National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, May; ISSN 2583-7524

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

The Journal is indexed in

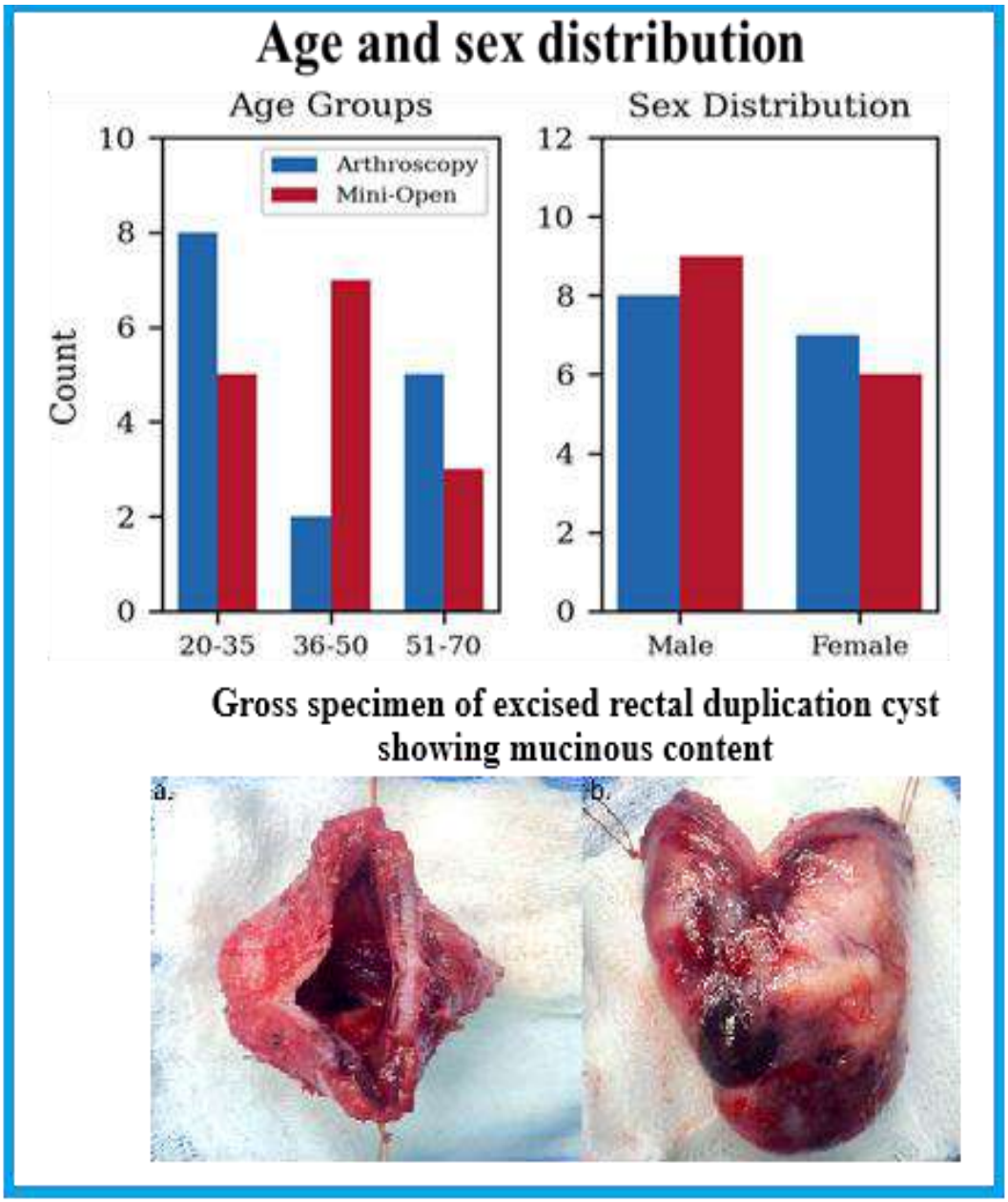
NEW

NBEJMS

N
B
E

J

M
S



Gross specimen of excised rectal duplication cyst showing mucinous content

NATIONAL BOARD OF EXAMINATIONS –
JOURNAL OF MEDICAL SCIENCES

Volume 4 • Issue 5 • May 2026

EDITORIALS

India's Critical Transition in Regenerative Medicine: Confronting the Structural Challenges & A Solutions Framework
Minu Bajpai and Abhijat C. Sheth **645**

India's Critical Transition from Exploratory Stem Cell Research to Scalable, Evidence-Based Regenerative Medicine & The Role of National Biobank Repositories
Minu Bajpai and Abhijat C. Sheth **651**

ORIGINAL ARTICLES

Diabetic Retinopathy Screening with Artificial Intelligence in Remote Areas
Ajit Pal Singh, Vijay Singh, Sujeet Kumar Jain, Aisha Beg, Suyash Saxena and Rahul Saxena **655**

Serum Adropin Levels as a Potential Biomarker in Diabetic Nephropathy: An Analytical Cross-Sectional Analytical Study
B. Priyadharsini, S. Sangeethapriya and K. Magila **667**

Phytochemical Profiling and Experimental Validation of Wound and Burn Wound Healing Activity of the Whole Plant of *Euphorbia hirta* Linn
R. Vidhya, Sheshagiri Dixit, B.R. Prashantha Kumar and Sudharsan S **681**

A Retrospective CT Study to Evaluate the Horizontal and Vertical Positions of the Mental Foramen and the Prevalence of Accessory Mental Foramen in Western Tamilnadu, India
Ravikumar R, Sriram Balaji, Sabari Arasu Palanisamy, Arun Kumar Subramaniam and Jeevithan Shanmugam **693**

Effectiveness of Silodosin versus Tadalafil as Medical Expulsive Therapy for Lower Ureteric Calculi: A Randomized Controlled Trial
Aquinas Benedict, R Vinoth Kumar and Jeyapal Parthiban **702**

Study of Factors Associated with Trends in Utilization of Childbirth Services in Tribal Visakhapatnam: A Mixed Method Approach
JK Burila, Devi Madhavi Bhimarasetty, JV Siva Priya and Kiran Pamarthi **715**

Maternal Serum Cholesterol levels in Early Pregnancy as a Predictor for Preterm Delivery
Ajmun Nisha Fathima M, Rajeshwari S, Vanitha Nallathambi and Jeevithan Shanmugam **729**

A Comparative Study of Functional Outcomes of Rotator Cuff Repairs Using Arthroscopy Versus Mini-Open Techniques
Varun GBS, Gurucharan S, Somasundaram Sekar, Darshan T and Shuchindra R Chowdhary **739**

(Contents Continued)

Smartphone Usage, Sleep and Depression Among the Students' Community Emerging from the Covid-19 Pandemic: A Cross Sectional Study
Anisha D.P., Mubeen Taj, Arnab Saha, Preethi S, Dhanraj Jalindar Bhore and Rubhika G **751**

Management Outcome of Odontoid Fracture: Conservative vs Surgical Treatment: A Comparative Study
V Sureshkumar and M. Makesh Kumar **773**

Evaluating Knowledge, Attitude, and Perception on Needle Stick Injuries among Medical Students in a Tertiary Care Centre: A Cross-sectional Observational Study
Vinni Greesha V, Naveena Arulanandan, Soundarya R, B. Ananthi, Sivaharivelan Thiagarajan and Balakumar M **785**

A Prospective Study on Manipulation with Hydrodilatation and Steroid Injection in the Management of Frozen Shoulder
V. Ramson, T. Thirumalaiswamy and Ranjithkumar R **797**

Evaluation of Post-Assessment Remedial Training for Competency-Based Biochemistry Education for Medical Undergraduates in Haveri district of Karnataka in India
Ashakiran Srinivasaiah, Mahalaxmi S Petimani, Siddharameshwar M Kantikar and Harish Rangareddy **810**

Predictive Value of Serum Fetuin-A in the Assessment of Disease Severity in Alcoholic Liver Cirrhosis
B. Anitha, S. Vinitha and B.S. Sobia **836**

CASE SERIES

Perioperative Anesthetic Management of Ruptured Aortic Aneurysms: A Case Series from a Tertiary Care Hospital
Jeenu D, Rahavi R, Meenu Anna John, Nitish Vijayanand, Kirubakaran Davis and Sathish Kumar Dharmalingam **847**

Isolated Giant Ureteric Calculus in an Otherwise Healthy Adult: A Case Report
Shitangsu Kakoti and Dharitri Dutta **856**

Rectal Duplication Cyst: An Eye Opener
Suvam Kumar, Sharada Sundaramurthy and Temsula Alinger **862**

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 645–650, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.001

EDITORIAL

India's Critical Transition in Regenerative Medicine: Confronting the Structural Challenges & A Solutions Framework

Minu Bajpai[1,*] and Abhijat C. Sheth[2]
[1]*Vice-President & Honorary Executive Director, National Board of Examinations in Medical Sciences, New Delhi*
[2]*Chairman of National Medical Commission & President, National Board of Examinations in Medical Sciences, New Delhi*

Accepted: 4-May-2026 / Published Online: 6-May-2026

India stands at a decisive juncture in the evolution of regenerative medicine. Over the past two decades, the country has developed a strong foundation in stem cell science, supported by academic excellence, clinical diversity, and a growing innovation ecosystem. However, the transition from exploratory research to **scalable, evidence-based regenerative medicine** remains incomplete. The core issue is not the absence of scientific capability, but the absence of **systemic coherence across regulation, translation, manufacturing, and delivery**.

At the forefront of this challenge is **regulatory fragmentation and enforcement**. Despite well-articulated national guidelines by the Indian Council of Medical Research and the Department of Biotechnology, oversight remains distributed across multiple bodies with overlapping mandates. This has resulted in inconsistent implementation and, more concerningly, the proliferation of unregulated stem cell clinics offering unproven therapies. Such practices not only expose patients to harm but also undermine the credibility of legitimate research efforts. The erosion of public trust is perhaps the most significant long-term consequence.

Closely linked to this is the **limited generation of high-quality clinical evidence**. While numerous pilot studies and early-phase trials have been conducted, there is a conspicuous absence of large, multicentric Phase II and III trials. Small sample sizes, heterogeneous methodologies, and inadequate long-term follow-up have prevented the establishment of robust evidence. Consequently, most stem cell applications remain confined to the experimental domain, unable to transition into standard-of-care protocols. This evidence deficit creates a paradox: innovation exists, but validation is insufficient.

*Corresponding Author: Minu Bajpai
Email: bajpai2b@gmail.com

The **translational gap between bench and bedside** further compounds this problem. India has demonstrated considerable strength in basic and early-stage research; however, the pipeline for late-stage translation remains weak. The absence of clinical-grade validation platforms, coordinated translational hubs, and integrated trial networks means that promising laboratory discoveries often fail to reach patients. This disconnect reflects a structural weakness in aligning scientific discovery with clinical application.

Equally critical is the **inadequate GMP (Good Manufacturing Practice) manufacturing capacity**. Regenerative therapies, by their very nature, require highly controlled, standardized production environments. India currently has a limited number of GMP-compliant facilities, and those that exist are often concentrated in a few urban centres. The high cost of establishing and maintaining such facilities further restricts expansion. Without scalable manufacturing infrastructure, even validated therapies cannot be delivered at population scale.

The human resource dimension reveals another layer of complexity. There is a **significant deficit of trained personnel in translational medicine**, including clinician-scientists, GMP specialists, and cell biologists with clinical orientation. This workforce gap disrupts the continuum from discovery to delivery, resulting in siloed operations rather than integrated systems. The absence of interdisciplinary training pathways exacerbates this divide, limiting the development of a cohesive translational ecosystem.

From a health systems perspective, **cost and affordability remain formidable barriers**. Advanced regenerative therapies are inherently expensive, often confined to private sector settings with minimal integration into public health financing mechanisms. This creates inequities in access, particularly in a country where a large proportion of healthcare expenditure is out-of-pocket. Without mechanisms to reduce costs and expand coverage, regenerative medicine risks becoming an exclusive domain rather than a public health solution.

Ethical and governance concerns add further complexity. Issues surrounding informed consent, the use of embryonic stem cells, and the commercialization of experimental therapies require careful navigation. In the absence of robust and enforceable ethical frameworks, there is a risk of both exploitation and regulatory overcorrection, the latter potentially stifling innovation. Maintaining a balance between ethical vigilance and scientific progress is therefore essential.

Another critical gap is the **Lack of National Data Systems**

The absence of unified registries, standardized outcome tracking, and adverse event monitoring limits the ability to generate real-world evidence. Data fragmentation not only hampers research but also weakens regulatory oversight and policy responsiveness. In an era where data-driven decision-making is paramount, this represents a significant structural deficiency.

Infrastructure fragmentation further undermines efficiency. Research efforts are often dispersed across multiple institutions with limited coordination. The absence of nationally networked centres of excellence leads to duplication of effort, suboptimal resource utilization, and missed opportunities for collaboration. A more integrated infrastructure model is necessary to maximize impact.

The weak linkage between academia and industry is another critical bottleneck. While academic institutions excel in discovery, the translation of innovations into market-ready products requires industrial collaboration. Limited engagement between these sectors slows commercialization, delays innovation scaling, and reduces the overall efficiency of the ecosystem.

Financial constraints compound these challenges. Regenerative medicine is capital-intensive, requiring substantial investment in GMP facilities, clinical trials, and long-term research programs. The availability of risk capital remains limited, particularly for late-stage translation. Without innovative financing mechanisms, the pace of ecosystem development will remain slow.

Finally, **public awareness and misinformation** present a unique challenge. The gap between scientific evidence and public perception is often filled by exaggerated claims and misleading marketing. This not only exposes patients to potential harm but also creates unrealistic expectations that can ultimately undermine trust in the field.

Taken together, these challenges highlight a central truth: **India's regenerative medicine landscape is constrained not by a lack of innovation, but by a lack of integration**. The system is characterized by islands of excellence operating in relative isolation, without the connective infrastructure required for scale.

The strategic imperative is clear. Without addressing these structural challenges—particularly in regulation, evidence generation, manufacturing, and system integration—India risks remaining in a prolonged exploratory phase. The transition to scalable, evidence-based regenerative medicine will require not just scientific advancement, but systemic transformation.

From Fragmentation to Integration: A Solutions Framework for India's Regenerative Medicine Future

If India's challenge in regenerative medicine is fundamentally one of system integration, then the pathway forward must be equally systemic. Incremental reforms will not suffice. What is required is a **mission-mode, coordinated framework** that aligns regulation, research, manufacturing, financing, and delivery into a unified ecosystem capable of translating scientific potential into population-level impact.

The starting point must be regulatory reform through unified and enforceable governance. The alignment of existing frameworks under the Indian Council of Medical Research, Department of Biotechnology, and CDSCO into a single apex regulatory architecture is essential. This must be accompanied by mandatory licensing of all stem cell facilities, standardized accreditation processes, and a national inspection system based on risk stratification. Crucially, enforcement mechanisms must include meaningful penalties—closure of non-compliant facilities, financial sanctions, and legal action against the promotion of unproven therapies. Regulation must shift from advisory to authoritative.

Scaling regenerative therapies demands the creation of a **national manufacturing grid**. Regional GMP hubs, developed through public–private partnership models such as DBFOT, can provide shared infrastructure and reduce capital barriers. Standardized operating procedures, harmonized quality control systems, and pooled procurement of inputs can drive down costs and improve efficiency. Viability gap funding for initial infrastructure development, combined with tiered pricing models for public patients, can ensure both sustainability and equity.

Human resource development must be reimagined as a strategic priority. A **structured national skilling framework** is required, beginning with the integration of regenerative medicine modules into undergraduate medical education and extending to specialized DrNB, DM and fellowship programs. Certification pathways for GMP technologists, biobank managers, and clinical trial coordinators must be established. Importantly, training must be interdisciplinary, combining clinical exposure with laboratory and manufacturing experience to create a workforce capable of operating across the translational continuum.

Parallel to regulatory strengthening is the urgent need to build a robust clinical evidence ecosystem. The creation of a National Regenerative Clinical Trials Network can transform the landscape by enabling large-scale, multicentric Phase II and III trials. Standardization of protocols, endpoints, and follow-up durations will enhance comparability and reliability of results. Financial incentives, including per-patient reimbursement and fast-track approvals for priority conditions, can encourage institutional participation. Without such a coordinated trial ecosystem, the transition from experimental to evidence-based practice will remain elusive.

Bridging the translational divide requires the establishment of dedicated bench-to-bedside pipelines. Translational hubs must be designed to integrate preclinical research, GMP manufacturing, and early-phase clinical trials within a single ecosystem. Funding mechanisms should be milestone-driven, with clear go/no-go decision points to ensure accountability and efficiency. The development of clinician-scientists through structured translational fellowships will be critical in sustaining this interface, ensuring that scientific insights are aligned with clinical realities.

Addressing affordability requires **innovative financing and pricing models**. Inclusion of validated regenerative therapies within public health packages—such as those under national insurance schemes—can expand access. Outcome-based payment models, where reimbursement is linked to clinical effectiveness, can align incentives across stakeholders. Public–private partnerships with regulated tariffs and reserved capacity for public patients can further ensure equitable access. Fiscal measures, including tax incentives and import duty relief, can reduce production costs and encourage investment.

Ethical governance must be strengthened through a **national ethics and consent framework**. Mandatory Institutional Committees for Stem Cell Research (IC-SCRs), standardized informed consent processes, and transparent disclosure of trial status and risks are essential. The establishment of an independent Ethics Audit Board can provide ongoing oversight, ensuring compliance while maintaining public confidence.

A transformative enabler will be the development of a national data and digital ecosystem. A unified stem cell registry capturing clinical trials, treatment outcomes, and adverse events can serve as the backbone of evidence generation. Real-time dashboards for regulators and payers, combined with mandatory reporting requirements, can enhance transparency and accountability. Integration with national digital health systems will enable longitudinal tracking and data-driven decision-making.

Infrastructure must transition from fragmentation to networked integration. The designation of 20–30 Centres of Excellence, linked to medical colleges and supported by regional hubs and district-level spokes, can create a coherent national network. Shared resources—including biobanks, clinical trial units, and simulation facilities—can optimize utilization and reduce duplication. Performance-based funding tied to outcomes and throughput can ensure accountability.

Strengthening industry–academia collaboration is essential for innovation scaling. Joint intellectual property frameworks, co-funded research programs, and the development of contract manufacturing ecosystems can facilitate the translation of discoveries into market-ready products. Regulatory sandboxes can provide a controlled environment for testing innovative approaches, balancing flexibility with oversight.

Financial sustainability will depend on **blended capital models**. Viability gap funding can attract private investment into high-capital infrastructure projects, while access to development finance and credit guarantees can reduce risk. Availability payments and minimum offtake agreements can provide revenue stability for PPP projects. A dedicated National Regenerative Medicine Fund can support late-stage clinical trials and high-risk innovation.

Finally, addressing **public awareness and misinformation** is critical. A national information portal distinguishing approved therapies from investigational interventions can empower patients. Strict regulation of advertising,

combined with public education campaigns, can align expectations with scientific reality. Annual publication of safety and outcome data can further enhance transparency.

Cross-cutting these interventions is the need for **efficient governance mechanisms**, including single-window clearance systems, standardized treatment guidelines, and robust program management units at national and state levels.

The central insight is unequivocal: **the future of regenerative medicine in India depends on synchronization**. Regulation, manufacturing, clinical trials, financing, and delivery must function as interconnected components of a unified system. Piecemeal interventions will not achieve scale; only a coordinated, mission-driven approach can.

If implemented with clarity and commitment, this solutions framework can transform India's regenerative medicine landscape—from fragmented innovation to a globally competitive, evidence-based, and equitable healthcare paradigm.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 651–654, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.002

EDITORIAL

India's Critical Transition from Exploratory Stem Cell Research to Scalable, Evidence-Based Regenerative Medicine & The Role of National Biobank Repositories

Minu Bajpai[1,*] and Abhijat C. Sheth[2]

[1]*Vice-President & Honorary Executive Director, National Board of Examinations in Medical Sciences, New Delhi*
[2]*Chairman of National Medical Commission & President, National Board of Examinations in Medical Sciences, New Delhi*

Accepted: 4-May-2026 / Published Online: 6-May-2026

India's engagement with stem cell science has traversed a remarkable arc—from early exploratory research to the threshold of clinically meaningful, technology-driven regenerative medicine. Yet, the next phase of evolution will not be defined merely by incremental scientific advances, but by the country's ability to **translate biological promise into scalable, evidence-based, and equitable healthcare solutions**. This transition is being shaped by converging technological trajectories—gene editing, tissue engineering, artificial intelligence, and advanced manufacturing—while simultaneously demanding the creation of robust foundational infrastructure. Among these, **national biobank repositories stand out as a strategic cornerstone**, enabling precision, reproducibility, and acceleration of translational pipelines.

India must develop a tiered national biobank architecture. At the apex would be a National Biobank Grid responsible for governance, standard setting, and interoperability. Regional biobanks would handle processing and storage, while institutional nodes—located in medical colleges and hospitals—would serve as collection points. Integration with digital health systems, unique identifiers for samples, and dynamic consent frameworks will be essential to ensure traceability, ethical compliance, and data security.

*Corresponding Author: Minu Bajpai
Email: bajpai2b@gmail.com

At present, India occupies a distinctive position in the global regenerative medicine landscape. It benefits from a large and diverse patient population, expanding clinical research capacity, and a strong base of academic and translational institutions. National guidelines developed by the Indian Council of Medical Research and the Department of Biotechnology have provided a regulatory scaffold, although implementation variability persists. Importantly, while hematopoietic stem cell transplantation remains the only widely accepted standard therapy, multiple other applications—ranging from orthopaedic regeneration to neurological repair—are being actively explored. The critical question, therefore, is not whether India can innovate, but whether it can **scale innovation responsibly and efficiently**.

The future trajectory of stem cell research in India will be anchored in **precision regenerative medicine**. The advent of induced pluripotent stem cells (iPSCs) has fundamentally altered the therapeutic paradigm, allowing patient-specific cell lines to be generated, manipulated, and potentially reintroduced with minimal immunogenicity. In a country characterised by immense genetic heterogeneity, this opens unprecedented opportunities for **population-scale precision medicine**. Disease modelling using patient-derived cells can inform not only individualised therapies but also public health strategies tailored to specific genetic subgroups.

In parallel, stem cell science is converging **with gene editing technologies**, particularly CRISPR-based platforms. This integration is poised to transform the management of inherited disorders such as thalassemia and other hemoglobinopathies, which are highly prevalent in India. The emergence of **cell–gene hybrid therapies**—where defective genes are corrected ex vivo and reintroduced through stem cell platforms—signals a shift from symptomatic management to potential cures. However, such advances also demand stringent regulatory oversight, robust manufacturing systems, and long-term safety monitoring.

Another transformative trajectory lies in the development of **organoids and advanced disease models**. Stem cell–derived organoids—miniaturised, functional representations of organs—are rapidly becoming indispensable tools for drug discovery, toxicity testing, and understanding disease pathophysiology. In the Indian context, organoid technology holds particular promise for studying infectious diseases, metabolic disorders, and cancers that exhibit unique regional patterns. By reducing dependence on animal models and enhancing translational relevance, organoids can significantly accelerate the journey from laboratory discovery to clinical application.

The future of stem cell research in India will be determined not only by scientific breakthroughs but by the systems that enable their translation into practice. Biobanks, by linking biology with data and clinical outcomes, will play a central role in this transformation. They will determine how quickly discoveries move from bench to bedside, how effectively therapies are tailored to patients, and how reliably outcomes are measured and improved.

Closely related is the field of **tissue engineering and 3D bioprinting**, which aims to reconstruct or replace damaged tissues using a combination of stem cells, biomaterials, and engineering principles. While fully functional organ replacement remains a long-term goal, nearer-term applications such as cartilage repair, skin regeneration for burns, and vascular grafts are already within reach. Given India's burden of trauma, chronic disease, and organ failure, these technologies have the potential to address substantial unmet clinical needs.

Equally important is the emergence of **cell-free regenerative therapies**, particularly those based on exosomes and extracellular vesicles. These approaches circumvent many of the challenges associated with live cell transplantation, including immunogenicity and complex storage requirements. Their relative simplicity and scalability make them particularly attractive for a resource-constrained healthcare system, and they may represent the first wave of regenerative therapies to achieve widespread adoption in India.

The industrialization of stem cell therapies represents another defining trajectory. The field is moving away from bespoke, patient-specific interventions toward **standardized, allogeneic "off-the-shelf" products** that can be manufactured at scale. This shift necessitates the development of **GMP-compliant manufacturing ecosystems**, automation technologies, and rigorous quality control systems. For India, achieving cost-effective scale will be essential to ensure that regenerative therapies do not remain confined to elite institutions but become accessible across the health system.

Overlaying all these developments is the growing role of **artificial intelligence and data science**. AI-driven analytics can optimize cell differentiation protocols, predict therapeutic outcomes, and refine clinical trial design. However, the effectiveness of such tools depends on the availability of high-quality, well-annotated datasets—a requirement that brings biobanks' role into sharp focus.

National biobank repositories are no longer passive storage facilities; they are **active engines of translational science**. By systematically collecting, processing, and storing biological samples—along with associated clinical and genomic data—biobanks provide the raw material for discovery, validation, and innovation. In the context of regenerative medicine, their importance is multifaceted.

First, biobanks enable **standardization and reproducibility**, which are essential for scientific credibility. Variability in sample quality and processing protocols has long been a barrier to reproducible research. A nationally coordinated biobank system, operating under uniform standards, can address this challenge and facilitate multicentric collaboration.

Second, they are central to **precision medicine**. Large-scale biobanks capturing the genetic and phenotypic diversity of India's population can support biomarker discovery, patient stratification, and the development of targeted therapies. This is particularly important in a country where disease patterns and treatment responses vary widely across regions and communities.

Third, biobanks play a critical role in **clinical trials and evidence generation**. Longitudinal sample collection allows

researchers to track disease progression, therapeutic response, and long-term outcomes. When integrated with clinical trial networks, biobanks can significantly enhance the quality and depth of evidence generated.

Fourth, they serve as a **resource for manufacturing pipelines**. Access to well-characterized cell lines and donor tissues is essential for the development of GMP-grade products. A robust biobank infrastructure can thus directly support the scaling of regenerative therapies.

However, significant challenges remain. Biobanking is resource-intensive, requiring sustained investment in infrastructure, cold-chain logistics, and data management systems. Ethical concerns related to consent, privacy, and data sharing must be addressed through transparent and robust governance mechanisms. Moreover, the success of biobanks depends on a skilled workforce, including biobank managers, data scientists, and quality assurance specialists—roles that are currently in limited supply.

Policy action must therefore be proactive and strategic. A **National Biobank Mission**, aligned with a broader regenerative medicine strategy, could provide the necessary impetus. Public–private partnerships can help distribute costs and enhance sustainability, while mandatory linkage of biobanking with clinical trials can ensure continuous data generation. Capacity-building programs must be instituted to develop the human resources required to manage and utilise these repositories effectively.

The integration of biobanks with other elements of the regenerative medicine ecosystem—such as clinical trial networks, manufacturing hubs, and digital health platforms—will be critical. Only through such integration can India create a **learning health system**, where data generated at the point of care feeds back into research and innovation, creating a virtuous cycle of continuous improvement.

India's opportunity is significant. With its scale, diversity, and growing scientific capacity, the country is uniquely positioned to become a global leader in regenerative medicine. However, realizing this potential will require a shift from fragmented efforts to a **coordinated, mission-driven approach**. Investment in biobank infrastructure, integration of translational pipelines, and alignment of policy, regulation, and practice are essential steps in this direction.

In conclusion, the next decade will define India's trajectory in regenerative medicine. If the country succeeds in building a **data-rich, ethically governed, and technologically integrated ecosystem**, it can deliver not only cutting-edge therapies to its population but also set global benchmarks for affordability and scale. National biobank repositories will be at the heart of this transformation—serving as the connective tissue that binds discovery, development, and delivery into a unified, impactful whole.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 655–666, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.003

ORIGINAL ARTICLE

Diabetic Retinopathy Screening with Artificial Intelligence in Remote Areas

Ajit Pal Singh,[1] Vijay Singh,[2] Sujeet Kumar Jain,[3] Aisha Beg,[4] Suyash Saxena[5] and Rahul Saxena[6,*]

[1]*Associate Professor, Department of Medical Lab Technology, School of Allied Health and Sciences, Galgotias University, Greater Noida, U.P.*
[2]*Assistant Professor, Department of Medical Lab Technology, School of Medical and Allied Sciences, Galgotias University, Greater Noida, U.P.*
[3]*Associate Professor, Department of Radiology, Santosh Medical College & Hospital, Ghaziabad, U.P.*
[4]*Associate Professor, Department of Biochemistry, Integral Institute of Medical Sciences & Research, Integral University, Lucknow, U.P.*
[5]*Associate Professor, Department of Biochemistry, SSAHS, Sharda University, Greater Noida, U.P.*
[6]*Professor, Department of Biochemistry, SSAHS, Sharda University, Greater Noida, U.P.*

Accepted: 10-March-2026 / Published Online: 6-May-2026

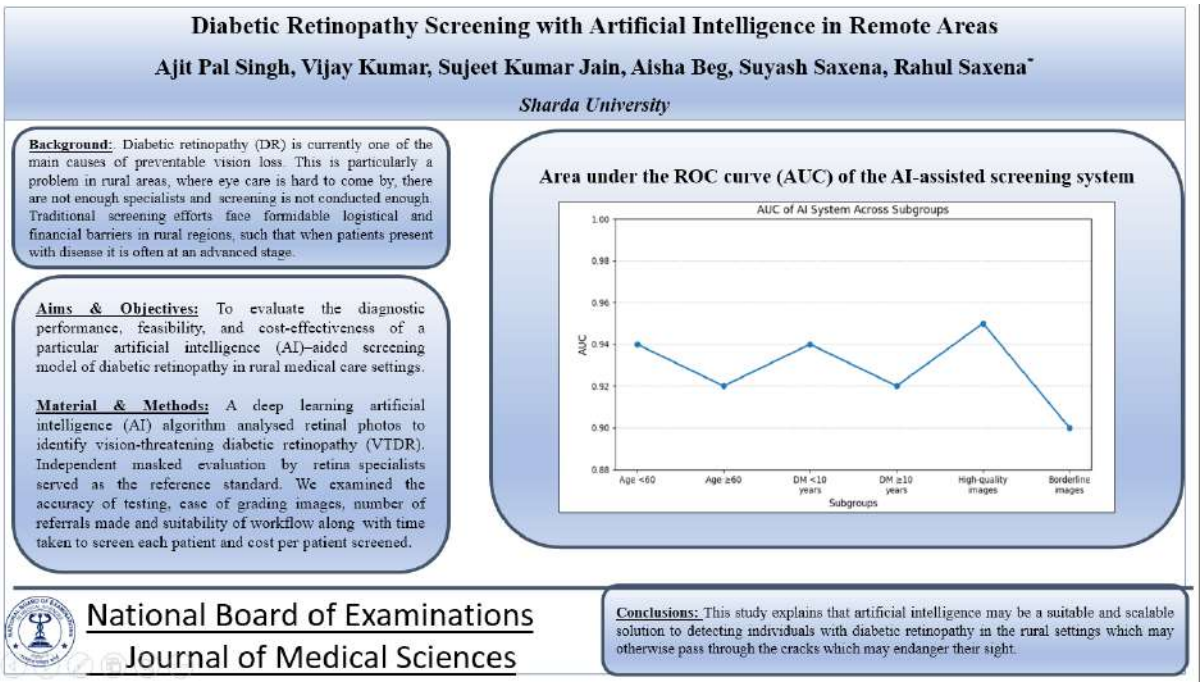
Abstract

Background: Diabetic retinopathy (DR) is currently one of the main causes of preventable vision loss. This is particularly a problem in rural areas, where eye care is hard to come by, there are not enough specialists and screening is not conducted enough. Traditional screening efforts face formidable logistical and financial barriers in rural regions, such that when patients present with disease it is often at an advanced stage. **Objective**: We aimed to evaluate the diagnostic performance, feasibility, and cost-effectiveness of a particular artificial intelligence (AI)–aided screening model of diabetic retinopathy in rural medical care settings. **Methods**: A prospective cross-sectional diagnosis accuracy trial conducted in rural primary health centres and outreach clinics. All diabetic participants had non-mydriatic fundus photography performed by trained technicians. A deep learning artificial intelligence (AI) algorithm analysed retinal photos to identify vision-threatening diabetic retinopathy (VTDR). Independent masked evaluation by retina specialists served as the reference standard. **Results:** We screened 240 individuals or 480 eyes. For detecting VTDR, the sensitivity and specificity of AI system were 89.4 and 87.2%, respectively. Its positive and negative predictive values were 61.8% and 96.3%, respectively, with an area under the ROC curve of 0.93 as well. When AI assisted screening was compared to standard practice, that approach screened more people about 35% more and cut the cost per person screened by roughly 40%. **Conclusion**: AI aided DR screening is a reliable, feasible and cost-effective method for early detection of VTDR in remote populations with great potential for reducing unnecessary blindness in underserved regions.

Keywords: Diabetic retinopathy, Deep learning, Rural healthcare delivery, Screening programs, Diagnostic accuracy

*Corresponding Author: Rahul Saxena
Email: rahul.saxena@sharda.ac.in

Graphical Abstract



Introduction

Diabetic retinopathy (DR) remains one of the leading causes of preventable blindness and visual impairment in the working-age population globally. Introduction Diabetic retinopathy (DR) is forecasted to rise dramatically in the next decades due to the worldwide epidemic of diabetes mellitus. So overall, about one out of every three patients with diabetes will have some degree of diabetic retinopathy (DR), and a large number approximately one-third according to a recent systematic review and meta-analysis—of those will go on to developing vision-threatening forms or variants of DR, namely proliferative DR and/or diabetic macular edema.

Although screening and treatment that can prevent most cases exist, diabetic retinopathy remains a significant cause of visual impairment, particularly in low- and middle-income settings. In remote and deprived areas, where access to ophthalmic services is limited, diabetic retinopathy has more serious implications. However, in rural areas, many specialized ophthalmologists are not available, and the full diagnostic machines like OCTs are also inadequate. In addition, tertiary eye care centers can be hours away from the nearest health facility. The screening process is immensely limited by barriers such as time constraints, lack of follow-up, and noncompliance with the advised yearly retinal evaluations. Eye care service delivery is also impeded by several socioeconomic factors, including low health literacy and an obsession with economic concerns. This problem often leads to patients with Diabetic Retinopathy (DR) in developing countries presenting at health care institutions with cases of DR that have worsened stage, and thus making treatment options costlier and difficult, possibly resulting in failed therapy. As a result, fewer light and more health expenses [1].

Most of the traditional methods to screen DR is to get screened manually by either an ophthalmologist or a retinal specialist. However, these are great concepts but hard to put into action at the hospital level and needs many resources to run effectively as well as not being easily implementable in rural areas, where there is an insufficient amount of such facilities with uneven distribution across the country. The need for additional infrastructure, indirect outlays by patients (eg, travel expenses, income lost due to taking time off from work), etc can make it exponentially more challenging to meme people. As a result, early-stage diagnosis fills almost all of the cases as low levels of screening uptake. This defeats the purpose of routine screening as far as conventional methods of screening are concerned [2].

As a result, artificial intelligence (AI) has become the recent technological answer for these problems and the application of advanced deep learning in retinal imaging. Micro aneurysms, haemorrhages, exudates and neovascularization are pathological characteristics that can be objectively identified. Convolutional neural network algorithms trained on large image datasets have been shown to perform highly accurate detection and classification of diabetic retinopathy. Several AI-based diabetic retinopathy screening systems have been approved by the FDA and Conformité Européenne. This means they are both safe and clinically effective [3].

On the one hand, a lot of what exists regarding the evidence base that is being used to support AI-assisted screening tasks (still quite limited) may be heavily focused on urban and tertiary care based segments where referral pathways exist, excellent infrastructure capabilities exist, and optimal imaging conditions are there. The effectiveness of these systems in more rural and low-resource environments, where image quality will vary, infrastructure will be limited, and follow-up may not always occur, remains unclear. In addition, published reports of the integration of this novel tool with workflows, technician training costs, patient acceptance rates, referral compliance rates and cost effectiveness also appear exceedingly limited in the case of rural areas [4]. The present study evaluated the diagnostic accuracy, feasibility, and cost-effectiveness of an AI-assisted diabetic retinopathy screening model from rural healthcare settings with a focus on identifying vision-threatening non proliferative disease [5].

Methodology

Diagnosis accuracy and feasibility were evaluated in rural primary health centres and mobile eye clinics. The present study was prospective cross-sectional study. This study aimed to evaluate the diagnostic accuracy, operational feasibility and deployability of an artificial intelligence (AI) assisted screening system for vision-threatening diabetic retinopathy (VTDR) in resource-limited rural settings. Recruitment took place over a predetermined period of research time during which consecutive eligible subjects attending diabetes clinics or community screenings were invited to participate after taking Ethical clearance (Ref. no. SU/SMSR/76-A/2019/20) from Institutional Ethical Committee of the University.

Inclusion Criteria

Adults 18 years or older with confirmed diagnosis of type-1 and/or type-2 diabetes mellitus requiring treatment for

at least one year were eligible. Written informed consent was obtained from all participants prior to enrolment.

Exclusion criteria

Patients were not eligible if they had ocular media opacities (e.g. dense cataract, corneal scar, or vitreous haemorrhage) precluding adequate fundus photography. Persons with previous treatment of the retina (e.g., laser photocoagulation, intravitreal injections of anti-VEGF substances) or vitreoretinal surgery were not included in the study to avoid confounding evaluations assessing AI performance. Those who were unwilling or unable to provide informed consent were also excluded.

Sample size calculation

The sample size was calculated for valid estimation of the diagnostic accuracy. Based on previous studies that employed AI as a screening tool for diabetic retinopathy, the assumed sensitivity and specificity were 85% and 90%, respectively. Another assumption was that 15% of rural diabetics would have VTDR. We selected the larger sample size yielded by estimating sensitivity and specificity based on Z = 1.96 for a confidence level of 95% and absolute precision of ±5%. The sample size was inflated for ungradable photographs and loss to follow up (10–15%), thus the final sample size needed was 240**.**

Screening

Non-mydriatic fundus photography was provided by trained technicians at rural health clinics or in mobile screening units for all eligible individuals. The eyes were imaged in their entirety whenever possible, using established imaging methods. Dilation of the pupil was not universally employed to mimic screen testing. The AI system analyzed retinal images either in real-time or using a secure cloud-based connection, depending on the local infrastructure. This allowed for patients to be triaged by risk, and recommendations made in the same visit for referrals [6].

Description of AI System, testing & checking

The AI-aided screening method employed fine-tuned retinal fundus image analysis using a convolutional neural network (CNN) model structure. The algorithm had been developed to detect features of diabetic retinopathy, including microaneurysms, hemorrhages, hard exudates, venous beading, intraretinal microvascular anomalies and neovascularization [7].

The AI model was trained using a large, clinically representative, publicly-available annotated Eye PACS moderate and above disc grades fundus image dataset (GitHub). The International Clinical Diabetic Retinopathy (ICDR) severity scale was used to grade the images, which were intended to mimic clinical screening settings. We performed external validation in the Messidor 2 dataset with expert-graded fundus images. These databases are composed of all forms of diabetic retinopathy, even those that could lead to loss of vision. Internal and external validation confirmed that the test was pretty good at finding VTDR. The Artificial Intelligence (AI) system has the FDA approval for clinical screening of diabetic retinopathy and CE certification processed [8].

Types of AI Output

Using AI algorithm images were categorized into three subgroups for each eye:

i) No diabetic retinopathy (No DR)
ii) Mild to moderate non-proliferative diabetic retinopathy (NPDR)
iii) Severe NPDR, proliferative DR, or DME (VTDR) -induced blindness
iv) VTDR or ungradable eyes were referred for specialist assessment.

Reference standard was judged by 2 qualified retinal experts who were not aware of the AI output and findings of the other rater. The work was graded using the International Clinical Diabetic Retinopathy (ICDR) severity scale. Differences were finally adjudicated by a senior retinal specialist, resulting in limited inconsistency between observers.

The AI system's diagnostic accuracy in identifying VTDR using reference standards for sensitivity and specificity. The percentage of referrals that underwent follow-up, the screening turnaround time, the image gradability rate, positive and negative predictive values, and operational feasibility parameters pertinent to rural implementation were examples of secondary outcomes [9].

Statistical analysis

Using 95% confidence intervals, we computed the diagnostic accuracy. To assess the model's ability to differentiate between groups, we looked at the area under the curve (AUC) and the receiver operating characteristic (ROC) curve. The degree of agreement between AI outputs and retinal specialist grading, as well as between them, was evaluated using Cohen's kappa coefficient. According to Bellemo et al., the predetermined subgroup analysis was based on age, the length of diabetes, and the quality of the picture. [10].

Continuous variables are reported as mean ± SD or median (interquartile range) and categorical data as frequencies and percentages. All analyses were conducted using SPSS version 27.0, and the graph was plotted using GraphPad Prism. A two-tailed p-value below 0.05 was considered as statistically significant.

Results

A total of 240 participants (480 eyes) were ultimately analyzed. The people in the study were, on average, 54.2 years old and 34.2 percent of them were at least 60 years old. Men constituted 57.5% of the group, and most of them (94.2%) had type 2 DM. The middle duration of diabetes was 8 years (interquartile range: 4–13); 40.0% patients had been diagnosed with diabetics for≥10 years. Telemedicine also allowed care where those patients wouldn’t be seen at all, because they were uncomfortable leaving home or didn’t have the necessary gear to travel to a health facility.” Half of the study’s participants had high blood pressure. Just 25.8% reported they had been screened for diabetic retinopathy in the past. Summary of the baseline demographic and clinical characteristics are presented in Table 1.

Table 1. Baseline Characteristics of the Study Population (n = 240)

Characteristic	**Value**
Age, mean ± SD (years)	54.2 ± 10.6
Age ≥60 years, n (%)	82 (34.2)
Male sex, n (%)	138 (57.5)
Female sex, n (%)	102 (42.5)
Duration of diabetes, median (IQR), years	8 (4–13)
Diabetes duration ≥10 years, n (%)	96 (40.0)
Type 2 diabetes mellitus, n (%)	226 (94.2)
Known hypertension, n (%)	121 (50.4)
Previous DR screening, n (%)	62 (25.8)

General diagnostic performance of the AI system

VTDR was defined based on reference grading by masked retinal specialists; 14.6% of eyes had VTDR. AI-assisted screening (VTDR) The AI-assisted approach demonstrated a high level of diagnostic accuracy for detection of VTDR, with sensitivity and specificity estimates of 89.4 (95% CI: 80.5–95.3) and 87.2% (95% CI: 83.4–90.5), respectively. The negative predictive value was 96.3 percent, indicating that the test did a very good job at ruling out VTDR in people who were screened. Positive predictive value was 61.8%. The sensitivity of all the tests was 87.6%. The ROC curve analysis demonstrated an area under the curve (AUC) of 0.93, indicating that the discriminatory accuracy of a test is satisfactory. You can receive detailed diagnosis accuracy metrics at Table 2.

Table 2. Diagnostic Accuracy of AI-Assisted Screening for Vision-Threatening Diabetic Retinopathy (Per-Eye Analysis)

Metric	**Value (95% CI)**
Sensitivity	89.4% (80.5–95.3)
Specificity	87.2% (83.4–90.5)
Positive Predictive Value (PPV)	61.8% (52.0–70.8)
Negative Predictive Value (NPV)	96.3% (93.9–98.1)
Overall accuracy	87.6%
Area under ROC curve (AUC)	0.93

Subgroup Analysis and Consistency of Effect

Subgroup analyses of the AI system showed consistent performance in all critical baseline, clinical characteristics, and image-quality subgroups (Table 3). Sensitivity and specificity remained above 85% in all subgroups, including age (<60 vs ≥60 years), duration of diabetes (<10 vs ≥10 years), and image quality categories. High-quality images had the highest diagnostic accuracy, sensitivity of 91.8%, specificity of 89.5%, and AUC = 0.95. There was a small performance decrease in low-quality images (AUC 0.90), but sensitivity and specificity remained within clinically acceptable limits. There were no significant differences of AUC between subgroups, indicating good and stable performance of the AI system under real-world rural screening condition.

Table 3. Subgroup Performance of the AI-Assisted Screening System for Vision-Threatening Diabetic Retinopathy

Subgroup	**Sensitivity (%)**	**Specificity (%)**	**AUC**
Age <60 years	90.1	88.3	0.94
Age ≥60 years	88.6	86.1	0.92
Diabetes duration <10 years	91.3	89.0	0.94
Diabetes duration ≥10 years	87.9	85.4	0.92
High-quality images	91.8	89.5	0.95
Borderline-quality images	85.7	83.2	0.90

Performance Assessment Based on Figures

Figure 1 Comparative ROC curve analysis among demographic, clinical and image quality subgroups is shown in Figure 1. It indicates that all groups will have AUCs in the same range. Sensitivity and specificity differ between subgroups, as shown in Figure 2, which also shows that AI-assisted screening performance remains constant despite changes in real-world conditions.

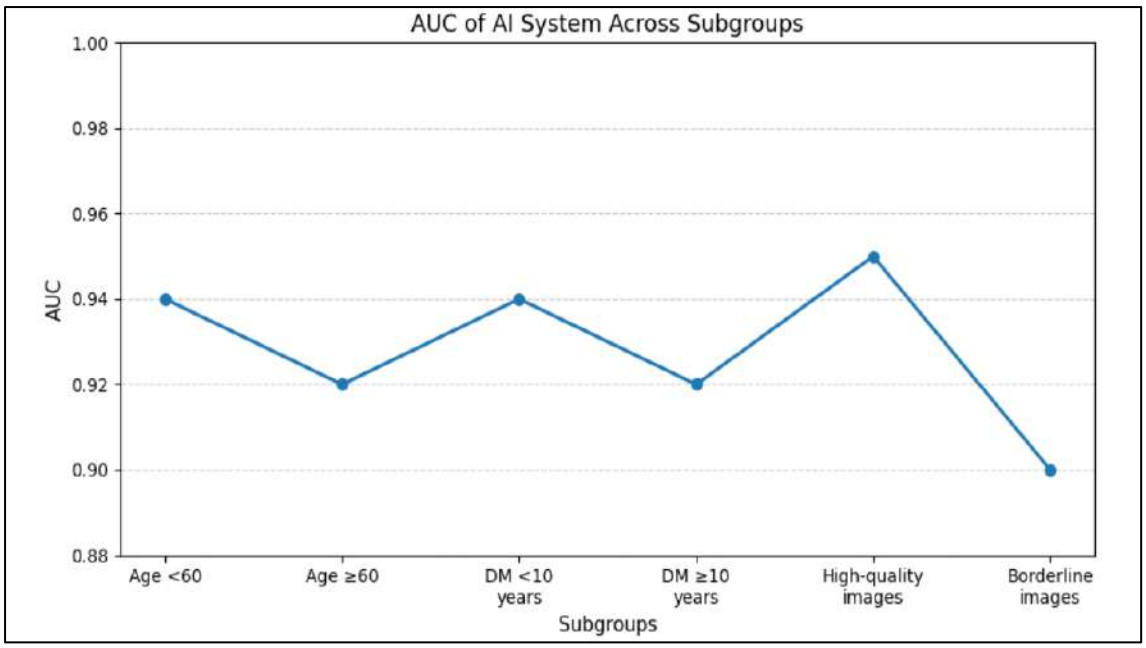


Figure 1. Area under the ROC curve (AUC) of the AI-assisted screening system across demographic, clinical, and image-quality subgroups, demonstrating consistent diagnostic performance.

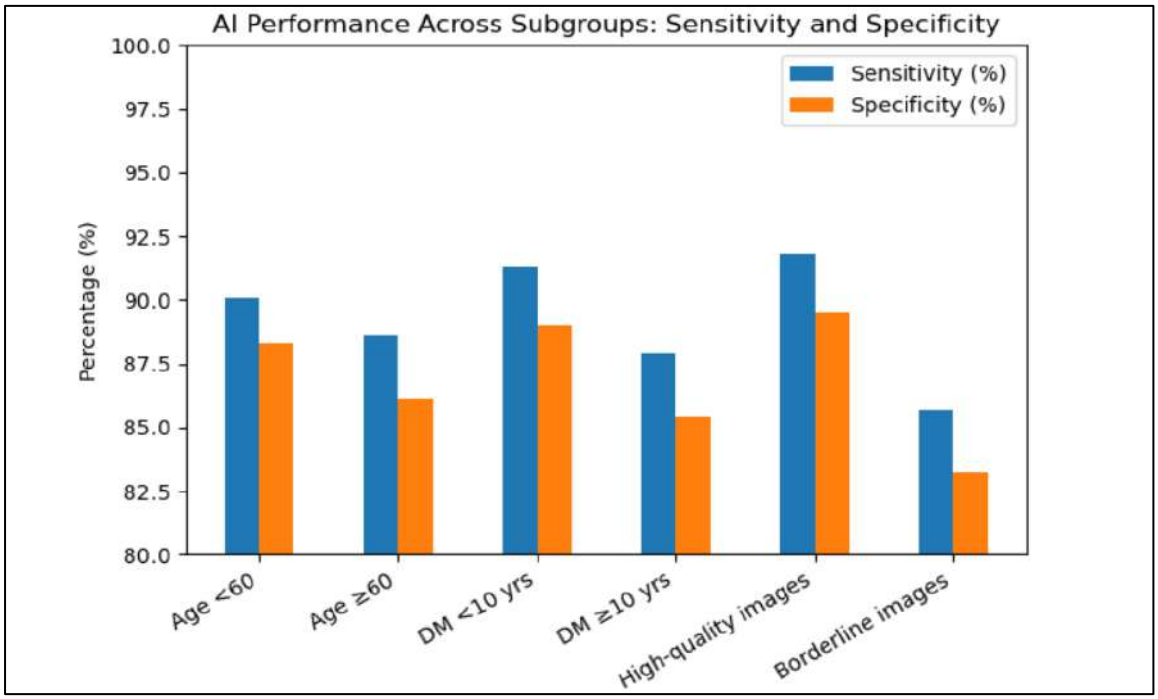


Figure 2. Sensitivity and specificity of the AI-assisted screening system across subgroups, showing stable performance under real-world rural screening conditions.

Discussion

In rural and resource-limited healthcare facilities, the artificial intelligence-based diabetic retinopathy (DR) screening methods demand high diagnostic accuracy, working feasibility, and robustness of the system. The model sensitivity and specificity to VTDR are compared to values of both the previously validated AI-based screening systems and the trained retina experts [11]. Notably, the diagnostic accuracy did not significantly differ between diverse image quality conditions and demographic subgroups which means that AI-aided screening can be trusted in the real rural world.

These findings indicate that AI-based screening can be effectively applied in low infrastructure, technician-created images, and primary or mobile care processes, which aligns with the previously existing studies that were mainly performed in an urban or tertiary care environment. The systems were more efficient with regards to the requirement of having specialized personnel in order to have SSS in that they could give instant feedback on the quality of images, the turnaround time in the screening process, and the advise to make a referral. The fact that the model can be easily adapted to work in resource-constrained environments as shown by very small training required to produce good quality image acceptance proved the model. Publicly speaking, AI-based screening led to a higher level of efficiency in terms of referrals, increased the overall coverage, and the discovery of high-risk individuals who had never been screened. The economic efficiency of the solution can be supported by other reports on cost-effective AI-based diabetic retinopathy screening programs [12], as the reports confirm a reduction in the costs per patient and the effort of specialists reading data. This study provides important real-world level information to demonstrate similar performance in such conditions as non-mydriatic imaging, media opacities, and variable patient compliance although performance figures of diagnostic metrics in tertiary care studies often exceed 85-90% in the detection of VTDR.

This contrasts with most of the previous works which only examined the precision of algorithms. It also put into consideration the aspect of economics, image gradability, referral adherence, and workflow efficiency, which provided a more realistic view of how AI-assisted screening processes in real-life scenarios. The study's methodological robustness was enhanced by its prospective design, sequential recruitment, and hidden specialist reference standard. These factors also reduced the possibility of selection bias, which in turn increased external validity in rural health care settings.

There are several boundaries that must be highlighted. It may be challenging to use in remote areas because cloud-based AI, which is used to conduct the analysis, requires an internet connection. However, the new OC/EC technologies for offline or edge-computing support (OC/EC support) may help to mitigate such problems [13]. Due to patient factors or media limitations, a few images could not be graded. It may have an impact on the number of referrals and is comparable to screening in the real world. Finally, residual biases related to demographic (or ophthalmic) factors cannot be completely ruled out, and the algorithm should be validated on various populations even though it is trained on a diverse dataset. Inadequate follow-up for referral visits in a portion of patients perpetuates ongoing geographic and

socioeconomic issues that may necessitate a combination of tele-ophthalmology and patient navigation. Did this support the way the technology was being used, Ayushi P. Singh? Generally speaking, these findings support an increasing amount of data showing that AI-driven DR screening is a successful strategy for addressing inequalities in access to eye care, especially for underprivileged people in rural areas who are not getting enough care [14].

Conclusion

This study explains that artificial intelligence may be a suitable and scalable solution to detecting individuals with diabetic retinopathy in the rural settings which may otherwise pass through the cracks which may endanger their sight. The AI solution could be considered as a part of primary care, along with mobile screening initiatives and was able to diagnose as well as an expert retinal grader. In the long term, AI-augmented reading is a solution to the low screening coverage and referral efficiency since the task is simplified to the technicians with appropriate skills to perform it, the expert resources are optimized and impediments to patients seeking care are reduced. The illustration of the implementation feasibility and the economic viability suggest the possibility of the AI-based screening programs to diminish the disparities in diabetic ocular care in low resources settings. With appropriate legislative assistance, infrastructure creation (around the world) and integrated as a component of regular patient diabetes treatment strategies, AI-assisted screening can save thousands of individuals with no valid justification of losing their sight. Further multicentre and longitudinal studies are needed to evaluate the long-term outcomes, the scalability, as well as the effect on health systems in diverse rural settings.

Limitation of the study

Despite the encouraging findings, few limitations of this study should be acknowledged. The present study was conducted at a limited number of rural primary health centers and outreach clinics, which may restrict the generalizability of the findings to other rural regions with different healthcare infrastructures, population characteristics, and referral systems. In addition, although the sample size was adequate to estimate diagnostic accuracy, it remains relatively modest compared with large-scale population-based screening studies, and larger multicenter investigations would provide more robust estimates and broader external validity.

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 received (Ref. no. SU/SMSR/76-A/2019/20) from Institutional Ethical Committee of the University.

References

1. Dongling N, Ziwei K, Juanling S, Li Z, Chang W, Ting L, Hongli L, Yanchun Z. Universal nomogram for predicting referable diabetic retinopathy: a validated model for community and ophthalmic

outpatient populations using easily accessible indicators. Front Endocrinol (Lausanne). 2025;16:1557166. doi: 10.3389/fendo.2025.1557166.

2. Hao S, Liu C, Li N, Wu Y, Li D, Gao Q, Yuan Z, Li G, Li H, Yang J, Fan S. Clinical evaluation of AI-assisted screening for diabetic retinopathy in rural areas of midwest China. PLoS One. 2022;17(10):e0275983. doi: 10.1371/journal.pone.0275983.
3. Zhang Y, Shi J, Peng Y, Zhao Z, et al. Artificial intelligence-enabled screening for diabetic retinopathy: a real-world, multicenter and prospective study. BMJ Open Diabetes Res Care. 2020;8(1):e001596. doi: 10.1136/bmjdrc-2020-001596.
4. Uy H, Fielding C, Hohlfeld A, Ochodo E, Opare A, et al. Diagnostic test accuracy of artificial intelligence in screening for referable diabetic retinopathy in real-world settings: A systematic review and meta-analysis. PLOS Global Public Health 2023;3(9):e0002160. https://doi.org/10.1371/journal.pgph.0002160
5. Huang XM, Yang BF, Zheng WL, Liu Q, Xiao F, Ouyang PW, Li MJ, Li XY, Meng J, Zhang TT, Cui YH, Pan HW. Cost-effectiveness of artificial intelligence screening for diabetic retinopathy in rural China. BMC Health Serv Res. 2022;22(1):260. doi: 10.1186/s12913-022-07655-6.
6. Chen Y, Song F, Zhao Z, Wang Y, To E, Liu Y, Shi D, Chen X, Xu L, Shang X, Lai M, He M. Acceptability, applicability, and cost-utility of artificial-intelligence-powered low-cost portable fundus camera for diabetic retinopathy screening in primary health care settings. Diabetes Res Clin Pract. 2025;223:112161. doi: 10.1016/j.diabres.2025.112161.
7. Whitestone N, Nkurikiye J, Patnaik JL, Jaccard N, Lanouette G, Cherwek DH, Congdon N, Mathenge W. Feasibility and acceptance of artificial intelligence-based diabetic retinopathy screening in Rwanda. Br J Ophthalmol. 2024;108(6):840-845. doi: 10.1136/bjo-2022-322683.
8. Scheetz J, Koca D, McGuinness M, Holloway E, Tan Z, et al. Real-world artificial intelligence-based opportunistic screening for diabetic retinopathy in endocrinology and indigenous healthcare settings in Australia. Sci Rep. 2021;11(1):15808. doi: 10.1038/s41598-021-94178-5.
9. Hu W, Joseph S, Li R, Woods E, Sun J, Shen M, Jan CL, Zhu Z, He M, Zhang L. Population impact and cost-effectiveness of artificial intelligence-based diabetic retinopathy screening in people living with diabetes in Australia: a cost effectiveness analysis. EClinical Medicine. 2024;67:102387. doi: 10.1016/j.eclinm.2023.102387.
10. Bellemo V, Lim G, Rim TH, Tan GSW, Cheung CY, Sadda S, He MG, Tufail A, Lee ML, Hsu W, Ting DSW. Artificial Intelligence Screening for Diabetic Retinopathy: the Real-World Emerging Application. Curr Diab Rep. 2019;19(9):72. doi: 10.1007/s11892-019-1189-3.
11. Li H, Li G, Li N, Liu C, Yuan Z, Gao Q, Hao S, Fan S, Yang J. Cost-effectiveness analysis of artificial intelligence-based diabetic

retinopathy screening in rural China based on the Markov model. PLoS One. 2023;18(11):e0291390. doi: 10.1371/journal.pone.0291390.

12. Singh A J, Singh A P. Evolution of Information Technology: A Comprehensive Review. Asian Journal of Current Research. 2024;9(4): 78-90.
13. Singh AP, Saxena R, Saxena S, Maurya NK. Artificial Intelligence Revolution in Healthcare: Transforming Diagnosis, Treatment, and Patient Care. AJOAIR. 2024;7(1):241-63.
14. Singh AP, Saxena R, Saxena S. The Future of Learning: AI-Driven Personalized Education. Asian J. Curr. Res. 2024; 9(4):207–26.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 667–680, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.004

ORIGINAL ARTICLE

Serum Adropin Levels as a Potential Biomarker in Diabetic Nephropathy: An Analytical Cross-Sectional Analytical Study

B. Priyadharsini,[1,*] S. Sangeethapriya[2] and K. Magila[3]
[1]*Assistant Professor, Department of Biochemistry, Dr.B.R.Ambedkar Medical College, Bengaluru*
[2]*Assistant Professor, Department of Biochemistry, Government Medical College Krishnagiri, Tamilnadu*
[3]*Assistant Professor, Department of Biochemistry, Annapoorna Medical College, Salem*

Accepted: 4-April-2026 / Published Online: 6-May-2026

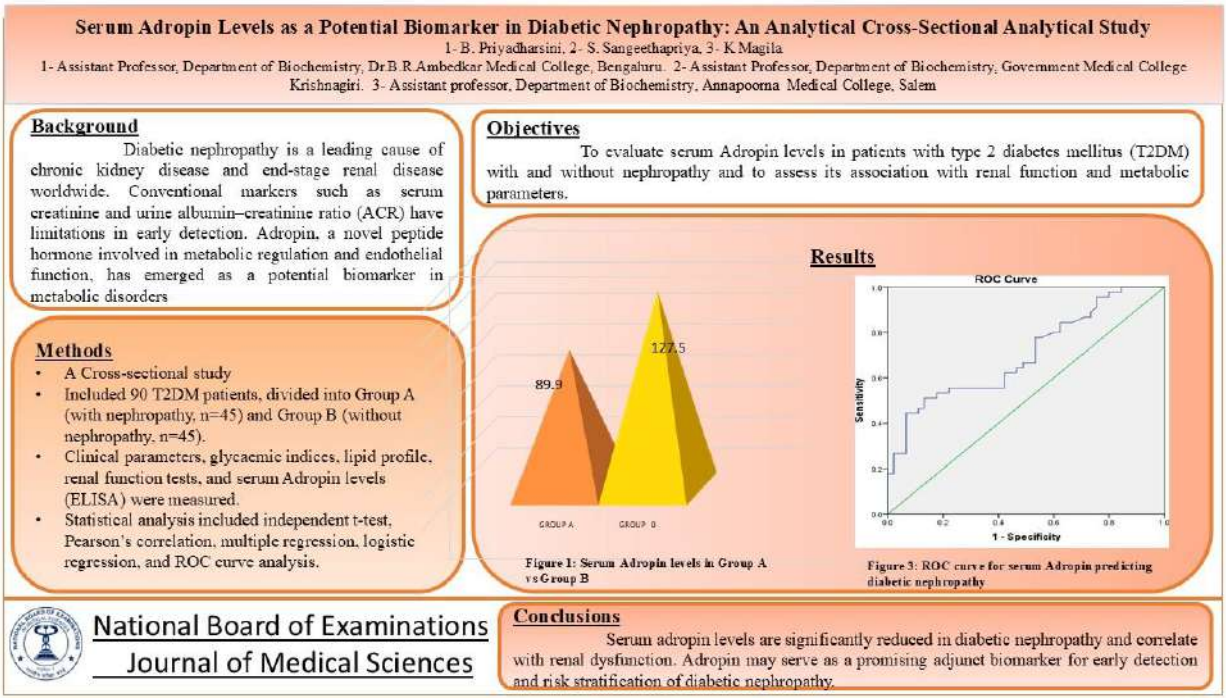
Abstract

Background: Diabetic nephropathy is a leading cause of chronic kidney disease and end-stage renal disease worldwide. Conventional markers such as serum creatinine and urine albumin–creatinine ratio (ACR) have limitations in early detection. Adropin, a novel peptide hormone involved in metabolic regulation and endothelial function, has emerged as a potential biomarker in metabolic disorders. **Objectives:** To evaluate serum adropin levels in patients with type 2 diabetes mellitus (T2DM) with and without nephropathy and to assess its association with renal function and metabolic parameters. **Materials and Methods:** This cross-sectional study included 90 T2DM patients, divided into Group A (with nephropathy, n=45) and Group B (without nephropathy, n=45). Clinical parameters, glycaemic indices, lipid profile, renal function tests, and serum adropin levels (ELISA) were measured. Statistical analysis included independent t-test, Pearson's correlation, multiple regression, logistic regression, and ROC curve analysis. **Results:** Patients with nephropathy had significantly higher BMI, blood pressure, fasting blood glucose, HbA1C, and ACR, along with lower eGFR compared to those without nephropathy ($p<0.05$). Serum adropin levels were significantly reduced in Group A (89.9$\pm$55.2 vs 127.5$\pm$51.9 in Groip B) Adropin showed a negative correlation with BMI, glycaemic parameters, and ACR, and a positive correlation with eGFR and HDL cholesterol. Logistic regression identified adropin as an independent predictor of nephropathy. ROC analysis demonstrated moderate diagnostic accuracy (AUC=0.701), with an optimal cut-off of 80 ng/L (sensitivity 75%, specificity 72%). **Conclusion:** Serum adropin levels are significantly reduced in diabetic nephropathy and correlate with renal dysfunction. Adropin may serve as a promising adjunct biomarker for early detection and risk stratification of diabetic nephropathy.

Keywords: Adropin, Diabetic nephropathy, ACR, eGFR, Type 2 diabetes mellitus

*Corresponding Author: B. Priyadharsini
Email: priyadharshiniboopathy@gmail.com

Graphical Abstract



Background

Chronic kidney disease (CKD) has emerged as a significant global public health concern, with its burden steadily increasing across both developed and developing nations. Recent global estimates indicate that CKD-related mortality has risen by nearly one-third, approximately 31.5%, over the past decade, reflecting its growing contribution to morbidity and mortality worldwide [1]. Among the various etiological factors, diabetic nephropathy remains the leading cause of CKD and end-stage renal disease (ESRD), accounting for a substantial proportion of patients requiring renal replacement therapy. It is estimated that nearly 20–40% of individuals with type 1 or type 2 diabetes mellitus eventually develop diabetic nephropathy, underscoring its critical role in the natural history of diabetes [2]. In the Indian context, the burden is particularly alarming, with approximately 72 million individuals affected by diabetes as of 2019, and nearly one-third, around 34.4%, progressing to nephropathy, thereby placing a considerable strain on healthcare resources [3].

The pathogenesis of diabetic nephropathy is multifactorial and involves complex metabolic and hemodynamic alterations triggered by chronic hyperglycaemia. Key biochemical pathways implicated include the formation of advanced glycation end products (AGE), activation of protein kinase C (PKC), and increased flux through the polyol and hexosamine pathways [4]. These mechanisms converge to induce oxidative stress and inflammatory responses, primarily mediated through activation of nuclear factor-kappa B (NF-κB), leading to increased production of pro-inflammatory cytokines and growth factors. Consequently, these processes promote mesangial expansion, extracellular matrix accumulation, fibrosis, and ultimately

glomerulosclerosis, which are hallmark features of progressive renal damage [5]. Clinically, the assessment of diabetic nephropathy relies on conventional markers such as urine albumin–creatinine ratio (ACR) and estimated glomerular filtration rate (eGFR). However, these markers have inherent limitations; serum creatinine levels typically rise only after nearly 50% of renal function has already been compromised, while ACR may not consistently detect early glomerular injury or reflect subtle structural changes [6]. Therefore, there is an increasing need to identify sensitive and specific biomarkers that can facilitate early detection and timely intervention in diabetic nephropathy [7].

Adropin, a recently identified peptide hormone consisting of 76 amino acids and encoded by the ENHO gene located on chromosome 9p13.3, has gained attention for its potential role in metabolic regulation [8]. It is widely expressed in various tissues, including the liver, brain, kidney, heart, and vascular endothelium, suggesting its systemic physiological significance. Functionally, adropin is involved in maintaining energy homeostasis by modulating glucose metabolism, enhancing insulin sensitivity, regulating lipid metabolism, and preserving endothelial integrity [9]. At the molecular level, adropin exerts vasoprotective effects by activating endothelial nitric oxide synthase (eNOS), thereby increasing nitric oxide (NO) bioavailability and improving endothelial function [10]. Additionally, it exhibits anti-inflammatory properties by downregulating pro-inflammatory cytokines such as tumor necrosis factor-alpha (TNF-α) and interleukin-6 (IL-6) at the mRNA level [11]. Adropin also influences lipid metabolism by suppressing the expression of lipogenic genes through peroxisome proliferator-activated receptor gamma (PPAR-γ) pathways, thereby contributing to metabolic balance [12].

