatory activation, and oxidative damage [5]. The ferritin levels may increase in such a situation as part of the systemic inflammatory response and thereby reflect the severity of tissue injury.

The Scientific relevance of ferritin in ischemic stroke is also linked with iron-mediated oxidative stress. Excessive iron can initiate in the generation of reactive oxygen species, thereby aggravating damage to neurons during and after ischemia [5]. Previous Literature have documented that increase in serum ferritin levels are associated with more extensive brain injury, greater neurological impairment, and poorer clinical outcomes in participants affected with ischemic stroke [6]. Erdemoglu et al. reported that elevated serum ferritin levels were

significantly linked with poor early prognosis among stroke participants [7]. Similarly in a study done by Guo et al. the relationship between iron metabolism, oxidative stress, and ischemic stroke, supporting the possible role of ferritin as a marker of stroke-related injury is explained [8]. However, in spite of these evidences, the exact prognostic role of serum ferritin in acute ischemic stroke remains debatable.

The National Institutes of Health Stroke Scale (NIHSS) is a widely accepted clinical tool used for the standardized assessment and interpretation of neurological impairment in patients with acute stroke. It evaluates multiple domains of neurological function, including level of consciousness, motor function, sensory impairment, language, speech, and visual field and thereby provides a standardized measure for stroke severity [9]. Higher NIHSS scores generally indicate that more severe the neurological deficits, more poorer the clinical outcomes [10]. Hence, understanding the relationship between serum ferritin levels and NIHSS score may help in determining whether ferritin can serve as a useful biomarker for assessing stroke severity.

In addition to the biochemical markers, conventional vascular and lifestyle-related risk factors namely hypertension, diabetes mellitus, dyslipidemia, smoking, and alcohol consumption contribute significantly to the occurrence and severity of ischemic stroke. All these factors are significantly associated with inflammation, endothelial dysfunction, atherosclerosis, and oxidative stress, which may also influence both serum ferritin levels and neurological outcomes. Evaluating the ferritin levels and their relation to stroke severity and associated risk factors may therefore provide a more

comprehensive understanding of its clinical relevance in acute ischemic stroke.

Hence, the present hospital-based cross-sectional study was conducted to assess serum ferritin levels in participants with acute ischemic stroke and to correlate them with stroke severity as measured by the NIHSS score. The study also aims to evaluate the association of serum ferritin and NIHSS score with selected clinical and lifestyle-related risk factors among participants with acute ischemic stroke.

### **Materials and Methods**

This hospital-based cross-sectional analytical study was conducted in a tertiary care teaching hospital over a period of two years. The study population included participants aged more than 45 years who were admitted with acute ischemic stroke. Participants of both sexes who presented within 48 hours of onset of stroke and whose diagnosis was confirmed by neuroimaging were considered eligible for inclusion. Participants with known infectious diseases, connective tissue disorders, features of haemorrhagic stroke, and participants aged below 45 years were excluded from the study. A total of 106 eligible participants were included in the study.

Prior approval was obtained from the Institutional Ethics Committee. The study was conducted in accordance with laid down ethical principles, including respect for autonomy, beneficence, non-maleficence, and confidentiality. Eligible participants or their legally acceptable representatives were approached after an initial clinical stabilization. The purpose of the study, nature of participation, procedures involved, possible risks, benefits, and the right to withdraw from the study at any stage without affecting routine

treatment were explained in their local vernacular. Adequate space was provided to ask questions and clarify their doubts if any. Written informed consent was obtained before enrolment once they give their oral consent. For those eligible participants who were unable to provide consent due to neurological impairment or altered sensorium, consent was obtained from the legally acceptable representative as per ethical norms. No additional financial burden was imposed on the participants for study-related data collection.

Confidentiality of the information obtained was maintained throughout the study. Each participant was assigned a study identification number, and personal identifiers were not used during data entry or analysis to ensure confidentiality. Clinical and laboratory data were recorded in a structured proforma and all the data was stored securely. All procedures performed as part of the study were carried out with utmost consideration to patient safety, privacy, and dignity.

After obtaining informed consent, a detailed history was collected from each participant, including the demographic details, time of onset of stroke symptoms, presenting complaints, past medical history, and about the history of vascular and lifestyle-related risk factors such as hypertension, diabetes mellitus, dyslipidemia, smoking, alcohol consumption, and also family history of stroke. Blood pressure at the time of admission was recorded, and relevant clinical findings were documented.

Neuroimaging was done as a routine to confirm the diagnosis of acute ischemic stroke and to exclude haemorrhagic stroke. Non-contrast computed tomography of the brain was used for confirmation wherever applicable, and imaging findings were

interpreted by qualified personnel as part of routine clinical care. Only participants with imaging-confirmed acute ischemic stroke were included in the final analysis.

Stroke severity was assessed using the National Institutes of Health Stroke Scale. The NIHSS score was recorded after clinical evaluation by assessing neurological domains including level of consciousness, gaze, visual field, facial palsy, motor function, limb ataxia, sensory function, language, speech, and neglect. Based on the NIHSS score, participants were classified according to the degree of neurological impairment. The NIHSS score was used as the clinical measure of stroke severity for correlation with serum ferritin levels.

Blood samples were collected from all study participants under aseptic precautions after enrolment. Serum ferritin levels were measured using standard laboratory methods. In addition, relevant hematological and biochemical investigations were recorded, including complete blood count, liver function tests, renal function tests, thyroid profile, lipid profile, random blood sugar, systolic blood pressure, and diastolic blood pressure. All laboratory procedures were usual routing followed for the patients, and the results were entered into the study proforma for analysis.

The data collected were compiled, coded, and was entered into a spreadsheet, and statistical analysis was performed. Descriptive statistics was used to summarize demographic variables, clinical characteristics, risk factors, NIHSS scores, serum ferritin levels, and laboratory parameters. Continuous variables were expressed as mean and standard deviation, while categorical variables were expressed as frequency and percentage. The

association between serum ferritin levels and the stroke severity categories was performed using one-way analysis of variance. Comparisons of serum ferritin levels and NIHSS scores between groups based on the presence or absence of selected risk factors were evaluated using the independent samples t-test. The correlation between serum ferritin levels and lipid parameters was assessed using Pearson's correlation coefficient. A p value of less than 0.05 was considered statistically significant.

### Results

The study included 106 participants with acute ischemic stroke. The majority of participants belonged to the 51–60 years and 61–70 years age groups, with each group contributing 32 participants (30.2%). Participants aged 71–80 years constituted 25 cases (23.6%), while those aged 45–50 years accounted for 17 cases (16.0%). Male predominance was observed, with 78 males

(73.58%) and 28 females (26.42%). Among the comorbidities, diabetes mellitus was the most common, present in 73 participants (68.9%), followed by hypertension in 62 participants (58.5%) and dyslipidemia in 50 participants (47.2%). With regard to lifestyle-related risk factors, alcohol consumption was reported by 67 participants (63.2%) and smoking by 60 participants (56.6%). Family history of stroke was present in 21 participants (19.81%). Based on NIHSS classification, most participants had moderately severe neurological impairment, accounting for 87 cases (82.1%), followed by severe impairment in 10 participants (9.4%) and very severe neurological impairment in 9 participants (8.5%). None of the participants had mild impairment. These findings indicate that the study population predominantly consisted of middle-aged to elderly males with a high burden of vascular and lifestyle-related risk factors (Table 1).

Table 1. Baseline sociodemographic and clinical characteristics of the study population

Variable	Category	Frequency (n)	Percentage (%)
Age group (years)	45–50	17	16.0
	51–60	32	30.2
	61–70	32	30.2
	71–80	25	23.6
Sex	Male	78	73.58
	Female	28	26.42
Comorbidities	Hypertension	62	58.5
	Diabetes mellitus	73	68.9
	Dyslipidemia	50	47.2
Risk factors	Smoking	60	56.6
	Alcohol consumption	67	63.2
	Family history of stroke	21	19.81
NIHSS classification	Mild impairment	0	0

	Moderately severe impairment	87	82.1
	Severe impairment	10	9.4
	Very severe neurological impairment	9	8.5

**Note:** Total study population = 106. NIHSS: National Institutes of Health Stroke Scale.

Serum ferritin levels showed a statistically significant association with stroke severity. The mean serum ferritin level was lowest among participants with moderately severe neurological impairment and increased progressively among participants with severe and very severe neurological impairment. Participants with moderately severe impairment had a mean serum ferritin level of  $135.76 \pm 13.68$ , while those with severe impairment had a mean level of  $236.15 \pm 49.51$ . The highest

mean serum ferritin level was observed among participants with very severe neurological impairment, measuring  $288.17 \pm 41.67$ . The difference between the groups was statistically significant on one-way analysis of variance ( $F = 27.885$ ,  $p < 0.001$ ). This suggests that increasing serum ferritin levels are significantly associated with increasing stroke severity in participants with acute ischemic stroke (Table 2).

Table 2. Association between serum ferritin levels and stroke severity

NIHSS classification	n	Serum ferritin, Mean	SD	F value	p value
Moderately severe impairment	87	135.76	13.68	27.885	<0.001
Severe impairment	10	236.15	49.51		
Very severe neurological impairment	9	288.17	41.67		

**Note:** Statistical test used: One-way ANOVA. SD: Standard deviation.

Serum ferritin levels were significantly higher among participants with selected vascular and lifestyle-related risk factors. Smokers had higher mean serum ferritin levels compared with non-smokers, and this difference was statistically significant. Similarly, participants with alcohol consumption, hypertension, diabetes mellitus, and dyslipidemia showed significantly higher serum ferritin levels compared with their

respective comparison groups. The mean difference in serum ferritin was highest for smoking, followed by alcohol consumption, hypertension, diabetes mellitus, and dyslipidemia. These findings suggest that the presence of conventional stroke risk factors is associated with higher serum ferritin levels, possibly reflecting increased inflammatory and oxidative stress burden among these participants (Table 3).

Table 3. Comparison of serum ferritin levels with selected risk factors

Risk factor	Absent, Mean	Absent, SD	Present, Mean	Present, SD	Mean difference	t value	p value
Smoking	204.66	49.03	251.35	55.81	46.68	-4.496	<0.001
Alcohol consumption	227.37	57.82	257.49	57.48	30.124	2.592	0.011
Hypertension	218.94	55.58	249.12	60.90	30.18	2.647	0.009
Diabetes mellitus	222.90	58.24	248.16	56.49	25.261	2.087	0.039
Dyslipidemia	223.17	51.12	248.16	62.48	24.99	2.237	0.027

**Note:** Statistical test used: Independent samples t-test. Serum ferritin values are expressed as mean  $\pm$  SD. For smoking, the negative t value reflects the direction of group comparison in the original analysis. The p value 0.000 has been presented as  $p < 0.001$ . The mean difference for dyslipidemia has been corrected mathematically as 24.99.

NIHSS scores were also significantly higher among participants with major vascular and lifestyle-related risk factors. Participants with smoking habit had higher NIHSS scores compared with non-smokers. Similarly, participants with alcohol consumption, hypertension, diabetes mellitus, and dyslipidemia had significantly higher NIHSS scores than their respective comparison groups. Among

these risk factors, hypertension showed the highest mean difference in NIHSS score, followed by diabetes mellitus, smoking, alcohol consumption, and dyslipidemia. These findings indicate that the presence of these risk factors is associated with greater neurological impairment and increased stroke severity in participants with acute ischemic stroke (Table 4).

Table 4. Comparison of NIHSS score with selected risk factors

Risk factor	Absent, Mean	Absent, SD	Present, Mean	Present, SD	Mean difference	t value	p value
Smoking	20.16	5.365	24.93	6.04	4.76	-4.136	<0.001
Alcohol consumption	22.43	6.36	26.60	6.23	4.166	3.28	0.001
Hypertension	22.64	5.99	29.16	6.78	6.52	5.226	0.001
Diabetes mellitus	21.42	6.24	26.82	6.51	5.398	4.07	<0.001
Dyslipidemia	21.88	5.52	25.73	6.87	3.850	3.156	<0.001

**Note:** Statistical test used: Independent samples t-test. NIHSS: National Institutes of Health Stroke Scale; SD: Standard deviation. The smoking absent SD was written as 5365 in the original table and has been corrected to 5.365.

Serum ferritin levels showed significant correlations with lipid profile parameters. A strong positive correlation was observed between serum ferritin and total cholesterol, indicating that higher ferritin levels were associated with higher total cholesterol levels. Serum ferritin also showed a moderate positive correlation with triglycerides and a strong positive correlation with LDL cholesterol. In

contrast, HDL cholesterol showed a weak but statistically significant negative correlation with serum ferritin, suggesting that higher ferritin levels were associated with lower HDL cholesterol levels. Overall, these findings indicate that elevated serum ferritin levels are associated with a more atherogenic lipid profile in participants with acute ischemic stroke (Table 5).

Table 5. Correlation between serum ferritin levels and lipid profile parameters

Lipid parameter	Correlation coefficient (r)	p value
Total cholesterol	0.718	0.001
Triglycerides	0.682	0.035
HDL cholesterol	-0.262	0.045
LDL cholesterol	0.735	0.015

**Note:** Statistical test used: Pearson's correlation coefficient. HDL: High-density lipoprotein; LDL: Low-density lipoprotein.

## Discussion

The present study evaluated the relationship between serum ferritin levels and stroke severity among participants with acute ischemic stroke, with stroke severity assessed using the National Institutes of Health Stroke Scale. The study also examined the association of serum ferritin and NIHSS score with selected vascular and lifestyle-related risk factors. The findings demonstrated that higher serum ferritin levels were significantly associated with increasing stroke severity. In addition, participants with smoking habit, alcohol consumption, hypertension, diabetes mellitus, and dyslipidemia had significantly higher serum ferritin levels and NIHSS scores compared with their respective comparison groups. Serum ferritin also showed significant positive correlations with total cholesterol, triglycerides, and LDL cholesterol, and a significant negative correlation with HDL cholesterol.

In the present study, most participants belonged to the 51–60 years and 61–70 years age groups, indicating that acute ischemic stroke was more common among middle-aged and elderly individuals. This finding is consistent with the established association between advancing age and increased stroke risk. Age is one of the most important non-modifiable risk factors for stroke, and the risk of stroke increases substantially with advancing age due to progressive vascular changes, atherosclerosis, endothelial dysfunction, and accumulation of comorbidities. Yousufuddin and Young highlighted the close relationship between aging and ischemic stroke, emphasizing that age-related vascular and metabolic alterations contribute significantly to cerebrovascular events [11]. Similarly, the American Heart Association has reported that stroke risk increases with age, particularly after middle age [12].

Male predominance was observed in the present study, with males constituting nearly three-fourths of the study population. This finding is comparable with previous studies reporting a higher incidence of ischemic stroke among males, especially in younger and middle-aged groups. Sex-related differences in stroke risk may be influenced by hormonal factors, lifestyle exposures, smoking, alcohol intake, and the higher burden of vascular risk factors among men. Rexrode et al. described the influence of sex and gender on stroke epidemiology and outcomes, while Norman et al. also reported sex differences in ischemic stroke among younger participants [13,14]. However, it should be noted that the sex difference in stroke risk may narrow with advancing age, particularly after menopause in women, as described in population-based studies [15].

The study population had a high burden of conventional stroke risk factors. Diabetes mellitus was the most common comorbidity, followed by hypertension and dyslipidemia. Smoking and alcohol consumption were also frequent among the participants. These findings reflect the well-established contribution of vascular and lifestyle-related risk factors to ischemic stroke. Hypertension remains the most important modifiable risk factor for stroke, mainly through its effects on endothelial injury, arterial stiffness, atherosclerosis, and small vessel disease. Even modest blood pressure reduction has been shown to reduce stroke risk significantly [16]. Diabetes mellitus contributes to ischemic stroke through endothelial dysfunction, accelerated atherosclerosis, chronic inflammation, and increased platelet activation [17]. Dyslipidemia promotes atherogenesis and vascular occlusion, thereby contributing to ischemic

cerebrovascular disease. The high prevalence of these comorbidities in the present study emphasizes the need for early identification and aggressive control of modifiable risk factors among high-risk individuals.

Smoking was reported by more than half of the study participants. Smoking is a well-known risk factor for ischemic stroke because it promotes oxidative stress, endothelial dysfunction, platelet activation, thrombosis, and atherosclerotic plaque instability. Gallucci et al. described the cardiovascular risk associated with smoking and the benefits of smoking cessation [18]. Hackshaw et al. also demonstrated that even low levels of cigarette consumption are associated with an increased risk of coronary heart disease and stroke. [19]. In the present study, smokers had significantly higher serum ferritin levels and NIHSS scores compared with non-smokers. This suggests that smoking may be associated not only with stroke occurrence but also with greater inflammatory burden and more severe neurological impairment. The higher ferritin levels among smokers may reflect increased oxidative stress and systemic inflammation, which can aggravate ischemic neuronal injury.

Alcohol consumption was also common among the study participants and was significantly associated with higher serum ferritin levels and higher NIHSS scores. The relationship between alcohol and stroke is complex and depends on the pattern and quantity of intake. Heavy alcohol consumption has been associated with hypertension, arrhythmias, dyslipidemia, inflammation, and increased stroke risk. Chung et al. reported that cumulative alcohol consumption burden is associated with increased stroke risk,

particularly among young adults [20] O'Donnell et al. also identified alcohol intake as one of the potentially modifiable risk factors associated with acute stroke in the INTERSTROKE study [21]. The present findings suggest that alcohol consumption may be linked to higher inflammatory and oxidative stress activity, as reflected by increased ferritin levels, and may also be associated with more severe neurological presentation.

NIHSS classification showed that most participants had moderately severe neurological impairment, followed by severe and very severe impairment. The mean NIHSS score in the study population indicated a clinically significant burden of neurological deficit. NIHSS is widely used for quantifying stroke severity and has strong prognostic value in acute ischemic stroke. Higher NIHSS scores are associated with larger infarct burden, poorer functional outcome, and increased mortality. Farooque et al. emphasized the importance of NIHSS in assessing stroke severity and predicting clinical outcomes [22]. In the present study, NIHSS score was significantly higher among participants with smoking, alcohol consumption, hypertension, diabetes mellitus, and dyslipidemia, suggesting that these risk factors may contribute to greater neurological impairment at presentation.

The central finding of this study was the significant association between serum ferritin levels and stroke severity. Serum ferritin levels increased progressively with worsening NIHSS severity category, and the association was statistically significant. Participants with very severe neurological impairment had the highest mean ferritin levels, while those with moderately severe impairment had the lowest mean ferritin levels. This finding supports the possible role of ferritin as a marker of stroke

severity. Ferritin is not only a marker of iron stores but also an acute-phase reactant that increases in response to inflammation and tissue injury. In acute ischemic stroke, ischemia-induced neuronal injury, inflammatory activation, blood–brain barrier disruption, and oxidative stress may contribute to increased ferritin levels [23].

The biological plausibility of this association is supported by the role of iron in oxidative injury. Excess iron can participate in the generation of reactive oxygen species, which may worsen lipid peroxidation, mitochondrial dysfunction, and neuronal cell injury during ischemia. Kell and Pretorius discussed the role of ferritin and iron metabolism in inflammatory and oxidative processes [24]. Wang et al. also suggested that elevated ferritin in acute stroke may reflect inflammatory response and oxidative stress rather than body iron stores alone [25]. Thus, in acute ischemic stroke, serum ferritin may represent a combined marker of iron metabolism, inflammation, and oxidative injury.

The findings of the present study are consistent with earlier studies that reported an association between elevated ferritin levels and poor stroke outcomes. Millerot et al. examined serum ferritin in stroke and discussed whether it reflects increased body iron stores or stroke severity [6]. Erdemoglu and Ozbakir reported that serum ferritin levels were associated with early prognosis in stroke participants [7]. Similarly, other studies have suggested that higher serum ferritin levels are associated with larger infarct size, poorer functional outcome, and increased mortality among participants with acute ischemic stroke [26]. The present study adds to this evidence by showing that ferritin levels are significantly associated with NIHSS-based

stroke severity in a hospital-based population.

The study also found that serum ferritin levels were significantly higher among participants with hypertension, diabetes mellitus, and dyslipidemia. These conditions are closely linked to chronic vascular inflammation, endothelial dysfunction, oxidative stress, and atherosclerosis, all of which may contribute to ferritin elevation. Hypertension causes vascular injury and promotes atherosclerosis, while diabetes mellitus accelerates endothelial dysfunction and inflammatory vascular damage [16,17]. Dyslipidemia contributes to plaque formation and vascular occlusion, which are central mechanisms in ischemic stroke. The coexistence of these risk factors with elevated ferritin levels may indicate a higher inflammatory and metabolic burden among participants with more severe stroke.

Serum ferritin showed significant correlations with lipid profile parameters in the present study. A strong positive correlation was observed with total cholesterol and LDL cholesterol, while triglycerides showed a moderate positive correlation. HDL cholesterol showed a significant negative correlation with serum ferritin. These findings suggest that elevated ferritin levels are associated with an atherogenic lipid profile. Dyslipidemia is an important contributor to atherosclerotic disease and ischemic stroke. Elevated LDL cholesterol and total cholesterol promote plaque formation, while low HDL cholesterol reduces reverse cholesterol transport and vascular protection. Grundy et al. described the importance of lipid management for cardiovascular and cerebrovascular risk reduction [27]. The SPARCL study also

demonstrated the role of aggressive cholesterol reduction in reducing recurrent stroke risk [28].

The negative correlation between serum ferritin and HDL cholesterol is clinically relevant because HDL has anti-inflammatory, antioxidant, and endothelial protective effects. Lower HDL levels may therefore indicate reduced vascular protection in participants with elevated ferritin. In contrast, the positive correlation of ferritin with LDL cholesterol and total cholesterol suggests that ferritin elevation may coexist with a pro-atherogenic and pro-inflammatory metabolic state. These findings support the concept that ferritin may be linked not only to acute stroke severity but also to underlying vascular risk burden.

In the present study, family history of stroke was present in a smaller proportion of participants compared with those without family history. However, family history remains an important non-modifiable risk factor for stroke, as it may reflect genetic predisposition as well as shared environmental and lifestyle factors. Bevan et al. reported that family history contributes to stroke risk independent of traditional vascular risk factors [29]. Although family history was not the major risk factor observed in this study population, it remains relevant in comprehensive stroke risk assessment.

The present study has important clinical implications. Serum ferritin is a relatively accessible laboratory parameter and may be useful as an adjunct marker for assessing stroke severity in participants with acute ischemic stroke. Its association with NIHSS score suggests that ferritin may reflect the biological severity of ischemic injury, particularly through inflammatory and oxidative stress pathways. However,

serum ferritin should not be interpreted in isolation, as it can be influenced by infection, inflammation, liver disease, iron metabolism disorders, and other systemic conditions. In clinical practice, ferritin may be considered along with NIHSS score, imaging findings, and vascular risk profile to improve risk stratification.

The findings also emphasize the importance of aggressive management of modifiable stroke risk factors. Smoking, alcohol consumption, hypertension, diabetes mellitus, and dyslipidemia were associated with higher serum ferritin levels and greater NIHSS scores. This highlights the need for comprehensive preventive strategies, including smoking cessation, alcohol risk reduction, blood pressure control, glycemic control, and lipid management. Such interventions may reduce both the risk of stroke and the severity of neurological outcomes.

### Conclusion

The present study demonstrated a significant association between elevated serum ferritin levels and increased stroke severity among participants with acute ischemic stroke. Serum ferritin levels were also significantly associated with major vascular and lifestyle-related risk factors and showed significant correlation with lipid profile parameters. These findings suggest that serum ferritin may serve as a useful biomarker of stroke severity and inflammatory burden in acute ischemic stroke. However, as this was a cross-sectional study, causality cannot be established. Further longitudinal and multicentric studies are required to validate the prognostic value of serum ferritin and to determine whether it can independently predict stroke outcomes after adjusting for potential confounding factors.

### Statements and Declarations

#### Conflicts of interest

The authors declare that they do not have conflict of interest.

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ORIGINAL ARTICLE

**Knowing but Not Doing: A Study on the Knowledge–Practice Gap in Autopsy Training Among Undergraduate Students in a Tertiary Care Institution**

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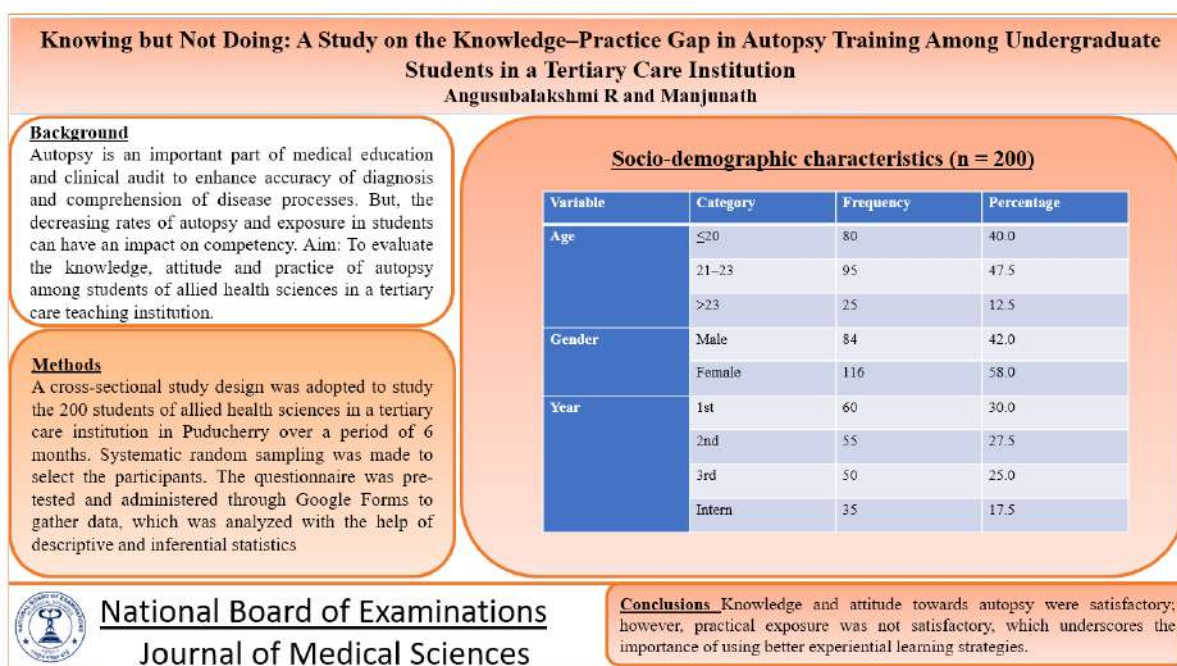
**Abstract**

**Background:** Autopsy is an important part of medical education and clinical audit to enhance accuracy of diagnosis and comprehension of disease processes. But, the decreasing rates of autopsy and exposure in students can have an impact on competency. **Aim:** To evaluate the knowledge, attitude and practice of autopsy among students of allied health sciences in a tertiary care teaching institution. **Methods:** A cross-sectional study design was adopted to study the 200 students of allied health sciences in a tertiary care institution in Puducherry over a period of 6 months. Systematic random sampling was made to select the participants. The questionnaire was pre-tested and administered through Google Forms to gather data, which was analyzed with the help of descriptive and inferential statistics. **Results:** A total of 200 subjects found that 69.0% of participants were well informed and 62.0% positively oriented toward autopsy but just 36.0% were well exposed. The knowledge and year of study were statistically significantly correlated ( $p < 0.001$ ). The logistic regression analysis revealed that academic year and previous experience with autopsy were big predictors of proper knowledge. **Conclusion:** Knowledge and attitude towards autopsy were satisfactory; however, practical exposure was not satisfactory, which underscores the importance of using better experiential learning strategies.

**Keywords:** Autopsy, Knowledge–Practice Gap

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## Graphical Abstract



### Introduction

The gold standard of establishing the cause of death and developing an improved insight on the mechanisms of diseases has long been attributed to autopsy [1]. It is central to the medical education process since it helps to bridge the gap between theoretical and clinical knowledge by allowing students to directly observe pathological changes and relate them to clinical findings, thus, leading to a better quality of care and improved diagnostic accuracy [2]. It is also invaluable in medico-legal investigations, epidemiological surveillance and medical research [3].

Exposure to autopsy is an indispensable aspect of the training of students of health sciences, especially in such fields as pathology and forensic medicine. It promotes critical thinking, clinical reasoning and understanding of anatomical and pathological concepts, but the world has witnessed a clear drop in the rate of autopsy, which has consequences on

medical education and quality of healthcare [4]. This drop has been blamed on a number of reasons such as ignorance, insufficient exposure, emotional uneasiness and sociocultural or religious convictions [5].

