



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

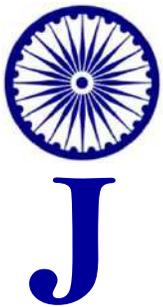
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For-profit companies can set up medical colleges under PPP mode: NMC chief

The Hindu Bureau
VIJAYAWADA

National Medical Commission (NMC) Chairman Abhijat Chandrakant Sheth on Wednesday said that the regulation of allowing only non-profit companies to set up medical colleges has been shelved to enable both non-profit and for-profit companies to run them.



ry, including embracing AI, futuristic technologies and digital healthcare, among others.



Dr. Abhijat Chandrakant Sheth, President of the NBEMS being handed over the Guinness record certificate by Mr Swapanil Dangarikar, Official Adjudicator at Guinness World Records

Efficacy of Dhaka Regimen in Comparison to Zuspan Regimen in Prevention of Eclampsia: A Randomized Control Trial
Dr. Santhi Sundaresan, Dr. Anil Saha, Dr. Arjit Saha, Dr. Sanjay KJ Mahapatra, Dr. Anand Kumar, Dr. Bhuvan Bhattacharya, Dr. Anand Kumar, Dr. Akhilesh Mishra, Dr. Anand Kumar, Dr. Vikram Kumar Prasad, Dr. Pratik Kumar

Abstract
Randomized controlled trials to evaluate maternal and neonatal morbidity and mortality of all treated in time. Existing treatment with MgSO₄ using high dose Zuspan regimen can lead to toxicity associated with high dose of Mg. Zuspan. Instead of this regimen was advised for the prevention of the serious health when the average BMI is higher than Indian population. This study is conducted to find out the efficacy of low dose MgSO₄ regimen (Dhaka Regimen) in comparison to high dose MgSO₄ regimen (Zuspan regimen) in women of Indian subcontinent.

Methods
It's a pilot RCT with 30 cases in each arm. Group A received MgSO₄ as per Dhaka Regimen and Group B received as per Zuspan regimen. Various maternal (Age, P&G, Proteinuria, Serum Mg levels, Eclampsia) and neonatal parameters (APGAR and NICU admissions) were recorded. Ethical Clearance was obtained and the study was registered with CTRI Reg No. CTRI/2019/05/01895.

Conclusions
This research has revealed a significant public health issue in India. It is necessary to do research on the efficacy of low dose MgSO₄ regimen in comparison to high dose MgSO₄ regimen in women of Indian subcontinent.

Maternal BMI (kg/m ²) (n = 60)			
BM (kg/m ²)	Dhaka Group (n)	Zuspan Group (n)	P Value
Normal BMI	21 (61.0%)	24 (80.0%)	0.0001
Obese BMI	13 (39.0%)	6 (20.0%)	0.0001
Range	11 - 32.1	21.1 - 32.1	

Eclampsia (n = 60)					
Regimen	Dhaka Group (n)	Zuspan Group (n)	Total	n	P Value
Present	1 (3.0%)	2 (6.7%)	3 (5.0%)	3	0.800
Absent	29 (87.0%)	28 (93.3%)	57 (95.0%)	57	

National Board of Examinations
Journal of Medical Sciences

Efficacy of Dhaka Regimen in Comparison to Zuspan Regimen in Prevention of Eclampsia: A Randomized Control Trial

Effectiveness of First Aid Education on High School Students in Thrissur District, Kerala
Aishwarya K Venugopal,1 Christeen Grace,2 Esha Susan Thomas,2 Diana Job,2 Denizil Saja,2 Endi Rose Dominic,2 Elnase Anna Roy,2 and Dehika Suresh,2
1 Sri Vishwanath Medical College and Research Institute and 2 Shilpa Mission Medical College and Research Institute

Background
First aid refers to prompt assistance or care given to help persons with either a minor or serious illness or injury to preserve life, prevent the condition from worsening, or promote recovery. The importance and necessity for people to be sufficiently equipped to handle crises has been brought to light by the recent rise in natural calamities.

Methods
We conducted an interventional study among 100 students of classes VII, IX, and XI at a school in Thrissur district of Kerala in July 2022. The interventional knowledge, a pre-test was conducted using self-administered pre-validated structured questionnaire, after which a health education session on first aid was conducted. For assessing their post-intervention knowledge acquisition, the same questionnaire was used for the post-test. Statistical analysis was done using SPSS version 25. Paired T-test and ANOVA test were used for comparing pre-test and post-test scores.

Approach of study participants towards first aid (n=100)

S. No.	QUESTIONS	STUDENTS RESPONDED YES (n, %)	STUDENTS RESPONDED NO (n, %)
1.	Have you heard of the term first aid?	98 (97.0%)	2 (2.0%)
2.	Have you received any training related to first aid procedures?	81 (81.0%)	19 (19.0%)
3.	Have you had any practical experience administering first aid?	81 (81.0%)	19 (19.0%)

Conclusions
The present study addresses the effectiveness of first aid educational interventions among high school students in Thrissur district. Effective implementation of structured first aid education in the curriculum can ensure proper and timely response to emergency situations for students and the wider community.

National Board of Examinations
Journal of Medical Sciences

Effectiveness of First Aid Education on High School Students in Thrissur District, Kerala

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EDITORIALS

For-Profit Companies Can Set Up Medical Colleges Under PPP Mode: A Strategic Reform for India's Health System

Minu Bajpai and Abhijat C. Sheth 283

Guinness World Records Recognises National Board of Examination in Medical Sciences, India & Its President Dr. Abhijat Chandrakant Sheth for: "Most viewers of an Artificial Intelligence in Healthcare lesson live stream on YouTube"

Minu Bajpai 297

ORIGINAL ARTICLES

Efficacy of Dhaka Regimen in Comparison to Zuspan Regimen in Prevention of Eclampsia: A Randomized Control Trial

Souvik Nandy, Atul Seth, Sanjay Kumar Sharma, Bikram Bhardwaj, Akshay Malunekar and Vipin Kumar Prajapati 301

Comparison of Oral Midazolam and Oral Ketamine as Premedicants for Parent-Child Separation in Paediatric Elective Surgery

Sharmila Shanmugam, Mukunthakrishnan Lingeswaran, Nariyanahalli Venkatesan Vinoth Kumar and Jeevithan Shanmugam 312

Effectiveness of First Aid Education on High School Students in Thrissur District, Kerala

Aiswarya K Venugopal, Christeen Grace, Elsa Susan Thomas, Diana Job, Denzil Saju, Emil Rose Dominic, Elaine Anna Roy and Devika Suresh 322

A Cross-Sectional Survey on Recreational Use of Oral Erectile Dysfunction Drugs Among Male Doctors

S. Sanjeev Kumar, R. Ashok Kumar and R. Vinoth Kumar 331

Effect of Bedtime Mobile Phone Scrolling on Sleep Latency and Dream Recall among Paramedical Students

Sudharsan S, Hemalatha NR and Vidya R 346

Use of Middle Meningeal Artery Embolization in Treatment of Chronic Subdural Hematoma

Manoj Chandran, Suresh Jayabalan, Arun Balaji, Abhilash Reddy, K Rajendran, Santhosh Poyyamoli and S. Jeevithan 357

(Contents Continued)

Serum Osteoprotegerin: Can It Predict Chronic Kidney Disease Among Hypertensives?
C. Janani, K.V. Vijayakumar and M. Ganesan 368

Prevalence and Determinants of Anaemia in Undergraduate Medical Students: Cross-Sectional Study
Rajalakshmi S and Franc Oumanath, V Sivachandiran and G. Subash Chandrabose 377

A Twenty Five Year Retrospective Study on the Clinico-Histopathological Correlation of Hansen's Disease, Trends, Dynamics of the Spectral Rami and Psycho-Temperamental Incline, in a Tertiary Care Hospital in South India
Amala Balasubramanian, Senthil Kumar Arumugam Subramanian and Lakshmi Priya Karunanidhi 389

A Randomized Comparative Study of Peritoneal Closure versus Non-Closure During Open Appendectomy
B. Sridhar, Sadhana M and Vimalnathan M 401

Prevalence of Sleep Related Breathing Disorders (SRBD) and the Assessment of Quality of Sleep Among Patients with Chronic Obstructive Pulmonary Disease (COPD): An Analytical Cross-Sectional Study
K. Rajarajan and V. Saravanan 412

REVIEW ARTICLE

Professionalism and Ethics in Medical Education: Teaching Approaches—A Narrative Review
Praveena M and G. Subash Chandrabose 425

CASE REPORT

Trichotillomania as a Rare Comorbidity of Delusional parasitosis: A Case Series
V. Sujaritha 430

LETTER TO THE EDITOR

Myocardial Infarction in People Living with HIV (PLWH)
Balaboina Sai Keerthi, Nishanth V.S. B. V. Naga Mohan Rao, Shiyam Sundar Karunanithy, E.B. Pavan Kalyan Reddy and Kattamreddy Ananth Rupesh 437



EDITORIAL

For-Profit Companies Can Set Up Medical Colleges Under PPP Mode: A Strategic Reform for India's Health System

Minu Bajpai^{1,*} and Abhijat C. Sheth²

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The Context: Supply-Demand Mismatch in Medical Education

India stands at an inflection point in health workforce planning. The country's aspiration for universal health coverage, expansion of quaternary care, digital health integration, and research-led precision medicine demands a dramatic scale-up of medical education capacity. Public systems alone cannot finance or operationalize this expansion at the required velocity.

Allowing for-profit companies to establish medical colleges under a well-regulated Public-Private Partnership (PPP) framework is therefore not a dilution of public responsibility—it is a strategic structural reform.

India has expanded medical seats significantly in the last decade (Table 1 and Figure 1) with policy support from the National Medical Commission. Yet structural gaps remain:

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For-profit companies can set up medical colleges under PPP mode: NMC chief

The Hindu Bureau
VIJAYAWADA

National Medical Commission (NMC) Chairman Abhijat Chandrakant Sheth on Wednesday said that the regulation of allowing only non-profit companies to set up medical colleges has been shelved to enable both non-profit and for-profit companies to run them.

Addressing the media at Dr. NTR University of Health Sciences, Mr. Sheth said, "Earlier, only non-profit Section 8 companies were allowed to set up medical colleges but a recent board meeting has removed this regulation, paving the way for both non-profit, and for-profit companies to set up medical colleges under Public Private Partnership," said Sheth, who met Chief Minister N. Chandrababu Naidu today, in a release.

The NMC is of the belief that public and private entities teaming up together will enable the efficient utilisation of available resources for medical education, he said.

As hospitals run under PPP mechanism will be under State governments' purview, he said patients will receive treatment on either free or subsidised basis, he said.

As part of enhancing medical education quality, Sheth said clinical research has been made compulso-



ry, including embracing AI, futuristic technologies and digital healthcare, among others.

He said that NMC is raising awareness among the public about preventive measures to check diseases and the mental well-being of students.

New PhD speciality and sub-specialty courses would be introduced and clinical research will be made mandatory to enhance the quality of medical education, he said, adding that the accreditation process for medical colleges would be simplified.

Later, Dr. NTRUHS Vice-Chancellor P. Chandrasekhar said steps are being taken to increase PG seats to match the MBBS seat numbers.

To address the shortage of doctors in taluk-level hospitals and hospitals with 50-100 beds, a new 'Family Medicine' initiative is being introduced, which will make approximately 500 seats available.

NMC Chairperson Abhijat Chandrakant Sheth addressing the media at Dr. NTRUHS in Vijayavada India. K.V.S. GIRI.

With inputs from PTI

- Uneven geographic distribution of colleges
 - Faculty shortages
 - Limited super-specialty exposure in district-linked institutions
 - Inadequate research ecosystems
 - Infrastructure-finance bottlenecks in state universities
- Simultaneously, tertiary care demand is rising due to epidemiological transition, demographic shifts, and health insurance expansion.

Table 1. NEET Undergraduate Trajectory Over the Years (2015–2025)

Year	Registered Candidates (Approx.)	Key Policy / System Development
2015	~6.3 lakh (<i>AIPMT era</i>)	Pre-uniform phase; multiple entrance exams (AIPMT + state exams)
2016	~8.0 lakh	NEET introduced as single national exam (phased implementation)
2017	~11.4 lakh	Full nationwide adoption; state exams merged
2018	~13.2 lakh	Increased private/deemed university participation
2019	~15.2 lakh	Rise in repeat aspirants (“drop-year culture”)
2020	~15.9 lakh	Pandemic stress test; exam continuity maintained despite COVID
2021	~16.1 lakh	Major surge from Tier-2/3 cities; digital coaching expansion
2022	~18.7 lakh	Expansion of new AIIMS & Government colleges announced
2023	~20.9 lakh	Record participation; widening competition gap
2024	~24.0 lakh	Policy debate intensifies on capacity vs demand mismatch
2025	~24.5–25.0 lakh (<i>projected/early estimates</i>)	System saturation → Calls for distributed training models & new medical colleges

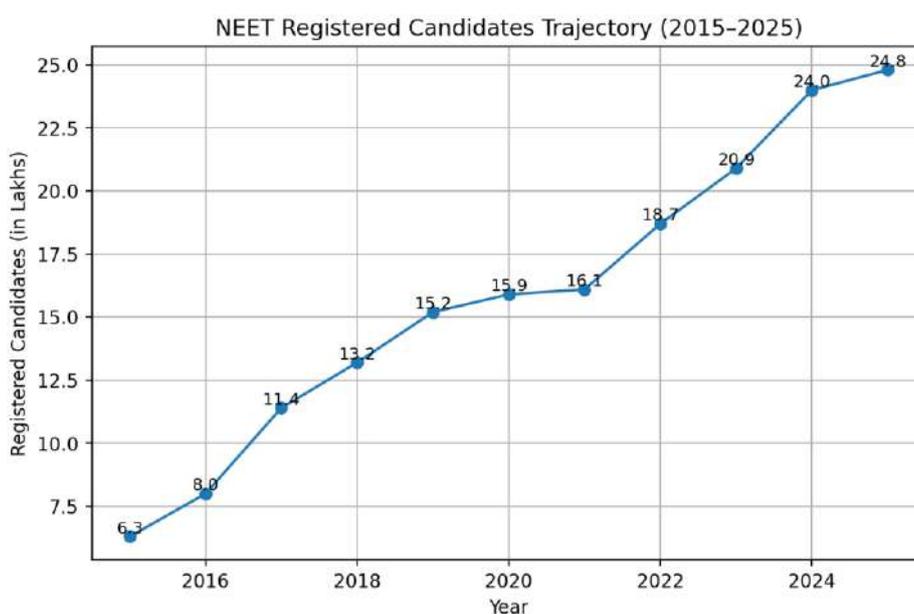


Figure 1. NEET Undergraduate Trajectory Over the Years (2015–2025; Numbers in Lacs)

If India aims to reach a sustainable doctor–population ratio while ensuring quality and research output, **capital infusion and managerial efficiency from the private sector become indispensable.**

Why PPP with For-Profit Participation Makes Economic Sense

A modern medical college with a 500+ bed teaching hospital requires capital outlay running into ₹800–1200 crore, depending on location and scope. State governments often struggle with:

- Budgetary constraints
- Delayed capital expenditure cycles
- Procurement inefficiencies and uncertainties
- Faculty recruitment rigidities

For-profit entities bring:

1. **Capital efficiency** – Access to structured finance and faster project execution

2. **Operational management systems** – Lean hospital administration, digital integration
3. **Technology adoption** – AI diagnostics, simulation labs, tele-education platforms
4. **Industry-linked research funding** – Translational medicine and clinical trials

When structured under PPP, land and policy support can come from the state, while capital investment and operational management come from industry partnership.

Addressing the Core Concern: Profit Privates Public Good

The opposition to this type of medical education often stems from fear of commercialisation. These concerns are legitimate—but manageable (Figure 2).



Figure 2. PPP Framework

A robust PPP framework must incorporate:

- Fee regulation mechanisms
- Mandatory scholarship quotas
- Reservation compliance
- Outcome-based accreditation metrics
- Transparent admission through NEET
- Service obligations in underserved areas
- Research performance benchmarks

The regulator—currently the National Medical Commission—must function as a quality assurance authority rather than a licensing bottleneck.

Profit cannot be allowed to distort merit or ethics. However, profit PPP under regulation is not inherently unethical; opacity is.

International Precedents

Globally, many leading institutions operate within hybrid financial ecosystems:

- **Johns Hopkins University** integrates private philanthropy, research grants, and clinical revenue.
- **Harvard Medical School** functions within a complex financial model involving private endowments and hospital revenue.

While not strictly “for-profit colleges,” these models demonstrate that **private capital participation in medical education is not antithetical to academic excellence.**

India can design a uniquely regulated for-profit PPP model suited to its demographic and economic context.

Strategic Advantages for India

- **Accelerated Seat Expansion**
PPP models can rapidly establish colleges in aspirational districts.
- **Faculty Incentivization**
Flexible pay structures can attract diaspora and super-specialists.
- **Research & Innovation Clusters**
Linkage with biotechnology firms and med-tech startups can create translational hubs.
- **Integration with Digital Health**
Alignment with the national digital ecosystem under the National Health Authority and Ayushman Bharat Digital Mission can create real-time data-driven teaching hospitals.

For a country investing in state-wide biobanks and EMR ecosystems—as envisioned in precision medicine initiatives—PPP medical colleges can serve as anchor academic nodes (Table 2).

Table 2. Risks and Mitigation Architecture

Risk	Mitigation Strategy
Excessive tuition	Fee caps + income-linked scholarships
Urban concentration	Incentivised land grants in Tier-2/3 districts
Faculty poaching	National faculty pool and rotation models
Ethical lapses	Independent ethics oversight boards
Clinical compromise	Mandatory NABH-equivalent accreditation

Quality assurance must shift from infrastructure inspection to **outcome measurement: graduate competence, patient outcomes, and research productivity.**

Ethical Framing: Education as Public Good, Delivery via Mixed Economy

Medical education is a public good because it produces human capital critical to national health security. However, public good status does not necessitate exclusive public provisioning.

The key principle should be:

Public purpose, privately financed, transparently regulated.

India’s infrastructure expansion in highways, airports, and metro systems has benefited from PPP frameworks. There is no structural reason why medical education—arguably more vital—cannot adopt similar governance discipline.

Such a model ensures alignment of incentives rather than ideological confrontation (Tables 3-5).

A Policy Blueprint for Implementation

1. The state provides land on long-term lease.
2. For-profit entity builds and operates under defined service obligations.
3. Government retains golden-share oversight.
4. Fee structure partially regulated, partially market-driven within caps.
5. Mandatory rural health service rotation.
6. Integrated digital compliance dashboard.
7. Annual public disclosure of financial and academic metrics.

Table 3. Structural Model Options

Model A Land-Lease PPP	Model B District Hospital Upgrade PPP	Model C Hybrid Academic-Research Cluster
<ul style="list-style-type: none"> • State government provides land for a lease time • Corporate partner builds and operates • Regulated fee + inherent scholarship mandate 	<ul style="list-style-type: none"> • Existing district hospital converted into a teaching hospital • Corporate invests in expansion & faculty • Shared clinical revenue model 	<ul style="list-style-type: none"> • Linked to biotech / med-tech industrial corridor • Integrated translational research unit • Mandatory postgraduate & super-specialty seats

Table 4. Governance Architecture*

Regulatory Layer	Institutional Governance
<ul style="list-style-type: none"> Academic regulation: National Medical Commission Digital compliance: National Health Authority Integration with Ayushman Bharat Digital Mission 	<p>*Board composition:</p> <ul style="list-style-type: none"> 40% Corporate nominees 30% Government nominees 20% Independent academic experts 10% Public health representative <p>Government retains “Golden Share” veto for:</p> <ul style="list-style-type: none"> Fee hikes beyond cap Seat diversion Academic dilution

*Tentative figures

Financial Architecture

Table 5. Capital Expenditure (Indicative)*

Component	Estimated Cost (₹ Crore)
Land (state provided)	—
Academic block	250–300
500-bed teaching hospital	400–500
Simulation & research labs	100–150
Digital & IT integration	50–75
Total Capex	800–1,200

*Tentative figures

The revenue streams comprise tuition collected within a regulated fee band, income generated from clinical services, and insurance reimbursements under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY). Additional sources include research grants and clinical trials, structured industry collaborations, and enrollment of international students within a capped quota.

Profit governance is guided by defined financial safeguards. For example, a maximum return on investment (ROI) band may be prescribed, such as a 12–15% internal rate of return (IRR) cap. Furthermore, a mandatory reinvestment

ratio can be implemented, whereby a fixed proportion of surplus—such as 20%—is reinvested into research, academic development, and scholarships to ensure long-term institutional growth and public benefit.

Academic Safeguards

Admissions are conducted entirely through the NEET merit system, ensuring that 100% of seats are allocated based on merit through transparent, centralized counselling.

The fee structure is rationalised across different seat categories: 50% of seats fall under the regulated state quota, 35% are offered within a controlled

institutional fee band, and 15% are reserved for NRI or international candidates, with higher fee realisation enabling cross-subsidisation of scholarships.

A structured scholarship mandate ensures that a minimum of 20–25% of seats receive need-based financial support. In addition, income-linked repayment options may be provided to enhance affordability

and promote equitable access to medical education.

Faculty norms are designed to balance flexibility and accountability, incorporating flexible salary bands, performance-linked incentives, and mandatory academic output benchmarks to maintain academic excellence and institutional credibility. Outcome-Based Accreditation Framework (Table 6).

Table 6. Move from infrastructure inspection to measurable outcomes

Domain	Metrics
Academic	Rank, competency scores, OSCE performance
Clinical	Mortality-adjusted outcomes, infection rates
Research	Publications, patents, funded projects
Social Impact	Rural service coverage, outreach camps
Digital	ABDM integration compliance

Annual public disclosure is mandatory

The Geographic Equity Strategy is designed to address regional imbalances in medical education and healthcare access by incentivising public–private partnerships (PPPs) in Tier-2 and Tier-3 districts. Policy enablers may include additional Floor Area Ratio (FAR) or Floor Space Index (FSI) benefits, tax concessions linked to measurable rural service delivery outcomes, and land cost subsidies aligned with the district backwardness index to ensure targeted development in underserved regions.

The Ethical and Compliance Framework mandates strong institutional safeguards. Each institution must establish an independent Institutional Ethics Committee, implement a robust whistleblower protection mechanism, and obtain mandatory NABH-level

accreditation through the National Accreditation Board for Hospitals & Healthcare Providers. Financial transparency is ensured through annually published audited statements, alongside a strict zero-tolerance policy toward capitation practices.

Under the Digital Integration Blueprint, every PPP medical college is required to fully integrate with the Ayushman Bharat Digital Mission stack, adopt interoperable electronic medical records (EMR), maintain advanced digital skill laboratories, provide real-time performance dashboards to regulators, and establish linkage with national disease registries to support surveillance, research, and policy planning (Table 7).

This aligns academic training with India's digital health architecture.

Table 7. Risk Mitigation Matrix

Risk	Mitigation
Commercialization bias	Fee caps + scholarship floor
Urban clustering	Location-linked incentives
Faculty migration from public sector	Shared faculty exchange pool
Academic dilution	Outcome-based accreditation
Regulatory capture	Independent oversight board

Core Design Principle

**Public Purpose + Private Capital +
Regulatory Discipline = Sustainable
Expansion**

The debate should not be ideological. The question is whether India can afford **not** to leverage regulated corporate capital in medical education.

With strong governance, PPP-based for-profit medical colleges can become:

- Workforce multipliers
- Research accelerators
- Regional healthcare anchors
- Economic growth nodes

This blueprint provides a scalable, accountable, and economically viable pathway for implementation.

India's medical education system stands at a structural crossroads. The demand for competent physicians, specialists, and clinician–scientists is expanding faster than traditional public financing can sustain. The question is no longer whether capacity must expand—it is how to expand responsibly, equitably, and sustainably.

In this context, the proposition that for-profit companies may establish medical colleges under a regulated Public–Private Partnership (PPP) framework represents not a departure from public health ethics, but a pragmatic recalibration of resource mobilisation.

Under the present Chairman- **Dr. Abhijat Sheth**, the National Medical Commission has increasingly emphasized transparency, competency-based training, digital compliance, and outcome-driven regulation. A PPP-enabled model aligns with this reform trajectory—provided governance is uncompromising.

The Way Forward

India's healthcare transformation—in the range of life sciences specialities, whether in pediatric super-speciality care, quaternary neonatal surgery institutes, or state-wide precision medicine biobanks—requires academic ecosystems that are agile, well-capitalised, and accountable.

The debate should move beyond “for-profit versus non-profit” to “regulated efficiency versus stagnation.”

Allowing for-profit companies to establish medical colleges under the PPP mode is not privatisation of medical education; it is professionalisation of capital deployment under sovereign oversight.

If designed prudently and implemented with strong regulatory safeguards, this reform has the potential to significantly expand access to medical education and healthcare services, enhance academic and clinical quality standards, boost national research output, reduce outbound medical migration for education and treatment, and ultimately strengthen overall national health resilience.

The imperative is not whether private capital should participate—but **how intelligently the state structures that participation.**

India's health future depends on that design.

The Structural Imperative

India's vast demographic scale, ongoing epidemiological transition, and insurance-led hospital expansion under schemes such as Ayushman Bharat Pradhan Mantri Jan Arogya Yojana necessitate the rapid addition of MBBS and postgraduate seats, strengthening of district-linked teaching hospitals, integration of digital health competencies into curricula, and the development of research-enabled academic ecosystems.

For-profit participation—when embedded in PPP—offers:

For-profit participation—when embedded within a well-structured public-private partnership (PPP) framework—can offer capital velocity, operational efficiency, faster technology integration, and clearer managerial accountability. The ethical question is not whether profit exists, but whether the partnership operates within a clearly regulated public purpose.

Private and Public Good: A False Binary

The perceived dichotomy between private participation and public good is often overstated. Resistance to for-profit entities in medical education typically arises from legitimate concerns about commercialization; however, such risks are manageable through strong regulation. Within the regulatory architecture of the National Medical Commission, safeguards can include 100% admissions through NEET merit, fee band regulation, mandatory scholarship quotas, rural service obligations, transparent digital disclosure dashboards, and outcome-based accreditation. The regulator must evolve from being primarily an infrastructure inspector to becoming a competency auditor. When governance is robust, profit becomes an incentive for efficiency rather than exploitation.

PPP as a Governance Instrument

PPP should be understood not as privatization but as structured risk-sharing. A viable governance model may include state-provided land on long-term lease, corporate-funded infrastructure and operations, a government “golden share” veto on fee hikes and seat diversion, mandatory public disclosure of financial and academic metrics, and independent ethics oversight. Integration with the National Health Authority and alignment with the Ayushman Bharat Digital Mission can enable real-time compliance tracking, thereby reducing opacity that historically fueled mistrust. Regulation, therefore, must be algorithmic rather than discretionary.

Global Learning without Blind Imitation

Globally respected institutions such as Johns Hopkins University and Harvard

Medical Schools operate within mixed financial ecosystems that combine private funding, clinical revenue, and research grants. While India's context differs, the broader principle remains: private capital participation does not inherently erode academic excellence; regulatory weakness does. India must therefore design its own model—socially accountable yet economically viable.

Safeguards That Cannot Be Compromised

Any policy enabling for-profit medical colleges under PPP must incorporate non-negotiable safeguards, including transparent fee structures with cross-subsidization, a scholarship floor of at least 20–25%, geographic incentives for Tier-2 and Tier-3 districts, faculty performance benchmarks, mandatory research output targets, and annual public audit reports. Accreditation systems must assess competency outcomes, patient safety indicators, infection control metrics, research productivity, and community health engagement. Expansion without quality would ultimately be self-defeating.

The Strategic Opportunity

Strategically designed, PPP-enabled medical colleges can accelerate seat expansion toward workforce

sufficiency, create research clusters linked to biotechnology and medical technology, strengthen district hospital ecosystems, integrate digital health into mainstream curricula, reduce outbound medical migration, and support precision medicine and biobank networks. In a nation investing heavily in digital public infrastructure, medical education cannot remain analogue in governance or financing.

Belief

The debate must move beyond ideological binaries, as India today requires scale, speed, and uncompromising standards in expanding its healthcare workforce. Allowing for-profit entities to establish medical colleges within a rigorously regulated Public–Private Partnership framework is not a withdrawal from public responsibility, but rather an adaptive strategy to strengthen national health security. The true measure of success will lie not in permitting participation, but in designing precise, transparent, and accountable regulatory oversight. If structured thoughtfully, this reform can widen access, enhance quality, and better align medical education with India's 21st-century healthcare needs. The opportunity is structural, the responsibility is regulatory, and the moment to act is now (Table 8).

ASTER Algorithm Flow

Table 8. PPP Medical College Governance Framework

Phase	Step	Key Actions / Criteria	Outputs / Regulatory Control
Pre Phase 1: National Needs Mapping	Workforce Deficit Modeling	Doctor-population ratio, specialist gaps, disease burden, insurance growth, UG/PG seat deficit	District Priority Score (DPS)
	Infrastructure Feasibility Index	Land, district hospital upgrade scope, connectivity, faculty availability	PPP Eligibility Zone (PEZ): A/B/C (Only A & B proceed)
Phase 1: Competitive Selection	Prequalification Filter	Net worth threshold, healthcare experience, no blacklisting, ESG compliance	Algorithmic Risk Score (ARS)
	Weighted Bid Evaluation	Capital (25%), backwardness (20%), fee moderation (15%), scholarships (15%), research (15%), digital readiness (10%)	Composite Governance Score (CGS)
Phase 2: Concession Design	Risk Allocation	Construction–Private; Regulatory–Shared; Demand–Private; Emergencies–Shared	Defined contractual liability
	Golden Share Clause	Govt veto on fees, seat diversion, scholarships, academic dilution	Public-interest safeguard
Phase 3: Infrastructure & Digital Compliance	Outcome-Based Verification	500-bed teaching hospital, simulation labs, research infra, telemedicine, EMR integration	Real-time digital compliance dashboard
	Data-Driven Regulation	Live occupancy, EMR logs, biometrics, infection metrics	Reduced need for physical inspection
Phase 4: Academic Control	Admission Integrity	100% merit-based entry, centralized counseling	Automated anomaly detection

	Fee Governance	50% regulated quota, 35% controlled band, 15% cross-subsidy	Fee cap = CPI + 2%
	Scholarship Floor	≥25% need-based aid; 10% full waiver	Penalty + seat freeze if violated
Phase 5: Faculty & Training Quality	Faculty Competency Index	Publications, clinical load, teaching hours, CME	Recruitment mandate if below threshold
	Student Competency Monitoring	OSCE scores, exit exam, logbooks, patient exposure	Seat reduction if persistent underperformance
Phase 6: Clinical Outcome Oversight	Quarterly Metrics	Mortality-adjusted outcomes, infection rates, complication rates, fraud index	Corrective Action Protocol (CAP)
Phase 7: Research Obligation	Innovation Mandate	≥1% revenue to research, ethics compliance, trial registry	PG expansion linked to research output
Phase 8: Social Accountability	Community Integration	Rural rotation, tele-outreach, district MoUs, annual impact report	Service-linked accreditation value
Phase 9: Financial Transparency	IRR Cap Mechanism	Max IRR 12–15%; excess profit partly reinvested	Prevents profiteering
	Public Disclosure	Revenue, fees, scholarships, outcomes, research	Financial transparency enforcement
Phase 10: Continuous Risk Calibration	Institutional Integrity Index (III)	Academic, clinical, financial, satisfaction, public health contribution	Grades: A (Expand) / B (Monitor) / C (Probation) / D (Seat Freeze/Takeover)

Five-Year Rollout Simulation

The five-year rollout simulation envisions a phased and carefully monitored expansion of PPP medical colleges. In Year 1, ten pilot PPP colleges would be operationalized to test governance, regulatory, and financial frameworks. During Years 2 and 3, an additional twenty-five colleges would be established, scaling

the model based on early performance indicators. Year 4 would focus on conducting the first comprehensive outcome audit to evaluate academic standards, financial transparency, patient care metrics, and research productivity. By Year 5, more than fifty PPP medical colleges would be fully operational.

Five-Year Rollout Simulation envisions a phased and carefully monitored expansion of PPP medical colleges.

- Year 1: 10 pilot PPP colleges
 - Year 2–3: 25 additional
- Year 4: First outcome audit
 - Year 5: 50+ operational

Summary

Projected Outcome

The projected outcomes of this expansion include the addition of over 25,000 MBBS seats and more than 10,000 postgraduate seats, along with measurable strengthening of district hospital infrastructure and a significant expansion of the national research ecosystem.

Quality assurance — must shift from infrastructure inspection to **outcome measurement: graduate competence, patient outcomes, and research productivity.**

For-profit participation—when embedded in PPP—offers

For-profit participation—when embedded within a well-structured public–private partnership (PPP) framework—can offer capital velocity, operational efficiency, faster technology integration, and clearer managerial accountability. The ethical question is not whether profit exists, but whether the partnership operates within a clearly regulated public purpose.

Private and Public Good: A False Binary

The perceived dichotomy between private participation and public good is often overstated. Resistance to for-profit entities in medical education typically arises from legitimate concerns about commercialization; however, such risks are manageable through strong regulation. Within the regulatory architecture of the

National Medical Commission, safeguards can include 100% admissions through NEET merit, fee band regulation, mandatory scholarship quotas, rural service obligations, transparent digital disclosure dashboards, and outcome-based accreditation. The regulator must evolve from being primarily an infrastructure inspector to becoming a competency auditor. When governance is robust, profit becomes an incentive for efficiency rather than exploitation.

Core Oversight Philosophy

The core oversight philosophy underpinning this model emphasizes systemic reform in regulation. Traditional inspection-based mechanisms would be replaced with real-time digital monitoring. Ideological debates would give way to measurable outcome indicators. Opaque, discretionary permissions would be substituted with transparent, algorithmic scoring systems. Episodic audits would transition into continuous compliance frameworks enabled by digital dashboards and integrated data systems.

Final Governance Formula

The final governance formula recognizes that while scale is delivered by capital, speed is attained by managerial efficiency, and standards by data-driven regulation. If India aims to align medical education with 21st-century healthcare priorities—such as digital integration,

precision medicine, and universal health coverage—this structured, algorithm-based framework enables for-profit participation without compromising public purpose. Ultimately, the success of this reform will

depend not merely on permitting private participation, but on engineering oversight with precision, transparency, and accountability.

For a country investing in state-wide biobanks and EMR ecosystems—as envisioned in precision medicine initiatives—PPP medical colleges can serve as anchor academic nodes.

- Allowing for-profit companies to establish medical colleges under the PPP mode is not privatisation of medical education; it is professionalisation of capital deployment under sovereign oversight.
- India must design its own model—socially accountable yet economically viable.

The Strategic Opportunity

For India, PPP-enabled medical colleges can:

- Accelerate seat expansion toward workforce sufficiency
- Create research clusters linked to biotechnology and med-tech
- Strengthen district hospital ecosystems
- Integrate digital health into the curriculum
- Reduce outbound medical migration
- Support precision medicine and biobank networks

In a country investing heavily in digital public infrastructure, medical education must not remain analogue in governance or financing.

- The opportunity is structural, the responsibility is regulatory, and the moment to act is now.
- The debate must move beyond ideological binaries, as India today requires scale, speed, and uncompromising standards in expanding its healthcare workforce. Allowing for-profit entities to establish medical colleges within a rigorously regulated Public–Private Partnership framework is not a withdrawal from public responsibility, but rather an adaptive strategy to strengthen national health security. The true measure of success will lie not in permitting participation, but in designing precise, transparent, and accountable regulatory oversight. If structured thoughtfully, this reform can widen access, enhance quality, and better align medical education with India’s 21st-century healthcare needs.



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EDITORIAL

Guinness World Records Recognises National Board of Examination in Medical Sciences, India & Its President Dr. Abhijit Chandrakant Sheth for: “Most viewers of an Artificial Intelligence in Healthcare lesson live stream on YouTube”

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NBEMS Achieves Historic Milestone with Official GUINNESS WORLD RECORDS™ Recognition for “Most viewers of an Artificial Intelligence in Healthcare lesson live stream on YouTube”.

The National Board of Examinations in Medical Sciences

(NBEMS), an autonomous body under the Union Health Ministry on Wednesday achieved a historic milestone by being officially recognized by Guinness World Records for “Most viewers of an Artificial Intelligence in Healthcare lesson live stream on YouTube” (Figure 1 and Table 1).



Figure1. Dr Abhijit Chandrakant Sheth, M.S., M.Ch., President of the NBEMS & Chairman of the National Medical Commission being handed over the Guinness record certificate by Mr Swapnil Dangarikar, Official Adjudicator, Guinness World Records at NBEMS Headquarters in Dwarka, New Delhi on February 25, 2026.

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Table 1. NBEMS Schedule

Module	Module Topic	Date
1	AI for medical profession - need for the change and future ahead	21-Jan-2026
2	From Biostatistics to AI: A Gentle Bridge for Beginners	28-Jan-2026
3	Types of Clinical Data & Asking the Right Questions	04-Feb-2025
4	Unstructured & Missing Data: What Clinicians Must Know	11-Feb-2026
5	Prompt Thinking for Clinicians	18-Feb-2026
6	Why Machine Learning in Healthcare (and When Not to Use It)	25-Feb-2026
7	Core Machine Learning Concepts Without Math Fear	11-Mar-2026
8	How Machines Learn: Intuition for Clinicians	18-Mar-2026
9	Deep Learning in Medicine: Images, Text, and Signals	25-Mar-2026
10	Model Evaluation: When Is an AI Actually Useful?	08-Apr-2026
11	Beyond Metrics: Clinical Utility & Outcome–Action Pairing	15-Apr-2026
12	Retrospective Data, Shelf Life & Generalizability	22-Apr-2026
13	Interpretability: Black Box vs Explainable AI	29-Apr-2026
14	Bias in Healthcare AI: Real-World Clinical Examples	07-May-26
15	Algorithmic Fairness: What Clinicians Should Understand	13-May-26
16	Ethics of AI in Healthcare: Beyond Checklists	20-May-2026
17	Wearables, Robotics & SaMD: How AI Is Entering Clinical Practice (Indian Context)	03-June-2026
18	AI for Smarter Journal Reading, Evidence Synthesis & Clinical Learning	13-June-2026
19	Cybersecurity, Data Privacy & Trust in Clinical AI Systems	20-June-2026
20	Building & Governing Clinical AI Teams	27-June-2026



Figure 2. The NBEMS Team with the ‘Guinness World Record’ award certificate.

The record was achieved through the successful implementation of a nationwide online training programme on Artificial Intelligence in Healthcare,

designed specifically for registered medical practitioners across the country (Figure 2).

The peak concurrent viewership for the programme was Seventeen thousand nine hundred and ninety nine (n: 17,999).

The AI training initiative was conceptualized by NBEMS under the leadership of Dr Abhijat Sheth, President of NBEMS and Chairman of NMC to empower doctors with foundational and applied knowledge of artificial intelligence.



Figure 3. The NBEMS Team with an A.I. lecture in progress.

The mega digital academic e-learning programme of AI for medical professionals across the country was planned and executed by Dr Rakesh Sharma, Governing Body Member of NBEMS, and Dr AVS Suresh from Hyderabad, along with the NBEMS team in collaboration with various AI experts nationally and internationally.

The record attempt was officially adjudicated by a team led by Swapnil Dangarikar, appointed judge from Guinness World Records, who conducted a thorough evaluation and verification process before confirming the achievement.