Emerging evidence suggests that circulating adropin levels are significantly reduced in several metabolic and cardiovascular disorders, including type 2 diabetes mellitus [13], obesity [14], non-alcoholic fatty liver disease (NAFLD) [15], hypertension and coronary artery disease [10]. In the context of diabetic nephropathy, previous studies have demonstrated a significant association between decreased adropin levels and worsening renal function. Notably, Hu and Chen [16] reported that patients with diabetic nephropathy had significantly lower serum adropin concentrations, which showed a negative correlation with urine ACR and a positive correlation with eGFR, indicating its potential utility as a biomarker of renal dysfunction. However, despite these promising findings, there is a paucity of data from the Indian population. In view of this gap in literature, the present study was undertaken to evaluate the role of serum adropin in diabetic nephropathy and its association with renal function parameters.

Objectives

To evaluate serum adropin levels in patients with type 2 diabetes mellitus (T2DM) with and without nephropathy and to assess its association with renal function and metabolic parameters.

Materials and Methods

This cross-sectional analytical study was conducted at the Institute of Diabetology and Nephrology, Rajiv Gandhi Government General Hospital, a tertiary care teaching institution affiliated with Madras Medical College over a period of one year from December 2018 to December

2019. Participants were recruited from outpatient and inpatient services of the study centre. Participants diagnosed with type 2 diabetes mellitus as per American Diabetes Association (ADA) criteria with age between 35 and 70 years who provided informed written consent were included in the study. Patients with severe cardiovascular disease, malignancy, acute infections, chronic inflammatory conditions and other endocrine disorders were excluded. A total of 90 participants diagnosed with type 2 diabetes mellitus (T2DM) were included in the study and categorized into two groups:

- Group A: 45 patients with diabetic nephropathy
- Group B: 45 patients without diabetic nephropathy

Diabetic nephropathy was defined based on the presence of persistent albuminuria (ACR ≥30 mg/g) and/or reduced estimated glomerular filtration rate (eGFR <60 mL/min/1.73 m^2), in accordance with established clinical guidelines [6].

Venous blood samples were collected from all participants after an overnight fasting period of 8–12 hours under aseptic conditions. Serum was separated by centrifugation at 3000 revolutions per minute for 15 minutes. EDTA-anticoagulated samples were used for glycated hemoglobin (HbA1C) estimation. Serum aliquots of 1 mL were stored at –20°C for subsequent adropin analysis. Additionally, spot urine samples were collected for estimation of urine albumin–creatinine ratio (ACR).

Biochemical parameters were measured using standardized laboratory methods. Serum adropin levels were quantified using enzyme-linked immunosorbent assay (ELISA). Fasting blood glucose was estimated by the hexokinase end-point method. Blood urea levels were measured using the kinetic urease–glutamate dehydrogenase (GLDH) method, while serum creatinine was assessed using Jaffé's kinetic method traceable to isotope dilution mass spectrometry (IDMS). Estimated glomerular filtration rate (eGFR) was calculated using the CKD-EPI equation. Glycated hemoglobin (HbA1C) was determined using capillary electrophoresis (Sebia Capillarys 2 system). Lipid profile parameters, including total cholesterol, triglycerides, and high-density lipoprotein, were estimated by enzymatic spectrophotometric methods, and low-density lipoprotein was calculated using the Friedewald formula. Urine albumin–creatinine ratio was measured using immunoturbidimetric methods for albumin and Jaffé method for creatinine.

Data were analysed using SPSS. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies and percentages. The Chi-square test was used to compare categorical variables between groups. Student's independent t-test was applied to compare continuous variables between the two groups. Pearson's correlation analysis was performed to evaluate associations between serum adropin levels and clinical as well as biochemical parameters. Multiple linear regression analysis was used to identify independent determinants of eGFR. Logistic regression analysis was performed to assess serum adropin as an independent predictor of diabetic nephropathy. Receiver operating characteristic (ROC) curve analysis was conducted to determine the optimal cut-off

value of serum adropin for predicting nephropathy. A p-value of less than 0.05 was considered statistically significant, while p-values less than 0.001 were considered highly significant.

Results

Table 1 presents a comparative analysis of demographic, clinical, and biochemical parameters between Group A (type 2 diabetes mellitus with nephropathy) and Group B (type 2 diabetes mellitus without nephropathy).

The two groups were comparable with respect to age and gender distribution, showing no statistically significant difference. However, BMI was marginally higher in Group A and reached statistical significance. The duration of diabetes was significantly longer in Group A, indicating a strong association between prolonged disease duration and development of nephropathy. Both systolic and diastolic blood pressures were significantly higher in Group A, reflecting poorer cardiovascular risk profiles in patients with nephropathy. Glycaemic parameters demonstrated significantly elevated fasting blood glucose and HbA1C levels in Group A, indicating poorer glycaemic control among patients with nephropathy. Regarding renal parameters, serum urea did not differ significantly between groups, whereas serum creatinine was higher and eGFR was significantly lower in Group A, confirming impaired renal function. Urine albumin–creatinine ratio (ACR) was markedly elevated in Group A, consistent with established nephropathy.

The primary outcome, serum adropin levels, was significantly lower in Group A compared to Group B. Lipid profile parameters showed atherogenic dyslipidaemia in Group A, with higher total cholesterol, triglycerides, LDL cholesterol, and lower HDL cholesterol, all statistically significant.

Figure 1 illustrates the comparison of serum adropin levels between the two groups. Group A (with nephropathy) demonstrates markedly lower mean serum adropin levels (89.9 ng/L), whereas Group B (without nephropathy) shows significantly higher levels (127.5 ng/L), with a highly significant difference.

Table 1. Comparison of all clinical and biochemical parameters between Groups

Parameter	Group A (n=45) Mean ± SD	Group B (n=45) Mean ± SD	p Value
DEMOGRAPHIC & ANTHROPOMETRIC			
Age (years)	58.8 ± 5.1	58.1 ± 7.0	0.72 NS
Gender (M/F)	24 / 21	24 / 21	1.00 NS
BMI (Kg/m²)	24.11 ± 1.04	23.51 ± 1.07	0.05 *
Duration of DM (years)	8.2 ± 1.2	7.6 ± 1.2	0.003 **
Systolic BP (mmHg)	126 ± 18.6	116.4 ± 10	0.005 **
Diastolic BP (mmHg)	81.7 ± 11.1	76 ± 7.5	0.001 **
GLYCAEMIC PARAMETERS			
FBG (mg/dL)	**190.1 ± 69**	**118.7 ± 19.5**	**0.001 ** **
HbA1C (%)	**8.44 ± 1.3**	**6.9 ± 0.65**	**0.001 ** **
RENAL PARAMETERS			

Urea (mg/dL)	27 ± 6.06	25.07 ± 6.42	0.24 NS
Creatinine (mg/dL)	0.87 ± 0.25	0.61 ± 0.07	0.05 *
eGFR (mL/min/1.73m²)	**84.82 ± 20.6**	**106.6 ± 5.4**	**0.001 ** **
ACR (mg/g)	**124.8 ± 66.9**	**16.6 ± 7.14**	**0.001 ** **
PRIMARY OUTCOME: SERUM ADROPIN			
Serum Adropin (ng/L)	**89.9 ± 55.2**	**127.5 ± 51.9**	**0.001 ** **
LIPID PROFILE			
Total Cholesterol (mg/dL)	209.5 ± 40.8	140 ± 26.5	0.001 **
Triglycerides (mg/dL)	180 ± 59.6	103.5 ± 25.7	0.001 **
HDL Cholesterol (mg/dL)	23.4 ± 4.7	49.8 ± 4.0	0.001 **
LDL Cholesterol (mg/dL)	150.7 ± 39.7	69.6 ± 24.8	0.001 **

*Group A = Type 2 DM with nephropathy; Group B = Type 2 DM without nephropathy. NS = Not Significant; *Significant (p<0.05); **Highly Significant (p<0.001).*

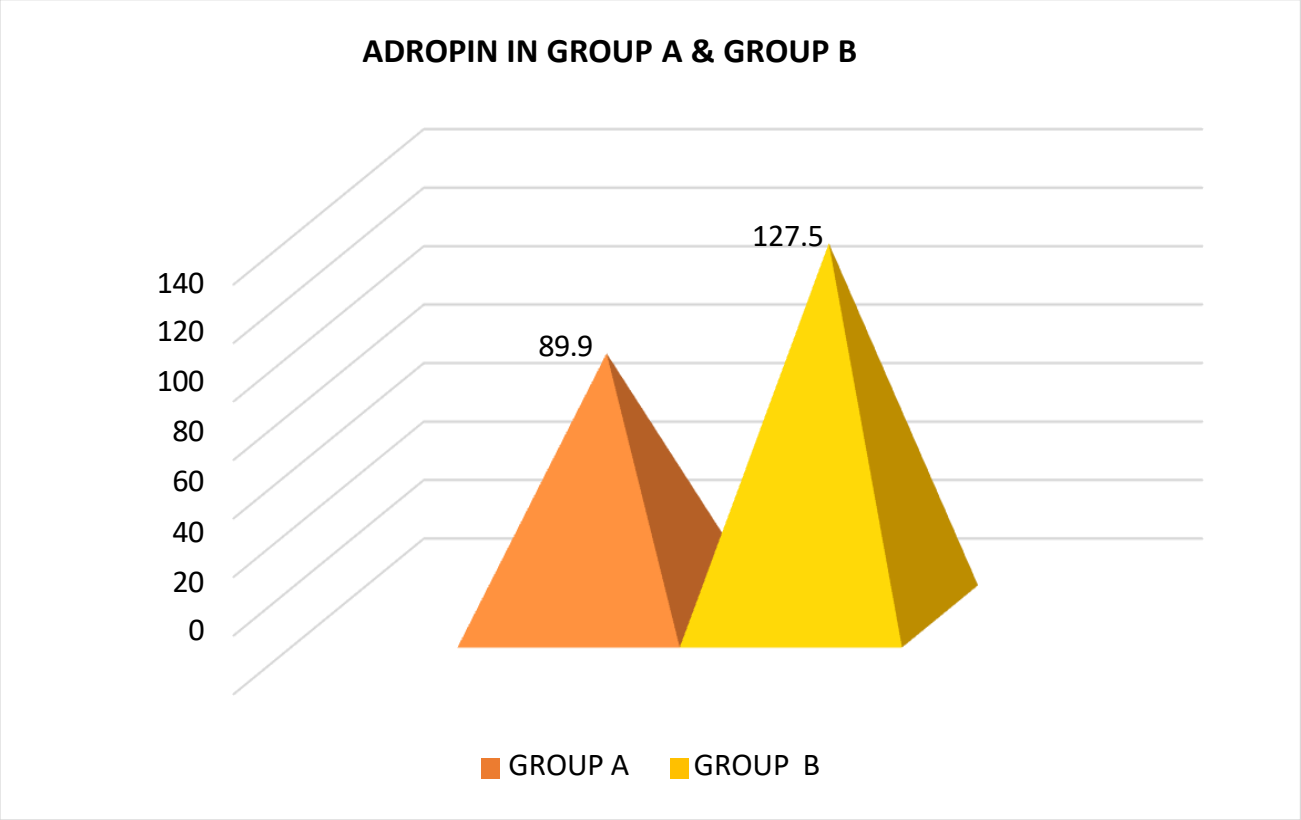


Figure 1. Serum Adropin levels in Group A vs Group B

Table 2 depicts Pearson's correlation analysis between serum adropin levels and various clinical and biochemical parameters in both Group A (type 2 diabetes mellitus with nephropathy) and Group B (without nephropathy).

In Group A, serum adropin demonstrated significant negative correlations with BMI, fasting blood glucose (FBG), HbA1C and urine albumin–creatinine ratio (ACR). Among these, the strongest negative correlation (r=-0.779, p<0.001) was observed with ACR,

indicating that lower adropin levels are associated with higher albuminuria. Adropin also showed a significant positive correlation with eGFR (r=0.594, p<0.001), suggesting better renal function with higher adropin levels. Additionally, a mild but significant positive correlation was noted with HDL cholesterol (r=0.32, p<0.05). Other lipid parameters, urea, creatinine, and total cholesterol did not show statistically significant correlations.

In Group B, no significant correlations were observed between serum adropin and most clinical or biochemical parameters. The relationships were weak and statistically non-significant, indicating a relatively stable metabolic and renal profile in patients without nephropathy.

Table 2. Pearson's correlation coefficients of serum adropin with clinical parameters

Parameter	Group A r value	Group A p value	Group B r value	Group B p value
ANTHROPOMETRIC				
BMI (Kg/m²)	**−0.60**	**<0.0001***	−0.12	0.434
GLYCAEMIC PARAMETERS				
FBG (mg/dL)	**−0.36**	**0.013***	−0.02	0.896
HbA1C (%)	**−0.51**	**<0.0001***	−0.04	0.751
RENAL PARAMETERS				
Urea (mg/dL)	−0.10	0.493 NS	−0.01	0.928
Creatinine (mg/dL)	−0.20	0.241 NS	−0.04	0.751
ACR (mg/g)	**−0.779**	**<0.0001***	−0.07	0.613
eGFR (mL/min/1.73m²)	**+0.594**	**<0.0001***	+0.11	0.471
LIPID PROFILE				
Total Cholesterol (mg/dL)	−0.25	0.09 NS	−0.03	0.831
Triglycerides (mg/dL)	−0.16	0.281 NS	−0.16	0.273
HDL Cholesterol (mg/dL)	**+0.32**	**0.031***	+0.08	0.574
LDL Cholesterol (mg/dL)	−0.24	0.117 NS	+0.01	0.925

*Pearson's correlation. *Significant at 0.05 level, 2-tailed. NS=Not significant. Highlighted cells = strongest correlations.*

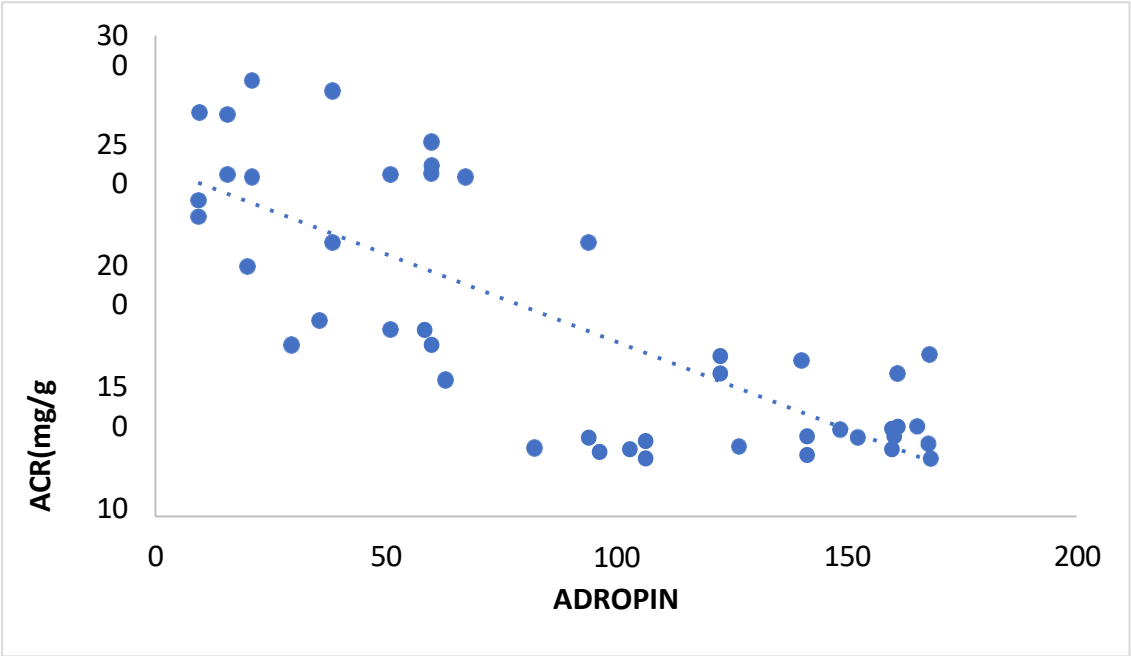


Figure 2. Scatter plot —Correlation between serum Adropin and urine ACR in Group A.

Figure 2 presents a scatter plot illustrating the correlation between serum adropin levels and urine ACR in Group A. The plot shows a clear downward trend, indicating a negative correlation between adropin and ACR. As serum adropin levels increase, urine ACR values decrease.

Table 3 presents the results of linear regression analysis with eGFR as the dependent variable to identify independent determinants of renal function.

Among the variables analysed, urine albumin–creatinine ratio (ACR) showed a strong and statistically significant negative association with eGFR, indicating that higher albuminuria is independently associated with reduced renal function. Serum adropin demonstrated a positive association with eGFR, suggesting a potential protective role; however, this association was borderline significant. Fasting blood glucose (FBG) and HbA1C did not show statistically significant associations with eGFR in the multivariate model, indicating that their effects may be mediated through other variables or are less influential when adjusted for confounders.

Table 3. Linear regression (eGFR as dependent variable)

Variable	B	Std. Error	Beta	p Value
ACR	−0.131	0.030	−0.530	**0.000 ***
Adropin	0.061	0.032	0.184	0.051
FBG	0.043	0.034	0.142	0.219 NS
HbA1C	0.642	1.679	0.045	0.703 NS

**Significant at 0.05 level, 2-tailed. NS=Not significant.*

Table 4 shows the results of logistic regression analysis with diabetic nephropathy as the dependent variable, identifying independent predictors of nephropathy.

Serum adropin demonstrated a statistically significant inverse association with diabetic nephropathy, with lower levels associated with higher odds of nephropathy. Duration of diabetes, systolic blood pressure, fasting blood glucose, and HbA1C were all significantly associated with increased risk of nephropathy, indicating their role as established risk factors. Conversely, eGFR showed a protective association, with higher eGFR linked to reduced odds of nephropathy.

Table 4. Logistic Regression Analysis (Diabetic Nephropathy as dependent variable)

Variable	Adjusted Odds Ratio (95% CI)	p Value
Serum Adropin	**0.987 (0.97–0.99)**	**0.002 ***
Duration of DM	1.5 (1.06–2.16)	0.021
Systolic BP	1.04 (1.01–1.07)	0.005
FBG	1.08 (1.05–1.12)	0.001
HbA1C	5.1 (2.57–10.2)	0.001
eGFR	0.79 (0.70–0.90)	0.001

**Significant at 0.05 level, 2-tailed. NS=Not significant.*

Figure 3 illustrates the Receiver Operating Characteristic (ROC) curve for serum adropin in predicting diabetic nephropathy. The ROC curve demonstrates the trade-off between sensitivity and specificity across various cut-off values of serum adropin. The curve lies above the diagonal reference line, indicating that serum adropin has discriminatory ability in differentiating patients with and without nephropathy. The area under the curve (AUC) is 0.701 with a standard error of 0.055 and is statistically significant ($p = 0.001$). The 95% confidence interval ranges from 0.594 to 0.809, indicating moderate diagnostic accuracy. A cut-off value of 80 ng/L for serum adropin was identified as optimal, yielding a sensitivity of 75% and specificity of 72%.

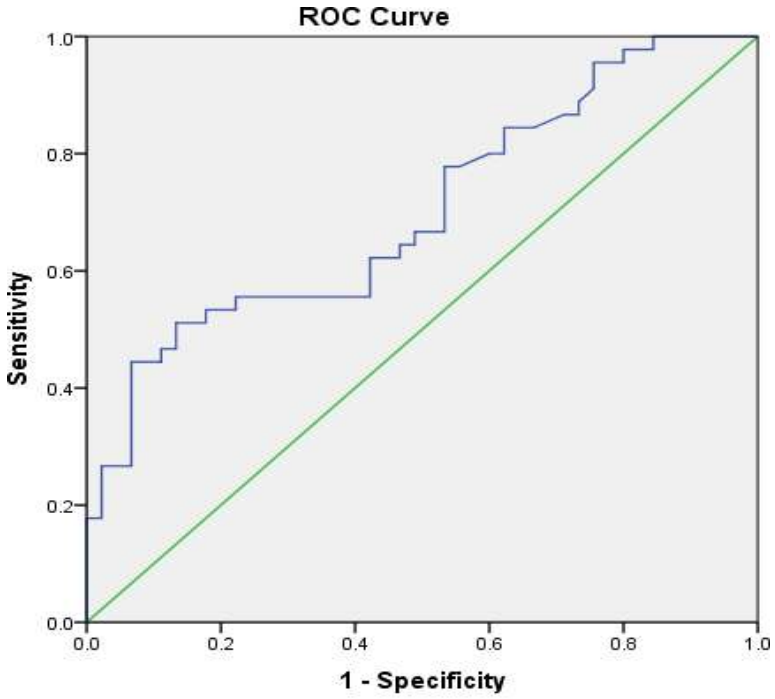


Figure 3. ROC curve for serum Adropin predicting diabetic nephropathy.

Discussion

The present study evaluated the role of serum adropin in type 2 diabetes mellitus (T2DM) patients with and without nephropathy and explored its association with clinical, metabolic, and renal parameters. The findings demonstrate that patients with diabetic nephropathy exhibit significantly poorer glycaemic control, higher cardiovascular risk factors, and marked renal dysfunction, along with significantly reduced serum adropin levels. These observations are consistent with the established pathophysiological understanding of diabetic kidney disease (DKD), where chronic hyperglycaemia and metabolic dysregulation contribute to progressive renal damage [1,3].

In the current study, patients with nephropathy had a significantly longer duration of diabetes, higher systolic and diastolic blood pressure, and increased BMI compared to those without nephropathy. These findings align with previous reports identifying duration of diabetes, hypertension, and obesity as major risk

factors for DKD progression [17-19]. The strong association between elevated blood pressure and nephropathy observed in our study supports the concept of hemodynamic stress contributing to glomerular injury and sclerosis [20]. Similarly, the higher BMI observed in Group A reflects the contributory role of obesity in accelerating renal damage through inflammatory and metabolic pathways [19].

Glycaemic parameters in our study revealed significantly higher fasting blood glucose and HbA1C levels in patients with nephropathy, indicating poor glycaemic control. This is in agreement with earlier studies which have demonstrated that chronic hyperglycaemia drives renal injury through mechanisms such as advanced glycation end product formation and activation of protein kinase C pathways. [4,5] Hussain et al. [3] and Tziomalos et al. [7] also emphasized that poor glycaemic control is a key determinant in the onset and progression of diabetic nephropathy. However, in multivariate analysis, glycaemic parameters did not independently predict eGFR decline in our study, suggesting that their effect may be mediated through downstream renal damage markers such as albuminuria.

Renal parameters in our study showed significantly higher serum creatinine and ACR levels along with reduced eGFR in patients with nephropathy. The markedly elevated ACR in Group A confirms its role as a sensitive marker of glomerular damage. However, as highlighted by Persson and Rossing,[6] traditional markers such as creatinine and ACR may not reliably detect early renal injury, underscoring the need for novel biomarkers. In our regression analysis, ACR emerged as the strongest independent predictor of reduced eGFR, reinforcing its importance in assessing renal disease severity.

The primary finding in this study is the significantly lower serum adropin in Group A (89.9±55.2 ng/L) vs Group B (127.5±51.9 ng/L, $p<0.001$) that supports the hypothesis that adropin deficiency plays a role in nephropathy, which is consistent with Hu and Chen who observed lower adropin in diabetic patients with nephropathy and negative correlation with ACR. [16] Similarly, Maciorkowska et al. [21] reported reduced adropin in CKD patients.

Correlation analysis in our study further demonstrated that serum adropin levels were negatively associated with BMI, FBG, HbA1C, and ACR, and positively associated with eGFR and HDL cholesterol in patients with nephropathy. The strong inverse correlation between adropin and ACR suggests that adropin may reflect the severity of albuminuria and glomerular damage. These findings are biologically plausible, as adropin is known to regulate endothelial function, reduce inflammatory cytokine expression, and improve nitric oxide bioavailability [10,11]. Its anti-inflammatory and vasoprotective effects may help attenuate renal injury, thereby explaining its positive association with preserved renal function.

The lipid profile findings in our study showed significant dyslipidaemia in patients with nephropathy, characterized by elevated triglycerides, total cholesterol, and LDL levels, along with reduced HDL cholesterol. This is consistent with previous literature indicating that dyslipidaemia contributes to renal injury through lipid accumulation, oxidative stress, and inflammatory pathways [20]. The observed positive correlation between adropin and

HDL cholesterol supports earlier reports suggesting that adropin plays a role in lipid metabolism and may exert protective cardiovascular effects [9,22].

In multiple regression analysis, although serum adropin showed a positive association with eGFR, it did not reach strong statistical significance, suggesting that while adropin may influence renal function, its independent predictive value requires further validation. However, in logistic regression analysis, serum adropin emerged as a significant independent predictor of diabetic nephropathy, even after adjusting for conventional risk factors such as duration of diabetes, BMI, blood pressure, and glycaemic parameters. This finding highlights the potential of adropin as a clinically relevant biomarker for nephropathy risk stratification.

The ROC curve analysis in our study demonstrated that serum adropin has moderate diagnostic accuracy for predicting diabetic nephropathy, with an AUC of 0.701. This indicates that while adropin alone may not be sufficient as a standalone diagnostic tool, it can serve as a valuable adjunct marker in combination with traditional parameters such as ACR and eGFR. Similar studies evaluating emerging biomarkers in DKD have also reported moderate predictive performance, emphasizing the need for multi-marker approaches for early detection [18].

Limitations

The study population of 90 needs to be expanded for better generalizability. The absence of a healthy control group limits comparisons across the disease spectrum. The cross-sectional design of the study and unaddressed potential confounders like Diet, Medications etc., prevents causal inferences, and a prospective study is recommended. Additionally, patients with end-stage renal disease (ESRD) on renal replacement therapy were excluded, which limits conclusions in advanced stages of the disease.

Conclusion

The findings from this study demonstrates that reduced serum adropin levels are significantly associated with diabetic nephropathy and correlate with key markers of renal dysfunction. These results suggest that serum adropin may serve as a potential adjunct biomarker and an independent predictor for risk stratification in diabetic nephropathy. However, its role in early detection warrants further validation through larger, prospective studies.

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 of Madras Medical College carrying certificate number 25082018.

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.

Acknowledgements

Use of AI: Authors declare the use of Claude (Claude.ai) to assist with manuscript preparation and improving overall language clarity. After using this tool, the authors reviewed and edited the content and took full responsibility for the contents of this article.

References

1. Alicic RZ, Rooney MT, Tuttle KR. Diabetic kidney disease: challenges, progress, and possibilities. Clin J Am Soc Nephrol. 2022;17(10):1514–25.
2. Gheith O, Farouk N, Nampoory N, Halim MA, Al-Otaibi T. Diabetic kidney disease: worldwide difference of prevalence and risk factors. J Nephropharmacol. 2016;5(1):49–56.
3. Hussain S, Chand Jamali M, Habib A, Hussain MS, Akhtar M, Najmi AK. Diabetic kidney disease: an overview of prevalence, risk factors, and biomarkers. Clin Epidemiol Glob Health. 2021;9:2–6.
4. Noh H, King GL. The role of protein kinase C activation in diabetic nephropathy. Kidney Int Suppl. 2007;(106):S49–53.
5. Pérez-Morales RE, del Pino MD, Valdivielso JM, Ortiz A, Mora-Fernández C, Navarro-González JF. Inflammation in diabetic kidney disease. Nephron. 2019;143(1):12–6.
6. Persson F, Rossing P. Diagnosis of diabetic kidney disease: state of the art and future perspective. Kidney Int Suppl (2011). 2018;8(1):2–7.
7. Tziomalos K, Athyros VG. Diabetic nephropathy: new risk factors and improvements in diagnosis. Rev Diabet Stud. 2015;12(1-2):110–8.
8. Marczuk N, Cecerska-Heryć E, Jesionowska A, Dołęgowska B. Adropin - physiological and pathophysiological role. Postepy Hig Med Dosw (Online). 2016;70:981–8.
9. Jasaszwili M, Billert M, Strowski MZ, Nowak KW, Skrzypski M. Adropin as a fat-burning hormone with multiple functions: review of a decade of research. Molecules. 2020;25(3):549.
10. Sato K, Yamashita T, Shirai R, Shibata K, Okano T, Yamaguchi M, et al. Adropin contributes to anti-atherosclerosis by suppressing monocyte-endothelial cell adhesion and smooth muscle cell proliferation. Int J Mol Sci. 2018;19(5):1293.
11. Zhang S, Chen Q, Lin X, Chen M, Liu Q. A review of adropin as the medium of dialogue between energy regulation and immune regulation. Oxid Med Cell Longev. 2020;2020:3947806.
12. Gao S, Ghoshal S, Zhang L, Stevens JR, McCommis KS, Finck BN, et al. The peptide hormone adropin regulates signal transduction pathways controlling hepatic glucose metabolism in a mouse model of diet-induced obesity. J Biol Chem. 2019;294(36):13366–77.
13. Zang H, Jiang F, Cheng X, Xu H, Hu X. Serum adropin levels are decreased in Chinese type 2 diabetic patients and negatively correlated with body mass index. Endocr J. 2018;65(7):685–91.

14. Butler AA, Tam CS, Stanhope KL, Wolfe BM, Ali MR, O'Keeffe M, et al. Low circulating adropin concentrations with obesity and aging correlate with risk factors for metabolic disease and increase after gastric bypass surgery in humans. J Clin Endocrinol Metab. 2012;97(10):3783–91.
15. Chen X, Xue H, Fang W, Chen K, Chen S, Yang W, et al. Adropin protects against liver injury in nonalcoholic steatohepatitis via the Nrf2-mediated antioxidant capacity. Redox Biol. 2019;21:101068.
16. Hu W, Chen L. Association of serum adropin concentrations with diabetic nephropathy. Mediators Inflamm. 2016;2016:6038261.
17. Umanath K, Lewis JB. Update on diabetic nephropathy: core curriculum 2018. Am J Kidney Dis. 2018;71(6):884–95.
18. Radcliffe NJ, Seah J, Clarke M, MacIsaac RJ, Jerums G, Ekinci EI. Clinical predictive factors in diabetic kidney disease progression. J Diabetes Investig. 2017;8(1):6–18.
19. Maric-Bilkan C. Obesity and diabetic kidney disease. Med Clin North Am. 2013;97(1):59–74.
20. Su W, Cao R, He YC, Guan YF, Ruan XZ. Crosstalk of hyperglycemia and dyslipidemia in diabetic kidney disease. Kidney Dis (Basel). 2017;3(4):171–80.
21. Maciorkowska M, Musiałowska D, Małyszko J. Adropin and irisin in arterial hypertension, diabetes mellitus and chronic kidney disease. Adv Clin Exp Med. 2019;28(11):1571–5.
22. Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: results from the International Diabetes Federation Diabetes Atlas, 9th edition. Diabetes Res Clin Pract. 2019;157:107843.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 681–692, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.005

ORIGINAL ARTICLE

Phytochemical Profiling and Experimental Validation of Wound and Burn Wound Healing Activity of the Whole Plant of *Euphorbia hirta* Linn

R. Vidhya,[1,*] Sheshagiri Dixit,[2] B.R. Prashantha Kumar[2] and Sudharsan S[3]
[1]*Department of Pharmacology, Mandya Institute of Medical Sciences, Mandya, Karnataka, India*
[2]*Department of Pharmaceutical Chemistry, JSS College of Pharmacy, Mysore, Karnataka, India*
[3]*Postgraduate and Tutor, Department of Physiology, Mandya Institute of Medical Sciences, Mandya, Karnataka, India*

Accepted: 15-April-2026 / Published Online: 6-May-2026

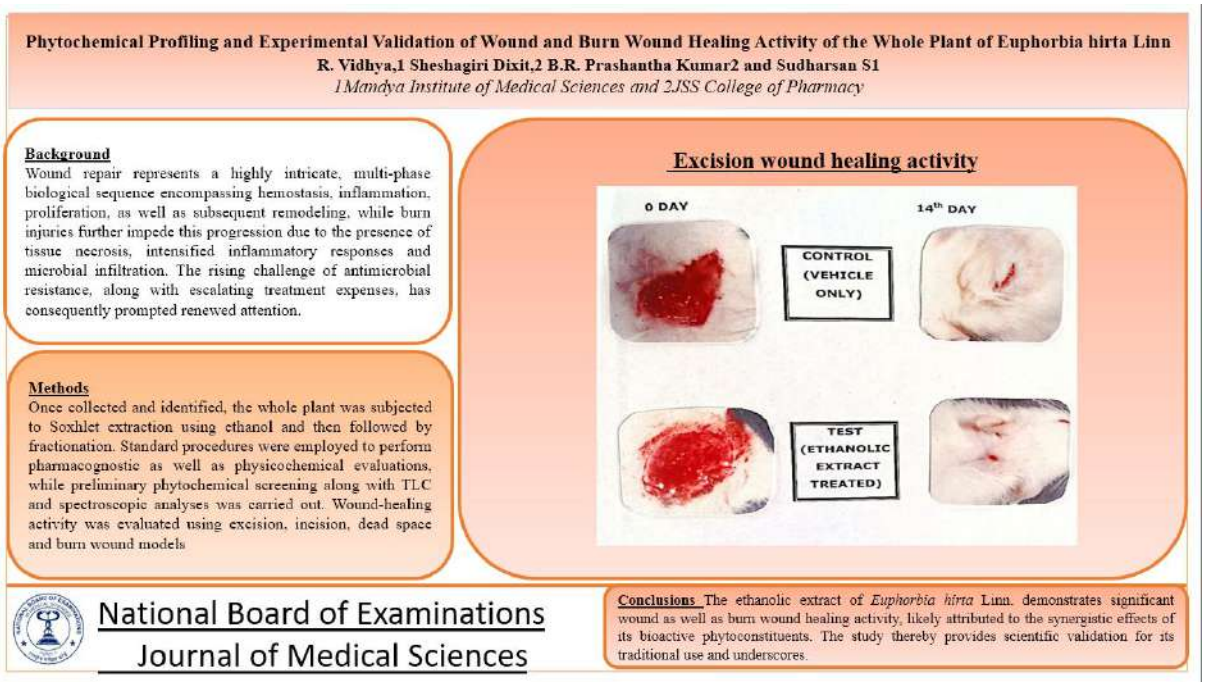
Abstract

Background: Wound repair represents a highly intricate, multi-phase biological sequence encompassing hemostasis, inflammation, proliferation, as well as subsequent remodeling, while burn injuries further impede this progression due to the presence of tissue necrosis, intensified inflammatory responses and microbial infiltration. The rising challenge of antimicrobial resistance, along with escalating treatment expenses, has consequently prompted renewed attention toward plant-derived therapeutics, and Euphorbia hirta Linn., long utilized across diverse traditional medicinal systems, contains numerous bioactive constituents that exhibit considerable potential in facilitating wound healing. **Objectives:** To evaluate the effectiveness of the ethanolic extract derived from the entire *Euphorbia hirta* Linn. plant in promoting wound and burn healing is assessed through pharmacognostic and phytochemical approaches, along with the use of animal-based experimental models. **Methods:** Once collected and identified, the whole plant was subjected to Soxhlet extraction using ethanol and then followed by fractionation. Standard procedures were employed to perform pharmacognostic as well as physicochemical evaluations, while preliminary phytochemical screening along with TLC and spectroscopic analyses was carried out. Wound-healing activity was evaluated using excision, incision, dead space and burn wound models, during which parameters such as wound contraction, epithelialization period and tensile strength were recorded. **Results:** With physicochemical parameters remaining within acceptable limits, the quality of the plant material was thereby confirmed. Phytochemical screening revealed the presence of flavonoids, tannins, phenolics, saponins as well as glycosides, particularly in the ethanolic extract. In comparison to the control, the extract showed a significant increase in wound contraction (92 ± 1.2% on day 12), enhanced tensile strength (378 ± 14 g) and a shortened epithelialization period (12 ± 0.9 days. **Conclusion:** The ethanolic extract of *Euphorbia hirta* Linn. demonstrates significant wound as well as burn wound healing activity, likely attributed to the synergistic effects of its bioactive phytoconstituents. The study thereby provides scientific validation for its traditional use and underscores its potential as a cost-effective herbal alternative for wound management, particularly in resource-limited settings.

Keywords: Euphorbia hirta, wound healing, burn injury, phytochemicals, flavonoids, antioxidant

*Corresponding Author: R. Vidhya
Email: vcm2004@gmail.com

Graphical Abstract



Introduction

A tightly controlled and intricate biological sequence, wound healing entails coordinated interplay among diverse cell types along with extracellular matrix components, growth factors, cytokines and signaling molecules, thereby enabling restoration of tissue integrity following injury. Proceeding through overlapping stages—namely hemostasis, inflammation, proliferation and remodelling—the process initially limits excessive blood loss through hemostasis immediately after injury, after which the inflammatory phase, marked by infiltration of neutrophils and macrophages, functions to clear debris as well as prevent infection. Subsequently, the proliferative stage is characterized by fibroblast migration, angiogenesis, collagen synthesis and re-epithelialization, whereas the remodeling phase ultimately facilitates maturation and reorganization of collagen fibers, resulting in restored tensile strength [1,2].

Impairment of any of these phases can hinder the healing progression, with commonly observed causes including microbial infection, oxidative stress, ischemia, impaired perfusion, metabolic disorders along with prolonged inflammation, which may consequently result in delayed wound closure or chronic non-healing wounds. Characterized by persistent inflammation, chronic wounds also exhibit elevated protease activity, diminished responsiveness to growth factors and inadequate extracellular matrix formation, all of which contribute to poor clinical outcomes as well as an increased healthcare burden [3,4].

Representing a severe form of tissue trauma, burn injuries are associated with extensive tissue necrosis together with loss of skin barrier function, while also demonstrating microbial colonization and imbalance in fluid and electrolytes, alongside an exaggerated local as well as systemic inflammatory response. Such alterations can delay epithelialization and

enhance scar formation, in addition to increasing the risk of secondary infections, and in severe cases, burn injuries may lead to systemic inflammatory response syndrome and multiorgan dysfunction, which further complicates wound management and delays recovery [5,6].

Although modern wound care techniques have advanced, complications remain common despite the use of advanced dressings, antibiotics and surgical interventions, and wound- as well as burn-related complications continue to be a major cause of morbidity and mortality worldwide, with the burden being greater in low- and middle-income countries where limited healthcare access, high treatment costs and poor wound hygiene act as important contributing factors, while increasing antimicrobial resistance further compromises effective wound management [7].

Growing antimicrobial resistance along with the high cost of synthetic drugs has prompted increased interest in medicinal plants, with adverse drug reactions also contributing to this shift, as these plants are utilized as alternative as well as complementary therapies for wound and burn management due to their easy availability, cost-effectiveness and cultural acceptability, while containing multiple bioactive constituents that may act synergistically to promote healing [8,9].

Traditional systems such as Ayurveda, Sidha and Unani describe the use of medicinal plants for the treatment of wounds, burns, ulcers and other skin diseases, and these systems generally favor the use of whole plants or crude extracts, which is considered to provide balanced therapeutic effects owing to the combined action of phytoconstituents [10].

Euphorbia hirta Linn. (family Euphorbiaceae), commonly referred to as the “asthma plant,” is widely distributed across tropical and subtropical regions of Asia, Africa and South America, and is traditionally employed for respiratory as well as gastrointestinal disorders, while also being used for skin infections, wounds, ulcers and burns, where it is applied in the form of paste, decoction or latex and utilized for cuts, boils along with inflammatory skin conditions in many communities [11–13].

Phytochemical investigations of Euphorbia hirta indicate the presence of flavonoids, tannins, phenolic compounds and saponins, which exhibit antimicrobial, antioxidant and anti-inflammatory activities along with wound healing properties, as flavonoids and phenolic compounds facilitate free radical scavenging and enhance collagen synthesis, whereas tannins promote wound contraction and epithelialization; however, comprehensive evaluation of the whole plant using multiple wound healing models remains limited, which constituted the basis for the present study [14–16].

Materials and Methods

Collection and Authentication of Plant Material

The whole plant of Euphorbia hirta Linn. was collected from in and around the Mandya region during the monsoon as well as winter seasons, which were selected since phytoconstituent concentration is reported to be optimal [17], while seasonal variation can influence the biosynthesis and accumulation of secondary metabolites in medicinal plants, thereby affecting their pharmacological activity; only healthy plants were chosen, with care taken to avoid

diseased specimens, insect infestation and environmental contamination.

The collected plant material was subsequently authenticated by a qualified taxonomist, and a voucher specimen was deposited in the departmental herbarium for future reference [18], as authentication ensures accurate botanical identification while also supporting reproducibility of the study, which is essential for pharmacognostic standardization and future investigations.

Preparation of Extracts

The collected plant material of Euphorbia hirta was thoroughly washed with water to remove soil and debris, after which it was shade dried to preserve thermolabile constituents, as this method helps prevent degradation of heat-sensitive phytoconstituents; the dried material was then coarsely powdered using a mechanical grinder, thereby increasing the surface area for extraction, and subsequently subjected to Soxhlet extraction using ethanol as the solvent [19]. The resulting total alcoholic crude extract was further fractionated using petroleum ether, solvent ether, ethyl acetate, butanol and butanone, where the use of solvents with increasing polarity facilitates extraction of different phytoconstituents, and each extract was filtered and concentrated under reduced pressure using a rotary evaporator before being stored in airtight containers at low temperature to prevent degradation.

Pharmacognostic Evaluation

Macroscopic as well as microscopic evaluation was performed to establish pharmacognostic standards [20], wherein macroscopic analysis included assessment of size, shape, color, surface and texture of plant parts, while microscopic examination identified features such as trichomes, stomata, vascular bundles and cellular inclusions, which aid in identification and detection of adulteration. Physicochemical parameters including total ash, acid-insoluble ash, water-soluble ash, extractive values and loss on drying were determined using standard methods [21], as these parameters reflect purity and quality of the plant material and contribute to quality control.

Phytochemical Investigation

Preliminary phytochemical screening was conducted using standard qualitative tests [14,22] to identify various classes of phytoconstituents, revealing the presence of alkaloids, flavonoids, tannins, saponins, glycosides, phenolics and steroids, thereby providing basic insight into the chemical nature of the plant and enabling correlation of pharmacological activity with its constituents. Thin-layer chromatography was performed to confirm flavonoids as well as phenolic compounds and to examine the chemical profile of the extracts using suitable solvent systems and detecting reagents, while UV–visible and FT-IR spectroscopy were carried out for characterization of phytoconstituents, aiding in identification of functional groups and preliminary structural features [23].

Pharmacological Evaluation

Acute Toxicity Studies

Acute oral toxicity studies were carried out in accordance with OECD guidelines [24], during which animals were monitored for behavioral changes, signs of toxicity and mortality, and the ethanolic extract was found to be safe at the tested doses, thereby indicating safety and supporting further investigations.

Evaluation of Wound Healing Activity

Wound healing activity was assessed using excision, incision, dead space and burn wound models [25,26], which are standard experimental approaches, and the use of multiple models enables evaluation of different aspects of wound healing including wound contraction, collagen formation, tensile strength and tissue repair. Parameters such as wound contraction, epithelialization period, tensile strength, granuloma formation and histopathological changes were measured [27], as these indicators reflect the rate as well as quality of healing and provide evidence for the activity of the extract.

Anti-inflammatory and Haemostatic Activity

Anti-inflammatory activity was evaluated by assessing inhibition of inflammatory mediators [28], given that inflammation plays a critical role in the early phase of wound healing and regulation of excessive inflammation supports proper healing, while haemostatic activity was determined by measuring bleeding time and clotting time [29], since rapid hemostasis is essential for wound repair and facilitates early stabilization of the wound.

Biochemical Investigation

Biochemical parameters including total protein, carbohydrate and antioxidant enzymes were estimated [30], as these factors contribute to collagen synthesis, fibroblast activity and tissue regeneration, thereby supporting the wound healing effects observed in experimental models.

Results

According to Table 1, the physicochemical parameters of Euphorbia hirta were found to be within acceptable pharmacopoeial limits, indicating good quality as well as purity of the plant material, where the total ash value (7.8%) reflects total inorganic content, the low acid-insoluble ash value (1.9%) suggests minimal siliceous contamination, and the water-soluble ash value (3.2%) indicates the presence of water-soluble inorganic salts; moreover, the alcohol-soluble extractive value (22.7%) being higher than the water-soluble extractive value (18.4%) implies that a greater proportion of phytoconstituents are soluble in organic solvents, while the loss on drying (6.3%) denotes low moisture content, which is beneficial for preventing microbial growth and maintaining stability of the crude drug.

Table 1. Physicochemical Parameters of *Euphorbia hirta*

Parameter	**Value**
Total ash (%)	7.8
Acid-insoluble ash (%)	1.9
Water-soluble ash (%)	3.2
Alcohol-soluble extractive (%)	22.7
Water-soluble extractive (%)	18.4
Loss on drying (%)	6.3

According to Table 2, the percentage yield of extracts varied with solvent polarity, with the aqueous extract showing the highest yield (14.2%), followed by ethanolic (12.6%) and methanolic extract (10.9%), thereby indicating the predominance of polar constituents, whereas petroleum ether (3.4%) and chloroform (5.8%) extracts exhibited lower yields, suggesting fewer non-polar constituents, and these findings support the selection of the ethanolic extract for further study as it provides a good yield while extracting a wide range of bioactive compounds.

Table 2. Percentage Yield of Various Extracts

Solvent	**Yield (%)**
Petroleum ether	3.4
Solvent Ether	5.8
Ethyl Acetate	12.6
Butanol	10.9
Butanone	14.2

According to Table 3, preliminary phytochemical screening revealed the presence of diverse phytoconstituents, with ethanolic as well as aqueous extracts containing a greater number of bioactive compounds, where flavonoids and phenolic compounds were present in high amounts (+++) in the ethanolic extract, while tannins and saponins were more abundant in the aqueous extract, and glycosides were detected in both extracts; in contrast, the petroleum ether extract showed minimal phytochemical presence, indicating limited non-polar constituents, and these observations suggest that polar extracts possess greater therapeutic potential.

Table 3. Preliminary Phytochemical Screening

Phytoconstituent	**Petroleum ether**	**Chloroform**	**Ethanol**	**Aqueous**
Flavonoids	–	+	+++	++
Tannins	–	+	++	+++
Phenolics	–	+	+++	++
Saponins	–	–	++	+++
Glycosides	–	+	++	++

According to Table 4, the ethanolic extract demonstrated a significant increase in wound contraction compared to the control at all time points, with wound contraction reaching 41 ± 2.3% on day 4, which was higher than the control and comparable to the standard group, increasing to 71 ± 1.9% on day 8 and further to 92 ± 1.2% on day 12, thereby indicating that the ethanolic extract facilitates faster wound closure.

Table 4. Effect of Ethanolic Extract on Wound Contraction (%)

Day	**Control**	**Standard**	**Extract**
4	22 ± 2.1	35 ± 1.8	41 ± 2.3
8	45 ± 2.4	62 ± 2.0	71 ± 1.9
12	68 ± 1.7	85 ± 1.5	92 ± 1.2

According to Table 5, tensile strength in the incision wound model was higher in the extract-treated group (378 ± 14 g) compared to the control (210 ± 12 g) and was also slightly greater than the standard group (345 ± 15 g), suggesting enhanced collagen synthesis along with improved tissue maturation, where increased tensile strength reflects better quality of healing.

Table 5. Tensile Strength in Incision Wound Model

Group	**Tensile Strength (g)**
Control	210 ± 12
Standard	345 ± 15
Extract	378 ± 14

According to Table 6, the epithelialization period was reduced in the extract-treated group, with complete epithelialization occurring in 12 ± 0.9 days compared to 21 ± 1.3 days in the control group and 14 ± 1.1 days in the standard group, indicating faster epithelial regeneration and further supporting the wound healing activity of the ethanolic extract of *Euphorbia hirta.*

Table 6. Effect on Epithelialization Period

Group	Days for Complete Epithelialization
Control	21 ± 1.3
Standard	14 ± 1.1
Extract	12 ± 0.9

Figure 1 showing the macroscopic morphology of the whole plant of *Euphorbia hirta* Linn., highlighting the characteristic erect stem, opposite leaves and clustered inflorescences at the nodes. The image represents the plant material used for pharmacognostic evaluation, phytochemical investigation and experimental wound healing studies.

Figure 1. Whole plant of *Euphorbia hirta* Linn.

Figure 2 showing *Euphorbia hirta* Linn. growing in its natural habitat on dry, open soil. The image highlights the prostrate to semi-erect growth habit of the plant, opposite elliptic leaves and clustered inflorescences at the nodes, characteristic of the species. The photograph represents the natural ecological distribution of the plant from which the material used in the present study was collected.

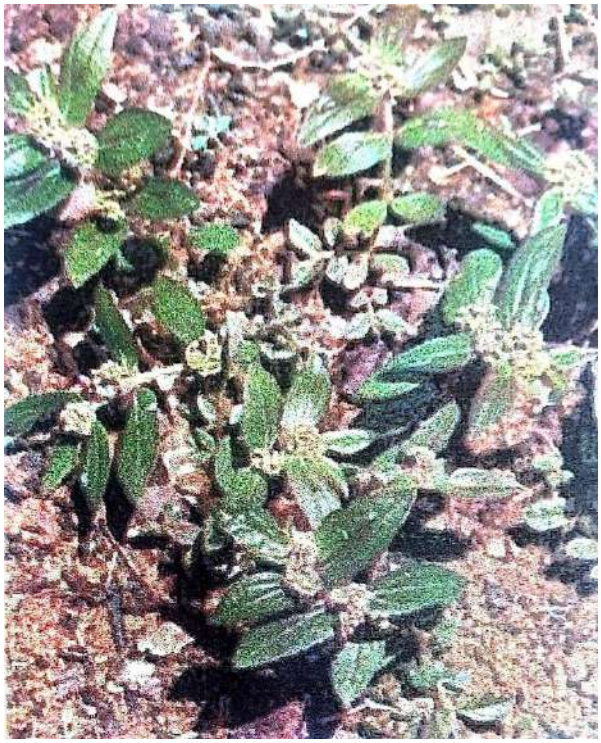


Figure 2. Natural habitat of *Euphorbia hirta* Linn.

Figure3 depicting the effect of ethanolic extract of *Euphorbia hirta* Linn. on excision wound healing in experimental animals. Images show wounds on **day 0** and **day 14** in the **control group (vehicle only)** and **test group (ethanolic extract treated)**. The test group demonstrates enhanced wound contraction and faster epithelialization compared to the control group, indicating significant wound healing activity of the ethanolic extract.

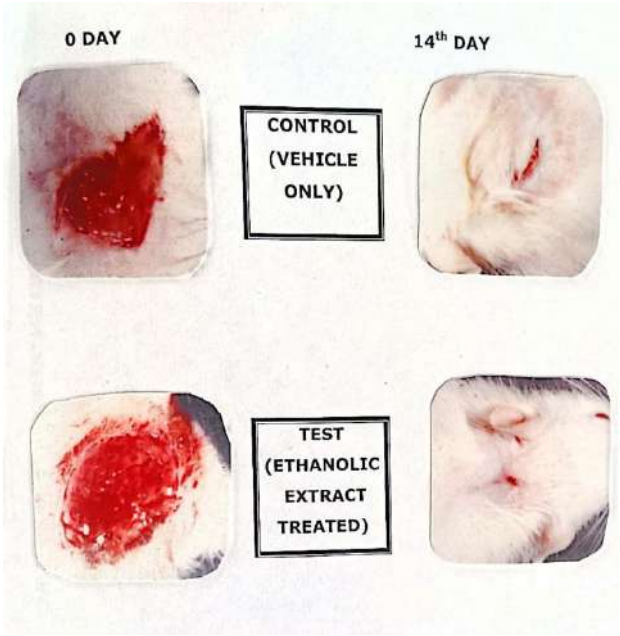


Figure 3. Excision wound healing activity

Discussion

The enhanced wound healing activity of the ethanolic extract of Euphorbia hirta may be attributed to the combined action of flavonoids, tannins and phenolic compounds present in the plant [14–16], where the presence of multiple phytoconstituents acting synergistically can produce a better therapeutic effect than isolated compounds, thereby supporting the use of whole plant extracts in traditional medicine; flavonoids facilitate fibroblast proliferation, collagen synthesis and angiogenesis, which are critical processes in the proliferative phase of wound healing, while also modulating growth factors and promoting re-epithelialization, leading to faster wound closure [15,22].

Tannins likewise contribute to wound healing by promoting wound contraction and epithelialization through their astringent action, as they induce precipitation of proteins and form a protective layer over the wound, thereby facilitating faster tissue repair while reducing the risk of infection and fluid loss from the wound [15,22], whereas phenolic compounds exert their effect through free radical scavenging and stabilization of the extracellular matrix, which enhances tissue strength and integrity [14–16].

The antimicrobial activity of the extract plays a crucial role in wound healing, since infection represents a major cause of delayed healing and chronic wounds [8,27], and microbial proliferation prolongs inflammation while impairing tissue regeneration; by inhibiting microorganisms, the extract helps maintain a clean wound environment, thereby supporting proper healing and reducing the risk of wound sepsis [8,27].

Antioxidant activity mitigates oxidative stress at the wound site, which promotes faster tissue regeneration and prevents cellular damage [28,30], as reactive oxygen species can damage cell membranes, proteins and nucleic acids, thereby delaying healing, whereas the antioxidant effect of Euphorbia hirta may protect newly formed tissue and facilitate the transition from the inflammatory to the proliferative phase [28,30].

Anti-inflammatory as well as haemostatic activities further support wound and burn healing, since appropriate regulation of inflammation is essential for effective healing while excessive inflammation can delay recovery and increase scarring, and haemostatic activity promotes early wound stabilization by reducing blood loss and facilitating clot formation, which serves as a matrix for cell migration and tissue repair, thereby collectively explaining the wound and burn healing effects observed in this study.

Conclusion

The present study offers scientific validation for the traditional use of Euphorbia hirta Linn. in the management of wounds as well as burn injuries, as the ethanolic extract of the whole plant demonstrated significant wound healing, burn wound healing, antimicrobial, antioxidant, anti-inflammatory and haemostatic activities, which were evidenced by increased wound contraction, reduced epithelialization period and enhanced tensile strength in experimental models, and these effects may be attributed to the combined action of bioactive phytoconstituents present in the plant.

Being widely distributed and readily available as a weed, Euphorbia hirta is also low in cost, and due to these advantages it exhibits considerable potential for development into a herbal

wound care formulation, while the findings of this study support its traditional use and provide a foundation for further formulation development as well as clinical investigations; with appropriate standardization and safety evaluation, it may serve as a cost-effective alternative for wound and burn management, particularly in resource-limited settings.

Acknowledgements

The authors are grateful to the Department of Pharmaceutical Chemistry, JSS college of pharmacy, Mysore, for providing the necessary laboratory facilities to carry out this research work.

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.

References

1. Clark RAF. Cutaneous wound repair: basic biological considerations. N Engl J Med. 1996;276:121–132.
2. Diegelmann RF, Evans MC. Wound healing: an overview of acute, fibrotic and delayed healing. Front Biosci. 2004;9:283–289.
3. Guo S, DiPietro LA. Factors affecting wound healing. J Dent Res. 2010;89:219–229.
4. Boateng J, Catanzano O. Advanced therapeutic dressings for effective wound healing. J Pharm Sci. 2015;104:3653–3680.
5. Church D, Elsayed S, Reid O, Winston B, Lindsay R. Burn wound infections. Clin Microbiol Rev. 2006;19:403–434.
6. Atiyeh BS, Costagliola M, Hayek SN. Burn prevention mechanisms. Ann Burns Fire Disasters. 2009;22:171–178.
7. Cowan MM. Plant products as antimicrobial agents. Clin Microbiol Rev. 1999;12:564–582.
8. Newman DJ, Cragg GM. Natural products as sources of new drugs. J Nat Prod. 2016;79:629–661.
9. Sharma PV. Dravyaguna Vijnana. Chaukhambha Bharati Academy; 2003.
10. Kirtikar KR, Basu BD. Indian Medicinal Plants. Vol II. Lalit Mohan Basu; 2001.
11. Kumar S, Malhotra R, Kumar D. Euphorbia hirta: its chemistry, traditional and medicinal uses. Pharm Rev. 2010;4:58–61.
12. Johnson PB, Abdurahman EM, Tiam EA. Euphorbia hirta: ethnomedicinal uses and pharmacology. Fitoterapia. 1999;70:457–463.
13. Harborne JB. Phytochemical Methods. Springer; 1998.
14. Trease GE, Evans WC. Pharmacognosy. Elsevier; 2009.
15. Lodhi S, Singhai AK. Wound healing activity of flavonoids. J Pharm Sci. 2013;45:123–130.
16. Biswas TK, Mukherjee B. Plant medicines of Indian origin for wound healing. Phytother Res. 2003;17:971–980.
17. Kumar B, Vijayakumar M, Govindarajan R, Pushpangadan P. Ethnopharmacological approaches to wound healing. Indian J Exp Biol. 2007;45:345–356.

18. OECD. Guidelines for Testing of Chemicals: Acute Oral Toxicity. OECD; 2001.
19. Morton JJ, Malone MH. Evaluation of vulnerary activity. Arch Int Pharmacodyn. 1972;196:117–126.
20. Bairy KL, Rao CM. Wound healing profiles of herbal drugs. Indian J Pharmacol. 2010;42:14–20.
21. Khandelwal KR. Practical Pharmacognosy. Nirali Prakashan; 2016.
22. Nayak BS, Pinto Pereira L. Catharanthus roseus flower extract in wound healing. BMC Complement Altern Med. 2006;6:41.
23. Ghosh PK, Gaba A. Phyto-extracts in wound healing. J Pharm Pharm Sci. 2013;16:760–820.
24. Midwood KS, Williams LV, Schwarzbauer JE. Tissue repair and extracellular matrix. Nat Rev Mol Cell Biol. 2004;5:517–528.
25. Gupta A, Upadhyay NK. Antioxidant activity in wound healing. Pharmacogn Rev. 2014;8:29–36.
26. Soni H, Singhai AK. Evaluation of wound healing activity of medicinal plants. Int J Pharm Sci Res. 2012;3:123–128.
27. Patil MB, Jalalpure SS, Prakash NS. Antimicrobial activity of Euphorbia species. Indian Drugs. 2008;45:886–890.
28. Velnar T, Bailey T, Smrkolj V. The wound healing process. J Int Med Res. 2009;37:1528–1542.
29. Sen CK, Roy S. Redox signals in wound healing. Biochim Biophys Acta. 2008;1780:1348–1361.
30. Martin P. Wound healing—aiming for perfect skin regeneration. Science. 1997;276:75–81.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 693–701, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.006

ORIGINAL ARTICLE

A Retrospective CT Study to Evaluate the Horizontal and Vertical Positions of the Mental Foramen and the Prevalence of Accessory Mental Foramen in Western Tamilnadu, India

Ravikumar R,[1] Sriram Balaji,[2] Sabari Arasu Palanisamy,[3] Arun Kumar Subramaniam[1] and Jeevithan Shanmugam[4,*]

[1]*Professor of Radiodiagnosis, KMCH Institute of Health Sciences and Research, Coimbatore - 14*
[2]*Associate Professor of Dentistry, KMCH Institute of Health Sciences and Research, Coimbatore - 14*
[3]*Associate Professor of Radiodiagnosis, KMCH Institute of Health Sciences and Research, Coimbatore - 14.*
[4]*Professor of Community Medicine, KMCH Institute of Health Sciences and Research, Coimbatore – 14*

Accepted: 25-March-2026 / Published Online: 6-May-2026

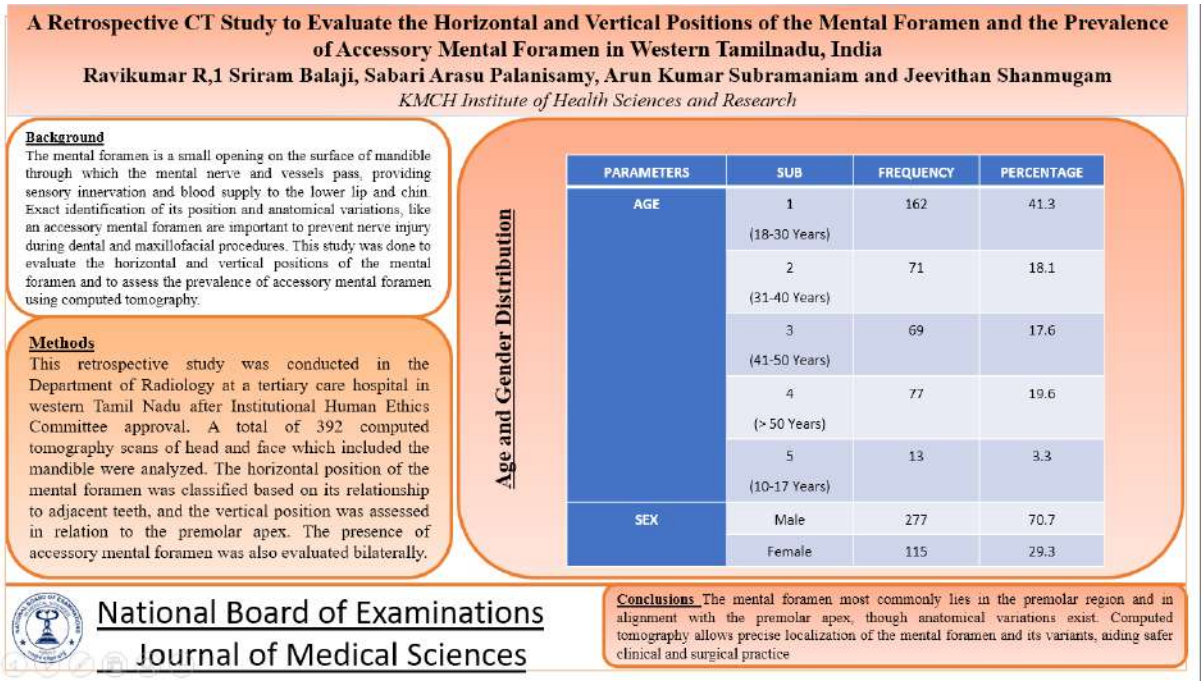
Abstract

Introduction: The mental foramen is a small opening on the surface of mandible through which the mental nerve and vessels pass, providing sensory innervation and blood supply to the lower lip and chin. Exact identification of its position and anatomical variations, like an accessory mental foramen are important to prevent nerve injury during dental and maxillofacial procedures. This study was done to evaluate the horizontal and vertical positions of the mental foramen and to assess the prevalence of accessory mental foramen using computed tomography. **Materials and Methods:** This retrospective study was conducted in the Department of Radiology at a tertiary care hospital in western Tamil Nadu after Institutional Human Ethics Committee approval. A total of 392 computed tomography scans of head and face which included the mandible were analyzed. The horizontal position of the mental foramen was classified based on its relationship to adjacent teeth, and the vertical position was assessed in relation to the premolar apex. The presence of accessory mental foramen was also evaluated bilaterally. **Results:** The most common horizontal position of the mental foramen was position 4 on both right (56.6%) and left (53.1%) sides, followed by position 3. Vertically, position 2 was the most frequent location on both sides. Accessory mental foramen was present in 6.9% of the individuals on right-side and in 6.4% on left-side. A high degree of bilateral symmetry was observed. **Conclusion:** The mental foramen most commonly lies in the premolar region and in alignment with the premolar apex, though anatomical variations exist. Computed tomography allows precise localization of the mental foramen and its variants, aiding safer clinical and surgical practice.

Keywords: Mental Foramen, Computed tomography, Mental Foramen, Accessory Mental Foramen

*Corresponding Author: Jeevithan Shanmugam
Email: dr.jeevithan@gmail.com

Graphical Abstract



Introduction

The mental foramen is one of the important anatomical landmarks located on the external surface of the body of the mandible. Mental Foramen serves as the point of exit for the mental nerve, artery, and vein, which provides sensory innervation and blood supply to the lower lip, chin, and adjacent labial mucosa. The mental foramen is visualised as a round or oval radiolucent shadow and may sometimes be mistaken for a pathological lesion. In spite of being small in size, the mental foramen plays an important role in oral and maxillofacial surgery and forensic anthropology [1].

The mental foramen can be located in different places and can vary based on age, bone resorption, tooth loss, genetic makeup, and racial differences. Accurate localization of the foramen is important during procedures like mental nerve block, placing a dental implant, mandibular osteotomies and fracture fixation. Mental nerve injury can cause life long sensory disturbances and discomfort, with varied symptoms like numbness, paraesthesias and discomfort [2]. Accurate knowledge of the anatomical position of the mental foramen is important.

The mental foramen can be visualised both in horizontal and vertical planes. In the horizontal plane, position of the mental foramen was classified by Al Jasser and Nwoku. They classified it into six positions based on its relationship to adjacent teeth [2].

Position 1: Situated anterior to the first premolar, Position 2: In line with the first premolar, Position 3: Between the first and second premolar, Position 4: In line with second premolar, Position 5: Between the second premolar and first molar and Position 6: In line with the first molar.

Vertically, Fishel et al. [3] classified the foramen based on its relationship to the apex of the premolar teeth (3) as follows - Position 1: coronal to

the apex, position 2: at the apex, position 3: apical to the apex. Studies have shown variability in these positions across different populations, highlighting the importance of population-specific anatomical data [4,5]. Advanced imaging modalities such as computed tomography (CT), cone-beam computed tomography (CBCT), and panoramic radiographs play a vital role in accurately identifying these variations.

Few individuals have an accessory mental foramen (AMF) along with a primary, which is an additional anatomical opening present on the buccal surface of the mandible [6,7]. The accessory branches of the mental nerve and accompanying vessels can pass through the AMF and may cause incomplete anesthesia or nerve injury if not recognized. Though the prevalence of AMF is relatively low, its presence carries significant clinical implications during surgical and anesthetic procedures [8,9]. In view of the importance of accurate anatomical localization and lack of regional data, this study was done using computed tomography to determine the prevalence of accessory mental foramen and to evaluate the mental foramen's horizontal and vertical positions in a tertiary care hospital in Western Tamil Nadu, India

Materials and Methods

This Retrospective imaging based Cross sectional study was done in the Department of Radiology at a Tertiary care teaching hospital in Western Tamil Nadu. Prior approval was obtained from the Institutional Human Ethics Committee (IHEC). The study involved only retrospective analysis of archived computed tomography (CT) images with no direct patient contact or intervention hence no informed consent was required. Confidentiality of patient data was strictly maintained throughout the study and all images were anonymized prior to analysis in accordance with ethical guidelines.

CT images acquired during routine clinical evaluation were retrospectively reviewed over the study period (June 2023 to May 2025). All CT scans that included the mandible with facial bones were considered for inclusion. Scans showing mandibular fractures, cysts, tumors, congenital or developmental anomalies of the mandible, or poor image quality obscuring visualization of the mental foramen were excluded from the study. Both right and left sides of the mandible were evaluated independently in all included scans.

The CT images were assessed to determine the horizontal and vertical positions of the mental foramen. The horizontal position was classified according to the system described by Jasser and Nwoku [2] based on the relationship of the mental foramen to adjacent teeth, while the vertical position was classified based on the criteria proposed by Fishel et al. [3], using the relationship of the foramen to the apex of the premolar teeth. The presence or absence of accessory mental foramen was also evaluated on both sides of the mandible. All observations were recorded systematically for further analysis.

Demographic details were collected from patient records. The findings related to the position of the mental foramen and the presence or absence of an accessory mental foramen was entered into a Microsoft Excel spreadsheet for data organization, verification and coding.