It is important to assess knowledge, attitude, and practice (KAP) of autopsy amongst the students to help reveal the existing gaps and barriers. The knowledge indicates the awareness of the purpose, procedures, and importance of the autopsy and the attitude is the perceptions, beliefs, and readiness to participate in the activities associated with autopsy and practice is the actual exposure and involvement in the autopsy procedure. Past research has shown that despite students having a rudimentary background concerning autopsy, their hands-on experience is usually restricted, and they tend to be fearful, ethically sensitive and culturally biased [6].

The KAP of students towards autopsy is crucial in designing specific educational interventions and enhancing curriculum delivery. Improving exposure

and dealing with myths can lead to a more favorable attitude and improved involvement with the practice of autopsy. Thus, the purpose of the study was to evaluate the knowledge, attitude and practice of autopsy among the students of the allied health sciences in a tertiary care teaching hospital.

### **Objectives**

1. To determine the level of knowledge, attitude and practice of autopsy among allied health sciences students.
2. To determine the factors that affect knowledge and attitude towards autopsy among the study participants.

### **Methodology**

The study was descriptive cross-sectional in nature, where the study participants were students of allied health sciences in a tertiary care teaching institution in Puducherry covering a period of 6 months.

### **Study Population**

The population used in the study was the students in the allied health sciences at the institution during the study period.

### **Sample Size and Sampling Technique**

A previous Indian study that indicated that about 70% percent of the students were well informed about autopsy [7] was used to determine the sample size; a final sample size of 200 study participants was used in the study to be representative and to maintain a reasonable non-response bias.

The sampling frame was the total number of eligible students in the institution, which was about 500. The systematic random sampling method was

used. The sampling frame consists of all eligible students; all second students were chosen based on the first two students, but a random starting point was chosen. This was repeated until a sample of 200 people had been reached.

The systematic random sampling method was used to select study participants. A complete list of eligible students served as the sampling frame. After selecting a random starting point, every kth student was recruited until the required sample size was achieved. This approach reduced selection bias and ensured adequate representation of students across different academic years, thereby improving the representativeness of the study population.

### **Inclusion Criteria**

- Allied health science students who were willing to participate
- Students who gave informed consent

### **Exclusion Criteria**

- Students who did not agree to participate
- Questionnaire that was not filled to completion was not analyzed

### **Study Tool**

A semi-structured questionnaire was pre-designed based on a review of the literature available and used to gather data. The questionnaire had sections on the knowledge, attitude and practice of autopsy.

Subject experts in community medicine and forensic medicine were consulted and verified the tool. It was also tested in a small number of students who did not belong to the final study population and appropriate adjustments were made so as to make it clear and understandable.

### Data Collection Procedure

The questionnaire was turned into Google Forms and distributed to participants via institutional communication, including email and messaging. Participation was voluntary. The questionnaire contained an informed consent form at the start and only the people who agreed were allowed to continue. During the research, confidentiality and anonymity of responses were ensured.

### Data Analysis

The responses of the Google Forms were exported to Microsoft Excel and processed in Statistical Package of the Social Sciences (SPSS 31.0 version) software. The data were summarized by descriptive statistics, which included frequency, percentage, mean and standard deviation.

The Chi-square test of inferential statistics was used to evaluate relationships between

categorical variables. The knowledge was analyzed using multivariate logistic regression analysis to determine the independent predictors. The p-value of below 0.05 was deemed to be significant.

### Results

A total of 200 students participated in the study.

### Socio-demographic characteristics (Table 1)

The majority of participants were in the 21–23 years age group (47.5%), followed by  $\leq 20$  years (40.0%) and  $> 23$  years (12.5%). The percentage of females (58.0%) was higher than males (42.0%). Regarding academic distribution, first-year students made 30.0%, second-year (27.5%), third-year (25.0%), and interns (17.5%). This shows a relatively even spread of the years.

Table 1. Socio-demographic characteristics (n = 200)

Variable	Category	Frequency	Percentage
Age	$\leq 20$	80	40.0
	21–23	95	47.5
	$> 23$	25	12.5
Gender	Male	84	42.0
	Female	116	58.0
Year	1st	60	30.0
	2nd	55	27.5
	3rd	50	25.0
	Intern	35	17.5

**Knowledge, Attitude, and Practice (Table 2)**

Of the participants, 69.0% exhibited sufficient knowledge with only 31.0% exhibiting insufficient knowledge. On attitude, 62.0% indicated a positive attitude

with 38.0% indicating a negative attitude towards autopsy. Nevertheless, the proportion of individuals who were adequately exposed to autopsy practices was only 36.0% demonstrating a huge disparity between theory and practice.

Table 2. Knowledge, Attitude, and Practice levels

Domain	Category	Frequency	Percentage
Knowledge	Adequate	138	69.0
	Inadequate	62	31.0
Attitude	Positive	124	62.0
	Negative	76	38.0
Practice	Adequate	72	36.0
	Inadequate	128	64.0

**Association between year of study and knowledge (Table 3)**

The knowledge level and academic year were statistically significantly correlated ( $p < 0.001$ ). The proportion of students with sufficient knowledge rose with academic progressively, with 50.0% in first-year students and 84.0% in third-year students, which demonstrates the importance of clinical exposure.

The p-value of less than 0.001 indicates a highly statistically significant association between academic year and knowledge level. This suggests that the observed increase in knowledge across academic years is unlikely to have occurred by chance and reflects the positive impact of academic progression and clinical exposure on autopsy-related knowledge.

Table 3. Association between year of study and knowledge

Year	Adequate	Inadequate	p-value
First	30	30	<0.001
Second	38	17	
Third	42	8	
Intern	28	7	
Total	138	62	

### Factors associated with knowledge (Table 4)

The multivariate logistic regression analysis identified academic year and previous autopsy exposure as significant independent predictors of adequate knowledge. Third-year students demonstrated the highest likelihood of adequate knowledge (AOR = 4.50; 95% CI:

1.95–10.38;  $p < 0.001$ ). Students with previous autopsy exposure had 3.25 times higher odds of possessing adequate knowledge compared to those without exposure (AOR = 3.25; 95% CI: 1.75–6.02;  $p < 0.001$ ). Since the 95% confidence intervals did not include the null value of 1, these predictors were considered statistically significant.

Table 4. Multivariate logistic regression analysis

Variable	Category	AOR	95% CI	p-value
Gender	Female	1.42	0.78–2.58	0.24
Year	2nd	2.10	1.02–4.32	0.04
	3rd	4.50	1.95–10.38	<0.001
	Intern	3.80	1.55–9.28	0.003
Exposure	Yes	3.25	1.75–6.02	<0.001

### Discussion

The current study evaluated the levels of knowledge, attitude, and practice among students of allied health sciences and revealed that 69% of the respondents were well informed, which is comparable with the results of recent Indian studies [3,7]. The same levels of awareness have been observed in other more recent studies showing that the knowledge among the students in as far as autopsy is concerned is relatively well established [8,9].

In the recent literature, the significance of autopsy in medical education has been highlighted especially with the advent of newer modalities in teaching that include post-mortem imaging and virtual autopsy that supplement the traditional instructional mode and enhance learning outcomes [10,11]. These approaches may help bridge the gap between theoretical knowledge and practical exposure among students.

Autopsy remains an indispensable component of medical education because it provides direct clinicopathological correlation, enhances diagnostic reasoning, and strengthens understanding of disease processes. It also serves as an important quality assurance tool by identifying discrepancies between clinical diagnoses and pathological findings, thereby contributing to improved patient care and medical training.

The positive attitude towards autopsy was noted in 62% of the respondents, which is in line with other past and recent research reports that found that students understood the educational and medico-legal significance of autopsy [4,5]. A significant number of the respondents however had negative attitude towards autopsy, which could be attributed to emotional discomfort, cultural beliefs and fear of being exposed to dead bodies as reported in the past literature [12,13].

Autopsy is still essential in revealing cases of discrepancies between clinical and pathological diagnoses and thus enhancing the quality of care and diagnostic accuracy [14]; hence, its persistence in the face of modern diagnostic methods [15,16].

The significant disparity between knowledge and practice is one of the most significant results of the current study as only 36% of the participants were properly exposed to autopsy. This result is in line with multiple recent studies that point to the decreasing trend in autopsy rates and inaccessibility to practical training that can potentially impact the competency of future medical workers [16-18].

The relevance of autopsy in medical training has also been highlighted in the recent literature that has indicated its contribution to improving clinical competence, diagnostic reasoning and disease process knowledge [19,20]. This gap between knowledge and practice may also be explained by the lack of direct exposure, logistical issues and lower rates of autopsy in teaching hospitals. The implications of this gap are significant because, without sufficient practice training, the development of key clinical and medico-legal competencies in future healthcare providers can be hindered.

The study also found out that academic year and knowledge had significant association, with higher-year students having a higher level of knowledge. This result is consistent with the earlier literature, which demonstrated that more clinical practice and academic advancement help to enhance knowledge [7].

Multivariate logistic regression demonstrated that previous autopsy exposure was a strong independent

predictor of adequate knowledge. Students who had prior exposure were more than three times as likely to demonstrate adequate knowledge compared with unexposed students (AOR = 3.25; 95% CI: 1.75–6.02;  $p < 0.001$ ). This finding highlights the importance of experiential learning and suggests that direct participation or observation of autopsy procedures substantially improves understanding of autopsy-related concepts [10,11].

There was no significant difference in gender and knowledge levels as it was found to be related with other studies, which argue that exposure to education is a more critical factor than demographic factors [16].

On the whole, the conclusions of the current research point to the fact that despite the rather high level of knowledge and attitude towards autopsy, the level of practical exposure is still insufficient and requires the redesign of the curriculum and new approaches to teaching to improve the learning process.

### **Conclusion and Recommendations**

The current study has shown that most students of the allied health sciences had sufficient knowledge and a positive attitude towards autopsy. Practical experience on the process of autopsy was, however, found to be very wanting. Knowledge of progression in academics and previous exposure emerged as the determinants of knowledge. The results reveal a crucial gap between theoretical knowledge and practical exposure in medical education. Although most students demonstrated adequate knowledge and a positive attitude towards autopsy, only a minority reported adequate practical exposure, highlighting the need for

enhanced experiential learning opportunities.

To address the identified knowledge–practice gap, structured autopsy-based teaching sessions should be incorporated into undergraduate training. Increased opportunities for supervised autopsy observation and clinical postings should be provided wherever feasible. In settings where direct exposure is limited, simulation-based learning, virtual autopsy platforms, and video-assisted demonstrations may serve as effective alternatives. In addition, sensitization programmes addressing emotional, ethical, and cultural concerns related to autopsy should be conducted to improve student acceptance and participation. These strategies may strengthen experiential learning and enhance competency among future healthcare professionals.

### Statements and Declarations

#### Conflicts of interest

The authors declare that they do not have conflict of interest.

#### Funding

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ORIGINAL ARTICLE

**Association of Maternal Cobalamin Status in Gestational Diabetes Mellitus: A Prospective Cross-Sectional Study**

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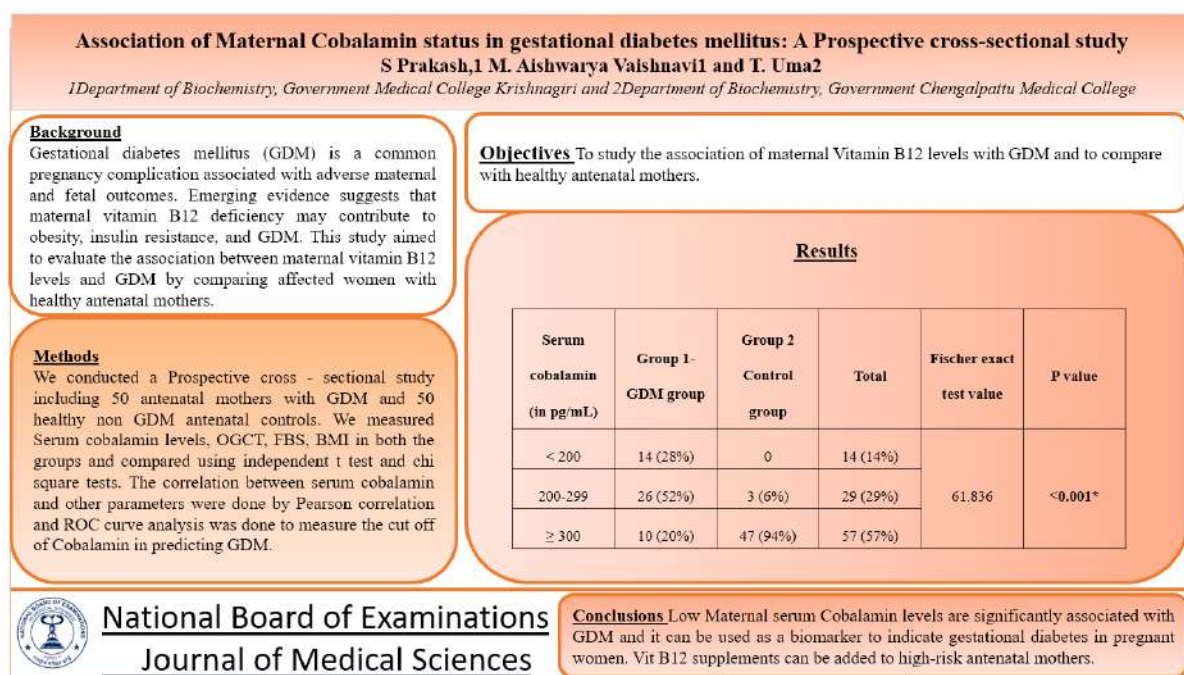
**Abstract**

**Background:** Gestational Diabetes mellitus is the most common complications affecting pregnancy which impacts the maternal as well as foetal outcome. Maternal obesity is one among the various risk factors for GDM which can be contributed by Cobalamin (Vitamin B12) deficiency. So, we aimed to measure Serum Cobalamin levels in GDM mothers and compared with Non GDM mothers. **Materials and Methods:** We conducted a Prospective cross - sectional study including 50 antenatal mothers with GDM and 50 healthy non GDM antenatal controls. We measured Serum cobalamin levels, OGCT, FBS, BMI in both the groups and compared using independent t test and chi square tests. The correlation between serum cobalamin and other parameters were done by Pearson correlation and ROC curve analysis was done to measure the cut off of Cobalamin in predicting GDM. **Results:** Maternal serum cobalamin was significantly lower in GDM mothers than controls ( $246.78 \pm 60.52$  pg/ml vs  $410.89 \pm 145.9$  pg/ml  $p < 0.001$ ). OGCT, FBS and BMI were significantly increased in GDM mothers than controls ( $p$  value  $< 0.001$ ). OGCT and FBS showed significant negative correlation with Cobalamin ( $p$  value  $< 0.001$ ). ROC curve analysis of serum cobalamin showed cut-off threshold value as 301.7 pg/ml with AUC of 0.954 (95% C.I = 0.892-0.986) with a statistically significant  $p$  value ( $p < 0.001$ ). **Conclusion:** Low Maternal serum Cobalamin levels are significantly associated with GDM and it can be utilised as a biomarker to indicate gestational diabetes in pregnant women. Vit B12 supplements can be added to high-risk antenatal mothers.

**Keywords:** Gestational Diabetes mellitus, Serum Cobalamin, Oral Glucose Challenge Test, Maternal age, Body Mass index

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## Graphical Abstract





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**Conclusions** Low Maternal serum Cobalamin levels are significantly associated with GDM and it can be used as a biomarker to indicate gestational diabetes in pregnant women. Vit B12 supplements can be added to high-risk antenatal mothers.

## Introduction

Gestational Diabetes mellitus is the most common complications affecting pregnancy. It is categorized by varying degrees of carbohydrate intolerance and hyperglycemia that is observed only during pregnancy [1]. The prevalence of GDM was estimated to be approximately 14% globally. Its prevalence is higher in Asian countries accounting for about 20.8% [2]. Both the mother and the fetus are impacted by the effects of GDM. In Fetus, Macrosomia, preterm birth, stillbirth, shoulder dystocia, and unexplained fetal deaths are just a few of the pregnancy complications that can be caused by gestational diabetes mellitus. Poor glycemic control during pregnancy, vulnerability to infections, cephalo-pelvic disproportion, and type II diabetes in later life are all maternal consequences [3–5]. It has been observed that the adverse effects for the fetus might have happened as early as around 20th week which is well prior to

diagnose GDM [6]. It is very crucial to identify the risk factors and prevent GDM to decrease adverse fetal and maternal outcomes.

Maternal obesity is one of the common modifiable risk factors. Maternal Vitamin B12 levels are inversely associated with maternal BMI [7]. It has been hypothesized that low vitamin B12, at a cellular level can cause adipocyte dysfunction and obesity-related complications [8]. Vitamin cobalamin (vitamin B12) along with folic acid is an important micronutrient needed for the synthesis of protein, DNA and lipids, in a series of cellular reactions which is collectively called as one-carbon metabolism [9,10]. The cobalamin vitamin is important for the development of red blood cells, neural growth, and brain myelination [1,11,12]. Homocysteine is converted into the methyl donor, methionine as part of one carbon metabolism, which also requires cofactors

vitamin B12 and folate. Furthermore, the alteration of methyl malonyl-CoA to succinyl-CoA in mitochondria requires the coenzyme B12, and in its absence, an accumulation of the previous substance inhibits fatty acid oxidation and encourages lipogenesis [13,14]. According to a recent systematic review, vitamin B12 insufficiency in pregnant women around the world was more common in all trimesters (20%–30%) [15]. Low B12 levels during pregnancy have an impact on the health of the mother and fetus, including maternal obesity, maternal and fetal insulin resistance, and adverse lipid profile in the newborns [16–18].

In a prospective, longitudinal study in early pregnancy, vitamin B12 deficiency independently helped in predicting gestational diabetes mellitus (GDM) and type 2 diabetes (T2D) at 5-years after post-delivery. The fact that this association was mediated by obesity highlights the possible contribution of low vitamin B12 levels to adipocyte dysfunction [16]. Currently, the issue of vitamin B12 deficiency and gestational diabetes mellitus (GDM) has been hardly hinted in medical literature, hence there is a need to study the association of maternal cobalamin levels and GDM. In this study, we aimed to study the association of maternal Vitamin B12 levels with GDM and to compare with health antenatal mothers.

## **Materials and Methods**

### ***Study Participants and Methods***

We conducted hospital-based prospective cross-sectional study in Department of Biochemistry after obtaining approval from Institutional Ethics Committee (Madras Medical College) vide letter no: 11052021 dated on 05-05-2021. The study participants were recruited from

Obstetrics OPD during the period of March 2021– March 2022. The written informed consent was obtained from the Study Participants after explaining about the study protocol.

### ***Study Population***

In this study 100 Antenatal mothers were selected from antenatal OPD based on the inclusion and exclusion criteria and are categorized into 2 groups.

Group I – Cases involving 50 antenatal mothers with Gestational Diabetes Mellitus

Group II – Controls involving 50 apparently healthy antenatal mother

### ***Inclusion criteria***

Antenatal mother of age group 20-40 years in > 20 weeks of gestation with OGCT values > 140 mg/dL were included and the diagnosis of GDM was made with 3 sample OGTT using the recommendations given by the International Association of the Diabetes and Pregnancy Study Groups Consensus Panel [19].

### ***Exclusion criteria***

Antenatal mother with Pre gestational diabetes mellitus, Multiple pregnancy, Previous history of large babies, chronic hypertension and those received B12 injection in last six months or those on B12 supplements and women undergoing concurrent Metformin pharmacological therapy were excluded from the study.

### ***Study Procedure***

Detailed demographic and clinical information, including age, height, weight, and relevant medical history, were recorded for all participants. Following a comprehensive clinical examination, 5 mL

of venous blood was collected from the antecubital vein under strict aseptic conditions. The blood sample collected in a serum tube was allowed to clot, and serum was separated by centrifugation at 3000 rpm for 15 minutes. The separated serum was used for the estimation of overnight (at least 8 hrs) fasting blood glucose, urea, and creatinine levels. Approximately 2 mL of serum was aliquoted and stored at  $-20^{\circ}\text{C}$  until further analysis of serum cobalamin levels.

### ***Study Parameters***

Serum cobalamin levels were estimated using the Electrochemiluminescence Immunoassay (ECLIA) technique on the Cobas e 411, a fully automated immunoassay analyzer. Fasting blood Sugar (FBS) was analyzed by the hexokinase endpoint method. Blood urea estimation was performed using the kinetic urease–glutamate dehydrogenase method, while serum creatinine was measured by Jaffe’s kinetic method with an IDMS-traceable calibrator. All biochemical analyses were carried out in accordance with the laboratory's standard operating procedures, and internal quality control measures were employed throughout the study period. Body mass index (BMI) was calculated for each participant using the recorded height and weight measurements.

### ***Statistical analysis***

Continuous variables were summarized as mean  $\pm$  standard deviation

(SD) or median with interquartile range (IQR), as appropriate. The normality of data distribution was assessed using the Kolmogorov–Smirnov test. Comparative analyses were performed using the independent t-test for continuous variables and the chi-square test for categorical variables. The relationship between serum vitamin B12 levels and other study parameters was evaluated using Pearson’s correlation analysis, while Receiver Operating Characteristic (ROC) curve analysis was carried out to assess the diagnostic performance of the studied variables. Statistical analyses were conducted using SPSS software version 21.0, and a p-value less than 0.05 was considered statistically significant.

### ***Results***

In this study the GDM group, 68% were primi, 16% were 2<sup>nd</sup> gravida 6% were 3<sup>rd</sup> gravida, 8% were 4<sup>th</sup> gravida and 2% were 5<sup>th</sup> gravida. In the controls, 64% were primi, 24% were 2<sup>nd</sup> gravida and 12% were 3<sup>rd</sup> gravida. There was no statistically significant difference between the two groups by Fischer exact test. In the GDM group, 8% were less than 28 weeks, 78% were from 29 to 34 weeks and 14% were more than 34 weeks. In the controls, 6% were less than 28 weeks, 66% were from 29 to 34 weeks and 28% were more than 34 weeks. There was no statistically significant difference between the two groups by Fischer exact test (Table 1).

Table 1. Clinical Parameters of the study participants in both the groups (n=100)

Variables		Group I - GDM	Group II - Control	Total	Fischer exact test value	P value
Gravida	Primi	34 (68%)	32 (64%)	66 (66%)	6.461	0.131
	2	8(16%)	12 (24%)	20 (20%)		
	3	3 (6%)	6 (12%)	9 (9%)		
	4	4 (8%)	0	4(4%)		
	5	1 (2%)	0	1 (1%)		
Gestational age	≤ 28 weeks	4 (8%)	3 (6%)	7 (7%)	2.980	0.259
	29 to 34 weeks	39 (78%)	33 (66%)	72 (72%)		
	>34 weeks	7 (14%)	14 (28%)	21 (21%)		
Family history of DM	Yes	28 (56%)	8 (16%)	36 (36%)	17.361	<0.001*
	No	22 (44%)	42 (84%)	64 (64%)		

In GDM group, 56% had a family history of Diabetes and 44% did not have a family history of Diabetes. In controls group, 16% had a family history of Diabetes and 84% did not have a family history of Diabetes. The difference between the two groups with respect to family history of Diabetes mellitus was statistically significant by Chi square test.

The mean age of the study participants in Gestational diabetes mellitus group was  $25.06 \pm 4.24$  years and the mean age of study participants in control group was  $23.84 \pm 3.67$  years. There was no statistically significant difference between the two groups by independent t test. The two groups are comparable with respect to

age of the study participants. The mean weight and BMI of the participants in GDM group was significantly higher than in controls ( $p$  Value  $< 0.001$ ). Systolic BP was significantly higher in GDM mothers than control mothers and no statistically significant difference is seen in diastolic BP. OGCT values were significantly higher in GDM mothers than Non GDM mothers ( $p$  Value  $< 0.001$ ). Fasting blood sugar was significantly higher in GDM mothers than control mothers ( $p$  Value  $< 0.001$ ). Serum Cobalamin levels were significantly lower in GDM mothers than Non GDM mothers ( $246.78 \pm 60.52$  Vs  $410.89 \pm 145.9$ ,  $p$  Value  $< 0.001$ ) (Table 2).

Table 2. Study parameters in in both the groups (n=100)

Parameters	Group I – GDM	Group II -Control	T test value	P value
Age (in Yrs)	$25.06 \pm 4.24$	$23.84 \pm 3.67$	1.536	0.128
Weight (kg)	$59.20 \pm 5.35$	$55.08 \pm 3.57$	4.524	<b>&lt;0.001*</b>
BMI (kg/m <sup>2</sup> )	$23.87 \pm 1.54$	$22.68 \pm 1.07$	4.445	<b>&lt;0.001*</b>
Systolic BP (mm Hg)	$112.92 \pm 5.99$	$108.64 \pm 7.85$	30.64	<b>0.003*</b>
Diastolic BP (mm Hg)	$73.16 \pm 5.17$	$71.28 \pm 4.97$	0.118	0.906
OGCT (mg/dL)	$160.74 \pm 15.37$	$113.90 \pm 14.27$	0.852	<b>&lt;0.001*</b>
FBS (mg/dl)	$137.44 \pm 26.71$	$88.90 \pm 12.11$	11.703	<b>&lt;0.001*</b>

<b>Serum cobalamin (pg/mL)</b>	246.78 ± 60.52	410.89 ± 145.9	7.344	<b>&lt;0.001*</b>
<b>Blood urea(mg/dl)</b>	26.30 ± 3.91	23.98 ± 4.59	2.718	<b>0.008*</b>
<b>Serum creatinine (mg/dL)</b>	0.828 ± 0.185	0.840 ± 0.199	0.312	0.756

\*p values < 0.05 are considered statistically significant.

In renal function parameters, Blood Urea levels were significantly higher in GDM mother with p value of 0.008 and serum creatinine levels showed no statistical difference between GDM mothers and control. We have compared

both GDM and Control group based on the serum cobalamin levels and the difference between two groups with respect to serum cobalamin were statistically significant by Fischer Exact test (p value < 0.001) (Table 3 and Figure 1).

Table 3. Serum cobalamin of study participants

<b>Serum cobalamin (in pg/mL)</b>	<b>Group 1- GDM group</b>	<b>Group 2 Control group</b>	<b>Total</b>	<b>Fischer exact test value</b>	<b>P value</b>
< 200	14 (28%)	0	14 (14%)	61.836	<b>&lt;0.001*</b>
200-299	26 (52%)	3 (6%)	29 (29%)		
≥ 300	10 (20%)	47 (94%)	57 (57%)		

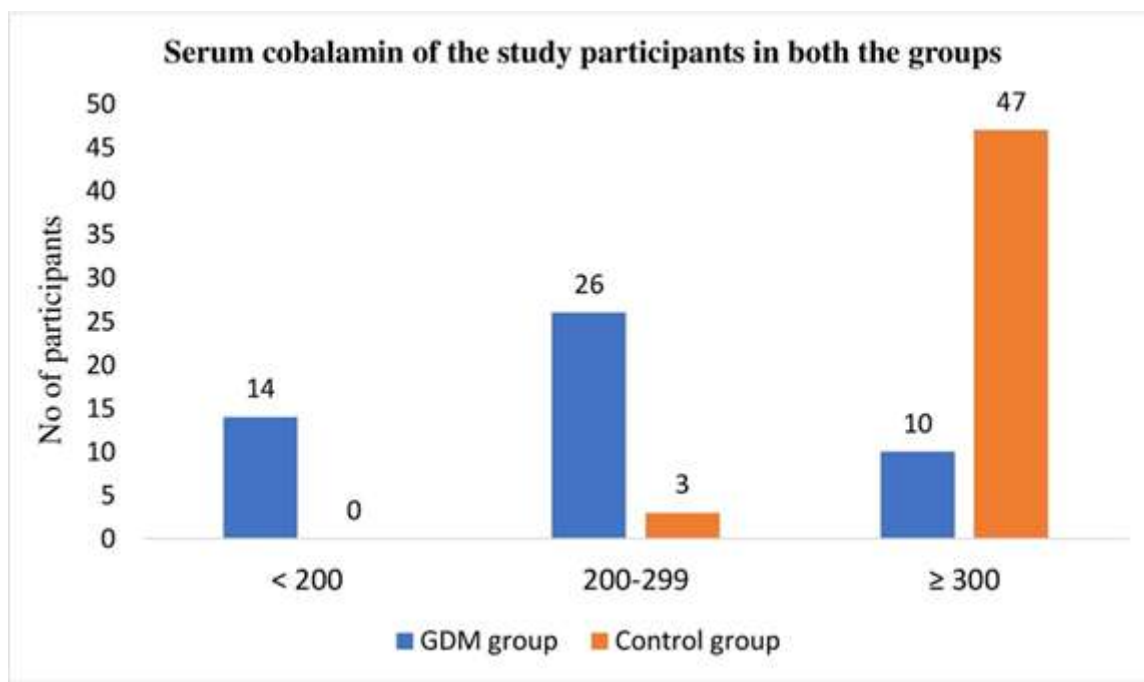


Figure 1. Serum cobalamin of the study participants in both the groups

We have correlated the study parameters with Serum cobalamin levels. OGCT and FBS showed statistically significant strong negative correlation ( $r = -0.764$ ,  $P < 0.001^*$ ) and ( $r = -0.728$ ,  $P <$

$0.001^*$ ), respectively (Figures 2 and 3). There was no correlation between Serum cobalamin with age, gestational age, BMI, Blood urea and serum creatinine (Table 4).