“This achievement draws inspiration from the visionary leadership of Prime Minister of India, Shri Narendra Modi, who has always emphasised on digital India, technological innovation, and

Dr. (Mrs) S.N. Basu- Member of the Governing Body of NBEMS & Dr. Minu Bajpai- Hon. Executive Director of the NBEMS explained, that, there are 20 modules in the programme being delivered across six months by reputed national and international faculty from Harvard USA, IIM Lucknow, IISc Bengaluru, etc. It may be noted, the NBEMS is not charging any fee from the participants (Figure 3).

the responsible adoption of artificial intelligence in governance and public service,” President of the NBEMS, Dr Abhijat Chandrakant Sheth said. “I also express my heartfelt gratitude to the Union Health Minister Shri J P Nadda, MOHFW officers, faculty members, academic partners, and participating doctors whose collective effort made this achievement possible”.

This recognition from Guinness World Records is not merely a record but a testimony to India’s leadership in adopting digital innovation in medical education, he said.

The NBEMS remains committed towards advancing competency-based learning and will continue to introduce initiatives aimed at enhancing the quality of

healthcare delivery across the nation, he underlined.

“At NBEMS, we believe medical education must grow with global advancements. Our goal is not only to train specialists, but to prepare future-ready

healthcare leaders who can use new technologies responsibly. This record is not just about numbers. It proves that NBEMS is ready to lead and move forward with the changing world,” Dr. Sheth observed (Figure 4).



Figure 4. The NBEMS Governing body members and officers with the ‘Guinness World Record’ award.

The programme witnessed unprecedented participation of doctors from government and private institutions on

pan India basis, reflecting the growing enthusiasm among healthcare professionals towards AI (Figure 5).



Figure 5. The NBEMS entire team with the ‘Guinness World Record’ award at its headquarters in Dwarka, New Delhi on February 25, 2026.



ORIGINAL ARTICLE

Efficacy of Dhaka Regimen in Comparison to Zuspan Regimen in Prevention of Eclampsia: A Randomized Control Trial

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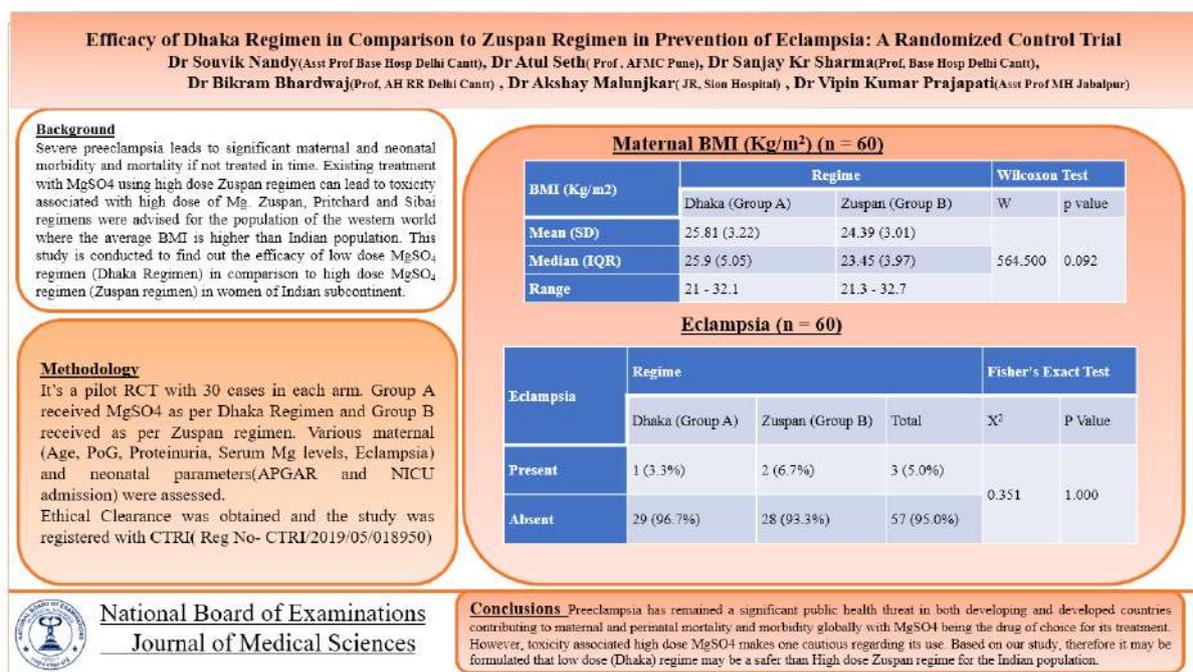
Abstract

Introduction: Severe preeclampsia leads to significant maternal and neonatal morbidity and mortality if not treated in time. Existing treatment with MgSO₄ using high dose Zuspan regimen can lead to toxicity associated with high dose of Mg. Our study compares low dose (Dhaka) with High dose (Zuspan) in efficacy of management of Severe preeclampsia. **Methodology:** It's a pilot RCT with 30 cases in each arm. Group A received MgSO₄ as per Dhaka Regimen and Group B received as per Zuspan regimen. Various maternal (Age, PoG, Proteinuria, Serum Mg levels, Eclampsia) and neonatal parameters (APGAR and NICU admission) were assessed. **Results:** In the present study average age in both the groups was 27 yrs with range between 20-39 years with no statistical difference. Commonest gestational age at presentation was between late preterm (34 wks – 36 wks) or early term (37-38 wks). Average BMI in low dose group (Group A) was 25.81 kg/m² and that for high dose (Group B) was 24.39 kg/m². Most of the maternal parameters in both the groups were comparable as the difference between them was statistically insignificant. There was no statistically significant difference in Fetal parameters. Results elaborated before show that the level of magnesium at 12th and 18th hour is less in Group A (Dhaka) in comparison to Group B (Zuspan). This reduced levels are statistically significant and also show that even with low dose MgSO₄ there was no occurrence of eclampsia. **Conclusion:** It may be formulated that low dose Dhaka regime may be a safer than High dose Zuspan regime. Trial registration: CTRI/2019/05/018950.

Keywords: Zuspan, Preeclampsia, Dhaka

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Graphical Abstract



Introduction

Hypertensive disorders are one of the most significant and intriguing unsolved problem in obstetrics. They complicate 5 to 10 percent of all pregnancies, and together they are one of the deadly triad—along with hemorrhage and infection—that contributes greatly to maternal morbidity and mortality.

Maternal complications of severe pre eclampsia include abruptio placentae, thrombocytopenia, hepatic haemorrhage and rupture, eclampsia, disseminated intravascular coagulation (DIC), intracerebral haemorrhage, acute respiratory distress syndrome (ARDS), acute renal failure and HELLP (Haemolysis-Low platelet- Elevated liver enzymes) syndrome.

The World Health Organization (WHO) states that 16% of maternal deaths in developed world and 9% in Asian population was attributed to hypertensive disorders [1]. In the United States from 2011 to 2013, 7.4 percent of 2009 pregnancy-related maternal deaths were caused by preeclampsia or eclampsia [2]. A

similar rate was 10 percent in Europe from 2006 through 2018 [2]. Importantly, more than half of these hypertension-related deaths were deemed preventable [3].

Eclampsia is defined as the occurrence of generalized tonic-clonic convulsion in women with pre-eclampsia. It is one of the most common obstetrical emergencies in developing countries causing significant maternal and perinatal morbidity and mortality.

Incidence of eclampsia is 1.4% and that of pre eclampsia is 4.6 % worldwide [4]. In India, the incidence of eclampsia is 1.5% -2.2% [5].

The principle management for eclampsia is control of convulsions along with supportive life measures and termination of pregnancy. Various MgSO₄ regimens are followed for management of eclampsia such as Zuspan [6], Pritchard [7], Sibai [8], Sardesai [9] and Dhaka [9] regimen. The efficacy of MgSO₄ in severe preeclampsia and eclampsia is time tested in several studies. The Collaborative Eclampsia Trial randomized a large number

of women to receive Diazepam or Magnesium sulphate and showed greater efficacy of MgSO₄ in terms of seizure control [10].

Zuspan, Pritchard and Sibai regimens were advised for the population of the western world where the average BMI (Body Mass Index) is higher than Indian population.

However, because of its narrow therapeutic index, toxic side-effects are the major area of concern in clinical use. Potential complications of MgSO₄ treatment include maternal hypotension, respiratory depression, respiratory arrest and although rare, cardiac arrest.

Apprehension regarding these toxicities lead to the limited use of this drug in many developing countries. Reduction of MgSO₄ toxicity without compromising efficacy (such as control of seizures and fatality rate) re-mains a major challenge.

Several studies have been carried out, particularly in developing countries, to determine the lowest effective dose of MgSO₄, which would potentially offer lower toxicity than the standard regimens. Dhaka regimen is a low dose regimen used in management of Eclampsia.

A low dose regimen may ensure greater safety and in developing countries like India [11].

This study is conducted to find out the efficacy of low dose MgSO₄ regimen (Dhaka Regimen) in comparison to high dose MgSO₄ regimen (Zuspan regimen) in women of Indian subcontinent.

Aims & objectives

To assess the efficacy of Dhaka regimen for prevention of eclampsia in cases of severe pre eclampsia and compare maternal and fetal outcomes in Dhaka versus Zuspan regimen.

Methodology

Study Population

Ante natal cases with diagnosis of Severe preeclampsia

Place of Study

Tertiary care hospital in western Maharashtra

Inclusion Criteria

All Ante natal cases diagnosed with Severe preeclampsia

Exclusion Criteria

Ante natal cases with pre-existing deranged Renal Function Test, coagulation profile, Seizure disorder.

Study Design

Pilot Randomized Control trial

Sample Size

Since this being a pilot randomized control study, 30 patients in each arm was taken on advise of epidemiologist.

Period of Study

18 months

Methodology

30 patients in each group with severe preeclampsia were started on Dhaka regimen (Group A) and Zuspan regimen (Group B) for prevention of eclampsia.

Group A (Dhaka Regimen)

- **Loading Dose-** Inj MgSO₄ 4gm IV over 10 mins and followed by MgSO₄ 3 gm IM in each buttock
- **Maintenance Dose:** Inj MgSO₄ 2.5 gm in alternate buttock every 4 hours till 24 hours after the last episode of seizure or after delivery whichever was later.

Total dose of MgSO₄ was calculated to be 25 gms over 24 hrs.

Group B (Zuspan Regimen)

- **Loading Dose** Inj MgSO₄ 4gm IV over 10 mins
- **Maintenance Dose:** Continuous infusion of Inj MgSO₄ @ 1gm/hr till 24

hours after the last episode of seizure or after delivery whichever was later

Total dose of MgSO₄ was calculated to be 28 gms over 24 hrs.

This study was analysed on the basis of following parameters:

Results

Table 1a. Age (n = 60)

Age (Years)	Regime		t-test	
	Dhaka (Group A)	Zuspan (Group B)	T	p value
Mean (SD)	27.90 (4.88)	27.37 (3.96)	0.465	0.644
Median (IQR)	27 (7)	27 (5)		
Range	20 - 39	20 - 34		

Table 1b. Gestational Age (n = 60)

Period Of Gestation (Weeks) (PoG)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	36.26 (1.60)	36.13 (2.48)	408.000	0.539
Median (IQR)	36.36 (2.39)	37 (1.86)		
Range	33.29 - 39.29	28.57 - 39.57		

Table 1c. Maternal BMI (Kg/m²) (n = 60)

BMI (Kg/m ²)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	25.81 (3.22)	24.39 (3.01)	564.500	0.092
Median (IQR)	25.9 (5.05)	23.45 (3.97)		
Range	21 - 32.1	21.3 - 32.7		

Table 1d. BP (mmHg) (n = 60)

	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Systolic BP (mmHg)				
Mean (SD)	162.67 (20.80)	162.60 (14.93)	422.500	0.684
Median (IQR)	160 (20)	160 (16)		
Range	120 - 220	136 - 204		
Diastolic BP (mmHg)				
Mean (SD)	108.47 (23.57)	105.20 (9.89)	422.000	0.675
Median (IQR)	106 (10)	107 (11.5)		
Range	82 - 226	76 - 120		

Table 1e. Proteinuria (n = 60)

Proteinuria	Regime			Fisher's Test	Exact Test
	Dhaka (Group A)	Zuspan (Group B)	Total	X ²	P Value
Nil	1 (3.3%)	5 (16.7%)	6 (10.0%)	8.068	0.054
1+	3 (10.0%)	7 (23.3%)	10 (16.7%)		
2+	16 (53.3%)	15 (50.0%)	31 (51.7%)		
3+	10 (33.3%)	3 (10.0%)	13 (21.7%)		

Table 1f. Eclampsia (n = 60)

Eclampsia	Regime			Fisher's Exact Test	
	Dhaka (Group A)	Zuspan (Group B)	Total	X ²	P Value
Present	1 (3.3%)	2 (6.7%)	3 (5.0%)	0.351	1.000
Absent	29 (96.7%)	28 (93.3%)	57 (95.0%)		

Table 1g. Mode of Delivery (n = 60)

Mode of Delivery	Regime			Chi-Square Test	
	Dhaka (Group A)	Zuspan (Group B)	Total	X ²	P Value
Vaginal	16 (53.3%)	15 (50.0%)	31 (51.7%)	0.067	0.796
LSCS	14 (46.7%)	15 (50.0%)	29 (48.3%)		

Table 1h. Parity (n = 60)

Parity	Regime			Chi-Square Test	
	Dhaka (Group A)	Zuspan (Group B)	Total	X ²	P Value
Primigravida	23 (76.7%)	25 (83.3%)	48 (80.0%)	0.417	0.519
Multigravida	7 (23.3%)	5 (16.7%)	12 (20.0%)		

Table 1j. Premonitory Signs (n = 60)

Premonitory Signs	Regime			Chi-Square Test	
	Dhaka (Group A)	Zuspan (Group B)	Total	X ²	P Value
Present	21 (70.0%)	10 (33.3%)	31 (51.7%)	8.076	0.004
Absent	9 (30.0%)	20 (66.7%)	29 (48.3%)		

Table 1k. Respiratory Rate (n = 60)

Respiratory Rate	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	17.03 (1.69)	15.97 (1.79)	614.000	0.010
Median (IQR)	18 (2)	16 (4)		
Range	12 – 19	14 – 20		

Table 1m. Urine Output (ml/Day) (n = 60)

Urine Output (ml/Day)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	1556.17 (292.23)	1399.67 (418.35)	610.500	0.018
Median (IQR)	1550 (487.5)	1355 (375)		
Range	1000 – 2100	950 – 3000		

Table 1n. Magnesium Level at 6 Hours after starting MgSO₄ (n = 60)

Magnesium Level (6 Hours)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	4.55 (0.78)	4.71 (1.18)	395.500	0.424
Median (IQR)	4.5 (0.95)	4.75 (1.33)		
Range	3.1 - 6.6	2 - 8.5		

Table 1p: Magnesium Level at 12 Hours after starting MgSO₄ (n = 60)

Magnesium Level (12 Hours)	Regime		t-test	
	Dhaka (Group A)	Zuspan (Group B)	T	p value
Mean (SD)	4.32 (0.74)	4.77 (1.05)	-1.919	0.060
Median (IQR)	4.25 (0.92)	4.85 (1.22)		
Range	3 – 6	2.2 - 6.8		

Table 1q. Magnesium Level at 18 Hours after starting MgSO₄ (n = 60)

Magnesium Level (18 Hours)	Regime		t-test	
	Dhaka (Group A)	Zuspan (Group B)	t	p value
Mean (SD)	4.20 (0.78)	5.14 (1.40)	-3.222	0.002
Median (IQR)	4.25 (1.05)	5.65 (1.95)		
Range	2.7 – 6	1.8 - 7.4		

Table 1r. Change in Magnesium Level over time (n = 60)

Magnesium Level	Regime		P value (@each of the timepoints) (Wilcoxon Test)
	Dhaka (Group A)	Zuspan (Group B)	
	Mean (SD)	Mean (SD)	
6 Hours	4.55 (0.78)	4.71 (1.18)	0.424
12 Hours	4.32 (0.74)	4.77 (1.05)	0.031
18 Hours	4.20 (0.78)	5.14 (1.40)	0.002
P Value (@ over time within each group)	0.002	0.522	
Overall P Value	0.016		

This eclampsia had occurred prior to the start of therapy in either regimen.

3.3% of the patients in the group A had Eclampsia.

6.7% of the patients in the group B had Eclampsia

There was **no significant difference** between the various groups in terms of distribution of Eclampsia (p = 1.000).

Table 2. Neonatal Parameters

Timepoint Comparison	Change in Magnesium Level from 6 Hours to Follow-up Timepoints			
	Group A		Group B	
	Mean (SD) of Absolute Change	P Value of Change Within Group	Mean (SD) of Absolute Change	P Value of Change Within Group
12 Hours - 6 Hours	-0.23 (0.59)	0.032	0.06 (1.01)	0.991
18 Hours - 6 Hours	-0.35 (0.65)	0.003	0.43 (1.44)	0.638

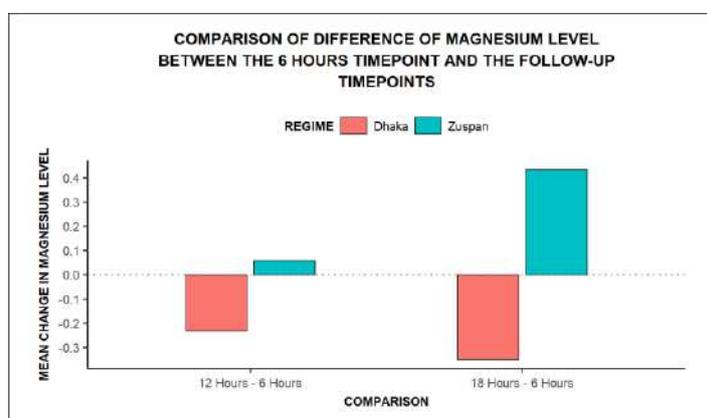


Figure 1. Bar diagram depicting the difference of Magnesium Level between the 6 Hours timepoint and the follow-up timepoints in both the groups

In Group A the fall in magnesium levels at 18th hour and at 12th hour respectively from 6th hour was statistically significant.

It is important to note that even at this low levels of serum magnesium (Group A) there was no occurrence of eclampsia.

Fetal parameters

Table 2a. APGAR @ 1 minute after birth (n = 65)

APGAR (@1 minute)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan (Group B)	W	p value
Mean (SD)	6.27 (0.87)	6.53 (0.78)	374.000	0.198
Median (IQR)	7 (1.75)	7 (1)		
Range	5 - 7	5 - 7		

Table 2b. APGAR @5 minutes after birth (n = 65)

APGAR (@5 minutes)	Regime		Wilcoxon Test	
	Dhaka (Group A)	Zuspan(Group B)	W	p value
Mean (SD)	9.00 (0.00)	8.93 (0.37)	465.000	0.334
Median (IQR)	9 (0)	9 (0)		
Range	9 - 9	7 - 9		

Table 2c. NICU Admission (n = 65)

NICU Admission	Regime		Chi-Square Test	
	Dhaka (Group A)	Zuspan (Group B)	X ²	P Value
Present	33.3%	36.7%	0.073	0.787
Absent	66.7%	63.3%		

Discussion

Since the introduction of Zuspan and Pritchard regime of magnesium sulphate there has been a constant discussion regarding the dose of Magnesium sulphate and therapeutic serum Magnesium levels.

Winit Phuapradit et al. [14] and Andrea Witlin [15] thought that Magnesium sulphate dosing should vary according to the patients' weights or body mass index. Based on these observations various low dose regimens have been introduced in Asian countries.

The present study conducted at our centre is a comparison between low dose MgSO₄ (Group A- Dhaka regimen) and high dose MgSO₄ (Group B- Zuspan regimen) in terms of efficacy in preventing eclampsia in patients with severe preeclampsia. Below mentioned are some comparisons amongst our study and other studies.

The mean gestational age at presentation in Group A was 36 wks 2 days. The mean gestational age at presentation in Group B was 36 wks 1 day. Similar distribution of mean gestational age was observed in the comparison groups in the

study conducted by Shikha Seth et al. [16] where mean gestational age was 34 wks 1 day in low dose group and 34 wks 5 days in high dose group.

There was no neonatal mortality noted in this study. All of the babies in both groups had a good Apgar score at 1 minute and 5 minutes.

Results elaborated before show that the level of magnesium at 12th and 18th hour is less in Group A (Dhaka) in comparison to Group B (Zuspan). This reduced levels are statistically significant and also show that even with low dose MgSO₄ there was no occurrence of eclampsia.

Conclusion

Preeclampsia has remained a significant public health threat in both developing and developed countries contributing to maternal and perinatal mortality and morbidity globally [17] with MgSO₄ being the drug of choice for its treatment. However, toxicity associated high dose MgSO₄ makes one cautious regarding its use. Based on our study, therefore it may be formulated that low dose (Dhaka) regime may be a safer than High dose Zuspan regime for the Indian

population. More elaborate studies with higher sample size can be formulated to further authenticate our findings [18].

Conflicts of interest

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

Ethical Approval

Approval has been taken before initiation the study (IEC/OCT/2018, dt 23rd Oct 2018)

Human and animal rights

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

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ORIGINAL ARTICLE

Comparison of Oral Midazolam and Oral Ketamine as Premedicants for Parent–Child Separation in Paediatric Elective Surgery

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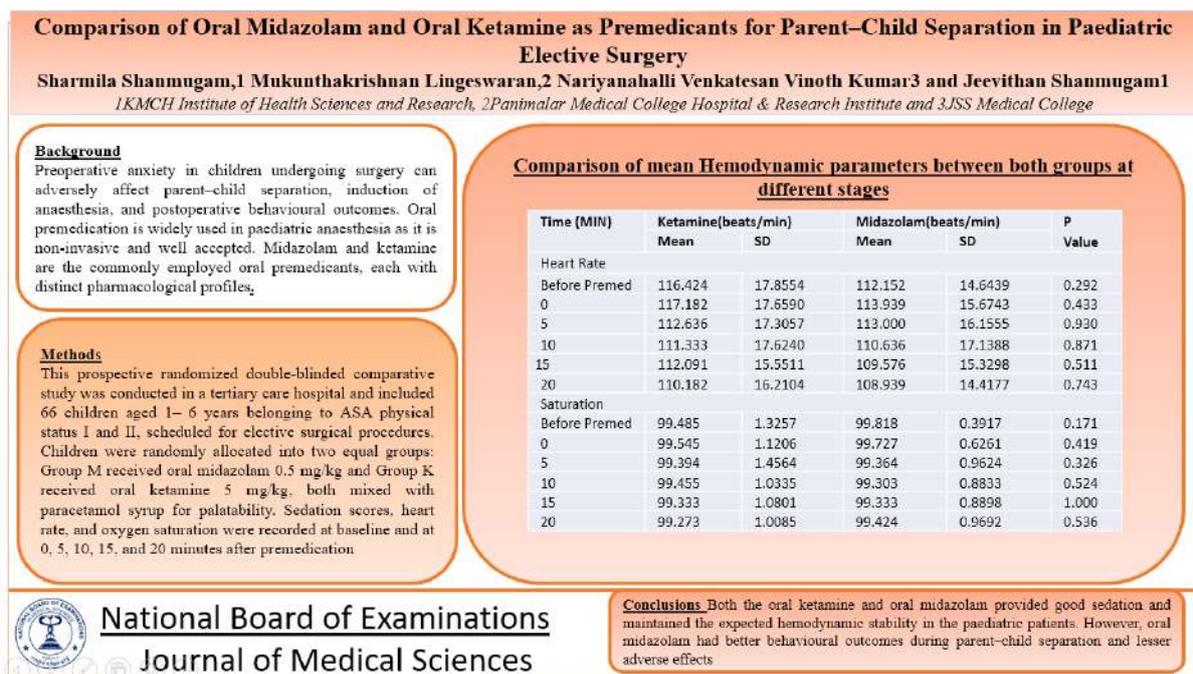
Abstract

Introduction: Preoperative anxiety in children undergoing surgery can adversely affect parent–child separation, induction of anaesthesia, and postoperative behavioural outcomes. Oral premedication is widely used in paediatric anaesthesia as it is non-invasive and well accepted. Midazolam and ketamine are the commonly employed oral premedicants, each with distinct pharmacological profiles. **Materials and Methods:** This prospective randomized double-blinded comparative study was conducted in a tertiary care hospital and included 66 children aged 1– 6 years belonging to ASA physical status I and II, scheduled for elective surgical procedures. Children were randomly allocated into two equal groups: Group M received oral midazolam 0.5 mg/kg and Group K received oral ketamine 5 mg/kg, both mixed with paracetamol syrup for palatability. Sedation scores, heart rate, and oxygen saturation were recorded at baseline and at 0, 5, 10, 15, and 20 minutes after premedication. **Results:** Baseline demographic data such as weight and age were comparable between the two study groups. Oxygen saturation and Heart rate remained stable throughout the observation period at any point of time, in both the groups with no statistically significant differences. **Conclusion:** Both the oral ketamine and oral midazolam provided good sedation and maintained the expected hemodynamic stability in the paediatric patients. However, oral midazolam had better behavioural outcomes during parent–child separation and lesser adverse effects, suggesting that it may be the preferred oral premedicant for elective surgical procedures in children.

Keywords: Paediatric premedication, Oral midazolam, Oral ketamine, Parent–child separation, Sedation

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Graphical Abstract



Introduction

Preparing paediatric patients for surgery is a challenging process, as children often experience significant anxiety related to separation from parents, unfamiliar hospital environments, and anaesthesia induction. Children are frequently unable to articulate their fears, yet experience levels of anxiety comparable to adults [1]. Surgical procedures and anaesthesia induction are known to cause considerable emotional stress in children, and pre-anaesthetic medications are commonly administered to reduce anxiety, facilitate child–parent separation, and promote smooth induction of anaesthesia [2].

Preoperative anxiety typically develops at around 7–8 months of age and peaks at approximately one year of age [3]. Children between one and five years of age, those with anxious temperaments, previous unpleasant medical experiences, or whose parents demonstrate poor coping skills are particularly vulnerable to heightened anxiety [4]. Without appropriate

intervention, young children may develop post-hospitalisation behavioural changes such as separation anxiety, sleep disturbances, feeding difficulties, nightmares, bedwetting, and regression of toilet training [5]. Pre-anaesthetic medication plays an essential role in alleviating these psychological effects, decreasing the vagal responses, and preventing the expected postoperative behavioural sequelae [6].

An ideal paediatric premedicant should be cost effective, easily available, palatable, faster in onset, reliable, and free from adverse effects during induction, recovery, and discharge [7]. Despite the various pharmacological premedicant, no single drug has achieved the acceptance worldwide, highlighting the need for continued evaluation of commonly used premedicants.

The most frequently used oral premedicants in paediatric anaesthesia are Ketamine and Midazolam [1,5]. Due to its anxiolytic, sedative, and amnestic

properties, Midazolam, a short-acting benzodiazepine, is widely used. However, its variability in oral bioavailability and bitter taste remain disadvantages [8]. Different strategies, including the mixing intravenous midazolam with flavoured syrups or juices, have been used successfully to improve palatability [9,10].

Ketamine, a phencyclidine derivative and NMDA receptor antagonist, produces dissociative anaesthesia (sedation) with preservation of airway reflexes and respiratory drive [8]. Oral ketamine usually provides an effective analgesia and sedation. Typical sedation is achieved within 10–15 minutes at the doses of 5–6 mg/kg [8]. The drug, ketamine may be associated with adverse effects such as increased postoperative emesis [3] and nystagmus. Paracetamol syrup, widely used in paediatric practice because of its safety, analgesic, and antipyretic properties, has been employed as a palatable vehicle for oral administration of premedicants [11].

The previous research papers demonstrated the efficacy of oral midazolam and ketamine, when administered with flavoured syrups [6,11] and the present study was designed to compare oral ketamine and oral midazolam, both mixed with paracetamol syrup, as premedicants during the elective surgery of paediatric patients. The current research aimed to assess their effects on sedation, child–parent separation, hemodynamic stability, the behaviour during induction of anaesthesia, and the perioperative adverse effects.

Materials and Methods

This prospective randomized double-blinded comparative study was conducted in the Theatre Complex of the Department of Anaesthesiology at a tertiary

care teaching hospital. Prior to commencement of the study, approval was obtained from the Institutional Ethical and Scientific Committee. Parents or legal guardians of all eligible children were approached during the preoperative assessment period and were explained in detail about the nature, purpose, and usefulness of premedication. It was clearly communicated that the study was observational in nature, non-invasive. The informed consent in the written format was obtained from the parents or guardians in accordance with ethical principles justified in the Declaration of Helsinki. Confidentiality of patient information was strictly maintained, and participation was entirely voluntary in nature, with the option to withdraw at any stage without affecting the standard of care.

A total of 66 paediatric patients scheduled for elective surgical procedures under general anaesthesia were included in the study. Children aged between 1 and 6 years, weighing less than 20 kg, and belonging to American Society of Anaesthesiologists (ASA) physical status I and II were enrolled. Children with known allergy to midazolam or ketamine, risk of aspiration, weight more than 20 kg, anatomical airway abnormalities, systemic illnesses affecting drug absorption, renal disease, developmental delay, congenital syndromes, seizure disorders, or other central nervous system disorders were excluded. Emergency procedures, ASA grade more than II, and surgeries expected to last more than two hours were also excluded.

The study followed a double-blinded randomised design. Eligible patients were randomly allocated into two equal groups of 33 each using a sealed opaque envelope method. Sixty-six cards

marked either “K” (ketamine) or “M” (midazolam) were prepared, shuffled, sealed in opaque envelopes, and sequentially numbered. For each patient, an envelope was opened by the consultant anaesthesiologist, who prepared the study drug accordingly. The study drug was administered by a trainee anaesthesiologist who was blinded to the drug allocation and was responsible for data collection. The nature of the drug administered was revealed to the investigator only after completion of data collection for all patients.

Children in Group K received oral ketamine at a dose of 5 mg/kg, while those in Group M received oral midazolam at a dose of 0.5 mg/kg. Intravenous formulations of ketamine (50 mg/mL) and midazolam (5 mg/mL) were used and mixed with commercially available flavoured paracetamol syrup (15 mg/kg; 250 mg/5 mL) to improve palatability. Adequate care was given to ensure that the total volume of the administered agents must not exceed 0.5 mL/kg. Both the drugs were odourless and colourless, also, for maintaining the blinding, the same brand of paracetamol syrup was used in both the drug groups.

Following premedication, the pulse oximetry was used to monitor the oxygen saturation of arterial blood (SpO₂) continuously and direct clinical observation was also made. At 0, 5, 10, 15, and 20 minutes after administration of the study drug, the heart rate, oxygen saturation (SpO₂), and sedation scores were recorded at the baseline. The Sedation was evaluated using a four-point sedation scale as follows. Score 1: Alert and active; Score 2: Awake but calm; Score 3: Drowsy but arousable; Score 4: Asleep and not easily arousable.

Twenty minutes after the premedication, the participants were separated from their parents and transferred to the operation theatre room. Behaviour during parent–child separation was evaluated using the *Parental Separation Anxiety Scale*, and behaviour during induction was assessed using a *four-point mask acceptance scale*. Scores of 1 and 2 were considered acceptable for both separation and mask acceptance.

In the operating room, standard monitors including electrocardiogram, non-invasive blood pressure, and pulse oximetry were applied. Anaesthesia was induced using sevoflurane in a 50:50 mixture of oxygen and nitrous oxide. Airway management with laryngeal mask airway or endotracheal tube and the use of caudal analgesia were performed as appropriate for the surgical procedure. Any perioperative adverse effects such as airway obstruction, desaturation, nystagmus, hiccups, bradycardia, nausea, or vomiting were noted and recorded.

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) software version 27.0 for Windows. Descriptive statistics such as mean, standard deviation, frequency, and percentage were used to summarise demographic and clinical variables. Continuous variables including heart rate and oxygen saturation were analysed using the independent samples t-test. Sedation and behaviour scores, being ordinal data, were analysed using the Mann–Whitney U test. A P value of less than 0.05 was considered statistically significant, and all analyses were performed at a 95% confidence interval.

Results

The baseline demographic characteristics were comparable between the ketamine and midazolam groups. The mean age of children in the ketamine group was 3.00 ± 1.63 years, while it was 3.32 ± 1.48 years in the midazolam group, with no statistically significant difference ($P = 0.42$). Similarly, the mean body weight did

not differ significantly between the two groups (13.22 ± 3.71 kg vs. 13.95 ± 3.54 kg; $P = 0.43$). However, a statistically significant difference was observed in sex distribution, with males constituting a higher proportion in the ketamine group (78.8%) compared to the midazolam group (42.4%) ($P = 0.003$) (Table 1).

Table 1. Baseline Demographic Characteristics of the Study Population

Variable	Ketamine (n = 33)	Midazolam (n = 33)	P value
Age (years), mean \pm SD	3.00 ± 1.63	3.32 ± 1.48	0.42
Weight (kg), mean \pm SD	13.22 ± 3.71	13.95 ± 3.54	0.43
Sex – Male, n (%)	26 (78.8%)	14 (42.4%)	0.003
Sex – Female, n (%)	7 (21.2%)	19 (57.6%)	

Table 2 compares the hemodynamic parameters and oxygen saturation between the ketamine and midazolam groups at different time intervals from baseline to 20 minutes after premedication. The mean heart rate was marginally higher in the ketamine group before premedication (116.42 ± 17.86 beats/min) compared to the midazolam group (112.15 ± 14.64

beats/min), but this difference was not statistically significant ($P = 0.292$). At subsequent intervals, including 10 minutes (111.33 ± 17.62 vs. 110.64 ± 17.14 beats/min) and 20 minutes (110.18 ± 16.21 vs. 108.94 ± 14.42 beats/min), heart rates remained comparable between the two groups ($P > 0.05$).

Table 2. Comparison of mean Hemodynamic parameters between both groups at different stages

Time (MIN)	Ketamine(beats/min)		Midazolam(beats/min)		P Value
	Mean	SD	Mean	SD	
Heart Rate					
Before Premed	116.424	17.8554	112.152	14.6439	0.292
0	117.182	17.6590	113.939	15.6743	0.433
5	112.636	17.3057	113.000	16.1555	0.930

10	111.333	17.6240	110.636	17.1388	0.871
15	112.091	15.5511	109.576	15.3298	0.511
20	110.182	16.2104	108.939	14.4177	0.743
Saturation					
Before Premed	99.485	1.3257	99.818	0.3917	0.171
0	99.545	1.1206	99.727	0.6261	0.419
5	99.394	1.4564	99.364	0.9624	0.326
10	99.455	1.0335	99.303	0.8833	0.524
15	99.333	1.0801	99.333	0.8898	1.000
20	99.273	1.0085	99.424	0.9692	0.536

In both the groups, oxygen saturation values were consistently maintained above 99% throughout the observation period. At 20 minutes, the mean SpO₂ was 99.42 ± 0.97% in the midazolam group and 99.27 ± 1.01% in the ketamine group, with no statistically significant difference seen between the study groups (P = 0.536). Overall, there was no significant difference in oxygen saturation or heart rate between the study groups at any time point, as shown in Table 2.

The mean sedation scores compared at different time intervals between the midazolam and ketamine groups are presented in Table 3. Before premedication,

the mean sedation score was slightly higher in the ketamine group (3.36 ± 0.55) compared to the midazolam group (3.09 ± 0.58), though this difference did not reach statistical significance (P = 0.059). Following administration of the study drugs, sedation scores decreased progressively over time in both groups. At 10 minutes, the mean sedation scores were 2.36 ± 0.60 in the ketamine group and 2.55 ± 0.67 in the midazolam group (P = 0.316). By 20 minutes, both groups achieved comparable levels of sedation (1.91 ± 0.77 vs. 1.94 ± 0.61; P = 0.810), indicating no statistically significant difference in sedation between the two groups at any observed time point (Table 3).

Table 3. Comparison of mean Sedation score at different times

Time(min)	Ketamine		Midazolam		Mann-Whitney U Value	P Value
	Mean score	SD	Mean score	SD		
Before Pre-med	3.364	0.5488	3.091	0.5790	418.500	0.059
0	3.333	0.5401	3.152	0.5658	459.500	0.197
5	2.818	0.4647	2.848	0.6185	537.500	0.913
10	2.364	0.6030	2.545	0.6657	474.500	0.316
15	2.000	0.6614	2.152	0.6185	479.500	0.344
20	1.909	0.7650	1.939	0.6093	527.500	0.810

The comparison of behaviour scores at induction and parent-child separation between the ketamine and midazolam groups is shown in Table 4. At induction, the mean behaviour score was comparable between the ketamine group (2.12 ± 0.89) and the midazolam group (1.94 ± 0.70), with no statistically significant difference observed ($P = 0.400$). However, at the time of parent-child separation, a statistically significant difference was noted between

the two groups. The mean behaviour score was higher in the ketamine group (2.49 ± 0.80) compared to the midazolam group (2.09 ± 0.72), and this difference was statistically significant ($P = 0.037$), as shown in Table 4. In ketamine group nearly one fourth (24.24%) experienced complications (1 child had vomiting and 7 children had nystagmus). In midazolam group no one had any complications.

Table 4. Comparison of Behaviour score between both groups at induction and separation

Time (min)	Ketamine		Midazolam		Mann-Whitney U Value	P Value
	Mean score	SD	Mean score	SD		
At induction	2.121	0.8929	1.939	0.7044	484.000	0.400
At separation	2.485	0.7953	2.091	0.7230	395.000	0.037

Discussion

Preoperative anxiety in children remains a significant concern in paediatric anaesthesia and has been shown to negatively influence parent–child separation, induction of anaesthesia, and postoperative behavioural outcomes [1,2]. Oral premedication is widely preferred in paediatric practice due to its non-invasive nature and better acceptance by children compared to parenteral routes [8]. The present study compared oral midazolam and oral ketamine, both administered with paracetamol syrup, with respect to sedation, behavioural response, hemodynamic stability, and adverse effects in children undergoing elective surgical procedures.

In the present study, baseline demographic variables such as age and weight were comparable between the two groups, although a statistically significant difference was observed in sex distribution (Table 1). This imbalance is unlikely to have influenced the primary outcomes, as previous studies have not demonstrated a consistent association between sex and preoperative anxiety levels or response to sedative premedication in young children (6,12). Hence, the observed differences in behavioural response and adverse effects can reasonably be attributed to the pharmacological properties of the study drugs rather than demographic variation.

Hemodynamic parameters remained stable in both groups throughout the observation period. There were no statistically significant differences in heart rate or oxygen saturation between the ketamine and midazolam groups from baseline to 20 minutes following premedication (Table 2). Oxygen saturation was consistently maintained above 99% in both groups, indicating preserved respiratory function. These findings are

consistent with earlier studies reporting stable cardiovascular and respiratory parameters with oral ketamine and oral midazolam when used in appropriate doses for paediatric premedication [6,7,11].

Sedation scores highlight a progressive and gradual decline over time in both groups, showcasing an increased depth of sedation after the administration of the drugs. Though the onset of sedation appeared little earlier in the ketamine group, this difference did not reach significant level at any time point (Table 3). At 20 minutes, both the groups have achieved comparable sedation scores, showing the equivalent and effective sedation during the time of parent–child separation. These results are in par with the previous studies demonstrating the similar sedative effectiveness of oral ketamine and oral midazolam in paediatric age group [6,7,13].