A minimum required sample size of 380 scans was calculated based on previously published literature. Statistical analysis was done using SPSS 27. Categorical variables were expressed as frequencies and percentages. Continuous variables were summarized as mean and standard deviation. The chi-square test was used to find associations between categorical variables. P-values less than 0.05 were considered statistically significant.

Results

A total of 392 CT scans were included in the study. The study population mainly consisted of young adults, majorly, the 18–30 years age group (41.3%), followed by patients aged more than 50 years (19.6%). Patients aged 31–40 years and 41–50 years constituted 18.1% and 17.6% of the study population respectively. The group with the lowest number of participants was 10–17 years (3.3%). A clear cut male predominance was noted among the study population (70.7%) (Table 1).

Evaluation of the horizontal position of the mental foramen showed a consistent distribution pattern bilaterally. On the right side, the mental foramen was most commonly located at position 4 (56.6%), followed by position 3 (24.2%). Other locations were less common (position 5 (15.8%), position 6 (2.8%), positions 1 and 2 (0.3% each)). Similarly, on the left side, position 4 was the most prevalent location (53.1%), followed by position 3 (28.3%). While position 2 was found in just 1% of cases, positions 5 and 6 were noted in 15.3% and 2.3% of cases, respectively. On the left side, Position 1 was not seen. Positions 3 and 4 accounted for more than 80% of horizontal locations bilaterally.

On analysis of the vertical position of the mental foramen it was observed that second position was the most common location on either sides of the mandible. On the right side, second position was observed in nearly half (50.8%) of the study participants, followed by position 3 among 44.1% and position 1 in 5.1% of the study participants. A more or less similar pattern was noted on the left side, where position 2 was noted in 52.3% of cases, position 3 among 42.3%, and position 1 in 5.4%.

Assessment of the accessory mental foramen revealed that majority of the study participants did not exhibit this anatomical variation. Accessory mental foramen was absent in 93.1% of scans on the right side and 93.6% on the left side. The presence of accessory mental foramen was noted in 6.9% on right-side and in 6.4% on left-side of mandible, thereby indicating a relatively low but clinically relevant prevalence, with no marked lateral predominance (Table 2).

Statistical analysis using chi-square test was performed to assess the association between the position of the mental foramen on the right and left sides. However, no statistically significant difference was observed ($p > 0.05$), indicating a symmetrical distribution of the mental foramen bilaterally.

Table 1. Age and Gender Distribution

PARAMETERS	SUB	FREQUENCY	PERCENTAGE
AGE	1 (18-30 Years)	162	41.3
	2 (31-40 Years)	71	18.1
	3 (41-50 Years)	69	17.6
	4 (> 50 Years)	77	19.6
	5 (10-17 Years)	13	3.3
SEX	Male	277	70.7
	Female	115	29.3

Table 2. Anatomical distribution of mental foramen

PARAMETERS	SUB	FREQUENCY	PERCENTAGE
POSITION OF MENTAL FORAMEN IN HORIZONTAL PLANE (RIGHT)	1	1	0.3
	2	1	0.3
	3	95	24.2
	4	222	56.6
	5	62	15.8
	6	11	2.8
POSITION OF MENTAL FORAMEN IN HORIZONTAL PLANE (LEFT)	2	4	1.0
	3	111	28.3
	4	208	53.1
	5	60	15.3
	6	9	2.3
POSITION OF	1	20	5.1

MENTAL FORAMEN IN VERTICAL PLANE (RIGHT)	2	199	50.8
	3	173	44.1
POSITION OF MENTAL FORAMEN IN VERTICAL PLANE (LEFT)	1	21	5.4
	2	205	52.3
	3	166	42.3
ACCESSORY MENTAL FORAMEN (RIGHT)	Absent	365	93.1
	Present	27	6.9
ACCESSORY MENTAL FORAMEN (LEFT)	Absent	367	93.6
	Present	25	6.4

Discussion

Understanding the position of mental foramen is essential as sensitive nerves pass through it and it is of great importance in shaping the neurovascular pattern. Adequate knowledge about its precise location helps us in avoiding mistakes during nerve repair surgeries and anesthetic procedures. Since there are many variations, it is essential to take radiographs before resorting to tunneling procedures to avoid complications and improve clinical outcomes.

In horizontal plane position 4 (In line with second premolar) was observed in more than half of the study participants bilaterally. Similar report was observed in a study done by Al Jaser et al. and this destination at the second premolar site seems to be reported as a common infallible fixed point during practice [2]. Similar results were observed in other studies too.[16-18,20] The next most frequent position was at 3 (between the first and second premolars). It is found approximatively among 25% of all cases bilaterally. Overall positions 3 and 4 comprised one fourth of the sites observed thereby indicating a strong bilateral symmetry. Similar reports were observed in other studies too [10-12,16–18,20].

Position 5 in horizontal plane was observed less frequently, which was close to the second premolar/first molar area and it accounted for about 15% of cases bilaterally. Similar result was observed by a study done by Philips et al. [17] and Neiva et al. [18]. Anterior positions 1, 2 and posterior position 6 were rarely observed. Although the observations are less frequent, they can't be neglected and are important from the clinical perspective, since the anterior position may predispose to nerve injury during procedures involving canine or premolar region, while the posterior position may pose difficulties in surgeries involving molar area. These data clearly highlights the need for individual imaging assessment before any surgical procedure.

Position 2 on vertical plane, which aligns with the premolar apex was

observed as the most common position bilaterally (more than 50%). This adds evidence to the use of the premolar apex as a reliable landmark for mental nerve block procedures and implant placement (3). The Position 3, at which the foramen is below the apex, was observed as the second most frequent position. This downward position relates to many factors like age-related alveolar bone loss and reduced bone height, especially in participants who are partially edentulous [10–12,14,16-18,20].

Position 1, which indicates a higher position when compared to the premolar apex, was rarely seen. Although this is uncommon, it may increase the risk of accidental exposure of nerves during dental procedures like extractions or surgeries in the front of the mandible. It is essential to understand and recognize this variation so as to avoid unintended complications, particularly in those with altered mandibular anatomy [10,11,16-18,20].

This current study noticed a low incidence of accessory mental foramen (AMF), seen among 6.9% on right-side and among 6.4% on left side. This aligns with the reported rates of 1.4% to 10% in various studies (15). In a study done by Naitoh et al. [19] accessory mental foramen was reported in 7% of the study population. The absence of a significant lateral preference shows that these variations are evenly distributed. Although it is observed rare, the incidence of AMF is clinically important. If accessory nerve branches are not recognized, it can lead to incomplete anaesthesia or sensory issues after surgery [6–9].

Conclusion

The findings of our study shows that while the mental foramen has a clear anatomical pattern among most people, significant variations do also occur. Advanced imaging techniques like computed tomography help us in identifying these variations, which helps us in improving our surgical precision and also lowers the risk of nerve injury. Anatomical Position data specific to certain populations, like what this study provides, are highly useful for increasing the safety during dental procedures thereby improving the patient outcomes in local clinical settings.

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.

References

1. Muinelo-Lorenzo J, Suárez-Quintanilla JA, Fernández-Alonso A, Varela-Mallou J, Suárez-Cunqueiro MM. Anatomical characteristics and visibility of mental foramen and accessory mental foramen: Panoramic radiography vs. cone beam CT. Med Oral Patol Oral Cir Bucal. 2015 Nov 1;20(6):e707-14.
2. al Jasser NM, Nwoku AL. Radiographic study of the mental foramen in a selected Saudi population. Dentomaxillofac Radiol. 1998 Nov;27(6):341-3.
3. Fishel D, Buchner A, Hershkowith A, Kaffe I. Roentgenologic study of the mental foramen. Oral Surg Oral Med Oral Pathol. 1976 May;41(5):682-6.

4. Bello SA, Adeoye JA, Ighile N, Ikimi NU. Mental Foramen Size, Position and Symmetry in a Multi-Ethnic, Urban Black Population: Radiographic Evidence. J Oral Maxillofac Res. 2018 Dec 30;9(4):e2.
5. Green RM. The position of the mental foramen: a comparison between the southern (Hong Kong) Chinese and other ethnic and racial groups. Oral Surg Oral Med Oral Pathol. 1987 Mar;63(3):287-90.
6. Balcioglu HA, Kocaelli H. Accessory mental foramen. N Am J Med Sci. 2009 Nov;1(6):314-5.
7. Torres MG, Valverde Lde F, Vidal MT, Crusoé-Rebello IM. Accessory mental foramen: A rare anatomical variation detected by cone-beam computed tomography. Imaging Sci Dent. 2015 Mar;45(1):61-5.
8. Zmysłowska-Polakowska E, Radwański M, Łęski M, Ledzion S, Łukomska-Szymańska M, Polguj M. The assessment of accessory mental foramen in a selected polish population: a CBCT study. BMC Med Imaging. 2017 Feb 20;17(1):17.
9. Thomaidi ZM, Tsatsarelis C, Papadopoulos V. Accessory Mental Foramina in Dry Mandibles: An Observational Study Along with Systematic Review and Meta-Analysis. Dent J (Basel). 2025 Feb 22;13(3):94.
10. Charalampakis A, Kourkoumelis G, Psari C, Antoniou V, Piagkou M, Demesticha T, Kotsiomitis E, Troupis T. The position of the mental foramen in dentate and edentulous mandibles: clinical and surgical relevance. Folia Morphol (Warsz). 2017;76(4):709-714.
11. Gershenson A, Nathan H, Luchansky E. Mental foramen and mental nerve: changes with age. Acta Anat (Basel). 1986;126(1):21-8
12. Le LN, Do TT, Truong LT, Dang The AT, Truong MH, Huynh Ngoc DK, Nguyen LM. Cone Beam CT Assessment of Mandibular Foramen and Mental Foramen Positions as Essential Anatomical Landmarks: A Retrospective Study in Vietnam. Cureus. 2024 Apr 30;16(4):e59337.
13. Asaumi R, Kawai T, Ogura S. Analysis of the structure of the mandibular bone around mental foramen using MDCT images. Clin Oral Impl Res. 2018: 29; 248-248.
14. Kawamoto M, Kondou H, Ichioka H, Kimura S, Bandou R, Matsunari R, Deng T, Ikegaya H. Age- and sex-related changes in the position of the mental foramina and age estimation methods that use these changes. Sci Rep. 2024 Dec 30;14(1):31560.
15. Kalender A, Orhan K, Aksoy U. Evaluation of the mental foramen and accessory mental foramen in Turkish patients using cone-beam computed tomography images reconstructed from a volumetric rendering program. Clin Anat. 2012 Jul;25(5):584-92.
16. Phillips JL, Weller RN, Kulild JC. The mental foramen: 1. Size, orientation, and positional relationship to the mandibular second premolar. J Endod. 1990 May;16(5):221-3. doi: 10.1016/s0099-2399(06)81674-2.
17. Neiva RF, Gapski R, Wang HL. Morphometric analysis of implant-related anatomy in Caucasian skulls. J Periodontol. 2004 Aug;75(8):1061-7. doi: 10.1902/jop.2004.75.8.1061.

18. von Arx T, Friedli M, Sendi P, Lozanoff S, Bornstein MM. Location and dimensions of the mental foramen: a radiographic analysis by using cone-beam computed tomography. J Endod. 2013 Dec;39(12):1522-8. doi: 10.1016/j.joen.2013.07.033.
19. Naitoh M, Hiraiwa Y, Aimiya H, Gotoh K, Ariji E. Accessory mental foramen assessment using cone-beam computed tomography. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2009 Feb;107(2):289-94. doi: 10.1016/j.tripleo. 2008.09.010.
20. Apinhasmit W, Methathrathip D, Chompoopong S, Sangvichien S. Mental foramen in Thais: an anatomical variation related to gender and side. Surg Radiol Anat. 2006 Oct;28(5):529-33. doi: 10.1007/s00276-006-0119-7.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 702–714, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.007

ORIGINAL ARTICLE

Effectiveness of Silodosin versus Tadalafil as Medical Expulsive Therapy for Lower Ureteric Calculi: A Randomized Controlled Trial

Aquinas Benedict,[1,*] R Vinoth Kumar[2] and Jeyapal Parthiban[3]
[1]*Department of Urology, ACS Medical College and Hospital, Chennai, Tamil Nadu, India*
[2]*Department of Urology, Aarupadai Veedu Medical College and Hospital, Vinayaka Mission's Research Foundation (Deemed to be University), Puducherry, India*
[3]*Department of General Surgery, Aarupadai Veedu Medical College and Hospital, Vinayaka Mission's Research Foundation (Deemed to be University), Puducherry, India*

Accepted: 16-March-2026 / Published Online: 6-May-2026

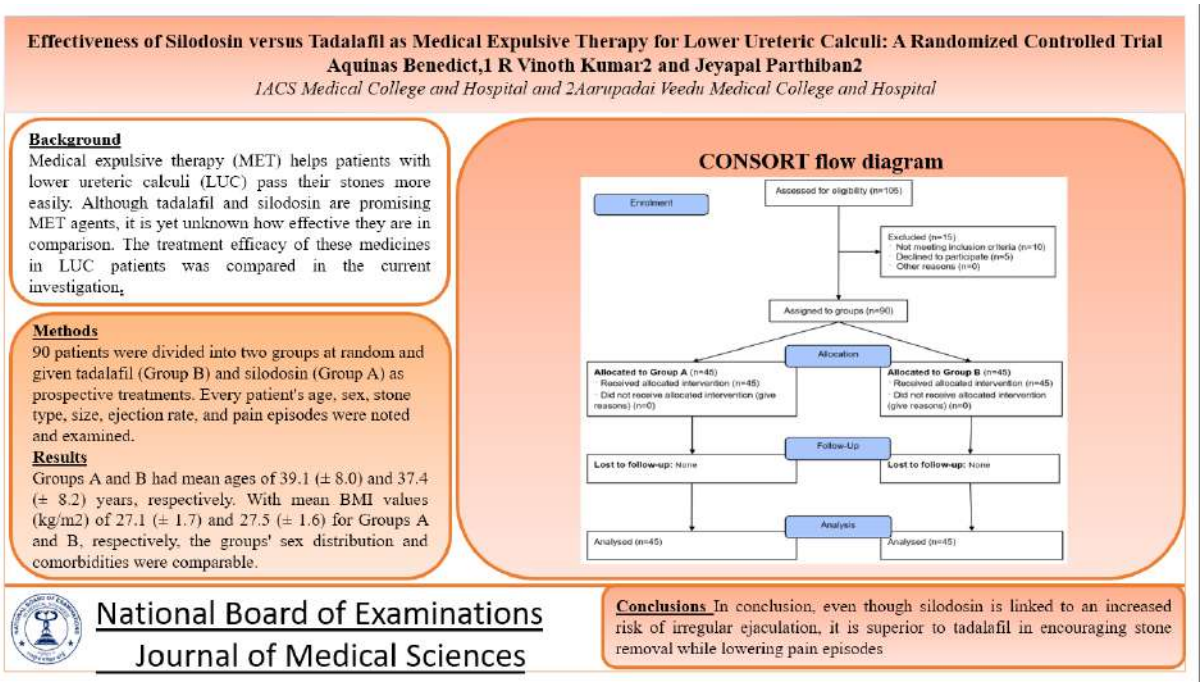
Abstract

Background: Medical expulsive therapy (MET) helps patients with lower ureteric calculi (LUC) pass their stones more easily. Although tadalafil and silodosin are promising MET agents, it is yet unknown how effective they are in comparison. The treatment efficacy of these medicines in LUC patients was compared in the current investigation. **Methods:** 90 patients were divided into two groups at random and given tadalafil (Group B) and silodosin (Group A) as prospective treatments. Every patient's age, sex, stone type, size, ejection rate, and pain episodes were noted and examined. **Results:** Groups A and B had mean ages of 39.1 (± 8.0) and 37.4 (± 8.2) years, respectively. With mean BMI values (kg/m2) of 27.1 (± 1.7) and 27.5 (± 1.6) for Groups A and B, respectively, the groups' sex distribution and comorbidities were comparable. Additionally, the mean stone type (radiopaque: 75.6% vs. 80.0%) and size (7.6 mm vs. 7.8 mm) were comparable. Silodosin treatment, however, resulted in a lower use of analgesics (198.8 mg vs. 247.8 mg, $p < 0.001$), fewer pain episodes (1.1 vs. 2.5, $p < 0.001$), and a greater expulsion rate (80.0% vs. 60.0%) and shorter expulsion duration (14.4 vs. 17.7 days, $p < 0.001$). With the exception of frequent irregular ejaculation with silodosin (17.8% vs. 4.4%), the side effects were comparable. **Conclusion:** In conclusion, even though silodosin is linked to an increased risk of irregular ejaculation, it is superior to tadalafil in encouraging stone removal while lowering pain episodes. Clinical Trial Registration: CTRI/2025/03/082491

Keywords: Ureteric calculi, Medical expulsive therapy, Silodosin, Tadalafil, Stone expulsion rate, Pain management

*Corresponding Author: Aquinas Benedict
Email: aquin87@gmail.com

Graphical Abstract



Introduction

One major source of morbidity is ureteric calculi, also called ureteral stones [1]. Over time, medical expulsive therapy (MET) has become a commonly recognized non-invasive therapeutic option for distal ureteric calculi [2]. MET seeks to enhance patient outcomes, lessen the need for surgical intervention, and promote spontaneous stone passage [3]. Several pharmacological types have been investigated for their potential to improve stone removal, including corticosteroids, nonsteroidal anti-inflammatory medicines (NSAIDs), calcium channel blockers, and adrenergic blockers [2]. The importance of adrenergic blockers, especially alpha-blockers, has grown. Both calcium channel blockers and adrenergic blockers dramatically boosted stone passing rates, according to a research by Hollingsworth et al. [4]. Meta-analyses by the American Urological Association (AUA) and the European Association of Urology (EAU) [2,5,6] later supported this conclusion, showing that adrenergic blockers were better than calcium channel blockers such nifedipine. Alpha-blockers are therefore frequently advised for MET in ureteral stone patients.

Silodosin, a selective alpha-1A adrenergic receptor antagonist, has been extensively studied and found to be one of the most effective alpha-blockers for facilitating ureteral stone passage. Several randomized controlled trials and meta-analyses have supported its use for lower ureteric calculi (LUC) less than 10 mm in size, leading to its endorsement by the EAU and AUA guidelines [7-11]. Tadalafil and other phosphodiesterase type-5 (PDE5) inhibitors may have a role in MET, however this is still unknown. Sildenafil, Vardenafil, and Tadalafil are examples of PDE5 inhibitors that have been demonstrated to have relaxing effects on isolated human ureteral smooth muscle in vitro [2]. Tadalafil has been studied for the treatment of benign prostatic hyperplasia (BPH) and has shown effectiveness in

reducing lower urinary tract symptoms. [12,14] This begs the question of whether tadalafil would be a useful substitute for alpha-blockers, like silodosin, for MET in LUC patients.

PDE5 inhibitors' function in MET is yet unknown, despite alpha-blockers like silodosin having a well-established effect. The current study specifically assessed the efficacy of silodosin versus tadalafil as MET for LUC because prior research has mostly compared the two medications in relation to BPH.

Methodology

Study design

After receiving the required consent from the Institutional Human Ethics Committee, this prospective, randomized controlled experiment was carried out at the tertiary medical center Aarupadai Veedu Medical College and Hospital between July 2023 and December 2024. Patients between the ages of 18 and 60 who had ureteric calculi with a maximum diameter of 5 to 10 mm, as determined by CT-KUB and X-ray KUB, were enrolled in the study after providing informed written consent.

Patients with functional and/or anatomical ureteric abnormalities, multiple and bilateral ureteric stones, pregnant and lactating mothers, history of hypotension, vertigo, dizziness, headache, and cardiac abnormalities were excluded. Patients who were not willing to provide informed written consent were also excluded from the study. Based on the predetermined inclusion and exclusion criteria, 90 patients were included in the study and divided into two groups of 45 patients each. A non-probability sampling technique, purposive sampling/consecutive enumeration, was used to enrol patients in accordance with the specified inclusion and exclusion criteria.

Randomization and Blinding

A computer-generated random number sequence was used to assign participants at random to either the tadalafil (Group B) or silodosin (Group A) groups. To ensure impartial participant distribution, randomization was carried out utilizing the SNOOZE (Sealed Envelope Online Open-Label Enrollment) approach. By distributing individuals equally across the two treatment arms, this technique reduced selection bias. The investigation was carried out as an open-label trial because blinding was not practical due to the nature of the pharmaceutical interventions. For a maximum of four weeks, Group A LUC patients were treated with silodosin 8 mg once daily until the stone was expelled. Tadalafil 5 mg was given once daily to Group B LUC patients until the stones were expelled, or for a maximum of 4 weeks.

Method of data collection

Detailed baseline data were collected for each patient after obtaining their consent, including medical history, vital signs such as Non-Invasive Blood Pressure (NIBP), Heart Rate (HR), and Oxygen Saturation (SpO_2), along with laboratory investigations including Complete Blood Count, Blood Sugar, Blood Urea, and Serum Creatinine. Radiological assessments were conducted using CT-KUB and X-ray KUB, with follow-up imaging performed using ultrasonography KUB as needed. Throughout the study, all patients underwent regular assessments, including physical examinations, blood urea and serum creatinine levels, urine cultures, and repeated radiological investigations as

needed. In addition to the allocated treatment, patients were advised to increase their fluid intake and were prescribed diclofenac 50 mg orally during pain episodes. Patients were followed up for four weeks, during which the primary and secondary endpoints were assessed. The primary endpoint was the stone expulsion rate, while secondary endpoints included stone expulsion time, defined as the number of days from randomization to the confirmed expulsion of the stone, intervention rates, such as the need for ureteroscopy in cases where spontaneous expulsion did not occur, the number of pain episodes experienced by the patient, and adverse effects associated with MET use. Stone expulsion was confirmed using CT-KUB and X-ray KUB imaging. Patients who did not pass the stone spontaneously within the four-week period underwent ureteroscopic lithotripsy for definitive stone removal. Age, gender, body mass index (BMI; kg/m2), silodosin (8 mg once daily), and tadalafil (5 mg once daily) were the independent factors of interest. Stone ejection rate, time to stone expulsion, need for extra intervention, number of pain episodes, and side effects were the dependent variables of interest.

Statistical analysis

The Statistical Package for Social Sciences (SPSS) v23 was used to analyze the collected data. Frequency and percentage were used to describe categorical variables. The Kolmogorov-Smirnov and Shapiro-Wilk tests were used to determine the normality of the data before calculating the mean and standard deviation for continuous variables. The independent t-test for continuous variables and the chi-square test or Fisher's exact test for categorical variables were used to assess statistical significance. The threshold for statistical significance was fixed at $p < 0.05$.

The enrolment of study participants and group allocation is given as a CONSORT flow diagram in Figure 1, and the overall workflow of the study is shown in Figure 2. A total of 105 participants were assessed for eligibility, and 90 were included in the study based on the inclusion and exclusion criteria. The participants were randomly assigned to two groups: Group A (n=45; received silodosin tablets 8 mg once daily) and Group B (n = 45; received tadalafil tablets 5 mg once daily). Table 1 displays the study population's demographic characteristics. Participants in Group B (tadalafil) were 37.4 years old (± 8.2) on average, while those in Group A (silodosin) were 39.1 years old (± 8.0). There was no statistically significant difference in the two groups' mean ages ($p = 0.325$). Compared to 62.2% (n = 28) of the participants in Group B, 46.7% (n = 21) of the participants in Group A were under 40 years old. In contrast, 37.8% (n = 17) of participants in Group B were over 40, but 53.3% (n = 24) of individuals in Group A were. The age distribution between the two groups did not, however, differ statistically significantly ($p = 0.138$). Gender distribution analysis revealed that Group A comprised 68.9% (n = 31) male and 31.1% (n = 14) female participants. Group B comprised 77.8% (n=35) men and 22.2% (n=10) women. The sex distribution difference was not statistically significant, according to statistical analysis ($p = 0.340$). Comorbidities were present in 13.3% (n=6) and 17.8% (n=8) of the patients in Groups A and B, respectively. There was no statistically significant difference in the presence of comorbidities between the two groups ($p = 0.561$). Participants in Group A

(silodosin) had a mean BMI of 27.1 kg/m² (± 1.7), whereas those in Group B (tadalafil) had a mean BMI of 27.5 kg/m² (± 1.6). There was no statistically significant difference in BMI between the two groups (p = 0.254).

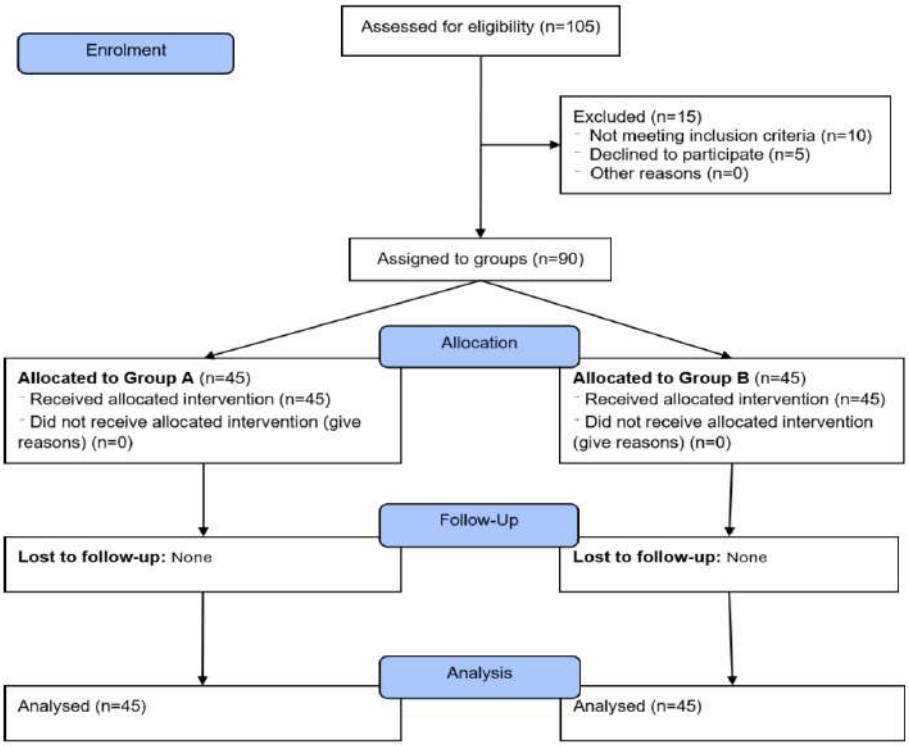


Figure 11. CONSORT flow diagram.

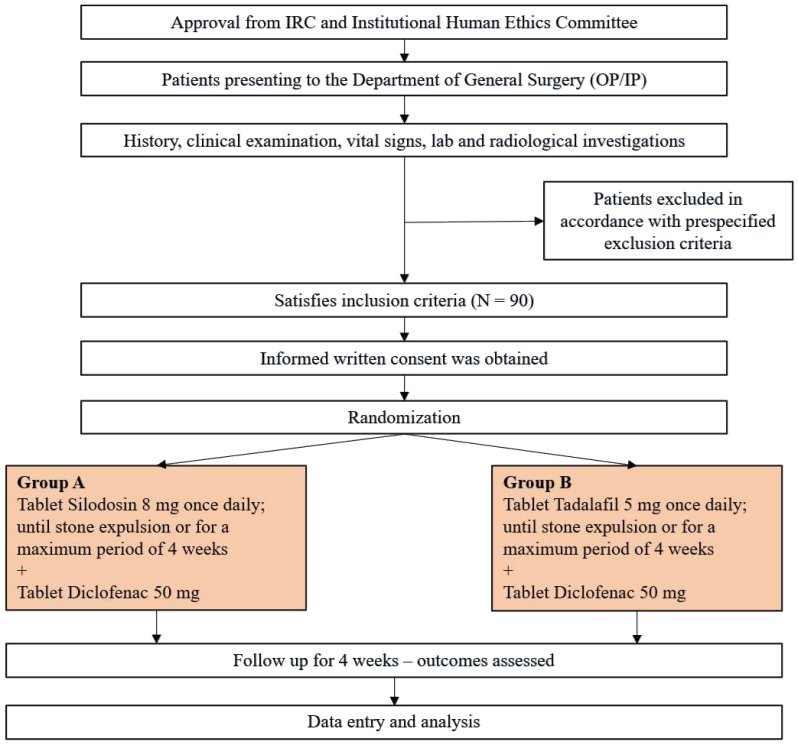


Figure 2. Schematic representation of the workflow.

Results

Table 1. Demographic characteristics of the study population.

Criteria		**Group A (n = 45)**	**Group B (n = 45)**	**P value**
Age (in years), mean ± SD		39.1 ± 8.0	37.4 ± 8.2	0.325
Age (in years), n (%)	≤40	21 (46.7)	28 (62.2)	0.138
	>40	24 (53.3)	17 (37.8)	
Gender, n (%)	Male	31 (68.9)	35 (77.8)	0.340
	Female	14 (31.1)	10 (22.2)	
Comorbidity, n (%)	Present	6 (13.3)	8 (17.8)	0.561
	Absent	39 (86.7)	37 (82.2)	
Body mass index (in kg/m2), mean ± SD		27.1 ± 1.7	27.5 ± 1.6	0.254

Table 2. Comparison of study population by the nature of stone, expulsion, pain episodes and analgesic usage

Criteria		**Group A (n = 45)**	**Group B (n = 45)**	**P value**
Stone size (in mm), mean ± SD		7.6 ± 1.0	7.8 ± 1.0	0.196
Type of stone, n (%)	Radiopaque	34 (75.6)	36 (80.0)	0.612
	Radiolucent	11 (24.4)	9 (20.0)	
Expulsion, n (%)	Yes	36 (80.0)	27 (60.0)	0.038*
	No	9 (20.0)	18 (40.0)	
Expulsion time (in days), mean ± SD		14.4 ± 2.2	17.7 ± 3.4	<0.001*
Number of pain episodes, mean ± SD		1.1 ± 0.9	2.5 ± 1.1	<0.001*
Total analgesic use (in mg), mean ± SD		198.8 ± 42.0	247.8 ± 71.5	<0.001*
*Statistically significant data, $p < 0.001$				

The study population's statistics regarding stone features, ejection, pain episodes, and painkiller use are displayed in Table 2. Group A (silodosin) and Group B (tadalafil) had mean stone sizes of 7.6 mm (± 1.0) and 7.8 mm (± 1.0), respectively, which were not statistically significant (p = 0.196). In terms of stone type, radiopaque stones were found in 75.6% (n = 34) of Group A individuals and radiolucent stones in 24.4% (n = 11) of Group A participants and 20.0% (n = 9) of Group B participants.

The distribution of stone types in the two groups did not differ statistically significantly (p = 0.612). Compared to 60.0% (n = 27) in Group B (tadalafil), 80.0% (n = 36) of participants in Group A (silodosin) were able to successfully evacuate their stones. In contrast, 20.0% (n = 9) of Group A individuals and 40.0% (n = 18) of Group B participants did not have stone-expulsion. There was a statistically significant difference between the two groups' expulsion rates (p = 0.038). Group A's mean expulsion time was 14.4 days ± 2.2, whereas Group B's was 17.7 days ± 3.4. Additionally, the difference in expulsion time was statistically significant (p < 0.001), meaning that silodosin caused a quicker expulsion time than tadalafil. Participants in Group A (silodosin) suffered an average of 1.1 (± 0.9) pain episodes, while those in Group B (tadalafil) experienced an average of 2.5 (± 1.1). The silodosin group experienced fewer pain episodes, as indicated by this statistically significant difference (p < 0.001). In a similar vein, Group A's mean total analgesic consumption (198.8 mg (± 42.0)) was considerably lower than Group B's (247.8 mg (± 71.5)) (p < 0.001). These results imply that compared to individuals receiving tadalafil, those getting silodosin had less pain and needed fewer analgesic dosages.

Table 3: Adverse effect of drug across study population.

Adverse effects, n (%) (numbers not mutually exclusive)	**Group A** **(n = 45)**	**Group B** **(n = 45)**	**P value**
Headache	5 (11.1)	8 (17.8)	0.368
Dizziness	4 (8.9)	10 (22.2)	0.081
Backache	4 (8.9)	9 (20.0)	0.134
Orthostatic hypotension	2 (4.4)	5 (11.1)	0.238
Abnormal ejaculation	8 (17.8)	2 (4.4)	0.044*
*Statistically significant data, p < 0.05			

Both groups experienced adverse pharmacological treatment effects, as seen in Table 3. 11.1% (n = 5) of individuals in Group A (silodosin) and 17.8% (n = 8) in Group B (tadalafil) reported having headaches (p = 0.368). 8.9% (n = 4) of participants in Group A experienced dizziness, compared to 22.2% (n = 10) in Group B (p = 0.081). Backache was reported by 20.0% (n = 9) in Group B and 8.9% (n = 4) in Group A (p = 0.134). 4.4% (n = 2) of patients in Group A and 11.1% (n = 5) in Group B (p = 0.238) had orthostatic hypotension. However, there was a statistically significant difference in the prevalence of aberrant ejaculation, with 17.8% (n = 8) of participants in Group A and only 4.4% (n = 2) in Group B (p = 0.044).

Discussion

The purpose of this study was to evaluate the efficacy of tadalafil and silodosin as medical expulsive therapy for lower ureteric calculi. The baseline characteristics of the study participants were comparable between the two groups, ensuring that any differences in outcomes could be attributed to the medical expulsive therapy rather than confounding factors. There was no discernible difference in the age distribution between the study groups (p = 0.138). According to earlier research, younger individuals typically had higher ureteric stone passing rates because of increased ureteric peristalsis and reduced ureteric wall calcification [15]. However, the current study's lack of substantial age differences guaranteed that age-related factors had no bearing on the two treatments' relative efficacy.

The study groups' male predominance was in line with worldwide epidemiological patterns, and the sex and comorbidity distributions among the groups were likewise not statistically significant. According to studies, urolithiasis is more common in men [16], presumably as a result of hormonal variations, dietary patterns, and metabolic variables that make them more susceptible to the development of stones [17,18]. The male-to-female ratio found in this study shows that urolithiasis is roughly two to three times more common in males than in women, which is consistent with findings from previous studies [19].

There was no discernible difference in the two groups' comorbidity prevalence. Due to changes in urine pH, increased calcium excretion, and decreased citrate levels, comorbid diseases like obesity, diabetes, and metabolic syndrome have been associated with an increased risk of stone development [20]. Comorbidities probably had little effect on stone expulsion since they were equally distributed throughout the groups. Participants in the tadalafil group had a mean BMI of 27.5 kg/m², whereas those in the silodosin group had a mean BMI of 27.1 kg/m². There was no statistically significant difference (p = 0.254). According to earlier studies, metabolic problems including insulin resistance and hypercalciuria are linked to a greater BMI and a higher risk of developing stones [21]. Nevertheless, there is no clear association between BMI and the probability of stone passage, and it does not seem to have a substantial impact on spontaneous stone passage [22].

The two groups' mean stone sizes were similar (p = 0.196). Larger stones (≥10 mm) frequently require surgical care, while smaller stones (<5 mm) are more likely to pass without assistance. Stone size is a crucial factor in determining spontaneous passing [23]. The study's mean

stone size (7.6 mm in Group A and 7.8 mm in Group B) is within the range where MET is often advised, which supports the justification for assessing tadalafil and silodosin in this situation. The distribution of radiopaque and radiolucent stone types was likewise comparable among the groups ($p = 0.612$). While radiolucent stones (24.4% in Group A and 20.0% in Group B) were frequently made of uric acid or cystine, radiopaque stones (about 75.6% of cases in Group A and 80.0% in Group B) were more frequently made of calcium oxalate or phosphate [24]. The same distribution of stone types among the groups guaranteed that the study's confounding factor was not the effect of stone composition on expulsion rates.

The current study's findings show that silodosin is a much better MET for lower ureteric calculi than tadalafil. The silodosin group's expulsion rate (80.0%) was considerably greater than the tadalafil group's (60.0%), indicating that silodosin is more effective at promoting stone passage. This is consistent with previous research demonstrating that silodosin, a highly selective α1A-adrenoceptor antagonist, is superior to non-selective α-blockers or phosphodiesterase inhibitors like tadalafil in terms of relaxing the distal ureter and improving stone ejection. (10–12). Additionally, the silodosin group's stone expulsion time was significantly shorter (14.4 days) than the tadalafil group's (17.7 days). This is clinically significant because prolonged stone retention raises the risk of complications like UTIs, hydronephrosis, and the need for surgery [12]. Silodosin's high selectivity for α1A-adrenergic receptors, which are mostly found in the lower ureter, is responsible for its higher efficacy. This results in maximal ureteric relaxation and reduced resistance to stone passage [25].

One of the most upsetting signs of ureteral calculi is pain. Compared to the tadalafil group (2.5 episodes), the silodosin group had considerably fewer pain episodes (1.1 episodes) ($p < 0.001$). Furthermore, compared to the tadalafil group (247.8 mg), the silodosin group's total analgesic intake was considerably lower (198.8 mg) ($p < 0.001$). This is consistent with earlier research showing that silodosin's strong inhibitory effects on ureteral contractions were linked to fewer bouts of renal colic [9]. The ability of silodosin to diminish intraureteral pressure, which lessens colicky discomfort brought on by sporadic ureteric contractions, is probably the reason for the decreased pain burden in the silodosin group [26]. The main way that the phosphodiesterase-5 inhibitor tadalafil works is by raising the amounts of cyclic guanosine monophosphate (cGMP), which causes smooth muscle relaxation. However, its effects on the ureter are not as strong as those of α1A-selective blockers, which could account for the tadalafil group's higher analgesic needs and more pain episodes [27].

With the exception of aberrant ejaculation, which was considerably more frequent in the silodosin group (17.8% vs. 4.4%, $p = 0.044$), the prevalence of side effects was similar in both groups. Because silodosin has a large affinity for α1A-receptors in the bladder neck and prostate, it has been shown in previous investigations to increase the occurrence of retrograde ejaculation. [7] One well-known adverse effect of selective α1A-adrenoceptor antagonists is retrograde ejaculation, which is usually reversible after stopping the medication. The tadalafil group experienced more adverse effects, such as

headache (11.1% vs. 17.8%, p = 0.368), dizziness (8.9% vs. 22.2%, p = 0.081), backache (8.9% vs. 20.0%, p = 0.134), and orthostatic hypotension (4.4% vs. 11.1%, p = 0.238). However, these differences were not statistically significant. Because tadalafil inhibits phosphodiesterase-5, which causes systemic vascular relaxation, it is known to have negative effects associated to vasodilation. [9,28]. Tadalafil may have a part in ureteral smooth muscle relaxation, but its systemic vasodilatory effects may limit its practical usage as a MET, according to the trend of increased dizziness and hypotension in the tadalafil group.

The current study had a number of shortcomings. First, the results may not be as applicable to other healthcare facilities because the study was limited to a single tertiary healthcare facility. Second, the study was carried out as an open-label experiment, which raises the risk of observer bias when evaluating results like discomfort and side effects. Furthermore, the study did not assess long-term impacts including recurrence rates, quality of life, or the effects of continuous pharmaceutical use; instead, it concentrated exclusively on short-term outcomes like stone ejection rate and time. The subjective evaluation of pain and analgesic use, which may have been impacted by reporting biases and individual pain tolerance, is another drawback. Furthermore, there was no control or standardization of variables that could affect stone ejection, such as food habits, hydration levels, and physical activity. Lastly, the lack of a placebo control group in the trial made it challenging to assess the absolute efficacy of Tadalafil and Silodosin in comparison to no medical expulsive medication. Despite these drawbacks, the study's findings demonstrate that silodosin is more effective than tadalafil at promoting stone expulsion, decreasing pain episodes, and lowering the need for analgesics. Silodosin may be the best choice for MET in patients with lower ureteric calculi because of its quicker expulsion time and greater success rate. Clinicians should be aware of the possibility of abnormal ejaculation, though, as this can be upsetting for certain patients, especially younger ones who are worried about their fertility.

Conclusion

The current study examined the safety and effectiveness of tadalafil and silodosin as medicinal expulsive treatments for lower ureteric calculi. The results show that silodosin is a more successful treatment choice than tadalafil, with a considerably greater stone expulsion rate (80.0% vs. 60.0%) and shorter expulsion duration (14.4 vs. 17.7 days). Furthermore, participants in the silodosin group needed fewer analgesic dosages and had fewer pain episodes, suggesting that it may be beneficial for enhancing patient comfort during the transit of stones. While abnormal ejaculation was far more common in the silodosin group, other side effects did not significantly differ across the groups, despite the fact that both drugs were generally well tolerated.

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.

Human and animal rights

This article does not contain any studies with human participants or animals performed by any of the authors.

References

1. Khan SR, Pearle MS, Robertson WG, Gambaro G, Canales BK, Doizi S, et al. Kidney stones. Nat Rev Dis Primers 2016;2:16008. https://doi.org/10.1038/nrdp.2016.8
2. Bos D, Kapoor A. Update on medical expulsive therapy for distal ureteral stones: Beyond alpha-blockers. Can Urol Assoc J 2014;8(11–12):442–445. https://doi.org/10.5489/cuaj.2472
3. Lim I, Sellers DJ, Chess-Williams R. Current and emerging pharmacological targets for medical expulsive therapy. Basic Clin Pharmacol Toxicol 2012;130(Suppl 1):16–22. https://doi.org/10.1111/bcpt.13613
4. Hollingsworth JM, Rogers MA, Kaufman SR, Bradford TJ, Saint S, Wei JT, et al. Medical therapy to facilitate urinary stone passage: a meta-analysis. Lancet 2006;368(9542):1171–1179. https://doi.org/10.1016/s0140-6736(06)69474-9
5. Campschroer T, Zhu X, Vernooij RW, Lock MT. Alpha-blockers as medical expulsive therapy for ureteral stones. Cochrane Database Syst Rev 2018;4(4):CD008509. https://doi.org/10.1002/14651858.cd008509.pub3
6. K S, L A, Sathish V, Achar MU, Raj KCB, Pai N. An update on efficacy and safety of alpha-blockers in the treatment of distal ureteric stones: narrative review. Afr J Urol 2022;28(1):43. https://doi.org/10.1186/s12301-022-00310-w
7. Sadasivam B, Chenchula S, Ray A. Systematic review of efficacy and safety of silodosin in medical expulsive therapy for the management of ureteral stones – based on Indian evidences. Biomed Pharmacol J 2021;14(2):733–738. https://doi.org/10.13005/bpj/2176
8. Yoshida M, Kudoh J, Homma Y, Kawabe K. New clinical evidence of silodosin, an α1A-selective adrenoceptor antagonist, in the treatment for lower urinary tract symptoms. Int J Urol 2012;19(4):306–316. https://doi.org/10.1111/j.1442-2042.2011.02957.x
9. Gur M, Ulu MB, Caliskan ST, Ozturk K, Akdeniz E. Dexketoprofen vs. tamsulosin vs. silodosin vs. tadalafil as medical expulsive therapy for distal ureteral stones in men. J Coll Physicians Surg Pak 2021;31(8):947–952. https://doi.org/10.29271/jcpsp.2021.08.947
10. Pal DK, Kumar A, Sarkar D. A comparative study of the efficacy of silodosin versus tamsulosin versus oral hydration therapy in medical expulsion therapy for ureteral calculi. Urol Sci 2022;33(1):1–5. https://doi.org/10.4103/uros.uros_16_21
11. Ahmed M, Saha PK, Ghosh KC, Islam SKA, Mondal N. Comparative study between silodosin alone and silodosin plus tadalafil for the medical management of lower ureteric stone in south-western part of Bangladesh. Bangladesh J Urol 2020;23(1):67–71.

https://doi.org/10.3329/bju.v23i1.50293

12. Kumar S, Jayant K, Agrawal MM, Singh SK, Agrawal S, Parmar KM. Role of tamsulosin, tadalafil, and silodosin as medical expulsive therapy in lower ureteric stone: a randomized trial (a pilot study). Urology 2015;85(1):59–63. https://doi.org/10.1016/j.urology.2014.09.022
13. Jaffal W. The role of tadalafil in lower ureteric stone expulsion. Iraqi Postgrad Med J 2011;10(1):1–4.
14. Falahatkar S, Akhavan A, Esmaeili S, Amin A, Kazemnezhad E, Jafari A. Efficacy of tamsulosin versus tadalafil as medical expulsive therapy on stone expulsion in patients with distal ureteral stones: a randomized double-blind clinical trial. Int Braz J Urol 2021;47(5):982–988. https://doi.org/10.1590/s1677-5538.ibju.2020.1007
15. Kalorin CM, Zabinski A, Okpareke I, White M, Kogan BA. Pediatric urinary stone disease—does age matter? J Urol 2009;181(5):2267–2271. https://doi.org/10.1016/j.juro.2009.01.050
16. Ferraro PM, Taylor EN, Curhan GC. Factors associated with sex differences in the risk of kidney stones. Nephrol Dial Transplant 2023;38(1):177–183. https://doi.org/10.1093/ndt/gfac037
17. Gillams K, Juliebø-Jones P, Juliebø S, Somani BK. Gender differences in kidney stone disease (KSD): findings from a systematic review. Curr Urol Rep 2021;22(10):50. https://doi.org/10.1007/s11934-021-01066-6
18. Xu JZ, Li C, Xia QD, Lu JL, Wan ZC, Hu L, et al. Sex disparities and the risk of urolithiasis: a large cross-sectional study. Ann Med 2022;54(1):1627–1635. https://doi.org/10.1080/07853890.2022.2085882
19. Sorokin I, Mamoulakis C, Miyazawa K, Rodgers A, Talati J, Lotan Y. Epidemiology of stone disease across the world. World J Urol 2017;35(9):1301–1320. https://doi.org/10.1007/s00345-017-2008-6
20. Curhan GC. Epidemiology of stone disease. Urol Clin North Am 2007;34(3):287–293. https://doi.org/10.1016/j.ucl.2007.04.003
21. Poore W, Boyd CJ, Singh NP, Wood K, Gower B, Assimos DG. Obesity and its impact on kidney stone formation. Rev Urol 2020;22(1):17–23.
22. DiBianco JM, Jarrett TW, Mufarrij P. Metabolic syndrome and nephrolithiasis risk: should the medical management of nephrolithiasis include the treatment of metabolic syndrome? Rev Urol 2015;17(3):117–128. https://doi.org/10.3909/riu0650
23. Türk C, Petřík A, Sarica K, Seitz C, Skolarikos A, Straub M, et al. EAU guidelines on diagnosis and conservative management of urolithiasis. Eur Urol 2016;69(3):468–474. https://doi.org/10.1016/j.eururo.2015.07.040
24. Thongprayoon C, Krambeck AE, Rule AD. Determining the true burden of kidney stone disease. Nat Rev Nephrol 2020;16(12):736–746.

https://doi.org/10.1038/s41581-020-0320-7

25. Hsu YP, Hsu CW, Bai CH, Cheng SW, Chen KC, Chen C. Silodosin versus tamsulosin for medical expulsive treatment of ureteral stones: a systematic review and meta-analysis. PLoS One 2018;13(8):e0203035. https://doi.org/10.1371/journal.pone.0203035
26. Jindan L, Xiao W, Liping X. Evolving role of silodosin for the treatment of urological disorders – a narrative review. Drug Des Devel Ther 2022;16:2861–2884. https://doi.org/10.2147/dddt.s373659
27. Bai Y, Yang Y, Wang X, Tang Y, Han P, Wang J. Tadalafil facilitates distal ureteral stone expulsion: a meta-analysis. J Endourol 2017;31(6):557–563. https://doi.org/10.1089/end.2016.0837
28. Forgue ST, Patterson BE, Bedding AW, Payne CD, Phillips DL, Wrishko RE, et al. Tadalafil pharmacokinetics in healthy subjects. Br J Clin Pharmacol 2006;61(3):280–288. https://doi.org/10.1111/j.1365-2125.2005.02553.x

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 715–728, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.008

ORIGINAL ARTICLE

Study of Factors Associated with Trends in Utilization of Childbirth Services in Tribal Visakhapatnam: A Mixed Method Approach

JK Burila,[1] Devi Madhavi Bhimarasetty,[2] JV Siva Priya[3,*] and Kiran Pamarthi[4]
[1]*Assistant Professor, Department of Community Medicine, Great Eastern Medical School & Hospital, Ragolu, Srikakulam, Andhra Pradesh, India*
[2]*ADME& Professor of Community Medicine, Government Medical College, Vizianagaram, Andhra Pradesh, India*
[3]*Assistant Professor, Department of Community Medicine, Panimalar Medical College Hospital & Research Institute, Chennai, Tamil Nadu, India*
[4]*Assistant Professor, Department of Community Medicine, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India*

Accepted: 29-March-2026 / Published Online: 6-May-2026

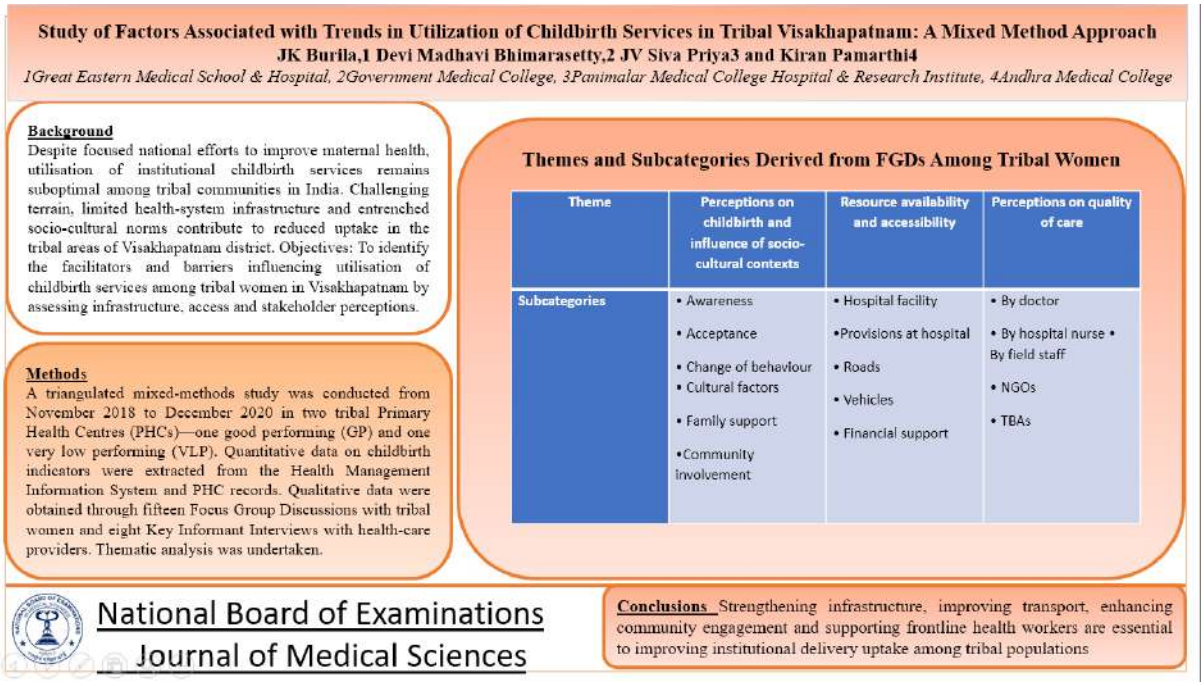
Abstract

Background: Despite focused national efforts to improve maternal health, utilisation of institutional childbirth services remains suboptimal among tribal communities in India. Challenging terrain, limited health-system infrastructure and entrenched socio-cultural norms contribute to reduced uptake in the tribal areas of Visakhapatnam district. Objectives: To identify the facilitators and barriers influencing utilisation of childbirth services among tribal women in Visakhapatnam by assessing infrastructure, access and stakeholder perceptions. **Methods:** A triangulated mixed-methods study was conducted from November 2018 to December 2020 in two tribal Primary Health Centres (PHCs)—one good performing (GP) and one very low performing (VLP). Quantitative data on childbirth indicators were extracted from the Health Management Information System and PHC records. Qualitative data were obtained through fifteen Focus Group Discussions with tribal women and eight Key Informant Interviews with health-care providers. Thematic analysis was undertaken. **Results:** In the GP PHC, skilled birth attendance increased from 94.6% to 97.7% between 2017 and 2020, and institutional deliveries rose from 72.1% to 82%. In contrast, the VLP PHC showed lower performance (skilled attendance: 68.4% to 75.1%; institutional deliveries: 69.3% to 68.1%). Caesarean section proportions were lower in GP (0.8–1.7%) than VLP (1.1–4.7%). Major barriers identified through FGDs included poor transport connectivity, fear of hospital procedures and household responsibilities. Facilitators included Accredited Social Health Activist support, incentive schemes and ambulance availability. **Conclusion:** Strengthening infrastructure, improving transport, enhancing community engagement and supporting frontline health workers are essential to improving institutional delivery uptake among tribal populations.

Keywords: Tribal health, Institutional delivery, Maternal services, Barriers, Mixed-methods

*Corresponding Author: JV Siva Priya
Email: drjvsivapriya@gmail.com

Graphical Abstract



Introduction

A nation is regarded as developed when it succeeds in safeguarding its most vulnerable populations, including pregnant women, new-borns, infants, the elderly and tribal communities [1]. The day of childbirth is the riskiest for both the mother and the new-born, with nearly 40% of new-born deaths and half of maternal deaths occurring on this single day [2]. Sustainable Development Goal (SDG) 3 emphasises the reduction of maternal, new-born and child mortality [1].

In India, the Reproductive, Maternal, New-born, Child and Adolescent Health (RMNCH+A) strategy was introduced to reduce maternal and child mortality by strengthening the health-care delivery system. As part of this initiative, the Ministry of Health and Family Welfare (MoHFW) developed a Score Card to assess and improve service delivery through routine monitoring and cross-comparison across sub-districts, districts and states [3]. Sixteen Key Performance Indicators (KPIs) are used to calculate the composite index for dashboard monitoring of Reproductive and Child Health services within the Health Management Information System (HMIS) [4]. These KPIs cover four life-cycle stages: (a) pregnancy care, (b) childbirth/delivery, (c) post-natal, maternal and new-born care and (d) pre-pregnancy/reproductive age.

Across India, a total of 1,593,534 deliveries were reported, of which 53,221 occurred in Visakhapatnam district. Among these, 6048 deliveries were reported from tribal Visakhapatnam. Of these tribal deliveries, 3901 were institutional and 2147 occurred at home. Tribal communities consistently lag behind national averages on several core public health indicators, with women and children being disproportionately affected [5,6].

The Visakhapatnam district of Andhra Pradesh has a substantial tribal

population of 6.8 lakh (14.25% of the district population) residing in 3636 habitats within agency areas. Approximately 3.75% of all deliveries in the district occur at home, and 88.9% of these are in tribal regions, with only 75% attended by skilled birth attendants [7]. Performance on key indicators is shaped by both the provision of services and the behaviours and preferences of beneficiaries [2]. Major factors limiting the utilisation of maternal health services include poverty, geographical distance, lack of information, inadequate or poor-quality services and cultural beliefs and practices [1,2]. Ensuring that every woman delivers in a health facility under the care of a skilled birth attendant is critical, particularly as nearly five million deliveries still take place at home in India annually [2].

Aim:

To identify the facilitators and barriers associated with the utilisation of childbirth services among the tribal population of Visakhapatnam and to generate insights that may strengthen programme implementation and improve service uptake.

Objectives

1. To describe the accessibility, infrastructure and manpower at the selected Primary Health Centres (PHCs).
2. To assess trends in key performance indicators of childbirth services in the selected PHCs.
3. To explore the perceptions of tribal women regarding facilitators and barriers to childbirth service utilisation.
4. To explore the perceptions of health-care providers regarding facilitators and barriers to childbirth service utilisation.

Methodology

A mixed-methods triangulated design was adopted, incorporating both qualitative and quantitative components. The qualitative arm employed Grounded Theory principles through Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs). The quantitative arm utilised secondary data on selected childbirth service indicators obtained from the Health Management Information System (HMIS) through the District Medical and Health Office (DMHO), Primary Health Centres (PHCs) and linked Sub-centres.

The study was conducted in Visakhapatnam district, Andhra Pradesh, which comprises urban, rural and tribal populations. Of the total population of 4.63 million (2020), approximately 6.8 lakh (14.25%) belong to tribal communities predominantly residing in agency areas.

Study Population

The study population included tribal women of reproductive age (15–49 years) residing in selected PHC areas who had delivered within the previous five years, as well as health-care providers serving in those PHCs (Medical Officers, Auxiliary Nurse Midwives (ANMs), Accredited Social Health Activists (ASHAs) and traditional birth attendants).

Inclusion Criteria

- Tribal women who had delivered within the past five years and provided informed consent.

- Health providers working in the selected PHCs and associated Sub-centres.

Exclusion Criteria

- Women unable to comprehend the study objectives.
- Women who did not consent or were unavailable for the full duration of FGDs.

Sampling Technique

PHC Selection: All 36 tribal PHCs in the district were arranged in ascending order using the indicator institutional delivery performance against the total registered pregnancies (HMIS 16 Key Performing Indicators), data was taken from the District DMHO office Visakhapatnam. As Feasibility is the main factor and for In-depth Qualitative Research we selected one Good Performing (GP) PHC and one Very Low Performing (VLP) PHC based on Extreme case sampling technique. All Sub-centres under these PHCs were included (Figure 1).

Village and Participant Selection

From each Sub-centre, one hard-to-reach village was purposively selected, while the remaining villages were chosen through simple random sampling until data saturation was achieved. Eligible tribal women were purposively selected for FGDs. Health-care providers (Medical Officers, ANMs and ASHAs) were purposively selected for KIIs.

A total of 15 FGDs were conducted (six in the GP PHC and nine in the VLP PHC) and eight KIIs were carried out (including ASHAs, ANMs, Medical Officers and Health Extension staff from each PHC group).

Study Tools

- Semi-structured interview guides for FGDs and KIIs.
- Audio and video recording devices.
- Data collection formats for record review from PHC and Sub-centre registers.

Data Collection

Ethical approval was obtained from the Institutional Ethics Committee (IEC), King George Hospital/Andhra Medical College (66/IECAMC/OCT/2020). Permissions were taken from Integrated Tribal Development Agency (ITDA), Paderu; DMHO, Visakhapatnam; and Additional DMHO, Paderu. Written informed consent was obtained from all participants.

Secondary data relating to institutional deliveries in the selected PHCs were collected using a predesigned format. Field staff were met during review meetings for rapport building. Village-wise lists of antenatal registrations, total deliveries, institutional deliveries, home deliveries and caesarean deliveries were obtained from the MPHW(F) in the prescribed format.

Scheduled field visits were undertaken to conduct FGDs based on the feasibility of the study population and health-care staff. During field visits, a village walk-through was conducted with the assistance of the village head, and contextual observations were documented. FGDs were conducted in neutral community venues such as Anganwadi centres, schools or village secretariats as preferred by local residents. After introductions, ice-breaking activities were used to build participant comfort. A trained note-taker documented key points, and audio-video recordings were made

with participants' consent. Debriefing followed each FGD to ensure completeness.

For KIIs, purposive sampling was used to select one ASHA, one ANM, one Supervisor and one Medical Officer in the GP PHC; and one ASHA, two MPHW(F)s and one Health Extension Officer in the VLP PHC.

Data Analysis

Quantitative Component: Only descriptive analysis of Secondary data from PHCs and Sub-centres was done using Microsoft Excel to assess trends in three key performance indicators related to childbirth services, adapted from the 16 HMIS KPIs. Indicators included were Skilled Birth Attendance (SBA) delivery rate, Institutional delivery rate against antenatal registration, and Caesarean section rate as a percentage of total institutional deliveries.

Qualitative Component: Personal identifiers were removed, and audio files were anonymised. Both deductive and inductive approaches were employed. Grounded theory principles were used for general observations and to guide the recording of present study findings. Thematic analysis was mainly applied to data obtained from Focus Group Discussions (FGDs) and Key Informant Interviews (KIIs). The deductive approach was guided by the primary aim of exploring facilitators and barriers to institutional deliveries. Coding was independently done by two investigators and subsequently reviewed and jointly summarised by all three investigators to ensure reliability and consistency. Codes were tested on a subset of interviews, refined and organised into broader conceptual categories. Space was maintained for emergent themes reflecting inductive insights.

Thematic analysis was conducted to identify relationships across categories and participant types, enhancing internal validity. Regular discussions among investigators ensured consensus on coding and theme development. Data saturation was considered when no new themes or information emerged after two consecutive FGD's/ Interviews. The final themes reflected the major facilitators and barriers influencing institutional deliveries among tribal women and health-care providers.

Results

Characteristics of the Selected Primary Health Centres

Substantial differences were observed between the two selected Primary Health Centres (PHCs)—the Good Performing (GP) PHC and the Very Low Performing (VLP) PHC—particularly in relation to their geographical setting and service environment. The GP PHC was located in a scheduled tribal area, whereas the VLP PHC catered to a non-scheduled tribal population. The GP PHC was situated in predominantly hilly terrain with multiple water crossings, while the VLP PHC covered both hilly and plain areas, similarly characterised by several water streams. Road connectivity was notably better for the GP PHC, located along the main route between two major tribal towns, whereas the VLP PHC was positioned along a loop line with poor road access.

Distances to higher-level health facilities also varied distinctly. The GP PHC was 140 km from the district headquarters, 25 km from the nearest secondary-level care centre and 140 km from the tertiary care hospital. In

comparison, the VLP PHC was 90 km from the district headquarters, 65 km from the nearest secondary-level facility (including an additional 25 km to the neighbouring district's Community Health Centre) and 90 km from the tertiary hospital.

Both PHCs functioned as 24×7 facilities, with buildings and labour rooms in good working condition. Each centre had six inpatient beds and maintained functional laboratory services, a pharmacy and an ambulance. Staff quarters were absent in both facilities. The GP PHC was established in 1976, whereas the VLP PHC became operational in 2010.

Human resource availability was similar across PHCs, with each having two Medical Officers, four staff nurses, one pharmacist and one laboratory technician. The GP PHC additionally had one Community Health Officer (CHO), which was not available in the VLP PHC. Regarding multipurpose health supervisors, the GP PHC had two male and two female MPHS staff, while the VLP PHC had one male and two female MPHS personnel. Both PHCs had one MPHEO/PHN.

Field-level staffing corresponded with population coverage. The GP PHC serviced a population of 16,265 with five Sub-centres, seven MPHW(F) staff, 79 villages and 78 ASHAs. The VLP PHC covered a population of 11,449, with an equal number of Sub-centres and MPHW(F) staff, while covering 82 villages supported by 79 ASHAs.

Trends in Key Performance Indicators of Childbirth Services

Over the three-year period from 2017–18 to 2019–20, both PHCs exhibited consistent service utilisation patterns, although notable differences existed between the two centres. Antenatal registrations at the GP PHC declined from 467 in 2017–18 to 423 in 2019–20, with a similar decline observed at the VLP PHC from 370 to 342.

Total deliveries at the GP PHC remained stable (347–355), whereas the VLP PHC showed a slight decline (314–310). Institutional deliveries at the GP PHC increased modestly from 334 to 347 over the three years, while the VLP PHC demonstrated a moderate rise from 215 to 233. Home deliveries showed a decreasing trend in both PHCs. The GP PHC recorded a reduction from 19 to 8 home deliveries, while the VLP PHC saw a larger drop from 99 to 77. Caesarean section numbers rose gradually in both centres, from 3 to 6 at the GP PHC and from 4 to 11 at the VLP PHC.

Key performance indicators indicated stronger outcomes at the GP PHC than at the VLP PHC. Deliveries conducted by skilled birth attendants exceeded 94% consistently at the GP PHC, increasing from 94.6% to 97.7% between 2017–18 and 2019–20. In contrast, the VLP PHC recorded substantially lower figures, rising gradually from 68.4% to 75.1%. The proportion of institutional deliveries against antenatal registrations increased at the GP PHC from 72.1% to 82%, whereas the VLP PHC displayed fluctuating and declining values from 69.3% to 68.1%.

Caesarean sections remained low in both centres but displayed divergent patterns. While the GP PHC showed a modest rise from 0.8% to 1.7%, the VLP PHC demonstrated a sharper increase from 1.1% to 4.7%.

A. Thematic Analysis of Focus Group Discussions Among Tribal Women

Three principal themes emerged from the FGDs (Table 1)

1. Perceptions on childbirth and socio-cultural influences
2. Resource availability and accessibility
3. Perceptions on quality of care

Table 1. Themes and Subcategories Derived from FGDs Among Tribal Women

Theme	**Perceptions on childbirth and influence of socio-cultural contexts**	**Resource availability and accessibility**	**Perceptions on quality of care**
Subcategories	• Awareness • Acceptance • Change of behaviour • Cultural factors • Family support •Community involvement	• Hospital facility •Provisions at hospital • Roads • Vehicles • Financial support	• By doctor • By hospital nurse • By field staff • NGOs • TBAs

Codes identified during analysis were categorised into subdomains that functioned as either facilitators or barriers from the participants' perspectives.

1. Facilitators and Barriers Related to Socio-cultural Influences (Table 2)

Representative paraphrased quotations included:

- "They will take care of delivery at the hospital; injections are given." (FGD-W1)
- "At home delivery happens — nothing happened before." (FGD-W3)
- "Only after pains, we go to hospital." (FGD-W5)
- "If the baby does not come out, there is danger to both mother and baby." (FGD-W2)
- "Some elders deliver at home; younger people go to hospital." (FGD-W6)

2. Resource Accessibility and Availability (Table 3)

Representative paraphrased quotations included

- "Hospital has come and it is nearby, so we went for delivery." (FGD-W7)
- "If we go to a hospital nearby, they say it is not your PHC and do not treat us well." (FGD-W9)
- "For any issue, we have to walk 20 km — that is why we deliver at home." (FGD-W4)
- "Roads are bad; water streams overflow when it rains." (FGD-W8)
- "Money will be credited to bank accounts for hospital delivery." (FGD-W2)
- "If we miss a day in the field, monkeys eat the crop." (FGD-W11)

3. Perceptions on Quality of Care (Table 4)

Representative paraphrased quotations included:

- "Now the new doctor is not attending us like the previous doctor." (FGD-W12)
- "Hospitals do not receive us well; staff may abuse during delivery — this makes us prefer home." (FGD-W10)

- "ASHA and ANM ask us to admit early." (FGD-W14)
- "No ASHA in our village — we do not know whom to talk to." (FGD-W13)

B. Thematic Analysis of Focus Group Discussions Among Tribal Women (Table 5).

Table 2. Facilitators and Barriers Related to Socio-cultural Influences

Subcategories	Facilitators (codes)	Barriers (codes)
Awareness	• Hospital is safe. • Fear of home deliveries • Education • Selection of hospital • Awareness about complications • Move to hospital when pain starts.	• No harm for home delivery • Home delivery is easy • Fear of cutting and kidney removal in hospital • Go to hospital only after labour pains start.
Acceptance	• Better to go for hospital delivery with regular food • Hospital delivery is usual practice in changing times	• Unable to stay at hospital.
Family support	• Mothers suggest hospital delivery	• Require person to cook and care for children at home • Pressure from in-laws and husband for home delivery
Community involvement	• Youth help for emergency transport	—
Cultural factors	—	• Drinking of homemade liquor
Change of behaviour	• Prior admission for delivery • Stopped alcohol	—

Table 3. Facilitators and Barriers in Resource Accessibility and Availability

Subcategory	Facilitators	Barriers
Hospital facility	• Availability • Nearby location	• Poor facilities • Private hospital costly • Very far
Roads	• Road point • Good roads	• No roads • Water streams • Poor roads
Vehicles	• Ambulance picks up and drops • Own arrangement of	• Lack of transport

	autorickshaw/two-wheeler	
Financial support	• Free of cost • Money benefit for hospital delivery	• Preference for agriculture over hospital delivery
Provisions at hospital	• Vaccines given • Food supply • Baby kits	• Food provision only for patient, not for family members • No traditional food at hospital

Table 4. Facilitators and Barriers in Perceptions on Quality of Care

Subcategory	Facilitators	Barriers
By doctor	• Complications managed • Prompt services	• Not available • Irregular • Poor care
By hospital nurse	• Conduct delivery	• Abuse at delivery
By field staff	• Motivation by Accredited Social Health Activist (ASHA) • Follow-up after delivery by ASHA and Auxiliary Nurse Midwife (ANM) • Advice from ASHA	• No ASHA • No one to advise
NGO's	• NGO Manasa • NGO Aasara	—
TBA's	• ASHAs are earlier Traditional Birth Attendants (TBAs)	—

Table 5. Thematic Analysis of KIIs

Category	Community-related	Accessibility	Health system-related
Facilitators	• Preferring hospital deliveries • Education • Family support	• Local youth help in emergency transport	• Work recognition • Counselling by health workers • Supervision • Incentives • Quality of care • Dedicated staff • Good leadership
Barriers	• Consumption of homemade liquor • Illiteracy • Inability to track	• Lack of transport • Poor network connectivity	• Financial burden on Accredited Social Health Activist (ASHA) • Lack of periodic trainings •

	menstruation • Multigravida status • Lack of family support • Poverty • No bank accounts	• Water streams • Distant Primary Health Centre (PHC) • Hilly terrain	Illiteracy among ASHAs • No family planning services • Stress due to reporting workload • Inadequate funds • Over-reporting of institutional deliveries • Escapism from work

Themes were categorised into community-related, accessibility-related and health-system-related facilitators and barriers. Findings mirrored those from FGDs, highlighting intersecting socio-cultural, infrastructural and systemic challenges influencing institutional delivery.