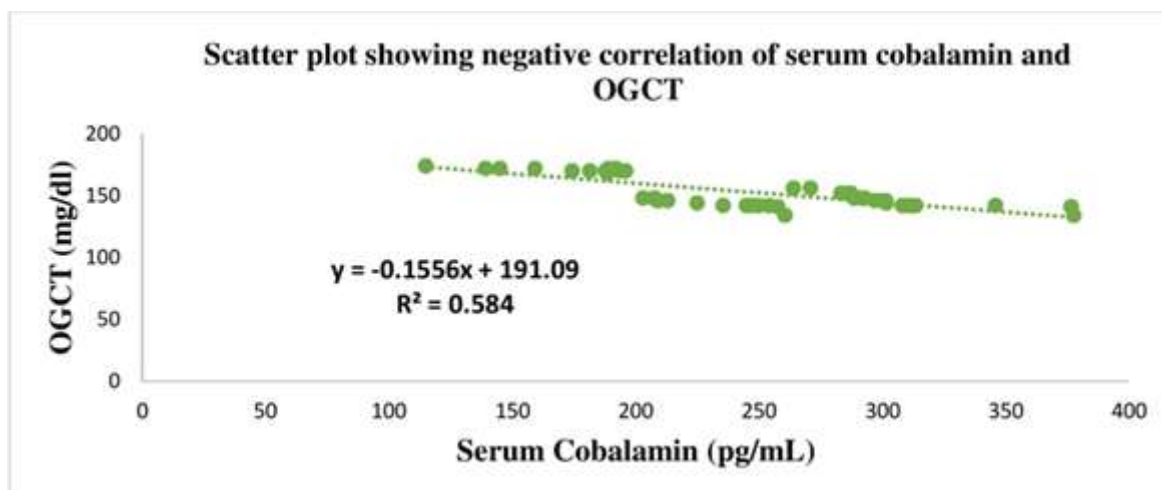


Figure 2. Scatter plot showing negative correlation of serum cobalamin and OGCT

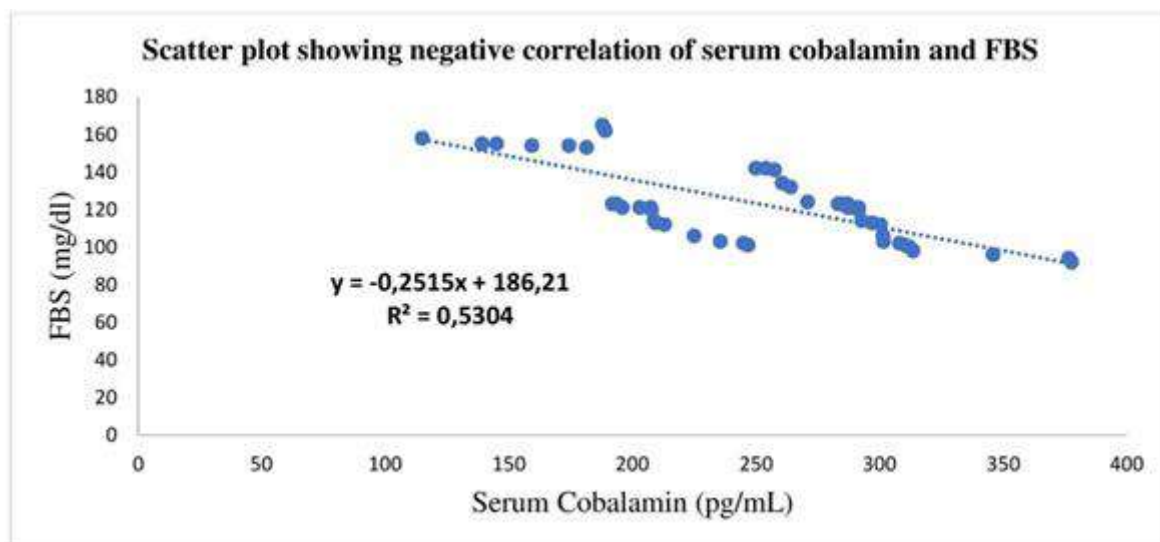


Figure 3. Scatter plot showing negative correlation of serum cobalamin and FBS

Table 4. Correlation of serum cobalamin in GDM group

Parameter	Pearson correlation coefficient	P value
Age	-0.064	0.660
Gestational age	-0.225	0.116
BMI	-0.135	0.350
OGCT	-0.764	<0.001*
FBS	-0.728	<0.001*
Blood urea	0.056	0.699
S. Creatinine	0.064	0.661

The Receiver Operating Characteristic (ROC) curve analysis of serum cobalamin showed cut-off threshold value as 301.7 (95% C.I = 287.2 to 313.6), with a sensitivity of 86%, and a specificity

of 92%. The area under the curve (AUC) was 0.954 (95% C.I = 0.892-0.986) with a statistically significant p value ( $p < 0.001$ ) (Table 4).

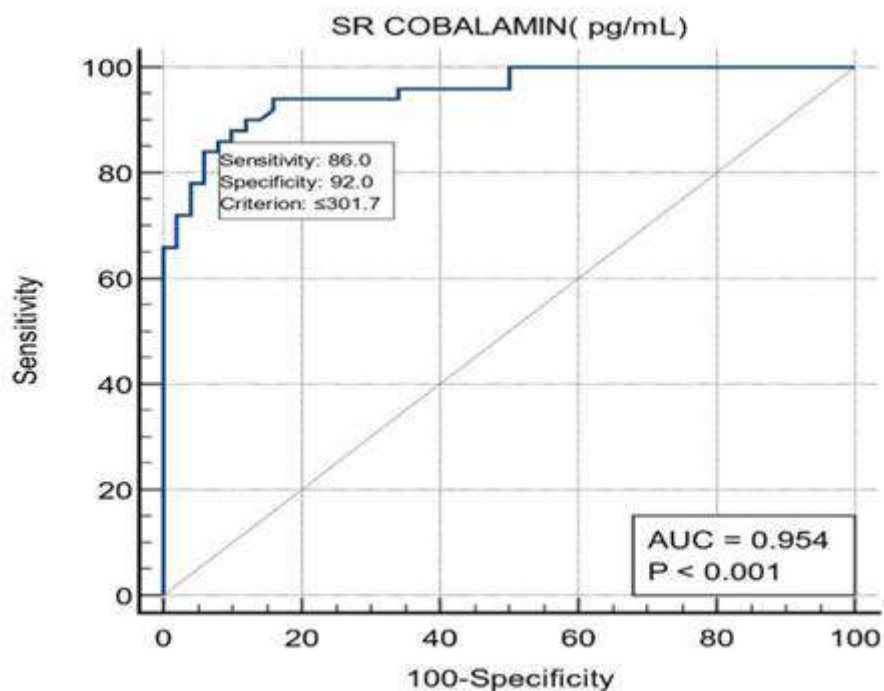


Figure 4. ROC curve for Serum Cobalamin levels

### Discussion

We have conducted a hospital based cross sectional study to find the serum cobalamin levels in GDM and non GDM Antenatal mothers. We have found that maternal serum cobalamin levels were low in GDM mothers than non GDM mothers and a negative correlation was seen with cobalamin and OGCT as well FBS levels which was similar to previous studies conducted by Saher Fatima<sup>1</sup> et al. [20] and Aesha Sadaf Rizwan et al. [21]. With a cut off of 300 pg/ml, our study has found 40 (80%) of 50 GDM mother had low cobalamin and only 3(6%) out of 50 non GDM mothers. The correlation we found in our study was in line with several international studies from various ethnicities and countries. Since metformin therapy was an exclusion criterion in the current study, the data hint to a more general vitamin B<sub>12</sub> insufficiency. Prior studies had shown that hypovitaminosis B<sub>12</sub> was common in GDM as a result of

metformin therapy. Maternal obesity being a modifiable risk factor for GDM as well as Insulin resistance, we have calculated BMI in both groups and it showed significant difference between both groups. Krishnaveni et al. [22] found a link between insulin resistance, obesity, serum cobalamin insufficiency and GDM.

The Receiver Operating Characteristic (ROC) curve analysis of serum cobalamin showed cut-off threshold value as 301.7 pg/ml with a significant AUC which was higher than optimal cutoff point for indicating gestational diabetes noted by Ambreen Butt et al. [23] (301.7 Vs 113 pg/mL). The exact mechanism by which low maternal B<sub>12</sub> contributing to the development of GDM is not well known. According to Adaikalakoteswari et al. [24], low cobalamin levels during pregnancy can increase the levels of adipose-derived circulating microRNAs, which may contribute to the development of insulin resistance. Low B<sub>12</sub> levels will lead to

hyperhomocysteinemia which in turn can have harmful effects on pancreatic  $\beta$ -cell metabolism and insulin secretion [25]. To support these facts, a trial conducted by Setola et al. [26] showed an improvement in insulin resistance after supplementation with Cobalamin. Therefore, it is considered that there are multiple contributing reasons to GDM, with B<sub>12</sub> deficiency being one of the major ones.

### Limitations

The sample size of the present study was relatively small. However, the participants were recruited from a similar socioeconomic background and ethnic group, and no significant difference in age was observed among them, thereby minimizing potential confounding effects related to these factors. Dietary habits and preconception vitamin B<sub>12</sub> status of the participants were not assessed, which may have influenced the study findings. Additionally, biochemical markers such as homocysteine and methylmalonic acid, which are considered more sensitive and specific indicators of vitamin B<sub>12</sub> deficiency, were not measured. The inclusion of these parameters could have provided a more comprehensive assessment of vitamin B<sub>12</sub> status.

### Conclusions

Maternal serum cobalamin levels may serve as a useful biomarker for identifying the risk of gestational diabetes mellitus (GDM) during pregnancy. Pregnant women with low serum cobalamin concentrations can be monitored more closely, enabling early intervention and reducing the risk of adverse outcomes for both the mother and the fetus. Since GDM is often diagnosed only after the first trimester, the fetus may already have been

exposed to elevated maternal glucose levels and associated metabolic disturbances during a critical period of development. Such exposure may contribute to fetal metabolic programming through epigenetic modifications, thereby increasing susceptibility to various chronic metabolic disorders later in life.

Early screening, timely diagnosis, and appropriate management of GDM can help prevent these unfavorable maternal and fetal outcomes. Furthermore, vitamin B<sub>12</sub> supplementation should be considered for populations at risk of deficiency, particularly in developing countries where malnutrition remains prevalent. Adequate vitamin B<sub>12</sub> status is important for optimal neurological development and may influence epigenetic mechanisms that affect long-term health. Therefore, serum vitamin B<sub>12</sub> levels should be taken into account when developing predictive and prognostic models for GDM, especially among women with established risk factors for the condition.

### Authors' Contributions

SP has contributed to the conceptualization and definition of the intellectual content of the manuscript, design of the study and Manuscript preparation. MAV contributed to the literature search, manuscript editing, and manuscript review. TU contributed towards data acquisition. Statistical analysis, Manuscript review and editing. SP will act as the corresponding author of the manuscript.

### Data availability statement

The datasets generated and analysed in this study are available from the corresponding author on reasonable request. They are not publicly shared.

because they contain sensitive information that could indirectly identify participants.

### **Ethical approval**

This study has been approved by the Institution Ethics Committee, Madras Medical College, Chennai. Ref.No:11052021 dated: 05-05-2021.

### **Informed Consent**

Written informed consent was obtained from all participants after explaining the study procedures, potential risks and benefits. Consent covered both participation and publication of anonymised findings, with assurance of confidentiality and data privacy.

### **Conflicts of interest**

The authors declare that they do not have conflict of interest.

### **Funding**

No funding was received for conducting this study.

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ORIGINAL ARTICLE

**A Prospective Comparative Study of Minimally Invasive Dynamic Hip Screw and Proximal Femoral Nailing in Intertrochanteric Femur Fractures**

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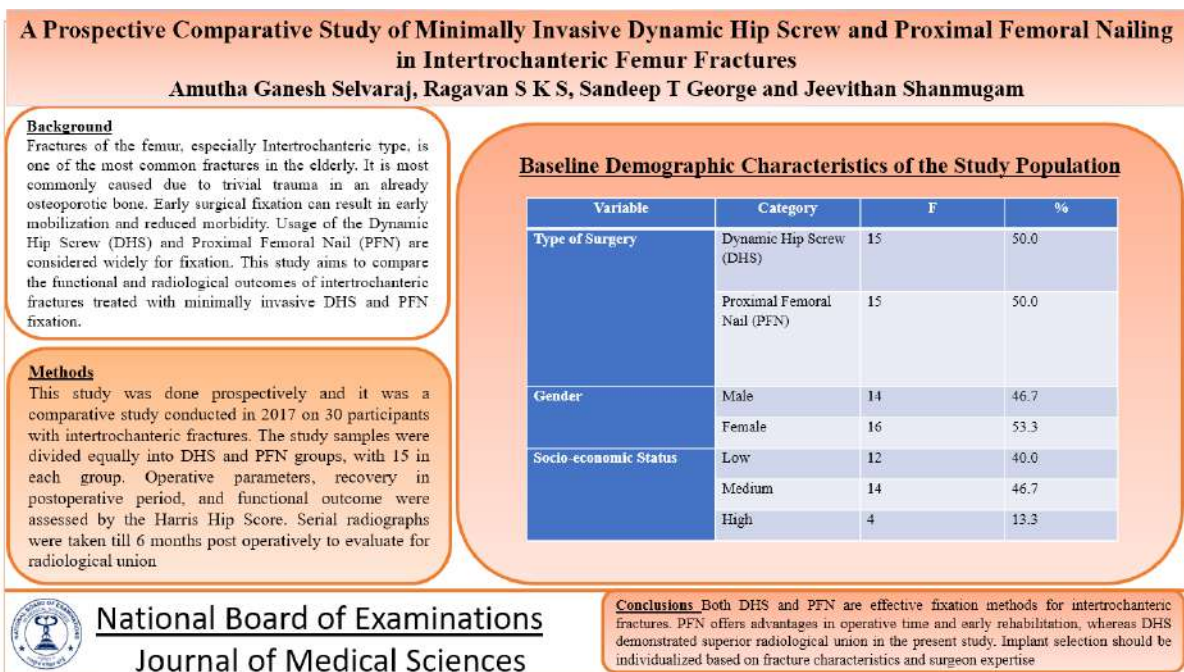
**Abstract**

**Introduction:** Fractures of the femur, especially Intertrochanteric type, is one of the most common fractures in the elderly. It is most commonly caused due to trivial trauma in an already osteoporotic bone. Early surgical fixation can result in early mobilization and reduced morbidity. Usage of the Dynamic Hip Screw (DHS) and Proximal Femoral Nail (PFN) are considered widely for fixation. This study aims to compare the functional and radiological outcomes of intertrochanteric fractures treated with minimally invasive DHS and PFN fixation. **Materials and Methods:** This study was done prospectively and it was a comparative study conducted in 2017 on 30 participants with intertrochanteric fractures. The study samples were divided equally into DHS and PFN groups, with 15 in each group. Operative parameters, recovery in postoperative period, and functional outcome were assessed by the Harris Hip Score. Serial radiographs were taken till 6 months post operatively to evaluate for radiological union. **Results:** The mean operative time was significantly lower in the PFN group (52.1 minutes) than in the DHS group (69.9 minutes). PFN allowed earlier full weight bearing (mean 3.6 weeks) compared to DHS (9.5 weeks). The mean Harris Hip Score at six weeks was significantly higher in the PFN group, but by 20 weeks, the difference was not statistically significant. Radiological assessment at six months showed excellent union in 73.3% of DHS cases and 26.7% of PFN cases (p=0.027). **Conclusion:** Both DHS and PFN are effective fixation methods for intertrochanteric fractures. PFN offers advantages in operative time and early rehabilitation, whereas DHS demonstrated superior radiological union in the present study. Implant selection should be individualized based on fracture characteristics and surgeon expertise.

**Keywords:** Intertrochanteric fracture, Dynamic Hip Screw, Proximal Femoral Nail, Functional outcome

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## Graphical Abstract



### Introduction

Intertrochanteric fractures of the femur are one of the most common fractures seen in the elderly, especially in women with osteoporosis in the postmenopausal age group. These types of injuries usually follow low-energy trauma like simple falls, which might also occur in younger individuals following high-energy impacts. With the betterment of life expectancy and the increasing prevalence of osteoporosis all around the world, the incidence of intertrochanteric fractures has been slowly increasing. This is an important cause of morbidity, mortality, and functional disability in the elderly. [1,2].

The main objectives in the treatment of intertrochanteric fractures are to achieve stable internal fixation, help with early mobilization, and restore the pre-injury functional status of the patients. Prolonged immobilisation is a complication of conservative treatment along with other complications like deep

vein thrombosis, pressure sores and lung infections. Therefore, the gold standard of management of Intertrochanteric fractures is surgical management as it allows early ambulation and reduces both mortality and morbidity [3].

The implant of choice for fixing of stable intertrochanteric fractures has been the Dynamic Hip Screw (DHS) since a few years, offering the advantage of controlled collapse and compression at the fracture site helping in faster union of the fracture. But for comminuted or unstable fracture patterns or with posteromedial cortical disruption, the DHS has few biomechanical limitations like excessive sliding of the lag screw, varus collapse, and potential cut-out of the screw through the femoral head which can lead to implant failure [4].

The Proximal Femoral Nail (PFN) is an Intramedullary device which was invented to tackle implant failure. Using PFN has many mechanical advantages because of its shorter length of lever arm

and placing the PFN closer to the mechanical axis of the femur in a closed insertion technique that reduces soft tissue injury and blood loss. Many older previous studies have shown that PFN allows better biomechanical stability, lesser operative time and intraoperative blood loss, and leads to earlier mobilization compared to DHS, particularly in unstable fracture configurations [5–7].

Although both DHS and PFN have established roles in the management of intertrochanteric fractures, the superiority of one implant over the other with respect to functional and radiological outcomes remains a subject of ongoing debate. Few studies have found comparable long-term outcomes between the two methods, while others have highlighted the earlier rehabilitation potential associated with PFN. Hence, there is a high need for prospective comparative analyses assessing the two implants under similar clinical conditions.

In this context, our present study was done to assess the functional and radiological outcomes of intertrochanteric fractures managed with less invasive Dynamic Hip Screw and Proximal Femoral Nail, and to compare their results in terms of operative details, postoperative recovery, and early functional outcome.

### **Materials and Methods**

The present study was a prospective comparative study done in the Department of Orthopaedics at a tertiary care teaching hospital in Tamilnadu in the year 2017. Institutional ethical committee approval was obtained before the start of the study. Written informed consent was obtained from all patients who were included in the study. The patients were managed surgically either by minimally

invasive Dynamic Hip Screw (DHS) fixation or by Proximal Femoral Nailing (PFN). Confidentiality was maintained and principles of Declaration of Helsinki was adhered to throughout the study.

30 patients were included in the study where 15 patients were managed using minimally invasive DHS and 15 were managed with PFN. All patients above 40 years of age presenting with closed intertrochanteric fractures of the femur were included in the study and patients with open fractures, pathological fractures, associated shaft or neck femur fractures, or previous ipsilateral hip surgery were excluded from the study. Based on preoperative radiographs, the fractures were classified according to the classification system of Boyd and Griffin. Patients were allocated alternately into either group to be able to compare demographic and clinical distribution between the two modalities of treatment.

All patients underwent routine preoperative evaluation including clinical assessment, routine hematological investigations with radiographic confirmation of the pattern of fracture. Surgery was done under spinal or general anesthesia which was chosen based on the fitness levels of the patients. For the DHS group, a lateral approach was used with a small incision technique, and fixation was achieved using a standard 135° barrel plate after guidewire placement under fluoroscopic guidance. For the PFN group, a closed intramedullary technique was employed using a proximal femoral nail of appropriate size, inserted through a small incision over the tip of the greater trochanter. All procedures were performed by surgeons experienced in both techniques to minimize operator-related bias.

Intraoperative parameters like duration of surgery, estimated blood loss, and length of incision were noted and postoperatively, patients were administered analgesics and antibiotics according to standard protocol. Early mobilization and physiotherapy were initiated depending on the stability of fixation and tolerance of pain. The duration of hospital stay along with time taken for partial and full weight bearing were noted. Suture removal was done on the 10th postoperative day, and radiographic assessment was performed to confirm alignment and position of implant.

All patients were followed up at 6, 12 and 20 weeks postoperatively and 6 months for functional and radiological union. Functional outcome was assessed using the Harris Hip Score which evaluated pain, function, absence of deformity, and range of motion. Radiological assessment of union was done using serial anteroposterior and lateral radiographs of the hip, and fracture union was defined as cortical continuity in at least three cortices. Depending on the alignment and consolidation of the fractures, the radiological outcomes at 6 months were graded as fair, good, or excellent.

All collected data were compiled and tabulated for analysis. Operative

details, postoperative recovery parameters, and functional outcomes were compared between the DHS and PFN groups to evaluate the relative efficacy of both fixation methods in achieving stable fixation and early rehabilitation among patients with intertrochanteric fractures. Frequencies and percentages were used to summarize categorical variables, while continuous variables were expressed as mean  $\pm$  standard deviation. Continuous variables were compared using the Mann–Whitney U test. Categorical variables were compared using the Chi-square test. A p value  $<0.05$  was considered statistically significant.

## Results

The study included 30 patients, with an equal number in the DHS group and the PFN group (15 each). A slight female predominance was seen, with 53.3% females and 46.7% males. Most patients belonged to the medium socio-economic class (46.7%), followed by the low-income group (40%) and 13.3% were from the high socio-economic group. (Table 1) The baseline demographic characteristics of the two study groups were comparable, thereby permitting meaningful comparison of operative, functional, and radiological outcomes.

Table 1. Baseline Demographic Characteristics of the Study Population

Variable	Category	F	%
Type of Surgery	Dynamic Hip Screw (DHS)	15	50.0
	Proximal Femoral Nail (PFN)	15	50.0
Gender	Male	14	46.7
	Female	16	53.3
Socio-economic Status	Low	12	40.0
	Medium	14	46.7
	High	4	13.3

Table 2 compares the side of fracture among patients treated with DHS and PFN. Left-sided intertrochanteric fractures were more common in both groups, accounting for 73.3% in the DHS group and 53.3% in the PFN group.

Although right-sided fractures were relatively more frequent in the PFN group (46.7% vs 26.7%), the difference in side distribution between the two groups was not statistically significant ( $\chi^2 = 1.292$ ,  $p = 0.260$ ).

Table 2. Distribution of Side of Fracture Between DHS and PFN

Side of Fracture	DHS (n=15)	PFN (n=15)	$\chi^2$	p-value
Right	4 (26.7%)	7 (46.7%)	1.292	0.260
Left	11 (73.3%)	8 (53.3%)		

Table 3 summarizes the comparison of operative, post-operative, and functional parameters between the two surgical techniques. The mean duration of surgery was significantly lower in the PFN group (52.1 minutes) compared to the

DHS group (69.9 minutes), and this difference was highly significant ( $p < 0.001$ ). Similarly, patients treated with PFN were operated earlier following the fracture than those treated with DHS (mean 5.8 vs 7.2 days,  $p = 0.014$ ).

Table 3: Comparison of Operative and Post-operative Parameters in DHS and PFN Groups

Parameter	DHS (Mean $\pm$ SD)	PFN (Mean $\pm$ SD)	p-value
<b>Operative details</b>			
Time from fracture to surgery (days)	7.2 $\pm$ 1.85	5.8 $\pm$ 0.95	0.014
Duration of surgery (minutes)	69.9 $\pm$ 3.21	52.1 $\pm$ 2.81	<0.001
<b>Implant details</b>			
Lag screw length (mm)	84.5 $\pm$ 4.56	86 $\pm$ 4.35	0.364
<b>Post-operative outcome</b>			
Duration of hospital stay (days)	6.8 $\pm$ 1.23	6.2 $\pm$ 1.01	0.155
Time to full weight bearing (weeks)	9.5 $\pm$ 1.65	3.6 $\pm$ 0.95	<0.001
<b>Functional outcome</b>			
Harris Hip Score – 6 weeks	69.34 $\pm$ 3.56	81.23 $\pm$ 4.21	<0.001
Harris Hip Score – 20 weeks	80.2 $\pm$ 4.65	83.57 $\pm$ 4.93	0.064

Although there was no significant difference in hospital stay ( $p = 0.155$ ), PFN allowed significantly earlier full weight bearing (mean 3.6 weeks) compared to DHS (9.5 weeks,  $p < 0.001$ ). Functional outcomes were assessed using the Harris Hip Score, which showed better

scores in the PFN group at 6 weeks ( $p < 0.001$ ), although by 20 weeks, the difference between the two groups was not statistically significant ( $p = 0.064$ ), suggesting eventual functional convergence over time.

Table 4 presents the radiological outcomes at six months. A significantly higher proportion of patients in the DHS

group achieved excellent radiological union (73.3%) compared with the PFN group (26.7%) ( $p = 0.027$ ).

Table 4: Radiological Outcome at 6 Months (X-ray Assessment)

Category	DHS (n=15)	PFN (n=15)	p-value
Fair	0 (0%)	2 (13.3%)	0.027
Good	4 (26.7%)	9 (60.0%)	
Excellent	11 (73.3%)	4 (26.7%)	

## Discussion

In the present prospective study, comparison between the minimally invasive Dynamic Hip Screw (DHS) and the Proximal Femoral Nail (PFN) was done mainly focusing on the functional and radiological outcomes in the management of intertrochanteric fractures of the femur. The mean age group corresponded to the typical demographic profile of intertrochanteric fractures noted by most studies, showing that it is most common among elderly osteoporotic females, attributed to increased susceptibility to low-energy trauma [1,2]. The slight female predominance noted in our study is similar to previous reports linking the higher incidence to post-menopausal bone loss, osteoporosis and fragility due to increased age [3].

The mean operative duration in our study was lesser in the PFN group compared to the DHS group, underscoring the procedural advantage of intramedullary fixation. This observation is consistent with previous studies done by Zhang et al. (2014) [4], who observed that a smaller incision was only needed for PFN fixation, thereby minimal soft-tissue dissection, and reduced blood loss. Similar findings were made by Saudan et al. (2002) [5], who observed that PFN attains fixation through

a closed technique with lesser operative trauma. In the present study, the mean time from fracture to surgery was also lesser in the PFN group. This fact could be due to its simpler preoperative preparation and shorter operative setup time.

The postoperative recovery outcomes were favourable for PFN in terms of earlier full weight bearing achieved in an average of 3.6 weeks compared to 9.5 weeks in the DHS group. This finding is consistent with the studies done by Jonnes et al. (2016) [6] and Kumar et al. (2013) [7], both of whom delineated that intramedullary fixation, especially of unstable fractures enables early rehabilitation and mobilization. Early ambulation allows better functional outcomes, and also reducing the incidence of complications of surgery and immobilisation in elderly.

The functional outcomes were assessed using the Harris Hip Score. It showed a statistically significant difference in favour of PFN at 6 weeks, though the difference became insignificant by 20 weeks. This finding substantiates the conclusions of previous studies which showed faster and earlier recovery with PFN but comparable long-term outcomes with DHS [6,8]. Hence, while PFN offers mechanical and early functional

advantages, both implants can provide satisfactory long-term results when appropriately indicated and technically executed.