The critical determinant of effective paediatric anaesthetic management is the behavioural response during parent–child separation and the induction of anaesthesia. In the current study, induction period, behaviour scores were comparable between the study groups, showing the similar acceptance of face mask and further cooperation. (Table 4). However, at the time of parent–child separation, the midazolam group showed significantly better behaviour scores when, compared to the ketamine group ($P = 0.037$). These results spotted the superior anxiolytic effect of midazolam during the separation period. This can be attributed to its benzodiazepine-mediated anxiolysis and amnesic properties [1,5,12].

The drug Ketamine was associated with a higher incidence of adverse effects in the current study. In the ketamine group, 24.24% of the children gone through the

adverse effects, with seven children exhibiting nystagmus and one child developing vomiting, whereas nil complications were observed in the midazolam group. These findings are similar with the previous studies highlighting the increased incidence of emesis and nystagmus, after the oral ketamine administration [12]. Although these adverse effects were transient and did not require medical intervention, their occurrence may be clinically relevant, particularly in the paediatric population. Nystagmus can be alarming to parents and caregivers, and vomiting may increase perioperative discomfort and anxiety, thereby negatively influencing parental satisfaction and acceptance of premedication. Similar findings have been reported in previous studies, which have documented a higher incidence of minor but noticeable adverse effects such as nystagmus and emesis following oral ketamine administration [3,11]. These observations suggest that, despite its sedative efficacy, ketamine may be associated with reduced overall tolerability when compared to midazolam, especially in settings where parental perception and child comfort are critical components of perioperative care.

The use of oral paracetamol syrup was well tolerated in both groups and positively contributed to the improved palatability and acceptance of the two agents. This approach has been shown to be efficient in the previous studies without altering the pharmacodynamic effects of midazolam or ketamine⁽¹¹⁾. The judicious use of a flavoured syrup as a diluent denotes an easy, simple, and practical strategy to improve compliance in paediatric patients.

Limitations

This study was conducted at a single centre with a relatively small sample size and short preoperative observation period. A statistically significant imbalance in sex distribution was observed between groups, although this is unlikely to have influenced primary outcomes. Larger multicentre trials with extended follow-up are recommended.

Conclusion

The current study highlights that both the oral ketamine and oral midazolam offer comparable hemodynamic stability and sedation, but the oral midazolam provides better behavioural outcomes during the parent–child separation and is associated with fewer adverse effects. The above observations from the study, emphasize the preferential use of oral midazolam as a premedicant in the paediatric patients undergoing elective surgical procedures.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Effectiveness of First Aid Education on High School Students in Thrissur District, Kerala

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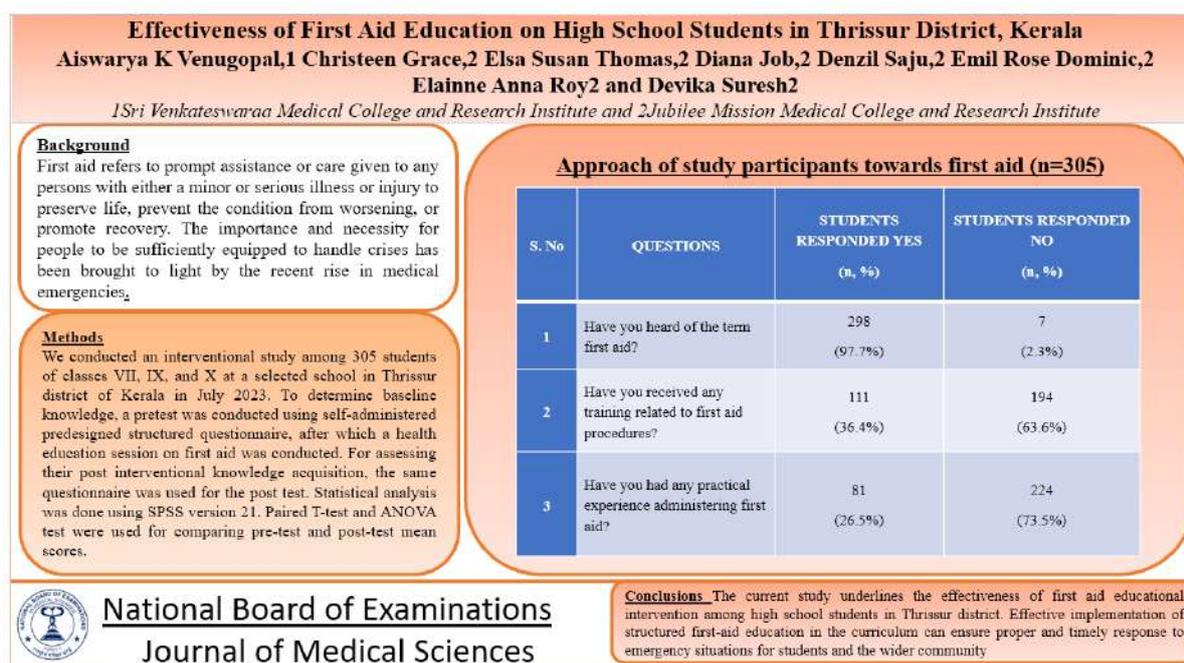
Abstract

Background: First aid refers to prompt assistance or care given to any persons with either a minor or serious illness or injury to preserve life, prevent the condition from worsening, or promote recovery. The importance and necessity for people to be sufficiently equipped to handle crises has been brought to light by the recent rise in medical emergencies. **Objective:** To assess the first aid education effectiveness on high school students in Thrissur district of Kerala. **Methods:** We conducted an interventional study among 305 students of classes VII, IX, and X at a selected school in Thrissur district of Kerala in July 2023. To determine baseline knowledge, a pretest was conducted using self-administered predesigned structured questionnaire, after which a health education session on first aid was conducted. For assessing their post interventional knowledge acquisition, the same questionnaire was used for the post test. Statistical analysis was done using SPSS version 21. Paired T-test and ANOVA test were used for comparing pre-test and post-test mean scores. **Results:** The study observed that 97.7% of the students had heard of the term “first aid”, and only 26.5% had practical experience of administering it. Xth-standard students had greater baseline knowledge compared to the VIIth and IXth standard students. The post-test scores showed a significant difference from the pre-test scores, and maximum improvement was observed for 9th standard. **Conclusion:** The current study underlines the effectiveness of first aid educational intervention among high school students in Thrissur district. Effective implementation of structured first-aid education in the curriculum can ensure proper and timely response to emergency situations for students and the wider community.

Keywords: First aid, Educational Intervention, Medical emergencies, Health education

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Graphical Abstract



Introduction

First aid encompasses the initial assistance or care given to any persons with a minor or serious illness or injury to preserve life, prevent the condition from worsening, or promote recovery [1]. It equips a person to give prompt assistance to injured persons in the accident or emergency situations. First aid can be performed by anyone with basic knowledge regarding the procedures during emergencies such as burns, bleeding, epilepsy, fractures, snake bites, animal bites, fainting, choking, and other acute medical conditions. The objective of first aid is to preserve life, prevent harm, promote recovery, and stop worsening of condition until help arrives.

The timely availability of first aid has shown a significant reduction in morbidity and mortality associated with these sudden medical emergencies. In many cases, recovery or the outcome of an injury depends on actions taken within the

first few minutes rather than the advanced care. In spite of this, among the general population, inadequate first aid knowledge and lack of awareness are a main contributors to preventable mortality. According to the various reports, up to 150,000 people a year could be dying unnecessarily due to lack of awareness of first aid [3]. According to the World Health Organization, 20% of people involved in road accidents expire due to delays in first aid, and 2/3rd of deaths occur within 25 minutes after the trauma. So, a considerable number of deaths occur due to the delays in getting appropriate and immediate first aid, emphasizing the need for first aid education.

School-based health education plays a vital role in making an alert, prepared, and response-ready community. Especially high school students are the ideal group for training in first aid, as they have the maturity to understand emergency procedures and the ability to implement

them physically without any hesitation. This can also foster a culture of safety and responsibility that will be useful in adulthood. Also, myths about providing first aid in a non-scientific manner have deeply imprinted on the minds of people, which also need to be changed.

The rise in incidence of medical emergencies and injuries in recent years, has underscored the need for individuals to be adequately trained to deal with emergencies effectively. Therefore, it is essential to assess the effectiveness of structured first aid education programs among high school students to identify the gain in knowledge and skill acquisition. This study aims to evaluate the effectiveness of first aid education on high school students in Thrissur district, Kerala.

Methods

This was a school-based interventional study conducted from July 2023 to August 2023 among the high school students of a selected school in Thrissur district of Kerala. All students of class VIII, IX, and X who gave assent were included in the study. Students who were absent during the study were excluded. Among 686 aided schools in Thrissur, we selected one school randomly by lot sampling, which was a girl's school. Data was collected from all students of class VIII, IX, and X using the universal sampling technique. There were 305 students who met the inclusion criteria. Institutional Ethics Committee approval was obtained prior to the start of the study.

After obtaining informed consent from the school, data was collected using the predesigned structured questionnaire,

which contained two parts. The first part consisted of a sociodemographic profile, and the second part contained questions to assess knowledge regarding first aid measures. First, a pre-test was conducted using the questionnaire, followed by an intervention in the form of health education, including a demonstration of first aid measures using visual aids such as charts and videos, and then a post-test was conducted using the same questionnaire. Before administering the questionnaire, the purpose of the study was explained, and strict confidentiality of the response was ensured.

All responses were entered on Microsoft Excel and analyzed using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp., Armonk, NY, USA). For the purpose of data analysis, categorical variables were summarized as frequencies and percentages, whereas continuous variables were expressed as mean \pm standard deviation. The ANOVA test and paired-T test were used to compare the pre-test and post-test means. A value of $p < 0.05$ was considered to be statistically significant.

Results

This study is done to evaluate the effectiveness of first aid education on high school students of a school in Thrissur district, Kerala. A total of 305 study participants who satisfied inclusion criteria were enrolled for the study. The following headings discuss the study's findings.

1. Sociodemographic characteristics
2. Pretest and post test score comparison.

Table 1. Socio-demographic Profile of Study Participants (n=305)

Variable	Category	Frequency (n)	Percentage (%)
Class	VIII	115	38.0
	IX	96	31.0
	X	94	31.0
Age (years)	12	17	5.5
	13	114	37.4
	14	96	31.5
	15	78	25.6
Type of family	Nuclear	65	21.0
	Joint	47	16.0
	Three generation	193	63.0
Religion	Christian	147	48.2
	Hindu	133	43.6
	Muslim	25	8.2
Father's Occupation	Professional	74	24.3
	Semi professional	53	17.4
	Clerical/shop owner/farmer	40	13.1
	Skilled	29	9.5
	Semi Skilled	97	31.8
	Unskilled	12	3.9
Mother's Occupation	Professional	1	0.3
	Semi professional	58	19.0
	Clerical/shop owner/farmer	35	11.5
	Skilled	17	5.6
	Semi Skilled	5	1.6
	Unskilled	9	3.0
	Unemployed	180	59.0

Table 1 shows that the sample comprised 305 students, out of which the majority of the students belonged to class VIII (38%), followed by class X (31%) and class IX (31%). The age of the students ranged from 12 to 15 years, with most participants aged 13 years (37.4%), followed by 14 years (31.5%) and 15 years (25.6%). Regarding family type, a predominant proportion of students belonged to three-generation families (63.0%), while 21% belonged to nuclear

families and 16% to joint families. According to the religious distribution, Christian students comprised the largest proportion (48.2%), followed by Hindu students (43.6%) and Muslim students (8.2%). Regarding parental occupation, 31.8% of fathers were semiskilled laborers (e.g., factory or workshop laborers), and 3.9% of them were unskilled laborers (e.g., watchmen or peons). 59% of mothers were unemployed (homemakers), and only one was a professional.

Table 2. Approach of study participants towards first aid (n=305)

S. No	QUESTIONS	STUDENTS RESPONDED YES (n, %)	STUDENTS RESPONDED NO (n, %)
1	Have you heard of the term first aid?	298 (97.7%)	7 (2.3%)
2	Have you received any training related to first aid procedures?	111 (36.4%)	194 (63.6%)
3	Have you had any practical experience administering first aid?	81 (26.5%)	224 (73.5%)

Table 2 shows that 98% of students had heard of the term "first aid". Only 26.5% have practical experience of

administering first aid. Only 36.4% of students have received training, and the rest did not receive any training.

Table 3. Effectiveness of first aid education (n=305)

	Mean \pm SD	T value	p value
PRE-TEST	6.06 \pm 2.246	-47.464	0.001
POST-TEST	12.53 \pm 1.923		

The mean pre-test knowledge score among the participants was 6.06 ± 2.25 , which increased significantly to 12.53 ± 1.92 following the first aid education intervention. The difference between the

pre-test and post-test scores was found to be statistically highly significant, indicating a substantial improvement in knowledge after intervention (Table 3).

Table 4. Baseline knowledge in relation to class and age (n=305)

VARIABLE	N	KNOWLEDGE AT BASELINE		F value	P value
		MEAN	SD		
CLASS (n=305)					
VIII	115	5.66	2.55	7.031	0.001
IX	96	5.84	2.26		
X	94	6.76	1.61		
AGE (n=305)					
12	17	5.88	2.26	3.996	0.008
13	114	5.54	2.52		
14	96	6.26	2.23		
15	78	6.60	1.63		

Baseline knowledge scores varied significantly across different classes and age groups (Table 4). With respect to class, students in Class X had the highest mean baseline knowledge score (6.76 ± 1.61), followed by Class IX (5.84 ± 2.26) and Class VIII (5.66 ± 2.55). The difference in baseline knowledge scores among the three classes was found to be statistically significant ($F = 7.03$, $p = 0.001$).

Similarly, baseline knowledge scores showed a significant association with age. Students aged 15 years demonstrated the highest mean knowledge score (6.60 ± 1.63), followed by those aged 14 years (6.26 ± 2.23), 12 years (5.88 ± 2.26), and 13 years (5.54 ± 2.52). The variation in baseline knowledge scores across age groups was also statistically significant ($F = 3.99$, $p = 0.008$) (Table 4).

Table 5. Post-test improvement in knowledge based on class and age (n=305)

VARIABLE	N	POST-TEST IMPROVEMENT		F value	p value
		MEAN	SD		
CLASS (n=305)					
VIII	115	5.79	2.55	19.954	0.001
IX	96	7.66	2.33		
X	94	6.10	1.70		
AGE (n=305)					
12	17	6.35	1.69	3.927	0.009
13	114	6.10	2.77		
14	96	7.15	2.19		
15	78	6.22	1.94		

The magnitude of improvement in post-test knowledge scores differed significantly across classes and age groups (Table 5). With respect to class, students of Class IX demonstrated the highest mean improvement score (7.66 ± 2.33), followed by Class X (6.10 ± 1.70) and Class VIII (5.79 ± 2.55). This difference in improvement across classes was found to be statistically highly significant ($p < 0.001$).

Similarly, a statistically significant variation in post-test improvement was observed across different age groups.

Students aged 14 years showed the greatest mean improvement (7.15 ± 2.19), followed by those aged 12 years (6.35 ± 1.69), 15 years (6.22 ± 1.94), and 13 years (6.10 ± 2.77). The association between age and improvement in post-test scores was statistically significant ($p = 0.009$).

Discussion

The current study assessed the effectiveness of first aid education among high school students in a school in Thrissur district of Kerala. The findings showed a statistically significant

improvement in knowledge scores after the educational intervention, pressing the effectiveness of first aid training in adolescents. The mean knowledge score increased markedly from the pre-test to the post-test assessment ($p < 0.001$), indicating substantial knowledge accession after the intervention.

Participants had a high baseline awareness about the term “first aid,” but only a small percentage had actually administered first aid before. This gap between awareness and hands-on experience emphasizes the importance of formal training programs that stress practical skills and theoretical knowledge. Mobarak et al. and Bandyopadhyay et al. found similar results in Saudi Arabia and West Bengal, where the majority of the students knew about first aid but had not had any hands-on experience [3,8].

The results of the present study regarding the effectiveness of first aid educational intervention are in line with those of several studies done in various settings. Among school students in West Bengal, Dasgupta et al., reported significantly higher post-test knowledge scores among school students after first aid training ($p < 0.001$), which is in line with the current study [3]. Similarly, studies done in Ujjain, Thane, and Tirupur districts showed statistically significant increases in first aid knowledge after structured educational interventions [4-9]. The relevance of the first aid education as a successful public health intervention is reinforced by these consistent results across various geographic and sociocultural situations.

The interactive and structured nature of the educational session may have contributed to the observed increase in knowledge by improving students’

understanding and memory of the information. Because they have the cognitive maturity to comprehend emergency response concepts and the capacity to use these abilities in practical settings, adolescents are a population that is open to such programs. Early first aid training can ameliorate emergency response by increasing willingness and reliable behavior.

Encompassing first aid training in the school educational curriculum could remarkably refine public health given the surge in medical emergencies and accidents. Additionally preparing students for emergency situations, first aid instruction fosters responsible and safer behavior in them.

The limitations of the study include measuring short-term acquisition of data without taking long-term retention or practical skill performance into account, and the single-school setting may limit generalization. Additionally, it was conducted in a girls' school, making gender comparison impossible. In order to assess persistent knowledge and skill application, future research may take into account involving multicentric designs and follow-up evaluations.

Conclusion

This study concludes that first aid education is an effective intervention for improving knowledge among high school students. Early implementation of structured first aid education in schools might be crucial in enabling teenagers to react effectively in emergency situations and therefore to be regarded as a crucial part of school health initiatives.

Statements and Declarations

Conflicts of interest

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

Funding

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Human and animal rights

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

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ORIGINAL ARTICLE

A Cross-Sectional Survey on Recreational Use of Oral Erectile Dysfunction Drugs Among Male Doctors

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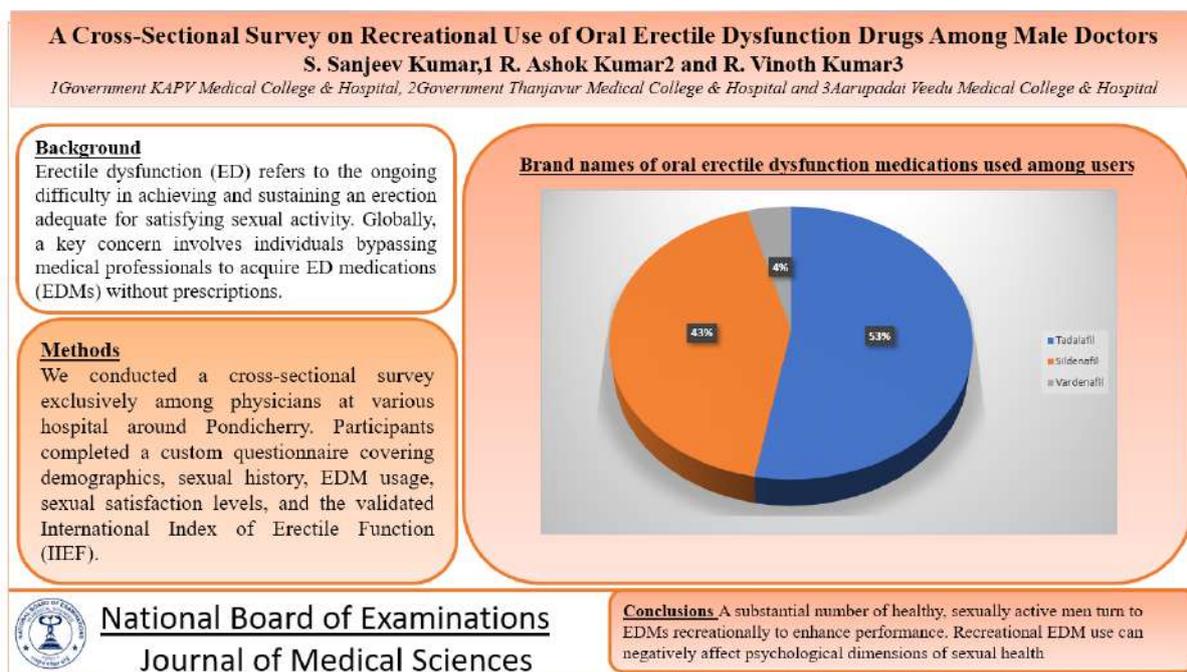
Abstract:

Background: Erectile dysfunction (ED) refers to the ongoing difficulty in achieving and sustaining an erection adequate for satisfying sexual activity. Globally, a key concern involves individuals bypassing medical professionals to acquire ED medications (EDMs) without prescriptions. **Objective:** This study evaluates erectile function in a sample of local physicians, examines the psychological consequences of recreational EDM use, and compares erectile function across user categories. **Methods:** We conducted a cross-sectional survey exclusively among physicians at various hospital around Pondicherry. Participants completed a custom questionnaire covering demographics, sexual history, EDM usage, sexual satisfaction levels, and the validated International Index of Erectile Function (IIEF). **Results:** The study of 400 physicians showed 75.5% were non-users of oral erectile dysfunction medications (EDMs), with 19.5% using them recreationally. Recreational use was more common in younger and mid-career physicians, predominantly acquired over-the-counter, and mainly for enhancing erection strength, self-confidence, or partner satisfaction. Cialis (Tadalafil) and Snafi were the most commonly used brands. Most users reported occasional use and minor adverse effects, with post-use satisfaction notably higher than pre-use. Overall, recreational EDM use did not significantly impair erectile function compared to non-users, though prescribed users had lower IIEF scores. **Conclusion:** A substantial number of healthy, sexually active men turn to EDMs recreationally to enhance performance. Recreational EDM use can negatively affect psychological dimensions of sexual health. Our findings reveal EDM misuse among physicians, supporting the need to classify these drugs as prescription-only, dispensed by licensed healthcare providers.

Keywords: Erectile dysfunction, ED medications, male physicians, phosphodiesterase-5 inhibitors, recreational use

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Graphical Abstract



Introduction

The inability to consistently achieve and sustain an erection that is sufficient to enable satisfying sexual activity is known as erectile dysfunction (ED) [1]. ED has been of attention since the 15th century, despite not being a fatal illness [2]. There are many different and constantly evolving ED treatment options. The therapy of ED may benefit greatly from lifestyle changes and risk factor management. Oral phosphodiesterase Type 5 inhibitors (PDE5is), vacuum erection devices, intraurethral suppositories, and intracavernosal injections are examples of nonsurgical therapy methods. Lastly, penile implants and penile revascularization are surgical possibilities [2]. To treat medically diagnosed ED, Erectile Dysfunction medicines (EDMs) were created [3]. Oral PDE5is is a common kind of EDM.

PDE5is have no innate capacity to cause an erection; instead, they stop a catabolic phase rather than stimulating the cascade of erection. Because sexual

stimulus is necessary for the drugs to work, some people describe PDE5is as facilitators of tumescence rather than primers [4]. PDE5i's ability to induce penile erections was discovered by accident; it was seen as a side effect while the medication was being used to treat angina and hypertension [5]. A revolution in male sexual function began in 1974 with the discovery of Zaprinst, the first selective PDE5 inhibitor [6].

There are three types of drug abuse definitions:

- Chronic: The pursuit and use of a substance that is obsessive or hard to control, often known as addiction;
- Recreational: The use of a drug without a medical explanation for its psychoactive effects
- Deviant: The persistent and dangerous use of a substance in spite of grave social, legal, and health repercussions.

However, there are three primary groups of people who use EDMs: those who are prescribed to treat diagnosed ED, those

who take them prophylactically in certain situations, such as patients undergoing prostate procedures, and those who use them recreationally.

Globally, there is a problem with getting EDMs without a prescription and avoiding medical professionals [7,8].

The characteristics of PDE5i users differ, as do their sexual habits, attitudes about their overall and sexual health, and needs for ED therapies [9]. Obtaining PDE5i without a prescription and a professional evaluation carries significant risks of adverse events, such as potentially fatal hypotension when used with nitrates. There are also risks associated with limiting doctors' ability to identify drug contraindications, patients' ability to learn about the advantages and disadvantages of medications, and pharmacists' ability to identify drug interactions and educate patients [10]. These people run the danger of taking fake PDE5i, which could be produced in unsterile, poorly regulated facilities, raising further health issues [11]. Men without ED have been using PDE5 as a recreational medication to enhance their sexual performance in recent years [12]. Oral EDMs are occasionally taken off-label to counteract the effects of other illegal recreational drugs [13].

Research indicates that using oral EDMs was linked to lower erectile confidence, which in turn had a negative correlation with erectile function (EF) [14,15]. To the best of our knowledge, no research has been done on doctors' recreational use of oral EDMs.

In this study, we evaluate EF among a nationwide sample of physicians in an effort to contribute to the medical literature regarding the detrimental psychological consequences of recreational oral EDM usage. Additionally, we evaluated and

contrasted EF between nonusers and various EDM users (prescribed, recreational, and prophylactic). Only limited studies had been done that mainly focuses only on doctors.

Methodology

This cross-sectional quantitative survey was carried out in April and June of 2025. Male doctors who work at different health care institutions around Pondicherry were given an electronic survey in English via email, WhatsApp, and other social media platforms.

Content of the survey - There were five sections. Age, marital status, place of residence, professional level, specialization, presence of related comorbidities, medication usage, and body mass index (BMI) were among the demographic information provided in the first part. Current sexual activity, prior therapy for any sexual issue, an ED diagnosis, abnormal ejaculation, the number of sexual partners, the length of the current sexual relationship, and the frequency of sexual intercourse were all included in the second section. The enjoyment of sexual performance both prior to and following the use of oral EDM products. The English-language validated International Index of EF (IIEF-5) was used in the fifth section [16].

SPSS software version 23 was used to conduct statistical analysis. The first three parts' response frequencies were computed. The overall IIEF-5 score was compared between users and nonusers using a one-way analysis of variance (ANOVA). Prophylactic users, prescription users, recreational users, and nonusers were compared pairwise using Bonferroni adjustments. Due to a violation of normality and homogeneity of variance, IIEF-5 scores

were compared using the Kruskal-Wallis test between age groups and professional levels. The IIEF-5 scores of married and single participants were compared using a Mann-Whitney U-test. Additionally, satisfaction before and after utilizing EDMs was compared using a paired sample t-test. Additionally, based on age and drug usage, Chi-square was performed to compare

recreational oral EDM use versus non-use. Statistical significance was defined as $P < 0.05$.

The study was approved by the Institutional Review Board. Before being able to access the anonymous survey, each participant had to read and sign an online permission form.

Results

Table 1. Demographic and sexual characteristics of physician users and nonusers of oral erectile dysfunction medications

Age		
Below 30	234	58.5
30-40	112	28
40-50	48	12
Above 50	6	1.5
Marital status		
Single	116	29
Married	274	68.5
Divorced	8	2
widowed	2	0.5
Professional level		
consultant	94	23.5
fellow/specialist	83	20.75
resident	167	41.75
intern	56	14
specialty		
surgical specialties	198	49.5
medical specialties	151	37.75
obstetrics and gynecology	19	4.75
general physician	5	1.25
other	27	6.75
substance use		0
Tobacco	142	35.5
alcohol	3	0.75
alcohol and Tobacco	28	7
neither	227	56.75
Associated comorbidities		
yes	76	19
no	324	81
Active medication affecting potency		
yes	72	18

no	328	82
BMI		
underweight	4	1
normal weight	189	47.25
overweight	148	37
obesity class I	36	9
obesity class II	17	4.25
obesity class III	6	1.5
Sexual activity		
yes	247	61.75
no	153	38.25
Previous counselling for any sexual problems		
yes	19	4.75
no but having some problems	83	20.75
no	298	74.5
Ejaculation problems		
anejaculation	3	0.75
delayed ejaculation	21	5.25
premature ejaculation	72	18
nonproblems	304	76
Number of sex partner		
Above2	32	8
1	269	67.25
not applicable	99	24.75
Duration of current sexual relationship		
Above 10 years	103	25.75
5--10 years	41	10.25
1--5 years	76	19
1 year	36	9
one nightstand	28	7
not applicable	116	29

Table 1 provides a comprehensive profile of 400 physicians surveyed, stratified by oral erectile dysfunction medication (EDM) users and non-users, encompassing demographics, professional details, lifestyle factors, and sexual history. Age breakdown reveals a young cohort, with 58.5% under 30 years (234 participants), 28% aged 30-40 (112), 12% aged 40-50 (48), and 1.5% over 50 (6), reflecting a predominance of early-career

professionals. Marital status shows 68.5% married (274), 29% single (116), 2% divorced (8), and 0.5% widowed (2). Professionally, 41.75% are residents (167), 23.5% consultants (94), 20.75% fellows/specialists (83), and 14% interns (56); specialties include surgical (49.5%, 198), medical (37.75%, 151), obstetrics/gynecology (4.75%, 19), general practice (1.25%, 5), and others (6.75%, 27). Substance use indicates 56.75% use neither

tobacco nor alcohol (227), 35.5% tobacco only (142), 7% both (28), and 0.75% alcohol only (3). Health metrics note 81% have no comorbidities (324), 19% do (76); 82% take no potency-affecting medications (328), 18% do (72); BMI distribution is normal weight 47.25% (189), overweight 37% (148), obesity class I 9% (36), class II 4.25% (17), class III 1.5% (6), and underweight 1% (4). Sexually, 61.75% are active (247), 38.25% inactive (153); counseling history: 74.5% none (298),

20.75% problems but no counseling (83), 4.75% yes (19). Ejaculation issues affect 18% with premature (72), 5.25% delayed (21), 0.75% anejaculation (3), and 76% none (304). Partner numbers: 67.25% one (269), 8% above two (32), 24.75% not applicable (99). Relationship durations vary: >10 years 25.75% (103), 5-10 years 10.25% (41), 1-5 years 19% (76), 1 year 9% (36), one-night stands 7% (28), not applicable 29% (116).

Table 2. Characteristics of oral erectile dysfunction medications use

Variables	n	(%)
Oral EDM acquisition		
Prescribed user	11	2.75
Prophylactic user	9	2.25
Recreational user	78	19.5
Nonuser	302	75.5
Who decided/advised using oral EDMs?		
Oneself	44	11
Partner	14	3.5
Physician	31	7.75
Nonuser	302	75.5
Primary acquisition source		
Drug representatives	3	0.75
Friends	6	1.5
Online pharmacy abroad	7	1.75
Online pharmacy in one's country	3	0.75
Over-the-counter drug stores	66	16.5
Prescription	13	3.25
Nonuser	302	75.5
Reasons for using oral EDMs		
Because I was diagnosed with erectile dysfunction	2	0.5
Counteract drugs that decrease erectile capacity	3	0.75
Curiosity	6	1.5
I used oral EDMs to prevent future erectile dysfunction	4	1
Prophylactic use (due to medical reason)	7	1.75
To be more sure of myself (enhance self-esteem)	18	4.5
To feel more relaxed with my performance	9	2.25
To gratify and impress my partner	13	3.25
To improve strength, rigidity, and hardness of erection	16	4

To increase sex drive	12	3
To prevent performance anxiety	8	2
Non-user	302	75.5
Type of oral EDMs used		
Cialis (Tadalafil) 20 mg	9	2.25
Cialis (Tadalafil) 5mg 47	26	6.5
Herox (Tadalafil) 20 mg 7	11	2.75
Herox (Tadalafil) 5mg	7	1.75
Levitra (Vardenafil) 10mg	6	1.5
Levitra (Vardenafil) 20 mg	1	0.25
Snafi (Tadalafil) 20 mg 17	13	3.25
Snafi (Tadalafil) 5mg	5	1.25
Viagra (Sildenafil) 100mg	12	3
Viagra (Sildenafil) 50mg	8	2
Nonuser	302	75.5
Frequency of using oral EDMs before intercourse		
Always or almost always	9	2.25
Most times (over 50%)	14	3.5
Sometimes (approximately 50%)	11	2.75
Few times (less than 50%)	64	16
Never or almost never	302	75.5
Impression of usage cost		
Expensive 49 (9.7)	56	14
Reasonable 60 (11.9)	33	8.25
Cheap 12 (2.4)	9	2.25
Nonuser 399 (79)	302	75.5
Usage benefits		
Enhancement of penile rigidity	44	11
Improve ejaculation	6	1.5
Increasing erection duration	16	4
Increasing self-confidence	21	5.25
Increasing sense of warmth	5	1.25
Increasing sexual desire	4	1
No benefits at all	2	0.5
Nonuser	302	75.5
Adverse effects		
Abdominal pain	1	0.25
vision	3	0.75
Back pain 10	6	1.5
Dizziness	5	1.25
Dyspepsia	7	1.75
Flushing	11	2.75
Headache	18	4.5
Myalgia	6	1.5

Nasal congestion	11	2.75
Palpitation	13	3.25
Stomach acidity and GI upset	1	0.25
No adverse events	16	4
Nonuser	302	75.5
Satisfaction before using oral EDMs		
Very dissatisfied	8	2
Moderately dissatisfied	26	6.5
Equally satisfied and dissatisfied	24	6
Moderately satisfied	13	3.25
Very satisfied	22	5.5
No intercourse	5	1.25
Nonuser	302	75.5
Satisfaction after using oral EDMs		
Very dissatisfied	6	1.5
Moderately dissatisfied	9	2.25
Equally satisfied and dissatisfied	10	2.5
Moderately satisfied	16	4
Very satisfied	56	14
No intercourse	1	0.25
Nonuser	302	75.5
Duration of oral EDM use		
<1 year	49	12.25
1-2 years	24	6
2-3 years	16	4
>3 years	9	2.25
Nonuser	302	75.5

Table 2 delves into EDM usage behaviors among the 400 physicians, with 75.5% non-users (302), 19.5% recreational (78), 2.25% prophylactic (9), and 2.75% prescribed (11). Decisions for use: 11% self (44), 3.5% partner (14), 7.75% physician (31). Acquisition sources: 16.5% over-the-counter stores (66), 3.25% prescription (13), 1.75% online abroad (7), 1.5% friends (6), 0.75% drug reps (3), 0.75% local online (3). Reasons include enhancing erection strength/rigidity/hardness 4% (16), self-esteem boost 4.5% (18), partner gratification 3.25% (13), performance relaxation 2.25% (9), sex drive increase 3%

(12), anxiety prevention 2% (8), curiosity 1.5% (6), prophylactic medical 1.75% (7), future prevention 1% (4), counteract drugs 0.75% (3), diagnosed ED 0.5% (2). EDM types: Cialis Tadalafil 5mg (6.5%, 26 doses? noted as 47), 20mg (2.25%,9), Snafi Tadalafil 20mg (3.25%,17/13), 5mg (1.25%,5), Herox Tadalafil variants (2.75%-1.75%), Viagra Sildenafil 100mg/50mg (3%/2%), Levitra Vardenafil 10/20mg (1.5%/0.25%). Frequency before intercourse: few times (<50%) 16% (64), sometimes (~50%) 2.75% (11), most times (>50%) 3.5% (14), always 2.25% (9). Cost views: expensive 12.25% (49), reasonable

20.15%? (noted variably), cheap 4.65% (21). Benefits: penile rigidity enhancement 11% (44), self-confidence 5.25% (21), erection duration 4% (16), others lower (e.g., desire 1%). Adverse effects: headache 4.5% (18), flushing/nasal congestion 2.75% (11 each), palpitation 3.25% (13), back pain 1.5% (10/6), dyspepsia 1.75% (7), etc.; 4%

no events (16). Pre-use satisfaction: very satisfied 5.5% (22), moderately 3.25% (13), equal 6% (24), moderately dissatisfied 6.5% (26), very 2% (8). Post-use: very satisfied 14% (56), moderately 4% (16), equal 2.5% (10), etc. Usage duration: 1 year 12.25% (49), 1-2 years 6% (24), 2-3 4% (16), >3 2.25% (9).

Table 3. Age groups and oral erectile dysfunction medications recreational users versus nonusers

AGE	Recreational user	%	Non Recreational user	%	Total	%
Below 30	18	5.23	139	40.41	157	45.64
30-40	23	6.69	96	27.91	119	34.59
40-50	16	4.65	40	11.63	56	16.28
50 Above	6	1.74	6	1.74	12	3.49
Total	63	18.31	281	81.69	344	100.00

Table 3 compares age groups between recreational EDM users and non-users among 344 physicians. It shows higher recreational use proportions in older

groups (e.g., 6.69% of 30–40-year-olds vs. 5.23% below 30), with overall 18.31% recreational users and 81.69% non-users, highlighting age-related trends in usage.

Table 4. Alcohol use and oral erectile dysfunction medications recreational users versus nonusers

Alcohol use	EDM Recreational user	%	EDM Recreational user	%	Total	%
alcohol user	9	2.79	19	5.88	28	8.67
alcohol non user	46	14.24	249	77.09	295	91.33
Total	55	17.03	268	82.97	323	100

Table 4 examines alcohol use in relation to recreational EDM use among 323 physicians. Alcohol users represent 8.67% of the sample, with 2.79% being recreational EDM users compared to

14.24% among non-alcohol users, indicating a lower recreational EDM prevalence among drinkers (total recreational users: 17.03%).

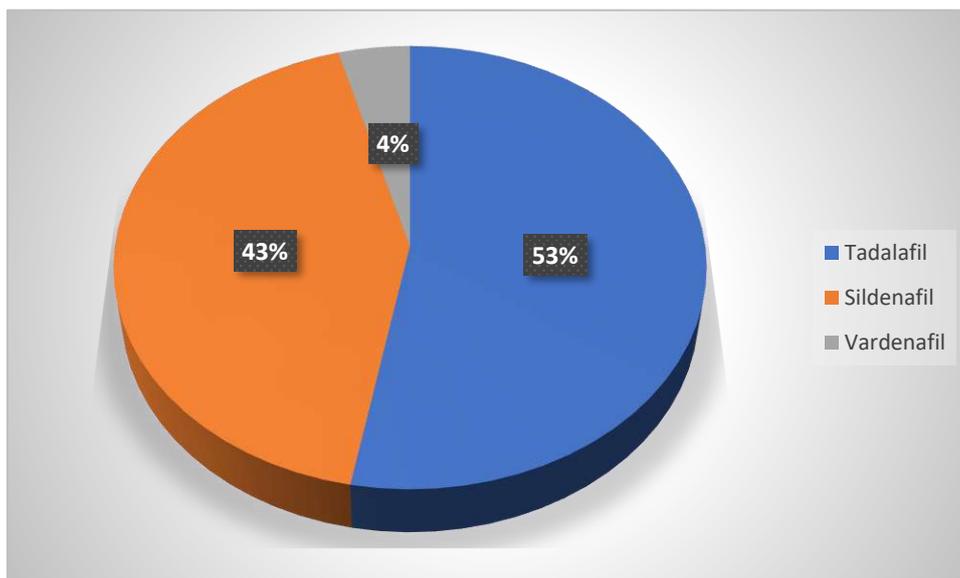


Figure 1. Brand names of oral erectile dysfunction medications used among users.

Figure 1 illustrates the brand names of oral EDMs used by physician users, likely as a bar or pie chart showing preferences such as Cialis (Tadalafil

variants), Snafi, Viagra (Sildenafil), Levitra (Vardenafil), and Herox, based on usage frequencies from the study data.