Discussion

In tribal areas, difficult terrain and sparsely populated habitations result in Primary Health Centres (PHCs) serving populations lower than the Indian Public Health Standards (IPHS) norm of 20,000. Both PHCs included in this study catered to populations below this threshold, likely due to administrative reorganisation undertaken to improve service delivery. Despite this, both PHCs met IPHS requirements for Maternal and Child Health (MCH) services and functioned as 24-hour delivery facilities with newborn care services. Availability of round-the-clock delivery care is known to enhance institutional deliveries and subsequently reduce maternal mortality.

Although both PHCs were equipped with labour rooms, pharmacies, operation theatres, laboratories and ambulance services, utilisation differed markedly. The good-performing (GP) PHC demonstrated substantial outpatient turnover, whereas the very low-performing (VLP) PHC had minimal utilisation. Locational differences may explain this contrast; GP PHC was situated on a main transit route, whereas VLP PHC lay on a loop line with limited oversight by supervisory teams. Absence of residential staff quarters at both facilities may further impede 24/7 service provision due to long-distance travel by health workers.

Perceptions on Childbirth and Socio-cultural Influences

This study aligns with existing literature indicating that women's autonomy in deciding the place of delivery remains limited. Cephas Sialubanje et al. reported that husbands and elder family members hold predominant decision-making power [8], a barrier similarly reflected in this study where in-laws and husbands encouraged home births. However, maternal support for hospital delivery emerged as a facilitating factor, reflecting intergenerational shifts in attitudes. Consistent with Tina Miller et al. [9], traditional norms and resistance to behavioural change hindered institutional delivery. Yet, community involvement and evolving social norms helped to reposition hospital deliveries as acceptable. Traditional postpartum practices—such as consumption of customary foods—previously noted as barriers, were less influential in the present study, with many women adapting to hospital food. Mosley et al. highlighted the dual roles of

Traditional Birth Attendants (TBAs)—publicly endorsing hospital births but conducting home deliveries—and the resulting trust deficits [10]. Similar patterns emerged here, where TBAs' continued involvement in home births and dominant family influence contributed to persistent hesitancy. In contrast to Sana Q. Contractor (2018), who found that women viewed childbirth as a natural process unless complications occurred [11], participants in the current study showed greater awareness of hospital safety, although myths such as fears of organ removal persisted. A shift towards institutional delivery, noted by Kristi Sidney (2016) [12], was also evident, though some participants still perceived home births as easier and more convenient.

Resource Availability and Accessibility

Barriers related to transport, distance and time were consistent with findings from Onouma Thummapol et al., who described geographic and logistical constraints in similar settings [13]. This study corroborated these challenges while also identifying facilitators such as proximity to hospitals, free services, financial incentives and ambulance services. Distance-related barriers documented by Sana Q. Contractor [11] were mirrored here. Opportunity costs associated with agriculture—also noted by Kristi Sidney [12]—influenced decisions to forgo hospital delivery despite incentives. While system-level financial protection efforts have been described [11], practical concerns persisted locally, including lack of food for attendants and absence of culturally familiar foods in hospital settings. Nonetheless, availability of vaccines, hospital food supply and baby care kits served as facilitators.

Perceptions of Quality of Care

Consistent with previous research, participants highlighted concerns regarding staffing irregularities, low perceived quality of care and discriminatory or disrespectful treatment in facilities (8,11,10,12,13). At the same time, the ability of hospitals to manage complications and provide prompt care functioned as strong facilitators. Irregular availability of doctors, hostile behaviour from staff and negative past experiences—findings consistent with earlier studies—contributed to mistrust and reluctance to seek institutional care.

Overall Implications

This study assessed PHC performance on key childbirth indicators and explored the underlying factors shaping institutional delivery among tribal populations. A clear performance gap was observed, with institutional delivery coverage significantly lower in the VLP PHC. Although this PHC reported a higher proportion of caesarean deliveries, indicating readiness for referral, overall utilisation remained inadequate.

The thematic analysis identified multifactorial barriers including sociocultural norms, transport limitations, financial constraints and health system challenges. Addressing these requires improving quality of care, strengthening transport infrastructure, ensuring adequate manpower and incorporating culturally sensitive practices. It is also essential to address the concerns of Accredited Social Health Activists (ASHAs) and other healthcare providers.

Facilitating factors such as strong community involvement, volunteer support and engagement of non-profit organisations represent valuable

opportunities. Leveraging these community-based assets and scaling supportive mechanisms can significantly enhance the reach and effectiveness of maternal and child health services.

Despite the comparable infrastructure and manpower, the most important factors which contributed for this difference in utilisation were accessibility, road connectivity, geographical location with GP – PHC located in the main transit while LP- PHC located in corner loop with seasonal streams disturbing the access to services. In addition, the involvement of medical officer and supportive staff active involvement has increased the service uptake. These factors collectively played a crucial role in this difference between utilisations patterns beyond the availability of infrastructure.

Generalisability and Limitations

This study was exploratory in nature, and we focussed on understanding the factors that contributes to performance in two different tribal PHC's. The findings are not intended for statistical generalisability. The results are context specific and is completely restricted to the characteristics in that study population. If we understand the factors responsible, we can apply that knowledge in others Tribal PHC's with similar contextual settings particularly in terms of terrain, accessibility, and community dynamics. Thus, direct generalisation is limited and study offers programmatic insights that can inform us of interventions in comparable settings.

Conclusion

This study identified significant gaps in the utilisation of institutional childbirth services between the two selected Primary Health Centres in the tribal regions of Visakhapatnam. While the good-performing PHC showed consistent improvement in key performance indicators, the very low-performing PHC continued to demonstrate suboptimal utilisation despite comparable infrastructure and manpower. Multiple interlinked barriers—including socio-cultural influences, transport challenges, financial constraints and limitations within the health system—continue to restrict access to safe childbirth services. Strengthening the quality of care, improving transport and communication networks, ensuring availability of trained and motivated healthcare personnel and integrating culturally sensitive practices are essential to increasing institutional deliveries. Addressing concerns raised by Accredited Social Health Activists and healthcare providers will further enhance service delivery. Importantly, leveraging existing facilitating factors such as community participation, volunteer networks and the involvement of non-governmental organisations offers a promising pathway to improve maternal and newborn health outcomes in tribal communities.

Acknowledgements

The authors express our sincere gratitude to Dr. Vijaya Lakshmi (DMHO, Visakhapatnam), Dr. Venkateswarlu IAS (PO, Paderu), Dr. K. Leela Prasad (Addl. DMHO, Paderu), and Dr. B. Umavati (Women Health Officer, Visakhapatnam) for their valuable support. We are thankful to Dr. B. Naik (MO, Lothugedda PHC), Dr. T. Satish (MO), and Dr. K. Aruna (MO, Bheemavaram PHC) for their cooperation during the study. we

appreciate the support of the staff at Lothugedda and Bheemavaram PHCs, particularly A. Laxmi (ANM, Lothugedda Subcentre), Mr. Nagesh Patnaik (HEO), and V. V. V. Laxmi (HV, Bheemavaram PHC) for their assistance and accommodation during the study. We are thankful to Dr. ABHISHEK RAUT MD, Assistant professor, MGIMS, Sewagram, for his valuable support. We are deeply grateful to all study participants for their trust and cooperation, without whom this work would not have been possible.

Conflicts of interest

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

Funding

No funding was received for conducting this study.

Informed Consent

Written informed consent was obtained from all study participants before data collection.

Ethical Approval

Ethical approval for this study was obtained from the Institutional Ethics Committee, Andhra Medical College, Visakhapatnam (Approval No: 66/IECAMC /OCT/2020). All procedures performed were in accordance with institutional guidelines and the Declaration of Helsinki.

References

1. World Health Organization. Global action for skilled attendants for pregnant women. Geneva: WHO; 2019. Available from: http://www.who.int/maternal_child_adolescent/documents/who_fch_rhr_0203/en/
2. UNICEF India. Health. 2021. Available from: https://www.unicef.org/india/what-we-do/health
3. National Health Mission. RMNCH+A: Reproductive, Maternal, Newborn, Child and Adolescent Health. 2021. Available from: https://nhm.gov.in/index1.php?lang=1&level=1&sublinkid=794&lid=168
4. Government of Odisha, National Health Mission. 16 Dashboard Analysis: Composite Index Methodology. Bhubaneswar: NHM Odisha; 2024 Feb. Available from: https://nhmodisha.gov.in/wp-content/uploads/2024/02/16-DASHBOARD-ANALYSIS.pdf
5. World Health Organization. Maternal mortality: fact sheet. 2021. Available from: https://www.who.int/news-room/fact-sheets/detail/maternal-mortality
6. Ministry of Health and Family Welfare. Reproductive Child Health (RCH) Dashboard. Government of India; 2021. Available from: https://rchrpt.nhm.gov.in/RCHRPT/Dashboard/PortalDashboard.aspx
7. Census of India. Search Details: Population Census Data. 2021. Available from: https://www.censusindia.gov.in/pca/SearchDetails.aspx?Id=659707
8. Sialubanje C, Massar K, Hamer DH, Ruiter RAC. Reasons for home delivery and use of traditional birth attendants in rural Zambia: a qualitative study. BMC Pregnancy

Childbirth. 2015;15(1):216. doi:10.1186/s12884-015-0652-7.

9. Miller T, Smith H. Establishing partnership with traditional birth attendants for improved maternal and newborn health: a review of factors influencing implementation. BMC Pregnancy Childbirth. 2017;17(1):365. doi:10.1186/s12884-017-1534-y.
10. Mosley PD, Saruni K, Lenga B. Factors influencing adoption of facility-assisted delivery: a qualitative study of women and stakeholders in a Maasai community in Tanzania. BMC Pregnancy Childbirth. 2020;20(1):100. doi:10.1186/s12884-020-2728-2
11. Contractor SQ, Das A, Dasgupta J, van Belle S. Beyond the template: the needs of tribal women and their experiences with maternity services in Odisha, India. Int J Equity Health. 2018;17(1):130. doi:10.1186/s12939-018-0850-9.
12. Sidney K, Tolhurst R, Jehan K, Diwan V, De Costa A. "The money is important but all women anyway go to hospital for childbirth nowadays": a qualitative exploration of participation in a conditional cash transfer program in Madhya Pradesh, India. BMC Pregnancy Childbirth. 2016;16(1):47. doi:10.1186/s12884-016-0834-y.
13. Thummapol O, Barton S, Park T. Healthcare access experiences among indigenous women in northern rural Thailand: a focused ethnographic study. Cent Asian J Glob Health. 2018;7(1):328. doi:10.5195/cajgh.2018.328.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 729–738, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.009

ORIGINAL ARTICLE

Maternal Serum Cholesterol levels in Early Pregnancy as a Predictor for Preterm Delivery

Ajmun Nisha Fathima M,[1] Rajeshwari S,[2] Vanitha Nallathambi[3] and Jeevithan Shanmugam[4,*]
[1]*Assistant Surgeon, Ariyappapuram PHC, Pavourchatram, Tamil Nadu 627808*
[2]*Assistant Professor in OBG, Thoothukudi Medical College and Hospital, Thoothukudi-8*
[3]*Consultant OBGYN, KMCH Sulur Hospital, Coimbatore – 641402*
[4]*Professor in Community Medicine, KMCH Institute of Health Sciences and Research, Coimbatore – 14*

Accepted: 13-April-2026 / Published Online: 6-May-2026

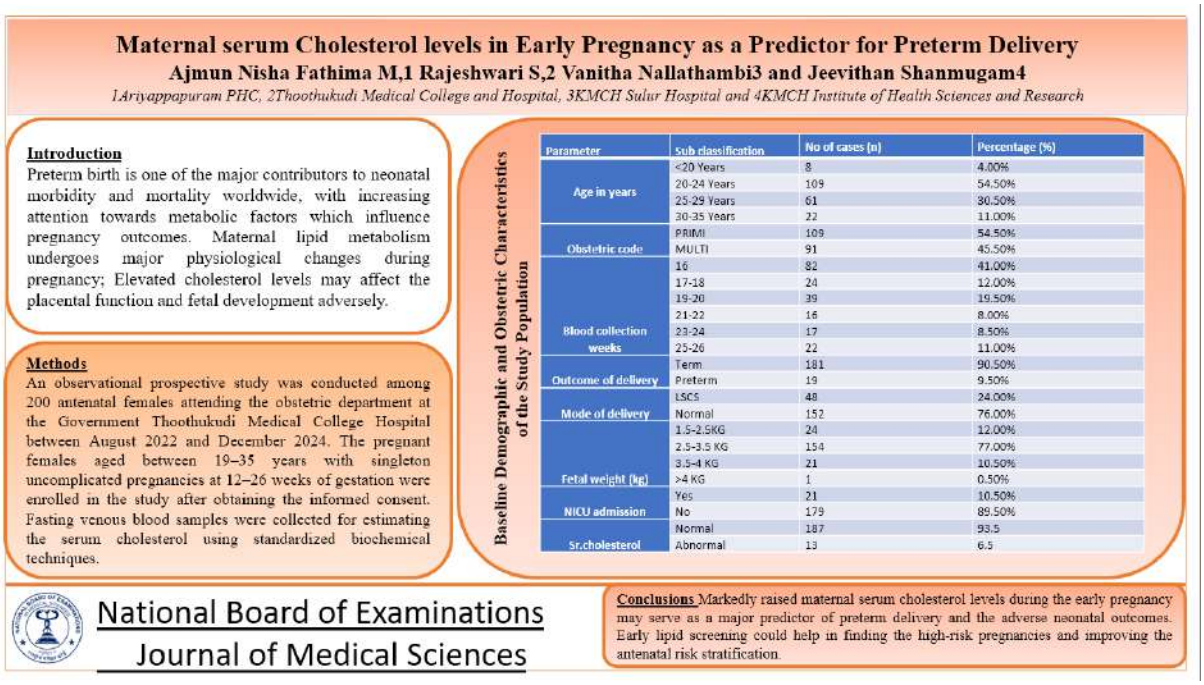
Abstract

Introduction: Preterm birth is one of the major contributors to neonatal morbidity and mortality worldwide, with increasing attention towards metabolic factors which influence pregnancy outcomes. Maternal lipid metabolism undergoes major physiological changes during pregnancy; Elevated cholesterol levels may affect the placental function and fetal development adversely. **Materials and Methods:** An observational prospective study was conducted among 200 antenatal females attending the obstetric department at the Government Thoothukudi Medical College Hospital between August 2022 and December 2024. The pregnant females aged between 19–35 years with singleton uncomplicated pregnancies at 12–26 weeks of gestation were enrolled in the study after obtaining the informed consent. Fasting venous blood samples were collected for estimating the serum cholesterol using standardized biochemical techniques. **Results:** The incidence of preterm delivery was found to be 9.5%. Mothers with serum cholesterol levels exceeding 300 mg/dL showed a higher proportion of preterm births (69.23%) compared to those with lower cholesterol levels ($p < 0.001$). The Mean maternal cholesterol levels were significantly higher in the preterm delivery (277.26 ± 68.90 mg/dL) than in the term delivery group (223.23 ± 43.20 mg/dL). Elevated cholesterol was also linked with a higher proportion of low birth weight infants and increased NICU admissions, while maternal age, gestational age and parity were not significantly associated with the outcome of the delivery. **Conclusion:** Markedly raised maternal serum cholesterol levels during the early pregnancy may serve as a major predictor of preterm delivery and the adverse neonatal outcomes. Early lipid screening could help in finding the high-risk pregnancies and improving the antenatal risk stratification.

Keywords: Pregnancy dyslipidaemia, Maternal cholesterol, Fetal birth weight, Preterm birth, Neonatal outcomes

*Corresponding Author: Jeevithan Shanmugam
Email: dr.jeevithan@gmail.com

Graphical Abstract



Introduction

Preterm birth, is defined as delivery occurring before 37 completed weeks of gestation. It remains as a major global public health concern and it is a major contributor to neonatal morbidity and mortality. Nearly 15 million premature babies are born every year, accounting for a major proportion of neonatal deaths and a long-term neurodevelopmental complication. Prematurity is associated with adverse outcomes like intraventricular haemorrhage, respiratory distress syndrome, necrotizing enterocolitis, and long-term cognitive impairment, thereby causing substantial socioeconomic and emotional burden on healthcare systems and families [1]. Despite the recent advances in obstetric and neonatal care, finding the modifiable risk factors for preterm delivery continues to be a clinical priority.

The aetiology of preterm labor is multifactorial and it involves a complex interaction of inflammatory, genetic, environmental, and endocrine mechanisms. Risk assessment has focused on the uterine overdistension, maternal infections, cervical insufficiency, and obstetric history. But the recent evidences prove that metabolic alterations during pregnancy, mainly disturbances in lipid metabolism, may play an essential role in triggering early parturition [2-4]. Pregnancy itself induces the physiological hyperlipidaemia, which is characterized by elevated triglycerides, total cholesterol, and lipoproteins. These may support fetal growth and steroid hormone synthesis. The metabolic changes are considered to be adaptive, more elevations in lipid levels may contribute to, oxidative stress, endothelial dysfunction and inflammatory responses within the uteroplacental circulation [3,4].

Cholesterol, is a fundamental lipid molecule which is essential for cell membrane integrity and steroidogenesis. It

assumes vital importance during gestation due to its role in fetal growth and neurodevelopment. The cholesterol metabolism dysfunction has been mentioned in adverse pregnancy outcomes, including the fetal growth restriction, preeclampsia, and preterm birth [3]. Elevated maternal low-density lipoproteins and cholesterol can promote impair vascular inflammation, nitric oxide signalling. It can also induce placental ischemia, which activates pathways involved in uterine contractions and cervical ripening [4,5]. Oxidized lipid particles may stimulate the cytokine synthesis and matrix metalloproteinase activation, which in turn may lead to premature rupture of membranes and early labor initiation [4,5].

Several observational studies have showed an association between preterm delivery and maternal lipid abnormalities. Mudd et al. reported that women with more mid-pregnancy cholesterol levels showed more risk of spontaneous preterm birth, proving that lipid profiling may serve as an essential biomarker for adverse obstetric outcomes [6]. Similarly, Smith et al demonstrated an independent association between higher maternal total cholesterol levels and spontaneous preterm labor reinforcing the hypothesis that lipid metabolism plays an essential role in maintaining duration of pregnancy [7]. Other researchers have also highlighted the contribution of maternal dyslipidaemia to endothelial dysfunction, and altered fetal growth patterns, placental inflammation, further supporting the biological plausibility of this association [3,4,8].

Although evidence from Western and International populations are present, the region-specific data from low and middle-income countries are less. Indian women are experiencing a greater epidemiological transition characterized by sedentary lifestyle, changing dietary patterns, and growing prevalence of metabolic disorders, which may influence the lipid profiles during pregnancy. Also, routine lipid screening is not incorporated into antenatal care protocols, largely due to insufficient local evidence. Assessing the relationship between preterm delivery and the maternal cholesterol levels within the Indian population is therefore essential for developing cost-effective screening strategies and preventive interventions.

In this context, the present prospective observational study was undertaken to evaluate the association between maternal serum cholesterol levels measured during early to mid-pregnancy and the risk of preterm delivery. By examining both maternal and neonatal outcomes, this study aims to contribute to the growing evidences exploring metabolic determinants of preterm birth and to identify potential markers that may aid in early risk stratification during antenatal care.

Materials and Methods

This prospective observational study was conducted among antenatal mothers attending Government Thoothukudi Medical College Hospital over a study period extending from August 2022 to December 2024. Prior to initiation of the study, approval was obtained from the Institutional Human Ethics Committee, and the study was done in accordance with the ethical principles outlined in the Declaration of Helsinki. Eligible participants were approached during usual antenatal visits and were provided with detailed verbal and written information regarding the procedures, purpose,

confidentiality, potential benefits of the study. Participation was entirely voluntary, and written informed consent was obtained from all mothers before enrolment. The participants were assured that withdrawal at any stage of the study would not affect their routine clinical care.

Pregnant women aged between 19 - 35 years with gestational age of 12–26 weeks and uncomplicated singleton pregnancies were included in the study. Mothers with a previous history of uterine anomalies, preterm delivery, pregnancy-induced hypertension, gestational diabetes mellitus, multiple gestation, cervical incompetence, fetal anomalies, or known chronic illnesses such as cardiac, hepatic, renal, thyroid, or metabolic disorders were excluded to minimize the confounding factors. 200 eligible participants who fulfilled the inclusion criteria were enrolled for the study. After enrolment, a detailed clinical evaluation was conducted, including dietary habits, demographic profile, obstetric history, and general physical examination. Obstetric examination was conducted based on standard antenatal protocols.

An overnight fasting venous blood sample was taken under strict aseptic precautions from each participant during the specified gestational window for estimation of maternal serum cholesterol levels. The analysis of lipid profile was performed using standardized biochemical tests in the institutional laboratory, ensuring quality control measures. The gestational age at blood collection was recorded, and participants were followed prospectively until delivery through routine antenatal follow-up visits and hospital records. Outcomes of Delivery was classified as term or preterm based on the gestational age at the time of birth. In addition, the maternal and neonatal parameters, including the mode of delivery, requirement for admission in neonatal intensive care unit (NICU) and birth weight of the fetus were documented.

All the clinical procedures were conducted in accordance with the standard obstetric practice, ensuring that there was no invasive intervention or additional risk introduced only for research purposes. Ethical Principles of non-maleficence, voluntary participation, confidentiality in maintenance of medical records, and respect for the patient's autonomy were strictly upheld. All the data collection forms were recorded in order to prevent identification of each participant, and the access to that dataset was restricted to maintain data confidentiality and integrity.

Statistical analysis was performed using SPSS 27. All c*ontinuous variables* were expressed as mean ± standard deviation, while all *categorical variables* were summarized as percentages and frequencies. Normality of the data was assured with Kolmogorov-Smirnov test. The associations between categorical variables were assessed using the Chi-square test, and comparison of continuous variables between delivery groups (term and preterm) was performed using the independent t-test. A p-value of less than 0.05 was considered as statistically significant. Multivariable logistic regression analysis was not undertaken in this study due to quasi-complete separation observed in the dataset, where increased cholesterol levels strongly predicted the preterm delivery thereby limiting reliable model estimation.

Results

While analysing the baseline characteristics of the study population, predominance of younger antenatal mothers, with 54.5% in the 20–24 years age group and a mean maternal age of 24.55 years was observed. Primigravida women constituted 54.5% of the study participants, while multigravida mothers accounted for 45.5%, showing a relatively balanced obstetric distribution. Blood cholesterol testing was most frequently performed before 16 weeks of gestation (41%), reflecting need for early antenatal screening practices. Most pregnancies resulted in term delivery (90.5%), whereas preterm birth was seen in 9.5% of cases. Normal vaginal delivery was the frequent mode of birth (76%), with caesarean section conducted in 24% of mothers. Most neonates had weight between 2.5–3.5 kg (77%) at birth, and only 12% of them weighed below 2.5 kg. NICU admission was required in 10.5% of newborns, suggesting the favourable neonatal outcomes in the study cohort (Table 1).

Table 1. Baseline Demographic and Obstetric Characteristics of the Study Population

Parameter	Sub classification	No of cases (n)	Percentage (%)
Age in years	<20	8	4.00%
	20-24	109	54.50%
	25-29	61	30.50%
	30-35	22	11.00%
Obstetric code	PRIMI	109	54.50%
	MULTI	91	45.50%
Blood collection weeks	16	82	41.00%
	17-18	24	12.00%
	19-20	39	19.50%
	21-22	16	8.00%
	23-24	17	8.50%
	25-26	22	11.00%
Outcome of delivery	Term	181	90.50%
	Preterm	19	9.50%
Mode of delivery	LSCS	48	24.00%
	Normal	152	76.00%
Fetal weight (kg)	1.5-2.5	24	12.00%
	2.5-3.5	154	77.00%
	3.5-4	21	10.50%
	>4	1	0.50%
NICU admission	Yes	21	10.50%
	No	179	89.50%
Sr.cholesterol	Normal	187	93.5
	Abnormal	13	6.5

Analysis of maternal serum cholesterol proved a significant association with delivery outcome. Among mothers with cholesterol levels below 200 mg/dL, 91.89% delivered at term, while only 8.11% were delivered as preterm birth. Similarly, in the 200–300 mg/dL category, term delivery became predominant at 96.46%, with preterm delivery was seen in only 3.54% of cases. In contrast, mothers with cholesterol levels exceeding 300 mg/dL showed a markedly different pattern, with 69.23% delivering the preterm and only 30.77% reaching the term gestation. This high-cholesterol group is present in only 6.5% of the total population, it accounted for a disproportionately greater proportion of preterm births. The difference across these cholesterol categories was statistically significant (p <0.001), indicating that elevated maternal cholesterol, especially values above 300 mg/dL, may act as a strong predictor of preterm delivery (Table 2).

Table 2. Association Between Maternal Serum Cholesterol Levels and Delivery Outcome

S.CHOLESTEROL	OUTCOME OF DELIVERY				**CSV**	**P value**
	Term		Preterm			
	No of cases (n)	Percentage (%)	No of cases (n)	Percentage (%)		
<200	68	91.89	6	8.11		
200-300	109	96.46	4	3.54		<0.001
>300	4	30.77	9	69.23	58.783	

Maternal serum cholesterol levels proved a significant relationship with neonatal birth weight distribution. In mothers with cholesterol levels below 200 mg/dL, 78.38% of neonates had a birth weight between 2.5–3.5 kg, while only 10.81% weighed less than 2.5 kg. A similar pattern was observed in the 200–300 mg/dL group, where 80.53% of neonates fell within the normal weight range and 12.39% weighed above 3.5 kg. However, among mothers with cholesterol levels exceeding 300 mg/dL, a notable shift toward lower birth weight was observed, with 61.54% of neonates weighing less than 2.5 kg and none exceeding 3.5 kg. This trend suggests that markedly increased maternal cholesterol may influence the fetal growth patterns. The link between fetal weight and cholesterol level was statistically significant (p <0.001), supporting a possible metabolic influence on intrauterine growth (Table 3).

Table 3. Relationship Between Maternal Serum Cholesterol Levels and Fetal Birth Weight

Sr. CHOLESTEROL (mg/dL)	**FETAL WEIGHT (kg)**			**CSV**	**P Value**
	<2.5	2.5-3.5	>3.5		
<200	8 (10.81)	58 (78.38)	8(10.81)	27.412	<0.001
200-300	8 (7.08)	91 (80.53)	14 (12.39)		
>300	8 (61.54)	5 (38.46)	0		

No significant association was seen between age, outcome of delivery, obstetric code and mode of delivery. Comparison of continuous variables between the preterm and term delivery groups proved a significant difference in the serum cholesterol levels, while the gestational age at blood collection did not differ significantly. The mean serum cholesterol level among mothers delivering at term was 223.23 ± 43.20 mg/dL, whereas mothers with preterm delivery exhibited a higher mean value of 277.26 ± 68.90 mg/dL, and this difference was statistically significant ($p < 0.001$). In contrast, the mean blood collection week was comparable between term group (18.17 ± 4.83 weeks) and preterm group (17.16 ± 4.49 weeks), with no significant difference observed ($p = 0.383$). These results indicate that elevated maternal cholesterol, rather than timing of lipid assessment, is more strongly linked with the risk of preterm birth (Table 4).

Table 4. Comparison of Continuous Variables Between Term and Preterm Delivery Groups

Parameter	OUTCOME OF DELIVERY				T value	P value
	Term		Preterm			
	Mean	SD	Mean	SD		
BLOOD COLLECTION WEEKS	18.171	4.835	17.158	4.488	0.874	0.383
S.CHOLESTEROL	223.233	43.202	277.263	68.900	-4.856	<0.001

Discussion

The present prospective observational study assessed the association between maternal serum cholesterol levels measured during early to mid-pregnancy and the observed risk of preterm delivery. The overall incidence of preterm delivery in this cohort was 9.5%, which is consistent with previously proven prevalence rates in similar populations [2]. Baseline obstetric and maternal characteristics, including parity, age distribution, gestational age at blood collection, and mode of delivery, did not show a statistically significant association with delivery outcome, suggesting that these variables were unlikely to confound the primary relationship observed between cholesterol levels and preterm birth. In our study most participants were primigravida, and young mothers aged between 20 and 24 years. Similar results were observed in a study done by Catov et al. where in they demonstrated elevated maternal lipid concentration in early pregnancy were significantly associated with high risk of spontaneous preterm birth [9]. Kramer et al. also reported that mid-trimester maternal lipid concentrations were independently associated with spontaneous preterm birth, indicating that lipid abnormalities during the second trimester may have predictive value for adverse pregnancy outcomes [10].

The important findings observed in this study were the strong association between elevated maternal cholesterol levels and preterm delivery. While most of the mothers with cholesterol levels below

300 mg/dL delivered at term, a considerable proportion of preterm births was seen among those with cholesterol levels exceeding 300 mg/dL. This group (elevated cholesterol) accounts for a disproportionately high number of preterm deliveries, substantiating the potential predictive value of higher cholesterol levels. Similar results have also been reported in prior studies, where in maternal dyslipidaemia was linked with an increased risk of spontaneous preterm labor, possibly mediated through the vascular and inflammatory mechanisms affecting the placental function [3-7]. The significant difference in the mean cholesterol levels between preterm and term in this study further strengthens this association and also appreciates our hypothesis that more maternal lipid levels during pregnancy may play a vital role in the pathophysiology of early parturition. The findings of the present study are in agreement with those of Vrijkotte et al., who observed that abnormal maternal lipid profiles in early pregnancy were associated with adverse outcomes including preterm birth and low birth weight, highlighting the broader impact of lipid metabolism on fetal growth [11]. A meta-analysis by Spracklen et al. further confirmed that maternal hyperlipidemia is significantly associated with an increased risk of preterm birth, reinforcing the importance of lipid abnormalities as a modifiable risk factor in pregnancy [12]. Wiznitzer et al. also demonstrated that elevated maternal lipid levels during pregnancy are associated with multiple adverse obstetric outcomes, suggesting that dyslipidemia may contribute to a spectrum of complications including preterm birth [13].

Physiological hyperlipidaemia during pregnancy is now considered a normal adaptive mechanism to support the steroid hormone synthesis and fetal growth: however, excessive accumulation of lipids may induce endothelial dysfunction, oxidative stress, and inflammatory responses within the uteroplacental circulation [4,5]. Elevated cholesterol levels can also impair the nitric oxide bioavailability thereby activating cytokine-mediated pathways, and hence promote vascular inflammation, all of which can lead to premature cervical remodelling and uterine contractility [4,5]. These findings align with the hypothesis, that maternal hypercholesterolemia may be an important metabolic trigger in the cascade leading to preterm birth.

Another observation in this study was the association between maternal cholesterol levels and the fetal birth weight. While neonates born to mothers with cholesterol levels below 300 mg/dL had adequate birth weights, a higher proportion of low birth-weight infants were observed among mothers with significantly elevated cholesterol levels. This pattern supports the evidence that maternal lipid imbalance may not only influence the gestational duration but also affects intrauterine growth of the fetus. Earlier studies have also reported that dyslipidaemia during pregnancy may affect the placental lipid transport and thereby lead to inflammatory changes. These changes may reduce the nutrient exchange and thereby affect fetal growth outcomes [3,4].

It was also observed that gestational age at blood collection did not differ significantly between term and preterm groups, indicating that the timing of lipid assessment was unlikely to influence the observed association. These finding suggests that elevated cholesterol alone, rather than the gestational window of

testing, may be the primary factor linked to risk of preterm. Similar findings have been reported in earlier cohort studies where mid-pregnancy lipid levels were predictive of adverse outcomes irrespective of the exact timing of measurement within the second trimester [6,7]. The lack of association between maternal age, parity, and mode of delivery with preterm outcome in the current study further highlights the independent role of metabolic factors in determining the duration of pregnancy.

The biological plausibility of these findings is evidenced by the maternal cholesterol which plays a key role in placental development and immune modulation. The excess cholesterol may accumulate within the placental macrophages, triggering pro-inflammatory signalling pathways and increase the production of cytokines such as IL-6 and TNF-α, which are the known mediators of early parturition [4,5]. Also, oxidative modification of low-density lipoproteins may increase the prostaglandin synthesis and matrix metalloproteinase activation, leading to premature rupture of membranes and early labor onset [4]. These mechanisms provide a pathophysiological basis for the strong relationship between the increased maternal cholesterol and preterm birth in the present study.

The statistically significant associations demonstrated through continuous and categorical variable analyses provide solid evidence supporting the role of maternal cholesterol as an essential predictor of preterm delivery. The results of this research are consistent with the prior research proving the importance of metabolic risk factors in pregnancy and underscore the potential value of estimating lipid profile as part of antenatal risk assessment [3,6,7].

Conclusion

The current research adds to the growing literature suggesting that maternal lipid metabolism may influence both the gestational duration, fetal growth, and neonatal outcomes. Identification of increased cholesterol levels during the early antenatal care may allow the obstetricians to identify the pregnant mothers at higher risk for preterm birth and implement closer surveillance strategies. Further large-scale studies are needed to establish threshold values and explore whether targeted interventions aimed at reducing the maternal lipid profiles could decrease the burden of preterm delivery.

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.

References

1. Coutinho CM, Sotiriadis A, Odibo A, Khalil A, D'Antonio F, Feltovich H et al. ISUOG Practice Guidelines: role of ultrasound in the prediction of spontaneous preterm birth. Ultrasound Obstet Gynecol. 2022 Sep;60(3):435-456. doi: 10.1002/uog.26020.
2. Preda A, Preda SD, Mota M, Iliescu DG, Zorila LG, Comanescu AC et al. Dyslipidemia in Pregnancy: A Systematic Review of Molecular Alterations and Clinical Implications. Biomedicines. 2024 Oct 3;12(10):2252. doi: 10.3390/biomedicines12102252.

3. Xiao S, Wei C. Lipid metabolism and inflammation as key drivers in preterm birth: A comprehensive analysis. Int J Gynaecol Obstet. 2025 Dec;171(3):1212-1222. doi: 10.1002/ijgo.70285.
4. Bashir M, Navti OB, Ahmed B, Konje JC. Hyperlipidaemia and severe hypertriglyceridaemia in pregnancy. Obstet Gynecol. 2023;25:196–209. doi:10.1111/tog.12887.
5. Herrera E, Ortega-Senovilla H. Disturbances in lipid metabolism in diabetic pregnancy - Are these the cause of the problem? Best Pract Res Clin Endocrinol Metab. 2010 Aug;24(4):515-25. doi: 10.1016/j.beem.2010.05.006.
6. Mudd LM, Holzman CB, Catov JM, Senagore PK, Evans RW. Maternal lipids at mid-pregnancy and the risk of preterm delivery. Acta Obstet Gynecol Scand. 2012 Jun;91(6):726-35. doi: 10.1111/j.1600-0412.2012.01391.x.
7. Smith CJ, Baer RJ, Oltman SP, Breheny PJ, Bao W, Robinson JG, Dagle JM, Liang L, Feuer SK, Chambers CD, Jelliffe-Pawlowski LL, Ryckman KK. Maternal dyslipidemia and risk for preterm birth. PLoS One. 2018 Dec 21;13(12):e0209579. doi: 10.1371/journal.pone.0209579.
8. Sławek-Szmyt S, Kawka-Paciorkowska K, Ciepłucha A, Lesiak M, Ropacka-Lesiak M. Preeclampsia and Fetal Growth Restriction as Risk Factors of Future Maternal Cardiovascular Disease-A Review. J Clin Med. 2022 Oct 13;11(20):6048. doi: 10.3390/jcm11206048.
9. Catov JM, Bodnar LM, Kip KE, Hubel C, Ness RB, Harger G, Roberts JM. Early pregnancy lipid concentrations and spontaneous preterm birth. Am J Obstet Gynecol. 2007 Dec;197(6):610.e1-7. doi: 10.1016/j.ajog.2007.04.024.
10. Kramer MS, Kahn SR, Platt RW, Genest J, Rozen R, Chen MF, Goulet L, Séguin L, Dassa C, Lydon J, et al. Mid-trimester maternal plasma lipid concentrations and risk of spontaneous preterm birth. BJOG. 2009;116(9):1203–1210.
11. Vrijkotte TG, Krukziener N, Hutten BA, Vollebregt KC, van Eijsden M, Twickler MB. Maternal lipid profile during early pregnancy and pregnancy complications and outcomes: the ABCD study. J Clin Endocrinol Metab. 2012;97(11):3917–3925.
12. Spracklen CN, Smith CJ, Saftlas AF, Robinson JG, Ryckman KK. Maternal hyperlipidemia and the risk of preeclampsia and preterm birth: a meta-analysis. Am J Epidemiol. 2014;180(4):346–358.
13. Wiznitzer A, Mayer A, Novack V, Sheiner E, Gilutz H, Malhotra A, Novack L. Association of lipid levels during gestation with preeclampsia and gestational diabetes mellitus: a population-based study. Am J Obstet Gynecol. 2009;201(5):482.e1–482.e8.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 739–750, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.010

ORIGINAL ARTICLE

A Comparative Study of Functional Outcomes of Rotator Cuff Repairs Using Arthroscopy Versus Mini-Open Techniques

Varun GBS,[1] Gurucharan S,[2] Somasundaram Sekar,[3] Darshan T[4,*] and Shuchindra R Chowdhary[5]

[1]*Professor and Unit Chief, Department of Orthopaedics, Vydehi Institute of Medical Sciences and Research Centre, Whitefield, Bengaluru – 560066, Karnataka, India*
[2]*Assistant Professor, Department of Orthopaedics, Vydehi Institute of Medical Sciences and Research Centre, Bengaluru, India*
[3]*Assistant Professor, Department of Orthopaedics, Vydehi Institute of Medical Sciences and Research Centre, Bengaluru, India*
[4]*Senior Resident, Department of Orthopaedics, Sanjay Gandhi Institute of Trauma and Orthopedics, India*
[5]*Senior Resident, Department of Orthopaedics, Chitradurga Medical College and Research Institute, Karnataka, India*

Accepted: 11-April-2026 / Published Online: 6-May-2026

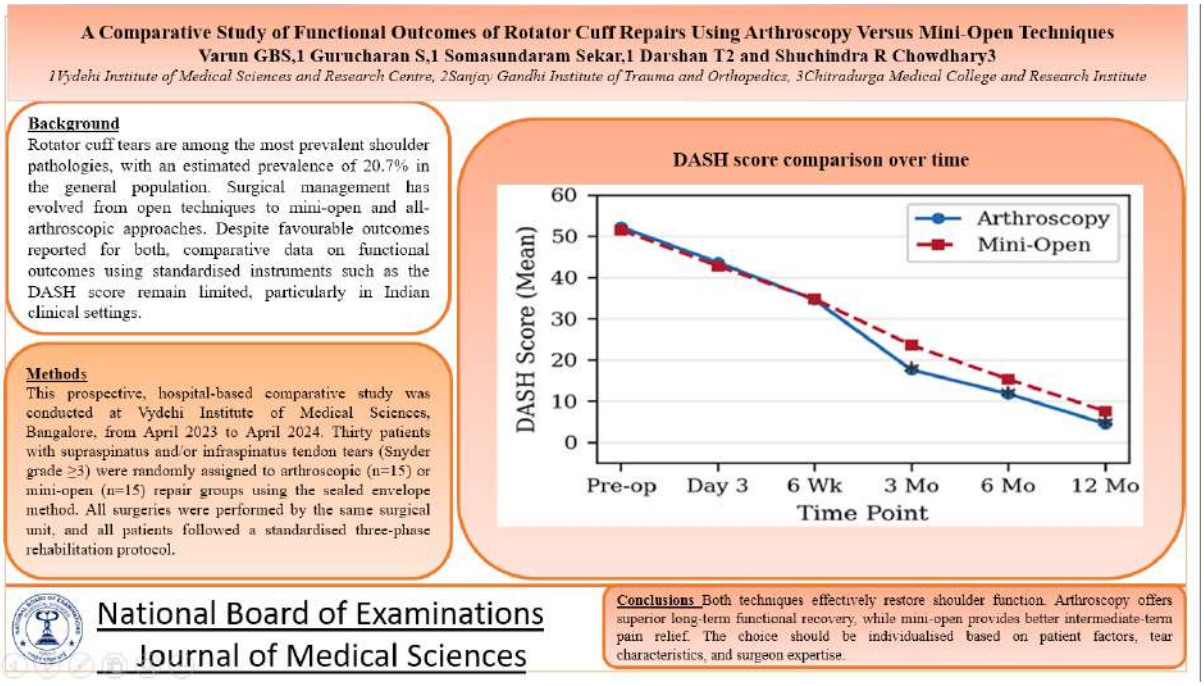
Abstract

Background: Rotator cuff tears are among the most prevalent shoulder pathologies, with an estimated prevalence of 20.7% in the general population. Surgical management has evolved from open techniques to mini-open and all-arthroscopic approaches. Despite favourable outcomes reported for both, comparative data on functional outcomes using standardised instruments such as the DASH score remain limited, particularly in Indian clinical settings. **Objectives:** To compare the functional outcomes of rotator cuff repairs performed using arthroscopy versus mini-open techniques as measured by the DASH score, VAS pain scores, and postoperative rehabilitation progress. **Methods:** This prospective, hospital-based comparative study was conducted at Vydehi Institute of Medical Sciences, Bangalore, from April 2023 to April 2024. Thirty patients with supraspinatus and/or infraspinatus tendon tears (Snyder grade ≥3) were randomly assigned to arthroscopic (n=15) or mini-open (n=15) repair groups using the sealed envelope method. All surgeries were performed by the same surgical unit, and all patients followed a standardised three-phase rehabilitation protocol. **Results:** Both techniques showed significant improvements over time. Preoperative and early postoperative DASH scores were similar ($p>0.05$). Arthroscopy showed significantly lower DASH scores at 3 months (17.60 ± 11.64 vs. 23.60 ± 10.90; $p=0.02$), 6 months (11.80 ± 12.03 vs. 15.33 ± 10.25; $p=0.03$), and 12 months (4.53 ± 5.90 vs. 7.60 ± 5.19; $p=0.04$). Mini-open surgery had lower VAS pain scores at 3 months ($p=0.04$) and 6 months ($p=0.01$), though pain equalized by 12 months ($p=0.43$). Rehabilitation outcomes were comparable, with all patients achieving "Excellent" ratings by 6 months. **Conclusion:** Both techniques effectively restore shoulder function. Arthroscopy offers superior long-term functional recovery, while mini-open provides better intermediate-term pain relief. The choice should be individualised based on patient factors, tear characteristics, and surgeon expertise.

Keywords: Rotator cuff repair, Arthroscopy, Mini-open repair, DASH score, Functional outcome, VAS pain score, Shoulder surgery

*Corresponding Author: Darshan T
Email: darshan.ortho@vims.ac.in

Graphical Abstract



Introduction

Rotator cuff tears are among the most frequent musculoskeletal pathologies encountered in orthopaedic practice. Estimates suggest that 20.7% of the total adult population (ages 18–87) experience at least one traumatic or degenerative rotator cuff tear, with prevalence increasing significantly with advancing age. The primary symptoms include chronic pain, muscle weakness, and loss of shoulder function, leading to significant disability and decreased quality of life [3].

Once conservative treatment has been exhausted, three primary surgical options are available: mini-open surgery, arthroscopically assisted mini-open procedures, and all-arthroscopic rotator cuff repair [1–3]. Arthroscopic repairs are increasingly regarded as the standard of care, with their incidence growing sixfold over the past two decades [1–3].

Although mini-open procedures have produced favourable results, concerns persist regarding increased early postoperative pain, deltoid injury, and the risk of arthrofibrosis. Recent technological advances have led to a preference for arthroscopic repair, despite its higher cost [4,5]. For many years, the mini-open repair was considered the gold standard, with satisfactory to excellent outcomes in 90% of patients [6]. However, many surgeons now favour arthroscopy for its association with expedited healing, enhanced aesthetic outcomes, diminished postoperative pain, reduced deltoid morbidity, shorter hospital stays, and faster recovery.

To date, limited randomised studies have compared these two approaches using standardised composite functional outcome instruments such as the DASH score. This study was conducted to compare the functional outcomes of rotator cuff repairs using arthroscopy versus mini-open techniques over a 12-month follow-up period.

Materials and Methods

Study Design

This was a prospective, hospital-based comparative study.

Study Period

The study was conducted from April 2023 to April 2024.

Study Setting

The study was carried out in the Department of Orthopaedics, Vydehi Institute of Medical Sciences and Research Centre, Whitefield, Bangalore, Karnataka, India.

Study Population and Sample Size

The sample size was determined through a formal a priori power calculation using the formula: $N = 2SD^2(Z\alpha/2 + Z\beta)^2/d^2$, based on mean DASH score differences from the study by van der Zwaal et al. (66 ± 3 vs. 71 ± 3.5) [7]. At 99% confidence limit ($Z\alpha/2 = 2.58$) and 90% statistical power ($Z\beta = 1.28$), a minimum of 13 patients per group was required. With 10% non-response adjustment, 15 patients per group were included, yielding a total sample size of 30. This sample size was specifically powered to detect a clinically meaningful difference in DASH scores between groups. Patients were randomly assigned to two groups using the sealed envelope method.

Inclusion Criteria

Patients aged 18–70 years with supraspinatus and/or infraspinatus tendon tears (Snyder grade ≥3) confirmed on MRI, with impingement and Type 2 or 3 acromion morphology, and willing to provide informed consent.

Exclusion Criteria

Glenohumeral instability, acromioclavicular joint arthritis, restricted glenohumeral movement (FF<90°) due to adhesive capsulitis or glenohumeral arthritis, rheumatoid arthritis, patients medically unfit or unwilling for surgery, and age <18 or >70 years.

Surgical Techniques

All surgeries were performed at a single centre by surgeons from the same orthopaedic unit, minimising inter-surgeon variability. For the arthroscopic group, the arthroscope was inserted via a posterior portal with lateral and posterolateral working portals. The tear was mobilised and repaired using suture anchors. The choice between single-row and double-row fixation was made intraoperatively based on tear size, morphology, tissue quality, and footprint coverage, reflecting standard clinical decision-making. For the mini-open group, a 5-cm lateral incision was made at the anterior acromion margin with blunt deltoid splitting, axillary nerve preservation, and partial bursectomy. The core repair steps (anchor placement, suture passage, knot tying, and footprint preparation) were identical in both groups.

Postoperative Rehabilitation Protocol

All patients in both groups followed a standardised three-phase postoperative rehabilitation protocol supervised by the same physiotherapy team. The acute phase (weeks 0–6) comprised pain management, immobilisation in an abduction brace, and passive range of motion exercises. The recovery phase (weeks 6–12) focused on scapular stabilisation, active-assisted range of motion, and progressive strengthening. The functional phase (months 3–12) included advanced strengthening, eccentric exercises, and activity-specific training. This standardisation ensured that rehabilitation was not a confounding variable between groups.

Outcome Measures

The primary outcome measure was the DASH (Disabilities of the Arm, Shoulder, and Hand) score, a validated 30-item self-administered patient-reported outcome measure (PROM). The DASH score was assessed preoperatively and at Day 3, 6 weeks, 3 months, 6 months, and 12 months. As the DASH is self-administered by the patient, investigator scoring bias was inherently minimised. Secondary outcomes included the Visual Analog Scale (VAS) for pain, also patient-reported, and postoperative rehabilitation grading (Poor, Fair, Good, Excellent) assessed by the clinical team. Blinding of patients to their surgical technique was not feasible given the different incision sizes; however, the reliance on self-administered PROMs as primary and key secondary outcomes mitigated assessor bias.

Statistical Analysis

Data were analysed using SPSS version 22. Continuous variables were expressed as mean ± SD with independent t-test. Categorical data were represented as frequencies with chi-square test. A p-value <0.05 was considered statistically significant.

Results

The study population consisted of 30 patients equally distributed between groups. Baseline demographics are presented in Table 1 and Figure 1. No significant differences were found in age (p=0.14) or sex distribution (p=0.71), confirming successful randomisation and baseline comparability between groups.

Table 1. Baseline demographics

	Arthro (n=15)	**Mini-Open (n=15)**	**p**
Age group			0.14
20–35	8	5	
36–50	2	7	
51–70	5	3	
Sex			0.71
Male	8	9	
Female	7	6	

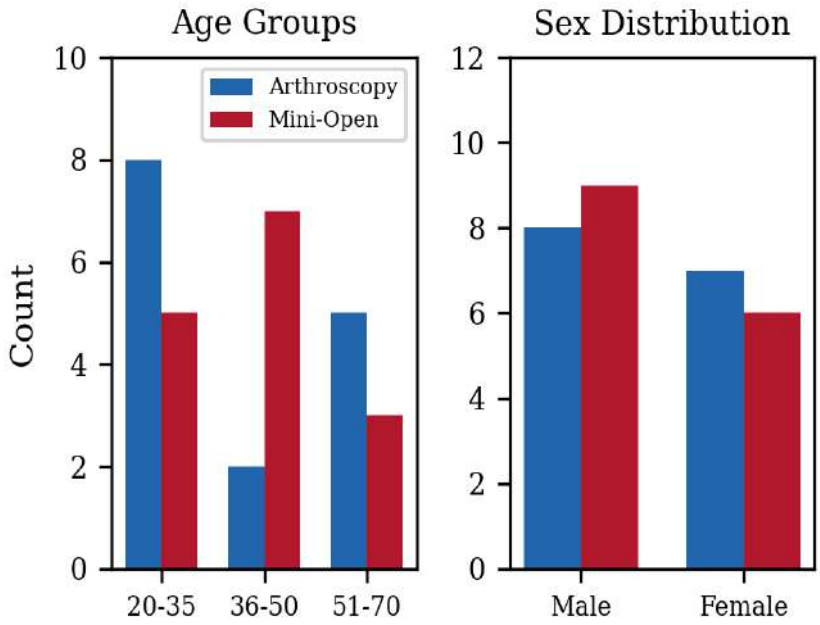


Figure 1. Age and sex distribution

Table 2 and Figure 2 present DASH score comparisons. Preoperative scores were equivalent (p=0.84). Significant arthroscopic superiority emerged at 3 months (p=0.02), 6 months (p=0.03), and 12 months (p=0.04).

Table 2. DASH scores (Mean ± SD)

Time	Arthro	Mini-Open	p
Pre-op	52.27±10.29	51.53±8.92	0.84
Day 3	43.67±9.90	42.80±8.64	0.80
6 Wk	34.60±9.96	34.80±11.41	0.96
3 Mo	17.60±11.64	23.60±10.90	**0.02***
6 Mo	11.80±12.03	15.33±10.25	**0.03***
12 Mo	4.53±5.90	7.60±5.19	**0.04***

**p<0.05*

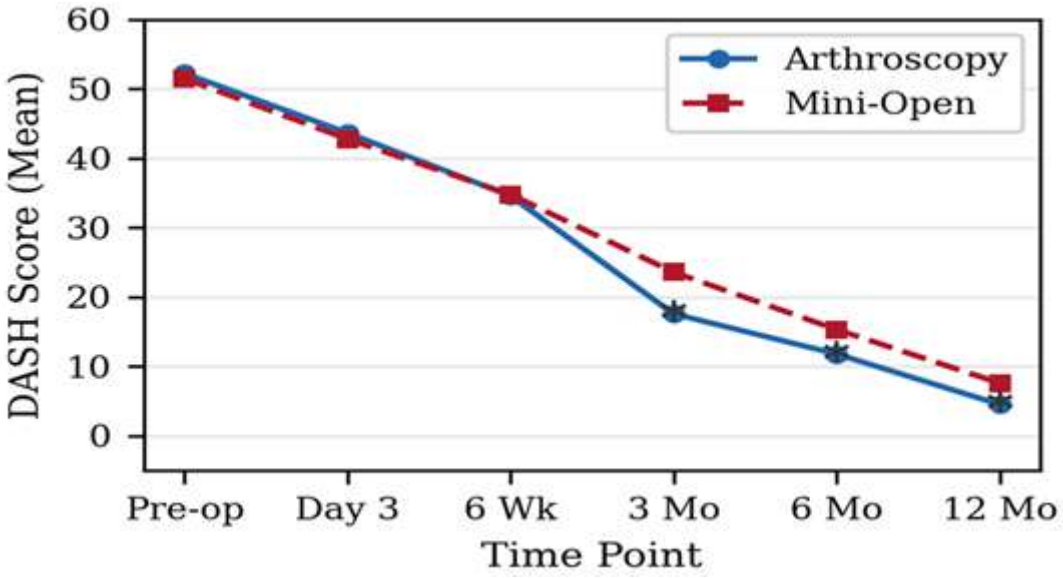


Figure 2. DASH score comparison over time

Table 3 and Figure 3 present VAS pain scores. Mini-open showed significantly lower pain at 3 months (p=0.04) and 6 months (p=0.01), equalizing by 12 months (p=0.43).

Table 3. VAS pain scores (Mean ± SD)

Time	Arthro	Mini-Open	p
Pre-op	7.27±0.96	6.93±1.10	0.38
Day 3	5.60±1.12	5.27±0.96	0.39
6 Wk	4.07±1.03	4.07±1.28	1.00
3 Mo	3.60±1.12	2.93±1.22	**0.04***
6 Mo	2.47±1.41	1.22±1.55	**0.01***
12 Mo	1.20±0.86	0.93±0.96	0.43

*$p<0.05$

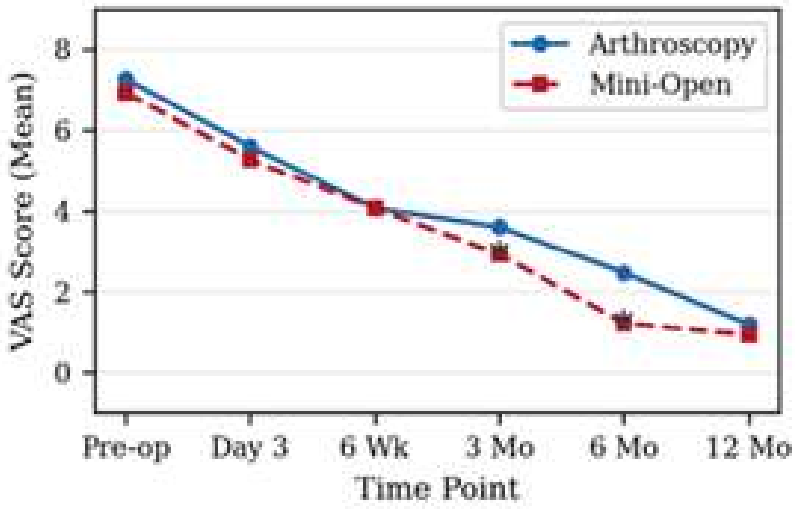


Figure 3. VAS pain score comparison over time

Table 4 and Figure 4 present rehabilitation outcomes. By 6 and 12 months, all patients in both groups achieved "Excellent" ratings (p=1.00).

Table 4. Post-operative rehabilitation

Time	Arthroscopy	Mini-Open	p
Day 3	P:3 F:12	P:4 F:11	0.67
6 Wk	F:2 G:7 E:6	F:4 G:5 E:6	0.61
3 Mo	G:8 E:7	G:9 E:6	0.71
6 Mo	E:15	E:15	1.00
12 Mo	E:15	E:15	1.00

P=Poor; F=Fair; G=Good; E=Excellent

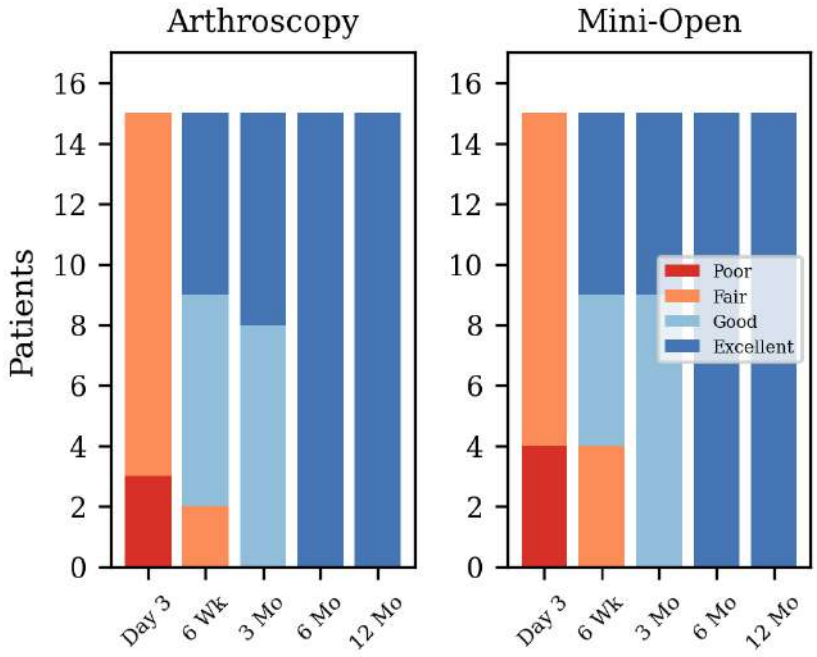


Figure 4. Rehabilitation outcomes by group

Table 5 and Figure 5 present DASH score classification. By 12 months, all arthroscopic patients achieved Minimal Disability; one mini-open patient remained in Moderate Disability (p=0.31).

Table 5. DASH score classification

Time	Arthroscopy	Mini-Open	p
Pre-op	C:4 S:9 M:2	C:3 S:11 M:1	0.59
Day 3	C:1 S:7 M:7	S:8 M:7	0.30
6 Wk	S:6 M:9	S:4 M:9 N:2	0.71
6 Mo	M:4 N:11	M:4 N:11	1.00
12 Mo	N:15	M:1 N:14	0.31

C=Crippled; S=Severe; M=Moderate; N=Minimal

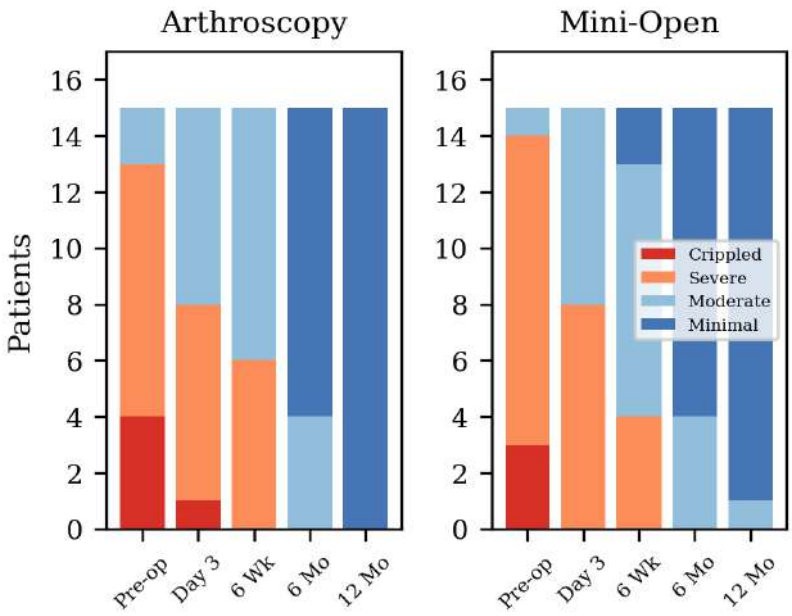


Figure 5. DASH score classification by group

Discussion

This prospective comparative study found that both arthroscopic and mini-open rotator cuff repair techniques effectively restore shoulder function, with distinct temporal differences in recovery patterns.

Functional Outcomes

The DASH score revealed no significant preoperative or early postoperative differences, confirming baseline equivalence. By three months, statistically significant arthroscopic superiority emerged. The arthroscopic group demonstrated a total improvement of 47.74 points (from 52.27 to 4.53 at 12 months), and the mini-open group showed an improvement of 43.93 points (from 51.53 to 7.60). Both groups clearly exceeded the established minimum clinically important difference (MCID) for DASH of 10–15 points, confirming clinically meaningful improvement with both techniques.

However, the between-group differences at significant time points were 6.0 points at 3 months, 3.53 points at 6 months, and 3.07 points at 12 months. These inter-group differences fall below the traditional MCID threshold, indicating that while the differences are statistically significant, the clinical magnitude of the between-group difference is modest. Both groups achieved clinically excellent outcomes; arthroscopy reached that level more rapidly and completely. The clinical relevance lies in the consistent trend of arthroscopic superiority across three consecutive time points rather than the absolute magnitude of any single difference.

These findings are consistent with Liu et al. (2017) and van der Zwaal et al. (2013), who reported earlier arthroscopic benefits [7,8]. In contrast, Migliorini et al. (2023) found no difference in a meta-analysis [9], whereas Sakha et al. (2021) indicated better patient-reported outcomes with arthroscopy [10].

Pain Outcomes

The mini-open group reported significantly lower pain at 3 and 6 months. This dissociation between superior functional outcomes (DASH) and lower

intermediate pain (VAS) in the mini-open group reflects the fact that these instruments assess fundamentally different constructs. The DASH is a composite 30-item measure capturing disability across daily activities, work, and recreation, while the VAS is a unidimensional pain intensity measure.

The mini-open technique's blunt deltoid splitting involves a single incision with muscle-sparing fibre separation, which may produce less localised inflammatory response than arthroscopy's multiple portal insertions, intra-articular fluid distension, and capsular manipulation. However, arthroscopy's minimally invasive nature results in less overall soft tissue disruption, superior intra-articular visualisation, and better tendon mobilisation — advantages that translate into superior long-term functional restoration.

Crucially, the pain advantage is transient: VAS scores equalised by 12 months (1.20 vs. 0.93, p=0.43), consistent with Sharma et al. (2024) [11] and Ji et al. (2015) [12]. This suggests the intermediate pain reflects a short-lived inflammatory response rather than a structural problem, whereas the functional difference reflects cumulative biomechanical advantages of the minimally invasive approach. This dissociation has important implications for preoperative counselling: patients prioritising early pain control may benefit from mini-open repair, while those prioritising long-term function may be better served by arthroscopy.

Rehabilitation Outcomes

Rehabilitation outcomes were remarkably uniform, with all patients achieving "Excellent" ratings by 6 months. This uniform outcome is itself clinically meaningful, demonstrating that standardised rehabilitation protocols emphasising scapular stabilisation and incremental tendon loading are effective regardless of surgical technique. However, we acknowledge that the ordinal rehabilitation grading system (Poor/Fair/Good/Excellent) has limited granularity and is susceptible to ceiling effects at later follow-up time points. The primary endpoint (DASH score), a validated continuous instrument with demonstrated sensitivity to change, successfully discriminated between groups at 3, 6, and 12 months. Future studies should incorporate more sensitive continuous rehabilitation measures such as the Constant-Murley Score or the ASES score.

Comparative Analysis

DeHaan et al. (2012) reported lower retear rates with double-row repairs (27.2% vs. 43.1%, p=0.057), although functional scores did not differ significantly (ASES: p=0.72; Constant: p=0.65) [13]. Within our arthroscopic group, the choice between single-row and double-row fixation was made intraoperatively based on tear characteristics, reflecting real-world clinical practice. While this introduces potential heterogeneity, DeHaan's null functional findings suggest that the functional outcomes we report are unlikely to be meaningfully confounded by repair configuration. Musil et al. (2006) recommended mini-open for large tears [14].

Barnes et al. (2017) reported superior structural repair integrity with mini-open (91% vs. 60% for arthroscopy) [15]. The absence of postoperative imaging in our study precluded assessment of repair integrity, which is a significant limitation. However, the relationship between structural integrity and functional outcome is not strictly linear — patients with structural retears can still achieve excellent functional results. Nonetheless, without structural data,

we cannot determine whether the functional superiority of arthroscopy will be sustained beyond 12 months, particularly if retear rates differ between techniques.

Clinical Implications

Arthroscopy's long-term functional advantage suggests it may be preferred for patients prioritising sustained shoulder function, such as younger active individuals and manual labourers. The mini-open technique's intermediate pain relief may benefit patients concerned about early postoperative discomfort, and it remains a highly effective option in resource-limited settings where arthroscopic infrastructure is unavailable. Despite the evolution of arthroscopic techniques, the traditional mini-open repair must not be dismissed, as rehabilitation outcomes were comparable and both approaches provide equitable long-term results in daily life activities.

Conclusion

Both arthroscopic and mini-open repair effectively restored shoulder function. Arthroscopic repair demonstrated superior long-term functional recovery (DASH scores at 3, 6, and 12 months), while mini-open repair provided better intermediate-term pain control (VAS at 3 and 6 months). Both groups exceeded the minimum clinically important difference for DASH, confirming clinically meaningful improvement with both techniques, though between-group differences were modest in absolute magnitude. Rehabilitation outcomes were equivalent. Using composite outcome measurements including the DASH score alongside pain measures can assist surgical decision-making. Future research should incorporate larger multicentre cohorts, postoperative imaging to assess repair integrity, blinded outcome assessment, and extended follow-up of 5–10 years to determine long-term durability of these findings.