Radiological outcomes in the current study illustrated that DHS attains a higher rate of excellent union at 6 months compared to PFN, in contrast with earlier studies done by Zhang et al. (2014) [4] and Parker and Handoll (2010) [9], which reported marginally faster union rates with intramedullary devices. The difference in our present study can be attributed to variations in fracture pattern, implant positioning, or the learning curve associated with PFN insertion. However, both groups achieved satisfactory union without major complications such as implant breakage or non-union, consistent with the results of previous randomized and meta-analytic trials [5,7,9].

Overall, the present study reiterates that minimally invasive DHS and PFN are effective treatment options for intertrochanteric fractures. PFN has an upper hand in terms of lesser operative time and soft-tissue disruption, and earlier functional recovery, whilst DHS demonstrated superior radiological union in the present study with fewer technical difficulties. The choice of implant should therefore be individualized based on fracture stability, patient comorbidity, and surgeon expertise.

The findings of the present study are also supported by recent evidence. A large systematic review and meta-analysis by Rasul et al. [10] demonstrated that PFN offers significant advantages in operative parameters and early postoperative recovery while maintaining comparable long-term functional outcomes to DHS. Similarly, Backman et al. [11] reported superior postoperative rehabilitation

outcomes with intramedullary devices compared to DHS. Recent studies by Ripon et al. [12] and Zhou et al. [13] further confirmed the benefits of PFN in terms of shorter operative duration, earlier mobilization, and improved early functional scores. These contemporary findings reinforce the observation of the present study that PFN provides superior early functional recovery, although both fixation methods yield satisfactory long-term outcomes.

### **Limitations**

The present study has certain limitations. The sample size was relatively small, with only 30 patients included, which may limit the generalizability of the findings. The follow-up period was limited to six months and may not fully reflect long-term functional and radiological outcomes. Although fractures were classified according to the Boyd and Griffin classification, subgroup analysis according to fracture stability was not performed. Larger multicentric studies with longer follow-up are recommended to validate these findings.

### **Conclusion**

Both minimally invasive Dynamic Hip Screw (DHS) fixation and Proximal Femoral Nailing (PFN) were successful in the surgical management of intertrochanteric fractures. PFN offered advantages of shorter operative time, reduced soft-tissue injury, and earlier mobilization, while DHS demonstrated superior radiological union in the present study. Although PFN showed earlier functional recovery, long-term outcomes were comparable between the two techniques. Hence, implant selection should be individualized based on fracture

characteristics, patient factors, and surgeon expertise.

### Statements and Declarations

#### Conflicts of interest

The authors declare that they do not have conflict of interest.

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ORIGINAL ARTICLE

**Factors Influencing the Success of Optical Internal Urethrotomy for Short-Segment Bulbar Urethral Strictures**

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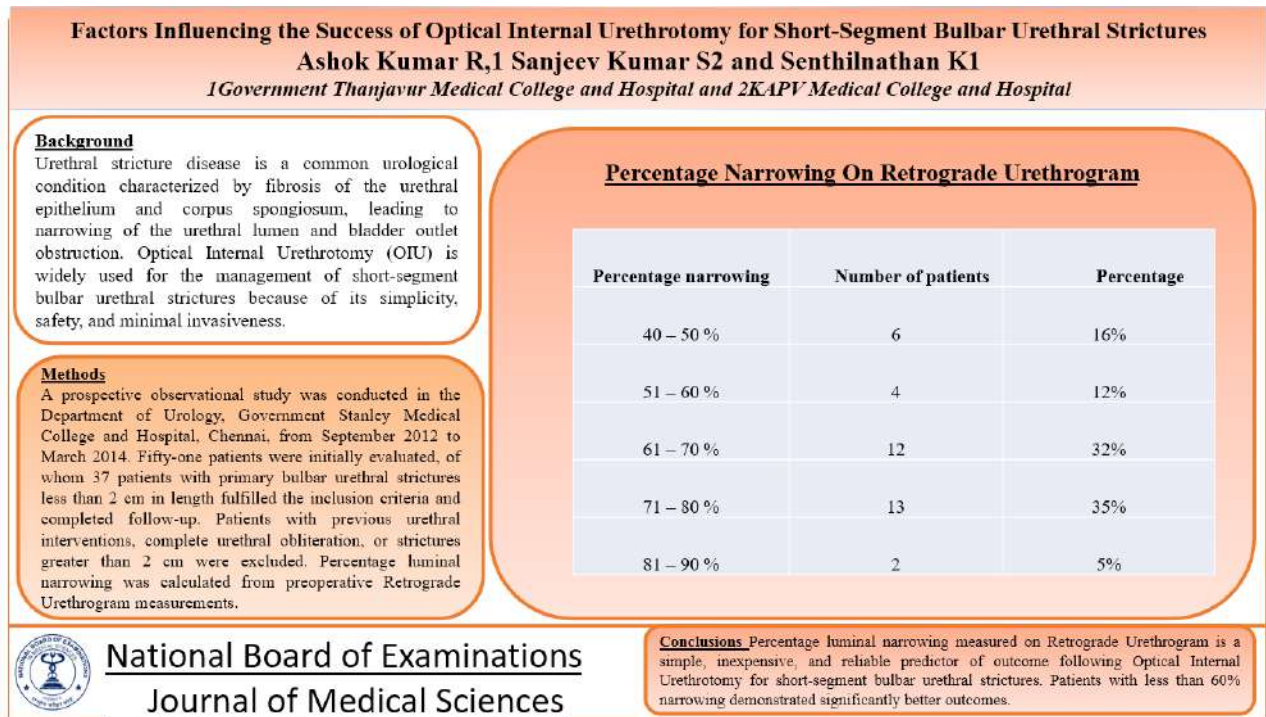
**Abstract**

**Background:** Urethral stricture disease is a common urological condition characterized by fibrosis of the urethral epithelium and corpus spongiosum, leading to narrowing of the urethral lumen and bladder outlet obstruction. Optical Internal Urethrotomy (OIU) is widely used for the management of short-segment bulbar urethral strictures because of its simplicity, safety, and minimal invasiveness. However, recurrence following OIU remains a major challenge. Several factors have been studied as predictors of recurrence, but the role of percentage luminal narrowing on Retrograde Urethrogram (RGU) has not been extensively evaluated. **Methodology:** A prospective observational study was conducted in the Department of Urology, Government Stanley Medical College and Hospital, Chennai, from September 2012 to March 2014. Fifty-one patients were initially evaluated, of whom 37 patients with primary bulbar urethral strictures less than 2 cm in length fulfilled the inclusion criteria and completed follow-up. Patients with previous urethral interventions, complete urethral obliteration, or strictures greater than 2 cm were excluded. Percentage luminal narrowing was calculated from preoperative Retrograde Urethrogram measurements. **Results:** The study included 37 patients, with the majority belonging to the 31–40 years age group (32%). Idiopathic stricture was the most common etiology (41%), followed by traumatic (27%), iatrogenic (19%), and lichen sclerosus-related strictures (13%). Eleven patients (29.7%) achieved successful outcomes, whereas 26 patients (70.3%) experienced recurrence. All patients with luminal narrowing between 40% and 60% had successful outcomes. Among patients with luminal narrowing greater than 60%, 25 out of 28 experienced recurrence. Most recurrences occurred within the first 10 months following surgery. A statistically significant association was observed between percentage luminal narrowing and treatment outcome ( $p < 0.001$ ). **Conclusion:** Percentage luminal narrowing measured on Retrograde Urethrogram is a simple, inexpensive, and reliable predictor of outcome following Optical Internal Urethrotomy for short-segment bulbar urethral strictures. Patients with less than 60% narrowing demonstrated significantly better outcomes than those with greater than 60% narrowing.

**Keywords:** Urethral stricture, Optical Internal Urethrotomy, Retrograde Urethrogram, Bulbar urethral stricture, Luminal narrowing, Spongiofibrosis, Recurrence

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## Graphical Abstract



### Introduction

Urethral stricture disease is a common urological disorder that continues to pose a significant clinical and economic burden worldwide. The condition is characterized by fibrosis of the urethral epithelium and corpus spongiosum, resulting in narrowing of the urethral lumen and varying degrees of bladder outlet obstruction [2]. Historically, urethral stricture was described by the ancient Indian surgeon Sushruta as “Mutra Marga Sankocha,” which was managed by dilatation using lubricated instruments [1].

The incidence of urethral stricture disease in Western populations has been estimated at approximately 0.6%, although the actual incidence may be higher in developing countries such as India [2]. Over the years, the etiology of urethral stricture disease has undergone a significant shift. While infectious causes were previously predominant, trauma

and iatrogenic instrumentation have now emerged as the leading causes of urethral strictures [3]. Additionally, inflammatory conditions such as lichen sclerosus contribute significantly to the burden of urethral stricture disease [7].

The pathological hallmark of urethral stricture disease is spongiofibrosis, which results in progressive narrowing of the urethral lumen and deterioration of urinary flow [5,6]. Patients commonly present with lower urinary tract symptoms including poor urinary stream, straining, hesitancy, intermittency, post-void dribbling, recurrent urinary tract infections, and urinary retention. Severe untreated disease may lead to complications such as urethrocutaneous fistula, Fournier’s gangrene, and renal dysfunction [2].

Retrograde urethrography (RGU) remains the standard imaging modality for evaluating urethral strictures, providing

valuable information regarding stricture location, length, and severity. Although sonourethrography is useful for assessing the degree of spongiofibrosis, its availability is limited and it remains highly operator dependent [6,22]. Consequently, there is a need for a simple, reproducible, and widely available method of predicting treatment outcomes.

Optical Internal Urethrotomy (OIU), first popularized by Sachse, remains one of the most commonly performed minimally invasive procedures for short-segment bulbar urethral strictures due to its simplicity, safety, and short learning curve [12,13]. However, long-term outcomes following OIU remain variable, with recurrence rates ranging from 25% to 68% in different studies [20,21]. Several factors including stricture length, location, degree of spongiofibrosis, previous interventions, infection, and urethral calibre have been identified as predictors of recurrence [15–27].

Mandhani et al. demonstrated that the degree of luminal narrowing on Retrograde Urethrogram could serve as a predictor of OIU outcome in short-segment bulbar strictures [27]. However, limited data exist regarding its applicability in routine clinical practice. Therefore, the present study was undertaken to evaluate whether the percentage luminal narrowing measured on preoperative Retrograde Urethrogram can predict the outcome of Optical Internal Urethrotomy in patients with short-segment bulbar urethral strictures.

### **Aims and objectives**

To predict the outcome of Optical Internal Urethrotomy in patients with short-segment bulbar urethral strictures by

measuring the percentage luminal narrowing at the stricture site on Retrograde Urethrogram.

## **Materials and Methods**

### ***Study Design***

This prospective observational study was conducted in the Department of Urology, Government Stanley Medical College and Hospital, Chennai, between September 2012 and March 2014.

### ***Study Population***

Patients presenting with primary bulbar urethral strictures were considered for inclusion in the study.

### ***Inclusion Criteria***

- Primary bulbar urethral stricture.
- Stricture length less than 2 cm.

### ***Exclusion Criteria***

- Previous intervention in the form of urethral dilatation, Optical Internal Urethrotomy, or urethroplasty.
- Complete obliteration of the urethral lumen.
- Stricture length greater than 2 cm.

### **Methodology**

A total of 51 patients were initially evaluated, of whom 37 fulfilled the study criteria and completed follow-up. All patients underwent detailed clinical evaluation, routine laboratory investigations, uroflowmetry, and high-quality Retrograde Urethrogram.

On the Retrograde Urethrogram, the site of maximum narrowing was identified and measured. The diameter of the normal distal urethral lumen was used as the reference diameter because this segment was maximally distended during contrast injection. The

percentage luminal narrowing was calculated by comparing the diameter at the stricture site with the normal distal urethral diameter.

All patients subsequently underwent Optical Internal Urethrotomy using a standard 20 Fr Sachse urethrotome. Following surgery, a Foley catheter was retained for seven days. After catheter removal, patients were instructed to perform Clean Intermittent Self-Catheterization (CISC) using a 14 Fr Tiemann catheter once daily for one month and subsequently once every three days.

Follow-up evaluation included clinical assessment and uroflowmetry at three and six months. Treatment failure was defined as recurrence of symptoms, inability to pass the self-catheter, or the requirement for repeat Optical Internal Urethrotomy.

### Statistical Analysis

The relationship between percentage luminal narrowing and treatment outcome was analyzed. A p-value <0.001 was considered statistically significant.

## Results

Table 1. Age distribution

Age in years	Number of patients	Percentage
21 – 30	4	11%
31 – 40	12	32%
41 – 50	10	27%
>50	11	30%

In our study of 37 patients, majority of the patients, i.e., 32% of them were in the age group of 31–40 years;30% more than 50 years;

27 % in 41–50 years and 4 patients in the age group 21–30 years.

Table 2. Etiology distribution

Etiology	Number of patients	Percentage
Idiopathic	15	41%
Traumatic	10	27%
Iatrogenic	7	19%
Lichen sclerosus	5	13%

In our study, the most common etiology was found to be idiopathic (41%) followed by traumatic (10%), iatrogenic (19%)

and finally lichen sclerosus (13%). Iatrogenic causes include traumatic catheterization or instrumentation.

Table 3. Stricture Length distribution

<b>Stricture length</b>	<b>Number of patients</b>	<b>Percentage</b>
< 1cm	15	41 %
1 – 2 cm	22	59%

In our study, 15 patients (41%) had a stricture length below 1 cm and 22 patients. (59%) had a stricture length between 1 and 2 cm.

Table 4. Percentage Narrowing on Retrograde Urethrogram

Percentage narrowing	Number of patients	Percentage
40 – 50 %	6	16%
51 – 60 %	4	12%
61 – 70 %	12	32%
71 – 80 %	13	35%
81 – 90 %	2	5%

The percentage narrowing was calculated from the retrograde urethrogram as described previously with the help of a scale or a vernier calipers. It was found that out of the 37 cases, 13 patients had a

narrowing in the range of 71 – 80%; 12 patients in the range of 62 – 70%; 6 patients in the range of 40 – 50%; 4 patients in the range of 51 – 60% and 2 patients in the range of 81 – 90%.

Table 5. Treatment Result According to Percentage Narrowing on the Retrograde Urethrogram

Percentage Narrowing	Treatment Success	Treatment Failure
40 – 50%	6	-
51– 60%	4	-
61 – 70%	1	11
71 – 80%	-	13
81 – 90%	-	2

In our study, out of the 11 patients who did not have recurrence, 6 patients had a percentage narrowing in the range of 40 – 50%; 4 patients had a percentage narrowing

in the range of 51–60% and one patient had a percentage narrowing in the range of 61–70%.

Table 6. Time of Recurrence in Failure Cases

Time of Recurrence	Number of Patients
5 – 7 months	13
8 – 10 months	8
>10 months	5

Most of the recurrences in the failure patients occurred in the first 5 to 7 months. In our study, out of the 26 treatment failure cases, around 13 patients failed in the first 5 to 7 months. Around 8 patients failed in the first 8 to 10 months and the remaining 5 failure patients had recurrence after 10 months.

## Discussion

Optical Internal Urethrotomy remains one of the most frequently performed procedures for short-segment bulbar urethral strictures because of its technical simplicity, low morbidity, and ease of learning [12,13]. Despite its widespread use, recurrence remains a major limitation, with reported long-term success rates varying considerably across different studies [18–21].

In the present study, the percentage luminal narrowing measured on Retrograde Urethrogram was found to be significantly associated with treatment outcome. Among the 11 patients who achieved successful outcomes, 10 had luminal narrowing between 40% and 60%, whereas 26 of the 28 patients with narrowing greater than 60% experienced recurrence. This association was statistically significant ( $p < 0.001$ ).

The degree of luminal narrowing can be considered a surrogate marker for the severity of underlying spongiosclerosis. Previous studies have demonstrated that dense spongiosclerosis is associated with poorer outcomes following Optical Internal Urethrotomy and often necessitates urethroplasty [22]. Sonourethrography has traditionally been used to assess spongiosclerosis; however, its utility is limited by availability and operator dependency [6,22]. In contrast, Retrograde Urethrogram is routinely performed in

almost all patients undergoing evaluation for urethral stricture and therefore offers a practical alternative for predicting outcomes.

The findings of the present study are consistent with those of Mandhani et al., who reported that the degree of narrowing on urethrography could predict the success of Optical Internal Urethrotomy in short-segment bulbar strictures [27]. Similarly, Pansadoro and Emiliozzi demonstrated that shorter strictures with larger luminal calibres had better long-term outcomes following OIU [21]. Albers et al. also reported recurrence rates ranging from 26.9% to 44.6% depending on patient characteristics and duration of follow-up [20].

Several additional factors have been implicated in recurrence following OIU, including stricture length, site, prior intervention, infection, and number of strictures [15,19,23–26]. Bulbar strictures less than 2 cm in length are generally associated with more favourable outcomes because of their superior vascularity and lower degree of fibrosis [15,24].

Most recurrences in the present study occurred within the first 10 months following surgery. This observation is in agreement with previous studies demonstrating that the majority of restriures develop during the first postoperative year [18–21]. Consequently, careful follow-up during this period is essential for early detection and intervention.

The present study suggests that percentage luminal narrowing measured on Retrograde Urethrogram is a simple, inexpensive, reproducible, and clinically useful predictor of OIU outcome. Patients demonstrating severe narrowing ( $>60\%$ ) should be counselled regarding the high

likelihood of recurrence and may benefit from early consideration of definitive reconstructive procedures such as urethroplasty [8,9].

### Conclusion

Optical Internal Urethrotomy remains a safe and effective minimally invasive treatment option for carefully selected patients with short-segment bulbar urethral strictures. However, the procedure should not be performed indiscriminately because inappropriate patient selection may result in repeated interventions, increased healthcare costs, and reduced quality of life.

The present study demonstrates that percentage luminal narrowing measured at the site of maximum stricture on Retrograde Urethrogram serves as a practical surrogate marker for the degree of spongiofibrosis and can be used to predict treatment outcome following Optical Internal Urethrotomy.

Patients with less than 60% luminal narrowing experienced significantly better outcomes than those with narrowing greater than 60% ( $p < 0.001$ ). Therefore, measurement of percentage narrowing on Retrograde Urethrogram should be considered during preoperative assessment to facilitate patient counseling, optimize treatment selection, and improve long-term outcomes.

### Statements and Declarations

#### Conflicts of interest

The authors declare that they do not have conflict of interest.

#### Funding

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ORIGINAL ARTICLE

**Reward Hijack: Does Social Media Over Usage, Reduce the Brain's Sensitivity to Study-Related Effort? A Cross-sectional Questionnaire Based Study in MBBS and Paramedical Students**

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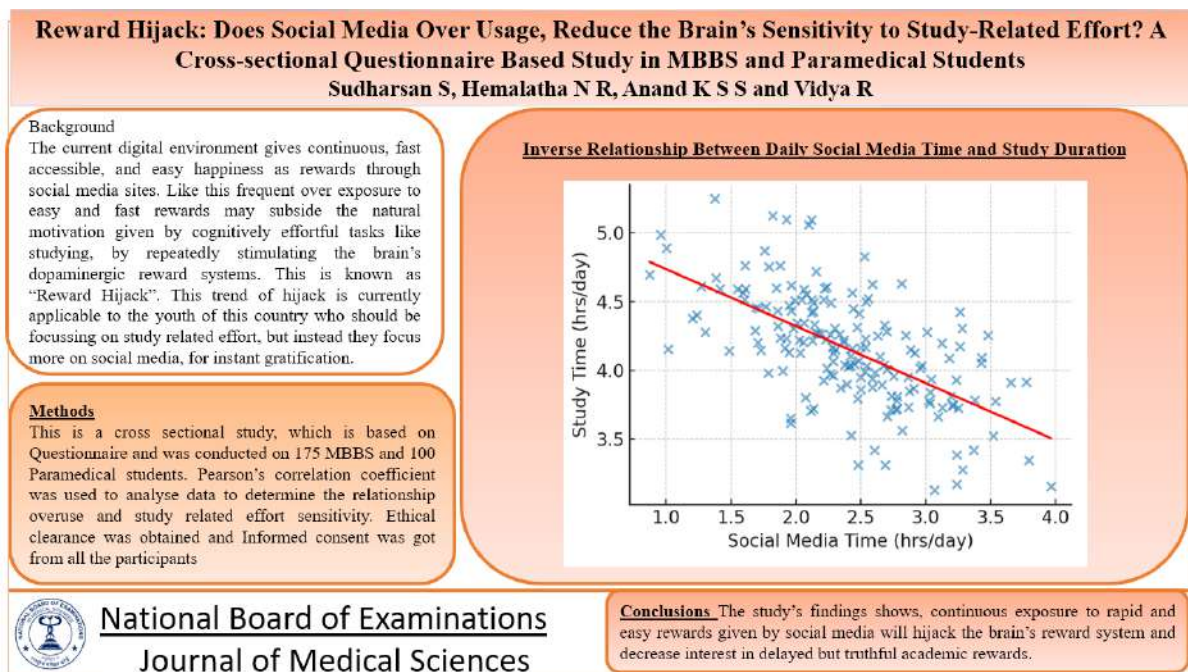
**Abstract**

**Background:** The current digital environment gives continuous, fast accessible, and easy happiness as rewards through social media sites. Like this frequent over exposure to easy and fast rewards may subside the natural motivation given by cognitively effortful tasks like studying, by repeatedly stimulating the brain's dopaminergic reward systems. This is known as "Reward Hijack". This trend of hijack is currently applicable to the youth of this country who should be focussing on study related effort, but instead they focus more on social media, for instant gratification. **Objectives:** To find the association between Social Media Over usage and Study related effort sensitivity among Medical and Paramedical students in India. **Materials and Methods:** This is a cross sectional study, which is based on Questionnaire and was conducted on 175 MBBS and 100 Paramedical students. Pearson's correlation coefficient was used to analyse data to determine the relationship overuse and study related effort sensitivity. Ethical clearance was obtained and Informed consent was got from all the participants. **Results:** The results showed that the mean social media overuse score was  $3.18 \pm 0.82$ , and the mean effort sensitivity score was  $3.52 \pm 0.74$ . These two variables suggest a moderate negative correlation ( $r = -0.41$ ,  $p = 0.0002$ ), which indicate that higher social media usage was associated with decreased motivation and sensitivity toward study related effort. **Conclusion:** The study's findings shows, continuous exposure to rapid and easy rewards given by social media will hijack the brain's reward system and decrease interest in delayed but truthful academic rewards. Such reward hijacks could be prevented by conducting awareness programmes and teaching strategies to come out of the social media usage.

**Key words:** Reward Hijack, Social Media over usage, Study related effort, Dopaminergic system, Medical Students, Paramedical students

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## Graphical Abstract



### Introduction

The Social Media platforms provides instant happiness by activating dopaminergic reward pathways [1], through Likes, Comments, Reels, Easy chatting texts and their notifications. When students repeatedly use social media, after they think it gives a happy feeling, then they will start to decrease focus on natural rewards like studying for exams and achieving good grades, which are slow but meaningful rewards. This is known as "Reward Hijack phenomenon" [2]. The students who are addicted to social media over usage will struggle to engage in study related activities [3]. This in turn leads to altering the reward sensitivity and also causes decreased study related motivation, distraction, smartphone addiction and short attention spans among these students [4].

The current study aims to find whether the Social Media over usage, reduces the brain's sensitivity for study related effort in medical and paramedical students in India. This study also aims to

find and express neurobehavioral perspective for this Reward Hijack phenomenon in Medical and paramedical students in India.

### Materials and Methods

#### Study design

This study is a cross sectional study and was conducted on Medical (MBBS) and paramedical students, to find whether the Social Media over usage, reduces the brain's sensitivity for study related effort sensitivity [5]. The cross sectional design helped in simultaneous assessment of various behavioural patterns and motivational patterns along with their outcomes in a natural academic setting. This study design was very much appropriate because it covered prevalence and intensity of student's digital usage behaviours in a single time frame, in which participant's habits were not influenced. To ensure realistic assessment of study related behaviours, this study was conducted in a

period of 3 months which coincides with their academic semester.

### **Ethical considerations**

The Ethical approval was received from Institutional Ethics Committee. All participants gave written informed content, before starting the study. The study followed the ethical rules directed by Declaration of Helsinki (2013) [6]. The information of the participants like name, age, registration numbers and contact details were maintained confidentially. The participants were not forced and their participation for study was entirely voluntary and also they were allowed to withdraw at any point of time of the study.

### **Participants**

A total of 275 students were recruited for the study. Out of which 175 were MBBS students and 100 were undergraduate paramedical students. Both MBBS and Paramedical students were from different colleges in Mandya district, Karnataka and the study was not conducted in the same institution as that of the researchers to avoid selection bias. The Inclusion criteria was set as, active usage of atleast one social media platform, age above 18 years & willingness to participate in the study [7]. The students with Neurological, Psychiatric disorders were excluded from the study. The demographic data was also collected to include subgroup analysis in the study. These data included age, gender, academic year and average social media usage time. Diversity was ensured during sampling, by including students from preclinical and also clinical phases of study.

### **Data collection**

The data was collected using a validated, structured, self administered online questionnaire, which was designed in a way such that it included both social media behaviour and academic motivation [8]. The average time for completion of this questionnaire was around 10 - 12 minutes. Initially pilot testing was done 20 students to ensure content clarity and it's validity, so that modifications could be made on feedback from them. There was no negative feedbacks or changes suggested by these students. So the main study was continued without any changes. The following scales and their components were incorporated in the questionnaire of the study

1. **Social Media Overuse Scale (SMOS):** This scale was used to evaluate the frequency, duration and dependence of social media overusage [9]. In the questionnaire, the following components from this scale were asked as questions, like Daily usage, Compulsive checking, how social media interferes with academic work and how it makes a student getting addicted to it like dependence. The responses were scored on a Likert scale with 5 points (1= strongly disagree, 5=strongly agree). The higher score indicated more social media overusage. This SMOS indicated high internal consistency (Cronbach's alpha = 0.87).
2. **Study related Effort Sensitivity Scale (SRESS):** This scale evaluated participant's willingness, motivation and perceived reward for effortful academic tasks [10]. From this scale, the following components were asked as questions like, sustained study duration, preference for immediate vs delayed academic rewards and

satisfaction perceived after completing difficult academic tasks. The responses were scored on a Likert scale with 5 points (1=strongly disagree, 5=strongly agree). The higher score indicated more study related effort sensitivity. This SRESS indicated high internal reliability (Cronbach's alpha = 0.83).

Both the scales were used after adaptation for contextual relevance among India medical and paramedical students. The Higher SMOS and Lower SRESS scores indicated the "REWARD HIJACK" phenomenon, which means, academic, study related meaningful but slow rewards were hijacked by instant & fast social media digital rewards.

#### **Statistical Analysis**

The collected data was analysed using SPSS software (IBM corp). The continuous variables were reported as Mean & Standard Deviation. The categorical variables were reported as counts and percentages. The normality of continuous variables were assessed using Shapiro Wilk tests and Q-Q plots. The Pearson's correlation coefficient [11]. was used to analyse the linear association between SMOS and SRESS scores. A simple linear

model was developed to examine the predictive effect of social media overusage on study related effort sensitivity. The results with  $p < 0.05$  is set as statistically significant.

#### **Results**

##### ***Demographics and social media behaviour***

Among the 275 total participants included in the analysis, 154 were males which amount to 56% and 121 were females which amounts to 44%. There existed gender differences in the result. Males were spending more time on social media than females ( $p = 0.02$ ). The mean age for the study was  $20.6 \pm 1.8$  years. Among the 275 participants, 175 (63.6%) were MBBS students and 100 were paramedical students (36.4%). The study participants reported an average daily social media usage of  $3.6 \pm 1.9$  hours. Around 75.4% students reported frequent daytime distractions due to social media notifications and online engagement [12].

The study participants expressed a marked decrease in focus, concentration and study planning, immediately post social media usage ( $p < 0.01$ ). These details are expressed in Table 1.

Table 1. Participant Characteristics (n = 275)

<b>Variable</b>	<b>n / mean <math>\pm</math> SD</b>	<b>% or range</b>
Age (years)	20.6 $\pm$ 1.8	—
Gender		
— Male	154	56%
— Female	121	44%

— Other	0	0%
Course		
— MBBS	175	63.6%
— Paramedical	100	36.4%
Daily social media use (hours)	3.6 ± 1.9	0–12
Frequent daytime distraction	207	75.4%

### Scale Scores (Table 2)

The average of SMOS (Social Media Overuse Score) was  $3.18 \pm 0.82$ , which reflects moderate to high levels of habitual Social Media Usage. The average of SRESS (Study Related Effort Sensitivity

Score) was  $3.52 \pm 0.74$ , which indicated moderately high academic motivation overall, but it had variability indicating differential sensitivity to effort based rewards.