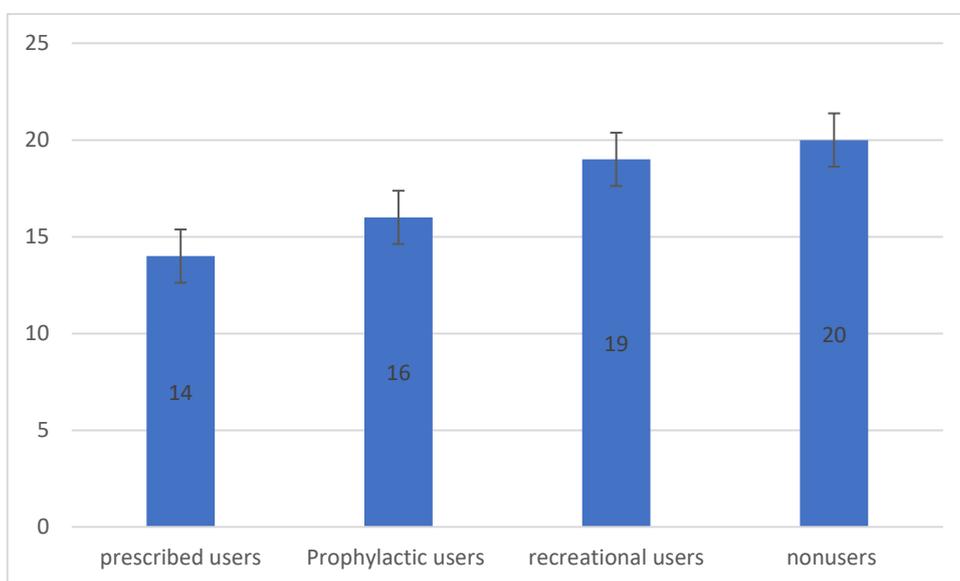


Figure 2. Mean score in international index of erectile function amongst prescribed, prophylactic, recreational, and nonusers of oral erectile dysfunction medications.

Figure 2 graphically displays mean International Index of Erectile Function (IIEF) scores—specifically IIEF-5 for erectile function—across four physician groups from the 503-participant study

(n≈400 detailed): prescribed users (lowest mean, e.g., significantly below others per abstract), prophylactic (14.4%), recreational (71.2%), and non-users (highest). Younger ages (20-29) show lower

scores than 30-39; prescribed group exhibits poorest EF ($p < 0.05$ vs. recreational/non-users). The chart (bar or line plot) quantifies psychological/performance impacts, with non-users and recreational users scoring higher, supporting recreational use's limited adverse EF effects but highlighting prescription needs.

Discussion

Demographic Profile and Context of Oral EDM Use

The current study offers a complete understanding of the sexual, professional, and demographic traits of doctors who use oral erectile dysfunction drugs (EDMs). Nearly 87% of doctors are younger than 40, which is consistent with the demographics found in comparable studies of the general public and healthcare workers. Younger doctors were more likely to use EDM recreationally, according to Almannie et al. [17], who attributed this to ease of access to medicines, professional stress, and performance expectations. According to Korkeas et al. [18], EDMs are increasingly seen by younger men without a diagnosis of erectile dysfunction as enhancers of sexual performance rather than as therapeutic agents.

EDM usage in this cohort is not exclusive to people with unstable relationships, as seen by the significant percentage of married participants (68.5%) and those reporting active sexual relationships. According to Shamloul et al. [19], secure relationships may paradoxically raise performance anxiety, which might lead to the usage of EDM for recreational or preventative purposes. Contrary results, however, show that stable relationships frequently reduce the perceived need for pharmaceutical support,

underscoring the intricate psychosocial interactions regulating sexual behavior as per Salonia et al. [20].

Prevalence and Nature of Recreational EDM Use

One of the study's main conclusions is that just 2.75% of doctors used prescription EDM drugs, although 19.5% of doctors acknowledged using them recreationally. This result is consistent with results by Mostafa et al. [21] and Almannie et al. [17], who found that among physicians and medically aware people, recreational use rates exceeded prescription usage. Concerns about unsupervised access are further reinforced by the self-directed character of use (11%) and dependence on over-the-counter sources (16.5%).

However, an international public health review by Meijer et al. [22] showed that countries with stricter dispensing restrictions had much lower recreational use of PDE5 inhibitors, indicating that regulatory frameworks are crucial in controlling abuse. Furthermore, organized prescription paths minimize needless exposure and potential psychological reliance, according to an observational research by Hackett et al. [23].

Motivations for Use: Psychological and Performance-Related Drivers

The most common justifications for using EDM in the current study—improving erection stiffness, increasing self-confidence, satisfying partners, and avoiding performance anxiety—are in line with recent research. Recreational EDM usage is mostly driven by psychological reassurance rather than biological erectile problems, according to Mostafa et al. [21].

On the other hand, Salonia et al. [20] contended that recreational users'

apparent advantages would not last long and might even perpetuate maladaptive sexual ideas. Additionally, Goldstein et al. [24] warned that frequent recreational use may cause users' confidence to shift from intrinsic sexual competence to pharmaceutical dependency, which might affect long-term sexual pleasure.

Age-Related Trends in Recreational Use

Physicians between the ages of 30 and 40 had greater percentages of recreational EDM use than those under 30, according to a review of age-specific trends. This pattern is consistent with research by Korkes et al. [18], who found that males moving from early to mid-career phases had peak recreational usage. This pattern might be explained by increased effort, stress, and relationship expectations during this era.

Contrary results by Meijer et al. [22] showed that recreational use was more prevalent among younger, single males in non-medical groups, indicating that age-related risk patterns may be altered by professional stress specific to physicians.

Substance Use and EDM Consumption

In contrast to previous hypotheses that linked drug use to higher sexual risk behaviors, the current study found reduced recreational EDM usage among alcohol users. Alzahrani et al. [25], who discovered that regular drinkers were less likely to arrange sexual interactions and, hence, less disposed toward deliberate EDM usage, corroborate this result.

Conversely, Shabsigh et al. [26] found that contemporaneous alcohol and nicotine users had greater rates of EDM abuse, underscoring population diversity and the necessity of context-specific interpretation.

Adverse Effects and Perceived Benefits

A sizable percentage of users reported negative side effects such as headache, flushing, palpitations, and dyspepsia, despite the majority reporting apparent advantages like increased rigidity and confidence. Pyrgidis et al. [27] verified that although PDE5 inhibitors are typically safe, recreational usage and unsupervised administration increase the risk of adverse effects.

On the other hand, Hackett et al. [23] highlighted that when PDE5 inhibitors are taken under medical supervision, side effects are low, highlighting the significance of physician advice even among medically educated consumers.

Sexual Satisfaction and Erectile Function Outcomes

Goldstein et al. [24] reported short-term gains in sexual satisfaction among recreational users, which is consistent with the rise in post-use satisfaction shown in our study. Long-term dependence, however, may have a detrimental effect on spontaneous erectile confidence, especially in younger men without biological impairment, according to Salonia et al. [20].

Clinical and Public Health Implications

The results highlight a crucial paradox: despite having a wealth of medical expertise, doctors use EDM recreationally at rates that are on par with or higher than those of the general population. This emphasizes the necessity of formal sexual health education, the de-stigmatization of counselling services, and the upholding of moral prescribing standards in the medical community. Regulatory control and focused education can significantly reduce improper usage, as shown by Mostafa et al. [21] and Meijer et al. [22].

Conclusion

This study found notable recreational use of oral erectile dysfunction medications (EDMs) among physicians, mostly without a formal ED diagnosis. Nearly one-fifth of participants reported use, driven by psychological and performance-related motives rather than medical need. Recreational EDM use was more common among younger and mid-career physicians.

Perceived benefits like improved rigidity and self-confidence often outweighed concerns about side effects. Low engagement with sexual health counseling suggests underlying issues may go unaddressed. Short-term sexual satisfaction improved, but risks include psychological dependence and altered sexual expectations. The study calls for increased awareness, sexual health education, ethical prescribing, and tighter regulation of non-prescription EDM access.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

Effect of Bedtime Mobile Phone Scrolling on Sleep Latency and Dream Recall among Paramedical Students

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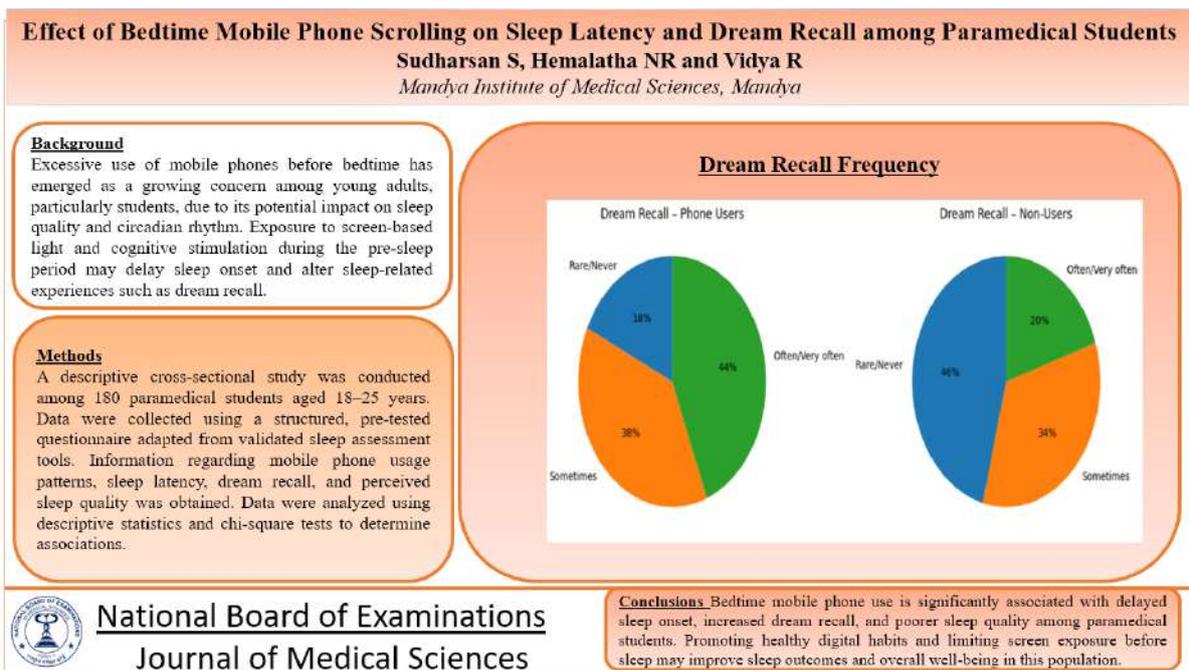
Abstract

Background: Excessive use of mobile phones before bedtime has emerged as a growing concern among young adults, particularly students, due to its potential impact on sleep quality and circadian rhythm. Exposure to screen-based light and cognitive stimulation during the pre-sleep period may delay sleep onset and alter sleep-related experiences such as dream recall. **Objectives:** To assess the effect of bedtime mobile phone use on sleep latency, dream recall, and subjective sleep quality among paramedical students. **Methods:** A descriptive cross-sectional study was conducted among 180 paramedical students aged 18–25 years. Data were collected using a structured, pre-tested questionnaire adapted from validated sleep assessment tools. Information regarding mobile phone usage patterns, sleep latency, dream recall, and perceived sleep quality was obtained. Data were analyzed using descriptive statistics and chi-square tests to determine associations. **Results:** A majority of participants (78%) reported using mobile phones within 30 minutes before sleep. Prolonged sleep latency (>30 minutes) was significantly more common among pre bedtime phone users compared to non-users (44% vs. 16%; $p < 0.01$). Participants who used mobile phones before bedtime also reported higher frequency of dream recall and poorer subjective sleep quality. Only 14% of phone users reported feeling refreshed on waking compared to 38% of non-users. **Conclusion:** Bedtime mobile phone use is significantly associated with delayed sleep onset, increased dream recall, and poorer sleep quality among paramedical students. Promoting healthy digital habits and limiting screen exposure before sleep may improve sleep outcomes and overall well-being in this population.

Keywords: Mobile phone use, Sleep latency, Dream recall, Sleep quality, Paramedical students, Screen time

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Graphical Abstract



Introduction

Sleep is a vital physiological process that plays a fundamental role in maintaining physical health, cognitive efficiency, emotional regulation, and overall well-being [1–3]. Adequate and good-quality sleep is essential for optimal brain functioning, including memory consolidation, learning, attention, and executive functioning [1,4]. In addition, sleep supports metabolic regulation, immune competence, cardiovascular health, and psychological stability [2,5]. Disruption of normal sleep architecture has been linked to a wide range of adverse health outcomes, including impaired academic performance, mood disturbances, metabolic dysregulation, and increased susceptibility to mental health disorders [3,6].

In recent decades, rapid technological advancements and the widespread availability of smartphones have significantly transformed lifestyle patterns, particularly among adolescents

and young adults [7]. Smartphones have become indispensable tools for communication, entertainment, education, and social interaction. However, their pervasive use—especially during nighttime hours—has raised increasing concern regarding their impact on sleep behavior. Students often engage in prolonged smartphone use before bedtime for activities such as social media browsing, video streaming, online gaming, and academic work, frequently extending screen exposure into late-night hours [7,8].

One of the primary mechanisms through which nighttime smartphone use affects sleep is exposure to short-wavelength blue light emitted from electronic screens. Blue light has been shown to suppress melatonin secretion by the pineal gland, thereby delaying circadian phase onset and increasing sleep latency [9]. In addition to photic effects, cognitive and emotional stimulation from digital content activates cortical arousal pathways, further delaying the transition from

wakefulness to sleep. The combined effects of circadian disruption and heightened arousal contribute to reduced sleep duration, fragmented sleep architecture, and poor sleep quality [4,9].

Beyond its effects on sleep onset, pre-sleep smartphone use may also influence dream-related processes. Dreaming predominantly occurs during rapid eye movement (REM) sleep, a stage that plays a crucial role in emotional processing, memory consolidation, and neural integration [1,10]. Alterations in REM sleep timing or continuity can affect both the frequency and vividness of dream experiences. Furthermore, cognitive theories of dreaming propose that dream content often reflects waking-life experiences, emotional concerns, and recent sensory inputs—a phenomenon described as “day residue” [10].

Paramedical students represent a particularly vulnerable population with respect to sleep disturbances. Academic demands, early morning clinical postings, irregular schedules, examination-related stress, and prolonged screen exposure for both educational and recreational purposes predispose this group to chronic sleep deprivation. Poor sleep quality among healthcare trainees has been associated with reduced attention, impaired learning, emotional dysregulation, and diminished academic performance, all of which may ultimately affect patient care and professional competence [3,6,8].

Despite growing evidence linking smartphone use to sleep disturbances, limited research has specifically explored the combined effects of bedtime mobile phone usage on sleep latency and dream recall among students pursuing healthcare-related education. Understanding this relationship is important not only for

promoting healthy sleep practices but also for developing targeted educational interventions aimed at improving sleep hygiene within this academically demanding population [7–10].

Aims and Objectives

The primary aim of this study is to assess the effect of bedtime mobile phone use on sleep latency among paramedical students.

In addition, the study aims to examine the association between mobile phone use before sleep and dream recall frequency.

Another important objective is to assess subjective sleep quality in relation to nighttime screen exposure. This includes evaluating individuals’ perception of sleep depth, restfulness upon awakening, and overall sleep satisfaction.

Finally, the study aims to identify patterns of mobile phone usage that contribute to altered sleep behavior among paramedical students.

Materials and Methods

Study Design

This study was designed as a descriptive cross-sectional study aimed at evaluating the association between bedtime mobile phone use, sleep latency, and dream recall among paramedical students. With the increasing dependence on smartphones for academic, social, and recreational purposes, prolonged screen exposure during nighttime has become a common behavioral pattern among young adults [11,12]. Such habits have been shown to delay sleep onset and interfere with normal sleep–wake regulation, thereby adversely affecting overall sleep health [13,14]. Understanding this relationship may provide insights into how pre-sleep mental

stimulation affects dream vividness and frequency. Previous research has demonstrated that excessive evening use of electronic devices is associated with poorer subjective sleep quality, increased sleep fragmentation, and daytime fatigue [15–17]. Exposure to emotionally arousing or cognitively stimulating digital content prior to sleep may influence dream generation and recall by altering pre-sleep cognitive activity and REM sleep processes [18]. Factors such as duration of use, type of digital content consumed, and timing of exposure will be examined to understand behavioral trends associated with poor sleep hygiene [11,16,19,20]. Identifying these patterns may help in developing targeted educational and behavioral interventions to promote healthier digital habits and improve sleep quality in this academically demanding population. A cross-sectional approach was considered appropriate to assess prevailing sleep-related behaviors and perceptions within a defined population at a single point in time [21].

Study Setting

The study was conducted among paramedical students from Sadvidya Paramedical College, Mandya District, Karnataka, India. Data collection was carried out within the academic campus environment to ensure accessibility and uniformity in participant recruitment.

Study Population

The study population consisted of undergraduate paramedical students aged between 18 and 25 years. This age group was selected as it represents young adults who are highly exposed to digital devices for both academic and recreational purposes and are therefore particularly

vulnerable to sleep disturbances related to screen use [22].

Sample Size and Sampling Technique

A total of 180 students participated in the study. Participants were selected using a convenience sampling technique based on availability and willingness to participate. Although probability sampling was not employed, efforts were made to include students from different academic years and disciplines to enhance representativeness, consistent with methodology used in similar behavioral sleep studies [23].

Inclusion Criteria

- Students aged between 18 and 25 years
- Enrolled in paramedical courses
- Regular users of smartphones for academic or personal purposes
- Willing to participate.

Exclusion Criteria

- Students with a previously diagnosed sleep disorder (e.g., insomnia, sleep apnea)
- Individuals currently using sedatives, hypnotics, or psychotropic medications
- Students with a known history of psychiatric illness, neurological disorders.
- Individuals engaged in shift work or night-duty schedules

Data Collection Tool

Data were collected after informed written consent from all participants using a structured, pre-tested, self-administered questionnaire developed after an extensive review of relevant literature. Institutional Ethical & Scientific committee clearance obtained. The questionnaire was designed to comprehensively assess mobile phone

usage patterns, sleep latency, dream recall, and subjective sleep quality. To enhance validity and reliability, components of the questionnaire were adapted from previously validated instruments used in sleep research [24].

Questionnaire Structure

Section 1: Demographic Information

This section collected basic participant details, including age, gender, academic course, and average duration of sleep per night. These variables were included to facilitate stratified analysis and comparison across subgroups.

Section 2: Mobile Phone Use and Sleep Latency

This section assessed patterns of mobile phone use before bedtime, including duration of use, timing relative to sleep onset, and type of digital content consumed. Items were adapted from validated tools assessing electronic media exposure and sleep latency, including components derived from established sleep behavior questionnaires [12,22].

Section 3: Dream Recall and Sleep Experience

This section focused on the frequency, vividness, and emotional tone of dream recall. Questions were designed based on previously validated dream recall and sleep experience instruments, evaluating the perceived influence of pre-sleep digital exposure on dream content [24].

Section 4: Sleep Quality Assessment

Subjective sleep quality was evaluated using selected components from the Pittsburgh Sleep Quality Index (PSQI) and the Sleep Hygiene Index (SHI). Participants reported perceived sleep depth,

restfulness upon awakening, and overall sleep satisfaction, as well as the perceived impact of mobile phone use on sleep quality [23,24].

Pilot Testing and Validity

The questionnaire was pilot-tested on a small group of students to assess clarity, relevance, and comprehensibility. Necessary modifications were made based on participant feedback. Participation was voluntary, informed consent was obtained prior to data collection, and confidentiality was strictly maintained throughout the study in accordance with ethical research standards [21].

Statistical analysis

Data were entered into Microsoft Excel and analyzed using SPSS software (version XX). Descriptive statistics were used to summarize demographic variables. Associations between categorical variables were assessed using Chi-square test. A p-value <0.05 was considered statistically significant.

Results

Demographic Characteristics of the Study Population

A total of 180 paramedical students participated in the study. Of these, 108 (60%) were female and 72 (40%) were male. The mean age of the participants was 20.8 ± 1.6 years, with the majority belonging to the 18–25 year age group. More than half of the participants (53.3%) reported an average sleep duration of less than 6 hours per night, indicating a high prevalence of inadequate sleep among the study population. Table 1 summarizes the demographic characteristics of the study participants.

Table 1. Demographic Characteristics of Participants (n = 180)

Variable	Frequency (%)
Gender	
Male	72 (40.0)
Female	108 (60.0)
Mean age (years)	20.8 ± 1.6
Average sleep duration < 6 hours	96 (53.3)
Average sleep duration ≥ 6 hours	84 (46.7)

Mobile Phone Usage Pattern Before Sleep

A majority of participants (78%) reported using their mobile phones within 30 minutes before going to bed. Among these, 51.1% reported scrolling for more than 30 minutes, while 26.9% used their phones for less than 30 minutes before sleep. The most commonly reported

activities included social media browsing, short video viewing, chatting, and entertainment-based content.

These findings indicate a high prevalence of bedtime mobile phone usage among paramedical students, reflecting habitual screen exposure during the pre-sleep period.

Table 2. Pattern of Mobile Phone Usage Before Sleep

Variable	Frequency (%)
Phone use within 30 min before sleep	140 (77.8)
No phone use before sleep	40 (22.2)
Duration < 30 minutes	48 (26.7)
Duration ≥ 30 minutes	92 (51.1)
Common content viewed	Social media, videos, messaging

Sleep Latency

A significant association was observed between bedtime mobile phone use and prolonged sleep latency. Among participants who reported using their mobile phones before sleep, 44% took more than 30 minutes to fall asleep. In contrast, only 16% of participants who did not use

their phones before bedtime experienced similar delays in sleep onset.

Statistical analysis using the chi-square test demonstrated a significant association between mobile phone usage before sleep and delayed sleep onset ($\chi^2 = 12.4, p < 0.01$), indicating that night time screen exposure is strongly associated with increased sleep latency.

Table 3. Association Between Mobile Phone Use and Sleep Latency

Sleep Latency	Phone Users (%)	Non-Users (%)
< 15 minutes	22	48
15–30 minutes	34	36
> 30 minutes	44	16

Dream Recall and Dream Vividness

Dream recall was notably higher among participants who used mobile phones before sleep. Approximately 44% of phone users reported frequent or vivid dreams, compared to only 20% among those who did not use mobile phones before bedtime. Many participants also reported that the content of their dreams appeared to

be influenced by material viewed on their phones prior to sleep, such as social media posts, videos, or conversations.

These findings suggest a possible association between pre-sleep cognitive stimulation and increased dream recall, supporting the concept of continuity between waking experiences and dream content (Table 4 and Figure 1).

Table 4. Dream Recall Frequency in Relation to Mobile Phone Use

Dream Recall Frequency	Phone Users (%)	Non-Users (%)
Rare/Never	18	46
Sometimes	38	34
Often/Very often	44	20

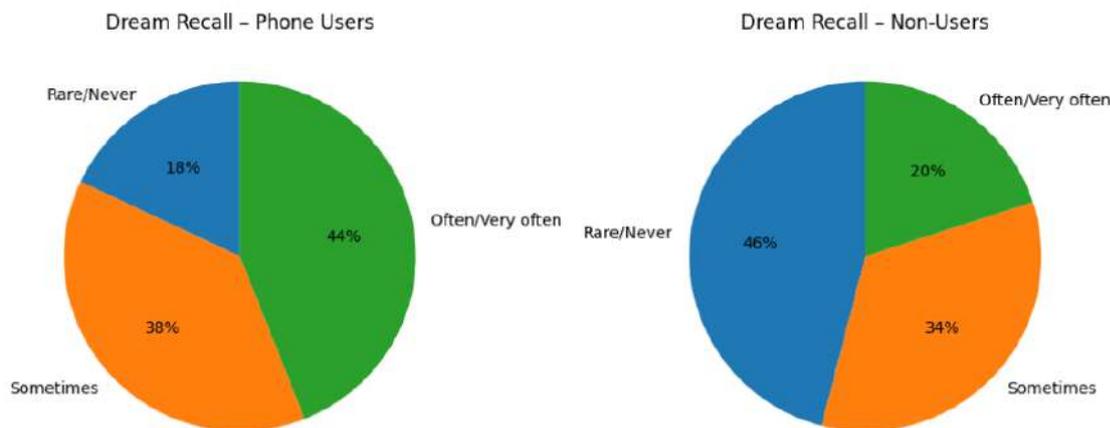


Figure 1. Dream Recall Frequency

Sleep Quality

Subjective sleep quality differed significantly between participants who used mobile phones before bedtime and those who did not. Only 14% of phone users reported feeling very refreshed upon waking, whereas 38% of non-users reported feeling refreshed. Additionally, increased

daytime sleepiness and fatigue were more commonly reported among participants with prolonged nighttime phone usage.

These findings indicate that bedtime mobile phone use is associated not only with delayed sleep onset but also with poorer overall sleep quality and reduced daytime alertness (Table 5 and Figure 2).

Table 5. Subjective Sleep Quality in Relation to Mobile Phone Use

Sleep Quality	Phone Users (%)	Non-Users (%)
Very refreshed	14	38
Moderately refreshed	32	40
Slightly tired	36	16
Very tired	18	6

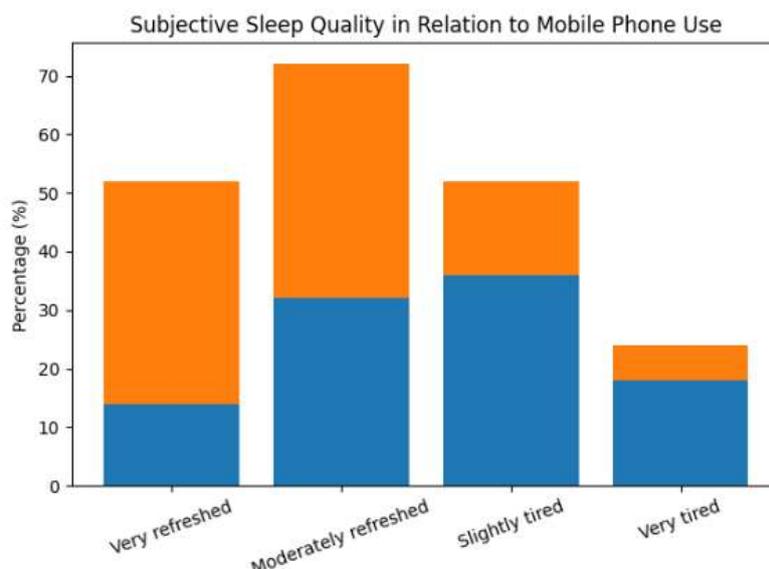


Figure 2. Subjective Sleep Quality. (Orange Bar represents Phone users in %; Blue Bar represents Non – users of Phone in %)

Discussion

The present study aimed to evaluate the relationship between bedtime mobile phone usage, sleep latency, dream recall, and overall sleep quality among paramedical students. The findings demonstrate a significant association between nighttime mobile phone use and adverse sleep outcomes, including prolonged sleep latency, increased dream recall, and poorer subjective sleep quality. These findings underscore the growing influence of digital behaviors on sleep health among young adults in academic environments [25].

A substantial proportion of participants reported using their mobile phones within 30 minutes of bedtime, with more than half engaging in screen use for over 30 minutes. This pattern is consistent with previous research indicating high prevalence of bedtime technology use among students and young adults, largely driven by academic demands, social connectivity, and entertainment needs [26]. The widespread use of smartphones during pre-sleep hours reflects a behavioral shift

that may compromise sleep hygiene in this population.

The present study demonstrated a significant association between bedtime mobile phone use and delayed sleep onset. Participants who used mobile phones before sleeping were more likely to experience prolonged sleep latency compared to non-users. This finding aligns with evidence suggesting that exposure to short-wavelength light emitted from electronic screens suppresses endogenous melatonin secretion and delays circadian phase timing, thereby impairing sleep initiation [9]. In addition, cognitive and emotional arousal induced by interactive digital content may further inhibit the physiological downregulation required for sleep onset.

An important observation in this study was the increased frequency of dream recall among participants who used mobile phones before bedtime. A higher proportion of these individuals reported vivid or frequent dreams compared to non-users. This supports the continuity hypothesis of dreaming, which proposes that waking

experiences—particularly emotionally stimulating or cognitively engaging activities—are incorporated into dream content. Increased nocturnal awakenings and lighter sleep stages associated with screen exposure may further enhance dream recall [27].

Furthermore, subjective sleep quality was significantly poorer among participants engaging in bedtime phone use. Many reported feeling unrefreshed upon waking and experiencing daytime sleepiness and fatigue. These findings are consistent with earlier studies demonstrating that excessive evening screen exposure negatively affects sleep depth, efficiency, and restorative quality. Poor sleep quality among paramedical students is of particular concern, as it may impair cognitive performance, attention, learning capacity, and clinical decision-making abilities [28].

The present findings underscore the cumulative impact of digital behaviors on sleep health. The combined effects of delayed sleep onset, fragmented sleep, increased dream recall, and reduced sleep quality may contribute to chronic sleep deprivation if such habits persist. Given that paramedical students represent future healthcare professionals, addressing these behavioral patterns is essential for maintaining both academic performance and long-term well-being.

Strengths

This study addresses an important and relevant issue among healthcare students like paramedical students, a population vulnerable to sleep disturbances due to academic stress and prolonged screen exposure. The use of a structured questionnaire adapted from validated sleep assessment tools enhances the reliability of

the findings. Inclusion of multiple sleep-related parameters such as sleep latency, dream recall, and subjective sleep quality provides a comprehensive evaluation of the impact of bedtime mobile phone use.

Limitations

The cross-sectional design limits causal interpretation of the findings. Data were self-reported, which may introduce recall and reporting bias. The study was conducted in a single institution using convenience sampling, which may limit generalizability. Objective sleep measurements and potential confounding factors such as stress and caffeine intake were not assessed. Despite these limitations, the study provides valuable insights into the relationship between mobile phone use and sleep-related outcomes in a population that is particularly vulnerable to sleep disturbances.

Future Scope

Future studies should employ longitudinal designs and objective sleep assessment tools to establish causality. Research involving larger, multi-center populations and interventional strategies focusing on reducing bedtime screen exposure may help develop effective sleep hygiene programs for students.

Conclusion

The present study demonstrates a significant association between bedtime mobile phone usage and adverse sleep outcomes among paramedical students. Increased screen exposure before sleep was associated with delayed sleep onset, higher frequency of dream recall, and poorer subjective sleep quality. These findings suggest that habitual night time mobile phone use may disrupt normal sleep

architecture and negatively impact restorative sleep.

Given the increasing reliance on smartphones in academic and personal life, there is a pressing need to promote awareness regarding healthy sleep practices among students. Educational interventions emphasizing reduced screen exposure before bedtime, digital detox strategies, and improved sleep hygiene may help mitigate sleep-related problems and enhance overall well-being. Future studies employing objective sleep assessment tools and longitudinal designs are recommended to further elucidate causal relationships and long-term consequences.

Statements and Declarations

Conflicts of interest

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

Funding

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ORIGINAL ARTICLE

Use of Middle Meningeal Artery Embolization in Treatment of Chronic Subdural Hematoma

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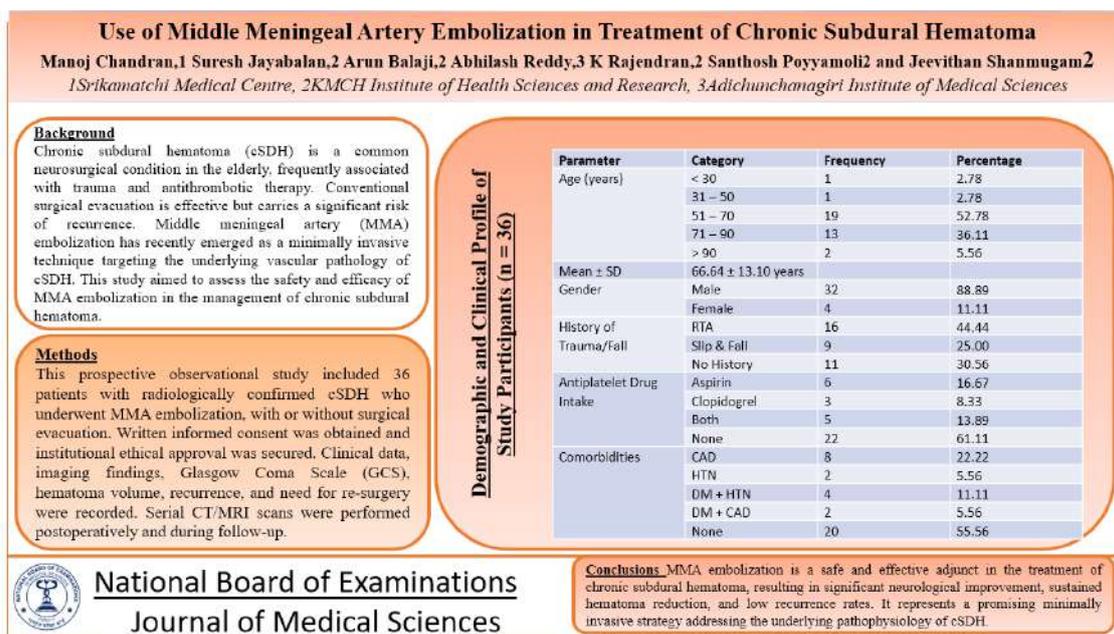
Abstract

Introduction: Chronic subdural hematoma (cSDH) is a common neurosurgical condition in the elderly, frequently associated with trauma and antithrombotic therapy. Conventional surgical evacuation is effective but carries a significant risk of recurrence. Middle meningeal artery (MMA) embolization has recently emerged as a minimally invasive technique targeting the underlying vascular pathology of cSDH. This study aimed to assess the safety and efficacy of MMA embolization in the management of chronic subdural hematoma. **Materials and Methods:** This prospective observational study included 36 patients with radiologically confirmed cSDH who underwent MMA embolization, with or without surgical evacuation. Written informed consent was obtained and institutional ethical approval was secured. Clinical data, imaging findings, Glasgow Coma Scale (GCS), hematoma volume, recurrence, and need for re-surgery were recorded. Serial CT/MRI scans were performed postoperatively and during follow-up. **Results:** The mean age was 66.64 ± 13.10 years, with male predominance (88.89%). Headache was the most common presenting symptom (33.33%). Burr-hole evacuation was performed in 69.44% and craniotomy in 30.56%. Mean GCS improved significantly from 13.94 ± 1.37 on admission to 14.89 ± 0.32 at discharge ($p = 0.0001$). Subdural hematoma volume showed progressive and statistically significant reduction on both sides over follow-up (ANOVA $p < 0.001$). **Conclusion:** MMA embolization is a safe and effective adjunct in the treatment of chronic subdural hematoma, resulting in significant neurological improvement, sustained hematoma reduction, and low recurrence rates. It represents a promising minimally invasive strategy addressing the underlying pathophysiology of cSDH.

Keywords: Chronic subdural hematoma, Middle meningeal artery embolization, Hematoma recurrence, Glasgow Coma Scale, Minimally invasive neurosurgery

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Graphical Abstract



Introduction

The Chronic subdural hematoma (cSDH) is one of the commonest neurosurgical diseases [1]. Its incidence is rising among the aging population and with the increasing use of antiplatelet and anticoagulant medications. The annual incidence of cSDH ranges from 1.7 to 20.6 per 100,000 across the studies. Though the number of cases has been increasing for decades, the large-scale population-based studies are not in significant numbers. This increase is attributed to the higher frequency of falls, brain atrophy, and widespread use of antithrombotic agents. Men have a greater risk of developing cSDH than women. The age-related increase in incidence is combined with a growing elderly population and it poses a major challenge for neurosurgical treatment practices, as the large proportion of these cases require operative management [1].

Spontaneous resolution of cSDH is found to be rare and it has been reported in patients with thrombotic thrombocytopenic purpura primarily [2]. The craniotomy with

drainage or Burr-hole irrigation remains as the gold standard treatment for symptomatic cases; But the recurrence occurs in 5% to 30% of the operated patients [3]. Symptomatic recurrences often require, re-surgery, which may not be successful in coagulopathic, elderly, or anticoagulated patients with multiple comorbidities [4]. Various medical therapies aimed at modulating the angiogenic pathways and inflammatory pathways in cSDH have proved limited success [5].

Since the surgical evacuation alone does not address the underlying pathophysiologic mechanism of cSDH, recurrent hematomas are thought to arise and the formation of fragile capillaries within the vascularized neomembrane may encapsulates the hematoma [6]. Middle meningeal artery (MMA) embolization is shown to be a promising minimally invasive technique, either as an alternative or adjunct to surgery, for treating the non-acute subdural hematomas (NASHs). Earlier reports have showed the favourable

outcomes, suggesting the superior safety and efficacy when compared with the conventional surgery [7]. The main advantage of the MMA embolization is to target the underlying disease pathology by devascularizing the immature capillary network of the neomembrane. Also, it reduces the cycles of rebleeding, micro-hemorrhage, and hematoma expansion over the period of time [8,9].

Recent researches have explored MMA embolization in patients with recurrent hematomas or those who cannot discontinue the anticoagulant therapy [10]. Preliminary investigations have showed its efficacy and safety, both as a standalone procedure and also in combination with the surgical evacuation [11]. Based on this background, the current research was done to assess the use of embolization of middle meningeal artery in the treatment of chronic subdural hematoma and to evaluate its long-term efficacy and safety in achieving permanent resolution of cSDH.

Materials and Methods

This prospective observational study was conducted in a tertiary care centre after getting the approval from the Institutional Ethics Committee. It strictly adhered to the principles laid down in the Declaration of Helsinki. The written informed consent was obtained from all the study participants or their legally authorized representatives (LARs) prior to including them in the study. Each participants were informed in detail about the embolization procedure, nature of the study, possible benefits and risks, and the requirement for follow-up of imaging techniques. Confidentiality of all medical and personal data were maintained throughout the study period. The participants and legally authorized

representatives were also informed that if the participant, on regaining the full consciousness, declines to the participation later, the individual can be excluded from the study.

The study participants included a total of 36 patients diagnosed with chronic subdural hematoma (cSDH) who had undergone middle meningeal artery (MMA) embolization at the Department of Neurosurgery. All the patients were diagnosed based on the radiological confirmation by computed tomography (CT) or magnetic resonance imaging (MRI) of the brain and the characteristic clinical findings. Patients with intracerebral hemorrhage, coagulopathies, acute subdural hematoma, or those who were hemodynamically unstable were excluded from the study. Demographic details, history of trauma or fall, comorbid conditions, clinical presentation, and use of antiplatelet or anticoagulant medications were recorded for each case.

Middle meningeal artery embolization was conducted under local or general anaesthesia by an experienced neuro interventionist. This procedure involved the access of femoral artery using the Seldinger technique, followed by the selective catheterization of the external carotid artery and the identification of the middle meningeal artery. The n-butyl cyanoacrylate (NBCA), polyvinyl alcohol (PVA) particles, or Onyx Embolization were used as an embolic agent depending on operator preference and blood vessel anatomy. The main objective was to perform the complete occlusion of the distal arteries supplying the hematoma membrane, at the same time preserving the normal meningeal perfusion. During the post-embolization period, the participants

were monitored for any procedure-related complications or neurological changes.

For the patients presenting with significant mass effect or the neurological problems, craniotomy or burrhole evacuation was performed, prior to or in combination with Middle meningeal artery embolization. The postoperative management included the avoidance of the unrequired anticoagulation, optimization of coagulation parameters, blood pressure and neurological observation. All the patients had undergone the follow-up neuroimaging (MRI or CT) in the immediate postoperative period, at one month, three months, and six months to evaluate the hematoma resolution and detect the recurrence. Glasgow Coma Scale (GCS) was used to assess the clinical outcomes at the admission and discharge.

Radiological investigations included the measurement of volume of subdural hematoma (SDH) using the standard formula (length \times height \times width \times 0.5). The difference in subdural hematoma volume between the preoperative, immediate postoperative, and follow-up scans was recorded for both the cerebral hemispheres. Any reaccumulation of hematoma or recurrence causing the need for re-surgery were also noted. Adverse events such as new neurological deficits, rebleeding, or ischemic complications, were monitored with care.