Limitations

Several limitations should be acknowledged. First, the sample size (n=30), while adequately powered for the primary outcome (DASH score), limits generalisability and precludes meaningful subgroup analyses. Second, this single-centre study at a tertiary care institution may not reflect outcomes achievable in community or rural settings with different infrastructure and expertise. Third, the absence of postoperative imaging (MRI or ultrasound) precluded assessment of structural repair integrity, a critical determinant of long-term success. Fourth, the variable use of single-row and double-row fixation within the arthroscopic group introduces potential heterogeneity, though this reflects pragmatic clinical decision-making. Fifth, blinding of patients was not feasible given different incision sizes, and rehabilitation grading was not performed by blinded assessors, introducing potential performance and detection bias; however, the primary and key secondary outcomes (DASH and VAS) were self-administered patient-reported measures, reducing assessor influence. Sixth, patient satisfaction was not formally evaluated. Seventh, the 12-month follow-up may miss long-term retear risks. Eighth, individual compliance with rehabilitation was not formally tracked. Future studies should employ computer-generated randomisation with centralised allocation concealment, blinded outcome assessors, routine postoperative imaging, objective rehabilitation compliance measures, and follow-up extending to 5–10 years.

Ethical Considerations

The study was approved by the Institutional Ethics Committee of Vydehi Institute of Medical Sciences and Research Centre. Written informed consent was obtained from all participants.

Statements and Declarations

Conflicts of interest

The authors declare no conflict of interest.

Funding

No funding was received for this study.

References

1. Piper CC, Hughes AJ, Ma Y, Wang H, Neviaser AS. Operative versus nonoperative treatment for the management of full-thickness rotator cuff tears: a systematic review and meta-analysis. J Shoulder Elbow Surg. 2018;27(3):572–6.
2. Mitchell C, Adebajo A, Hay E, Carr A. Shoulder pain: diagnosis and management in primary care. BMJ. 2005;331(7525):1124–8.
3. Zhang Z, Gu B, Zhu W, Zhu L, Li Q. Arthroscopic versus mini-open rotator cuff repair: a prospective, randomized study with 24-month follow-up. Eur J Orthop Surg Traumatol. 2014;24(6):845–50.
4. Ames JB, Horan MP, Van der Meijden OAJ, et al. Association between acromial index and outcomes following arthroscopic repair. J Bone Joint Surg Am. 2012;94(20):1862–9.
5. Bartl C, Scheibel M, Magosch P, et al. Open repair of isolated traumatic subscapularis tendon tears. Am J Sports Med. 2011;39(3):490–6.
6. Randelli P, Cucchi D, Ragone V, et al. History of rotator cuff surgery. Knee Surg Sports Traumatol Arthrosc. 2015;23(2):344–62.
7. van der Zwaal P, Thomassen BJW, Nieuwenhuijse MJ, et al. Clinical outcome in all-arthroscopic versus mini-open rotator cuff repair: a randomized controlled trial. Arthroscopy. 2013;29(2):266–73.
8. Liu J, Fan L, Zhu Y, et al. Comparison of clinical outcomes in all-arthroscopic versus mini-open repair of rotator cuff tears. Medicine (Baltimore). 2017;96(11):e6322.
9. Migliorini F, Maffulli N, Eschweiler J, et al. Arthroscopic versus mini-open rotator cuff repair: a meta-analysis. The Surgeon. 2023;21(1):e1–12.
10. Sakha S, Erdogan S, Shanmugaraj A, et al. Update on all-arthroscopic vs. mini-open rotator cuff repair: a systematic review and meta-analysis. J Orthop. 2021;24:254–63.
11. Sharma D, Tolani M, Pathan SR, et al. A comparative analysis of functional recovery in surgical rotator cuff tear repair. Cureus. 2024;16(4):e57529.
12. Ji X, Bi C, Wang F, Wang Q. Arthroscopic versus mini-open rotator cuff repair: meta-analysis of RCTs. Arthroscopy. 2015;31(1):118–24.
13. DeHaan AM, Axelrad TW, Kaye E, et al. Does double-row rotator cuff repair improve functional outcome? Am J Sports Med. 2012;40(5):1176–85.
14. Musil D, Sadovský P, Stehlík J. Massive tears of rotator cuff: mini-open vs arthroscopic techniques. Acta Chir Orthop Traumatol Cech. 2006;73(6):387–93.

15. Barnes LAF, Kim HM, Caldwell JM, et al. Satisfaction, function and repair integrity after arthroscopic versus mini-open rotator cuff repair. Bone Joint J. 2017;99-B(2):245–9.
16. Karjalainen TV, Jain NB, Heikkinen J, et al. Surgery for rotator cuff tears. Cochrane Database Syst Rev. 2019;12:CD013502.
17. Moosmayer S, Lund G, Seljom US, et al. At a 10-year follow-up, tendon repair is superior to physiotherapy for rotator cuff tears. J Bone Joint Surg Am. 2019;101(12):1050–60.
18. Moosmayer S, Lund G, Seljom US, et al. Fifteen-year results of tendon repair versus physiotherapy for rotator cuff tears. J Bone Joint Surg Am. 2024;106(19):1785–96.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 751–772, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.011

ORIGINAL ARTICLE

Smartphone Usage, Sleep and Depression Among the Students' Community Emerging from the Covid-19 Pandemic: A Cross Sectional Study

Anisha D.P.,[1,*] Mubeen Taj,[2] Arnab Saha,[1] Preethi S,[3] Dhanraj Jalindar Bhore[1] and Rubhika G[4]

[1]*Postgraduate, Department of Psychiatry, ACS Medical College and Hospital, Maduravoyal, Chennai*
[2]*Head of the Department, Department of Psychiatry, ACS Medical College and Hospital, Maduravoyal, Chennai*
[3]*Postgraduate, Department of Pharmacology, ACS Medical College and Hospital, Maduravoyal, Chennai*
[4]*Undergraduate, ACS Medical College and Hospital, Maduravoyal, Chennai*

Accepted: 9-April-2026 / Published Online: 6-May-2026

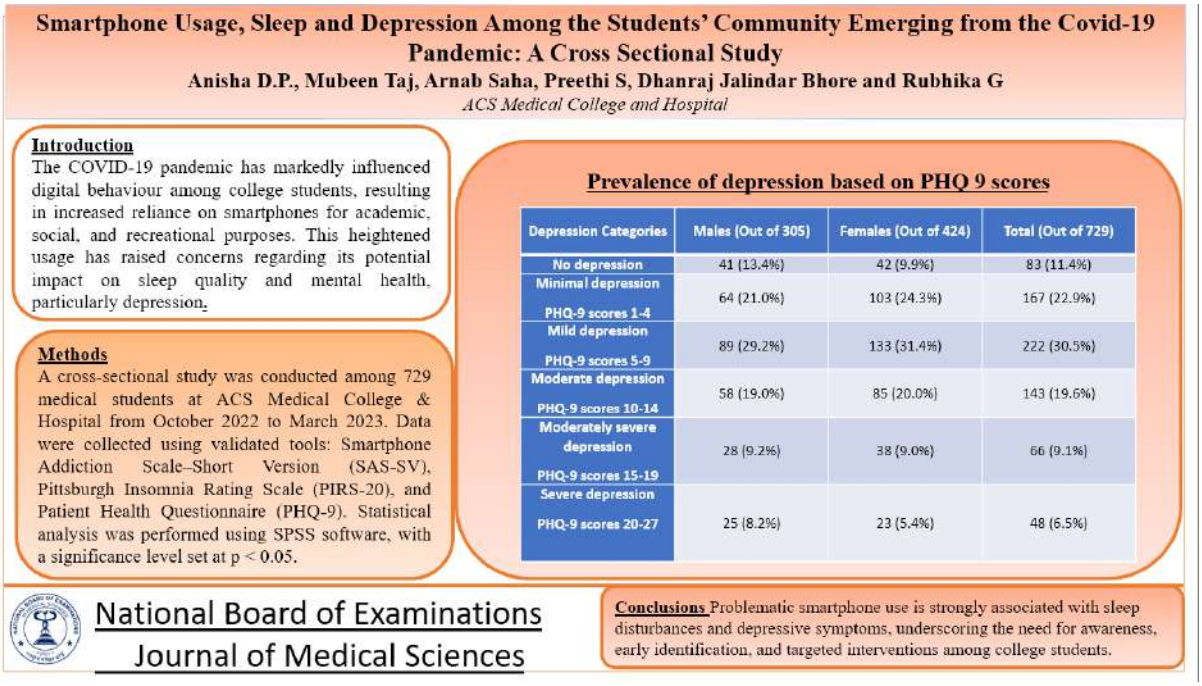
Abstract

Introduction: The COVID-19 pandemic has markedly influenced digital behaviour among college students, resulting in increased reliance on smartphones for academic, social, and recreational purposes. This heightened usage has raised concerns regarding its potential impact on sleep quality and mental health, particularly depression. **Aim:** To estimate the prevalence of problematic smartphone use and examine its association with sleep disturbances and depression among college students in the post-COVID-19 period. **Objectives:** To determine the prevalence of smartphone addiction, identify factors contributing to excessive use, and evaluate its relationship with sleep disturbances and depressive symptoms. **Methodology:** A cross-sectional study was conducted among 729 medical students at ACS Medical College & Hospital from October 2022 to March 2023. Data were collected using validated tools: Smartphone Addiction Scale–Short Version (SAS-SV), Pittsburgh Insomnia Rating Scale (PIRS-20), and Patient Health Questionnaire (PHQ-9). Statistical analysis was performed using SPSS software, with a significance level set at $p < 0.05$. **Results:** Smartphone addiction was observed in 24.55% of participants, with a higher prevalence among males (29.18%). Clinical insomnia was reported in 42.7% of students, while 88.6% exhibited varying degrees of depression, including 6.5% with severe depression. Significant positive correlations were found between smartphone addiction and insomnia ($r = 0.533$), smartphone addiction and depression ($r = 0.532$), and depression and insomnia ($r = 0.727$) ($p < 0.001$). Increased daily screen time, predominant use for social media, and longer duration of smartphone ownership were significantly associated with these outcomes. **Conclusion:** Problematic smartphone use is strongly associated with sleep disturbances and depressive symptoms, underscoring the need for awareness, early identification, and targeted interventions among college students.

Keywords: Mental health, Insomnia, Screen time

*Corresponding Author: Anisha D.P.
Email: anishjei@gmail.com

Graphical Abstract



Introduction

The COVID-19 pandemic has significantly altered social, academic, and personal lives, with students being the most affected. This change, with the shift to online classes, saw the number of people using digital gadgets, specifically smartphones, increase significantly [1]. Smartphone usage increased significantly during the pandemic compared to pre-pandemic usage, including the increased use of social media platforms to address the lack of face-to-face interaction during the lockdown [2]. School and college students were restricted from face-to-face classes during the pandemic, with the ASER Report 2022 indicating that the number of people using smartphones increased from 67.6% to 74.8% between 2021 and 2022 [3]. While smartphones serve as vital tools for communication, education, and entertainment, excessive usage has been increasingly associated with negative psychological and physiological effects, including sleep disturbances and depressive symptoms [4,5].

Behavioral addiction can also be seen in the way in which an individual can spend hours on a single activity, as well as in the way in which an individual can function in life, the driving force to continue to participate in the activity, cravings for the activity, inattention to other sources of pleasure and an inability to stop the behavior. A major step forward for the DSM-5 was to formally recognize Gambling Disorder as the first behavioral addiction under the category of Substance-Related and Addictive Disorders [6]. Internet Gaming Disorder has also been recognized in Section III of the DSM-5 the research appendix indicating that this disorder warrants more research to support its inclusion as a behavioral disorder in future editions of the manual once research evidence supports its inclusion. The prefrontal cortex of the brain, which controls planning, decision-making, and impulse control, continues to develop

throughout adolescence and young adulthood; therefore, there are more risks for addictive behaviors to occur during these periods of development [7]. The constant connectedness of smartphones creates FoMO Fear of Missing Out addiction as well as instant gratification, making this a very prevalent problem among young adults who are growing up in a highly technological society. Smartphone addiction being recognized as a behavioral disorder is imperative to create effective interventions to enhance the lives of students [8].

The Annual Status of Education Report (ASER) 2023 (9) highlights significant trends in digital device usage, learning patterns, and mental health concerns among Indian students post-pandemic. However, smartphone overuse among young students has also posed problems such as sleeplessness, physical inactivity, and addiction in many cases. According to the ASER 2023 report, excessive use of smartphones has not only affected the students' concentration but also caused disturbances in their social life and well-being in general. In addition, there are still discrepancies in the availability of digital education opportunities for students with different socio-economic backgrounds, as some of them are unable to combine digital learning and regular lessons. Based on these observations, scholars stress the importance of formulating relevant educational policies aimed at responsible smartphone usage and addressing mental issues associated with increased exposure to screens.

According to the research conducted by experts, prolonged smartphone usage negatively affects sleep due to several reasons. First, as it was mentioned earlier, extended exposure to light emitted by smartphones leads to melatonin deficiency, thus making it harder for people to fall asleep [10,11]. Secondly, obsessive behavior, when a person spends hours engaging with social networks or playing video games, may lead to bedtime delays and nocturnal arousals [12]. On the other hand, poor sleep hygiene has, in its turn, been linked to higher daytime fatigue, cognitive impairment, and emotional instabilities [13].

Apart from disrupting the sleep process, another significant danger to the well-being of an individual caused by excessive mobile phone usage is social isolation, cyberbullying, and academic stress experienced by students as demonstrated by studies undertaken during the period of the pandemic. FoMO is a result of a constant urge to be connected with social media and can cause both anxiety and depression. Lastly, using smartphones to cope with pandemic-related stress may create dependency, leading to vicious cycles of mental issues.

The importance of knowing how the long-term effect of digital dependency brought by pandemic affects people should be considered once students return to regular classrooms. This post-pandemic period serves as an excellent chance for evaluating shifts in the use of smartphones, including any consequences on the quality of sleep and mental well-being [18]. The adoption of measures that would encourage digital detoxification, education about the importance of maintaining proper sleep, and taking care of one’s mental well-being could significantly contribute to a healthier life of students [19]. This study aims to explore the intricate relationship between smartphone

usage, sleep disturbances, and depression among students in the post-pandemic context. By analyzing these interconnections, the research seeks to provide valuable insights that can inform policy recommendations, enhance digital well-being initiatives, and contribute to the broader discourse on student mental health in the digital age.

Aim

To assess the prevalence of problematic smartphone use among college students and examine its association with sleep disturbances and depression in the post-COVID-19 period.

Objectives

1. To determine the prevalence of smartphone addiction among college students.
2. To identify factors associated with excessive smartphone use among college students.
3. To evaluate the relationship between smartphone addiction, sleep disturbances and depression

Methodology

In this cross-sectional study, consenting college students of ACS medical College and Hospital which has 5 faculties on one campus (Faculty of Medicine, Nursing, Pharmacy, Physiotherapy and Allied health sciences) were assessed for problematic smartphone use, sleep and depression between the period of october 2022 to march 2023.The study was approved by the Ethical Committee [IEC Approval No:590/2022/IEC/ACSMCH] at ACS Medical College and Hospital for further proceedings.

Sample size

729 college students were recruited for the study and this was a time bound study

Inclusion criteria

The study included all the students of the Private University who were willing to participate in the study and sign the informed consent.

Exclusion criteria

Students with pre-existing mental illness or chronic medical illness those who were taking medications for any mental or physical health conditions were excluded from the study.

Study Procedure

The study participants were gathered in small groups and given a brief introduction, after which they filled out the necessary questionnaires. A sociodemographic proforma was used to collect details about the participants, such as age, gender, type of family, course enrolled in, presence of siblings, and lifestyle habits (smoking, oral tobacco use, alcohol use). Additionally, smartphone-related variables were recorded, including age at first smartphone use, number of hours used, and the main purpose of smartphone use. The Smartphone Addiction Scale-Short Version (SAS-SV) was used to assess smartphone addiction, the Pittsburgh Insomnia Rating Scale (PIRS-20) was used to evaluate the severity of insomnia, and the Patient Health Questionnaire (PHQ-9) was used to assess depression.

The SAS-SV (Kwon et al., 2013) is a 10-item scale assessing smartphone addiction using a 6-point Likert scale (1 = strongly disagree to 6 = strongly agree).

Scores range from 10 to 60, with higher scores indicating problematic use. Cut-off scores of ≥31 for males and ≥33 for females indicate addiction [20].

The PIRS-20 is a 20-item self-report questionnaire assessing insomnia severity over the past week. It includes 12 items on distress symptoms, 4 on sleep parameters, and 4 on sleep quality. Each item is rated on a 4-point scale (0–3), with total scores ranging from 0 to 60. A score ≥20 indicates clinical insomnia [21].

The PHQ-9 is 9-item depression screening tool scoring DSM-IV criteria from 0 (not at all) to 3 (nearly every day). Scores range from 0 to 27, with higher scores indicating greater depression severity [22].

Statistical Analysis

Data collected in the study was analyzed using SPSS software version 11. For establishing the association between two categories, the Chi-square independence test was employed. A t-test was performed to establish the comparison between means of two groups, while Pearson correlation coefficient was used to establish the statistical relationship between two variables. P-value less than 0.05 was considered statistically significant (Table 1).

Results

Table 1. Distribution of sociodemographic variables among the study participants (N=729)

S. No.	Variable	Category	n (%)
1	Age	18–21 years	634 (87.0)
		22–25 years	95 (13.0)
2	Gender	Female	424 (58.2)
		Male	305 (41.8)
3	Course	MBBS	470 (64.5)
		Nursing	147 (20.2)
		Pharmacy	39 (5.3)
		Physiotherapy	73 (10.0)
4	Type of family	Extended	28 (3.8)
		Joint	165 (22.6)
		Nuclear	536 (73.5)

5	Siblings	Yes No	623 (85.5) 106 (14.5)
6	Birth order (Rank)	Oldest child Middle child Youngest child Single child	277 (38.0) 54 (7.4) 292 (40.1) 106 (14.5)

There were a total of 729 subjects involved in the research, with the majority of the subjects being in the age group of 18-21 years (87%) while others (13%) belonged to the age group of 22-25 years. The female respondents were more (58.2%) as compared to the male respondents (41.8%). With respect to the educational background of the respondents, MBBS was the leading education background for the respondents, accounting for (64.5%), followed by nursing (20.2%), physiotherapy (10.0%) and pharmacy (5.3%) (Table 2).

Table 2. Distribution of usage of smartphone among the study participants (N=729)

S. No.	Variable	Frequency	Percentage
1.	**Usage of Smartphone**		
	Yes	729	100%
2.	**Own a smartphone**		
	Yes	702	96.3%
	No	27	3.7%
3.	**Years of owning a smartphone**		
	3-5 years	201	27.6%
	Less than 3 years	342	46.9%
	More than 5 years	159	21.8%
	Does not own	27	3.7%
4.	**Chief use**		

	Gaming	16	2.2%
	Making calls	214	29.4%
	Online classes	109	15.0%
	OTT platforms	50	6.9%
	Social Media	340	46.6%
5.	**Age at first use**		
	10-15 years	194	26.6%
	Less than 10 years	60	8.2%
	More than 15 years	475	65.2%
6.	**Hours of use on weekday**		
	2 to 5 hours	343	47.1
	Less than 2 hours	179	24.6
	More than 5 hours	207	28.4

All respondents have used smartphones, with 96.3% having one but only 3.7% lacking a personal smartphone. Almost half of them (46.9%) have used smartphones for less than three years, while 27.6% and 21.8% used the devices for 3 to 5 years and more than five years, respectively. The most prevalent activity done by means of smartphones is social media (46.6%), then call usage (29.4%), online learning (15.0%), over-the-top services (OTT) (6.9%), and games (2.2%). Almost all respondents (65.2%) started using smartphones for more than 15 years, while 26.6% and 8.2% started using them from 10 to 15 years and less than 10 years, respectively (Table 3).

Table 3. Prevalence of depression based on PHQ 9 scores.

Depression Categories	**Males (Out of 305)**	**Females (Out of 424)**	**Total (Out of 729)**
No depression	41 (13.4%)	42 (9.9%)	83 (11.4%)
Minimal depression PHQ-9 scores 1-4	64 (21.0%)	103 (24.3%)	167 (22.9%)
Mild depression PHQ-9 scores 5-9	89 (29.2%)	133 (31.4%)	222 (30.5%)
Moderate depression PHQ-9 scores 10-14	58 (19.0%)	85 (20.0%)	143 (19.6%)
Moderately severe depression PHQ-9 scores 15-19	28 (9.2%)	38 (9.0%)	66 (9.1%)
Severe depression PHQ-9 scores 20-27	25 (8.2%)	23 (5.4%)	48 (6.5%)

The depression score for the subjects was measured based on the PHQ-9 scale. The subjects who had no depression accounted for 11.4%, while those with minimal depression, mild depression, and moderate depression were 22.9%, 30.5%, and 19.6%, respectively. Some subjects had more severe cases of depression, and these comprised 9.1% of moderately severe depression and 6.5% of severe depression cases (Table 4).

Table 4. Prevalence of smartphone addiction

Variable	**Frequency**	**Percentage (%)**	**95% C. I**
Males (Out of 305) SAS-SV score >/= 31	89	29.18%	24.14 – 34.63
Females (Out of 424) SAS-SV scores >/= 33	90	21.23%	17.43 – 25.43
Total (Out of 729)	179	24.55%	21.47 – 27.85

The study found that 24.55% of participants met the criteria for smartphone addiction based on SAS-SV scores. Males had a higher addiction rate (29.18%) compared to females (21.23%) (Table 5)

Table 5. Prevalence of clinical insomnia based on PIRS scores

Insomnia categories	Males (Out of 305)	Females (Out of 424)	Total (Out of 729)
No insomnia	170 (55.7%)	248 (58.5%)	418 (57.3%)
Clinical Insomnia PIRS scores >/=20	135 (44.3%)	176 (41.6%)	311 (42.7%)

Clinical insomnia was present in 42.7% of participants, with males (44.3%) showing a slightly higher prevalence than females (41.6%). The remaining 57.3% of participants did not report significant insomnia symptoms (Table 6).

Table 6. Association between PIRS scores and SAS SV scores

Sample size	Variable	Mean	Standard Deviation	Correlation Coefficient (r)	p - Value
729	SAS SV Score	23.86	11.88	1	<0.001*
729	PIRS Score	17.83	13.39	0.533	

* Statistically significant

A statistically significant association ($r = 0.533$, $p < 0.001$) was found between smartphone addiction (SAS-SV scores) and insomnia (PIRS scores) (Table 7).

Table 7. Correlation between PHQ 9 scores and SAS SV scores

Sample size	Variable	Mean	Standard Deviation	Correlation Coefficient (r)	p - Value
729	SAS SV Score	23.86	11.88	1	<0.001*
729	PHQ 9 score	8.10	6.42	0.532	

* Statistically significant

Smartphone addiction was also statistically significantly associated with depression, with a correlation coefficient of r = 0.532 ($p < 0.001$) (Table 8)

Table 8. Correlation between PHQ 9 scores and PIRS scores

Sample size	Variable	Mean	Standard Deviation	Correlation Coefficient (r)	p - Value
729	PHQ 9 score	8.10	6.42	1	<0.001*
729	PIRS Score	17.83	13.39	0.727	

* Statistically significant

A statistically significant association ($r = 0.727$, $p < 0.001$) was found between depression (PHQ-9 scores) and insomnia (PIRS scores) (Table 9).

Table 9. Correlation between hours of use on a weekday and PHQ 9 scores (N=729)

Hours of use	No Dep	Minimal Depression	Mild Depression	Mod Dep	Mod severe Dep	Severe Dep	X^2 (df), p
< 2 hours	42(50.6%)	59(35.3%)	33 (14.9%)	23(16.1%)	8(12.1%)	14(29.2%)	85.73
2 – 5 hrs	31(37.4%)	80(47.9%)	122(54.9%)	68(47.5%)	29(43.9%)	13(27.1%)	(10)
> 5 hours	10(12%)	28(16.8%)	67((30.2%)	52(36.4%)	29(43.9%)	21(43.7%)	<0.001*
Total	83	167	222	143	66	48	

*Statistically significant.

Participants who used their smartphones for more than five hours per day had higher rates of moderate to severe depression compared to those who used them for shorter durations. Minimal and mild depression were more common in participants using smartphones for 2-5 hours per day, while those using smartphones for less than two hours had the lowest depression levels. Hours of use on weekdays was also statistically significantly associated to PHQ-9 scores. ($p<0.001$) (Table 10).

Table 10. Association between chief use of the smartphone and PHQ 9 scores (N=729)

Chief use	No Dep	Minimal Depression	Mild Depression	Mod Dep	Mod severe Dep	Severe Dep	X^2 (df), p
Social media	29(34.9%)	66(39.5%)	108 (48.6%)	72(50.3%)	36(54.5%)	29(60.4%)	34.136 (20) 0.025*
Gaming	2(2.4%)	2(1.2%)	6(2.7%)	2(1.4%)	3(4.5%)	1(2.1%)	
Making calls	31(37.3%)	61(36.5%)	64((28.8%)	37(25.9%)	12(18.2%)	9(18.7%)	
Online classes	16(19.3%)	33(19.8%)	24(10.8%)	22(15.4%)	8(12.1%)	6(12.5%)	
OTT platforms	5(6%)	5(3%)	20(9%)	10(7%)	7(10.6%)	3(6.2%)	
Total	83	167	222	143	66	48	

* Statistically significant

Participants who primarily used smartphones for social media had the highest depression rates, while those who used them for gaming had the lowest. Making calls, online classes, and OTT platform usage also contributed to varying levels of depression, with social media showing the strongest association. There was a statistically significant association between the chief use of smartphones and PHQ-9 scores. (p=0.025) (Table 11).

Table 11. Association between years of owning a smartphone and PHQ 9 scores (N=729)

Years of owning	No Dep	Minimal Depression	Mild Depression	Mod Dep	Mod severe Dep	Severe Dep	X^2 (df), p
No phone owned	5(6%)	7(4.2%)	7 (3.1%)	5(3.5%)	2(3%)	1(20.8%)	31.488 (15) 0.008*
Less than 3 years	49(59%)	96(57.5%)	88(39.6%)	60(4.2%)	29(44%)	20(41.7%)	
3 to 5 years	18(21.7%)	37(22.1%)	71((32%)	49(34.3%)	15(22.7%)	11(23%)	
More than 5 years	11(13.2%)	27(16.2%)	56(25.2%)	29(20.3%)	20(30.3%)	16(33.3%)	
Total	83	167	222	143	66	48	

* Statistically significant

A statistically significant association was found between the duration of smartphone ownership and depressive symptoms, as measured by PHQ-9 scores (p = 0.008). People who owned the smartphones for less than three years and more than five years displayed moderate to severe depression than those who had used the smartphone for three to five years. It is worth noting that people who did not own a smartphone also exhibited depressive conditions (Table 12).

Table 12. Association between chief use of smartphone and SAS-SV scores (N=729)

Chief use	**Addiction**	**No Addiction**	**Total**	**X^2 (df), p**
Social media	111(62%)	229(41.6%)	340	
Gaming	10(5.6%)	6(1.1%)	16	
Making calls	25(13.9%)	189(34.4%)	214	45.919 (4)
Online classes	20(11.2%)	89(16.2%)	109	<0 .001*
OTT platforms	13(7.3%)	37(6.7%)	50	
Total	179	550	729	

* Statistically significant

A significant statistical relationship (p<0.001) between the main reason for using smartphones and the degree of smartphone addiction (SAS-SV results) was detected. The highest levels of smartphone addiction were identified in respondents that use smartphones mostly for social media purposes (62%), as well as for gaming/OTT content. On the other hand, smartphone addiction is relatively low for respondents that use smartphones for phone calling purposes or for attending online classes (Table 13).

Table 13. Association between years of owning a smartphone & SAS-SV scores (N=729)

Years of owning	**Addiction**	**No Addiction**	**Total**	**X^2 (df), p**
No phone owned	8(4.5%)	19(3.4%)	27	10.029 (3)
Less than 3				

years 3 to 5 years	66(36.9%)	276(50.2%)	342	0.018*
More than 5 years	56(31.3%)	145(26.4%)	201	
	49(27.4%)	110(20%)	159	
Total	179	550	222	

* Statistically significant

A statistically significant association (p = 0.018) was seen between years of smartphone ownership and smartphone addiction. Higher addiction rates were observed among individuals who had owned smartphones for less than 3 years and 3–5 years, compared to those who had used them for more than 5 years or did not own a smartphone (Table 14).

Table 14. Association between hours of use of smartphone on a weekday and SAS-SV scores (N=729)

Hours of use	**Addiction**	**No Addiction**	**Total**	**X^2 (df), p**
Less than 2 hours	20(11.2%)	159(28.9%)	179	
2 – 5 hours	73(40.8%)	270(49.1%)	343	51.544 (2) <0 .001*
More than 5 hours	86(48%)	121(22%)	207	
Total	179	550	729	

* Statistically significant

Weekday smartphone usage duration was significantly associated with smartphone addiction (p < 0.001). Participants who used smartphones for more than 5 hours daily were found to have the highest prevalence of addiction (48%) (Table 15).

Table 15. Association between substance use and SAS-SV scores

Substance use	**Addiction**	**No Addiction**	**Total**	**X^2 (df), p**
Alcohol	4 (2.2%)	8 (1.4%)	12	
Oral tobacco	0 (0%)	1 (0.01%)	1	
Smoking	6(3.3%)	4(0.7%)	10	
Smoking, alcohol use	6(3.3%)	5(0.9%)	11	22.095 (5)
Smoking, oral tobacco, alcohol use	4(2.2%)	1(0.2%)	5	<0 .001*
None of the above	159(88.8%)	531(96.5%)	690	
Total	179	550	729	

* Statistically significant

A statistically significant association was seen between substance use and smartphone addiction ($p < 0.001$). While most addicted individuals did not report substance use, the prevalence of addiction was higher among those who consumed substances such as alcohol or smoked (Table 16).

Table 16. Association between type of family and PIRS scores

Type of family	**No insomnia**	**Clinical Insomnia**	**Total**	**X^2 (df), p**
Nuclear	302 (72.2%)	234(75.2%)	536	
Extended	8 (1.9%)	20 (6.4%)	28	14.133 (2)
Joint	108(25.8%)	57(18.3%)	165	<0 .001*
Total	418	311	729	

* - Statistically significant

A statistically significant relationship ($p < 0.001$) was seen between family structure and clinical insomnia (PIRS scores). Clinical insomnia was more frequently observed in participants from nuclear families, followed by those from joint and extended families (Table 17).

Table 17. Association between Years of owning a smartphone and PIRS scores

Years of owning a smartphone	**No insomnia**	**Clinical Insomnia**	**Total**	**X^2 (df), p**
No phone owned	17 (4%)	10(3.2%)	27	
Less than 3 years	212 (50.7%)	130 (41.8%)	342	
3 to 5 years	120(28.7%)	81(26%)	201	16.466 (3) <0 .001*
More than 5 years	69(16.5%)	90(28.9%)	159	
Total	418	311	729	

* Statistically significant

A significant association ($p < 0.001$) was seen between years of smartphone ownership and insomnia. Clinical insomnia was more prevalent in participants who had owned smartphones for less than 3 years or more than 5 years (Table 18).

Table 18. Association between hours of use on a weekday and PIRS scores

Hours of use	**No insomnia**	**Clinical Insomnia**	**Total**	**X^2 (df), p**
Less than 2 hours	128 (30.6%)	51(16.4%)	179	
2 to 5 hours	207 (49.5%)	136 (43.7%)	343	41.121 (2) <0 .001*
More than 5 hours	83(19.8%)	124(39.9%)	207	
Total	418	311	729	

* - Statistically significant

A strong association ($p < 0.001$) was observed between hours of smartphone use on weekdays and clinical insomnia. The highest prevalence of clinical insomnia (39.9%) was reported among those who used smartphones for more than 5 hours daily (Table 18).

Table-19: Association between chief use of smartphone and PIRS scores

Chief use	**No insomnia**	**Clinical insomnia**	**Total**	**X^2 (df), p**
Social media	179(42.8%)	161(51.8%)	340	
Gaming	8(1.9%)	8(2.6%)	16	
Making calls	149(35.6%)	65(20.9%)	214	24.274 (4)
Online classes	63(15.1%)	46(14.7%)	109	<0 .001*
OTT platforms	19(4.5%)	31(10%)	50	
Total	418	311	729	

* Statistically significant

A statistically significant association ($p < 0.001$) between the primary use of smartphones and insomnia. Participants using smartphones mainly for social media or OTT content were found to have the highest rates of clinical insomnia, whereas those using them for calls or academic activities reported comparatively lower rates (Table 20).

Table 20. Association between substance use and PIRS scores

Substance use	**No insomnia**	**Clinical insomnia**	**Total**	**X^2 (df), p**
Alcohol	8 (1.9%)	4 (1.3%)	12	
Oral tobacco	1 (0.2%)	0 (0%)	1	
Smoking	2(0.5%)	8(2.6%)	10	
Smoking, alcohol use	3(0.7%)	8(2.6%)	11	14.106 (5)
Smoking, oral tobacco, alcohol use	1(0.2%)	4(1.3%)	5	0 .015*
None of the above	403(96.4%)	287(92.3%)	690	
Total	418	311	729	

* Statistically significant

A statistically significant relationship ($p = 0.015$) was found between substance use and clinical insomnia. Higher rates of insomnia were reported among participants who used substances such as alcohol, tobacco, or smoked, as compared to those who did not use any substances.

Discussion

This study investigates the prevalence of problematic smartphone use among college students and its associations with sleep disturbances and depression in the context of a post-pandemic world. The findings highlight an escalating concern: excessive smartphone use is not just a behavioural trend but a pressing public health issue with profound psychological implications.

Prevalence and Patterns of Smartphone Use

It was established that 24.55% of respondents had problems with smartphone addiction, with males having a significantly higher percentage of 29.18% than females with 21.23%. This result can be explained by the results of other studies, which show that males use their smartphones more actively when it comes to games and watching videos. As a result, they become addicted to their smartphones more often than women (Kuss & Griffiths, 2015) [23]. This situation can be affected not only by cultural aspects but also by different coping strategies used by people under stress.

The major function of smartphone use was social media, which accounted for 46.6% of the uses, followed by calling, which contributed 29.4%, and online learning, which contributed 15%. It is noteworthy that people preferred using their smartphones for social media, which has been found to be connected with compulsion, instant gratification, and fear of missing out (FoMO). Such phenomena were linked to problematic smartphone use and poor mental health (Elhai et al., 2016; Przybylski et al., 2013) [14-16]. Therefore, the identified trends require a comprehensive examination of the effects of social media use.

It is important to note that smartphone addiction was more prevalent among users who had used smartphones for less than three years and more than five years. In the first case, such users might not have gained sufficient control over themselves and could not use their phones responsibly. On the contrary, users who had used their phones for more than five years might have developed some maladaptive patterns in the process. The observed trend correlates with the findings of Andreassen et al. (2012) about digital behavioural reinforcement [24].

Smartphone Use and Depression

It is noteworthy that depression among participants occurred at different levels; 11.4% did not have any depressive symptoms, while 6.5% suffered from severe depression. There is a statistically significant positive correlation between smartphone addiction and depression ($r = 0.532$, $p < 0.001$), which reveals the mutual effect of high smartphone usage and poor mental well-being. Prolonged engagement in online spaces may increase social isolation, cyberbullying experiences, and distorted social comparison. These factors are widely recognized for their

contribution to depressive symptoms (Twenge et al., 2017) [25].

The results of our study showed that a significant correlation exists between long-term smartphone use, mostly more than five hours a day, and moderate-to-severe depression ($p < 0.001$). This correlation is consistent with the findings of the research studies by Thomée et al. (2011) [26] and Lin et al. (2016) [27].

It is worth mentioning that participants who used their smartphones for social media activities had a greater chance to suffer from depression. The results align with those of previous research conducted by Bányai et al. (2017) [28], where it was shown that social media addiction was positively associated with depression. In turn, people who mostly used smartphones for calling someone and education did not have high scores concerning depression.

Smartphone Use and Sleep Disturbances

The prevalence of clinical insomnia in this study was found to be 42.7%. The significance level of the positive correlation established between insomnia and smartphone addiction was $r = 0.533$ ($p < 0.001$). These results corroborate many previous findings on the negative effect of smartphones on circadian rhythms and melatonin production as a result of blue light emitted by the devices, causing problems with sleep (Carter et al., 2016; Exelmans & Van den Bulck, 2016) [11,29].

Furthermore, a higher level of correlation was detected between depression and insomnia, which is characterized by a correlation coefficient $r = 0.727$ ($p < 0.001$). The strong correlation reflects the well-established clinical connection between the two variables. Importantly, it was found that students who were addicted to using their smartphones and had low-quality sleep were much more prone to experiencing depression than those not having such features. The harmful triad of smartphone addiction, insomnia, and depression emphasizes the necessity for clinical intervention (Alfonsi et al., 2020) [30].

Additionally, those who were using the smartphones for over five hours per day had the highest levels of insomnia cases recorded, with an astonishing rate of 39.9% who suffered from sleeplessness. This is consistent with the findings of Li et al. (2017) [31] that established a dose-response association between screen usage and poor quality of sleep. Social media and OTT content turned out to be the main sources leading to insomnia among the students. This could be linked to the stimulant effect associated with such types of media, as suggested by Demirci et al. (2015) [32].

Sociodemographic and Lifestyle Associations

Results indicated a statistically significant relationship between family background and insomnia, with higher rates of clinical insomnia being reported by those raised in nuclear families ($p<0.001$). It can be presumed that students from such families had less social support or no family supervision at all, which has proven its critical importance when helping people cope with stressors and regulating the use of screens (Chang et al., 2019) [10].

Furthermore, substance use was identified as an indicator of both smartphone addiction and insomnia, implying co-occurrence of several pathological behaviour traits among the

students. Although causation cannot be established on the basis of these results, they correspond with literature claiming that stress management techniques involving substance abuse and high screen usage can be present in one's lifestyle simultaneously (Walsh et al., 2020) [33].

Firstly, one of the key strengths of this research is that it takes a holistic approach in determining the linkages between smartphone addiction, sleep disorders, and depression in a broad sample of college students who lived through the pandemic. The employment of reliable and proven scales, such as the Smartphone Addiction Scale–Short Version (SAS-SV), Pittsburgh Insomnia Rating Scale (PIRS-20), and Patient Health Questionnaire (PHQ-9), allows for obtaining more reliable data. In addition, the study provides useful information about behavioral patterns and how various smartphone-related activities affect health, and it also highlights some sociodemographic factors that put young people at a higher risk of developing digital health issues.

Limitations

There are several limitations in this study. Firstly, since it uses a cross-sectional approach, causal relationship cannot be established. It also makes the research difficult to identify whether there is a cause-and-effect relationship between the use of smartphone and its psychological consequences. Another potential bias might occur from self-reporting, which means that the accuracy of the responses provided by the subjects may be questionable due to their possible tendency to remember inaccurately and to give socially desirable answers. Moreover, the study involved only participants from one private university, which makes it harder to generalize findings to the other contexts. There is also no control over the confounding variables in this research.

Conclusion

This research makes a clear indication on the relationship between smartphone addiction, depression, and insomnia among university students. Given the fact that digital gadgets have been assuming a more prominent position in both educational and social settings, it is imperative to come up with preventive strategies that promote the well-being of students. Since the misuse of smartphones constitutes a changeable factor, there are many chances of preventing such health problems among youth.

Conflict of interest:

The authors declare that there is no conflict of interest regarding the publication of this study.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethical Approval

The study was approved by the Institutional Ethics Committee of A.C.S. medical college and Hospital, and was conducted in accordance with the ethical standards laid down in the Declaration of Helsinki. IEC Approval No:590/2022/IEC/ACSMCH.

Informed Consent

Informed consent was obtained from all participants prior to data collection.

Authors contribution

ADP, AS, PS, RG were involved in the conceptualization, design, and execution of the study, data collection, and statistical analysis. MT as the research guide, provided guidance in study design, supervised the research process, and critically revised the manuscript for intellectual content. All authors have read and approved the final version of the manuscript.

References

1. Zhou J, Yu H. Contribution of smartphone addiction to sleep disturbance and depression among college students: A structural equation model. Sleep Med. 2021;84:156–162.
2. Chemnad K, Alshakhsi S, Almourad MB, Altuwairiqi M, Phalp K, Ali R. Smartphone usage before and during COVID-19: A comparative study based on objective recording of usage data. Informatics. 2022;9(4):98. doi:10.3390/informatics9040098.
3. ASER Centre. Annual status of education report (rural) 2022. New Delhi: ASER Centre; 2023.
4. Alhassan AA, Alqadhib EM, Taha NW, Alahmari RA, Salam M, Almutairi AF. The relationship between addiction to smartphone usage and insomnia among medical students in Saudi Arabia. Sleep Biol Rhythms. 2018;16(1):45–51.
5. Wang W, Riedo J, Allemand M, Aybek S, Chiu VW, Holtforth MG, et al. Smartphone use and mental health among young adults during COVID-19: A systematic review. BMC Psychol. 2023;11(1):27.
6. Pandya A, Lodha P. Social connectedness, excessive screen time during COVID-19 and mental health: A review of current evidence. Front Public Health. 2021;9:687449. doi:10.3389/fpubh.2021.687449.
7. American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed. Arlington (VA): American Psychiatric Publishing; 2013.
8. Jadhav KS, Boutrel B. Prefrontal cortex development and emergence of self-regulatory competence: The two cardinal features of adolescence disrupted in context of alcohol abuse. Eur J Neurosci. 2019;50(3):2274–2281. doi:10.1111/ejn.14316.
9. Pratham Education Foundation. Annual status of education report (ASER) 2023: Main findings. New Delhi: Pratham Education Foundation; 2023. Available from: https://asercentre.org/wp-content/uploads/2022/12/ASER-2023-Report-1.pdf
10. Chang AM, Aeschbach D, Duffy JF, Czeisler CA. Evening use of light-emitting eReaders negatively affects sleep, circadian timing, and next-morning alertness. Proc Natl Acad Sci U S A. 2015;112(4):1232–1237.
11. Carter B, Rees P, Hale L, Bhattacharjee D, Paradkar MS. Association between portable screen-based media device use and sleep outcomes: A systematic review and meta-analysis. JAMA Pediatr. 2016;170(12):1202–1208.
12. Lemola S, Perkinson-Gloor N, Brand S, Dewald-Kaufmann JF, Grob A. Adolescents' sleep patterns and psychological functioning: A

mediation model linking sleep to academic performance. J Adolesc. 2015;45:45–54.
13. Becker SP, Gregory AM, Sidol CA, Van Dyk TR, Epstein JN, Beebe DW. Predicting academic achievement and grade retention with attention deficit hyperactivity disorder symptom dimensions. J Clin Child Adolesc Psychol. 2018;47(5):667–677.
14. Elhai JD, Dvorak RD, Levine JC, Hall BJ. Problematic smartphone use: A conceptual overview and systematic review of relations with anxiety and depression psychopathology. J Affect Disord. 2017;207:251–259.
15. Sohn SY, Rees P, Wildridge B, Kalk NJ, Carter B. Prevalence of problematic smartphone usage and associated mental health outcomes among adults: A meta-analysis. J Affect Disord. 2019;246:125–133.
16. Przybylski AK, Murayama K, DeHaan CR, Gladwell V. Motivational, emotional, and behavioural correlates of fear of missing out. Comput Human Behav. 2013;29(4):1841–1848.
17. Wolniewicz CA, Tiamiyu MF, Weeks JW, Elhai JD. Problematic smartphone use and relations with negative affect, fear of missing out, and fear of negative and positive evaluation. Psychiatry Res. 2018;262:618–623.
18. Bennett KP, Lugo RN, Robinson KA, Wang L. Digital media usage and its association with sleep and mental health post-COVID-19 lockdown: A cross-sectional study of university students. Front Public Health. 2022;10:876529.
19. Keles B, McCrae N, Grealish A. The influence of social media on depression, anxiety and psychological distress in adolescents: A systematic review. Int J Adolesc Youth. 2020;25(1):79–93.
20. Kwon M, Kim DJ, Cho H, Yang S. The smartphone addiction scale: Development and validation of a short version for adolescents. PLoS One. 2013;8(12):e83558. doi:10.1371/journal.pone.0083558.
21. Moul DE, Pilkonis PA, Miewald JM, Carey TJ, Buysse DJ. Preliminary study of the test-retest reliability and concurrent validities of the Pittsburgh Insomnia Rating Scale (PIRS). Sleep. 2002;25(Abstract Suppl):A246–A247.
22. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med. 2001;16(9):606–613. doi:10.1046/j.1525-1497.2001.016009606.x.
23. Kuss DJ, Griffiths MD. Social networking sites and addiction: Ten lessons learned. Int J Environ Res Public Health. 2015;12(3):1286–1306. doi:10.3390/ijerph120201286.
24. Andreassen CS, Torsheim T, Brunborg GS, Pallesen S. Development of a Facebook addiction scale. Psychol Rep. 2012;110(2):501–517. doi:10.2466/02.09.18.PR0.110.2.501-517.
25. Twenge JM, Campbell WK. Associations between screen time and lower psychological well-being among children and adolescents: Evidence from a population-based study. Prev Med Rep. 2018;12:271–283.

26. Thomée S, Härenstam A, Hagberg M. Mobile phone use and stress, sleep disturbances, and symptoms of depression among young adults: A prospective cohort study. BMC Public Health. 2011;11:66. doi:10.1186/1471-2458-11-66.
27. Lin YH, Lin YC, Lee YH, Lin PH, Lin SH, Chang LR, et al. Time distortion associated with smartphone addiction: Identifying smartphone addiction via a mobile application (App). J Psychiatr Res. 2015;65:139–145. doi:10.1016/j.jpsychires.2015.11.003 .
28. Bányai F, Zsila Á, Király O, Maraz A, Elekes Z, Griffiths MD, et al. Problematic social media use: Results from a large-scale nationally representative adolescent sample. PLoS One. 2017;12(1):e0169839. doi:10.1371/journal.pone.0169839.
29. Exelmans L, Van den Bulck J. Bedtime mobile phone use and sleep in adults. Soc Sci Med. 2016;148:93–101.
30. Alfonsi V, Scarpelli S, D'Atri A, Stella G, De Gennaro L. Later school start time: The impact of sleep on academic performance and health in the adolescent population. Int J Environ Res Public Health. 2020;17(7):2574.
31. Li L, Griffiths MD, Niu Z, Mei S, Zhang W. The mediating role of rumination between depression and smartphone addiction among Chinese college students. J Behav Addict. 2017;6(4):554–563. doi:10.1556/2006.6.2017.085.
32. Demirci K, Akgönül M, Akpinar A. Relationship of smartphone use severity with sleep quality, depression, and anxiety in university students. J Behav Addict. 2015;4(2):85–92.
33. Walsh SP, White KM, Young RM. Needing to connect: The effect of self and others on young people's involvement with their mobile phones. Aust J Psychol. 2020;72(1):25–35.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 773–784, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.012

ORIGINAL ARTICLE

Management Outcome of Odontoid Fracture: Conservative vs Surgical Treatment: A Comparative Study

V Sureshkumar[1,*] and M. Makesh Kumar[2]
[1]*Associate Professor, Department of Neurosurgery, Govt Mohan Kumaramangalam Medical College, Salem, Tamilnadu*
[2]*Neurosurgery Post Graduate, Government Mohan Kumaramangalam Medical College, Salem, Tamilnadu*

Accepted: 15-April-2026 / Published Online: 6-May-2026

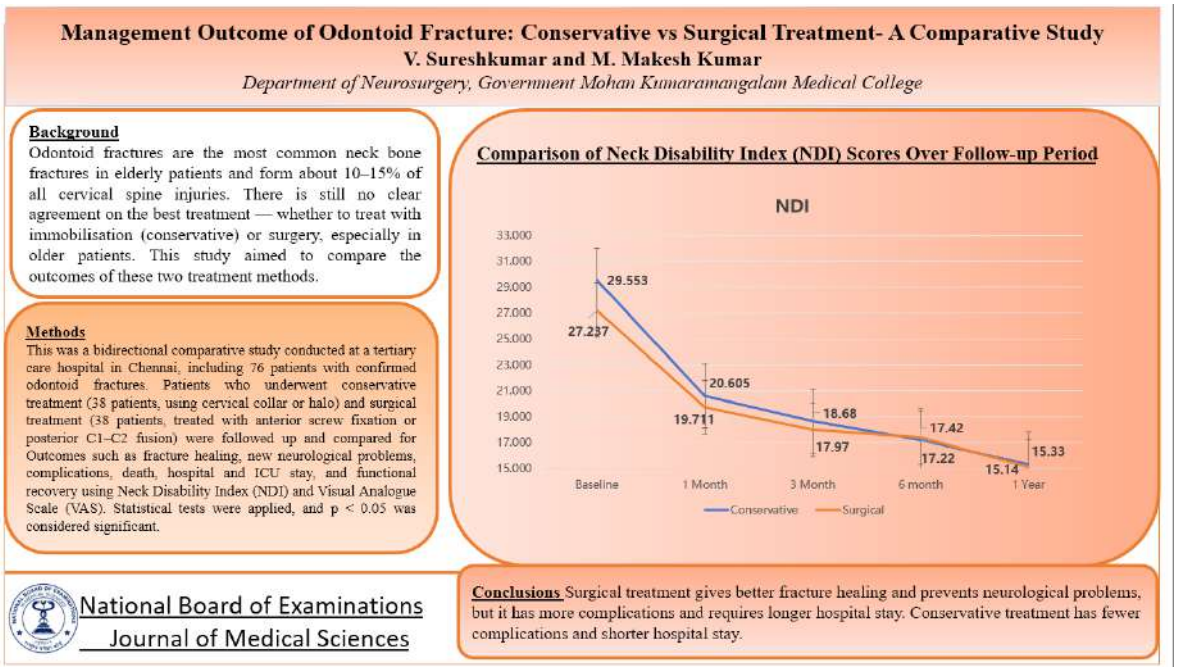
Abstract

Background: Odontoid fractures are the most common neck bone fractures in elderly patients and form about 10–15% of all cervical spine injuries. There is still no clear agreement on the best treatment — whether to treat with immobilisation (conservative) or surgery, especially in older patients. This study aimed to compare the outcomes of these two treatment methods. **Methods:** This was a bidirectional comparative study conducted at a tertiary care hospital in Chennai, including 76 patients with confirmed odontoid fractures. Patients who underwent conservative treatment (38 patients, using cervical collar or halo) and surgical treatment (38 patients, treated with anterior screw fixation or posterior C1–C2 fusion) were followed up and compared for Outcomes such as fracture healing, new neurological problems, complications, death, hospital and ICU stay, and functional recovery using Neck Disability Index (NDI) and Visual Analogue Scale (VAS). Statistical tests were applied, and $p < 0.05$ was considered significant. **Results:** Fracture healing was much higher in the surgical group (73.3% compared to 26.7%). New neurological problems occurred only in the conservative group. Patients who underwent surgery had longer hospital stay (28.08 ± 9.27 days vs 14.87 ± 4.39 days) and ICU stay (12.95 ± 3.74 days vs 5.18 ± 2.57 days). Complications were more common in the surgical group (75% vs 25%). Death was higher in the conservative group, but this was not statistically significant. Both groups showed improvement in NDI and VAS scores, with slightly better results in the surgical group at one year. Logistic regression did not show any independent factors predicting outcomes. **Conclusion:** Surgical treatment gives better fracture healing and prevents neurological problems, but it has more complications and requires longer hospital stay. Conservative treatment has fewer complications and shorter hospital stay. Treatment should be decided based on patient condition, fracture type, neurological status, and fitness for surgery.

Keywords: Odontoid fracture, Conservative management, Surgical stabilisation, Cervical spine injury, Neck Disability Index

*Corresponding Author: V Sureshkumar
Email: drsuresh33@gmail.com

Graphical Abstract



Introduction

Odontoid fractures (fractures of the dens of the axis) are one of the most common neck spine injuries seen in clinical practice. They account for about 10–15% of all cervical spine fractures and up to 20% in people older than 70 years [1]. The odontoid process plays an important role in neck movement, especially rotation between the first and second cervical vertebrae, and its damage can affect both stability and nerve safety.

The Anderson and D'Alonzo classification system divides these fractures into Type I, Type II, and Type III, and it is widely used to guide treatment decisions [2]. Among these, Type II fractures occur at the base of the dens and are the most common. They also have the highest risk of non-healing (non-union), which makes treatment decisions more difficult, especially in elderly patients who often have other medical conditions that increase surgical risk [3].

Conservative treatment mainly involves immobilisation using a rigid cervical collar or a halo-vest. This method is often chosen for elderly patients who are not fit for surgery or for fractures that are not significantly displaced. However, the rate of non-union with conservative treatment is high, ranging from 26% to 67% in Type II fractures. This can lead to complications such as delayed neurological problems, instability between C1 and C2, and long-term neck pain [4-6].

Surgical treatment includes methods such as anterior odontoid screw fixation and posterior C1–C2 fusion techniques (like Harms-Goel screw-rod fixation and transarticular screws). These methods have better fracture healing rates but are associated with risks such as difficulty in swallowing, implant failure, wound infection, blood clots, and longer hospital stay [7-9].

Even though many studies are available, there is still no clear agreement on the best treatment method for odontoid fractures, especially in elderly patients. Many studies have limitations such as small sample sizes, different types of patients,

and varying follow-up periods. Therefore, this study was conducted at Madras Medical College, a tertiary care centre in South India, to compare the outcomes of conservative and surgical treatment in a single group of patients and to help guide better clinical decision-making [10].

Aims and Objectives

Primary Objective

To compare the clinical outcomes — including fracture union rate, secondary neurological deficits, complication profile, and mortality — between conservative and surgical management groups in patients with odontoid fractures.

Secondary Objectives

1. To compare functional recovery using Neck Disability Index (NDI) and Visual Analogue Scale (VAS) scores at baseline, 3 months, 6 months, and 12 months across both groups.
2. To analyse the influence of demographic and clinical variables (age, gender, fracture stability) on treatment selection.
3. To determine independent predictors of treatment outcome using logistic regression analysis.

Materials and Methods

Study Design and Setting

This was a retrospective comparative study conducted in the Department of Neurosurgery at a tertiary care institute in Chennai, Tamil Nadu. The study was carried out over one year (2023–2024).

Study Population

Patients with confirmed odontoid fractures as established by X-ray of the cervical spine, CT scan with fine cuts, or MRI were included of which 40 patients, underwent conservative management - cervical collar or halo and 42 patients underwent surgical treatment with anterior screw fixation or posterior C1–C2 fusion.

Inclusion Criteria

Adult patients aged 18 years and above with odontoid fractures (Type I, II, or III); availability of proper radiological records; available for a minimum follow-up of 12 months; were included in the study by convenient sampling and consent obtained from the patient or legal guardian (in patients with neurological deficits).

Exclusion Criteria

Patients with fractures due to tumors or metastasis; patients with additional atlantoaxial instability needing further surgery; incomplete medical records; patients lost to follow-up before 12 months; and patients who had surgery in another hospital and came only for follow-up.

Treatment Protocol

Conservative treatment included immobilisation using a rigid cervical collar (Philadelphia or Miami-J collar) for Type I, Type III, and mildly displaced Type II fractures. Halo-vest was used for unstable or displaced fractures when surgery was not suitable. Immobilisation was continued for 8 to 12 weeks depending on fracture healing.

Surgical treatment was done under general anaesthesia. Anterior odontoid screw fixation was used for suitable Type II fractures. Posterior C1–C2 fusion (Harms-Goel technique) was done for complex fractures, reverse fracture pattern, or when

conservative treatment failed. A cervical collar was used after surgery for 6 weeks.

Outcome Assessment

Main outcomes included: fracture healing confirmed by CT scan at 6 months, with signs such as bony callus, cortical bridging and reduction in the fracture gap; development of new or worsening neurological problems; complications such as pneumonia, urinary infection, implant failure, wound infection, blood clots, and swallowing difficulty; and in-hospital death.

Functional outcomes were assessed using the Neck Disability Index (NDI) and Visual Analogue Scale (VAS) for pain at baseline, 3 months, 6 months, and 12 months. Duration of hospital stay and ICU stay were also recorded.

Statistical Analysis

Data were analysed using SPSS version 16. Categorical data were analysed using Chi-square test. Continuous data were analysed using independent t-test. Logistic regression was used to identify factors affecting outcomes. A p-value less than 0.05 was considered statistically significant. Results were presented as numbers, percentages, mean values with standard deviation, odds ratios with confidence intervals, and regression values.

Results

A total of 76 patients were included, equally distributed among conservative and surgical groups (38 each). Age showed a significant association with treatment modality, with ≥80 years predominantly managed conservatively (88.5%) and 60–69 years mainly treated surgically (91.3%) ($\chi^2 = 31.117$, $p < 0.001$) (Table 1). Females were more often treated conservatively (62.8%), while males predominantly underwent surgery (66.7%), which was statistically significant ($\chi^2 = 6.481$, $p = 0.011$) (Table 2). Fracture stability did not differ significantly between groups ($p = 0.293$). However, fracture union was significantly higher in the surgical group (73.3% vs 26.7%) ($\chi^2 = 23.213$, $p < 0.001$). Secondary neurological deficits occurred exclusively in the conservative group (100%) ($\chi^2 = 8.941$, $p = 0.003$). Mortality was higher in the conservative group (71.4% vs 28.6%), though not statistically significant ($p = 0.234$). Complications were significantly more frequent in the surgical group (75% vs 25%) ($\chi^2 = 8.769$, $p = 0.003$) (Table 3).

Table 1. Distribution of Study Population According to Age and Treatment Modality

Age	Group		Total	Chi Square Value	p value
	Conservative	Surgical			
≥80 years	23	3	26	31.117	**<0.001***
	88.5%	11.5%	100.0%		
60-69 yrs	2	21	23		
	8.7%	91.3%	100.0%		
70-79 yrs	13	14	27		
	48.1%	51.9%	100.0%		
Total	38	38	76		
	50.0%	50.0%	100.0%		

*p<0.05-Statistical significance

Table 2. Gender-wise Distribution of Patients Based on Treatment Modality

Gender	Group		Total	Chi Square Value	p value
	Conservative	Surgical			
Female	27	16	43	6.481	**0.011***
	62.8%	37.2%	100.0%		
Male	11	22	33		
	33.3%	66.7%	100.0%		
Total	38	38	76		
	50.0%	50.0%	100.0%		

*p<0.05-Statistical significance

Table 3. Comparison of Clinical Outcomes Between Conservative and Surgical Groups

Clinical Parameters	Group		Total	Chi Square Value	p value
	Conservative	Surgical			
Fracture Stability	32	36	68	1.107	0.293
	47.1%	52.9%	100.0%		
Fracture Union	12	33	45	23.213	**<0.001***
	26.7%	73.3%	100.0%		
Secondary Neurological Deficit	8	0	8	8.941	**0.003***
	100.0%	0.0%	100.0%		
Mortality	5	2	7	1.416	0.234
	71.4%	28.6%	100.0%		
Complication	6	18	24	8.769	**0.003***
	25.0%	75.0%	100.0%		

*p<0.05-Statistical significance

The conservative group had fewer complications, mainly pneumonia and urinary infections, whereas the surgical group showed higher rates of pneumonia, hardware failure, wound infection, DVT, dysphagia, and urinary infection (Figure 1). NDI and VAS scores improved progressively in both groups, with slightly better outcomes in the surgical group at one year (Figures 2 and 3). The conservative group had a higher mean age (79.61 ± 6.64 vs 70.32 ± 6.48 years), while hospital stay (28.08 ± 9.27 vs 14.87 ± 4.39 days) and ICU stay (12.95 ± 3.74 vs 5.18 ± 2.57 days) were significantly longer in the surgical group ($p < 0.001$) (Table 4). Logistic regression showed no independent predictors (Table 5).

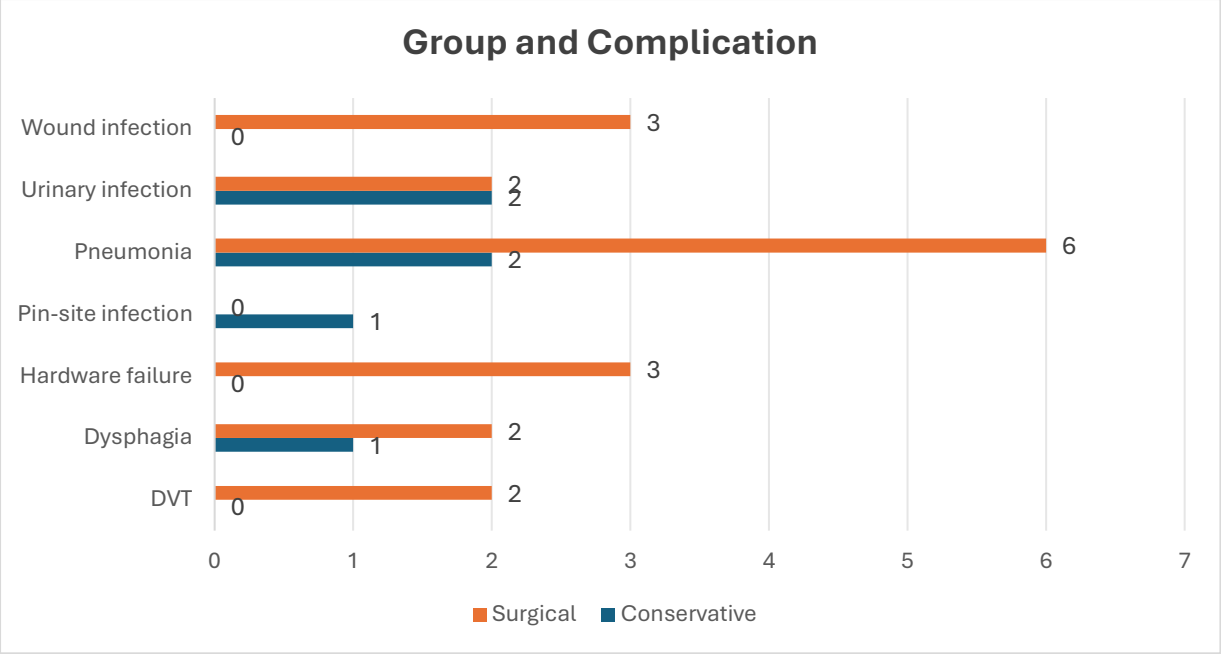


Figure 1. Distribution of Complication Profile in Conservative and Surgical Groups

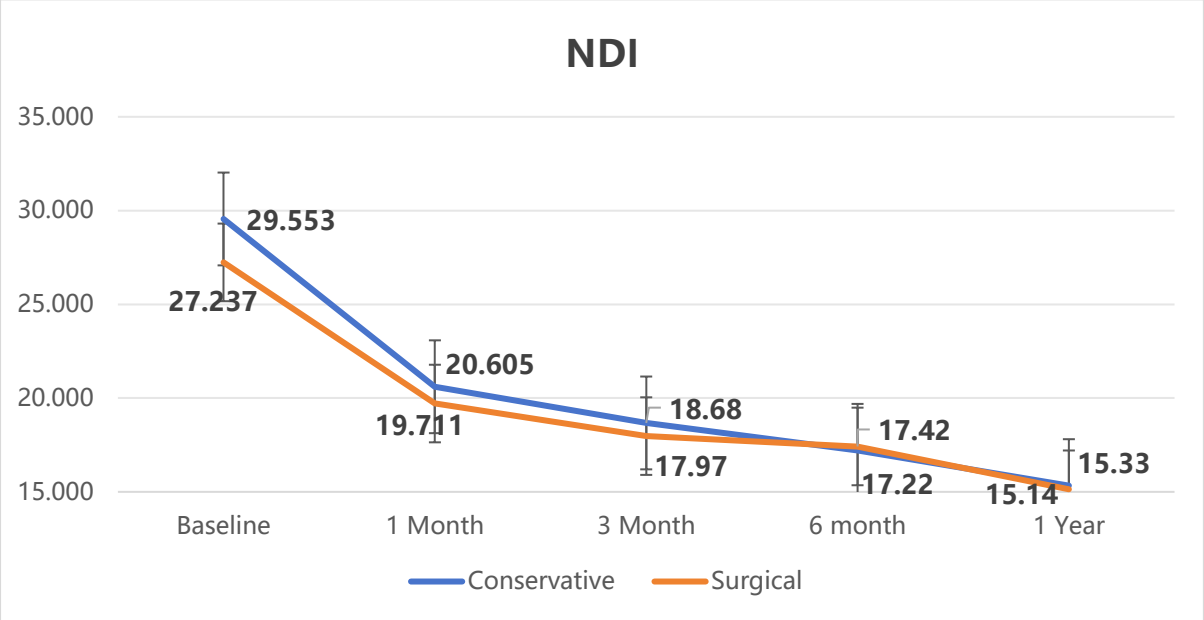


Figure 2. Comparison of Neck Disability Index (NDI) Scores Over Follow-up Period

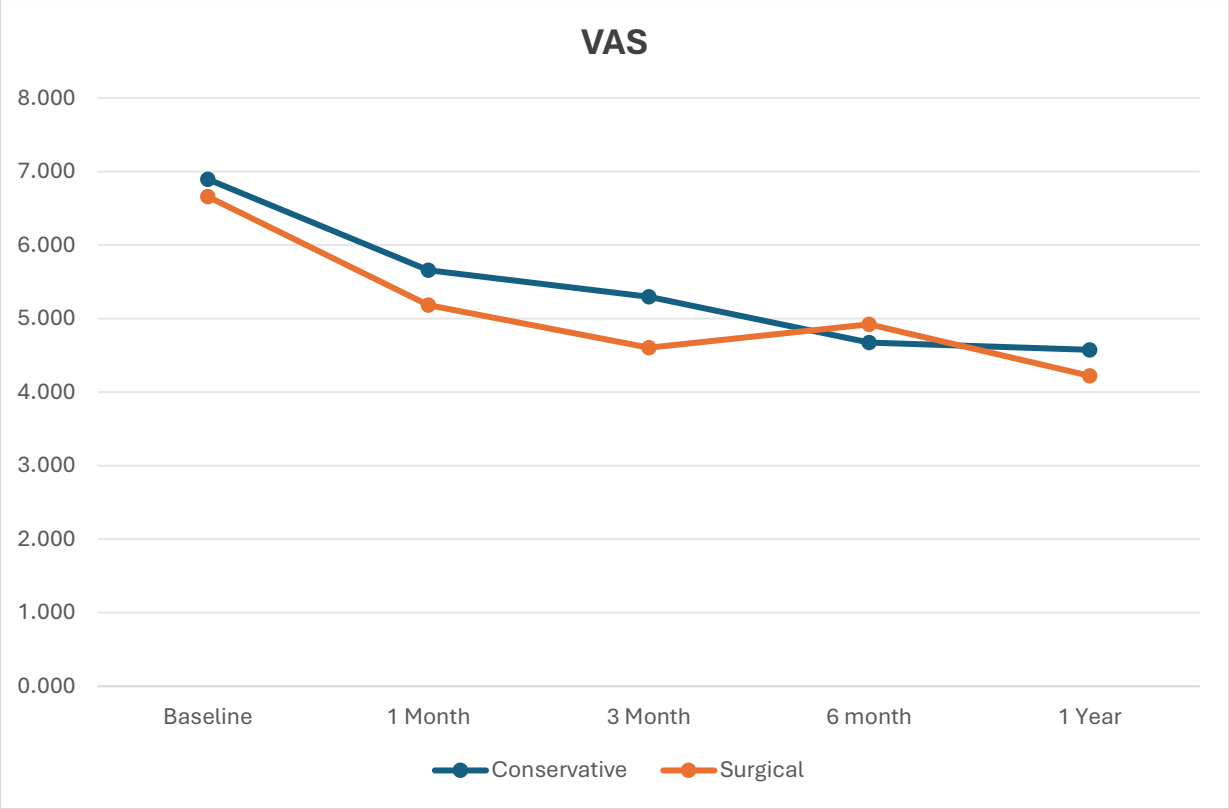


Figure 3. Comparison of Visual Analogue Scale (VAS) Scores Over Follow-up Period

Table 4. Comparison of Continuous Variables (Age, Hospital Stay, ICU Stay) Between Study Groups

Variables	**Group**	**Mean ± SD**	**t value**	**p value**
Age in years	Conservative	79.61±6.64	6.172	**<0.001***
	Surgical	70.32±6.48		
Hospital Stay days	Conservative	14.87±4.39	-7.941	**<0.001***
	Surgical	28.08±9.27		
ICU Stay Days	Conservative	5.18±2.57	-10.548	**<0.001***
	Surgical	12.95±3.74		

*p<0.05-Statistical significance

Table 5. Logistic Regression Analysis of Factors Associated with Treatment Outcomes

Group	**Parameters**	**B**	**S.E.**	**Wald**	**p value**	**OR**	**95% C.I. for EXP(B)**	
							Lower	**Upper**
Conservative	Age in years	-.026	.074	.125	.724	.974	.842	1.126
	Hospital Stay days	-.093	.210	.197	.658	.911	.603	1.376
	ICU Stay Days	.100	.366	.074	.785	1.105	.540	2.262

Surgical	Age in years	-.032	.121	.069	.793	.969	.764	1.228
	Hospital Stay days	.196	.158	1.542	.214	1.217	.893	1.659
	ICU Stay Days	-.327	.533	.375	.540	.721	.254	2.051

Overall, the findings indicate that surgical management is associated with significantly higher fracture union rates and prevention of secondary neurological deficits, albeit at the expense of increased complications and longer hospital and ICU stays. Conservative management, while associated with fewer complications and shorter hospital stay, demonstrated lower union rates and a higher incidence of neurological deterioration.