Table 2. Descriptive Statistics of Main Scales

Scale	Range	Mean ± SD	Median	Skewness (SE)
SMOS	1–5	$3.18 \pm 0.82$	3.2	0.12 (0.18)
SRESS	1–5	$3.52 \pm 0.74$	3.6	-0.08 (0.18)

Normality testing indicated approximately normal distribution for both the scales, (SMOS = -0.40; SRESS = -0.35), which supports the use of parametric analysis [13].

### Correlation analysis

According to Table 3, there existed a moderate, statistically significant negative correlation between Social Media overusage and study related effort sensitivity ( $r = -0.41$ , 95% CI -0.526 to 0.279,  $p < 0.001$ ) [14]. This means, the participants who expressed higher levels of

social media engagement, showed decreased intrinsic motivation for study related academic tasks and also they expressed reduced sensitivity to delayed effort based rewards which corresponds to academic rewards in the study participants. Also subgroup analysis done and which also proved the same results both in MBBS ( $r = -0.39$ ,  $p < 0.001$ ) and also in paramedical students ( $r = -0.42$ ,  $p < 0.001$ ), which suggests that the above mentioned effect is consistent among both the academic disciplines [15].

Table 3. Pearson Correlation

Variables	1	2
1. SMOS	1.00	-0.41*
2. SRESS	-0.41*	1.00

$p < 0.001$ ; 95% CI for  $r = -0.526$  to  $-0.279$

#### Regression analysis (Table 4)

A simple model of linear regression predicted SRESS from SMOS was statistically significant ( $F(1,173) = 34.16$ ,  $p,0.001$ ), with variance of 16.5% ( $R^2=0.165$ ). The regression coefficient for

social media overuse  $\beta = -0.340$  ( $SE = 0.058$ ,  $t = -5.84$ ,  $p < 0.001$ ), which indicates that each 1 point increase in SMOS, corresponds to 0.34 point decrease in SRESS [16].

Table 4. Regression Analysis Predicting SRESS from SMOS

Predictor	B	SE	t	p	95% CI
Constant	4.62	0.196	23.56	<0.001	[4.24, 5.00]
SMOS	-0.340	0.058	-5.84	<0.001	[-0.454, -0.226]

Model  $R^2 = 0.165$ ;  $F(1,173) = 34.16$ ,  $p < 0.001$

Further multiple regression analysis depicted that, each additional hour spent on social media was in turn associated with an average reduction of 20 minutes in focussed study time, after controlling for age and gender.

These above findings, infer the substantial behavioural impact of prolonged social media usage and exposure on student's academic routines, also these findings highlight that, social media

overusage has a potential of reward hijack through dopamine mediated gratification, impair time management of students, reduces attention span and also increase procrastination tendencies. If such overusage of social media continues, in overtime may affect student's academic performance, their mental well being and their ability to involve in deep meaningful learning (Figure 1).

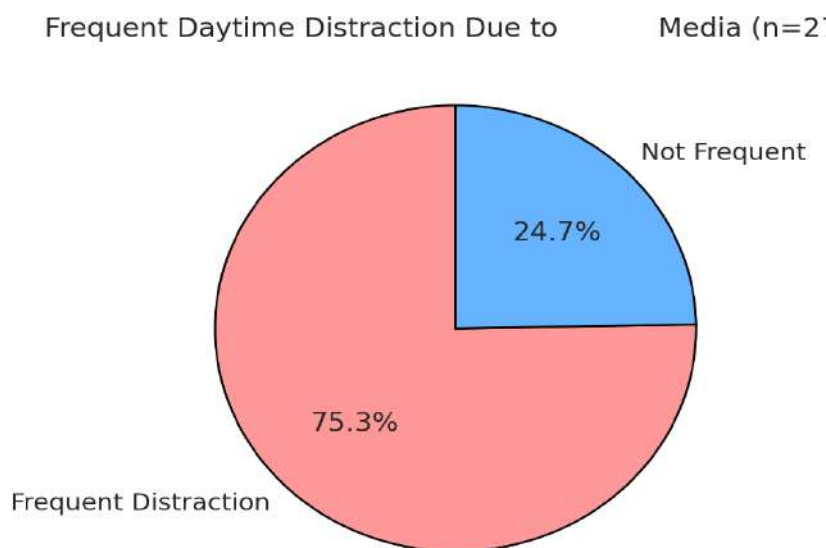


Figure 1. Frequent Daytime Distraction Due to Social Media Use.

Pie chart showing the proportion of participants reporting frequent daytime distraction attributable to social media usage. A majority (75.3%) reported frequent distraction, while 24.7% did not, indicating a high prevalence of attention disruption during daytime activities (n = 275).

### Discussion

The present study, had revealed a significant inverse relationship between social media overusage and study related brain sensitivity in undergraduate medical and paramedical students. The findings of the study affirms the reward hijack hypothesis, which suggests that repetitive exposure to rapid digital gratifications decreases responsiveness to natural and

effort based meaningful rewards [17]. There reflected a competition between instant online reinforcement and intrinsic academic motivation to study because increased social media engagement was linked to reduced motivation towards cognitively demanding tasks like meaningful concentrated studying (Figure 2).

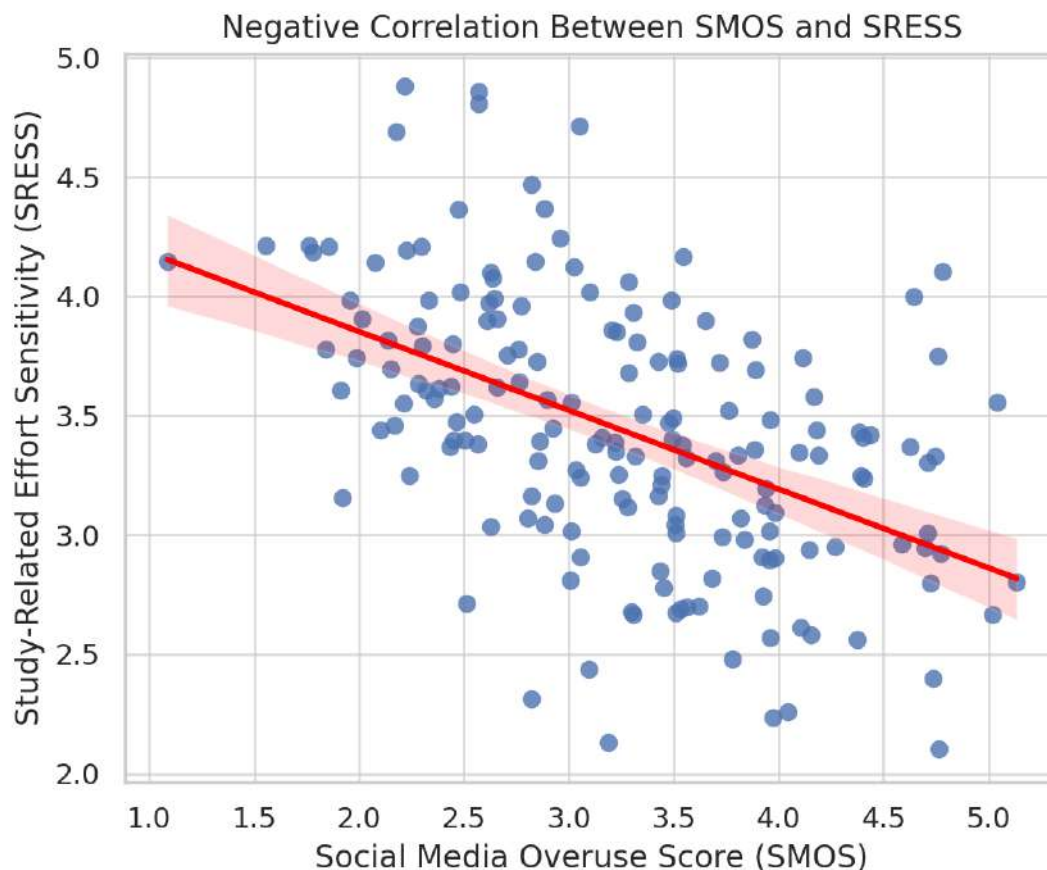


Figure 2. Negative Correlation Between Social Media Overuse Score (SMOS) and Study-Related Effort Sensitivity Score (SRESS).

Scatter plot depicting a significant negative correlation between SMOS and SRESS, suggesting that higher levels of social media overuse are associated with reduced sensitivity to study-related effort. The red regression line represents the line of best fit with 95% confidence interval (shaded area).

According to Neurobiological sciences, this can be attributed to down regulation of the mesolimbic dopaminergic pathway – mainly projections from the ventral tegmental area (VTA) to the Nucleus accumbens and prefrontal cortex [18]. Frequent and unpredictable rewards (like, likes, comments, chat notifications) hyper activate the dopaminergic circuits,

leading to craving and compulsive checking behaviours [19]. Also, dopaminergic down regulation blunts the responses to delayed rewards, like academic achievements and accomplishments [20]. These neurological patterns are similar to those patterns seen in behavioural addictions, with hyper activation in the striatum and orbitofrontal cortex (Figure 3).

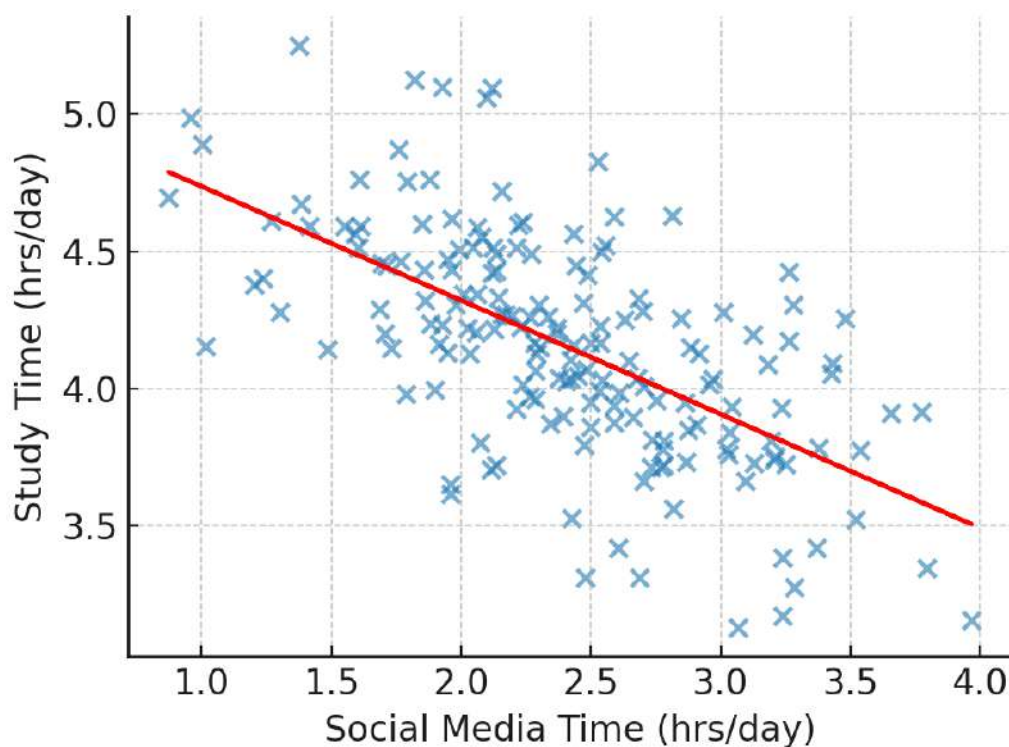


Figure 3. Inverse Relationship Between Daily Social Media Time and Study Duration. Scatter plot showing a significant negative linear relationship between time spent on social media (hours/day) and study time (hours/day). Increased social media engagement corresponds with a reduction in total study duration, highlighting potential interference with academic productivity.

Behaviourally, reduced effort sensitivity is manifested as shorter attention spans, lower persistence, and difficulty in willing delayed gratification. The observed moderate negative correlation ( $r = -0.41$ ) aligns with previous studies which were linking excessive social media use to academic disengagement and reduced attention [21]. The consistency of this finding across both MBBS and paramedical students suggests that even high achieving learners are also vulnerable to reward driven desensitization.

These results also align with Effort Discounting Theory, which states that the subjective value of a reward decreases as the required effort increases [22]. Continuous digital overstimulation may exaggerate this process, leading students to

overestimate the effort of studying while underestimating its late but meaningful rewards. Consequently, it leads to a state of mind where motivation fades, even when students understand the long-term benefits of academic effort.

Some Indian and some global research also depict these trends, proving that excessive digital media use correlates with sleep disruption, poor academic performance, and diminished self regulation [23–25]. Our study adds a neurobehavioral dimension, demonstrating how persistent social media engagement may recalibrate motivational circuits which will further affect the study related brain's effort sensitivity in Medical (MBBS) and Para medical students. Such reward desensitization reduces not only academic

productivity but also reduces well-being, which may be evident in dopamine's role in emotional stability and executive control.

This phenomenon of "Reward Hijack" also aligns with the concept of hedonic adaptation, in which the individuals gradually require higher stimulation to achieve the same level of satisfaction. Social media platforms are specifically designed knowingly or unknowingly, to exploit this principle through algorithmic repetition patterns, maintaining engagement by delivering unpredictable, different types of rewards, similar to slot machine mechanics. Such continuous cycles of micro rewarding can biologically re-assemble intermittent reinforcement, a schedule known to generate the strongest conditioned behaviours. Over time, this dampens the student's academic motivational capacity, prioritizing digital stimuli over sustained academic effort.

Emerging research in cognitive neuroscience further indicates that prefrontal cortical regions which are responsible for planning, impulse control, and sustained attention, are functionally weakened in heavy digital media users [26]. Further, functional MRI studies demonstrate reduced gray matter volume and activity in the anterior cingulate cortex (ACC) and dorsolateral prefrontal cortex (DLPFC) among individuals who have compulsive mobile screen use [27]. These same regions are crucial for cognitive endurance and effort allocation, offering biological evidence for diminished study-related motivation [28].

In the academic context, this neural adaptation means a preference for low-effort, high-feedback activities, such as scrolling or watching reels (short forms of videos which can be watched in seconds to

few minutes), rather than engaging in tasks requiring concentrated mental effort, like reading a huge portion for exams or problem-solving [29]. The constant influx of digital stimuli, distracts attention and weakens the brain's ability to maintain deep focus, which is very much needed by the students for conceptual learning and understanding.

From a psychological perspective, social media overuse can also be classified under the Self-Determination Theory (SDT) [30]. SDT states that intrinsic motivation thrives when individuals experience autonomy & competence. However, social media distorts these motivational needs. Consequently, students may lack intrinsic motivation for proper learning experiences.

Furthermore, another explanatory model is there known as Dual-System Theory of cognition [31]. According to this model, System 1 (fast, impulsive, emotional) and System 2 (slow, deliberate, logical) compete for behavioural control. Excessive social media use overstimulates System 1, leading to habitual, reflexive behaviours and reducing the engagement of System 2 processes which are required for disciplined academic study. This imbalance exaggerates impulsivity, procrastination, and diminished tolerance for cognitive delay, all of which will definitely impair sustained learning.

The reward prediction error mechanism offers another neurobiological insight. Each time a social media notification is received unexpectedly, dopamine neurons fire strongly, signalling a positive prediction error [32]. The brain learns to anticipate these signals and becomes hypersensitive to potential digital cues. In contrast, studying offers delayed and predictable outcomes, eliciting

comparatively less immediate dopaminergic excitement. Over time, this differential conditioning may lead the brain to subconsciously prioritize quick, uncertain online rewards over stable, delayed academic satisfaction.

Other cross cultural studies also suggests this trend. Korean, Chinese, and Western data all depict increasing levels of “digital reward dependency” among adolescents and young adults, with measurable effects on executive function and learning outcomes [33]. In India, where digital access is rapidly expanding, the absence of structured digital literacy programs amplifies the risk. Students often lack awareness of how their attention is modified, making them susceptible to compulsive behaviours without recognizing the neurocognitive consequences.

Medical and Paramedical curriculums demand prolonged cognitive focus, empathy, and delayed gratification which are the qualities inversely related to the instant reward algorithms of social media. If the reward system becomes chronically biased toward immediacy and fastness, students may struggle to find satisfaction in the slow process of mastering their subjects in curriculum like Physiology, Pharmacology, Medicine, Clinical reasoning, etc. This represents not merely a lifestyle concern but a neurological shift that can undermine professional competence.

Integrating neuroscience-based awareness programs into academic schedules could therefore serve a preventive function. Workshops that visualize brain reward pathways, show fMRI images of digital addiction, or discuss the neuroplasticity effects of attention training may strengthen student's

metacognitive control. Similarly, interventions such as Pomodoro -based study techniques, pranayama & yoga before study sessions, and reward substitution strategies (e.g., pairing study sessions with non-digital rewards) have shown promise in rebalancing dopaminergic tone [34].

From a public health view, the findings highlight a broader societal concern of how the digital economical needs spoils the young adult's neurodevelopmental stages. The late adolescence and early adulthood period is marked by continued maturation of the prefrontal cortex. Chronic overstimulation during this phase may result in enduring alterations in motivational circuits [35]. Therefore, early educational interventions are not merely about productivity but about safeguarding neurodevelopmental integrity.

Furthermore, interdisciplinary collaboration is crucial. Doctors, Psychologists, and Educators must work jointly to design interventions that address both the neurochemical and behavioural aspects of reward hijack. Neurological feedback (like EEG), biofeedback, and cognitive training tools may complement conventional counselling to restore balance between the mesolimbic and prefrontal systems.

The social media over usage not only affects the academic stability of students, but also affects emotional stability of students. Students may experience mood swings due to digital media use, leading to stress, anxiety, and self comparison fatigue. Such emotional consequences further reduces study efficiency, as anxiety competes for cognitive resources, which are essential for working memory. Emotional exhaustion, in turn, can reduce dopamine

availability, causing a vicious cycle of avoidance and procrastination.

It is also important to acknowledge that social media's architecture leverages attention as a currency, converting user engagement into commercial value. In this framework, the user's neural reward system becomes a site of economic exploitation which is a phenomenon some researchers call neuro - marketing colonization. Understanding this manipulation may empower students to reclaim consciousness over their attention and re-establish healthier digital boundaries.

Finally, some of its implications extend beyond academics. Chronic dopaminergic blunting has been linked to anhedonia, apathy and emotional fatigue, which are conditions that may precede to depressive states. Therefore, monitoring digital habits can serve as an early indicator for mental health risks. Embedding digital well-being modules within medical education can, not only protect cognitive performance but also provide emotional resilience in future healthcare professionals.

If these adverse effects are unaddressed, reward hijack could erode deep learning, self-discipline, and intrinsic motivation which are the major key aspects in medical education. Interventions such as mindfulness-based training, structured digital detox programs, and reinforcement of delayed gratification may help restore dopaminergic sensitivity and improve student's academic focus & learning.

Integrating digital hygiene and neurobehavioral education into the curriculum could further enhance awareness of, how compulsive online behaviours alter motivation. These strategies, grounded in neuroscience, could

help students reclaim control over cognitive effort and reward balance.

### **Strengths and Limitations of the study**

This study's strength lies in its interdisciplinary framework combining neurophysiology and behavioural science, which were supported by validated scales. The adequate sample size ensured statistical reliability and cross-discipline generalizability.

However, the cross-sectional design limits causal inference [36]. Self-reporting may introduce bias, and confounders such as stress, sleep disorders were not controlled. Future longitudinal and neuroimaging studies should be done to clarify causality and identify neural reversibility following behavioural interventions.

### **Conclusion**

Excessive social media use appears to hijack the brain's reward mechanisms, reducing sensitivity to effort based academic rewards. Students with higher online engagement exhibited lower motivation for sustained study, which was consistent with the neurobehavioral reward hijack model. This desensitization reflects not only mere distraction but also a shift in motivational neurochemistry, in which an immediate digital gratification replaces curiosity-driven reinforcement.

Such dopaminergic desensitization erodes perseverance, patience and acceptance, qualities which are vital in health science education. Academic institutions should therefore promote digital literacy, mindful engagement, and delayed non digital reward strategies to restore intrinsic motivation. Structured interventions like scheduled social media breaks, digital hygiene training, and

mindfulness based focus programs can recalibrate reward pathways and enhance learning architecture of the student.

Beyond academics, chronic dopamine imbalance may contribute to attentional deficits, emotional fatigue, and anhedonic symptoms. Early behavioural modifications done through awareness and institutional support [37-40] can serve both preventive and therapeutic functions.

Ultimately, social media overuse should be viewed as a neurobehavioral condition, not a acute habit. Combating reward hijack requires collaboration between neuroscience, medicine, psychology, and education. Re-establishing the values of delayed gratification and intellectual satisfaction in students is essential for restoring balance between instant pleasure and long-term meaningful academic fulfilment.

By promoting mindful technology use and neuroscience aligned learning strategies, educators can help students rebuild intrinsic motivation and cognitive focus, ensuring that effort, patience, and curiosity remain important to meaningful academic growth in the digital era.

## Statements and Declarations

### Conflicts of interest

The authors declare that they do not have conflict of interest.

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ORIGINAL ARTICLE

**Intramedullary Interlocking Nailing Versus Minimally Invasive Percutaneous Plate Osteosynthesis for Extra-Articular Distal Third Tibial Fractures: A Prospective Comparative Study**

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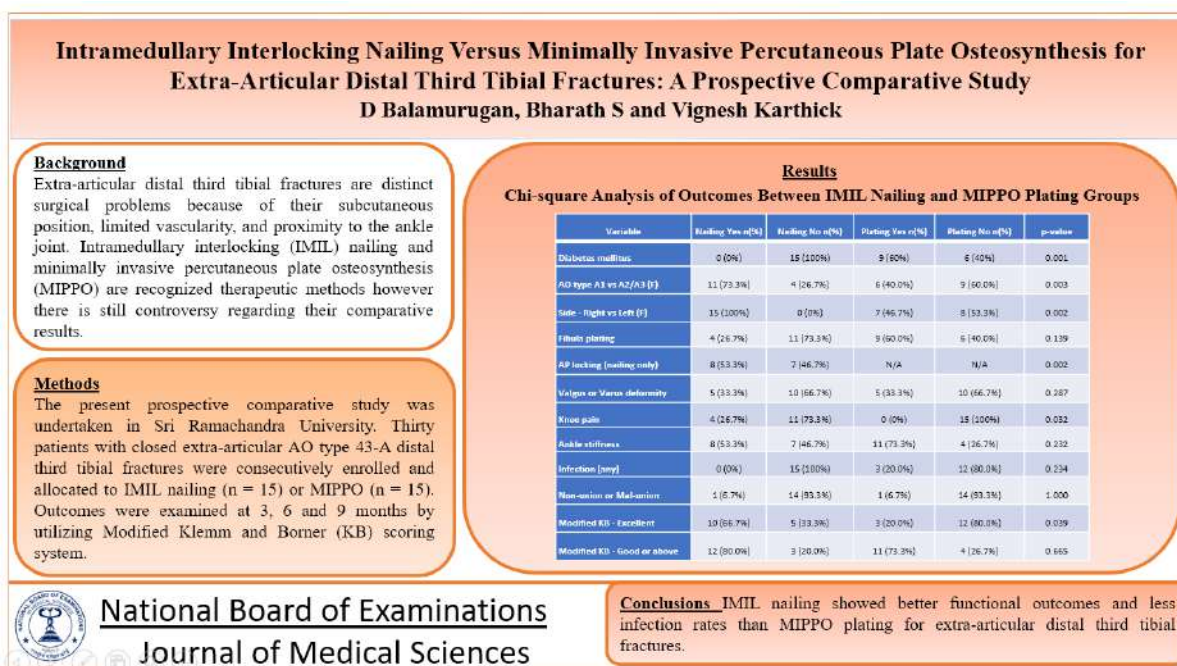
**Abstract**

**Background:** Extra-articular distal third tibial fractures (4 cm to 11 cm proximal to the tibial plafond) are distinct surgical problems because of their subcutaneous position, limited vascularity, and proximity to the ankle joint. Intramedullary interlocking (IMIL) nailing and minimally invasive percutaneous plate osteosynthesis (MIPPO) are recognized therapeutic methods however there is still controversy regarding their comparative results. **Objectives:** To compare clinical and radiological outcomes of IMIL nailing and MIPPO plating in extra-articular distal third tibial fractures. **Methods:** The present prospective comparative study was undertaken in Sri Ramachandra University. Thirty patients with closed extra-articular AO type 43-A distal third tibial fractures were consecutively enrolled and allocated to IMIL nailing (n = 15) or MIPPO (n = 15). Outcomes were examined at 3, 6 and 9 months by utilizing Modified Klemm and Borner (KB) scoring system. **Results:** Mean age was 29.87 years; 73.3% were men. Mean union time was substantially less in the nailing group (15.0 weeks vs 17.7 weeks). Nailing led to shorter post-operative immobilisation (6.27 vs 9.20 weeks; p=0.017). The Modified KB score showed excellent results in 66.7% in the nailing group and 20.0% in the plating group (p=0.039). Infection was not seen in the nailing group but occurred in three patients (20%) post plating. Incidence of mal-alignment was similar between groups (33.3% each; p=0.287). **Conclusions:** IMIL nailing showed better functional outcomes and less infection rates than MIPPO plating for extra-articular distal third tibial fractures. In the nailing procedure, correct guide-wire placement and AP locking are important in reducing mal-alignment. These results need to be confirmed in further randomized controlled trials with larger sample numbers.

**Keywords:** Distal tibia fracture, Intramedullary interlocking nailing, minimally invasive percutaneous plate osteosynthesis, MIPPO, AO classification, Functional outcome

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## Graphical Abstract



## Introduction

Extra-articular fractures of the distal portion of the tibia constitute over 10% of all tibial fractures and nevertheless pose a significant treatment challenge [1]. Anatomically adverse region: the bone is subcutaneous, the muscle envelope is sparse and the vascularity is intrinsically limited with respect to the diaphysis [2]. These factors predispose to wound problems, infection, delayed and non-union [3]. These fractures occur just proximal to the ankle joint and are therefore markedly different in etiology, displacement and prognosis from pilon injuries [4]. Historically the gold standard was open reduction and internal fixation (ORIF). However, infection (8.3-23%) and non-union (8.3-35%) rates led to the use of less invasive methods [5,6]. MIPPO was introduced as a biologically advantageous option by retaining the periosteal vascularity and fracture haematoma [7,8], but had the inherent risk of mal-union due

to indirect reduction and interposition of soft tissue between fracture segments. IMIL nailing has been established for diaphyseal tibial fractures for a long time, but has been extended to the distal metaphysis with some hesitancy due to concerns over the hourglass form of the distal canal, potential nail failure and the risk of propagating fracture lines into the ankle [9–11]. These restrictions have been mainly resolved by modifications such as antero-posterior (AP) locking screws and Poller blocking screws [12].

There is a large amount of research for both strategies, but there are few direct comparisons due to small sample numbers and insufficient randomisation. The present study was designed for the prospective comparison of clinical and radiological result of IMIL nailing and MIPPO plating in closed extra articular AO 43-A distal third tibial fractures.

## **Materials and Methods**

### ***Study design and setting***

The present prospective comparative study was undertaken in the Department of Orthopaedics, Sri Ramachandra Medical College and Research Institute, Chennai. Ethical approval was taken from the Institutional Ethics Board of the Institute before the start of the study.

### ***Study Participants***

Patients with closed extra-articular AO type 43-A distal one-third tibial fractures 4–11 cm proximal to the tibial plafond were included. Exclusion criteria included compound (open) fractures, intra-articular fractures, pathological fractures and pediatric fractures. All thirty eligible participants presented during the study period were included consecutively and non-randomly assigned to IMIL nailing (n=15) or MIPPO plating (n=15) according to fracture morphology and surgeon's evaluation. Fractures with AO 43-A1 morphology were nailed preferentially and plating was used for comminuted A3 patterns.

### ***Surgical Procedure***

MIPPO was done through an anteromedial incision of 3–5 cm in the distal tibia with a separate proximal stab incision. A locking compression plate (LCP) of 3.5 mm or 4.5 mm was tunneled subcutaneously and secured with distal locking head screws and proximal cortical screws. IMIL nailing was conducted with the patient in the supine position and the knee flexed at 90°. A reamed cannulated tibial nail was placed by an infrapatellar route. Cases at risk of mal-alignment had AP locking. The concomitant fixation of

the fibula was undertaken at the discretion of the surgeon.