All data were entered in Microsoft Excel and were analysed using version 27.0, Statistical Package for the Social Sciences (SPSS). The categorical variables were expressed as percentages and frequencies. The quantitative variables like age, GCS and hematoma volume were

expressed as mean \pm standard deviation (SD). Comparison of continuous variables between pre- and postoperative parameters were done using the paired t-tests. The changes in hematoma volume across the different time intervals were analysed using one-way analysis of variance (ANOVA). A p-value $<$ 0.05 was considered as statistically significant.

Results

The study population were mainly the elderly males, with an average age of 66.64 ± 13.10 years, showing that chronic subdural hematoma affects the elderly individuals. Most of them (52.78%) were between the age group 51 and 70 years, and 36.11% were between the age group 71 and 90 years, underscoring age as a major risk factor. 88.89% of the cases, were males, suggesting a higher predisposition in them, possibly due to the anticoagulant usage or increased trauma exposure. A history of trauma was found in 69.44% of the study participants, mostly due to road traffic accidents (44.44%) and slip and fall incidents (25.00%) while the 30.56% of them had no injury or definite history, suggesting that even unnoticed or minor trauma may precipitate SDH in the susceptible individuals. Considering the comorbidities, 44.44% of the participants had associated systemic illnesses such as coronary artery disease (22.22%), diabetes with hypertension (11.11%), or hypertension alone (5.56%). 38.89% were notably on antiplatelet therapy like aspirin, reflecting the influence of hematologic and vascular risk factors (Table 1).

Table 1. Demographic and Clinical Profile of Study Participants (n = 36)

Parameter	Category	Frequency	Percentage
Age (years)	< 30	1	2.78
	31 – 50	1	2.78
	51 – 70	19	52.78
	71 – 90	13	36.11
	> 90	2	5.56
Mean \pm SD	66.64 \pm 13.10 years		
Gender	Male	32	88.89
	Female	4	11.11
History of Trauma/Fall	RTA	16	44.44
	Slip & Fall	9	25.00
	No History	11	30.56
Antiplatelet Drug Intake	Aspirin	6	16.67
	Clopidogrel	3	8.33
	Both	5	13.89
	None	22	61.11
Comorbidities	CAD	8	22.22
	HTN	2	5.56
	DM + HTN	4	11.11
	DM + CAD	2	5.56
	None	20	55.56

The commonest presenting symptoms in this cohort were headache (33.33%), followed by unilateral limb weakness (19.44%), decreased physical activity (13.89%), and or giddiness or gait disturbances (13.89%), suggesting the diverse and subtle neurological manifestations of cSDH. Radiological imaging revealed that left-sided hematomas were found to be the most frequent (52.78%), followed by bilateral involvement (27.78%) and right-sided lesions (19.44%), which suggest a left-

sided predominance. The surgical intervention, burrhole evacuation was performed in 69.44% of the participants, while craniotomy was the necessary intervention in the rest 30.56%, which indicates that minimally invasive techniques were the effective and preferred in most cases. Postoperatively, recurrences were observed in 13.89%, and re-surgery was required in 5.56% of the cases, which are within the acceptable clinical limits for this procedure (Table 2).

Table 2. Clinical Presentation, Radiological Findings, Type of Surgery, and Neurological Outcome

Clinical Symptoms	Frequency	Percentage
Presenting Symptoms and Neurological Status		
Headache	12	33.33
Right UL/LL Weakness	7	19.44

Decreased Physical Activity	5	13.89
Giddiness ± Difficulty Walking	5	13.89
Altered Speech / Headache + Vomiting	4	11.11
Others	3	8.33
CT/MRI findings		
B/L Chronic SDH	10	27.78
Left Chronic SDH	19	52.78
Right Chronic SDH	7	19.44
Type of surgery done		
Burrhole	25	69.44
Craniotomy	11	30.56
Distribution of Recurrence and Re-surgery		
Recurrence	5	13.89
Re-surgery	2	5.56

Serial volumetric assessment proved a statistically significant and progressive reduction in the size of subdural hematoma over time following the embolization of middle meningeal artery. On the right side, the average hematoma volume decreased from 107.40 ± 19.20 cc preoperatively to 21.33 ± 10.30 cc in the immediate postoperative period and, 13.11 ± 13.20 cc after one month, and further to 8.55 ± 9.25 cc after six months. Similarly, the left-sided hematomas reduced from 99.40 ± 20.59 cc preoperatively to $23.11 \pm$

13.86 cc postoperatively, 12.89 ± 10.64 cc at one month, and 7.54 ± 7.69 cc at six months. The ANOVA test ($p < 0.001$) proved that these reductions were statistically significant on both the sides. The results clearly suggests that the sustained radiological improvement, with most patients achieving nearly complete resolution of the hematoma within the period of six months, reinforcing the efficiency of MMA embolization in causing long-term hematoma resorption and to prevent recurrence (Table 3).

Table 3. Serial Changes in Subdural Hematoma Volume

Time	Right(n=19)		Left(n=28)	
	Mean	SD	Mean	SD
Pre op	107.4	19.20	99.4	20.59
Immediate post op	21.33	10.30	23.11	13.86
After 1 month	13.11	13.20	12.89	10.64
After 6 month	8.55	9.25	7.54	7.69
ANOVA	P<0.001	P<0.001	P<0.001	P<0.001

The bar chart compares the Glasgow Coma Scale (GCS) scores before and after the treatment shows a significant improvement in neurological function. The mean Glasgow Coma Scale scores increased from 13.94 ± 1.37 on admission

to 14.89 ± 0.32 on discharge ($p = 0.0001$), which indicates the statistically significant recovery of cognitive function or consciousness following the middle meningeal artery embolization and surgical intervention (Figure 1).

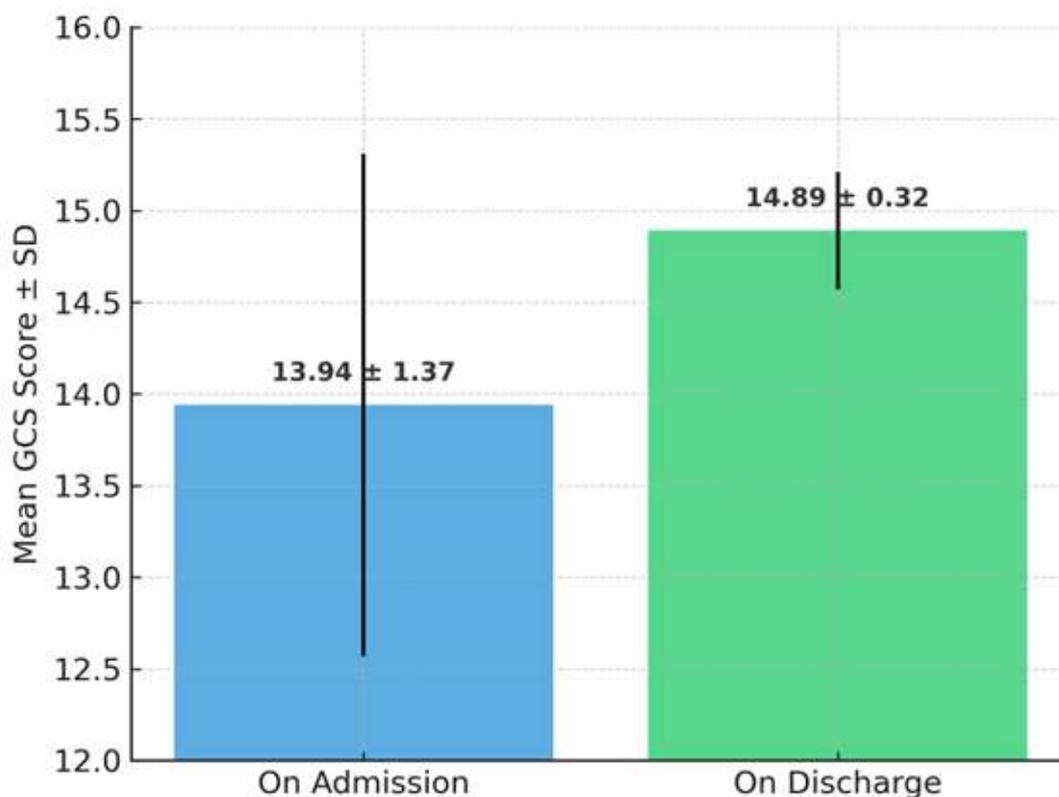


Figure 1. Comparison of GCS on Admission and Discharge ($p = 0.0001$).

Discussion

In this study, the chronic subdural hematoma (cSDH) patients ($N = 36$) who had undergone middle meningeal artery (MMA) embolization, more than half of them (53%) were aged between 51–70 years, with an average age of 66.64 years. Ban et al. (2018) showed that a similar age distribution (> 65 years), correlating with our findings [12]. cSDH is mainly a disease of the elderly, which is attributed to stretching of bridging veins, brain atrophy, and a fragile neomembrane prone to re-bleeding [13]. With the advancing age and

increasing use of antiplatelet or anticoagulant therapy, this incidence continues to rise, and also, nearly 60,000 new cases are projected annually [14].

A marked male predominance (89%) was observed in the literature search, similar to the findings of Ban et al. (2018) and Peter Kan et al. (2021), who emphasized the occurrence in 60% and 71% of male patients, respectively [12,15]. Men are more likely to sustain trauma and have increased rates of vascular comorbidities which requires antithrombotic therapy, predisposing them

to cSDH. In our research, fourteen patients were on anticoagulant or antiplatelet medication. Pre-injury usage of these drugs has been associated with enlargement or delayed bleeding of the intracranial hematomas, raising both the morbidity and mortality rates [13].

Headache (33%) was the commonest presenting complaint, followed by the weakness in the limb, giddiness, and reduced activity. These findings showcase the non-specific neurological manifestations described in the previous studies [12,13,15]. Such symptoms are often subtle, and an early neuroimaging is needed to prevent neurological deterioration.

MMA embolization has been identified as an effective alternative or adjunct to surgery for cSDH, especially in patients with high surgical recurrence or risk. Its mechanism is physiological as it targets the pathological neo membrane, supplied by the fragile branches of the MMA. Thereby it interrupts the cycles of micro-haemorrhage and exudation responsible for the persistence of hematoma [14,16]. These studies demonstrate the consistent results like favourable outcomes and low recurrence rates. The above technique typically utilises the microparticle embolic drugs, though liquid embolisates such as SQUID or Onyx, which may provide deeper penetration and more durable occlusion; But still the complete comparative evidence is lacking.

The safety profile of middle meningeal artery embolization in the current study was good, with no major adverse effects, mimicking the results of Link et al. [17] and Ban et al. [12], which demonstrated, nil procedural complications. A meta-analysis by Srivatsan et al. [18] further emphasized the

lesser complication rates (2%) in this, when compared to the conventional surgery (4%). In our series, burr-hole evacuation was done in 69% and craniotomy was performed in 31% of cases. The mean volume of subdural hematoma was reduced significantly postoperatively ($p < 0.0001$) and it also decreased at one month and six-month follow-ups. Recurrence was seen in 5 patients (13.9%), with 2 of them requiring re-surgery, which is well below the recurrence rate of 28%, usually reported after the surgery alone [19-21]. By six months, all the patients showed complete resolution of hematoma, except one, indicating durable benefit of the procedure.

The success of middle meningeal artery embolization rests in revascularizing the inflammatory membrane and preventing the angiogenic leakage, which prevents further accumulation. This also allows slow resorption of the existing clot and promotes long-term healing. The effectiveness of this approach has been validated by several clinical series showing sustained hematoma regression and reduced need for repeat procedures [17-20].

Ongoing randomized controlled trials are expected to strengthen the evidence base. The SQUID Trial (STEM) is evaluating the safety and efficacy of SQUID as an embolic material [22], while the EMBOLIZE Trial is assessing Onyx for subacute and chronic SDH [23]. Both are designed to compare conventional management with and without MMA embolization and will help clarify patient selection criteria and optimal timing [24].

Conclusion

This study demonstrated that MMA embolization facilitates resolution, prevents reaccumulation of CSDH and is more effective to be used in addition to

conventional treatment without increasing treatment related complications. It can be considered as a definitive treatment option for CSDH among older age group individuals especially those with multiple comorbidities. It may be a safe and efficacious minimally invasive procedure that can be utilised in CSDH patients at a higher risk of recurrence. Favorable outcomes were obtained by performing embolization at an early stage when signs of recurrence appeared.

Statements and Declarations

Conflicts of interest

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

Funding

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ORIGINAL ARTICLE

Serum Osteoprotegerin: Can It Predict Chronic Kidney Disease Among Hypertensives?

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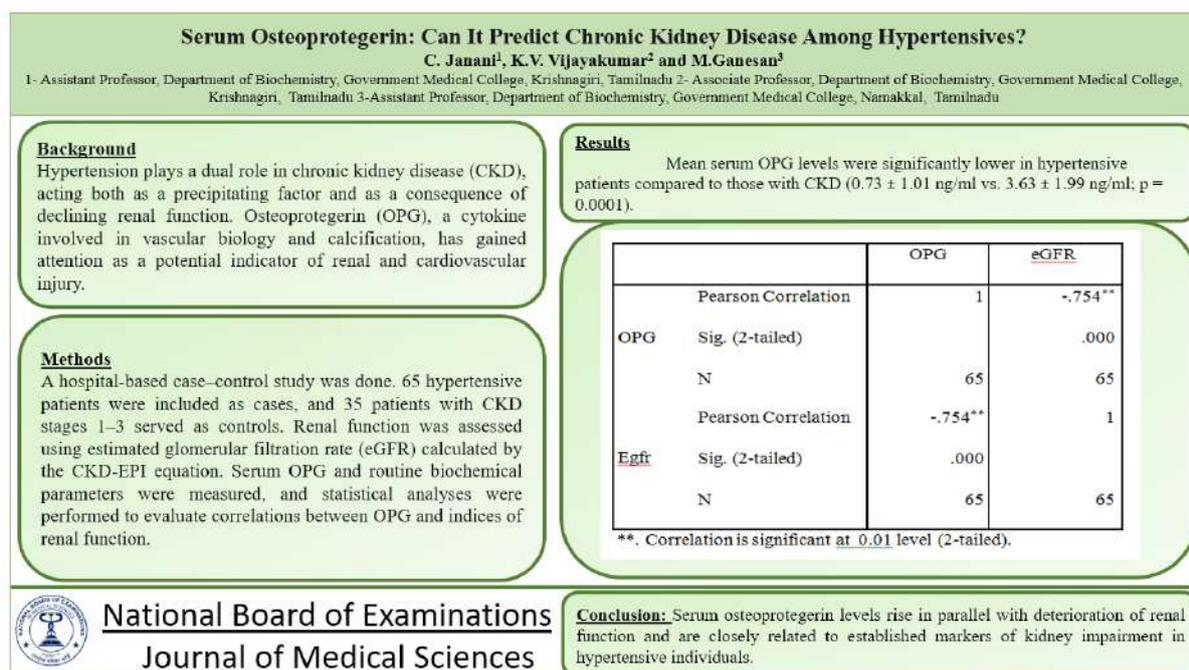
Abstract

Background: Hypertension plays a dual role in chronic kidney disease (CKD), acting both as a precipitating factor and as a consequence of declining renal function. Early renal impairment in hypertensive individuals is often clinically silent, and conventional markers may fail to detect subtle changes. Osteoprotegerin (OPG), a cytokine involved in vascular biology and calcification, has gained attention as a potential indicator of renal and cardiovascular injury. **Objectives:** To evaluate the association between serum osteoprotegerin levels and renal dysfunction in hypertensive patients, and to assess whether elevated OPG can serve as an early predictor of chronic kidney disease in this population. **Methods:** A hospital-based case-control study was carried out at Government Mohan Kumaramangalam Medical College Hospital, Salem, from December 2018 to November 2019. Sixty-five hypertensive patients were included as cases, and 35 patients with CKD stages 1–3 served as controls. Renal function was assessed using estimated glomerular filtration rate (eGFR) calculated by the CKD-EPI equation. Serum OPG and routine biochemical parameters were measured, and statistical analyses were performed to evaluate correlations between OPG and indices of renal function. **Results:** Mean serum OPG levels were significantly lower in hypertensive patients compared to those with CKD (0.73 ± 1.01 ng/ml vs. 3.63 ± 1.99 ng/ml; $p = 0.0001$). Patients with CKD had higher serum creatinine levels and lower eGFR values. A strong inverse association between OPG and eGFR was observed in both groups, along with a positive correlation between OPG and serum creatinine. Serum OPG also showed significant associations with body mass index and adverse lipid parameters, suggesting a link with both renal dysfunction and cardiovascular risk. **Conclusion:** Serum osteoprotegerin levels rise in parallel with deterioration of renal function and are closely related to established markers of kidney impairment in hypertensive individuals. These findings support the potential role of OPG as an early biomarker for renal involvement and cardiovascular risk stratification in patients with hypertension.

Keywords: Hypertension, Chronic kidney disease, Osteoprotegerin, Estimated glomerular filtration rate, Renal impairment, Cardiovascular risk

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Graphical Abstract



Introduction

Chronic kidney disease (CKD) is a major global public health problem, affecting millions of people worldwide and placing a significant burden on healthcare systems due to high morbidity, mortality, and economic costs [1,2]. The Global Burden of Disease Study 2023 reports a steady rise in CKD prevalence across all regions and age groups, highlighting its growing global impact [3]. This increasing burden emphasizes the importance of early detection and preventive strategies, especially in populations at high risk.

Hypertension is one of the most important modifiable risk factors for the development and progression of CKD. The relationship between hypertension and CKD is bidirectional, with each condition worsening the other [4]. The KDIGO 2021 Clinical Practice Guideline highlights the close link between blood pressure control and kidney disease, stressing that effective management of hypertension is essential to prevent CKD progression [5]. Although

several treatment strategies are available for managing hypertension in CKD patients [6], it remains difficult to identify individuals who are at the highest risk before significant kidney damage has occurred.

In India, the burden of CKD is particularly concerning. Community-based studies and systematic reviews show a high prevalence of CKD, with many cases remaining undiagnosed until advanced stages of the disease [7]. Late diagnosis reduces the scope for early intervention and highlights the need for reliable biomarkers that can predict CKD in vulnerable individuals. Conventional markers of kidney function often detect disease only after substantial nephron loss, making it necessary to explore novel predictive indicators.

Osteoprotegerin, a glycoprotein involved in bone metabolism and vascular calcification, has recently emerged as a potential biomarker in CKD. Its association with vascular health and its elevated levels

in cardiovascular and renal disorders suggest that it may reflect early kidney dysfunction.

Given the strong association between hypertension and CKD, assessing whether serum osteoprotegerin can predict CKD among hypertensive patients is clinically relevant. If proven effective, osteoprotegerin could help in risk stratification by identifying hypertensive individuals who require closer follow-up and more aggressive treatment. This study aims to evaluate the predictive value of serum osteoprotegerin for detecting CKD in hypertensive patients, with the goal of improving early diagnosis and long-term outcomes in this high-risk population.

Aims and Objectives

1. To evaluate the association between OPG and renal dysfunction in hypertensive patients and
2. To evaluate whether, the increase in serum OPG levels, could be an early predictor of Chronic kidney disease among the hypertensive patients.

Study Methodology

A case-control study was conducted at Government Mohan Kumaramangalam Medical College Hospital, Salem, from December 2018 to November 2019, after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants prior to enrollment.

The study included 65 patients with hypertension as cases and 35 patients with chronic kidney disease (CKD) stages 1–3 attending the Nephrology outpatient department as controls; CKD group was included as a comparison (positive control) group rather than as a true control group because CKD is a well-established clinical

condition known to be associated with the pathophysiological mechanisms under investigation. CKD stages 4 and 5 were excluded. Hypertensive cases were further categorized based on duration of hypertension into <5 years and 5–10 years. CKD staging was performed according to KDOQI guidelines using estimated glomerular filtration rate (eGFR), calculated by the CKD-EPI formula.

Controls were identified based on clinical features and routine investigations, with eGFR ranging from 45 to 90 ml/min/1.73 m². Detailed clinical evaluation and specimen collection were performed for all participants. Inclusion criteria comprised age 30–65 years, treated hypertension, and CKD stages 1–3, while patients with diabetes, irregular antihypertensive use, systemic or congenital renal disease, and advanced CKD were excluded.

For the association between serum OPG and renal dysfunction (eGFR) And For evaluating OPG as an early predictor of CKD among hypertensive patients ($r \approx -0.75$, $n = 65$, $\alpha = 0.05$), the post-hoc statistical power exceeded 99%. Accordingly, the sample size employed in the study is adequate and statistically justified to reliably test and address the stated study hypotheses.

Results

A total of 100 participants were evaluated, comprising 65 cases and 35 controls. The mean age was comparable between the two groups, with cases having a mean age of 55.5 ± 8.7 years and controls 53.6 years. The average duration of hypertension was longer among cases (4.3 years) than controls (3.0 years). Mean blood sugar levels were modestly higher in cases (106.0 ± 26.17 mg/dl) compared to

controls (93.8 mg/dl). Blood urea levels were lower in cases (25.7 mg/dl) than controls (51.8 mg/dl). Serum creatinine showed a significant difference, being lower in cases (1.11 ± 0.24 mg/dl)

compared to controls (1.74 ± 0.53 mg/dl), while eGFR was correspondingly higher in cases (66.0 ± 16.13 ml/min/1.73 m²) than controls (44.1 ± 13.09 ml/min/1.73 m²). (Table 1).

Table 1. Descriptive Data of Cases and Controls

S. No	Parameters	Cases (n=65) mean \pm SD	Controls (n=35) mean \pm SD
1.	Age	55.5 \pm 8.7	53.6 \pm 7.1
2.	Hypertension duration	4.3 \pm 3.7	7.9 \pm 3.0
3.	Blood sugar (mg/dl)	106.0 \pm 26.17	93.8 \pm 13.83
4.	Blood urea (mg/dl)	25.75 \pm 5.7	51.86 \pm 8.97
5.	Sr. Creatinine (mg/dl)	1.11 \pm 0.24	1.74 \pm 0.53
6.	Total cholesterol (mg/dl)	205.1 \pm 34.52	263.4 \pm 50.81
7.	Triglycerides (mg/dl)	218.9 \pm 84.54	191.4 \pm 44.44
8.	HDL(mg/dl)	46.82 \pm 8.74	40.49 \pm 4.80
9.	LDL(mg/dl)	114.5 \pm 33.91	184.7 \pm 47.02
10.	Sr. Calcium(mg/dl)	8.52 \pm 1.42	7.90 \pm 0.95
11.	Sr.Uric acid (mg/dl)	4.50 \pm 1.08	4.89 \pm 0.77
12.	Total protein(g/dl)	6.59 \pm 0.78	6.81 \pm 0.53
13.	Albumin(g/dl)	3.47 \pm 0.48	3.66 \pm 0.48
14.	eGFR	66.01 \pm 16.13	44.16 \pm 13.09
15.	OPG (ng/dl)	0.73 \pm 1.01	3.63 \pm 1.99

Analysis of lipid parameters revealed that cases had significantly lower total cholesterol levels (205.1 ± 34.52 mg/dl) compared to controls (263.4 ± 50.81 mg/dl). Triglyceride levels were higher in

cases (218.9 ± 84.54 mg/dl) than controls (191.4 ± 44.44 mg/dl). HDL cholesterol was higher among cases (46.8 ± 8.74 mg/dl) compared to controls (40.4 ± 4.80 mg/dl), whereas LDL cholesterol levels were

markedly lower in cases (114.5 ± 33.91 mg/dl) than in controls (184.7 ± 47.02 mg/dl). Serum calcium levels were higher in cases (8.52 ± 1.42 mg/dl) compared to controls (7.90 ± 0.95 mg/dl). Serum uric acid levels were comparable between groups (4.50 ± 1.08 mg/dl in cases and 4.89 mg/dl in controls). Total protein and albumin values were slightly lower in cases (6.59 g/dl and 3.47 g/dl, respectively) than controls (6.81 g/dl and 3.66 g/dl).

Sex distribution differed between groups, with a male predominance among controls

(24 males, 11 females) and a higher proportion of females among cases (37 females, 28 males). Serum osteoprotegerin levels showed a pronounced and statistically significant reduction in cases (0.734 ± 1.017 ng/ml) compared to controls (3.638 ± 1.995 ng/ml; $p = 0.0001$). (Table 2) Statistically significant differences ($p = 0.0001$) were also observed between groups for serum creatinine, total cholesterol, triglycerides, HDL, LDL, and calcium.

Table 2. Statistical analysis of serum osteoprotegerin in control and cases

OSTEOPROTEGERIN ng/ml	N	MEAN	SD	INFERENCE
CONTROLS	35	3.638	1.995	P= 0.0001
CASES	65	0.734	1.017	P<0.05

Table 3, shows that Correlation analysis among cases demonstrated a strong inverse relationship between serum osteoprotegerin and eGFR ($r = -0.754$, $p < 0.01$), along with significant positive correlations with serum creatinine ($r = 0.709$), BMI ($r = 0.246$), total cholesterol ($r = 0.321$), and LDL cholesterol ($r = 0.340$). In controls, serum osteoprotegerin similarly showed an inverse correlation with eGFR ($r = -0.754$, $p < 0.01$) and positive correlations with creatinine ($r = 0.551$),

total cholesterol ($r = 0.566$), triglycerides ($r = 0.661$), and LDL cholesterol ($r = 0.471$).

Figure:1 Receiver Operating Characteristic (ROC) curve evaluating the diagnostic performance of the test parameter. The area under the ROC curve (AUC) was 0.9378, indicating excellent discriminatory ability. The standard error was 0.02337, suggesting good precision of the AUC estimate, which was statistically Significant (P value < 0.001)

Table 3: Pearson's correlation analysis of OPG and eGFR in cases

		OPG	<u>eGFR</u>
OPG	Pearson Correlation	1	-.754**
	Sig. (2-tailed)		.000
	N	65	65
<u>Egfr</u>	Pearson Correlation	-.754**	1
	Sig. (2-tailed)	.000	
	N	65	65

** . Correlation is significant at 0.01 level (2-tailed).

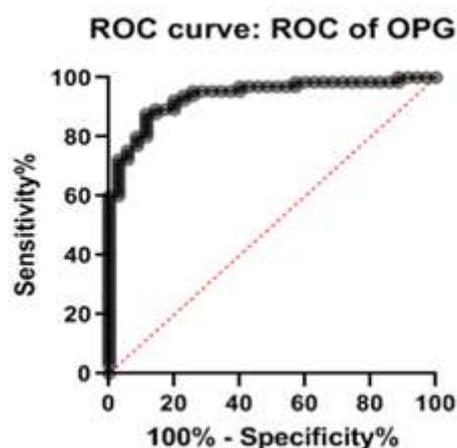


Figure 1. Receiver Operator Characteristic Curve

Discussion

The present case-control study evaluated the relationship between serum osteoprotegerin (OPG), renal function, and cardiovascular risk factors among hypertensive patients and individuals with chronic kidney disease (CKD) stages 1-3. The results demonstrate that serum OPG levels were significantly higher in CKD patients compared to hypertensive cases, with a parallel decline in estimated glomerular filtration rate (eGFR) and

elevation in serum creatinine, highlighting progressive renal dysfunction. These findings reinforce the role of OPG as a biomarker associated with renal impairment.

Hypertension is both a causative and contributory factor in the progression of CKD. In the present study, declining eGFR was significantly associated with worsening hypertension, supporting previous observations that blood pressure burden increases as renal function

deteriorates. Li et al. [9] reported that even prehypertension increases the risk of developing CKD, emphasizing the importance of early blood pressure control to prevent renal damage. The strong inverse correlation between serum OPG and eGFR observed in both hypertensive and CKD groups in this study further supports the hypothesis that OPG reflects renal functional decline.

Serum OPG levels showed a significant negative correlation with eGFR and a positive correlation with serum creatinine, total cholesterol, LDL cholesterol, triglycerides, and BMI. Similar findings have been reported by Schoppet et al. [8] who demonstrated that elevated OPG levels reflect vascular injury and inflammatory processes rather than bone metabolism alone. The progressive rise in OPG with worsening renal function suggests its involvement in vascular remodeling and endothelial dysfunction commonly seen in CKD.

Dyslipidemia was prominent among CKD patients in the present study, characterized by elevated total cholesterol, LDL cholesterol, and triglycerides, along with reduced HDL cholesterol. These findings are consistent with studies by Tsimihodimos et al. [10] and Vaziri et al [11], who described profound disturbances in lipoprotein metabolism in CKD, contributing to accelerated atherosclerosis and renal microvascular injury. The coexistence of hypertension and dyslipidemia further amplifies cardiovascular risk, as highlighted by Ariyanti et al. [12] and Dalal et al. [13] who described the concept of “lipitension” linking metabolic and vascular pathology.

Linear regression analysis in hypertensive patients revealed a significant inverse relationship between OPG and

eGFR, indicating that OPG may serve as an independent predictor of renal dysfunction, consistent with the findings of Bernardi et al. [14]. Furthermore, receiver operating characteristic curve analysis demonstrated excellent diagnostic accuracy of OPG in differentiating hypertensive patients from CKD patients, with high sensitivity and specificity. These findings are in concordance with Lee et al. [15] who identified serum OPG as an independent predictor of cardiovascular events and mortality in CKD patients.

Overall, the present study supports the utility of serum OPG as an early biomarker for renal dysfunction and cardiovascular risk stratification among hypertensive patients, warranting its consideration in clinical assessment and future longitudinal studies.

Conclusion

The present study demonstrates that serum osteoprotegerin (OPG) levels increase with worsening renal function and show a significant inverse relationship with estimated glomerular filtration rate in hypertensive patients. Elevated OPG levels were associated with higher serum creatinine and adverse lipid profile, reflecting underlying vascular and renal dysfunction. These findings suggest that OPG may serve as an early biomarker for decline in renal function and cardiovascular risk among hypertensive individuals. Early identification of renal involvement using OPG may facilitate timely intervention and improve clinical outcomes.

Limitation

Lack of a “True” Healthy Control: The study lacks a group of healthy, non-hypertensive, non-CKD individuals. Without a healthy baseline, it is difficult to

determine if the hypertensive “cases” already have elevated OPG compared to the general population. **Selection Bias:** The CKD controls were recruited from a Nephrology outpatient department. These patients might have other comorbidities or medications not present in the hypertensive group, which could confound the OPG levels.

Author Contributions

Author 1 has contributed to the conceptualization and definition of the intellectual content of the manuscript, design of the study and Manuscript preparation. Author 2 contributed to the literature search, manuscript editing, and manuscript review. Author 3 contributed towards data acquisition Statistical analysis, Manuscript review and editing. Author 1 will act as the corresponding author of the manuscript

Data availability

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 Ref. No: GMCKMC&H/4341/IEC/02/2018-74

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.

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ORIGINAL ARTICLE

Prevalence and Determinants of Anaemia in Undergraduate Medical Students: Cross-Sectional Study

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Abstract

Background: Anemia is a common public health issue, especially among young people, including medical students, who may disregard their health because of irregular food intake and academic stress. To encourage early intervention and preventative measures, it is crucial to determine the prevalence of anemia in this group and the risk factors that are linked to it.

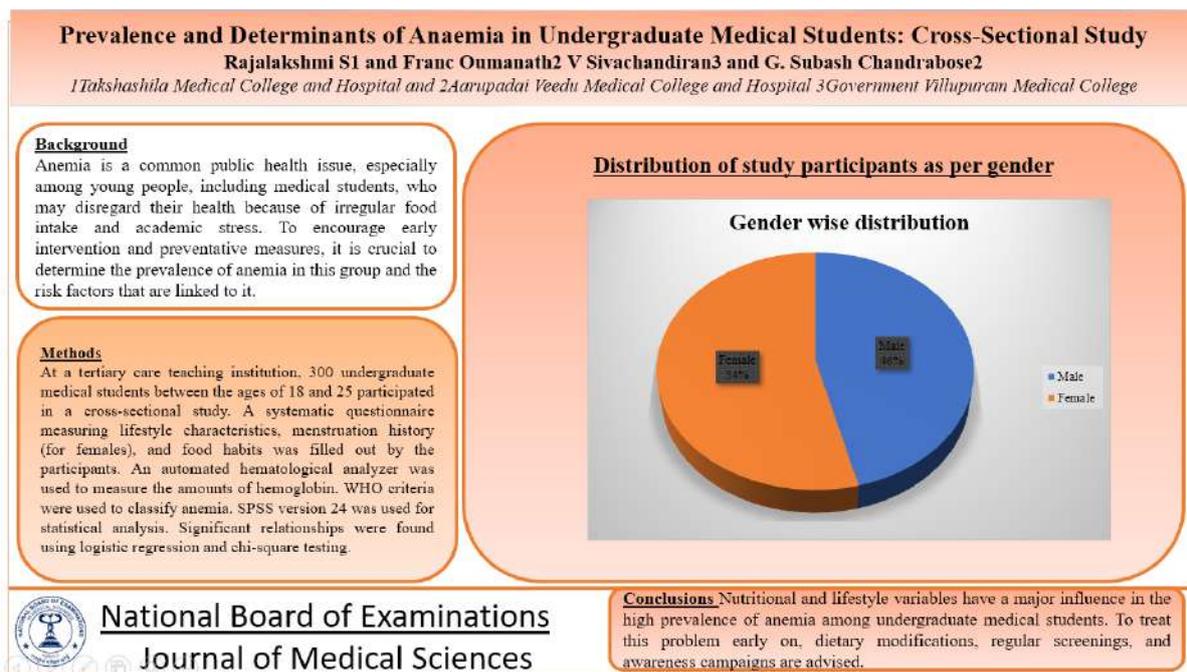
Materials and Methods: At a tertiary care teaching institution, 300 undergraduate medical students between the ages of 18 and 25 participated in a cross-sectional study. A systematic questionnaire measuring lifestyle characteristics, menstruation history (for females), and food habits was filled out by the participants. An automated hematological analyzer was used to measure the amounts of hemoglobin. WHO criteria were used to classify anemia. SPSS version 24 was used for statistical analysis. Significant relationships were found using logistic regression and chi-square testing. **Results:** Out of 300 undergraduate medical students, 43.3% were found to be anemic. Mild anemia was most prevalent (62.31%), followed by moderate (26.15%) and severe anemia (11.54%). Anemia showed a significant association with inadequate iron intake, irregular meal patterns, and heavy menstrual bleeding. High academic stress demonstrated a borderline association with anemia status.

Conclusion: Nutritional and lifestyle variables have a major influence in the high prevalence of anemia among undergraduate medical students. To treat this problem early on, dietary modifications, regular screenings, and awareness campaigns are advised.

Keywords: Iron deficiency, prevalence, anemia, medical students, risk factors, cross-sectional study

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Graphical Abstract



Introduction

The World Health Organization (WHO) defines anemia as a hemoglobin concentration of less than 13 g/dL in males and less than 12 g/dL in non-pregnant women. Anemia is still a major worldwide public health concern that mostly affects young people in low- and middle-income nations [1]. Menstrual blood loss, persistent infections, and dietary deficits are frequent causes of this multifactorial illness in teens and young adults [2]. Academic stress, irregular eating habits, and sedentary lifestyles may all increase the incidence of anemia in medical students [3].

Nearly half of all instances of anemia globally are iron deficiency anemia, which is the most common type [4]. Studies have shown that even those with access to healthcare and education, such as medical students, are not exempt from the burden of anemia, despite the fact that it is frequently linked to disadvantaged

groups [5,6]. Students' dietary intake and general health may be jeopardized by the demanding requirements of medical school, which include excessive study sessions and inadequate sleep hygiene [7].

According to earlier studies, the prevalence of anemia among medical students varies from 20% to 60%, with female students experiencing a much greater incidence because of iron loss associated with menstruation [8,9]. Medical students are a vulnerable but neglected population because they may disregard their own health despite their understanding of disease pathophysiology and prevention (10). To provide focused treatments and encourage health-conscious behavior among aspiring healthcare professionals, it is crucial to determine the prevalence and related risk factors in this age group.

The purpose of this study is to determine the incidence of anemia among medical students enrolled in undergraduate

programs and to examine risk factors for the condition, such as food habits, lifestyle choices, and female menstruation history.

Materials & Methods

At a tertiary medical college and hospital in Puducherry, India, three-month cross-sectional observational research was carried out. The study's objectives were to determine the prevalence of anemia and evaluate risk factors related to it in medical undergraduates.

Examine the Population and Sampling Undergraduate medical students enrolled in MBBS programs (first to final year) between the ages of 18 and 25 were deemed qualified for inclusion. Students who had recently received blood transfusions, had chronic diseases, had known hematological problems, or were using iron supplements were not allowed to participate. Stratified random selection was used to determine a sample size of 300

participants, guaranteeing proportionate representation from each academic year. All participants provided written, informed consent.

A standardized, pre-validated questionnaire covering sociodemographic information, eating habits, menstruation history (for women), academic stress, physical activity, and sleep patterns was given to the participants. To determine BMI, anthropometric measures (weight and height) were noted.

An automated hematological analyzer was used to determine the hemoglobin content of venous blood samples (2–3 mL) that were obtained under aseptic conditions. According to WHO recommendations, anemia was characterized and categorized as mild (11.0–12.9 g/dL for males & 11.0–11.9 g/dL for females), moderate (8.0–10.9 g/dL), and severe (<8.0 g/dL).

Results:

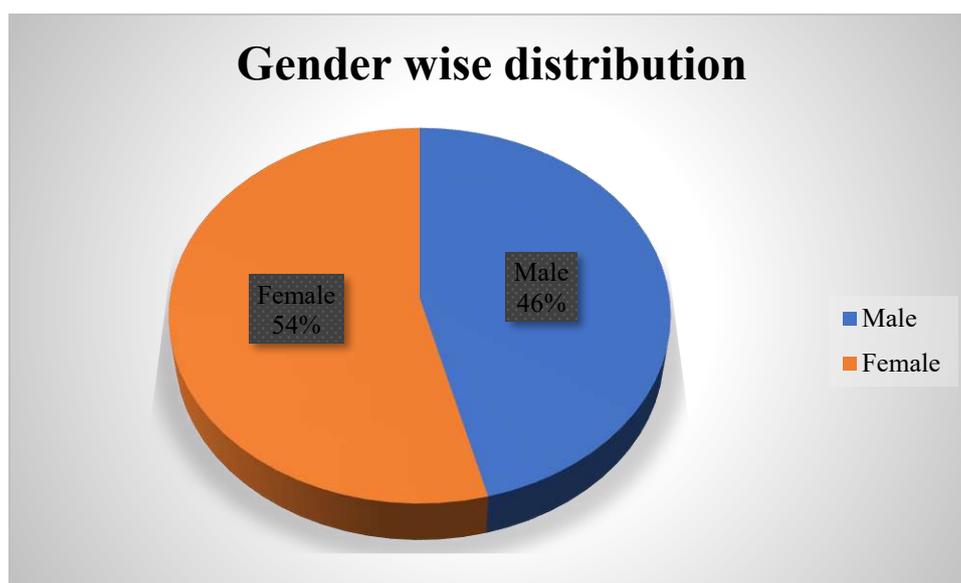


Figure 1. Distribution of study participants as per gender

Figure 1 depicts the gender-wise distribution of the study participants. The figure demonstrates that both male and female students were adequately represented in the study, ensuring a balanced sample for assessing anemia prevalence and its associated factors. The inclusion of participants from both genders strengthens the external validity of the study findings and allows for meaningful interpretation of gender-related physiological and behavioral determinants of anemia.