Discussion

This study compared the outcomes of conservative and surgical treatment of odontoid fractures in 76 patients treated at a tertiary care centre in South India. The results show that surgical treatment gives better fracture healing and protects against neurological problems, while conservative treatment has fewer complications and shorter hospital stay.

The average age was higher in the conservative group (79.61 ± 6.64 years) compared to the surgical group (70.32 ± 6.48 years). This shows that older patients with more health problems are usually treated without surgery due to higher operative risk. This finding is similar to Govind et al. (2022), who reported that age ≥80 years was the main factor for choosing conservative treatment [11]. The higher number of female patients in the conservative group may be due to osteoporosis-related fractures being more common in elderly women, as also reported by Pearson et al. (2016) [12].

Fracture healing was much better in the surgical group (73.3% vs 26.7%; $p < 0.001$). This is in agreement with previous studies. Luksanapruksa et al. (2018) showed in a meta-analysis that surgery leads to better healing rates, especially in Type II fractures [13]. Rocha et al. (2020) also reported similar healing rates (74%) with anterior screw fixation [14]. Poor healing (non-union) can lead to instability and neurological problems later, as shown by Smith et al. (2015), who found worse long-term outcomes in such patients [15].

New neurological problems occurred only in the conservative group ($p = 0.003$). This is an important finding. It may happen due to improper alignment, movement during immobilisation, or instability due to non-union. Patel et al. (2015) also reported that neurological worsening occurred only in conservatively treated patients (14.3%) [6]. Lenarz et al. (2019) similarly found that surgery prevents such neurological complications [16]. The risk of progressive cervical myelopathy from untreated instability is well recognised, and early surgical stabilisation may prevent irreversible cord damage in susceptible patients, as highlighted by Fehlings et al. (2015) [17].

Mortality was higher in the conservative group (71.4% of deaths), but this was not statistically significant ($p = 0.234$). This may be due to older age and more comorbidities in this group rather than the treatment itself. Schoenfeld et al. (2017) also reported no significant difference in

mortality between the two groups after adjusting for age [9]. In geriatric patients undergoing posterior C1-C2 arthrodesis, Molinari et al. (2016) reported acceptable morbidity and mortality outcomes, suggesting that surgical risk can be managed appropriately with careful patient selection [18].

Complications were more common in the surgical group (75% vs 25%; $p = 0.003$). These included problems like implant failure, swallowing difficulty, wound infection, and blood clots. Guo et al. (2018) reported dysphagia in 7.8% of patients after cervical spine surgery [19]. However, infections like pneumonia and urinary infection were seen in both groups, as elderly patients are generally more vulnerable.

Hospital stay (28.08 vs 14.87 days; $p < 0.001$) and ICU stay (12.95 vs 5.18 days; $p < 0.001$) were longer in the surgical group. This is due to surgery, need for monitoring, and management of complications. Elgafy et al. (2015) also reported longer hospital stay and higher costs in surgical patients [7]. Odontoid fractures contribute significantly to the overall burden of traumatic spinal cord injury, and reducing associated complications through optimised treatment pathways remains a priority, as emphasised by Jain et al. (2015) [20].

Both groups showed improvement in functional outcomes (NDI and VAS scores) over one year, but the surgical group had slightly better results. Vaccaro et al. (2013) also found that surgery allows earlier recovery due to better stability and early mobilisation [4].

No independent predictors of outcome were identified in logistic regression analysis. This suggests that outcome depends on multiple factors such as fracture type, patient health, and treatment method, rather than a single factor. Ryken et al. (2013) also reported similar findings [10].

Conclusion

Surgical management of odontoid fractures is associated with higher fracture union rates and a lower risk of secondary neurological deterioration, making it the preferred option in medically fit patients, particularly those with unstable or displaced fractures. However, this benefit comes at the cost of increased complications and longer hospital stay. Conservative management remains a reasonable alternative in elderly or high-risk patients, offering fewer complications but with a higher likelihood of non-union and delayed neurological worsening. From a clinical perspective, treatment should be individualized, balancing fracture characteristics, patient age, comorbidities, neurological status, and surgical fitness to optimize outcomes, especially in resource-limited settings. Further large-scale prospective studies with longer follow-up are needed to establish standardized treatment guidelines.

Limitations

This study was conducted as a retrospective comparative observational study with prospective follow-up, and patients were not randomized to treatment groups. Treatment allocation was based on clinical judgment, including age, fracture characteristics, neurological status, and fitness for surgery, which may introduce selection bias and confounding. Baseline differences in demographic variables, particularly age and gender, were observed between groups and could have influenced outcomes. The study was performed at a

single tertiary care center with a relatively small sample size, which may limit generalizability and reduce the power to detect significant associations. Although fracture healing was assessed using CT-based criteria, the absence of blinded or multiple observer assessment may introduce measurement bias. Mortality was not analyzed based on cause, limiting interpretation of treatment-related outcomes. The follow-up period of 12 months may not adequately capture long-term outcomes such as delayed instability or late neurological deterioration. Detailed analysis of treatment crossover (conversion from conservative to surgical management), including fracture-type-specific indications and duration of prior conservative treatment, was not performed.

Statements and Declaration

Authors' Contributions

VS has contributed to the conceptualization, design of the study, literature search, data acquisition, manuscript editing and review. MMK contributed towards data acquisition Statistical analysis, Manuscript review and editing. VS 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.

Human and animal rights

This article does not contain any studies with human participants or animals performed by any of the authors.

References

1. Iyer S, Hurlbert RJ, Albert TJ. Management of Odontoid Fractures in the Elderly: A Review of the Literature and an Evidence-Based Treatment Algorithm. Neurosurgery. 2018;82(4):419-430. doi: 10.1093/neuros/nyx546.
2. Graffeo CS, Perry A, Puffer RC, et al. Deadly falls: operative versus nonoperative management of Type II odontoid fractures in octogenarians. J Neurosurg Spine. 2017;26(1):4-11. doi: 10.3171/2016.5.SPINE151371.
3. Joaquim AF, Patel AA. Surgical treatment of Type II odontoid fractures: anterior odontoid screw fixation or posterior cervical instrumented fusion? Neurosurg Focus. 2015;38(4):E11. doi: 10.3171/2015.1.FOCUS14781.
4. Vaccaro AR, Kepler CK, Kopjar B, Anderson PA, Harrop J, Arnold P, et al. Functional and quality-of-life outcomes in geriatric patients with type II dens fracture. J Bone Joint Surg Am. 2013;95(8):729-735. doi: 10.2106/JBJS.K.01366.
5. Wang H, Ou L, Zhou Y, Li C, Liu J, Xiang L. Causes and treatment of nonunion in patients with type II odontoid fractures. Medicine (Baltimore). 2015;94(52):e2340. doi: 10.1097/MD.0000000000002340.
6. Patel A, Zakaria R, Al-Mahfoudh R, Clark S, Sarsam Z, Bhatt H. Conservative management of type II and III odontoid fractures in the elderly at a regional neurosurgical centre: a prospective and retrospective cohort study. Br J Neurosurg. 2015;29(2):249-253. doi: 10.3109/02688697.2014.987165.

7. Elgafy H, Potluri T, Goel VK, Foster J, Fauth AR, Rui Z. Cost-effectiveness analysis comparing anterior odontoid screw fixation and posterior cervical fusion for type II odontoid fracture. Spine J. 2015;15(5):1-7. doi: 10.1016/j.spinee.2014.09.001.
8. Guo Q, Deng Y, Wang J, Lu X, Liu Y, Yang H, et al. Comparison of anterior odontoid screw fixation and posterior C1-C2 fusion for type II odontoid fractures: a meta-analysis. Eur Spine J. 2018;27(4):814-824. doi: 10.1007/s00586-017-5391-1.
9. Schoenfeld AJ, Bono CM, Reichmann WM, Warholic N, Wood KB, Losina E, et al. Type II odontoid fractures of the cervical spine: do treatment type and medical comorbidities affect mortality in elderly patients? Spine. 2017;36(11):879-885. doi: 10.1097/BRS.0b013e3181e5efeb.
10. Ryken TC, Hadley MN, Aarabi B, Dhall SS, Gelb DE, Hurlbert RJ, et al. Management of isolated fractures of the axis in adults. Neurosurgery. 2013;72(Suppl 2):132-150. doi: 10.1227/NEU.0b013e318276ee3e.
11. Govind SK, Banu A, Mohamed Yusoff MN, Mohamed Saufi HA, Abdullah S. Outcome of odontoid fractures in elderly patients: conservative versus surgical management. Asian Spine J. 2022;16(5):704-712. doi: 10.31616/asj.2021.0237.
12. Pearson AM, Martin BI, Lindsey M, Mirza SK. C2 fracture types, comorbidities, and factors associated with surgical treatment. J Bone Joint Surg Am. 2016;98(10):815-823. doi: 10.2106/JBJS.15.00920.
13. Luksanapruksa P, Millhouse PW, Carlson VR, Lentz SL, Kepler CK, Vaccaro AR. Surgical versus conservative treatment of type II odontoid fractures in patients 65 years and older: a meta-analysis. Spine J. 2018;18(1):195-208. doi: 10.1016/j.spinee.2017.06.016.
14. Rocha ID, Joaquim AF, Ghizoni E, Tedeschi H. Surgical and clinical outcomes of patients with type II odontoid fractures treated with anterior odontoid screw fixation. World Neurosurg. 2020;138:e1-e7. doi: 10.1016/j.wneu.2019.11.099.
15. Smith JS, Kepler CK, Kopjar B, Harrop JS, Arnold P, Chapman JR, et al. Effect of type II odontoid fracture nonunion on outcome among elderly patients treated without surgery. Neurosurgery. 2015;72(4):525-531. doi: 10.1227/NEU.0000000000000344.
16. Lenarz CJ, Golob JF, Finer G, Devin CJ, Shedid D. Surgical versus conservative management of type II odontoid fractures: a retrospective multicenter study. Clin Spine Surg. 2019;32(7):E313-E317. doi: 10.1097/BSD.0000000000000816.
17. Fehlings MG, Tetreault LA, Wilson JR, Skelly AC. Cervical spondylotic myelopathy: current state of the art and future directions. Spine. 2015;40(24):E1298-E1299. doi: 10.1097/BRS.0000000000001203.
18. Molinari RW, Khera OA, Molinari WJ. Functional outcomes, morbidity, mortality, and fracture healing in 26 geriatric patients with type II dens fractures treated with posterior C1-C2 arthrodesis. J Spinal Disord Tech. 2016;22(6):399-405. doi: 10.1097/BSD.0b013e318181c595.

19. Guo Q, Wang L, Zhang S, Zhang Z, Chen L, Xu B, et al. Symptomatic dysphagia following anterior cervical spine surgery: incidence, risk factors, and short-term outcomes. World Neurosurg. 2018;113:e579-e586. doi: 10.1016/j.wneu.2018.02.091.

20. Jain NB, Ayers GD, Peterson EN, Harris MB, Morse L, O'Connor KC, et al. Traumatic spinal cord injury in the United States, 1993-2012. JAMA. 2015;313(22):2236-2243. doi: 10.1001/jama.2015.6250.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 785–796, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.013

ORIGINAL ARTICLE

Evaluating Knowledge, Attitude, and Perception on Needle Stick Injuries among Medical Students in a Tertiary Care Centre: A Cross-sectional Observational Study

Vinni Greesha V,[1] Naveena Arulanandan,[2] Soundarya R,[2] B. Ananthi,[3] Sivaharivelan Thiagarajan[4,*] and Balakumar M[4]

[1]*Postgraduate, Department of Microbiology, ACS Medical College and Hospitals, Dr. M.G.R. Educational and Research Institute, Maduravoyal, Chennai*
[2]*Assistant Professor, Department of Microbiology, ACS Medical College and Hospitals, Dr. M.G.R. Educational and Research Institute, Maduravoyal, Chennai*
[3]*Professor and Head, Department of Microbiology, ACS Medical College and Hospitals, Dr. M.G.R. Educational and Research Institute, Maduravoyal, Chennai*
[4]*Assistant Professor, Department of Community Medicine, ACS Medical College and Hospitals, Dr. M.G.R. Educational and Research Institute, Maduravoyal, Chennai*

Accepted: 14-April-2026 / Published Online: 6-May-2026

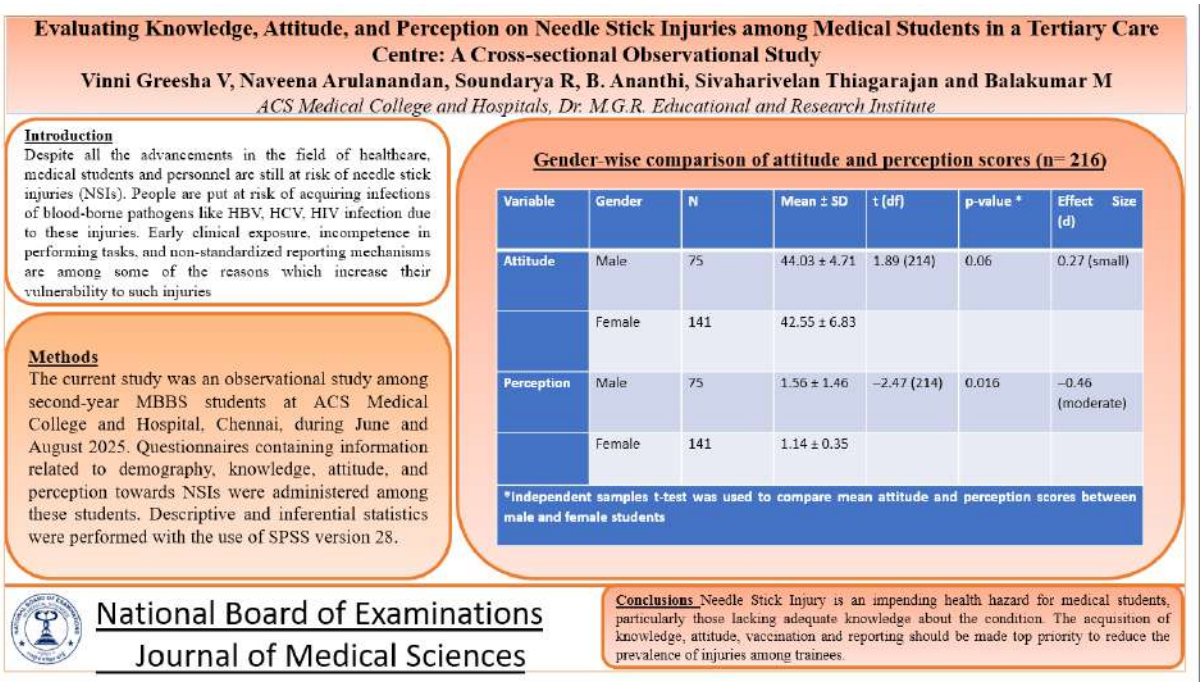
Abstract

Introduction: Despite all the advancements in the field of healthcare, medical students and personnel are still at risk of needle stick injuries (NSIs). People are put at risk of acquiring infections of blood-borne pathogens like HBV, HCV, HIV infection due to these injuries. Early clinical exposure, incompetence in performing tasks, and non-standardized reporting mechanisms are among some of the reasons which increase their vulnerability to such injuries. **Objective:** The purpose of this research paper is to determine the KAP of second-year MBBS students about NSIs and find out any risk factors and underreporting. **Material and Methods:** The current study was an observational study among second-year MBBS students at ACS Medical College and Hospital, Chennai, during June and August 2025. Questionnaires containing information related to demography, knowledge, attitude, and perception towards NSIs were administered among these students. Descriptive and inferential statistics were performed with the use of SPSS version 28. **Results:** In total, among the 216 participants, 53.4% had adequate knowledge about NSIs while 46.6% of the respondents had inadequate knowledge. However, there was no association between knowledge and gender, although there was a statistical difference in perceptions of knowledge based on gender ($P = 0.016$). The prevalence rate of NSIs was significantly higher among respondents having inadequate knowledge (23.5%) compared to those having adequate knowledge (6.8%) ($P = 0.001$). There was a significant positive association of knowledge with attitude but not with perceptions ($P<0.05$). Underreporting of injuries and incomplete vaccination coverage against hepatitis B were noted. **Conclusion:** Needle Stick Injury is an impending health hazard for medical students, particularly those lacking adequate knowledge about the condition. The acquisition of knowledge, attitude, vaccination and reporting should be made top priority to reduce the prevalence of injuries among trainees.

Keywords: Needle stick injuries, Medical students, Occupational hazard, Reporting behaviour

*Corresponding Author: Sivaharivelan Thiagarajan
Email: sivaharivelantry@gmail.com

Graphical Abstract



Introduction

Needle Stick Injury (NSI) can be termed as one of the frequent hazards experienced in the work environment by healthcare professionals. The frequency of this risk is higher in underdeveloped countries owing to the absence of an internationally accepted protocol that can help prevent these risks. According to the World Health Organization (WHO) statistics, about three million health care professionals suffer from NSIs every year, exposing themselves to the risk of blood-borne infections like HBV, HCV, and HIV infection [1].

Being inexperienced, unmonitored, and ashamed of their mistakes make medical students particularly susceptible to NSIs. These students have to carry out invasive procedures on patients as part of their initial training which makes them even more vulnerable to NSIs, hence reducing the likelihood of reporting them. As a result, the utilization of post-exposure prophylaxis becomes impossible. However, aside from the physical impact of NSIs, other repercussions of NSIs include stress and decreased confidence in carrying out clinical procedures [14-17].

Knowledge, attitudes, and perception (KAP) have a profound effect on safety results. Knowledge can be defined as awareness concerning modes of transmission, precautionary measures, vaccines, and post-exposure treatment. Although guidelines have been set by the WHO and CDC, the level of knowledge is still relatively low [3]. Attitudes dictate whether students will comply with safety protocols; however, some students exhibit dangerous behavior such as recapitulating needles and not using gloves. Perception affects reporting practices and research indicates that students fear stigmatization and distrusting the reporting process cause underreporting [3,4].

Infection due to NSIs occurs frequently across the globe. In India, it is

estimated that one out of three students experience an accidental prick wound during training. The problem is further aggravated in resource-poor settings because of poor waste disposal. KAP evaluation can assist in addressing problems, modifying curriculum, and fostering proactive safety measures. Measures such as workshops and vaccine drives can create a conducive atmosphere for safe practice [5].

What sets this research apart from the others is that it considers the second-year medical students as its target population when they are still at the initial stages of exposure to clinical practice, which makes it relatively easier to determine the risk factors in these situations, even before the bad practices become habitual among them.

This study is the first to capture KAP during the early stages of training; much of the material currently in print focuses on interns and senior workers. The KAP paradigm was adopted because NSIs are caused by a combination of perceptual limitations, attitude inadequacies, and knowledge gaps. A cross-sectional design was selected as appropriate for a prevalence and KAP survey, according to Alsabaani et al. (2022) and Datar et al. (2022) [3,4].

The primary purpose of the current study is to estimate the frequency and risk factors of these events and to assess the knowledge, attitude, and perceptions of the second-year MBBS students.

Principal Objective

Evaluation of the knowledge, attitude, and perception of second-year MBBS students towards needle stick injury.

Secondary Objectives

1. Estimating the prevalence rate of needle stick injury among second-year MBBS students.
2. Investigation into the relationship between the frequency of needle stick injury and knowledge level.
3. Relationship investigation of demography factors like age and gender in relation to knowledge, attitude, and perception.
4. Hepatitis B vaccination evaluation of subjects under study.

Materials and Methods

A cross-sectional descriptive study was carried out for a duration of three months from June 2025 to August 2025 in ACS Medical College and Hospital in Chennai. A stratified sampling method was employed, which resulted in a sample size of 216 second-year MBBS students. Before carrying out the process of data collection, informed consent was taken from all participants, and permission for the study was granted by the Institutional Human Ethics Committee of ACS Medical College and Hospital, Chennai (IEC approval no.: No.110/2025/IEC/ACSMCH dt22.07.2025).

Inclusion Criteria

Second-year MBBS students who volunteered to participate in the study (n=216). Second-year MBBS students were selected for the study as they represent one of the initial stages of clinical experience which is relevant for assessing the knowledge, attitudes, and perceptions amongst various stages of clinical training; whereas other stages of MBBS, CRRIs, and paramedical students were not considered for the study.

Exclusion Criteria

First-year, third-year, and fourth-year MBBS students, CRRIs, and paramedical students were not considered for the study.

The survey was conducted with the help of a well-prepared, structured questionnaire after conducting a thorough literature search. The total number of questions used in the questionnaire was thirty, ten being based on knowledge in multiple choice form, ten on attitudes using five-point Likert scale, and ten on perception either yes/no or frequency type. The questionnaire was designed by the researchers after literature review and considering the suggestions of subject matter experts from the fields of Community Medicine and Microbiology to ensure inclusion of only relevant questions. Content validity was established through expert assessment. Prior to the major data collection, a pilot study was carried out to evaluate feasibility and clarity; small changes were made in response to comments.

The principal investigator of this research is a post-graduate in the field of Microbiology who is experienced in questionnaire-based researches; the language of the questionnaire is English.

Statistical Package for Social Sciences (SPSS) version 27 was used for analysis, where the data were entered into an Excel sheet. The data analysis was done using descriptive statistics, where the results were summarized by frequency, percentage, mean, and standard deviation. Inferential statistics were done by the Chi-Square test to show the relationship between demographics and knowledge, attitude, and perception scores. Statistical significance level was considered as p-value < 0.05.

Results

The maximum number of respondents belongs to the age range between 15 and 20 years old that formed 68.1% of the total respondents (n = 147). The next age range is between 21 and 25 years old, constituting 31.1% (n = 68) of the total respondents. There was only one respondent belonging to the age range between 26 and 30 years old (Table 1).

Table 1. Age Distribution of Participants (n= 216)

Age	Frequency	Percent (%)
15-20	147	68.1
21-25	69	31.9
Total	216	100.0

Table 2. Descriptive statistics of age and gender distribution of participants (n= 216)

Variable	Category	Value
Age (years)	Mean ± SD	20.47 ± 1.89
	Minimum	18
	Maximum	30
Gender	Female	141 (65.28%)
	Male	75 (35.72%)
	Total	216 (100.0%)

The participants were 216 second-year MBBS students, whose mean age was 20.47±1.89 years, reflecting a smaller age range than normally observed in undergraduate medical students. The minimum age of the participants was 18 years, while the maximum age was 30 years. In terms of gender distribution, females were more in number compared to males, accounting for 65.8% and 35.2%, respectively (Table 2).

Table 3. Knowledge levels by gender among study participants (n = 216)

Gender	Inadequate Knowledge n (%)	Adequate Knowledge n (%)	Total n (%)
Female (n = 141)	67 (47.52%)	74 (52.48%)	141 (65.28%)
Male (n = 75)	34 (45.33%)	41 (54.67%)	75 (34.72%)
Total (n = 216)	101 (46.76%)	115 (53.24%)	216 (100.00%)

From a total of 216 respondents, 53.24% of them had sufficient knowledge regarding needle-sticks injury whereas 46.76% of them had insufficient knowledge. The proportion of females who had sufficient knowledge was 52.48% whereas those with insufficient knowledge comprised 47.52%. The same was true for males; 54.67% of them had sufficient knowledge and 45.33% had insufficient knowledge. It is evident from the above data that both genders had equal knowledge levels. Therefore, statistically there was no difference between sex and knowledge level (Table 3).

Table 4. Gender-wise comparison of attitude and perception scores (n= 216)

Variable	Gender	N	Mean ± SD	t (df)	p-value *	Effect Size (d)
Attitude	**Male**	**75**	**44.03 ± 4.71**	**1.89 (214)**	**0.06**	**0.27 (small)**
	Female	**141**	**42.55 ± 6.83**			
Perception	**Male**	**75**	**1.56 ± 1.46**	**–2.47 (214)**	**0.016**	**–0.46 (moderate)**
	Female	**141**	**1.14 ± 0.35**			
*Independent samples t-test was used to compare mean attitude and perception scores between male and female students						

The mean score of attitudes was greater among the male students (44.03 ± 4.71) compared to the female students (42.55 ± 6.83), but there was no statistical significance in their means (t = 1.89, df = 214, p = 0.06). Contrarily, there was statistical significance in the mean score of perception, whereby men performed better with the mean score of 1.56 ± 1.46 compared to women with mean score 1.14 ± 0.35 (t = -2.47, df = 214, p = 0.016), which is a moderate effect size (Table 4).

Table 5. Age-wise comparison of attitude and perception scores (n= 216)

Age Group (Years)	n (%)	Attitude Score (M±SD)	Perception Score* (M±SD)
15–20	147 (68.1%)	43.26 ± 5.17	12.50 ±10.90
21-30	69 (31.9%)	43.85 ± 6.35	13.60 ± 4.90
Total	**216 (100%)**	**43.49 ± 5.58**	**12.90 ± 9.30**
t-statistic (df)		t (214) = -0.715	t (214) = -0.812
p-value		0.475	0.417

There was no statistical significance in terms of attitude between the age groups of 15-20 years (43.26 ± 5.17) and the age group of 21-30 years (43.85 ± 6.35). This is evident from the t-statistic (-0.715), degree of freedom (214), and probability value (0.475). In addition, there was also no statistical significance in the mean scores of perceptions between the two age groups. The mean scores of the perceptions among the respondents aged between 15-20 years were 12.50 ± 10.90 compared to the mean score of the perceptions among the respondents aged between 21-30 years which were 13.60 ± 4.90 (Table 5).

Table 6. Correlation between knowledge level, attitude score, and perception score (n = 216)

S.No	Variable	Mean ± SD	1	2	3
1.	Knowledge (Categorical)	N/A*	1		
2.	Attitude Score	43.51 ± 5.57	r_{pb} = .281**	1	
3.	Perception Score	12.90 ± 9.30	r_{pb} = .092	r =.159*	1

Knowledge is reported as a categorical variable; Mean/SD is omitted as it is non-continuous. **Correlation is significant at the 0.01 level (2-tailed). *Correlation is significant at the 0.05 level (2-tailed). r = Pearson's correlation coefficient (for continuous variables); r_{pb} used for associations with Knowledge.

There was a positive relationship between knowledge and attitude scores (rpb=0.281; p<0.01), which means that knowledgeable individuals held positive attitudes towards preventing needlestick injuries. There was no relationship between knowledge and perception scores (rpb=0.092). A significant yet weak correlation was observed between attitude and perception scores (r=0.159; p<0.05). Based on the results above, there is evidence to suggest that improving knowledge levels can have a positive effect on attitudes, but other variables may affect perceptions and reporting behaviors (Table 6).

Table 7. Association of Knowledge with Prevalence of Needle Stick Injuries (n= 216)

Knowledge Category	NSI: Yes (n, %)	NSI: No (n, %)	Total (n)
Inadequate	**24 (23.5%)**	**78 (76.5%)**	**102**
Adequate	**8 (7.0%)**	**106 (93.0%)**	**114**
Total	**32 (14.8%)**	**184 (85.2%)**	**216**
Statistical Test		**χ^2 = 11.58**	**p < 0.001***
* p value < 0.05 is statistically significant			

In terms of the frequency of needle-stick injury among the respondents, a significantly higher proportion of students with low knowledge (23.5%) were recorded compared to those with high knowledge (7%). There was also a significantly significant association between knowledge level and needle stick injury (χ^2 = 11.58; df = 1; p < 0.001) (Table 7).

Discussion

This study was conducted among second-year MBBS students and shows that more than half the respondents had adequate knowledge concerning needlestick injuries (NSIs). However, there were also a considerable number of students who showed inadequate knowledge about NSIs. This suggests that even in the very early stages of clinical practice, there is a significant lack of knowledge concerning NSIs, which can cause health complications in the future. Previous studies have shown similar findings among medical students from India and other developing nations, who are exposed to invasive procedures prior to receiving formal training in infection control.

Bhattarai et al. (2014) and Sharma et al. (2010) reported similar levels of expertise [5,8]. Our 14.8% NSI prevalence is in line with studies conducted in India (Salelkar et al., 2010; Giri et al., 2013) [6,18]. The modest correlation (r=0.159) between attitude and perception suggests that stigma and institutional barriers affect perceptions in addition to attitude.

Our finding that 53.24% of participants had sufficient knowledge on NSIs is consistent with prior data from developing nations like India. Similar trends were found by Bhattarai et al. (2014) [8] among Nepali medical students, while Sharma et al. (2010) [5] found that healthcare personnel in a Delhi tertiary care facility had modest levels of expertise. Although it is lower than global meta-analytic estimates (Auta et al., 2018) [22], the prevalence of NSIs in our study (14.8%) is consistent with estimates from similar cross-sectional studies in India (Salelkar et al., 2010; Giri et al., 2013) [6,18], which may reflect the early-stage clinical exposure of second-year students. The substantial positive association between knowledge and attitude ($r_s b = 0.281$, $p < 0.01$) supports the findings of Datar et al. (2022) [4] and Alsabaani et al. (2022) [3], who also discovered that knowledge significantly influenced safe attitudes. The results of our study regarding underreporting of NSIs and inadequate hepatitis B immunization are in line with other South Asian contexts (Bekele et al., 2015; Kessler et al., 2011) [16,21].

The weak but statistically significant relationship ($r = 0.159$, $p < 0.05$) between attitude and perception evaluations is an interesting and complicated discovery. This can be explained by the fact that different underlying variables drive attitudes, which indicate intention and value-based ideas about safety, and perceptions, which represent subjective risk interpretation and reporting behaviour. Even though a student might be in favour of wearing gloves and following standard precautions, they might misjudge the severity of an accidental needle prick or be terrified of the social stigma associated with reporting it (perception). This distinction between attitude and perception has been noted in several occupational health studies, highlighting the need for behavioural interventions to address perceptual social barriers to safe reporting in addition to altering attitudes.

Based on the findings regarding the comparison of different age groups, it became clear that there was no difference between younger and older individuals regarding attitude and perception measures. This may be explained by the fact that a small range of age groups were chosen for the study and had similar levels of involvement in practicing medicine. Other studies conducted with a greater number of

respondents, including interns and senior medical students, reported a lot of differences between perception and attitude levels of respondents based on their experience in the field.

It is evident from the results of correlation analysis that a statistically significant relationship exists between the variables knowledge and attitude, which implies that the more knowledge there is, the more positive attitude towards NSI prevention will exist among healthcare students. This conclusion is based on the evidence provided by the studies carried out by Datar et al. (2022) [4] and Alsabaani et al. (2022) [3], who found that awareness of the risks associated with transmission and the corresponding preventive measures affects positively the adherence to standard precautions. However, since no significant correlation was found between attitude and perception, it is clear that the latter may be influenced by other factors apart from knowledge.

A relationship existed in that the prevalence of NSIs was significantly high in people having inadequate knowledge as compared to those with adequate knowledge. The same relationship could be seen from various studies that have been done in countries like India, Pakistan, and Nepal. According to these findings, a lack of adequate knowledge on the risk of hepatitis B vaccination and non-completion of vaccination were major reasons for NSIs and their under-reporting. There is need for adopting measures like compulsory hepatitis B vaccination, education on handling sharp objects, and reporting of the injuries within the medical colleges.

Conclusion

Needle stick injury continues to pose a significant occupational danger to medical students, particularly during their initial encounters in practical settings. In this investigation, roughly fifty percent of the subjects possessed adequate knowledge about the topic; nevertheless, many were found to have inadequate knowledge on the same, as well as insufficient knowledge regarding the proper procedures for reporting and managing needle stick injuries. Students who possess minimal knowledge are more prone to being injured; therefore, knowledge affects the degree of safety measures adopted. Although no gender difference was observed in relation to knowledge levels among the students, various perspectives emerged, which could affect safety practices. It is imperative that such safety measures are adopted to enhance safety among the students.

Recommendation

In light of the results of the current study, we recommend the following lines of investigation for more research:

1. Longitudinal or prospective cohort studies that track changes in KAP and NSI incidence during all clinical years of MBBS training could establish causal links.
2. Research carried out at several institutions in diverse institutional and geographical settings would improve generalizability outside of a single tertiary care center.
3. Interventional research evaluating the effectiveness of targeted educational seminars, simulation-based training, and structured reporting systems would provide evidence for best practices.
4. Qualitative research investigating the reasons for underreporting, such as institutional barriers, fear of stigma, or ignorance about post-exposure

prophylaxis, would improve the quantitative results of this study.

Limitations

1. Cross-sectional design: The study cannot establish a causal relationship between KAP variables and the incidence of NSI because it only examines a single point in time.
2. Single-institution setting: Because the study was conducted exclusively at ACS Medical College and Hospital in Chennai, its application to other healthcare institutions, regions, and systems is restricted.
3. Self-reported data: Responses are prone to recall bias and social desirability bias because participants may have overreported knowledge or underreported NSI incidents and risky behaviors.
4. Limited study population: Our understanding of how KAP changes during clinical training was limited since only second-year MBBS students were included, making it impossible to compare data across academic years.

Acknowledgments

We wish to express our sincere appreciation to all those undergraduate medical students who participated voluntarily in this study. We are thankful to the staff and administration of ACS Medical College & Hospital, Chennai, for their cooperation in conducting this research.

Ethical Approval

Ethics Committee approval received from ACS Medical College and Hospital, Chennai (IEC approval no.: No.110/2025/IEC/ACSMCH dt22.07.2025).

Conflicts of interest

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

Funding

No funding was received for conducting this study.

References

1. Himmelsreich H, Rabenau HF, Rindermann M, Stephan C, Bickel M, Marzi I, Wicker S. The management of needlestick injuries. Deutsches Ärzteblatt International. 2013;110(5):61–67. doi:10.3238/arztebl.2013.006
2. Saleem T, Khalid U, Ishaque S, Zafar A. Knowledge, attitudes and practices of medical students regarding needle stick injuries. Journal of Pakistan Medical Association. 2010;60(2):151–156.
3. Alsabaani A, Alqahtani NSS, Alqahtani SSS, Al-Lugbi JHJ, Asiri MAS, Salem SEE, Alasmari AA, Mahmood SE, Alalyani M. Incidence, knowledge, attitude, and practice toward needle stick injury among healthcare workers in Abha City, Saudi Arabia. Frontiers in Public Health. 2022;10:771190. doi:10.3389/fpubh.2022.771190
4. Datar UV, Kamat M, Khairnar M, Wadgave U, Desai KM. Needlestick and sharps injury in healthcare students: prevalence, knowledge, attitude and practice. Journal of Family Medicine and Primary Care. 2022;11(10):6327–6333. doi: 10.4103/jfmpc.jfmpc_155_22

5. Sharma R, Rasania SK, Verma A, Singh S. Study of prevalence and response to needle stick injuries among health care workers in a tertiary care hospital in Delhi, India. Indian J Community Med. 2010;35(1):74–77.
6. Salelkar S, Motghare DD, Kulkarni MS, Vaz FS. Study of needle stick injuries among health care workers at a tertiary care hospital. Indian J Public Health. 2010;54(1):18–20.
7. Afridi AAK, Kumar A, Sayani R. Needle stick injuries—risk and preventive factors: a critical appraisal. Int J Occup Med Environ Health. 2013;26(4):593–600.
8. Bhattarai S, KC S, Pradhan PM, Lama S, Rijal S. Hepatitis B vaccination status and needle-stick and sharps-related injuries among medical students in Nepal: a cross-sectional study. BMC Res Notes. 2014;7:774.
9. Krishna C, Sah S, Reddy S, et al. Hepatitis B coverage and its awareness among medical students. J Dr DY Patil Vidyapeeth. 2024;13(4):267–272.
10. Tarantola A, Golliot F, Astagneau P, Fleury L, Brucker G, Bouvet E. Occupational blood and body fluids exposures in health care workers: four-year surveillance from the Northern France network. Am J Infect Control. 2003;31(6):357–363.
11. Trim JC, Elliott TSJ. A review of sharps injuries and preventative strategies. J Hosp Infect. 2003;53(4):237–242.
12. Wicker S, Rabenau HF. Occupational exposures to blood-borne viruses among German medical students and physicians: risk awareness and infection control practices. J Hosp Infect. 2010;76(3):258–259.
13. Prüss-Üstün A, Rapiti E, Hutin Y. Estimation of the global burden of disease attributable to contaminated sharps injuries among health-care workers. Am J Ind Med. 2005;48(6):482–490.
14. Trim JC, Elliott TSJ. A review of sharps injuries and preventative strategies. J Hosp Infect. 2003;53(4):237–242.
15. Nsubuga FM, Jaakkola MS. Needle stick injuries among nurses in sub-Saharan Africa. Trop Med Int Health. 2005;10(8):773–781.
16. Bekele T, Gebremariam A, Kaso M, Ahmed K. Attitude, reporting behaviour and prevention of needle stick injuries among healthcare workers. BMC Res Notes. 2015;8:555.
17. Centers for Disease Control and Prevention (CDC). Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV. MMWR Recomm Rep. 2013;62(RR-10):1–24.
18. Giri PA, Waghmare MM, Phalke DB. Knowledge and practice of needle stick injuries among healthcare workers in a tertiary care hospital of rural India. Natl J Community Med. 2013;4(2):284–288.
19. Yazie TD, Chufa KA, Tebeje MG. Prevalence of needlestick injury among healthcare workers in Ethiopia: a meta-analysis. Environ Health Prev Med. 2019;24:52.
20. Deisenhammer S, Radon K, Nowak D, Reichert J. Needlestick injuries

during medical training. J Hosp Infect. 2006;63(3):263–267.
21. Kessler CS, McGuinn M, Spec A, et al. Underreporting of blood and body fluid exposures among health care students and trainees: a systematic review. Acad Med. 2011;86(12):1581–1587.
22. Auta A, Adewuyi EO, Tor-Anyiin A, et al. Global prevalence of occupational exposure to needle stick injury among healthcare workers: a systematic review and meta-analysis. Can J Infect Dis Med Microbiol. 2018;2018:4878359.
23. Makary MA, Al-Attar A, Holzmueller CG, et al. Needlestick injuries among surgeons in training. N Engl J Med. 2007;356(26):2693–2699.
24. Do AN, Ciesielski CA, Metler RP, et al. Occupationally acquired human immunodeficiency virus (HIV) infection: national case surveillance data during 20 years of the HIV epidemic in the United States. Infect Control Hosp Epidemiol. 2003;24(2):86–96.
25. Rampal L, Zakaria R, Sook LW, Zain AM. Needle stick and sharps injuries and factors associated among health care workers in a Malaysian hospital. Epidemiol Infect. 2010;138(5):709–16.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 797–809, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.014

ORIGINAL ARTICLE

A Prospective Study on Manipulation with Hydrodilatation and Steroid Injection in the Management of Frozen Shoulder

V. Ramson,[1,*] T. Thirumalaiswamy[2] and Ranjithkumar R[1]

[1]*Assistant Professor, Department of Orthopaedics, Government Medical College and ESIC Hospital, Coimbatore, Tamil Nadu*
[2]*Associate Professor, Department General Surgery, Dhanalakshmi Srinivasan Medical College, Siruvachur, TamilNadu*

Accepted: 12-April-2026 / Published Online: 6-May-2026

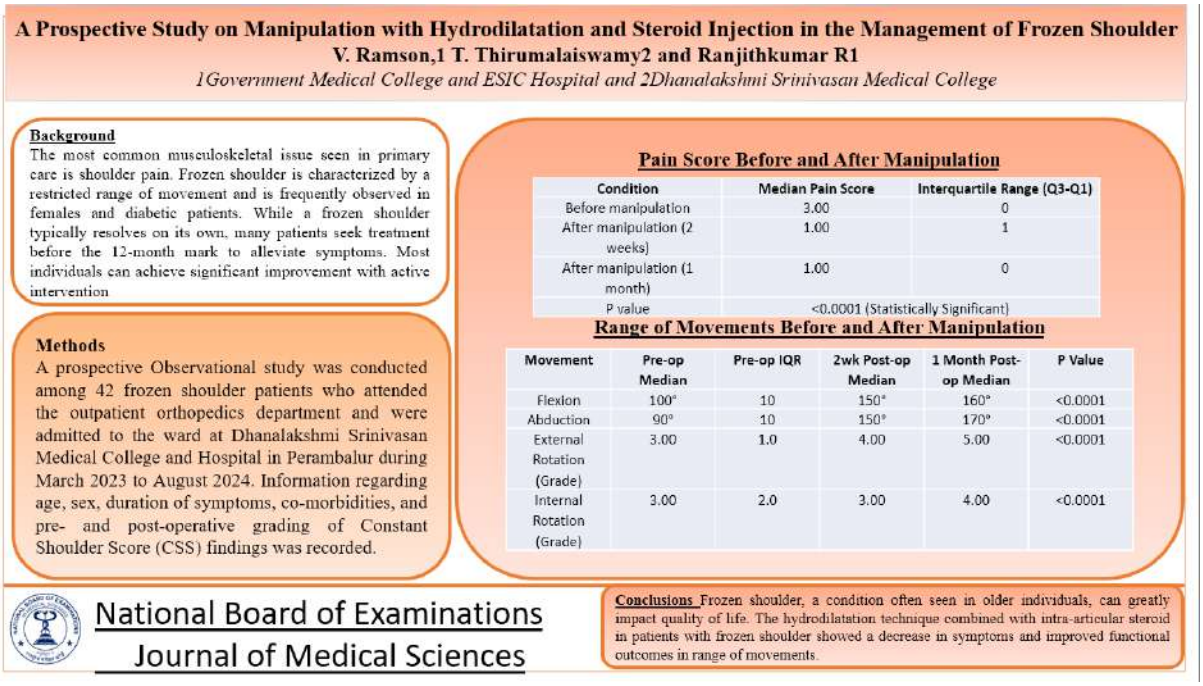
Abstract

Background: The most common musculoskeletal issue seen in primary care is shoulder pain. Frozen shoulder is characterized by a restricted range of movement and is frequently observed in females and diabetic patients. While a frozen shoulder typically resolves on its own, many patients seek treatment before the 12-month mark to alleviate symptoms. Most individuals can achieve significant improvement with active intervention. **Objective:** To evaluate the pain severity and range of movements in patients with frozen shoulders using the Constant Shoulder Score (CSS) after manipulation with hydrodilatation and steroid treatment. **Methodology:** A prospective Observational study was conducted among 42 frozen shoulder patients who attended the outpatient orthopedics department and were admitted to the ward at Dhanalakshmi Srinivasan Medical College and Hospital in Perambalur during March 2023 to August 2024. Information regarding age, sex, duration of symptoms, co-morbidities, and pre- and post-operative grading of Constant Shoulder Score (CSS) findings was recorded. **Results:** Frozen shoulder was commonly observed in females between 40 and 49 years of age, with the left shoulder most frequently affected. Diabetes mellitus was the most commonly associated risk factor. Following manipulation using the hydrodilatation technique and steroid injection, there was a significant improvement in shoulder pain and range of movements, assessed using Constant Shoulder Score ($p=0.000$). **Conclusion:** Frozen shoulder, a condition often seen in older individuals, can greatly impact quality of life. The hydrodilatation technique combined with intra-articular steroid in patients with frozen shoulder showed a decrease in symptoms and improved functional outcomes in range of movements. This treatment is also cost-effective and allows for early mobilization and return to day-to-day activities.

Keywords: Frozen shoulder, Periarthritis shoulder, Hydrodilatation technique, Intra-articular corticosteroid injection, Constant shoulder score

*Corresponding Author: V. Ramson
Email: vtramu@gmail.com

Graphical Abstract



Introduction

Shoulder pain is the third most frequent musculoskeletal problem. In primary care, the reported yearly incidence of shoulder discomfort is 14.7 per 1000 patients per year, with a lifetime prevalence of up to 70% [1]. Frozen shoulder (adhesive capsulitis) is a common debilitating disorder characterized by shoulder pain and progressive loss of shoulder movement [2]. The American Shoulder and Elbow Surgeons' currently accepted definition is “a condition of uncertain etiology characterized by significant restriction of both active and passive shoulder motion that occurs in the absence of a known intrinsic shoulder disorder” [3].

Neviaser coined the term "adhesive capsulitis" for the idiopathic form of shoulder mobility loss caused by capsular contractures and adhesions. Patients with idiopathic stiffness are typically between the ages of 40 and 60, with the non-dominant arm more commonly implicated [2]. Women account for roughly 70% of patients. In 20% to 30% of those affected, the problem rarely returns in the same shoulder [4].

Adhesive capsulitis affects approximately 2-5% of the general population, with a higher prevalence in patients with diabetes mellitus (up to 20%), thyroid disorders, prolonged immobilization, hyperlipidemia, cerebrovascular accident or myocardial ischemia, and autoimmune diseases [1,5]. Millar et al. (2022) described frozen shoulder as a fibroproliferative disorder characterized by fibroblast transformation into myofibroblasts, accompanied by inflammation, neoangiogenesis and neoinnervation leading to capsular fibrotic contracture [2].

The association between diabetes mellitus and frozen shoulder is well established. Dyer et al. (2023) conducted a systematic review and meta-analysis of six longitudinal observational studies and found that people with diabetes had 3.69 (95% CI 2.99 to 4.56) times the risk of

developing frozen shoulder compared to those without diabetes [5]. Kim et al. (2023) confirmed in a large nationwide population-based study that both prediabetes and type 2 diabetes significantly increase the risk of shoulder adhesive capsulitis [6].

The reduction in passive range of movements is important to determine the presence of frozen shoulder. Frozen shoulder is a self-limiting illness that lasts 12 to 18 months in most patients with no long-term consequences; however, approximately 10% of people suffer long-term issues [2]. Treatment options include supervised physical therapy, nonsteroidal anti-inflammatory medications, oral corticosteroids, intraarticular steroid injections, hydrodistension, closed manipulation, and arthroscopic capsular release [7].

First described by Andren and Lundberg in 1965, hydrodilatation involves injecting a large volume of fluid (80–100 ml normal saline) into the shoulder joint to dilate the capsule. This causes capsular rupture and is both minimally invasive and technically simple. Lädermann et al. (2021), in an overview of meta-analyses, found that arthrographic distension/hydrodilatation with corticosteroid is the most effective conservative management for frozen shoulder, providing superior pain relief in the short term and improvement in ROM across all time frames [8].

Poku et al. (2023) in a systematic review and meta-analysis published in British Medical Bulletin confirmed that hydrodilatation leads to at least transient improvements in shoulder disability and passive external rotation compared with intra-articular corticosteroid injections alone [9]. Although arthroscopic capsular release is effective, it is more invasive and costly compared to hydrodilatation [10].

There is limited literature available in South India regarding the combined impact of corticosteroids and hydrodilatation for frozen shoulder. The current study evaluates both intra-articular steroids and hydrodilatation to enhance the functional outcome of periarthritic shoulder patients in a tertiary care setting.

Materials And Methods

A prospective Observational study was conducted among patients with periarthritis shoulder who were admitted in the Department of Orthopedics at Dhanalakshmi Srinivasan Medical College Hospital, a tertiary care teaching hospital located in Siruvachur, Perambalur, were enrolled during the period of March 2023 to August 2024. Participants aged 18 to 75 years, of either gender, presenting with restricted active and passive shoulder movements and experiencing worsening of symptoms despite undergoing physiotherapy and analgesic treatment for a duration exceeding one month were included in the study. Exclusion criteria comprised the presence of glenohumeral arthritis, any history of prior shoulder surgery, previous shoulder dislocation or fracture-dislocation, malignancy, post-infective conditions, rotator cuff tear, and psychological disorders such as dementia. By universal sampling method, all 42 patients who satisfied the inclusion and exclusion criteria during the study period were included in the study.

Pre-operative Assessment

A detailed history was taken with reference to the frozen shoulder. A preliminary general physical examination was done. Systemic examination of CVS,

Respiratory, and GI was performed routinely. All active shoulder movements were measured using a goniometer. Pre-operative pain score as assessed by VAS, range of movements, and functional ability were documented using Constant Shoulder Score (CSS).

Inspection

The patient's two shoulders were sufficiently exposed to compare and the following observations were made

1. Attitude
2. Scar, sinus and swelling
3. Deformities
4. Muscle wasting

Palpation

Local warmth, tenderness over joint and bony prominence, swelling are noted.

Movements

All active shoulder movements measured. Forward flexion measured with the patient in a standing lateral position and measured the angle between the arm and chest using a goniometer (Figure 1).

Abduction is measured in standing position using goniometer angle between arm and trunk noted (Figure 2).

Figure 1. Measurement of Forward flexion

Figure 2. Measurement of Forward flexion

External Rotation is noted based on level of hand behind or above head with level of elbow held forward or back. Active Internal Rotation noted based on the level of hand back to lateral thigh, back to the buttock, back to Lumbosacral junction, back to L3 spine, back to D12 spine, and interscapular level. Pre-op pain score, range of movements, and functional ability documented using Constant shoulder score (CSS).

Investigations

Before starting treatment, the following routine investigations were carried out: Complete Blood Count, Blood Sugar values, Urine Complete, Renal Function Test (Urea and Creatinine), Viral markers (HIV, HBsAg, HCV), X-ray AP view of shoulder joint. Further treatment was initiated only after blood sugar control in diabetic patients.

Operative Procedure

Patient in beach chair position; shoulder painted and draped under strict aseptic precaution. Anatomical landmarks (angle of acromion and coracoid process) were marked. An 18-gauge spinal needle was inserted into the shoulder joint through a posterior approach under fluoroscopy guidance (1 cm inferior to the angle of the acromion, directed towards coracoid process) (Figure 3).

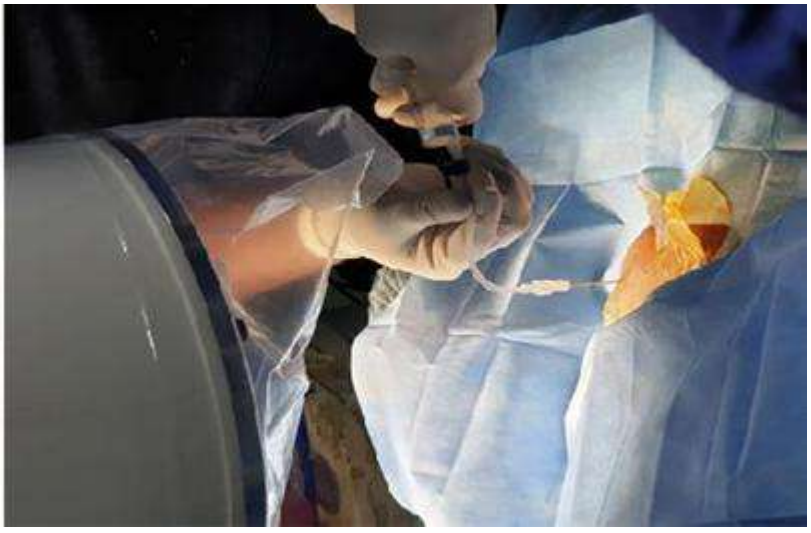


Figure 3. Injection of Omnipaque contrast dye (Iohexol)

2 ml omnipaque contrast dye (iohexol) was injected and needle position confirmed under fluoroscopy. 80 mg Triamcinolone and 5 ml local anesthetic agent (2% lignocaine 2 ml + 0.5% Bupivacaine 3 ml) injected for postoperative pain relief. 80 ml of cold normal saline was injected into the joint using a 3-way adaptor. Shoulder manipulation was performed using a short lever arm with a fixed scapula — flexion, extension, abduction, adduction, external and internal rotation. Post-procedure fluoroscopy image was taken to rule out fractures.

Post-Operative Protocol

Adequate post-operative analgesics given. Intravenous antibiotics — 3 doses. Immediate shoulder ROM exercises initiated once patient recovered from anesthesia. Patient pain score (VAS) and

ROM documented at immediate post-op, 2 weeks, and 1 month using Constant Shoulder Score (CSS). Physiotherapy continued for 3 months post-operatively.

The procedures were performed by multiple orthopedic surgeons; however, all interventions were carried out following a standardized institutional protocol to ensure consistency in technique. Furthermore, all patients were managed with a uniform post-procedure physiotherapy protocol.

Statistical Analysis

Data were analysed using paired sample T-test or Wilcoxon signed-rank whichever applicable. For all statistical evaluations. p-value <0.05 was considered statistically significant. All analyses were performed using SPSS software.

Results

This prospective study enrolled 42 patients with frozen shoulder. The majority were between 40-49 years of age (40.50%), followed by 60-69 years (26.20%) and 50-59 years (21.40%). Of the 42 patients, 28 were female and 14 were male; the female sex (66.7%) was most frequently affected. The left shoulder was predominantly affected (66.7%) compared to the right shoulder (33.3%). Co-morbidities identified included: diabetes mellitus in 16 patients (44.4%), hypertension in 2, bronchial asthma in 2, peptic ulcer disease in 1, chronic kidney disease in 1, and thyroid/seizure disorder in 1 each.

Table 1. Pain Score Before and After Manipulation

Condition	Median Pain Score	Interquartile Range (Q3-Q1)
Before manipulation	3.00	0
After manipulation (2 weeks)	1.00	1
After manipulation (1 month)	1.00	0
P value	<0.0001 (Statistically Significant)	

Following manipulation, all 42 patients experienced a considerable reduction in pain. Before starting MUA, the median pain score was 3.00; by the end of 1 month, it had dropped to 0. The P value was statistically significant (p<0.0001) (Table 1).

Table 2. Range of Movements Before and After Manipulation

Movement	Pre-op Median	Pre-op IQR	2wk Post-op Median	1 Month Post-op Median	P Value
Flexion	100°	10	150°	160°	<0.0001
Abduction	90°	10	150°	170°	<0.0001
External Rotation (Grade)	3.00	1.0	4.00	5.00	<0.0001
Internal Rotation (Grade)	3.00	2.0	3.00	4.00	<0.0001

There was significant improvement in all ROM following manipulation. Flexion improved from median 100° to 160°, abduction from 90° to 170°, external rotation from grade 3 to grade 5, and internal rotation from grade 3 to grade 4. All P values were <0.0001, which is statistically significant (Table 2).

Table 3. Grading of Constant Shoulder Score Before and After Manipulation

Description of CSS	**Grade**	**Pre-op (n)**	**Immed. POD1 (n)**	**POD 2 wks (n)**	**POD 1 Month (n)**	**Pre-op %**	**POD 2 wks %**	**POD 1 Month %**
Poor (0–55)	1	42	19	3	2	100	7.1	4.8
Mediocre (56–70)	2	0	19	16	5	0	38.1	11.9
Good (71–85)	3	0	4	19	8	0	45.2	19.0
Excellent (86–100)	4	0	0	4	27	0	9.5	64.3

The functional assessment in the range of movements of the shoulder was assured using a constant shoulder score. In this study, Out of 42 patients,27 showed excellent cores (64.3%), 8 showed good results (19.0%) and 2 showed poor performance (4.8%) (Table 3).

Figures 4-6 shows the Pre-operative, Intra-operative and 1 month Post-operative representative images.

Figure 4. Pre-Operative images (Representative)

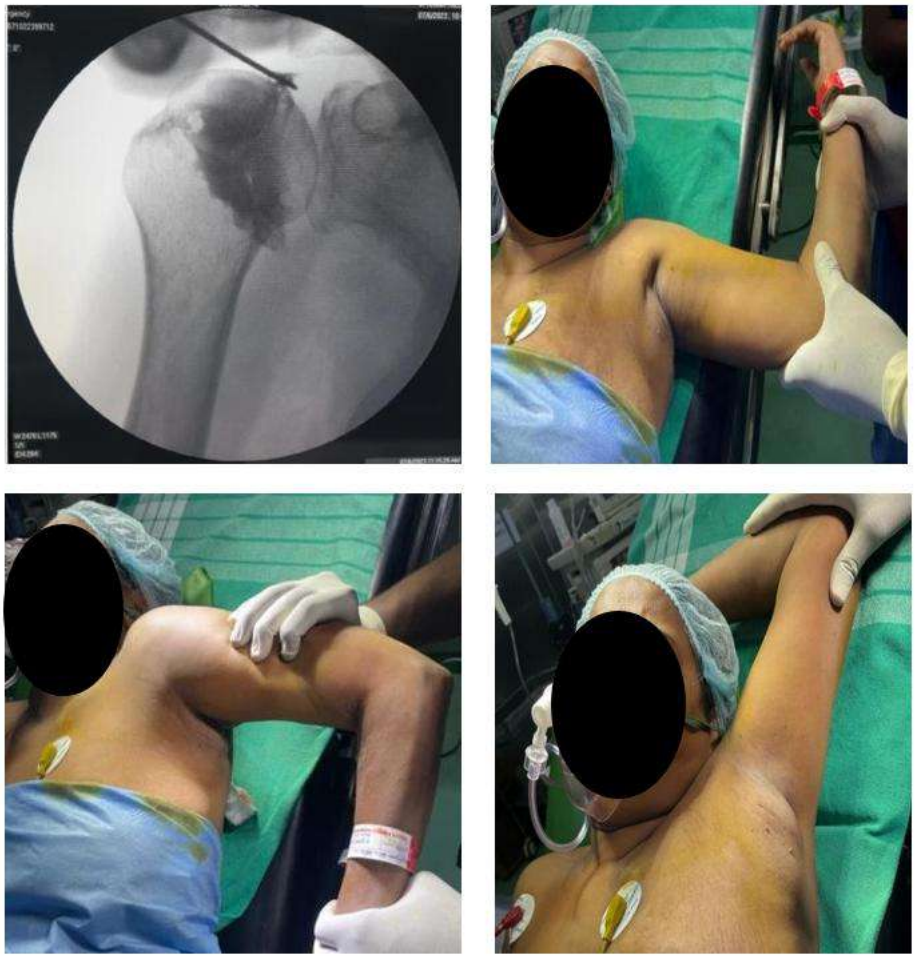


Figure 5. Intra-Operative images (Representative)

Figure 6: 1-month post-operative images (Representative)

Discussion

This prospective study evaluated the range of movements and pain using a Constant Shoulder Score after manipulation with hydrodilatation in 42 frozen shoulder patients over a 17-month period. Our findings are consistent with recent literature confirming the efficacy of hydrodilatation combined with intra-articular corticosteroid for frozen shoulder management.

In the present study, most cases belonged to the 40–49 age group (40.50%), consistent with the epidemiological data from Millar et al. (2022) who reported frozen shoulder most commonly in the fifth and sixth decades of life [2]. A similar age distribution was noted by Kraal et al. (2020) in their scoping review of frozen shoulder pathophysiology [11]. Pandey and Madi (2021) in their Indian clinical guidelines update also reported peak incidence in the 40–60 age group [7].

Female predominance was observed in our study (66.7%), which is in keeping with available literature. Millar et al. (2022) reported that frozen shoulder affects approximately 8% of men and 10% of women globally, with a slight female preponderance [2]. StatPearls (2023) confirms a female-to-male ratio of approximately 1.4:1 with hormonal and immunological factors contributing to this disparity [3].

Left shoulder involvement was more frequent in our study (66.7%) — consistent with published data indicating greater involvement of the non-dominant arm. Frozen shoulder is known to preferentially affect the non-dominant extremity, possibly due to differential use patterns and biomechanical stress responses [3,12].

Diabetes mellitus was the most commonly associated risk factor (44.4%) in this study. This is strongly supported by recent evidence. Dyer et al. (2023) in a systematic review and meta-analysis found diabetes confers a 3.69 times higher risk for developing frozen shoulder (95% CI 2.99 to 4.56). [5] Kim et al. (2023) in a nationwide longitudinal cohort study confirmed that both prediabetes and type 2 diabetes significantly increase the risk of adhesive capsulitis. [6] Dyer et al. (2021) further demonstrated that diabetic patients with frozen shoulder may experience worse long-term outcomes than non-diabetic counterparts [13].

In the present study, following manipulation with hydrodilatation and steroid injection, all 42 patients experienced a significant reduction in pain (median pain score decreased from 3.00 to 0 at one month). This is comparable to results reported by Avulapatti et al. who found mean VAS scores decreased from 7.29 to 1.71 at four months following manipulation under anesthesia [14]. Latzka et al. (2023) in a comparative study found that hydrodilatation achieved equivalent or superior outcomes compared to corticosteroid injection alone for adhesive capsulitis [10].

Regarding range of movements, flexion improved from median 100° to 160° and abduction from 90° to 170°. Yao et al. (2024) in a systematic review and meta-analysis confirmed that hydrodistension combined with conventional treatment provided significantly better analgesic effect and improved mobility function compared with other treatment measures [15]. Wang et al. (2023) demonstrated in a randomized controlled trial that ultrasound-guided glenohumeral hydrodilatation significantly improved range of motion in adhesive capsulitis patients [16].

Lädermann et al. (2021), in an overview of eight meta-analyses, concluded that arthrographic distension/hydrodilatation with corticosteroid provides superior pain relief in the short term and improvement in ROM across all time frames for frozen shoulder when compared to corticosteroid injection alone or physiotherapy [8]. Poku et al. (2023) corroborated these findings, stating that hydrodilatation leads to at least transient marked improvements in shoulder disability and passive external rotation [9].

Manipulation under anesthesia (MUA) combined with hydrodilatation remains a safe and effective intervention for refractory frozen shoulder. Song et al. (2021) in a retrospective cohort study of 141 patients found that MUA combined with intra-articular steroid injection significantly improved pain severity and shoulder function compared to MUA alone [17]. Xu et al. (2022) in a randomized controlled trial using the Constant-Murley Score as the primary outcome confirmed MUA significantly improved functional outcomes in secondary frozen shoulder [18].

Salomon et al. (2022) in a systematic review of randomized controlled trials noted that MUA was not inferior to cortisone injections with hydrodilatation in terms of pain reduction and functional improvement [19]. Kraal et al. (2024) in a randomized controlled trial found that MUA provided better ROM in the short term compared to physiotherapy alone for stage 2 frozen shoulder, though the long-term difference was marginal [20].

The combination approach of hydrodilatation with physiotherapy and steroid provides optimal outcomes. Cho et al. (2024) in a randomized controlled trial demonstrated that combination therapy (hydrodilatation plus subdeltoid bursa injection with corticosteroid and mobilization) was superior to physiotherapy alone, with effects persisting for at least 6 months [21]. Challoumas et al. (2020) in a JAMA Network Open systematic review and meta-analysis confirmed that combined approaches yielded the most consistent improvements across pain, function, and ROM outcomes [22].

In our study, at one month, 64.3% achieved excellent CSS scores, 19% good, 11.9% mediocre, and 4.8% poor outcomes. These results are comparable with Sundharajan et al. who found significant improvement in pain, ROM, and functional ratings ($P<0.001$) with both MUA and arthroscopic capsular release, without significant difference between the two groups at 24 weeks. Our study aligns with Zhang et al. (2021), who in a network meta-analysis confirmed hydrodilatation with corticosteroid as one of the most effective non-surgical treatment strategies for frozen shoulder [23].

There is a significant improvement in the entire range of shoulder movements in our study, but further long-term follow-up is needed to assess any recurrence of symptoms. Castelhano et al. (2023) emphasised that optimizing physiotherapy after MUA reduces recovery time and recurrence rates [24]. Takahashi et al. (2024) identified diabetes mellitus as a significant risk factor for recurrence after shoulder manipulation, highlighting the need for closer monitoring in this subgroup [25].

Conclusion

Frozen shoulder was more commonly observed among females in the 40–49-year age group, with a higher

involvement of the non-dominant shoulder and a notable association with diabetes mellitus. The present study demonstrates that manipulation with hydrodilatation combined with intra-articular corticosteroid is associated with significant short-term improvement in pain, range of motion, and functional status as assessed by the Constant Shoulder Score. These findings suggest that the intervention may be an effective option for early symptomatic relief in patients not responding to conservative management.

The findings of this study have important clinical implications, particularly in resource-limited settings, where access to advanced surgical interventions may be constrained. Manipulation with hydrodilatation combined with intra-articular corticosteroid represents a relatively simple, cost-effective, and minimally invasive treatment option that can be performed in a tertiary care setting, offering early symptomatic relief and improved functional outcomes in patients with frozen shoulder who do not respond to initial conservative management

Limitations

This study has certain limitations that should be considered while interpreting the findings. A formal sample size calculation was not performed, and a universal sampling method was adopted, wherein all eligible patients presenting during the study period were included, resulting in a relatively small sample size. The absence of a control or comparison group limits the ability to draw definitive conclusions regarding the comparative effectiveness of the intervention. The follow-up duration was limited to one month, as the study was designed to assess short-term outcomes, and therefore long-term functional improvement, recurrence, and sustainability of treatment effects could not be evaluated. Being a single-center study, the generalizability of the findings may also be limited. Further studies with larger sample sizes, appropriate control groups, and longer follow-up are warranted to validate these findings.

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.

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

Ethical approval was obtained from the Institutional Ethics Committee of Dhanalakshmi Srinivasan Medical College and Hospital (Certificate No. IECHS/IRCHS/DSMCH/293, dt:07.03.2023).

Informed Consent

Informed consent was obtained from all participants after explaining the study procedures, risks, and benefits, including consent for participation and publication of anonymised data with assurance of confidentiality and privacy.