Postoperative regimen. All patients were given intravenous broad-spectrum antibiotics for 5 postoperative days. Mobilisation of knee and ankle started on first post surgical day. Full weight-bearing was permitted once clinical and radiographic signs of fracture healing were obtained. Clinical and radiological follow up was done at 12, 18, 24, 30 and 36 weeks.

### ***Outcome evaluation***

The key end point was the Modified Klemm and Borner (KB) score at final follow-up. The KB score categorizes patients as Excellent (15 to 19), Good (10 to 14), Fair (5 to 9) or Poor (<5) on the basis of range of motion, discomfort, muscle atrophy, limb alignment and time to union. Time to fracture healing, period of post-operative immobilisation, incidence of infection, mal-alignment and necessity for subsequent surgical treatments were the secondary outcomes.

### ***Statistics***

Data were entered in excel and analysed using SPSS. Categorical variables were expressed in frequency, percentage. Continuous variables were expressed as mean with SD. Independent samples t-test was used for comparison of continuous variables and Chi-square or Fisher's exact test for categorical variables. Statistical significance was defined as a p-value of less than 0.05.

## **Results**

### ***Demographics and baseline attributes***

It included 30 patients (men, 22; women, 8; mean age, 29.87 years; range, 24 to 77 years). There were 13 patients with AO type 43-A1 fracture, 6 with 43-A2 and

11 with 43-A3. Nine had pre-existing diabetes mellitus ( $p = 0.001$ ) and five had hypertension ( $p = 0.330$ ). Eleven were smokers and seven consumed alcohols. All patients receiving nailing had fractures on the right side, whereas the plating group showed an equal incidence of right sided and left sided fractures. AP locking was used in eight patients in the nailing group and dramatically reduced mal-alignment ( $p=0.002$ ).

#### **Union and immobilization**

The mean time to union was 15.0 weeks (range, 6 to 52) in the nailing group and 17.7 weeks (range, 6 to 32) in the plating group. Union was earlier with nailing but this difference was not statistically significant ( $p=0.308$ ). Post-operative immobilisation was considerably less in the nailing group (6.27 vs 9.20 weeks,  $p=0.017$ ). One patient in the nailing group had a non-union. Two patients in the dynamised group had become unionised by nine months. The plating group had no nonunion, however one patient had malunion with severe valgus deformity needing corrective surgery.

#### **Complications**

In nailing group no patient had wound infection. There were three infections in plating patients (superficial two, deep one). The deep infection resulted in plate exposure and was handled with medicated dressings. The implant was held until radiological union and was removed after one year. Deformity was valgus in three nailing and five plating patients and varus in two nailing patients and none with plating ( $p=0.287$ ). Four nailing patients (26.7%) had anterior knee pain and none in the plating group. Ankle stiffness was seen in 53.3% (nailing) and 73.3% (plating) of the patients. One patient in the nailing group had a 0.3 cm tibial shortening.

#### **Functional result**

The modified KB score at nine months was considerably better in the nailing group ( $p=0.039$ ). Excellent: 10 patients (66.7%) versus 3 (20.0%) with plating; Good: 2 (13.3%) versus 8 (53.3%); Fair: 3 (20.0%) versus 3 (20.0%); Poor: 0 versus 1 (6.7%) (Tables 1 and 2).

Table 1. Distribution of Variables by Treatment Group (IMIL Nailing vs MIPPO Plating)

<b>Variable</b>	<b>IMIL Nailing (n=15)</b>	<b>MIPPO Plating (n=15)</b>	<b>Total (n=30)</b>
<b>Gender</b>			
Male	11 (73.3%)	11 (73.3%)	22 (73.3%)
Female	4 (26.7%)	4 (26.7%)	8 (26.7%)
<b>Pre-existing Illness</b>			

<b>Variable</b>	<b>IMIL Nailing (n=15)</b>	<b>MIPPO Plating (n=15)</b>	<b>Total (n=30)</b>
Diabetes mellitus	0 (0.0%)	9 (60.0%)	9 (30.0%)
Hypertension	2 (13.3%)	3 (20.0%)	5 (16.7%)
Smoking	6 (40.0%)	5 (33.3%)	11 (36.7%)
Alcohol use	3 (20.0%)	4 (26.7%)	7 (23.3%)
<b>AO Fracture Type</b>			
43-A1 (Simple)	11 (73.3%)	2 (13.3%)	13 (43.3%)
43-A2 (Wedge)	2 (13.3%)	4 (26.7%)	6 (20.0%)
43-A3 (Complex)	2 (13.3%)	9 (60.0%)	11 (36.7%)
<b>Side of Fracture</b>			
Right	15 (100.0%)	7 (46.7%)	22 (73.3%)
Left	0 (0.0%)	8 (53.3%)	8 (26.7%)
<b>Concomitant Fibula Plating</b>			
Yes	4 (26.7%)	9 (60.0%)	13 (43.3%)
No	11 (73.3%)	6 (40.0%)	17 (56.7%)
<b>AP Locking (Nailing group only)</b>			
Yes	8 (53.3%)	N/A	N/A
No	7 (46.7%)	N/A	N/A

<b>Variable</b>	<b>IMIL Nailing (n=15)</b>	<b>MIPPO Plating (n=15)</b>	<b>Total (n=30)</b>
<b>Post-operative Immobilisation</b>			
Mean (weeks)	6.27	9.20	--
Range (weeks)	6 - 10	6 - 20	--
<b>Post-operative Deformity</b>			
Normal alignment	10 (66.7%)	10 (66.7%)	20 (66.7%)
Valgus deformity	3 (20.0%)	5 (33.3%)	8 (26.7%)
Varus deformity	2 (13.3%)	0 (0.0%)	2 (6.7%)
<b>Surgical Outcome - Modified KB Score</b>			
Excellent (15-19)	10 (66.7%)	3 (20.0%)	13 (43.3%)
Good (10-14)	2 (13.3%)	8 (53.3%)	10 (33.3%)
Fair (5-9)	3 (20.0%)	3 (20.0%)	6 (20.0%)
Poor (< 5)	0 (0.0%)	1 (6.7%)	1 (3.3%)
<b>Mean union time</b>	15.0 weeks	17.7 weeks	

Table 2. Chi-square Analysis of Categorical Outcomes Between IMIL Nailing and MIPPO Plating Groups

Variable	Nailing Yes n (%)	Nailing No n (%)	Plating Yes n (%)	Plating No n (%)	p-value
Diabetes mellitus	0 (0%)	15 (100%)	9 (60%)	6 (40%)	<b>0.001</b>
AO type A1 vs A2/A3 (F)	11 (73.3%)	4 (26.7%)	6 (40.0%)	9 (60.0%)	<b>0.003</b>
Side - Right vs Left (F)	15 (100%)	0 (0%)	7 (46.7%)	8 (53.3%)	<b>0.002</b>
Fibula plating	4 (26.7%)	11 (73.3%)	9 (60.0%)	6 (40.0%)	0.139
AP locking (nailing only)	8 (53.3%)	7 (46.7%)	N/A	N/A	<b>0.002</b>
Valgus or Varus deformity	5 (33.3%)	10 (66.7%)	5 (33.3%)	10 (66.7%)	0.287
Knee pain	4 (26.7%)	11 (73.3%)	0 (0%)	15 (100%)	<b>0.032</b>
Ankle stiffness	8 (53.3%)	7 (46.7%)	11 (73.3%)	4 (26.7%)	0.232
Infection (any)	0 (0%)	15 (100%)	3 (20.0%)	12 (80.0%)	0.234
Non-union or Mal- union	1 (6.7%)	14 (93.3%)	1 (6.7%)	14 (93.3%)	1.000
Modified KB - Excellent	10 (66.7%)	5 (33.3%)	3 (20.0%)	12 (80.0%)	<b>0.039</b>
Modified KB - Good or above	12 (80.0%)	3 (20.0%)	11 (73.3%)	4 (26.7%)	0.665

## Discussion

The treatment of extra-articular distal third tibial fractures remain a subject of ongoing debate. Both IMIL nailing and MIPPO plating are biological load sharing constructions that minimize further harm of the already degraded soft tissue envelope, but each technique has its own technical demands and complication profiles.

The present study showed that IMIL nailing achieved union approximately 2.7 weeks earlier than MIPPO plating with a considerably lesser length of immobilisation ( $p=0.017$ ) resulting in early functional rehabilitation. These results are in keeping with the findings of Im and Tae [13] who found union at 18 and 20 weeks respectively in a randomised study and Vallier et al. [14] who found union at 22.6 and 27.8 weeks. It is interesting to note that there were no infections in the nailing group, especially as open plating procedures have been documented in the literature with significant infection rates (up to 20%) [5]. Closed reduction and restricted contact with the nail are used to minimize bacterial colonization of the fracture hematoma.

The higher Modified KB scores in the nailing group (66.7% excellent vs 20.0%;  $p = 0.039$ ) represent the combined effect of quicker union, shorter immobilisation and retained periosteal circulation. Similar preponderance of excellent and good results with IMIL nailing in similar fracture patterns has also been observed by Singh et al. [15] and Mohamed et al. [16].

Mal-alignment was noted in five patients in each group (33.3%), a figure that lies between that reported by Vallier et al. [14] (23% nailing, 8.3% plating) and Natarajan et al. [17] (40% nailing, 13.3% plating). The use of AP locking screws in

the nailing group showed considerable reduction in mal-alignment ( $p=0.002$ ) validating the efficacy of this adjunct as stated by Krettek et al. with Poller blocking screws [12]. In the plating group mal-alignment was probably caused by indirect fracture reduction with soft tissue interposition between pieces as stated before [9].

Plating was associated with increased ankle stiffness (73.3% vs 53.3%), probably due to a longer time of immobilisation and more disturbance of periarticular soft tissue by the distal plate build. Anterior knee pain, a known consequence of the transpatellar nailing method, was seen in 26.7% of nailing patients and is in keeping with the literature of 10–40% [18].

Fibula fixation was performed concomitantly in 43.3% of the patients. Attal et al. [19] reported an 8-fold increase in delayed union with fibula fractures; however, the current study did not show a significant effect of fibula fixation on the union or functional outcome. This discovery needs additional study.

## Limitations

Certain limitations has to be considered while interpreting the findings. Baseline characteristics were not completely balanced between the treatment groups, with a higher prevalence of diabetes mellitus and a greater proportion of AO type 43-A3 comminuted fractures in the MIPPO group. These factors may have independently influenced fracture healing, infection rates, and functional outcomes, thereby introducing potential confounding. Similarly, concomitant fibular fixation was performed more frequently in the plating group and may have influenced fracture alignment and healing characteristics. Also,

the study included a relatively small sample of 30 patients, which was based on the number of eligible patients presenting during the study period rather than a formal sample size calculation. Consequently, the study may have been underpowered to detect differences in certain secondary outcomes. Owing to the limited sample size, subgroup analyses evaluating the independent effects of fracture pattern, comorbidities, and fibular fixation were not feasible. Future larger, adequately powered randomized studies with balanced baseline characteristics are warranted to validate these findings.

### **Conclusion**

IMIL nailing resulted in considerably better functional outcomes, quicker union time, shorter immobilisation and lower infection load compared to MIPPO plating for closed extra-articular AO 43-A distal third tibial fractures. The guide wire must be placed accurately and AP locking screws are important to avoid mal-alignment during nailing. MIPPO plating still remains a viable solution especially for comminuted fractures when nailing is technically difficult. Randomised controlled trials with bigger homogeneous samples are required for the ultimate establishment of the superiority of one technique over the other [20].

### **Statements and Declaration**

#### **Author Contributions**

BD has contributed to the conceptualization, design of the study, literature search, data acquisition, manuscript editing and review. BS contributed towards conceptualization, Statistical analysis, Manuscript review and editing. VK contributed towards literature search, data analysis, manuscript writing,

review and editing. BD acted as the corresponding author for this manuscript.

### **Conflicts of interest**

The authors declare that they do not have conflict of interest.

### **Funding**

No funding was received for conducting this study.

### **Ethical Approval**

Obtained approval from the Institutional Research Ethics Committee, Sri Ramachandra University (REF: CSP-MED/17/JAN/33/05)

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ORIGINAL ARTICLE

**Effect of Antenatal Breastfeeding Counselling on Early Initiation of Breastfeeding Among Mothers Delivering at a Tertiary Care Hospital in Tamilnadu: A Quasi-Experimental Study**

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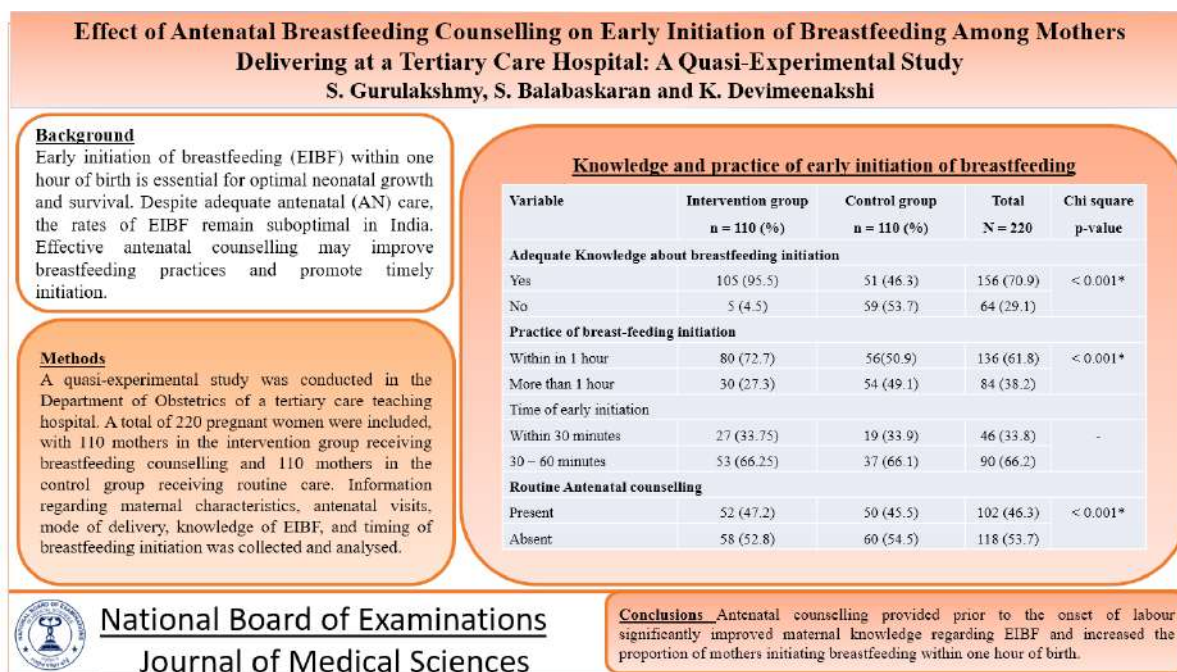
**Abstract**

**Background:** Early initiation of breastfeeding (EIBF) within one hour of birth is essential for optimal neonatal growth and survival. Despite adequate antenatal (AN) care, the rates of EIBF remain suboptimal in India. Effective antenatal counselling may improve breastfeeding practices and promote timely initiation. **Materials and Methods:** A quasi-experimental study was conducted in the Department of Obstetrics of a tertiary care teaching hospital. A total of 220 pregnant women were included, with 110 mothers in the intervention group receiving breastfeeding counselling and 110 mothers in the control group receiving routine care. Information regarding maternal characteristics, antenatal visits, mode of delivery, knowledge of EIBF, and timing of breastfeeding initiation was collected and analysed. **Results:** Among mothers in the intervention group, 80 (72.7%) initiated breastfeeding within one hour of birth compared to 56 (50.9%) in the control group. Adequate knowledge regarding EIBF was observed among 105 (95.5%) mothers in the intervention group compared to 51 (46.3%) mothers in the control group. The common reasons for delayed initiation of breastfeeding were lack of awareness, perceived inadequate breast milk secretion, and administration of pre-lacteal feeds. **Conclusion:** Antenatal counselling provided prior to the onset of labour significantly improved maternal knowledge regarding EIBF and increased the proportion of mothers initiating breastfeeding within one hour of birth. Simple and cost-effective interventions such as focused antenatal breastfeeding counselling may help improve early breastfeeding practices and contribute to better neonatal health outcomes.

**Keywords:** Early initiation of breastfeeding (EIBF); Antenatal counselling; Maternal health; Breastfeeding promotion; Neonatal health; Health education

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## Graphical Abstract



## Introduction

“Early Initiation of Breast Feeding” (EIBF) refers to provision of mother’s breast milk to infants within one hour of birth and ensures that the infant receives the colostrum, or “first milk”, which is rich in protective factors. According to World Health Organization (WHO), optimal breastfeeding includes early initiation of breastfeeding, exclusive breastfeeding for six months, frequent feeding, continuous breastfeeding for two years and increase in frequency of feeding during illness. UNICEF and WHO recommend to initiate breastfeeding within the first hour of birth and exclusive breastfeeding for the first six months of life – meaning no other foods or liquids are provided, including water [1].

Breast milk contains all the nutrients an infant need in the first six months of life. Early initiation of breastfeeding has many health benefits

both for the mother and infant. It increases ability to fight infections, reduces the risk of diarrhoea, pneumonia, reduces the risk of overweight and obesity in childhood and adolescence thereby increasing the survival rate of children [2]. Colostrum is the first milk that is very vital for newborns in protecting against infections. It is rich in immunoglobulin G, and has a great role in disease resistance. It has been found that bacterial, viral, fungal and protozoal infections of the newborn baby can be reduced by feeding colostrum. According to different studies, children who were not initiated breastfeeding early were more likely to develop recurrent infections, stunting, underweight, and wasting [3].

According to World Health Organization (WHO) report 2018 globally, 3 in 5 babies are not breastfed in the first hour of life. Only 41% of infants under 6 months of age are exclusively breastfed

[1]. Early initiation of breastfeeding and exclusive breastfeeding for the first 6 months of life prevents around 20% newborn deaths and 13% under-five deaths [4]. It can also reduce mortality due to neonatal infections (sepsis, pneumonia, tetanus, and diarrhoea) which contribute to 36% of neonatal deaths from all causes [4]. According to a systematic review, infants who were initiated breastfeeding after first hour were at 33% risk of neonatal mortality [5].

India has not made much progress in increasing Early Initiation of Breast Feeding (EIBF) rates, which was 41.6 % in 2015-16 (NFHS 4) and 41.8% in 2019-21 (NFHS 5). In Tamil Nadu, 54.7% children were breastfed within one hour of delivery (NFHS 4) [6] and 60.2 in the 2019-2021 data of NFHS 5 [7]. Caesarean sections are one of the biggest hurdles in initiation of breastfeeding in hospital-born babies. Various studies have shown that infants born by caesarean section were less likely to receive breastfeeding within first hour of birth, than vaginally delivered infants [8,9]. After caesarean section, mothers and babies are frequently monitored in separate rooms depriving them from the opportunity of breastfeeding and bonding.

Prenatal counselling plays a vital role in early initiation of breastfeeding. Even with adequate antenatal care, our NFHS data reveals that EIBF is not adequate. Hence the present study was conducted to evaluate the role of counselling prior to onset of labour on the rates of early initiation of breast feeding and to identify factors influencing it.

## Material and Methods

The present study was conducted in Department of Obstetrics of a tertiary care medical college hospital after obtaining approval from the Institutional Ethics Committee (IEC). It was a quasi-experimental study which was conducted from August 2021 to October 2021. Pregnant women with term gestation who were admitted for safe confinement were included in the study. Mothers whose neonates required NICU admission and mothers with severe postnatal complications were excluded from the study. Informed consent was obtained from the antenatal mothers and they were allotted to intervention group and control groups. Intervention group included AN mothers admitted with no labour pain for safe confinement. Control group was AN mothers admitted with labour pain. Basic details were obtained from the both groups.

Mothers in the Intervention group were given counselling on benefits of early initiation of breastfeeding using counselling charts. No counselling was provided to mothers in the control group. Baseline knowledge regarding early initiation of breastfeeding was not formally assessed before administration of counselling. The study was designed to evaluate the effect of immediate antenatal counselling provided prior to delivery on maternal knowledge and breastfeeding initiation practices. After the delivery, both groups were followed-up. Mothers who met the exclusion criteria in both groups were excluded. During the post natal period all the mothers were asked about early initiation of breastfeeding, reasons for non-initiating of early breastfeeding.

The impact of sociodemographic factors on initiation of breastfeeding in both groups was compared. Factors such as maternal age, education, morbidity, number of antenatal visits, order of birth, mode of delivery, gender of baby, maturity of baby, birth weight of the baby were studied. Data were analysed using SPSS version 23.0 software which included frequency, percentages were used to describe the data. Categorical variables were expressed as frequencies and percentages. Differences between groups were assessed using the Chi-square test. A

p-value <0.05 was considered statistically significant. Sample size calculation: Sample size was calculated based on study done by Phuljhele et al. [10] who reported the proportion of mothers who breastfed within 1 hour in the counselled group was 73.6% and control group was 46%, with alpha error 1%, Beta error 5% and 1:1 ratio, number of mothers required in each group was calculated to be 109. Hence, we included 110 pregnant mothers in each group (intervention and control group) (Table 1).

## Results

Table 1: Baseline characteristics of the study population among intervention and control group

Characteristics	Intervention Group n = 110 (%)	Control Group n = 110 (%)	Total N = 220 (%)
<b>Age of mother</b>			
< 30 years	104 (94.5)	97 (88.2)	201 (91.4)
≥ 30 years	6 (5.5)	13 (11.8)	19 (8.6)
<b>Educational qualification</b>			
Illiterate	2 (1.8)	3 (2.7)	5 (2.3)
Primary and middle school	10 (9.1)	10 (9.1)	20 (9.1)
Secondary and higher secondary	56 (50.9)	55 (50.0)	111 (50.5)
Graduate	42 (38.2)	42 (38.2)	84 (38.2)
<b>Number of antenatal visits</b>			
< 4 visits	1 (0.9)	3 (2.7)	4 (1.8)
≥ 4 visits	109 (99.1)	107 (97.3)	216 (98.2)
<b>Morbidity</b>			
Gestational diabetes mellitus	5 (4.5)	11 (10.0)	16 (7.3)
Pregnancy-induced hypertension	42 (38.2)	17 (15.5)	59 (26.8)
Anaemia	46 (41.8)	30 (27.3)	76 (34.5)

Cardiac problems	0 (0.0)	1 (0.9)	1 (0.5)
No health issues	17 (15.5)	51 (46.4)	68 (30.9)
<b>Mode of delivery</b>			
Vaginal delivery	76 (69.1)	56 (50.9)	132 (60.0)
Instrumental delivery	1 (0.9)	2 (1.8)	3 (1.4)
Caesarean section	33 (30.0)	52 (47.3)	85 (38.6)
<b>Order of birth</b>			
First	37 (33.6)	52 (47.3)	89 (40.5)
Second	55 (50.0)	44 (40.0)	99 (45.0)
Third or above	18 (16.4)	14 (12.7)	32 (14.5)
<b>Gender of the baby</b>			
Male	48 (43.6)	56 (50.9)	104 (47.3)
Female	62 (56.4)	54 (49.1)	116 (52.7)
<b>Birth weight</b>			
< 2.5 kg	19 (17.3)	31 (28.2)	50 (22.7)
≥ 2.5 kg	91 (82.7)	79 (71.8)	170 (77.3)

The mean age of the mothers was 26.5 ±3.8 (SD) years. Majority of the mothers (91.6%) were less than 30 years. Nearly (50.4%) had completed secondary and higher education. About 216 (98.8%) mothers had more than 4 Antenatal visits. 76 (34.5%) mothers were anaemic, 59 (26.8%) had PIH and 16 (7.27%) had

gestational diabetes. Majority 99 (45%) of the babies belong to second order of birth. Among participants, 132 (60%) had vaginal delivery and 85 (38.6%) underwent caesarean section. About 50 (22.73%) babies had birth weight were less than 2.5kg (Table 2).

Table 2. Knowledge and practice of early initiation of breastfeeding in the intervention and control groups

Variable	Intervention group n = 110 (%)	Control group n = 110 (%)	Total N = 220	Chi square p-value
<b>Adequate Knowledge about breastfeeding initiation</b>				
Yes	105 (95.5)	51 (46.3)	156 (70.9)	< 0.001*

No	5 (4.5)	59 (53.7)	64 (29.1)	
<b>Practice of breast-feeding initiation</b>				
Within in 1 hour	80 (72.7)	56(50.9)	136 (61.8)	< 0.001*
More than 1 hour	30 (27.3)	54 (49.1)	84 (38.2)	
<b>Time of early initiation</b>				
Within 30 minutes	27 (33.75)	19 (33.9)	46 (33.8)	-
30 – 60 minutes	53 (66.25)	37 (66.1)	90 (66.2)	
<b>Routine Antenatal counselling</b>				
Present	52 (47.2)	50 (45.5)	102 (46.3)	< 0.001*
Absent	58 (52.8)	60 (54.5)	118 (53.7)	

Among intervention group, 105 (95.5%) mothers had acquired knowledge about early initiation of breastfeeding due to counselling while in the control group, 51 (46.3%) had prior knowledge about early initiation without intervention and it was statistically significant ( $p=0.001$ ) In intervention group, 80 (72.7%) mothers started early initiation of breastfeeding within an hour. Whereas, in control group 56 (50.9%) started early initiation of breastfeeding within an hour and 54 (49.1%) failed to provide breast milk within first hour of baby birth. There was a

significant difference in early initiation of breastfeeding between the two groups. (chi-square test,  $p<0.001$ ) Among the mothers who initiated breastfeeding within an hour, 27 (33.75%) initiated breastfeeding in intervention group and 19 (33.9%) in control group within 30 minutes.

Nearly, 52 (47.2%) in intervention group and 50 (45.5%) in control group received antenatal breastfeeding counselling during their antenatal visits, which is almost similar in both groups.

Table 3. Reasons for delay in initiation of breastfeeding among intervention and control group

Reasons	Intervention group n = 30 (%)	Control group n = 54 (%)	Total N=84 (%)
Not aware	2 (6.7)	34 (63)	36 (43)
Mother felt tired	17 (56.6)	4 (7.3)	21 (25)
Not enough breast milk	9 (30)	8 (14.8)	17 (20)
Given pre-lacteal feeds	2 (6.7)	7 (13)	9 (10.8)
Discarding initial breast milk	0 (0.0)	1 (1.9)	1 (1.2)

Among selected samples, the reasons for not initiating breastfeeding early in intervention group, were tiredness which was observed in 17 (56.6%) mothers while 9 (30%) mothers perceived that breast milk was inadequate. Around 34 (63%) mothers were not aware of early initiation, 8 (14.8%) mothers felt inadequate secretion of breast milk, 7 (13%) mothers had given pre-lacteal feeds and 4 (7.3%) mothers felt tired in control group.

### Discussion

While breast feeding practices in India have improved over time, some of harmful practices are still continuing like use of prelacteal feeds, avoiding colostrum, early top feeding etc. In this study, it was investigated whether antenatal breastfeeding counselling prior to delivery improved outcomes of breastfeeding practices in terms of early initiation and knowledge about EIBF. The present study revealed that majority of the mothers-initiated breastfeeding within an hour with significant increase in the knowledge about early initiation of breast feeding after antenatal counselling prior to onset of labour. Antenatal counselling prior to onset of labour had a positive impact on improving the knowledge about breast feeding initiation. Counselling had also resulted in improved rates of early breastfeeding.

Out of 220 mothers, majority 201 (91.4%) were less than 30 years. The mean age of the mothers was  $26 \pm 3.8$  (SD) years. Phuljhele al. [10] reported 98.8% mothers less than 30 years of age which was higher in their study. About 111 (50.5%) mothers had studied up to higher

secondary classes. Another similar study has reported majority (34%) of the participants were illiterate [7]. Among selected samples, 60% mothers delivered by vaginal delivery, whereas 38.6% of mothers delivered their baby by caesarean section. Phuljhele al. [10] reported 52.5% had normal vaginal delivery and 47.5% underwent caesarean section. In the present study, male neonates were marginally less than female neonates (47.3% vs 52.7%). Another study has reported percentage of male neonates was marginally high 51.5% compared to 48.8% female neonates [7]. Around 77.27% neonates weighed more than 2.5 kg and 22.73% neonates were low birth weight.

In present study, 105 (95.5%) mothers acquired knowledge about EIBF (after counselling). Among them, 80 (72.7%) mothers breastfed their babies within an hour of birth. We found a significant increase in EIBF in counselled group. A study conducted by Phuljhele et al. [10] found that, 70.4% mothers acquired knowledge about EIBF (after counselling). Among them, 65.5% breastfed babies within an hour of birth. Koli et al reported, post counselling improved knowledge regarding breastfeeding practices significantly reflected in EIBF (91.85%) in their intervention group [11].