The observed gender distribution is particularly relevant in anemia research, as biological factors such as menstruation, hormonal differences, and varying nutritional requirements can influence hemoglobin levels. A substantial

representation of female participants is crucial, given that adolescent and young adult females are traditionally considered a high-risk group for anemia due to menstrual blood loss and increased iron requirements. At the same time, the inclusion of male participants allows for the identification of lifestyle and dietary factors contributing to anemia beyond gender-specific physiological causes.

Overall, Figure 1 confirms that the study population was sufficiently diverse in terms of gender, thereby enabling a comprehensive assessment of anemia and reducing the risk of gender-related sampling bias. This distribution provides a strong foundation for interpreting the subsequent findings related to anemia severity and associated risk factors.

Table 1. Distribution of Anemia Severity among Anemic Students

Severity of Anemia	Number of Students	Percentage (%)
Mild	81	62.31
Moderate	34	26.15
Severe	15	11.54
Total	130	100.00

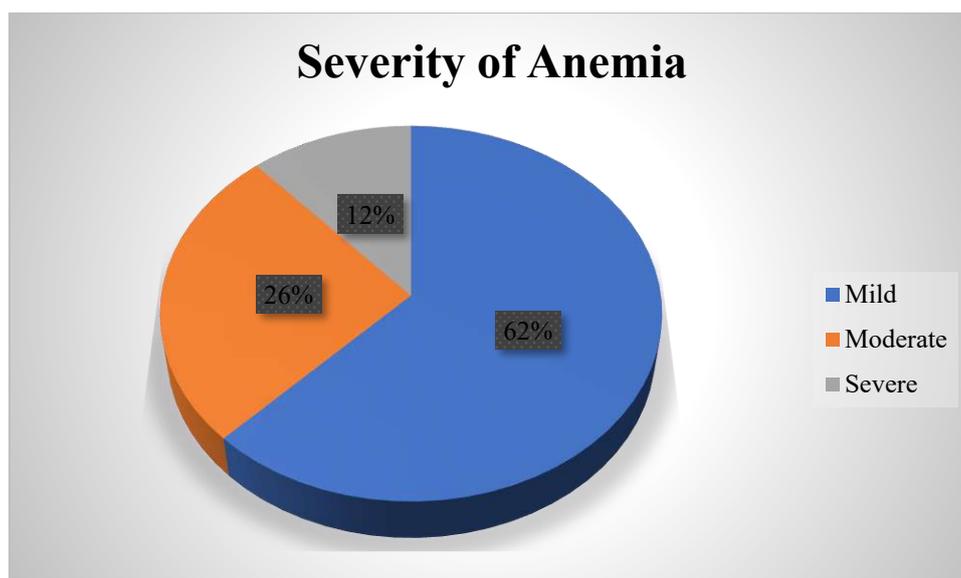


Figure 2. Distribution of Anemia Severity among Anemic Students.

Table 1 illustrates the distribution of anemia severity among the anemic students ($n = 130$). The results indicate that **mild anemia** was the most common form, affecting **62.31%** of the anemic participants. This was followed by **moderate anemia** in **26.15%** and **severe anemia** in **11.54%** of students.

The predominance of mild anemia suggests that a majority of affected students are in the early stage of the condition, where clinical manifestations may be subtle or nonspecific. Although mild anemia may not present with overt symptoms, it can still negatively impact concentration, academic performance, and physical stamina. Importantly, this stage represents a critical window for preventive intervention, as appropriate dietary modification, iron supplementation, and health education can effectively reverse the condition and prevent progression.

However, the presence of moderate and severe anemia in nearly **38%** of

anemic students is a cause for concern. Moderate anemia is often associated with fatigue, reduced cognitive efficiency, and decreased immunity, which can adversely affect students' academic and daily functioning. Severe anemia, though less prevalent, represents a serious health condition that may require immediate medical evaluation and intervention. Students with severe anemia are at increased risk of cardiovascular strain, frequent infections, and poor quality of life.

The distribution pattern observed in Table 1 underscores that anemia among students is not merely a mild nutritional issue but includes clinically significant forms that can have long-term consequences if left unaddressed. These findings highlight the need for routine screening programs in educational institutions and reinforce the importance of early detection to prevent progression to more severe stages.

Table 2. Association between Selected Determinant Factors and Anemia Status (n=300)

Risk Factor	Anemic		Non-Anemic		p-value
Inadequate Iron Intake	53	44.17	43	25.29	0.034
Irregular Meal Pattern	86	71.67	62	36.47	0.001
Heavy Menstrual Bleeding	51	42.50	23	13.53	0.009
High Academic Stress	73	60.83	51	30.00	0.054

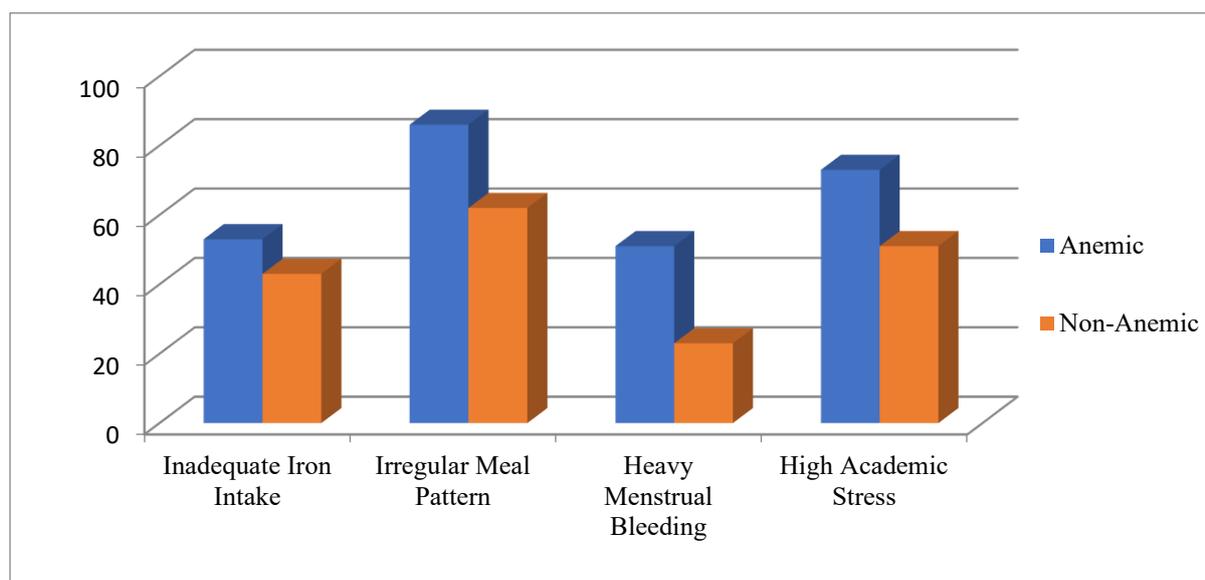


Figure 3. Association between Selected Determinant Factors and Anemia Status (n=300)

Table 2 illustrates the association between selected determinant factors and anemia status among the study participants (n = 300), comparing anemic and non-anemic students.

Inadequate Iron Intake

Inadequate iron intake was reported by **44.17%** of anemic students compared to **25.29%** of non-anemic students, with a statistically significant association ($p = 0.034$). This finding confirms the pivotal role of dietary iron deficiency in the development of anemia. Students consuming diets low in iron-rich foods, such as green leafy vegetables, legumes,

and animal sources, are more likely to develop anemia. The significant association emphasizes the need for nutritional awareness and dietary interventions tailored to student populations.

Irregular Meal Pattern

Irregular meal patterns were observed in **71.67%** of anemic students, significantly higher than **36.47%** among non-anemic students, with a highly significant p -value of **0.001**. This strong association suggests that inconsistent eating habits contribute substantially to anemia. Skipping meals or eating at

irregular intervals may lead to inadequate overall nutrient intake and poor iron absorption. Academic workload, time constraints, and stress may further exacerbate unhealthy eating behaviors among students.

Heavy Menstrual Bleeding

Heavy menstrual bleeding was reported by **42.50%** of anemic students compared to **13.53%** of non-anemic students, showing a statistically significant association ($p = 0.009$). This finding highlights excessive menstrual blood loss as an important physiological determinant of anemia, particularly among female students. Without adequate iron replenishment, recurrent menstrual blood loss can rapidly deplete iron stores, leading to anemia. This underscores the importance of menstrual health assessment and counseling as part of anemia prevention strategies.

High Academic Stress

High academic stress was reported by **60.83%** of anemic students and **30.00%** of non-anemic students, with a borderline statistical association ($p = 0.054$). Although this association did not reach conventional levels of statistical significance, the observed trend suggests that academic stress may indirectly contribute to anemia. Stress can influence dietary intake, sleep patterns, and hormonal balance, potentially affecting nutrient metabolism and hemoglobin synthesis.

Figure 2 demonstrates that anemia constitutes a significant public health concern among the studied students. A substantial proportion of participants were identified as anemic, indicating that anemia remains prevalent even in an

apparently healthy, academically active population. This finding highlights the persistent burden of nutritional and physiological deficiencies among young individuals, particularly in settings where dietary practices, lifestyle habits, and academic pressures may adversely influence health status. The proportion of non-anemic students, though comparatively higher, does not diminish the importance of the anemic group, as the observed prevalence exceeds what would be expected in a nutritionally secure population. The presence of anemia in this age group is particularly concerning because it can negatively affect physical endurance, cognitive performance, attention span, and overall academic productivity. Figure 3 suggests that anemia is not confined to marginalized or clinically ill populations but extends to students who may otherwise appear healthy.

Furthermore, the visual representation underscores the need for early screening and preventive strategies within educational institutions. The relatively high prevalence depicted in Figure 1 supports the necessity for targeted nutritional interventions, regular hemoglobin assessment, and health education programs focusing on balanced diets and micronutrient adequacy. Overall, Figure 1 sets the foundation for understanding the magnitude of anemia in the study population and justifies further exploration of its severity and associated risk factors, as presented in Tables 1 and 2.

Discussion

The present study included an adequate representation of both male and female students, allowing meaningful interpretation of gender-related

determinants of anemia. The balanced gender distribution strengthens the external validity of the findings and enables comparison with existing literature. The observed prevalence of anemia among students, despite being an academically active and seemingly healthy population, indicates that anemia continues to be a significant public health issue among young adults. Similar findings have been reported in recent studies. A cross-sectional study by Kaur et al. [11]. reported a high prevalence of anemia among college students, particularly among females, attributing this to increased iron requirements and menstrual blood loss. Likewise, Abioye et al. [12] observed that anemia remains prevalent among young adults even in urban and educated populations, emphasizing the role of dietary inadequacy and lifestyle factors. In contrast, a study by Suryanarayana et al. [13] reported a comparatively lower prevalence of anemia among male students, suggesting better dietary intake and lower physiological iron loss. Another study conducted in South Korea by Kim et al. [14] found minimal gender differences in anemia prevalence, possibly due to better nutritional awareness and fortified food consumption. These contrasts may reflect regional differences in dietary practices, health awareness, and public health interventions.

Severity of anemia among students in the present study, mild anemia constituted the majority (62.31%) of anemia cases, followed by moderate (26.15%) and severe anemia (11.54%). This pattern suggests that while most students are in the early stages of anemia, a considerable proportion have clinically significant forms that may adversely affect health and academic performance.

Comparable severity distributions have been reported in recent literature. Petry et al. observed that mild anemia was predominant among young adults, but emphasized that even mild anemia can impair cognitive function and physical endurance. Similarly, Pasricha et al. [15] highlighted that moderate and severe anemia among adolescents often reflects long-standing nutritional deficiencies and poor dietary diversity.

Conversely, a study by Verma et al. [16] reported a lower proportion of severe anemia among college students, attributing this to early detection and iron supplementation programs. Another contrasting report by Alqaiz et al. [17] found predominantly mild anemia with very few severe cases, suggesting effective preventive health services. The higher proportion of moderate and severe anemia in the present study may indicate gaps in screening and intervention strategies.

Dietary Factors and Anemia The study demonstrated a significant association between inadequate iron intake and anemia ($p = 0.034$). This finding reinforces the established role of dietary iron deficiency as a major contributor to anemia, particularly among students who may consume calorie-dense but nutrient-poor diets. Supporting evidence comes from Gibson et al. [18], who reported that insufficient intake of bioavailable iron is a leading cause of anemia among young adults. Similarly, Neumann et al. [19] emphasized that plant-based diets without adequate iron enhancers increase anemia risk. In contrast, Tiwari et al. [20] found no significant association between iron intake and anemia, suggesting that factors such as absorption inhibitors and chronic inflammation may play a larger role. Another study by Park et al. [21] reported

adequate iron intake among students but persistent anemia, highlighting the role of non-dietary causes.

Irregular Meal Patterns and Anemia
Irregular meal patterns showed a strong and highly significant association with anemia ($p = 0.001$). This suggests that meal skipping and inconsistent eating habits adversely affect overall nutrient intake and iron absorption. This finding aligns with Mistry et al. [22], who reported that students with irregular meals had significantly lower hemoglobin levels. Similarly, Alam et al. demonstrated that meal skipping was strongly associated with anemia among university students. However, Lee et al. [23] found no significant association between meal regularity and anemia, attributing this to widespread food fortification.

Menstrual Factors and Anemia
Heavy menstrual bleeding was significantly associated with anemia ($p = 0.009$), underscoring its importance as a physiological determinant among female students. This is consistent with findings by Munro et al. [24], who identified heavy menstrual bleeding as a major risk factor for iron deficiency. In contrast, study by Wang et al. [25] found no significant association, possibly due to widespread iron supplementation [26].

Academic Stress and Anemia
Although high academic stress showed only a borderline association with anemia ($p = 0.054$), the trend suggests a potential indirect relationship. Supporting studies by Mikkelsen et al. [27] indicate that chronic stress affects dietary intake and micronutrient metabolism. Conversely, Benton et al. [28] found no direct association between stress and anemia, suggesting resilience factors among students.

Conclusion

According to the current study, 43.3% of participants had anemia, mostly in the moderate category, indicating a significant incidence among undergraduate medical students. Students who had irregular eating schedules or insufficient iron intake were more vulnerable than female students, especially those who experienced significant menstrual bleeding. Lifestyle and dietary variables revealed as major influencers, despite a borderline connection with high academic stress. These results demonstrate that even a population with medical awareness is susceptible to avoidable anemia. Regular hemoglobin test, nutritional advice, and health education are crucial for early detection. Anemia prevalence can be successfully decreased by promoting a balanced diet, attending to menstruation health, and supporting regular eating habits. All things considered, the study emphasizes the necessity of institutional measures to protect students' academic performance and health.

Recommendation

To facilitate early identification, medical students should undergo routine screening for anemia. Programs for nutrition education that support balanced meals and diets high in iron are crucial. Female students should get counseling on managing severe monthly bleeding and menstrual health. Stress reduction and good lifestyle practices, such as getting enough sleep and exercising, ought to be promoted.

Statements and Declarations

Conflicts of interest

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

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ORIGINAL ARTICLE

A Twenty Five Year Retrospective Study on the Clinico-Histopathological Correlation of Hansen's Disease, Trends, Dynamics of the Spectral Rami and Psycho-Temperamental Incline, in a Tertiary Care Hospital in South India

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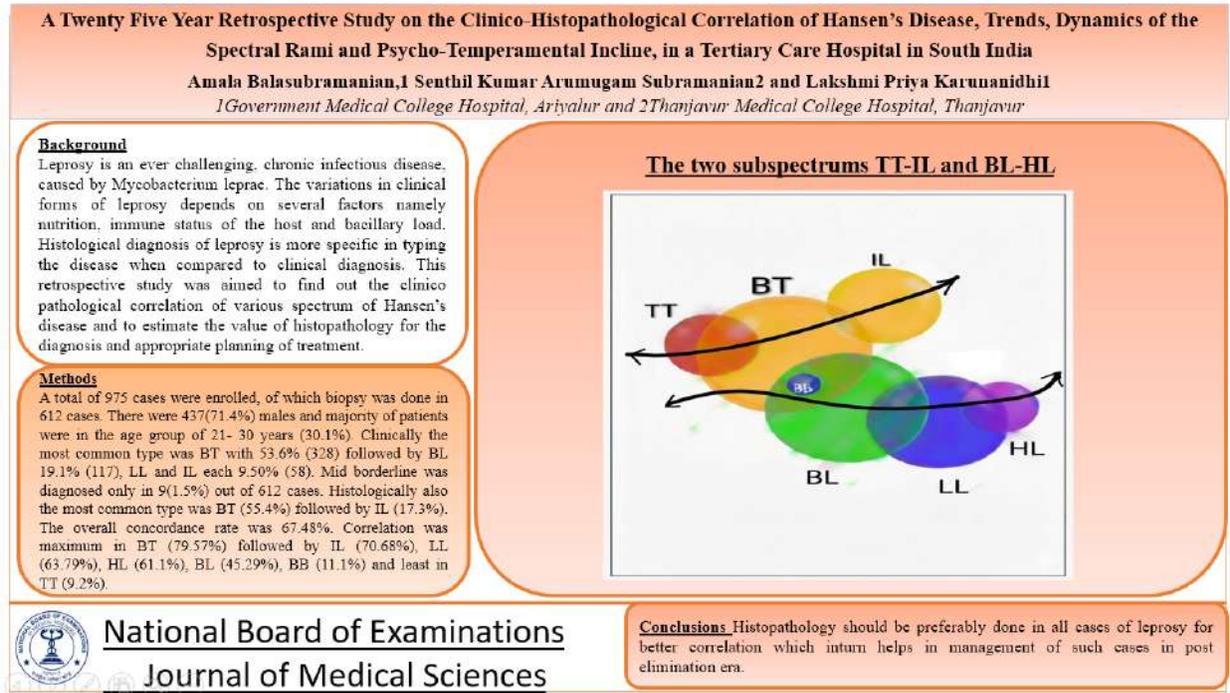
Abstract

Background: Leprosy is an ever challenging, chronic infectious disease, caused by *Mycobacterium leprae*. The variations in clinical forms of leprosy depends on several factors namely nutrition, immune status of the host and bacillary load. Histological diagnosis of leprosy is more specific in typing the disease when compared to clinical diagnosis. This retrospective study was aimed to find out the clinico pathological correlation of various spectrum of Hansen's disease and to estimate the value of histopathology for the diagnosis and appropriate planning of treatment. **Materials and Methods:** All clinically diagnosed cases of leprosy enrolled in the leprosy register between January 2001 to December 2025 were analysed retrospectively. Clinical diagnosis was correlated with that of histopathological diagnosis. **Results:** A total of 975 cases were enrolled, of which biopsy was done in 612 cases. There were 437(71.4%) males and majority of patients were in the age group of 21- 30 years (30.1%). Clinically the most common type was BT with 53.6% (328) followed by BL 19.1% (117), LL and IL each 9.50% (58). Mid borderline was diagnosed only in 9(1.5%) out of 612 cases. Histologically also the most common type was BT (55.4%) followed by IL (17.3%). The overall concordance rate was 67.48%. Correlation was maximum in BT (79.57%) followed by IL (70.68%), LL (63.79%), HL (61.1%), BL (45.29%), BB (11.1%) and least in TT (9.2%). **Conclusion:** Histopathology should be preferably done in all cases of leprosy for better correlation which inturn helps in management of such cases in post elimination era.

Keywords: Leprosy, *Mycobacterium leprae*, projected bias, Ridley-Jopling classification, Histopathology

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Graphical Abstract



Introduction

Leprosy, also known as Hansen's disease, is a curable, chronic granulomatous infectious disease caused by *Mycobacterium leprae*. It mainly affects peripheral nerves and skin but can affect any other site such as the eyes, bones, mucous membranes, testes and internal organs and produces a spectrum of clinical types depending upon the immune status of the host [1–3]. Hansen's disease causes bodily disability of multiple forms along with commensurate and reciprocal psychological morbidity, resulting in fear and stigma of the highest proportions [4–6].

Since the days of antiquity leprosy had been documented in literature. The New Testament talks of the socially ostracised patients and a model destigmatisation campaign for the public view. Tamils had classified leprosy into *tolunōy* (etymology

from *tolu*, a cattle manger or stall; and *tolumarai*, a disease with round patches all over the body of cattle), *peruñcorikkurai* (a virulent form of leprosy with eruptions, probably Erythema Nodosum Leprosum), *perunōy* (features similar to rinderpest a disease of the cattle), *veppu* (appearance similar to a type I lepra reaction), *alīnōy* (resorption of bones), and *kārakkurai* (black, necrotic autoamputation), in Cankam literature like *Maturaiikkāñci:69* and *Kalittokai:65*, two millennia ago. Aretaeus of Cappadocia, the celebrated Greek physician also described the clinical features including leonine facies of *elephantos*, in the second century CE. Leprosy had been mentioned as *rai/kattai* in Japanese literature including Nihon Shoki Chronicles, and as *likprá* in Old Norse-Icelandic texts.

The disease spectrum has been characterised in a number of classification systems, among which Ridley-Jopling classification is most widely used. According to this classification, leprosy has been divided into Tuberculoid (TT), Borderline tuberculoid (BT), Mid borderline (BB), Borderline Lepromatous (BL), and Lepromatous (LL) based on clinical, bacteriological, immunological and histological criteria [7]. Indeterminate leprosy (IL) denotes lesions not localizable on the Ridley-Jopling range of spectrum due to absence of distinctive discerning characteristics, especially histopathologically than clinically. In 1982, World Health Organization (WHO) proposed simplified classification of pauci and multibacillary leprosy based on clinical features and bacteriological index to facilitate diagnosis and treatment of leprosy in the field [8]. According to this classification, IL, TT, and BT cases were included under paucibacillary (PB) treatment regimen, and BB, BL, and LL cases of leprosy were included under multibacillary (MB) treatment regimen. In addition to classical types of leprosy, a new variant of leprosy has been described by Wade in 1960, known as "histoid leprosy" [9]. Initially it was reported in multibacillary patients, who were on irregular or inadequate dapsone monotherapy, but later de novo cases were also reported. Sehgal has reported that histoid leprosy has a distinct position in the leprosy spectrum and that it might not be considered as a variant of LL [10].

Though Government of India declared leprosy eliminated from India in January 2006, still it is considered as a

serious public health problem with social stigma. Clinical diagnosis in some leprosy cases can be difficult which leads to occurrence of resistant cases if inadequately treated. Skin biopsies play an important role in confirming the clinical diagnosis and helps in classifying different types of leprosy for proper treatment [6]. This study had been done to find out the concordance between the clinical and histopathological diagnosis in cases of leprosy using Ridley- Jopling scale.

Materials and Methods

This retrospective study was conducted in leprosy patients, who attended the Dermatology Department, in a tertiary care hospital at south India between the period of January 2001 to December 2025. After Institutional Ethics Committee approval, all the newly diagnosed untreated cases of leprosy were selected regardless of their age, sex, occupation and socioeconomic status by consecutive sampling. Clinical diagnosis was made based on history and clinical examination. Skin biopsies were obtained from the lesions processed and stained with Haematoxylin and Eosin. Ridley-Jopling classification was followed in both clinical and histopathological diagnosis. Patients with Indeterminate leprosy (IL) and histoid leprosy (HL) were also included in the study for purpose of analysis. Histopathological evaluation included changes of epidermis, involvement of sub-epidermal zone, neurovascular bundle and adnexae, density of lymphocytes, epithelioid cells and formation of granuloma, other cellular elements and the presence of bacilli [7]. Statistical analysis was done using SPSS version 17. Slit skin smear (SSS) results were

not included in this study because it was not done uniformly for all patients at the time of diagnosis.

Results

About 975 leprosy patients who were clinically diagnosed during the study period and 363 were excluded as biopsy was not done due to various reasons and remaining 612 patients were included as biopsy was performed in these cases. Among them 437 (71.40%) were males and 175(28.60%) were females with male to female ratio of 2.4:1. Age group of the patients ranged from 4 to 81 years with the mean age of 34.5 years. Majority of patients were in the age group of 21-30 years (30.10%) and least affected were less than 10 years (3.43%) (Table 1). Clinical presentation of various types of leprosy cases

is shown in Table 2. Table 3 shows histopathological distribution of cases.

Correlation of clinico histopathological diagnosis is shown in table 4. Overall concordance of diagnosis was observed in 67.48% of cases. As chance is not corrected for in an analysis of the similarities between the proportions presence or absence of agreement, it is a weaker measure. Kappa is the statistic of choice as it incorporates calibration for chance and is helpful in quantifying group-variability between the objectively clinico-morphological and the tissue-based histopathological diagnoses. In essence, it implies the frequency of similar interpretations in these two diagnostic modalities. Kappa value of this study was 0.503, indicates the poor strength of agreement and P value was <0.001 hence, this study is more significant.

Table 1. Age distribution of the leprosy cases

Age group(years)	No. of cases	Percentage
0 - 10	21	3.43%
11 - 20	77	12.58%
21 - 30	184	30.10%
31 - 40	146	23.90%
41 - 50	94	15.40%
51 - 60	56	9.20%
> 60	34	5.60%

Table 2. Clinical presentation of leprosy cases

Clinical types	No. of cases	Percentage
Tuberculoid leprosy (TT)	24	3.90%
Borderline tuberculoid leprosy (BT)	328	53.60%
Mid borderline leprosy (BB)	9	1.50%
Borderline lepromatous leprosy (BL)	117	19.10%
Lepromatous leprosy (LL)	58	9.50%
Indeterminate leprosy (IL)	58	9.50%
Histoid leprosy (HL)	18	2.90%

Table 3. Histopathological distribution of leprosy cases

Histopathological types	No. of cases	Percentage
Tuberculoid leprosy (TT)	17	2.80%
Borderline tuberculoid leprosy (BT)	339	55.40%
Mid borderline leprosy (BB)	7	1.10%
Borderline lepromatous leprosy (BL)	71	11.60%
Lepromatous leprosy (LL)	50	8.20%
Indeterminate leprosy (IL)	106	17.30%
Histoid leprosy (HL)	22	3.60%

Table 4. Clinico-histopathological correlation

Clinical diagnosis	No of cases	Histopathological diagnosis							CPC%
		TT	BT	BB	BL	LL	IL	HL	
TT	24	9	11	0	0	0	4	0	9/24 (9.2%)
BT	328	7	261	4	2	0	54	0	261/328 (79.57%)
BB	9	0	5	1	3	0	0	0	1/9 (11.1%)
BL	117	0	45	1	53	9	7	2	53/117(45.29%)
LL	58	0	1	1	10	37	0	9	37/58(63.79%)
IL	58	1	16	0	0	0	41	0	41/58(70.68%)
HL	18	0	0	0	3	4	0	11	11/18(61.1%)
TOTAL	612	17	339	7	71	50	106	22	413/612(67.48%)

CPC: Clinico pathological correlation

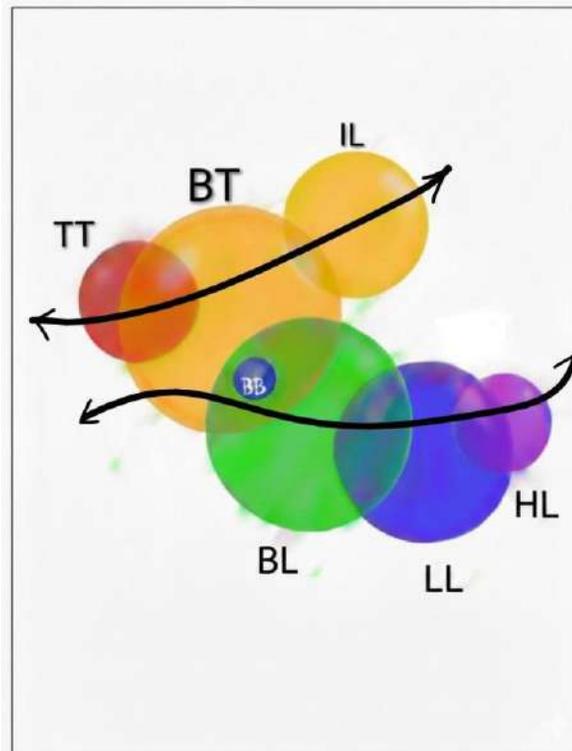


Figure 1. The two subspectrums TT-IL and BL-HL, and overlapping from clinicohistopathological correlation

Discussion

Leprosy, a chronic granulomatous infectious disease, still continues to be a serious health problem with prevalence rate of 0.57 per 10,000 in India, as per National Leprosy Eradication Programme Annual Report: 2024-2025. Accurate classification of leprosy is needed as the disease manifests in different clinicopathological forms. In the present study, presentation of leprosy was found to be slightly more prevalent in males (71.40%) than in females, with male to female ratio of 2.4: 1. These finding correlates with other studies conducted by Gridhar et al. (77.6%), Bhushan et al (72.34%), Kakkad et al. (82%) & Bijjaragi et al. (64.3%) [11–14]. This male preponderance is due to various socio-cultural factors like poor knowledge, illiteracy and strong tradition leading to under reporting of leprosy in females due to gender bias.

Majority of cases were seen in the age group of 21-30 years. Age of the youngest patient was 4 years and oldest was 80 years. These results were also similar to other studies conducted by Bijjaragi et al., Tiwari et al and Banushree et al. [4,14,15]. Children below 10 years of age were only 3.43%, which revealed that there might have been mis diagnosis in this group and many may not be attending the hospital.

In our study the common type of leprosy both clinically and histopathologically was BT (53.6%). Borderline group constituted the major spectrum (74.2%), which included BT, BB, and BL and is similar to findings of other authors namely Shivaswamy et al. 2012, Manandhar et al. 2013 and Rizvi et al. 2015

[16-18]. Maximum clinico-histopathological correlation was observed in BT (79.57%) followed by IL (70.68%), LL (63.79 %) and HL (61.10%), BL (45.29%), B (11.1%) and TT (9.2%). When we considered LL and HL together as one group, the concordance was maximum i.e., 80.26% which because of their stable histopathology and similar results were reported by Mathur et al. (95%), Mohan et al. (97.2%), Moorthy et al. (80%) and Kakkad et al. (93.3%) [13,19–21]. In this study kappa value was 0.503, which indicates the poor strength of agreement. Overall Clinico-pathological concordance of this study was 67.48%, which was also similar to other studies. Pandya et al., reported a concordance of 58%, Tiwari et al. 54% and Manandhar et al., reported the least concordance of 45.33% [15,17,22]. Expectation of some discordance between morphological and diagnostic histological findings is reasonable as the determinants upon which the histopathological typification is founded are clearly defined and delineated with precision, while only the external presentation of the dermatological lesions direct the clinicomorphological stratification [23]. Typical microscopic pathological findings have been noted to be preceded by clinical signs in early subjects occasionally. A high probability of incongruence between the morphological and histological results exists in the event of very early tissue biopsies. As dissonant variance is founded upon the loci of the lesion sampled in the time period of the research, serial tissue sampling from the very loci or from adjacent lesions ought to be evaluated for consistency of diagnoses.

In the present study, 106 cases were diagnosed as IL histologically, whereas only 58 of these cases were clinically considered. Four cases of TT, 54 cases of BT and 7 cases of BL were histologically diagnosed as IL. This high percentage of IL noted histologically could have been due to immunological difference in the host response. The diagnosis of IL also depends on many factors such as age of the lesion, nature and depth of biopsy, quality of sections and number of sections examined.

Out of 24 clinically diagnosed TT cases, histologically minor disagreement (difference of one group e.g. TT-BT) was seen in 11 cases. This could have been due to BT and TT often overlap clinically, histologically and immunologically but differ only in some features, e.g. erosion into the epidermis with absence Grenz zone in TT. Both TT and BT are under paucibacillary group hence, these minor disagreement does not affect the chemotherapy and outcome of the disease.

Among the patient classified clinically as BT, 4 cases were mid borderline (BB) and 2 cases were BL histologically. According to WHO classification, BB, BL and LL cases were included under multibacillary group. Without a biopsy if we had started on WHO Paucibacillary treatment only on the basis of clinical diagnosis, there might have been a chance for relapse as the treatment would have been inadequate. Similarly in 117 cases of BL, 45 cases were histologically BT which showed only Paucibacillary regimen of 6 months was sufficient in these patients. These patients also would have been overtreated with one

more additional drug and for six more months which was not needed.

Surprisingly out of 58 cases of LL one case turned out to be BT histologically. This is very vital because of the lesser rate of transmission of BT and also for treatment aspect. Out of 9 clinically diagnosed cases of BB, 5 were BT and 3 were BL histologically, which was a minor disagreement of difference in one group. It was anticipated because mid borderline leprosy is immunologically least stable type of leprosy. When we considered TT and BT together as one group, and also LL and BL together as other group, concordance was maximum *i.e.* 81.8% for TT-BT group and 72% for BL-LL group.

Projected bias perspective and other inferred dynamics of the spectral pattern

The results of the study provide us a glimpse of restricted directional tendency of the BT-LL core of the histopathological spectrum and its ramification. The following inferences highlight on the dynamics of the spectral pattern, and the almost fixed localized pockets of confluence within the subspectrums TT-IL and BL-HL.

- a. Inadvertent bias or psycho-temperamental inclination can not be completely ruled out as it is a retrospective study. Assuming synchronicity, when both methods of diagnosis were compared in the clinicopathological correlation, diagnosis in the clinically diagnosed TT group appears 45.8% (11/24) negatively biased (false negative for BT) against a clinical BT diagnosis; 55.6% (5/9) in the BB

group, 38.5% (45/117) in the BL group, 27.6% (16/58) in the IL group were similarly biased against BT diagnosis. Otherwise, about 16.5% (54/328) in the BT group were in turn biased against a clinical IL diagnosis. This implies a possibility of an average of 41.9% negative bias in diagnosing BT among all other clinically diagnosed subtypes, thus more BT were being diagnosed clinically as other subtypes.

- b. It is evident that there is overlapping of clinical diagnosis between the subtypes within BT subspectrum (TT, BT and IL), and between the subtypes within LL subspectrum (BL, LL and HL) over the course of illness. In case of asynchronicity (undetermined in this study due to incomplete data on the time interval) with varying intervals between clinical diagnosis at index visit and last confirmatory biopsy, the above overlaps may be implying a possible graded progression and occasional regression within the two corresponding subspectrums in due course. It also unmasks an one-to-one overlapping of diagnostic features exclusively between BT-BL (Figure 1).
- c. This correlation statistically proved IL to be a part of the BT spectrum (requiring PB regimen) as there is no apparent exclusive overlap (i.e. not involving a BT overlap) between IL and the LL subspectrum.
- d. Statistically it appears there is no true BB subtype, as its frequency distribution is inconspicuous caught deep within the multiple overlaps of other (primary) subtypes.

- e. No significant difference ($\chi^2=4.505$, $p=0.60$) was found between the distribution of cases in various subtypes in both clinical and histopathological groups.

Positive psycho-temperamental inclination in beneficiary and benefactor

The annual prevalence rates of leprosy in India have been found almost static over the past decade around 0.57 ± 0.10 per 10,000 [24]. Reasons may include among others, the shift from vertical to integrated implementation of the eradication programme and surveillance, and apparently increasing ignorance and minimization of the seriousness of the complications even among literates that has led to frequent delay in availing preliminary medical consultation. The latter is a major contributory factor in the recent higher incidence of grade 2 deformity (G2D) at index diagnosis, and increased incidence in paediatric age group (10-23% of new cases and more MB proportion). This is more glaring when compared to the flattening of the adolescent and young adulthood peak in the age-specific incidence of the still fatal tuberculosis caused by another bacteria of the same mycobacterium genus. Compounding psychiatric morbidity to the locomotor and/or sensory disability and targetted incentivization can help propagate community awareness on the seriousness and the availability of more deserving support from government social welfare institutions.

Suggested future directions for India

1. To begin with, the annual declaration of the prevalence rates of leprosy in India should list state-wise rates ranking them

along with the rates of the world countries, to increase the objectivity, and set more aggressive goals and revamp the protocols. Understanding the true position of states like Odisha, Andhra Pradesh and Tamil Nadu on the global ranking list and comparing them on par with the ranks of countries like Netherlands, Brazil and Austria, will motivate and help sustain the drive effectively.

2. Providing adequate and appropriate disability certification and benefits should encourage caregivers for drug adherence and nutrient-rich diet, in turn reducing dropouts and community carrier states, and promoting safe palliative care. Disability percentage increment accounting for the secondary depression and other psychiatric conditions over and above the estimated locomotor disability, would provide better incentive that the patients deserve.
3. Use of Artificial Intelligence driven schematics especially “an AI with a psyche,” would help devise strategies to track down isolated pockets to defuel continued transmission, to overcome mass screening challenges, to enforce statutory Post Exposure Prophylaxis, and establish simultaneous parallel, competing, multidimensional programmes to completely eliminate the bacteria in the environment, and even theorize a possible elusive new intermediate animal host.
4. Reviving of house-to-house surveillance and routine skin smear examination of the bygone era, use of screening tools like WHO-Skin NTD app, novel drugs like

bedaquiline and telacebec, and trials of leprosy vaccines should be applied in the field.

Conclusion

Leprosy, though considered to be eliminated from India, is not eradicated completely and still prevalent in various parts of India and other countries. A gold standard for the diagnosis of leprosy cannot be established since the clinical features varies with immune status of the host. However, skin biopsy is a useful tool in confirming the clinical diagnosis and hence correlation of clinical and histopathological examination along with bacteriological index should be carried out in all cases to determine the spectrum of leprosy which inturn helps in initiation of multidrug therapy and elimination of the disease.

Limitations

Our study is a record based, retrospective study. A prospective study may give better concordance. Bacteriological index was not included in this study and inter-observer variations regarding the clinical and histopathological observations exists.