References

1. Singh S, Gill S, Mohammad F, Kumar S, Kumar D, Kumar S. Prevalence of shoulder disorders in tertiary care centre. Int J Res Med Sci. 2015;3(4):917.
2. Millar NL, Meakins A, Struyf F, Willmore E, Campbell AL, Kirwan PD, et al. Frozen shoulder. Nat Rev Dis Primers. 2022;8(1):59. doi:10.1038/s41572-022-00386-2
3. St Angelo JM, Fabiano SE. Adhesive Capsulitis. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023.
4. Kraal T, Lubbers J, van den Bekerom MPJ, Alessie J, van Kooyk Y, Eygendaal D. The puzzling pathophysiology of frozen shoulders: a scoping review. J Exp Orthop. 2020;7(1):91. doi:10.1186/s40634-020-00307-w
5. Dyer BP, Rathod-Mistry T, Burton C, van der Windt D, Bucknall M. Diabetes as a risk factor for the onset of frozen shoulder: a systematic review and meta-analysis. BMJ Open. 2023;13(1):e062377. doi:10.1136/bmjopen-2022-062377
6. Kim JH, Kim BS, Han K, Kwon HS. The risk of shoulder adhesive capsulitis in individuals with prediabetes and type 2 diabetes mellitus: a longitudinal nationwide population-based study. Diabetes Metab J. 2023;47(6):869-878. doi:10.4093/dmj.2022.0275
7. Pandey V, Madi S. Clinical guidelines in the management of frozen shoulder: an update! Indian J Orthop. 2021;55(2):299-309. doi:10.1007/s43465-020-00313-x
8. Lädermann A, Piotton S, Abrassart S, Mazzolari A, Ibrahim M, Stirling P. Hydrodilatation with corticosteroids is the most effective conservative management for frozen shoulder. Knee Surg Sports Traumatol Arthrosc. 2021;29(8):2553-2563. doi:10.1007/s00167-020-06390-x
9. Poku D, Hassan R, Migliorini F, Maffulli N. Efficacy of hydrodilatation in frozen shoulder: a systematic review and meta-analysis. Br Med Bull. 2023;147(1):121-147. doi:10.1093/bmb/ldad018
10. Latzka J, Shoup L, Baird MH, et al. Hydrodilatation versus corticosteroid injection in treatment for adhesive capsulitis. PM&R. 2023;15(12):1580-1587. doi:10.1002/pmrj.13094
11. Leafblad N, Mizels J, Tashjian R, Chalmers P. Adhesive capsulitis. Phys Med Rehabil Clin N Am. 2023;34(2):453-468. doi:10.1016/j.pmr.2022.12.009
12. Challoumas D, Biddle M, McLean M, Millar NL. Comparison of treatments for frozen shoulder: a systematic review and meta-analysis. JAMA Netw Open. 2020;3(12):e2029581. doi:10.1001/jamanetworkopen.2020.29581
13 Dyer BP, Burton C, Rathod-Mistry T, Blagojevic-Bucknall M, van der Windt DA. Diabetes as a prognostic factor in frozen shoulder: a systematic review. Arch Rehabil Res Clin Transl. 2021;3(3):100141. doi:10.1016/j.arrct.2021.100141
14. Krishna Avulapatti S. Periarthritis shoulder: Effect of manipulation under general anesthesia on pain and range of movement. IJOS. 2020;4(4):342-347.
15. Yao H, Wu G, Zhong Y. Efficacy of hydrodistension for frozen shoulder: a systematic review and meta-analysis. Medicine (Baltimore).

2024;103(22):e38388. doi:10.1097/MD.0000000000038388

16. Wang JC, Hsu PC, Wang KA, et al. Comparative effectiveness of corticosteroid dosages for ultrasound-guided glenohumeral joint hydrodilatation in adhesive capsulitis: a randomized controlled trial. Arch Phys Med Rehabil. 2023;104(5):745-752. doi:10.1016/j.apmr.2022.11.009
17. Song C, Yu W, Jiang W, et al. Outcome of manipulation under anesthesia with or without intra-articular steroid injection for treating frozen shoulder: a retrospective cohort study. Medicine (Baltimore). 2021;100(13):e23893. doi:10.1097/MD.0000000000023893
18. Xu Q, Li H, Jiang D, et al. The effect of manipulation under anesthesia for secondary frozen shoulder: a randomized controlled trial. Pain Ther. 2022;11(4):1373-1387. doi:10.1007/s40122-022-00438-1
19. Salomon M, Pastore C, Maselli F, Di Bari M, Pellegrino R, Brindisino F. Manipulation under anesthesia versus non-surgical treatment for patients with frozen shoulder contracture syndrome: a systematic review. Int J Environ Res Public Health. 2022;19(15):9715. doi:10.3390/ijerph19159715
20. Kraal T, de Wit Y, The B, van Boekel L, Koenraadt-van Oost I, Boer R, et al. Improved range of motion after manipulation under anesthesia versus physiotherapy for stage two frozen shoulder: a randomized controlled trial. JSES Int. 2024;8(2):293-298. doi:10.1016/j.jseint.2023.11.004
21. Cho CH, Kim DH, Lee YK, Bae KC. Efficacy of combination therapy (hydrodilatation and subdeltoid bursa injection with corticosteroid, mobilization, and physical therapy) vs physical therapy alone for treating frozen shoulder: a randomized single-blind controlled trial. Arch Phys Med Rehabil. 2024;105(4):725-732. doi:10.1016/j.apmr.2023.11.010
22. Zhang J, Zhong S, Tan T, et al. Comparative efficacy and patient-specific moderating factors of nonsurgical treatment strategies for frozen shoulder: an updated systematic review and network meta-analysis. Am J Sports Med. 2021;49(6):1669-1679. doi:10.1177/0363546520956293
23. Pimenta M, Vassalou EE, Dimitri-Pinheiro S, Klontzas ME, Ramos I, Karantanas AH. Ultrasound-guided hydrodistension for adhesive capsulitis: is there any adjunct effect of immediate post-procedural manipulation over instructed physical therapy? J Ultrasound Med. 2022;42(3):665-674. doi:10.1002/jum.16063
24. Castelhano R, Woods J, Akehurst H, Mitra A, James M, Berntzen B, et al. Optimising the use of physiotherapy resources after manipulation under anaesthetic for frozen shoulder. Ann R Coll Surg Engl. 2023;105(2):136-141. doi:10.1308/rcsann.2022.0016
25. Takahashi R, Kajita Y, Harada Y, Iwahori Y, Miyashita N, Deie M. Risk factors for recurrence of frozen shoulder after shoulder manipulation under ultrasound-guided cervical nerve root block. JSES Int. 2024;8(1):90-94. doi:10.1016/j.jseint.2023.09.002

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 810–835, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.015

ORIGINAL ARTICLE

Evaluation of Post-Assessment Remedial Training for Competency-Based Biochemistry Education for Medical Undergraduates in Haveri district of Karnataka in India

Ashakiran Srinivasaiah,[1] Mahalaxmi S Petimani,[2] Siddharameshwar M Kantikar[3] and Harish Rangareddy[4,*]

[1]*Professor and HOD, Department of Biochemistry, Haveri Institute of Medical Sciences, Haveri-581110*
[2]*Associate Professor, Department of Biochemistry, Haveri Institute of Medical Sciences, Haveri-581110*
[3]*Associate Professor, Department of Pathology, Subbaiah Institute of Medical Sciences, Shivamogga, India*
[4]*Assistant Professor, Department of Biochemistry, Haveri Institute of Medical Sciences, Haveri-581110*

Accepted: 16-April-2026 / Published Online: 6-May-2026

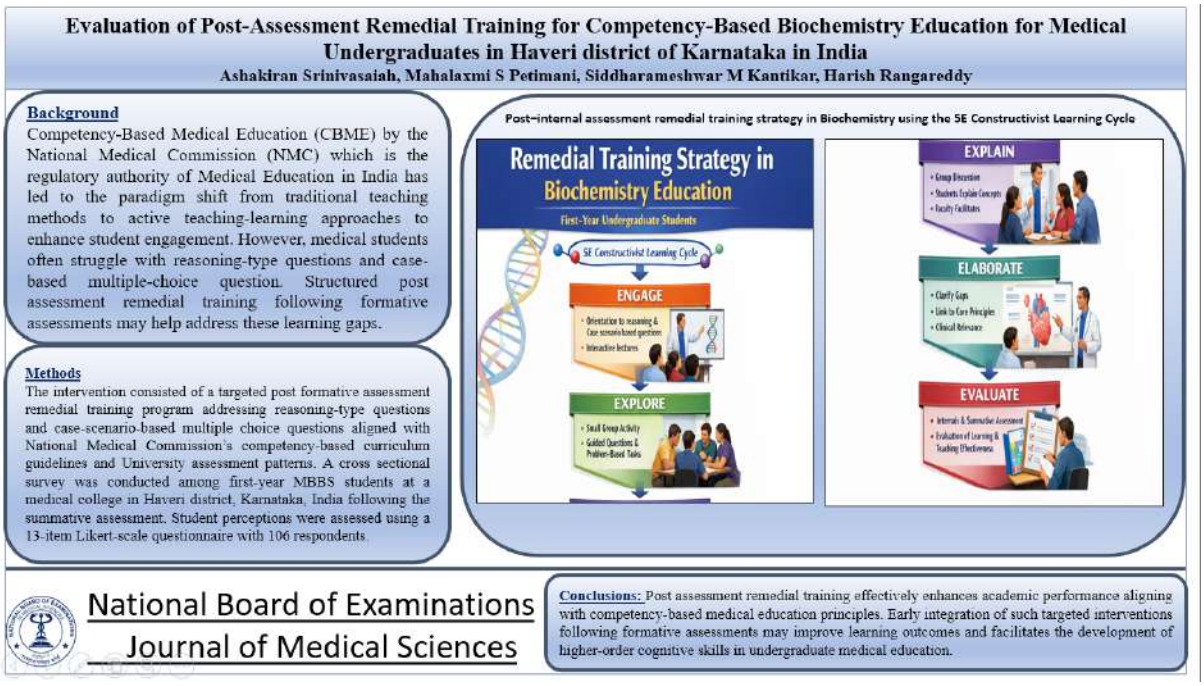
Abstract

Background: Competency-Based Medical Education (CBME) by the National Medical Commission (NMC) which is the regulatory authority of Medical Education in India has led to the paradigm shift from traditional teaching methods to active teaching-learning approaches to enhance student engagement. However, medical students often struggle with reasoning-type questions and case-based multiple-choice question. Structured post assessment remedial training following formative assessments may help address these learning gaps. **Methods:** The intervention consisted of a targeted post formative assessment remedial training program addressing reasoning-type questions and case-scenario-based multiple choice questions aligned with National Medical Commission's competency-based curriculum guidelines and University assessment patterns. A cross sectional survey was conducted among first-year MBBS students at a medical college in Haveri district, Karnataka, India following the summative assessment. Student perceptions were assessed using a 13-item Likert-scale questionnaire with 106 respondents. **Results:** Students reported positive perceptions of the training program with >80% of students agreed or strongly agreed that the sessions improved their understanding of reasoning-type questions, analytical skills, and application of biochemical knowledge to clinical scenarios. Nearly 81% students reported increased confidence in answering case-scenario based questions, and 83% students indicated their willingness to recommend the training to their juniors. No significant differences in perceptions were observed between gender groups or across age categories. The intervention demonstrated a large educational impact (Cohen's d = 1.58). **Conclusion:** Post assessment remedial training effectively enhances academic performance aligning with competency-based medical education principles. Early integration of such targeted interventions following formative assessments may improve learning outcomes and facilitates the development of higher-order cognitive skills in undergraduate medical education.

Keywords: Competency-based medical education, Remedial training, Case-scenario based learning, Analytical reasoning

*Corresponding Author: Harish Rangareddy
Email: harishreddy1349@gmail.com

Graphical Abstract



Introduction

Implementation of Competency-Based Medical Education (CBME) by the National Medical Commission (NMC) which is the regulatory authority of Medical Education in India has led to the paradigm shift from traditional teaching methods to active teaching-learning approaches to enhance student engagement [1]. These innovative teaching-learning approaches viz., concept mapping, reflective self-assessment, Multiple Choice Questions (MCQs) when introduced gradually after proper orientation of the students and teachers of Biochemistry in Phase I MBBS Curriculum based on Competencies it has been observed that the students gained confidence in performing better in both the formative assessments as well as summative assessment University examination [2].

The interactive "lecture-tutorial-classroom assessment-feedback" method serves as an ongoing learning tool to identify conceptual gaps, which can be corrected through feedback, leading to significantly improvement in formative assessment scores and practical understanding in first-year MBBS despite time constraints indicating that feedback plays a crucial role in implementation of CBME [3].

Following the implementation of the revised Graduate Medical Education Regulations (GMER) 2024, NMC has shifted the focus of CBME towards the development of clinical reasoning and application of knowledge [4]. Accordingly, the assessment strategies shall incorporate reasoning-based questions to evaluate students' ability to interpret information, integrate concepts and apply the knowledge in problem-solving contexts. This is outlined in the Annexure 9 of the CBME assessment framework of the revised GMER which mandates the inclusion of reasoning-oriented questions and case-based multiple-choice questions in Biochemistry assessments to promote higher-order

cognitive skills and clinically relevant learning among medical undergraduates [4]. However, it has observed that first-year MBBS students often struggle with these formats of assessment for higher-order thinking [5]. The same Assessment of CBME is adopted by Rajiv Gandhi University of Health Sciences (RGUHS), Bangalore which emphasizes reasoning questions and case-based MCQs in Biochemistry assessments. Post-assessment remedial training addresses this gap [6].

For addressing learning gaps, post-assessment remedial training specifically targeting Biochemistry's reasoning (Q3: 5×3 marks) and case-based MCQs is needed. No prior studies from Haveri Institute of Medical Sciences or similar resource-limited settings have psychometrically validated structured questionnaires to evaluate such remedial interventions' effectiveness, alignment with NMC/RGUHS patterns, perceived learning gains, teaching processes, and satisfaction—essential for institutional adoption and scalability across Indian medical colleges. This study aimed to assess the effectiveness of post assessment remedial training using a structured student feedback questionnaire assessing remedial training on reasoning questions and case scenario based MCQs in Biochemistry for first-year MBBS students and the study was presented at was presented as an Oral paper at the "Virtual International Conference on Health Professions Education" organized on 12th and 13th January, 2026 by University Center for Health Professions Education, Sri Devaraj Urs Academy of Higher Education and Research in Kolar, Karnataka.

Methods

Study Design

This study was conducted among first-year medical undergraduates (MBBS) students at a medical college who had enrolled for the program for the academic year 2024-25 at Haveri Institute of Medical Sciences. A structured remedial training intervention was implemented for first-year undergraduate medical students in Biochemistry who were identified as underperformers based on their performance in the second formative assessment. Students scoring below the predefined competency threshold were enrolled in the remediation programme. The intervention was conducted over a defined period following the second formative assessment and was designed using the 5E constructivist learning cycle (Engage, Explore, Explain, Elaborate, Evaluate) to promote active, learner-centered engagement [7].

During the Engage phase, students were oriented to reasoning- and case scenario–based questions through brief interactive lectures. Subsequently, the students were involved in small group discussions wherein the students articulated their understanding in the Explain phase. Following this the faculty addressed the learning gaps and emphasized the importance of reasoning and clinical relevance while reinforcing the core concepts of Biochemistry in the Elaborate phase. The Evaluate phase included continuous formative assessments integrated with feedback, along with structured assignments, quizzes, mind maps, and quick revision exercises to reinforce learning as depicted in Figure 1.

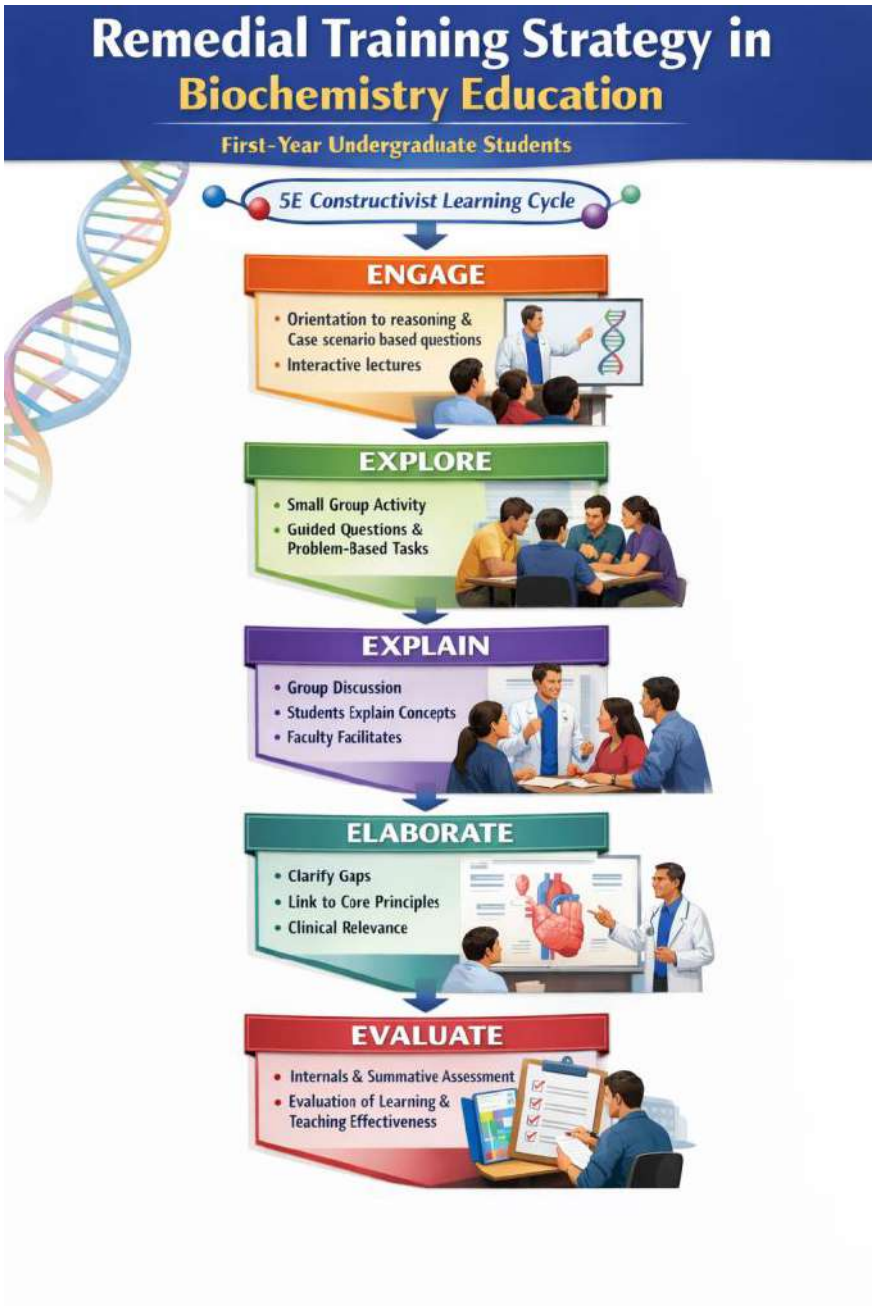


Figure 1. Flowchart showing the 5E Constructivist Learning Cycle used in the remedial training intervention

Following the completion of the intervention, a post-intervention formative assessment was conducted to evaluate the effectiveness of the remedial strategy. Student performance before and after the intervention was compared to assess improvement in learning outcomes. Additionally, formative feedback was provided throughout the intervention to support progressive learning and self-improvement. Cross sectional survey was conducted after the summative assessment to assess the effectiveness of the remedial training and also to obtain feedback.

Participants and Sampling

Students were briefed in person about the study's purpose and procedures. All first-year MBBS students were included using universal sampling.

Although a sample size was estimated using the formula for finite population correction:

$$n = \frac{N \cdot Z^2 \cdot p(1-p)}{(N-1) \cdot d^2 + Z^2 \cdot p(1-p)}$$

where N is the population size (11,745), Z is the standard normal deviate corresponding to a 95% confidence level (1.96), p is the expected proportion (0.5), and d is the margin of error (10%), the calculated sample size was approximately 96 using Raosoft® (Sample Size Calculator; Raosoft inc.) [8]. However, since all eligible students were included, universal sampling was adopted.

Data Collection Tool

A simple structured survey questionnaire was developed by the authors and was used for data collection (Appendix I). To validate the content, the initial version of the questionnaire was reviewed by a panel of subject-matter experts, including faculty members from the Medical Education Unit. Cronbach's alpha was used to assess the internal consistency of the questionnaire which yielded a high reliability co-efficient of 0.963 as shown in Table 1.

Table 1. Internal Consistency Reliability of the Biochemistry Training Feedback Questionnaire

Measure	**Value**
Number of Questions	13
Cronbach's Alpha	0.963

The study was approved by the institutional ethics committee of Haveri Institute of Medical Sciences. The objectives of the study were explained to the students before administering the questionnaire to ensure informed participation and enhance the validity of the feedback collected. Universal sampling of all first year medical undergraduates was carried out with a response rate of 70.66% (n=106). Google form was used for data collection which was configured to allow only one response per participant to ensure data integrity by preventing multiple submissions. Informed consent was obtained from the students in the Google form itself. Before responding to the questions, the participants were presented with a consent statement on the first page of the Google form. Only after clicking the consent box to indicate their agreement to participate in the study could they proceed to the next section of the survey. Participation in the survey was voluntary, and the data collected was anonymized, accessible only to the research team.

Data Analysis

Descriptive statistics was employed and Microsoft excel was used to analyze and store the data, with results presented as percentages. Data analysis was performed using Jamovi software for

descriptive and inferential statistical methods. Prior to the inferential analysis, assumptions for parametric testing were evaluated:

- Normality was assessed using the Shapiro–Wilk test
- Homogeneity of variances was assessed using Levene's test

Since the normality assumption was violated for all questionnaire items ($p < 0.001$), non-parametric statistical tests were used:

- Mann–Whitney U test to compare perception scores between male and female students
- Kruskal–Wallis test to compare perception scores across different age groups

A p-value < 0.05 was considered statistically significant.

Results

This study comprised of 106 first year medical undergraduate from 2024-25 batch whose responses to the self-administered questionnaire provided critical insights into the effectiveness post assessment remedial training in competency based medical education.

Descriptive statistics showed higher mean perception score across the questionnaire items among female students in relative comparison to male students. However, median responses for both gender was consistently "agree" indicating an uniform favourable response for biochemistry training program.

Table 2. Comparison of Students' Perception of Biochemistry Training Programme Between Male and Female Students (Descriptive Statistics)

Group Descriptive	**Group**	**N**	**Mean**	**SD**
The reason for organizing this training (poor performance in reasoning and case-based MCQs in the 2nd internal assessment) was clearly explained to us.	Female	50	4.06	0.652
	Male	56	3.95	0.749
The sessions helped me understand the pattern and expectations of the NMC Annexure 9 UG theory paper in Biochemistry.	Female	50	4.16	0.584
	Male	56	4.07	0.783
The training helped me understand how Biochemistry assessment in RGUHS (including reasoning questions and case-based MCQs) has changed in the new curriculum.	Female	50	4.14	0.535
	Male	56	4.04	0.713
The sessions reflected the NMC Annexure 9 pattern and current RGUHS Biochemistry curriculum accurately.	Female	50	4.16	0.468
	Male	56	4.09	0.695
The training improved my understanding of Biochemistry reasoning-type questions (Q3: 5 questions × 3 marks).	Female	50	4.16	0.548
	Male	56	3.98	0.7

The training in Biochemistry case scenario–based MCQs improved my analytical and problem-solving skills.	Female	50	4.06	0.512
	Male	56	3.96	0.762
The training helped me relate biochemical pathways and core concepts to applied/clinical scenarios.	Female	50	4.18	0.523
	Male	56	3.98	0.726
The difficulty level of the questions practiced during training was similar to what is expected in the summative university examination.	Female	50	4.16	0.548
	Male	56	4	0.739
The teaching methods used (e.g., discussion of answers, explanation of reasoning steps, use of clinical vignettes) were effective for my style of learning.	Female	50	4.12	0.594
	Male	56	4.05	0.84
The training addressed the main difficulties I faced in the 2nd internal assessment Biochemistry paper.	Female	50	4.06	0.586
	Male	56	3.95	0.796
The overall organization of the training (timing, duration, sequence of topics) was appropriate.	Female	50	4.02	0.515
	Male	56	4	0.763
My confidence to attempt reasoning-type questions and case-based MCQs in the university summative examination has increased after this training.	Female	50	4.14	0.572
	Male	56	3.93	0.735
I would recommend this type of training to my juniors for better preparation for internal assessment and university examinations.	Female	50	4.28	0.607
	Male	56	4.02	0.863

The normality of the data collected was assessed using Shapiro-Wilk test and the test yielded significant results ($p < 0.001$) for all items confirming non-normal distributions and necessitating non-parametric analyses as shown in Table 3.

Table 3. Assessment of Normality Assumption Using Shapiro–Wilk Test for Perception by Gender

Normality Test (Shapiro-Wilk Test)	**Test Statistic**	**p-value**
The reason for organizing this training (poor performance in reasoning and case-based MCQs in the 2nd internal assessment) was clearly explained to us.	0.867	<0.001
The sessions helped me understand the pattern and expectations of the NMC Annexure 9 UG theory paper in Biochemistry.	0.847	<0.001

The training helped me understand how Biochemistry assessment in RGUHS (including reasoning questions and case-based MCQs) has changed in the new curriculum.	0.831	<0.001
The sessions reflected the NMC Annexure 9 pattern and current RGUHS Biochemistry curriculum accurately.	0.796	<0.001
The training improved my understanding of Biochemistry reasoning-type questions (Q3: 5 questions × 3 marks).	0.863	<0.001
The training in Biochemistry case scenario–based MCQs improved my analytical and problem-solving skills.	0.801	<0.001
The training helped me relate biochemical pathways and core concepts to applied/clinical scenarios.	0.874	<0.001
The difficulty level of the questions practiced during training was similar to what is expected in the summative university examination.	0.86	<0.001
The teaching methods used (e.g., discussion of answers, explanation of reasoning steps, use of clinical vignettes) were effective for my style of learning.	0.822	<0.001
The training addressed the main difficulties I faced in the 2nd internal assessment Biochemistry paper.	0.864	<0.001
The overall organization of the training (timing, duration, sequence of topics) was appropriate.	0.764	<0.001
My confidence to attempt reasoning-type questions and case-based MCQs in the university summative examination has increased after this training.	0.89	<0.001
I would recommend this type of training to my juniors for better preparation for internal assessment and university examinations.	0.9	<0.001

Note: p-value <0.05 indicates violation of the assumption of normality

The variance homogeneity was tested using Levene's test and the p-value was observed to be for $p > 0.05$ for the majority of items, though select items exhibited heterogeneity ($p < 0.05$) as depicted in Table 4.

Table 4. Homogeneity of Variance Assessment Using Levene's Test Between Male and Female Students

Homogeneity of Variances Test (Levene's Test)	**Test Statistic**	**p-value**
The reason for organizing this training (poor performance in reasoning and case-based MCQs in the 2nd internal assessment) was clearly explained to us.	0.921	0.339
The sessions helped me understand the pattern and expectations of the NMC Annexure 9 UG theory paper in Biochemistry.	3.364	0.069

The training helped me understand how Biochemistry assessment in RGUHS (including reasoning questions and case-based MCQs) has changed in the new curriculum.	2.643	0.107
The sessions reflected the NMC Annexure 9 pattern and current RGUHS Biochemistry curriculum accurately.	5.675	**0.019**
The training improved my understanding of Biochemistry reasoning-type questions (Q3: 5 questions × 3 marks).	1.057	0.306
The training in Biochemistry case scenario–based MCQs improved my analytical and problem-solving skills.	3.432	0.067
The training helped me relate biochemical pathways and core concepts to applied/clinical scenarios.	1.255	0.265
The difficulty level of the questions practiced during training was similar to what is expected in the summative university examination.	2.351	0.128
The teaching methods used (e.g., discussion of answers, explanation of reasoning steps, use of clinical vignettes) were effective for my style of learning.	2.217	0.14
The training addressed the main difficulties I faced in the 2nd internal assessment Biochemistry paper.	4.355	**0.039**
The overall organization of the training (timing, duration, sequence of topics) was appropriate.	3.399	0.068
My confidence to attempt reasoning-type questions and case-based MCQs in the university summative examination has increased after this training.	1.869	0.175
I would recommend this type of training to my juniors for better preparation for internal assessment and university examinations.	1.505	0.223

Note: p-value <0.05 indicates violation of the assumption of normality

As the data was not normally distributed, non-parametric tests viz., Mann-Whitney U test and Kruskal-Wallis test were employed for subsequent group comparisons. Mann–Whitney U test demonstrated no statistically significant differences in the perceptions regarding training between male and female students for any of the questionnaire items ($p > 0.05$). This indicates that the students perceived the effectiveness of training, teaching methods, improvement in reasoning skills, alignment with curriculum, and confidence in examination preparation were consistent across gender groups as shown in Table 5.

Table 5. Comparison of Students' Perceptions Regarding Biochemistry Training Programme Between Male and Female Students Using Mann–Whitney U Test

Mann-Whitney U Test	**Statistic**	**p-value**
The reason for organizing this training (poor performance in reasoning and case-based MCQs in the 2nd internal assessment) was clearly explained to us.	1293	0.457
The sessions helped me understand the pattern and expectations of the NMC Annexure 9 UG theory paper in Biochemistry.	1338	0.666
The training helped me understand how Biochemistry assessment in RGUHS (including reasoning questions and case-based MCQs) has changed in the new curriculum.	1296	0.454
The sessions reflected the NMC Annexure 9 pattern and current RGUHS Biochemistry curriculum accurately.	1340	0.66
The training improved my understanding of Biochemistry reasoning-type questions (Q3: 5 questions × 3 marks).	1209	0.17
The training in Biochemistry case scenario–based MCQs improved my analytical and problem-solving skills.	1332	0.611
The training helped me relate biochemical pathways and core concepts to applied/clinical scenarios.	1205	0.156
The difficulty level of the questions practiced during training was similar to what is expected in the summative university examination.	1236	0.246
The teaching methods used (e.g., discussion of answers, explanation of reasoning steps, use of clinical vignettes) were effective for my style of learning.	1391	0.952
The training addressed the main difficulties I faced in the 2nd internal assessment Biochemistry paper.	1310	0.527
The overall organization of the training (timing, duration, sequence of topics) was appropriate.	1382	0.893
My confidence to attempt reasoning-type questions and case-based MCQs in the university summative examination has increased after this training.	1187	0.128
I would recommend this type of training to my juniors for better preparation for internal assessment and university examinations.	1192	0.152

The Mann–Whitney U test showed no statistically significant differences between male and female students across all questionnaire items ($p > 0.05$). This indicates that students' perceptions regarding the effectiveness, organization, and impact of the Biochemistry training programme were same across genders.

To assess age group differences in perceptions of the biochemistry training program, normality (Shapiro-Wilk test) and variance homogeneity (Levene's test) were evaluated. The null hypothesis (H_0: data normally distributed) versus alternative (H_1: non-normal) was tested.

The Shapiro-Wilk test indicated significant deviations from normality ($p < 0.001$) across all items, precluding parametric methods as shown in Table 6. Levene's test confirmed variance homogeneity for most items ($p > 0.05$), with isolated exceptions as depicted in Table 7.

Table 6. Assessment of Normality Assumption Using Shapiro–Wilk Test Across Different Age Groups

Normality Test (Shapiro-Wilk)	**Test Statistic**	**p-value**
The reason for organizing this training (poor performance in reasoning and case-based MCQs in the 2nd internal assessment) was clearly explained to us.	0.858	<.001
The sessions helped me understand the pattern and expectations of the NMC Annexure 9 UG theory paper in Biochemistry.	0.852	<.001
The training helped me understand how Biochemistry assessment in RGUHS (including reasoning questions and case-based MCQs) has changed in the new curriculum.	0.815	<.001
The sessions reflected the NMC Annexure 9 pattern and current RGUHS Biochemistry curriculum accurately.	0.794	<.001
The training improved my understanding of Biochemistry reasoning-type questions (Q3: 5 questions × 3 marks).	0.824	<.001
The training in Biochemistry case scenario–based MCQs improved my analytical and problem-solving skills.	0.768	<.001
The training helped me relate biochemical pathways and core concepts to applied/clinical scenarios.	0.804	<.001
The difficulty level of the questions practiced during training was similar to what is expected in the summative university examination.	0.809	<.001
The teaching methods used (e.g., discussion of answers, explanation of reasoning steps, use of clinical vignettes) were effective for my style of learning.	0.837	<.001
The training addressed the main difficulties I faced in the 2nd internal assessment Biochemistry paper.	0.859	<.001
The overall organization of the training (timing, duration, sequence of topics) was appropriate.	0.78	<.001
My confidence to attempt reasoning-type questions and case-based MCQs	0.866	<.001

in the university summative examination has increased after this training.		
I would recommend this type of training to my juniors for better preparation for internal assessment and university examinations.	0.846	<.001

Note: p-value <0.05 indicates violation of the assumption of normality

Table 7. Homogeneity of Variance Assessment across Age Groups Using Levene's Test

Homogeneity of Variances Test (Levene's)	**Test Statistic**	**p-value**
The reason for organizing this training (poor performance in reasoning and case-based MCQs in the 2nd internal assessment) was clearly explained to us.	0.3285	0.721
The sessions helped me understand the pattern and expectations of the NMC Annexure 9 UG theory paper in Biochemistry.	0.3364	0.715
The training helped me understand how Biochemistry assessment in RGUHS (including reasoning questions and case-based MCQs) has changed in the new curriculum.	0.0586	0.943
The sessions reflected the NMC Annexure 9 pattern and current RGUHS Biochemistry curriculum accurately.	0.0669	0.935
The training improved my understanding of Biochemistry reasoning-type questions (Q3: 5 questions × 3 marks).	0.0775	0.926
The training in Biochemistry case scenario–based MCQs improved my analytical and problem-solving skills.	0.1747	0.84
The training helped me relate biochemical pathways and core concepts to applied/clinical scenarios.	0.5953	0.553
The difficulty level of the questions practiced during training was similar to what is expected in the summative university examination.	0.3614	0.698
The teaching methods used (e.g., discussion of answers, explanation of reasoning steps, use of clinical vignettes) were effective for my style of learning.	1.7621	0.177
The training addressed the main difficulties I faced in the 2nd internal assessment Biochemistry paper.	1.0683	0.347
The overall organization of the training (timing, duration, sequence of topics) was appropriate.	1.0709	0.346
My confidence to attempt reasoning-type questions and case-based MCQs in the university summative examination has increased after this	1.1066	0.335

training.		
I would recommend this type of training to my juniors for better preparation for internal assessment and university examinations.	1.0938	0.339

Non-parametric Kruskal-Wallis tests were employed for multi-group comparisons, with post-hoc Dunn's tests adjusted via Bonferroni correction (Table 8).

Table 8. Comparison of Students' Perceptions Across Age Groups Using Kruskal–Wallis Test

Kruskal-Wallis	**Test statistic**	**df**	**p-value**
The reason for organizing this training (poor performance in reasoning and case-based MCQs in the 2nd internal assessment) was clearly explained to us.	5.2614	2	0.072
The sessions helped me understand the pattern and expectations of the NMC Annexure 9 UG theory paper in Biochemistry.	0.4141	2	0.813
The training helped me understand how Biochemistry assessment in RGUHS (including reasoning questions and case-based MCQs) has changed in the new curriculum.	0.1919	2	0.908
The sessions reflected the NMC Annexure 9 pattern and current RGUHS Biochemistry curriculum accurately.	0.3059	2	0.858
The training improved my understanding of Biochemistry reasoning-type questions (Q3: 5 questions × 3 marks).	0.31	2	0.856
The training in Biochemistry case scenario–based MCQs improved my analytical and problem-solving skills.	0.1192	2	0.942
The training helped me relate biochemical pathways and core concepts to applied/clinical scenarios.	0.0646	2	0.968
The difficulty level of the questions practiced during training was similar to what is expected in the summative university examination.	0.0617	2	0.97
The teaching methods used (e.g., discussion of answers, explanation of reasoning steps, use of clinical vignettes) were effective for my style of learning.	1.6607	2	0.436
The training addressed the main difficulties I faced in the 2nd internal assessment Biochemistry paper.	0.9504	2	0.622

The overall organization of the training (timing, duration, sequence of topics) was appropriate.	0.8415	2	0.657
My confidence to attempt reasoning-type questions and case-based MCQs in the university summative examination has increased after this training.	1.4715	2	0.479
I would recommend this type of training to my juniors for better preparation for internal assessment and university examinations.	1.2152	2	0.545

The Kruskal–Wallis test showed no statistically significant differences among age groups for any questionnaire item ($p > 0.05$). This indicates consistent perception of the training programme among students across different age categories.

A majority of students reported that the purpose of the training programme was clearly communicated, with 76.8% indicating agreement or strong agreement regarding clarity of objectives. Most students perceived that the purpose of organizing the training programme was clearly explained. A majority of students either agreed (53.8%) or strongly agreed (23.6%), while only 0.9% disagreed. This indicates effective communication regarding the objectives of the training programme as depicted in Table 9.

Table 9. Distribution of Students' Responses Regarding Clarity about Purpose of Organizing the Biochemistry Training Programme

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	1	0.90%
Neutral	23	21.70%
Agree	57	53.80%
Strongly Agree	25	23.60%
Total	**106**	**100.00%**

In understanding the pattern and expectations of the recently introduced changes in the assessment methods in Annexure 9 of GMER by NMC it was observed that more than 80% of students agreed or strongly agreed that the sessions helped them understand the examination pattern and expectations as depicted in Table 10. However, there was minimal disagreement by the students reflecting the usefulness of the sessions in clarifying assessment requirements and early implementation of the remedial training.

Table 10. Distribution of Students' Responses on Understanding the Pattern and Expectations of NMC Annexure 9 in context to UG Theory Paper

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	1	0.90%
Neutral	17	16.00%
Agree	57	53.80%
Strongly Agree	31	29.20%
Total	**106**	**100.00%**

Table 11 shows that a large majority of students reported improved understanding of changes in assessment methods in Biochemistry under the new curriculum, with 59.4% agreeing and 24.5% strongly agreeing, indicating successful orientation to curriculum reforms by the faculty.

Table 11. Distribution of Students' Responses on Understanding Changes in Biochemistry Assessment under the New Curriculum

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	0	0.00%
Neutral	17	16.00%
Agree	63	59.40%
Strongly Agree	26	24.50%
Total	**106**	**100.00%**

The strong alignment between training content and expected examination standards was observed as 88% of students agreed or strongly agreed that the sessions accurately reflected the curriculum requirements as depicted in Table 12.

Table 12. Distribution of Students' Responses for Alignment of Training Sessions with NMC Annexure 9 and RGUHS Curriculum

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	0	0.00%
Neutral	13	12.30%

Agree	67	63.20%
Strongly Agree	26	24.50%
Total	**106**	**100.00%**

The responses further revealed that the training effectively addressed analytical components of the examination as 83% students perceived improvement in their understanding of reasoning-type questions as depicted in Table 13.

Table 13. Distribution of Students' Responses on Improvement in Understanding of Reasoning-Type Questions

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	0	0.00%
Neutral	18	17.00%
Agree	63	59.40%
Strongly Agree	25	23.60%
Total	**106**	**100.00%**

The effectiveness of case scenario–based MCQs using in the remedial training improved their analytical and problem-solving skills as 84% of the students agreed or strongly agreed as depicted in Table 14 indicating that the curricular reforms by the NMC in incorporating the reasoning type questions and focusing on applied learning methods is very pertinent for the Indian Medical Graduate in being locally competent and globally relevant.

Table 14. Distribution of Students' Responses on Improvement in Analytical and Problem-Solving Skills through Case-Based MCQs

Opinion	**Counts**	**% of Total**
Strongly Disagree	1	0.90%
Disagree	0	0.00%
Neutral	16	15.10%
Agree	69	65.10%

Strongly Agree	20	18.90%
Total	**106**	**100.00%**

The successful integration of theoretical knowledge with clinical application was observed with more than 84% of students agreeing or strongly agreeing that the training helped them relate biochemical pathways to clinical scenarios as depicted in Table 15.

Table 15. Distribution of Students' Responses on their Ability to Relate Biochemical Concepts to Clinical Scenarios

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	1	0.90%
Neutral	15	14.20%
Agree	65	61.30%
Strongly Agree	25	23.60%
Total	**106**	**100.00%**

A majority of students perceived that the difficulty level of practice questions matched university examination expectations, with over 82% agreement or strong agreement as shown in Table 16. This further supports the guidelines set forth by NMC that the final formative assessment shall be along the lines of the summative assessment.

Table 16. Distribution of Students' Responses on Similarity of Training Question Difficulty Level to University Examination

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	0	0.00%
Neutral	19	17.90%
Agree	60	56.60%
Strongly Agree	27	25.50%
Total	**106**	**100.00%**

Approximately 84% of students reported that teaching methods such as answer discussions and clinical vignettes were effective for their learning style. Very low disagreement indicates overall satisfaction with teaching strategies as shown in Table 17.

Table 17. Distribution of Students' Responses on Effectiveness of Teaching Methods Used During Training

Opinion	**Counts**	**% of Total**
Strongly Disagree	1	0.90%
Disagree	1	0.90%
Neutral	15	14.20%
Agree	60	56.60%
Strongly Agree	29	27.40%
Total	**106**	**100.00%**

Nearly 79% of students agreed or strongly agreed that the training addressed their difficulties from the second internal assessment. Minimal disagreement suggests that the intervention effectively targeted learning gaps as depicted in Table 18.

Table 18. Distribution of Students' Responses on Addressing Difficulties Faced in Second Internal Assessment

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	2	1.90%
Neutral	20	18.90%
Agree	60	56.60%
Strongly Agree	24	22.60%
Total	**106**	**100.00%**

Most students perceived the organization of the training programme as appropriate, with more than 84% expressing agreement or strong agreement. This indicates satisfaction with timing, duration, and sequencing of sessions as shown in Table 19.

Table 19. Distribution of Students' Responses on Organization and Structure of the Training Programme

Opinion	**Counts**	**% of Total**
Strongly Disagree	1	0.90%
Disagree	0	0.00%
Neutral	16	15.10%
Agree	69	65.10%
Strongly Agree	20	18.90%
Total	**106**	**100.00%**

A large proportion of students reported increased confidence in attempting reasoning-type and case-based MCQs, with more than 81% agreement or strong agreement. This reflects the positive impact of the training on examination preparedness as Table 20.

Table 20. Distribution of Students' Responses on Improvement in Confidence to Attempt Reasoning and Case-Based Questions

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	1	0.90%
Neutral	19	17.90%
Agree	62	58.50%
Strongly Agree	24	22.60%
Total	**106**	**100.00%**

More than 83% of students indicated willingness to recommend the training programme to their juniors, demonstrating overall satisfaction and perceived usefulness of the intervention as depicted in Table 21.

Table 21. Distribution of Students' Responses on Recommendation of Training Programme to Juniors

Opinion	**Counts**	**% of Total**
Strongly Disagree	0	0.00%
Disagree	3	2.80%
Neutral	15	14.20%
Agree	52	49.10%
Strongly Agree	36	34.00%
Total	**106**	**100.00%**

The mean assessment score of the students increased by 18.74 percentage points following the structured post-assessment remedial training demonstrating a substantial improvement in academic performance as indicated by a highly significant difference between pre- and post-intervention scores as shown in Table 22.

Table 22. Comparison of Pre- and Post-Intervention Assessment Scores

Assessment	**Mean (%)**	**SD**	**Mean Difference**	**t value**	**p value**	**Effect Size (Cohen's d)**
Pre-intervention Internal Assessment	35.99	12.49	**18.74**	−19.25	**<0.001**	1.58 (Large)
Post-intervention Internal Assessment	54.72	13.18				

Discussion

The results of this study show that structured post assessment remedial training facilitates first-year medical students studying biochemistry to perform much better academically. The intervention had a considerable educational impact as evident from the large effect size, supporting the principles of competency-based medical education, which emphasize continuous formative assessment & targeted remediation facilitate mastery of higher-order thinking while the reasoning-type questions and case-scenario-based MCQs can effectively bridge learning gaps in foundational biomedical sciences.

There has been a major paradigm shift with competency based medical education towards an outcomes based learner progression which prioritizes demonstrable competencies and certifiable

skills as against the time based training of the traditional curriculum [9]. In his commentary, Harden RM has highlighted that competency-based frameworks require educational strategies that actively support learners who struggle to achieve expected competencies through timely feedback and targeted interventions [10]. Frank JR et al, in their comprehensive systematic review have found that outcomes based education represents a shift away from time-based progression toward competency attainment, and there is an emphasis on demonstrable abilities assessed through structured evaluation methods [11]. CBME is characterized by its learner-centered approach and alignment with societal and healthcare needs, ensuring that training is relevant to real-world clinical practice [11].

This study findings concur with previous research by Panchbude S et al, demonstrating the effectiveness of structured formative assessment strategies in improving learning outcomes in Biochemistry [12]. Panchbudhe S et al, used Google Form-based MCQ assessments, which was shown to significantly enhance student performance and engagement by providing immediate feedback and reinforcing conceptual understanding [12]. Similar to these findings, the remedial training intervention in our study utilized the Elaborate phase of the learner driven strategy to identify learning gaps and faculty provided feedback to facilitate targeted improvement. The substantial gain in academic performance observed in both studies highlights the importance of integrating regular formative assessments with feedback mechanisms to promote active learning and competency development.

Padwal M et al, compared facilitated learning and self-paced self-directed learning (SDL) and found that though both approaches significantly improved student performance, facilitated learning tends to yield superior outcomes due to guided interaction, feedback and clarification of concepts [13]. Similarly, our study also emphasizes the importance of learner engagement and structured guidance in achieving better learning outcomes [13].

Hauer et al, described remedial training as an essential component of medical education designed to support struggling learners and prevent long-term academic failure in his thematic analysis and also further suggested that effective remediation requires a structured approach incorporating multiple assessment methods, individualized instructions with opportunities for deliberate practice with feedback and reflection [14]. Our study aligns with this based on targeted identification of learning gaps and structured post assessment remedial training. Cleland J et al, found that there was a significant variability in the design and implementation of remediation programs with limited clarity regarding the specific components responsible for improved outcomes [15]. This necessitates a need for multi-institutional, outcomes-based research to establish standardized and evidence-based remediation strategies.

Pawade et al, have identified “blueprinting” as a systematic approach to align assessments with defined competencies, ensuring that the assessment methods comprehensively reflect both curricular content and expected learning outcomes. By mapping syllabus components to the competencies and assigning appropriate weightage across

recall, reason and apply questions facilitate balanced assessment of knowledge, application, and higher-order thinking skills [16]. Our study similarly highlights the importance of assessment driven learning. Furthermore, the National Medical Commission continues to emphasize outcome-based and learner-centred assessment strategies to strengthen competency development in undergraduate medical education through the recent GMER [4].

In addition to improving the academic performance of students in formative assessment, the effectiveness of the structured post assessment remedial training was observed in the university summative examination as reflected by the students' performance with 98.66% of students successfully passing Biochemistry and a substantial number achieving distinctions. This indicates that structured post-assessment training not only improves students' performance in formative assessment but also helps reinforce key concepts and enhance students' preparedness for summative assessment.

Strengths of the Study

This study addresses an important yet underexplored area in competency-based medical education, firstly the role of structured remedial training interventions following formative assessments in Biochemistry. A validated questionnaire with excellent internal consistency was used ensuring reliability in measuring students' perceptions of the intervention. The analysis employed appropriate statistical methods after evaluating assumptions of normality and subsequently non-parametric tests were employed to test the significance, thereby strengthening the methodological rigor of the findings.

Limitations

Despite its strengths, this study has certain limitations. The study relied primarily on self-reported student perceptions, which may not directly reflect objective improvements in academic performance. However, to circumvent this paired t test was performed to objectively assess the improvements in academic performance. The study was conducted at a single medical institution, which may limit the generalizability of the findings and hence future prospective multi center studies are needed to further evaluate the effectiveness of such interventions. Further a control group was not used to establish causal inference and this may introduce potential bias in attributing improvements solely to the intervention. However, this may be considered for future multi center studies.

Conclusion

This study depicts the critical importance of early identification and structured remediation for underperforming first-year medical students in Biochemistry. The study further demonstrates that structured post assessment remedial training substantially enhances both formative and summative assessment outcomes with constructivist principles as a sustainable approach to improving academic performance and fostering learner confidence in medical education. Students also reported improved conceptual understanding, improved exam preparedness, enhanced time management, and more positive attitudes toward the subject. Overall, these findings align. The study strongly supports

the principles of competency-based medical education, which emphasize continuous formative assessment & targeted remediation facilitate mastery of higher-order thinking while the reasoning-type questions and case-scenario-based MCQs can effectively bridge learning gaps in foundational subject like Biochemistry.

Acknowledgements

The authors would like to express their gratitude to Dr. Sagar Matur, Assistant Professor (Statistics) of Community Medicine, Haveri Institute of Medical Sciences for his support in the statistical analysis. The authors would also like to acknowledge the cooperation of the MBBS students of 2024-25 of Haveri Institute of Medical Sciences who actively took part in this study. Their feedback shall be instrumental in the successful implementation of the remedial training program for the next batches.

Conflict of Interest

The authors declare that there are no conflicts of interest related to this study.

Funding

This research received no external funding from any public, commercial, or not-for-profit funding agencies.

Ethical Considerations

The study was conducted in accordance with ethical principles governing biomedical and educational research involving human participants. Ethical approval for the study was obtained from the Institutional Ethics Committee, Haveri Institute of Medical Sciences, Haveri. Participation in the study was voluntary, and informed consent was obtained from the participating students. All responses were anonymized to ensure confidentiality and privacy.

Data Availability Statement

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request. Data are not publicly available due to institutional policies regarding student academic records and confidentiality.

References

1. Rangareddy H, Govinda Swamy KS, S A, Petimani MS. Enhancing Student Engagement Through Active Teaching-Learning Approaches Among First-Year Medical Undergraduates. Cureus. 2025 Jun 13;17(6):e85921. doi: 10.7759/cureus.85921.
2. Santra R, Saha S, Barua N, et al. Introducing various formative assessment methods in Biochemistry of Phase I MBBS Curriculum. National Journal of Physiology, Pharmacy and Pharmacology. 2025 May 1;15(4):267-271.
3. Hemal Panchal, Minal Patel, Sarmishtha Ghosh et al. From Passive Reception to Active Engagement: Transforming learning for first-year medical students under the Competency based medical curriculum, 02 June 2025, PREPRINT (Version 1) available at Research Square https://doi.org/10.21203/rs.3.rs-6427549/v1
4. National Medical Commission. Competency-Based Medical Education (CBME) Curriculum Guidelines 2024. New Delhi:

National Medical Commission; 2024. Available from: https://www.nmc.org.in/wp-content/uploads/2026/02/12bCompetencyBasedMedicalEducationCBMECurriculum12092024.pdf

5. Sadath A, Unnikrishnan B, Sharma A, et al. Perception of MBBS Students in Mangalore Regarding Assessment Patterns in Competency-Based Medical Education Curriculum: A Cross-Sectional Study. Indian Journal of Community Medicine. 2025 Nov 1;50(6):1064-8.
6. Japa PK, Fathima M, Samudrala S, et al. Competency-based Medical Education of Biochemistry: The Students' Feedback. Indian Journal of Medical Biochemistry. 2025 May 20;29(2):141-6.
7. Burrowes, PA. A Student-Centered Approach to Teaching General Biology That Really Works: Lord's Constructivist Model Put to a Test. The American Biology Teacher. 2003; 65(7): 491-502.
8. Raosoft I. Sample Size Calculator by Raosoft Inc. [Online] [(accessed on 16 September 2025)]. Available online: http://www.raosoft.com/samplesize.html
9. Frank JR, Snell LS, Cate OT, et al. Competency-based medical education: theory to practice. Med Teach. 2010;32(8):638-45. doi: 10.3109/0142159X.2010.501190.
10. Harden RM. Outcome-Based Education: the future is today. Med Teach. 2007 Sep;29(7):625-9. doi: 10.1080/01421590701729930.
11. Frank JR, Mungroo R, Ahmad Y, et al. Toward a definition of competency-based education in medicine: a systematic review of published definitions. Med Teach. 2010;32(8):631-7. doi: 10.3109/0142159X.2010.500898.
12. Panchbudhe S, Shaikh S, Swami H, Kadam CY, Padalkar R, Shivkar RR, Gulavani G, Gulajkar S, Gawade S, Mujawar F. Efficacy of Google Form-based MCQ tests for formative assessment in medical biochemistry education. J Educ Health Promot. 2024 Mar 28;13:92. doi: 10.4103/jehp.jehp_981_23.
13. Padwal M, Takale L, Phadke A, et al. Self-Directed Learning Strategies: A Comparative Evaluation of Facilitated and Self-Paced Methods. Cureus. 2025 Jul 29;17(7):e88982. doi: 10.7759/cureus.88982.
14. Hauer KE, Ciccone A, Henzel TR, et al. Remediation of the deficiencies of physicians across the continuum from medical school to practice: a thematic review of the literature. Acad Med. 2009 Dec;84(12):1822-32. doi: 10.1097/ACM.0b013e3181bf3170.
15. Cleland J, Leggett H, Sandars J, et al. The remediation challenge: theoretical and methodological insights from a systematic review. Med Educ. 2013 Mar;47(3):242-51. doi: 10.1111/medu.12052.
16. Pawade YR, Chalak AS. Unlock the Secret to Effective Biochemistry Assessment: A Blueprinting Approach for CBME Mastery in India. Indian Journal of Medical Biochemistry. 2025 May;29(2):81.

Appendix 1. Study Questionnaire

Section	Question	Options
Section 1: Demographics	What is your age?	17-19 years, 20-22 years, 23-25 years, 26 years and above
	What is your gender?	Male, Female, Prefer not to say
Section 2: Assessment alignment	The reason for organizing this training (poor performance in reasoning and case-based MCQs in the 2nd internal assessment) was clearly explained to us.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
	The sessions helped me understand the pattern and expectations of the NMC Annexure 9 UG theory paper in Biochemistry.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
Section 3: Perceived learning gain	The training helped me understand how Biochemistry assessment in RGUHS (including reasoning questions and case-based MCQs) has changed in the new curriculum.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
	The sessions reflected the NMC Annexure 9 pattern and current RGUHS Biochemistry curriculum accurately.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
	The training improved my understanding of Biochemistry reasoning type questions (Q3: 5 questions × 3 marks).	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
	The training in Biochemistry case scenario–based MCQs improved my analytical and problem-solving skills.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
	The training helped me relate biochemical pathways and core concepts to applied/clinical scenarios.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
Section 4: Teaching process and	The difficulty level of the questions practiced during training was similar to what is expected in the summative university examination.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree

resources	The teaching methods used (e.g., discussion of answers, explanation of reasoning steps, use of clinical vignettes) were effective for my style of learning.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
	The training addressed the main difficulties I faced in the 2nd internal assessment Biochemistry paper.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
	The overall organization of the training (timing, duration, sequence of topics) was appropriate.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
Section 5: Satisfaction and future preference for such training	My confidence to attempt reasoning-type questions and case-based MCQs in the university summative examination has increased after this training.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree
	I would recommend this type of training to my juniors for better preparation for internal assessment and university examinations.	Strongly agree, Agree, Neutral, Disagree, Strongly disagree

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 836–846, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.016

ORIGINAL ARTICLE

Predictive Value of Serum Fetuin-A in the Assessment of Disease Severity in Alcoholic Liver Cirrhosis

B. Anitha,[1,*] S. Vinitha[2] and B.S. Sobia[1]

[1]*Assistant Professor, Department of Biochemistry, Coimbatore Medical College, Coimbatore*
[2]*Assistant Professor, Department of Biochemistry, Government Medical College and ESI Hospital, Coimbatore*

Accepted: 20-April-2026 / Published Online: 6-May-2026

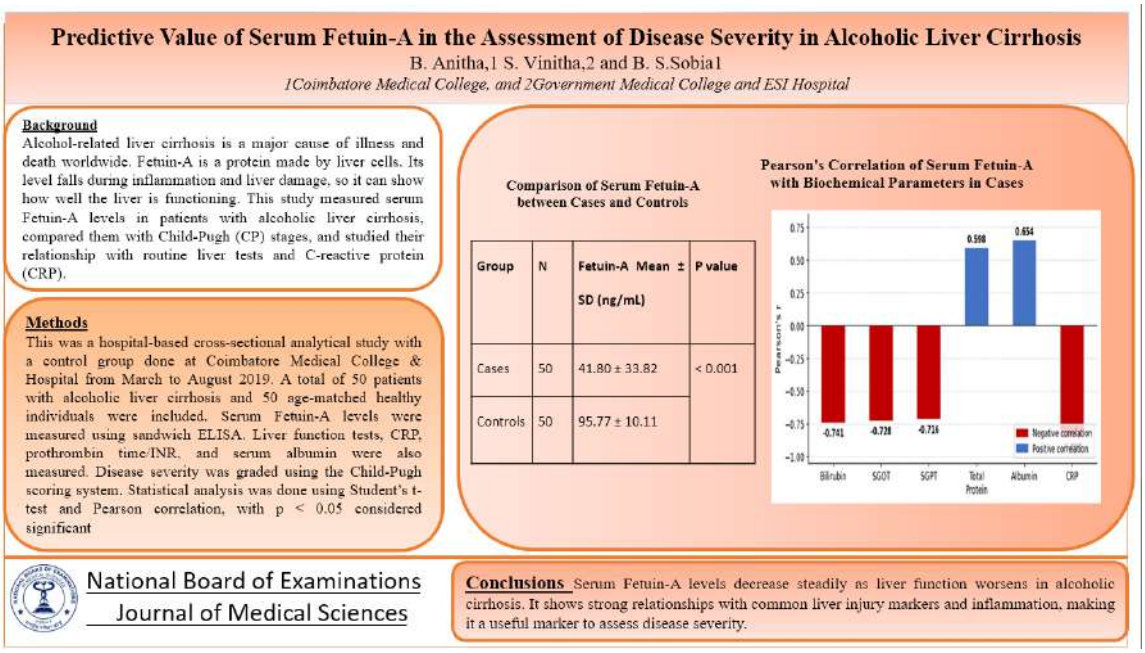
Abstract

Background: Alcohol-related liver cirrhosis is a major cause of illness and death worldwide. Fetuin-A (also called AHSG) is a protein made by liver cells. Its level falls during inflammation and liver damage, so it can show how well the liver is functioning. This study measured serum Fetuin-A levels in patients with alcoholic liver cirrhosis, compared them with Child-Pugh (CP) stages, and studied their relationship with routine liver tests and C-reactive protein (CRP). **Methods:** This was a hospital-based cross-sectional analytical study with a control group done at Coimbatore Medical College & Hospital from March to August 2019. A total of 50 patients with alcoholic liver cirrhosis and 50 age-matched healthy individuals were included. Serum Fetuin-A levels were measured using sandwich ELISA. Liver function tests, CRP, prothrombin time/INR, and serum albumin were also measured. Disease severity was graded using the Child-Pugh scoring system. Statistical analysis was done using Student's t-test and Pearson correlation, with $p < 0.05$ considered significant. **Results:** Serum Fetuin-A levels were much lower in cirrhosis patients at 41.80 ± 33.82 ng/mL compared to healthy controls at 95.77 ± 10.11 ng/mL with a significant difference. Levels decreased as disease severity increased: CP-A 92.39 ± 32.11 ng/mL, CP-B 56.95 ± 8.92 ng/mL, and CP-C 13.71 ± 3.48 ng/mL, with all comparisons showing strong significance. Fetuin-A showed a strong negative correlation with total bilirubin, SGOT, SGPT, and CRP, meaning levels decreased as these increased. It showed a positive correlation with total protein and albumin, meaning levels increased along with better liver function. All these correlations were statistically significant. **Conclusion:** Serum Fetuin-A levels decrease steadily as liver function worsens in alcoholic cirrhosis. It shows strong relationships with common liver injury markers and inflammation, making it a useful marker to assess disease severity.

Keywords: Fetuin-A, AHSG, Alcoholic Liver Cirrhosis, Child-Pugh Score, C-Reactive Protein, Liver Biomarker

*Corresponding Author: B. Anitha
Email: anithabose1987@gmail.com

Graphical Abstract



Introduction

Alcoholic liver disease (ALD) includes a range of liver damage, starting from simple fat accumulation in the liver, progressing to alcoholic hepatitis, and finally to irreversible cirrhosis. It remains a major global health problem [1]. Worldwide, liver disease causes about two million deaths each year, which is about 4% of all deaths [2]. In India, alcohol is the most common cause of cirrhosis in adults, responsible for 43.2% of cases as shown in a recent national review and meta-analysis [3].

Even with progress in hepatology, the assessment of severity in alcoholic cirrhosis still mainly depends on scoring systems such as the Child-Pugh classification and the Model for End-Stage Liver Disease score. A single blood marker that can reflect both liver synthetic function and inflammation would be very useful in clinical practice.

Fetuin-A (also called AHSG) is a 59 kDa protein mainly produced by liver cells, contributing to more than 95% of its levels in the blood in adults [4]. It is coded by the AHSG gene on chromosome 3q27 and has several functions, including preventing abnormal calcification, acting as a negative acute phase reactant, inhibiting insulin receptor activity, and regulating TGF-β signalling [5]. Its levels decrease when inflammatory cytokines such as IL-1, IL-6, and TNF-α increase, and it also falls significantly when the liver's synthetic function is impaired [6]. Earlier studies have shown reduced Fetuin-A levels in primary biliary cirrhosis, chronic hepatitis, and liver cancer, and low levels are associated with poor short-term outcomes in advanced liver disease [7].

However, there are limited studies that specifically evaluate Fetuin-A as a marker of severity across different Child-Pugh stages in alcoholic cirrhosis. Therefore, this study was conducted to determine serum Fetuin-A levels in alcoholic cirrhosis and compare them with healthy individuals, to correlate Fetuin-A with disease severity using the Child-Pugh classification, and to study its relationship

with liver function test parameters and CRP.

Materials and Methods

Study Design and Setting

This was a hospital-based cross-sectional analytical study with a control group carried out in the Department of Biochemistry at Coimbatore Medical College & Hospital, Tamil Nadu, India, over a period of six months. Approval was obtained from the Institutional Ethics Committee, and written informed consent was taken from all participants.

Study Population

Fifty patients diagnosed with alcoholic liver cirrhosis were included from the Medical Gastroenterology outpatient and inpatient departments. Diagnosis was based on a history of long-term alcohol intake, abnormal liver function tests, and ultrasound findings.

Fifty healthy individuals of similar age, with no liver disease, were selected from the Master Health Check-Up programme as controls. A formal a priori sample size calculation was not performed. The study was conducted over a predefined study period, and all eligible patients with alcoholic liver cirrhosis and age-matched healthy controls presenting during this period were consecutively included.

Selection Criteria

Inclusion

Patients with confirmed alcoholic liver cirrhosis and age above 18 years.

Exclusion

Patients with non-alcoholic cirrhosis, age below 18 years, or those having diabetes, hypertension, heart failure, or chronic kidney disease. Patients with hepatorenal or hepatopulmonary syndrome were also excluded.

Sample Collection and Biochemical Estimation

Six millilitres of venous blood was collected under sterile conditions. Out of this, 4 mL was used for serum separation by centrifugation at 2000 rpm for 15 minutes. A portion was stored at −20°C for Fetuin-A estimation, and the remaining serum was used for liver function tests within 6 hours. Another 2 mL was collected in sodium citrate for coagulation studies. Serum Fetuin-A was measured using sandwich ELISA with a commercial kit. The test involved antibody-coated plates, enzyme-linked detection, and measurement of absorbance at 450 nm. C-Reactive Protein was measured using a quantitative turbidimetric method, with normal values up to 6 mg/L. Liver function tests included total bilirubin, AST, ALT, ALP, total protein, and albumin, measured using standard methods on a fully automated analyser. Coagulation tests included prothrombin time and activated partial thromboplastin time, with INR calculated.

Disease Severity Assessment

All patients were clinically examined for ascites and hepatic encephalopathy using standard criteria. Disease severity was graded using the Child-Pugh classification into Class A, Class B, and Class C based on scoring.

Statistical Analysis

Data analysis was done using SPSS version 20. Continuous values were expressed as mean and standard deviation. Student's t-test was used to compare two groups. One-way ANOVA with post-hoc tests was used to compare between different

Child-Pugh classes. Pearson correlation was used to study relationships between variables. A p value less than 0.05 was considered statistically significant.

Results

Demographic Profile

The average age was 47.26 ± 8.59 years in the patient group and 45.58 ± 10.53 years in the control group, and the difference was not statistically significant with p = 0.36, showing both groups were similar in age. Most of the patients were men at 96%, compared to 70% in the control group, which reflects the higher alcohol use among men in this region (Table 1).

Table 1. Age Comparison between Cases and Controls

Group	N	Mean ± SD (years)	t value	P value
Cases	50	47.26 ± 8.59	2.98	0.36 (NS)
Controls	50	45.58 ± 10.53		

NS = Not significant

Serum Fetuin-A: Cases vs Controls

Serum Fetuin-A levels were much lower in cirrhosis patients at 41.80 ± 33.82 ng/mL compared to 95.77 ± 10.11 ng/mL in healthy controls, and this difference was highly significant with t = −10.81 and p < 0.001. The mean difference was −53.97 ng/mL. This shows that as liver function decreases in cirrhosis, Fetuin-A levels also fall markedly (Table 2).

Table 2. Comparison of Serum Fetuin-A between Cases and Controls

Group	N	Fetuin-A Mean ± SD (ng/mL)	t value	P value
Cases	50	41.80 ± 33.82	−10.81	< 0.001
Controls	50	95.77 ± 10.11		

Liver Function Test Parameters

All liver function test values were significantly abnormal in patients compared to controls, with p < 0.001 for all. Total bilirubin was much higher in patients at 8.18 ± 7.41 mg/dL compared to 0.59 ± 0.20 mg/dL in controls. SGOT and SGPT levels were increased about 6 times and 5 times respectively. Total protein and albumin levels were clearly lower in patients, showing reduced liver synthetic function (Table 3).

Table 3. Comparison of Liver Function Test Parameters between Cases and Controls

Parameter	Cases Mean ± SD	Controls Mean ± SD	t value	P value
Total Bilirubin (mg/dL)	8.18 ± 7.41	0.59 ± 0.20	7.22	< 0.001
SGOT/AST (U/L)	132.72 ± 96.22	21.40 ± 4.88	8.17	< 0.001
SGPT/ALT (U/L)	107.80 ± 86.22	20.82 ± 8.08	7.10	< 0.001
ALP (U/L)	160.48 ± 74.94	79.04 ± 25.06	7.28	< 0.001
Total Protein (g/dL)	5.87 ± 1.25	7.40 ± 0.36	−8.27	< 0.001
Serum Albumin (g/dL)	2.72 ± 0.78	4.33 ± 0.94	−9.25	< 0.001

C-Reactive Protein

Serum CRP levels were much higher in patients at 52.48 ± 34.11 mg/L compared to 2.69 ± 2.21 mg/L in controls, and this difference was highly significant with $t = 10.29$ and $p < 0.001$. This shows that alcoholic cirrhosis is associated with a strong systemic inflammatory state (Table 4).

Table 4. Comparison of C-Reactive Protein (CRP) between Groups

Group	N	CRP Mean ± SD (mg/L)	t value	P value
Cases	50	52.48 ± 34.11	10.29	< 0.001
Controls	50	2.69 ± 2.21		

Fetuin-A across Child-Pugh Classes

Among the 50 patients, 8 patients had CP-A, 16 had CP-B, and 26 had CP-C. Serum Fetuin-A levels decreased as disease severity increased: 92.39 ± 32.11 ng/mL in CP-A, 56.95 ± 8.92 ng/mL in CP-B, and 13.71 ± 3.48 ng/mL in CP-C. All comparisons between the groups were highly significant with $p < 0.001$. This shows that Fetuin-A levels fall as liver disease becomes more severe (Table 5).