After counselling, majority of mothers acquired knowledge and breastfed the babies within an hour of birth. In control group, 51 (46.3%) had knowledge about EIBF while 59 (53.7%) were not aware of early initiation of breastfeeding which led to delayed initiation of breastfeeding in 54 (49.1%) mothers.

In our study, 72.7% initiated breastfeeding within one hour in intervention group and 56(50.9%) initiated breastfeeding within an hour in control group. Mullany et al. [12] in their study from Nepal reported that though majority of the mothers adopt breastfeeding practice, the initiation of breastfeeding within one hour was only in 3.4% of mothers. Phuljhele et al. [10] in their study among freshly counselled mothers, 65.5% initiated early compared to 46% early initiation in control group. With interventional counselling to AN mother immediately prior to delivery, we found significant increase in EIBF in our study. In a recent study done by Sunil P et al it was found that the rate of early initiation of breast feeding was found to be 80.8% (95%CI 76.4 to 84.6) [13].

In our study, 47.2% received AN counselling about EIBF during their AN visit but after intervention we found significant improvement in knowledge and early initiation of breastfeeding in intervention group. In control group (without intervention), 45.5% received counselling about EIBF in AN visit, 46.3% had knowledge about EIBF and only 50.9% initiated breastfeeding within 1 hour. Majority (99.1% intervention, 97.3% control) of mothers had more than 4 antenatal visits. With adequate AN visits in both groups, we found that counselling and awareness about EIBF was minimal in both groups. Phuljhele al. [10] reported 39.8% mothers received breastfeeding counselling during routine AN visit which was lower than our observations.

Bimerew et al. found that timely initiation of breastfeeding was significantly associated with the presence

of four and more antenatal appointments [14]. Tilahun et al. reported that advice on timely initiation of breast-feeding during ANC visits had shown association with early initiation of breastfeeding [15]. Another study found that advice given to mother on breast feeding during antenatal care visits and knowing importance of colostrum were positively associated with timely initiation of breastfeeding [16]. Koli et al. reported structured effective breastfeeding counselling in prenatal period resulted in an increase in rates of EIBF. It increased the knowledge regarding EIBF and also increased confidence of mothers and enabled them to breast feed their babies with least assistance [11]. In our study, due to immediate counselling prior to delivery, we found marked increase in the knowledge about EIBF in intervention group. Thus, our study emphasizes the importance of increasing awareness about EIBF during AN visit and also prior to delivery.

In our study, 63% were not aware about EIBF, 14.8% mothers had inadequate breastmilk, 13% gave prelacteal feeds, 7.3% mothers felt tired and 1.9% mothers discarded initial breastmilk in control group. Another study has found 94% mothers were unaware about EIBF which was higher when compared with our study. In addition, other factors responsible for delay in initiation in their study was: giving prelacteal feeds, delay in milk production, belief that colostrum is not good to the baby, fear of handling newborn baby etc. [17]. Their observations concurred with the findings of our study.

### **Limitation**

This study had certain limitations. It was a single-centre, quasi experimental study and therefore selection bias cannot be ruled out. The findings may not be generalizable to other settings. Long-term breastfeeding outcomes such as exclusive breastfeeding was not assessed.

### **Conclusion**

Antenatal counselling prior to onset of labour was associated with improved maternal knowledge regarding breastfeeding initiation and higher rates of early initiation of breastfeeding. However, given the quasi-experimental design and potential confounding factors, further randomized studies are warranted to confirm these findings.

### **Statements and Declarations**

#### **Conflict of interest**

The authors have no relevant financial or non-financial interests to disclose.

#### **Funding**

No funding was received for conduct of the study or preparation of the manuscript

#### **Data availability statement**

The data collected and utilized in the study are available from the corresponding author and will be shared on request.

#### **Ethical approval**

The study was performed after obtaining approval from the Institutional ethics committee (meeting held on 02/09/2021, Protocol ID 593/2021).

### **Informed consent**

Written informed consent was obtained from all the participants after duly explaining the details of the study. Consent was also obtained for publication ensuring confidentiality.

### **Authors' contribution**

SG: Concept of the study, data collection, data analysis, interpretation of data, drafting the article, reviewing the article, approval of version submitted; SB: Concept of the study, data analysis, interpretation of data, drafting the article, reviewing the article, approval of the version submitted; KD: Concept of the study, data analysis, interpretation of data, drafting the article, reviewing the article, approval of version submitted

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ORIGINAL ARTICLE

**Synchronous Double Primary Malignancies: Clinical and Pathological Analysis Report From Tertiary Cancer Center**

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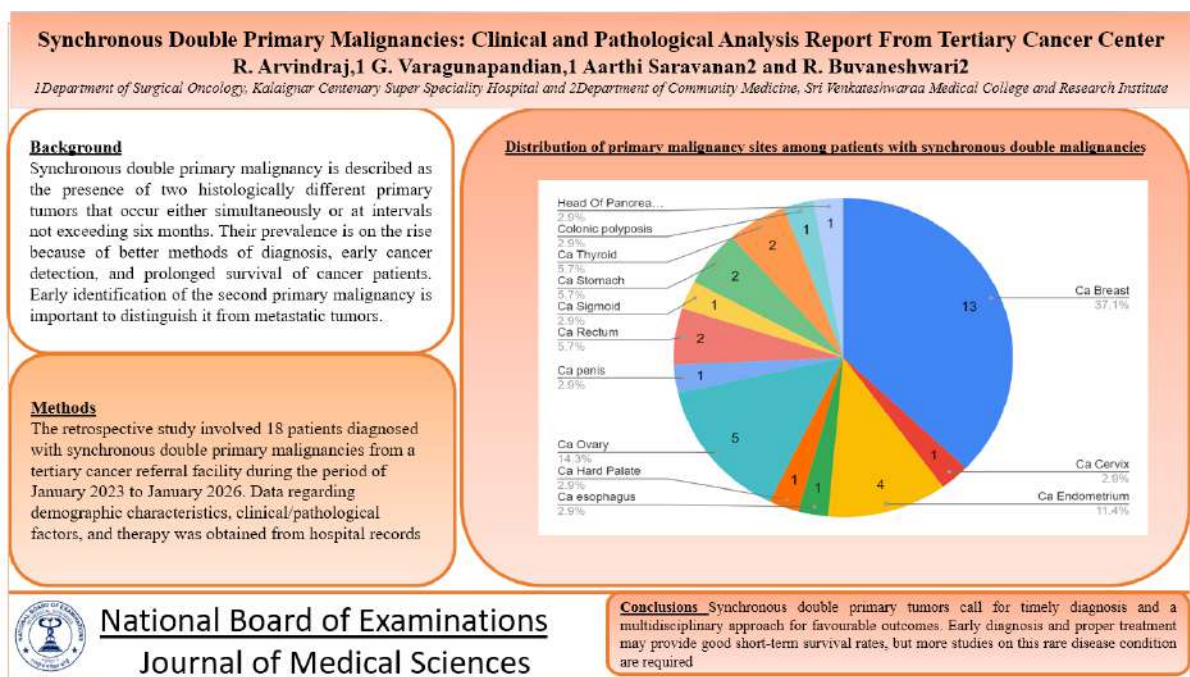
**Abstract**

**Background:** Synchronous double primary malignancy is described as the presence of two histologically different primary tumors that occur either simultaneously or at intervals not exceeding six months. Their prevalence is on the rise because of better methods of diagnosis, early cancer detection, and prolonged survival of cancer patients. Early identification of the second primary malignancy is important to distinguish it from metastatic tumors. **Methods:** The retrospective study involved 18 patients diagnosed with synchronous double primary malignancies from a tertiary cancer referral facility during the period of January 2023 to January 2026. Data regarding demographic characteristics, clinical/pathological factors, and therapy was obtained from hospital records. **Results:** Out of the 18 patients included in the study, 15 (83.3%) were females with a median age of 53.5 years. The most frequent cancer type was breast carcinoma, with ovarian and endometrial cancers coming second. Combination of bilateral breast carcinomas and synchronous ovarian-endometrial carcinomas was the most frequent combination among these tumors. Majority of the cases had positive family history of cancer. All of the patients underwent therapeutic procedures, where 10 patients underwent neoadjuvant therapy with subsequent surgery and 8 underwent surgery alone. **Conclusion:** Synchronous double primary tumors call for timely diagnosis and a multidisciplinary approach for favourable outcomes. Early diagnosis and proper treatment may provide good short-term survival rates, but more studies on this rare disease condition are required.

**Keywords:** Multiple primary neoplasm, Synchronous Neoplasm, Ovarian neoplasm, Clinicopathological features

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## Graphical Abstract



### Introduction

Multiples primaries malignancies (MPMs) are characterized by having two or more primary malignant tumors of different origins in the same person. The tumors should be independent of one another without any connection of metastasis from one lesion to another. Diagnostic criteria laid down by Warren and Gates are considered essential and fundamental for determining multiple primaries cancers. In this regard, each cancer should be proven to be malignant, histologically different, and non-metastasized, with each being separated from the other with normal tissue [1].

Classification of MPMs includes synchronic and metachronous depending upon the time interval between two cancer diagnoses. According to the classification, MPMs that occur together or within six months of each other are considered synchronic cancer, whereas those that occur after an interval of more than six months are metachronous cancers [2].

However, there has been an observed rise in the occurrence of multiple primary cancers in recent decades. Cases of double primary cancers have been predominant. Several factors have been attributed to this trend, including advances in diagnostic imaging, endoscopy, pathology, cancer screening programs, prolonged survival after cancer therapy, and increased life expectancy. Also, genetic predisposition, exposure to environmental carcinogens, smoking and alcohol use, lifestyle habits, and therapies like chemotherapy and radiation therapy have played a role in developing multiple primary cancers [2,3].

Synchronous double primary cancers pose a great diagnostic and treatment problem because distinguishing a secondary cancer from metastasis may be very problematic. It is extremely important to differentiate a secondary primary cancer from metastasis because their management differs significantly and affects patients' prognosis differently. Clinical examination,

imaging studies, pathology confirmation, and consultation are necessary for correct management [3,4].

Despite the rising prevalence of multiple primary malignancies globally, the Indian scenario with regard to existing data has been relatively underexplored. There have been mainly case reports and small series of cases available. There have been more studies involving the metachronous type than the synchronous type of multiple primary malignancy. Clinicopathological studies involving synchronous double primary malignancies are very rare [4,5].

The current retrospective study was performed for the purpose of understanding the clinicopathological features of cases with simultaneous double primaries encountered in the Department of Surgical Oncology within a tertiary cancer center during the past three years. The objectives of the study include an evaluation of the demographic features, localization of lesions, pathologic features, and management practices among these patients, thus adding to the scarce Indian data on this important issue.

## Materials and Methods

This retrospective observational study was conducted in the Department of Surgical oncology at a tertiary care center and included patients diagnosed with synchronous double primary malignancies between January 2023 and January 2026. After obtaining institutional ethical clearance and waiver of consent from the head of the institution, clinical records of 18 patients were retrieved and reviewed from the institutional database. Patients were included if they had at least two histopathological confirmed primary malignant tumors occurring simultaneously or within six months of each other with

each tumor demonstrating distinct histopathological features suggestive of an independent primary origin. Patients without clear histopathological confirmation of both tumors or those in whom the second lesion was suspected to be a metastasis or recurrence of the first primary malignancy were excluded from the study. The diagnosis of synchronous double primary malignancies was established based on clinical evaluation, radiological investigations and histopathological findings after excluding metastatic disease. Data regarding demographic characteristics, including age and sex, anatomical sites of the primary tumors, mode of diagnosis, histopathological subtype, clinical stage at presentation and treatment modalities were collected from the medical records, pathological reports and operative notes. The collected data were entered in Microsoft excel and analyzed using SPSS version 21. Patient confidentiality was maintained throughout the study by anonymizing all identifying information and the study was conducted in accordance with institutional ethical guidelines.

## Results

The total number of patients with simultaneous double cancers was 18, which were diagnosed in the period between January 2023 and January 2026. There was a significantly high occurrence of the condition among women, as there were 15 (83.3%) females and only 3 (16.7%) males, making a female/male ratio of 5:1. The ages of the subjects varied from 43 to 77 years, with an average age of 53.5 years.

Breast malignancies were most commonly involved, with nine cases (50%) followed by ovary (four cases, 22.2%) and endometrium (four cases, 22.2%). In

women, carcinoma ovary and endometrium (three patients) and bilateral breast carcinoma (three patients) were more common combinations of the synchronous malignancies. Other combinations included breast with rectal carcinoma, breast with renal cell carcinoma, breast with ovarian carcinoma, breast with endometrial carcinoma, and cervix with ovarian malignancy. The predominant sites of malignancies in males were the gastrointestinal tract, including one case each with carcinoma stomach with carcinoma hard palate and carcinoma penis. One patient had carcinoma rectum and papillary carcinoma thyroid.

A positive familial background for any form of cancer in first- or second-degree relatives was noted among 10 of the 18 participants (55.6%), which may imply hereditary susceptibility to the disease among a considerable number of patients. Biopsy diagnosis of all primary tumors was successfully confirmed in all patients. Most of the breast cancers were characterized by the histologic subtype of invasive ductal carcinoma of no special type (IDC-NOS), while the ovarian cancers were primarily high-grade serous carcinoma. On the other hand, the endometrial malignancies were primarily endometrioid adenocarcinoma and papillary serous carcinoma, whereas most of the gastrointestinal cancers were adenocarcinomas or squamous cell carcinomas.

The staging of all tumors was done in accordance with the 8th edition of AJCC

staging system. All patients were evaluated to undergo curative intent treatment. Out of the total number of patients studied, ten patients, constituting 55.6% of patients, underwent pre-surgical treatments while eight other patients, 44.4% of patients, had surgical resection performed first followed by adjuvant treatments. Definitive histopathological diagnosis was established prior to any form of treatment in all patients except those who had either renal or pancreatic tumors, whose histological diagnosis were confirmed following surgery.

Out of the total number of patients, one patient was documented to have experienced an anastomotic leak following the surgery, which led to his death. The patient had a concurrent carcinoma stomach and carcinoma penis. Thus, there was a postoperative mortality rate of 5.6% in this study. Disease recurrence occurred in four patients during the follow-up period (Figures 1 and 2).

Overall, the present study demonstrates that synchronous double primary malignancies occur predominantly in females with breast and gynaecological cancers constituting the most frequent combinations. Early recognition through comprehensive diagnostic evaluation and multidisciplinary management enabled curative treatment in the majority of patients and resulted in favourable short-term outcomes (Table 1).

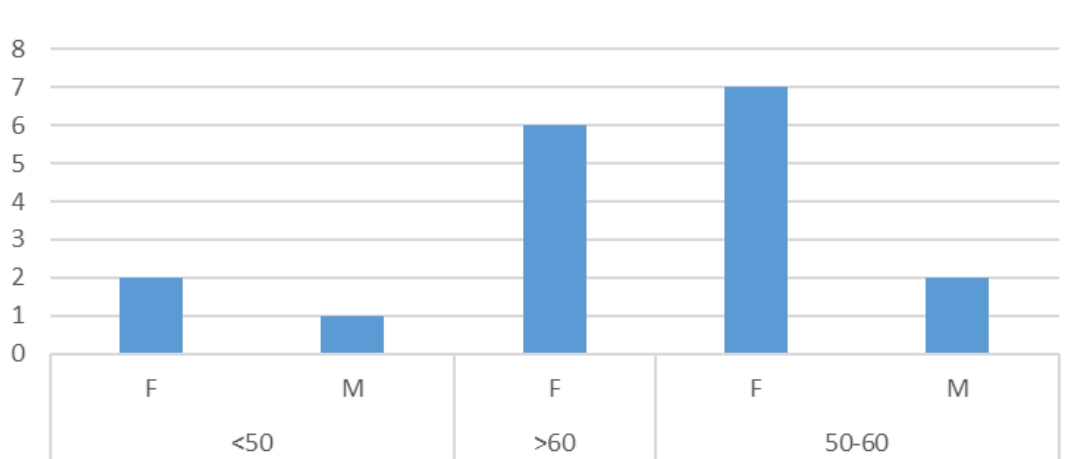


Figure 1. Distribution of synchronous double primary malignancy cases according to age group and gender

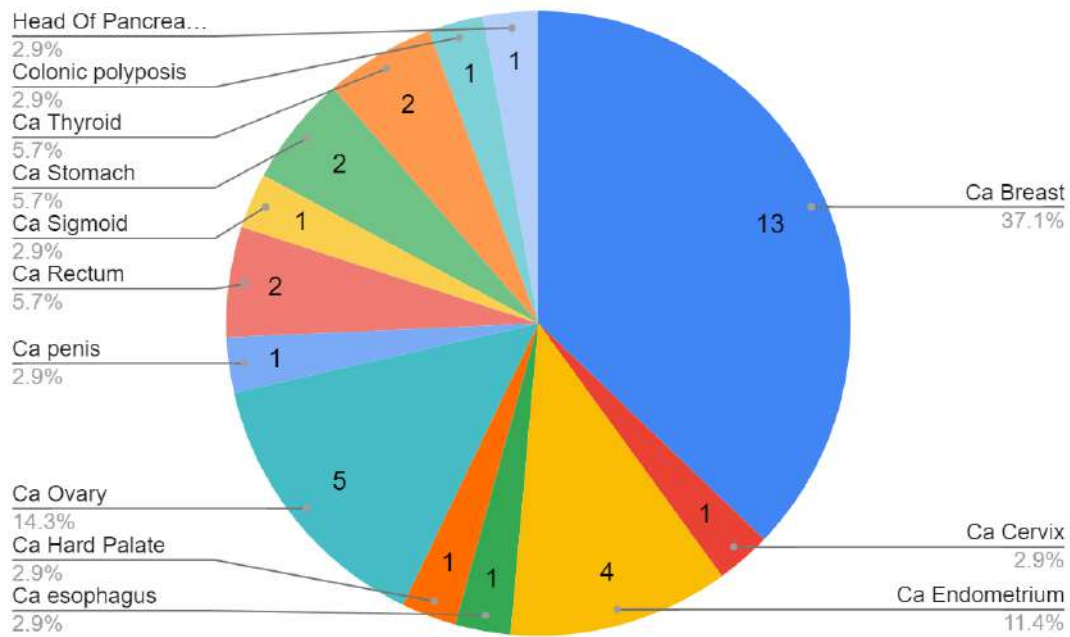


Figure 2. Distribution of primary malignancy sites among patients with synchronous double malignancies

Table 1. Clinicopathological characteristics and treatment details of patients with synchronous double primary malignancies

S. No	Age	Sex	First site	Treatment	HPE	2nd Site	Treatment	HPE
1.	56	F	Ca Cervix-	CCRT + Brachy	MD - Squamous cell carcinoma ((FIGO 2B)	Ca Ovary	NACT f/b Cytoreduction	Adult Granulosa cell tumor (FIGO 3C)
2.	64	F	Ca Ovary -	NACT f/b Cytoreduction	HG pap serous Ca (FIGO 3C)	Ca Endometrium	Cytoreduction	Endometroid AdenoCa Gr1 (FIGO 1A)
3	48	M	Ca Stomach	D2 Subtotal Gastrectomy f/b adj chemo	Poorly Diff AdenoCa (signet ring type)- pT4N1	Ca Hard Palate	Wide excision	MD SCC - pT2Nx
4	65	F	Ca Breast	MRM f/b Adj. chemo + RT	IDC-NOS G2 - pT2N2	Colonic polyposis	Total Proctocolectomy	Adenomatous polyposis with High Grade dysplasia
5	56	F	Ca Ovary	NACT f/b Cytoreduction	HG pap serous Ca (FIGO 3C)	Ca Endometrium	Cytoreduction	Endometroid AdenoCa Gr1 (FIGO 1A)
6	53	F	Ca Endometrium	NACT f/b Staging f/b EBRT & brachy	Pap Serous Ca (FIGO 2)	Ca ovary	NACT f/b Staging	Pap serous Ca (FIGO 3C)
7	54	M	Ca stomach	D2 Subtotal Gastrectom	PD adenoCa - pT4aN3b	Ca penis	Partial Penectomy + B/L IBD	MD SCC - pT3N3
8	77	F	Head Of Pancreas Mass	Whipple's procedure	Benign serous Cystadenoma	Ca breast	MRM	HG solid papillary DCIS
9	65	F	Ca R. Breast	NACT f/b MRM f/b Adjuvant	IDC NOS G2 ypT2N0	Ca L. Breast	NACT f/b MRM f/b Adjuvant	IDC NOS G3 ypT4bN3

				chemo + PMRT	(Luminal A)		chemo + PMRT	(TNBC)
10	57	F	Ca R. Breast	MRM	IDC-NOS G3 - pT2N0	R. Renal mass	Partial Nephrectomy	ccRCC-Gr1-pT1aNx
11	43	F	Ca Breast	MRM	IDC NOS Gr2 - pT2N0	Ca endometrium	Surgical Staging	PD adenoCa - FIGO 1A
12	53	M	Ca rectum	NACRT f/b LAR -> chemo	MD-AdenoCa ypT2N0	Ca Thyroid	TT + CCND+ R.FND	Pap Ca (classical) - pT2N1b
13	64	F	Ca Breast	MRM f/b Adj Chemo	IDC - NOS gr1 (Luminal A)	Ca Rectum	NACRT f/b LAR f/b Adj.Chemo	MD infiltrating AdenoCa ypT2N0
14	57	F	Ca Breast	NACT f/b MRM	IDC NOS - Gr2 (TNBC)	Ca Ovary	NACT f/b Cytoreduction	LG serous Ca
15	67	F	Ca esophagus	VATS Esophagectomy	MD - SCC - pT1bN0	Ca thyroid	Total Thyroidectomy + CCND	Invasive Follicular variant of Pap Ca - pT2N0
16	60	F	Ca R breast	MRM	IDC - NOS GR1 (luminal A)	Ca L Breast	MRM	HG-DCIS (Luminal A)
17	52	F	Ca Sigmoid	Anterior Resection	Tubulovillous adenoma with invasive Adenoca - Gr 2	Ca Breast	MRM	IDC - NOS Gr2-pT1N0
18	44	F	Ca R Breast	NACT f/b MRM f/b PMRT	IDC NOS Gr2 - ypT2N1 (Luminal A)	Ca L Breast	NACT f/b MRM f/b PMRT	IDC NOS Gr2 - ypT1N0 (TNBC)

## Discussion

Double synchronous primaries are rare, but increasingly recognized entities due to improvement in cancer detection methods, imaging, pathology, and prolonged survival in cases of malignancies. Simultaneous existence of two independent primaries creates considerable diagnostic difficulties and raises issues concerning differential diagnosis between secondary tumor and metastasis. It is important to make the correct diagnosis since there are vast differences in treatment strategies for both these diseases [6].

This study showed a distinct preponderance of females, with over four-fifths of subjects being women. This is mainly due to the prevalence of breast cancer and ovarian cancers seen in the current group of patients. Other institutional studies have shown similar findings in cases wherein there was a synchronous presence of tumors arising from the breast, ovary, and endometrium, the most frequent combination [7].

Breast carcinoma was the most frequent form of malignancy found among the participants, followed by ovarian and endometrial malignancies. Three patients had synchronous bilateral breast carcinomas, and three others had concurrent ovarian and endometrial carcinomas. The simultaneous occurrence of such tumors is known to be related to hereditary cancers, especially those caused by genetic mutations affecting BRCA1/BRCA2 genes and genes responsible for the mismatch repair deficiency syndrome. With the progress made by the use of next-generation sequencing technology, more emphasis should be placed on susceptibility genes

among individuals with multiple primary malignancies [8].

The common cancer sites in male patients included those from the gastrointestinal tract, which were linked to malignancies from the penis, thyroid gland, and mouth. This type of combination highlights the importance of synchronous malignancies occurring from different organ systems that could easily go undetected if attention is only focused on the initial site of malignancy. Proper imaging and pathology tests should thus be conducted before surgery [9].

Over 50% of the patients in this current study showed the presence of malignancy in their family history, including their first- and second-degree relatives. This may imply a potential hereditary factor, hence the need for a comprehensive family history among patients with multiple primary tumors. In recent molecular research, changes in the cancer susceptibility gene at a germline level have been shown to play an important role in the etiology of both synchronous and metachronous tumors [10].

Each of our patients was treated for their cancer on a curative basis after multidisciplinary assessment of the situation. Treatment modalities have been chosen depending on the specific stage of the tumor, its histology, as well as behavior. The presence of synchronous tumors may imply that priority of treatment should be given to certain aspects of management by coordinating efforts between surgical, medical, and radiation oncologists, weighing the risk-to-benefit ratio of therapy [11].

Of the studied cases, there was 1 postoperative death and 4 cases of recurrence, while other cases were disease-free at their last follow-up visits. According

to current literature, the prognosis of patients with simultaneous double primary cancers mainly depends on the stage and aggressiveness of each individual cancer and not because of the presence of more cancers in one patient.

Thus, the accurate diagnosis by thorough staging followed by prompt multi-specialty treatment is still the key to effective management [12].

This current research provides relevant information on the clinico-pathological aspects of synchronous double primary cancers in an Indian tertiary cancer institution; however, owing to its retrospective nature and limited sample size, the results obtained are not generalizable. It would be appropriate to conduct a multicentric prospective study with the inclusion of molecular genetic testing in future to elucidate the issues of risk factors, prognosis, and management of this rare but important condition.

### **Conclusion**

Double primary synchronous tumors are relatively uncommon but have been increasingly diagnosed in clinical practice owing to the advancement in diagnosis methods as well as enhanced cancer survivorship. The combination of breast and gynaecologic tumors was the most prevalent type of double primary tumors in the current study population, and they were predominantly observed in females. Timely detection of such tumors through meticulous patient examination, imaging analysis, and biopsy plays a significant role in distinguishing between metastatic disease and synchronous primaries for better management. Curative surgery could be successfully performed in most of our patients who had satisfactory early post-operative results. Prospective

multicentre studies with the inclusion of genetic testing are required in the future.

### **Limitations**

This retrospective study is a single centered study with a small sample size of 18 patients which limits the generalizability of the findings. Additionally, the lack of long term follow up and molecular genetic evaluation restricted assessment of survival outcomes and hereditary cancer predisposition. Larger multicentre prospective studies are needed to validate these findings

### **Statements and Declarations**

#### **Conflicts of interest**

The authors declare that they do not have conflict of interest.