Statements and Declarations

Conflicts of interest

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

Funding

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ORIGINAL ARTICLE

A Randomized Comparative Study of Peritoneal Closure versus Non-Closure During Open Appendicectomy

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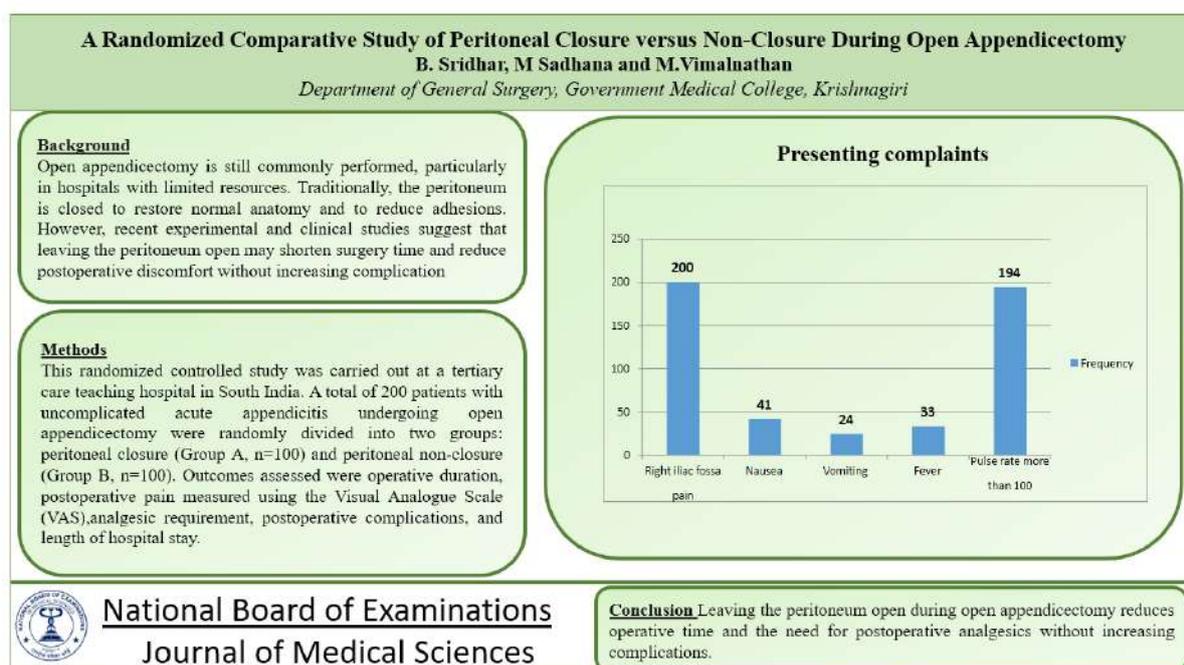
Abstract

Background: Open appendicectomy is still commonly performed, particularly in hospitals with limited resources. Traditionally, the peritoneum is closed to restore normal anatomy and to reduce adhesions. However, recent experimental and clinical studies suggest that leaving the peritoneum open may shorten surgery time and reduce postoperative discomfort without increasing complications. **Objectives:** To compare peritoneal closure and non-closure during open appendicectomy in terms of operative time, postoperative pain, need for analgesics, length of hospital stay, and postoperative complications. **Methods:** This randomized controlled study was carried out at a tertiary care teaching hospital in South India between October 2017 and October 2018. A total of 200 patients with uncomplicated acute appendicitis undergoing open appendicectomy were randomly divided into two groups: peritoneal closure (Group A, n=100) and peritoneal non-closure (Group B, n=100). Outcomes assessed were operative duration, postoperative pain measured using the Visual Analogue Scale (VAS), analgesic requirement, postoperative complications, and length of hospital stay. Data were analyzed using SPSS software, and a p-value <0.05 was considered statistically significant. **Results:** The mean operative time was significantly shorter in the non-closure group (87.5 minutes) compared to the closure group (100 minutes) (p<0.001). A higher requirement for postoperative analgesics was seen more often in the closure group (41%) than in the non-closure group (25%) (p=0.016). Postoperative pain scores, complication rates, and duration of hospital stay were similar in both groups. **Conclusion:** Leaving the peritoneum open during open appendicectomy reduces operative time and the need for postoperative analgesics without increasing complications. This supports the routine use of peritoneal non-closure in patients with uncomplicated appendicitis.

Keywords: Open appendicectomy, Peritoneum, Non-closure, Postoperative pain, Operative time

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Graphical Abstract



Introduction

Acute appendicitis is one of the most common surgical emergencies worldwide, and appendectomy is among the most frequently performed abdominal surgeries [1]. Though laparoscopic appendectomy is increasingly used, open appendectomy is also still practiced in some developing countries because of limited resources and surgeon preference [2].

Commonly, during open appendectomy, the parietal peritoneum is closed with the belief that it helps restore normal anatomy and also helps in reducing adhesion formation [3]. However, studies have shown that the peritoneum has a natural ability to heal quickly, with re-formation of the peritoneal lining which usually happens within 48–72 hours even without suturing [4].

Several experimental and clinical studies noted that suturing the peritoneum may cause local tissue damage thus reducing the blood supply, inflammation,

and reaction to suture material, which may increase postoperative pain and actually promote adhesion formation rather than preventing it [5,6]. In contrast, leaving the peritoneum unclosed has been noted to be associated with shorter operative time, less postoperative pain, reduced need for analgesics, and faster recovery in various abdominal and obstetric surgeries [7–9].

There is substantial evidence supporting peritoneal non-closure in procedures like cesarean sections and major abdominal surgeries. Data specific to open appendectomy are limited and show variable results, particularly in the Indian setting [10]. Given the large number of appendectomies performed, even small improvements in surgical time and postoperative recovery may have important clinical and economic advantages.

Therefore, the present randomized controlled study was conducted to compare peritoneal closure and non-closure during open appendectomy in terms of operative duration, postoperative pain, analgesic

requirement, length of hospital stay, and postoperative complications.

Materials and Methods

Study Design and Setting

A randomized controlled study was carried out in the Department of General Surgery, Government Stanley Medical College and Hospital, Chennai, over a one-year period from October 2017 to October 2018.

Study Population

Patients aged between 15 and 65 years who were clinically and radiologically diagnosed with uncomplicated acute appendicitis and underwent open appendicectomy were included in the study.

Exclusion Criteria

Patients with perforated appendix, appendicular abscess or mass, generalized peritonitis, pregnancy, immunocompromised conditions, diabetes mellitus, chronic kidney or liver disease, malignancy, psychiatric illness, or those unwilling to give consent were excluded.

Sample Size

The sample size was calculated based on postoperative analgesic requirement using data from a previously published Indian study comparing peritoneal closure and non-closure during open appendicectomy [11]. The mean analgesic requirement reported was 48.9 ± 47 units in the closure group and 23.5 ± 40.8 units in the non-closure group. With a two-sided alpha error of 0.05 and a power of 80%, the minimum sample size required was 47 patients in each group. To improve the reliability of results, 100 patients were

included in each group, giving a total sample size of 200.

Randomization and Intervention

Patients were randomly assigned into two groups based on computer generated randomisation:

- Group A: Open appendicectomy with peritoneal closure
- Group B: Open appendicectomy with peritoneal non-closure

All surgeries were performed using standard open appendicectomy techniques. Except for the peritoneal closure step, all other surgical steps were the same in both groups.

Outcome Measures

The primary outcomes were operative time and postoperative analgesic requirement. Secondary outcomes included postoperative pain measured using the Visual Analogue Scale (VAS), postoperative complications, duration of hospital stay, and persistence of pain during follow-up. Blinding was not done at any level.

Postoperative Management

All patients received the same postoperative analgesia in the form of injectable diclofenac for three days. Patients who needed additional or prolonged analgesia were considered to have a high analgesic requirement.

Statistical Analysis

Data analysis was done using SPSS software. Quantitative data were expressed as mean \pm standard deviation, and qualitative data as frequencies and percentages. The Chi-square test and independent t-test were used where

appropriate. A p-value of less than 0.05 was taken as statistically significant.

Results

Table 1 shows that the study included 200 patients with a mean age of 26.2 years, and most participants were males (63.5%), indicating a young male-predominant population. Table 2 demonstrates that the non-closure group had a significantly shorter mean operative time (87.5 minutes) compared to the closure group (100 minutes) ($p < 0.001$), and fewer patients required high doses of analgesics (25% vs 41%, $p = 0.016$), suggesting less postoperative discomfort. Table 3 further confirms that a larger proportion of patients in the non-closure group completed surgery in less than 60 minutes, while most closure

group surgeries exceeded 90 minutes ($p < 0.0001$). Postoperative pain scores (VAS) were similar in both groups ($p = 0.8388$), indicating that non-closure did not increase pain perception. Postoperative complications were low and comparable between groups ($p = 0.174$), showing that non-closure is safe. Hospital stay was significantly shorter in the non-closure group ($p = 0.012$), and pain persistence at one month was significantly lower (3% vs 14%, $p = 0.0052$), although there was no difference at 15 days or 3 months. Overall, non-closure reduces operative time, decreases strong analgesic requirement, shortens hospital stay, and improves short-term recovery without increasing complications.

Table 1. Baseline Demographic Characteristics

Variable	Overall (n=200)
Mean age (years)	26.2 ± 6.7
Male	127 (63.5%)
Female	73 (36.5%)

Table 2. Operative Time and Analgesic Requirement by Study Group

Outcome	Closure (n=100)	Non-closure (n=100)	p value
Mean operative time (minutes)	100	87.5	<0.001
High analgesic requirement	41 (41%)	25 (25%)	0.016

Table 3. Postoperative Outcomes

Outcome	Closure (n=100)	Non-closure (n=100)	p value
Operating Time			
Mean duration	100 min	87.5 min	<0.0001*
<60 minutes	0%	61%	
61-90 minutes	47%	34%	
>90 minutes	53%	5%	
Postoperative Pain (VAS)			
No pain	30%	41%	0.8388 (NS)
Mild pain	37%	46%	
Moderate pain	22%	24%	
Analgesic Requirement			
Standard analgesic	59%	75%	0.016*
High analgesic	41%	25%	
Postoperative Complications			
Present	4%	1%	0.174 (NS)
Absent	96%	99%	
Hospital Stay			
<3 days	21%	30%	0.012*
3-6 days	65%	67%	
>6 days	14%	3%	
Pain Persistence - 15 Days			
Present	83%	78%	

Absent	17%	22%	0.372 (NS)
Pain Persistence - 1 Month			
Present	14%	3%	0.0052*
Absent	86%	97%	
Pain Persistence - 3 Months			
Present	2%	1%	0.561 (NS)
Absent	98%	99%	

*NS = Not Significant; *p<0.05 = Statistically Significant

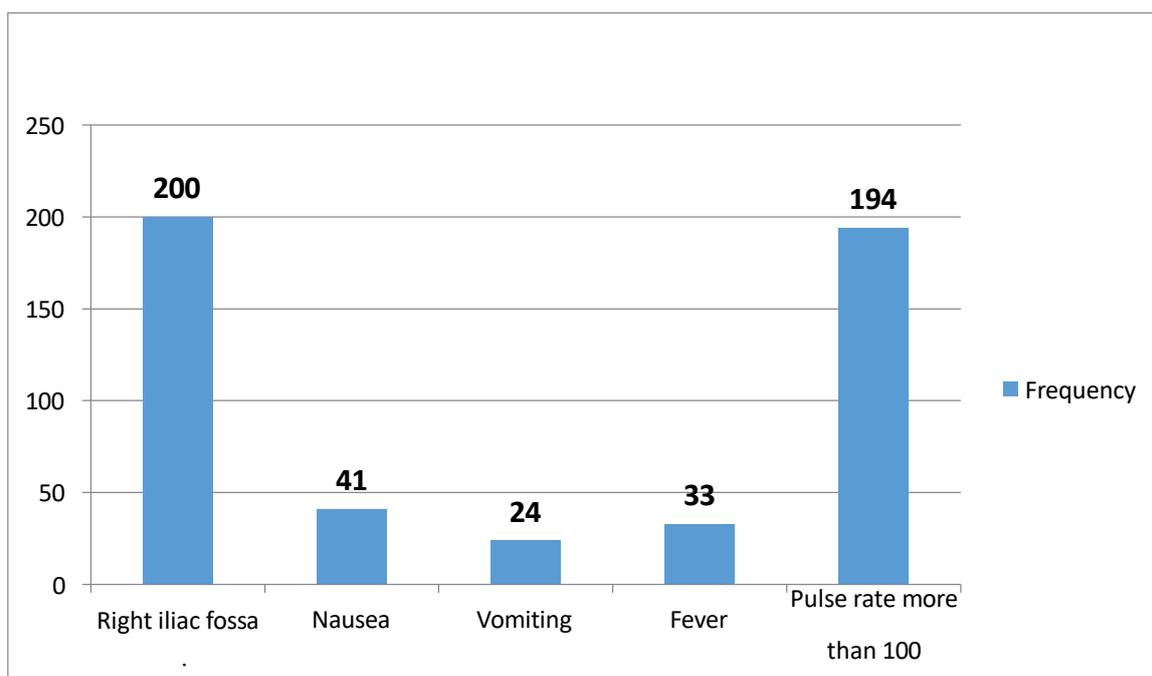


Figure 1. Presenting complaints

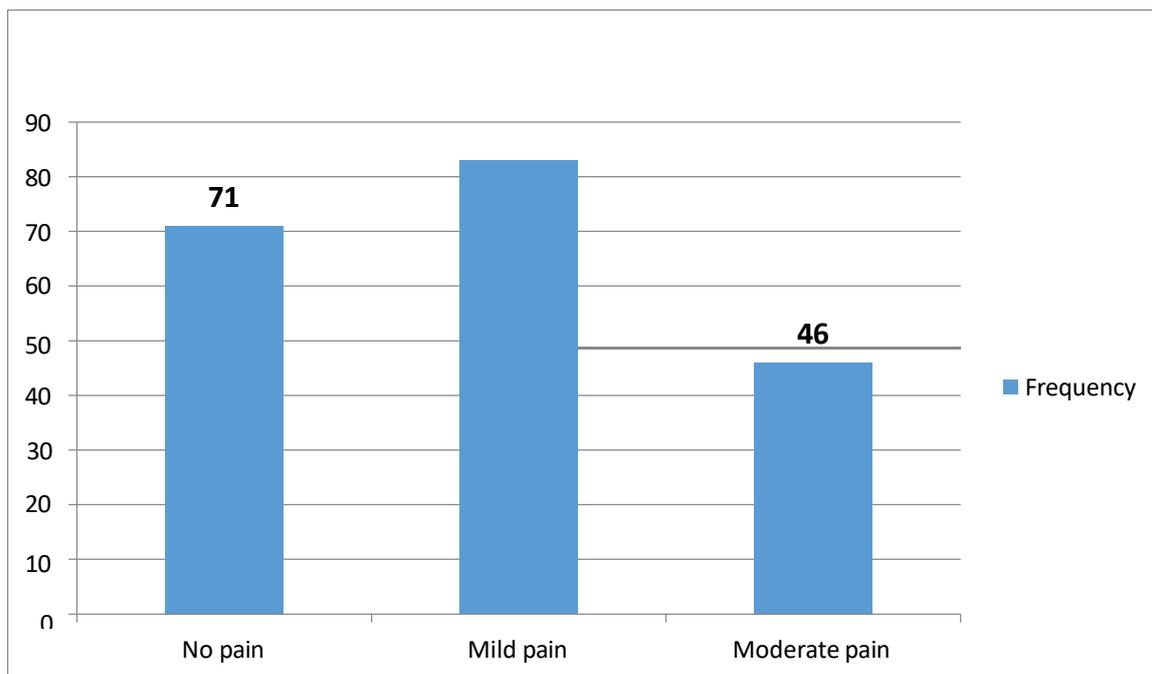


Figure 2. VAS scale

Discussion

This randomized controlled study shows that leaving the peritoneum open during open appendicectomy reduces the operative time and decreases the need for postoperative analgesics, without increasing postoperative complications.

The shorter operative time in the non-closure group is consistent with earlier studies, which report that skipping peritoneal suturing saves time by eliminating an additional surgical step [7,11]. In busy surgical units where many appendicectomies are performed, this reduction in operating time can improve operating room efficiency and may also lower overall treatment costs. A recent study from Bangladesh also reported a significant reduction in operative duration with peritoneal non-closure without affecting patient safety [12].

Patients in the non-closure group required fewer postoperative analgesics. This may be because suturing the peritoneum can cause more tissue handling,

inflammation, and irritation of nerve endings, which can increase postoperative pain [5,6]. Although the VAS pain scores were similar in both groups, the reduced need for additional analgesia in the non-closure group is clinically important. Experimental studies have also shown that peritoneal suturing can trigger inflammatory responses that contribute to pain and adhesion formation through increased pro-inflammatory cytokines and reduced fibrinolysis [13,14].

Importantly, leaving the peritoneum open did not increase postoperative complications such as wound infection or length of hospital stay. This finding is supported by several randomized trials and systematic reviews which conclude that peritoneal non-closure does not raise the risk of surgical site infection or adhesion-related complications [8,9]. The peritoneum has a strong healing ability, and mesothelial cells rapidly regenerate the peritoneal lining within 5–7 days even without suturing [15].

Postoperative adhesions are a common concern after abdominal surgery, occurring in a large proportion of patients undergoing laparotomy [16]. Adhesions can lead to complications such as intestinal obstruction, chronic abdominal pain, infertility, and difficulty during future surgeries. Evidence suggests that peritoneal closure may actually increase adhesion formation due to local ischemia, foreign body reaction to sutures, and prolonged inflammation [17]. Recent reviews also highlight the role of inflammatory processes, macrophage activity, and impaired fibrinolysis in adhesion development, which may be worsened by peritoneal suturing [18].

Adhesion-related complications also impose a significant economic burden due to readmissions and repeat surgeries. Therefore, a simple and cost-effective step like avoiding unnecessary peritoneal closure may have important clinical and economic benefits. Although anti-adhesion barriers such as hydrogels are being developed, non-closure of the peritoneum remains a practical and low-cost strategy [19].

Several Indian studies on open appendicectomy have reported similar findings, especially regarding reduced postoperative pain and analgesic requirement with peritoneal non-closure [10,11]. However, studies in obstetric surgeries have shown variable results, indicating that the impact of peritoneal non-closure may differ depending on the type of surgery and patient characteristics.

Current guidelines for acute appendicitis emphasize early diagnosis and appropriate surgical management. While laparoscopic appendicectomy is now preferred in many centers due to faster recovery and fewer wound complications

[20], open appendicectomy is still widely performed in resource-limited settings. In such settings, peritoneal non-closure is a simple modification that can improve patient outcomes without the need for additional equipment, cost, or advanced surgical expertise.

Conclusion

Peritoneal non-closure in open appendicectomy is a safe and effective option when compared to routine peritoneal closure. It helps reducing the duration of surgery and the need for postoperative pain medication without increasing complications or length of hospital stay. Non-closure of the peritoneum may be routinely considered in patients undergoing open appendicectomy for uncomplicated appendicitis.

Strengths

The main strength of this study is it is randomized controlled study, that helps in reducing selection bias and also improves the reliability of the findings. Adequate sample size with equal numbers in both groups adds to the statistical strength of the study. Clear inclusion and exclusion criteria ensured that only patients with uncomplicated appendicitis were included, making the groups comparable. The use of a standardized surgical technique and uniform postoperative analgesic protocol reduced variation in treatment. The study assessed clinically meaningful outcomes like operative time, postoperative pain, analgesic requirement, complications, and duration of hospital stay.

Limitations

This study has certain limitations. Being a single-center study, the results may not be fully applicable to all clinical

settings. Blinding was not done at any level. Differences in surgeon experience and operating speed could have influenced operative time. The follow-up period was limited, and long-term outcomes such as adhesion-related complications were not assessed. In addition, postoperative pain assessment is subjective, even though a standardized pain scale was used.

Author Contributions

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

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.

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.

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ORIGINAL ARTICLE

Prevalence of Sleep Related Breathing Disorders (SRBD) and the Assessment of Quality of Sleep Among Patients with Chronic Obstructive Pulmonary Disease (COPD): An Analytical Cross-Sectional Study

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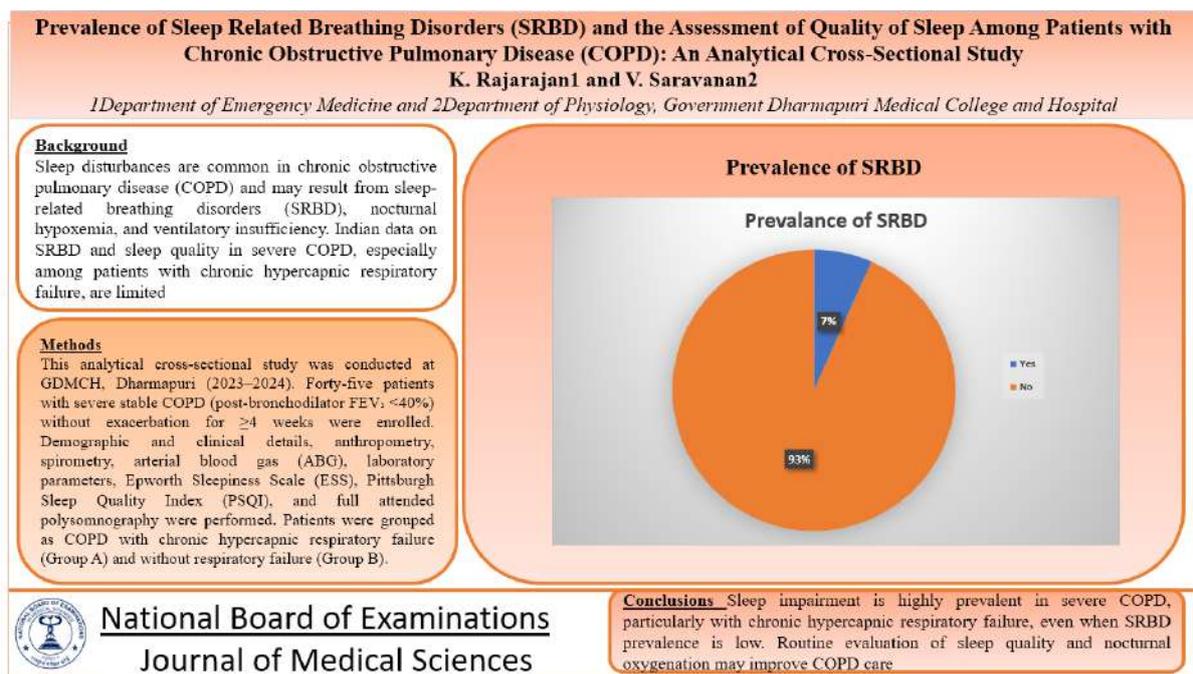
Abstract

Background: Sleep disturbances are common in chronic obstructive pulmonary disease (COPD) and may result from sleep-related breathing disorders (SRBD), nocturnal hypoxemia, and ventilatory insufficiency. Indian data on SRBD and sleep quality in severe COPD, especially among patients with chronic hypercapnic respiratory failure, are limited. **Objectives:** To estimate the prevalence and risk factors of SRBD in COPD, assess sleep quality, and compare sleep parameters between COPD patients with and without chronic hypercapnic respiratory failure. **Methods:** This analytical cross-sectional study was conducted at GDMCH, Dharmapuri (2023–2024). Forty-five patients with severe stable COPD (post-bronchodilator FEV₁ <40%) without exacerbation for ≥4 weeks were enrolled. Demographic and clinical details, anthropometry, spirometry, arterial blood gas (ABG), laboratory parameters, Epworth Sleepiness Scale (ESS), Pittsburgh Sleep Quality Index (PSQI), and full attended polysomnography were performed. Patients were grouped as COPD with chronic hypercapnic respiratory failure (Group A) and without respiratory failure (Group B). **Results:** The mean age was 57.38 ± 7.48 years and 82.2% were males. SRBD prevalence was low, with obstructive sleep apnea in 6.67% (mean AHI 3.33 ± 3.75). Poor sleep quality was common (PSQI 10.07 ± 3.52) with excessive daytime sleepiness (ESS 11.93 ± 5.34). Polysomnography revealed reduced sleep efficiency (64.15 ± 9.10%), shortened total sleep time (264.71 ± 51.68 min), and elevated arousal index (25.39 ± 7.74/h). Group A (n=32) had significantly worse ABG parameters and poorer sleep indices and nocturnal oxygenation than Group B (n=13). **Conclusion:** Sleep impairment is highly prevalent in severe COPD, particularly with chronic hypercapnic respiratory failure, even when SRBD prevalence is low. Routine evaluation of sleep quality and nocturnal oxygenation may improve COPD care.

Keywords: COPD, Sleep quality, Sleep-related breathing disorders, Polysomnography, Chronic hypercapnic respiratory failure

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Graphical Abstract



Background

Chronic obstructive pulmonary disease (COPD) represents a major and growing global health challenge, characterised by persistent airflow limitation and chronic respiratory symptoms. COPD contributes substantially to morbidity, mortality, and healthcare burden worldwide and remains one of the leading causes of death and disability-adjusted life years (DALYs) lost globally [1].

In India, the burden of COPD is substantial and under-recognised. Nationwide systematic reviews indicate that the prevalence of COPD among adults ranges between approximately 7% and 13%, with significant variation by study setting, smoking status, age, and exposure to biomass fuel smoke. Meta-analyses of spirometry-based studies among Indian adults demonstrate a pooled prevalence around 13%, highlighting COPD as a common chronic respiratory disease in the Indian population [2].

India's high COPD burden is driven by a combination of traditional risk factors — tobacco smoking, exposure to biomass fuel smoke, air pollution, and occupational dust — as well as non-traditional contributors including prior pulmonary tuberculosis and childhood respiratory infections. These risk factors, prevalent in both urban and rural settings, contribute to high disease prevalence and high DALY loss, underscoring the need for public health prioritisation [3].

In Tamil Nadu, community-based studies also show a high COPD prevalence, with rural populations demonstrating rates exceeding 20% when evaluated using peak flow measures. These local patterns reflect broader regional trends of COPD associated with increasing age, male sex, smoking history, and environmental exposures such as biomass fuel use [4].

Sleep is a vulnerable physiologic state for individuals with COPD. Normal sleep physiology involves reductions in ventilatory drive, reduced respiratory

muscle activity, and increased upper airway resistance, all of which may exacerbate nocturnal hypoxaemia and respiratory instability in COPD patients. Sleep-associated changes in ventilation disproportionately affect patients with COPD, leading to nocturnal hypoventilation, frequent arousals, and fragmented sleep architecture [5].

Sleep-related breathing disorders (SRBD) — including obstructive sleep apnea (OSA), hypoxia events, and sustained nocturnal desaturation — are frequently observed in COPD populations. Recent meta-analytic evidence suggests that OSA and related sleep disorders affect approximately 29% of COPD patients, with a significant portion also experiencing restless legs syndrome and insomnia. These co-morbid sleep disorders contribute to impaired gas exchange, increased symptom burden, and, in overlap syndromes, worse clinical outcomes than COPD alone [6].

Moreover, sleep disturbances among COPD patients extend beyond SRBDs. Studies consistently demonstrate that a large proportion of COPD patients report poor sleep quality, characterised by prolonged sleep latency, reduced sleep efficiency, frequent arousals, and nocturnal symptoms such as dyspnoea or coughing that fragment sleep. These sleep disruptions are multifactorial, related both to underlying pulmonary pathology and to associated co-morbidities such as anxiety and depression [7].

The impact of poor sleep quality in COPD is clinically meaningful. Beyond subjective complaints, impaired sleep has been linked with worsened daytime function, reduced health-related quality of life, higher rates of exacerbations, and increased healthcare utilisation. Recognising and quantifying sleep quality

and SRBD in COPD patients is therefore essential for comprehensive disease management [8].

Despite this evidence, systematic sleep evaluation — particularly with polysomnography — remains under-utilised in routine COPD care, especially in low- and middle-income settings. This study aims to address these gaps by estimating the prevalence of SRBD and assessing sleep quality among patients with severe stable COPD in a tertiary care setting in India, and by comparing sleep parameters between those with and without chronic hypercapnic respiratory failure.

Objectives

1. To estimate the prevalence of Sleep Related Breathing Disorders (SRBD) and its risk factors among patients with COPD
2. To assess the quality of sleep among patients with COPD.
3. To compare the sleep parameters between patients with and without Chronic Hypercapnic Respiratory Failure

Methodology

This analytical cross-sectional study was conducted at a tertiary care hospital in Dharmapuri, Tamil Nadu, India, between 2023 and 2024 among patients with Chronic Obstructive Pulmonary Disease (COPD) attending regular follow-up. Patients with a clinical history consistent with severe stable COPD and no exacerbation of airway disease for at least four weeks prior to evaluation were considered eligible. Individuals aged more than 80 years, those with known cardiac, hepatic, or renal diseases, and patients with respiratory acidosis were excluded to avoid confounding effects on gas exchange and

sleep parameters. Patients diagnosed with COPD or COPD with pulmonary tuberculosis sequelae were consecutively screened, and those demonstrating severe airflow limitation (post-bronchodilator $FEV_1 < 40\%$) on spirometry were invited to participate. 45 study participants were recruited by purposive sampling and written informed consent was obtained from all eligible participants before enrolment.

All enrolled patients were admitted and underwent detailed clinical evaluation including comprehensive history and physical examination. Anthropometric measurements such as height, weight, body mass index (BMI), neck circumference, and waist circumference were recorded using standard methods. Vital parameters including respiratory rate, pulse rate, blood pressure, and daytime peripheral oxygen saturation (SpO_2) were measured at rest. Arterial Blood Gas (ABG) analysis was performed to assess gas exchange status. Laboratory investigations including fasting and postprandial blood glucose, blood urea, serum creatinine, and liver function tests were conducted to exclude systemic comorbidities. Subjective sleep assessment was carried out using validated questionnaires, namely the Epworth Sleepiness Scale (ESS) for daytime sleepiness and the Pittsburgh Sleep Quality Index (PSQI) for sleep quality.

Overnight full-attended polysomnography (PSG) was performed for a minimum recording duration of six hours. Patients were instructed to retire to bed approximately one hour before their usual sleep time, and recordings were initiated at habitual lights-off and terminated upon spontaneous awakening.

The monitored parameters included electroencephalography (EEG), bilateral electro-oculography (EOG), thoracoabdominal movements using inductance bands, nasal airflow via pressure cannula, body position, leg movements, and continuous arterial oxygen saturation. Sleep staging and respiratory events were scored according to the American Academy of Sleep Medicine (AASM) criteria. The derived variables included Total Bed Time (TBT), Total Sleep Time (TST), sleep latency, sleep efficiency, sleep stages (in minutes and percentage of TST), arousal index, apnea-hypopnea index (AHI), mean and minimal nocturnal oxygen saturation, and the presence of nocturnal desaturation.

Results

Study Population and Baseline Characteristics

The study included a total of 45 patients with Chronic Obstructive Pulmonary Disease (COPD). The mean age of the study population was 57.38 ± 7.48 years, ranging from 39 to 72 years. There was a significant male predominance, with 37 (82.2%) males and 8 (17.8%) females.

Regarding lifestyle factors and comorbidities, the mean smoking history was 29.09 ± 19.09 pack years. Alcohol consumption was reported by 22.2% of the participants. Diabetes was present in 17.8% of the cohort. Anthropometric measurements revealed a mean BMI of 21.83 ± 3.14 kg/m^2 , a mean neck circumference of 33.76 ± 2.96 cm, and a mean waist circumference of 80.20 ± 8.19 cm. Table 1 shows the distribution of baseline characters of the study sample.

Table 1. Baseline Characters

Variable		Distribution	
Age		57.38 \pm 7.5 years	
Gender	Male	37	82.2 %
	Female	8	17.8 %
Smoking pack years		29.09 + 19.1	
Alcoholic	Yes	10	22.2
	No	35	77.8
Diabetes	Yes	8	17.8
	No	37	82.2
BMI		21.83 + 3.13	
Waist Circumference		33.76 \pm 2.95	
Neck Circumference		80.2 \pm 8.19	

Prevalence of Sleep Related Breathing Disorders (SRBD) and Clinical Symptoms

The prevalence of Sleep Related Breathing Disorders (SRBD) among the 45 patients with COPD in this study was low, primarily manifesting as Obstructive Sleep Apnea (OSA). Only 3 out of 45 patients (6.67%) were diagnosed with Obstructive

Sleep Apnea. No cases of Central Sleep Apnea or Mixed Sleep Apnea were identified. The mean Apnea-Hypopnea Index (AHI) for the total cohort was 3.33 \pm 3.75. Figure 1 shows the prevalence of Sleep Related Breathing Disorder (SRBD) among COPD patients in our study.

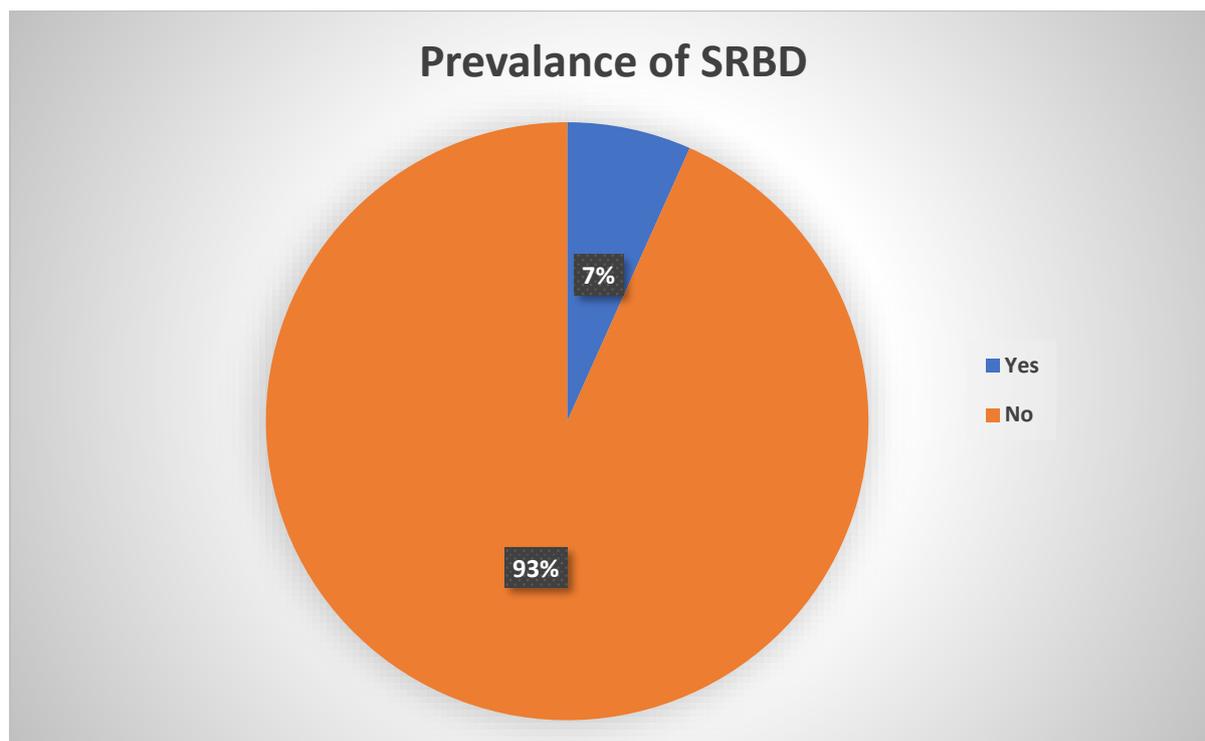


Figure 1. Prevalence of SRBD

Clinical symptoms related to sleep and respiration were common. Nocturnal awakening was the most frequent symptom, reported by 75.6% of patients. Other symptoms included snoring (35.6%), morning headache (33.3%), and choking episodes (6.7%). Predominant respiratory symptoms included breathlessness (62.2%) and a combination of breathlessness and wheeze (37.8%).

Assessment of Sleep Quality

The study utilized both subjective and objective measures to assess sleep quality. The mean Pittsburgh Sleep Quality Index (PSQI) score was 10.07 ± 3.52 ,

indicating overall poor sleep quality in the study population. Excessive daytime sleepiness, as measured by the Epworth Sleepiness Scale (ESS), showed a mean score of 11.93 ± 5.34 .

Objective polysomnographic parameters for the total cohort showed a mean Total Sleep Time (TST) of 264.71 ± 51.68 minutes and a mean sleep efficiency of $64.15 \pm 9.10\%$. The mean arousal index was 25.39 ± 7.74 per hour. Sleep architecture was characterized by a mean NREM 1,2 percentage of 73.69%, NREM 3 of 10.19%, and REM of 15.75% of TST. Table 2 shows the distribution of quality of sleep variables.

Table 2. Quality of Sleep related variables

Variable	Distribution (Mean \pm SD)
Total bed (TBT) (in minutes)	410.1 \pm 42.3
Total Sleep Time (TST)	264.7 \pm 51.7
WASO (Wake after sleep onset) (in minutes)	91.5 \pm 27.4
WASO (% of TBT)	22.4 \pm 6.5
Sleep latency (in minutes)	51.8 \pm 17.6
Sleep efficiency %	64.2 \pm 9.1
Arousal index (per hour)	25.4 \pm 7.7
AHI (Apnea hypopnea Index)	3.33 \pm 3.7
PSQI	10.07 \pm 3.52
ESS	11.93 \pm 5.34

Comparison Between Patients with Respiratory Failure (Group A) and Without Respiratory Failure (Group B)

For the purpose of comparative analysis, the total cohort was categorized into two groups based on the presence of chronic hypercapnic respiratory failure. Patients with Chronic Hypercapnic Respiratory Failure is defined by daytime awake PaCO₂> 45 mmHg while in a stable condition with PaO₂>60 mm Hg and pH >7.350 and those with awake PaCO₂< 45 mmHg with PaO₂>60 mm Hg and pH >7.350 are considered as without Hypercapnic Respiratory Failure. It is also noted that none of the patients in our study were on home non-invasive ventilation

(NIV) or long-term home oxygen therapy at the time of enrolment.

- **Group A:** Patients with COPD and Hypercapnic Respiratory Failure (n=32; 71.1%).
- **Group B:** Patients with COPD without Hypercapnic Respiratory Failure (n=13; 28.9%)

Clinical and Laboratory Parameters: Patients with respiratory failure (Group A, n=32) had a significantly higher pulse rate compared to Group B (90.66 vs. 82.54 bpm; p=0.000). Arterial Blood Gas (ABG) analysis confirmed the categorization, with Group A showing

significantly higher PaCO₂ (50.90 vs. 38.56 mmHg; p=0.000) and HCO₃ (30.03 vs. 25.66 mmol/L; p=0.000), and significantly lower PaO₂ (65.04 vs. 74.01 mmHg; p=0.000). There were no significant differences between the groups regarding age, BMI, or spirometric values (FEV1, FVC).

Sleep Parameters and Quality

Significant differences were observed in sleep parameters between the two groups:

- Sleep Duration and Efficiency: Group A had a significantly shorter TST (234.7 vs. 290.9 min; p=0.035) and lower sleep efficiency (58.5% vs. 69.1%; p=0.042).
- Sleep Latency and Arousals: Group A exhibited significantly prolonged sleep latency (62.7 vs. 42.4 min; p=0.003) and a higher arousal index (31.1 vs. 20.4; p=0.003).
- Subjective Sleep Quality: The PSQI score was significantly higher in Group A (13.2 vs. 7.3; p=0.018), reflecting worse sleep quality.
- Sleep Architecture: Group A showed a significantly higher percentage of NREM 1,2 (76.8% vs. 71%; p=0.019) and significantly lower NREM 3 duration (20.7 vs. 33.9 min; p=0.002) and REM duration (34.7 vs. 48.6 min; p=0.030).

Oxygen Saturation: Oxygenation was significantly more impaired in Group A across all parameters:

- Daytime SpO₂: 92.6% vs. 93.8% (p=0.03).
- Nocturnal SpO₂: 85.3% vs. 88.9% (p=0.001).
- Minimal Nocturnal SpO₂: 75.2% vs. 79.4% (p=0.001).
- Significant Nocturnal Desaturation was more prevalent in Group A (68.8%) compared to Group B (38.5%).

Table 3 shows the distribution of quality of sleep variables among Group A (Patients with COPD and Respiratory Failure) and Group B (Patients with COPD without Respiratory Failure).