Table 5. Serum Fetuin-A Levels across Child-Pugh Classes in Cases

CP Class	**N (%)**	**Fetuin-A Mean ± SD (ng/mL)**	**Pairwise Comparison**	**P value**
CP-A	8 (16%)	92.39 ± 32.11	CP-A vs CP-B	< 0.001
CP-B	16 (32%)	56.95 ± 8.92	CP-A vs CP-C	< 0.001
CP-C	26 (52%)	13.71 ± 3.48	CP-B vs CP-C	< 0.001

Correlation of Fetuin-A with LFT and CRP

Fetuin-A levels showed a strong negative correlation with total bilirubin, SGOT, SGPT, and CRP, meaning that as these values increased, Fetuin-A levels decreased. It also showed a positive correlation with total protein and albumin, meaning that higher Fetuin-A levels were seen with better liver function. The strongest negative correlation was with CRP at $r = -0.853$, showing a clear opposite relationship between Fetuin-A and CRP (Table 6 and Figure 1).

Table 6. Pearson's Correlation Coefficients of Serum Fetuin-A with Biochemical Parameters in Cases

Parameter	**Pearson r**	**P value**
Total Bilirubin	−0.741	< 0.001
SGOT (AST)	−0.728	< 0.001
SGPT (ALT)	−0.716	< 0.001
Total Protein	+0.598	< 0.001
Serum Albumin	+0.654	< 0.001
C-Reactive Protein (CRP)	−0.853	< 0.001

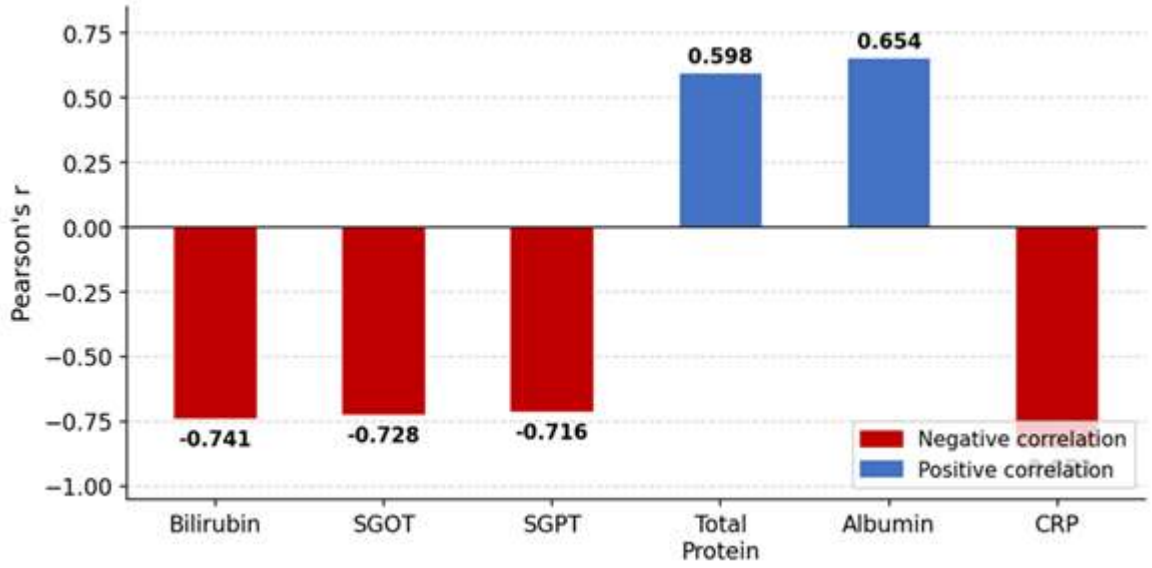


Figure 1. Pearson's Correlation of Serum Fetuin-A with Biochemical Parameters in Cases (all $p < 0.001$). Red bars = negative correlation; blue bars = positive correlation.

Discussion

The present study shows that serum Fetuin-A levels are much lower in patients with alcoholic liver cirrhosis and decrease further as the disease becomes more severe based on the Child-Pugh classification. These findings show that Fetuin-A can act as a marker for both reduced liver function and increased inflammation in these patients.

Fetuin-A is mainly produced by liver cells, with more than 95% of its level in the blood coming from the liver [4]. It is a negative acute phase reactant, which means its production decreases during inflammation. In cirrhosis, inflammatory cytokines such as IL-1, IL-6, and TNF-α increase and reduce Fetuin-A production [8]. The low Fetuin-A levels seen in cirrhosis patients in this study can be explained by both poor liver function and reduced production due to inflammation.

The decrease in Fetuin-A from CP-A to CP-C stages in this study is similar to earlier studies. Prystupa et al. [9] and Köklü et al. [10] also found that Fetuin-A levels are lower in more advanced stages of alcoholic liver disease, supporting its role as a marker of disease severity. Kalabay et al. [7] showed that very low Fetuin-A levels are linked to poor survival in alcoholic cirrhosis and can be compared with Child-Pugh and MELD scores. Their earlier study also showed that Fetuin-A reflects liver cell function and survival [11]. The current study supports these findings in an Indian population, where alcohol is a major cause of cirrhosis [3].

The strong negative relationship between Fetuin-A and CRP shows that as inflammation increases, Fetuin-A decreases. CRP increases in response to inflammation, while Fetuin-A decreases, showing an opposite pattern. Previous studies have also shown that high CRP is associated with worse outcomes in cirrhosis [12,13]. Fetuin-A also showed negative correlation with bilirubin, SGOT, and SGPT, and positive correlation with total protein and albumin. This means that as liver damage increases and liver function worsens, Fetuin-A levels decrease. Similar

findings have been reported in other studies [14–16].

Recent studies have also shown that Fetuin-A may play a role in the disease process itself. Chen et al. [17] found that Fetuin-A can affect inflammation and immune responses in alcoholic liver disease. Other studies have also described its role in controlling inflammation and tissue stress [18].

Globally, cirrhosis is a major cause of death, with alcohol being one of the leading causes worldwide and in India [19–21]. Fetuin-A, which can be measured easily using ELISA, may be a useful and affordable marker that reflects both liver function and inflammation in a single test. The global prevalence of alcohol-related liver disease is about 4.8%, with cirrhosis forming a significant part of it [22].

Patients with common comorbidities such as diabetes and hypertension were excluded to minimize metabolic and inflammatory confounding; however, this may limit the generalizability of the findings to the broader cirrhosis population where such conditions are prevalent. Potential confounding factors such as body mass index, nutritional status, smoking, and other subclinical inflammatory conditions were not assessed in this study and may have influenced serum Fetuin-A levels. This should be considered while interpreting the observed associations.

Although a formal a priori sample size estimation was not undertaken, the study demonstrated a large and statistically significant difference in serum Fetuin-A levels between cases and controls. This suggests that the sample size was adequate to detect meaningful differences for the primary outcome. However, this inference is based on post hoc assessment and should be interpreted cautiously.

Conclusion

This study demonstrates that serum Fetuin-A levels decrease significantly with increasing severity of alcoholic liver cirrhosis and show strong correlations with established biochemical markers of liver dysfunction and inflammation. These findings highlight the potential of Fetuin-A as a simple, non-invasive biomarker reflecting both hepatic synthetic function and systemic inflammatory status. Incorporating Fetuin-A into clinical assessment may aid in better stratification of disease severity alongside conventional scoring systems. Further large-scale and longitudinal studies are warranted to validate its prognostic utility and clinical applicability.

Limitations

The absence of a priori sample size estimation and reliance on a time-bound sample may affect the precision of the findings. Potential residual confounding cannot be excluded, as factors such as nutritional status, body composition, smoking, and other inflammatory conditions were not comprehensively evaluated. Additionally, the exclusion of patients with common comorbidities and the skewed distribution of patients across Child-Pugh classes, with a predominance of advanced disease (CP-C), may have influenced severity comparisons and limits the generalizability of these findings across all stages of cirrhosis. A degree of selection bias may also be present due to imbalance in gender distribution between cases and controls. Due to the sample size and study design, multivariable adjustment was not performed.

Future Scope

Longitudinal evaluation of Fetuin-A as a prognostic marker for decompensation events and mortality; comparative studies across non-alcoholic aetiologies of cirrhosis; genetic studies on AHSG gene expression modulation in ALD.

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.

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 Institutional Human Ethics Committee of Coimbatore Medical College, Coimbatore carrying certificate number 0173/2018, dt 15.12.2018

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.

References

1. O'Shea RS, Dasarathy S, McCullough AJ. Alcoholic liver disease. Hepatology. 2010;51(1):307–328. doi: 10.1002/hep.23258
2. Devarbhavi H, Asrani SK, Arab JP, Nartey YA, Pose E, Kamath PS. Global burden of liver disease: 2023 update. J Hepatol. 2023;79(2):516–537. doi: 10.1016/j.jhep.2023.03.017
3. Shalimar, Sheikh MF, Mahl TC, et al. Etiological spectrum of cirrhosis in India: a systematic review and meta-analysis. J Clin Exp Hepatol. 2023;13(6):1051-1062. doi: 10.1016/j.jceh.2023.09.004
4. Chekol Abebe E, Tilahun Muche Z, Behaile T, et al. The structure, biosynthesis, and biological roles of fetuin-A: a review. Front Cell Dev Biol. 2022;10:945287. doi: 10.3389/fcell.2022.945287
5. Jahnen-Dechent W, Heiss A, Schäfer C, Ketteler M. Fetuin-A regulation of calcified matrix metabolism. Circ Res. 2011;108(12):1494-1509. doi: 10.1161/CIRCRESAHA.110.234260
6. Gangneux C, Daveau M, Hiron M, et al. The inflammation-induced down-regulation of plasma fetuin-A in liver results from the loss of interaction between long C/EBP isoforms at two neighbouring binding sites. Nucleic Acids Res. 2003;31(20):5957-5970. doi: 10.1093/nar/gkg794
7. Kalabay L, Gráf L, Vörös K, et al. Human serum fetuin A/alpha2HS-glycoprotein level is associated with long-term survival in patients with alcoholic liver cirrhosis, comparison with the Child-Pugh and MELD scores. BMC Gastroenterol.

2007;7:15. doi: 10.1186/1471-230X-7-15

8. Kezer CA, Simonetto DA, Shah VH. Sex differences in alcohol use and alcohol-related liver disease. Mayo Clin Proc. 2021;96(4):1006-1016. doi: 10.1016/j.mayocp.2020.11.012
9. Prystupa A, Dąbrowska A, Sak JJ, et al. Concentrations of fetuin-A, osteoprotegerin and α-Klotho in patients with alcoholic liver cirrhosis. Exp Ther Med. 2016;12(5):3464-3470. doi: 10.3892/etm.2016.3754
10. Köklü S, Demir G, Yüksel ES, et al. Fetuin-A can assess the severity of alcohol-related liver disease. Medicina (Kaunas). 2025;61(7):1147. doi: 10.3390/medicina61071147
11. Kalabay L, Jakab L, Prohászka Z, et al. Human fetuin/alpha2HS-glycoprotein level as a novel indicator of liver cell function and short-term mortality in patients with liver cirrhosis and liver cancer. Eur J Gastroenterol Hepatol. 2002;14(4):389-394. doi: 10.1097/00042737-200204000-00006
12. Di Martino V, Coutris C, Cervoni JP, et al. Prognostic value of C-reactive protein levels in patients with cirrhosis of the liver. Liver Transpl. 2015;21(12):1474-1481. doi: 10.1002/lt.24313
13. Kerner A, Avizohar O, Sella R, et al. Association between elevated liver enzymes and C-reactive protein: possible hepatic contribution to systemic inflammation in the metabolic syndrome. Arterioscler Thromb Vasc Biol. 2005;25(1):193-197. doi: 10.1161/01.ATV.0000148324.63685.4f
14. Mohamed SY, Amin AI, Farouk HM, et al. Serum fetuin-A levels in patients with hepatocellular carcinoma and liver cirrhosis: correlation with liver function parameters and inflammatory markers. Arab J Gastroenterol. 2021;22(3):220-226. doi: 10.1016/j.ajg.2021.05.007
15. Kamada Y, Takehara T, Hayashi N. Fetuin-A negatively correlates with liver and vascular fibrosis in nonalcoholic fatty liver disease subjects. J Gastroenterol. 2014;50(4):440-451. doi: 10.1007/s00535-014-0986-1
16. Liu S, Xiao J, Zhao Z, Wang M, Wang Y, Xin Y. Systematic review and meta-analysis of circulating fetuin-A levels in nonalcoholic fatty liver disease. J Clin Transl Hepatol. 2021;9(1):3-10. doi: 10.14218/JCTH.2020.00095
17. Chen X, Zhang H, Liu X, et al. Hepatocyte-derived fetuin-A promotes alcohol-associated liver disease in mice by inhibiting autophagy-lysosome degradation of TLR4 and M2 macrophage polarization. Free Radic Biol Med. 2024;224:338-350. doi: 10.1016/j.freeradbiomed.2024.08.029
18. Jahnen-Dechent W, Schäfer C, Ketteler M, McKee MD. Mineral chaperones: a role for fetuin-A and osteopontin in the inhibition and regression of pathologic calcification. J Mol Med (Berl). 2020;99(4):419-436. doi: 10.1007/s00109-020-01958-7

19. Huang DQ, Mathurin P, Cortez-Pinto H, Loomba R. Global epidemiology of alcohol-associated cirrhosis and HCC: trends, projections and risk factors. Nat Rev Gastroenterol Hepatol. 2023;20(1):37-49. doi: 10.1038/s41575-022-00688-6
20. Sharma M, Gora BA, Venishetty V, et al. The pattern of alcohol use in alcohol-related cirrhosis in Indian patients: AUDIT Indian Liver Study. J Clin Exp Hepatol. 2023;13(3):437-446. doi: 10.1016/j.jceh.2022.12.009
21. Ginès P, Krag A, Abraldes JG, Solà E, Fabrellas N, Kamath PS. Liver cirrhosis. Lancet. 2021;398(10308):1359-1376. doi: 10.1016/S0140-6736(21)01374-X
22. Wang L, Chen C, Xu S, et al. Global prevalence, incidence, and outcomes of alcohol-related liver diseases: a systematic review and meta-analysis. BMC Public Health. 2023;23(1):1516. doi: 10.1186/s12889-023-15749-x

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 847–855, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.017

CASE SERIES

Perioperative Anesthetic Management of Ruptured Aortic Aneurysms: A Case Series from a Tertiary Care Hospital

Jeenu D,[1] Rahavi R,[1] Meenu Anna John,[1] Nitish Vijayanand,[1] Kirubakaran Davis[2] and Sathish Kumar Dharmalingam[2,*]

[1]*Assistant Professor, Department of Anaesthesiology, Christian Medical College, Vellore – 632004, Tamil Nadu, India*
[2]*Professor, Department of Anaesthesiology, Christian Medical College, Vellore – 632004, Tamil Nadu, India*

Accepted: 16-April-2026 / Published Online: 6-May-2026

Abstract

A ruptured aortic aneurysm is an ASA physical class 5 emergency associated with high perioperative morbidity and mortality, necessitating rapid multidisciplinary decision-making and intervention. The ruptured aortic aneurysm cases must be centralized to high-volume centers capable of performing both open and endovascular repair to minimize morbidity and mortality. During intervention, the priorities include goal-directed fluid resuscitation, implementing permissive hypotension without compromising end-organ perfusion, and managing massive transfusion while counteracting the lethal triad of acidosis, hypothermia, and coagulopathy. Based on the patient's status and procedural management, anesthesia will be tailored to general or local/monitored anesthesia. This case series highlights outcomes and discharge dispositions of various procedural interventions for ruptured aortic aneurysms.

Keywords: Aortic aneurysm, massive blood transfusion, coagulopathy, aortic cross-clamping

*Corresponding Author: Sathish Kumar Dharmalingam
Email: drsathish78@yahoo.com

Introduction

An aneurysm is an abnormal, localized widening of an artery. An abdominal aortic aneurysm (AAA) is typically defined as a permanent dilation of the abdominal aorta to at least 30 mm or more than 50% of its original diameter at the level of the renal arteries, most often involving the infrarenal segment. Risk factors include smoking, male sex, older age, systemic hypertension, hypercholesterolemia, a history of peripheral and coronary artery disease, connective tissue disorders, and a family history of aneurysm [1].

Population-based studies have estimated that the prevalence of AAA is 3–5% in elderly men aged 65 years or older, whereas it has doubled to 10% in those aged 80 years or older. The dreaded complication of any AAA is rupture, whether contained or free, and the formation of an intraperitoneal or retroperitoneal hematoma. Nearly 50% of the patients with ruptured aortic aneurysm die before reaching the hospital, and another one-third of the patients die during interventions or postoperatively [2]. The Society for Vascular Surgery (SVS) recommended that the "door to intervention" time be 90 minutes within a 30/30/30 framework for diagnosis, transfer, anesthesia preparation, and surgical intervention [3].

We report a case series of five patients who underwent emergency aortic repair (three open surgical repairs [OSR] for ruptured abdominal aortic aneurysms and two endovascular repairs [EVAR]) for ruptured thoracoabdominal aortic aneurysms. This case series highlights the role of goal-directed fluid resuscitation, advanced hemodynamic monitoring, massive blood transfusion, and permissive hypotension in managing ASA class 4 and 5 of ruptured aortic aneurysms.

Case 1: open surgical repair of ruptured infrarenal AAA

An elderly man in his sixties presented with sudden acute abdominal pain, profuse sweating, and agitation. On examination, he revealed a pulsatile mass with relative hemodynamic instability, requiring rapid-sequence intubation (RSI), and was started on vasopressor and inotropic support in ED. Computed Tomography angiography (CTA) imaging showed a 10 x 7 cm infrarenal ruptured aortic aneurysm with retroperitoneal hematoma (Figure 1).

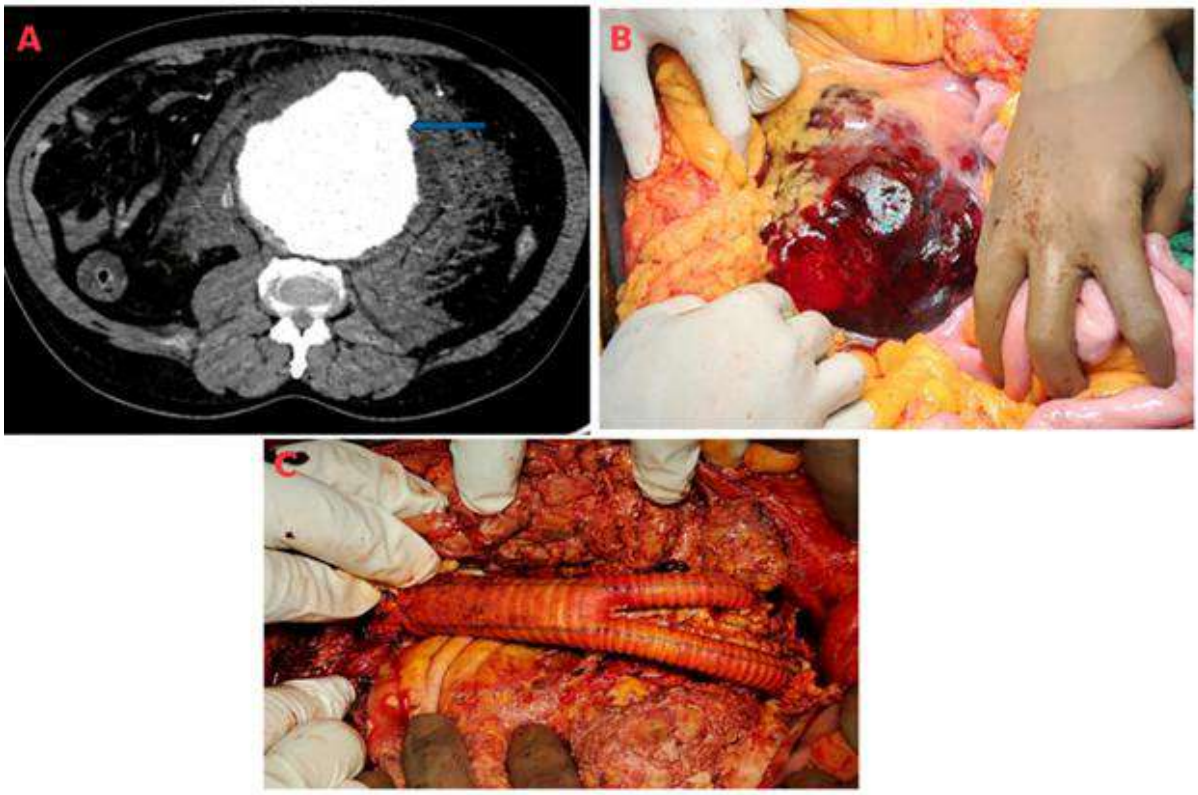


Figure 1. A: CT angiogram showing an infrarenal abdominal aortic aneurysm measuring 10 × 7 cm (blue arrow), B: intraoperative visualization of posterior wall rupture, and C: surgical repair with placement of a Dacron bifurcated graft (16 × 8 mm).

In the Operating Room (OR), an Invasive left brachial arterial line (peripheral pulses feeble) and a left Internal jugular vein (IJV) central line (Right external jugular vein venous access was started in the ED) were placed for an OSR. Aortic cross-clamping caused hypertension, managed with glyceryl trinitrate (GTN). Acidosis and reperfusion injury were treated with sodium bicarbonate and mannitol. Tranexamic acid infusion was started to reduce bleeding. Estimated blood loss was 4,500 mL with massive transfusion. Postoperatively, he was shifted and mechanically ventilated in the ICU, extubated after 48 hours, and discharged stable on postoperative day 10.

Case 2 – Open rAAA Repair with Axillobifemoral Bypass

An elderly man in his sixties presented with sudden abdominal and back pain along with fever. His examination revealed a pulsatile abdominal mass measuring 7 x 7 cm with absent distal pulses. In the ED, he experienced syncope and hypotension and was started on norepinephrine**.** Due to hemodynamic instability and suspected rupture, emergency laparotomy and aneurysm repair with axillobifemoral bypass were undertaken. The decision to proceed with axillobifemoral bypass was made in view of an infected mycotic aneurysm. In the operating theatre, he was intubated with RSI with a MAP of 80 mmHg using a video laryngoscope. An invasive right radial arterial line and a right IJV central line were

placed, along with advanced monitoring of FloTrac, in view of LV dysfunction with RWMA.

A 9 × 8.5 cm infrarenal aneurysm with posterior rupture and 2,000 mL hemoperitoneum was found. Stepwise supraceliac followed by infrarenal clamping–induced hypertension was managed with GTN. To mitigate acidosis and reperfusion injury, sodium bicarbonate infusion was given. The estimated blood loss was 7500 ml, which was replaced with albumin and blood products. He was shifted to the ICU and ventilated mechanically for 24 hours and discharged on day 8.

Case 3 – Open ruptured infrarenal AAA repair

An elderly man in his sixties presented with abdominal pain radiating to the back for 10 days. Examination revealed a 10 × 8 cm pulsatile mass in the abdomen, and a CTA scan confirmed a ruptured abdominal aortic aneurysm. Upon arrival at the operating theatre, his SBP was 90 mmHg, and he was intubated by RSI. A right radial arterial line and right IJV were inserted under local anesthesia before induction. Advanced FloTrac cardiac output monitoring was connected. During surgery, a 14 × 10 cm ruptured infrarenal aneurysm was discovered. Stepwise supraceliac then infrarenal clamping was performed. Clamp-induced hypertension was managed with GTN, while hypotension from declamping was treated with Norepinephrine and vasopressin. To reduce reperfusion injury and acidosis, sodium bicarbonate was administered. Approximately 3500 ml of blood loss was replaced with albumin and blood products, with the cell saver recovering about 1650 ml of blood. Postoperatively, he was transferred to the ICU, mechanically ventilated for 24 hours, and moved to the ward on day 5 and was discharged on day 15.

Case 4 – Ruptured Thoracoabdominal Aneurysm Managed with TEVAR [thoracic endovascular aortic repair]

A female in her fifties presented with severe abdominal pain, fever, and vomiting. Her CTA showed a descending thoracic aortic aneurysm at the T12 level in a size of 4 x5 cm with contained rupture planned for TEVAR. In OR, TEVAR was done under monitored anesthesia care with an invasive arterial line. Intraoperatively, there was no hemodynamic instability, and the patient was not on any vasopressors. Post-procedure aortogram showed no endoleak. She was shifted to HDU for monitoring and discharged on day 5.

Case 5 – Ruptured Thoracoabdominal Aneurysm Managed with TEVAR

An elderly man in his fifties presented with back pain, fever, and features of hemorrhagic shock of SBP 90 mmHg and respiratory rate of 40/min with decreased left lung air entry to the ED. He was rushed to the theater after CTA, where a thoracoabdominal aortic aneurysm type 5 was intubated by RSI, and the right radial artery and right IJV were inserted and started on vasopressors. After TEVAR, his right lower limb pulses were absent, and he was immediately taken up for right femoral artery thrombectomy and left Intercostal drain [ICD] placement for hemothorax. He lost around 300 mL of blood and has received one unit of packed cell transfusion. He was transferred to the ICU for mechanical ventilation, extubated after 48 hours, and discharged on the 3rd week.

Discussion

Ruptured abdominal aortic aneurysm (rAAA) is defined as rupture of the AAA with bleeding from outside the true aortic wall with an intra- or retroperitoneal hematoma. Ruptured aortic aneurysms (RAA) are associated with high prehospital and in-hospital mortality. The key challenge in reducing mortality is diagnosing rAAA early in the ED/ward and shifting to the interventional place. Earlier, rAAA was diagnosed with STS (standard triad signs), including abdominal pain, hypotension, and a pulsatile mass. The classical triad is absent in 70% of rAAA due to the absence of palpable pulsatile mass and unreliable atypical symptoms. The newer score, MARS [Modified Abdominal Aortic Rupture Signs], was introduced, which encompasses 1) the registered pain-associated symptoms or signs, 2) all hypovolemic-associated signs, and 3) pulsatile abdominal mass and/or ultrasound finding[4]. Risk stratification is crucial for predicting outcomes and making decisions for patients with ruptured aortic aneurysms. The Hardman Index and the Glasgow Aneurysm Score (GAS) are among the most used tools for estimating mortality risk associated with a given procedure. The Hardman Index considers five variables: age >76 years, loss of consciousness, hemoglobin <9 g/dL, serum creatinine >190 µmol/L, and ischemic changes on ECG, while GAS evaluates age, shock, myocardial disease, cerebrovascular disease, and renal disease. In our case series, we noted that GAS scores were low and Hardman Index scores ranged from 0 to 1 (Table 1), which may have contributed to the good outcomes given the emergency nature of the situation.

Table 1. Demographic, clinical, and perioperative characteristics of patients with ruptured aortic aneurysm

Variable	**Case 1**	**Case 2**	**Case 3**	**Case 4**	**Case 5**
Age (years)	69	63	65	59	51
Smoking status	Yes	Yes	Yes	No	No
Hardman index score	1	1	1	0	0
Glasgow Aneurysm Score (GAS)	86	72	79	59	68
Aneurysm size (cm)	10 × 7	9 × 8.5	14 × 10	4 × 5	8.5 × 6
Haemoglobin (g/dL)	13.8	9.6	9.3	10.8	13.6
Creatinine (mg/dL)	1.29	1.08	2.02	0.43	1.01
Initial arterial pH	7.24	7.40	7.31	NA	7.38
Base deficit (mEq/L)	-11.1	-3.9	-8.7	NA	-6.6
Initial lactate (mmol/L)	8.7	1.1	1.6	NA	2.6
Advanced monitoring	FloTrac	FloTrac	FloTrac	None	NIRS
Aortic clamp site	Supraceliac	Supraceliac	Supraceliac	None	None
Tranexamic acid used	Yes	Yes	Yes	No	No
Packed red blood cells (units)	6	9	4	None	1
Estimated blood loss (mL)	4500	7500	3500	150	300
Fresh frozen plasma / Cryoprecipitate (units)	4 / 3	10 / 16	0	None	None

Lowest intraoperative pH	7.12	7.40	7.17	NA	7.37
Peak intraoperative lactate (mmol/L)	7.1	8.7	5.7	NA	2.6
Outcome	Good	Good	Good	Good	Good

The potential for rupture is related to the aneurysm's size. The aneurysm of size 5 – 6 cm has a 3-15% risk of rupture, whereas the 6-7 cm aneurysm has a 10 – 20%, and the 7-8 cm aneurysm has a 20-40% risk of rupture, and more than 8 cm has a 50% risk of rupture [5]. In our series, all patients have an aneurysm >7 cm, except case 4, which had a smaller aneurysm with contained rupture, indicating that rupture does not depend solely on aneurysm size. The aneurysm diameter threshold for elective repair is 55 mm in men and 50 mm in women. To consider elective repair, an ultrasonogram was the initial choice to determine the diameter, whereas CTA is used for treatment planning. In an emergency setting, a patient with hemodynamically stable conditions should consider EVAR as the best option, even for a hemodynamically unstable patient; if possible, so the patient can undergo CTA and EVAR as per the 2024 European guidelines [6]. In a meta-analysis study, the patients with hemodynamically unstable conditions who underwent EVAR have an in-hospital mortality of 37%, whereas for OSR, it is 62% [7]. The IMPROVE trial supports an endovascular-first strategy in ruptured AAA, demonstrating comparable mortality with potential advantages in recovery and discharge outcomes [8].

Often, OSR requires general anesthesia for a ruptured aortic aneurysm, whereas EVAR can be performed under local anesthesia in a hemodynamically stable patient. The intervention for the RAA depends on multiple factors, including age, comorbidities, suitability of the aortic anatomy, infected versus non-infected aorta, the center's expertise, the patient's hemodynamic status, and the cost of the procedure. For RAA, the more invasive the procedure, the greater the need for advanced monitoring, such as invasive lines, cardiac output monitoring, and TEG/ROTEM. Multiple studies have shown that incorporating viscoelastic assays into RAA management is a powerful tool to guide safe transfusion, as it reflects both hypercoagulability and fibrinolysis, thereby reducing unnecessary transfusions that can further increase morbidity and mortality [9]. We used FloTrac for real-time monitoring in 3 cases, TEG/ROTEM to guide transfusion in 4 cases, and level 1 and 2 warming devices for open repair cases and to maintain normothermia. In EVAR, warming must be limited to the upper body; the lower limbs must be spared due to increased burn risk, as there is no circulation during graft deployment.

There is substantial evidence that permissive hypotension is advantageous for RAA outcomes by allowing stable clot formation, preventing blown-out clots, decreasing bleeding, and preventing coagulopathy, whereas normotensive resuscitation might exacerbate bleeding and compromise outcomes. The target systolic BP for RAA is 70-90 mmHg until the surgeon achieves proximal aortic control [10]. The ROSE concept defines the Resuscitation phase in the ED as restrictive rather than aggressive fluid management to maintain higher SBP. The Optimization

phase occurs in the OR, where optimization should be with blood and blood products rather than crystalloids, in a ratio of FFP: Blood 1:1. The stabilization phase starts once the repair has been completed, by avoiding excessive fluid administration and giving only maintenance fluids. The evacuation phase is the de-escalation phase, during which excess fluids are removed from the body [11]. The ESVS [European Society for Vascular Surgery] has recommended the intraoperative use of cell salvage to reduce intraoperative bleeding and the need for allogenic transfusion. Our cases have emphasized this permissive hypotension, maintaining systolic BP at 70-90 mmHg while preserving end-organ perfusion and restricting aggressive fluid management through early use of blood and blood products, thereby mitigating the lethal triad of acidosis, hypothermia, and coagulopathy by incorporating the ROSE concept. We have used cell salvage [1690 ml blood] in our case 3.

Aortic aneurysm during repair often requires cross-clamping. The level and duration of aortic cross-clamping determine the extent of postoperative complications, driven by hypoperfusion followed by ischemia-reperfusion injury. Cross-clamping increases preload proximal to the clamp and cuts off the blood supply distal to it. At which level to be cross-clamped is often decided by the extent of the aneurysm and the diseased aortic wall. Suprarenal and supraceliac aortic cross-clamping will increase the workload to the heart and cause proximal arterial hypertension, which has to be treated with vasodilators like sodium nitroprusside or glyceryl trinitrate. Once the clamp has been released, a declamping shock will occur due to mediators' release, which must be treated with vasopressors, inotropes, and sodium bicarbonate. Both clamping and declamping should be performed stepwise to avoid severe arterial hypertension and sudden bursts of massive mediators [6,12]. In all 3 OSRs, cross-clamping at the supraceliac level is associated with greater hemodynamic instability during clamping and declamping, which was proactively managed with pharmacological agents and advanced monitoring. In case 5, an ICD for hemothorax was placed after TEVAR. Intercostal drainage is typically deferred until after endovascular exclusion of the rupture, as premature pleural decompression may abolish any potential containment effect and precipitate uncontrolled hemorrhage.

Aortic aneurysm repair can lead to a multitude of complications, such as myocardial infarction [MI], arrhythmia, Acute Kidney Injury and Acute Tubular Necrosis [ischemia and contrast dye], ACS (abdominal compartment syndrome), including paralytic ileus, bowel ischemia and perforation, and rarely lower limb ischemia. Lower limb pulses have to be verified in all cases of aortic repair [13]. None of our cases had MI and colonic ischemia, and 3 of our OSR cases had AKI, which resolved before discharge. In case 5, the patient had an absent right lower limb pulse and underwent immediate femoral thrombectomy. EVAR patients were discharged in the 1st week, whereas the first 2 OSRs were discharged in the 2nd week, and the 3rd was discharged in the 3rd week. These differences should be viewed with caution, as the decision between EVAR and open surgical repair was influenced by factors such as anatomical suitability, hemodynamic status, comorbidities, and institutional expertise, which may introduce selection bias.

Conclusion

To manage a ruptured aortic aneurysm effectively, a rapid multidisciplinary, integrated action is important. Timely intervention, ideally within 90 minutes within a 30/30/30 framework for diagnosis, transfer, anesthesia preparation, and procedural intervention, is crucial for improving outcomes. The perioperative management of these complex cases was guided by the patient's hemodynamic stability, comorbidities, and planned intervention. The open approach may have a longer postoperative stay than EVAR. In rAAA cases, better outcomes result from regionalization to high-volume centers of excellence that offer both surgical and endovascular options, thereby reducing morbidity and mortality.

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.

Informed Consent

Informed consent was obtained from the patient's next of kin, and anonymity will be maintained.

References

1. Wanhainen A, Mani K, Modrau IS. Pathogenesis and management of abdominal aortic aneurysm. Eur Heart J. 2023;44(29):2682-789.
2. Scali ST, Stone DH. Modern management of ruptured abdominal aortic aneurysm. Front Cardiovasc Med. 2023;10:1323465.
3. Chaikof EL, Dalman RL, Eskandari MK, Jackson BM, Lee WA, Mansour MA, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. J Vasc Surg. 2018;67(1):2-77.e2.
4. Bergmark P, Sadeghi M, Talvitie M, Hultgren R. Initial signs in patients with ruptured abdominal aortic aneurysms: time for an expanded triad? Scand J Trauma Resusc Emerg Med. 2024;32:94.
5. Haque K, Bhargava P. Abdominal Aortic Aneurysm. Am Fam Physician. 2022;106(2):165-172.
6. Wanhainen A, Mani K, Björck M, Borhani S, Chakfe N, Debus S, et al. Editor’s Choice -- European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-Iliac Artery Aneurysms. Eur J Vasc Endovasc Surg. 2024;67(2):192-331.
7. Zhang S, Feng J, Li H, Zhang Y, Lu Q, Jing Z. Open surgery (OS) versus endovascular aneurysm repair (EVAR) for hemodynamically stable and unstable ruptured abdominal aortic aneurysm (rAAA). Heart Vessels. 2016;31(8):1291-302.
8. Powell JT, Sweeting MJ, Thompson MM, Ashleigh R, Bell R, Gomes M, et al. Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30-day outcomes from the IMPROVE randomized trial. Lancet. 2014;384(9947):811–820.
9. Gniedziejko M, Halman J, Kimilu N, Folwarski M, Siemiński M. Thromboelastography in ruptured abdominal aortic aneurysm management: lessons from vascular,

cardiac, and trauma surgery. Front Cardiovasc Med. 2025;12:1668165.
10. Leonard A, Thompson J. Anaesthesia for ruptured abdominal aortic aneurysm. CEACCP. 2008;8(1):11-5.
11. Willam C, Herbst L. The ROSE concept: modern fluid management in intensive care medicine. Med Klin Intensivmed Notfmed. 2024;119(8):634-9.
12. Zammert M, Gelman S. The pathophysiology of aortic cross-clamping. Best Pract Res Clin Anaesthesiol. 2016;30(3):257-69.
13. Kyriacou H, Mostafa AMHAM, Sumal AS, Hellawell HN, Boyle JR. Abdominal aortic aneurysms part two: Surgical management, postoperative complications and surveillance. J Perioper Pract. 2021;31(9):319-25.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 856–861, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.018

CASE REPORT

Isolated Giant Ureteric Calculus in an Otherwise Healthy Adult: A Case Report

Shitangsu Kakoti[1,*] and Dharitri Dutta[2]

[1]*Department of Urology, All India Institute of Medical Sciences, Guwahati*
[2]*Department of Anaesthesiology, All India Institute of Medical Sciences, Guwahati*

Accepted: 4-February-2026 / Published Online: 6-May-2026

Abstract

Giant ureteric calculus is a rare entity nowadays, particularly in young patients without known metabolic or anatomical conditions. We present a case of a 26-year-old healthy male who was diagnosed with an isolated left-sided giant ureteric calculus. Considering the stone size, laparoscopic ureterolithotomy was done, leading to complete stone-free status and excellent postoperative recovery. This case highlights the rarity of large ureteric stones in a healthy individual, which can remain dormant for a long time and may require traditional surgery, such as laparoscopy, rather than the more popular endoscopic treatment.

Keywords: Ureteral Calculi**,** Giant, Laparoscopy, Ureterolithotomy

*Corresponding Author: Shitangsu Kakoti
Email: drshitangsu@gmail.com

Introduction

Urinary calculi, or stones in the urinary tract, are a common phenomenon worldwide. However, giant stones measuring more than 5 cm or weighing over 50 grams are very scarce and need special surgical attention [1,2]. In this modern era, endourology has revolutionized the management of all types of urinary stones, be it in the kidneys, ureters, or urinary bladder. Yet sometimes we encounter certain urinary stones that become too large in size, so that they defy endoscopic fragmentation and require traditional surgical interventions [3]. Giant ureteric stones are one of such rare entities that have been phased out slowly due to improved and accessible diagnostics and very early interventions [4]. However, when they occur in a patient with no identifiable metabolic predisposition or anatomical risk factors, it raises some questions about our current understanding of the subject. Here we are going to report one such case.

Case presentation

A 26-year-old man presented to us with acute pain in the left flank for the past 5 days. Initially, the pain was colicky in nature, moderate in intensity, and radiating to the groin. It was also associated with nausea. But gradually, the characteristic of the pain changed to a constant dull aching pain over the left loin, not relieved by any analgesics. There was no associated fever, dysuria, or hematuria. The patient had no previous urological issues or any significant past medical history. The patient was an active army personnel with a fit body and a healthy routine. Upon enquiring his family history, there was no suggestion of any inherited renal disease or urolithiasis. The physical examination revealed tenderness over the left costovertebral angle. Laboratory tests were unremarkable with normal kidney function results.

Routine Urine examinations showed microscopic hematuria with a few pus cells. Ultrasonography of the abdomen revealed a 7 cm calculus in the left ureter with moderate hydroureteronephrosis. An emergency double-J stent insertion was done for decompression. Later, he underwent a Computer Tomography (CT) scan of the Kidneys and Bladder (KUB) region with Urography. The report confirmed the existence of a giant mid-ureteric radio-opaque measuring 7.5 x 2.0 x 2.0 cm calculus with mild hydroureteronephrosis (HDUN). The CT scan also showed normal Genitourinary anatomy without any evidence of predisposing factors (Figure 1).

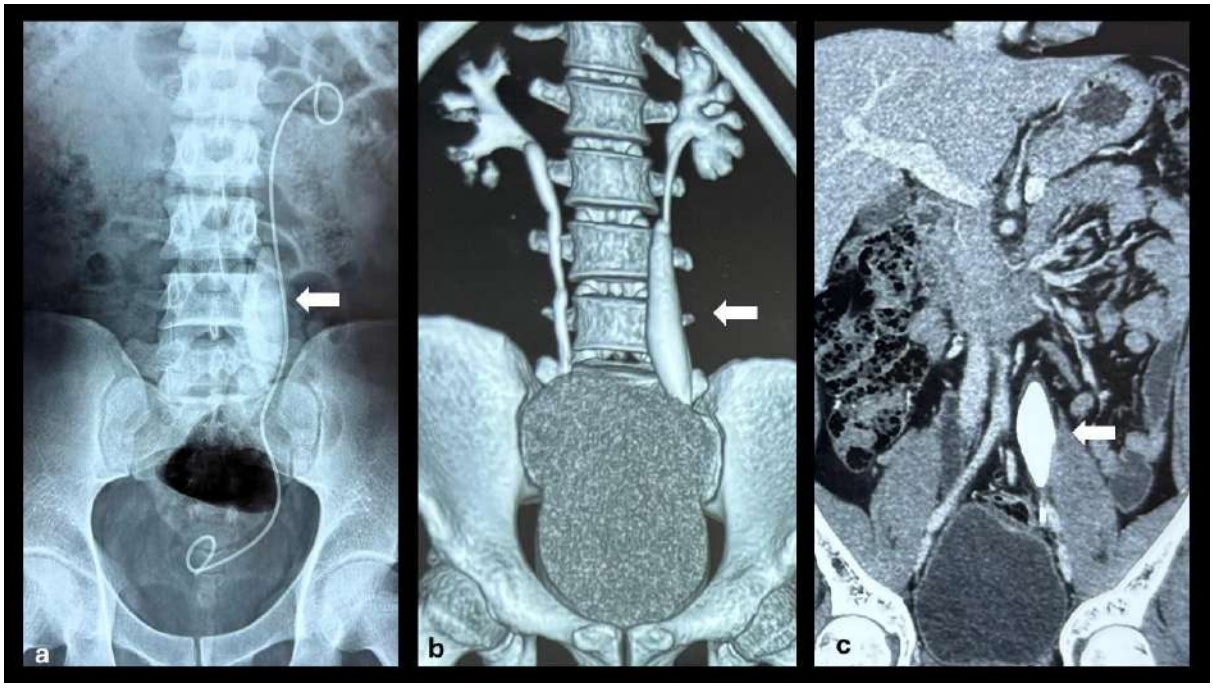


Figure 1. a) Plain X-Ray KUB showing a large radio-opaque density in the region of left ureter (arrow) with a left Double-J stent in situ, b) CT Urography showing a left ureteric calculus (arrow) with a double-J stent in situ with mild hydronephrosis of left kidney, c) CT scan showing left ureteric calculus in coronal plane (arrow).

A laparoscopic transperitoneal ureterolithotomy was planned and performed under general anaesthesia with one 10 mm port and two 5mm ports, as ureteric lithotripsy was deemed unfeasible. Intraoperatively, the left ureter was found to be dilated as it encases the whole calculus, but interestingly, the ureteric wall was not thinned out as expected. A brownish-black stone of size 7 cm x 2 cm x 2cm was removed, after making a longitudinal incision over the bulged ureter, and the incision was repaired with an interrupted absorbable suture over a double-J stent. (Figure 2) The stone was then sent for analysis.

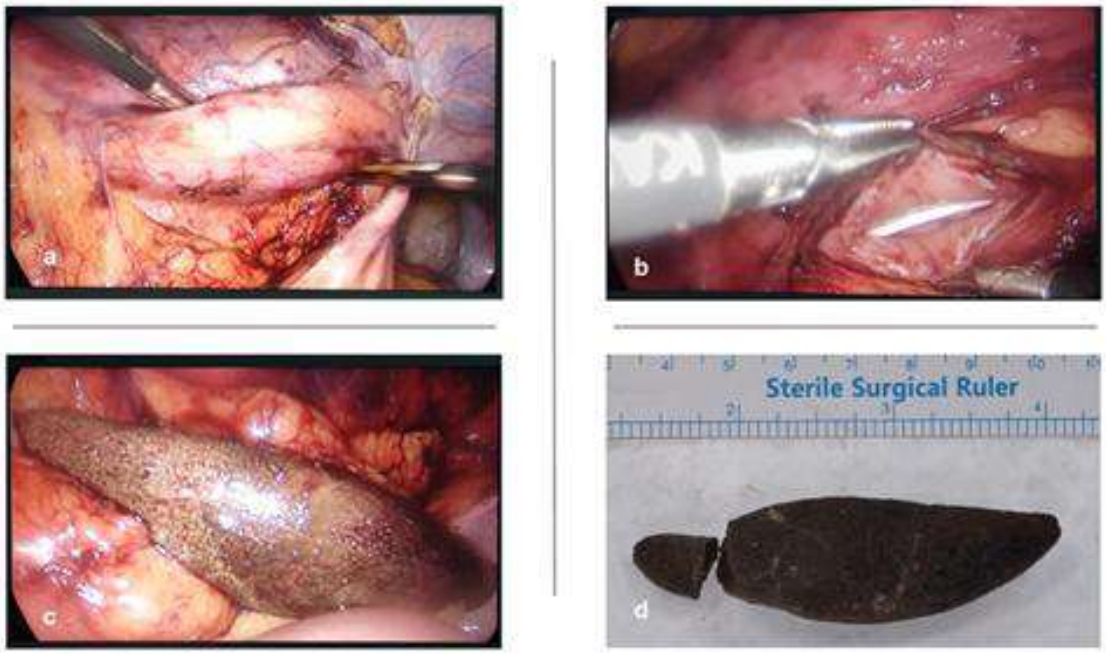


Figure 2. Intraoperative laparoscopic view showing a) Dilated left ureter encasing the giant calculus, b) Longitudinally incised ureter with stent inside following removal of calculus, c) Giant ureteric calculus in the peritoneal cavity, d) Retrieved calculus.

The postoperative recovery was uneventful, and stent removal was done after 6 weeks. The stone analysis revealed calcium oxalate monohydrate (90%) and calcium oxalate dihydrate (10%) composition. Additionally, he also underwent a metabolic workup, including a 24-hour urine analysis; however, the results did not reveal any specific abnormality. A follow-up imaging was also done after 3 months from the operation, which revealed preserved renal function.

Discussion

Giant ureteric stones are rare, and only a small number of cases are reported in the literature. These ureteric stones can reach up to 21.5 cm in length and 286 grams in weight, as reported by Taylor and Mayer in their respective papers [4,5]. More often, they are multiple or present with stones in some other parts of the urinary system [1,2,6]. When they are found in young patients without anatomical abnormalities or metabolic predispositions, they become more uncommon [7]. Giant urinary stones generally result from anatomical defects that obstruct the urinary tract or from metabolic or genetic disorders. Their presentation is often delayed due to the slow formation process. More than eighty percent of cases are calcium oxalate or calcium phosphate stones [1]. This case highlights that such large stones can also be formed spontaneously due to some yet unidentifiable factors.

When the question of choice of surgical intervention is raised for these stones, the obvious fact is that these cannot be treated safely with ureteroscopic lithotripsy. The risk of urosepsis, ureteric injury, avulsion, stricture formation, and repeat intervention increases disproportionately [2,8]. Therefore, the options that remain are either open surgery or laparoscopic ureterolithotomy. Between these, Laparoscopy provides a good minimally invasive option with minimal

postoperative morbidity and shorter hospital stay [4,7]. Our case, like many others, reaffirms that laparoscopic ureterolithotomy is still a better treatment option for giant ureteric stones. Limudomporn et al. once tried and successfully treated a similar calculus with mini-endoscopic combined intrarenal surgery [9]. This case adds to the scarce literature on giant ureteric calculi without predisposing factors, though its relevance is limited by being a single case.

Conclusion

Although very rare, giant ureteric calculi may still be found in young adults without any underlying abnormalities. Whenever any stone exceeds the practical limits of endoscopic lithotripsy, laparoscopy can provide a minimally invasive yet definite solution without much postoperative morbidity. This case underscores the unpredictable nature of stone disease and reminds us that even large stones can go unnoticed for a long time.

Patient's Perspective

I never thought I could develop such a large stone. The diagnosis surprised me, but I am relieved the surgery went well. I think everybody should seek timely medical care.

Statements and Declarations:

Conflicts of interest

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

Consent to participate and publish

Consent was taken from the patient.

Funding

No funds, grants, or other support were received

Competing Interest

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

Data availability statement

Data supporting the findings of this case are available within the article

References

1. Natami M, Makarem A, Ahmed F, Dastgheib N, Zahraei A Hossein. A giant ureteral stone in a 32-year-old man: a case report. Int Med Case Rep J. 2019 Feb 18;12:43–6.
2. Yasseri AF, Seyed Esmaili SN, Asadi M, Mohammad Kazem Aghamir S. Laparoscopic removal of a giant middle ureteral stone: A case report and review of literature. Ann Med Surg 2012. 2020 Dec;60:126–9.
3. Jawad MJ, Azim Amiri A, Saljuqi AT. A giant ureteral stone in a young adult: A case report. Urol Case Rep. 2024 Dec 18;60:102915.
4. Magdum PV, Nerli RB, Devaraju S, Hiremath MB. Laparoscopic Ureterolithotomy for Giant Ureteric Calculus: A Case Report. Urol Case Rep. 2015 Jul 17;3(5):135–7.
5. Taylor WMN. Large Ureteral Calculi1. Report of a Case. J Urol [Internet]. 1934 Jul [cited 2025 Aug 20]; Available from: https://www.auajournals.org/doi/10.1016/S0022-5347%2817%2972338-5
6. Mak D, Wragg R, Chandran H, McCarthy R, Parashar K. Silent But Giant: Giant ureteric calculus in a 7-year-old boy. J Surg Case Rep. 2010 Jul 1;2010(5):8.
7. Rathod R, Bansal P, Gutta S. A giant ureteric calculus. Indian J Urol IJU J Urol Soc India. 2013;29(3):263–4.

8. Rashid AO. Largest ureteric stone in Iraq. Urol Case Rep. 2020 Nov;33:101319.
9. Limudomporn P, Phengsalae Y, Ketsuwan C. A giant ureteric calculus successfully removed by mini-endoscopic combined intrarenal surgery: A case report. Urol Case Rep. 2022 Nov;45:102270.

National Board of Examinations - Journal of Medical Sciences
Volume 4, Issue 5, Pages 862–868, May 2026
DOI 10.61770/NBEJMS.2026.v04.i05.019

CASE REPORT

Rectal Duplication Cyst: An Eye Opener

Suvam Kumar,[1,*] Sharada Sundaramurthy[2] and Temsula Alinger[1]

[1]*Department of General Surgery, Christian Institute of Health Sciences and Research, Dimapur, India*
[2]*Department of Paediatric Surgery, Christian Institute of Health Sciences and Research, Dimapur, India*

Accepted: 13-January-2026 / Published Online: 6-May-2026

Abstract
Rectal duplication cysts are rare congenital malformations, accounting for approximately 4% of all gastrointestinal duplication cysts. While these anomalies often remain asymptomatic or present with vague gastrointestinal symptoms, acute urinary retention is an exceptionally rare manifestation. We report the case of a 3-year-old male child with recurrent episodes of acute urinary retention and constipation for three months, ultimately diagnosed as having a rectal duplication cyst. The child presented with a grossly distended urinary bladder and failed trials of catheter removal. Detailed clinical evaluation, imaging with contrast-enhanced CT scan, and per rectal examination led to the diagnosis. Laparotomy revealed a thick-walled retrorectal cyst without communication to the rectum. Complete surgical excision was performed, followed by a protective colostomy. Histopathological examination confirmed a rectal duplication cyst lined by preserved colonic mucosa. This case adds to the sparse literature of this rare entity presenting with bladder outlet obstruction symptoms and emphasizes the importance of thorough clinical and radiological evaluation in pediatric patients with recurrent urinary retention.

Keywords: Rectal duplication cysts, pediatric urinary retention, retrorectal cyst, congenital malformation, case report

*Corresponding Author: Suvam Kumar
Email: suvam.kumar29@gmail.com

Introduction

Intestinal duplication cysts are rare congenital anomalies of the gastrointestinal tract that may occur anywhere from the esophagus to the anus [1]. These developmental malformations are characterized by the presence of a well-formed smooth muscle wall and a mucosal lining similar to the adjacent gastrointestinal segment. While their exact embryological origin remains uncertain, they are believed to arise from aberrant recanalization or partial twinning of the primitive gut during early fetal life. These cysts are typically located on the mesenteric side of the bowel and may be cystic or tubular in shape. Among all gastrointestinal duplications, rectal duplication cysts are the least common, accounting for only about 4% of cases [2]. They usually present in childhood with nonspecific symptoms like constipation, a palpable rectal mass, tenesmus, and in rare cases rectal bleeding may occur, because of their deep pelvic location, rectal duplication cysts can cause mass effect on adjacent pelvic organs, including the bladder and urethra, potentially leading to obstructive urinary symptoms [3]. However, presentation with acute urinary retention is extremely uncommon and can often mislead clinicians toward a primary urological diagnosis such as posterior urethral valves or neurogenic bladder. Due to their rarity and nonspecific presentation, these lesions are often under-diagnosed or misdiagnosed, especially in resource-limited settings. Radiological imaging, particularly ultrasonography and contrast-enhanced computed tomography (CECT), plays a crucial role in their identification, while definitive diagnosis is established intraoperatively and confirmed through histopathology [4]. In this report, we present an unusual case of a rectal duplication cyst in a 3-year-old male child who presented with recurrent episodes of acute urinary retention and constipation, initially suspected to have a urological etiology. This case highlights the importance of clinical suspicion, thorough examination, diagnostic value of per rectal examination and targeted imaging for guiding early intervention and management of rectal duplication cyst.

The Case

A 3-year-old male child presented with acute urinary retention and constipation with a history of similar episodes over the last 1 year. The child had undergone three failed attempts of catheter removal and trial of voiding at a rural healthcare facility over the last 3 months. On referral to our center, clinical examination revealed a massively distended, tender abdomen from the suprapubic region to the epigastrium, suggesting severe bladder fullness. Per rectal examination demonstrated a tense cystic lesion extending lateral and anterior to the rectum, with the upper limit not palpable, approximately 6 cm from the anal verge. No other mass was appreciated following bladder decompression via catheterization. CECT abdomen revealed a well-defined thick-walled hypodense cystic lesion 6.7x4.8x6.3cm in retro rectal region with mild bilateral (HDUN) hydroureteronephrosis and cystitis (Figure 1).

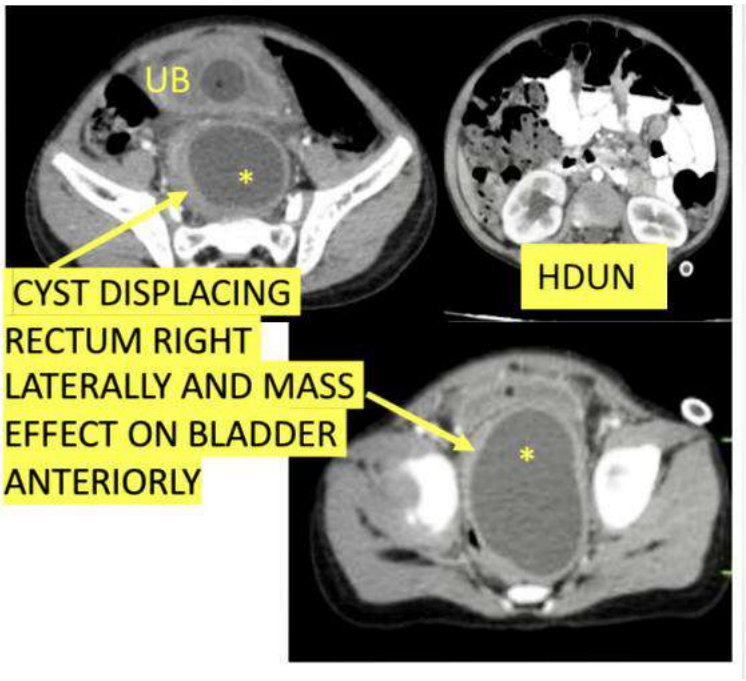


Figure 1. Axial CECT showing a thick-walled hypodense retrorectal cyst with its anatomical relation to surrounding structures

Laboratory investigations showed leukocytosis, and urinalysis revealed numerous pus cells and red blood cells. Serum HCG and AFP levels were within normal limits. Ultrasonography demonstrated a cyst with a gut signature that could not be clearly differentiated from the rectal wall. A contrast-enhanced CT (CECT) scan of the abdomen and pelvis identified a well-defined, thick-walled hypodense cystic lesion measuring 6.7 × 4.8 × 6.3 cm in the retrorectal region. The lesion displaced the rectum laterally and exerted anterior mass effect on the bladder, resulting in mild bilateral hydroureteronephrosis and features of cystitis.

A working diagnosis of rectal duplication cyst was made. Urinary retention was relieved immediately with per urethral Foley catheterization. Definitive management involved laparotomy and total excision of the cyst. Intraoperatively, the duplication cyst was found to be adherent but not communicating with the rectum. The common wall between the cyst and the rectum was carefully dissected without breaching the rectal mucosa. The seromuscular defect was closed meticulously, and a protective sigmoid colostomy was created to prevent postoperative complications (Figure 2).

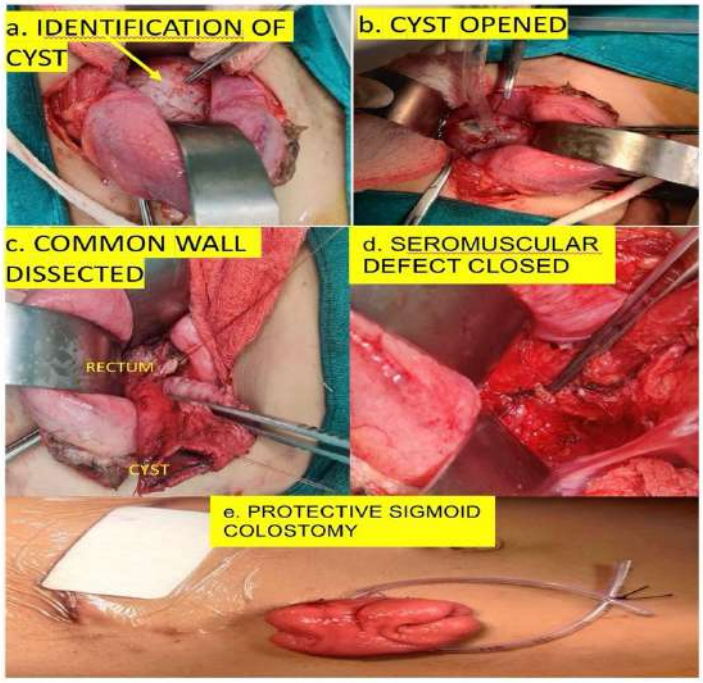


Figure 2. Intraoperative clinical images demonstrating the surgical management of rectal duplication cyst.

(a) Identification of the cyst in the presacral space. (b) Cyst opened to reveal mucinous contents. (c) Dissection of the common wall between the cyst and rectum without breaching the rectal mucosa. (d) Closure of the seromuscular defect following cyst excision. (e) Protective sigmoid colostomy to prevent postoperative complications.

The postoperative course was uneventful. The urinary catheter was removed after monitoring for signs of neurogenic bladder or retention. Histopathological examination confirmed the diagnosis of a rectal duplication cyst, revealing preserved colonic mucosa with crypts, submucosa, and muscularis propria, without evidence of heterotopic tissue (Figures 3 and 4).

Stoma reversal was done within 2 months and the child was discharged in 5 days with normal bowel movements. On regular follow-ups till 1 year, there has been no late complications.

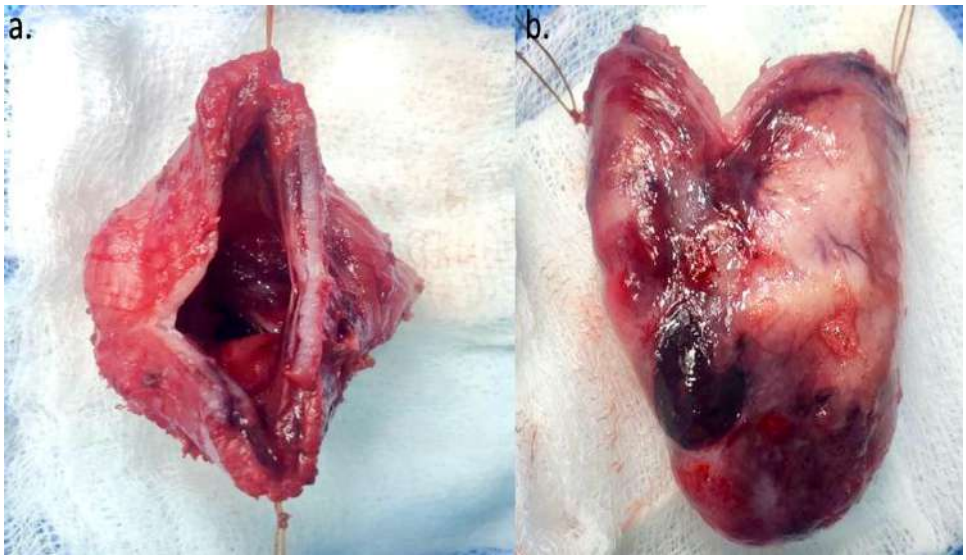


Figure 3. Gross specimen of excised rectal duplication cyst showing mucinous content.

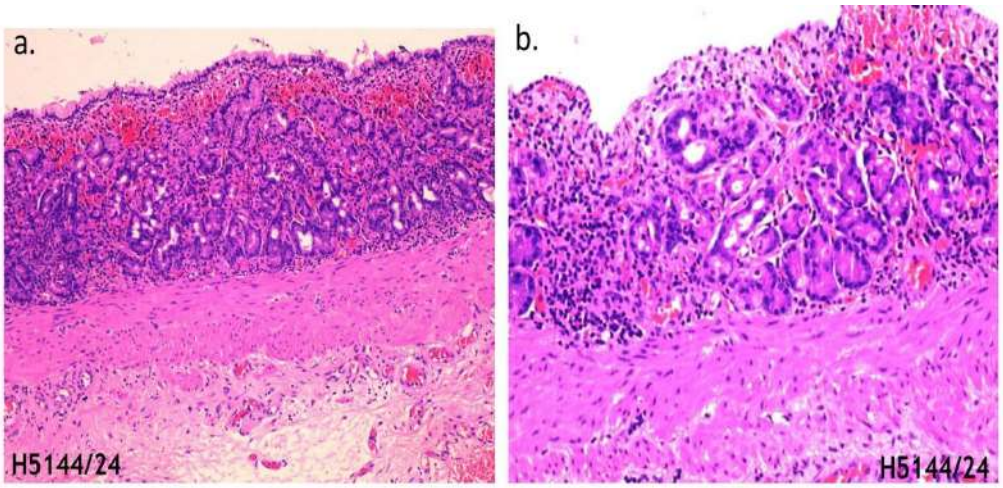


Figure 4. Histopathology showing colonic-type mucosa with well-preserved crypts, submucosa, and muscularis propria. No heterotopic tissue identified.

Discussion

Rectal duplication cysts are rare anomalies that present a diagnostic challenge due to their variable presentation and location. Although most often asymptomatic or detected due to local compressive symptoms in the anorectal region, presentation with acute urinary retention is extremely uncommon and can easily be mistaken for primary urological pathology such as posterior urethral valves or neurogenic bladder. Hence a proper history and thorough clinical examination can pave way to the accurate diagnosis, thereby allowing early definitive treatment reducing morbidity of the patient. This condition can be differentiated from other retrorectal cystic lesions based on age,

digital rectal examination and computed tomography findings with histopathology confirming the diagnosis.

Jackson et al. reported a pediatric case of rectal duplication cyst that presented with urinary retention and was initially suspected to be of urologic origin [5]. Similarly, Anastasiadou et al reported a case where the diagnosis was delayed due to non-specific obstructive symptoms [6]. In our patient, the initial presentation involved recurrent urinary retention, failed catheter removal, and progressive abdominal distension findings that mimicked lower urinary tract obstruction. A key turning point was the digital rectal examination, which revealed a tense cystic mass, and radiological imaging, particularly contrast-enhanced CT, which delineated a retrorectal cyst compressing the bladder. The presence of a gut signature on ultrasonography and the absence of communication with the rectum during surgical exploration confirmed the diagnosis of a rectal duplication cyst.

Management requires prompt bladder decompression and complete surgical excision to prevent recurrence, infection or malignant transformation [7]. The surgical challenge lies in excising the cyst without breaching the rectal mucosa or injuring adjacent pelvic structures [8]. In this case, successful resection was achieved without full-thickness rectal injury, and the protective colostomy helped ensure uneventful healing. Histologically, these cysts are lined by colonic or enteric mucosa and may contain muscular layers. Although rare, these lesions must be considered in the differential diagnosis of recurrent urinary retention in children, especially when accompanied by constipation or a palpable mass [9]. Although rare, rectal duplication cysts should be considered in the differential diagnosis of recurrent urinary retention, especially in children presenting with overlapping gastrointestinal and urinary symptoms. This case adds to the limited literature emphasizing the diagnostic value of per rectal examination and targeted imaging to guide early intervention.

Conflicts of interest

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

Funding

No funding was received for conducting this study.

Consent to participate and publish

Written informed consent was obtained from the patient for publication of this case report and accompanying images.

References

1. Khushbakht S, ul Haq A. Rectal duplication cyst: a rare cause of rectal prolapse in a toddler. J Coll Physicians Surg Pak. 2015;25:909–10.
2. Silva BM, Onofre AL, Comes GT, et al. Externalized Rectal Duplication in a Newborn - A Differential Diagnosis of Meningomyelocele. Cureus. 2023; doi:10.7759/cureus.51306.
3. Jackson KL, Peche WJ, Rollins MD. An unusual presentation of a rectal duplication cyst. Int J Surg Case Rep. 2012;3:314–5.
4. Kitazono M, Fujita M, Oyama T, et al. Robot-assisted excision of rectal duplication cysts: a case report. Clin Case Rep. 2022;10:e05457. doi:10.1002/ccr3.5457.
5. Kumar PM, Kotaiah MT, Keerthi G. A rare case of antenatally ruptured

rectal duplication cyst in a newborn with spina bifida and ectopic kidney: diagnostic and surgical challenges. J Indian Assoc Pediatr Surg. 2025;30:101–3.

6. Kodia K, Huerta CT, Perez EA. Rectal prolapse in the pediatric population - a narrative review of medical and surgical management. Transl Gastroenterol Hepatol. 2024;9:47. doi:10.21037/tgh-23-128.
7. Anastasiadou S, Tekkis P, Kontovounisios C. An unusual rectal duplication cyst. Surg Case Rep. 2019;5:75. doi:10.1186/s40792-019-0631-8.
8. Hartin CW Jr, Lau ST, Escobar MA, et al. Laparoscopic excision of a newborn rectal duplication cyst. J Pediatr Surg. 2008;43:1572–4.
9. Akahane K, Uehara K, Yoshioka Y, et al. Rectal duplication cyst successfully treated by laparoscopic total mesorectal excision using the prolapsing technique. Asian J Endosc Surg. 2011; 4:174–7.