#### **Funding**

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ORIGINAL ARTICLE

**Assessment of HbA1c and Vitamin D Levels in Type 2 Diabetes Mellitus in a Tertiary Care Hospital**

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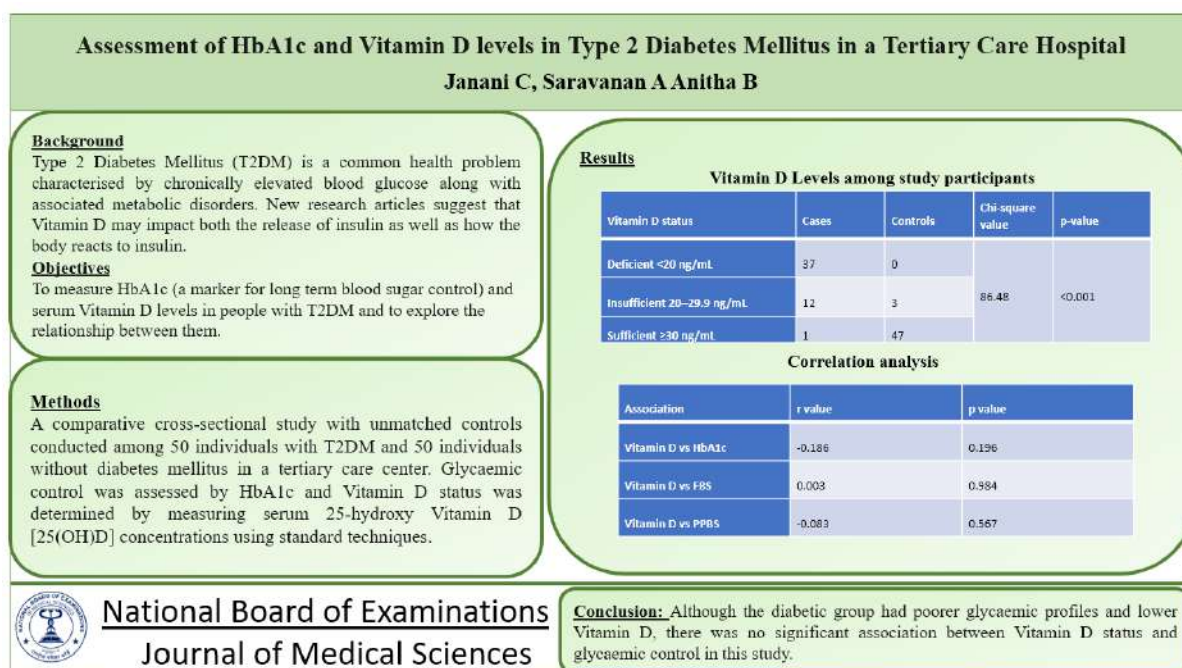
**Abstract**

**Background:** Type 2 Diabetes Mellitus (T2DM) is a common health problem characterised by chronically elevated blood glucose along with associated metabolic disorders. New research articles suggest that Vitamin D may impact both the release of insulin as well as how the body reacts to insulin. **Objective:** To measure HbA1c (a marker for long term blood sugar control) and serum Vitamin D levels in people with T2DM and to explore any relationship between them. **Materials and Methods:** A comparative cross-sectional study with unmatched controls conducted among 50 individuals with T2DM and 50 individuals without diabetes mellitus in a tertiary care center. Glycaemic control was assessed by HbA1c and Vitamin D status was determined by measuring serum 25-hydroxy Vitamin D [25(OH)D] concentrations using standard techniques. **Results:** Vitamin D levels in those with diabetes ( $17.76 \pm 5.29$  ng/mL) were significantly lower than controls ( $44.31 \pm 11.87$  ng/mL,  $p < 0.001$ ). The mean HbA1c values were also higher in the diabetic group ( $11.43 \pm 1.88\%$ ) than controls ( $5.41 \pm 0.58\%$ ,  $p < 0.001$ ). In the diabetic subjects, 74% were deficient in vitamin D. Diabetic patients also had higher levels of fasting and postprandial glucose, total cholesterol and triglycerides and lower HDL cholesterol ( $p < 0.001$ ). There was a weak negative correlation between Vitamin D and HbA1c ( $r = -0.186$ ), fasting blood sugar ( $r = 0.003$ ) and postprandial blood sugar ( $r = -0.083$ ) but these were not statistically significant. **Conclusion:** Although the diabetic group had poorer glycaemic profiles and lower Vitamin D, there was no significant association between Vitamin D status and glycaemic control in this study.

**Keywords:** Type 2 DM; Vit D Deficiency; HbA1c; 25-Hydroxy Vitamin D

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## Graphical Abstract



## Introduction

Diabetes mellitus, Type 11 (T2DM) is an important non-communicable disease worldwide and a major public health challenge in India. Diabetes is rising due to rapid urbanisation, sedentary lifestyles, changing diets, obesity, an ageing population and genetic factors. The ICMR-INDIAB study has revealed a massive burden of metabolic diseases in India, with nearly 101 million people having diabetes and 136 million having prediabetes [1].

HbA1c- Glycated haemoglobin is a well-recognised marker of glycaemic control on a long-term basis, which reflects the mean blood glucose level over the last 3 months. It is often used in diagnosis, monitoring and management of diabetes. The ADA - American Diabetes Association suggests a HbA1c threshold of 6.5% or more for the diagnosis of DM, and this marker is used to assess both treatment adequacy and the risk of chronic complications in people with diabetes [2].

Vitamin D is recognised less for its function in bone and calcium metabolism, than its extra-skeletal functions. The presence of receptors for Vitamin D in the pancreatic beta cells and other insulin responsive tissues stresses that there is a possibility of an effect on insulin secretion and sensitivity. Vitamin D may influence glucose metabolism through various mechanisms such as regulation of insulin receptor expression, promotion of calcium-mediated insulin secretion, decrease of inflammation, and enhancement of peripheral insulin sensitivity [3–5].

Vitamin D deficiency is frequently reported in individuals with T2DM. Several observational studies and systematic reviews have shown an association of lower levels of serum 25-hydroxyvitamin D with poorer glycaemic control, higher HbA1c and increased insulin resistance [6-8]. This is particularly the case in India, where, several factors such as reduced sun exposure, darker skin pigmentation,

traditional clothing, poor dietary intake and insufficient food fortification influence the Vitamin D deficiency prevalence [9].

Previous studies have shown that in T2DM patients, serum Vitamin D is inversely related to HbA1c, suggesting that those with lower Vitamin D have poorer glycaemic control [7,8]. However, results are not completely consistent because the association might be influenced by variables such as age, duration of diabetes, obesity, kidney function, medications, sunlight exposure and dietary patterns. Recent meta-analyses also suggest that Vitamin D supplementation may improve fasting blood glucose, HbA1c and insulin resistance in individuals with T2DM, though more population specific research is needed [10].

Therefore, the estimation of HbA1c and vitamin D among patients with Diabetes Mellitus (Type II) in tertiary care hospitals is of clinical significance. This approach can help to estimate the Vitamin D deficiency prevalence and examine their relationship with glycaemic control which may support more comprehensive diabetes management by highlighting modifiable nutritional factors.

### ***Aim***

To evaluate HbA1c levels and serum Vitamin D in patients with Type 2 Diabetes Mellitus in a tertiary care hospital.

### ***Objectives***

- To assess the levels of HbA1C and Vitamin D among patients with and without T2DM.
- To assess the relationship between serum Vitamin D levels and glycaemic status (HbA1c) in patients with and without T2DM.

## **Methodology**

### ***Study Design***

A comparative cross-sectional study with unmatched controls was done in the Department of Biochemistry in a tertiary care teaching hospital in Salem.

### ***Study Setting***

Participants were recruited from the Diabetology and General Medicine outpatient clinics and among the inpatients at Government Mohan Kumaramangalam Medical College Hospital, Salem.

### ***Study Period***

Data collection was conducted from April 2020 to September 2020.

### ***Study Population***

The study population included the adult patients diagnosed with Type 2 Diabetes Mellitus who visited the tertiary care hospital during the study period and non-Diabetic visitors accompanying the study recruits.

### ***Inclusion Criteria***

Adults aged 30 or above.

With established Diagnosis as Diabetes Mellitus (Type II) according to ADA Criteria [1].

Willing to participate and give written informed consent.

### ***Exclusion Criteria***

Type I Diabetes Mellitus

Pregnancy

Vitamin D supplements in the past 6 months.

Chronic kidney or liver disease.

Known malabsorption syndromes.

Concurrent intake of medications known to have interactions with metabolism of Vitamin D (e.g.,

anticonvulsants, glucocorticoids, anti-tubercular drugs).

### **Sample Size**

A convenient sample of 50 patients with Type 2 Diabetes Mellitus who fulfilled the inclusion criteria was recruited during the study period. The control group comprised 50 accompanying caregivers/attendants or visitors of patients attending the hospital who had no prior diagnosis of diabetes mellitus. Controls were selected concurrently during the same study period and were not matched to cases. Individuals with a history of diabetes mellitus, pregnancy, chronic liver disease, chronic kidney disease, malabsorption syndromes, recent Vitamin D supplementation, or medications known to affect Vitamin D metabolism were excluded from the control group.

### **Data collection**

After obtaining consent, demographic and clinical data including age, sex, duration of diabetes, treatment history, body mass index (BMI) and co-existing conditions were collected via a structured questionnaire.

### **Sample Collection**

An overnight fasted 5 mL blood sample was collected aseptically from each participant. Blood for estimation of HbA1c was collected in EDTA tube. Blood for estimation of Vitamin D was collected in a plain tube. Serum was separated by centrifugation and either analysed immediately or stored at  $-20^{\circ}\text{C}$  until required.

### **Laboratory Tests**

HbA1c was estimated by HPLC-High Performance Liquid Chromatography or immunoturbidimetric technique (as per laboratory standard operating procedures) [2].

Vitamin D Serum 25-hydroxy Vitamin D [25(OH)D] concentration was determined by the Chemiluminescence Immunoassay (eCLIA) method [3]

Vitamin D status was classified as follows:

Sufficient:  $\geq 30\text{ng/ml}$

Insufficient: 20-29 ng/mL

Deficient:  $< 20\text{ ng/ml}$

### **Primary Outcome**

Serum Vitamin D in patients with T2DM.

### **Secondary Outcomes**

HbA1c levels in the same patient group; correlation between Vitamin D and HbA1c values; relationship between Vitamin D deficiency and glycaemic control.

### **Statistical Analysis**

All data collected were entered into MS Excel and analysed using SPSSv16.0. Continuous variables were summarised as mean  $\pm$  standard deviation (SD) and categorical variables as counts and percentages. An independent Student's t-test was used to compare group means and a chi-square test was used for categorical variables. Statistical significance was defined as a p-value of  $< 0.05$ .

### **Results**

The mean age of the individuals with Type 2 Diabetes Mellitus (T2DM) in this study was  $48.38 \pm 8.26$  years while the mean age in the control group was  $50.66 \pm$

7.84 years. No statistically significant differences in age were found between the groups ( $p = 0.160$ ). The diabetic cohort had a higher proportion of female participants

(58.0%) compared to males (42.0%). In the control group males and females were equally represented (50% males, 50% females) (Table 1).

Table 1. Distribution of Continuous variables

Variable	Cases: Mean $\pm$ SD	Controls: Mean $\pm$ SD	p value
Age	48.38 $\pm$ 8.26	50.66 $\pm$ 7.84	0.160
FBS	161.22 $\pm$ 42.04	87.82 $\pm$ 9.76	<0.001
PPBS	233.64 $\pm$ 52.31	150.40 $\pm$ 24.42	<0.001
Total cholesterol	211.60 $\pm$ 33.05	157.54 $\pm$ 18.94	<0.001
Triglycerides	205.74 $\pm$ 67.15	115.46 $\pm$ 19.84	<0.001
HDL	23.84 $\pm$ 7.94	50.88 $\pm$ 6.97	<0.001
Vitamin D	17.76 $\pm$ 5.29	44.31 $\pm$ 11.87	<0.001
HbA1c	11.43 $\pm$ 1.88	5.41 $\pm$ 0.58	<0.001

The fasting blood sugar (FBS) levels were significantly higher in diabetic group (161.22  $\pm$  42.04 mg/dL) than in controls (87.82  $\pm$  9.76 mg/dL) and this difference was highly statistically significant ( $p < 0.001$ ). A similar trend was

observed in the post prandial blood sugar (PPBS) values, where the mean PPBS values for T2DM participants were higher (233.64  $\pm$  52.31 mg/dL) when compared to controls (150.40  $\pm$  24.42 mg/dL;  $p < 0.001$ ) (Table 2).

Table 2. Vitamin D Levels among study participants

Vitamin D status	Cases	Controls	Chi-square value	p-value
Deficient <20 ng/mL	37	0	86.48	<0.001
Insufficient 20–29.9 ng/mL	12	3		
Sufficient $\geq$ 30 ng/mL	1	47		

Lipid profile analysis revealed that T2DM subjects had higher mean total cholesterol ( $211.60 \pm 33.05$  mg/dL vs.  $157.54 \pm 18.94$  mg/dL), triglycerides ( $205.74 \pm 67.15$  mg/dL vs.  $115.46 \pm 19.84$

mg/dL) and lower HDL cholesterol ( $23.84 \pm 7.94$  mg/dL vs.  $50.88 \pm 6.97$  mg/dL) than healthy controls. All differences were significant ( $p < 0.001$ ) (Table 3).

Table 3. Correlation analysis

Association	r value	p value
Vitamin D vs HbA1c	-0.186	0.196
Vitamin D vs FBS	0.003	0.984
Vitamin D vs PPBS	-0.083	0.567

Serum Vitamin D concentrations were significantly lower in the diabetic group ( $17.76 \pm 5.29$  ng/mL) compared to controls ( $44.31 \pm 11.87$  ng/mL;  $p < 0.001$ ). The mean HbA1c was also significantly higher in diabetics ( $11.43 \pm 1.88\%$ ) than in controls ( $5.41 \pm 0.58\%$ ;  $p < 0.001$ ), confirming poor glycaemic control in the diabetic population.

Vitamin D status was deficient in 74%, insufficient in 24% and sufficient in 2% of patients with T2DM. In contrast, none of the controls were deficient, with most (94%) being sufficient in Vitamin D and 6% being insufficient. The difference in vitamin D status between groups was highly significant ( $\chi^2 = 86.48$ ,  $p < 0.001$ ).

Correlation analysis revealed a weak negative relation between serum

Vitamin D and HbA1c among diabetic patients ( $r = -0.186$ ,  $p = 0.196$ ). Weak nonsignificant correlations were also found between Vitamin D and fasting blood sugar ( $r = 0.003$ ,  $p = 0.984$ ) and postprandial blood sugar ( $r = -0.083$ ,  $p = 0.567$ ). These findings suggest that serum Vitamin D is not significantly associated with long- or short-term glycaemic control in this study cohort.

### Discussion

In this study, T2DM patients presented significantly lower serum Vitamin D levels than controls, consistent with the previous findings of Kostoglou-Athanassiou et al. who also reported an inverse association between Vitamin D and HbA1c levels [11]. Vitamin D deficiency was found in 74% of diabetic subjects in the present study, which is in agreement with Olt's finding of a 98.3% deficiency rate in diabetic patients [12].

Mean HbA1c among diabetics in the present study ( $11.43 \pm 1.88\%$ ) was significantly higher than controls. Similar observations were also reported by Zhang et al., who reported higher HbA1c levels and a significant negative correlation between HbA1c and Vitamin D in patients with deficiency of Vitamin D [13].

In this study, we did see a weak negative correlation between Vitamin D and HbA1c, but it was not statistically significant. In the presence of a high prevalence of deficiency, Olt et al. similarly reported no significant association between Vitamin D levels and glycaemic control [12]. Similarly, Dutta et al. reported high prevalence of Vitamin D deficiency in both diabetic and non-diabetic Indian populations, but no significant association between Vitamin D and either HbA1c or

insulin resistance, in agreement with these findings [14].

In contrast, some studies such as that of Kostoglou-Athanassiou et al. showed a significant inverse association between Vitamin D and HbA1c, indicating that lower Vitamin D concentrations may be associated with poor glycaemic control [11]. Vitamin D deficiency was also an independent predictor for higher HbA1c levels after adjusting for confounders, as was found by Zhang et al. [13]. Differences in findings may be due to differences in sample size, ethnicity, obesity rates, duration of diabetes, dietary and sun exposure patterns, or other clinical characteristics.

Moreover, a significant increase in cholesterol and triglyceride levels and a significant decrease in HDL levels were observed in diabetics supporting the concept that Vitamin D deficiency is often related to metabolic perturbations and dyslipidaemia in T2DM that could elevate the overall cardiometabolic risk [13].

These observations are in line with previous evidences that reported a high prevalence of Vitamin D deficiency among T2DM patients. However, no significant association between Vitamin D and glycaemic control was found in this cohort, although a weak negative trend was observed [12,14].

Although a high prevalence of Vitamin D deficiency was observed among patients with Type 2 Diabetes Mellitus, no statistically significant correlation was found between serum Vitamin D levels and HbA1c in the present study. Several factors may explain this finding. First, the relatively small sample size may have limited the statistical power to detect a weak association. Second, glycaemic control in T2DM is influenced by multiple

factors, including duration of diabetes, medication adherence, dietary practices, obesity, physical activity, and genetic predisposition, which may have a greater impact on HbA1c than Vitamin D status alone. Third, the high prevalence of Vitamin D deficiency among diabetic participants may have reduced variability in Vitamin D levels, making it difficult to demonstrate a significant relationship. In addition, unmeasured factors such as sunlight exposure, nutritional intake, and seasonal variation in Vitamin D status may have acted as confounders. Therefore, while Vitamin D deficiency appears to be highly prevalent in individuals with T2DM, its independent influence on glycaemic control remains uncertain and warrants further investigation through larger prospective studies incorporating adjustment for potential confounding variables.

### **Conclusion**

This study showed significantly lower serum Vitamin D levels in individuals with Type 2 DM, as well as higher HbA1c, fasting and postprandial blood glucose, triglycerides, total cholesterol and lower HDL cholesterol levels when compared to healthy controls. There was a higher vitamin D deficiency prevalence in the group with diabetes, with about three-quarters of them classified as deficient. A weak inverse relationship between Vitamin D and glycaemic parameters was noted, however the association was not statistically significant. Despite a high prevalence of Vitamin D deficiency among patients with T2DM and association with poorer metabolic profiles, this study did not demonstrate a significant relationship between serum Vitamin D and glycaemic control. Larger, prospective interventional

works are required to define the role of Vitamin D in diabetes pathogenesis and management.

### **Limitations**

The study was conducted at a single tertiary care centre with a relatively small sample size, and no formal a priori sample size calculation was performed, which may have limited the power to detect modest associations between Vitamin D status and glycaemic parameters. The control group consisted of unmatched accompanying caregivers/attendants, which may have introduced selection bias, and the analyses were based on unadjusted comparisons and correlation tests; therefore, potential confounding factors such as body mass index, duration of diabetes, dietary habits, sunlight exposure, physical activity, and other metabolic variables were not accounted for. Therefore, the findings should be interpreted with caution and validated through larger prospective studies with comprehensive adjustment for potential confounders.

### **Statements and Declarations**

#### **Conflicts of interest**

The authors declare that they do not have conflict of interest.

#### **Funding**

No funding was received for conducting this study.

#### **Ethical Approval**

Ethical approval for the research was obtained from the Institutional Ethics Committee of Government Mohan Kumaramangalam Medical College and Hospital, Salem (Ref No. GMKMC&H/4341/IEC/2019-314).

### Informed Consent

Written informed consent was obtained from all participants prior to enrolment in the study.

### Authors Contributions

CJ: has contributed to the conceptualization, design of the study, literature search, data acquisition, manuscript editing and review; AS: contributed towards conceptualization, Manuscript review and editing. BA: contributed towards literature search, data analysis, manuscript writing, review and editing. CJ: Acted as the corresponding author for this.

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## LESSONS

### Low-cost Outpatient Manual Separation of Labial Adhesions Avoids Robotic Surgery in A 3-Month-Old Infant

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#### Case Report

A 3-month-old female infant presented to the outpatient department with a 2-week history of *post-void dribbling*, which was noticed by parents after each urination. There was mild local irritation but no history of any fever, urinary retention, recurrent urinary tract infections, or systemic symptoms. The infant was born at term via normal vaginal delivery with an uneventful perinatal period. No history of trauma, prior genital manipulation, or significant diaper dermatitis was reported.

On genital examination, complete labial adhesions were present with the fusion of the labia minora from the posterior fourchette up to near the clitoral hood, leaving only a small anterior opening for urine passage (Figures 1 A and B). The

adhesion was thin and filmy and a midline raphe was visible on examination.

Informed consent of the parents was taken and a manual separation of the adhesions was performed by the pediatric surgeon in the OPD procedure room under sterile and aseptic precautions. The thin adhesion was removed by a gentle lateral traction with gloved fingers without using any sharp instruments. There was minimal ooze, which stopped with gentle pressure. The procedure was well tolerated with minimal distress to the infant. The separation of the adhesions was achieved easily, with minimal resistance, without any blood loss or significant pain or distress to the infant. Post-separation, the urethral meatus and vaginal introitus were clearly visualized and patent (Figure 1 C).

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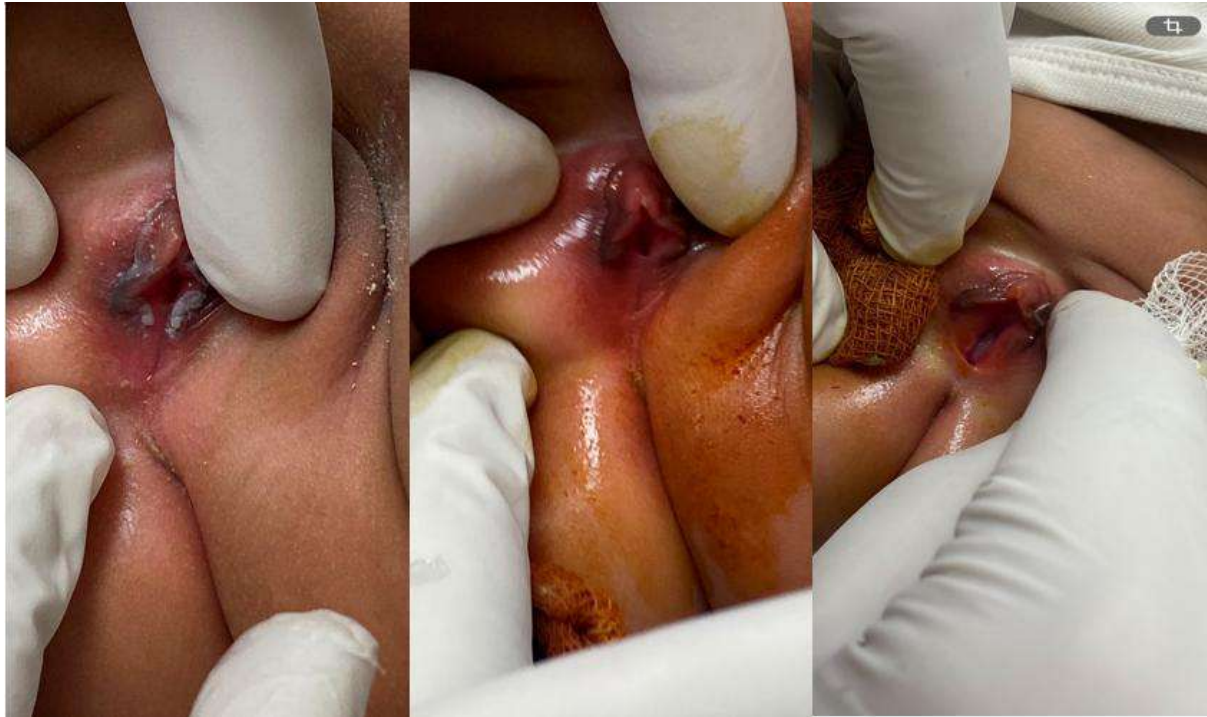


Figure 1. A & B. Pre-procedure clinical photographs of the infant showing complete labial adhesions with narrow urinary stream outlet. C: Immediate post-procedure photographs demonstrating successful manual release of the labial adhesions with restored normal anatomy (separate urethral and vaginal openings).

Local hygiene was explained to baby's parents and were advised to apply neomycin-polymyxin B-bacitracin ointment twice daily for 7–10 days to prevent infection and re-adhesion. A barrier ointment (e.g., petroleum jelly) application was advised for a few weeks. Parents were instructed to report on noting any signs of recurrence.

Follow-up examination at 1 week and 4 weeks showed complete resolution of post-void dribbling, no recurrence of adhesions, and normalisation of voiding pattern. The parents were reassured and educated about the condition.

The patient had previously been evaluated elsewhere. She was suspected to have Vesico-Vaginal fistula & advised robotic surgery. This was due to lack of performing a thorough clinical

examination. This procedure had a high estimated cost and potential anesthetic risks for a 3-month-old infant. In contrast, a simple, low-cost manual separation was successfully performed in the pediatric surgery outpatient department (OPD) procedure room under aseptic conditions using gentle lateral traction with gloved fingers. No sedation or general anesthesia was required. Post-procedure application of Neosporin ointment and appropriate aftercare prevented recurrence, demonstrating that timely intervention by an experienced pediatric surgeon can safely avoid the need for more invasive and expensive surgical approaches.

This case illustrates a successful, minimally invasive management of symptomatic labial adhesions in early infancy in an outpatient setting.

## Lessons

Labial adhesions remain a common acquired condition in prepubertal girls caused by hypoenestrogenism, local inflammation, and minor trauma leading to midline fibrous bridging [1]. Although most common between 13–23 months of age, presentation in early infancy (including at 3 months) is recognized, particularly when symptoms such as *post-void dribbling* occur due to urine pooling in the vaginal vestibule behind the adhesion.

Classic symptoms include post-void dribbling, urinary stream abnormalities, recurrent vulvovaginitis, dysuria, or (rarely) acute urinary retention [2-4]. In this infant, post-void dribbling was the predominant and easily noticeable symptom that prompted medical attention. Early recognition during routine well-baby visits or parental reporting is important.

## Management Considerations in Young Infants

While topical estrogen or corticosteroid creams are usually first-line for most cases, thin adhesions in very young infants can often be gently separated manually in the outpatient setting by an experienced pediatric surgeon [5,6], as illustrated in Figure 2. Our approach prevents the need of prolonged topical therapy, reduces parental anxiety, and provides immediate symptomatic relief. Key prerequisites include:

- Thin/filmy adhesions (not dense or scarred)
- Availability of topical anesthesia if needed
- Strict asepsis
- Comprehensive aftercare with barrier/antibiotic ointment

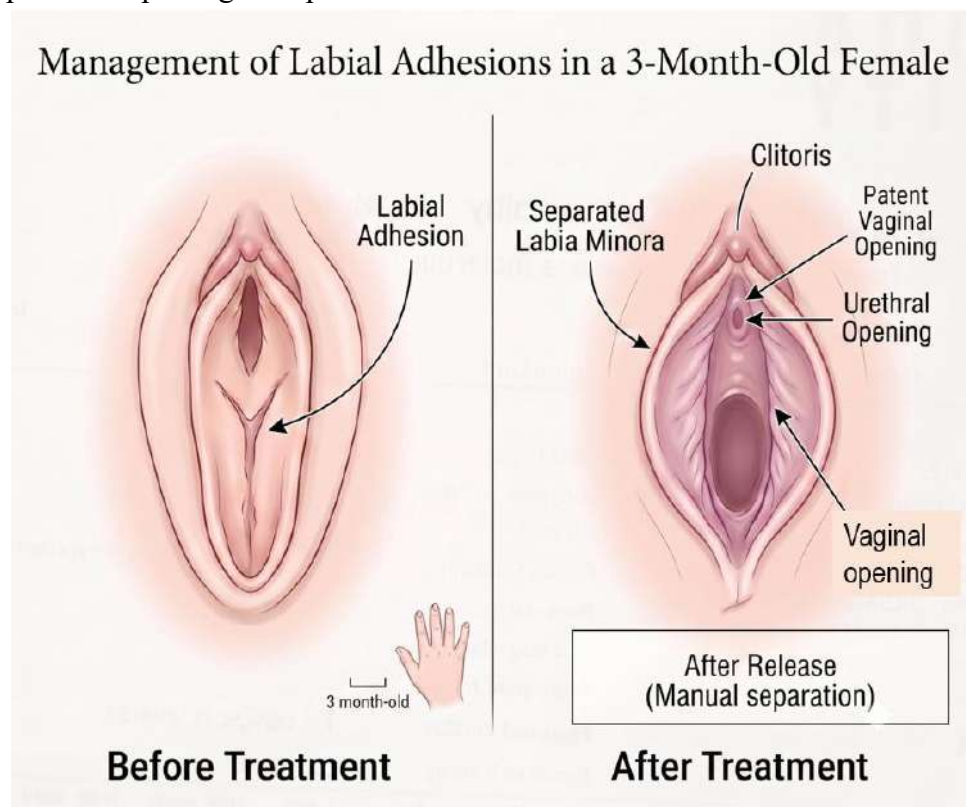


Figure 2. Schematic diagram illustrating pre- and post-separation anatomy of labial adhesions. These figures have been made with the use of an AI tool (Google Gemini).

Recurrence rates after manual separation range from 10–30% [1,7-9]. Hence, meticulous post-procedure care with emollients for at least 4–8 weeks is essential. Surgical lysis of adhesions under anesthesia is reserved for those with failure of manual separation or thick adhesions.

### **Advantages of Outpatient Approach**

In resource-appropriate settings, this is a safe and cost-effective method. It also avoids the risks of general anesthesia in neonates and infants.

### **Lessons**

This case reiterates the importance of tailoring the management based on age, adhesion characteristics, and symptom severity. Post-void dribbling in female infants should raise suspicion for labial adhesions. Prompt and gentle intervention by pediatric surgeon when indicated can yield excellent outcomes with minimal morbidity. Clinicians should maintain a high index of suspicion and counsel parents pragmatically. There should also be proper documentation of images of the procedure (with informed consent) for medicolegal purposes.

### **Conclusion**

The successful OPD manual separation in this 3-month-old with post-void dribbling highlights that even in early infancy, symptomatic labial adhesions can be managed effectively with a minimally invasive approach.

### **Statements and Declarations**

#### **Conflicts of interest**

The authors declare that they do not have conflict of interest.

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