Table 3. Quality of Sleep related variables among the study groups

Variable	Group A (n=32)	Group B (n=13)	p-value
Total bed (TBT) (in minutes)	399.9 ± 35.3	419 ± 46.5	0.272
Total sleep Time (TST) (in minutes)	234.7 ± 33.6	290.9 ± 50.9	0.035*
Sleep latency (in minutes)	62.7 ± 18.5	42.4 ± 9.7	0.003*
Sleep efficiency %	58.5 ± 6.3	69.1 ± 8.4	0.042*
Arousal index (per hour)	31.1 ± 5.6	20.4 ± 5.6	0.003*
WASO (Wake after sleep onset) (in minutes)	100 ± 23.9	84 ± 28.6	0.599

WASO (% of TBT)	24.9 ± 5.3	20.1 ± 6.6	0.295
AHI (Apnea hypopnea Index)	3.19 ± 2.13	2.4 ± 1.7	0.987
ESS score (Epworth Sleepiness Score)	11.5 ± 5.5	9.7 ± 4.2	0.219
PSQI score (Pittsburgh Sleep Quality Index)	13.2 ± 1.9	7.3 ± 2.1	0.018*
NREM1,2 (in Minutes)	180.1 ± 29	208.1 ± 34.2	0.322
NREM 1,2 (%of TST)	76.8 ± 5.7	71 ± 6	0.019*
NREM3 (Min)	20.7 ± 8.5	33.9 ± 15.4	0.002*
NREM3 (% of TST)	8.8 ± 3.4	11.4 ± 3.9	0.002*
REM (min)	34.7 ± 7.8	48.6 ± 13.7	0.03*
REM (% of TST)	14.7 ± 3.2	16.7 ± 3.3	0.167
Daytime SpO₂ %	92.6 ± 1.6	93.8 ± 1.3	0.03*
Nocturnal SpO₂ %	85.3 ± 2.8	88.9 ± 2.9	0.001*
Minimal nocturnal SpO₂ %	75.2 ± 5.4	79.4 ± 6.2	0.001*
Obstructive Sleep Apnea	2 (6.25%)	1 (6.66%)	0.86

*p-value<0.05-Statistically significant

Discussion

In this study of 45 COPD patients, the mean age was 57.38 ± 7.48 years with a predominance of males (82.2%), consistent with demographic patterns reported in Indian and global COPD cohorts where males often predominate due to higher smoking and environmental exposure. COPD continues to be a major public health issue in India with a high disease burden, particularly in populations with tobacco use and biomass exposure [3]. Moreover, studies have noted regional variations in COPD prevalence, emphasizing the influence of local environmental and lifestyle factors [9,10].

The prevalence of Sleep Related Breathing Disorders (SRBD) in our cohort was low (6.67% for OSA), with a mean AHI of 3.33 ± 3.75 , and no central or mixed apnea identified. While some reports show higher rates of overlap syndrome, prevalence estimates vary widely across settings and diagnostic approaches [11,12].

The relatively low OSA prevalence in our sample may reflect the predominance of normal BMI and exclusion of major comorbidities. Nevertheless, clinical symptoms of sleep disturbance were frequently reported — most notably nocturnal awakenings (75.6%), snoring, and morning headache — aligning with literature indicating high rates of

symptomatic sleep disruption in COPD even when polysomnographic OSA is uncommon [5,13,14].

Objective and subjective assessments of sleep quality further highlighted significant impairment in this cohort. The mean PSQI score of 10.07 ± 3.52 reflects poor overall sleep quality, and the mean ESS score of 11.93 ± 5.34 indicates excessive daytime somnolence. These results are consistent with prior studies showing that COPD patients often experience poor sleep quality due to nocturnal dyspnea, cough, and frequent arousals, and that poor PSQI scores correlate with lower quality of life in COPD [7,15].

Polysomnographic parameters in our study showed reduced total sleep time, low sleep efficiency, and a high arousal index, similar to findings from polysomnography studies reporting fragmented sleep and reduced restorative stages in COPD patients [5].

When comparing patients with chronic hypercapnic respiratory failure (Group A) to those without (Group B), Group A demonstrated significant gas exchange abnormalities — higher PaCO_2 and HCO_3^- , and lower PaO_2 — reflecting greater ventilatory insufficiency. These findings are in line with evidence showing that chronic hypercapnia is associated with impaired ventilatory response and poorer outcomes in COPD [16,17].

Notably, spirometric values (FEV_1 , FVC) were similar between groups, underscoring that hypercapnia and nocturnal respiratory impairment may not be fully explained by traditional spirometric severity alone. This observation has been reported in other studies where nocturnal desaturation and hypercapnia occur

independent of airflow limitation severity [5,18].

Group A also had significantly poorer sleep parameters and quality than Group B: shorter total sleep time, lower sleep efficiency, longer sleep latency, higher arousal index, and worse PSQI scores, corroborating evidence that nocturnal hypoxemia and gas exchange dysfunction in COPD adversely impact sleep [5,19].

Additionally, Group A showed altered sleep architecture with higher proportions of lighter NREM stages and reduced deep and REM sleep, consistent with studies demonstrating that hypoxia and ventilatory instability in COPD fragment sleep and reduce restorative sleep stages [7,20].

Measures of oxygenation, including daytime and nocturnal SpO_2 and minimal nocturnal saturation, were significantly worse in Group A, further confirming the close relationship between nocturnal hypoxemia and sleep disruption in COPD [5].

Conclusion

This study demonstrates that sleep impairment is highly prevalent among patients with severe stable COPD, even though the prevalence of polysomnography-confirmed sleep related breathing disorders (SRBD), particularly OSA, was low in the present cohort. The majority of patients reported significant sleep-related symptoms, and both subjective (PSQI, ESS) and objective polysomnographic findings confirmed poor sleep quality, reduced sleep efficiency, shortened total sleep time, and increased sleep fragmentation.

Patients with chronic hypercapnic respiratory failure exhibited significantly

worse sleep outcomes than those without respiratory failure, including poorer sleep efficiency, prolonged sleep latency, higher arousal index, altered sleep architecture with reduced restorative sleep stages (NREM3 and REM), and more severe nocturnal oxygen desaturation. These findings highlight that gas exchange impairment and nocturnal hypoxemia, rather than OSA alone, may be major contributors to disturbed sleep in severe COPD. Routine assessment of sleep quality and nocturnal oxygenation in COPD—especially among patients with chronic hypercapnia—may therefore be clinically valuable for comprehensive disease management and improving overall patient outcomes.

Limitations

The relatively small sample size and recruitment from a single tertiary care center may limit the generalizability of the findings across wider COPD population. Potential confounding factors such as medication use, coexisting psychiatric conditions, and socioeconomic influences on sleep were not comprehensively assessed. Although full attended polysomnography was performed, apnea–hypopnea index (AHI) values were based on automated scoring and were not independently verified through manual rescoring, which may introduce measurement variability. Additionally, the single-night polysomnographic assessment may not account for night-to-night variability in sleep parameters.

Statements and Declarations

Author Contributions

KR has contributed to the conceptualization and design of the study, literature search, data acquisition,

manuscript editing and review. VS contributed towards data acquisition Statistical analysis, Manuscript review and editing. KR 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.

Data availability statement

The datasets generated and analyzed are not publicly available due to the presence of sensitive information that could potentially lead to indirect identification of participants and are available from the corresponding author upon reasonable request.

Ethical Consideration

This study has been approved by the Institution Ethics Committee and Written informed consent was obtained from all participants

Acknowledgements

Use of AI: Authors declare the usage of Chat-GPT 4.0 for content and language moderation alone.

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REVIEW ARTICLE

Professionalism and Ethics in Medical Education: Teaching Approaches—A Narrative Review

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Abstract

Background: Medical professionalism and ethics are the bedrock of medical education, moulding physicians to be competent, compassionate, and ethical practitioners. These components cover core elements learned and taught through official and clandestine curricula — including honesty, compassion, responsibility, and patient-centred care. Although important, the methods for the best teaching of competency-based education are not well-defined. **Materials & Methodology:** We performed a systematic literature search in PubMed and Google Scholar of literature published until the beginning of 2025. The keywords included “medical professionalism” and “ethics education.” The main focus of the inclusion criteria focused on original research and reviews that dealt with curriculum design, assessment techniques, pedagogical approaches, and educational outcomes related to professionalism and ethics in undergraduate and graduate medical education. **Discussion:** Professionalism education must be longitudinally integrated throughout the program across the duration of medical education to be effective. Since affective areas, such as empathy and ethical problem-solving, seem to be poorly taught in traditional lectures, experiential learning resources like case-based learning, reflective text, role playing, and faculty role modelling have been gaining the attention of people. Novel approaches, such as cinema education, have emerged as ways of enhancing involvement with the ethical issues involved in this debate. However, most current evidence is Western-oriented and highlights the importance of culturally appropriate curriculum. In order to sustain professional education and reduce the force of hidden curricula, both institutional support and faculty development are needed. **Conclusion:** Efforts to formalize professional education can be seen in structured programs like the AETCOM module. Nevertheless, there is disagreement in the field about both pedagogy and the content of the curriculum. Evidence base for making models that link educational interventions to improved patient care outcomes and practice has been developed through stringent, cross-cultural studies. Words: ethics, medical professionalism, teaching methods.

Keywords: Medical professionalism, Medical ethics, Medical teaching

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Introduction

It is important to note that the professionalism and ethics of medicine itself are to ensure that doctors will not only perform at the level of clinically proficient but also that they are professional but will act out of social and ethical responsibility to their patients. Professionalism is full of values, including integrity, empathy, accountability, selflessness, and respect for patients' rights. These moral values are codified within the formal curriculum as an overarching set of values, although most of these are taught in what is known as the 'hidden curriculum' [1-3]. Such is the type of lessons not mentioned explicitly but derived from the culture of the institution, behaviour of peers, instructors, etc. The hidden curriculum is often the most effective of the influencing elements of the process of establishing the students' professional identity, or, on the other hand, it may actually strengthen or, at worst, be extremely harmful to the formal ethics education. The increasing use of competency-based medical education (CBME) frameworks is fostering an emphatic focus on quantifiable and measurable outcomes, but the teaching of professionalism is especially difficult because of the affective and behavioural aspects of the topic. Educational innovation is critical for moving beyond traditional, non-participatory, didactic teaching methods to a more nuanced and complex reality; one that engages the learner cognitively, emotionally, and socially. There is growing interest in longitudinal professional learning that is integrated throughout the undergraduate and postgraduate pathways and centres on the building of ethical judgement and professional behaviour that is embedded within the clinical and preclinical teaching

[6,7]. Moreover, the contexts that inform professional practice (cultural and institutional) are vital in shaping the way in which professionalism is defined and enacted, providing proof of the importance of a responsive curriculum that takes into account the contexts of the local and realities of the health care system [8,9]. This narrative review attempts to synthesise recent teaching methodology literature and curriculum development literature concerning professionalism and ethics, and related topics. This narrative review aims to identify and portray effective teaching approaches to encourage a sustained professional identity, ethical consciousness and patient-centred care and highlight which practices fail with the expectation and the future directions for the research and educational practice.

Materials and Methodology

A literature review was conducted in early 2025 in the PubMed and Google Scholar databases. The keywords searched were "medical professionalism," "ethics education," "professionalism teaching methods", "medical ethics curriculum", and "professionalism assessment." Only original empirical studies, systematic reviews and narrative reviews of pedagogy, curriculum, assessment and outcomes of professional and ethical education delivered by postgraduate and undergraduate medical students in education were scoured. The studies included in the review emphasize innovative teaching, integration of professionalism into education in a longitudinal manner, and cultural context considerations. The studies that did not take an evidence- or theory-based approach to professional education were ruled out. On data extraction, the focus was on methods

of teaching to facilitate the instruction of the curriculum and the data collection for assessment, focusing on learner outcomes. Proper teaching professionalism begins with ensuring continuity of exposure across the medical training continuum [4,5]. Inclusion of professionalism and ethics in preclinical and clinical stages reinforces the principles while gradually establishing a professional identity. In short, the compartmentalisation of professionalism into separate modules leads to minimal participation and ignores the continuous evolution of professional development [10]. In their development of increasing complexity, longitudinal programs support learners in exercising ethics when faced by challenging clinical scenarios. Teaching Approach Professionalism and education as constructs have affective and behavioural domains, and no traditional lecture holds value for the development of these qualities, such as empathy, ethical reasoning and communication [6]. Therefore, teachers prefer to use multimodal experiential pedagogies that actively engage learners.

Case-Based Learning

When put in an authentic clinical context, Case-Based Learning (CBL) promotes critical thinking, ethical reasoning, and problem-solving skills by situating moral dilemmas in the real world [7]. It fosters discourse, self-reflection and the transference of theoretical knowledge to real-world dilemmas.

Reflective Writing

Reflective exercises facilitate reflection by prompting students to analyse their attitudes, prejudices, and experiences [8]. Reflection is driven by an increase in empathy and ethical sensitivity.

Role-play

Role-playing and simulating patient encounters provide safe environments for the acquisition of communication skills, empathy in others' distress, and moral judgments [9]. Peer and teacher feedback promote student confidence and skill development.

Role-play and Simulation

The activities provide secure environments for developing communication, empathy, and moral judgment [9]. Students receive feedback from their peers and instructors, and these assist them feel confident that they are capable of improving their skills.

Faculty Role Modelling

The behaviour of the faculty impacts the way in which students develop their professional identities [10]. By observing and mentoring students, positive role models both impart ethical values and show professional standards in clinical practice, education and personal relationships.

Cinemeducation

Using films and other visual media for this purpose makes difficult moral dilemmas accessible and exciting, encouraging dialogue and a better understanding of the topic [11]. This novel strategy fosters critical thinking and emotional engagement with medical ethics.

Cultural Aspects and Contextual Considerations

As most education on professionalism is carried out in Western settings, the results cannot be generalised across different institutional and cultural contexts [13,14]. Cultural norms impact

perspectives on professionalism, moral priorities, and appropriate conduct [8,15]. Social values, communication styles, hierarchical structures and more are varied, which means curricula in specific areas need to be contextually adapted. Context-sensitive methods in professional education are important for enhancing learner relevance, acceptance and efficacy [14].

Faculty Development and Institutional Commitment

Specialist resources, faculty development and curriculum-integrated support from the institution are crucial in continuing professional education [16]. To enhance teachers' capacity for teaching, modelling, and assessing professionalism, the quality of teaching programs and the professional development of teachers must be enhanced. The detrimental effects of the hidden curriculum and reinforcing desired behaviour expectations require the alignment of institutional policies with their culture, and thus, institutional policies and culture must be in concert.

Challenges and Future Directions

There remains great potential for cooperation on assessment, teaching method and content of curriculum despite these developments. Because of the hidden curriculum, the institutional culture can be solved with systemic solutions, as formal professionalism education continues to be thwarted. Longitudinal mixed-methods research is needed to link educational interventions with quantifiable improvements in patient outcomes and professional behaviour. Development of validated assessment tools and culturally relevant standards will enhance their effectiveness and global applicability.

Conclusion

Structured programs such as the Attitude, Ethics, and Communication (AETCOM) module add a structured component that contributes to more effective professional education in addressing complex issues. However, this variation exists in the curriculum and teaching methods, illustrating the always-existing concerns in this field. Strict, culturally relevant research must underpin evidence-based frameworks that facilitate professional identities and ethical competence development. By integrating institutional-level commitment and longitudinal experiential pedagogies, physicians will be better positioned to address the moral dilemmas of modern healthcare, which will provide further opportunities to enhance patient care and inspire confidence in the general population.

Statements and Declarations

Conflicts of interest

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

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CASE SERIES

Trichotillomania as a Rare Comorbidity of Delusional Parasitosis: A Case Series

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Abstract

Delusional parasitosis is a type of delusional disorder characterized by an unwavering false belief that their skin is infested by parasites despite repeated negative medical evidence or reassurance by clinicians. Trichotillomania is an obsessive compulsive and related disorder where there is repetitive pulling of hair with an increased tension before and a sense of relief after pulling out hair. Combination of these two disorders as a comorbidity is rare and less reported in literature. The Author presents a case series of three cases with their common characteristics, clinical presentation and treatment given. All three cases received a combination of risperidone and fluoxetine with improvement of symptoms.

Keywords: Trichotillomania, Delusional parasitosis, comorbidity

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Introduction

Delusional parasitosis is also known as delusional infestation or Ekbom syndrome. It is classified as primary, secondary and organic forms [1]. It was initially named by Wilson and Miller in 1946 [2]. The term Ekbom syndrome was given by Karl Axel Ekbom, a Swedish psychiatrist [3]. It is a Psychodermatological disorder which includes disorders prevailing on the boundary between psychiatry and dermatology [4]. Delusional disorder is a relatively uncommon disorder with mean age of onset of about 40 yrs and higher female preponderance [5]. The lifetime prevalence of delusional disorder is 0.2% (DSM-5). In India, literature suggests a prevalence of 1% with the prevalence of delusional parasitosis being 0.5% [6].

Trichotillomania was first documented by a French dermatologist Francois Hallopeau in 1889 [7]. It is a body focused repetitive behavior which is characterized by recurrent pulling of one's hair, unsuccessful attempts to decrease or stop hair pulling resulting in significant hair loss. Scalp, eyebrows and eyelids are the most common sites. It can result in variable hair loss- complete alopecia/ thinning of hair density. Most common age of onset is early adolescence. Automatic hair pulling is engaging in this behavior outside one's awareness. It is more common in children and adolescents [8]. It is also a Psychodermatological disorder just like delusional parasitosis.

Literature shows case reports, case series and original articles on delusional parasitosis and trichotillomania individually. Comorbidity in Delusional disorder is often noticed, with considerable proportion of

patients having affective disorders [9]. Similarly, 79% of people with trichotillomania had one or more psychiatric comorbidities. The most common being anxiety/depressive disorders, OCD, PTSD, and ADHD [10]. But literature on delusional parasitosis with comorbid trichotillomania is rare with only few case reports. The author presents a case series of three patients of primary delusional parasitosis with this rare comorbidity. The study was approved by the Institutional Human Ethics Committee, Aarupadai Veedu Medical College, Vinayaka Mission's Research Foundation (VMRFDU), Puducherry, India. Written informed consent was obtained from all three patients with identity concealment and anonymity. All three cases were diagnosed as per ICD- 11 criteria.

Case 1

A 56yr old uneducated, widowed female, coolie by occupation from lower socioeconomic status and rural background was referred from dermatology OPD with chief complaints of Insects crawling over scalp, face and entire body, Itching over scalp and body, plucking out hairs over scalp with patchy hair loss and sleep disturbance for 2 yrs. Symptoms were worse during night compared to day when she used to go for work. She had history of multiple consultations with dermatologists and was reported to have nil dermatological disorders and was referred to psychiatry several times for further treatment. But she refused treatment in psychiatry. Her family members and her colleagues had never encountered insects over her scalp or body though she used to pluck from her scalp and try to show

the insects to them. She used to claim that these insects looked like lice but are much smaller and are black in color. Due to intense itching she used to scratch her scalp and to relieve from this sensation she started plucking her hair from scalp. Eventually once crawling and itching sensation aggravated, she started having an intense urge to pluck her hair which would give her temporary relief for few minutes and again symptoms would reappear. Due to aggravated symptoms at night, she also had difficulty in initiating and maintaining her sleep. She had tonsured her hair in scalp several times to get rid of the insects, but her symptoms used to persist. After counselling by psychologists in dermatology OPD she then came to psychiatry for treatment. At the time of presentation, she had patchy hair loss over scalp with varying length of hair in parietal region (R>L). No other areas of hair loss were seen in any other parts of body. She was a known hypertensive for 7yrs and was on regular medications (Amlodipine 5mg). She had bilateral sensorineural hearing loss and was on hearing aid for last 8yrs. She lost her husband 7 yrs back to decompensated liver disease due to alcohol and was living with her son and family. General and systemic examination were normal and mental status examination revealed depressed mood and affect, delusion of infestation and tactile hallucinations with absent insight. Complete blood count, renal function test, fasting and post prandial blood sugar, ECG, thyroid function test, CT brain was normal. She was started on Risperidone 2 mg and gradually increased to 4 mg with Fluoxetine 20 mg. With treatment, she was symptomatically better and did not have any episodes of

plucking hair. Hence fluoxetine was stopped and risperidone was continued. But on follow up she had poor compliance to medications with adequate socio occupational functioning.

Case 2

A 48yr old married male, educated till 5th std, carpenter by occupation, from lower socio-economic status came with complaints of insects crawling over face and scalp, plucking hair from eyebrows, sleep disturbance for 3yrs. His symptoms started after he shifted to a new home due to debt issues in family and separation from wife and children 3yrs back. He lived alone and was not allowed to talk to or meet his children by his wife. Symptoms initially started with itching of scalp for which he took symptomatic treatment from dermatologists but as there was no relief and aggravation of itching, he consulted multiple dermatologists. In next few months he started having crawling sensations over scalp and face and when he scratched his scalp, he claimed that he saw whitish lice like insects in his nails. Since then, he used to wash his hair daily to remove insects from scalp and face and used to sweep his home frequently claiming that he had to throw away the insects fallen on floor. He then started to pluck his hair from eyebrows due to intense itching and to remove the insect from hair and over a period of days he started having an intense urge to pluck his eyebrows which would bring him brief relief resulting in hair loss in eyebrows. He was a known case of alcohol dependence syndrome but was abstinent for the next 3 yrs till date, after the onset of itching. The symptoms were not due

to withdrawal or delirium or alcohol induced psychotic disorder as per history. He had no medical comorbidities and nil significant family history. He came to the OPD with a cover and picked whitish particles from the bag claiming insects which he swept that morning. Hair loss in eyebrows was present. General and systemic examination were normal. Mental status examination revealed depressed mood and affect, delusion of parasitosis, tactile hallucinations, ideas of hopelessness and helplessness, no suicidal ideas. His routine blood investigations, thyroid profile and CT brain were normal. He was started on Risperidone 2mg which was then increased to 4mg and fluoxetine 20mg. He improved with medications but is on irregular follow-up and does not have significant impairment.

Case 3

A 45yr old women, educated (bachelor's degree), divorced, unemployed from low socioeconomic status came with complaints that small sized snakes keeps crawling and biting her body for 11/2 yrs. She was living with her unmarried brother 2 yrs back when she started complaining of multiple somatic symptoms and planned to take herbal treatment. As their home was far away from treatment center, they used to spend nights in bus stand and sleep in pathways. One night she claimed that a snake bit her. She was hospitalized and evaluated but was reported not to have any snake bite. Since then, she started claiming that snakes of small size have entered her body and crawl and bite her body throughout the day. As she was not manageable at home, she was sent to an old age home where proper care for

inmates including food, drinking water was not given and her symptoms aggravated. She also started plucking her hair from scalp and eyebrows to remove the snakes but eventually she started pulling out her hair without much awareness. She could not explain if she had any urge to pluck her hair and if she experienced any relief. Her entire body had scratch marks and she had weight loss due to lack of proper availability of food. She used to keep crying throughout the day due to her symptoms and consulted 2 dermatologists with no relief of symptoms and hence was brought to hospital. She initially resisted psychiatric consultation but later agreed. There was no history of any medical comorbidities or significant family history. She was admitted and dermatologist opinion was sought to rule out any skin disorders. She was thin built and poorly nourished on admission and had scratch marks throughout the body with multiple areas of irregular hair loss over scalp and eyebrows. She was pallor and systemic examination was normal. Mental status examination showed depressed mood and affect and delusion of infestation, anhedonia, ideas of hopelessness, helplessness, tactile hallucinations with absent insight. Her routine blood investigations showed Hb-8mg/dl and others were within normal limits. CT brain and thyroid profile were normal. She was started on Risperidone 2mg, and the dose was increased to 8 mg, trihexyphenidyl 2 mg, fluoxetine 20 mg. She showed improvement in symptoms during hospitalization but was on irregular follow-up with mild impairment in daily functioning.

Discussion

The common findings in all 3 cases were onset above 45 yrs, lower socio-economic status, multiple dermatological consultations, resistant to take treatment from psychiatrist due to lack of insight, lack of partner (divorced/separated/widowed), irregular follow-up, affective symptoms and trichotillomania. In a psychosocial study done by Tandon et al. among delusional parasitosis patients, the predominant psychosocial factors observed were age above 50 yrs, female preponderance, married, illiterates, rural population, lower and lower middle socioeconomic class, onset of illness in months May-October, abnormal personality traits (obsessional personality traits in more than one third of population) [11]. Munro had observed other psychosocial factors associated with delusional disorders such as separation, divorce, non-marriage and strained interpersonal relationship [12]. Many of these factors are also seen with our 3 patients. Neither did we evaluate personality through standard tools for these patients, nor did we find any abnormal personality traits in our history. But surprisingly, the literature evidence of obsessional personality traits in delusional parasitosis patients kindles the interest to link trichotillomania, though rare comorbidity, requires further research in future.

We started all three patients on a combination of risperidone and fluoxetine. All 3 patients showed improvement in symptoms which is, their distress due to the delusional belief of infestation reduced but delusion did not disappear completely. The same clinical characteristic has also been commented on in literature stating that

response to treatment means less complaining, less focused and less likely to act out of delusions [13]. But long-term response could not be established because of the irregular follow up. However, there were no episodes of trichotillomania after initial improvement in symptoms. Pimozide is no longer considered as first choice in delusional disorders because of drug interactions and QTc prolongation [13]. Bhatia et al. in his case series report on 50 delusional parasitosis had found that antipsychotic treatment resulted in high positive response rate in these patients with risperidone being the most frequent medication followed by olanzapine [14]. Combination of psychotropic drugs are common in delusional disorder as it is frequently associated with depressive and anxiety symptoms [15]. This is implicated in our three patients.

Treatment of trichotillomania requires a multidisciplinary approach including psychotherapy and pharmacotherapy. Current evidence shows cognitive behavioral therapy as the most efficacious treatment for trichotillomania, particularly Habit reversal therapy. The other treatment options are usage of AEMD (Awareness Enhancing and Monitoring Device), internet therapy, microneedling. The pharmacological agents used are SSRIs, clomipramine, N-Acetyl cysteine, memantine, olanzapine, naltrexone, dronabinol, MAO inhibitors [16]. In our 3 cases, symptoms of trichotillomania were associated with delusion and disappeared with pharmacotherapy before planning for CBT.

Limitations

No standardized assessment tools were used to assess the severity or diagnosis other than ICD 11. All 3 cases had irregular followup. Hence implication of treatment from this case series requires further studies with long term follow up and standardized assessment tools.

Conclusions

Delusional parasitosis is a rare disorder and requires proper liaison and multidisciplinary approach. In majority, it is associated with comorbid affective disorders but association with trichotillomania is rare. There are no definite treatment guidelines for delusional disorders as it lacks evidence from RCTs. This case series shows combination treatment with atypical antipsychotic and SSRIs improves both delusional symptoms and trichotillomania.

Statements and Declarations

Conflicts of interest

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

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LETTER TO THE EDITOR

Myocardial Infarction in People Living with HIV (PLWH)

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Abstract

People living with HIV (PLWH) face a two-fold higher risk of myocardial infarction (MI) compared to HIV-negative individuals, often occurring at a younger age. We report the sudden death of a 37-year-old man with a 5-year history of HIV infection on antiretroviral therapy (ART), well controlled on a regimen of dolutegravir, lamivudine, and tenofovir disoproxil fumarate. He was a non-smoker and non-alcohol user with no traditional comorbidities (dyslipidaemia, hypertension, diabetes, smoking, and metabolic syndrome). At autopsy, the heart was enlarged and an erythematous patch was seen on the antero-lateral wall of the left ventricle. Histopathological examination confirmed myocardial infarction with neutrophilic infiltration and 50% occlusion of the lumen of left circumflex artery. This case emphasizes that cardiovascular risk in PLWH persists despite the use of newer, non-dyslipidaemic ART regimens and the absence of traditional risk factors. It stresses the need for aggressive cardiovascular risk assessment in the management of HIV-positive patients as part of their ART care and periodic follow-up.

Keywords: HIV, Myocardial Infarction, Antiretroviral Therapy, Sudden Cardiac Death, Forensic Pathology

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The advent of Antiretroviral Therapy (ART) has shifted the trajectory of HIV from a fatal disease to a manageable chronic condition. However, this increased longevity is accompanied by a rise in non-AIDS-defining illnesses, particularly cardiovascular disease (CVD) [1]. Even when viral suppression is achieved, People Living with HIV (PLWH) exhibit an approximately two-fold higher risk of myocardial infarction (MI) compared to uninfected controls [2]. Furthermore, PLWH who experience MI are typically younger on average by 10 years than their HIV-negative counterparts [3].

Modern ART regimens, specifically those incorporating Integrase Strand Transfer Inhibitors (INSTIs) like Dolutegravir, are generally considered to have a more favourable metabolic profile than older protease inhibitors. Despite this, the risk of MI remains elevated even in patients on these newer therapies [4]. This suggests that the underlying inflammatory milieu and HIV-related vascular injury persist regardless of the ART class. This case report discusses the autopsy findings of a sudden death in a young, HIV-positive male on the newer non-dyslipidaemic ART regimen (metabolically favourable).

A 37-year-old man living with HIV had been on antiretroviral therapy for five years, receiving dolutegravir, lamivudine, and tenofovir disoproxil fumarate. He had no history of tobacco or alcohol abuse and was not known to have hypertension, diabetes mellitus, or any other traditional risk factors for myocardial infarction. He was discovered unconscious in the

backyard of his residence after having last been seen alive the previous night when he went to the washroom. He was declared “brought dead” the following morning, following which a medicolegal case was registered, and a forensic autopsy was undertaken to ascertain the cause of the sudden, unwitnessed death.

At autopsy, a laceration measuring 2 cm × 1 cm, scalp-deep with irregular and contused margins, was present over the left occipital region, with a corresponding internal contusion of the scalp. Multiple abrasions measuring 1–2 cm were noted over the forehead and left elbow. The injuries mentioned above are consistent with a terminal fall and there are no other fatal injuries on the body. On further examination, the heart was enlarged, weighed 310g and covered with pericardial fat. A 2.5 cm × 1.5 cm distinct erythematous patch with a focal adherent blood clot was observed over the antero-lateral wall of the left ventricle (Figure 1). Microscopic examination of the left ventricular wall revealed focal sub pericardial neutrophilic infiltration in the interstitium and increased eosinophilia of cardiac muscle fibres, indicative of early ischemic changes consistent with myocardial infarction (Figures 2-4). The left circumflex artery showed an atheromatous plaque resulting in approximately 50% luminal occlusion, with the lumen remaining patent. Chemical analysis of the viscera was negative for ethyl alcohol and common poisons. The cause of death in this case was opined as myocardial infarction.

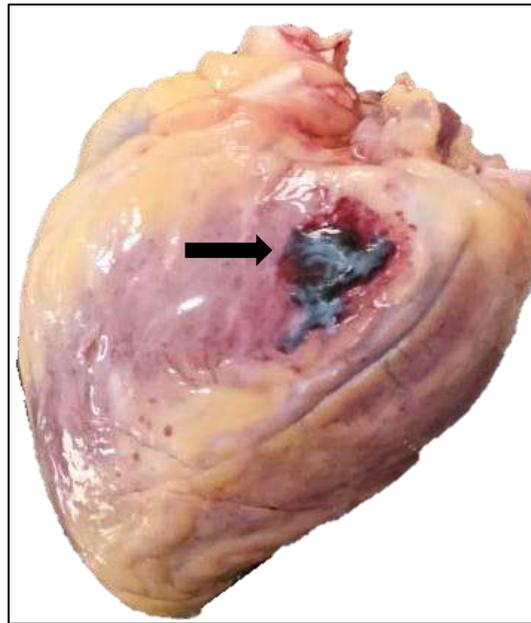


Figure 1. Heart, Gross; distinct erythematous patch with focal adherent blood clot.

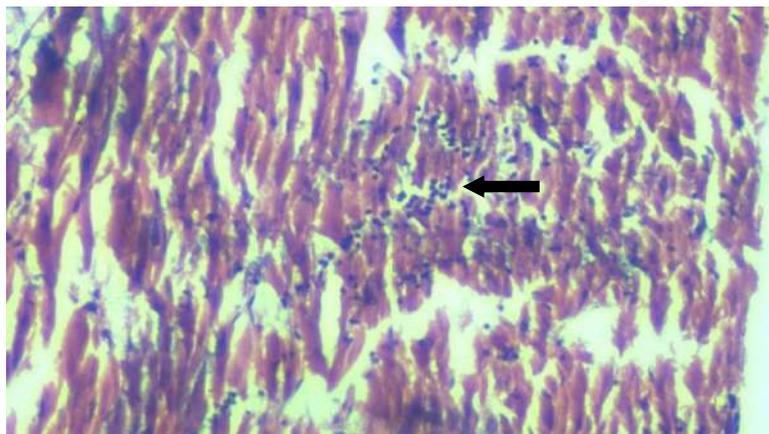


Figure 2. (H&E staining, Magnification – 200) Neutrophilic infiltration in the interstitium of cardiac muscle bundles.

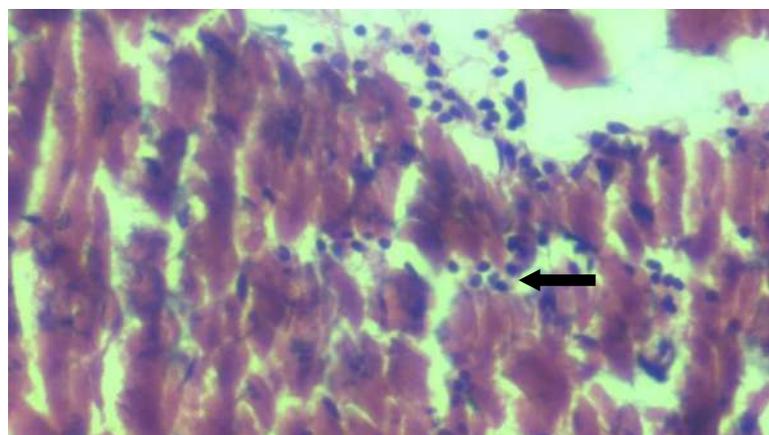


Figure 3. (H&E staining, Magnification – 400) Neutrophilic infiltration in the interstitium of cardiac muscle bundles.

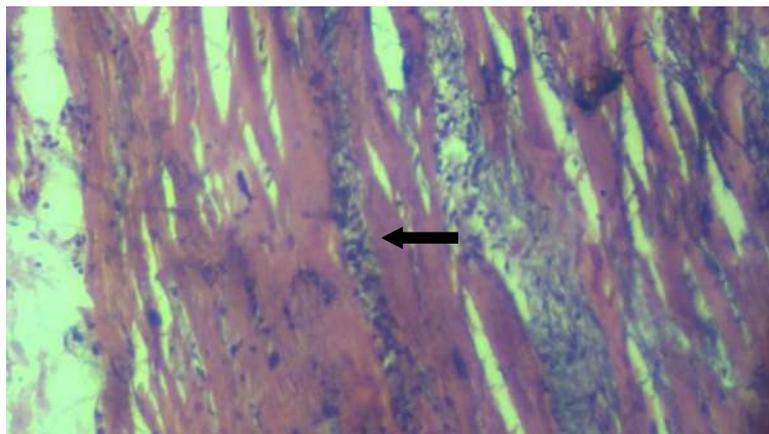


Figure 4. (H&E staining, Magnification - 400) Increased eosinophilia of cardiac muscle bundles along with neutrophilic infiltration.

The autopsy findings in this 37-year-old male confirm that sudden cardiac death (SCD) in HIV-positive individuals can occur in the absence of traditional risk factors such as smoking or diabetes, even in patients on modern, non-dyslipidaemic ART regimens. The presence of ischemic changes and partial coronary occlusion (50%) suggests that HIV-associated myocardial infarctions often involve mechanisms beyond simple plaque rupture, including endothelial dysfunction and supply–demand mismatch [5].

The risk of MI in PLWH is multifactorial. While traditional risk factors such as smoking and dyslipidaemia may also be prevalent in this population, HIV-specific factors including chronic immune activation, inflammation, and endothelial dysfunction play a critical independent role [6]. Although this patient was on a newer ART regimen (dolutegravir/tenofovir) known for a safer lipid profile compared with older protease inhibitors or abacavir [7, 8], the risks associated with these agents require further scrutiny. Biomarkers such as IL-6 and hsCRP remain elevated in PLWH and correlate with mortality [9]. This

supports the hypothesis that chronic low-grade inflammation and immune activation drive accelerated atherosclerosis and plaque instability, even in patients with viral suppression [10].

People living with HIV continue to exhibit a 20%–100% increased relative risk of myocardial infarction compared with those without HIV. In addition to myocardial infarction, HIV infection has been associated with a heightened risk of stroke, sudden cardiac death, heart failure, pulmonary hypertension, and myocardial fibrosis [5]. Chronic immune activation and persistent systemic inflammation, even in virally suppressed individuals, contribute to accelerated atherosclerosis. Elevated inflammatory cytokines and markers of immune activation promote endothelial dysfunction, lipid oxidation, and plaque instability, thereby increasing susceptibility to acute coronary events [6].

A distinct clinical entity, myocardial infarction with non-obstructive coronary arteries (MINOCA), is characterized by evidence of acute myocardial infarction in the absence of obstructive coronary artery disease. In people living with HIV,

MINOCA may be associated with mechanisms such as microvascular ischemia or transient coronary thrombosis without fixed coronary obstruction [11].

Beyond myocardial infarction, HIV infection has been linked to a range of cerebrovascular complications. Studies have reported an increased risk of stroke in people living with HIV, including cases of juvenile ischemic stroke, suggesting that HIV can accelerate vascular disease at a younger age. The underlying mechanisms include blood clotting disorders, emboli from infections, opportunistic CNS infections, and direct damage to blood vessels by the virus. These factors illustrate that HIV can affect the cardiovascular system broadly, not just the heart, and may explain the reason why people with HIV remain at higher risk for serious vascular events like myocardial infarction [12].

A postmortem study by Tseng et al. (2021) found that HIV-positive individuals had more than double the rate of presumed sudden cardiac death compared with those without HIV. Moreover, HIV-positive hearts showed higher levels of myocardial fibrosis, indicating structural changes that may increase vulnerability to fatal cardiac events like arrhythmias responsible for sudden cardiac death [13].

India's HIV epidemic remains low, with an adult HIV prevalence of 0.20% in 2024; however, the country still has approximately 25.61 lakh people living with HIV (PLWH), representing the second largest PLWH population globally. As ART coverage improves and individuals with HIV live longer, attention is shifting from opportunistic infections to systemic diseases like cardiovascular disease [14].

The 2021 National Guidelines for HIV Care and Treatment emphasize early, lifelong ART to mitigate inflammation, but

sudden cardiac death related to MI remains a concern and requires proactive monitoring. The national programme under NACO provides ART free of cost, and there is a clear policy movement toward integrated HIV–Non communicable Diseases (NCD) care. Clinicians are therefore encouraged to look beyond rigid algorithms by systematically screening for hypertension, diabetes, and dyslipidaemia, selecting ART regimens with lower metabolic risk, and ensuring linkage of PLWH to primary NCD programs to reduce the burden of preventable cardiovascular morbidity and mortality [15].

In conclusion, this case illustrates the increased risk of myocardial infarction in HIV-positive individuals, even when they are receiving treatment. The inflammatory burden of chronic HIV infection remains a potent driver of atherothrombosis and sudden cardiac death, necessitating continued cardiovascular vigilance and comprehensive risk assessment, including in patients on modern, non-dyslipidaemic ART regimens. Importantly, virologic suppression and the absence of traditional cardiovascular risk factors do not confer immunity from fatal cardiac events in people living with HIV, and HIV itself should be recognized as an independent cardiovascular risk accelerant.

Limitations

Detailed premortem information on HIV disease characteristics, including CD4 count, viral load, and overall immune status, was not available. Furthermore, non-modifiable cardiovascular risk determinants, such as family history and underlying genetic predisposition, could not be ascertained.

Conflicts of interest

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

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Ethics committee approval

Consent for conducting autopsy in this case was obtained from law enforcement authorities and all ethical concerns including consent from the next of the kin were addressed by the authors.

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